Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

K072870

510(k) Summary

JAN 14 2008

General Information

Classification	Class II
Trade Name	Microwave Tissue Coagulation System (MTCS)
Submitter	Foundry Newco X, Inc. 199 Jefferson Drive Menlo Park, CA 94045 USA Tel: 650-326-2656 Fax: 650-326-3108
Contact	Steven Kim Chief Technology Officer

Intended Use

The Microwave Tissue Coagulation System (MTCS) is intended for coagulation of soft tissue.

Predicate Devices

K011676	VivaWave Microwave Ablation System
K052919	Microsulis MTA System
K984552	Radionics Cool-Tip RF System
K021368	Medela Vacuum Pump Model 30
K003978	AFX Microwave Generator

Device Description

The Microwave Tissue Coagulation System (MTCS) is designed to coagulate soft tissue using a surface contact applicator. The system consists of an applicator, external microwave generator, vacuum pump, and a cooling fluid pump and tubing. The desired power and delivery time are set manually by the operator.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The generator contains electric circuits, circuit boards, and integrated control panel. The major components of the generator are cooling fans, power supply, microwave module and the front panel/control board assembly.

The applicator is a specifically designed to deliver microwave energy at the frequency and power levels that the generator outputs. The proximal end of the applicator has a microwave connector that fits onto the generator and allows the energy to be delivered to the applicator.

Materials

All materials used in the manufacture of the MTCS are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification.

The results showed the system met specification.

Summary of Substantial Equivalence

The MTCS is equivalent to the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2008

Foundry Newco X, Inc.
% Mr. Steven Kim
Chief Technology Officer
199 Jefferson Drive
Menlo Park, California 94025

Re: K072870
Trade/Device Name: Microwave Tissue Coagulation System (MTCS)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NEY
Dated: December 19, 2007
Received: December 20, 2007

Dear Mr. Kim:

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

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

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

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

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

Sincerely yours,

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

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

K072870

Indications for Use

Device Name: Microwave Tissue Coagulation System (MTCS)

510(k) Number (if known):

Indications for Use: The Microwave Tissue Coagulation System (MTCS) is intended for coagulation of soft tissue.

X
Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K072870

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2008

Foundry Newco X, Inc.
% Mr. Steven Kim
Chief Technology Officer
199 Jefferson Drive
Menlo Park, California 94025

Re: K072870
Trade/Device Name: Microwave Tissue Coagulation System (MTCS)
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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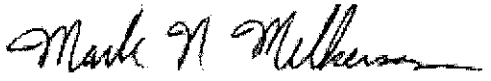
Sincerely yours,



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

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

K072870

Indications for Use

Device Name: Microwave Tissue Coagulation System (MTCS)

510(k) Number (if known):

Indications for Use: The Microwave Tissue Coagulation System (MTCS) is intended for coagulation of soft tissue.

X

Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K072870

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

November 21, 2007

FOUNDRY NEWCO X, INC.
199 JEFFERSON DRIVE
MENLO PARK, CA 94025
ATTN: GREGORY MATHISON

510(k) Number: K072870
Product: MICROWAVE TISSUE COAGULATION SYSTEM (MTCS)

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

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

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

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

Sincerely yours,

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

October 09, 2007

FOUNDRY NEWCO X, INC.
199 JEFFERSON DRIVE
MENLO PARK, CA 94025
ATTN: GREGORY MATHISON

510(k) Number: K072870
Received: 09-OCT-2007
Product: MICROWAVE TISSUE COAGULATION SYSTEM (MTCS)

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

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

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "FDA and Industry Actio on Premarket Notification (510(k))Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how variou FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2)Guidance for Industry an FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an origin submission for a Traditional or Abbreviated 510(k). 3)Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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

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

Sincerely yours,

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

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

K072870

Foundry Newco X, Inc

October 8, 2007

FDA CDRH DMC

OCT 09 2007

Received

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

Re: 510(k) Premarket Notification

Microwave Tissue Coagulation System (MTCS)

Pursuant to the regulations regarding 510(k) applications, Foundry Newco X Inc. intends to market the Microwave Tissue Coagulation System for soft tissue coagulation. The indications for use and clinical applications are equivalent to current medical practice and existing legally marketed microwave tissue coagulation products.

We consider our intent to market these devices as confidential commercial information and request that FDA consider it as such.

The submission and attachments are submitted in duplicate as required by regulation. A copy of a Premarket Submission Cover Sheet is enclosed for your convenience. If you have any questions regarding this 510(k) submission, please contact Gregory Mathison at your earliest convenience.

Thank you for your expeditious review of this application.

Sincerely,

Steven Kim
Chief Technology Officer

Submission Contact:

Gregory Mathison
Tel: (218) 387-1559
Email: gmathison@att.net

K15 SU 1/1

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

510(k) Premarket Notification

Microwave Tissue Coagulation System (MTCS)

Submitted by

Foundry Newco X, Inc.
199 Jefferson Drive
Menlo Park, CA 94025

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachments

A	Instructions for Use
B	Product Labeling
C	Engineering & Product Drawings
D	Animal Tissue Testing Data
E	510(k) Summary
F	Predicate Product Information
G	Sterilization Information
H	Biocompatibility Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

CDRH SUBMISSION COVER SHEET

Date of Submission: **October 8, 2007**	FDA Document Number:

Section A Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
o Original Submission o Modular Submission o Amendment o Report o Report Amendment	o Regular o Special o Panel Track o 30-day Supplement o 30-day Notice o 135-day Supplement o Real-time Review o Amendment to PMA Supplement	o Presubmission summary o Original PDP o Notice of Intent to start clinical trials o Intention to submit o Notice of Completion o Notice of Completion o Amendment to PDP o Report	■ Original submission: ■ Traditional o Special o Abbreviated o Additional Information: o Traditional o Special o Abbreviated	o Pre-IDE meeting o Pre-PMA meeting o Pre-PDP meeting o 180-day meeting o Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
o Original submission o Amendment o Supplement	o Original submission o Amendment o Supplement o Report	o Original submission o Additional information	o Original submission o Additional information	Describe submission:

Section B Applicant or Sponsor

Company / Institution name: **Foundry Newco X, Inc.**		Establishment registration number: **pending**
Division name (if applicable):		Phone number (include area code): **(650) 326-2656**
Street Address: **199 Jefferson Drive**		FAX number (include area code): **(650) 326-3108**
City: **Menlo Park**	State / Province: **CA 94025**	Country: **USA**
Contact Name: **Steven Kim**		
Contact Title: **Chief Technology Officer**		Contact e-mail address: **skim@thefoundry.com**

Section C Submission correspondent (if different from above)

Company / Institution name: **Foundry Newco X, Inc.**		Establishment registration number:
Division name (if applicable):		Phone number (include area code): **(218) 387-1559**
Street Address: **199 Jefferson Drive**		FAX number (include area code): **(650) 326-3108**
City: **Menlo Park**	State / Province: **CA 94025**	Country: **USA**
Contact Name: **Gregory Mathison**		
Contact Title: **Regulatory Affairs Consultant**		Contact e-mail address: **gmathison@att.net**

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section D1 — Reason for Submission—PMA, PDP, or HDE

- o New device
- o Withdrawal
- o Additional or expanded indications
- o Licensing agreement
- o Process Change
  - o Manufacturing
  - o Sterilization
  - o Packaging
  - o Other (specify below)
- o Response to FDA correspondence:
- o Request for applicant hold
- o Request for removal of applicant hold
- o Request for extension
- o Request to remove or add manufacturing site
- o Other reason (specify):
- o Change in design, component, or specification
  - o Software
- o Color Additive
  - o Material
  - o Specifications
- o Other (specify below)
- o Labeling change:
  - o Indications
  - o Instructions
  - o Performance Characteristics
- o Shelf life
- o Trade Name
- o Other (specify below)
- o Location change:
  - o Manufacturer
- o Sterilizer
- o Packager
  - o Distributor
- o Report submission:
  - o Annual or periodic
  - o Post-approval study
  - o Adverse reaction
- o Device defect
- o Amendment
- o Change in ownership
  - o Change in correspondent

Section D2 — Reason for Submission—IDE

- o New device
- o Addition of institution
- o Expansion / Extension of study
- o IRB certification
- o Request hearing
- o Request waiver
- o Termination of study
- o Withdrawal of application
- o Unanticipated adverse effect
- o Notification of emergency use
- o Compassionate use request
- o Treatment IDE
- o Continuing availability request
- o Other (specify):
- o Change in:
  - o Correspondent
  - o Design
  - o Informed Consent
  - o Manufacturer
  - o Manufacturing process
  - o Protocol—feasibility
  - o Protocol —other
  - o Sponsor
- o Report Submission:
  - o Current investigator
  - o Annual progress
  - o Site waiver limit reached
  - o Final
- o Response to FDA letter concerning:
  - o Conditional approval
  - o Deemed approved
  - o Deficient final report
  - o Deficient progress report
  - o Deficient investigator report
  - o Disapproval
  - o Request extension of time to respond to FDA
  - o Request meeting

Section D3 — Reason for Submission—510(k)

- ■ New Device
- o Additional or expanded indications
- o Other reason (specify):
- o Change in technology
- o Change in design
- o Change in materials
- o Change in manufacturing process

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Section E — Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 **GEI**	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:
■ 510(k) summary attached
o 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1. **K984552**	1. **Radionics Cool-Tip RF System**	1. **Radionics, Inc**
2. **K011676**	2. **VivaWave Microwave Ablation System**	2. **Vivant Medical, Inc.**
3. **K052919**	3. **Microsulis Tissue Ablation System**	3. **Microsulis Americas, Inc.**
4.	4.	4.
5.	5.	5.
6.	6.	6.

Section F — Product Information—Applicable to All Applications

Common or usual name or classification name:
Tissue coagulation system

Trade or proprietary or model name	Model Number
1 **Microwave Tissue Coagulation System (MTCS)**	1
2	2
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 Testing o Human trials

Section G — Product Classification—Applicable to All Applications

Product code	CFR Section:	Device Class:
GEI	**878.4400**	o Class I ■ Class II o Class III o Unclassified

Classification panel:
General Surgery

Indications (from labeling):

The Microwave Tissue Coagulation System (MTCS) is intended for coagulation of soft tissue.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Note: Submission of this information does not affect the need to submit a 2891 or a 2891a Device Establishment Registration Form.	FDA Document Number:

Section H Manufacturing / Packaging / Sterilization Sites Relating to a Submission

■ Original o Add o Delete	FDA Establishment Registration number: **Pending**	■ Manufacturer o Contract Sterilizer o Contract manufacturer o Repackager / relabeler	
Company / Institution name: **Foundry Newco X, Inc.**		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): **(650) 326-2656**	
Street Address: **199 Jefferson Drive**		FAX number (include area code): **(650) 326-3108**	
City: **Menlo Park**	State / Province: **CA 94025**		Country: **USA**
Contact Name: **Steven Kim**			
Contact Title: **Chief Technology Officer**		Contact e-mail address: **skim@thefoundry.com**	
■ Original o Add o Delete	FDA Establishment Registration number: **1721676**	o Manufacturer ■ Contract Sterilizer o Contract manufacturer o Repackager / relabeler	
Company / Institution name: **Sterigenics**		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): **(801) 328-9901**	
Street Address: **5725 West Harold Gatty Drive**		FAX number (include area code):	
City: **Salt Lake City**	State / Province: **UT 84116**		Country: **USA**
Contact Name: **Shawn Pollino**			
Contact Title: **General Manager**		Contact e-mail address: **saltlakecity@sterigenics.com**	
o Original o Add o Delete	FDA Establishment Registration number:	o Manufacturer o Contract Sterilizer o Contract manufacturer o Repackager / relabeler	
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street Address:		FAX number (include area code):	
City:	State / Province:		Country:
Contact Name:			
Contact Title:		Contact e-mail address:	

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted]
Write the Payment Identification number on your check.

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

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

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

FOUNDRY NEWCO X
199 JEFFERSON DR.
Menlo Park CA 94025
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4) [redacted]

2. CONTACT NAME
Steve Kim

2.1 E-MAIL ADDRESS
skim@thefoundry.com

2.2 TELEPHONE NUMBER (include Area code)
650-3262656 134

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
null-null

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

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

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)
[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) [redacted]

04-Oct-2007

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

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STATEMENT OF CONFIDENTIALITY

Foundry Newco X, Inc. considers the information in this submission to be confidential commercial information. We have not, to our knowledge, released this information through advertising or any other manner to anyone outside the employ of Foundry Newco X, Inc. Foundry Newco X, Inc. has taken precautions to protect the confidentiality of this information under Section 807.95, Confidentiality of Information. We ask that this notification and proprietary information herein be treated as confidential in accordance with the freedom of Information Act.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PREMARKET NOTIFICATION

TRUTHFUL AND ACCURACY STATEMENT

As required by 21 CFR §807.87(j) k

I certify that, in my capacity as Chief Technology Officer of Foundry Newco X, Inc., I believe to the best of my knowledge, that the data and information submitted in this premarket notification application are truthful and accurate and that no material fact has been knowingly or willfully omitted.

(Signature)

STEVEN KIM
(Printed Name)

10/8/07
(Dated)

THIS SUBMISSION
(Premarket Notification Number)

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K072870

Indications for Use

Device Name: Microwave Tissue Coagulation System (MTCS)

510(k) Number (if known):

Indications for Use: The Microwave Tissue Coagulation System (MTCS) is intended for coagulation of soft tissue.

X

Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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I. Administrative Information

A. Manufacturer Identification

1. Company Name and Address

Foundry Newco X, Inc.
199 Jefferson Dr.
Menlo Park, CA 94025

2. Establishment Registration Number

Pending

3. Official Contact

Steven Kim
Chief Technology Officer
Foundry Newco X, Inc.
199 Jefferson Drive
Menlo Park, CA 94025
Tel: 650-326-2656
Fax: 650-326-3108
Email: skim@thefoundry.com

B. Sterilization Site Information

1. Company Name and Address

Sterigenics
5725 West Harold Gatty Drive
Salt Lake City, UT 84116

2. Establishment Registration Number

1721676

3. Official Contact

Shawn Pollino
General Manager
Tel: (801) 328-9901
Email: saltlakecity@sterigenics.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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II. Device Identification

A. Proprietary Name

Microwave Tissue Coagulation System (MTCS)

B. Common Name

Tissue coagulation system

C. Classification Name and Reference

Electrosurgical, cutting & coagulation & accessories, 21 CFR §878.4400

D. Intended Use

The Microwave Tissue Coagulation System (MTCS) is intended for coagulation of soft tissue.

E. Proposed Regulatory Class

Class II

F. Device Product Code

GEI

G. Performance Standards

No performance standards applicable to this product have been promulgated by FDA.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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III. Device Information

Background

Electrical energy, in the form of Radiofrequency (RF) and Microwave, has been used in medical applications for many years. The application of these energy types to tissue can result in controlled heating of the tissue over the normal range. The absorption of the energy by the tissue cells can raise the temperature of the tissue to levels that cause tissue coagulation. The level of coagulation is controlled by the operator based on the energy delivered (combination of power and time).

Generally, both RF and Microwave coagulation devices have an external energy generator which is connected to an antenna or energy probe. The probe directs the energy to the target tissue and is specifically designed for the type and amount of energy delivered. Both methods require tissue contact to operate.

Device Description

The Microwave Tissue Coagulation System (MTCS) is designed to coagulate soft tissue using a surface contact applicator. The applicator has a suction chamber to acquire and isolate the target tissue. The applicator also has an optional surface cooling feature, which can keep the surface of the target tissue protected at certain power delivery conditions while coagulating the tissue below it. The microwave energy is delivered through 2 microwave antennae embedded in the applicator housing. The antennae are specifically designed to operate at 2450MHz to deliver the energy provided by the generator. There is also a temperature sensor placed on the inside surface of the suction chamber to monitor the tissue surface temperature. The temperature sensor is not part of an active feedback mechanism. It is strictly for information purposes only.

(b)(4)

[redacted]

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System Overview

The MTCS consists of the following major components (see Figure 2):

1. MTCS Microwave Generator
2. MTCS Applicator
3. MTCS Vacuum Pump
4. MTCS Chiller Pump and Pump Tubing

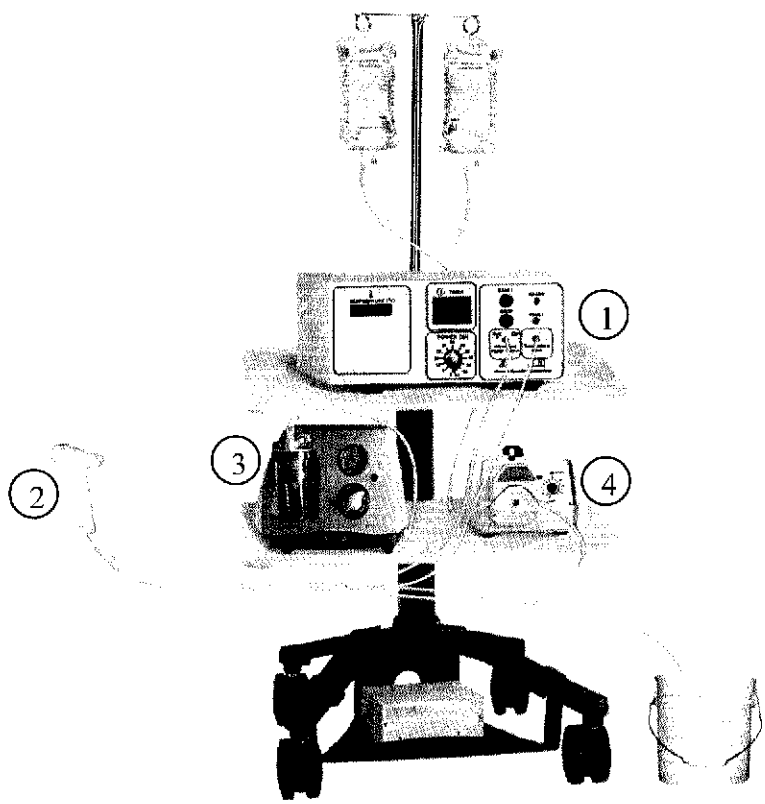

Figure 2. Picture of MTCS System

As shown in the Figure 3 below, the system uses AC mains power and interfaces with both the user and the patient. On the front panel of the generator, the user interface allows for manual setting of the power and duration of treatment. Microwave energy is delivered at 2450MHz for the user-set duration. The maximum output power level is 60 watts. The vacuum pump has a power button to activate vacuum for target tissue acquisition into the applicator. The vacuum pump has a knob to adjust the vacuum level. If target tissue surface cooling is desired, the MTCS Chiller Pump with the MTCS Pump Tubing can circulate sterile saline through the MTCS Applicator.

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(b) (4)

Figure 3. Block diagram of MTCS

Generator

The generator unit contains electric circuits, circuit boards, and integrated control panel. The major components of the generator are cooling fans, power supply, microwave module and the front panel/control board assembly. A block diagram of the components of the generator is included in Attachment C.

The control panel has an overlay that meets IEC60601 requirements and has the following features:

- Start & Stop buttons
- Energy delivery indicator light (Ready LED)
- Probe cable connector (microwave power output)
- Elapsed time indicator
- Power setting up/down via rotary knob (Watts)
- Duration setting up/down (seconds)
- Fault indicator light
- Temperature input connector (from applicator)
- Temperature display (from applicator)

The generator is powered by 120 VAC line power. The system does not contain any software.

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Applicator

The applicator includes a vacuum acquisition chamber, a surface cooling feature, and two microwave antennae. The vacuum acquisition chamber is a void within the applicator where the target tissue can be localized for focused treatment. The surface cooling feature allows the user to minimize or prevent coagulation at the surface of the target soft tissue, if desired. The microwave antennae are specifically designed from semi-rigid microwave coaxial cables and are embedded within the applicator. The applicator is permanently attached to a flexible microwave cable that carries the energy from the generator to the antennae. The applicator also has 3 permanently attached polymer tubes. One for vacuum transmission and two for the chiller fluid flow in and out. See Figure 4. Device drawings are attached in Appendix C.

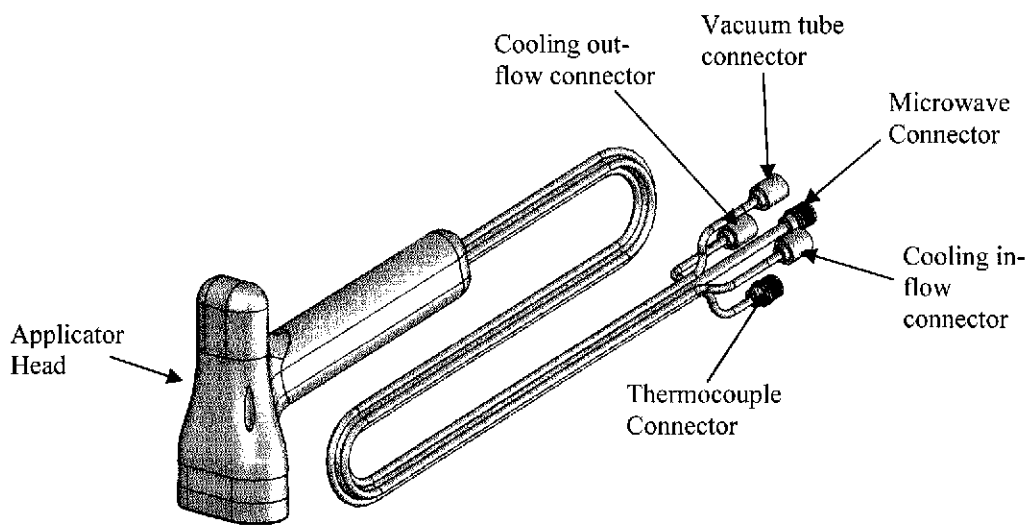

Figure 4: Applicator with connectors

Vacuum Pump

The vacuum pump is a multi-purpose pump supplied by Medela as the "Basic 30" which was developed for medical applications. The Basic 30 aspirator is powerful, quiet, and provides rapid vacuum buildup in a compact design. The most important features of the suction pump are the drive system and the vacuum regulator. The drive system provides a quick and reliable vacuum build-up. The regulator guarantees a precise vacuum setting. These components are designed to function reliably in every situation.

The pump has a maximum flow capacity of 30 liters per minute and a maximum vacuum of -85 kPa/-638 mm Hg (-13.05 psi/-26.57 inch Hg) at an altitude of 0 meters. The unit has a vacuum power on switch button and a vacuum/flow level adjustment knob. The actual measured vacuum level is displayed on the front panel dial in both kPa and mm

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Hg. A green light is illuminated when power is applied to the pump and indicates that the pump is in standby mode (no vacuum pumping).

The pump is designed to operate from 100-120 V 60 Hz. It contains one T 3.15A 6.3x32 fuse. The dimensions are 290 mm high by 305 mm wide by 325 mm deep (11.4 inches high by 12.0 inches wide by 12.8 inches deep). The pump weighs 10 kg (22 pounds). It is designed to operate over a temperature range of +10 to +40 degrees C and a storage temperature range of -20 to +50 degrees C. It can be operated in an altitude environment that ranges from 70 to 106 kPa. It can operate over a 20% to 95% relative humidity range.

The User Manual of the vacuum pump is included in Attachment A.

Chiller Pump and Pump Tubing

The MTCS Chiller Pump is a simple peristaltic pump designed to create fluid flow through the MTCS Applicator. The flow is created with the use of the MTCS Pump Tubing. One end of the Pump Tubing is connected to the fluid source (i.e. sterile saline bag) and the other end is connected to the MTCS Applicator. The middle section of the Pump Tubing is loaded into the drive head of the Chiller Pump. A roller compresses the tubing inside an occlusion bed which forces the fluid to flow through the tubing, thereby driving the sterile saline into the Applicator. The outflow from the Applicator is sent to a disposal receptable (i.e. bucket) via the outflow tubing.

Following are the specifications of the MTCS Chiller Pump.

Dimensions (L x W x H)	11" x 7" x 7" (27cm x 18cm x 19cm)
Weight	10 lb. (4.5 kg)
(b)(4) [redacted]	
Storage/Shipping Temperature	0°C to 50°C
Relative Humidity	10% to 90%
Shipped Non-sterile	

Nominal Voltage	115 Volts RMS (60Hz)
Operating Range	100-240 VAC (50-60 Hz)
Power Supply	80 VA
Inlet Fuses	2x T1 0.1A 250V

(b)(4) [redacted]	
Speed Regulation (% of max RPM)	
Line	±1%
Load	±5%
Temperature (warm-up)	±10%

The User Manual of the MTCS Chiller Pump is included in Attachment A.

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Method of Operation

The operation of the product follows these steps:

1. The Applicator is connected to the Generator, Vacuum Pump, and Pump Tubing.
    a. Microwave cable of Applicator is connected to the Generator through a microwave connector.
    b. The vacuum tube of the Applicator is connected to the Vacuum Pump through a luer-type connector.
    c. The Pump Tubing is connected to a bag(s) of sterile saline and the applicator. The Pump Tubing is loaded into the drive head of the Chiller Pump.
2. The Generator is powered on and the parameters (power and duration) are set by the user.
3. The Chiller Pump is powered on and the cooling flow is turned on, if desired by the user.
4. The Vacuum Pump is powered on and the vacuum level is set by the user to the desired level.
5. The user places the Applicator onto the target tissue surface.
6. The user activates the Generator which delivers microwave energy to the target site.
7. When energy delivery is complete, the vacuum is powered off and the Applicator is removed from the tissue surface.
8. The Generator, Vacuum pump, and Chiller Pump are turned off, and the Applicator is disconnected from the equipment.

Materials

All patient contact materials used in the manufacture of the MTCS are suitable for this application and have been used in numerous previously cleared products. Table 1 lists the patient contacting materials as shown in Figure 5 in the MTCS device.

No materials used in the construction of the MTCS have been reformulated or recompounded by Foundry Newco X, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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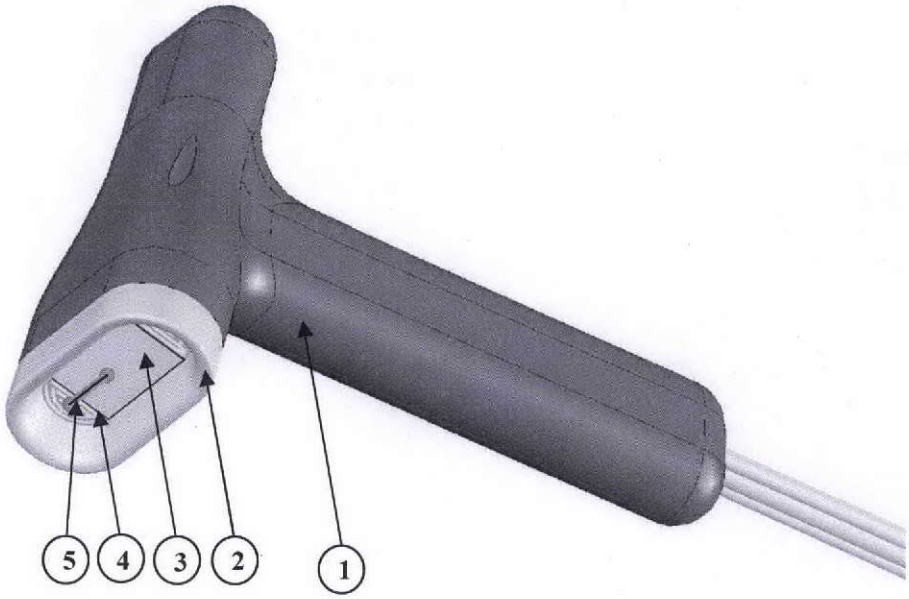

Figure 5: Applicator

The patient contacting materials in the MTCS are listed below:

ID	Component	Material	Patient Contact
1	Handle	ABS	Yes
2	Head	Polycarbonate	Yes
3	Cooling Plate	Ceramic - Aluminum oxide, Al_2O_3	Yes
4	Adhesive	UV Curing Acrylated Urethane Adhesive	Yes
5	Thermocouple: T-Type	UV Curing Acrylated Urethane Adhesive	Yes (thermocouple is completely encapsulated in adhesive)

Table 1: Patient contacting materials

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Biocompatibility

All materials used to construct the MTCS are well-characterized, medical-grade materials previously used in other medical applications. Additional biocompatibility information for the materials used is contained in Appendix H.

Material	Company	Device	K number
ABS	Somnus Medical	SP1010 Somnoplasty device	K982717
Polycarbonae	Depuy Spine	Healos FX Graft Mixing and Delivery System	K062495
Aluminum oxide, Al_2O_3	Smith and Nephew	Biolox Alumina Ceramic Femoral Head	K981847
UV adhesive	VeinRx	InfusionCath	K052738

Table 2. Materials use in cleared devices.

As all of the materials used in the manufacture of the MTCS are ISO 10993 compliant and **Foundry Newco X, Inc. has not modified or recompounded any of the materials,** no additional biocompatibility testing was conducted.

Labeling

Instructions for Use are contained in Appendix A.
Product labeling is contained in Attachment B.

Packaging and Expiration Dating

The applicator will be packaged in an industry standard thermoplastic tray with a heat sealed Tyvek sterile barrier film. Sterile barrier packaging will be validated prior to market release. The tray will be provided inside a paper carton.

As all materials used to construct the MTCS are well characterized and have been used in numerous previously cleared devices, initial expiration dating will be six (6) months. Accelerated and real-time aging tests will be performed in accordance with accepted methods in order to extend expiration dating.

Sterilization

The MTCS applicator will be supplied sterile. The device will be sterilized with Ethylene Oxide and is for single use only. The device is not intended to be re-used or re-sterilized by the user.

The sterilization process of the MTCS applicator will be validated to a sterility assurance level (SAL) of 10^{-6} in accordance with ANSI/AAMI/ISO 11135 (Guideline for Industrial

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Ethylene Oxide Sterilization of Medical Devices: Process Design, Validation, Routine Sterilization, and Contract Sterilization)

Sterilization cycle information is in Attachment G.

Product Testing

Samples of the device were subjected to clinical simulation testing with animal tissue. Results showed the product met specification in the following areas:

(b)(4) [redacted]

Additional testing to be completed prior to product release:

- Generator
  The generator is designed to comply with the electrical safety (IEC60601-1) and electromagnetic compatibility (IEC60601-1-2) standards. All product safety testing will be completed prior to market release.

- Vacuum Pump and Peristaltic Pump.
  The vacuum pump and peristaltic pump are designed to comply with the electrical safety (IEC60601-1) and electromagnetic compatibility (IEC60601-1-2) standards. All product safety testing will be completed prior to market release.

Animal Tissue Testing

Lesion creation testing on various ex-vivo soft tissues was performed and the results are summarized in the tables below. The results are also included in the applicator Instructions for Use (Attachment A). This serves as guidance for the user to understand the effects of varying energy delivery parameters.

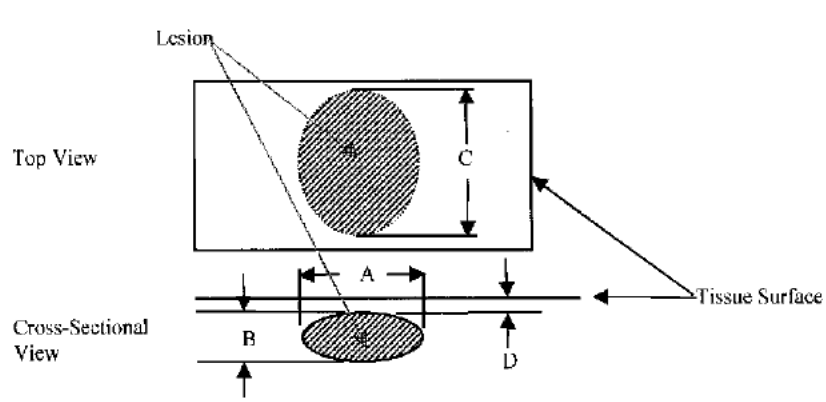

Figure 6. Lesion size dimensions and distance from the tissue surface

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The following tables show the approximate lesion size created by the MTCS Applicator at various power/time settings. The results are from Ex-Vivo liver, muscle, and kidney animal tissue models, respectively. **Lesion size may vary in clinical setting**. All lesion size dimensions are in millimeters. There are 2 sets of numbers in each box. The top set is created using chilled saline at 10 degrees Celsius and flow turned on. The bottom set is without cooling flow. (AxBxC – D See Figure 6 above for details of the dimensions)

Liver	10 seconds	15 seconds	20 seconds
40 Watts	5x2x2 – 2 5x2.5x2 – 1.5	10x2.5x3 – 1.5 10x4.5x7 – 1	15x4x5 – .5 15x5x9.5 – 0
50 Watts	7.5x3x3.5 – 1.5 8.5x4x3.5 – 1	13x3.5x5.5 – .5 14x6x9 – 0	14x5.5x6.5 – .5 16x7x11 – 0
60 Watts	11x4.5x4 – 1 14x3x8 – .5	15x5x5.5 – .5 15x6x10 – 0	16x6x7 – .5 24x9x11 – 0

Muscle	10 seconds	15 seconds	20 seconds
40 Watts	9x2.5x2.5 – 2.5 10x4x5 – 0	12x5x5 – .5 15x7x6 – 0	17x6x5.5 – .5 18x6x7 – 0
50 Watts	11x4x3.5 – 1 15x6x6 – 0	14x6x5 – 0 16x6.5x7.5 – 0	16x6.5x6.5 – 0 19x7x9 – 0
60 Watts	12x5x5 – .5 14.5x6x7 – 0	16x6.5x6 – 0 18x7x8 – 0	22x8x7.5 – 0 21x9x9 – 0

Kidney	10 seconds	15 seconds	20 seconds
40 Watts	6x3x3 – 1.5 8x4x4 – 1	9x5x6 – 2 13x6.5x8.5 – 0	12x6x6 – 1 13x6x9 – 0
50 Watts	6.5x4x4 – 1 10x4x6 – .5	12x6x7 – .5 13x5x8.5 – 0	14.5x6.5x7 – .5 15x8x9.5 – 0
60 Watts	10x4.5x5.5 – 1 10x5.5x7.5 – 0	12x6.5x7.5 – 0 15x6.5x8.5 – 0	17x7x7 – 0 18x7.5x9.5 – 0

Figure 7: Photo of lesion created by MTCS on Ex-Vivo Kidney Tissue (40W/15sec/10 deg. C cooling)

Attachment D contains all of the photos from the animal tissue testing.

Software

The MTCS does not contain any software.

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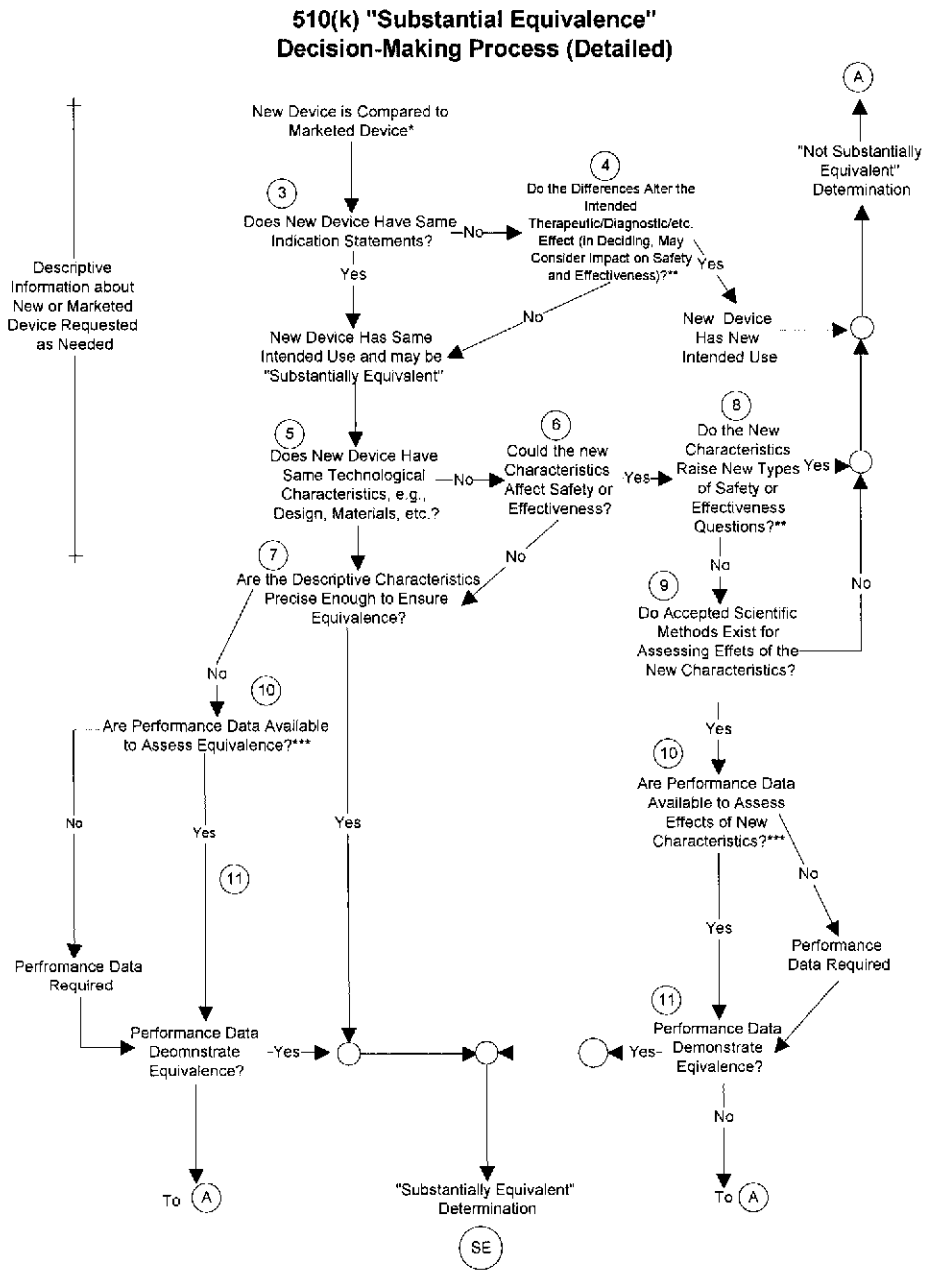
Substantial Equivalence

A. Predicate Device Comparison

Feature	MTCS	Microsulis MTA System	Vivant Medical VivaWave	Radionics Cool-Tip RF Ablation
510(k) Number	This Application	K052919	K011676	K984552
Product Code	GEI	GEI	GEI	GEI
CFR Reference	21CFR§878.4400	21CFR§878.4400	21CFR§878.4400	21CFR§878.4400
Manufacturer	Foundry Newco X, Inc.	Microsulis Americas, Inc.	Vivant Medical, Inc.	Radionics, Inc.
Indications for Use	Indicated for coagulation of soft tissue	Indicated for intraoperative coagulation of soft tissue	Indicated for coagulation of soft tissue.	Indicated for coagulation of tissue during percutaneous, laparscopic and intraoperative procedures
Manual or automatic	Manual setting	Manual setting	Manual setting	Manual setting
Software	No	Yes	No	No
Energy	Microwave	Microwave	Microwave	RF
Frequency	2450 MHz	2450 MHz	915 MHz	480 KHz
Power - maximum	60 Watts	Unknown	60 Watts	200 Watts
Supplied Sterile	Yes – disposable hand piece	Yes – disposable hand piece	Yes – disposable probe	Yes – disposable probe
Cooling	Yes	No	No	Yes
Method of cooling	Saline flowing through Applicator	None	None	Saline flowing through tip
Vacuum	Yes	No	No	No

B. FDA Decision Tree for Substantial Equivalence

The FDA decision tree for substantial equivalence was followed and is shown here, for reviewer convenience, with numbered references at each step to substantial equivalence rationale that follow (Figure 4, Table 11).



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (Pre-Amendments or reclassified post-Amendments) of devices is unclear

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Figure 4: FDA Decision Tree for Substantial Equivalence

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Substantial Equivalence Discussion

3. Does new device have same indication statement?

Yes. The basic indications for use are the same, i.e., soft tissue coagulation.

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

Yes. The technological characteristics are basically the same; microwave energy delivered to a specific area through a probe or hand piece in a controlled manner.

7. Are the descriptive characteristics precise enough to ensure equivalence?

Yes. The product specifications and tissue study results show MTCS successful operation. The MTCS device is equivalent to the existing products. Foundry Newco X believes the characteristics of the product are sufficient to determine substantial equivalence. The methods of operation, the clinical application and the materials used in manufacture are similar as well. The MTCS probe contains internal cooling with saline equivalent to the Radionics Cool-Tip device. The microwave frequency of 2450 Mhz is the same as for the Microsulis MTA product.

IV. Conclusion

The MTCS is substantially equivalent to the predicate devices.

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ATTACHMENT A

INSTRUCTIONS FOR USE

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List of Contents in Attachment A:

1. **MTCS Generator User Manual – DRAFT**
2. **MTCS Applicator Instructions for Use – DRAFT**
3. **MTCS Chiller Pump User Manual – DRAFT**
4. **MTCS Pump Tubing Instructions for Use – DRAFT**
5. **Medela Basic 30 Vacuum Pump User Manual**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Foundry
NewCo X

MTCS Generator
User Manual

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1. CONTACT INFORMATION

Foundry NewCo X
199 Jefferson Drive
Menlo Park
CA 90245
United States
1-650-326-2656 (telephone)
1-650-326-3108 (fax)

1.1. EXPLANATION OF SYMBOLS

	Attention: Refer to Instructions for Use
CAUTION	Warning: Dangerous Voltage
	Fuse
	Non-Ionizing Radiation
	Type BF (Body Floating) Applied Part
	Applicator (Microwave Delivery)
SERIAL #	Serial Number
I	On (Main Power)
O	Off (Main Power)
	Start (Coagulation)
	Stop (Coagulation)

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2. GENERATOR DESCRIPTION

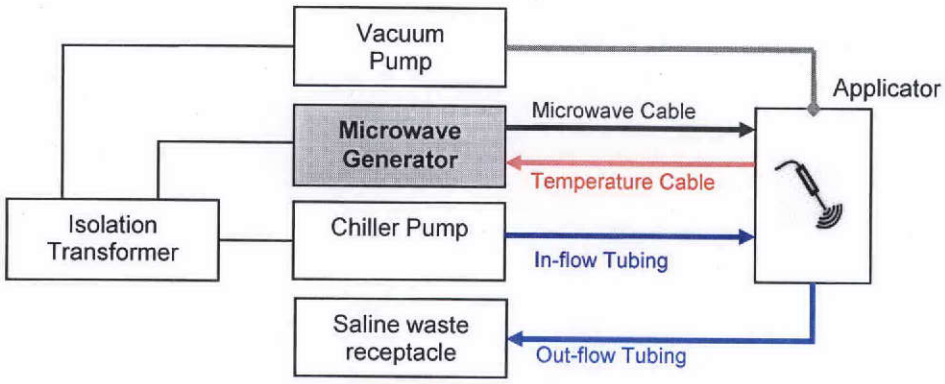
The Foundry NewCo X Microwave Generator is designed for use in the Foundry NewCo X Microwave Tissue Coagulation System (MTCS). The generator connects to the Foundry NewCo X Applicator. Together the generator and the applicator deliver energy for the purpose of soft tissue coagulation.

