U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K080093 - 466 pages
COMPANY:	GYRUS ACMI, INC. (GYRUACMI)
PRODUCT:	ELECTROSURGICAL, CUTTING & COAGULATION & ACCESSORIES (GEI)
SUMMARY:	Product: PKS PLASMA MORCELLATOR, MODELS 962000PK, 3620PK
DATE REQUESTED:	Oct 5, 2015
DATE PRINTED:	Oct 5, 2015

Note: Printed

510(k) Summary of Safety and Effectiveness
Gyrus ACMI, Inc.
Gyrus ACMI PKS Plasma Morcellator

General Information

Manufacturer:	Gyrus Medical Ltd. Fortran Road, St. Mellons Cardiff UNITED KINGDOM CF3 0LT
Establishment Registration Number:	9617070
510(k) Submitter:	Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Terrence E. Sullivan Vice President, Regulatory Affairs
Date Prepared:	January 11, 2008

Device Description

Classification Name:	Laparoscope, Gynecologic and accessories (21 CFR 884.1720), Class II, Obstetrics/Gynecology Panel; Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400), Class II General and Plastic Surgery Panel
Project Name:	Gyrus Medical Solid Organ Resection Device (SORD)
Trade Name:	Gyrus ACMI PKS Plasma Morcellator
Generic/Common Name:	Electrosurgical Instruments

Predicate Devices

Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula	K041633
Ethicon Inc. Gynecare Laparoscopic Morcellator	K993801

Intended Uses

The Gyrus ACMI PKS Plasma Morcellator is intended for cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynecologic procedures.

Product Description

The Gyrus ACMI PKS Plasma Morcellator consists of two main elements: a Morcellator that includes a cutting shaft and handle with an integrated electrical cable that connects to a Gyrus Medical generator; and a Grasper that passes through the hollow shaft of the Morcellator, to grasp tissue and retract it toward the cutting element on the Morcellator shaft tip. An obturator may also be used to assist in the introduction of the device in laparoscopic procedures, and like the grasper, is positioned through the shaft of the Morcellator tube when being utilized

Technological Characteristics and Substantial Equivalence

The Gyrus ACMI PKS Plasma Morcellator utilizes features incorporated into the following legally marketed predicate devices:

The Gyrus ACMI PKS Plasma Morcellator utilizes the same bipolar electrosurgical energy to cut tissue as that used in the predicate Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula.

The Gyrus ACMI PKS Plasma Morcellator connects to the same electrosurgical generators, the currently marketed Gyrus PlasmaKinetic SuperPulse System and Gyrus General Purpose Electrosurgical System generators, as the predicate Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula. These generators were cleared under K031085 and K050550, respectively.

The Gyrus ACMI PKS Plasma Morcellator is dimensionally similar to the predicate Ethicon Gynecare Laparoscopic Morcellator, having similar Morcellator shaft diameters.

Like the predicate Ethicon Gynecare Laparoscopic Morcellator, the Gyrus ACMI PKS Plasma Morcellator utilizes a pistol grip Morcellator with a hollow shaft through which a grasper is passed to grasp tissue to be resected.

Like the predicate Ethicon Gynecare Laparoscopic Morcellator, the Gyrus ACMI PKS Plasma Morcellator is indicated for cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynecologic procedures.

The Gyrus ACMI PKS Plasma Morcellator uses patient-contacting materials that are utilized in the predicate devices, as well as other legally marketed devices manufactured by Gyrus ACMI.

During design verification, the performance of the PKS Plasma Morcellator was compared against the known performance characteristics of the predicate Gynecare Laparoscopic Morcellator using the bipolar tissue cutting technology of the predicate Gyrus PlasmaCision Laparoscopic Spatula. Testing demonstrated that the performance requirements were met, and that the PKS Plasma Morcellator exhibited comparable performance characteristics to both the predicate care Laparoscopic Morcellator and predicate Gyrus PlasmaCision Laparoscopic Spatula.

In summary, the Gyrus ACMI PKS Plasma Morcellator is substantially equivalent to the predicate devices and presents no new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2008

Gyrus ACMI, Inc.
% Mr. Terrence E. Sullivan
VP, Regulatory Affairs
136 Turnpike Road
Southborough, Massachusetts 01772

Re: K080093
Trade/Device Name: Gyrus ACMI PKS Plasma Morcellator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, HET
Dated: April 17, 2008
Received: April 18, 2008

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Gyrus ACMI PKS Plasma Morcellator

510(k) Number: K 080093

Statement of Intended use:

The Gyrus ACMI PKS Plasma Morcellator is intended for cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynecologic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: __ X __ **OR** Over-the-Counter Use: _____

(Per 21 CFR 801.109)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080093

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Your Vision, Our Future

K080093/A002

January 13, 2015

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Document Control Center
10903 New Hampshire Avenue
WO66-G609
Silver Spring, MD 20993-0002

FDA CDRH DMC
JAN 14 2015
Received

VIA FEDRAL EXPRESS

RE: Add to File K080093

To whom it may concern,

Pursuant to FDA's *Immediately In Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators*, issued November 25, 2014, Gyrus ACMI is submitting the enclosed revised labeling materials to add to the Agency's records in the cleared 510(K) file (K080093). One paper copy and an electronic copy that is a duplicate of the paper copy are submitted for the Agency's records.

Specifically, the Instructions for Use (document 174003-EH) have been amended to exactly incorporate the language reflected in the Guidance Document. In addition, Gyrus ACMI conducted a review of other promotional and labeling materials and similarly incorporated the requested language where necessary. Copies of these labeling materials are also enclosed with this letter for inclusion in the Agency's K080093 file.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Terrence E. Sullivan
Executive Director, Regulatory Affairs

Enclosures

OLYMPUS SURGICAL TECHNOLOGIES AMERICA
Gyrus ACMI, Inc. • 136 Turnpike Road • Southborough, MA 01772 • USA
508.804.2600 • *Fax:* 508.804.2624 • www.olympus-osta.com

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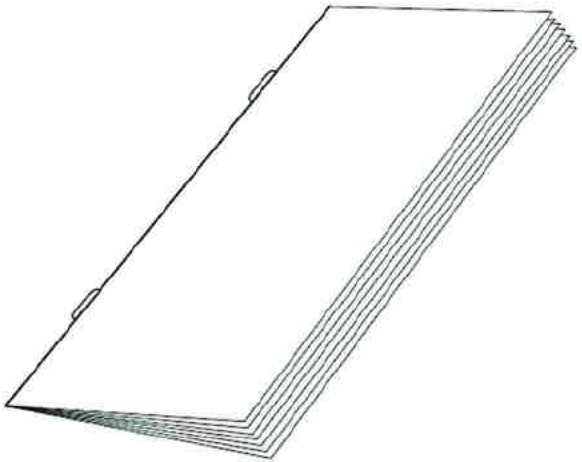
List of Attachments

Attachment 1: PKS PlasmaSORD Instructions for Use, document 174003 rev EH
Attachment 2: PKS PlasmaSORD Sell Sheet, document SS329-sord_0115
Attachment 3: PK Family Brochure, document 6906-PK family_0115
Attachment 4: Laparoscopic Hysterectomy Brochure, document BR316-LSH-TLH_0115
Attachment 5: PK Technology Product Catalog, document 02-pk-section

Attachment 1:
PKS PlasmaSORD Instructions for Use,
document 174003 rev EH

DRAWING REVISIONS	
REV	DESCRIPTION
	REFER TO PREVIOUS REVISION FOR OLD REVISIONS
EH	CO-305615 TEMPLATE CHANGED TO INDESIGN, FDA CAUTION ADDED TO PAGE 1 UNDER CONTRAINDICATIONS, TEXT FROM PAGE 3 MOVED TO PAGE 2, NEW WARNING ADDED PAGE 2, UP-REVED TO EH AND DATE CHANGED TO 2014-12 DRN / DATE: M MATTHEWS 22-DEC-2014



NOTES:
1. BOOKLET MADE UP OF 80 PRINTED PAGES FOLDED VERTICALLY & STAPLED TWICE IN THE FOLD
   FINISHED BOOKLET MEASURES 148 X 210mm ±1mm
2. REFER TO THE FOLLOWING PAGES FOR ARTWORK
3. FRONT PAGE TO BE IN COLOUR ONLY.
4. All DIMENSION +/- 1mm

MATERIAL
80 GRAM OPAQUE PAPER
RoHS ALL MATERIALS SPECIFIED ON THIS DRAWING MUST BE RoHS COMPLIANT

FINISH
CLEAN & FREE FROM VISIBLE PARTICULATES

DRAWN M MATTHEWS 22-DEC-2014

IF IN DOUBT ASK
REFER TO BS 8888:2011 | 3RD ANGLE | SIZE A3

DIMENSIONS IN MILLIMETRES [INCH]
TOLERANCE UNLESS SPECIFIED
X ± 0.2 [.006"] X.X ± 0.1 [.004"]
X.XX(X) ± 0.05 [.002"] ANGLES ± 0.5°

SCALE UNLESS SPECIFIED 1:1

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Fortran Road, St Mellons, Cardiff. UK. CF3 0LT
Tel: +44 (0)29 2077 6300 Fax: +44 (0)29 2077 6301

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DESCRIPTION
SORD INSTRUCTIONS FOR USE

SHEET	PART No	REV
1 of 81	174003	EH

GYRUS ACMI

PKS™ PLASMASORD™

Part No: 174003-EH
2014-12

CE 0344

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INTENTIONALLY.

GB USA

GYRUS ACMI

PKS™ PlasmaSORD™

REF 962000PK PKS™ PlasmaSORD™ w/cord

Instructions for use

IMPORTANT: This package insert is designed to provide instructions for use of the PKS PlasmaSORD instrument when used with the Gyrus ACMI G400 Workstation. It is not a reference to electrosurgical technique.

CAUTION

Rx only-Federal (USA) law restricts this device to sale by or on the order of a physician.

Read all instructions, including CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS prior to use. Failure to follow these instructions could result in serious patient injury.

INTENDED USE

The PKS PlasmaSORD, when used with the Gyrus ACMI G400 Workstation, is intended for cutting, coring and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures and laparoscopic gynecologic procedures.

CONTRAINDICATIONS

Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.

Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are:

- peri- or post-menopausal, or
- candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision.

The use of the Gyrus ACMI G400 Workstation is contraindicated when, in the judgment of the physician, bipolar electrosurgical procedures would be contrary to the best interests of the patient.

For patients with active electronic devices implanted, refer to the instructions for use for those devices before using bipolar electrosurgery.

WARNINGS

***WARNING:* Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.**

Please read all information carefully, including the user manual, which is provided with the Gyrus ACMI G400 Workstation prior to using the instrument. The workstation, generator footswitch and PKS PlasmaSORD are designed to be used together as a system. Failure to properly follow instructions may lead to electrical or thermal injury and result in improper functioning of the instrument.

Do not attempt to use this instrument with generators from other manufacturers. Use with generators other than the Gyrus ACMI G400 Workstation may result in injury to the user or patient.

Safe and effective electrosurgery is dependent upon factors under the control of the user. The user should be experienced in laparoscopic surgical techniques with electrosurgical equipment or obtain training prior to use.

Inappropriate use of electrosurgery instruments can cause damage to tissue, both electrically and thermally. This instrument should not be used in close proximity to tissue structures (including the bladder, bowel or abdominal wall) susceptible to damage in this way unless it is the intention to resect the tissue.

The PKS PlasmaSORD grasper teeth are sharp to allow tough tissue to be grasped. They can damage collateral tissue if due care is not taken. Only open the PKS PlasmaSORD grasper jaws in good visibility and when in close proximity to the target tissue.

Activation of the device when the distal tip is not in the field of view and may be in contact with the abdominal wall may result in stimulation of nervous tissue within the abdominal wall.

Keep the instrument tip in sight during use. Inadvertent activation or movement of the instrument outside the field of vision may result in patient injury. To prevent accidental injuries to the abdominal wall, bladder, bowel or other structures, or nerve stimulation, the tissue to be morcellated should be completely exposed and fixed to prevent large pieces of tissue from moving before applying the device. Depress the foot pedal to activate the device only when the distal tip is in the field of view.

If visualization of the treatment site or device is lost during the procedure, STOP IMMEDIATELY. Do not proceed until visibility is restored.

Although the PKS PlasmaSORD instrument has means to rapidly dissipate any heat that is generated during use, the instrument tip and the shaft immediately proximal to the tip may remain hot enough to cause damaged to tissue immediately after the electrosurgical current is deactivated. Avoid contact with sensitive tissue, including the abdominal port site, which may result in unintended thermal damage.

When not in use, the instrument should be placed in a clean non-conductive and highly visible area not in contact with the patient or other devices. Inadvertent activation while the morcellator or grasper are in contact with the patient or surgical personnel may result in burns.

Do not touch or clean the instrument tip when power is activated.

Do not use this instrument with insufflation gasses other than air or carbon dioxide.

As with all electrosurgical devices, the sparking and heating associated with electrosurgery has the potential for providing a source of ignition. Observe fire precautions at all times. Do not use in the presence of flammable anesthetics or oxidizing gases, such as nitrous oxide or oxygen. Endogenous gases which accumulate in body cavities can also be a source of ignition.

Do not place active accessories near or in contact with flammable materials (such as gauze or surgical drapes).

Do not use this device with tissue removal bags.

Flammable substances such as alcohol-based skin prepping agents and tinctures will contribute to increased fire and explosion hazard. Non-flammable agents should be used for cleaning and disinfection and solvents must be allowed to evaporate prior to the application of electrosurgery.

Do not activate the PKS PlasmaSORD instrument while adjacent to or in contact with metallic objects other than dedicated Gyrus ACMI grasper as unintended tissue injury, damage to the contacted object or instrument tip may occur.

Use only with the dedicated Gyrus ACMI grasper supplied with the morcellator, or genuine Gyrus ACMI grasper accessories intended for use with this device.

Do not wrap the connector cable around metal objects. Wrapping the connector cable around metal objects may induce currents that could lead to shock, fires, or injury to the patient or surgical personnel.

Do not attempt to remove the grasper cable from the grasper handle.

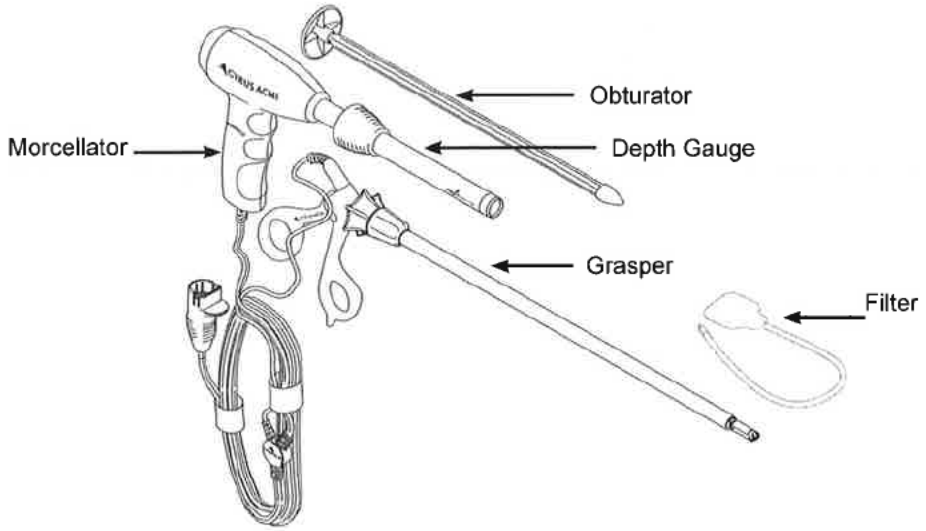
This product is for single-use only.
It has not been designed to be re-used or re-sterilized. Reprocessing may lead to changes in material characteristics such as metallic corrosion and dulled edges, ceramic and plastic deformation or splitting which may impact the strength of the device and compromise device performance. Reprocessing of single use devices can also cause cross-contamination leading to patient infection. These risks may potentially affect patient safety.

IMPORTANT: The contents are sterile unless the package is opened or damaged. Do not resterilize. If the product package is opened or damaged the instrument should be discarded and not used.

TRAINING

The PKS PlasmaSORD is recommended for use by surgeons experienced in laparoscopic electrosurgery. If you have any questions regarding the proper use of this device please contact your sales representative for in-servicing and / or training prior to the first use.

DEVICE DESCRIPTION



The PKS PlasmaSORD is an advanced bipolar electrosurgical instrument with the capability to cut and extract soft tissue in laparoscopic surgery. The instrument can be used directly or introduced through a separate 15mm cannula to access the operative site. The device consists of a Radio Frequency (RF) electrosurgical tissue morcellator, a dedicated and permanently connected grasper and an obturator. When used with the Gyrus ACMI G400 Workstation, the device can be used to remove tissue from the operative site by introducing the grasper through the morcellator working channel, grasping the target tissue and withdrawing it into the morcellator while activating the RF cutting output.

Morcellator
The morcellator consists of an active RF electrode mounted at the distal end of a working cannula. A handpiece allows for controlled positive grip and contains a sealing system to prevent excessive loss of insufflation during use. The cordset provides the RF connection from the workstation to both the morcellator and grasper

Grasper
The grasper is permanently connected to the morcellator to allow proper electrical function of the device.

Depth Gauge
A depth gauge is supplied with the instrument, but may be removed. This should only be used as an indicator. Care should always be taken to control insertion of the instrument. The gauge may be removed to allow use with separate cannulas.

Filter
A passive smoke evacuation filter is supplied to assist in the removal of smoke from the visual field by attaching to the luer lock of an available cannula. It is recommended to attach the filter to a cannula other than the one used for the morcellator.

CAUTIONS

Prior to initial use, ensure that all package inserts including warnings, cautions, and Instructions For Use (IFU) are read and understood. Safe and effective electrosurgery is dependent not only on equipment design, but also on factors under the control of the user (Refer to Gyrus ACMI G400 Workstation User Manual).

Ensure that the instrument connector(s) fully engage with the workstation socket prior to use. Avoid fluid contact with the proximal end of the instrument.

Ensure that the workstation settings are appropriate for the electrosurgery that is to be carried out.

Avoid unnecessary activation. This may result in excessive heating which could damage the instrument tip or could damage sensitive tissue structures brought into inadvertent contact with the instrument tip, or the shaft immediately proximal to the tip.

Ensure that the supplied obturator is fitted to the device for the obturation process and that the force applied is directed through the obturator and not applied directly to the handle of the device.

Excessive force applied to the handle will weaken the device and may cause damage or failure.

See sketches below for clarification.

✘ ✓

Ensure that the morcellator shaft is inserted far enough such that the entirety of the PK technology logo is visible and the tip is clear of the abdominal wall to prevent thermal tissue damage.

Do not attempt to bend the rigid shaft of this instrument. Attempting to bend the shaft may result in device failure.

Do not insert or withdraw the PKS PlasmaSORD morcellator shaft from the procedure site while power is activated.

If used with a separate cannula, ensure the tip of the PKS PlasmaSORD instrument is inserted sufficiently to extend beyond the cannula before and during activation. Do not activate while any portion of the tip is within the cannula sheath.

Only use insulated instruments and insulated cannulas.

Always ensure compatibility and use care when inserting / removing instruments through cannulas to avoid damage. As with other cannulas, opening the grasper within the shaft is not advised since this can damage the internal seal. If tissue is left within the device which cannot be cleaned by reintroducing the closed grasper, care should be taken when removing trapped tissue in the vicinity of the seal to avoid damage.

Carefully insert and withdraw the instrument to avoid possible instrument damage and/or injury to the patient or surgical personnel.

The patient should not be allowed to come in contact with grounded metal objects.

Do not use the Gyrus ACMI G400 Workstation concurrently with other electrosurgical generators.

Do not use abrasives or other aggressive means to clean the device tip.

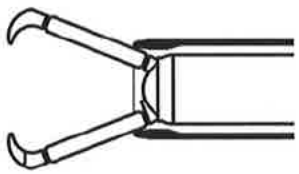
TISSUE EFFECTS
DEVICE APPLICATION

All RF electrosurgery produces vapor byproducts including smoke or steam which can obscure vision. It is recommended that this device is used with an appropriate smoke extraction system or other means to manage these byproducts if necessary.

A passive smoke filter is provided to assist in maintaining the visual field. Passive smoke filters tend to operate with greater efficiency when connected to a port other than that used for the morcellator. Refer to steps 7-9 under morcellator set-up section for appropriate usage.

GRASPER USAGE

As with other morcellator devices, care should be taken to ensure that the grasper has closed sufficiently to enter the shaft. Excess force should never be used to retract tissue. If resistance is felt as the grasper enters the shaft, the tissue should be re-grasped to promote better closure.



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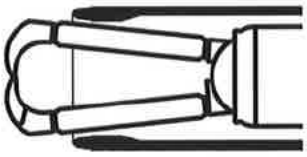


✓

If insufflation pressure is being lost through a leak from the morcellator, the valve may be damaged. It may be possible to assess if the valve is damaged by looking down the morcellator shaft. If damage is observed, ensure that any valve fragments are located and retrieved from the abdomen.

MORCELLATOR SETUP

1. Please refer to the Gyrus ACMI G400 Workstation User Manual for step-by-step instructions regarding the assembly and initial system check of the Gyrus ACMI G400 Workstation.
2. Turn on the Gyrus ACMI G400 Workstation. Follow the instructions in the workstation user manual.
3. The PKS PlasmaSORD and filter accessory are provided sterile for single use. Inspect packaging before use to ensure integrity of the sterile barrier.
4. Remove the PKS PlasmaSORD from the package. Inspect the device for damage. The device should not be used if there is any damage to the instrument or packaging. Do not use the device beyond the expiration date indicated on the label.
5. Connect the PKS PlasmaSORD to the workstation. Check that the connector is properly aligned with the sockets on the workstation before connecting.

   Software enablement may be required to use this instrument. If the device is not recognized when plugged in, contact your local Gyrus ACMI representative or customer service to ensure the proper version of the software is installed.
6. Confirm that the Gyrus ACMI G400 Workstation displays the correct instrument name. If a different name is displayed, contact Gyrus ACMI Customer Service and do not use the device.

   For safety and convenience, the PKS PlasmaSORD automatically presets the generator to appropriate output settings and restricts output levels to preserve electrode integrity.
7. If required, the passive smoke filter accessory should be attached to the luer lock connector of an available cannula. It is preferable to use a cannula other than that used for the morcellator.
8. The flow rate through the filter accessory can be controlled by adjusting the cannula's stopcock valve.
9. Position the head of the filter such that moisture condensing in the tube cannot migrate into the filter, since this may impair function.

MORCELLATOR INSERTION AND USE

1. Tissue for removal should be devascularized before morcellation.
2. The PKS PlasmaSORD should be carefully introduced to the operative site either directly or through a separate 15mm cannula as the physician deems appropriate. Care should be taken to avoid over insertion or other means which could result in damage to collateral tissue structures. Enlarge the incision at the existing port-site to ease insertion if necessary.

   Insert the PKS PlasmaSORD using the obturator under direct visualization. Ensure the obturator is fully inserted into the morcellator and apply continuous but controlled pressure with a deliberate rotating motion of approximately 180°.
3. Ensure the grasper jaws are closed when inserting them through the PKS PlasmaSORD working channel. As with any morcellator, care should be taken to avoid damage to collateral tissue and specific attention should be paid to the sharp grasper teeth.
4. Target tissue can now be grasped and retracted. Device activation using the yellow pedal will cut the tissue that comes into contact with the leading edge of the morcellator tube.

   Since the PKS PlasmaSORD achieves its effect using an electrical, non-mechanical cut, tissue resection is best achieved with a steady motion requiring little force. If resistance is felt or there is no cut effect after 5 seconds it is advisable to re-grasp the tissue and activate.

   Using excessive retraction force can lead to a greater incidence of tissue tearing.

   Build up of tissue coagulum at the tip can cause a noticeable reduction of the cutting effect. In such cases, wipe with gauze that has been moistened with sterile water. Replace the instrument if the problem persists. Do not use abrasives or other aggressive means to clean the device tip.

   Keep the instrument tip in sight during use. Inadvertent activation or movement of the instrument outside the field of vision may result in patient injury. To prevent accidental injuries to the abdominal wall, bladder, bowel or other structures, or nerve stimulation, the tissue to be morcellated should be completely exposed and fixed to prevent large pieces of tissue from moving before applying this device. Depress the foot pedal to activate the device only when the distal tip is in the field of view.

POST MORCELLATION

1. Disconnect the PKS PlasmaSORD from the workstation.

   CAUTION: Always detach by grasping the connector grips and not the cable. Failure to do so may result in product damage.

2. Turn off the workstation power.
3. Inspect the device immediately upon removal from the patient for any signs of breakage or fragmentation. If the device is damaged retain it to assist with the manufacturer's analysis of the event.
4. Dispose of all elements of the single-use instrument and accessories according to your facility's policy on the destruction of surgical waste.

HOW SUPPLIED

The PKS PlasmaSORD Instrument and accessories are supplied sterile for single use only.

STORAGE

Store below 25°C (77°F) away from moisture and direct heat. Do not use after use by date printed on the instrument label.

PKS™ and PlasmaSORD™ is a trademark of Gyrus ACMI, Inc., and/or its affiliated entities, in the U.S., and/or other countries.

SYMBOLS

STERILE EO	- Sterilized using Ethylene Oxide
LOT	- Lot Number
	- Keep away from Direct Sunlight
	- Keep Dry
	- Fragile, Handle with Care
QTY	- Represents the quantity of saleable units inside the package.
	- Represents the quantity of devices inside the package. # Numeral corresponds to the number of devices inside the package.
	- Storage Temperature Range (°C)
	- Single use only
	- Use by date shown
Manufactured for	- When a product is manufactured for Gyrus ACMI
Rx only	- **CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.
	- Do not use if package is damaged
	- ISO 7010-M002 Follow instructions for use

Manufactured in UK.

EC REP

Gyrus Medical Ltd.
Fortran Road, St Mellons
Cardiff CF3 0LT, UK.

Manufactured for:
Gyrus ACMI Inc.
136 Turnpike Road
Southborough
MA 01772-2104
USA

Customer Service
Customer Service: 1-888-524-7266
Technical Service: 1-800-621-3739
www.gyrusacmi.comctured in UK.

FR

GYRUS ACMI

PKS™ PlasmaSORD™

PKS™ PlasmaSORD™ réf. 962000PK avec cordon

Mode d'emploi

IMPORTANT : La documentation contenue dans l'emballage contient le mode d'emploi de l'instrument PKS PlasmaSORD utilisé en association avec la station de travail Gyrus ACMI G400. Il ne s'agit pas d'une référence à l'électrochirurgie.

ATTENTION

Rx only - Conformément à la législation fédérale américaine, ce dispositif ne peut être vendu que par un médecin ou sur prescription médicale.

Avant toute utilisation, lire toutes les instructions, y compris les CONTRE-INDICATIONS, les AVERTISSEMENTS et les PRÉCAUTIONS. Le non-respect de ces instructions pourrait causer de sérieux dommages au patient.

UTILISATION

Lorsqu'il est utilisé avec la station de travail Gyrus ACMI G400, l'instrument PKS PlasmaSORD est destiné à sectionner, évider et extraire des tissus dans le cadre d'opérations de chirurgie laparoscopique diverses, telles que les procédures de chirurgie laparoscopique générales, urologiques et gynécologiques.

CONTRE-INDICATIONS

Les bistouris électriques pour chirurgie laparoscopique sont contre-indiqués pour les chirurgies gynécologiques lorsque les tissus à fragmenter présentent une malignité suspectée ou avérée.

Les bistouris électriques pour chirurgie laparoscopique sont contre-indiqués pour le retrait de tissus utérins comprenant des léiomyomes suspectés chez les patientes qui sont :

- en prémémopause ou postmonopause, ou
- candidates à une ablation de tissus en bloc, par exemple, par le vagin ou l'incision effectuée pour une mini laparotomie.

L'utilisation de la station de travail Gyrus ACMI G400 est contre-indiquée lorsque, selon l'avis du médecin, une procédure d'électrochirurgie bipolaire serait contraire à l'intérêt du patient.

Pour les patients disposant d'un dispositif électronique actif implanté, se reporter à son mode d'emploi avant d'envisager une procédure d'électrochirurgie bipolaire.

AVERTISSEMENTS

***MISE EN GARDE :* Le tissu utérin peut être cancéreux sans qu'on le sache. L'utilisation de bistouris électriques pour chirurgie laparoscopique lors d'une myomectomie peut propager le cancer et réduire la survie à long terme des patientes. Cette information doit être communiquée aux patientes lorsqu'une chirurgie impliquant l'utilisation de ces appareils est envisagée.**

Avant d'utiliser cet instrument, lire attentivement toutes les informations, y compris le manuel d'utilisation fourni avec la station de travail Gyrus ACMI G400. La station de travail, la pédale du générateur et l'instrument PKS PlasmaSORD ont été conçus pour être utilisés comme un système entier. Le non-respect des instructions risque d'entraîner des lésions d'origine électrique ou thermique et de provoquer le dysfonctionnement de l'instrument.

Ne pas utiliser cet instrument avec un générateur d'une autre marque. L'utilisation de générateurs autres que la station de travail Gyrus ACMI G400 peut causer des blessures pour le patient ou l'utilisateur.

L'efficacité et la sécurité de l'électrochirurgie dépendent de facteurs associés à l'utilisateur. L'utilisateur doit être familier avec les techniques de chirurgie laparoscopique ayant recours à un équipement électrochirurgical. Si ce n'est pas le cas, il doit suivre une formation.

L'utilisation inappropriée d'instruments d'électrochirurgie peut causer des lésions d'origine électrique et thermique aux tissus. Cet instrument ne doit pas être utilisé à proximité réduite de structures tissulaires (telles que la vessie, l'intestin ou la paroi abdominale) susceptibles d'être endommagées à moins que l'opération ne vise à réséquer ces tissus.

Les mors de l'extracteur PKS PlasmaSORD sont tranchants pour pouvoir agripper les tissus durs. Ils peuvent endommager les tissus collatéraux si cette opération n'est pas effectuée avec la précaution requise. N'ouvrir les mors de l'extracteur PKS PlasmaSORD que dans des conditions de bonne visibilité et à proximité du tissu cible.

Lorsque l'extrémité distale de l'instrument ne se trouve pas dans le champ de vision et qu'elle risque d'entrer en contact avec la paroi abdominale, la mise sous tension de l'instrument peut entraîner la stimulation des tissus nerveux de cette paroi abdominale.

Ne pas perdre de vue l'extrémité de l'instrument au cours de l'intervention. Une activation ou un mouvement accidentel de l'instrument en dehors du champ de vision risque de blesser le patient. Pour éviter toute stimulation nerveuse ou lésion accidentelle de la paroi abdominale, de la vessie, de l'intestin ou d'autres structures, le tissu à morceler doit être complètement exposé et immobilisé afin d'éviter le déplacement de grands morceaux de tissus avant la mise en place de l'instrument. Appuyer sur la pédale pour activer l'instrument, et ce, uniquement lorsque l'extrémité distale se trouve dans le champ de vision.

Si la visualisation du site d'intervention ou de l'instrument est momentanément impossible au cours de la procédure, CESSER IMMÉDIATEMENT TOUTE UTILISATION. Attendre que la visibilité soit restaurée avant de continuer.

Bien que l'instrument PKS PlasmaSORD soit capable de dissiper rapidement la chaleur générée au cours de son utilisation, son extrémité et le corps immédiatement en amont de l'extrémité risquent de rester suffisamment chauds pour causer des lésions au tissu

tout de suite après la désactivation du courant électrochirurgical. Éviter tout contact avec les tissus sensibles, notamment le site d'accès abdominal, car cela pourrait causer des lésions involontaires d'origine thermique.

Lorsqu'il n'est pas utilisé, placer l'instrument sous tension dans un endroit propre, non conducteur et bien visible, suffisamment éloigné du patient et des autres dispositifs. L'activation accidentelle de l'instrument peut causer des brûlures si le bistouri électrique ou l'extracteur est en contact avec le patient ou le personnel participant à l'intervention.

Ne pas toucher ni nettoyer l'extrémité de l'instrument lorsqu'il est sous tension.

Ne pas utiliser cet instrument avec des gaz d'insufflation autres que l'air ou le dioxyde de carbone.

Comme pour tous les instruments électrochirurgicaux, la décharge disruptive et l'échauffement associés à l'électrochirurgie peuvent créer une source d'inflammation. Observer en permanence les précautions anti-incendie. Ne pas utiliser en présence d'anesthésiques inflammables ou de gaz comburants, tels que l'oxyde nitreux ou l'oxygène. Les gaz endogènes s'accumulant dans les cavités corporelles peuvent également être une source d'inflammation.

Ne pas placer d'accessoires activés à proximité ou au contact de matériaux inflammables (tels que de la gaze ou des champs opératoires).

Ne pas utiliser cet instrument avec des sachets d'extraction des tissus.

Des substances inflammables telles que les teintures et les agents de préparation de la peau à base d'alcool augmentent les risques d'incendie et d'explosion. Utiliser des agents ininflammables pour le nettoyage et la désinfection. Laisser les solvants s'évaporer avant d'effectuer une intervention électrochirurgicale.

Ne pas activer l'instrument PKS PlasmaSORD lorsqu'il se trouve à proximité ou au contact d'objets métalliques autres que l'extracteur Gyrus ACMI pour ne pas entraîner de lésions tissulaires accidentelles, ni endommager l'objet en contact ou l'extrémité de l'instrument.

Utiliser uniquement avec l'extracteur Gyrus ACMI fourni avec le bistouri électrique ou des accessoires pour extracteur Gyrus spécialement conçus pour être utilisés avec l'instrument.

Ne pas enrouler le câble de raccordement autour d'objets métalliques. Ceci pourrait induire des courants et provoquer ainsi des commotions électriques ou des incendies, voire même blesser le patient ou le personnel participant à l'intervention.

Ne pas tenter de retirer le câble de la poignée de l'extracteur.

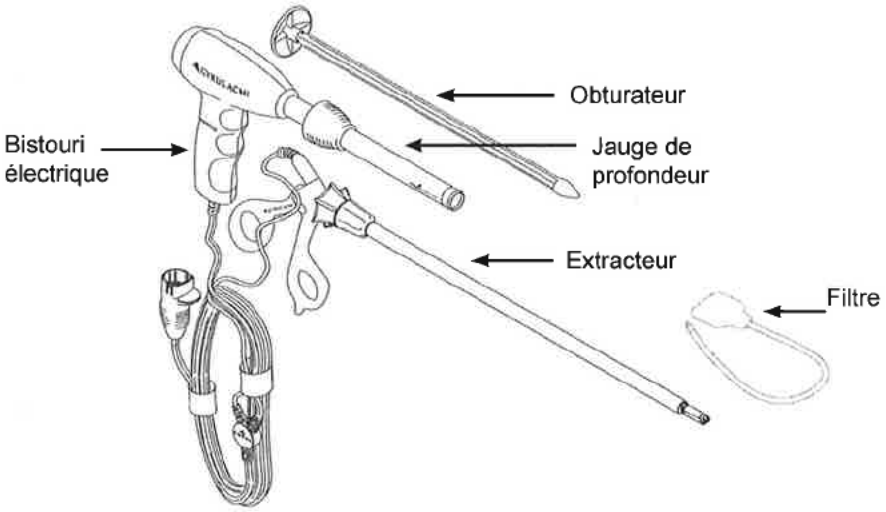
Ce produit est seulement à usage unique.
Il n'est pas conçu pour être réutilisé ou restérilisé. Le retraitement risquerait d'entraîner une modification de ses caractéristiques matérielles, comme la corrosion métallique et l'émoussement des bords, la déformation ou la cassure des parties en céramique ou en plastique pouvant affecter la résistance du dispositif et compromettre ses performances. Le retraitement des dispositifs à usage unique peut également entraîner une contamination croisée et l'infection du patient. Ces risques représentent un danger potentiel pour le patient.

IMPORTANT : Le contenu demeure stérile tant que l'emballage n'a pas été ouvert ou endommagé. Ne pas restériliser. Si l'emballage du produit est ouvert ou endommagé, ne pas utiliser l'instrument et le jeter.

FORMATION

L'utilisation du PSK PlasmaSORD n'est recommandée que pour les chirurgiens expérimentés dans les interventions d'électrochirurgie laparoscopique. Si vous avez des questions concernant l'utilisation correcte de ce dispositif, consulter votre représentant commercial pour demander une démonstration d'utilisation et/ou une formation avant la première utilisation.

DESCRIPTION DU DISPOSITIF



L'instrument PKS PlasmaSORD est un instrument d'électrochirurgie bipolaire avancée présentant la capacité de sectionner et d'extraire des tissus mous dans le cadre d'une intervention de chirurgie laparoscopique. Il peut être utilisé directement ou introduit à travers une canule distincte de 15 mm pour accéder au site opératoire. L'instrument se compose d'un bistouri d'électrochirurgie à radiofréquence, d'un extracteur associé fixé de manière permanente et d'un obturateur. Lorsqu'il est utilisé avec la station de travail Gyrus ACMI G400, l'instrument permet d'extraire des tissus du site opératoire en introduisant l'extracteur dans le canal de travail du bistouri, en saisissant les tissus cibles et en les extrayant vers le bistouri électrique, le sectionnement étant activé par radiofréquence.

Bistouri électrique
Le bistouri électrique comprend une électrode à radiofréquence active à l'extrémité distale de la canule de travail. Une poignée offre un assemblage indesserrable contrôlé et comprend un système d'obturation permettant d'éviter une perte excessive d'insufflation au cours de l'intervention. Le cordon transmet le courant de radiofréquence depuis la station de travail vers le bistouri électrique et l'extracteur.

Extracteur
L'extracteur est assemblé définitivement au bistouri électrique afin d'assurer un fonctionnement électrique correct de l'instrument.

Jauge de profondeur
Une jauge de profondeur est fournie avec l'instrument. Elle est amovible. Elle doit uniquement servir d'indicateur. Toujours surveiller avec précaution l'insertion de l'instrument. Il est possible de retirer la jauge pour permettre l'utilisation de canules distinctes.

Filtre
Un filtre passif d'évacuation de fumée peut être fixé à l'embout Luer lock d'une canule disponible afin de libérer le champ de vision. Il est recommandé de fixer le filtre à une canule autre que celle utilisée par le bistouri électrique.

MISES EN GARDE

Avant l'utilisation initiale, s'assurer d'avoir lu et compris toute la documentation contenue dans l'emballage, y compris les avertissements, les mises en garde et le mode d'emploi. Une intervention d'électrochirurgie sûre et efficace dépend non seulement de la fiabilité des équipements, mais également de différents facteurs dépendants du contrôle de l'utilisateur (voir le manuel d'utilisation de la station de travail Gyrus ACMI G400).

Avant l'utilisation, s'assurer que le ou les connecteurs de l'instrument sont entièrement engagés dans la prise de la station de travail. Empêcher l'extrémité proximale de l'instrument d'entrer en contact avec du liquide.

S'assurer que les réglages de la station de travail sont adaptés à l'intervention d'électrochirurgie à réaliser.

Éviter toute activation inutile. Cela pourrait causer un échauffement excessif qui endommagerait l'extrémité de l'instrument ou les structures tissulaires sensibles entrées accidentellement en contact avec l'extrémité ou le corps immédiatement en amont de l'extrémité.

S'assurer que l'obturateur fourni est monté sur le dispositif pour la procédure d'obturation et que la force appliquée est transmise via l'obturateur au lieu d'être directement exercée sur la poignée du dispositif.

L'application d'une force excessive sur la poignée affaiblira le dispositif et pourra entraîner des dommages ou une défaillance.

Voir les illustrations ci-dessous pour plus de précisions.

✗ ✓

S'assurer que le corps du bistouri électrique est inséré suffisamment loin de sorte que l'intégralité du logo de la technologie PK soit visible et que son extrémité ne soit pas à proximité de la paroi abdominale pour éviter toute lésion thermique des tissus.

Ne pas tenter de courber le corps rigide de l'instrument. Toute courbure du corps de l'instrument risque de l'endommager.

Ne pas introduire ni extraire le corps du bistouri électrique PKS PlasmaSORD du site opératoire lorsqu'il est sous tension.

Si une canule distincte est utilisée, s'assurer que l'extrémité de l'instrument PKS PlasmaSORD est suffisamment insérée de façon à dépasser la canule avant et pendant l'activation. Ne pas activer l'instrument si son extrémité se trouve dans la gaine de la canule.

N'utiliser que des instruments isolés et des canules isolées.

Pour éviter tout dommage, vérifier les compatibilités et procéder avec précaution lors de l'insertion ou du retrait de l'instrument des canules. De même que pour les autres canules, l'ouverture de l'extracteur dans le corps de l'instrument est déconseillée car cela pourrait endommager le revêtement étanche interne. Si des tissus sont restés à l'intérieur du dispositif et qu'il est impossible de les retirer en introduisant l'extracteur fermé, procéder avec précaution lors de l'accès dans le corps de l'instrument pour retirer ces tissus.

Introduire et extraire l'instrument avec précaution pour ne pas l'endommager et / ou ne pas blesser le patient ou le personnel intervenant.

Le patient ne doit jamais être en contact avec des objets métalliques reliés à la masse.

Ne pas utiliser la station de travail Gyrus ACMI G400 en même temps que d'autres générateurs électrochirurgicaux.

Ne pas utiliser de substances abrasives ou d'autres moyens agressifs pour nettoyer l'extrémité de l'instrument.

EFFETS SUR LES TISSUS
APPLICATION DU DISPOSITIF

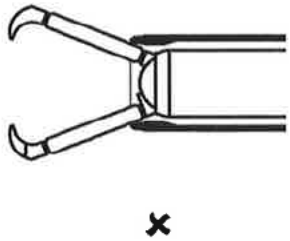
Toute intervention d'électrochirurgie à radiofréquence produit de la fumée ou de la vapeur pouvant entraver la visibilité. Il est donc recommandé d'utiliser un système

d'évacuation des fumées approprié ou tout autre moyen permettant de prendre en charge ces émissions, si nécessaire.

Un filtre à fumée passif est fourni pour maintenir un bon champ de vision. Les filtres à fumée passifs tendent à fonctionner plus efficacement lorsqu'ils sont connectés à un port autre que celui utilisé pour le bistouri électrique. Se référer aux étapes 7 à 9 de la section Préparation du bistouri électrique pour savoir comment l'utiliser de façon appropriée.

UTILISATION DE L'EXTRACTEUR

De la même façon qu'avec les bistouris électriques, veiller à ce que l'extracteur soit suffisamment fermé avant son introduction dans le corps. Ne jamais forcer lors de l'extraction des tissus. Si une résistance se fait sentir au moment où l'extracteur entre dans le corps de l'instrument, saisir à nouveau le tissu pour mieux fermer l'extracteur.



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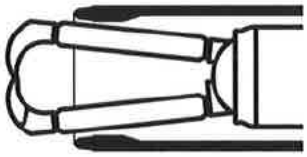

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Si la pression d'insufflation diminue en raison d'une fuite dans le bistouri électrique, il est alors possible que la valve soit endommagée. Inspecter le corps du bistouri électrique pour déterminer si la valve est endommagée. Si c'est le cas, s'assurer de repérer les fragments de la valve endommagée et de les enlever de l'abdomen.

PRÉPARATION DU BISTOURI ÉLECTRIQUE

1. Consulter le manuel d'utilisation de la station de travail Gyrus ACMI G400 pour obtenir des instructions étape par étape sur l'assemblage et les vérifications initiales de la station de travail Gyrus ACMI G400.
2. Mettre sous tension la station de travail Gyrus ACMI G400. Suivre les instructions fournies dans le manuel d'utilisation de la station de travail.
3. L'instrument PKS PlasmaSORD et le filtre sont fournis stériles et à usage unique. Avant toute utilisation, inspecter l'emballage pour vérifier l'intégrité de la barrière stérile.
4. Sortir l'instrument PKS PlasmaSORD de l'emballage. Vérifier l'absence de dommages. Ne pas utiliser si l'instrument ou l'emballage est endommagé. Ne pas utiliser l'instrument au-delà de la date de péremption indiquée sur l'étiquette.
5. Raccorder l'instrument PKS PlasmaSORD à la station de travail. Vérifier que le connecteur est correctement aligné avec les prises de la station de travail avant de le brancher.

   L'activation du logiciel peut être requise pour utiliser cet instrument. Si l'instrument n'est pas reconnu par l'appareil, contacter votre représentant Gyrus ACMI local ou le service clientèle pour vérifier que la version du logiciel installé est correcte.
6. S'assurer que la station de travail Gyrus ACMI G400 affiche le nom correct de l'instrument. Si un autre nom apparaît, contacter le service clientèle de Gyrus ACMI et ne pas utiliser l'instrument.

   Par souci pratique et pour des raisons de sécurité, l'instrument PKS PlasmaSORD configure automatiquement la station de travail selon les réglages par défaut et restreint les niveaux de courant de sortie pour conserver l'intégrité de l'électrode.
7. Si nécessaire, fixer le filtre à fumée passif au connecteur Luer lock d'une canule disponible. Il est recommandé d'utiliser une canule autre que celle utilisée par le bistouri électrique.
8. Le débit d'évacuation de fumée passant par le filtre est réglable à partir du robinet de la canule.
9. Positionner la tête du filtre de façon à ce que la condensation créée dans le tube ne migre pas dans le filtre car cela gênerait son fonctionnement.

INSERTION ET UTILISATION DU BISTOURI ÉLECTRIQUE

1. Avant le morcellement, le tissu à extraire doit être dévascularisé.
2. Introduire avec précaution l'instrument PKS PlasmaSORD dans le site opératoire soit directement, soit à travers une canule distincte de 15 mm, à la discrétion du médecin. Procéder avec précaution pour éviter une insertion excessive ou d'autres actions pouvant causer des lésions dans les structures tissulaires collatérales. Agrandir l'incision au niveau du site existant pour faciliter l'insertion, si nécessaire.

   Insérer l'instrument PKS PlasmaSORD en utilisant l'obturateur sous visualisation directe. S'assurer que l'obturateur est totalement inséré dans le bistouri électrique et appliquer une pression continue et contrôlée avec un mouvement délibéré de rotation d'environ 180°.
3. S'assurer que les mors de l'extracteur sont fermés quand ils sont insérés dans le canal interventionnel du PKS PlasmaSORD. De même qu'avec le bistouri, procéder avec précaution pour éviter toute lésion des tissus collatéraux, en faisant particulièrement attention aux mors tranchants de l'extracteur.
4. Le tissu cible peut désormais être saisi et extrait. L'activation de l'instrument avec la pédale jaune sectionne le tissu en contact avec l'extrémité du bistouri électrique.

   L'instrument PKS PlasmaSORD fonctionnant de manière électrique et non mécanique, une meilleure résection des tissus sera obtenue en appliquant un mouvement constant nécessitant une faible force. Si une résistance se fait sentir ou qu'aucun sectionnement ne se produit après 5 secondes, il est recommandé de saisir à nouveau le tissu et d'activer l'instrument.

   Une force d'extraction excessive risque d'entraîner le déchirement des tissus.

   L'accumulation de tissus sur l'extrémité peut entraîner une réduction notable du sectionnement. Dans ce cas, nettoyer à l'aide d'une gaze humidifiée avec de l'eau stérile. Si le problème persiste, remplacer l'instrument. Ne pas utiliser de substances abrasives ou d'autres moyens agressifs pour nettoyer l'extrémité de l'instrument.

   Ne pas perdre de vue l'extrémité de l'instrument au cours de l'intervention. Une activation ou un mouvement accidentel de l'instrument en dehors du champ de vision risque de blesser le patient. Pour éviter toute stimulation nerveuse ou lésion accidentelle de la paroi abdominale, de la vessie, de l'intestin ou d'autres structures, le tissu à morceler doit être complètement exposé et immobilisé afin d'éviter le déplacement de grands morceaux de tissus avant la mise en place de l'instrument. Appuyer sur la pédale pour activer l'instrument, et ce, uniquement lorsque l'extrémité distale se trouve dans le champ de vision.

APRÈS L'UTILISATION DU BISTOURI ÉLECTRIQUE

1. Débrancher l'instrument PKS PlasmaSORD de la station de travail.

   ATTENTION : Toujours débrancher le cordon en saisissant les passe-mains du connecteur. Ne jamais tirer sur le câble lui-même. Le non-respect de cette consigne risque d'endommager le produit.

2. Mettre la station de travail hors tension.
3. Inspecter le dispositif dès son retrait du corps du patient à la recherche d'éventuels signes de rupture ou de fragmentation. Si le dispositif est endommagé, le conserver pour aider le fabricant à analyser la situation.
4. Mettre au rebut tous les composants de l'instrument et des accessoires jetables selon les directives de l'établissement concernant la destruction des déchets chirurgicaux.

PRÉSENTATION

L'instrument PKS PlasmaSORD et les accessoires sont fournis stériles et à usage unique.

CONSERVATION

Conserver à une température inférieure à 25 °C (77 °F), à l'abri de l'humidité et des sources de chaleur directes. Ne pas utiliser après la date limite d'utilisation figurant sur l'étiquette de l'instrument.

PKS™ et PlasmaSORD™ sont des marques de commerce de Gyrus ACMI, Inc. et/ou de ses filiales, aux États Unis et/ou dans d'autres pays.

SYMBOLES

STERILE EO	- Stérilisé à l'oxyde d'éthylène
LOT	- Numéro de lot
	- Tenir à l'abri de la lumière directe
	- Tenir à l'abri de l'humidité
	- Fragile - Manipuler avec précaution
QTY	- Indique la quantité d'unités commercialisables à l'intérieur de l'emballage.
	- Indique la quantité de dispositifs à l'intérieur de l'emballage. # Chiffre correspondant au nombre de dispositifs à l'intérieur de l'emballage.
	- Plage de températures de stockage (°C)
	- À usage unique
	- Date de péremption
Manufactured for	- Indique qu'un produit est fabriqué pour Gyrus ACMI
Rx only	- **ATTENTION :** Conformément à la législation fédérale américaine, ce dispositif ne peut être vendu que par un médecin ou sur prescription médicale.
	- Ne pas utiliser si l'emballage est endommagé
	- ISO 7010-M002 Suivre les consignes d'utilisation

Fabriqué au Royaume-Uni.

EC REP

Gyrus Medical Ltd.
Fortran Road, St Mellons
Cardiff CF3 0LT, Royaume-Uni.

Fabriqué pour :
Gyrus ACMI Inc.
136 Turnpike Road
Southborough
MA 01772-2104
États-Unis

Service clientèle
Service clientèle : 1-888-524-7266
Service technique : 1-800-621-3739
www.gyrusacmi.com

DE

GYRUS ACMI

PKS™ PlasmaSORD™

REF 962000PK PKS™ PlasmaSORD™ mit Kabel

Gebrauchsanweisung

WICHTIG: In dieser Packungsbeilage werden Anweisungen für die Verwendung des PKS PlasmaSORD Instruments in Verbindung mit dem Gyrus ACMI G400 Generator bereitgestellt. Sie dient nicht als Referenz für elektrochirurgische Verfahrenstechniken.

VORSICHT

Rx only-Laut Bundesgesetz der USA darf diese Vorrichtung ausschließlich an einen Arzt oder auf dessen Anordnung verkauft werden.

Vor Gebrauch alle Anweisungen, einschließlich KONTRAINDIKATIONEN, WARNHINWEISEN UND VORSICHTSMASSNAHMEN, gründlich lesen. Nichtbeachtung dieser Anweisungen kann schwerwiegende Verletzungen des Patienten zur Folge haben.

VERWENDUNGSZWECK

Das PKS PlasmaSORD Instrument ist in Verbindung mit dem Gyrus ACMI G400 Generator für Gewebeschnitte, -stanzen und -entnahmen bei verschiedenen operativen laparoskopischen Verfahren vorgesehen, einschließlich allgemeinen chirurgischen Laparoskopien sowie urologischen und gynäkologischen Laparoskopien.

KONTRAINDIKATIONEN

Motorbetriebene laparoskopische Morcellatoren sind kontraindiziert bei gynäkologischen operativen Eingriffen, wo bekannt ist oder der Verdacht besteht, dass das zu morcellierende Gewebe eine Malignität enthält.

Motorbetriebene laparoskopische Morcellatoren sind kontraindiziert zur Resektion von Uterusgewebe, bei dem Verdacht auf vorhandene Fibroide besteht, bei:

- Patientinnen in der Peri- oder Postmenopause oder
- Kandidatinnen für eine En-bloc-Geweberesektion, beispielsweise durch die Vagina oder durch eine Minilaparotomie.

Die Verwendung des Gyrus ACMI G400 Generators ist kontraindiziert, wenn nach Ermessen des Arztes ein bipolares elektrochirurgisches Verfahren nicht im besten Interesse des Patienten liegt.

Bei Patienten mit aktiven elektronischen Implantaten müssen vor der Anwendung von bipolarer Elektrochirurgie die Gebrauchsanweisungen der jeweiligen Implantate zu Rate gezogen werden.

WARNHINWEISE

WARNUNG: **Uterusgewebe kann unverdächtige Krebszellen enthalten. Die Verwendung eines motorbetriebenen laparoskopischen Morcellators bei einer operativen Fibroidresektion kann die Krebszellen verbreiten und die langfristige Lebenserwartung der Patientinnen verkürzen. Patientinnen müssen hierüber informiert werden, wenn sie einen operativen Eingriff unter Verwendung dieser Vorrichtungen erwägen.**

Vor dem Gebrauch dieses Instruments alle Informationen sorgfältig lesen, einschließlich der mit dem Gyrus ACMI G400 Generator gelieferten Bedienungsanleitung. Der Generator, der Fußschalter des Generators und das PKS PlasmaSORD Instrument sind für die gemeinsame Verwendung als System konzipiert. Eine Nichtbeachtung der Anweisungen kann zu Verletzungen durch Elektrizität oder Verbrennungen führen und die Funktionsfähigkeit des Instruments beeinträchtigen.

Dieses Instrument nicht mit Generatoren anderer Hersteller verwenden. Die Verwendung mit anderen Generatoren als dem Gyrus ACMI G400 kann zu Verletzungen des Arztes bzw. des Patienten führen.

Sichere und wirkungsvolle Elektrochirurgie hängt von Faktoren ab, die der Kontrolle des Arztes unterliegen. Der Arzt muss in der Durchführung chirurgischer Laparoskopien mit elektrochirurgischer Ausrüstung geschult sein oder vor dem Gebrauch eine entsprechende Schulung erhalten.

Eine unsachgemäße Verwendung von elektrochirurgischen Instrumenten kann Gewebeschäden durch Elektrizität bzw. durch Verbrennungen hervorrufen. Um solche Schäden möglichst zu vermeiden, darf dieses Instrument nur dann in unmittelbarer Nähe von Gewebestrukturen (z. B. Blase, Darm oder Bauchdecke) verwendet werden, wenn das Gewebe resektiert werden soll.

Die Klemmbacken des PKS PlasmaSORD Greifers sind so scharf, dass sie auch festes Gewebe greifen können. Daher kann benachbartes Gewebe verletzt werden, wenn sie nicht mit größter Vorsicht gehandhabt werden. Die Klemmbacken des PKS PlasmaSORD Greifers erst dann öffnen, wenn sie gut sichtbar und in direkter Nähe des Zielgewebes sind.

Eine Aktivierung der Vorrichtung, solange sich die distale Spitze nicht im Sichtfeld befindet und möglicherweise in Kontakt mit der Bauchdecke ist, kann zur Stimulation von Nervengewebe in der Bauchdecke führen.

Die Instrumentenspitze während der Verwendung immer im Sichtfeld halten. Eine unbeabsichtigte Aktivierung oder Bewegung des Instruments außerhalb des Sichtfelds kann zu Verletzungen des Patienten führen. Zur Vermeidung von versehentlichen Verletzungen der Bauchdecke, der Blase, des Darms und anderer Gewebestrukturen sowie von unbeabsichtigter Nervenstimulation sollte das Gewebe, an dem der Morcellator angewendet werden soll, vollständig freigelegt und fixiert werden, um zu verhindern, dass sich größere Gewebeteile vor Anwendung der Vorrichtung verschieben. Den Fußschalter zur Aktivierung der Vorrichtung nur dann betätigen, wenn sich die distale Spitze im Sichtfeld befindet.

Wenn während des Verfahrens die Visualisierung der Eingriffsstelle oder der Vorrichtung verloren geht, DAS VERFAHREN SOFORT ABBRECHEN. Erst fortfahren, wenn die Sichtbarkeit wiederhergestellt ist.

Das PKS PlasmaSORD Instrument ist zwar dahingehend ausgestattet, dass beim Gebrauch entstehende Wärme schnell abgeleitet wird, aber die Instrumentenspitze und der Schaft direkt proximal zur Spitze können unmittelbar nach Deaktivierung des elektrochirurgischen Stroms noch heiß genug sein, um Schäden am Gewebe zu verursachen. Kontakt mit empfindlichem Gewebe, einschließlich der abdominalen Eintrittsstelle, vermeiden, da ansonsten unbeabsichtigte Verbrennungen die Folge sein können.

Zwischen den Anwendungen muss das Instrument an einem sauberen und trockenen, nicht leitenden und gut sichtbaren Ort vom Patienten und anderen Vorrichtungen entfernt aufbewahrt werden. Eine versehentliche Aktivierung des Instruments, während Kontakt zwischen dem Morcellator oder Greifer und dem Patienten oder OP-Personal besteht, kann zu Verbrennungen führen.

Die Spitze des Instruments nicht berühren oder reinigen, während der Strom aktiviert ist.

Dieses Instrument nicht mit anderen Insufflationsgasen als Luft oder Kohlendioxid verwenden.

Wie bei allen elektrochirurgischen Geräten stellt die mit Elektrochirurgie verbundene Funkenbildung und Erhitzung eine Feuergefahr dar. Stets die entsprechenden Brandvorschriften beachten. Nicht in der Nähe entflammbarer Betäubungsmittel oder oxidierender Gase wie Stickstoffoxid oder Sauerstoff verwenden. Endogene Gase, die sich in Körperhöhlen ansammeln, können ebenfalls entzündlich sein.

Keine aktiven Zubehörteile in der Nähe von oder in Kontakt mit entflammbaren Materialien ablegen (z. B. Gaze oder chirurgischen Abdeckungen).

Diese Vorrichtung nicht mit Beuteln zur Gewebeentfernung verwenden.

Entflammbare Substanzen wie auf Alkohol basierende Hautvorbereitungsmittel und Tinkturen tragen ebenfalls zu erhöhter Feuer- und Explosionsgefahr bei. Zur Reinigung und Desinfektion müssen nicht entflammbare Mittel verwendet werden. Lösungsmittel müssen vor der Anwendung von Elektrochirurgie verdunsten können.

Das PKS PlasmaSORD Instrument nicht aktivieren, während es sich in der Nähe von oder in Kontakt mit anderen metallischen Objekten als dem zugehörigen Gyrus ACMI Greifer befindet, um versehentliche Gewebeverletzungen, Schäden am anderen Objekt oder an der Instrumentenspitze auszuschließen.

Nur den zugehörigen, mit dem Morcellator gelieferten Gyrus ACMI Greifer oder Original-Zubehörteile für den Gyrus ACMI Greifer verwenden, die für die Verwendung mit dieser Vorrichtung vorgesehen sind.

Das Verbindungskabel nicht um Metallobjekte wickeln. Dadurch können Strombahnen entstehen, die elektrischen Schock, Feuer und Verletzungen des Patienten oder OP-Personals verursachen können.

Nicht versuchen, das Kabel des Greifers vom Griff des Greifers zu entfernen.

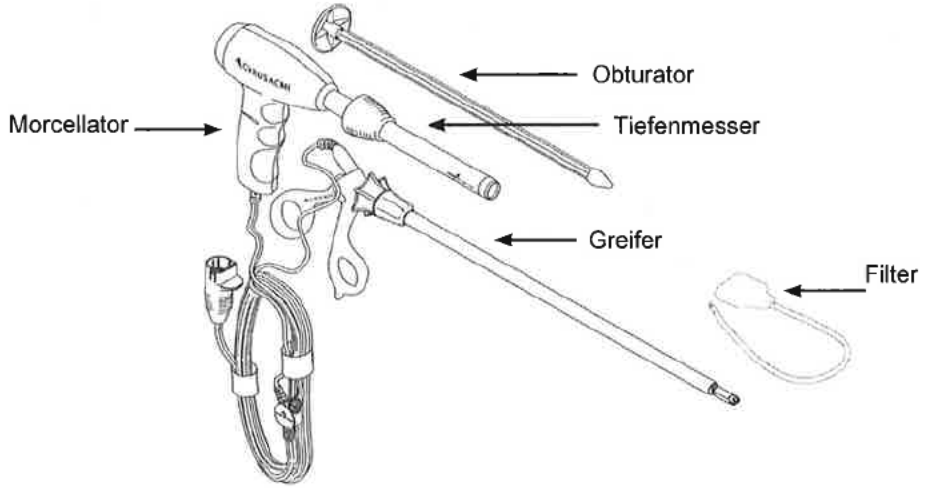
Diese Vorrichtung ist nur zum einmaligen Gebrauch vorgesehen.
Sie darf nicht wiederverwendet oder resterilisiert werden. Eine Wiederaufbereitung kann zur Veränderung von Materialeigenschaften führen, wie z. B. Metallkorrosion, Abstumpfung, Bruch oder Verformung von Keramik- und Plastikelementen, wodurch möglicherweise die Leistungsfähigkeit des Geräts beeinträchtigt wird. Die Wiederaufbereitung von für den einmaligen Gebrauch vorgesehenen Vorrichtungen kann außerdem eine Querkontamination verursachen, die bei Patienten zu Infektionen führt und deren Sicherheit gefährdet.

WICHTIG: Bei ungeöffneter und unbeschädigter Verpackung ist der Inhalt steril. Nicht resterilisieren. Wenn die Verpackung des Produkts geöffnet oder beschädigt ist, darf das Instrument nicht verwendet werden, sondern muss entsorgt werden.

EINWEISUNG

Das PKS PlasmaSORD ist für die Verwendung durch Ärzte mit entsprechender Erfahrung in der laparoskopischen Elektrochirurgie empfohlen. Falls Sie Fragen hinsichtlich der ordnungsgemäßen Verwendung dieser Vorrichtung haben, wenden Sie sich bitte an Ihren Außendienstmitarbeiter, um eine praktische Einweisung und/oder Schulung vor dem ersten Gebrauch zu erhalten.

BESCHREIBUNG DER VORRICHTUNG



Das PKS PlasmaSORD ist ein hochentwickeltes bipolares elektrochirurgisches Instrument, mit dem bei laparosokopischen Eingriffen Weichgewebe geschnitten und entnommen werden kann. Das Instrument kann direkt angewendet oder durch eine separate 15-mm-Kanüle eingeführt werden, um die Eingriffsstelle zu erreichen. Die Vorrichtung besteht aus einem elektrochirurgischen Hochfrequenz (HF)-Gewebe-Morcellator, einem zugehörigen, fest verbundenen Greifer und einem Obturator. Bei Verwendung mit dem Gyrus ACMI G400 Generator kann die Vorrichtung dazu dienen, Gewebe von der Eingriffsstelle zu entfernen. Dazu wird der Greifer durch

den Arbeitskanal des Morcellators geführt und das Zielgewebe ergriffen und in den Morcellator zurückgezogen, während die HF-Schneideleistung aktiviert wird.

Morcellator
Der Morcellator besteht aus einer aktiven HF-Elektrode, die am distalen Ende einer Arbeitskanüle angebracht ist. Ein Handgriff gibt kontrollierten Halt und enthält zudem ein Dichtungssystem, um übermäßigen Insufflationsverlust bei der Verwendung zu vermeiden. Das Kabelset wird für die HF-Verbindung vom Generator zum Morcellator und zum Greifer verwendet.

Greifer
Der Greifer ist fest mit dem Morcellator verbunden, um die elektrische Funktionsfähigkeit der Vorrichtung zu gewährleisten.

Tiefenmesser
Ein Tiefenmesser ist im Lieferumfang des Instruments enthalten, kann aber entfernt werden. Der Tiefenmesser kann nur als Indikator dienen. Bei der Einführung des Instruments stets vorsichtig und kontrolliert vorgehen. Der Tiefenmesser kann entfernt werden, um die Verwendung mit separaten Kanülen zu ermöglichen.

Filter
Ein passiver Filter zur Evakuation von Rauch ist im Lieferumfang enthalten. Er wird an den Luer-Lock-Anschluss einer verfügbaren Kanüle angebracht, um das Entfernen von Rauch aus dem Sichtfeld zu unterstützen. Es wird empfohlen, den Filter an eine andere Kanüle anzubringen als die, die für den Morcellator verwendet wird.

VORSICHTSHINWEISE

Vor der erstmaligen Verwendung sicherstellen, dass alle Packungsbeilagen, einschließlich Warnhinweisen, Vorsichtshinweisen sowie Gebrauchsanweisungen gelesen und verstanden wurden. Die sichere und wirksame Durchführung eines elektrochirurgischen Eingriffs hängt nicht nur von der Konstruktion der Vorrichtungen ab, sondern auch von Faktoren, die der Kontrolle des Arztes unterliegen (siehe Bedienungsanleitung des Gyrus ACMI G400 Generators).

Vor Gebrauch sicherstellen, dass der/die Stecker des Instruments vollständig in die Buchse des Generators eingesteckt wurden. Das proximale Ende des Instruments darf nicht mit Flüssigkeiten in Berührung kommen.

Sicherstellen, dass die Einstellungen des Generators für den geplanten elektrochirurgischen Eingriff geeignet sind.

Unnötige Aktivierung vermeiden. Dadurch kann es zu übermäßiger Erhitzung kommen, die zu Schäden an der Instrumentenspitze bzw. zu Schäden an empfindlichen Gewebestrukturen, die versehentlich in Kontakt mit der Instrumentenspitze oder dem Schaft direkt proximal zur Spitze kommen, führen kann.

Sicherstellen, dass der mitgelieferte Obturator für das Obturationsverfahren an der Vorrichtung befestigt ist und dass die angewandte Kraft durch den Obturator gerichtet ist, nicht direkt auf den Griff der Vorrichtung.

Durch eine übermäßige Kraft auf den Griff wird die Vorrichtung geschwächt, und sie kann beschädigt werden oder versagen.

Siehe Abbildungen zur Verdeutlichung.

✗ ✓

Sicherstellen, dass der Schaft des Morcellators so weit eingeführt wird, dass das gesamte PK Technology-Logo sichtbar ist und die Spitze sich in sicherem Abstand von der Bauchdecke befindet, um Gewebeschäden durch Verbrennungen zu vermeiden.

Nicht versuchen, den steifen Schaft dieses Instruments zu biegen, da dies zum Ausfall der Vorrichtung führen kann.

Den Schaft des PKS PlasmaSORD Morcellators nicht in die Eingriffsstelle einführen bzw. herausziehen, während der Strom aktiviert ist.

Bei Verwendung mit einer separaten Kanüle sicherstellen, dass die Spitze des PKS PlasmaSORD Instruments weit genug eingeführt wird, um vor und während der Aktivierung über die Kanüle hinaus zu reichen. Nicht aktivieren, solange sich ein Teil der Spitze noch innerhalb der Kanülenschleuse befindet.

Nur isolierte Instrumente und isolierte Kanülen verwenden.

Stets sicherstellen, dass die Vorrichtungen kompatibel sind, und bei der Einführung/ Entfernung von Instrumenten durch eine Kanüle vorsichtig vorgehen, um Schäden zu vermeiden. Wie bei anderen Kanülen ist ein Öffnen des Greifers innerhalb des Schafts nicht zu empfehlen, weil dadurch die interne Dichtung beschädigt werden kann. Wenn sich noch Gewebe in der Vorrichtung befindet, das nicht durch ein erneutes Einführen des geschlossenen Greifers gesäubert werden kann, muss beim Entfernen von eingeklemmtem Gewebe in der Nähe der Dichtung vorsichtig vorgegangen werden, um Schäden zu vermeiden.

Das Instrument vorsichtig einführen und herausziehen, um Beschädigungen des Instruments und/oder Verletzungen des Patienten oder des OP-Personals zu vermeiden.

Der Patient darf nicht mit geerdeten Metallobjekten in Kontakt kommen.

Den Gyrus ACMI G400 Generator nicht gleichzeitig mit anderen elektrochirurgischen Generatoren verwenden.

Keine Scheuermittel oder anderen aggressiven Reinigungsmittel zum Säubern der Instrumentenspitze verwenden.

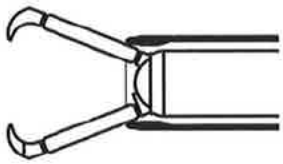
GEWEBEEFFEKTE
ANWENDUNG DER VORRICHTUNG

Bei der HF-Elektrochirurgie entstehen dampfhaltige Nebenprodukte wie Rauch und Wasserdampf, die die Sichtbarkeit beeinträchtigen können. Es wird empfohlen, diese Vorrichtung bei Bedarf mit einem geeigneten Rauchextraktionssystem oder anderen Mitteln zur Beseitigung dieser Nebenprodukte zu verwenden.

Ein passiver Rauchfilter ist im Lieferumfang enthalten, um den Erhalt des Sichtfelds zu unterstützen. Passive Rauchfilter funktionieren im Allgemeinen besser, wenn sie an einen anderen als den für den Morcellator verwendeten Anschluss angeschlossen werden. Für den richtigen Gebrauch siehe Schritte 7-9 im Abschnitt „Einrichten des Morcellators".

GEBRAUCH DES GREIFERS

Wie auch bei anderen Morcellator-Vorrichtungen muss darauf geachtet werden, dass der Greifer ausreichend geschlossen ist, um in den Schaft einzutreten. Keine übermäßige Kraft aufwenden, um Gewebe zurückzuziehen. Falls beim Eintritt der Greifers in den Schaft Widerstand spürbar wird, das Gewebe erneut greifen, so dass der Greifer besser geschlossen werden kann.



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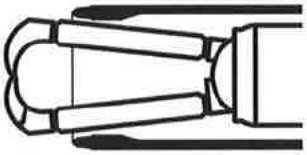

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Wenn der Insufflationsdruck durch eine Undichtigkeit im Morcellator abnimmt, kann das Ventil beschädigt sein. Durch Hineinsehen in den Morcellatorschaft kann möglicherweise beurteilt werden, ob das Ventil beschädigt ist. Falls Schäden am Ventil vorliegen, muss sichergestellt werden, dass alle Ventilfragmente gefunden und aus dem Bauchraum entfernt werden.

EINRICHTEN DES MORCELLATORS

1. Siehe Bedienungsanleitung des Gyrus ACMI G400 Generators für schrittweise Anweisungen zum Zusammenbau und zur ersten Systemprüfung des Gyrus ACMI G400 Generators.
2. Den Gyrus ACMI G400 Generator einschalten. Die Anweisungen in der Bedienungsanleitung des Generators befolgen.
3. Das PKS PlasmaSORD Instrument und Filter-Zubehörteil werden steril für den einmaligen Gebrauch geliefert. Vor Gebrauch die Verpackung überprüfen, um die Unversehrtheit des sterilen Verpackungssiegels sicherzustellen.
4. Das PKS PlasmaSORD Instrument aus der Verpackung nehmen. Die Vorrichtung auf Beschädigungen untersuchen. Die Vorrichtung darf nicht verwendet werden, wenn eine Beschädigung am Instrument oder an der Verpackung vorliegt. Die Vorrichtung nicht nach Ablauf des auf dem Produktetikett angegebenen Verfallsdatums verwenden.
5. Das PKS PlasmaSORD Instrument an den Generator anschließen. Vor dem Anschluss überprüfen, ob der Stecker ordnungsgemäß mit den Buchsen am Generator ausgerichtet ist.

   Gegebenenfalls ist eine Software-Aktivierung zur Verwendung dieses Instruments erforderlich. Wenn die Vorrichtung beim Anschluss nicht erkannt wird, mit dem zuständigen Vertreter von Gyrus ACMI oder dem Kundendienst in Verbindung setzen, um sicherzustellen, dass die richtige Softwareversion installiert ist.
6. Überprüfen, ob der Gyrus ACMI G400 Generator den korrekten Instrumentennamen anzeigt. Falls ein anderer Name angezeigt wird, den Gyrus ACMI Kundendienst kontaktieren und die Vorrichtung nicht verwenden.

   Zu Ihrer Sicherheit und zur einfacheren Handhabung stellt das PKS PlasmaSORD Instrument den Generator automatisch auf die entsprechenden Ausgangseinstellungen ein und beschränkt die Ausgangspegel, um die Integrität der Elektrode zu bewahren.
7. Falls erforderlich, sollte der passive Rauchfilter an den Luer-Lock-Anschluss einer verfügbaren Kanüle angeschlossen werden. Vorzugsweise sollte dafür eine andere Kanüle verwendet werden als die, die für den Morcellator verwendet wird.
8. Die Durchflussrate durch das Filter-Zubehörteil kann durch Einstellen des Absperrventils an der Kanüle gesteuert werden.
9. Den Kopf des Filters so positionieren, dass die Kondensfeuchtigkeit im Rohr nicht in den Filter eindringen kann, da dessen Funktionsfähigkeit dadurch beeinträchtigt werden kann.

EINFÜHRUNG UND GEBRAUCH DES MORCELLATORS

1. Das zu entfernende Gewebe sollte vor dem Morcellement devaskularisiert werden.
2. Das PKS PlasmaSORD Instrument wird nach Ermessen des Arztes vorsichtig entweder direkt oder durch eine separate 15-mm-Kanüle bis zur Eingriffsstelle eingeführt. Darauf achten, dass das Instrument nicht zu weit eingeführt wird bzw. die umliegenden Gewebestrukturen beschädigt werden. Bei Bedarf die Inzision an der bestehenden Eintrittsstelle vergrößern, um die Einführung zu erleichtern.

   Das PKS PlasmaSORD Instrument mit Hilfe des Obturators unter direkter Visualisierung einführen. Sicherstellen, dass der Obturator vollständig in den Morcellator eingeführt ist, und kontinuierlichen, aber kontrollierten Druck mit einer vorsichtigen Drehbewegung von circa 180° anwenden.
3. Sicherstellen, dass die Klemmbacken des Greifers geschlossen sind, wenn sie durch den PKS PlasmaSORD Arbeitskanal eingeführt werden. Wie bei allen Morcellator-Vorrichtungen sollten Sie vorsichtig vorgehen, um Verletzungen des benachbarten Gewebes zu vermeiden. Dabei sollte besonders auf die scharfen Zähne des Greifers geachtet werden.
4. Das Zielgewebe kann nun ergriffen und zurückgezogen werden. Durch Aktivierung der Vorrichtung mit dem gelben Pedal wird das Gewebe, das in Kontakt mit dem vorderen Rand des Morcellator-Rohrs kommt, geschnitten.

   Da das PKS PlasmaSORD Instrument den gewünschten Gewebeeffekt durch einen elektrischen, nicht mechanischen Schnitt erzielt, wird die Geweberesektion am besten in einer gleichmäßigen Bewegung ohne großen Kraftaufwand erreicht. Falls Widerstand spürbar wird oder nach 5 Sekunden kein Schneideeffekt erzielt wird, ist es empfehlenswert, das Gewebe erneut zu greifen und zu aktivieren.

   Durch übermäßigen Kraftaufwand beim Zurückziehen können mehr Geweberisse auftreten.

   Durch eine Ansammlung von koaguliertem Gewebe an der Spitze kann eine deutliche Reduzierung des Schneideeffekts auftreten. In solchen Fällen mit sterilem Wasser befeuchtete Gaze zum Abwischen verwenden. Das Instrument austauschen, wenn sich dieses Problem nicht beheben lässt. Keine Scheuermittel oder anderen aggressiven Reinigungsmittel zum Säubern der Instrumentenspitze verwenden.

   Die Instrumentenspitze während der Verwendung immer im Sichtfeld halten. Eine unbeabsichtigte Aktivierung oder Bewegung des Instruments außerhalb des Sichtfelds kann zu Verletzungen des Patienten führen. Zur Vermeidung von versehentlichen Verletzungen der Bauchdecke, der Blase, des Darms und anderer Gewebestrukturen sowie von unbeabsichtigter Nervenstimulation sollte das Gewebe, an dem der Morcellator angewendet werden soll, vollständig freigelegt und fixiert werden, um zu verhindern, dass sich größere Gewebeteile vor Anwendung dieser Vorrichtung verschieben. Den Fußschalter zur Aktivierung der Vorrichtung nur dann betätigen, wenn sich die distale Spitze im Sichtfeld befindet.

NACH DEM MORCELLIEREN

1. Das PKS PlasmaSORD Instrument vom Generator trennen.

   VORSICHT: Den Anschluss stets an den Steckergriffen und nicht am Kabel abziehen. Nichtbeachtung kann zu Produktbeschädigung führen.

2. Die Stromversorgung des Generators ausschalten.
3. Die Vorrichtung unmittelbar nach der Entfernung vom Patienten auf Anzeichen von Beschädigung oder Bruchstellen überprüfen. Bei sichtbaren Schäden die Vorrichtung aufbewahren, um eine Herstelleranalyse des Vorfalls zu ermöglichen.
4. Das Einweg-Instrument und alle Zubehörteile gemäß Klinikvorschriften zur Entsorgung chirurgischer Abfälle entsorgen.

LIEFERFORM

Das PKS PlasmaSORD Instrument und die Zubehörteile werden steril nur für den einmaligen Gebrauch geliefert.

LAGERUNG

Unter 25 °C (77 °F) vor Feuchtigkeit und direkter Wärmeeinwirkung geschützt aufbewahren. Nicht nach Ablauf des auf dem Instrumentenetikett angegebenen Verfallsdatums verwenden.

PKS™ und PlasmaSORD™ sind Marken von Gyrus ACMI, Inc., und/oder seiner Tochtergesellschaften in den USA und/oder anderen Ländern.

SYMBOLE

STERILE EO	- Mit Ethylenoxid sterilisiert
LOT	- Chargennummer
	- Vor direktem Sonnenlicht schützen
	- Trocken aufbewahren
	- Zerbrechlich – vorsichtig handhaben
QTY	- Gibt die Anzahl der Verkaufseinheiten in der Packung an.
	- Gibt die Anzahl der Vorrichtungen in der Packung an. Die Ziffer (#) bezieht sich auf die Anzahl der Vorrichtungen in der Packung.
	- Lagertemperaturbereich (°C)
	- Für den einmaligen Gebrauch
	- Verfallsdatum
Manufactured for	- Das Produkt wurde für Gyrus ACMI hergestellt
Rx only	- **VORSICHT:** Laut Bundesgesetz der USA darf diese Vorrichtung ausschließlich an einen Arzt oder auf dessen Anordnung verkauft werden.
	- Bei beschädigter Verpackung nicht verwenden
	- ISO 7010-M002 Follow instructions for use

Hergestellt in Großbritannien.

EC REP

Gyrus Medical Ltd.
Fortran Road, St Mellons
Cardiff CF3 0LT, Großbritannien

Hergestellt für:
Gyrus ACMI Inc.
136 Turnpike Road
Southborough
MA 01772-2104
USA

Kundendienst
Kundendienst: 1-888-524-7266
Technischer Kundendienst: 1-800-621-3739
www.gyrusacmi.com

IT

GYRUS ACMI

PKS™ PlasmaSORD™

PKS™ PlasmaSORD™ rif. 962000PK con cavo

Istruzioni per l'uso

IMPORTANTE: il presente inserto fornisce le istruzioni per l'uso dello strumento PKS PlasmaSORD quando usato con la stazione di lavoro G400 Gyrus ACMI ma non è inteso come guida alle tecniche elettrochirurgiche.

ATTENZIONE

RX only – La legge federale degli Stati Uniti autorizza la vendita di questo prodotto esclusivamente a medici o dietro prescrizione medica.

Prima dell'uso, leggere attentamente le istruzioni, incluse le CONTROINDICAZIONI, AVVERTENZE E PRECAUZIONI. In caso contrario, si possono causare lesioni gravi al paziente.

USO PREVISTO

Lo strumento PKS PlasmaSORD, usato con la stazione di lavoro G400 Gyrus ACMI, è indicato per il taglio, lo svuotamento e l'estrazione di tessuto nel corso di varie procedure laparoscopiche generali, procedure laparoscopiche urologiche e procedure laparoscopiche ginecologiche.

CONTROINDICAZIONI

L'uso dei morcellatori elettrici per laparoscopia è controindicato negli interventi di chirurgia ginecologica in cui è noto o si sospetta che il tessuto da sottoporre a morcellazione contenga una componente neoplastica maligna.

L'uso dei morcellatori elettrici per laparoscopia è controindicato per la rimozione di tessuto uterino contenente fibromi sospetti nei seguenti tipi di pazienti:

- pazienti in età perimenopausale o postmenopausale, oppure
- pazienti candidate per l'asportazione in blocco del tessuto, ad esempio attraverso la vagina o tramite mini-incisione laparotomica.

L'uso della stazione di lavoro G400 Gyrus ACMI è controindicato quando, a giudizio del medico, un intervento di elettrochirurgia bipolare può comportare conseguenze negative per il paziente.

Prima di usare l'elettrochirurgia bipolare su pazienti portatori di dispositivi elettronici attivi impiantati, leggere attentamente le istruzioni per l'uso di tali dispositivi.

AVVERTENZE

***AVVERTENZA:* il tessuto uterino può contenere una neoplasia maligna non sospetta. L'uso dei morcellatori elettrici per laparoscopia durante interventi chirurgici a carico dei fibromi può comportare la diffusione della neoplasia e ridurre la sopravvivenza a lungo termine delle pazienti. Questa informazione deve essere comunicata alle pazienti quando si prende in considerazione un intervento chirurgico eseguito con l'uso di questi dispositivi.**

Prima dell'uso del dispositivo, leggere attentamente tutte le informazioni e in particolare il manuale dell'utente in dotazione con la stazione di lavoro G400 Gyrus ACMI. La stazione di lavoro, l'interruttore a pedali del generatore e lo strumento PKS PlasmaSORD sono concepiti per essere usati come un unico sistema. La mancata osservanza delle istruzioni comporta il rischio di scosse elettriche o di ustioni e può compromettere il funzionamento corretto dello strumento.

Non utilizzare lo strumento con generatori di altri produttori. L'uso con generatori diversi dalla stazione di lavoro G400 Gyrus ACMI può causare infortuni all'operatore o al paziente.

La sicurezza e l'efficacia delle procedure di elettrochirurgia dipendono da fattori controllati dall'operatore. Il dispositivo deve essere usato soltanto da chirurghi che siano esperti negli interventi elettrochirurgici laparoscopici o abbiano ricevuto la formazione necessaria.

L'uso scorretto di strumenti elettrochirurgici può provocare scosse elettriche e ustioni ai tessuti. Non usare lo strumento in prossimità di tessuti predisposti a questo tipo di danni (come la vescica, l'intestino o la parete addominale), tranne che nel caso in cui si intenda procedere alla resezione.

I denti del grasper PKS PlasmaSORD sono affilati per permettere di afferrare il tessuto duro. Se non viene prestata attenzione, i denti possono danneggiare i tessuti collaterali. Aprire le ganasce del grasper PKS PlasmaSORD solamente quando sono bene in vista e in stretta prossimità con il tessuto d'interesse.

Se si attiva il dispositivo quando la punta distale non si trova nel campo visivo, si rischia la stimolazione del tessuto nervoso della parete addominale in caso la punta sia a contatto con essa.

Durante l'uso, mantenere la punta dello strumento in vista. L'attivazione o un movimento accidentale dello strumento al di fuori della visuale dell'operatore possono provocare lesioni al paziente. Per evitare la stimolazione nervosa o lesioni accidentali alla parete addominale, alla vescica, all'intestino o ad altre strutture, prima di applicare il dispositivo, esporre completamente e fissare il tessuto da morcellare per evitare che grosse porzioni di tessuto si spostino. Attivare il dispositivo premendo il pedale solo con la punta distale nel campo visivo.

Se durante l'operazione il sito di intervento o il dispositivo scompaiono dalla visuale, INTERROMPERE IMMEDIATAMENTE LA PROCEDURA. Non proseguire senza aver prima ristabilito la piena visibilità.

Anche se lo strumento PKS PlasmaSORD è in grado di dissipare rapidamente il calore generato durante l'uso, la punta e la sezione del corpo dello strumento immediatamente prossimale alla punta possono rimanere abbastanza calde da causare lesioni ai tessuti,

anche dopo che è stata disattivata la corrente elettrochirurgica. Evitare il contatto con tessuti sensibili, incluso il sito di accesso addominale, per evitare ustioni accidentali.

Quando non viene usato, conservare lo strumento bene in vista in un luogo pulito, lontano da corpi conduttivi e lontano dal paziente e da altri dispositivi. L'attivazione accidentale durante il contatto del morcellatore o del grasper con il paziente o il personale medico può causare ustioni.

Non pulire e non toccare la punta dello strumento con l'alimentazione attivata.

Non usare questo strumento con gas per insufflazione diversi da aria o anidride carbonica.

Come ogni dispositivo elettrochirurgico, lo strumento può generare scintille e surriscaldarsi e può quindi essere causa di incendi. Osservare le consuete precauzioni per la prevenzione di incendi. Non usare il dispositivo in presenza di prodotti anestetici o gas ossidanti infiammabili, quali protossido d'azoto e ossigeno. Anche eventuali gas endogeni presenti all'interno del corpo possono risultare infiammabili.

Non collocare accessori in funzione in prossimità o a contatto con materiali infiammabili, quali garze o teli chirurgici.

Non usare questo dispositivo con sacchetti per la rimozione del tessuto.

Il rischio di incendi e di esplosioni è reso più grave dalla presenza di sostanze infiammabili, quali prodotti per il trattamento della pelle e tinture a base di alcol. Usare solo prodotti non infiammabili per la pulizia e la disinfezione e attendere che i solventi evaporino prima di eseguire interventi elettrochirurgici.

Non attivare lo strumento PKS PlasmaSORD in prossimità o a contatto con altri oggetti metallici, ad eccezione del grasper Gyrus ACMI dedicato, per evitare lesioni tissutali accidentali o danni agli oggetti o alla punta dello strumento.

Usare solo con il grasper Gyrus ACMI dedicato, in dotazione con il morcellatore, o con accessori originali del grasper Gyrus ACMI indicati per l'uso con questo dispositivo.

Non avvolgere il cavo di collegamento attorno a oggetti metallici, per evitare eventuali correnti indotte che possono causare scosse elettriche, incendi o lesioni al paziente o al personale medico.

Non tentare di rimuovere il cavo del grasper dalla relativa impugnatura.

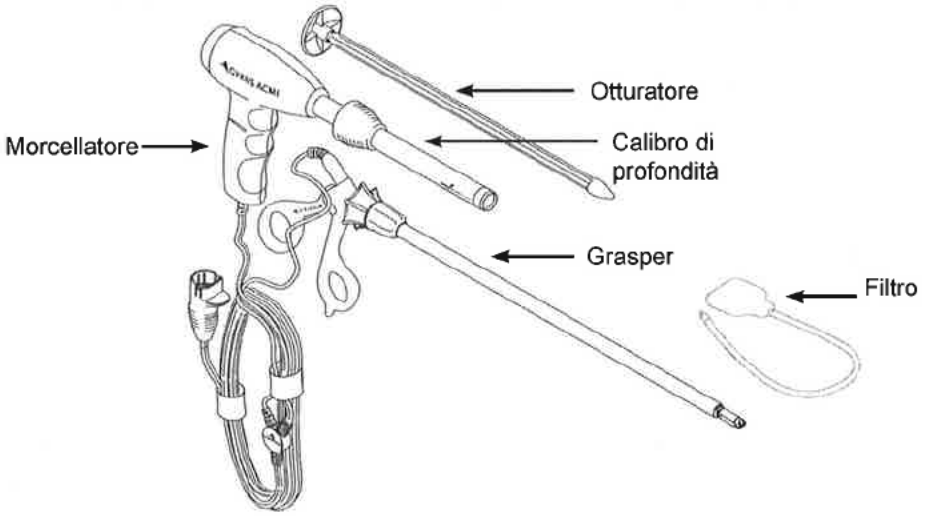
Questo prodotto è monouso.
Il dispositivo non è concepito per essere riutilizzato o risterilizzato. Il riprocessamento potrebbe causare modifiche alle caratteristiche del materiale, come corrosione metallica e bordi smussati, deformazione o scissione della ceramica e della plastica. Ciò potrebbe ripercuotersi sulla resistenza del dispositivo e comprometterne le prestazioni. Il riprocessamento di dispositivi monouso può anche causare la contaminazione crociata e provocare infezioni al paziente. Questi rischi possono potenzialmente mettere a repentaglio la sicurezza del paziente.

IMPORTANTE: il contenuto è sterile se la confezione non è stata aperta o danneggiata. Non risterilizzare. Se la confezione è stata aperta o danneggiata, gettare lo strumento senza utilizzarlo.

FORMAZIONE

Lo strumento PKS PlasmaSORD è consigliato per l'utilizzo da parte di chirurghi esperti in elettrochirurgia laparoscopica. Per qualsiasi domanda relativa all'uso corretto di questo dispositivo, rivolgersi al rappresentante locale per il tirocinio pratico e/o la formazione prima dell'uso iniziale.

