



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (kml)
FOLDER: K141122 - 3982 pages
COMPANY: ETHICON ENDO-SURGERY, LLC (ETHIENDOSURGB)
PRODUCT: ELECTROSURGICAL, CUTTING & COAGULATION & ACCESSORIES (GEI)
SUMMARY: Product: HARMONIC SCALLOP BLADE, GENERATOR G11

DATE REQUESTED: Jan 4, 2016

DATE PRINTED: Jan 4, 2016

Note: Printed



1-TD

K141122

Ethicon Endo-Surgery, LLC, 510(k) Premarket Notification (Traditional) for Harmonic® Scallop Blade

April 25, 2014
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of General and Plastic Surgery Devices
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

APR 30 2014

Received

Re: Traditional 510(k) Premarket Notification, Harmonic Scallop Blade with Software

Dear Sir or Madam:

Pursuant to 21 CFR 807.90, Ethicon Endo-Surgery is submitting two copies of this 510(k) notification for the Harmonic Scallop Blade with software. The design of the device is based upon the Predicate Device Harmonic Combination Hook Blade HK105 cleared under K072203 and Medtronic Integrated Power Console System, cleared under K081475. This device works with the Generator G11 cleared in K101990 with updates to the software that is described in this submission. The basis of this submission is that the Harmonic Scallop Blade is a new device that is substantially equivalent to legally marketed devices. There have been no prior submissions for this device.

The following information is provided in this cover letter per the guidance document *Format for Traditional and Abbreviated 510(k)s*:

Submission Type: Traditional 510(k)
Submission Date: April 25, 2014
510(k) Submitter: Ethicon Endo-Surgery, LLC
Contact Information: Emily Kruetzkamp, Regulatory Affairs Associate
Phone: 513.337.1546
Fax: 513.337.2802
Email: ekruetzk@its.jnj.com

Device Common Name: Instrument, Ultrasonic Surgical
Trade Name: Harmonic Scallop Blade
Classification Names: Instrument, ultrasonic surgical
Device Class: Unclassified
Panel: 79, General and Plastic Surgery
Classification Code: LFL
Classification Regulation: Unclassified

Device Common Name: Electrosurgical & Ultrasonic Surgical Generator
Trade Name: Generator G11

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Ethicon Endo-Surgery, LLC, 510(k) Premarket Notification (Traditional) for Harmonic® Scallop Blade

Classification Names: Electrosurgical, Cutting & Coagulation & Accessories;
Electrocautery, Gynecologic (and Accessories);
Instrument, Ultrasonic Surgical
Device Class: Class II
Panel: 79, General and Plastic Surgery
Classification Code: GEI, HGI, LFL
Classification Regulation: 21 CFR 878.4400, 21 CFR 884.4120, & Unclassified (LFL)

Predicates: Harmonic 10cm Combination Hook Blade, K072203
Ethicon Endo-Surgery Generator G11, K101990
Medtronic Integrated Power Console (IPC®) System, K081475
Codman Cobb Spinal Elevator, Class I exempt per CFR 878.4800

Establishment Registration: 3005075853

Confidentiality Preference: Please keep this submission confidential per 21 CFR 807.95.
The following table contains answers to general questions regarding this submission.

Questions	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does the device type require reprocessed validation data?		
Does the device contain a drug?		X
Does the device contain biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

The unique payment identification number (PIN) assigned to this submission is

(b) (4) [REDACTED] copy of the Medical Device User Fee Cover Sheet is included in Section I.

Per the instructions accessed at "eCopy Program for Medical Device Submissions" an electronic copy is provided with this submission and it is an exact duplicate of the original paper submission. The electronic copy is accompanied by extra copies of the 510(k) cover letter and the 510(k) Truthful and Accuracy Statement with original signatures.

Ethicon Endo-Surgery, LLC, 510(k) Premarket Notification (Traditional) for Harmonic® Scallop Blade

All information necessary for a substantial equivalence determination is included herein. If there are any questions concerning this notification, please contact me at 513.337.1546 or by email at ekruetzk@its.inj.com. If I am not available, the alternate contact person for this submission is Kim Shoemaker, Director of Regulatory Affairs, at 513.337.8123.

Sincerely,



Emily Kruetzkamp
Regulatory Affairs Associate

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Section 1: Medical Device User Fee Cover Sheet (Form FDA 3601)

The Medical Device Use Fee Cover Sheet for this device is provided on the following page.

Form Approved OMB No. 0910-0511 Expiration Date April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) ETHICON ENDO SURGERY INC 4545 CREEK RD CINCINNATI OH 45242 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****7572		2. CONTACT NAME Emily Kruezkamp 2.1 E-MAIL ADDRESS ekruezk@its.jnj.com 2.2 TELEPHONE NUMBER (include Area code) 513-3371546 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm Select an application type:			
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. 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). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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 the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b) (4)		10-Jan-2014	

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

CONFIDENTIAL

3

ETHICON ENDO-SURGERY, INC
P.O. BOX 16500-6500
NEW BRUNSWICK, NJ 08906

Johnson & Johnson
SERVICES, INC.
As Paying Agent

RETURN SERVICE REQUESTED

Check No. (b) (4)
Check Date 01/28/2014
Check Amount \$5,170.00
Vendor No. (b) (4)



OD-000140 0001 0001 000140
FOOD AND DRUG ADMINISTRATION
P.O. BOX 956733
ST. LOUIS, MO 63195-6733

Invoice Date	Invoice Number	Description	Gross Amount	Discount Amount	Net Amount
01/27/2014	CR2529025	PREMARKET NOTIFICATION (510 (K))	\$5,170.00		\$5,170.00
TOTAL					\$5,170.00

PLEASE FOLD ON PERFORATION AND DETACH HERE

Page 1 of 1

VERIFY THE AUTHENTICITY OF THIS MULTI-TONE SECURITY DOCUMENT.

CHECK BACKGROUND AREA CHANGES COLOR GRADUALLY FROM TOP TO BOTTOM.

ETHICON ENDO-SURGERY, INC
P.O. BOX 16500-6500
NEW BRUNSWICK, NJ 08906

Johnson & Johnson
SERVICES, INC.
As Paying Agent

(b) (4)
January 28, 2014
64-1278/611
VOID AFTER 180 DAYS

Amount: **Five Thousand One Hundred Seventy dollars and 00 cents**

Pay to the order of
FOOD AND DRUG ADMINISTRATION
P.O. BOX 956733
ST. LOUIS, MO 63195-6733

Bank of America N.A.
Atlanta, Dekalb County, GA

AUTHORIZED SIGNATURE

CONFIDENTIAL

Section 2: CDRH Premarket Review Submission Cover Sheet

The CDRH Premarket Review Submission Cover Sheet for this device is provided on the following page.

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission April 25, 2014	User Fee Payment ID Number (b) (4)	FDA Submission Document Number (if known)
--------------------------------------	--	---

SECTION A TYPE OF SUBMISSION

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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 Ethicon Endo-Surgery, LLC	Establishment Registration Number (if known) 3005075853		
Division Name (if applicable) N/A	Phone Number (including area code) (b) (4)		
Street Address 475 Calle C	FAX Number (including area code) (b) (4)		
City Guaynabo	State / Province Puerto Rico	ZIP/Postal Code 00969	Country USA
Contact Name (b) (4)			
Contact Title Director, Plant Quality	Contact E-mail Address (b) (4)		

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

Company / Institution Name Ethicon Endo-Surgery, Inc	Phone Number (including area code) (513) 337-1546		
Division Name (if applicable) N/A	FAX Number (including area code) (513) 337-2802		
Street Address 4545 Creek Road	FAX Number (including area code) (513) 337-2802		
City Cincinnati	State / Province OH	ZIP Code 45242	Country USA
Contact Name Emily Kruezkamp			
Contact Title Regulatory Affairs Associate	Contact E-mail Address ekruezk@its.jnj.com		

SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D2

REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D3

REASON FOR SUBMISSION - 510(k)

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	LFL	2	HGI	3	GEI	4		
5		6		7		8		

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

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K072203	1 Harmonic 10cm Combination Hook Blade	1 Ethicon Endo-Surgery, LLC
2	K020069	2 Midas Rex Legend System	2 Medtronic Medtronic Rex
3	K101990	3 Ethicon Endo-Surgery Generator G11	3 Ethicon Endo-Surgery, LLC
4	Exempt	4 Cobb Spinal Elevator	4 Codman & Shurtleff, Inc., Depuy Synthes
5		5	5
6		6	6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

	Trade or Proprietary or Model Name for This Device	Model Number
1	Harmonic Scallop Blade	1 HARSB
2	Generator G11	2 GEN11
3		3
4		4
5		5

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

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

Data Included in Submission Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code LFL	C.F.R. Section (if applicable) Unclassified	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General & Plastic Surgery		

Indications (from labeling)
The Harmonic Scallop Blade is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.		FDA Document Number <i>(if known)</i>	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 3005075853	
<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer		<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Ethicon Endo-Surgery, LLC		Establishment Registration Number 3005075853	
Division Name <i>(if applicable)</i> N/A		Phone Number <i>(including area code)</i> (787) 653-4603	
Street Address 475 Calle C		FAX Number <i>(including area code)</i> (787) 653-4630	
City Guaynabo		State / Province Puerto Rico	ZIP Code 00969 Country USA
Contact Name Leo Rivera	Contact Title Director, Plant Quality	Contact E-mail Address lriver22@its.jnj.com	

(b)(4) Contract Manufacturer

(b)(4) Contract Manufacturer

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 (Continued)

(b) (4)

(b) (4)

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> 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 Code	Country
Contact 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	10993-7	AAMI/ANSI/ISO	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	2008	12/10/2008
2	11135-1	ISO	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2007	
3	10993-1	AAMI/ANSI/ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2009	10/15/2009
4	60601-1	IEC	Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance	2005	12/1/2005
5	60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	2007	03/01/2007
6	60601-1-8	IEC	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	2006	
7	62304	IEC	Medical device software - software life cycle processes.	2006	

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
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 number.

Section 3: 510(k) Cover Letter

The signed cover letter for this submission is provided on the following pages.

April 25, 2014

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of General and Plastic Surgery Devices
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Traditional 510(k) Premarket Notification, Harmonic Scallop Blade with Software

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(b) (4) The basis of this submission is that the Harmonic Scallop Blade is a new device that is substantially equivalent to legally marketed devices. There have been no prior submissions for this device.

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Submission Date: April 25, 2014
510(k) Submitter: Ethicon Endo-Surgery, LLC
Contact Information: Emily Krueztzkamp, Regulatory Affairs Associate
Phone: 513.337.1546
Fax: 513.337.2802
Email: ekruetzk@its.jnj.com

Device Common Name: Instrument, Ultrasonic Surgical
Trade Name: Harmonic Scallop Blade
Classification Names: Instrument, ultrasonic surgical
Device Class: Unclassified
Panel: 79, General and Plastic Surgery
Classification Code: LFL
Classification Regulation: Unclassified

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Trade Name: Generator G11

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Electrocautery, Gynecologic (and Accessories);
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Classification Regulation: 21 CFR 878.4400, 21 CFR 884.4120, & Unclassified (LFL)

Predicates: Harmonic 10cm Combination Hook Blade, K072203
Ethicon Endo-Surgery Generator G11, K101990
Medtronic Integrated Power Console (IPC®) System, K081475
Codman Cobb Spinal Elevator, Class I exempt per CFR 878.4800

Establishment Registration: 3005075853

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Does the device contain components derived from tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does the device type require reprocessed validation data?		
Does the device contain a drug?		X
Does the device contain biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

The unique payment identification number (PIN) assigned to this submission is (b) (4) [REDACTED] copy of the Medical Device User Fee Cover Sheet is included in Section 1.

Per the instructions accessed at "eCopy Program for Medical Device Submissions" an electronic copy is provided with this submission and it is an exact duplicate of the original paper submission. The electronic copy is accompanied by extra copies of the 510(k) cover letter and the 510(k) Truthful and Accuracy Statement with original signatures.

Ethicon Endo-Surgery, LLC, 510(k) Premarket Notification (Traditional) for Harmonic® Scallop Blade

All information necessary for a substantial equivalence determination is included herein. If there are any questions concerning this notification, please contact me at 513.337.1546 or by email at ekruetzk@its.inj.com. If I am not available, the alternate contact person for this submission is Kim Shoemaker, Director of Regulatory Affairs, at 513.337.8123.

Sincerely,

A handwritten signature in black ink that reads "Emily Kruetzkamp". The signature is written in a cursive style with a large initial "E".

Emily Kruetzkamp
Regulatory Affairs Associate

Section 4: Indications for Use Statement

The Indication for Use statements for the proposed devices are provided on the following page.

Indications for Use

510(k) Number (if known)

Device Name

Harmonic Scallop Blade

Indications for Use (Describe)

The Harmonic Scallop Blade is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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PRASStaff@fda.hhs.gov

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Indications for Use

510(k) Number (if known)

Device Name
Generator G11

Indications for Use (Describe)

The Generator G11 provides radiofrequency power to drive EnSeal electrosurgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissues. In addition, the generator provides power to drive Harmonic ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. EnSeal and Harmonic instruments when used with the Generator G11 have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

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Department of Health and Human Services
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Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“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 number.”

Section 5: 510(k) Summary

The 510(k) Summary for the Subject Devices is on the following pages.

510(k) Summary

Company

Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969

Contact

Emily Kruezkamp, Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc.
Telephone: (513) 337-1546
Fax: (513) 337-2802
Email: ekruezk@its.jnj.com

Date Prepared: April 25, 2014

Trade Name: Harmonic® Scallop Blade
Common Name: Instrument, ultrasonic surgical
Classification Name: Instrument, ultrasonic surgical
Device Class: Unclassified
Classification Regulation: Unclassified
Panel: 79, General and Plastic Surgery
Classification Code: LFL

Trade Name: Generator G11
Common Name: Electrosurgical & Ultrasonic Surgical Generator
Classification Names: Electrosurgical, Cutting & Coagulation & Accessories;
Electrocautery, Gynecologic (and Accessories);
Instrument, Ultrasonic Surgical
Device Class: Class II
Classification Regulations: 21 CFR 878.4400, 21 CFR 884.4120,
and Unclassified (LFL)
Panel: 79, General and Plastic Surgery
Classification Codes: GEI, HGI, LFL

Predicate Devices Harmonic® 10cm Combination Hook Blade, K072203
Generator G11, K101990
Medtronic Integrated Power Console (IPS®) System, K081475
Codman® Cobb Spinal Elevator, Class I exempt per
CFR 878.4800

Device Description:

The Harmonic® Scallop Blade is a sterile, single patient use device, consisting of a titanium blade with a non-removable gray sheath. The Harmonic® Scallop Blade instrument allows for the cutting of soft tissue and coagulation of vessels up to and including 2 mm in diameter. A soft grip pad on the handle housing facilitates grasping. The instrument is equipped with an integrated internal torque wrench, which is used for assembly to the Harmonic® Hand Piece.

The device system has four essential parts: the generator, the Footswitch, the Hand Piece, and the instrument. The Generator G11 supplies energy to Enseal® electrosurgical instruments and Harmonic® ultrasonic surgical instruments. The generator utilizes a touchscreen display interface and has a receptacle port that accepts either Enseal® or Harmonic® devices. Connectors (one for Harmonic® and one for Enseal® instruments) are used to enable the generator to power currently cleared surgical instruments. The Generator G11 hardware has not changed from the Predicate. The Harmonic® Scallop Blade instrument is designed for use exclusively with the Generator G11 software version 2013_1 or later, which has been updated to increase the maximum Power output to 60W required to power the Harmonic Scallop Blade.

Indications for Use:

Harmonic Scallop Blade

The Harmonic Scallop Blade is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

Generator G11

The Generator G11 provides radiofrequency power to drive EnSeal electrosurgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissues. In addition, the generator provides power to drive Harmonic ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. EnSeal and Harmonic instruments when used with the Generator G11 have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures.

Technological Characteristics:

The Harmonic® Scallop Blade is similar in technological characteristics to the Predicate Device, the Harmonic® Combination Hook Blade HK105. The Harmonic Scallop Blade end effector design is different in that it incorporates a wide concave blade design.

The Subject Device Harmonic® Scallop Blade is similar to the Predicate Device Cobb Spinal Elevator in its ability to scrape soft tissue from orthopedic structures. The Subject Device Harmonic Scallop Blade is similar to the Predicate Device Medtronic IPC® System with Midas Rex® Legend® instruments in that the devices have the same durability when touching orthopedic structures in removing soft tissue from bone.

The Generator G11 supplies power to both the Enseal® electrosurgical and Harmonic® ultrasonic surgical devices. The Subject Device Generator G11 software version 2013_1 enables the maximum ultrasonic power output to 60W.

Performance Data:

Ex-vivo and in-vivo tests were performed to verify that the performance of the Harmonic Scallop Blade instrument meets the definition of substantial equivalence to the Predicate Devices, Harmonic® Blade HK105, Codman Cobb, and Medtronic Integrated Power Console (IPC®) System, Midas Rex® Legend® instruments. Device performance was assessed against design requirements, including bench and preclinical testing. Applicable software verification and validation testing was completed per FDA Guidance for industry and staff “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” and “General Principles of Software Validation; Final Guidance for Industry and FDA Staff.” Bench testing includes device durability, acoustics, and reliability testing. Preclinical studies include acute and 30-day survival studies, and demonstrate device performance on spot coagulation, general

procedure capability, hemostasis following muscle transection, tissue effects and healing response, and blade strength to access orthopedic procedures. These testing criteria demonstrate that the Harmonic® Scallop Blade performs as intended and is substantially equivalent to the Predicate Devices.

This submission does not include data from Clinical Studies.

Section 6: Truthful and Accuracy Statement

The Truthful and Accuracy Statement for the device is provided on the following page.

Truthful and Accuracy Statement

The Truthful and Accuracy Statement, as required by 21 CFR 807.87(k) is provided below.

I certify that in my capacity as Regulatory Affairs Associate for Ethicon Endo-Surgery 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 fact has been omitted.



Emily Kruezkamp
Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc.



Date

Section 7: Class III Summary and Certification

This section does not apply; the Harmonic Scallop Blade is a Class II device.

Section 8: Financial Certification or Disclosure Statement

This section does not apply because this submission does not reference any clinical trial, 21 CFR 807.87(i). There were no Clinical Trials or Clinical Investigators referenced.

Section 9: Declarations of Conformity and Summary Reports

This section does not apply; this submission is a Traditional 510(k).

Section 10: Executive Summary

The purpose of this 510(k) submission is to provide FDA information to review the design of the Harmonic® Scallop Blade. Special Controls do not apply to this device. This submission provides information for a modified Harmonic blade design and a (b) (4) [REDACTED] [REDACTED] to power the Subject Device Harmonic Scallop Blade. In addition, this submission provides data to support remove the contraindication that the device is not indicated for incising bone.

Device Description

The Subject Device Harmonic Scallop Blade HARSB is an ultrasonic energy device, designed for open surgical procedures. The Harmonic Scallop Blade consists of a titanium blade with a non-removable gray sheath. A soft grip pad on the handle housing facilitates grasping. The blade has an angled edge to cut and seal tissue, and a flat side for coagulation. A scalloped, concave shape aids in the dissection and removal of soft tissue in surgical procedures.

The Harmonic Scallop Blade HARSB instrument works with the Generator G11 as part of a system. The device system has four essential parts: the Generator G11, the Footswitch, the Hand Piece, and the blade instrument. The Subject Device has an internal torque wrench, for assembly to the Harmonic Hand Piece. The Hand Piece connects the Harmonic devices to the Generator G11, and converts electronic energy into ultrasonic vibration. The high-frequency mechanical vibration at 55.5 kHz in the Harmonic device blade cuts and coagulates tissue, and seals vessels up to 2 mm. This ultrasonic vibration is a form of mechanical energy, and no electricity passes to or through the patient. This technology and blade design is ideal for achieving hemostasis and tissue dissection during surgical procedures. The Generator G11 has been modified with software version 2013_1 to allow the Subject Device to operate on an increased Power output of 60W. The Generator G11 hardware, dimensions, touchscreen interface are unchanged from the Predicate Generator cleared in K101990..

The Subject Device Harmonic Scallop Blade is a sterile, single patient use device. The device is not reusable and “cleaning” instructions for the end-user are not relevant.

Table 10.1 provides a detailed side-by-side comparison of the Subject Device and the Predicate Devices with respect to technology and device performance.

Table 10.1: Device Comparison Tables:

Instrument Technology and Performance

Characteristic	Subject Blade Device Description	Predicate Blade Device K072203 Description
Indication	The instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).	
Product Code	(b)(4) Trade Secret Process-Product Specs	
Device Length (end to end)		
Blade Length		
Handle Length		
Shaft Diameter		
Blade Thickness		
Blade Amplitude		
Handle Feature		
Blade Geometry		
Blade Material		
Device Assembly		
Seals Vessel Size		
Cutting Performance		
Energy Activation Method		
Sterilization Method		
Sterility Assurance Level (SAL)		
Packaging		
Operating Principle		
Generator Compatibility		
Software Compatibility, Generator		

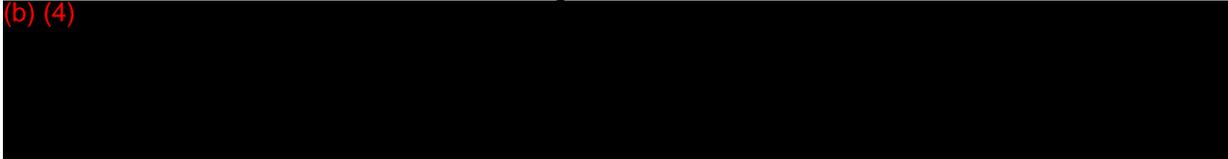
Generator G11 Technology and Performance

Characteristic	Subject Generator Device Description	Predicate Generator Device Description K101990
Indication	The Generator G11 provides radiofrequency power to drive EnSeal electrosurgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissues. In addition, the generator provides power to drive Harmonic ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. Enseal and Harmonic instruments when used with the Generator G11 have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures.	
Product Code	GEN11	Identical
Sterility Level	b(4)Trade Secret Process-Product Specs	
Supports instruments	b(4)Trade Secret Process-Product Specs	
Operator Interface	b(4)Trade Secret Process-Product Specs	
Overall Dimensions	b(4)Trade Secret Process-Product Specs	
Ultrasonic Output, Waveform Generation	b(4)Trade Secret Process-Product Specs	
Min Power Setting	b(4)Trade Secret Process-Product Specs	
Max Power Setting	b(4)Trade Secret Process-Product Specs	
Voltage Input	b(4)Trade Secret Process-Product Specs	
Ultrasonic Output Frequency, (Blade Frequency)	b(4)Trade Secret Process-Product Specs	
Ultrasonic Output Max, Power	b(4)Trade Secret Process-Product Specs	
Ultrasonic Output Max, Voltage	b(4)Trade Secret Process-Product Specs	
Ultrasonic Output Max, Current	b(4)Trade Secret Process-Product Specs	
Ultrasonic Output Diagnostics, Error Detection	b(4)Trade Secret Process-Product Specs	
Interface	b(4)Trade Secret Process-Product Specs	
Connectors for Legacy Devices	b(4)Trade Secret Process-Product Specs	

Summary of Performance Testing

Ex-vivo and in-vivo tests were performed to verify that the performance of the Harmonic Scallop Blade is substantially equivalent to the Predicate Devices: Harmonic® Combination Hook Blade, K072203; Medtronic Integrated Power Console (IPC®) System, K081475; and the Codman® Cobb Spinal Elevator, Class I exempt per CFR 878.4800. Details concerning the test methods, acceptance criteria, results and discussion are contained in Section 18 Performance Testing - Bench and Section 19 Performance Testing - Animal.

(b) (4)



Device performance was assessed against the design requirement for each of the following test requirements:

Ex-vivo Testing, Section 18 Performance Testing - Bench:

(b) (4)



In-vivo Testing, Section 19 Performance Testing - Animal

(b) (4)



Please note that the original documentation and some testing reports included in this submission may refer to the Subject Device Harmonic Scallop Blade as “Aries,” “Exposure Blade,” or “Spine Dissector.” These terms refer to the code name of the development project prior to the determination of the final device name. The term “HARSB” is the device product code. Thus all references to “Aries,” “Exposure Blade,” “Spine Dissector,” or “HARSB” refer to the Subject Device Harmonic Scallop Blade.

Section 11: Device Description

Device Design Overview and Principles of Operation

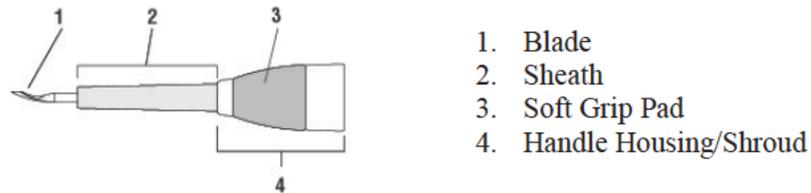
The Subject Device Harmonic® Scallop Blade HARSB is an ultrasonic energy device designed for open surgical procedures. The Harmonic Scallop Blade HARSB consists of a titanium blade with a non-removable gray sheath. A soft grip pad on the handle housing facilitates grasping.

The device uses electric power to create mechanical power in the end-effector blade, which vibrates at 55.5 kHz. This action cuts and coagulates tissue at the same time, and seals vessels up to 2 mm. Ultrasonic vibration is a form of mechanical energy, and no electricity passes to or through the patient. The Harmonic Scallop Blade HARSB instrument is powered by the Generator G11, and is considered part of the system. The device system has four essential parts: the Generator G11, the Footswitch, the Hand Piece, and the blade. The selection of the appropriate instrument is a matter of surgeon preference. The Subject Device is equipped with an integrated internal torque wrench to enable device assembly to the Hand Piece that connects to the Generator G11.

The Subject Device Harmonic Scallop Blade is a sterile, single patient use device. The device is not reusable and “cleaning” instructions for the end-user are not applicable. Special Controls have not been defined for this type of device.

The Subject Device has 4 main components. Figure 11.1 shows the Subject Device components.

Figure 11.1: Subject Device Components

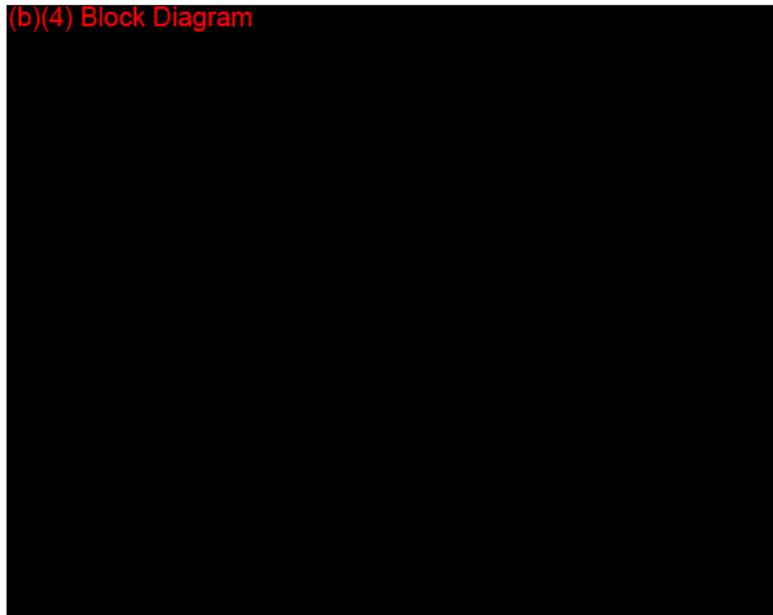


Device Name: Harmonic Scallop Blade. **Subject Device Code:** HARSB.

Device Dimensions

(b) (4) . Individual component dimensions are listed in Figure 11.2.

Figure 11.2: Subject Device Harmonic Scallop Blade Dimensions



Blade Design

The blade was designed with a scalloped concave shape to aid in the dissection and removal of soft tissue. The blade has an angled edge to cut through tissue and a flat side for broad tissue coagulation. These blade dimensions are ideal for soft tissue dissection and removal and coagulation. Additionally, the wide titanium blade creates a robust surface (for when the device is used on tough tissue). The figures 11.3 and 11.4 illustrate the Subject Device blade.

Figure 11.3: Subject Device Blade, Front



Figure 11.4: Subject Device Blade, Back



Generator System Components, Software, and Principles of Operation

The Harmonic Scallop Blade is designed for use exclusively with the Generator G11 (GEN11, cleared K101990), software version 2013_1 or later, the Harmonic Hand Piece (HP054, cleared K002906), and Harmonic Footswitch (FSW11, cleared K101990), each of which are packaged separately. The Subject Device is assembled to the Harmonic Hand Piece by twisting the device which contains an integrated torque wrench.

The generator supplies power to the instrument, and can automatically identify the type of instrument which is connected to it. The Subject Device contains an EEPROM chip that stores device identification, usage tracking, and operating parameters for use by the generator. The EEPROM is read by the Generator G11, so that the generator can identify the device and run the specified outputs. Then, based on the Footswitch command from the surgeon, the generator provides electrical power to activate the Hand Piece at the appropriate ultrasonic frequency, which then induces mechanical vibration at the appropriate amplitudes in the Harmonic Scallop Blade.

(b) (4)

The operating principle to create ultrasonic energy is identical to the Predicate Device Harmonic Combination Hook Blade (HK105), except that (b) (4)

This ultrasonic vibration is a form of mechanical energy, and no electricity

passes to or through the patient. (b) (4)

(b) (4) The Subject Device aims to reduce the frequency of the false error code by creating a more robust blade and allowing the system to operate under higher levels of system power. (b) (4)

(b) (4) The Subject Device testing shows the electrical safety of the increased output for the user and patient. The software testing demonstrates that the interaction between the software in the generator, the Hand Piece, and the Subject Device enables the correct energy output from the generator to the Subject Device, and does not introduce new safety or efficacy concerns. Additionally, validation testing demonstrates that the software does not inadvertently impact legacy devices and will not provide increased power to a legacy device that also operates on the same generator.

The generator provides two power levels: minimum (MIN) and maximum (MAX). The minimum power level may be adjusted by the user from Level 1 to Level 5, and the maximum level is always set to Level 5. The lower power level allows for increased coagulation, whereas the higher power level is used for increased tissue cutting and speed. The instrument is solely operated using the Harmonic Footswitch. Refer to Figures 11.5, 11.6 and 11.7 for illustrations of the Generator G11 and system components.

Figure 11.5: Generator G11



Figure 11.6: Hand Piece HP054



Figure 11.7: Footswitch FSW11



Table 11.1: The device is intended to be marketed with multiple components, each packaged separately.

Name	Product Code	510k Clearance	Description
Generator G11	GEN11	K101990	The Generator G11 supplies energy to the Harmonic and EnSeal surgical instruments. The generator uses a touchscreen display interface.
Footswitch	FSW11	K101990	The left pedal activates minimum power. The right pedal activates maximum power. The Footswitch connects to the generator with a cord, and is plugged into a receptacle at the back of the generator.
Harmonic Scalpel Hand Piece	HP054	K002906	The Hand Piece is designed to convert electrical energy from a compatible Harmonic Generator to mechanical motion for the instrument blades.

Hemostasis, Durability, and Clinical Use

The Subject Device mechanism of action and energy type are unchanged from the Predicate Device HK105. The Harmonic Scallop Blade device is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to, or substitute for electro surgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), and thoracic surgery, including mobilization of the internal mammary Artery (IMA).

(b) (4)

Cavitation, a side effect of the ultrasonic waves, occurs when the high-frequency vibration of a Harmonic device is transmitted to the surrounding tissue, causing rapid volume changes of the tissue and cell fluid. Vapor bubbles are then formed at body temperature. This cavitation effect aids in tissue plane dissection, and dissecting tissue planes enhances visibility in the operative field, which can be especially beneficial in anatomically remote regions or near vital structures. The Harmonic blade technology allows for soft tissue hemostasis, and transection of vessels up to 2 mm in size.

In a surgical orthopedic procedure, various devices can be used to scrape away soft tissue in order to access the orthopedic structure. For example, in order to access the spine, a surgeon may use a combination of devices, including the Predicate Device Harmonic Combination Hook Blade, to dissect soft tissue, a Cobb Spinal Elevator to release the tissue from bone, and then a Medtronic Integrated Power Console System (IPC®), Midas Rex® Legend® instruments to create bone defects.

The Subject Device, as well as the Predicate Device HK105, contains the indication to access orthopedic structures. The Subject Device has a wide, scallop-shaped titanium blade, which is ideal for transecting, and promotes blade durability and hemostasis. This design modification enables the device to not only transect soft tissue, but to scrape soft tissue from bone. The ultrasonic energy is beneficial because the dissection, hemostatic and cavitation effects enable visualization when accessing orthopedic structures and cleaning soft tissue from bone.

The bench and preclinical studies demonstrate that the Subject Device is (b) (4)



The Preclinical Testing, Section 19 demonstrates the blade durability by demonstrating device performance on creating bone defects, in comparison to the Predicate Device Medtronic IPC System, Midas Rex Legend instruments. The Medtronic IPC System and instruments were included as Predicates due to the durability of the end-effector when touching orthopedic structures.

The software has been updated to prevent Generator G11 false errors messages due to high pressure on the blade. Although the software has been updated to address higher load forces on the blade, the control mechanism has not changed. The ultrasonic energy continues to vibrate 55,500 times per second. Section 16 Software contains the full software verification testing. Since the energy type is unchanged, the thermal effects and opportunity for damage to adjacent structures, organs, or other tissue is equivalent to the Predicate Device Harmonic Combination Hook Blade HK105. The Subject Device will help minimize tissue damage while maximizing access to targeted anatomy. The Harmonic technology enhances the ergonomic ease of operating, while maintaining multi-functionality for various general procedures. The Subject Device Harmonic Scallop Blade provides tissue hemostasis, minimal tissue thermal effects, and the durability to access orthopedic structures by removing soft tissue from bone.

Summary of Differences from the Predicate Devices

The Predicate Device Harmonic Combination Hook Blade (HK105) Device was chosen as a predicate device because of the similar device technological characteristics. The Predicate Device HK105 utilizes ultrasonic power, which is a well-characterized energy type. The Subject Device has many of the same design characteristics as the Predicate Device.

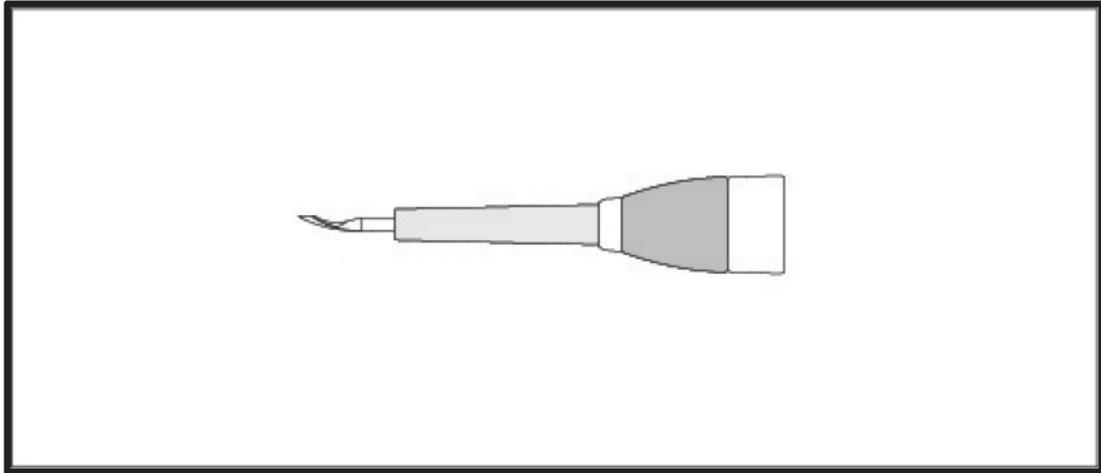
The Predicate Medtronic Integrated Power Console System, K081475, was chosen as a predicate device due to its similar properties such as end effector durability used to access orthopedic structures.

Figure 11.8: Predicate Device Harmonic Combination Hook Blade, HK105



Figure 11.9: Line Drawings of Subject Device Harmonic Scallop Blade HARSB and Predicate Device Harmonic Combination Hook Blade (HK105)

Subject Device HARSB:



Predicate Device HK105 (K072203):

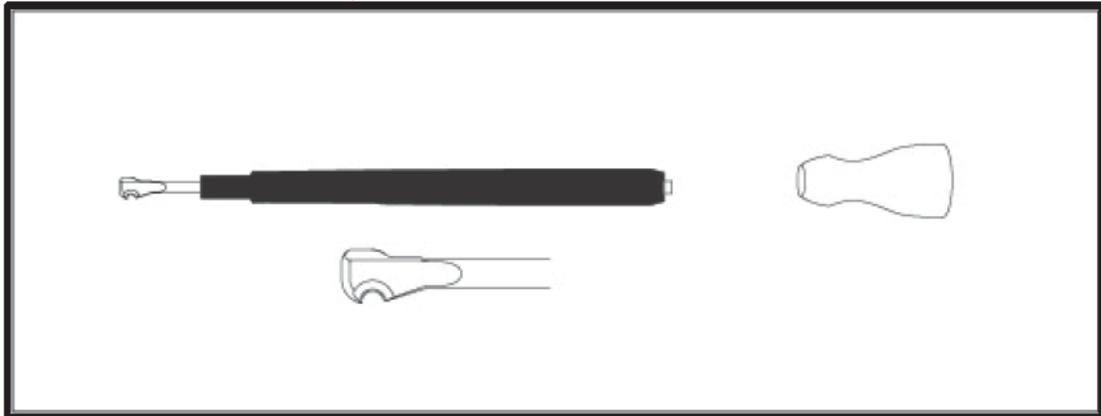
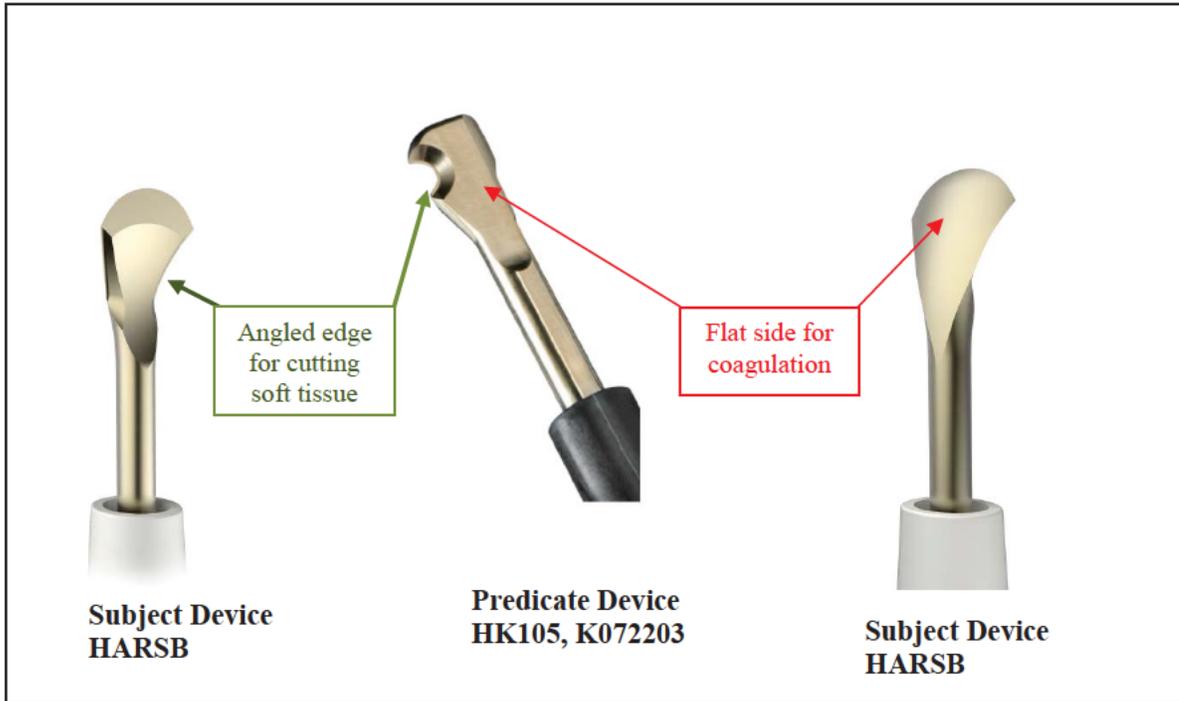


Figure 11.10: Features of the Subject Device blade compared to the Predicate Device HK105 blade



Summary of Differences from the Predicate Device, Related to Power and Software

There are no changes to the Generator G11 hardware. The Generator G11 supplies regulated power to both the electrosurgical and ultrasonic surgical instruments (i.e. Enseal and Harmonic products). The Generator G11 has the same diagnostic and error detection capabilities as described in K101990.

The generator does not require periodic calibration. The generator software has been updated for the Subject Device. The power curve for all Harmonic devices, including the Predicate Device HK105, reaches a maximum power output of 35 Watts. (b)(4)Trade Secret Process-Product Specs. When the Predicate Device HK105 encounters tougher tissue or higher loads, the generator will produce an error code "relax pressure on blade." (b)(4)Trade Secret Process-Product Specs

(b)(4)Trade Secret Process-Product Specs which minimizes the occurrence of false error codes during surgical procedures which place the device blade under high impedance. This type of tough tissue is prevalent in surgical procedures when accessing orthopedic structures. Scraping soft tissue from bone is a common step in orthopedic procedures. The Subject Device was designed to (b)(4)Trade Secret Process-Product Specs

Please refer to Section 16 for the full software validation data, as directed by FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. All verification and validation activities for the updated software version have been completed. Any

unresolved anomalies are addressed in Section 16. The Generator G11 with previous versions of software will not be able to run the Subject Device.

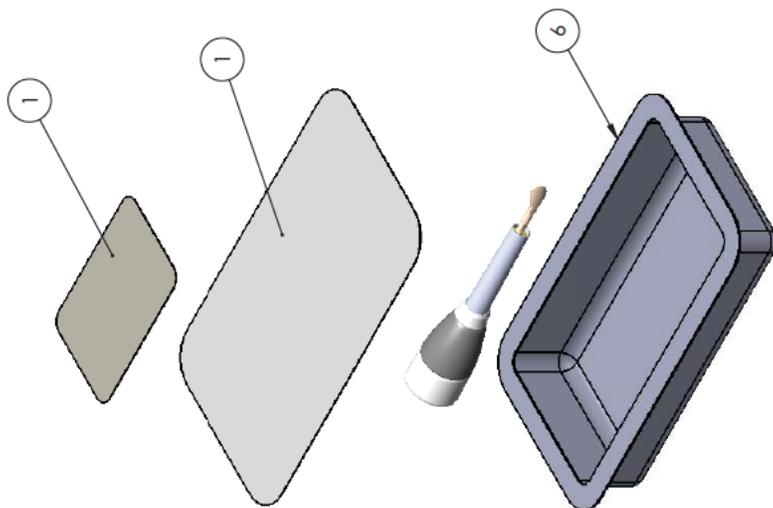
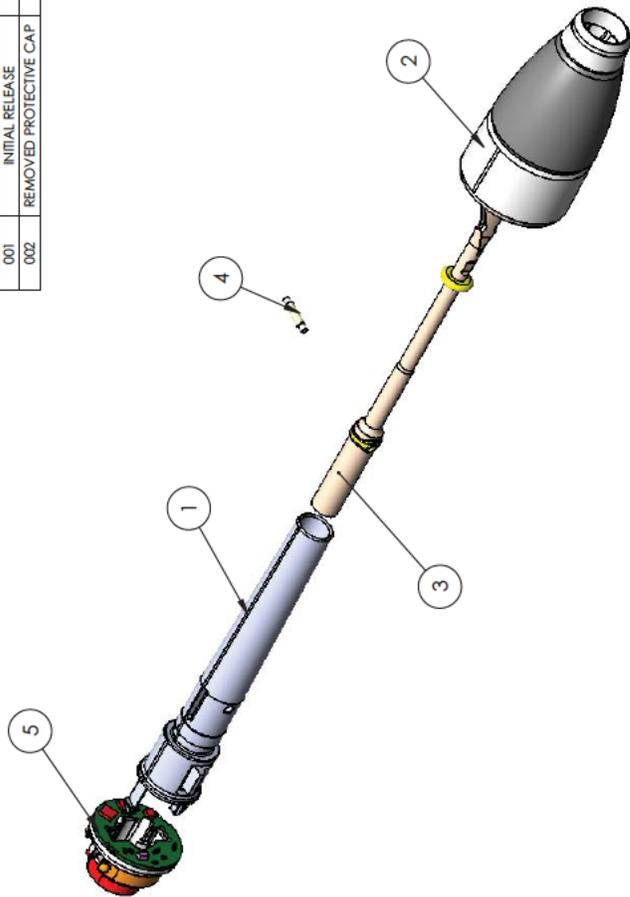
Please note the original documentation and some testing reports included in this submission may refer to the Harmonic Scallop Blade as the “Aries,” “Exposure Blade,” or “Spine Dissector.” These terms refers to the code name of the development project. The term “HARSB” is the device product code. Thus all references to “Aries,” “Exposure Blade,” “Spine Dissector,” or “HARSB” refer to the Harmonic Scallop Blade.

The Assembly Drawing is provided on the following page.

Issued By: pauld
 2 Initial Release Wednesday, April 16, 2008 11:03:19 AM

REV	DESCRIPTION	BY	DATE	ECO#
001	INITIAL RELEASE	PD	SEE ECO	549
002	REMOVED PROTECTIVE CAP	PD	SEE ECO	TBD

REVISIONS				
REV	DESCRIPTION	BY	DATE	ECO#
001	INITIAL RELEASE	PD	SEE ECO	549
002	REMOVED PROTECTIVE CAP	PD	SEE ECO	TBD



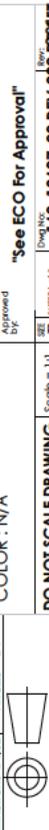
ITEM NO.	PART NUMBER	DESCRIPTION	Exploded View/QTY.
1	110-13589-00	SHEATH, SLIP SHROUD	1
2	110-13588-00	SHROUD	1
3	110-13604-00	ARIES BLADE - OVER MOLD	1
4	110-13591-00	INSULATED PIN	1
5	110-13608-00	ASSEMBLY, ARIES PC BOARD TRAY	1
6	110-13807-00	TYVEK LID	1
7	110-13808-00	TYVEK LID	1
8	110-13809-00	LABEL, TYVEK LID	1

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TOLERANCES
 UNLESS OTHERWISE SPECIFIED ALL DIMENSIONS ARE TO BE HOLD TO THE CLOSEST TOLERANCE AND ACCORDANCE WITH ASME Y14.5M-2009

INCHES		MM	
X	± .01	X	± 0.2
XX	± .005	X	± 0.1
XXX	± .0005	XX	± 0.05
XXXX	± 0.0005	XXX	± 0.010

FRACTIONS ± 1/32 ANGLES ± 1°



THIRD ANGLE PROJECTION

NOTES:
 1. NO LATEX OR NATURAL RUBBER SUCH AS GLOVES OR ELASTIC BANDS MAY COME IN CONTACT WITH THE PRODUCT OR BE USED IN THE MANUFACTURING PROCESS.

PARAMETRIC MODEL IS REFERENCED BY THIS DOCUMENT. CHANGES MUST BE VERIFIED.



ARIES HARMONIC BLADE FG ASSY
 Date: 12-10-2013
 Approved By: Paul Daly

"See ECO For Approval"

160-13607-00 REV 002 DDDRAFT

CONFIDENTIAL
 131-12817-01 REV. A

ECO 4929

APPROVAL DATE: 09-28-2010

EFFECTIVE DATE: 09-30-2010

DO NOT SCALE DRAWING Scale = 1:1

42

Section 12: Substantial Equivalence Discussion

The “510(k) Substantial Equivalence Decision Making Process (Detailed) Decision Tree” (Blue Book Memorandum K86-3, 1986) was used in determining substantial equivalence of the Ethicon Endo-Surgery ARIES.

New device is compared to Predicate Devices

Predicate Devices: Harmonic Combination Hook Blade HK105, K072203; Medtronic Integrated Power Console System K081475; Codman Cobb Spinal Elevator, Class I exempt per CFR 878.4800; Generator G11 GEN11, K101990

Subject Device: Harmonic Scallop Blade

Does new device have same indications statement?

No. The differences do not alter the intended therapeutic effect. The intended use is the same as the Predicate Device HK105.

Does the device have same technological characteristics, (e.g., design, materials, etc.)?

No. The device has been modified to enhance robustness. Additionally, different materials have been used on the Subject Device, as compared to the Predicate Device Harmonic Hook Blade.

Biocompatibility was evaluated based on the ISO 10993-1 Standard and FDA Guidelines. Refer to Section 15 Biocompatibility.

Could the new characteristics affect safety or effectiveness?

Yes

Do the new characteristics raise new types of safety or effectiveness questions?

No. The safety or effectiveness questions raised by the design changes are minor changes to enhance device robustness. The safety or effectiveness questions raised by the increased power output have been tested according to FDA Guidance and are not shown to raise new types of safety or effectiveness questions.

Do accepted scientific methods exist for assessing effects of new characteristics?

Yes. Refer to testing criteria identified in Section 16 Software which addresses criteria addressed by FDA Guidance General Principles of Device Validation and Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Section 17: Electromagnetic Compatibility and Electrical Safety, Section 18 Performance Testing – Bench, and Section 19 Performance Testing – Animal, which include the testing objectives, test articles, and methods for Subject Device testing. Additionally, the recognized ISO standards, listed in applicable sections, further confirm the existence of the scientific test methods used to assess the effect of new characteristics.

Are performance data available to assess effects of new characteristics?

Yes. Refer in Section 16 Software, Section 17: Electromagnetic Compatibility and Electrical Safety, Section 18 Performance Testing – Bench, and Section 19 Performance Testing – Animal, which includes the results and discussion for Subject Device testing.

Do performance data demonstrate equivalence?

Yes. Refer to Section 16 Software, Section 17: Electromagnetic Compatibility and Electrical Safety, Section 18 Performance Testing – Bench, and Section 19 Performance Testing – Animal, which includes the conclusion for Subject Device verification testing.

Substantially Equivalent Determination

In summary, the provided data supports the conclusion that the Harmonic Scallop Blade meets the definition of substantial equivalence to the Predicate Devices.

In accordance with the Safe Medical Devices Act of 1990 (SMDA), a summary upon which this substantial equivalence determination is based is enclosed in Section 5 510(k) Summary. This summary may be released to the public.

The Substantial Equivalence Decision Making Process Decision Tree, with the path applicable to this submission highlighted, is provided on the following page in Figure 12.1.

Ethicon Endo-Surgery, LLC, 510(k) Premarket Notification (Traditional) for Harmonic® Scallop Blade

The Harmonic Scallop Blade indication is similar to the marketed Predicate Devices, Harmonic Combination Hook Blade and the Medtronic Integrated Power Console (IPC) System. Please refer to Tables 12.1 and Table 12.2 for the Indications and Contraindications of the Subject Device Harmonic Scallop Blade. Please refer to Tables 12.3 and Table 12.4 for the Indications and Contraindications of the Subject Device Generator G11.

Table 12.1: Subject Device Harmonic Scallop Blade Indication

<p>Subject Device, Harmonic Scallop Blade</p>	<p>Predicate Device, K072203, Harmonic Combination Hook Blade</p>	<p>Predicate Device, K081475 Medtronic IPC System</p>
<p>The Harmonic Scallop Blade is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).</p>	<p>The Harmonic™ instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).</p>	<p>The IPC System is indicated for the incision/cutting, removal, drilling and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial), Orthopedic, Arthroscopic, Spinal, Stenotomy, and General surgical procedures.</p>

Table 12.2: Subject Device Harmonic Scallop Blade Contraindications

Subject Device, Harmonic Scallop Blade	Predicate Device, K072203, Harmonic Combination Hook Blade	Predicate Device, K081475 Medtronic IPC System
The instruments are not intended for contraceptive tubal occlusion.	The instruments are not indicated for incising bone. The instruments are not intended for contraceptive tubal occlusion.	The IPC System is contraindicated for arthroscopic microdiscectomy in individuals with the following: <ul style="list-style-type: none"> • Severe/progressive neurological deficits • Cauda equine syndrome • Active infection Arthroscopic microdiscectomy is not indicated for individuals with sequestered disc fragments, discogenic pain, internal disc destruction, or lumbago

Table 12.3: Subject Device Generator G11 Indication

Subject Device, Generator G11	Predicate Device, K101990, Generator G11
The Generator G11 provides radiofrequency power to drive EnSeal electrosurgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissues. In addition, the generator provides power to drive Harmonic ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. EnSeal and Harmonic instruments when used with the Generator G11 have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures	Identical

Table 12.4: Subject Device Generator G11 Contraindication

Subject Device, Generator G11	Predicate Device, K0, Generator G11
<ul style="list-style-type: none"> • The use of the Generator G11 and the attached instruments are contraindicated, when in the judgment of the physician, radiofrequency or ultrasonic surgery would be contrary to the best interest of the patient. • The instruments are not indicated for incising bone. 	Identical

The Harmonic Scallop Blade is similar to the legally marketed Predicate Device, the Harmonic Combination Hook Blade, in technology characteristics and Steps for Use. Differences in the steps for use include device assembly and disassembly that use the integrated torque wrench, generator software compatibility, as well as additional information to promote clarity of instructions, and Warnings and Precautions. Refer to Table 12.5 for the comparisons in the Steps for Use text, and Table 12.6 for comparisons in the Warnings and Precautions text. Key differences have been identified in bold font.

Table 12.5: Comparisons between the Subject Device and Predicate Device Harmonic Combination Hook Blade Steps for Use

IFU Text	Subject Device, Harmonic Scallop Blade, HARSB	Predicate Device, Harmonic Comb. Hook Blade, HK 105
<p>Steps For Use, Assembly</p>	<p>2. While holding the Hand Piece in a vertical orientation, align the proximal end of the device with the threads of the Hand Piece. Use fingers to grasp the soft grip pad on the handle housing and rotate the instrument onto the Hand Piece in a clockwise rotation (as viewed from the distal end of the instrument) until it clicks twice, indicating that sufficient torque has been applied to secure the instrument to the Hand Piece. WARNING: Take care to avoid injury from the blade tip when attaching the instrument to the Hand Piece. Caution: To avoid damage to the Hand Piece, do not use an external torquing device to attach or detach the instrument from the Hand Piece.</p>	<p>4. Attach the blade manually to the Hand Piece by turning it clockwise (finger tight only). Note: Take care to avoid injury from the blade tip when attaching the blade to the Hand Piece and while sliding the blade wrench onto or off of the blade.</p> <p>5. Use the blade wrench to tighten the blade. Slide the wrench over the blade until it stops at the flats on the blade. Align the flats on the wrench with the flats on the blade. Turn the wrench clockwise until it “clicks” twice, indicating that sufficient torque has been applied to secure the blade</p> <p>Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.</p> <p>6. Remove the blade wrench by sliding it straight back over the blade. Do not dispose of the reusable blade wrench. It is used for removal of the blade following the procedure.</p>

IFU Text	<p align="center">Subject Device, Harmonic Scallop Blade, HARSB</p>	<p align="center">Predicate Device, Harmonic Comb. Hook Blade, HK105</p>
<p>Steps For Use, Operation: Power Level Selection</p>	<p>2. Select the desired power level using the INCREASE and DECREASE buttons on the generator. Minimum starting power level defaults to power level 3 (Illustration 4). For greater tissue cutting speed use a higher generator power level, and for greater coagulation use a lower generator power level. The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors, including the power level selected, blade characteristics, tissue tension, tissue type, pathology, and surgical technique. Caution: The Harmonic Scallop Blade instrument is solely operated using the Footswitch. Refer to the Harmonic Generator G11 (GEN11) System User Manual for further detail and system operation instructions.</p>	<p>2. Select the desired power level using the INCREASE and DECREASE buttons on the generator.</p>
<p>Steps For Use, Operation: Footswitch</p>	<p>3. Remove the generator from STANDBY mode by depressing the standby button on the generator. Allow the generator to complete the test cycle before continuing with the surgical procedure.</p> <p>4. The instrument blade is ultrasonically energized when the Footswitch pedal is depressed. Press the left foot pedal of the Footswitch to activate the selected minimum power level (MIN). Press the right foot pedal of the Footswitch to activate the maximum power level (MAX).</p>	<p>3. The blade is ultrasonically energized when either Footswitch pedal or hand switching action button is depressed.</p>

IFU Text	Subject Device, Harmonic Scallop Blade, HARSB	Predicate Device, Harmonic Comb. Hook Blade, HK 105
<p>Steps For Use, Operation: Usage Steps</p>	<p>5. After inserting the instrument through an incision, press the blade against tissue during ultrasonic activation to cut and/or coagulate tissue under direct visualization. In general, sharper ultrasonically activated edges cut faster with less hemostasis while more blunt edges and surfaces coagulate more and cut less rapidly. For optimal performance, clean the instrument blade throughout the procedure by activating the blade tip in sterile saline.</p> <p>WARNING: Because the gray sheath may become hot, measures should be taken to provide a barrier between the sheath and tissue not intended for coagulation.</p> <p>Caution: Avoid accidental contact with other instruments during use. Do not clean the instrument with abrasives. The instrument can be wiped with a sterile moist gauze sponge to remove tissue, if necessary. Do not touch the blade to metal while activated. Scratches on the blade may lead to premature instrument failure.</p>	<p>- Avoid accidental contact with other instruments during use.</p> <p>- Do not use any other means than the blade wrench to attach or detach the blade.</p> <p>4. After inserting the blade through an incision, press the blade against tissue during ultrasonic activation to cut and/or coagulate tissue under direct visualization.</p> <p>Note: In general, sharper ultrasonically activated edges cut faster with less hemostasis, while more blunt edges and surfaces coagulate more and cut less rapidly. The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors, including the power level selected, blade characteristics, tissue tension, tissue type, pathology, and surgical technique.</p>
<p>Steps For Use, Disassembly, Turn Off Device</p>	<p>At the end of the procedure, unplug the Hand Piece from the generator. Caution: The Harmonic Scallop Blade is a sharp instrument. Take care to avoid injury from the blade tip while removing the instrument from the Hand Piece.</p>	<p>Turn the generator OFF at the power switch or enter STANDBY mode.</p>

IFU Text	Subject Device, Harmonic Scallop Blade, HARSB	Predicate Device, Harmonic Comb. Hook Blade, HK105
<p>Steps For Use, Disassembly with Integrated Torque Wrench</p>	<p>2. Hold the Hand Piece with one hand and use the other to grasp the soft grip pad on the handle housing. Loosen the instrument from the Hand Piece by turning the handle housing counterclockwise. Continue to loosen the handle housing manually to unscrew it completely from the Hand Piece. Caution: Do not grasp blade to disassemble.</p> <p>3. Dispose of the instrument in an appropriate container.</p>	<p>2. Slide the wrench over the blade until it stops at the flats on the blade. Align the flats on the wrench with the flats on the blade. Loosen the blade by turning the wrench counterclockwise. Continue to loosen by turning the wrench or blade manually to unscrew it completely.</p> <p>3. Remove the blade wrench by pulling it straight back over the blade. Save the blade wrench for future use. Note: Take care to avoid injury from the blade tip while sliding the blade wrench onto or off of the blade.</p> <p>4. Remove the blade and dispose of it in an appropriate container.</p> <p>5. Remove the adaptor and save it for future use if appropriate.</p>

Table 12.6: Comparisons between the Subject Device and Predicate Device Warnings and Precautions

IFU Text	Subject Device, Harmonic Scallop Blade	Predicate Device, K072203, Harmonic Combination Hook Blade
<p>Warnings and Precautions, General Statement Updates</p>	<ul style="list-style-type: none"> • Surgical procedures should be performed only by persons having adequate training and familiarity with surgical techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any surgical procedure. • Surgical instruments may vary from manufacturer to manufacturer. When surgical instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure. 	<ul style="list-style-type: none"> • Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure. • Minimally invasive instruments may vary from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
<p>Warnings and Precautions, Generator and Software Compatibility</p>	<p>Verify compatibility with generators. Use the Harmonic Scallop Blade instrument only with the Harmonic Generator G11 (GEN11) version 2013_1 or later.</p>	<p>Not present, this device is not limited by software version</p>
<p>Warnings and Precautions, Sounds</p>	<p>Audible high-pitched ringing, resonating from the blade or Hand Piece, is an abnormal condition and an indicator that the blade or Hand Piece is not operating properly. The ringing may be an indicator that the Hand Piece is beyond its useful life or that the blade has not been attached properly, which may result in abnormally high sheath temperatures and user or patient injury.</p>	<p>Audible high-pitched tones, resonating from the blade or Hand Piece, are an abnormal condition and an indicator that the blade or Hand Piece is not operating properly. The tones may be an indicator that the Hand Piece is beyond its useful life or that the blade has not been attached properly, which may result in abnormally high sheath temperatures and user or patient injury</p>
<p>Warnings and Precautions, Adaptor</p>	<p>Not present, not applicable</p>	<ul style="list-style-type: none"> • Do not use the Harmonic Combination Hook Blade without the proper adaptor. Failure to use the proper adaptor as described in the device description may result in user or patient burn injury.

IFU Text	Subject Device, Harmonic Scallop Blade	Predicate Device, K072203, Harmonic Combination Hook Blade
Warnings and Precautions, Intermittent Testing	Not applicable, as supported by testing in Section 17	<ul style="list-style-type: none"> The blade has been designed to meet the international safety standard EN60601-1 based on an intermittent operation of 15 second on/off intervals. For activation times of longer duration and under certain fault conditions, the blade sheath may become hot. To prevent burn injury, avoid direct tissue contact with the blade sheath or take preventative measures to protect tissue that comes in contact with the sheath.
Warnings and Precautions, Device Compatibility	Use only the Harmonic Footswitch and Hand Piece to ensure that they are compatible with the Generator.	Use only the Harmonic Footswitch, Hand Piece, blade accessories, and power cord to ensure that they are compatible with the generator.
Warnings and Precautions, Assembly	<ul style="list-style-type: none"> The Harmonic Scallop Blade is a sharp instrument. Take care to avoid injury from the blade tip while removing the instrument from the Hand Piece. Do not grasp blade to disassemble. 	Not present

IFU Text	Subject Device, Harmonic Scallop Blade	Predicate Device, K072203, Harmonic Combination Hook Blade
<p>Warnings and Precautions, Single Use Only</p>	<p>This device is packaged and sterilized for single use only. Multiple patient use may compromise the device integrity or create a risk of contamination that, in turn, may result in patient injury or illness.</p>	<p>This device is packaged and sterilized for single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness or death. Cleaning and resterilization of single patient use Harmonic devices can also result in abnormally high sheath temperatures and burn injury to user or patient when the blade is activated. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.</p>

Please note, minor verbiage, grammar and punctuation were adjusted to enhance readability.

Table 12.7: Comparison between the Subject Device and Predicate Device Generator G11 Manual Text

IFU Text	Subject Device, Generator G11	Predicate Device, K0, Generator G11
<p>System Specifications, Output</p>	<p>Harmonic Output: 150 VAC RMS maximum (Unless otherwise specified in the instrument IFU) 35 watts continuous (Unless otherwise specified in the instrument IFU) 30 - 80 kHz (55.5 kHz unless otherwise marked in instrument IFU)</p>	<p>Harmonic Output: 150 VAC RMS maximum 35 watts continuous 30 - 80 kHz (55.5 kHz)</p>

Please note, minor verbiage, grammar and punctuation were adjusted to enhance readability. Other updates to the manual include added language translations, and text to screens for address new instrumentation used with the Generator G11.

Table 12.8 provides a detailed side-by-side comparison of the proposed and Predicate Devices with respect to technology and device performance.

Table 12.8: Device Comparison Tables:

Instrument Technology and Performance

Characteristic	Subject Blade Device Description	Predicate Blade Device K072203 Description
Indication	The instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).	
Product Code	b(4)Trade Secret Process-Product Specs	
Device Length (end to end)		
Blade Length		
Handle Length		
Shaft Diameter		
Blade Thickness		
Blade Amplitude		
Handle Feature		
Blade Geometry		
Blade Material		
Device Assembly		
Seals Vessel Size		
Cutting Performance		
Energy Activation Method		
Sterilization Method		
Sterility Assurance Level (SAL)		
Packaging		
Operating Principle		
Generator Compatibility		
Software Compatibility, Generator		

Generator G11 Technology and Performance

Characteristic	Subject Generator Device Description	Predicate Generator Device Description K101990
Indication	<p>The Generator G11 provides radiofrequency power to drive EnSeal electrosurgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissues. In addition, the generator provides power to drive Harmonic ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. Enseal and Harmonic instruments when used with the Generator G11 have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these</p>	
Product Code	(b)(4)Trade Secret Process-Product Specs	
Sterility Level		
Supports instruments		
Operator Interface		
Overall Dimensions		
Ultrasonic Output, Waveform Generation		
Min Power Setting		
Max Power Setting		
Voltage Input		
Ultrasonic Output Frequency, (Blade Frequency)		
Ultrasonic Output Max, Power		
Ultrasonic Output Max, Voltage		
Ultrasonic Output Max, Current		
Ultrasonic Output Diagnostics, Error Detection		
Interface		
Connectors for Legacy Devices		

For a full material comparison, please refer to Section 15: Biocompatibility.

The Subject Device is substantially equivalent to the Predicate Device Harmonic Combination Hook Blade in that it has the same technical characteristics, such as ultrasonic energy type, hemostasis performance, and tissue effect. (b)(4)Trade Secret

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

Testing demonstrates that these changes do not introduce new types of concerns of safety or efficacy. The bench and animal testing protocols present the accepted scientific methods for assessing the effects of the blade dimension and software changes, the criteria for success, and the results.

Preclinical testing shows the Subject Device Harmonic Scallop Blade is substantially equivalent to the Predicate Device Harmonic Combination Hook Blade performance on tissue effects, ability to seal vessels up to and including 2 mm, and maintain hemostasis. Preclinical testing demonstrates the Subject Device Harmonic Scallop Blade is substantially equivalent to the Predicate Device Cobb Spinal Elevator performance to scrape soft tissue from bone. Preclinical testing demonstrates the Subject Device Harmonic Scallop Blade is substantially equivalent to the Predicate Device Medtronic Integrated Power Console System, Midas Rex Legend instruments in that it has the same durability to touch bone and create bone defects, and therefore demonstrates the capability of the Subject Device to touch orthopedic structures when scraping soft tissue from bone.

Contraindication Removal for Incising Bone

Performance data and information within this 510(k) Premarket Notification demonstrate that when the device is used in accordance with direction of the IFU on tissue and vessels up to 2 mm, it is not necessary that it be contraindicated for incising bone. There is no evidence that this usage is unadvisable or that the contraindication should remain. The manufacturer has not had any reported adverse events on the device, when interfacing with bone or accessing orthopedic structures. There is no demonstrated hypersensitivity to a device material if used to incise bone. There is no substantial risk of a patient or user being harmed because the device was used to incise bone.

It has been the collective industry understanding that only known hazards, and not theoretical possibilities, can be the basis for a contraindication. This understanding is also reinforced by FDA Device Labeling Guidance #G91-1 (blue book memo) Section IV. In order to present the most accurate labeling to the user, the manufacturer would like to remove this contraindication because there is no basis for its presence based on the new testing and performance. There is no known reason the contraindication should remain.

Acute and survival preclinical testing was performed to compare the Subject Device to a Predicate Device Medtronic Integrated Power Console System, which is indicated for incising soft and hard tissue and bone. Performance testing includes preclinical studies which assess gross tissue observations and histopathologic assessment including soft tissue effects and bone effects (refer to Section 19). Based on performance data and information in this submission, Ethicon Endo-Surgery is removing the following

contraindication updating and warnings and precaution for the Subject Device Harmonic Scallop Blade.

- Remove the Contraindication: The instruments are not indicated for incising bone.
- Warning/Precaution: Prolonged activation against solid surfaces, such as bone, may result in blade heating and subsequent blade failure, and should be avoided.

Section 13: Proposed Labeling

This section contains the proposed labeling for the Subject Devices, the labeling for the marketed Predicate Device Harmonic Combination Hook Blade, and the Instructions For Use (IFU) for the marketed Predicate Device Medtronic Integrated Power Console System. Please note that the Subject Device Harmonic Scallop Blade legal manufacturer is Ethicon Endo-Surgery LLC, but the device will be sold by Depuy Synthes Sales Force. Therefore, the Depuy Synthes logo is printed on portions of the Subject Device Harmonic Scallop Blade labeling.

Applicable pages if the Predicate Device Medtronic Integrated Power Console System are pages 152, 181, and 187.

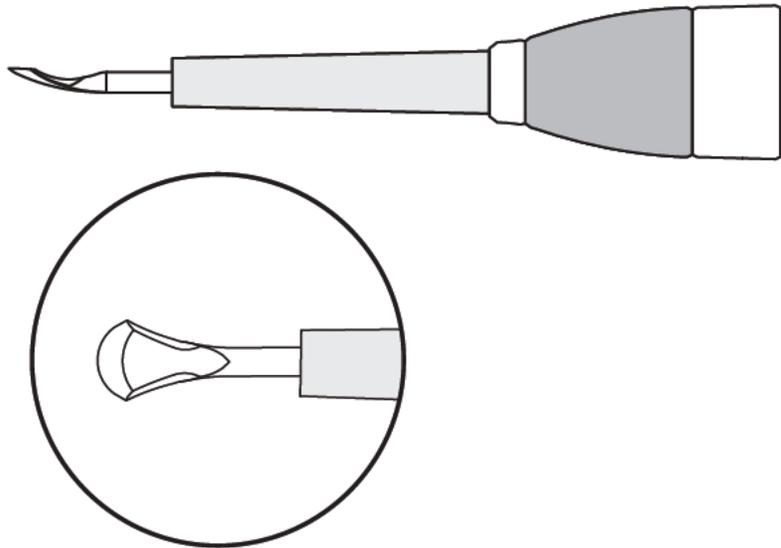
The labeling includes:

- Instructions for Use
- Primary Labels (also known as Tyvek labels)
- Carton Labels

Subject Device Harmonic Scallop Blade HARSB Package Insert

The Package Inserts will be supplied in multiple languages. This section includes only the English portions of the Package Insert.

HARMONIC® Scallop Blade



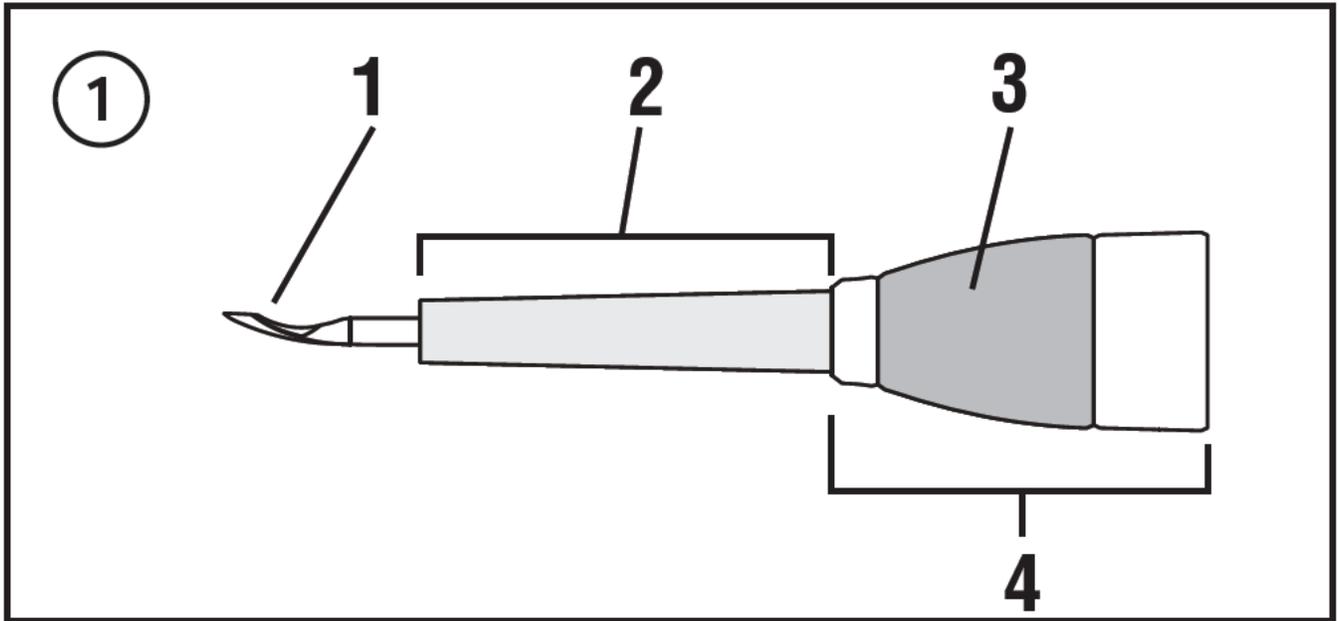
Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences, such as failure to ligate.

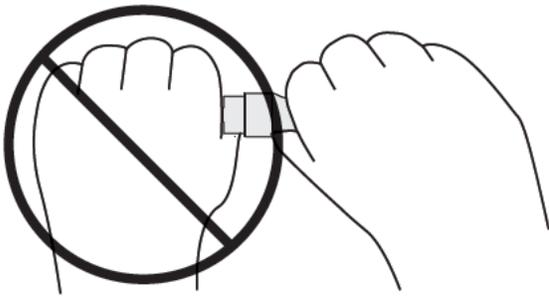
Important: This package insert is designed to provide instructions for use of the HARMONIC® Scallop Blade. It is not a reference to surgical techniques.

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**Instructions, Instructions, Gebrauchsanweisung, Istruzioni, Instruções, Instrucciones,
Gebruiksaanwijzing, Brugsvejledning, Ohje, Οδηγίες, Bruksanvisning, Instrukcja,
Utasítások, Návod k použití, Návod, 使用说明**

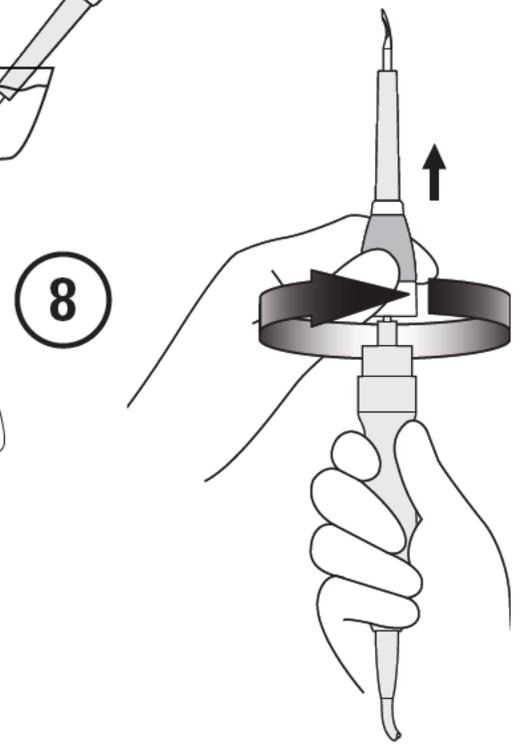
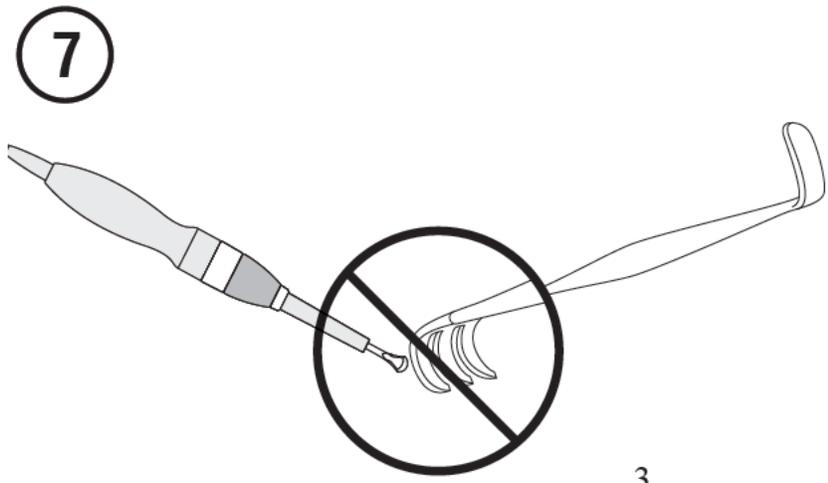
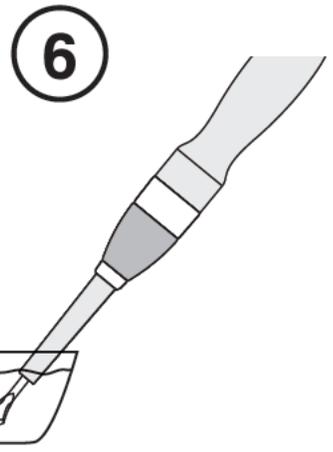
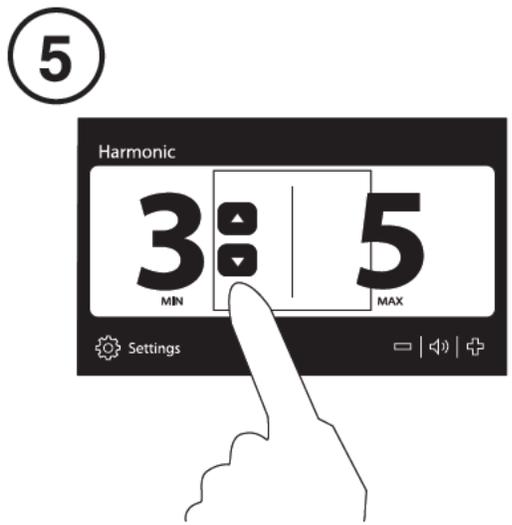
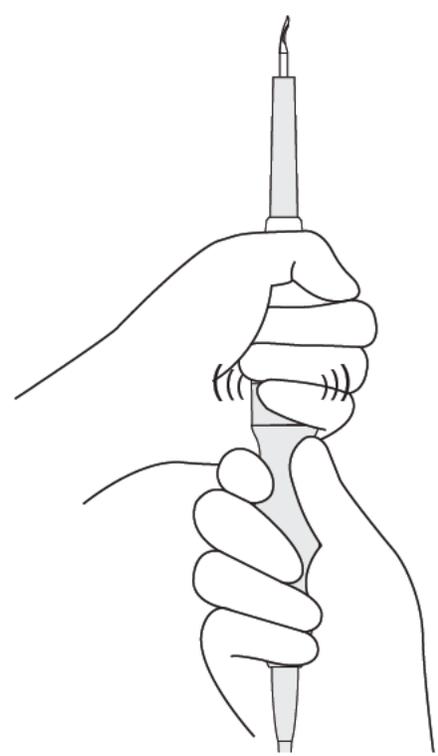
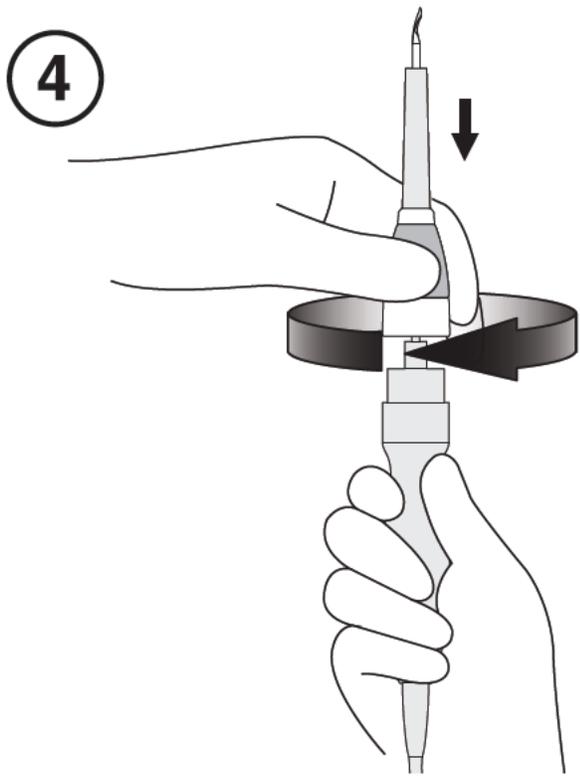


②



③





3

Indications

The HARMONIC Scallop Blade instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

Contraindications

- The instruments are not intended for contraceptive tubal occlusion.