Power and time controls are provided on the front panel. When activated, the generator delivers a set energy dose. The power control regulates the power output (in Watts). The timer control sets the duration (in seconds).

Energy is delivered to the applicator via the Microwave Cable. Tissue surface temperatures at the applicator are sent via the Temperature Cable and displayed on the front panel of the generator.

During the energy delivery cycle the generator activates microwave energy delivery for the pre-set power and time given by the user.

See the Applicator Instructions for Use on guidelines for setting power and time.



Foundry NewCo X MTCS

The generator delivers microwave power at a frequency of 2450MHz. The generator automatically stops microwave energy whenever the contact between the applicator and the target tissue surface of the patient is sub-optimal, (see Applicator Instructions for Use on correctly positioning the applicator) or if the generator detects that no applicator is connected at the front panel. The generator will stop energy delivery if it detects an excessive temperature inside the generator enclosure.

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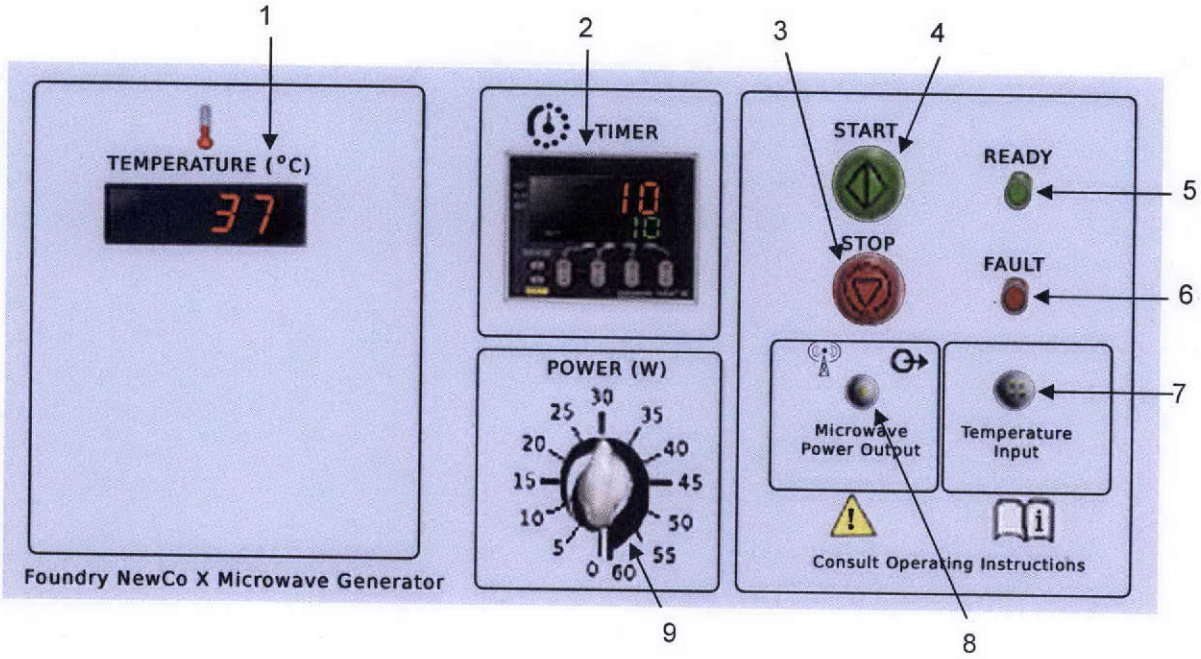
2.1. FRONT PANEL: DISPLAY AND CONTROL FEATURES



1. **SURFACE TEMPERATURE METER** – Displays the surface temperature reading from the Applicator (°C)
2. **TIMER** – Displays the microwave activation time. Upon initiation the timer will count down the SET TIME. The timer displays zero when the generator is first switched on or when a fault condition has been detected.
   a. **SET** – The SET button sets the time on the timer (is not re-settable/functional during energy delivery).
   b. ∨ **(TIME DOWN)** – Decreases the activation time (is not re-settable/functional during energy delivery).
   c. ∧ **(TIME UP)** – Increases the activation time (is not re-settable/functional during energy delivery).
3. **STOP** – The STOP button immediately stops energy delivery. When the STOP button is pressed the timer is reset to zero and the READY LED is OFF.
4. **START** – The START button initiates energy delivery. The START button is enabled when the generator READY LED is ON.
5. **READY** – The READY LED illuminates when the timer is set.
6. **FAULT** – The FAULT LED illuminates when a factory preset fault condition occurs (see Troubleshooting, section 12), (or if the system detects a malfunction).
7. **TEMPERATURE INPUT** – Provides a thermocouple connection to the Applicator.
8. **MICROWAVE POWER OUTPUT** – Provides connector for Applicator cable connection.
9. **POWER** – Displays the set microwave output power from the generator (Watts)

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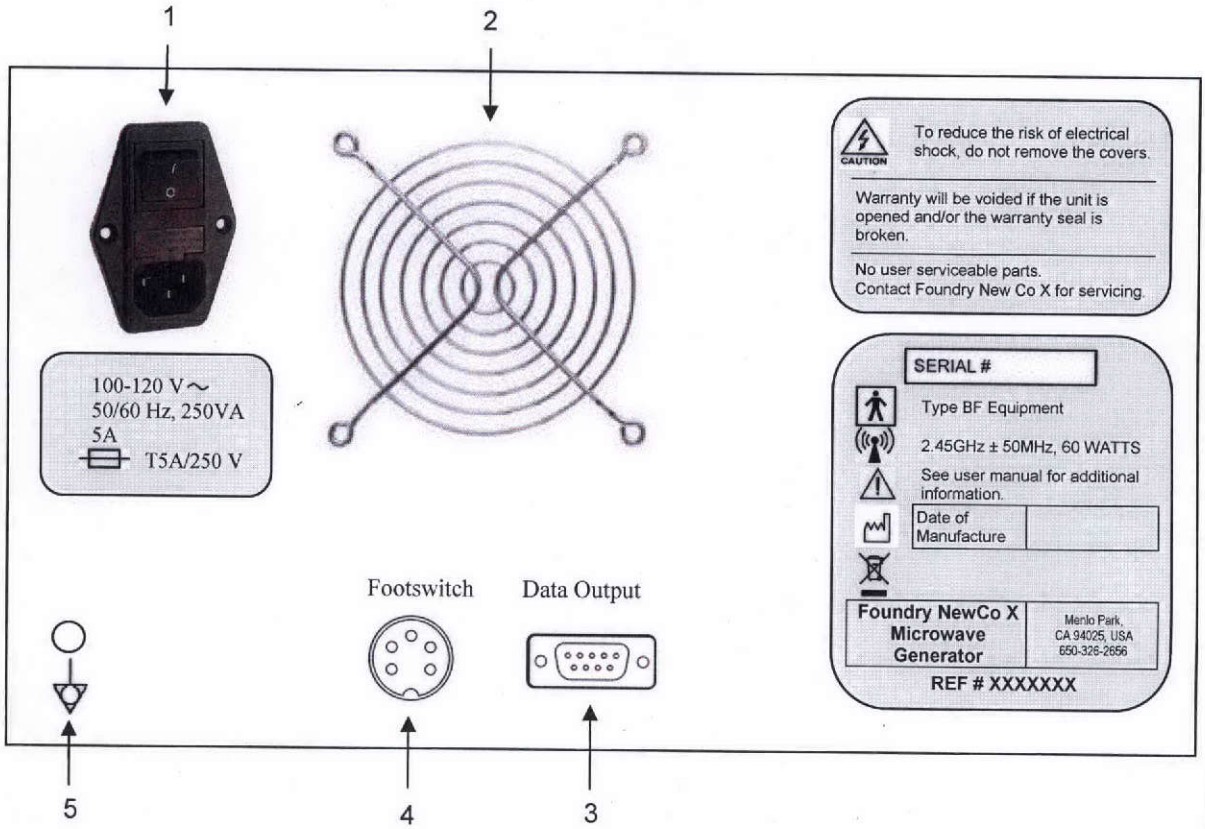
2.2. REAR PANEL: FEATURES



1. **A/C RECEPTACLE – ON/OFF SWITCH** – The receptacle contains the generator fuses. (See instructions on How to Change the Fuses, section 2.3). Provides power cord connection.
2. **FAN** – Provides airflow to ensure proper cooling of the generator.
3. **DATA OUTPUT** – RS-232 socket for data capture.
4. **FOOTSWITCH INPUT** – Socket for connecting to an external footswitch.
5. **EQUIPOTENTIAL GROUNDING** – Ensures that the generator is at the same ground potential as other equipment in the vicinity.

2.3. HOW TO CHANGE THE FUSES

CAUTION: Do not use repaired fuses or short-circuited fuse holders.

Only use standard fuses, current rated T5A/250 V @ 100-120 V ~

1. Ensure the generator is in the OFF (0) position.
2. Unplug the power cord from the generator.
3. Snap the A/C RECEPTACLE-ON/OFF switch cap open by placing a flat screwdriver in the pre-marked slot located on top of the switch.
4. Remove fuses from either side of the holder and replace with standard time delay fuses, current rated T5A/250 V @ 100-120 V ~.
5. Replace holder and snap the cap closed.

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3. CAUTIONS

Federal US law restricts this device to sale by or on the order of a licensed physician.

4. INDICATIONS FOR USE

The Microwave Tissue Coagulation System (MTCS) is intended for coagulation of soft tissue.

5. CONTRAINDICATIONS

The MTCS is contraindicated for patients with heart pacemakers and other electronic device implants.

6. ADVERSE EVENTS

There are no known adverse events specific to the use of the generator. See Applicator Instructions for Use.

7. WARNINGS AND PRECAUTIONS

- ❑ Carefully read the User Manual for the Foundry NewCo X MTCS Generator and the Applictor IFU prior to use. Observe all warnings and precautions. Failure to do so may result in complications.
- ❑ The Foundry NewCo X MTCS Generator is for use by qualified clinical personnel who have been instructed and trained in the correct use of the equipment by designated Company representatives.
- ❑ Operate the Foundry NewCo X MTCS Generator in environmental temperatures between 10˚C and 40°C; and between 30% and 75% relative humidity (non-condensing).
- ❑ Use only the components and parts supplied by Foundry NewCo X.
- ❑ DO NOT attempt to repair or alter any of the System components.
- ❑ DO NOT allow fluid to contact generator, cables or connectors unless the generator is being cleaned. Do not hang fluids above the generator. The generator may not function correctly if the electronic circuitry or the connectors are wet. Do not soak cables.
- ❑ DO NOT operate if wet. Electrical shock may occur.
- ❑ DO NOT operate if no applicator is connected or if the applicator is not properly positioned. See Applicator IFU for proper positioning of the applicator.

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- Clean, disinfect, and maintain the electrical units in accordance with the operating instructions.
- Turn the electrical units Off using the main power On/Off switch and disconnect the power cord from the AC supply before cleaning.
- DO NOT remove the cover of the generator. There are no user-serviceable parts inside the generator. Opening the generator may result in electrical shock or thermal burns.
- For warnings and precautions on other equipment used in the Foundry NewCo X MTCS, see corresponding User Manuals for the MTCS Chiller Pump and the MTCS Vacuum Pump. Also read the MTCS Applicator IFU.
- This equipment/system is intended for use by healthcare professionals only. The use of any electrosurgical device can cause electromagnetic interference (EMI) with other electrical medical equipment. Provide as much distance as possible between the MTCS Generator and other electronic equipment. Precautions should be taken to ensure that the well-being of the patient is maintained in the event of such interteference. It may be necessary to take mitigation measures, such as reorientating or relocating the microwave generator or shielding the location.
- The MTCS should not be used on patients with heart pacemakers or other electronic device implants.
- Do not use this device in the presence of flammable anesthetics; other flammable gases; near flammable fluids such as skin prepping agents and tinctures; flammable objects; or with oxidizing agents. Observe appropriate fire precautions at all times.
- Do not use this device in oxygen enriched atmospheres, nitrous oxide (N_2O) atmospheres, or in the presence of other oxidizing agents. Be sure that all oxygen connections do not leak.
- Electrosurgical components, such as the applicator, may remain hot after activation. Keep all electrosurgical equipment away from flammable materials to avoid combustion.
- While using this device during a procedure, the patient should not be allowed to come into direct contact with grounded metal objects such as a surgical table frame, an instrument table, etc.
- Prolonged or unneccessary activation of the MTCS may lead to unintentional damage to surrounding tissue.
- The output power selected should be as low as possible for the intended purpose.
- Do not obstruct the activation light or tone. The activation tone and light are important safety features.
- Use only MTCS Apllicators with the MTCS Generator.
- Do not bend cables at acute angles of coil them tightly; the cable might break.

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- ❑ The main power cord of the MTCS Generator must be connected to a properly grounded receptacle. Extension cords and/or adaptor plugs must not be used.
- ❑ Do not wrap MTCS Applicator microwave cables around metal objects. Wrapping cables around metal objects may induce hazardous currents.

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8. UNPACKING AND EQUIPMENT SETUP

- ❑ Inspect generator and its components for shipping damage. If damage has occurred, contact Foundry NewCo X.
- ❑ Verify all components are present (see section 11).
- ❑ Position the generator close to the patient.
- ❑ (APPLICABLE ONLY IF USING THE FOOTSWITCH). Connect the Footswitch to the FOOTSWITCH INPUT, located on the rear panel.
- ❑ Ensure the chiller/pump system and associated fluid tubing are away from the generator to prevent fluid ingress. Fluid tubing should not be placed over or on top of the generator.
- ❑ Ensure all air vents are not obstructed.
- ❑ Ensure the A/C RECEPTACLE-ON/OFF switch, located on rear panel is OFF (O).
- ❑ Set the POWER switch, located on the front panel, to Zero (0) Watts.
- ❑ Attach the jumper power cord between the A/C RECEPTACLE-ON/OFF receptacle and the isolation transfromer.
- ❑ Connect the isolation transformer to an appropriate AC outlet and switch on the isolation transformer.
- ❑ Switch the generator A/C RECEPTACLE-ON/OFF switch, located on rear panel, to the ON (I) position.
- ❑ Verify the following indications on the front of the generator:
    - The TIMER display is on and displays Zero (0) seconds.
    - The READY LED is not illuminated.
    - The FAULT LED is illuminated.
- ❑ Connect the Temperature Cable, from the applicator, to the Temperature input connector, located on front panel.
- ❑ Verify FAULT LED is no longer illuminated, after connecting the Temperature Cable to the front panel. (Ensure footswitch cable is plugged into the rear panel if operating in Footswitch operation mode).

  WARNING: The FAULT LED is illuminated if the system detects a malfunction; (see Troubleshooting, section 12).
- ❑ Connect the Applicator cable to the Microwave Power Output connector, located on front panel.

  CAUTION: Ensure that the Applicator cable is fully connected and the connector is tight. If an improper connection is suspected then disconnect the Applicator cable and retry to make the connection. If the connector is damaged, contact a Company Representative.

  CAUTION: DO NOT force the Applicator cable onto the Microwave Power Output connector, located on front panel.

  CAUTION: DO NOT operate if the applicator is not connected or if the applicator is not correctly positioned on the patient. See Applicator Instructions for Use for correct positioning of the applicator on the patient.

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9. OPERATING INSTRUCTIONS

9.1. OPERATION

STEP 1: Ensure that the FAULT LED and the READY LED are not illuminated after initial equipment setup (see Troubleshooting, section 12).

STEP 2: Rotate the POWER switch to the appropriate power level. See the Applicator IFU for guidelines.

STEP 3: SET TIME for microwave activation using the TIME UP and TIME DOWN buttons. See the Applicator IFU for guidelines.

STEP 4: Set the timer to the SET TIME using the SET button. This will cause the READY LED to illuminate.

WARNING: Ensure the Applicator is properly positioned and in contact with tissue and all components of the MTCS are properly setup. See Applicator IFU for proper positioning of the applicator and the required setup of the system.

STEP 5: Press the START button (or depress the FOOTSWITCH) to initiate microwave energy delivery. Verify the following:

- The TIMER begins to countdown.
- A "beeping" sound is audible, whenever microwave energy is being delivered.

NOTE: After the countdown is complete, microwave activation stops. The TIMER resets the display to the Set Time.

SUBSEQUENT ABLATIONS

- Subsequent ablations can be performed by pressing the START button (or by depressing the FOOTSWITCH). Ensure that the previous energy delivery cycle is finished and that the timer has completed the countdown.

ABORT PROCEDURE

- Depress the FOOTSWITCH whenever microwave energy is activated,
- or, press the STOP button, located on the front panel,
- or switch off the A/C RECEPTACLE-ON/OFF switch, located on the rear panel.

9.2. GENERATOR SHUTDOWN PROCEDURE

- Switch off the generator using the A/C RECEPTACLE-ON/OFF switch and disconnect from power source.
- Disconnect the Applicator cable from the Microwave Power Output, located on front panel.
- Disconnect the Temperature Cable from the Temperature Cable input, located on front panel.
- (APPLICABLE ONLY IF USING THE FOOTSWITCH). Disconnect the Footswitch cable from the FOOTSWITCH INPUT, located on the rear panel

CAUTION: DO NOT kink, or agressively flex the Applicator cable when returning it to its storage location.

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10. CLEANING AND MAINTENANCE

10.1. CLEANING

- Disconnect generator from all accessories, and from power source.
- Dampen a clean dry cloth with a multi-purpose hospital grade detergent.
- Gently wipe down all cords, switches, buttons, and device housing, taking special care not to get liquid into the housing or electrical components.
- Gently dry the entire generator, including cords.
- Do not soak any of the cords or cables, especially the connectors, since this can affect electrical performance.

10.2. STORAGE

The generator, plus cord should be stored in a cool, dry place out of direct sunlight.

10.3. SERVICE INFORMATION

The generator has been Manufacturer tested. Damaged, removed or dislodged label (located on the left and right hand side of generator) voids Manufacturer's testing. There are no serviceable parts inside the generator.

11. HOW SUPPLIED

The microwave generator is supplied with the following components:

11.1. DESCRIPTION OF MICROWAVE GENERATOR COMPONENTS

Item	Description	Qty
1	Generator User Manual	1
2	Microwave Generator	1
3	10A C13 Jumper Cordset	1

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12. TROUBLESHOOTING GUIDE

Problem	Troubleshooting Tips
No, or irregular generator operation.	Ensure the cord is plugged into the isolation transformer, and that the isolation transformer is plugged into a proper electrical outlet matching its electrical specification.
No power.	Replace Fuse (see How to Change Fuses, section 2.3).
"FAULT" LED remains illuminated; preventing energy activation.	1. Ensure that the Temperature Cable is correctly fitted to the connector on the front panel, (see Unpacking and Equipment Setup, section 8). 2. Check the temperature reading on front panel, if no reading is displayed this may suggest a broken cable. 3. (APPLICABLE ONLY IF USING THE FOOTSWITCH). Ensure that the Footswitch cable is plugged into the FOOTSWITCH INPUT, located on rear panel. 4. Turn the power off for 5 minutes to allow the generator to cool. Repeat equipment setup procedure. If problem persists contact a Foundry NewCo X representative.
"READY" LED does not illuminate prior to energy activation.	Ensure that the timer has been set to a non-zero time. Ensure that the SET button has been pressed to set the time.
"FAULT" LED is illuminated after energy activation; energy delivery is quickly stopped by the generator.	1. Ensure that device applicator positioning instructions have been followed, (see Applicator Instructions for Use). 2. Ensure the applicator cable is correctly fitted to the connector on the front panel, (see Unpacking and Equipment Setup, section 8). 3. Ensure that the Temperature Cable is correctly fitted to the connector on the front panel, (see Unpacking and Equipment Setup, section 8). 4. Check the temperature reading on front panel, if no reading is displayed this may suggest a broken cable. 5. Turn the power off for 5 minutes to allow the generator to cool. Repeat equipment setup procedure. If problem persists contact a Foundry NewCo X representative.
Tone sounds continuously.	Turn power off and then back on. If the problem persists, contact a Foundry NewCo X representative.

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13. SPECIFICATIONS

AC input voltage	100-125V AC, 50/60 Hz
AC input fusing	Two standard time delay fuses (in the power entry module in the rear panel), current rated T5A/250 V @ 100-120 V ~
AC input VA	250VA
Protection	Protectively earthed, Class I
Microwave Output Frequency	2450MHz ± 50 MHz
Microwave Output Power	Adjustable from 0 to 60 Watts in 5 Watt increments
Output Time Setting	Adjustable from 0 seconds to 30 seconds in 1 second increments.
Patient Isolation	Class BF (body floating) for applied parts
Duty Cycle	Continuous
Dimensions: Generator	32.8 cm x 18.3 cm x 38.1 cm (width x height x depth) 12.9" x 7.2" x 15"
Weight: Generator	13.6 kg. (30 lbs.)
Environmental Operating Temperature/Humidity	Ambient Temperature: +10°C - +40°C Relative Humidity (Non-condensing): 30% - 75%
Environmental Storage/Shipping Temperature/Humidity	Ambient Temperature: 0°C - +50°C Relative Humidity (Non-condensing): 20% - 85%
Classification	Type BF Applied Part
CONFORMS TO	UL/IEC 60601-1-1, General requirements for safety – Section 1: Collateral standard: Safety requirements for medical electrical systems CAN/CSA-C22.2 No.601.1-M90 with updates 1 and 2 UL/IEC 60601-1-2, General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.

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14. WARRANTY AND LIMITATIONS

Foundry NewCo X, warrants that this product has been manufactured, packaged and tested with reasonable care and will be free from defects in workmanship and material for a period of one year. This warranty shall not apply to products that been repaired, altered, or modified in any way, or to products which been improperly stored or improperly installed, operated or maintained. Foundry NewCo X will not be liable for any incidental, special or consequential loss, damage, or expense resulting, directly or indirectly, from the use of this product. Foundry NewCo X's sole obligation shall be to repair or replace, at its own option, any generator that Foundry NewCo X determines was defective at time of shipment. Buyer assumes all liability, whether based upon warranty, contract, negligence, or otherwise, for damages resulting from the handling, possession, use or misuse of this product. Because Foundry NewCo X has no control over the operation, inspection, maintenance, or use of its products after sale and has no control over the selection patients, THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, AND OF ANY OTHER OBLIGATION ON THE PART OF THE SELLER. The remedies set forth in this Warranty and Limitations shall be the exclusive remedy available to any person. No agent, employee, or representative of Foundry NewCo X has any authority to change any of the foregoing or assume or bind Foundry NewCo X to any additional liability or responsibility in connection with the product. Buyer's use of this product shall be deemed acceptance of the terms and conditions of the Warranty and Limitations

Manufactured by:

Foundry NewCo X
199 Jefferson Drive
Menlo Park
CA 90245
United States
1-650-326-2656 (telephone)
1-650-326-3108 (fax)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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INSTRUCTIONS FOR USE

MTCS APPLICATOR

Foundry Newco X, Inc.

199 Jefferson Dr.
Menlo Park, CA 94025
Phone: 650-326-2656
Fax: 650-326-3108

DRAFT

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MTCS Applicator
Instructions for Use

Federal Law (U.S.A.) restricts this device to sale by or on the order of physician.

BEFORE USING THE SYSTEM:

Please refer to Microwave Tissue Coagulation System (MTCS) Generator User Manual for detailed instructions on connecting and operating the entire system. Components of the MTCS System are designed to be used together as a single unit.

Failure to understand and follow provided instructions, may cause injury to the patient and/or user and may cause improper functioning of the system.

INTENDED USE:

- The Microwave Tissue Coagulation System (MTCS) is intended for coagulation of soft tissue.

IMPORTANT:

- The procedures should only be performed by physicians and operating room staff familiar with the equipment and techniques involved.
- The MTCS Applicators are shipped as sterile products and are intended to be used one time only. Please discard after one use. Do not attempt to resterilize.
- Product is sterile unless package has been damaged or opened.

WARNINGS AND CAUTIONS:

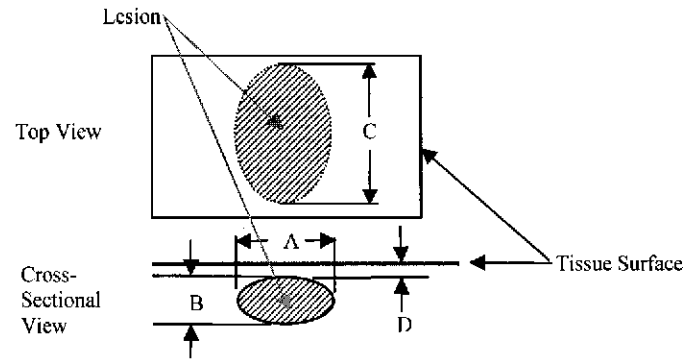
- DO NOT use on patients with heart pacemaker or other electronic device implants.
- DO NOT use in presence of flammable anesthetics or oxidizing gases (e.g. nitrous oxide, oxygen, accumulation of endogenous gases in body, etc.) due to high possibility of combustion.
- DO NOT place finger into the tissue acquisition chamber of the Applicator at any time during application of power.
- DO NOT use Applicator if there are cuts or nicks in the outer insulation of the microwave cable, as unintended thermal injury could occur.
- DO NOT apply power with Applicator not in contact with the target tissue
- Localized burns to patient or physician may result from electric currents being carried through conductive objects or from metal objects in close proximity to Probe.
- DO NOT allow patient to come in contact with grounded metal objects.
- Always use the lowest possible power necessary to achieve the desired effect.

BEFORE THE PROCEDURE:

- Refer to MTCS Generator User Manual for detailed instructions on how to activate system generator and properly connect associated components.
- Refer to the Vacuum Pump User Manual for detailed instructions on how to activate and adjust the vacuum level.
- Refer to the Chiller User Manual for detailed instructions on how to set chiller temperature and activate the flow.
- Place the Applicator on the target tissue.
- Activate the vacuum to acquire and localize the tissue. Adjust vacuum setting accordingly to user desired level.
- Activate the cooling flow for surface cooling, if desired.
- Set power and duration of treatment to desired levels. Confirm the generator settings before proceeding with the procedure.

NOTE:

The following tables show the approximate lesion size created by the MTCS Applicator at various power/time settings. The results are from ex-vivo liver, muscle, and kidney animal tissue models, respectively. **Lesion size may vary in clinical setting.**



All lesion size dimensions are in millimeters. There are 2 sets of numbers in each box. The top set is created using chilled saline at 10 degrees Celsius and flow turned on. The bottom set is without cooling flow. (AxBxC – D See figure above for details of the dimensions)

Liver	10 seconds	15 seconds	20 seconds
40 Watts	5x2x2 – 2 5x2.5x2 – 1.5	10x2.5x3 – 1.5 10x4.5x7 – 1	15x4x5 – .5 15x5x9.5 – 0
50 Watts	7.5x3x3.5 – 1.5 8.5x4x3.5 – 1	13x3.5x5.5 – .5 14x6x9 – 0	14x5.5x6.5 – .5 16x7x11 – 0
60 Watts	11x4.5x4 – 1 14x3x8 – .5	15x5x5.5 – .5 15x6x10 – 0	16x6x7 – .5 24x9x11 – 0

Muscle	10 seconds	15 seconds	20 seconds
40 Watts	9x2.5x2.5 – 2.5 10x4x5 – 0	12x5x5 – .5 15x7x6 – 0	17x6x5.5 – .5 18x6x7 – 0
50 Watts	11x4x3.5 – 1 15x6x6 – 0	14x6x5 – 0 16x6.5x7.5 – 0	16x6.5x6.5 – 0 19x7x9 – 0
60 Watts	12x5x5 – .5 14.5x6x7 – 0	16x6.5x6 – 0 18x7x8 – 0	22x8x7.5 – 0 21x9x9 – 0

Kidney	10 seconds	15 seconds	20 seconds
40 Watts	6x3x3 – 1.5 8x4x4 – 1	9x5x6 – 2 13x6.5x8.5 – 0	12x6x6 – 1 13x6x9 – 0
50 Watts	6.5x4x4 – 1 10x4x6 – .5	12x6x7 – .5 13x5x8.5 – 0	14.5x6.5x7 – .5 15x8x9.5 – 0
60 Watts	10x4.5x5.5 – 1 10x5.5x7.5 – 0	12x6.5x7.5 – 0 15x6.5x8.5 – 0	17x7x7 – 0 18x7.5x9.5 – 0

DURING THE PROCEDURE

- If for any reason the Applicator becomes disengaged from the tissue, discontinue energy delivery by pressing the stop button on the generator.
- If an error occurs during use, refer to MTCS Generator User Manual for troubleshooting.

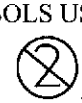
AFTER THE PROCEDURE:

- Disconnect used Applicator and its cables and tubing from generator, vacuum pump, and chiller pump and discard.
- Turn off generator after procedure.

STORAGE:

- Store Probe away from moisture and direct heat.
- Discard product if damaged.

SYMBOLS USED:


.....Single Use

.....Read Instructions

STERILE EO ..... Sterilized by EtO

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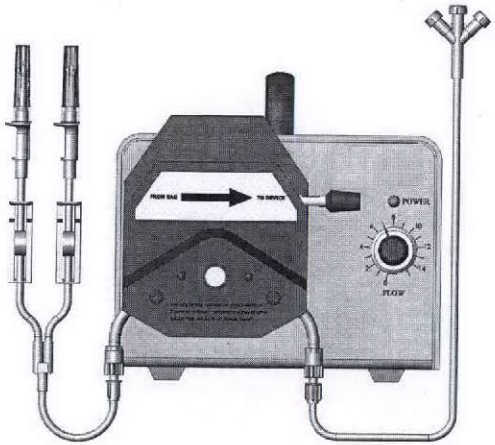
Foundry Newco X

MTCS
CHILLER PUMP



USER MANUAL

Draft

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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I. INDICATIONS

The Foundry Newco X MTCS Chiller Pump is intended for delivering cooling fluid to the MTCS Applicator.

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II. WARNINGS AND CAUTIONS

Please read this entire manual as well as all User Inserts for associated components and follow their instructions carefully.

NOTE: Foundry Newco X reserves the right to make improvements in the product(s) described herein. Product(s) therefore may not agree in detail to the published design or specifications. All specifications are subject to change without notice. Please contact your local Foundry Newco X sales representative or agent for information on changes and new products.

USER AND PATIENT SAFETY:

WARNINGS:

- Do not use this device in the presence of flammable anesthetics; other flammable gases; near flammable fluids such as skin prepping agents and tinctures; flammable objects; or with oxidizing agents. Observe appropriate fire precautions at all times.
- Do not use this device in oxygen-enriched atmospheres, nitrous oxide (N_2O) atmospheres, or in the presence of other oxidizing agents. Be sure that all oxygen connections do not leak.
- DO use all proper fittings when connecting Pump Tubing. Make sure all connections are tight, to avoid disconnection during use.
- ONLY use MTCS Pump Tubing with the MTCS Chiller Pump. Use of other Pump Tubing can result in compromised patient safety and/or improper device performance.
- Do not attempt to reuse or resterilize any product labeled "SINGLE USE" as this may lead to malfunctioning of the equipment, injury to the patient/user, and/or cross contamination.
- Do not allow the Pump to become wet. If Pump does get wet, remove the power cord from the mains outlet before handling the pump

CAUTIONS:

- Use only MTCS Applicators with the MTCS Chiller Pump.
- Do not bend tubing at acute angles or coil them tightly; they may break.
- The main power cord of the MTCS Chiller Pump must be connected to a properly grounded receptacle.

OPERATOR QUALIFICATION

The physician using the MTCS system should:

- Be a qualified physician, having complete knowledge of the use of this equipment.
- Read this operating manual thoroughly and be familiar with its contents prior to operating the equipment.

WARNING: Federal law (U.S.A.) restricts use of this device by, or, on order of a physician.

GENERAL WARNINGS AND CAUTIONS:

TO AVOID POTENTIAL SERIOUS INJURY TO THE USER AND THE PATIENT AND/OR DAMAGE TO THIS DEVICE, THE USER MUST:

1. Carefully unpack the unit and check to ensure that all pertinent equipment is accounted for and that no damage has occurred during shipment. If damage is detected, please see the Service and Claims section in this manual.
2. Do not remove cover on MTCS Chiller Pump to avoid electric shock and damage to the unit.
3. Attempt no internal repairs or adjustments, unless specified otherwise in this manual. Units requiring repair should be returned to Foundry Newco X for repair.
4. Pay close attention to the care, cleaning, sterilization, and disinfection instructions in this manual. A deviation may cause damage to the equipment.
5. Disconnect the MTCS Chiller Pump from the electrical outlet when inspecting fuses.

Foundry Newco X accepts full responsibility for the effects on safety, reliability, and performance of the equipment ONLY if:

- Re-adjustments, modifications, and/or repairs are carried out exclusively by Foundry Newco X.
- The electrical installation of the relevant operating room complies with the applicable IEC, CEC, and NEC requirements.

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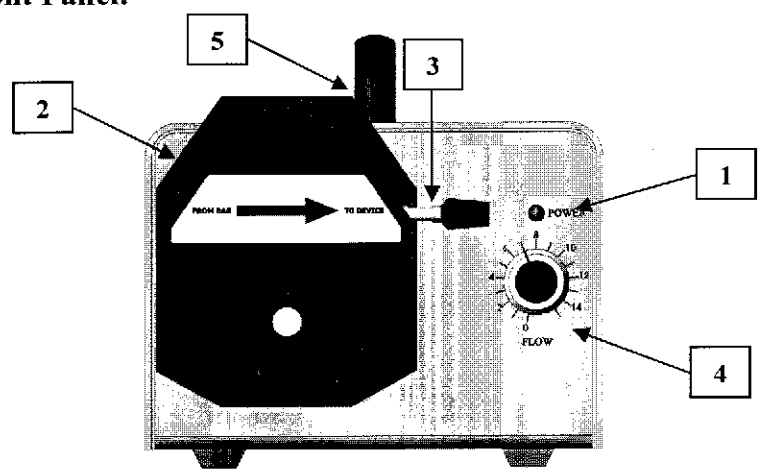
III. PRODUCT DESCRIPTION

The MTCS Chiller Pump System consists of two components— a Pump and Pump Tubing. Other components of the MTCS System are specifically designed to connect with the MTCS Chiller Pump System and are intended to be used together as a single system. This system should only be used as indicated in this manual in Section I.

PUMP:

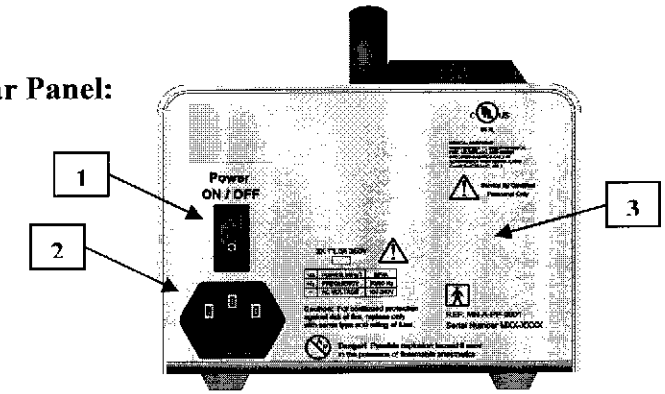
NOTE: Refer to Appendix A for front and back panel labeling definitions.

Front Panel:



1. ***Mains Power LED***: The LED illuminates when the Mains Power to the Pump is turned ON.
2. ***Pump Head:*** The Pump Head receives the Pump Tubing.
3. ***Pump Head Lever***: The Pump Head Lever allows for appropriate feeding of Pump Tubing.
4. ***Flow Knob:*** The flow knob controls the Pump speed.
5. ***Handle:*** The Handle can be used to carry the Pump.

Rear Panel:

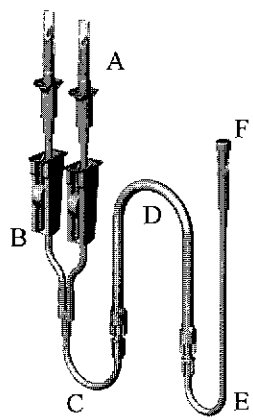


1. ***Mains Power Switch***: The mains connection to Pump can be turned ON/OFF using this switch.
2. ***Power Entry Module:*** This module has a fuse drawer that contains fuses.
3. ***Label:*** Pump label information.

DISPOSABLE PUMP TUBING:

NOTE: Use only MTCS Pump Tubing with MTCS Pump. Pump tubing appearance may vary. See Pump Tubing IFU for details.

NOTE: The Pump Tubing is shipped sterile and is for single use only. Do not attempt to re-sterilize.



A. ***Spikes***: The spikes are to be used to insert the tubing into a saline bag. The spikes are covered with Spike Caps.

B. ***Roller Clamps:*** These clamps are used to stop flow through the particular segment of the tubing.

C. ***Tubing 1***: This Y-Tubing connects the rest of the tubing to the Spikes.

D. ***Tubing 2:*** This tubing is fed through the Pump Head.

E. ***Tubing 3:*** This tubing connects Tubing 2 to the 3-port Y-connector.

F. ***Female luer connector:*** The female luer connector is intended for connection to the MTCS Applicator.

NOTE: Use 1000ml to 3000ml IV Bag for Saline.

NOTE: Use a plastic bucket for outflow (preferably larger than 3000ml).

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IV. INSTRUCTIONS FOR USE

INITIAL SET-UP:

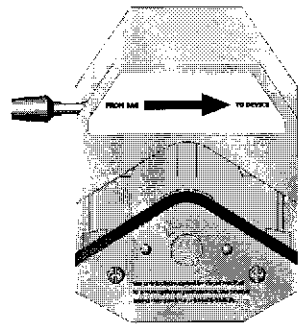
1. The Pump should be placed on a cart or on any sturdy table or platform. Refer to hospital procedures or local codes for detailed information.
2. Provide at least four to six inches of space around the rear and top of the Pump for convection cooling. It is normal for the top and rear panel to be warm when system is used continuously for extended periods of time.
3. The Pump is shipped with an approved hospital grade mains power cord. Plug the Pump into a grounded receptacle. DO NOT use extension cords or three-prong to two-prong adapters. The mains power cord assembly should be checked periodically for damaged insulation or connectors.
4. Press the Pump power switch to the ON position.
5. Be sure that the LED indicator on the front panel is lit.

CONNECTING PUMP TUBING TO PUMP:

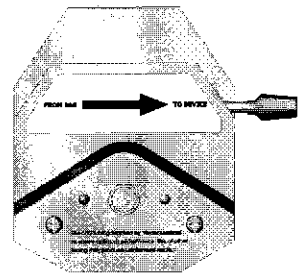
1. Suspend IV Bag on IV pole. Confirm that all air bubbles rise to the top.
2. Using the Pump Head Lever open the Pump Head.
3. Insert Tubing through Pump Head in the direction shown on the Pump Head. Improperly feeding the Pump Tubing can result in patient injury and/or device malfunction.
4. Close one roller clamp. Connect Pump Tubing to Saline Bag by removing the other Spike Cap and inserting the Spike into the bag.
5. Connect other end of Pump Tubing to the device(s) after removing the appropriate cap(s) on the 3-port Y-connector. See Applicator IFU for details.
6. Close Pump Head. Flush the fluid through the device(s). The fluid flow through the device can be stopped by (a) turning power to the Pump off or (b) opening the Pump Head and closing the appropriate Roller Clamp.
7. For more information regarding use of Pump Tubing, refer to IFU accompanying the Tubing.

MODES OF OPERATION:

The MTCS Chiller Pump has 2 modes of operation—the Standby Mode and the Delivery Mode. The position of the Pump Head lever determines the mode of operation, as shown below. The Pump Motor is inactive in the Standby Mode and is active in the Delivery Mode.



STANDBY MODE
(Pump Head Open)



DELIVERY MODE
(Pump Head Closed)

DURING PROCEDURE:

1. To allow for fluid flow through tubing, open the appropriate roller clamp. Confirm that the other roller clamp is closed.
2. To change saline bags, insert the unused spike into a second saline bag. Open the appropriate roller clamp, to allow for fluid flow. Before disconnecting the spike from the saline bag, make sure that the roller clamp is closed.

WARNING: Change fluid bags before the current bag is empty. Cessation of fluid delivery can result in degraded performance or injury to patient.

3. If replacing Applicators, turn Pump off to prevent fluid spills.

AFTER PROCEDURE:

1. Return Pump to Standby Mode by opening the Pump Head.
2. Turn off power to the Pump using the mains switch on the rear panel of the Pump.
3. Dispose Pump Tubing with the Applicator.
4. Unplug Pump from the mains (power outlet).
5. See Section V for Cleaning and Disposal guidelines.

NOTE: The Pump can be left in the Standby Mode between cases, but should be turned off at the end of an operating session.

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V. CLEANING AND STERILIZATION

PUMP

The Pump cannot be sterilized. Refer to hospital procedures for proper cleaning of equipment. Use only non-abrasive cleaning agents and DO NOT allow liquid to enter the Pump.

WARNING: Make sure power to the Pump is turned OFF before cleaning.

CAUTION: Do not spray or pour cleaners or any other liquids on the Pump.

TUBING

The Pump Tubing is shipped sterile and is intended to be used ONE TIME ONLY. Do not attempt to resterilize or reuse Pump Tubing. Dispose of Pump Tubing after single use.

