

Cambridge Endoscopic Devices, Inc.
119 Herbert Street
Framingham, MA 01702

KO 61425

**510K Summary of Safety and Effectiveness
May 17, 2006**

Page 1 of 2

1. **Sponsor Name**
Cambridge Endoscopic Devices, Inc.
2. **Device Name**
Proprietary Name: pureWrist™ electrocautery laparoscopic instruments
Common/Usual Name: Electrosurgical cutting and coagulation device and accessories
3. **Identification of Predicate or Legally Marketed Device**
The Cambridge Endoscopic Devices, Inc. pureWrist™ electrocautery laparoscopic instruments are substantially equivalent to the Ethicon Endo-Surgery, Inc. ENDOPATH® Endoscopic Instruments cleared and under K984240.
4. **Device Description**
The pureWrist™ electrocautery laparoscopic instruments are sterile, single use disposable instruments for use through appropriately sized surgical trocars. The instruments consist of a rotating insulated shaft with a 5mm diameter. The distal end of the shaft has the respective end effector attached (scissors, dissector, or hook). The proximal end of the shaft is attached to an ergonomically shaped handle with a rotating knob that allows the shaft to rotate 360 degrees in either direction. The handle contains the actuation mechanism for the respective end effector. The lever on the handle is compressed and released to activate the instrument jaws or scissor blades. Each instrument has a monopolar cautery connector that extends from the bottom of the handle. The connector is used for electrosurgery when properly attached to a standard cautery cable and proper generator.
5. **Intended Use**
The pureWrist™ electrocautery laparoscopic instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transection of tissue.

Cambridge Endoscopic Devices, Inc.
119 Herbert Street
Framingham, MA 01702

K061425

510K Summary of Safety and Effectiveness (Continued)
May 17, 2006

Page 2 of 2

6. Comparison of Technological Characteristics

The pureWrist™ electrocautery laparoscopic instruments have the same technological characteristics as the predicate devices. Each of the devices are scissors, graspers, or dissectors that coagulate tissue using monopolar technology. Each use sharp objects to permit the surgeon to cut or dissect tissue. Each of the devices are connected to the same or similar electrosurgical generators and use similar power ranges for operation. The devices have the same intended use, indications for use, technological features including similar design, performance, and material characteristics which further supports the concept of substantial equivalence.

7. Performance Testing

Pre-clinical testing was used to evaluate performance to ensure that the device can be used as designed. The testing evaluated ergonomics of the handle and rotating knob, tissue trauma, grasping and dissecting ability, and electrical insulation requirements. The studies demonstrated acceptable reliability and design performance relative to the predicate device.

8. Statement of Equivalency

Based on the design and intended use, the Cambridge Endoscopic Devices, Inc. pureWrist™ electrocautery laparoscopic instruments are substantially equivalent to the Ethicon Endo-Surgery, Inc. ENDOPATH® instruments cleared under K984240.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 2006

Cambridge Endoscopic Devices, Inc.
% Mr. Jacob Jacobson
Chairman
119 Herbert Street
Framingham, Massachusetts 01752

Re: K061425

Trade/Device Name: pureWrist™ Electrocautery Laparoscopic Instrument
Regulatory Number: 21 CFR 878.4400
Regulatory Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 17, 2006
Received: May 24, 2006

Dear Mr. Jacobson:

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.

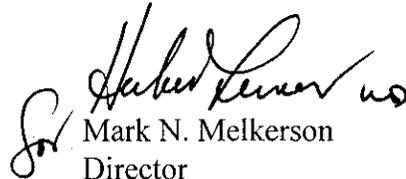
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 -- Mr. Jacob Jacobson

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

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

Enclosure

Indications for Use

510(k) Number (if known): ~~Not Assigned~~ K061425

Device Name: pureWrist™ Electrocautery Laparoscopic Instruments

Indications for Use:

The pureWrist™ electrocautery laparoscopic instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transection of tissue.

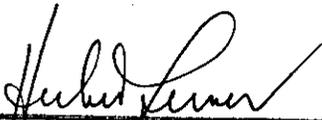
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(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

Page 1 of 1

510(k) Number K061425

K061425/A1

CAMBRIDGETMENDO

Aug 7, 2006

TO:

General Surgery Devices Branch
DGRND/ODE/CDRH/FDA
9200 Corporate Blvd.
Rockville, MD20850

FROM:

Jacob L. Jacobson
Cambridge Endoscopic Devices, Inc.
119 Herbert St., Suite 103
Framingham, MA 01702
(508) 302-1402, ext. 102

RECEIVED
MAY 10 2006
CDRH/ODE

RE: Additional Documentation for 510k Notification # K061425

COMMENTS:

Enclosed please find hard copies of the following documents requested by Dr. George Mattamal:

- 1) Addendum to 510k Notification #K061425 (Summary of Pre-clinical Animal Trials)
- 2) Revised IFU for pureWrist Scissors
- 3) Revised IFU for pureWrist Dissector
- 4) Revised IFU for pureWrist Hook

K12 1

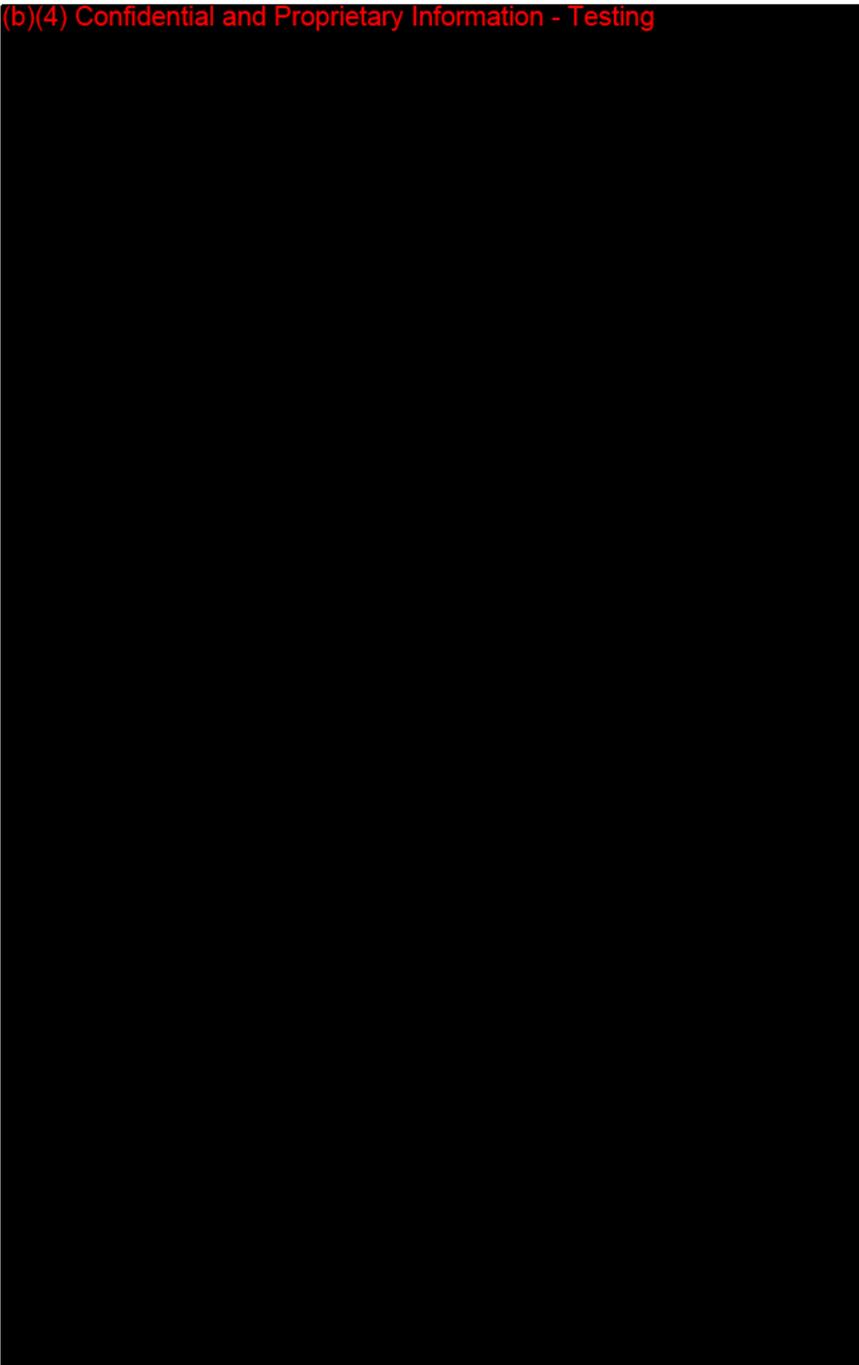
Cambridge Endoscopic Devices, Inc.

Aug. 4, 2006

Addendum to 510k Notification # K061425

SUBJECT: Summary of Results of Pre-clinical Animal Trials

(b)(4) Confidential and Proprietary Information - Testing



CONCLUSION:

Product exceeded surgeons' expectations for dissection, grasping and electrosurgery. Product met expectations for cutting.

CAMBRIDGEENDO™

pureWrist™ Scissors

Diameter: 5 mm, Usable Length: 34 cm

Reorder Number: PW1101-01



BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT

This book is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested, and manufactured for single patient use only. Reuse or reprocessing may lead to device failure and subsequent patient injury. Reprocessing and/or reesterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess, or reesterilize this device.

DESCRIPTION

The CambridgeEndo™ pureWrist™ Scissors, with a 5 mm diameter insulated shaft and 34 cm usable length, is designed for use through trocars that accommodate 5 mm devices. This device can be used for monopolar cautery when attached to an appropriate electrocautery generator via the male banana plug on the bottom of the handle. Articulation of the device's handle results in corresponding motion of the articulating tip. The articulating tip may also be rotated independently of the handle using the axial rotation knob at the distal end of the handle. The tip may be straight or in any articulated position when rotated.

INDICATIONS

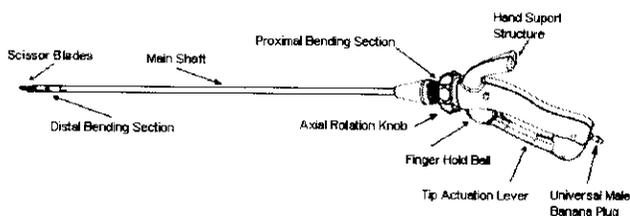
The CambridgeEndo™ pureWrist™ Scissors 5 mm single use instrument with monopolar cautery has application in a variety of minimally invasive procedure to facilitate mobilization, transection, and dissection of tissue.

CONTRAINDICATIONS

1. The pureWrist™ Scissors single use instrument with monopolar cautery is NOT intended for contraceptive coagulation of fallopian tissue, but may be used to achieve hemostasis following transection of the fallopian tube.
2. The device is intended for use only as indicated.

WARNINGS AND PRECAUTIONS

1. User should be trained in the use of the device before using in a surgical procedure.
2. Prior to inserting and removing device through a trocar, ensure that the scissor blades are closed and the distal tip is straight.
3. Only physicians having adequate training and familiarity with endoscopic techniques should perform endoscopic procedures. Consult the medical literature relative to techniques, complications, and hazards prior to performing endoscopic procedures.
4. A thorough understanding of the principle and techniques involved in electro-surgical procedures is necessary to avoid shock and burn hazard to both patient and user. Verify compatibility of instrumentation to ensure that electrical isolation or grounding is not compromised.
5. Do not use power settings that may result in more than 3000 Volts being delivered to the pureWrist™ Scissors. Excessive power levels may result in instrument malfunctions and possible patient or user injury.
6. The instrument is not intended for use when minimally invasive techniques are contraindicated.
7. This device is provided STERILE and is intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT REUSE, REPROCESS, OR RESTERILIZE THIS DEVICE.



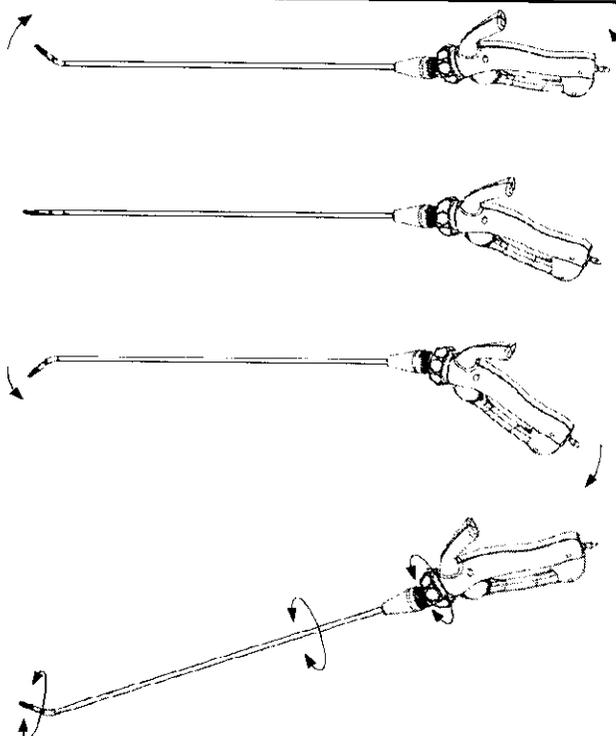
SCHEMATIC VIEW

- Tip (Scissor Blades) – Used for transection and blunt dissection of tissue
- Distal Bending Section – Provides articulation of the distal tip
- Main Shaft – Rigid insulated shaft
- Proximal Bending Section – Articulates the distal bending section
- Axial Rotation Knob – Allows user to rotate shaft independent of handle

- Jaw Actuation Lever – Used to open and close the scissor blades
- Handle – User holds the device here

ELECTROCAUTERY COMPATIBILITIES

The pureWrist™ Scissors are compatible with the following manufacturer's electro-surgical generators: Valleylab, Conmed, and Circon.



MOTION

- Upward articulation of the handle relative to the main shaft causes corresponding upward articulation of the tip relative to the main shaft.
- When the handle is straight/in line with the main shaft, the tip is also straight/in line with the main shaft.
- Axial rotation while the tip is articulated causes the tip to rotate about its center axis, while remaining articulated.
- Articulating the handle in any direction (upwards, downwards, or sideways) relative to the main shaft causes corresponding articulation of the tip relative to the main shaft.

INSTRUCTIONS FOR USE

1. If the electrocautery function of the device will be used, connect to an appropriate monopolar generator using a standard cautery cable attached to the male banana plug at the back of the handle.
2. Prior to inserting the device through a trocar, ensure that the scissor blades are closed by depressing the *Tip Actuation Lever* and ensure that the distal tip is straight relative to the main shaft.
3. Once the device is inside the body, the blades can be opened and closed by depressing and releasing the *Tip Actuation Lever*.
4. Tip articulation can be obtained by articulating the handle relative to the main shaft.
5. Tip rotation can be obtained by rotating the *Axial Rotation Knob* relative to the handle.
6. Prior to removing the device from the trocar, ensure that the blades are closed by depressing the *Tip Actuation Lever* and ensure that the distal tip is straight relative to the main shaft.



Sterile R



**STORE AT ROOM TEMPERATURE.
AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.
DO NOT EXPOSE TO TEMPERATURES ABOVE 130°F (54°C).**

CAUTION: Federal (USA) law restricts this device for sale and use by, or on the order of, a physician.

*Trademark
US Patents Pending
Manufactured in the USA for: Cambridge Endoscopic Devices, Inc., Framingham, MA 01702

CB2124-01 Rev R01

CAMBRIDGEENDO™

pureWrist™ Dissector

Diameter: 5 mm, Usable Length: 34 cm

Reorder Number: PW1201-01

- Tip Actuation Lever – Used to open and close the jaws
- Handle – User holds the device here

ELECTROCAUTERY COMPATIBILITIES

The pureWrist™ Dissector is compatible with the following manufacturer's electrocautery generators: Valleylab, Conmed, and Circon.



BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT

This book is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested, and manufactured for single patient use only. Reuse or reprocessing may lead to device failure and subsequent patient injury. Reprocessing and/or reesterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess, or reesterilize this device.

DESCRIPTION

The CambridgeEndo™ pureWrist™ Dissector, with a 5 mm diameter insulated shaft and 34 cm usable length, is designed for use through trocars that accommodate 5 mm devices. This device can be used for monopolar cautery when attached to an appropriate electrocautery generator via the male banana plug on the bottom of the handle. Articulation of the device's handle results in corresponding motion of the articulating tip. The articulating tip may also be rotated independently of the handle using the axial rotation knob at the distal end of the handle. The tip may be straight or in any articulated position when rotated.

INDICATIONS

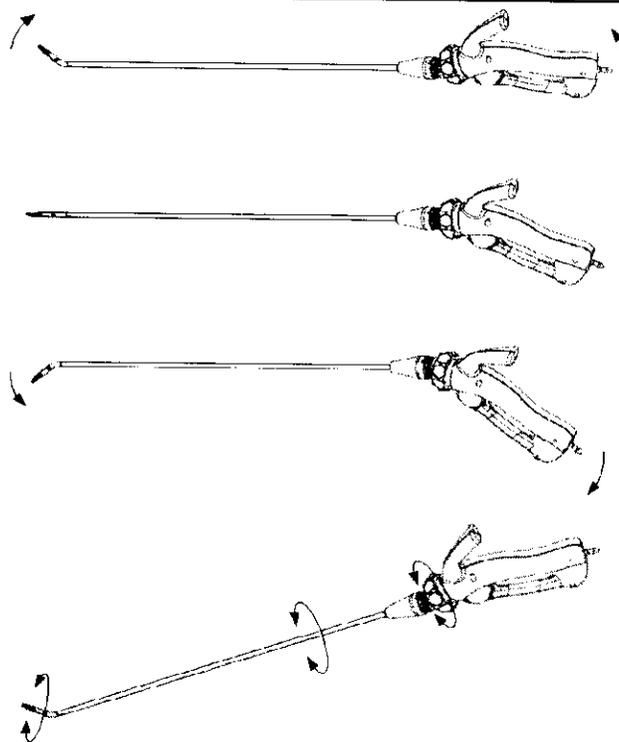
The CambridgeEndo™ pureWrist™ Dissector 5 mm single use instrument with monopolar cautery has application in a variety of minimally invasive procedure to facilitate grasping, mobilization, and dissection of tissue.

CONTRAINDICATIONS

1. The pureWrist™ Dissector single use instrument with monopolar cautery is NOT intended for contraceptive coagulation of fallopian tissue, but may be used to achieve hemostasis following transection of the fallopian tube.
2. The device is intended for use only as indicated.

WARNINGS AND PRECAUTIONS

1. User should be trained in the use of the device before using in a surgical procedure.
2. Prior to inserting and removing device through a trocar, ensure that the jaw is closed and the distal tip is straight.
3. Only physicians having adequate training and familiarity with endoscopic techniques should perform endoscopic procedures. Consult the medical literature relative to techniques, complications, and hazards prior to performing endoscopic procedures.
4. A thorough understanding of the principle and techniques involved in electrocautery procedures is necessary to avoid shock and burn hazard to both patient and user. Verify compatibility of instrumentation to ensure that electrical isolation or grounding is not compromised.
5. Do not use power settings that may result in more than 3000 Volts being delivered to the pureWrist™ Dissector. Excessive power levels may result in instrument malfunctions and possible patient or user injury.
6. The instrument is not intended for use when minimally invasive techniques are contraindicated.
7. This device is provided STERILE and is intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT REUSE, REPROCESS, OR RESTERILIZE THIS DEVICE.

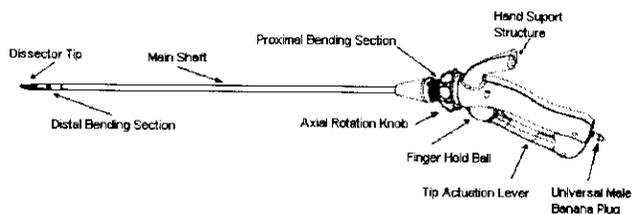


MOTION

- Upward articulation of the handle relative to the main shaft causes corresponding upward articulation of the tip relative to the main shaft.
- When the handle is straight/in line with the main shaft, the tip is also straight/in line with the main shaft.
- Axial rotation while the tip is articulated causes the tip to rotate about its center axis, while remaining articulated.
- Articulating the handle in any direction (upwards, downwards, or sideways) relative to the main shaft causes corresponding articulation of the tip relative to the main shaft.

INSTRUCTIONS FOR USE

1. If the electrocautery function of the device will be used, connect to an appropriate monopolar generator using a standard cautery cable attached to the male banana plug at the back of the handle.
2. Prior to inserting the device through a trocar, ensure that the jaw is closed by depressing the *Tip Actuation Lever* and ensure that the distal tip is straight relative to the main shaft.
3. Once the device is inside the body, the jaws can be opened and closed by depressing and releasing the *Tip Actuation Lever*.
4. Tip articulation can be obtained by articulating the handle relative to the main shaft.
5. Tip rotation can be obtained by rotating the *Axial Rotation Knob* relative to the handle.
6. Prior to removing the device from the trocar, ensure that the jaw is closed by depressing the *Tip Actuation Lever* and ensure that the distal tip is straight relative to the main shaft.

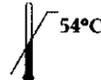


SCHEMATIC VIEW

- Dissector Tip – Used for grasping and blunt dissection of tissue
- Distal Bending Section – Provides articulation at the distal tip
- Main Shaft – Rigid insulated shaft
- Proximal Bending Section – Articulates the distal bending section
- Axial Rotation Knob – Allows user to rotated shaft independent of handle



Sterile R



STORE AT ROOM TEMPERATURE. AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES. DO NOT EXPOSE TO TEMPERATURES ABOVE 130°F (54°C).

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*Trademark
US Patents Pending
Manufactured in the USA for: Cambridge Endoscopic Devices, Inc., Framingham, MA 01702

CB2123-01 Rev R01

CAMBRIDGEENDO™

pureWrist™ Hook

Diameter: 5 mm, Usable Length: 33 cm

Reorder Number: PW1301-01



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DESCRIPTION

The CambridgeEndo® pureWrist® Electrocautery Hook, with a 5 mm diameter insulated shaft and 33 cm usable length, is designed for use through trocars that accommodate 5 mm devices. This device can be used for monopolar cautery when attached to an appropriate electrocautery generator via the male banana plug on the bottom of the handle. Articulation of the device's handle results in corresponding motion of the articulating tip. The articulating tip may also be rotated independently of the handle using the axial rotation knob at the distal end of the handle. The tip may be straight or in any articulated position when rotated.

INDICATIONS

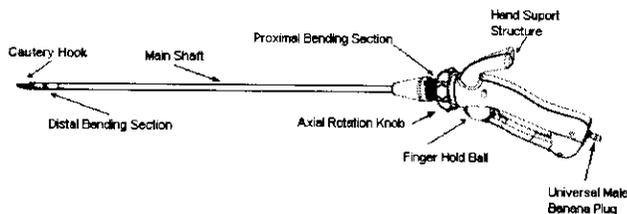
The CambridgeEndo® pureWrist® Hook 5 mm single use instrument with monopolar cautery has application in a variety of minimally invasive procedure to facilitate mobilization and electrocautery of tissue.

CONTRAINDICATIONS

1. The pureWrist® Hook single use instrument with monopolar cautery is NOT intended for contraceptive coagulation of fallopian tissue, but may be used to achieve hemostasis following transection of the fallopian tube.
2. The device is intended for use only as indicated.

WARNINGS AND PRECAUTIONS

1. User should be trained in the use of the device before using in a surgical procedure.
2. Prior to inserting and removing device through a trocar, ensure that the distal tip is straight.
3. Only physicians having adequate training and familiarity with endoscopic techniques should perform endoscopic procedures. Consult the medical literature relative to techniques, complications, and hazards prior to performing endoscopic procedures.
4. A thorough understanding of the principle and techniques involved in electrosurgical procedures is necessary to avoid shock and burn hazard to both patient and user. Verify compatibility of instrumentation to ensure that electrical isolation or grounding is not compromised.
5. Do not use power settings that may result in more than 3000 Volts being delivered to the pureWrist® Hook. Excessive power levels may result in instrument malfunctions and possible patient or user injury.
6. The instrument is not intended for use when minimally invasive techniques are contraindicated.
7. This device is provided STERILE and is intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT REUSE, REPROCESS, OR RESTERILIZE THIS DEVICE.



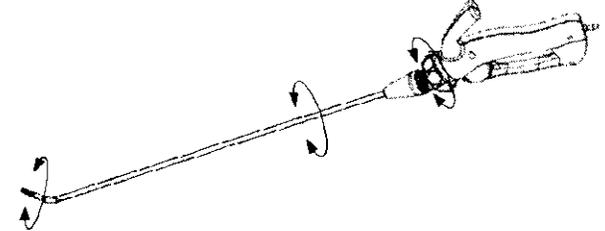
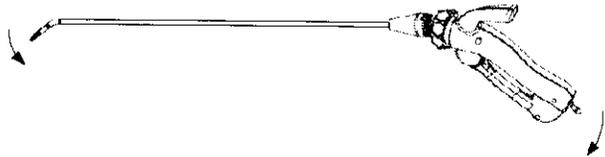
SCHEMATIC VIEW

- Tip (Hook) – Used for mobilization and cautery of tissue
- Distal Bending Section – Provides articulation of the distal tip
- Main Shaft – Rigid insulated shaft

- Proximal Bending Section – Articulates the distal bending section
- Axial Rotation Knob – Allows user to rotated shaft independent of handle
- Handle – User holds the device here

ELECTROCAUTERY COMPATIBILITIES

The pureWrist® Hook is compatible with the following manufacturer's electrocautery generators: Valleylab, Conmed, and Circon.



MOTION

- Upward articulation of the handle relative to the main shaft causes corresponding upward articulation of the tip relative to the main shaft.
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INSTRUCTIONS FOR USE

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2. Prior to inserting the device through a trocar, ensure that the the distal tip is straight relative to the main shaft.
3. Tip articulation can be obtained by articulating the handle relative to the main shaft.
4. Tip rotation can be obtained by rotating the Axial Rotation Knob relative to the handle.
5. Prior to removing the device from the trocar, ensure that the distal tip is straight relative to the main shaft.



Sterile



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*Trademark
US Patents Pending
Manufactured in the USA for: Cambridge Endoscopic Devices, Inc., Framingham, MA 01702

CB2125-01 Rev R01



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 2006

Cambridge Endoscopic Devices, Inc.
% Mr. Jacob Jacobson
Chairman
119 Herbert Street
Framingham, Massachusetts 01752

Re: K061425

Trade/Device Name: pureWrist™ Electrocautery Laparoscopic Instrument
Regulatory Number: 21 CFR 878.4400
Regulatory Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 17, 2006
Received: May 24, 2006

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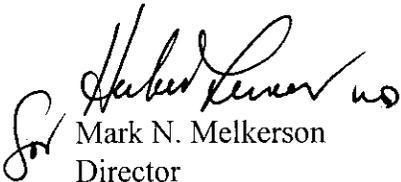
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Page 2 – Mr. Jacob Jacobson

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Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized initial "M" on the left.

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

Enclosure

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

May 25, 2006

CAMBRIDGE ENDOSCOPIC DEVICES
C/O TDC MEDICAL
261 CEDAR HILL STREET
QUALITY AND REGULATORY AFFAIRS
MARLBOROUGH, MA 01752
ATTN: LYNN BOUGIE

510(k) Number: K061425
Received: 24-MAY-2006
Product: PUREWRIST SCISSORS,
MODEL
PW1101-01;PUREWRIST
DISSECTOR, MODEL

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions 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 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. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.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).

In 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 eCopy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please see www.fda.gov/cdrh/elecsb.html.

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 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.

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

May 23, 2006

CAMBRIDGE ENDOSCOPIC DEVICES
C/O TDC MEDICAL
261 CEDAR HILL STREET
QUALITY AND REGULATORY AFFAIRS
MARLBOROUGH, MA 01752
ATTN: LYNN BOUGIE

510(k) Number: K061425
Received: 23-MAY-2006
Product: PUREWRIST SCISSORS,
User Fee ID Number: 6025824
PW1101-01; PUREWRIST
DISSECTOR, MODEL

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail

Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

By Private Courier (e.g., Fed Ex, UPS, etc.)

U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101
(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at <http://www.fda.gov/oc/mdufma>.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-free number (800)638-2041, or contact them at their Internet address <http://www.fda.gov/cdrh/dsmamain.html>, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

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

K061425

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

PAYMENT IDENTIFICATION NUMBER:

(b)(4) Confidential and Proprietary Information

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)

CAMBRIDGE ENDOSCOPIC DEVICES
 INC
 119 Herbert Street
 Framingham MA 01752
 US

1.1 EMPLOYER IDENTIFICATION
 NUMBER (EIN)
 201925995

2. CONTACT NAME
 Jacob Jacobson

2.1 E-MAIL ADDRESS
 jjacobson@cambridgeendo.com

2.2 TELEPHONE NUMBER (include Area code)
 508-302-1402-102

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
 508-405-0134

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:

- Premarket notification(510(k)); except for third party
- Biologics License Application (BLA)
- Premarket Approval Application (PMA)
- Modular PMA
- Product Development Protocol (PDP)
- Premarket Report (PMR)

3.1 Select one of the types below

- Original Application
- Supplement Types:
- Efficacy (BLA)
 - Panel Track (PMA, PMR, PDP)
 - Real-Time (PMA, PMR, PDP)
 - 180-day (PMA, PMR, PDP)

19

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 NO, I am not a small business
 4.1 If Yes, please enter your Small Business Decision Number: SBD068212

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

<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population
<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The 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 NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
 (b)(4) Confidential and Proprietary Information 16-May-2006

Form FDA 8601 (08/2003)

[Close Window](#)

[Print Cover sheet](#)

Cambridge Endoscopic Devices, Inc.
119 Herbert Street
Framingham, MA 01702

May 17, 2006

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

RE: Premarket Notification for the pureWrist™ electrocautery laparoscopic instruments

Dear Sir/Madam:

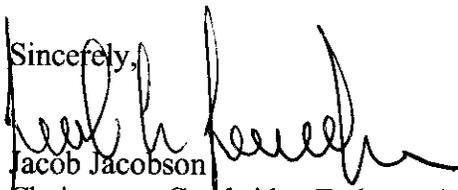
Pursuant to 21 CFR 807.90, Cambridge Endoscopic Devices, Inc., 119 Herbert Street, Framingham, MA 01702 is submitting two copies of this 510(k) notification for the pureWrist™ electrocautery laparoscopic instruments.

Section I of this document contains a completed copy of the “Premarket Submission Cover Sheet” and the “Premarket Notification 510(k) Checklist for Acceptance Decision,” with reference to the sections of this document that contain the required information, and an “Indications For Use Statement”. The “510(k) Summary of Safety and Effectiveness Information” can be found in Section VIII.

This notification thoroughly describes the intended use and technological features of the pureWrist™ electrocautery laparoscopic instruments and those of their predicates.

Cambridge Endoscopic Devices, Inc. requests that the FDA keeps and maintains confidential both the existence and the contents of this Premarket Notification in accordance with 21 CFR 807.95(b). Cambridge Endoscopic Devices, Inc. also requests that the FDA keeps and maintains confidential the contents of this letter.

We are eager to provide any necessary assistance during your evaluation of this submission. If you have any questions about this Premarket notification, the contact person is: Jacob Jacobson; Phone 508-302-1402 x102.

Sincerely,

Jacob Jacobson
Chairman – Cambridge Endoscopic Devices, Inc.

K-24

6480 0 2006 0 2149
05/17/06 10:00 AM

Sy II 21

Cambridge Endoscopic Devices, Inc.