DESCRIZIONE DEL DISPOSITIVO



Il sistema plasmacinetico (PKS) PlasmaSORD è uno strumento elettrochirurgico bipolare avanzato per il taglio e l'estrazione di tessuto molle in laparoscopia. Lo strumento può essere utilizzato direttamente o introdotto attraverso una cannula separata da 15 mm per l'accesso al sito operatorio. Il dispositivo consiste di un morcellatore tissutale elettrochirurgico a radiofrequenza (RF), un grasper dedicato collegato in permanenza e un otturatore. Il dispositivo può essere usato assieme alla stazione di lavoro G400 Gyrus ACMI per rimuovere tessuto dal sito operatorio; per far ciò, introdurre il grasper attraverso il canale operativo del morcellatore, afferrare il tessuto d'interesse e retrarlo nel morcellatore, attivando contemporaneamente l'erogazione di energia RF per il taglio.

Morcellatore
Il morcellatore consiste di un elettrodo RF attivo montato sull'estremità distale di una cannula di lavoro. Un manipolo, contenente un sistema di tenuta per prevenire una perdita eccessiva di insufflazione durante l'uso, ne consente un'impugnatura positiva controllata. Il cavo fornisce la connessione RF dalla stazione di lavoro sia al morcellatore che al grasper.

Grasper
Il grasper è collegato in permanenza al morcellatore per consentire il corretto funzionamento elettrico del dispositivo.

Calibro di profondità
Con lo strumento è fornito un calibro di profondità, che può essere rimosso; tale calibro va considerato soltanto un'indicazione. È necessario controllare sempre l'inserimento dello strumento. Il calibro può essere rimosso per consentire l'uso di cannule separate.

Filtro
Viene inoltre fornito un filtro passivo per l'eliminazione del fumo dal campo visivo, che viene collegato al raccordo Luer Lock di una cannula disponibile; si consiglia di non collegarlo alla cannula usata per il morcellatore.

PRECAUZIONI

Prima di usare il dispositivo per la prima volta, leggere attentamente tutto il materiale informativo, comprese le avvertenze, le precauzioni e le istruzioni per l'uso. Affinché le procedure elettrochirurgiche siano efficaci e non presentino rischi per il paziente, è necessario non solo disporre dell'attrezzatura adeguata ma anche tenere in considerazione i fattori che dipendono dall'operatore (fare riferimento al manuale dell'utente della stazione di lavoro G400 Gyrus ACMI).

Prima dell'uso, controllare che i connettori dello strumento si innestino completamente nella presa della stazione di lavoro. Verificare che l'estremità prossimale dello strumento non venga a contatto con liquidi.

Controllare che le impostazioni della stazione di lavoro siano corrette per l'intervento elettrochirurgico da eseguire.

Evitare attivazioni non necessarie, in quanto possono causare surriscaldamento che a sua volta può comportare danni alla punta dello strumento o lesioni a strutture tissutali sensibili in caso di contatto accidentale con la punta dello strumento o con la sezione del corpo immediatamente prossimale alla punta.

Assicurarsi che l'otturatore in dotazione venga inserito nel dispositivo per la procedura di otturazione e che la forza applicata venga guidata attraverso l'otturatore e non applicata direttamente all'impugnatura del dispositivo.

Non applicare una forza eccessiva all'impugnatura, per evitare di indebolire il dispositivo e di causare danni o guasti.

Fare riferimento alle figure seguenti per ulteriori chiarificazioni.

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Assicurarsi che il corpo del morcellatore sia inserito abbastanza lontano, in modo che l'intero logo PK technology sia visibile e che la punta sia lontana dalla parete addominale, per evitare danni termici ai tessuti.

Non tentare di piegare il corpo rigido dello strumento, per non compromettere il corretto funzionamento del dispositivo.

Non introdurre né estrarre il corpo del morcellatore PKS PlasmaSORD dal sito di intervento con l'alimentazione attivata.

Se usato con una cannula separata, accertarsi che la punta dello strumento PKS PlasmaSORD sia sufficientemente inserita da estendersi oltre la cannula prima e durante l'attivazione. Non attivare se la punta si trova anche solo parzialmente all'interno della guaina della cannula.

Utilizzare solo strumenti e cannule isolati.

Per evitare danni, esercitare sempre la massima cautela quando si inseriscono o estraggono gli strumenti dalle cannule e accertarsi che siano compatibili tra loro. Come per altre cannule, si sconsiglia di aprire il grasper all'interno del corpo, per evitare danni alla tenuta interna. Se all'interno del dispositivo rimane del tessuto che non è possibile eliminare reintroducendo il grasper chiuso, fare attenzione quando si rimuove il tessuto nei pressi della tenuta, per evitare di danneggiare quest'ultima.

Eseguire l'introduzione e l'estrazione dello strumento con cautela per evitare danni al dispositivo e/o lesioni al paziente e al personale medico.

Verificare che il paziente non possa venire a contatto con oggetti metallici messi a terra.

Non usare la stazione di lavoro G400 Gyrus ACMI contemporaneamente ad altri generatori elettrochirurgici.

Non pulire la punta del dispositivo con sostanze abrasive o altri metodi aggressivi.

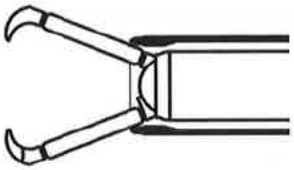
EFFETTI SUL TESSUTO
APPLICAZIONE DEL DISPOSITIVO

Tutti gli interventi elettrochirurgici RF generano vapori o fumo che possono compromettere la visibilità. Si consiglia di usare questo dispositivo con un appropriato sistema per l'eliminazione del fumo o altri strumenti per eliminare tali sottoprodotti.

In dotazione viene fornito un filtro per fumo passivo che contribuisce a mantenere libero il campo visivo. I filtri per fumo passivi tendono a funzionare con maggiore efficienza se collegati a un ingresso diverso da quello usato per il morcellatore. Per l'uso del filtro, fare riferimento alle fasi 7-9 riportate alla sezione sulla configurazione del morcellatore.

USO DEL GRASPER

Come per altri morcellatori, accertarsi che il grasper sia sufficientemente chiuso da poter entrare agevolmente nel corpo. Non applicare mai una forza eccessiva per l'estrazione del tessuto. Se si avverte resistenza quando il grasper entra nel corpo, aprire il grasper e poi riafferrare il tessuto, in modo che il grasper sia più chiuso.



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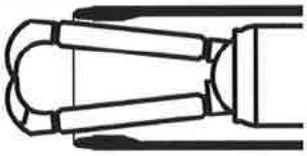

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Se si verifica una diminuzione di pressione di insufflazione a causa di una perdita nel morcellatore, la valvola potrebbe essere danneggiata. Controllare nel corpo del morcellatore per vedere se la valvola è danneggiata. Se affermativo, assicurarsi di recuperare i frammenti della valvola danneggiata dall'addome.

CONFIGURAZIONE DEL MORCELLATORE

1. Per una descrizione dettagliata delle fasi di montaggio e del controllo iniziale della stazione di lavoro G400 Gyrus ACMI, consultare il manuale dell'utente della stazione di lavoro G400 Gyrus ACMI.
2. Accendere la stazione di lavoro G400 Gyrus ACMI. Attenersi alle istruzioni del manuale dell'utente della stazione di lavoro.
3. Lo strumento PKS PlasmaSORD e il filtro accessorio sono forniti sterili e sono monouso. Prima dell'uso, ispezionare la confezione per accertarsi dell'integrità della barriera sterile.
4. Rimuovere lo strumento PKS PlasmaSORD dalla confezione. Controllare che il dispositivo non sia danneggiato. In caso si rilevino danni allo strumento o alla confezione, non usare il dispositivo. Non usare il dispositivo oltre la data di scadenza indicata sull'etichetta.
5. Collegare lo strumento PKS PlasmaSORD alla stazione di lavoro. Controllare che il connettore sia correttamente allineato alle prese della stazione di lavoro prima di eseguire il collegamento.

   Per l'uso di questo strumento potrebbe essere necessario abilitare il software. Se il dispositivo non viene riconosciuto automaticamente quando viene collegato, rivolgersi al rappresentante locale Gyrus ACMI o al servizio clienti per accertarsi che sia stata installata la versione corretta del software.
6. Confermare che sulla stazione di lavoro G400 Gyrus ACMI sia visualizzato il nome dello strumento corretto. Se è visualizzato un nome diverso, non usare il dispositivo e rivolgersi al servizio clienti Gyrus ACMI.

   Per ragioni di comodità e sicurezza, lo strumento PKS PlasmaSORD imposta automaticamente il generatore in base a valori di uscita appropriati e controlla i livelli in uscita per proteggere l'integrità degli elettrodi.
7. Se necessario, collegare il filtro per fumo passivo accessorio al connettore Luer Lock di una cannula disponibile (è consigliabile usare una cannula diversa da quella usata per il morcellatore).
8. È possibile controllare la portata attraverso il filtro regolando la valvola del rubinetto di arresto della cannula.
9. Posizionare la testa del filtro in modo che la condensa che si forma nel tubo non possa passare nel filtro, in quanto potrebbe compromettere il funzionamento.

INSERIMENTO E UTILIZZO DEL MORCELLATORE

1. Prima di eseguire la morcellazione, devascolarizzare il tessuto da rimuovere.
2. Introdurre con cautela lo strumento PKS PlasmaSORD fino al sito d'intervento, direttamente o tramite una cannula da 15 mm separata, a discrezione del medico. Evitare di inserire troppo a fondo lo strumento e qualsiasi altra manovra che possa causare lesioni a strutture tissutali collaterali. Se necessario, ingrandire l'incisione al sito di accesso esistente per facilitare l'inserimento.

   Inserire lo strumento PKS PlasmaSORD utilizzando l'otturatore in visualizzazione diretta. Assicurarsi che l'otturatore sia completamente inserito nel morcellatore e applicare una pressione continua ma controllata con un movimento rotatorio e deciso di circa 180°.
3. Assicurarsi che le ganasce del grasper siano chiuse mentre vengono inserite nel canale operativo dello strumento PKS PlasmaSORD. Come per il morcellatore, esercitare cautela, per evitare di danneggiare tessuti collaterali, prestando particolare attenzione ai denti affilati del grasper.
4. Afferrare e retrarre il tessuto d'interesse. Attivando il dispositivo con il pedale giallo si taglierà il tessuto a contatto con il bordo anteriore del tubo del morcellatore.

   Poiché lo strumento PKS PlasmaSORD agisce tramite taglio elettrico, non meccanico, la resezione del tessuto si otterrà nel modo ottimale con un movimento controllato, applicando una forza minima. Se si avverte resistenza o non si ha un effetto di taglio dopo cinque secondi, si consiglia di riafferrare il tessuto e attivare.

   Se si usa una forza eccessiva durante la retrazione, si aumenta il rischio di lacerazione del tessuto.

   Un accumulo di coaguli di tessuto sulla punta può causare una riduzione notevole dell'effetto di taglio. In tal caso, pulire con una garza inumidita con acqua sterile. Se il problema persiste, sostituire lo strumento. Non pulire la punta del dispositivo con sostanze abrasive o altri metodi aggressivi.

   Durante l'uso, mantenere la punta dello strumento in vista. L'attivazione o un movimento accidentale dello strumento al di fuori della visuale dell'operatore possono provocare lesioni al paziente. Per evitare la stimolazione nervosa o lesioni accidentali alla parete addominale, alla vescica, all'intestino o ad altre strutture, prima di applicare il dispositivo, esporre completamente e fissare il tessuto da morcellare per evitare che grosse porzioni di tessuto si spostino. Attivare il dispositivo premendo il pedale solo con la punta distale nel campo visivo.

DOPO LA MORCELLAZIONE

1. Scollegare lo strumento PKS PlasmaSORD dalla stazione di lavoro.

   ATTENZIONE: per scollegare lo strumento, afferrare i punti di presa sul connettore, non il cavo. In caso contrario, il dispositivo può subire danni.

2. Spegnere la stazione di lavoro.
3. Controllare il dispositivo immediatamente dopo averlo rimosso dal paziente per la presenza di eventuali segni di rottura o frantumazione. Se il dispositivo è danneggiato, conservarlo perché il produttore possa analizzare tale evento.
4. Eliminare tutti i componenti dello strumento monouso e gli accessori usati secondo le procedure di smaltimento dei rifiuti chirurgici adottate nel proprio reparto.

DOTAZIONE E USO

Lo strumento PKS PlasmaSORD e gli accessori sono forniti sterili e sono monouso.

CONSERVAZIONE

Conservare a una temperatura inferiore ai 25 °C (77 °F), al riparo da umidità e da fonti di calore. Non usare oltre la data di scadenza stampata sull'etichetta dello strumento.

PKS™ e PlasmaSORD™ sono marchi di fabbrica di Gyrus ACMI, Inc. e/o delle sue entità affiliate, negli Stati Uniti e/o in altri paesi.

SIMBOLI

STERILE EO	- Sterilizzato mediante ossido di etilene
LOT	- Numero lotto
	- Proteggere dalla luce diretta del sole
	- Mantenere asciutta l'attrezzatura
	- Fragile, maneggiare con cura
QTY	- Rappresenta la quantità di unità vendibili contenute nella confezione.
	- Rappresenta la quantità di dispositivi contenuti nella confezione. # Il numero corrisponde alla quantità di dispositivi contenuti nella confezione.
	- Gamma di temperatura di conservazione (°C)
	- Monouso
	- Data di scadenza
Manufactured for	- Quando un prodotto viene fabbricato per Gyrus ACMI
Rx only	- **ATTENZIONE:** la legge federale degli Stati Uniti autorizza la vendita di questo prodotto esclusivamente a medici o dietro prescrizione medica.
	- Non utilizzare se la confezione è danneggiata
	- ISO 7010-M002 – Attenersi alle istruzioni per l'uso

Prodotto nel Regno Unito.

EC REP

Gyrus Medical Ltd.
Fortran Road, St Mellons
Cardiff CF3 0LT, Regno Unito.

Prodotto per:
Gyrus ACMI Inc.
136 Turnpike Road
Southborough
MA 01772-2104
USA

Servizio clienti
Servizio clienti: +1-888-524-7266
Assistenza tecnica: +1-800-621-3739
www.gyrusacmi.com

ES

GYRUS ACMI

PKS™ PlasmaSORD™

PKS™ PlasmaSORD™ con cable ref 962000PK

Instrucciones de uso

IMPORTANTE: En esta documentación adjunta se ofrecen instrucciones para utilizar el instrumento PKS PlasmaSORD conjuntamente con la estación de trabajo Gyrus ACMI G400. No es una guía para la técnica electroquirúrgica.

PRECAUCIÓN

Rx only: las leyes federales de Estados Unidos limitan la venta de este dispositivo a personal médico o bajo prescripción médica.

Lea todas las instrucciones incluidas las CONTRAINDICACIONES, ADVERTENCIAS Y PRECAUCIONES antes del uso. De lo contrario, el paciente podría sufrir graves lesiones.

USO PREVISTO

El PKS PlasmaSORD, cuando se utiliza conjuntamente con la estación de trabajo Gyrus ACMI G400, está indicado para cortar, vaciar y extraer tejidos en diversas intervenciones de cirugía laparoscópica, como por ejemplo en los procedimientos de cirugía laparoscópica general, cirugía laparoscópica urológica y cirugía laparoscópica ginecológica.

CONTRAINDICACIONES

Los fragmentadores eléctricos laparoscópicos están contraindicados en aquellas cirugías ginecológicas en las que se sepa o presuma que los tejidos que se van a fragmentar contienen una malignidad.

Los fragmentadores eléctricos laparoscópicos están contraindicados en la eliminación de tejido uterino que contenga presuntos fibromas en pacientes que sean:

- perimenopáusicas o postmenopáusicas, o bien
- candidatas a la eliminación de tejido en bloque, por ejemplo, a través de la vagina o por medio de una incisión de minilaparotomía.

El uso de la estación de trabajo Gyrus ACMI G400 está contraindicado cuando, a juicio del médico, la intervención electroquirúrgica bipolar pueda resultar perjudicial para el paciente.

En el caso de pacientes con dispositivos electrónicos activos implantados consulte las instrucciones de uso de los dispositivos en cuestión antes de llevar a cabo cualquier intervención electroquirúrgica bipolar.

ADVERTENCIAS

***ADVERTENCIA:* El tejido uterino puede contener un cáncer no previsto. El uso de fragmentadores eléctricos laparoscópicos durante la cirugía de fibromas puede extender el cáncer y reducir la supervivencia a largo plazo de las pacientes. Esta información debe compartirse con las pacientes cuando se considere la cirugía mediante estos dispositivos.**

Antes de usar este instrumento, lea atentamente toda la información, incluido el manual del usuario que se suministra con la estación de trabajo Gyrus ACMI G400. La estación de trabajo, el conmutador de pedal del generador y el PKS PlasmaSORD están diseñados para usarse simultáneamente como un sistema. De no seguir las instrucciones de forma correcta, se podrían causar lesiones térmicas o eléctricas y provocar el funcionamiento incorrecto del instrumento.

No intente utilizar este instrumento con generadores de otros fabricantes. El uso con generadores que no sean la estación de trabajo Gyrus ACMI G400 podría causar lesiones al usuario o al paciente.

La eficacia y seguridad de la electrocirugía depende de factores que están bajo el control del usuario. El usuario debe estar capacitado en las técnicas de cirugía laparoscópica con equipo electroquirúrgico u obtener formación en este ámbito antes de utilizarlo.

El uso incorrecto de los instrumentos de electrocirugía puede dañar el tejido eléctrica y térmicamente. Este instrumento no se debe usar cerca de las estructuras de tejidos (incluidos la vejiga, el intestino o la pared abdominal) que sean susceptibles de sufrir lesiones de este tipo a menos que se desee realizar la resección del tejido.

Los dientes del mecanismo de sujeción PKS PlasmaSORD son afilados para poder agarrar tejidos duros. Si no se tiene cuidado, se pueden dañar los tejidos colaterales. Abra las mordazas del mecanismo de sujeción PKS PlasmaSORD solo cuando haya buena visibilidad y esté cerca del tejido a tratar.

La activación del dispositivo cuando la punta distal no está dentro del campo de visión y pudiera estar en contacto con la pared abdominal podría originar la estimulación del tejido nervioso dentro de la pared abdominal.

Durante el uso, mantenga la punta del instrumento visible. Un movimiento o una activación accidental del instrumento fuera del campo de visión podrían causar lesiones al paciente. Para evitar que se produzcan lesiones accidentales en la pared abdominal, vejiga, intestino u otras estructuras, o estimulaciones nerviosas, el tejido que se va a fragmentar debe estar completamente expuesto y sujeto, para evitar que grandes porciones del tejido puedan desplazarse antes de aplicar el dispositivo. Pise el pedal para activar el dispositivo sólo cuando la punta distal esté dentro del campo de visión.

Si durante el procedimiento perdiera la visualización del lugar del tratamiento o del dispositivo, DETÉNGASE INMEDIATAMENTE. No continúe hasta que recupere la visibilidad.

Aunque el instrumento PKS PlasmaSORD cuenta con medios para disipar con rapidez el calor generado durante el uso, la punta del instrumento y el cuerpo inmediatamente proximal a la punta pueden permanecer lo bastante calientes como para causar daños en el tejido inmediatamente después de desactivar la corriente electroquirúrgica. Evite

el contacto con tejido sensible, incluida la zona del orificio abdominal, ya que podrían producirse lesiones accidentales por calor.

Cuando no se esté usando, el instrumento debe colocarse en una zona limpia, aislante, de alta visibilidad y que esté alejada del paciente o de otros dispositivos. La activación accidental mientras el fragmentador o el mecanismo de sujeción está en contacto con el paciente o con el personal quirúrgico puede causar quemaduras.

No toque ni limpie la punta del instrumento cuando esté activado.

No utilice este instrumento con gases de insuflación distintos al aire o al dióxido de carbono.

Al igual que ocurre con todos los dispositivos electroquirúrgicos, el chispeo y el calentamiento relacionados con la electrocirugía pueden representar una fuente de ignición. Observe en todo momento las precauciones contra incendios. No lo use cerca de anestésicos inflamables o gases oxidantes, como el óxido nitroso o el oxígeno. Los gases endógenos que se acumulan en las cavidades corporales también pueden ser una fuente de ignición.

No coloque accesorios activos cerca de o en contacto con materiales inflamables (como gasas o paños quirúrgicos).

No utilice este dispositivo con bolsas de extracción de tejido.

Las sustancias inflamables como los agentes de preparación de la piel basados en alcohol y los tintes también pueden contribuir a aumentar el riesgo de explosión o incendio. Se deben usar agentes no inflamables para la limpieza y desinfección, y dejar que los disolventes se evaporen antes de aplicar electrocirugía.

No active el instrumento PKS PlasmaSORD mientras esté cerca o en contacto con otros objetos metálicos que no sea el mecanismo de sujeción especializado Gyrus ACMI, ya que se podría dañar de forma accidental el tejido, el objeto con el que se ha hecho contacto o la punta del instrumento.

Utilícelo sólo con el mecanismo de sujeción Gyrus ACMI especializado suministrado con el fragmentador, o los accesorios del mecanismo de sujeción Gyrus ACMI originales diseñados para su uso con este dispositivo.

No enrolle el cable del conector alrededor de objetos metálicos, ya que se podrían provocar corrientes que, a su vez, podrían causar descargas, incendios o lesiones al paciente o al personal quirúrgico.

No intente retirar el cable del mecanismo de sujeción del mango del mismo.

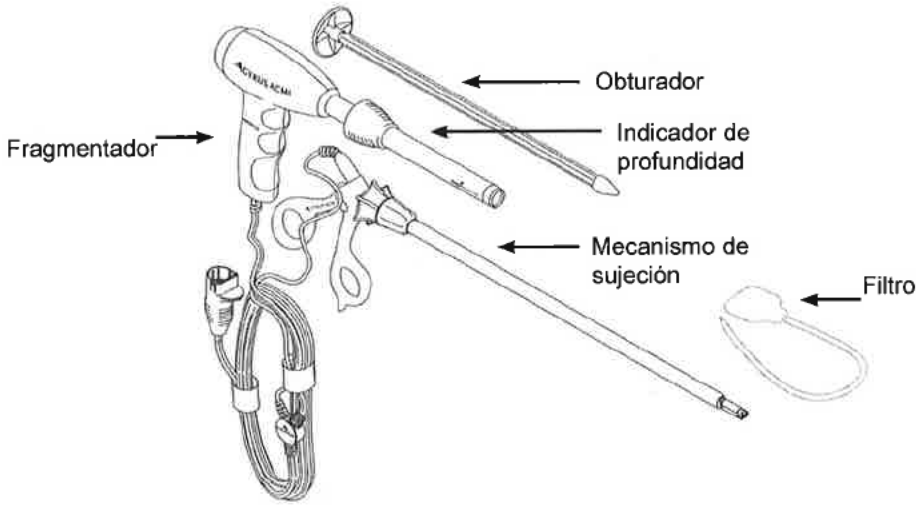
Este producto es para un solo uso.
No está diseñado para volverse a utilizar ni esterilizar. Si se reprocesa pueden producirse cambios en las características del material, como corrosión metálica y bordes romos, y deformación o agrietamiento de los materiales cerámicos o plásticos, que podrían reducir la resistencia del dispositivo y poner en peligro su rendimiento. Asimismo, el reprocesamiento de los dispositivos de un solo uso puede causar contaminación cruzada y provocar una infección en el paciente. Estos riesgos podrían afectar a la seguridad del paciente.

IMPORTANTE: El contenido permanece estéril a menos que el envase esté abierto o dañado. No lo vuelva a esterilizar. Si el producto está abierto o dañado, no se debe usar y se debe desechar.

FORMACIÓN

Se recomienda que sólo cirujanos especializados en intervenciones electroquirúrgicas laparoscópicas utilicen el dispositivo PKS PlasmaSORD. En caso de tener dudas sobre el uso correcto de este dispositivo, póngase en contacto con su representante de ventas para recibir formación en el trabajo y/o formación antes de usarlo.

DESCRIPCIÓN DEL DISPOSITIVO



El PKS PlasmaSORD es un instrumento electroquirúrgico bipolar avanzado que permite cortar y extraer tejidos blandos durante los procedimientos de cirugía laparoscópica. El instrumento puede utilizarse directamente o introducirse a través de una cánula independiente de 15 mm para acceder al lugar de la intervención. Este consta de un fragmentador de tejido electroquirúrgico de radiofrecuencia, un mecanismo de sujeción especializado y permanentemente conectado y un obturador. Cuando se usa conjuntamente con la estación de trabajo Gyrus ACMI G400, puede utilizarse para extraer el tejido del lugar de la intervención; para ello se introduce el mecanismo de sujeción a través del canal de trabajo del fragmentador, se sujeta el tejido objetivo y se retrae hacia el fragmentador al tiempo que se activa la salida de corte de radiofrecuencia.

Fragmentador

El fragmentador consta de un electrodo de radiofrecuencia activo montado en el extremo distal de una cánula de trabajo. Una pieza de mano permite una sujeción positiva controlada y su sistema de cierre hermético evita que se produzca una pérdida de insuflación excesiva durante el uso. El cableado ofrece conexión de radiofrecuencia entre la estación de trabajo y el fragmentador y el mecanismo de sujeción.

Mecanismo de sujeción
El mecanismo de sujeción está permanentemente conectado al fragmentador para que la función eléctrica del dispositivo sea correcta.

Indicador de profundidad
El instrumento se suministra con un indicador de profundidad, pero este puede extraerse. Debe usarse únicamente a modo de indicador. Deberán adoptarse precauciones en todo momento para controlar la introducción del instrumento. El indicador puede extraerse y utilizarse con cánulas independientes.

Filtro
Para facilitar la eliminación del humo del campo visual se suministra un filtro de evacuación de humo pasivo que se acopla al cierre luer de una cánula disponible. Se recomienda acoplar el filtro a una cánula distinta a la utilizada para el fragmentador.

PRECAUCIONES
Antes del uso inicial, asegúrese de que toda la documentación adjunta, incluidas las advertencias, precauciones e instrucciones de uso, sean legibles y se entiendan. La seguridad y eficacia de la electrocirugía no dependen exclusivamente del diseño de los equipos, sino también de los factores que están bajo control del usuario (consulte el Manual del usuario de la estación de trabajo Gyrus ACMI G400).

Asegúrese de que el/los conector(es) del instrumento esté(n) bien acoplado(s) en el tomacorriente de la estación de trabajo antes del uso. Evite el contacto de líquido con el extremo proximal del instrumento.

Asegúrese de que los parámetros de la estación de trabajo sean adecuados para el procedimiento de electrocirugía que se va a llevar a cabo.

Evite una activación innecesaria, ya que podría originarse un calentamiento excesivo que dañaría la punta del instrumento o las estructuras de tejidos sensibles que estuvieran accidentalmente en contacto con la punta del instrumento, o con el cuerpo inmediatamente proximal a la punta.

Asegúrese de que el obturador suministrado esté insertado en el dispositivo para el proceso de obturación y que la fuerza aplicada se dirija a través del obturador y no se aplique directamente al mango del dispositivo.

Si se aplica una fuerza excesiva al mango, se debilitará el dispositivo y podría dañarse o fallar.

Consulte los esquemas a continuación para disipar dudas.

✗ ✓

Asegúrese de que el cuerpo del fragmentador se haya introducido lo suficientemente lejos para que todo el logotipo de la tecnología PK resulte visible y la punta esté separada de la pared abdominal para evitar daños en los tejidos por calor.

No intente doblar el cuerpo rígido de este instrumento, ya que se podría provocar el fallo del mismo.

No introduzca ni retire el cuerpo del fragmentador PKS PlasmaSORD del lugar del procedimiento mientras esté activado.

Si se usa con una cánula independiente, asegúrese de que la punta del instrumento PKS PlasmaSORD se introduzca suficientemente para sobrepasar la cánula antes y durante la activación. No lo active mientras alguna sección de la punta esté dentro de la vaina de la cánula.

Utilice únicamente instrumentos y cánulas aislados.

Asegúrese de que exista compatibilidad en todo momento y tenga cuidado cuando introduzca/retire los instrumentos a través de las cánulas para evitar daños. Al igual que ocurre con otras cánulas, no se recomienda abrir el mecanismo de sujeción dentro del cuerpo, ya que se podría dañar el sellado interno. Si ha quedado tejido dentro del instrumento y no puede limpiarse volviendo a introducir el mecanismo de sujeción cerrado, será necesario extremar las precauciones cuando se extraiga el tejido atrapado cerca del sellado para evitar daños.

Introduzca y extraiga el instrumento con cuidado para evitar posibles daños al instrumento y lesiones al paciente o al personal quirúrgico.

No debe permitir que el paciente entre en contacto con objetos metálicos conectados a tierra.

No use la estación de trabajo Gyrus ACMI G400 al mismo tiempo que otros generadores electroquirúrgicos.

No utilice productos abrasivos o cualquier otro medio agresivo para limpiar la punta del instrumento.

EFECTOS DEL TEJIDO
APLICACIÓN DEL DISPOSITIVO

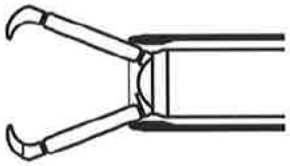
Todos los procedimientos de electrocirugía de radiofrecuencia producen emanaciones, como vapor o humo, que pueden dificultar la visión. Se recomienda utilizar el instrumento

con un sistema de extracción de humo adecuado o cualquier otro medio para eliminar dichas emanaciones.

El filtro de humo pasivo incluido ayuda a mantener el campo visual libre de obstáculos. Los filtros de humo pasivos suelen funcionar con mayor eficacia cuando se conectan a un orificio distinto al que se usa para el fragmentador. Consulte los pasos del 7 al 9 de la sección Instalación del fragmentador para un uso correcto.

USO DEL MECANISMO DE SUJECIÓN

Al igual que ocurre con otros fragmentadores, se deben tomar las precauciones necesarias para asegurarse de que el mecanismo de sujeción se haya cerrado lo necesario para introducirse en el cuerpo. No debe emplearse nunca una fuerza excesiva para retraer el tejido. Si se observa resistencia al introducir el mecanismo de sujeción en el cuerpo, será necesario volver a sujetar el tejido para facilitar un mejor cierre.



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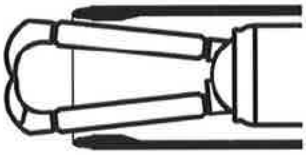

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Si se ha perdido presión de insuflación debido a una fuga en el fragmentador, es probable que la válvula se haya dañado. Cabe la posibilidad de evaluar si la válvula está dañada examinado el cuerpo del fragmentador. Si se observan daños, asegúrese de localizar los fragmentos dañados de la válvula y retirarlos del abdomen.

INSTALACIÓN DEL FRAGMENTADOR

1. Consulte el Manual del usuario de la estación de trabajo Gyrus ACMI G400 para obtener instrucciones detalladas del montaje y la comprobación inicial del sistema de la estación de trabajo Gyrus ACMI G400.
2. Active la estación de trabajo Gyrus ACMI G400.
3. El PKS PlasmaSORD y el filtro se suministran estériles para un solo uso. Inspeccione el envase antes del uso para comprobar la integridad de la barrera estéril.
4. Retire el PKS PlasmaSORD del envase. Examine el dispositivo para comprobar que no esté dañado. El dispositivo no debería utilizarse si se observan daños en el instrumento o en el envase. No utilice el producto una vez transcurrida la fecha de caducidad indicada en la etiqueta.
5. Conecte el PKS PlasmaSORD a la estación de trabajo. Compruebe que el conector esté correctamente alineado con los tomacorrientes en la estación de trabajo antes de efectuar la conexión.

   Es posible que para poder utilizar este instrumento sea necesario habilitar el software. Si no se reconoce el instrumento al enchufarlo, póngase en contacto con el representante local de Gyrus ACMI o con el servicio de atención al cliente para asegurarse de que se instala la versión del software correcta.
6. Confirme si en la estación de trabajo Gyrus ACMI G400 se muestra el nombre del instrumento correcto. Si aparece un nombre diferente, póngase en contacto con el servicio de atención al cliente de Gyrus ACMI y no utilice el dispositivo.

   Por razones de seguridad y comodidad, el PKS PlasmaSORD preajusta automáticamente el generador a los valores de salida correctos y restringe los niveles de salida para preservar la integridad del electrodo.
7. Si es necesario, el filtro de humo pasivo deberá acoplarse al conector de cierre luer de una de las cánulas disponibles. Es preferible emplear una cánula distinta a la utilizada con el fragmentador.
8. La tasa de flujo que atraviesa el filtro y por tanto la tasa de humo eliminado puede controlarse ajustando la válvula de la llave de paso de la cánula.
9. Coloque el cabezal del filtro de manera que la humedad que se condensa en el tubo no pueda desplazarse hacia el filtro, ya que podría perjudicar el funcionamiento.

INTRODUCCIÓN Y USO DEL FRAGMENTADOR

1. El tejido que va a ser extraído debe desvascularizarse antes de fragmentarse.
2. El PKS PlasmaSORD debe introducirse cuidadosamente en el lugar de la intervención ya sea directamente o a través de una cánula independiente de 15 mm, lo que el médico considere más apropiado. Se deben extremar las precauciones para evitar una introducción excesiva, ya que podría ocasionar daños a las estructuras de tejido colaterales. Aumente la incisión en la zona del orificio existente para facilitar la introducción si es necesario.

   Introduzca el PKS PlasmaSORD con el obturador bajo visualización directa. Asegúrese de que el obturador se haya introducido por completo en el fragmentador y aplique presión continua pero controlada con un movimiento giratorio deliberado de 180° aproximadamente.
3. Seguidamente, el mecanismo de sujeción Gyrus ACMI se introduce cuidadosamente en su posición cerrada a través del canal de trabajo del PKS PlasmaSORD. Al igual que ocurre con el fragmentador, se deberá tener sumo cuidado para evitar que se produzcan daños en los tejidos colaterales; hay que prestar especial atención a los dientes afilados del mecanismo de sujeción.
4. El tejido objetivo puede sujetarse ya y retraerse. La activación del dispositivo mediante el pedal amarillo cortará el tejido que entre en contacto con el extremo delantero del tubo del fragmentador.

   Dado que el PKS PlasmaSORD consigue su efecto mediante un corte eléctrico no mecánico, la resección del tejido es más eficaz cuando se aplica un movimiento firme y de poca fuerza. Si se observa resistencia o no hay efecto de corte al cabo de 5 segundos, se recomienda volver a sujetar el tejido y activar.

   Si se aplica una fuerza de retracción excesiva la incidencia de desgarro del tejido puede ser mayor.

   Si se produce una reducción significativa en la tasa de corte del tejido, puede ser debido a que se haya producido una acumulación de coágulo en la punta. En dichos casos, limpie con una gasa humedecida en agua estéril. Si el problema persiste, cambie el instrumento. No utilice productos abrasivos o cualquier otro medio agresivo para limpiar la punta del dispositivo.

   Durante el uso, mantenga la punta del instrumento visible. Un movimiento o una activación accidental del instrumento fuera del campo de visión podrían causar lesiones al paciente. Para evitar que se produzcan lesiones accidentales en la pared abdominal, vejiga, intestino u otras estructuras, o estimulaciones nerviosas, el tejido que se va a fragmentar debe estar completamente expuesto y sujeto para evitar que grandes porciones del tejido puedan desplazarse antes de aplicar el dispositivo. Pise el pedal para activar el dispositivo sólo cuando la punta distal esté dentro del campo de visión.

DESPUÉS DE LA FRAGMENTACIÓN

1. Desconecte el PKS PlasmaSORD de la estación de trabajo.

   PRECAUCIÓN: Sepárelo siempre sujetando el conector y no el cable. De lo contrario, se puede dañar el producto.

2. Apague la estación de trabajo.
3. Inspeccione el dispositivo inmediatamente tras extraerlo del paciente por si presentara signos de rotura o fragmentación. Si el dispositivo está dañado, guárdelo para poder ayudar al fabricante durante el análisis del evento.
4. Deseche todos los componentes del instrumento y los accesorios de un solo uso según la política de su centro para la destrucción de desechos quirúrgicos.

PRESENTACIÓN

El instrumento PKS PlasmaSORD y los accesorios se suministran estériles para un solo uso.

ALMACENAMIENTO

Almacénelo a una temperatura inferior a 25 °C (77 °F) y alejado de la humedad y del calor directo. No lo use una vez transcurrida la fecha de caducidad impresa en la etiqueta del instrumento.

PKS™ y PlasmaSORD™ son marcas comerciales de Gyrus ACMI y/o de sus entidades afiliadas, en EE.UU. y en otros países.

SÍMBOLOS

STERILE EO	- Esterilizado mediante óxido de etileno
LOT	- Número de lote
	- Manténgase alejado de la luz solar directa
	- Manténgase seco
	- Frágil, manipúlese con cuidado
QTY	- Representa la cantidad de dispositivos comercializables que contiene el envase.
	- Representa la cantidad de dispositivos que contiene el envase. # El número corresponde a la cantidad de dispositivos que hay en el interior del envase.
	- Intervalo de temperaturas de almacenamiento (°C)
	- De un solo uso
	- Fecha de caducidad
Manufactured for	- Cuando el producto está fabricado para Gyrus ACMI
Rx only	- **PRECAUCIÓN:** Las leyes federales (EE.UU.) sólo permiten la venta de este dispositivo bajo prescripción facultativa.
	- No usar si el envase está dañado
	- ISO 7010-M002 Seguir las instrucciones de uso

Fabricado en el Reino Unido.

EC REP

Gyrus Medical Ltd.
Fortran Road, St Mellons
Cardiff CF3 0LT, Reino Unido.

Fabricado para:
Gyrus ACMI Inc.
136 Turnpike Road
Southborough
MA 01772-2104
EE.UU.

Servicio de atención al cliente
Servicio de atención al cliente: 1-888-524-7266
Servicio técnico: 1-800-621-3739
www.gyrusacmi.com

SV

GYRUS ACMI

PKS™ PlasmaSORD™

REF 962000PK PKS™ PlasmaSORD™ med sladd

Bruksanvisning

VIKTIGT! Denna bipacksedel är avsedd att tillhandahålla bruksanvisningar för PKS PlasmaSORD-instrumentet när det används tillsammans med Gyrus ACMI G400 arbetsstation. Det är inte en referens för elektrokirurgisk teknik.

VAR FÖRSIKTIG!

Rx only-Enligt federal lag (USA) får denna anordning endast säljas av läkare eller på läkares ordination.

Läs alla anvisningar före användning, inklusive BRUKSANVISNINGAR, KONTRAINDIKATIONER, VARNINGAR och FÖRSIKTIGHETSÅTGÄRDER. Svåra patientskador kan uppstå om inte dessa anvisningar följs.

AVSEDD ANVÄNDNING

PKS PlasmaSORD är, när den används tillsammans med Gyrus ACMI G400 arbetsstation, avsedd för att skära, holka ur och extrahera vävnad i olika laparaskopiska ingrepp, inklusive allmänna kirurgiska ingrepp, urologiska ingrepp samt gynekologiska ingrepp.

KONTRAINDIKATIONER

Laparoskopiska elektriska morcellatorer är kontraindicerade för gynekologisk kirurgi om den vävnad som ska morcelleras innehåller eller misstänks innehålla malignitet.

Laparoskopiska elektriska morcellatorer är kontraindicerade för avlägsnande av livmodersvävnad som innehåller misstänkta fibroider hos patienter som är:

- peri- eller postmenopausala, eller
- kandidater för att avlägsna vävnadsblock, exempelvis genom vaginan eller ett minilaparotomisnitt.

Användning av Gyrus ACMI G400 arbetsstation kontraindiceras när läkaren bedömer att bipolära elektrokirurgiska ingrepp inte är gynnsamt för patienten.

Beträffande patienter med aktiva elektroniska implantat, bör man läsa bruksanvisningarna till dessa enheter innan bipolär elektrokirurgi utförs.

VARNINGAR!

***VARNING!* Livmodersvävnad kan innehålla oväntad cancer. Om laparoskopiska elektriska morcellatorer används vid fibroid kirurgi kan cancern spridas och försämra patienternas långsiktiga överlevnad. Denna information ska överlämnas till patienterna när operation med denna typ av enheter övervägs.**

Läs noga igenom all information, inklusive den användarhandbok som följer med Gyrus ACMI G400 arbetsstation, innan instrumentet används. Arbetsstation, fotpedal till generator samt PKS PlasmaSORD är alla utformade för att användas tillsammans som ett system. Om man underlåter att följa instruktionerna på ett korrekt sätt, kan elektrisk eller termisk skada uppstå och instrumentet kan fungera felaktigt.

Försök inte använda detta instrument med generatorer från andra tillverkare. Användare eller patient kan skadas, om andra generatorer än Gyrus ACMI G400 arbetsstation används.

Säker och effektiv elektrokirurgi är beroende på faktorer som styrs av användaren. Användaren måste vara väl förtrogen med laparaskopisk kirurgi med elektrokirurgisk utrustning, eller ha erhållit utbildning före användning.

Olämplig användning av elektrokirurgiska instrument kan medföra både elektriska och termiska vävnadsskador. Detta instrument får inte användas i närheten av vävnadsstrukturer (inklusive urinblåsans, tarmens eller bukens vägg) som kan skadas på detta sätt, om inte avsikten är resektion av denna vävnad.

PKS PlasmaSORD-pincettens käftar är vassa för att kunna få fäste i vävnaden. Det finns risk för att intilliggande vävnad skadas om inte försiktighet iakttas. Öppna endast PKS PlasmaSORD-pincettens käftar vid god sikt och när målvävnaden är nära.

Aktivering av anordningen när den distala spetsen befinner sig utanför synfältet och kan vara i kontakt med bukväggen kan medföra att nervvävnader i bukväggen stimuleras.

Håll instrumentspetsen i sikte under användning. Oavsiktlig aktivering eller förflyttning av instrumentet utanför synfältet kan resultera i patientskada. För att förhindra oavsiktliga skador på bukvägg, urinblåsa, tarm eller andra strukturer eller nervstimulering, bör den vävnad som ska morcelleras vara helt exponerad och fixerad för att förhindra att stora vävnadsbitar förflyttas, innan anordningen används. Tryck endast ner fotpedalen för att aktivera anordningen när den distala spetsen befinner sig i synfältet.

SLUTA OMEDELBART, om behandlingsstället eller anordningen försvinner ur synfältet under ingreppet. Fortsätt inte förrän sikten är återställd.

PKS PlasmaSORD-instrumentet kan visserligen snabbt avleda eventuell värme som genereras under användning, men instrumentspetsen och skaftet närmast spetsen kan förbli tillräckligt heta för att orsaka vävnadsskador omedelbart efter det att den elektrokirurgiska strömmen deaktiveras. Undvik kontakt med känslig vävnad, inklusive buk-port, som kan resultera i oavsiktlig termisk skada.

När det inte används, skall instrumentet placeras på en ren, oledande och väl synlig plats som inte har kontakt med patienten eller andra instrument. Oavsiktlig aktivering medan morcellatorn eller pincetten är i kontakt med patienten eller operationspersonal kan resultera i brännskador.

Rör inte vid eller rengör instrumentspetsen när strömmen är på.

Använd inte detta instrument med några andra gaser för insufflation än luft eller koldioxid.

I likhet med alla elektrokirurgiska instrument, finns det risk för brand till följd av gnistor och hetta som förknippas med elektrokirurgi. Vidta alltid försiktighetsåtgärder för brand. Använd inte instrumentet i närheten av lättantändliga anestesimedel eller oxiderande gaser, t.ex. lustgas eller syrgas. Endogena gaser som ansamlas i kroppskaviteter kan också utgöra en antändningskälla.

Placera inte aktiva tillbehör nära eller i kontakt med lättantändligt material (t.ex. gasväv eller operationslakan).

Denna anordning får inte används med påsar för extrahering av vävnad.

Lättantändliga ämnen som t.ex. alkoholbaserade hudberedningsmedel och tinkturer, bidrar till ökad risk för brand och explosion. Ej antändliga medel bör användas för rengöring och desinficering och lösningsmedel måste få tid att avdunsta innan elektrokirurgi inleds.

Aktivera inte PKS PlasmaSORD-instrumentet då det befinner sig i närheten av eller i kontakt med andra metallföremål än den särskilda Gyrus ACMI-pincetten, eftersom oavsiktliga vävnadsskador, skada på det föremål som kommit i kontakt med anordningen eller instrumentspetsen kan uppstå.

Får endast användas med särskild Gyrus ACMI-pincett som tillhandahålls med morcellatorn eller med äkta tillbehör till Gyrus ACMI-pincett som är avsedda för användning med denna anordning.

Linda inte anslutningssladden runt metallföremål. Om anslutningssladden lindas runt metallföremål kan ström induceras som orsakar elchock, brand eller skador på patient eller operationspersonal.

Försök inte avlägsna pincettkabeln från pincettens handtag.

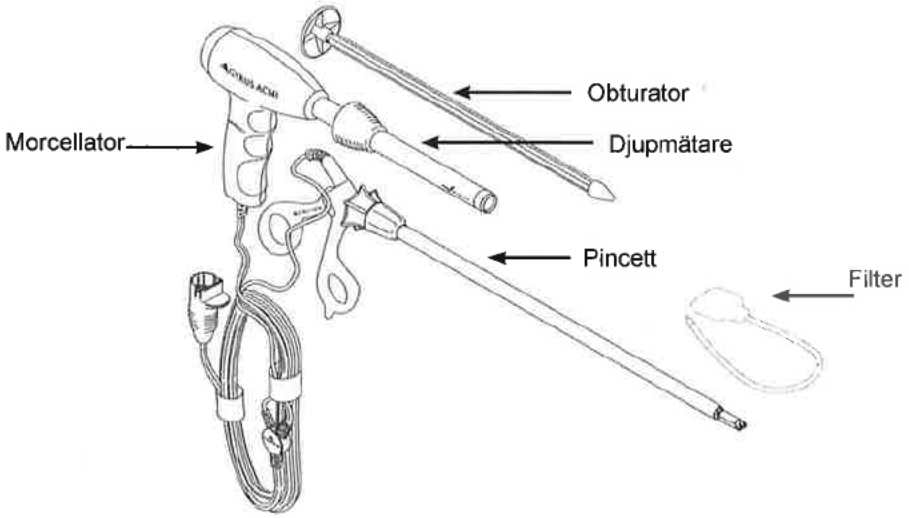
Denna produkt är endast avsedd för engångsbruk.
Den har inte utformats för återanvändning eller omsterilisering. Omsterilisering kan medföra ändrade materialegenskaper, t.ex. korrosion, trubbiga kanter, deformering och sönderdelning av keramik och plast vilket kan påverka produktens styrka och försämra prestandan. Omsterilisering av engångsprodukter kan också leda till korskontaminering med patientinfektion som följd. Dessa risker kan påverka patientsäkerheten.

VIKTIGT! Innehållet är sterilt under förutsättning att förpackningen är oöppnad och oskadad. Får ej omsteriliseras. Om produktförpackningen är öppnad eller skadad ska instrumentet kasseras och inte användas.

UTBILDNING

PKS PlasmaSORD rekommenderas för användning av kirurger med erfarenhet av laparoskopisk elektrokirurgi. Om du har några frågor rörande korrekt användning av denna produkt, ska du kontakta din försäljningsrepresentant för service på plats och/ eller utbildning före första användningstillfället.

PRODUKTBESKRIVNING



PKS PlasmaSORD är ett avancerat bipolärt elektrokirurgiskt instrument med kapacitet att skära och extrahera mjuk vävnad under laparaskopi. Instrumentet kan användas direkt eller genom att föras in via en separat 15 mm kanyl för åtkomst till operationsstället. Anordningen består av en radiofrekvent (RF) elektrokirurgisk vävnadsmorcellator, en permanent ansluten särskild vävnadspincett samt en obturator. När den används tillsammans med Gyrus ACMI G400 arbetsstation, kan enheten användas för att avlägsna vävnad från operationsstället genom att pincetten förs in via morcellatorns arbetskanal, greppar målvävnaden och för in den i morcellatorn medan RF-skärningen aktiveras.

Morcellator
Morcellatorn består av en aktiv RF-elektrod som monterats i arbetskanylens distala ände. Ett handtag ger ett kontrollerat positivt grepp och består av ett tätningssystem för att förhindra att för mycket insufflation går förlorad under användning. Sladduppsättningen ger RF-anslutning från arbetsstationen till både morcellator och pincett.

Pincett
Pincetten är permanent ansluten till morcellatorn för att medge korrekt elektrisk funktion hos instrumentet.

Djupmätare
En djupmätare levereras med instrumentet, men kan avlägsnas. Denna bör endast användas som en indikator. Var noga med att styra införseln av instrumentet. Mätaren kan avlägsnas för att medge användning med separata kanyler.

Filter
Ett passivt rökevakueringsfilter tillhandahålls som hjälper till att avlägsna rök ur synfältet, genom att det monteras vid en tillgänglig kanyls luerlock. Vi rekommenderar att filtret monteras vid en annan kanyl än den som används för morcellatorn.

FÖRSIKTIGHETSÅTGÄRDER

Innan instrumentet används skall man tillförsäkra att man har läst igenom och förstått alla bipacksedlar med varningar, försiktighetsåtgärder och bruksansvisningar. Säker och effektiv elektrokirurgi är inte bara beroende av utrustningens utformning, utan även på faktorer som styrs av användaren (se handboken till Gyrus ACMI G400 arbetsstation).

Kontrollera att instrumentets kontakt(er) är helt anslutna till uttaget i arbetsstationen före användning. Låt inte instrumentets proximala ände komma i kontakt med vätska.

Kontrollera att arbetsstationens inställningar är lämpliga för det elektrokirurgiska ingrepp som ska utföras.

Undvik onödig aktivering. Detta kan medföra alltför stor upphettning som kan orsaka skada på instrumentspetsen eller på känsliga vävnadsstrukturer som av misstag kommer i kontakt med instrumentspetsen, eller skaftet närmast spetsen.

Kontrollera att den medföljande obturatorn sitter på enheten vid obturatorprocessen och att den kraft som används riktas genom obturatorn och inte direkt på enhetens handtag.

Om handtaget utsätts för alltför stor kraft kommer enheten att försvagas, vilket kan leda till skada eller haveri.

Se nedanstående skisser för ett förtydligande.

✗ ✓

Kontrollera att morcellatorns skaft sitter tillräckligt långt inne så att hela PK technology-logotypen är synlig och så att spetsen inte rör vid bukväggen, för att undvika termiska vävnadsskador.

Försök inte att böja det styva skaftet på detta instrument. Enheten kan haverera om man försöker att böja skaftet.

För inte in eller dra tillbaka PKS PlasmaSORD morcellatorskaft från ingreppsstället medan strömmen är aktiverad.

Om instrumentet används med en separat kanyl, ska man kontrollera att PKS PlasmaSORD-instrumentets spets förs in tillräckligt långt så att det sticker ut utanför kanylen före och under aktivering. Aktivera inte instrumentet om någon del av spetsen finns kvar i kanylhylsan.

Endast isolerade instrument och kanyler får användas.

För att undvika skada skall man alltid kontrollera kompatibiliteten och vara försiktig vid införsel/avlägsnande av instrument genom en kanyl. I likhet med andra kanyler, är det inte tillrådligt att öppna pincetten inuti skaftet, eftersom detta kan skada den interna förseglingen. Om vävnad finns kvar i anordningen som inte kan rensas genom att man åter för in den stängda pincetten, ska man vara försiktig vid avlägsnande av fastnad vävnad i närheten av förseglingen, så att inte skada uppkommer.

För försiktigt in och dra tillbaka instrumentet för att undvika eventuella skador på instrumentet och/eller personskador på patient eller operationspersonal.

Patienten får inte komma i kontakt med jordade metallytor.

Använd inte Gyrus ACMI G400 arbetsstation samtidigt med andra elektrokirurgiska generatorer.

Rengör inte anordningens spets med slipmedel eller andra aggressiva rengöringsmetoder.

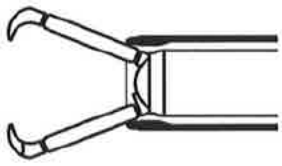
VÄVNADSEFFEKTER
ANVÄNDNING AV ANORDNINGEN

Alla elektrokirurgiska RF-ingrepp orsakar biprodukter i form av rök eller ånga som kan dölja sikten. Vi rekommenderar att denna anordning används med ett lämpligt rökextraheringssystem eller annan metod för hantering av sådana biprodukter vid behov.

Ett passivt rökfilter tillhandahålls för att underlätta bibehållande av sikten. Passiva rökfilter tenderar att fungera mera effektivt när de ansluts till en annan port än den som används för morcellatorn. Se steg 7-9 under avsnittet om förberedelse av morcellatorn beträffande korrekt användning.

ANVÄNDNING AV PINCETTEN

I likhet med andra morcellator-instrument ska man vara noga med att pincetten är tillräckligt stängd för att kunna komma in i skaftet. Man får aldrig använda för stor kraft för att dra in vävnad. Om motstånd upplevs när pincetten kommer in i skaftet, ska man ta ett nytt tag med pincetten för att skapa bättre tillslutning.



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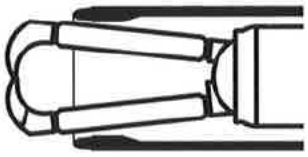


✓

Om insufflationstryck går förlorat på grund av en läcka i morcellatorn, kan det bero på att ventilen är skadad. Det kan vara möjligt att fastställa om ventilen är skadad genom att titta i morcellatorns skaft. Om detta är fallet måste man se till att eventuella ventilfragment hittas och avlägsnas från buken.

FÖRBEREDELSE AV MORCELLATORN

1. Läs i bruksanvisningen till Gyrus ACMI G400 arbetsstation för stegvisa instruktioner beträffande montering och inledande systemkontroll av Gyrus ACMI G400 arbetsstation.
2. Slå på Gyrus ACMI G400 arbetsstation. Följ anvisningarna i arbetsstationens handbok.
3. PKS PlasmaSORD och filtertillbehöret levereras sterila, avsedda för engångsbruk. Undersök förpackningen före användning för att tillförsäkra att den sterila barriären är intakt.
4. Ta ut PKS PlasmaSORD ur förpackningen. Kontrollera att anordningen inte är skadad. Anordningen får inte användas om instrumentet eller förpackningen har skadats på något vis. Använd inte anordningen efter det utgångsdatum som anges på etiketten.
5. Anslut PKS PlasmaSORD till arbetsstationen. Kontrollera att kontakten är korrekt inriktad med uttagen på arbetsstationen innan den ansluts.

   Det kan vara nödvändigt att aktivera programvaran innan instrumentet kan användas. Om anordningen inte identifieras vid inkoppling, ska du kontakta din lokala representant för Gyrus ACMI eller kundtjänst för att kontrollera att rätt version av programvaran har installerats.
6. Kontrollera att Gyrus ACMI G400 arbetsstation visar rätt instrumentnamn. Kontakta Gyrus ACMI kundtjänst och låt bli att använda instrumentet om ett annat namn visas.

   Av säkerhets- och bekvämlighetsskäl, förinställer PKS PlasmaSORD automatiskt generatorn till lämpliga effektinställningar och begränsar effektnivåerna för att bevara elektrodens integritet.
7. Vid behov ska det passiva rökfiltret monteras vid luerlock-kontakten på en tillgänglig kanyl. Det är bäst att använda en annan kanyl än den som används för morcellatorn.
8. Flödeshastigheten genom filtertillbehöret, och därmed hastigheten för rökavlägsnande kan styras genom att man justerar kanylens kranventil.
9. Placera filterhuvudet så att fukt som ansamlas i slangen inte kan förflyttas in i filtret, eftersom detta kan försämra funktionen.

INFÖRSEL OCH ANVÄNDNING AV MORCELLATORN

1. Vävnad som ska avlägsnas bör devaskulariseras före morcellering.
2. PKS PlasmaSORD bör försiktigt föras in i operationsstället, antingen direkt eller via en separat 15 mm kanyl, beroende på vad kirurgen bedömer vara lämpligt. Var försiktig så att den inte förs in för långt eller på annat sätt skadar intilliggande vävnadsstrukturer. Förstora incisionen vid existerande inträdesställe för att vid behov underlätta införseln.

   För under direkt visualisering in PKS PlasmaSORD med användning av obturatorn. Kontrollera att obturatorn är helt införd i morcellatorn och applicera kontinuerligt och kontrollerat tryck med en försiktig vridande rörelse i cirka 180°.
3. Kontrollera att pincetten är stängd och för in den genom arbetskanalen i PKS PlasmaSORD. I likhet med alla morcellatorer bör man vara försiktig för att undvika skada på intilliggande vävnader. Var extra uppmärksam på pincettens vassa käftar.
4. Målvävnaden kan nu gripas och dras tillbaka. Vid aktivering av instrumentet med den gula pedalen, kommer den vävnad som kommer i kontakt med morcellatorrörets framkant att skäras.

   Eftersom PKS PlasmaSORD uppnår sin effekt med användning av elektrisk, icke-mekanisk skärning, uppnås vävnadsresektion bäst med en stadig rörelse som inte kräver stor kraft. Om motstånd uppstår eller om ingen skäreffekt uppstår efter fem sekunder, bör man ta ett nytt tag med pincetten och aktivera.

   Om man använder för stor kraft vid indragningen av pincetten finns en större risk för vävnadsskador.

   Ansamling av vävnadskoagel på spetsen kan medföra märkbart minskad skäreffekt. Under sådana omständigheter ska man torka av den med en kompress som fuktats med sterilt vatten. Byt ut instrumentet om problemet kvarstår. Rengör inte anordningens spets med slipmedel eller andra aggressiva rengöringsmetoder.

   Håll instrumentspetsen i sikte under användning. Oavsiktlig aktivering eller förflyttning av instrumentet utanför synfältet kan resultera i patientskada. För att förhindra oavsiktliga skador på bukvägg, urinblåsa, tarm eller andra strukturer eller nervstimulering, bör den vävnad som ska morcelleras vara helt exponerad och fixerad för att förhindra att stora vävnadsbitar förflyttas, innan anordningen används. Tryck endast ner fotpedalen för att aktivera anordningen när den distala spetsen befinner sig i synfältet.

EFTER MORCELLERING

1. Koppla loss PKS PlasmaSORD från arbetsstationen.

   VAR FÖRSIKTIG! Koppla alltid loss genom att ta tag i anslutningens grepp och inte i kabeln. Annars kan skada på produkten uppstå.

2. Stäng av strömmen till arbetsstationen.
3. Undersök instrumentet omedelbart efter avlägsnande från patienten för eventuella tecken på skador eller fragmentering. Om instrumentet är skadat ska det bevaras för att underlätta tillverkarens analys av händelsen.
4. Kassera alla komponenter i engångsinstrumentet och tillbehören, enligt avdelningens standardprotokoll för kassering av operationsavfall.

LEVERANS

PKS PlasmaSORD instrument och tillbehör levereras sterila, endast avsedda för engångsbruk.

FÖRVARING

Förvaras under 25°C (77°F) på avstånd från fukt och direkt värme. Får ej användas efter det datum som anges på instrumentets etikett.

PKS™ och PlasmaSORD™ är varumärken som tillhör Gyrus ACMI, Inc. och/eller dess dotterbolag i USA och/eller andra länder.

SYMBOLER

STERILE EO	- Steriliserad med etylenoxid
LOT	- Lotnummer
	- Bör ej förvaras i direkt solljus
	- Förvaras torrt
	- Bräcklig - hanteras varsamt
QTY	- Anger antal försäljningsenheter i förpackningen.
	- Anger antal enheter i förpackningen. # Siffran motsvarar antalet enheter i förpackningen.
	- Temperaturområde vid förvaring (°C)
	- Engångsbruk
	- Utgångsdatum
Manufactured for	- När en produkt är tillverkad för Gyrus ACMI
Rx only	- **VAR FÖRSIKTIG!** Enligt federal lag (USA) får denna produkt endast säljas av eller på ordination av läkare.
	- Får ej användas om förpackningen är skadad
	- ISO 7010-M002 Följ bruksanvisningen

Tillverkad i Storbritannien.

EC REP

Gyrus Medical Ltd.
Fortran Road, St Mellons
Cardiff CF3 0LT, UK.

Tillverkad för:
Gyrus ACMI Inc.
136 Turnpike Road
Southborough
MA 01772-2104
USA

Kundtjänst
Kundtjänst: 1-888-524-7266
Teknisk service: 1-800-621-3739
www.gyrusacmi.com

RU

GYRUS ACMI

PKS™ PlasmaSORD™

REF 962000PK PKS™ PlasmaSORD™ с электрическим шнуром

Инструкции по применению

ЭТО ВАЖНО! В данном листке-вкладыше содержатся инструкции по эксплуатации устройства PKS PlasmaSORD совместно с рабочей станцией Gyrus ACMI G400. Эти инструкции не являются справочными материалами по электрохирургическим процедурам.

ВНИМАНИЕ!

По предписанию врача. В соответствии с федеральным законодательством США продажа данного устройства разрешена только врачам или по их поручению.

Перед началом работы следует прочитать все инструкции, включая ПРОТИВОПОКАЗАНИЯ, ПРЕДУПРЕЖДЕНИЯ и ПРЕДОСТЕРЕЖЕНИЯ. Невыполнение этих инструкций может привести к получению пациентом тяжелых травм.

ОБЛАСТЬ ПРИМЕНЕНИЯ

Устройство PKS PlasmaSORD при использовании совместно с рабочей станцией Gyrus ACMI G400 предназначено для рассечения, взятия биопсии и экстракции тканей в ходе различных лапароскопических операций, включая общехирургические, урологические и гинекологические операции.

ПРОТИВОПОКАЗАНИЯ

Лапароскопические электромеханические морцелляторы не должны использоваться в ходе гинекологических хирургических вмешательств, если известно или предполагается, что в удаляемых тканях имеются злокачественные образования.

Лапароскопические электромеханические морцелляторы не предназначены для удаления маточных тканей с предполагаемыми фиброзными опухолями у пациенток:

- в период пери- или постменопаузы; или
- у которых планируется удаление тканей единым блоком, например, с доступом через влагалище или минилапаротомический разрез.

Применение рабочей станции Gyrus ACMI G400 противопоказано в случаях, когда, по мнению лечащего врача, электрохирургические биполярные процедуры противоречат интересам пациента.

Перед проведением электрохирургических биполярных процедур у пациентов с имплантированными активными электронными устройствами см. инструкции по эксплуатации этих устройств.

ОСТОРОЖНО!

ОСТОРОЖНО! **Маточная ткань может содержать непредвиденные злокачественные образования. Применение лапароскопических электромеханических морцелляторов в ходе хирургического удаления фиброзных опухолей может привести к распространению раковых опухолей и уменьшить таким образом продолжительность жизни пациенток в долгосрочной перспективе. Эту информацию необходимо довести до ведома пациенток, если в ходе хирургического вмешательства планируется использовать такие устройства.**

Перед началом работы с устройством необходимо внимательно прочитать всю сопроводительную документацию к рабочей станции Gyrus ACMI G400, включая руководство пользователя. Рабочая станция, ножной включатель генератора и устройство PKS PlasmaSORD используются как единая система. Ненадлежащее выполнение инструкций может привести к получению электротравмы или термическому ожогу и некорректной работе инструмента.

Запрещается использовать данный инструмент с генераторами других производителей. Применение генераторов, отличных от рабочей станции Gyrus ACMI G400, может привести к травмированию оператора или пациента.

Безопасное и эффективное проведение электрохирургических операций зависит от подконтрольных оператору факторов. Оператор должен иметь опыт проведения лапароскопических операций с применением электрохирургических инструментов или пройти надлежащее обучение.

Ненадлежащее применение электрохирургических инструментов может привести к электротравме или термическому ожогу ткани. Не следует использовать данный инструмент в непосредственной близости от легко повреждаемых тканевых структур (например, мочевого пузыря, кишечника или брюшной стенки), кроме случаев, когда целью является резекция именно этих тканей.

Щипцы для резекции солидных тканей PKS PlasmaSORD имеют острые зубья, позволяющие захватывать твердые ткани. Если не соблюдать меры предосторожности, они могут повредить прилегающие ткани. Поэтому бранши щипцов PKS PlasmaSORD следует открывать только при хорошей видимости и в непосредственной близости от целевой ткани.

Активация устройства, когда дистальный конец расположен вне поля зрения и может касаться брюшной стенки, может привести к стимуляции нервов брюшной стенки.

Во время работы наконечник инструмента должен находиться в зоне видимости. Непреднамеренная активация инструмента или его вывод из зоны видимости может привести к травмированию пациента. Во избежание случайных повреждений брюшной стенки, мочевого пузыря, кишечника, других структур или стимуляции нервов, предназначенная для удаления ткань должна быть полностью доступна и зафиксирована так, чтобы избежать значительных смещений во время применения устройства. Нажимать педальный включатель для активации устройства можно, только когда дистальный наконечник находится в поле зрения.

Если во время процедуры теряется визуальный контроль за областью оперативного вмешательства или за устройством, нужно НЕМЕДЛЕННО ОСТАНОВИТЬ ПРОЦЕДУРУ. Запрещается продолжать работу до восстановления видимости.

Хотя устройство PKS PlasmaSORD рассчитано на быстрый отвод образующегося во время его применения тепла, наконечник и участок держателя, проксимальный к наконечнику, некоторое время после отключения электрохирургического инструмента могут оставаться достаточно горячими и способны травмировать ткань. Следует избегать контактов с чувствительной тканью, включая брюшную стенку, которые могут привести к непреднамеренному термическому ожогу.

Когда инструмент не используется, его следует держать в чистом и хорошо просматривающемся месте, исключающем контакт с пациентом или другими устройствами и не содержащем электропроводящих материалов. Непреднамеренная активация устройства в момент, когда морцеллятор или щипцы касаются пациента или оператора, может привести к получению ожогов.

Запрещается касаться наконечника инструмента или чистить его при включенном электропитании.

При работе с данным инструментом допускается использовать для инсуффляции только воздух и диоксид углерода.

Как и для любых электрохирургических устройств, искрение и нагрев, сопутствующие их применению, могут стать причиной возгорания. Необходимо постоянно соблюдать меры противопожарной безопасности. Запрещается использовать это устройство в присутствии горючих анестетиков или газообразных окислителей, таких как закись азота или кислород. Также источником возгорания могут стать эндогенные газы, способные накапливаться в полостях тела.

Запрещается размещать питающиеся от электросети принадлежности в непосредственной близости от горючих материалов (например, марлевых или хирургических салфеток).

Запрещается использовать данное устройство с мешочками для удаляемой ткани.

Применение горючих веществ, таких как средства и препараты для обработки кожи на спиртовой основе, повышает уровень взрывопожароопасности. Для чистки и дезинфекции допускается использовать только негорючие средства, при этом перед применением электрохирургического оборудования следует дождаться, пока растворители испарятся.

Запрещается активировать инструмент PKS PlasmaSORD, когда он находится вблизи от металлических предметов (за исключением специальных щипцов Gyrus ACMI) или касается их, поскольку это может привести к непреднамеренному повреждению ткани, этих предметов или наконечника инструмента.

Допускается использовать только специальные щипцы Gyrus ACMI, входящие в комплект поставки морцеллятора, или фирменные принадлежности для щипцов Gyrus ACMI, предназначенные для применения с данным устройством.

Не следует оборачивать соединительный кабель вокруг металлических предметов. Это может приводить к возникновению наведенных токов и, соответственно, к поражению током, возгоранию, травмированию пациентов или медперсонала.

Запрещается отсоединять кабель щипцов от рукоятки щипцов.

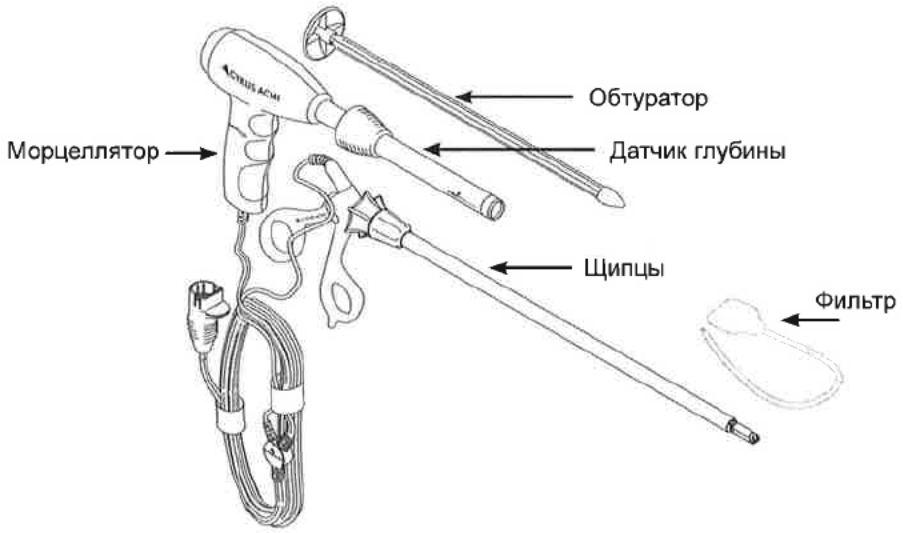
Данное устройство является одноразовым.
Оно не предназначено для повторного использования или повторной стерилизации. Его повторная обработка способна привести к изменению свойств материалов, в т. ч. коррозии металла и затуплению режущих кромок, деформации и расслоению керамических и пластиковых деталей, что может повлиять на прочность устройства и ухудшить его рабочие характеристики. Повторная обработка одноразовых устройств может также привести к перекрестному инфицированию пациентов и потенциально повлиять на их безопасность.

ЭТО ВАЖНО! Содержимое упаковок считается стерильным, только если упаковка не вскрыта или не повреждена. Повторная стерилизация не допускается. Если упаковка была вскрыта или повреждена, инструмент следует выбросить, его применение не допускается.

ОБУЧЕНИЕ

Устройство PKS PlasmaSORD рекомендуется для использования хирургами, имеющими опыт выполнения электрохирургических лапароскопических процедур. Если у вас имеются какие-либо вопросы относительно надлежащего применения данного устройства, обратитесь к своему торговому представителю для вводного инструктажа и/или обучения перед первым использованием.

ОПИСАНИЕ УСТРОЙСТВА



Выдвижной электрохирургический биполярный инструмент PKS PlasmaSORD предназначен для рассечения и экстракции мягких тканей в ходе лапароскопических операций. Это устройство можно вводить к области оперативного вмешательства без использования дополнительных принадлежностей или с помощью канюли диаметром 15 мм. Устройство состоит из радиочастотного электрохирургического морцеллятора ткани, несъемных щипцов специальной конструкции и обтуратора. При использовании совместно с рабочей станцией Gyrus ACMI G400 это устройство позволяет удалять ткань из области оперативного вмешательства путем выдвижения

щипцов через рабочий канал морцеллятора, захвата целевой ткани и втягивания щипцов обратно в морцеллятор в процессе работы режущего РЧ-инструмента.

Морцеллятор
Морцеллятор представляет собой активный РЧ-электрод, который закреплен на дистальном конце рабочей канюли. Его наконечник позволяет надежно осуществлять захват целевой ткани, а система уплотнений снижает потери инсуффлируемого газа во время работы. Шнуровой набор позволяет подключить морцеллятор и щипцы к рабочей станции по РЧ-каналу.

Щипцы
Несъемные щипцы, закрепленные на морцелляторе, обеспечивают надлежащее выполнение электрических функций устройства.

Датчик глубины
Датчик глубины входит в комплект поставки устройства, но его можно отсоединить. Этот прибор следует использовать только в качестве индикатора. Во всех случаях необходимо тщательно контролировать процесс введения инструмента. Датчик отсоединяется, что позволяет использовать отдельные канюли.

Фильтр
В комплект поставки входит пассивный фильтр дымоотсоса. Он подсоединяется к люэровскому соединителю используемой канюли и упрощает удаление дыма из поля зрения. Рекомендуется подсоединять фильтр не к той канюле, которая выделена для введения морцеллятора.

ВНИМАНИЕ!

Перед первым применением устройства следует внимательно ознакомиться со всеми прилагаемыми листками-вкладышами, включая сведения по безопасности и инструкции по эксплуатации. Безопасность и эффективность электрохирургических процедур зависит не только от конструкции оборудования, но и от факторов, находящихся под контролем оператора (см. руководство оператора к рабочей станции Gyrus ACMI G400).

Перед началом работы нужно проверить, чтобы разъемы прибора были до конца вставлены в гнезда рабочей станции. Следует избегать попадания жидкостей на проксимальный конец инструмента.

Необходимо проверить, чтобы настройки рабочей станции соответствовали выполняемой электрохирургической процедуре.

Не следует активировать устройство без необходимости, поскольку это может привести к чрезмерному нагреву и к повреждению наконечника прибора или чувствительных тканевых структур в результате непреднамеренного касания наконечника инструмента или участка держателя, проксимального к наконечнику.

Убедитесь, что поставляемый обтуратор вставлен в устройство для проведения процесса обтурации, и что прилагаемое усилие направлено непосредственно на обтуратор, а не на ручку устройства.

Чрезмерное давление на ручку снизит эффективность устройства и может привести к его повреждению или поломке.

Смотрите изображения ниже.

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Держатель морцеллятора следует вставить достаточно глубоко, так чтобы был полностью виден логотип PK Technology, при этом наконечник не должен касаться брюшной стенки, чтобы не допустить термического ожога ткани.

Запрещается изгибать жесткий держатель данного инструмента. Попытки изогнуть держатель могут привести к поломке устройства.

Запрещается вводить держатель морцеллятора PKS PlasmaSORD к области оперативного вмешательства или отводить его от этой области при включенном электропитании.

Если используется отдельная канюля, инструмент PKS PlasmaSORD до активации и во время нее должен находиться на достаточной глубине, позволяющей наконечнику выдвигаться за пределы канюли. Запрещается активировать инструмент, когда его наконечник полностью или частично находится в канюле.

Допускается использовать только изолированные инструменты и канюли.

Следует использовать только совместимые компоненты и соблюдать осторожность при введении и отводе инструментов через канюли во избежание их повреждения. Как и при использовании любых других канюль, раскрывать щипцы внутри держателя не рекомендуется, поскольку при этом можно повредить внутреннее уплотнение. Если внутри устройства осталась ткань, которую нельзя удалить путем повторного введения закрытых щипцов, следует соблюдать осторожность при удалении захваченной ткани вблизи от уплотнения, чтобы не повредить его.

Вводить и извлекать инструмент следует осторожно, чтобы не нанести травму пациенту или персоналу и не повредить сам инструмент.

Пациент не должен касаться заземленных металлических предметов.

Запрещается использовать рабочую станцию Gyrus ACMI G400 одновременно с другими электрохирургическими генераторами.

Запрещается использовать абразивные и иные агрессивные средства для чистки наконечника устройства.

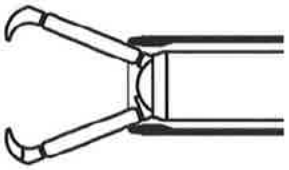
ВОЗДЕЙСТВИЕ УСТРОЙСТВА НА ТКАНИ

При работе всех высокочастотных электрохирургических устройств выделяются летучие побочные продукты, включая дым или пар, которые могут ухудшать видимость. Рекомендуется использовать данное устройство с соответствующими дымоотсосами или иными системами, обеспечивающими удаление этих побочных продуктов.

Прилагаемый пассивный фильтр дыма помогает поддерживать видимость в области вмешательства. Как правило, пассивные фильтры дыма более эффективны, если их подключать к канюле, отличной от канюли, которая выделена для морцеллятора. Инструкции по применению см. в пунктах 7–9 раздела по установке морцеллятора.

ИСПОЛЬЗОВАНИЕ ЩИПЦОВ

Как и при работе с другими морцелляторами, необходимо внимательно следить, чтобы щипцы были достаточно закрыты к моменту отвода в держатель. Запрещается прикладывать чрезмерные усилия при заборе ткани. Если при отводе щипцов в держатель ощущается повышенное сопротивление, ткань следует захватить повторно, создав условия для более легкого закрытия.



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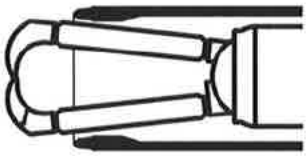

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Падение давления инсуффляции в результате утечки через морцеллятор может свидетельствовать о повреждении клапана. Следует попытаться оценить исправность клапана, заглянув в держатель морцеллятора. При обнаружении неисправности необходимо проверить, чтобы все компоненты клапана были найдены и извлечены из брюшной полости.

УСТАНОВКА МОРЦЕЛЛЯТОРА

1. Для получения пошаговых инструкций по сборке и первоначальным системным проверкам рабочей станции Gyrus ACMI G400 смотрите руководство оператора рабочей станции.
2. Включить рабочую станцию Gyrus ACMI G400 в соответствии с инструкциями, приведенными в руководстве оператора рабочей станции.
3. Устройство PKS PlasmaSORD и фильтр являются одноразовыми и поставляются стерильными. Перед применением проверить целостность стерильной упаковки.
4. Извлечь устройство PKS PlasmaSORD из упаковки. Проверить устройство на наличие повреждений. Запрещается использовать устройство с признаками повреждений или из нарушенной упаковки. Запрещается использовать устройство с истекшим сроком годности (указывается на упаковке).
5. Подсоединить устройство PKS PlasmaSORD к рабочей станции. Перед подключением проверить соответствие разъема гнездам на рабочей станции.

   Для работы с данным устройством может потребоваться разблокировка программного обеспечения. Если при подключении устройство не распознается автоматически, следует связаться с местным представительством или службой по работе с покупателями компании Gyrus ACMI и убедиться, что установлена подходящая версия программного обеспечения.
6. Проверить правильность отображения названия устройства на экране рабочей станции Gyrus ACMI G400. Если отображается другое название, устройством пользоваться запрещается; нужно обратиться в службу по работе с покупателями компании Gyrus ACMI.

   По соображениям безопасности и удобства применения устройство PKS PlasmaSORD автоматически задает необходимые настройки вывода на генераторе и ограничивает уровень выходного тока для сохранения целостности электрода.
7. При необходимости подключить пассивный фильтр дыма к люэровскому соединителю на свободной канюле. Рекомендуется использовать канюлю, отличную от той, которая выделена для морцеллятора.
8. Поток через фильтр можно регулировать с помощью запорного крана на канюле.
9. Крышку фильтра следует разместить так, чтобы влага, конденсирующаяся в трубке, не попадала в фильтр, поскольку это может ухудшить его рабочие характеристики.

ВВЕДЕНИЕ И ИСПОЛЬЗОВАНИЕ МОРЦЕЛЛЯТОРА

1. Удаляемую ткань перед морцелляцией следует подвергнуть деваскуляризации.
2. Устройство PKS PlasmaSORD осторожно вводится к области оперативного вмешательства без использования дополнительных принадлежностей или с помощью канюли диаметром 15 мм — на усмотрение врача. Следует соблюдать осторожность, чтобы не ввести устройство слишком глубоко и не травмировать смежные тканевые структуры. При необходимости можно увеличить надрез в месте введения, чтобы упростить процедуру.

   Ввести устройство PKS PlasmaSORD в зону прямой видимости с использованием обтуратора. Проверить, чтобы обтуратор был полностью вставлен в морцеллятор и, приложив постоянное, но контролируемое усилие, осторожно повернуть устройство примерно на 180°.
3. Перед введением щипцов в рабочий канал устройства PKS PlasmaSORD проверить, чтобы бранши были закрыты. Как и при работе с любым другим морцеллятором, следует соблюдать осторожность, чтобы исключить повреждение смежных тканей, обращая особое внимание на острые зубья щипцов.
4. Теперь можно захватить и забрать целевую ткань. При активации устройства с помощью желтой педали выполняется рассечение ткани, контактирующей с передней кромкой трубки морцеллятора.

   Поскольку устройство PKS PlasmaSORD осуществляет рассечение не механическим, а электрическим методом, наилучший результат достигается, когда резекция ткани выполняется при равномерном перемещении и минимальном нажиме. Если ощущается сопротивление или рассечения не удается достичь в течение 5 секунд, рекомендуется повторно захватить ткань и снова активировать устройство.

   Применение чрезмерного усилия может с большой вероятностью привести к отрыву ткани.

   Нарастающая на наконечнике коагулированная ткань может заметно снизить эффективность резания. В таких случаях его следует протереть марлевым тампоном, смоченным стерильной водой. Если проблему не удастся устранить, заменить инструмент. Запрещается использовать абразивные и иные агрессивные средства для чистки наконечника устройства.

   Во время работы наконечник инструмента должен находиться в зоне видимости. Непреднамеренная активация инструмента или его вывод из зоны видимости может привести к травмированию пациента. Во избежание случайных повреждений брюшной стенки, мочевого пузыря, кишечника, других структур или стимуляции нервов, предназначенная для удаления ткань должна быть полностью доступна и зафиксирована так, чтобы избежать значительных смещений во время применения устройства. Нажимать педальный включатель для активации устройства можно, только когда дистальный наконечник находится в поле зрения.

ДЕЙСТВИЯ ПОСЛЕ МОРЦЕЛЛЯЦИИ

1. Отсоединить устройство PKS PlasmaSORD от рабочей станции.

   ВНИМАНИЕ! При отсоединении следует тянуть за разъем, а не за кабель. Невыполнение этого требования может привести к поломке устройства.

2. Выключить питание рабочей станции.
3. Сразу после извлечения из тела пациента осмотреть устройство на наличие повреждений или дефектов. В случае повреждения сохранить устройство для проведения изготовителем анализа причины поломки.
4. Утилизировать все компоненты одноразового инструмента и принадлежности к нему в соответствии с правилами медицинского учреждения по уничтожению хирургических отходов.

ПОСТАВКА

Устройство PKS PlasmaSORD и принадлежности являются одноразовыми и поставляются стерильными.

ХРАНЕНИЕ

Хранить при температуре до 25 °C (77 °F) вдали от источников тепла и влаги. Не использовать после даты, напечатанной на упаковке инструмента.

PKS™ и PlasmaSORD™ являются товарными знаками компании Gyrus ACMI, Inc. и ее филиалов в США и/или других странах.

УСЛОВНЫЕ ОБОЗНАЧЕНИЯ

STERILE EO	- Стерилизовано с помощью оксида этилена
LOT	- Номер партии
	- Беречь от воздействия прямого солнечного света
	- Беречь от влаги
	- Осторожно, хрупкое
QTY	- Обозначает количество единиц товара в упаковке.
	- Обозначает количество изделий в упаковке. # Число соответствует количеству изделий в упаковке.
	- Диапазон температуры хранения (°C)
	- Только для одноразового применения
	- Использовать до указанной даты
Manufactured for	- Когда изделие изготовлено для Gyrus ACMI
Rx only	- **ВНИМАНИЕ!** В соответствии с федеральным законодательством США продажа данного устройства разрешена только врачам или по их поручению.
	- Запрещается использовать, если упаковка повреждена
	- ISO 7010-M002. Следуйте инструкции по эксплуатации

Изготовлено в Великобритании.

EC REP

Gyrus Medical Ltd.
Fortran Road, St Mellons
Cardiff CF3 0LT, UK (Великобритания).

Изготовлено по заказу:
Gyrus ACMI Inc.
136 Turnpike Road
Southborough
MA 01772-2104
USA (США)

Служба работы с покупателями:
Служба работы с покупателями: 1-888-524-7266
Служба технической поддержки: 1-800-621-3739
www.gyrusacmi.com

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Attachment 2:
PKS PlasmaSORD Sell Sheet,
document SS329-sord_0115

OLYMPUS®

Your Vision, Our Future

PK TECHNOLOGY

PKS™ PlasmaSORD™
BIPOLAR MORCELLATOR

The First Completely Bladeless SORD
(SOLID ORGAN REMOVAL DEVICE)

- **Efficient bipolar energy** to morcellate tissue instead of sharp, spinning blades.
- **Lightweight, ergonomic handle** designed to reduce hand fatigue in prolonged cases.
- **Easy-to-use** "plug and play" PK® Technology with the G400 Generator requires little setup for O.R. staff.
- **Durable and economical** because only one bipolar device is required per case.

WARNING: Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.

CONTRAINDICATION: Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.

CONTRAINDICATION: Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are:

- peri- or post-menopausal, or
- candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision.

PKS™ PlasmaSORD™ Bipolar Morcellator

ORDERING INFORMATION

PKS PLASMASORD	
962000PK‡	PKS™ PlasmaSORD™

PK TECHNOLOGY G400 & ACCESSORIES	
777000	G400 Generator w/9-Pin Inputs
744010	G400 Footswitch
560085-002	Generator Power Cord
710003	Dual Footswitch Connector Cord
700000	PKS™ and G400 Generator Cart

PK TECHNOLOGY INSTRUMENTS	
HACF0533‡	HALO™ PKS™ Cutting Forceps 5 mm, 33 cm
BL0533‡	PKS™ BiLL Bipolar Laparoscopic Loop, 5 mm, 33 cm
970000PC‡	PKS™ Omni,™ 5 mm, 15 cm
970005PC‡	PKS™ Omni,™ 5 mm, 24 cm
970010PC‡	PKS™ Omni,™ 5 mm, 33 cm
970015PC‡	PKS™ Omni,™ 5 mm, 45 cm
956000PC‡	PKS™ Plasma J-Hook,™ 5 mm, 15 cm
956005PC‡	PKS™ Plasma J-Hook,™ 5 mm, 24 cm
956010PC‡	PKS™ Plasma J-Hook,™ 5 mm, 33 cm
956015PC‡	PKS™ Plasma J-Hook,™ 5 mm, 45 cm

PK TECHNOLOGY INSTRUMENTS, CONTINUED	
952005PK‡	PKS™ PlasmaSpatula,® 5 mm, 33 cm
921015PK‡	PKS™ Cutting Forceps, 10 mm, 15 cm
920000PK‡	PKS™ Cutting Forceps, 5 mm, 24 cm
920005PK‡	PKS™ Cutting Forceps, 5 mm, 33 cm
921020PK‡	PKS™ Cutting Forceps, 10 mm, 33 cm
920010PK‡	PKS™ Cutting Forceps, 5 mm, 45 cm
950000PK‡	PKS™ Needle, 5 mm, 33 cm
942000PK‡	PKS™ LYONS™ Dissecting Forceps, 24 cm
942005PK‡	PKS™ LYONS™ Dissecting Forceps, 33 cm
942010PK‡	PKS™ LYONS™ Dissecting Forceps, 45 cm
954000PK‡	PKS™ L-Hook,™ 5 mm, 33 cm
954005PK‡	PKS™ L-Hook,™ 5 mm, 45 cm
910000PK‡	PKS™ MOLly® Forceps, 3 mm, 33 cm
910005PK‡	PKS™ MOLly® Forceps, 5 mm, 33 cm
910010PK‡	PKS™ MOLly® Forceps, 5 mm, 45 cm
960000PK‡	PKS™ LP Scissors, 5 mm, 33 cm
915000PK‡	PKS™ SEAL Open Forceps, Curved Jaw, w/Cord, 25 cm

‡ Supplied sterile, single-use, disposable.

* All come 5 per package.

SPECIFICATIONS

PKS™ PLASMASORD™

Shaft Length:	6.69 in (170 mm)
Shaft Diameter:	0.59 in (15 mm)
Grasper Diameter:	0.39 in (10 mm)
Depth Gauge:	
Length	0.79 in (20 mm)
Diameter	≤ 1.57 in (40 mm)

PKS™ PLASMASORD™ CORD

Length:	12 ft (3.65 m)

PK® G400 GENERATOR

Voltage:	Nominal 100–120/230 Volts RMS 50/60 Hz, 600 VA Source Operating Range
Waveform:	315–480 kHz
Dimensions (W x D x H):	16 x 16 x 5.3 in (410 x 410 x 135 mm)
Weight:	17.6 lbs (8.0 kg)
Electro-medical:	Class I (IEC 60601-1), Class IIb (MDD)

PK® G400 GENERATOR, Continued

Maximum output:	
PK & PC Modes	200 W into 150 ohms
DES Modes	128 W into 70 ohms
VP Modes	90 W into 80 ohms

PK® G400 FOOTSWITCH

Dimensions (W x H x D):	13.5 x 2.25 x 9 in
Weight:	4.4 lbs (2.0 kg)
Classification:	IPX8 watertight type (except plug)

PK TECHNOLOGY including the PKS™ PlasmaSORD™ is The Most Comprehensive Bipolar Energy Platform Available for LSH & TLH

HALO PKS™ Cutting Forceps

The unique five-in-one design grasps, dissects, coagulates, transects and retracts tissue all-in-one, ergonomic, hand-activated device.

PKS™ Omni

Advanced bipolar coagulation & cutting reduces OR time. True bipolar cutting for fast, precise tissue transection. Dual-action jaws facilitate mechanical dissection.

PKS™ BiLL™ Bipolar Loop

Advanced bipolar energy to safely and effectively amputate the uterus. Retractable loop allows insertion into any 5 mm trocar.

PKS™ Lyons™ Dissecting Forceps

Two-tiered, tapered jaw design with serrated surfaces provides secure grasping and retraction of tissue as well as pinpoint or wide based coagulation.

PKS™ Plasma Spatula®

Unique angled tip and broad surface provide the ability to precisely cut, coagulate and dissect in a variety of procedures.

PKS™ Plasma J-Hook

Simultaneously cuts and coagulates to reduce procedure time. Tip design is excellent for skeltonization & mobilization.