EQUIPMENT DISPOSAL GUIDELINES

- The MTCS Chiller Pump contains electronic printed circuit assemblies. Equipment should be disposed of at the end of its useful life in accordance with applicable national or institutional related policies relating to obsolete electronic equipment.
- Dispose of any system accessories according to normal institution practice relating to potentially contaminated items.

VI. TROUBLESHOOTING GUIDE

Issue	*Resolution*
Pump does not turn ON	Check power cord connection to Pump
	Check and replace Fuse, if necessary (see Maintenance Section of Manual)
	Check power availability at outlet
Pump Head does not operate	Check to make sure that Pump Head is closed properly
	Check power cord connection to Pump
	Check and replace Fuse, if necessary (see Maintenance Section of Manual)
	Check power availability at outlet
Inadequate flow through Pump Tubing	Check Pump Tubing. Make sure it is not defective
	Check spike for complete insertion into IV Bag
	Check position of both roller clamps
	Check active IV Bag to make sure it is not empty
	If none of the above steps solve the problem, replace Applicator

NOTE: If the problem persists, refer to the Service and Claims section of this manual to obtain repair service.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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VII. TECHNICAL SPECIFICATIONS

MTCS Chiller Pump

Dimensions (L x W x H)	11" x 7" x 7" (27cm x 18cm x 19cm)
Weight	10 lb. (4.5 kg)
Operating Temperature	15°C to 35°C
Storage/Shipping Temperature	0°C to 50°C
Relative Humidity	10% to 90%
Shipped Non-sterile	

Nominal Voltage	115 Volts RMS (60Hz)
Operating Range	100-240 VAC (50-60 Hz)
Power Supply	80 VA
Inlet Fuses	2x T1 0.1A 250V

Pump Speed Range	12 – 200 rpm
Max. Load	40 psi
Flow (Speed)	10-160 ml/min (with MTCS Pump Tubing)
Speed Regulation (% of max RPM)	
Line	±1%
Load	±5%
Temperature (warm-up)	±10%

CLASSIFICATION SPECIFICATIONS

- Class 1, ordinary equipment as per IEC 60601-1
- Type BF
- Mode of operation - Continuous

NOTE: Use only MTCS Pump Tubing and MTCS Applicators with the MTCS Chiller Pump

VIII. MAINTENANCE

FUSE REPLACEMENT INSTRUCTIONS:

1. Unplug Pump from electrical outlet and unplug power cord from Pump.
2. Locate Fuse Box on rear panel of the Pump.
3. Unlatch fuse holder below the AC Inlet and remove. You may need to press the tab on the fuse holder with a slender screwdriver to release the latch.
4. Replace the fuse with a new fuse of the same value rating.

WARNING: To avoid risk of fire, replace only with a fuse of the value specified on the fuse label on back of the Pump.

5. Reinstall the fuse holder until the tab snaps in place.

NOTE: Refer calibration and operating difficulties not detailed in this manual to Foundry Newco X Customer Service (1-650-326-2656).

IX. SERVICE AND CLAIMS

If repair is needed either during or after the warranty period:

1. Contact Foundry Newco X at 1-650-326-2656.
2. Package all the components carefully in the original shipping container if possible.
3. Ship the MTCS Chiller Pump, pre-paid and insured to:

   Foundry Newco X Customer Service
   Attention: Repair Department
   199 Jefferson Dr.
   Menlo Park, CA 94025
   USA

NOTE: The MTCS Chiller System described in this manual is constantly being reviewed and improvements may be made without notice.

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APPENDIX A

DESCRIPTION OF LABELING (Pump: Front and Rear Panels)

Alternating Current	~
Attention: consult accompanying documents	
Patient Isolated (BF) equipment	
Non-AP Equipment (not for use in presence of flammable gases)	A P
Fuses	2X
Power OFF	○
Power ON	|

FOUNDRY NEWCO X
199 JEFFERSON DR.
MENLO PARK, CA 94025
PHONE: (650) 326-2656
FAX: (650) 326-3108

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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INSTRUCTIONS FOR USE,

MTCS PUMP TUBING
REF XXXXX

1. Remove Tubing from Package
2. Close both Roller Clamps
3. Remove Spike Cap off one roller clamp
4. Insert Spike into saline bag
5. Feed appropriate section of the Tubing through the pump
6. Close the pump head
7. Connect Applicator to luer connector
8. Open Roller clamp connected to saline bag
9. To switch saline bags: a) follow steps 3 and 4 with second Spike, b) open second Roller Clamp, c) close first Roller Clamp
10. Dispose Tubing after use

For more details refer to MTCS Chiller Pump User Manual

NOTE: USE ONLY WITH MTCS CHILLER PUMP

DRAFT

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READ ALL INSTRUCTIONS BEFORE USE

LIRE L'INTEGRALITE DES INSTRUCTIONS D'EMPLOI AVANT UTILISATION

LEA TODAS LAS INSTRUCCIONES ANTES DE USAR EL BASIC 30

basic 30

1 check vacuum controller

2 plug in remote exhaust

«Standby»

switch on vacuum connector

Option Optional

3 Before use, always check for correct operation!

Toujours vérifier le bon fonctionnement de l'appareil avant utilisation.

Es imprescindible probar el funcionamiento antes del uso!

Select maximum vacuum

Sélectionner le dépression maximale

Seleccionar el nivel máximo de vacío

Seal of the suction connection

Obturer le raccord de la prise d'aspiration

Cerrar la conexión de aspiración

Maximum vacuum according to technical specifications

Dépression maximale selon les caractéristiques techniques

Vacío máximo según especificaciones técnicas

Adjust the vacuum to use

Régler le vacuo pour l'usage

Regular el vacío para el uso

ok

4 switch off

mettre hors vacuum

desconectar

Clean the unit with a damp cloth and a nonabrasive detergent

Nettoyer l'appareil avec un chiffon humide et un détergent non abrasif

Limpiar el aparato con un paño húmedo y usando un detergente no agresivo

cleaning • nettoyer • limpiar

Comply with hygiene directives or hygiene

Respecter les règles d'hygiène en vigueur en hôpital

Observar las disposiciones de higiene vigentes del establecimiento

Auto-clave

Auto-clave

The Basic 30 is a high-quality suction apparatus developed for medical applications. Its well-proven piston/cylinder system guarantees maximum suction performance and, depending the operation. Additional advantages of the Medela apparatus are its simple dismantling and easy handling.

The Basic 30 is universally applicable in hospitals, private practice and nursing homes, etc. This pump is highly suitable for medical applications involving surgical fluids, blood, secretions and tissues including bones in emergency rooms, isolated hygiene, wound or fluids drainage as well as endoscopy. In addition, the Basic 30 is also used in dentistry, in ENT wards, in obstetrics, wards and many other medical medicine. Accessories such as gynaecological accessories makes the Basic 30 readily suited for each sector of medical applications. Contact us – we will be pleased to advise you!

Le Basic 30 est un aspirateur de haute qualité développé pour les besoins médicaux. Son système de piston/cylindre éprouvé est synonyme d'aspiration performante et, en fonction de l'application, il peut être grandement bénéfique dans une série de domaines. Les produits Medela sont les suivants: simplicité d'emploi, facilité du nettoyage et bon rendement.

Le Basic 30 est un aspirateur universel utilisable en milieu hospitalier, cabinet privé, cliniques, etc. Cet appareil convient aussi bien pour les liquides chirurgicaux, le sang, les secrétions et les tissus y compris crânes aux urgences, l'hygiène isolée, le drainage des plaies et de l'endoscopie. Le Basic 30 est par ailleurs employé en gynécologie, en médecine dentaire, dans les salles ORL et les cabinets en général et s'avère indispensable dans bien d'autres secteurs médicaux.

Contactez-nous – nous nous ferons un plaisir de vous conseiller!

El Basic 30 es un aspirador de excelente calidad para utilizaciones médicas, de gran calidad. Se basa en el probado sistema pistón/cilindro que garantiza la máxima succión y, en función de la aplicación, puede ser muy beneficioso en una serie de ámbitos. Otras ventajas de este aparato de Medela son la sencillez de la limpieza y su fácil manejo, la sencillez de la limpieza y su cómodo manejo.

El Basic 30 es universalmente adaptable en hospitales, consultas privadas, residencias, etc. La bomba es muy adecuada para aplicaciones de succión en relación con líquidos quirúrgicos, sangre, secreciones y tejidos incluidos los huesos en salas de urgencias, higiene aislada, drenaje de heridas y endoscopia. Además, el Basic 30 se utiliza en ginecología, y otorrinolaringología, en consultas de medicina y en muchos otros campos de la medicina.

Póngase en contacto con nosotros – ¡estaremos encantados de asesorarle!

Accessories • Accessoires • Accesorios

Medela's extensive range of disposable and reusable accessories

La vaste gamme d'accessoires Medela, qu'ils soient jetables ou réutilisables

El amplio surtido de accesorios de Medela con sus ventajas desechable o de uso múltiple

medela

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Troubleshooting • Dépannage • Resolver problemas

Motor not running
Moteur ne fonctionne pas
El motor no funciona

Voltage
Tension de la ...
Tensión de la red

Switched on
Commutateur
Conect

Fuse
Fusible
Fusible

Insufficient vacuum
Vide est insuffisant
Vacío insuficiente

Position of regulator
Position du régulateur
Posición de ajuste

Tubing
Tubes
Tubos flexibles

Plug-in connections
Raccord
Conexiones de enchufe

Overflow protection device
Dispositif de protection
Protección antirrebose

Sensitive container; lid, seals
Collecteur de ...; joints, ...
Colocar de ...; tapa, ...

Cause – Inst. ...
Cause – Cause ...
Causa – Causa ...

Technical specifications • Caractéristiques techniques • Especificaciones técnicas

basic 30

Suction
Aspiration
Aspiración
–85 kPa / –638 mmHg

Flow
Débit
Flujo
30 l/m

Power
Puissance
Potencia
• 230–240 V 50 Hz 110 W
• 210–240 V 60 110 W
• 100–120 V 50/60 110 W
• 100–120 V 60 110 W

Fuse
Fusible
Fusible
T 2.5A 5x20 230–240 V
T 3.15A 6.3x32 100–120 V

Dimensions
Dimensions
Dimensiones
• 265 (310) 480 mm
• 240 305 325 mm

Weight
Poids
Peso
16 kg
10 kg

Operating temperature
Température de service
Temperatura de servicio
Transport/Storage temperature
Température de transport/stockage
Temperatura de transporte/almacenamiento

Operating humidity
Humidité de service
Humedad de servicio
Transport/Storage humidity
Humidité de transport/stockage
Humedad de transporte/almacenamiento

Noise
Niveau sonore
Nivel de ruido
MDD 93/42 EEC classe IIa
IPX1
ISO 9001
ISO 13485
CE (93/42/EEC)
CE 0123

Serial number
Numéro de série
Número de serie

Date of production
Date de production
Fecha de producción

Switzerland & international Sales
Medela AG
Medical technology
Lättenstrasse 4b
6341 Baar/Switzerland
Phone +41 (0)41 769 51 51
Fax +41 (0)41 769 51 00
email info@medela.ch
www.medela.ch

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42908 Skidmore Cres. Unit 2
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Fax + 905 608 8720
email customer.service@medela.ca
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email info@medela.de
www.medela.de

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Medela, Inc.
1101 Corporate Drive
McHenry, IL 60050
Phone +1 815 363 1166
Fax +1 815 363 1246
email customer@medela.com
www.medelaauction.com

Brunnen 42/17 2003-06-2000/B

medela

Safety instructions & Guarantee • Consignes de sécurité & Garantie • Indicaciones de seguridad & Garantía

This device complies with IEC60601-1-2, "Medical electrical equipment - Electromagnetic compatibility" and is therefore unlikely to interfere with other electrical equipment. In case there is interference which can be determined by disconnecting the device from the mains supply, try the following: Reorienting or relocating the device with respect to the other device or connecting the device's power cord to another power outlet.

Usage — The appliance may only be operated by persons qualified in medical applications and familiar with infection hygiene guidelines.

Mains voltage — Separation by unplugging the power cord.

Overflow — Contact your service center immediately. Work in accordance with the Service Manual.

Routine inspection — According to the service manual – once a year.

Disposal — The unit is made of metals and plastics and may only be disposed of in accordance with local regulations. The unit must be disinfected before disposal.

Warranty — 3-year warranty from the date of delivery for the unit. The manufacturer is not liable for any damage or consequential damage caused by incorrect operation, inappropriate usage as well as use by unauthorized persons. Routine inspections and servicing work must only be carried out by personnel authorized by Medela.

Cet appareil est fait au crité IEC60601-1-2, "Equipement médical électrique – compatibilité électromagnétique", et il n'est donc guère probable qu'il interfère avec des dispositifs électriques. En cas d'interférence (qui peut être identifiée en déconnectant l'appareil de la source principale), procéder comme suit: réorienter ou relocaliser l'appareil par rapport à l'autre dispositif, ou connecter le câble électrique de l'appareil à une autre source de courant.

Utilisation — L'appareil ne doit être utilisé que par des personnes disposant des connaissances médicales requises et parfaitement informées des règles d'hygiène en vigueur sur le site.

Tension — Mettre l'appareil hors tension et débranché: le cordon d'alimentation.

Trop plein — Informer immédiatement le service technique. Se référer méticuleusement au manuel de service.

Contrôle de routine — Effectuer une fois par an, conformément aux Instructions de service.

Recyclage — L'appareil est constitué de composants en métal et en plastique qui peuvent être recyclés selon la réglementation locale en vigueur. Ne pas oublier de vendre l'appareil l'appareil inutilisable.

Garantie — 3 ans à partir de la date de livraison pour l'appareil. Le fabricant endosse toute responsabilité en cas de dommages directs ou indirects dus à un mauvais usage, une utilisation impropre de l'appareil, ou à des interventions effectuées par des personnes non autorisées. Les contrôles de routine et les réparations doivent exclusivement être effectués par des techniciens autorisés par le constructeur.

Este unidad cumple con la norma IEC60601-1-2, "Equipo eléctrico médico – Compatibilidad electromagnética", y por ello es muy poco probable que interfiera con otro equipo eléctrico. En el caso de que se produzcan interferencias (lo cual se puede determinar desconectando la unidad de la red de alimentación), intente la solución siguiente: Orientar o colocar de diferente manera la unidad en relación con el otro equipo o enchufar el cable de la unidad en una toma distinta de la eléctrica.

Uso — El aparato sólo debe ser manejado por personas que cuentan con la cualificación necesaria para usos medicativos y están al tanto de las reglas básicas de higiene del establecimiento en materia de ...

Corriente eléctrica — Apagado por desenchufe del cable de alimentación.

Rebose — Informar al servicio de reparación inmediatamente. Trabajar según instrucciones de servicio.

Control rutinario — Según las instrucciones de servicio – realizar una vez al año.

Eliminación — El aparato está formado por piezas de metal y plástico. Eliminar respetando las disposiciones locales. Antes de su eliminación, hacer inutilizable el aparato.

Garantía — 3 años de garantía para el aparato a partir de la fecha de compra. La garantía no es válida para daños inmediatos o accesorios debidos a un manejo indebido, un uso no conforme a la prensa o si el aparato lo manejan personas no autorizadas. Los controles rutinarios y los trabajos de reparación deben ser realizados exclusivamente por especialistas o centros de servicio autorizados por Medela.

Medical Electrical Equipment
Model Basic 30
CLASSIFIED WITH RESPECT TO ELECTRIC SHOCK, FIRE
MECHANICAL AND OTHER SPECIFIED HAZARDS ONLY
IN ACCORDANCE WITH UL Std. 544NE AND CSA C22.2 NO. 601.1-225

Check
Contrôler
Control

Follow the accompanying papers
Respecter les consignes ci-jointes
Cumplir el manual de instrucciones

AP (Applied Part)
Partie appliquée
Pieza de ...

Alternating current
Courant alternatif
Corriente alterna

IPX1
Splashproof
Protégé contre les projections d'eau
Protegido contra el goteo de agua

Keep dry
Tenir à l'abri
Mantener ...

Type B
Type B
Type B

Protection class II (double insulated)
Classe de protection II (double isolation)
Clase de protección II (doble aislamiento)

Contact your service center
Contactez votre centre ...
Llamar al servicio ...

Subject to changes
Sous réserve de modifications techniques
Sujeto a modificaciones técnicas

Valid from • valable à partir de • válido a partir de • 03/2005

medela

MEDELA FLUID MANAGEMENT SYSTEM
THE INNOVATIVE SOLUTION FOR THE FUTURE

INSTRUCTIONS FOR USE
MODE D'EMPLOI
INSTRUCCIONES DE USO

basic 30

medela

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ATTACHMENT B

PRODUCT LABELING

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List of Contents in Attachment B:

1. **MTCS Applicator Label – DRAFT**
2. **MTCS Pump Tubing Label – DRAFT**

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Foundry Newco X
199 Jefferson Dr.
Menlo Park, CA 94025
TEL: 650-326-2656
FAX: 650-326-3108

MTCS APPLICATOR

Tissue Acquisition Chamber:

XX mm x XX mm x XXmm

STERILE EO

DO NOT RESTERILIZE

MADE IN USA

PATENTS PENDING

CAUTION: Federal law (USA) restricts the sale, distribution and use of this device to, by or on the lawful order of a health care professional

FOUNDRY NEWCO X, INC.

This package contains MTCS Applicator.

LOT XXXXXX

DRAFT

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Foundry Newco X, Inc.
199 Jefferson Dr.
Menlo Park, CA 94025
TEL: 650-326-2656
FAX: 650-326-3108

MTCS PUMP TUBING

REF XXXXX

USE ONLY WITH MTCS CHILLER PUMP
XXXXXX

Read Instructions
Before Use

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

STERILE | EO

SINGLE USE ONLY
DO NOT RESTERILIZE

CONTENTS STERILE IF PACKAGE
IS UNOPENED AND UNDAMAGED

This package contains (1) MTCS Pump
Tubing

LOT XXXXX REF XXXXX

DRAFT

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ATTACHMENT C

ENGINEERING & PRODUCT DRAWINGS

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List of Contents in Attachment C:

1. **System Interconnect Block Diagram**
2. **MTCS Applicator Assembly Drawing**

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(b)(4) Diagram

(b)(4) Diagram

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ATTACHMENT D

ANIMAL TISSUE TESTING DATA

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(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

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ATTACHMENT E

510(k) SUMMARY

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K072870

510(k) Summary

General Information

Classification	Class II
Trade Name	Microwave Tissue Coagulation System (MTCS)
Submitter	Foundry Newco X, Inc. 199 Jefferson Drive Menlo Park, CA 94045 USA Tel: 650-326-2656 Fax: 650-326-3108
Contact	Steven Kim Chief Technology Officer

Intended Use

The Microwave Tissue Coagulation System (MTCS) is intended for coagulation of soft tissue.

Predicate Devices

K011676	VivaWave Microwave Ablation System
K052919	Microsulis MTA System
K984552	Radionics Cool-Tip RF System

Device Description

The Microwave Tissue Coagulation System (MTCS) is designed to coagulate soft tissue using a surface contact applicator. The system consists of an applicator, external microwave generator, vacuum pump, and a cooling fluid pump and tubing. The desired power and delivery time are set manually by the operator.

The generator contains electric circuits, circuit boards, and integrated control panel. The major components of the generator are cooling fans, power supply, microwave module and the front panel/control board assembly.

The applicator is a specifically designed to deliver microwave energy at the frequency and power levels that the generator outputs. The proximal end of the

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applicator has a microwave connector that fits onto the generator and allows the energy to be delivered to the applicator.

Materials

All materials used in the manufacture of the MTCS are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification.

The results showed the system met specification.

Summary of Substantial Equivalence

The MTCS is equivalent to the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

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ATTACHMENT F

PREDICATE PRODUCT INFORMATION

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List of Contents in Attachment F:

1. **K011676**
   - **510(k) Premarket Notification Database printout from FDA website**
   - **VivaWave Microwave System User Manual – DRAFT**
   - **VivaWAve Probe Label - DRAFT**

2. **K984552**
   - **510(k) Premarket Notification Database printout from FDA website**
   - **Radionics Cool-tip RF System Operator's Manual**

3. **K052919**
   - **510(k) Premarket Notification Database printout from FDA website**

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510(k) Premarket Notification Database

Device Classification Name	system, ablation, microwave and accessories
510(k) Number	K011676
Device Name	VIVAWAVE MICROWAVE SYSTEM
Applicant	VIVANT MEDICAL, INC. 1916-a old middlefield way mountain view, CA 94043
Contact	steven kim
Regulation Number	878.4400
Classification Product Code	NEY
Subsequent Product Code	GEI
Date Received	05/30/2001
Decision Date	06/18/2002
Decision	substantially equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Summary/purged 510(k)
summary	summary
Type	Traditional
Reviewed by Third Party	No
Expedited Review	No

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VIVAWAVE™

DRAFT

MICROWAVE SYSTEM

USER MANUAL

PN01XX, Rev. Draft

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I. INDICATIONS/CONTRAINDICATIONS

INDICATIONS:

The Vivant Medical VivaWave™ System is designed and intended to be used for coagulation of soft tissue.

CONTRAINDICATIONS:

The VivaWave™ System is contraindicated in patients with heart pacemakers and other electronic device implants.

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II. WARNINGS AND CAUTIONS

Please read this entire manual as well as all user inserts for associated components and follow their instructions carefully. The words WARNING, CAUTION, and NOTE are followed by important information and should be carefully reviewed.

WARNING: The personal safety of the patient may be involved. Disregarding this information could result in injury to the patient.

CAUTION: Special service procedures or precautions must be followed to avoid damaging the instrument.

NOTE: Special information to make maintenance easier or important information clearer.

A lightning bolt within a triangle is intended to warn of the presence of hazardous voltage. Refer all service to authorized personnel.

NOTE: Vivant Medical reserves the right to make improvements in the product(s) described herein. Product(s) therefore may not agree in detail to the published design or specifications. All specifications are subject to change without notice. Please contact your local Vivant Medical sales representative or agent for information on changes and new products.

DRAFT

USER AND PATIENT SAFETY

WARNINGS:

- The VivaWave™ System should not be used on patients with heart pacemaker or other electronic device implants.
- Do not use this device in the presence of flammable anesthetics; other flammable gases; near flammable fluids such as skin prepping agents and tinctures; flammable objects; or with oxidizing agents. Observe appropriate fire precautions at all times.
- Do not use this device in oxygen enriched atmospheres, nitrous oxide (N_2O) atmospheres, or in the presence of other oxidizing agents. Be sure that all oxygen connections do not leak.
- Electrosurgical components, such as the Probe, may remain hot after activation. Keep all electrosurgical equipment away from flammable materials to avoid combustion.
- While using this device during a procedure, the patient should not be allowed to come into direct contact with grounded metal objects such as a surgical table frame, an instrument table, etc.
- Prolonged or unnecessary activation of the VivaWave™ System may lead to unintentional damage to surrounding tissue.
- The use of any electrosurgical device can cause electromagnetic interference (EMI) with other electrical medical equipment. Provide as much distance as possible between Generator and other electronic equipment. Precautions should be taken to ensure that the well-being of the patient is maintained in the event of such interference.
- The output power selected should be as low as possible for the intended purpose.
- Do not attempt to reuse or resterilize any product labeled "SINGLE USE" as this may lead to malfunctioning of the equipment, injury to the patient/user, and/or cross contamination.

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CAUTIONS:

- Do not activate the VivaWave™ system until Probe is properly positioned in the patient.
- Do not touch Probe tip at any time during application of power. After application, tip may still remain hot enough to cause burns.
- Do not obstruct the activation light or tone. The activation tone and light are important safety features.
- Use only VivaWave™ Probes with the VivaWave™ Generator.
- Do not bend cables at acute angles or coil them tightly; the cable might break.
- Do not drop or bend Probes, as Probe may develop flaws even when re-shaped. Examine Probes prior to each use. Replace damaged Probes promptly.
- The main power cord of VivaWave™ Generator must be connected to a properly grounded receptacle. Extension cords and/or adapter plugs must not be used.
- Do not wrap the VivaWave™ Probe cable around metal objects. Wrapping cables around metal objects may induce hazardous currents.

OPERATOR QUALIFICATION

The physician using the VivaWave™ system should:

- Be a qualified physician, having complete knowledge of the use of this equipment.
- Have current knowledge of technological advances in surgical products and techniques.
- Read this operating manual thoroughly and be familiar with its contents prior to operating the equipment.
- Test this equipment prior to a surgical procedure. The VivaWave™ System was fully tested at the factory before shipment.

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GENERAL WARNINGS AND CAUTIONS:

TO AVOID POTENTIAL SERIOUS INJURY TO THE USER AND THE PATIENT AND/OR DAMAGE TO THIS DEVICE, THE USER MUST:

1. Carefully unpack the unit and check to ensure that all pertinent equipment is accounted for and that no damage has occurred during shipment. If damage is detected, please see the Service and Claims section in this manual.
2. Do not remove cover on VivaWave™ Generator; an electric shock to operator or damage to the unit may occur.
3. Attempt no internal repairs or adjustments, unless specified otherwise in this manual. Units requiring repair should be returned to Vivant Medical for repair.
4. Pay close attention to the care, cleaning, sterilization, and disinfection instructions in this manual. A deviation may cause damage to the equipment.
5. Disconnect the VivaWave™ Generator from the electrical outlet when inspecting fuses.

NOTE: The VivaWave™ System warranty is void if any of these warnings are disregarded.

Vivant Medical accepts full responsibility for the effects on safety, reliability, and performance of the equipment ONLY if:

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- Re-adjustments, modifications, and/or repairs are carried out exclusively by Vivant Medical
- The electrical installation of the relevant operating room complies with the applicable IEC, CEC, and NEC requirements.

WARNING: Federal law (U.S.A.) restricts this device to use by, or on order of a physician.

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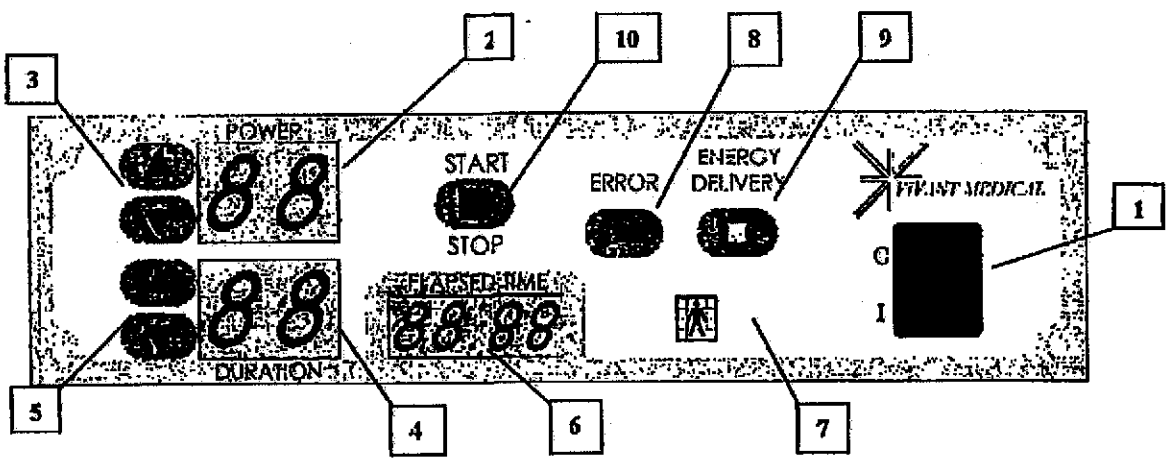
III. PRODUCT DESCRIPTION AND USE

The VivaWave™ Microwave Coagulation System consists of two components—a Generator and a Probe. The Generator is a microwave energy-generating unit, designed to deliver a high frequency output. The Generator supplies energy at 915 MHz to the Probe (via an integrated cable) that directs the energy to the treatment location. Other components of the VivaWave™ System are specifically designed to connect with Generator and are intended to be used together as a single system. This system should only be used as indicated in this manual in Section I.

GENERATOR:

Front Panel:

NOTE: Refer to Appendix A for front panel labeling definitions.



1. ***Mains Power Switch*** – The mains connection to Generator can be turned ON/OFF using this switch. The switch will illuminate when mains power to the unit is turned on.
2. ***Power Level.*** This display shows the set point power-output in watts. The range of power setting is zero (0) to sixty (60) Watts.
3. ***Power level control buttons***: The power level delivered to the Probe is controlled by these two buttons. Output level selected should be as low as possible for the intended purpose and cannot be changed while power is being delivered. To scroll through levels, hold down either the UP or DOWN button until desired level is reached.
4. ***Duration Timer***: This display shows the time setting (in minutes) for the length of energy delivery to antenna. The range of timer setting is zero (0) to thirty (30) minutes.
5. ***Timer Up/Down Control***: The duration of power delivery to the Probe is controlled by these two buttons. The duration selected should be as small as possible for the intended purpose and cannot be changed while power is being delivered. To scroll through levels, hold down either the UP or DOWN button until desired level is reached.
6. ***Elapsed Time / Error Code Display***: This display shows the elapsed time (in minutes and seconds). The four digits signify the number of minutes and seconds that have elapsed from the time when the START/STOP button is turned on. In case of an error, the Elapsed Time display will show the corresponding error code.
7. ***Cable Connector:*** The connector at which the Probe cable is connected.

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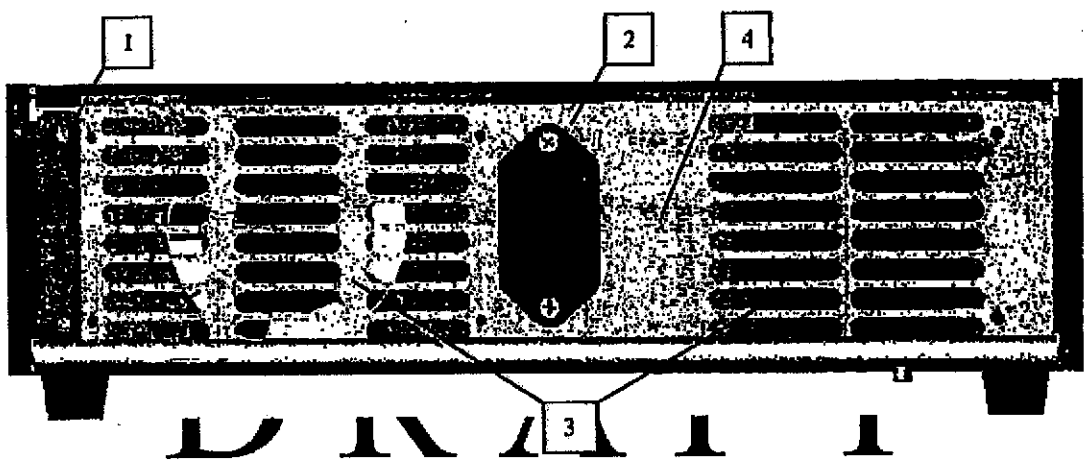
8. ***Error indicator:*** A red indicator is located above the connector. The activated indicator signifies termination of energy delivery due to an error condition (the corresponding code is displayed on the Elapsed Time display, see Section VII).
9. ***Energy Delivery Indicator***: The green indicator is activated while energy is being delivered to Probe due to the START/STOP button being pressed.
10. ***"Start/Stop" button***: This button toggles between delivery and non-delivery of energy. The button causes energy to flow (or cease to flow) to Probe. The elapsed time display is reset and begins tracking time when this button is pressed.

Rear Panel:

NOTE: Refer to Appendix A for rear panel labeling definitions.



1. **Data collection Port – A covered port for manufacturing and test purposes only.**
2. **Power Entry Module – This module has a fuse drawer that contains two fuses.**
3. **Fans – For cooling purposes.**
4. **Label – Position for Generator label.**

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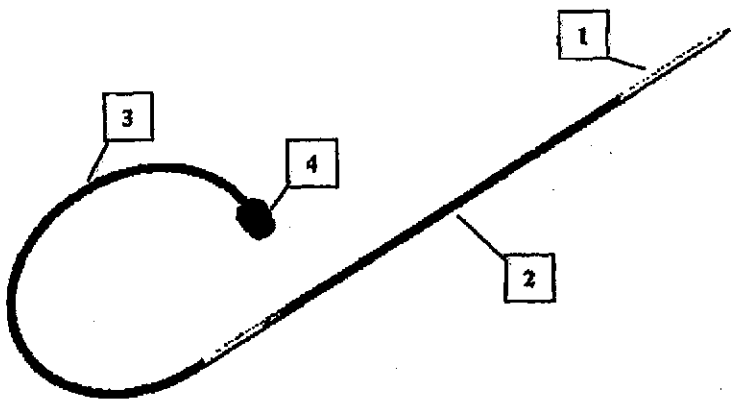
DISPOSABLE PROBES:

NOTE: Probe appearance and functions will vary depending on Probe used.
NOTE: Probe is shipped sterile and is for single use only. Do not attempt to resterilize.



DRAFT

1. Probe Tip – point of delivery of microwave energy used to coagulate tissue.
2. Probe Shaft – insulated
3. Probe Cable – cable that carries microwave energy from Generator to the Probe tip
4. Probe Connector – connects the Probe cable to Generator

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IV. SET UP AND INTERCONNECT SECTION

INITIAL SET-UP OF GENERATOR:

1. Generator should be placed on a cart or on any sturdy table or platform. Refer to hospital procedures or local codes for detailed information.
2. Provide at least four to six inches of space around the sides and top of Generator for convection cooling. It is normal for the top and rear panel to be warm when system is used continuously for extended periods of time.
3. Generator is shipped with an approved hospital grade mains power cord. Plug Generator into a grounded receptacle. DO NOT use extension cords or three-prong to two-prong adapters. The mains power cord assembly should be checked periodically for damaged insulation or connectors.

CONNECTING SYSTEM ACCESSORIES:

GENERATOR

1. Plug power cord into back of Generator.
2. Plug power cord into AC mains.

PROBE

1. Connect the Probe connector to the front panel of Generator.
2. Screw in the connector by hand until it fits snugly into the receptacle on Generator.

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V. INSTRUCTIONS FOR USE

NOTE: Be sure that Generator and all components are properly connected before use.

CAUTION: Improper connection may lead to arcing, sparking or malfunction of the unit, which can result in injury to the patient, user, and/or damage to the system.

NOTE: A sterile Probe should be used for each new procedure. Discard after one use. DO NOT attempt to resterilize.

1. Press the green Generator power switch to the ON position.
2. Be sure that all indicators on the front panel are lit during Generator initialization, and that tone sounds during system self-test.
3. Be sure that Generator and all components are properly connected. After initialization the following are present on the front panel of Generator:
   - Power Level window displays "0"
   - Duration window displays "0"
   - Elapsed time window displays "00:00"

MODES OF OPERATION:

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POWER DELIVERY

1. Power output level can be adjusted by using the Power Level Control buttons (Up/Down arrow buttons) on the front panel of Generator. The maximum power level for Generator is 60 Watts.
2. Duration timer can be adjusted by using the Timer Level Control buttons (Up/Down arrow buttons) on the front panel of Generator. The maximum time duration setting for Generator is 30 minutes.
3. Activation of the energy delivery to the Probe can be achieved by pressing the Start/Stop button on the front panel of Generator.
4. When the Start/Stop button is pressed
   4.1. Elapsed Time display will reset to zero
   4.2. The yellow Energy Delivery indicator will be activated
   4.3. An associated audio signal will sound for the duration of the activation.
   4.4. Power will be delivered to the Probe.
   4.5. Power Level Control Buttons and Timer Control Buttons are disabled
   4.6. Start displaying Elapsed Time in *MM:SS* format.
5. Power delivery to the Probe ends when one of the following situations occur
   5.1. At the completion of time set in the Duration Timer (*i.e.* Elapsed Time = Set Time)
   5.2. If Start/Stop Button is pressed again
6. Upon termination of energy delivery
   6.1. Energy Delivery light turned OFF
   6.2. Audio indicator turned OFF
   6.3. Elapsed Time display stops counting. The display resets on any other button-press

NOTE: The VivaWave™ System contains several safety features. Energy delivery to the Probe will stop if reflected energy exceeds a preset limit or if an error condition is encountered (see Section VII for details).

NOTE: The Power level control buttons and Timer level control buttons on the front panel are disabled during energy delivery.

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CHANGING PROBES DURING PROCEDURE:

NOTE: Be sure that system is not delivering microwave energy while changing Probes.

1. Unscrew the connector at Generator front panel.
2. Properly dispose of the used Probe. Probes are for single use only. DO NOT attempt to reuse.
3. Attach new Probe cable to Generator.

WARNING: Do not insert or withdraw Probe while activated. Injury to patient/operator and/or damage to the equipment may result.

NOTE: If Generator is turned off while Probe is still attached or there is a loss of power to the unit, Generator will automatically return to the default output level "0" when power is restored. Power can be increased/decreased using the level control buttons on Generator.

DURING PROCEDURE:

- To promote patient and user safety, operate the unit at the lowest setting needed for the intended effect.

AFTER PROCEDURE:

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1. Turn off power to Generator using the mains switch on the front panel of Generator.
2. Withdraw Probe from patient. Be sure that Probe is NOT activated during withdrawal.
3. Detach Probe cable from Generator front panel.
4. Unplug Generator from the mains (power outlet).
5. See Section VI for Cleaning and Disposal guidelines.

NOTE: When Probe is disconnected, Generator will not deliver power. Generator can be left in this state between cases, but should be turned off at the end of an operating session.

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VI. CLEANING AND STERILIZATION

GENERATOR

Generator cannot be sterilized. Refer to hospital procedures for proper cleaning of equipment. Use only non-abrasive cleaning agents and DO NOT allow liquid to enter connectors on Generator.

WARNING: Make sure power to Generator is turned OFF before cleaning.

CAUTION: Do not spray or pour cleaners or any other liquids on Generator.

PROBES

Probes are shipped sterile and are intended to be used ONE TIME ONLY. Do not attempt to resterilize or reuse Probes. Dispose of Probes after single use. The cable is a part of the disposable Probe.

EQUIPMENT DISPOSAL GUIDELINES

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- The VivaWave™ Generator contains electronic printed circuit assemblies. Equipment should be disposed of at the end of its useful life in accordance with applicable national or institutional related policies relating to obsolete electronic equipment.
- Dispose of all system accessories according to normal institutional practice relating to potentially contaminated items.

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VII. ERROR CODES & TROUBLESHOOTING GUIDE

If an error condition should occur, the "Elapsed Time" display on the front panel displays an error code and an error beep will sound. The interpretation of the error code, as well as possible causes and solutions are listed in the Table 1.

NOTE: To recover system from recoverable errors, press any button. If errors persist, refer to Solution section in *Table1*. If solutions do not prevent error occurrence, refer to the Service and Claims section of this manual to obtain repair service.

Table 1. Error code interpretation.

RECOVERABLE ERRORS & CORRESPONDING CODES		
Error Code	***Reason for error***	***Solution***
E10	Probe error alarm	• If Probe was activated outside tissue, insert into tissue and then activate • Probe cable may not be properly connected to Generator, reconnect cable or inspect connection • If error persists, replace Probe

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NON-RECOVERABLE ERRORS & CORRESPONDING CODES		
Error Code	***Reason for error***	***Solution***
E30	Switch failure (during Generator initialization)	• Cycle power to the unit (turn unit off and then on)
E40	Overheat	• Cycle power to the unit • If ventilation access to fan is blocked, remove the obstruction or reposition Generator.
E50	Output power error	• Cycle power to the unit (turn unit off and then on)
E60	Hardware shutdown (Switch failure)	• Same as above
E70	Hardware shutdown (5V)	• Same as above
E80	Hardware shutdown (28V)	• Same as above
E90	Hardware shutdown (clock)	• Same as above

NOTE: If non-recoverable errors persist, refer to the Service and Claims section of this manual to obtain repair service.

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VIII. TECHNICAL SPECIFICATIONS

VivaWave™ Generator

Dimensions	13" x 18" x 4" (33cm x 45cm x 10cm)
Weight	15 lb. (7 kg)
Operating Temperature Range	10°C to 40°C
Operating Relative Humidity Range	15% to 80%
Storage/Shipping Temperature Range	0°C to 50°C
Shipping Relative Humidity Range	10% to 85%
Shipped Non-sterile	

Nominal Voltage	115 Volts RMS (60Hz)
Operating Range	90-264 VAC (47-63 Hz)
Power Supply	225W
Inlet Fuses	6.3A, 250V, 5x20mm, UL/CSA
Leakage Currents	Within limits of Class BF equipment as per IEC 60601-1
Continuous Operation	Under maximum power setting and rated load conditions, generator is suitable for continuous operation.