Premarket Notification

for

pureWrist™ Electrocautery Laparoscopic Instruments

**pureWrist™ Electrocautery Laparoscopic Instruments
 Premarket Notification**

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CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 5/17/06	User Fee Payment ID Number (b)(4) Confidential	FDA Submission Document Number (if known) Unknown
-------------------------------	--	--

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name Cambridge Endoscopic Devices, Inc.		Establishment Registration Number (if known) 3005256487	
Division Name (if applicable) N/A		Phone Number (including area code) (508) 302-1402 x102	
Street Address 119 Herbert Street		FAX Number (including area code) (508) 405-0134	
City Framingham	State / Province MA	ZIP/Postal Code 01702	Country USA
Contact Name Jacob Jacobson			
Contact Title Chairman		Contact E-mail Address jjacobson@cambridgeendo.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name TDC Medical		Phone Number (including area code) (508) 597-1809	
Division Name (if applicable) Quality and Regulatory Affairs		FAX Number (including area code) (508) 481-6238	
Street Address 261 Cedar Hill Street		FAX Number (including area code) (508) 481-6238	
City Marlborough	State / Province MA	ZIP/Postal Code 01752	Country USA
Contact Name Lynn Bougie			
Contact Title QA/RA Engineer		Contact E-mail Address lbougie@tdcmedical.com	

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

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

SECTION D2 REASON FOR APPLICATION - IDE

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

SECTION D3 REASON FOR SUBMISSION - 510(k)

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

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 information

- 510 (k) summary attached
 510 (k) statement

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

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K984240	1	ENDOPATH Endoscopic Instruments	1	Ethicon Endo-Surgery, Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F

PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Laparoscopic Electrocautery Instruments

	Trade or Proprietary or Model Name for This Device		Model Number
1	pureWrist Scissors	1	PW1101-01
2	pureWrist Dissector	2	PW1201-01
3	pureWrist Hook	3	PW1301-01
4		4	
5		5	

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

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

Data Included in Submission

- Laboratory Testing Animal Trials Human Trials

SECTION G

PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code GEI	C.F.R. Section (if applicable) 878.4400	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General & Plastic Surgery		

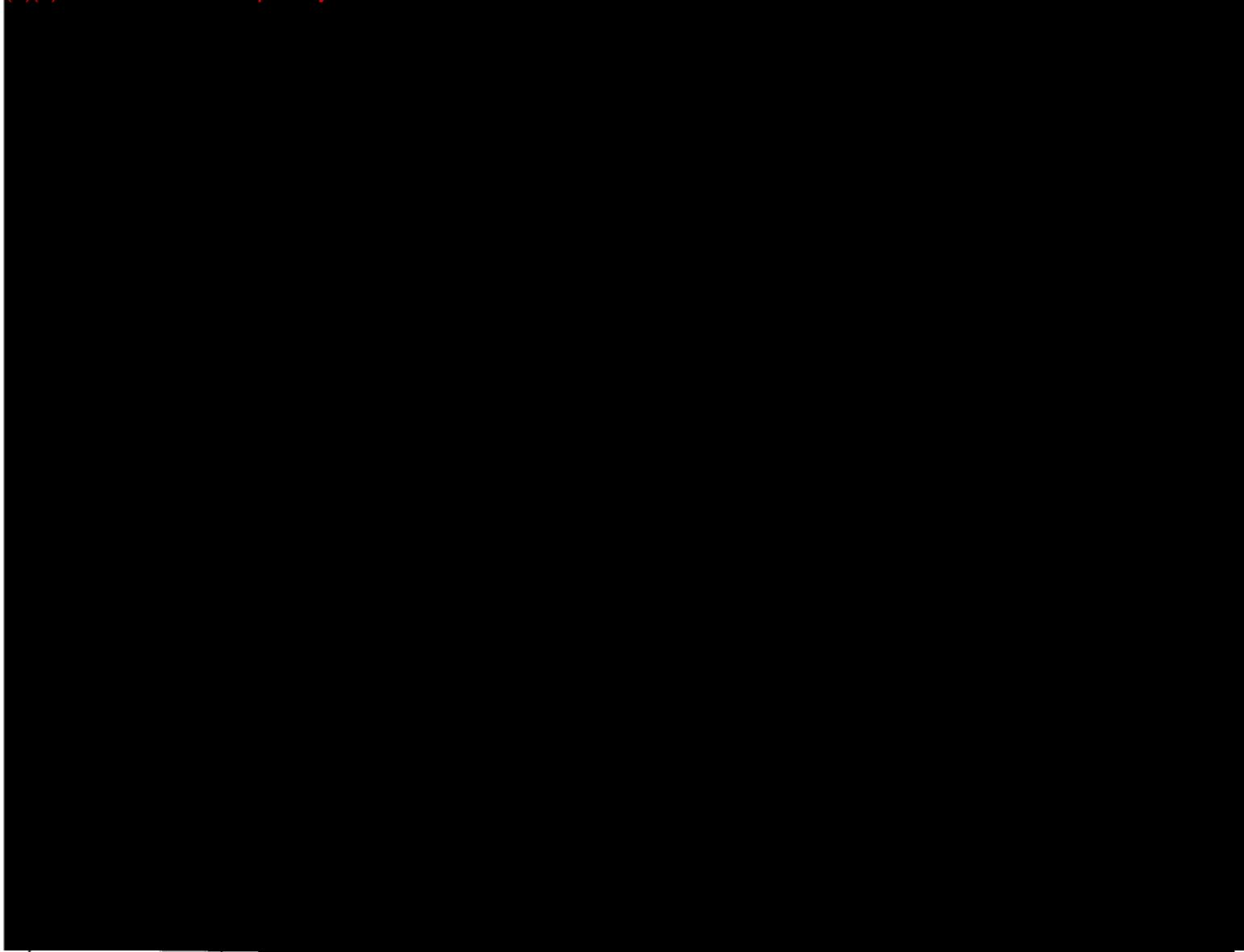
Indications (from labeling)

The CambridgeEndo™ pureWrist™ X* 5 mm single use instrument with monopolar cautery has application in a variety of minimally invasive procedures to facilitate grasping, mobilization, and dissection of tissue.

*X = Instrument Name – Scissors, Dissector, or Hook

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

(b)(4) Confidential and Proprietary Information



<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) ()		
Street Address			FAX Number (including area code) ()		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

SECTION I

UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1	IEC	IEC 60601-1 (1998): Medical Electrical Equipment Part 1: General Requirements for Safety	2 nd Edition	1988
2	60601-2-18	IEC	IEC 60601-1 (1998): Medical Electrical Equipment Part 2: Particular Requirements for Safety of Endoscopic Equipment	2 nd Edition	1996
3	60601-2-2	IEC	IEC 60601-1 (1998): Medical Electrical Equipment Part 2-2: Particular Requirements for Safety of High Frequency Surgical Equipment	3 rd Edition	1998
4					
6					
7					

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

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

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

. agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

**SCREENING CHECKLIST
 FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: Not Assigned

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present	Inadequate or Missing
Cover letter, containing the elements listed on page 3-2 of the <u>Premarket Notification [510)] Manual</u> .	XX	
Table of Contents.	XX	
Truthful and Accurate Statement.	Page 10	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	Page 12	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	Page 12	
Proposed Labeling including the material listed on page 3-4 of the <u>Premarket Notification [510)] Manual</u> .	Page 12	
Statement of Indications for Use that is on a separate page in the premarket submission.	Page 11	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the <u>Premarket Notification [510)] Manual</u> .	Page 17	
510(k) Summary or 510(k) Statement.	Page 26	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	Page 14	
Identification of legally marketed predicate device. *	Page 14	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	Page 12	
Class III Certification and Summary. **	NA	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	NA	
510(k) Kit Certification ***	NA	

* - May not be applicable for Special 510(k)s.
 ** - Required for Class III devices, only.
 *** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission: Not applicable

	Present	Inadequate or Missing
Name and 510(k) number of the sponsor's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.		
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.		
A Design Control Activities Summary that includes the following elements (a-e):	(no entry here)	(no entry here)
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission: NA

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard , which is posted with the 510(k) boilers on the H drive .]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

		Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	Page 23	
b) Sterilization and expiration dating information:	Page 22	
i) sterilization process	Page 22	
ii) validation method of sterilization process	Page 22	
iii) SAL	Page 22	
iv) packaging	Page 22	
v) specify pyrogen free	NA	
vi) ETO residues	NA	
vii) radiation dose	Page 22	
c) Software Documentation:	NA	

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the "Missing" column must be submitted before substantive review of the document.

Passed Screening Yes No

Reviewer: _____

Concurrence by Review Branch: _____

Date: _____

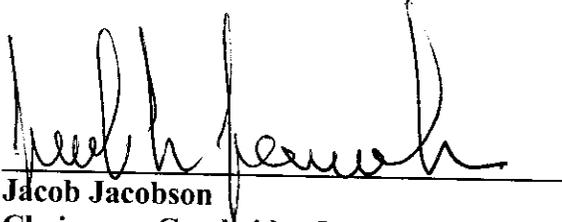
The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, 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>

Cambridge Endoscopic Devices, Inc.
510K

5/17/2006

Truthful and Accuracy Statement

Pursuant to 21 CFR § 807.87(j), I certify that, in my capacity as the Chairman of Cambridge Endoscopic Devices, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

A handwritten signature in black ink, appearing to read "Jacob Jacobson", written over a horizontal line.

Jacob Jacobson
Chairman, Cambridge Endoscopic Devices, Inc.

May 17, 2006

Indications for Use

510(k) Number (if known): ~~Not Assigned~~ K061425

Device Name: pureWrist™ Electrocautery Laparoscopic Instruments

Indications for Use:

The pureWrist™ electrocautery laparoscopic instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transection of tissue.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Section I. General Information

Company Name and Address

510(k) Sponsor/Manufacturer: Cambridge Endoscopic Devices, Inc.
119 Herbert Street
Framingham, MA 01702
Telephone: 508-302-1402
Contact Individual: Mr. Jacob Jacobson
Manufacturing Site: (b)(4) Confidential and Proprietary Information

Telephone:
Contact Individual:

Device Name

Proprietary Name: pureWrist™ Electrocautery Laparoscopic Instruments
Common/Usual Name: Electrosurgical cutting and coagulation device and accessories

Establishment Registration Number(s)

Manufacturer: 3005256487
Owner/Operator: 9075325
(b)(4) Confidential and Proprietary Information

Device Classification

Panel: General & Plastic Surgery
Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories
CFR Number: 878.4400
Product Code: GEI

According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the devices described in this submission are classified as Class II medical devices. Cambridge Endoscopic Devices, Inc. intends to comply with all regulatory controls appropriate for Class II medical devices.

Performance Standards

Cambridge Endoscopic Devices is not aware of any performance standards applicable to this device adopted under section 514 of the Act.

Labeling and Instructions for Use

The labeling and instructions for use for the pureWrist™ electrocautery laparoscopic instruments can be found in Appendix 1.

Contact Persons/Authorized Representatives

The authorized representatives for Cambridge Endoscopic Devices, Inc. for purposes of interacting and corresponding with FDA on all matters relating to this current 510(k) Premarket Notification are as follows:

Jacob Jacobson
Cambridge Endoscopic Devices, Inc.
119 Herbert Street
Framingham, MA
(508) 302-1402
Fax: (508) 405-0134

Lynn Bougie
TDC Medical, Inc.
261 Cedar Hill Street
Marlborough, MA
(508) 597-1809
Fax: (508) 481-6238

Section II Device Description

Introduction

Cambridge Endoscopic Devices, Inc. intends to market a line of manual electro-surgical instruments. The devices are substantially equivalent to those cleared and marketed by Ethicon Endo-Surgery, Inc. under K984240. The devices are manufactured by (b)(4) Confidential and Proprietary [REDACTED] for Cambridge Endoscopic Devices, Inc.

System Intended Use

The pureWrist™ electrocautery laparoscopic instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transection of tissue.

Device Configuration and Materials

The pureWrist™ electrocautery laparoscopic instruments (scissors, dissector, and hook) are sterile, single use disposable instruments for use through appropriately sized surgical trocars. Table 1 provides a summary of the device specifications. Drawings of each device are provided in Appendix 2.

The instruments consist of a rotating insulated shaft with a 5mm diameter. The distal end of the shaft has the respective end effector attached (scissors, dissector, or hook). A detailed view of the end effector design for each device is included in Appendix 2.

The proximal end of the shaft is attached to an ergonomically shaped handle with a rotating knob. Articulation of the device's handle results in corresponding motion of the articulating tip. The articulating tip may also be rotated independently of the handle, 360 degrees in either direction, using the axial rotation knob. The tip may be straight or in any articulated position when rotated.

The handle also contains the actuation mechanism for the respective end effector. The lever on the handle is compressed and released to activate the instrument scissor blades or jaws. The hook does not have any moving components and therefore is not actuated with a lever.

Each instrument has a monopolar cautery connector that extends from the bottom of the handle. The connector is used for electro-surgery when attached to a standard cautery cable and a proper generator. In typical use the surgeon places the jaws, blades, or hook on the target tissue. The surgeon may then energize the RF generator with the generator's footswitch, causing desiccation of the targeted tissue.

A pureWrist™ electrocautery laparoscopic instrument consists of an end effector, insulated shaft, ergonomically shaped handle, and a monopolar cautery connection. The cable and generator used in the electrosurgical applications are not supplied with the instrument.

The pureWrist™ instruments are compatible with FDA cleared standard cables and RF generators which provide monopolar energy output. Most common cables and generators may be used. The devices are rated for a maximum of 3000 Volts. In accordance with the ANSI/AAMI HF-18 standard, the insulation breakdown is tested to 1.5 times this voltage or 4,500 volts p-p.

Table 1: Device Specifications

Feature	Specification
Shaft diameter	5 mm
Shaft working length	15-45 cm nominal
End Effector Types	Curved Scissors, Maryland Dissector forceps (5mm jaws), Hook
Electrical connector	Banana plug at the bottom of the handle
Electrosurgical Unit	Circon Conmed Valleylab

Safety:

- The electrical components of the pureWrist™ electrocautery laparoscopic instruments meet the applicable sections of IEC 60161-2-2; Particular requirements for the safety of high frequency surgical equipment
- The material components of the device are biocompatible and have been previously shown to meet the safety standards established in ISO 10993-1. The materials used in the device are provided in Table 2
- The device is sterilized with gamma radiation and validated to SAL of 10⁻⁶

Table 2: Materials Table

Part Name/Description	Material	Patient Contacting (Y/N)
Handle and Proximal Flex	Polycarbonate	N
	Pebax	N
	PEEK	N
	Glass Filled Polycarbonate	N
Shaft, including distal flex and insulation material	Stainless Steel	Y
	FEP	Y
	PEEK	Y
	Pebax	Y
	Tecoflex, Black	Y
	Cyanoacrylate	Y
	PET	Y
End Effector (jaws, blades, and hook)	Stainless Steel	Y
	Ultem, Black	Y

Section III. Substantial Equivalence

Section Summary

Based on the information provided herein and the 510(k) Substantial Equivalence Decision-Making Process we conclude that the pureWrist™ electrocautery laparoscopic instruments are substantially equivalent to the predicate devices under the Federal Food, Drug, and Cosmetic Act. A comparison of the New Devices to the Predicate Devices is provided in Table 3.

