

# Hydratome<sup>®</sup> RX Cannulating Sphincterotome

## HYDRATOME RX CANNULATING SPHINCTEROTOME

Order Number	Description	Autotome Length (mm)	Guidewire Length (cm)	O.D. (in)
M00583000.....	Hydratome RX 49.....	20.....	260 .....	0.035.....
M00583010.....	Hydratome RX 49.....	30.....	260 .....	0.035.....
M00583020.....	Hydratome RX 49.....	20.....	450 .....	0.035.....
M00583030.....	Hydratome RX 49.....	30.....	450 .....	0.035.....
M00583040.....	Hydratome RX 44.....	20.....	260 .....	0.035.....
M00583050.....	Hydratome RX 44.....	30.....	260 .....	0.035.....
M00583060.....	Hydratome RX 44.....	20.....	450 .....	0.035.....
M00583070.....	Hydratome RX 44.....	30.....	450 .....	0.035.....

### INSTRUCTIONS FOR USE

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

### INDICATIONS

The Hydratome RX Sphincterotome is indicated for use in the selective cannulation of the biliary ducts and the transendoscopic sphincterotomy of the Papilla of Vater and/or the Spincter of Oddi. The Hydratome RX 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 sterilize. Reuse, reprocessing or sterilization 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 or reprocessing 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 government policy.

### POTENTIAL ADVERSE EFFECTS

Potential complications include, but are not 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 operator.

Potential 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

Safe and effective electrosurgery is dependent not only on equipment design, but also, to a large extent, on factors under the control of the operator. It is important that the following precautions be read, understood and followed:

- The Hydratome RX Cannulating Sphincterotome should only be used by or under the supervision of physicians trained in endoscopic retrograde cholangiopancreatography (ERCP) or endoscopic sphincterotomy (ES). A thorough understanding of the technical principles, clinical applications and risks associated with ERCP/ES is necessary before using this device.
- Monitor sphincterotomy under fluoroscopy.
- Avoid bowing of the sphincterotome while it is in a coiled position. Kinking of the catheter shaft may occur, rendering the device inoperable.
- Any use of this device, other than those indicated in these instructions, is not recommended.

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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