

Reprocessed by



Instructions for Use Reprocessed GI Biopsy Forceps


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

REF Ascent 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 electrocautery 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, electrocautery 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.
- Microvase 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 Ascent for Reprocessing:

- Ascent 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 Ascent collection container. Keep the collection container in a cool, dry place.
- The container is ready for shipping when it is at most $\frac{3}{4}$ 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.

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Wilson Cook® is a registered trademark of Wilson-Cook Medical, Inc.

Reprocessed GI Biopsy Forceps

Warranty

Ascent Healthcare Solutions (**ASCENT**) will reprocess medical instruments, including cleaning, testing, and sterilization, as appropriate. Such activities will be conducted in compliance with the FDA Quality System Regulations and the ISO 13485:2003 standard for medical devices and the Canadian Medical Device Regulation designation.

ASCENT warrants the sterility of reprocessed medical instruments unless the packaging of the medical instrument has been opened or damaged, or the expiration date has been exceeded. ASCENT warrants the functionality of reprocessed medical instruments until such medical instruments have been used in one medical procedure. Medical Facility has sole responsibility for deciding to use any reprocessed Medical Device, and the obligation to use the same, if at all, in accordance with such Device's instructions for use.

ASCENT shall indemnify and hold harmless MEDICAL FACILITY, PHYSICIANS AND CLINICIANS against claims, demands and liability for sums which MEDICAL FACILITY, PHYSICIANS AND CLINICIANS shall become legally obligated to pay as damages caused by bodily injury to patients as a result of ASCENT's negligent performance of services under this Agreement. This indemnity and hold harmless obligation shall not apply to damages arising out of misuse of medical instruments which are the subject of this Agreement. ASCENT shall only be liable to Medical Facility for incidental or consequential damages arising out of or related to any act or omission of ASCENT and ASCENT makes no warranty, express or implied, other than such warranties as expressly described in this Agreement.

Ascent does not warrant reprocessed (in full or in part) Medical Devices that have been or will be resold, modified or treated by Medical Facility or any other party.

This Warranty is in lieu of and excludes all other warranties not expressly set forth herein.

Only Ascent Healthcare Solutions bears the responsibility for this device. 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.