Table 3: Substantial Equivalence Comparison Table

Feature/Area of Comparison	Cambridge Endoscopic Devices, Inc., pureWrist™ Electrocautery Laparoscopic Instruments This Submission	Ethicon Endo-Surgery, Inc., ENDOPATH® Endoscopic Instruments K984240
Intended use	The pureWrist™ electrocautery laparoscopic instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transection of tissue.	The ENDOPATH® Endoscopic Instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transection of tissue.
Indication for use	The pureWrist™ electrocautery laparoscopic instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transection of tissue.	The ENDOPATH® Endoscopic Instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transection of tissue.
Anatomical Sites	General surgery	General surgery
Where Used/Users	Hospitals/Laparoscopic Surgeons	Hospitals/Laparoscopic Surgeons
Energy Use and/or Delivered	Electricity delivered for cauterizing tissue	Electricity delivered for cauterizing tissue
Used with	Designed for use through appropriately sized surgical trocars	Designed for use through appropriately sized surgical trocars
Compatibility with other devices	The devices are compatible with standard cautery cables and appropriate electrosurgical generators	The devices are compatible with standard cautery cables and appropriate electrosurgical generators

40

Feature/Area of Comparison	Cambridge Endoscopic Devices, Inc., pureWrist™ Electrocautery Laparoscopic Instruments This Submission	Ethicon Endo-Surgery, Inc., ENDOPATH® Endoscopic Instruments K984240
Human Factors	Rotation knob on handle rotates the shaft 360 degrees in either direction	Rotation knob on handle rotates the shaft 360 degrees in either direction
Design – Scissors	Two curved blades, 5mm diameter	Two curved blades, 5mm diameter
Design – Dissector	Maryland Dissector, curved upper and lower jaws, 5mm diameter	Various types of dissector jaws, 5mm diameter
Design – Hook	Curved hook, 5mm diameter	Curved hook, 5mm diameter
Design – Shaft	360 degree rotating insulated shaft, 5mm diameter, 15-45cm lengths	360 degree rotating insulated shaft, 3, 5, or 10mm diameter, 18-45 cm lengths
Design – Handle	The instrument jaws or scissor blades are activated by compression and release of the handle actuation lever	The instrument jaws or scissor blades are activated by compression and release of the ring handles
Design – Cautery type	Monopolar cautery	Monopolar cautery
Sterility	Sterile, single patient use instruments.	Sterile, single patient use instruments.
Electrical Safety	The device will comply with the requirements in the General Standard, IEC 60601-1, and the applicable sections of the particular standards, IEC 60601-2-2 and IEC 60601-2-18	The device complies with the requirements in the General Standard, IEC 60601-1, and the applicable sections of the particular standards, IEC 60601-2-2 and IEC 60601-2-18

The 510(k) "Substantial equivalence decision making process flow chart (detailed)" (from CDRH 510(k) manual 92-4158) was utilized to make the following determination of substantial equivalence.

New Device Compared to Marketed Device (Predicate)

- ③ **Does the new device have the same indication statement as the predicate device?** Yes, both devices have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transection of tissue.

New device has same Intended Use and May be "Substantially Equivalent"

Both devices are intended to be used by qualified physicians for manipulating soft tissue (grasping, cutting, coagulating, and dissecting) in a variety of minimally invasive procedures.

- ⑤ **Does the new device have the same technological characteristics, e.g. design, materials, etc.?** Yes, technological characteristics for the New Device are the same as the Predicate Device. The devices have similar design features and dimensions including rotating insulated shafts, ergonomically shaped handles, and end effectors (jaws, blades, or hook) used for grasping, dissecting, and cutting of tissue. Both devices are equipped with monopolar cautery connections and can be used to cauterize tissue when the instrument is attached to standard cautery cables and electrosurgical generators.

- ⑦ **Are the Descriptive Characteristics precise enough to ensure equivalence?** Yes. Labeling and bench testing demonstrate equivalency. The safety and effectiveness of electrosurgery as a cutting and coagulation method is extensively documented and well known. The new devices and its predicates all meet the applicable sections of IEC 60601-2-2 (1998) standards for safety.

The material components of the device that are in-vivo are biocompatible. The devices are single use instruments provided sterile and validated to an SAL of 10^{-6} .

"Substantially Equivalent" Determination

Statement of Substantial Equivalence

Based on the information provided herein, the Cambridge Endoscopic Devices, Inc. pureWrist™ electrocautery laparoscopic instruments are substantially equivalent to the Ethicon Endo-Surgery, Inc. ENDOPATH® instruments cleared under K984240 as well as a number of currently marketed instruments that have been reviewed by the FDA and cleared for marketing via the 510(k) process.

All of the devices are scissors, graspers, dissectors, or hooks that coagulate tissue using monopolar technology. All of the devices use sharp objects to permit the surgeon to cut or dissect tissue. All of the devices are connected to the same or similar electrosurgical generators and use similar power ranges for operation. The devices have the same intended use, indications for use, technological features including similar design, performance, and material characteristics which further supports the concept of substantial equivalence.

Section IV: Performance Testing

The safety and effectiveness of electrosurgery as a cutting and coagulation method is extensively documented and well known. Preliminary Electrical Testing was performed on the device to ensure that adequate insulation was provided to meet the insulation breakdown requirement in ANSI/AAMI HF-18. The results are provided in Appendix 4.

Additional testing will be performed on production devices prior to marketing. The testing will confirm that the devices comply with the applicable sections of the following FDA recognized standards:

IEC 60601-1 (1988): Medical Electrical Equipment. Part 1: General requirements for safety

IEC 60601-2-18 (1996): Medical electrical equipment. Part 2: Particular requirements for the safety of endoscopic equipment

IEC 60601-2-2 (1998): Medical Electrical Equipment. Part 2-2: Particular requirements for the safety of high frequency surgical equipment

In addition, animal studies were performed on prototype devices to evaluate the ergonomics of the handle and to obtain feedback from surgeons on design and performance features. The results are provided in Appendix 4.

Section V: Sterilization and Biocompatibility

Sterilization:

Sterilization is accomplished by γ -radiation (Co^{60}) to an SAL level of 10^{-6} in accordance with AAMI TIR27:2001 Sterilization of health care products- Radiation sterilization-Substantiation of 25kGy as a sterilization dose-Method VD_{max} .

The device is packaged in a plastic tray sealed with a tyvek lid to maintain the sterile barrier. The sealed tray will be placed inside a display box. The individually packaged devices will be placed into a corrugated shipper.

The device is labeled with an expiration date of two years from the date of manufacture. The expiration date has been validated to confirm that the product and sterile barrier remain adequate until the expiration date.

Biocompatibility:

The patient-contact materials used in the pureWrist™ electrocautery laparoscopic instruments are identified in Table 4. Biocompatibility testing has been performed on these materials in accordance with ISO 10993-1. According to ISO 10993-1 the device is classified as “External Communicating, Limited Duration <24hrs.” Tests for cytotoxicity, sensitization, and intracutaneous reactivity are required. The systemic injection test was performed as a suggested optional test.

Table 4: Biocompatibility Test Results

Component	Material	Test Result
Shaft, including distal flex and insulation material	Stainless Steel	Well characterized material, previous history of usage Passed testing in accordance with ISO 10993
	FEP	Previous usage in K010473
	PEEK	Passed testing in accordance with ISO 10993
	Pebax	Passed testing in accordance with ISO 10993
	Tecoflex, Black	Passed testing in accordance with ISO 10993
	Cyanoacrylate	Previous usage in K013680
	PET	Previous usage in K980096
End Effector (jaws and blades)	Stainless Steel	Well characterized material, previous history of usage Passed testing in accordance with ISO 10993

Since the materials of use are well known and characterized and have either passed testing to ISO 10993 or shown biocompatible in previous usage of other cleared devices Cambridge Endoscopic Devices, Inc. believes no further testing is needed.

Section VI: Kit Certification

This device is not part of a kit. This section is not applicable.

Section VII: Software

The devices do not utilize software. This section is not applicable.

Section VIII: Summary of Safety and Effectiveness

As required by the Safe Medical Devices Act of 1990 and 21 CFR 807.92, a 510K summary is provided in Appendix 5.

Section IX. Appendices

1. Device Labeling
2. Device Drawings
3. Predicate Device Information
4. Performance Data
5. 510K Summary of Safety and Effectiveness

APPENDIX 1 Labeling and Instructions for Use

Labeling

The labels will be printed on white general purpose roll stock. The dimensions are 4 in. wide by 6 in. long. A sample of the label that will be used on each device is provided below. The asterisks on the sample labels pertain to the following information:

- * Device Usable Length
- ** Lot Number
- *** Expiration Date

CAMBRIDGETMENDOTM

pureWristTM

Scissors

Diameter 5mm, Usable Length XX cm*

LOT XXYYYYY**

REF PW1101-01

 MM-YYYY***

Contents:

- (1) Disposable Laparoscopic Scissors



Prior to use, see instructions



Single Patient Use

For Monopolar Electrosurgical Use

Sterile R Sterile unless package opened or damaged.
Do Not Resterilize.

CAUTION: Federal (USA) law restricts this device for sale and use by, or on the order of a physician.

US Patents Pending

Manufactured in the USA for:
Cambridge Endoscopic Devices, Inc.
119 Herbert St.
Frammingham, MA 01702

CB2128-01 Rev R01

CAMBRIDGEENDO™

pureWrist™

Dissector

Diameter 5mm, Usable Length XXcm*

LOT XYYYYY**

 MM-YYYY***

REF PW1201-01

Contents:

(1) Disposable Laparoscopic Dissector

 Prior to use, see instructions

 Single Patient Use

For Monopolar Electrosurgical Use

Sterile R Sterile unless package opened or damaged.
Do Not Resterilize.

CAUTION: Federal (USA) law restricts this device for sale and use
by, or on the order of a physician.

US Patents Pending

Manufactured in the USA for:
Cambridge Endoscopic Devices, Inc.
119 Herbert St.
Framingham, MA 01702

CB2127-01 Rev R01

CAMBRIDGEENDO™
pureWrist™
Hook
Diameter 5mm, Usable Length XXcm*

LOT XXYYYYY**

REF PW1301-01

 MM-YYYY***

Contents:

(1) Disposable Laparoscopic Hook

 Prior to use, see instructions

 Single Patient Use

For Monopolar Electrosurgical Use

Sterile R Sterile unless package opened or damaged.
Do Not Resterilize.

CAUTION: Federal (USA) law restricts this device for sale and use by, or on the order of a physician.

US Patents Pending

Manufactured in the USA for:
Cambridge Endoscopic Devices, inc.
119 Herbert St.
Framingham, MA 01702

CB2129-01 Rev R01

APPENDIX 1 Labeling and Instructions for Use

Instructions for Use

The sample instructions for use for each device are provided below. The sample instructions are for a device with a 34cm usable length. The actual usable length of the device being manufactured will be provided on the instructions for use at the time of manufacture. The model number will also reflect the actual usable length (i.e. Model Number PW1201-01 corresponds to a dissector with a 34cm usable length).

CAMBRIDGEENDO™

pureWrist™ Scissors

Diameter: 5 mm, Usable Length: 34 cm

Reorder Number: PW1101-01



BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT

This book is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested, and manufactured for single patient use only. Reuse or reprocessing may lead to device failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess, or resterilize this device.

DESCRIPTION

The CambridgeEndo™ pureWrist™ Scissors, with a 5 mm diameter insulated shaft and 34 cm usable length, is designed for use through trocars that accommodate 5 mm devices. This device can be used for monopolar cautery when attached to an appropriate electrocautery generator via the male banana plug on the bottom of the handle. Articulation of the device's handle results in corresponding motion of the articulating tip. The articulating tip may also be rotated independently of the handle using the axial rotation knob at the distal end of the handle. The tip may be straight or in any articulated position when rotated.

INDICATIONS

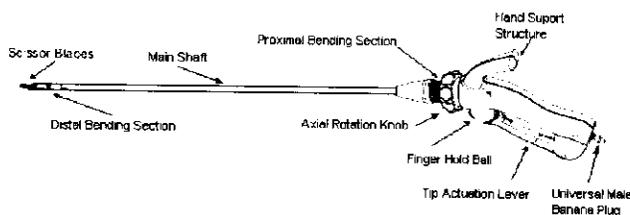
The CambridgeEndo™ pureWrist™ Scissors 5 mm single use instrument with monopolar cautery has application in a variety of minimally invasive procedure to facilitate mobilization, transection, and dissection of tissue.

CONTRAINDICATIONS

1. The pureWrist™ Scissors single use instrument with monopolar cautery is NOT intended for contraceptive coagulation of fallopian tissue, but may be used to achieve hemostasis following transection of the fallopian tube.
2. The device is intended for use only as indicated.

WARNINGS AND PRECAUTIONS

1. User should be trained in the use of the device before using in a surgical procedure.
2. Prior to inserting and removing device through a trocar, ensure that the scissor blades are closed and the distal tip is straight.
3. Only physicians having adequate training and familiarity with endoscopic techniques should perform endoscopic procedures. Consult the medical literature relative to techniques, complications, and hazards prior to performing endoscopic procedures.
4. A thorough understanding of the principle and techniques involved in electrocautery procedures is necessary to avoid shock and burn hazard to both patient and user. Verify compatibility of instrumentation to ensure that electrical isolation or grounding is not compromised.
5. Do not use power settings that may result in more than 3000 Volts being delivered to the pureWrist™ Scissors. Excessive power levels may result in instrument malfunctions and possible patient or user injury.
6. This device is provided STERILE and is intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT REUSE, REPROCESS, OR RESTERILIZE THIS DEVICE.



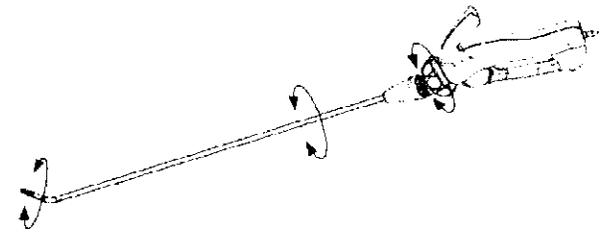
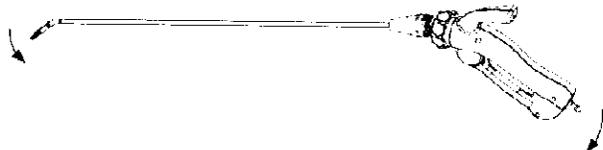
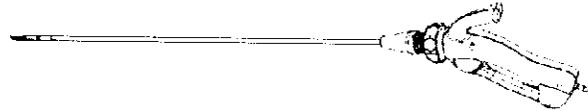
SCHEMATIC VIEW

- Tip (Scissor Blades) – Used for transection and blunt dissection of tissue
- Distal Bending Section – Provides articulation of the distal tip
- Main Shaft – Rigid insulated shaft
- Proximal Bending Section – Articulates the distal bending section
- Axial Rotation Knob – Allows user to rotated shaft independent of handle

- Jaw Actuation Lever – Used to open and close the scissor blades
- Handle – User holds the device here

ELECTROCAUTERY COMPATIBILITIES

The pureWrist™ Scissors are compatible with the following manufacturer's electrocautery generators: Valleylab, Conmed, and Circon.



MOTION

- Upward articulation of the handle relative to the main shaft causes corresponding upward articulation of the tip relative to the main shaft.
- When the handle is straight/in line with the main shaft, the tip is also straight/in line with the main shaft.
- Axial rotation while the tip is articulated causes the tip to rotate about its center axis, while remaining articulated.
- Articulating the handle in any direction (upwards, downwards, or sideways) relative to the main shaft causes corresponding articulation of the tip relative to the main shaft.

INSTRUCTIONS FOR USE

1. If the electrocautery function of the device will be used, connect to an appropriate monopolar generator using a standard cautery cable attached to the male banana plug at the back of the handle.
2. Prior to inserting the device through a trocar, ensure that the scissor blades are closed by depressing the *Tip Actuation Lever* and ensure that the distal tip is straight relative to the main shaft.
3. Once the device is inside the body, the blades can be opened and closed by depressing and releasing the *Tip Actuation Lever*.
4. Tip articulation can be obtained by articulating the handle relative to the main shaft.
5. Tip rotation can be obtained by rotating the *Axial Rotation Knob* relative to the handle.
6. Prior to removing the device from the trocar, ensure that the blades are closed by depressing the *Tip Actuation Lever* and ensure that the distal tip is straight relative to the main shaft.