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Attachment 3:
PK Family Brochure,
document 6906-PK family_0115

PK® Technology is the Only Platform to Offer Four Uniquely-Designed Bipolar Cutting Instruments

PKS™ OMNI™

- Advanced bipolar coagulation and cutting designed to reduce OR time
- True bipolar cutting for fast, precise tissue transection
- Dual action jaws facilitate mechanical dissection
- Redesigned tip for improved spot coagulation and grasping
- For laparoscopic and open procedures

PKS™ PLASMA J-HOOK™

- Rapid hemostatic cutting improves procedural efficiency
- Simultaneously cuts and coagulates to reduce OR time
- Excellent for skeletonization and mobilization
- For laparoscopic and open procedures

PKS™ PLASMASPATULA®

- Unique angled tip design and broad surface enhances procedural effectiveness
- Precisely cuts, coagulates and dissects
- Excellent for spot coagulation
- For laparoscopic procedures

PKS™ NEEDLE

- Fast bipolar cutting with minimal thermal spread
- Adjustable needle electrode allows the surgeon to adjust the depth of the cut for precise control while preserving surrounding tissues
- Extendable outer sheath allows for tissue dissection and protects electrode while passing through the trocar

PK® Technology Family

ORDERING INFORMATION

PK TECHNOLOGY G400 & ACCESSORIES	
777000	G400 Generator w/6-Pin Inputs
744010	G400 Footswitch
500045-002	Generator Power Cord
710003	Dual Footswitch Connector Cable
760000	PKS™ and G400 Generator Cart

PK TECHNOLOGY INSTRUMENTS	
HACP0533	HALO™ PKS™ Cutting Forceps, 5 mm, 33 cm
BL00331	PKS™ BLL Bipolar Laparoscopic Loop, 5 mm, 33 cm
962000PK	PKS™ PlasmaSPRO™
970000PC	PKS™ Omni™ Stem, 35 cm
970005PC	PKS™ Omni™ Stem, 24 cm
970010PC	PKS™ Omni™ Stem, 33 cm
970015PC	PKS™ Omni™ Stem, 45 cm
956000PC	PKS™ Plasma J-Hook™ 5 mm, 33 cm
956005PC	PKS™ Plasma J-Hook™ 5 mm, 24 cm
956010PC	PKS™ Plasma J-Hook™ 5 mm, 33 cm
956015PC	PKS™ Plasma J-Hook™ 5 mm, 45 cm

PK TECHNOLOGY INSTRUMENTS, CONTINUED	
952005PK	PKS™ PlasmaSpatula™ 5 mm, 33 cm
921010PK	PKS™ Cutting Forceps, 10 mm, 18 cm
920000PK	PKS™ Cutting Forceps, 5 mm, 24 cm
920005PK	PKS™ Cutting Forceps, 5 mm, 33 cm
921020PK	PKS™ Cutting Forceps, 10 mm, 33 cm
920010PK	PKS™ Cutting Forceps, 5 mm, 45 cm
950000PK	PKS™ Hook, 5 mm, 33 cm
942000PK	PKS™ LYONS™ Dissecting Forceps, 5 mm, 24 cm
942005PK	PKS™ LYONS™ Dissecting Forceps, 5 mm, 33 cm
942010PK	PKS™ LYONS™ Dissecting Forceps, 5 mm, 45 cm
954000PK	PKS™ L-Hook™ 5 mm, 33 cm
954005PK	PKS™ L-Hook™ 5 mm, 45 cm
910000PK	PKS™ MOLly® Forceps, 3 mm, 33 cm
912005PK	PKS™ MOLly® Forceps, 5 mm, 33 cm
912010PK	PKS™ MOLly® Forceps, 5 mm, 45 cm
960000PK	PKS™ LP Scissors, 5 mm, 33 cm
893000PK	PKS™ SEAL Open Forceps, Curved Jaw, w/Cleat, 35 cm

Five Instruments Complete the PK® Technology Family of Products

PKS™ LYONS™ DISSECTING FORCEPS
Uniquely designed for secure grasping, dissecting, retracting & pinpoint or broad coagulation.

PKS™ L-HOOK
Efficiently dissects, coagulates and transects. Features extendable sheath to add safety.

PKS™ MOLly® FORCEPS
Unique jaw design for concentrated energy delivery grasps, coagulates and retracts tissue with precision.

PKS™ LP SCISSORS
Multifunctional device for mechanical cutting and coagulation.

PKS™ SEAL® OPEN FORCEPS
Seals a wide range of tissue types and vessels up to 7 mm, eliminating the need for most sutures, clips or staples in open procedures.

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OLYMPUS
Your Vision, Our Future

PK TECHNOLOGY

The Most Comprehensive Advanced Bipolar Energy Platform Available

PK® Technology Surgical Tissue Management Platform

SURGEON CONTROL

PK® Technology allows the surgeon, rather than the device or system, to choose how long energy is applied. It eliminates the frustrating lag between generator and desired tissue effect with instantaneous, consistent energy delivery. Other systems predict and dictate an end-point that the surgeon cannot override. PK® Technology puts control right in the surgeon's hands.

COOL POWER DELIVERY

PK® Technology delivers a proprietary, pulsing ultra-low voltage and high-current RF energy waveform to create a broad range of tissue effects, and allows the tissue and device tip to cool during the "energy off" phase minimizing sticking and charring.

MOST VERSATILE PLATFORM AVAILABLE

The PK® Technology platform offers a range of multi-functional instruments designed to reduce blood loss, improve operating room efficiency and minimize post-operative pain. It provides surgeons with the ability to seal, transect, coagulate, dissect, vaporize, resect and mobilize tissue all with precision and control from one workstation. With twelve different tips to choose from, PK® Technology provides the versatility to perform specific procedure applications on multiple tissue types.

HALO PKS Cutting Forceps

PKS PlasmaSORD

PKS Omni

PKS BiLL

PKS Plasma Spatula

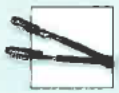
PKS Plasma J-Hook

PKS Lyons Dissector

PKS Needle

PKS SEAL Open Forceps

PKS L-Hook


PKS MOLly Forceps

PKS LP Scissors

HALO PKS™ Cutting Forceps

(Hand Activation for Laparoscopy and Open)

LED indicates the device is selected on the generator.

Rotation Wheel provides finger-tip control for up to 330° of distal tip rotation.

Easy-to-access **Hand Activation Coagulation Button** eliminates the need for a foot pedal and puts control right in the surgeon's hand.

Features an advanced **Tip Design with Serrated Jaws** for secure tissue grasping, coagulation, dissection and retraction.

The **Cut Blade Trigger** is ergonomically positioned to provide easier access with one hand and to minimize fatigue.

Optional Latch Slide provides consistent grasp on tissue to reduce hand fatigue.

HALO™ PKS™ Cutting Forceps offers excellent performance across a wide variety of procedures. The unique five-in-one design grasps, dissects, coagulates, transects and retracts tissue all in one easy-to-use, ergonomic hand-activated device.

- **Multi-Functional Instrument** Designed to reduce instrument exchanges and increase efficiency.
- **Serrated Jaws** Securely grasp tissue.
- **Hollow Jaw design** Allows for visualization of tissue during transecting or coagulating.

PKS™ PlasmaSORD™ Bipolar Morcellator: The First Completely Bladeless SORD (Solid Organ Removal Device)

- **Efficient bipolar energy** To morcellate tissue instead of sharp, spinning blades.
- **Lightweight, ergonomic handle** Reduces hand fatigue in prolonged cases.
- **Easy to use** "Plug and play" PK® Technology with the G400 Generator requires little setup for O.R. staff.
- **Durable and economical** Only one device is required per case.

WARNING: Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.

CONTRAINDICATION: Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.

CONTRAINDICATION: Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are

- peri- or post-menopausal, or
- candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision.

Efficient Bipolar Energy is delivered at the tip without mechanical spinning blades.

PKS™ BiLL: The First Laparoscopic Loop Using Advanced Bipolar PK® Energy

- **Safety of advanced bipolar energy** To effectively amputate the uterus or resect myomas
- **Retractable loop** Allows insertion into a 5 mm trocar
- **Easy visualization** Vivid blue insulated loop wires
- **Simple to use** "Plug and play" PK® Technology with the G400 Generator requires little setup by O.R. staff
- **Comprehensive LSH procedure solution** When used in combination with other PK® Technology devices

Attachment 4:
Laparoscopic Hysterectomy Brochure,
document BR316-LSH-TLH_0115

PK TECHNOLOGY for Laparoscopic Hysterectomy

PK TECHNOLOGY G400 & ACCESSORIES	
777000	G400 Generator w/9-Pin Inputs
744010	G400 Footswitch
560085-002	Generator Power Cord
710003	Dual Footswitch Connector Cable
700000	PKS™ and G400 Generator Cart

PK TECHNOLOGY INSTRUMENTS*	
HACF0533	HALO™ PKS™ Cutting Forceps 5 mm, 33 cm
BL0533	PKS™ BILL Bipolar Laparoscopic Loop, 5 mm, 33 cm
962000PK	PKS™ PlasmaSORD Morcellator
970000PC	PKS™ Omni,™ 5 mm, 15 cm
970005PC	PKS™ Omni,™ 5 mm, 24 cm
970010PC	PKS™ Omni,™ 5 mm, 33 cm
970015PC	PKS™ Omni,™ 5 mm 45 cm
956000PC	PKS™ Plasma J-Hook,™ 5 mm, 15 cm
956005PC	PKS™ Plasma J-Hook,™ 5 mm, 24 cm
956010PC	PKS™ Plasma J-Hook,™ 5 mm, 33 cm
956015PC	PKS™ Plasma J-Hook,™ 5 mm, 45 cm

PK TECHNOLOGY INSTRUMENTS, CONTINUED	
952005PK	PKS™ PlasmaSpatula,® 5 mm, 33 cm
920000PK	PKS™ Cutting Forceps, 5 mm, 24 cm
920005PK	PKS™ Cutting Forceps, 5 mm, 33 cm
920010PK	PKS™ Cutting Forceps, 5 mm, 45 cm
921015PK	PKS™ Cutting Forceps, 10mm, 15 cm
921020PK	PKS™ Cutting Forceps, 10mm, 33 cm
950000PK	PKS™ Needle, 5 mm, 33 cm
942000PK	PKS™ LYONS™ Dissecting Forceps, 5mm, 24 cm
942005PK	PKS™ LYONS™ Dissecting Forceps, 5mm, 33 cm
942010PK	PKS™ LYONS™ Dissecting Forceps, 5mm, 45 cm
954000PK	PKS™ L-Hook,™ 5mm, 33 cm
954005PK	PKS™ L-Hook,™ 5mm, 45 cm
910000PK	PKS™ MOLly® Forceps, 3 mm, 33 cm
910005PK	PKS™ MOLly® Forceps, 5mm, 33 cm
910010PK	PKS™ MOLly® Forceps, 5mm, 45 cm
960000PK	PKS™ LP Scissors, 5mm, 33 cm
915000PK	PKS™ SEAL Open Forceps, Curved Jaw, w/Cord, 25 cm

*5 per package

SPECIFICATIONS

PK® G400 GENERATOR

Voltage:	Nominal 100–120 / 230 Volts RMS 50/60 Hz, 600 VA Source Operating Range
Waveform:	315–480 kHz
Dimensions (W x D x H):	16 x 16 x 5.3 in. (410 x 410 x 135 mm)
Weight:	17.6 lbs (8.0 kg)
Electro-medical:	Class I (IEC 60601-1), Class IIb (MDD)
Maximum output:	
PK & PC Modes	200 W into 150 ohms
DES Modes	128 W into 70 ohms
VP Modes	90 W into 80 ohms

FOOTSWITCH

Dimensions (W x H x D):	13.5 x 2.25 x 9 in.
Weight:	4.4 lbs (2.0 kg)
Classification:	IPX8 watertight type (except plug)

HALO™ PKS™ Cutting Forceps
Hand Activation for Laparoscopy and Open

Features the same great tip design with serrated jaws for secure tissue grasping, coagulation, dissection and retraction.

The cut blade activation is ergonomically positioned to provide easier access with one hand and minimize fatigue.

The select button with LED indicates the device is selected on the generator.

Easy-to-access hand activation button eliminates the need for a foot pedal and puts coag control right in the surgeon's hand.

Rotation wheel provides finger-tip control for up to 330 degrees of rotation.

Optional latch slide provides consistent grasp on tissue to reduce hand fatigue.

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PK TECHNOLOGY

The Most Comprehensive Bipolar Energy Platform Available

LAPAROSCOPIC HYSTERECTOMY

PK® Technology Surgical Tissue Management Platform

Cool Power

PK® Technology delivers a proprietary, pulsing, ultra-low voltage (110 V_{RMS}) and high-current RF energy waveform to create a broad range of tissue effects, and allows the tissue and device tip to cool during the "energy off" phase minimizing sticking and charring.

Versatile Choices

PK® Technology offers a range of multi-functional instruments designed to reduce blood loss, improve operating room efficiency and minimize post-operative pain. It provides surgeons with the ability to seal, transect, coagulate, dissect, vaporize, resect and mobilize tissue all with precision and control from one workstation.

Surgeon Driven

PK® Technology allows the surgeon, rather than the device or system, to choose how long energy is applied. PK® Technology eliminates the frustrating lag between generator and desired tissue effect with instant, consistent energy delivery. As changes in tissue impedance occurs, an audible tone changes to indicate tissue desiccation to the user. Other systems predict and dictate an endpoint that the surgeon cannot override. Under the surgeon's control, PK® Technology reduces failure rates and enhances clinical outcomes.

One Safe, Efficient Advanced Bipolar Platform

The PK® Technology advanced bipolar energy platform has a full line of multifunctional instruments designed to shorten procedure times and help improve patient outcomes for:

- Laparoscopic Supracervical Hysterectomy (LSH)
- Total Laparoscopic Hysterectomy (TLH)
- Myomectomy
- Bilateral Salpingo-Oophorectomy
- Oophorectomy

The World's First Bipolar Laparoscopic Loop

PKS™ BiLL

PKS™ BiLL is the world's first Bipolar Laparoscopic Loop, providing a comprehensive LSH procedural solution with the safety and convenience of one bipolar platform when used in combination with other PK® Technology devices.

- **Safety of advanced bipolar energy** To effectively amputate the mobilized uterus or resect myomas
- **Retractable loop** Allows insertion into any 5 mm trocar
- **Vivid blue insulated loop wires** For easy visualization

PK® Technology Offers a Range of Multifunctional Instruments

HALO™ PKS™ Cutting Forceps

Offers reliable performance across a wide variety of procedures. The unique five-in-one design grasps, dissects, coagulates, transects and retracts tissue all in one easy-to-use, ergonomic hand-activated device.

- **Multi-functional instrument** Reduces instrument exchanges, increases efficiency and reduces OR time
- **Serrated jaws** Securely grasp tissue
- **Hollow jaw design** Allows for visualization of tissue during transecting or coagulating

PKS™ Omni™

Offers exceptional functionality from a single instrument.

- **Advanced bipolar coagulation and cutting** Reduces OR time
- **True bipolar cutting** Provides fast, precise tissue transection
- **Dual-action jaws** Facilitate mechanical dissection
- **Improved tip design** Allows spot coagulation and improved grasping capabilities
- **Outstanding Versatility** For laparoscopic and open procedures

PKS™ PlasmaSORD™*

PKS™ PlasmaSORD bipolar morcellator is the first completely bladeless SORD (Solid Organ Removal Device).

- **Efficient bipolar energy** Morcellates tissue instead of sharp, spinning blades.
- **Lightweight, ergonomic handle** Reduces hand fatigue in prolonged cases.
- **Durable and economical** Only one bipolar device is required per case.

WARNING: Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.

CONTRAINDICATION: Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.

CONTRAINDICATION: Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are:

- peri- or post-menopausal, or
- candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision.

PKS™ Lyons™ Dissecting Forceps

Uniquely designed for secure grasping, dissecting, retracting and coagulating. The PKS™ LYONS™ Dissector is the one instrument no surgeon should be without.

- **Two-tier jaw design with serrated surfaces** Provides secure grasping and retraction of tissue
- **Curved, fine-rounded tip** Provides atraumatic dissection and assists with vessel skeletonization
- **Tapered jaw design** Provides pinpoint or wide-based coagulation
- **360° shaft rotation** Makes difficult angles more accessible

PKS™ PlasmaSpatula®

A unique multifunctional device with the ability to electrosurgically cut & coagulate for use in a variety of procedures.

- **Multifunctional device** Precisely cuts, coagulates and dissects
- **Safe and efficient** Instrument tip stays cool minimizing thermal spread
- **Unique tip design** Angled tip and broad surface enhances procedural effectiveness

PKS™ Plasma J-Hook™

The PKS™ Plasma J-Hook provides a rapid and precise hemostatic cut & excellent coagulation in one instrument.

- **Simultaneously cuts and coagulates** Reduces OR time
- **Rapid hemostatic cutting** Improves procedural efficiency
- **Unique tip design** Excellent for skeltonization and mobilization

Attachment 5:
PK Technology Product Catalog,
document 02-pk-section

OLYMPUS®

Your Vision, Our Future

PK® TECHNOLOGY FOR LAPAROSCOPIC AND OPEN SURGERY

PK® TECHNOLOGY

PK® Technology is the most versatile surgical tissue management technology available from a single workstation. PK® Technology provides surgeons with unique RF energy to seal, transect, coagulate, dissect, vaporize, resect and mobilize tissue all with the precision and control from one workstation. The PK® Technology generators and devices were developed in unison to optimize the performance of over 13 tip configurations to deliver desired effect to a wide range of tissue types and conditions. PK® Technology offers a range of multifunctional instruments designed to reduce blood loss, improve operating room efficiency and minimize post-operative pain. Instruments are available for laparoscopic and open surgery.

POWERFUL.

PK® Technology delivers a proprietary pulsed RF energy waveform to create a broad range of tissue effects for a multitude of surgical applications giving the surgeon optimal, precise control. PK® Technology eliminates the frustrating lag between generator activity and the desired tissue effect. Instant energy delivery from initial activation provides complete and consistent performance to seal thoroughly and quickly, and to transect with precision at high resistances.

PRECISE.

PK® Technology provides advanced sealing and cutting with superior hemostasis delivering minimal energy to achieve the desired tissue effect. By pulsing the energy, ultra-low voltage (110 V_{RMS}) and high current is delivered to create a broad range of tissue effects allowing the tissue and device tip to cool during the "energy off" phase minimizing sticking and charring. PK® Technology adjusts the current as resistance increases to optimize performance and reduce thermal spread

PREDICTABLE.

PK® Technology allows the physician — rather than the device or system — to choose how long energy is applied. As changes in tissue impedance occurs, an audible tone changes to indicate tissue desiccation to the user. Other systems predict and dictate an endpoint that the surgeon cannot override. Under the control of the physician, PK® Technology reduces failure rates and enhances clinical outcomes.

PK® TECHNOLOGY

PK® G400 Generator 12
PK® SuperPulse® Generator 12
HALO™ PKS™ Cutting Forceps 13
PKS™ Cutting Forceps 13
PKS™ Omni™ 14
PKS™ Plasma J-Hook™ 14
PKS™ PlasmaSpatula® 15
PKS™ PlasmaSORD™ 15
PKS™ LYONS™ Dissecting Forceps 16
PKS™ Needle 16
PKS™ L-Hook™ 17
PKS™ Scissors 17
PKS™ MOLly® 18
PKS™ Macro & Micro Forceps 18
PKS™ SEAL Open Forceps 19

PK® Technology G400 Generator

The PK® Technology G400 Generator delivers a proprietary pulsed RF energy waveform to create a broad range of tissue effects for a multitude of surgical applications giving the surgeon optimal, precise control.

- **Powerful, instant energy delivery** Provides complete and consistent tissue effect
- **Pulsed RF energy** Adjusts current delivery based on tissue resistance
- **Optimal cutting and coagulating effect over a wide variety of tissue types and conditions** Minimal thermal spread and sticking
- **Dual device ports** Two instruments can be used during a case
- **Compatible with the da Vinci® Robot System** Easy upgrade to enable connectivity

PK G400 GENERATOR	
777000	G400 Generator with 9-Pin Inputs
744010	PK® Footswitch
560085-002	Generator Power Cord
710003	Dual Footswitch Connector Cable
700000	PKS™ and G400 Generator Cart

PK SUPERPULSE GENERATOR	
744000	PK® SuperPulse® Generator 110 V–220 V, 60 Hz
744010	PK® Foot Switch
710003	Dual Footswitch Connector Cable
3900	PK® Reusable Connector Cable (3-Pin)
3905	PK® Reusable Connector Cable (5-Pin)

777000 & 744010

700000

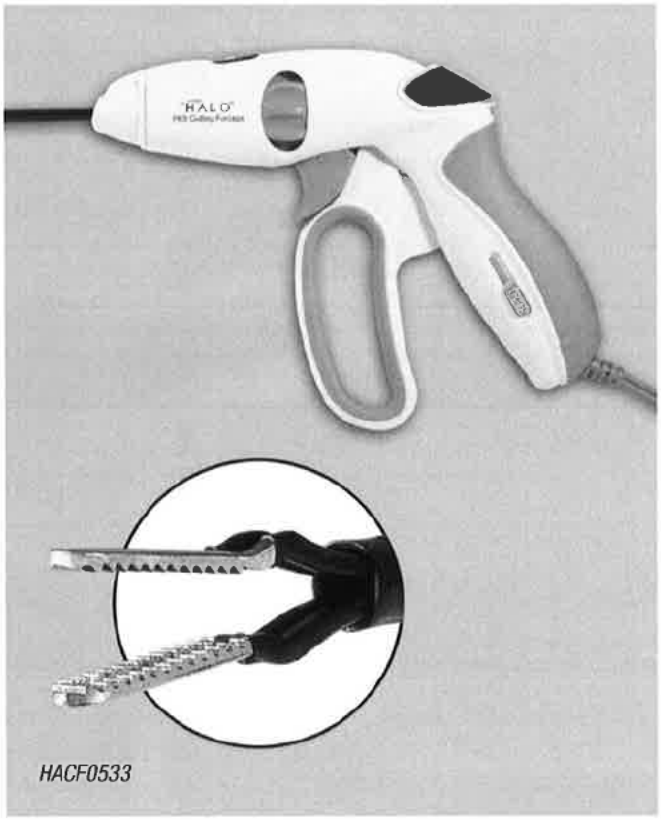
HALO™ PKS™ Cutting Forceps

Hand Activation for Laparoscopy & Open

Features the same great tip design as the Cutting Forceps with serrated jaws for secure tissue grasping, coagulation, dissection and retraction.

- **Cut blade trigger is ergonomically positioned** Provides easier access with one hand and to minimize fatigue
- **Rotation wheel** Provides finger-tip control for up to 330° of distal tip rotation
- **Easy-to-access hand activation coagulation button** Eliminates the need for a foot pedal and puts control right in the surgeon's hand
- **Optional latch slide** Provides consistent grasp on tissue to reduce hand fatigue
- **LED indicator** Shows the device is selected on the generator

HALO PKS CUTTING FORCEPS	
HACF0533	HALO PKS™ Cutting Forceps 5 mm, 33 cm



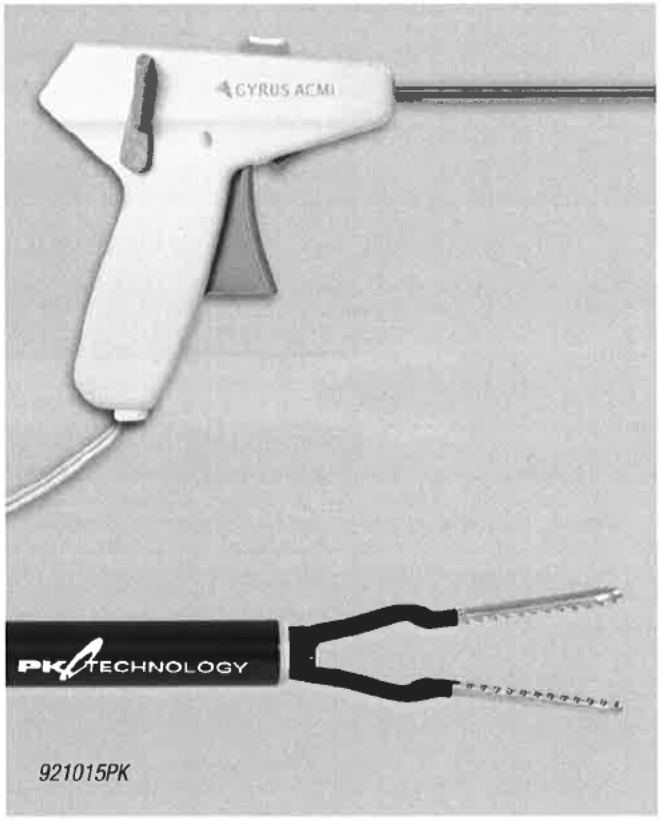
HACF0533

PKS™ Cutting Forceps

The PKS™ Cutting Forceps offers superior performance and versatility across a wide variety of procedures. The unique five-in-one design grasps, dissects, coagulates, transects and retracts tissue all in one easy-to-use device.

- **Multi-functional instrument** Reduces instrument exchanges, increases efficiency and reduces OR time
- **Serrated jaws** Securely grasp tissue
- **Hollow jaw design** Allows for visualization of tissue during transecting or coagulating

PKS CUTTING FORCEPS	
For use with PK® G400 Generator only	
920000PK‡	PKS™ Cutting Forceps, with Cord, 5 mm, 24 cm
920005PK‡	PKS™ Cutting Forceps, with Cord, 5 mm, 33 cm
920010PK‡	PKS™ Cutting Forceps, with Cord, 5 mm, 45 cm
921015PK‡	PKS™ Cutting Forceps, with Cord, 10 mm, 15 cm
921020PK‡	PKS™ Cutting Forceps, with Cord, 10 mm, 33 cm
For use with PK® SuperPulse® Generator only	
3025PK‡	PKS™ Cutting Forceps, 5 mm, 24 cm
3005PK‡	PKS™ Cutting Forceps, 5 mm, 33 cm
3045PK‡	PKS™ Cutting Forceps, 5 mm, 45 cm
3015PK‡	PKS™ Cutting Forceps, 10 mm, 15 cm
3000PK‡	PKS™ Cutting Forceps, 10 mm, 33 cm
3900	PK™ Reusable Connector Cable (3-Pin)



921015PK

PKS™ Omni™

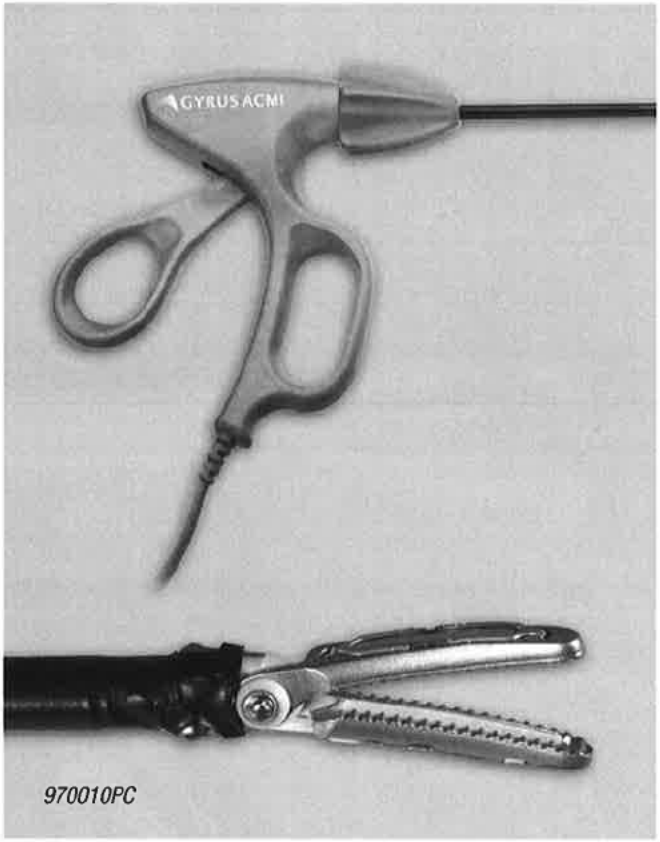
The PKS™ Omni™ delivers multiple tissue effects from a single instrument with exceptional bipolar cutting and coagulation. For use with the G400 Generator only.

- **Advanced bipolar coagulation and cutting** Reduces OR time
- **True bipolar cutting** Provides fast, precise tissue transection
- **Dual action jaws** Facilitate mechanical dissection
- **Improved tip design** Allows spot coagulation and improved grasping capabilities
- **Outstanding versatility** For laparoscopic and open procedures

PKS OMNI	
For use with PK® G400 Generator only	
970000PC‡	PKS™ Omni™ with Cord, 5 mm, 15 cm
970005PC‡	PKS™ Omni™ with Cord, 5 mm, 24 cm
970010PC‡	PKS™ Omni™ with Cord, 5 mm, 33 cm
970015PC‡	PKS™ Omni™ with Cord, 5 mm, 45 cm

ACCESSORIES	
9005PK	Instrument Cleaning Brush 10/box

‡ Supplied sterile, single-use, disposable



970010PC

PKS™ Plasma J-Hook

The PKS™ Plasma J-Hook provides a rapid and precise hemostatic cut and excellent coagulation in one instrument.

- **Simultaneously cuts and coagulates** Reduces OR time
- **Rapid hemostatic cutting** Improves procedural efficiency
- **Unique tip design** Excellent for skeltonization and mobilization

PKS PLASMA J-HOOK	
For use with PK® G400 Generator only	
956000PC‡	PKS™ Plasma J-Hook, with Cord, 5 mm, 15 cm
956005PC‡	PKS™ Plasma J-Hook, with Cord, 5 mm, 24 cm
956010PC‡	PKS™ Plasma J-Hook, with Cord, 5 mm, 33 cm
956015PC‡	PKS™ Plasma J-Hook, with Cord, 5 mm, 45 cm

‡ Supplied sterile, single-use, disposable

956000PC

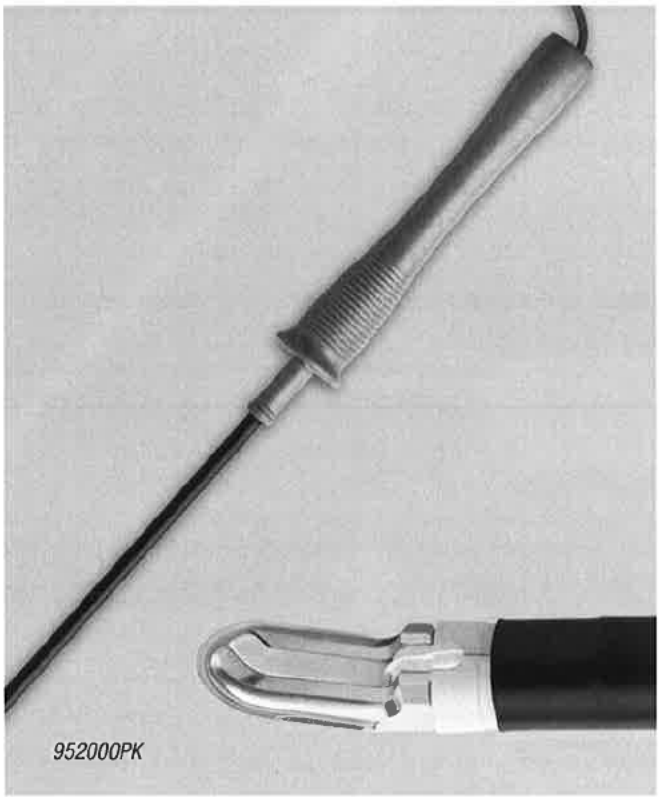
PKS™ PlasmaSpatula®

The PKS™ PlasmaSpatula is a unique multifunctional device that has the ability to electrosurgically cut and coagulate for use in a variety of procedures.

- **Multifunctional device** Precisely cuts, coagulates and dissects
- **Instrument tip stays cool** Minimizes thermal spread
- **Unique tip design** Angled tip and broad surface enhances procedural effectiveness

PKS PLASMASPATULA	
For use with PK® G400 Generator only	
952005PK‡	PKS™ PlasmaSpatula,® with Cord, 5 mm, 33 cm
For use with PK® SuperPulse® Generator only	
3200PK‡	PKS™ PlasmaSpatula,® 5 mm, 33 cm
3905	PK® Reusable Connector Cable (5-Pin)

‡ Supplied sterile, single-use, disposable

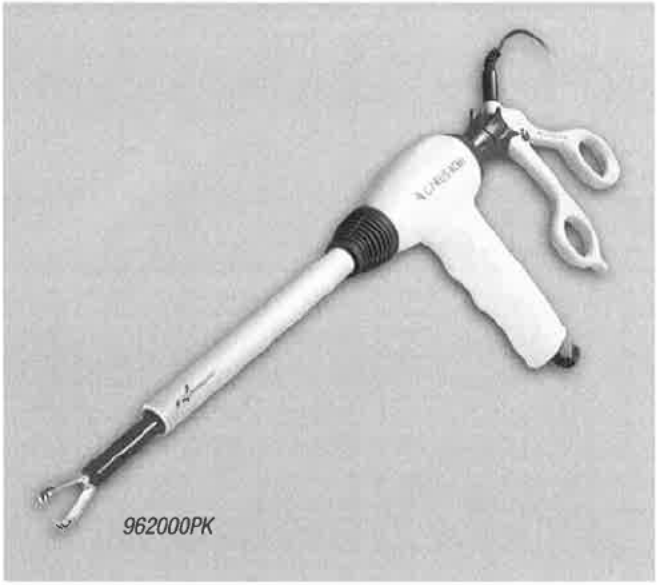

952000PK

PKS™ PlasmaSORD™

PKS™ PlasmaSORD bipolar morcellator is the first completely bladeless SORD (Solid Organ Removal Device).

- **Safe bipolar energy** Morcellates tissue instead of sharp, spinning blades
- **Efficient bipolar energy** Creates fewer tissue fragments to clean up
- **Lightweight, ergonomic handle** Reduces hand fatigue in prolonged cases
- **Easy to use "plug and play" PK® Technology with the G400 Generator** Requires little setup for O.R. staff
- **Durable and economical** Only one bipolar device is required per case

PKS PLASMASORD	
For use with PK® G400 Generator only	
962000PK	PKS™ PlasmaSORD™ with cord


962000PK

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CONTRAINDICATION: Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are:

- peri- or post-menopausal, or
- candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision.

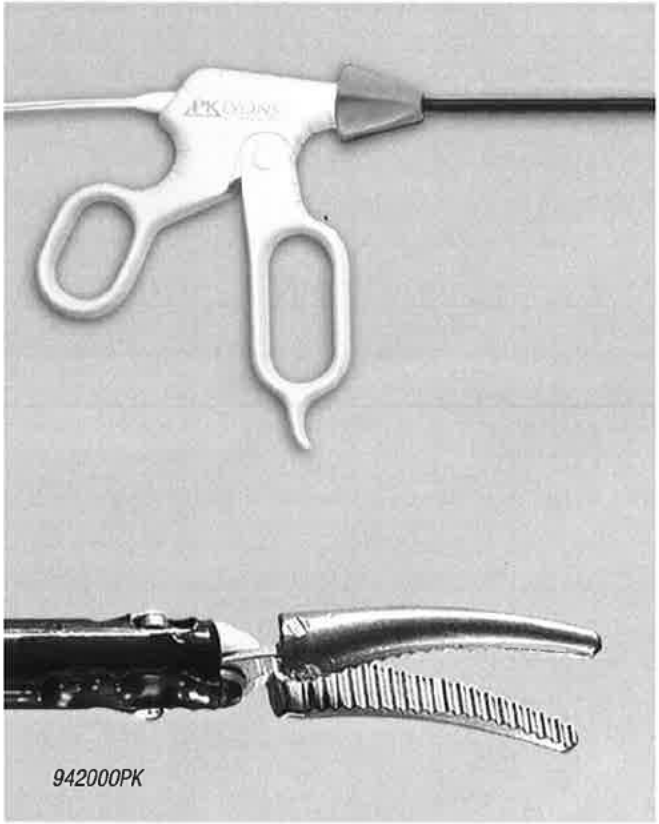
PKS™ LYONS™ Dissecting Forceps

The PKS™ LYONS™ Dissecting Forceps is uniquely designed for secure grasping, dissecting, retracting and coagulating. With its unparalleled versatility, the PKS™ LYONS™ is the one instrument no surgeon should be without.

- **Two-tier jaw design with serrated surfaces** Provides secure grasping and retraction of tissue
- **Curved, fine-rounded tip** Provides atraumatic dissection and assists with vessel skeletonization
- **Tapered jaw design** Provides pinpoint or wide-based coagulation
- **360° shaft rotation** Makes difficult angles more accessible

PKS LYONS	
For use with PK® G400 Generator only	
942000PK‡	PKS™ LYONS™ Dissecting Forceps, with Cord, 5 mm, 24 cm
942005PK‡	PKS™ LYONS™ Dissecting Forceps, with Cord, 5 mm, 33 cm
942010PK‡	PKS™ LYONS™ Dissecting Forceps, with Cord, 5 mm, 45 cm
For use with PK® SuperPulse® Generator only	
3720PK‡	PKS™ LYONS™ Dissecting Forceps, 5 mm, 24 cm
3700PK‡	PKS™ LYONS™ Dissecting Forceps, 5 mm, 33 cm
3740PK‡	PKS™ LYONS™ Dissecting Forceps, 5 mm, 45 cm
3900	PK® Reusable Connector Cable (3-Pin)

‡ Supplied sterile, single-use, disposable



942000PK

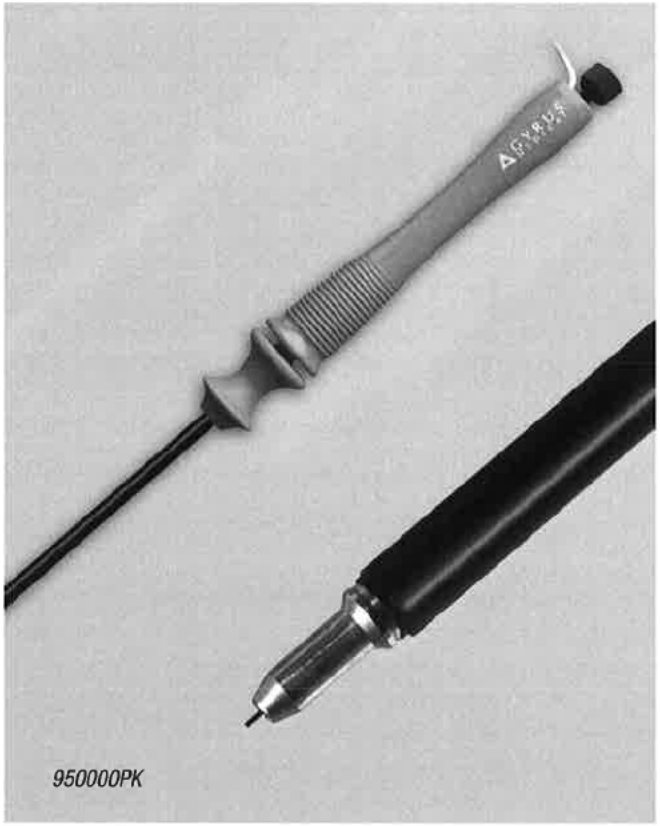
PKS™ Needle

The PKS™ Needle for laparoscopic surgery enables the surgeon to precisely cut while preserving surrounding tissues.

- **Adjustable needle electrode** Allows the surgeon to adjust the depth of the cut for precise control
- **Extendable outer sheath** Allows for tissue dissection and protects electrode while passing through the trocar
- **Tapered hub** Minimizes damage to tissue

PKS NEEDLE	
For use with PK® G400 Generator only	
950000PK‡	PKS™ Needle, with Cord, 5 mm, 33 cm
For use with PK® SuperPulse® Generator only	
3400PK‡	PKS™ Needle, 5 mm, 33 cm
3900	PK® Reusable Connector Cable (3-Pin)

‡ Supplied sterile, single-use, disposable



950000PK

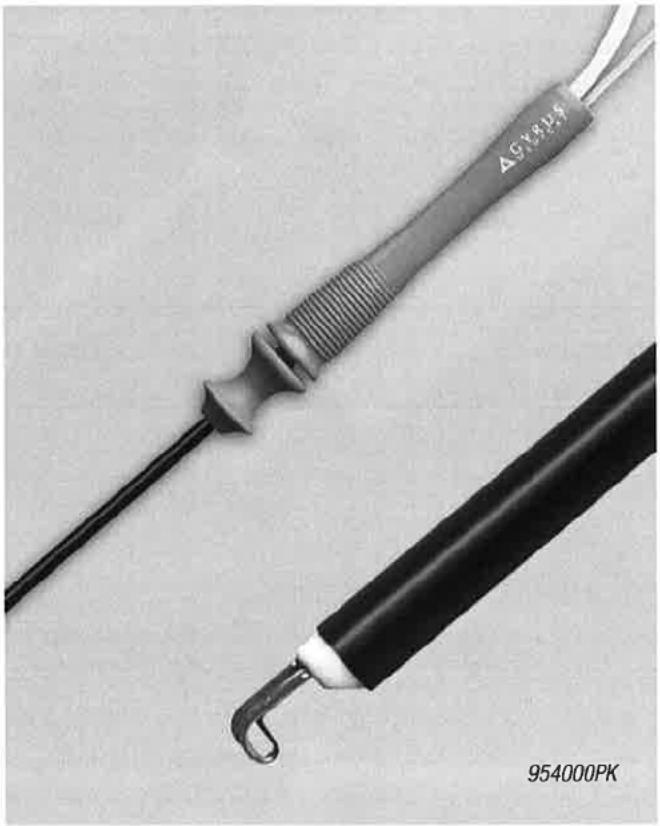
PKS™ L-Hook

The PKS™ L-Hook features a unique tip shaped to enable the surgeon to pull tissue away from surrounding areas while offering the ability to efficiently dissect, coagulate, and transect.

- **Multifunctional device** Efficiently retracts, dissects, coagulates and transects tissue
- **Extendable sheath** Locks in places to perform blunt tissue dissection and facilitate aspiration at the tip
- **Provides suction and irrigation port** Adapts to existing hospital suction/irrigation systems for a clean surgical field

PPKS L-HOOK	
For use with PK® G400 Generator only	
954000PK‡	PKS™ L-Hook, with Cord, 5 mm, 33 cm
954005PK‡	PKS™ L-Hook, with Cord, 5 mm, 45 cm

‡ Supplied sterile, single-use, disposable



954000PK

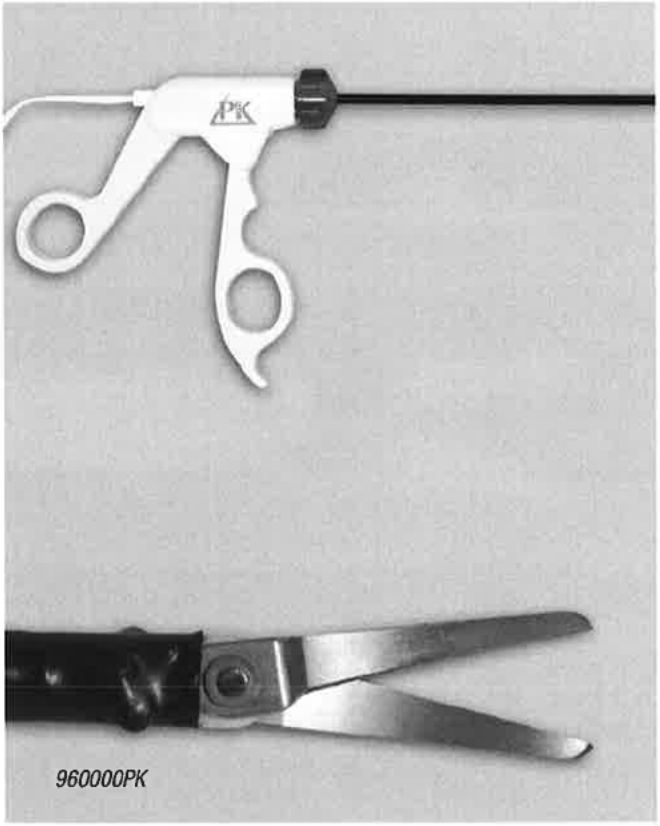
PKS™ Scissors

The PKS™ Scissors has a proprietary metal blade design that provides precise cutting during laparoscopic surgical procedures. The handle offers easy fingertip rotation.

- **Curved, dual action beveled blades** Provides simultaneous cutting and coagulation
- **Fingertip rotation** Allows for accurate jaw orientation

PKS SCISSORS	
For use with PK® G400 Generator only	
960000PK‡	PKS™ LP Scissors, with Cord, 5 mm, 33 cm
For use with PK® SuperPulse® Generator only	
3804PK‡	PKS™ LP Scissors, 5 mm, 33 cm
3900	PK® Reusable Connector Cable (3-Pin)

‡ Supplied sterile, single-use, disposable



960000PK

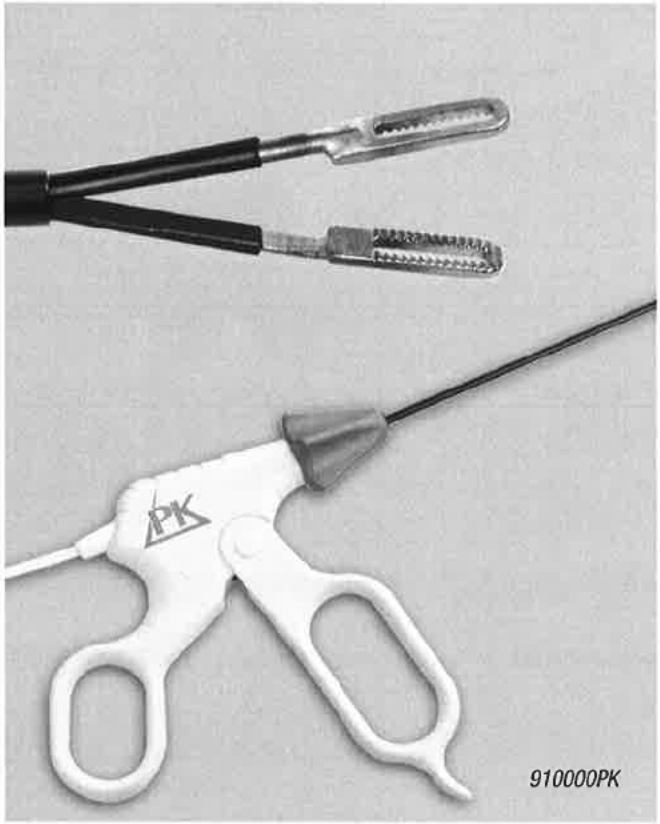
PKS™ MOLly® Forceps

The PKS™ MOLly Forceps is a multifunctional instrument for grasping, coagulating, and retracting tissues.

- **Grasps, coagulates and retracts tissue** Excellent complimentary device
- **Serrated oval tip** Improves tissue manipulation and dual site coagulation
- **Finger tip rotation** Allows for accurate jaw orientation
- **3 mm shaft** Enables the surgeon to use a 3 mm trocar

PKS MOLLY	
For use with PK® G400 Generator only	
910000PK‡	PKS™ MOLly® Forceps, with Cord, 3 mm, 33 cm
910005PK‡	PKS™ MOLly® Forceps, with Cord, 5 mm, 33 cm
910010PK‡	PKS™ MOLly® Forceps, with Cord, 5 mm, 45 cm
For use with PK® SuperPulse® Generator only	
3300PK‡	PKS™ MOLly® Forceps, 3 mm, 33 cm
3330PK‡	PKS™ MOLly® Forceps, 5 mm, 33 cm
3345PK‡	PKS™ MOLly® Forceps, 5 mm, 45 cm
3900	PK® Reusable Connector Cable (3-Pin)

‡ Supplied sterile, single-use, disposable



910000PK

PKS™ Forceps

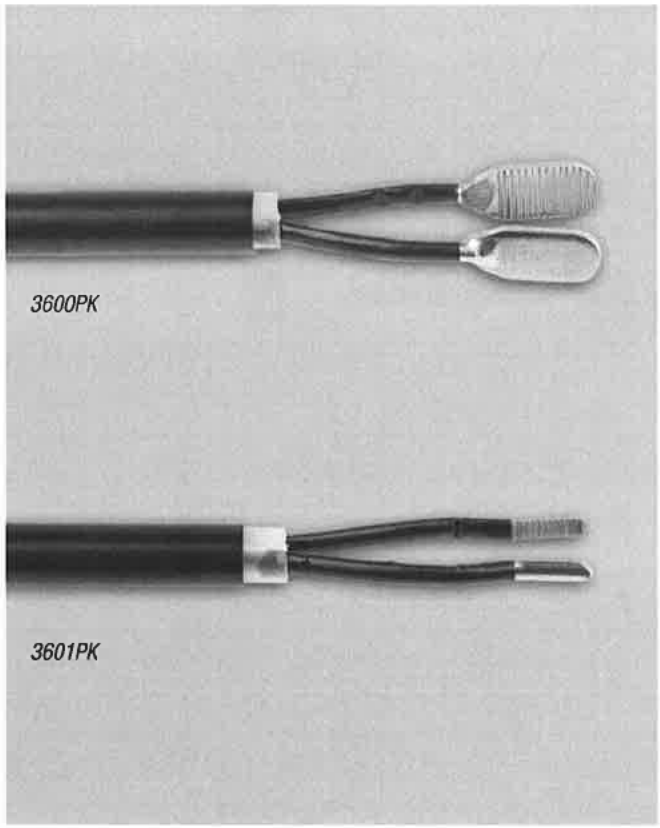
The PKS™ Forceps features both Macro-jaw and Micro-jaw designs for effective use in a variety of surgical procedures.

- **Macro jaw design** Large vessel and tissue coagulation
- **Micro jaw design** Precise and delicate grasping and coagulation
- **Finger tip rotation** Allows for accurate jaw orientation
- **Serrated jaws** Enable easy, atraumatic grasping

PKS FORCEPS	
For use with PK® SuperPulse® Generator only	
3600PK‡	PKS™ Macro Jaw Forceps, 5 mm, 33 cm
3640PK‡	PKS™ Macro Jaw Forceps, 5 mm, 45 cm
3601PK‡	PKS™ Micro Jaw Forceps, 5 mm, 33 cm
3900	PK® Reusable Connector Cable (3-Pin)

Not available for G400 Generator

‡ Supplied sterile, single-use, disposable


3600PK

3601PK

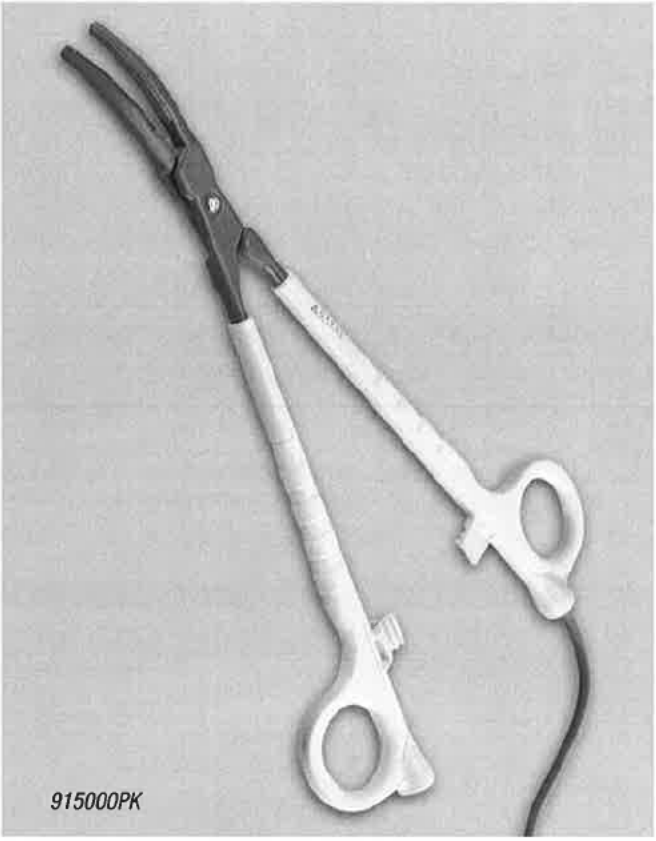
PKS™ SEAL™ Open Forceps

The PKS™ SEAL® Open Forceps effectively coagulates the targeted vessel providing an even, uniform seal with enhanced hemostasis.

- **Seal vessels with confidence** Effectively seals vessels up to 7 mm virtually eliminating the need for sutures and staples
- **Low profile design** Improves access to tight working spaces
- **Non-conductive outer jaw coating** Protects adjacent tissue from unintended thermal effect

PKS SEAL	
For use with PK® G400 Generator only	
915000PK‡	PKS™ SEAL™ Open Forceps, Curved Jaw, with Cord, 25 cm
For use with PK® SuperPulse® Generator only	
3103PK‡	PKS™ SEAL™ Open Forceps, Curved Jaw, 25 cm
3900	PK® Reusable Connector Cable (3-Pin)

‡ Supplied sterile, single-use, disposable



915000PK

915000PK & 3103PK

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2008

Gyrus ACMI, Inc.
% Mr. Terrence E. Sullivan
VP, Regulatory Affairs
136 Turnpike Road
Southborough, Massachusetts 01772

Re: K080093
Trade/Device Name: Gyrus ACMI PKS Plasma Morcellator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, HET
Dated: April 17, 2008
Received: April 18, 2008

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Gyrus ACMI PKS Plasma Morcellator

510(k) Number: K080093

Statement of Intended use:

The Gyrus ACMI PKS Plasma Morcellator is intended for cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynecologic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: __ X __ **OR** Over-the-Counter Use: _____

(Per 21 CFR 801.109)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080093

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 01, 2008

GYRUS ACMI, INC.
136 TURNPIKE RD.
SOUTHBOROUGH, MA 01772
ATTN: TERRENCE E. SULLIVAN

510(k) Number: K080093
Product: PKS PLASMA MORCELLATOR, MODELS 962000PK, 3620PK

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.
Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40
9200 Corporate Blvd.
Rockville, Maryland 20850

January 14, 2008

GYRUS ACMI, INC.
136 TURNPIKE RD.
SOUTHBOROUGH, MA 01772
ATTN: TERRENCE E. SULLIVAN

510(k) Number: K080093
Received: 14-JAN-2008
Product: PKS PLASMA MORCELLATOR, MODELS 962000PK, 3620PK

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federa Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited abov Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you whe the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medica device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, th Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/cdrh/mdufma/index.html for more information regardin fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) nee to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf.

A new provision of the Food and Drug Administration Amendments Act of 2007, 42 U.S.C. 282(j)(5)(B), requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany all 510(k)/HDE/PMA submissions on or after December 26, 2007. You are responsible for registering certain device clinical trials in the Clinical Trials Data Bank (http://prsinfo.clinicaltrials.gov). If your submission does not include FDA Form 3674, please send 2 hardcopies of the completed certification form referencing the submission number identified above. Additional information about the new certification

form may be found at the following link to the Federal Register Notice (http://www.fda.gov/OHRMS/DOCKETS/98fr/07-6023.htm).

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1655.pdf. Please refer to this guidance for information on a formalized interactive review process. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditiona or Abbreviated 510(k). 3)Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electron copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/" If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Heal

K080093

Gyrus ACMI PKS Plasma Morcellator

TRADITIONAL PREMARKET [510(k)] NOTIFICATION

January 11, 2008

Gyrus ACMI, Inc.
SOUTHBOROUGH, MA

K25 OB II

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: **MD6034334-956733** Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
ACMI CORP Gyrus ACMI, Inc. 136 Turnpike Road Southborough MA 01772 US	Terrence Sullivan
	2.1 E-MAIL ADDRESS Terry.Sullivan@gyrusacmi.com
	2.2 TELEPHONE NUMBER (include Area code) 508-804-2739
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 953079904	2.3 FACSIMILE (FAX) NUMBER (Include Area code) 508-804-2624

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:

[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select one of the types below

[X] Original Application

Supplement Types:

[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms

[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

$3,404.00 03-Jan-2008

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INVOICE DATE	INVOICE NUMBER	CONTROL NUMBER	AMOUNT	DISCOUNT	AMOUNT PAID	REMARKS
01/03/2008	03-JAN-2008	C(b)(4)	3,404.00	0.00	3,404.00	BWL-SORD 510K USER
					3,404.00	

VENDOR NO.	CHECK NO.	CHECK AMOUNT
962675	(b)(4)	3,404.00 USD

Gyrus ACMI, Inc.
136 Turnpike Road
Southborough MA 01772

WELLS FARGO BANK N.A.
MINNESOTA

Check Number 2000008

01/04/2008

17-1
910

PAY Three Thousand Four Hundred Four Dollars And No Cents

******$3,404.00

VOID AFTER SIX MONTHS

THE ORDER OF FOOD & DRUG ADMINISTRATION
P.O. BOX 956733
ST. LOUIS, MO 63195-6733

Lisa Martin

MF

(b)(4) Trade Secret Process-Product Specs

[redacted]

From: Origin ID: KCRA (508)804-2739
Terrence Sullivan
Gyrus ACMI, Inc.
136 TURNPIKE ROAD

SOUTHBOROUGH, MA 01772

FedEx. Express

E

CLS090607/21/23

Ship Date: 07JAN08
ActWgt: 1 LB
System#: 3002112/INET7091
Account#: S *********

Delivery Address Bar Code

SHIP TO: (314)418-4821 BILL SENDER

Attn: Government Lockbox 956733
US Bank
1005 Convention Plaza

St. Louis, MO 63101

Ref # 4756
Invoice #
PO #
Dept #

TRK# 0201 7988 4565 1518

TUE - 08JAN A1
STANDARD OVERNIGHT

XH-CPSA

STL
MO-US
63101

Shipping Label: Your shipment is complete

1. Use the 'Print' feature from your browser to send this page to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com.
FedEx will not be responsible for any claim in excess of $100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of $100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is $500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
01/11/2008	MD6034334-956733	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☑ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☑ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☑ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Gyrus ACMI, Inc.	Establishment Registration Number *(if known)*: 3003790304
Division Name *(if applicable)*:	Phone Number *(including area code)*: (508) 804-2739
Street Address: 136 Turnpike Road	FAX Number *(including area code)*: (508) 804-2624
City: Southborough	State / Province: MA; ZIP/Postal Code: 01772; Country: USA
Contact Name: Terrence E. Sullivan	
Contact Title: Vice President, Regulatory Affairs	Contact E-mail Address: Terry.Sullivan@gyrusacmi.com

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name:	
Division Name *(if applicable)*:	Phone Number *(including area code)*: ( )
Street Address:	FAX Number *(including area code)*: ( )
City:	State / Province: ; ZIP/Postal Code: ; Country:
Contact Name:	
Contact Title:	Contact E-mail Address:

PSC Graphics: (301) 443-1090 EF

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☑ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

☐ Other Reason *(specify)*:

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	HET	2	GEI	3		4	
		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K041633	1	PlasmaCision Laparoscopic Spatula	1	Gyrus Medical Inc., a subsidiary of Gyrus ACMI, Inc.
2	K993801	2	Gynecare Laparoscopic Morcellator	2	Ethicon Inc.
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Electorsurgical Instruments

	Trade or Proprietary or Model Name for This Device		Model Number
1	PKS Plasma Morcellator	1	962000PK
2	PKS Plasma Morcellator	2	3620PK
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K063134	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
HET, GEI	884.1720, 884.4400	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

Obstetrics/Gynecology

Indications *(from labeling)*

The Gyrus ACMI PKS Plasma Morcellator is intended for cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynecologic procedures.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☑ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number	☑ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name Gyrus Medical Ltd.		Establishment Registration Number 9617070		
Division Name *(if applicable)*		Phone Number *(including area code)* (+44) 29 20 776 349		
Street Address Fortran Road, St. Mellons		FAX Number *(including area code)* (+44) 29 20 776 591		
City Cardiff		State / Province Wales	ZIP/Postal Code CF3 0LT	Country UK
Contact Name Andrew Dzimitrowicz	Contact Title Director, Quality Assurance		Contact E-mail Address Andrew.Dzimitrowicz@gyrusacmi.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
ontact Name	Contact Title		Contact E-mail Address	

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1	IEC	Medical Electrical Equipment - Part 1: General Requirements for Safety, incl Amend. 1 & 2	1995	10/31/2005
2	60601-2-2	IEC	Medical Electrical Equipment - Part 2-2: Particular Requirements for the Safety of High Frequency Surgical Equipment	2006	09/12/2007
3	11135	AAMI/ANSI/ISO	Medical devices - Validation and Routine Control of Ethylene Oxide Sterilization	1994	05/31/2002
4	11607	AAMI/ANSI/ISO	Packaging for terminally sterilized medical devices	2000	09/01/2004
5	10993-1	AAMI/ANSI/ISO	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing	2003	08/01/2003
6	10993-5	AAMI/ANSI/ISO	Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity	1999	05/15/1999
7	10993-10	AAMI/ANSI/ISO	Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity	2002	09/01/2002

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

Addendum to Form FDA-3514

Standards No.	Standards Organization	Standards Title	Version	Date
10993-7	AAMI/ANSI/ISO	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals	2001	6/1/2004

GYRUS ACMI

FDA CDRH DMC

JAN 1 4 2008

Received

January 11, 2008

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: Traditional Premarket [510(k)] Notification
Gyrus ACMI PKS Plasma Morcellator

Dear Sir/Madam:

As required in Section 510(k) of the Federal Food, Drug and Cosmetic Act and in accordance with FDA regulations in 21 CFR 807, Gyrus ACMI, Inc. is submitting the original and one copy of this cover letter and a **Traditional Premarket [510(k)] Notification** for the **Gyrus ACMI PKS Plasma Morcellator.**

The Gyrus ACMI PKS Plasma Morcellator is classified by the **Division of Reproductive, Abdominal, and Radiological Devices (Obstetrics/Gynecology Branch)** as a Class II device:

1. 21 CFR 884.1720 (Laparoscope, Gynecologic and accessories) and 21 CFR 884.4400 (Electrosurgical Cutting & Coagulation Device and accessories)
2. Product Code: 85 HET, 79 GEI
3. The predicate devices include the Gyrus Medical Inc.'s PlasmaCision Laparoscopic Spatula, cleared under K041633, and Ethicon Inc.'s Gynecare Laparoscopic Morcellator cleared under K993801.

Gyrus ACMI plans to market the PKS Plasma Morcellator for use with the currently marketed Gyrus ACMI PlasmaKinetic SuperPulse System and Gyrus ACMI General Purpose Electrosurgical System generators. These devices were cleared under K031085 and K050550, respectively.

Please note that many of the enclosures refer to the "Gyrus Solid Organ Resection Device" or "SORD". This was this internal name of the project while the device was under development. Gyrus ACMI plans to market the proposed device by the name "PKS Plasma Morcellator".

In accordance with the Safe Medical Devices Act of 1990, as well as 21 CFR 807.92, a 510(k) Summary has been included in Section 7.0 of this application. Enclosed also are the "Premarket Submission Cover Sheet" and a "510(k) Filing Checklist", as recommended to be included by the FDA.

Gyrus ACMI requests that the FDA keep confidential both the existence and the content of this premarket notification and cover letter in accordance with 21 CFR 807.95(b).

Please feel free to contact me if you have any questions or require further information.

Sincerely,

Terrence E. Sullivan
Vice President, Regulatory Affairs

Phone: 508-804-2739
FAX: 508-804-2624
Email: Terry.Sullivan@gyrusacmi.com

Gyrus ACMI PKS Plasma Morcellator

TRADITIONAL PREMARKET [510(k)] NOTIFICATION

January 11, 2008

Gyrus ACMI, Inc.
SOUTHBOROUGH, MA

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Gyrus ACMI PKS Plasma Morcellator

SECTION 5.0: PREMARKET [510(k)] CHECKLIST

Gyrus ACMI, Inc.
SOUTHBOROUGH, MA

PREMARKET [510(k)] CHECKLIST

	Yes Present Omission Justified	No Inadequate Omitted	Page or Section #
I. Critical Elements:			
A. Is the product a device?	Yes		Section 3.0
B. Is the device exempt from 510(k) by regulation or policy?		No	Section 3.0
C. Is device subject to review by CDRH?	Yes		Section 3.0
D. (i) Are you aware that this device has been the subject of a previous NSE decision?		No	
(ii) If yes, does this new 510(k) address the NSE issue(s) (e.g., performance data)?			Not Applicable
E. (i) Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer.		No	
(ii) Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N-0332, September 10, 1991)		No	Not Applicable
F. Does the submission contain the information required under Sections 510(k), 513(f), and 512(i) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?:	Yes		Sections 3.0 & 7.0
1. Device trade or proprietary name	Yes		Section 7.0
2. Device common or usual name or classification name	Yes		Section 7.0
3. Establishment registration number (only applies if establishment is registered)	Yes		Section 2.0
4. Class into which the device is classified under (21 CFR Parts 862 to 892)	Yes		Sections 3.0 & 7.0
5. Classification Panel	Yes		Section 3.0
6. Action taken to comply with Section 514 of the Act	Yes		Section 3.0
7. Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo #G91-1)	Yes		Section 12.0
8. A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request	Yes		Section 7.0
9. For class III devices only, a class III certification and a class III summary			Not Applicable

PREMARKET [510(k)] CHECKLIST (continued)

	Yes Present Omission Justified	No Inadequate Omitted	Page or Section #
10. Photographs of the device	Yes		Section 10.0
11. Engineering drawings for the device with dimensions and tolerances	Yes		Appendix 10A
12. The marketed device(s) to which equivalence is claimed including labeling and description of the device	Yes		Sections 9.0, 11.0, & 12.0
13. Statement of similarities and/or differences with marketed device(s).	Yes		Sections 9.0 & 11.0
14. Data to show consequences and effects of a modified device(s)			Not Applicable
15. Truthfulness and Accuracy Statement	Yes		Section 8.0
16. Intended Use Statement	Yes		Section 6.0
II. Additional Information that is necessary under 21 CFR 807.87:			
A. Submitter's name and address	Yes		Sections 2.0 & 7.0
B. Contact person, telephone number and fax number	Yes		Sections 2.0 & 7.0
C. Representative/Consultant if applicable		No	Not Applicable
D. Table of Contents with pagination	Yes		Section 4.0
E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	Yes		Section 2.0
III. Additional Information that may be necessary under 21 CFR 807.87:			
A. Comparison table of the new device to the marketed device(s)	Yes		Table III in Section 11.0
B. Action taken to comply with voluntary standards	Yes		Section 16.0
C. Performance Data			Not Applicable
Marketed Device	Yes		Electrical Safety Testing Section 16.0
Bench Testing	Yes		Bench Testing Section 17.0
Animal Testing		No	Not Applicable
Clinical Testing		No	Not Applicable

PREMARKET [510(k)] CHECKLIST (continued)

	Yes Present Omission Justified	No Inadequate Omitted	Page or Section #
D. Biocompatibility Data	Yes		Section 14.0
E. Sterilization Information	Yes		Section 13.0
F. Software Information		No	Not Applicable
G. Hardware Information		No	Not Applicable
H. If this 510(k) is for a kit, has the kit certification statement been provided?		No	Not Applicable
I. Is this device subject to issues that have been addressed in specific guidance document(s)?		No	Not Applicable
J. Other (specify)		No	Not Applicable

Gyrus ACMI PKS Plasma Morcellator

510(k) PREMARKET NOTIFICATION

SECTION 6.0: STATEMENT OF INTENDED USE

Gyrus ACMI, Inc.
SOUTHBOROUGH, MA

Device Name: Gyrus ACMI PKS Plasma Morcellator

510(k) Number: K 080093

Statement of Intended use:

The Gyrus ACMI PKS Plasma Morcellator is intended for cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynecologic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: __ **X** __ **OR** Over-the-Counter Use: _____

(Per 21 CFR 801.109)

Gyrus ACMI PKS Plasma Morcellator

510(K) PREMARKET NOTIFICATION

SECTION 7.0: 510(k) SUMMARY

Gyrus ACMI, Inc.
SOUTHBOROUGH, MA

K080093

510(k) Summary of Safety and Effectiveness
Gyrus ACMI, Inc.
Gyrus ACMI PKS Plasma Morcellator

General Information

Manufacturer:	Gyrus Medical Ltd. Fortran Road, St. Mellons Cardiff UNITED KINGDOM CF3 0LT
Establishment Registration Number:	9617070
510(k) Submitter:	Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Terrence E. Sullivan Vice President, Regulatory Affairs
Date Prepared:	January 11, 2008

Device Description

Classification Name:	Laparoscope, Gynecologic and accessories (21 CFR 884.1720), Class II, Obstetrics/Gynecology Panel; Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400), Class II General and Plastic Surgery Panel
Project Name:	Gyrus Medical Solid Organ Resection Device (SORD)
Trade Name:	Gyrus ACMI PKS Plasma Morcellator
Generic/Common Name:	Electrosurgical Instruments

Predicate Devices

Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula	K041633
Ethicon Inc. Gynecare Laparoscopic Morcellator	K993801

Like the predicate Ethicon Gynecare Laparoscopic Morcellator, the Gyrus ACMI PKS Plasma Morcellator is indicated for cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynecologic procedures.

The Gyrus ACMI PKS Plasma Morcellator uses patient-contacting materials that are utilized in the predicate devices, as well as other legally marketed devices manufactured by Gyrus ACMI.

During design verification, the performance of the PKS Plasma Morcellator was compared against the known performance characteristics of the predicate Gynecare Laparoscopic Morcellator using the bipolar tissue cutting technology of the predicate Gyrus PlasmaCision Laparoscopic Spatula. Testing demonstrated that the performance requirements were met, and that the PKS Plasma Morcellator exhibited comparable performance characteristics to both the predicate care Laparoscopic Morcellator and predicate Gyrus PlasmaCision Laparoscopic Spatula.

In summary, the Gyrus ACMI PKS Plasma Morcellator is substantially equivalent to the predicate devices and presents no new questions of safety or efficacy.

Intended Uses

The Gyrus ACMI PKS Plasma Morcellator is intended for cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynecologic procedures.

Product Description

The Gyrus ACMI PKS Plasma Morcellator consists of two main elements: a Morcellator that includes a cutting shaft and handle with an integrated electrical cable that connects to a Gyrus Medical generator; and a Grasper that passes through the hollow shaft of the Morcellator, to grasp tissue and retract it toward the cutting element on the Morcellator shaft tip. An obturator may also be used to assist in the introduction of the device in laparoscopic procedures, and like the grasper, is positioned through the shaft of the Morcellator tube when being utilized

Technological Characteristics and Substantial Equivalence

The Gyrus ACMI PKS Plasma Morcellator utilizes features incorporated into the following legally marketed predicate devices:

The Gyrus ACMI PKS Plasma Morcellator utilizes the same bipolar electrosurgical energy to cut tissue as that used in the predicate Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula.

The Gyrus ACMI PKS Plasma Morcellator connects to the same electrosurgical generators, the currently marketed Gyrus PlasmaKinetic SuperPulse System and Gyrus General Purpose Electrosurgical System generators, as the predicate Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula. These generators were cleared under K031085 and K050550, respectively.

The Gyrus ACMI PKS Plasma Morcellator is dimensionally similar to the predicate Ethicon Gynecare Laparoscopic Morcellator, having similar Morcellator shaft diameters.

Like the predicate Ethicon Gynecare Laparoscopic Morcellator, the Gyrus ACMI PKS Plasma Morcellator utilizes a pistol grip Morcellator with a hollow shaft through which a grasper is passed to grasp tissue to be resected.

Gyrus ACMI PKS Plasma Morcellator

510(k) PREMARKET NOTIFICATION

SECTION 8.0: TRUTHFULNESS AND ACCURACY STATEMENT

Gyrus ACMI, Inc.
SOUTHBOROUGH, MA

TRUTHFULNESS AND ACCURACY STATEMENT [as required by 21 CFR 807.87(k)]

I certify that, in my capacity as Vice President of Regulatory Affairs for Gyrus ACMI, Inc., I believe to the best of my knowledge that all data and information submitted in this premarket notification are truthful and accurate and that no material facts have been omitted.

1/11/08

Terrence E. Sullivan — Date

Vice President, Regulatory Affairs
Gyrus ACMI, Inc.

Gyrus ACMI PKS Plasma Morcellator

510(K) PREMARKET NOTIFICATION

SECTION 9.0: EXECUTIVE SUMMARY

Gyrus ACMI, Inc.
SOUTHBOROUGH, MA

9.0 Executive Summary

Device Description

The Gyrus ACMI PKS Plasma Morcellator is a tissue morcellator that incorporates the Gyrus Bipolar PlasmaCision technology to cut tissue in place of a powered rotating blade offered in several currently marketed morcellators, such as the predicate Gynecare Laparoscopic Morcellator. The device consists of two main elements, a Morcellator and a Grasper that are connected to a Gyrus bipolar generator, such as the Gyrus SuperPulse Generator or Gyrus General Surgery Workstation. The Grasper is introduced to the tissue site through an axially oriented hollow shaft in the Morcellator body. The distal tip of this hollow shaft contains an active circular electrode that provides the bipolar energy to cut or core tissue. The bipolar energy return path is provided by an electrically isolated return electrode embedded in the hollow shaft, as well as through the Grasper.

The Gyrus ACMI PKS Plasma Morcellator can be introduced to the tissue site either through a previously placed trocar cannula, or may be introduced through a 10mm incision, dilated to accommodate the PKS Plasma Morcellator through the use of an optional Obturator provided with the PKS Plasma Morcellator.

Discussion of Substantial Equivalence Comparison

The Gyrus ACMI PKS Plasma Morcellator has essentially the same intended use as the predicate Gynecare Laparoscopic Morcellator (K993801).

The Gyrus ACMI PKS Plasma Morcellator is dimensionally similar to the predicate Gynecare Laparoscopic Morcellator, having the same Morcellator shaft diameter and similar shaft lengths.

Like the predicate Gynecare Laparoscopic Morcellator, the PKS Plasma Morcellator utilizes a pistol grip design with a hollow Morcellator shaft. Like the predicate Gynecare Laparoscopic Morcellator, the PKS Plasma Morcellator pistol grip handle incorporates a seal mechanism to prevent loss of pneumoperitoneum.

The Gyrus ACMI PKS Plasma Morcellator utilizes the same PlasmaCision bipolar technology as the predicate Gyrus PlasmaCision Laparoscopic Spatula (K041633).

To further illustrate the similarities between the proposed PKS Plasma Morcellator and the predicate Gynecare Laparoscopic Morcellator and PlasmaCision Laparoscopic Spatula devices, please refer to **Table I** on the following page.

Table I - Comparison Table

Feature	**Proposed** **Gyrus ACMI PKS Plasma Morcellator**	**Predicate** **Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula**	**Predicate** **Ethicon Inc. Gynecare Laparoscopic Morcellator**
Mode of tissue dissection	PlasmaCision Bipolar RF energy	PlasmaCision Bipolar RF energy	Motor-driven rotating blade
Overall working length	15 cm	24 - 45 cm	17.5 cm
Morcellator Shaft Inner Diameter	12 mm	N/A	12 mm
Morcellator Shaft Outer Diameter	15 mm	N/A	15 mm
Patient-contacting materials	Active electrode: Type 303 Stainless Steel Return electrode: Gold plated Copper Morcellator Shaft Sleeve: Braided Polymer Active Overmold; Valve: Silicone Elastomer Grasper Jaw: Type 303 Stainless Steel Grasper Jaw and Grasper Shaft Insulation: Polyolefin tubing (Altera MT-2000 medical grade, USP class VI)	Active electrode: Type 303 Stainless Steel Return electrode: Gold plated Copper Morcellator Shaft Sleeve: N/A Active Overmold; Wire Sleeve; Valve: Silicone Rubber (insulator) Grasper Jaw: Type 303 Stainless Steel (in shaft assembly) Grasper Jaw and Grasper Shaft Insulation: N/A	Active electrode: N/A Return electrode: N/A Morcellator Shaft Sleeve: Braided Polymer Valve: Unknown Grasper Jaw: Unknown Grasper Jaw and Grasper Shaft Insulation: Unknown
Indications for use	The Gyrus ACMI PKS Plasma Morcellator is intended for cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynecologic procedures.	The Gyrus PlasmaCision Laparoscopic Spatula is indicated for resection and coagulation of soft tissue and blood vessels in laparoscopic and general surgical procedures when used with the Gyrus PlasmaKinetic Generator or the Gyrus PlasmaKinetic SuperPulse Generator.	The Gynecare Laparoscopic Morcellator is indicated for cutting, coring, and extracting tissue in operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, such as nephrectomy, and laparoscopic gynecologic procedures such as myomectomy and hysterectomy.

Discussion of Bench Testing Performed

During design verification, the output of the design process was evaluated against the requirements specifications. In general, the evaluation compared the function of the Gyrus ACMI PKS Plasma Morcellator against these specified requirements. The evaluation also included comparisons of the PKS Plasma Morcellator against the physical performance characteristics of the predicate Gynecare Laparoscopic Morcellator and Gyrus PlasmaCision Laparoscopic Spatula.

Specific criteria evaluated included: function of the depth stop, function of the seal within the handle body, general grasper performance, cutting ability in several animal tissue and extirpated human tissue models, ergonomics, thermal performance, smoke generation, and the likelihood of nerve stimulation. Testing demonstrated that the performance requirements were met. The PKS Plasma Morcellator exhibited comparable performance characteristics to the tissue resection capabilities of the Gynecare Laparoscopic Morcellator. The PKS Plasma Morcellator also demonstrated comparable bipolar performance characteristics to the Gyrus PlasmaCision Laparoscopic Spatula.

Gyrus ACMI PKS Plasma Morcellator

SPECIAL 510(k) PREMARKET NOTIFICATION

SECTION 10.0: DEVICE DESCRIPTION AND SPECIFICATIONS

Gyrus ACMI, Inc.
SOUTHBOROUGH, MA

10.0 Device Description

General Description

The Gyrus ACMI PKS Plasma Morcellator is intended to cut, core, and extract tissue in various general surgical, urological, and gynecologic operative laparoscopy procedures. Tissue effects include the gross resection of tissue (such as uterine tissue and fibroids following Laparoscopic Supracervical Hysterectomy) allowing removal of this tissue through a laparoscopic port. The device would be used in a CO_2 or Air insufflated environment at standard laparoscopic abdominal pressures (up to 15 mm Hg). As a bipolar electrosurgical device, the PKS Plasma Morcellator would operate on irrigated tissue (e.g., Saline, Ringer's, Sterile Water) to enhance the PlasmaCision tissue effect, and without undue effect on safety or efficacy.

The PKS Plasma Morcellator device consists of two main elements (the entire device is illustrated in **Figure 10.1** below). The first is a Morcellator (see **Figure 10.2** below), which includes a cutting shaft and handle with an integrated electrical cable that connects to either a Gyrus General Surgery Workstation (cleared under 510(k) K050550) or Gyrus SuperPulse Generator (cleared under 510(k) K031085). The second element consists of a Grasper (see **Figure 10.3** below) that passes through the hollow shaft of the Morcellator, to grasp tissue and retract it toward the cutting element on the Morcellator shaft tip. An obturator (not pictured) may also be used to assist in the introduction of the device in laparoscopic procedures, and like the grasper, is positioned through the shaft of the Morcellator tube when being utilized.

Figure 10.1 – PKS Plasma Morcellator

Figure 10.2 – PKS Plasma Morcellator – Morcellator

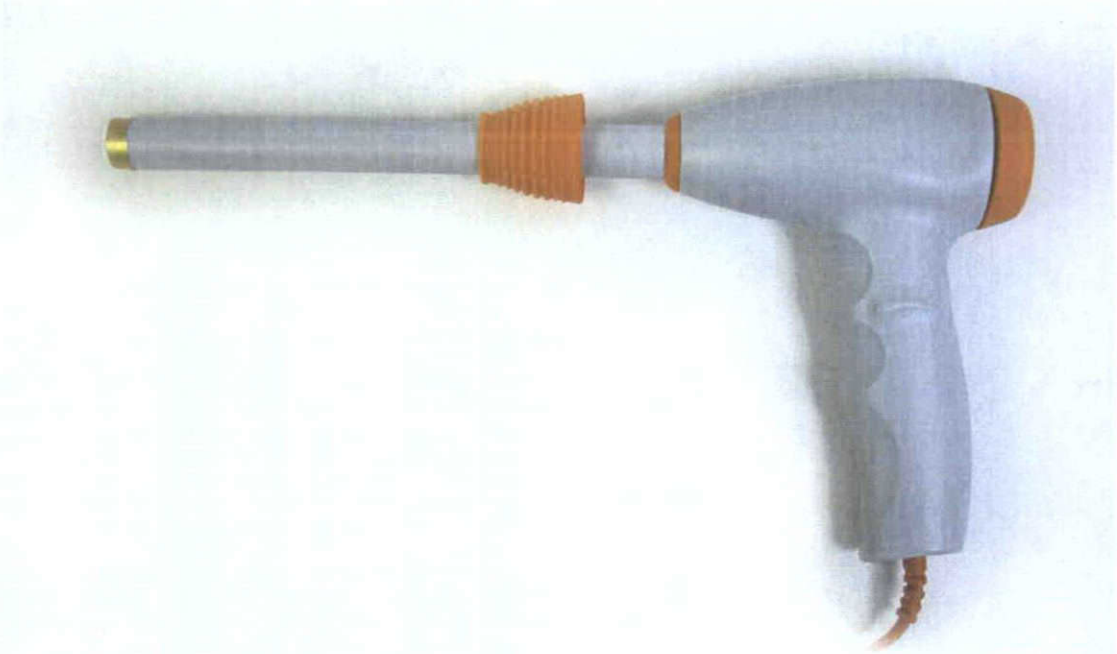


Figure 10.3 – PKS Plasma Morcellator – Grasper Element

Several tissue morcellators presently on the market, such as the predicate Gynecare Laparoscopic Morcellator (K993801) and the Gynecare *Morcellex** Tissue Morcellator (K061050), utilize a powered rotating cutting blade to dissect tissue. The PKS Plasma Morcellator device uses Gyrus ACMI's unique Bipolar PlasmaCision technology to cut, core, and extract devascularized, dissected tissue in operative laparoscopy.

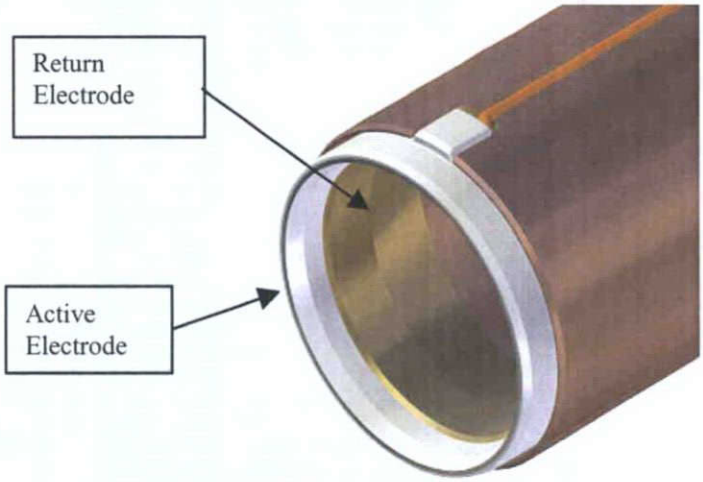
Detailed Description of the Morcellator

The Morcellator is configured in an ergonomically friendly pistol grip configuration, and includes an axially oriented hollow shaft. The pistol grip integrates the electrical connection cable that allows bipolar RF energy to be supplied by a Gyrus generator to the tissue site. The design of the pistol grip body is such that a clinician may utilize a "ski-pole" grip on the Morcellator body, if that is their preference.

The hollow shaft of the Morcellator has an operative length of approximately 15 cm, extending distally from the pistol grip body. The surface of the Morcellator shaft is smooth, allowing the device to be introduced to the operative site through a trocar cannula seal, or with the use of the optional obturator, through an abdominal port. To facilitate optimal placement of the device during laparoscopic procedures, a depth stop normally located at the distal end of the pistol grip (at the junction of the pistol grip and Morcellator shaft), may be moved distally along the Morcellator shaft. The shaft has a nominal outer diameter of 15 mm, and a nominal inner diameter of 12 mm. The proximal end of the shaft also includes an elastomeric reducer that permits the passage of the grasper to the operative site and removal of tissue slugs from the operative site, while preventing loss of pneumoperitoneum.

As indicated above, the Morcellator includes an integrated electrical connector cable, with either a 5-pin or 9-pin connector plug that may be inserted into the Gyrus SuperPulse Generator or Gyrus General Surgery Workstation, respectively. Bipolar electrosurgical energy is applied through the use of a foot pedal that is supplied with the respective Generator. The active loop of the PKS Plasma Morcellator's integrated electrical cable is connected to leads within the Morcellator body that are in turn connected to a circular active electrode integrated into the distal tip of the device (see **Figure 10.4** below).

Figure 10.4 – Distal Tip Electrode Configuration



As indicated in Figure 10.4, the distal tip of the device also includes an axially oriented return electrode that is electrically isolated from the active electrode and connects through the Morcellator body to the return loop of the electrical cable. Due to the placement of the active electrode ring and insulating overmold on the distal tip of the shaft, the internal and external return electrodes are simply contiguous parts of the same copper tube. The terms "internal return" and "external return" essentially refer to the respective face of the copper tube surface that may act as a return to complete the current path. More detailed illustrations of the Morcellator shaft and grasper, enlarged illustration of the distal tip showing the relationship between the internal and external return electrode, as well as an illustration showing the possible return paths of the bipolar energy are provided in **Appendix 10.A**.

In addition to these contact points, there is also a return electrode integrated into the Grasper that connects to the return loop of the electrical cable. This is more fully described in the "Detailed Description of the Grasper" section below. A more detailed illustration of the major assemblies and the RF Workstation connections is also provided in **Appendix 10.B**.

When the PKS Plasma Morcellator is applied to an operative site, the Grasper is introduced through the Morcellator shaft, and draws the tissue to be morcellated into close proximity to the active electrode (see **Figures 10.5 through 10.9** below). Bipolar PlasmaCision energy is applied; cutting the tissue into a plug that may be extracted through the Morcellator shaft. The electrosurgical effect is delivered via two poles, the active electrode and the combined return electrodes contained in the Morcellator shaft and Grasper. The narrow distal surface of the circular active electrode results in a local high current density at the point of tissue application, which promotes arcing leading to localized tissue vaporization. The large area of the combined return electrodes results in a significantly lower current density, which prevents arcing at the return electrode.

With the exception of the necessary exposed region at the functional tip, all conductors carrying electrosurgical current are insulated from the user and patient. This is primarily achieved by local insulation around each of the conductors with secondary insulation provided by the shaft coating, the polymer hand piece and the cable jacket. The external surface of the Morcellator shaft is electrically insulated to withstand a minimum of 750VDC (approximately twice the output of the respective Gyrus Generators), so that the electrical energy return path is through the axially oriented electrode within the Morcellator shaft, or through the Grasper return electrode.

(b)(4) Schematics

[redacted]

(b)(4) Schematics

[redacted]

Top-level diagrams of the PKS Plasma Morcellator as well as drawings of the Overmolded Active Ring, Bonded Tip Assembly, Plug Cable Assembly, and Morcellator Sub Assembly are provided in **Appendix 10.B.**

Detailed Description of the Grasper

The Grasper consists of an ergonomically friendly proximal handle, a rotating insulated shaft, and a pair of symmetrically opening jaws. The jaws themselves are insulated along their length to prevent shorting in the event of contact with the active circular electrode. The handle body also includes a banana plug allowing for attachment of the second return loop of the electrical cable assembly referenced in the Morcellator description above.

The jaws are dual action, and able to open to at least an angle of approximately 50° by the activation of a pair of fully enclosed finger loops on the proximal handle body. The jaws utilize interlocking teeth to allow the Grasper to be easily introduced through the seals in the Morcellator body, and allow secure grasping of tissue (including penetration of fibroid tissue). The standard Grasper offering will be a 2x3 jaw configuration (2 teeth on one jaw and 3 teeth on the opposite jaw), since the pre-

clinical studies (discussed at greater length in Section 17.0) indicated that this configuration was better able to handle soft tissue and small strands of tissue common towards the latter stages of morcellation. These and other study results also suggested that a 2x1 jaw configuration (2 teeth on one jaw and 1 tooth on the opposite jaw) performed better with respect to grasping dense indurated tissue, such as uterine fibroids. As a result, a second grasper, with a 2x1 jaw tooth configuration, will be offered as an accessory to the PKS Plasma Morcellator. Other than the jaw tooth configuration, all other aspects of this accessory grasper will be the same as the grasper with the standard 2x3 jaw tooth configuration.

The outer diameter of the Grasper shaft is approximately 10mm, and the shaft of the grasper is approximately 336 mm in length (not including the handle body). Since the overall length of the Morcellator pistol grip is approximately 270 mm in length, with a working length of approximately 150 mm, the distal tip of the graspers can extend beyond the distal tip of the pistol grip a maximum of approximately 66 mm. This allows the jaws to extend sufficiently beyond the Morcellator shaft so that they may fully open and grasp tissue. To better illustrate these dimensions, please refer to **Appendix 10.A**. The outer surface of the Grasper shaft is enclosed in insulation to maintain a continuous electrical return path to the Grasper handle's banana plug and PKS Plasma Morcellator connector cable.

Detailed Description of the Obturator

The Obturator is disposable, and constructed of polymer materials. Since the user has the option of introducing the Morcellator shaft through a previously placed trocar cannula, use of the Obturator is not mandatory with each use of the PKS Plasma Morcellator. The distal tip is rounded, with an approximate diameter of 6mm, which conically tapers up to the inner diameter of the hollow Morcellator shaft. The length of the Obturator is such that the distal tip extends beyond the Morcellator shaft, forming a "bullet nose", allowing the Obturator to sufficiently dilate a 10mm incision so that the external diameter of the PKS Plasma Morcellator shaft may be accommodated.

Summary of Specifications

The proposed PKS Plasma Morcellator will be manufactured at the Gyrus Medical Ltd., facility in Cardiff, United Kingdom, using procedures and materials common with other Gyrus devices.