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Output

Frequency	915 MHz ±13 MHz
Waveform	Sinusoid
Maximum Power Output	60 Watts @ 50 ohms
Power increments/decrements	5 Watts
Maximum Duration Setting	30 minutes
Duration increments/decrements	1 minute
Maximum open-circuit voltage	*TO BE PROVIDED*

CLASSIFICATION SPECIFICATIONS

- Class 1, ordinary equipment as per IEC 60601-1
- Type BF
- Liquid Spillage as per IEC 60601-2-2

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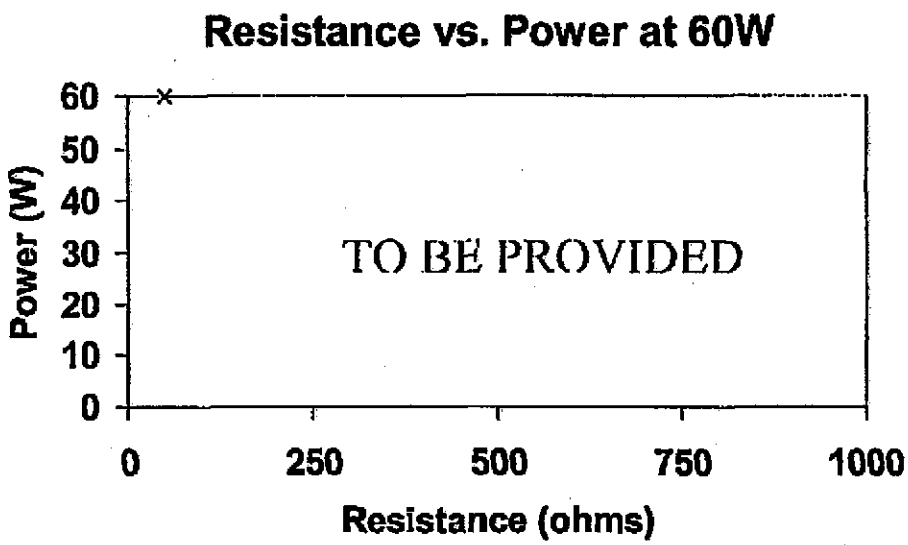

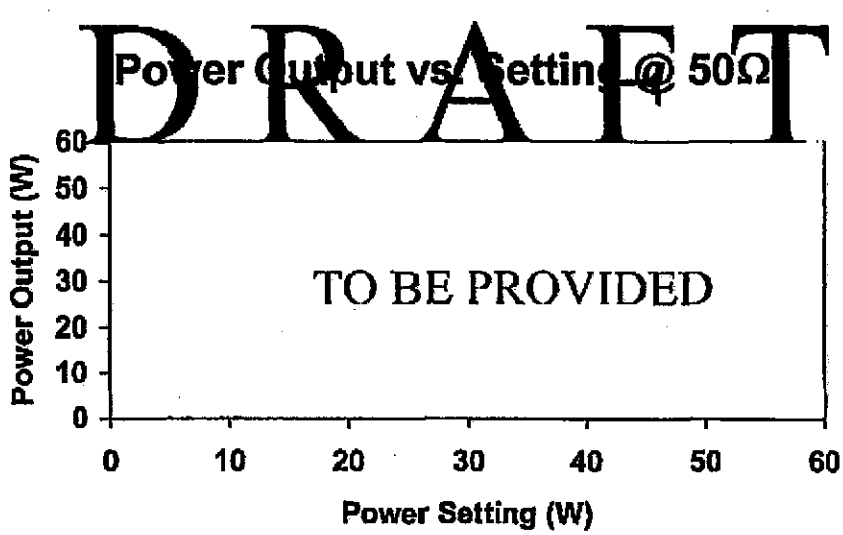

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IX. MAINTENANCE

FUSE REPLACEMENT INSTRUCTIONS:

1. Unplug Generator from electrical outlet and unplug power cord from Generator.
2. Locate Fuse Box on rear panel of Generator.
3. Unlatch fuse holder below the AC Inlet and remove. You may need to press the tab on the fuse holder with a slender screwdriver to release the latch.
4. Replace the fuse with a new fuse of the same value rating.

WARNING: To avoid risk of fire, replace only with a fuse of the value specified on the fuse label on back of Generator.

5. Reinstall the fuse holder until the tab snaps in place.

NOTE: Refer calibration and operating difficulties not detailed in this manual to Vivant Medical Customer Service (1-650-694-2900).

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X. SERVICE AND CLAIMS

SERVICE

If service is needed either during or after the warranty period:

1. Contact Vivant Medical at 1-650-694-2900.
2. Package all the components carefully in the original shipping container if possible.
3. Ship the VivaWave™ System, pre-paid and insured to:

   Vivant Medical Customer Service
   Attention: Repair Department
   1916-A Old Middlefield Way
   Mountain View, CA 94043
   USA

NOTE: The VivaWave™ System described in this manual is constantly being reviewed and improvements may be made without notice.

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XI. WARRANTY

The warranty periods for components of the VivaWave™ System are as follows:

Generator	TBD
Probes	Single Use Only

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APPENDIX A

DESCRIPTION OF LABELING (Generator: Front and Rear Panels)

Alternating Current	~
Attention: consult accompanying documents	
Dangerous Voltage	
Patient Isolated (BF) equipment	
Fuses	2x
Non-Ionizing Radiation	
Power OFF	
Power ON	

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VIVANT MEDICAL
...technology for life
1916 A Old Middlefield Way
Mountain View, CA 94043
TEL: 650-694-2900
FAX: 650-694-2910

VIVAWAVE™ PROBE

REF: MN-X-XX-XXXX

Tip: X cm x Y ga.

Probe Length: Z cm

D R A F T

STERILE | EO

DO NOT RESTERILIZE

MADE IN USA

PATENTS PENDING

CAUTION: Federal law (USA) restricts the sale, distribution and use of this device to, by or on the lawful order of a health care professional

VIVANT MEDICAL, INC.
This package contains (1) VivaWave™ Probe, Y ga.

LOT XXXXXX REF MN-X-XX-XXXX

PN XXX, Rev.draft

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510(k) Premarket Notification Database

Device Classification Name	electrosurgical, cutting & coagulation & accessories
510(k) Number	K984552
Device Name	COOL-TIP RF SYSTEM
Applicant	RADIONICS, INC. 22 terry ave. burlington, MA 01803 2516
Contact	jeffrey r mannion
Regulation Number	878.4400
Classification Product Code	GEI
Date Received	12/22/1998
Decision Date	03/05/1999
Decision	substantially equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Statement only
statement	statement
Type	Traditional
Reviewed by Third Party	No
Expedited Review	No

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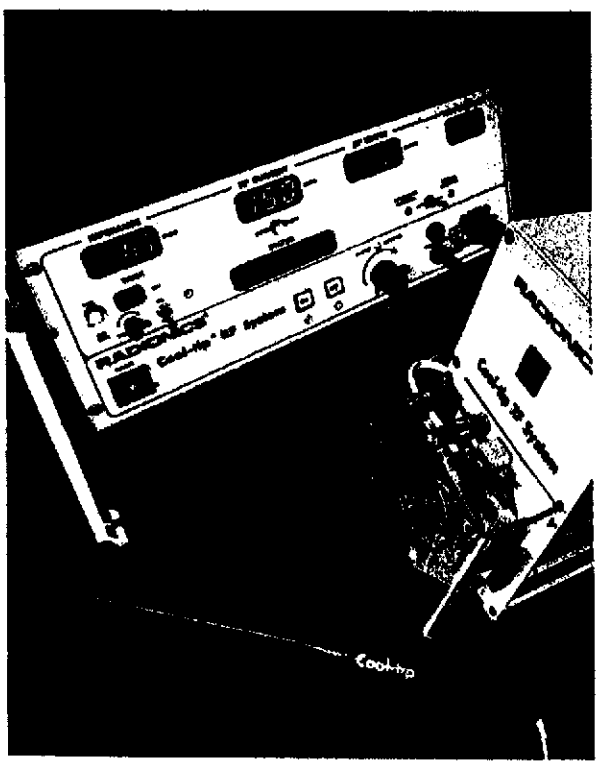
RADIONICS®

Cool-tip® RF System



Operator's Manual

921-68-004 Rev. C

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TITLE AND PUBLICATION NUMBER

Cool-tip® RF System Operator's Manual
921-60-004 Rev. C

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CAUTION

U.S. Federal law restricts this device to sale by or on the order of a physician.

LIMITED WARRANTY

The Seller warrants to the original purchaser of this product that the product substantially conforms to its written specifications current at the date of delivery of such product and shall perform for a period of one year from such date of delivery substantially in accordance with those specifications. The obligations of the Seller and any affiliate of the Seller under this warranty shall be limited to repair or replacement of a non-conforming product, at the option of the Seller. The above warranty is contingent upon use of the product in accordance with its intended use and pursuant to operating instructions contained in the specifications. This warranty does not cover products that have been modified without the Seller's prior approval or which have been subject to unusual physical or electrical stress. EXCEPT AS STATED ABOVE, THERE ARE NO OTHER WARRANTIES. THE SELLER EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, WRITTEN OR ORAL, WITH RESPECT TO PRODUCTS, INCLUDING WITHOUT LIMITATION, IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE AND NON-INFRINGEMENT.

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TRADEMARKS

Cool-tip® RF System is a trademark of Radionics.
Cool-tip® is registered by Radionics.
All trade names referenced are the trademarks, registered trademarks, or products of their respective manufacturers.

CE 0120 Device is compliant with the European Communities Council Directive 93/42/EEC, Medical Device Directive.

MANUFACTURED BY

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	Attention: Refer to Operator's Manual	LOT	Lot Number
REF	Reorder Number / Catalog Number		Non-Sterile
SN	Serial Number		Date of Manufacture

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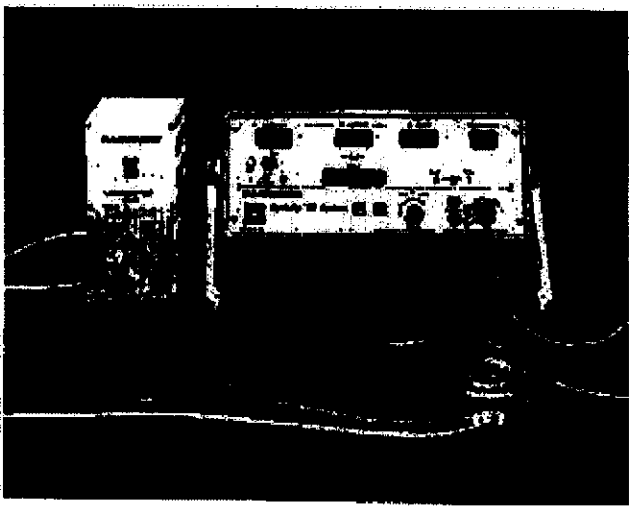
CHAPTER 1 - Cool-tip RF SYSTEM OVERVIEW



Electrical Warnings/Precautions

General Safety Information

Intended Use

Contraindications

Environmental Conditions for Use

Unpacking

Checklist of Components

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cool-tip RF System
Safe and effective coagulation is dependent not only on equipment design, but also on factors under the control of the operator. Do not attempt to operate the Coagulator and/or the Pump prior to completely reading and understanding the directions for use.

Warning:
Electric Shock Hazard
There are no user serviceable parts inside the Cool-tip RF System. To avoid electric shock, return the device to Radionics for servicing.

Warning:
Hazardous Electrical Output
This equipment is intended for use by qualified personnel only.

Do not use within 15 feet (4 meters) of a cardiac pacemaker.

This equipment has an output that is capable of causing a physiological effect.

Risk of Burns and Fire: Do not use near conductive materials such as metal bed parts or inner spring mattresses.

Warning:

Protective Earth Grounding
Reliable grounding can only be achieved when the equipment is plugged into a receptacle marked "Hospital Grade." Any interruption of the Protective Earth conductor will result in a potential shock hazard which could cause injury to patient or operator.

Caution:
If the coagulator is used to deliver ≥50W of RF output and/or sourcing loads of <100Ω, the coagulator should be allowed sufficient time to cool between coagulations. A duty cycle of 30% should be used, with a maximum ON time of twenty minutes.

SYSTEM PUMP

Warning:
Electric Shock Hazard
If the pump becomes wet, either from a leaking tube or liquid being sprayed on it, remove the electrical cord from the main outlet before proceeding to handle the pump.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Warning:
Electric Shock Hazard
If the pump becomes wet, either from a leaking tube or liquid being sprayed on it, remove the electrical cord from the main outlet before proceeding to handle the pump.

Warning:
Electric Shock Hazard
There are no user serviceable parts inside the Perfusion Pump. To avoid electric shock, return the device to Radionics for servicing.

Warning:
This pump is not explosion proof and must not be used in an explosive atmosphere.

Warning:
Potentially hazardous conditions may exist when accessories of similar connector types are combined. Use only Radionics recommended accessories listed in the back of this manual.

GENERAL SAFETY INFORMATION

The Cool-tip RF Generator is a radio frequency coagulator designed to produce local tissue heating at the tip of a electrode by presence of radiofrequency current. The Cool-tip RF System has been designed to comply with the requirements and standards of the international electrical safety codes. Special isolation transformers are imposed between power lines and internal Cool-tip RF Generator circuitry, resulting in very low leakage current.

The Cool-tip Generator meets EN 60 601-1 and EN 60 601-2-2 and is designated Class I Type BF equipment. This means it was designed to be patient connected. The patient applied part is isolated from earth at high frequencies, and has been designed for continuous commercial service (CCS) operation with intermittent loading.

The risk of igniting flammable gases or other materials is inherent in electrosurgery and cannot be eliminated by device design. Precautions must be taken to restrict flammable materials and substances from the electrosurgical site. The use of flammable anesthetics and nitrous oxide and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away or ANESTHETIC-PROOF EQUIPMENT is used. Flammable agents used for cleaning or disinfecting or as solvents of adhesives should be allowed to evaporate before the application of RF surgery. There is a risk of pooling of flammable solutions under the patient and in body cavities. Any fluid pooled in these areas should be removed before the equipment is used. Attention should be called out to the danger of ignition of endogenous gases. Some materials, such as cotton wool and gauze when saturated with oxygen may be ignited by sparks produced in normal use of the device.

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Cool-tip SYSTEM

Warning:
Radionics recommends the use of the Radionics system pump with Radionics electrode and electro-surgical unit within the context of their instructions for use.

When installing the tubing, please note the following:

> **Caution:**
> Make sure to use proper fittings and retaining clamps to avoid disconnection during use.
> Always use a Radionics tubing kit. Always change tubing with every patient use.

Warning:
If RF energy being delivered to the patient is suspected after pressing the OFF button or releasing the footswitch, immediately turn the main Power switch to the Off position and disconnect the electrode from the Coagulator. Do not use the coagulator. Call Radionics for service.

Precaution:
Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the dispersive electrode or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication. Effective contact between the patient and the dispersive electrode must be verified whenever the patient is repositioned after the initial application of the dispersive electrode.

Precaution:
The output power setting should be set as low as possible for the intended purpose.

Precaution:
Electromagnetic interference (EMI) produced by the Coagulator or the Pump during normal operation may adversely affect the performance of other equipment. If this occurs, increase distance between devices and cables. Plug devices into separate branch circuit outlets. Call Radionics for support.

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DISPERSIVE ELECTRODES

Warning:
The use and proper placement of dispersive electrodes is a key element in the safe and effective use of this coagulator, particularly in the prevention of burns. Read and follow the dispersive electrode manufacturer's instructions for preparation, placement, surveillance, removal and use of any dispersive electrode. The use of dispersive electrodes which meet or exceed ANSI/AAMI requirements (HF18) is recommended.

Warning:
A needle electrode should not be used as a dispersive electrode, as it is possible to burn the patient at this site due to high current densities.

Use two dispersive electrodes when using the single Cool-tip electrode, and four dispersive electrodes when using the cluster Cool-tip electrode, to disperse and return RF current over as large an area as possible, and thus minimize heating effects at that electrode. In all applications, care should be taken to maximize the surface area of the dispersive electrode. Each grounding pad should be reliably attached with its entire area to the patient's body and as close to the operating field as possible to avoid high current densities and resultant burns in adjacent tissue. Follow instructions for use that are provided with the grounding pad.

Warning:
Attention should be given to the dispersive electrodes while coagulating for signs of excess heating.

Warning:
Skin-to-skin contact should be avoided to prevent the possibility of accidental burns. It is recommended to place gauze pads in probable skin-to-skin contact sites (e.g., armpits, etc.)

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Cool-tip ELECTRODES

Precaution:
Electrodes and probes of monitoring, stimulating, and imaging devices can provide paths for high frequency currents even if they are battery powered, insulated, or isolated at line frequency. The risk of burns can be reduced, but not eliminated, by placing the electrodes or probes as far away as possible from the coagulation site and from the dispersive electrode. Protective impedance incorporated into the monitoring leads may further reduce the risk of these burns and permit continuous monitoring during energy delivery. Do not use needles as monitoring electrodes during such procedures.

Warning:
Always inspect insulated electrodes and cables for chips or cracks before each use. If an electrode or cable has cracked or scraped insulation, RF current will flow out these cracks, reducing the concentration at the tip. This manifests itself by an inability to get a temperature rise, and abnormally high current and low voltage readings on the meters (similar to a short circuit).

Warning:
Never proceed in a temperature monitored procedure if the generator does not read body temperature with the pump off, before beginning to deliver RF energy for pump applications. Temperature will drop to the approximate temperature of the pump fluid once the pump is enabled.

Warning:
Do not raise the temperature too quickly, particularly with large electrodes, for the displayed temperature lags behind the actual temperature due to the thermal mass of the electrode.

Warning:
To get consistent results in Manual mode, increase the power and temperature at a slow and steady rate so as to prevent temperature overshoots.

Warning:
Verify the functional safety of this device before each use.

Precaution:
Reusable cables and accessories should be function-tested and safety-tested periodically.

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Notice: Always have accessories on hand in case a problem arises with one during a procedure.
Always record all parameters at regular intervals and at key times for a given technique. This gives extra guidance and helps Radionics diagnose any problem that might arise.

Safe and effective coagulation is dependent not only on equipment design, but also on factors under the control of the operator. Do not attempt to operate the Cool-tip RF system prior to completely reading and understanding the directions for use. Please provide this manual to all personnel who will be operating or maintaining this system to ensure that you continue to get the full benefits.

INTENDED USE

The Cool-tip RF system is intended for use in general surgical applications.

CONTRAINDICATIONS

The Cool-tip RF System is contraindicated for use in patients with Implantable Pacemakers and Automatic Implantable Cardioverter/Defibrillators (AICDs), as they maybe adversely affected by radio frequency (RF) current.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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UNPACKING

The Cool-tip Generator and the System Pump come packed in a double walled box with foam surrounding it on all sides. All packing information and manuals are placed in the top portion of the box. This includes the test data sheet and final inspection report. Remove the manuals and shipping paperwork. Put these materials in a safe storage place for later reference. All cables and accessories are packed in a separate box.

CHECKLIST OF COMPONENTS

Description	Catalog Number
Cool-tip RF System (a and b below)	**CTRF-A (117V)** **CTRF-B (230V)**
a) Cool-tip RF Generator	**CC-1-A (117V)** **CC-1-B (230V)**
(2) System Operator's Manual (w/Test Record)	921-60-004
(1) Power Cord (destination dependent)	C119, C118-F, or C120
(1) Adapter Cable (connects electrode to Coagulator)	C123
(2) Spare Fuses	CON-FU-0051 or CON-FU-0050
b) System Pump	**PE-PM-A (117V)** **PE-PM-B (230V)**
(1) Power Cord (destination dependent)	C119, C118F, or C120
Cool-tip electrode Kit – Single Electrode	***PE-D( ) ( )-K**
(2) Disposable Grounding Pads	DGP-HP
(1) Disposable Grounding Pad Extension Cord	DGP-HP-EXT
(1) Disposable Inflow Tubing	PE-IV
(1) Disposable Outflow Tubing	PE-TO
Cool-tip electrode Kit – Cluster Electrode	****PE3-D( ) (2.5)-K**
(4) Disposable Grounding Pads	DGP-HP
(1) Disposable Grounding Pad Extension Cord	DGP-HP-EXT
(1) Disposable Inflow Tubing	PE-IV
(1) Disposable Outflow Tubing	PE-TO
(1) Introducer	PE-IN

* Single electrodes available in 10, 15, 20, and 25 cm lengths with 2 and 3 cm exposures. Example Order: PE-D(10) (3)-K

** Cluster electrodes available in 10, 15, and 20 cm lengths. Ex.: PE3-D(10)(2.5)-K

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Additional Necessary Items Not Included:

Description	Purpose
Chilled Sterile Water	1-3 liter IV bag containing sterile water, chilled in refrigerator.
Container for fluid outflow	Chilled water outflow

SYSTEM DESCRIPTION

The Cool-tip RF Generator is a microprocessor-based coagulator capable of supplying up to 200 watts of radio frequency power in manual mode and 100 watts in constant power, and constant temperature modes. The system continuously monitors impedance, current, power and temperature. The Cool-tip RF system includes a Radionics System Pump that is a peristaltic pump. This type of pump uses rotating rollers that squeeze the tubing and push cooled fluid through the Cool-tip electrode. The Cool-tip electrodes can be used in percutaneous, laparoscopic and open surgical procedures. The Cool-tip electrodes include single electrodes, and cluster electrodes. All electrodes are provided in kits containing grounding pads and a tubing kit. In addition, the cluster electrode kits include an introducer to ease placement of the electrode.

SYSTEM SETUP

After unpacking the **Cool-tip RF Generator** from the shipping box, plug the provided power cord into the rear of the unit. Note the voltage requirement of the unit. Plug the power cord into a hospital grade AC receptacle of the proper voltage.

> **Notice:** The unit may be altered to operate at different voltage settings. The voltage selector insert and its use are described later.

Rotate the handle downward by pressing the buttons on both sides of the unit. The handle locks into a number of different positions, allowing it to be used as an adjustable tilt stand or as a carrying handle.

When powered on, the Cool-tip RF System defaults to thermocouple (TC) temperature monitoring mode. Described for your use are tests that confirm proper operation of the Generator in each mode. These tests serve also as functional tests of each item's circuitry, confirming that the Generator is wired and working properly. Turn to "*Chapter 2 Cool-tip RF Generator*" for a complete description of these tests.

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After unpacking the System Pump from the shipping box, remove packing materials between rollers and shoe. Plug the power cord into the rear of the unit. Note the voltage requirement of the unit. Plug the power cord into a hospital grade AC receptacle of the proper voltage.

Do not adjust the tension arm. This has been properly set at the factory.

Prepare the Cooling Fluid

IMPORTANT: Place the IV bag(s) into a refrigerator the day before or 4 hours prior to the RF session.

Remove bag(s) from the ice bath just prior to the procedure. Fluid should be close to 0°C.

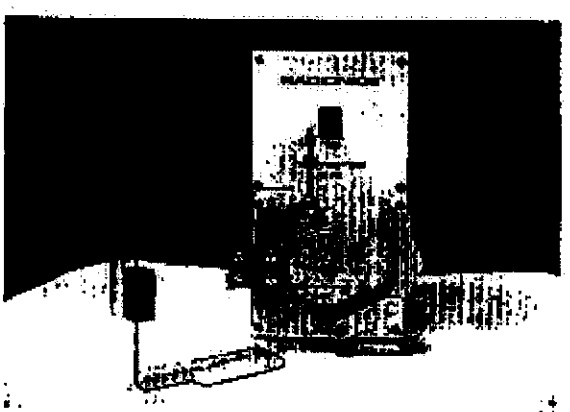
Note: Three liters should be sufficient for two 12-minute treatments (example) since the pump uses approximately 100 ml/min (2.4L). If only one treatment is planned, one 2 liter bag should be sufficient.

Cool-tip Electrode and Tubing Set-Up

Place the grounding pads provided with the kit on a well-vascularized area (use the two grounding pads provided with the single electrode and the four grounding pads provided with the cluster electrode). For all intra-abdominal applications, place all grounding pads horizontally, around thighs, anteriorly and posteriorly after shaving any hair, e.g. both thighs. (See grounding pad insert for further details).

With the Coagulator and the System pump plugged in and turned off, proceed to set-up the perfusion tubing and electrode using the following steps:

1. Suspend the IV bag on IV pole, ensuring that air bubbles rise to the top.
2. Open protective cover and release the pressure shoe.



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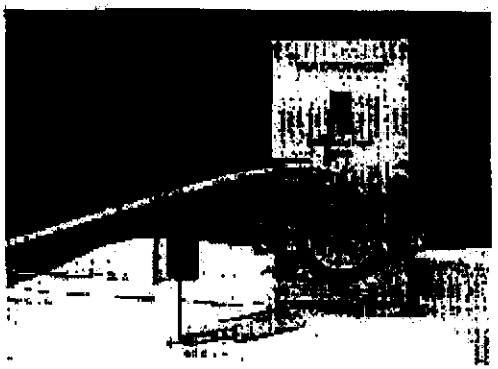
3. Thread Inflow Tubing into Lower Roller Clamp. Keep clear tubing section about 10-15cm from clamp.



4. Wrap tubing around rollers and secure in upper roller clamp. Tubing should be taunt (tight but not stretched).

5. Secure the pressure shoe in place using the shoe latch.

Notice:	The latch is adjusted and set at the factory to provide the recommended pressure on the tubing and therefore does not need further adjustment. Further adjustment may produce improper forces on the tubing, leading to premature wear and poor pump performance.

6. Close cover. (Pump will not operate if the cover is not closed all the way.)

7. Attach Inflow Tubing to IV bag by inserting spike into bag.(Roller clamp can be temporarily closed prior to procedure.)

8. Attach Outflow Tubing set to the outlet irrigation port of the electrode and connect the free end to an outflow container. Insert the IV spike part of the inflow tubing set into the IV bag.

9. Release roller clamp.

10. (See Cool-tip electrode page for comments on tubing attachments to electrode.)

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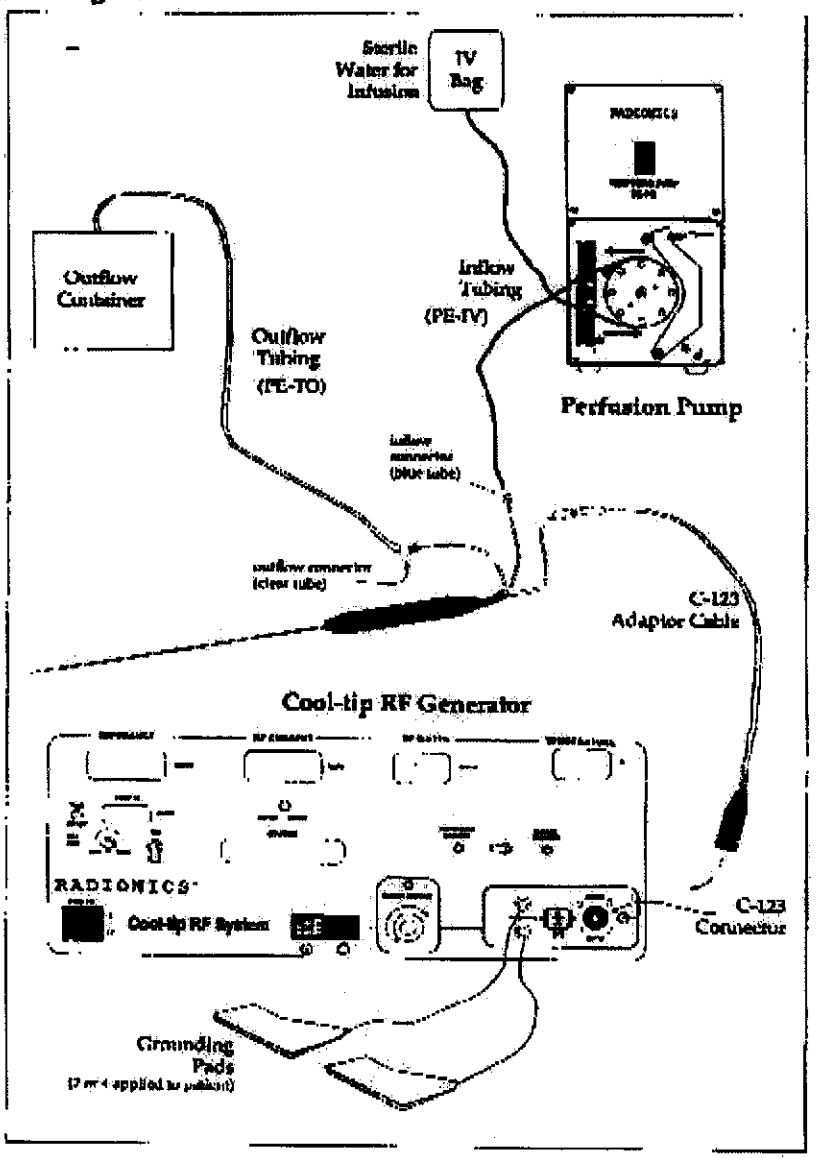
System Connection Diagram



Warning: The Radionics Cool-tip Electrode and Tubing Kit are single use disposable items. Do not sterilize and reuse.

Warning: After the system is completely set up, do not proceed if the Coagulator does not read body temperature before you begin delivering RF energy. Temperature will drop to approximately the temperature of the pump fluid once the pump is engaged.

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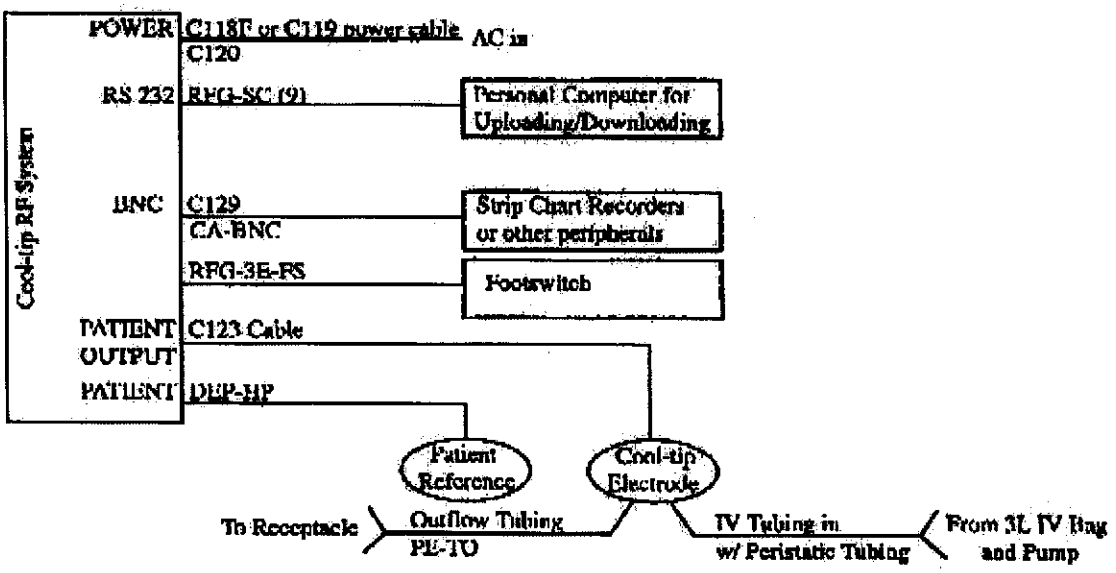
Cool-tip RF System Schematic Diagram



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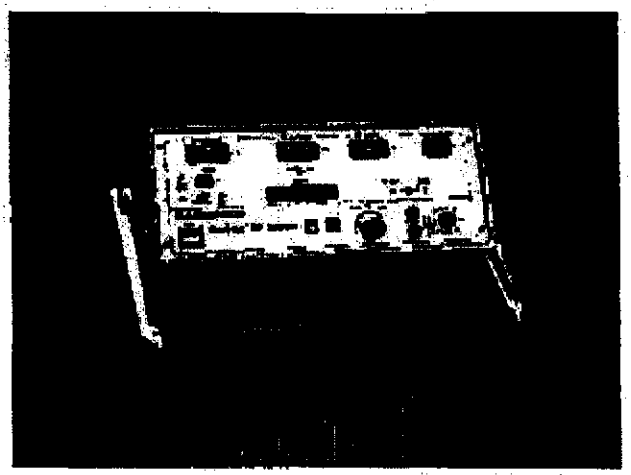
CHAPTER 2 - Cool-tip RF Generator



Description

Testing Procedures

Troubleshooting

Specifications

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DESCRIPTION

The Cool-tip RF Generator is a microprocessor-based coagulator capable of supplying up to 200 watts of radio-frequency power. The system also continuously monitors both the tissue impedance and the temperature at the tip of the electrode. Additionally, there are several built-in features, such as over temperature cut-off and audio tones that indicate impedance and temperature. Finally, a status display window indicates the selected mode and provides other important information (such as open circuit, temperature over boiling, etc.). All of these functions are described in more detail in subsequent chapters.

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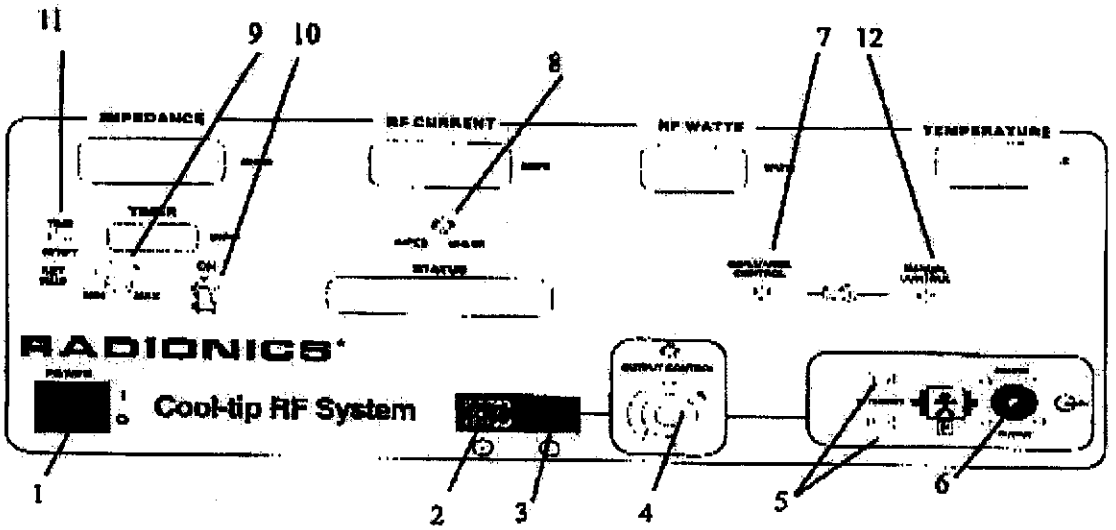

FRONT PANEL		
No.	Feature	Description
1	POWER	System power.
2	ON	Enables RF output.
3	OFF	Disables RF output.
4	OUTPUT CONTROL	For manual control of RF power.
5	REFERENCE JACKS	Attaches to the reference box and dispersive electrodes (Ground pads).
6	PATIENT OUTPUT	Attaches to the C123 adapter cable and Cool-tip electrode. (RF output and temperature sensor signal.)
7	IMPEDANCE CONTROL	Output current regulated by impedance.
8	IMPEDANCE CHECK	Momentary switch. Displays starting impedance for use with RF outputdisabled ("OFF").
9	SET TIMER	Pre-sets a duration time for coagulation.
10	TIMER ON/OFF	Used to enable timer.
11	TIMER RESET	Resets elapsed time.
12	MANUAL CONTROL	Allows manual operation of the system.

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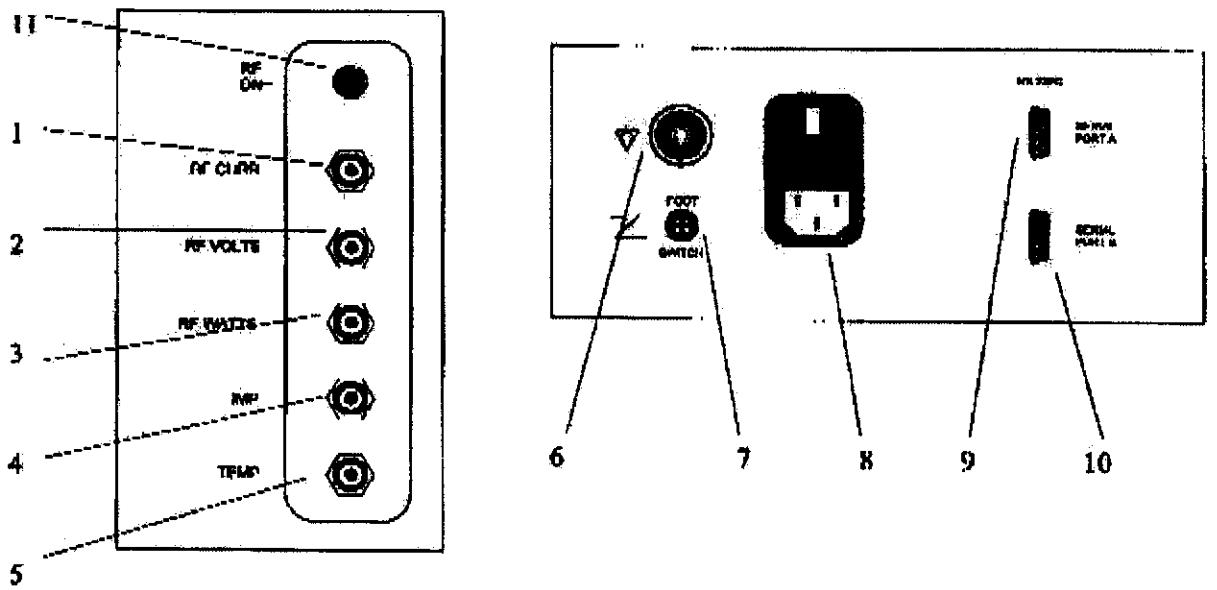

REAR PANEL		
No.	**FeatureDescription**	
1	RF CURRENT	Analog BNC output
2	RF VOLTS	Analog BNC output
3	RF WATTS	Analog BNC output
4	IMPEDENCE	Analog BNC output
5	TEMPERATURE	Analog BNC output
6	GROUNDING POST	Can be used to connect different pieces of equipment together to maintain equal grounding.
7	FOOT SWITCH	Enables and disables RF output.
8	FUSE DRAWER/OUTLET	FUSE DRAWER holds a voltage selector insert and (2) fuses. The window on the fuse drawer will display which voltage selection the Cool-tip RF System is set for.
9	SERIAL PORT	ANot used at this time.
10	SERIAL PORT B	Attaches to a PC to optionally review values and parameters using real- time graphics software.
11	RF ON	TTL signal asserted by ON light

Warning: Risk of fire. Replace fuses as marked.

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The Cool-tip RF Generator is capable of handling input voltage of 100, 120, 220 and 240 volts AC. On the back of the unit is a fuse drawer that holds a voltage selector insert and two fuses. To open the fuse drawer, lift up on the lower tab marked by the indicator arrow. The fuses remain held in the drawer, while the voltage selector can be removed and re-inserted for the proper voltage. The window on the fuse drawer will display which voltage selection the Coagulator is set for.

Caution: Failure to correctly set a voltage may permanently damage the unit.

Caution: If the voltage selection is changed, the fuses must also be changed to the value that corresponds to the voltage selected (see information on back panel).

DISPLAY FEATURES

IMPEDANCE

The Cool-tip RF Generator continuously measures IMPEDANCE between the electrode tip and the dispersive electrode when in ON mode. The Coagulator has an integral Differential Impedance CUTOUT which is set to 1000 Ohms. The Cool-tip RF System turns off the RF power whenever the currently measured impedance increases from the baseline impedance by 1000 Ohms. (Baseline impedance is the minimum impedance recorded during the RF power delivery.) In this way, the impedance is tracked so that the impedance rise allowed before cutoff is constant, independent of the current impedance reading. If the impedance decreases as the coagulation continues, then the cutoff level decreases a corresponding amount, thus making the cutoff a true differential impedance cutoff.

The Coagulator also has an Impedance CUTOUT (absolute) which is set to 25 Ohms.

There is also an impedance check button located below the RF CURRENT window. This is a momentary button that, when pressed, shows the patient's starting impedance before delivering RF energy.

Notice The ON button lights during the impedance check. This is because a small voltage is applied to allow measurement of impedance. The status display indicates if in Test mode.

RF CURRENT

The Cool-tip RF Generator continuously measures and displays RF CURRENT when in On mode. Current is displayed in Amps.

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RF WATTS

The RF Watts display shows how many Watts* the system is outputting through the attached electrode, or in test mode, to the internal test load. In Manual mode, watts are set with the Output Control knob. As the output is increased (achieved by turning the output control knob in a clockwise direction), the watts reading increases. Turning the output control knob fully clockwise in Manual mode will output roughly 200 watts into a 50 Ohm load. This is the maximum power available in Manual mode.

* Displayed Watts is the product of RMS Current and RMS Voltage over a short time interval. This is valid for resistive loads, such as human tissue.

The temperature sensor can also be monitored in the temperature window and, if desired, the timer can be used to limit the amount of time of energy delivery. If a temperature sensor is not connected, the temperature will be blank in constant power mode.

TEMPERATURE

The temperature sensor can also be monitored in the temperature window. If a temperature sensor is not connected, the temperature will be blank.
"LL" indicates a temperature <10°C
"HH" indicates a temperature >99°C

Notice: Maximum output power will vary with mains voltage ±20% and is calibrated at a nominal line voltage, which is printed on the back of the generator.

CONTROL FEATURES

TIMER

The TIMER section on the front panel of the Cool-tip RF System allows the user to set a duration time for coagulation. To set the timer, move the time toggle switch to ON and use the SET TIME knob to set the duration time for coagulation. To use the unit without this timing feature, set the toggle switch to the OFF position.

If activated, the timer increments from zero in one second intervals once the delivery of RF energy begins with either the On button or the footswitch. When the timer reaches its preset time the unit shuts off and the Status Display reads "Complete." If the OFF button, or Off function of the foot pedal is selected before the timed duration is complete, the timer freezes at the time the unit was stopped and the status window reports that the delivery of RF energy was interrupted. Press the time reset button to acknowledge the system message.

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The timer may be enabled (turned on) or disabled (turned off) at any time during energy delivery.

The time RESET button is found in the TIMER section. This button sets the timer back to zero (if the timer is running), thus allowing longer energy delivery. When the timer is not running, pressing this button releases the time out number in the time display and allows another SET TIME to be dialed in. This button is also used to acknowledge error messages in the status window.

The status window is next to the TIMER section. This alphanumeric display provides the user with status and error messages, as well as instructions.

IMPEDANCE CONTROL MODE

When operated in the Impedance Control Mode, the Coagulator automatically monitors rises in impedance and adjusts RF output accordingly. When the system detects a rise in impedance, the output is cut back from maximum output to .10A for a period of 15 seconds. The output is then increased and decreased in this fashion for a number of cycles throughout the duration of treatment. The maximum output is gradually decreased with each cycle until the impedance does not rise for a period of 10 seconds. The resultant pulsing effect reduces the impedance rises that would normally limit the RF output power. By operating at intervals of low output and high output, the local tissue is allowed to partially cool. Consequently, the tissue is able to accept greater energy.

Use the following steps to operate Impedance Control Mode:

Start-Up Sequence

1. Place the mode switch into Impedance Control Mode
2. Set the Timer switch to "ON"
3. **Ensure that the RF Output Control is set to Min.**
4. Press the "ON" button
5. Gradually increase the RF Output Control to Maximum.

Note: If the *Start-Up* sequence is not followed, the Impedance Control function will not become active.