Sterile R



**STORE AT ROOM TEMPERATURE.
AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.
DO NOT EXPOSE TO TEMPERATURES ABOVE 130°F (54°C).**

CAUTION: Federal (USA) law restricts this device for sale and use by, or on the order of, a physician.

®Trademark
US Patents Pending
Manufactured in the USA for: Cambridge Endoscopic Devices, Inc., Framingham, MA 01702

CB2124-01 Rev R01

CAMBRIDGEENDO™

pureWrist™ Dissector

Diameter: 5 mm, Usable Length: 34 cm

Reorder Number: PW1201-01



BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT

This book is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested, and manufactured for single patient use only. Reuse or reprocessing may lead to device failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess, or resterilize this device.

DESCRIPTION

The CambridgeEndo™ pureWrist™ Dissector, with a 5 mm diameter insulated shaft and 34 cm usable length, is designed for use through trocars that accommodate 5 mm devices. This device can be used for monopolar cautery when attached to an appropriate electrocautery generator via the male banana plug on the bottom of the handle. Articulation of the device's handle results in corresponding motion of the articulating tip. The articulating tip may also be rotated independently of the handle using the axial rotation knob at the distal end of the handle. The tip may be straight or in any articulated position when rotated.

INDICATIONS

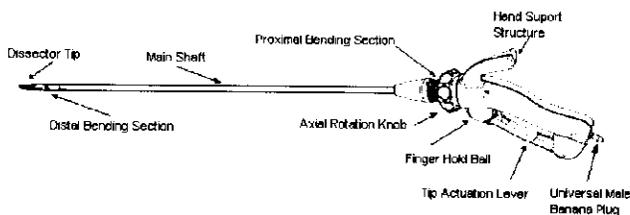
The CambridgeEndo™ pureWrist™ Dissector 5 mm single use instrument with monopolar cautery has application in a variety of minimally invasive procedure to facilitate grasping, mobilization, and dissection of tissue.

CONTRAINDICATIONS

1. The pureWrist™ Dissector single use instrument with monopolar cautery is NOT intended for contraceptive coagulation of fallopian tissue, but may be used to achieve hemostasis following transection of the fallopian tube.
2. The device is intended for use only as indicated.

WARNINGS AND PRECAUTIONS

1. User should be trained in the use of the device before using in a surgical procedure.
2. Prior to inserting and removing device through a trocar, ensure that the jaw is closed and the distal tip is straight.
3. Only physicians having adequate training and familiarity with endoscopic techniques should perform endoscopic procedures. Consult the medical literature relative to techniques, complications, and hazards prior to performing endoscopic procedures.
4. A thorough understanding of the principle and techniques involved in electrosurgical procedures is necessary to avoid shock and burn hazard to both patient and user. Verify compatibility of instrumentation to ensure that electrical isolation or grounding is not compromised.
5. Do not use power settings that may result in more than 3000 Volts being delivered to the pureWrist™ Dissector. Excessive power levels may result in instrument malfunctions and possible patient or user injury.
6. This device is provided STERILE and is intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT REUSE, REPROCESS, OR RESTERILIZE THIS DEVICE.



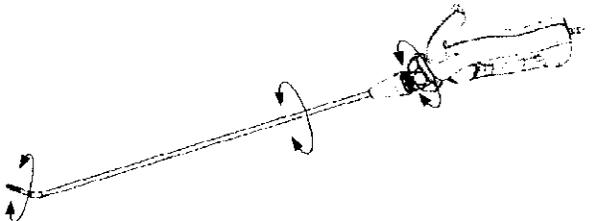
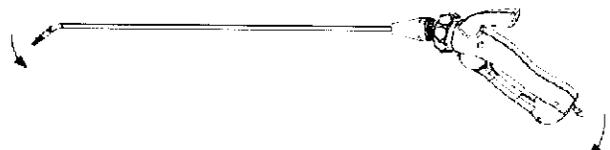
SCHEMATIC VIEW

- Dissector Tip – Used for grasping and blunt dissection of tissue
- Distal Bending Section – Provides articulation at the distal tip
- Main Shaft – Rigid insulated shaft
- Proximal Bending Section – Articulates the distal bending section
- Axial Rotation Knob – Allows user to rotated shaft independent of handle

- Tip Actuation Lever – Used to open and close the jaws
- Handle – User holds the device here

ELECTROCAUTERY COMPATIBILITIES

The pureWrist™ Dissector is compatible with the following manufacturer's electrosurgical generators: Valleylab, Conmed, and Circon.



MOTION

- Upward articulation of the handle relative to the main shaft causes corresponding upward articulation of the tip relative to the main shaft.
- When the handle is straight/in line with the main shaft, the tip is also straight/in line with the main shaft.
- Axial rotation while the tip is articulated causes the tip to rotate about its center axis, while remaining articulated.
- Articulating the handle in any direction (upwards, downwards, or sideways) relative to the main shaft causes corresponding articulation of the tip relative to the main shaft.

INSTRUCTIONS FOR USE

1. If the electrocautery function of the device will be used, connect to an appropriate monopolar generator using a standard cautery cable attached to the male banana plug at the back of the handle.
2. Prior to inserting the device through a trocar, ensure that the jaw is closed by depressing the *Tip Actuation Lever* and ensure that the distal tip is straight relative to the main shaft.
3. Once the device is inside the body, the jaws can be opened and closed by depressing and releasing the *Tip Actuation Lever*.
4. Tip articulation can be obtained by articulating the handle relative to the main shaft.
5. Tip rotation can be obtained by rotating the *Axial Rotation Knob* relative to the handle.
6. Prior to removing the device from the trocar, ensure that the jaw is closed by depressing the *Tip Actuation Lever* and ensure that the distal tip is straight relative to the main shaft.



Sterile R



**STORE AT ROOM TEMPERATURE.
AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.
DO NOT EXPOSE TO TEMPERATURES ABOVE 130°F (54°C).**

CAUTION: Federal (USA) law restricts this device for sale and use by, or on the order of, a physician.

*Trademark
US Patents Pending
Manufactured in the USA for: Cambridge Endoscopic Devices, Inc., Framingham, MA 01702

CB2123-01 Rev R01

CAMBRIDGEENDO™

pureWrist™ Hook

Diameter: 5 mm, Usable Length: 33 cm

Reorder Number: PW1301-01



BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT

This book is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested, and manufactured for single patient use only. Reuse or reprocessing may lead to device failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess, or resterilize this device.

DESCRIPTION

The CambridgeEndo™ pureWrist™ Electrocautery Hook, with a 5 mm diameter insulated shaft and 33 cm usable length, is designed for use through trocars that accommodate 5 mm devices. This device can be used for monopolar cautery when attached to an appropriate electrocautery generator via the male banana plug on the bottom of the handle. Articulation of the device's handle results in corresponding motion of the articulating tip. The articulating tip may also be rotated independently of the handle using the axial rotation knob at the distal end of the handle. The tip may be straight or in any articulated position when rotated.

INDICATIONS

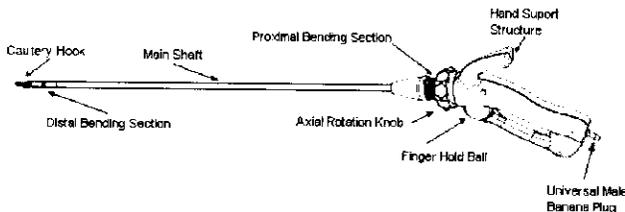
The CambridgeEndo™ pureWrist™ Hook 5 mm single use instrument with monopolar cautery has application in a variety of minimally invasive procedure to facilitate mobilization and electrocautery of tissue.

CONTRAINDICATIONS

1. The pureWrist™ Hook single use instrument with monopolar cautery is NOT intended for contraceptive coagulation of fallopian tissue, but may be used to achieve hemostasis following transection of the fallopian tube.
2. The device is intended for use only as indicated.

WARNINGS AND PRECAUTIONS

1. User should be trained in the use of the device before using in a surgical procedure.
2. Prior to inserting and removing device through a trocar, ensure that the distal tip is straight.
3. Only physicians having adequate training and familiarity with endoscopic techniques should perform endoscopic procedures. Consult the medical literature relative to techniques, complications, and hazards prior to performing endoscopic procedures.
4. A thorough understanding of the principle and techniques involved in electrocautery procedures is necessary to avoid shock and burn hazard to both patient and user. Verify compatibility of instrumentation to ensure that electrical isolation or grounding is not compromised.
5. Do not use power settings that may result in more than 3000 Volts being delivered to the pureWrist™ Hook. Excessive power levels may result in instrument malfunctions and possible patient or user injury.
6. This device is provided STERILE and is intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT REUSE, REPROCESS, OR RSTERILIZE THIS DEVICE.



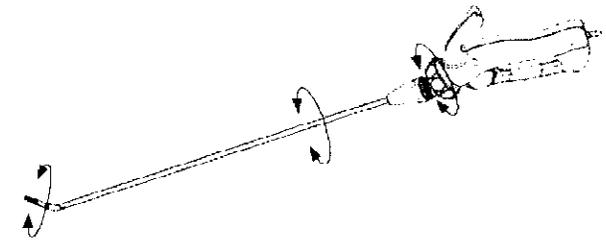
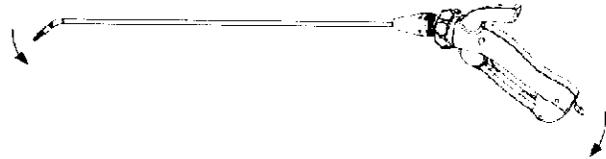
SCHEMATIC VIEW

- Tip (Hook) – Used for mobilization and cautery of tissue
- Distal Bending Section – Provides articulation of the distal tip
- Main Shaft – Rigid insulated shaft
- Proximal Bending Section – Articulates the distal bending section

- Axial Rotation Knob – Allows user to rotated shaft independent of handle
- Handle – User holds the device here

ELECTROCAUTERY COMPATIBILITIES

The pureWrist™ Hook is compatible with the following manufacturer's electrocautery generators: Valleylab, Conmed, and Circon.



MOTION

- Upward articulation of the handle relative to the main shaft causes corresponding upward articulation of the tip relative to the main shaft.
- When the handle is straight/in line with the main shaft, the tip is also straight/in line with the main shaft.
- Axial rotation while the tip is articulated causes the tip to rotate about its center axis, while remaining articulated.
- Articulating the handle in any direction (upwards, downwards, or sideways) relative to the main shaft causes corresponding articulation of the tip relative to the main shaft.

INSTRUCTIONS FOR USE

1. If the electrocautery function of the device will be used, connect to an appropriate monopolar generator using a standard cautery cable attached to the male banana plug at the back of the handle.
2. Prior to inserting the device through a trocar, ensure that the the distal tip is straight relative to the main shaft.
3. Tip articulation can be obtained by articulating the handle relative to the main shaft.
4. Tip rotation can be obtained by rotating the Axial Rotation Knob relative to the handle.
5. Prior to removing the device from the trocar, ensure that the distal tip is straight relative to the main shaft.



Sterile R



STORE AT ROOM TEMPERATURE. AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES. DO NOT EXPOSE TO TEMPERATURES ABOVE 130°F (54°C).

CAUTION: Federal (USA) law restricts this device for sale and use by, or on the order of, a physician.

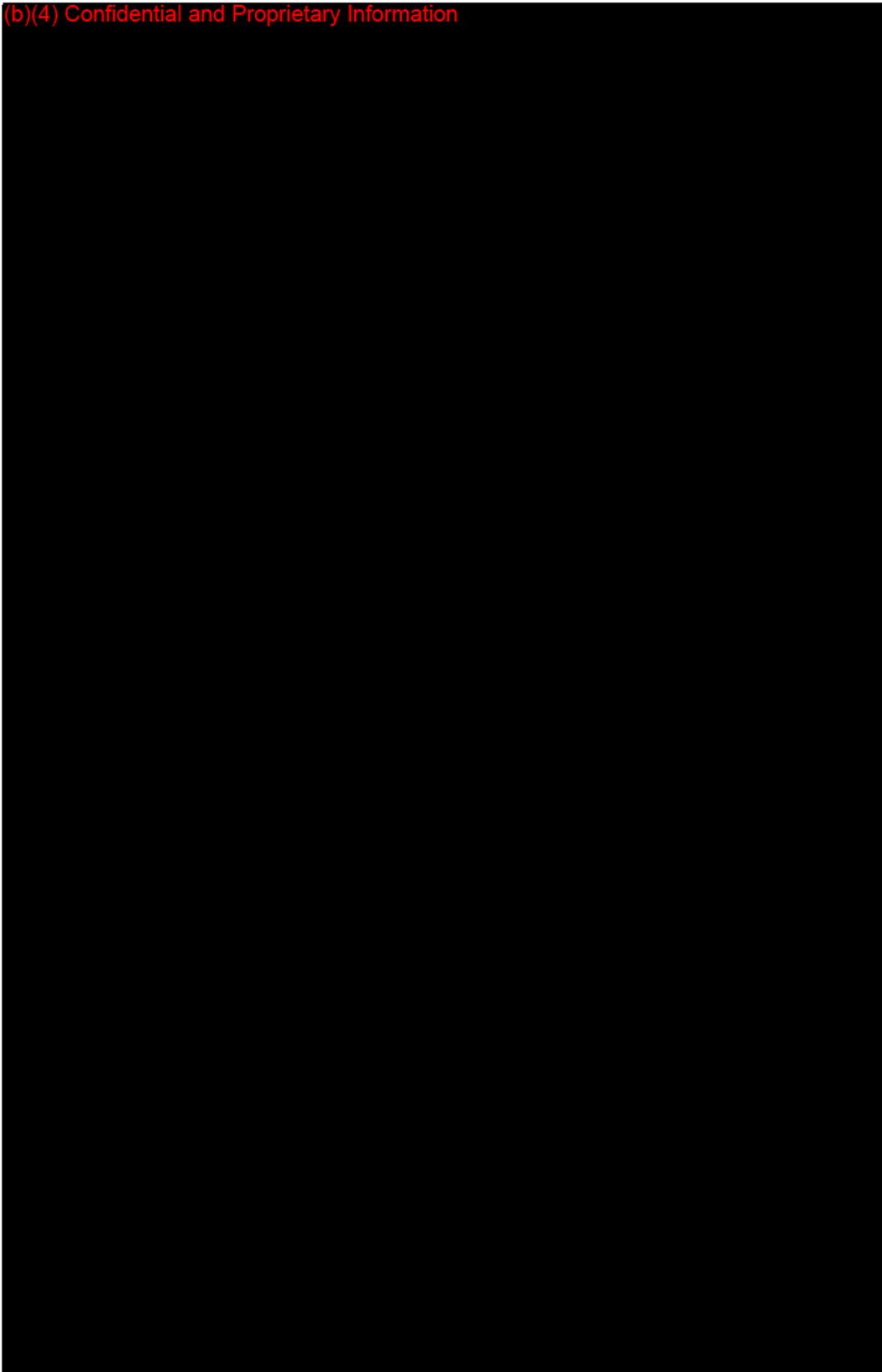
*Trademark
US Patents Pending
Manufactured in the USA for: Cambridge Endoscopic Devices, Inc., Framingham, MA 01702