The proposed PKS Plasma Morcellator will be used in the same clinical applications as the predicate Gynecare Laparoscopic Morcellator. A more detailed comparison of similarities and differences between the predicate Gynecare Laparoscopic Morcellator, Gyrus. PlasmaCision Laparoscopic Spatula, and proposed PKS Plasma Morcellator may be found in **Section 11.0**.

For reviewer convenience, a summary of the specifications for the proposed PKS Plasma Morcellator is provided in **Table II**.

Table II: Summary of Specifications

Gyrus ACMI PKS Plasma Morcellator	
Dimensional Specifications:	
Morcellator Shaft Working Length:	15 cm
Distal Tip:	15 mm
Morcellator Shaft Outer Diameter:	15 mm
Morcellator Shaft Inner Diameter:	12 mm
Graspers Length:	33 cm
Grasper Diameter:	10mm
Obturator Diameter:	6mm at tip, conical taper to 12mm
Depth Stop Length:	30mm
Depth Stop Diameter:	40mm
Generator Compatibility:	5-pin socket version for use with Gyrus PlasmaKinetic SuperPulse Generator, 9-pin socket version for use with Gyrus General Surgery Workstation
Power Specifications:	(b)(4) Trade Secret Process-Product Specs [redacted]
Power Input	
Pulse length	
On-time	
Operating Environment:	
Temperature:	
Relative Humidity:	
Atmospheric Pressure:	
Storage and Transport Environment:	
Temperature:	-10° to 40°C (14° to 140° F)
Relative Humidity:	10-95%, non-condensing
Atmospheric Pressure:	500-1060 hPa
Materials	
Grasper Jaw	Type 303 Stainless Steel
Grasper Jaw and Grasper Shaft Insulation	Polyolefin tubing (Altera MT-2000- medical grade, USP class VI);
Grasper Shaft	Anodized Aluminum
Active Ring Electrode	Type 316 Stainless Steel
Return Tube	Gold plated Copper
Active Overmold; Wire Sleeve; Valve	Silicone Elastomer
Active Tip Adhesive	Silicone RTV Adhesive
Shaft Sleeve	Braided Polymer
Depth Stop	TPE: Thermolast K TF6STE
Obturator	Terluran HD15
Valve Housing; Valve Spacer	MABS Terlux 2802HD

Appendix 10.A

Proposed Gyrus ACMI PKS Plasma Morcellator

Detail of Shaft and Grasper
Detail of Active and Return Electrodes
Detail of Return Paths
Diagram of PKS Plasma Morcellator and shaft lengths

(b)(4) Schematics

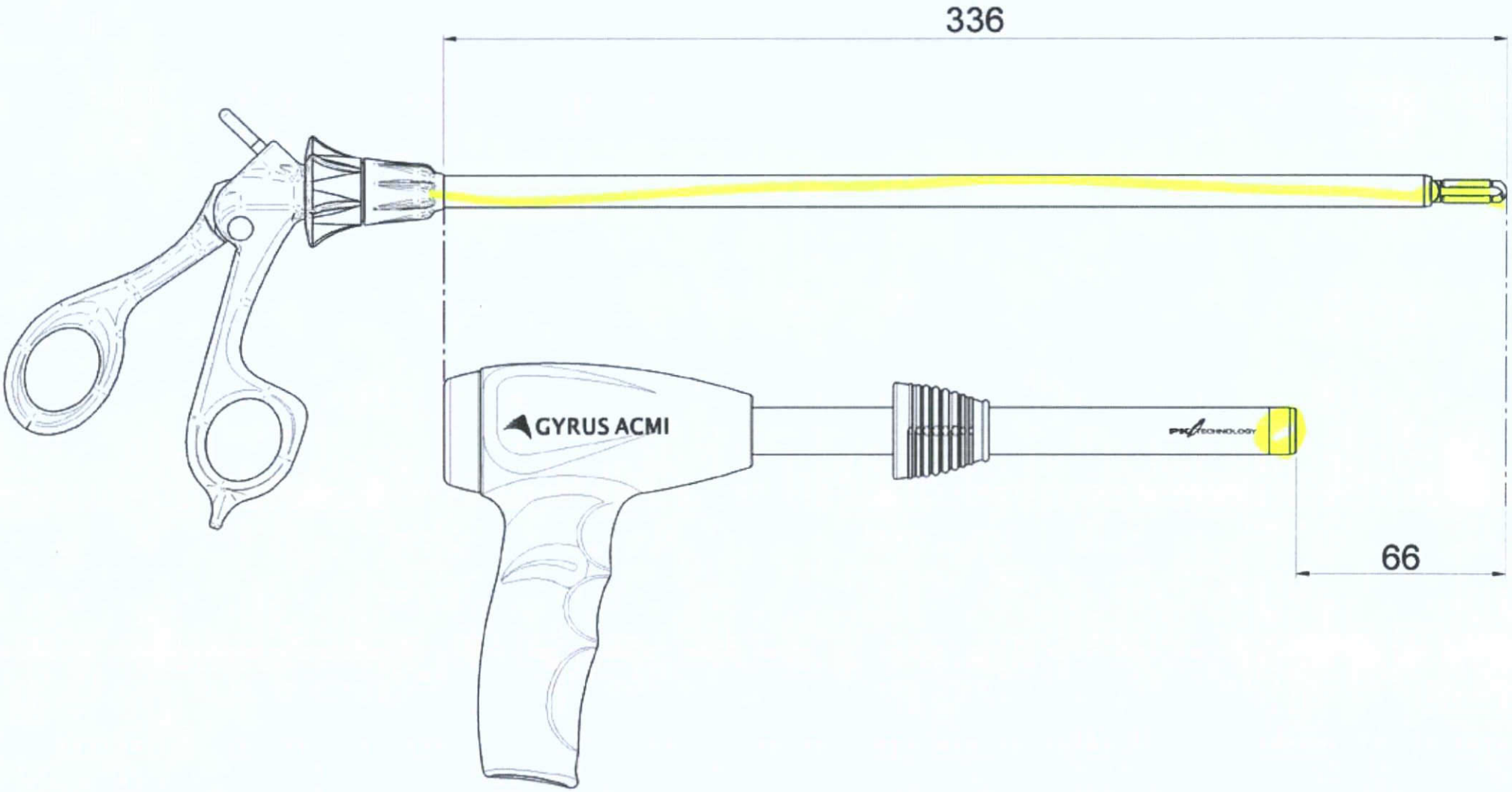
[redacted]

(b)(4) Schematics

[redacted]

(b)(4) Schematics

[redacted]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GYRUS ACMI
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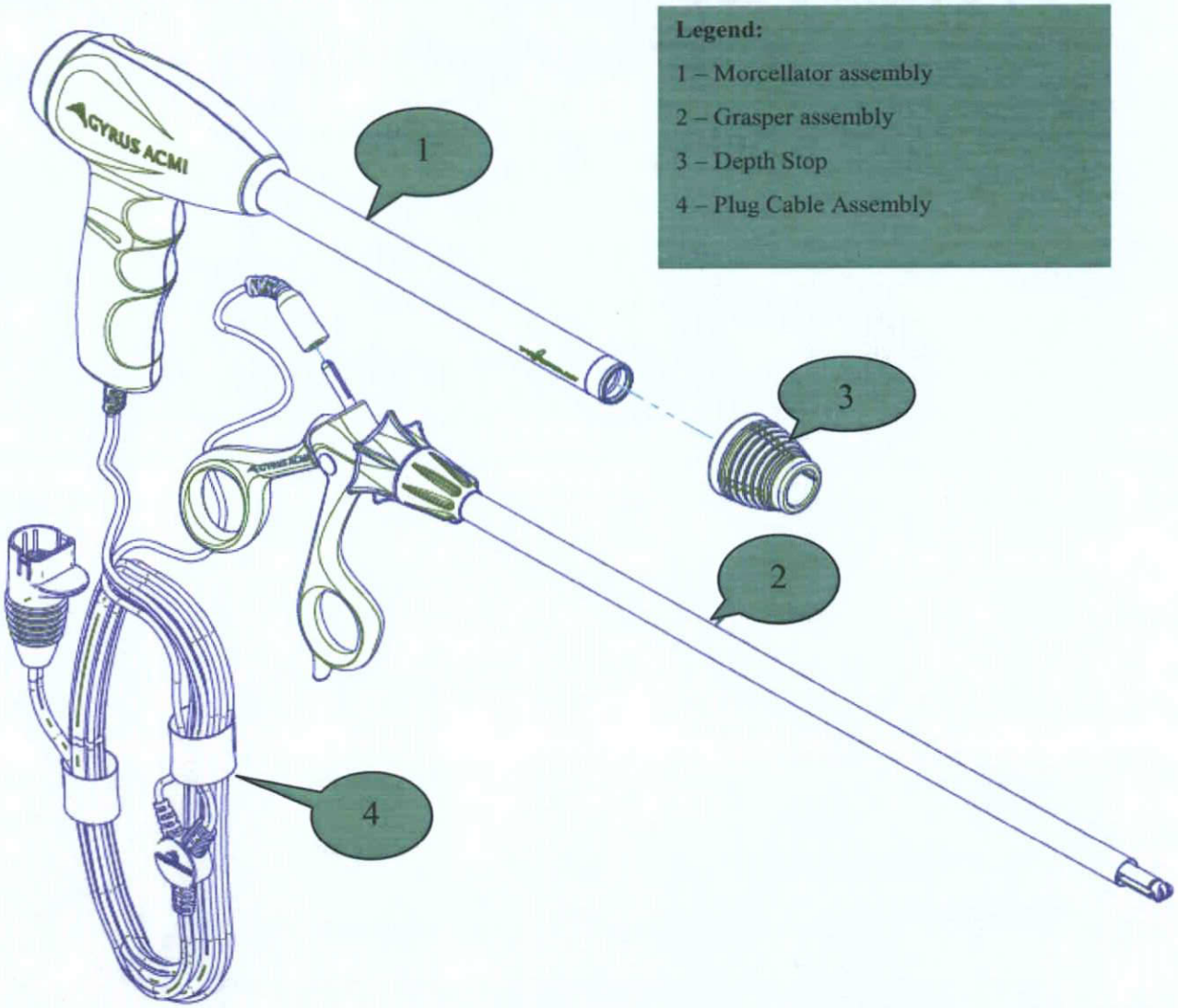
Appendix 10.B

Proposed Gyrus ACMI PKS Plasma Morcellator

Diagram of PKS Plasma Morcellator Assemblies
Exploded view of PKS Plasma Morcellator Assemblies
Diagram of PKS Plasma Morcellator in PETG Tray
Overmolded Active Ring, P/N 274002
Bonded Tip Assembly, P/N 274011
Plug Cable Assembly, P/N 174008
Morcellator Sub Assembly, P/N 274006

Please note that the enclosures refer to the "Gyrus Solid Organ Resection Device" or "SORD". This was this internal name of the project while the device was under development. Gyrus ACMI plans to market the proposed device by the name "PKS Plasma Morcellator".



Legend:

1 – Morcellator assembly

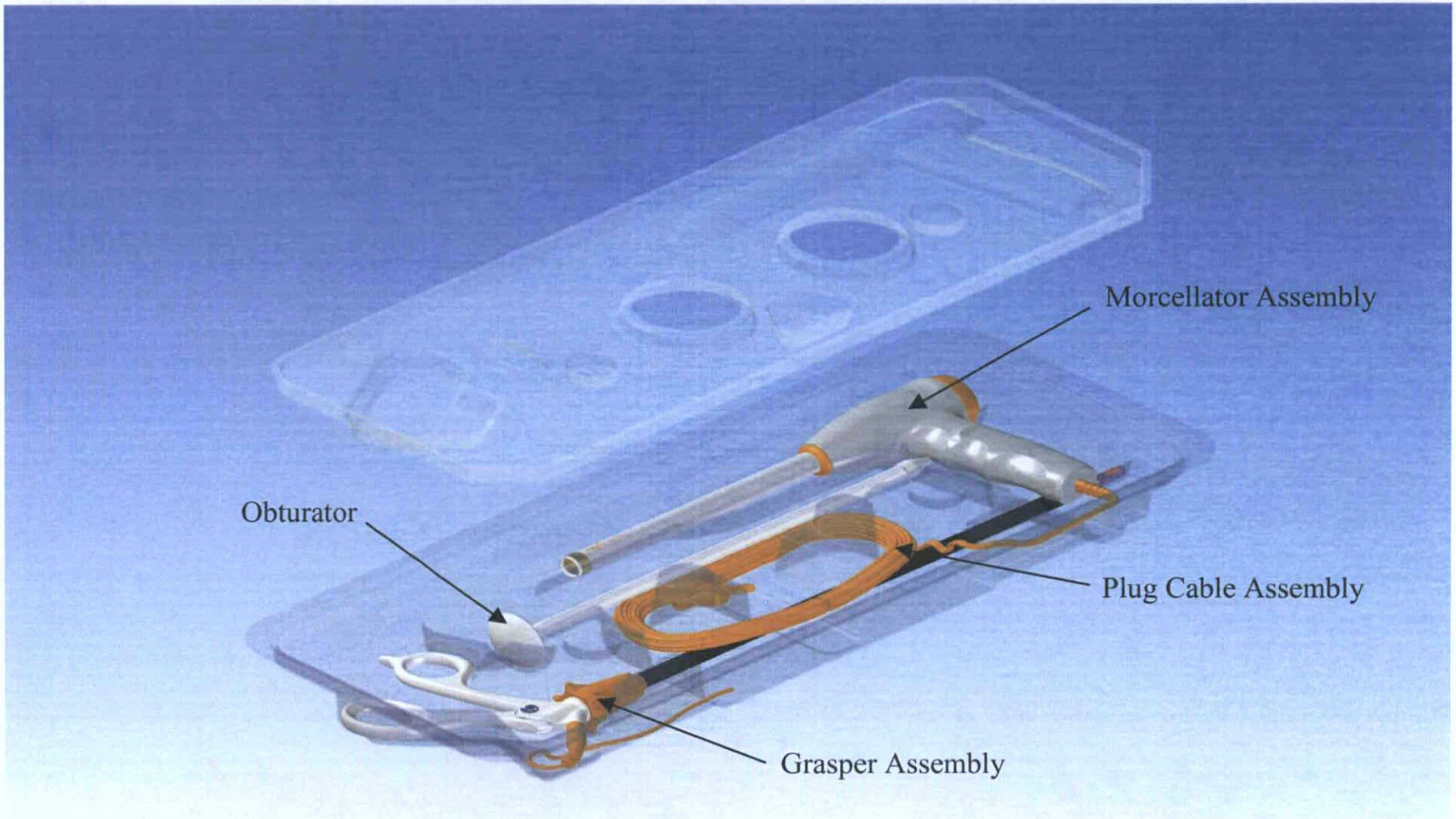
2 – Grasper assembly

3 – Depth Stop

4 – Plug Cable Assembly

(b)(4) Schematics

[redacted]


Morcellator Assembly
Obturator
Plug Cable Assembly
Grasper Assembly

(b)(4) Schematics

(b)(4) Schematics

(b)(4) Schematics

(b)(4) Schematics

Gyrus ACMI PKS Plasma Morcellator

510(K) PREMARKET NOTIFICATION

SECTION 11.0: SUBSTANTIAL EQUIVALENCE DISCUSSION

Gyrus ACMI, Inc.
SOUTHBOROUGH, MA

11.0 Substantial Equivalence Discussion

Introduction

The proposed Gyrus ACMI PKS Plasma Morcellator is substantially equivalent to the following legally marketed devices:

- Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula (K041633)
- Ethicon Inc. Gynecare Laparoscopic Morcellator (K993801)

Gyrus ACMI bases the claim of substantial equivalence on similarities in indications for use, design, materials, technological characteristics, and operational characteristics. Additional product information for the predicate devices cited above is provided in **Appendix 11.A** and **Appendix 11.B**. **Table III** below provides a side-by-side comparison of the similarities and differences between the proposed PKS Plasma Morcellator and the predicate Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula and Ethicon Inc. Gynecare Laparoscopic Morcellator.

Indications for Use

The proposed PKS Plasma Morcellator is substantially equivalent in the specified indications for use to the Ethicon Inc. Gynecare Laparoscopic Morcellator predicate device. The Ethicon Inc. Gynecare Laparoscopic Morcellator is cleared for marketing for cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynecologic procedures.

Materials

The proposed PKS Plasma Morcellator is substantially equivalent to the cited predicate devices, as well as other legally marketed devices, in the use of patient contacting materials. The PKS Plasma Morcellator uses the same braided polymer material for the shaft outer surface as the predicate Gynecare Laparoscopic Morcellator. The PKS Plasma Morcellator uses 300-series Stainless Steel (specifically Type 303), as does the predicate Gyrus PlasmaCision Laparoscopic Spatula. The PKS Plasma Morcellator also uses gold plated copper in the return electrode assembly, as does the predicate Gyrus PlasmaCision Laparoscopic Spatula.

Other materials used in the PKS Plasma Morcellator are also used in other legally marketed devices manufactured by Gyrus Medical and Gyrus ACMI, Inc. The Altera MT-2000 medical grade polyolefin tubing used on the PKS Plasma Morcellator is also used in the Gyrus ACMI DUR-Digital Ureteroscope, cleared under K060269. The Silicone Elastomer and Silicone RTV Adhesive are also used in the Gyrus ENT G2 Generator Accessories, cleared under K021777, but were nevertheless re-evaluated as part of the Outer Tube Assembly subsequent to a determination on K063134 (please refer to **Section 14.0** for more detail).

Like the predicate Gyrus PlasmaCision Laparoscopic Spatula, the PKS Plasma Morcellator will be manufactured at the Gyrus Medical Ltd. facility located in Cardiff, United Kingdom.

Design and Operation

The proposed PKS Plasma Morcellator is substantially equivalent to the predicate Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula in that each is connected to a Gyrus Medical Generator, specifically the PlasmaKinetic SuperPulse or Gyrus General Surgery Workstation. Appropriate voltage current and power limits are set automatically when the instrument is connected to either generator type. By comparison, the predicate Ethicon Inc. Gynecare Laparoscopic Morcellator uses a rotating blade powered by an external motor drive unit.

Like the predicate Gyrus PlasmaCision Laparoscopic Spatula, the PKS Plasma Morcellator utilizes the same PlasmaCision Bipolar energy in order to cut tissue. The electrosurgical effect is delivered via two poles, the active electrode and the combined return electrodes contained in the Morcellator shaft and Grasper. The narrow distal surface of the circular active electrode results in a local high current density at the point of tissue application, which promotes arcing leading to localized tissue vaporization. The large area of the combined return electrodes results in a significantly lower current density, which prevents arcing at the return electrode. The cutting effect is available around the profile of the active electrode, giving tissue effects as shown in **Figures 11.1 and 11.2** below.

(b)(4) Schematics

[redacted]

Like the predicate Ethicon Inc. Gynecare Laparoscopic Morcellator, the proposed PKS Plasma Morcellator utilizes a Morcellator with a pistol-grip handle to facilitate manipulation of the device by the clinician. Each Morcellator incorporates a hollow shaft to permit the passage of a Grasper to grasp tissue to be removed, and each Morcellator incorporates a distally mounted blade on the hollow shaft to cut and core tissue.

Like both predicates, the PKS Plasma Morcellator is a single-use device that is provided to the user in a sterile package configuration.

Summary and Conclusions

Based on the information presented above, Gyrus ACMI, Inc. believes that the Gyrus ACMI PKS Plasma Morcellator) is substantially equivalent to the cited predicate devices and that the differences between devices are minor and raise no new issues of safety or effectiveness.

TABLE III: Comparison of Proposed and Predicate Devices

Feature		Proposed Gyrus ACMI PKS Plasma Morcellator	Predicate Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula	Predicate Ethicon Inc. Gynecare Laparoscopic Morcellator	Comments on Comparison
Working Length		15 cm	24 - 45 cm	17.5 cm	Working length is similar for the proposed PKS Plasma Morcellator and predicate Gynecare Laparoscopic Morcellator
Morcellator Shaft Inner Diameter		12 mm	N/A	12 mm	Morcellator shaft inner diameter is the same for both the proposed PKS Plasma Morcellator and predicate Gynecare Laparoscopic Morcellator
Morcellator Shaft Outer Diameter		15 mm	N/A	15mm	Morcellator shaft outer diameter is the same for both the proposed PKS Plasma Morcellator and predicate Gynecare Laparoscopic Morcellator
Mode of tissue dissection		PlasmaCision Bipolar RF energy	PlasmaCision Bipolar RF energy	Motor-driven rotating blade	The proposed PKS Plasma Morcellator utilizes the same PlasmaCision Bipolar RF energy to dissect tissue as the predicate Gyrus PlasmaCision Laparoscopic Spatula
Patient-Contacting Materials	Active electrode	Type 303 Stainless Steel	Type 303 Stainless Steel	N/A	The proposed PKS Plasma Morcellator uses similar materials to those used in the predicate Gynecare Laparoscopic Morcellator and Gyrus PlasmaCision Laparoscopic Spatula. The PKS Plasma Morcellator also uses materials (i.e., Silicone Elastomer, Altera MT-2000) that are used in other legally marketed Gyrus ACMI devices.
	Return electrode	Gold plated Copper	Gold plated Copper	N/A	
	Morcellator Shaft Sleeve	Braided Polymer	N/A	Braided Polymer	
	Active Overmold; Wire Sleeve; Valve	Silicone Elastomer	Silicone Rubber (insulator)	Unknown	
	Grasper Jaw	Type 303 Stainless Steel	Type 303 Stainless Steel (in shaft assembly)	Unknown	
	Grasper Jaw and Grasper Shaft Insulation	Polyolefin tubing (Altera MT-2000-medical grade, USP class VI)	N/A	Unknown	
Indications for Use		The Gyrus ACMI PKS Plasma Morcellator is intended for cutting, coring, and extracting tissue in various operative	The Gyrus PlasmaCision Laparoscopic Spatula is indicated for resection and coagulation of soft tissue and blood vessels in	The Gynecare Laparoscopic Morcellator is indicated for cutting, coring, and extracting tissue in operative laparoscopy	The proposed PKS Plasma Morcellator has essentially the same intended uses as the predicate Gynecare Laparoscopic Morcellator.

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	laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynecologic procedures.	laparoscopic and general surgical procedures when used with the Gyrus PlasmaKinetic Generator or the Gyrus PlasmaKinetic SuperPulse Generator.	procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, such as nephrectomy, and laparoscopic gynecologic procedures such as myomectomy and hysterectomy.	
Sterilization	10^{-6} SAL, by Ethylene Oxide	10^{-6} SAL, by Gamma Radiation	10^{-6} SAL, by Gamma Radiation	The proposed PKS Plasma Morcellator will have the same SAL as the predicate devices, and the sterilization process will be validated in accordance with ISO 11135.
Electrical Safety	Meets IEC 60601-1, IEC60601-2-2	Meets IEC 60601-1, IEC60601-2-2	Unknown	The proposed PKS Plasma Morcellator will meet the same electrical safety standards as the predicate Gyrus PlasmaCision Laparoscopic Spatula.

Appendix 11.A

Predicate Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula

510(K) Summary - K041633

OCT 2 2 2004

K041633

510(k) Summary of Safety and Effectiveness

Gyrus PlasmaCision Laparoscopic Spatula

Submitted by: Gyrus Medical Inc.
6655 Wedgwood Road
Maple Grove, MN 55311-3602

Contact Person: David E. Chadwick, Ph.D., RAC
Director, Regulatory Affairs/Quality Assurance/Clinical

763-416-7239 direct
763-416-3070 fax
david.chadwick@gyrusmed.com

Date Summary Prepared: June 15, 2004

Name of the Device:

Proprietary Name:	Gyrus PlasmaCision Laparoscopic Spatula
Project Name:	Laparoscopic Spatula
Common/Usual Name:	Electrosurgical Generator and Accessories
Classification Name:	Electrosurgical Cutting & Coagulation Device and Accessories (per 21 CFR 878.4400)
Brand Name:	Not yet assigned
Predicate Devices:	Gyrus PK Bipolar Needle Electrode K031079 Gyrus PK Bipolar L Hook Electrode K031082 Gyrus PlasmaCision Scimitar Instrument K021777

Description:

The Gyrus PlasmaCision Laparoscopic Spatula is a bipolar electrosurgical instrument with the capability to cut and coagulate soft tissue and blood vessels in laparoscopic surgery under carbon dioxide gas or air insufflation. The instrument will pass through a 5mm cannula or through an operating laparoscope's working channel of 5mm minimum diameter.

The instrument is to be used only with the Gyrus PlasmaKinetic Generator, the Gyrus SuperPulse Generator and associated 5 way connector cable.
The device is intended for use in a non-irrigated (dry) environment.

The device has the functionality to dissect, resect or vaporise tissue with haemostasis, to coagulate tissue and blood vessels and to blunt (cold) dissect tissue.

Statement of Intended Use:

The Gyrus PlasmaCision Laparoscopic Spatula is indicated for resection and coagulation of soft tissue and blood vessels in laparoscopic surgery when used with the Gyrus PlasmaKinetic Generator or the Gyrus SuperPulse Generator. This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

Comparison to Predicate Devices:
The Gyrus PlasmaCision Laparoscopic Spatula has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, performance testing has been done to validate the performance of the device. The comparison and validation results presented in this 510(k) notification to the FDA show that the device is substantially equivalent to predicate devices and is safe and effective in its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2004

David E. Chadwick, Ph.D., RAC
Director, Regulatory Affairs/Quality Assurance/
Clinical
Gyrus Medical, Inc.
6655 Wedgwood Road
Maple Grove, Minnesota 55311

Re: K041633
Trade/Device Name: Gyrus PlasmaCision Laparoscopic Spatula
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 6, 2004
Received: October 7, 2004

Dear Dr. Chadwick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041633

Device Name: Gyrus PlasmaCision Laparoscopic Spatula

Indications For Use:

The Gyrus PlasmaCision Laparoscopic Spatula is indicated for resection and coagulation of soft tissue and blood vessels in laparoscopic and general surgical procedures when used with the Gyrus PlasmaKinetic Generator or the Gyrus PlasmaKinetic SuperPulse Generator.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use __
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041633

Appendix 11.B

Predicate Ethicon Inc. Gynecare Laparoscopic Morcellator

510(K) Summary - K993801

K993801

FEB 7 2000

SECTION 7

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

MODIFIED DEVICE NAME:	Gynecare Laparoscopic Morcellator
PREDICATE DEVICE NAME:	Gynecare Laparoscopic Morcellator

510(k) SUMMARY

Device Description

The modified Laparoscopic Morcellator is comprised of two major components: the Laparoscopic Morcellator and the Motor Drive Unit (MDU). The Gynecare Laparoscopic Morcellator is a disposable device which is provided sterile. It is essentially a rotating, cylindrical (tubular) razor blade, with a blade guard, which allows tissue to be grasped with a standard grasper type instrument extending through the central lumen of the device and then drawn up inside the rotating cutter as the cutter cuts with a coring action. The cutting is powered by the Gynecare Laparoscopic Motor Drive Unit (MDU) via a flexible drive cable (see drawing). The physician can turn the Gynecare Laparoscopic Morcellator on and off via a foot pedal. The direction and speed of rotation are controlled on the face of the MDU by a nurse outside the sterile field.

Continued on next page

Device Description, Continued	The variable-speed, reversible MDU is an integral part of the Gynecare Laparoscopic Morcellator since it drives the rotation of the cutter/Morcellator at a controlled speed and torque. The Gynecare Motor Drive Unit provides a user-selectable speed range at which to drive (rotate) the cutter/Morcellator. The torsional output of the motor is sufficient at all speeds to drive the cutter while cutting tough tissue. The direction of rotation of the motor is user-selectable.
Indications For Use	Indicated for cutting, coring and extracting tissue in operative laparoscopy, including laparoscopic general surgical procedures, laparoscopic urologic procedures such as nephrectomy, and laparoscopic gynecologic procedures such as myomectomy and hysterectomy.
Intended Use	The Gynecare Laparoscopic Morcellator is intended for gynecologic, urologic, and general surgical endoscopic use by trained professionals in hospital environments.
Technological Characteristics	The modified device has identical technological characteristics to the predicate device.
Performance Data	Nonclinical laboratory was deemed unnecessary.
Clinical Data	No clinical data was deemed necessary to support this premarket notification; however, published literature is available to support the use of a laparoscopic morcellation device for laparoscopic hysterectomies.

Continued on next page

Conclusions

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food, Drug, and Cosmetic Act.

Contact

Gregory R. Jones
Director, Regulatory Affairs
ETHICON, Inc.
Rt. #22, West
Somerville, NJ 08876-0151

Date

November 8, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 7 2000

Mr. Gregory R. Jones
Director, Regulatory Affairs
Ethicon, Inc., a Johnson & Johnson Co.
P.O. Box 151
Somerville, NJ 08876-0151

Re: K993801
Gynecare Laparoscopic Morcellator
Dated: November 8, 1999
Received: November 9, 1999
Regulatory Class: II
21CFR §884.1720/Procode: 85 HET

Dear Mr. Jones:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K993801

Device Name: Laparoscopic Morcellator

Indications For Use:

Indicated for cutting, coring and extracting tissue in operative laparoscopy, including laparoscopic general surgical procedures, laparoscopic urologic procedures such as nephrectomy, and laparoscopic gynecologic procedures such as myomectomy and hysterectomy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-9G)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993801

Gyrus ACMI PKS Plasma Morcellator

510(K) PREMARKET NOTIFICATION

SECTION 12.0: PROPOSED LABELING

Gyrus ACMI, Inc.
SOUTHBOROUGH, MA

12.0. Proposed Labeling

Both the predicate and proposed device labeling is provided in the following **Appendices** in this section.

Appendix 12.A:	Proposed Gyrus ACMI PKS Plasma Morcellator Instructions for Use and Labels
Appendix 12.B:	Predicate Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula Instructions for Use and Labels
Appendix 12.C:	Predicate Ethicon Inc. Gynecare Laparoscopic Morcellator Instructions for Use

Appendix 12.A

Proposed Gyrus ACMI PKS Plasma Morcellator

Instructions for Use and Labels

GYRUS ACMI

PKS Plasma Morcellator
Instructions For Use

CE 0344

Part No: 174003-A

174

PKS Plasma Morcellator

Model 962000PK PKS Plasma Morcellator w/cord
Model 3620PK PKS Plasma Morcellator

Instructions for use

IMPORTANT: This package insert is designed to provide instructions for use of the PKS Plasma Morcellator instrument when used with the Gyrus ACMI G400 or SP Workstation. It is not a reference to electrosurgical technique.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician. Read all instructions, including CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS prior to use. Failure to follow these instructions could result in serious patient injury.

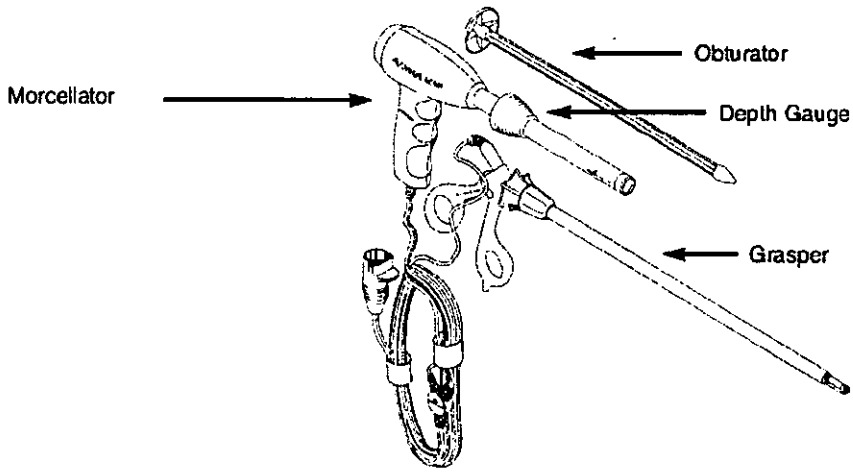
INTENDED USE

The PKS Plasma Morcellator, when used with the Gyrus ACMI Workstation, is intended for cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynecologic procedures.

CONTRAINDICATIONS

The use of the GyrusACMI Workstation is contraindicated when, in the judgment of the physician, bipolar electrosurgical procedures would be contrary to the best interests of the patient.

For patients with active electronic devices implanted, refer to the instructions for use for those devices before using bipolar electrosurgery.


Morcellator
Obturator
Depth Gauge
Grasper

DEVICE DESCRIPTION

The PKS Plasma Morcellator is an adaptive bipolar electrosurgical instrument with the capability to cut and extract soft tissue in laparoscopic surgery. The instrument can be used directly or introduced through a separate 15mm cannula to access the operative site. The device consists of a Radio Frequency (RF) electrosurgical tissue Morcellator, a dedicated and permanently connected Grasper and an obturator. When used with the Gyrus ACMI G400 or SP Workstation, the device can be used to remove tissue from the operative site by introducing the Grasper through the Morcellator working channel, grasping the target tissue and withdrawing it into the Morcellator while activating the RF cutting output.

There are compatible versions of the PKS Plasma Morcellator for the Gyrus ACMI G400 and SP Workstations. Where reference is made to the Workstation, this applies to either G400 or SP versions

Morcellator
The Morcellator consists of an active RF electrode mounted at the distal end of a working cannula. A handpiece allows for controlled positive grip and contains a sealing system to prevent excessive loss of insufflation during use. The Cordset provides the RF connection from the Workstation to both the Morcellator and Grasper

Grasper
The Grasper is permanently connected to the Morcellator to allow proper electrical function of the device.

Depth Gauge
A depth gauge may be supplied with the instrument. This should only be used as an indicator. Care should always be taken to control insertion of the instrument. The gauge may be removed to allow use with separate cannulas.

WARNINGS

Please read all information carefully, including the User Manual, which is provided with the Gyrus ACMI Workstation prior to using the instrument. The Workstation, generator footswitch and PKS Plasma Morcellator are designed to be used together as a system. Failure to properly follow instructions may lead to electrical or thermal injury and result in improper functioning of the instrument.

Do not attempt to use this instrument with generators from other manufacturers. Use with generators other than the Gyrus ACMI G400 or SP Workstation may result in injury to the user or patient.

Safe and effective electrosurgery is dependent upon factors under the control of the user. The user should be experienced in laparoscopic surgical techniques with electrosurgical equipment or obtain training prior to use.

Inappropriate use of electrosurgery instruments can cause damage to tissue, both electrically and thermally. This instrument should not be used in close proximity to tissue structures (including the bladder, bowel or abdominal wall) susceptible to damage in this way unless it is the intention to resect the tissue.

Activation of the device when the distal tip is not in the field of view and may be in contact with the abdominal wall may result in stimulation of nervous tissue within the abdominal wall.

Keep the instrument tip in sight during use. Inadvertent activation or movement of the instrument outside the field of vision may result in patient injury. To prevent accidental injuries to the abdominal wall, bladder, bowel, or other structures, or nerve stimulation, the tissue to be morcellated should be completely exposed and fixed to prevent large pieces of tissue from moving before applying the device. Depress the foot pedal to activate the device only when the distal tip is in the field of view.

If visualization of the treatment site or device is lost during the procedure, STOP IMMEDIATELY. Do not proceed until visibility is restored.

Although the PKS Plasma Morcellator instrument has means to rapidly dissipate any heat that is generated during use, the instrument tip and the shaft immediately proximal to the tip may remain hot enough to cause burns immediately after the electrosurgical current is deactivated. Avoid contact with sensitive tissue, including the abdominal port site, which may result in unintended thermal damage.

When not in use, the instrument should be placed in a clean non-conductive and highly visible area not in contact with the patient or other devices. Inadvertent activation while in contact with the patient or surgical personnel may result in burns.

Do not touch or clean the instrument tip when power is activated.

Do not use this instrument with insufflation gasses other than air or carbon dioxide.

As with all electrosurgical devices, the sparking and heating associated with electrosurgery has the potential for providing a source of ignition. Observe fire precautions at all times. Do not use in the presence of flammable anesthetics or oxidizing gases, such as nitrous oxide or oxygen. Endogenous gases which accumulate in body cavities can also be a source of ignition.

Do not place active accessories near or in contact with flammable materials (such as gauze or surgical drapes).

Do not use this device with tissue removal bags

Flammable substances such as alcohol-based skin prepping agents and tinctures will contribute to increased fire and explosion hazard. Non-flammable agents should be used for cleaning and disinfection and solvents must be allowed to evaporate prior to the application of electrosurgery.

Do not activate the PKS Plasma Morcellator instrument while adjacent to or in contact with metallic objects other than dedicated Gyrus ACMI Grasper as

unintended tissue injury, damage to the contacted object or instrument tip may occur.

Use only with the dedicated Gyrus ACMI Grasper supplied with the Morcellator, or genuine Gyrus ACMI Grasper accessories intended for use with this device.

Do not wrap the connector cable around metal objects. Wrapping the connector cable around metal objects may induce currents that could lead to shock, fires, or injury to the patient or surgical personnel.

Do not attempt to remove the Grasper cable from the Grasper handle

DO NOT REUSE THIS SINGLE USE DEVICE. Attempting to sterilize this device may result in degradation of the electrical insulation rendering the instrument unsafe to use.

IMPORTANT: The contents are sterile unless the package is opened or damaged. Do not resterilize. If the product package is opened or damaged the instrument should be discarded and not used.

CAUTIONS

Prior to initial use, ensure that all package inserts including warnings, cautions, and Instructions For Use are read and understood. Safe and effective electrosurgery is dependent not only on equipment design, but also on factors under the control of the user (Refer to Workstation User Manual).

Ensure that the instrument connector(s) fully engage with the Gyrus ACMI Workstation socket prior to use. Avoid fluid contact with the proximal end of the instrument.

Ensure that the generator settings are appropriate for the electrosurgery that is to be carried out.

Avoid unnecessary activation. This may result in excessive heating which could damage the instrument tip or could damage sensitive tissue structures brought into inadvertent contact with the instrument tip, or the shaft immediately proximal to the tip.

Do not attempt to bend the rigid shaft of this instrument. Attempting to bend the shaft may result in device failure.

Do not insert or withdraw the PKS Plasma Morcellator instrument from the procedure site while power is activated.

If used with a separate cannula, ensure the tip of the PKS Plasma Morcellator instrument is inserted sufficiently to extend beyond the cannula before and during activation. Do not activate while any portion of the tip is within the sheath.

Always ensure compatibility and use care when inserting / removing instruments through cannulas to avoid damage.

Carefully insert and withdraw the instrument to avoid possible instrument damage and/or injury to the patient or surgical personnel.

The patient should not be allowed to come in contact with grounded metal objects.

Do not use the Gyrus ACMI Workstation concurrently with other electrosurgical generators.

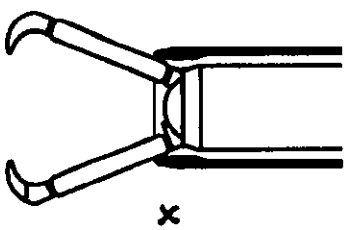
Do not use abrasives or other aggressive means to clean the device tip.

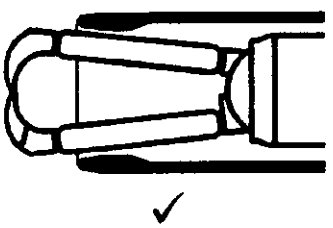
TISSUE EFFECTS
DEVICE APPLICATION

All RF electrosurgery produces vapor byproducts including smoke or steam which can obscure vision. It is recommended that this device is used with an appropriate smoke extraction system or other means to manage these byproducts if necessary.

GRASPER USAGE

As with other morcellator devices, care should be taken to ensure that the Grasper has closed sufficiently to enter the shaft. Excess force should never be used to retract tissue. If resistance is felt as the Grasper enters the shaft, the tissue should be re-grasped to promote better closure.

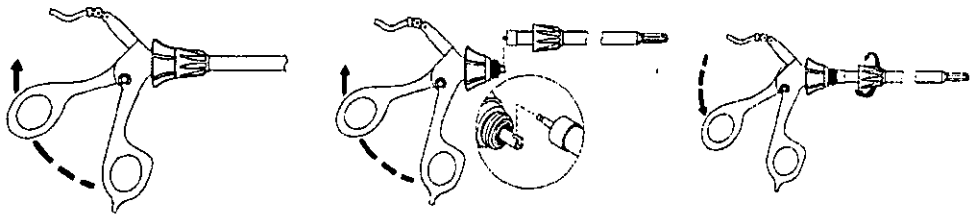




GRASPER INTERCHANGE

Do not use graspers other than the dedicated Gyrus ACMI Grasper supplied with the Plasma Morcellator, or genuine Gyrus ACMI Grasper accessories intended for use with this device.

To change the Gyrus ACMI Grasper jaw, follow the assembly / disassembly instructions below.



Fully open handles | Insert proximal jaw shaft ball end into socket in handle | Close Handles and screw Connection nut onto the rotation cone

BEFORE SURGERY

1. Please refer to the Workstation User Manual for step-by-step instructions regarding the assembly and initial system check of the GyrusACMI Workstation.

2. Turn on the GyrusACMI Workstation. Follow the instructions in the workstation user manual.

3. The PKS Plasma Morcellator is provided sterile for single use. Inspect packaging before use to ensure integrity of the sterile barrier.

4. Remove the PKS Plasma Morcellator from the package. Inspect the device for damage. The device should not be used if there is any damage to the instrument or packaging. Do not use the device beyond the expiration date indicated on the label.

5. Connect the PKS Plasma Morcellator to the workstation. Check that the connector is properly aligned with the sockets on the workstation before connecting. The SP version of the instrument connects to the GyrusACMI reusable connector cord (part no. 3905). The G400 version connects directly to the Workstation.

   Software enablement may be required on first use of this instrument. If prompted, enter the code supplied with the instrument by using the up/down buttons on the Workstation. Refer to the Workstation user manual for further details.

6. Confirm that the GyrusACMI Workstation displays the correct instrument name. If a different name is displayed, contact GyrusACMI Customer Service and do not use the device.

For safety and convenience, the PKS Plasma Morcellator automatically presets the generator to appropriate output settings and restricts output levels to preserve electrode integrity.

DURING SURGERY

1. Tissue for removal should be devascularised before morcellation.

2. The PKS Plasma Morcellator should be carefully introduced to the operative site either directly or through a separate 15mm cannula as the physician deems appropriate. Care should be exercised to avoid over insertion or other means which could result in damage to collateral tissue structures.

3. The GyrusACMI Grasper, in its closed state, is then inserted carefully through the Morcellator working channel. As with the Morcellator, care should be taken to avoid damage to collateral tissues.

4. Target tissue can now be grasped and retracted. Device activation will cut the tissue that comes into contact with the leading edge of the Morcellator tube.

   Since the PKS Plasma Morcellator achieves its effect using an electrical, non-mechanical cut, tissue resection is best achieved with a steady motion requiring little force. If resistance is felt, it may be that the graspers are not closed sufficiently to enter the Morcellator. In this case, it is advisable to re-grasp a smaller volume of tissue.

   Using excessive retraction force can lead to a greater incidence of tissue tearing.

   If a reduction in tissue cutting rate occurs, tissue may have dried upon the electrode between applications or a tissue build-up may have occurred on the electrode during use. In such cases, wipe with gauze that has been moistened with sterile water. Replace the instrument if the problem persists. Do not use abrasives or other aggressive means to clean the device tip.

   Keep the instrument tip in sight during use. Inadvertent activation or movement of the instrument outside the field of vision may result in patient injury. To prevent accidental injuries to the abdominal wall, bladder, bowel, or other structures, or nerve stimulation, the tissue to be morcellated should be completely exposed and fixed to prevent large pieces of tissue from moving before applying the device. Depress the foot pedal to activate the device only when the distal tip is in the field of view.

   Although the PKS Plasma Morcellator instrument has means to rapidly dissipate any heat that is generated during use, the instrument tip and the shaft immediately proximal to the tip may remain hot enough to cause burns immediately after the electrosurgical current is deactivated. Avoid contact with sensitive tissue, including the abdominal port site, which may result in unintended thermal damage.

AFTER SURGERY

1. Carefully remove the instrument from the treatment site. Do not withdraw the instrument while power is activated.

2. Disconnect the PKS Plasma Morcellator from the Workstation.

   CAUTION: Always detach by grasping the connector grips and not the cable. Failure to do so may result in product damage.

3. Turn off the workstation power.

4. Dispose of all elements of the single-use instrument according to your facility's policy on the destruction of surgical waste.

HOW SUPPLIED

The PKS Plasma Morcellator Instrument is supplied sterile for single use only.

WARNING

STORAGE

Store below 25°C (77°F) away from moisture and direct heat. Do not use after use by date printed on the instrument label.

SYMBOLS

Attention, refer to Instructions

Single Use

Storage Temperature Range (°C)

Fragile, Handle with Care

Keep away from Direct Sunlight

Latex Free

Expiration Date

Manufactured in UK.

EC REP (symbol)
Gyrus Medical Ltd.
Fortran Road, St Mellons
Cardiff CF3 0LT, UK.

Customer Service International (non USA):
Tel. +44 (0)118 9219700
Fax. +44 (0)118 9219800

Manufactured for:
Gyrus ACMI, Inc.
136 Turnpike Road
Southborough, MA 01772-2104
USA

Customer Service USA:
Customer Service: 1-800-852-9361
Technical Service: 1-800-621-3739
www.gyrusacmi.com

GYRUS ACMI

2x1 Grasper
For The PKS Plasma Morcellator

Instructions For Use

CE 0344

Part No. 174043-A

186

2x1 Grasper for the PKS Plasma Morcellator

Model 36309PK 2x1 Grasper for the PKS Plasma Morcellator

Instructions for Use

IMPORTANT: This packaged insert is designed to provide instructions for use for changing of the 2x1 Grasper insert for the PKS Plasma Morcellator instrument (Model 962000PK PKS Plasma Morcellator w/cord and Model 3620PK PKS Plasma Morcellator). It is not a reference to electrosurgical technique.

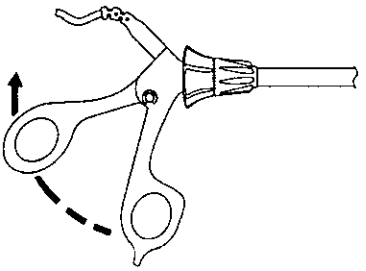
For full instructions, warnings and cautions, please refer to the PKS Plasma Morcellator Instructions For Use.

CAUTION

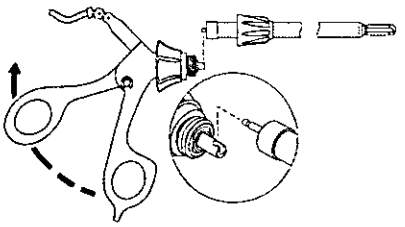
Federal (USA) law restricts this device to sale by or on order of a physician.

GRASPER INTERCHANGE

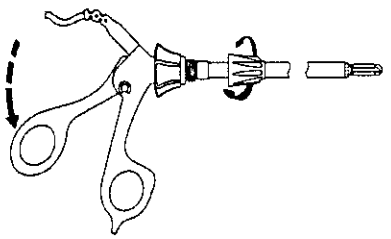
Do not use graspers other than the dedicated Gyrus Grasper supplied with the PKS Plasma Morcellator, or genuine Gyrus grasper accessories intended for use with the PKS Plasma Morcellator.
Remove protective cap from jaws before use.
To change the Gyrus Grasper jaw, follow the assembly / disassembly instructions below.



Step 1:
Fully open handle



Step 2:
Insert proximal jaw shaft ball end into socket in handle.



Step 3:
Close handles and rotate connection nut onto the rotation cone.

Manufactured in UK.

EC REP
Gyrus Medical Ltd.
Fortran Road, St Mellons
Cardiff CF3 0LT, UK

Customer Service International (non USA):
Tel. +44 (0)118 9219700
Fax. +44 (0)118 9219800

Manufactured for:
136 Turnpike Road
Southborough
MA 01772-2104
USA

Customer Service USA
Customer Service: 1-800-852-9361
Technical Service: 1-800-621-3739
www.gyrusacmi.com

Symbols

Attention, refer to instructions

Single Use

Storage Temperature Range (°C)

Fragile, Handle With Care

Keep away from Direct Sunlight

Latex Free

Expiration Date

ISSUE DETAILS

ISSUE A ECO 100010
FIRST RELEASE
DRN / DATE: B PUNTER 30/11/06
CHK / DATE:

GYRUS ACMI

MODEL 962000PK

LOT XXXXXXX 20XX-XX

PKS PLASMA MORCELLATOR, w/cord 1

SEE INSTRUCTIONS FOR USE

DO NOT REUSE/ RESTERILIZE

STERILE EO

CAUTION Federal law (USA) restricts this device to sale by or on the order of a physician

MANUFACTURED FOR:
GYRUS ACMI INC
136 TURNPIKE ROAD
SOUTHBOROUGH, MA 01772-2104, USA

EC REP
GYRUS MEDICAL LIMITED
FORTRAN ROAD, ST MELLONS
CARDIFF CF3 0LT, UK

+H891962000PK3C

+$$XXXXXXXXXXXXCL

25°C 0°C LATEX

CE 0344 174000-A

1. BROKEN LINE REPRESENTS MATERIAL.
2. SEQUENTIAL 7 DIGIT NUMBER TO BE PRINTED ALONGSIDE 'LOT' SYMBOL AS DETAILED ON THE PRODUCTION ORDER. NUMBER SHOWN IS FOR ILLUSTRATION PURPOSES ONLY.
3. SECONDARY BARCODE CONTAINS VARIABLE INFORMATION DISPLAYED AS 'XXXX'. THE LAST ALPHA NUMERIC CHARACTER WILL VARY AS THIS IS A CHECK SUM CHARACTER.

APPROVED:

MATERIAL 144105			GYRUS ACMI
FINISH FREE FROM VISIBLE PARTICULATES			© GYRUS MEDICAL LTD Fortran Road, St Mellons, Cardiff. UK. CF3 0LT Tel: +44 (0)29 2077 6300 Fax: +44 (0)29 2077 6301
DRN / DATE	CHK / DATE		Copyright in this drawing, and the design right in any article shown in the drawing are the property of Gyrus Medical Ltd. Information given is confidential and should not be disclosed to any third party without prior written permission of Gyrus Medical Ltd.
IF IN DOUBT ASK REFER TO BS 8888:2006	3RD ANGLE	SIZE A4	DESCRIPTION BOX LABEL
DIMENSIONS IN MILLIMETRES [INCH] TOLERANCE, UNLESS SPECIFIED X ± 0.2 X.X ± 0.1 X.XX(X) ± 0.05 ANGLES ± 0.5°		SCALE 1 : 1 UNLESS SPECIFIED	SHEET 1 of 1 / PART No 174000 / ISSUE A

1	2	3	4	5	6

ISSUE DETAILS

ISSUE A ECO 100010
FIRST RELEASE
DRN / DATE: B PUNTER 30/11/06

CHK / DATE:

GYRUS ACMI

PRODUCT DESCRIPTION	MODEL	QTY	LOT
PKS PLASMA MORCELLATOR, w/cord	962000PK		XXXXXXX

MANUFACTURED FOR:
GYRUS ACMI INC
136 TURNPIKE ROAD
SOUTHBOROUGH, MA 01772-2104, USA

EC REP
GYRUS MEDICAL LIMITED
FORTRAN ROAD, ST MELLONS
CARDIFF CF3 0LT, UK

CE 0344

174002-A

NOTES

1. LOT NUMBER AND USE BY DATE SHOWN ARE FOR ILLUSTRATION PURPOSES ONLY.
2. BROKEN LINE REPRESENTS MATERIAL.

APPROVED:

MATERIAL
144105

FINISH
FREE FROM VISIBLE PARTICULATES

DRN | CHK
DATE | DATE

IF IN DOUBT ASK
REFER TO BS 8888:2006
3RD ANGLE

SIZE A4
SCALE 1 : 1 UNLESS SPECIFIED

DIMENSIONS IN MILLIMETRES [INCH]
TOLERANCE, UNLESS SPECIFIED
X ± 0.2 X.X ± 0.1 X.XX(X) ± 0.05
ANGLES ± 0.5°

GYRUS ACMI

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Tel: +44 (0)29 2077 6300 Fax: +44 (0)29 2077 6301
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DESCRIPTION
SHIPPER LABEL

SHEET	PART No	ISSUE
1 of 1	174002	A

ISSUE DETAILS
ISSUE A ECO 100010 FIRST RELEASE DRN / DATE: B PUNTER 30/11/06 CHK / DATE:

APPROVED:

GYRUS ACMI

PKS PLASMA MORCELLATOR, w/cord

MODEL 962000PK LOT XXXXXXX XXXX-XX

See instructions for use

Do not reuse/resterilize

STERILE EO

LATEX

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician

MANUFACTURED FOR
GYRUS ACMI INC
136 TURNPIKE ROAD
SOUTHBOROUGH, MA 01772-2104 USA

CUSTOMER SERVICE 1-800-862-9061
TECHNICAL SERVICE 1-800-521-3739

EC REP
GYRUS MEDICAL LIMITED
FORTRAN ROAD, ST MELLONS
CARDIFF CF3 0LT, UK

CUSTOMER SERVICE +44 (0)118 921 9700

CE 0344

174034-A

GYRUS ACMI MODEL 962000PK LOT XXXXXXX XXXX-XX PKS PLASMA MORCELLATOR, w/cord *+H891962000PK1A*

GYRUS ACMI MODEL 962000PK LOT XXXXXXX XXXX-XX PKS PLASMA MORCELLATOR, w/cord *+H891962000PK1A*

GYRUS ACMI MODEL 962000PK LOT XXXXXXX XXXX-XX PKS PLASMA MORCELLATOR, w/cord *+H891962000PK1A*

NOTES

1. LOT NUMBER AND USE BY DATE SHOWN ARE FOR ILLUSTRATION PURPOSES ONLY.
2. BROKEN LINE REPRESENTS MATERIAL.

MATERIAL 144107		GYRUS ACMI © GYRUS MEDICAL LTD Fortran Road, St Mellons, Cardiff, UK. CF3 0LT Tel: +44 (0)29 2077 6300 Fax: +44 (0)29 2077 6301
FINISH FREE FROM VISIBLE PARTICULATES		Copyright in this drawing, and the design right in any article shown in the drawing are the property of Gyrus Medical Ltd. Information given is confidential and should not be disclosed to any third party without prior written permission of Gyrus Medical Ltd.
DRN / DATE	CHK / DATE	
IF IN DOUBT REFER TO BS 8888:2006 ASK	3RD ANGLE	SIZE A3
DIMENSIONS IN MILLIMETRES [INCH] TOLERANCE, UNLESS SPECIFIED X ± 0.2 X.X ± 0.1 X.XX(X) ± 0.05 ANGLES ± 0.5°		SCALE 1 : 1 UNLESS SPECIFIED
DESCRIPTION PATIENT LABEL		
SHEET 1 of 1	PART No 174034	ISSUE A

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Appendix 12.B

Predicate Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula
Instructions for Use and Labels

Manufactured in UK.

Manufactured by:
Gyrus Medical Ltd.
Fortran Road, St Mellons
Cardiff CF3 0LT, UK.
Tel. +44 (0)29 20 776300
Fax. +44 (0)29 20 776301

Customer Service International (non USA):
Gyrus International Ltd.
410 Wharfedale Road
Winnersh Triangle
Wokingham
Berkshire
RG41 5RA
UK
Tel. +44 (0)118 9219700
Fax. +44 (0)118 9219800

Manufactured for/Customer Service USA:
Gyrus Medical Inc.
6655 Wedgewood Road, Suite 160
Maple Grove
MN 55311-3602
USA
Tel. 763 416 3000
Fax. 763 416 3001
Toll Free: 800 852 9361

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

GYRUS
MEDICAL

PKS PLASMASPATULA™ W/ 9-PIN

INSTRUCTIONS FOR USE

CE 0123

140407-B

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CHANGING PKS PLASMASPATULA™ INSTRUMENTS DURING SURGERY

1. Carefully remove the instrument from the treatment site. Do not withdraw the instrument while power is activated.

2. Unplug the instrument from the workstation.

   CAUTION: Always detach by grasping the connector grips and not the cable. Failure to do so may result in product damage.

3. Attach a new sterile instrument to the workstation. The G400 Workstation will automatically reconise the instrument, and providing it is the same type of device, will restore the settings that were last used by the previous instrument.

4. Confirm that the correct instrument name is displayed and check to ensure the settings are appropriate before proceeding.

AFTER SURGERY

1. Disconnect the PKS PlasmaSpatula™ from the workstation.

2. Turn off the generator power.

3. Dispose of the single-use instrument according to your facility's policy on the destruction of surgical waste.

4. Prepare reusable accessories for cleaning and sterilization.

HOW SUPPLIED

The PKS PlasmaSpatula™ Instrument is supplied sterile for single use only.

WARNING

Do not attempt to reuse a PKS PlasmaSpatula™ instrument. Heat or chemical sterilization may render the instrument mechanically or electrically unsafe.

IMPORTANT: The contents are sterile unless the package is opened or damaged. Do not resterilize. If the product package is opened or damaged the instrument should be discarded and not used.

STORAGE

Store below 25°C (77°F) away from moisture and direct heat. Do not use after use by date printed on the instrument pouch label.

GB USA

GYRUS MEDICAL

PKS PLASMASPATULA™ W/ 9-PIN

Model 952000PK PKS PlasmaSpatula™ w/ 9-pin, 5mm/24cm
Model 952005PK PKS PlasmaSpatula™ w/ 9-pin, 5mm/33cm
Model 952010PK PKS PlasmaSpatula™ w/ 9-pin, 5mm/45cm

Instructions for use

IMPORTANT: This package insert is designed to provide instructions for use of the PKS PlasmaSpatula™ instrument when used with the Gyrus G400 Workstation. It is not a reference to electrosurgical technique.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

The PKS PlasmaSpatula™ is a bipolar electrosurgical instrument with the capability to cut and coagulate soft tissue and blood vessels in laparoscopic surgery under carbon dioxide gas or air insufflation. The instrument will pass through a 5mm cannula or through an operating laparoscope working channel of 5mm or larger diameter.

The instrument is to be used only with the Gyrus G400 Workstation.

WARNINGS

Please read all information carefully, including the User Manual, which is provided with the Gyrus G400 Workstation prior to using the instrument. The Gyrus G400 Workstation, the generator foot switch, and the PKS PlasmaSpatula™ are designed to be used together as a system. Failure to properly follow instructions may lead to electrical or thermal injury and result in improper functioning of the instrument.

Do not attempt to use this instrument with generators from other manufacturers. Use with generators other than the Gyrus G400 Workstation may result in injury to the user or patient.

Safe and effective electrosurgery is dependent upon factors under the control of the user. The user should be experienced in laparoscopic surgical techniques with electrosurgical equipment or obtain training prior to use.

Inappropriate use of electrosurgery instruments can cause damage to tissue, both electrically and thermally. This instrument should not be used in close proximity to tissue structures susceptible to damage in this way unless it is the intention to resect or coagulate the tissue.

DO NOT REUSE THIS SINGLE USE DEVICE. Attempting to sterilize this device may result in degradation of the electrical insulation rendering the instrument unsafe to use.

Do not touch or clean the instrument tip when power is activated.

Do not use this instrument with insufflation gasses other than air or carbon dioxide.

Keep the instrument tip in sight during use. Inadvertent activation or movement of the instrument outside the field of vision may result in patient injury.

If visualization of the treatment site or device is lost during the procedure, STOP IMMEDIATELY. Do not proceed until visibility is restored.

When not in use, the instrument should be placed in a clean non-conductive and highly visible area not in contact with the patient or other devices. Inadvertent activation while in contact with the patient or surgical personnel may result in burns.

As with all electrosurgical devices, the sparking and heating associated with electrosurgery has the potential for providing a source of ignition. Observe fire precautions at all times. Do not use in the presence of flammable anesthetics or oxidizing gases, such as nitrous oxide or oxygen. Endogenous gases which accumulate in body cavities can also be a source of ignition.

Do not place active accessories near or in contact with flammable materials (such as gauze or surgical drapes).

Flammable substances such as alcohol-based skin prepping agents and tinctures will contribute to increased fire and explosion hazard. Non-flammable agents should be used for cleaning and disinfection and solvents must be allowed to evaporate prior to the application of electrosurgery.

Do not activate the PKS PlasmaSpatula™ instrument while adjacent to or in contact with other metallic objects as unintended tissue injury may occur.
Damage to the contacted object or instrument tip may occur.

Do not wrap the connector cable around metal objects. Wrapping the connector cable around metal objects may induce currents that could lead to shock, fires, or injury to the patient or surgical personnel.

CAUTIONS

Prior to initial use, ensure that all package inserts including warnings, cautions, and Instructions For Use are read and understood. Safe and effective electrosurgery is dependent not only on equipment design, but also on factors under the control of the user (Refer to Generator User Manual).

Ensure that the instrument connector is fully engaged with the Gyrus G400 Workstation socket prior to use. Avoid fluid contact with the proximal end of the instrument.

Ensure that the generator settings are appropriate for the electrosurgery that is to be carried out.

The instrument tip may remain hot enough to cause burns after the electrosurgical current is deactivated. Avoid contact with sensitive tissue which may result in unintended thermal damage.

Avoid unnecessary and prolonged activation. This may result in excessive heating which could damage the instrument tip or could damage sensitive tissue structures brought into inadvertent contact with the instrument tip.

Do not attempt to bend the rigid shaft of this instrument. Attempting to bend the shaft may result in device failure.

Avoid touching the distal tip of the instrument to other metal instruments or to other electrosurgical instruments.

Do not insert or withdraw the instrument from the procedure site while power is activated.

Do not activate the instrument while any portion of the tip is within the laparoscope working channel or the cannula.

Carefully insert and withdraw the instrument to avoid possible instrument damage and/or injury to the patient or surgical personnel.

The patient should not be allowed to come in contact with grounded metal objects.

Do not use the Gyrus G400 Workstation concurrently with other electrosurgical generators.

When coagulation is selected the back face, top face and tip coagulation regions are active simultaneously (see diagrams on page 3).

When cut is selected the instrument is active around the tip profile as indicated by "Region of Cutting" in the diagram on page 2.

INDICATIONS FOR USE

The PKS PlasmaSpatula™ is indicated for resection and coagulation of soft tissue and blood vessels in laparoscopic and general surgery when used with the Gyrus G400 Workstation.

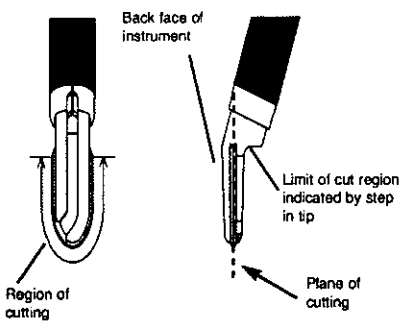
CONTRAINDICATIONS

The PKS PlasmaSpatula™ is not intended to effect female sterilization.

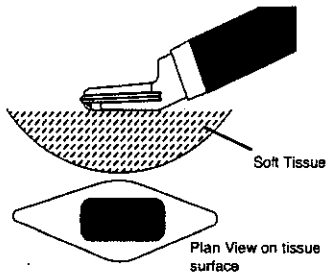
The use of the Gyrus G400 Workstation is contraindicated when, in the judgment of the physician, bipolar electrosurgical procedures would be contrary to the best interests of the patient.

For patients with active electronic devices implanted, refer to the instructions for use for those devices before using bipolar electrosurgery.

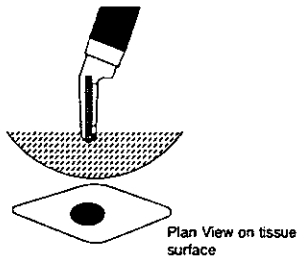
TISSUE EFFECTS
APPLICATION OF INSTRUMENT TIP



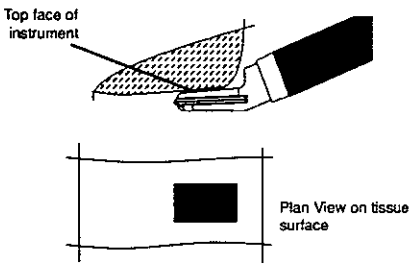
Cutting



Broad Area Coagulation (back face)



Point Coagulation



Broad Area Coagulation (top face)

BEFORE SURGERY

1. Please refer to the Generator User Manual for step-by-step instructions regarding the assembly and initial system check of the Gyrus G400 Workstation.
2. Switch on the Gyrus G400 Workstation . Follow the instructions in the workstation user manual.
3. Remove the PKS PlasmaSpatula™ from the package. Inspect the device for damage.
4. Connect the PKS PlasmaSpatula™ to the workstation. Check that the connector is properly aligned with the sockets on the workstation before connecting.
5. For safety and convenience, the PKS PlasmaSpatula™ automatically presets the generator to default output settings and restricts output levels to preserve electrode integrity. If alternate power levels are desired, adjust the generator to the desired settings using the appropriate UP & DOWN arrows on the front of the workstation. Use the lowest power possible to achieve the desired tissue effect. NOTE: If the workstation power has been turned on with the instrument already attached, the workstation will display the default settings, which must be accepted by pressing the mode button.

DURING SURGERY

1. Carefully insert the non-activated instrument into the treatment area where electrosurgery is to be performed. Do not force the device if resistance is met during insertion.
2. For best results, activate the footswitch only when the tip of the instrument is touching the tissue to be cut or coagulated. Press the Yellow foot pedal for cut and the Blue foot pedal for coagulation.
3. If a reduction in tissue cutting rate occurs, tissue has dried upon the electrode between applications or a tissue build-up has occurred on the electrode during use, wipe with a gauze that has been dampened with sterile water. Replace the instrument if the problem persists.

IF IN DOUBT ASK

ISS	ECN No.	AMENDMENT	DATE	INTL	CHK.
B		DEFAULT SETTINGS REMOVED	20/04/06	BP	

GYRUS

THE ENERGY TO CHANGE SURGERY

MODEL 952005PK LOT XXXXXXX XXXX-XX

PKS PlasmaSpatula™ w/ 9-pin, 5mm/33cm QTY 1

See instructions for use

Do not reuse/resterilize

STERILE R

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician

MANUFACTURED FOR/CUSTOMER SERVICE USA
GYRUS MEDICAL INC
6655 WEDGWOOD ROAD, SUITE 160
MAPLE GROVE, MN 55311-3602
USA
TEL. 800 862 9361

CUSTOMER SERVICE INTERNATIONAL (non USA)
GYRUS INTERNATIONAL LTD
410 WHARFEDALE ROAD
WINNERSH TRIANGLE
WOKINGHAM, BERKSHIRE RG41 5RA, UK

MANUFACTURED BY
GYRUS MEDICAL LIMITED
FORTRAN ROAD, ST MELLONS
CARDIFF CF3 0LT, UK

CE 0123 140401-B

GYRUS MODEL 952005PK LOT XXXXXXX XXXX-XX PKS PlasmaSpatula™ w/ 9-pin, 5mm/33cm *+H891952005PK1E*

GYRUS MODEL 952005PK LOT XXXXXXX XXXX-XX PKS PlasmaSpatula™ w/ 9-pin, 5mm/33cm *+H891952005PK1E*

GYRUS MODEL 952005PK LOT XXXXXXX XXXX-XX PKS PlasmaSpatula™ w/ 9-pin, 5mm/33cm *+H891952005PK1E*

NOTE:-

1. BROKEN LINE REPRESENTS MATERIAL
2. SEQUENTIAL 7 DIGIT NUMBER TO BE PRINTED ALONGSIDE 'LOT' SYMBOL, AS DETAILED ON PRODUCTION ORDER. NUMBER SHOWN IS SAMPLE ONLY.

ITEM NO	PART NO	DESCRIPTION	No OFF	MATERIAL

MATERIAL: 140234

FINISH: REFER TO APPROVED SAMPLE U. O. S.

REMOVE ALL BURRS & BREAK ALL SHARP EDGES. ON MOULDINGS, REMOVE ALL FLASH & GATE MARKS

TOLERANCE U. O.S.
X +/- 0.2
X.X +/- 0.1
X.XX +/- 0.05
+/- 1/2

APPROVALS		DATE
DRAWN	B ARNOLD	10/11/05
CHECKED	AF	21/11/05
RELEASED TO PRODUCTION ECN No.		8735

SCALE: 1 : 1

THIRD ANGLE PROJECTION

GYRUS MEDICAL

GYRUS MEDICAL LTD.
Fortran Road, St Mellons, Cardiff, CF3 0LT, UK
Tel: (0)29 2077 6300 Fax: (0)29 2077 6301

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TITLE: PATIENT LABEL

SIZE: A3 PART No. 140401 ISSUE: B

REV No. SHEET 1 OF 1

ALL DIMENSIONS IN MM U.O.S.

IF IN DOUBT ASK

ISS	ECN No.	AMENDMENT	DATE	INTL.	CHK.
B	8254	REF CHANGED FROM 3200 TO 3200PK	30/11/04	BP	HC
C	8473	PRODUCT NAME CHANGED FROM SUPRASPATULA TO PLASMASPATULA	25/05/05	BP	AF
D		DEFAULT SETTINGS REMOVED	20/04/06	BP	

GYRUS

THE ENERGY TO CHANGE SURGERY

PlasmaSpatula 33cm

REF 3200PK LOT XXXXXXX XXXX-XX

QTY 1

See instructions for use

Do not reuse/resterilize

STERILE R

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician

MANUFACTURED FOR/CUSTOMER SERVICE USA:
GYRUS MEDICAL INC
6655 WEDGWOOD ROAD, SUITE 100
MAPLE GROVE, MN 55311-3602
USA
TEL: 800 852 9361

CUSTOMER SERVICE INTERNATIONAL (non USA)
GYRUS INTERNATIONAL LTD
410 WHARFEDALE ROAD
WINNERSH TRIANGLE
WOKINGHAM, BERKSHIRE RG41 5RA, UK

MANUFACTURED BY:
GYRUS MEDICAL LIMITED
FORTRAN ROAD, ST MELLONS
CARDIFF CF3 0LT, UK

CE 0123

140233-D

GYRUS REF 3200PK LOT XXXXXXX XXXX-XX PlasmaSpatula 33cm *+H8913200PK1+*

GYRUS REF 3200PK LOT XXXXXXX XXXX-XX PlasmaSpatula 33cm *+H8913200PK1+*

GYRUS REF 3200PK LOT XXXXXXX XXXX-XX PlasmaSpatula 33cm *+H8913200PK1+*

NOTE:-

1. BROKEN LINE REPRESENTS MATERIAL
2. SEQUENTIAL 7 DIGIT NUMBER TO BE PRINTED ALONGSIDE 'LOT' SYMBOL, AS DETAILED ON PRODUCTION ORDER. NUMBER SHOWN IS SAMPLE ONLY.

ITEM NO	PART NO	DESCRIPTION	No OFF	MATERIAL

MATERIAL: 140258

FINISH: REFER TO APPROVED SAMPLE U. O. S.

REMOVE ALL BURRS & BREAK ALL SHARP EDGES. ON MOULDINGS, REMOVE ALL FLASH & GATE MARKS

TOLERANCE U. O. S.

X +/- 0.2
X.X +/- 0.1
X.XX +/- 0.05

APPROVALS	DATE
DRAWN B ARNOLD	16/08/04
CHECKED T ATWELL	21/10/04
RELEASED TO PRODUCTION ECN No.	8146

SCALE: 1 : 1

THIRD ANGLE PROJECTION

GYRUS MEDICAL

©GYRUS MEDICAL LTD.
Fortran Road, St Mellons, Cardiff, CF3 0LT, UK
Tel: (0)29 2077 6300 Fax: (0)29 2077 6301

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TITLE: PATIENT LABEL

SIZE: A3

PART No. 140233 ISSUE D

REV No.

SHEET 1 OF 1

ALL DIMENSIONS IN MM U.O.S.

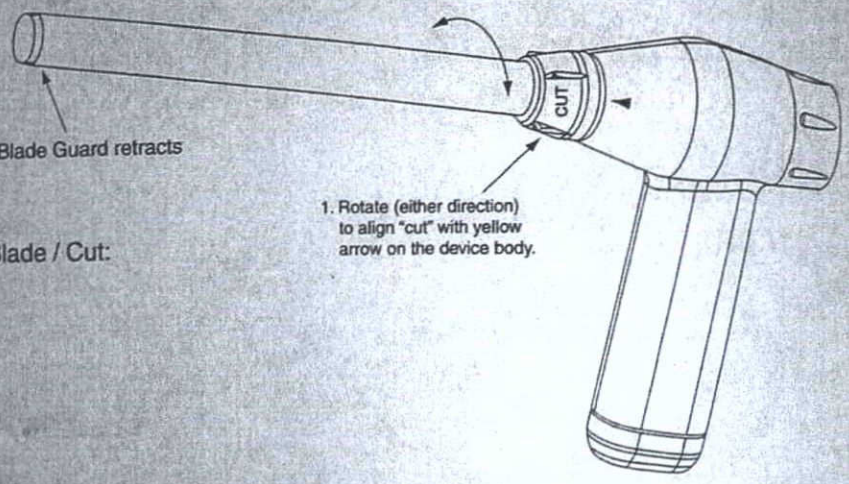
Appendix 12.C

Predicate Ethicon Inc. Gynecare Laparoscopic Morcellator
Instructions for Use

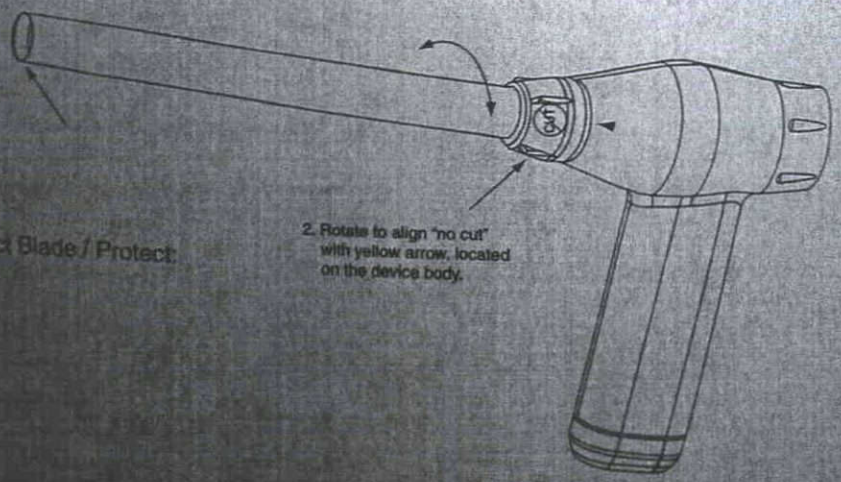
GYNECARE X-TRACT
Tissue Morcellator

ENGLISH

Blade Guard Extension/Retraction



To Extend Blade / Cut:



To Retract Blade / Protect:

GYNECARE X-TRACT
Tissue Morcellator

ENGLISH

INSTRUCTIONS FOR USE

1.0 INTENDED USE

The GYNECARE X-TRACT™ Tissue Morcellator is intended for gynecologic, urologic and general surgical endoscopic use by trained professionals in hospital environments.

INDICATIONS:

Indicated for cutting, coring and extracting tissue in operative laparoscopy, including laparoscopic general surgical procedures, laparoscopic urologic procedures such as nephrectomy, and laparoscopic gynecologic procedures such as myomectomy and hysterectomy.

CONTRAINDICATIONS:

Contraindicated for use on vascularized tissue and as a dissecting tool. (Ovaries, fallopian tubes, myomata and other structures must be devascularized and dissected before morcellation.)

2.0 WARNINGS

2.1 Failure to carefully follow all applicable instructions may result in significant injury to the patient, physician or attendants and may have an adverse effect on the outcome of procedures performed.

2.2 The GYNECARE X-TRACT Tissue Morcellator is a precision instrument that must be handled with care by well trained and knowledgeable professionals. Carefully inspect the device and all associated equipment, instrumentation and cabling for damage prior to use. DO NOT attempt to operate this instrument if any damage is observed. Contact 1-877-ETHICON for replacement of damaged devices or cabling.

2.3 Use ONLY the GYNECARE Motor Drive Unit to connect to the GYNECARE X-TRACT Tissue Morcellator. Use of any other drive mechanism may result in failure of the Laparoscopic Morcellator to operate.

2.4 To prevent accidental injuries to the abdominal wall or similar structure, the tissue to be morcellated should be completely exposed before applying the device. In addition, it is recommended that a second pair of grasping forceps or a fixation instrument be used to prevent large pieces of tissue from uncontrollably moving. Slippage of the cutting tube can cause significant injury.

3.0 PRECAUTIONS

3.1 The physician must be thoroughly familiar with and carefully follow all manufacturer's instructions pertaining to this device and all associated accessories, equipment and instrumentation.

3.2 Procedures performed using the GYNECARE X-TRACT Tissue Morcellator, as with any endoscopic instrument, require adequate knowledge, training and preparation on the part of the physician/surgeon.

3.3 Exercise care when inserting or removing instrument. Use the retractable Blade Guard to prevent lateral injury to tissue from the sharp edged cutting tube. Insertion and removal should be performed under direct visual control at all times.

3.4 Follow local governing ordinances and recycling plans regarding disposal or recycling of the device.

3.5 The disposable GYNECARE X-TRACT Tissue Morcellator is shipped sterile. The product is intended for single use only. Attempts to clean and resterilize the device result in a risk of device malfunction and/or erroneous pathology specimen collection due to residual tissue in the morcellator.

3.6 CAUTION: The Tissue Morcellator blade guard should be used to prevent tissue damage even while the sharp cutting edge is stationary. Exercise caution while manipulating the Morcellator. Do not place cutter into contact with tissue which is not intended to be morcellated.

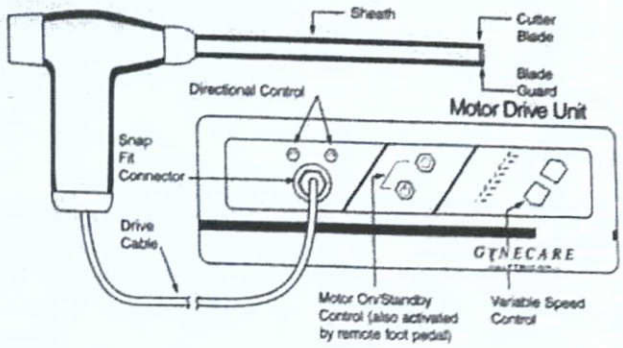
3.7 CAUTION: The use of a tissue extraction bag is recommended for the morcellation of malignant tissue or tissue suspected of being malignant and for tissue the surgeon may consider to be potentially harmful when disseminated in a body cavity.

4.0 DESCRIPTION AND FUNCTION

The GYNECARE X-TRACT Tissue Morcellator is comprised of two major components: the Tissue Morcellator and the Motor Drive Unit (MDU). The GYNECARE X-TRACT Tissue Morcellator is a disposable device which is provided sterile. It is essentially a rotating, cylindrical (tubular) razor blade, with a blade guard, which allows tissue to be grasped with a standard grasper type instrument extending through the central lumen of the device and then drawn up inside and past the rotating cutting edge and into the inner stationary sheath as the cutter cuts with a coring action. The cutter is powered by the GYNECARE Motor Drive Unit (MDU) via a flexible drive cable (see drawing). The physician can turn the GYNECARE X-TRACT Tissue Morcellator on and off via a foot pedal. The direction and speed of rotation are controlled on the face of the MDU by a nurse outside the sterile field.

The variable-speed, reversible MDU is an integral part of the GYNECARE X-TRACT Tissue Morcellator since it drives the rotation of the cutter/Morcellator at a controlled speed and torque. The GYNECARE Motor Drive Unit provides a user-selectable speed range at which to drive (rotate) the cutter/Morcellator. The torsional output of the motor is sufficient at all speeds to drive the cutter while cutting tough fibroid tissue. The direction of rotation of the motor is user-selectable.

The GYNECARE X-TRACT
Tissue Morcellator System



5.0 TECHNICAL SPECIFICATIONS

Specifications

Functional:	Speed Range	125 to 1000 rpm

6.0 DIRECTIONS

Note: To avoid inadvertent damage it is important to be thoroughly familiar with these instructions before handling instrument components.

6.1 UNPACKING AND GENERAL INSPECTION

6.1.1 Thoroughly inspect the outside of all shipping containers for indications of damage. Contact the shipping firm as necessary to resolve shipping damage.

6.1.2 Do not use the GYNECARE X-TRACT Tissue Morcellator if the package (sterile barrier) appears to be damaged or compromised.

6.1.3 Do not use the GYNECARE X-TRACT Tissue Morcellator past the expiration date.

6.1.4 Carefully remove components from shipping cartons and packing material. Inspect all components carefully to make certain that they have not been damaged in shipment. Contact 1-877-ETHICON with any questions or concerns.

6.1.5 Obtain a Return Goods Authorization Number from 1-877-ETHICON or representing company prior to returning any materials.

6.2 ASSEMBLY:

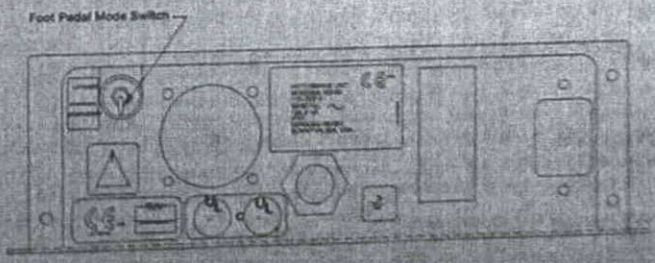
Connect the GYNECARE X-TRACT Tissue Morcellator Drive Cable to the GYNECARE Motor Drive Unit as follows:

6.2.1 The Drive Cable receptacle is located on the front of the Motor Drive Unit. Press down on the metal tab until it locks in place.

6.2.2 Remove the yellow cap from the proximal end of the drive cable on the GYNECARE X-TRACT Tissue Morcellator and carefully insert it into the receptacle on the MDU. Rotate it from side-to-side until it engages.

6.2.3 Press the surrounding plastic fitting in firmly until the metal tab releases and springs upward into place.

6.2.4 Ensure the foot pedal mode switch, located on the back panel of the Motor Drive Unit, is set to "Morcellator" mode.



Motor Drive Unit

6.3 OPERATION

6.3.1 The physician should read this entire manual with particular attention to the Warnings and Precautions sections and be thoroughly familiar with the use of the instrument prior to performing any clinical procedure.

6.3.2 DO NOT ATTEMPT TO SHARPEN OR MODIFY THE MORCELLATOR CUTTER. Bent or distorted cutters can result in patient or physician injury and equipment damage.

6.3.3 DO NOT ATTEMPT TO SHARPLY BEND THE MOTOR DRIVE CABLE in a diameter of less than 8 inches (20 centimeters). Sharply bent or kinked Motor Drive Cables may cause the Motor Drive Unit to overheat and stop. During a procedure, a minimum distance of 1.5 meters should be maintained between the Motor Drive Unit and the Morcellator to allow the Drive Cable to hang in a large arc with no bends or loops.

6.3.4 PREVENTIVE INSPECTION AND TEST:

Prior to operation:

6.3.4.1 The rotational speed may be increased in increments of 45 rpm by pressing on the upward-pointing yellow membrane switch. The number of lights in the switch will increase thus indicating that speed has been increased. The recommended speed for optimal Morcellator performance is 900 to 1000 rpm; this speed is indicated by the illumination of 2 lights on the speed switch.

6.3.4.2 If it appears that the Morcellator has stopped rotating during a procedure, check to ensure that all connections to the morcellator and MDU (both mechanical and electrical) are secure and that the drive cable has not wrapped up into a loop.

6.3.4.3 The Motor Drive Unit contains an internal switch to shut the unit off upon overheating. In this event, switch the main power switch (on the back of the unit) OFF and allow the unit to cool for several seconds before restarting.

6.3.4.4 If the drive cable wraps up and stalls the motor, press the pink stop button, reverse the direction of rotation with the direction arrow button, and intermittently run the motor in 1 second intervals until the drive cable unwraps and hangs freely with no loops.

6.3.5 OPERATIVE INSTRUCTIONS:

6.3.5.1 In laparoscopic procedures, a separate trocar/sheath assembly is normally used as the access port for the device to be introduced into the operative site. The GYNECARE X-TRACT Tissue Morcellator with obturator is subsequently inserted into the abdomen through the 15mm sheath under direct visual control.

6.3.5.2 In order to remove tissue, a 10mm claw forceps or similar instrument is inserted through the central lumen of the Morcellator and into the abdomen. The tissue to be extracted is then grasped and pulled up through the rotating Morcellator. In order to prevent injury to the abdominal wall, the tissue to be morcellated should be completely exposed before attempting to extract through the GYNECARE X-TRACT Tissue Morcellator. It is recommended that a second pair of grasping forceps or fixation instrument be used to help control tissue movement.

6.3.5.3 The high volume cutting capacity of the GYNECARE X-TRACT Tissue Morcellator makes it possible to extract large amounts of tissue in short periods of time.

7.0 TRANSPORT, STORAGE, CARE AND MAINTENANCE

The GYNECARE X-TRACT Tissue Morcellator components should be transported, stored and used at temperatures between -18°C and 55°C, 30 to 75% relative humidity, and -0.5 to +1.5 atmospheric pressure (507 to 1520 hPa). Care should be taken to avoid dropping or immersing the Motor Drive Unit in liquid.

8.0 CLEANING / REUSE

The GYNECARE X-TRACT Tissue Morcellator is a single-use disposable device and should NOT be cleaned and reused. Since the GYNECARE Motor Drive Unit is reusable many times, spilled fluids may be wiped clean from the outer case with a damp (not wet) cloth or sponge and soapy water after a procedure. BE CERTAIN THAT THE MOTOR DRIVE UNIT IS DISCONNECTED FROM THE POWER SUPPLY BEFORE CLEANING.

9.0 DISPOSAL

For proper disposal of the GYNECARE X-TRACT Tissue Morcellator, insert the obturator thru the center of the cutter and extend the blade guard over the cutting edge. The morcellator may now be disposed of safely in accordance with local governing ordinances and recycling plans.

10.0 WARRANTY AND TECHNICAL / CUSTOMER SERVICE

This device is warranted against defects in workmanship and material for one year from the date of delivery to the extent that GYNECARE will, at our option, replace, repair, or refund in full the purchase price of the device or any part thereof which in our opinion is defective, provided that the device has not been subjected to tampering, modification, or accidental abuse (such as dropping or immersion). A device that has been improperly used cannot be considered under this warranty.

WE MAKE NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTIES OF FITNESS OR MERCHANTABILITY, EXCEPT AS EXPRESSLY SET FORTH ABOVE. WE SHALL NOT BE LIABLE FOR ANY ANTICIPATED OR LOST PROFITS, INCIDENTAL DAMAGES, CONSEQUENTIAL DAMAGES, COSTS, TIME CHARGES, OR OTHER LOSSES IN CONNECTION WITH THE DEVICE OR ANY REPLACEMENT PARTS THEREFORE OTHER THAN AS EXPRESSLY PROVIDED BY SPECIFIC LAW.

If a manufacturing defect is found during a period of up to one year from date of delivery, GYNECARE will repair or replace the device or replace any defective part thereof without charge to the purchaser; however, GYNECARE's obligation thereunder does not include the cost of transportation which must be borne by the customer. GYNECARE assumes no responsibility for damage in transit, and any claims for such damage should be presented to the carrier.

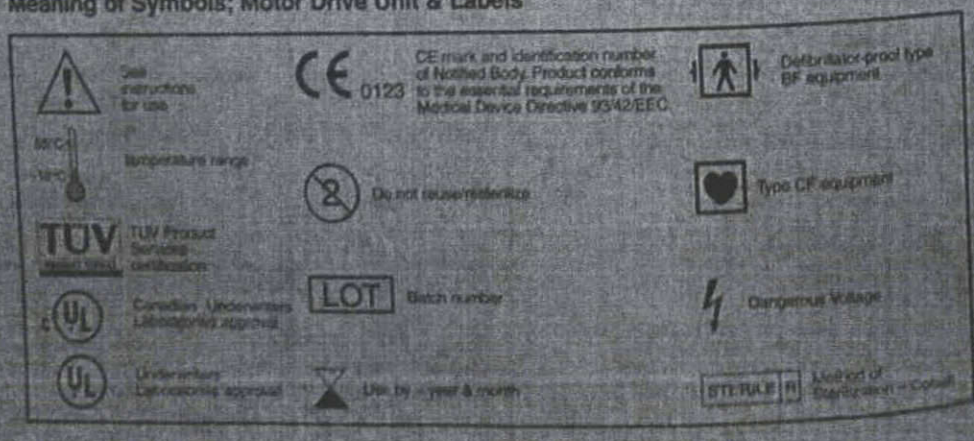
11.0 CAUTION

Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

Manufactured For:
GYNECARE
A division of ETHICON, INC.
a Johnson & Johnson company
Somerville, New Jersey 08876-0151
1-877-ETHICON

Product names in caps are trademarks of ETHICON, INC.

Meaning of Symbols; Motor Drive Unit & Labels



Gyrus ACMI PKS Plasma Morcellator

510(K) PREMARKET NOTIFICATION

SECTION 13.0: PACKAGING, STERILIZATION AND SHELF-LIFE

Gyrus ACMI, Inc.
SOUTHBOROUGH, MA

13.0 Packaging, Sterilization, and Shelf Life

Packaging

The PKS Plasma Morcellator instrument will be placed in a thermoformed PETG tray, which will be sealed with a Tyvek lid. This packaging will then be placed into a multi-unit shelf box with the Instructions for Use. The shelf boxes will be placed into shipping boxes for transit. Labels will be affixed to the shelf boxes.

