# Autotome™ RX, Jagtome™ RX, Hydratome™ RX, Dreamtome™ RX, Ultratome™ XL, Ultratome, Ultratome RX, MicroKnife™ XL, RX Needle Knife XL

## Cannulating Sphincterotome

*Prescriptive Information*

Refer to the device directions for use for complete instructions on device use.

### Caution/Rx Only:

Federal Law (USA) restricts this device to sale by or on the order of a physician.

### Warnings:

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

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 policy.

Only a recommended guidewires may be left in place during sphincterotomy. All other guidewires must be removed prior to energizing the cut wire to prevent injury to the patient.

It is suggested that the operator and the assistant wear protective gloves to prevent accidental burns. Universal precautions should be used in all cases.

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. Any electrosurgical device constitutes a potential electrical hazard to the patient and/or the operator.

- No modification of this equipment is allowed.
- Fluids or flammable agents that may pool under the patient or in body depressions or cavities should be mopped prior to electrosurgery.

### Intended Use / Indications for Use:

The Sphincterotome is indicated for use in the selective cannulation of the Common Bile Ducts (CBD) and the 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).



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*Prescriptive Information*

Refer to the device directions for use for complete instructions on device use.

### Precautions:

The Sphincterotome must be used in conjunction with a Type BF or CF generator.

It is recommended that the operator not use the device with any generator setting which may output a voltage exceeding the Maximum Voltage Rating. Sphincterotome Maximum Voltage Rating: 750 V peak (1500 V peak-to-peak). Active accessories (such as Active Cord) should be selected that have an Accessory Voltage Rating equal to or greater than 750 V peak.

### Adverse Events:

Potential Complications include, but are not limited to:

- Pancreatitis
- Perforation
- Hemorrhage
- Hematoma
- Cholangitis
- Stone Impaction
- Septicemia/Infection
- Allergic Reaction to Contrast Medium.

Possible electrosurgical adverse effects include:

- Fulguration
- Burns
- Stimulation
- Cardiac Arrhythmias



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