CB2125-01 Rev R01

Cambridge Endoscopic Devices, Inc.
510K

5/17/2006

APPENDIX 2
Device Drawings



(b)(4) Confidential and Proprietary Information

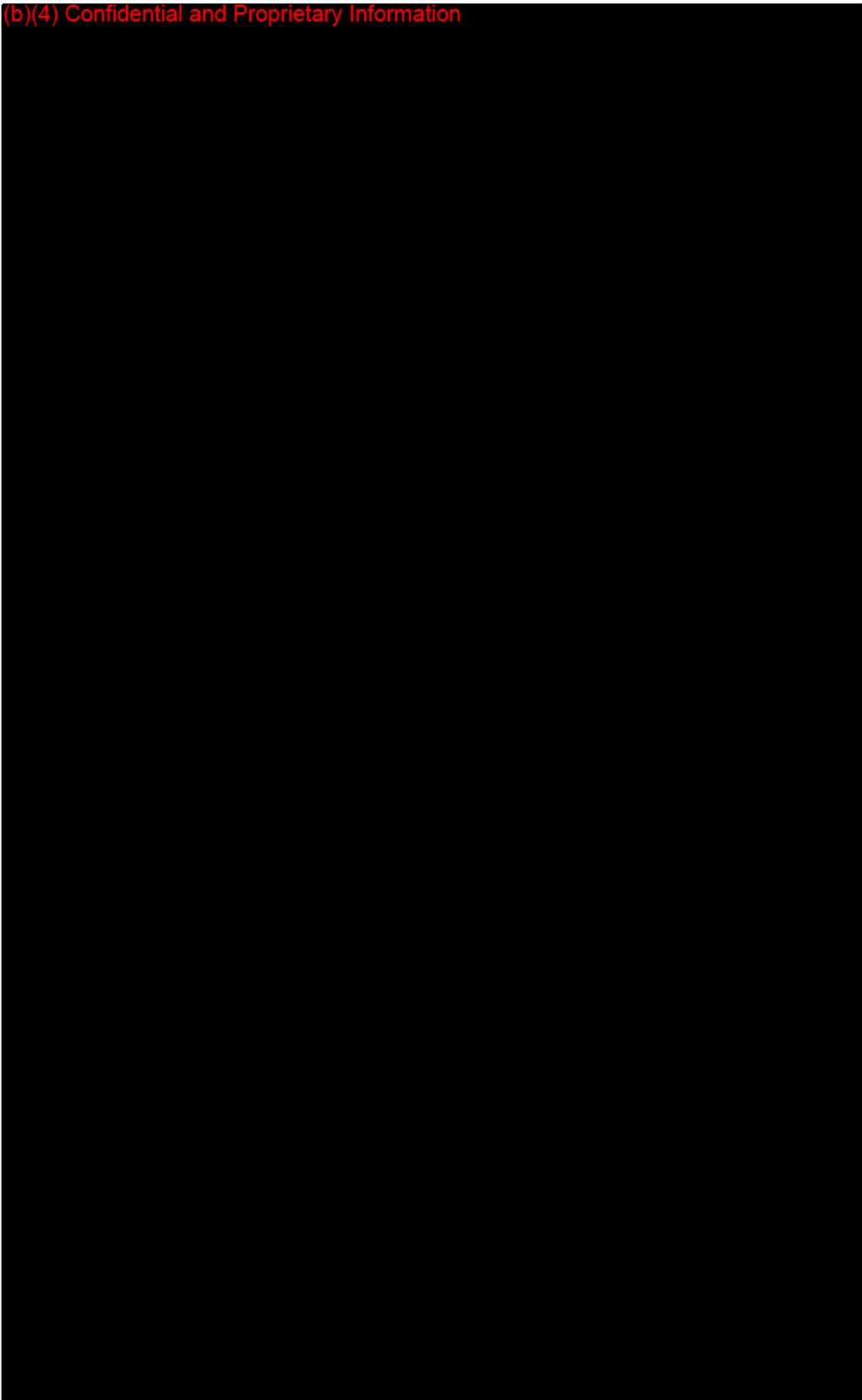
Appendix 2

59

Cambridge Endoscopic Devices, Inc.
510K

5/17/2006

APPENDIX 2
Device Drawings



(b)(4) Confidential and Proprietary Information

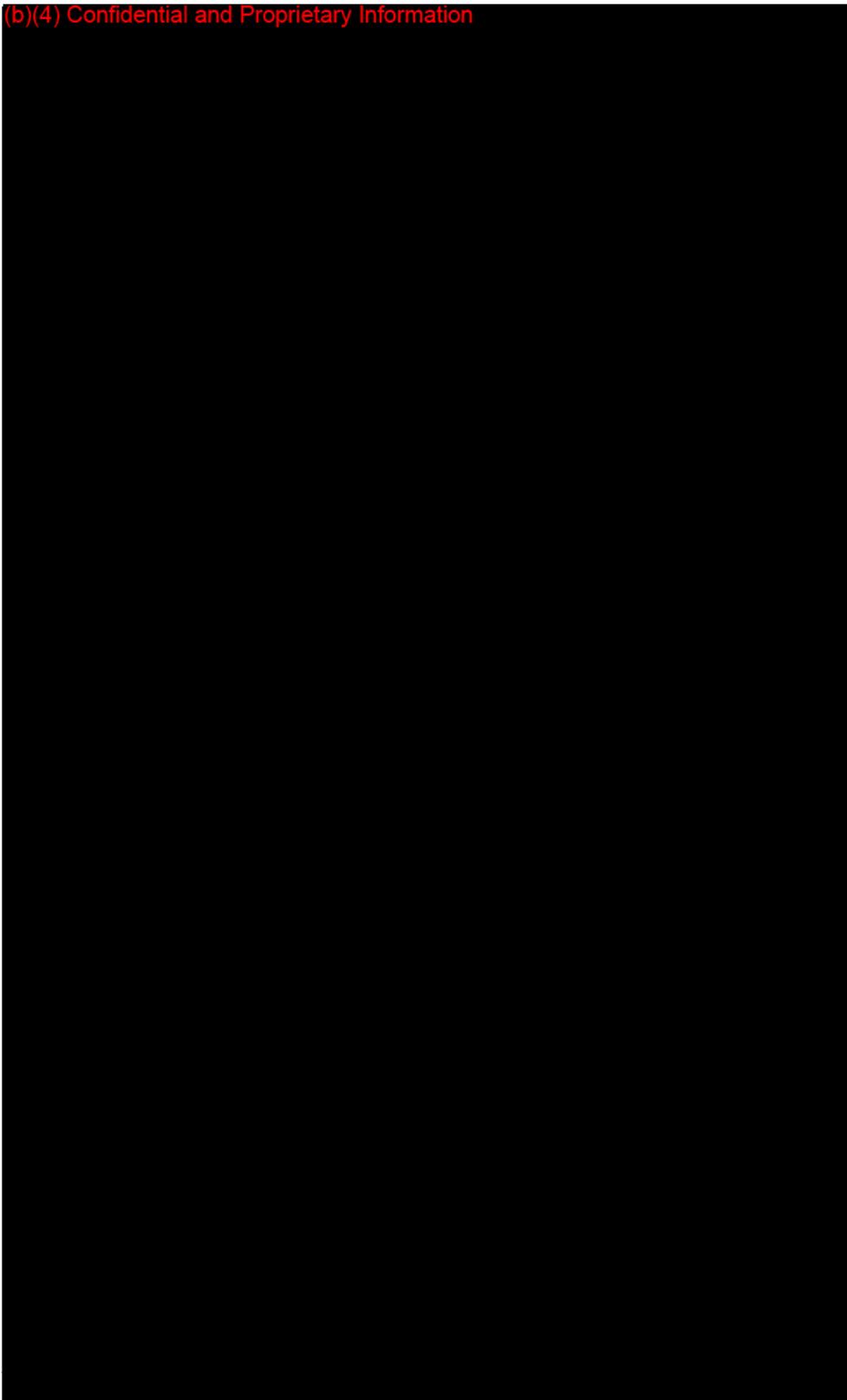
Appendix 2

60

Cambridge Endoscopic Devices, Inc.
510K

5/17/2006

APPENDIX 2
Device Drawings



Appendix 2

61

APPENDIX 3 Predicate Device Information

FROM REGULATORY AFFAIRS

1 513 786 7134

1998-02-11

17:57

F010 P.09/10

K 984240

JUN 22 1998

510(k) Summary of Safety and Effectiveness

Submitter	Edison Endo-Surgery, Inc. 4545 Creek Rd. Cincinnati, OH 45242
Contact	Jackie A. Strasser, MT (ASCP), MS Regulatory Affairs Associate Telephone: (513) 786-7978 Fax (513) 786-7134
Date	November 23, 1998
New Device	<ul style="list-style-type: none">• Name: ENDOPATH® Endoscopic Instruments• Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories• Common Name: Laparoscopic Surgical Instruments• Trade Name/Proprietary Name: ENDOPATH® Endoscopic Instruments
Legally marketed device	The Predicate Device legally marketed under K910831: (Symbiosis) ENDOPATH Endoscopic Instruments
Device description	The ENDOPATH Endoscopic Instruments are sterile, single patient use instruments designed for use through appropriate ENDOPATH Surgical Trocars and FLEXIPATH® Flexible Surgical Trocars. The instruments have a rotating insulated shaft with a diameter of either 3mm, 5mm or 10mm. The rotation knob located on the handle rotates the shaft 360 degrees in either direction. The ring handles are compressed and released to activate the instrument jaws or scissor blades. Each of the curved scissors and dissectors has a monopolar cautery connector that extends from the top of the handle. The connector is used for electrosurgery when properly attached to a standard cautery cable and a proper generator.

Continued on next page

APPENDIX 3 Predicate Device Information

FROM REGULATORY AFFAIRS

1 613 786 7114

1009.02-11

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0219 P. 12/10

510(k) Summary of Safety and Effectiveness, Continued

Intended use	The ENDOPATH Endoscopic Instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection and transection of tissue.
Technological characteristics	The technological characteristics of the New Device are the same as the Predicate Device.
Performance data	Pre-clinical data were used to evaluate the performance to ensure that the device can be used as designed. The studies demonstrated acceptable performance to the Predicate Device in reliability and design. The performance evaluated are ergonomics of the handle and rotating knob tissue trauma, grasping, dissecting, cauterizing ability and cutting ability. From the data generated, it can be concluded that the New Device performs equivalent to the Predicate Device.
Conclusion	Based on the information provided herein and the Decision-Making Process Chart (Appendix E), we conclude that the New Device is substantially equivalent to the Predicate Device under the Federal Food, Drug and Cosmetic Act.

APPENDIX 3 Predicate Device Information

FROM REGULATORY AFFAIRS

1 513 707 7134

1999.02-11

17:50

#018 P.04/10

Appendix A Indications for Use Statement

Statement

The following is the Indications for Use Statement:

510(k) Number: K 984240

Device Name: ENDOPATH Endoscopic Instruments

Indications for Use:

The ENDOPATH Endoscopic Instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection and transection of tissue.

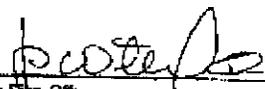
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K984240

APPENDIX 4 Performance Data

Electrical Test Results

Preliminary Electrical Testing was performed on the device to ensure that adequate insulation was provided to meet the insulation breakdown requirement in ANSI/AAMI HF-18.

Summary

The device withstood voltages up to 10,000 Volts. This is well above its maximum rating (3000 Volts) and 1.5 times the maximum rating (4500 Volts), as required by ANSI/AAMI HF-18.

Conclusion

The pureWrist™ electrocautery laparoscopic instruments met the required electrical safety requirements used as acceptance criteria in this testing. The pureWrist™ electrocautery laparoscopic instruments performed similarly to the predicate device.

Cambridge Endoscopic Devices intends to comply with the following voluntary standards prior to marketing.

IEC 60601-1 (1988): Medical Electrical Equipment. Part 1: General requirements for safety

IEC 60601-2-18 (1996): Medical electrical equipment. Part 2: Particular requirements for the safety of endoscopic equipment

IEC 60601-2-2 (1998): Medical Electrical Equipment. Part 2-2: Particular requirements for the safety of high frequency surgical equipment

APPENDIX 4 Performance Data

Animal Study Results

The results of the testing performed in animal labs are provided in the table below.

Feature Tested	Results
Handle Ergonomics	The handle allowed for comfortable use of the instrument with one hand
	The handle design provided good control of the instrument
	Intuitive to use, most surgeons easily picked up device and held in correct orientation
	Handle feels comfortable on the hand
Jaw Opening	Maximum Opening sufficient to perform targeted procedure
Jaw Strength	Holds well, no loss of grip, grasp strength similar to Predicate Device
Jaw Shape	Shape of tip is adequate for dissecting around intestines
Jaw Function	Sharp enough to dissect, but not cause damage
	Instrument tip and handle remained stable when opening and closing handle lever with all three fingers
Performance	Insertion through both 8mm and 5mm cannula was smooth and insufflation pressure was adequately maintained while using the instrument
	No glare was observed
Dimensional	The device was compatible with a 5mm trocar

Summary

The handle was comfortable and intuitive to use. The dimensions were adequate to allow surgeons to perform the targeted procedure. The pureWrist™ electrocautery laparoscopic instruments performed similar to the predicate device with respect to jaw strength and grasp strength. The device was able to maintain dimensional and performance characteristics throughout the procedure.

Conclusion

The design specifications met the user needs. The pureWrist™ electrocautery laparoscopic instruments are effective at performing the targeted procedure. The pureWrist™ electrocautery laparoscopic instruments performed similarly to the predicate device in the areas tested.

APPENDIX 5
510K Summary of Safety and Effectiveness

Cambridge Endoscopic Devices, Inc.
119 Herbert Street
Framingham, MA 01702

KO 61425

**510K Summary of Safety and Effectiveness
May 17, 2006**

Page 1 of 2

1. **Sponsor Name**
Cambridge Endoscopic Devices, Inc.
2. **Device Name**
Proprietary Name: pureWrist™ electrocautery laparoscopic instruments
Common/Usual Name: Electrosurgical cutting and coagulation device and accessories
3. **Identification of Predicate or Legally Marketed Device**
The Cambridge Endoscopic Devices, Inc. pureWrist™ electrocautery laparoscopic instruments are substantially equivalent to the Ethicon Endo-Surgery, Inc. ENDOPATH® Endoscopic Instruments cleared and under K984240.
4. **Device Description**
The pureWrist™ electrocautery laparoscopic instruments are sterile, single use disposable instruments for use through appropriately sized surgical trocars. The instruments consist of a rotating insulated shaft with a 5mm diameter. The distal end of the shaft has the respective end effector attached (scissors, dissector, or hook). The proximal end of the shaft is attached to an ergonomically shaped handle with a rotating knob that allows the shaft to rotate 360 degrees in either direction. The handle contains the actuation mechanism for the respective end effector. The lever on the handle is compressed and released to activate the instrument jaws or scissor blades. Each instrument has a monopolar cautery connector that extends from the bottom of the handle. The connector is used for electrosurgery when properly attached to a standard cautery cable and proper generator.
5. **Intended Use**
The pureWrist™ electrocautery laparoscopic instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transection of tissue.

Cambridge Endoscopic Devices, Inc.
119 Herbert Street
Framingham, MA 01702

K061425

510K Summary of Safety and Effectiveness (Continued)
May 17, 2006

Page 2 of 2

6. Comparison of Technological Characteristics

The pureWrist™ electrocautery laparoscopic instruments have the same technological characteristics as the predicate devices. Each of the devices are scissors, graspers, or dissectors that coagulate tissue using monopolar technology. Each use sharp objects to permit the surgeon to cut or dissect tissue. Each of the devices are connected to the same or similar electro-surgical generators and use similar power ranges for operation. The devices have the same intended use, indications for use, technological features including similar design, performance, and material characteristics which further supports the concept of substantial equivalence.

7. Performance Testing

Pre-clinical testing was used to evaluate performance to ensure that the device can be used as designed. The testing evaluated ergonomics of the handle and rotating knob, tissue trauma, grasping and dissecting ability, and electrical insulation requirements. The studies demonstrated acceptable reliability and design performance relative to the predicate device.