Device Description

The HARMONIC Scallop Blade instrument is a sterile, single patient use device, consisting of a titanium blade with a non-removable gray sheath. The HARMONIC Scallop Blade instrument allows for the cutting of soft tissue and coagulation of vessels up to and including 2 mm in diameter.

A soft grip pad on the handle housing facilitates grasping. The instrument is equipped with an integrated internal torque wrench.

The HARMONIC Scallop Blade instrument is designed for use exclusively with the Generator G11 (GEN11) software version 2013_1 or later and the HARMONIC Hand Piece (HP054), packaged separately. The instrument is solely operated using the HARMONIC Foot Switch (FSW11). Refer to the HARMONIC™ Generator G11 System User Manual before using this instrument.

Output Specifications

340 VAC RMS

60 watts continuous

Illustration and Nomenclature (Illustration 1)

- 1 Blade
- 2 Sheath
- 3 Soft Grip Pad
- 4 Handle Housing

Transport and Storage Conditions

Temperature: -22°C to +60°C

Relative Humidity: 10-80%

Throughout the device labeling, the temperature and humidity recommendations and symbols are intended to provide guidance on short-term temperature and humidity excursions during transportation and storage.

For optimal long-term storage, it is recommended to store the instruments dry, at room temperature.

Instructions for Use

Verify compatibility of all instruments and accessories prior to using the instrument (refer to **Warnings and Precautions**).

The HARMONIC Hand Piece and Test Tip, packaged separately, are shipped non-sterile and must be sterilized per the insert instructions prior to each use.

Assembly

- Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
WARNING: The HARMONIC Scallop Blade is a sharp instrument. Take care to avoid injury from the blade tip when attaching the instrument to the Hand Piece.
WARNING: Do not grasp blade to assemble (Illustrations 2 & 3).
Caution: To avoid damage to the Hand Piece, do not use an external torquing device to attach or detach the instrument from the Hand Piece.
- While holding the handpiece in a vertical orientation, align the proximal end of the device with the threads of the Hand Piece. Use fingers to grasp the soft grip pad on the handle housing and rotate the instrument onto the Hand Piece in a clockwise rotation (as viewed from the distal end of the instrument) until it clicks twice, indicating that sufficient torque has been applied to secure the instrument to the Hand Piece (Illustration 4).

Operation

Refer to the HARMONIC Generator G11 (GEN11) System User Manual for Hand Piece attachment and system operation instructions.

- Connect the assembled HARMONIC Hand Piece and HARMONIC Scallop Blade instrument to the generator and turn the generator power on. Do not turn the generator power on before the Hand Piece and instrument are connected to the generator. Ensure the footswitch is connected to the generator.
- Select the desired power level using the INCREASE and DECREASE buttons on the generator. Minimum starting power level defaults to power level 3 (Illustration 5). For greater tissue cutting speed use a higher generator power level, and for greater coagulation use a lower generator power level. The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors, including the power level selected, blade characteristics, tissue tension, tissue type, pathology, and surgical technique.
Caution: The HARMONIC Scallop Blade instrument is solely operated using the Foot Switch. Refer to the HARMONIC Generator G11 (GEN11) System User Manual for further detail and system operation instructions.
- Remove the generator from STANDBY mode by depressing the standby button on the generator. Allow the generator to complete the test cycle before continuing with the surgical procedure.
- The instrument blade is ultrasonically energized when the Foot Switch pedal is depressed. Press the left foot pedal of the Foot Switch to activate the selected minimum power level (MIN). Press the right foot pedal of the Foot Switch to activate the maximum power level (MAX).
- After inserting the instrument through an incision, press the blade against tissue during ultrasonic activation to cut and/or coagulate tissue under direct visualization. In general, sharper ultrasonically activated edges cut faster with less hemostasis while more blunt edges and surfaces coagulate more and cut less rapidly. For optimal performance, clean the instrument blade throughout the procedure by activating the blade tip in sterile saline (Illustration 6).
WARNING: Because the gray sheath may become hot, measures should be taken to provide a barrier between the sheath and tissue not intended for coagulation.
Caution: Avoid accidental contact with other instruments during use. Do not clean the instrument with abrasives. The instrument can be wiped with a sterile moist gauze sponge to remove tissue, if necessary. Do not touch the blade to metal while activated (Illustration 7). Scratches on the blade may lead to premature instrument failure.

Disassembly

- At the end of the procedure, unplug the Hand Piece from the generator.
WARNING: The HARMONIC Scallop Blade is a sharp instrument. Take care to avoid injury from the blade tip while removing the instrument from the Hand Piece.

WARNING: Do not grasp blade to disassemble (Illustrations 2 & 3).

- 2 Hold the Hand Piece with one hand and use the other to grasp the soft grip pad on the handle housing. Loosen the instrument from the Hand Piece by turning the handle housing counterclockwise. Continue to loosen by turning the handle housing manually to unscrew it completely from the Hand Piece. (Illustration 8)
- 3 Dispose of the instrument in an appropriate container.

Warnings and Precautions

- Surgical procedures should be performed only by persons having adequate training and familiarity with surgical techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any surgical procedure.
- Surgical instruments may vary from manufacturer to manufacturer. When surgical instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse instruments in liquid unless the instruments are designed and labeled to be immersed.
- Verify compatibility with generators. Use the HARMONIC Scallop Blade instrument only with the HARMONIC Generator G11 (GEN11) version 2013_1 or later.
- In case of system failure, ensure the availability of the appropriate back-up equipment relevant to the specific procedure.
- Audible high-pitched ringing, resonating from the blade or Hand Piece, is an abnormal condition and an indicator that the blade or Hand Piece is not operating properly. The ringing may be an indicator that the Hand Piece is beyond its useful life or that the blade has not been attached properly, which may result in abnormally high sheath temperatures and user or patient injury.
- Blood and tissue buildup between the blade and sheath may result in abnormally high temperatures at the distal end of the sheath. To prevent burn injury, remove any visible tissue buildup at the distal end of the sheath.
- As with all energy sources (Electrosurgery, Laser, or Ultrasound), there are concerns about the carcinogenic and infectious potential of the by-products, such as tissue smoke plume and aerosols. Appropriate measures, such as protective eyewear, filtration masks, and effective smoke evacuation equipment, should be used.
- Do not attempt to bend, sharpen, or otherwise alter the shape of the blade. Doing so may cause instrument failure and user or patient injury.
- To avoid user or patient injury, in the event that accidental activation occurs, the instrument blade and distal end of the sheath should not be in contact with the patient, drapes, or flammable materials while not in use.
- Because the gray sheath may become hot, measures should be taken to provide a barrier between the sheath and tissue not intended for coagulation.
- During and following activation in tissue, the instrument blade may become hot. Avoid unintended contact with tissue, drapes, surgical gowns, or other unintended sites at all times.
- Prolonged activation against solid surfaces, such as bone, may result in blade heating and subsequent blade failure, and should be avoided.
- Avoid contact with any and all metal or plastic instruments or objects when the instrument is activated. Contact with staples, clips, or other instruments while the instrument is activated may result in cracked or broken blades, which may be identified by generator solid tone or instrument error.

- To avoid user or patient injury, do not activate an active electrosurgery device in close proximity to the HARMONIC Scallop Blade instrument. The aerosols created by the activation of the HARMONIC Scallop Blade instrument in fatty tissue are potentially flammable.
- The entire exposed blade tip and any exposed blade shaft is active and will cut/coagulate tissue when the instrument blade is activated. Be careful to avoid inadvertent contact between all exposed blade surfaces and surrounding tissue when using the HARMONIC Scallop Blade instrument.
- Use only the HARMONIC Foot Switch and Hand Piece to ensure that they are compatible with the Generator.
- After removing the instrument, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- Minimum starting power level defaults to power level 3.
- Use caution when using HARMONIC Scallop Blade instruments on solid organs. Due to the limited ability of the instruments to occlude vascular structures of this nature, hemostasis may not be predictable and may require adjunct measures for coagulation.
- Products manufactured or distributed by companies not authorized by Ethicon Endo-Surgery may not be compatible with the HARMONIC Scallop Blade instrument. Use of such products may lead to unanticipated results and possible injury to the user or patient.
- The HARMONIC Scallop Blade is a sharp instrument. Take care to avoid injury from the blade tip while attaching the instrument to the Hand Piece or removing the instrument from the Hand Piece.
- Do not grasp blade to assemble or disassemble.
- Instruments or devices that come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- Dispose of all opened instruments, whether used or unused.
- This device is packaged and sterilized for single use only. Multiple patient use may compromise the device integrity or create a risk of contamination that, in turn, may result in patient injury or illness.

How Supplied

The HARMONIC Scallop Blade instrument and removable cap are supplied sterile for single patient use. Discard after use.

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Follow Instructions For Use (Refer to blue symbol on outer packaging.)
Voir la notice d'utilisation (se reporter au symbole bleu sur l'emballage extérieur).
Bitte Gebrauchsanweisung beachten (siehe blaues Symbol an der äußeren Verpackung).
Vedere le Istruzioni per l'uso (vedere il simbolo blu sulla confezione esterna).
Consulte as Instruções de utilização (consulte o símbolo azul na embalagem exterior).
Ver instrucciones de uso (refiérase al símbolo azul en el envase exterior).
Zie de gebruiksaanwijzing (zie het blauwe symbool op de buitenste verpakking).
Se betjeningsvejledning (der henvises til det blå symbol på yderemballagen).
Katso käyttöohjeita (katso sinistä symbolia ulkopakkauksessa).
Δείτε τις Οδηγίες Χρήσης (ανατρέξτε στο μπλε σύμβολο, στο εξωτερικό της συσκευασίας).
Se bruksanvisningen (se den blå symbolen på yttre förpackningen).
Należy zapoznać się z instrukcją użytkowania (patrz niebieski symbol na zewnętrznym opakowaniu).
Lásd a használati útmutatót (lásd a külső csomagoláson található kék szimbólumot).
Viz návod k použití (informace jsou uvedeny u modrého symbolu na vnějším balení).
Prečítajte si návod na použitie (vzťahuje sa na modrý symbol na vonkajšom obale).

.....



Relative Humidity
Humidité relative
Relative Feuchte
Umidità relativa
Humidade relativa
Humedad relativa
Relativ fugtighed
Relativ fugtighed
Suhteellinen kosteus
Σχετική υγρασία
Relativ fuktighet
Wilgotność względna
Relatív páratartalom
Relativní vlhkost
Relatívna vlhkost

.....



Temperature
Température
Temperatur
Temperatura
Temperatura
Temperatura
Temperatuur
Temperatur
Lämpötila
Θερμοκρασία
Temperatur
Temperatura
Hőmérséklet
Teplota
Teplota

.....



Do not use the HARMONIC FOCUS Shears with ULTRACISION® Generator (GEN01/GEN32/GEN04).

Ne pas utiliser les ciseaux HARMONIC FOCUS avec le générateur ULTRACISION® (GEN01/GEN32).

Die HARMONIC FOCUS Schere darf nicht mit dem ULTRACISION® Generator (GEN01/GEN32) eingesetzt werden.

Non usare la forbice HARMONIC FOCUS con il generatore ULTRACISION® (GEN01/GEN32).

Não utilize a tesoura HARMONIC FOCUS com o Gerador ULTRACISION® (GEN01/GEN32).

No utilice las tijeras HARMONIC FOCUS con el generador ULTRACISION® (GEN01/GEN32).

Gebruik de HARMONIC FOCUS schaar niet met de ULTRACISION® generator (GEN01/GEN32).

Brug ikke HARMONIC FOCUS saksen sammen med ULTRACISION® generatoren (GEN01/GEN32).

HARMONIC FOCUS -saksia ei saa käyttää ULTRACISION®-generaattorin (GEN01/GEN32) kanssa.

Μη χρησιμοποιείτε το ψαλίδι HARMONIC FOCUS με τη γεννήτρια ULTRACISION® (GEN01/GEN32).

Använd inte HARMONIC FOCUS-saxen tillsammans med ULTRACISION®-generatorm (GEN01/GEN32).

Nie wolno używać nożyc HARMONIC FOCUS z generatorem ULTRACISION® (GEN01/GEN32).

A HARMONIC FOCUS metszőket tilos az ULTRACISION® generátorral (GEN01/GEN32) használni!

Nůžky HARMONIC FOCUS nepoužívejte s generátorem ULTRACISION® (GEN01/GEN32).

Nožnice HARMONIC FOCUS nepoužívajte s generátorom ULTRACISION® (GEN01/GEN32).

.....

QTY

Quantity
Quantity

STERILE EO

Sterilized by Ethylene Oxide.
Sterility Guaranteed Unless Package Opened or Damaged. Do Not Resterilize.
Stérilisé à l'oxyde d'éthylène.
Stérilité garantie si l'emballage n'a pas été ouvert ou endommagé. Ne pas restériliser.
EO-sterilisiert.
Nicht verwenden, wenn die Sterilverpackung geöffnet oder beschädigt ist.
Nicht reesterilisieren.
Sterilizzato ad ossido di etilene.
Sterilità garantita, a meno che la confezione non venga aperta o danneggiata.
Non risterilizzare.
Esterilização por óxido de etileno.
Esterilização garantida excepto se a embalagem estiver aberta ou danificada.
Não reesterilizar.
Esterilizado por óxido de etileno.
Esterilización garantizada mientras el envase esté íntegro. No reesterilizar.
Gesteriliseerd met ethyleenoxide.
Steriliteit gegarandeerd tenzij de verpakking is geopend of beschadigd. Niet opnieuw steriliseren.
Steriliserede med ethylenoxid.
Garanteret sterilt, med mindre pakken er åbnet eller beskadiget. Må ikke gensteriliseres.
Steriloitu etyleenioksidilla.
Tuote on steriili, kun pakkaus on avaamaton ja ehjä. Ei saa steriloida uudestaan.
Αποστειρωμένα με αιθυλενοξείδιο.
Η στειρότητα είναι εγγυημένη εφόσον δεν ανοιχθεί η συσκευασία ή δεν προκληθεί ζημιά σε αυτήν. Μην επαναποστειρώνετε.
Steriliserade med etylenoxid.
Steriliteten garanteras under förutsättning att förpackningen inte är öppnad eller skadad. Får ej omsteriliseras.
Produkt sterylizowany tlenkiem etylenu.
Jałowość gwarantowana pod warunkiem, że opakowanie nie zostało otwarte lub uszkodzone. Nie sterylizować ponownie.
Etilén-oxiddal sterilizálva.
A sterilitása addig garantálható, amíg ki nem nyitják, illetve meg nem sérül a csomagolás. Tilos újra sterilizálni.
Sterilizováno etylenoxidem.
Sterilnost je zaručena, pokud balení není otevřené nebo poškozené. Nástroj znovu nesterilizujte.
Sterilizované etylén oxidom.
Sterilita je zarucená, ak nie je otvorený alebo poškodený obal. Neresterilizujte.

• • • • •
• • • • •

	<p>Single Patient Use À utiliser sur un seul patient lors d'une seule et même intervention Einweg-Instrument, nur für den Einsatz bei einem Patienten Per l'uso su un singolo paziente Para ser utilizado num único doente Uso en un solo paciente Voor gebruik bij één pati</p>	<p>Til anvendelse på én patient Potilaskohtainen Χρήση σε έναν μόνον ασθενή Endast för en patients bruk Do użytku u jednego pacjenta Egyetlen betegnél használható fel Nástroj je určený pouze pro jednoho pacienta Určené iba pre jedného pacienta • • • • • • • • • • • • • • • •</p>
	<p>Lot N° de lot Ch.-B. Lotto Nº do lote Nº de lote Lotnr. Parti</p>	<p>Erän koodi Αρ. παρτίδας Batchnummer Numer partii produkcyjnej Tétel Šarže Šarža • • • •</p>
	<p>Use Until Date À utiliser avant Verw. bis Utilizzare entro Validade A utilizar antes de Gebruik vóór Holdbar til angivne dato</p>	<p>Käytettävä viimeistään Χρησιμοποιείτε μέχρι την Använd före Koniec okresu przydatności do użytku A feltüntetett dátumig használható fel Použit do data Použitel'né do • • • • • •</p>
	<p>Manufacturer/Date of Manufacture Fabricant Hersteller Fabbricante Fabricante Fabricante Fabrikant Producent</p>	<p>Valmistaja Κατασκευαστής Tillverkare Producent Gyártó Výrobce Výrobca • • • • • •</p>
	<p>Authorized Representative in the European Community Représentant autorisé dans la Communauté européenne Bevollmächtigter in der Europäischen Gemeinschaft Rappresentante autorizzato nella Comunità Europea Representante autorizado na Comunidade Europeia Representante autorizado en la Comunidad Europea Bevoegd vertegenwoordiger bij de Europese Gemeenschap Autoriseret repræsentant i det europæiske fællesskab Valtuutettu edustaja Euroopan yhteisön alueella Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα Auktoriserad representant i Europeiska gemenskapen Autoryzowany przedstawiciel w Unii Europejskiej Az Európai Közösség meghatalmazott képviselője Autorizovaný zástupce v Evropském společenství Autorizovaný zástupca EU • • • • • • • • • • • • • • • •</p>	



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Mise en garde : La Loi Fédérale (États-Unis d'Amérique) n'autorise la vente de ce dispositif que par un médecin ou sur sa prescription.

Achtung: Laut Gesetz darf dieses Instrument in den USA nur an einen Mediziner oder eine in seinem Auftrag handelnde Person verkauft werden.

Attenzione: la legge federale americana consente la vendita di questo dispositivo solo dietro richiesta medica.

Atenção: A lei federal (dos Estados Unidos) só permite a venda deste dispositivo a médicos ou sob receita destes.

Atención: La ley federal de EE.UU. impone que este producto sólo puede ser vendido por un médico o bajo prescripción médica.

Waarschuwing: De Federale wetgeving (in de VS) eist dat dit apparaat uitsluitend door of in opdracht van een arts wordt verkocht.

Forsigtig: I henhold til gældende lov må denne anordning kun sælges til eller bruges af en læge.

Varoitus: Yhdysvaltain lain mukaan tämän tuotteen saa myydä vain lääkäri tai lääkärin määräyksestä.

Προσοχή: Το ομοσπονδιακό δίκαιο των ΗΠΑ περιορίζει την πώληση του εργαλείου αυτού μόνον από ιατρούς ή κατόπιν εντολής ιατρού.

Varning: Enligt amerikansk lag får detta instrument endast säljas till läkare eller på läkares anmodan.

Przestroga: Prawo federalne (USA) zezwala na sprzedaż tego urządzenia wyłącznie lekarzowi lub na jego zamówienie.

Figyelem! Az USA szövetségi törvényei értelmében az eszköz csak orvos megrendelésére értékesíthető.

Upozornění: Podle federálních zákonů USA je prodej tohoto zařízení omezen na prodej v lékárnách nebo na lékařský předpis.

Pozor: Podľa federálnych zákonov (v USA) sa toto zariadenie smie predávať iba lekárom alebo na lekársky predpis.

.....



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Meghatalmazott képviselő az Egyesült Államokban
Autorizovaný zástupce v USA
Autorizovaný zástupca v USA
.....

REF
HARSB



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Rev. 2014-XX-XX

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110-13806-00

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Subject Device Harmonic Scallop Blade HARSB Primary Package Labels

DePuy Synthes
SPINE

**ETHICON
Harmonic™**

QTY 1
REF
HARSB

HARMONIC Scallop Blade - 7 cm Length

110-13808-00

LOT IZR123456
YYYY-MM
XXXXXX REV 001



STERILE EO Sterilized by Ethylene Oxide.
Sterility Guaranteed Unless Package
Opened or Damaged. Do Not Resterilize.

Single Patient Use

See Instructions For Use

Rx
Only



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DEPUY SPINE, INC.
325 Paramount Drive
Raynham, MA 02767-0350 USA

ETHICON ENDO-SURGERY, LLC
475 Calle C
Guaynabo, Puerto Rico 00969 USA

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A	ECN00XXXX	KU	03-07-14
PRODUCT CODE	ARTWORK NUMBER	PACKAGE COMPONENT NUMBER	
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PMS 424 **DIE**

Subject Device Harmonic Scallop Blade HARSB Carton Package Labels

Subject Device Generator G11 Manual

Generator G11 (GEN11)

Operator's Manual

For use with Software Version 2013_1



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Overview

Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences. This manual contains important information for operation of GEN11. It should be kept where it may be referenced during usage, especially for screen translations. Print or copy pages as necessary to keep nearby.

Important: This manual is designed to provide instructions for use of the Generator G11. It is not a reference to surgical techniques. Go to www.e-ifu.com for the latest version of this manual.

HARMONIC® and ENSEAL® are trademarks of Ethicon Endo-Surgery.

Standard Conventions Used

The Use of Caution, Warning, and Note Statements

Information relative to the completion of a task in a safe and thorough manner will be supplied in the form of a Caution, a Warning, or a Note statement. These statements are found throughout the documentation.

These statements should be read before continuing to the next step in a procedure.

Warning: A Warning statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in personal injury or loss of life.

Caution: A Caution statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in damage to or destruction of the equipment.

Note: A Note statement indicates an operating or maintenance problem, practice, or condition that is necessary to accomplish a task efficiently.

Chapter 1 - General Information

Indications

The Generator G11 provides radiofrequency power to drive ENSEAL electro-surgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissues. In addition, the generator provides power to drive HARMONIC ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired.

ENSEAL and HARMONIC instruments when used with the Generator G11 have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures.

Contraindications

- The use of the Generator G11 and the attached instruments are contraindicated, when in the judgment of the physician, radiofrequency or ultrasonic surgery would be contrary to the best interest of the patient.
- The instruments are not indicated for incising bone.

Device Description

The Generator G11 supplies energy to the HARMONIC and ENSEAL surgical instruments. The generator uses a touchscreen display interface and has a unique receptacle port that accepts either a HARMONIC or an ENSEAL device. Connectors (HGA11 for HARMONIC and EGA11 for ENSEAL) are used to enable the generator to power legacy devices.

How Supplied

The Generator G11 is supplied in a semi-ready-to-use state. The shipping box contains the Generator G11, power cord and user manual. The disposable Ethicon Endo-Surgery ENSEAL or HARMONIC instruments are not included in this packaging and must be purchased separately. The HARMONIC device connector (HGA11), ENSEAL device connector (EGA11), footswitch (FSW11) and cart (CRT11) are also available separately.

Illustration and Nomenclature

Front Panel of the Generator

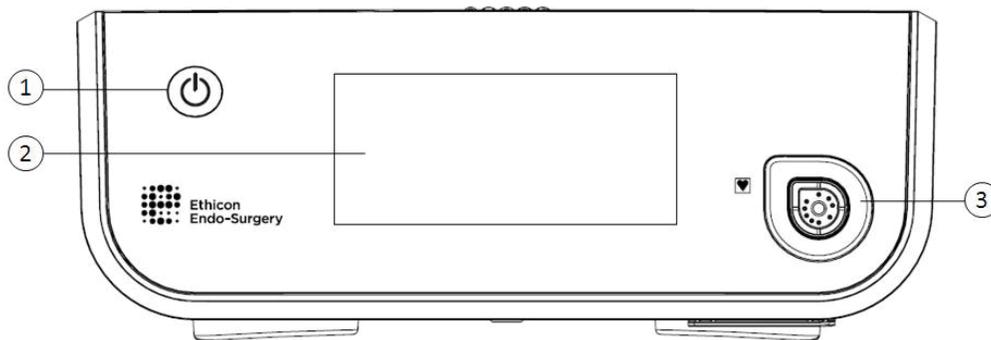


Figure 1

- | | | |
|---|------------------------------|--|
| 1 | POWER ON/OFF SWITCH | Glows green when the generator is powered up. |
| 2 | DISPLAY/TOUCH SCREEN | Displays system information and serves as interface for adjusting controls and settings. |
| 3 | CONNECTOR/ DEVICE RECEPTACLE | Receptacle used to attach the connectors or devices to the generator. |

Back Panel of the Generator

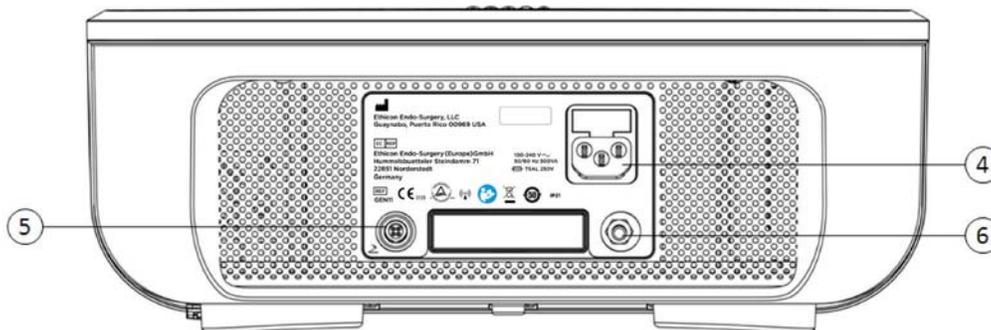


Figure 2

- | | | |
|---|---------------------------------|--|
| 4 | POWER CORD RECEPTACLE | Receptacle used to attach the power cord to the generator. |
| 5 | FOOTSWITCH RECEPTACLE | Receptacle used to connect the footswitch to the generator. |
| 6 | POTENTIAL EQUALIZATION TERMINAL | Provides means for connection to a potential equalization conductor. |

Footswitch

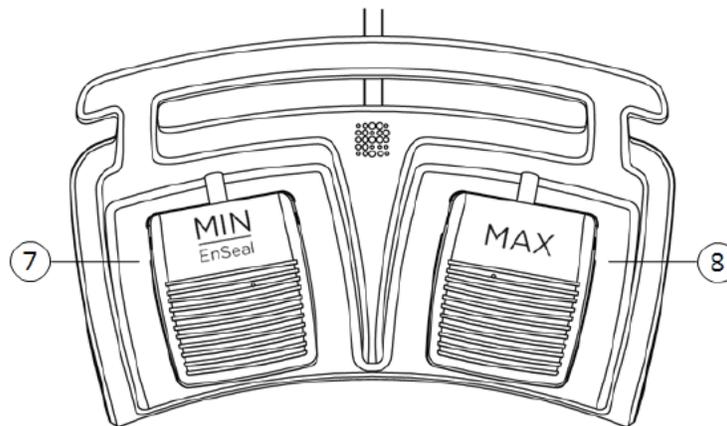


Figure 3

- 7 MIN (LEFT PEDAL) Activates power for ENSEAL or minimum power for HARMONIC.
- 8 MAX (RIGHT PEDAL) Activates maximum power for HARMONIC.

General Warnings

- Verify that the unit is fully operational prior to administering power output for tissue sealing.
- This equipment is for use only by qualified medical personnel trained in the use of ultrasonic surgery or electrosurgery. Inappropriate use of the equipment by untrained medical personnel may result in hazardous electrical output.
- Do not use in the presence of flammable anesthetics or oxidizing gases such as nitrous oxide (N₂O) and oxygen as explosion may occur.
- Non-flammable agents should be used for cleaning and disinfection wherever possible. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of HF surgery. There is a risk of pooling of flammable solutions under the patient 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 the electrosurgery. Attention should be called to the danger of ignition of endogenous or other flammable gases. Some materials, for example cotton and gauze, when saturated with oxygen may be ignited by sparks produced in normal use during electrosurgery.
- Do not operate the Generator G11 in a moist environment as a shock hazard may exist. If liquids have entered the Generator G11 the unit must be returned to the manufacturer for testing prior to use.
- Do not operate the unit in close proximity to volatile solvents such as methanol or alcohol as explosion may occur.
- Avoid use of Generator G11 adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, monitor the Generator G11 and the other equipment to assure normal operation.
- Interference produced by the operation of high-frequency surgical equipment may adversely affect the operation of other electronic medical equipment such as monitors and imaging systems.
- Check if the patient has a pacemaker or implanted cardioverter/defibrillator. Consult the pacemaker or implanted cardioverter/defibrillator manufacturer for information about the effects of radiofrequency energy on these devices.
- Use of accessories and cables other than those specified may result in unpredictable performance, increased electromagnetic emissions, or decreased electromagnetic immunity. No customer modification of this equipment is allowed; modification of this equipment could have a negative impact on electrical safety and electromagnetic emissions.
- No internal user serviceable parts. For service, return the generator to an authorized Ethicon Endo-Surgery service facility.
- To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- To isolate the Generator G11 from supply mains power, disconnect the power cord either from the back panel of the generator or from the wall. Ensure access to these points are kept clear.
- This device is not MR safe and is not MR compatible.
- This device seals vessels up to a maximum diameter of 7 mm depending on the instrument used. Refer to the instrument IFU for further information.

Generator G11 Operator's Manual

- As with all energy sources (Electrosurgery, Lasers, or Ultrasound) there are concerns about the carcinogenic and infectious potential of the by-products such as tissue smoke plume and aerosols. Appropriate measures such as protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- In case of system failure, ensure availability of the appropriate backup equipment relevant to the specific procedure.
- After removing the instrument, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.

General Cautions

- The touch screen display of the generator is very sensitive. Do not use sharp metal objects on the touch screen.
- Removing bottom screws or opening of this device invalidates the warranty and could create hazardous condition.
- Read instructions prior to use and follow the hospital's clinical practice guidelines for ultrasonic surgery, electrosurgery, gynecology and laparoscopic procedures.
- Replace fuses only with the appropriate type and rating. See *System Specifications*.
- Do not sterilize the Generator G11. Sterilization will damage the unit.
- Do not restrict the openings on the bottom and the back panel of the Generator G11, as they provide the required airflow for cooling.
- If electromagnetic interference with other equipment is suspected, reorient the device or remove possible sources of interference (for example, cellular phones, radios, etc.) from the room.
- Monitoring electrodes should be placed as far as possible from the disposable device tips when high frequency surgical equipment and physiological monitoring equipment are used simultaneously. Monitoring systems incorporating high frequency current-limiting devices are recommended for use.
- Needle monitoring electrodes are not recommended.
- Activation of a radiofrequency device when not in contact with target tissue or in a position to deliver energy may cause capacitive coupling.
- The patient should not come in contact with metal parts which are earthed (grounded) or which have appreciable capacitance to earth (for example operating table supports, etc.).
- Cables to the surgical electrodes should be positioned so that contact with patient or other leads is avoided.
- CRT11 is recommended if Generator G11 is moved out of the operating room. Maintain control of the generator and cart when moving over thresholds.

Customer Service

Warranty

This warranty and the rights and obligations hereunder shall be construed under and governed by the laws of the State of Ohio, U.S.A.

Ethicon Endo-Surgery warrants this product to be free from defects in material and workmanship under normal use and preventive maintenance for the respective warranty period shown below. Ethicon Endo-Surgery's obligation under this warranty is limited to the repair or replacement, at its option, of any product, or part thereof, which has been returned to Ethicon Endo-Surgery or its distributor within the applicable time period shown below and which examination disclosed, to Ethicon Endo-Surgery's satisfaction, to be defective. This warranty does not apply to any product, or part thereof, that has been: (1) adversely affected due to use with devices manufactured or distributed by parties not authorized by Ethicon Endo-Surgery (2) repaired or altered outside Ethicon Endo-Surgery's factory in a way so as to, in Ethicon Endo-Surgery's judgement, affect its stability or reliability, (3) subjected to improper use, negligence or accident, or (4) used other than in accordance with the design and use parameters, instructions and guidelines for the product or with functional, operational or environmental standards for similar products generally accepted in the industry.

Ethicon Endo-Surgery's products are warranted for the following periods after delivery to the original purchaser:

Generator and power cord	One (1) year, parts and labor
Footswitch	One (1) year, parts and labor
Cart	One (1) year, parts and labor

UNLESS SUPERCEDED BY APPLICABLE LOCAL LAW, THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON THE PART OF ETHICON ENDO-SURGERY AND IS A PURCHASER'S EXCLUSIVE REMEDY. IN NO EVENT SHALL ETHICON ENDO-SURGERY BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, PROFITS, BUSINESS OR GOODWILL, OTHER THAN AS EXPRESSLY PROVIDED BY A SPECIFIC LAW. Ethicon Endo-Surgery neither assumes

nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of Ethicon Endo-Surgery products. There are no warranties that extend beyond the terms hereof. Ethicon Endo-Surgery reserves the right to make changes to products built and/or sold by them at any time without incurring any obligation to make the same or similar changes on products previously built and/or sold by them.

Customer Service

Contact the Ethicon Endo-Surgery Customer Service Department or your local representative for any customer or technical support. Call 1-800-USE-ENDO (1-800-873-3636) in the U.S. only.

Chapter 2 - Instructions for Use - HARMONIC Devices

Setup

Caution: Do not block the air vents of the generator to avoid generator overheating.

- 1 Examine the Generator G11 and the HARMONIC device for damage. Do not use damaged devices.
- 2 Secure the generator on its cart or any other suitable fixture in the appropriate position.
- 3 Connect the power cord to the power cord receptacle on the back panel of the generator and to a grounded electrical outlet. The power requirements for the Generator G11 are listed on the label on the back panel of the generator.
- 4 Connect the footswitch connector to the footswitch receptacle on the back panel of the generator if applicable.
- 5 Connect the HARMONIC instrument to the Generator G11.
 - If the plug looks like the image below, connect the device directly to the Generator G11 receptacle.



Figure 4

- If the plug looks like the image below, use the connector as an interface between the device and the generator.



Figure 5

Caution: Verify that the generator is secured to the cart or any other suitable fixture before powering up.

Generator G11 Operator's Manual

- 6 Turn on the generator using the On/Off switch on the front panel of the generator.
- 7 The green standby indicator illuminates and the system will run its initiation sequence. A tone is heard during the initiation sequence. When the initiation sequence is complete the test prompt screen appears.
- 8 Follow the instructions on the screen to run the test.
- 9 The HARMONIC ready screen appears and the generator is ready for use.

Ready Screen Features

The HARMONIC ready screen has the following features:

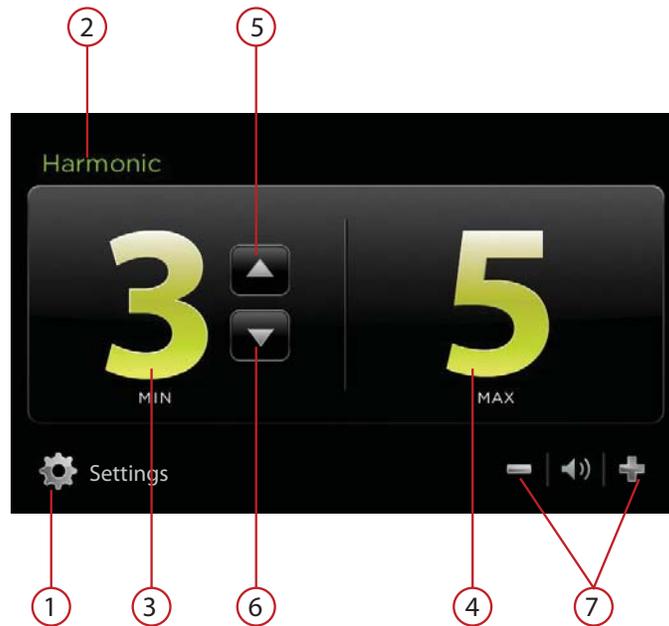


Figure 6

- | | | |
|---|----------------------|--|
| 1 | SETTINGS | Touch this button to go to the system settings. |
| 2 | DEVICE SPECIFICATION | Indicates the device in use. |
| 3 | MIN | Indicates the user-adjustable minimum power level setting. When this power level is activated (by footswitch or handswitch), the 'MIN' indicator will flash. The system defaults to 'MIN' power level 3. Refer to the individual instrument package inserts for the recommended minimum power level. |
| 4 | MAX | Indicates the maximum power level setting. This setting is always 5. When this power level is activated (by footswitch or handswitch) the 'MAX' indicator will flash. |
| 5 | POWER LEVEL INCREASE | Touch this button to increase the minimum (MIN) power setting to the desired level (from 1 to 5). The level chosen will be shown on the screen. The power level may be adjusted when the generator is ready. |
| 6 | POWER LEVEL DECREASE | Touch this button to decrease the minimum (MIN) power setting to the desired level (from 1 to 5). The level chosen will be shown on the screen. The power level may be adjusted when the generator is ready. |
| 7 | VOLUME | Touch the plus or minus button to adjust the volume of the activation tones. A tone is heard to indicate the volume level selected. |

Operation

Minimum or maximum power is activated from the HARMONIC device or from the footswitch.

Use the left pedal on the footswitch for activating minimum power and use the right pedal for maximum power.

During minimum activation, the MIN area on the generator screen will glow green and pulse. During maximum activation the MAX area will glow green and pulse. As the power is activated, audio feedback is initiated.

The default power level value is 3 for the minimum. Touch the power level increase or the power level decrease button to increase or decrease the level of power to be generated in this mode.

Note: Only the MIN power level setting is adjustable. The MAX power level setting is always set to 5.

Volume

Adjust the volume using the plus or minus button. Default volume setting is 5.

Shutdown

Turn off the generator using the On/Off switch on the front panel of the unit.

The shutdown sequence cannot be initiated during power activation. During shutdown, the generator clears content from the screen, informs the user if 10 or fewer hand piece uses remain for the attached hand piece and displays the shutdown animation.

Settings

Basic Navigation

Touch the 'Settings' button to make adjustments in the system settings and access system information.

The settings screen opens. Scroll down for further options.

Note: If power is activated while in the Settings menu, the Settings window automatically closes and returns to the ready screen.

Touch the close button 'X' to exit from anywhere within the Settings menu. Touch the back arrow to go to the previous menu from the submenu screens.



Figure 7

Display Brightness

Select 'Display Brightness' to see a preview of the ready screen while adjusting the brightness.

Touch the plus or minus button to adjust the brightness.

Touch the back arrow or close button after adjusting the settings to exit. Once a new brightness setting is selected that setting becomes the new system default.

Hand / Foot Activation

Select the handswitch activation or the footswitch activation or both on the 'Hand / Foot Activation' screen during startup. This selection can be changed during use.

A dot is used to indicate the current setting while a green glow highlights the current selection.

Touch the back arrow or close button after adjusting the settings to exit.

Language

Select the preferred language from the options in the 'Language' screen. There are multiple language options, English being the default. Once the user selects and confirms the selection of a new language, that language becomes the new system default.

Touch the desired option, a confirmation screen will appear.

Select 'OK' to confirm the language selection or 'Cancel' to cancel the language change.

Tone Change ON/OFF

Some instruments enable additional tone changes within the generator. When this option is selected, the Tone Change ON/OFF screen will appear, allowing the user to select the Tone Change ON or Tone Change OFF options. Refer to the instrument instructions for use to determine if your instrument has this feature.

Convert MIN to Adv Hemostasis

Some instruments enable this menu option. When this option is selected, the MIN button will function as the Advanced Hemostasis Mode button, and the Advanced Hemostasis Mode button will be disabled. Refer to the instrument instructions for use to determine if your instrument has this feature.

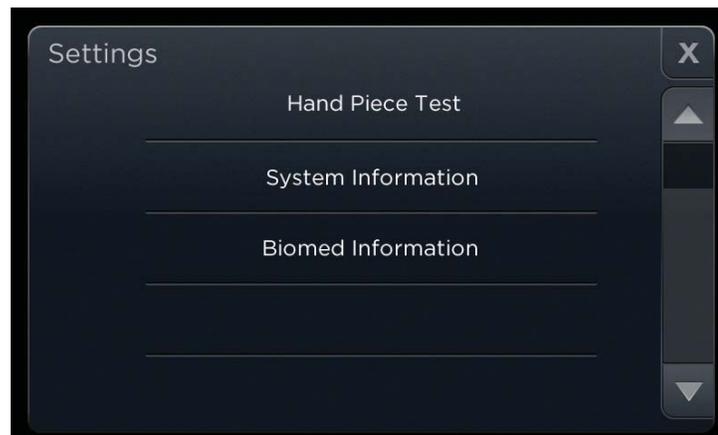


Figure 8

Hand Piece Test

Select 'Hand Piece Test' to check if the hand piece is functioning properly by installing a test tip and running the test with no instrument attached. Screen instructions and results are given for the specific hand piece to be tested.

System Information

Select 'System Information' to see the high-level information about the generator and the device currently connected to the generator. The hospital staff can use the information to determine if a new hand piece should be ordered. The screen will also allow determination of the currently installed generator software revision.

Biomed Information

'Biomed Information' allows the technicians to access information about each error that has occurred on the generator and allows access to a 'Biomed Mode' display that streams data during instrument use. Touch the back arrow or close button to exit.

Warning

The active blade of a HARMONIC instrument heats the tissue by friction and is intended to supply sufficient friction and shearing effect to cut and coagulate tissue in contact with the active blade. As a result, the user should use caution with the blade, clamp arm, and distal part of the shaft as they may exhibit an elevated temperature. Additional temperature information may be contained in individual instrument instructions for use.

Chapter 3 - Instructions for Use - ENSEAL Devices

Setup

Caution: Do not block the air vents of the generator to avoid generator overheating.

- 1 Examine the Generator G11 and the ENSEAL device for damage. Do not use damaged devices.
- 2 Secure the generator on its cart or any other suitable fixture in the appropriate position.
- 3 Connect the power cord to the power cord receptacle on the back panel of the generator and to a grounded electrical outlet. The power requirements for the Generator G11 are listed on the label on the back panel of the generator.
- 4 Connect the footswitch connector to the footswitch receptacle on the back panel of the generator if applicable.
- 5 Connect the ENSEAL tissue sealing device to the Generator G11. Refer to instrument instructions for use.
 - If the plug looks like the image below, connect the device directly to the Generator G11 receptacle.



Figure 9

- If the plug looks like the image below, use the connector as an interface between the device and the generator.



Figure 10

Caution: Verify that the generator is secured to the cart or any other suitable fixture before powering up.

- 6 Turn on the generator using the On/Off switch on the front panel of the generator.
- 7 The green standby indicator illuminates and the system will run its initiation sequence. A tone is heard during the initiation sequence. When the initiation sequence is complete the ENSEAL ready screen appears and the generator is ready for use.

Ready Screen Features

The ENSEAL ready screen has the following features:



Figure 11

- | | | |
|---|----------------------|---|
| 1 | SETTINGS | Used to go to the system settings. |
| 2 | DEVICE SPECIFICATION | Indicates the device in use. |
| 3 | READY | System ready display. |
| 4 | VOLUME | Touch the plus or minus button to adjust the volume of the activation tones. A tone is heard to indicate the volume level selected. |

Operation

Power is activated from the ENSEAL device or from the left pedal of the footswitch. The ENSEAL device has only one mode of operation. There are no power level settings. When power is activated audio feedback is initiated. When the upper impedance threshold is reached and before the knife has been fully advanced, the audio feedback changes into a higher pitch tone. When both the upper impedance threshold has been reached and the knife has been fully advanced (handle is fully closed), a single tone sounds, indicating a complete cycle. Always advance the knife under power. The single tone for a complete cycle is the only indication of a complete cycle and cut.

Volume

Adjust the volume using the plus or minus button. Default volume setting is 7.

Shutdown

Turn off the generator using the On/Off switch on the front panel of the unit.

The shutdown sequence cannot be initiated during power activation. During shutdown, the generator clears content from the screen and displays the shutdown animation.

Settings

Basic Navigation

Touch the 'Settings' button to make adjustments in the system setup and access system information.

The settings screen opens. Scroll down for further options.

Note: If power is activated while in the Settings menu, the Settings window automatically closes and returns to the ready screen.

Touch the close button 'X' to exit from anywhere within the Settings menu. Touch the back arrow to go to the previous menu from the submenu screens.



Figure 12

Display Brightness

Select 'Display Brightness' to see a preview of the ready screen while adjusting the brightness.

Touch the plus or minus button to adjust the brightness.

Touch the back arrow or close button after adjusting the settings to exit. Once a new brightness setting is selected that setting becomes the new system default.

Hand / Foot Activation

Select the handswitch activation or footswitch activation or both on the 'Hand / Foot Activation' screen during startup. This selection can be changed during use.

A dot is used to indicate the current setting while a green glow highlights the current selection.

Touch the back arrow or close button after adjusting the settings to exit.

Language

Select the preferred language from the options in the 'Language' screen. There are multiple language options, English being the default. Once the user selects and confirms the selection of a new language that language becomes the new system default.

Touch the desired option, a confirmation screen will appear.

Select 'OK' to confirm the language selection or 'Cancel' to cancel the language change.

System Information

Select 'System Information' to see the high-level information about the generator and the device currently connected to the generator. The screen will also allow determination of the currently installed generator software revision.

Biomed Information

'Biomed Information' allows the technicians to access information about each error that has occurred on the generator.

Chapter 4 - Troubleshooting and Screen Guide

General Troubleshooting

Informative

The user interface for the Generator G11 has a number of informative screens to guide the efficient use of the generator. Informative screens will maintain a consistent dark background to differentiate them from the alarm screens shown below.

Alarm System

The Generator G11 includes integrated diagnostics that monitor the operation of the generator and accessories and flash either informative screens or alarms with no delay. In addition to audible alarm sounds, the display of alarms on the front panel is easily observable by the surgeon or nursing staff from the surgical field. All alarms are technical alarms and are based on electrical parameters. There are no physiological alarms that are produced by the Generator G11.

Alarm settings are not adjustable by the operator nor can priority be reassigned. Alarm settings also do not adjust to operator inputs nor do they change through power loss. The Power on Self Test (POST) verifies that the generator is operational. Since the alarms are integrated into the software algorithms responsible for running the appropriate instruments, the POST also verifies alarm operation. Therefore, a separate test for verifying the alarm output is not required. During the POST an audio tone is emitted from the generator so the user can verify that the audio output is operational. Visual output can also be verified through the start up screens. Alarm audio cannot be paused but audio automatically ends when the user discontinues activation of the instrument.

Alarms and other events are logged in the generator. The log is retained after power is removed and is accessed through the biomed screen. There is no reminder signal.

Audio Sound Pressure Levels

- Medium level alarms: Greater than 75 dBA (not adjustable)
- Low level alarms: Within 70 - 75 dBA (not adjustable)

Alarm Definitions

The following alarm priorities are used for the Generator G11. All alarms stop generator output and high priority alarms will take precedence over lower priority alarms. Only one alarm will be displayed at a time since any alarm stops output.

Low Priority Alarms

Requires surgical staff attention for continued, efficient procedural progress. A low priority issue will not generally progress to a hazardous condition even if not addressed promptly but it must be addressed to continue the procedure. The screen shows a solid yellow background with a low priority alarm symbol. A two-tone audio alarm sound accompanies a low priority alarm.

Medium Priority Alarms

Requires prompt surgical staff attention to reduce or mitigate a hazardous condition. Ignoring this alarm can result in a serious injury or death. The screen shows a solid yellow background with a flashing medium priority alarm symbol. A three-tone audio alarm sound accompanies a medium priority alarm.

High Priority Alarms

There are no high priority alarm conditions in Generator G11.

The following are the general low priority alarms:

Visual Alarms	Description	Troubleshooting Steps
 <p>Reactivate Two switch activations detected: HANDSWITCH FOOTSWITCH Reactivate instrument to continue.</p>	<p>Two activation switches are closed in the system. This may be due to a stuck switch or the inadvertent closure of an additional switch.</p>	<p>Reactivate instrument to continue. If the surgical staff has activated only one switch, replace the instrument or footswitch that may have the stuck switch.</p>
 <p>Restart Generator Restart generator to reset system and continue. If problem persists, please contact your EES representative.</p>	<p>A system reset is required.</p>	<p>Remove the instrument from the incision and cycle the generator power using the Power On/Off switch on the front of the panel. If problem persists, please send the generator to an authorized Ethicon Endo-Surgery service center.</p>
 <p>Press OK to Continue Press OK to reset system and continue. If problem persists, please contact your EES representative.</p> <p>OK</p>	<p>A system reset is required.</p>	<p>Press OK to return to the state the system was in when the error occurred. If problem persists, please send the generator to an authorized Ethicon Endo-Surgery service center.</p>
 <p>Please Contact Your EES Representative Cooling fan error detected.</p>	<p>Indicates an internal error with the cooling fans of the generator.</p>	<p>Please send the generator to an authorized Ethicon Endo-Surgery service center.</p>
 <p>Generator Overheating Remove any obstructions from air vents.</p>	<p>The generator is overheating.</p>	<p>Remove any obstructions from the air vents at the back and bottom of the generator. If the air vents are not blocked and the problem persists return the generator to an authorized Ethicon Endo-Surgery service facility.</p>
 <p>Software Upgrade Required to Run Device Please contact your EES representative</p>	<p>The device requires a generator software upgrade.</p>	<p>Contact your Ethicon Endo-Surgery representative for a software upgrade.</p>
 <p>Please contact your EES representative</p>	<p>Any general issue with the system.</p>	<p>Contact your Ethicon Endo-Surgery representative.</p>

HARMONIC Troubleshooting

Note: The following alarms are specific to HARMONIC devices used with Generator G11.

Alarms

The Generator G11 supports the following alarms to help in the identification and troubleshooting of component problems when using a HARMONIC device. The following list is meant as an adjunct to, but not a substitute for clinical judgment and observation.

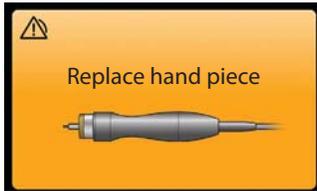
Other than fuses, there are no operator-serviceable parts in the Generator G11. For replacement or service, contact the Ethicon Endo-Surgery Customer Service Department or your local representative.

Visual Alarms	Description	Troubleshooting Steps
	<p>The hand piece has reached the end of life.</p>	<p>Replace the hand piece. Contact the Ethicon Endo-Surgery Customer Service Department (call 1-800-USE-ENDO (1-800-873-3636) in the U.S. only) or contact your local sales representative to discuss local waste disposal solutions and processes.</p>
		
	<p>The instrument has reached the end of life.</p>	<p>Unplug and replace instrument. Dispose of instrument per instrument instructions for use.</p>
		



The hand piece has failed to perform the internal diagnostic routines and the generator will not be able to operate the hand piece reliably.

Replace the hand piece. Contact the Ethicon Endo-Surgery Customer Service Department (call 1-800-USE-ENDO (1-800-873-3636) in the U.S. only) or contact your local sales representative to discuss local waste disposal solutions and processes.



The instrument has been loaded to the point where output has stopped.

Relax pressure on the instrument or reposition so there is less tissue in the jaws. Release the activation switch and reactivate the instrument to continue.



This screen is a prelude to further diagnostics. To avoid inadvertent tissue damage during diagnostics the surgeon is guided to remove the instrument from the incision before proceeding.

Remove the instrument from the incision. When the instrument is clear, touch the 'Next' button for further diagnostic guidance.



The HARMONIC instrument may be damaged and cannot be activated.

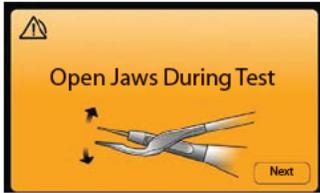
Unplug the hand piece and replace the instrument.



The instrument may not be properly assembled to the hand piece.

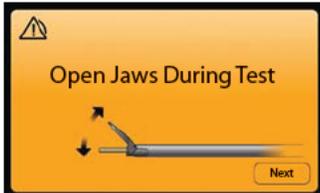
Press the 'Next' button to continue. Re-tighten the instrument. Ensure that one hand is holding the appropriate torque wrench and the other hand is holding the hand piece (not the instrument).





If using shears, keep jaws of device open during test.

Press 'Next' to advance, to retry test with jaws open.



If using shears, keep jaws of device open during test.

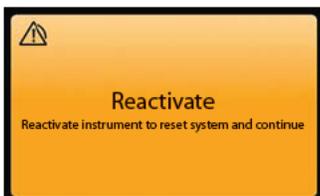
Press 'Next' to advance, to retry test with jaws open.



Indicates an internal error with the instrument that prevents it from being used.

Unplug the hand piece and replace the instrument.

Note: If multiple instruments have indicated an instrument error on the same hand piece, try replacing the hand piece to ensure that the issue is related to the instruments.



A system reset is required.

Reactivate instrument to reset system and continue.



Indicates an internal error with the identification circuitry in the instrument. Special circuitry is installed on certain advanced devices to identify the device to the generator and tailor the generator's output to the device.

Unplug hand piece and replace instrument.



Indicates an internal error that may be either with the hand piece or the instrument.

Change hand piece first. Please contact your EES representative to screen current hand piece for errors. If problem persists, unplug hand piece and replace instrument.



ENSEAL Troubleshooting

Note: The following alarms are specific to ENSEAL devices used with Generator G11.

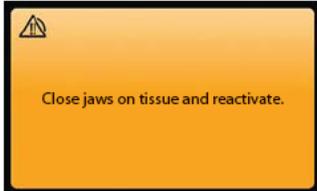
Alarms

The Generator G11 supports the following alarms to help in the identification and troubleshooting of component problems when using an ENSEAL tissue sealing device. The following list is meant as an adjunct to, but not a substitute for clinical judgment and observation.

Other than fuses, there are no operator-serviceable parts in the Generator G11. For replacement or service contact the Ethicon Endo-Surgery Customer Service Department or your local representative.

Caution: When an alarm sounds, the generator output stops. If the jaws are closed on tissue and an alarm sounds, do not advance the knife. If the knife is advanced, do not release the instrument. Add additional clamping as necessary to prevent blood loss before releasing the instrument.

Visual Alarms	Description	Troubleshooting Steps
 <p>Reposition Jaws and Reactivate</p>	<p>Instrument is being activated on low impedance (thin) tissue or metal (such as staples, clips, retractors, or clamps).</p>	<p>Reposition the instrument jaws and reactivate.</p>
 <p>Replace instrument</p>	<p>The same alarm has triggered three times in a row. There may be an issue in the instrument.</p>	<p>Replace the instrument.</p>
 <p>Replace instrument</p>	<p>Indicates an internal issue with the identification circuitry in the instrument. Special circuitry is installed on certain advanced devices to identify the device to the generator and tailor the generator's output to the device.</p>	<p>Replace the instrument.</p>
 <p>Replace Instrument <small>Instrument error detected.</small></p>	<p>A system reset is required.</p>	<p>Reactivate instrument to reset system and continue. If problem persists, replace instrument.</p>
 <p>Reactivate <small>Reactivate instrument to reset system and continue. If problem persists, replace instrument.</small></p>		



This is a medium priority alarm. The generator cannot deliver energy. (The instrument may cut tissue without a seal if the surgeon advances the knife.)

If the instrument jaws are open, close jaws on tissue and reactivate.

If the jaws are closed on tissue and this alarm sounds, do not advance the knife. If the knife is advanced, do not release the instrument. Add additional clamping as necessary to prevent blood loss before releasing the instrument.

Screen Guide

General Screens

Screen	Description
	Ethicon Endo-Surgery (Note: Appears during system startup.)
	Starting Up (Note: System is starting up.)
	Device Not Found: Plug in device to continue. (Note: Press 'Settings' for Settings Menu.)
	System Ready (Note: System startup is complete.)
	Hand / Foot Activation: Both handswitch and footswitch active Only handswitch active Only footswitch active



Language:
English
German
French
Italian
Spanish



Language:
Spanish
Russian
Swedish
Finnish
Danish



Language:
Danish
Dutch
Portuguese
Norwegian
Greek



Language:
Greek
Polish
Czech
Slovak
Hungarian



Language:
Hungarian
Romanian
Turkish
Chinese
Japanese



Language:
Japanese
Korean



Language is now set to (name of language). Cancel to return to the previous language selected.



Identifying Device
(Note: System identifying new device just plugged into generator.)



Shutting down
(Note: System is shutting down.)

HARMONIC Screens

Screen

Description



(Number of Uses) Remaining: Replace hand piece after (blank) uses.



(Number of Uses) Remaining: Replace hand piece after (blank) uses.



Activate instrument for 2 seconds to run test. If using shears, open jaws during test.
(Note: Press 'Settings' for Settings Menu.)



Activate instrument for 2 seconds to run test. If using shears, open jaws during test.
(Note: Press 'Settings' for Settings Menu.)



Testing
(Note: Running system test.)



Foot Activation Off

(**Note:** Reactivate with handswitch, or adjust settings. Press 'Settings' for Settings Menu.)



Hand Activation Off

(**Note:** Reactivate with footswitch, or adjust settings. Press 'Settings' for Settings Menu.)



Relax Pressure on Blade.

(**Note:** Press 'Settings' for Settings Menu.)



Clean Blade. Remove any tissue which may be lodged inside end of instrument sheath.

(**Note:** Press 'Next' to advance.)



Tighten Assembly

(**Note:** Press 'Next' to advance.)



Tighten Assembly

(**Note:** Press 'Next' to advance.)



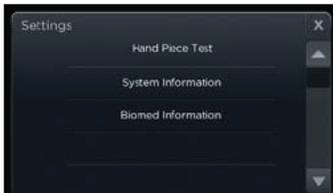
Activate instrument outside patient to run test. If using shears, open jaws during test.



Activate instrument outside patient to run test. If using shears, open jaws during test.



HARMONIC Settings:
 Display Brightness
 Hand / Foot Activation
 Language
 Tone Change ON/OFF
 Convert MIN to Adv Hemostasis



HARMONIC Settings:
 Hand Piece Test
 System Information
 Biomed Information



HARMONIC Display Brightness.



Hand Piece Test. Assemble Test Tip to begin.
 (Note: Press 'Test' to run test.)



Hand Piece Test. Assemble Test Tip to begin.
 (Note: Press 'Test' to run test.)



Test Complete



Hand Piece Test Results:
Hand Piece Uses Remaining
Phase Margin
Impedance
Hand Piece is Functioning Normally



System Information:
Software Version
Hand Piece
Hand Piece Uses Remaining



Tone Change ON/OFF
Tone Change ON
Tone Change OFF



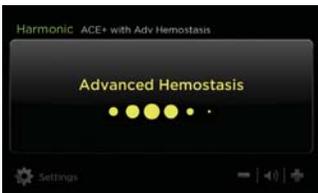
Convert MIN to Advanced Hemostasis
Default Activation Settings
Convert MIN Activation to Adv Hemostasis



Harmonic ACE+ with Adv Hemostasis



Harmonic ACE+ with Adv Hemostasis



Harmonic ACE+ with Adv Hemostasis
Advanced Hemostasis



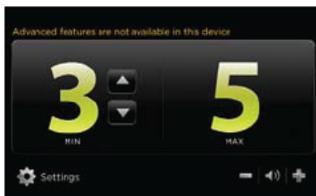
Maintain Full Jaw Closure
During Adv Hemostasis



Advanced Features Are Not Available In This Device
 Adaptive Tissue Technology
 Regulated Energy Delivery
 Enhanced Audible Feedback



Advanced Features Are Not Available In This Device
 Adaptive Tissue Technology
 Regulated Energy Delivery
 Enhanced Audible Feedback
 Advanced Hemostasis



Advanced features are not available in this device

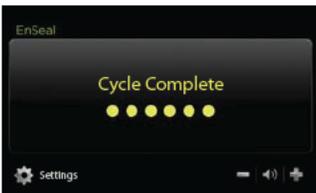
ENSEAL Screens

Screen

Description



Activating
 (Note: Power is being activated.)



Cycle Complete
 (Note: Cut is complete. Press 'Settings' for Settings Menu.)



Activation Cycle Timed Out: Reactivate
 (Note: Cycle Complete was not reached. Reactivate to continue. Press 'Settings' for Settings Menu.)



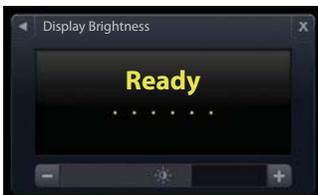
Hand Activation Off: Ready
(**Note:** Reactivate with footswitch, or adjust settings. Press 'Settings' for Settings Menu.)



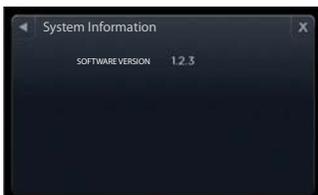
Foot Activation Off: Ready
(**Note:** Reactivate with handswitch, or adjust settings. Press 'Settings' for Settings Menu.)



ENSEAL Settings:
Display Brightness
Hand / Foot Activation
Language
System Information
Biomed Information



ENSEAL Display Brightness: Ready.



System Information: Software Version.

Chapter 5 - Cleaning, Disinfection, Preventive Maintenance and Repair

Electrical Safety Checks

- The hospital is responsible for ensuring that the unit has an electrical safety check performed by qualified service personnel at least once a year.
- Do not remove the cover of the Generator G11. Removing the cover voids the Generator G11 warranty.

Cleaning and Disinfection Instructions

Before cleaning, thoroughly inspect the device(s) for any signs of damage, cracks, or improper mechanical function. Do not use the device(s) if there are signs of damage. Discard and replace device or send device to an authorized Ethicon Endo-Surgery service facility for repair where appropriate, if damage or degradation is present.

- Operators in North America should refer to appropriate sections of *AORN Standards & Recommended Practices* for additional guidance on cleaning. All other localities should refer to appropriate guidelines.
- The operator must qualify cleaning effectiveness when deviating from the instructions in this manual.

Generator G11 and Touchscreen

Cleaning

Clean the generator and the touchscreen following the hospital protocol. Before cleaning, turn the generator main power off and unplug the power cord from the grounded electrical outlet.

Warning: Spilling or spraying fluids on or into the generator or immersing the generator may result in damage to the device and creates a risk of shock or fire.

Proceed with cleaning as follows:

1. Prepare a neutral pH detergent or a neutral pH enzymatic detergent according to the manufacturer's directions.
2. Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean the surfaces. Pay special attention to cracks and crevices.
3. Wipe thoroughly using a soft, clean cloth lightly moistened with warm tap water.
4. Dry with a soft, clean cloth.

Disinfecting

If the generator becomes contaminated with blood or bodily fluids, it must be wiped down with a disinfectant before reuse. The following chemical disinfectants are approved for use with the generator: Isopropyl Alcohol - 70%, Sodium hypochlorite solutions (0.25% - 0.50%), Cidex OPA, Dispatch, and Gigasept FF.

Disinfectants should be prepared and used according to the manufacturer's recommendations for use, concentration, and contact time.

The use of disinfectants other than those specified in these instructions should be assessed for material compatibility before using. At a minimum, intermediate level* disinfectants should be used. Technical data sheets are typically available on the manufacturer's web site to assist in this assessment.

* "Intermediate level" is a classification applicable in the US. Intermediate disinfectants kill viruses, mycobacteria, fungi, and vegetative bacteria.

Any disinfection process including tools and solutions may influence the wear and tear of the device or equipment. In some instances, changing to another disinfectant may be required.

Within the applied decontamination process ensure that the detergent or disinfectant residuals are completely removed after wipe down. If detergent or disinfectant residuals remain, moisten a soft, clean cloth with purified or deionized water and wipe down affected areas (multiple wipes may be required to remove any remaining residue) or refer to the manufacturer's recommendations for the removal of the disinfectant residuals.

Connectors (HGA11 and EGA11)

Cleaning

Warning: Spilling or spraying fluids on or into the connectors or immersing the connectors may result in damage to the connectors.

Proceed with cleaning as follows:

1. Prepare a neutral pH detergent or a neutral pH enzymatic detergent according to the manufacturer's directions.
2. Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean the surfaces. Pay special attention to cracks and crevices.
3. Wipe thoroughly using a soft, clean cloth lightly moistened with warm tap water.
4. Dry with a soft, clean cloth.

Note: Disinfection with the listed chemicals may cause discoloration or wet spots on the central metallic post of the connector that interfaces with the Generator G11 receptacle. Discoloration or wet spots on the central metallic post of the connector should not affect the connector function.

Disinfecting

If the connectors become contaminated with blood or bodily fluids, they must be wiped down with a disinfectant before reuse. The following chemical disinfectants are approved for use with the connectors: Isopropyl Alcohol - 70%, Sodium hypochlorite solutions (0.25% - 0.50%), Cidex OPA, Dispatch, and Gigasept FF.

Disinfectants should be prepared and used according to the manufacturer's recommendations for use, concentration, and contact time.

The use of disinfectants other than those specified in these instructions should be assessed for material compatibility before using. At a minimum, intermediate level* disinfectants should be used. Technical data sheets are typically available on the manufacturer's web site to assist in this assessment.

* "Intermediate level" is a classification applicable in the US. Intermediate disinfectants kill viruses, mycobacteria, fungi, and vegetative bacteria.

Any disinfection process including tools and solutions may influence the wear and tear of the device or equipment. In some instances, changing to another disinfectant may be required.

Within the applied decontamination process ensure that the detergent or disinfectant residuals are completely removed after wipe down. If detergent or disinfectant residuals remain, moisten a soft, clean cloth with purified or deionized water and wipe down affected areas (multiple wipes may be required to remove any remaining residue) or refer to the manufacturer's recommendations for the removal of the disinfectant residuals.

Cart (CRT11)

Cleaning

Proceed with cleaning as follows:

1. Prepare a neutral pH detergent or a neutral pH enzymatic detergent according to the manufacturer's directions.
2. Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean the surfaces. Pay special attention to cracks and crevices.
3. Wipe thoroughly using a soft, clean cloth lightly moistened with warm tap water.
4. Dry with a soft, clean cloth.

Disinfecting

If the cart becomes contaminated with blood or bodily fluids, it must be wiped down with a disinfectant before reuse. The following chemical disinfectants are approved for use with the cart: Isopropyl Alcohol - 70%, Sodium hypochlorite solutions (0.25% - 0.50%), Cidex OPA, Dispatch, and Gigasept FF.

Disinfectants should be prepared and used according to the manufacturer's recommendations for use, concentration, and contact time.

The use of disinfectants other than those specified in these instructions should be assessed for material compatibility before using. At a minimum, intermediate level* disinfectants should be used. Technical data sheets are typically available on the manufacturer's web site to assist in this assessment.

* "Intermediate level" is a classification applicable in the US. Intermediate disinfectants kill viruses, mycobacteria, fungi, and vegetative bacteria.

Any disinfection process including tools and solutions may influence the wear and tear of the device or equipment. In some instances, changing to another disinfectant may be required.

Within the applied decontamination process ensure that the detergent or disinfectant residuals are completely removed after wipe down. If detergent or disinfectant residuals remain, moisten a soft, clean cloth with purified or deionized water and wipe down affected areas (multiple wipes may be required to remove any remaining residue) or refer to the manufacturer's recommendations for the removal of the disinfectant residuals.

Footswitch (FSW11)

Cleaning

Note: Always keep the generator connector dry.

Proceed with wipe-down cleaning as follows:

1. Prepare a neutral pH detergent or a neutral pH enzymatic detergent according to the manufacturer's directions.
2. Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean the surfaces. Pay special attention to cracks and crevices.
3. Wipe thoroughly using a soft, clean cloth lightly moistened with warm tap water.
4. Dry with a soft, clean cloth.

If necessary, the footswitch may be immersed for cleaning as follows:

1. Immerse the footswitch and cordset (not the generator connector) in a neutral pH enzymatic detergent, prepared according to the manufacturer's recommendations.

2. Use a soft bristle brush or soft, clean cloth to manually clean the device in the detergent solution. Pay special attention to cracks and crevices.
3. Rinse off detergent thoroughly using a soft clean cloth soaked with warm tap water or by placing the footswitch under running lukewarm tap water.
4. Dry the device with a clean absorbent cloth.

Disinfecting

If the footswitch becomes contaminated with blood or bodily fluids, it must be wiped down with a disinfectant or immersed in disinfectant before reuse. The following chemical disinfectants are approved for use with the footswitch: Isopropyl Alcohol - 70%, Sodium hypochlorite solutions (0.25% - 0.50%), Cidex OPA, Dispatch, and Gigasept FF.

Disinfectants should be prepared and used according to the manufacturer's recommendations for use, concentration, and contact time.

The use of disinfectants other than those specified in these instructions should be assessed for material compatibility before using. At a minimum, intermediate level* disinfectants should be used. Technical data sheets are typically available on the manufacturer's web site to assist in this assessment.

* "Intermediate level" is a classification applicable in the US. Intermediate disinfectants kill viruses, mycobacteria, fungi, and vegetative bacteria.

Any disinfection process including tools and solutions may influence the wear and tear of the device or equipment. In some instances, changing to another disinfectant may be required.

Within the applied decontamination process ensure that the detergent or disinfectant residuals are completely removed after wipe down or immersion. If detergent or disinfectant residuals remain, moisten a soft, clean cloth with purified or deionized water and wipe down affected areas (multiple wipes may be required to remove any remaining residue), run affected areas under running lukewarm tap water or refer to the manufacturer's recommendations for the removal of the disinfectant residuals.

Other Instruments and Accessories

For other reusable accessories not listed in this manual consult the appropriate instructions for use for guidance on disinfecting and sterilization, if required.

Maintenance and Repair

Periodic calibration is not required for Generator G11. Periodic check of output using GEN11VK is recommended per facility guidelines. Service of Generator G11 would be required if GEN11VK shows the generator is out of tolerance. See GEN11VK Instructions For Use for guidance on performing the output check. For servicing activities, Generator G11 may also be returned to an authorized Ethicon Endo-Surgery service facility at any time.

The Generator G11 contains a Potential Equalization Terminal on the back panel. This is provided for compatibility with other medical systems requiring such connections. This conductor is not intended for protective earthing.

The software revision may be displayed on the biomed screen in the user interface.

Disposing of Ethicon Endo-Surgery Generator G11 (Environmental Protection)

The Generator G11 and accessories must not be disposed of at the end of life with other waste. To recycle the waste equipment, get return instructions from the Ethicon Endo-Surgery Customer Service Department (call 1-800-USE-ENDO (1-800-873-3636) in the U.S. only) or contact your local sales representative to discuss local waste disposal solutions and processes. Generator G11 poses disposal risks similar to consumer electronics such as computers. There are no radioactive substances, batteries, or hazardous liquids that may leak in Generator G11.

Chapter 6 - Conformance to Standards

The Generator G11 conforms to the following international standards:

EN (IEC) 60601-1 (with Canadian and US National Deviations)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN (IEC) 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN (IEC) 60601-2-2	Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment

Generator G11 Operator's Manual

EN (IEC) 60601-1-8

Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

Appendix

System Specifications

Main Fuses	T5AL 250 V (Time-delay, 5 Amp, glass body, 5x20 mm package size, quantity: 2)
Degree of Protection Against Electric Shock	Type CF applied part consisting of the HARMONIC or ENSEAL instruments
Class of Protection Against Electric Shock	Class 1
Ingress Protection G11 Enclosure	IP21
Ingress Protection G11 Footswitch	IP68
Main Input	100 - 240 V ~, 50/60 Hz, 500 VA
Output	<p>ENSEAL Output: Bipolar, no neutral electrode required 100 VAC RMS maximum 135 watts maximum (rated load 15 ohms) 300 - 490 kHz (330 kHz unless otherwise marked in instrument IFU)</p> <p>HARMONIC Output: 150 VAC RMS maximum 35 watts continuous 30 - 80 kHz (55.5 kHz unless otherwise marked in instrument IFU)</p>
Ambient Operating Conditions	Temperature: 15 °C to 27 °C Humidity: 30% - 75% non-condensing Atmospheric Pressure Range: 700 hPa - 1060 hPa
Transport and Storage Conditions	Temperature: -35 °C to +54 °C Humidity: 10% - 95% non-condensing Atmospheric Pressure Range: 700 hPa - 1060 hPa
Weight	Generator: 5.9 kg Cart: 16.8 kg Footswitch: 3.6 kg
Overall Dimensions	Generator: 35.0 cm x 35.5 cm x 13.6 cm Cart: 48.0 cm x 56.2 cm x 95.3 cm Footswitch: 34.2 cm x 19.0 cm x 10.4 cm
Power Cord	<p>North American removable power cord set with the following characteristics: Plug Style: NEMA 5-15 (clear) North American Hospital Grade Receptacle: IEC 60320 C13 with straight non-angled cord entry Cord Length: 4.6 meters nominal Current Rating: 13A Voltage Rating: 125 VAC minimum Wiring Code: North American Cordage Description: SJT (UL) or SJT (CSA) Conductors: 16 AWG 3C Agency Approvals Required: UL and CSA</p> <p>International removable power cord set with the following characteristics: Plug Style: as needed by particular country requirements Receptacle: IEC 60320 C13 with straight non-angled cord entry Cord Length: 2.44 - 4.6 meters nominal Current Rating: 10A Minimum conductor size cross-sectional area: 1.0 mm² copper Voltage Rating: 250 VAC minimum Wiring: International Cordage Type: HAR Item to have certification by at least one of the following agencies: VDE, ASTA, SEMKO, KEMA, LCIE, DFT, IMQ, SEV</p>

Generator G11 Operator's Manual

Electromagnetic Compatibility (EMC)

The Generator G11 requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and used in accordance with the EMC information provided in this guide. The Generator G11 is intended for use in the electromagnetic environments specified below.

Caution: Ensure that the Generator G11 is used only in these environments.

Electromagnetic Emissions

Emissions Test	Compliance	Guidance
RF emissions CISPR 11	Group 1 (per IEC 60601-2-2:2009)	The Generator G11 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Generator G11 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic Immunity Guidance

For electromagnetic immunity, essential performance is: activation tones are coupled with energy output, energy output ceases when activation switches are opened, and no energy output without activation switch closure.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge IEC 61000-4-2	± 6kV Contact ± 8kV Air	± 6kV Contact ± 8kV Air	Relative humidity should be at least 30%.
Electrical fast Transient/ Burst IEC 61000-4-4	± 2 kV on Power Supply Lines ± 1 kV on Input/Output Lines	± 2 kV on Power Supply Lines ± 1 kV on Input/Output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	± 1kV Differential Mode ± 2kV Common Mode	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency Magnetic Fields IEC 61000-4-3	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage Dips, Short Interrupts, and Variations on Power Supply Lines IEC 61000-4-11	<5% U_T (95% dip in U_T for 0.5 cycles) <40% U_T (60% dip in U_T for 5 cycles) <70% U_T (30% dip in U_T for 25 cycles) <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (95% dip in U_T for 0.5 cycles) <40% U_T (60% dip in U_T for 5 cycles) <70% U_T (30% dip in U_T for 25 cycles) <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Generator G11 requires continued operation during power mains interruptions, it is recommended that the Generator G11 be powered from an uninterruptible power supply or a battery.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Generator G11, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 4,066 MHz to 4,070 MHz.

^b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

Recommended separation distances between portable and mobile RF communications equipment and the Generator G11

The Generator G11 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Generator G11 can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile

RF communications equipment (transmitters) and the Generator G11 as recommended below, according to the maximum output power of the communications equipment.

	Rated maximum output power of transmitter (W)		Separation distance according to frequency of transmitter (m)	
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1.0	1.20	1.20	2.30	
10	3.79	3.79	7.27	
100	12	12	23	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Go to www.e-ifu.com for latest revision of service manual.