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MANUAL CONTROL MODE

The Manual Mode allows the operator to monitor impedance rises and adjust RF output. The RF output can be adjusted based on the clinical objectives. In order to operate the system in the manual mode, use the following sequence of steps:

1. Ensure that the mode switch is in the Manual Control position
2. Set the Timer to "OFF"
3. **Ensure that the RF Output Control is set to Min.**
4. Press the "ON" button
5. If you wish to use the Timer, set the Timer switch to "ON"
6. Gradually increase the RF Output Control to the desired level

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OUTPUT CONNECTIONS

Patient Connections

Type BF Defibrillator Protected

F High Frequency Leakage Current Isolated

Patient connections are made via the output jacks in the lower right hand corner of the front panel. The PATIENT OUTPUT is used to deliver RF through the electrode. It is also the input from the temperature sensor. There are two reference jacks that accept reference electrode cables from dispersive pad. Radionics recommends the use of two dispersive pads when using a single Cool-tip electrode and 4 dispersive pads when using a cluster Cool-tip electrode. The dispersive electrodes attach to a reference jack using the grounding pad extension cable (provided in the electrode kits). The C123 adapter cable attaches the Cool-tip electrode to the PATIENT OUTPUT.

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141 201

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TESTING PROCEDURE

Manual Mode Test

Note: For this test, connect the foot switch to the rear panel. No other cables should be connected to the Coagulator.

1. Confirm that the Mode toggle switch is in Manual Control Mode. **This is very important.** If this is not done, the unit will display an error message instructing you to place this switch in the start-up position.

2. Press the green POWER switch to "|" position.

3. The Cool-tip RF Generator will run an internal self-test of RAM and ROM, displaying the results on the status display.

4. The system tests the displays (Note: This is a visual display. The user must observe the unit's ability to display all numbers).

5. Next, the system tests the Impedance measurement and RF circuitry, displaying the results in the Impedance Window in status display.

6. Finally, the unit performs a Temperature Test of 40 degrees and then 90 degrees. After a short delay for internal testing, the status window displays the following messages ending with "Generator Ready - TC Manual Mode."

Notice:	If the temperature exceeds 99° C, the display reads **HH**, and the status window reads **Temp over Boiling**. The system will automatically shut off.

If any questions arise during this test procedure, call Radionics Technical Support at (781) 272-1233.

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TROUBLESHOOTING

The following table lists common problems and possible causes for service.

PROBLEM	POSSIBLE CAUSES
Unit will not turn on	No power at wall receptacle Defective power cord Blown fuses
No output	Unit in TEST MODE No reference electrode connection Improper cabling
No Impedance readings	Unit OFF Improper cabling
RF will not turn on	Output control not at minimum Output level (Manual mode) Time set to zero and timer on Impedance too high (cutoff)

Please check the items on this list prior to contacting Radionics for service.

If you are unable to resolve any problem, please contact Radionics Technical Support at (781) 272-1233.

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EXPLANATION OF SYMBOLS

	Type BF degree of protection against electric shock, defibrilla tor protected.
F	Floating Return (high frequency)
CAUTION	No user-serviceable parts inside
I O	ON/OFF (for a mains switch).
	Timer (lesion mode).
	Volume control (knob).
	Footswitch input jack.
	Signal Output DC volts.
	Signal Input/output port.
	Print
	Warning: Replace Fuses as marked
	Warning: Consult Operator's Manual.
	RS232 Port.
	Equal potential jack terminal.
	ON/OFF (for mode).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cool-tip RF GENERATOR SPECIFICATIONS

Electrical Supply

Volts:	100/120/220/240 VAC
Volts input range:	90-110/105-125/200-240/220-260 V
Maximum input voltage:	260 Vac
Maximum voltage on any output connector:	260 Vac Maximum input power:420VA

Maximum supply current:

4.0 AMP ~ alternating current sinusoidal wave (100/120vunits)
2.0 AMP ~ alternating current sinusoidal wave (220/240vunits)

Fusing:	T 4.0 A/250V(100/120 V units) Domestic
	T 2.0 A/250V (220/240 V units) Foreign
Frequency:	50/60 Hz Must be specified at time of purchase

Impedance Monitor

Range:		0-1000 Ohms
Resolution:		1 ohm
Accuracy:		
	50 - 500 Ohms	±10% or ±10 ohms of reading
	500 -1000 Ohms	±20% of reading

Output

Timing:	Selectable:	0-990 seconds in ten second intervals
	Accuracy:	±1 second
	Resolution:	1 second
Watts:	Manual Mode:	0-200 watts Max output @ 50 Ohms Load
	Automatic Temperature and Power Modes:	0-100 watts Max output @ 100 Ohms Load
	Test Mode:	50 watts Max
	Accuracy:	±15% or +2W, whichever is greater
	Resolution:	1 watt
Frequency:	480 kHz ± 10%	

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Temperature Monitor

TC and TM

Range: 10° C - 99° C

Resolution: 1° C

Accuracy: ±1° C

Chart Recorder Output Jacks (BNCs on Back Panel)

RF Current: 0-1000 RF mA 0-1 Vdc +/-10%

RF Volts: 0-100 RF volts 0-1 VDC +/-10%

RF Watts: 0-100 RF watts 0-1 VDC +/-10%

Impedance: 0-1000 ohm 0-1 VDC +/-10%

Temperature: 0-100° C 0-1 VDC +/-10%

Notice:	The previous voltages are nominal since exact calibration is achieved by adjusting the offset and gain controls on the recording device to which this is connected.

RF ON Output

3.5 mm Phono Jack: 0-5V DC ±10%

RS-232C Serial Output Ports

Port A: Not used at this time.

Port B: Serial Data Out supports Real Time Graphics Display, +9V signal levels.

Storage Environment

Clean, dry area 15-40° C15-80% Non-condensing relative humidity
700 KPA-1600 KPA Atmospheric pressure

Operating Environment

Same as storage environment.

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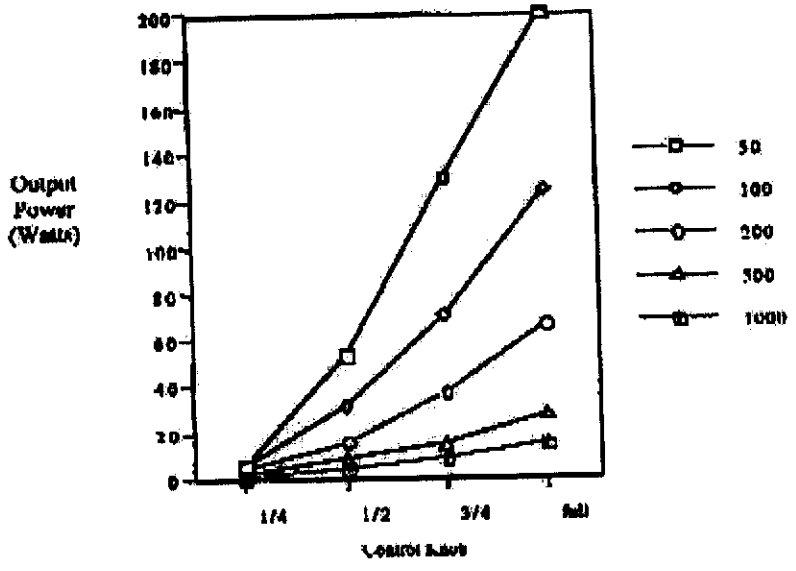
COAGULATOR OUTPUT POWER CHARACTERIZATION

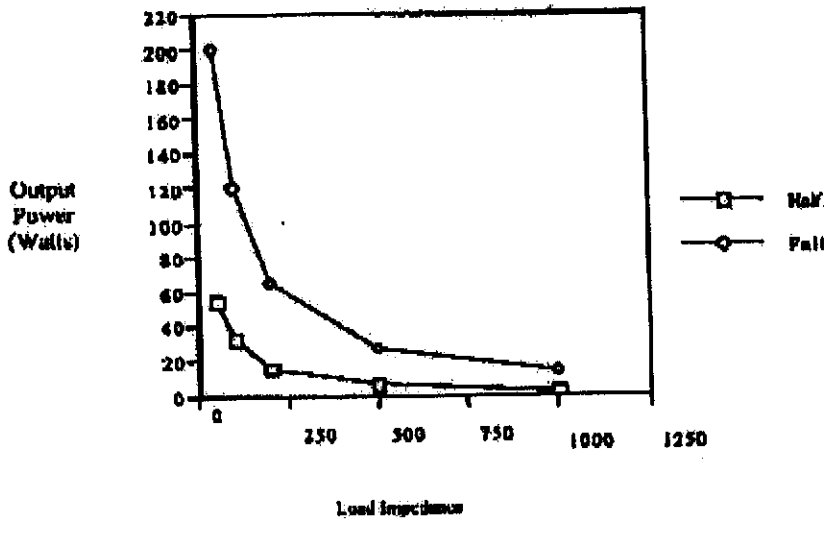
Output Power vs Control Knob Setting



NOTE: Output automatically disables impedances > 1000 Ohms

COAGULATOR OUTPUT POWER CHARACTERIZATION

Output Power at full and half settings · output load range from 50-1000 Ohms



NOTE: Output automatically disables impedances > 1000 Ohms

28 *Cool-Up RF System 971-00-004*

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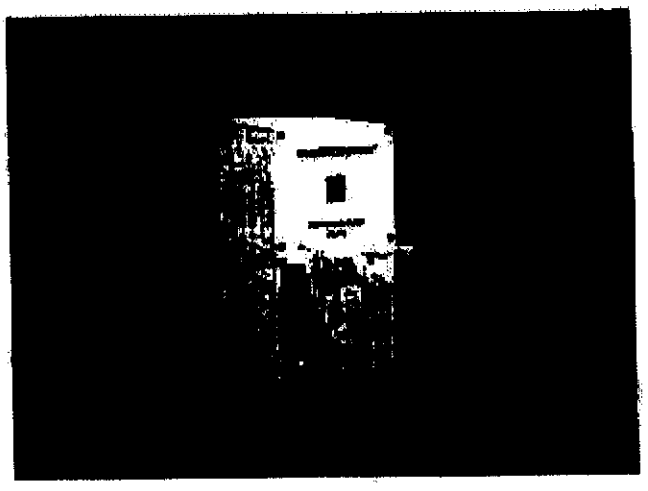
CHAPTER 3 - SYSTEM PUMP



Description

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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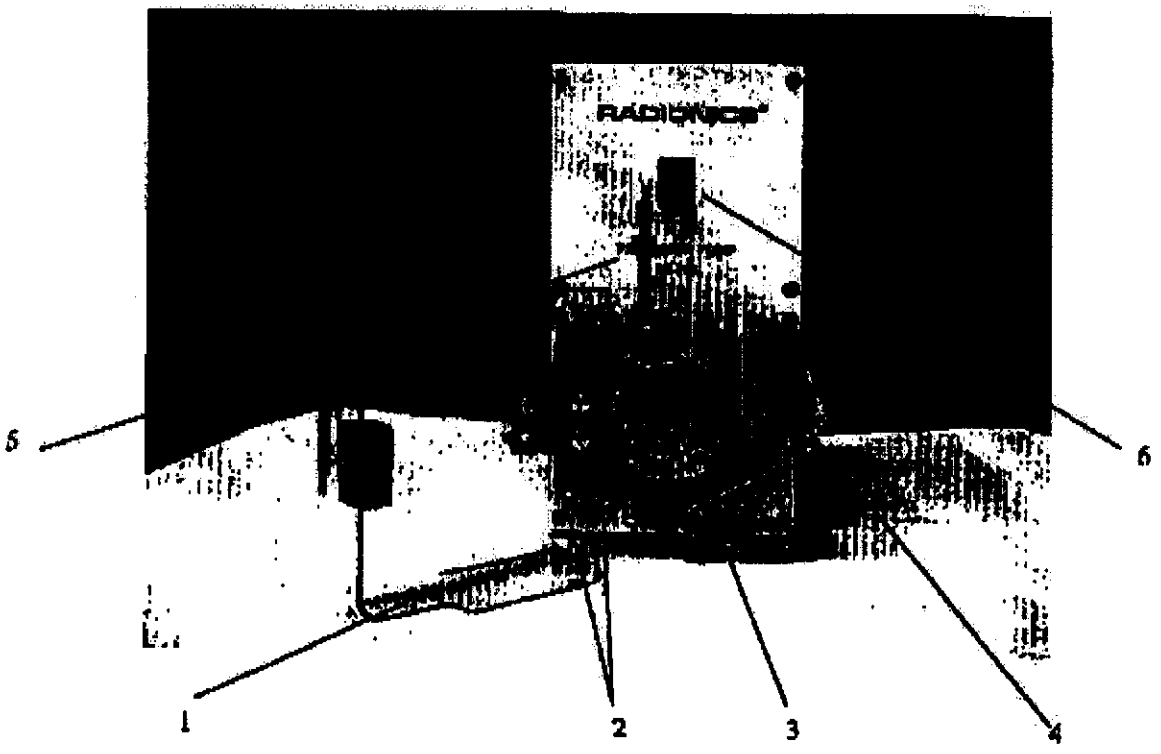

PERFUSION PUMP		
No.	Feature	Description
1	PUMP HEAD SAFETY COVER	Protects moving parts during pump operation. Protects operator.
2	ROLLER (BLACK) CLAMPS	Spring loaded clamps that keep tubing in position
3	PUMP ROLLERS	Rotate to compress tubing, pushing fluid forward
4	PRESSURE SHOE	Maintains contact between tubing and rollers
5	PRESSURE SHOE LATCH	Secures the pressure shoe. Adjusted and set in factory.
6	ON/OFF SWITCH	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SYSTEM PUMP SPECIFICATIONS

Electrical Supply

Input Voltage:	115 / 230 V Specified at time of purchase (internally wired).
Voltage Range:	± 10% of rated voltage
Input current:	100 mA Max.
Fusing (2):	175 mA Time Lag
Frequency:	50 / 60 Hz

Flow Rate (using Radionics Disposable Tubing Kit # PE-TO, PE-IV)

Maximum output flow rate:	140 mL/Min.
Minimum output flow rate:	80 mL/Min. through 1.6 mm (I.D.) tubing.

Operating, Storage and Transport Environment

Temperature	15° C -40° C
Humidity	15 - 80% relative non-condensing
Atmospheric pressure	700 - 1060 KPa

The pump may be used within the following environmental conditions:

- Indoor use

- Maximum relative humidity 80% for temperatures up to 31 degrees Celsius, and a linear decrease to 50% relative humidity at 40 degrees

- Mains supply voltage fluctuations not to exceed ±10% of the nominal voltage

- Transient over-voltages according to installation category 2

- Pollution degree 2 in accordance with IEC 664

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CHAPTER 4 - Cool-tip ELECTRODE KITS

Description

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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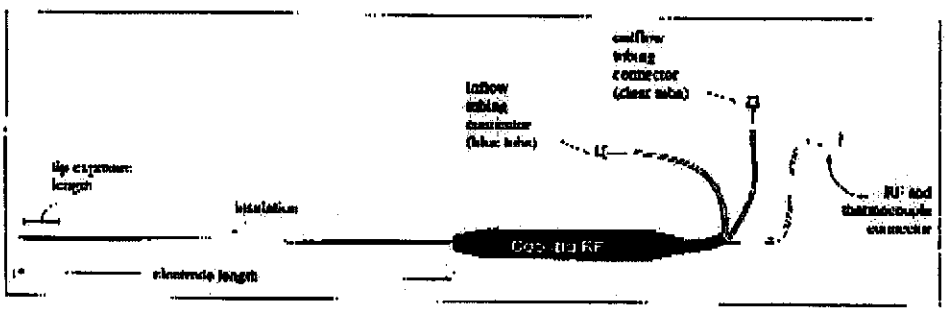
DESCRIPTION

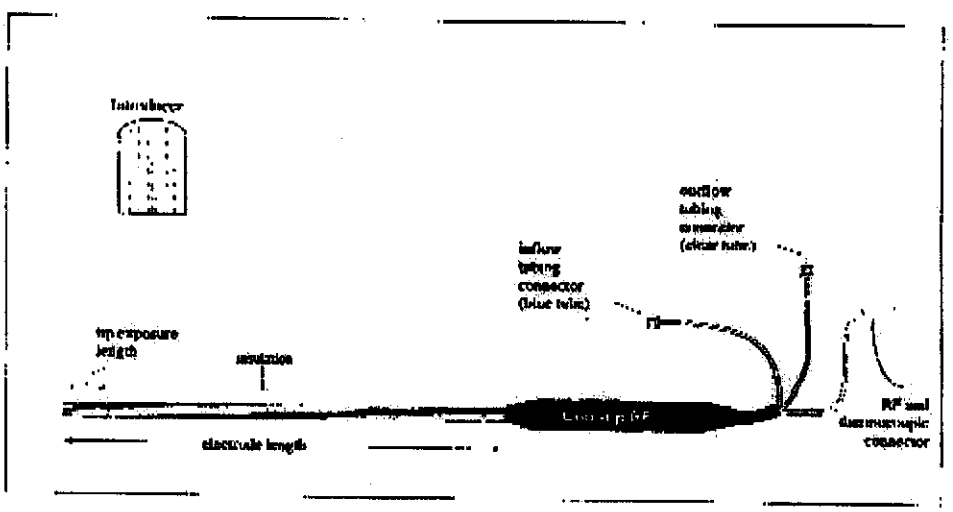
The Radionics Cool-tip RF electrodes are designed to be used in percutaneous, laparoscopic, and open surgical procedures. The Cool-tip electrodes include single and cluster electrodes.

RF energy is transmitted outward along the entire length of the exposed tip. The shape of the resulting lesion is roughly spherical. **Ensure that the exposed tip is centered in the intended target site.**

SINGLE COOL-TIP RF ELECTRODE



CLUSTER COOL-TIP RF ELECTRODE



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CHAPTER 5 – TECHNICAL REFERENCE

Device Classification

Electrical Safety and EMC

Sterilization

Cleaning

Maintenance and Service

Warranty

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEVICE CLASSIFICATION

Classifications as per IEC 601-1/1988, the manufacturer describes the Cool-tip RF Generator and the System Pump as:

Type of protection against Electric Shock:	Class I
Degree of protection against Electric Shock:	Type BF Defibrillator
Degree of harmful ingress of water:	IPX Ø (ordinary)
Mode of Operation:	Continuous use with Intermittent Loading
Degree of Safety in the Presence of Flammable Anesthetic Mixture with Air, Oxygen or Nitrous Oxide:	Not suitable for use

ELECTRICAL SAFETY AND EMC

The Radionics Cool-tip RF Generator has been tested to and meets the requirements of the following Electrical Safety Standards:

EN 60601-1 Medical Electrical Equipment (1988)
EN 60601-2-2 Particular Requirements for the Safety of High Frequency Surgical Equipment (1992)
UL 2601 Medical Electrical Equipment (1994)

The Radionics Cool-tip RF Generator has been tested to and meets the requirements of the following EMC Standards:

EN 60601-1-2 Collateral Standards: Electromagnetic Compatibility (1993)

The following standards being applied include:

EN 55011 Group 1, Class A, ISM
EN 61000-4-2, 1000-4-3, 1000-4-4, 1000-4-5

The Radionics System Pump has been tested to and meets the requirements of the following Electrical Safety Standards :

EN60601-1 Medical Electrical Equipment (1988) Requirement for safety.
UL 2601 Medical Electrical Equipment (1994) Requirement for safety.
UL 22.2#601-1M90 Medical Electrical Equipment

The Radionics System Pump has been tested to and meets the requirements of the following EMC Standards:

EN60601-1-2 Collateral Standards: Electromagnetic Compatibility (1993)
The following standards being applied include:
EN 55011 Class 1, Group A, ISM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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STERILIZATION

Caution: Do not sterilize the Cool-tip RF Generator or the System Pump. Sterilization will destroy the unit's electronic components.

Refer to the manufacturer's instructions for use for the sterilization of applied parts connected to this device.

CLEANING AND DISINFECTION

The Cool-tip RF Generator and the System Pump may be cleaned with mild cleaning solutions such as 70% Isopropyl alcohol. Care should be taken to keep moisture out of the connectors. Store both units and accessories in a clean, dry and non-corrosive atmosphere. The Coagulator and the Pump are designed to withstand all normally encountered environmental conditions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MAINTENANCE AND SERVICE

The Cool-tip RF Generator and System Pump are not user serviceable, and both units should be returned to Radionics if any problems arise. Please call your local Radionics representative for support. To ensure accuracy of unit output and displays, the unit must be returned to Radionics every year for calibration.

The Coagulator and Pump are designed to be durable medical equipment. Physical impact, however, such as dropping the unit, may result in damage to the coagulator and subsequent injury to the patient or operator. If the Coagulator or Pump is subjected to impact, discontinue use and immediately return the coagulator to Radionics for evaluation.

The pump itself does not need any regular service or lubrication.

You must replace the tubing with each patient use.

Caution:	Remove the tubing after each use to minimize risks, and to prevent contamination.

WARRANTY

The Cool-tip RF Generator and the System Pump are sold with a one year, limited warranty starting at the delivery date. It is the customers' responsibility to pay for the transportation back to the factory. Please contact Radionics to get a "Return authorization number." Please include the serial numbers on any correspondence.

The warranty is only valid for production errors, and does not cover faults caused by misuse or failure to follow the manual. Unauthorized repair also makes the warranty invalid. Secondary failures can not be considered as basis for a claim in any case.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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APPENDIX

Serial Ports

Patient Outputs

Accessories

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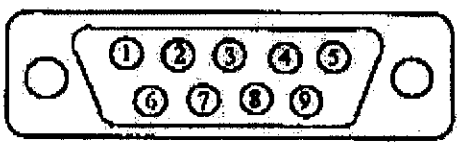
SERIAL PORTS

Serial Port A

Not supported at this time.



2 TXD
3 RXD
4 DTR
5 SG
All other pins N/C

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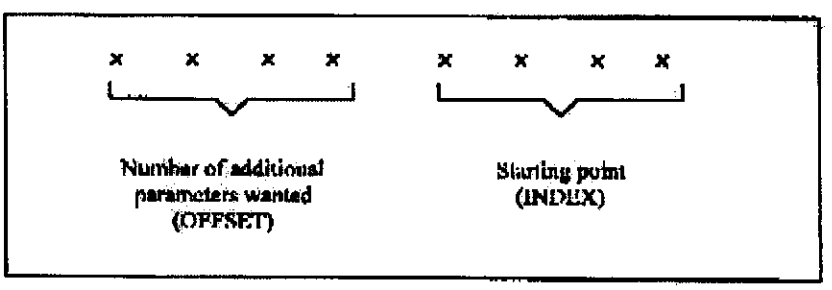
Serial Port B

Serial port B outputs watts, temperature, and power information that can be used by an intelligent peripheral device.

Used As	RS-232 Port B 9-Pin Female	Cable 9-Pin Male/ 9-Pin Female	Laptop Computer Port 9-Pin Male
		1 —— 1	1 CD
Out	TX1 2	2 —— 2	2 RXD
In	RX1 3	3 —— 3	3 TXD
In	DTR 4	4 —— 4	4 DTR
	ADGND 5	5 —— 5	5 SG
		6 —— 6	6 DSR
		7 —— 7	7 RQS
		8 —— 8	8 CTS
		9 9	9 RI
		Shell —— Shell	Shell GND

The Cool-tip RF System Port B is configured for 9600 baud, no parity, 8 data bits, one stop-bit. It is configured to wait for a one byte (8 bits) word from an external device in the following format:



This byte specifies the start address and number of parameters after the start address to read. The Cool-tip RF System will then transmit the requested information. After the last byte has been sent, the port will remain idle until a new request is sent from the external device.

Valid starting point: 0000 to1000 (9 addresses)
Valid offset: 0000 to 1000(9 items)

Each item returned is two bytes long.

Warning:	When connecting any non-medical peripheral equipment to this device, it must be ensured that the equipment combination meets the requirements of IEC 601-1-1.

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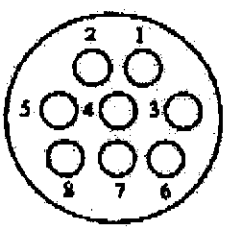
Index Address	
0000 - Temp	approx. 239 counts per degree C
0001 - Watts	approx. 320 counts per watts
0010 - A/D Impedance	approx. 32 counts per ohm
0011 - Knob position	approx. 370 counts per degree of rotation
0100 - AOC set	approx. 64 counts per ohm
0101 -CPM/CTM set	approx. 512counts per watt/degree C
0110 - Current	approx. 31 counts per mA
0111 - Timer set	approx. 64 counts per second
1000 - Volts	approx. 523 counts per volt

PATIENT OUTPUT

The PATIENT OUTPUT is an AMP CPC Series #2 connector that has the following pin-outs.



1 = Active
2 = TM
5 = TC Cu
6 = TC Co
8 = TM
All other pins N/C

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ACCESSORIES

REF	Description
RFG-3E-FS	**Footswitch:** allows remote/hands off operation of ON/OFF functions
C118-F	**Power Cord, Plugless**
C119	**Power Cord,** 117V Hospital Grade
C120	**Power Cord,** European
C123	**Cool-tip RF electrode Adapter Cable**
C126-C	**Control Cable:** Allows the coagulator to control an external switching device.
C129	**Chart Recorder Cable,** 5 coaxial
RFG-SC(9)	**9 Pin Serial Cable:** Used for gathering serial data from the coagulator onto a laptop computer.
CA-BNC	**Connector Adaptor,** BNC/Dual Banana
DGP-HP-EXT	**Dispersive Pad Extension Cable**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Premarket Notification Database

Device Classification Name	system, ablation, microwave and accessories
510(k) Number	K052919
Device Name	MICROSULIS TISSUE ABLATION SYSTEM
Applicant	MICROSULIS AMERICAS, INC. 275 wyman street,suite 12 waltham, MA 02451
Contact	timothy y cowart
Regulation Number	878.4400
Classification Product Code	NEY
Date Received	10/21/2005
Decision Date	01/13/2006
Decision	substantially equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Summary only
summary	summary
Type	Traditional
Reviewed by Third Party	No
Expedited Review	No

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT G

STERILIZATION INFORMATION

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Sterilization Cycle Parameters

Prehumidification cycle:

Temperature: 52.0°C
Vacuum: 1.30 psia
Humidity Set Point: 2.39 psia
Humidity: 55%
Time: 60 min

EO Exposure Cycle:

Gas Type: 100% EO
Temperature: 52.0°C
Humidity 55%
Gas Pressure: 8.18 psia
Gas Concentration 650 mg/L
Time: 300 min (half cycle) + 600 min (full cycle)
Note: once the 300 min half cycle was complete, the 600 minute full cycle was started. After the 600 minute full cycle was completed, the products were placed in the degassing cycle.

Degassing Cycle:

Temperature: 55 ± 4°C
Time: 24 hours minimum

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DET NORSKE VERITAS

MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 2004-OSL-AQ-0176

This is to certify that

THE QUALITY MANAGEMENT SYSTEM

of

Sterigenics

at

4900 Gifford Avenue, Los Angeles, CA 90058 USA
687 S. Wanamaker Avenue, Ontario, CA 91761 USA
2973 Olympic Industrial Blvd., Smyrna, GA 30080 USA
10821 Withers Cove Park Drive, Charlotte, NC 28278 USA
5725 W. Harold Gatty Drive, Salt Lake City, UT 84116 USA
2400 Airport Road, Santa Teresa, NM 88008 USA
84 Park Road, Queensbury, NY 12804 USA
1302 Avenue T, Grand Prairie, 75050 USA
7775 South Quincy Street, Willowbrook, IL 60521 USA
781 Pharmacy Avenue, Toronto, Ontario M1L3K2 Canada
James Watt No. 22, Zona Industrial Cuamatla, Cuatitlan Izcalli Estado De Mexico, C.P. 54730
Calle Norte 7 s/n, Parque Industrial Tepeji, Tepeji del Rio de O., Hidalgo. Mexico 42850

has been found to conform to the Quality Management System Standard

ISO 13485 : 2003

This Certificate is valid for the following product or service ranges:

The provision of Ethylene Oxide and Radiation Sterilization Services in accordance with EN 550, ISO 11135, EN 552 and ISO 11137.
(Excluding Clause 7.3: Design and Development)

Original certificate valid from
2004-10-04

This Certificate with Appendix is valid until
2007-10-04

Joseph T. Bosler
Lead Auditor

NORWEGIAN ACCREDITATION

QUAL 002

Place and date
Høvik, 2004-12-17

For the accredited unit
Det Norske Veritas Certification AS

Eugenie Winger Husebye
Management Representative

Lack of fulfilment of conditions as set out in the Appendix may render this Certificate invalid.

DET NORSKE VERITAS REGION NORGE AS, Veritasveien 1, N-1322 Høvik. Tel.: +47 67 57 99 00. Fax +47 67 57 99 11
AQV-21dk 13.11.2000

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT H

BIOCOMPATIBILITY INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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List of Contents in Attachment H:

1. **Certificates of Compliance for UV cured adhesives used**
2. **Internet article sighting use of ABS used**
3. **510(k) Summary of Safety and Effectiveness of Biolox Alumina Ceramic Femoral Head device**
4. **Bayer MaterialScience catalog of medical grade materials – Makrolon polycarbonate**
5. **510(k) Summary of HEALOS FX Graft Mixing and Delivery System – use of Makrolon polycarbonate in the device**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) CCI

[redacted]

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

Test Article: Loctite 3311 Medical Device Adhesive

(b)(4) CCI

[redacted]

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(b)(4) CCI

[redacted]

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

HEMOCOMPATIBILITY (ISO):

(b)(4) CCI

[redacted]

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(b)(4) CCI

[redacted]

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

Test Article: Loctite 3321 Medical Device Adhesive

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

(b)(4) CCI

[redacted]

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Lustran Polymers Products Meet Stringent Requirements Of Medical Industry

12/15/2006

Medical OEMs and specifiers rely on Lustran® ABS and SAN resins

Addyston, OH - – Materials used in the production of medical devices must be screened for biocompatibility, ensuring that they do not cause adverse local or systemic effects in the body. The Lustran Polymers business unit of LANXESS has tested several resin grades according to the FDA-modified ISO 10993: Part 1 (including US Pharmacopeia Class VI) and can confirm compliance with this standard.

One such product, Lustran ABS 348, is a resin of choice for many of the leading medical device producers in North America and overseas. Typical applications for this resin include piercing pins, roller clamps, filters and housings, diagnostic test kits and instrument handles.

Two medical devices using Lustran ABS 348 are helping to bring relief to sufferers of habitual snoring and chronic nasal obstruction. The SP 1010 and SP 1100 Somnoplasty® devices from Somnus Medical Technologies use an electrode to emit low-power, low-temperature radio frequency energy that shrinks tissue in the mouth and nose. The disposable portions of both devices use medical-grade Lustran ABS 348 resin. This material was selected because of its good moldability, texture, colorability, appearance and ability to withstand gamma radiation.

Dura Pharmaceuticals Inc. chose to use high-gloss Lustran ABS 348 in the mouthpiece of its durable, lightweight and compact Spiros inhaler. In this application, the resin offers a good balance of physical properties and is easily processed due to good flow properties. The glossy surface formed by the Lustran resin reduces the chances of the powder medication sticking to the inside of the mouthpiece during use.

Surgical instruments from Guidant Corporation's Cardiac and Vascular Surgery Group use Lustran ABS 348 resin in multiple components, including the handle of the VasoView 1 Balloon Dissection Cannula and the orbit handle, dissector handle and swivel cap of the VasoView Orbital Dissection Cannula. Guidant also makes a universal seal for surgical trocars made from Lustran ABS 348.

QuickScript System automated prescription-filling machines from AutoMed Technologies Inc. contain hundreds of canisters and trays that were designed and manufactured as injection-molded parts using Lustran ABS 348. The material meets the durability requirements and offers a very good surface finish as molded.

Additional Lustran Polymers products that comply with the FDA-modified ISO 10993: Part 1 standard include Lustran ABS 248FC grades, which are designed for use in drug inhaler device components, and Lustran SAN 31, which is used in the manufacture of transparent components including disposable diagnostic devices, labware, rigid IV and fluid handling components.

SOURCE: LANXESS Corporation

Forward This Article To An Associate

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K981847

JUL 17 1998

510(k) Summary of Safety and Effectiveness
Biolox Alumina Ceramic Femoral Head

Submitter's name:	Smith & Nephew, Inc
Submitter's address:	1450 Brooks Road, Memphis, TN 38116
Submitter's telephone number:	901/396-2121
Contact person:	JoAnn Kuhne
Date summary prepared:	June 11, 1998
Trade or proprietary device name:	Biolox Alumina Ceramic Femoral Head
Common or unusual name:	Ceramic Femoral Head
Classification name:	21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis Class II
Legally marketed predicate device:	Biolox Alumina Ceramic Femoral Head

Subject device description:
The Biolox Alumina Ceramic Femoral Head is manufactured from aluminum oxide, Al_2O_3 and is designed for use with both titanium and cobalt chromium alloy femoral components with a 12/14 taper. The 28 long size will not be marketed in the USA for use with a Co-Cr-Mo taper.

Subject device intended use:
Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

The Biolox Alumina Ceramic Femoral Head is designed for single use only.

Technological characteristics:
The Biolox Alumina Ceramic Femoral Head with a 12/14 taper is similar to the devices listed below.

- Biolox Alumina Ceramic Femoral Head - Smith & Nephew
- Zirconia Ceramic Femoral Head - Smith & Nephew
- Alumina C-Taper Ceramic Femoral Head - Osteonics

All of the devices listed above are indicated for total hip replacement and are similar in design to the Biolox Alumina Ceramic Femoral Head. The new device has the same technological characteristics as the predicate device.

Performance characteristics:
Mechanical testing was performed according to the requirements in the ceramic femoral head draft guidance document. All of the test results indicate that the Biolox Alumina Ceramic Femoral Head is equivalent to devices currently on the market and capable of withstanding *in vivo* loading without failure.

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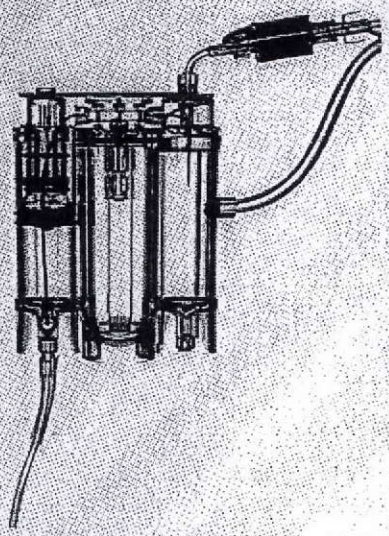
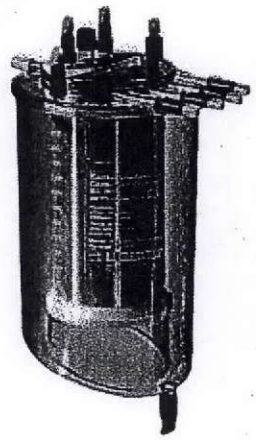
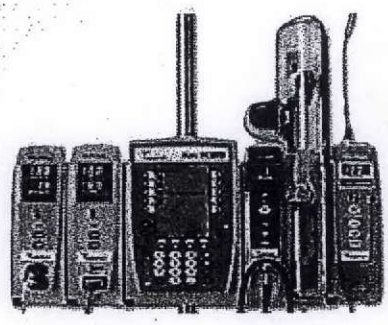
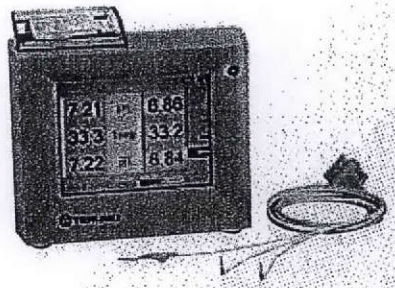
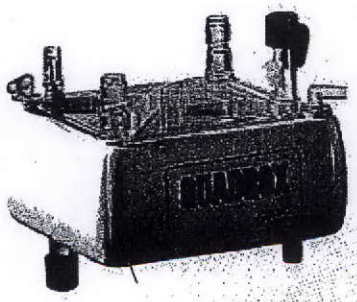
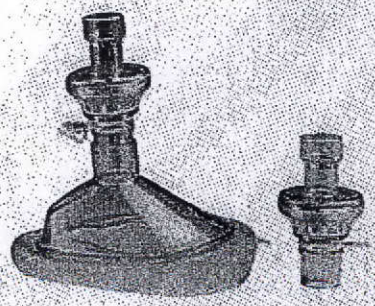
Bayer MaterialScience





REFERENCE GUIDE

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Helping make our customers' vision a reality. Bayer MaterialScience where **VisionWorks.**

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INTRODUCTION

Bayer MaterialScience produces a wide range of proven and innovative materials including polycarbonates, polyurethanes, thermoplastic polyurethanes, coatings, adhesives and sealants. Bayer's materials and solutions are used to develop the next generation products in the medical industry. Over the years, medical product manufacturers have come to rely on Bayer to provide technically advanced materials that can help meet the critical design, manufacturing and end-use performance parameters of a variety of medical device and packaging applications.

Among the many successful applications of Bayer's materials are: X-ray development tanks; diagnostic devices such as transducers; cardiovascular devices, including oxygenators, blood-heat exchangers and blood reservoirs; intravenous devices such as manifolds used in coronary arteriography, stopcocks, IV connection mechanisms, coronary control syringes and transfer devices, to name a few.

For more information about Bayer MaterialScience, visit www.bayermaterialsciencenafta.com *or* call 1-800-662-2927.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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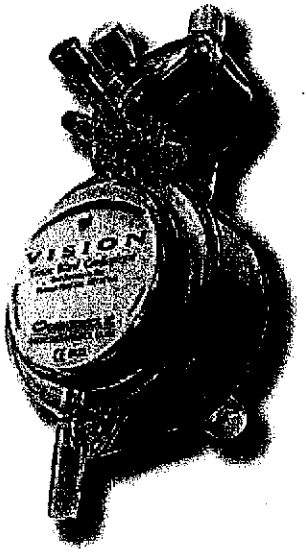
BAYER HIGH-PERFORMANCE POLYMERS FOR MEDICAL APPLICATIONS: A REFERENCE GUIDE

This booklet reviews Bayer's thermoplastic polymers for use in medical applications. Included are typical applications, their performance requirements and the Bayer materials that may meet those requirements. The intention is to provide a general overview of these products and their performance characteristics specific to the medical industry. For additional information, please refer to the list of appropriate contacts at Bayer on page 15.



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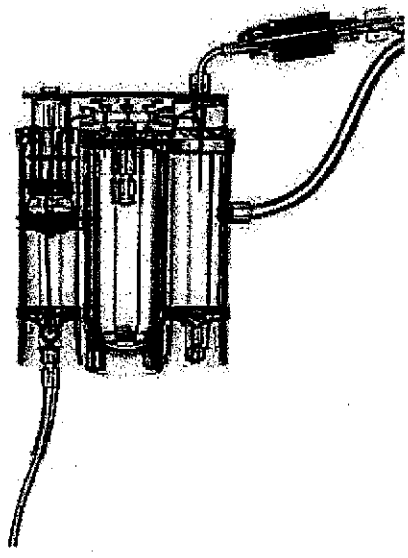
BIOCOMPATIBILITY TESTING

All Bayer resins, films, etc. (hereinafter "Products") designated as "medical-grade" have met the requirements of the FDA-Modified ISO 10993, Part 1 "Biological Evaluation of Medical Devices" tests with human tissue contact time of 30 days or less. These tests are conducted under Good Laboratory Practices as defined by the FDA in 21 CFR Part 58. The products were sterilized by ethylene oxide and gamma radiation prior to testing. *Only these Products may be considered candidates for applications requiring biocompatibility.* No "medical-grade" Product will be available for sale until successful completion of testing.

Regrind resins must not be used in medical applications requiring biocompatibility.

FDA-Modified ISO 10993, Part 1 "Biological Evaluation of Medical Devices" tests with human tissue contact time of 30 days or less have largely supplanted older USP Plastics Class VI and other standards for biocompatibility. These tests include:

- Acute system toxicity
- Intracutaneous toxicity
- Muscle implantation
- Cytotoxicity - (MEM Elution)
- Hemolysis - direct and extraction
- Physicochemical tests
- Heavy metal analysis
- Pyrogen study
- Sensitization (maximization method) - saline extract, oil extract
- Mutagenicity, Ames test - saline extract, and 95% ethanol extract



Test data will be mailed on request. Please see *Medical Contacts* on page 15.

MANUFACTURER'S RESPONSIBILITY

It is the responsibility of the medical device, biological product or pharmaceutical manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials used in its final product in order to ensure safety and compliance with FDA requirements. This determination must include, as applicable, testing for suitability as an implant device and suitability as to contact with and/or storage of human tissue and liquids including, without limitation, medication, blood, or other bodily fluids.

Under no circumstances, however, may any Bayer Product be used in any cosmetic, reconstructive, or reproductive implant applications. Nor may any Bayer Product be used in any other bodily implant applications, or any applications involving contact with or storage of human tissue, blood, or other bodily fluids, for greater than 30 days, based on FDA-Modified ISO 10993, Part 1 "Biological Evaluation of Medical Devices" tests. Furthermore, for aromatic grades of Texin® resins, such longer-term uses are not permissible also because possible hydrolysis of solid polyurethane may produce aromatic amines, such as methylene dianiline (MDA).

The suitability of a Bayer Product in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, processing parameters, residual stresses, or external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

Single-use medical devices made from a Bayer Product are not suitable for multiple uses. If the medical device is designed for multiple uses, it is the responsibility of the Manufacturer to determine the appropriate number of permissible uses by evaluating the device under actual sterilization and end-use conditions and to adequately advise and warn purchasers and users thereof.

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STERILIZATION

Medical devices typically require sterilization before use. There are three sterilization methods prevalent in the medical industry:

- Heat (both steam autoclave and, to a lesser extent, dry heat)
- Ethylene oxide (EtO) gas
- Irradiation (both gamma and electron beam methods)

The table below shows which Bayer products are suitable for each sterilization method. However, the sterilization method and the number of sterilization cycles a medical device made from a Bayer Product can withstand will vary depending upon the type/grade of Product, part design, processing parameters, sterilization temperature and chemical environment. Therefore, the Manufacturer must evaluate each device to determine the sterilization method and the number of permissible sterilization cycles appropriate for actual end-use requirements and must adequately advise and warn purchasers and users thereof.