Evaluation of the packaging configuration was performed in accordance with EN 868-5 and ISO 11607, and included a range of tests to confirm package integrity. A Design of Experiments (DOE) analysis was performed to establish the operating conditions for the designated sealing equipment. From this DOE, it was determined that acceptable seals could be produced, with minimum peel strengths of 6N per 25mm strip (well above the >2N per 25mm strip minimum limit indicated by EN 868-5). This DOE and subsequent process qualification resulted in the establishment of a minimum continuous seal width requirement of >4.0mm (or 0.158").

Transportation testing has been conducted in accordance with ISTA (International Safe Transit Association) recommendations. This testing included preconditioning the test articles to temperature and relative humidity conditions ranging from $-10^{o}C$ and uncontrolled RH, to $40^{o}C$ and 85% RH, then subjecting the test articles to compression and vibration testing. The test articles were then inspected to determine whether seal integrity had been maintained, i.e., presence of cracks, voids, tears, or holes, as well as presence of humidity, moisture or staining on the interior of the package. After inspection, the test articles were separated into two approximately even pools and subjected to burst testing and peel strength testing, or dye penetration testing.

In addition, qualifications were run to establish a specification for a burst tester apparatus to be utilized for routine in-process inspections during production runs. This apparatus is intended to provide further assurance of seal integrity during routine processing, in addition to the seal integrity validation work indicated above. This routine burst test can also serve as an early process indicator in the event processing conditions drift toward any of the limits established during the DOE. Evaluations of this apparatus and its possible effect on integrity following sterilization showed no difference in burst test results in samples tested pre- and post-sterilization.

Sterilization

The PKS Plasma Morcellator will be shipped sterile. Each device will be sterilized using Ethylene Oxide, using a cycle validated in accordance with ISO 11135 to provide a sterility assurance level of 10^{-6}. Validation of the sterilization cycle efficacy was conducted using a half-cycle method, using Biological Indicators inoculated with a

minimum certified population of 1 x 10^6 *B. subtilis var. niger* organisms. At full exposure time, this will provide at least a minimum sterility assurance level of 10^{-6}.

The maximum levels of sterilant residuals are defined as part of the validation process to be consistent with ISO 10993-7. Evaluations were conducted using simulated-use extraction as defined by ISO 10993-7, and use the specifications indicated in Clause 4.3.3 for limited exposure devices (EO: <20mg, ECH: <12mg). The test articles were subjected to a minimum aeration time of 48 hours at >20°C (this will also be the routine processing specification as well), and for reference are compared to test articles selected after 0 hours of aeration time.

The rationale for using these levels is that the PKS Plasma Morcellator is a limited exposure device as defined by ISO 10993-1 and 10993-7, since the patient's exposure to the device is less than 24 hours.

Shelf Life

The PKS Plasma Morcellator will be initially marketed with a 1-year expiration date. This period was determined through an analysis of the shelf-life stability of the materials used in the design of the PKS Plasma Morcellator, as well as an analysis of the packaging materials and processes used with other Gyrus Medical devices. Accelerated shelf-life studies are planned to support a three-year expiration date.

Gyrus ACMI PKS Plasma Morcellator

510(K) PREMARKET NOTIFICATION

SECTION 14.0: BIOCOMPATIBILITY

Gyrus ACMI, Inc.
SOUTHBOROUGH, MA

14.0 Biocompatibility

The proposed PKS Plasma Morcellator uses a number of the same patient contacting materials as those used in a number of devices currently marketed by Gyrus ACMI and other firms. In particular, the materials used in the Grasper assembly are used in several currently marketed devices as noted in **Table IV** below.

Data supporting the biocompatibility of the remaining patient contacting materials (both Direct and Indirect contact), and located within the Morcellator handle, specifically the Outer Tube Assembly, was previously provided to the Agency as part of K063134. The Outer Tube Assembly consists of the following components with potential for patient contact:

- Active Ring Electrode
- Active Overmold
- Active Tip Adhesive
- Return Tube
- Wire Sleeve
- Valve
- Inner/Outer Shaft Sleeves
- Shaft/Return Tube Adhesives

Subsequently, Outer Tube Assemblies with a Depth Stop, consisting of those components that have the potential for patient contact, were submitted to NAMSA for cytotoxicity, intracutaneous irritation, and maximization sensitization studies. The Outer Tube Assemblies were evaluated to determine whether these components when used together would elicit a negative biocompatibility response. The results of these tests demonstrate that the components do not elicit a negative biocompatibility response. Copies of these test reports are provided in **Appendix 14.A**. Copies of the test reports supporting the [redacted] used in the Obturator are provided in **Appendix 14.B**.

(b)(4) Trade Secret Process

For reviewer convenience, a summary of the patient contacting materials used in the proposed PKS Plasma Morcellator, their potential for patient contact, and the basis for their biocompatibility are indicated below in **Table IV**.

Table IV – Patient Contacting Materials

Assembly/Component	Material Used in Proposed PKS Plasma Morcellator	Nature of Contact (All Limited Duration, Surface contact, breached, or compromised surface)	Basis for Biocompatibility Determination
Grasper Jaw	Type 303 Stainless Steel	Direct	Used in Gyrus ENT Cogent G2 Generator Accessories, cleared under K021777, also used in predicate PlasmaCision Laparoscopic Spatula, K041633
Grasper Jaw and Shaft Insulation	Polyolefin tubing (Altera MT-2000- medical grade, USP class VI);	Indirect	Used in ACMI DUR-D, cleared under K060269
Grasper Shaft	Aluminum ENAW5083 Hard Drawn Tube with BS1615 Sulphuric Black Anodizing Process	Indirect	Used in Surgical Innovations PLC Laparoscopic Monopolar Scissors, K063485 (Manufacturer of this device provides the same grade of Aluminum to Gyrus for the PKS Plasma Morcellator)
Active Ring Electrode	Type 316 Stainless Steel	Direct	Cytotoxicity Study Using the ISO MEM Elution Method, NAMSA Report 07C_52130_02; ISO Intracutaneous Study – Extract, NAMSA Report 07C_52130_06/07; ISO Maximization Study Extract, NAMSA Report 07C_52130_04/05
Return Tube	Gold plated Copper C101. It is electroless nickel plated (3-5um), then flash coated with electrolytic hard gold (0.5 – 1um).	Direct	
Active Overmold	Grade MED-4970 LSR Silicone Elastomer	Direct	
Active Tip Adhesive	MED1014 Silicone RTV Adhesive	Direct	
Inner/Outer Shaft Sleeves	Braided Polymer	Direct	
Depth Stop	TPE: Thermolast K TF6STE	Direct	
Obturator	Terluran HD15	Direct	Cytotoxicity Study Using the ISO Elution Method, NAMSA Report 05T_49333_01; USP and ISO Systemic Toxicity Study Extract, NAMSA Report 05T_49333_02/03/04/05; USP Intracutaneous Study Extract, NAMSA Report 05T_49333_06/07/08/09; USP Muscle Implantation Study – 5 Day, NAMSA Report 05T_49333_12
Valve	Grade MED-4970 LSR Silicone Elastomer	Indirect	Material tested as part of Outer Tube Assembly above

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Appendix 14.A

Outer Tube Assembly Data

Cytotoxicity Study Using the ISO MEM Elution Method,
NAMSA Report 07C_52130_02

ISO Intracutaneous Study – Extract,
NAMSA Report 07C_52130_06/07

ISO Maximization Study Extract,
NAMSA Report 07C_52130_04/05

Please note that the enclosures refer to the "Gyrus Solid Organ Resection Device" or "SORD". This was this internal name of the project while the device was under development. Gyrus ACMI plans to market the proposed device by the name "PKS Plasma Morcellator".

GLP REPORT

TEST FACILITY

NAMSA
9 Morgan
Irvine, CA 92618
949.951.3110

SPONSOR

Luke Gallagher
Gyrus Medical Limited
Fortran Road, St. Mellons
Cardiff CF3 OLT
United Kingdom

CONFIDENTIAL

STUDY TITLE

Cytotoxicity Study Using the ISO Elution Method
(1X MEM Extract)

TEST ARTICLE NAME

SORD Outer Tube Assembly 274018-1 with fitted SORD Depth Stop 174024-3

TEST ARTICLE IDENTIFICATION

Lot: WO522791

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Summary

An *in vitro* biocompatibility study, based on the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity: *in vitro* Methods guidelines, was conducted on the test article, SORD Outer Tube Assembly 274018-1 with fitted SORD Depth Stop 174024-3, Lot: WO522791, to determine the potential for cytotoxicity. A single extract of the test article was prepared using single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (1X MEM). This test extract was placed onto three separate monolayers of L-929 mouse fibroblast cells propagated in 5% CO_2. Three separate monolayers were prepared for the reagent control, negative control and for the positive control. All monolayers were incubated at 37°C in the presence of 5% CO_2 for 48 hours. The monolayer in the test, reagent control, negative control and positive control wells was examined microscopically at 48 hours to determine any change in cell morphology.

Under the conditions of this study, the 1X MEM test extract showed no evidence of causing cell lysis or toxicity. The 1X MEM test extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity). The reagent control, negative control and the positive control performed as anticipated.

Study and Supervisory Personnel:

Leilani C. Halili, B.S.
America Salvador, B.A., ALAT
Sergio M. Fujino, B.S.
Jeffrey M. Kuhnlein, B.S.

Approved by:

Marcia Mestre, B.S.
Study Director

10-31-07
Date Completed

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

mlm

Statement of GLP Compliance

This study was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58).

There were no deviations from the protocol, standard operating procedures or the GLP Regulations which were judged to have had any significant impact on the validity or interpretation of the data.

All laboratory data has been accurately recorded and verified, as indicated by the signature below.

Study Director: Marcia Mestre, B.S. 10-31-07 Date

1. Introduction

Purpose
The test article identified below was extracted, and the extract was subjected to an *in vitro* cytotoxicity study for biocompatibility based on the requirements of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity: *in vitro* Methods. The test was performed to determine whether leachables extracted from the material would cause cytotoxicity.

Dates
The test article was received on October 3, 2007. The cells were first exposed to the extract October 11, 2007, and the observations were concluded on October 13, 2007.

GLP Compliance
The study initiated by protocol signature on October 8, 2007, was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations, 21 CFR 58. A Statement of Quality Assurance Activities was issued with this report.

2. Materials

The test article provided by the sponsor was identified and handled as follows:

Test Article Name:	SORD Outer Tube Assembly 274018-1 with fitted SORD Depth Stop 174024-3
Test Article Identification:	Lot: WO522791
Stability Testing:	In progress (per sponsor)
Expiration Date:	Stable for duration of intended testing (per sponsor)
Strength, Purity and Composition:	Strength: Not Applicable. Purity: Not Applicable. Samples sterilized by Ethylene Oxide (EO). Composition: See Appendix 2.
Physical Description of the Test Article:	See Appendix 2
Storage Conditions:	Room Temperature
Extraction Vehicle:	Single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (1X MEM)
Test Article Preparation:	Based on the USP ratio of 120 cm^2:20 ml, a 80 cm^2 portion of the test article was covered with 13 ml of 1X MEM. A single preparation was extracted at 37°C for 24 hours. Per protocol amendment II, agitation was not performed during extraction. The Depth Stop, orange component of the device, was positioned at 70 mm from the end of the device. The device was extracted up to the 85 mm markings. The surface area of 80 cm^2 per component was provided by the sponsor. The component was not cut.
Negative Control Preparation:	High density polyethylene was used as the negative control. Based on the USP ratio of 60 cm^2:20 ml, a single 30.2 cm^2 portion of the control material was covered with 10 ml of 1X MEM. The preparation was extracted with agitation at 37°C for 24 hours.
Reagent Control Preparation:	A single aliquot of 1X MEM without test material was extracted with agitation at 37°C for 24 hours.
Positive Control Preparation:	The current NAMSA positive control, tin stabilized polyvinylchloride, was used. Based on the USP ratio of 60 cm^2:20 ml, a single 29.6 cm^2 portion of the control material was covered with 9.9 ml of 1X MEM and extracted with agitation at 37°C for 24 hours.

Positive Control Preparation: The current NAMSA positive control, tin stabilized polyvinylchloride, was used. Based on the USP ratio of 60 cm^2:20 ml, a single 29.6 cm^2 portion of the control material was covered with 9.9 ml of 1X MEM and extracted with agitation at 37°C for 24 hours.

Condition of Extracts:
Test: Clear
Reagent Control: Clear
Negative Control: Clear
Positive Control: Clear

Sample Disposition Discard all remaining samples

3. Test System

Test System Management
L-929, mouse fibroblast cells, (ATCC CCL 1, NCTC Clone 929, of strain L, or equivalent source) were propagated and maintained in open wells containing single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (1X MEM) in a gaseous environment of 5% carbon dioxide (CO_2). For this study, 10 cm^2 wells were seeded, labeled with passage number and date, and incubated at 37°C in 5% CO_2 to obtain sub-confluent monolayers of cells prior to use. Aseptic procedures were used in the handling of the cell cultures following approved NAMSA Standard Operating Procedures.

4. Method

Triplicate culture wells were selected which contained a sub-confluent cell monolayer. The growth medium contained in triplicate cultures was replaced with 2 ml of the test extract. Similarly, triplicate cultures were replaced with 2 ml of the reagent control, negative control and the positive control. Each well was labeled with the corresponding lab number, replicate number and the dosing date. The wells were incubated at 37°C in 5% CO_2 for 48 hours.

Following incubation, the cultures were examined microscopically (100X) to evaluate cellular characteristics and percent lysis. The color of the test medium was observed. A color shift toward yellow was associated with an acidic pH range and a color shift toward magenta to purple was associated with an alkaline pH range.

Each culture well was evaluated for percent lysis and cellular characteristics using the following table (direct excerpt from USP):

Grade	Reactivity	Conditions of all Cultures
0	None	Discrete intracytoplasmic granules; no cell lysis
1	Slight	Not more than 20% of the cells are round, loosely attached, and without intracytoplasmic granules; occasional lysed cells are present
2	Mild	Not more than 50% of the cells are round and devoid of intracytoplasmic granules; no extensive cell lysis and empty areas between cells
3	Moderate	Not more than 70% of the cell layers contain rounded cells or are lysed
4	Severe	Nearly complete destruction of the cell layers

For the test to be valid, the reagent control and the negative control must have had a reactivity of none (grade 0) and the positive control must have been a grade 3 or 4. The test sample met the requirements of the test if the biological response was less than or equal to grade 2 (mild). The test would have been repeated if the controls did not perform as anticipated and/or if all three test wells did not yield the same conclusion.

5. Results

See Appendix 1 for results.

pH Observation: No pH shift observed at 48 hours.

6. Conclusion

Under the conditions of this study, the 1X MEM test extract showed no evidence of causing cell lysis or toxicity. The 1X MEM test extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity). The reagent control, negative control and the positive control performed as anticipated.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other samples is the sponsor's responsibility. All procedures were conducted in conformance with good manufacturing practices and certified to ISO 13485:2003.

7. Quality Assurance

Inspections were conducted at intervals adequate to assure the integrity of the study in conformance with 21 CFR 58.35(b)(3). The final report was reviewed for conformance to Section 58.185, Subpart J, of the GLP Regulations. A Statement of Quality Assurance Activities was issued with the report.

8. Proposed Dates

The study dates were finalized by the study director following receipt of the sponsor approved protocol and appropriate material for the study. Initiation of the study was the date on which the study director signed the GLP protocol. Projected dates for starting the study (first treatment) and for the completion of the study (final report release) were provided to the sponsor (or representative of the sponsor).

9. Records

All raw data pertaining to this study and a copy of the final report are retained in designated NAMSA archive files.

10. References

21 CFR 58 (GLP Regulations).

ISO 10993-5 (1999) Biological evaluation of medical devices – Part 5: Tests for cytotoxicity, *in vitro* methods.

USP 30-NF 25, General Chapter <87> BIOLOGICAL REACTIVITY TESTS, IN VITRO.

Wilsnack, R. E., "Quantitative Cell Culture Biocompatibility Testing of Medical Devices and Correlation to Animal Tests," *Biomaterials, Medical Devices and Artificial Organs* 4 (1976): 235-261.

Wilsnack, R. E., F. J. Meyer and J. G. Smith, "Human Cell Culture Toxicity Testing of Medical Devices and Correlation to Animal Tests," *Biomaterials, Medical Devices and Artificial Organs* 1 (1973): 543-562.

11. Protocol Changes

Any necessary changes to the protocol after sponsor approval or study initiation were documented and approved by the study director as protocol amendments. Copies were distributed to the sponsor, the raw data file, and the NAMSA Quality Assurance department.

Appendix 1 - Reactivity Grades For Elution Testing

Well	Percent Rounding	Percent Cells Without Intracytoplasmic Granules	Percent Lysis	Grade	Reactivity
Test (1A)	0	0	0	0	None
Test (1B)	0	0	0	0	None
Test (1C)	0	0	0	0	None
Negative Control (1A)	0	0	0	0	None
Negative Control (1B)	0	0	0	0	None
Negative Control (1C)	0	0	0	0	None
Reagent Control (1A)	0	0	0	0	None
Reagent Control (1B)	0	0	0	0	None
Reagent Control (1C)	0	0	0	0	None
Positive Control (1A)	Not Applicable	Not Applicable	100	4	Severe
Positive Control (1B)	Not Applicable	Not Applicable	100	4	Severe
Positive Control (1C)	Not Applicable	Not Applicable	100	4	Severe

Appendix 2 – Test Article Composition and Physical Description

Composition:	Silicone SORD active overmould assembly 274016, fibre-reinforced epoxy Shaft inner tube SORD 174045 and painted fibre-reinforced epoxy Shaft Outer Tube SORD 174023 are bonded to gold plated SORD Welded Return Assembly 274017 using Med2-4013 HTC adhesive and MED6-161 Primer. Tube Blue SORD is assembled onto wire of SORD Welded Return Assembly 274017 and thermoplastic elastomer Depth Stop SORD 174023 is inserted onto Shaft outer Tube SORD 174023.
Physical Description:	SORD Active Overmould 274016 (E017465, E017496), SORD Welded Return Assembly 274017 (E017437), Shaft Inner Tube SORD 174045 (E017105), Shaft Outer Tube SORD 174023 (E017693), Depth Stop SORD 174023 (E013955), Med2-4013 HTC Adhesive 080051 (G025803), Primer MED6-161 080052 (E017538) Tube Blue SORD 174049 (E017394)

Statement of Quality Assurance Activities

Phase Inspected	Auditor	Date
Dose	W. Wooten	October 11, 2007
Raw Data Approval	S. Uvina	October 16, 2007
Final Report Review	W. Wooten	October 31, 2007

Reports to Management and Study Director(s)	Date
Periodic GLP Status Report	October 10, 2007

This study will be included in the next periodic status report as completed.

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: _____ 10-31-07
William Wooten, ASQ-CQA — Date
Quality Assurance

GLP REPORT

TEST FACILITY

NAMSA
9 Morgan
Irvine, CA 92618
949.951.3110

SPONSOR

Luke Gallagher
Gyrus Medical Limited
Fortran Road, St. Mellons
Cardiff, CF3 OLT
United Kingdom

CONFIDENTIAL

STUDY TITLE

ISO Intracutaneous Study - Extract

TEST ARTICLE NAME

SORD Outer Tube Assembly 274018-1 with fitted SORD Depth Stop 174024-3

TEST ARTICLE IDENTIFICATION

Lot: WO522791

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Summary

The test article, SORD Outer Tube Assembly 274018-1 with fitted SORD Depth Stop 174024-3, Lot: WO522791, was extracted in 0.9% sodium chloride USP solution (SC) and sesame oil, NF (SO). These extracts were evaluated for intracutaneous reactivity based on the requirements of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity.

A 0.2 ml dose of the appropriate test article extract was injected into five separate sites on each rabbit. Similarly, the corresponding control was injected into the same rabbit. The injection sites were observed immediately after injection. Observations for erythema and edema were conducted at 24, 48, and 72 hours after injection.

Under the conditions of this study, there was no erythema and no edema from the SC extract injected intracutaneously into rabbits. There was very slight to well-defined erythema and very slight edema from the SO extract injected intracutaneously into rabbits. The test article extracts met the requirements of the test since the difference between the test extracts and corresponding control mean score was 1.0 or less.

Study and Supervisory Personnel:

Robert Villani, AALAS Certified
David Vergil
Thanh N. Nguyen, B.S.
Jeffrey M. Kuhnlein, B.S.

Approved by:

Marcia Mestre, B.S.
Study Director

11-26-07
Date Completed

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

nee

Statement of GLP Compliance

This study was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58).

There were no deviations from the protocol, standard operating procedures or the GLP Regulations which were judged to have had any significant impact on the validity or interpretation of the data.

All laboratory data has been accurately recorded and verified, as indicated by the signature below.

Study Director: Marcia Mestre, B.S. 11-26-07 Date

1. Introduction

Purpose
The test article identified below was extracted and the extracts were evaluated for biocompatibility based on the requirements of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. The purpose of the study was to determine whether leachables extracted from the material would cause local dermal irritant effects following injection into rabbit skin.

Dates
The test article was received on October 3, 2007. The animals were injected on November 5, 2007, and the observations were concluded on November 8, 2007.

GLP Compliance
The study initiated by protocol signature on October 26, 2007, was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations, 21 CFR 58. A Statement of Quality Assurance Activities was issued with this report.

Duplication of Experimental Work
By signature on the protocol, the sponsor confirmed that the conduct of this study did not unnecessarily duplicate previous experiments.

2. Materials

The test article provided by the sponsor was identified and handled as follows:

Test Article Name:	SORD Outer Tube Assembly 274018-1 with fitted SORD Depth Stop 174024-3
Test Article Identification:	Lot: WO522791
Stability Testing:	In progress (per sponsor)
Expiration Date:	Stable for duration of intended testing (per sponsor)
Strength, Purity and Composition:	Strength: Not Applicable. Purity: Not Applicable. Samples sterilized by Ethylene Oxide (EO). Composition: See Appendix 2.
Physical Description of the Test Article:	See Appendix 2
Storage Conditions:	Room Temperature
Vehicles:	0.9% sodium chloride USP solution (SC) Sesame oil, NF (SO)
Preparation:	Based on a ratio of 120 cm^2:20 ml, an 80 cm^2 portion of the test article was covered with 13 ml of the vehicle. The test article was extracted in SC and SO at 50°C for 72 hours. Manual agitations were performed twice daily. The extraction vehicles without test article were similarly prepared to serve as controls. The test article was extracted up to the 85mm markings.

		Test	Control
Condition of Extracts:	SC:	Clear	Clear
	SO:	Clear	Clear

Sample Disposition:	Any remaining samples will be discarded.

3. Test System

Test System

Species:	Rabbit (*Oryctolagus cuniculus*)
Breed:	New Zealand White
Source:	Myrtle's Rabbitry, Inc.
Sex:	Female
Body Weight Range:	3.0 kg to 3.8 kg at selection
Age:	Young adult
Acclimation Period:	Minimum 5 days
Number of Animals:	Two
Identification Method:	Ear tag

Justification of Test System

The intracutaneous injection test in rabbits is specified in the current ISO testing standards and has been used historically to evaluate biomaterial extracts.

4. Animal Management

Husbandry:	Conditions conformed to Standard Operating Procedures that are based on the "Guide for the Care and Use of Laboratory Animals."
Food:	A commercially available rabbit feed was provided daily.
Water:	Potable water was provided *ad libitum* through species appropriate water containers or delivered through an automatic watering system.
Contaminants:	Reasonably expected contaminants in feed or water supplies did not have the potential to influence the outcome of this test.
Housing:	Animals were individually housed in stainless steel suspended cages identified by a card indicating the lab number, animal number, test code, sex, and date dosed.
Environment:	The room temperature was monitored daily. The temperature range for the room was within a range of 61-72°F. The room humidity was monitored daily. The humidity range for the room was 30-70%. The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).
Accreditation:	NAMSA is an AAALAC International accredited facility and is registered with the United States Department of Agriculture. Additionally, NAMSA maintains an approved Animal Welfare Assurance on file with the National Institutes of Health, Office for Laboratory Animal Welfare.
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy, previously unused, thin-skinned animals free of mechanical irritation or trauma that could interfere with the test were selected.
Sedation, Analgesia or Anesthesia:	Sedation, analgesia or anesthesia was not necessary during the routine course of this procedure.
Veterinary Care:	No animal became injured, ill, or moribund during the course of this study. The study was given due consideration in any decision and the study sponsor was advised. No veterinary care was necessary.
IACUC:	This procedure has been approved by NAMSA Institutional Animal Care and Use Committees (IACUC), and is reviewed at least annually by the same committees. Any significant changes to this procedure were approved by the IACUC prior to conduct.

5. Method

Within a 4 to 18 hour period before treatment, each rabbit was clipped free of fur from the back and both sides of the spinal column to yield a sufficient injection area. Two rabbits were prepared per pair of extracts. A 0.2 ml dose of the appropriate test article extract was injected into five separate sites on the back of each rabbit. Similarly, the corresponding control was injected into the same rabbit. The appearance of each injection site was noted immediately after injection. The animals were returned to their respective cages following the procedure.

Observations for erythema and edema were conducted at 24, 48, and 72 hours after injection. Reactions were scored on a 0 to 4 basis. Any reaction at the injection sites was also noted. The reactions were evaluated according to the following subjective rating scale:

SCORE	ERYTHEMA (ER)	EDEMA (ED)
0	No erythema	No edema
1	Very slight erythema (barely perceptible)	Very slight edema (barely perceptible)
2	Well-defined erythema	Well-defined edema (edges of area well-defined by definite raising)
3	Moderate erythema	Moderate edema (raised approximately 1 mm)
4	Severe erythema (beet redness) to eschar formation preventing grading of erythema	Severe edema (raised more than 1 mm, and extending beyond exposure area)

6. Evaluation and Statistical Analysis

The mean erythema and edema scores for the test and control extracts for each animal at each scoring interval were calculated. All mean erythema and edema scores for the test and control extracts were totaled and divided by 12 (2 animals x 3 grading periods x 2 grading categories) to determine the overall mean score for the test extract and corresponding control. The difference between the overall mean score of the test and corresponding control extracts was calculated by subtracting the overall mean score for the control from the overall mean score for the test extract.

The requirements of the test were met if the difference between the test extract mean score and corresponding control mean score was 1.0 or less.

7. Results

All animals appeared normal throughout the study. Results of scores for individual rabbits appear in Appendix 1. All injection sites appeared normal immediately following injection. However, some animals showed some bruising at the injection site at 24, 48, and 72 hours after injection. During injection blood vessels are damaged, causing blood vessels to leak at the injection site. Therefore, a skin discoloration occurs (bruising). The overall mean difference for the extracts is summarized below:

Extract	Overall Test Group Mean	Overall Control Group Mean	Overall Mean Difference (Test – Control)
SC	0.0	0.0	0.0
SO	1.0	1.0	0.0

8. Conclusion

Under the conditions of this study, there was no erythema and no edema from the SC extract injected intracutaneously into rabbits. There was very slight to well-defined erythema and very slight edema from the SO extract injected intracutaneously into rabbits. The test article extracts met the requirements of the test since the difference between the test extracts and corresponding control mean score was 1.0 or less.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other samples is the sponsor's responsibility. All procedures were conducted in conformance with good manufacturing practices and certified to ISO 13485:2003.

9. Quality Assurance

Inspections were conducted at intervals adequate to assure the integrity of the study in conformance with 21 CFR 58.35(b)(3). The final report was reviewed for conformance to Section 58.185, Subpart J, of the GLP Regulations. A Statement of Quality Assurance Activities was issued with the report.

10. Proposed Dates

The study dates were finalized by the study director following receipt of the sponsor approved protocol and appropriate material for the study. Initiation of the study was the date on which the study director signed the GLP protocol. Projected dates for starting the study (first treatment) and for the completion of the study (final report release) were provided to the sponsor (or representative of the sponsor).

11. Records

All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSA archive files.

12. References

21 CFR 58 (GLP Regulations).

Guide for the Care and Use of Laboratory Animals, Institute for Laboratory Animal Research, National Academy of Sciences (Washington: National Academy Press, 1996).

ISO 10993-10 (2002) Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity.

OLAW, Public Health Service Policy on Humane Care and Use of Laboratory Animals.

United States Code of Federal Regulation (CFR) 9: The Animal Welfare Act.

USP 30 - NF 25 General Chapter <88> BIOLOGICAL REACTIVITY TESTS, IN VIVO.

13. Protocol Changes

Any necessary changes to the protocol after sponsor approval or study initiation were documented and approved by the study director as protocol amendments. Copies were distributed to the sponsor, the raw data file, and the NAMSA Quality Assurance department.

Appendix 1 - ISO Intracutaneous Observations

Rabbit Number/ Gender	Body Weight (kg)	Extract	Scoring Interval											
			24 Hours				48 Hours				72 Hours			
			Test		Control		Test		Control		Test		Control	
			ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED
84859 Female	3.8	SC	0	0	0	0	0	0	0	0	0	0	0	0
			0[1]	0[1]	0	0	0[1]	0[1]	0	0	0[1]	0[1]	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0[1]	0[1]	0	0	0[1]	0[1]	0	0	0[1]	0[1]	0	0
Mean Score			0.0	0.0	0.0	0.0	0.0	0.0	0.0	.0.0	0.0	0.0	0.0	0.0
84939 Female	3.0	SC	0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
Mean Score			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
84859 Female	3.8	SO	2	1	1	1	2	1	1	1	1	1	1	1
			1	1	1	1	1	1	1	1	1	1	1	1
			1	1	1	1	1	1	1	1	1	1	1	1
			1	1	1	1	1	1	1	1	1	1	1	1
			1	1	1	1	1	1	1	1	1	1	1	1
Mean Score			1.2	1.0	1.0	1.0	1.2	1.0	1.0	1.0	1.0	1.0	1.0	1.0
84939 Female	3.0	SO	1	1	1	1	1	1	1	1	1	1	1	1
			1	1	1	1	1	1	1	1	1	1	1	1
			1	1	1	1	1	1	1	1	1	1	1	1
			1	1	1	1	1	1	1	1	1	1	1	1
			1	1	1	1	1	1	1	1	1	1	1	1
Mean Score			1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0

[1]Bruising near the injection site. See Results.

ER = Erythema
ED = Edema

SC = 0.9% sodium chloride USP solution
SO = sesame oil, NF

Appendix 2 – Test Article Composition and Physical Description

Composition:	Silicone SORD active overmould assembly 274016, fibre-reinforced epoxy Shaft inner tube SORD 174045 and painted fibre-reinforced epoxy Shaft Outer Tube SORD 174023 are bonded to gold plated SORD Welded Return Assembly 274017 using Med2-4013 HTC adhesive and MED6-161 Primer. Tube Blue SORD is assembled onto wire of SORD Welded Return Assembly 274017 and thermoplastic elastomer Depth Stop SORD 174023 is inserted onto Shaft outer Tube SORD 174023.
Physical Description:	SORD Active Overmould 274016 (E017465, E017496), SORD Welded Return Assembly 274017 (E017437), Shaft Inner Tube SORD 174045 (E017105), Shaft Outer Tube SORD 174023 (E017693), Depth Stop SORD 174023 (E013955), Med2-4013 HTC Adhesive 080051 (G025803), Primer MED6-161 080052 (E017538) Tube Blue SORD 174049 (E017394)

Statement of Quality Assurance Activities

Phase Inspected	Auditor	Date
Dose	W. Wooten	November 6, 2007
Raw Data Approval	A.Yi	November 12, 2007
Final Report Review	W. Wooten	November 26, 2007

Reports to Management and Study Director(s)	Date
Periodic GLP Status Report	November 9, 2007

This study will be included in the next periodic status report as completed.

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: _____ 11-26-07
William Wooten, ASQ-CQA
Quality Assurance
Date

GLP REPORT

TEST FACILITY

NAMSA
9 Morgan
Irvine, CA 92618
949.951.3110

SPONSOR

Luke Gallagher
Gyrus Medical Limited
Fortran Road, St. Mellons
Cardiff, CF3 OLT
United Kingdom

CONFIDENTIAL

STUDY TITLE

ISO Maximization Sensitization Study - Extract

TEST ARTICLE NAME

SORD Outer Tube Assembly 274018-1 with fitted SORD Depth Stop 174024-3

TEST ARTICLE IDENTIFICATION

Lot: WO522791

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Summary

A guinea pig maximization test of SORD Outer Tube Assembly 274018-1 with fitted SORD Depth Stop 174024-3, Lot: WO522791, was conducted to evaluate the potential for delayed dermal contact sensitization. This study was conducted based on the requirements of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity.

The test article was extracted in 0.9% sodium chloride USP (SC) and sesame oil, NF (SO). Each extract was intradermally injected and occlusively patched to ten test guinea pigs (per extract) in an attempt to induce sensitization. The vehicle was similarly injected and occlusively patched to five control guinea pigs (per vehicle). Following a recovery period, the test and control animals received a challenge patch of the appropriate test article extract and the reagent control. All sites were scored at 24 and 48 hours after patch removal.

Under the conditions of this study, the SC and SO test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

Study and Supervisory Personnel:

Robert Villani, AALAS Certified
David Vergil
Thanh N. Nguyen, B.S.
Carlos Ramos
Jeffrey M. Kuhnlein, B.S.
Jesus Aceves
Angel Mandujano
Faustino Gomez
Benjamin Islas

Approved by: Marcia Mestre, B.S.
Study Director

12-13-07
Date Completed

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

nee

Statement of GLP Compliance

This study was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58).

There were no deviations from the protocol, standard operating procedures or the GLP Regulations which were judged to have had any significant impact on the validity or interpretation of the data.

All laboratory data has been accurately recorded and verified, as indicated by the signature below.

Study Director: Marcia Mestre, B.S. 12-13-07 Date

1. Introduction

Purpose
A guinea pig maximization test of the material identified below was conducted to evaluate the potential to cause delayed dermal contact sensitization. This study was conducted based on the requirements of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity.

Dates
The test article was received on October 3, 2007. Treatment began on November 5, 2007, and the observations were concluded December 1, 2007.

GLP Compliance
The study initiated by protocol signature on October 26, 2007, was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations, 21 CFR 58. A Statement of Quality Assurance Activities was issued with this report.

Duplication of Experimental Work
By signature on the protocol, the sponsor confirmed that the conduct of this study did not unnecessarily duplicate previous experiments.

2. Materials

The test article provided by the sponsor was identified and handled as follows:

Test Article Name:	SORD Outer Tube Assembly 274018-1 with fitted SORD Depth Stop 174024-3
Test Article Identification:	Lot: WO522791
Stability Testing:	In progress (per sponsor)
Expiration Date:	Stable for duration of intended testing (per sponsor)
Strength, Purity and Composition:	Strength: Not Applicable. Purity: Not Applicable. Samples sterilized by Ethylene Oxide (EO). Composition: See Appendix 1.
Physical Description of the Test Article:	See Appendix 1.
Storage Conditions:	Room Temperature
Vehicles:	0.9% sodium chloride USP solution (SC) Sesame oil, NF (SO)
Preparation:	Based on a ratio of 120 cm^2:20 ml, an 80 cm^2 portion of the test article was covered with 13 ml of the vehicle. The test article was extracted with manual agitations performed twice daily in SC and SO at 50°C for 72 hours. The vehicles (without test article) were similarly prepared to serve as the reagent control. The test article was extracted up to the 85mm markings.

Condition of Extracts:

	SC Test	SC Control
Induction I:	Clear	Clear
Induction II:	Clear	Clear
Challenge:	Clear	Clear

	SO Test	SO Control
Induction I:	Clear	Clear
Induction II:	Clear	Clear
Challenge:	Clear	Clear

Additional Materials: Freund's Complete Adjuvant (FCA) was mixed 50:50 (v/v) with the chosen vehicle and used at induction I. A 10% (w/w) sodium lauryl sulfate (SLS) suspension in petrolatum was used for induction II. These materials were provided by the test facility.

Sample Disposition: A representative portion of the test article and control will be retained at NAMSA (9 Morgan, Irvine CA 92618). Any remaining samples will be discarded.

3. Test System

Test System

Species:	Guinea pig (*Cavia porcellus*)
Strain:	Hla®:(HA)CVF®
Source:	Hilltop Lab Animals, Inc.
Sex:	Female (nulliparous)
Body Weight Range:	327 grams to 442 grams at study initiation
Age:	Young adult
Acclimation Period:	Minimum 5 days
Number of Animals:	Thirty
Identification Method:	Ear punch

Justification of Test System

The Hartley albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1970). The guinea pig is believed to be the most sensitive animal model for this type of study. The susceptibility of the Hartley guinea pig strain to a known sensitizing agent, 1-chloro-2,4-dinitrobenzene (DNCB), has been substantiated at NAMSA with this method under lab number 07C_36274_02 completed on July 8, 2007.

4. Animal Management

Husbandry: Conditions conformed to Standard Operating Procedures that are based on the "Guide for the Care and Use of Laboratory Animals."

Food: A commercially available guinea pig feed was provided daily.

Water: Potable water was provided *ad libitum* through species appropriate water containers or delivered through an automatic watering system.

Contaminants: Reasonably expected contaminants in feed or water supplies did not have the potential to influence the outcome of this test.

Housing: Animals were housed in groups in stainless steel suspended cages identified by a card indicating the lab number, animal numbers, test code, sex, animal code and first treatment date.

Environment: The room temperature was monitored daily. The temperature range for the room was within a range of 64-79°F.

The room humidity was monitored daily. The humidity range for the room was 25-70% (see Deviation).

The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).

Accreditation: NAMSA is an AAALAC International accredited facility and is registered with the United States Department of Agriculture. Additionally, NAMSA maintains an approved Animal Welfare Assurance on file with the National Institutes of Health, Office for Laboratory Animal Welfare.

Personnel: Associates involved were appropriately qualified and trained.

Selection: Only healthy, previously unused animals were selected.

Sedation, Analgesia or Anesthesia:	Sedation, analgesia or anesthesia was not necessary during the routine course of this procedure.
Veterinary Care:	No animal became injured, ill, or moribund during the course of this study. The study was given due consideration in any decision and the study sponsor was advised. No veterinary care was necessary.
IACUC:	This procedure has been approved by NAMSA Institutional Animal Care and Use Committees (IACUC), and is reviewed at least annually by the same committees. Any significant changes to this procedure were approved by the IACUC prior to conduct.

5. Method

On the first day of treatment, fifteen guinea pigs per extract (ten test, five control) were weighed and identified. The fur over the dorsoscapular region was removed with an electric clipper.

Induction I

The test animals were injected with the test article extract and the control animals were injected with the reagent control. Three rows of intradermal injections (two per row) were given to each animal within an approximate 2 cm x 4 cm boundary of the fur clipped area as illustrated below:

4 cm

2 cm

a.	a.
b.	b.
c.	c.

Control Animals:

a. 0.1 ml of 50:50 (v/v) mixture of FCA and the chosen vehicle
b. 0.1 ml of vehicle
c. 0.1 ml of a 1:1 mixture of the 50:50 (v/v) vehicle/FCA mixture and the vehicle

Test Animals:

a. 0.1 ml of 50:50 (v/v) mixture of FCA and the chosen vehicle
b. 0.1 ml of test extract
c. 0.1 ml of a 1:1 mixture of the 50:50 (v/v) vehicle/FCA mixture and the test extract

To minimize tissue sloughing the "a" and "c" injections were slightly deeper than "b". Site "c" was injected slightly more caudal than site "b".

Induction II

The day prior to conducting the Induction II patch, the fur over the dorsoscapular region (same area as used during induction I) was removed with an electric clipper and the area was treated with 0.5 to 1 gram of a 10% sodium lauryl sulfate (SLS) suspension in petrolatum. The SLS suspension, applied to provoke a mild acute inflammation, was massaged into the skin over the injection site. The area was left uncovered.

At 7 days (±1 day) after completion of the Induction I injection, any remaining SLS residue was gently removed with a gauze pad. A 2 cm x 4 cm section of filter paper, saturated with approximately 0.3 ml of freshly prepared test article extract, was then topically applied to the previously injected sites of the test animals. The control animals were similarly patched with the appropriate reagent control. Each patch was secured with a nonreactive tape and the trunk of each animal was wrapped with an elastic bandage. At 48 hours, the binders and patches were removed.

Challenge

At 14 days (±1 day) after unwrapping the Induction II wraps, the fur was removed from the sides and flank areas with an electric clipper. The nonwoven cotton disk contained in a Hill Top Chamber® was saturated with approximately 0.3 ml of the test article extract or reagent control. The test extract was applied to the right flank of each animal and the control vehicle was applied to the left flank of each animal. Each patch was secured to the skin with semiocclusive hypoallergenic adhesive tape. The trunk of each animal was wrapped with an elastic bandage to maintain well-occluded sites. At 24 hours, the wraps and patches were removed and any residue remaining at the sites was removed.

Laboratory Observations

1. Animals were observed daily for general health.
2. Body weights were recorded at pretreatment.
3. Observations for dermal reactions were conducted at 24 and 48 hours after challenge patch removal. Prior to each scoring interval, the sites were wiped with 35% isopropyl alcohol. If necessary, the fur was clipped from each site to facilitate scoring. Scores were recorded in accordance with the criteria shown below:

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

6. Evaluation and Statistical Analysis

The responses from the challenge phase were compared within the test animal group and between test and control conditions. Control conditions were (1) the vehicle control solution on the test animals and (2) the test extract, control solution and biomaterial (if applied) on the control animals.

In the final analysis of data, consideration was given to the overall pattern, intensity, duration and character of reactions of the test as compared to the control conditions. Statistical manipulation of data was not applicable to this study. Grades of 1 or greater in the test group generally indicated sensitization, provided that grades of less than 1 were observed on the control animals. If grades of 1 or greater were noted on control animals, then the reactions of test animals that exceeded the most severe control reaction were considered to be due to sensitization.

7. Results

Body Weights and Clinical Observations
Individual body weights are presented in Appendix 1. All animals appeared clinically normal throughout the study.

Dermal Observations
Individual results of dermal scoring for the challenge phase appear in Appendix 2. No evidence of sensitization was observed.

8. Deviation

During the study, the relative humidity in the animals' room fell below the required range of 30-70%. Routine animal examinations conducted by the attending veterinarian indicated that the animals appeared healthy and clinically normal. Daily animal health observations indicated that the animals appeared and behaved normal. No adverse effects were attributed to this low humidity.

9. Conclusion

Under the conditions of this study, the SC and SO test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other samples is the sponsor's responsibility. All procedures were conducted in conformance with good manufacturing practices, certified to ISO 13485:2003 and accredited to ISO 17025:2005.

10. Quality Assurance

Inspections were conducted at intervals adequate to assure the integrity of the study in conformance with 21 CFR 58.35(b)(3). The final report was reviewed for conformance to Section 58.185, Subpart J, of the GLP Regulations. A Statement of Quality Assurance Activities was issued with the report.

11. Proposed Dates

The study dates were finalized by the study director following receipt of the sponsor approved protocol and appropriate material for the study. Initiation of the study was the date on which the study director signed the GLP protocol. Projected dates for starting the study (first treatment) and for the completion of the study (final report release) were provided to the sponsor (or representative of the sponsor).

12. Records

All raw data pertaining to this study and a copy of the final report are retained in designated NAMSA archive files.

13. References

21 CFR 58 (GLP Regulations).

Guide for the Care and Use of Laboratory Animals, Institute for Laboratory Animal Research, National Academy of Sciences (Washington: National Academy Press, 1996).

ISO 10993-10 (2002) Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity.

Magnusson, B. and A. Kligman, *Allergic Contact Dermatitis in the Guinea Pig* (Springfield: C.H. Thomas, 1970).

OLAW, Public Health Service Policy on Humane Care and Use of Laboratory Animals (NIH Publication)

United States Code of Federal Regulation (CFR) 9: The Animal Welfare Act.

14. Protocol Changes

There were no changes to the protocol after sponsor approval or study initiation.

Appendix 1 - Individual Body Weights and Clinical Observations

SC Group

Group	Animal Number	Individual Observation	
		Pretreatment Body Weight (g)	Clinical Observations
Test	91	375	Appeared normal
	92	349	Appeared normal
	93	383	Appeared normal
	94	381	Appeared normal
	95	389	Appeared normal
	96	377	Appeared normal
	97	380	Appeared normal
	98	379	Appeared normal
	99	370	Appeared normal
	100	332	Appeared normal
Control	101	378	Appeared normal
	102	361	Appeared normal
	103	327	Appeared normal
	104	438	Appeared normal
	105	357	Appeared normal

Appendix 1 (continued) - Individual Body Weights and Clinical Observations

SO Group

Group	Animal Number	Individual Observation	
		Pretreatment Body Weight (g)	Clinical Observations
Test	106	338	Appeared normal
	107	348	Appeared normal
	108	346	Appeared normal
	109	340	Appeared normal
	110	341	Appeared normal
	111	370	Appeared normal
	112	350	Appeared normal
	113	343	Appeared normal
	114	348	Appeared normal
	115	393	Appeared normal
Control	116	438	Appeared normal
	117	442	Appeared normal
	118	428	Appeared normal
	119	424	Appeared normal
	120	394	Appeared normal

Appendix 2 - Dermal Reactions – Challenge

SC Group

Group	Animal Number	Hours Following Patch Removal			
		24 Hour Score		48 Hour Score	
		Control	Test Extract	Control	Test Extract
Test	91	0	0	0	0
	92	0	0	0	0
	93	0	0	0	0
	94	0	0	0	0
	95	0	0	0	0
	96	0	0	0	0
	97	0	0	0	0
	98	0	0	0	0
	99	0	0	0	0
	100	0	0	0	0
Control	101	0	0	0	0
	102	0	0	0	0
	103	0	0	0	0
	104	0	0	0	0
	105	0	0	0	0

Appendix 2 (continued) - Dermal Reactions – Challenge

SO Group

Group	Animal Number	Hours Following Patch Removal			
		24 Hour Score		48 Hour Score	
		Control	Test Extract	Control	Test Extract
Test	106	0	0	0	0
	107	0	0	0	0
	108	0	0	0	0
	109	0	0	0	0
	110	0	0	0	0
	111	0	0	0	0
	112	0	0	0	0
	113	0	0	0	0
	114	0	0	0	0
	115	0	0	0	0
Control	116	0	0	0	0
	117	0	0	0	0
	118	0	0	0	0
	119	0	0	0	0
	120	0	0	0	0

Appendix 3 - Test Article Composition and Physical Description

Composition:	Silicone SORD active overmould assembly 274016, fibre-reinforced epoxy Shaft inner tube SORD 174045 and painted fibre-reinforced epoxy Shaft Outer Tube SORD 174023 are bonded to gold plated SORD Welded Return Assembly 274017 using Med2-4013 HTC adhesive and MED6-161 Primer. Tube Blue SORD is assembled onto wire of SORD Welded Return Assembly 274017 and thermoplastic elastomer Depth Stop SORD 174023 is inserted onto Shaft outer Tube SORD 174023.
Physical Description:	SORD Active Overmould 274016 (E017465, E017496), SORD Welded Return Assembly 274017 (E017437), Shaft Inner Tube SORD 174045 (E017105), Shaft Outer Tube SORD 174023 (E017693), Depth Stop SORD 174023 (E013955), Med2-4013 HTC Adhesive 080051 (G025803), Primer MED6-161 080052 (E017538) Tube Blue SORD 174049 (E017394)

Statement of Quality Assurance Activities

Phase Inspected	Auditor	Date
Induction II	W. Wooten	November 12, 2007
Observation	A. Yi	November 21, 2007
Raw Data Approval	B. Admans	December 6, 2007
Final Report Review	A. Yi	December 13, 2007

Reports to Management and Study Director(s)	Date
Periodic GLP Status Report	November 9, 2007 December 10, 2007

This study will be included in the next periodic status report as completed.

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: _____ 12/17/07

Angela Yi
Quality Assurance

Date

Appendix 14.B

Terluran HD 15 Data
Cytotoxicity Study Using the ISO Elution Method,
NAMSA Report 05T_49333_01

USP and ISO Systemic Toxicity Study Extract,
NAMSA Report 05T_49333_02/03/04/05

USP Intracutaneous Study Extract,
NAMSA Report 05T_49333_06/07/08/09

USP Muscle Implantation Study – 5 Day,
NAMSA Report 05T_49333_12

STUDY TITLE:

CYTOTOXICITY STUDY USING THE ISO ELUTION METHOD

(1X MEM Extract)

TEST ARTICLE:

TERLURAN HD 15

TEST FACILITY:

NAMSA
6750 Wales Road
Northwood, OH 43619

SPONSOR:

Dr. Sabine Vogt
BASF Aktiengesellschaft
KS/KS-E100
Ludwigshafen, 67056
Germany

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SUMMARY

An *in vitro* biocompatibility study, based on the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity: *in vitro* Methods guidelines, was conducted on the test article, TERLURAN HD 15, to determine the potential for cytotoxicity A single extract of the test article was prepared using single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (1X MEM). This test extract was placed onto three separate confluent monolayers of L-929 mouse fibroblast cells propagated in 5% CO_2. Three separate monolayers were prepared for the reagent control, negative control and for the positive control. All monolayers were incubated at 37°C in the presence of 5% CO_2 for 48 hours. The monolayer in the test, reagent control, negative control and positive control wells was examined microscopically at 48 hours to determine any change in cell morphology.

Under the conditions of this study, the 1X MEM test extract showed no evidence of causing cell lysis or toxicity. The 1X MEM test extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity). The reagent control, negative control and the positive control performed as anticipated.

Study and Supervisory Personnel:

Shelly L. Smallman, BS
Jamie Szych
Anthony M. Jackson, BA
Christina L. Ovall, BA

Approved by: Amy L. Ebersole, B.A. Technical Reviewer — 9-1-05 Date Completed

/mdo

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INTRODUCTION

The test article identified below was extracted, and the extract was subjected to an *in vitro* cytotoxicity study for biocompatibility based on the requirements of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity: *in vitro* Methods. The test was performed to determine whether leachables extracted from the material would cause cytotoxicity. The test article was received on August 19, 2005. The cells were first exposed to the extract on August 26, 2005, and the observations were concluded on August 28, 2005.

MATERIALS

The sample provided by the sponsor was identified and handled as follows:

Test Article:	TERLURAN HD 15
Identification No.:	Not Supplied
Storage Conditions:	Room Temperature
Extraction Vehicle:	Single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (1X MEM)
Test Article Preparation:	Based on the USP ratio of 4 g:20 ml, a 2.0 g portion of the test article was covered with 10 ml of 1X MEM. A single preparation was extracted and agitated at 37°C for 24 hours.
Negative Control Preparation:	High density polyethylene was used as the negative control. Based on the USP ratio of 60 cm^2:20 ml, a single 30.8 cm^2 portion of the control material was covered with 10 ml of 1X MEM. The preparation was subjected to the extraction conditions previously described for the test article.
Reagent Control Preparation:	A single aliquot of 1X MEM without test material was subjected to the same extraction conditions as described for the test article.
Positive Control Preparation:	The current NAMSA positive control, tin stabilized polyvinylchloride, was used to determine a cytotoxic end-point. Based on the USP ratio of 60 cm^2:20 ml, a single 60.8 cm^2 portion of the control material was covered with 20 ml of 1X MEM and extracted and agitated at 37°C for 24 hours. Serial dilutions were prepared (1:2, 1:4, 1:8, 1:16, 1:32) for an end-point titration.
Condition of Extracts:	Test: clear Reagent Control: clear Negative Control: clear Positive Control (undiluted): clear

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METHODS

Test System Management:

L-929, mouse fibroblast cells, (ATCC CCL 1, NCTC Clone 929, of strain L, or equivalent source) were propagated and maintained in open wells containing single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (1X MEM) in a gaseous environment of 5% carbon dioxide (CO_2). For this study, 10 cm^2 wells were seeded, labeled with passage number and date, and incubated at 37°C in 5% CO_2 to obtain confluent monolayers of cells prior to use. Aseptic procedures were used in the handling of the cell cultures following approved NAMSA Standard Operating Procedures

Experimental Procedure:

Triplicate culture wells were selected which contained a confluent cell monolayer. The growth medium contained in triplicate cultures was replaced with 2 ml of the test extract. Similarly, triplicate cultures were replaced with 2 ml of the reagent control, negative control and the undiluted and each titer of the positive control. Each well was labeled with the corresponding lab number, replicate number, dilution (as applicable) and the dosing date. The wells were incubated at 37°C in 5% CO_2 for 48 hours.

Following incubation, the cultures were examined microscopically (100X) to evaluate cellular characteristics and percent lysis.

Evaluation Criteria:

The confluency of the monolayer was recorded as (+) if present and (-) if absent. In addition, the color of the test medium was observed and compared to the negative control medium A color shift toward yellow was associated with an acidic pH range and a color shift toward magenta to purple was associated with an alkaline pH range. Each culture well was evaluated for percent lysis and cellular characteristics using the following USP based criteria:

Grade	Reactivity	Observations	
0	None	Discrete intracytoplasmic granules	No lysis
1	Slight	Not more than 20% of the cells are round, loosely attached, and without intracytoplasmic granules	Not more than 20% lysis
2	Mild	Not more than 50% of the cells are round and devoid of intracytoplasmic granules	Not more than 50% lysis
3	Moderate	Not more than 70% of the cell monolayer contains rounded cells	Not more than 70% lysis
4	Severe	Nearly complete destruction of the cell monolayer	Greater than 70% lysis

For the test to be valid, the reagent control and the negative control must have had a reactivity of none (grade 0) and the positive control must have been a grade 3 or 4. The test sample met the requirements of the test if the biological response was less than or equal to grade 2 (mild). The test would have been repeated if the controls did not perform as anticipated and/or if all three test wells did not yield the same conclusion.

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RESULTS

See Table I for results.

pH Observation: The test medium was similar to the negative control medium at 48 hours.

Results and conclusions apply only to the test article tested. No further evaluation of these results is made by NAMSA. Any extrapolation of these data to other samples is the responsibility of the sponsor. All procedures were conducted in conformance with good laboratory practice and ISO 17025

CONCLUSION

Under the conditions of this study, the 1X MEM test extract showed no evidence of causing cell lysis or toxicity. The 1X MEM test extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity). The reagent control, negative control and the positive control performed as anticipated.

RECORD STORAGE

All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSA archive files for a period of 5 years.

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TABLE I

REACTIVITY GRADES FOR ELUTION TESTING

Well	Confluent Monolayer	Percent Rounding	Percent Cells Without Intracytoplasmic Granules	Percent Lysis	Grade	Reactivity
Test (1A)	(+)	0	0	0	0	None
Test (1B)	(+)	0	0	0	0	None
Test (1C)	(+)	0	0	0	0	None
Negative Control (1A)	(+)	0	0	0	0	None
Negative Control (1B)	(+)	0	0	0	0	None
Negative Control (1C)	(+)	0	0	0	0	None
Reagent Control (1A)	(+)	0	0	0	0	None
Reagent Control (1B)	(+)	0	0	0	0	None
Reagent Control (1C)	(+)	0	0	0	0	None
Positive Control (1A) 1:4 Dilution	(-)	70	70	70	3	Moderate
Positive Control (1B) 1:4 Dilution	(-)	70	70	70	3	Moderate
Positive Control (1C) 1:4 Dilution	(-)	70	70	70	3	Moderate

(+) = Present (-) = Absent

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3CC Raw Data

I mailed Nicole/MedNet to help get PO#. MJS 8-30-05

PO# Dr. Vogt MJS 8-30-05

05T_49333_01

Latest Start Date: Not Assigned

Customer ID: 20787
BASF Aktiengesellschaft

Lab Number: 05T_49333_01
Due Date: 9/1/2005 5:08:43 PM
Special Instr.:

Comments:

2 1X MEM
V0014_130 CYTOTOXICITY STUDY USING THE ISO ELUTION METHOD (EXTRACT)

DOSE PROCEDURE:

See Control ID (W_V0014_DOS): V082505-012 for corresponding control ids, lab numbers, and cell information.
Tech/Date: SLS 8-26-05

TEST ARTICLE PREPARATION: See Biomaterial Preparation Record

CULTURE PREPARATION:

NA A 50% concentration (1 part extract + 1 part 2X MEM) of the **SC/PW** test extract was prepared by mixing _____ ml of the **SC/PW** test extract with _____ ml of 2X MEM (lot no.:_____, exp. date:_____).
Tech/Date: SLS 8-26-05

2 ml of the test extract was added to three separate test wells and incubated at 37°C in a 5% CO_2 incubator for 48 hours.
Hood no.: 947 Incubator no.: 9164 Tech/Date/Time In: SLS 8-26-05 2:17 pm

RESULTS:

he contents of each well were examined microscopically (100X) and scored as indicated below.
Microscope no: 935

	Confluent Monolayer	Percent Rounding	Percent Cells Without Intracytoplasmic Granules	Percent Lysis	Grade	Reactivity
Test (1A)	(+)	0	0	0	(0) 1 2 3 4	none
Test (1B)	(+)	0	0	0	(0) 1 2 3 4	none
Test (1C)	(+)	0	0	0	(0) 1 2 3 4	none

N = None Sl = Slight Mi = Mild Mo = Moderate Se = Severe

pH Observation:
The test medium was **MORE ACIDIC THAN/MORE ALKALINE THAN/SIMILAR TO** the negative control medium at 48 hours.

Tech/Date/Time Scored: Ams 8-28-05 1:44 pm

CONCLUSION:

The test extract **SHOWED/SHOWED NO** evidence of causing **SLIGHT/MILD/MODERATE/SEVERE** cell lysis or toxicity.

The test extract **MET/DID NOT MEET** the requirements of the test since the grade was **LESS/GREATER** than a grade 2 (mild reactivity).

Tech/Date: Ams 8-28-05

COMPLETED 8-30-05 TECH SLS/JMS/AMJ APPROVED BY [signature]

NAMSA™ LABORATORIES:
866.666.9455 (phone toll free)

6750 Wales Road
Northwood, OH 43619-1011
419.662.4386 (fax)

9 Morgan
Irvine, CA 92618
949 951.3280 (fax)

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Sponsor (final report will be addressed and mailed to):	Send Invoice To:
Company Name: BASF Aktiengesellschaft	Company Name: BASF Aktiengesellschaft
Street Address: KS/KS – E 100	Address: KS/KS – E 100
City, State, Zip: 67056 Ludwigshafen, Germany	City, State, Zip 67056 Ludwigshafen, Germany
Attn: Dr. Sabine Vogt	Attn: Dr. Sabine Vogt
Phone: +49 621 60 49143	Phone: +49 621 60 49143
Fax: +49 621 60 93253	Fax: +49 621 60 93253
e-mail address: sabine.vogt@basf-ag.de	e-mail address: sabine.vogt@basf-ag.de

Check if you wish your test(s) to be conducted STAT: ☐ STAT (adds 50% of test fee or $100.00 minimum fee)

Purchase Order: PENDING LVM Aug 1905 Cost Estimate and Proposal Number:_____

Credit Card: Mastercard/Visa Card #/Card Holder Name:_____ Exp _____

Test Article Name (use EXACT wording desired on final report)*:

TERLURAN HD 15

Identification Number Batch/Code/Lot (circle one): NOT supplied 10-8-19-05

Storage Conditions: X Room Temperature; ☐Refrigeration; ☐Freezer; ☐Other_____

Physical description of test article (chemical/material type/color):_
Acrylonitrile/Butadiene/Styrene Copolymer (ABS)

Control article Submitted By Sponsor*: X No ☐Yes; Identification:_____

Identification Batch/Code/Lot (circle one):_____

Storage Conditions: ☐Room Temperature; ☐Refrigeration; ☐Freezer; ☐Other_____

***If your test or control article is a liquid, powder, or gel, the sponsor must submit a detailed description of the composition of the material and whether or not the sample is biologic, human tissue derived, or hazardous in nature. Please check the appropriate box below.**

- The above test article is not biologic, human tissue derived, or hazardous in nature.
- The above test article is a hazardous in nature. An MSDS sheet is required before testing can be initiated Please ensure an MSDS is submitted along with the test sample to expedite handling
- The above test article is biologic in nature or human tissue derived. A certificate stating the sample is viral and pathogen free (e.g., hepatitis, HIV) must be submitted along with the test article t

NOTE: Biologic or hazardous test articles require additional fees

T081905_012
FEDEX BASF AG

2-REV102102
CM
8-19-05

05T_49333

Perfor 20787_001 20787

	Test Code	Description of Test(s)	Extraction Variables* Temp.Time	Extraction Variables* Extracts
(b)	V0014-130	Cytotoxicity using the ISO	D	C K-[illegible]
(c)	TCLAS_V15	USP Class VI		
(b)	TU012-500	USP Systemic Toxicity	B	G A E D SC-per KDC 8-22-05 [illegible]
(b)	TU013-800	USP Intracutaneous Toxicity	B	G A E D SC-per KDC 8-22-05 [illegible]
(c)	TU014-805	USP Muscle Implantation		

*Extraction variables (insert letters on appropriate lines to the left).

Temp./Time	Extracts
A. 121°C/1 hour	A. Alcohol in Saline
B. 70°C/24 hours	B. Balanced Salt Solution
C. 50°C/72 hours	C 1X MEM
D. 37°C/24 hours	D. Vegetable Oil
E. 37°C/72 hours	E. Polyethylene Glycol

(c) = place on sub-rer until sterilization method & pressing temp are obtained by client 11-8-19-05

For EO Residual Tests Only: Date Test Article Sterilized:_____ Extraction Date Requested:_____

(b) = OK to Log in 11-8-19-05

For Implant, sterilize by (check on): ☐Steam ☐Submitted Sterile ☐EO (EO sterilization will incur an additional $350.00 fee per test article)

Reporting Service: NAMSA normally provides one original report. To obtain additional copies, originals, or electronic versions of reports, please check the appropriate box(es) below. Some of these options may incur additional fees.

x Fax Final Report
x Additional report copies Number of copies requested:____3____
[Duplicate original reports. Number of originals requested :_____ ($15.00 per report)
x Photocopies of raw data.
[Electronic report on CD Rom ($1.00 per page, minimum $15.00 per report)

Disposition of Test/Control Article: Remaining test/control articles are discarded upon completion of testing unless otherwise indicated below.

[Ship remaining test article to sponsor requested address
[Ship study-related tissues or specimens to requested destination
[Ship test article dilutions outside of NAMSA for concentration analysis or other formulation stability
[Ship test article to sterilizer

Courier:_____ Account:_____
Destination Requested:_____

Raw Data and Report Storage: All data including raw data, protocols, reports, and specimens will be archived for 5 years from completion of the final report. After the 5 year period has expired, these items will be destroyed unless specific instruction to return them to the sponsor is provided to NAMSA. Blocks and slides will be returned to the sponsor upon completion of the final report.

Special Instructions:_____ **Terluran HD 15 granulate is not sterilized** _____

Name of Principal Investigator (Sponsor):_____**Sabine Vogt**_____ **Title:**___**Dr.**_____

Signature:_____ **Date:**___15.08.2005_____

To be completed at NAMSA Test Facility

Technical Analyst/Specialist (GMP)_____ Date:_____

ORDER ENTRY CLIENT CONTACT FO

CLIENT: BAOP

LAB NUMBER: 05T_49333
20787_001 20787

DATE RECEIVED: 8-19-05

UNCLEAR/MISSING:

___ ATTN:
___ ADDRESS
___ DATE STERILIZED
___ EXTRACTION DATE
___ EXTRACTS
___ I.D. NUMBER
___ POSITIVE CONTROL

___ PO NUMBER
___ SAMPLES
___ SIGNATURE
___ TEST ARTICLE DESCRIPTION
___ TEST NAME
___ SAMPLE SUBMISSION
___ TIME/TEMPERATURE

DATE	TECH(S)	COMMENTS
8-19-05	bc	Called to verify method of sterilization
		and pressing temp for Implant of pellets
8-19-05	bc	Log in V14, T12, T13
		place class code: T14 on out-rev
		until sterilization process and press
		temp. for pellets are obtained from
		client

FORM_00042-01

Merle Heineke

From: Nicole Boehnisch [nicole.boehnisch@medneteurope.com]
Sent: Wednesday, August 31, 2005 4:07 AM
To: Merle Heineke
Subject: re: Pending PO

Merle, they do not use a PO number system. For her last order she stated "Dr. Vogt".
Please use this or use the testing date if your system needs a number.
Could you please let Customer Service know to use my email address for such requests, as David is not the right contact here. Usually he forwards such messages to me, but this one seems to have gotten lost.
Nicole

--- original message ---

> Nicole,
We have a cyto for BASF Aktiengesellschaft, Dr. Sabine Vogt. We need a PO# in order to release the report (due Sept 1). Customer Service has tried emailing the client and David but have not received a response (they didn't realize thatDavid was on Holiday).
Thanks - Merle <

STUDY TITLE:

USP AND ISO SYSTEMIC TOXICITY STUDY

EXTRACT

TEST ARTICLE:

TERLURAN HD 15

TEST FACILITY:

NAMSA
6750 Wales Road
Northwood, OH 43619

SPONSOR:

Dr. Sabine Vogt
BASF Aktiengesellschaft
KS/KS-E100
Ludwigshafen, 67056
Germany

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Lab No. 05T_49333_02
05T_49333_03
05T_49333_04
05T_49333_05

SUMMARY

The test article, TERLURAN HD 15, was extracted in 0.9% sodium chloride USP solution, alcohol in saline, polyethylene glycol, and sesame oil, NF. These extracts were evaluated for systemic toxicity in accordance wi guidelines of the current United States Pharmacopeia and the International Organization for Standardization 1(Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity (ISO)

A single dose of the appropriate test article extract was injected into each of five mice per extract by either the intravenous or intraperitoneal route. Similarly, five mice were dosed with each corresponding blank vehicle. animals were observed immediately and at 4, 24, 48, and 72 hours after systemic injection.

Under the conditions of this study, there was no mortality or evidence of systemic toxicity in the test mice fron extracts. One control mouse was found dead during the 24 hour observation. Each test article extract met the requirements.

Study and Supervisory Personnel:

Austin M. Zdawczyk, B.S.
Jamie M. Szych
Diane L. Miller
Jessica L. Peters
Nicole R. Chvala, B.I.S.
Amy L. Ebersole, B.A.

Approved by:

Christina L. Ovall, B.A.
Technical Reviewer

9-6-05
Date Completed

/pfk

INTRODUCTION

The test article identified below was extracted and the extracts were evaluated for biocompatibility in accordan with the guidelines of the current USP and ISO. The purpose of the study was to determine whether leachable: extracted from the material would cause acute systemic toxicity following injection into mice. The test article received on August 19, 2005. The animals were dosed on August 30, 2005, and the observations were conclud September 2, 2005.

MATERIALS

The sample provided by the sponsor was identified and handled as follows:

Test Article: TERLURAN HD 15

Identification No : Not Supplied

Storage Conditions: Room Temperature

Vehicles: 0.9% sodium chloride USP solution (SC)
alcohol in saline 1:20 solution (AS)
polyethylene glycol 400 (PEG)
sesame oil, NF (SO)

Preparation: Based on a USP ratio of 4 g:20 ml, a 4.0 g portion of the test article was cc with 20 ml of the vehicle. The test article was extracted in SC, AS, PEG, a SO at 70°C for 24 hours. The extraction vehicles without test article were similarly prepared to serve as control blanks. The PEG test extract and coı blank were diluted with SC after extraction to obtain 200 mg of PEG/ml.

Condition of Extracts:		Test	Control
	SC:	clear with particulates	clear
	AS:	clear with particulates	clear
	PEG:	clear with particulates	clear
	Diluted PEG:	clear	clear
	SO:	clear with particulates	clear

METHODS

Test System:

Species:	Mouse (*Mus musculus*)
Strain:	Crl:CF-1 BR
Source:	Charles River Laboratories
Sex:	Male
Body Weight Range:	19 grams to 23 grams at injection
Age:	Approximately 4 weeks of age at injection
Acclimation Period:	Minimum 1 day
Number of Animals:	Forty
Identification Method:	Ear punch

Justification of Test System:

Mice have historically been used to evaluate biomaterial extracts. The use of albino mice injected with a singl intravenous (IV) or intraperitoneal (IP) dose of test article extract or control blank has been suggested by the c USP and ISO standards for evaluation of medical plastics.

Animal Management:

Husbandry:	Conditions conformed to Standard Operating Procedures which are based on the "Guid the Care and Use of Laboratory Animals."
Food:	PROLAB® R-M-H 1000 Rodent Diet was provided daily.
Water:	Potable, municipal water was provided ad libitum through water bottles or delivered th an automatic watering system.
Contaminants:	Reasonably expected contaminants in feed or water supplies did not have the potential influence the outcome of this test.
Housing:	Animals were housed in groups of five in stainless steel suspended cages or polycarbor shoebox cages identified by a card indicating the lab number, animal numbers, test cod animal code and date dosed.
Environmental:	The room temperature was monitored daily. The temperature range for the room was v a range of 64-79°F.
	The room humidity was monitored daily. The humidity range for the room was 30-70%
	The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark)
Facility:	NAMSA is an AAALAC International accredited facility and is registered with the Un States Department of Agriculture. Additionally, NAMSA maintains an approved Anin Welfare Assurance on file with the National Institutes of Health, Office for Laboratory Animal Welfare.
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy, previously unused animals were selected.

Experimental Procedure:

Prior to dosing, the mice were identified and weighed. Five animals (per extract) were each injected with the t extract at a dose of 50 ml/kg (SC, AS, SO) or 10 g/kg (PEG). Five mice were similarly injected with the corresponding control The SC and AS were injected by the intravenous (IV) route while the PEG and SO wer injected by the intraperitoneal (IP) route. The animals were then returned to their cages.

Mice were observed for adverse reactions immediately after dosing, and at 4, 24, 48, and 72 hours. On day 3, t animals were weighed. Any animal found dead was subjected to a gross necropsy of the viscera.

Evaluations and Statistics:

If during the observation period, none of the mice treated with the individual test extract exhibited a significan greater reaction than the corresponding control mice, the test extract met the requirements. If two or more mic died, or if abnormal behavior such as convulsions or prostration occurred in two or more mice, or if body weig loss greater than 2 grams occurred in three or more mice, the test sample did not meet the test requirements.

RESULTS

Individual observations appear in Appendix 1.

Body Weight: Body weight data were acceptable

Mortality: There was no mortality in the test mice during the study. One control mouse was found dear durin 24 hour observation.

Clinical Observations: Animal number 15 of the control group was found dead at the 24 hour observations. T and control mice injected with AS appeared lethargic immediately after the injection; this was considered an expected pharmacological effect due to the alcohol content of the extract The test and control animals injecte SO appeared ungroomed at 4, 24 and 48 hours after dosing. The test and control animals injected with PEG appeared ungroomed at 4 hours after dosing. These observations were considered an expected effect due to th unctuous nature of the extracts. Otherwise, all animals appeared clinically normal throughout the study.

Results and conclusions apply only to the test article tested. No further evaluation of these results is made by NAMSA. Any extrapolation of these data to other samples is the responsibility of the sponsor. All procedure conducted in conformance with good laboratory practice and ISO 17025.

CONCLUSION

Under the conditions of this study, there was no mortality or evidence of systemic toxicity in the test mice fro extracts. One control mouse was found dead during the 24 hour observation. Each test article extract met the requirements.

RECORD STORAGE

All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSA ar files for a period of 5 years

APPENDIX I

SYSTEMIC TOXICITY OBSERVATIONS

MORTALITY AND BODY WEIGHT DATA:

	TEST EXTRACT				CONTROL BLANK			
Extract, Route and Dose	Animal Number	Weight (g) Day 0	Weight (g) Day 3	#Dead/ #Tested	Animal Number	Weight (g) Day 0	Weight (g) Day 3	#Dead/ #Tested
0.9% sodium chloride USP solution (SC) IV; 50 ml/kg	21	20	24	0/5	1	22	25	0/5
	22	20	22		2	22	25	
	23	21	25		3	23	25	
	24	20	23		4	21	25	
	25	20	25		5	21	25	
alcohol in saline 1:20 solution (AS) IV; 50 ml/kg	26	21	24	0/5	6	23	24	0/5
	27	21	23		7	22	24	
	28	22	24		8	23	24	
	29	20	22		9	21	25	
	30	19	23		10	22	26	
polyethylene glycol (PEG) IP; 10 g/kg	31	19	23	0/5	11	21	25	1/5
	32	20	25		12	22	22	
	33	20	24		13	22	23	
	34	20	24		14	21	25	
	35	18	24		15	20	*	
sesame oil, NF (SO) IP; 50 ml/kg	36	20	23	0/5	16	20	24	0/5
	37	20	25		17	20	24	
	38	20	23		18	22	26	
	39	19	24		19	20	26	
	40	20	25		20	21	26	

*Died at the 24 hour observations.

CLINICAL OBSERVATIONS:

	TEST EXTRACT				CONTROL BLANK			
	SC	AS	PEG	SO	SC	AS	PEG	S
Immediate	AN	L	AN	AN	AN	L	AN	A
4 Hours	AN	AN	U	U	AN	AN	U	U
24 Hours	AN	AN	AN	U	AN	AN	AN	U
48 Hours	AN	AN	AN	U	AN	AN	AN	U
72 Hours	AN	AN	AN	AN	AN	AN	AN	A

AN = Appeared Normal
L = Lethargic
U = Ungroomed
* This mouse was found dead at the 24 hour observations. Cause of death could not be determined.

Raw Data

05T_49333_02

Latest Start Date: 8/26/05 12:00 AM

Shared Ext

Customer ID: 20787
BASF Aktiengesellschaft

Lab Number: 05T_493
Due Date: 9/2
Special I

Comments:

2 0.9% SC
TU012_500 USP AND ISO SYSTEMIC TOXICITY STUDY - EXTRACT

CONTROL ID T083005-001

PREPARATION: See Biomaterial Extraction Record

Room No. 234 Animal Code 5084 Gender Male/Female

Supplier: Charles River Laboratories/Other: NA

Tech/Date: JLP 8-30-05

Vehicle: SC/AS/PEG/SO

Animal ID	Dose Volume and Bodyweight Data		
	Dose (ml)	Weight (g) Initial	Weight (g) Final
21	1.0	20	24
22	1.0	20	22
23	1.1	21	25
24	1.0	20	23
25	1.0	20	25
Tech/Date	NRC 8-30-05	NRC 8-30-05	JLP 9-2-05
	Balance ID	4158	4158

Dose calculations verified. Tech/Date: JLP 8-30-05

Interval	Clinical Observations				
	Immediate	4 Hour	24 Hour	48 Hour	72 Hour
Observation	An	An	An	An	An
Tech/Date	NRC 8-30-05	JLP 8-30-05	JLP 8-31-05	JLP 9-1-05	JLP 9-2-05
Time	12:23pm	4:26pm	12:09pm	12:07pm	11:58am

RESULTS: Passed/Failed/Required Retest Tech/Date: JLP 9-2-05

COMPLETED 9-2-05 TECH AMZ/OMS/PCM/JLP/NRC APPROVED BY AME pg 1-2

Numeric Footnote	Comment	Tech/Date

NA DLP 9-2-05

Shared E

05T_49333_03

Latest Start Date: 8/26/05 12:00 AM

Customer ID: 20787
BASF Aktiengesellschaft

Lab Number: 05T_493
Due Date: 9/2
Special I

Comments:

2 AS
TU012_500 USP AND ISO SYSTEMIC TOXICITY STUDY - EXTRACT

CONTROL ID T083005 - 003

PREPARATION: See Biomaterial Extraction Record

Room No 234 Animal Code 5084 Gender Male/Female

Supplier: Charles River Laboratories/Other: NA

Tech/Date: JLP 8-30-05

Vehicle: SC/AS/PEG/SO

	Dose Volume and Bodyweight Data		
	Dose	Weight (g)	
Animal ID	(ml)	Initial	Final
26	1.1	21	24
27	1.1	21	23
28	1.1	22	24
29	1.0	20	22
30	1.0	19	23
Tech/Date	NRC 8-30-05	NRC 8-30-05	JLP 9-2-05
	Balance ID	4158	4158

Dose calculations verified. Tech/Date: JLP 8-30-05

	Clinical Observations				
Interval	Immediate	4 Hour	24 Hour	48 Hour	72 Hour
Observation	L	An	An	An	An
Tech/Date	NRC 8-30-05	JLP 8-30-05	JLP 8-31-05	JLP 9-1-05	JLP 9-2-05
Time	12:25pm	4:27pm	12:10pm	12:07pm	12:01pm

RESULTS: Passed/Failed/Required Retest Tech/Date: JLP 9-2-05

COMPLETED 9-2-05 TECH AMZ/FMS/DLM/JLP/NRC APPROVED BY AHE pg 1-2

Numeric Footnote	Comment	Tech/Date
	NA JLD 9-2-05	

Shared Ext

05T_49333_04

Latest Start Date: 8/26/05 12:00 AM

Customer ID: 20787
BASF Aktiengesellschaft

Lab Number: 05T_4933
Due Date: 9/2
Special I

Comments:

2 PEG
TU012_500 USP AND ISO SYSTEMIC TOXICITY STUDY - EXTRACT

CONTROL ID T082405-011

PREPARATION: See Biomaterial Extraction Record (1)

Room No. 234 Animal Code 5084 Gender: Male/Female

Supplier: Charles River Laboratories/Other: NA

Tech/Date: JLP 8-30-05

Vehicle: SC/AS/PEG/SO

	Dose Volume and Bodyweight Data		
	Dose	Weight (g)	
Animal ID	(ml)	Initial	Final
31	1.0	19	23
32	1.0	20	25
33	1.0	20	24
34	1.0	20	24
35	0.9	18	24
Tech/Date	NRC 8-30-05	NRC 8-30-05	REB 9-2-05
	Balance ID	4156	4158

Dose calculations verified. Tech/Date: JLP 8-30-05

	Clinical Observations				
Interval	Immediate	4 Hour	24 Hour	48 Hour	72 Hour
Observation	An	U	An	An	AN
Tech/Date	NRC 8-30-05	JLP 8-30-05	JLP 8-31-05	JLP 9-1-05	REB 9-2-05
Time	12:27 pm	4:27 pm	12:10 pm	12:08 pm	12:07 pm

RESULTS: Passed/Failed/Required Retest Tech/Date: JLP 9-2-05

COMPLETED 9-2-05 TECH AMZ/DMS/DUM/JLP/NRC/REB APPROVED BY AME

Numeric Footnote	Comment	Tech/Date
1	SC lot # S-094-T-02	
	T12/T2S4: 8.2 ml SC + 1.8 ml PEG — Exp date 8-06	
	condition of diluted extract - clear	AMZ 8-30-0
	NA JLP 9-7-05	

05T_49333_05

Latest Start Date: 8/26/05 12:00 AM

Shared Ext

Customer ID: 20787
BASF Aktiengesellschaft

Lab Number: 05T_493
Due Date: 9/2
Special I

Comments:

2 SO
TU012_500 USP AND ISO SYSTEMIC TOXICITY STUDY - EXTRACT

CONTROL ID T083005-002

PREPARATION: See Biomaterial Extraction Record

Room No. 234 Animal Code ~~5084~~ ② 5084 Gender: Male/Female

Supplier: Charles River Laboratories/Other: NA

Tech/Date: JLP 8-30-05

Vehicle: SC/AS/PEG/SO

	Dose Volume and Bodyweight Data		
Animal ID	Dose (ml)	Weight (g) Initial	Final
36	1.0	~~18~~ 20	23
37	1.0	20	25
38	1.0	20	23
39	1.0	19	24
40	1.0	20	25
Tech/Date	NRC 8-30-05	NRC 8-30-05	REB ① 9-2-05
	Balance ID	4158	4158

Dose calculations verified. Tech/Date: JLP 8-30-05

	Clinical Observations				
Interval	Immediate	4 Hour	24 Hour	48 Hour	72 Hour
Observation	AN	U	U	U	AN
Tech/Date	NRC 8-30-05	JLP 8-30-05	JLP 8-31-05	JLP 9-1-05	REB 9-2-05
Time	12:29pm	4:27pm	12:11pm	12:08pm	12:07pm

RESULTS: Passed/Failed/Required Retest Tech/Date: JLP 9-2-05

COMPLETED 9-2-05 TECH AM2/JMG/DLM/JLP/NRC/REB APPROVED BY ALE pg 1-2

Numeric Footnote	Comment	Tech/Date
1	incorrect entry	NRC 8-30-05
2	To clarify number 5084	JLP 9-1-05
3	incorrect entry	REB 9-2-05
	NA JLP 9-2-05	

NAMSA™ LABORATORIES:
866.666.9455 (phone toll free)

6750 Wales Road
Northwood, OH 43619-1011
419.662.4386 (fax)

9 Morgan
Irvine, CA 92618
949.951.3280 (fax)

3400 Cobb Int'l Blvd
Kennesaw, GA 30152
770 426.5692 (fax)

NAMSA™ GMP SAMPLE SU

05T_49333
20787_001 20787

Sponsor (final report will be addressed and mailed to):
Company Name: BASF Aktiengesellschaft
Street Address: KS/KS – E 100
City, State, Zip: 67056 Ludwigshafen, Germany
Attn: Dr. Sabine Vogt
Phone: +49 621 60 49143
Fax: +49 621 60 93253
e-mail address: sabine.vogt@basf-ag.de

Send Invoice To:
Company Name: BASF Aktiengesellschaft
Address: KS/KS – E 100
City, State, Zip 67056 Ludwigshafen, Germany
Attn: Dr. Sabine Vogt
Phone: +49 621 60 49143
Fax: +49 621 60 93253
e-mail address: sabine.vogt@basf-ag.de

Check if you wish your test(s) to be conducted STAT: ☐ **STAT (adds 50% of test fee or $100.00 minimum fee)**

Purchase Order: PENDING LVM 10/19/05 **Cost Estimate and Proposal Number:**_____
Credit Card: Mastercard/Visa Card #/Card Holder Name:_____ Exp._____

Test Article Name (use EXACT wording desired on final report)*:

TERLURAN HD 15

Identification Number Batch/Code/Lot (circle one): Not supplied 10-8-19-05

Storage Conditions: X Room Temperature; ☐Refrigeration; ☐Freezer; ☐Other_____

Physical description of test article (chemical/material type/color):
Acrylonitrile/Butadiene/Styrene Copolymer (ABS)

Control article Submitted By Sponsor*: X No ☐Yes; Identification:_____

Identification Batch/Code/Lot (circle one):_____

Storage Conditions: ☐Room Temperature; ☐Refrigeration; ☐Freezer; ☐Other_____

***If your test or control article is a liquid, powder, or gel, the sponsor must submit a detailed description of the compositio the material and whether or not the sample is biologic, human tissue derived, or hazardous in nature. Please check the appropriate box below.**

☐ The above test article is not biologic, human tissue derived, or hazardous in nature.
☐ The above test article is a hazardous in nature. An MSDS sheet is required before testing can be initiated. Please ensure a MSDS is submitted along with the test sample to expedite handling.
☐ The above test article is biologic in nature or human tissue derived. A certificate stating the sample is viral and pathogen f (e g . hepatitis, HIV) must be submitted along with the test article t

NOTE: Biologic or hazardous test articles require additional fees

T081905_012

2-REVI

274

05T_49333

Perfor. 20787_001 20787

	Test Code	Description of Test(s)	Extraction Variables* Temp.Time	Extracts
(b)	V0014-130	Cytotoxicity using the ISO	D	C [illegible]
@	TCLAS_V15	USP Class VI		
(b)	TU012-500	USP Systemic Toxicity	B	G A E D
(b)	TU013-800	USP Intracutaneous Toxicity	B	G A E D
@	TU014-805	USP Muscle Implantation		

*Extraction variables (insert letters on appropriate to the left).

Temp./Time	Extracts
A. 121°C/1 hour	A. Alcohol in Saline
B. 70°C/24 hours	B. Balanced Salt Sol
C. 50°C/72 hours	C. 1X MEM
D. 37°C/24 hours	D. Vegetable Oil
E. 37°C/72 hours	E. Polyethylene Glyc

@ = place on sub_rer until sterilization method & pressing temp are obtained by client [illegible]

For EO Residual Tests Only: Date Test Article Sterilized:_____ Extraction Date Requested:_____

(b) = OK to Log in [illegible] 8-19-05

For Implant, sterilize by (check on): ☐Steam ☐Submitted Sterile ☐EO (EO sterilization will incur an additional $350.00 fee per test artic

Reporting Service: NAMSA normally provides one original report. To obtain additional copies, originals, or electronic version reports, please check the appropriate box(es) below. Some of these options may incur additional fees.

x Fax Final Report
x Additional report copies. Number of copies requested:____3____
[Duplicate original reports. Number of originals requested :_____ ($15.00 per report)
x Photocopies of raw data.
[Electronic report on CD Rom ($1.00 per page, minimum $15.00 per report)

Disposition of Test/Control Article: Remaining test/control articles are discarded upon completion of testing unless otherwise indicated below.

[Ship remaining test article to sponsor requested address
[Ship study-related tissues or specimens to requested destination
[Ship test article dilutions outside of NAMSA for concentration analysis or other formulation stability
[Ship test article to sterilizer

Courier:_____ Account:_____
Destination Requested:_____

Raw Data and Report Storage: All data including raw data, protocols, reports, and specimens will be archived for 5 years from completion of the final report. After the 5 year period has expired, these items will be destroyed unless specific instruction to ret them to the sponsor is provided to NAMSA. Blocks and slides will be returned to the sponsor upon completion of the final repor

Special Instructions:_____ **Terluran HD 15 granulate is not sterilized** _____

Name of Principal Investigator (Sponsor):_____**Sabine Vogt**_____ **Title:**___**Dr.**_____

Signature:_____ **Date:**___15.08.2005_____

To be completed at NAMSA Test Facility

Technical Analyst/Specialist (GMP)_____ Date_____

ORDER ENTRY CLIENT CONTACT FO

CLIENT: BAOP

LAB NUMBER: 05T_49333
20787_001 20787

DATE RECEIVED: 8-19-05

UNCLEAR/MISSING:

___ ATTN:
___ ADDRESS
___ DATE STERILIZED
___ EXTRACTION DATE
___ EXTRACTS
___ I.D. NUMBER
___ POSITIVE CONTROL

___ PO NUMBER
___ SAMPLES
___ SIGNATURE
___ TEST ARTICLE DESCRIPTION
___ TEST NAME
___ SAMPLE SUBMISSION
___ TIME/TEMPERATURE

DATE	TECH(S)	COMMENTS
8-19-05	bc	Called to verify method of sterilization
		and pressing temp for Implant of pellets
8-19-05	bc	Log in V14, T12, T13
		place class code: T14 on outer
		until sterilization process and press
		temp. for pellets are obtained from
		client

FORM_00042-01

erial Preparation Data and Pour and Deca Data
*********9/6/2005 5:32:55 PM T082205_02_ **********

Number	Param. List	Parameter	Dataset	ParamType	DisplayValue	DisplayUnits
_49333_02	Shared_Ext	Ext_to_be_Used	1	Standard	0.9% SC	
_49333_02	Shared_Ext	Tests_Shared_Witn	1	Standard	T13_06	
_49333_02	Shared_Ext	This_Test_Is	1	Standard	T12_02	

ified/Created by: JMS0789
********* END **********

:erial Preparation Data and Pour and Deca Data
**********9/6/2005 5:33:08 PM T082205_02 **********

) Number	Param. List	Parameter	Dataset	ParamType	DisplayValue	DisplayUnits
C_49333_03	Shared_Ext	Ext_to_be_Used	1	Standard	AS	
C_49333_03	Shared_Ext	Tests_Shared_With	1	Standard	T13_07	
C_49333_03	Shared_Ext	This_Test_Is	1	Standard	T12_03	

lified/Created by: JMS0789
********** END **********

:erial Preparation Data and Pour and Deca' Data
**********9/6/2005 5:33:20 PM T082205_02. **********

) Number	Param. List	Parameter	Dataset	ParamType	DisplayValue	DisplayUnits
[_49333_04	Shared_Ext	Ext_to_be_Used	1	Standard	PEG	
[_49333_04	Shared_Ext	Tests_Shared_With	1	Standard	T13_08	
[_49333_04	Shared_Ext	This_Test_Is	1	Standard	T12_04	

lified/Created by: JMS0789
********** END **********

:erial Preparation Data and Pour and Deca' Data
:*********9/6/2005 5:33:32 PM T082205_02U. :**********

) Number	Param. List	Parameter	Dataset	ParamType	DisplayValue	DisplayUnits
'_49333_05	Shared_Ext	Ext_to_be_Used	1	Standard	SO	
'_49333_05	Shared_Ext	Tests_Shared_With	1	Standard	T13_09	
'_49333_05	Shared_Ext	This_Test_Is	1	Standard	T12_05	

lified/Created by: JMS0789
:********* END **********

STUDY TITLE:

USP INTRACUTANEOUS STUDY

EXTRACT

TEST ARTICLE:

TERLURAN HD 15

TEST FACILITY:

NAMSA
6750 Wales Road
Northwood, OH 43619

SPONSOR:

Dr. Sabine Vogt
BASF Aktiengesellschaft
KS/KS-E100
Ludwigshafen, 67056
Germany

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Lab No. 05T_49333_06
05T_49333_07
05T_49333_08
05T_49333_09

SUMMARY

The test article, TERLURAN HD 15, was extracted in 0.9% sodium chloride USP solution, alcohol in saline, polyethylene glycol, and sesame oil, NF. These extracts were evaluated for intracutaneous toxicity in accorda with the guidelines of the current USP.

A 0.2 ml dose of the appropriate test article extract was injected by the intracutaneous route into five separate on the right side of the back of each rabbit. Similarly, the corresponding blank vehicle was injected on the lef of the back of each rabbit. Observations for erythema and edema were conducted at 24, 48, and 72 hours afte intracutaneous injection.