	Footswitch
	Non-ionizing Radiation
	Equipotential Ground Lug
	Electrical and Electronic equipment. Return waste to a collection system or treatment and recycling facilities. Applicable in the EU. Follow decontamination instructions before returning waste.
	Authorized Representative in the European Community
	Manufacturer
	Power On/Off Switch

	<p>Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.</p>
	<p>Keep Dry</p>
	<p>Date of Manufacture</p>
	<p>Reorder Number</p>
	<p>Serial Number</p>
	<p>Authorized Representative in the USA</p>
	<p>Non-sterile</p>
	<p>CF Applied Part (Device Connector)</p>
	<p>The electronic information product (EIP) has met the requirements set forth by the People's Republic of China for marking of EIPs, and can be used during its environmental protection use period of 50 years. After the environmental protection period has expired, the EIP should be recycled. Applicable in the People's Republic of China.</p>
	<p>Fuse</p>
	<p>Product is certified by a Nationally Recognized Testing Laboratory.</p>
	<p>Consult the Generator G11 Operator's Manual.</p>

Generator G11 Operator's Manual

	Refer to instruction manual/booklet for information related to safety.
	Recyclable Packaging
	Relative Humidity
	Temperature
	Low Alarm
	Medium Alarm

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REF
GEN11, HGA11, EGA11, CRT11, FSW11

EC REP Ethicon Endo-Surgery (Europe) GmbH
Hummelsbuetteler Steindamm 71
22851 Norderstedt
GERMANY

USA REP Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242-2839 USA
1-800-USE-ENDO



**Ethicon
Endo-Surgery**



ETHICON ENDO-SURGERY, LLC ©EES, LLC 2013
475 Calle C
Guaynabo, PR 00969 USA

Rev. 2013-03



P43569P01 ENG

Subject Device Generator G11 Carton Label

Latest Released: YES

P4505/P97

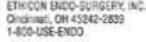
 **Ethicon**
Endo-Surgery

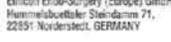
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Générateur G11
Generator G11
Generatore G11
Gerador G11
Generator G11
Jenerator G11
ジェネレーター G11

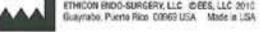
 GEN11

 USA REP

 EC REP


ETHICON ENDO-SURGERY, INC.
Orionville, OH 43042-2839
1-800-USE-ENDO


Ethicon Endo-Surgery (Europe) GmbH
Hennelstraße 71, Steinbühl
22551 Nordstedt, GERMANY


ETHICON ENDO-SURGERY, LLC ©EES, LLC 2010
Guaynabo, Puerto Rico 00969 USA Made in USA

 NON-STERILE

 Rx Only



 CE 0128



 1 REF

GEN11

Predicate Device Harmonic Combination Hook Blade HK105 Package Inserts

The Package Inserts are supplied in multiple languages. This section includes only the English portions of the Package Inserts, for reference.



10 cm Combination Hook Blade



- Lame à crochet combinée de 10 cm
- 10 cm Kombinationshaken
- Lama uncinata da 10 cm
- Lâmina com gancho combinado de 10 cm
- Lámina de gancho combinado de 10 cm
- 10 cm Combinatiehoek-snijblad
- 10 cm Kombinations-hookblad
- Yhdistelmäkoukkuterä (10 cm)
- Συνδυαστική αγκιστροειδής λεπίδα 10 cm
- 10 cm kombinationskrokblad
- Ostrze zakrzywione złożone 10 cm
- 10 cm-es kombinált horgas penge
- 10 cm kombinovaná háková čepel
- 10 cm kombinovaná háková čepel'
- 10 cm•

Please read all information carefully.

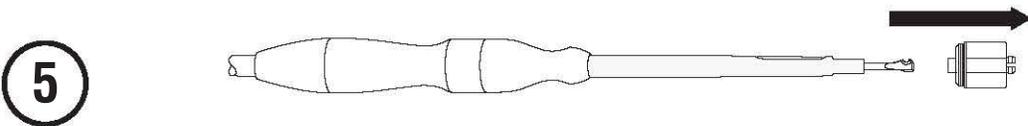
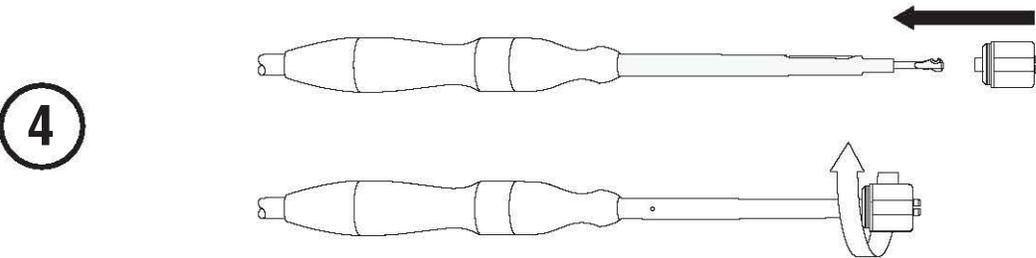
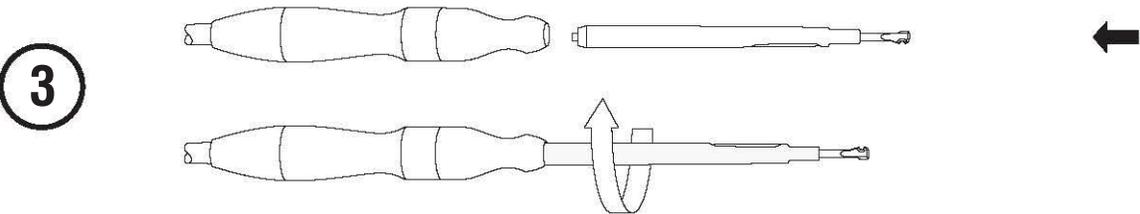
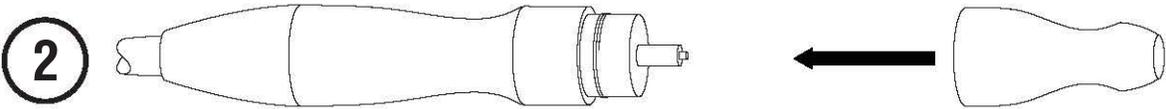
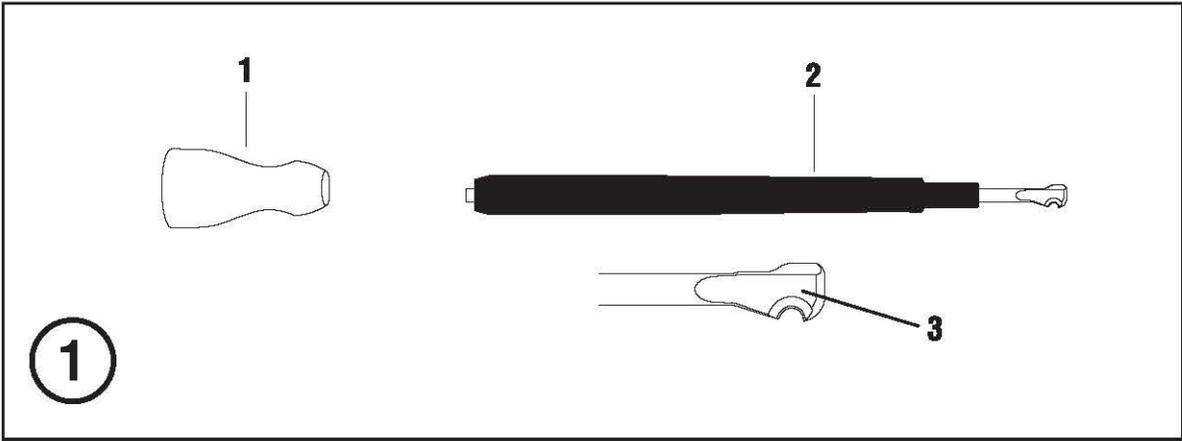
Failure to properly follow the instructions may lead to serious surgical consequences.

Important: This package insert is designed to provide instructions for use of the HARMONIC® 5 mm Instruments. It is not a reference to surgical techniques.

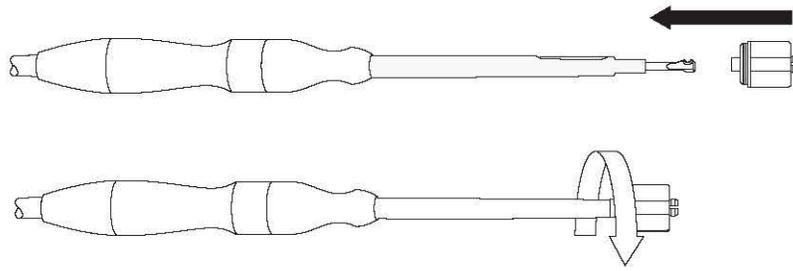
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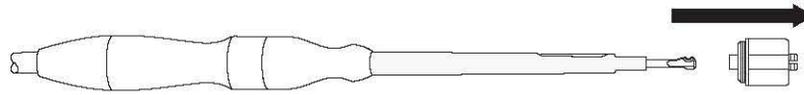
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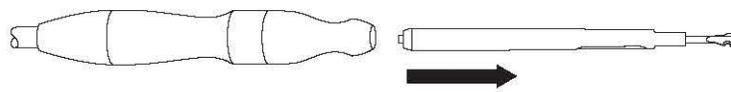
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Indications

The HARMONIC instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

Contraindications

- The instruments are not indicated for incising bone.
- The instruments are not intended for contraceptive tubal occlusion.

Device Description

The HARMONIC 10 cm Combination Hook Blade is a sterile, single patient use instrument consisting of a titanium blade with a non-removable sheath.

The working instrument length is 10 cm and the outer shaft diameter tapers from 8.5 mm proximally to 5.5 mm distally. The HARMONIC 10 cm Combination Hook Blade must be used with the 5 mm Adaptor or Hand Switching Adaptor and connected to the HARMONIC Hand Piece and Generator prior to use.

The HARMONIC 10 cm Combination Hook Blade is designed for use exclusively with a compatible HARMONIC Generator and HARMONIC Hand Piece, packaged separately. Refer to a compatible HARMONIC Generator User Manual before using these instruments. The HARMONIC 10 cm Combination Hook Blade allows for the coagulation of vessels up to and including 2 mm in diameter.

Illustration and Nomenclature (Illustration 1)

- | | | | |
|----|--|----|---------------------------|
| 1. | 5 mm Adaptor or Hand Switching Adaptor | 3. | Combination Hook (Detail) |
| 2. | 5 mm Blade and Sheath | | |

Transport and Storage Conditions

Temperature: -20°C to +60°C

Relative Humidity: 10 – 80%

Instructions for Use

Verify compatibility of all instruments and accessories prior to using the instrument (refer to **Warnings and Precautions**).

The hand piece and blade wrench are reusable and shipped non-sterile. These components must be sterilized per their insert instructions prior to each use. The adaptor can be either sterile or non-sterile depending on product code; please refer to the appropriate Instructions for Use for these devices prior to use with the HARMONIC 10 cm Combination Hook Blade.

Attachment of Blade to Hand Piece

- 1 Attach the 5 mm adaptor or hand switching adaptor to the hand piece. (Illustration 2)
- 2 Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
- 3 Remove the protective cap from the blade tip.
Note: Take care to avoid injury from the blade tip when removing the protective cap.
- 4 Attach the blade manually to the hand piece by turning it clockwise (finger tight only).
Note: Take care to avoid injury from the blade tip when attaching the blade to the hand piece and while sliding the blade wrench onto or off of the blade. (Illustration 3)
- 5 Use the blade wrench to tighten the blade. Slide the wrench over the blade until it stops at the flats on the blade. Align the flats on the wrench with the flats on the blade. Turn the wrench clockwise until it “clicks” twice, indicating that sufficient torque has been applied to secure the blade. (Illustration 4)
Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.
- 6 Remove the blade wrench by sliding it straight back over the blade. (Illustration 5)

Do not dispose of the reusable blade wrench. It is used for removal of the blade following the procedure.

Operation of the Blade

Refer to a compatible HARMONIC Generator User Manual and hand piece package insert for hand piece attachment and system operation instructions.

- 1 Connect the assembled hand piece, adaptor, and blade to the generator and turn the generator power on.
Note: Do not turn the generator power on before the hand piece, adaptor, and blade are connected to the generator.
- 2 Select the desired power level using the INCREASE and DECREASE buttons on the generator.
- 3 The blade is ultrasonically energized when either foot switch pedal or hand switching action button is depressed.
 Note: Scratches on the blade may lead to premature blade failure.
 - Avoid accidental contact with other instruments during use.
 - Do not use any other means than the blade wrench to attach or detach the blade.
- 4 After inserting the blade through an incision, press the blade against tissue during ultrasonic activation to cut and/or coagulate tissue under direct visualization.
 Note: In general, sharper ultrasonically activated edges cut faster with less hemostasis, while more blunt edges and surfaces coagulate more and cut less rapidly. The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors, including the power level selected, blade characteristics, tissue tension, tissue type, pathology, and surgical technique.

Blade Disassembly

- 1 Turn the generator **OFF** at the power switch or enter **STANDBY** mode.
- 2 Slide the wrench over the blade until it stops at the flats on the blade. Align the flats on the wrench with the flats on the blade. Loosen the blade by turning the wrench counterclockwise. Continue to loosen by turning the wrench or blade manually to unscrew it completely. (Illustration 6)
- 3 Remove the blade wrench by pulling it straight back over the blade. **Save the blade wrench for future use.** (Illustration 7)
 Note: Take care to avoid injury from the blade tip while sliding the blade wrench onto or off of the blade.
- 4 Remove the blade and dispose of it in an appropriate container. (Illustration 8)
- 5 Remove the adaptor and save it for future use if appropriate.

Warnings and Precautions

- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Minimally invasive instruments may vary from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse instruments in liquid unless the instruments are designed and labeled to be immersed.
- Audible high-pitched tones, resonating from the blade or hand piece, are an abnormal condition and an indicator that the blade or hand piece is not operating properly. The tones may be an indicator that the hand piece is beyond its useful life or that the blade has not been attached properly, which may result in abnormally high sheath temperatures and user or patient injury.
- Do not use the HARMONIC Combination Hook Blade without the proper adaptor. Failure to use the proper adaptor as described in the device description may result in user or patient burn injury.
- The blade has been designed to meet the international safety standard EN60601-1 based on an **intermittent operation of 15 second on/off intervals**. For activation times of longer duration and under certain fault conditions, the blade sheath may become hot. To prevent burn injury, avoid direct tissue contact with the blade sheath or take preventative measures to protect tissue that comes in contact with the sheath.

- Blood and tissue buildup between the blade and sheath may result in abnormally high temperatures at the distal end of the sheath. To prevent burn injury, remove any visible tissue buildup at the distal end of the sheath.
- As with all energy sources (Electrosurgery, Laser, or Ultrasound), there are concerns about the carcinogenic and infectious potential of the by-products, such as tissue smoke plume and aerosols. Appropriate measures such as protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- In case of system failure, ensure the availability of the appropriate back-up equipment relevant to the specific procedure.
- Do not attempt to bend, sharpen or otherwise alter the shape of the blade. Doing so may cause blade failure and user or patient injury.
- To avoid user or patient injury in the event that accidental activation occurs, the instrument blade and distal end of the sheath should not be in contact with the patient, drapes, or flammable materials while not in use.
- During and following activation in tissue, the instrument blade may become hot. Avoid unintended contact with tissue, drapes, surgical gowns, or other unintended sites at all times.
- To avoid user or patient injury, do not activate an active electrosurgical device in close proximity to the HARMONIC instruments. The aerosols created by the activation of the HARMONIC instruments in fatty tissue are potentially flammable.
- The entire exposed blade tip and any exposed blade shaft is active and will cut/coagulate tissue when the instrument blade is activated. Be careful to avoid inadvertent contact between all exposed blade surfaces and surrounding tissue when using the HARMONIC instruments.
- Minimum starting power level defaults to power level 3.
- Use caution when using HARMONIC instruments on solid organs. Due to the limited ability of the instruments to occlude vascular structures of this nature, hemostasis may not be predictable and may require adjunct measures for coagulation.
- Incidental and prolonged activation against solid surfaces, such as bone, may result in blade heating and subsequent blade failure, and should be avoided.
- Avoid contact with any and all metal or plastic instruments or objects when the instrument is activated. Contact with staples, clips, or other instruments while the instrument is activated may result in cracked or broken blades which may be identified by generator solid tone or instrument error.
- Use only the HARMONIC Foot Switch, Hand Piece, blade accessories, and power cord to ensure that they are compatible with the generator.
- Products manufactured or distributed by companies not authorized by Ethicon Endo-Surgery may not be compatible with the HARMONIC System. Use of such products may lead to unanticipated results and possible injury to the user or patient.
- After removing the instrument, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- Dispose of all opened instruments whether used or unused.
- This device is packaged and sterilized for single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness or death. Cleaning and resterilization of single patient use HARMONIC devices can also result in abnormally high sheath temperatures and burn injury to user or patient when the blade is activated. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

How Supplied

The HARMONIC Combination Hook Blade is supplied sterile for single patient use. Discard after use.

	<p>See Instructions For Use (Refer to blue symbol on outer packaging.) Voir notice d'utilisation (se reporter au symbole bleu sur l'emballage extérieur). Bitte Gebrauchsanweisung beachten (siehe blaues Symbol an der äußeren Verpackung). Vedere le Istruzioni per l'uso (vedere il simbolo blu sulla confezione esterna). Consulte as Instruções de utilização (consulte o símbolo azul na embalagem exterior). Ver instrucciones de uso (refiérase al símbolo azul en el envase exterior). Zie de gebruiksaanwijzing (zie het blauwe symbool op de buitenste verpakking). Se betjeningsvejledningen (der henvises til det blå symbol på yderemballageen). Katso käyttöohjeita (katso sinistä symbolia ulkopakkauksessa). Δείτε τις Οδηγίες Χρήσης (ανατρέξτε στο μπλε σύμβολο, στο εξωτερικό της συσκευασίας). Se bruksanvisningen (se den blå symbolen på yttre förpackningen). Należy zapoznać się z instrukcją użytkowania (patrz niebieski symbol na zewnętrznym opakowaniu). Lásd a használati útmutatót (lásd a külső csomagoláson található kék szimbólumot). Viz návod k použití (informace jsou uvedeny u modrého symbolu na vnějším balení). Prečítajte si návod na použitie (vzťahuje sa na modrý symbol na vonkajšom obale).</p> <p>.....</p>
	<p>Relative Humidity Humidité relative Relative Feuchte Umidità relativa Humidade relativa Humedad relativa Relatieve vochtigheid Relativ fuktighed Suhteellinen kosteus Σχετική υγρασία Relativ fuktighet Wilgotność względna Relatív páratartalom Relativní vlhkost Relatívna vlhkosť</p> <p>.....</p>
	<p>Temperature Température Temperatur Temperatura Temperatura Temperatura Temperatuur Temperatur Lämpötila Θερμοκρασία Temperatur Temperatura Hőmérséklet Teplota Teplota</p> <p>.....</p>



Do not use this instrument with ULTRACISION® Generator (GEN01/GEN32).
Ne pas utiliser cet instrument avec le générateur ULTRACISION® (GEN01/GEN32).
Das Instrument ist nicht mit dem ULTRACISION® Generator (GEN01/GEN32) kompatibel.
Non utilizzare questo strumento con il generatore ULTRACISION® (GEN01/GEN32).
Não utilize este instrumento com o gerador ULTRACISION® (GEN01/GEN32).
No utilice este instrumento con el generador ULTRACISION® (GEN01/GEN32).
Gebruik dit instrument niet met de ULTRACISION® generator (GEN01/GEN32).
Brug ikke dette instrument sammen med ULTRACISION® generatoren (GEN01/GEN32).
Älä käytä tätä instrumenttia ULTRACISION®-generaattorin (GEN01/GEN32) kanssa.
Μη χρησιμοποιείτε αυτό το εργαλείο με τη γεννήτρια ULTRACISION® (GEN01/GEN32).
Använd inte detta instrument tillsammans med ULTRACISION® -generatoren (GEN01/GEN32).
Nie stosować tego instrumentu z generatorem ULTRACISION® (GEN01/GEN32).
Ne használja ezt műszert ULTRACISION® generátorral (GEN01/GEN32).
Nepoužívejte tento nástroj s generátorem ULTRACISION® (GEN01/GEN32).
Tento inštrument nepoužívajte s generátorom ULTRACISION® (GEN01/GEN32).

.....

<p>STERILE R</p>	<p>Sterilized by Irradiation. Sterility Guaranteed Unless Package Opened or Damaged. Do Not Resterilize. Stérilisé par irradiation. Stérilité garantie si l'emballage n'a pas été ouvert ou endommagé. Ne pas restériliser. Strahlensterilisiert. Nicht verwenden, wenn die Sterilverpackung geöffnet oder beschädigt ist. Nicht reesterilisieren. Sterilizzato con radiazioni. Sterilità garantita, a meno che la confezione non venga aperta o danneggiata. Non risterilizzare. Esterilizado por irradiação. Esterilização garantida excepto se a embalagem estiver aberta ou danificada. Não reesterilizar. Estéril por radiación. Esterilización garantizada mientras el envase esté íntegro. No reesterilizar. Gesteriliseerd met straling. Steriliteit gegarandeerd tenzij de verpakking is geopend of beschadigd. Niet opnieuw steriliseren. Steriliseret ved stråling. Garanteret sterilt, med mindre pakken er åbnet eller beskadiget. Må ikke gensteriliseres. Steriloitu säteilyttämällä. Tuote on steriili, kun pakkaus on avaamaton ja ehjä. Ei saa steriloida uudestaan. Αποστειρωμένοι με ακτινοβολία. Η στειρότητα είναι εγγυημένη εφόσον δεν ανοιχθεί η συσκευασία ή δεν προκληθεί ζημιά σε αυτήν. Μην επαναποστειρώνετε. Steriliserad med bestrålning. Steriliteten garanteras under förutsättning att förpackningen inte är öppnad eller skadad. Får ej omsteriliseras. Urządzenie/sprzet sterylizowane promieniowaniem. Jakość gwarantowana pod warunkiem, że opakowanie nie zostało otwarte lub uszkodzone. Nie steryliżować ponownie. Besugárzással sterilizálva. A sterilitása addig garantálható, amíg ki nem nyitják, illetve meg nem sérül a csomagolás. Tilos újra sterilizálni! Sterilizace se provádí ozářením. Sterilnost je zaručena, pokud balení není otevřené nebo poškozené. Nástroj znovu nesterilizujte. Sterilizované ožarováním. Sterilita je zaručená, ak nie je otvorený alebo poškodený obal. Neresterilizujte.</p> <p>• • • • •</p> <p>• • • • •</p>		
<p></p>	<table border="0"> <tr> <td data-bbox="440 1386 860 1986"> <p>Single Patient Use À utiliser sur un seul patient Einweg-Instrument, nur für den Einsatz bei einem Patienten Per l'uso su un singolo paziente Para ser utilizado num único doente Uso en un solo paciente Voor gebruik bij één pati Til anvendelse på én patient</p> </td> <td data-bbox="860 1386 1401 1986"> <p>Potilaskohtainen Χρήση σε έναν μόνον ασθενή Endast för en patients bruk Do użytku u jednego pacjenta Egyetlen betegnél használható fel Nástroj je určený pouze pro jednoho pacienta Určené iba pre jedného pacienta</p> <p>• • • • •</p> </td> </tr> </table>	<p>Single Patient Use À utiliser sur un seul patient Einweg-Instrument, nur für den Einsatz bei einem Patienten Per l'uso su un singolo paziente Para ser utilizado num único doente Uso en un solo paciente Voor gebruik bij één pati Til anvendelse på én patient</p>	<p>Potilaskohtainen Χρήση σε έναν μόνον ασθενή Endast för en patients bruk Do użytku u jednego pacjenta Egyetlen betegnél használható fel Nástroj je určený pouze pro jednoho pacienta Určené iba pre jedného pacienta</p> <p>• • • • •</p>
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	<p>Lot Nº de lot Ch.-B. Lotto Nº do lote Nº de lote Lotnr. Parti</p>	<p>Erän koodi Αρ. παρτίδας Batchnummer Numer partii produkcyjnej Tétel Šarže Šarža • • • •</p>
	<p>Use Until Date À utiliser avant Verw. bis Utilizzare entro Validade A utilizar antes de Gebruik vóór Holdbar til angivne dato</p>	<p>Käytettävä viimeistään Χρησιμοποιείτε μέχρι την Använd före Koniec okresu przydatności do użytku A feltüntetett dátumig használható fel Použit do data Použiteľné do • • • • •</p>
	<p>Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.</p> <p>Mise en garde : La loi fédérale (États-Unis d'Amérique) n'autorise la vente de ce dispositif que par un médecin ou sur sa prescription.</p> <p>Achtung: Laut Gesetz darf dieses Instrument in den USA nur an einen Mediziner oder eine in seinem Auftrag handelnde Person verkauft werden.</p> <p>Attenzione: la legge federale americana consente la vendita di questo dispositivo solo dietro richiesta medica.</p> <p>Atenção: A lei federal (dos Estados Unidos) só permite a venda deste dispositivo a médicos ou sob receita destes.</p> <p>Atención: La ley federal de EE.UU. impone que este producto sólo puede ser vendido por un médico o bajo prescripción médica.</p> <p>Waarschuwing: De Federale wetgeving (in de VS) eist dat dit apparaat uitsluitend door of in opdracht van een arts wordt verkocht.</p> <p>Forsigtig: I henhold til gældende lov må denne anordning kun sælges til eller bruges af en læge.</p> <p>Varoitus: Yhdysvaltain lain mukaan tämän tuotteen saa myydä vain lääkäri tai lääkärin määräyksestä.</p> <p>Προσοχή: Το ομοσπονδιακό δίκαιο των ΗΠΑ περιορίζει την πώληση του εργαλείου αυτού μόνον από ιατρούς ή κατόπιν εντολής ιατρού.</p> <p>Varning: Enligt amerikansk lag får detta instrument endast säljas till läkare eller på läkares anmodan.</p> <p>Przestroga: Prawo federalne (USA) zezwala na sprzedaż tego urządzenia wyłącznie lekarzowi lub na jego zamówienie.</p> <p>Figyelem! Az USA szövetségi törvényei értelmében az eszköz csak orvos megrendelésére értékesíthető.</p> <p>Upozornění: Podle federálních zákonů USA je prodej tohoto zařízení omezen na prodej v lékárnách nebo na lékařský předpis.</p> <p>Pozor: Podľa federálnych zákonov (v USA) sa toto zariadenie smie predávať iba lekárom alebo na lekársky predpis.</p> <p>• • • • •</p>	

	<p> Manufacturer Fabricant Hersteller Fabbricante Fabricante Fabricante Fabrikant Producent Valmistaja Κατασκευαστής Tillverkare Producent Gyártó Výrobce Výrobca • • • • • </p>
<div style="border: 1px solid black; padding: 2px; display: inline-block;"> <div style="border-right: 1px solid black; padding: 2px 5px;">EC</div> <div style="padding: 2px 5px;">REP</div> </div>	<p> Authorized Representative in the European Community Représentant autorisé dans la Communauté européenne Bevollmächtigter in der Europäischen Gemeinschaft Rappresentante autorizzato nella Comunità Europea Representante autorizado na Comunidade Europeia Representante autorizado en la Comunidad Europea Bevoegd vertegenwoordiger bij de Europese Gemeenschap Autoriseret repræsentant i det europæiske fællesskab Valtuutettu edustaja Euroopan yhteisön alueella Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα Auktoriserad representant i Europeiska gemenskapen Autoryzowany przedstawiciel w Unii Europejskiej Az Európai Közösség meghatalmazott képviselője Autorizovaný zástupce v Evropském společenství Autorizovaný zástupca EU • • • • • </p>
<div style="border: 1px solid black; padding: 2px; display: inline-block;"> <div style="border-right: 1px solid black; padding: 2px 5px;">USA</div> <div style="padding: 2px 5px;">REP</div> </div>	<p> Authorized Representative in the USA Représentant autorisé aux États-Unis Bevollmächtigter in den USA Rappresentante autorizzato per gli Stati Uniti Representante autorizado nos EUA Representante autorizado en EE.UU. Bevoegd vertegenwoordiger in de VS Bemyndiget repræsentant i USA Valtuutettu edustaja Yhdysvalloissa Εξουσιοδοτημένος αντιπρόσωπος στις ΗΠΑ Auktoriserad representant i USA Autoryzowany przedstawiciel w Stanach Zjednoczonych Ameryki Meghatalmazott képviselő az Egyesült Államokban Autorizovaný zástupce v USA Autorizovaný zástupca v USA • • • • • </p>



P40599P04

REF
HK105



Ethicon Endo-Surgery (Europe) GmbH
Hummelsbuetteler Steindamm 71
22851 Norderstedt
GERMANY



Ethicon Endo-Surgery, Inc.
Cincinnati, OH 45242-2839 USA
1-800-USE-ENDO



ETHICON ENDO-SURGERY, LLC
a *Johnson & Johnson* company



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Guaynabo, Puerto Rico 00969 USA

Rev. 2012-04



P40599P04

Predicate Device Harmonic Combination Hook Blade HK105 Primary Package Labels

Harmonic **5 mm**

Combination Hook Blade - 10 cm *Lâmina com gancho combinado - 10 cm*
Lame à crochet combinée - 10 cm *Láminas de gancho combinado - 10 cm*
Kombinationshaken - 10 cm *Combinatiehoek-snijblad - 10 cm*
Lama uncinata - 10 cm *コンビネーションフックブレード - 有効長10 cm (1本入) *商標*

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 Guaynabo, Puerto Rico 00969 USA Assembled in Mexico

ULTRACISION GENERATOR (GEN01)(DE N&Z)

STERILE R Sterilized by Irradiation. Sterility Guaranteed Unless Package Opened or Damaged.

REF **HK105**

Harmonic **5 mm**

Combination Hook Blade - 10 cm *Lâmina com gancho combinado - 10 cm*
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STERILE R Sterilized by Irradiation. Sterility Guaranteed Unless Package Opened or Damaged.

REF **HK105**

REVISIONS			
LTR	CAF NO.	CHNG	DATE
A	12-00829	KWU	3-9-12
PRODUCT CODE	ARTWORK NUMBER	PACKAGE COMPONENT NUMBER	
HK105	A95485P00	P30118P01	

ETHICON ENDO-SURGERY, INC.
 CONFIDENTIAL: NOT TO BE REPRODUCED OR USED IN ANY WAY WITHOUT WRITTEN ETHICON ENDO-SURGERY APPROVAL. CINCINNATI, OHIO

DIE PMS 424 (GRAY)

Group: Package Labeling Drawing
 Type: FFS

State: Released
 NSR/SR:

Predicate Device Harmonic Combination Hook Blade HK105 Carton Package Labels

Latest Released: YES

Harmonic 5 mm
Combination Hook Blades - 10 cm

ETHICON ENDO-SURGERY, LLC
REF HK105

Harmonic 5 mm
Combination Hook Blades - 10 cm

ETHICON ENDO-SURGERY, LLC
REF HK105

Harmonic 5 mm
Combination Hook Blades - 10 cm

ETHICON ENDO-SURGERY, LLC
REF HK105

Harmonic 5 mm
Combination Hook Blades - 10 cm

ETHICON ENDO-SURGERY, LLC
REF HK105

REVISIONS

LTR	CHG	DATE
C	12-08-27	KWU
B	10-04-71	AD

PRODUCT CODE	PRINTED PARTNO	ETHICON PARTNO					
HK105	A94578P02	P4605P01	A85121P02	R302402	SR		

ETHICON ENDO-SURGERY, LLC
11-24-10

PMSPROCESS BLACKCVC PMSPROCESS BLUECVC
PMSPROCESS BLACKCVC DIELINE CAFBLOCK AUXDIELINE

CAF copy

CONFIDENTIAL

Group: Scanned (Hardcopy) Item
Type: Pressure-Sensitive Label

PRESSURE SENSITIVE LABEL CREATE OR MODIFY
LABEL PROOF SAMPLES



ETHICON ENDO-SURGERY
a Johnson & Johnson company



P40052P02

Assembled in Mexico

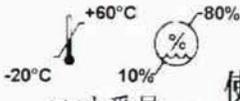
PROD CODE: HK105 03
CASE CONTENTS: 30 BOXES
(30 SALES UNITS OF 6 EACH)

04/18/2012 AV

ETHICON ENDO-SURGERY, LLC Guaynabo, Puerto Rico 00969 USA
Assembled in Mexico

Covered by one or more of the following US Patents:
5810859 6423082 8057498

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ロツト番号
LOT SAMPLE

使用期限 放射線滅菌済

YYYY-MM
USE UNTIL DATE

STERILE R



H208HK1053R



12109SAMPLESU

00001 31160 03



H208HK1052R



12109SAMPLER



ロツト番号 使用期限
LOT SAMPLE YYYY-MM
Use Until Date
00001 31160 03

State: Released

Latest Released: NO

Predicate Device Medtronic Integrated Power Console System Manual



Medtronic

Integrated Power Console (IPC[®]) System

MODEL: EC300



User's Guide

Rx Only

CUSTOMER SERVICE

Medtronic Powered Surgical Solutions US Help Line
4620 North Beach Street 1-800-468-9710
Fort Worth, Texas 76137 USA
www.medtronic.com

International Service

International Customers should contact their local Medtronic Neurologic Technologies representative.

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Triton Electric High-Torque Handpiece..... M000030A322

Endo-Scrub 2..... 68E4005

Midas Rex Spine Shaver, StraightShot M4, StraightShot Magnum II or StraightShot III 68E3282

Legend EHS and Legend EHS Stylus M000030A234

Stylus Touch 68E4132

Legend Attachments..... M000030A235

Skeeter Oto-flex Burs..... 68E3968

Skeeter Handpiece 68E3969

Visao 68E3281

Indigo High-Speed Otologic Drill 68E4187

Indigo High-Speed Otologic Drill Attachments 68E4188

Microsaws..... M000030A231

POWEEASE Driver..... 68E4189

SYMBOLS

The following symbols can appear on this device and related packaging.

	On Off Button		Package Contents		Follow Instructions For Use		Conforms to ANSI/AAMI ES 60601-1, IEC/EN 60601-1. Certified to CSA C22.2 No.601.1
	EMC Compliance Mark		Do Not Oil		Do Not Immerse	Rx Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
	Fuse	IPX1	Protected Against Vertical Water Drops		Oscillate	EC REP	Authorized Representative in the European Community
	Use By Date	IPX7	Protected Against The Effects Of Temporary Immersion In Water	F	Forward		Precaution: Pinch Hazard. Keep Fingers Clear Of Rollers
ACC	Accessory		Type BF Applied Part	R	Reverse		Contains DEHP (di-2-ethyl hexyl phthalate)
	AC Power		Start/Stop		Foot Pedal Connector		Protective Earth
	Output		RF Transmitter (Interference May Occur)		Fine Irrigant Adjustment		Equipotential Ground Connector
	Is Approximately Equal To		Consult Instructions for Use		Left Foot Control Unit Button / Mode Button		Use With
STERILE	Non-Sterile	BUR	Stim Bur Connector		Right Foot Control Unit Button / Control Button		RoHS - Environmental friendly use period - China (SJ/T 11364-2006)
	Quantity	NIM	NIM Console Connector		Top Foot Control Unit Button / Handpiece Button		Do Not Dispose Of This Product In The Unsorted Municipal Waste Stream. Dispose Of This Product According To Local Regulations. See Recycling. Medtronic.Com For Instructions On Proper Disposal Of This Product.
	Not Greater Than 120vac	EHS	Electrical High Speed Handpiece Connector		Locked		If the single use symbols is on the device label then this device is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
	Caution	Fr	World Wide Standard for Medical Tubing Diameter		Unlocked		
	Applied Party Duty Cycle		Date of Manufacture		Handpiece	Accessory	
REF	Catalog Number		Manufacturer		Skeeter	Adapter	
LOT	Lot Number	STERILE R	Sterilized by Radiation	1	Pump Head 1	Attachment	
SN	Serial Number		Temperature Limitation	2	Pump Head 2	Bone Mill	
!USA	USA Only					Brush	
						Control Unit	
						Dissecting Tool	
						Instrument Case	
						Lubricant/Diffuser	
						Motor	
						Multi-Use Disposable Attachment	
						Refurbished	
						Regulator	

GLOSSARY

The following words and acronyms may be used in this guide.

FCU	Foot Control Unit
IPC	Integrated Power Console
I.V.	Intravenous
NIM	Nerve Integrity Monitor - One or all of the Nerve Integrity Monitor units: NIM-Response 2.0, NIM-Neuro 2.0, NIM-Response 3.0 and NIM-Neuro 3.0
NIM-ECLIPSE	Nerve Integrity Monitor for spinal surgeries
XPS	Xomed Power System
FWD	Forward - Rotation is clockwise
OSC	Oscillate
REV	Reverse - Rotation is counter-clockwise

INDICATIONS FOR USE

The IPC is indicated for the incision / cutting, removal, drilling, and sawing of soft and hard tissue and bone, and biomaterials in Neurosurgical (Cranial, Craniofacial) Orthopedic, Arthroscopic, Spinal, Sternotomy, and General surgical procedures.

DEVICE DESCRIPTION

The IPC System is a powered microdebrider, drill and saw system that will remove soft tissue, hard tissue and bone during surgical procedures. The system consists of a power control console, footpedal, connection cables and assorted handpieces to drive various burs, blades, drills, rasps, cannulae and saws. It includes integrated irrigation pumps for irrigation of blades, burts and for motor coolant.

In addition to the handpieces and pumps there is a connection for continuous stimulation of the Visao straight burs that enables nerve integrity monitoring during surgical procedures. The Nerve Integrity Monitor (NIM) is a separate device that stimulates and monitors the nerve. This system has connections that allow the NIM to be connected with the Visao handpiece and Stimulating Bur Guard, enabling the NIM to stimulate and monitor the nerve at the surgical site.

The system can be used to clear the end of a rigid rod endoscope in order to maintain good visualization of endoscopic procedures without having to remove the scope from the surgical site.

This device is intended for use by physicians trained in the procedures described.

CONTRAINDICATIONS

The IPC system is contraindicated for arthroscopic microdiscectomy in individuals with the following:

- Severe/progressive neurological deficits
- Cauda equine syndrome
- Active infection.

Arthroscopic microdiscectomy is not indicated for individuals with sequestered disc fragments, discogenic pain, internal disc destruction, or lumbago.

WARNINGS**System Warnings**

- W1 It is important that the IPC system operator be familiar with the system User's Guide, its precautions, procedures and safety issues.
- W2 Do not use the IPC POWEREASE system in the presence of flammable anesthetics. Avoid potential ignition or explosion of gases.
- W3 When not operating handpiece, eliminate accidental foot control activation. Control energy to and through the handpiece to prevent unintended tissue, bone, or nerve resection.
- W4 Disconnect power to the IPC system before cleaning the unit to avoid electrical macro shock.
- W5 Do not attach unapproved components to the IPC system to avoid electrical macro shock.
- W6 To avoid the risk of electrical shock, achieve electrical grounding reliability with proper connections. Connect the IPC system to hospital grade receptacles only.
- W7 This medical device complies with EN60601-1-2 safety standard for electromagnetic compatibility, requirements and test. However, if this equipment is operated in the presence of high levels of electromagnetic interference (EMI) or highly sensitive equipment, interference may be encountered and the user should take whatever steps are necessary to eliminate or reduce the source of the interference. Diminished performance may lengthen operating time for anesthetized patient.
- W8 Medical Electrical Equipment needs special Precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Guide.
- W9 Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
- W10 Do not operate the IPC POWEREASE system in the presence of Magnetic Resonance Imaging devices.
- W11 Use of accessories and cables other than those specified and sold by Medtronic may result in increased emissions and decreased immunity of this unit.
- W12 The IPC system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the IPC system should be observed to verify normal operation in the configuration in which it will be used.
- W13 Do not attempt to run the IPC POWEREASE system handpiece immediately after autoclaving. Allow an adequate "cool down" period (Typically 1 hour).
- W14 Consult the Legend Bone Mill product insert before use with the Integrated Power Console system.
- W15 For metal transection, observe the following safety precautions:
- W15a Eye wear protection is essential.
 - W15b Irrigate well to cool the cutting surfaces.
 - W15c Protect the wound site from metal debris.
 - W15d Use a clamp or grasping device to control loose fragments during transection of any metal component.

- W16 Do not operate the IPC POWEREASE system without eye protection.
- W17 All service must be performed by Medtronic qualified personnel only.
- W18 Repair and/or modification to the IPC system by anyone other than qualified service personnel may significantly compromise the unit's ability to perform effectively and/or void the equipment warranty.

Component Warnings

- W19 Do not use any parts other than Medtronic system components as damage or substandard performance could result.
- W20 Always inspect the components before and after use for any damage. If damage is observed, do not use damaged part until it is repaired or replaced. Damaged parts may deposit metal shavings on surgical site.
- W21 When precise location of blade tip is required, engage the rotation lock on the handpiece, then calibrate and verify the blade tip on Image Guided Surgery (IGS) system. Always lock M4 handpiece when driving non-rotatable blades to maintain their IGS calibration.
- W22 Employ visualization, including use of imaging techniques (e.g., fluoroscopy, image guided surgery) when using rotating powered accessories. Discontinue powered application in the event of lack of visualization of surgical site.
- W23 Midas Rex Variable Exposure attachments. Surgeons should familiarize themselves with the performance of dissecting tools before use, and should explore the effect of various levels of tool exposure on dissection stability. If the tool exhibits excessive chatter, vibration, or movement, decrease the tool exposure.
- W24 Motors and attachments may fail due to extended use and allow a component to detach and fall from the motor or attachment, causing patient injury.
- W25 Electrical contacts must be dry prior to use.
- W26 Heavy side loads and/or long operating periods may cause the device to overheat.
- W27 Do not use an overheated device, as it may cause thermal injury to the patient or operator.
- W28 Use adequate irrigation. The use of a tool without irrigation may cause an inordinate amount of heat buildup resulting in a thermal injury to tissue. Depending on the amount of irrigation used, the drill bits and saw blades can achieve temperatures in excess of 50°C.
- W29 Do not attempt to change a dissecting tool, saw blade, or attachment while the motor is running, or when the motor or attachment is in an overheated state.
- W30 Do not immerse the system components, except as noted.
- W31 Do not place motor, attachment and tool on the patient or in an unsecured location during surgery.
- W32 A system that is not functioning properly should not be used until all necessary repairs have been made and the unit is tested to ensure that it is functioning in accordance with Medtronic specifications.
- W33 Match the nomenclature and color code on the tool packaging to the same nomenclature and color code on the Attachment.
- W34 Make sure that the attachment is still in the locked position after each adjustment of the tool exposure, as attempting to increase the tool exposure too far, may result in the attachment accidentally being unlocked.
- W35 Midas Rex Legend EHS Motor and Midas Rex Legend EHS Stylus Motor should only be operated when the attachment is in the locked position.
- W36 Smoke and/or excessive heat may be generated if attachment is not in the fully locked position. This may result in thermal injury to the surgeon or staff.
- W37 The Indigo and Legend EHS motors will not run properly unless the attachment is in the locked position.
- W38 DO NOT change accessory with handpiece running to prevent laceration of user and cross-contamination through compromised glove.
- W39 Remove Legend Footed Attachments cautiously and slowly as per instructions to avoid injury to the operator.
- W40 DO NOT modify accessories used with the handpiece. Performance could be diminished with modified accessories.
- W41 The safe use of the Endo-Scrub 2 System in procedures where surgical lasers are also employed has not been clinically demonstrated.
- W42 In order to ensure compliance with requirements of IEC 60601-1, use a Medtronic approved power cable.
- W43 To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- W44 Keep NIM Muting Probe cable away from IPC system cables.
- W45 Verify reusable device was sterilized prior to use. If not sterilized, do not use.

Disposable Warnings

- W46 Tools are available for resection of soft tissue and bone for surgical procedures. Use of tools depends on the intended application and patient needs. Sharp-cutting powered tools induce bleeding and removal of significant tissue and bone.
- W47 Use methods at the operative site to control bleeding that do not compromise patient safety during at-risk surgery.
- W48 Always keep the cutting area of the tool/saw blade away from fingers and loose clothing. Prevent laceration of user and cross-contamination through compromised glove.
- W49 Operate the tool only after the appropriate anatomical landmarks and the intended surgical site have been confirmed.
- W50 Use care in application of the moving cutting end to only appropriate anatomical landmarks and the intended surgical site when using powered accessories.
- W51 Insertion of metal objects in accessory tip may cause the accessory to break leaving fragments in the wound. The fragments may be difficult to remove, causing irritation, inflammation and foreign-body response at surgical site.
- W52 Bending or prying may break the accessory, causing harm to patient or staff.
- W53 Do not use excessive force to pry or push bone with the attachment, tool or blade during dissection.
- W54 A tool's size and geometry may create excessive vibration at certain speeds. Increase or decrease speed on console. Change to a new tool to prevent unintended tissue removal from patient.
- W55 Test for wobble at desired speed prior to use. Discontinue use of accessory if tip begins to wobble and replace accessory to prevent unintended tissue removal from patient.
- W56 Eccentricity of the tool can cause tool vibration and may result in excess tissue and bone destruction and hearing damage.
- W57 Excessive noise from the tool when drilling close to the cochlea or ossicular chain may cause hearing damage.
- W58 CONSULT the cranial perforator device labeling for the recommended speed specifications.
- W59 Tools with "L" identification are longer tools intended for light bone dissection. The increased tool head/stem configuration may affect dissection stability.
- W60 Tool flutes and blade teeth are sharp and may perforate surgical gloves. Tools/blades may be grasped with a hemostat to aid in installation and removal.
- W61 DO NOT attempt to sharpen used tools. Worn tools should be replaced with new ones frequently to ensure effective cutting and control.
- W62 Carefully inspect tool both prior to and following each use for signs of excessive wear, fragmentation, eccentricities or other defects. Replace any suspicious tools with a new one prior to use.
- W63 Excessive pressure applied to bur may cause bur fracture. Should a tool fracture in use, extreme care must be exercised to ensure that all fragments of the tool are retrieved and removed from the patient. Unremoved tool fragments may cause tissue damage to the patient.
- W64 Do not use metal-cutting tools on bone.
- W65 Use only rotary tools specifically designed for use with this drill system.
- W66 When using non-rotatable tools, ensure rotation lock is engaged to prevent inadvertent rotation.
- W67 The use of powered reciprocating instruments may result in vibration / related injury.
- W68 Powered blades should be operated in the oscillate mode only. Operating in the forward mode may cause damage to the blade.
- W69 Do not attempt to sterilize disposable devices. The disposables are packed sterile and are not intended for repeat use. To prevent contamination, use only once.

INTEGRATED POWER CONSOLE (IPC)

- W70 Any tubing or other tip protectors used during shipping must be removed prior to cleaning and sterilization.
- W71 Do not use accessory if package is opened or damaged. Broken seal offers no protection against cross-contamination.
- W72 Properly dispose of single-use devices removed from sterile packages. Devices lose sterility upon removal from packaging.
- W73 Do not use dull, damaged or bent tools. Use of dull tools can reduce handpiece effectiveness and cause the handpiece temperature to increase.
- W74 T&A Blades: Gently remove the inner tube from the outer tube. The inner tube may elongate upon removal from the outer tube. If this occurs, the inner tube may not lock properly into the handpiece or the blade may not work properly.
- W75 T&A Blades: Rotate the inner tube when removing and inserting it in the outer tubes to prevent damage to the internal seal. If the seal is damaged, the blade will leak at the handpiece.
- W76 Always ensure that the drill is securely engaged into the handpiece prior to operating the system.
- W77 Always examine operation of each tool in a handpiece before use.
- W78 Powered burs and drills should be operated in the forward mode only.
- W79 This system requires insulated connectors for the StraightShot M4 Microdebrider, StraightShot Magnum II Microdebrider, StraightShot III Microdebrider, Midas Rex SC1, Visao, or Skeeter handpieces and the Multi Function Foot Control Unit.
- W80 Sterilize and dry reusable device before storing the system. Decrease likelihood of cross-contamination with timely sterilization.
- W81 After each procedure, properly clean all reusable system components.
- W82 Auxiliary Power Outlet with protective cover is for use with the Hydrodebrider or Bone Mill consoles only.
- W83 Place Stylus Touch in safe mode while not in use.
- W84 Do not place Stylus Touch handpiece in the proximity of magnetic field, such as magnetic drape and MRI equipment, to avoid inadvertent handpiece activation.
- W85 Do not apply excessive side loading. Excessive side loading could cause angled attachments to unlock accidentally from motor.

PRECAUTIONS

- P1 PRIME/FLUSH Priming is a feature designed to purge air out of the tubing set(s) during setup. The first time a Prime or Flush button is pressed it will turn on pump 1 and/or 2 long enough to purge air out of the tubing set(s). Turning power Off and On resets the PRIME feature. Once pressed all Prime buttons will change to Flush buttons.
- P2 To prevent damage to curved tools, disconnect suction tube prior to changing tool during procedure.
- P3 When using an angled attachment, hold the handpiece assembly by the attachment so that the attachment does not inadvertently loosen from the handpiece.
- P4 For Legend tools only:
If a tool package is opened, but the tool is not used or contaminated, the tool can be re-sterilized. Remove tool from original packaging and place into an approved autoclave package. Steam sterilize as follows:
High-Vacuum Steam 132°C for 5 minutes
Gravity Displacement 132°C for 15 minutes
The re-sterilized tool must be used promptly following re-sterilization. If rust or corrosion is encountered after re-sterilization, do not use the re-sterilized tool.
- P5 DO NOT run the 16-MF attachment with operating speed above 62,000 rpm. This may cause over heating and damage to internal gears of attachment.
- P6 DO NOT use twist drill or Contra-Angle tool at an operating speed over 62,000 rpm.
- P7 Do not attempt to disconnect the cable from the Midas Rex Legend EHS Stylus Motor.
- P8 Do not kink cables. Inspect cables and pins for cracks, tears or corrosion.
- P9 Do not use anti-fog on scope or sheath, as weeping or leaking may result.
- P10 Disconnect cable from Midas Rex Legend EHS motor prior to sterilization.
- P11 The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance.
- P12 Remove devices from instrument case before placing into washer disinfector and allow devices to drain.
- P13 Orient devices in the washer-disinfector by following manufacturer recommendations.
- P14 DO NOT use low-temperature hydrogen peroxide gas plasma sterilization due to the lumen internal diameter and length restrictions.
- P15 DO NOT use low-temperature liquid peracetic acid sterilization due to immersion procedure.
- P16 DO NOT steam or EO sterilize the Legend Attachment Cleaning Nozzle.
- P17 Remove and discard accessories following local regulations for proper disposal of contaminated materials.
- P18 Disposable devices are for single-use only.
- P19 Clean the motor and cable while still connected together. This will help to reduce ingress of debris.
- P20 Use ONLY recommended cleaning agents.
- P21 Do not use excessive force to insert the endoscope into the Endo-Scrub 2 sheath. This will damage the endoscope as well as the Endo-Scrub 2 sheath.
- P22 If the endoscope tip can be seen extending beyond the tip of the Endo-Scrub 2 sheath, then the sheath has been damaged. Damaged product must be immediately discarded.

SYSTEM REQUIREMENTS AND SPECIFICATIONS

Console Specifications

Functional Standards for Electrical Systems

ANSI/AAMI ES60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005
EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)	2006
IEC 60601-1-4	Medical electrical equipment - Part 1: General Requirements for Safety, Part 4: Programmable Electrical Medical Systems	2000
EN 60601-1-2	Medical electrical equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	2001/ A1: 2006
CSA-C22.2 No. 601.1	Medical Electrical Equipment - Part 1: General Requirements for Safety	2005

Physical Dimensions

Size	277 mm W x 353 mm H x 267 mm D
Weight	7.3 kg

Operational Environment

Temperature	+10°C to +33°C
Humidity	30% to 75% RH
Barometric Pressure	700 - 1060 hPa

Transport and Storage Environment

Temperature	-40°C to +70°C
Humidity	10% to 95% RH
Barometric Pressure	500 to 1060 hPa

Display / Touchscreen

Type	High contrast, digital, graphic color, visible in complete darkness
Resolution	Display 21 cm diagonal, resolution 480 X 640 pixels

Audio Output

Baseline Audio Sound Level 60 dBA minimum SPL (1 m)

Electrical

Input Voltage	100 V-240 V ± 10%
Frequency	50/60 Hz
Power Consumption	500 VA
Auxiliary AC output	200 VA Max.
Internal Fuse	5 x 20 mm T. L. 5 A, 250 V Medtronic Xomed P/N 11270066
Duty Cycle for Applied Part	Maximum On Time 120 Seconds Minimum Off Time 180 Seconds

Power Cord Product Numbers

North America: USA, Barbados, Belize, Bolivia, Canada, Columbia, Ecuador, Venezuela Standard P/N EA600 or 1895820 6 meter P/N EA650 or 189721	United Kingdom, Ireland, Hong Kong, Malaysia, Singapore P/N EA606 or 1895821	Continental Europe: Austria, Belgium, Finland, France, Germany, Greece, Korea, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden P/N EA602 or 1895822
China P/N EA604	India, South Africa P/N EA607	Switzerland P/N EA601
Argentina P/N EA608	Israel P/N EA609	Denmark P/N EA610
Australia, New Zealand P/N EA605	Japan P/N EA603 or 1895823	Italy, Chile P/N EA611

SYSTEM SOUNDS AND FIGURES

Audible Alarms and Tones

The following alarms and tones can sound while using the IPC Console.

Audible Alarm

When the system detects an error, a message appears on the touchscreen and the system emits a sequence of three tones.

Audible Tones

IPC Tone	Cause(s)
1 Tone	<ul style="list-style-type: none"> Confirmation of change button pressed. Change from forward to oscillate. Change of active handpiece.
2 Tones	Change from oscillate to forward.
3 Tones	<ul style="list-style-type: none"> Audible Alarm. Error detected. See screen for error message. Active handpiece is in reverse and foot pedal pressed. First time accessory changes from forward to reverse.
Long Tone	Change from handpiece to drill.

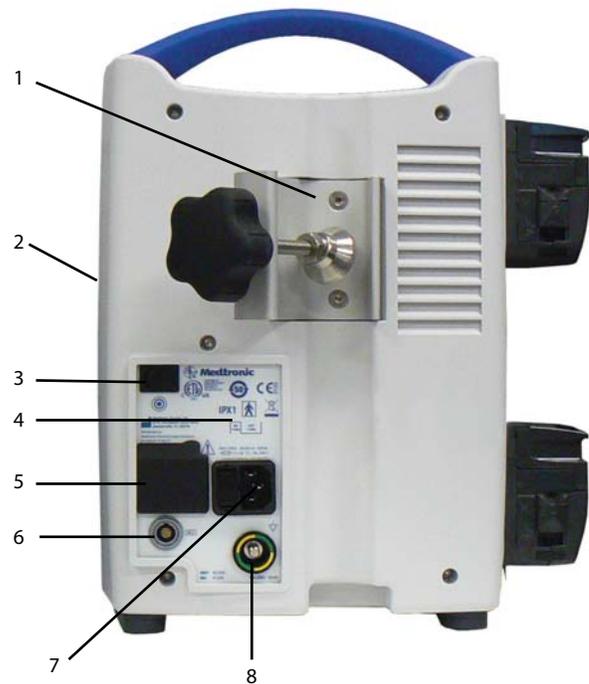
System Figures

Figure 1-1. IPC Console Front



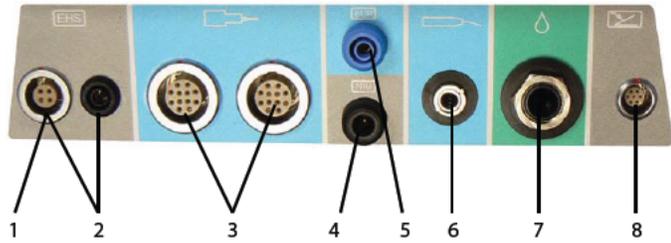
- 1 Pump 1: Coolant, lense cleaning or irrigation
- 2 Touchscreen
- 3 Power on/off
- 4 Pump 2: Irrigation or lense cleaning
- 5 Console connector panel for peripheral devices

Figure 1-2. IPC Console Back



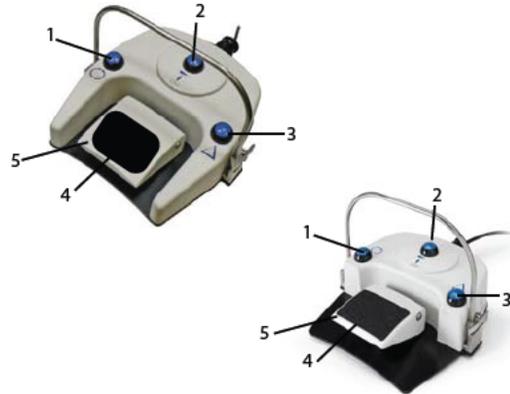
- 1 Pole clamp
- 2 Compact flash card port (Medtronic Use)
- 3 Manual start/stop
- 4 Fuse access
- 5 Auxillary power outlet
- 6 Endo-Scrub 2 connector
- 7 Hospital grade power cord connector
- 8 Equipotential. Apply potential equalization conductor.

Figure 1-3. IPC Console Connector Panel



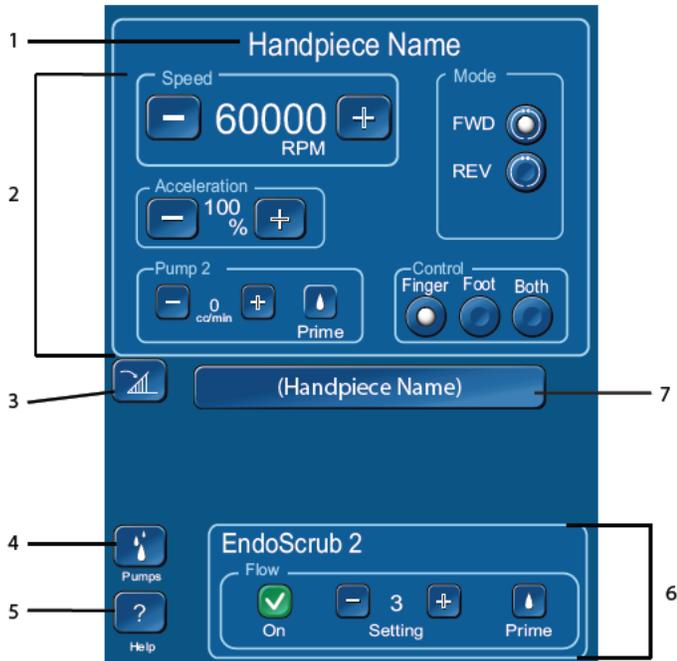
- | | |
|---|---|
| 1 Legend EHS motor | 4 Stimulus input from patient interface (NIM or NIM-Eclipse) |
| 2 Legend EHS Stylus motor | 5 Stimulus output to stim bur guard or Powerease |
| 3 Spine shaver handpiece, StraightShot M4 microdebrider, StraightShot Magnum II microdebrider, StraightShot III microdebrider, Stylus Touch motor, Visao drill, Indigo drill, Midas Rex microsaws, Triton drill | 6 Skeeter handpiece |
| | 7 Endo-Scrub 2 finger switch, Endo-Scrub 2 footpedal, Intelliflow irrigation remote control |
| | 8 Multifunction footpedal |

Figure 1-4. Multifunction Footpedal



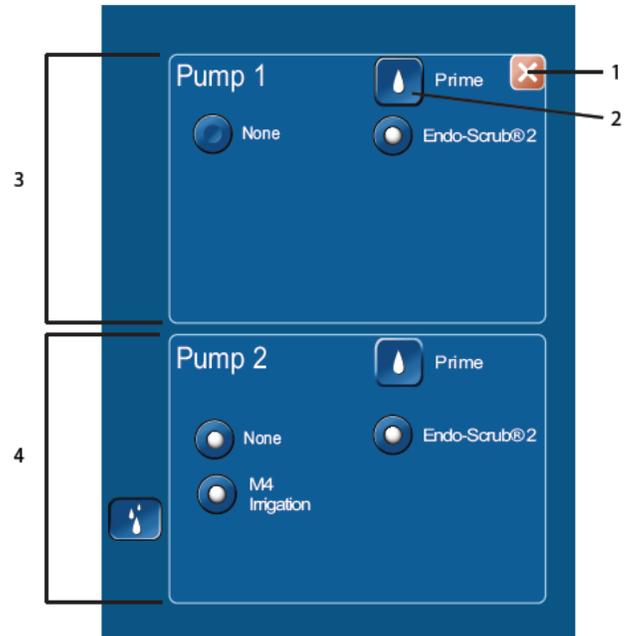
- | | |
|--------------------|---------------------------|
| 1 Mode button | 4 Slip-resistant foot pad |
| 2 Handpiece button | 5 Foot pedal |
| 3 Control button | |

Figure 1-5. IPC Touchscreen



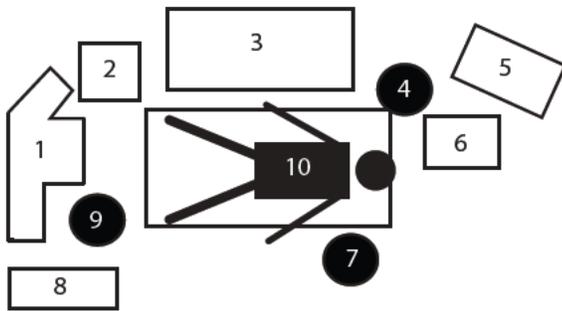
- | | |
|------------------------------|------------------------------|
| 1 Displays active handpiece | 5 Opens Help screen |
| 2 Accessory control panel | 6 Irrigation accessory panel |
| 3 Footpedal variable control | 7 Inactive handpiece |
| 4 Opens Pumps screen | |

Figure 1-6. IPC Pumps Screen



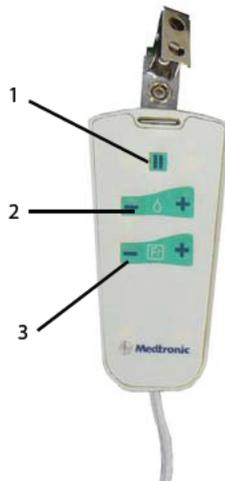
- | | |
|----------------------|--------------------------------------|
| 1 Close Pumps screen | 3 Pump 1 panel available accessories |
| 2 Prime/Flush pump | 4 Pump 2 panel available accessories |

Figure 1-7. Operating Room Setup



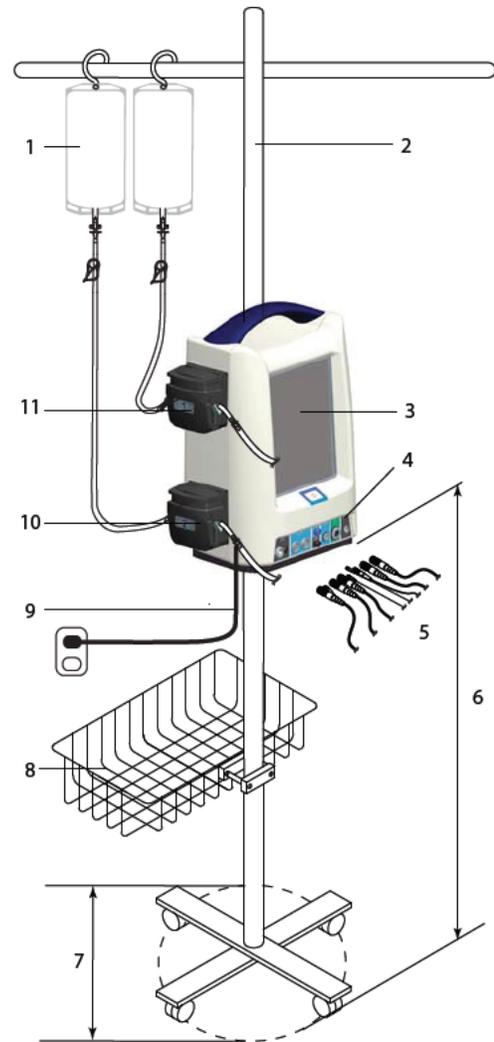
- | | | | |
|---|---------------------------------------|----|-----------------------|
| 1 | Mode anesthesia equipment | 6 | Microscope |
| 2 | IPC system | 7 | Surgeon |
| 3 | Nursing supplies/Surgical instruments | 8 | Electro-Surgical unit |
| 4 | Scrub nurse | 9 | Anesthesiologist |
| 5 | NIM Monitor | 10 | Patient |

Figure 1-9. IntelliFlow Remote Control



- | | |
|---|--|
| 1 | Pause/On-Off |
| 2 | Increase/Decrease Fine Adjustment |
| 3 | Increase/Decrease Coarse Adjustment OR
Select stainless steel tubing size (French size) for
suction irrigator. |

Figure 1-8. IPC System Configuration



- | | | | |
|---|-------------------------------------|----|---------------------------------|
| 1 | Irrigation and coolant bags | 7 | Minimum base diameter is 53 cm. |
| 2 | Irrigation pole | 8 | Irrigation pole basket |
| 3 | IPC console | 9 | Power cord |
| 4 | Console connector panel | 10 | Pump 2 |
| 5 | Accessory cables | 11 | Pump 1 |
| 6 | Maximum height from floor is 89 cm. | | |

PRE-OPERATING INSTRUCTIONS

The following are general IPC pre-operating instructions. "Accessories or Additional Devices Operating Instructions" contains individual accessory operating instructions.

When the System Arrives

- Verify the contents of the box match the packing slip. If incomplete or damaged, notify Medtronic Customer Service.
- If container is damaged, or cushioning material shows stress, notify carrier and Medtronic Customer Service. Keep shipping materials for carrier inspection.
- Save the cartons and packing material. If the instrument is to be shipped the shipping package will provide proper protection.

Set up the IPC

Refer the related topics for detailed instruction.

1. Install pump cartridges or irrigation tubing.
2. Prepare IPC for use.
3. Calibrate touchscreen, if necessary.
4. Change system settings, if necessary.
5. Set up and prime pumps.
6. Confirm system operation.
7. Press the manual start/stop button on the back of the console (Figure 1-2) and verify you can start/stop the handpiece, irrigation and/or coolant flow.

Install the Pump Cartridges or Irrigation Tubing

1. Locate the correct pump and lift up the lock (Figure 1-10).

Pump 1: Coolant, lens cleaning or irrigation

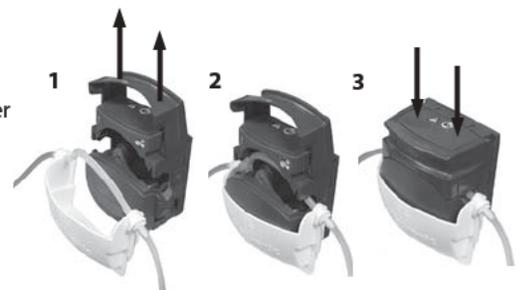
Pump 2: Irrigation

Important: The number on the pump must match the number on the cartridge (either 1/1 or 2/2). If the cartridge does not have a pump designator number, use the Pump Setup Screen to install the pump cartridge.

2. Insert the pump cartridge.
3. Snap the pump lock shut.

Warning: Ensure the pump cartridge does not crimp the tubing.

Figure 1-10. Install Pump Cartridge



Prepare IPC for Use

1. Verify Operation Room set up (Figure 1-7). The surgeon may have preferences to the location and visibility.
2. Verify the wheels are locked on the IPC cart.
3. Inspect all components for damage and determine if the system is ready for use.
4. Mount the IPC and irrigation/coolant bags on the IV pole (Figure 1-8).
Important: Mount irrigant and coolant bags above the IPC to ensure adequate flow.
5. Plug the IPC into the power source. Position the IPC so that it does not obstruct the power source for the purpose of disconnecting the Main voltage by the power cord.
6. Locate the correct footpedal or accessory connection port on the connector panel (Figure 1-3), align the mark on the connector to the mark on the console, and then insert the connector.
7. Connect suction, cooling and/or irrigation tubing.
8. Turn on the IPC and verify the system passes the self-test.
Note: If the IPC does not detect a handpiece or footpedal the Connect Handpiece/Connect Footswitch screen appears. Do the following:
 - Verify the cable is connected to the correct connection port.
 - Press [OK] in the Connect Handpiece/Connect Footswitch message window to continue use of the IPC without the handpiece or footpedal.

Calibrate Touchscreen

Note: This step is optional.

1. Turn on the IPC console.
2. When the system starts, on the Splash screen, press [Settings].
3. On the Settings screen, press **Touch Screen Calibration** and follow the screen prompts.

Change System Settings

Note: During surgery, system settings can be overwritten.

1. Turn on the IPC console.
2. While the system starts, on the Splash screen, press **[Settings]**.
3. To change the language, press the appropriate language.
4. To change the default settings, press **[Default]**.
 - On the Default screen, press the forward or backward arrow to change the accessory.
 - Make changes to the default settings.
 - To confirm system settings and return to the Splash screen, press **[OK]**.
5. For accessories with audible tones, press the REV Audible Tones button to control the following:
 - The system delivers one set of reverse beeps when the reverse mode is activated.
 - The system delivers one set of reverse beeps the first time the drill is used in reverse mode after the reverse mode has been activated.
6. To confirm system settings and continue to the IPC touchscreen, press **[OK]**.
7. To restore settings to factory default, press **[Restore]**.

Handpiece Default Settings

The system configuration is dependent on the handpiece(s) connected to the console. The following table defines the default configurations, default settings (X) and default options (O).

Table 1. IPC Touchscreen Default Configurations												
Handpiece	Speed			Mode or Mode Select Switch				Acceleration	Size	Flow	Irrigation	Control
	rpm	cpm	%	Forward	Oscillate	Reverse						
Visao	80000			X		O					30	
Indigo	52000			X		O					30	
Midas Rex SC1		3400		O	X						60	
StraightShot M4	5000			O	X						30	
StraightShot III, Magnum II	5000			O	X						30	
Legend EHS Stylus	60000			X		O	45%				0	
Legend EHS	70000			X		O					0	
Stylus Touch	60000			X		O	100%				0	Finger
Skeeter	16000			X		O					0	
Endo-Scrub 2										3		
Suction Irrigator									8	50%		
Triton			100	X								
			100			X						
Midas Rex Microsaws			100								0	
Powerase	120			X								
	200				X							
	250					X						

Set up and Prime Pumps

- The IPC turns on pump 1 and/or 2 long enough to purge air out of the tubing set(s) the first time the prime button is pressed. 
- The IPC resets the prime feature when you turn IPC power Off and On.
- After you prime the pump, the prime button and functionality become flush functionality.
 1. Connect tubing from an IPC cartridge to irrigation or coolant tubing on an accessory.
 2. On the irrigation tubing, turn the clamp to OPEN.
 3. If an accessory uses the clear drip chamber (Visao), fill the clear drip chamber with coolant. To fill, squeeze and release the chamber until full.
 4. On the IPC touchscreen (Figure 1-5), press the pumps button. 

Note: The IPC pumps screen is also available from the Connect Handpiece/Connect Footswitch screen which the system displays during IPC preparation for use if a handpiece or footswitch is not detected by the system.
 5. On the IPC pumps screen (Figure 1-6), select the accessory for each pump.
 6. For each pump, press the prime button  and verify the following:
 - Pump(s) run until air is completely purged from tubing.
 - Small amount of lubricate flows at the tip of the irrigation device.
 - Pump(s) turns off.
 7. Press the close button. 

Pump Default Configurations

The pump configuration is dependent on the handpiece(s) connected to the console. The following table defines the pump default settings (X) and default options (O).

Table 2. IPC Pumps Screen Default Configurations

Handpiece	Pump 1		Pump 2		Endo-Scrub 2		Suction Irrigator	
	Cooling	Irrigation	Irrigation	Pump 1	Pump 2	Pump 1	Pump 2	
Visao	X		X		O		O	
Indigo		O	X	O	O	O	O	
Midas Rex SC1		O	X	O	O			
StraightShot M4		O	X*	X	O			
StraightShot III, Magum II		O	X*	X	O			
Legend EHS Stylus		X	O*	O	O	O	O	
Legend EHS		X	O	O	O	O	O	
Stylus Touch		X	O	O	O	O	O	
Skeeter				O	O	O	O	
Endo-Scrub 2		X	O	X	O			
Suction Irrigator		O	O			O	O	
Midas Rex Microsaws		O	X	O	O	O	O	
Powerease				O	O	O	O	
				O	O	O	O	
				O	O	O	O	

* When the IPC detects both the Straightshot M4 and the Legend EHS Stylus Touch handpiece, by default, the system sets pump 2 as a "shared" irrigation pump. You must manually connect the irrigation tubing to the active handpiece.

Confirm System Operation

1. Confirm the irrigation pedal starts handpiece and irrigation flow. Verify the speed changes from white to yellow in the Speed box on the touchscreen.
2. Confirm the footpedal buttons operate. Refer to "Operate Multifunction Footpedal" for details.
3. On the touchscreen, verify you can do all of the following:
 - Adjust Speed: In the Speed box, press the plus and minus buttons. 
 - Change Modes: In a Mode box, press any mode button. 
 - Adjust Flow Rate: In the Irrigation box, press the plus and minus buttons. 

IPC COMPONENTS

Auxillary Power to Console

Warning: The auxillary power outlet is available for use with the Hydrodebrider and Bone Mill IPC consoles only (see W 82). The auxillary power outlet is for use at grid voltage ≤120 VAC only.

Multifunction Footpedal

You can use the multifunction footpedal (Figure 1-4) to start/stop the handpiece, control handpiece speed, handpiece selection and mode of operation. Refer to the Multifunction Footpedal Controls topic for each handpiece for specific use and control.

Multifunction Footpedal Failure

Use the manual start/stop button (Figure 1-2) on the back of the IPC Console to operate the handpiece if the multifunction footpedal fails during a procedure.

IntelliFlow Irrigation Remote Control

Use the IntelliFlow irrigation remote control (Figure 1-9) to start/stop and change irrigation flow while in the sterile field.

If you are using handpiece irrigation:

- To pause irrigation flow, press the Pause/On-Off button.
- To adjust flow rate, press the Fine Adjustment or Coarse Adjustment Increase/Decrease button.

If you are using the Suction Irrigator:

- To pause or turn on/off the Suction Irrigator, press the Pause/On-Off button.
- To adjust flow rate, press the Fine Adjustment Increase/Decrease button.
- To select the stainless steel tubing size (French size), press the Stainless Steel Tubing Size button.

GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC IMMUNITY

Part I

Guidance and manufacturer’s declaration – electromagnetic immunity – Part I			
The IPC is intended for use in the electromagnetic environment specified below. The customer or the user of the IPC should assure that it is used in such an environment.			
Immunity test	IEC/EN60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle	<5 % UT (>95 % dip in UT) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the IPC requires continuous operation during power mains interruptions, it is recommended that the IPC be powered from an uninterruptible power supply or a battery.
	40 % UT (60 % dip in UT) for 5 cycles	40 % UT (60 % dip in UT) for 5 cycles	
	70 % UT (30 % dip in UT) for 25 cycles	70 % UT (30 % dip in UT) for 25 cycles	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer’s declaration – electromagnetic emissions		
The IPC is intended for use in the electromagnetic environment specified below. The customer or the user of the IPC should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The IPC uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class A	The IPC is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the IPC			
The IPC is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IPC can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IPC as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum power of transmitter W	Separation distance according to frequency of transmitter meters		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.10	0.38	0.38	0.73
1.00	1.20	1.20	2.30
10.00	3.80	3.80	7.30
100.00	12.00	12.00	23.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Part II

<p align="center">The IPC is intended for use in the electromagnetic environment specified below. The customer or the user of the IPC should assure that it is used in such an environment.</p>			
Immunity test	IEC/EN60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the IPC , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF	3 Vrms	3 Vrms	$d = 1.2 \sqrt{P}$
IEC 61000-4-6	150 kHz to 80 MHz		
Radiated RF	3 V / m	3 V / m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz
IEC 61000-4-3	80 MHz to 2.5 GHz		$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
			<p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. NOTE 3 When operating the IPC with Stylus Touch, the compliance level is 3 V/m except from 88 MHz to 91 MHz where it is 1 V/m. The formula for separation distance for the IPC with Stylus Touch will be $d = 3.5 \sqrt{P}$ in that frequency range.</p>			
<p>a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the IPC is used exceeds the applicable RF compliance level above, the IPC should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the IPC .</p>			
<p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

LIMITED WARRANTY

- A. This Limited Warranty provides the following assurance for the customer who purchases a Medtronic IPC System. This Limited Warranty is extended only to the buyer purchasing the IPC System directly from Medtronic or from its affiliate or its authorized distributor or representative. The IPC System includes the console, motor or handpiece, foot control, motor cables, instrumentation cases and trays (hereafter referred to as System Components), straight and angled motor attachments (hereinafter referred to as "Attachments"), bur guards and telescoping tubes (hereinafter referred to as Semi-reusable Components) and dissecting tools, irrigation and coolant tubing, and Intelliflow remote control (hereinafter referred to as Single Use Components) and jointly referred to as the IPC System, unless specifically noted.
- i. Should a System Component fail to function to Medtronic's published specifications during the term of this Limited Warranty (one year from the date of sale of a new System Component or 90 days from the date of sale of a refurbished or used System Component), Medtronic will either repair or replace the Motor Component or any portion thereof.
 - ii. Should an Attachment fail to function to Medtronic's published specifications during the term of this Limited Warranty (90 days from the date of sale of a new Attachment), Medtronic will either repair or replace the Attachment or any portion thereof.
 - iii. Should a Semi-reusable Component fail to function to Medtronic's published specifications during the term of this Limited Warranty (30 days from the date of sale of a new Semi-reusable Component), Medtronic will replace the Semi-reusable Component or any portion thereof.
 - iv. Should a Single Use Component fail to function to Medtronic's published specifications prior to its "use by" date Medtronic will replace the Single Use Component.
- B. To qualify for this Limited Warranty, the following conditions must be met:
- i. The Product must be used on or before its "Use By" or "Use Before" date, if applicable.
 - ii. The Product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.
 - iii. Medtronic must be notified in writing within thirty (30) days following discovery of a defect.
 - iv. The Product must be returned to Medtronic within thirty (30) days of Medtronic receiving notice as provided for in (3) above.
 - v. Upon examination of the Product by Medtronic, Medtronic shall have determined that: (i) the Product was not repaired or altered by anyone other than Medtronic or its authorized representative, (ii) the Product was not operated under conditions other than normal use, and (iii) the prescribed periodic maintenance and services, if applicable, have been performed on the Product.
- C. This Limited Warranty is limited to its express terms. THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED WHETHER STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. In no event shall Medtronic be liable for any consequential, incidental, prospective or other similar damage resulting from a defect, failure, or malfunction of the IPC System, whether a claim for such damage is based upon the warranty, contract, negligence or otherwise.
- D. The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. Users may benefit from statutory warranty rights under legislation governing the sale of consumer goods. If any part or term of this Limited Warranty is held by any court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portion of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid.

FOR ITEMS CONTAMINATED WITH TSE AGENTS

Medtronic ENT/NT Transmissible Spongiform Encephalopathy (TSE) Return Policy

Medtronic will not authorize or accept the return of products that directly contact patients or is contaminated with a patient's body fluids suspected or confirmed with a Transmissible Spongiform Encephalopathy / Creutzfeldt-Jakob Disease (TSE/CJD) diagnosis.

The following are recommended guidelines and may vary according to specific policy and procedures among hospitals. Hospital personnel should contact their infection control personnel for current procedures and policy for reusable equipment processing when suspected of contamination with Creutzfeldt-Jakob Disease (CJD) or other Transmissible Spongiform Encephalopathy (TSE) agent.