Parts molded or extruded from Texin® resins are sterilizable using ethylene oxide, radiation or dry heat. Parts made of Texin® resins must not be sterilized using steam auto-claving or boiling water techniques. Furthermore, these sterilization methods must not be used with aromatic grades of Texin® resin because possible hydrolysis of solid polyurethane may produce aromatic amines, such as methylene dianiline (MDA).

Acceptable Sterilization Methods for Bayer Medical Products*

	Ethylene Oxide Sterilization	Gamma Radiation	Electron Beam Radiation	Steam Autoclave	High-Heat Steam Autoclave
Makrolon® PC	Yes	Yes	Yes	Yes**	No
Apec® High-Heat PC	Yes	Yes	Yes	Yes**	Yes**
Makrofol® PC Film	Yes	Yes	Yes	Yes**	No
Makroblend® PC/PET	Yes	Yes	Yes	Yes**	No
Bayblend® PC/ABS	Yes	Yes	Yes	No	No
Texin® TPU	Yes	Yes	Yes	No	No

**The suitability of a specific grade of a Bayer product for a particular sterilization method must be evaluated by the Manufacturer as described above.*
***Refer to guidelines in* Autoclaving (Saturated Steam Sterilization) *below.*

AUTOCLAVING (SATURATED STEAM STERILIZATION)

Several Bayer thermoplastic products are suitable for applications that undergo steam sterilization under standard auto-claving conditions, i.e., 250°F (121°C) for 15 to 30 minutes. These products include Makrolon® polycarbonate, Apec® high-heat polycarbonate, Makrofol® polycarbonate film, and Makroblend® polycarbonate/PET blend. The number of allowable sterilization cycles must be evaluated and determined by the Manufacturer (see sterilization guidelines below).

Sterilization temperatures for parts made of Makrolon® polycarbonate (as well as Makrofol® PC film and Makroblend® PC/PET blend) must not exceed 250°F (121°C) to avoid part deformation. Parts made of Apec® high-heat polycarbonate, however, may be subjected to sterilization temperatures up to 275°F (135°C), thus reducing the amount of time needed for sterilization.

It is necessary to thoroughly rinse germicides and detergents from parts made from polycarbonate prior to autoclaving. Failure to thoroughly remove germicides and detergents from the part prior to autoclaving may cause accelerated degradation of the polycarbonate.

*Please note that **permanent immersion of polycarbonate parts in water above 140°F (60°C) or in steam causes loss of material properties and must be avoided.** Furthermore, condensed steam should not be allowed to accumulate as this may also cause damage to the parts. Parts made from polycarbonate should also be protected from damage by substances such as alkaline corrosion inhibitors, which are frequently added to boiler feed water.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MEDICAL-GRADE PRODUCTS FOR BIOCOMPATIBILITY USE (ISO 10993-1)*

MAKROLON® Polycarbonate	
Grade Color No.	Color/Property
Makrolon® Rx1452 550115	Clear tint/Easy-flow, easy-release
Makrolon® Rx2530 558994	Radiation-stable tint/Easy-flow
Makrolon® Rx2530 451118	Radiation-stable tint/Easy-flow
Makrolon® Rx1805 558994	Radiation-stable tint/Lipid-resistant
Makrolon® Rx1805 451118	Radiation-stable tint/Lipid-resistant
Makrolon® Rx1805 013771	Cool white/Lipid-resistant
Makrolon® 2458 551117	Radiation-stable tint/High-flow
Makrolon® 2458 550115	Clear tint/High-flow
Makrolon® 2558 550115	Clear tint
Makrolon® 2558 013282	Cool white
Makrolon® 2658 550115	Clear tint
Makrolon® 2858 550115	Clear tint
Makrolon® 3158 550115	Clear tint

NOTE: All colors listed above are standard colors. Custom colors that meet ISO biocompatibility requirements may be available on special request subject to standard lead time.

MAKROBLEND® Polycarbonate/PET Blend	
Grade Color No.	Color/Property
Makroblend® DP4-1386 550197	Clear tint/Transparent blend

APEC® High-Heat Polycarbonate	
Grade Color No.	Color/Property
Apec® 1745 551022	Clear tint/Release

TEXIN® Thermoplastic Polyurethane	
Grade Color No.	Durometer/Color/Description
Texin® RxT85A 000000	85A/Natural clear/polyether
Texin® RxT90A 000000	90A/Natural clear/polyether
Texin® RxT50D 000000	50D/Natural clear/polyether
Texin® RxT65D 000000	65D/Natural clear/polyether
Texin® 4210 000000	70D/Natural translucent/TPU/PC blend

MAKROFOL® Polycarbonate Film	
Grade Color No.	Color/Property
Makrofol® DE1-1 550115	Clear tint/Graphic-arts quality
Makrofol® DE1-1 558905	Blue tint/Graphic-arts quality

NOTE: Thickness ranges from 0.005 to 0.040 inch. Above films are smooth-texture with high gloss front and back. Other textures may be available on special request.

PRODUCTS FOR NON-BIOCOMPATIBILITY USE

BAYBLEND® Polycarbonate/ABS Blend	
Grade	Color/Description
Bayblend® T85	Opaque/General purpose, tough
Bayblend® FR2010	Opaque/Flame-retardant, tough, easy flow
Bayblend® FR3010	Opaque/Flame-retardant, high heat, tough

For information on available colors, refer to the list of contact names on page 15.

TEXIN® Thermoplastic Polyurethane
Please contact Bayer for recommendation (p. 15)

MAKROBLEND® Polycarbonate/PET Blend	
Grade	Color/Description
Makroblend® UT403	Opaque/Tough, chemically resistant, weatherable
Makroblend® UT408	Opaque/FDA food-contact compliant, tough, chemically resistant
Makroblend® EL700	Opaque/Flame-retardant, tough, chemically resistant
Makroblend® EL703	Opaque/Flame-retardant, tough, chemically resistant, weatherable

For information on available colors, refer to the list of contact names on page 15.

** Bayer MaterialScience medical-grade products for biocompatibility use are in compliance with the requirements of FDA-Modified ISO 10993, Part 1 "Biological Evaluation of Medical Devices" tests with human tissue contact time of 30 days or less. See Biocompatibility Testing section on page 3.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

makrofol® POLYCARBONATE RESINS

Typical Properties*	ASTM Test Method (Other)	U.S. Conventional Units	Makrofol® DE 1-1
PHYSICAL			
Specific Gravity	D 792		1.20
Conversion Factor		ft./lb-mil	180
Water Absorption (Immersion @ 73°F 24 hours)	D 570	%	0.33
First Surface Gloss - 80° angle, black inked second surface	D 2457	gloss unit	≥98
First Surface Roughness R3Z	ISO 4288	microns	≤0.5
OPTICAL			
Haze	D 1003	%	0.3
Light Transmission	D 1003	%	91
Yellowness Index	E 313		1
MECHANICAL			
Tensile Strength, Yield	D 882	psi	8,800
Tensile Strength, Break	D 882	psi	8,700
Elongation @ Break	D 882	%	120
Tear Strength	D 1004	lb/in	1,100
THERMAL			
Heat Deflection	ISO 75		
Temperature	(UL94)		
1.82 Mps		°F	270
0.45 Mps		°F	288
Viscat Softening Temperature	ISO 306	°F	315
FLAMMABILITY			
UL Listing	UL 94	min.	V-2
		thickness	
		0.015"	
	UL 94	min.	VTM-2
		thickness	
		0.005"	
Burn Rate	FMV88302		S100

These items are provided as general information only. They are approximate values and are not part of the product specifications.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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makrolon® POLYCARBONATE RESINS

Typical Properties*	ASTM Test Method (Other)	U.S. Conventional Units	Makrolon® Rx1452	Makrolon® Rx1805
GENERAL				
Specific Gravity	D 792		1.20	1.20
Density	D 792	lb/in³	0.043	0.043
Specific Volume	D 792	in³/lb	23.1	23.1
Mold Shrinkage	D 955	in/in	0.006–0.008	0.006–0.008
Water Absorption, Immersion at 73°F:	D 570			
24 Hours		%	0.12	0.12
Equilibrium		%	0.30	0.30
Melt Flow Rate[a] at 300°C/1.2-kg Load	D 1238	g/10 min	17	6.5
OPTICAL				
Transmittance at 0.125-in Thickness	D 1003	%	86	76
Haze at 0.125-in Thickness	D 1003	%	1	1
Refractive Index	D 542			1.586
MECHANICAL				
Tensile Stress at Yield	D 638	lb/in²	9,000	9,400
Tensile Stress at Break	D 638	lb/in²	10,000	10,200
Tensile Elongation at Yield	D 638	%	6	6
Tensile Elongation at Break	D 638	%	120	120
Tensile Modulus	D 638	lb/in²	330,000	350,000
Flexural Stress at 5% Strain	D 790	lb/in²	14,000	13,000
Flexural Modulus	D 790	lb/in²	330,000	340,000
Impact Strength, Notched Izod:	D 256			
0.125-in Thickness, 73°F		ft·lb/in	15	18
0.250-in Thickness, 73°F		ft·lb/in	1.4	2.4
Rockwell Hardness	D 785	M Scale		
THERMAL				
Deflection Temperature, Unannealed:	D 648			
264-psi Load		°F	250	259
66-psi Load		°F	270	273
Coefficient of Linear Thermal Expansion	D 696	in/in/°F		3.34 E-05
Thermal Conductivity	C 177	Btu·in/(h·ft²·°F)	1.39	1.39
Specific Heat	D 2766	Btu/(lb·°F)	0.28	0.28
Relative Temperature Index at 0.059-in Thickness:	(UL746B)			
Electrical		°C		
Mechanical with Impact		°C		
Mechanical without Impact		°C		
Vicat Softening Temperature, Rate A	D 1525	°F	289	291
FLAMMABILITY**				
UL94 Flame Class:	(UL94)			
0.059-in (1.5-mm) Thickness		Rating		
0.118-in (3.0-mm) Thickness		Rating		
ELECTRICAL				
Volume Resistivity (Tinfoil Electrodes)	D 257	ohm·cm	1.0 E + 14	
Surface Resistivity	D 257	ohm		
Dielectric Strength (Short Time Under Oil, 73°F)[b]	D 149	V/mil		
Dielectric Constant (Tinfoil Electrodes): 60 Hz	D 150			
1 MHz				
Dissipation Factor (Tinfoil Electrodes): 60 Hz	D 150			
1 MHz				
Arc Resistance: Stainless Steel Electrodes	D 495	s		
Tungsten Electrodes		s		

These items are provided as general information only. They are approximate values and are not part of the product specifications.
[a]*For information on using melt flow as a quality control procedure, see the Bayer publication* Makrolon Polycarbonate – A Processing Guide for Injection Molding.
[b]*Reported at 0.062-in thickness*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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makrolon® POLYCARBONATE RESINS continued

Makrolon® Rx2530	Makrolon® 2458	Makrolon® 2558	Makrolon® 2658	Makrolon® 2858	Makrolon® 3158
1.20	1.20	1.20	1.20	1.20	1.20
0.043	0.043	0.043	0.043	0.043	0.043
23.1	23.1	23.1	23.1	23.1	23.1
0.006 – 0.008	0.005 – 0.007	0.006 – 0.008	0.006 – 0.008	0.006 – 0.008	0.006 – 0.008
0.12	0.12	0.12	0.12	0.12	0.12
0.30	0.30	0.30	0.30	0.30	0.30
15	20	15	13	10	6.5
78	88	88	88	88	88
1.2	<0.8	<0.8	<0.8	<0.8	<0.8
1.586	1.586	1.586	1.586	1.586	1.587
9,400	9,400	9,400	9,400	9,400	9,400
9,400	8,700	8,700	9,400	10,200	10,200
6	6	6	6	6	6.5
115	115	115	115	115	115
350,000	350,000	350,000	350,000	350,000	350,000
12,500	12,000	12,500	12,500	12,500	12,500
340,000	340,000	340,000	340,000	340,000	340,000
16	14	16	16	17	18
1.4	2	2	2.2		2.4
87	75	75	75	75	75
259	259	266	268	268	270
273	273	275	280	280	288
3.34 E-05	3.34 E-05	3.34 E-05	3.34 E-05	3.34 E-05	3.34 E-05
	1.39	1.39	1.39	1.39	1.39
	0.28	0.28	0.28	0.28	0.28
	125	125	125	125	125
	115	115	115	115	115
	125	125	125	125	125
286	291	291	291	291	295
	V-2	V-2	V-2	V-2	HB
	HB	HB	HB	HB	HB
1.0 E+16	1.0 E+14	1.0 E+14	1.0 E+14	1.0 E+14	1.0 E+14
1.0 E+15	1.0 E+16	1.0 E+16	1.0 E+16	1.0 E+16	1.0 E+16
760	810	810	810	810	810
3.0	3.0	3.0	3.0	3.0	3.0
3.0	2.9	2.9	2.9	2.9	2.9
0.001	0.0008	0.0009	0.0009	0.0009	0.0009
0.01	0.01	0.01	0.01	0.01	0.01
11	11	11	11	11	11
30–90	120	120	120	120	120

***Flammability results are based on small-scale laboratory tests for purposes of relative comparison and are not intended to reflect the hazards presented by this or any other material under actual fire conditions.*

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Apec® 1745 HIGH-HEAT POLYCARBONATE RESINS

Typical Properties* for Natural Resin	ASTM Test Method (Other)	U.S. Conventional Units	Apec® 1745
GENERAL			
Specific Gravity	D 792		1.17
Density	D 792	lb/in³	0.042
Specific Volume	D 792	in³/lb	23.7
Mold Shrinkage	D 955	in/in	0.007–0.008
Water Absorption, Immersion at 73°F:	D 570		
24 Hours		%	0.2
Equilibrium		%	0.4
Melt Flow Rate[a] at 330°C/2.16-kg Load	D 1238	g/10 min	15
OPTICAL			
Transmittance at 0.125-in Thickness	D 1003	%	88
Haze at 0.125-in Thickness	D 1003	%	1
Refractive Index	D 542		1.578
MECHANICAL			
Tensile Stress at Yield	D 638	lb/in²	9,400
Tensile Stress at Break	D 638	lb/in²	9,300
Tensile Elongation at Yield	D 638	%	7
Tensile Elongation at Break	D 638	%	80
Tensile Modulus	D 638	lb/in²	330,000
Flexural Stress at 5% Strain	D 790	lb/in²	12,500
Flexural Modulus	D 790	lb/in²	330,000
Impact Strength, 0.125-in Thickness:			
Notched Izod, 73°F	D 256	ft·lb/in	6
Unnotched, 73°F	D 4812	ft·lb/in	No break
Unnotched, -40°F	D 4812	ft·lb/in	No break
Instrumented Impact, Total Energy:[b]	D 3763		
0.125-in Thickness, 73°F		ft·lb	50
0.125-in Thickness, -20°F		ft·lb	48
Rockwell Hardness	D 785	M/R Scale	83/127
THERMAL			
Deflection Temperature, Unannealed:	D 648		
0.250-in Thickness, 264-psi Load		°F	302
0.250-in Thickness, 66-psi Load		°F	324
Coefficient of Linear Thermal Expansion	D 696	in/in/°F	3.9 E-05
Vicat Softening Temperature, Rate B	D 1525	°F	338
ELECTRICAL			
Volume Resistivity (Tinfoil Electrodes)	D 257	ohm·cm	1.0 E+14
Surface Resistivity	D 257	ohm	1.0 E+16
Dielectric Strength (Short Time Under Oil	D 149		
at 73°F and 0.125-in Thickness)		V/mil	>400
Dielectric Constant (Tinfoil Electrodes): 60 Hz	D 150		2.9
1 MHz			2.9
Dissipation Factor (Tinfoil Electrodes): 60 Hz	D 150		0.001
1 MHz			0.01

These items are provided as general information only. They are approximate values and are not part of the product specifications.
[a]*For information on using melt flow as a quality control procedure, see the Bayer publication* Apec High-Heat Polycarbonate – Injection Molding Guidelines.
[b]*0.5-in dart, 3-in clamp, 15 mph.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Texin® THERMOPLASTIC POLYURETHANE RESINS

Typical Properties* for Natural Resin	ASTM Test Method (Other)	U.S. Conventional Units	Texin® 4210	Texin® RxT85A	Texin® RxT90A	Texin® RxT50D	Texin® RxT65D
GENERAL							
Specific Gravity	D 792		1.21	1.12	1.13	1.15	1.17
Shore Hardness	D 2240	A or D	70 D	85 A	90 A	50 D	65D
Taber Abrasion:	D 3489						
H-18 Wheel, 1,000-g Load, 1,000 Cycles		mg Loss	65	30	25	75	75
Bayshore Resilience	D 2632	%	45	45	40	35	50
Mold Shrinkage at 100-mil Thickness:	D 955						
Flow Direction		in/in	0.008	0.008	0.008	0.008	0.008
Cross-Flow Direction		in/in	0.008	0.008	0.008	0.008	0.008
Processing Methods							
• Injection Molding			•	•	•	•	•
• Extrusion – Hose, Tubing, Profiles				•	•	•	•
– Wire & Cable				•	•	•	•
– Film & Sheet			•	•	•	•	•
• Blow Molding				•	•	•	•
MECHANICAL							
Tensile Strength	D 412	lb/in²	6,000	5,500	5,000	6,000	6,000
Tensile Stress at 50% Elongation	D 412	lb/in²	4,100	700	1,000	1,750	2,900
Tensile Stress at 100% Elongation	D 412	lb/in²	4,500	800	1,100	2,000	3,300
Tensile Stress at 300% Elongation	D 412	lb/in²		1,200	2,000	4,000	4,450
Ultimate Elongation	D 412	%	180	500	450	400	300
Flexural Modulus	D 790	lb/in²	100,000	3,900	6,000	16,500	61,000
Tear Strength, Die C	D 624	lbf/in	900	500	550	750	1,200
Compression Set:	D 395-B						
As Molded [Post-Cured]**							
22 Hours at 158°F	%			80 [40]	75 [35]	70 [40]	88 [35]
22 Hours at 73°F	%			19 [16]	20 [13]	20 [15]	28 [20]
Compressive Load:	D 575						
2% Deflection		lb/in²	500	50	100	150	200
5% Deflection		lb/in²	2,000	150	250	425	800
10% Deflection		lb/in²	4,600	300	450	800	1,500
15% Deflection		lb/in²	6,000	450	650	1,100	1,950
20% Deflection		lb/in²	8,200	625	850	1,500	2,400
25% Deflection		lb/in²	10,000	800	1,050	1,800	2,950
50% Deflection		lb/in²	18,900	2,400	2,800	4,500	7,950
THERMAL							
Deflection Temperature Under Load:	D 648						
264 psi		°F	139				
66 psi		°F	208				
Coefficient of Linear Thermal Expansion	D 696	in/in/°F	5.7 E-05			7.3 E-05	
Low-Temperature Brittle Point	D 746	°F	<-90	<-90	<-90	<-90	<-90
Glass Transition Temperature (Tg)	(DMA#)	°F	-31	-51	-47	-17	14

These items are provided as general information only. They are approximate values and are not part of the product specifications.
***Post-cured 16 hours at 230°F (110°C).*
 # DMA: Dynamic Mechanical Analysis.

Other Texin resins may apply for medical applications. Contact Bayer at TPUinfo@bayer.com.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

makroblend® PC/PET BLENDS

Typical Properties* for Natural Resin	ASTM Test Method (Other)	U.S. Conventional Units	Makroblend® UT403[b]	Makroblend® UT408[c]	Makroblend® EL700	Makroblend® EL703[b]	Makroblend® DP4-1386
GENERAL							
Specific Gravity	D 792		1.22	1.22	1.28	1.29	1.20
Density	D 792	lb/in³	0.044	0.044	0.046	0.047	0.043
Specific Volume	D 792	in³/lb	22.7	22.7	21.6	21.5	23.1
Mold Shrinkage	D 955	in/in	0.006–0.008	0.005-0.007	0.006-0.008	0.006-0.008	0.006-0.008
Water Absorption, Immersion at 73°F:	D 570						
24 Hours		%	0.11	0.17	0.09	0.16	
Equilibrium		%	0.25		0.28	0.34	0.17
Melt Flow Rate[a] at 265°C/5-kg Load	D 1238	g/10 min	24-34	14-20	10-20	20-30	15-20
Spiral Flow Length at 0.100-in Thickness:	(Bayer)						
525°F Melt Temperature		in	28	20	19	30	
MECHANICAL							
Tensile Stress at Yield	D 638	lb/in²	8,100	8,200	8,400	8,000	8,900
Tensile Stress at Break	D 638	lb/in²	8,000	7,900	8,000	7,400	8,700
Tensile Elongation at Yield	D 638	%	5	5	5	5	5
Tensile Elongation at Break	D 638	%	151	115	120	110	110
Flexural Stress at 5% Strain	D 790	lb/in²	12,400	13,000	12,000	13,000	12,000
Flexural Modulus	D 790	lb/in²	338,000	340,000	340,000	350,000	330,000
Impact Strength, Notched Izod:	D 256						
0.125-in Thickness, 73°F		ft·lb/in	15	15	15	14	15
0.125-in Thickness, -40°F		ft·lb/in	2	3	4	2	
Instrumented Impact, Total Energy:[d]	D 3763						
0.125-in Thickness, 73°F		ft·lb	41	36	40	37	51
0.125-in Thickness, -40°F		ft·lb	41	37	35	33	51
Rockwell Hardness	D 785	R Scale	121	117	120	117	124
THERMAL							
Deflection Temperature, Unannealed:	D 648						
0.250-in Thickness, 264 psi		°F	248	240	222	212	220
0.250-in Thickness, 66 psi		°F	273	271	255	246	240
Coefficient of Linear Thermal Expansion	D 696	in/in/°F	3.7 E-05	3.5 E-05	3.7 E-05	3.6 E-05	
Relative Temperature Index at 0.059-in Thickness:	(UL746B)						
Electrical		°C	75	75	75	105	95
Mechanical with Impact		°C	75	75	75	90	85
Mechanical without Impact		°C	75	75	75	105	90
FLAMMABILITY**							
UL94 Flame Class:	(UL94)						
0.059-in (1.5-mm) Thickness		Rating	HB	HB	V-0	V-0	HB
0.118-in (3.0-mm) Thickness		Rating	HB	HB	V-0/5VA	V-0/5VA	HB
ELECTRICAL							
Volume Resistivity (Tinfoil Electrodes)	D 257	ohm·cm	>7.4E+15		1.7 E+16	4.6 E+15	
Dielectric Strength (Short Time Under Oil	D 149						
at 73°F, 0.062-in. Thickness)		V/mil	704		>734	>708	
Dielectric Constant (Tinfoil Electrodes), 1 MHz	D 150		3.1		3.08	3.31	
Dielectric Factor (Tinfoil Electrodes), 1 MHz	D 150		0.009		0.0080	0.0122	

These items are provided as general information only. They are approximate values and are not part of the product specifications.

***Flammability results are based on small-scale laboratory tests for purposes of relative comparison and are not intended to reflect the hazards presented by this or any other material under actual fire conditions.*

[a]*For information on using melt flow as a quality control procedure, see the* Bayer publication Makroblend Polycarbonate Blend – Injection Molding Guidelines.

[b]*Makroblend UT 403 and EL 703 resins are rated f1 for all colors in accordance with UL746C (exposure to ultraviolet light, water exposure and immersion).*

[c]*Makroblend UT 408 resin (natural color) can be used for food-contact applications except for those in which the temperature exceeds 250°F and the food contains more than 50% alcohol.*

[d]*0.5-in dart, 3-in clamp, 7.6 mph.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request #2013-3311. Released by CDRH on 9/10/2015

BAYBLEND® PC/ABS BLENDS

Typical Properties* for Natural Resin	ASTM Test Method (Other)	U.S. Conventional Units	Bayblend® T85	Bayblend® FR2010[a]	Bayblend® FR3010[a]
GENERAL					
Specific Gravity	D 792		1.15	1.18	1.18
Density	D 792	lb/in³	0.042	0.043	0.043
Specific Volume	D 792	in³/lb	24.1	23.5	23.3
Mold Shrinkage	D 955	in/in	0.005–0.007	0.005–0.007	0.005–0.007
Spiral Flow Length at 0.100-in Thickness:	(Bayer)				
490°F Melt Temperature		in	20	24	21
MECHANICAL					
Tensile Stress at Yield	D 638	lb/in²	8,000	8,700	8,700
Tensile Stress at Break	D 638	lb/in²	7,000	7,250	7,250
Tensile Elongation at Yield	D 638	%	4.7	4	4
Tensile Elongation at Break	D 638	%	>50	>50	>50
Flexural Stress at 5% Strain	D 790	lb/in²	13,000	13,800	13,775
Flexual Modulus	D 790	lb/in²	335,000	390,000	362,500
Impact Strength, Notched Izod:	D 256				
0.125-in Thickness, 73°F		ft·lb/in	13	10	14
Instrumented Impact, Total Energy:[b]	D 3763				
0.125-in Thickness, 73°F		ft·lb	33	38	40
THERMAL					
Deflection Temperature, Unannealed:	D 648				
0.125-in Thickness, 264 psi		°F	226	200	194
Coefficient of Linear Thermal Expansion	E 831	in/in/°F	4.6 E-05	4.3 E-05	4.2 E-05
Relative Temperature Index at 0.059-in Thickness:	(UL746B)				
Electrical		°C	60	95	95
Mechanical with Impact		°C	60	85	85
Mechanical without Impact		°C	60	85	85
Vicat Softening Temperature, Rate B/120	(ISO 306)	°F	268	226	230
FLAMMABILITY					
Oxygen Index	D 2863	%	24	34	
UL94 Flame Class:	(UL94)				
0.059-in (1.5-mm) Thickness		Rating	HB	V-0	V-0
0.079-in (2.0-mm) Thickness		Rating			5VB
0.118-in (3.0-mm) Thickness		Rating	HB	5VA[c]	5VA
ELECTRICAL					
Volume Resistivity	(IEC 60112)	ohm·cm	1.0 E + 14	1.0 E + 14	1.0 E + 14
Surface Resistivity	(IEC 60093)	ohm	1.0 E + 16	1.0 E + 16	1.0 E + 16
Dielectric Strength	(IEC 60243)	V/mil	890	760	760
Relative Permittivity: 100 Hz	(IEC 60250)		3.1	3.2	3.2
1 MHz			3.0	3.1	3.1
Dissipation Factor: 100 Hz	(IEC 60250)		0.002	0.004	0.005
1 MHz			0.009	0.007	0.007
Comparative Tracking Index	(IEC 60112)	V	225	350	350

These items are provided as general information only. They are approximate values and are not part of the product specifications.

***Flammability results are based on small-scale laboratory tests for purposes of relative comparison and are not intended to reflect the hazards presented by this or any other material under actual fire conditions.*

[a]Flame-retardant additive is antimony/bromine/chlorine-free.

[b]0.5-in dart, 3-in clamp, 15 mph.

[c]5VA rating is for gray color.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8110

Records processed under FOIA Request #2013-3311. Released by CDRH on 9/10/2015

TYPICAL CHEMICAL RESISTANCE OF BAYER RESINS

Key: ■ = Resistant ▲ = Limited Resistance ● = Not Tested

Media	Makrolon® Rx1805	Makrolon® 2558/Rx2530	Apec® 1745	Makroblend® DP4-1386	Texin® RxT85A
Dioctyl Phthalate	▲	▲	▲	▲	▲
Trioctyl Trimellitate	■	▲	●	●	●
20% Lipid Emulsion	■	▲	▲	▲	●
1% Saline Solution	■	■	■	■	■
Deionized Water	■	■	■	■	■
Methanol	▲	▲	▲	■	▲
Isopropyl Alcohol	■	▲	▲	■	▲
Petroleum Ether	●	▲	▲	●	■
Betadine*	■	■	■	●	●
10% Bleach	■	▲	▲	■	▲
Bleach, Full Strength	■	▲	●	■	●
2% Glutaraldehyde	■	■	■	▲	●
3% Hydrogen Peroxide	■	■	■	●	■
Mineral Oil	■	■	■	■	■

This table lists test results after exposure to various chemicals typically encountered in medical environments. Exposure conditions were 24 hours at 73°F. The ratings are based on strain-limit testing described in the Bayer publication Chemical Compatibility Test for Unreinforced Thermoplastic Resins. As is the case with any compatibility test, the results are dependent on such variables as concentration, time, temperature, part design, and residual stresses and should serve only as a guideline. It is imperative that production parts be evaluated under actual application conditions prior to commercial use.

* Betadine is a trademark of The Purdue Frederick Co.

JOINING TECHNIQUES FOR BAYER RESINS

Key: ■ = Excellent ▲ = Fair ● = Poor

Polymer	Snap Fits	Molded-In Inserts	Solvent Bonding	Adhesive Bonding
Makrolon® PC	Yes	No	■	■
Apec® High-Heat PC	Yes	No	■	■
Makroblend® PC/PET	Yes	No	▲	■
Bayblend® PC/ABS	Yes	No	■	■
Texin® TPU	Yes	Yes	▲*	▲*

Polymer	Vibration Welding	Ultrasonic Welding	Thermal Welding
Makrolon® PC	■	■	■
Apec® High-Heat PC	■	■	■
Makroblend® PC/PET	■	■	■
Bayblend® PC/ABS	■	■	■
Texin® TPU	●▲*	●▲*	■*

For a detailed discussion of various joining techniques, please refer to the Bayer design guide Engineering Polymers Joining Techniques.
**Will depend on specific grade of Texin® Thermoplastic Polyurethane*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TYPICAL PROCESSING PROFILES FOR BAYER RESINS*

	U.S. Conventional Units	Apec® 1745	Bayblend® FR2010	Bayblend® FR3010	Makroblend® UT403	Makroblend® UT408	Makroblend® EL700	Makroblend® EL703
DRYING CONDITIONS								
Moisture Content	%	<0.02	<0.02	<0.02	≤0.01	≤0.01	≤0.01	≤0.01
Drying Time	Hours	4	4	4	4–6	4–6	4–6	4–6
Inlet Air Temperature	°F	265	200	200	220–230	220–230	220–230	220–230
Dew Point	°F	≤-20	≤-20	≤-20	≤-20	≤-20	≤-20	≤-20
TEMPERATURE SETTINGS								
Barrel:								
Rear	°F	590–610	430–445	430–445	470–490	500–545	470–490	470–490
Middle	°F	595–615	435–455	435–455	480–500	500–545	480–500	480–500
Front	°F	600–620	445–465	445–465	490–510	500–545	490–510	490–510
Nozzle	°F	590–610	485–505	485–505	495–515	490–535	495–515	495–515
Melt	°F	590–630	465–520	465–520	500–530	530–555	500–530	500–530
Mold	°F	175–250	140–175	140–175	65–180	130–180	65–180	65–180
MACHINE CONDITIONS								
Injection Pressure	x1000 psi	15–20	10–16	10–16	10–20	10–20	10–20	10–20
Injection Speed		Slow-Moderate	Slow-Moderate	Slow-Moderate	Slow-Moderate	Slow-Moderate	Slow-Moderate	Slow-Moderate
Hold Pressure *(as % Inj. Press.)*	%	40–60	50–75	50–75	50–75	50–75	50–75	50–75
Back Pressure	psi	50–100	50–100	50–100	50–100	50–100	50–100	50–100
Screw Speed	rpm	50–100	40–70	40–70	40–70	40–70	40–70	40–70
Cushion	in	1/8–1/4	1/8–1/4	1/8–1/4	1/8–1/4	1/8–1/4	1/8–1/4	1/8–1/4
Clamp	ton/in²	3–5	3–5	3–5	3–5	3–5	3–5	3–5

	U.S. Conventional Units	Makrolon® 2658	Makrolon® 3158	Makrolon® 2458	Makrolon® 2558, Rx2530, Rx1805, Rx1452	Texin® RxT50D, RxT 85A, RxT90A	Texin® 4210	Texin® RxT65D
DRYING CONDITIONS								
Moisture Content	%	<0.02	<0.02	<0.02	<0.02	<0.03	<0.03	<0.03
Drying Time	Hours	4	4	4	4	2 min.	2 min.	2
Inlet Air Temperature	°F	250	250	250	250	210–230	240–250	210–230
Dew Point	°F	≤-20	≤-20	≤-20	≤-20	≤-20	≤-20	≤-20
TEMPERATURE SETTINGS								
Barrel:								
Rear	°F	480–520	520–560	445–495	465–510	360–390	410–455	410–455
Middle	°F	520–560	540–580	510–550	510–550	360–400	415–460	415–460
Front	°F	545–585	565–605	530–570	530–570	360–410	420–460	420–460
Nozzle	°F	515–585	540–605	510–530	515–585	370–415	425–460	425–460
Melt	°F	550–580	570–600	535–565	540–575	385–400	425–465	430–460
Mold	°F	150–220	150–220	150–220	150–220	60–110	60–110	60–110
MACHINE CONDITIONS								
Injection Pressure	x1000 psi	10–20	10–20	10–20	10–20	6–15	6–15	6–15
Injection Speed		Moderate-High	Moderate-High	Moderate-High	Moderate-High	Slow	Moderate	Slow-Moderate
Hold Pressure *(as % Inj. Press.)*	%	50–70	50–70	50–70	50–70	60–80	60–80	60–80
Back Pressure	psi	50–100	50–100	50–100	50–100	200 max.	200 max.	200 max.
Screw Speed	rpm	50–75	50–75	50–75	50–75	40–80	40–80	40–80
Cushion	in	1/8–1/4	1/8–1/4	1/8–1/4	1/8–1/4	1/8 max.	1/8 max.	1/8 max.
Clamp	ton/in²	3–5	3–5	3–5	3–5	3–5	3–5	

** Regrind resins must not be used in medical applications requiring biocompatibility. Please see Bayer processing literature for important information on regrind usage in non-biocompatibility applications.*
***Drying time depends on initial moisture content.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PRODUCT AND PROCESSING INFORMATION

The property tables for the products listed in this reference guide are presented as a general overview. Please refer to the individual product information bulletins for these and other Bayer products to obtain detailed information on properties and applications. Also, please refer to the list of appropriate Bayer MaterialScience medical contacts below.

Typical processing conditions for injection molding are given on page 14. Actual processing conditions will depend on machine size, mold design, material residence time, shot size, etc. Additional information on processing may be obtained by consulting individual processing guides and by contacting a Bayer MaterialScience technical service representative.

MEDICAL CONTACTS

Responsibility	Contact	Phone
Industry Manager	Kevin Dunay	1.412.777.2316
REGIONAL SPECIALISTS:		
Northeast/Mid-Atlantic	Thom Hemler	1.609.261.0947
Midwest	Lou Madrid	1.636.458.0353
Midwest – Chicago	Karen Heroldt	1.847.310.2557
Midwest – Minnesota	Lanette Brennan	1.651.430.9033
Southeast	Vaughn Smith	1.843.971.1239
West	Brody Hammond	1.760.231.7877
Southwest	Rick Kerr	1.210.493.3700

PRODUCT APPLICATION INFORMATION/TECHNICAL SUPPORT

Product	Contact	Phone
APEC® High-Heat Polycarbonate	John Charles	1.412.777.2195
BAYBLEND® PC/ABS Blend	John Charles	1.412.777.2195
MAKROBLEND® PC/PET Blend	John Charles	1.412.777.2195
MAKROFOL® Polycarbonate Film	Pat Griffin	1.412.777.7453
MAKROLON® Polycarbonate	John Charles	1.412.777.2195
TEXIN® Thermoplastic Polyurethane	Jim Charron	1.412.777.2674
Product Literature	*www.bayermaterialsciencenafta.com*	1.877.229.3781
Technical Questions	*www.bayermaterialsciencenafta.com*	1.800.662.2927

BAYER REGULATORY INFORMATION

Product	Contact	Phone
Regulatory Affairs Manager	Don Naragon	1.412.777.3491
Test Data	Susan Hoag	1.412.777.2039
Material Safety Data Sheets	MSDS Coordinator	*www.bayermaterialsciencenafta.com*

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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GENERAL INFORMATION

Developmental Product Information

Developmental products (noted as such or designated by the letters DP, KU or KL in the grade name) are not considered part of the Bayer line of standard commercial products. Complete commercialization and continued supply are not assured. *The purchaser/user agrees that Bayer reserves the right to discontinue supply at any time.*

Regulatory Compliance Information

Some of the end uses of the products described in this booklet must comply with applicable regulations, such as FDA, NSF, USDA and CPSC. If you have any questions on the regulatory status of these products, contact your Bayer representative or Bayer's Regulatory Affairs Manager in Pittsburgh, Pennsylvania.

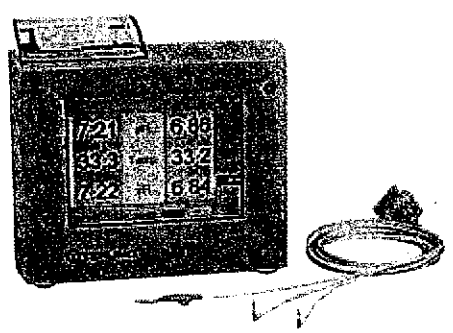
Health and Safety Information

Appropriate literature has been assembled which provides information concerning the health and safety precautions that must be observed when handling the Bayer products mentioned in this publication. Before working with any of these products, you must read and become familiar with the available information on their hazards, proper use and handling. This cannot be over emphasized. Information is available in several forms, e.g., material safety data sheets and product labels. Consult your Bayer representative or contact Bayer's Product Safety and Regulatory Affairs Department in Pittsburgh, Pennsylvania.

Technical Support

To get material selection or design assistance, just write or call and let us know who you are and what your needs are. So that we can respond efficiently to your inquiry, here are some of the points of information we might need to know: physical description of your part and engineering drawings if possible; material currently being used; service requirements, such as mechanical stress and/or strain, peak and continual service temperature, types of chemicals to which the part may be exposed, stiffness required to support the part itself or another item, impact resistance, and assembly techniques; applicable government or regulatory agency test standards; tolerances that must be held in the functioning environment of the part; and any other restrictive factors or pertinent information of which we should be aware.

In addition, we can provide processing assistance nation-wide through a network of regional Field Technical Service Representatives. We can help customers optimize the quality and performance of their parts by offering the following types of assistance: on-site processing, equipment and productivity audits, start-up and trouble-shooting support, and tool design.



Upon request, Bayer will furnish such technical advice or assistance it deems to be appropriate in reference to your use of our products. It is expressly understood and agreed that, since all such technical advice or assistance is rendered without compensation and is based upon information believed to be reliable, the customer assumes and hereby expressly releases Bayer from all liability and obligation for any advice or assistance given or results obtained. Moreover, it is your responsibility to conduct end-use testing and to otherwise determine to your own satisfaction whether or not Bayer products and information are suitable for your intended uses and applications.

For assistance, contact any of our regional sales offices listed on the back cover.

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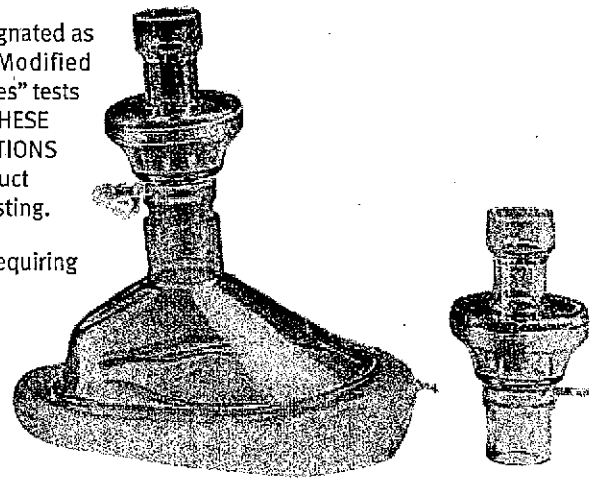
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

SUMMARY OF BAYER GUIDELINES FOR MEDICAL APPLICATION OF BAYER MATERIALSCIENCE PRODUCTS

The guidelines for using Bayer products in medical applications that are contained in this reference guide are summarized below:



1. All Bayer resins, films, etc. (hereinafter "Product(s)") designated as "medical-grade" have met the requirements of the FDA-Modified ISO 10993, Part 1 "Biological Evaluation of Medical Devices" tests with human tissue contact time of 30 days or less. ONLY THESE PRODUCTS MAY BE CONSIDERED CANDIDATES FOR APPLICATIONS REQUIRING BIOCOMPATIBILITY. No "medical-grade" Product will be available for sale until successful completion of testing.

2. Regrind resins must not be used in medical applications requiring biocompatibility.

3. It is the responsibility of the medical device, biological product or pharmaceutical manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Bayer Product, used in its final product in order to ensure safety and compliance with FDA requirements. This determination must include, as applicable, testing for suitability as an implant device and suitability as to contact with and/or storage of human tissue and liquids including, without limitation, medication, blood or other bodily fluids.

4. Under no circumstances may any Bayer Product be used in any cosmetic, reconstructive or reproductive implant applications. Nor may any Bayer Product be used in any other bodily implant applications, or any applications involving contact with or storage of human tissue, blood or other bodily fluids, for greater than 30 days, based on the FDA-Modified ISO 10993-1 tests. Furthermore, for aromatic grades of Texin® resins, such longer-term uses are not permissible also because possible hydrolysis of solid polyurethane may produce aromatic amines, such as methylene dianiline (MDA).

5. The suitability of a Bayer Product in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses or external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

6. Single-use medical devices made from a Bayer Product are not suitable for multiple uses. If the medical device is designed for multiple uses, it is the responsibility of the Manufacturer to determine the appropriate number of permissible uses by evaluating the device under actual sterilization and end-use conditions and to adequately advise and warn purchasers and users thereof.

7. The sterilization method and the number of sterilization cycles a medical device made from a Bayer Product can withstand will vary depending upon type/grade of Product, part design, processing parameters, sterilization temperature and chemical environment. Therefore, the Manufacturer must evaluate each device to determine the sterilization method and the number of permissible sterilization cycles appropriate for actual end-use requirements and must adequately advise and warn purchasers and users thereof.

8. Parts molded or extruded from Texin® resins are sterilizable using ethylene oxide, radiation or dry heat. Parts made of Texin® resins must not be sterilized using steam autoclaving or boiling water techniques. Furthermore, these sterilization methods must not be used with aromatic grades of Texin® resin because possible hydrolysis of solid polyurethane may produce aromatic amines, such as methylene dianiline (MDA).

