Reprocessed Device for Single Use

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

- STERILE
- 100% LATEX FREE

Explanation of Icons

- Sterilized by Ethylene Oxide Gas
- Date of Reprocessing
- Use by Date
- Product Code
- Do Not Reuse
- See Instructions For Use
Reprocessed GI Biopsy Forceps

Device Description
Reprocessed Biopsy Forceps consists of a flexible sheath with distal grasping cups controlled by a proximal handle. Forceps cups are available in alligator and smooth oval styles with or without a biopsy collection needle. Forceps are designed to be guided into the gastrointestinal (GI) tract by endoscopy through a biopsy channel with minimum dimension of 2.8 mm (2.0 mm for gastropediatric forceps). “Hot” biopsy forceps are equipped with a pin for electrical connection to a compatible monopolar electrosurgical unit; their use for electrocautery requires simultaneous use of an appropriate patient grounding pad.

Indications
GI forceps are designed for insertion through an appropriately sized endoscopy channel for removal and histological sampling of tissue. When used with a compatible ESU and patient grounding pad, “hot” biopsy forceps are intended for electrocautery and removal of polyps and/or tissue within the gastrointestinal tract.

Contraindications
This GI biopsy forceps should not be used:
- for pulmonary biopsy procedures;
- when contraindications to GI endoscopy are present, e.g. acute abdominal peritonitis, toxic megacolon, or active colitis;
- in the possible presence of combustible gases (e.g. anesthetic);
- in patients with bleeding disorders;
- in a side viewing endoscope.

Warnings
- Prior to use, read and follow these instructions as well as those of the manuals for the endoscopy system, electrosurgical unit (ESU) and patient grounding pad.
- This package is provided sterile by method of ethylene oxide gas. Do not use if there is any evidence of damage to the sterile package.
- Endoscopy, biopsy, and electrocautery are procedures which should only be performed by trained and qualified personnel.
- To prevent patient injury (e.g. perforation), advance the forceps slowly and remove tissue only under direct endoscopic visualization.
- Hemostasis should be monitored during the procedure and an inspection of the biopsy area conducted prior to conclusion of the procedure.
- Do not forcibly advance or withdraw the forceps as this can cause patient injury or damage to the forceps jaws, e.g. detachment, failure to open/close, etc.
- Should a forceps jaw become detached within the patient, compare the risks and benefits of retrieval carefully with those of allowing it to remain in the patient.
- Microvasive coated forceps are manufactured with a black ink on its sheath. Minor smearing of the ink may occur during wipe down or use of this device.
- Potential adverse events associated with use of this device include:
  - Patient or operator injury during electrocautery.
  - Breakage and retention of a forceps jaw within the patient.
  - Bowel perforation.
  - Hemorrhage due to inadvertent damage of organs and vessels.
  - Explosion of intraluminal gases.
  - Localized or systemic infections.
  - Coagulation syndrome due to a localized peritoneal reaction, with possible abdominal tenderness/pain or leukocytosis fever.
- Monopolar electrocautery requires proper use of a patient grounding pad. Prior to use, verify electrical compatibility of forceps and grounding pad to the ESU.
- Electrocautery can disrupt a pacemaker or other medical equipment, such as electrocardiograph, pulse oximeter, endoscopy photo exposure circuit.
- Biopsy samples acquired with simultaneous electrocautery may be damaged and unsuitable for histopathology.
- Accidental burns to the operator can be prevented by wearing protective gloves during electrocautery.
- To avoid patient injury or equipment damage, the ESU should be switched OFF during insertion, removal, or positioning of the forceps.
Suggested Directions for Use

1) Preliminary:
   - The package label is detachable and may be affixed to the medical record of the patient.
   - Peel the pouch open and remove the forceps.
   - Operate the handle to verify that the forceps jaws open and close smoothly.
   - Verify that there are no loose, bent, or broken parts and that the shaft has no apparent kinks or nicks in its jacket.
   - DO NOT USE OR ATTEMPT TO REPAIR a device that appears damaged or does not operate properly. Return the product to Ascent.

2) Insertion:
   - Insert the endoscope. If an elevator-equipped endoscope is used, lower the elevator until forceps are in their final position and then raise the jaws into view.
   - If electrocautery is planned, attach the grounding pad to the patient and ESU as directed in their operator manuals. Do not attach forceps to ESU at this time.
   - With its jaws in a firmly closed position, insert the forceps through the endoscopy channel using short and deliberate strokes.
   - If resistance is encountered, DO NOT force forceps through the channel. The angle of the endoscope may be adjusted until a smooth passage of the forceps is possible.

3) Tissue Removal:
   - Biopsy samples should only be acquired under direct visualization.
   - Open the jaws by pulling back on the handle, advance the open jaws carefully against the tissue to be sampled, and close the jaws firmly by pushing in on the handle. Gently pull the closed jaws away from the tissue wall.
   - If electrocautery is desired, attach the active power cord of the ESU to the electrical connector on the forceps handle, turn the ESU power ON, adjust the unit to the desired energy output, and perform cautery. When completed, turn the ESU OFF and detach the power cord.
   - With the jaws firmly closed, slowly withdraw the forceps through the channel. (An endoscope elevator should be lowered prior to withdrawing forceps.)
   - DO NOT attempt to withdraw a forceps with partially closed jaws through the channel. If the forceps jaws fail to close completely, retract the forceps to the channel opening and then withdraw the endoscope and forceps together.
   - Once the forceps is removed from the patient, open its jaws and retrieve the tissue sample.

Returning the Forceps to Stryker Sustainability Solutions for Reprocessing:
   - Stryker Sustainability Solutions reprocesses GI biopsy forceps only. DO NOT PLACE PULMONARY FORCEPS IN THE COLLECTIONS CONTAINER.
   - Care must be taken so that the forceps is not kinked, nicked, or otherwise damaged during handling.
   - Rinse or wipe down the forceps with clean saline or tepid water. All visible gross matter should be removed. If rinsing, wipe down the device after with a clean gauze sponge to remove any excess fluids. The forceps should be rinsed or wiped immediately after use, or at the latest, immediately after the procedure.
   - DO NOT IMMERSE THE CONNECTOR OR HANDLE IN WATER.
   - Loosely coil the forceps and place in the Stryker Sustainability Solutions collection container. Keep the collection container in a cool, dry place.
   - The container is ready for shipping when it is at most ¾ full, but not later than one week following deposit of the first forceps within the container. Adding filler packing material to the container is unnecessary.
   - Place the container in the pre-addressed carton provided by Ascent, seal the carton, and deliver it to the hospital shipping department.

Microvasive® is a registered trademark of Boston Scientific Corp.
Wilson Cook® is a registered trademark of Wilson-Cook Medical, Inc.
Warranty

Stryker Sustainability Solutions, Inc. ("Stryker") warrants all products, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product (the "Warranty Period"). This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

If a valid warranty claim is received within thirty (30) days of the expiration of the Warranty Period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker’s property. In any event, Stryker’s liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, or tampered with; (2) products that have been reprocessed or repaired by any person other than Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; or (4) products on which any original serial numbers or other identification marks have been removed or destroyed. If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination.

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

BSF Rev D 07-2011 RM702003