8. Statement of Equivalency

Based on the design and intended use, the Cambridge Endoscopic Devices, Inc. pureWrist™ electrocautery laparoscopic instruments are substantially equivalent to the Ethicon Endo-Surgery, Inc. ENDOPATH® instruments cleared under K984240.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) GEORGE J. MATTAMAL

Subject: 510(k) Number K061425

To: The Record - It is my recommendation that the subject 510(k) Notification: SE

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

GEI + class II
[CFR 878.4400]

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):
 No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 day

Predicate Product Code with class: subject Additional Product Code(s) with panel (optional):

GEI + class II GEI + class II

Review: [Signature] QSD3 8/9/06
 (Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 8/10/06
 (Division Director) (Date)

8

REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 061425
 Reviewer: GEORGE J. MATTIAMAL
 Division/Branch: DGRND / CSDB
 Device Name: PureWrist Ele. Lap. 9 nts.
 Product To Which Compared (510(K) Number If Known): K98240

	YES	NO	
1. Is Product A Device	X		If NO = Stop
2. Is Device Subject To 510(k)?	X		If NO = Stop
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 NE
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 NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

6

**MEMO TO THE RECORD
510(k) REVIEW
K061425**

DATE: August 7, 2006
FROM: Polymer Chemist

OFFICE: HFZ-410
DIVISION: DGRD/GSDB

DEVICE NAME: PureWrist™ Electrocautery Laparoscopic Instruments

COMPANY NAME: Cambridge Endoscopic Devices, Inc.

CONTACT: Mr. Jacob Jacobson, Chairman
(Tel. 508-302-1402, Ext. 102 & Fax. 508)

DEVICE DESCRIPTION AND PERFORMANCE: The sponsor was submitted the above referenced K061425 submission to notify FDA that their company intends to market the subject PureWrist™ Electrocautery Laparoscopic Instruments which are a line of manual electrosurgical instruments. They are single use, sterile disposable devices for use through appropriately sized surgical trocars. The sponsor has claimed their device SE to the predicate device, ENDOPATH Endoscopic Instruments (K984240). The intended use of subject K061425 device will be, as its predicate K984240 device, is indicated for use in endoscopic surgical procedures. And they have application in a variety of minimally invasive procedure to facilitate **“grasping, mobilization, dissection, and transaction of tissue.”**

The subject device, as its predicate K984240 device, consists of a rotating insulated shaft with a 5mm diameter. The distal end of the shaft (shaft diameter: 5mm, shaft working length: 15-45cm) has the respective end effector attached (scissors, dissector, or hook). The proximal end of the shaft is attached to an ergonomically shaped handle with a rotating knob. Articulation of the device's handle results in corresponding motion of the articulating tip. The articulating tip may also be rotated independently of the handle, 300 degrees in either direction, using the axial rotation knob. The tip may be straight or in any articulated position when rotated. The handle also contains the actuation mechanism for the respective end effector. The lever on the handle is compressed and released to activate the instrument scissor blades or jaws. The hook does not have moving components and therefore is not actuated with lever. Each instrument has a monopolar cautery connector that extends from the bottom of the handle. The connector is used for electrosurgery when attached to a standard cautery cable and a generator. In a surgical setting, the surgeon places the jaws, blades, or hook on the target tissue and then energizes the RF generator with the generator's footswitch, causing desiccation of the targeted tissue.

The sponsor has provided a complete engineering diagram with specifications of the subject device. Also, the sponsor has provided with an explanation of subject device as it compares with the predicate K984240 device. Specifically, the sponsor has provided a substantial equivalence comparison table of the subject PureWrist™ Electrocautery Laparoscopic Instruments and its

predicate K984240 device with side by side comparison (listing similarities and/or differences) in terms of energy used, materials, anatomical sites, compliance with standards, biocompatibility, intended use, etc. The subject device is very similar to its predicate K984240 device (**Chart 3**). As its predicate K984240 device, the proposed device is also a sterile, single-use device.

On 8/3/06 and 8/4/06 the sponsor (**Mr. Jacob Jacobson**) was contacted requested more information about:

- 1) **Summary results of Animal studies; and**
- 2) A revised draft labeling (warning section) which contains wording such as “**The Cambridge Endo pureWist Dissector 5mm single use instrument with monopolar cautery is NOT intended for contraceptive coagulation of fallopian tube..... . The device is not intended for use when minimally invasive techniques are contraindicated....**

The required information was received by e-mail on 8/7/06, and the hard copies of the same follow later.

Animal studies: The sponsor has performed two animal studies using pig model, in order to determine the dimensions of the device were adequate to allow surgeons to perform the targeted procedure. Also the comparison study with the predicate device demonstrated that the subject device performed similar to the predicate device with respect to jaw strength and grasp strength. The device was able to maintain dimensional and performance characteristics through out the procedure. Also the subject device performed similarly to predicate device in the areas tested.

Electrical testing: The sponsor has certified that the design of subject device has been subjected to electrical testing in order to ensure compliance with the relevant portions of the ANSI/AAMI HF-18-1993, "the American National Standards on Electrosurgical Devices". For example, the test procedure outlined in ANSI/AAMI HF 18, has been in place to perform HF-18 requirements to ensure that adequate insulation was provided to meet the insulation breakdown requirement in ANSI/AAMI HF-18. Additionally, the sponsor has certified that the following electrosurgical testing will be conducted prior to marketing:

1. IEC 60601-1-1:1998

Medical electrical equipment – Part 1: General requirements for basic safety and essential performance-Edition 3.0;

2. IEC 60601-1-2:1996

Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests-Edition 2.1; Consolidated Reprint; and

3. IEC 60601-2-2:1998

Medical Electrical Equipment Part 2-2: Particular Requirements for the Safety of High Frequency Surgical Equipment-Edition 4.0.

The patient contacting materials of the device, such as FEP, PEEK, Pebax, Tecoflex, Black, Cyanoacrylate, PET, etc were subject to the following biocompatibility testing on the patient contacting materials in according to Tripartite Guidance's requirements of ISO 10993-1, Biological

Evaluation of Medical Devices:

- Cytotoxicity Test
- Intracutaneous Reactivity Test, and
- Sensitization Test

The test results adequately demonstrated that the subject non-sterile, single-use device is non-cytotoxic, non-irritating, and non-sensitizing. There is no safety concern with this proposed device.

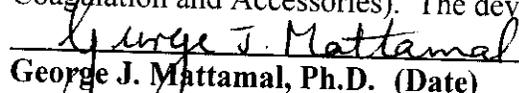
INTENDED USE/INDICATIONS FOR USE: The subject single-use, disposable PureWrist™ Electrocautery Laparoscopic Instruments have application in a variety of minimally invasive procedures “to facilitate grasping, mobilization, dissection, and transaction of tissue”. This claim is SE (**Chart 3**) to its predicate device, ENDOPATH Endoscopic Instruments (K984240).

PREDICATE DEVICE (S): The subject PureWrist™ Electrocautery Laparoscopic Instruments are SE (**Chart 3**) in technological characteristics (**Chart 5**), function, materials and intended use to predicate device, ENDOPATH Endoscopic Instruments (K984240).

STERILITY, PACKAGING, and LABELING: The proposed products, PureWrist™ Electrocautery Laparoscopic Instruments will be supplied as sterile and the devices are designed for single use. The sterilization is accomplished using gamma radiation to achieve a SAL of 10^{-6} in accordance with AAMI TIR27:2001, Sterilization of Health Care Products- Radiation Sterilization-Substantiation of 25kGy as a Sterilization dose-Method VDmax. The sponsor has provided a revised draft labeling that contains instructions for use statement, contraindications, warning and caution statements as per “**the Guidance Document for General Surgical Electrosurgical Devices**”. And the draft labeling is found to be satisfactory.

SAFETY AND EFFECTIVENESS INFORMATION & TRUTHFUL AND ACCURATE STATEMENT: The sponsor has provided 1) a 510 (k) summary of safety and effectiveness information and 2) a truthful and accurate statement about the device.

RECOMMENDATION: The subject PureWrist™ Electrocautery Laparoscopic Instruments are SE (**Chart 7**) in technological characteristics (**Chart 5**), function, and intended use to predicate devices, in particular to ENDOPATH Endoscopic Instruments (K984240). The device is associated with Electrosurgical Surgery and is categorized as 79 GEI (Electrosurgical Device, Cutting & Coagulation and Accessories). The device is Class II based on 21 CFR 878.4400.


George J. Mattamal, Ph.D. (Date)

8/8/06

General and Surgery Devices Branch

Division of General, Restorative, and Neurological Devices

CONTACT HISTORY: The sponsor (**Mr. Jacob Jacobson**) was contacted on 8/3/06 to discuss more about the device and to provide AI. The required information was received by e-mail 8/7/06, and the hard copies of the same follow later.

Mattamal, George

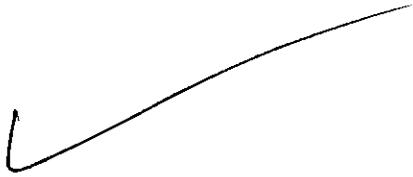
From: Jack Jacobson [jjacobson@cambridgeendo.com]
Sent: Monday, August 07, 2006 12:20 PM
To: Mattamal, George
Subject: Additional Information for CambridgeEndo 510(k) Notification

Attachments: CED510K-Addendum-RE-Animal_Trial_Results.pdf; pW_Device_IFU_Rev.ZIP



CED510K-Addendum-RE-Animal_Trial_Results.pdf (417 KB)...

Dear Dr. Mattamal,



Thank you for your feedback and helpful suggestions.

Attached some additional information per your request:

- 1) Summary results of Animal Trials. See attached PDF file
- 2) Revised IFUs for the 3 devices in the notification. See attached ZIP file.

Also please note that there is further information on the results of the 1st animal trial in the original Notification in Appendix 4 on page 2 of the appendix.

Thank you for your feedback

Regards,

Jack Jacobson

Jack Jacobson
Chair and CEO Cambridge Endoscopic Devices, Inc
O 508-302-1402 x102
C 617-968-1661

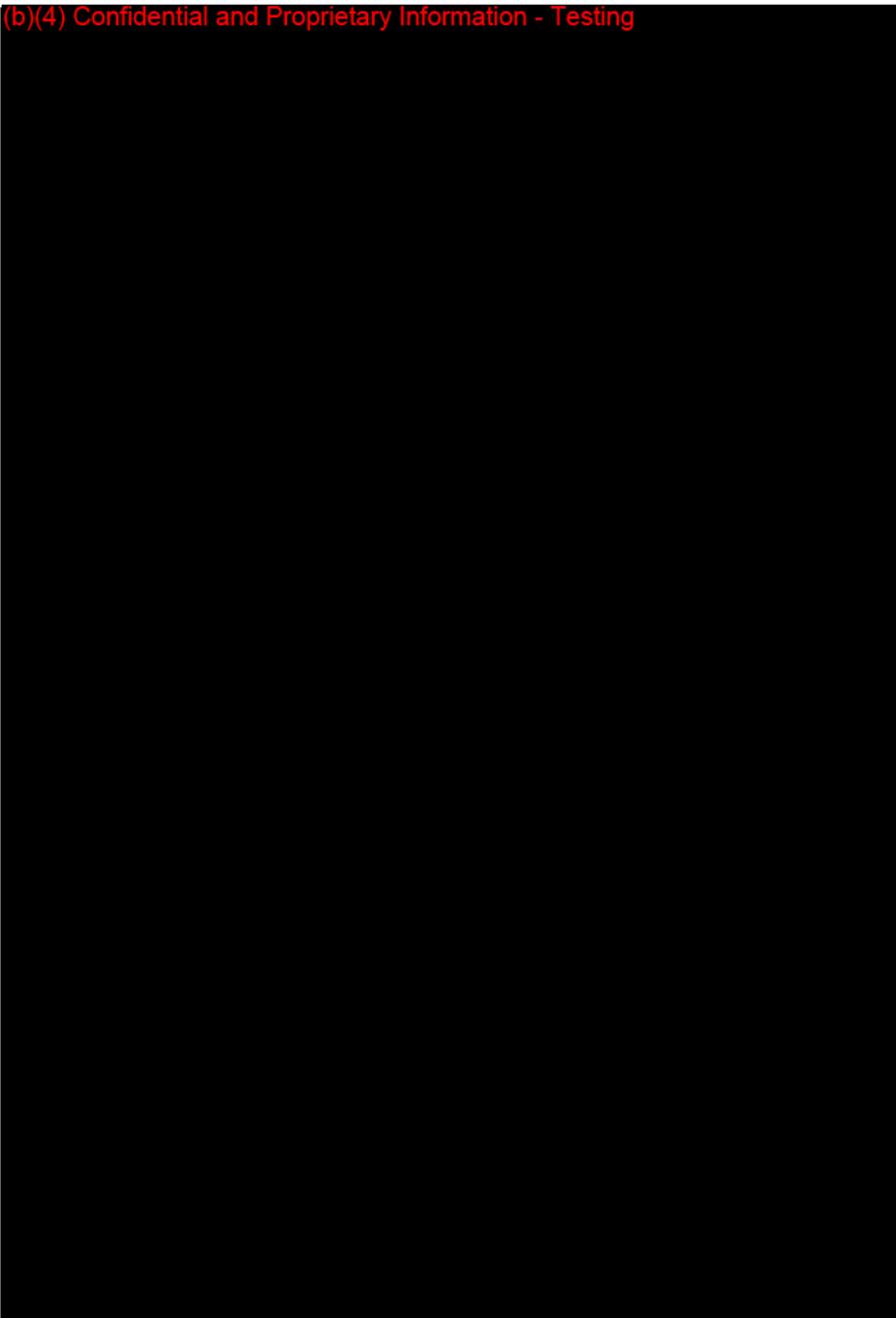
Cambridge Endoscopic Devices, Inc.

Aug. 4, 2006

Addendum to 510k Notification # K061425

SUBJECT: Summary of Results of Pre-clinical Animal Trials

(b)(4) Confidential and Proprietary Information - Testing



CONCLUSION:

Product exceeded surgeons' expectations for dissection, grasping and electrosurgery. Product met expectations for cutting.

CAMBRIDGEENDO™

pureWrist™ Dissector

Diameter: 5 mm, Usable Length: 34 cm

Reorder Number: PW1201-01



BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT

This book is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested, and manufactured for single patient use only. Reuse or reprocessing may lead to device failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess, or resterilize this device.

DESCRIPTION

The CambridgeEndo* pureWrist* Dissector, with a 5 mm diameter insulated shaft and 34 cm usable length, is designed for use through trocars that accommodate 5 mm devices. This device can be used for monopolar cautery when attached to an appropriate electrocautery generator via the male banana plug on the bottom of the handle. Articulation of the device's handle results in corresponding motion of the articulating tip. The articulating tip may also be rotated independently of the handle using the axial rotation knob at the distal end of the handle. The tip may be straight or in any articulated position when rotated.

INDICATIONS

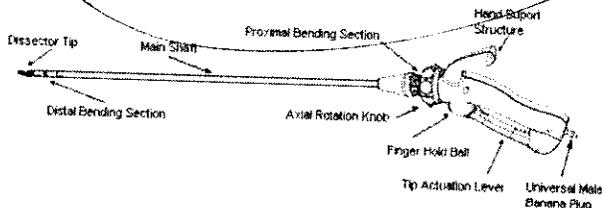
The CambridgeEndo* pureWrist* Dissector 5 mm single use instrument with monopolar cautery has application in a variety of minimally invasive procedure to facilitate grasping, mobilization, and dissection of tissue.

CONTRAINDICATIONS

1. The pureWrist* Dissector single use instrument with monopolar cautery is NOT intended for contraceptive coagulation of fallopian tissue, but may be used to achieve hemostasis following transection of the fallopian tube.
2. The device is intended for use only as indicated.