Under the conditions of this study, there was no evidence of significant irritation or toxicity from the extracts injected intracutaneously into rabbits. Each test article extract met the USP requirements.

Study and Supervisory Personnel:

Austin M. Zdawczyk, BS
Colleen M. Stevenson, AA
Nicole R. Chvala
Nicole J. Fragoso
Deedee M. Shoe, BA
Jamie M. Szych
Amy L. Ebersole, BA
Bryan M. Szych, BS
Diana L. Miller

Approved by: Debra S. Dunn, Technical Reviewer

9-6-05
Date Completed

/amd

INTRODUCTION

The test article identified below was extracted and the extracts were evaluated for biocompatibility in accordar with the guidelines of the current USP. The purpose of the study was to determine whether leachables extract from the material would cause local dermal irritant or toxic effects following injection into rabbit skin. The te article was received on August 19, 2005. The animals were injected on August 30, 2005, and the observations concluded on September 2, 2005.

MATERIALS

The sample provided by the sponsor was identified and handled as follows:

Test Article: TERLURAN HD 15

Identification No.: Not Supplied

Storage Conditions: Room Temperature

Vehicles:
0.9% sodium chloride USP solution (SC)
alcohol in saline 1:20 solution (AS)
polyethylene glycol 400 (PEG)
sesame oil, NF (SO)

Preparation: Based on a ratio of 4 g:20 ml, a 4.0 g portion of the test article was covere 20 ml of the vehicle. The test article was extracted and agitated in SC, AS PEG, and SO at 70°C for 24 hours. The extraction vehicles without test a were similarly prepared to serve as control blanks. The PEG test extract a control blank were diluted with SC after extraction to provide 120 mg of PEG/ml.

Condition of Extracts:

	Test	Control
SC:	clear with particulates	clear
AS:	clear with particulates	clear
PEG:	clear with particulates	clear
Diluted PEG:	clear	clear
SO:	clear with particulates	clear

METHODS

Test System:

Species:	Rabbit (*Oryctolagus cuniculus*)
Breed:	New Zealand White
Source:	Myrtle's Rabbitry, Inc.
Sex:	Male
Body Weight Range:	No particular body weight range was prescribed for this test
Age:	No particular age was prescribed for this test
Acclimation Period:	Minimum 5 days
Number of Animals:	Four
Identification Method:	Ear tag

Justification of Test System:

The intracutaneous injection test in rabbits is specified in the current USP and has been used historically to ev biomaterial extracts.

Animal Management:

Husbandry:	Conditions conformed to Standard Operating Procedures which are based on the "Guic the Care and Use of Laboratory Animals."
Food:	PROLAB® High Fiber Rabbit Diet was provided daily.
Water:	Provided *ad libitum* and delivered through an automatic watering system.
Contaminants:	Reasonably expected contaminants in feed or water supplies did not have the potential influence the outcome of this test.
Housing:	Animals were individually housed in stainless steel suspended cages identified by a ca indicating the lab number, animal number, test code, sex, and date dosed.
Environmental:	The room temperature was monitored daily. The temperature range for the room was a range of 61-72°F.
	The room humidity was monitored daily. The humidity range for the room was 30-70
	The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark
Facility:	NAMSA is an AAALAC International accredited facility and is registered with the Ur States Department of Agriculture. Additionally, NAMSA maintains an approved Ani Welfare Assurance on file with the National Institutes of Health, Office for Laborator Animal Welfare.
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Healthy, previously unused, thin-skinned animals free of mechanical irritation or traur could interfere with the test were selected.

Experimental Procedure:

Prior to treatment, each rabbit was clipped free of fur from the back and both sides of the spinal column to yie sufficient injection area. Two rabbits were prepared per pair of extracts. A 0.2 ml dose of test article extract v injected intracutaneously into five separate sites on the right side of the back of each rabbit; 0.2 ml of the cont blank was injected into five separate sites on the corresponding left side of the back. Injections were spaced approximately 2 cm apart. The animals were returned to their respective cages following the procedure.

Observations for erythema and edema were conducted at 24, 48, and 72 hours after injection. Reactions were on a 0 to 4 basis. Any reaction at the injection sites was also noted. The reactions were evaluated according t following subjective rating scale:

ERYTHEMA (ER)		EDEMA (ED)	
0	No erythema	0	No edema
1	Very slight (barely perceptible)	1	Very slight (barely perceptible)
2	Well-defined (pink)	2	Slight (edges of area well-defined by definite swelling)
3	Moderate to severe (red)	3	Moderate (raised approximately 1 mm)
4	Severe (beet redness) to slight eschar formation (injuries in depth)	4	Severe (raised more than 1 mm, may extend beyond the area of exposure)

The cumulative average erythema and edema score for each test extract and corresponding control blank was calculated. For each extract, a difference in average scores (test minus control blank) of 1.0 or less was consi to be acceptable. A difference of 0.6 to 1.0 indicated a slight, but acceptable, reaction. A difference >1.0 was considered to be unacceptable. Additionally, the average score for each test extract and blank was calculated each interval. Any adverse reaction noted in the test extract was compared to the corresponding blank.

RESULTS

All animals appeared clinically normal throughout the study. Results of scores for individual rabbits appear i Appendix 1. The findings are summarized below:

Extract	Average Test (-) Average Control = Difference = Assessment			
SC	0.0	0.0	0.0	Passed
SO	0.5	0.5	0.0	Passed
AS	0.0	0.0	0.0	Passed
PEG	0.2	0.3	0.0	Passed

The difference in average scores was considered acceptable. The difference between test and control average did not exceed 1.0 at any observation interval.

Results and conclusions apply only to the test article tested. No further evaluation of these results is made by NAMSA. Any extrapolation of these data to other samples is the responsibility of the sponsor. All procedur conducted in conformance with good laboratory practice and ISO 17025

CONCLUSION

Under the conditions of this study, there was no evidence of significant irritation or toxicity from the extracts injected intracutaneously into rabbits. Each test article extract met the USP requirements.

RECORD STORAGE

All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSA arc files for a period of 5 years.

APPENDIX 1

USP INTRACUTANEOUS OBSERVATIONS

Rabbit Number	Gender	Extract	Scoring Interval										
			24 Hours				48 Hours				72 Hours		
			Test		Control		Test		Control		Test		Con
			ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER
46157	Male	SC	0	0	0	0	0	0	0	0	0	0	0
46153	Male	SC	0	0	0	0	0	0	0	0	0	0	0
46157	Male	SO	1	0	1	0	1	0	1	0	1	0	1
46153	Male	SO	1	0	1	0	1	0	1	0	1	0	1
46162	Male	AS	0	0	0	0	0	0	0	0	0	0	0
46163	Male	AS	0	0	0	0	0	0	0	0	0	0	0
46163	Male	PEG	0	0	1	0	0	0	1	0	0	0	0
46162	Male	PEG	1	0	1	0	1	0	1	0	0	0	0

ER = Erythema
ED = Edema

SC = 0.9% sodium chloride USP solution
SO = sesame oil, NF
AS = alcohol in saline (1:20)
PEG = polyethylene glycol

05T_49333_08

Latest Start Date: 8/26/05 12:00 AM

Shared Extr

Customer ID: 20787
BASF Aktiengesellschaft

Lab Number: 05T_4933
Due Date: 9/2
Special I

Comments:

2 PEG
TU013_800 USP INTRACUTANEOUS STUDY - EXTRACT

PREPARATION: See Biomaterial Extraction Record (1)

Observation: All AN

Room No.: 211

Supplier: Myrtle's Rabbitry Inc./Other: NA

Fur Clip. Tech/Date: CMS / NJF 8-30-05

70% isopropyl alcohol lot no. L90202FR01 Intracutaneous Injections.

Tech/Date/Time NRC 8-30-05 2:36pm

			24 Hour				48 Hour				72 Hour			
			Test		Control		Test		Control		Test		Control	
Extract	Animal ID	Gender	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED
PEG	46163	♂	0	0	1	0	0	0	1	0	0	0	0	0
	46162	♂	1	0	1	0	1	0	1	0	0	0	0	0
		Observation	All An				All An				All An			
		Tech/Date	NRC 8-31-05				NRC 9-1-05				NRC 9-2-05			
		Time	3:32pm				3:34pm				3:27pm			
		35% IPA Lot No.	083005R01				083005R01				083005R01			

NA Previous use history traceable in laboratory records. Tech/Date: NJF 8-30-05

COMPLETED 9-6-05 TECH AMZ/JMS/CMS/NJF/NRC/DMS/BMS/DLM APPROVED BY AME pgs 1-2

Lab Number: 05T_4933

TU013_800 USP INTRACUTANEOUS STUDY - EXTRACT

	Test Average	Control Average	Difference
24 Hour	0.3	0.5	0.0
48 Hour	0.3	0.5	0.0
72 Hour	0.0	0.0	0.0
Overall	0.2	0.3	0.0
Tech/Date	DMS 9-2-05		

Calculations verified. Tech/Date: BMS 9-2-05

Results: Passed/Failed/Required Retest Tech/Date: DMS 9-2-05

Numeric Footnote	Comment	Tech/Date
1	SC lot #5-094-T-02	
	exp date 8-06	
	313/T251: 7.4 ml SC + 0.9ml PEG	
	condition of diluted test: clear	
	condition of diluted control: clear	AMZ 8-30-05

NA BMS 9-2-05

Raw Data

05T_49333_06

Latest Start Date: 8/26/05 12:00 AM

Shared Ext

Customer ID: 20787
BASF Aktiengesellschaft

Lab Number: 05T_4933
Due Date: 9/2
Special I

Comments:

2 0.9% SC
TU013_800 USP INTRACUTANEOUS STUDY - EXTRACT

PREPARATION: See Biomaterial Extraction Record

Observation: All AN

Room No.: 211

Supplier: Myrtle's Rabbitry Inc. Other: NA

Fur Clip. Tech/Date: CMS/NJF 8-30-05

70% isopropyl alcohol lot no. L90202FR01 Intracutaneous Injections.

Tech/Date/Time NRC 8-30-05 2:25pm

			24 Hour				48 Hour				72 Hour			
			Test		Control		Test		Control		Test		Control	
Extract	Animal ID	Gender	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED
SC	46157	♂	0	0	0	0	0	0	0	0	0	0	0	0
	46153	♂	0	0	0	0	0	0	0	0	0	0	0	0
Observation			All An				All An				All An			
Tech/Date			NRC 8-31-05				NRC 9-1-05				NRC 9-2-05			
Time			3:29pm				3:21pm				3:22pm			
35% IPA Lot No.			~~082~~ incorrect entry 083005R01				083005R01				083005R01			

NA Previous use history traceable in laboratory records. Tech/Date: NJF 8-30-05

COMPLETED 9-6-05 TECH AMZ/CMS/NRC/NJF/DMS/JMS/ APPROVED BY [signature] pg 1-2

Lab Number: 05T_493

TU013_800 USP INTRACUTANEOUS STUDY - EXTRACT

	Test Average	Control Average	Difference
24 Hour	1.0	0.0	0.0
48 Hour	0.0	0.0	0.0
72 Hour	0.0	0.0	0.0
Overall	0.0	0.0	0.0
Tech/Date	DMS 9-2-05		

Calculations verified. Tech/Date: BMS 9-2-05

Results: Passed/Failed/Required Retest Tech/Date: DMS 9-2-05

Numeric Footnote	Comment	Tech/Date
1	incorrect date.	MRS 9-1-05

NA BMS 9-2-05

Shared Exa

05T_49333_09

Latest Start Date: 8/26/05 12:00 AM

Customer ID: 20787
BASF Aktiengesellschaft

Lab Number: 05T_493
Due Date: 9/2
Special Instr

Comments:

2 SO
TU013_800 USP INTRACUTANEOUS STUDY - EXTRACT

PREPARATION: See Biomaterial Extraction Record

Observation: All AN

Room No.: 211

Supplier: Myrtle's Rabbitry Inc. Other: NA

Fur Clip. Tech/Date: CMS/NJF 8-30-05

70% isopropyl alcohol lot no. L90202FR01 Intracutaneous Injections.

Tech/Date/Time NRC 8-30-05 2:29pm

			24 Hour				48 Hour				72 Hour			
			Test		Control		Test		Control		Test		Control	
Extract	Animal ID	Gender	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED
SO	46157	♂	1	0	1	0	1	0	1	0	1	0	1	0
	46153	♂	1	0	1	0	1	0	1	0	1	0	1	0
Observation			All An				All An				All An			
Tech/Date			NRC 8-31-05				NRC 9-1-05				NRC 9-2-05			
Time			3:30pm				3:22pm				3:23pm			
35% IPA Lot No.			083005R01				083005R01				083005R01			

NA Previous use history traceable in laboratory records. Tech/Date: NJF 8-30-05

COMPLETED 9-6-05 TECH AM2/JMS/CMS/NJF/NRC/BMS/DMS/DLM APPROVED BY AME 8-1-2

Lab Number: 05T_4933

TU013_800 USP INTRACUTANEOUS STUDY - EXTRACT

	Test Average	Control Average	Difference
24 Hour	0.5	0.5	0.0
48 Hour	0.5	0.5	0.0
72 Hour	0.5	0.5	0.0
Overall	0.5	0.5	0.0
Tech/Date	DMS 9-2-05		

Calculations verified. Tech/Date: BMS 9-2-05

Results: Passed/Failed/Required Retest Tech/Date: DMS 9-2-05

Numeric Footnote	Comment	Tech/Date

NA BMS 9-2-05

For approval signature, completed date, and technician initials, see page 1

05T_49333_07

Latest Start Date: 8/26/05 12:00 AM

Shared Ext

Customer ID: 20787
BASF Aktiengesellschaft

Lab Number: 05T_4933
Due Date: 9/2/
Special I

Comments:

2 AS
TU013_800 USP INTRACUTANEOUS STUDY - EXTRACT

PREPARATION: See Biomaterial Extraction Record

Observation: All AN

Room No.: 211

Supplier: Myrtle's Rabbitry Inc/Other: NA

Fur Clip. Tech/Date: CMS / NJF 8-30-05

70% isopropyl alcohol lot no. L90202FR01 Intracutaneous Injections.

Tech/Date/Time nrc 8-30-05 2:33pm

			24 Hour				48 Hour				72 Hour			
			Test		Control		Test		Control		Test		Control	
Extract	Animal ID	Gender	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED
AS	46162	♂	0	0	0	0	0	0	0	0	0	0	0	0
	46163	♂	0	0	0	0	0	0	0	0	0	0	0	0
		Observation	All An				All An				All An			
		Tech/Date	nrc 8-31-05				nrc 9-1-05				nrc 9-2-05			
		Time	3:31pm				3:33pm				3:26pm			
		35% IPA Lot No.	083005R01				083005R01				083005R01			

NA Previous use history traceable in laboratory records. Tech/Date: NJF 8-30-05

COMPLETED 9-6-05 TECH AM2/DMS/CMS/NJF/NRC/BMS/DMS/DLM APPROVED BY ALE pg 1-2

Lab Number: 05T_4933

TU013_800 USP INTRACUTANEOUS STUDY - EXTRACT

	Test Average	Control Average	Difference
24 Hour	0.0	0.0	0.0
48 Hour	0.0	0.0	0.0
72 Hour	0.0	0.0	0.0
Overall	0.0	0.0	0.0
Tech/Date	DMS 9-2-05		

Calculations verified. Tech/Date: BMS 9-2-05

Results: Passed/Failed/Required Retest Tech/Date: DMS 9-2-05

Numeric Footnote	Comment	Tech/Date

NA BMS 9-2-05

For approval signature. completed date. and technician initials. see page 1

erial Preparation Data and Pour and Deca Data
*********9/6/2005 4:21:16 PM T082205_01 **********

Number	Param. List	Parameter	Dataset	ParamType	DisplayValue	DisplayUnits
_49333_06	ControlVehicleDecant	Comments	1	Decant	na	
_49333_06	ControlVehicleDecant	Condition_of_Ext	1	Standard	clear	
_49333_06	ControlVehicleDecant	Time_Out	1	Date	8/30/05 8:37 AM	
_49333_06	ControlVehiclePour	Comments	1	Pour	dlm/amz	
_49333_06	ControlVehiclePour	Equipment_ID	1	Standard	4534o	
_49333_06	ControlVehiclePour	Ext_Conditions	1	Standard	70°C/24 Hours	
_49333_06	ControlVehiclePour	Ext_Vehicle	1	Standard	0.9% SC	
_49333_06	ControlVehiclePour	Lot_No	1	Standard	5-094-T-02	
_49333_06	ControlVehiclePour	Time_In	1	Date	8/29/05 9:54 AM	
_49333_06	ControlVehiclePour	Volume_Poured	1	Standard	5	ml
_49333_06	Wt_Plastic_Ratio	Balance_ID	1	Standard	7390	
_49333_06	Wt_Plastic_Ratio	Ext_to_be_Used	1	Standard	0.9% SC	
_49333_06	Wt_Plastic_Ratio	Line_Clearance_Done	1	Standard	Previously conducted for this	
mission/Control ID during this prep session.						
_49333_06	Wt_Plastic_Ratio	Ext_Conditions	1	Standard	70°C/24 Hours	
_49333_06	Wt_Plastic_Ratio	Comments	1	Standard	N/A	
_49333_06	Wt_Plastic_Ratio	Number_Pieces_Used	1	Standard		
_49333_06	Wt_Plastic_Ratio	Sample_Subdivided	1	Standard	No	
_49333_06	Wt_Plastic_Ratio	ml_Vehicle _Needed	1	Standard	20	ml
_49333_06	Wt_Plastic_Ratio	Type_of_Container	1	Standard	Sterilized Borosilicate Glass	
_49333_06	Wt_Plastic_Ratio	Type_of_Agitation	1	Standard	Automated Agitation	
_49333_06	Wt_Plastic_Ratio	Total_Wt	1	Standard	4	g
_49333_06	Wt_Plastic_Ratio	Number_of_Pours	1	Standard	1	
_49333_06	Decant_Data	Comments	1	Standard	na	
_49333_06	Decant_Data	Condition_of_Ext	1	Standard	clear w/ particulates	
_49333_06	Decant_Data	Time_Out	1	Date	8/30/05 8:37 AM	
_49333_06	Pour_Data	Comments	1	Standard	na	
_49333_06	Pour_Data	Equipment_ID	1	Standard	4534o	
_49333_06	Pour_Data	Ext_Conditions	1	Standard	70°C/24 Hours	
_49333_06	Pour_Data	Ext_Vehicle	1	Standard	0.9% SC	
_49333_06	Pour_Data	Lot_No	1	Standard	5-094-T-02	
_49333_06	Pour_Data	Time_In	1	Date	8/29/05 9:54 AM	
_49333_06	Pour_Data	Volume_Poured	1	Standard	20	ml

lified/Created by: AMZ0849, JMS0789
********* END **********

.erial Preparation Data and Pour and Deca- Data
*********9/6/2005 4:21:30 PM T082205_01 **********

Number	Param. List	Parameter	Dataset	ParamType	DisplayValue	DisplayUnits
_49333_07	ControlVehicleDecant	Comments	1	Decant	na	
_49333_07	ControlVehicleDecant	Condition_of_Ext	1	Standard	clear	
_49333_07	ControlVehicleDecant	Time_Out	1	Date	8/30/05 8:37 AM	
_49333_07	ControlVehiclePour	Comments	1	Pour	dlm/amz	
_49333_07	ControlVehiclePour	Equipment_ID	1	Standard	4534o	
_49333_07	ControlVehiclePour	Ext_Conditions	1	Standard	70°C/24 Hours	
_49333_07	ControlVehiclePour	Ext_Vehicle	1	Standard	AS	
_49333_07	ControlVehiclePour	Lot_No	1	Standard	05T-40122-01	
_49333_07	ControlVehiclePour	Time_In	1	Date	8/29/05 9:54 AM	
_49333_07	ControlVehiclePour	Volume_Poured	1	Standard	5	ml
_49333_07	Wt_Plastic_Ratio	Balance_ID	1	Standard	7390	
_49333_07	Wt_Plastic_Ratio	Ext_to_be_Used	1	Standard	AS	
_49333_07	Wt_Plastic_Ratio	Line_Clearance_Done	1	Standard	Previously conducted for this	
omission/Control ID during this prep session.						
_49333_07	Wt_Plastic_Ratio	Ext_Conditions	1	Standard	70°C/24 Hours	
_49333_07	Wt_Plastic_Ratio	Comments	1	Standard	N/A	
_49333_07	Wt_Plastic_Ratio	Number_Pieces_Used	1	Standard		
_49333_07	Wt_Plastic_Ratio	Sample_Subdivided	1	Standard	No	
_49333_07	Wt_Plastic_Ratio	ml_Vehicle _Needed	1	Standard	20	ml
_49333_07	Wt_Plastic_Ratio	Type_of_Container	1	Standard	Sterilized Borosilicate Glass	
_49333_07	Wt_Plastic_Ratio	Type_of_Agitation	1	Standard	Automated Agitation	
_49333_07	Wt_Plastic_Ratio	Total_Wt	1	Standard	4	g
_49333_07	Wt_Plastic_Ratio	Number_of_Pours	1	Standard	1	
_49333_07	Decant_Data	Comments	1	Standard	na	
_49333_07	Decant_Data	Condition_of_Ext	1	Standard	clear w/ particulates	
_49333_07	Decant_Data	Time_Out	1	Date	8/30/05 8:37 AM	
_49333_07	Pour_Data	Comments	1	Standard	na	
_49333_07	Pour_Data	Equipment_ID	1	Standard	4534o	
_49333_07	Pour_Data	Ext_Conditions	1	Standard	70°C/24 Hours	
_49333_07	Pour_Data	Ext_Vehicle	1	Standard	AS	
_49333_07	Pour_Data	Lot_No	1	Standard	05T-40122-01	
_49333_07	Pour_Data	Time_In	1	Date	8/29/05 9:54 AM	
_49333_07	Pour_Data	Volume_Poured	1	Standard	20	ml

lified/Created by: AMZ0849. JMS0789
********* END **********

.erial Preparation Data and Pour and Deca' Data
*********9/6/2005 4:21:43 PM T082205_01 **********

Number	Param. List	Parameter	Dataset	ParamType	DisplayValue	DisplayUnits
_49333_08	ControlVehicleDecant	Comments	1	Decant	see raw data for dilution	
_49333_08	ControlVehicleDecant	Condition_of_Ext	1	Standard	clear	
_49333_08	ControlVehicleDecant	Time_Out	1	Date	8/30/05 8:37 AM	
_49333_08	ControlVehiclePour	Comments	1	Pour	dlm/amz	
_49333_08	ControlVehiclePour	Equipment_ID	1	Standard	4534o	
_49333_08	ControlVehiclePour	Ext_Conditions	1	Standard	70°C/24 Hours	
_49333_08	ControlVehiclePour	Ext_Vehicle	1	Standard	PEG	
_49333_08	ControlVehiclePour	Lot_No	1	Standard	a34582	
_49333_08	ControlVehiclePour	Time_In	1	Date	8/29/05 9:54 AM	
_49333_08	ControlVehiclePour	Volume_Poured	1	Standard	5	ml
_49333_08	Wt_Plastic_Ratio	Balance_ID	1	Standard	7390	
_49333_08	Wt_Plastic_Ratio	Comments	1	Standard	N/A	
_49333_08	Wt_Plastic_Ratio	Ext_to_be_Used	1	Standard	PEG	
_49333_08	Wt_Plastic_Ratio	Number_Pieces_Used	1	Standard		
_49333_08	Wt_Plastic_Ratio	Sample_Subdivided	1	Standard	No	
_49333_08	Wt_Plastic_Ratio	Total_Wt	1	Standard	4	g
_49333_08	Wt_Plastic_Ratio	Number_of_Pours	1	Standard	1	
_49333_08	Wt_Plastic_Ratio	Line_Clearance_Done	1	Standard	Previously conducted for this	
omission/Control ID during this prep session.						
_49333_08	Wt_Plastic_Ratio	Ext_Conditions	1	Standard	70°C/24 Hours	
_49333_08	Wt_Plastic_Ratio	Type_of_Agitation	1	Standard	Automated Agitation	
_49333_08	Wt_Plastic_Ratio	ml_Vehicle _Needed	1	Standard	20	ml
_49333_08	Wt_Plastic_Ratio	Type_of_Container	1	Standard	Sterilized Borosilicate Glass	
_49333_08	Pour_Data	Comments	1	Standard	na	
_49333_08	Pour_Data	Equipment_ID	1	Standard	4534o	
_49333_08	Pour_Data	Ext_Conditions	1	Standard	70°C/24 Hours	
_49333_08	Pour_Data	Lot_No	1	Standard	a34582	
_49333_08	Pour_Data	Volume_Poured	1	Standard	20	ml
_49333_08	Pour_Data	Time_In	1	Date	8/29/05 9:54 AM	
_49333_08	Pour_Data	Ext_Vehicle	1	Standard	PEG	
_49333_08	Decant_Data	Comments	1	Standard	see raw data for dilution	
_49333_08	Decant_Data	Condition_of_Ext	1	Standard	clear w/ particulates	
_49333_08	Decant_Data	Time_Out	1	Date	8/30/05 8:37 AM	

lified/Created by: AMZ0849, JMS0789
********** END **********

erial Preparation Data and Pour and Deca Data
*********9/6/2005 4:21:56 PM T082205_01. **********

Number	Param. List	Parameter	Dataset	ParamType	DisplayValue	DisplayUnits
_49333_09	ControlVeniclePour	Comments	1	Pour	dlm/amz	
_49333_09	ControlVehiclePour	Equipment_ID	1	Standard	4534o	
_49333_09	ControlVehiclePour	Ext_Vehicle	1	Standard	SO	
_49333_09	ControlVehiclePour	Ext_Conditions	1	Standard	70°C/24 Hours	
_49333_09	ControlVehiclePour	Lot_No	1	Standard	5-181-T-03	
_49333_09	ControlVeniclePour	Volume_Poured	1	Standard	5	ml
_49333_09	ControlVehiclePour	Time_In	1	Date	8/29/05 9:54 AM	
_49333_09	ControlVehicleDecant	Comments	1	Decant	na	
_49333_09	ControlVehicleDecant	Condition_of_Ext	1	Standard	clear	
_49333_09	ControlVehicleDecant	Time_Out	1	Date	8/30/05 8:37 AM	
_49333_09	Wt_Plastic_Ratio	Balance_ID	1	Standard	7390	
_49333_09	Wt_Plastic_Ratio	Comments	1	Standard	N/A	
_49333_09	Wt_Plastic_Ratio	Ext_to_be_Used	1	Standard	SO	
_49333_09	Wt_Plastic_Ratio	Number_Pieces_Used	1	Standard		
_49333_09	Wt_Plastic_Ratio	Sample_Subdivided	1	Standard	No	
_49333_09	Wt_Plastic_Ratio	Type_of_Agitation	1	Standard	Automated Agitation	
_49333_09	Wt_Plastic_Ratio	ml_Vehicle _Needed	1	Standard	20	ml
_49333_09	Wt_Plastic_Ratio	Type_of_Container	1	Standard	Sterilized Borosilicate Glass	
_49333_09	Wt_Plastic_Ratio	Total_Wt	1	Standard	4	g
_49333_09	Wt_Plastic_Ratio	Number_of_Pours	1	Standard	1	
_49333_09	Wt_Plastic_Ratio	Line_Clearance_Done	1	Standard	Yes	
_49333_09	Wt_Plastic_Ratio	Ext_Conditions	1	Standard	70°C/24 Hours	
_49333_09	Pour_Data	Comments	1	Standard	na	
_49333_09	Pour_Data	Equipment_ID	1	Standard	4534o	
_49333_09	Pour_Data	Ext_Conditions	1	Standard	70°C/24 Hours	
_49333_09	Pour_Data	Lot_No	1	Standard	5-181-T-03	
_49333_09	Pour_Data	Volume_Poured	1	Standard	20	ml
_49333_09	Pour_Data	Time_In	1	Date	8/29/05 9:54 AM	
_49333_09	Pour_Data	Ext_Vehicle	1	Standard	SO	
_49333_09	Decant_Data	Comments	1	Standard	na	
_49333_09	Decant_Data	Condition_of_Ext	1	Standard	clear w/ particulates	
_49333_09	Decant_Data	Time_Out	1	Date	8/30/05 8:37 AM	

lified/Created by: AMZ0849, JMS0789
********** END **********

STUDY TITLE:

USP MUSCLE IMPLANTATION STUDY

5 DAY

TEST ARTICLE:

TERLURAN HD 15

TEST FACILITY:

NAMSA
6750 Wales Road
Northwood, OH 43619

SPONSOR:

Dr. Sabine Vogt
BASF Aktiengesellschaft
KS/KS-E100
Ludwigshafen, 67056
Germany

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SUMMARY

The test article, TERLURAN HD 15, was implanted in muscle tissue of the rabbit. The muscle tissue was eva for evidence of irritation or toxicity in accordance with the guidelines of the current USP.

Implant samples and negative control samples were sterilized by ethylene oxide and then degassed for 5 days. Rabbits were implanted and were then euthanized 5 days later. Muscle tissues were excised and the implant si were examined macroscopically.

Under the conditions of this study, the macroscopic reaction was not significant as compared to the negative c implant material. The implanted test article met the USP requirements.

Study and Supervisory Personnel:

Megan L. Shea
Melva Fix
Christine M. Szych, RVT, ALAT
Mark J. Menzel, RVT
Jamie M. Szych
Tiffany M. Volkman, RVT
Deedee M. Shoe, BA
Debra S. Dunn

Approved by: Amy L. Ebersole, BA
Technical Reviewer

9-15-05
Date Completed

/amd

INTRODUCTION

The test article identified below was evaluated for biocompatibility in accordance with the guidelines of the cu USP. The purpose of the study was to evaluate the potential for a local irritant or toxic response to material implanted in direct contact with muscle tissue. The test article was received on August 19, 2005. The animals implanted on September 7, 2005, and muscles were explanted on September 12, 2005.

MATERIALS

The sample provided by the sponsor was identified and handled as follows:

Test Article:	TERLURAN HD 15
Identification No.:	Not Supplied
Storage Conditions:	Room Temperature
Negative Control Article:	USP polyethylene negative reference strips were purchased by NAMSA fi the offices of the US Pharmacopeial Convention and were cut into approx 1 mm x 10 mm sections.
Preparation:	The test article was pressed into a sheet using a heat press and cut into approximate 1mm x 10 mm sections were loaded into 14 gauge needles. I each rabbit, a minimum of four negative control samples were loaded into same size needles as used for the test article. Test and control articles wei sterilized by ethylene oxide gas (EO) and then degassed for 5 days prior t implantation

METHODS

Test System:

Species:	Rabbit (*Oryctolagus cuniculus*)
Breed:	New Zealand White
Source:	Myrtle's Rabbitry, Inc.
Sex:	Female
Body Weight Range:	3.6 kg at implantation
Age:	No particular age was prescribed for this test
Acclimation Period:	Minimum 5 days
Number of Animals:	Two
Identification Method:	Ear tag

Justification of Test System:

The rabbit is suggested as an appropriate animal model for evaluating polymer materials by the current USP t guidelines. The muscle tissue has been used historically because the response to implanted material is easily and compared to a known negative control material.

Water: Provided *ad libitum* and delivered through an automatic watering system.

Contaminants: Reasonably expected contaminants in feed or water supplies did not have the potential influence the outcome of this test.

Housing: Animals were individually housed in stainless steel suspended cages identified by a ca indicating the lab number, animal number, test code, sex, and date implanted.

Environmental: The room temperature was monitored daily. The temperature range for the room was a range of 61-72°F.

The room humidity was monitored daily. The humidity range for the room was 30-70

The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark)

Facility: NAMSA is an AAALAC International accredited facility and is registered with the Un States Department of Agriculture. Additionally, NAMSA maintains an approved Anin Welfare Assurance on file with the National Institutes of Health, Office for Laboratory Animal Welfare.

Personnel: Associates involved were appropriately qualified and trained.

Selection: Healthy, previously unused animals were selected.

Experimental Procedure:

Rabbits were clipped free of fur over the paravertebral muscles. An intramuscular injection of a combination ketamine hydrochloride and xylazine general anesthetic was administered to each animal at a dose of 0.6 ml/k Each rabbit was then injected subcutaneously with 0.02 mg/kg buprenorphine. After the anesthetic had taken the back was scrubbed with a germicidal soap, wiped with 70% isopropyl alcohol and the surgical site was pa with an antiseptic solution.

One incision was made on each side of the back through the skin and parallel to the lumbar region of the verte column. A stylet was placed in the hub of a loaded needle. The skin was moved to the desired location and th needle was inserted through the incision into the muscle at a 45° angle. The needle was withdrawn over the st leaving the sample in the paravertebral muscle. Six test article sections were implanted in the right paraverteb muscle of each rabbit. In the opposite muscle, four negative control sections were similarly implanted. The s were placed at appropriately spaced intervals. The skin was closed with tissue glue. The rabbits were returned their respective cages and monitored for recovery from the anesthetic. The following day, a second dose of 0.02 mg/kg buprenorphine was injected subcutaneously into each rabbit.

Rabbits were observed daily for general health. Body weights were recorded prior to implantation and at termination.

At 5 days, the rabbits were euthanized by an intravenous injection of a sodium pentobarbital based drug. The paravertebral muscles were dissected free and methodically cut to locate four test article sites and two negativ control sites in each rabbit. Capsule formation or other evidence of irritation was scored using low magnificat and the scores were recorded as follows:

0 No capsule, no adverse reaction (other than minimal hemorrhage)
1 Up to 0.5 mm capsule or reaction area
2 0.6 to 1.0 mm capsule or reaction area
3 1.1 to 2.0 mm capsule or reaction area
4 >2.0 mm capsule or reaction area

Evaluations and Statistics:

The average macroscopic score for test implants was compared with the average score of the control sites. Calculations were rounded off to the nearest 0.1. A Reaction Index difference of 0.0 to 0.5 in scores (test min control) was regarded as "not significant," 0.6 to 1.0 as a "trace," 1.1 to 2.0 as "slight," 2.1 to 3.0 as "moderate ≥3.1 as "marked." The requirements of the USP test were met if the difference between test and control score averages was not greater than 1.0. The requirements of the test were not met if the difference between the tesi control score for two (or more) implant sites exceeded 1 for any animal implanted.

RESULTS

Clinical Observations: All animals appeared clinically normal throughout the duration of the study. Body we data for individual rabbits were considered acceptable

Macroscopic Observations: There was no visible reaction at any test or control site. This resulted in a macro: reaction of "not significant" tissue contact irritation. The findings for the macroscopic evaluation are shown i Appendix I.

Results and conclusions apply only to the test article tested. No further evaluation of these results is made by NAMSA. Any extrapolation of these data to other samples is the responsibility of the sponsor. All procedure conducted in conformance with good laboratory practice and ISO 17025.

CONCLUSION

Under the conditions of this study, the macroscopic reaction was not significant as compared to the negative c implant material. The implanted test article met the USP requirements.

RECORD STORAGE

All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSA ar files for a period of 5 years.

APPENDIX 1

BODY WEIGHTS AND MACROSCOPIC OBSERVATIONS

Rabbit Number/ Gender	Weight (kg)		Test	Negative Control
	Day 0	Day 5		
46036 Female	3.6	3.5	0 0 1 0	0 0
46033 Female	3.6	3.6	0 0 0 0	0 0
		Average:	0.1	0.0

Gyrus ACMI PKS Plasma Morcellator

510(K) PREMARKET NOTIFICATION

SECTION 15.0: SOFTWARE INFORMATION

Gyrus ACMI, Inc.
SOUTHBOROUGH, MA

15.0 Software Information

The Gyrus ACMI PKS Plasma Morcellator itself contains no software. The Gyrus SuperPulse and Gyrus General Surgery Workstation Generators have the ability to recognize a device that is plugged into it, and setting the default power outputs. Other than enabling that feature of software to recognize the PKS Plasma Morcellator, no other changes to the Generator software are anticipated.

Gyrus ACMI PKS Plasma Morcellator

510(K) PREMARKET NOTIFICATION

SECTION 16.0: ELECTRICAL SAFETY AND ELECTROMAGNETIC INTERFERENCE

Gyrus ACMI, Inc.
SOUTHBOROUGH, MA

16.0 Electrical Safety and Electromagnetic Interference

The Gyrus ACMI PKS Plasma Morcellator has been designed to conform to the following voluntary consensus standards relating to electrical safety and electromagnetic compatibility:

- IEC 60601-1:2005 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-2: 2006 - Medical electrical equipment - Part 2-2: Particular Requirements for the safety of High Frequency Surgical Equipment.

As indicated elsewhere in this submission, the Morcellator shaft is insulated to withstand a minimum of 750VDC. This device will be Protection Class 1, with Type BF degree of protection.

In order to demonstrate conformance to the relevant IEC requirements, an analysis of applicable IEC requirements and their mitigating actions or verifications was undertaken during the development process. As part of the analysis, design specification criteria related to electrical safety were included for consideration, and were identified within the aforementioned analysis. A copy of this analysis (Document 874038) is enclosed in **Appendix 16.A**. Please note that the report references BSEN60601-1 and BSEN60601-2-2, which are identical to IEC 60601-1 and IEC 60601-2-2.

Particular electrical safety testing referenced by the 874038 analysis was further identified and evaluated in the Design Verification Protocol, Document 874033 (enclosed in **Appendix 16.A**). The specific methods and acceptance criteria were stated in Document 874053 (also enclosed in **Appendix 16.A**). Testing conducted to date has met the criteria established in the protocol and procedure documents.

Appendix 16.A

Document 874038 – BSEN60601 Compliance, SORD
Document 874033 – Design Verification Protocol
Document 874053 – Design Verification Test Procedures

Please note that the enclosures refer to the "Gyrus Solid Organ Resection Device" or "SORD". This was this internal name of the project while the device was under development. Gyrus ACMI plans to market the proposed device by the name "PKS Plasma Morcellator".

TITLE: BSEN60601 Compliance, SORD

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PRODUCT: SORD

ASSOCIATED DOCUMENTS:

(1) 874002 Design Specification, SORD
(2) 874035 Design Verification Technical Summary (not issued as time of release)
(3) 877103 IEC60601 compliance G400 Generator
(4) 874033 Verification Test Protocol, SORD

REVISION TABLE:	
ISSUE:	REVISION
1	1st release

SUMMARY
It is a general requirement of electrosurgical devices that they should comply with relevant electrical safety standards. The SORD device Design Specification contains the following items relating to electrical safety:

Spec	Description	Test Method	Cross-ref	Criteria
2.1.4.c	Morcellator shaft shall be insulated to withstand 1.5x output voltage (recommended min 750Vpk)	Verification Protocol No. 874033	BSEN60601-2-2 (1.5x hf voltage)	No breakdown
2.5.5.a	Cable exit points from grasper and morcellator to have integrally moulded strain relief which retain cables relative to mouldings, thereby resisting forces anticipated in normal use	Verification Protocol No. 874033	Clinical Model DS 2.2.8 & 2.5.5	Continuity test pass following pull test.
2.6.1.c	Generator to revert to minimal output after mains failure, as defined by BSEN60601-2-2 [preference for 0 output, i.e. 'off' setting]	Verification Protocol No. 874033	Ref G400 and SP specification	<5% of max power
3.3.1	Designed to comply with BSEN 60601-1:1998 & BSEN60601-2-2:1998	601 Review Summary No. 874038 (this doc)	—	Various (see individual requirements)

This document details a review that has been conducted of BSEN60601-1 and relevant sub-standard BS EN60601-2-2 to identify compliance of the SORD to these standards.

TITLE: BSEN60601 Compliance, SORD

REVIEW

The following clauses have been highlighted as bearing possible relevance to the SORD Applied Part ('instrument') of the G400 or SP RF System. Other clauses relate to the generator RF Workstation ('generator') and are therefore covered by a separate review (document 877103).

BSEN60601-1:1990 Medical Electrical Equipment, General requirements for safety

Clause	Result
5.1Class I (Relates to generator)	177012, Generator User Manual (UM)
5.2Type BF defibrillator proof floating applied part	Symbol DII 10 adjacent to generator socket
5.4Method of Sterilisation	Single Use, shown on label 174034 and in Instructions for Use (IFU) 174003
5.5Suitability for use with anaesthetic gasses	Not suitable. Stated in IFU 174003
5.6Mode of Operation	Intermittent. Stated in UM 177012
6.1 e Origin	Supplier address on label 174034
6.1 f Model Ref	Part Number on label 174034
6.1 l Classification	On generator (as 5.2 above)
6.4Symbols conform to Appendix D	All symbols used on label 174034 comply
6.8 IFU / labels show correct info	IFU174003 and Labels 174034 & 174000 include: device description, intended use; supplier address; function; application; warning of interference; note of single use; symbols are explained; conditions for storage
10.1 Transportation conditions	Stated on labelling, and tested under ISTA 2a test protocol (803000)
17 Separation: Leakage currents	N/A Generator
17 c) Connection to accessible metal parts	No conductive connection
19 e) Patient Leakage currents	N/A Generator
19 f) Patient Auxiliary currents	N/A Generator
20 Dielectric requirements	Ref BSEN60601-2-2 (below)
21.5 Free fall test for hand held equipment	Instrument is sterile single use device, therefore this requirement is not applicable
23 Rough edges	Instrument has no rough surface, sharp corners or edges which may cause unintentional injury other than those intended for function of the device.
42.2 Excessive Temperatures	Instrument cable has been identified as the region of highest surface temperature likely to come into contact with user or patient (other than those intended for the function of the device). The cable shall be modelled using FE analysis to predict maximum service temperature, and thermal imaging used to confirm the model. Present estimates are for a max temperature rise = 17°C, leading to max service temperature of **42°C** at 25°C ambient. This would be within the requirement of 60°C for flexible cords (table Xb)
44.3 Fluid ingress	Ref BSEN60601-2-2 (below)
48 Biocompatibility	All patient contact parts assessed and compliant with the guidelines of IEC10993
52.1 Single fault conditions	All foreseeable single fault conditions have been identified and reviewed in documents 874023 (Design FMEA) and 874015 (Risk Analysis). Consequent risks to safety have been quantified, and shall be shown to be acceptably small before product release by verification testing, labelling or other suitable means
56.3 a) Connectors	Instrument plug cannot be connected to other outlets due to unique design. (Keyway dedicated to G400)

TITLE: BSEN60601 Compliance, SORD

Clause	Result
57.10 Creepage & Clearance	N/A Generator

BSEN60601-2-2:1998 Medical Electrical Equipment, Particular Requirements for the safety of high frequency surgical equipment

Clause	Result
6.8.2 Instructions for Use	See separate table below
6.8.3 Technical Description	UM contains power and voltage output diagrams
44.3 Spillage & Fluid ingress	Instrument shall be tested against accidental fluid contact
52.101 Protection against short circuit	Generator detects and limits output
59.103.1 Cable Insulation	Equivalent cable to 140278, tested 840240
59.103.2 Device Dielectric	Equivalent cable to 140278, tested 840240
59.105 Capacitance between outputs	N/A Generator

6.8.2 Instructions for use

Additional items:

Part	Applies
*aa) Information concerning the use of suitable cables, ACCESSORIES, ACTIVE and NEUTRAL ELECTRODES, including values for the highest allowed h.f. peak voltage, in order to avoid incompatibility and unsafe operation.	Not Applicable (N/A) Device is dedicated to the Gyrus G400 or SP system, and electrical output is defined by auto-recognition of the type of instrument fitted
Advice for the OPERATOR to ensure that connected ACCESSORIES are rated for at least the maximum peak output voltage of the HF SURGICAL EQUIPMENT set at the intended output control setting in the intended operating mode, with reference to the diagrams required by 6.8.2 ee).	Not Applicable Device is dedicated to the Gyrus G400 or SP system, and electrical output is defined by auto-recognition of the type of instrument fitted
*bb) Notes on the application of HF SURGICAL EQUIPMENT. These notes shall draw the attention of the OPERATOR to certain precautions which are necessary in order to reduce the risk of accidental burns. In particular, advice, when appropriate, shall be given on the following:	See Below
*1) The entire area of the NEUTRAL ELECTRODE should be reliably attached to the PATIENT'S body and as close to the operating field as possible (see notes I and 2).	N/A – Bipolar system
*2) The PATIENT should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.). The use of antistatic sheeting is recommended for this purpose.	N/A – Bipolar system with floating output. Advisory against use with grounded systems and metallic objects noted in IFU.
*3) Skin-to-skin contact (for example between the arms and body of the PATIENT) should be avoided, for example by insertion of dry gauze (see notes 1 and 2).	N/A – Bipolar system
*4) When HF SURGICAL EQUIPMENT and physiological monitoring EQUIPMENT are used simultaneously on the same PATIENT, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended. In all cases, monitoring systems incorporating high frequency current-limiting devices are recommended.	Stated in UM
*5) The cables to the surgical electrodes should be positioned in such a way that contact with the PATIENT or other leads is avoided.	Stated in UM
Temporarily unused ACTIVE ELECTRODES should be stored so that they are isolated from the PATIENT.	Stated in IFU
*6) For surgical procedures where the h.f. current could flow through parts of the body having a relatively small cross-sectional area, the use of bipolar techniques may be desirable in order to avoid unwanted coagulation.	N/A – Bipolar system
7) The output power selected should be as low as possible for the intended purpose.	N/A – output power is not user adjustable. Settings are optimised for safe use by the system.
*8) Apparent low output or failure of the HF SURGICAL EQUIPMENT to function correctly at the normal operating settings may indicate faulty application of the NEUTRAL ELECTRODE or poor contact in its connections. In this case, the application of the NEUTRAL ELECTRODE and its connections should be checked before selecting a higher output power (see notes 1 and 2).	N/A – Bipolar system
9) The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (N2O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the	Stated in UM

head, unless these agents are sucked away.	
Non-flammable agents should be used for cleaning and disinfection wherever possible.	Stated in UM
Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of h.f. surgery. There is a risk of pooling of flammable solutions under the PATIENT or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before HF SURGICAL EQUIPMENT is used. Attention should be called to the danger of ignition of endogenous gases. Some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in NORMAL USE of the HF SURGICAL EQUIPMENT.	Stated in UM
10) For PATIENTS with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the pacemaker may occur, or the pacemaker may be damaged. In case of doubt, approved qualified advice should be obtained.	Stated in UM & IFU
11) For HF SURGICAL EQUIPMENT with an operating mode as described in 46.103 b), a warning is required to the effect that the output from either ACTIVE ELECTRODE may change during use. NOTE 1 - This requirement does not apply to HF SURGICAL EQUIPMENT only incorporating bipolar output. NOTE 2 - This requirement does not apply to HF SURGICAL EQUIPMENT intended for use without a NEUTRAL ELECTRODE.	N/A Bipolar System
cc) A warning that interference produced by the operation of HF SURGICAL EQUIPMENT may adversely influence the operation of other electronic EQUIPMENT.	Stated in UM
dd) Advice for the USER regularly to inspect the ACCESSORIES. In particular, electrode cables and ENDOSCOPICALLY USED ACCESSORIES should be checked for possible damage to the insulation.	Inspect on unpacking stated in IFU. Otherwise, single use device.
*ee) Information shall include diagrams showing the maximum possible peak output voltage of the HF SURGICAL EQUIPMENT versus the output control setting for all operating modes available.	Stated in UM
ff) A warning that failure of the HF SURGICAL EQUIPMENT could result in an unintended increase of output power.	Stated in UM

CONCLUSION

All testing required to demonstrate IEC60601 compliance shall be conducted as part of the device verification. Labelling and IFU drafts contain the required information. On conclusion of the testing and following controlled issue of the relevant documentation, this document shall be up-issued to provide links to supporting evidence of compliance.

D.H.F REVIEW: Add to T.D.I.: NO: ☐ YES: ☐

This document supersedes: _____

Customer Approval Required: NO: ☐ YES: ☐ _____ _____

Customer Date

Approved by:

Originator: _____ Date: _____

Technical Authority: _____ Date: _____

Quality: _____ Date: _____

Design Verification Protocol : SORD.

ASSOCIATED DOCUMENTS:

(1) 840017 CLINICAL MODEL FOR LAPAROSCOPIC PROCEDURES
(2) 874053 SORD DESIGN VERIFICATION TEST PROCEDURES
(3) 874002 DESIGN SPECIFICATION: SORD
(4) 874034 DESIGN VERIFICATION REPORT: SORD

Protocol Origination, Review and Approval

Completion of each of the following signature blocks signifies that the signatory has read, understands and agrees with the content of this document.

Name	Job Title or Role	Signature	Date (dd-mmm-yy)
The author is signing to confirm that this Design Verification Protocol has been prepared in accordance with 910202: Design Control within Product Development.			
Authored by: P J Wootton	Product Evaluation Manager		
The Project Manager is signing to confirm that the Design Verification Protocol meets project and techical requirements.			
Reviewed by: A. Fleming	SORD Project Manager.		
Quality Engineering is signing to confirm that verification / validation requirements have been addressed.			
Approved by: M. Lunn	Senior Quality Engineer.		

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1. Objective

This Design Verification Protocol relates to the Solid Organ Resection Device (SORD).

This intent of this Protocol is to detail the testing necessary to verify that the relevant criteria stated in the Design Specification have been met

Data shall be collected and collated through the performance of pre determined tests and hence verifying the safety and efficacy of the design against the Design Specification.

2. Purpose

The work conducted will be used to verify the design of the Solid Organ Resection Device (SORD).

3. Scope

This protocol applies to the Solid Organ Resection Device (SORD) only.

4. Equipment

As specified in the Test Procedures for SORD, Document Number 874053.

5. Components and Tests

Attached as Appendix One.

6. Sample Size Justification

For attribute analysis (i.e. where the sample is tested at the specified minimum or maximum requirement and the result is success or failure), the sample size will be that, for a confidence of 95%, that at least 90% of the population will exceed the requirement.

BS ISO 16269-6:2005 STATISTICAL INTERPRETATION OF DATA - is used to determine sample sizes as given below.

Data Type	Interval	BS ISO 16269-6 Annex	1 - σ	P	K Factor	Sample Size	Tests
Attribute (Non-parametric)	1 sided	F	0.95	0.90	---	29	6.1, 6.3 – 6.10

From this table a sample size of 29 has been selected as detailed in the testing section.

A sample size of 1 off has been selected for 6.2, which tests the system and is based on BS EN 60601-1-1 section 4.3 number of samples.

7. Responsibilities

The Product Evaluation Department shall execute, supervise and document the testing as detailed in this Protocol and the Test Procedures Document. The Quality Engineering Department will review and approve the Protocol and the Test Procedures Document.

Product Evaluation shall compile the Verification Report; this shall be reviewed by the SORD Project Manager and approved by the responsible SORD Quality Engineer.

Revision History

Date	Version	Revised By	Reason For Revision
20 Dec 06	01	P J Wootton	This is the first issue of this document

1. Components and Tests.

Tests are detailed in SORD Design Verification Test Procedures Document No. 874053. The test parameters not specified in Document No. 874053 will be set as shown below.

Note: The 3x2 graspers supplied are to be changed to 2x1 graspers for the test program. This change ensures that the worst case scenario is tested, the 2 x1 graspers have been subjected to double dose irradiation and due to their smaller jaw size will provide more pressure onto the morcellator during the force tests.

Design Spec Doc. No. 874002 Section	Document No. 874053		Test Details			Component Details					Acceptance Criteria
	Section	Test	Parameter	Setting	Justification	Device	P/N	Set / Order	Sample Size	Sterilisation	
S2.2.1a S2.5.1b	6.2	System Compatibility	Generator	G400 Generator	Provides an output representative of both the G400 and SuperPulse Generator	SORD	774000	A1	1	Double dosage of Et0 to ISO 11135 as section 6.1.1 and 2.2.1a of DS	As 874053
			Generator setting	MR2 200	This is the only waveform and power setting available.						
			Number of connections	5	Design Specification Doc. No. 874002 Section 2.5.1b						
S2.5.6c S2.2.1a	6.10	Capacitance Test	Parameters as detailed in 874053			SORD	774000	A2		Double dosage of Et0 to ISO 11135 as section 6.1.1 and 2.2.1a of DS	As 874053
S2.5.5a S2.2.1a	6.4	Cable Cyclic Tensile	Applied Load	≥18.75N	Clinical Model Doc No 840017 section 7.2 (FOS 1.25 applied)	SORD	774000	A3	29	Double dosage of Et0 to ISO 11135 as section 6.1.1 and 2.2.1a of DS	As 874053
S2.1.4c S2.2.3d S2.2.1a	6.5	Device Insulation Dielectric Strength	Generator	G400 Generator	Provides an output representative of both the G400 and SuperPulse Generator	SORD	774000	A4	29	Double dosage of Et0 to ISO 11135 as section 6.1.1 and 2.2.1a of DS	As 874053
			Activation Mode	Cut	This device has cut mode only, there is no coag function.						
			Generator setting	MR2 200	This is the only waveform and power setting available						
S2.1.9	6.7	Insufflation / Leak Test	Parameters as detailed in 874053			SORD	774000	A5	29	Double dosage of Et0 to ISO 11135 as section 6.1.1 and 2.2.1a of DS	As 874053
S3.3.3 S2.2.1a	6.6	Fluid Ingress	Generator	G400 Generator	Provides an output representative of both the G400 and SuperPulse Generator	SORD	774000	A6	29	Double dosage of Et0 to ISO 11135 as section 6.1.1 and 2.2.1a of DS	As 874053
			Activation Mode	Cut	This device has cut mode only, there is no coag function.						
			Generator setting	MR2 200	This is the only waveform and power setting available						
S4.6.1	6.9	Cannula Insertion Test	Cannula	Taut 15mm	This cannula is typical of the type expected to be used with the device	SORD	774000	A7	29	Double dosage of Et0 to ISO 11135 as section 6.1.1 and 2.2.1a of DS	As 874053
			No of insertions	3	No more than 2 insertions into cannula expected per case plus a FOS of 0.5						
S2.4.1a	6.8	Depth Stop Removal Test	Generator	G400 Generator	Provides an output representative of both the G400 and SuperPulse Generator	SORD	774000	A8	29	Double dosage of Et0 to ISO 11135 as section 6.1.1 and 2.2.1a of DS	As 874053
			Generator setting	MR2 200	This is the only waveform and power setting available						
			Morbid Tissue	Bovine Tongue	Clinical Model Doc No 840017 section 4						
S4.6.1	6.3	Distal Tip Force Tests (pre tissue tests)	Applied Load	56N	Clinical Model Doc No 840017 section 7.1 (56N includes a FOS of 2 applied to the normal cutting force)	SORD	774000	A9	29	Double dosage of Et0 to ISO 11135 as section 6.1.1 and 2.2.1a of DS	As 874053
S2.2.8a S2.2.8b S4.3.9 S4.5.1 S2.2.1a	6.1	Tissue Test SORD	Total Removal Capacity	620g	Clinical Model Doc No 840017 section 8.	SORD	774000	A10	29	Double dosage of Et0 to ISO 11135 as section 6.1.1 and 2.2.1a of DS	As 874053
			Generator	G400 Generator	Provides an output representative of both the G400 and SuperPulse Generator						
			Generator Settings	MR2 200	This is the only waveform and power setting available						
			Morbid tissue	Bovine tongue	Clinical Model Doc No 840017 section 4						
S4.6.1	6.3	Distal Tip Force Tests (post tissue tests)	Applied Load	56N	Clinical Model Doc No 840017 section 7.1 (56N includes a FOS of 2 applied to the normal cutting force)	SORD	774000	A11	29	Double dosage of Et0 to ISO 11135 as section 6.1.1 and 2.2.1a of DS	As 874053
			Generator	G400 Generator	Provides an output representative of both the G400 and SuperPulse Generator						
			Generator Settings	MR2 200	This is the only waveform and power setting available						
			Morbid tissue	Bovine tongue	Clinical Model Doc No 840017 section 4						
S4.6.1	6.9	Cannula Insertion Test	Cannula	Taut 15mm	This cannula is typical of the type expected to be used with the device	SORD	774000	A12	29	Double dosage of Et0 to ISO 11135 as section 6.1.1 and 2.2.1a of DS	As 874053
			No of insertions	3	No more than 2 insertions into cannula expected per case plus a FOS of 0.5						

Design Verification Test Procedures:

SORD.

ASSOCIATED DOCUMENTS:

(1) 840017 CLINICAL MODEL FOR LAPAROSCOPIC PROCEDURES
(2) 874002 DESIGN SPECIFICATION SORD

Protocol Origination, Review and Approval

Completion of each of the following signature blocks signifies that the signatory has read, understands and agrees with the content of this document.

Name	Job Title or Role	Signature	Date (dd-mmm-yy)
The author is signing to confirm that these Design Verification Test Procedures have been prepared in accordance with 910202: Design Control within Product Development.			
Authored by: P J Wootton	Product Evaluation Manager		
The Project Manager is signing to confirm that the Design Verification Test Procedures meet project and technical requirements.			
Reviewed by: A. Fleming	SORD Project Manager.		
Quality Engineering is signing to confirm that verification / validation requirements have been addressed.			
Approved by: M Lunn	Senior Quality Engineer.		

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1. Objective

These procedures shall be used to conduct Design Verification activities relating to the Solid Organ Resection Device (SORD).

The intent of these Procedures is to detail the test methods that shall be used during Design Verification testing of the Solid Organ Resection Device (SORD).

Data shall be collected and collated through the performance of the tests, this data shall be used to verify the safety and efficacy of the design against the Design Specification Document No 874002 for the Solid Organ Resection Device (SORD).

2. Purpose

The work conducted shall be used to verify the design of the Solid Organ Resection Device (SORD).

3. Scope

This protocol applies to the Solid Organ Resection Device (SORD) only

4. Tissue Model

4.1 Tissue Model Justification

The tissue types encountered during use of the SORD *in vivo*, and the morbid tissue model that can represent them are as proposed in the Clinical Model for Laparoscopic Procedures Doc No. 840017.

The choice of these morbid tissue models is based on comparison of the consistency of mechanical and electrical properties between the morbid model and the target tissue type, and on availability of tissue material such that reliable test data can be achieved in the laboratory.

4.2 Tissue Preparation

Tissue can be used either fresh or defrosted.

Defrosted tissue shall be supplied fresh and then frozen. It shall be defrosted once only. Defrosting shall be either by placing in ambient air or by placing the tissue in a sealed zip lock bag and placing in hot water at <40°C until the tissue reaches 22±5°C.

Do not soak the tissue in saline as excessive saline causes inappropriate arcing of the device.

5. Responsibilities

Product Evaluation shall compile the SORD Test Procedures; this document shall be reviewed by the SORD Project Manager and approved by the responsible SORD Quality Engineer.

6. Tests

6.1 Tissue Test –SORD

6.1.1 Objectives

- To verify the devices ability to withstand the electrical, thermal and mechanical stresses generated during a Laparoscopic Morcellation procedure using a simulated bench-top test.

6.1.2 Equipment

Item	GML No.
Generator	See device protocol
Thermometer	1133 or equivalent
Scales	1200 or equivalent
Pyrex dish	---

6.1.3 Test Procedure

Place a section of tissue in a Pyrex dish. Set up the generator and attach the device.

Use the device to morcellate the tissue. Ensure that the morcellator remains stationary during morcellation, the retraction of the tissue should be achieved only by movement of the graspers through the morcellator. Use the scales to record the mass of tissue removed via the morcellation process. Do not clean the device during testing. Activate the device on the tissue using the following parameters:

Parameter	Setting	Units	Justification
Tissue temperature at start of test	22±5	°C	Clinical Model for Laparoscopic Procedures Doc No. 840017
Cutting Speed	13	mm/sec	Clinical Model for Laparoscopic Procedures Doc No. 840017
Duty cycle	8 ON / 9 OFF	seconds	Clinical Model for Laparoscopic Procedures Doc No. 840017 Note that the test will attempt to simulate this duty cycle but will not use an electronic duty cycle timer to deliver this timing.
Activation mode	RF Vaporisation	---	Clinical Model for Laparoscopic Procedures Doc No. 840017
Total Removal Capacity	See Device Protocol		
Generator	See Device Protocol		
Generator settings	See Device Protocol		
Morbid tissue	See Device Protocol		

On completion of the test clean the morcellator and graspers with IPA wipes, inspect and photograph the distal portions of both the morcellator and grasper. Particular attention should be paid to the retention of the active ring and the active wire to active ring joint.

6.1.4 Acceptance Criteria

The device shall survive the full tissue test.
No device failures due to flare out should occur.
No persistent generator error reporting due to shorts to occur (>3 occurrences per procedure is regarded as persistent).

6.2 System Compatibility

6.2.1 Objective

To verify the compatibility of the device with the system.

6.2.2 Equipment

Item	GML No.
Timer	1199 or equivalent
Generator	See device protocol

6.2.3 Procedure

Switch on the generator to be tested and connect the device to the generator, record the settings displayed by the generator.

To ensure the system is operational after multiple connections of the electrode, connect/disconnect the electrode to the generator for the number of times specified.

Activate the electrode in air using the following parameters.

Parameter	Setting	Units	Justification
Activation time	>10	Seconds	Sufficient time to enable a fault condition to occur.
Activation mode	Vaporisation	---	Worst case use
Generator settings	See device protocol		
Number of connections	See device protocol		

6.2.4 Acceptance Criteria

No electrical shorting resulting in the generator displaying an error message shall have occurred.

The correct default shall be displayed after each connection.

6.3 Distal Tip Force Tests on Device

6.3.1 Objective

To verify the mechanical strength of the distal portion of the device during application of mechanical loads.

6.3.2 Equipment

Item	GML No.
Hand Held Tensiometer	676 or equivalent
Generator	See device protocol
Timer	5 or equivalent
5mm Spacer	-

6.3.3 Procedure – Pre Tissue Test Conditioning

Clasp and lock the graspers onto a spacer approximately 5mm thick, this will ensure that the graspers are in a position that will prevent them from entering into the morcellator. Use the hand held tensiometer to pull the graspers into the morcellator and apply the force specified to the grasper.

Test using the following parameters:

Parameter	Setting	Units	Justification
Tensiometer movement	Tensile Maximum	---	Load applied as per clinical use.
Applied load:	See device protocol		
Duty cycle	8 ON / 9 OFF	secs	Clinical Model for Laparoscopic Procedures Doc No. 840017
Activation mode	RF Vaporisation	---	Clinical Model for Laparoscopic Procedures Doc No. 840017
Generator	See Device Protocol		
Generator settings	See Device Protocol		
Morbid tissue	See Device Protocol		

6.3.4 Procedure – Post Tissue Test

Repeat the load applications and then perform the following:

Three activations on tissue using the duty cycle (8sON 9sOFF), generator settings and morbid tissue type as specified in the device protocol.

6.3.5 Acceptance Criteria – Post Tissue Test

The Design Specification (874002) forces shall be applied.

The device shall activate in the expected manner.

No device shorting resulting in the generator displaying an error message shall have occurred.

6.4 Cable Cyclic Tensile Test

6.4.1 Objective

To verify the mechanical strength of the cable connections within the device under cyclic tension.

6.4.2 Equipment

Item	GML No.
5kLRX Tensiometer	651 or equivalent
500N load cell	1356 or equivalent
Tensiometer wire grips	1374 or equivalent
Low Ohm meter	807 or equivalent
Vice	---

6.4.3 Procedure

This test is based on BS EN 60601-1 section 57.4 (a) with the applied force modified to reflect the clinical application.

A series of three tests are necessary to test all of the connections and joints.

- Secure the morcellator to the base of the tensiometer, secure the cable to the tensiometer crosshead using the wire grips (clamp between Y connector and the morcellator).
- Secure the grasper to the base of the tensiometer, secure the cable to the tensiometer crosshead using the wire grips (clamp between Y connector and the grasper).

Test using the following parameters:

Parameter	Setting	Units	Justification
Strain Rate in tension	50	mm/min	Specified to avoid jerking as required by BS EN 60601-1 section 57.4 (a)
Strain rate in return stroke	100	mm/min	No load applied. Fastest controlled speed used.
Tensiometer movement	Tension cyclic	---	First stroke shall be in tension.
Hold time for applied force	1	second	Specified in BS EN 60601-1 section 57.4 (a)
Number of cycles	25	---	Specified in BS EN 60601-1 section 57.4 (a)
Applied Force	See device protocol		

Upon completion of the cyclic test conduct continuity test as detailed below.

Connect the meter leads to the device to measure continuity between:

- Grasper jaw and connector return pin (this test needs to be carried out whilst something is being grasped within the grasper jaws to put the linkages in tension).
- Active tip to connector active pin.
- Return tube to connector return pin.

Record the meter reading in ohms.

6.4.7 Acceptance Criteria

The continuity results shall achieve the requirements as stated in the Design Specification Document No 874002 for SORD.

6.5 Device Insulation Dielectric Strength Test

6.5.1 Objective

To assess the capability of the device insulation to withstand the dielectric test referenced in part 59.103.2 of BS EN 60601-2-2

6.5.2 Equipment

Item	GML No.
Generator	See device protocol
1.5 Step-up Test Jig	1461 or equivalent
Timer	1199 or equivalent
Vernier	873 or equivalent
Metal foil	---

6.5.3 Procedure.

Place the device horizontally on a non-conductive bench with morcellator and grasper separated ensuring that the distal portions and plug pins are placed in air.

Wrap the entire device including connector cord in metal foil up to no less than 10mm and no more than 15mm from the exposed return ring, the distal most section of the grasper heatshrink and the exposed portion of the plug.

Ensure the metal foil does not contact any metallic components connected to the bench.

Connect the 1.5 step-up jig to the generator socket and connect the red output of the jig to the device plug pins (active and return pins wired together) and the black output to the foil wrapping.

Activate the electrode in air for the time specified checking for visual indications of insulation breakdown.

Warning: Do not touch the electrode or metal foil during activation

Test using the following parameters:

Parameter	Setting	Units	Justification
Total activation time	30	seconds	As specified in BS EN 60601 –2-2 section 59.103.2
Activation mode	See Device Protocol		
Generator Settings	See Device Protocol		

Remove foil and inspect the device and foil for indications of arcing.

6.5.4 Acceptance Criteria

No breakdown or flashover shall occur on the electrode insulating parts.

6.6 Fluid Ingress Test

6.6.1 Objective

To assess if fluid spilt on the morcellator/grasper will cause ingress sufficient to create an internal electrical short circuit.

6.6.2 Equipment

Item	GML No.
Scales	1200 or equivalent
Vernier	873 or equivalent
Bench top Timer	1199 or equivalent
Generator	See device protocol
Pyrex container	---
Saline	---
Retort stand	---

6.6.3 Procedure

The test will indicate the effect of saline inside the proximal section and is based on BS EN 60601-2-2 section 44.6 (bb).
Support the morcellator/grasper horizontally at least 50 mm above any surface.
Connect to the generator with the power set as detailed below but not activating.
Pour at least 1 litre of saline steadily within 15 seconds over the full length of the morcellator/grasper including :

- Morcellator shaft / handle interface
- Morcellator handle and handle/cable interface.
- Grasper handle and grasper/cable interface.

Allow the saline to drain away freely.
Immediately afterwards position the device at 45° with the active tip higher that the handle. Active the device 10 times as detailed below.

Test using the following parameters [not specified in BS EN60601-2-2 section 44.6 (bb)]:

Parameter	Setting	Units	Justification
Maximum single activation time for each cycle	≥11	seconds	Maximum single activation expected in clinical use.
Activation mode	See device protocol		
Generator settings	See device protocol		

6.6.4 Acceptance Criteria

No electrical shorting resulting in the generator displaying an error message shall have occurred.

6.7 Insufflation / Leak Test

6.7.1 Objective

To verify the leak rate of the morcellator seals when subjected to insufflation pressure with and without a grasper inserted.

6.7.2 Equipment

Item	GML No.
Insufflator	2317 or equivalent
Timer	1199 or equivalent

6.7.3 Procedure

Without Grasper - Connect a tubing set to the primary outlet of the Turboflow 8000 insufflator. Set the abdominal pressure, set the gas flow rate. Seal the entral adaptor from the tube set onto the front of the morcellator and press the flow On/Off switch. When the pressure reaches 15mmHg start the timer and time for one minute. At the end of the minute record the gas volume used in Litres from the insufflators display.
With Grasper – Repeat the test above but with the grasper inserted.
Test using the following parameters:

Parameter	Setting	Units	Justification
Abdominal Pressure	15	mmHg	Clinical model 840017
Gas Flow Rate	20	ltrs/min	This is the max setting for the primary outlet of the insufflator and will ensure that the insufflator does not limit the output.

If a very good seal is present the insufflator will indicate a "Flow Restriction" . If the display of this message occurrs the device will be deemed acceptable.

6.7.4 Acceptance Criteria

The leak rate shall achieve the device specification (874002: Design Specification for SORD) requirements.

6.8 Depth Stop Removal Test.

6.8.1 Objective

To verify that the depth stop can be removed without damaging the morcellator tip.

6.8.2 Equipment

Item	GML No.
Generator	See device protocol
Morbid tissue	See device protocol

6.8.3 Procedure

Remove the depth stop from the morcellator by hand and inspect the morcellator tip for damage.
To establish that the device remains functional, activate the device for three duty cycles on tissue using the following parameters.

Parameter	Setting	Units	Justification
Duty cycle	8 ON / 9 OFF	secs	Clinical Model for Laparoscopic Procedures Doc No. 840017
Activation mode	RF Vaporisation	---	Clinical Model for Laparoscopic Procedures Doc No. 840017
Generator	See Device Protocol		
Generator settings	See Device Protocol		
Morbid tissue	See Device Protocol		

6.8.4 Acceptance Criteria

No damage to the morcellator tip shall be visible.
The device shall remain functional after removal of the stop.

6.9 Cannula Insertion/Retraction Test.

6.9.1 Objective

To verify the morcellators ability to withstand the mechanical forces encountered during insertion and retraction from a cannula.

6.9.2 Equipment

Item	GML No.
Cannula	See device protocol

6.9.3 Procedure

Insert and retract the morcellator into the cannula for the number of times detailed below.

Parameter	Setting	Units	Justification
No of insertions	See Device Protocol		

Remove the morcellator and inspect.

6.9.4 Acceptance Criteria

No damage to the morcellator shall be visible.

6.10 Capacitance Test.

6.10.1 Objective

To verify the capacitance of the identification capacitors of the device

6.10.2 Equipment

Item	GML No.
LCR Bridge	1879 or equivalent

6.10.3 Procedure

Use the LCR Bridge to measure and record the capacitance values by connecting as follows:

- Between pin 1 and pin 2
- Between pin 1 and pin 3

6.10.4 Acceptance Criteria

The acceptance criteria will be as detailed in the Design Specification.

7. Glossary of Terms Used

SORD:
Solid Organ Resection Device.

8. References

1. 840017: Clinical Model For Laparoscopic Procedures
2. 874002: Design Specification for SORD
3. 874033: Design Verification Protocol for SORD
4. 874034: Design Verification Report for SORD.

9. Revision History

Date	Version	Revised By	Reason For Revision
20-Dec- 06	01	P J Wootton	This is the first issue of this document

Gyrus ACMI PKS Plasma Morcellator

510(K) PREMARKET NOTIFICATION

SECTION 17.0: PERFORMANCE TESTING - BENCH

Gyrus ACMI, Inc.
SOUTHBOROUGH, MA

17.0 Performance Testing – Bench

Performance requirements for the Gyrus ACMI PKS Plasma Morcellator were established in a User Requirements Specification document. These requirements were based in part on the known properties of currently marketed rotating cutting blade morcellators, such as the predicate Gynecare Laparoscopic Morcellator. These requirements were also in part based on the bipolar tissue management properties of the predicate Gyrus PlasmaCision Laparoscopic Spatula.

The general performance requirements defined in the User Requirements Specification were refined into a Design Specification. The Design Specification requirements included particular performance specifications and target values, and acceptance criteria. During design verification, the outputs of the design process were evaluated against the criteria defined in the initial User Requirements Specification and the Design Specification. In general, the evaluations compared the function of the PKS Plasma Morcellator against the performance characteristics defined by the Design Specification, and in comparison to the known performance characteristics of the rotating cutting blade morcellators in general, and the predicate Gynecare Laparoscopic Morcellator in particular.

Specific criteria evaluated included the function of the depth stop, function of the seal within the handle body, general grasper performance, cutting ability in several animal tissue and extirpated human tissue models, ergonomics, thermal performance, smoke generation, and the likelihood of nerve stimulation. Additional studies were also conducted to determine the optimal configuration of the grasper jaw, given the need to securely grasp tissue that varies in texture from spongy (i.e., uterine muscle wall) to tough (e.g., fibroid tissue). Testing demonstrated that the performance requirements defined in the User Requirements Specification and Design Specification were met, and that the PKS Plasma Morcellator exhibited comparable performance characteristics to both the predicate Gynecare Laparoscopic Morcellator and Gyrus PlasmaCision Laparoscopic Spatula. A summary of the evaluations conducted is included in **Appendix 17.A**.

During the development process, detailed analyses of risks were performed, which addressed amongst other things, the potential for damage to non-target tissue, as queried by the Agency during review of K063134. Assessment of risk was based on a scale adapted from IEC 60601-1-4. In addition, the source of the risk was identified, the probable outcome determined, and a mitigation measure identified in the assessment document to assure that the risk was reduced to an "Acceptable" or "As Low as Reasonably Practical" (ALARP) level. In order to address the questions previously posed by the Agency, we have extracted the information pertinent to effects on non-target tissue from these risk analyses and summarized them **Table V**. These measures are discussed in greater detail below.

In our analyses, there were three outcomes identified that were pertinent to the Agency's previous inquiries. Each of these outcomes relate to a scenario where the device is activated while in contact with tissue other than the intended target tissue, or comes into contact with non-target tissue shortly after cessation of RF energy application.

In the first two outcomes, the device is activated while in contact with non-target tissue, such as the abdominal wall. In the first case, collateral damage may occur to the target tissue where the severity rating is "Moderate", indicating that there is potential of injury. In the second case, where nerve or muscle stimulation may be observed, the severity rating is "Negligible", indicating that there is little or no potential for injury.

It either case, the scenario exists only when the user fails to exercise sufficient caution when activating the device. It should be noted however that failure to exercise sufficient caution presents similar risks regarding non-target tissue for competitor devices, such as the predicate X-Tract. While the user population of trained surgeons should be acutely aware of such risks, there exists a possibility that due caution may not be exercised.

As indicated in **Table V**, these scenarios are being mitigated in part through the inclusion of Warning statements in the Instructions for Use (see **Appendix 12.A** of this submission). These Warnings remind the surgeon that the tip should be kept in view at all times, and only activated when addressing the target tissue. Indeed, this language is similar to the language included in the Warnings and Precautions section of the Instructions for Use that accompanies the predicate X-Tract device. Because of these factors, the likelihood of the risk resulting in harm is rated as "occasional".

The third pertinent outcome relates to the degree of risk resulting from inadequate dissipation of residual heat at the active tip after cessation of energy application. The risk is essentially that the device does not dissipate this heat fast enough. In this scenario, the active ring may remain at a high enough temperature for a sufficient period of time to cause blanching of collateral tissue structures should the surgeon inadvertently touch the tip against such a structure, e.g. the bowel after cutting. The severity is rated as "Moderate" since there is a potential of injury.

The likelihood is considered to be "occasional", as labs have consistently shown that it is very difficult indeed to cause any visible tissue damage by this means. Ongoing thermal modeling is also demonstrating that the more appropriate final likelihood rating for this risk shall be improbable or even incredible. Nevertheless, this outcome is also being mitigated through the inclusion of a Warning statement in the Instructions For Use.

Table V

Nature of Risk	Source of Risk	Outcome(s) / harm	Mitigation Measures	Summary Grid #
Patient muscle stimulation	Stray currents through motor nerve tissue.	Inappropriate tissue effect; twitching	910220 requires limited capacitive coupling of RF output to instruments Validation protocol and report 861025 demonstrates use of filtered outputs to reduce low frequency components (nerve stimuli) User manual to include warning statement - Labelling	5
Unintentional depression of footswitch pedal by OR staff (including user) with electrode in tissue	User error	Damage to tissue	910220, audible alarm intensity, User training and awareness User manual to include warning statement - Labelling	10
Tip remains hot after use	Inadequate design / inappropriate use Activation related heat does not disperse as quickly as user perceives.	User / patient burn	Labs 10 April, 26th June. 874013 and 874021 User Requirement User manual to include warning statement - Labelling	10

Assessment Key:

Severity	Definition
Negligible	Little or no potential of injury
Moderate	Potential of injury.
Critical	Potential of death or serious injury.
Catastrophic	Potential of multiple deaths or serious injuries occurring from a single failure event..

Likelihood	Definition
Incredible	Extremely unlikely that the harm will occur at all, given the assumptions recorded about the domain and the system.
Improbable	Unlikely, but may exceptionally occur
Remote	Likely to occur some time
Occasional	Likely to occur several times
Probable	Likely to occur often
Frequent	Likely to be continually experienced

Summary Grid:

LIKELIHOOD					
Frequent	6	12	18	24	
Probable	**5**	11	17	23	
Occasional	4	**10**	16	22	
Remote	3	9	15	21	
Improbable	2	8	14	20	
Incredible	1	7	13	19	
	Negligible	Moderate	Critical	Catastrophic	**SEVERITY**

Appendix 17.A

Summary of Bench Testing

Please note that the enclosures refer to the "Gyrus Solid Organ Resection Device" or "SORD". This was this internal name of the project while the device was under development. Gyrus ACMI plans to market the proposed device by the name "PKS Plasma Morcellator".

Summary of SORD Bench Testing

As part of the design process, verification work was performed at the Gyrus Medical Ltd. facilities to confirm fulfillment of physical characteristics, such as dimensions and material characteristics. In addition, a series of evaluations were performed to verify performance of the SORD in tissue. Each of these evaluations is summarized below.

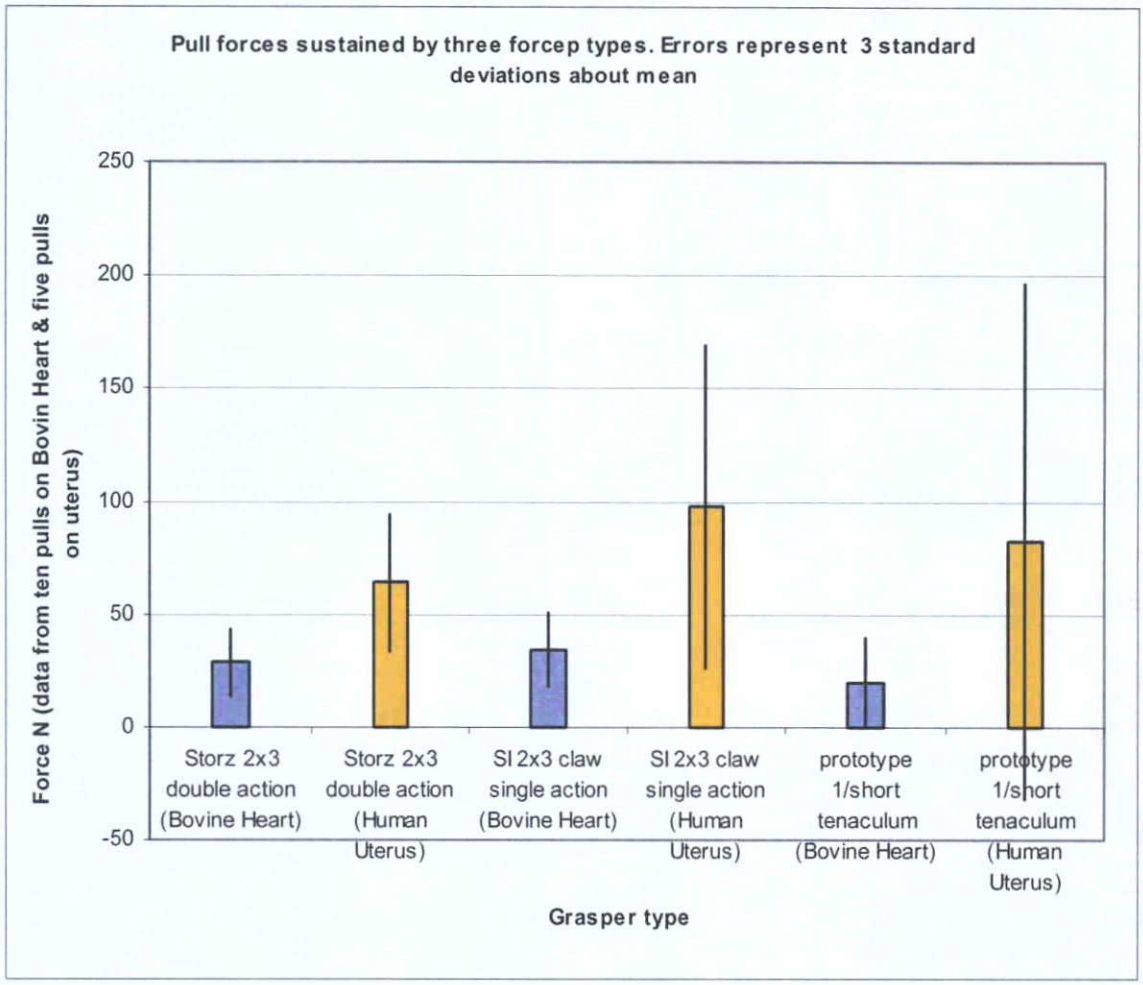
SORD Grasper Trials held at QEH lab on 5/16/06, Document #874004, serial #2

Introduction: A surgeon lab was held on 16th May 2006 to evaluate the performance of a 2x3 grasper compared to that of a single tooth grasper on extirpated human uterus. Trials already conducted on bovine heart demonstrated that the 2x3 grasper had better grip and less tearing characteristics than a single tooth grasper. However this lab was required to evaluate performance on tougher fibroid tissue.

Devices tested: SORD instrument.
2x3 single actuating Surgical Innovations grasper,
Single toothed Gyrus ACMI prototype grasper,
Storz single toothed grasper & 2x3 grasper inc. spike on mid point of bottom jaw (x3 teeth)

Results: Trial was conducted to establish the pull to tear force of the human uterus when being held with the graspers. A similar trial had been conducted on bovine heart with the 2x3 grasper having a higher pull force (grip) than the single tooth. Results recorded at lab were combined to produce the following data table showing direct comprasion between bovine heart and human uterus (fibriod wall as opposed to uterine muscle wall) pull testing.

	Storz 2x3 double action (Bovine Heart)	Storz 2x3 double action (Human Uterus)	SI 2x3 claw single action (Bovine Heart)	SI 2x3 claw single action (Human Uterus)	Prototype 1/short tenaculum (Bovine Heart)	Prototype 1/short tenaculum (Human Uterus)
	27N	65N	29N	68.2N	25N	135N
	32	53	44	81	13	106
	33	61	32	97	31	76
	34	77	37	122	12	43
	28		28	121	14	53
	20		33		22	
	30		34		28	
	25		30		16	
	33		38		19	
	22		42		21	
Av	28N	64N	35N	97.8N	20N	82.6N
Stdev	5	10	5	23.9	7	38.0171
Stdev*3	15	30	16	71.7	20	114.0513



Conclusions: The two distinct tissue types presented within the procedure are the fibroid wall, which is very tough to penetrate, and the uterine muscle wall, which can be described as a spongy texture. The single tooth grasper penetrated the fibroid wall easier than the 2x3 grasper because it has a higher point contact force, but tears the tissue when pulling through the SORD instrument if any resistance is encountered, due to the configuration of the teeth being pointed. The 2x3 works better on the spongy uterine muscle wall due its ability to grasp tissue and hold firmly while retracting through the SORD instrument. However it is hard, but not impossible to use the 2x3 on the fibroid wall and it was noted that smaller bits of tissue were successful removed using the 2x3 on fibroid wall. From the results recorded it is evident that the 2x3 grasper offers better grip characteristics on both the bovine heart and more importantly the human uterus model. It should be noted however, that subsequent to the performance of this study, a decision was made to offer an accessory grasper with a 2x1 tooth configuration in addition to the standard 2x3 tooth configuration grasper.

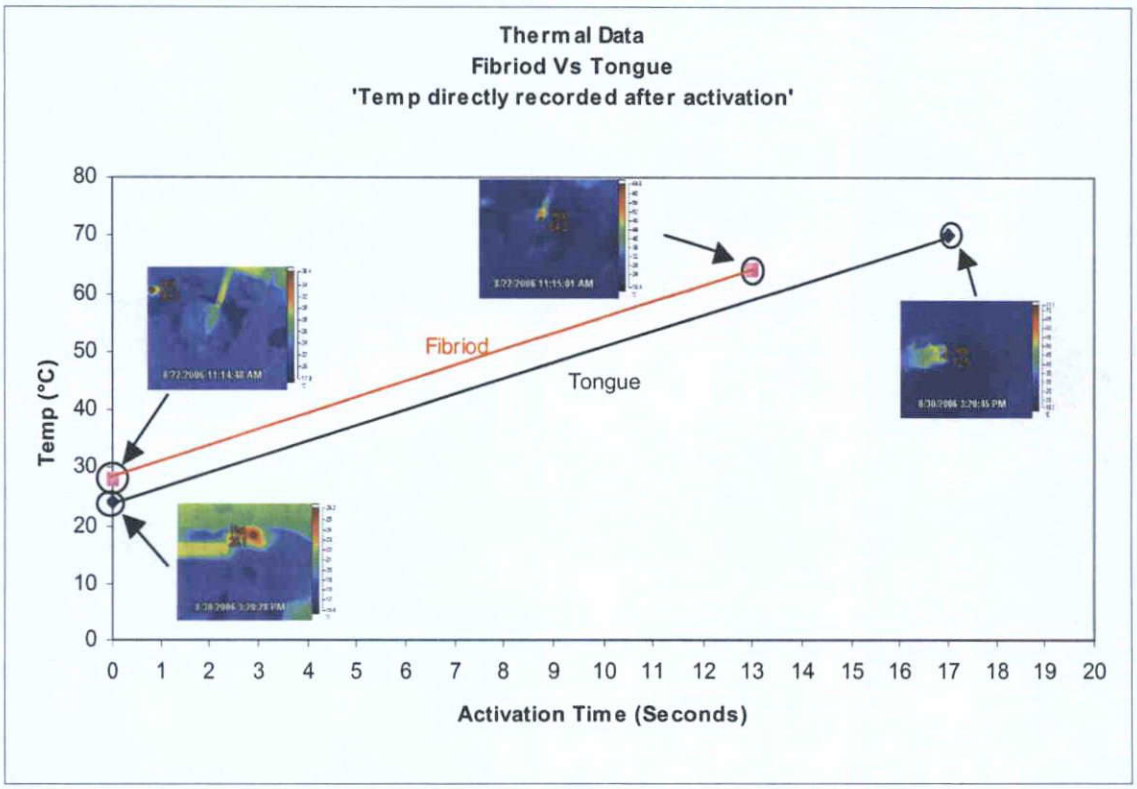
SORD Trial held at QEH lab on 8/22/06, Document #874004, serial #3

Introduction: A surgeon lab was held on 22nd August 2006 to provide Dr R McDonald with an update of the SORD project. This lab provided the opportunity to obtain comments on the performance of SORD device and to obtain opinion on a second grasper option, which is currently being, decided upon between a single tooth grasper and a 2x1 grasper. This lab also provided the opportunity to obtain thermal camera data. The tissue model available was extirpated human fibroid from an open Myomectomy procedure.

Devices tested: SORD instrument – Black valve.
2x3 Surgical Innovations grasper,
Single toothed Gyrus ACMI prototype grasper,
2x1 modified from a 2x3 Surgical Innovations grasper
G400 generator, serial number 0523424, SW version 1.03.99
Thermal Camera GML 2136

Results: Thermal camera data was obtained with Dr McDonald and Elaine Jones using the SORD instrument. This data was reviewed along with the video footage taken from the lab and an appropriate clip (from video footage 36mins 05secs to 36mins 30secs, Elaine Jones testing) selected to establish a time Vs temp profile of a suitable average activation. This data was then replicated on tongue by ensuring that the device start temp and activation times were similar. Care was taken to ensure spot readings were taken immediately prior to and subsequently to activation to prevent spurious register of plasma or tissue temperature readings.

The data collected produced the following temp profile.



Conclusions:
Grasper: At the previous meeting with Dr McDonald, he indicated his preference for the 2x3, finding the 1x1 to struggle to retain soft tissue. At this lab, with the new 2x1 present, he found this format preferable to the 2x3 for fibroid tissue. He was not able to assess its performance on soft tissue due to availability of tissue.

There were two key advantages of the 2x1 that Dr McDonald noted; the first being its more slender profile, promoting greater tissue penetration and the second being its ability to allow the tissue to 'hang', promoting peeling as compared to the 2x3 which, by virtue of its more

aggressive grasp, holds the tissue face normal to the axis of the device promoting coring. Whether these characteristics are detrimental to soft tissue performance is unclear from this lab.

Thermal Data: The objective of collecting thermal profiles on fibroid and tongue was to develop an understanding of the thermal stress on the SORD insulator in actual fibroid and the proposed tissue model. Typically, the amount of thermal build-up is PlasmaCision devices correlates to the resilience of the insulator to degradation and breakdown.

The data collected shows a very close equivalence between the two types in relation to the rate of heat build up in the device tip. This would suggest that beef tongue would present an equivalent thermal stress on the target tissue.

Pre-Clinical Report, SORD Evaluation conducted at University of Minnesota Dept of Experimental Surgery on 6/26/06, Document #874021

Introduction: A Pre-clinical study to evaluate efficacy, ergonomics and safety of the Solid Organ Resection Device (SORD) in development at Gyrus Medical Ltd. The study presented in this report was set up primarily to evaluate the functional efficacy of SORD prototypes and the driving generator software thereby ensuring continued confidence in the design intent prior to final design freeze. It was a further aim of this study to gather supporting data on the general safety of the product. The study included three (3) clinicians, and each was presented with the opportunity to utilize five (5) devices in the study.