Medtronic dissecting tools, burs, or blades used on a patient suspected of a TSE/CJD diagnosis should be incinerated. Reusable equipment that has been used on patients with suspected Creutzfeldt-Jakob Disease (CJD) or other Transmissible Spongiform Encephalopathy (TSE) should be quarantined and not reused until diagnosis is confirmed or excluded. Reusable equipment should be quarantined after having been cleaned, decontaminated, sterilized and packed in a rigid sealed container until final diagnosis. If TSE/CJD is excluded as a diagnosis, the quarantined reusable equipment may be returned for use after appropriate cleaning, decontamination and sterilization.

Medtronic recommends that all Medtronic products used directly on a patient confirmed with a TSE diagnosis be incinerated. Contact your Sales Representative to purchase replacement products or secure loaner equipment.

For additional information contact your Customer Service Representative.

TRITON ELECTRIC HIGH-TORQUE HANDPIECE

DEVICE DESCRIPTION

The Triton Electric High-Torque Handpiece is capable of removing hard and soft tissue, drilling pilot holes, and driving screws, wires, and pins during spinal, cranial, and small-bone surgical procedures performed in an operating-room environment by surgeons trained in its use.

The following instructions for the Triton Electric High-Torque Handpiece are in addition to "Set up the IPC" general assembly instructions. Complete IPC setup, then continue to the instructions below.

BEFORE USE

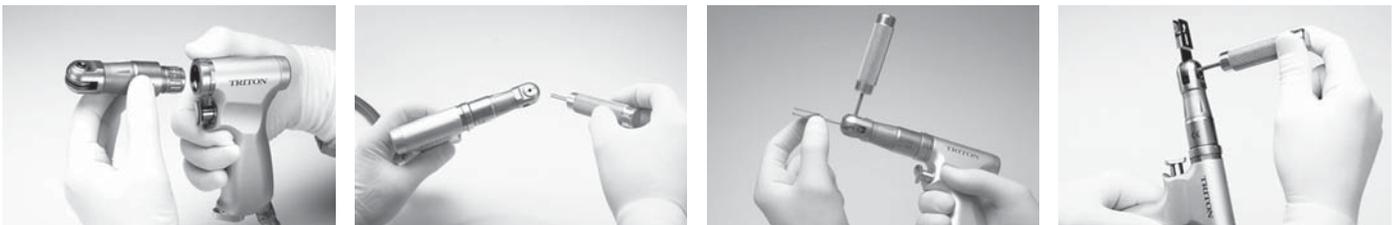
Clean and sterilize the device, prior to first use. Refer to the reprocessing instructions contained in this manual for additional information.

TRITON SAGITTAL SAW ASSEMBLY

Warning: Triton saw attachments should only be used with Medtronic Triton saw blades. Refer to the Triton Quick Reference Saw Blade Guide (LIT200017) for additional information on Triton saw blades.

1. Insert the Sagittal Saw Attachment into the handpiece in a position to allow easy insertion of the Sagittal Saw Key (Figure 2-1).
Note: You can install the attachment in 12 different positions to facilitate proper surgical access.
2. Insert the Sagittal Saw Key into the attachment and turn counterclockwise until there is slight resistance.
3. Insert the blade into the space between the two jaws, ensuring that the blade is fully seated.
4. Turn the Sagittal Saw Key clockwise to lock the blade. Run briefly, then retighten blade.
Caution: Do not over-tighten.

Figure 2-1. Sagittal Saw Assembly



TRITON SAGITTAL SAW DISASSEMBLY

To remove the Triton saw blade, insert the Sagittal Saw Key into the Attachment and turn counterclockwise.

TRITON RECIPROCATING SAW ASSEMBLY

Warning: Triton saw attachments should only be used with Medtronic Triton saw blades. Refer to the Triton Quick Reference Saw Blade Guide (LIT200017) for additional information on Triton saw blades.

1. Loosen the collet nut then insert the blade until it is fully seated (Figure 2-2).
Note: You can install the attachment in different positions to facilitate proper surgical access.
2. Finger-tighten the collet nut. Run briefly, then retighten collet nut.

Figure 2-2. Reciprocating Saw Assembly



TRITON RECIPROCATING SAW DISASSEMBLY

To remove the Triton Reciprocating Saw blade, unscrew the collet nut.

TRITON AO/SYNTHES CHUCK AND TRINKLE CHUCK ASSEMBLY

1. To install a drill bit, pull back on the attachment collar (Figure 2-3).
2. Insert the drill bit and release the attachment collar.

Figure 2-3. AO/Synthes Chuck and Trinkle Chuck Assembly



TRITON AO/SYNTHES CHUCK AND TRINKLE CHUCK DISASSEMBLY

1. To remove a drill bit, pull back on the attachment collar.
2. Remove the drill bit and release the attachment collar.

TRITON JACOBS CHUCK ASSEMBLY

1. To install a drill bit, turn the key to open the chuck or spin the collar if using a keyless chuck attachment (Figure 2-4).
2. Insert the drill bit.

Figure 2-4. Jacobs Chuck Assembly



TRITON JACOBS CHUCK DISASSEMBLY

1. To remove a drill bit, turn the key to open the chuck or spin the collar if using a keyless chuck attachment.
2. Remove the drill bit.

TRITON HUDSON AND ZIMMER CHUCK ASSEMBLY

To install an instrument, pull back on the attachment collar, then insert the male end of the instrument into the chuck.

Figure 2-5. Hudson and Zimmer Chuck Assembly



TRITON HUDSON AND ZIMMER CHUCK DISASSEMBLY

To remove an instrument, pull back on the attachment collar, then remove the instrument from the chuck.

TRITON WIRE AND PIN COLLET ASSEMBLY

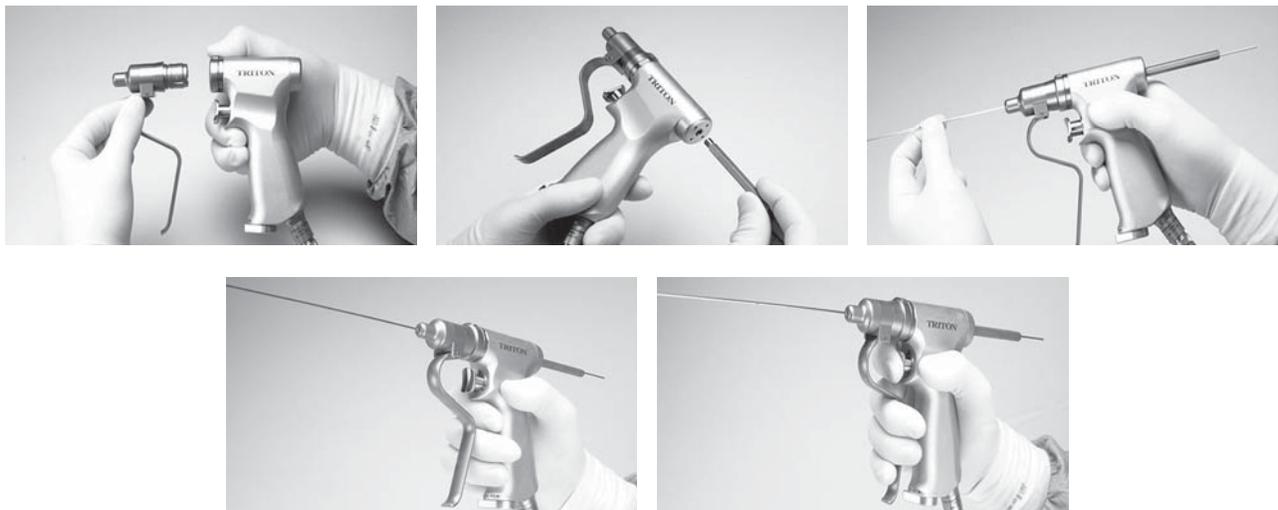
The Wire Collet accepts wires up to 1.6mm (.062") in diameter. The Pin Collet accepts pins up to 3.2mm (.125") in diameter.

1. Insert the Wire or Pin Collet (Figure 2-6) while the handpiece is in the SAFE position (Figure 2-7).
2. Screw the Cannulated Extension in the back of the handpiece to protect the operator from the point of the wire or pin, as necessary.
3. Insert the wire or pin into the front or back of the handpiece.
4. Put the instrument in the RUN position by positioning the trigger control vertically.
5. Turn the Mode select switch at the base of the handle to the FORWARD position.
6. Squeeze the Wire/Pin Advance lever and hold it down.
7. Press the trigger control to drive the wire/pin. The pressure-sensitive trigger allows variable speed operation.
8. To obtain additional wire/pin length, release the wire/pin.
9. Advance the lever and trigger control.
10. Pull back on the instrument.
11. Squeeze the Wire/Pin Advance lever and trigger control to drive the wire.

TRITON WIRE AND PIN COLLET DISASSEMBLY

To remove threaded wire/pin, put the Mode select switch in REVERSE, squeeze the Wire/Pin Advance lever and press the trigger control.

Figure 2-6. Wire and Pin Collet Assembly



TRITON ELECTRIC HIGH-TORQUE HANDPIECE OPERATION

You can preload attachments before insertion into the handpiece.

Caution: Insert all attachments into the handpiece with the handpiece in the SAFE position (Figure 2-7).

Note: The handpiece has an Extension Handle that screws into the back of the handpiece. The handle extension provides balance and two-handed control for various drilling and cutting applications.

1. With the handpiece in the SAFE position (Figure 2-7), insert a preloaded attachment by pressing the quick-release button on top of the handpiece. Snap the attachment into the handpiece with a slight twisting motion until it is seated.
2. Place the handpiece in the RUN position, with the trigger control vertical. The Mode select switch at the base of the handle should be in the FORWARD position.
3. After use, return the trigger control to the SAFE position prior to removing the attachment.
4. Remove the attachment by pressing the quick-release button on top of the handpiece.

Safe Position

The handpiece will not operate in the SAFE position. To operate the handpiece, activate and press the trigger control.

Figure 2-7. Triton Handpiece Safe and Run positions



SAFE: Turn trigger control to either side to lock handpiece in SAFE mode.

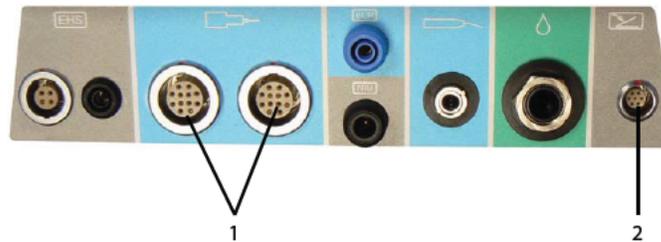
RUN: Trigger control in the vertical position will allow activation of the handpiece.

CONNECT TRITON ELECTRIC HIGH-TORQUE HANDPIECE TO IPC

Locate the Triton Electric High-Torque Handpiece connection port on the connector panel (Figure 2-8) and insert the connector.

Note: To insert multi-pin connectors (indicated by a silver or red mark on the connector), align the mark on the connector to the mark on the console, then insert the connector.

Figure 2-8. Triton IPC Connection Ports



1 Triton handpiece connection port

2 Multifunction footpedal connection port

TRITON ELECTRIC HIGH-TORQUE HANDPIECE TOUCHSCREEN CONTROLS

To adjust Triton Electric High-Torque Handpiece variable speed, on the IPC touchscreen, in the FWD Speed or REV Speed control box (Figure 2-9), press the plus button to increase variable speed or the minus button to decrease variable speed.

Figure 2-9. Triton Touchscreen



TRITON ELECTRIC HIGH-TORQUE HANDPIECE MODE SELECT SWITCH

Use the mode select switch to change the handpiece from forward to reverse when the handpiece is the active handpiece. When the handpiece is the inactive handpiece, use the mode select switch to activate the handpiece.

TRITON ELECTRIC HIGH-TORQUE HANDPIECE MULTIFUNCTION FOOTPEDAL CONTROLS

Important: By default, press each button on the footpedal for at least 100 mS for the selection to become active. Use the IPC touchscreen Settings screen to change the default value.

To use the multifunction footpedal (Figure 12-10) to control the handpiece do the following:

- To toggle between the start/stop mode and variable speed mode, press the control button. 
- To change the handpiece, press the handpiece button. 

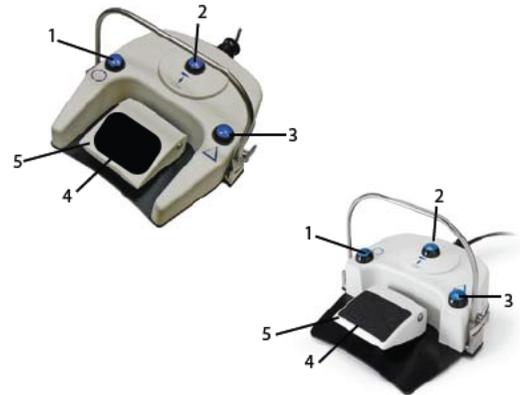
Triton Electric High-Torque Handpiece Reverse Footpedal Control

When you connect the optional foot pedal to the IPC console, the pedal can be used as an alternative method of activating Reverse mode (without manipulating the Mode select switch at the bottom of the handpiece). When the pedal is connected, the Reverse Pedal control box appears on the screen (Figure 2-11).

Note: By default, pedal functionality is turned OFF.

1. To use the pedal, press ON in the Reverse Pedal control box on the IPC touch screen.
2. With the pedal turned on, step on the foot pedal to put the handpiece into Reverse mode (regardless of what position the Mode select switch is in).
NOTE: The trigger control must be pressed to activate the handpiece, even when you are stepping on the foot pedal.
3. Remove your foot from the pedal to return the handpiece to the mode currently defined by the Mode select switch on the handpiece.

Figure 2-10. Multifunction Footpedal



- | | |
|--------------------|---------------------------|
| 1 Mode button | 4 Slip-resistant foot pad |
| 2 Handpiece button | 5 Foot pedal |
| 3 Control button | |

Figure 2-11. Reverse Pedal Control Box



TRITON ELECTRIC HIGH-TORQUE HANDPIECE CLEANING AND STERILIZATION INSTRUCTIONS

Refer to document M000030A322 in the Cleaning and Sterilization section.

TRITON ELECTRIC HIGH-TORQUE HANDPIECE TECHNICAL SPECIFICATIONS

Triton Electric High-Torque Handpiece ED500

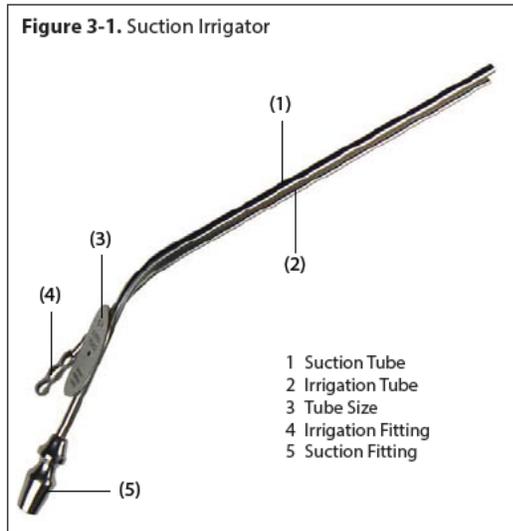
Size	3.5 in L x 5.4 in H x 1.1 in W
Weight	2.1 lbs
Speed	180-1800 rpm (actual speed depends on attachment used)
Duty Cycle for Applied Part	Cycle Time: 20 seconds on maximum / 20 seconds off minimum Maximum number of cycles before resting handpiece: 6 Maximum number of cycles before resting attachment: 3 Minimum rest period: 25 minutes

SUCTION IRRIGATOR

The following instructions for the Suction Irrigator are in addition to “Set up the IPC” general assembly instructions. Complete IPC setup, then continue to the instructions below.

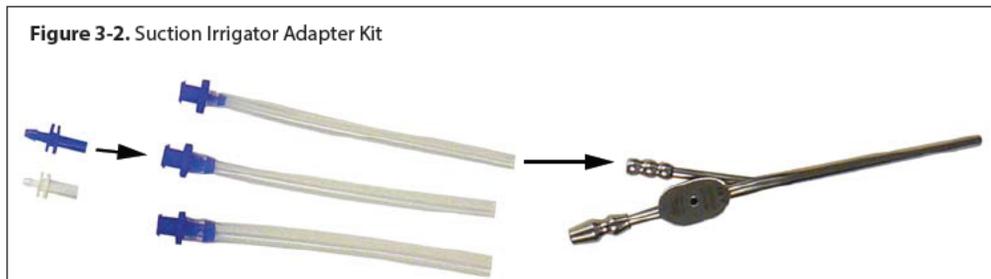
SUCTION IRRIGATOR ASSEMBLY

1. Connect suction tubing from a suction source to the suction fitting on the Suction Irrigator (Figure 3-1).
2. On the IPC touchscreen (Figure 1-5), press the pumps button. 
3. On the IPC pumps screen (Figure 1-6), select a pump for the Suction Irrigator.
Note: When using a handpiece that connects to a pump, the IPC automatically incorporates the Suction Irrigator at the pump not in use by the handpiece.
4. Connect irrigation tubing from the IPC cartridge (Figure 1-8) to irrigation fitting on the Suction Irrigator (Figure 3-1).
5. On the irrigation tubing, turn the clamp to OPEN.



SUCTION IRRIGATOR ADAPTER KIT

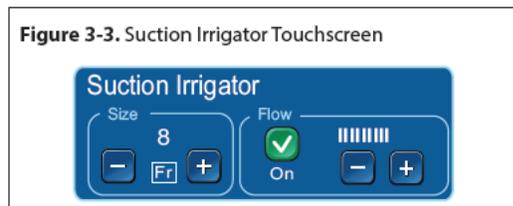
1. Connect an adapter to the high-speed irrigation tubing (blue adapter) or the IPC tubing (white adapter).
2. Connect an adapter to the irrigation connector tube (Figure 3-2).
3. Connect an irrigation connector tube to the irrigation fitting on the Suction Irrigator.



SUCTION IRRIGATOR TOUCHSCREEN CONTROLS

To set or adjust Suction Irrigator controls, on the IPC touchscreen, in the Suction Irrigator control box (Figure 3-3), do the following:

- To set the tubing size, in the Size control box, press the plus and minus buttons.  
- **Note:** The system defaults to size 8.
- To enable or disable the irrigation flow, in the Flow control box, select the On/Off box.
- To adjust the flow rate, in the Flow control box, press the plus and minus buttons.



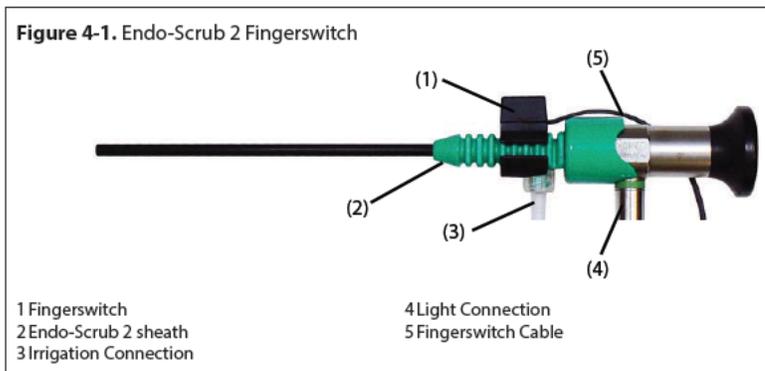
ENDO-SCRUB 2

The following instructions for the Endo-Scrub 2 are in addition to "Set up the IPC" general assembly instructions. Complete IPC setup, then continue to the instructions below. Refer to the Endo-Scrub 2 System Instructions for Use, Endo-Scrub Sheaths Instructions for Use and Endo-Scrub 2 Finger Switch Instructions for Use for additional information.

The IPC System incorporates Endo-Scrub 2 functionality by using irrigation pump number one (1) and controlling operation with the touch screen and an external footswitch or finger switch.

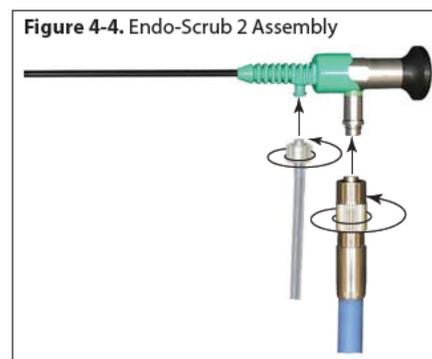
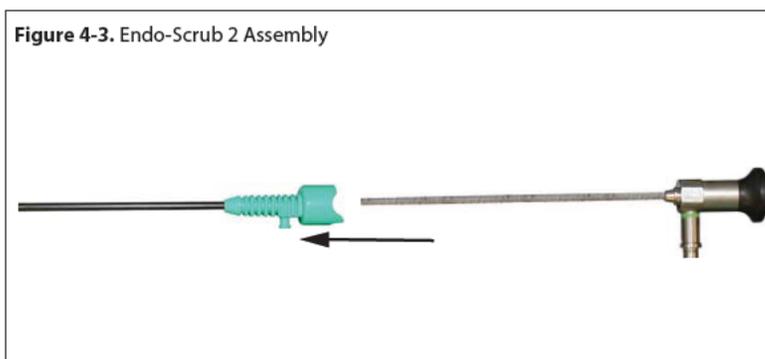
DO NOT use the Endo-Scrub 2 for infusion, for disinfection or sterilization of an endoscope, or for suction removal of blood and debris.

Use the Endo-Scrub 2 sheath only with an endoscope listed on the sheath product label, as malfunction or poor performance could result.



ENDO-SCRUB 2 ASSEMBLY

1. Wet the endoscope.
2. Slowly, slide the approved endoscope into the Endo-Scrub 2 sheath (Figure 4-3).
3. Connect the irrigation tubing and a light source (Figure 4-4).



ENDO-SCRUB 2 FINGERSWITCH ASSEMBLY

If using the Endo-Scrub 2 fingerswitch, complete the following:

1. Slide the fingerswitch onto the Endo-Scrub 2 sheath (Figure 4-1). Align the cutout section of the ring with the luer connector of the tubing set. The fingerswitch is properly installed when the cutout section of the ring is firmly seated against the luer connector.
2. Activate the pump by pressing the actuator button located on the fingerswitch.

ENDO-SCRUB 2 ACTIVATION

Note: The procedure below also applies if using the multifunction footpedal.

1. To activate the Endo-Scrub wash cycle, press and release the fingerswitch.
2. To initiate a continuous flow of irrigant, press and hold the fingerswitch.

CONNECT ENDO-SCRUB 2 TO IPC CONSOLE

1. Locate the Endo-Scrub 2 connector cover on the back of the IPC console (Figure 1-2).
2. Insert a small screwdriver in the notch on the cable connector cover and pull.
3. Connect the control switch cable to the cable connector.
4. Connect the Endo-Scrub 2 fingerswitch (Figure 4-1) or the footpedal (Figure 4-2) to the console (Figure 4-5).



ENDO-SCRUB 2 TOUCHSCREEN CONTROLS

To set or adjust Endo-Scrub 2 controls, on the IPC touchscreen, in the Flow section of the Endo-Scrub 2 control box (Figure 4-6), do the following:

- To enable the Endo-Scrub 2, press the On/Off check-box.
- To adjust the flow rate, press the plus button to increase flow rate or the minus button to decrease flow rate.  
- To prime the pump, press the prime button. 

Figure 4-6. Endo-Scrub 2 Touchscreen



ENDO-SCRUB 2 CLEANING AND STERILIZATION INSTRUCTIONS

Refer to document 68E4005 in the Cleaning and Sterilization section.

Endo-Scrub 2 Foot Pedal Cleaning

Important: If debris is found under the foot pedal boot, return for warranty service.

DO NOT immerse or sterilize the foot pedal unit.

DO NOT use alcohol, other solvents or abrasive cleaners.

1. Wipe down the Endo-Scrub 2 foot pedal with a cloth dampened with a neutral enzymatic detergent, pH 6.0-8.0 or phenol based disinfectant.
2. Dry the unit with a clean, non-abrasive cloth.

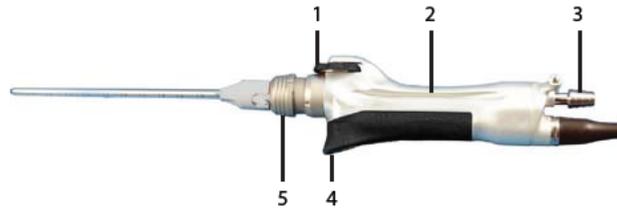
SPINE SHAVER (SC1) HANDPIECE

DEVICE DESCRIPTION

The following instructions for the Spine Shaver (SC1) Handpiece are in addition to "Set up the IPC" general assembly instructions. Complete IPC setup, then continue to the instructions below. Refer to the Midas Rex User's Guide for additional information.

The IPC incorporates the Midas Rex Spine Shaver (SC1) at pump 2. Control operation of the Midas Rex Spine Shaver (SC1) with the IPC touchscreen and the multifunction footpedal.

Figure 5-1. Spine Shaver (SC1) Handpiece



- | | |
|----------------------------|---------------------|
| 1 Finger Wheel | 4 Finger Wheel Lock |
| 2 Irrigation Tubing Groove | 5 Locking Collar |
| 3 Suction Barb | |

SPINE SHAVER (SC1) BLADE OR BUR ASSEMBLY

1. Insert the tool aligning the tabs with the notches (Figure 5-2). Orientate the irrigation barb to the left or right side.

Note: The StraightShot M4 uses a four-tab alignment system.

 - For rotating straight blades, orient the irrigation barb at the 3 o'clock position for right-handed surgeons and 9 o'clock for left-handed surgeons.
 - For rotating curved blades, orient the irrigation barb at 3 o'clock.
2. Press the locking collar (Figure 5-3).
3. Release the locking collar.

Note: If collar does not return to full out position adjust the finger wheel with small back-and-forth motions until collar pops out.
4. Pull on the blade or bur to ensure engagement and visually check to make sure the distal tip of the inner blade is in contact with the distal tip of the outer cannula (Figure 5-4).

Figure 5-2. Spine Shaver (SC1) Assembly



Figure 5-3. Spine Shaver (SC1) Assembly

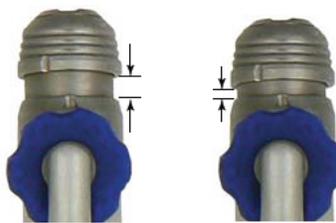


Figure 5-4. Spine Shaver (SC1) Assembly



SPINE SHAVER (SC1) SUCTION AND IRRIGATION TUBE ASSEMBLY

1. Attach a suction tube to the suction source (Figure 5-5) and an irrigation tube on the irrigation barb (Figure 5-5).
2. Secure suction and irrigation in the irrigation groove on the handpiece (Figure 5-6).

Figure 5-5. Spine Shaver (SC1) Suction Irrigation Assembly

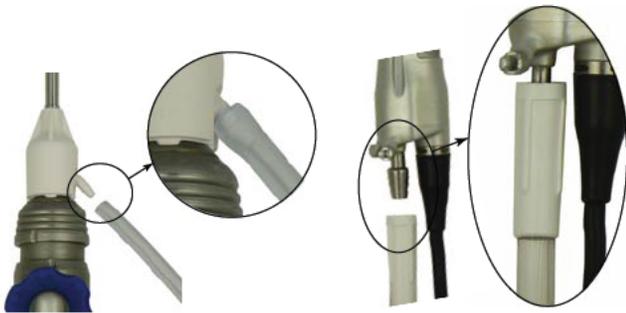


Figure 5-6. Spine Shaver (SC1) Suction Irrigation Assembly

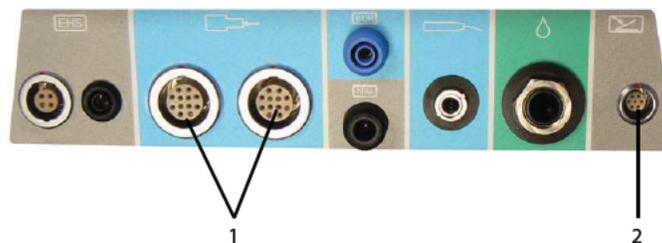


CONNECT SPINE SHAVER (SC1) TO IPC CONSOLE

Locate the Spine Shaver (SC1) connection port on the connector panel (Figure 5-7) and insert the connector.

Note: To insert multi-pin connectors (indicated by a silver or red mark on the connector), align the mark on the connector to the mark on the console, then insert the connector.

Figure 5-7. Spine Shaver (SC1) IPC Connection Ports



- 1 Spine Shaver (SC1) handpiece connection port
- 2 Multifunction footpedal connection port

SPINE SHAVER (SC1) TOUCHSCREEN CONTROLS

To set or adjust Spine Shaver (SC1) controls, on the IPC touchscreen, in the control box (Figure 5-8), do the following:

- To change rotation mode, in the Mode control box select OSC (oscillating) or FWD (forward).
- To adjust speed, in the Speed control box, press the plus button to increase speed and the minus button to decrease speed. 

Forward Mode: Default, 12000 rpm; variable adjustment from 50 to 12000 rpm.

Oscillate Mode: Default, 3400 cpm; variable adjustment from 50 to 5000 rpm.

- To adjust the irrigation flow rate, in the Pump control box, press the plus button to increase flow rate or the minus button to decrease flow rate. If intermittent flow is available, pressing the plus or minus button progresses the system through intermittent and continuous flow. The system displays **Intermittent** when in intermittent flow mode.

Forward Mode: Default, 30cc per minute.

Oscillate Mode: Default, 60cc per minute.

Note: To adjust flow rate, you can use the touchscreen or the IntelliFlow Irrigation remote control.

- **In oscillating mode only**, you can use the Blade Position control box to do any of the following:

To rotate the inner blade 180° press the delta button. 

To rotate the inner blade in small increments, press the clockwise or counter-clockwise buttons. 

Note: The motion indicator indicates rotation direction of the blade. 

- To rotate the outer blade, use the finger wheel (Figure 5-1).

Figure 5-8. Spine Shaver (SC1) Touchscreen



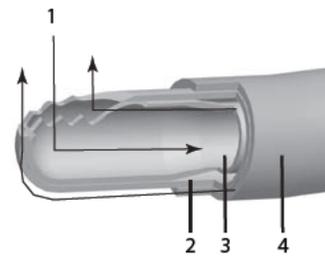
MICRODEBRIDER BLADE CONTROL

Important: If airway blade becomes clogged during use, 1-5cc of irrigant could be aspirated by the patient before you detect the clog.

Note: Periodically submerge blade tip in sterile water, with suction on, to keep blades clear during the procedure.

- To rotate the outer blade (Figure 5-9), use the finger wheel (Figure 5-1).
- To rotate the inner blade, use the Blade Position control box on the IPC touchscreen.

Figure 5-9. Blade Dissection



- 1 Suction flow in through inner blade
Irrigation flow between inner and outer blades
- 2 Outer blade
- 3 Inner blade
- 4 Outer sleeve

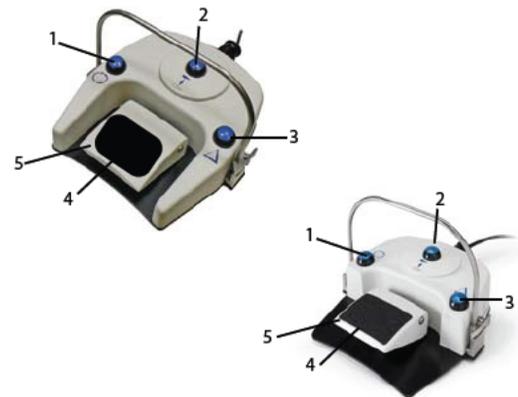
SPINE SHAVER (SC1) MULTIFUNCTION FOOTPEDAL CONTROLS

Important: By default, press each button on the footpedal for at least 100 mS for the selection to become active. Use the IPC touch screen Settings screen to change the default value.

Use the multifunction footpedal (Figure 5-10) to control the following:

- To select forward or oscillating mode, press the mode button.
- To start or adjust the speed of a handpiece in variable mode, press the foot pedal.
- To rotate the inner blade (180°) press the control button.
- To change the handpiece, press the handpiece button.

Figure 5-10. Multifunction Footpedal



- 1 Mode button
- 2 Handpiece button
- 3 Control button
- 4 Slip-resistant foot pad
- 5 Foot pedal

SPINE SHAVER (SC1) CLEANING AND STERILIZATION INSTRUCTIONS

Refer to document 68E3282 in the Cleaning and Sterilization section.

SPINE SHAVER (SC1) TECHNICAL SPECIFICATIONS

Spine Shaver (SC1) ED100

Size	14.3 cm length x 1.8 cm width (1898200T)
Weight	228g 1898200T 240g 1897200, 1897201 254g 1897200T
Speed	50-5000 rpm oscillate 50-12000 rpm forward
Duty Cycle for Applied Part	Maximum on time = 60 seconds. Minimum off time = 30 seconds.

STRAIGHTSHOT M4, STRAIGHTSHOT MAGNUM II AND STRAIGHTSHOT III

DEVICE DESCRIPTION

Note: The StraightShot III is not for sale in the United States.

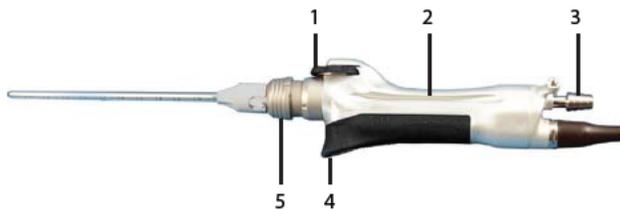
The following instructions for the StraightShot M4, the StraightShot Magnum II and the StraightShot III are in addition to "Set up the IPC" general assembly instructions. Complete IPC setup, then continue to the instructions below.

The IPC incorporates the microdebrider at pump 2. Control operation of the microdebrider with the IPC touchscreen and the multifunction footpedal.

When the IPC detects both the StraightShot M4 and the Legend EHS Stylus handpieces, the system defaults Pump 2 to the **Shared** configuration. You must manually move the irrigation tubing from the inactive to the active handpiece. Use the pumps screen to override the **Shared** default by selecting the StraightShot M4 or the Legend EHS Stylus for Pump 1. Refer to "Set up and Prime Pumps" for more information.

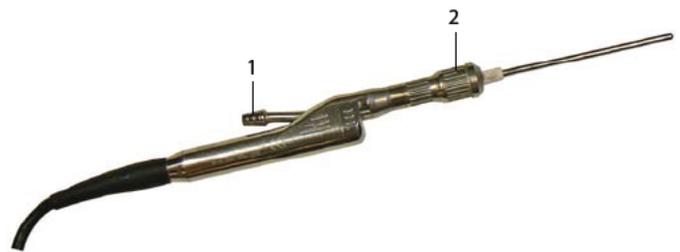
Note: The Endo-Scrub 2 is available to all microdebriders. The system automatically turns on the Endo-Scrub 2 only when it also detects the StraightShot M4. You must manually set the Endo-Scrub 2 for all other microdebriders. Refer to "Set up and Prime Pumps" for details.

Figure 6-1. StraightShot M4 Handpiece



- | | |
|----------------------------|---------------------|
| 1 Finger wheel | 4 Finger wheel lock |
| 2 Irrigation tubing groove | 5 Locking collar |
| 3 Suction barb | |

Figure 6-2. StraightShot Magnum II and III Handpiece



- | | |
|----------------|------------------|
| 1 Suction barb | 2 Locking collar |
|----------------|------------------|

STRAIGHTSHOT M4 BLADE OR BUR ASSEMBLY

1. Insert the tool aligning the tabs with the notches (Figure 6-3). Orientate the irrigation barb to the left or right side.
 - Note:** The StraightShot M4 uses a four-tab alignment system.
 - For rotating straight blades, orient the irrigation barb at the 3 o'clock position for right-handed surgeons and 9 o'clock for left-handed surgeons.
 - For rotating curved blades, orient the irrigation barb at 3 o'clock.
 - For the M4 rotating blade, adjust the finger wheel with small back-and-forth motions.
2. Press the locking collar (Figure 6-4).
3. Release the locking collar.
 - Note:** If the collar does not return to full out position adjust the finger wheel with small back-and-forth motions until collar pops out.
4. Pull on the blade or the bur to ensure engagement and visually check to make sure the distal tip of the inner blade is in contact with the distal tip of the outer cannula (Figure 6-5).

Figure 6-3. M4 Blade or Bur Assembly



Figure 6-4. M4 Blade or Bur Assembly

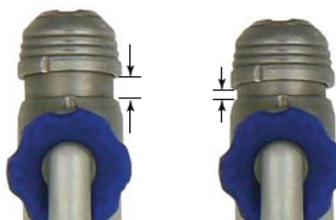


Figure 6-5. M4 Blade or Bur Assembly



STRAIGHTSHOT M4 SUCTION AND IRRIGATION TUBE ASSEMBLY

1. Attach a suction tube to the suction source and an irrigation tube on the irrigation barb (Figure 6-6).
2. Secure suction and irrigation in the irrigation groove on the handpiece (Figure 6-7).

Figure 6-6. M4 Suction and Irrigation Assembly



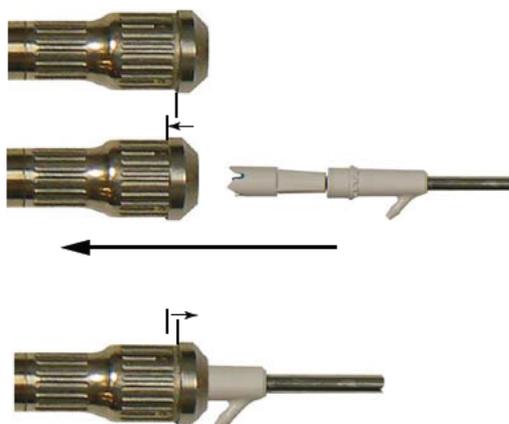
Figure 6-7. M4 Suction and Irrigation Assembly



STRAIGHTSHOT MAGNUM II AND STRAIGHTSHOT III BLADE AND BUR ASSEMBLY

1. Press the collet and insert blade in collet (Figure 6-8).
2. Release the collet (Figure 6-8).
3. Pull on the tool to ensure engagement and check distal tip of inner blade is in contact with the distal tip of the outer cannula.

Figure 6-8. StraightShot II and III Blade and Bur Assembly



STRAIGHTSHOT MAGNUM II AND STRAIGHTSHOT III SUCTION AND IRRIGATION ASSEMBLY

1. Attach a suction tube to the suction source and an irrigation tube on the irrigation barb (Figure 6-9).
2. Secure suction and irrigation tubing with tubing clips.

Figure 6-9. StraightShot II and III Suction and Irrigation Assembly

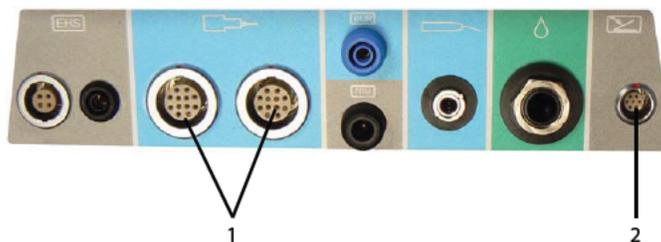


CONNECT STRAIGHTSHOT TO IPC CONSOLE

Locate the StraightShot connection port on the connector panel (Figure 6-10) and insert the connector.

Note: To insert multi-pin connectors (indicated by a silver or red mark on the connector), align the mark on the connector to the mark on the console, then insert the connector.

Figure 6-10. M4 and Magnum II and III IPC Connection Ports



- 1 M4 and Magnum II and III handpiece connection port
- 2 Multifunction footpedal connection port

STRAIGHTSHOT M4, STRAIGHTSHOT MAGNUM II AND STRAIGHTSHOT III TOUCHSCREEN CONTROLS

Note: The StraightShot M4, StraightShot Magnum II and StraightShot III handpiece screens feature the same controls as those shown on the StraightShot M4 Control Box.

Note: When you stop the blade, one of the following occurs:

- If the IPC button is visible on the touchscreen, the inner blade returns to the same position it began.
- If the XPS button is visible on the touchscreen, the inner blade stops the current position.

To set or adjust StraightShot controls, on the IPC touchscreen, in the StraightShot Handpiece control box (Figure 6-11), do the following:

- To change rotation mode, select OSC (oscillating) or FWD (forward).

Note: The system displays the default oscillating or forward mode speed.

- To adjust speed, in the Speed control box, press the plus to increase speed or the minus button to decrease speed.

Forward Mode: Default, 12000 rpm; variable adjustment from 50 to 12000 rpm.

Oscillate Mode: Default, 5000 rpm; variable adjustment from 50 to 5000 rpm.

- To adjust the irrigation flow rate, in the Pump control box, press the plus button to increase flow rate or the minus button to decrease flow rate. If intermittent flow is available, pressing the plus or minus button progresses the system through intermittent and continuous flow. The system displays **Intermittent** when in intermittent flow mode.

Forward Mode: Default, 30cc per minute.

Oscillate Mode: Default, 60cc per minute.

Note: To adjust flow rate, you can use the touchscreen or the IntelliFlow Irrigation remote control.

- To rotate outer blade, use the finger wheel (Figure 6-1).
- **In oscillating mode only**, you can use the Blade Position control box to do any of the following:

Note: The motion indicator indicates rotation direction of the blade.

To enable the multifunction footpedal to change rotation displacement, press the delta

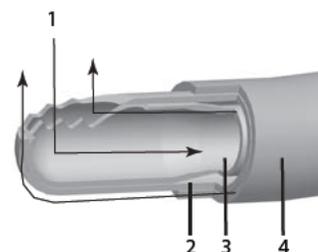
button.

To rotate inner blade in small increments, press the counter-clockwise buttons.

Figure 6-11. Spine Shaver (SC1) Touchscreen



Figure 6-12. Blade Dissection



MICRODEBRIDER BLADE CONTROL

Important: If airway blade becomes clogged during use, 1-5cc of irrigant could be aspirated by the patient before you detect the clog.

Note: Periodically submerge blade tip in sterile water, with suction on, to keep blades clear during the procedure.

- To rotate the outer blade (Figure 5-8), use the finger wheel (Figure 6-12).
- To rotate the inner blade, use the Blade Position control box on the IPC touchscreen. Refer to the related accessory Controls topic for further information.

- 1 Suction flow in through inner blade
Irrigation flow between inner and outer blades
- 2 Outer blade
- 3 Inner blade
- 4 Outer sleeve

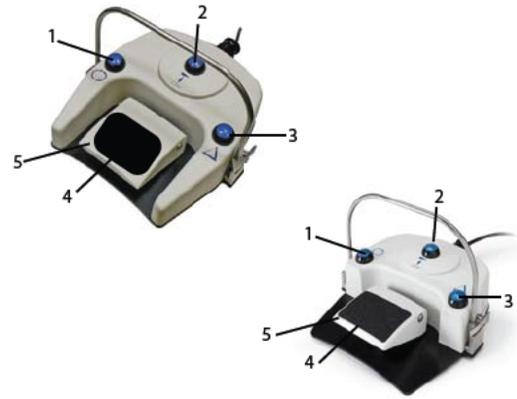
MULTIFUNCTION FOOTPEDAL CONTROLS

Important: By default, press each button on the footpedal for at least 100 mS for the selection to become active. Use the IPC touch screen Settings screen to change the default value.

To use the multifunction footpedal (Figure 6-13) to control the handpiece do the following:

- To select forward or oscillate mode, press the mode button. 
- To start or adjust the speed of a handpiece in variable mode, press the foot pedal. 
- To rotate the inner blade (60° or 180°), press the control button. 
- To change the handpiece, press the handpiece button. 

Figure 6-13. Multifunction Footpedal



- | | |
|--------------------|---------------------------|
| 1 Mode button | 4 Slip-resistant foot pad |
| 2 Handpiece button | 5 Foot pedal |
| 3 Control button | |

CLEANING AND STERILIZATION INSTRUCTIONS

Refer to document 68E3282 in the Cleaning and Sterilization section.

STRAIGHTSHOT M4 TECHNICAL SPECIFICATIONS

StraightShot M4 1898200T

Size	14.3 cm length x 1.8 cm width (1898200T)
Weight	228g 1898200T 240g 1897200, 1897201 254g 1897200T
Speed	50-5000 rpm oscillate 50-12000 rpm forward
Duty Cycle for Applied Part	The StraightShot M4 handpiece under full load is rated for intermittent operation per the following: Maximum On Time: 60 seconds Minimum Off Time: 30 seconds

STRAIGHTSHOT MAGNUM II AND STRAIGHTSHOT III TECHNICAL SPECIFICATIONS

StraightShot Magnum II 1897200

StraightShot III 1897201

Size	17 cm length x 1.6 cm width (1897200/1897201)
Weight	240g 1897200, 1897201
Speed	50-5000 rpm oscillate 50-12000 rpm forward
Duty Cycle for Applied Part	Under full load is rated for intermittent operation per the following: Maximum On Time: 60 seconds Minimum Off Time: 30 seconds

LEGEND EHS AND LEGEND EHS STYLUS

The Legend EHS motor (Figure 7-1) is a high speed, high torque, reversible electric motor used to dissect bone and biomaterial at selectable speeds from 200 to 75000 rpm.

The Legend EHS Stylus motor (Figure 7-2) is a smaller, compact, high speed, high torque, reversible electric motor used to dissect bone and biomaterials at selectable speeds from 200 to 75000 rpm.

The following instructions for the Legend EHS and Legend EHS Stylus are in addition to "Set up the IPC" general assembly instructions. Complete IPC setup, then continue to the instructions below.



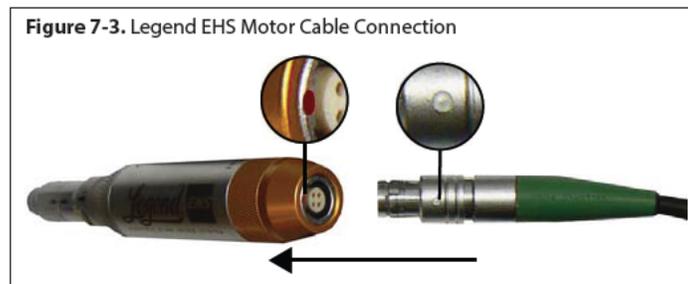
LEGEND EHS AND LEGEND EHS STYLUS ATTACHMENT ASSEMBLY

Refer to "Legend EHS, Legend EHS Stylus and Stylus Touch Attachments" for attachment assembly instructions.

CONNECT LEGEND EHS CABLE TO MOTOR

Note: The Legend EHS Stylus motor cable is integrated in the handpiece and cannot be removed from the motor.

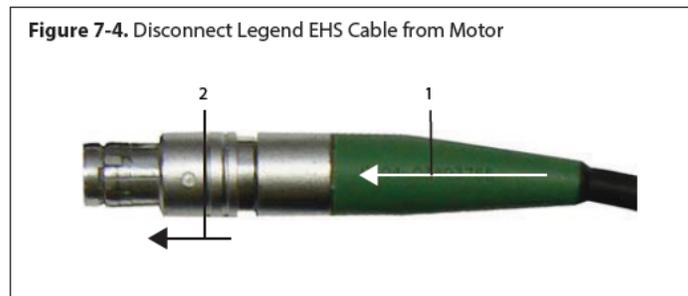
To connect the Legend EHS cable to the Legend EHS motor, align the mark on the cable to the red mark on the motor (Figure 7-3) and connect the two pieces.



REMOVE LEGEND EHS CABLE FROM MOTOR

Note: The Legend EHS Stylus motor cable is integrated in the handpiece and cannot be removed from the motor.

To remove the Legend EHS cable from the Legend EHS motor, (1) push the cable towards the motor, then (2) pull out the cable by the locking ring ONLY (Figure 7-4).



CONNECT LEGEND EHS OR LEGEND EHS STYLUS TO IPC

Locate the Legend EHS or Legend EHS Stylus connection port on the connector panel (Figure 7-5) and insert the connector.

Note: To insert multi-pin connectors (indicated by a silver or red mark on the connector), align the mark on the connector to the mark on the console, then insert the connector.

The IPC incorporates the Legend EHS or Legend EHS Stylus irrigation at pump 1. When the system detects the Legend EHS or Legend EHS Stylus, pump 2 defaults to **None**.

When the IPC detects both the Legend EHS Stylus handpieces and the StraightShot M4, the system defaults Pump 2 to the **Shared** configuration. You must manually move the irrigation tubing from the inactive to the active handpiece. Use the pumps screen to override the **Shared** default by selecting the StraightShot M4 or the Legend EHS Stylus for Pump 1. Refer to "Set up and Prime Pumps" for more information.

Control operation of the Legend EHS or Legend EHS Stylus with the IPC touchscreen and the multifunction footpedal.

Figure 7-5. Legend EHS and Legend EHS Stylus Connection Ports



- 1 Legend EHS Motor Connection Port
- 2 Legend EHS Stylus Motor Connection Port
- 3 Multifunction Footpedal Connectoin Port

LEGEND EHS AND LEGEND EHS STYLUS TOUCHSCREEN CONTROLS

To set or adjust Legend EHS or Legend EHS Stylus controls, on the IPC touchscreen, in the control box (Figure 7-6), do the following:

- To change rotation mode, in the Mode control box, select FWD (forward) or REV (reverse).

Important: System configuration may be different from the default. If the REV (reverse) button appears raised (Figure 7-7) and does not have a selectable radio button, you cannot select the reverse mode. If the REV button appears concave (Figure 7-7) and has a selectable radio button, you can select the reverse mode via the touchscreen or the multifunction footpedal.

- To adjust speed in forward (FWD) or reverse (REV) mode, in the Speed control box, press the plus button to increase speed or the minus button to decrease speed.  

Default, 70000 rpm; variable adjustment from 200 to 75000 rpm.

- To adjust the irrigation flow rate, in the Pump control box, press the plus button to increase flow rate or the minus button to decrease flow rate. If intermittent flow is available, pressing the plus or minus button progresses the system through intermittent and continuous flow. The system displays **Intermittent** when in intermittent flow mode. Default, 0cc per minute in forward or reverse mode.

Note: To adjust flow rate, you can use the touchscreen or the IntelliFlow Irrigation remote control.

- **Legend EHS Stylus ONLY:** To adjust the rate of the motor's acceleration and deceleration, in the Acceleration control box, press the plus button to increase acceleration or the minus button to decrease acceleration.

Figure 7-6. Legend EHS Stylus Touchscreen

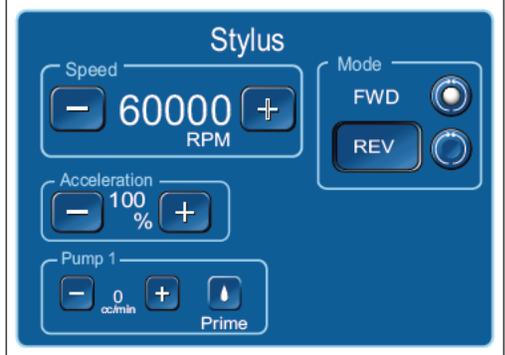
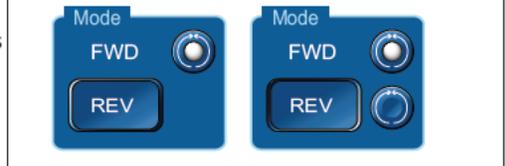


Figure 7-7. Legend EHS or Legend EHS Stylus Mode



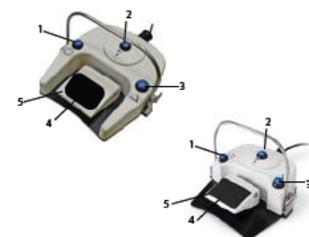
LEGEND EHS AND LEGEND EHS STYLUS MULTIFUNCTION FOOTPEDAL CONTROLS

Important: By default, press each button on the footpedal for at least 100 mS for the selection to become active. Use the IPC touch screen Settings screen to change the default value.

To use the multifunction footpedal (Figure 7-8) to control the handpiece do the following:

- To select forward or reverse mode, press the mode button. 
- To start or adjust the speed of a handpiece in variable mode, press the foot pedal. 
- To toggle between the start/stop mode and variable speed mode, press the control button. 
- To change the handpiece, press the handpiece button. 

Figure 7-8. Multifunction Footpedal



- 1 Mode Button
- 2 Handpiece Button
- 3 Slip-resistant foot pad
- 4 Control Button
- 5 Foot Pedal

LEGEND EHS AND LEGEND EHS STYLUS CLEANING AND STERILIZATION INSTRUCTIONS

Refer to documents M000030A234 and M000030A235 in the Cleaning and Sterilization section.

LEGEND EHS TECHNICAL SPECIFICATIONS

Legend EHS EM100-A

Size	9.02 cm length x 2.03 cm diameter
Weight	180g
Speed	75000 rpm forward/reverse
Duty Cycle for Applied Part	For use in operating room temperatures up to 40°C (104°F), the Legend EHS Motor is rated for a cutting time of 3 minutes at 70000 rpm.
	For normal operating room temperatures (typically 20°C/68°F), the Legend EHS Motor is rated for cutting time of 10 minutes followed by 25 minutes or rest.
	The Legend EHS Motor is rated for intermittent use of 20 seconds ON / 20 seconds OFF, indefinitely at 70000 rpm.

LEGEND EHS STYLUS TECHNICAL SPECIFICATIONS

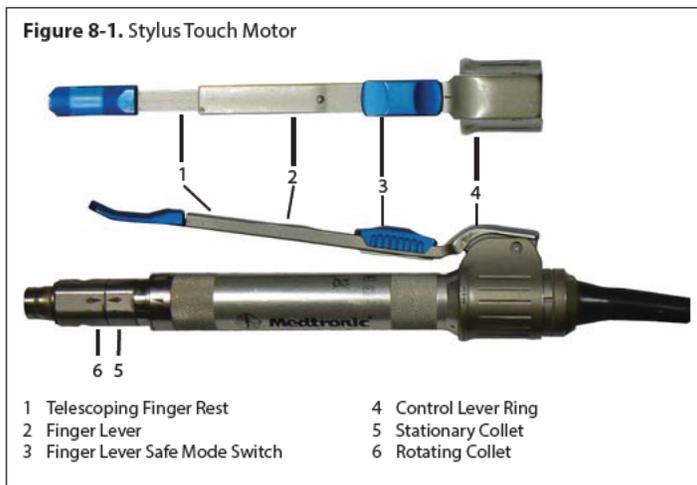
Legend EHS EM200

Size	7.77 cm length x 1.65 cm diameter
Weight	90g
Speed	75000 rpm forward/reverse
Duty Cycle for Applied Part	For use in operating room temperatures up to 40°C (104°F), the Legend EHS Stylus Motor is rated for 3 minutes at 60000 rpm followed by 25 minutes or rest.
	For normal operating room temperatures (typically 20°C/68°F), the Legend EHS Stylus Motor is rated for cutting indefinitely at 60000 rpm.

STYLUS TOUCH

The Stylus Touch (Figure 8-1) is a small, compact, high-speed, high-torque, reversible electric motor used to dissect bone and biomaterials at variable speeds from 200 to 75000 rpm. The Stylus Touch motor includes a rotating finger lever that emulates the functions of the multifunction footpedal.

The following instructions for the Stylus Touch are in addition to "Set up the IPC" general assembly instructions. Complete IPC setup, then continue to the instructions below.

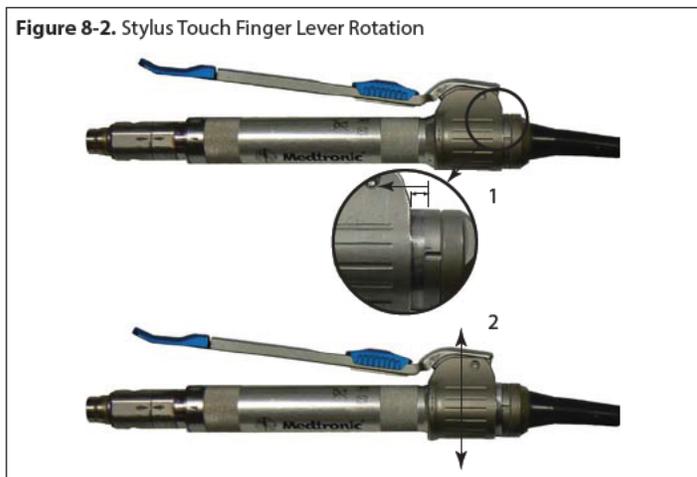


STYLUS TOUCH ATTACHMENT ASSEMBLY

Refer to "Legend EHS, Legend EHS Stylus and Stylus Touch Attachments" for attachment assembly instructions.

ROTATE STYLUS TOUCH FINGER LEVER

1. Press the control lever ring forward (Figure 8-2).
2. Rotate the lever clockwise or counter clockwise until the lever locks in a new position.



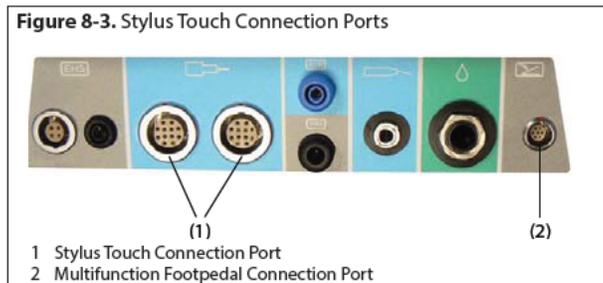
CONNECT STYLUS TOUCH TO IPC CONSOLE

Locate the Stylus Touch connection port on the connector panel (Figure 8-3) and insert the connector.

Note: To insert multi-pin connectors (indicated by a silver or red mark on the connector), align the mark on the connector to the mark on the console, then insert the connector.

The IPC incorporates the Stylus Touch at pump 1. If you do not use irrigation for the Stylus Touch, manually change the Pump 1 to **None**. Refer to "Set up and Prime Pumps" for more information.

Control operation of the Stylus Touch with the IPC touchscreen and the multifunction footpedal.



STYLUS TOUCH TOUCHSCREEN CONTROLS

To set or adjust Stylus Touch controls, on the IPC touchscreen, in the control box (Figure 8-4), do the following:

- To change rotation mode, in the Mode control box, select FWD (forward) or REV (reverse).
- To adjust speed, in the Speed control box, press the plus button to increase speed or the minus button to decrease speed.  Default, 60000 rpm; variable adjustment from 200 to 75000 rpm.
Note: When the handpiece is in safe mode, the Speed control box displays SAFE (Figure 8-5). Refer to the Stylus Touch Safe Mode topic for additional information.
- To adjust rate of the motors acceleration and deceleration, in the Acceleration control box, press the plus button to increase acceleration or the minus button to decrease acceleration.
- To adjust the irrigation flow rate, in the Pump control box, press the plus button to increase flow rate or the minus button to decrease flow rate. If intermittent flow is available, pressing the plus or minus button progresses the system through intermittent and continuous flow. The system displays Intermittent when in intermittent mode. Default, 0cc per minute.
Note: To adjust flow rate, you can use the touchscreen or the IntelliFlow Irrigation remote control.

Figure 8-4. Stylus Touch Touchscreen



Figure 8-5. Stylus Touch Safe Mode



STYLUS TOUCH SAFE MODE

When the handpiece is in safe mode, it is inoperable until the safety is turned off. The Speed control box on the Stylus Touch touchscreen displays SAFE when the handpiece is the active handpiece and in safe mode.

Switch the device to safe mode any time it is attached to the console, but not currently being used. To set the Stylus Touch to Safe Mode, on the Stylus Touch handpiece, switch the Safe Mode finger lever (Figure 8-1) to on.

When more than one handpiece is attached to the console, use the safety switch of an inactive handpiece to activate that handpiece and make it ready for use.

STYLUS TOUCH MULTIFUNCTION FOOTPEDAL CONTROLS

Important: By default, press each button on the footpedal for at least 100 mS for the selection to become active. Use the IPC touch screen Settings screen to change the default value. To use the multifunction footpedal (Figure 8-6) to control the handpiece do the following:

- To select forward or reverse mode, press the mode button. 
- To start or adjust the speed of a handpiece in variable mode, press the foot pedal.
- To toggle between the start/stop mode and variable speed mode, press the control button. 
- To change the handpiece, press the handpiece button. 

Figure 8-6. Multifunction Footpedal



STYLUS TOUCH CLEANING AND STERILIZATION INSTRUCTIONS

Refer to documents 68E4132 and M000030A235 in the Cleaning and Sterilization section.

STYLUS TOUCH TECHNICAL SPECIFICATIONS

Stylus Touch EM210

Size	15.26 cm length x 1.65 cm diameter
Weight	130g
Speed	75000 rpm forward/reverse
Duty Cycle for Applied Part	For use in operating room temperatures up to 40°C, the Legend EHS Stylus Touch Motor is rated for 3 minutes at 60000 rpm followed by 25 minutes or rest.
	For normal operating room temperatures (typically 20°C), the Legend EHS Stylus Touch Motor is rated for cutting indefinitely at 60000 rpm.

LEGEND EHS, LEGEND EHS STYLUS AND STYLUS TOUCH ATTACHMENTS

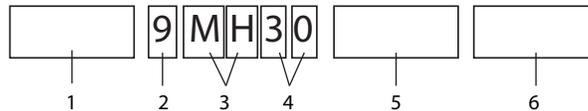
The following instructions for the Legend EHS, Legend EHS Stylus and Stylus Touch attachments are in addition to “Set up the IPC” and motor-specific general instructions. Complete IPC setup, motor specific instructions and then continue to the instructions below.

DISSECTING TOOLS NOMENCLATURE

Note: Match the nomenclature and color code on the dissecting tool packaging to the same nomenclature and color code on the attachment.

Part numbers for dissecting tools follow a standard naming convention (Figure 9-1). A basic part number consists of five characters, representing the associated attachment length, the tool-head shape, and the tool-head diameter. Part numbers can also include a variety of prefixes to identify specific attachment types, as well as a variety of suffixes to provide additional information about the dissecting tool. Tools that use a design taken from the Mednext line are designated by an additional “-MN” suffix.

Figure 9-1. Dissecting tool nomenclature naming convention



- | | | | |
|---|-------------------|---|--------------------------------------|
| 1 | Optional prefix | 4 | Tool head diameter (x.x millimeters) |
| 2 | Attachment length | 5 | Optional suffix |
| 3 | Tool head shape | 6 | Optional “-MN” suffix |

Tool Number Prefixes

- F For use with footed attachments.
- MC For use with metal-cutting attachments.
- T For use with telescoping attachments.

Tool Head Shapes

- | | | | |
|----|------------|----|---------------|
| AC | Acorn | MH | Match Head |
| BA | Ball | OV | Oval |
| CY | Cylinder | RT | Reverse Taper |
| HM | Hole Maker | TA | Tapered |
| HS | Hole Saw | TD | Twist Drill |

Tool Number Suffixes

Note: More than one suffix can be combined in a single part number.

- | | | | |
|---|---------|----|----------------------|
| L | Long | S | Spiral |
| D | Diamond | SH | Short |
| X | Extra | | |
| F | Fine | DC | Diamond Coarse |
| C | Carbide | DX | Diamond Extra Coarse |

ALIGN MOTOR COLLET

Note: An attachment will not seat on the Legend EHS, Legend EHS Stylus or Stylus Touch motor if the arrows on the collet flats are not aligned.

1. Verify alignment of arrows on motor collet flats. Prior to installation of an attachment and dissecting tool on the Legend EHS, Legend EHS Stylus or Stylus Touch motor, ensure that arrows on the motor collet flats are in proper alignment. (Figure 9-2).
2. If the arrows are not aligned (Figure 9-3), use the motor wrench (Figure 9-4) to turn the rotational collet until its arrow is aligned with the arrow on the stationary collet.

Note: DO NOT use any other components except for the motor wrench to align arrows on motor collet.

Figure 9-2. Correct alignment



Figure 9-3. Incorrect alignment



Figure 9-4. Motor wrench



STRAIGHT ATTACHMENT ASSEMBLY

Warnings: Refer to warnings W36 and W54.

Caution: Match the nomenclature and color code on the tool packaging to the same nomenclature and color code on the attachment.

Notes:

- An attachment will not seat on the motor if the arrows on the collet flats are not in alignment.
- The Legend EHS motors will not run properly unless the attachment is in the locked position.
- Smoke and/or excessive heat may be generated if attachment is not in the fully locked position. This may result in thermal injury to the surgeon or staff.

1. Slide a straight attachment over the motor collet aligning triangular arrows on the attachment and the motor case (Figure 9-5). An audible click, heard and perceptible by touch, confirms that the tool is fully seated.

Figure 9-5. Straight Attachment Assembly



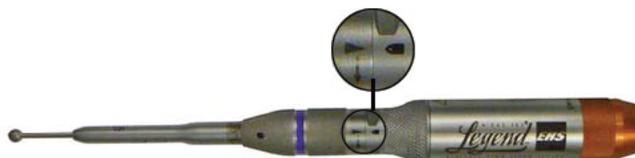
2. Insert the tool into the attachment with a slight rotational motion (Figure 9-6). An audible click, heard and perceptible by touch, confirms that the tool is fully seated.

Figure 9-6. Straight Attachment Assembly



3. Rotate the attachment in the direction indicated by arrow until the attachment alignment mark is directly in line with the locked symbol (Figure 9-7). You will hear two clicks as the attachment is rotated.

Figure 9-7. Straight Attachment Assembly



4. Gently pull on the tool to ensure that it is locked into the handpiece.
Note: Tool should rotate freely, if not, unlock the attachment, re-seat the tool, and re-lock the attachment.

STRAIGHT ATTACHMENT DISASSEMBLY

1. Hold the motor in palm of hand. Rotate the attachment to the unlocked position.
2. Remove the dissecting tool from the attachment and discard the tool.
3. Use thumb and index finger to lift the attachment off of the motor.

ANGLED ATTACHMENT ASSEMBLY

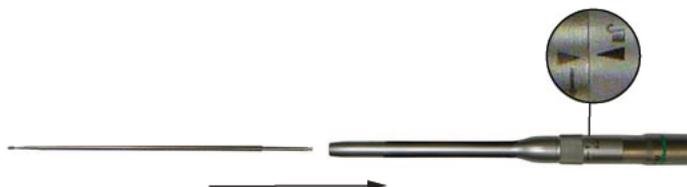
Caution: When using an angled attachment, hold the handpiece assembly by the attachment so that the attachment does not inadvertently loosen from the handpiece.

Notes:

- A dissecting tool may be installed and locked in the attachment before the angled attachment is installed onto the motor.
- Angled and straight attachments with the same length, marking and color band share the same dissecting tools.
- The Legend EHS Motors will not run properly unless the attachment is in the locked position.
- Smoke and/or excessive heat may be generated if attachment is not in the fully locked position. This may result in thermal injury to the surgeon or staff.

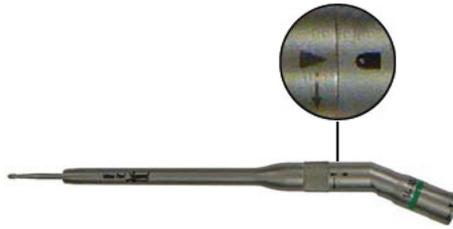
1. With the tool lock in the unlocked position, insert a tool into the angled attachment with a slight rotational motion (Figure 9-8). An audible click, heard and perceptible by touch, confirms that the tool is fully seated.

Figure 9-8. Angled Attachment Assembly



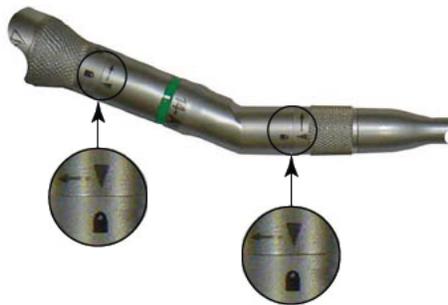
2. Rotate the tool lock in the direction indicated by arrow until the tool lock alignment mark is directly in line with the locked symbol (Figure 9-9).

Figure 9-9. Angled Attachment Assembly



3. Gently pull on the tool to ensure that it is locked into the handpiece.
Note: Tool should rotate freely, if not, unlock the attachment, re-seat the tool, and re-lock the attachment.
4. Slide the angled attachment over the motor collet aligning triangular arrows on the attachment and the motor case. An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
5. Rotate the attachment in the direction indicated by the arrow until attachment alignment mark is directly in line with the locked symbol. You will hear two clicks as the attachment is rotated.
6. Verify that both the attachment to motor alignment mark and the tool lock alignment mark are directly in line with the locked symbol (Figure 9-10).

Figure 9-10. Angled Attachment Assembly



ANGLED ATTACHMENT DISASSEMBLY

1. Rotate the Tool Lock to the unlocked position to remove the tool from the attachment.
2. Rotate the attachment to the unlocked position and lift attachment off of the motor.

FIXED FOOTED ATTACHMENT ASSEMBLY

Warning: Refer to Warning W37.

1. Insert a dissecting tool into the motor collet with a slight rotational motion (Figure 9-11). An audible click, heard and perceptible by touch, confirms that the tool is fully seated.

Figure 9-11. Footed Attachment Assembly



2. Slide the footed attachment over the dissecting tool onto the motor aligning triangular arrows on the attachment and the motor case (Figure 9-12).

Figure 9-12. Footed Attachment Assembly



3. Pull the footed attachment towards the motor and rotate the attachment to the locked position on the motor case (Figure 9-13).

Figure 9-13. Footed Attachment Assembly



FIXED FOOTED ATTACHMENT DISASSEMBLY

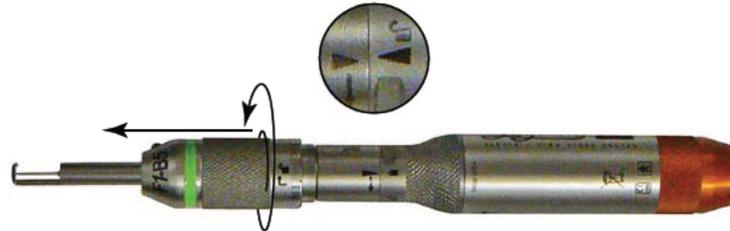
1. To remove the footed attachment, hold the motor in the palm of your hand. Push the sleeve on the footed attachment distally while rotating the attachment to the unlocked position on the motor case. Release the sleeve (Figure 9-14).

Figure 9-14. Footed Attachment Disassembly



2. To avoid injury from the dissecting tool, use thumb and index finger to cautiously and slowly lift the attachment off of the motor and away from the dissecting tool (Figure 9-15).

Figure 9-15. Footed Attachment Disassembly



3. Pull the dissecting tool out of the motor collet and discard the tool (Figure 9-16).

Figure 9-16. Footed Attachment Disassembly



ROTATING FOOTED ATTACHMENT ASSEMBLY

Warnings: Refer to Warnings, W20 and W52.

Notes:

- Rotating and fixed footed attachments with the same length, marking and color band share the same dissecting tools.
- The footed end of the attachment has 360° of unrestricted rotation.

Attach the Rotating Footed attachment using the Fixed Footed Attachment Assembly Instructions.

ROTATING FOOTED ATTACHMENT DISASSEMBLY

Remove the Rotating Footed attachment using the Fixed Footed Attachment Disassembly Instructions.

CONTRA-ANGLE ATTACHMENT 16-MF ASSEMBLY

1. On the IPC Touchscreen, adjust the speed setting to 62,000 rpm using the speed control buttons.
2. Slide the Contra-Angle Attachment over the motor collet aligning triangular arrows on the attachment and the motor case. An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
3. Rotate the attachment to the locked position on the motor case (Figure 9-17).

Figure 9-17. Contra-Angle Attachment Assembly



4. Rotate the attachment head's lever laterally to the open position and insert a dissecting tool (Figure 9-18).
5. Close lever (Figure 9-19).

Figure 9-18. Contra-Angle Attachment Assembly

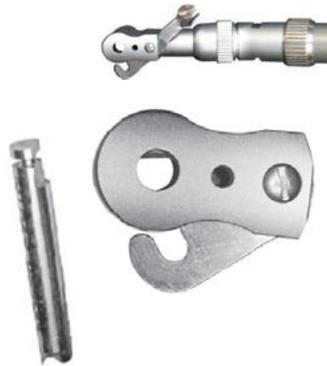


Figure 9-19. Contra-Angle Attachment Assembly



6. Gently pull on the dissecting tool shaft to ensure proper installation.

CONTRA-ANGLE ATTACHMENT 16-MF DISASSEMBLY

1. Rotate the lever on the attachment head laterally to remove the dissecting tool.
2. Discard the dissecting tool.
3. Rotate the 16-MF attachment to the unlocked position and lift the attachment off of the motor.

METAL CUTTING ATTACHMENT ASSEMBLY

Warning: Refer to Warning W15.

Important: The Metal Cutting attachment uses the tungsten carbide or diamond wheel dissecting tools. All metal cutting dissecting tools have an "MC" attachment prefix in their nomenclature, e.g , MC254, MC30. Metal cutting dissecting tools cannot be installed into any other Attachment.

1. Slide the Metal Cutting attachment over the motor collet aligning triangular markers on the attachment and the motor case. An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
2. Rotate the attachment to the locked position on the motor case.
3. With the tool lock unscrewed several turns and holding the attachment UPRIGHT, insert a dissecting tool into attachment (Figure 9-20).
4. Rotate the dissecting tool until it drops into position and is fully seated. You will feel a tactile click indicating that the tool is fully seated (Figure 9-20).

Figure 9-20. Metal Cutting Attachment Assembly



METAL CUTTING ATTACHMENT DISASSEMBLY

1. Unscrew the tool lock with several turns, then withdraw the dissecting tool.
2. Rotate the attachment to the locked position on the motor case and lift attachment off of the motor.

VARIABLE EXPOSURE ATTACHMENT ASSEMBLY

Warnings: Refer to Warnings W23, W34, W53 and W57.

The Variable Exposure attachments can be distinguished from standard attachments by the dual color bands on the attachment. Match the color band on the attachment to the color code on the dissecting tool packaging.

1. Assemble the attachment using the Straight Attachment Assembly Instructions.
2. After assembly, use the TUBE adjustment ring to adjust the exposure of the dissecting tool (Figure 9-21).

With the tool pointing away from you, turn the ring to the right to increase the length of the tube, thereby decreasing the exposure of the tool. Turn the ring to the left to decrease the length of the tube, thereby increasing the exposure of the tool.

Figure 9-21. Variable Exposure Attachment Assembly



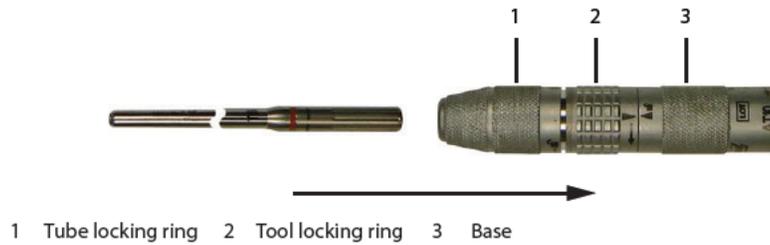
VARIABLE EXPOSURE ATTACHMENT DISASSEMBLY

Remove the Variable Exposure Attachment using the Straight Attachment Disassembly Instructions.

TELESCOPING STRAIGHT ATTACHMENT AT10 ASSEMBLY

1. Assemble the attachment using the Straight Attachment Assembly Instructions.
2. Insert the base end of the selected telescoping tube into the attachment.
3. To lock tube in place, turn the TUBE Locking Ring clockwise until finger tight (Figure 9-22).
Note: DO NOT over tighten.

Figure 9-22. Telescoping Straight Attachment Assembly



4. Be sure that the TOOL Locking Ring is in the unlocked position. Insert the dissecting tool into the telescoping tube (Figure 9-23). Tactile feedback is felt when the dissecting tool is fully seated.

Figure 9-23. Telescoping Straight Attachment Assembly



5. Turn the TOOL Locking Ring to the locked position (Figure 9-24).

Figure 9-24. Telescoping Straight Attachment Assembly



6. Verify that the tool is in place by gently pulling on the tool.
7. If the tube position needs to be changed, rotate the TUBE Locking Ring towards the unlocked position, re-position the tube, then rotate the TUBE Locking Ring towards locked.
8. Gently pull on the dissecting tool, then the tube, to ensure proper installation.

TELESCOPING CURVED ATTACHMENT AT10 ASSEMBLY

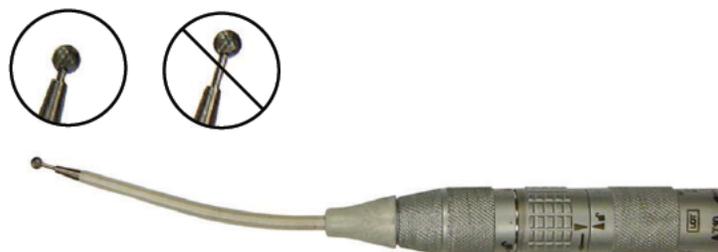
1. Assemble the attachment using the Straight Attachment Assembly Instructions.
2. Insert the base end of the curved bur into the attachment until the hub is fully seated. To lock in place, turn the TUBE Locking Ring until finger tight (Figure 9-25).
Note: DO NOT over tighten.

Figure 9-25. Telescoping Curved Attachment Assembly



3. Verify that the hub is in place by gently pulling on the tool.
4. Seat the tool in the tool Locking Ring by applying a slight amount of inward pressure on the bur (Figure 9-26). An audible click, heard and perceptible by touch, confirms that the tool is fully seated.

Figure 9-26. Telescoping Curved Attachment Assembly



5. Rotate the Tool Locking Ring until the tool lock alignment mark is directly in line with the locked symbol (Figure 9-27).
6. Verify that the bur is in place by gently pulling on the bur.
7. Prior to initial use, soak the cooling sleeve by dipping it into a cup of saline or DI water (Figure 9-28).
8. During use, maintain copious irrigation of the cooling sleeve and bur by dribbling saline or DI water along the entire length of the cooling sleeve.

Figure 9-27. Telescoping Curved Attachment Assembly



Figure 9-28. Curved Bur Cooling



TELESCOPING ATTACHMENT AT10 DISASSEMBLY

1. Rotate the TUBE Locking Ring towards the unlocked position.
2. Rotate the TOOL Locking Ring to the unlocked position.
3. Pull the telescoping tube out of the attachment.
4. Rotate the attachment to the unlocked position on the motor case and lift the attachment off the motor.

PERFORATOR ATTACHMENT AD01 & AD03 ASSEMBLY

Warning: Refer to Warning W56.

