Boston Scientific

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

Cannulating Sphincterotome

℞ ONLY

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

REUSE WARNING

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.

DEVICE DESCRIPTION

Contents

Each packaged pouch contains the following:

Each Autotome RX, Ultratome RX, MicroKnife XL and RX Needle Knife XL packaged pouch contains the Following:

- One (1) Cannulating Sphincterotome.

Each Preloaded Autotome RX (Jagtome, Hydratome, and Dreamtome) packaged pouch contains the following:

- One (1) Cannulating Sphincterotome RX preloaded with guidewire.

Operating Principle

The Sphincterotome is a 200 cm catheter that tapers from 7F (2.3 mm) to 5.5F (1.8 mm) with an atraumatic tip.

The Sphincterotome is capable of accepting a guidewire, injecting contrast and cutting. The Sphincterotome may be placed with or without the aid of a guidewire.

When connected to a monopolar current, the Sphincterotome may be used to incise the Papilla of Vater and/or the Sphincter of Oddi. The Sphincterotome is designed for use with endoscopes that have a working channel of 2.8 mm and larger. Color-coded, endoscopic visual markers are located on the distal tip to aid in the assessment of the catheter cannulation and insertion into the biliary system.

Catheter Shaft

The catheter shaft contains a lumen for the monofilament cutting wire, a guidewire channel and injection lumen to inject contrast medium by attaching a contrast filled syringe to the proximal luer.

Cutting Wire

The exposed monofilament cutting wire provides the necessary electrical continuity to facilitate proper controlled cutting of the sphincter and/or papilla. The Sphincterotome monofilament cutting wire is exposed with bowing of the distal tip by extending/retracting the handle. The MicroKnife XL and RX Needle Knife XL Sphincterotome monofilament cutting wire extends up to 7 mm beyond the distal tip by activating the handle.

Catheter Tip

The distal segment of the catheter has a curved distal profile. The distal tip of the catheter has a radiopaque distal marker that can be used to fluoroscopically monitor and/or confirm position.

RX Channel – For RX Sphincterotomes ONLY

The Guidewire Lumen on RX Sphincterotomes has an open channel that allows for rapid exchange of a guidewire.

Guidewire Compatibility

The Sphincterotomes are recommended to use the following Boston Scientific Pancreatic or Biliary Guidewire:

Product Tip Size	Recommended Guidewire
3.9F Sphincterotomes	Jagwire Guidewire 0.025 in (0.64 mm)
4.4F, 4.9F or larger Sphincterotomes	Jagwire Guidewire, Hydra Jagwire Guidewire and Dreamwire Guidewire 0.035 in (0.89 mm)

Note: Due to the various guidewire tolerances among manufacturers, only Boston Scientific Pancreatic or Biliary guidewires are recommended.

Warning: 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.

Generator Compatibility

Boston Scientific Sphincterotomes adapt to a variety of monopolar generators using the appropriate Active Cord (sold separately). Below is the indication for the Active Cord configuration and generator compatibility:

Active Cord Order Number	Generator Compatibility
M00561250	Olympus™ Generator
M00561270	Bovie™, Valleylab™, Aspen Labs™, ERBE™ Generators, Endostat™, Endostat™ II and Endostat™ III Generators

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

Precaution: 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.

Precaution: The active length information provided is intended to be used with the guidance from the Electrosurgical Generator manufacturer to determine if the overall length of an Electrosurgical Accessory remains within the maximum allowable length.The overall active length of each Electrosurgical Accessory is the following:

- Autotome RX / Jagtome RX / Hydratome RX / Dreamtome RX - 225 cm
- Ultratome XL/MicroKnife XL - 232 cm
- RX Needle Knife XL - 229 cm

The overall active length includes the connector, cord handle and cutting wire. The length of other connecting cords must be considered when used with the Sphincterotome.

Materials

Contains cobalt: CAS No. 7440-48-4; EN No. 231-158-0. Defined as a 1B carcinogen and reproductive toxicant according to the European Commission in a concentration above 0.1 % weight by weight.

Note: The Delivery System is made with stainless steel which contains cobalt. Current scientific evidence supports that stainless steels used in medical devices, do not cause an increased risk of cancer or adverse reproductive effects.

User Information

The 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. This device is intended for use in an adult patient population.

Note: The safety and effectiveness of this device for use in a pediatric patient population has not been established.

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.

Clinical Benefit Statement

The clinical benefit of the Sphincterotome is it provides selective cannulation of the Common Bile Duct (CBD), enables contrast injection for fluoroscopic visualization of the biliary and pancreatic ducts, and performs sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi to facilitate therapeutic procedures during an ERCP procedure.