The SORD device shall complement a range of instruments offered by Gyrus ACMI for laparoscopic procedures, and provide a means, using Gyrus' PlasmaKinetic technology for the effective removal of organs too large to be removed discretely through typical laparoscopic ports. The device shall morcellate, or separate into smaller portions, the target tissues and enable removal from the insufflate cavity through a 15mm diameter port.

In contrast to competitive devices, which use mechanical means of morcellation, the SORD device shall use RF plasma to cut the tissue. This offers certain advantages including the ability to resect calcified fibroid tissue where mechanical blade type devices may become blunted and ineffective.

Objectives

Primary objectives were to:

- Obtain surgeon assessment of the proposed Morcellator handle formats, leading to the selection of the most appropriate format for development from the options presented.
- Obtain assessment of the ability of the proposed grasper jaw format to pull tissue through the device
- Obtain assessment of the ability of the proposed seal arrangement to maintain pneumoperitoneum, whilst allowing tissue to pass though it during use.

Secondary objectives were to:

- Utilize the latest iteration of generator software in a pre-clinical environment, thereby obtaining surgeon assessment of it's efficacy.
- Assess key elements of the combined safety and efficacy of the system.

Study Procedure:
Since the study was intended to simulate Laparoscopic Supracervical Hysterectomy, the primary application of the SORD device, a 3-4 month old female Yorkshire pig, weighing approximately 46kg and in a good state of health was prepared for laparoscopic surgery. The intended target tissue for morcellation during this study was fresh beef heart, within 1-day post-mortem, placed within the pig's abdominal cavity to simulate uterine tissue. To simulate the laparoscopic environment, the pig's abdominal cavity was insufflated using an ACMI Turboflow 8000 insufflator. Utilization of the SORD on the target tissue in the abdominal cavity was imaged with a Stryker video system. During these evaluations, a distinct effort was made to replicate the laparoscopic environment in which the SORD will be used.

In previous testing conducted by Gyrus Medical, beef heart has been shown to give a good equivalence to the level of smoke produced by uterine muscle (ref document 874014). This tissue was used for the first and predominant part of the study, however the surgeon consensus was that heart tissue was not cohesive enough to closely model uterine wall muscle and that consequently, it was unfairly challenging the ability of the graspers to withdraw tissue without tearing.

Beef tongue has previously been shown to be a possible alternative model (ref 874014, where heart, tongue and uterine tissue was compared). The surgeons agreed that this would be less friable, and the beef tongue tissue better represented the target uterine tissue, therefore this was used for the later segment of testing. The size of the tissue selected was intended to approximate the maximum size of uterine tissue that would be considered for laparoscopic hysterectomies (the clinicians involved with the study indicated this should be a 22 week state).

Whilst tongue is more appropriate in terms of tear strength, the 874014 tissue comparison report showed that it produced greater levels of smoke than both uterine tissue and heart. Furthermore, there was no fresh source of tongue, and therefore frozen tissue was used. Smoke levels noted later in the procedure should therefore be regarded as greater than expected in human use.

Results:
Assessment of Depth Stop utility
The depth stop feature was liked by all three surgeons. One noted that it was somewhat stiff to move, but that it needed to be to achieve its purpose. It was generally seen as a competitive advantage, although its absence would not particularly discourage the surgeons from considering use of SORD over other competitor devices.

Assessment of Seal capability
Retention of insufflant
The static sealing performance of the SORD devices was very good. There were two main seal versions presented and used in the first stages of the lab, and both exhibited little or no leakage without the grasper inserted. The Liquid Molding Systems (LMS) inverting valve is the preferred choice, and was used for the remainder of the lab.

Assessment of Seal capability – Insertion of grasper
The performance of the combined sealing arrangement was initially good. The inter-seal distance worked as intended to prevent insufflant loss as the grasper is inserted or removed, although it was noted by surgeons that momentary loss of gas that might occur, as it does with the X–Tract, was not an issue since this would only effect a small drop in intra-abdominal pressure.

As the grasper was manipulated within the morcellator, the rear reducer seal did not function effectively. When the grasper shaft moves off centre, the reducer seal stretches out of shape, no

longer seals around the shaft and allows gas to escape freely. This issue was predicted prior to the lab, and it was believed could be remedied by constraining lateral motion of the grasper by way of revision to the device body design with no detrimental effect on overall performance.

Overall performance of the SORD seals was good. During assessment, the insufflator flow rate was set to a maximum of 4lpm (at 15mmHg), which replicates the worst-case performance of insufflators in the field. Other than the scenario described above, this flow rate was sufficient to maintain pneumoperitoneum, in fact much of the time the insufflator's actual flow was recorded as minimal or zero on the gauge.

Assessment of Grasper / Seal ability to remove tissue
The seals were effective at allowing unrestricted passage of tissue slugs. There were few instances of tissue becoming stuck in the seal and tearing as had occurred in previous labs. In this respect, the inverting LMS valve clearly performed well. Surgeons were questioned on the tactile feedback. It had been noted that as the seal inverts, grasper motion can feel slightly jerky, but the surgeons questioned were barely aware of this, and certainly did not regard it as an issue.

Being more friable than typical uterine muscle, the heart tissue did present some difficulties withdrawing to start with, but this was not a factor of the seal resistance so much as the tissue type, and technique. All three surgeons agreed that the heart tissue model was more friable than uterus. As feel for the lack of tissue cohesion developed, it was observed that the surgeons became more successful at removing appreciable tissue slugs (contiguous lengths of tissue). This learning curve existed with both 2x3 and 1x1 grasper formats, although surgeons noted that the 2x3 was more effective on this tissue type.

To confirm the SORD instrument's ability to remove tissue more comparable in terms of cohesiveness to uterine muscle, beef tongue was later used in place of heart. The surgeons agreed that this was a better model for healthy uterine muscle, and were immediately able to remove long tissue slugs with a much lower occurrence of tearing.

Whilst the 2x3 grasper format was accepted as the better able to grasp and retract soft tissues, none of the surgeons were able to ratify its suitability for tougher fibroid material. It is generally known that the 1x1 format is better able to close fully on fibroid tissue, and this was confirmed by the surgeons from previous experience. One of the primary concerns voice by the surgeons with existing bladed morcellators is blunting by drawing a grasper jaw that is not sufficiently closed back against the blade. It was noted that this possibility of damage is not an issue with SORD and that therefore the concern to attain full jaw closure should be much less. The insulated jaw of the SORD grasper intended to prevent shorting against the active in such circumstances performed well in the lab.

Typically, the surgeons present would make use of more than one grasper to address the shortcomings of each jaw format. Since the SI grasper can be configured to accept multiple jaws, this will be investigated as a parallel activity to supply separately. This is preferable to supplying only the handle in the primary pack, with a range of jaws requiring to be ordered separately.

The selection of 2x3 as the standard format to provide with the SORD morcellator was based on previous lab output where the 1x1 performed very poorly on soft tissue. Quantitative data on tear strength, and observations at a UK lab working with actual fibroid tissue had shown that the 2x3 was better than the 1x1 in this respect (ref memo to file 874004 serial 2). Since one grasper would be required to complete the entire morcellation procedure, it must be able to handle soft tissue and small strands of tissue common towards the latter stages of morcellation. Whilst it was

known that the 1x1 would perform better on fibroid, the same UK lab demonstrated that the 2x3 could be used effectively on fibroid by grasping only with the jaw teeth as opposed to engaging the entire jaw, hence the 2x3 was the only format found to be able to tackle the whole procedure. It should be noted however, that subsequent to the performance of this study, a decision was made to offer an accessory grasper with a 2x1 tooth configuration in addition to the standard 2x3 tooth configuration grasper.

Assessment of SORD / Software

Cutting ability

The ability of the SORD device to cut tissue was regarded by all surgeons as at least equivalent to competitor mechanical morcellators on the tissue models available. As discussed above, it was not possible to assess performance on tougher fibroid like tissue in this lab. (Previous lab data (ref memo to file 874004 serial 2) has shown cutting performance on fibroids to be notably better than mechanical devices)

The SORD morcellator cut effectively using both peeling and coring styles (i.e. partial and full tissue engagement), although it was noted by the surgeons that they would not choose to core since peeling maintains a more cohesive mass of remaining tissue, and allows longer tissue slugs to be removed.

Ergonomics

Various aspects of device ergonomics were assessed during the lab. Three shaft finishes were presented – grey, white and black. These were assessed for their reflectivity under laparoscopic illumination. Whilst the surgeons felt that the white shaft was acceptable, it did reflect more light and cause a higher level of glare than the grey or black shafts. It was concluded that under different vision systems or settings, the white shaft may be less acceptable and that overall the grey finish was preferred. Four handle versions were presented. All of these were of a pistol format, with differences limited to the sculpting of the main body and the sectional size of the pistol grip. The pistol format was generally well received, with Dr Bruck noting that he liked the stability it offers and that the cable exits away from the axis of the device.

Safety

Orange Glow

Device activation causes plasma to be created between active and tissue. This plasma is typically orange due to the presence of sodium from ionic salts in the body fluids. At the previous lab (ref document 874012), the prominence of this "orange glow" had been commented on by the surgeons. It was felt that whilst this was a general characteristic of RF device activation, it may be off-putting to users. However at this lab, the glow appeared less prominent. Whilst it is regarded by the surgeons that there is not a significant safety risk associated with this phenomenon, the negative perception is undesirable. Examination of the device from the two labs will be conducted to identify if there were indeed differences, or whether the apparent change was due to the set-up of the vision system.

Thermal dissipation

A common concern with mechanical morcellators is the risk of collateral damage caused by the presence of a sharp blade, whether rotating or not, at the device tip. An RF morcellator does not have this risk, however RF devices must manage the build up of heat from activation to minimise the possibility of collateral tissue damage by transfer of residual heat back in to underlying tissue structures. The SORD device manages heat dissipation by virtue of the copper heat sink provided by the main morcellator tube.

To assess the effectiveness of this characteristic, the SORD device was repeatedly activated in a stalled (non-moving) condition fully engaged on tissue for a period of approximately 10 seconds, and then immediately touched against a region of the subject's bowel tissue. This may be regarded as a worst-case scenario for heat build up. On each occasion the surgeons were impressed to find that there was no observable tissue effect on the bowel.

Smoke

Smoke levels were observed to be higher than those seen at a previous lab. The subject devices had been tested back to back with the previous devices before the lab, and smoke levels were comparable. The similarity of construction further confirms that this was not likely to be the cause for increased levels. Several other factors were noted that may have contributed to increased obscuration at this lab:

- Firstly, the seal performance was markedly better than the last lab (ref document 874012). With no leakage in the passive case, and minimal leakage in use, there was little throughput of insufflant to clear the field of view. Flow rates were observed to be commonly below 4lpm
- Secondly, the insufflator was set to an upper limit of 4lpm for the first part of the procedure, thereby further limiting throughput. (This was intentional, to test whether a low flow insufflator could maintain intra abdominal pressure.)
- Finally, the success of the SORD and grasper at removing tissue was in marked contrast to its inability to remove tissue at the last lab, so more activation contributed to more smoke.

Surgeons commented that whilst less smoke production would clearly be preferable, the levels observed were not off-putting, and did not unduly obscure visualisation. Dr Lyons also commented that he would expect this with an RF device, and that he would be happy to use smoke extraction, probably through one of the other ports

Nerve Stimulation

On several occasions during the lab, twitching of the abdominal wall muscle was observed. Dr Lyons commented that the placement of the epigastric nerve, which was believed to be the stimulated nerve, might not be as problematic in the human subject. This firstly occurred when the device tube was in contact with the wall, allowing a circuit to be made between external tube return and active. Insulating the external return with tape stopped this from happening.

A similar stimulation effect was noted when the now insulated tube was in contact at the same time as target tissue held by the grasper, again presenting a closed circuit for current. It is not clear whether the active contact was direct or capacitive. [Note also, the subject would have been earthed via a monopolar return pad.] It should be noted that in this study, there was no observed damage to the peritoneum when there was contact of the SORD distal tip with the abdominal wall. This suggests that no genuine plasma activation had occurred, and thus the risk of inadvertent tissue damage due to this condition was less than that presented by mechanical morcellators, such as the predicate X-Tract device, that may come in contact with the abdominal wall, where the potential exists to cause unwanted tissue effect in both its passive and activated state

Motor nerve stimulation was clearly possible, and may happen in the field where there is often little space for manoeuvre at the start of a procedure (surgeons noted that the maximum size of uterus to consider for laparoscopic hysterectomies was 22weeks). However, in each case where nerve stimulation was observed, the Active Ring (at the distal tip of the morcellator tube) was in contact with the abdominal wall, as well as either the external return on the morcellator shaft

tube, or the grasper. It should also be noted that not only must the Active Ring be in contact with tissue while one of the return electrodes is also in contact with same tissue, that tissue must be contiguous with a motor nerve.

Further investigation of the triggering mechanism revealed that an initial voltage step change present at the start of the 400ms pulse was the trigger mechanism for the observed instance of nerve stimulation. Since the output frequencies of the RF generators to be used with the SORD, especially the G400 Workstation, are typically 400kHz, these frequencies during each pulse should be high enough to minimize potential nerve response, although analysis indicates that it is possible to elicit a response at a pulse cycle time of 2Hz. However, this situation would only present itself in a misuse scenario. Additionally, it should be noted that the distal tip of the SORD would in the course of normal use and care be applied to tissue that has already been dissected, and thus would not be as likely to elicit a nerve response.

Finally, it should be noted that the device must be activated in order for the step change current referenced above to be created through the motor nerve by bridging it with the Active and Return electrodes, thereby creating a circuit between the electrodes through the tissue containing the nerve. In summary, the device must be activated, and the tip (distal most circumference) and a return must be in contact with the abdominal wall. It should be noted that the target tissue for application of the morcellator tip would have been dissected and should not be in a position to promulgate an electrical response to adjacent tissue.

As noted above, in each case where nerve stimulation was observed during the pre-clinical studies, the Active Ring (at the distal tip of the morcellator tube) was allowed to contact with the abdominal wall while one of the returns was also allowed to contact the abdominal wall. It is not clear that the investigators kept the distal tip in view at all times during conduct of the study. Nerve stimulation only resulted when the active ring located on morcellator tube's distal tip and either the external return or the grasper was also in contact with the abdominal wall while the device was activated. As a mitigating measure to this possibility, please refer to the Warnings section of the Instructions for Use provided in **Appendix 12A**.

The effort to insulate the tube described above provided an effective interruption to the current path while the active ring and external return were in contact with abdominal wall, and thus halted the nerve stimulation through that path. Complete masking of the external return does not necessarily resolve nerve stimulation, however it does limit the number of scenarios in which it can occur. The subsequent observation of nerve stimulation when the grasper was in contact with the target tissue was not a failure of this measure, but shared the common root cause of the active ring being in contact with the abdominal wall at the same time as a potential return path. Risk of collateral damage will have prevented X-Tract users from activating morcellators in such close proximity to the abdominal wall, and this device should command the same level of care, whilst apparently demonstrating a lower level of risk of damage if activated in such scenarios.

The presence of the external return at the tip is advantageous since it is the most likely of the three possible returns (internal, external and grasper) to maintain good tissue contact during normal use, and allow the circuit to be completed with a good electrical return path. As noted in the above excerpt, the internal return and grasper return may experience some variability in maintaining a good electrical return path. Good contact is necessary to ensure that the device does not experience a reduction in efficacy due to high resistance / poor continuity contact, whereby power delivery may diminish causing the tissue to be desiccated rather than cleanly cut. As indicated in the original submission (page 25, second paragraph), the external return is insulated

by both local insulation and the shaft coating, which can withstand a minimum of 750VDC, or approximately twice the output of the Gyrus Generators to which the SORD would be connected.

Also, the close proximity of the external return electrode to the active electrode on the distal tip also helps to draw heat away from the active electrode. The external return allows heat resulting from the application of the RF energy to be drawn proximally up into the shaft where it can be safely dissipated. This has the effect of rapidly cooling the active tip once cutting ceases, and therefore makes the device safer since it becomes very unlikely for accidental contact with collateral tissue to cause heat damage.

All surgeons agreed that the stimulation phenomenon was not a safety risk, but that the effect may be off-putting to users. The clinicians did not feel this was a safety problem *per se*, any more than those presented by operation of mechanical morcellators in proximity to the abdominal wall. As a morcellator, the SORD should be utilized with the same level of care as those currently required of a mechanical morcellator, such as the predicate X-Tract, where any abdominal wall contact is undesirable. Indeed, as a result of the risk analysis performed during the product's development, mitigation measures were instituted through the inclusion of specific Warnings in the Instructions for Use regarding the use of the device in close proximity to the abdominal wall, and keeping the tip of the device in the field of view at all times (please refer to Instructions for Use included in **Appendix 12.A** of this submission).

Nevertheless, Gyrus Medical conducted an additional study to assess several aspects of the device performance, including the nerve stimulation reported in the University of Minnesota study. The conditions observed in the University of Minnesota study were repeated and the above analysis affirmed. Specifically, nerve stimulation only resulted when the active ring located on morcellator tube's distal tip and either the external return or the grasper was also in contact with the abdominal wall. In other words, this would only be clinically relevant in a scenario where the user failed to observe the same level of care as would be utilized with a mechanical morcellator, i.e., a misuse scenario, and specifically failed to heed the Warnings included in the Instructions for Use. A comparison of the relative risks presented in such a scenario by the SORD and the predicate X-Tract is discussed further on page 10 of this report.

While the report notes some blanching occurring where there was activation and contact of the active ring with the abdominal wall, this was considered consistent with the operation of any other bipolar device that may inadvertently come into contact with non-target tissue. Again, as a result of the risk analysis performed during the product's development, mitigation measures were instituted through the inclusion of Warnings in the Instructions for Use regarding the familiarity of the user with electrosurgical devices, and the risk of tissue damage from inappropriate use of these devices (please see the Instructions for Use included in **Appendix 12.A** of this submission).

General Safety

Two further questions relating to device safety were posed to the surgeons. In respect of the risks associated with 'seeding' of cancerous or pre-cancerous cells, Dr Lyons commented that the SORD presented a lower risk in comparison to competitor products since RF cutting effectively destroys cells, and that without rotating parts, unlike mechanical morcellators the SORD morcellator does not cast tissue.

Dr Lyons made the further comment that in his opinion based on his prior experience with the X-Tract competitor device and his experience with the SORD device at this lab, the risk to benefit balance is overall positive in favor of adoption of the SORD device compared to competitor devices.

Conclusions:
All devices functioned correctly throughout the lab. Device 5 was used for most of the testing. Appendix 2 of the report shows the tip of this device after use, exhibiting little degradation of the silicone tip insulation.

All the surgeons present for this lab recorded positive feedback and expressed their desire to continue to assist in the development and ultimately use the device in the field. Any safety risks identified were felt by the surgeons to be at an acceptably low level and overall the device was felt to offer advantage over competitor morcellators in the field.

Key Lab Outputs:

- Depth stop acceptable
- Shaft to be light grey
- Handle to be 'Option 5' as presented
- 2x3 grasper jaw to proceed as primary format
- LMS inverting seal acceptable
- Cable exit from top of grasper handle
- Software performance appropriate on both G400 and SP workstations
- Clinical model should consider using tongue for duty cycle testing. Heart may present the better model for smoke assessment. Human fibroid should be pursued to support product validation

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name GEORGE J. MOTTAMAL

Subject: 510(k) Number K080073/S1

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			X
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		X

Regulation Number	Class*	Product Code
878.4400	II	GEI

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____ (Branch Chief) GSDB (Branch Code) 5/2/08 (Date)

Final Review: Mark N Melkerson (Division Director) 5/2/08 (Date)

MEMO TO THE RECORD
K080093/S1

DATE: May 2, 2008 **OFFICE:** HFZ-410
FROM: Polymer Chemist **DIVISION**: DGNRD/GSDB

DEVICE NAME: Gyrus ACMI PKS Plasma Morcellator

COMPANY NAME: Gyrus ACMI, Inc.

CONTACT: Terrence E. Sullivan, Director, Regulatory Affairs
(Tel. No. 508-804-2739& Fax. No. 508-804-2624,
Email: Terry.Sullivan @ gyrusacmi.com)

BACKGROUND:

The subject submission, K080093, is the same submission (K063134/S2) that the **Ob/Gyn Devices Branch, DRARD** previously reviewed and found NSE on July 13, 2007 due to the "failure of the sponsor (Gyrus ACMI, Inc) to provide "sufficient information to adequately respond to" FDA requests on material issues (**please see the copies of the NSE letter dated July 13, 2007, and the final review memo of the Lead reviewer of K063134/S2, Ms. Kathryn S. Daws-Koop, M.S. which are enclosed with this review**). The sponsor has claimed their device, Gyrus ACMI PKS Plasma Morcellator, SE to the following predicate devices:

- Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula (K041633);
- Ethicon Inc. Gynecare Laparoscopic Morcellar (K993801).

DEVICE DESCRIPTION AND PERFORMANCE: The Gyrus ACMI PKS Plasma Morcellator is intended to cut, core, and extract tissue in various general surgical, urological, and gynecologic operative laparoscopy procedures. Tissue effects include the gross resection of tissue (such as uterine tissue and fibroids following Laparoscopic Supracervical Hysterectomy) allowing removal of this tissue through a laparoscopic port. The device would be used in a CO_2 or Air insufflated environment at standard laparoscopic abdominal pressures (up to 15 mm Hg). As a bipolar electrosurgical device, the PKS Plasma Morcellator would operate on irrigated tissue (e.g., Saline, Ringer's, Sterile Water) to enhance the PlasmaCision tissue effect, and without undue effect on safety or efficacy.

The PKS Plasma Morcellator device consists of two main elements (the entire device is illustrated in **Figure 10.1** below). The first is a Morcellator (see **Figure 10.2** below), which includes a cutting shaft and handle with an integrated electrical cable that connects to either a Gyrus General Surgery Workstation (cleared under 510(k) K050550) or Gyrus SuperPulse Generator (cleared under 510(k) K031085). The second element consists of a Grasper (see

Figure 10.3 below) that passes through the hollow shaft of the Morcellator, to grasp tissue and retract it toward the cutting element on the Morcellator shaft tip. An obturator (not pictured) may also be used to assist in the introduction of the device in laparoscopic procedures, and like the grasper, is positioned through the shaft of the Morcellator tube when being utilized.

Figure 10.1 – PKS Plasma Morcellator

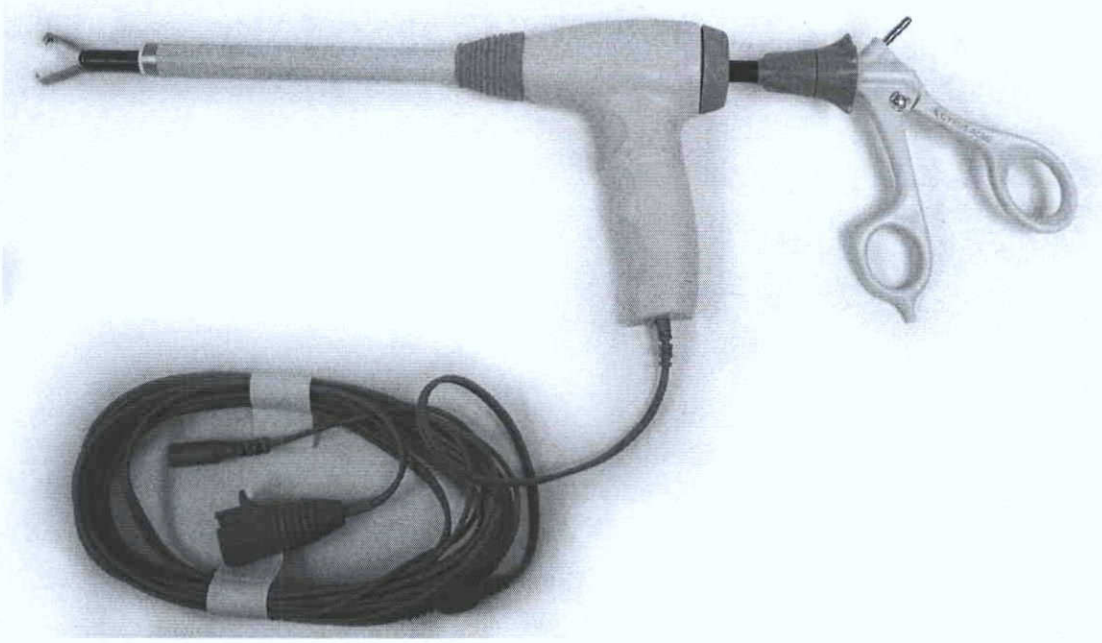


Figure 10.2 – PKS Plasma Morcellator – Morcellator

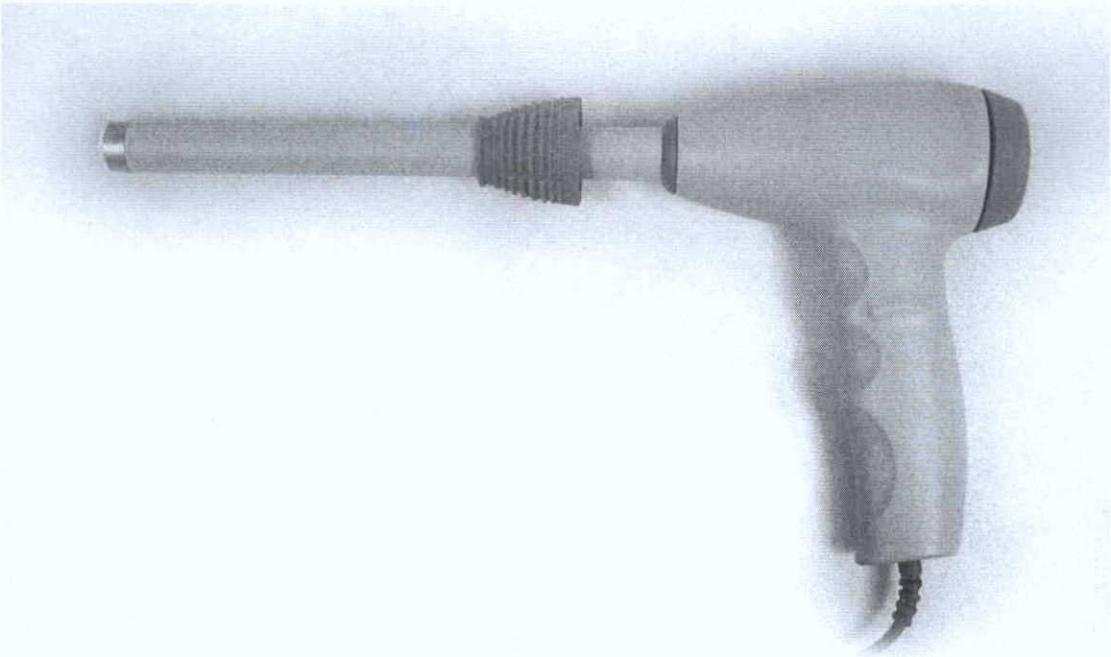
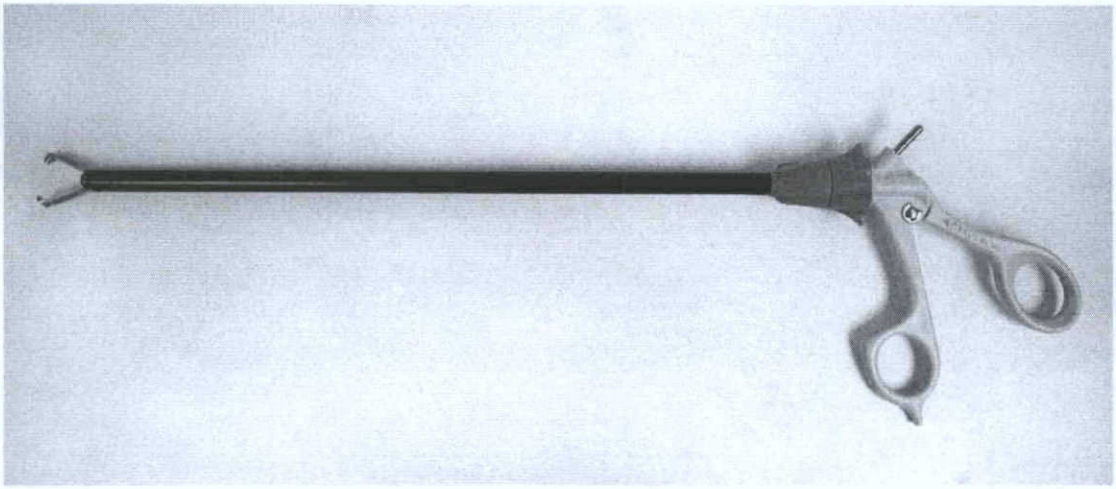


Figure 10.3 – PKS Plasma Morcellator – Grasper Element



COMPARISON WITH PREDICTE DEVICE: The main difference between this device and the other morcellators on the market is that this device uses electrosurgical energy to cut tissue rather than a mechanical system (sharpened metal blade). Specifically, Several tissue morcellators presently on the market, such as the predicate Gynecare Laparoscopic

Morcellator (K993801) and the Gynecare *Morcellex** Tissue Morcellator (K061050), utilize a powered rotating cutting blade to dissect tissue. The PKS Plasma Morcellator device uses Gyrus ACMI's **unique Bipolar PlasmaCision technology** to cut, core, and extract devascularized, dissected tissue in operative laparoscopy. Further, most, but not all, morcellators have a motorized system for grinding or chewing tissue into smaller pieces. This device and its mechanical predicate actually cut tissue plugs that are extracted through the hollow shaft of the device.

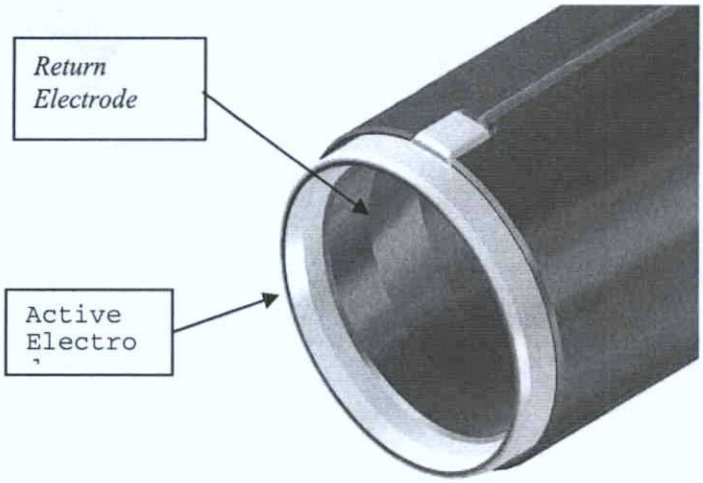
DRARD review solved issues regarding the nerve stimulation issues that were adequately resolved. **There remains an issue regarding material safety data.** According to DRARD, information was provided on the multiple individual materials. The information was adequate for the individual materials with the exception of a gold plated copper and a braided polymer. However, because of possible combined effects, DRARD wanted to see biocompatibility testing of the final finished product.

SURGICAL SETTING AND MODE OF OPERATION: The Morcellator is configured in an ergonomically friendly pistol grip configuration, and includes an axially oriented hollow shaft. The pistol grip integrates the electrical connection cable that allows bipolar RF energy to be supplied by a Gyrus generator to the tissue site. The design of the pistol grip body is such that a **clinician may utilize a "ski-pole" grip** on the Morcellator body, if that is their preference.

The hollow shaft of the Morcellator has an operative length of approximately 15 cm, extending distally from the pistol grip body. The surface of the Morcellator shaft is smooth, allowing the device to be introduced to the operative site through a trocar cannula seal, or with the use of the optional obturator, through an abdominal port. To facilitate optimal placement of the device during laparoscopic procedures, a depth stop normally located at the distal end of the pistol grip (at the junction of the pistol grip and Morcellator shaft), may be moved distally along the Morcellator shaft. The shaft has a nominal outer diameter of 15 mm, and a nominal inner diameter of 12 mm. The proximal end of the shaft also includes an elastomeric reducer that permits the passage of the grasper to the operative site and removal of tissue slugs from the operative site, while preventing loss of pneumoperitoneum.

As indicated above, the Morcellator includes an integrated electrical connector cable, with either a 5-pin or 9-pin connector plug that may be inserted into the Gyrus–SuperPulse Generator or Gyrus General Surgery Workstation, respectively. Bipolar electrosurgical energy is applied through the use of a foot pedal that is supplied with the respective Generator. The active loop of the PKS Plasma Morcellator's integrated electrical cable is connected to leads within the Morcellator body that are in turn connected to a circular active electrode integrated into the distal tip of the device (see **Figure 10.4** below).

Figure 10.4 – Distal Tip Electrode Configuration


Return
Electrode
Active
Electro

As indicated in Figure 10.4, the distal tip of the device also includes an axially oriented return electrode that is electrically isolated from the active electrode and connects through the Morcellator body to the return loop of the electrical cable. Due to the placement of the active electrode ring and insulating overmold on the distal tip of the shaft, the internal and external return electrodes are simply contiguous parts of the same copper tube. The terms "internal return" and "external return" essentially refer to the respective face of the copper tube surface that may act as a return to complete the current path. More detailed illustrations of the Morcellator shaft and grasper, enlarged illustration of the distal tip showing the relationship between the internal and external return electrode, as well as an illustration showing the possible return paths of the bipolar energy are provided in ***Appendix 10.A****.*

In addition to these contact points, there is also a return electrode integrated into the Grasper that connects to the return loop of the electrical cable. This is more fully described in the "Detailed Description of the Grasper" section below. A more detailed illustration of the major assemblies and the RF Workstation connections is also provided in ***Appendix 10.B****.*

When the PKS Plasma Morcellator is applied to an operative site, the Grasper is introduced through the Morcellator shaft, and draws the tissue to be morcellated into close proximity to the active electrode (see **Figures 10.5 through 10.9** below). Bipolar PlasmaCision energy is applied; cutting the tissue into a plug that may be extracted through the Morcellator shaft. The electrosurgical effect is delivered via two poles, the active electrode and the combined return electrodes contained in the Morcellator shaft and Grasper. The narrow distal surface of the circular active electrode results in a local high current density at the point of tissue application, which promotes arcing leading to localized tissue vaporization. The large area of the combined return electrodes results in a significantly lower current density, which prevents arcing at the return electrode.

With the exception of the necessary exposed region at the functional tip, all conductors carrying electrosurgical current are insulated from the user and patient. This is primarily achieved by local insulation around each of the conductors with secondary insulation provided by the shaft coating, the polymer hand piece and the cable jacket. The external surface of the Morcellator shaft is electrically insulated to withstand a minimum of 750VDC (approximately twice the output of the respective Gyrus Generators), so that the electrical energy return path is through the axially oriented electrode within the Morcellator shaft, or through the Grasper return electrode.

Figure 10.5 – Grasping Tissue

(b)(4) Schematics

[redacted]

Figure 10.8 – Detail of Current Flow through Grasper

(b)(4) Schematics

[redacted]

Figure 10.9 – Detail of Current Flow through shaft

(b)(4) Schematics

[redacted]

The **Grasper** consists of an ergonomically friendly proximal handle, a rotating insulated shaft, and a pair of symmetrically opening jaws. The jaws themselves are insulated along their length to prevent shorting in the event of contact with the active circular electrode. The handle body also includes a banana plug allowing for attachment of the second return loop of the electrical cable assembly referenced in the Morcellator description above.

The jaws are dual action, and able to open to at least an angle of approximately 50° by the activation of a pair of fully enclosed finger loops on the proximal handle body. The jaws utilize interlocking teeth to allow the Grasper to be easily introduced through the seals in the Morcellator body, and allow secure grasping of tissue (including penetration of fibroid tissue). The standard Grasper offering will be a 2x3 jaw configuration (2 teeth on one jaw and 3 teeth on the opposite jaw), since the pre-clinical studies (discussed at greater length in Section 17.0) indicated that this configuration was better able to handle soft tissue and small strands of tissue common towards the latter stages of morcellation. These and other study results also suggested that a 2x1 jaw configuration (2 teeth on one jaw and 1 tooth on the opposite jaw) performed better with respect to grasping dense indurated tissue, such as uterine fibroids. As a result, a second grasper, with a 2x1 jaw tooth configuration, will be offered as an accessory

to the PKS Plasma Morcellator. Other than the jaw tooth configuration, all other aspects of this accessory grasper will be the same as the grasper with the standard 2x3 jaw tooth configuration.

The outer diameter of the Grasper shaft is approximately 10mm, and the shaft of the grasper is approximately 336 mm in length (not including the handle body). Since the overall length of the Morcellator pistol grip is approximately 270 mm in length, with a working length of approximately 150 mm, the distal tip of the graspers can extend beyond the distal tip of the pistol grip a maximum of approximately 66 mm. This allows the jaws to extend sufficiently beyond the Morcellator shaft so that they may fully open and grasp tissue. To better illustrate these dimensions, please refer to **Appendix 10.A**. The outer surface of the Grasper shaft is enclosed in insulation to maintain a continuous electrical return path to the Grasper handle's banana plug and PKS Plasma Morcellator connector cable.

The **Obturator** is disposable, and constructed of polymer materials. Since the user has the option of introducing the Morcellator shaft through a previously placed trocar cannula, use of the Obturator is not mandatory with each use of the PKS Plasma Morcellator. The distal tip is rounded, with an approximate diameter of 6mm, which conically tapers up to the inner diameter of the hollow Morcellator shaft. The length of the Obturator is such that the distal tip extends beyond the Morcellator shaft, forming a "bullet nose", allowing the Obturator to sufficiently dilate a 10mm incision so that the external diameter of the PKS Plasma Morcellator shaft may be accommodated.

ANALYSIS OF SUBJECT SUBMISSION, K080093

The Original NSE submission (K063134/S2) 's lead reviewer was **Ms. Kathryn S. Daws-Koop, OGDB/DRARD,** and its clinical, biocomatability aspects were reviewed by, Julia Corrado,M.D., Mike Bailey, Ph.D, and Cotterel, Ph.D respectively under the direction of Herb Lerner, M.D.(currently DRARD's Deputy Director for Clinical). Discussing with these FDA personnel and Mr. Collin M. Pollard, Chief, Ob/Gyn Device Brach, DRARD, revealed that only issue regarding this submission is **material issues (please see the enclosed e-mail message)** such as the following:

Dr. Bailey reviewed the total information provided in the biocompatibility issues regarding the device and determined that there were issues with the information provided for the gold-plated copper and braided resin with polane gray paint. He also indicated in his review dated July 6, 2007, that all of the materials together may have a synergistic effect. Accordingly, he requested **full material safety testing** on the final finished product(i.e,S 2 submission) in the following question:

The company should provide independent biocompatibility testing on this device in accordance with ISO 10993-1 for a device with limited contact (<24h) with tissue. This would include cytotoxicity, irritation and sensitization testing of the patient contacting

portions of your device. For the irritation and sensitization testing, both polar and non-polar extracts of the device should be assessed. *If possible, provide a sample of your device to accompany the device photographs.*

In response to this request (S2), this deficiency was unanswered.

Accordingly, review the subject resubmitted submission, K080093, revealed that the sponsor has **responded this materials issues**, hence the material portion of this submission was reviewed by Dr. Mike Baily (**Please see the enclosed review of Dr. Bailey which is attached with this memo**).

According to Dr. Bailey," **The company has provided sufficient evidence to support the previous use of the grasper components in other devices. Results acceptable.**"

However, Dr. Bailey has the following two more concerns (questions) regarding the material issues of the device which he requests that sponsor should response:

Questions for the Company

1. Biocompatibility of the obturator potion of your device was done on the material used to make this portion of the device (Terluran HD 15), and not on finished sterilized obturators. Please justify why testing on Terluran HD 15 is supportive of the safety of your finished, sterilized device. This justification should state the similarities and differences between the material tested and the finished device component (e.g., mold release agents, colorants, sterilization procedures, etc.). A detailed discussion why any differences in materials tested should not impact the use of the data supplied should also be included in your response. Please note that an inadequate response to this question may require the need for additional biocompatibility testing on this device.

2. Biocompatibility testing to demonstrate the safety of the obturator material (Terluran HD 15) did not include sensitization testing for this portion of the device. Please provide sensitization testing (e.g., ISO Maximization Test) using both polar and non-polar extracts of your device. Alternatively, provide a justification why sensitization testing on your device is not needed. Please note that an inadequate response to this question may require the need for additional biocompatibility testing on this device.

After discussing these issues in the DGRND 510 (k) Round on March 24, 2008 and discussing with Mr. Neil Ogden, M.S., Chief, DGRND, these issues were discussed then with Collin M. Pollard, Chief, Ob/Gyn Device Brach, DRARD.

On 3/27/08, the sponsor (**Mr. Terrence E. Sullivan**) was contacted and requested the following:

1. Biocompatibility of the obturator potion of your device was done on the material used to make this portion of the device (Terluran HD 15), and not on finished sterilized obturators. Please justify why testing on Terluran HD 15 is supportive of the safety of your finished, sterilized device. This justification should state the similarities and differences between the material tested and the finished device component (e.g., mold release agents, colorants, sterilization procedures, etc.). A detailed discussion why any differences in materials tested should not impact the use of the data supplied should also be included in your response. Please note that an inadequate response to this question may require the need for additional biocompatibility testing on this device.

2. Biocompatibility testing to demonstrate the safety of the obturator material (Terluran HD 15) did not include sensitization testing for this portion of the device. Please provide sensitization testing (e.g., ISO Maximization Test) using both polar and non-polar extracts of your device. Alternatively, provide a justification why sensitization testing on your device is not needed. Please note that an inadequate response to this question may require the need for additional biocompatibility testing on this device.

3. the subject device shows that it has an annular cutting edge right at the distal end, with a grasping forceps to pull the tissue into the tube. So it looks like the device essentially "cores" the tissue. But what causes the tissue to break free from the fibroid, tumor, or whatever is being morcellated, in order to remove it from the surgical field? Also, please remind me what the indications for use are? Can it be used to morcellate an entire uterus during hysterectomy? Please provide a detailed explanation regarding this issue.

On 3/27/08, the subject K080093 submission was placed on hold. (**Please see the AI hold letter dated 3/27/08**) until the referenced additional information was received by the FDA On hold until the referenced additional information was received by the FDA. The submission, K080093/S1 was returned with the required AI on 4/22/08

ANALYSIS OF SUBJECT SUBMISSION, K080093/S1

The sponsor has **responded this materials issues** (The above mentioned two questions), hence the material portion of this submission was reviewed by Dr. Mike Baily **(Please see the enclosed review of Dr. Bailey which is attached with this memo)**.

According to Dr. Bailey," **The company has provided sufficient evidence to support the previous use of the grasper components in other devices. Accordingly, the results are acceptable**."

Specifically, Dr. Bailey's review is the following:

"For **question 1**, the company states that the material tested was not identical to the final material used in the finished obturator device. Differences include the inclusion of a grey colorant and the final devices are sterilized (devices tested do not appear to have been sterilized). The grey colorant makes up less than 1% of the total weight of the product and due to the nature of the solid polymer, has a limited potential for dye leaching (no testing provided). The device is also sterilized before use, but the levels of EtO residuals on finished devices are reported to be within acceptable limits per ISO 10993-7. Also, no mold release agents are used in the manufacture of this device. It should also be noted that this portion of the device will only have limited contact with the body < 1 minute during use. Due to the limited exposure potential (time and surface contact), the anticipated colorfastness of the colorant material, the lack of mold release agents, and the levels of EtO residuals within ISO 10993-7 limits, **I find this justification acceptable**.

For **question 2**, the company has decided to submit a justification for not conducting additional sensitization testing on the obturator portion of the device. The company refers to the results of other biocompatibility test data conducted, and their response to question 1 above regarding the potential contact potential of this portion of the device. Due to the limited contact potential of this device and the results of other biocompatibility testing conducted on this material, **I find the company's response adequate".**

Accordingly, the sponsor has adequately addressed.

Regarding Question #3 the sponsor has responded that "during the pre-clinical animal tissue evaluations, several morcellation techniwues were utilized, including the "peeling" and "coring" techniques. The clinician feed back during these animal studies indicated that "peeling" technique was preferred as it allowed for a more cohesive mass of remaining tissue, facilitating subsequent "peeling" passes, and allowed a longer slug of tissue to be removed at a single pass. As a result, this technique will be emphasized in future PKS Plasma Morcellator educational and training materials. The sponsor adds that "Unlike the predicate X-Tract device, the PKS Plasma Morcellator's active ring, located on the distal tip of the morcellator tube and which acts like the X-Tract's rotating cutting blade, does not become dull with use. As a result, the subject PKS Plasma Oscillator could be utilized to morcellate the entire uterus in a hysterectomy procedure if so desired by the clinician". I believe that the sponsor adequately explained our question in this regard. Accordingly, there are no new issues regarding this device.

1. **Administrative Requirement**

	Yes	No
Indications for Use page (Indicate if: Prescription)	X	
Truthful and Accuracy Statement	X	
510(k) Summary	X	
Standards Form		X

II. Device Description

	Yes	No
Is the device life-supporting or life sustaining?		X
Is the device an implant (implanted longer than 30 days)?		X
Does the device design use software?		X
Is the device sterile? The disposable electrode insertion device (EID) is supplied sterile for single use patient use only.	X	
Is the device reusable (not reprocessed single use)? cooling system hand piece are supplied non-sterile and are re-usable and		X

III. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?		X	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		X	If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: **SE**

INTENDED USE/INDICATIONS FOR USE: The subject device, **Gyrus ACMI PKS Plasma Morcellator,** is indicated for "cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynrcologic procedures". This intended use very similar **(Chart 3)** to its predicate devices in particular to the sponsor's Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula (K041633); and the Ethicon Inc. Gynecare Laparoscopic Morcellar (K993801).

PREDICATE DEVICE (S): The subject **Gyrus ACMI PKS Plasma Morcellator** is SE **(Chart 3)** in technological characteristics **(Chart 5)**, and function, to predicate devices, the sponsor's Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula (K041633); and the Ethicon Inc. Gynecare Laparoscopic Morcellar (K993801).

STERILITY, PACKAGING, AND LABELING: The subject **Gyrus ACMI PKS Plasma Morcellator** will be supplied sterile and disposable as its predicate device, the sponsor's Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula (K041633). It will be sterilized using Ethylene Oxide using a cycle validated per ISO 11135 to achieve a SAL of 10^{-6}. The sponsor has provided a draft labeling that contains Directions for Use Statement, Unit Operation, contraindications, warnings, and precautions, specifications, and necessary warning and

MEMO TO THE RECORD
K080093/S1

DATE: May 2, 2008 **OFFICE:** HFZ-410
FROM: Polymer Chemist **DIVISION**: DGNRD/GSDB

DEVICE NAME: Gyrus ACMI PKS Plasma Morcellator

COMPANY NAME: Gyrus ACMI, Inc.

CONTACT: Terrence E. Sullivan, Director, Regulatory Affairs
(Tel. No. 508-804-2739& Fax. No. 508-804-2624,
Email: Terry.Sullivan @ gyrusacmi.com)

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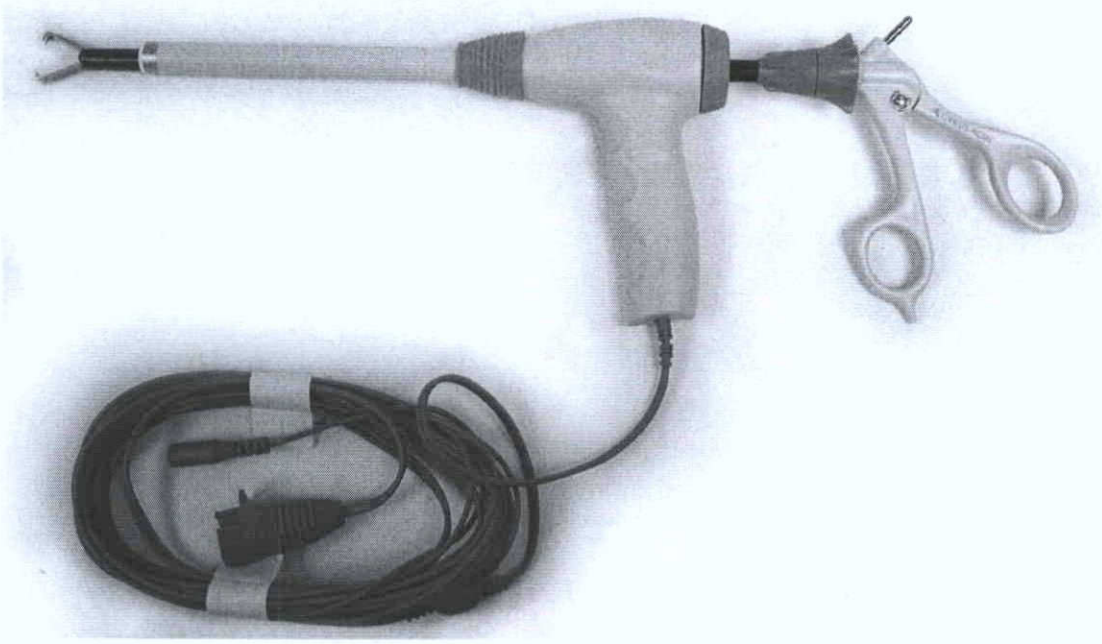


Figure 10.2 – PKS Plasma Morcellator – Morcellator

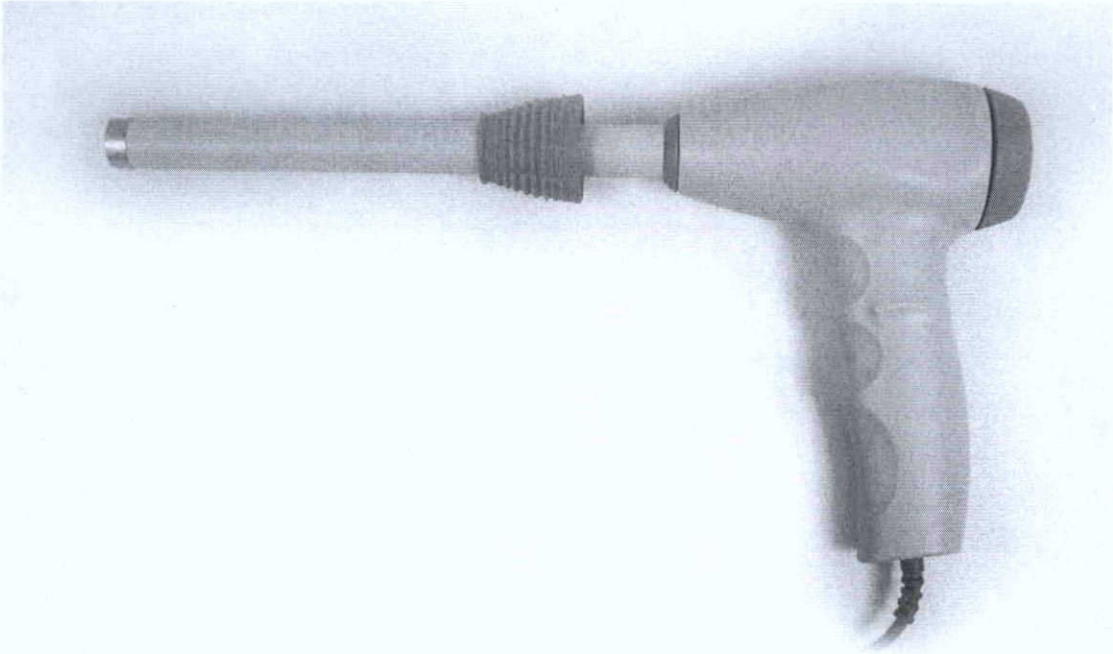
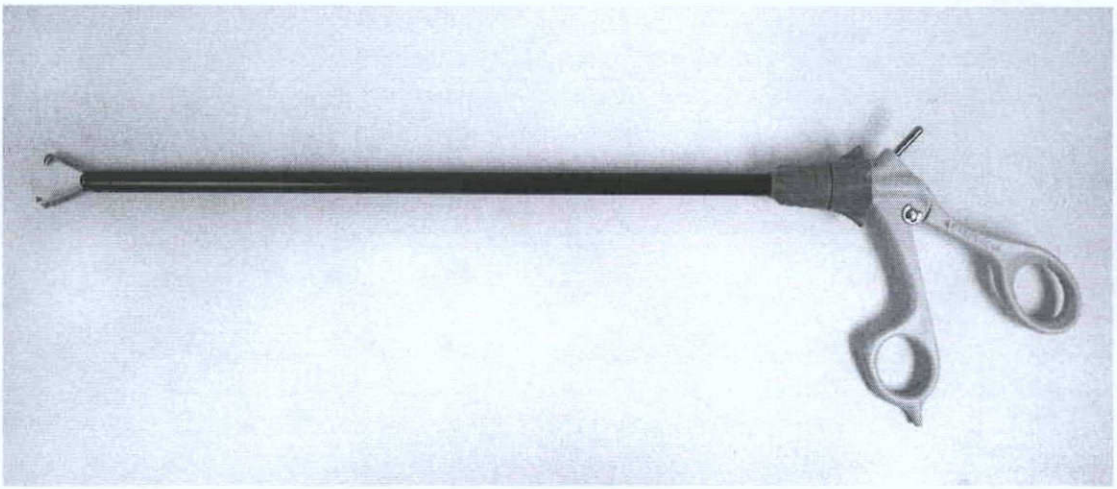


Figure 10.3 – PKS Plasma Morcellator – Grasper Element



COMPARISON WITH PREDICTE DEVICE: The main difference between this device and the other morcellators on the market is that this device uses electrosurgical energy to cut tissue rather than a mechanical system (sharpened metal blade). Specifically, Several tissue morcellators presently on the market, such as the predicate Gynecare Laparoscopic

Morcellator (K993801) and the Gynecare *Morcellex** Tissue Morcellator (K061050), utilize a powered rotating cutting blade to dissect tissue. The PKS Plasma Morcellator device uses Gyrus ACMI's **unique Bipolar PlasmaCision technology** to cut, core, and extract devascularized, dissected tissue in operative laparoscopy. Further, most, but not all, morcellators have a motorized system for grinding or chewing tissue into smaller pieces. This device and its mechanical predicate actually cut tissue plugs that are extracted through the hollow shaft of the device.

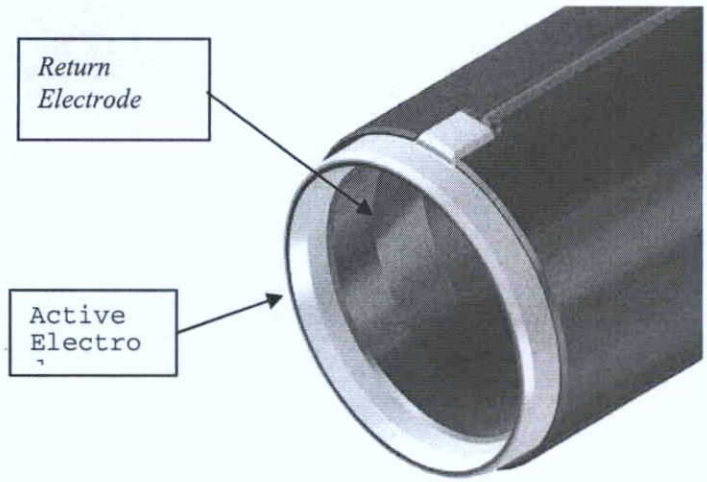
DRARD review solved issues regarding the nerve stimulation issues that were adequately resolved. **There remains an issue regarding material safety data.** According to DRARD, information was provided on the multiple individual materials. The information was adequate for the individual materials with the exception of a gold plated copper and a braided polymer. However, because of possible combined effects, DRARD wanted to see biocompatibility testing of the final finished product.

SURGICAL SETTING AND MODE OF OPERATION: The Morcellator is configured in an ergonomically friendly pistol grip configuration, and includes an axially oriented hollow shaft. The pistol grip integrates the electrical connection cable that allows bipolar RF energy to be supplied by a Gyrus generator to the tissue site. The design of the pistol grip body is such that a **clinician may utilize a "ski-pole" grip** on the Morcellator body, if that is their preference.

The hollow shaft of the Morcellator has an operative length of approximately 15 cm, extending distally from the pistol grip body. The surface of the Morcellator shaft is smooth, allowing the device to be introduced to the operative site through a trocar cannula seal, or with the use of the optional obturator, through an abdominal port. To facilitate optimal placement of the device during laparoscopic procedures, a depth stop normally located at the distal end of the pistol grip (at the junction of the pistol grip and Morcellator shaft), may be moved distally along the Morcellator shaft. The shaft has a nominal outer diameter of 15 mm, and a nominal inner diameter of 12 mm. The proximal end of the shaft also includes an elastomeric reducer that permits the passage of the grasper to the operative site and removal of tissue slugs from the operative site, while preventing loss of pneumoperitoneum.

As indicated above, the Morcellator includes an integrated electrical connector cable, with either a 5-pin or 9-pin connector plug that may be inserted into the Gyrus–SuperPulse Generator or Gyrus General Surgery Workstation, respectively. Bipolar electrosurgical energy is applied through the use of a foot pedal that is supplied with the respective Generator. The active loop of the PKS Plasma Morcellator's integrated electrical cable is connected to leads within the Morcellator body that are in turn connected to a circular active electrode integrated into the distal tip of the device (see **Figure 10.4** below).

Figure 10.4 – Distal Tip Electrode Configuration


Return
Electrode
Active
Electro

As indicated in Figure 10.4, the distal tip of the device also includes an axially oriented return electrode that is electrically isolated from the active electrode and connects through the Morcellator body to the return loop of the electrical cable. Due to the placement of the active electrode ring and insulating overmold on the distal tip of the shaft, the internal and external return electrodes are simply contiguous parts of the same copper tube. The terms "internal return" and "external return" essentially refer to the respective face of the copper tube surface that may act as a return to complete the current path. More detailed illustrations of the Morcellator shaft and grasper, enlarged illustration of the distal tip showing the relationship between the internal and external return electrode, as well as an illustration showing the possible return paths of the bipolar energy are provided in ***Appendix 10.A****.*

In addition to these contact points, there is also a return electrode integrated into the Grasper that connects to the return loop of the electrical cable. This is more fully described in the "Detailed Description of the Grasper" section below. A more detailed illustration of the major assemblies and the RF Workstation connections is also provided in ***Appendix 10.B****.*

When the PKS Plasma Morcellator is applied to an operative site, the Grasper is introduced through the Morcellator shaft, and draws the tissue to be morcellated into close proximity to the active electrode (see **Figures 10.5 through 10.9** below). Bipolar PlasmaCision energy is applied; cutting the tissue into a plug that may be extracted through the Morcellator shaft. The electrosurgical effect is delivered via two poles, the active electrode and the combined return electrodes contained in the Morcellator shaft and Grasper. The narrow distal surface of the circular active electrode results in a local high current density at the point of tissue application, which promotes arcing leading to localized tissue vaporization. The large area of the combined return electrodes results in a significantly lower current density, which prevents arcing at the return electrode.

With the exception of the necessary exposed region at the functional tip, all conductors carrying electrosurgical current are insulated from the user and patient. This is primarily achieved by local insulation around each of the conductors with secondary insulation provided by the shaft coating, the polymer hand piece and the cable jacket. The external surface of the Morcellator shaft is electrically insulated to withstand a minimum of 750VDC (approximately twice the output of the respective Gyrus Generators), so that the electrical energy return path is through the axially oriented electrode within the Morcellator shaft, or through the Grasper return electrode.

Figure 10.5 – Grasping Tissue

(b)(4) Schematics

[redacted]

Figure 10.6 – Initial Activation

(b)(4) Schematics

[redacted]

Figure 10.7 – Ongoing Activation

(b)(4) Schematics

[redacted]

Figure 10.8 – Detail of Current Flow through Grasper

(b)(4) Schematics

[redacted]

Figure 10.9 – Detail of Current Flow through shaft

(b)(4) Schematics

[redacted]

The **Grasper** consists of an ergonomically friendly proximal handle, a rotating insulated shaft, and a pair of symmetrically opening jaws. The jaws themselves are insulated along their length to prevent shorting in the event of contact with the active circular electrode. The handle body also includes a banana plug allowing for attachment of the second return loop of the electrical cable assembly referenced in the Morcellator description above.

The jaws are dual action, and able to open to at least an angle of approximately 50° by the activation of a pair of fully enclosed finger loops on the proximal handle body. The jaws utilize interlocking teeth to allow the Grasper to be easily introduced through the seals in the Morcellator body, and allow secure grasping of tissue (including penetration of fibroid tissue). The standard Grasper offering will be a 2x3 jaw configuration (2 teeth on one jaw and 3 teeth on the opposite jaw), since the pre-clinical studies (discussed at greater length in Section 17.0) indicated that this configuration was better able to handle soft tissue and small strands of tissue common towards the latter stages of morcellation. These and other study results also suggested that a 2x1 jaw configuration (2 teeth on one jaw and 1 tooth on the opposite jaw) performed better with respect to grasping dense indurated tissue, such as uterine fibroids. As a result, a second grasper, with a 2x1 jaw tooth configuration, will be offered as an accessory

to the PKS Plasma Morcellator. Other than the jaw tooth configuration, all other aspects of this accessory grasper will be the same as the grasper with the standard 2x3 jaw tooth configuration.

The outer diameter of the Grasper shaft is approximately 10mm, and the shaft of the grasper is approximately 336 mm in length (not including the handle body). Since the overall length of the Morcellator pistol grip is approximately 270 mm in length, with a working length of approximately 150 mm, the distal tip of the graspers can extend beyond the distal tip of the pistol grip a maximum of approximately 66 mm. This allows the jaws to extend sufficiently beyond the Morcellator shaft so that they may fully open and grasp tissue. To better illustrate these dimensions, please refer to **Appendix 10.A**. The outer surface of the Grasper shaft is enclosed in insulation to maintain a continuous electrical return path to the Grasper handle's banana plug and PKS Plasma Morcellator connector cable.

The **Obturator** is disposable, and constructed of polymer materials. Since the user has the option of introducing the Morcellator shaft through a previously placed trocar cannula, use of the Obturator is not mandatory with each use of the PKS Plasma Morcellator. The distal tip is rounded, with an approximate diameter of 6mm, which conically tapers up to the inner diameter of the hollow Morcellator shaft. The length of the Obturator is such that the distal tip extends beyond the Morcellator shaft, forming a "bullet nose", allowing the Obturator to sufficiently dilate a 10mm incision so that the external diameter of the PKS Plasma Morcellator shaft may be accommodated.

ANALYSIS OF SUBJECT SUBMISSION, K080093

The Original NSE submission (K063134/S2) 's lead reviewer was **Ms. Kathryn S. Daws-Koop, OGDB/DRARD,** and its clinical, biocomatability aspects were reviewed by, Julia Corrado,M.D., Mike Bailey, Ph.D, and Cotterel, Ph.D respectively under the direction of Herb Lerner, M.D.(currently DRARD's Deputy Director for Clinical). Discussing with these FDA personnel and Mr. Collin M. Pollard, Chief, Ob/Gyn Device Brach, DRARD, revealed that only issue regarding this submission is **material issues (please see the enclosed e-mail message)** such as the following:

Dr. Bailey reviewed the total information provided in the biocompatibility issues regarding the device and determined that there were issues with the information provided for the gold-plated copper and braided resin with polane gray paint. He also indicated in his review dated July 6, 2007, that all of the materials together may have a synergistic effect. Accordingly, he requested **full material safety testing** on the final finished product(i.e,S 2 submission) in the following question:

The company should provide independent biocompatibility testing on this device in accordance with ISO 10993-1 for a device with limited contact (<24h) with tissue. This would include cytotoxicity, irritation and sensitization testing of the patient contacting

portions of your device. For the irritation and sensitization testing, both polar and non-polar extracts of the device should be assessed. *If possible, provide a sample of your device to accompany the device photographs.*

In response to this request (S2), this deficiency was unanswered.

Accordingly, review the subject resubmitted submission, K080093, revealed that the sponsor has **responded this materials issues**, hence the material portion of this submission was reviewed by Dr. Mike Baily (**Please see the enclosed review of Dr. Bailey which is attached with this memo**).

According to Dr. Bailey," **The company has provided sufficient evidence to support the previous use of the grasper components in other devices. Results acceptable**."

However, Dr. Bailey has the following two more concerns (questions) regarding the material issues of the device which he requests that sponsor should response:

Questions for the Company

1. Biocompatibility of the obturator potion of your device was done on the material used to make this portion of the device (Terluran HD 15), and not on finished sterilized obturators. Please justify why testing on Terluran HD 15 is supportive of the safety of your finished, sterilized device. This justification should state the similarities and differences between the material tested and the finished device component (e.g., mold release agents, colorants, sterilization procedures, etc.). A detailed discussion why any differences in materials tested should not impact the use of the data supplied should also be included in your response. Please note that an inadequate response to this question may require the need for additional biocompatibility testing on this device.

2. Biocompatibility testing to demonstrate the safety of the obturator material (Terluran HD 15) did not include sensitization testing for this portion of the device. Please provide sensitization testing (e.g., ISO Maximization Test) using both polar and non-polar extracts of your device. Alternatively, provide a justification why sensitization testing on your device is not needed. Please note that an inadequate response to this question may require the need for additional biocompatibility testing on this device.

After discussing these issues in the DGRND 510 (k) Round on March 24, 2008 and discussing with Mr. Neil Ogden, M.S., Chief, DGRND, these issues were discussed then with Collin M. Pollard, Chief, Ob/Gyn Device Brach, DRARD.

On 3/27/08, the sponsor (**Mr. Terrence E. Sullivan**) was contacted and requested the following:

1. Biocompatibility of the obturator potion of your device was done on the material used to make this portion of the device (Terluran HD 15), and not on finished sterilized obturators. Please justify why testing on Terluran HD 15 is supportive of the safety of your finished, sterilized device. This justification should state the similarities and differences between the material tested and the finished device component (e.g., mold release agents, colorants, sterilization procedures, etc.). A detailed discussion why any differences in materials tested should not impact the use of the data supplied should also be included in your response. Please note that an inadequate response to this question may require the need for additional biocompatibility testing on this device.

2. Biocompatibility testing to demonstrate the safety of the obturator material (Terluran HD 15) did not include sensitization testing for this portion of the device. Please provide sensitization testing (e.g., ISO Maximization Test) using both polar and non-polar extracts of your device. Alternatively, provide a justification why sensitization testing on your device is not needed. Please note that an inadequate response to this question may require the need for additional biocompatibility testing on this device.

3. the subject device shows that it has an annular cutting edge right at the distal end, with a grasping forceps to pull the tissue into the tube. So it looks like the device essentially "cores" the tissue. But what causes the tissue to break free from the fibroid, tumor, or whatever is being morcellated, in order to remove it from the surgical field? Also, please remind me what the indications for use are? Can it be used to morcellate an entire uterus during hysterectomy? Please provide a detailed explanation regarding this issue.

On 3/27/08, the subject K080093 submission was placed on hold. (**Please see the AI hold letter dated 3/27/08**) until the referenced additional information was received by the FDA On hold until the referenced additional information was received by the FDA. The submission, K080093/S1 was returned with the required AI on 4/22/08

ANALYSIS OF SUBJECT SUBMISSION, K080093/S1

The sponsor has **responded this materials issues** (The above mentioned two questions), hence the material portion of this submission was reviewed by Dr. Mike Baily (**Please see the enclosed review of Dr. Bailey which is attached with this memo**).

According to Dr. Bailey," **The company has provided sufficient evidence to support the previous use of the grasper components in other devices. Accordingly, the results are acceptable.**"

Specifically, Dr. Bailey's review is the following:

"For **question 1**, the company states that the material tested was not identical to the final material used in the finished obturator device. Differences include the inclusion of a grey colorant and the final devices are sterilized (devices tested do not appear to have been sterilized). The grey colorant makes up less than 1% of the total weight of the product and due to the nature of the solid polymer, has a limited potential for dye leaching (no testing provided). The device is also sterilized before use, but the levels of EtO residuals on finished devices are reported to be within acceptable limits per ISO 10993-7. Also, no mold release agents are used in the manufacture of this device. It should also be noted that this portion of the device will only have limited contact with the body < 1 minute during use. Due to the limited exposure potential (time and surface contact), the anticipated colorfastness of the colorant material, the lack of mold release agents, and the levels of EtO residuals within ISO 10993-7 limits, **I find this justification acceptable**.

For **question 2**, the company has decided to submit a justification for not conducting additional sensitization testing on the obturator portion of the device. The company refers to the results of other biocompatibility test data conducted, and their response to question 1 above regarding the potential contact potential of this portion of the device. Due to the limited contact potential of this device and the results of other biocompatibility testing conducted on this material, **I find the company's response adequate".**

Accordingly, the sponsor has adequately addressed.

Regarding Question #3 the sponsor has responded that "during the pre-clinical animal tissue evaluations, several morcellation techniwues were utilized, including the "peeling" and "coring" techniques. The clinician feed back during these animal studies indicated that "peeling" technique was preferred as it allowed for a more cohesive mass of remaining tissue, facilitating subsequent "peeling" passes, and allowed a longer slug of tissue to be removed at a single pass. As a result, this technique will be emphasized in future PKS Plasma Morcellator educational and training materials. The sponsor adds that "Unlike the predicate X-Tract device, the PKS Plasma Morcellator's active ring, located on the distal tip of the morcellator tube and which acts like the X-Tract's rotating cutting blade, does not become dull with use. As a result, the subject PKS Plasma Oscillator could be utilized to morcellate the entire uterus in a hysterectomy procedure if so desired by the clinician". I believe that the sponsor adequately explained our question in this regard. Accordingly, there are no new issues regarding this device.

1. **Administrative Requirement**

	Yes	No
Indications for Use page (Indicate if: Prescription)	X	
Truthful and Accuracy Statement	X	
510(k) Summary	X	
Standards Form		X

II. Device Description

	Yes	No
Is the device life-supporting or life sustaining?		X
Is the device an implant (implanted longer than 30 days)?		X
Does the device design use software?		X
Is the device sterile? The disposable electrode insertion device (EID) is supplied sterile for single use patient use only.	X	
Is the device reusable (not reprocessed single use)? cooling system hand piece are supplied non-sterile and are re-usable and		X

III. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?		X	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		X	If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: **SE**

INTENDED USE/INDICATIONS FOR USE: The subject device, **Gyrus ACMI PKS Plasma Morcellator,** is indicated for "cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynrcologic procedures". This intended use very similar **(Chart 3)** to its predicate devices in particular to the sponsor's Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula (K041633); and the Ethicon Inc. Gynecare Laparoscopic Morcellar (K993801).

PREDICATE DEVICE (S): The subject **Gyrus ACMI PKS Plasma Morcellator** is SE (**Chart 3**) in technological characteristics (**Chart 5**), and function, to predicate devices, the sponsor's Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula (K041633); and the Ethicon Inc. Gynecare Laparoscopic Morcellar (K993801).

STERILITY, PACKAGING, AND LABELING: The subject **Gyrus ACMI PKS Plasma Morcellator** will be supplied sterile and disposable as its predicate device, the sponsor's Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula (K041633). It will be sterilized using Ethylene Oxide using a cycle validated per ISO 11135 to achieve a SAL of 10^{-6}. The sponsor has provided a draft labeling that contains Directions for Use Statement, Unit Operation, contraindications, warnings, and precautions, specifications, and necessary warning and

cautions statements as per "**the Guidance Document for General Surgical Electrosurgical Devices".** And the draft labeling for the subject device is found to be satisfactory.

SAFETY AND EFFECTIVENESS INFORMATION & TRUTHFUL AND ACCURATE STATEMENT: The sponsor has provided 1) a 510 (k) summary of safety and effectiveness information and 2) a truthful and accurate statement about the device.

RECOMMENDATION: The subject device, **Gyrus ACMI PKS Plasma Morcellator**, is SE (**Chart 7**) to predicate devices, the sponsor's Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula (K041633); and the Ethicon Inc. Gynecare Laparoscopic Morcellar (K993801). The device is associated with the Electrosurgical Surgery and is categorized as 79 GEI (Electrosurgical Device, Cutting & Coagulation and Accessories) and the device is Class II based on 21 CFR 878.4400. Also device is associated with gynecologic procedures and is categorized as 85 HET, and the device is Class II based on 21 CFR 884.1720.

George J. Mattamal 5/2/08

George J. Mattamal, Ph.D., Reviewer **Date**
General and Surgery Devices Branch
Division of General, Restorative, and Neurological Devices.

5/2/08

Tina Kiang, Ph.D. **Date**
Acting Chief, General and Surgery Devices Branch
Division of General, Restorative, and Neurological Devices.

Neil R. P. Ogden, M.S., Acting Deputy Director, DGRND **Date**

Mattamal, George

From: Bailey, Michael T
Sent: Friday, May 02, 2008 10:48 AM
To: Mattamal, George
Subject: Gyrus

George,

I have reviewed the company's response to my questions.

For **question 1**, the company states that the material tested was not identical to the final material used in the finished obturator device. Differences include the inclusion of a grey colorant and the final devices are sterilized (devices tested do not appear to have been sterilized). The grey colorant makes up less than 1% of the total weight of the product and due to the nature of the solid polymer, has a limited potential for dye leaching (no testing provided). The device is also sterilized before use, but the levels of EtO residuals on finished devices are reported to be within acceptable limits per ISO 10993-7. Also, no mold release agents are used in the manufacture of this device. It should also be noted that this portion of the device will only have limited contact with the body < 1 minute during use. Due to the limited exposure potential (time and surface contact), the anticipated colorfastness of the colorant material, the lack of mold release agents, and the levels of EtO residuals within ISO 10993-7 limits, **I find this justification acceptable**.

For **question 2**, the company has decided to submit a justification for not conducting additional sensitization testing on the obturator portion of the device. The company refers to the results of other biocompatibility test data conducted, and their response to question 1 above regarding the potential contact potential of this portion of the device. Due to the limited contact potential of this device and the results of other biocompatibility testing conducted on this material, **I find the company's response adequate.**

My questions have been adequately addressed. No further questions for the company.

Michael T. Bailey, Ph.D.
FDA/CDRH/OGDB
9200 Corporate Blvd
Rockville, MD 20850
(240)276-4100
michael.bailey@fda.hhs.gov

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name GEORGE J. MATTAMAL

Subject: 510(k) Number K080093

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☒ Hold (Additional Information or Telephone Hold). (Telephone Hold of time)

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			X
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Is clinical data necessary to support the review of this 510(k)?			X
Does this device include an Animal Tissue Source?			X
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		X

Regulation Number	Class*	Product Code
878.4400	II	GEJ

(*If unclassified, see 510(k) Staff)

Additional Product Codes: HET of Class II

Review: [signature] (Branch Chief) GSOB (Branch Code) 3/28/08 (Date)

Final Review: _____ (Division Director) (Date)

Rev. 5/30/07

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		**YES**	**NO**
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)			X
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?			X
3. Does this device type require a PMA by regulation? (Please see management.)			X
Questions 4-8 are intended to help you start your review:		**YES**	**NO**
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc)			X
5. a. Did the firm request expedited review? (See management,)			X
b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html)			X
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:		X
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:		X
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html)			X

Rev. 5/30/07

MEMO TO THE RECORD
K080093

DATE: March 27, 2008 **OFFICE:** HFZ-410
FROM: Polymer Chemist **DIVISION**: DGNRD/GSDB

DEVICE NAME: Gyrus ACMI PKS Plasma Morcellator

COMPANY NAME: Gyrus ACMI, Inc.

CONTACT: Terrence E. Sullivan, Director, Regulatory Affairs
(Tel. No. 508-804-2739& Fax. No. 508-804-2624,
Email: Terry. Sullivan @ gyrusacmi.com)

BACKGROUND:

The subject submission, K080093, is the same submission (K063134/S2) that the **Ob/Gyn Devices Branch, DRARD** previously reviewed and found NSE on July 13, 2007 due to the "failure of the sponsor (Gyrus ACMI, Inc) to provide "sufficient information to adequately respond to" FDA requests on material issues (**please see the copies of the NSE letter dated July 13, 2007, and the final review memo of the Lead reviewer of K063134/S2, Ms. Kathryn S. Daws-Koop, M.S. which are enclosed with this review**). The sponsor has claimed their device, Gyrus ACMI PKS Plasma Morcellator, SE to the following predicate devices:

- Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula (K041633);
- Ethicon Inc. Gynecare Laparoscopic Morcellar (K993801).

DEVICE DESCRIPTION AND PERFORMANCE: The Gyrus ACMI PKS Plasma Morcellator is intended to cut, core, and extract tissue in various general surgical, urological, and gynecologic operative laparoscopy procedures. Tissue effects include the gross resection of tissue (such as uterine tissue and fibroids following Laparoscopic Supracervical Hysterectomy) allowing removal of this tissue through a laparoscopic port. The device would be used in a CO_2 or Air insufflated environment at standard laparoscopic abdominal pressures (up to 15 mm Hg). As a bipolar electrosurgical device, the PKS Plasma Morcellator would operate on irrigated tissue (e.g., Saline, Ringer's, Sterile Water) to enhance the PlasmaCision tissue effect, and without undue effect on safety or efficacy.

The PKS Plasma Morcellator device consists of two main elements (the entire device is illustrated in **Figure 10.1** below). The first is a Morcellator (see **Figure 10.2** below), which includes a cutting shaft and handle with an integrated electrical cable that connects to either a Gyrus General Surgery Workstation (cleared under 510(k) K050550) or Gyrus SuperPulse Generator (cleared under 510(k) K031085). The second element consists of a Grasper (see **Figure 10.3** below) that passes through the hollow shaft of the Morcellator, to grasp tissue and retract it toward the cutting element on the Morcellator shaft tip. An obturator (not pictured)

may also be used to assist in the introduction of the device in laparoscopic procedures, and like the grasper, is positioned through the shaft of the Morcellator tube when being utilized.

Figure 10.1 – PKS Plasma Morcellator

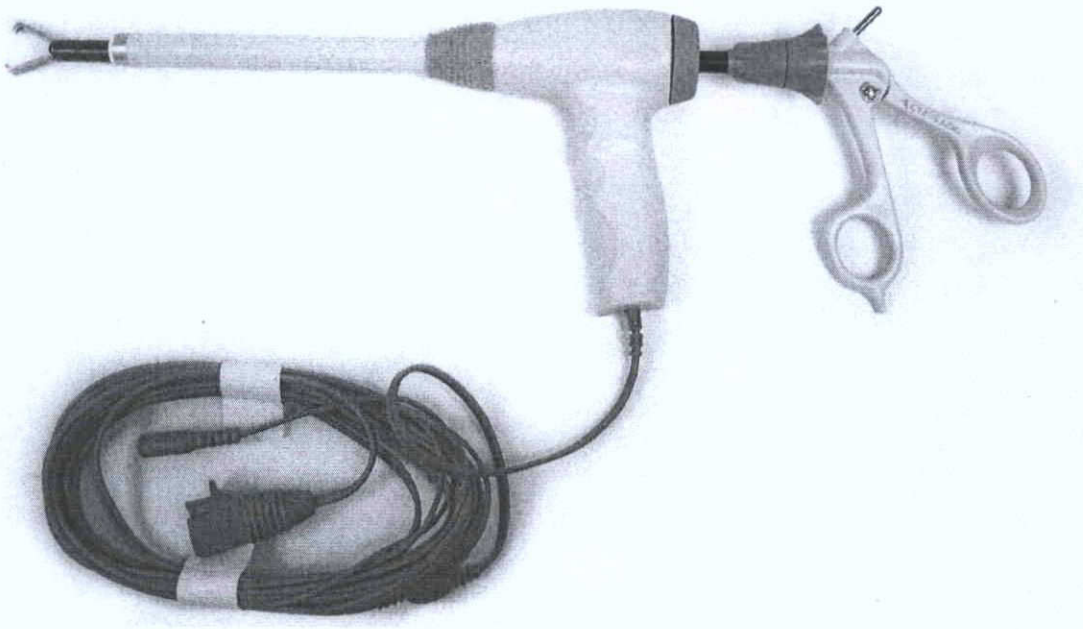


Figure 10.2 – PKS Plasma Morcellator – Morcellator

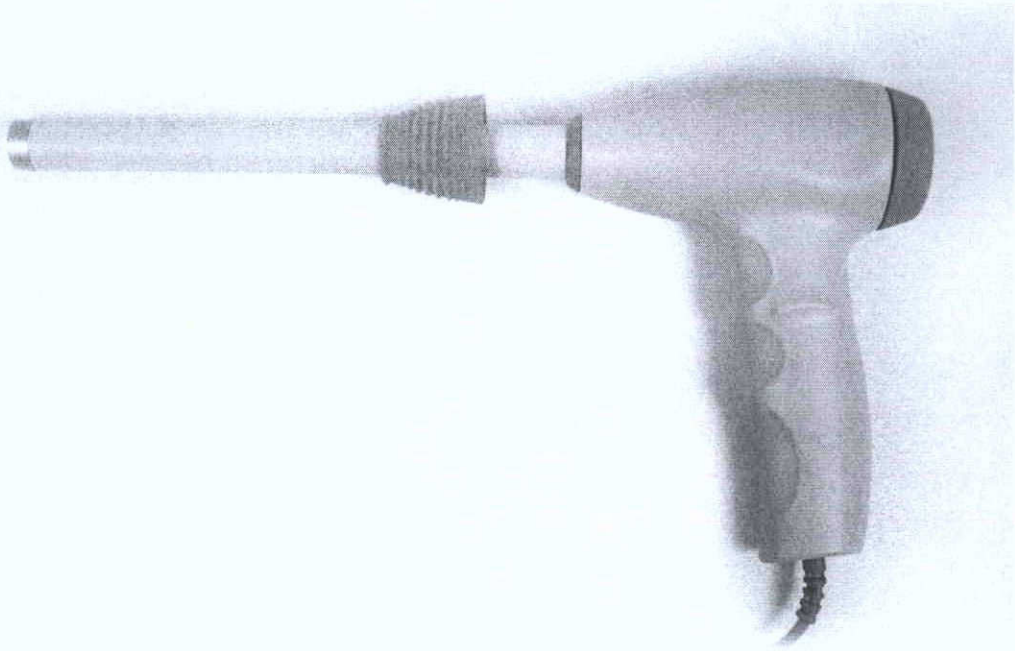
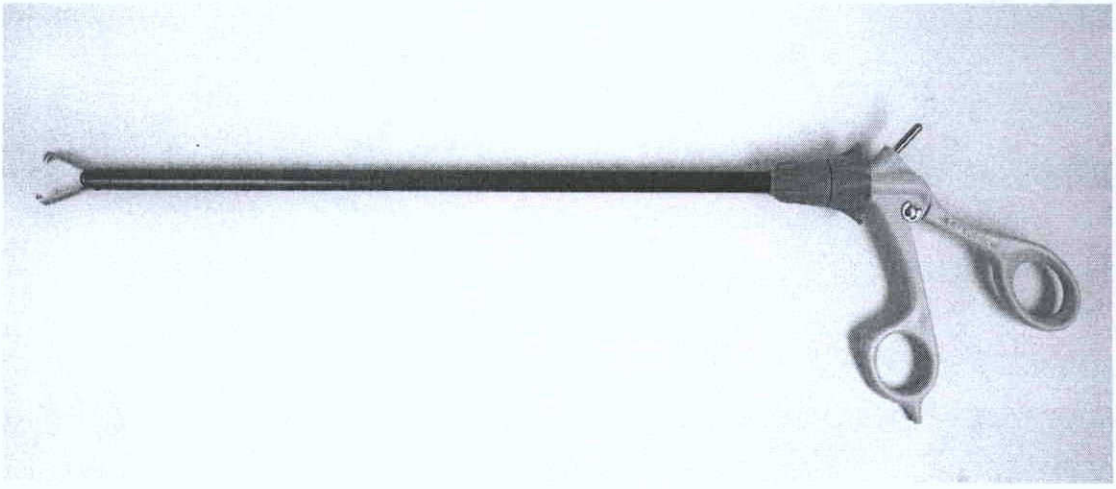


Figure 10.3 – PKS Plasma Morcellator – Grasper Element



COMPARISON WITH PREDICTE DEVICE: The main difference between this device and the other morcellators on the market is that this device uses electrosurgical energy to cut tissue rather than a mechanical system (sharpened metal blade). Specifically, Several tissue morcellators presently on the market, such as the predicate Gynecare Laparoscopic

Morcellator (K993801) and the Gynecare *Morcellex** Tissue Morcellator (K061050), utilize a powered rotating cutting blade to dissect tissue. The PKS Plasma Morcellator device uses Gyrus ACMI's **unique Bipolar PlasmaCision technology** (K041633) to cut, core, and extract devascularized, dissected tissue in operative laparoscopy. Further, most, but not all, morcellators have a motorized system for grinding or chewing tissue into smaller pieces. This device and its mechanical predicate actually cut tissue plugs that are extracted through the hollow shaft of the device.

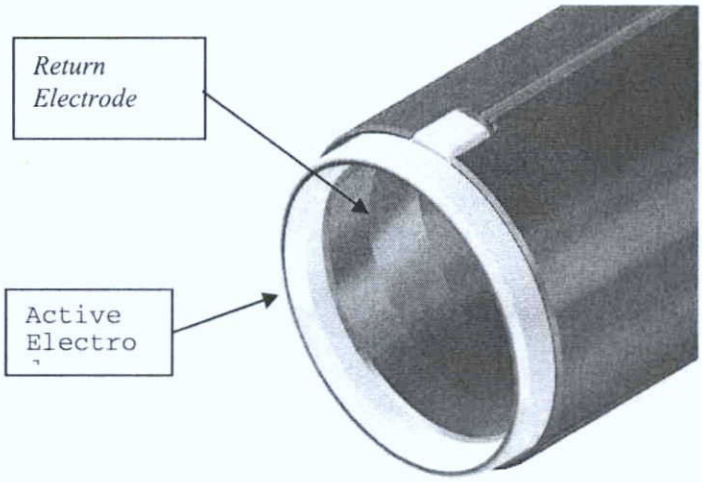
DRARD review solved issues regarding the nerve stimulation issues that were adequately resolved. **There remains an issue regarding material safety data.** According to DRARD, information was provided on the multiple individual materials. The information was adequate for the individual materials with the exception of a gold plated copper and a braided polymer. However, because of possible combined effects, DRARD wanted to see biocompatibility testing of the final finished product.

SURGICAL SETTING AND MODE OF OPERATION: The Morcellator is configured in an ergonomically friendly pistol grip configuration, and includes an axially oriented hollow shaft. The pistol grip integrates the electrical connection cable that allows bipolar RF energy to be supplied by a Gyrus generator to the tissue site. The design of the pistol grip body is such that a **clinician may utilize a "ski-pole" grip** on the Morcellator body, if that is their preference.

The hollow shaft of the Morcellator has an operative length of approximately 15 cm, extending distally from the pistol grip body. The surface of the Morcellator shaft is smooth, allowing the device to be introduced to the operative site through a trocar cannula seal, or with the use of the optional obturator, through an abdominal port. To facilitate optimal placement of the device during laparoscopic procedures, a depth stop normally located at the distal end of the pistol grip (at the junction of the pistol grip and Morcellator shaft), may be moved distally along the Morcellator shaft. The shaft has a nominal outer diameter of 15 mm, and a nominal inner diameter of 12 mm. The proximal end of the shaft also includes an elastomeric reducer that permits the passage of the grasper to the operative site and removal of tissue slugs from the operative site, while preventing loss of pneumoperitoneum.

As indicated above, the Morcellator includes an integrated electrical connector cable, with either a 5-pin or 9-pin connector plug that may be inserted into the Gyrus–SuperPulse Generator or Gyrus General Surgery Workstation, respectively. Bipolar electrosurgical energy is applied through the use of a foot pedal that is supplied with the respective Generator. The active loop of the PKS Plasma Morcellator's integrated electrical cable is connected to leads within the Morcellator body that are in turn connected to a circular active electrode integrated into the distal tip of the device (see **Figure 10.4** below).

Figure 10.4 – Distal Tip Electrode Configuration



As indicated in Figure 10.4, the distal tip of the device also includes an axially oriented return electrode that is electrically isolated from the active electrode and connects through the Morcellator body to the return loop of the electrical cable. Due to the placement of the active electrode ring and insulating overmold on the distal tip of the shaft, the internal and external return electrodes are simply contiguous parts of the same copper tube. The terms "internal return" and "external return" essentially refer to the respective face of the copper tube surface that may act as a return to complete the current path. More detailed illustrations of the Morcellator shaft and grasper, enlarged illustration of the distal tip showing the relationship between the internal and external return electrode, as well as an illustration showing the possible return paths of the bipolar energy are provided in ***Appendix 10.A****.*

In addition to these contact points, there is also a return electrode integrated into the Grasper that connects to the return loop of the electrical cable. This is more fully described in the "Detailed Description of the Grasper" section below. A more detailed illustration of the major assemblies and the RF Workstation connections is also provided in ***Appendix 10.B****.*

When the PKS Plasma Morcellator is applied to an operative site, the Grasper is introduced through the Morcellator shaft, and draws the tissue to be morcellated into close proximity to the active electrode (see **Figures 10.5 through 10.9** below). Bipolar PlasmaCision energy is applied; cutting the tissue into a plug that may be extracted through the Morcellator shaft. The electrosurgical effect is delivered via two poles, the active electrode and the combined return electrodes contained in the Morcellator shaft and Grasper. The narrow distal surface of the circular active electrode results in a local high current density at the point of tissue application, which promotes arcing leading to localized tissue vaporization. The large area of the combined return electrodes results in a significantly lower current density, which prevents arcing at the return electrode.