Note: A cranial perforator device may be installed in the attachment before the perforator attachment is installed on the motor.

Maximum Speed		
Console Setting	AD01 Output Speed (MAX)	AD03 Output Speed (MAX)
60000 rpm	645 rpm	830 rpm
70000 rpm	745 rpm	965 rpm
72000 rpm	770 rpm	995 rpm
74000 rpm	790 rpm	1020 rpm
75000 rpm	805 rpm	1035 rpm

Figure 9-29. Perforator Attachment Hudson Shank Assembly



1. Assemble the attachment using the Straight Attachment Assembly Instructions.
2. To install a cranial perforator device with a Hudson shank, pull back proximally on the collar of the Perforator Attachment. Insert a device and release the collar to its original position (Figure 9-29).

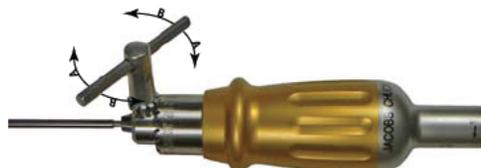
PERFORATOR ATTACHMENT AD01 & AD03 DISASSEMBLY

Pull back proximally on the collar of the Perforator Attachment to remove the cranial perforator device. Rotate the Perforator Attachment to the unlocked position and lift the attachment off of the motor.

JACOBS CHUCK ATTACHMENT ASSEMBLY

1. Assemble the attachment using the Straight Attachment Assembly Instructions.
2. To install a drill bit, turn Jacobs key to open ridged collar. Insert drill bit and tighten collar with key (Figure 9-30).

Figure 9-30. Jacobs Chuck Tool Assembly



JACOBS CHUCK ATTACHMENT DISASSEMBLY

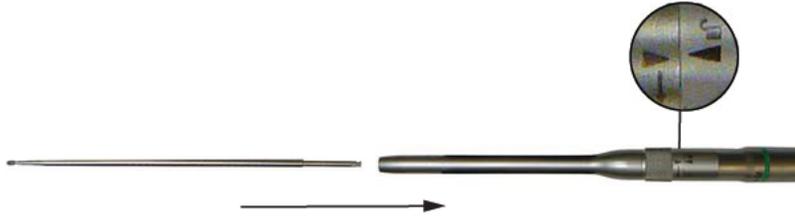
Use the Jacobs key to open the collar. Remove and discard the drill bit in an appropriate container. Rotate the Jacobs Chuck Attachment to the unlocked position and lift the attachment off of the motor.

ANGLED DOUBLE LOCK ATTACHMENT ASSEMBLY

Notes:

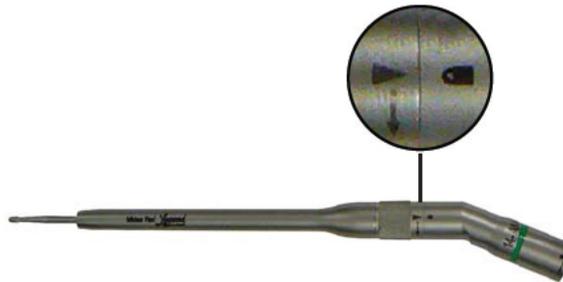
- Angled attachments with the same length, marking, and color band share the same dissecting tools.
 - You can insert and lock a tool in the attachment before the angled attachment is installed on the motor.
1. Assemble the attachment using the Straight Attachment Assembly Instructions.
 2. Insert the tool into the attachment with a slight rotational motion. An audible click, perceptible by touch, confirms that the tool is fully seated (Figure 9-31).

Figure 9-31. Angled Double Lock Attachment Assembly



3. Rotate the tool lock in direction indicated by arrow until the tool lock alignment mark is directly in line with the locked symbol (Figure 9-32).

Figure 9-32. Angled Double Lock Attachment Assembly

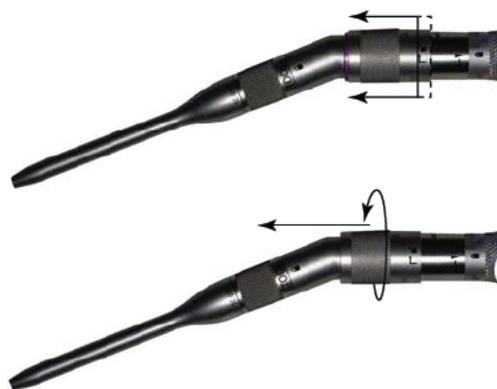


4. Pull on the tool to ensure that it is locked into the handpiece.
5. The tool should rotate freely. If not, unlock the attachment, re-seat the tool, and re-lock the attachment.
6. Verify that both the attachment to motor and the tool-lock alignment mark is directly in line with the locked symbol.

ANGLED DOUBLE LOCK ATTACHMENT DISASSEMBLY

1. To remove the attachment, hold the motor in the palm of your hand, and push the sleeve on the attachment distally while turning the attachment to the unlocked position (Figure 9-33).
2. Release the sleeve and remove the attachment.

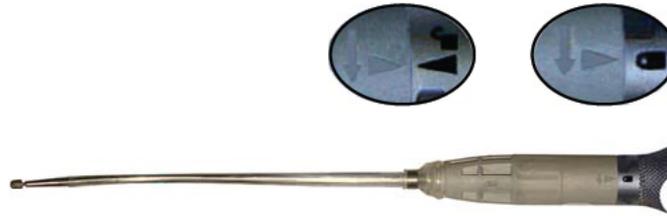
Figure 9-33. Angled Double Lock Attachment Disassembly



TRANS-NASAL SKULL BASE BUR ATTACHMENT ASSEMBLY

1. Slide the attachment over the motor collet aligning triangular arrows on the attachment and the motor case. An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
2. Rotate the attachment to the locked position on the motor case (Figure 9-34).

Figure 9-34. Trans-Nasal Skull Base Bur Assembly



3. Attach irrigation tubing (Figure 9-35).

Figure 9-35. Trans-Nasal Skull Base Bur Assembly



TRANS-NASAL SKULL BASE BUR ATTACHMENT DISASSEMBLY

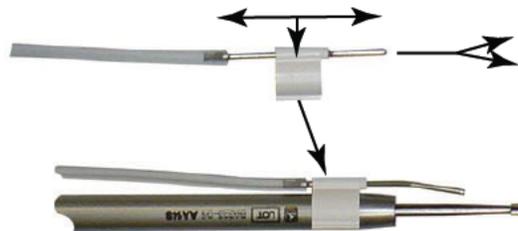
1. Remove irrigation tubing.
2. Rotate the attachment to the unlocked position on the motor case.
3. Remove the attachment from the motor.

IRRIGATION ASSEMBLY

NOTE: Clip may not fasten to small bore attachment after having been used on large bore attachment.

1. Adjust the plastic clip on the stainless-steel irrigation tube (Figure 9-36).
2. Bend the irrigation tube to the desired angle.
3. Snap the clip onto the handpiece near the tool.

Figure 9-36. Irrigation Assembly



LEGEND EHS, LEGEND EHS STYLUS AND STYLUS TOUCH CLEANING AND STERILIZATION INSTRUCTIONS

Refer to documents M000030A234, 68E4132 and M000030A235 in the Cleaning and Sterilization section.

Variable Exposure Attachment Cleaning

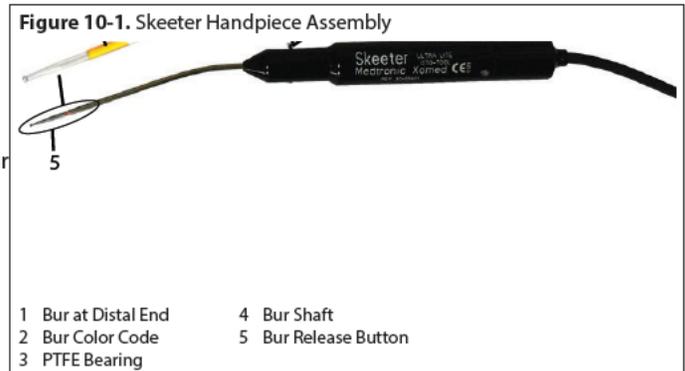
When cleaning, clean the attachment completely. First without adjusting the tube length, then with the tube fully extended, and finally with the tube fully retracted.

SKEETER ULTRA-LITE OTO-TOOL

The following instructions for the Skeeter Ultra-Lite Oto-Tool are in addition to “Set up the IPC” general assembly instructions. Complete the IPC setup, then continue to the instructions below. Refer to the Skeeter Ultra-Lite Oto-Tool System Instructions for Use for additional information.

SKEETER ASSEMBLY

1. Press the bur release button (Figure 10-1).
2. Load the desired bur for the procedure into the handpiece by inserting the bur shaft through the distal end of the handpiece with a slight twisting motion while simultaneously pressing the bur release button.
3. The bur is locked into place when a “click” is noted. Locking of the bur should be checked prior to use by firmly pulling on the bur after the “click” is noted.
4. Tug the bur to ensure it fits securely in the handpiece.
5. To remove the bur from the handpiece, press the bur release button on the handpiece and pull the bur out.



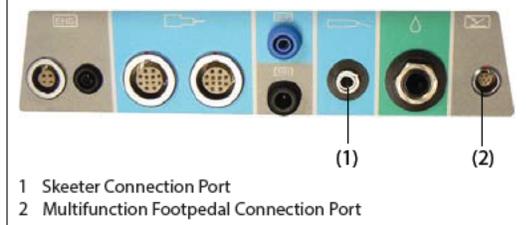
CONNECT SKEETER HANDPIECE TO IPC CONSOLE

On the IPC Console, locate the Skeeter accessory connection port on the connector panel (Figure 10-2), align the mark on the connector to the mark on the console, then insert the connector.

The Skeeter does not use irrigation. By default, the system sets both pumps to **None**.

Control the operation of the Skeeter with the IPC touchscreen and the multifunction footpedal.

Figure 10-2. IPC Skeeter Connection Port

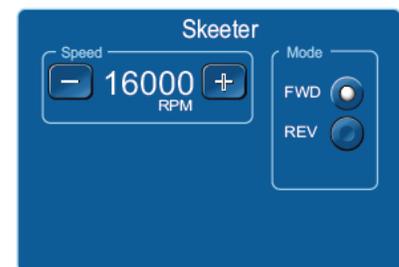


SKEETER TOUCHSCREEN CONTROLS

To set or adjust Skeeter controls, on the IPC touchscreen, in the Skeeter control box (Figure 10-3), do the following:

- To change rotation mode, in the Mode control box, select FWD (forward) or REV (reverse).
- To adjust speed, in the Speed control box, press the plus button to increase speed or the minus button to decrease speed.  Default, 16000 rpm; variable adjustment from 1000 to 16000 rpm.

Figure 10-3. Skeeter Touchscreen



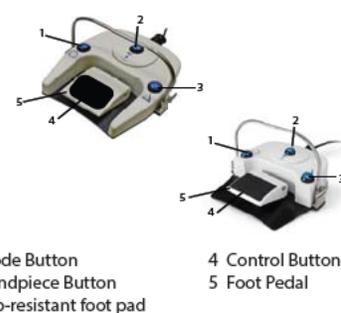
SKEETER MULTIFUNCTION FOOTPEDAL CONTROLS

Important: By default, press each button on the footpedal for at least 100 mS for the selection to become active. Use the IPC touch screen Settings screen to change the default value.

To use the multifunction footpedal (Figure 10-4) to control the handpiece do the following:

- To select forward or reverse mode, press the mode button. 
- To start or adjust the speed of a handpiece in variable mode, press the foot pedal.
- To toggle between the start/stop mode and variable speed mode, press the control button. 
- To change the handpiece, press the handpiece button. 

Figure 10-4. Multifunction Footpedal



SKEETER CLEANING AND STERILIZATION INSTRUCTIONS

Refer to documents 68E3968 and 68E3969 in the Cleaning and Sterilization section.

SKEETER TECHNICAL SPECIFICATIONS

Skeeter 3055601

Size	17cm length x 1.6cm diameter
Weight	57g
Speed	1000-16000 rpm forward/reverse
Duty Cycle for Applied Part	Continuous run
Storage Temperature	-40°C to +70°C
Humidity	10% to 100% RH
Barometric Pressure	500 to 1060 hPa

VISAO HIGH-SPEED DRILL

DEVICE DESCRIPTION

The IPC incorporates the Visao coolant at pump 1 and irrigation at pump 2. The Visao coolant pump cartridge uses both a pump tube and a drip chamber return tube. If you will not use irrigation, select None for pump 2. Refer to “Set up and Prime Pumps”. Control operation of the Visao with the IPC touchscreen and the multifunction footpedal.

Important: During use, maintain free flow irrigation to the cooling sleeve and bur by dribbling saline or DI water along the entire length of the cooling sleeve.

The following instructions are specific for the use of the Visao with the IPC. They are in addition to “Set up the IPC” general accessory instructions.

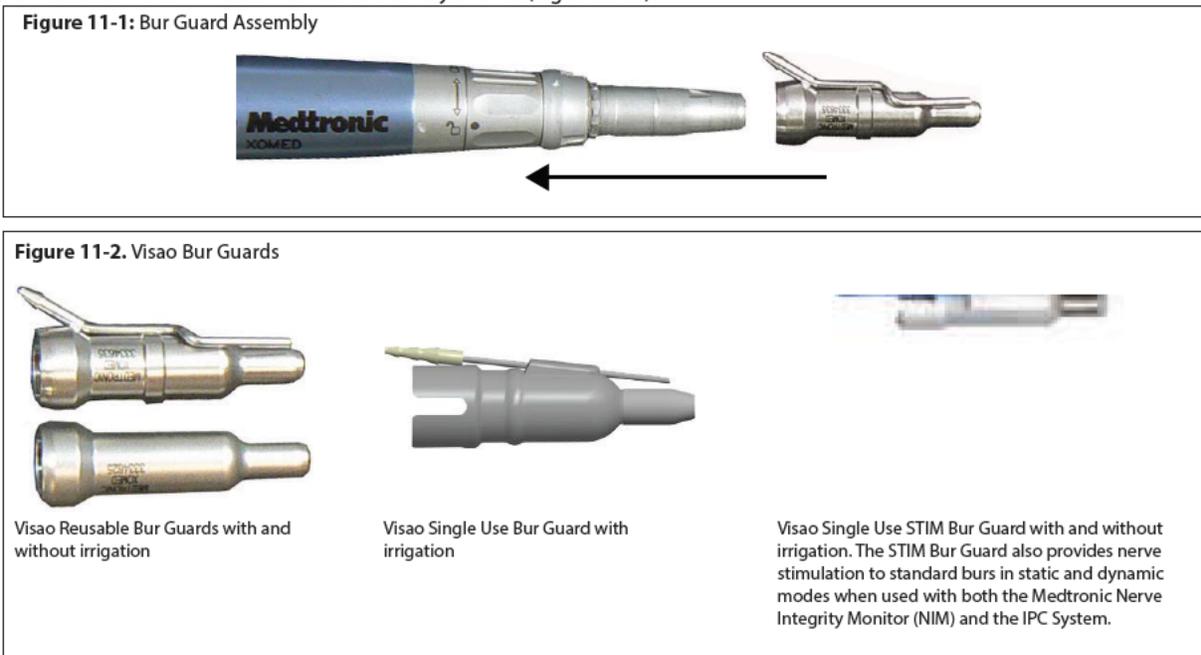
SET UP VISAO PUMP

Fill the clear-drip chamber with coolant before you prime the coolant system. Refer to “Set up and Prime Pumps” for instruction.

VISAO BUR GUARD ASSEMBLY

Important: On the Visao, a bur guard (Figure 11-2) is required for use with all burs.

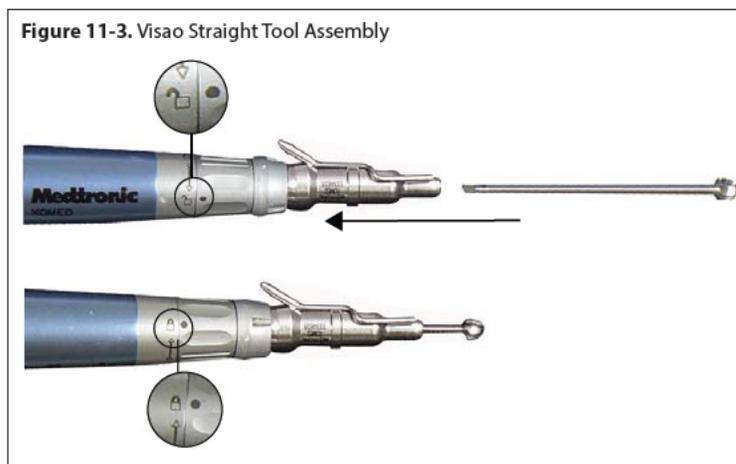
Slide bur guard over the front end of the Visao until fully seated (Figure 11-1).



VISAO STRAIGHT BUR ASSEMBLY

Important: On the Visao, a bur guard (Figure 11-2) is required for use with all burs.

1. Align the alignment point on the Visao locking collar with the unlock symbol (Figure 11-3).
2. Insert the tool until fully seated.
3. Move the locking collar so that the alignment point aligns with the lock symbol.
4. To ensure a secure fit, gently pull the tool.

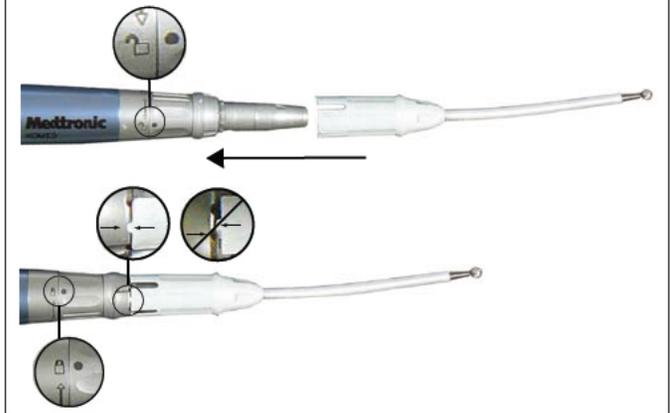


VISAO CURVED BUR ASSEMBLY

Important: On the Visao, a bur guard (Figure 11-2) is required for use with all burs.

1. Align the alignment point on the Visao locking collar with the unlock symbol (Figure 11-4).
2. Align the notch on the tool with the notch on the Visao collar.
3. Gently press on the tool until full seated.
4. Align the alignment point on the Visao locking collar with the lock symbol.
5. To ensure a secure fit, gently pull the tool.

Figure 11-4. Visao Curved Bur Assembly

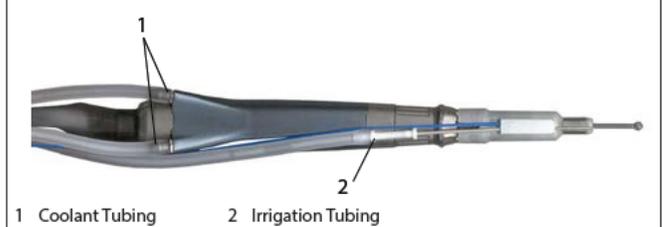


VISAO IRRIGANT AND COOLING TUBE ASSEMBLY

Caution: Do not confuse the coolant tube with irrigation tube.

1. Connect one coolant tube to each coolant port (Figure 11-5). The coolant can flow in the left or right port if you connect the return tubing to the opposite port.
2. Connect the free end of the irrigation tube to the irrigation barb.
3. Confirm the coolant pedal starts the handpiece and coolant flow.
Note: The coolant pump runs for 1 minute after you release the pedal.
4. Prior to initial use, soak the cooling sleeve in a cup of saline or DI water.
5. During use, maintain copious irrigation of the cooling sleeve and bur by dribbling saline or DI water along the entire length of the cooling sleeve.

Figure 11-5. Visao Irrigant and Cooling Assembly

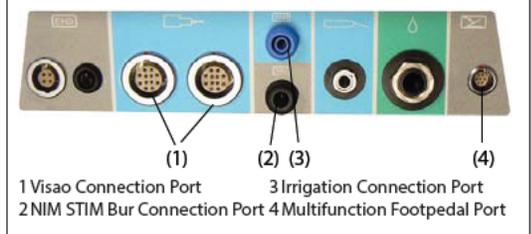


CONNECT VISAO TO IPC CONSOLE

Locate the Visao connection port on the connector panel (Figure 11-6) and insert the connector.

Note: To insert multi-pin connectors (indicated by a silver or red mark on the connector), align the mark on the connector to the mark on the console, then insert the connector.

Figure 11-6. IPC Visao Connection Port



VISAO TOUCHSCREEN CONTROLS

To set or adjust Visao controls, on the IPC touchscreen, in the Visao control box (Figure 11-7), do the following:

- To change rotation mode, in the Mode control box, select FWD (forward) or REV (reverse).
- To adjust speed, in the Speed control box, press the plus button to increase speed or the minus button to decrease speed. **+ -**
Default, 80000 rpm; variable adjustment from 200 to 80000 rpm.
- To adjust the irrigation flow rate, in the Pump control box, press the plus button to increase flow rate or the minus button to decrease flow rate. If intermittent flow is available, pressing the plus or minus button progresses the system through intermittent and continuous flow. The system displays Intermittent when in intermittent mode.
Forward Mode: Default, 30cc per minute.
Note: To adjust flow rate, you can use the touchscreen or the IntelliFlow Irrigation remote control.

Figure 11-7. Visao Touchscreen



VISAO MULTIFUNCTION FOOTPEDAL CONTROLS

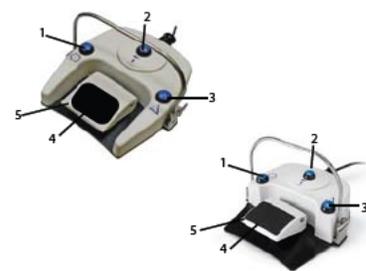
Important: By default, press each button on the footpedal for at least 100 mS for the selection to become active. Use the IPC touch screen

Settings screen to change the default value.

To use the multifunction footpedal (Figure 11-8) to control the handpiece do the following:

- To select forward or reverse mode, press the mode button. 
- To start or adjust the speed of a handpiece in variable mode, press the foot pedal.
- To toggle between the start/stop mode and variable speed mode, press the control button. 
- To change the handpiece, press the handpiece button. 

Figure 11-8. Multifunction Footpedal



- 1 Mode Button
- 2 Handpiece Button
- 3 Slip-resistant foot pad
- 4 Control Button
- 5 Foot Pedal

VISAO CLEANING AND STERILIZATION INSTRUCTIONS

Refer to document 68E3281 in the Cleaning and Sterilization section.

VISAO TECHNICAL SPECIFICATIONS

Visao 3334800

Size	16.0 cm length x 2.0 cm diameter
Weight	148g
Speed	200-80000 rpm forward/reverse. Visao High-Speed Drill, water cooled
Duty Cycle for Applied Part	The Visao High-Speed Drill under full load is rated for intermittent operation per the following:
	Maximum On Time: 60 seconds
	Maximum Off Time: 30 seconds

VISAO USE WITH IPC AND NIM

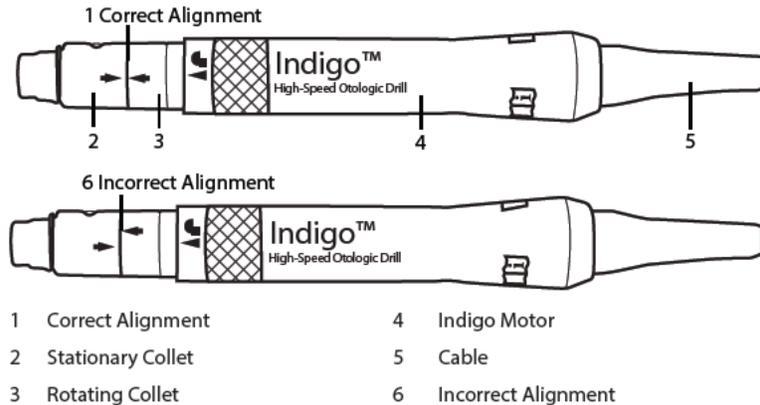
To use the NIM with the IPC use the Stim Bur Guard (Figure 11-2). The Stim Bur Guard connects the IPC to the NIM via the Stim bur stimulus output port (Figure 11-6). The Stim Bur Guard carries stimulating current to the tool's tip and provides nerve stimulation to standard burs in static and dynamic modes. Refer to the NIM User's Manual and Stim Bur Guard Product Information and Instructions for further information.

INDIGO HIGH-SPEED OTOLOGIC DRILL

DEVICE DESCRIPTION

The Indigo drill is a small, compact high-speed, high-torque, reversible electric drill that can be used to dissect bone and biomaterial at variable speeds from 200 to 60000 rpm. The cable cannot be removed from the drill. The following instructions for the Indigo drill are in addition to "Set up the IPC" general assembly instructions. Complete IPC setup, then continue to the instructions below.

Figure 12-1. Indigo Alignment



INDIGO DRILL STRAIGHT ATTACHMENT ASSEMBLY

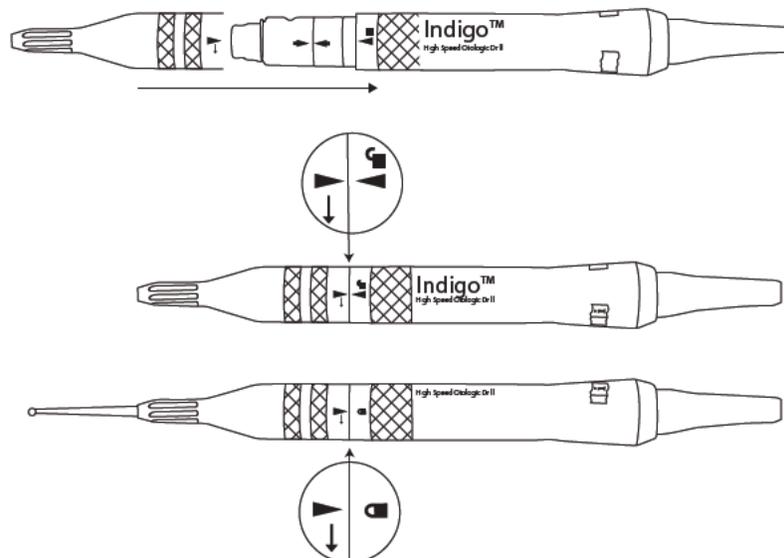
Important: The Indigo High-speed Otologic drill is designed to work only with Medtronic Xomed burs and Indigo attachments. The use of other burs and attachments may result in sub-standard performance and will void the manufacturer's warranty. Do not use with Midas Rex attachments or burs.

1. Verify the alignment marks on the motor collet are in alignment (Figure 12-1).
Note: If the marks are misaligned, turn the collet until the marks are aligned.
2. Slide the attachment over the motor collet (Figure 12-2) so that the alignment mark on the attachment aligns with the alignment mark (unlocked symbol) on the motor collet.
3. Insert the bur with a slight twisting motion until you feel it seat into position.
4. Turn the attachment so the alignment mark aligns with the locked symbol on the motor collet. You will hear two clicks while rotating the attachment.
5. To ensure a secure fit, gently pull the tool.

Important: The Indigo motor will not run correctly unless the attachment is in the locked position.

Warning: Smoke may be generated if attachment is not in the locked position (W 36).

Figure 12-2. Indigo Straight Attachment Assembly



INDIGO DRILL ANGLED ATTACHMENT ASSEMBLY

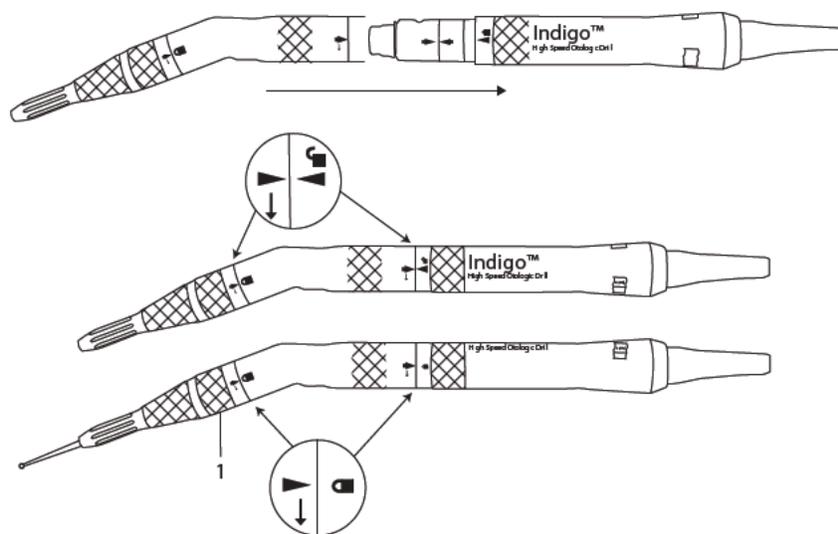
Important: The Indigo High-speed Otologic drill is designed to work only with Medtronic Xomed burs and Indigo attachments. The use of other burs and attachments may result in sub-standard performance and will void the manufacturer's warranty. Do not use with Midas Rex attachments or burs.

1. Verify the alignment marks on the motor collet are in alignment (Figure 12-1).
Note: If the marks are misaligned, turn the collet until the marks are aligned.
2. Slide the attachment over the motor collet (Figure 12-3) so that the alignment mark on the attachment aligns with the alignment mark (unlocked symbol) on the motor collet.
3. Turn the attachment so the alignment mark aligns with the locked symbol on the motor collet. You will hear two clicks while rotating the attachment.
4. Verify the alignment marks on the tool lock ring align with the unlocked symbol on the attachment.
5. Insert the bur with a slight twisting motion until you feel it seat into position.
6. Turn the lock ring so the alignment mark aligns with the locked symbol on the attachment. You will hear two clicks while rotating the attachment.
7. To ensure a secure fit, gently pull the tool.

Important: The Indigo motor will not run correctly unless the attachment and lock ring is in the locked position.

Warning: Smoke may be generated if attachment is not in the locked position (W 36).

Figure 12-3. Indigo Angled Attachment Assembly

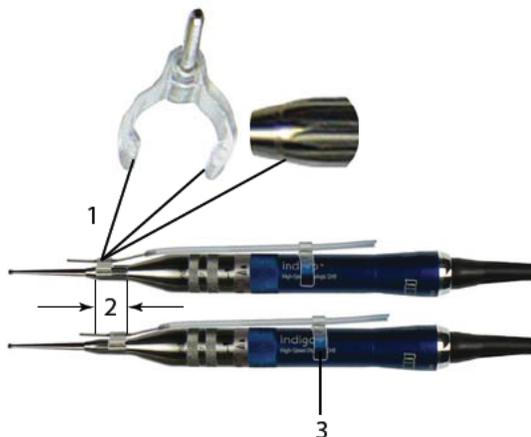


1 Tool Lock Ring

INDIGO DRILL IRRIGATION AND TUBING CLIP ASSEMBLY

1. Snap or slide the irrigation clip on to the attachment (Figure 12-4).
Note: The irrigation clip is designed with two nodules that fit in the grooves on the attachment.
2. Bend the irrigation tube to a desirable angle and adjust the clip closer to or farther from the bur, as necessary.
3. Snap the tubing clip on the handpiece or angled attachment.

12-4. Irrigation and Tubing Clip Assembly



CONNECT INDIGO DRILL TO IPC

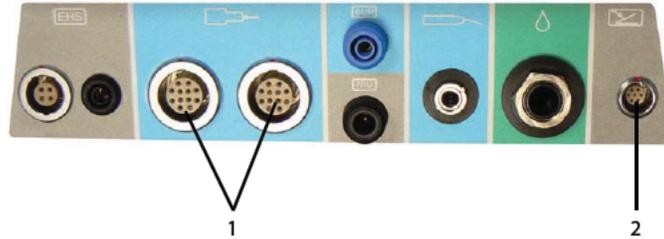
Locate the Indigo drill connection port on the connector panel (Figure 12-5) and insert the connector.

Note: To insert multi-pin connectors (indicated by a silver or red mark on the connector), align the mark on the connector to the mark on the console, then insert the connector.

The IPC incorporates Indigo on-drill irrigation at pump 2. If you do not use drill irrigation, select **None** for pump 2. If you will use a suction irrigator, you must manually select it for pump 1 or pump 2.

Control operation of the Indigo drill with the IPC touchscreen and the multifunction footpedal.

Figure 12-5. IPC Indigo Connection Ports



- 1 Indigo connection port
- 2 Multifunction Footpedal port

INDIGO DRILL TOUCHSCREEN CONTROLS

To set or adjust Indigo drill controls, on the IPC touchscreen, in the control box (Figure 12-6), do the following:

- To change rotation mode, in the Mode control box, select FWD (forward) or REV (reverse). **Important:** System configuration may be different from the default. If the REV (reverse) button appears raised and does not have a selectable radio button (Figure 12-7), you cannot select the reverse mode. If the REV button appears concave (Figure 12-7) and has a selectable radio button, you can select the reverse mode via the touchscreen or the multifunction footpedal.

- To adjust speed, in the Speed control box, press the plus button to increase speed or the minus button to decrease speed. **+** **-**
Default, 52000 rpm; variable adjustment from 200 to 60000 rpm in increments of 200, 500 and then 1000 until 60000.

Note: The speed you set remains constant when you switch between modes.

Warning: A tool's size and geometry may create excessive vibration at certain speeds. Increase or decrease speed on console. Change to a new tool to prevent unintended tissue removal from patient (W 54).

- To adjust the irrigation flow rate, in the Pump control box, press the plus button to increase flow rate or the minus button to decrease flow rate. If intermittent flow is available, pressing the plus or minus button progresses the system through intermittent and continuous flow of irrigation at 5, 10, 15 and 20 cc per minute. The system displays **Intermittent** when in intermittent mode.

Default, 30cc per minute.

Note: To adjust flow rate, you can use the touchscreen or the IntelliFlow Irrigation remote control.

Figure 12-6. Indigo Touchscreen



Figure 12-7. Indigo Mode



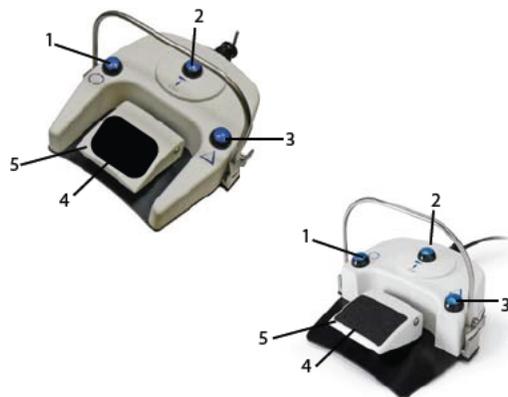
INDIGO DRILL MULTIFUNCTION FOOTPEDAL CONTROLS

Important: By default, press each button on the footpedal for at least 100 mS for the selection to become active. Use the IPC touchscreen Settings screen to change the default value.

To use the multifunction footpedal (Figure 12-8) to control the handpiece do the following:

- To select forward or reverse mode, press the mode button. 
- To start or adjust the speed of a handpiece in variable mode, press the foot pedal.
- To toggle between the start/stop mode and variable speed mode, press the control button. 
- To change the handpiece, press the handpiece button. 

Figure 12-8. Multifunction Footpedal



- | | |
|--------------------|---------------------------|
| 1 Mode button | 4 Slip-resistant foot pad |
| 2 Handpiece button | 5 Foot pedal |
| 3 Control button | |

INDIGO DRILL CLEANING AND STERILIZATION INSTRUCTIONS

Refer to documents 68E4187 and 68E4188 in the Cleaning and Sterilization section.

INDIGO DRILL TECHNICAL SPECIFICATIONS

Indigo Drill 1845000

Size	11.9 cm length x 1.53 cm diameter
Weight	102 g
Speed	60000 rpm forward/reverse
Duty Cycle for Applied Part	For continuous use in operating room temperatures up to 40°C, the Indigo motor is rated for 3 minutes at 60000 rpm, followed by 25 minutes of rest.
	For normal operating room temperatures (typically 20°C), the Indigo motor is rated for continuous cutting indefinitely at 60000 rpm.

MIDAS REX MICROSAWS

DEVICE DESCRIPTION

Use Midas Rex Microsaws to remove hard tissue and bone during surgical procedures. Both the foot and finger-controlled saws are powered by the IPC. Operate the foot-controlled saws via the multifunction footpedal. Operate the finger-controlled saws by pressing the finger lever.

The IPC incorporates microsaws irrigation at pump 2. If you do not use irrigation, select **None** for pump 2. Control operation of the microsaws with the IPC touchscreen and the multifunction footpedal.

Figure 13-1. Foot-Controlled Microsaw Handpieces



- 1 Reciprocating saw collet
- 2 Sagittal saw blade release button
- 3 Oscillating saw head
- 4 Oscillating saw collet
- 5 Color band

Figure 13-2. Finger-Controlled Microsaw (Microsaw Touch) Handpieces



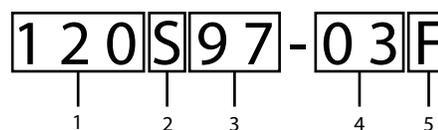
- 1 Reciprocating saw collet
- 2 Sagittal saw blade release button
- 3 Oscillating saw head
- 4 Oscillating saw collet
- 5 Color band
- 6 Finger lever safe mode switch
- 7 Finger lever

BLADE AND RASP NOMENCLATURE

Important: You can only use reciprocating blades and rasps with the reciprocating saw. You can use sagittal and oscillating blades interchangeably.

Saw blade part numbers follow a standard naming convention.

1	Cut Depth Limit	XX.X mm*			
2	Saw Type	S	Sagittal / Oscillating		
		R	Reciprocating		
3	Cut Width / Length	X.X mm			
4	Blade Thickness	X.X mm			
5	Other Identifiers	F	Fine Teeth	PT	Pointed Blade
		ARC	Rounded Blade	ST	Straight Rasp
		BAY	Bayoneted Blade	CC	Crosscut Rasp



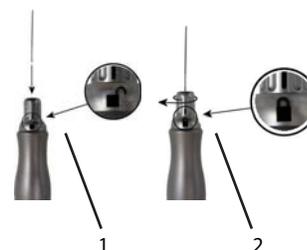
* Blade depth markings are approximate and should be used for reference only.

RECIPROCATING MICROSAW ASSEMBLY

Important: Verify that the color code on the blade package matches the color band on the handpiece (Figures 13-1 and 13-2).

1. On the reciprocating handpiece (red band), verify that the collet is in the unlocked position (Figure 13-3).
2. Insert the reciprocating blade into the collet.
3. Rotate the collet knob 90° to the locked position.
4. To ensure a secure fit, gently pull the blade.

Figure 13-3. Reciprocating Saw Assembly



SAGITTAL MICROSAW ASSEMBLY

Important: Verify that the color code on the blade package matches the color band on the handpiece (Figures 13-1 and 13-2).

1. On the sagittal handpiece (yellow band), press the blade release button (Figure 13-4).
2. Insert the blade at the desired angle (Figure 13-5).
3. Release the blade release button.
4. To ensure a secure fit, gently move the blade from side to side.

Figure 13-4. Sagittal Saw Assembly

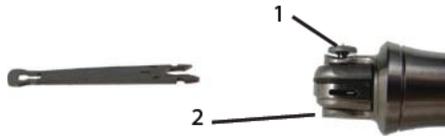


Figure 13-5. Blade Installation Angles



OSCILLATING MICROSAW ASSEMBLY

Important: Verify that the color code on the blade package matches the color band on the handpiece (Figures 13-1 and 13-2).

1. On the oscillating handpiece (blue band), verify that the collet is in the unlocked position (Figure 13-6).
2. Insert the blade into the collet. The blade “clicks” into place.
Note: You can insert the blade every 45° in a 360° circle in up to 8 locations (Figure 13-7).
3. Rotate the collet to the locked position (Figure 13-6).
4. To ensure a secure fit, gently move the blade from side to side.

Figure 13-6. Oscillating Saw Assembly

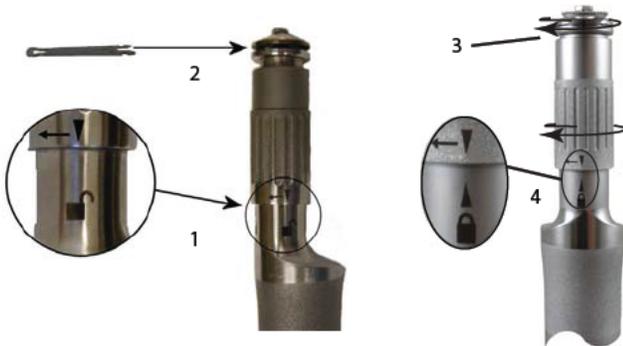
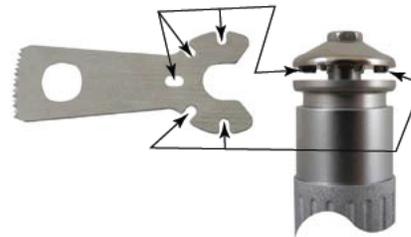


Figure 13-7. Oscillating Pin Alignment



MICROSAW IRRIGATION AND TUBING CLIPS ASSEMBLY

Note: Saw irrigation is optional.

1. Snap the irrigation clip on to the handpiece (Figures 13-8 and 13-9).
Note: On finger-controlled handpieces, attach the rear portion of the irrigation clip to the rotatable finger lever base (Figure 13-9).
2. Disengage the front of the irrigation clip to adjust the irrigation length, if necessary.
3. Snap the tubing clip on to the handpiece.

Figure 13-8. Foot-Controlled Microsaw Irrigation and Tubing Clip Assembly



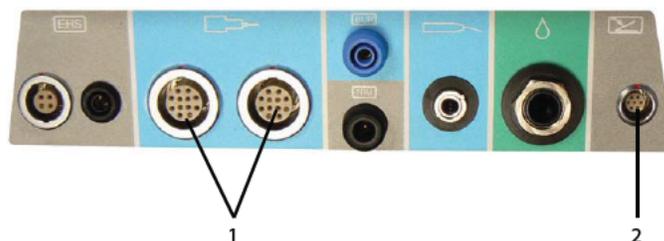
Figure 13-9. Finger-Controlled Microsaw Irrigation and Tubing Clip Assembly



CONNECT MICROSAW HANDPIECE TO IPC

On the IPC Console, locate a 12-pin port on the connector panel (Figure 13-10), align the mark on the connector to the mark on the console, then insert the connector.

Figure 13-10. Microsaws IPC Connection Ports



- 1 Microsaws handpiece connection port
- 2 Multifunction footpedal connection port

MICROSAWS TOUCHSCREEN CONTROLS

Important: The IPC recognizes the connected saw, then displays the appropriate name and color ring.

- To adjust speed, in the Speed control box (Figure 13-11), press the plus button to increase maximum speed and the minus button to decrease maximum speed. Variable adjustment ranges from 0% to 100%.
Note: When the Finger-Controlled Microsaw is in safe mode, the Speed control box displays SAFE (Figure 13-12). Refer to the Finger-Controlled Microsaw Safe Mode topic for additional information.
- To adjust acceleration, in the Acceleration control box, press the plus button to increase acceleration and the minus button to decrease acceleration. Variable acceleration ranges from 0% to 100%
- To adjust the irrigation flow rate, in the Pump control box, press the plus button to increase flow rate or the minus button to decrease flow rate. If intermittent flow is available, pressing the plus or minus button progresses the system through intermittent and continuous flow. The system displays Intermittent when in intermittent mode.
Default flow rate is 0 cc per minute. Maximum flow rate is 50 cc per minute.
Note: To adjust flow rate, you can use the touchscreen or the Intelliflow Irrigation remote control.
- To switch between foot and finger control or to use both, in the Control control box, select the appropriate option. Finger-controlled saws can be operated via the lever on the handpiece, or the footpedal.
Note: This option is only available when using a finger-controlled handpiece.

Figure 13-11. Microsaws Touchscreen



Figure 13-12. Finger-Controlled Microsaw Safe Mode



FINGER-CONTROLLED MICROSAW SAFE MODE

When the handpiece is in safe mode, it is inoperable until the safety is turned off. The Speed control box on the Microsaws touchscreen displays SAFE when the handpiece is the active handpiece and in safe mode. (Figure 13-12)

Switch the device to safe mode any time it is attached to the console, but not currently being used.

When more than one handpiece is attached to the console, use the safety switch of an inactive handpiece to activate that handpiece and make it ready for use.

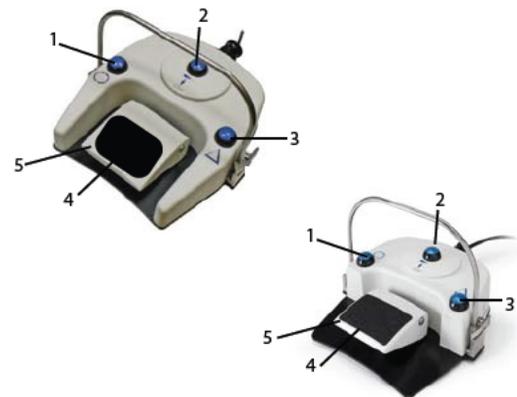
MICROSAW MULTIFUNCTION FOOTPEDAL CONTROLS

Important: By default, press each button on the footpedal for at least 100 mS for the selection to become active. Use the IPC Settings screen to change the default value.

To use the multifunction footpedal (Figure 13-13) to control the handpiece, do the following:

- To start or adjust the speed of a handpiece in variable mode, press the pedal.
- To toggle between the start/stop mode and variable-speed mode, press the control button. 
- To change the active handpiece, press the handpiece button.
Note: You can switch between finger-controlled handpieces by pressing the finger lever on the handpiece. 

Figure 13-13. Multifunction Footpedal



- | | |
|--------------------|---------------------------|
| 1 Mode button | 4 Slip-resistant foot pad |
| 2 Handpiece button | 5 Foot pedal |
| 3 Control button | |

MICROSAWS CLEANING AND STERILIZATION INSTRUCTIONS

Refer to document M000030A231 in the Cleaning and Sterilization section.

MICROSAWS TECHNICAL SPECIFICATIONS

Size	Reciprocating (ES200): 2.3 cm W x 20.3 cm L Sagittal (ES300): 2.3cm W x 17.3 cm L Oscillating (ES100): 2.3 cm W x 19.8 cm L Finger-Controlled Reciprocating (ES210): 2.3 cm W x 3.2 cm H x 20.3 cm L Finger-Controlled Sagittal (ES310): 2 3 cm W x 3.2 cm H x 17.8 cm L Finger-Controlled Oscillating (ES110): 2.3 cm W x 3 2 cm H x 21.0 cm L
Weight	Reciprocating (ES200): 300 g Sagittal (ES300): 250 g Oscillating (ES100): 300 g Finger-Controlled Reciprocating (ES210): 320 g Finger-Controlled Sagittal (ES310): 300 g Finger-Controlled Oscillating (ES110): 320 g
Speed	All Reciprocating: 1400-14000 cpm All Sagittal: 2000-20000 cpm All Oscillating: 1600-16000 cpm

Duty Cycle

≤ 20°C Ambient (one cut period = 20 seconds on / 20 seconds off)

Reciprocating: ≤ 15 cut periods¹

Sagittal: ≤ 6 cut periods²

Oscillating: ≤ 4 cut periods³

> 20°C Ambient (one cut period = 20 seconds on / 40 seconds off)

Reciprocating: ≤ 5 cut periods⁴

Sagittal: ≤ 6 cut periods⁵

Oscillating: ≤ 3 cut periods⁶

Time for cool down after maximum number of cut periods listed above: 25 minutes.

¹ 5 periods with Light Force (0.8 Lbf), 5 periods with Medium Force (2.1 Lbf), 5 periods with Heavy Force (3.9 Lbf)

² 2 periods with Light Force (0.8 Lbf), 2 periods with Medium Force (1.5 Lbf), 2 periods with Heavy Force (3.0 Lbf)

³ 1 period with Light Force (0.7 Lbf), 2 periods with Medium Force (1.5 Lbf), 1 period with Heavy Force (2.6 Lbf)

⁴ 1 period with Light Force (0.8 Lbf), 2 periods with Medium Force (2.1 Lbf), 2 periods with Heavy Force (3.9 Lbf)

⁵ 2 periods with Light Force (0.8 Lbf), 2 periods with Medium Force (1.5 Lbf), 2 periods with Heavy Force (3.0 Lbf)

⁶ 1 period with Light Force (0.7 Lbf), 1 period with Medium Force (1.5 Lbf), 1 period with Heavy Force (2.6 Lbf)

POWEEASE DRIVER

DEVICE DESCRIPTION

The IPC POWEEASE System is specifically designed for drilling, tapping, and driving screws during spine surgery.

The IPC POWEEASE system consists of a POWEEASE Driver (Figure 14-1) that is powered by the IPC, along with the following POWEEASE driver compatible working end instruments:

- Taps
- Drill Bits
- Screw Drivers
- Rod Cutter
- Post Cutter
- Set Screw Break-off Instrument (SSBO)

The POWEEASE System and accessories are compatible with the following implant systems:

- CD HORIZON SOLERA Spinal System
- TSRH 3Dx Spinal System

ASSEMBLE THE IPC

Important: The manual start/stop button on the IPC console (Figure 1-2) does not function with the POWEEASE driver.

Note: The POWEEASE driver does not use the IPC pump system. The pumps are available for use with other accessories requiring irrigation or cooling.

1. Verify the wheels are locked on the IPC cart.
2. Inspect all components for damage and determine if the system is ready for use.
3. Mount the IPC and irrigation/collant bags on the IV pole.

Important: Mount the irrigant and coolant bags above the IPC to ensure adequate flow.
4. Plug the IPC into the power source. Position the IPC so that it does not obstruct the power source for the purpose of disconnecting the Main voltage by the power cord.
5. Locate the POWEEASE connection port on the IPC connector panel (Figure 14-2) and insert the connector from the POWEEASE driver.
6. If using the NIM-Eclipse with the IPC POWEEASE, assemble the IPC POWEEASE and the NIM-Eclipse system.
7. Turn on the IPC and do the following:
 - Verify the system passes the self-test.
 - Verify the POWEEASE screen appears on the IPC monitor.
8. Confirm the IPC POWEEASE System Operation.

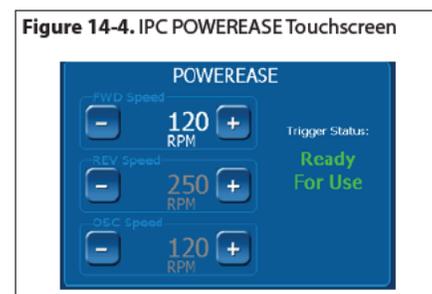
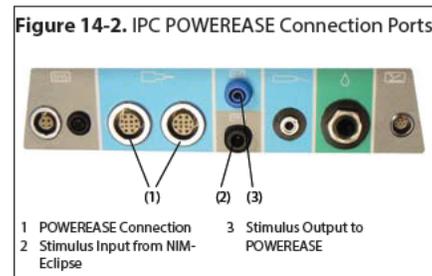
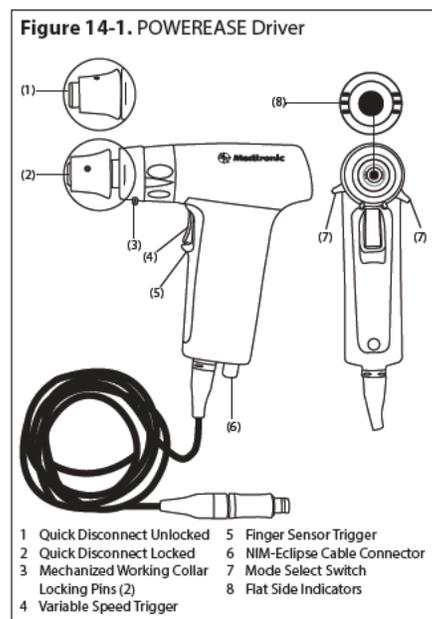
IPC POWEEASE MODE SELECT SWITCH

Use the mode select switch to change the handpiece from forward, reverse or oscillate when the handpiece is the active handpiece. When the handpiece is the inactive handpiece, use the mode select switch to activate the handpiece.

IPC POWEEASE SYSTEM OPERATION

1. On the POWEEASE driver, rotate the mode select switch (Figure 14-3) to **F** (forward).
2. On the IPC touchscreen, verify the following:
 - The FWD Speed box is active and the default speed appears in white.
 - The Trigger Status is Ready For Use.

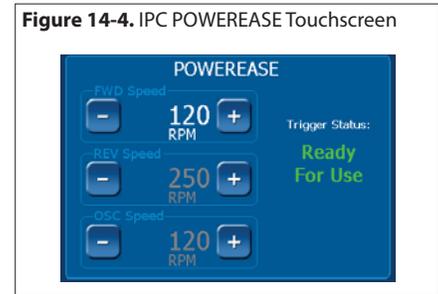
Note: If the trigger status is Locked, release and press the trigger to disengage the lock. Contact Customer Service if the trigger status does not change to Ready For Use.
3. On the POWEEASE driver, touch the trigger (Figure 14-4) and verify the speed in the FWD Speed box on the IPC touchscreen turns green.
4. On the POWEEASE driver, press the trigger and verify the following:
 - The speed increases as you increase pressure on the trigger.
 - The speed in the FWD Speed box on the IPC touchscreen turns yellow.
5. Remove finger from the POWEEASE driver trigger and verify the following:
 - The driver rotation stops.
 - The speed in the FWD Speed box on the IPC touchscreen turns white.
6. Repeat steps 1 through 5 for the reverse (R) and oscillate  modes.



POWEEASE TOUCHSCREEN CONTROLS

To adjust the maximum speed of the driver using the IPC POWEEASE touchscreen (Figure 14-4), in the relevant speed control box, press the plus button to increase maximum speed or minus button to decrease maximum speed.

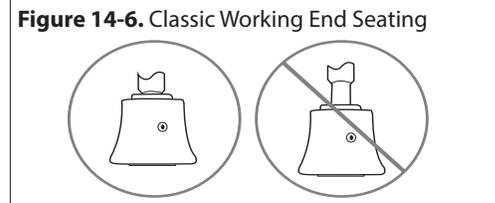
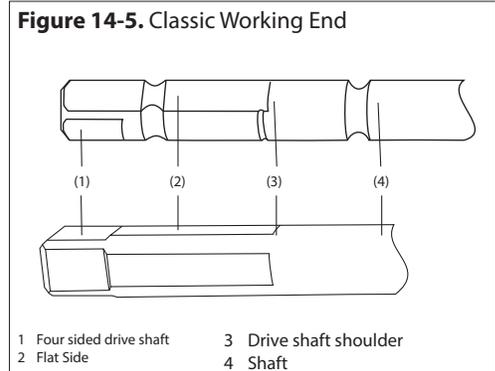
- Variable speed control:
 - FWD Speed: variable adjustment from 10 to 250 rpm in increments of 10 rpm.
 - REV Speed: variable adjustment from 10 to 250 rpm in increments of 10 rpm.
 - OSC Speed: variable adjustment from 10 to 200 rpm in increments of 10 rpm.
- IPC POWEEASE touchscreen color codes:
 - White: active speed at idle, finger off trigger.
 - Green: active speed at idle, finger on trigger.
 - Yellow: active speed in use.
 - Gray: inactive
- Trigger Status:
 - Ready For Use: Device is ready for use.
 - Locked: In the case of a trigger control anomaly, the trigger is locked until the anomaly has cleared and use of the POWEEASE may resume. To disengage the lock, release and press the trigger. Contact customer service if the device does not return to Ready For Use.



CLASSIC WORKING END ASSEMBLY AND OPERATION

NOTE: Please see the POWEEASE System Working Ends User's Manual and IFU for a complete listing of compatible working ends and further details regarding their proper use. Contact customer service or your sales representative for the most up-to-date version of the package insert or manual.

1. On the POWEEASE driver, pull back on and hold the quick disconnect to unlock the collet (Figure 14-1, 1).
 - NOTE:** The quick disconnect must be held in the unlocked position when inserting or removing tools.
2. Insert the classic working end drive shaft (Figure 14-5, 1) into the collet until fully seated. Fully seated is on or near the drive shaft shoulder (Figure 14-6).
 - NOTE:** If using a two sided shaft, align the flat sides on the drive shaft with the marks on the collet (Figure 14-1, 8).
3. Release the quick disconnect to place the working end in the locked position (Figure 14-1, 2).
4. To set the mode on the POWEEASE driver, rotate the mode select switch (Figure 14-3) to **F** (forward), **R** (reverse) or  (oscillate)
 - Place mode select switch in forward to drill, tap or insert screw.
 - Place mode select switch in reverse to back out drill, back out tap or back out screw.
 - Place mode select switch in oscillate to lock the tool in its current position. Refer to POWEEASE Driver Electronic Ratcheting for additional information.
5. To adjust the speed of the driver, increase pressure to increase speed or decrease pressure to decrease speed.
 - NOTE:** The IPC touchscreen displays the maximum speed for the selected mode.
6. Reverse procedure to remove the classic working end accessory.



POWEEASE Driver Electronic Ratcheting

Ratcheting is intended to permit manual motion in one direction only.

- FWD Mode: With the trigger released, the handpiece functions as a ratchet allowing the handpiece to be turned in a clockwise direction while ratcheting in a counter clockwise direction.
- REV Mode: With the trigger released, the handpiece functions as a ratchet allowing the handpiece to be turned in a counter clockwise direction while ratcheting in a clockwise direction.
- OSC Mode: With trigger released, the handpiece locks the tool in its current position, and the surgeon can manually rotate the handpiece in a clockwise or counter-clockwise direction.

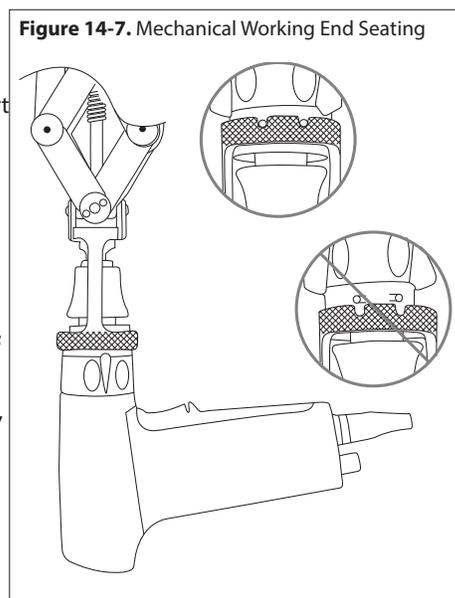
POWEEASE Ratchet Test

1. Load a drill, tap or screwdriver in the collet. Refer to Classic Working End Assembly and Operation for details.
2. On the POWEEASE driver, set the mode select switch to **F** (forward, Figure 14-3).
3. Hold the POWEEASE driver shaft firmly and verify the following:
 - Important: DO NOT** hold by the tool. **DO NOT** touch the trigger sensor.
 - The driver ratchets when rotated counter clockwise.
 - The driver does not ratchet when rotated clockwise.
4. Set the mode select switch to **R** (reverse) and verify the following:
 - The driver ratchets when rotated clockwise.
 - The driver does not ratchet when rotated counter clockwise.
5. Set the mode select switch to oscillate  and verify the driver does not ratchet when rotated clockwise or counter clockwise.

MECHANIZED WORKING END ASSEMBLY AND OPERATION

NOTE: Please see the POWEREASE System Working Ends User’s Manual and IFU for a complete listing of compatible working ends and further details regarding their proper use. Contact customer service or your sales representative for the most up-to-date version of the package insert or manual.

1. On the POWEREASE driver, pull back on and hold the quick disconnect (Figure 14-1, 1) to unlock the collet.
 - Note:** The quick disconnect must be held in the unlocked position when inserting or removing tools.
2. Align the slots on the working end collar with the mechanized working collar locking pins (Figure 14-7).
3. To set the mode on the POWEREASE driver, rotate the mode select switch (Figure 14-3) to **F** (forward), **R** (reverse) or  (oscillate).
 - Place the mode select switch in forward to cut/shear implantable rods, cut vertical posts, break set screws.
 - Place the mode select switch in reverse to open the tool.
 - Oscillate is intended as a rotational lock for classic working ends and has no function with mechanized working ends. However, if the trigger is pulled, the tool shaft will oscillate 60° clockwise and counter-clockwise.
4. To adjust the speed of the driver, increase pressure to increase speed or decrease pressure to decrease speed.
 - NOTE:** The IPC touchscreen displays the maximum speed for the selected mode.
5. Reverse this procedure to remove the classic working end accessory.



POWEREASE CLEANING AND STERILIZATION INSTRUCTIONS

Refer to document 68E4189 in the Cleaning and Sterilization section.

POWEREASE DRIVER TECHNICAL SPECIFICATIONS

POWEREASE Driver 234000

Size	175mm x 160mm x 42mm
Weight	900g (1200g including cable)
Speed	0 to 250 rpm (variable)
Torque	7Nm
Cable Length (Driver)	4.5m
Cable Length (IPC to Patient Interface Box)	4.5m
Cable Length (Driver to IPC)	4.5m
Duty Cycle for Applied Part	For continuous operating room temperatures up to 33°C, the POWEREASE driver rates for continuous operation. For normal operating room temperatures (below 25°C), the POWEREASE driver rates for continuous operation.

IPC POWEREASE WITH THE NIM-ECLIPSE SYSTEM

Important: Do not use the IPC POWEREASE - NIM-Eclipse System with multiple portable socket-outlet or extension cord.

The POWEREASE System is equipped with two cables that connect the IPC to the NIM-Eclipse. Wires within the POWEREASE make contact with the uncoated tool and carry stimulating current to the tool’s tip for nerve monitoring. Contact to your local NIM-Eclipse representative for more information.

Important: Only taps, screws and drills are available for nerve stimulation.

When the IPC POWEREASE driver is used in combination with the NIM-Eclipse, the combination creates a medical electrical system. The system components are as follows:

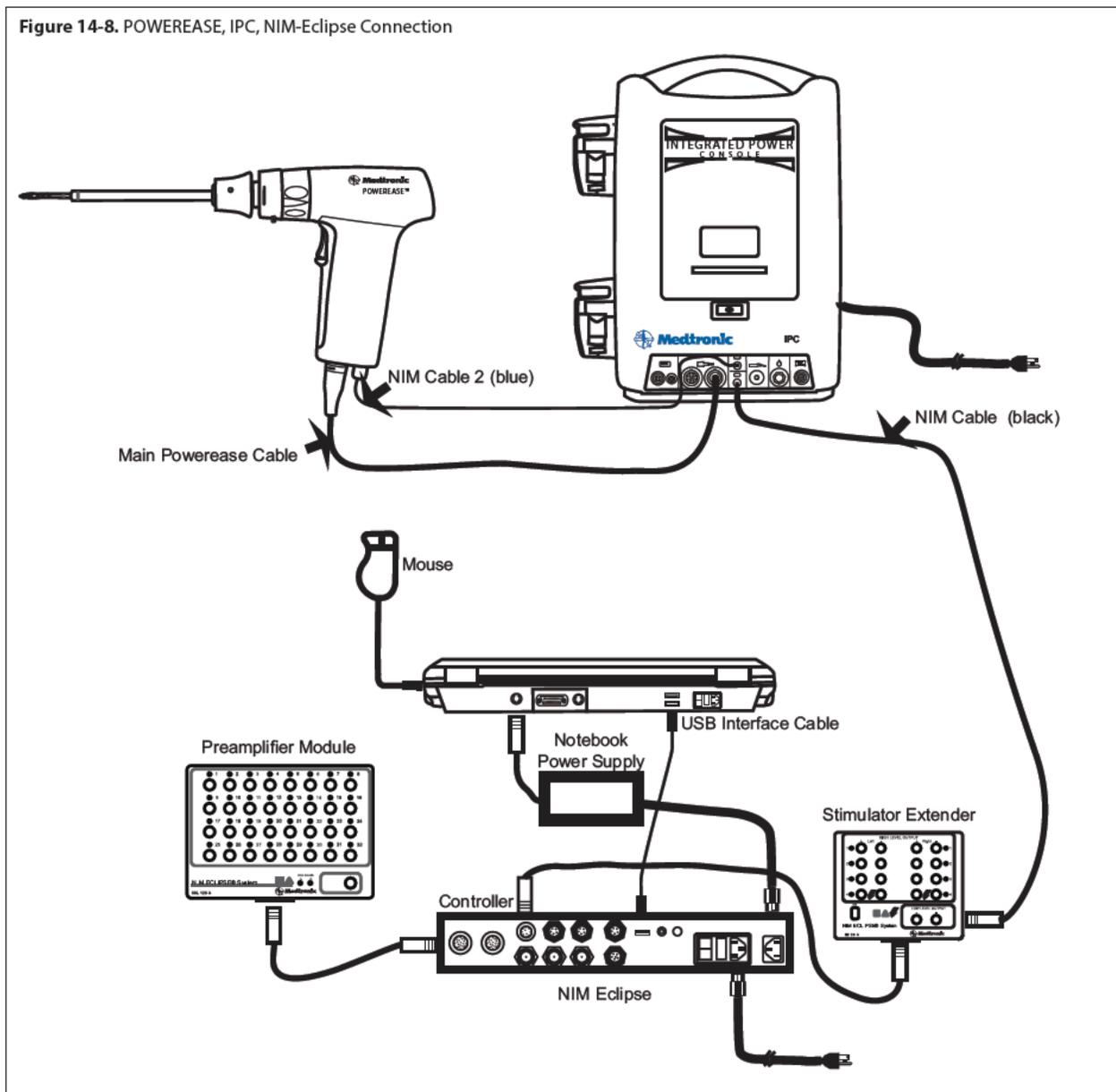
- IPC
- POWEREASE with accessories
- NIM-Eclipse
- NIM cable set

Assemble IPC POWEREASE and NIM-Eclipse System

Important: Refer to the NIM-Eclipse Users Guide for set up and use of the NIM-Eclipse system, including the laptop computer.

Warnings:

- Only the POWEREASE handpiece with its accessories are intended to be used within the patient environment. The NIM-Eclipse cannot be used in the patient vicinity (1.5 meter radius from patient).
 - Do not touch the patient and the enclosure parts of the NIM-Eclipse simultaneously.
 - Dispose of the single-use NIM cables after each procedure.
 - Any peripheral devices connected to the system must meet IEC60601-1 requirements. Consult with your biomedical engineering department to determine if the external devices meet this requirement.
1. Assemble the IPC and confirm IPC POWEREASE system operation.
 2. Assemble the NIM-Eclipse according to the instructions in the NIM-Eclipse Users Guide. Verify the laptop computer power cord is plugged into the NIM-Eclipse 945ECLC Controller.
 3. On the NIM-Eclipse stimulator extender, connect one end of the black NIM cable to the Stimulus Output connection port (Figure 14-8).
 4. On the IPC connector panel, connect the other end of the black NIM cable to the Stimulus Input connection port (Figure 14-8).
- Important:** Route the wire so that it does not interfere with operating room personnel.
5. Connect one end of the blue NIM cable to the Stimulus Output IPC connector panel (Figure 14-8).
 6. Connect the other end of the blue NIM cable to the NIM Stim Input on the POWEREASE driver.
- Important:** Route the wire so that it does not interfere with operating room personnel.



TRUBLESHOOTING

For any troubleshooting items not corrected by the actions below, contact Customer Service.

IPC and Multifunction Footpedal

Issue	Possible Cause	Action
Pump(s) does not run.	Failed internal components.	Contact Customer Service
	Moisture in cable conflicts with handpiece recognition.	Run a dry cycle when sterilizing.
Little or no irrigation flow.	Tubing Set improperly seated in pump.	Reposition tubing in pump, verify pump lid is fully closed with the fluid flow from left to right.
	Tubing is pinched or kinked.	Check tubing at side of pump, see Irrigation/Coolant Pumps Check remaining tubing for pinched or kinked areas, if necessary replace tubing.
	Tubing clamps are restricting flow.	Set tubing clamps in "open" position.
	Irrigation flow rate setting low.	Adjust irrigation flow rate.
	Irrigator obstructed.	Replace irrigator.
Pump stall error.	Tubing set improperly placed in pump.	Reposition tubing in pump, verify pump lid is fully closed with the fluid flow from left to right.
	Tubing is pinched or kinked.	Check tubing is not pinched or kinked on side of pump (see section on "Irrigation/Coolant Pumps").
Console default parameters incorrect.	Moisture in cable conflicts with handpiece recognition.	Run a dry cycle when sterilizing.
Handpiece connected but console reads "Connect Handpiece"		
Handpiece connected but console displays incorrect handpiece.		
Console does not power up.	Power cord not properly connected.	Connect power cord.
	No power.	Check power available (i.e. power strip is on, circuit breaker is closed etc.)
	Power Inlet Fuses blown.	Replace fuses with 5.00 A, 250V, time delayed fuses (P/N 11270066 Fuse Kit 1898125)
	Failed internal components.	Contact Customer Service.
Power switch light is on but Touchscreen does not come on.	Failed internal components.	Contact Customer Service.
Console does not power down.	Power switch failure.	Unplug power cord, Contact Customer Service.
Touchscreen does not respond.	Screen gasket displaced or failed internal components.	Contact Customer Service.
Touchscreen does not work properly.	Touchscreen not calibrated.	Calibrate Touchscreen.
Console displays wrong handpiece / motor type.	Console misidentified the handpiece / motor.	Disconnect and reconnect the motor cable. Turn console off then on. Change motor, motor cable, or console to isolate the problem.
	Moisture in cable conflicts with handpiece recognition.	Run a dry cycle when sterilizing.
Foot control unit buttons or pedal does not respond.	Incorrect use.	Press and hold buttons for at least 1 second, wait for console confirmation beep.
	Top button does not respond.	One (1) handpiece connected (top button has no function with 1 handpiece connected).
	Connector not fully inserted.	Disconnect and reconnect the FCU cable connector. Try different FCU or console to isolate the problem.
	Internal component failure.	Contact Customer Service.
Handpiece fails to rotate	Failed footswitch.	Disconnect footswitch, use manual start/stop rocker switch on rear of console.
	Failed handpiece motor or motor driver.	Contact Customer Service.

XOMED Blades or Burs

Issue	Possible Cause	Action
Appears to be damaged or defective.	Damaged or defective.	Remove and replace.
Tool vibrates excessively, abnormal noise movement.	Tool is not firmly seated.	Microdebriders, pull back locking collet and re-seat the tool. Visao, unlock collar, check/re-seat notch, lock collar.
No suction.	Blade opening is obstructed.	Use stylet to clear blade. Remove blade from surgical site and submerge the blade tip in sterile water with suction connected to the handpiece to evacuate the obstruction.
	Tubing obstructed.	Remove and inspect suction tubing, and if obstructed, remove obstruction, reconnect tubing.
Tool is leaking irrigant.	Tool not seated correctly in collet.	Check for proper tool insertion by pulling back locking collet, and re-seating tool.
	Low or no suction.	See Possible Cause, No Suction.
Tool wobbles in handpiece.	Tool wobbles in handpiece.	Reduce handpiece operating speeds. Use tools that are rated for the console speed selected. If necessary, use bur guard with burs medium, long and X-long. Operate handpiece at 50% of full speed for medium, long and X-long burs. Select a new tool.

Legend EHS, Legend EHS Stylus and Indigo Motors

Issue	Possible Cause	Action
Motor is too hot to touch/hold	Inadequate cool down period following sterilization. Attachment transferring heat to the motor. Heavy side loading during dissection. Inadequate irrigation.	Motor must be allowed to cool down following steam sterilization. Switch attachments to determine whether the heat is being generated by the motor or the attachment. Discontinue use and rest the motor by using it intermittently or wrap the motor with a moist sterile towel. Ensure adequate irrigation to surgical site during bone dissection.
Tool is difficult to remove from attachment	Aging of attachment Use of reprocessed tools Use of an unauthorized refurbisher Improper cleaning	Contact Customer Service. Clean the attachment thoroughly according to the instructions in this manual. Change tool.
Attachment will not seat properly on the motor	Motor collet flats are not aligned.	Use the Legend motor wrench to rotate the flat closest to the motor case until its marker is aligned with the marker on the flat farthest away from the motor case.
Motor does not run.	Cables not properly connected. Speed setting is too low. Attachment not properly installed and locked onto the motor. Internal failure of motor and/or console. Foot control not properly functioning. Cables damaged	Ensure motor and foot control cables are properly connected. Ensure that a speed greater than 10000 rpm (EHS) or 3000 rpm (Stylus) is selected. Remove and reinstall the attachment and dissecting tool to ensure proper installation. Change motor or console to isolate the problem. Check for obstruction under the foot pedal. Check cables for cracks, splits, or bent connector pins.

Issue	Possible Cause	Action
Motor with attachment rotates, but an abnormal noise is heard.	Bearings are worn.	Change the attachment to isolate the location of the problem.
	Poor electrical connection	Check all connections from electrical source to console. Ensure motor and foot control cables are properly connected.
	Internal failure of motor, console, or cable.	Change motor, console, or cable to isolate the failing component.
	Attachment not properly installed.	Remove and reinstall the attachment and dissecting tool.

Stylus Touch Motors

Issue	Possible Cause	Action
Motor does not run.	Finger switch not reaching maximum speed.	Check that the control lever ring is properly seated in one of the four possible positions.
	Finger switch not responding. Safety switch in safe mode.	Place switch in run mode.
	Finger control damaged.	Contact Customer Service.

Legend EHS, Legend EHS Stylus and Stylus Touch Attachments and Telescoping Tubes

Issue	Possible Cause	Action
Attachment or Telescoping Tube has uncomfortable temperature to touch/hold	Heat from worn attachment/tube bearings	DO NOT use. Try another attachment/tube. Telescoping Tubes are multi-use disposable. If problem is resolved with a new Telescoping Tube, discard the over-heated tube.
	Attachment/tube unclean due to improper cleaning procedures	Check that appropriate cleaning procedures are being followed.
	Heavy side loading during dissection	Discontinue use and rest the attachment by using intermittently, try another identical attachment or wrap the attachment interface with a moist sterile towel.
Attachment/telescoping tube is bent, loose, damaged or missing a component	Attachment mishandled, failed due to extended use or excessive force applied during use	DO NOT use. Dispose of telescoping tube. Telescoping Tubes are multi-use disposable. Contact Customer Service.
Color band on Attachment/Telescoping Tube fades or discolors	Incorrect cleaning or sterilization method	Use nomenclature markings on the attachment to match with a corresponding dissecting tool or Contact Customer Service.
	Use of chlorine based or corrosive agents Aging	Telescoping Tubes are multi-use disposable.
Attachment has excess lubrication	Over lubrication during cleaning process	Visually inspect and wipe excess lubrication.
Footed attachment has a component missing from leg/foot area or foot is bent	Attachment damaged by dissecting tool drilling out part or all of leg/foot area.	DO NOT use. Contact Customer Service.
	Bend caused by incorrect use.	
16-MF contra-angle attachment is overheating	The contra-angle attachment operates by a set of internal gears to engage the drive shaft. It is normal for some heat to be generated approximately 2 cm from the distal end of the attachment and at the right of the angle head.	If heat continues or is excessive, Contact Customer Service.
Smoke is generated by the attachment or motor	Attachment is not in the locked position.	Make sure the attachment is in the locked position.

Legend EHS, Legend EHS Stylus and Stylus Touch Tools

Issue	Possible Cause	Action
Tool wobbles	<p>A non-Legend tool is being used.</p> <p>Worn attachment or tube bearings.</p> <p>Attachment/tube and tool are not compatible.</p> <p>Motor is damaged.</p> <p>Tool's size and geometry may contribute to wobbling at certain speeds.</p>	<p>Replace with a Legend tool.</p> <p>Try another attachment or tube to isolate the location of the problem.</p> <p>If the attachment is failing, Contact Customer Service</p> <p>If the tube is failing, dispose of it and use a new tube.</p> <p>Match color code on the tool packaging to the color code on the attachment/tube.</p> <p>Contact Customer Service.</p> <p>Adjust the speed by changing the pressure setting or foot/finger control. Do not use if wobbling persists. Change tool.</p>
Tool vibrates excessively	<p>Tool's size and geometry may create excessive vibration at certain speeds.</p>	<p>Adjust the speed.</p> <p>Change tools.</p>
Tool dull	<p>Extended use</p> <p>Reprocessed tool was used</p> <p>Incorrect geometry</p>	<p>Change to a new tool</p> <p>Contact Customer Service.</p>
Tool will not seat properly in the motor or attachment collet	<p>Debris in collet of attachment or motor.</p> <p>A non-Legend tool is being used.</p>	<p>Clean the attachment or motor thoroughly according to the instructions in this manual.</p> <p>If cleaning does not correct the problem, Contact Customer Service.</p> <p>Replace with a Legend tool.</p>

ERROR CODES

Code #	Title	Cause	Description
1	MCB does not report that it booted within 5 seconds of AI telling it to start and subsequent reattempts fail.	System Error	Power off. Wait 10 seconds. Power on. If error persists, call Customer Service.
2	NOT USED	NOT USED	NOT USED
3	UI-MCB Com Failure - Max resends exceeded	System Error	Power off. Wait 10 seconds. Power on. If error persists, call Customer Service.
4	UI-MCB Com Failure - Get answer failed		
5	UI-MCB Com Failure - No status message received		
6	UI-MCB Com Failure - Serilization ID error		
7	UI-MCB Com Failure - Timeout exception		
8	UI-MCB Com Failure - Variable not recognized		
9	Pump 1 stalled (no transitions on opto sensor)	Pump #1 stalled	Check tubing connection.
10	Pump 2 stalled (no transitions on opto sensor)	Pump #2 stalled	Check tubing connection.
11	Unrecognized/damaged handpiece plugged in on port 1 (first 12 pin)	Handpiece	Unplug handpiece and plug back in. If error persists, replace handpiece.
12	Unrecognized/damaged handpiece plugged in on port 2 (second 12 pin)		
13	Unrecognized/damaged handpiece plugged in on port 3 (4 pin)		
14	Unrecognized/damaged handpiece plugged in on port 4 (Skeeter)		
15	Handpiece stalled	Handpiece stalled	Check accessory
16	MCB motor overcurrent detected.	Motor overcurrent	Unplug handpiece and plug back in. If error persists, replace handpiece.
17	Unrecognized/damaged multifunction footpedal plugged in	Footpedal Connection error	Unplug footpedal and plug back in. If error persists, replace footpedal or switch to manual control.
18	Damaged handpiece or finger lever base out of position.	Finger Control error	Stylus Touch - A finger control error has been detected. Check that the control lever ring is properly seated in one of the four possible positions. If error persists contact Medtronic support. Press OK to use alternate control method. Triton/Powerase - Please check mode select switch to ensure a mode has been selected by rotating mechanism until it rests in a detent. If error persists contact Medtronic support.
19	UI self test failure - culture (language) registry entry	Self Test Failed	Power off. Wait 10 seconds. Power on. If error persists, call Customer Service.
20	UI self test failure - sector configuration registry entry		
21	UI self test failure - corrupt usage data file or unable to create usage data file		
22	NOT USED	NOT USED	NOT USED
23	MCB non-specific self test failure	Self Test Failed	Power off. Wait 10 seconds. Power on. If error persists, call Customer Service.
24	MCB self test failure - port 1		
25	MCB self test failure - port 2		
26	MCB self test failure - port 3		
27	MCB self test failure - port 4		
28	MCB self test failure - bridge transitor 1 shorted		
29	MCB self test failure - bridge transitor 2 shorted		
30	MCB self test failure - bridge transitor 3 shorted		
31	MCB self test failure - bridge transitor 4 shorted		
32	MCB self test failure - bridge transitor 5 shorted		
33	MCB self test failure - bridge transitor 6 shorted		
34	MCB self test failure - A/D converter		
35	MCB self test failure - motor error		
36	MCB self test failure - 3.3 volt supply		
37	MCB self test failure - 12 volt supply		
38	MCB self test failure - 48 volt supply		
39	MCB self test failure - FCU port		

CLEANING AND STERILIZATION

Reprocessing Instructions are subject to change without notice. Refer to manuals.medtronic.com for current reprocessing instructions.

