

Reprocessed by



Sustainability Solutions

Instructions for Use Reprocessed Endoscopic Instruments (Model 5DCS)


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

 Product Code

 Do Not Reuse

 See Instructions For Use

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Reprocessed Endoscopic Instruments (Model 5DCS)

Reprocessed Endoscopic Instruments Description

The ENDOPATH Endoscopic Instruments (hereinafter Endoscopic Instruments) have a rotating 5mm diameter insulated shaft and are designed for use through appropriate Surgical Trocars and FLEXIPATH Flexible Surgical Trocars. The rotation knob located on the handle rotates the shaft 360 degrees in either direction. Most instruments have a monopolar cautery connector extending from the top of the handle and can be used for electrosurgery when properly attached to standard cautery cables and suitable generators. The instrument jaws or scissor blades are activated by compression and release of the ring handles.

Indications for Use

Scissor instruments are used during minimally invasive surgery in conjunction with an appropriately sized trocar and a compatible electrosurgical unit for mobilization, transection and/or cauterization of tissue.

The instrument, model 5DCS, is validated with the US Surgical Force FX-C generator and is only to be used with this generator.

Contraindications for Use

Reprocessed endoscopic instruments are contraindicated for:

- Contraceptive coagulation of fallopian tissue.
- Other conditions contraindicated for minimally invasive techniques.

Warnings and Precautions

- Package is provided sterile by method of ethylene oxide gas and is for single patient use only. Do not use if there is any evidence of damage to the package.
- These instruments are only intended for use by individuals with adequate training and familiarity with minimally invasive surgical techniques. For further information about techniques, complications and hazards, consult the medical literature.
- Minimally invasive procedures should be performed only by persons having sufficient training and familiarity with minimally invasive techniques. Prior to performance of any minimally invasive procedures, consult medical literature relative to techniques, complications, and hazards.
- A complete understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to other medical instruments. Ensure that insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid.
- Ensure the blades/jaws are fully visible to avoid inadvertent tissue damage, when using electrocautery.
- Instruments with monopolar cautery are not to be used as bipolar cautery instruments.
- Do not apply electrosurgical current directly to clips and/or staples.
- If cutting of staples or clips is attempted, damage to the instrument may occur.
- Do not introduce or withdraw the instrument through a trocar sleeve with the blade/jaws open.
- Inspect the site for hemostasis after removing the instrument. If hemostasis is not present, use appropriate techniques to attain hemostasis.
- The instrument will operate with electrosurgical generators having a high frequency maximum voltage of 3000 Volts peak. Ensure that all safety precautions are followed and refer to the electrosurgical generator's specification to verify compatibility and for indications and instructions.

Adverse Reactions

None.

Directions for Use

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Before beginning the procedure, verify compatibility of all instruments and accessories.
3. 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. If the package is damaged or if it was opened and the instrument not used, return the instrument and package to Stryker Sustainability Solutions.
4. Do not attempt to resterilize.
5. Remove the device from the packaging restraints using aseptic technique.
6. Remove the plastic tip protector that protects the scissor blades or dissector jaws.
7. Turn the knob to the desired position, to rotate the shaft.
8. Push the ratchet ON/OFF switch (located at the base of the ring handles) backwards to ON to clamp and lock the instrument jaws onto tissue. Position the jaws so that the tissue is between the jaws. Close the ring handles to the desired position.

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9. To release tissue from the jaws, push the ratchet switch forward to OFF. Press the handles together to disengage the ratchet mechanism and open the handles.

Warranty

Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing 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.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, 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 a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

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 OR 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.

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.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of 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; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable 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.

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 and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. 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.

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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.