

Autotome™ RX Cannulating Sphincterotomes

RX Biliary System™

- Compatible with the RX Biliary System
 - The Autotome RX Cannulating Sphincterotome is compatible with the RX Biliary System, which is designed to provide secure guidewire access during device advancement, manipulation and exchange

AUTOTOME RX CANNULATING SPHINCTEROTOME

| Order Number | Description | Cut-Wire (mm) | Tip Length (mm) | Tip O.D. (Fr) | Recommended Guidewire (in) |
|--------------|----------------|---------------|-----------------|---------------|--------------------------------|
| M00545150 | Autotome RX 49 | 20 | 5 | 4.9 | .035" Hydra Jagwire™ Guidewire |
| M00545160 | Autotome RX 49 | 30 | 5 | 4.9 | .035" Hydra Jagwire Guidewire |
| M00545170 | Autotome RX 44 | 20 | 5 | 4.4 | .035" Hydra Jagwire Guidewire |
| M00545180 | Autotome RX 44 | 30 | 5 | 4.4 | .035" Hydra Jagwire Guidewire |
| M00545190 | Autotome RX 39 | 20 | 5 | 3.9 | .025" Jagwire® Guidewire |
| M00545200 | Autotome RX 39 | 30 | 5 | 3.9 | .025" Jagwire Guidewire |

INSTRUCTIONS FOR USE

Refer to the operator's manual for complete instructions for use.

INDICATIONS

The sphincterotome is indicated for use in transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. The sphincterotome can also be used to inject contrast medium.

CONTRAINDICATIONS

Contraindications for this device are those specific to endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic sphincterotomy (ES).

WARNINGS

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policies.

Verify that the cutting wire has exited the endoscope by visualizing it on the endoscope monitor. Failure to do so may result in contact between the cutting wire and the endoscope while electrical current is applied. This may cause grounding, which can result in patient injury, operator injury, a broken cutting wire, and/or damage to the endoscope.

This device is not intended to be used in the presence of flammable liquid, in an oxygen enriched atmosphere or in the presence of explosive gases.

POTENTIAL ADVERSE EFFECTS

Potential adverse effects include, but may not be limited to: pancreatitis, perforation, hemorrhage, hematoma, cholangitis; septicemia/infection; and allergic reaction to contrast medium.

Any electrosurgical device constitutes a potential electrical hazard to the patient and/or the operator. Possible adverse effects include fulguration, burns, stimulation, and cardiac arrhythmias.

Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

CAUTIONS

Cautions can be found in the product labeling supplied with each device. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



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Ordering Information
1.800.225.3226

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