POST-OPERATIVE INSTRUCTIONS

Disconnect Accessory Cable from Console

To disconnect non-silicone multi-pin cables from the console, push the cable towards the console and then pull out by the lock ring.

Note: Silicone insulated multi-pin and single pin cable connectors do not have a lock ring (1). Remove these types of cable connectors straight from the connector panel.

Warning: After disconnecting insulated connectors (see W79) from the console, connectors that have debris under the insulator must be cleaned according to Cleaning and Sterilization instructions. If debris is still present after cleaning and sterilization, return for warranty servicing.



Clean the Multifunction Footpedal

Important: If debris is present under the footpedal's boot, return for warranty service.

DO NOT immerse or sterilize the footpedal.

DO NOT use alcohol, other solvents or abrasive cleaners.

1. On the slip resistant foot pad ONLY, spray a neutral enzymatic detergent, pH 6.0-8.0, or a phenol based disinfectant, mixed according to manufacturer's instructions.
2. Leave the solution on the foot pad for approximately 10 minutes.
3. Dampen a cloth with a neutral enzymatic detergent, pH 6.0-8.0, or a phenol based disinfectant, mixed according to manufacturer's instructions.
4. Wipe the footpedal with the damp cloth until visually clean.
5. Dry the unit with a clean, non-abrasive cloth.



Medtronic

Reprocessing Instructions Triton Electric High-Torque Handpiece

Reprocessing Instructions (Per ISO17664)
Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at manuals.medtronic.com.
M000030A322 B

Warnings and Precautions	<ul style="list-style-type: none"> Do not soak/submerge devices. Do not use ultrasound to clean Triton High-Torque Handpiece. Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hydroxide, formic acid, or solutions containing glutaraldehyde. Allow an adequate cooling period after steam sterilization. The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance. 				
Limitations	Verify functionality prior to re-use, by connecting the handpiece to the IPC and pressing the trigger. Verify that the drive shaft rotates.				
Point of Use	Disconnect device from the IPC. Remove and discard disposables.				
Containment and Transportation	It is recommended that devices are reprocessed as soon as is practical following use.				
Preparation for Decontamination	Disconnect device from the IPC. Remove and discard disposables.				
Cleaning: Automated (Do NOT use ultrasonic washer)	Handpiece and Attachments				
	<ul style="list-style-type: none"> Prior to placing devices in the automated washer, manually rinse under tap water, until no visible soil is noticed. Move any movable parts back and forth to allow water to reach hard-to-rinse areas. Transfer the devices into the washer for processing. Place the devices in the washer to facilitate drainage. Verify that devices are visually clean after automated cleaning. 				
	Recommended Washer Cycle	Phase	Recirculation Time	Water Temperature	Detergent Type and Concentration
		Pre-Wash	2 minutes	Cold tap water	not applicable
		Wash	5 minutes	66°C	Neutral enzymatic detergent, pH 6.0-8.0
	Rinse	1 minute	Hot tap water	not applicable	
Cleaning: Manual	Handpiece and Attachments				
	<ol style="list-style-type: none"> Rinse the entire device, including cable, thoroughly under running water. Wipe all external surfaces of the device and cable with a cloth dampened with a neutral enzymatic detergent pH 6.0-8.0 (henceforth referred to as "cleaning solution"). Scrub the device thoroughly with a soft bristled brush that has been dampened with the cleaning solution, paying close attention to rough surfaces, crevices, and difficult to reach areas. Move any moveable parts, to allow the solution to reach all areas. Clean central cannulation shaft of the handpiece with a cleaning brush (P/N 120-028-1 or equivalent) dampened with the cleaning solution. Insert the cleaning brush into the cannulation from the front and make at least 6 passes with the brush. If residual soil is seen on the cleaning brush in between strokes, rinse it off in the cleaning solution. Repeat the step above from the back side of the handpiece. Flush approximately 30 mL of cleaning solution from a syringe into the central cannulation shaft. Flush approximately 30 mL of cleaning solution from a syringe into the trigger and Forward / Reverse switch, while moving moveable parts. Repeat the flushing in steps 7 and 8, using water instead of cleaning solution. Rinse the entire device under running water. Move any moveable parts, to allow the water to reach all areas. Also, allow water to thoroughly clean the central cannulation shaft. Rinse until there is no visible evidence of soil or debris. Dry the entire device with a towel. 				
	Sagittal and Reciprocating Saw Attachments				
	<ol style="list-style-type: none"> Rinse the entire device thoroughly under running water. Wipe all external surfaces of the device with a cloth dampened with a neutral enzymatic detergent pH 6.0-8.0 (henceforth referred to as "cleaning solution"). Scrub the device thoroughly with a soft bristled brush that has been dampened with the cleaning solution, paying close attention to rough surfaces, crevices, and difficult to reach. Ensure to brush the blade opening, the gaps/details between and around the blade jaws. Dip the distal end of the saw body (up to approximately 1.25" from the distal end) into cleaning solution and agitate it for 10-15 seconds. Flush approximately 30 mL of cleaning solution from a syringe into the blade opening and the gaps and details between and around two jaws. Repeat the flushing using water, instead of cleaning solution. Repeat the previous step one more time. Rinse the device under running water. Allow water to thoroughly rinse the gaps and details between and around blade jaws. Rinse until there is no visible evidence of soil or debris. Dry the device with a towel. 				
Disinfection	Follow hospital procedures.				
Packaging	For sterilization, place devices in instrument tray. Devices may be unwrapped, or wrapped with up to two layers of 1-ply polypropylene wrap				
Sterilization (Temperatures are minimum required, times are minimum required)	Steam Sterilization				
	Cycle	Gravity	Pre-Vac	Pre-Vac (FR/WHO)	Pre-Vac (UK)
	Temperature	132°C	132°C	134°C	134°C
	Time	25 minutes	4 minutes	18 minutes	3 minutes
	Drying	30 minutes	20 minutes	30 minutes	22 minutes
	STERRAD	Do not use low temperature hydrogen peroxide gas plasma sterilization due to lumen internal diameter and length restrictions.			
	STERIS	Not applicable.			
	100% EtO Sterilization Parameters				
	Preconditioning	51-59°C, 70 ±5% relative humidity, 30 min.			
	Sterilization	Temperature	51-59°C		
		Relative Humidity	70 +/- 5%		
		Ethylene oxide concentration	725 +/- 25 mg/L		
Gas exposure time (full-cycle)		4 hours			
Aeration		51-59°C, 18 hours			
Maintenance, Inspection and Testing	<ul style="list-style-type: none"> Inspect devices for any damage before and after each use. If damage is observed, do not use the device until it is repaired. Verify functionality prior to re-use. 				
Storage	Store in a clean, dry area.				
Additional Information	None				

Note: The Pre-Vac (FR/WHO) and Pre-Vac (UK) sterilization cycles are not considered by the United States Food and Drug Administration (US FDA) to be standard sterilization cycles. Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).

Note: The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

Note: All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis. NHS Estates HTM 2010 Parts 4 & 6: Appendix 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies refers to a TSE decontamination cycle using a steam autoclave at a temperature of 134-137°C for a single cycle of 18 minutes or repeated for a total of six 3-minute cycles.

**Medtronic**

Reprocessing Instructions Indigo High-Speed Otologic Drill

Reprocessing Instructions (Per ISO17664)
Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at manuals.medtronic.com.
68E4187 B

Warnings and Precautions	<ul style="list-style-type: none"> Do not soak/submerge devices. Do not use ultrasound to clean devices. Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde. The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance. Allow an adequate cooling period after steam sterilization. 				
Limitations	Verify functionality prior to re-use.				
Point of Use	This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse.				
Containment and Transportation	It is recommended that devices are reprocessed as soon as is practical following use.				
Preparation for Decontamination	Follow hospital procedures.				
Cleaning: Detergent	Use a cleaning agent that is suitable for use on aluminum surfaces. A neutral enzymatic to mild alkaline agent (pH 6.0 to 10.5) is preferred. If a washer-disinfector is used, see the instructions supplied with the washer-disinfector machine to select the recommended cleaning agent.				
Cleaning: Automated (Do NOT use ultrasonic washer)	<ul style="list-style-type: none"> Remove devices from instrument trays before placing into washer baskets. Prior to cleaning, cover the drill cable connector end with Handpiece Cleaning Cap, catalog no. 3318520. Orient devices following recommendations of the washer/disinfector manufacturers. After completion of the cleaning steps, remove Handpiece Cleaning Cap or other protective components prior to sterilization. 				
	Recommended Washer Cycle	Phase	Recirculation Time	Water Temperature	Detergent Type and Concentration
		Pre-Wash	2 minutes	Cold tap water	not applicable
		Wash	5 minutes	66° (set point)	Neutral enzymatic to mild alkaline detergent, pH 6.0-10.5
	Rinse	1 minute	Hot tap water	not applicable	
Cleaning: Manual	<ul style="list-style-type: none"> Prior to cleaning, cover the drill cable connector end with Handpiece Cleaning Cap, catalog no. 3318520. Wipe all external surface of the motor and cable with a cloth dampened with the detergent prepared with lukewarm tap water. Brush motor case and collet with a nylon brush dampened with a neutral enzymatic detergent. Rinse motor thoroughly under running water, collet end pointed down. Dry collet and motor with lint free towel After completion of the cleaning steps, remove Handpiece Cleaning Cap or other protective components prior to sterilization. Verify that devices are visually clean after manual cleaning 				
Disinfection	Follow hospital procedures.				
Packaging	Place devices in instrument tray, and double wrap instrument case with 1-ply polypropylene wrap. In the US, an FDA approved surgical wrap must be used.				
Sterilization (Temperatures are minimum required, times are minimum required)	Steam Sterilization				
	Cycle	Gravity	Pre-Vac	Pre-Vac (FR/WHO)	Pre-vac (UK)
	Temperature	132°C	132°C	134°C	134°C
	Time	25 minutes	4 minutes	18 minutes	3 minutes
	Drying	20 minutes			
	STERRAD	Not validated			
	100% EtO Sterilization Parameters				
	Preconditioning	55°C, 70% relative humidity, 30 minutes			
	Sterilization	Temperature	55°C		
		Relative Humidity	70%		
		Ethylene oxide concentration	725 mg/L		
		Gas exposure time (full-cycle)	240 minutes		
Aeration	53-57°C, 18 hours				
Maintenance, Inspection and Testing	<ul style="list-style-type: none"> Inspect components for any damage before and after each use. If damage is observed do not use the instrument until it is repaired. After cleaning and sterilization, verify functionality prior to re-use. 				
Storage	Store with other sterile devices.				
Additional Information	None				

Note: The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

Note: All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

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Medtronic

Reprocessing Instructions Indigo High-Speed Otologic Drill Attachments

Reprocessing Instructions (Per ISO17664)
Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at manuals.medtronic.com.
68E4188 B

Warnings and Precautions	<ul style="list-style-type: none"> Do not soak/submerge devices. Do not use ultrasound to clean devices. Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde. The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance. Allow an adequate cooling period after steam sterilization. 				
Limitations	Verify functionality prior to re-use.				
Point of Use	This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse.				
Containment and Transportation	It is recommended that devices are reprocessed as soon as is practical following use.				
Preparation for Decontamination	Follow hospital procedures.				
Cleaning: Detergent	A neutral enzymatic to mild alkaline agent (pH 6.0 to 10.5) is preferred. If a washer-disinfector is used, see the instructions supplied with the washer-disinfector machine to select the recommended cleaning agent.				
Cleaning: Automated (Do NOT use ultrasonic washer)	<ul style="list-style-type: none"> All attachments must be thoroughly rinsed manually with tap water, ensuring all hard to reach areas are rinsed, prior to transfer to automatic washer for processing. Remove devices from instrument trays before placing into washer baskets. Orient devices following recommendations of the washer/disinfector manufacturers. 				
	Recommended Washer Cycle	Phase	Recirculation Time	Water Temperature	Detergent Type and Concentration
		Pre-Wash	2 minutes	Cold tap water	not applicable
		Wash	5 minutes	66° (set point)	Neutral enzymatic to mild alkaline detergent, pH 6.0-10.5
	Rinse	1 minute	Hot tap water	not applicable	
Cleaning: Manual	<ul style="list-style-type: none"> Use the detergent, prepared with lukewarm tap water for the cleaning process. Thoroughly wipe the straight and angled attachments with a cloth dampened with the detergent. Wipe entire attachment until all gross soil has been removed. Using a brush wetted with the detergent, brush the attachments to clean the external surfaces and internal connecting surfaces. For the angled attachment: Wet an appropriately sized cleaning brush (Ø 2.4mm) with the detergent. Insert the brush into the bore at the front of the attachment. Brush the bore to loosen debris trapped inside. Rinse the bore to remove debris. For the straight attachment: Wet an appropriately sized cleaning brush (Ø 2.4mm) with the detergent. Push the brush through the straight attachment from the rear to front to loosen and remove debris trapped inside. Rinse bore to remove debris. Place one half of the straight or angled attachment into the detergent. Do not immerse the entire attachment. Gently agitate the attachments in the detergent and actuate any moveable parts. Place the other half of the attachment into the detergent and repeat. Do not immerse the entire attachment. Rinse the attachment thoroughly with tap water. Flush both ends to remove detergent. Thoroughly dry the attachments. An air gun may be used on the straight attachment to blow moisture out from the rear to front. Using an aerosol spray lubricant (such as Pana Spray), perform the following steps to lubricate attachments: <ul style="list-style-type: none"> Holding the can approximately 10-15 cm (3-6 in) away from the attachment, spray all components that move, rotate, or slide with three quick squirts. Articulate movable components to ensure proper lubrication. Remove excess lubricant with a clean cloth. 				
	Follow hospital procedures.				
Packaging	Place devices in instrument tray, and double wrap instrument case with 1-ply polypropylene wrap. In the US, an FDA approved surgical wrap must be used.				
Sterilization (Temperatures are minimum required, times are minimum required)	Steam Sterilization				
	Cycle	Gravity	Pre-Vac	Pre-Vac (FR/WHO)	Pre-vac (UK)
	Temperature	132°C	132°C	134°C	134°C
	Time	25 minutes	4 minutes	18 minutes	3 minutes
	Drying	20 minutes			
	STERRAD	Not validated			
	100% EtO Sterilization Parameters				
	Preconditioning	55°C, 70% relative humidity, 30 minutes			
	Sterilization	Temperature	55°C		
		Relative Humidity	70%		
		Ethylene oxide concentration	725 mg/L		
		Gas exposure time (full-cycle)	240 minutes		
		Aeration	53-57°C, 18 hours		
Maintenance, Inspection and Testing	<ul style="list-style-type: none"> Inspect components for any damage before and after each use. If damage is observed do not use the instrument until it is repaired. After cleaning and sterilization, verify functionality prior to re-use. 				
Storage	Store with other sterile devices.				
Additional Information	None				

Note: The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

Note: All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

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Warnings and Precautions	<ul style="list-style-type: none"> Do not soak/submerge devices. Do not use ultrasound to clean Midas Rex Microsaw devices. Do not use chlorine-based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde. Allow an adequate cooling period after steam sterilization. The use of a washer-disinfector for cleaning may cause a premature degradation in performance. 				
Limitations	Verify functionality prior to reuse.				
Point of Use	Follow hospital procedures.				
Containment and Transportation	It is recommended that devices are reprocessed as soon as is practical following use.				
Preparation for Decontamination	<ul style="list-style-type: none"> Disconnect handpiece from console. Remove irrigation tubing/clips, saw blade, and cable management clamps. 				
Cleaning: Automated (Do NOT use ultrasonic washer)	<ul style="list-style-type: none"> Prior to placing the saws in the automated washer, manually rinse the saw body with the distal end pointed down under tap water, until no visible soil is noticed. Move any movable parts back and forth to allow water to reach hard-to-rinse areas. Transfer the devices into the washer for processing, making sure that the oscillating saw collet is open. Place the devices in the washer to facilitate drainage. Verify that devices are visually clean after automated cleaning. 				
	Recommended Washer Cycle	Phase	Recirculation Time	Water Temperature	Detergent Type and Concentration
		Pre-Wash	2 minutes	Cold tap water	not applicable
		Wash	5 minutes	66° (set point)	Neutral enzymatic detergent, pH 6.0-8.0
		Rinse	1 minute	Hot tap water	not applicable
Cleaning: Manual	<ul style="list-style-type: none"> Rinse the device thoroughly under running water, with the collet end pointed down. Wipe the saw body and cable with a cloth dampened with a neutral enzymatic detergent, pH 6.0-8.0 (henceforth referred to as "cleaning solution"). With the blade collet end pointed down, brush saw body, blade-release button, and extended lever tip (if applicable) with a nylon brush that has been dipped in cleaning solution. Sagittal Only: <ol style="list-style-type: none"> Dip the distal end of the saw in cleaning solution and agitate for 10-15 seconds. Press and hold the blade-release button, then repeat step 1. With the blade-release button pressed, flush approximately 15 mL of cleaning solution from a syringe into the blade opening. Flush all ports with 15 mL of cleaning solution. Repeat steps 1-4 using water instead of cleaning solution. Reciprocating Only: <ol style="list-style-type: none"> With the distal end facing up, squeeze 30 mL of cleaning solution from a syringe into the distal end of the device so that the solution thoroughly reaches the inside of the collet. While the device is in the vertical position, rotate the collet knob back and forth three times. Dump the solution from the device. Repeat steps 1-3 a second time with cleaning solution. Repeat steps 1-3 a third time with water. Rinse the device under running water, ensuring that water enters all ports/openings. Move any moveable parts to allow the solution to reach all areas. Rinse until there is no visible evidence of soil or debris. Dry the entire device with a lint-free towel. Reciprocating and Oscillating Only: If desired, complete the following steps using Pana Spray to lubricate the saw collet: <ol style="list-style-type: none"> Holding the can approximately 10-15 cm (4-6 in) away from the saw collet, spray into the hole of the shaft (reciprocating saw) or onto the proximal/bottom portion of the collet near the locked/unlocked indicators (oscillating saw) with three quick squirts. Articulate the collet to ensure proper lubrication. Remove excess lubricant with a clean cloth. 				
Disinfection	Follow hospital procedures.				
Packaging	For sterilization, place devices in instrument tray. Devices may be unwrapped, or wrapped with up to two layers of 1-ply polypropylene wrap.				
Sterilization (Temperatures are minimum required, times are minimum required)	Steam Sterilization				
	Cycle	Gravity	Pre-Vac	Pre-Vac (FR/WHO)	Pre-vac (UK)
	Temperature	132°C	132°C	134°C	134°C
	Time	25 minutes	4 minutes	18 minutes	3 minutes
	Drying	35 minutes	20 minutes	30 minutes	22 minutes
	STERRAD	Do not use low temperature hydrogen peroxide gas plasma sterilization due to lumen internal diameter and length restrictions.			
	STERIS	Do not use liquid peracetic acid sterilization due to immersion procedure.			
	100% EtO Sterilization Parameters				
	Preconditioning	51-59°C, 70% relative humidity, 30 minutes			
	Sterilization	Temperature	51-59°C		
Relative Humidity		70 +/- 5%			
Ethylene oxide concentration		725 +/- 25mg/L			
Gas exposure time (full-cycle)		4 hours			
	Aeration	51-59°C, 18 hours			
Maintenance, Inspection and Testing	<ul style="list-style-type: none"> Inspect components for any damage before and after each use. If damage is observed, do not use the instrument until it is repaired. After cleaning and sterilization, verify functionality prior to reuse. 				
Storage	Store with other sterile devices.				
Additional Information	None				

Note: The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for reuse. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

Note: All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

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Reprocessing Instructions

POWEREASE Driver

Reprocessing Instructions (Per ISO17664)
 Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at manuals.medtronic.com.
 68E4189 A

Warnings and Precautions	<ul style="list-style-type: none"> Do not soak/submerge devices. Do not use ultrasound to clean devices. Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde. The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance. Allow an adequate cooling period after steam sterilization. 				
Limitations	Verify functionality prior to re-use.				
Point of Use	No particular requirements.				
Containment and Transportation	It is recommended that devices are reprocessed as soon as is practical following use.				
Preparation for Decontamination	Disconnect handpiece from console.				
Cleaning: Manual	<ul style="list-style-type: none"> Rinse tap water through the open lumen of the handpiece, collet pointed down, until all evidence of soil and debris is removed. Actuate and rinse collet. Wipe external surface of the motor and cable with a cloth dampened with neutral enzymatic detergent, pH 6.0-8.0. Thoroughly clean the motor case, collet, and trigger area with a nylon brush dampened with neutral enzymatic detergent, pH 6.0-8.0. Actuate the collet and trigger while brushing. Use a lumen brush to brush the entire length of the lumen. Rinse entire device, with collet pointed down, under running tap water. Immerse the collet portion of the device into neutral enzymatic detergent, pH 6.0-8.0 for a minimum of 2 minutes. Actuate and thoroughly brush the collet while immersed. A syringe should be used to flush hard to reach areas. Rinse entire device, with collet pointed down, under running tap water. A syringe should be used to rinse hard to reach areas. Dry with lint free cloth. Verify that device is visually clean. 				
Cleaning: Automated (Do NOT use ultrasonic washer)	<p>The POWEREASE <u>must</u> undergo the manual cleaning process prior to processing in a washer/disinfector.</p> <ol style="list-style-type: none"> Rinse tap water through the open lumen of the handpiece, collet pointed down until all evidence of soil and debris is removed. Actuate and rinse collet. Wipe external surface of the motor and cable with a cloth dampened with neutral enzymatic detergent. Brush motor case, collet, and trigger area with a nylon brush dampened with neutral enzymatic detergent. Actuate the collet and trigger while brushing. Use a lumen brush to brush the entire length of the lumen. Rinse entire device, with the collet pointed down, under running tap water Immerse the collet portion of the device into neutral enzymatic detergent for a minimum of 2 minutes. Actuate and brush the collet while immersed. A syringe should be used to flush hard to reach areas. Rinse entire device, with the collet pointed down, under running tap water. A syringe should be used to rinse hard to reach areas. Place POWEREASE into a suitable washer/disinfector basket and process through a washer/disinfector cycle. 				
	Recommended Washer Cycle	Phase	Recirculation Time	Water Temperature	Detergent Type and Concentration
		Pre-Wash	2 minutes	Cold tap water	not applicable
		Wash	5 minutes	66°C (set point)	Neutral enzymatic detergent, pH 6.0-8.0
	Rinse	1 minute	Hot tap water	not applicable	
Disinfection	Follow hospital procedures.				
Packaging	Steam sterilization may be performed wrapped or unwrapped. If wrapped, in the US, an FDA approved surgical wrap must be used.				
Sterilization (Temperatures are minimum required, times are minimum required)	Steam Sterilization				
	Cycle	Gravity	Pre-Vac	Pre-Vac (FR/WHO)	Pre-Vac (UK)
	Temperature	132°C	132°C	134°C	134°C
	Time	25 minutes	4 minutes	3 minutes	18 minutes
	Drying	40 minutes			
	STERRAD	Not validated			
	STERIS	Not validated			
	100% EtO Sterilization Parameters	Not validated			
Maintenance, Inspection and Testing	<ul style="list-style-type: none"> Inspect devices for any damage before and after each use. If damage is observed, do not use the device until it is repaired. After cleaning and sterilization, verify functionality prior to re-use. 				
Storage	Store with other sterile devices.				
Additional Information	None				

Note: The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

Note: All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis. NHS Estates HTM 2010 Parts 4 & 6: Appendix 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies refers to a TSE decontamination cycle using a steam autoclave at a temperature of 134-137°C for a single cycle of 18 minutes or repeated for a total of six 3-minute cycles.

**Medtronic**

Reprocessing Instructions Endo-Scrub 2 Fingerswitch

Reprocessing Instructions (Per ISO17664)
Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at manuals.medtronic.com.
68E4005 B

Warnings and Precautions	Disconnect the finger switch from the Endo-Scrub 2 pump before cleaning.				
Limitations	After cleaning and sterilization, verify functionality prior to re-use.				
Point of Use	<ul style="list-style-type: none"> This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse. After use, remove the finger switch from the sheath and disconnect the plug from the pump. Thoroughly rinse with water following use. 				
Containment and Transportation	It is recommended that devices are reprocessed as soon as is practical following use.				
Preparation for Decontamination	Promptly and thoroughly rinse with deionized water after each use.				
Cleaning: Automated (Do NOT use ultrasonic washer)	Not validated				
Cleaning: Manual	<ul style="list-style-type: none"> Dip the finger switch housing in a diluted mixture of mild (pH 7.0 - 8.5) enzymatic detergent. (Follow detergent manufacturer's instructions for proper dilution.) Thoroughly clean the housing with a soft instrument brush to remove any blood and tissue. Rinse the housing thoroughly with tap water and wipe dry. Note: If wiping the cord dry, be sure to hold the cord and not the housing to avoid stressing or breaking the electrical connections located inside the housing. 				
Disinfection	Do not cold soak in glutaraldehyde, chlorine, or ammonium solutions, or dry heat sterilize, as damage to the instrument finish may occur.				
Packaging	<ul style="list-style-type: none"> A standard, sterilization wrap may be used. In the US, an FDA approved surgical wrap must be used. Ensure that the pack is large enough to contain the instrument without stressing the seals. In sets: Instruments may be loaded into dedicated instruments trays or general purpose sterilization trays. Ensure that cutting edges are protected. Wrap trays using appropriate method. 				
Sterilization (Temperatures are minimum required, times are minimum required)	<ul style="list-style-type: none"> Check the cleanliness and operation of the instrument. Clean again if debris is present and remove from use any damaged instrument. Close instruments with catches and racks on the first notch. Arrange the instruments in sterilization containers with perforations on the top and bottom, and on supports such as those used in microsurgery. Follow the appropriate cycle listed in the table below. The sterilization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instruments. All steam cycles have been validated in the wrapped configuration and can be sterilized wrapped or unwrapped. These devices have only been validated for steam sterilization methods. 				
	Steam Sterilization				
	Cycle	Gravity	Pre-Vac	Pre-Vac (FR/WHO)	Pre-vac (UK)
	Temperature	132°C	132°C	132°C	134°C
	Time	10 minutes	10 minutes	4 minutes	3 minutes
	Drying	15-30 minutes, or until visibly dry.			
	STERRAD	Not validated.			
100% EtO Sterilization Parameters	Not validated.				
Maintenance, Inspection and Testing	<ul style="list-style-type: none"> Inspect finger switch for any damage before and after each use. If damage is observed do not use the finger switch until it is repaired or replaced. After cleaning and sterilization, verify functionality prior to re-use. 				
Storage	Store in a clean, dry area.				
Additional Information	None				

Note: The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

Note: All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis. NHS Estates HTM 2010 Parts 4 & 6: Appendix 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies refers to a TSE decontamination cycle using a steam autoclave at a temperature of 134-137°C for a single cycle of 18 minutes or repeated for a total of six 3-minute cycles.



Medtronic

Reprocessing Instructions Microdebridors

Spine Shaver, StraightShot M4, StraightShot Magnum II or StraightShot III

Reprocessing Instructions (Per ISO17664)
Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at manuals.medtronic.com.
68E3282 C

Warnings and Precautions	<ul style="list-style-type: none"> Disconnect the power before cleaning. Do not fully immerse, or ultrasonically clean, this instrument. Do not cold soak sterilize this instrument in glutaraldehyde. This will void the warranty. Do not use organic solvents to clean the bur chuck. For drill handpiece cleaning, cover handpiece cable connector end with Handpiece Cable Cap, Small, catalog no. 3318510 or Handpiece Cleaning Cap, Universal, catalog no. 3318520. (Note: Use 3318520 for Straightshot M4, Visao, and Xcalibur Hi-Speed with angled cable. Use 3318510 for other handpieces.) After completion of the cleaning steps, remove Handpiece Cable Cap or other protective components installed prior to cleaning. 																																																																											
Limitations	After cleaning and sterilization, verify functionality prior to re-use.																																																																											
Point of Use	<ul style="list-style-type: none"> This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse. To remove occasional residual buildup on handpiece cable connector, use a soft brush and isopropyl alcohol. 																																																																											
Containment and Transportation	It is recommended that instruments are reprocessed as soon as is practical following use.																																																																											
Preparation for Decontamination	Remove the bur from the handpiece, otherwise disassembly is not required.																																																																											
Cleaning: Automated (Do NOT use ultrasonic washer)	<ul style="list-style-type: none"> Remove instruments and equipment from any sterilization trays before placing into washer baskets. Orient devices following recommendations of washer/disinfector manufacturers. Use alkaline or neutral pH detergent recommended by washer/disinfector or detergent manufacturers. These products have been validated for effective cleaning using an automatic washer/disinfector cycle consisting of a minimum 44 minutes total time, including a pre-wash, main wash & rinse, and thermal rinse. The thermal rinse shall be at least 10 minutes long at a minimum temperature of 60°C. 																																																																											
Cleaning: Manual	<ul style="list-style-type: none"> Do not immerse the handpiece. Wipe the handpiece and cable with disinfectant applied to a clean, non-abrasive cloth. Gently clean the handpiece with a moistened soft bristle brush or pipe cleaner, making sure to clean all passages. Use an enzymatic detergent solution to loosen and remove collected tissues from the unit. Hold the handpiece with the front end pointed downward during rinsing.* <ul style="list-style-type: none"> * Additional Cleaning Instructions for XPS Straightshot M4/Spine Shaver Microdebrider: <ul style="list-style-type: none"> During the normal cleaning cycle, run a gentle stream of warm water into the collet (front end), and into the lock lever of the Straightshot M4/Spine Shaver handpiece. While warm water is running into the collet, rotate the mechanism for several revolutions (rotate the wheel); and while water is running into the lock lever, actuate the lock lever several times (locking and unlocking). Shake excess water from the handpiece. PRECAUTION: Ensure the use of a very gentle stream of warm clean water during this additional cleaning step. Dry the handpiece and cable with a lint-free towel. Make sure to dry off the electrical connection on the cable ends. Apply a small amount of silicone spray into the front-end collet and outside of the handpiece. Sterilize the handpiece immediately after cleaning. 																																																																											
Disinfection	Do not cold soak in glutaraldehyde.																																																																											
Packaging	<ul style="list-style-type: none"> A standard, sterilization wrap may be used. In the US, an FDA approved surgical wrap must be used. Ensure that the pack is large enough to contain the instrument without stressing the seals. In sets: Instruments may be loaded into dedicated instrument trays or general purpose sterilization trays. Wrap trays using appropriate method. 																																																																											
Sterilization (Temperatures are minimum required, times are minimum required)	<p>The sterilization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instrument(s). All steam sterilization cycles have been validated in the wrapped configuration and instruments can be sterilized wrapped or unwrapped.</p> <table border="1"> <thead> <tr> <th colspan="6">Steam Sterilization</th> </tr> <tr> <th>Cycle</th> <th>Gravity</th> <th>Pre-Vac</th> <th>Pre-Vac (FR/WHO)</th> <th>Pre-vac (UK)</th> <th></th> </tr> </thead> <tbody> <tr> <td>Temperature</td> <td>121°C</td> <td>132°C</td> <td>134°C</td> <td>134°C</td> <td></td> </tr> <tr> <td>Time</td> <td>40 minutes</td> <td>4 minutes</td> <td>18 minutes</td> <td>3 minutes</td> <td></td> </tr> <tr> <td>Drying</td> <td colspan="5">8 minutes, or until visibly dry</td> </tr> <tr> <td>STERRAD</td> <td colspan="5">100S Compatible</td> </tr> <tr> <th colspan="6">100% EtO Sterilization Parameters</th> </tr> <tr> <td>Preconditioning</td> <td colspan="5">54±2°C, 60±5% relative humidity, 30 minutes</td> </tr> <tr> <td rowspan="4">Sterilization</td> <td>Temperature</td> <td colspan="2">54-55°C</td> <td></td> <td></td> </tr> <tr> <td>Relative Humidity</td> <td colspan="2">60 +/- 5%</td> <td></td> <td></td> </tr> <tr> <td>Ethylene oxide concentration</td> <td colspan="2">600 +/- 25 mg/L</td> <td></td> <td></td> </tr> <tr> <td>Gas exposure time (full-cycle)</td> <td colspan="2">120 minutes</td> <td></td> <td></td> </tr> <tr> <td>Aeration</td> <td colspan="2">48-52°C, 8 hours</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Steam Sterilization						Cycle	Gravity	Pre-Vac	Pre-Vac (FR/WHO)	Pre-vac (UK)		Temperature	121°C	132°C	134°C	134°C		Time	40 minutes	4 minutes	18 minutes	3 minutes		Drying	8 minutes, or until visibly dry					STERRAD	100S Compatible					100% EtO Sterilization Parameters						Preconditioning	54±2°C, 60±5% relative humidity, 30 minutes					Sterilization	Temperature	54-55°C				Relative Humidity	60 +/- 5%				Ethylene oxide concentration	600 +/- 25 mg/L				Gas exposure time (full-cycle)	120 minutes				Aeration	48-52°C, 8 hours				
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Maintenance, Inspection and Testing	<ul style="list-style-type: none"> Inspect components for any damage before and after each use. If damage is observed do not use the instrument until it is repaired. After cleaning and sterilization, verify functionality prior to re-use. 																																																																											
Storage	It is extremely important that the handpiece be rapidly and completely vacuum dried before storage to prevent corrosion and residue deposits in the bearing and motor.																																																																											
Additional Information	Increase temperatures higher than those stated when necessary to satisfy governmental or health care facility requirements so long as the temperature does not exceed 149° C. Heating above 149° C may damage the handpiece and will void the warranty.																																																																											

Note: The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

Note: All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

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Medtronic

Reprocessing Instructions Legend EHS and Legend EHS Stylus

Reprocessing Instructions (Per ISO17664)
Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at manuals.medtronic.com.
M000030A234 A

Warnings and Precautions	<ul style="list-style-type: none"> Do not soak/submerge devices. Do not use ultrasound to clean devices. Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde. The use of a washer-disinfector for cleaning may cause a degradation in performance. Allow an adequate cooling period after steam sterilization. 				
Limitations	Verify functionality prior to re-use.				
Point of Use	Follow hospital procedures.				
Containment and Transportation	It is recommended that devices are reprocessed as soon as is practical following use.				
Preparation for Decontamination	Follow hospital procedures.				
Cleaning: Automated (Do NOT use ultrasonic washer)	<ul style="list-style-type: none"> Review the washer-disinfector warning above, before using this cleaning method. Remove devices from instrument trays before placing into washer baskets. Orient devices following recommendations of the washer/disinfector manufacturers. 				
	Recommended Washer Cycle	Phase	Recirculation Time	Water Temperature	Detergent Type and Concentration
		Pre-Wash	5 minutes	35°C	not applicable
		Wash	30 minutes	93°C	not applicable
		Neutralize	2 minutes		
	Final Rinse	10 minutes	65°C	not applicable	
Cleaning: Manual	<ul style="list-style-type: none"> Wipe all external surfaces of the motor and cable with a cloth dampened with a neutral enzymatic detergent, pH 6.0-8.0. Brush motor case and collet with a nylon brush dampened with a neutral enzymatic detergent. Rinse motor thoroughly under running water, collet end pointed down. Dry collet and motor with towel. Verify that devices are visually clean after manual cleaning. Rinse thoroughly with tap water. 				
Disinfection	Follow hospital procedures.				
Packaging	For sterilization, place devices in instrument tray. Devices may be unwrapped, or wrapped with up to two layers of 1-ply polypropylene wrap				
Sterilization (Temperatures are minimum required, times are minimum required)	Steam Sterilization				
	Cycle	Gravity	Pre-Vac	Pre-Vac	
	Temperature	132°C	132°C	134°C	
	Time	25 minutes	4 minutes	3 minutes	
	Drying	15 minutes	15 minutes	10 minutes	
	STERRAD	Do not use low temperature hydrogen peroxide gas plasma sterilization due to lumen internal diameter and length restrictions.			
	STERIS	Do not use liquid peracetic acid sterilization due to immersion procedure.			
	100% EtO Sterilization Parameters				
	Preconditioning	51-59°C, 70 ±5% relative humidity, 30 min.			
	Sterilization	Temperature	51-59°C		
		Relative Humidity	70 +/- 5%		
		Ethylene oxide concentration	725 +/- 25 mg/L		
		Gas exposure time (full-cycle)	4 hours		
	Aeration	51-59°C, 18 hours			
Maintenance, Inspection and Testing	<ul style="list-style-type: none"> Inspect devices for any damage before and after each use. If damage is observed, do not use the device until it is repaired. Verify functionality prior to re-use. 				
Storage	Store with other sterile devices.				
Additional Information	None				

Note: The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

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Warnings and Precautions	<ul style="list-style-type: none"> Do not soak/submerge devices. Do not use ultrasound to clean devices. Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde. The use of a washer-disinfector for cleaning may cause a degradation in performance. Allow an adequate cooling period after steam sterilization. 					
Limitations	Verify functionality prior to re-use.					
Point of Use	This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse.					
Containment and Transportation	It is recommended that devices are reprocessed as soon as is practical following use.					
Preparation for Decontamination	Follow hospital procedures.					
Cleaning: Automated (Do NOT use ultrasonic washer)	Review the washer-disinfector warning above, before using this cleaning method. Remove devices from instrument trays before placing into washer baskets. Orient devices following recommendations of the washer/disinfector manufacturers. Verify that devices are visually clean after automated cleaning.					
	Recommended Washer Cycle	Phase	Recirculation Time	Water Temperature	Detergent Type and Concentration	
		Pre-Wash	2 minutes	Cold tap water	not applicable	
		Wash	5 minutes	66°C (set point)	Neutral enzymatic detergent, pH 6.0-8.0	
	Rinse	1 minute	Hot tap water	not applicable		
Cleaning: Manual	<ul style="list-style-type: none"> Wipe all external surfaces with a cloth dampened with a neutral enzymatic detergent, pH 6.0-8.0. Brush motor case and collet with a nylon brush dampened with a neutral enzymatic detergent. Rinse motor thoroughly under running water, collet end pointed down. Dry with towel. Verify that devices are visually clean after manual cleaning. 					
Disinfection	Follow hospital procedures.					
Packaging	For sterilization, place devices in instrument tray. Devices may be unwrapped, or wrapped with up to two layers of 1-ply polypropylene wrap.					
Sterilization (Temperatures are minimum required, times are minimum required)	Steam Sterilization					
	Cycle	Pre-Vac	Gravity	Pre-Vac	Pre-Vac	Flash (Pre-Vac Unwrapped)
	Temperature	132°C	132°C	134°C	134°C	132°C
	Time	4 minutes	25 minutes	3 minutes	18 minutes	4 minutes
	Drying	15 minutes	15 minutes	10 minutes	20 minutes	not applicable
	STERRAD	Not validated				
	100% EtO Sterilization Parameters					
	Preconditioning	55°C, 70% relative humidity, Vacuum Set Point: 1.3 psia, Time: 30 minutes				
	Sterilization	Temperature	55°C +/- 4°C			
		Relative Humidity	70 +/- 5%			
		Ethylene oxide concentration	725 +/- 25 mg/L			
Gas exposure time (full-cycle)		4 hours				
Aeration		55°C +/- 4°C, 12 hours				
Maintenance, Inspection and Testing	<ul style="list-style-type: none"> Inspect devices for any damage before and after each use. If damage is observed, do not use the device until it is repaired. After cleaning and sterilization, verify functionality prior to re-use. 					
Storage	Store with other sterile devices.					
Additional Information	None					

Note: The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

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Warnings and Precautions	<ul style="list-style-type: none"> Do not soak/submerge devices. Do not use ultrasound to clean devices. Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde. The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance. Allow an adequate cooling period after steam sterilization. 				
Limitations	Verify functionality prior to re-use.				
Point of Use	Follow hospital procedures.				
Containment and Transportation	It is recommended that devices are reprocessed as soon as is practical following use.				
Preparation for Decontamination	Follow hospital procedures.				
Cleaning: Automated (Do NOT use ultrasonic washer)	<ul style="list-style-type: none"> Review the washer-disinfector warning above, before using this cleaning method. Manually rinse attachments/tubes under tap water, until no visible soil is noticed, before placing them into the automatic washer. Remove devices from instrument trays before placing into washer baskets. Orient devices following recommendations of the washer/disinfector manufacturers. 				
	Recommended Washer Cycle	Phase	Recirculation Time	Water Temperature	Detergent Type and Concentration
		Pre-Wash	2 minutes	Cold tap water	not applicable
		Wash	5 minutes	66°C (set point)	Neutral enzymatic detergent, pH 6.0-8.0
	Rinse	1 minute	Hot tap water	not applicable	
Cleaning: Manual	<ol style="list-style-type: none"> Wipe all attachments and telescoping tubes with a cloth, dampened with a surgical instrument cleaning solution. Immerse the head of Contra-Angle attachments in surgical instrument cleaning solution and run the motor for 1 minute. Other attachments and tubes may be mechanically agitated in cleaning solution, but not soaked or immersed. A nylon brush dampened with a surgical instrument cleaning solution may be used to clean the external surfaces and internal connecting surfaces of the attachments and tubes. Straight attachments, footed attachments and telescoping straight tubes have special cleaning brushes sized to the attachment's or telescoping tube's internal diameter. Push the brush wet with surgical instrument cleaning solution through the attachment or telescoping tube from rear to front to loosen and remove debris trapped inside. Move any moveable parts back and forth to allow solution to thoroughly clean attachment, e.g., sleeve on footed attachment, perforator attachment. Rinse thoroughly with tap water. Thoroughly dry attachments. An air gun may be used to blow moisture out from rear to front of attachment. <p>Note: Medtronic no longer recommends using the Legend attachment cleaning nozzle (PA120), as this may cause some attachments to overheat.</p> <ol style="list-style-type: none"> Using an aerosol spray lubricant (such as Pana Spray), perform the following steps to lubricate attachments: <ul style="list-style-type: none"> Holding the can approximately 10-15 cm (3-6 in.) away from the attachment, spray all components that move, rotate, or slide with three quick squirts. Articulate movable components to ensure proper lubrication. Remove excess lubricant with a clean cloth. 				
Disinfection	Follow hospital procedures.				
Packaging	For sterilization, place devices in instrument tray. Devices may be unwrapped, or wrapped with up to two layers of 1-ply polypropylene wrap.				
Sterilization (Temperatures are minimum required, times are minimum required)	Steam Sterilization				
	Cycle	Gravity	Pre-Vac	Pre-Vac (FR/WHO)	Pre-vac (UK)
	Temperature	132°C	132°C	134°C	134°C
	Time	25 minutes	4 minutes	18 minutes	3 minutes
	Drying	15 minutes	15 minutes	20 minutes	10 minutes
	STERRAD	Do not use low temperature hydrogen peroxide gas plasma sterilization due to lumen internal diameter and length restrictions.			
	STERIS	Do not use liquid peracetic acid sterilization due to immersion procedure.			
	100% EtO Sterilization Parameters				
	Preconditioning	51-59°C, 70 ±5% relative humidity, 30 min			
	Sterilization	Temperature	51-59°C		
		Relative Humidity	70 ±5%		
		Ethylene oxide concentration	725 +/- 25 mg/L		
Gas exposure time (full-cycle)		4 hours			
Aeration		51-59°C, 18 hours			
Maintenance, Inspection and Testing	<ul style="list-style-type: none"> Inspect devices for any damage before and after each use. If damage is observed, do not use the device until it is repaired. Verify functionality prior to re-use. 				
Storage	Store with other sterile devices.				
Additional Information	None				

Note: The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

Note: All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

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Warnings and Precautions	<ul style="list-style-type: none"> • Before sterilization, carefully inspect the bur tips. • Burs exhibiting the following conditions should be replaced: <ul style="list-style-type: none"> • nicks on cutting surfaces • noticeable wear on PTFE bearings • severe bends or crimps on bur shaft • Cold soak in glutaraldehyde, chlorine, or ammonium solutions, or dry heat sterilization is not recommended as damage to the bur may occur. 																														
Limitations	Discard any burs that show signs of damage or wear.																														
Point of Use	<ul style="list-style-type: none"> • Remove burs from the handpiece before cleaning and sterilizing. • Promptly and thoroughly rinse instruments with deionized water after each use. 																														
Containment and Transportation	It is recommended that instruments are reprocessed as soon as is practical following use.																														
Preparation for Decontamination	Promptly and thoroughly rinse instruments with deionized water after each use.																														
Cleaning: Automated	<ul style="list-style-type: none"> • Remove burs from any sterilization trays before placing into washer baskets. • Orient burs following recommendations of washer/disinfector manufacturers. • Use alkaline or neutral pH detergent recommended by washer/disinfector or detergent manufacturers. • These products have been validated for effective cleaning using an automatic washer/disinfector cycle consisting of a minimum 44 minutes total time, including a pre-wash, main wash & rinse, and thermal rinse. The thermal rinse shall be at least 10 minutes long at a minimum temperature of 60°C. • Following cleaning, apply a light coating of silicone spray or Pana Spray in the following manner: grasp the PTFE bearing and rotate the bur to assure application of the spray inside the bearing. 																														
Cleaning: Manual	<ul style="list-style-type: none"> • Soak in lukewarm*, mild* enzymatic detergent (less than 43°C; pH 7.0 - 8.5), and deionized water for a minimum of two minutes. • Then clean ultrasonically in lukewarm* solution of mild* detergent (less than 43°C; pH 7.0 - 8.5) and deionized water for at least 30 seconds. • Rinse thoroughly with deionized water and wipe dry. • Following cleaning, apply a light coating of silicone spray or Pana Spray in the following manner: grasp the PTFE bearing and rotate the bur to assure application of the spray inside the bearing. • Note: When using an ultrasonic cleaner or a spray washing machine, follow the manufacturer's recommendations, particularly with regard to articulated instruments and positioning of instruments. 																														
Disinfection	Do not cold soak in glutaraldehyde.																														
Packaging	<ul style="list-style-type: none"> • A standard, sterilization wrap may be used. In the US, an FDA approved surgical wrap must be used. Ensure that the pack is large enough to contain the instrument without stressing the seals. • In sets: Instruments may be loaded into dedicated instrument trays or general purpose sterilization trays. Wrap trays using appropriate method. 																														
Sterilization (Temperatures are minimum required, times are minimum required)	<ul style="list-style-type: none"> • The sterilization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instrument(s). • All steam sterilization cycles have been validated in the wrapped configuration and instruments can be sterilized wrapped or unwrapped. 																														
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Maintenance, Inspection and Testing	Discard any burs that show signs of damage or wear.																														
Storage	Store in a clean, dry area.																														
Additional Information	None																														

Note: The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

Note: All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

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Medtronic

Reprocessing Instructions Skeeter Handpiece

Reprocessing Instructions (Per ISO17664)
Cleaning and Sterilization instructions are subject to change without notice. Up to date instructions are available online at manuals.medtronic.com.
68E3969 E

Warnings and Precautions	<ul style="list-style-type: none"> • Disconnect the power before cleaning. • Do not fully immerse, or ultrasonically clean, this instrument. • Do not use any cleaning instruments in the cannulated shaft of the handpiece. • Do not cold soak sterilize this instrument in glutaraldehyde. This will void the warranty. • Do not use organic solvents to clean the bur chuck. 																														
Limitations	After cleaning and sterilization, verify functionality prior to re-use.																														
Point of Use	<ul style="list-style-type: none"> • This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse. • To remove occasional residual buildup on handpiece cable connector, use a soft brush and isopropyl alcohol. 																														
Containment and Transportation	It is recommended that instruments are reprocessed as soon as is practical following use.																														
Preparation for Decontamination	Disassembly not required, other than removal of the bur.																														
Cleaning: Automated (Do NOT use ultrasonic washer)	<ul style="list-style-type: none"> • Remove instruments and equipment from any sterilization trays before placing into washer baskets. • Orient devices following recommendations of washer/disinfector manufacturers. • Use alkaline or neutral pH detergent recommended by washer/disinfector or detergent manufacturers. • These products have been validated for effective cleaning using an automatic washer/disinfector cycle consisting of a minimum 44 minutes total time, including a pre-wash, main wash & rinse, and thermal rinse. The thermal rinse shall be at least 10 minutes long at a minimum temperature of 60°C. 																														
Cleaning: Manual	<ul style="list-style-type: none"> • Carefully clean with an enzymatic detergent. Do not fully immerse. • The cannulated needle nose should be cleaned by immersing in the detergent solution up to the level of the Bur Release button. Do not use any cleaning instruments in the cannulated shaft of the handpiece. • Rinse by immersing the distal end of the handpiece (up to the Bur Release button) in distilled water, using a gentle swirling motion to flush away residual cleaning solution. Avoid water accumulation in the motor housing by shaking excess water out with a downward motion. • Silicone spray or Pana Spray should be sprayed into the cannulated shaft of the handpiece prior to sterilization. Apply silicone spray or Pana Spray until surplus lubricant is noted on the outside of the Bur Release Button. Wipe away excess lubricant from the handpiece. Following this procedure will insure that the bur release mechanism is well lubricated for proper functioning. • Sterilize the handpieces immediately after cleaning. 																														
Disinfection	Do not cold soak in glutaraldehyde.																														
Packaging	<ul style="list-style-type: none"> • A standard, sterilization wrap may be used. In the US, an FDA approved surgical wrap must be used. Ensure that the pack is large enough to contain the instrument without stressing the seals. • In sets: Instruments may be loaded into dedicated instrument trays or general purpose sterilization trays. Wrap trays using appropriate method. 																														
Sterilization (Temperatures are minimum required, times are minimum required)	<ul style="list-style-type: none"> • The sterilization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instrument(s). • All steam sterilization cycles have been validated in the wrapped configuration and instruments can be sterilized wrapped or unwrapped. 																														
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Maintenance, Inspection and Testing	<ul style="list-style-type: none"> • Inspect components for any damage before and after each use. If damage is observed do not use the instrument until it is repaired. • After cleaning and sterilization, verify functionality prior to re-use. 																														
Storage	It is extremely important that the handpiece be rapidly and completely dried before storage to prevent corrosion and residue deposits in the bearing and motor.																														
Additional Information	None																														

Note: The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

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Warnings and Precautions	<ul style="list-style-type: none"> • Disconnect the power before cleaning. • Do not fully immerse, or ultrasonically clean, this instrument. • Do not cold soak sterilize this instrument in glutaraldehyde. This will void the warranty. • Do not use organic solvents to clean the bur chuck. • For drill handpiece cleaning, cover handpiece cable connector end with Handpiece Cable Cap, Small, catalog no. 3318510 or Handpiece Cleaning Cap, Universal, catalog no. 3318520. (Note: Use 3318520 for Straightshot M4, Visao, and Xcalibur Hi-Speed with angled cable. Use 3318510 for other handpieces.) • After completion of the cleaning steps, remove Handpiece Cable Cap or other protective components installed prior to cleaning. 																									
Limitations	After cleaning and sterilization, verify functionality prior to re-use.																									
Point of Use	<ul style="list-style-type: none"> • This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse. • To remove occasional residual buildup on handpiece cable connector, use a soft brush and isopropyl alcohol. 																									
Containment and Transportation	It is recommended that instruments are reprocessed as soon as is practical following use.																									
Preparation for Decontamination	Remove the bur from the handpiece, otherwise disassembly is not required.																									
Cleaning: Automated	<ul style="list-style-type: none"> • Remove instruments and equipment from any sterilization trays before placing into washer baskets. Orient devices following recommendations of washer/disinfectant manufacturers. • Use alkaline or neutral pH detergent recommended by washer/disinfectant or detergent manufacturers. • These products have been validated for effective cleaning using an automatic washer/disinfectant cycle consisting of a minimum 44 minutes total time, including a pre-wash, main wash & rinse, and thermal rinse. The thermal rinse shall be at least 10 minutes long at a minimum temperature of 60°C. 																									
Cleaning: Manual	<ul style="list-style-type: none"> • After surgery, clean the irrigation sleeves and bur guards with an enzymatic detergent solution. Wipe the handpiece and cable with disinfectant applied to a clean, non-abrasive cloth. • A chuck brush cleaner (REF 3112500) or an appropriately sized small (plastic bristle) bore brush may be inserted into the distal end of the Visao handpiece, irrigation sleeves and bur guards to assist in removing fluids, tissue, or bone fragments, making sure to clean all passages. Use an enzymatic detergent solution to loosen and remove collected tissues from the unit. • Rinse out the distal end of the handpiece. Shake excess water from the handpiece. • Ensure all water is drained from the cooling housing. If saline was used for cooling during surgery, use distilled water to rinse the housing prior to draining. • Using distilled water, rinse saline from the irrigation nozzles. Drain the nozzle of all water. • Sterilize the handpiece immediately after cleaning. 																									
Disinfection	Do not cold soak in glutaraldehyde.																									
Packaging	<ul style="list-style-type: none"> • A standard, sterilization wrap may be used. In the US, an FDA approved surgical wrap must be used. Ensure that the pack is large enough to contain the instrument without stressing the seals. • In sets: Instruments may be loaded into dedicated instrument trays or general purpose sterilization trays. Wrap trays using appropriate method. 																									
Sterilization (Temperatures are minimum required, times are minimum required)	The sterilization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instrument(s). All steam sterilization cycles have been validated in the wrapped configuration and instruments can be sterilized wrapped or unwrapped.																									
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Aeration	48-52°C, 8 hours																									
Maintenance, Inspection and Testing	<ul style="list-style-type: none"> • Inspect components for any damage before and after each use. If damage is observed do not use the instrument until it is repaired. • After cleaning and sterilization, verify functionality prior to re-use. 																									
Storage	It is extremely important that the handpiece be rapidly and completely vacuum dried before storage to prevent corrosion and residue deposits in the bearing and motor.																									
Additional Information	Increase temperatures higher than those stated when necessary to satisfy governmental or health care facility requirements so long as the temperature does not exceed 149° C. Heating above 149° C may damage the handpiece and will void the warranty.																									

Note: The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

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Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
011.31.45.566.8000

Section 14: Sterilization and Shelf Life

Sterilization

The Harmonic Scallop Blade is a single use device and provided sterile. **(b)(4)Trade Secret Process-Product Specs**

[REDACTED]

(b)(4)Trade Secret Process-Product Specs an existing cycle. The sterilization process is validated and the sterilization parameters are established per the requirements of the following FDA recognized standards:

- AAMI / ANSI / ISO 10993-7: 2008, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

Please see Section 21 for the 3654 Forms, Standards Data Report for 510(k).

Packaging

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

The recommended transportation and storage conditions are:

Temperature: -22 °C to 60 °C
Relative Humidity: 10% to 80%

Please note that throughout the device labeling, the temperature and humidity recommendations and symbols are intended to provide guidance on transportation condition allowances. For optimal long-term storage, it is recommended to store the device(s) in a cool dry place.

Shelf Life

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

[REDACTED]

Aging Protocol

b(4)Trade Secret Process-Product Specs

The following testing will be used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the Predicate Device.

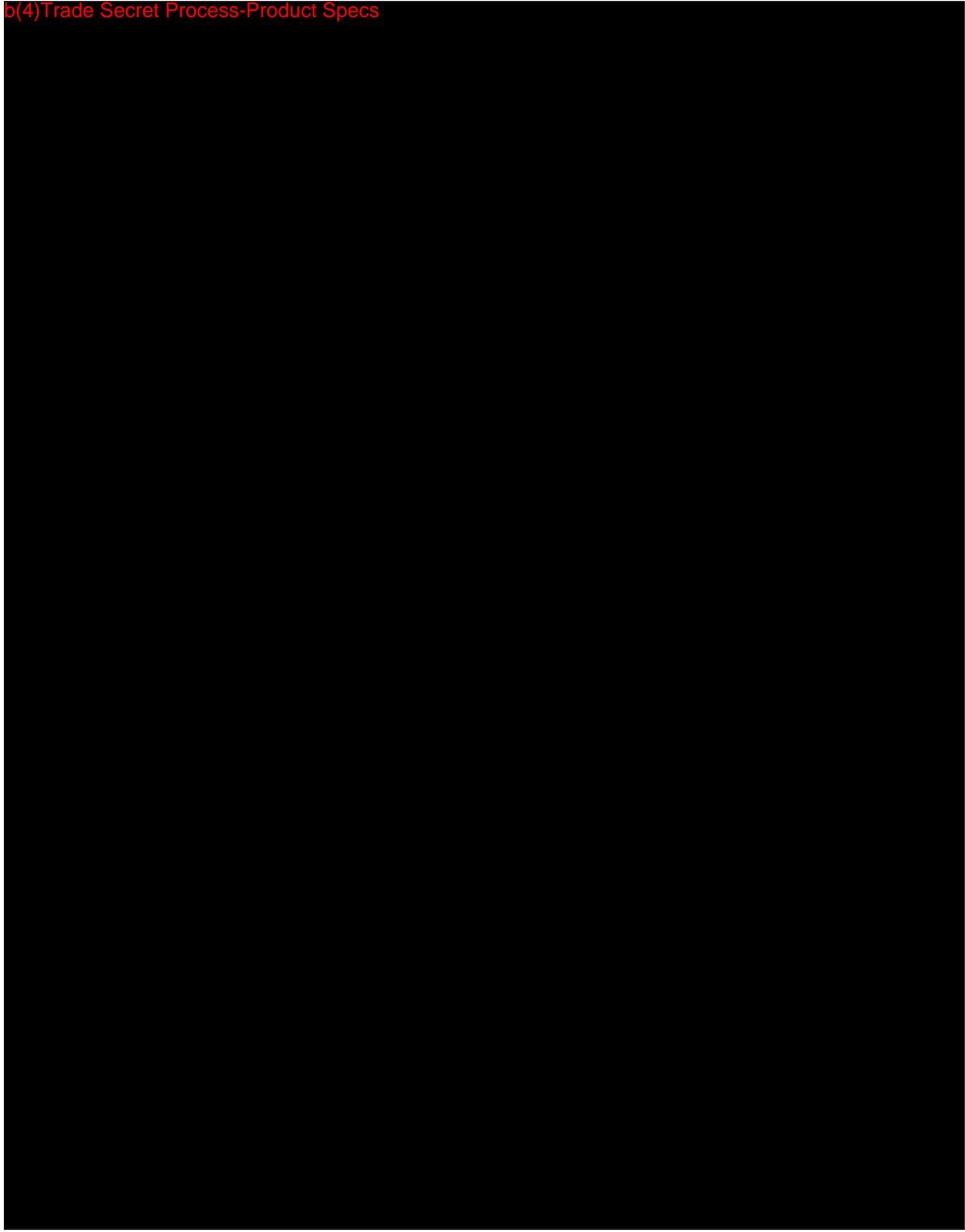
b(4)Trade Secret Process-Product Specs

Table 14.1: Summary of Aging Testing

Test Number	Performance Test	Description and Objective
b(4)Trade Secret Process-Product Specs		

Any inability of the test samples to meet requirements I-IV will be considered acceptable if hypothesis testing fails to reject the null hypothesis that the results after simulated aging are equivalent to those of the control group of devices that were not aged at 95% confidence

b(4)Trade Secret Process-Product Specs



b(4) Trade Secret Process-Product Specs



Section 15: Biocompatibility

The biocompatibility of materials used in the Subject Device were evaluated based on AAMI/ANSI/ISO 10993-1:2009 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process” and on FDA General Program Memorandum #G95-1: Use of International Standard ISO 10993, “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.” All tests were performed in accordance with FDA’s Good Laboratory Practice Standard. The Subject Device materials have been evaluated and meet the defined biocompatibility requirements.

The materials of the device listed in Table 15.1 are classified as Surface Devices Breached or Compromised Surfaces and External Communicating Devices Tissue/Bone/ Dentin Limited (less than 24 hours), or patient-contacting, as defined by ISO 10993-1.

Table 15.1: Patient-Contacting Materials of the Subject Device

Part Name	Subject Device Material	HK105 Predicate Device Material	Material Previously Cleared 510k Number
-----------	-------------------------	---------------------------------	---



*This design feature is not applicable to the Predicate Device.

Biocompatibility Evaluation

The Subject Device has the similar patient contacting materials as the Predicate Device. Many of these materials are identical to materials previously tested for biocompatibility and cleared in prior submissions. (b)(4) Trade Secret Process-Product Specs

The combination of different metals in one assembly can cause interactions under different environments and conditions, and therefore could affect biocompatibility of a device. The device materials were

tested on the device as a whole in order to assess for biocompatibility and material interactions. Biocompatibility testing and evaluation was performed on a representative of the final product and test summaries are provided. All materials in the Subject Device meet the biocompatibility requirements for the appropriate level of tissue contact.

Subject Device Assembly Materials

A representative Subject Device was built and submitted for biocompatibility testing. The Subject Device test article included the combination of materials listed in Table 15.2.

Table 15.2: Subject Device Test Article Materials

Part Name	Subject Device Material
b(4)Trade Secret Process-Product Specs	

Biocompatibility Tests

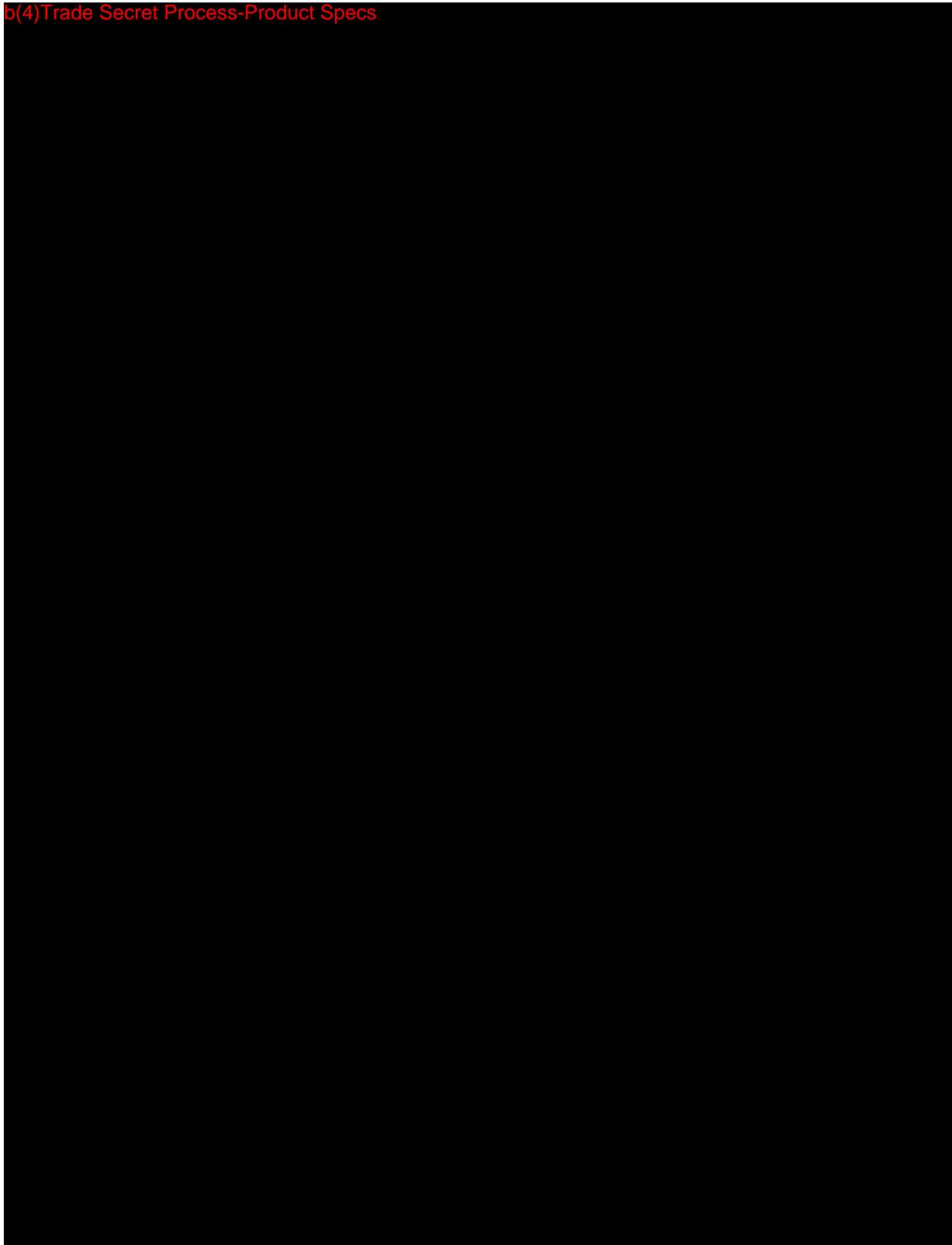
Table 15.3 includes the completed device testing, as recommended by ISO10993-1 and FDA Guidance Blue Book Memo, G95-1, Use of International Standard ISO-10993 and Biological Evaluation of Medical Devices Part 1: Evaluation and b(4)Trade Secret Process-Product Specs

Table 15.3: Biocompatibility Evaluation Summary

Test Type	Test Name	Report Number	Result
b(4)Trade Secret Process-Product Specs			

A summary of the biocompatibility tests demonstrates that the Subject Device has been evaluated and meets the defined biocompatibility requirements.

b(4)Trade Secret Process-Product Specs



b(4)Trade Secret Process-Product Specs



Section 16: Software

This submission include a an updated revision of software to the Generator G11. A summary of the documentation included in this section is listed in Table 16.1

Table 16.1: Summary of Software Documentation

b(4)Trade Secret Process-Product Specs



Software Level of Concern

Definition of Level of Concern

The Level of Concern refers to an estimate of the severity of injury that a device could permit or inflict, either directly or indirectly, on a patient or operator as a result of device failures, design flaws, or simply by virtue of employing the device for its intended use. There are 3 different levels of concern ('Major', 'Moderate' and 'Minor') and they are assessed within the context of the worst possible, reasonably foreseeable, clinical consequences of failure of the Software Device.

Determination of Level of Concern

In order to determine the level of concern for a particular software system, following questions are recommended by FDA and addressed in Table 16.2. If the answer to anyone question below is "Yes," the Level of Concern for the Software Device is likely to be Major.

Table 16.2: Major Level of Concern

Question	Answer
1. Does the Software Device qualify as Blood Establishment Computer Software?	No , this device is not intended for use in the manufacture of blood and blood components or for the maintenance of data that blood establishment personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture.
2. Is the Software Device intended to be used in combination with a drug or biologic?	No , this device is not intended to be used in combination with a drug or biologic.
3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?	No , this device is not an accessory to any other device.
4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following: a. Does the Software Device control a life supporting or life sustaining device b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators? c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury? d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death? e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	Yes , the system is designed to control the delivery of potentially harmful energy when used for soft tissue cutting and vessel sealing which could result in death or serious injury based upon the energy applied.
If the answer to any one question ,1-4 are yes, Software is likely to be MAJOR level of concern	
FDA GUIDANCE SUGGESTED SOFTWARE LEVEL OF CONCERN	MAJOR

Conclusion

Harmonic Scallop Blade device software has a Major software level of concern classification. Complications resulting from either accidental, unsuspected thermal injuries or incorrect vessel seals due to software control failure can have significant adverse medical impacts on patients, including organ damage and vessel hemorrhage, perforation, and peritonitis. If not detected expeditiously, any of these conditions can result in significant morbidity or even death.

Software Overview

The Generator G11 was submitted in K101990. Since this submission and release, the device hardware has not changed. **(b)(4)Trade Secret Process-Product Specs**

The Subject Device includes expanded output capabilities, including power, voltage, and current that are higher than the Predicate Device **(b)(4)Trade Secret Process-Product Specs**

The labeling which references these outputs is only present on the Subject Device. This submission addresses the expanded output capabilities with the Generator G11 and the Harmonic Scallop Blade as a system.

(b)(4)Trade Secret Process-Product Specs There are no changes to the Generator G11 hardware. There are no changes to the Generator G11 with regards to the high frequency surgical equipment/ bipolar software, compatibility, or software. The Generator G11 has the same diagnostic and error detection capabilities.

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

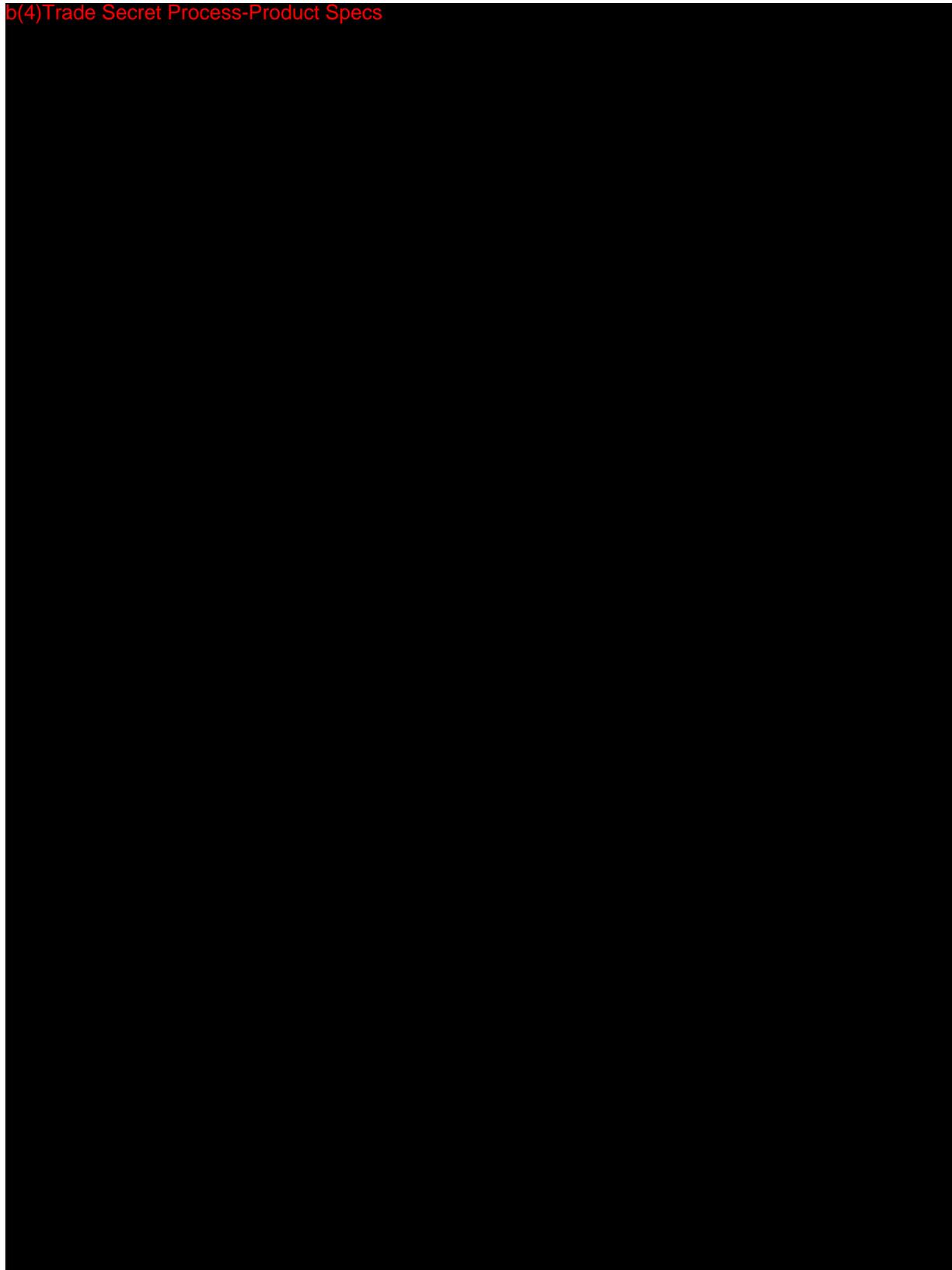
Software Description

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

Summary Overview of the Features

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

b(4)Trade Secret Process-Product Specs



Device Hazard Analysis

A tabular description of identified hardware and software hazards, including severity assessment and mitigations, is included in the following Appendix 16.1: Device Hazard Analysis.

b(4)Trade Secret

Process-Product Specs

Table 16.3: Software Revision Level History

Software Version	Phase	Description
------------------	-------	-------------

b(4)Trade Secret Process-Product Specs

b(4)Trade Secret Process-Product Specs

submission

may refer to the Harmonic Scallop Blade as the “Aries,” “Exposure Blade,” or “Spine Dissector.” These terms refers to the code name of the development project prior to the determination of the final device name. The term “HARSB” is the device product code. Thus all references to “Aries,” “Exposure Blade,” “Spine Dissector,” or “HARSB” refer to the Harmonic Scallop Blade.

DOCUMENT TITLE:	Software Verf. Test Results - DSP	DOCUMENT NUMBER:	D16039	PAGE:	822 of 878
PROJECT:	GEN11 Generator	REVISION DATE:	18 JUL 2013	REVISION:	K

- 20. VERIFY that the Tighten Assembly screen is displayed. PASS
- 21. Open the jaws of the HARH36 (Q) Instrument.
- 22. VERIFY that the Tighten Assembly screen is still displayed. PASS
- 23. Close the jaws of the HARH36 (Q) Instrument.
- 24. VERIFY that the Tighten Assembly screen is still displayed. PASS
- 25. Press the next button.
- 26. VERIFY that the Open Jaws screen is displayed. PASS
- 27. [Trial 2 - Transition from jaws closed to jaws open]
- 28. Open the jaws of the HARH36 (Q) Instrument.
- 29. VERIFY that the UI screen displays the Blade Integrity prompt. PASS
- 30. [Trial 3 - Transition from jaws open to jaws closed]
- 31. Close the jaws of the HARH36 (Q) Instrument.
- 32. VERIFY that the Open Jaws screen is displayed. PASS
- 33. Open the jaws of the HARH36 (Q) Instrument.
- 34. VERIFY that the UI screen displays the Blade Integrity prompt. PASS
- 35. [Trial 4 - Activation switches closed with jaws closed]
- 36. Close the jaws of the HARH36 (Q) Instrument.
- 37. VERIFY that the UI screen displays the Open Jaws prompt. PASS
- 38. Press the MIN handswitch.
- 39. VERIFY that the UI screen displays the Open Jaws prompt. PASS
- 40. Release the MIN handswitch.
- 41. Press the MAX handswitch.
- 42. VERIFY that the UI screen displays the Open Jaws prompt. PASS
- 43. Release the MAX handswitch.
- 44. Press the HEMO handswitch.
- 45. VERIFY that the UI screen displays the Open Jaws prompt. PASS
- 46. Release the HEMO handswitch.
- 47. Press the MIN footswitch.
- 48. VERIFY that the UI screen displays the Open Jaws prompt. PASS
- 49. Release the MIN footswitch.
- 50. Press the MAX footswitch.
- 51. VERIFY that the UI screen displays the Open Jaws prompt. PASS
- 52. Release the MAX footswitch.
- 53. Open the jaws of the HARH36 (Q) Instrument.
- 54. VERIFY that the UI screen displays the Blade Integrity prompt. PASS
- 55. [Trial 5 - Jaws close while test in progress]
- 56. Press the MIN handswitch and close the jaws shortly after the UI screen displays that the test is in progress.
- 57. VERIFY that the UI screen displays the Open Jaws prompt. PASS
- 58. Open the jaws of the HARH36 (Q) Instrument.
- 59. VERIFY that the UI screen displays the Blade Integrity prompt. PASS
- 60. Wait for a few seconds.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter Ethicon Endo Surgery, Inc		2. Date of the Application/Submission Which This Certification Accompanies	
3. Address		4. Telephone and Fax Numbers (Include country code if applicable and area code)	
Address 1 (Street address, P.O. box, company name c/o) 4545 Creek Road		(Tel): 513.337.1546	
Address 2 (Apartment, suite, unit, building, floor, etc.)		(Fax): 513.337-2802	
City Cincinnati	State/Province/Region OH		
Country USA	ZIP or Postal Code 45242		

PRODUCT INFORMATION

5. For Drugs/Biologics: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Harmonic Blade, Class II, HARSB and
Generator G11, Class II, GEN11

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

IND NDA ANDA BLA PMA HDE 510(k) PDP Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number (If number previously assigned) _____ If BLA was selected in item 6, provide Supplement Number _____

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies _____

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes (See instructions for additional information and explanation)
- A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.
 - B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.
 - C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

CERTIFICATION STATEMENT / INFORMATION (Continued)

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. (Add continuation page as necessary.)

