

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Guidewires
Manufactured by SterilMed, Inc.
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www.SterilMed.com

Caution: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

These devices are reprocessed guidewires from various original equipment manufacturers (OEM). These guidewires are intended to be used for selective cannulization of the biliary ducts, including but not limited to, the common bile, cystic, right and left hepatic ducts for use during endoscopic procedures for catheter introduction and exchanges.

Each OEM packaged an Instructions for Use (IFU) document with the original device. The health institution that wished the device to be reprocessed should retain this original document.

DEVICE DESCRIPTION

Reprocessed guidewires are constructed utilizing a metal alloy that is encapsulated in a striped covering and contains a radiopaque tip. The guidewires are manufactured in a wide range of diameters, lengths, tip angles, and stiffness.

Devices are reprocessed under contract with the health institution that previously used the device; the devices are used by the health institution, sent to SterilMed for reprocessing, and returned for reuse.

Reprocessed guidewires have been cleaned, evaluated for continued integrity, and resterilized prior to use. These devices were shipped from an owner, reprocessed, and returned for a single, subsequent use. Devices are tracked throughout the reprocessing steps to monitor and ensure the number of times reprocessed.

This device has been reprocessed for a single use. If the device is to be used again, it must undergo reprocessing prior to use.

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CONTRAINDICATIONS

1. These instruments are not intended for use when endoscopic techniques are contraindicated.

WARNINGS AND PRECAUTIONS

1. The user of the device should have adequate training and a thorough understanding of the use and applications of biliary guidewires.
2. Do not wipe guidewire with dry gauze.
3. Prior to use, inspect packaging and the guidewire for the following:
 - A. Roughness or abrasions at the tip
 - B. Kinking along the length of the guidewire
 - C. Enclosed torque vise (angled tip guidewires only.)
4. If product appears damaged do not use.
5. Do not use with metal-tip catheters. Withdrawing the guidewire through a metal tip catheter may damage the surface of the guidewire.

POTENTIAL ADVERSE EVENTS

Adverse events which maybe associated with guidewires include:

1. Perforation
2. Edema
3. Vascular Thrombosis
4. Hemorrhage
5. Hematoma
6. Vessel spasm

GENERAL INSTRUCTIONS AND INFORMATION

Verify product receipt and ensure that owner's name is appropriate on the label. Inspect package and product for signs of damage or sterility compromise.

Open product using appropriate sterile technique when needed for use.

Use of this reprocessed device should be limited to those physicians trained in use of this device and associated equipment. For specific information on clinical studies, individualization of treatment, patient counseling, and procedural use of this reprocessed device, consult instructions for use included with the original product. If the original instructions are not available, contact the original device manufacturer for instructions or training on proper procedural technique for this device.

If additional reprocessing of the product is desired, wipe the device with a moist sponge to remove any visible blood or tissue, package product, label as "biohazard", and ship product back to SterilMed.

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METHODS TO TEST REPROCESSED DEVICES

Devices have been tested to demonstrate biocompatibility following reprocessing as well as achievement of sterility. Validated methods are used for cleaning, packaging, and routine sterilization. Inspection and pre-release testing are used to ensure appropriate device integrity and function of each device prior to release of product for reuse.

** Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product 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.*

Instructions for Use can be found at www.SterilMed.com. Further questions or concerns by the health practitioner can be addressed directly by contacting your SterilMed Customer Service Associate and/or the SterilMed Quality Department at 1-888-541-0078.

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