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

K130311 Released by CDRH on 9/10/2015

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K062495 P1/2

XI. 510(k) Summary

SUBMITTER: DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02780
Tel: 508-828-3537
Fax: 508-828-3711

OCT 13 2006

CONTACT PERSON: Melanie Archer

DATE PREPARED: August 23, 2006

CLASSIFICATION NAME: Resorbable calcium salt bone void filler
Piston Syringe

PROPRIETARY NAME: HEALOS® FX Bone Graft Substitute
HEALOS® FX Graft Mixing and Delivery System

PREDICATE DEVICES: HEALOS® Bone Graft Substitute (K012751 and K043308)
Vitoss® Scaffold Foam Bone Graft Material (K032288)
Symphony® Graft Delivery System (K003286)
Harvest® Graft Delivery System (K043261)
Imbibe® II Syringe (K030208)

DEVICE DESCRIPTION:

HEALOS® FX Bone Graft Substitute:
HEALOS® FX Bone Graft Substitute ("HEALOS® FX"), combined with autogenous bone marrow, is intended for use in filling bony voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis) that are not intrinsic to the stability of the bony structure. The principal components of the HEALOS® FX Bone Graft Substitute are Type I bovine collagen and hydroxyapatite that are resorbed and remodeled into new bone as part of the natural healing process.

HEALOS® FX Graft Mixing and Delivery System:
The HEALOS® FX Graft Mixing and Delivery System is indicated for the mixing and delivery of HEALOS® FX to a surgical site.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K062455 2/2

INTENDED USE:

HEALOS® FX Bone Graft Substitute:

HEALOS® FX Bone Graft Substitute ("HEALOS FX"), combined with autogenous bone marrow, is intended for use in filling bony voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. HEALOS®FX is a bone graft substitute that is resorbed and remodeled into new bone as part of the natural healing process.

HEALOS® FX Graft Mixing and Delivery System Indications for Use:
The HEALOS® FX Graft Mixing and Delivery System is indicated for the mixing and delivery of HEALOS® FX to a surgical site.

MATERIALS:

HEALOS® FX Bone Graft Substitute:
Calcium salt with Type I bovine collagen.

HEALOS® FX Graft Mixing and Delivery System:
Makrolon Rx2530-1118, Cycolac ABS MG47MD, EPDM, Loctite cyanoacrylate, polyethylene, acrylic copolymer.

PERFORMANCE DATA:

HEALOS® FX Bone Graft Substitute:
A performance evaluation has been included to support the safety and effectiveness of HEALOS®FX compared to the predicate devices.

HEALOS® FX Graft Mixing and Delivery System:
No performance standards have been established for this type of device. The substantial equivalence of the HEALOS® FX Graft Mixing and Delivery System to the predicate devices (Symphony Graft Delivery System (K003286), Harvest Graft Delivery System (K043261), and Imbibe II Syringe (K030208) is based upon equivalence in design, principles of operation, indications and intended use.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Long Chen

Subject: 510(k) Number K072870/S1

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)?			X
Does this device include an Animal Tissue Source?			X
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number	Class*	Product Code
21 CFR 878.4400	II	NEY

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: [signature] (Branch Chief) GSD3 (Branch Code) 1/11/08 (Date)

Final Review: [signature] (Division Director) 1/14/08 (Date)

Rev. 5/30/07

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K072870/S1

Date: January 9, 2007
To: The Record
From: Long Chen, Ph.D. Chemical Engineer

Office: ODE
Division: DGRND/GSDB

510(k) Holder: FoundryNewco X, Inc., Menlo Park, CA
Device Name: **Microwave Tissue Coagulation System (MTCS)**
Contact: Mr. Gregory Mathison
Phone: (218)-387-1559
Fax: (650)-326-3108
Email: gmathison@att.net

I. Purpose

The 510(k) holder would like to introduce the subject Microwave Tissue Coagulation System (MTCS) into interstate commerce.

The Microwave Tissue Coagulation System is a microwave based tissue ablation system. It is designed to coagulate soft tissue using microwave energy.

The MTCS microwave generator operates at a frequency of 2450 MHz with a maximum power of 60 Watts using a surface contact applicator. The surface contact applicator has a suction chamber to acquire and isolate the target tissue. The applicator also has an optional surface cooling feature. There is a temperature sensor placed on the inside surface of the suction chamber to monitor the tissue surface temperature. However, according to the sponsor, this temperature sensor is not part of an active feedback mechanism. It is for information purposes only. The system is operated by setting the parameters (power and duration). The cooling feature is provided using the chiller pump that circulates the sterile saline through the MTCS applicator.

In this supplement, together with the e-mail clarification dated 1/8/2008, the sponsor has adequately addressed all deficiencies identified in the telephone hold letter dated November 20, 2007, in the following areas: substantial equivalence, performance testing - ex-vivo data, ablation probe temperature test, ablation guideline, performance testing - electrical safety, sterilization, biocompatibility, control & display, and labeling. An **SE** is recommended.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	x		
Truthful and Accuracy Statement	x		

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	Yes	No	N/A
510(k) Summary	x		
Standards Form			

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?		x	
Is the device sterile?	x	x	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	x	x	

The Microwave Tissue Coagulation System consists of a MTCS generator (non-sterile), a MTCS applicator (sterile, single use), a MTCS vacuum pump, and a MTCS chiller pump (non-sterile) and pump tubing (sterile and single use). The surface contact applicator has a suction chamber to acquire and isolate the target tissue. The applicator also has an optional surface cooling feature. There is a temperature sensor placed on the inside surface of the suction chamber to monitor the tissue surface temperature. The system is operated by setting the parameters (power and duration). The cooling feature is provided using the chiller pump that circulates the sterile saline through the MTCS applicator.

III. Indications for Use

The Microwave Tissue Coagulation System (MTCS) is intended for coagulation of soft tissue. This indication statement is similar to that of the predicates, Vivant Medical VivaWave (K011676), and Microsulis MTA System (K052919).

IV. Predicate Device Comparison

The proposed Microwave Tissue Coagulation System (MTCS) is SE in design configuration, technological characteristics, functions and intended use, indications to its predicates: VivaWave Microwave Ablation System (K011676), Microsulis Tissue Ablation (MTA) System (K052919), Radionics Cool-Tip RF System (K984552), and Afx Microwave Ablation System (K003978). The sponsor has revised the substantial equivalence table to include features and technological principles comparison (Attachment A, K072870/S1) to address the following additional features: indications for use, manual setting or automatic, software, energy, frequency, maximum power, supplied sterile, cooling, method of cooling, vacuum, monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, antenna/applicator design, operating procedure, operation mode, coagulation time, system output power, output temperature, maximum tip temperature, maximum shaft temperature, maximum coagulation cycle, and number of channel. The microwave frequency, 2450 MHz, is the same as the predicates, Microsulis Tissue Ablation (MTA) System (K052919) and Afx Microwave Ablation System (K003978). The maximum power level, 60 watts, is within the range of MTA System (100 Watts), and Afx Microwave Ablation System (75 Watts).

V. Labeling

The sponsor has provided user manuals for the MTCS generator, MTCS applicator, MTCS chiller pump (Attachment A, K072870), and MTCS vacuum pump (Attachment H, K072870/S1). The sponsor has also provided the revised package label for the MTCS applicator and MTCS pump tubing, in addition to

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

the package labels for the MTCS generator, MTCS chiller pump, and MTCS vacuum pump. They are found to be adequate.

VI. Sterilization/Shelf Life/Reuse

The MTCS generator will be provided as non-sterile. The MTCS applicator and MTCS pump tubing will be provided as sterile, for single use. They will be sterilized by EtO. According to the sponsor, the sterilization process will be validated to a SAL of 10^{-6} in accordance with ANSI/AAMI/ISO 11135. The sponsor also stated that acceptable EtO residuals levels will be in conformance with the requirements of ISO 10993-7 to meet the allowable limits for limited exposure devices as: 20 mg EtO and 12mg ECH (average daily dose). The MTCS applicator and MTCS pump tubing are not labeled "pyrogen free".

The applicator will be packaged in an industry standard thermoplastic tray with a heat seal Tyvek sterile barrier film. The shelf life will be 6 month.

1. Sterilant:	**YES**	**NO**
a. **Sterilization method** description (e.g., Steam, EtO, Radiation):	EtO	
b. **Dose**, for radiation (e.g., 25 – 50 kGy):		
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);	in conformance with the requirements of ISO 10993-7 to meet the allowable limits for limited exposure devices as: 20 mg EtO and 12mg ECH (average daily dose).	
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended (e.g., ANSI/AAMI/ISO 11135))	ANSI/AAMI/ISO 11135	
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	10^{-6}	
4. Is it labeled "Pyrogen Free"?		x
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))		
5. A description of the packaging (not including package integrity test data):	industry standard thermoplastic tray with a heat seal Tyvek sterile barrier film	

VII. Biocompatibility

The sponsor has identified the patient contact materials as: ABS, polycarbonate, Aluminium oxide, and UV adhesive. The sponsor also provides the predicates for the use of these materials in similar applications.

VIII. Software

	Yes	No
Version:		
Level of Concern:		
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

The subject device contains the hardware logic for the control and monitoring functions and features. The logic diagram, together with the device hazard analysis, is included in the supplement (Attachments F and G, K072870/S1).

VIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The sponsor certifies that their MTCS device (MTCS generator, MTCS applicator, MTCS vacuum pump, and MTCS chiller pump and connecting cables) will conform to the requirements of the following electrical safety standards prior to distribution (e-mail, 1/8/2008):

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems (1995)
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (2004)
- IEC 60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment (2006).

IX. Performance Testing – Bench

The sponsor has provided the test results for the applicator temperature measurement for the maximum power output and ablation time (60 Watts and 30 sec) (Attachment C, K072870/S1). The results indicate a maximum temperature of 26°C (78.8° F), which is within the Allowable Maximum Temperature defined in EN60601-1-1, Part 1, Section 7, Clause 42, Table Xa for the accessible surfaces of handles, knobs, grips and the like, which in Normal USE are held by the OPERATOR for short periods.

X. Performance Testing – Animal

The sponsor has provided ex-vivo animal data that demonstrate the ablation effect from the subject MTCS microwave device in three types of tissue: liver, muscle and kidney (K072870).

XI. Performance Testing – Clinical

XII. Substantial Equivalence Discussion

	Yes	No	
1. Is Product A Device	x		If **NO** = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	x		If **NO** = Stop, see 510(k) staff
3. Same Indication Statement?	x		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
5. Same Technological Characteristics?	x		If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?	x		If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification 510kProgram/0_4147/FLOWCHART 510K DECISION.PDF for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. Explain how the new indication differs from the predicate device's indication:
   Please see section III and IV

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XIII. Deficiencies

1) Substantial Equivalence

In the equivalence device comparison table (page 13), you include some of the technological characteristics such as: : indications for use, manual setting or automatic, software, energy, frequency, maximum power, supplied sterile, cooling, method of cooling, and vacuum. However, other technological characteristics and features are not adequately compared; those include, but not limited to, monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, antenna/applicator design, operating procedure (intraoperative, percutaneous), operation mode, coagulation time, system output power, output temperature, maximum tip temperature, maximum shaft temperature, maximum coagulation cycle, and number of channel, etc...

a. Please include in your comparison table the following additional technological characteristics and features, as a minimum: monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, antenna/applicator design, operating procedure (intraoperative, percutaneous), operation mode, coagulation time, system output power, output temperature, maximum tip temperature, maximum shaft temperature, maximum coagulation cycle, and number of channel.
b. Please revise the Substantial Equivalence table to include detailed information of each category and identify relevant similarities and differences.
c. Please provide additional predicate(s) for some of the different features, or
d. Please provide data and/or rationale to justify that the differences do not adversely affect the safety and effectiveness of your device.

Response:
The sponsor has revised the substantial equivalence table (Attachment A, K072870/S1) to include the comparison of following additional technological characteristics and features: monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, antenna/applicator design, operating procedure (intraoperative, percutaneous), operation mode, coagulation time, system output power, output temperature, maximum tip temperature, maximum shaft temperature, maximum coagulation cycle, and number of channel. In addition, two more predicates (Afx Microwave Ablation System, K003978, and Microtaze HS-15M Microwave Surgery Equipment, K8611904) were provided to demonstrate the substantial equivalence of the subject device.

2) Performance Testing - - Ex-Vivo Data
The tissue testing data you presented in page 11-12 is inadequate.
The ex-vivo data you provided in Figure 7 (page 12) and Attachment D is inadequate. You did not compare the histological results of the subject MTCS Generator to the predicate device(s). Please provide performance data to demonstrate the similarity of the clinical and pathological characteristics between your device and the predicate(s).

Response:
The sponsor stated that the target tissue ablation data by the predicate Vivant Vivawave (K011676) along with the ablation data by the subject MTCS device was reviewed by the pathologist, Dr. Marian Rippy, MS, DVM, PhD. He concluded that histological analysis is not necessary since the borders are clearly delineated grossly and accurate measurement of the lesion can be obtained grossly for comparison to the predicate device.
The sponsor provides additional predicate, AFx Microwave Ablation System (K003978), with the same microwave frequency 2450MHz and higher power output (75Watts vs. 60 Watts for the MTCS). Therefore, the ex-vivo data provided in Figure 7 (page 12, K072870) and Attachment D (K072870) are adequate to demonstrate the equivalence of the subject MTCS device.

3) Ablation Probe Temperature Test
Please provide bench test results that record the temperature profile of your ablation probes from the cable, handle to the applicator tip during simulation use for the maximum set time of 30 seconds activation at the maximum power of 60 Watts.

a. Please compare and provide justification that your maximum applicator tip temperature will be safe to the user or to the patient.

b. Please provide additional information in your labeling to describe the proper techniques for holding the applicator by the handle and positioning the aplicator during ablation with an illustrated diagram.
c. Please provide a warning and precaution statement to address the potential high temperature of the probe during and after use. Any undue handling or touching of the probe shaft during or following use could result in a thermal injury to the patient or user.

Response:
The sponsor has conducted the applicator temperature measurement for the maximum power output and ablation time (60 Watts and 30 sec). The results indicate a maximum temperature of 26°C (78.8° F), which is within the Allowable Maximum Temperature defined in EN60601-1-1, Part 1, Section 7, Clause 42, Table Xa for the accessible surfaces of handles, knobs, grips and the like, which in Normal USE are held by the OPERATOR for short periods.
The sponsor also included an illustration and simple instructions in the revised MTCS Applicator Instruction for Use (Attachment D, K072870/S1).

4) Ablation Guideline
You have provided the lesion sizes created by the MTCS applicator at 10, 15 and 20 seconds under 30, 50 and 60 watts (Instructions for Use, MTCS Applicator, Attachment A). This data is inadequate considering your generator output is designed for a maximum duration of 30 seconds and at a maximum power output of 60 watts (page 14, MTCS Generator User's Manual, Attachment A). Please provide the suggested lesion sizes for the whole operating range of the device.

Response:
The sponsor has revised the MTCS Applicator Instruction for Use (Attachment D, K072870/S1) to include the suggested lesion sizes of different tissues for the maximum duration of 30 seconds and at a maximum power output of 60 watts.

5) Performance Testing- Electrical Safety
Please provide the complete test results to demonstrate that your device including the MTCS generator, MTCS applicator, MTCS vacuum pump, and MTCS chiller pump and connecting cables has been evaluated for the electrical safety as well as its ability to function after exposure to environmental hazardous conditions. Recommended standards include, but not limited to, the following:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems (December, 2005)
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (March, 2007)
- IEC 60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment, March, 2007 (March, 2007).

Response:
The sponsor stated that final electrical safety, EMC, and high frequency testing will be completed prior to product release and distribution (e-mail 1/8/08).

6) Sterilization
You indicate that MTCS applicator and MTCS pump tubing will be sterilized by EtO. However, you have not provided the maximum residuals levels of ethylene oxide, ethylene chlorohydrin, and ethylene glycol. Please provide the maximum levels of residues of ethylene oxide, ethylene chlorohydrin, and ethylene glycol that will remain on the device.

Response:
The sponsor state that the acceptable EtO residuals levels will be in conformance with the requirements of ISO 1093-7 to meet the allowable limits for limited exposure devices as: 20 mg EtO and 12mg ECH (average daily dose).

7) Biocompatibility

You have provided the predicates for the use of the patient contacting materials (page 10). However, it was not clear whether the applications of the patient contacting materials in these predicates are the same. Please provide a comparison table that list the applications of the contacting material from the predicates, or please provide the following biocompatibility tests results per ISO-10993 for externally communicating devices, blood path indirect and tissue/bone/dentin communicating, limited contact duration (≤ 24 hours): cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, and hemocompatibility tests.

Response:
The sponsor has provided predicates for all patient contacting materials as listed in Attachment E (K072870/S1). The patient contacting materials include: ABS, polycarbonate, ceramic-aluminium oxide, and UV curing acrylated urethane adhesive.

9) Control & Display
You stated that the subject generator does not contain any software. However, you did not describe the mechanism that is utilized for the control and display of the parameters such as temperature, set power, timer, start/stop, etc.., as shown in the MTCS Generator User's Manual (page 5, Attachment A). Please describe in detail how these functions are accomplished. If there is any software and/or firmware being used, please provide required software documentation according to Software Guidance for FDA Reviewers and Industry in http://www.fda.gov/cdrh/ode/guidance/337.html. If hardware logic is used, please provide the Architectural Design of the hardware logic and the Device Hazard Analysis for the mitigation of potential hazards.

Response:
The sponsor has provided the hardware logic diagram for the control functions of the device (Attachment F, K072870/S1) that includes: control of power output, timer control of output delivery, temperature monitoring & display, data logging over RS232, and fault detecting & handling.
In addition, the sponsor also provided a copy of the device hazard analysis (Attachment G, K072870/S1).

10) Labeling
Please provide the following additional information:

a. user manual for the MTCS vacuum pump.
b. package labels for the MTCS generator, MTCS chiller pump, and MTCS vacuum pump.
c. the shelf life for the MTCS applicator and MTCS pump tubing in the package labels.

Response:
The sponsor has provided the user manual for the MTCS vacuum pump (Attachment H, K072870/S1) with the FDA clearance information (K021368) (e-mail, 1/8/2008).
The sponsor has provided the package labels for the MTCS generator, MTCS vacuum pump (Attachment I, K072870/S1), and MTCS chiller pump (e-mail, 1/8/2008). In addition, the sponsor has provided the updated package label for the MTCS applicator (e-mail, 1/8/2008) and MTCS pump tubing (Attachment I, K072870/S1).

XIV. Contact History

A telephone conversation with the sponsor (Mr. Gregory Mathison) followed up by an e-mail on 11/19/2007 asking for additional information.
A telephone message left with the sponsor (Mr. Gregory Mathison) followed up by an e-mail on 1/7/2008 asking for additional information.
Received sponsor's e-mail response on 1/8, and 1/9/2008 to the FDA questions dated 1/7/2008.

XV. Recommendation

Regulation Number: 21CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II

i2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Product Code: NEY

Long Chen
Lead Reviewer, GSDB/DGRND

1/9/08
Date

Neil Ogden
Branch Chief, GSDB/DGRND

1/11/08
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Chen, Long H

From: Greg Mathison [gmathison@att.net]
Sent: Wednesday, January 09, 2008 3:37 PM
To: Chen, Long H
Subject: Revised 510(k) Summary K072870
Attachments: 510(k) Summary updated.doc

Here is the revised summary with the AFX device added. Thanks for the quick call.

Sounds like you're getting close to moving this one off your desk. Let me know if you need anything else.

Best regards

Greg

Gregory J. Mathison
tel: (218) 387-1559
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14

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

510(k) Summary

General Information

Classification	Class II
Trade Name	Microwave Tissue Coagulation System (MTCS)
Submitter	Foundry Newco X, Inc. 199 Jefferson Drive Menlo Park, CA 94045 USA Tel: 650-326-2656 Fax: 650-326-3108
Contact	Steven Kim Chief Technology Officer

Intended Use

The Microwave Tissue Coagulation System (MTCS) is intended for coagulation of soft tissue.

Predicate Devices

K011676	VivaWave Microwave Ablation System
K052919	Microsulis MTA System
K984552	Radionics Cool-Tip RF System
K021368	Medela Vacuum Pump Model 30
K003978	AFX Microwave Generator

Device Description

The Microwave Tissue Coagulation System (MTCS) is designed to coagulate soft tissue using a surface contact applicator. The system consists of an applicator, external microwave generator, vacuum pump, and a cooling fluid pump and tubing. The desired power and delivery time are set manually by the operator.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The generator contains electric circuits, circuit boards, and integrated control panel. The major components of the generator are cooling fans, power supply, microwave module and the front panel/control board assembly.

The applicator is a specifically designed to deliver microwave energy at the frequency and power levels that the generator outputs. The proximal end of the applicator has a microwave connector that fits onto the generator and allows the energy to be delivered to the applicator.

Materials

All materials used in the manufacture of the MTCS are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification.

The results showed the system met specification.

Summary of Substantial Equivalence

The MTCS is equivalent to the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Chen, Long H

From: Greg Mathison [gmathison@att.net]
Sent: Tuesday, January 08, 2008 12:33 PM
To: Chen, Long H
Subject: K072870 Additional Information
Attachments: MTCS Chiller Pump Label.doc; MTCS Applicator Label.doc

Hi Long:

Thanks for your very prompt review and response to the additional information we provided for the MTCS 510(k). Per your email yesterday, please find the information requested below:

Your questions were:

I would appreciate your attention to the following additional information for the subject supplement (K072870/S1):
1) In your response to Q#5, please provide a statement that your device will conform to the following standards:
- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems (1995)
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (2004)
- IEC 60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment,(2006).

2) In your response to Q#10-a, please provide FDA clearance information for the Medela vacuum pump Model 30.
3) In your response to Q#10-b, please provide the package label for MTCS chiller pump.
4) In your response to Q#10-c, please provide the revised package label for MTCS applicator.

Response 1.

Foundry Newco X certifies that their MTCS device (MTCS generator, MTCS applicator, MTCS vacuum pump, and MTCS chiller pump and connecting cables) will conform to the requirements of the following electrical safety standards prior to distribution:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems (1995)
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (2004)
- IEC 60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment (2006).

Response 2.

The 510(k) number for the Medela vacuum pump Model 30 is K021368

Response 3.

The MTCS Chiller Pump Label is attached

Response 4:

The MTCS applicator label is attached

Please let me know if you need any additional information. Thanks again.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Br regards

Greg

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Foundry Newco X
199 Jefferson Dr.
Menlo Park, CA 94025
TEL: 650-326-2656
FAX: 650-326-3108

MTCS APPLICATOR

Tissue Acquisition Chamber:

XX mm x XX mm x XXmm

STERILE EO

DO NOT RESTERILIZE

MADE IN USA

PATENTS PENDING

CAUTION: Federal law (USA) restricts the sale, distribution and use of this device to, by or on the lawful order of a health care professional

FOUNDRY NEWCO X, INC.

This package contains (1) MTCS Applicator.

LOT XXXXXX	REF XXXXXXXX
⌛	

DRAFT

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Foundry Newco X, Inc.
199 Jefferson Dr.
Menlo Park, CA 94025
TEL: 650-326-2656
FAX: 650-326-3108

MTCS CHILLER PUMP

USE ONLY WITH MTCS APPLICATORS AND MTCS PUMP TUBING

⚠ Read Instructions Before Use

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

LOT XXXXX REF XXXXX

DRAFT

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Chen, Long H

From: Chen, Long H
Sent: Monday, January 07, 2008 1:54 PM
To: 'Greg Mathison'
Subject: RE: K072870 Responses (K072870/S1)

Greg,

I would appreciate your attention to the following additional information for the subject supplement (K072870/S1):
1) In your response to Q#5, please provide a statement that your device will conform to the following standards:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems (1995)
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (2004)
- IEC 60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment,(2006).

2) In your response to Q#10-a, please provide FDA clearance information for the Medela vacuum pump Model 30.
3) In your response to Q#10-b, please provide the package label for MTCS chiller pump.
4) In your response to Q#10-c, please provide the revised package label for MTCS applicator.

Let me know if you have any questions. Thanks.

L.
Long Chen, Ph.D.
(240)276-3628
GSDB/DGRND/ODE/FDA
long.chen@fda.hhs.gov

From: Greg Mathison [mailto:gmathison@att.net]
Sent: Friday, January 04, 2008 1:37 PM
To: Chen, Long H
Cc: 'Steven Kim'
Subject: K072870 Responses

Happy New Year !!

I hope you had a great holiday season.

The responses to your questions were sent in before the Christmas holidays. I was checking with you to make sure the responses arrived on your desk from the mail center.

Please let us know if you have any questions or would like any additional data.

Thanks again for your assistance in reviewing this application

Best regards

Greg

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Long Chen

Subject: 510(k) Number K072820

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)?			X
Does this device include an Animal Tissue Source?			X
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: (Branch Chief) GSDB (Branch Code) 11/19/07 (Date)

Final Review: (Division Director) (Date)

Rev. 5/30/07

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		**YES**	**NO**
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)			X
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?			X
3. Does this device type require a PMA by regulation? (Please see management.)			X
Questions 4-8 are intended to help you start your review:		**YES**	**NO**
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc)			X
5. a. Did the firm request expedited review? (See management.)			X
b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html)			X
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:		X
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:		X
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html)			X

Rev. 5/30/07

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K072870

Date: November 19, 2007
To: The Record
From: Long Chen, Ph.D. Chemical Engineer

Office: ODE
Division: DGRND/GSDB

510(k) Holder: FoundryNewco X, Inc., Menlo Park, CA
Device Name: **Microwave Tissue Coagulation System (MTCS)**
Contact: Mr. Gregory Mathison
Phone: (218)-387-1559
Fax: (650)-326-3108
Email: gmathison@att.net

I. Purpose

The 510(k) holder would like to introduce the subject Microwave Tissue Coagulation System (MTCS) into interstate commerce.

The Microwave Tissue Coagulation System is a microwave based tissue ablation system. It is designed to coagulate soft tissue using microwave energy.

The MTCS microwave generator operates at a frequency of 2450 MHz with a maximum power of 60 W using a surface contact applicator. The surface contact applicator has a suction chamber to acquire and isolate the target tissue. The applicator also has an optional surface cooling feature. There is a temperature sensor placed on the inside surface of the suction chamber to monitor the tissue surface temperature. However, according to the sponsor, this temperature sensor is not part of an active feedback mechanism. It is for information purposes only. The system is operated by setting the parameters (power and duration). The cooling feature is provided using the chiller pump that circulates the sterile saline through the MTCS applicator.

The sponsor did perform tissue test on ex-vivo liver, muscle, and kidney. However, without confirming the similarity of the technology characteristics with the predicate(s), these data is insufficient to support the substantial equivalence for the "soft tissue.

Furthermore, the sponsor stated that MTCS does not contain any software. However, the sponsor did not address the underlined technology used for the control and display functions and features described in the Device Description (page 5 of 15, K072870).

As a result, new deficiencies are identified in section XIII and need to be clarified.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	x		
Truthful and Accuracy Statement	x		
510(k) Summary	x		
Standards Form			

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?	x		
Is the device sterile?	x	x	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	x	x	

The Microwave Tissue Coagulation System consists of a MTCS generator (non-sterile), a MTCS applicator (sterile, single use), a MTCS vacuum pump, and a MTCS chiller pump (non-sterile) and pump tubing (sterile and single use). The surface contact applicator has a suction chamber to acquire and isolate the target tissue. The applicator also has an optional surface cooling feature. There is a temperature sensor placed on the inside surface of the suction chamber to monitor the tissue surface temperature. However, according to the sponsor, this temperature sensor is not part of an active feedback mechanism. It is for information purposes only. The system is operated by setting the parameters (power and duration). The cooling feature is provided using the chiller pump that circulates the sterile saline through the MTCS applicator.

III. Indications for Use

The Microwave Tissue Coagulation System (MTCS) is intended for coagulation of soft tissue. This indication statement is similar to that of the predicates, Vivant Medical VivaWave (K011676), and Microsulis MTA System (K052919).

IV. Predicate Device Comparison

The sponsor proposed following devices as the predicates: VivaWave Microwave Ablation System (K011676), Microsulis Tissue Ablation (MTA) System (K052919), and Radionics Cool-Tip RF System (K984552).

Although the sponsor has included in the substantial equivalence comparison table the following technological characteristics: indications for use, manual setting or automatic, software, energy, frequency, maximum power, supplied sterile, cooling, method of cooling, and vacuum. However, other technological characteristics and features are not adequately compared; those include, but not limited to, monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, antenna/applicator design, operating procedure, operation mode, coagulation time, system output power, output temperature, maximum tip temperature, maximum shaft temperature, maximum coagulation cycle, and number of channel, etc...

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V. Labeling

The sponsor has provided the user manuals for the MTCS generator, MTCS applicator, and MTCS chiller pump, as well as the package label for the MTCS applicator and MTCS pump tubing. However, the sponsor needs to provide the following additional information:

- the user manual for the MTCS vacuum pump.
- the package labels for the MTCS generator, MTCS chiller pump, and MTCS vacuum pump.

VI. Sterilization/Shelf Life/Reuse

The MTCS generator will be provided as non-sterile. The MTCS applicator and MTCS pump tubing will be provided as sterile, for single use. They will be sterilized by EtO. According to the sponsor, the sterilization process will be validated to a SAL of 10^{-6} in accordance with ANSI/AAMI/ISO 11135. However, the sponsor has not provided the maximum residuals level for the ethylene oxide, ethylene chlorohydrin, and ethylene glycol.

The applicator will be packaged in an industry standard thermoplastic tray with a heat seal Tyvek sterile barrier film. The shelf life will be 6 month. However, the sponsor has not described the packaging to be used for the MTCS pump tubing to maintain sterility.

VII. Biocompatibility

The sponsor has identified the patient contact materials as: ABS, polycarbonate, Aluminium oxide, and UV adhesive. The sponsor also provides the predicates for the use of these material. However, it was not clear whether the application of these predicates is the same.
As a minimum, the following biocompatibility tests should be conducted per ISO-10993 for externally communicating devices, blood path indirect and tissue/bone/dentin communicating, limited contact duration (≤ 24 hours): cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, and hemocompatibility tests.

VIII. Software

	Yes	No
Version:		
Level of Concern:		
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

The sponsor stated that MTCS does not contain any software. However, the sponsor did not address the underlined technology used for the control and display functions and features described in the Device Description (page 5 of 15, K072870).

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

VIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The sponsor has not provided test results for IEC 60601-1, IEC 601-1-2, and IEC60601-2-2. Recommended standards include, but not limited to, the following:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems (December, 2005)
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (March, 2007)
- IEC 60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment, March, 2007 (March, 2007).

IX. Performance Testing – Bench

The sponsor needs to provide bench test results that record the temperature profile of the device from the cable, handle to the applicator tip during simulation use for the maximum set time of 30 seconds activation at the maximum power of 60 watts and provide justification that the maximum applicator tip temperature is safe to the user or to the patient.

X. Performance Testing – Animal

The sponsor has provided ex-vivo animal data that demonstrate the ablation effect from the subject MTCS microwave device in three types of tissue: liver, muscle and kidney. However, no substantial equivalence comparison data was provided.

XI. Performance Testing – Clinical

XII. Substantial Equivalence Discussion

	Yes	No	
1. Is Product A Device	x		If **NO** = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	x		If **NO** = Stop, see 510(k) staff
3. Same Indication Statement?	x		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
5. Same Technological Characteristics?			If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?			If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification 510kProgram/0_4147/FLOWCHART 510K DECISION.PDF for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. Explain how the new indication differs from the predicate device's indication:
   Please see section III and IV

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XIII. Deficiencies

1) Substantial Equivalence
In the equivalence device comparison table (page 13), you include some of the technological characteristics such as: : indications for use, manual setting or automatic, software, energy, frequency, maximum power, supplied sterile, cooling, method of cooling, and vacuum. However, other technological characteristics and features are not adequately compared; those include, but not limited to, monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, antenna/applicator design, operating procedure (intraoperative, percutaneous), operation mode, coagulation time, system output power, output temperature, maximum tip temperature, maximum shaft temperature, maximum coagulation cycle, and number of channel, etc...

a. Please include in your comparison table the following additional technological characteristics and features, as a minimum: monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, antenna/applicator design, operating procedure (intraoperative, percutaneous), operation mode, coagulation time, system output power, output temperature, maximum tip temperature, maximum shaft temperature, maximum coagulation cycle, and number of channel.
b. Please revise the Substantial Equivalence table to include detailed information of each category and identify relevant similarities and differences.
c. Please provide additional predicate(s) for some of the different features, or
d. Please provide data and/or rationale to justify that the differences do not adversely affect the safety and effectiveness of your device.

3) Performance Testing - - Ex-Vivo Data
The tissue testing data you presented in page 11-12 is inadequate.
The ex-vivo data you provided in Figure 7 (page 12) and Attachment D is inadequate. You did not compare the histological results of the subject MTCS Generator to the predicate device(s). Please provide performance data to demonstrate the similarity of the clinical and pathological characteristics between your device and the predicate(s).

3) Ablation Probe Temperature Test

Please provide bench test results that record the temperature profile of your ablation probes from the cable, handle to the applicator tip during simulation use for the maximum set time of 30 seconds activation at the maximum power of 60 Watts.

a. Please compare and provide justification that your maximum applicator tip temperature will be safe to the user or to the patient.
b. Please provide additional information in your labeling to describe the proper techniques for holding the applicator by the handle and positioning the aplicator during ablation with an illustrated diagram.
c. Please provide a warning and precaution statement to address the potential high temperature of the probe during and after use. Any undue handling or touching of the probe shaft during or following use could result in a thermal injury to the patient or user.

4) Ablation Guideline

You have provided the lesion sizes created by the MTCS applicator at 10, 15 and 20 seconds under 30, 50 and 60 watts (Instructions for Use, MTCS Applicator, Attachment A). This data is inadequate considering your generator output is designed for a maximum duration of 30 seconds and at a maximum power output of 60 watts (page 14, MTCS Generator User's Manual, Attachment A). Please provide the suggested lesion sizes for the whole operating range of the device

5) Performance Testing- Electrical Safety

Please provide the complete test results to demonstrate that your device including the MTCS generator, MTCS applicator, MTCS vacuum pump, and MTCS chiller pump and connecting cables has been evaluated for the electrical safety as well as its ability to function after exposure to environmental hazardous conditions. Recommended standards include, but not limited to, the following:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems (December, 2005)
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (March, 2007)
- IEC 60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment, March, 2007 (March, 2007).

6) Sterilization

You indicate that MTCS applicator and MTCS pump tubing will be sterilized by EtO. However, you have not provided the maximum residuals levels of ethylene oxide, ethylene chlorohydrin, and ethylene glycol. Please provide the maximum levels of residues of ethylene oxide, ethylene chlorohydrin, and ethylene glycol that will remain on the device.

7) Biocompatibility

You have provided the predicates for the use of the patient contacting materials (page 10). However, it was not clear whether the applications of the patient contacting materials in these predicates are the same. Please provide a comparison table that list the applications of the contacting material from the predicates, or please provide the following biocompatibility tests results per ISO-10993 for externally communicating devices, blood path indirect and tissue/bone/dentin communicating, limited contact duration (≤ 24 hours): cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, and hemocompatibility tests.

9) Control & Display

You stated that the subject generator does not contain any software. However, you did not describe the mechanism that is utilized for the control and display of the parameters such as temperature, set power, timer, start/stop, etc.., as shown in the MTCS Generator User's Manual (page 5, Attachment A). Please describe in detail how these functions are accomplished. If there is any software and/or firmware being used, please provide required software documentation according to Software Guidance for FDA Reviewers and Industry in http://www.fda.gov/cdrh/ode/guidance/337.html. If hardware logic is used, please provide the Architectural Design of the hardware logic and the Device Hazard Analysis for the mitigation of potential hazards.

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

10) Labeling
Please provide the following additional information:

a. user manual for the MTCS vacuum pump.
b. package labels for the MTCS generator, MTCS chiller pump, and MTCS vacuum pump.
c. the shelf life for the MTCS applicator and MTCS pump tubing in the package labels.

XIV. Contact History

A telephone conversation with the sponsor (Mr. Gregory Mathison) followed up by an e-mail on 11/19/2007 asking for additional information.

XV. Recommendation

I recommend that this submission be placed on hold pending receipt of the response to the above questions.

Long Chen
Lead Reviewer, GSDB/DGRND

11/19/07
Date

for Neil Ogden
Neil Ogden
Branch Chief, GSDB/DGRND

11/19/07
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Chen, Long H

rom: Chen, Long H
Sent: Monday, November 19, 2007 4:59 PM
To: 'gmathison@att.net'
Subject: 510(k) submission - Microwave Tissue Coagulation System (MTCS) (K072870)

Attachments: k072870_email.1.doc

Greg,

I have enclosed a copy of the additional information request for the subject 510 (k) submission. Feel free to contact me for any further clarification.

k072870_em
l.1.doc (66 KE

Long Chen, Ph.D.
(240)276-3628
GSDB/DGRND/ODE/FDA
long.chen@fda.hhs.gov

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October 30, 2007

Mr. Gregory Mathison
FoundryNewco X, Inc., Menlo Park, CA
Ph#: (218)-387-1559
Fax#: (650)-326-3108
e-mail: gmathison@att.net

Re: 510(k) submission - Microwave Tissue Coagulation System (MTCS) (K072870)

Dear Mr. Mathison,

In reviewing the subject submission, we have the following additional questions that need to be clarified to facilitate our review process:

1) Substantial Equivalence

In the equivalence device comparison table (page 13), you include some of the technological characteristics such as: : indications for use, manual setting or automatic, software, energy, frequency, maximum power, supplied sterile, cooling, method of cooling, and vacuum. However, other technological characteristics and features are not adequately compared; those include, but not limited to, monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, antenna/applicator design, operating procedure (intraoperative, percutaneous), operation mode, coagulation time, system output power, output temperature, maximum tip temperature, maximum shaft temperature, maximum coagulation cycle, and number of channel, etc…

a. Please include in your comparison table the following additional technological characteristics and features, as a minimum: monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, antenna/applicator design, operating procedure (intraoperative, percutaneous), operation mode, coagulation time, system output power, output temperature, maximum tip temperature, maximum shaft temperature, maximum coagulation cycle, and number of channel.
b. Please revise the Substantial Equivalence table to include detailed information of each category and identify relevant similarities and differences.
c. Please provide additional predicate(s) for some of the different features, or
d. Please provide data and/or rationale to justify that the differences do not adversely affect the safety and effectiveness of your device.

3) Performance Testing - - Ex-Vivo Data

The tissue testing data you presented in page 11-12 is inadequate.
The ex-vivo data you provided in Figure 7 (page 12) and Attachment D is inadequate. You did not compare the histological results of the subject MTCS Generator to the predicate device(s). Please provide performance data to demonstrate the similarity of the clinical and pathological characteristics between your device and the predicate(s).

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3) Ablation Probe Temperature Test

Please provide bench test results that record the temperature profile of your ablation probes from the cable, handle to the applicator tip during simulation use for the maximum set time of 30 seconds activation at the maximum power of 60 Watts.

a. Please compare and provide justification that your maximum applicator tip temperature will be safe to the user or to the patient.
b. Please provide additional information in your labeling to describe the proper techniques for holding the applicator by the handle and positioning the aplicator during ablation with an illustrated diagram.
c. Please provide a warning and precaution statement to address the potential high temperature of the probe during and after use. Any undue handling or touching of the probe shaft during or following use could result in a thermal injury to the patient or user.

4) Ablation Guideline

You have provided the lesion sizes created by the MTCS applicator at 10, 15 and 20 seconds under 30, 50 and 60 watts (Instructions for Use, MTCS Applicator, Attachment A). This data is inadequate considering your generator output is designed for a maximum duration of 30 seconds and at a maximum power output of 60 watts (page 14, MTCS Generator User's Manual, Attachment A). Please provide the suggested lesion sizes for the whole operating range of the device

5) Performance Testing- Electrical Safety

Please provide the complete test results to demonstrate that your device including the MTCS generator, MTCS applicator, MTCS vacuum pump, and MTCS chiller pump and connecting cables has been evaluated for the electrical safety as well as its ability to function after exposure to environmental hazardous conditions. Recommended standards include, but not limited to, the following:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems (December, 2005)
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (March, 2007)
- IEC 60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment, March, 2007 (March, 2007).

6) Sterilization

You indicate that MTCS applicator and MTCS pump tubing will be sterilized by EtO. However, you have not provided the maximum residuals levels of ethylene oxide, ethylene chlorohydrin, and ethylene glycol. Please provide the maximum levels of residues of ethylene oxide, ethylene chlorohydrin, and ethylene glycol that will remain on the device.

7) Biocompatibility

You have provided the predicates for the use of the patient contacting materials (page 10). However, it was not clear whether the applications of the patient contacting materials in these predicates are the same. Please provide a comparison table that list the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

applications of the contacting material from the predicates, or please provide the following biocompatibility tests results per ISO-10993 for externally communicating devices, blood path indirect and tissue/bone/dentin communicating, limited contact duration (≤ 24 hours): cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, and hemocompatibility tests.

9) Control & Display

You stated that the subject generator does not contain any software. However, you did not describe the mechanism that is utilized for the control and display of the parameters such as temperature, set power, timer, start/stop, etc.., as shown in the MTCS Generator User's Manual (page 5, Attachment A). Please describe in detail how these functions are accomplished. If there is any software and/or firmware being used, please provide required software documentation according to Software Guidance for FDA Reviewers and Industry in http://www.fda.gov/cdrh/ode/guidance/337.html. If hardware logic is used, please provide the Architectural Design of the hardware logic and the Device Hazard Analysis for the mitigation of potential hazards.

10) Labeling

Please provide the following additional information:

a. user manual for the MTCS vacuum pump.
b. package labels for the MTCS generator, MTCS chiller pump, and MTCS vacuum pump.
c. the shelf life for the MTCS applicator and MTCS pump tubing in the package labels.