NCT Number(s): _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name Emily Kruetzkamp	Title Regulatory Affairs Associate
--------------------------	---------------------------------------

12. Address

Address 1 (Street address, P.O. box, company name c/o) 4545 Creek Road	
Address 2 (Apartment, suite, unit, building, floor, etc.)	
City Cincinnati	State/Province/Region OH
Country USA	ZIP or Postal Code 45242

13. Telephone and Fax Numbers

(Include country code if applicable and area code)

(Tel): 513.337.1546

(Fax): 513.337.2802

14. Date of Certification

04/23/2014

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative (Sign)

Sign



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Section 21: Other

This section contains completed copies of FDA Form 3654 for the standards referenced in this submission. The referenced standards include the following:

AAMI / ANSI / ISO 10993-7: 2008, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (FDA Recognition Number 14-278)

ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (FDA Recognition Number 14-331)

AAMI / ANSI / ISO 10993-1:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, (FDA Recognition Number 2-156)

IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (FDA Recognition Number 5-53)

IEC 60601-1-8:2006, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (FDA Recognition Number 5-86)

IEC 62304:2006, Medical device software - software life cycle processes. (FDA Recognition Number 13-8)

Attachment to FDA Form 3654, Options Selected for ISO 10993-1

Options Selected from Clause 4 of ISO 10993-1 for Form 3654, Section 4

For Surface Contacting Device the following options were selected: 4.2.2, Surface Contacting Devices (a) Skin Limited Contact (<24 hours); 4.2.3 External Communicating Devices (b) Tissue/bone/dentin Limited Contact (<24 hours); 4.2.4 Implant Devices (a) Tissue Bone Permanent Contact (>30 days).

Options Selected from Clause 5 of ISO 10993-1 for Form 3654, Section 5

For Surface contacting Device – Skin (Limited <24 hours) the following options were selected 5.2.2, Cytotoxicity utilized ISO 10993-5; 5.2.3. Sensitization utilized ISO 10993-10; 5.2.5 Intracutaneous Reactivity utilized ISO 10993-10.

For external communicating devices – Tissue/Bone/Dentin (Limited <24 hours)

The following options were selected: 5.2.2, Cytotoxicity utilized ISO 10993-5; 5.2.3. Sensitization utilized ISO 10993-10; 5.2.5 Intracutaneous Reactivity utilized ISO 10993-10.

Options Selected from Clause 6 of ISO 10993-1

All the tests in Table 1 that were recommended for this device have been conducted as discussed in Section 5 of FDA Form 3654. The following tests from Table 2 were conducted for implant devices tissue/bone, permanent contact >30 days: Chronic Toxicity (per ISO 10993-11) and Carcinogenicity (per ISO 10993-3).

Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
 (To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI ANSI ISO 10993-7: 2008, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-278

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: Use of International Standard ISO-10993-7, "Biological Evaluation of Medical Devices Part 7:EO

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
AAMI ANSI ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A, no deviations

DESCRIPTION
Scope of ISO-10993-8, EO Residuals

JUSTIFICATION
EO Sterilized Product - EO residual allowable levels

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative references	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terminology and definitions	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
AAMI ANSI ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Requirements	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Limited Exposure Devices - Simulated Use Extraction

DESCRIPTION
Limited exposure devices and simulated use extraction method used

JUSTIFICATION
Refer to IFU for the device intended use; simulated extraction method use - 24 hours extraction

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Product release	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Section 5.2 used - Release of products without dissipation curve data

DESCRIPTION
Simulated use extraction method to be used to qualify EO and ECH residuals after 24:00 hours heated aeration

JUSTIFICATION
Acceptable method for product release is based on Section 5.2 of the standard. Device to demonstrate EO and ECH levels below the specified limits in this guidance.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.3	Procedure for product release using residue dissipation curves	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Section of the Standard is being used for product release

DESCRIPTION
Acceptable method - Section 5.2 is being used for product release

JUSTIFICATION
Standard permits for either method for product release - Section 5.2 is being used for this product. Limited exposure device will demonstrate acceptable EO and ECH residual levels per ISO 10993-7.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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STANDARDS DATA REPORT FOR 510(k)s
 (To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-331

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: Use of International Std ISO-11135-1:2007 - Sterilization of health care product - Ethylene Oxide Part 1

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]
Medical device terminally sterilized using EO.

DESCRIPTION
Defines scope of guidance document and exclusions

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative references	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]
N/A

DESCRIPTION
Provides additional guidance references.

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terms and definitions	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

[♦] Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Quality management systems	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
The contract sterilizer is certified to ISO 13485 and has procedures in place specifying requirements for documentation, management responsibility, purchasing of components, calibration and control of non-conforming product.

JUSTIFICATION
ISO Certificate

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Sterilizing agent characterization	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
Sterilizing agent characterization

JUSTIFICATION
EO and its anti-microbial effectiveness is well established and documented. Its use as a terminal sterilization method is common in the medical industry particularly with sensitive materials that are not gamma stable.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Process and equipment characterization.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
Process and equipment characterization.

JUSTIFICATION
Steris-Isomedix is an established production sterilizer, and the facility and equipment have been fully validated on an annual basis by Depuy Synthes, a J&J Company. The cycle utilized is identical to the established Depuy Synthes production cycle.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 7	SECTION TITLE Product definition	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
Product Definition

JUSTIFICATION
Product performance and microbiological quality will be tested. Full sterilization validation activities for product adoption into the Depuy Synthes routine production cycle will be performed.

SECTION NUMBER 8	SECTION TITLE Process definition	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------	-------------------------------------	--

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
Process Definition

JUSTIFICATION
The production EO cycle to be used to terminally sterilize the device (achieving an SAL 10⁻⁶) is identical to the production cycle currently being used by Depuy Synthes devices, a J&J company.

SECTION NUMBER 9	SECTION TITLE Validation	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
Validation

JUSTIFICATION
IQ/OQ activities were performed on the chamber/equipment. The procedures to qualify, sustain & control, calibrate, and re-validate the EO are documented in the Qual System. Micro. and performance qualification will demonstrate the EO sterilization acceptability.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	Routine monitoring and control	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
Routine Monitoring and Control

JUSTIFICATION
Each production sterilization cycle will be monitored to ensure all parameters meet the required specifications.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11	Product release from sterilization	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
Product Release from Sterilization

JUSTIFICATION
Each production sterilization cycle will be monitored to ensure all parameters meet the required specifications. Non-conformances will be handled through the Quality System.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
12	Maintaining process effectiveness	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
Maintaining Process Effectiveness

JUSTIFICATION
Bioburden will be routinely monitored on a quarterly basis. All routine maintenance and calibration of EO sterilizing equipment will be performed and documented. Annual re-qualification will be completed. Changes to the device will be evaluated.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI ANSI ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk mngmnt process

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #2-156

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: FDA Bluebook Memorandum G95-1, Use of International Standard ISO 10993, "Biological Evaluation of

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
AAMI ANSI ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk mngmnt process

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 1	SECTION TITLE Scope, object and related standards	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 2	SECTION TITLE Normative references	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 3	SECTION TITLE Terminology and definitions	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------	--	--

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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SUMMARY REPORT TABLE**

STANDARD TITLE
AAMI ANSI ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk mngmnt process

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General principles applying to biological evaluation of medical devices	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Categorization of medical devices	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Biological evaluation process	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

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CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Interpretation of biological evaluation data and overall biological safety asses	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? Yes No

FDA Recognition number ³ # N/A

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? Yes No

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? Yes No
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? Yes No

Does this standard include acceptance criteria? Yes No
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? Yes No
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?..... Yes No
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If yes, was the guidance document followed in preparation of this 510k? Yes No

Title of guidance: _____

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 1	SECTION TITLE Scope, object, and related standards	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 2	SECTION TITLE Normative references	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------	---------------------------------------	--

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 3	SECTION TITLE Terminology and definitions	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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DESCRIPTION

JUSTIFICATION

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 4	SECTION TITLE General requirements	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 5	SECTION TITLE General requirements for testing ME equipment	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 6	SECTION TITLE Classification of ME equipment and ME systems	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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STANDARD TITLE
IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 7	SECTION TITLE ME equipment identifications, marking and documents	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 8	SECTION TITLE Protection against electrical hazards from ME equipment	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 9	SECTION TITLE Protection against mechanical hazards and ME equipment and ME systems	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 10	SECTION TITLE Protection against unwanted and excessive radiation hazards	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 11	SECTION TITLE Protection against excessive temperatures and other hazards	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 12	SECTION TITLE Accuracy of controls and instruments and protection against hazardous output	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 13	SECTION TITLE Hazardous situations and fault conditions	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 14	SECTION TITLE Programmable electrical medical systems (PEMS)	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 15	SECTION TITLE Construction of ME equipment	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 16	SECTION TITLE ME systems	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 17	SECTION TITLE Electromagnetic compatibility of ME equipment and ME systems	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #5-53

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 1	SECTION TITLE Scope, object, and related standards	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 2	SECTION TITLE Normative references	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 3	SECTION TITLE Terminology and definitions	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------	--	--

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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**EXTENT OF STANDARD CONFORMANCE
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STANDARD TITLE
IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 4	SECTION TITLE General requirements	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------	---------------------------------------	--

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 5	SECTION TITLE Identification, marking, and documents	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 6	SECTION TITLE Electromagnetic compatibility	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 60601-1-8:2006, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 5-86

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
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Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

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² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 60601-1-8:2006, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 1	SECTION TITLE Scope, object, and related standards	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 2	SECTION TITLE Normative references	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 3	SECTION TITLE Terms and definitions	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------	--	--

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 60601-1-8:2006, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 4	SECTION TITLE General requirements	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 5	SECTION TITLE ME equipment identification, marking and documents	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 6	SECTION TITLE Alarm systems	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------	--------------------------------	--

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 62304:2006, Medical device software - Software life cycle processes

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 13-8

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

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Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 62304:2006, Medical device software - Software life cycle processes

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 1	SECTION TITLE Scope	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 2	SECTION TITLE Normative references	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 3	SECTION TITLE Terms and definitions	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 62304:2006, Medical device software - Software life cycle processes

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General requirements	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Software development process	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Software maintenance process	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 62304:2006, Medical device software - Software life cycle processes

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 7	SECTION TITLE Software risk management process	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 8	SECTION TITLE Software configuration management process	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 9	SECTION TITLE Software problem resolution process	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---------------------	--	--

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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K 14 11 22 / 5001

August 19, 2014

Edwin Ramirez, FDA
General Surgery Devices Branch
US Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

FDA CDRH DMC
AUG 20 2014
Received

301.796.2690

Edwin.Ramirez@fda.hhs.gov

RE: Response to questions on the Ethicon Harmonic scallop blade, generator G11 (K141122)

Dear Mr. Ramirez:

Please find the attached response to the questions you raised in your request for additional information, dated June 24, 2014. Per the instructions accessed at “eCopy Program for Medical Device Submissions” an electronic copy is provided with this submission and it is an exact duplicate of the paper submission.

If there are any questions, please contact me via phone, 513.337.1546, or via email, ekruetzk@its.jnj.com. If I am not available, the alternate contact person for his submission is Kim Shoemaker, Director of Regulatory Affairs, at 513.337.8123.

Best Regards,



Emily Kruetzkamp
Senior Regulatory Affairs Associate, RAC

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1+12

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Best Regards,



Emily Kruetzka
Senior Regulatory Affairs Associate, RAC

Date: August 19, 2014

To: Emily Kruetzkamp, Ethicon Endo-Surgery, LLC

From: Edwin Ramirez, FDA

Subject: 510(k) review for the Ethicon Harmonic Scallop Blade, Generator G11 (K141122)

b(4)Trade Secret Process-Product Specs

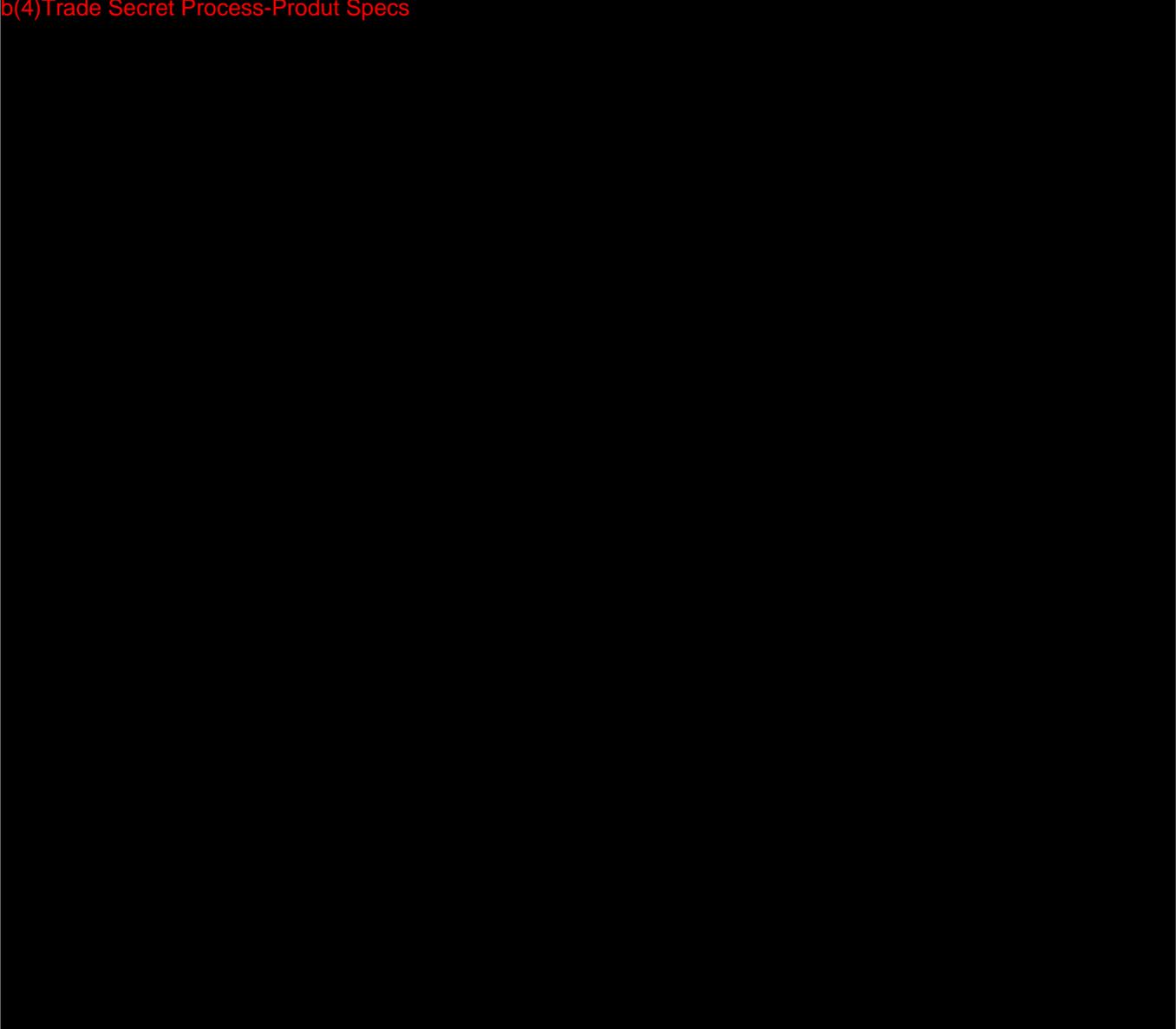
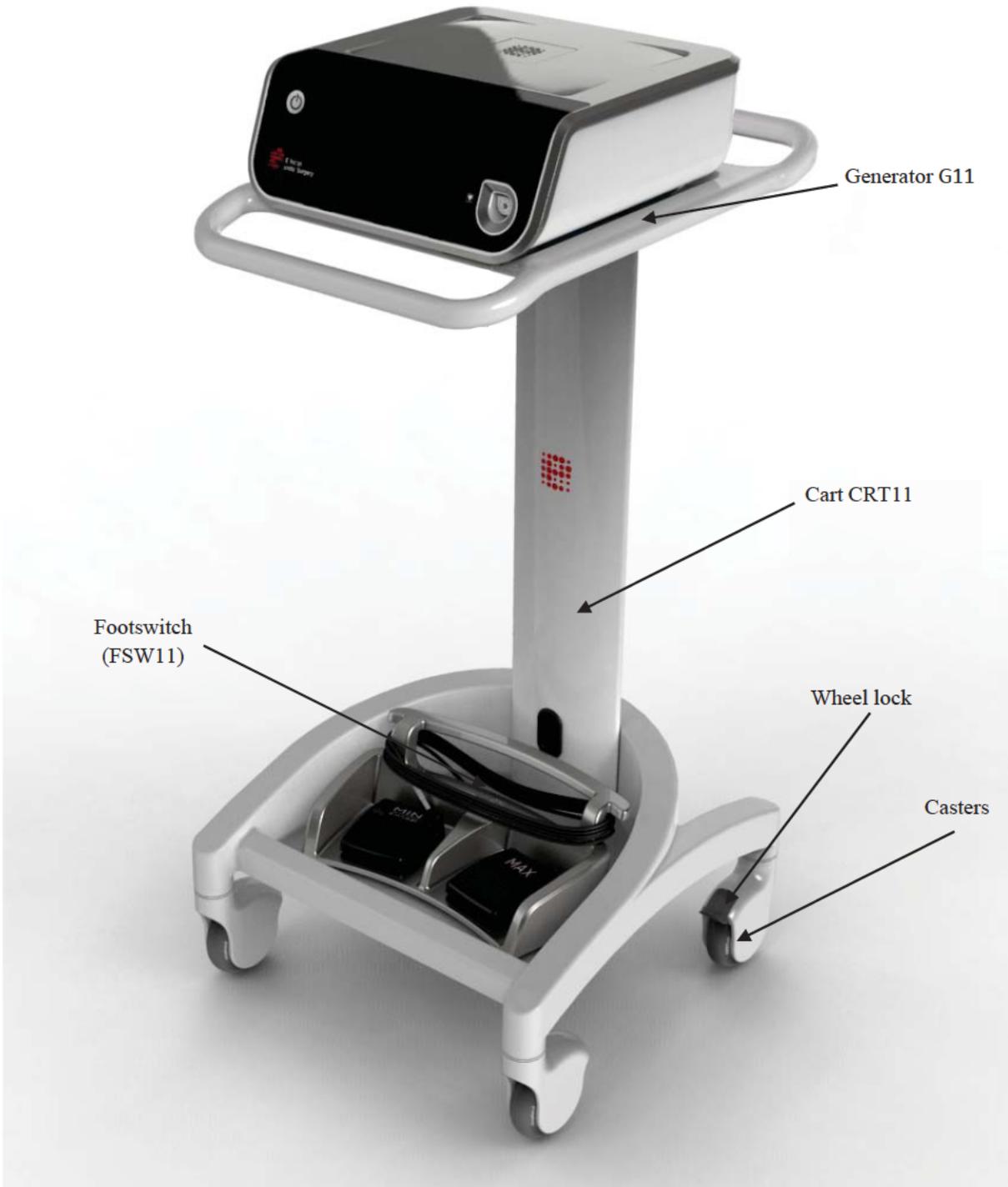


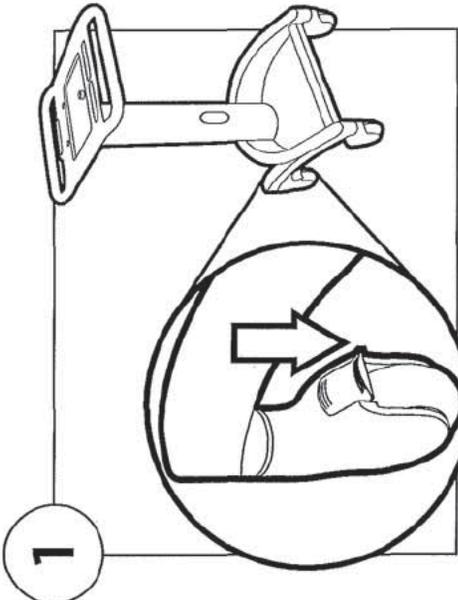
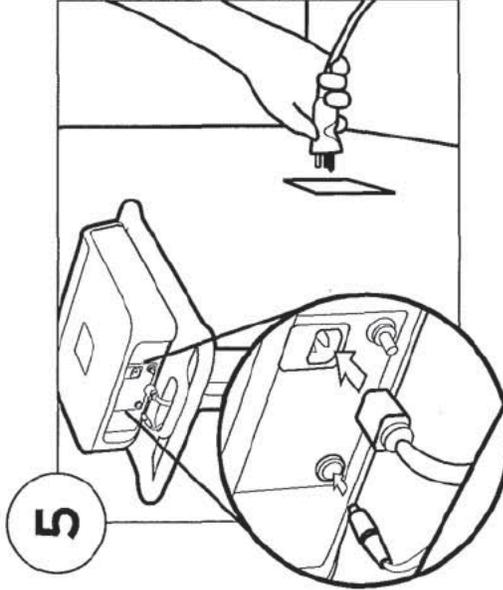
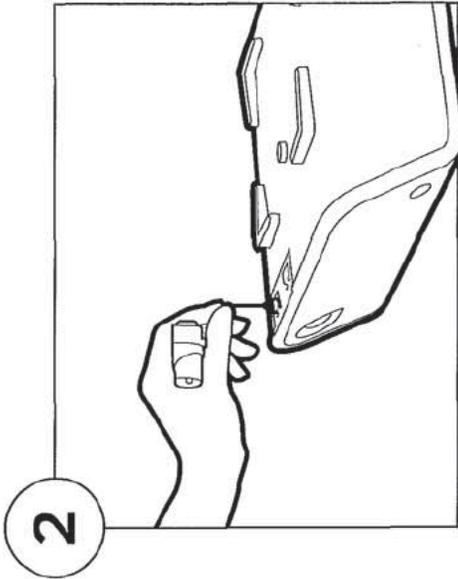
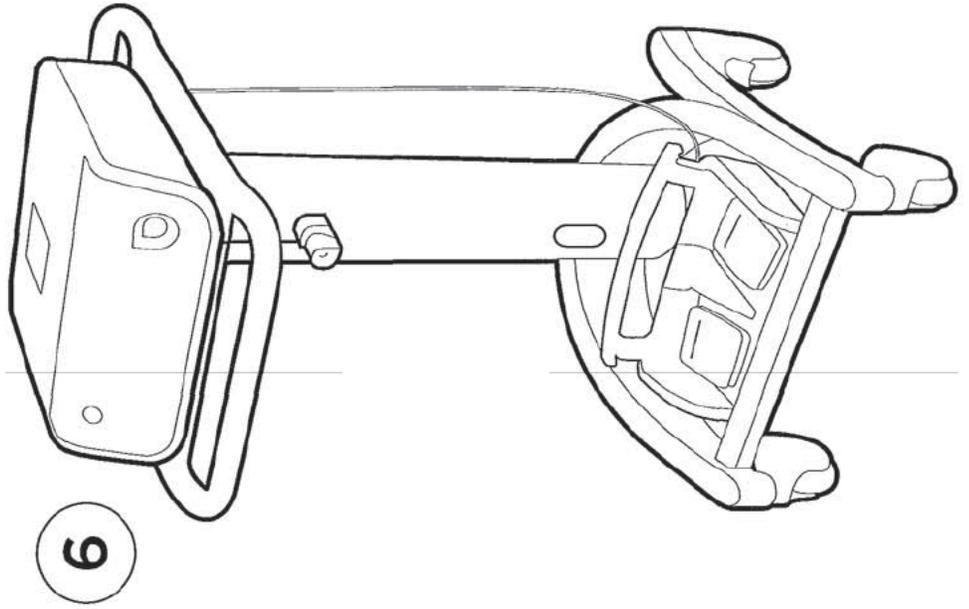
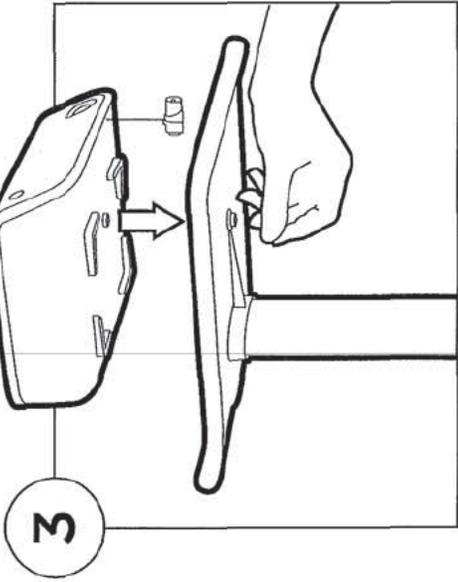
Table 1: The Subject Device is intended to be marketed with multiple components, each packaged separately.

Name	Product Code	510k Clearance	Description
Generator Cart	CRT11	K101990	The Generator Cart (CRT11) is an optional accessory that may be used to hold, transport, and storage of the Generator G11 and accessories.
Generator G11	GEN11	K101990	The Generator G11 supplies energy to the Harmonic and EnSeal surgical instruments. The generator uses a touchscreen display interface.
Footswitch	FSW11	K101990	The left pedal activates minimum power, The left pedal activates maximum power. The Footswitch connects to the generator with a cord, and is plugged into a receptacle at the back of the generator.
Harmonic Scalpel Hand Piece	HP054	K002906	The Hand Piece is designed to convert electrical energy from a compatible Harmonic Generator to mechanical motion for the instrument blades.

Figure 1: Generator G11 and Accessories on Cart CRT11



Implemented: 03/18/2011 Latest Released: YES



ETHICON ENDO-SURGERY, INC.
Cincinnati, OH 45242-2839
1-800-USE-ENDO

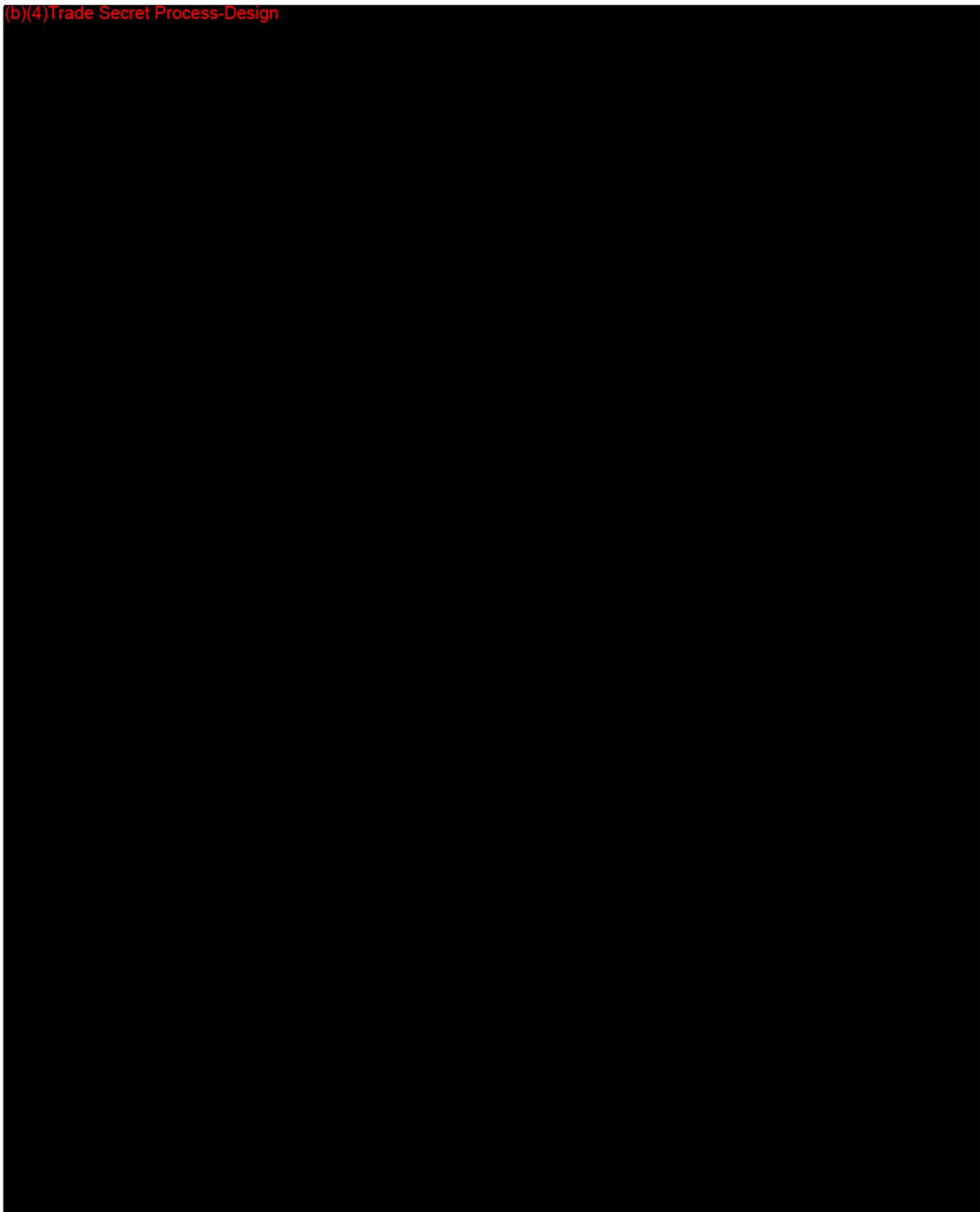
Ethicon Endo-Surgery (Europe) GmbH
Hummelsbuehler Steinlamm 71,
22851 Norderstedt, GERMANY

ETHICON ENDO-SURGERY, LLC ©EES, LLC 2010
Guaynabo, Puerto Rico 00969 USA Made in USA



P40659P02 Rev. 2011-02

(b)(4)Trade Secret Process-Design



2. Regarding the Device Labeling:

- a. In the Generator G11 Operator's Manual Appendix, under Harmonic Output the following specifications are stated: 150 VAC RMS maximum, 35 Watts (continuous).

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

- *The persons for whose use the device is represented or intended; The conditions of use for the device, including conditions of use prescribed, recommended or suggested in the labeling or advertising of the device, and other intended conditions of use; The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; The reliability of the device; and, Other relevant factors.*

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

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

All testing referenced in this submission was conducted under the new generator specifications.

Harmonic Output:

150 VAC RMS maximum (Unless otherwise specified in the instrument IFU)

35 watts continuous (Unless otherwise specified in the instrument IFU)

30 - 80 kHz (55.5 kHz unless otherwise marked in instrument IFU)

A copy of the relevant page from the Subject Device IFU is attached for your reference.

Appendix

System Specifications

Main Fuses	T5AL 250 V (Time-delay, 5 Amp, glass body, 5x20 mm package size, quantity: 2)
Degree of Protection Against Electric Shock	Type CF applied part consisting of the HARMONIC or ENSEAL instruments
Class of Protection Against Electric Shock	Class 1
Ingress Protection G11 Enclosure	IP21
Ingress Protection G11 Footswitch	IP68
Main Input	100 - 240 V ~, 50/60 Hz, 500 VA
Output	ENSEAL Output: Bipolar, no neutral electrode required 100 VAC RMS maximum 135 watts maximum (rated load 15 ohms) 300 - 490 kHz (330 kHz unless otherwise marked in instrument IFU) HARMONIC Output: 150 VAC RMS maximum (Unless otherwise specified in the instrument IFU) 35 watts continuous (Unless otherwise specified in the instrument IFU) 30 - 80 kHz (55.5 kHz unless otherwise marked in instrument IFU)
Ambient Operating Conditions	Temperature: 15 °C to 27 °C Humidity: 30% - 75% non-condensing Atmospheric Pressure Range: 700 hPa - 1060 hPa
Transport and Storage Conditions	Temperature: -35 °C to +54 °C Humidity: 10% - 95% non-condensing Atmospheric Pressure Range: 700 hPa - 1060 hPa
Weight	Generator: 5.9 kg Cart: 16.8 kg Footswitch: 3.6 kg
Overall Dimensions	Generator: 35.0 cm x 35.5 cm x 13.6 cm Cart: 48.0 cm x 56.2 cm x 95.3 cm Footswitch: 34.2 cm x 19.0 cm x 10.4 cm
Power Cord	North American removable power cord set with the following characteristics: Plug Style: NEMA 5-15 (clear) North American Hospital Grade Receptacle: IEC 60320 C13 with straight non-angled cord entry Cord Length: 4.6 meters nominal Current Rating: 13A Voltage Rating: 125 VAC minimum Wiring Code: North American Cordage Description: SJT (UL) or SJT (CSA) Conductors: 16 AWG 3C Agency Approvals Required: UL and CSA International removable power cord set with the following characteristics: Plug Style: as needed by particular country requirements Receptacle: IEC 60320 C13 with straight non-angled cord entry Cord Length: 2.44 - 4.6 meters nominal Current Rating: 10A Minimum conductor size cross-sectional area: 1.0 mm ² copper Voltage Rating: 250 VAC minimum Wiring: International Cordage Type: HAR Item to have certification by at least one of the following agencies: VDE, ASTA, SEMKO, KEMA, LCIE, DFT, IMQ, SEV

Indications

The HARMONIC Scallop Blade instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

Contraindications

- The instruments are not intended for contraceptive tubal occlusion.

Device Description

The HARMONIC Scallop Blade instrument is a sterile, single patient use device, consisting of a titanium blade with a non-removable gray sheath. The HARMONIC Scallop Blade instrument allows for the cutting of soft tissue and coagulation of vessels up to and including 2 mm in diameter.

A soft grip pad on the handle housing facilitates grasping. The instrument is equipped with an integrated internal torque wrench.

The HARMONIC Scallop Blade instrument is designed for use exclusively with the Generator G11 (GEN11) software version 2013_1 or later and the HARMONIC Hand Piece (HP054), packaged separately. The instrument is solely operated using the HARMONIC Foot Switch (FSW11). Refer to the HARMONIC™ Generator G11 System User Manual before using this instrument.

Output Specifications

340 VAC RMS

60 watts continuous

Illustration and Nomenclature (Illustration 1)

- 1 Blade
- 2 Sheath
- 3 Soft Grip Pad
- 4 Handle Housing

Transport and Storage Conditions

Temperature: -22°C to +60°C

Relative Humidity: 10-80%

Throughout the device labeling, the temperature and humidity recommendations and symbols are intended to provide guidance on short-term temperature and humidity excursions during transportation and storage.

For optimal long-term storage, it is recommended to store the instruments dry, at room temperature.

Instructions for Use

Verify compatibility of all instruments and accessories prior to using the instrument (refer to **Warnings and Precautions**).

The HARMONIC Hand Piece and Test Tip, packaged separately, are shipped non-sterile and must be sterilized per the insert instructions prior to each use.

3. Please address the following concerns in regards to Electrical testing:
 - a. The submission discloses that the Generator G11 device is in compliance with all applicable sections of IEC 60601-1-2. The submission provided a summary table (Form 3654) and a certificate of compliance from (b)(4)Trade Secret Process-Product Specs stating that the device meets the named standard. However, the certificate of compliance is ambiguous on what device(s) it tested for compliance as the submission utilizes the term HARSB to refer to the blade portion only in several instances of the submission. All electro-surgical devices should undergo basic electrical, thermal, and electromagnetic performance testing to evaluate the potential for insufficient electrical safety and electromagnetic compatibility. Please clarify if the IEC 60601-1-2 testing was for the whole device system (Harmonic Scallop Blade, Generator G11, Foot Switch FSW11) and / or provide a revised compliance certificate.

RESPONSE: Please see the attached Electromagnetic Compatibility Test Report pages for the Generator GEN11 and Subject Device (HARSB) which demonstrates compliance with IEC 60601-1-2. Section 7, Test Set-up Description, lists the devices tested for compliance. All of the subject electro-surgical devices underwent basic electrical, thermal, and electromagnetic performance testing to evaluate the potential for insufficient electrical safety and electromagnetic compatibility. The IEC 60601-1-2 testing was for the whole device system (Harmonic Scallop blade, Generator G11, Foot Switch FSW11), as shown in the test report. The IEC 60601-1-2 testing was for the whole device system, (Harmonic Scallop blade, Generator G11, Foot Switch FSW11). The subject device has to be connected to the system (Generator, handpiece, and footswitch) for it to be functional. So, even though the certificate lists HARSB, section 7 lists the total configuration used for the EMC tests. Our normal business practice is to list the amended device on the ICL Certificate. The certificate doesn't list the full Generator Gen11 system parts, but these components are described in the ICL test report, and for this testing the device was assembled according to the IFU.

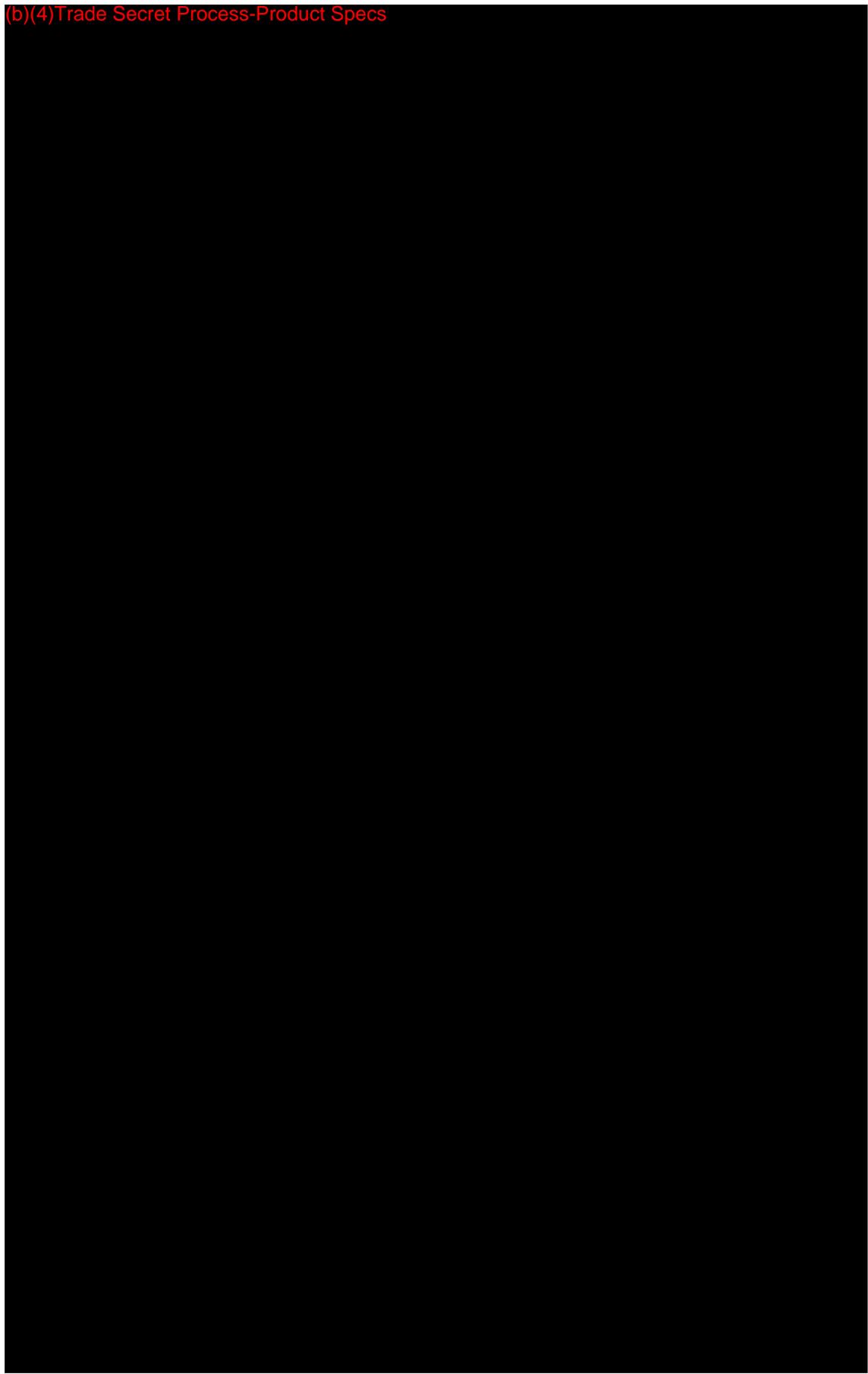
- b. The submission did not provide a risk analysis or risk management assessment of the possible problems / hazards the device (Harmonic Scallop blade, Generator G11, Foot Switch FSW11 and transportation Cart CRT11) might encounter by introducing a new harmonic blade tip device. A submission should provide Risk analysis / Risk Management with at a minimum a Failure mode effects analysis (FMEA) to ensure the proposed device will not create any new questions in regards to safety and / or effectiveness. This information will help demonstrate that the testing you have provided adequately mitigates the risks of your device. Please provide a Risk Analysis and / or an application of Risk Management document for your device.

RESPONSE: The 510k submission provided the performance data to show substantial equivalence to the predicate device. The bench studies and preclinical verification studies demonstrate that the Subject Device is substantially equivalent to the predicate device. The manufacturer believes that the Subject Device probability and duration of a harmful event is substantially equivalent to that of the Predicate Device. Post-market data from the Predicate Device does not indicate that the Subject Device will introduce new risks. In addition, the post market data suggests that the manufacturer's approach to mitigate known risks has proven to be effective. The following Risk Analysis is an assessment of the possible problems / hazards that the Subject Device Harmonic Scallop Blade, Generator G11, Foot Switch FSW11 and transportation Cart CRT11 might encounter by introducing a new Harmonic Blade tip device.

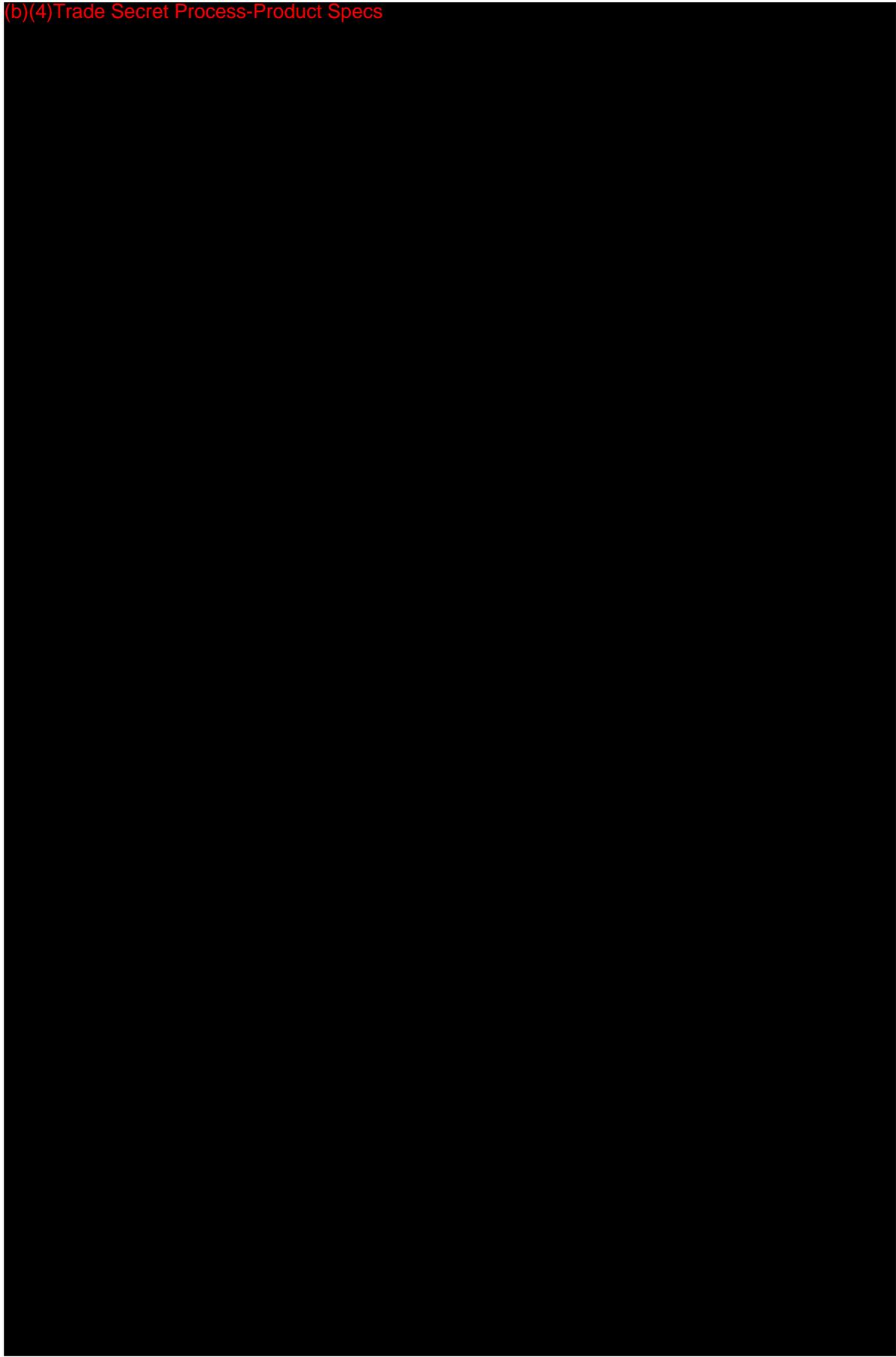
(b)(4)Trade Secret Process-Product Specs



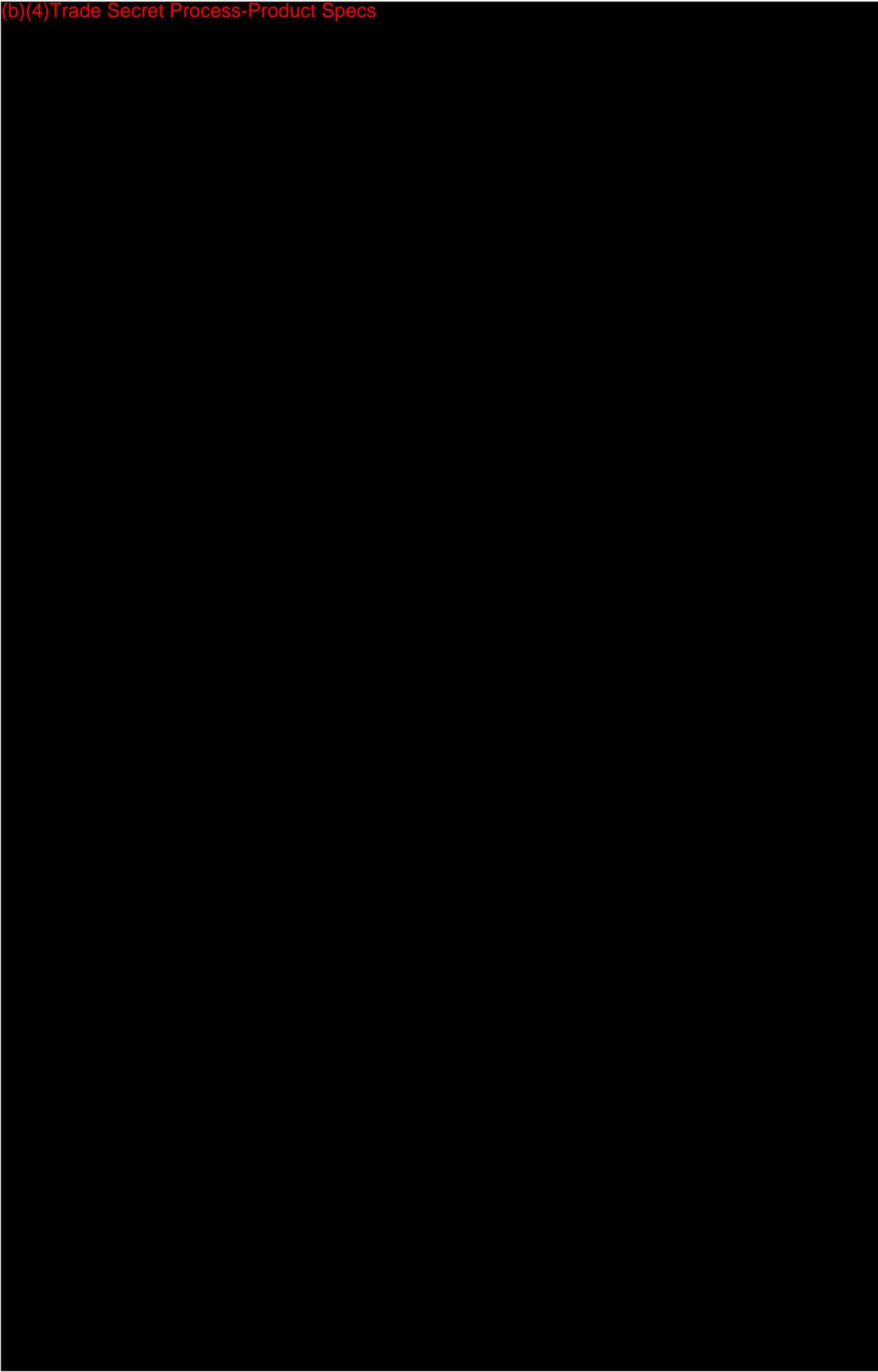
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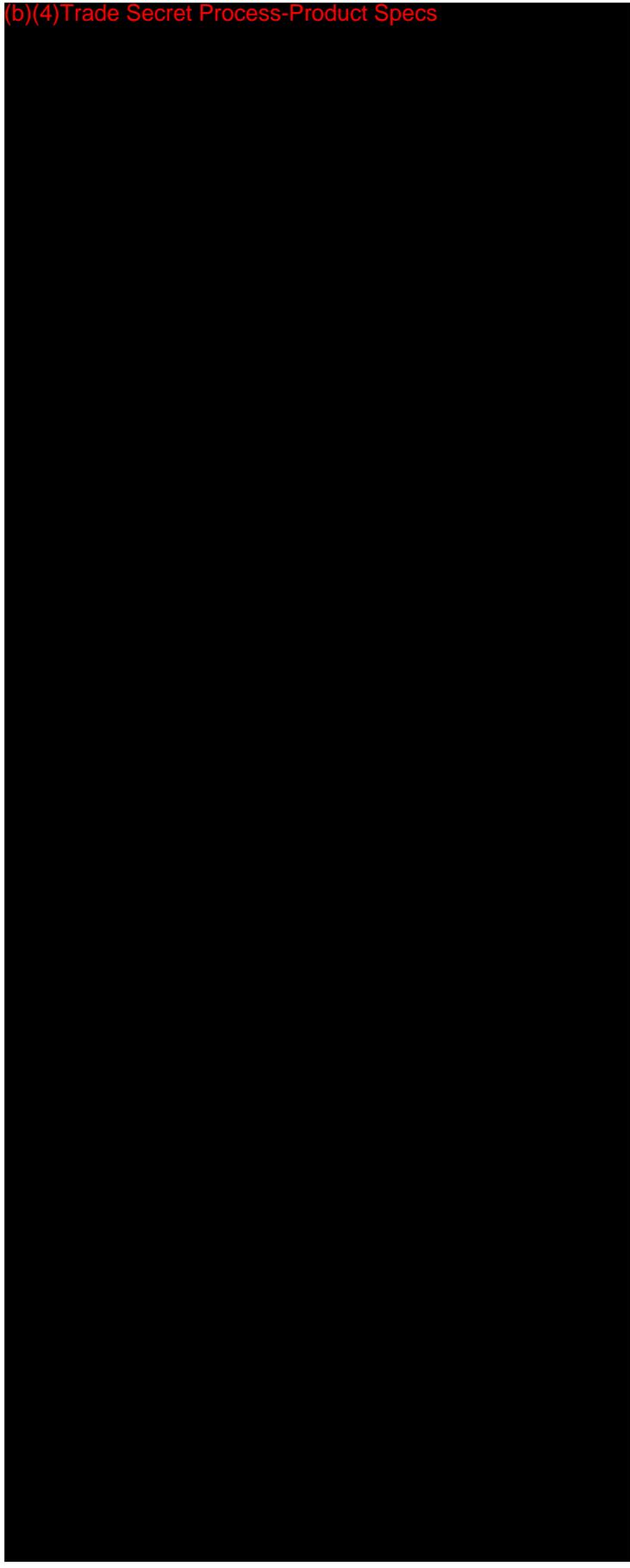
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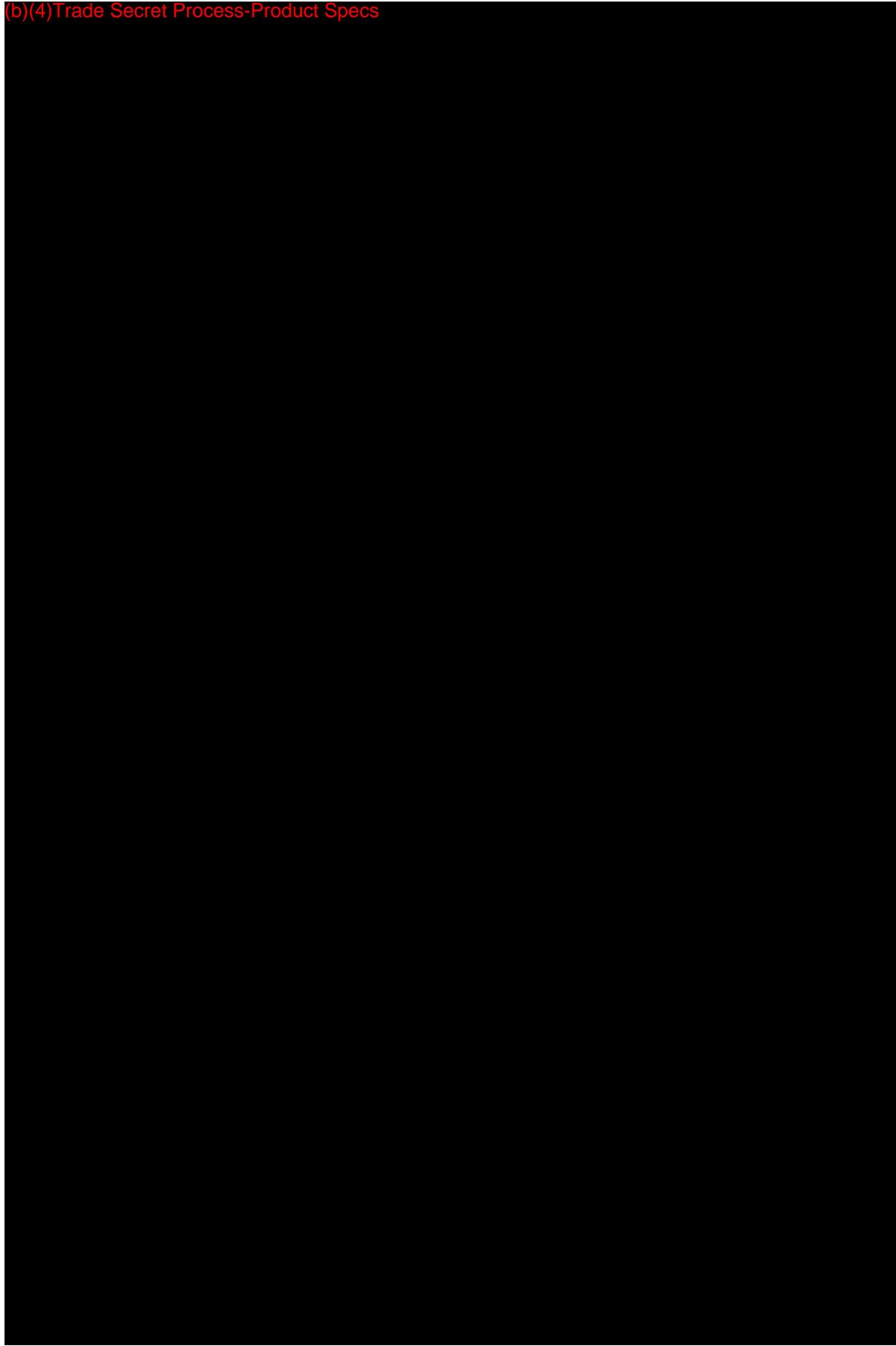
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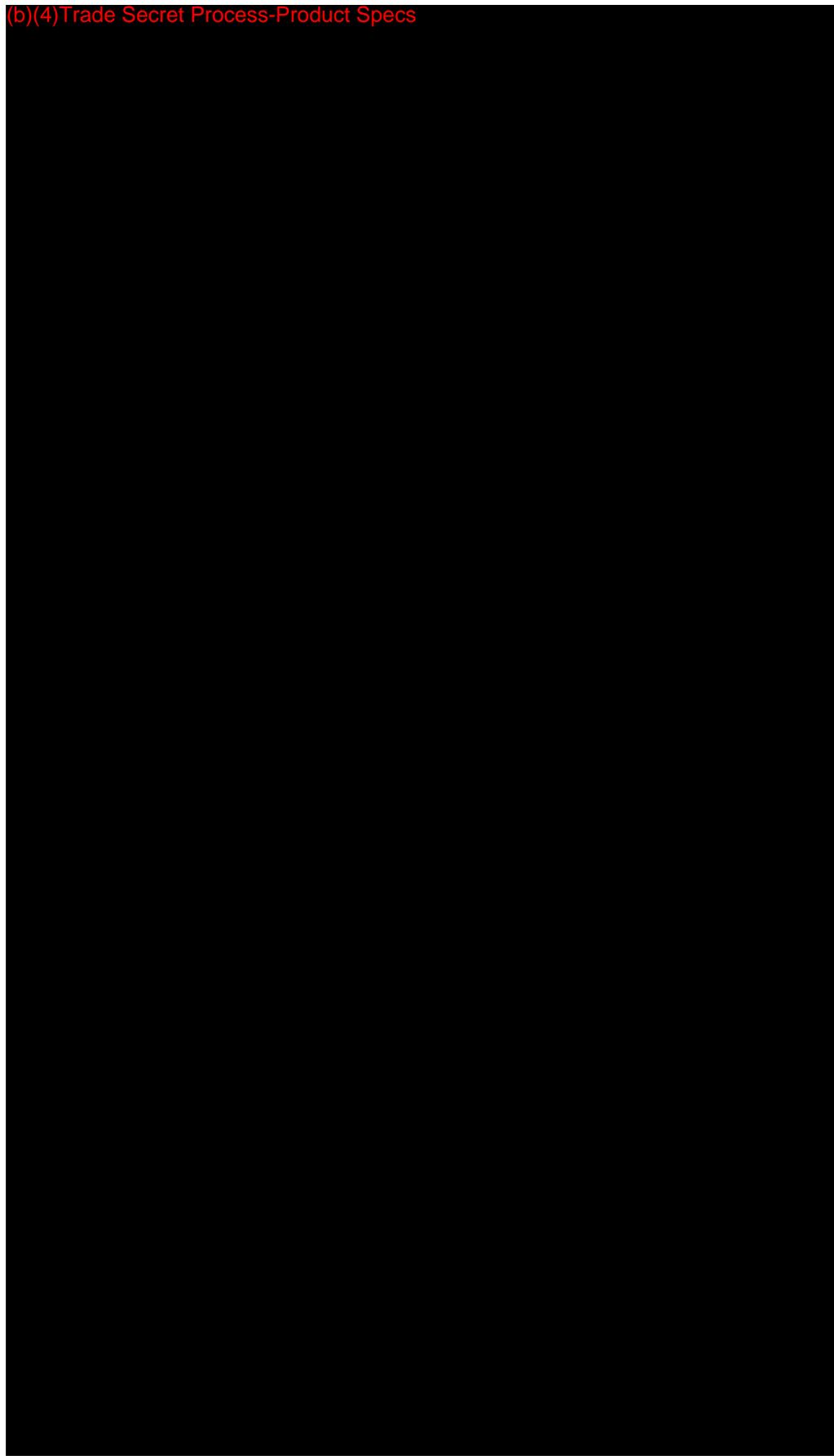
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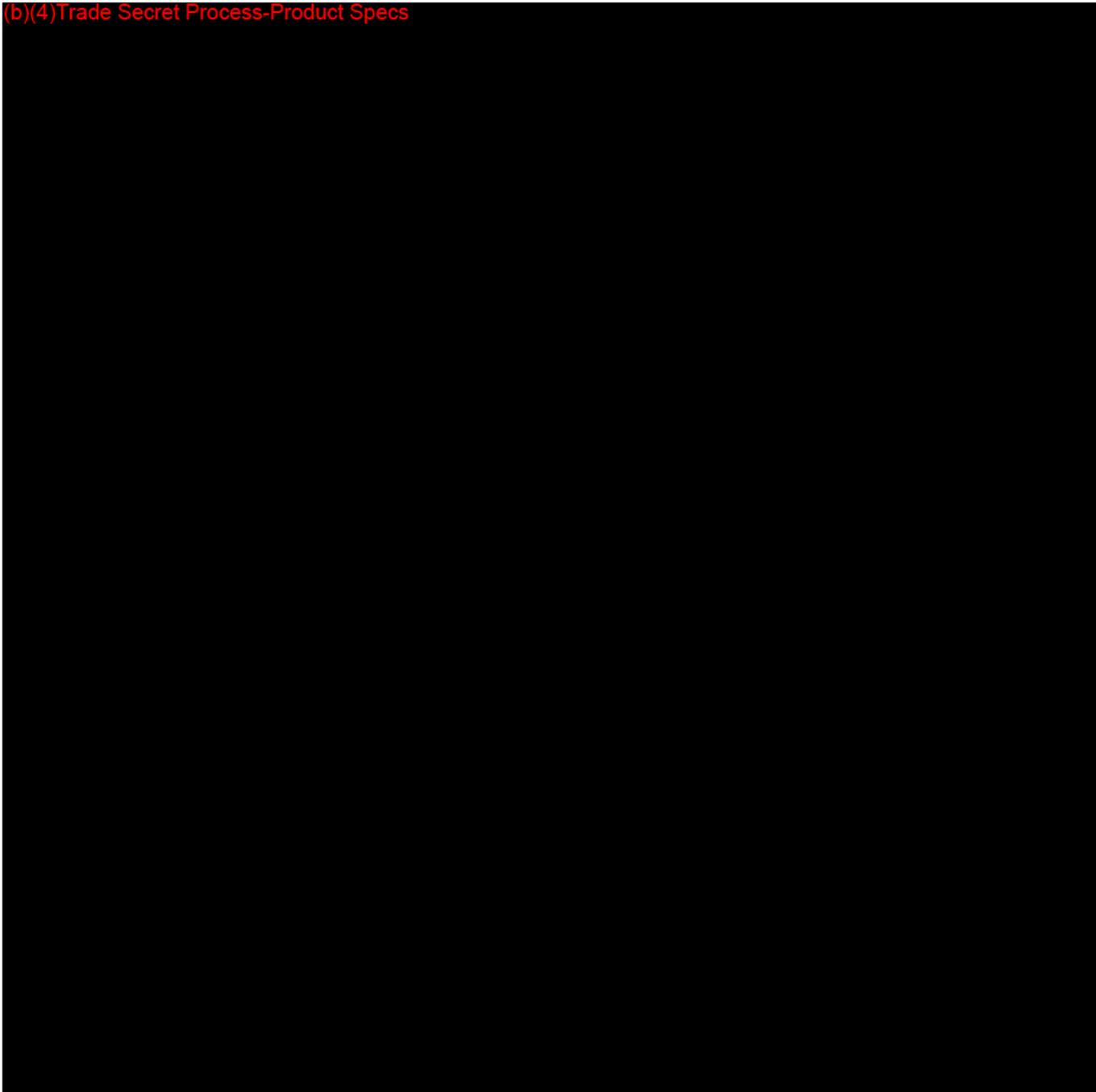


4. Regarding the provided Animal testing study:
 - a. The submission does not state whether the animal testing was done in compliance with

