



OPUS SMARTSTITCH® SUTURING DEVICE HANDLE Instructions For Use

DESCRIPTION

The Opus SmartStitch® Suturing Device Handle is a reusable device designed for use with an Opus SmartStitch® Connector and SmartStitch® Suture Cartridge for placing suture through soft tissue.

MATERIALS

Surgical grade stainless steel

INDICATIONS FOR USE

The Opus SmartStitch® Suturing Device Handle is indicated for placement of suture through soft tissue in endoscopic and other limited access procedures.

PREPARATION FOR USE

The Opus SmartStitch® Suturing Device Handle is provided NONSTERILE and must be cleaned and sterilized prior to use.

CLEANING

Immediately after each procedure and before sterilization, the Opus SmartStitch® Suturing Device Handle should be manually cleaned with a standard enzymatic detergent (ENZOL® or equivalent prepared per manufacturer's instructions)¹ and lukewarm water. Scrub with a soft brush to remove any visible debris. Instrument immersion is permitted. After cleaning, rinse with water and inspect. Repeat cleaning procedure if any visible debris remains. As an alternative to manual cleaning, devices may be machine cleaned using a suitable laboratory washer using the following cycle: (1) Prewash: 2 minutes minimum, cold water; (2) Enzyme Wash (Enzol or equivalent according to manufacturer's instructions): 2 minutes minimum, hot water; Wash Cycle (Renu-Klenz or equivalent according to manufacturer's instructions): 2 minutes minimum in hot water that is at least 66°C; Rinse: 1 minute minimum in hot water that is at least 66°C; Dry: 7 minutes minimum at a temperature of 115°C minimum.

STERILIZATION

The Opus SmartStitch® Suturing Device Handle may be steam autoclaved. The operator should follow the sterilizer manufacturer's instructions for steam sterilization cycle parameters. It is recommended that the Opus SmartStitch® Suturing Device Handle be steam autoclaved using the following sterilization times and temperatures:

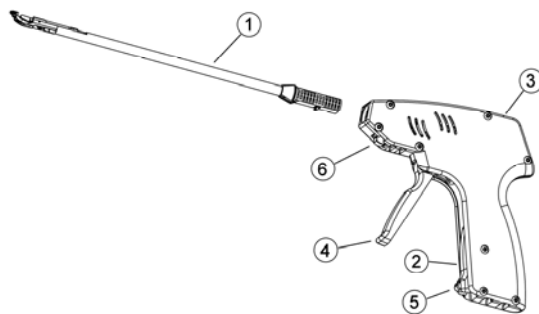
- Pre-vacuum Sterilization Cycle: 2.5 psia (pre-exposure evacuation)
- Exposure Temperature: 134° C (274° F)
- Exposure Time: 10 minutes

REUSE LIFE

The Opus SmartStitch® Suturing Device Handle has been qualified for up to fifty cleaning and sterilization cycles. However, any visible deterioration such as corrosion or damage resulting from use or handling is cause for retirement of the device from further use.

INSTRUCTIONS FOR USE

1. Remove a SmartStitch® connector (Item 1) from the packaging. As shown in the figure, squeeze and lock Clamp Jaw Lever (Item 2) in closed position and insert the plastic molded connector end into the SmartStitch® Suturing Device Handle (Item 3) until the connector is locked into position.



2. Ensure that the SmartStitch® connector is completely seated in the SmartStitch® Suturing Device Handle by actuating the Needle Driver Lever (Item 4) and the Clamp Jaw Lever to ensure controls move freely. (Note: The tip protector on the connector must be removed prior to actuating Needle Clamp Jaw Lever). To unlock the Clamp Jaw Lever, depress the Ratchet Release Lever (Item 5).

3. See Instructions for Use for the SmartStitch® connector for complete discussion of the use of the suturing system.

DISASSEMBLY

The Opus SmartStitch® Suturing Device Handle requires removal of the SmartStitch® connector prior to reprocessing. Press the connector release button (Item 6) to eject the used connector. Properly dispose of the connector.

PRECAUTIONS

A surgeon should not begin clinical use of the Opus SmartStitch® Suturing Device without reviewing the instructions for use and practicing the procedure in a skills laboratory.

WARNINGS

- 1) Endoscopic suturing requires specialized knowledge of knot tying and suture passing techniques. Knowledge of these and other appropriate techniques are important considerations for successful utilization of this equipment.
- 2) As with any surgical instrument, careful attention should be made to assure that excessive force is not placed on this instrument. Excessive force can result in failure.
- 3) Always actuate the SmartStitch® Suturing Device Handle with connector prior to clinical use. This will ensure that the Clamp Jaw Lever, Ratchet Release Lever, and Needle Driver Lever are functioning properly.
- 4) If the SmartStitch® Suturing Device does not function properly and smoothly, immediately discontinue use and contact a Service Representative.
- 5) Do not use or effect repair using the SmartStitch® Suturing Device if proposed tissue is not viable.

CUSTOMER SERVICE

Product Warranty

The product is guaranteed for materials, function and workmanship for patient use. ArthroCare shall not be liable, expressly or implied for:

Any damages which might arise or be caused, whether by the customer or by any of the users of the product, as a result of:

- a) Misuse, mishandling, and/or improper operation,
- b) Repairs or modifications performed other than by ArthroCare or a ArthroCare authorized repair facility,
- c) Use in any manner or medical procedure other than those for which it is designed; and

Any special, indirect and/or consequential damages of any kind and however caused arising from the sale or use of the product.

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Product Complaints

All questions or concerns related to the quality, reliability and/or durability of this product should be directed to Customer Service or an authorized ArthroCare representative. Please contact Customer Service or an authorized ArthroCare representative for a return authorization.

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MANUFACTURER

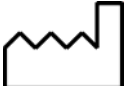



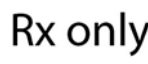
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Symbols Legend

Symbol	Definition
	Consult instructions for use
	Catalogue number
	Lot number
	Contents
	Manufacturer

	Date of Manufacture
	Non sterile
	Authorized representative in the European Community
	CE mark and Identification number of Notified Body. The product meets the essential requirements of Medical Device Directive (93/42/EEC).
	Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.

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