WARNINGS AND PRECAUTIONS

1. User should be trained in the use of the device before using in a surgical procedure.
2. Prior to inserting and removing device through a trocar, ensure that the jaw is closed and the distal tip is straight.
3. Only physicians having adequate training and familiarity with endoscopic techniques should perform endoscopic procedures. Consult the medical literature relative to techniques, complications, and hazards prior to performing endoscopic procedures.
4. A thorough understanding of the principle and techniques involved in electrocautery procedures is necessary to avoid shock and burn hazard to both patient and user. Verify compatibility of instrumentation to ensure that electrical isolation or grounding is not compromised.
5. Do not use power settings that may result in more than 8000 Volts being delivered to the pureWrist* Dissector. Excessive power levels may result in instrument malfunctions and possible patient or user injury.
6. The instrument is not intended for use when minimally invasive techniques are contraindicated.
7. This device is provided STERILE and is intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT REUSE, REPROCESS OR RESTERILIZE THIS DEVICE.



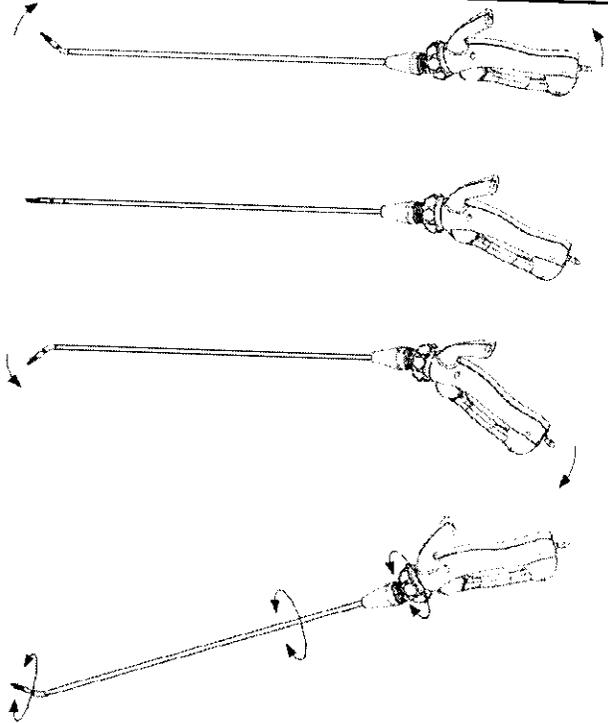
SCHEMATIC VIEW

- Dissector Tip – Used for grasping and blunt dissection of tissue
- Distal Bending Section – Provides articulation at the distal tip
- Main Shaft – Rigid insulated shaft
- Proximal Bending Section – Articulates the distal bending section
- Axial Rotation Knob – Allows user to rotated shaft independent of handle

- Tip Actuation Lever – Used to open and close the jaws
- Handle – User holds the device here

ELECTROCAUTERY COMPATIBILITIES

The pureWrist* Dissector is compatible with the following manufacturer's electrocautery generators: Valleylab, Conmed, and Circon.

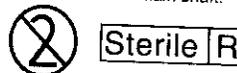


MOTION

- Upward articulation of the handle relative to the main shaft causes corresponding upward articulation of the tip relative to the main shaft.
- When the handle is straight/in line with the main shaft, the tip is also straight/in line with the main shaft.
- Axial rotation while the tip is articulated causes the tip to rotate about its center axis, while remaining articulated.
- Articulating the handle in any direction (upwards, downwards, or sideways) relative to the main shaft causes corresponding articulation of the tip relative to the main shaft.

INSTRUCTIONS FOR USE

1. If the electrocautery function of the device will be used, connect to an appropriate monopolar generator using a standard cautery cable attached to the male banana plug at the back of the handle.
2. Prior to inserting the device through a trocar, ensure that the jaw is closed by depressing the *Tip Actuation Lever* and ensure that the distal tip is straight relative to the main shaft.
3. Once the device is inside the body, the jaws can be opened and closed by depressing and releasing the *Tip Actuation Lever*.
4. Tip articulation can be obtained by articulating the handle relative to the main shaft.
5. Tip rotation can be obtained by rotating the *Axial Rotation Knob* relative to the handle.
6. Prior to removing the device from the trocar, ensure that the jaw is closed by depressing the *Tip Actuation Lever* and ensure that the distal tip is straight relative to the main shaft.



**STORE AT ROOM TEMPERATURE.
AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.
DO NOT EXPOSE TO TEMPERATURES ABOVE 130°F (54°C).**

CAUTION: Federal (USA) law restricts this device for sale and use by, or on the order of, a physician.

*Trademark
US Patents Pending
Manufactured in the USA for: Cambridge Endoscopic Devices, Inc., Framingham, MA 01702

CB2123-01 Rev R01

CAMBRIDGEENDO™

pureWrist™ Scissors

Diameter: 5 mm, Usable Length: 34 cm

Reorder Number: PW1101-01



BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT

This book is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested, and manufactured for single patient use only. Reuse or reprocessing may lead to device failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess, or resterilize this device.

DESCRIPTION

The CambridgeEndo™ pureWrist™ Scissors, with a 5 mm diameter insulated shaft and 34 cm usable length, is designed for use through trocars that accommodate 5 mm devices. This device can be used for monopolar cautery when attached to an appropriate electrocautery generator via the male banana plug on the bottom of the handle. Articulation of the device's handle results in corresponding motion of the articulating tip. The articulating tip may also be rotated independently of the handle using the axial rotation knob at the distal end of the handle. The tip may be straight or in any articulated position when rotated.

INDICATIONS

The CambridgeEndo™ pureWrist™ Scissors 5 mm single use instrument with monopolar cautery has application in a variety of minimally invasive procedure to facilitate mobilization, transection, and dissection of tissue.

CONTRAINDICATIONS

1. The pureWrist™ Scissors single use instrument with monopolar cautery is NOT intended for contraceptive coagulation of fallopian tissue, but may be used to achieve hemostasis following transection of the fallopian tube.
2. The device is intended for use only as indicated.

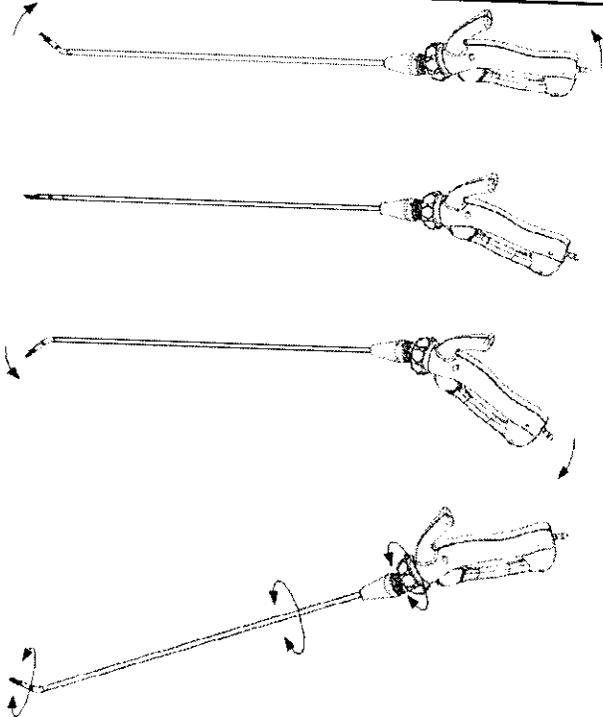
WARNINGS AND PRECAUTIONS

1. User should be trained in the use of the device before using in a surgical procedure.
2. Prior to inserting and removing device through a trocar, ensure that the scissor blades are closed and the distal tip is straight.
3. Only physicians having adequate training and familiarity with endoscopic techniques should perform endoscopic procedures. Consult the medical literature relative to techniques, complications, and hazards prior to performing endoscopic procedures.
4. A thorough understanding of the principle and techniques involved in electrosurgical procedures is necessary to avoid shock and burn hazard to both patient and user. Verify compatibility of instrumentation to ensure that electrical isolation or grounding is not compromised.
5. Do not use power settings that may result in more than 3000 Volts being delivered to the pureWrist™ Scissors. Excessive power levels may result in instrument malfunctions and possible patient or user injury.
6. The instrument is not intended for use when minimally invasive techniques are contraindicated.
7. This device is provided STERILE and is intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT REUSE, REPROCESS, OR RESTERILIZE THIS DEVICE.

- Jaw Actuation Lever – Used to open and close the scissor blades
- Handle – User holds the device here

ELECTROCAUTERY COMPATIBILITIES

The pureWrist™ Scissors are compatible with the following manufacturer's electrosurgical generators: Valleylab, Commed, and Circon.

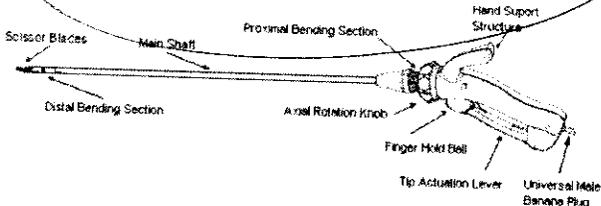


MOTION

- Upward articulation of the handle relative to the main shaft causes corresponding upward articulation of the tip relative to the main shaft.
- When the handle is straight/in line with the main shaft, the tip is also straight/in line with the main shaft.
- Axial rotation while the tip is articulated causes the tip to rotate about its center axis, while remaining articulated.
- Articulating the handle in any direction (upwards, downwards, or sideways) relative to the main shaft causes corresponding articulation of the tip relative to the main shaft.

INSTRUCTIONS FOR USE

1. If the electrocautery function of the device will be used, connect to an appropriate monopolar generator using a standard cautery cable attached to the male banana plug at the back of the handle.
2. Prior to inserting the device through a trocar, ensure that the scissor blades are closed by depressing the *Tip Actuation Lever* and ensure that the distal tip is straight relative to the main shaft.
3. Once the device is inside the body, the blades can be opened and closed by depressing and releasing the *Tip Actuation Lever*.
4. Tip articulation can be obtained by articulating the handle relative to the main shaft.
5. Tip rotation can be obtained by rotating the *Axial Rotation Knob* relative to the handle.
6. Prior to removing the device from the trocar, ensure that the blades are closed by depressing the *Tip Actuation Lever* and ensure that the distal tip is straight relative to the main shaft.



SCHEMATIC VIEW

- Tip (Scissor Blades) – Used for transection and blunt dissection of tissue
- Distal Bending Section – Provides articulation of the distal tip
- Main Shaft – Rigid insulated shaft
- Proximal Bending Section – Articulates the distal bending section
- Axial Rotation Knob – Allows user to rotate shaft independent of handle



Sterile R



STORE AT ROOM TEMPERATURE. AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES. DO NOT EXPOSE TO TEMPERATURES ABOVE 130°F (54°C).

CAUTION: Federal (USA) law restricts this device for sale and use by, or on the order of, a physician.

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US Patents Pending
Manufactured in the USA for: Cambridge Endoscopic Devices, Inc., Framingham, MA 01702

CB2124-01 Rev R01

CAMBRIDGEENDO™

pureWrist™ Hook

Diameter: 5 mm, Usable Length: 33 cm

Reorder Number: PW1301-01



BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT

This book is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested, and manufactured for single patient use only. Reuse or reprocessing may lead to device failure and subsequent patient injury. Reprocessing and/or reesterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess, or reesterilize this device.

DESCRIPTION

The CambridgeEndo™ pureWrist™ Electrocautery Hook, with a 5 mm diameter insulated shaft and 33 cm usable length, is designed for use through trocars that accommodate 5 mm devices. This device can be used for monopolar cautery when attached to an appropriate electrocautery generator via the male banana plug on the bottom of the handle. Articulation of the device's handle results in corresponding motion of the articulating tip. The articulating tip may also be rotated independently of the handle using the axial rotation knob at the distal end of the handle. The tip may be straight or in any articulated position when rotated.

INDICATIONS

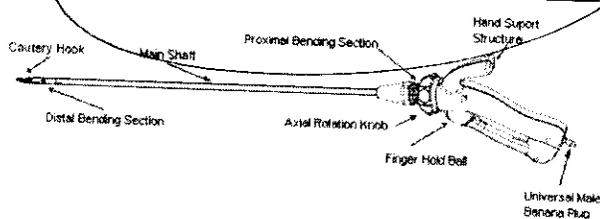
The CambridgeEndo™ pureWrist™ Hook 5 mm single use instrument with monopolar cautery has application in a variety of minimally invasive procedure to facilitate mobilization and electrocautery of tissue.

CONTRAINDICATIONS

1. The pureWrist™ Hook single use instrument with monopolar cautery is NOT intended for contraceptive coagulation of fallopian tissue, but may be used to achieve hemostasis following transection of the fallopian tube.
2. The device is intended for use only as indicated.

WARNINGS AND PRECAUTIONS

1. User should be trained in the use of the device before using in a surgical procedure.
2. Prior to inserting and removing device through a trocar, ensure that the distal tip is straight.
3. Only physicians having adequate training and familiarity with endoscopic techniques should perform endoscopic procedures. Consult the medical literature relative to techniques, complications, and hazards prior to performing endoscopic procedures.
4. A thorough understanding of the principle and techniques involved in electrocautery is necessary to avoid shock and burn hazard to both patient and user. Verify compatibility of instrumentation to ensure that electrical isolation or grounding is not compromised.
5. Do not use power settings that may result in more than 3000 Volts being delivered to the pureWrist™ Hook. Excessive power levels may result in instrument malfunctions and possible patient or user injury.
6. The instrument is not intended for use when minimally invasive techniques are contraindicated.
7. This device is provided STERILE and is intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT REUSE, REPROCESS, OR RESTERILIZE THIS DEVICE.



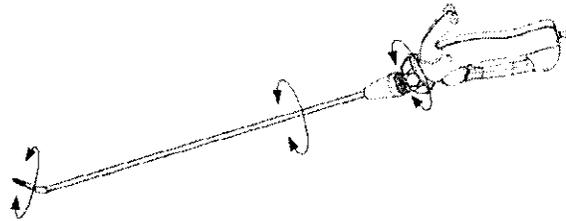
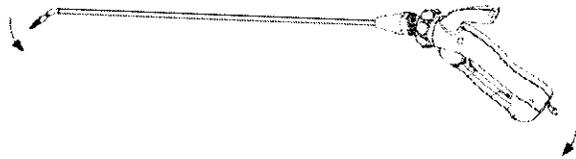
SCHEMATIC VIEW

- Tip (Hook) – Used for mobilization and cautery of tissue
- Distal Bending Section – Provides articulation of the distal tip
- Main Shaft – Rigid insulated shaft

- Proximal Bending Section – Articulates the distal bending section
- Axial Rotation Knob – Allows user to rotate shaft independent of handle
- Handle – User holds the device here

ELECTROCAUTERY COMPATIBILITIES

The pureWrist™ Hook is compatible with the following manufacturer's electrocautery generators: Valleylab, Conmed, and Circon.



MOTION

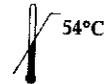
- Upward articulation of the handle relative to the main shaft causes corresponding upward articulation of the tip relative to the main shaft.
- When the handle is straight/in line with the main shaft, the tip is also straight/in line with the main shaft.
- Axial rotation while the tip is articulated causes the tip to rotate about its center axis, while remaining articulated.
- Articulating the handle in any direction (upwards, downwards, or sideways) relative to the main shaft causes corresponding articulation of the tip relative to the main shaft.

INSTRUCTIONS FOR USE

1. If the electrocautery function of the device will be used, connect to an appropriate monopolar generator using a standard cautery cable attached to the male banana plug at the back of the handle.
2. Prior to inserting the device through a trocar, ensure that the distal tip is straight relative to the main shaft.
3. Tip articulation can be obtained by articulating the handle relative to the main shaft.
4. Tip rotation can be obtained by rotating the Axial Rotation Knob relative to the handle.
5. Prior to removing the device from the trocar, ensure that the distal tip is straight relative to the main shaft.



Sterile



STORE AT ROOM TEMPERATURE. AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES. DO NOT EXPOSE TO TEMPERATURES ABOVE 130°F (54°C).

CAUTION: Federal (USA) law restricts this device for sale and use by, or on the order of, a physician.

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CB2125-01 Rev R01