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

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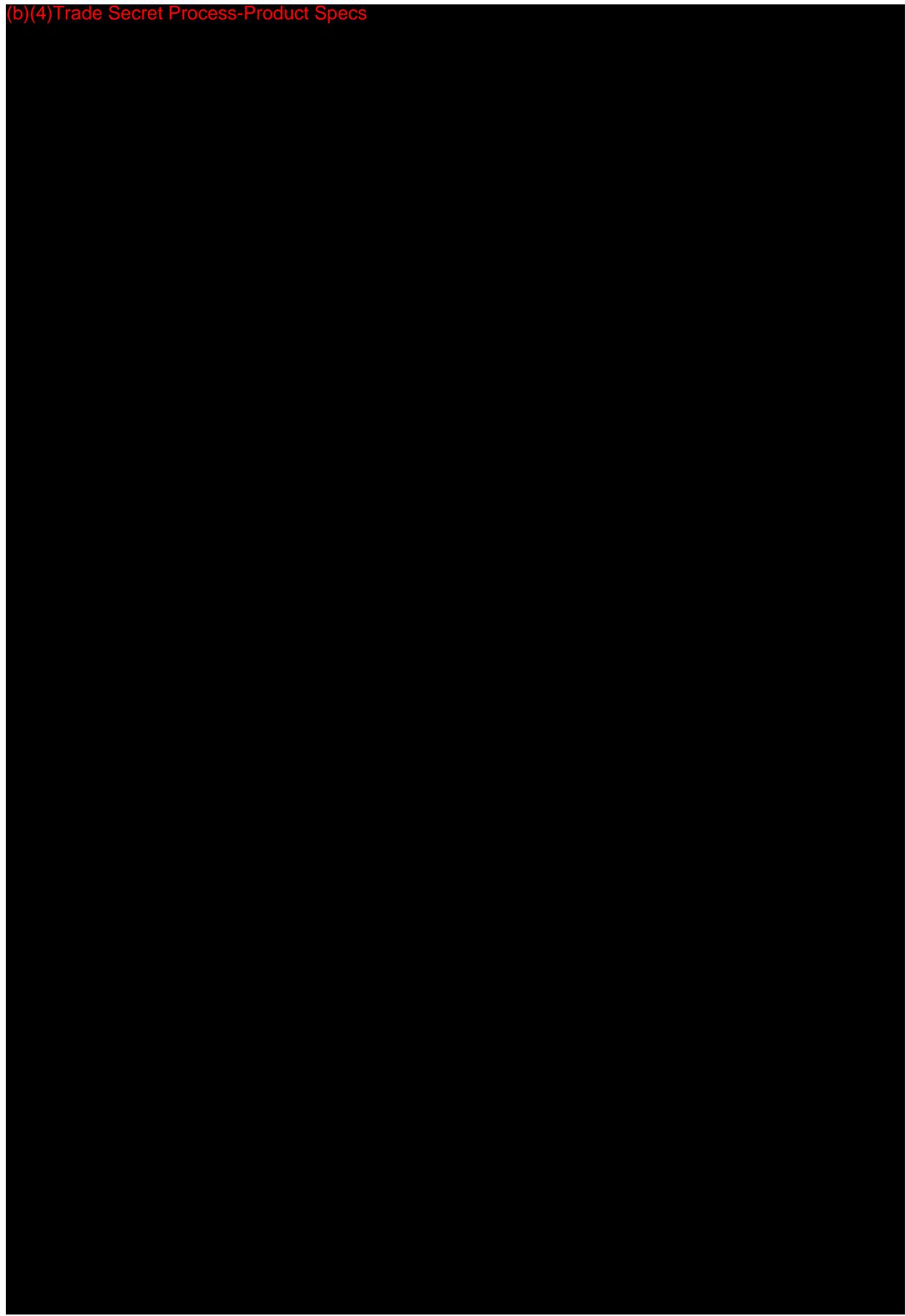
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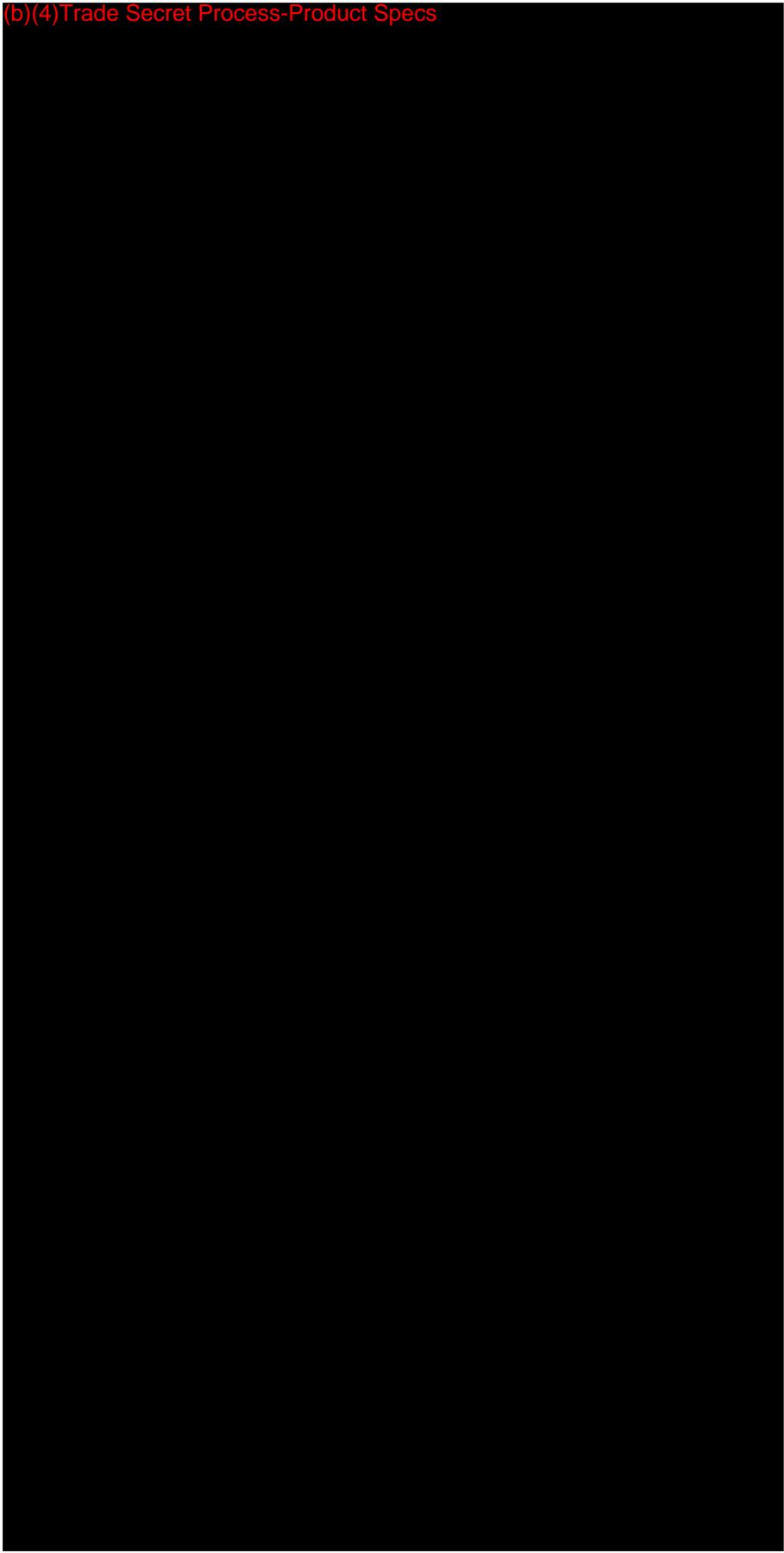
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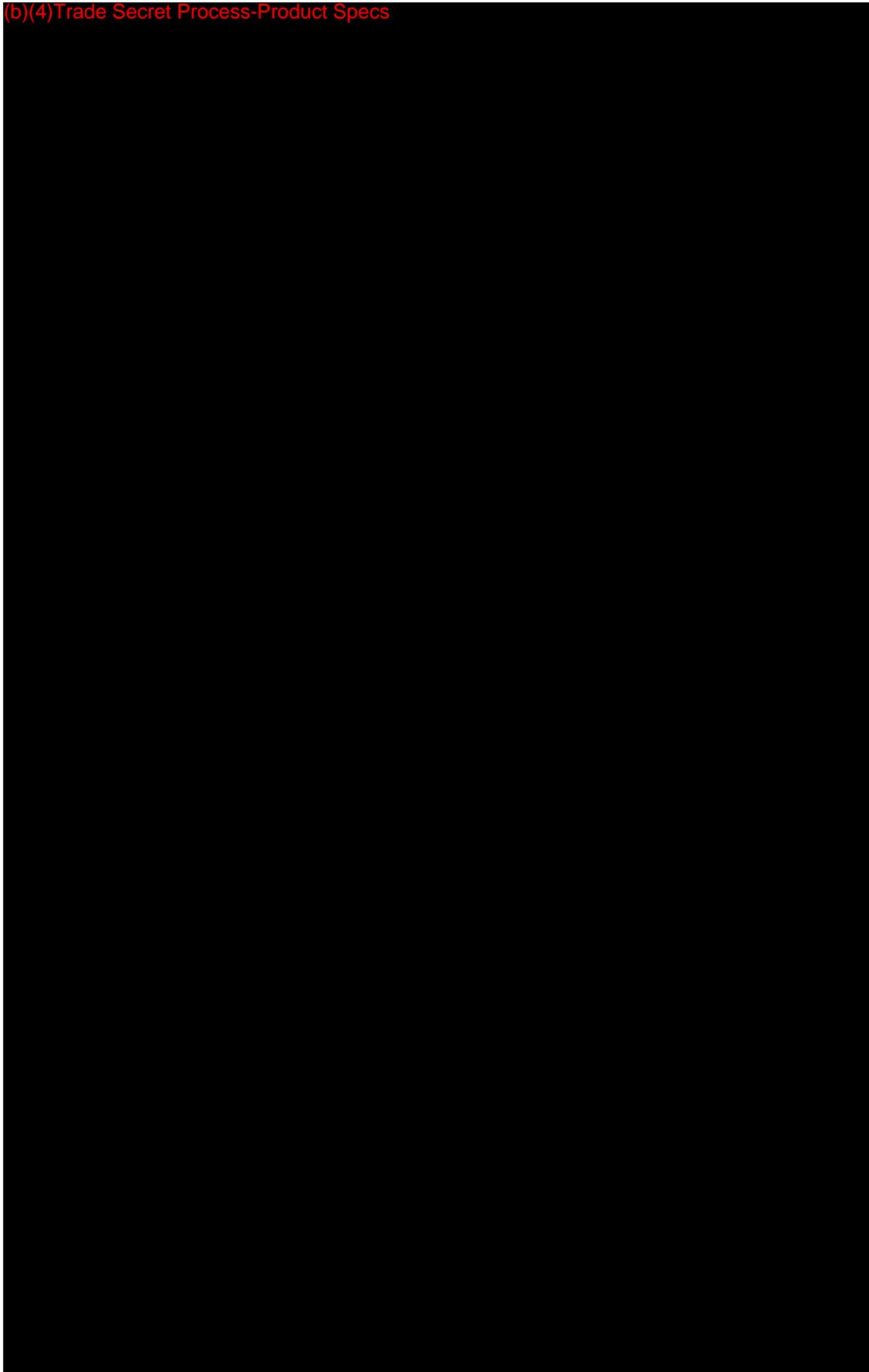
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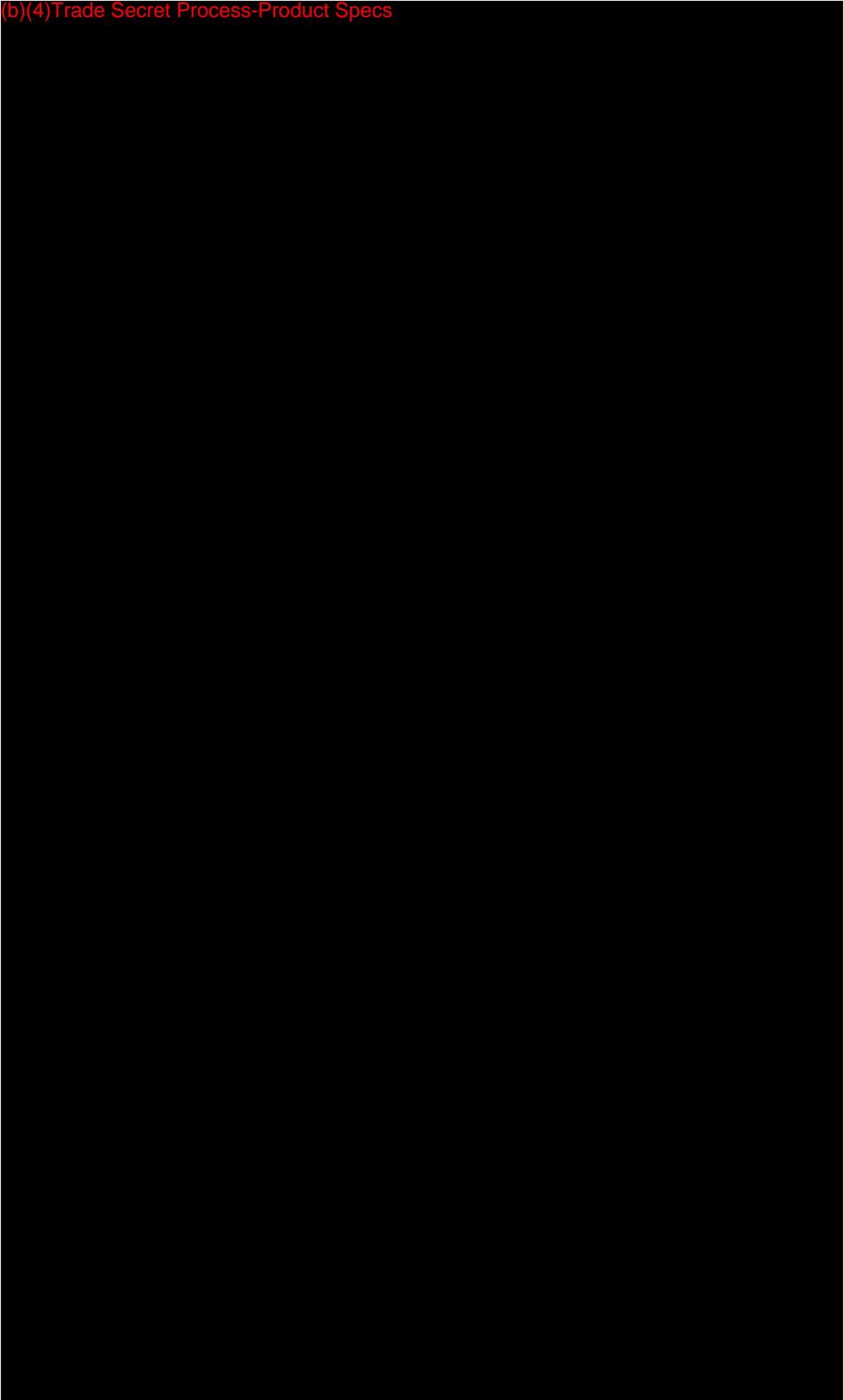
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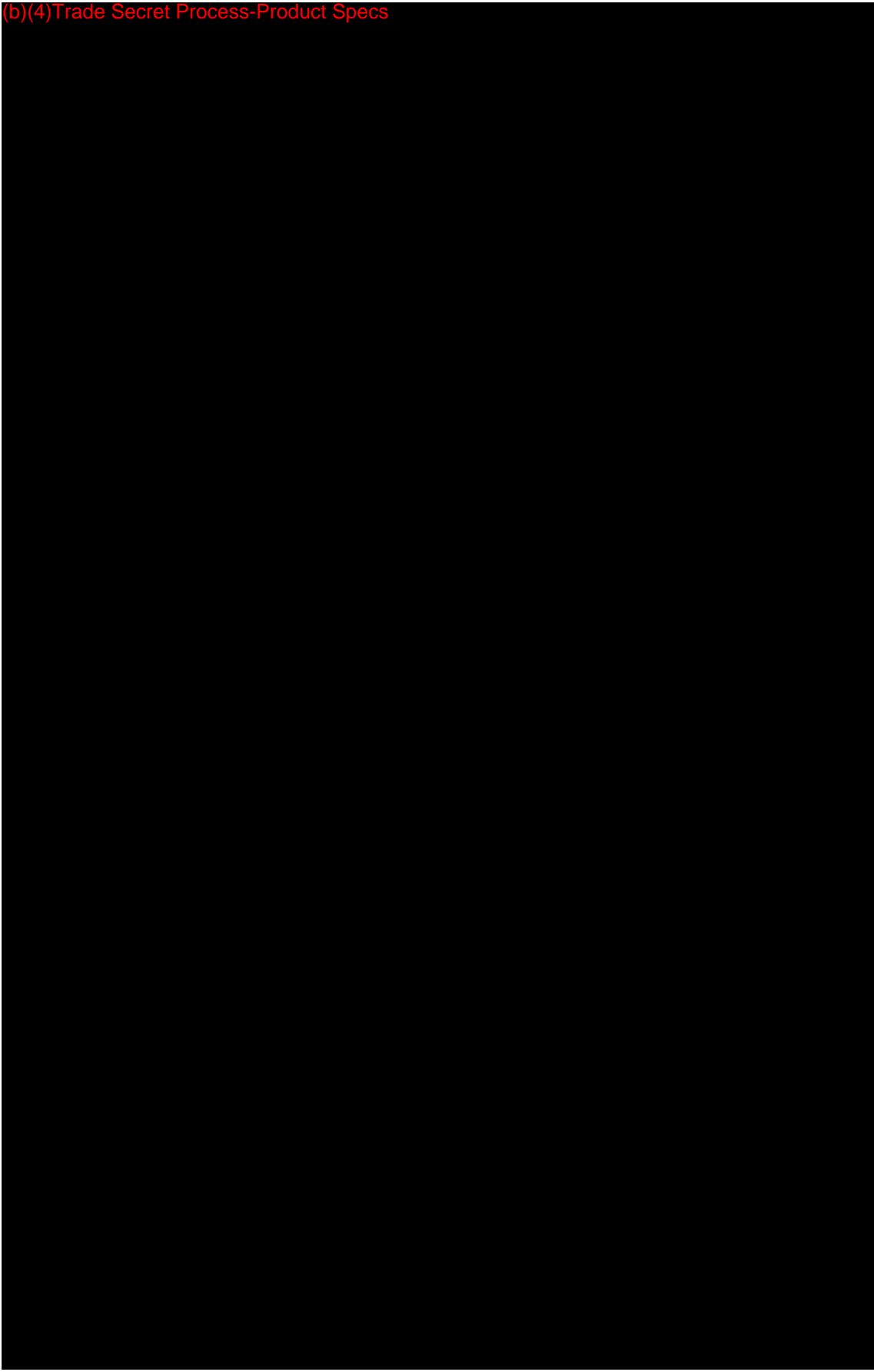
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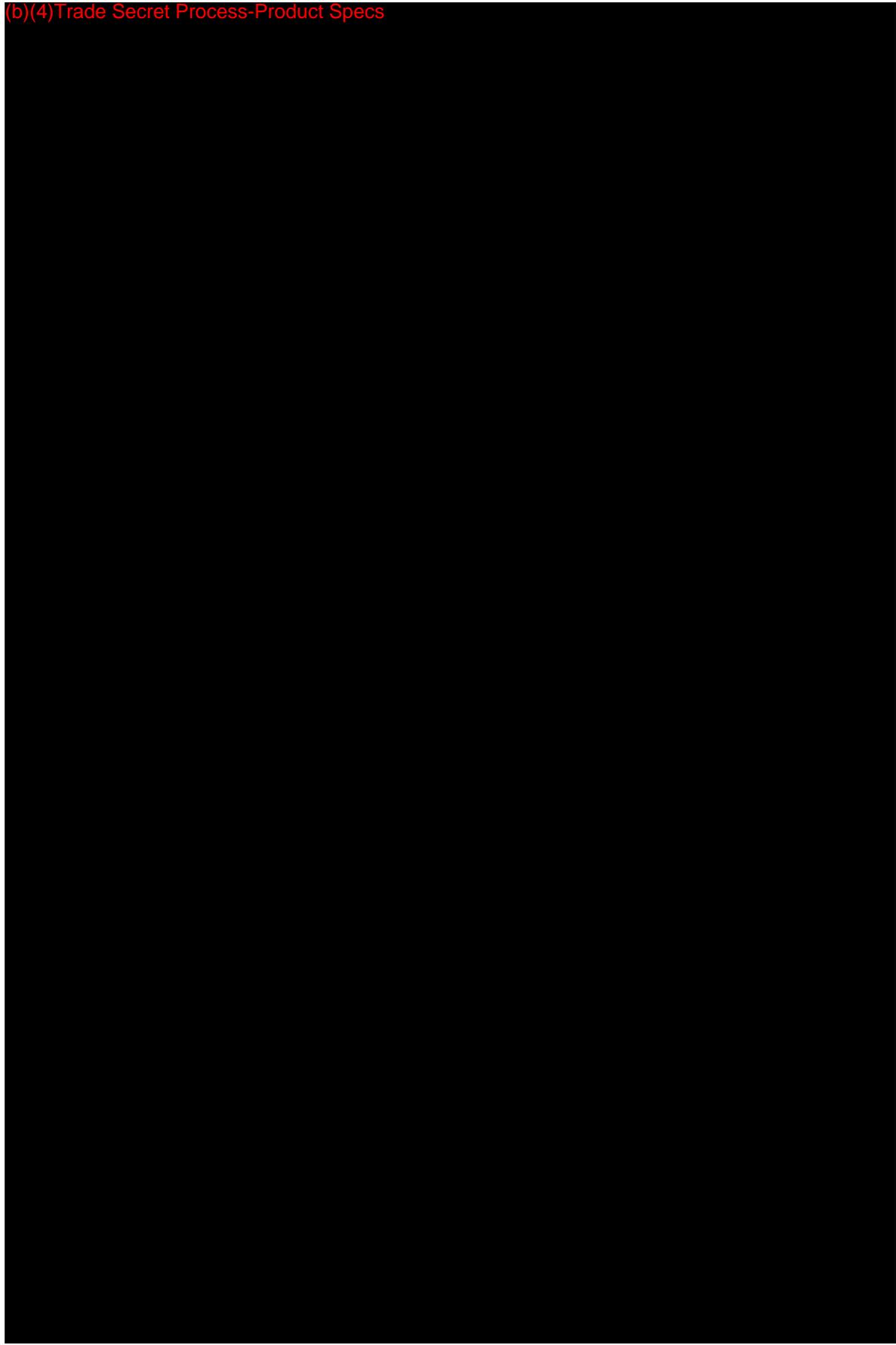
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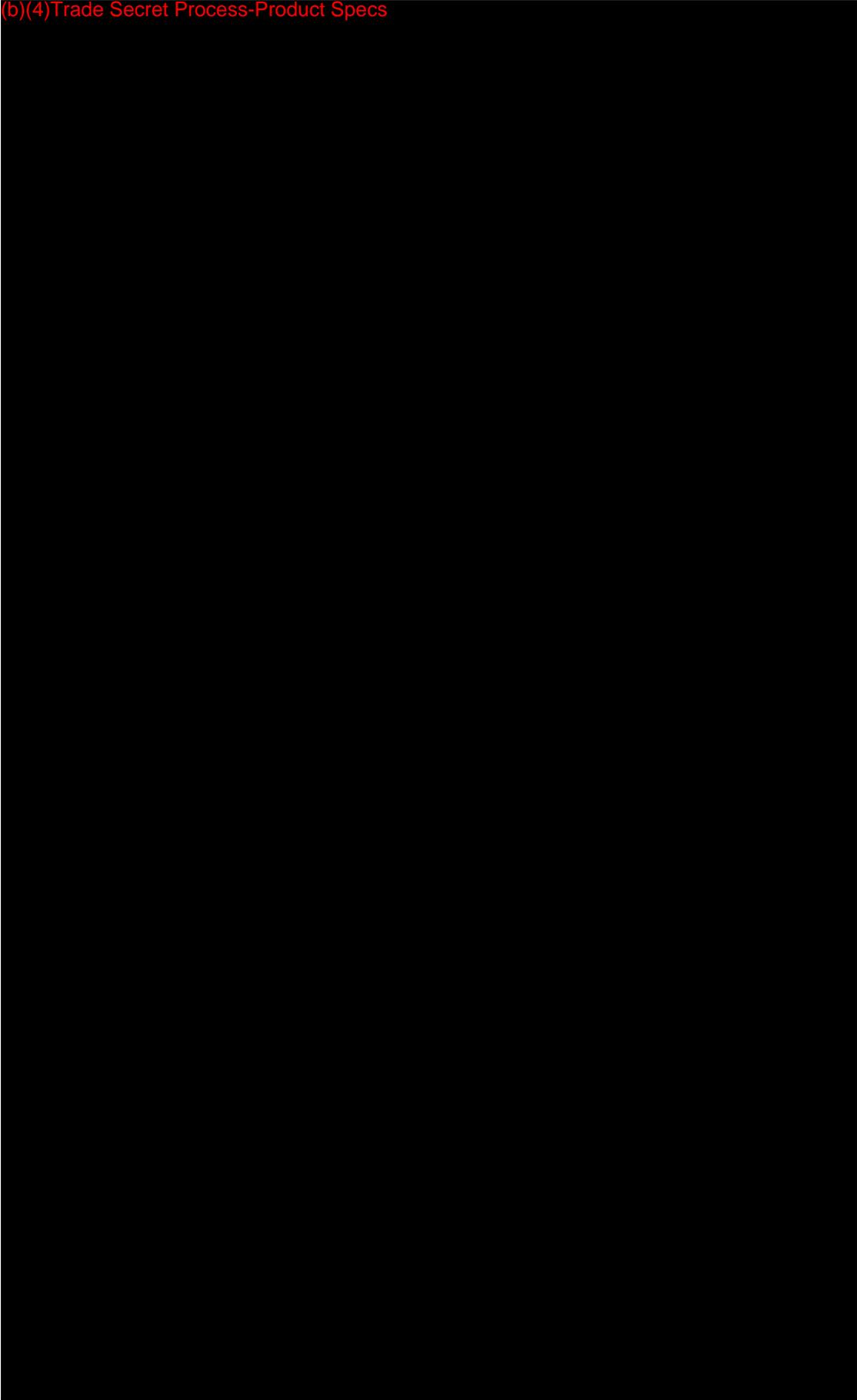
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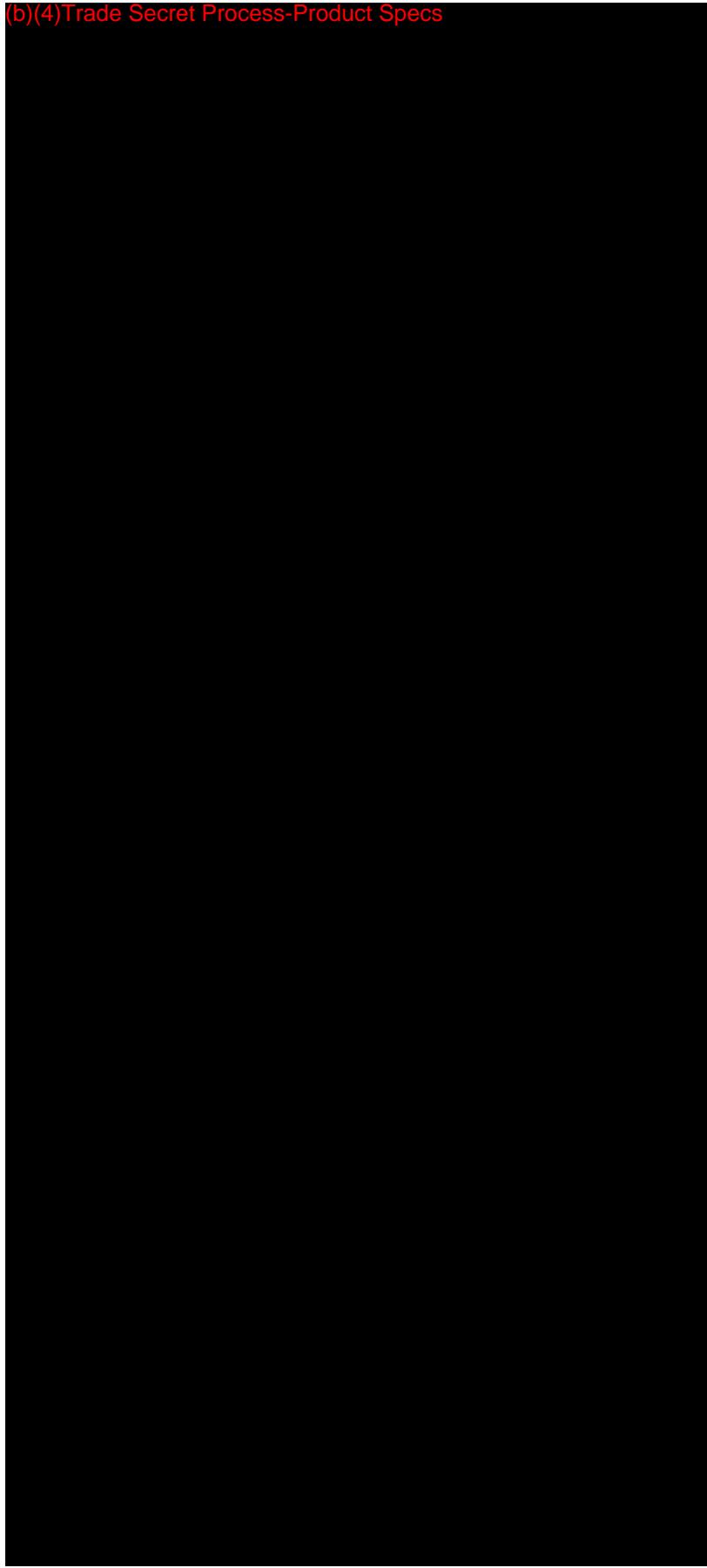
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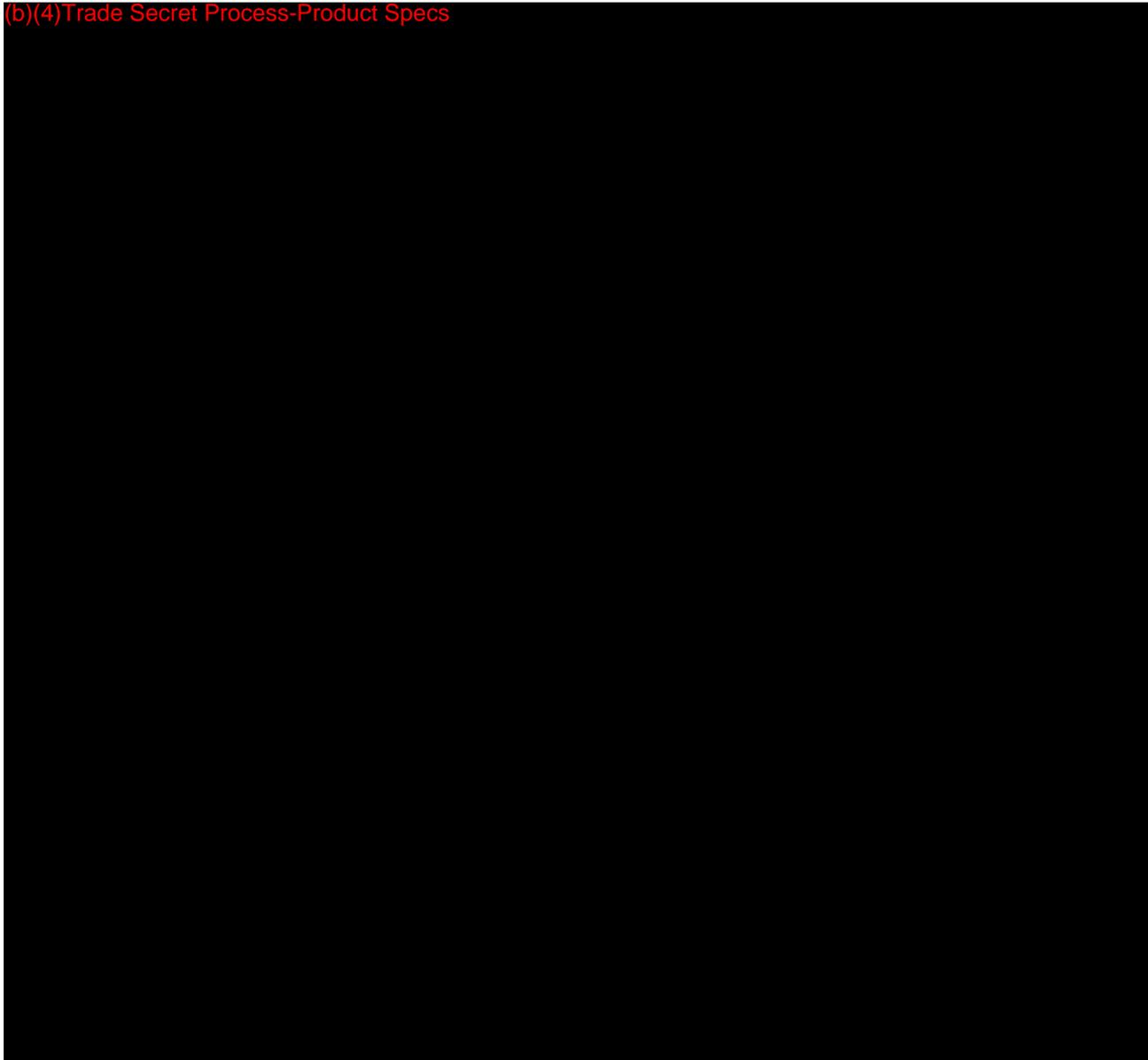


(b)(4)Trade Secret Process-Product Specs



- b. In regards to the Evaluation of Hemostasis following Muscle Transection portion of the testing, the submission stated that the information presented is based on tests that were re-run. There is no explanation as to why they were re-run. All deviations from the stated study protocol should have proper justification as to how the deviations do not affect the safety and / or effectiveness of the device. Please provide the justification for the results and why re-running does not affect the outcomes.

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



- c. In regards to the provided predicate testing, the predicate devices were tested performing specific general surgical procedures such as cholecystectomy, mastectomy, lymph node biopsy, etc. However, the submission did not state any full procedures for the new device. When conducting performance / animal comparison testing, the suggested device and predicate should undergo the same tests and / or procedures in order to determine substantial equivalency. Please provide a justification for why this is not necessary.

RESPONSE: Please see the following test which supports the Subject Device performance on specific general surgical procedures such as cholecystectomy, mastectomy, lymph node biopsy, etc. The Subject Device and Predicate Device were used in the same tests and procedures in order to establish substantial equivalence. This is not a new study, the study was conducted at the same time as the previously submitted Preclinical testing.

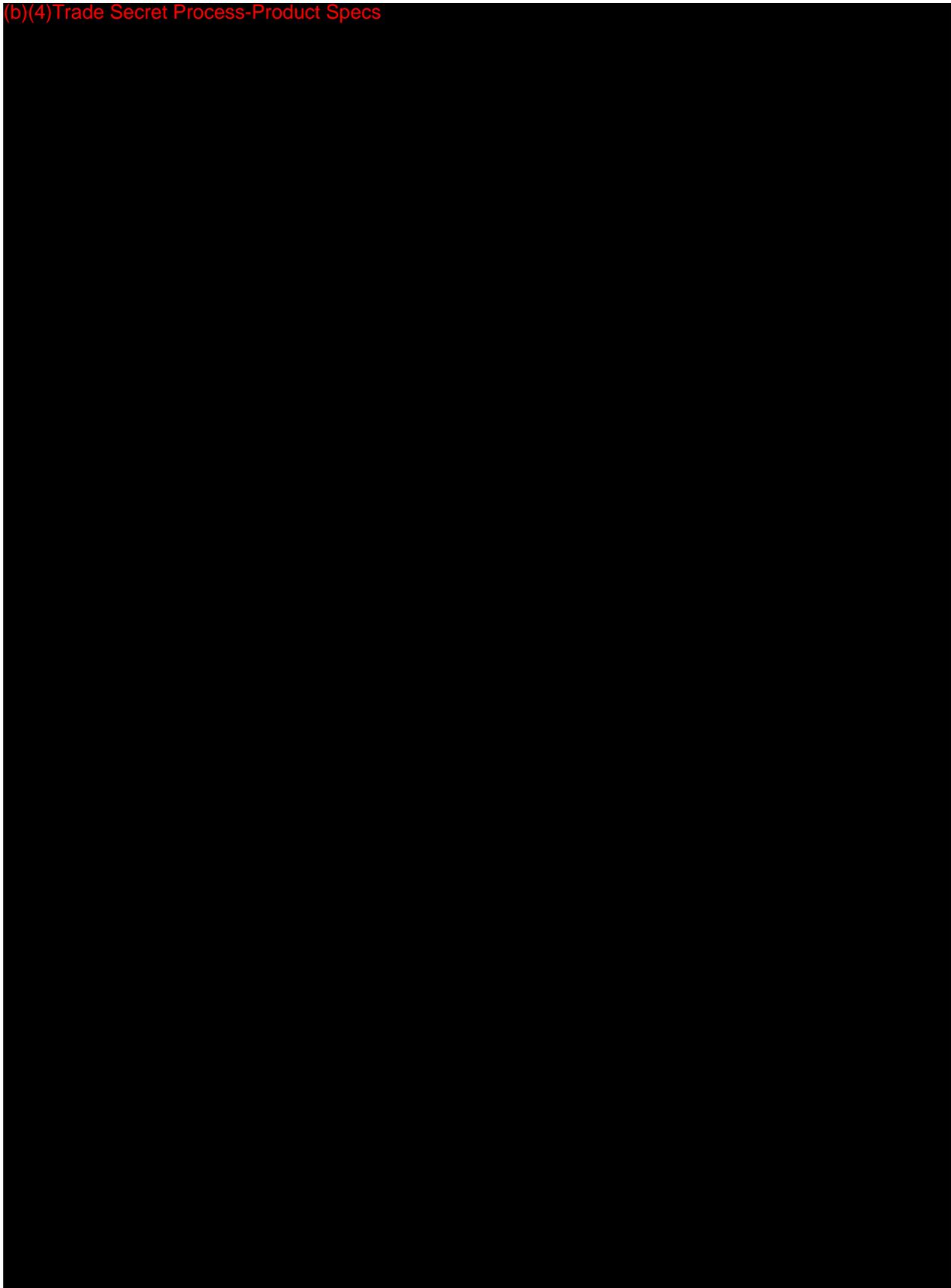
Test I-B: Evaluation of Capabilities in General Procedure Applications

1) Description of Test Protocol

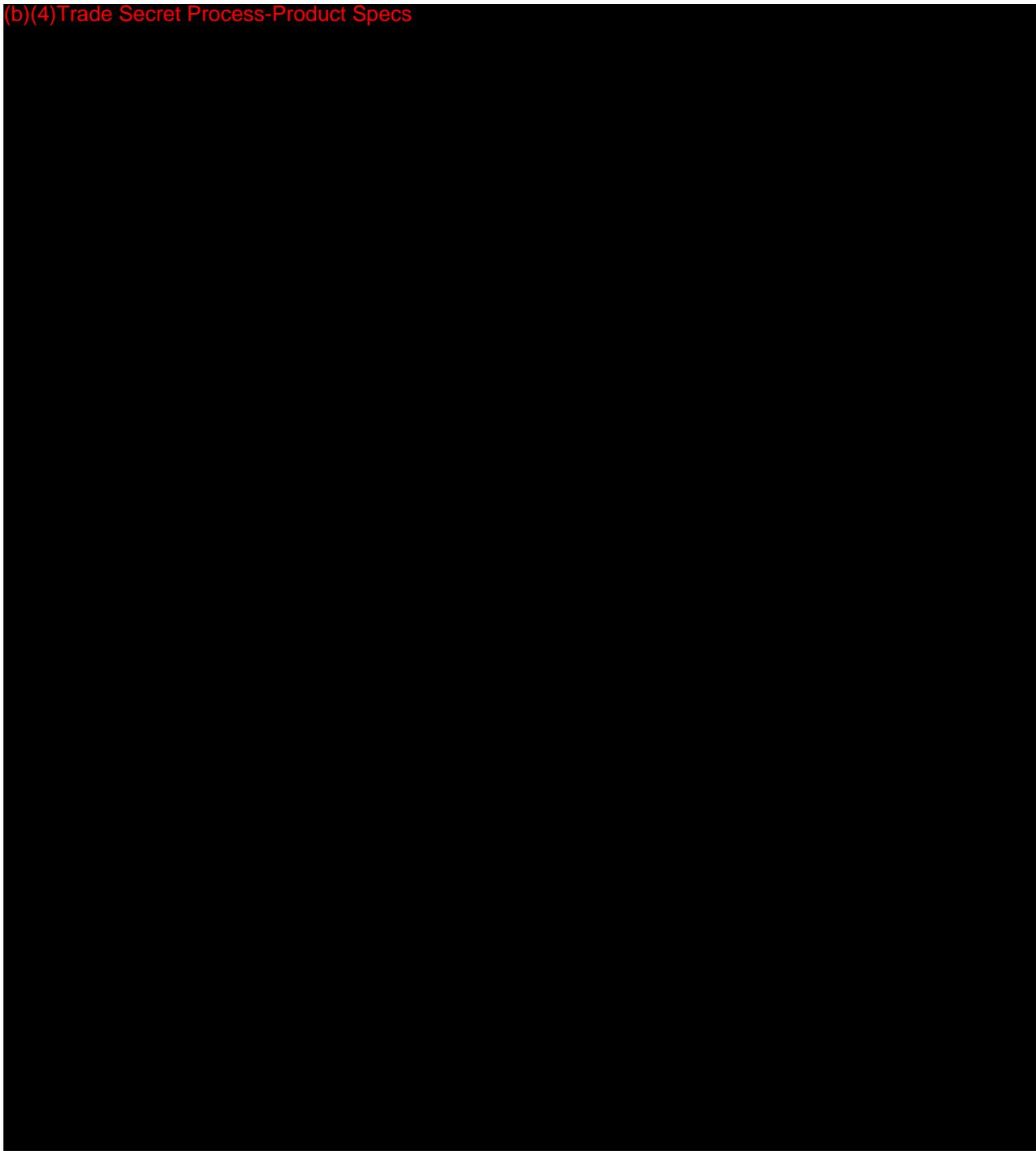
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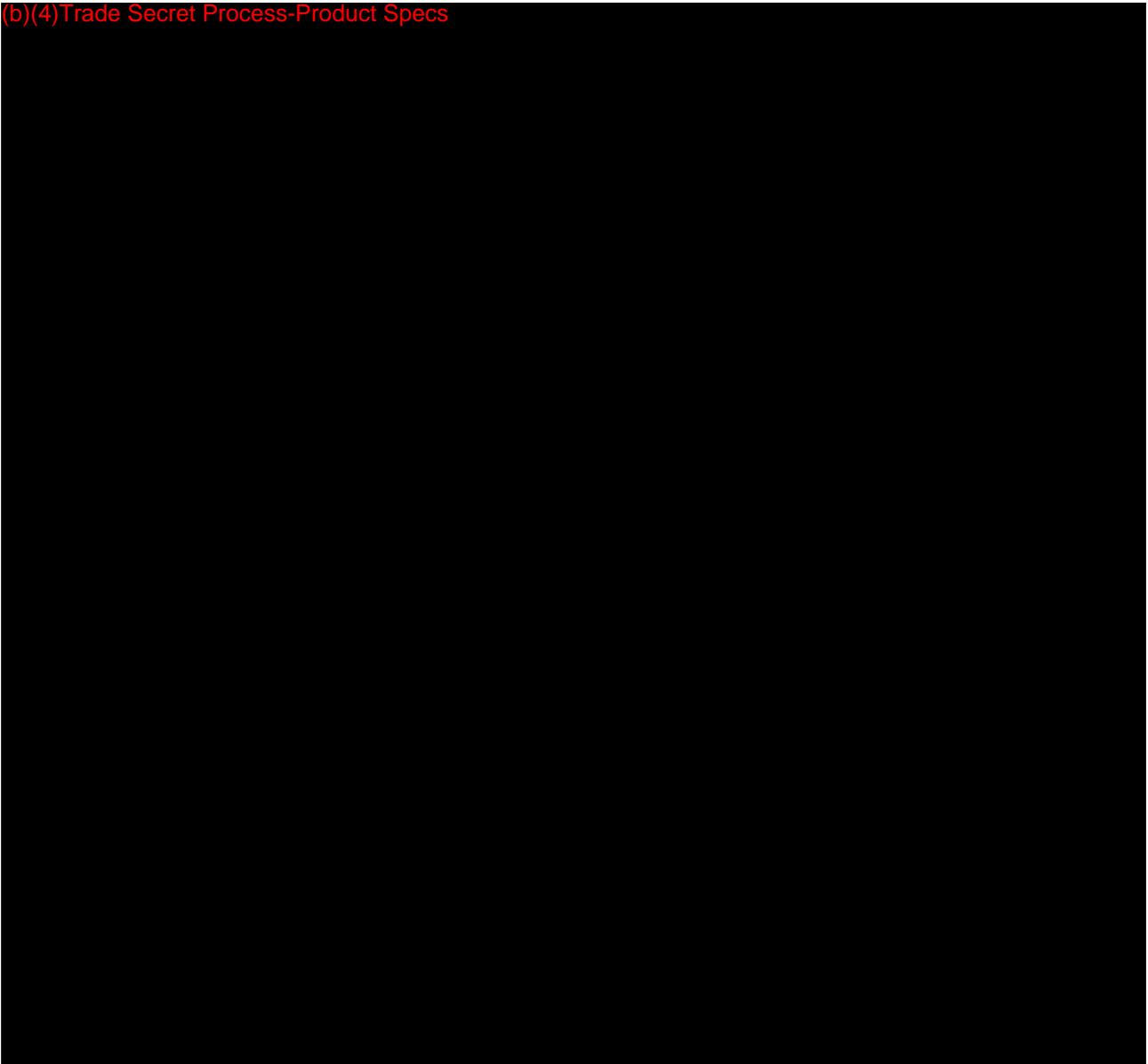
(b)(4) Trade Secret Process-Product Specs



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



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



5. Regarding device Performance testing:

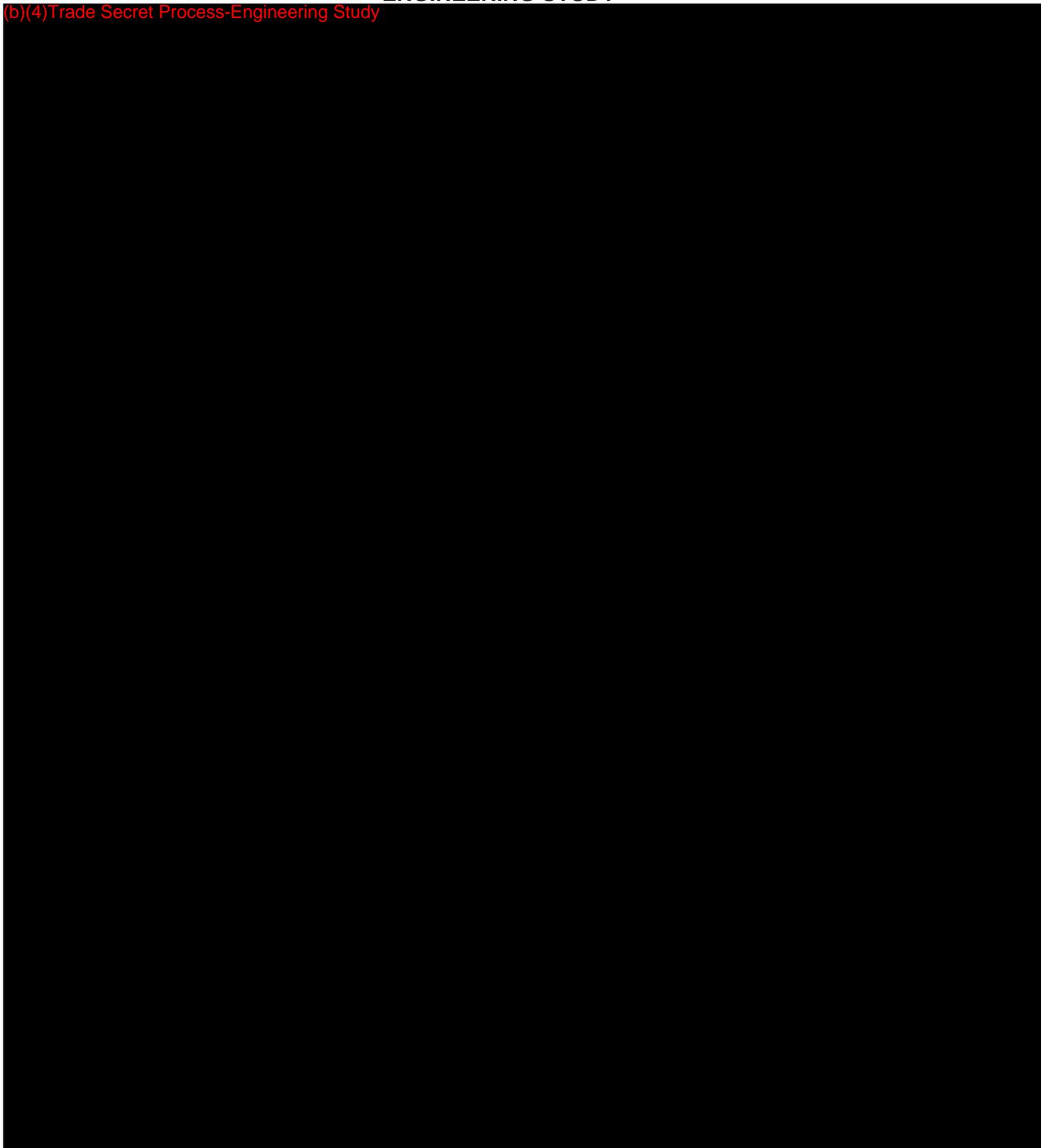
a. (b)(4)Trade Secret Process-Product Specs

However, the testing conducted was for simulated procedures in which power curve behavior was compared and did not encompass the full system the submission discloses (the Harmonic Scallop Blade was not used for any testing).

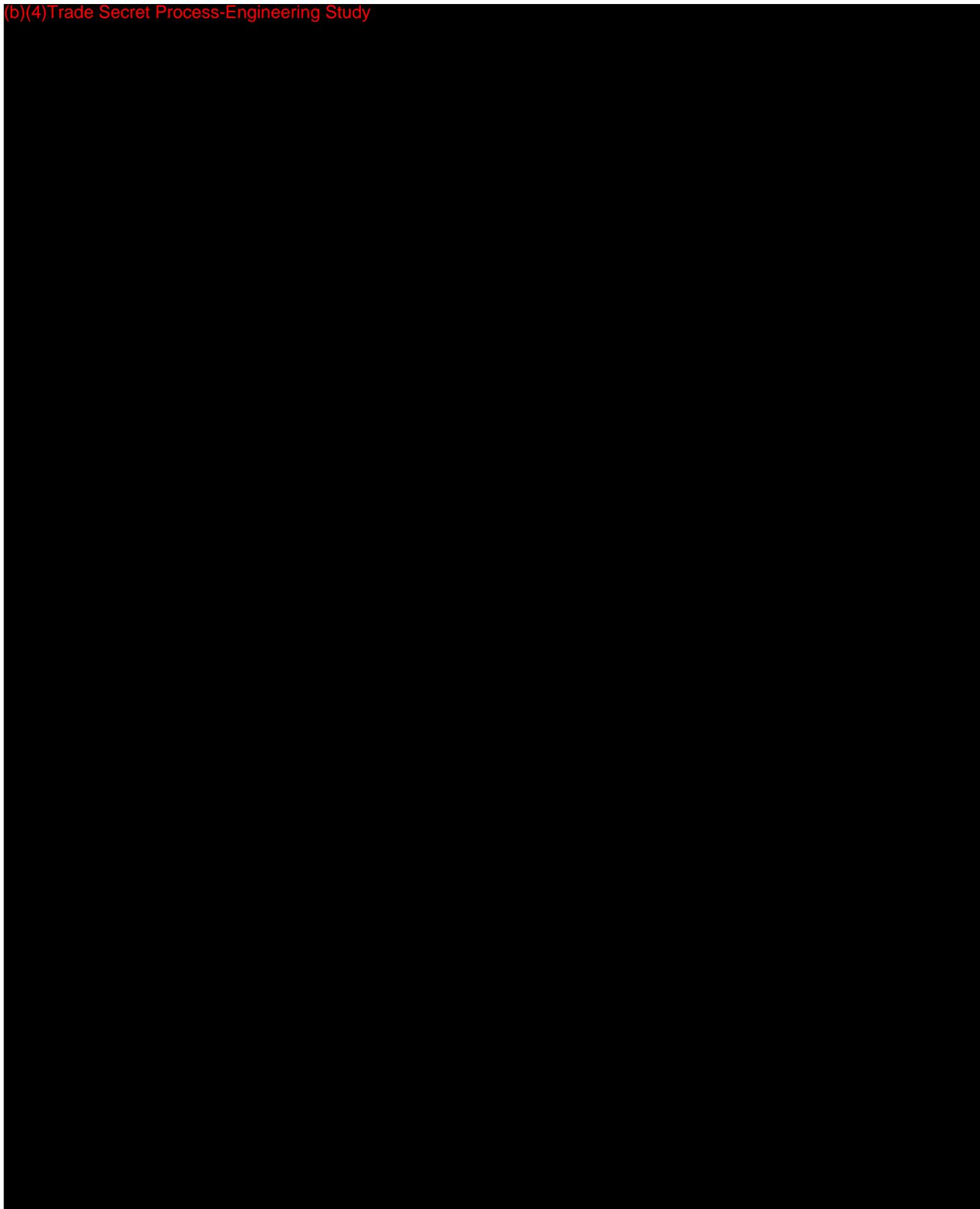
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ENGINEERING STUDY

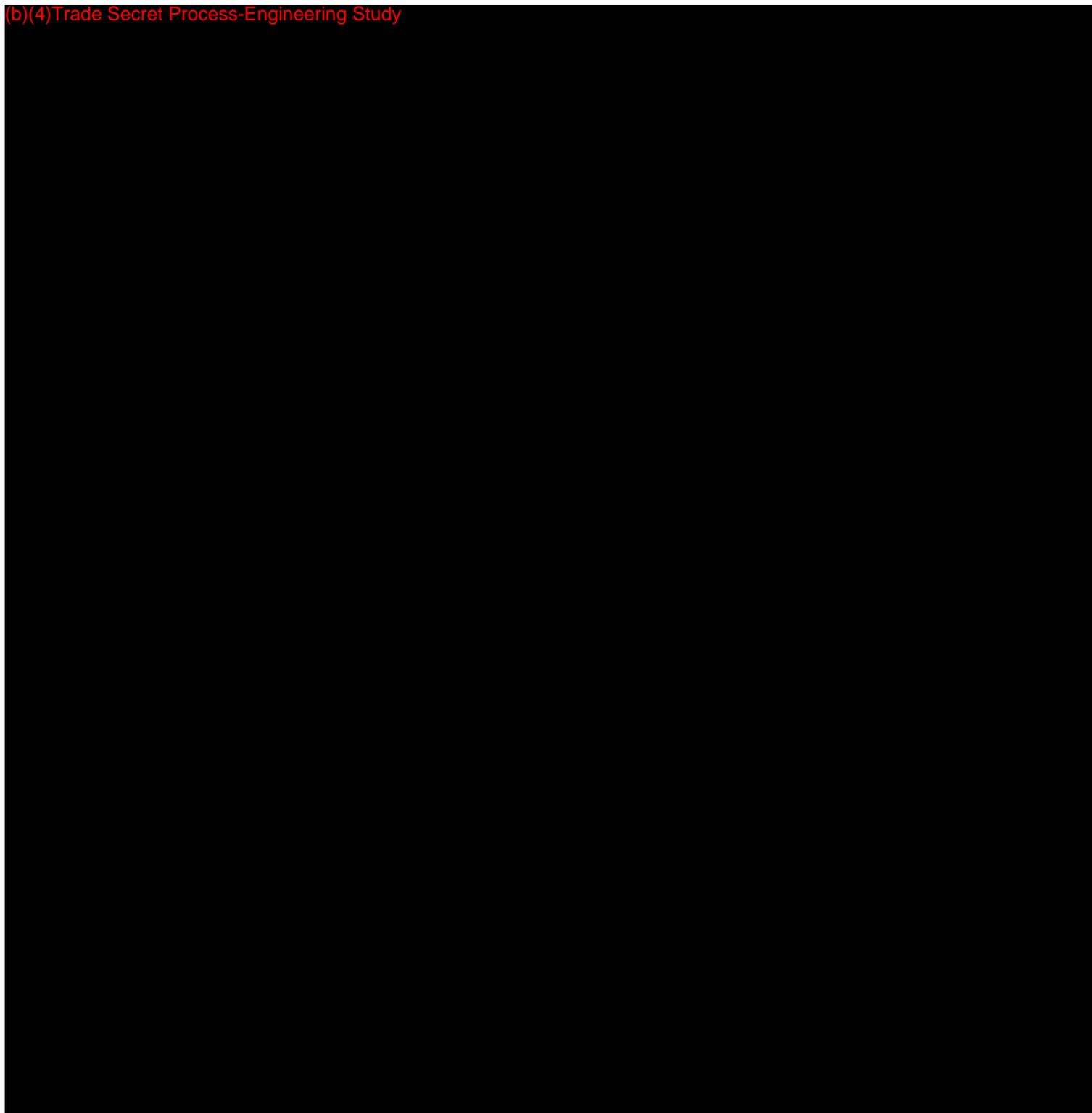
(b)(4) Trade Secret Process-Engineering Study



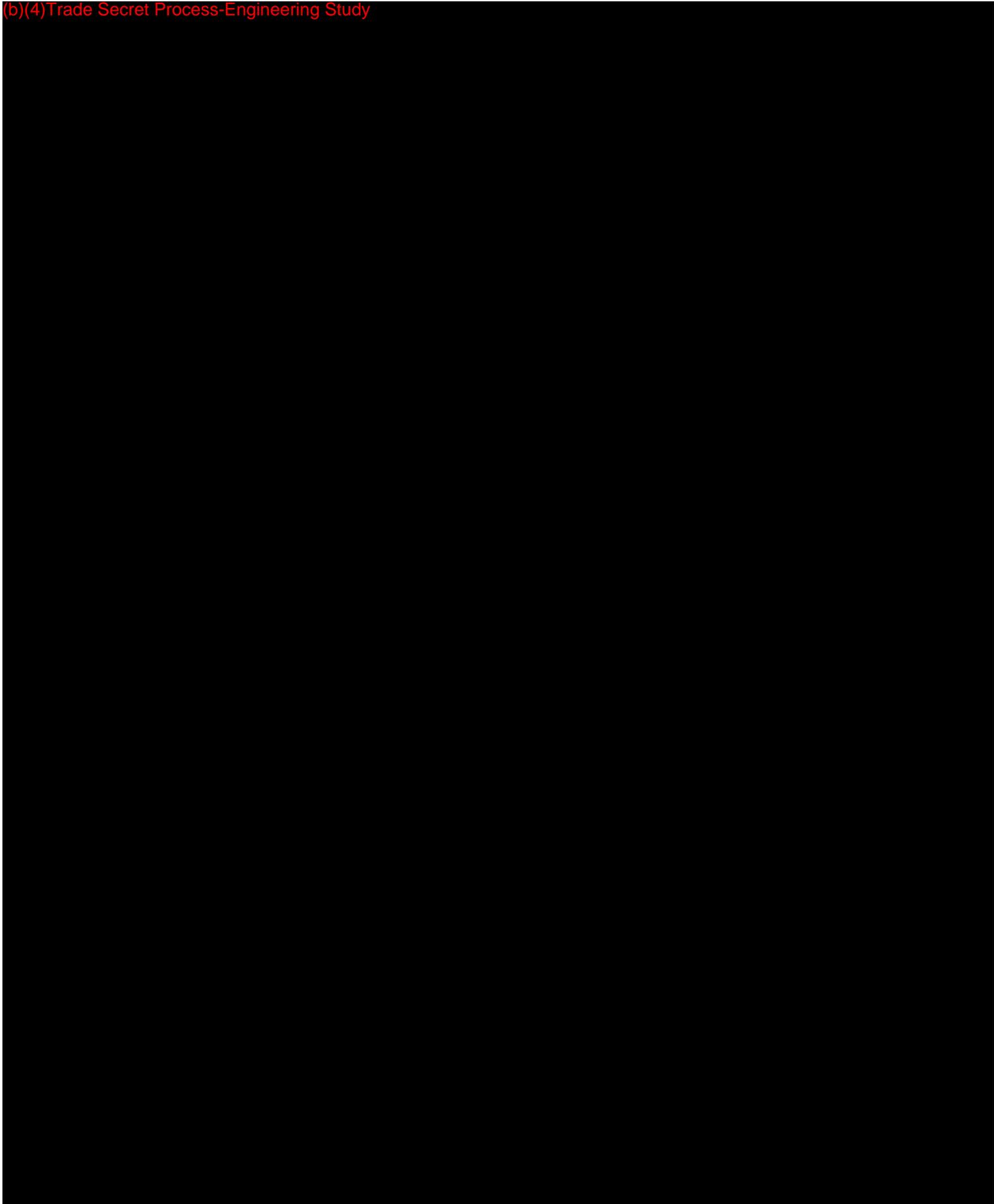
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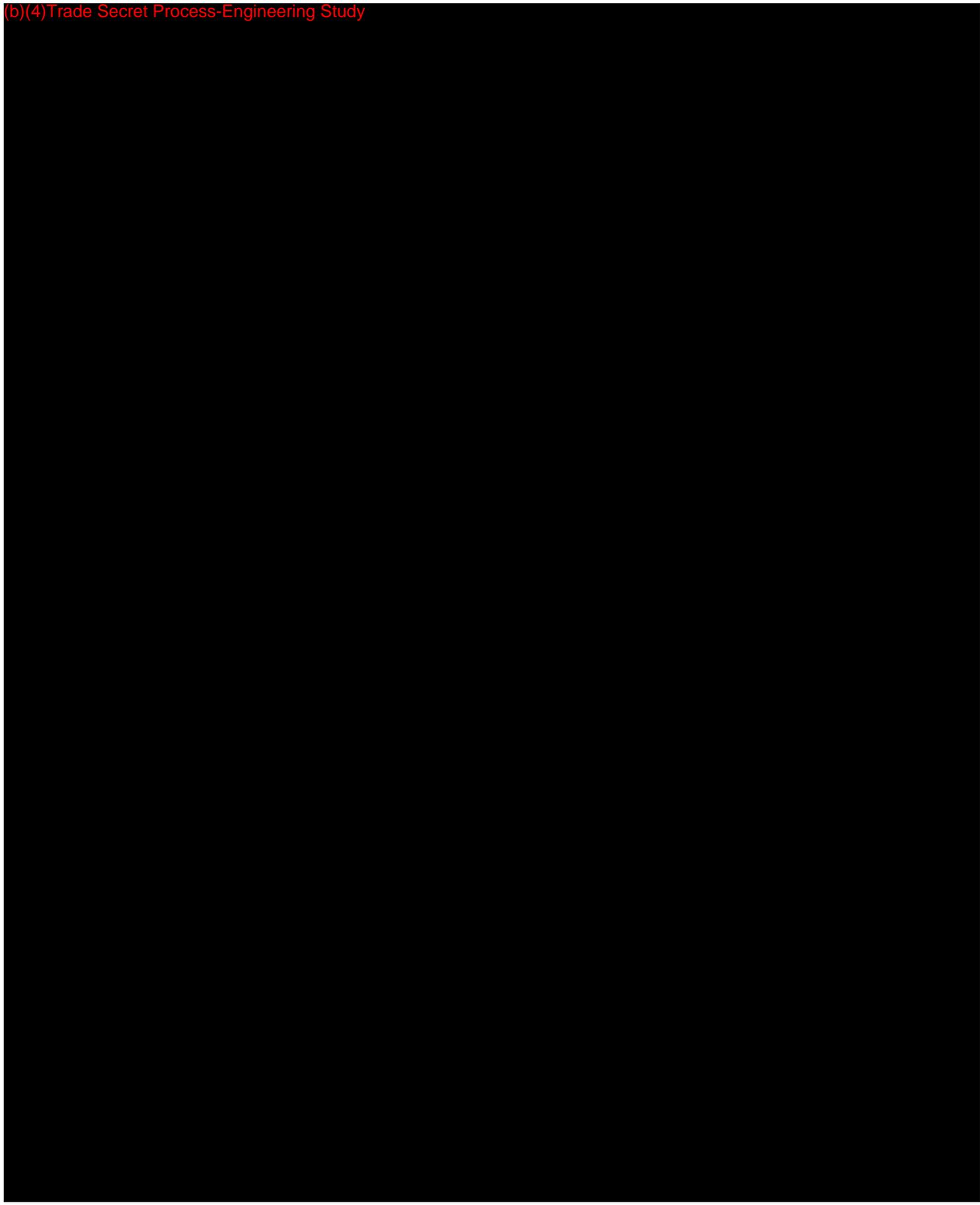
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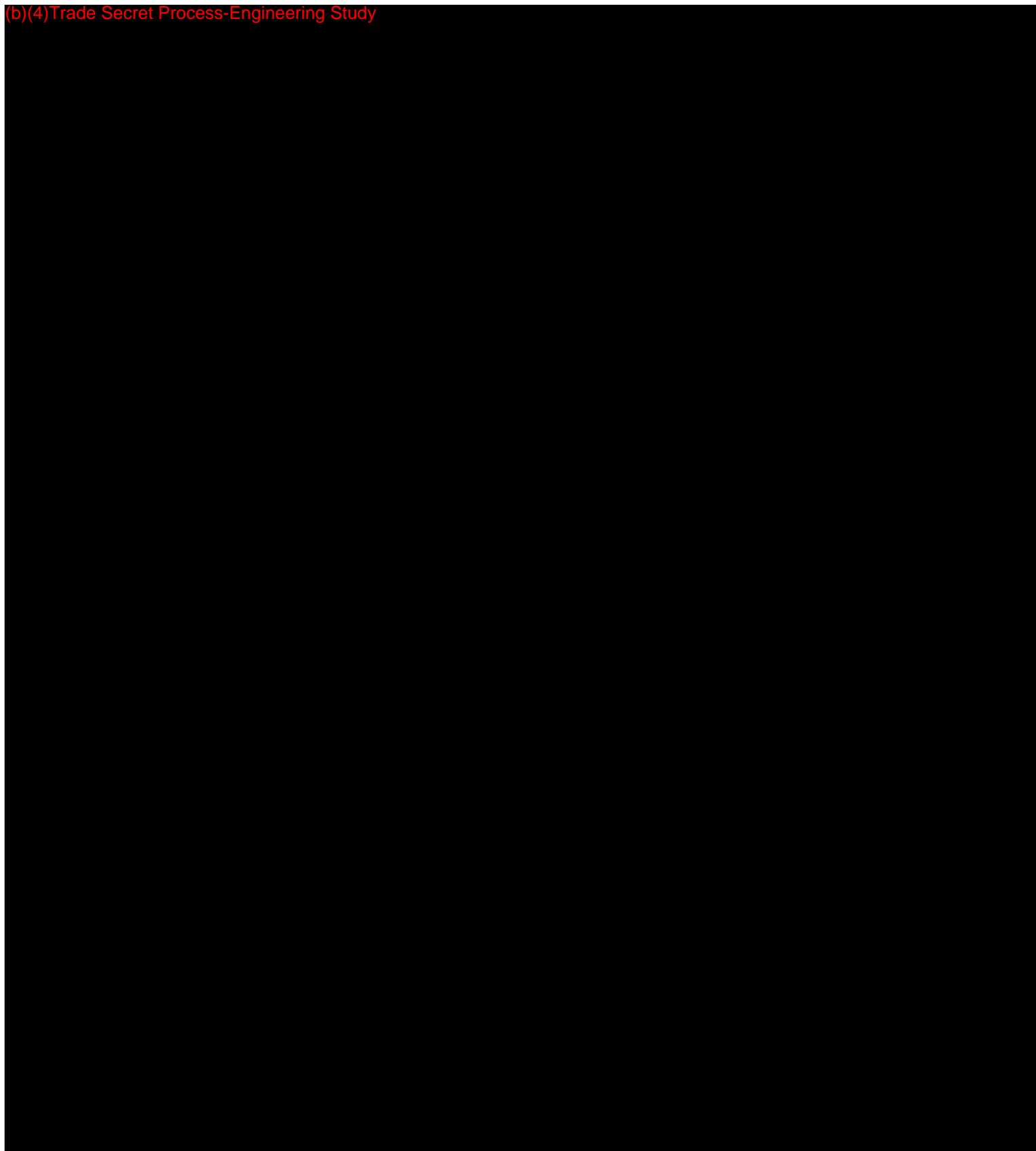
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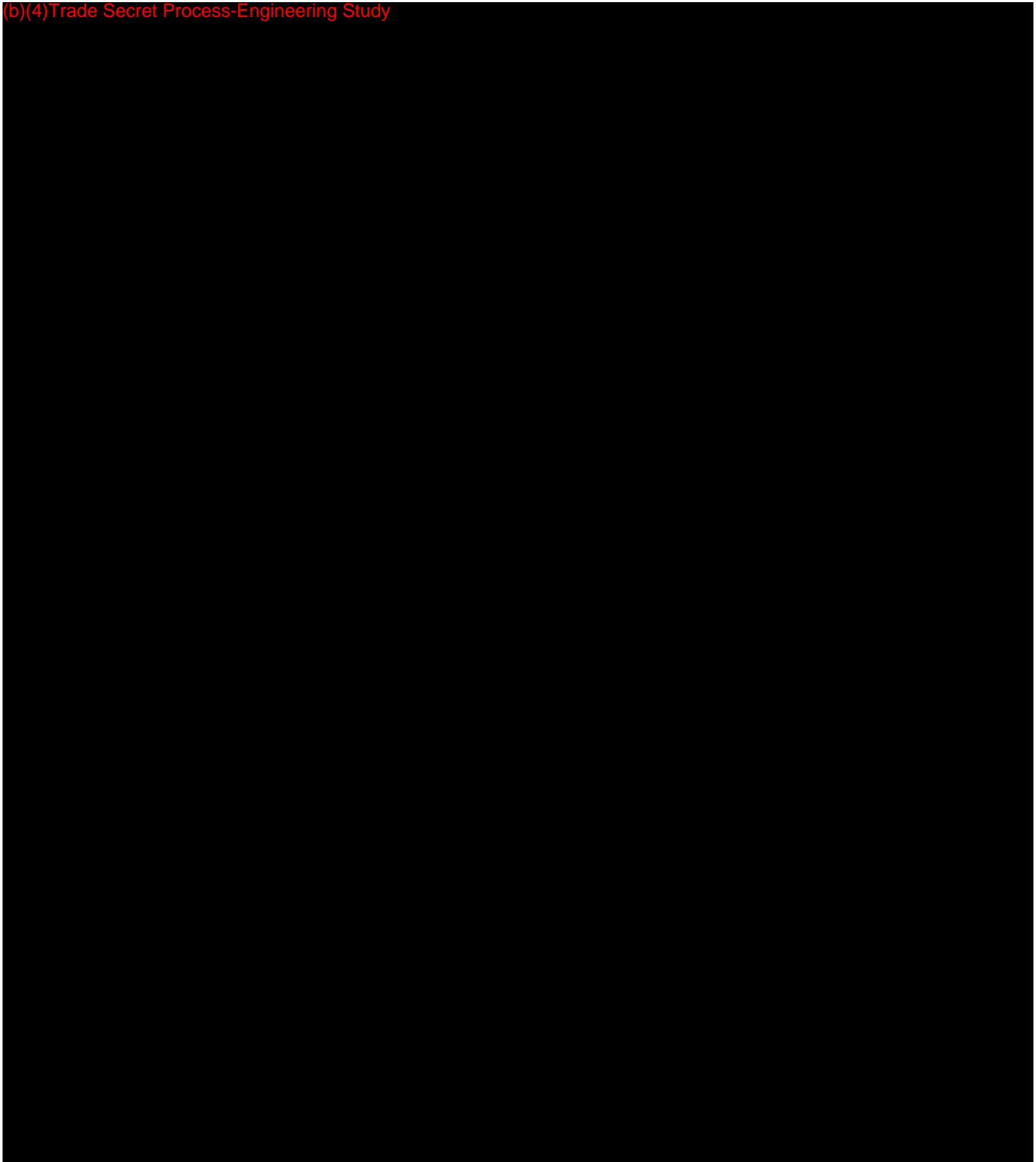
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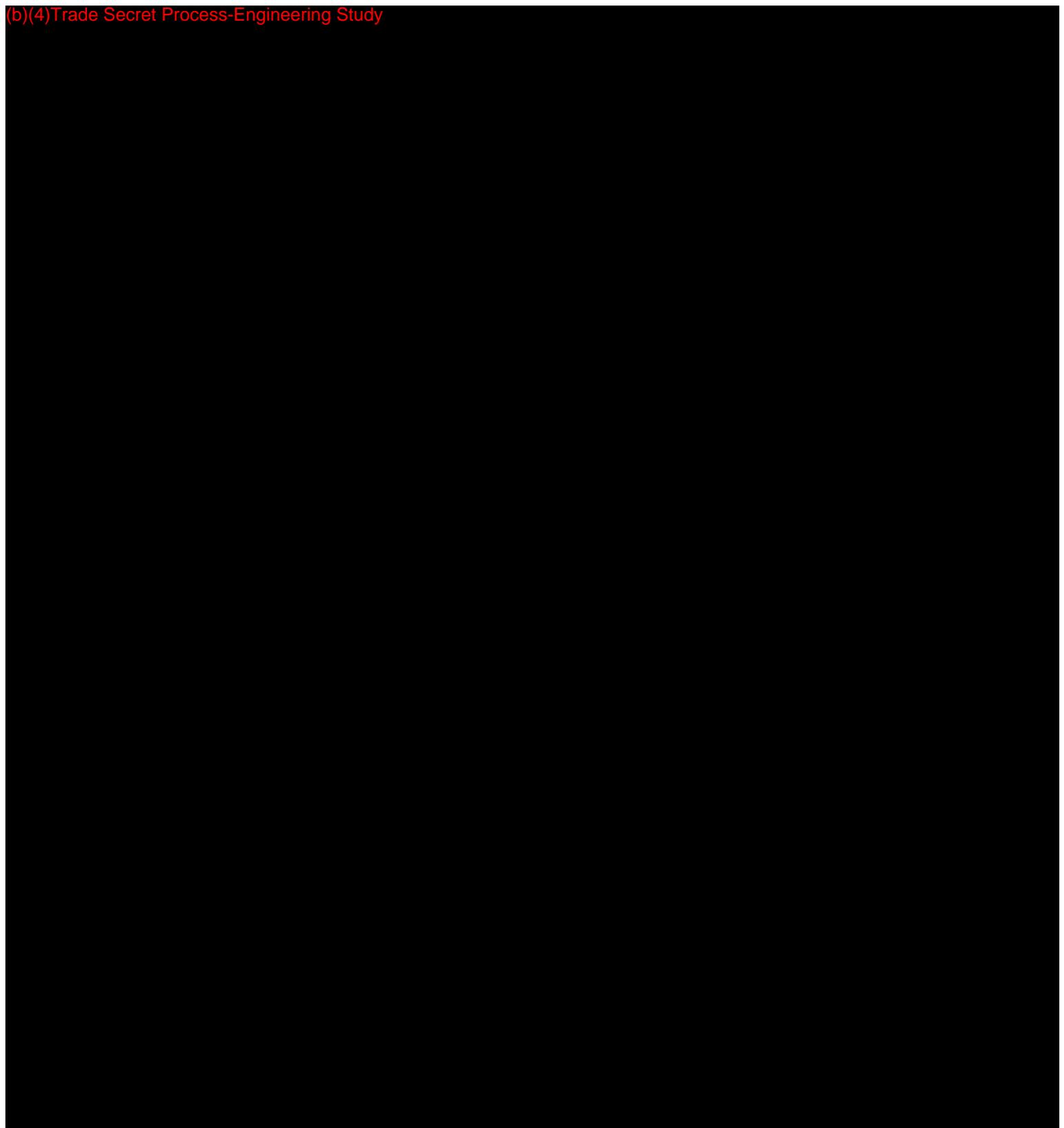
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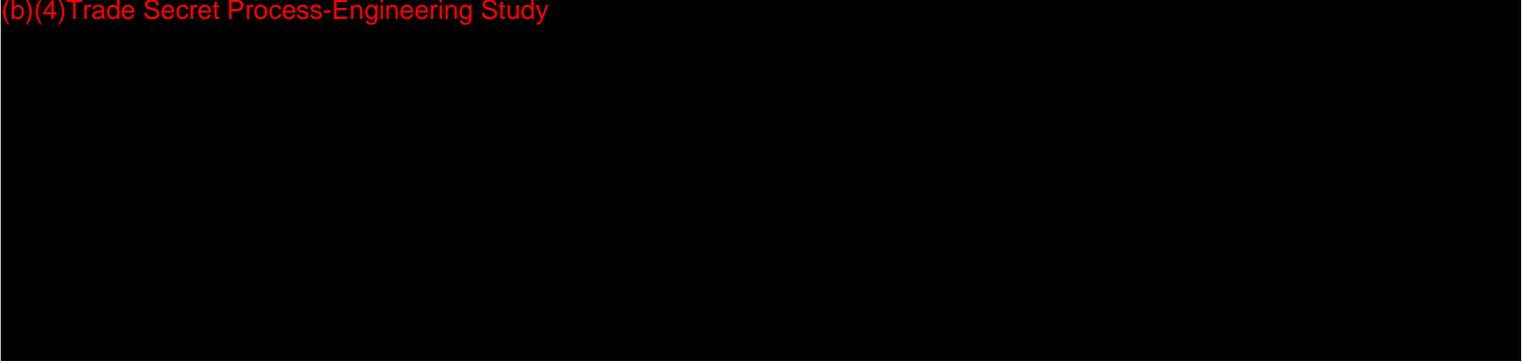
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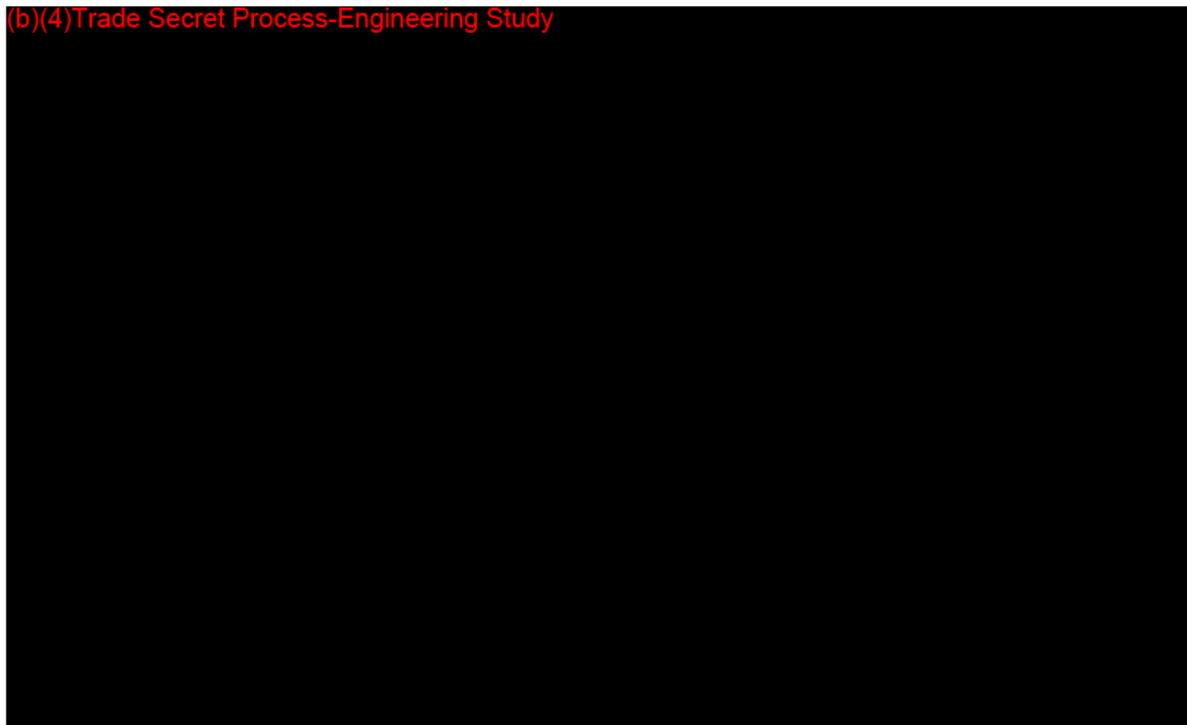
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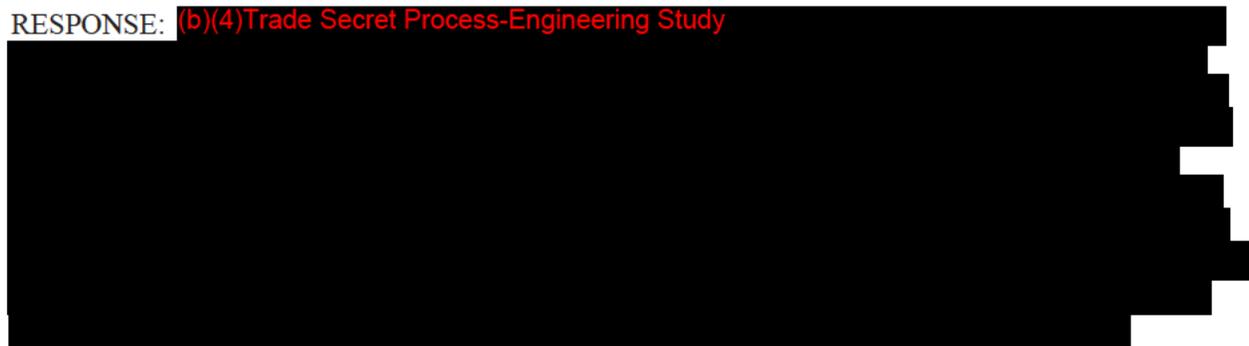
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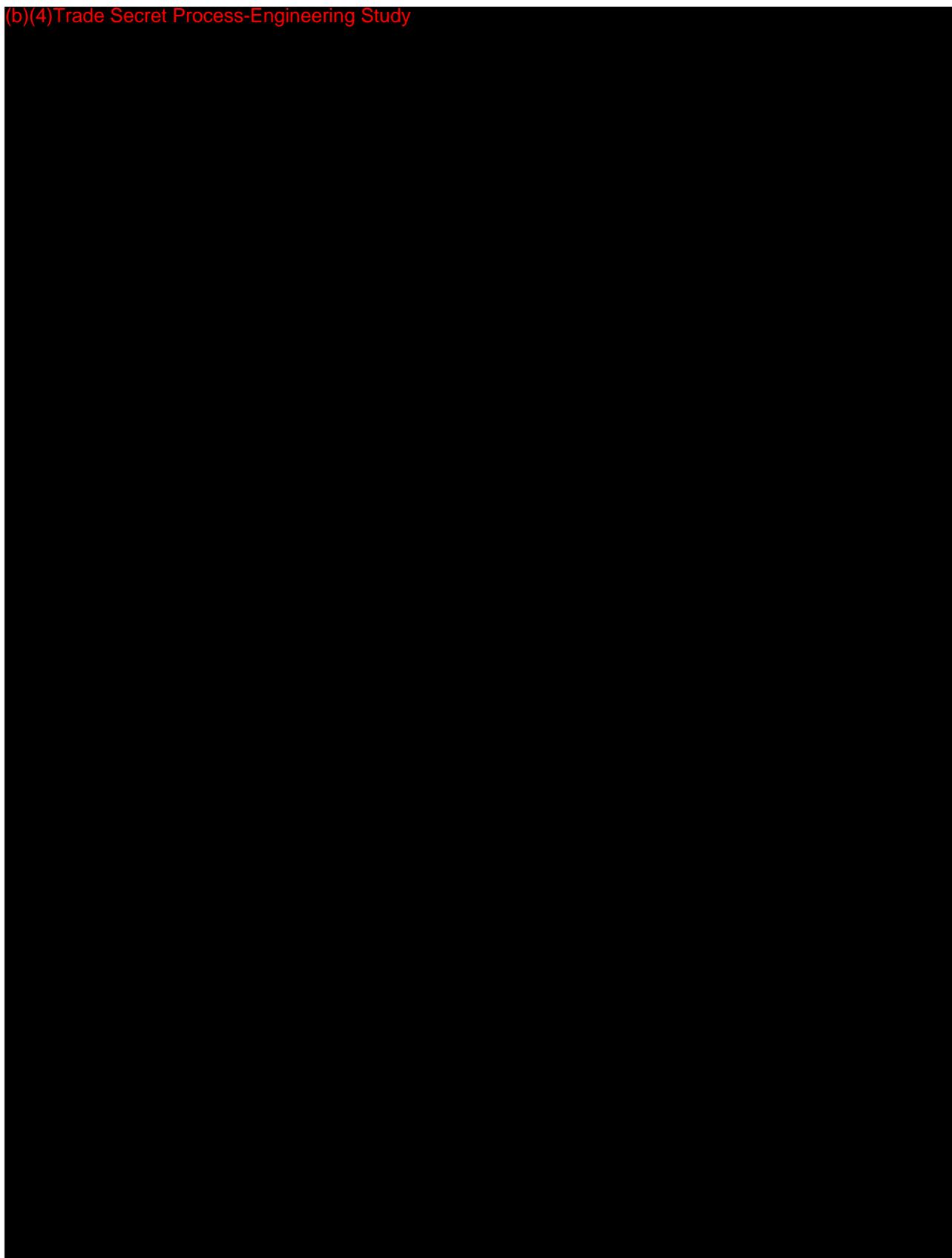
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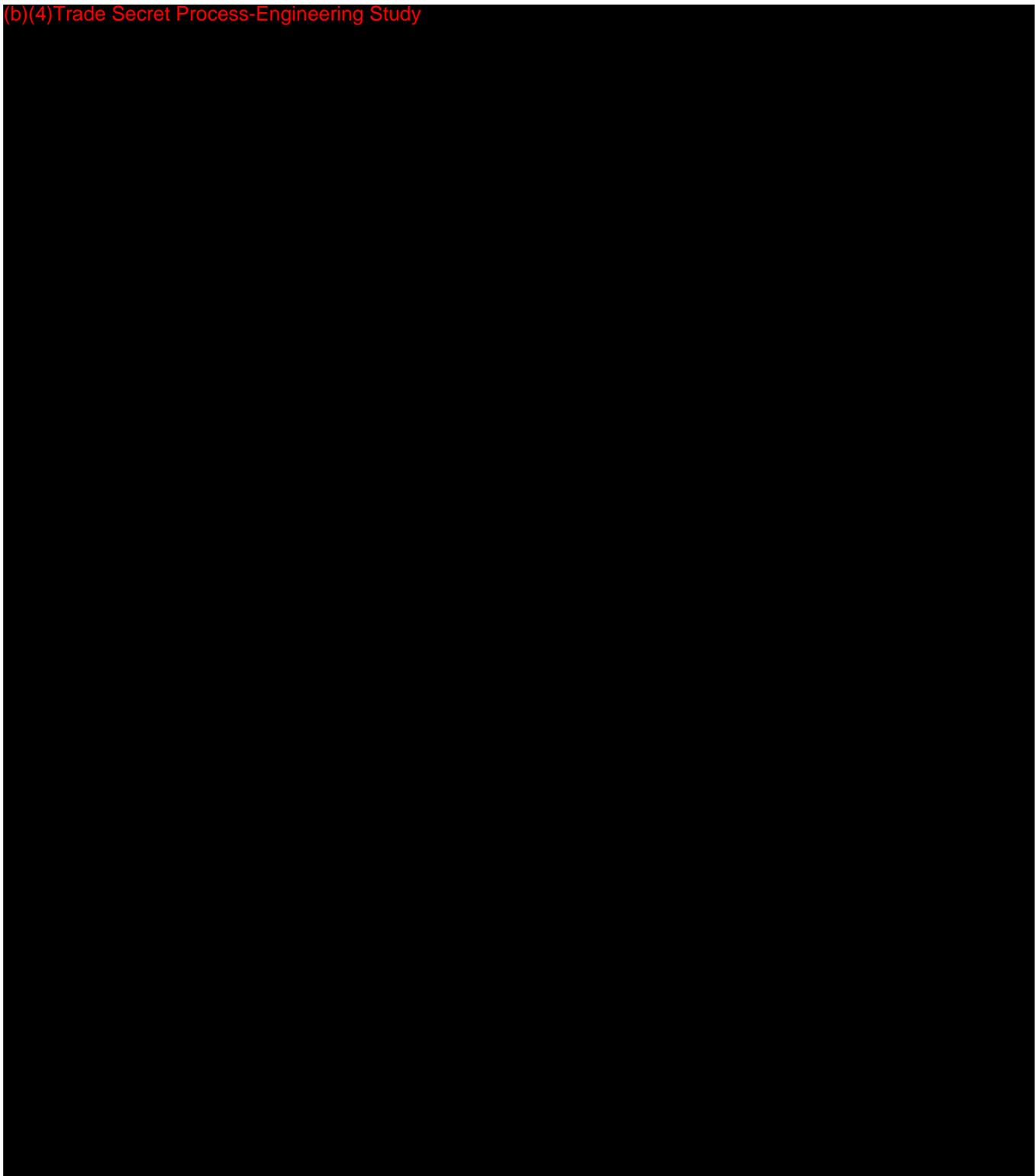
RESPONSE: (b)(4)Trade Secret Process-Engineering Study



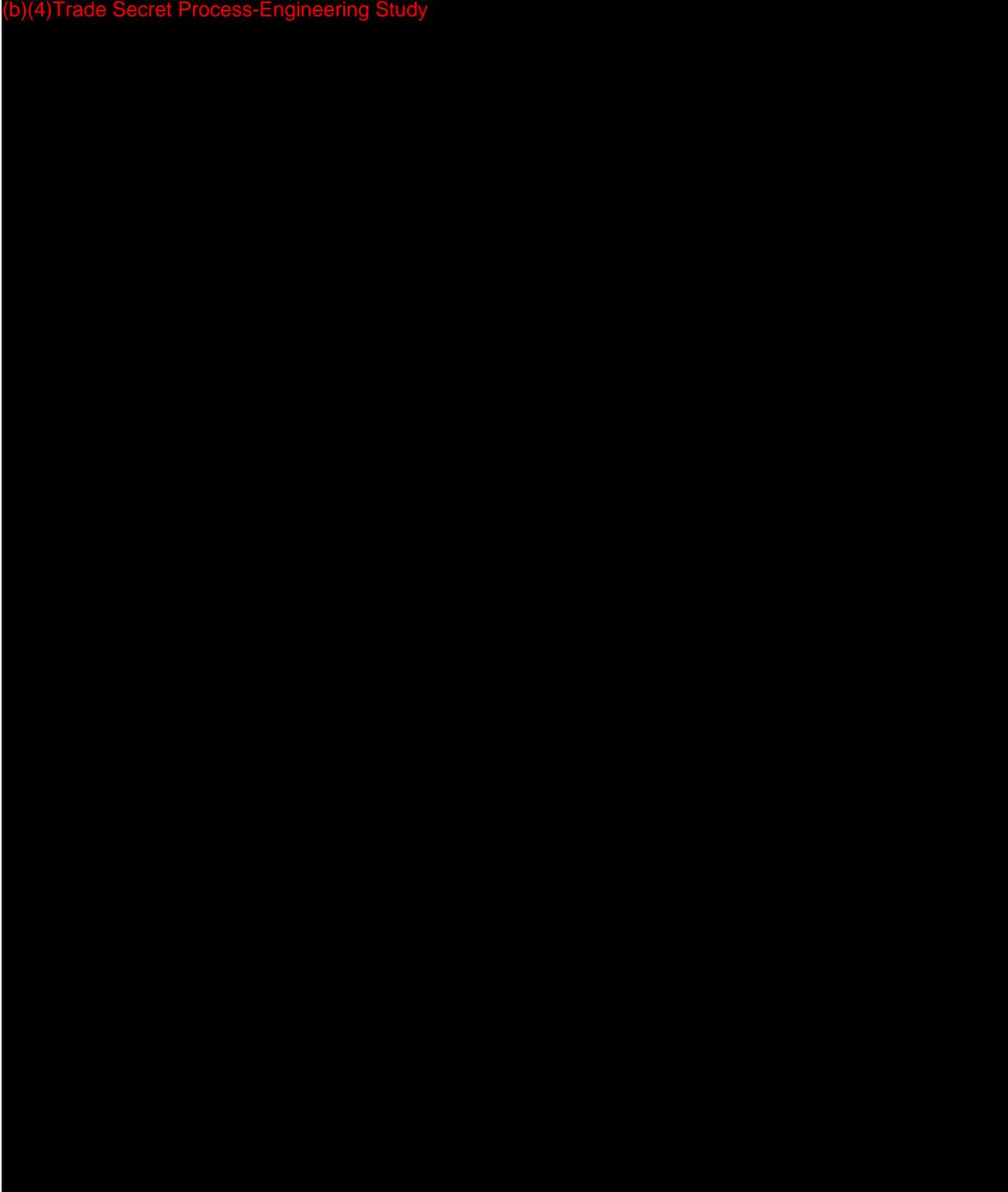
(b)(4)Trade Secret Process-Engineering Study



(b)(4) Trade Secret Process-Engineering Study



(b)(4) Trade Secret Process-Engineering Study



(b)(4) Trade Secret Process-Engineering Study

