

Reprocessed by



Instructions for Use
Reprocessed Bipolar Cutting Forceps
(3005PK, 3025PK, 920000PK, 920005PK)


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**

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

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Bipolar Cutting Forceps Description

The Cutting Forceps are intended to be passed through a 5mm endoscopic cannula. Coagulation is attained using electrosurgical energy under endoscopic visualization. The compatible generator for each model is listed in the following table:

Device Models	Generator
3005PK	Generator PKS
3025PK	Generator PKS
920000PK	Generator G400 only
920005PK	Generator G400 only

Indications for Use

Reprocessed bipolar cutting forceps are indicated for endoscopic bipolar coagulation, grasping and transection of tissue.

Contraindications for Use

Reprocessed bipolar cutting forceps are contraindicated for:

- Coagulation of the fallopian tube

Warnings

- The device is intended for use with compatible generators only.
- During the energy application, ensure the active electrodes are in the field of view.
- Do not extend knife during electrosurgical coagulation.
- Before engaging cutting blade, ensure tissue is fully desiccated.

Precautions

- These instruments are only intended for use by individuals with adequate training and familiarity with techniques associated with the surgical procedure employed. For further information about techniques, complications and hazards, consult the medical literature.
- Prior to use, read and follow all instructions. Failure to follow the instructions, cautions and warnings may lead to patient injury or cause serious surgical consequences.
- This package is provided sterile by ethylene oxide gas. Do not use if there is any evidence of damage to the sterile package.
- Check device and trocar compatibility prior to use, because the instrument may not be compatible with some reusable trocars.
- Unopened instruments must be stored in a cool dry place.

Adverse Reactions

None.

Directions for Use

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Inspect packaging before opening. The contents of the package are sterile if the package has not been compromised. Do not use the instrument if the sterility has been compromised. Remove the instrument from the package and place it in a sterile work area using aseptic technique. If the package is damaged or if it was opened and the instrument was not used, return the instrument and package to Ascent Healthcare Solutions.
3. Turn PKS electrical generator on. For model 3005PK and 3025PK insert the extension cord into the generator and connect the PKS Cutting Forceps to the extension cord. For models 920000PK and 920005PK insert the device cord into the generator. The generator automatically sets the appropriate power outputs for the device or can be manually adjusted.
4. Pre-Test Device - use the following steps to verify complete electrical activity and generator setting:
 - a. Saturate a 4" x 4" gauze pad with saline.
 - b. Touch the coagulation surfaces against the gauze pad.
 - c. CAUTION: While the device is activated, DO NOT touch the coagulating surfaces, this may cause injury.
 - d. Depress the ACTIVATION pedal on the footswitch to activate electrosurgical function.
 - e. A complete circuit and active power are indicated by steam generation from the gauze pad and the coagulation surfaces.
5. If no steam is generated:

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- f. Add more saline to the gauze pad.
 - g. Both coagulation surfaces should be in contact with the saturated pad.
 - h. Check that the generator power switch is ON.
 - i. Models 3005PK and 3025PK verify proper connection of the electrical connector on the cutting forceps to the extension cord and the extension cord to the generator. Models 920000PK and 920005PK verify proper connection of electrical connector to the generator.
 - j. Check setting and function of the electrical generator.
 - k. Increase power in increments of 2 watts.
 - l. Reduce the amount of pad surface contacting the coagulation surfaces.
 - m. DO NOT use the device if steam is still not observed.
6. Ensure the device is closed and not activated prior to insertion and withdrawal through the endoscopic cannula. Advance the device through the cannula until it exits and is in sight.
NOTE: During the "RACHET" mode, if the forceps grip is released the jaws will stay closed. Steps 6 through 9 indicate how to use the device in "RACHET" mode.
7. To engage RACHET make certain the forceps are open. Depress the white button in center of orange "RACHET" switch located on top of the device and slide the switch forward.
8. To release RACHET lift finger upward from forceps grip and push the release trigger inward.
9. To disengage RACHET depress the white button in center of orange "RACHET" and glide switch backward.
10. Position the device as desired. Place the anatomical structure to be coagulated between the open forceps jaws. Squeeze grip to close forceps jaws onto tissue. Do not grasp tissue past the serrated teeth. Ensure the forceps jaws are in connection only with the anatomical structure to be coagulated.
11. Use the footswitch to activate the electrosurgical unit. Coagulation effect will occur to the tissue between the coagulating surfaces. For optimum coagulation, ensure both coagulating surfaces are in equal contact with tissue.
CAUTION: THE DEVICE WILL SHORT OUT IF FORCEP JAWS CONTACT EACH OTHER WHEN THE POWER IS ACTIVATED. RELEASE THE JAWS SO THEY ARE NOT IN CONTACT AND THE DEVICE WILL BECOME OPERATIONAL.
12. To prevent tissue from sticking to the forceps, discontinue power application when the tissue has been desiccated and/or flush procedure site with sterile saline to keep tissue moist.
13. Transection of tissue may be accomplished after proper desiccation of tissue, by depressing thumb paddle and maintaining a firm grasp of the tissue using the forceps. Ensure blade advancement will cut only the desired tissue.
14. Use a 4" x 4" gauze pad saturated with saline solution to clean the coagulating surfaces by removing the debris. Keep the cutting blade retracted while cleaning. Keep the jaws free of debris to ensure optimum performance.

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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.

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