The subject submission will be placed on hold pending your response with the requested information. If you need more than 30 days to provide a full and complete response, you should submit a request for an extension of time to Document Mail Center (HFZ 401). For further information on how to apply for an extension and for general 510(k) information, please visit the FDA Website at: http://www.fda.gov/cdrh/devadvice/31435.html#link_6

Sincerely,

Long Chen, Ph.D.
Chemical Engineer
Phone#: (240)276-3600, Fax#: (240)276-3733
General and Surgical Devices Branch
Division of General, Restorative and Neurological Devices
FDA/ODE

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

December 20, 2007

FOUNDRY NEWCO X, INC.
199 JEFFERSON DRIVE
MENLO PARK, CA 94025
ATTN: GREGORY MATHISON

510(k) Number: K072870
Product: MICROWAVE TISSUE COAGULATION SYSTEM (MTCS)

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

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

Sincerely yours,

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Foundry Newco X, Inc.

December 19, 2007

FDA CDRH DMC
DEC 20 2007
Received

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

Re: K072870 Additional Information
Microwave Tissue Coagulation System (MTCS)

Pursuant to the letter dated November 21, 2007, Foundry Newco X is providing the attached information in response.

We consider this information confidential and request that FDA consider it as such.

The submission and attachments are submitted in duplicate as required by regulation. If you have any questions regarding this information, please contact the undersigned at your earliest convenience.

Thank you for your continued review of this application.

Sincerely,

Steven Kim
Chief Technology Officer

Submission Contact:

Gregory Mathison
Tel: (218) 387-1559
Email: gmathison@att.net

K1

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Question 1:

In the equivalence device comparison table (page 13), you include some of the technological characteristics such as: : indications for use, manual setting or automatic, software, energy, frequency, maximum power, supplied sterile, cooling, method of cooling, and vacuum. However, other technological characteristics and features are not adequately compared; those include, but not limited to, monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, antenna/applicator design, operating procedure (intraoperative, percutaneous), operation mode, coagulation time, system output power, output temperature, maximum tip temperature, maximum shaft temperature, maximum coagulation cycle, and number of channel, etc…

a. Please include in your comparison table the following additional technological characteristics and features, as a minimum: monitored parameters, display, shut-offs/alarms, antenna/applicator size, antenna/applicator use, antenna/applicator design, operating procedure (intraoperative, percutaneous), operation mode, coagulation time, system output power, output temperature, maximum tip temperature, maximum shaft temperature, maximum coagulation cycle, and number of channel.
b. Please revise the Substantial Equivalence table to include detailed information of each category and identify relevant similarities and differences.
c. Please provide additional predicate(s) for some of the different features, or
d. Please provide data and/or rationale to justify that the differences do not adversely affect the safety and effectiveness of your device.

Response 1:

The device comparison table has been updated to include the characteristics and features that you listed above. The table also includes two additional predicate devices that have similar features and functions. Some of the information on predicate devices was not available in the public domain, in which case, it was stated as such. The updated table is included in Attachment A.

Question 2:

The tissue testing data you presented in page 11-12 is inadequate.
The ex-vivo data you provided in Figure 7 (page 12) and Attachment D is inadequate. You did not compare the histological results of the subject MTCS Generator to the predicate device(s). Please provide performance data to demonstrate the similarity of the clinical and pathological characteristics between your device and the predicate(s).

Response 2:

The tissue testing provided is the same information that was provided by the predicate device from Vivant Medical. As the former Vice President of R & D at Vivant, I worked

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closely with Dr. George Mattamal during the review of K011676. Histological data was not supplied for the predicate device. Further, Dr. Marian Rippy, a noted expert in the field of pathology with specific expertise in the application of ablative technologies to target tissue, reviewed the information supplied by Vivant along with the information supplied by Foundry Newco X. Dr Rippy concluded that gross examination is by far the best means to assess energy delivery. Additionally, Dr. Rippy concluded that the amount of energy delivered by the MTCS is far less than that of the predicate devices, and that the extent of tissue damage will also be far less. Dr. Rippy's report is included as Attachment B.

Question 3:

Please provide bench test results that record the temperature profile of your ablation probes from the cable, handle to the applicator tip during simulation use for the maximum set time of 30 seconds activation at the maximum power of 60 Watts.

a. Please compare and provide justification that your maximum applicator tip temperature will be safe to the user or to the patient.
b. Please provide additional information in your labeling to describe the proper techniques for holding the applicator by the handle and positioning the aplicator during ablation with an illustrated diagram.
c. Please provide a warning and precaution statement to address the potential high temperature of the probe during and after use. Any undue handling or touching of the probe shaft during or following use could result in a thermal injury to the patient or user.

Response 3:

The MTCS Applicator does not reach harmful temperatures other than in the active zone. We performed a temperature monitor test on various locations of the Applicator, and the maximum temperature reached was 26 degrees Celsius. The summary report of the testing is included in Attachment C. For this reason, there is no need to provide a warning or precaution regards to handling the Applicator on any external surface. The only area that the user needs to keep his/her hands out of is the tissue acquisition chamber, which is already noted as a warning in the Applicator IFU. The handle of the Applicator was designed with human factors taken into consideration. It should be obvious to the user on how to hold the handle, but to make it clear, we have included an illustration and simple instructions in the Applicator IFU (Attachment D).

Question 4:

You have provided the lesion sizes created by the MTCS applicator at 10, 15 and 20 seconds under 30, 50 and 60 watts (Instructions for Use, MTCS Applicator, Attachment A). This data is inadequate considering your generator output is designed for a maximum duration of 30 seconds and at a maximum power output of 60 watts (page 14, MTCS Generator User's Manual, Attachment A). Please provide the suggested lesion sizes for the whole operating range of the device

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Response 4:

Additional testing was performed at the maximum power output of 60 watts for a duration of 30 seconds. The draft MTCS Applicator IFU was updated to include this information. An error was noticed in the draft IFU. Upon reviewing the tissue testing data, there was a measurement error on one of the settings. The lesion size for Liver without cooling was listed at 24x9x11, but it should be 17x7x11. Further testing was performed at this setting to confirm the revised lesion size. The draft IFU was also updated with this information, and a copy is included in Attachment D.

Question 5:

Please provide the complete test results to demonstrate that your device including the MTCS generator, MTCS applicator, MTCS vacuum pump, and MTCS chiller pump and connecting cables has been evaluated for the electrical safety as well as its ability to function after exposure to environmental hazardous conditions. Recommended standards include, but not limited to, the following:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems (December, 2005)
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (March, 2007)
- IEC 60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment, March, 2007 (March, 2007).

Response 5:

As stated in the 510(k) application, final electrical safety and EMC testing will be completed prior to product release and distribution. This is exactly the same as was done for the predicate device from Vivant, K011676, which Dr. Mattamal supported. Vivant completed the electrical and EMC testing after the 510(k) clearance was obtained but prior to product release. Foundry Newco X plans to follow the same path as was provided for the predicate device.

Question 6:

You indicate that MTCS applicator and MTCS pump tubing will be sterilized by EtO. However, you have not provided the maximum residuals levels of ethylene oxide, ethylene chlorohydrin, and ethylene glycol. Please provide the maximum levels of residues of ethylene oxide, ethylene chlorohydrin, and ethylene glycol that will remain on the device.

Response 6:

Acceptable EtO residual levels will be in conformance with the requirements of consensus standard ISO 10993-7: Biological Evaluation of Medical Devices Part 7

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Ethylene Oxide Sterilization Residuals. The MTCS Applicator is a "limited exposure" device in accordance with ISO 10993-1:2003, subclause 4.3 (limited exposure: devices whose single or multiple use or contact is likely to be up to 24 hours). Allowable limits for limited exposure devices are: 20 mg EtO and 12 mg ECH (average daily dose).

Verification that EtO and ECH residuals are below allowable limits shall be confirmed as part of the EtO cycle and product aeration validation. Manufactured product shall also be routinely monitored for EtO and ECH residuals (minimum quarterly).

Question 7:

You have provided the predicates for the use of the patient contacting materials (page 10). However, it was not clear whether the applications of the patient contacting materials in these predicates are the same. Please provide a comparison table that list the applications of the contacting material from the predicates, or please provide the following biocompatibility tests results per ISO-10993 for externally communicating devices, blood path indirect and tissue/bone/dentin communicating, limited contact duration ($\leq$ 24 hours): cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, and hemocompatibility tests.

Response 7:

An updated materials table is in Attachment E.

Question 8:

You stated that the subject generator does not contain any software. However, you did not describe the mechanism that is utilized for the control and display of the parameters such as temperature, set power, timer, start/stop, etc.., as shown in the MTCS Generator User's Manual (page 5, Attachment A). Please describe in detail how these functions are accomplished. If there is any software and/or firmware being used, please provide required software documentation according to Software Guidance for FDA Reviewers and Industry in http://www.fda.gov/cdrh/ode/guidance/337.html. If hardware logic is used, please provide the Architectural Design of the hardware logic and the Device Hazard Analysis for the mitigation of potential hazards.

Response 8:

The hardware logic diagram and a short explanation of the diagram are included in Attachment F. A draft Device Hazard Analysis is also included in Attachment G.

Question 9:

Please provide the following additional information:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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a. user manual for the MTCS vacuum pump.
b. package labels for the MTCS generator, MTCS chiller pump, and MTCS vacuum pump.
c. the shelf life for the MTCS applicator and MTCS pump tubing in the package labels.

Response 9:

a. The MTCS vacuum pump is the Medela vacuum pump Model 30. It may have been unclear in the original application, but the Medlea IFU was included. We include it here in this response in Attachment H.
b. Copies of package labels are in Attachment I.
c. The shelf life for the MTCS Applicator and MTCS pump tubing package is 6 months as the materials used and methods of sterilization are the same as for numerous existing medical products. The MTCS Applicator and MTCS Pump Tubing labels have been updated with the expiration date symbol (hourglass) and are included in Attachment I

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT A

DEVICE COMPARISON TABLE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Substantial Equivalence Comparison Table. K072870

Feature	MTCS	Microsulis MTA System	Vivant Medical VivaWave	Radionics Cool-Tip RF Ablation	Afx Microwave Ablation System	Microtaze HS-15M Microwave Surgery Equipment
510(k) Number	This Application	K052919	K011676	K984552	K003978	K861904
Product Code	GEI	GEI	GEI	GEI	NEY	KNS
CFR Reference	21CFR§878.4400	21CFR§878.4400	21CFR§878.4400	21CFR§878.4400	21CFR§878.4400	21CFR§876.4300
Manufacturer	Foundry Newco X, Inc.	Microsulis Americas, Inc.	Vivant Medical, Inc.	Radionics, Inc.	Afx, Inc.	Cooper Lasersonics, Inc.
Indications for Use	Indicated for coagulation of soft tissue	Indicated for intraoperative coagulation of soft tissue	Indicated for coagulation of soft tissue.	Indicated for coagulation of tissue during percutaneous, laparscopic and intraoperative procedures	Intended for the surgical ablation of the soft tissue, along with striated, cardiac and smooth muscles.	Gastrointestinal coagulation (hemostasis/ablation)
Manual or automatic	Manual setting	Manual setting	Manual setting	Manual setting	Manual setting	Manual setting
Software	No	Yes	No	No	Unknown	No
Energy	Microwave	Microwave	Microwave	RF	Microwave	Microwave
Frequency	2450 MHz	2450 MHz	915 MHz	480 KHz	2450 MHz	2450 MHz
Power - maximum	60 Watts	Unknown	60 Watts	200 Watts	75 Watts	150 Watts
Supplied Sterile	Yes – disposable hand piece	Yes – disposable hand piece	Yes – disposable probe	Yes – disposable probe	Yes – disposable probe	Yes – disposable probe
Cooling	Yes	No	No	Yes	No	No
Method of cooling	Saline flowing through Applicator	None	None	Saline flowing through tip	None	None
Vacuum	Yes	No	No	No	No	No

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Feature	MTCS	Microsulis MTA System	Vivant Medical VivaWave	Radionics Cool-Tip RF Ablation	Afx Microwave Ablation System	Microtaze HS-15M Microwave Surgery Equipment
Monitored parameters	Target tissue surface temperature – for information only. No active feedback.	Separate temperature measurement probes can be used to monitor temperature at desired locations	None	Probe tip temperature Tissue impedence	Microwave cable temperature	None
Display	Target tissue surface temperature (˚C) Set power (Watts) Set time (Seconds)	Not available in public domain	Set power (Watts) Set time (Minutes)	Set power (Watts) Set time (Seconds) RF current (amps) Tissue impedence Probe tip temperature (˚C)	Set power (Watts) Set time (Seconds) Cable temperature (˚C)	Set Power (Watts) Timer
Shut-offs/alarms	Shut offs: Broken applicator Microwave connector not securely connected to generator Thermocouple connector not securely connected to generator Faulty fuse Generator overtemp condition	Not available in public domain	Generator overtemp condition Broken applicator Applicator not properly connected to the generator.	Generator overtemp condition Broken applicator Applicator not properly connected to the generator	Generator shuts down power delivery if the "Wand" temperature exceeds 90 degrees Celsius.	Ground fault warning lamp; leakage current fault warning lamp; cooling system warning light; low output power; high output power; battery life indicator, ground fault indicator

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Feature	MTCS	Microsulis MTA System	Vivant Medical VivaWave	Radionics Cool-Tip RF Ablation	Afx Microwave Ablation System	Microtaze HS-15M Microwave Surgery Equipment
Antenna/applicator size	Head of the applicator has a footprint of approximately 6cm x 3cm The antenna itself inside the applicator is constructed of .141" (approximately 3.3mm) diameter coaxial cable Since this applicator is not designed to penetrate the target tissue, the size of the device is not relevant.	Not available in public domain	Shaft length: 7-35 cm Diameter: 1.5-3.3mm	Shaft length: 10-25 cm	Not available in public domain	Monopolar needle electrodes in 15mm, 30mm, 45mm, and 60mm lengths
Antenna/applicator use	Soft tissue coagulation	Soft tissue coagulation	Soft tissue coagulation	Soft tissue coagulation	Soft tissue coagulation including cardiac tissue	Soft tissue coagulation including gastrointestinal tissue
Antenna/applicator design	Coaxial microwave antenna	Unknown microwave antenna	Coaxial microwave antenna	RF conductive electrode	Unknown microwave antenna	Coaxial monopolar microwave antenna

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Feature	MTCS	Microsulis MTA System	Vivant Medical VivaWave	Radionics Cool-Tip RF Ablation	Afx Microwave Ablation System	Microtaze HS-15M Microwave Surgery Equipment
Operating procedure (intraoperative, percutaneous)	Intraoperative use	Intraoperative use	Not specified	Intraoperative, laparoscopic, and percutaneous	Intraoperative	Not specified.
Operation mode	Single mode: manually set power and time	Single mode: manually set power and time	Single mode: manually set power and time	Impedence control Manual control	Single mode: manually set power and time	Single mode: manually set power and time
Coagulation time	1-30 seconds set by user in 1 second intervals	Not available in public domain	1-30 minutes set by user in 1 minute intervals	0-990 seconds set by user in 10 second intervals	0-99 seconds set by user	Not available in public domain.
System output power	5-60 Watts set by user in 5 watt increments	Not available in public domain	5-60 Watts set by user in 5 watt increments	Upto 200 Watts	Upto 75 Watts	Upto 150 Watts
Output temperature	[possible measure surface temperature at the high and low settings]	Not available in public domain	N/A	N/A	N/A	N/A
Maximum tip temperature	Not Applicable	No mention of tip temperature measurement in the information available in public domain.	No mention of tip temperature measurement in the information available in public domain.	Tip temperature can be monitored. No mention of a maximum tip temperature in the information available in public domain.	No mention of tip temperature measurement in the information available in public domain.	No mention of tip temperature measurement in the information available in public domain.
Maximum shaft temperature	<30 degrees Celsius	Not available in public domain	Not available in public domain	Not available in public domain	Not available in public domain	Not available in public domain

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Feature	MTCS	Microsulis MTA System	Vivant Medical VivaWave	Radionics Cool-Tip RF Ablation	Afx Microwave Ablation System	Microtaze HS-15M Microwave Surgery Equipment
Maximum coagulation cycle	60W for 30 sec (1800 Joules)	Not available in public domain	60 watts for 30 minutes (108,000 Joules)	200 watts for 990 seconds (198,000 Joules)	75 watts for 99 seconds (7425 Joules)	The maximum duration of power not available in public domain.
Number of channels	1	1	1	1	1	1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT B

DR. RIPPY'S TISSUE REPORT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Performance Testing – Ex Vivo Data

The Sponsor adequately compared *ex vivo* data generated between their device and the predicate device by Vivant. In fact, the Sponsor's data is more thorough and contains 3 measurements from each tissue sample, including the height, depth, and width of each created lesion. Additionally, because they have incorporated a cooling mechanism in their device, the Sponsor measured the depth of surface tissue that was unaffected by various energy applications.

Histological processing of the samples with microscopic examination is not necessary since the borders are clearly delineated grossly and accurate measurements of the lesion can be obtained grossly for comparison to the predicate device. As can be seen in a comparison of the Sponsor's device to the Vivant predicate device, the lesions made by the Sponsor's device in all three tissues sampled (liver, kidney, skeletal muscle) were smaller than the predicate device and created with less energy and for a shorter amount of time. A side-by-side histological comparison cannot be made since the predicate device is not currently marketed. Use of tissues (liver, kidney, skeletal muscle) from a live animal for this type of testing is not warranted nor is it necessary to demonstrate and measure lesion size. One could not perform a histological assessment on these explanted tissues because of postmortem artifacts and the ability to clearly ascertain borders of the lesion, as it can take up to 24 hours to visualize a lesion histologically in these tissues. Therefore, a thorough gross examination with accurate measurements is the best method to assess device-induced lesion size within various tissues and compare these values to the values obtained for the predicate device.

Marian K. Rippy

Marian K. Rippy, MS, DVM, PhD
Diplomate, ACVP
Rippy Pathology Solutions, Inc.
Woodbury, MN

December 18, 2007
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT C

APPLICATOR TEMPERATURE TEST REPORT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Testing

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ATTACHMENT D

REVISED APPLICATOR IFU

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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INSTRUCTIONS FOR USE

MTCS APPLICATOR

Foundry Newco X, Inc.

199 Jefferson Dr.
Menlo Park, CA 94025
Phone: 650-326-2656
Fax: 650-326-3108

DRAFT

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MTCS APPLICATOR INSTRUCTIONS FOR USE

Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

BEFORE USING THE SYSTEM:

Please refer to Microwave Tissue Coagulation System (MTCS) Generator User Manual for detailed instructions on connecting and operating the entire system. Components of the MTCS System are designed to be used together as a single unit.

Failure to understand and follow provided instructions, may cause injury to the patient and/or user and may cause improper functioning of the system.

INTENDED USE:

- The Microwave Tissue Coagulation System (MTCS) is intended for coagulation of soft tissue.

IMPORTANT:

- The procedures should only be performed by physicians and operating room staff familiar with the equipment and techniques involved.
- The MTCS Applicators are shipped as sterile products and are intended to be used one time only. Please discard after one use. Do not attempt to resterilize.
- Product is sterile unless package has been damaged or opened.

WARNINGS AND CAUTIONS:

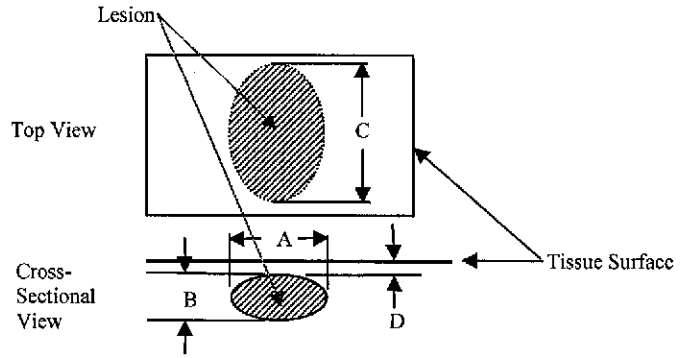
- DO NOT use on patients with heart pacemaker or other electronic device implants.
- DO NOT use in presence of flammable anesthetics or oxidizing gases (e.g. nitrous oxide, oxygen, accumulation of endogenous gases in body, etc.) due to high possibility of combustion.
- DO NOT place finger into the tissue acquisition chamber of the Applicator at any time during application of power.
- DO NOT use Applicator if there are cuts or nicks in the outer insulation of the microwave cable, as unintended thermal injury could occur.
- DO NOT apply power with Applicator not in contact with the target tissue
- Localized burns to patient or physician may result from electric currents being carried through conductive objects or from metal objects in close proximity to Probe.
- DO NOT allow patient to come in contact with grounded metal objects.
- Always use the lowest possible power necessary to achieve the desired effect.

BEFORE THE PROCEDURE:

- Refer to MTCS Generator User Manual for detailed instructions on how to activate system generator and properly connect associated components.
- Refer to the Vacuum Pump User Manual for detailed instructions on how to activate and adjust the vacuum level.
- Refer to the Chiller User Manual for detailed instructions on how to set chiller temperature and activate the flow.
- Place the Applicator on the target tissue (see figure below for proper technique of holding the handle.
- Activate the vacuum to acquire and localize the tissue. Adjust vacuum setting accordingly to user desired level.
- Activate the cooling flow for surface cooling, if desired.
- Set power and duration of treatment to desired levels.
- Confirm the generator settings before proceeding with the procedure.

Figure 1. Proper technique for holding the handle of the Applicator

NOTE:
The following tables show the approximate lesion size created by the MTCS Applicator at various power/time settings. The results are from ex-vivo liver, muscle, and kidney animal tissue models, respectively. **Lesion size may vary in clinical setting.**



All lesion size dimensions are in **millimeters**. There are 2 sets of numbers in each box. The top set is created using chilled saline at 10 degrees Celsius and flow turned on. The bottom set is without cooling flow. (AxBxC – D See figure above for details of the dimensions)

Liver	10 seconds	15 seconds	20 seconds
40 Watts	5x2x2 – 2 5x2.5x2 – 1.5	10x2.5x3 – 1.5 10x4.5x7 – 1	15x4x5 – .5 15x5x9.5 – 0
50 Watts	7.5x3x3.5 – 1.5 8.5x4x3.5 – 1	13x3.5x5.5 – .5 14x6x9 – 0	14x5.5x6.5 – .5 16x7x11 – 0
60 Watts	11x4.5x4 – 1 14x3x8 – .5	15x5x5.5 – .5 15x6x10 – 0	16x6x7 – .5 17x7x11 – 0
For the maximum energy delivery (60Watts for 30 seconds), the following lesion sizes were created 20x8x10 – 0 (with cooling) and 22x9x11.5 – 0 (without cooling).			

Muscle	10 seconds	15 seconds	20 seconds
40 Watts	9x2.5x2.5 – 2.5 10x4x5 – 0	12x5x5 – .5 15x7x6 – 0	17x6x5.5 – .5 18x6x7 – 0
50 Watts	11x4x3.5 – 1 15x6x6 – 0	14x6x5 – 0 16x6.5x7.5 – 0	16x6.5x6.5 – 0 19x7x9 – 0
60 Watts	12x5x5 – .5 14.5x6x7 – 0	16x6.5x6 – 0 18x7x8 – 0	22x8x7.5 – 0 21x9x9 – 0
For the maximum energy delivery (60Watts for 30 seconds), the following lesion sizes were created 22x9x7.5 – 0 (with cooling) and 23x10x9 – 0 (without cooling).			

Kidney	10 seconds	15 seconds	20 seconds
40 Watts	6x3x3 – 1.5 8x4x4 – 1	9x5x6 – 2 13x6.5x8.5 – 0	12x6x6 – 1 13x6x9 – 0
50 Watts	6.5x4x4 – 1 10x4x6 – .5	12x6x7 – .5 13x5x8.5 – 0	14.5x6.5x7 – .5 15x8x9.5 – 0
60 Watts	10x4.5x5.5 – 1 10x5.5x7.5 – 0	12x6.5x7.5 – 0 15x6.5x8.5 – 0	17x7x7 – 0 18x7.5x9.5 – 0
For the maximum energy delivery (60Watts for 30 seconds), the following lesion sizes were created 17.5x8.5x8.5 – 0 (with cooling) and 19x9.5x10 – 0 (without cooling).			

DURING THE PROCEDURE

- If for any reason the Applicator becomes disengaged from the tissue, discontinue energy delivery by pressing the stop button on the generator.
- If an error occurs during use, refer to MTCS Generator User Manual for troubleshooting.

AFTER THE PROCEDURE:

- Disconnect used Applicator and its cables and tubing from generator, vacuum pump, and chiller pump and discard.
- Turn off generator after procedure.

STORAGE:

- Store Probe away from moisture and direct heat.
- Discard product if damaged.

SYMBOLS USED:

⊗ .....**Single Use**

⚠ .....**Read Instructions**

STERILE EO ..... **Sterilized by EtO**

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ATTACHMENT E

UPDATE MATERIALS TABLE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Materials Table – Updated

MTCS Component	Material	Patient Contact	Predicate Device	Predicate Device Component	Predicate Device Tissue contact
Handle	ABS	Yes	SP1010 Somnoplasty Somnus Medical K982717	Device Handle	Oral cavity - surgical
Head	Polycarbonate	Yes	Realhand HD Instruments Novare Surgical Systems K071488	Surgical Instrument Handle	Blood & Tissue - surgical
Cooling Plate	Ceramic - Aluminum oxide, Al_2O_3	Yes	Biolox Alumina Ceramic Femoral Head Smith & Nephew K981847	Hip implant coating	Bone & tissue - surgical
Adhesive	UV Curing Acrylated Urethane Adhesive	Yes	InfusionCath VeinRx K052738	Bonding adhesive	Blood & tissue - surgical
Thermocouple: T-Type	UV Curing Acrylated Urethane Adhesive	Yes (thermocouple is completely encapsulated in adhesive)	InfusionCath VeinRx K052738	Bonding adhesive	Blood & tissue - surgical

The materials used in the MTCS Applicator that have patient contact have been used in previous cleared devices. The table above lists the application of each material. In every case, the materials used in the predicate devices contact surgically breached tissue, bone or blood.

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ATTACHMENT F

HARDWARE LOGIC DIAGRAM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Diagram

(b)(4) Diagram

(b)(4) Diagram

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ATTACHMENT G

HAZARD ANALYSIS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

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ATTACHMENT H

VACUUM PUMP IFU

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Important safeguards
READ ALL INSTRUCTIONS BEFORE USE
Consignes de sécurité importantes
LIRE L'INTEGRALITE DES INSTRUCTIONS D'EMPLOI AVANT UTILISATION
Instrucciones de seguridad importantes
LEA TODAS LAS INSTRUCCIONES ANTES DE USAR EL BASIC 30

When using electrical devices, basic safety precautions should always be followed, including the following:
Lors d'emploi d'appareils électriques, respecter le respect d'un certain nombre de consignes de sécurité de base, notamment les suivantes:
Cuando emplea dispositivos eléctricos hay que observar siempre unas precauciones básicas, entre otras las siguientes:

The Basic 30 may only be operated by persons qualified in medical applications.
Le Basic 30 est destiné à l'aspiration de liquides, à usage en milieu médical.
El Basic 30 sólo puede ser utilizado por profesionales de aplicaciones médicas.

The Basic 30 is conceived for suctioning bodily fluids in the medical area.
Le Basic 30 est destiné à l'aspiration de liquides, à usage en milieu médical.
El Basic 30 está concebido para succionar los líquidos del organismo en el área médica.

The device should not be used for suctioning explosive, flammable or corrosive gases/fluids.
L'appareil ne doit pas servir à l'aspiration de gaz/de liquides explosifs, inflammables ou corrosifs.
Este dispositivo no debe ser utilizado para succionar explosivos, líquidos inflamables o gases/líquidos corrosivos.

The connecting tubing which is delivered with the device should never come into direct contact with the suction area.
A suction catheter must always be used.
Le tuyau de raccordement fourni avec l'appareil ne doit jamais entrer en contact direct avec la zone d'aspiration.
Un cathéter d'aspiration doit toujours être utilisé.
Los tubos de conexión que se suministran con el dispositivo nunca deben entrar en contacto con el área de succión.
Siempre hay que utilizar un catéter de succión.

Before connecting with the electrical voltage, please check whether the voltage indicated on the identification plate corresponds with the voltage you have.
Avant le branchement électrique, vérifiez que le voltage indiqué sur la plaque d'identification correspond bien à votre voltage.
Antes de conectar con la red eléctrica, compruebe si la tensión indicada en la placa de identificación corresponde con la tensión de la red disponible.

Pull the power supply plug out of the socket before cleaning the device.
Débranchez l'appareil de la prise de courant avant de le nettoyer.
Antes de limpiar el dispositivo retire el enchufe.

Never pull the plug out of the outlet by tugging on the electrical cord.
Ne débranchez jamais l'appareil de la prise de courant en tirant sur le câble d'alimentation.
Nunca retire el enchufe tirando del cable.

Keep power cord away from heated surfaces.
Veillez bien à ce que le câble d'alimentation n'entre pas en contact avec des surfaces chaudes.
Coloque el cable lejos de las superficies calientes.

Avoid wetness at the plug and on/off switch.
Evitez tout contact de l'eau avec la fiche d'alimentation et le bouton Marche/Arrêt.
Proteja el cable y el interruptor de puesta en marcha contra la humedad.

In each of the following cases, the device must not be put into operation and has to be repaired by customer service.
Si vous vous trouvez dans l'un des cas ci-dessous, ne pas le mettre en marche et le faire réparer par le service après-vente.
En todos los casos siguientes no se debe poner en funcionamiento el Basic 30 y se enviará al servicio al cliente para reparación.

If the power cord or plug are damaged.
Câble ou fiche d'alimentation endommagés.
Cuando esté dañado el cable o el enchufe.

If it has been dropped or damaged.
Appareil tombé ou endommagé.
Cuando se haya caído o haya sido dañado.

If it is not working properly.
Appareil ne fonctionnant pas correctement.
Cuando no funcione adecuadamente.

If the device indicates obvious safety hazards.
Appareil présentant manifestement de sérieux risques pour la sécurité.
Cuando indique evidentes riesgos en cuanto a seguridad.

The Basic 30 is a high-quality secretion aspirator developed for medical applications. Its well-proven piston/cylinder system guarantees maximum suction performance and quiet, dependable operation. Additional advantages of the Medela secretion aspirators are: user-friendliness, simple cleaning and safety features.
The Basic 30 is universally applicable in hospitals, private practices and nursing homes, etc. The pump is highly suitable for suction applications involving surgical fluids, blood, secretions and tissue (including bone) in emergency rooms, tracheal hygiene, wound or thorax drainage as well as endoscopy. In addition, the Basic 30 is also used in dentistry, on ENT wards, in doctors' offices and many other areas of medicine. A comprehensive range of accessories makes the Basic 30 ideally suited to a wide range of medical applications. Contact us – we will be pleased to advise you!

Le Basic 30 est un aspirateur de mucosités de très haute qualité destiné au secteur médical. Son système de piston/cylindre éprouvé est synonyme d'extrême puissance d'aspiration et garantit un fonctionnement silencieux et d'une grande fiabilité. Les autres atouts des aspirateurs de mucosité Medela sont les suivants: simplicité d'emploi, facilité de nettoyage et haut niveau de sécurité.
Le Basic 30 est un aspirateur de mucosités universel trouvant son application dans les hôpitaux, les cabinets privés, les centres de soins, etc. Conçu pour aspirer aussi bien les liquides chirurgicaux, le sang, les sécrétions que les tissus (y compris osseux) aux soins intensifs, il est également utilisé pour assurer l'hygiène trachéale, le drainage des plaies et le drainage thoracique. Le Basic 30 est par ailleurs employé en endoscopie, en médecine dentaire, dans les salles ORL et les cabinets en général et s'avère indispensable dans bien d'autres secteurs médicaux.
Contactez-nous – nous nous ferons un plaisir de vous conseiller!

El Basic 30 es un aspirador de secreciones para aplicaciones médicas, de gran calidad. Su bien demostrado sistema garantiza la máxima succión y un funcionamiento fácil y seguro. Otras ventajas de este aspirador de secreciones de Medela son la comodidad para el usuario, la sencillez de la limpieza y sus características de seguridad.
El Basic 30 es universalmente aplicable en hospitales, medicina privada, sanatorios, etc. La bomba es muy adecuada para aplicaciones de succión en relación con líquidos resultantes de operaciones quirúrgicas, sangre, secreciones y tejidos (incluidos los huesos) en salas de urgencias, higiene de la traquea, drenaje de heridas o de tórax. Así como endoscopia. Además, el Basic 30 se utiliza en odontología, y otorrinolaringología, en consultas de médicos y en muchos otros campos de la medicina.
Póngase en contacto con nosotros – ¡tendremos mucho gusto en asesorarle!

Accessories • Accessoires • Accesorios

Medela's extensive range of disposable and reusable accessories
La vaste gamme d'accessoires Medela, réutilisables ou à usage unique
El amplio surtido de accesorios de Medela con sistema desechable o de uso múltiple

basic 30

Before use, always check for correct operation!
Toujours vérifier le bon fonctionnement de l'appareil avant utilisation!
Es imprescindible probar el funcionamiento antes del uso!

Select maximum vacuum
Sélectionner la dépression maximale
Seleccionar el nivel máximo de vacío

Seal off the suction connection
Obturer le raccord de la sortie aspiration
Cerrar la conexión de aspiración

Maximum vacuum according to technical specifications
Dépression maximale selon les caractéristiques techniques
Vacío máx. según especificaciones técnicas

+ 2000 m – 66 kPa
+ 1000 m – 75 kPa
+ 500 m – 80 kPa
0 m – 85 kPa

Adjust the vacuum for use
Réglage de la puissance d'aspiration
Regular el vacío para el uso

medela

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Troubleshooting • Dépannage • Resolver problemas

Motor not running
Moteur ne fonctionne pas
El motor no funciona

Voltage
Tension
Tensión de la red

Switched on
Sous tension
Connect.

Fuse
Fusible
Fusible

Insufficient vacuum
Vide est insuffisant
Vacio insuficiente

Position of regulator
Position du régulateur
Posición de ajuste

Tubing
Tuyaux
Tubos flexibles

Plug-in connections
Raccords
Conexiones de enchufe

Overflow protection device
Sécurité de trop-plein
Protección antirebase

Secretion container, lid, seals
Collecteur de mucosité, couvercle, joints
Colector de secreción, tapa, juntas

Cracks – brittle areas – blockage
Fissures – zones rugueuses – engorgement
Grietas – partes quebradizas – obstrucción

Technical specifications • Caractéristiques techniques • Especificaciones técnicas

basic 30

high vacuum
vacuum: –85 kPa / –638 mmHg

high flow
flow: 30 l/min.

230 – 240 V	50 Hz	110 W	
230 – 240	60	110	
100 – 120 V	50 Hz	110 W	
100 – 120	60	110	

T 1.25A 5x20 230 – 240 V
T 3.15A 6.3x32 100 – 120 V

965 510 480 mm
290 305 325 mm

16 kg
10 kg

Operation / Fonctionnement / Funcionamiento: +10 … +40 °C
Transport/Storage / Transport/Stockage / Almacenar/Transportar: –20 … +60 °C

Operation / Fonctionnement / Funcionamiento: 30 … 75 %
Transport/Storage / Transport/Stockage / Almacenar/Transportar: 10 … 90 %

kPa

MDD (93/42 EEC) class IIa
CLASS
IPX1

ISO 9001
ISO 13485
CE (93/42/EEC) 0123

Serial number

Date of purchase

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Safety instructions & Guarantee • Consignes de sécurité & Garantie • Indicaciones de seguridad & Garantía

This device complies with IEC60601-1-2: "Medical electrical equipment - Electromagnetic compatibility" and is therefore unlikely to interfere with other electrical equipment. In case there is interference (which can be determined by disconnecting the device from the mains supply), try the following: Reorienting or relocating the device with respect to the other device or connecting the device's power cord to another power outlet.

Usage — The appliance may only be operated by persons qualified in medical applications and familiar with in-house hygiene guidelines.

Mains voltage — Separation by unplugging the power cord.

Overflow — Contact your service center immediately. Work in accordance with the Service Manual.

Routine inspection — According to the service manual – once a year.

Disposal — The unit is made of metals and plastics and may only be disposed of in accordance with local regulations. The unit must be disabled before disposal.

Warranty — 5-year warranty from the date of delivery for the unit. The manufacturer is not liable for any damage or consequential damage caused by incorrect operation, inappropriate usage as well as use by unauthorized persons. Routine inspections and servicing work must only be carried out by personnel authorized by Medela.

Cet appareil [illegible] au critère IEC60601-1-[illegible] équipement médical électrique – compatibili[illegible] magnétique" et il n'est [illegible] probable qu'il interfère avec des d[illegible] électriques. En cas d'in[illegible] qui peut être identifiée en déconnectant l'appareil de la source principale, procéder comme suit: réorienter ou relocaliser l'appareil par rapport à l'autre dispositif, ou connecter le câble électrique de l'appareil à un autre source de courant.

Utilisation — L'appareil ne doit être utilisé que par des personnes disposant des connaissances médicales requises et parfaitement informées des règles d'hygiène en vigueur sur le site.

Tension — Mettre l'appareil hors tension et débrancher le cordon d'alimentation.

Trop plein — Informer immédiatement le service technique. Se référer impérativement au manuel de service.

Contrôle de routine — Effectuer une fois par an, conformément aux Instructions de service.

Recyclage — L'appareil est constitué de composants en métal ou en plastique qui peuvent être recyclés selon la réglementation locale en vigueur. Ne pas oublier de rendre auparavant l'appareil inutilisable.

Garantie — 5 ans à partir de la date de départ usine pour l'appareil. Le fabricant exclut toute responsabilité quant à d'éventuels dommages directs ou indirects dus à un maniement ou une utilisation impropre de l'appareil, ou à des interventions effectuées par des personnes non autorisées. Les contrôles de routine et les réparations doivent exclusivement être effectués par des techniciens autorisés par le constructeur.

Esta unidad cumple con la norma IEC60601-1-2: "Equipo eléctrico médico – Compatibilidad electromagnética" y por ello es muy poco probable que interfiera con otro equipo eléctrico. En el caso de que se produzcan interferencias (lo cual se puede determinar desconectando la unidad de la fuente de alimentación) intente Vd. la solución siguiente: Orientar o colocar de distinta manera la unidad en relación con el otro equipo o enchufar el cable de la unidad en una toma distinta de la anterior.

Uso — El aparato sólo debe ser manejado por personas que cuentan con la cualificación necesaria para usos medicinales y están familiarizadas con las disposiciones internas del establecimiento en materia de higiene.

Corriente eléctrica — Apagado por desenchufe del cable de alimentación.

Rebose — Informar al servicio de reparación inmediatamente. Trabajar según instrucciones de servicio.

Control rutinario — Según las instrucciones de servicio - realizar una vez al año.

Eliminación — El aparato está formado por piezas de metal y plástico. Eliminar respetando las disposiciones locales. Antes de su eliminación, hacer inutilizable el aparato.

Garantía — 5 años de garantía para el aparato a partir de la fecha de compra. La garantía no es válida para daños inmediatos o accesorios debidos a un manejo inadecuado, un uso no conforme a lo previsto o si el aparato fue manejado por personas no autorizadas. Los controles rutinarios y los trabajos de reparación deben ser realizados exclusivamente por especialistas o centros de servicio autorizados por Medela.

CLASSIFIED c UL us
Medical Electrical Equipment,
Model Basic 30
CLASSIFIED WITH RESPECT TO ELECTRIC SHOCK, FIRE, MECHANICAL AND OTHER SPECIFIED HAZARDS ONLY
IN ACCORDANCE WITH U. 2601-1 AND CAN/CSA C22.2 NO. 601.1, 22.9

Check / Contrôle / Control

Please see accompanying papers / Respecter les consignes des documents d'accompagnement / Consultar documentación adjunta

AP des appareils / Appareil de classe AP / Aparato de la clase AP

Alternating current / Courant alternatif / Corriente alterna

IPX1 Splashproof / Protégé contre les projections d'eau / Protegido contra el goteo de agua

Potential equalization / Équilibrage de potentiel / Compensación de potencial

Type CF / Type CF / Tipo CF

Protection class II (double insulation) / Appareil de classe II (double isolation) / Clase de protección II (aislamiento doble)

Contact your service center / Contacter le point SAV / Informar al servicio de reparación

Valid from • Valable à partir de • Válido a partir de • 01-2005

Subject to change / Sous réserve de modifications techniques / Sin reserva de modificaciones técnicas

MEDELA FLUID MANAGEMENT SYSTEM
THE INNOVATIVE SOLUTION FOR THE FUTURE

INSTRUCTIONS FOR USE
MODE D'EMPLOI
INSTRUCCIONES DE USO

basic 30

medela

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

ATTACHMENT I

LABELING

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

MTCS Generator Label

Foundry Newco X, Inc.
199 Jefferson Dr.
Menlo Park, CA 94025
TEL: 650-326-2656
FAX: 650-326-3108

MTCS Generator

USE ONLY WITH MTCS APPLICATORS

⚠ Read Instructions Before Use

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY

OR ON ORDER OF A PHYSICIAN

LOT XXXXX REF XXXXX

DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

MTCS Vacuum Pump Label

Foundry Newco X, Inc.
199 Jefferson Dr.
Menlo Park, CA 94025
TEL: 650-326-2656
FAX: 650-326-3108

MTCS Vacuum Pump

USE ONLY WITH MTCS APPLICATORS

⚠ Read Instructions Before Use

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY

OR ON ORDER OF A PHYSICIAN

LOT XXXXX REF XXXXX

DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-3311; Released by CDRH on 9/10/2015

MTCS Pump Tubing Label

Foundry Newco X, Inc.
199 Jefferson Dr.
Menlo Park, CA 94025
TEL: 650-326-2656
FAX: 650-326-3108

MTCS pump tubing

REF XXXXX

USE ONLY WITH MTCS CHILLER PUMP XXXXXX

Read Instructions Before Use

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY

OR ON ORDER OF A PHYSICIAN

STERILE EO

SINGLE USE ONLY
DO NOT RESTERILIZE

CONTENTS STERILE IF PACKAGE
is unopened and undamaged

This package contains (1) MTCS Pump Tubing

LOT XXXXX	REF XXXXX
⌛	

DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118