With the exception of the necessary exposed region at the functional tip, all conductors carrying electrosurgical current are insulated from the user and patient. This is primarily achieved by local insulation around each of the conductors with secondary insulation provided by the shaft coating, the polymer hand piece and the cable jacket. The external surface of the Morcellator shaft is electrically insulated to withstand a minimum of 750VDC (approximately twice the output of the respective Gyrus Generators), so that the electrical energy return path is through the axially oriented electrode within the Morcellator shaft, or through the Grasper return electrode.

Figure 10.5 – Grasping Tissue

(b)(4) Schematics

[redacted]

Figure 10.6 – Initial Activation

(b)(4) Schematics

[redacted]

Figure 10.7 – Ongoing Activation

(b)(4) Schematics

[redacted]

Figure 10.8 – Detail of Current Flow through Grasper

(b)(4) Schematics

[redacted]

Figure 10.9 – Detail of Current Flow through shaft

(b)(4) Schematics

[redacted]

The **Grasper** consists of an ergonomically friendly proximal handle, a rotating insulated shaft, and a pair of symmetrically opening jaws. The jaws themselves are insulated along their length to prevent shorting in the event of contact with the active circular electrode. The handle body also includes a banana plug allowing for attachment of the second return loop of the electrical cable assembly referenced in the Morcellator description above.

The jaws are dual action, and able to open to at least an angle of approximately 50° by the activation of a pair of fully enclosed finger loops on the proximal handle body. The jaws utilize interlocking teeth to allow the Grasper to be easily introduced through the seals in the Morcellator body, and allow secure grasping of tissue (including penetration of fibroid tissue). The standard Grasper offering will be a 2x3 jaw configuration (2 teeth on one jaw and 3 teeth on the opposite jaw), since the pre-clinical studies (discussed at greater length in Section 17.0) indicated that this configuration was better able to handle soft tissue and small strands of tissue common towards the latter stages of morcellation. These and other study results also suggested that a 2x1 jaw configuration (2 teeth on one jaw and 1 tooth on the opposite jaw) performed better with respect to grasping dense indurated tissue, such as uterine fibroids. As a result, a second grasper, with a 2x1 jaw tooth configuration, will be offered as an accessory

to the PKS Plasma Morcellator. Other than the jaw tooth configuration, all other aspects of this accessory grasper will be the same as the grasper with the standard 2x3 jaw tooth configuration.

The outer diameter of the Grasper shaft is approximately 10mm, and the shaft of the grasper is approximately 336 mm in length (not including the handle body). Since the overall length of the Morcellator pistol grip is approximately 270 mm in length, with a working length of approximately 150 mm, the distal tip of the graspers can extend beyond the distal tip of the pistol grip a maximum of approximately 66 mm. This allows the jaws to extend sufficiently beyond the Morcellator shaft so that they may fully open and grasp tissue. To better illustrate these dimensions, please refer to **Appendix 10.A**. The outer surface of the Grasper shaft is enclosed in insulation to maintain a continuous electrical return path to the Grasper handle's banana plug and PKS Plasma Morcellator connector cable.

The **Obturator** is disposable, and constructed of polymer materials. Since the user has the option of introducing the Morcellator shaft through a previously placed trocar cannula, use of the Obturator is not mandatory with each use of the PKS Plasma Morcellator. The distal tip is rounded, with an approximate diameter of 6mm, which conically tapers up to the inner diameter of the hollow Morcellator shaft. The length of the Obturator is such that the distal tip extends beyond the Morcellator shaft, forming a "bullet nose", allowing the Obturator to sufficiently dilate a 10mm incision so that the external diameter of the PKS Plasma Morcellator shaft may be accommodated.

ANALYSIS OF SUBJECT SUBMISSION, K080093

The Original NSE submission (K063134/S2) 's lead reviewer was **Ms. Kathryn S. Daws-Koop, OGDB/DRARD,** and its clinical, biocompatibility aspects were reviewed by, Julia Corrado,M.D., Mike Bailey, Ph.D, and Cotterel, Ph.D respectively under the direction of Herb Lerner, M.D.(currently DRARD's Deputy Director for Clinical). Discussing with these FDA personnel and Mr. Collin M. Pollard, Chief, Ob/Gyn Device Brach, DRARD, revealed that only issue regarding this submission is **material issues (please see the enclosed e-mail message)** such as the following:

Dr. Bailey reviewed the total information provided in the biocompatibility issues regarding the device and determined that there were issues with the information provided for the gold-plated copper and braided resin with Polaner gray paint. He also indicated in his review dated July 6, 2007, that all of the materials together may have a synergistic effect. Accordingly, he requested **full material safety testing** on the final finished product(i.e,S 2 submission) in the following question:

The company should provide independent biocompatibility testing on this device in accordance with ISO 10993-1 for a device with limited contact (<24h) with tissue. This would include cytotoxicity, irritation and sensitization testing of the patient contacting portions of your device. For the irritation and sensitization testing, both polar and non-polar

extracts of the device should be assessed. *If possible, provide a sample of your device to accompany the device photographs.*

In response to this request (S2), this deficiency was unanswered.

Accordingly, review of the subject resubmitted submission, K080093, revealed that the sponsor has **responded these materials issues**; hence the material portion of this submission was reviewed by Dr. Mike Bailey (**Please see the enclosed review of Dr. Bailey which is attached with this memo**).

According to Dr. Bailey," **The Company has provided sufficient evidence to support the previous use of the grasper components in other devices. Results acceptable.**"

However, Dr. Bailey has the following two more concerns (questions) regarding the material issues of the device which he requests that sponsor should response:

Questions for the Company

1. Biocompatibility of the obturator potion of your device was done on the material used to make this portion of the device (Terluran HD 15), and not on finished sterilized obturators. Please justify why testing on Terluran HD 15 is supportive of the safety of your finished, sterilized device. This justification should state the similarities and differences between the material tested and the finished device component (e.g., mold release agents, colorants, sterilization procedures, etc.). A detailed discussion why any differences in materials tested should not impact the use of the data supplied should also be included in your response. Please note that an inadequate response to this question may require the need for additional biocompatibility testing on this device.

2. Biocompatibility testing to demonstrate the safety of the obturator material (Terluran HD 15) did not include sensitization testing for this portion of the device. Please provide sensitization testing (e.g., ISO Maximization Test) using both polar and non-polar extracts of your device. Alternatively, provide a justification why sensitization testing on your device is not needed. Please note that an inadequate response to this question may require the need for additional biocompatibility testing on this device.

After discussing these issues in the DGRND 510 (k) Round on March 24, 2008 and discussing with Mr. Neil Ogden, M.S., Chief, DGRND, these issues again were discussed with Collin M. Pollard, Chief, Ob/Gyn Device Brach, DRARD.

On 3/27/08, the sponsor (**Mr. Terrence E. Sullivan**) was contacted and requested the following:

1. Biocompatibility of the obturator potion of your device was done on the material used to make this portion of the device (Terluran HD 15), and not on finished sterilized obturators. Please justify why testing on Terluran HD 15 is supportive of the safety of your finished, sterilized device. This justification should state the similarities and differences between the material tested and the finished device component (e.g., mold release agents, colorants, sterilization procedures, etc.). A detailed discussion why any differences in materials tested should not impact the use of the data supplied should also be included in your response. Please note that an inadequate response to this question may require the need for additional biocompatibility testing on this device.

2. Biocompatibility testing to demonstrate the safety of the obturator material (Terluran HD 15) did not include sensitization testing for this portion of the device. Please provide sensitization testing (e.g., ISO Maximization Test) using both polar and non-polar extracts of your device. Alternatively, provide a justification why sensitization testing on your device is not needed. Please note that an inadequate response to this question may require the need for additional biocompatibility testing on this device.

3. the subject device shows that it has an annular cutting edge right at the distal end, with a grasping forceps to pull the tissue into the tube. So it looks like the device essentially "cores" the tissue. But what causes the tissue to break free from the fibroid, tumor, or whatever is being morcellated, in order to remove it from the surgical field? Also, can it be used to morcellate an entire uterus during hysterectomy? Please provide a detailed explanation regarding all these issues.

The sponsor (**Terrence E. Sullivan**) was informed that the subject submission, K080093 would be placed on hold until the referenced additional information was received by the FDA.

RECOMMENDATION: The subject submission, K080093, will be placed on hold (**First time**) until the referenced additional information is received by the FDA.

George J. Mattamal 3/28/08

George J. Mattamal, Ph.D., Reviewer **Date**
General and Surgery Devices Branch
Division of General, Restorative, and Neurological Devices.

Neil I concur with AJ, 3/28/08

Neil R. P. Ogden, M.S., Chief **Date**
General and Surgery Devices Branch
Division of General, Restorative, and Neurological Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2007

Mr. Terrence E. Sullivan
Vice President, Regulatory Affairs
Gyrus ACMI, Inc.
136 Turnpike Road
SOUTHBOROUGH MA 01772

Re: K063134
Trade Name: Gyrus Medical Solid Organ Resection Device
Regulatory Class: III
Product Code: HET
Dated: April 13, 2007
Received: April 16, 2007

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We have determined the device is not substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to any device which has been reclassified into class I (General Controls) or class II (Special Controls), or to another device found to be substantially equivalent through the 510(k) process. This decision is based on the fact that we requested material safety data on December 13, 2006 and February 28, 2007 and you have failed to provide sufficient information to adequately respond to our requests. You may resubmit a new 510(k) if you have data you believe can show your device to be substantially equivalent. NSE

Therefore, this device is classified by statute into class III (Premarket Approval), under Section 513(f) of the Federal Food, Drug, and Cosmetic Act (Act).

Section 515(a)(2) of the Act requires a class III device to have an approved premarket approval application (PMA) before it can be legally marketed, unless the device is reclassified.

Any commercial distribution of this device prior to approval of a PMA, or the effective date of any order by the Food and Drug Administration re-classifying this device into class I or II, would be a violation of the Act. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations.

If you wish to pursue the marketing of this device and need information or assistance for preparing investigational or premarket submissions, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address www.fda.gov/cdrh/industry/support/index.html.

If you decide to submit a new 510(k) you should submit a complete submission which includes the information identified in Title 21, Code of Federal Regulations (21 CFR), Section 807.87 and follows the formatting specified in 21 CFR, Section 807.90, and also refer to our document, titled Guidance for Industry and FDA Staff - Format for Traditional and Abbreviated 510(k)s which is available from the Internet at: www.fda.gov/cdrh/ode/guidance/1567.pdf. In addition, please ensure that any new 510(k) includes information that addresses the following issues:

The information provided on material safety for the gold plated copper and braided resin with polane gray paint was not sufficient. Please provide biocompatibility testing information for these two materials, including cytotoxicity, irritation and sensitization. Irritation and sensitization test reports should include testing of both polar and non-polar extracts. Please be advised that if you can not provide this information, or if information provided in not sufficient, then independent biocompatibility testing on the final finished product should be conducted in accordance with ISO 10993-1 for a device with limited tissue contact (<24h).

The information requested above represents the issues that we believe need to be resolved before our review of a new 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies should you decide to submit a new 510(k). We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the document, "A Suggested Approach to Resolving Least Burdensome Issues". It is available on the Internet at www.fda.gov/cdrh/modact/leastburdensome.html

If you have any questions concerning the additional information that should be submitted in a new 510(k) submission, please contact Ms. Kathryn S. Daws-Kopp at (240) 276-4100.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Public Health Service

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandums

Date: July 6, 2007

From: Michael T. Bailey, Ph.D.
Ob/Gyn Devices Branch, DRARD (HFZ-470)

To: Kathy Daws-Kopp
Ob/Gyn Devices Branch, DRARD (HFZ-470)

Subject: K063134 Gyrus ACMI, SORD - Review of the company's responses to our questions regarding device material safety issues.

I was brought into the review of this device during Supplement 1 (S1). During my review of S1 I noted that the sponsor had not provided an adequate listing of all materials used in the device, and whether these materials had been used in 510(k) cleared devices or had sufficient data on them to assess their safe use. The AI letter sent to the company following the review of the S1 asked them to provide a more detailed table that listed each component, materials used in each component, materials patient contact potential, predicate devices using identical materials, and photographs or detailed drawings of the device that clearly show the location of each material.

In their response (S2), the sponsor provided the requested diagrams of the device and a more detailed table that listed the device components, materials used, contact potential, basis for biocompatibility determination. Following review of the information provided, it was determined that the stainless steel components of the device (Grasper Jaw – Type 303, and Active Ring Electrode – Type 316) had previously been used in other Gyrus devices. In addition, the Polyolefin tubing (MT-2000) used for insulation of the Grasper Jaw and Grasper Shaft had previously been used in other ACMI products. Therefore, these components were found to be acceptable.

However, the company did not provide detailed information on the remainder of the direct and indirect components of the device. Specifically, they mentioned that biocompatibility testing had been performed on certain components; however, for some of these components only partial testing (or no testing) had been performed. To address these issues, Kathy Daws-Kopp and I talked with our contact at Gyrus ACMI. During the call we informed them that with the exception of the stainless steel, Polyofelin, and non-contact portions of the device, additional information would be required regarding the other direct and indirect component materials. The company was asked to address the following issue:

- Put together a table that includes additional information on the exact trade name of each component and the manufacturer of each component. Identify the specific name of the material in each device identified as a predicate so that we can go back and cross reference the predicate file on Image. Describe the relative amount of material used in the proposed and predicate devices. Also, justify any differences in materials (from the identified predicate): contact potentials, amounts used, etc.

On May 14, 2007, the company responded to this question. The response consisted of a detailed table providing the information requested plus additional supporting materials. Identification of adequate predicate devices, test data and supporting justifications were sufficient to address issues regarding the anodized aluminum grasper shaft (indirect contact), and at the time, the gold-plated copper return tube (indirect contact) as well. However, the data supplied was not sufficient to assess the silicone materials used in the manufacture of the active overmold and valve components (MED-4970) or as the active tip

adhesive (MED 1014RTV). Also, the company did not supply complete information to support the safe use of TF6STE in the depth stop, or MABS Terlux 2802HD or MABS Terulan HD15 in the obturator.

To address these outstanding issues, the following questions were sent to the sponsor on May 31, 2007.

1. For silicone materials MED-4970 LSR and MED1014 please state whether the materials tested (identified as CH036 and CH041) are the same as the materials used in the device. Also, the cytotoxicity tests referred to samples A, B, and C. Please describe what each of these samples represents. Also, MED 1014 is stated to be a restricted version of MED 1514. Please comment on the "restricted" nature of this material.

2. The depth stop is stated to be made of TF6STE and you have provided data on systemic toxicity and cytotoxicity; however, you also state that intracutaneous irritation and intramuscular testing have been performed on this portion of the device; however, you have not provided this data for review. Please provide these additional test reports for review.

3. The obturator is stated to be composed of Teluran HD15 or Terlux 2802HD. The information provided states that the Terulan HD15 has undergone systemic toxicity, intracutaneous toxicity, muscle implantation, and cytotoxicity testing; however, with the exception of cytotoxicity testing, test reports for the other testing was not supplied. Please supply test reports for review. In regards to the Terlux 2802HD, you state that a number of tests have been performed including sensitization and cytotoxicity, but no reports of irritation testing (either intracutaneous or muscle implantation). Please provide test reports for sensitization and cytotoxicity, and comment on the lack of irritation testing, and how this could be covered by other testing provided. Also consider only using Teluran HD15, which appears to have more data available regarding its biocompatibility. Finally, please provide a detailed description regarding the use of the obturator, including its patient and other device components contact potential.

4. Also, do any of the materials used in the device have colorants that were not contained in the materials undergoing testing? If so, information on the use of these colorants in other cleared devices should be provided and a discussion of why the presence of these colorants would not impact of test results of materials not containing identical colorants.

The company responded to these questions on June 12, 2007. Their responses are summarized below.

Response to Question 1:
The company states that MED-4970 LSR and MED-1014 are the same materials used in the SORD, and that samples "A", "B" and "C" refer to the same material processed by the supplier NuSil under slightly different cure conditions.

NuSil has indicated to Gyrus ACMI that MED1014 and MED1514 are materially identical. The reason for the two material codes, and the restriction placed on MED1014 is a purely commercial (and confidential) decision by NuSil to limit the number of new customers / applications using this material thus satisfying a commitment to their original customer. It has no bearing on the suitability of the material. **Response acceptable.**

Response to Question 2:
The company states that the supplier (Kraiburg) has not provided Gyrus ACMI the additional test reports requested by the Agency.

To support the safety of this material the company refers to the summary report obtained from Kraiburg regarding testing of this material conducted by Toxikon. This summary indicates that both intracutaneous injection and intramuscular testing were performed on extracts of this material in addition to systemic

toxicity and cytotoxicity testing that has already been reviewed and found acceptable. The summary report's results section indicates "none of the rabbits injected intracutaneously with the test article extracts exhibited any signs of erythema, edema, or clinical toxicity." Additionally, the report states that the implant sites "exhibited no significant signs of hemorrhage, necrosis, discoloration, encapsulation, or infection compared with the control sites." It should also be noted that this material has not undergone sensitization testing; however, due to its contact potential (indirect and single-use treatment) and the relative safety reported in the irritation and implantation studies, I do not find that additional sensitization testing is required.

Overall, I would have preferred to have reviewed the test reports regarding this material; however, due to the patient contact potential, and the summary data on testing performed, I find that sufficient information regarding these materials have been submitted. **Response acceptable.**

Response to Question 3

The Obturator is disposable, and constructed of polymer materials. Since the user has the option of introducing the Morcellator shaft through a previously placed trocar cannula, use of the Obturator is not mandatory with each use of the SORD. The distal tip is rounded, with an approximate diameter of 6mm, which conically tapers up to the inner diameter of the hollow Morcellator shaft. The length of the Obturator is such that the distal tip extends beyond the Morcellator shaft, forming a "bullet nose", allowing the Obturator to sufficiently dilate a 10 mm incision so that the external diameter of the SORD Morcellator shaft may be accommodated.

The patient contact potential for the Obturator is limited to the initial application through a surgical stoma, when a trocar cannula is not utilized. Thus using the ISO 10993-1 definitions, the obturator's would be considered as an external communicating device with limited contact with tissue. Gyrus ACMI believes that the data previously supplied and the data enclosed with this submission demonstrate the biocompatibility of these materials.

Since the Obturator's use is limited to the initial insertion of the SORD, contact with other devices, or other elements of the SORD would similarly be limited to the internal shaft of the Morcellator tube, and the valve assembly in the proximal handle. The Obturator would be withdrawn prior to insertion of the graspers and prior to the activation of any bipolar energy.

The supplier, BASF, provided copies of the requested biocompatibility test reports to Gyrus ACMI on June 8. For Terluran, the company has supplied copies of Copies of the systemic toxicity, intracutaneous toxicity, and muscle implantation data related to Terluran. For Terlux, the company has supplied copies of cytotoxicity, sensitization, and muscle implantation testing.

For the Terluran HD15 material, intracutaneous reactivity and systemic toxicity testing on various extracts (saline, alcohol, sesame oil, and PEG, extracted under acceptable conditions) were shown to be non-irritants, and did not result in any noticeable systemic toxic effects. In addition, the company provided the results of a 5 day muscle implant study for review. Following 5 days of implantation, there were no signs of irritation, necrosis, or other negative material-mediated effects on local tissues. It should also be noted that this material has not undergone sensitization testing; however, due to its contact potential (indirect, single-use treatment, limited contact duration - <1 min) and the relative safety reported in the irritation and implantation studies, I do not find that additional sensitization testing is required.

For the Terlux 2802HD material, cytotoxicity (1X MEM elution), sensitization (saline and oil extracts), were shown to be non-cytotoxic and non-sensitizing. In addition, the company provided the results of a 7 day muscle implant study for review. Following 7 days of implantation, there were no signs of irritation, necrosis, or other negative material-mediated effects on local tissues. It should also be noted that this material has not undergone direct irritation testing; however, the muscle implant data can be used in place of irritation testing, and showed no that this device had no noticeable irritant effect. **Response to question 3 acceptable.**

Response to Question 4

All of the materials included in this submission have included colorants in the test articles for which reports have been supplied to the Agency with the exception of the colorants used in the depth stop (which utilizes the TPE TF6STE material) and the Obturator (which utilizes Terluran/Terlux). The two polymers have the respective gray or orange colorant master batched into the mix. Both of these materials are master batched at a very small proportion (around 2%) and are made by Clariant. Clariant has provided Gyrus ACMI with a letter indicating that the constituents are "...currently formulated and manufactured using constituent materials with following FDA compliances:

- Carrier Resin Polyolefin 21 CFR 177.1520
- Colorants Propriety formulation- all conforming to: 21 CFR 178.3297
- Wax as process lubricant/flow modifier 21 CFR 177.1 520 "

It should be noted that these CFR references are to food grade additives, and based on their use as a food grade additives. Due to the relatively small amounts used in these devices, their being encased in polymer, their indirect or minimal contact potential of these portions of the device, and their acceptability in food manufacture, I do not find that additional testing is required. **Response acceptable.**

MTB Comment: During the review of the materials above, I noted that the company had not supplied information on the materials used in the Shaft Sleeve (identified as braided polymer). On June 12, 2007, Kathy Daws-Kopp sent the company an e-mail asking them to supply the supporting biocompatibility test data for this portion of the device for review.

On June 12, 2007, the sponsor responded that the shaft sleeve was made from Braided Polymer (Polygon Company), and that these results were documented in NAMSA report #06G_28116_01 (provided along with the company's response). In this report, NAMSA subjected the Braided-Natural Resin Polymer to cytotoxicity, intracutaneous irritation, and maximization sensitization testing, and also subjected several colored variants, including one made with polane gray paint (which is the material used in the proposed device), to cytotoxicity testing. Results of testing on the Braided Base Resin – Natural showed this material to be non-cytotoxic, non-irritating with the saline extract, slightly irritating with the oil extract, and non-sensitizing. In addition, cytotoxicity testing on the polane gray paint version of this material was shown to be non-cytotoxic.

In addition to the basic biocompatibility tests performed, each sample was subjected to a variety of tests to evaluate the amount and characteristics of extractables using methodology prescribed in the United States Pharmacopeia (USP) Physicochemical Tests - Plastics <661> and ISO 10993-1 8: "Chemical Characterization of Materials." Total extractables for non-Volatile Residue were evaluated by the USP Physicochemical test method using purified water and isopropyl alcohol solvents. Infrared spectroscopy was also conducted to identify and fingerprint the extract for further analysis of compounds present.

Results from the additional extract testing showed that the base resin released 2 mg and <1 mg of "residues" after extraction in purified water or Isopropyl alcohol, respectively. The polane gray paint variant of this product released 2 mg of residue in the water extract and 12 mg in the alcohol extract. The company does not believe the alcohol results to be important as the device in normal operation will only be used in a polar solvent environment (e.g., saline). However, it is not known whether in the presence of heat, increased amounts of materials will be released from this device.

Other physiochemical tests were also performed on the water and alcohol extracts of the resin samples, including residue on ignition, heavy metals (water extract only) and buffering capacity (water extract only). Results of these tests showed similar results between the natural resin and the polane gray version of the device.

MTB Comment 1 – I do not find the information presented in this test report sufficient to address the sensitizing or irritating potential of this component of the device. The information provided suggests that this component of the device does not have any detectable cytotoxicity potential, and that when extracted in saline has a similar amount of extractables released. However, it is not clear whether the materials extracted from the natural resin and the polane gray paint version of the device are identical. Also, when exposed to an alcohol extraction, the amount of extractables recovered are much higher in the polane gray version of the material (12 mg vs. <1 mg in the natural resin), suggesting that significantly more materials are being released from this "painted" version of the device. The company suggests that this is not a critical finding as these devices are typically only going to be used in saline environments; however, we typically request that biocompatibility testing for irritation and sensitization be performed using both polar and non-polar extracts. Also, it is not clear what additional processing during the manufacture of the device, or heating during the use of the device may have on the release of materials from this component of the device. For this reason, and at this stage of the review process, the sponsor should provide independent biocompatibility testing on the SORD device.

MTB Comment 2 - Gold Return Tube – During my initial review of this material, I did not note that the reference material used was not gold platied copper, but rather chrome plated copper. The sponsor provided a test report to compare the equivalence of different platings to an ISO 10993 tested chrome plated copper material. Testing consisted of an extraction in saline followed by an assessment for 35 metals in the extractant. In addition, gold plating involves the use of cyanurate(I), which may lead to the release presence of cyanide residues after processing. Extracts obtained were also assessed for the total cyanide content. Results of testing showed that the relative amounts of metals released from the different plating materials were similar, and that no detectable amount of cyanide was present. From this information, the sponsor concluded that these different platings are materially similar.

I would agree that the data collected would suggest that the release of materials from these different plating materials are similar; however, the testing provided did not include both polar and non-polar extracts of the material, and did not include any bioassays of the material to show if anything outside of the 35 metals tested and cyanide were present in device extracts. For this reason, I do not find their justification for the gold material sufficient.

Conclusion

The company has been able to adequately address the safe use of a number of individual materials used in the manufacture of this device; however, the sponsor has not supplied sufficient information for the gold plated copper used in the return tube or the braided resin with polane gray paint to support safe use of these materials. The sponsor has provided assessments of these two materials; however, direct biocompatibility testing was not done, so a final definitive answer was not able to be determined. In addition, this is a complex device made up of many different materials (plastics, resins, colorants). Individually, each component may not raise any concerns; however, together, there may be some materials interactions resulting from methods used during the manufacturing process, or during use of the device that can not be observed individually. For these reasons, I recommend that the company conduct independent biocompatibility testing on this device in accordance with ISO 10993-1 for a device with limited contact (<24h) with tissue.

Michael T. Bailey Dated: 7/17/07

Michael T. Bailey, Ph.D.
Prepared: 7/6/07 MTB

Review Memorandum

K063134/S002	OGDB
GYRUS MEDICAL SOLID ORGAN RESECTION DEVICE (SORD) ACMI CORPORATION	

Date: July 13, 2007

Reviewer: Kathryn S Daws-Kopp
Electrical Engineer,
DRARD/OGDB (HFZ-470)

APPLICANT: ACMI Corporation Gyrus ACMI 136 Turnpike Road Southborough, MA 01772	**CONTACT:** Terrence E. Sullivan, Director, Reg Affairs Phone: 508-804-2739 FAX: 508-804-2624 Email: Terry.Sullivan@gyrusacmi.com

DEVICE TRADE NAME: Gyrus Medical Solid Organ Resection Device (SORD)

INDICATIONS FOR USE: "The Gyrus Medical Solid Organ Resection Device (SORD) is intended for cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedure, and laparoscopic gynecologic procedures. "

COMMON NAME: Morcellator, Laparoscopic Accessory and Electrosurgical Coagulator/Cutter
PRODUCT CODE/CLASSIFICATION: 21 CFR 884.1720, Class II, 85 HET and 21 CFR 878.4400, Class II, GEI.

PREDICATE DEVICE: Gyrus Medical PlasmaCision Laparoscopic Spatula (K041633) and Ethicon Gynecare Laparoscopic Morcellator (K993801)

	Yes	No
· Is the device life-supporting or life sustaining?		✓
· Is the device implanted (short-term or long-term)?		✓
· Does the device design use software?		✓
· Is the device sterile?	✓	
· Is the device single use?	✓	
· Is the device home use?		✓
· Is the device for prescription?	✓	
· Does the device contain a drug or biological product as a component?		✓
· Is this device a kit?		✓

ADMINISTRATIVE ACCOUNTING:

Indications for Use form ✓ section 6.0
510(k) summary or statement ✓ section 7.0
Truthful and Accurate statement ✓ section 8.0

History/Background

There is no specific background or history to this specific file prior to its submission. General Surgery Devices branch approved the predicate Gyrus Medical PlasmaCision Laparoscopic Spatula.

October 16, 2006	Login date of original submission
December 13, 2006	Email sent to company asking for additional information
January 4, 2007	Date of company response (S1)
February 28, 2007	AI letter sent to company, insufficient information in their response
May 4, 2007	Information on biocompatibility/materials is confusing—called the company
	We sent email summarizing biocompatibility issues phone call
	We sent email regarding a couple of labeling changes we were requesting
May 14, 2007	Received response to our May 4 questions with hard copy to follow
May 25, 2007	Received email with attached discussion of heat dissipation at the device tip
May 31, 2007	We sent email with additional biocompatibility questions to the company
June 11, 2007	Received responses to May 31 questions
June 12, 2007	We sent email asking for information on shaft sleeve material (missing from May 14 responses)
	We sent email asking for copy of draft package label per May 4 request
	Received information on shaft sleeve material
	We asked for color variant information on shaft sleeve material
	Received information on modified package label change we requested, May 25 email is justification
June 13, 2007	Brought the file and its issues to the attention of Heather Rosecrans
	Ms. Rosecrans advised that we should try and resolve our remaining issues in this round or identify the document as NSE for lack of response

Device Description

This device is a morcellator where the cannula has bipolar tissue cutting capabilities. The device has no motor or grinding capabilities and merely cuts tissue into plugs. The submission indicates that the device is composed of two components: morcellator and grasper. The grasper fits through the hollow shaft of the morcellator. The morcellator (and thus, the combined device with grasper retracted) has a full length of 27 cm, an operative length of 15 cm, and an outer diameter of 15 mm. In S1, the company clarifies that the grasper is 336 mm in length, not including the handle. The graspers can extend as much as about 6.6 cm beyond the end of the morcellator. In use, the graspers

are extended to grab tissue and pull it back to the morcellator tip. See more discussing of this issue under question 3, below.

The morcellator is a hollow shaft with a pistol grip handle that is integrated with the electrosurgical cable. The distal tip of the shaft is the active electrode with a circular cross section. The return electrode is offset from the end of the shaft. The morcellator also has an adjustable depth stop feature on the exterior surface of its shaft and a seal at the proximal end of the shaft.

The grasper is a 2 x 3 grasping tool with two teeth opposing 3 teeth at the distal end and a finger loop handle at the proximal end. As the grasper also works as a return electrode to the morcellator's active electrode, the shaft is insulated and the proximal end of the grasper cable includes a banana plug for connection to the electrosurgical generator. S1 adds an additional grasper that they state is identical to this grasper except that it has a 2 x 1 jaw configuration.

The device operates using the company's PlasmaCision technique (cleared under K041633) which causes a tissue vaporization effect in the area near the active electrode tip. The grasper pulls the tissue into the morcellator shaft which then cuts the tissue into plugs that are then removed through the shaft.

The device may be introduced to the abdominal cavity through a trocar or through its own port with the use of an optional obturator. The obturator is disposable and made of a polymer.

Performance Characteristics/Features of Device, both S&E

Performance of the device was compared to the predicate mechanical morcellator, the Ethicon Gynecare Laparoscopic Morcellator (K993801) in very gross terms. Several tests were performed to test device requirements, but the performance was compared to the 'know properties" of the existing mechanical morcellators. Se further discussion of this testing under Performance Testing below.

Areas of Review

SE comparison

The predicate Ethicon Gynecare Laparoscopic Morcellator (K993801) is a mechanical device (with a motor) that is otherwise similar in design to the subject device. The Ethicon device has an annular blade at the end of long tube that serves as the blade housing. The system includes a tube that may be used as a cannula for introducing appropriately sized instruments into the surgical field. The labeling advises use of a tenaculum for the purpose of pulling tissue that is to be removed into the cannula where the blade of the morcellator then cuts the tissue. Thus, the method of dissecting the tissue for removal is nearly identical between the subject device and this predicate.

The other predicate identified in the submission is the Gyrus Medical PlasmaCision Laparoscopic Spatula (K041633). This device is from this company and uses the same bipolar technology for

tissue cutting. The major difference here is the configuration of the active tip of the electrode and the purpose of the cutting.

The combination of the two predicates is sufficient, however, provided that no additional safety concerns are introduced by the difference in technology and the difference in use. There are no logical additional risks for this use of bipolar energy beyond those associated with other bipolar uses in laparoscopy. The cutting ability of the device is reported in their performance summary as being equivalent or better than the mechanical alternatives. While they do not provide data to support this claim, there is no reason to think that the cutting would be worse. General performance data is provided in summary, see discussion below.

Component Materials (functional performance, toxicity, etc.)

The original submission included a table of all the materials used. I asked Alison Cotterell to provide a review of the biocompatibility testing. As noted in her review, the information provided regarding biocompatibility testing was not sufficient. In S1, they provided more information per our request. When Dr. Cotterell reviewed the information she was not sure about a couple of aspects and asked that Mike Bailey review the information.

When Dr. Bailey reviewed the items that Dr. Cotterell had identified, he could not resolve the issues because he could not figure out what information applied to what device component. Thus he asked that the company submit a new table of materials used with a device diagram and a key for correlating the materials to the device component. As with the previous table, information on predicates or testing completed was also supposed to be identified.

The response provided in S2, included a table that was complete. However, the predicates identified did not all pan out—the materials were not exactly the same or could not be confirmed to be the same. Also, insufficient data or no data at all was provided for the biocompatibility testing referenced. We asked for additional information on May 4, May 31, and June 12.

Performance Testing

The following testing was conducted to evaluate the performance of the device on the bench:

- Pull forces with 3 types of graspers (beef heart and extirpated human uterus)
- Thermal camera study (extirpated human fibroid and beef tongue)
- Efficacy, Ergonomics, and Safety study (3-4 month pig, beef heart, and frozen beef tongue)

The pull force and thermal camera studies were conducted at a 'surgeon lab' (QEH lab) and addressed grasper design to try and minimize tissue tearing (and related traction) and the forces required to pull the tissue. Appropriate surrogate tissue selection was an issue in these studies. Tissue types and pull forces were compared. The conclusions included clinicians' preferences and

impressions of device use, which was mostly anecdotal. The 2 x 3 grasper was judged best both by user preference, pull force, and tearing.

The third study was conducted at the University of Minnesota and loosely addressed verification of the performance of various aspects of the device including: depth stop function, seal capability, grasper/seal and removing tissue, cutting ability, ergonomics (shaft finish and handle design), 'orange glow,' thermal dissipation, smoke, nerve stimulation, and general safety (cancer seeding and general physician comments).

Comments on cutting ability indicate that the clinicians (MDs) found the device to cut at least as easily as a mechanical morcellator. Further, they note that previous lab data (not provided) shows that cutting performance on fibroids is better than with the mechanical counterpart.

The 'orange glow' is described in the summary test report is a characteristic of the PlasmaCision electrosurgery. They explain that the glow is due to the presence of sodium in the body fluids. The 3 particular issues of device safety identified as thermal dissipation (managed by a copper heat sink), smoke, and nerve stimulation are identified as being common to all electrosurgery devices.

Julia Corrado reviewed the study summary and had concerns about the selection of the 2 x 3 grasper and the dismissal of nerve stimulation (and possible tissue blanching) as being common to all electrosurgery use. In response to her comments on the grasper's performance, the company added a second grasper as noted above. Further information was provided on the nerve stimulation issue, which points to misuse of the device. Dr. Corrado's review indicates that she is satisfied with the information provided. After discussion in Clinical rounds, Dr. Corrado determined that some labeling changes were required, however. This was relayed to the company on May 4. See attached email copies from May1-4, for further details on our labeling requests.

The company provided some revised Instructions for Use with their submission of materials information dated May 14, 2007. This revised labeling addressed concerns from our May 4 email. In lieu of making the requested change to the package label, they provided an email with an attached discussion of heat dissipation modeling and bench testing (see May 25 email) and stated that they would modify the package label to include an ISO symbol (per FDA recognized standard) that indicates the user should read the labeling. We asked the company for further changes as we found this to be insufficient to address the problem we saw. We still need to resolve these labeling issues.

Discussion with Herbert Lerner, MD, DRARD Chief Medical Officer:

We scheduled time to discuss this item with Dr. Lerner on Monday, February 19, 2007. Dr. Corrado expressed her concerns regarding the occurrence of nerve stimulation and (later) tissue blanching. She indicated that we had expressed concern in our letter to the company about the nerve stimulation and that we found their response lacking and did not feel that our issue had been adequately addressed. We discussed how I had assured her that their explanation of how the nerve stimulation or injury of non-target tissue had occurred (contact between the abdomen and the active electrode and one or more of the return electrodes) was

plausible from an electrical point of view. However, they had not provided an explanation of why the device had been in this type contact with the abdomen during the study. Dr. Corrado expressed concern that the use of the device would result in more injuries, including more serious injuries involving bowel and bladder.

We discussed the design of the device and how the use of a bipolar design makes the device a little more unpredictable in regard to issues such as these as compared to monopolar (though not necessarily less safe). We discussed how they had not provided the worst case risk analysis we had requested. We concluded that with adequate understanding, the device labeling could be revised to address the problem and likely reduce the occurrence of problems. Dr. Lerner expressed agreement with our plans to ask for more information about the problem and to suggest revisions to the labeling.

Presentation at DRARD Clinical Rounds (February 22 and May 3)

We presented the issue at Clinical Rounds on February 22, 2007. I provided an overview of the device, the 510(k) status, and the issue. Dr. Corrado elaborated on the clinical issue. In response to questions, we clarified aspects of the device design, described the animal study that resulted in the nerve stimulation issue, and clarified why the issue was so concerning to us. Dr. Corrado clarified that it was not the nerve stimulation itself that concerned her, but the tissue blanching that implied potential for greater problems, such as irreversible tissue destruction to bowel or bladder.

We presented the submission issues again at 510(k) rounds on May 3, 2007. At this time we summarized the device description, our interactions with the firm thus far, and the remaining issues. Dr. Corrado discussed the company's response regarding the nerve stimulation issue, which was basically a confirmation that the user may have had the device tip out of view during the procedure. Dr. Corrado acknowledged that this is a serious, but common problem with electrosurgical devices. We discussed labeling as mitigation for nerve stimulation and inadvertent burn problems. Mike Bailey also discussed the issue of missing materials information—lack of a predicate with the same material and lack of results/reports from biocompatibility testing.

Electrical Safety

The document indicates that the device has been designed to conform to the requirements of IEC 60601-1 General requirements for Safety and IEC 60601-2-2 for High Frequency Surgical Equipment. This section goes on to state that the company will assure that the device conforms to the named standards. In S1, the company provided test plans which include methods and pass/fail criteria for appropriate electrical as well as other testing consistent with IEC 60601-1. See further discussion under question 8, below. The information provided is adequate.

Sterilization

Alison Cotterell also provided a sterilization review. While the company did provide some information in the original submission on sterilization, it was not complete. In S1 they provided information providing their package integrity testing, limits for maximum levels of sterilant residuals, and sterilization cycle validation methods. See questions 9 and 10 below and Dr. Cotterell's review for more information on the sterilization issues and their resolution. All sterilization issues have been resolved.

Labeling

The labeling does includes the Indications statement and Contraindications, Warning, precautions, and Instructions for use. The labeling is generally adequate. There are a lot warnings and precautions, but they mostly seem appropriate and cover the concerns that FDA generally recommends for these types of devices. The one exception was addressing the nerve stimulation issue. Labeling to address this problem included items brought up at discussions during clinical round. These issues were discussed with the company via email. The bulk of labeling issues were resolved. Remaining issues will be resolved with the company if and when they submit a new 510(k).

Deficiency Responses:

The following paragraphs address the deficiencies from our letter dated February 28, 2007. The responses from the company and the resolution of these issues are discussed.

Administrative

1. *✓In response to question 1 of our December 13, email, where we requested clarification regarding what appeared to be 2 different trade names, you made revisions to the 510(k) summary as we requested. However, in reviewing the summary, it became apparent that the Intended Use statement included duplicates the statement from the Indications for Use form, except that it includes the sentence that we asked you to remove from the form in question 2 of our email. Please revise the summary to remove this sentence and revise the section heading to correctly identify the statement as Indications for Use or Intended Use (singular).*

Changes were made as requested to the Intended Use section of the 510(k) summary. The company apparently did not understand the question well, and another copy of the Indications form was also provided, but has been modified to use the term "Intended Use." We will stick with the Indications for Use form in S1. This deficiency is resolved.

2. *✓In response to question 2 of our email dated December 13, 2006, you revised the Indications for Use form as suggested. However, when reviewing your revised labeling, we discovered that the Indications statement in the labeling is not consistent with the one provided on the form. Please revise to make these statements exactly the same.*

The company revised the labeling as requested; it now matches the Indications statement on the form. This deficiency is resolved.

Clinical

3. *✓Your response to question 7 of our letter addressed some of our concerns, but did not completely explain how (sic) the circumstances that led to the stimulation events in the first study and did not provide a worst case risk analysis. We still have questions and concerns about how and why the nerve stimulation occurs. Please clarify the circumstances during the pre-clinical pig study when the twitching event occurred. Specifically, did the investigators in this pre-clinical trial keep the tip of the device in view at all times? Was the distal most circumference of the morcellator tube, which houses the active ring, touching the abdominal wall? (This question derives from a statement on page 9 of 15 of Attachment 8 that indicates such contact is a necessary condition for the adverse event to occur.) Was the device activated at the time of the twitching (does the electrode have to be activated for the stimulation to occur)?*

In response, the company clarified the conditions that have to be in place for the nerve stimulation to occur:

- Active tip has to be in contact with tissue (abdominal wall, in this case)
- One of the return electrodes must be in contact with the same tissue (return=external return or grasper)
- Device must be activated

They also indicate that it is not clear if the morcellator tip (distal most tip/active ring) was kept in view at all times during the procedure on the pigs. Dr. Corrado's review indicates that this alleviates her concerns about the potential to cause nerve stimulation while keeping track of where the tip is. The information provided is sufficient to address our concerns that they do understand the cause of the nerve stimulation and can address it adequately in the labeling. The company also directs us to the response to item 9 for their revisions to labeling to address safe use. This deficiency is resolved.

4. *✓In your response you have also indicated that complete masking of the external return electrode would resolve the nerve stimulation problem (page 10 of 15 of Attachment 8). However, you indicate that this is not a desirable solution along with some explanation. It is not completely clear to us, why this is not a desirable solution. Please explain why you don't want to mask the entire external electrode.*

In response, they indicate that complete masking of the external return will result in having to rely on the grasper and internal returns alone. They quote from their previous response and restate the previous comments that the other return electrodes have variable contact and efficacy during use of the device. In short, they indicate that the device will not work as well without the external return. Specifically, they state that the poor contact of the other electrodes will lead to poor performance

and may reduce the energy deliver to the extent that the device may be only capable of desiccation of tissue rather than cutting. This is consistent with my understanding of the design of the device, though I also think the device will experience power drop-outs from frequent loss of circuit continuity from active to return.

Further, they indicate that the proximity of the external electrode to the active tip results in more rapid cooling (once the footswitch is released) by drawing off the heat more rapidly and in a safe area. I don't know whether I follow their logic on this, but I don't think it matter whether this is true or not.

Dr. Corrado did not comment on this question, but did not express continued concern about the design of the device. She has, instead, indicated that she is satisfied with the risk as they now describe it.

This deficiency has been resolved.

5. *Please provide a worst case scenario clinical risk analysis. We need to know the potential for non-target tissue (e.g. bowel and bladder, and retroperitoneal structures such as ureter) to be damaged during laparoscopic hysterectomy using this device.*

In response, they provided the requested worst case scenario risk analysis. They indicate that this question was addressed during the design phase for the device. They also describe the 3 scenarios for damage to unintended tissue. These 3 scenarios are:

- Collateral damage to target tissue during procedure
- Nerve or muscle stimulation when inadvertent activation occurs (case in pig study)
- Damage to unintended tissue due to residual heat in tip after deactivation

They suggest that the 1st two cases occur only when the user fails to exercise sufficient caution during use of the device. Dr. Corrado indicates in her review that she agrees with this assessment. This response along with material supplied May 25, indicate that bench testing suggests that the dissipation of heat is rapid in the third case and should not cause tissue damage unless immediately brought into contact with tissue. Graphs provided indicate a conservative estimate suggests as much as 10 seconds, but quicker dissipation is more likely. We asked for changes to the device labeling to bring this issue to the user's attention. This issue is discussed above and in the labeling questions below.

Dr. Corrado's May 1 review indicates that she is satisfied with this response (though further discussion at clinical/510(k) rounds resulted in some suggestions for labeling). Her May 1 review indicates while these are real clinical problems they are shared with many other electrosurgical devices and require user attention to instructions and proper use of the device.

Per discussion, while we agree that these risks are common with electrosurgical device, we are concerned that every other morcellator on the market (to the best of our knowledge) is mechanical. Thus, we need to be diligent with labeling for users who are sued to a mechanical device for this function. See labeling comments under Performance testing above and item 9, labeling below.

6. *Prior to your response, we were not aware that there was an internal return electrode for the device. Please provide a more detailed drawing or photograph of the electrode tip (you may want to combine this response with item 4 below).*

In response, they provide several detailed drawings with the parts identified. They also point out that the internal and external electrodes are merely exposed parts of the same copper tube that serves as one return electrode. Most of this tube is covered with insulation. Further, the grasper, they indicate, is connected to the same electrical potential. We were already aware that this served as a return electrode as well. This deficiency is resolved.

Materials

7. *Your response to item 4 of our email explains why the testing that has been done should address FDA's biocompatibility concerns. However, to review whether this testing is sufficient, we need to clarify which testing applies to which components and the type contact each component has. Please provide a detailed list that includes each component, the materials used to manufacture each component, each components patient contact potential (direct, indirect, no contact), predicate devices using the identical component, and clear photographs that show each component referenced (e.g., arrow pointing to specific components).*

In response, they expanded the original table provided to include an explanation of patient contact. Further, each material is correlated to key components on the drawings provided and additional drawings are included.

They also respond to our use of the term "identical component." They read this as implying that the predicate devices must use materials in identical components and refute this as a requirement. Use of exact composition of predicate materials is not discussed, which was the intent of that concern on our part.

This response prompted our May 4 phone call with Terri Sullivan and subsequent email that summarized the issues from the phone call. Our email asks for another table with the following for specific materials we identified as critical (e.g., not stainless steel, not making minimal contact, etc.):

- Exact trade name of material
- Specific name of predicate material
- Relevant amount of each material in proposed and predicate device
- Justify differences in materials proposed vs. predicate

- Test reports for materials using USP test data
- Justify why testing is supportive of use if other than ISO testing
- Address possible negative synergistic effect

They provided the requested information to us on May 14. They gave us a lot of information, but it still was not complete. We asked for more information on May 31—specifically in regard to the silicone materials, the depth stop, the two versions of the obturator, and colorants in any of the materials. They responded to this on June 12 with more information. We then discovered that the material to a major component was missing—the shaft sleeve (insulation). They provided that information the same day, but did not specify the version used (several color versions were in the materials provided). They gave us the color version on June 12, also.

M8ike Bailey reviewed the total information provided and determined that there were issues with the information provided for the gold-plated copper and braided resin with polane gray paint. He also indicates in his review dated July 6, 2007, that all of the materials together may have a synergistic effect. He is requesting full material safety testing on the final finished product.

> The company should provide independent biocompatibility testing on this device in accordance with ISO 10993-1 for a device with limited contact (<24h) with tissue. This would include cytotoxicity, irritation and sensitization testing of the patient contacting portions of your device. For the irritation and sensitization testing, both polar and non-polar extracts of the device should be assessed.

8. *✓If possible, provide a sample of your device to accompany the device photographs.*

In response, they did not provide a sample, but said they are keeping track of units to see if one will come available for us to see. A sample is not required and we have sufficient information at this point for review without the sample. This deficiency is moot.

Labeling

9. *Your response to question 7 of our letter indicates that if the device is used in accordance with the existing labeling, nerve stimulation should not occur. Your labeling, however, does not appear to directly address the elements of nerve stimulation as you describe them. Please modify your labeling as follows:*

   a. *Add a Warning statement that describes the potential risk of nerve stimulation including the elements that need to be present to create the event (e.g., contact with the abdominal wall, activation of the tip when not in the visible field, etc.)*
   b. *Add additional Warning statements to address risks to bowel and bladder, etc. as appropriate.*
   c. *Add specific statements within the instructions for use that identify steps that should be taken for safe use (e.g., activation of the electrode only when the distal end of the*

device is visible and target tissue is in place, not leaving the device in place out of the field of view, having the footswitch where it will not be inadvertently stepped on, etc.)

d. *Add any other appropriate warnings from research conducted with the device.*

On May 1, via email, Julia Corrado indicated that the responses provided showed that the company had revised the labeling as requested. However, per discussion during 510(k) rounds on May 3, we had additional clarifications for the labeling that were sent to the company on May 4.

> *To ensure that users are aware that the SORD carries risks not associated with mechanical morcellators (to which they may be more accustomed), please move this item from "CAUTIONS" to the "WARNINGS" section after the Warning that begins "If visualization of the treatment site ...." In addition, please add the following to page 1 of the labeling after the CAUTION statement: "Read all instructions, including CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS prior to use. Failure to follow these instructions could result in serious patient injury."*
>
> *Also, please include the heat dissipation paragraph on the package label.*
>
> *Provide mock-ups for revised labeling.*

The company responded with a discussion of heat dissipation on May 25, 2007. I did not think to apply this discussion to the labeling question at the time and, thus, on June 12 I requested that the company provide a copy of the package label—it should be noted that the May 25 email did not include a draft package label. In response, Teri Sullivan directed my attention to the May 25 email response and also indicated that the intention was to leave the labeling as is. He pointed out that the labeling includes a triangular icon with an exclamation point, a symbol defined by ISO 15223 to mean "Caution, consult accompanying documents." He also points out that FDA has recently recognized this ISO standard. This is not strictly true. While the standard is recognized, OIVD is the Office that is listed and only IVD devices are affected.

We will address this item when/if the file is resubmitted in a new 510(k).

Provide an overview of the review principles and findings that were used to support the reviewer recommendation.

This file is for a morcellator device. The main difference between this device and the other morcellators on the market is that this device uses electrosurgical energy to cut tissue rather than a mechanical system (sharpened metal blade). Further, most, but not all, morcellators have a motorized system for grinding or chewing tissue into smaller pieces. This device and its mechanical predicate actually cut tissue plugs that are extracted through the hollow shaft of the device. Issues regarding the nerve stimulation issue were adequately resolved. There remains an issue regarding material safety data. Information was provided on the multiple individual materials. The information was adequate for the individual materials with the exception of a gold plated copper and

a braided polymer. However, because of possible combined effects, we would like to see biocompatibility testing of the final finished product.

SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

		YES	NO	
1.	Is Product A Device	☑		If **NO** = Stop
2.	Is Device Subject To 510(k)?	☑		If **NO** = Stop
3.	Same Indication Statement?	☑		If **YES** = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5.	Same Technological Characteristics?	☑		If **YES** = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7.	Descriptive Characteristics Precise Enough?		☑	If **NO** = Go To 10 If **YES** = Stop **SE**
8.	New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9.	Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10.	Performance Data Available?		☑	If **NO** = Request Data
11.	Data Demonstrate Equivalence?			Final Decision: **SE**

In addition to completing the form, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

7. No. The firm was required to provide results from the following tests to better characterize the device:

- Electrical Safety
- Material Safety

10. Yes. The firm provided data and method references for Electrical Safety Tests.

The firm provided equivalent products for some materials, testing information for some materials, and certifications for some materials. However, the information was not sufficient for two materials (gold plated copper and braided resin with polane gray paint). Further, all of the information provided addresses the material safety of individual materials, but not the combination of materials which together compose the final finished product. Safety issues may occur as a result of combination of all materials and we do not have any data on the combined materials.

REVIEWER RECOMMENDATION

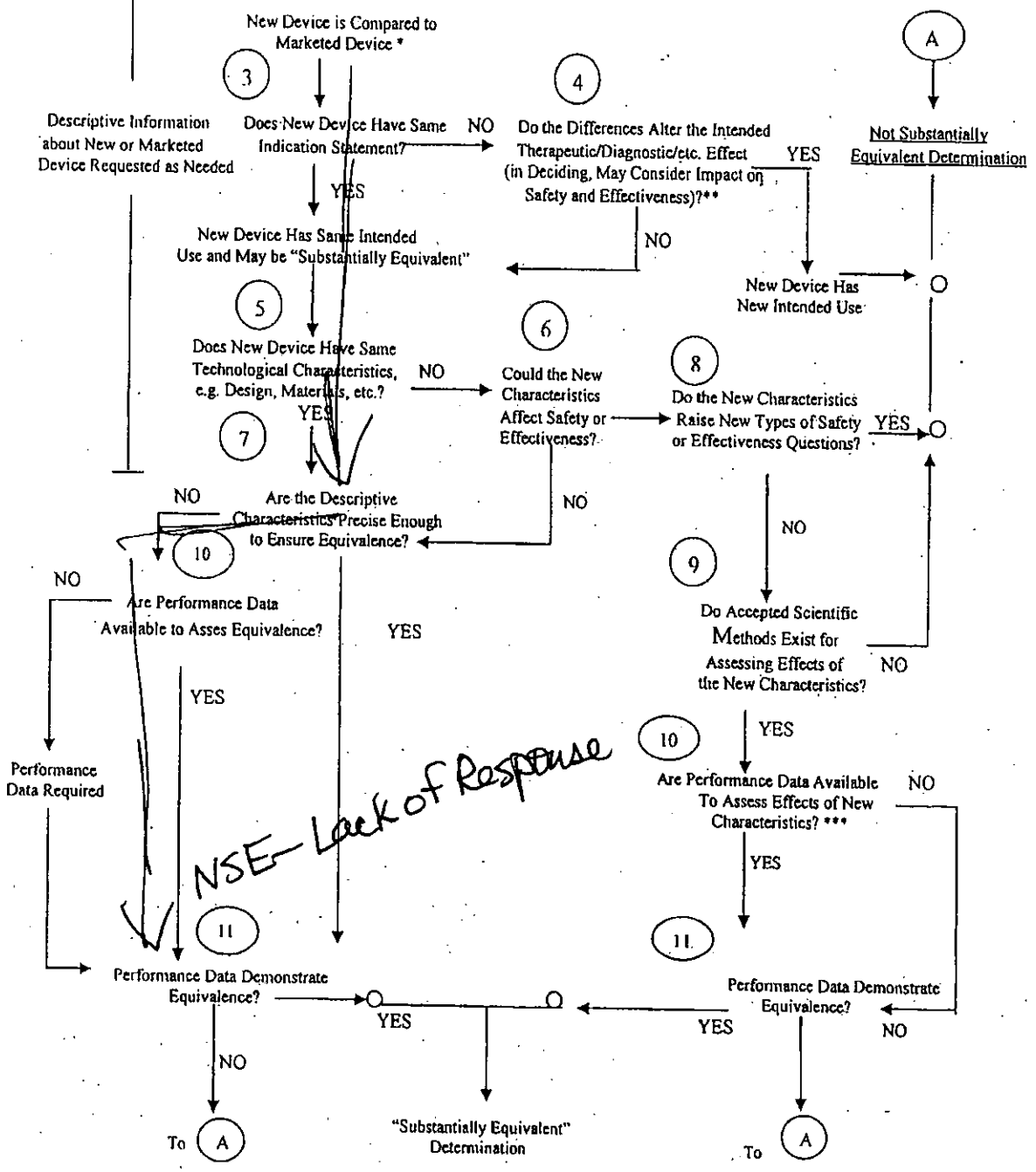
NSE for lack of response — three review cycles, extended back-and-forth

Kathryn S. Daws-Kopp 7/13/07
Kathryn S. Daws-Kopp Date

Colin M. Pollard 7/13/07
Colin M. Pollard Date
Chief, Ob/Gyn Devices Branch

/✓/ Concur
/ / Do not concur. Comment

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Public Health Service

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandums

Date: March 24, 2008

From: Michael T. Bailey, Ph.D.
Ob/Gyn Devices Branch, DRARD (HFZ-470)

To: George Mattamal
DGRND/GSDB (HFZ-410)

Subject: K080093 Gyrus ACMI, SORD – Biocompatibility data (Section 14)

Summary

I was brought into the review of this file with short notice before the due date. I have reviewed the biocompatibility test data supplied with this submission, and have generated a short description of the testing provided:

Section 14 includes a table describing the patient contacting materials of the device. The patient contacting materials can be broken down into 4 portions of the device as follows:

1. Outer tube assembly
2. Grasper
3. Depth Stop
4. Obturator

Outer Tube Assembly and Depth Stop

The company has provided biocompatibility data on the outer tube assembly (e.g., active ring electrode, active overmold, active tip adhesive, return tube, wire sleeve, valve, inner/outer shaft sleeve, shaft return tube adhesives). This portion of the device is considered an external communicating device with the potential for short term contact with tissue. Therefore, it is recommended that the company supply test data for cytotoxicity, sensitization, and irritation. The sponsor has supplied this testing for the outer tube assembly and depth stop portions of the device. A brief summary of the test data provided is presented below:

Cytotoxicity - This study was based on the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity: *in vitro* Methods guidelines. The test article was described as the SORD Outer Tube Assembly with fitted SORD Depth Stop. An extract of the test articles was prepared using single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (Test article extracted based on USP ratio of 120 cm^2:20 ml for 24h at 37°C). The test extracts were then placed onto three separate confluent monolayers of L-929 mouse fibroblast cells propagated in 5% CO_2. All monolayers were incubated at 37°C in the presence of 5% CO_2 for 48 hours. Following incubation, the cultures were examined microscopically to evaluate cellular characteristics and percent cell lysis. Results showed no evidence of the SORD Outer Tube Assembly or Depth Stop causing any cytotoxic effects of fibroblast cells. **Acceptable**

Sensitization- This study was based on the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Sensitization guidelines. The testing was performed on the SORD Outer Tube Assembly with fitted SORD Depth Stop. Extracts made from 0.9% sodium chloride and sesame oil were evaluated using the ISO Maximization Sensitization Study (extracted based on a ratio of 120 cm^2:20 ml for 72h at 50°C. Induction I: each extract was injected intradermally and occlusively pathched to 10 Guinea pigs (per extract). Induction II: six days after injection, injection sites treated with a 10% SLS in petroleum jelly. On day 7, a 2x4 cm patch containing 0.3 ml fresh extract applied to injection sites for 48h. Following a recovery period (14 days), test and control animals received a challenge patch of the appropriate test article extract or reagent control on the right an left flank, respectively (previously untreated areas) for 24h. All sites were scored at 24 and 48h after patch removal. Testing showed no evidence of sensitization from the materials tested. **Acceptable.**

Intracutaneous Reactivity- This study was based on the International Organization for Standardization 10993: Biological Evaluation of Medical Device, Part 10: Tests for Irritation and Sensitization. Extracts of the test article (SORD Outer Tube Assembly with fitted SORD Depth Stop) made from 0.9% sodium chloride and sesame oil were injected by the intracutaneous route into the back of rabbits (Test article extracted based on a ratio of 120 cm^2:20 ml for 72h at 50°C; injection dose of 0.2 ml per site). Observations for erythema and edema were made at 24, 48 and 72 hours. The testing showed no evidence of significant irritation from the SORD materials tested in this study. **Acceptable**

MTB Comment – The sponsor has provided sufficient information to demonstrate the biocompatibility of this portion of the device.

Obturator

The company has provided biocompatibility data on the obturator portion of the device. This portion of the device is also considered an external communicating device with the potential for short term contact with tissue. Therefore, it is recommended that the company supply test data for cytotoxicity, sensitization, and irritation. The company has supplied irritation, cytotoxicity, systemic toxicity, and muscle implantation testing on this potion of the device. A brief summary of the test data provided is presented below.

Cytotoxicity - This study was based on the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity: *in vitro* Methods guidelines. An extract of the test article, Terluran HD 15, was prepared using single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (Test article extracted based on USP ratio of 4 g:20 ml for 24h at 37°C). The test extracts were then placed onto three separate confluent monolayers of L-929 mouse fibroblast cells propagated in 5% CO_2. All monolayers were incubated at 37°C in the presence of 5% CO_2 for 48 hours. Following incubation, the cultures were examined microscopically to evaluate cellular characteristics and percent cell lysis. Results showed no evidence of the test material extract causing any cytotoxic effects of fibroblast cells. **Acceptable**

Intracutaneous Reactivity- This study was based on the International Organization for Standardization 10993: Biological Evaluation of Medical Device, Part 10: Tests for Irritation and Sensitization. Extracts of the test article (Terluran HD 15) were prepared in saline, alcohol in saline (1:20), PEG 400, and sesame oil (Test article extracted based on USP ratio of 4 g:20 ml for 24h at 70°C). The PEG test extract was diluted in saline to 120 mg PEG/ml before use. A 0.2 ml dose of each extract was injected intracutaneously into five separate sites on the back of each rabbit, while a similar volume of the extraction solution was injected on the other side of each

rabbits back. Observations for erythema and edema were made at 24, 48 and 72 hours. The testing showed no evidence of significant irritation from the test materials. **Acceptable**

Systemic Toxicity- This study was based on the International Organization for Standardization 10993: Biological Evaluation of Medical Device, Part 11: Tests for Systemic Toxicity guidelines. Extracts of the test article, Terluran HD 15, were prepared in saline, alcohol in saline (1:20), PEG 400, and sesame oil (Test article extracted based on USP ratio of 4 g:20 ml for 24h at 70°C). The PEG test extract was diluted in saline to 200 mg PEG/ml before use. Sodium chloride (IV), alcohol in saline (IV) and oil (IP) extracts were injected at a dose of 50 ml/kg, while the PEG extract was injected IP at a dose of 10 g/kg. Observations were made at 4, 24, 48 and 72 hours. The testing showed no evidence of mortality or systemic toxicity from the test materials. **Acceptable**

5 Day Rabbit Muscle Implantation- The purpose of this study was to evaluate the toxic effects of the test material in direct contact with living muscular tissue. The test article was described as Terluran HD 15. A minimum of 4 test or control EO sterilized samples (1 x10 mm) were implanted in the paravertebral muscle on the backs of rabbits of 3 rabbits (each rabbit received the test articles on one side of the back with the control articles on the other side of the back). After 5 days, the rabbits were euthanized, muscle tissue excised, and macroscopically assessed. Results of the macroscopic assessment showed no visible reaction associated with the presence of the test material. Therefore, the material was considered a non-irritant. **Muscle implantation studies generally consist of a microscopic analysis of the excised tissues; however, this was not done in this study. Generally, this would result in a question to the company. However, for this device, muscle implantation testing was not required, and the company has supplied sufficient Intracutaneous testing to assess the devices irritation potential. No further issues with the results of this test.**

MTB Comment - The company has provided testing for irritation, cytotoxicity, systemic toxicity, and muscle implantation. The results of these studies showed the Teluran HD 15 material to have acceptable biocompatibility. However, I do have two issues for the company to address. First, the company did not provided sensitization testing on this device material. The company will need to provided the results of sensitization testing on polar and non-polar extracts of the device, or provide a justification why additional testing is not required. Second, the company has not clearly stated whether the material tested is processed (e.g., mold release agents, colorants, sterilization process, etc.) the same as that used in their device. The company will also need to justify that the materials tested are representative of their device.

Grasper

The company has not provided independent test data on the materials used in the grasper portion of this device. The company has provided information from other 510(k) cleared devices to support the safe use of these materials. A review of the supporting information is provided below:

- Grasper Jaw (direct contact) – Made of type 303 stainless steel. The company states that this same material is used in the Gyrus ENT Cogent G2 Generator Accessories (K021777) and the predicate PlasmaCision Laparascopic Spatula (K041633)
- Grasper Jaw and Shaft Insulation (indirect contact) – Composed of polyolefin tubing (Altera MT-2000). Same material used in ACMI DUR-D device (K060269).

- Grasper Shaft (indirect contact) - Made of aluminum (ENAW5083) tube with sulfuric black anodizing process (BS1615). Same material used in the Surgical Innovations Laparoscopic Monopolar Scissors (K063485).

MTB Comment – The company has provided sufficient evidence to support the previous use of the grasper components in other devices. Results acceptable.

Questions for the Company

1. Biocompatibility of the obturator potion of your device was done on the material used to make this portion of the device (Terluran HD 15), and not on finished sterilized obturators. Please justify why testing on Terluran HD 15 is supportive of the safety of your finished, sterilized device. This justification should state the similarities and differences between the material tested and the finished device component (e.g., mold release agents, colorants, sterilization procedures, etc.). A detailed discussion why any differences in materials tested should not impact the use of the data supplied should also be included in your response. Please note that an inadequate response to this question may require the need for additional biocompatibility testing on this device.

2. Biocompatibility testing to demonstrate the safety of the obturator material (Terluran HD 15) did not include sensitization testing for this portion of the device. Please provide sensitization testing (e.g., ISO Maximization Test) using both polar and non-polar extracts of your device. Alternatively, provide a justification why sensitization testing on your device is not needed. Please note that an inadequate response to this question may require the need for additional biocompatibility testing on this device.

Recommendation
Request additional information.

_____ Dated: _____
Michael T. Bailey, Ph.D.
Prepared: 3/24/08 MTB

Mattamal, George

From: Daws-Kopp, Kathryn S.
Sent: Tuesday, March 25, 2008 3:24 PM
To: Mattamal, George
Cc: Ogden, Neil; Pollard, Colin M.; Bailey, Michael T
Subject: RE: Gyrus ACMI review

The only remaining issues were materials. So, Mike Bailey would be the one to talk to. Otherwise, the device was fine. I can forward my last review if you would like to see it.

Kathy

From: Mattamal, George
Sent: Monday, March 24, 2008 2:29 PM
To: Pollard, Colin M.
Cc: Ogden, Neil; Daws-Kopp, Kathryn S.
Subject: RE: Gyrus ACMI review

thanks Colin. I am waiting for Kathy tomorrow. Only after I discusses these issues with her, and then Neil, I will be finishing my review of this submission.

George J. Mattamal, Ph.D.

U.S. Food and Drug Administration
General Surgery Devices Branch
Division of General, Restorative and Neurological Devices
9200 Corporate Blvd
Rockville, MD 20850
Tel.# 240-276-3619
Fax # 240-276-3733
george.mattamal@fda.hhs.gov

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From: Pollard, Colin M.
Sent: Monday, March 24, 2008 1:31 PM
To: Mattamal, George
Cc: Daws-Kopp, Kathryn S.; Corrado, Julia A; Ogden, Neil
Subject: RE: Gyrus ACMI review

George:

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Kathy's out today, but she'll be in tomorrow. Could you visit us tomorrow or Wednesday and give us a brief overview of your review? I just would like to know how Gyrus addressed our questions.

Thanks!!

Colin

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Subject: RE: Gyrus ACMI review

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From: Bailey, Michael T
Sent: Monday, March 24, 2008 11:22 AM
To: Mattamal, George
Cc: Pollard, Colin M.
Subject: Gyrus ACMI review

Here it is. Let me know if you have any questions.

Michael T. Bailey, Ph.D.
FDA/CDRH/OGDB
9200 Corporate Blvd
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michael.bailey@fda.hhs.gov

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Mattamal, George

From: Daws-Kopp, Kathryn S.
Sent: Tuesday, March 25, 2008 5:31 PM
To: Mattamal, George
Subject: RE: Gyrus ACMI review
Attachments: K063134.S2.Gyrus.SORD.doc

No problem--Here it is.

Kathy

From: Mattamal, George
Sent: Tuesday, March 25, 2008 4:59 PM
To: Daws-Kopp, Kathryn S.
Cc: Ogden, Neil
Subject: RE: Gyrus ACMI review

Thanks Kathy, I will appreciate if you kindly send the final review. Thanks George

George J. Mattamal, Ph.D.

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Colin

Mattamal, George

From: Pollard, Colin M.
Sent: Tuesday, March 25, 2008 6:09 PM
To: Mattamal, George
Cc: Daws-Kopp, Kathryn S.; Bailey, Michael T; Ogden, Neil
Subject: RE: Gyrus ACMI review

George:

When Mike and I were looking at the 510(k), we were trying to understand how the device worked. It's got an annular cutting edge right at the distal end, with a grasping forceps to pull the tissue into the tube. So it looks like the device essentially "cores" the tissue. But what causes the tissue to break free from the fibroid, tumor, or whatever is being morcellated, in order to remove it from the surgical field?

Also, please remind me what the indications for use are? Can it be used to morcellate an entire uterus during hysterectomy?

If possible, maybe you could come down and just go over it briefly with me. I'll be in tomorrow by 9:30 am.

Thanks!

Colin

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Cc: Ogden, Neil; Pollard, Colin M.; Bailey, Michael T
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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 21, 2008

GYRUS ACMI, INC.
136 TURNPIKE RD.
SOUTHBOROUGH, MA 01772
ATTN: TERRENCE E. SULLIVAN

510(k) Number: K080093
Product: PKS PLASMA MORCELLATOR, MODELS 962000PK, 3620PK

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K080093/S1

GYRUS ACMI

FDA CDRH DMC

APR 18 2008

Received

April 17, 2008

Document Mail Center (HFZ-401)
Food and Drug Administration
Center for Devices and Radiological Health
Attn: Dr. George Mattamal
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: K080093; Premarket [510(k)] Notification - Gyrus ACMI PKS Plasma Morcellator – Request for additional information

Dear Dr. Mattamal:

As a follow up to your fax on March 28, and in response to the questions contained in the fax, Gyrus ACMI is submitting an original and one copy of this cover letter and enclosures through the Document Mail Center.

We request that the FDA keep confidential both the existence and the content of this premarket notification and cover letter in accordance with 21 CFR 807.95(b).

If you have any questions or require further information, please do not hesitate to contact me.

Sincerely,

Terrence E. Sullivan
Vice President, Regulatory Affairs

Phone: 508-804-2739
FAX: 508-804/2624
Email: Terry.Sullivan@gyrusacmi.com

Enclosures

Gyrus ACMI, Inc.
136 Turnpike Road
Southborough, MA 01772

office 508.804.2600
fax 508.804.2624
www.gyrusacmi.com

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K080093; Premarket [510(k)] Notification - Gyrus ACMI PKS Plasma Morcellator – Request for additional information

Question 1: Biocompatibility of the obturator portion of your device was done on the material used to make this portion of the device (Terluran HD 15), and not on finished sterilized obturators. Please justify why testing on Terluran HD 15 is supportive of the safety of your finished, sterilized device. This justification should state the similarities and differences between the material tested and the finished device component (e.g., mold release agents, colorants, sterilization procedures, etc.). A detailed discussion why any differences in materials tested should not impact the use of the data supplied should also be included in your response. Please note that an inadequate response to this question may require the need for additional biocompatibility testing on this device.

Response 1:
The obturator is manufactured from Terluran HD15, a type of ABS plastic provided by BASF. BASF provided biocompatibility test reports on natural Terluran HD15 for Cytotoxicity, Intracutaneous Reactivity, Muscle Implantation, and Systemic Toxicity. These reports were in turn provided to the Agency in the original submission.

In considering the suitability of the test data to support the biocompatibility of the final product, the following aspects may differ from the tested material, but all other aspects remain the same as the tested material:

Colorants: The obturator uses a 2% grey colorant, code 23335 manufactured by Clariant. This colorant is formulated using materials intended for food grade products, as defined by FDA guidelines. Gyrus ACMI consulted an independent toxicologist, who reviewed the material and its application and concluded:

> *"In view of the raw material supplier's declaration, the low amounts of colorant present in the Terluran HD 15, the probable poor leachability and the minimal contact time, in my opinion the amount of colorant releasable is likely to be well below any threshold of toxicological concern and testing on the colorant is scientifically unnecessary."*

The toxicologist's full assessment is enclosed as ***Attachment 1A*** (please note there is a typographic error in the date of the assessment, which should read 10 April 2008). Also, the manufacturer's declaration of colorant formulation is enclosed as ***Attachment 1B***. As noted in Attachment 1A, exposure to skin or sub-dermal muscle is limited to literally a few seconds, and the pigment in the colorant itself constitutes less than 1% of the total volume of the obturator.

Mold Release agents: A supplier, Trend Technologies, provides the fabricated obturator to Gyrus ACMI. Their manufacturing process takes place in a clean room, and Gyrus ACMI has confirmed with Trend Technologies that mold release agents are not used in the fabrication of the obturator. A letter from Trend Technologies attesting to this is enclosed as ***Attachment 1C***.

Sterilization procedures (Residuals): As part of the Ethylene Oxide sterilization process validation, the product has been tested for EtO residuals. The most absorbent part of the product was chosen (the PVC rubber cable), and residual result for EtO and EtOH were significantly below any level of concern directly after the EtO cycle. In reference to ISO 10993-7, Gyrus ACMI believes there is no risk to the patient from EtO residuals, and should not affect the data provided.

In summary, based on the potential differences discussed above, Gyrus ACMI does not believe that these potential differences would adversely impact the information provided, and believes that the information previously submitted suitably demonstrates the biocompatibility of this material.

Gyrus ACMI would like to note that the biocompatibility data for Terluran HD15 provided in K080093 was also previously provided during the review of K063134. Based on the feedback provided by the Agency during the review of K063134, as well as the specific materials cited in the NSE letter for K063134, it was Gyrus ACMI's understanding that the data provided concerning Terluran HD15 was deemed sufficient for demonstrating the biocompatibility of this material.

Question 2: Biocompatibility testing to demonstrate the safety of the obturator material (Terluran HD 15) did not include sensitization testing for this portion of the device. Please provide sensitization testing (e.g., ISO Maximization Test) using both polar and non-polar extracts of your device. Alternatively, provide a justification why sensitization testing on your device is not needed. Please note that an inadequate response to this question may require the need for additional biocompatibility testing on this device.

Response 2:
As part of the review of K063134, Gyrus ACMI had previously consulted with an expert toxicologist to review the Agency's questions, and develop a justification for the USP intradermal administration and intramuscular implant test data provided in that submission as well as submission K080093. A copy of the expert toxicologist's analysis is enclosed as ***Attachment 2***. As noted in the analysis, the sensitization testing requires repeated or prolonged administration to induce an immunologic response, and it is on re-administration after induction of the immunological response that the response is elicited in the form of a sensitization reaction. The Agency recently recognized the validity of the mouse local lymph node assay (or LLNA) as a substitute for the ISO recommended skin sensitization tests, which only examines for a response in the induction phase. As a result other methods could be considered suitable by the Agency for demonstrating sensitization suitability of materials, given their contact potential.

As noted by the independent toxicologist, it is recognized in skin sensitization testing that intradermal administration is a means of maximizing the sensitization effect occurring. Also as noted in the response to Question 1 above, the patient contact potential for the Obturator is limited to the initial application through a surgical stoma, a duration of literally seconds, when a trocar cannula is not utilized. Considering the contact duration of the Terluran material, the intradermal administration and intramuscular implant test data provided in the original submission, Gyrus ACMI believes that this data is sufficient to demonstrate the biocompatibility of the material and that further testing is not needed.

Question 3: The subject device shows that it has an annular cutting edge right at the distal end, with a grasping forceps to pull the tissue into the tube. So it looks like the device essentially "cores" the tissue. But what causes the tissue to break free from the fibroid, tumor, or whatever is being morcellated, in order to remove it from the surgical field? Also, can it be used to morcellate an entire uterus during hysterectomy? Please provide a detailed explanation regarding all these issues.

Response 3:
Essentially, the Agency's assessment regarding how tissue is removed is correct. It should be noted however that (as indicated in the "During Surgery" section of the Instructions for Use provided with the PKS Plasma Morcellator), tissue that is to be removed should be devascularized, fixed, and exposed prior to morcellation

Tissue to be morcellated is drawn with the grasper to the distal tip of the morcellator tube, where the active ring electrode is located. During the pre-clinical animal tissue evaluations, several morcellation techniques were utilized, including the "peeling" and "coring" techniques (please refer to report number 874021-01 in section 17.0 of the K080093 submission). It should be noted that clinician feedback during these animal studies indicated that the "peeling" technique was preferred as it allowed for a more cohesive mass of remaining tissue, facilitating subsequent "peeling" passes, and allowed a longer slug of tissue to be removed at a single pass. As a result, it is anticipated that the "peeling" technique will be emphasized in future PKS Plasma Morcellator educational and training materials.

Assuming a clinician will normally choose to utilize the peeling technique to morcellate target tissue, the target tissue would be drawn with the graspers to the distal tip of the morcellator tube. In an insufflated abdomen, the distal tip would remain relatively stationary, and the angle of the tube relative to the tissue would determine the length of the tissue slug. Other feedback obtained during the aforementioned evaluations also indicated that it is desirable and not uncommon (depending on surgeon skill), for an entire discrete tissue mass (e.g., fibroid tissue) to be morcellated in a single pass using the peeling technique. At this point, the morcellated tissue could be drawn out of the operative site with the graspers through the valve in the PKS Plasma Morcellator handle body. The morcellated tissue would then presumably be placed in a specimen tray (or however the clinician chooses to disposition the morcellated tissue), and the grasper reintroduced through the valve to the operative site.

Should a clinician choose to utilize a coring technique however, the grasper would again draw the tissue to the distal tip, although in a more tangential angle relative to the target tissue. As indicated above, the angle of the relatively stationary morcellator tube to the tissue would determine the length of the tissue slug. The morcellated tissue would then be removed as described above. It should be noted however, that while the clinician could use either technique, the Instructions for Use do contain specific Warnings about keeping the distal instrument tip in sight at all times, and as noted above it is anticipated that the "peeling" technique will be emphasized in future training and educational materials.

Unlike the predicate X-Tract device, the PKS Plasma Morcellator's active ring, located on the distal tip of the morcellator tube and which acts like the X-Tract's rotating cutting blade, does not become dull with use. As a result, the PKS Plasma Morcellator could be utilized to morcellate the entire uterus in a hysterectomy procedure if so desired by the clinician.

Finally, as discussed in the March 27 telephone call with Dr. Mattamal, Gyrus ACMI would like to reiterate that the PKS Plasma Morcellator is only compatible with Gyrus ACMI generators. Please note that the Instructions for Use provided in submission K080093 include a specific statement regarding the exclusive compatibility of the PKS Plasma Morcellator in the "Warnings" section. This statement is the second item in the Warnings section and may be found on page 2 of the IFU.

PICS Paul Illing Consultancy Services Ltd
Toxicology for Occupational Health, Product Safety and Environmental Protection
Sherwood, 37 Brimstage Road, HESWALL, Wirral CH60 1XE, UK
Tel/Fax: (+44) 151 342 1569; E.mail: paul@sherwood37.demon.co.uk

Alistair Fleming
Gyrus ACMI
Fortran Road
St Mellons
CARDIFF CF3 0LT

10 April 2007

Dear Alistair

As requested I set out my opinion on a comment raised by the US Authorities concerning the biocompatibility of the colorant in Terluran HD15 (Clariant 23335 [50% SAN {styrene-acrylonitrile copolymer} carrier CAS no 9003-54-7]).

For the device in question (the obturator) the material in contact with skin is Terluran HD 15 incorporating Clariant 23335 colorant. Biocompatibility testing provided by NAMSA for USPVI and cytotoxicity is for the natural HD15 material, without colorant. Whilst this testing is regarded as sufficient for the application of this device, consideration of the possible influence of the colorant is necessary.

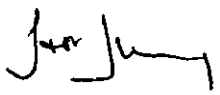
Exposure to skin / sub-dermal muscle is for a few seconds only, i.e. very short term single exposure. It is surface contact, breached or compromised surface, limited [officially defined as <24 hours; actually <<<<24 hours] contact. The Clariant 23335 colorant is present at ≤2% in the Terulan HD15. Given that the pigment is no more than 50% of the material present in Clariant 23335, it is ≤1% in the final product.

The attached declaration concerning Clariant 23335 indicates that the colorant meets the requirements of the FDA in terms of use as a food colorant in plastics intended for use in contact with food, including those intended for hot filling or pasteurisation above 150°F and those intended for ready prepared foods intended to be reheated in containers. Further, the attached information concerning regulatory compliance for Terulan HD 15 indicate that is intended for use in food contact applications. Any detectable leaching of the colouring from Terulan HD 15 would be unacceptable. Given the coloured nature of the colorant, this suggests that detection of release of colorant, should it take place, can be achieved by simple observation. As the colorant is acceptable to the FDA in food contact applications, it is apparently not detected.

Release is unlikely, even under conditions of exposure considerably more severe than those likely when it is used in the obturator. As detectable amounts of the colorant are not released from plastics intended for use in contact with food, and exposure to food is likely to be considerably longer than the skin exposure during obturator use, colorant will also not be released from plastic in much shorter contact with skin. No release means that there can be no bioincompatibility.

In view of the raw material suppliers declaration, the low amounts of colorant present in the Terluran HD 15, the probable poor leachability and the minimal contact time, in my opinion the amount of colorant releasable is likely to be well below any threshold of toxicological concern and testing on the colorant is scientifically unnecessary.

Yours sincerely



H P A Illing PhD, C Biol FIBiol, C Chem FRSC, etc.
Eurotox Registered Toxicologist

Clariant

To Whom It May Concern:

07.04.2008

23335

(50% SAN Carrier Cas Number 009003-54-7)

Declaration

Introduction

All statements refer exclusively to the above mentioned products. This confirmation, valid for plastic materials applications, does not consider or not take into consideration (apply to) the following matter:

- any future modification of the product whatever the nature of the added substances
- any processing likely to alter the product
- any checking of the inert nature of the finished product (extraction test according to the current regulations) and the non-modification of the organoleptic behaviour of the packed foodstuffs.

Since the manufacturer of this product has no influence on subsequent processing, the processor himself is requested, to carry out the corresponding tests in line with standard usage of the end article.

Following is the FDA status of the above Clariant Masterbatches product code:

Use Level
2%

The components of this product fall under one or more of the following categories for use in contact with food :

1. Colorants listed in 21CFR178.3297 *"Colorants for Polymers"*. Under conditions B-H
2. Components that are exempt from regulation under 21CFR170.39, "Threshold of Regulation for Substances Used In Food Contact Articles".
3. Polymers and/or additives listed in the appropriate parts of 21CFR(174,175,176,177,178,181,182,184, and 186).
4. Substances that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact applications in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.
5. Substances that are GRAS (Generally Recognized as Safe) for direct addition to food or for use in contact with food.

Please note that FDA maintains no regulations specifying the substances that may be used for the type device stated above. However, we consider the food contact status for the components used in this formulation to be appropriate support for the application.

If any of the use parameters listed above are contemplated to be changed, please contact us so that we may help you to determine whether this product will still be suitable.

Excerpted from 21 CFR 176.170, FDA (4-1-98 edition)

Table 2

The present declaration is compiled based on the best state of our knowledge and the laws in force according to the edition date of the document itself. It is forbidden to, entirely or partially, reproduce the present declaration and to issue it to a third party without written assent of Clariant

Clariant

Conditions of Use
A. High temperature heat-sterilized (e.g. over 212 ° F).
B. Boiling water sterilized
C. Hot filled or pasteurized above 150° F
D. Hot filled or pasteurized below 150° F
E. Room temperature filled and stored (no thermal treatment in the container).
F. Refrigerated storage (no thermal treatment in the container).
G. Frozen storage (no thermal treatment in the container).
H. Frozen or refrigerated storage: Ready-prepared foods intended to be re-heated in container at time of use: 1. Aqueous or oil-in-water emulsion of high- or low-fat. 2. Aqueous, high- or low-free oil or fat

Additional Information

Since the manufacturer of the masterbatch has no influence on subsequent processing, the processor is required to ascertain the conformity of the end article to the national and international regulations and laws. Due to the progress (evolution) of national and international regulations and laws the status of the above mentioned product could eventually change. If you have any doubt relating to the current correctness of this declaration, please contact us for an update.

Clariant Masterbatches Ireland Ltd.

Dermot Oakes
Quality Assurance Manager
Clariant Masterbatches Ireland Ltd
Monread Industrial Estate,
Naas
Co. Kildare
Ireland

The present declaration is compiled based on the best state of our knowledge and the laws in force according to the edition date of the document itself. It is forbidden to, entirely or partially, reproduce the present declaration and to issue it to a third party without written assent of Clariant

trend
TECHNOLOGIES MULLINGAR LIMITED

Zone C, Mullingar Business Park
Mullingar, Co. Westmeath, Ireland
Tel.: +353 44 9334300
Fax.: +353 44 9341448
www.trendtechnologies.com

Andrew Jenkins
Design & Development Engineer
Gyrus ACMI
Fortran Road
St. Mellons
Cardiff CF3 OLT
Wales

4th April 2008

RE: Gyrus Moulds

Dear Andrew,
Further to our conversation this week, I can confirm that Trend Technologies Mullingar do not use any silicone based chemicals, and do not use mould release sprays on any of the moulds used on any of the Gyrus programs. This practice applies to the production of all products for the Medical Device industry.

Heretofore this practice has not been documented, however I have taken this opportunity to include it in one of your Cleanroom Work Instructions. I have enclosed a copy of same with the letter.

If you require any further clarification on the above please let me know

Regards

Marie O'Toole
Quality & Cleanroom Manager

PICS *Paul Illing Consultancy Services Ltd*
Toxicology for Occupational Health, Product Safety and Environmental Protection
Sherwood, 37 Brimstage Road, HESWALL, Wirral CH60 1XE, UK
Tel/Fax: (+44) 151 342 1569; E.mail: paul@sherwood37.demon.co.uk

Alistair Fleming
Gyrus ACMI
Fortran Road
St Mellons
CARDIFF CF3 0LT

10 May 2007

Dear Alistair

As requested I attach my opinion on a comment raised by the US Authorities concerning biocompatibility.

'Justify why the testing conducted [USP VI test data] is supportive of safety if testing other than the suggested ISO testing for this type of device with similar contact potential is only available [presumably meaning is the only test undertaken]'

USP VI is a series of test protocols for *in vivo* tests for a substance intended for use in circumstances where there is a surface device in permanent contact through breached or compromised surfaces. The usual trio of tests are systemic injection (toxicity in mouse), intradermal administration (irritation) and intramuscular implantation (7 days). For the materials in question, test reports for these three tests are supplied.

The ISO 10993-1 recommendation for essentially similar circumstances is significantly heavier. ISO 10993-1 recommends genotoxicity and sub-acute/subchronic toxicity for a surface device in permanent [>30 days] contact with breached or compromised surfaces. In the two latter sets of circumstances I would not be able to accept USP VI as being an adequate substitute for the ISO recommendations for long-term exposure.

However, for the device in question (SORD), we are dealing with short term (few seconds in the case of Terluran HD15 (ABS polymer) and up to 2 hours in the case of TPE TF6STE (rubber)). These therefore are, in terms of ISO 10993-1, surface contact, breached or compromised surface, limited [<24 hours] contact, and the ISO 10993-1 recommendation is cytotoxicity, sensitisation and irritation/intracutaneous reactivity. The Table in which this is stated is headed 'Initial tests for consideration' and states as a footnote 'This table is a framework for the development of an assessment programme, *and is not a checklist'* (my italics). Further, when considering the assessment programme, in Europe it is necessary to comply with Directive 86/609/EEC

(on animal welfare), which requires that a test using vertebrates is not conducted when the necessary information is already available.

Cytotoxicity is, in essence, a non-animal substitute for the animal systemic injection study, and is preferable on animal welfare grounds. If one has already successfully undertaken a parenteral acute toxicity study *in vivo* I can see little point in conducting a cytotoxicity assay *in vitro* as essentially the same end point is being studied and an animal test is considered more relevant to the human situation. Conducting both tests is clearly undesirable on animal welfare grounds. The fact that the results are congruent does not excuse this duplication.

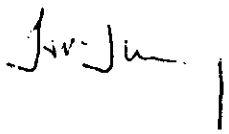
The intradermal assay is a test for irritancy/intracutaneous reactivity and is, I believe, rather more severe than a conventional Draize type assay. The ISO 10993 test permits surface application only, and it is generally recognised, in for example, skin sensitisation testing, that intradermal administration is a means of maximising the likelihood of the effect occurring. Thus the intradermal administration means that this test is likely to be more severe than the minimum ISO 10993 recommendation. As the ISO 10993 test is an *in vivo* test, it could not be undertaken in the European Union without breaching the requirements of Directive 86/609/EEC.

The more difficult question is whether the intramuscular implant test is an adequate substitute for a sensitisation assay, and, indeed, whether a sensitisation assay is required. Sensitisation required repeated or prolonged administration to induce an immunologic response, and it is on re-administration after induction of the immunological response that the response is elicited in the form of a sensitisation reaction. The substances in question are administered infrequently for very short times. Thus, in terms of risk, it is doubtful whether any test for skin sensitisation should be required. In addition, the ISO recommended skin sensitisation tests (the guinea pig maximisation test and the Buehler assay) have been superseded by the mouse local lymph node assay, which only examines for the induction phase. Thus undertaking one of the ISO 10993 tests in the European Union would breach the requirements of Directive 86/609/EEC and it is no longer considered by the UK Inspectorate concerned with animal welfare acceptable to perform either of the ISO recommended tests in the United Kingdom. In these circumstances, and in order to avoid unnecessary animal testing I accept that the intramuscular implantation test is an alternative way of investigating the sensitisation potential for very occasional limited contact [<<24 hour] duration but I would be unwilling to accept it for frequent repeated, prolonged [>24 h, but <30 days] or permanent exposure [>30 days]).

In terms of the science (and of the EU Medical Devices and Animal Welfare Directives), in my opinion the USP VI tests are adequate in the sense that they cover sufficiently the end-points required for testing medical devices/components intended for use as surface devices having limited contact with breached or compromised surfaces. Further, the ISO 10993 tests for skin irritation/intracutaneous reactivity and sensitisation could not

properly be conducted in addition to the USP VI tests in the in the European Union as to conduct them would be to breach the requirements of Directive 86/609/EEC on animal welfare.

Yours sincerely



H P A Illing PhD, C Biol FIBiol, C Chem FRSC, etc.
Eurotox Registered Toxicologist