CONTRAINDICATIONS

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

WARNINGS

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 be read, understood, and followed in order to enhance safety and effectiveness:

- The Sphincterotome is intended for single use. If reused, the material between the lumens may be compromised and may not be properly insulated for Sphincterotomy.
- Possible safety hazards may result from gas embolism caused by over-insufflation of air, inert gas prior to high frequency surgery, etc. Endogenous gases should be sucked away if possible prior to procedure. Failure to do so may result in patient injury.
- Patient leakage currents from endoscope, as well as energized Sphincterotome, are additive and may result in thermal/electrical injury. Consult the endoscope manufacturer about the proper grounding of the endoscope.
- Monopolar diathermy or electrosurgical cautery in patients with pacemakers or implantable cardiac defibrillators can result in electrical reset of the cardiac device, inappropriate sensing and/or therapy, tissue damage around the implanted electrodes, or permanent damage to the pulse generator. A cardiologist should be consulted prior to using Sphincterotome in these patients.
- Skin-to-skin contact should be avoided (for example between the patient's arms and body) by way of dry cloth or gauze in order to prevent possible thermal or electrical injury.
- Monitoring electrodes should be placed as far from the surgical area as possible. Failure to do so may result in injury or electrical shock to the patient or procedural room personnel.
- Needle monitoring electrodes are not recommended as they may cause patient injury such as burn.
- Avoid incidental contact between Active Cords and the patient's body, or any other electrodes to prevent electrosurgical harms such as burns, cardiac arrhythmias, fulguration, and stimulation.
- Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the procedure. Failure to do so may result in a fire and/or electrical injury to the patient or user.
- 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 as this may lead to patient and/or user injury and may cause fire.
- 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 may lead to injuries such as electric shock or burns or other patient injuries. Any fluids on the procedure room floor should be mopped prior to electrosurgery in order to avoid injury.
- Inappropriate use of the guidewire may result in damage to wire/tip, interfacing device and/or duct.

ADVERSE EVENTS

Possible complications include, but may not be limited to:

- Allergic Reaction
- Cholangitis
- Hematoma
- Hemorrhage
- Pancreatitis
- Perforation
- Septicemia/Infection
- Stone Impaction
- Tissue Damage

Possible electrosurgical adverse effects include:

- Burns
- Cardiac Arrhythmias
- Fulguration
- Stimulation

HOW SUPPLIED

Device is supplied sterile using an ethylene oxide (EO) process. The packaging and device should be inspected prior to use.

Device Details

Do not use if package is damaged or unintentionally opened before use.

Do not use if labeling is incomplete or illegible.

Handling and Storage

This product has no special handling or storage requirements. Check device label for expiration date.

OPERATIONAL INSTRUCTIONS

Preparation

1. Remove the Sphincterotome from the package.

   Note: For RX Preloaded devices ONLY – ensure that the pre-loaded guidewire portion stays in the guidewire lumen of the Sphincterotome.

2. Hold the distal tip and pull mandrel out of the Sphincterotome (be careful to keep precurved shape of tip).

   Precaution: Avoid handle extension/retraction while it is in a coiled position. Kinking of the catheter shaft may occur, rendering the device inoperable.

3. Uncoil and inspect the Sphincterotome for proper cutting wire movement and for any damage, such as kinks.

   Precaution: Kinks in the catheter will hinder injection capability. Do not use the Sphincterotome if any defect is found during inspection. Please notify Boston Scientific and return for replacement.

4. Attach the appropriate Boston Scientific Active Cord to themonopolar generator.
5. Attach neutral electrode.

   Warning: Consult the neutral electrode manufacturer about the proper grounding of the patient. Ensure proper placement of the neutral electrode on the patient and the connection to the generator. Failure to do so may result in harm to the patient including burns. It is recommended that a monitoring neutral electrode be used, if a contact quality monitor is available, or built into the generator. The entire area of the neutral electrode should be attached reliably to the patient's body, and as close to the operating field as possible.

   Warning: The patient should not come into contact with metal parts or objects that may be grounded to earth. Failure to do so may result in electrical/thermal injury.

6. Set the generator to the appropriate settings. Use the monopolar generator's recommended power settings for sphincterotomy.

   Warning: Always follow the manufacturer's suggestions for the operation of the unit to prevent unnecessary hazard to the operator and/or the patient. Excess power may lead to patient injury or may damage the integrity of the cutting wire.

   Warning: Prior to use, inspect guidewire for tip roughness, damage, and/or kinking. Do not use the guidewire if any defect is found during inspection to avoid potential patient injuries. Please return any defective product to Boston Scientific for replacement.

   Precaution: Please review the operations and service manuals of the electrosurgical generator for proper settings and operation prior to using the Sphincterotome.

7. If the Sphincterotome is to be used with a recommended Boston Scientific Biliary of Pancreatic Guidewire (see Guidewire Compatibility section):

   Precaution: Inspect the guidewire for roughness or abrasion at the tip.

   a. Insert the guidewire into the guidewire introducer at the proximal end of the Sphincterotome. While advancing the guidewire through the introducer, ensure that the movement is directed and aligned within the guidewire introducer.
   b. Advance the guidewire beyond the distal end of the Sphincterotome and dip the distal tip of the guidewire (the non-striped dark portion) in sterile water to activate the hydrophilic coating. This will make the coating lubricious for selective cannulation.
   c. Then, retract the guidewire into the distal end of the Sphincterotome after activation of the hydrophilic coating.
   d. For RX Sphincterotomes ONLY - It is recommended to use an RX Locking Device attached to the endoscope.

8. Flush the catheter with sterile water or saline to remove all air.
9. The use of biopsy cap is recommended during Sphincterotomy.
10. If contrast medium will be injected through the injection lumen, use a syringe ≤ 20 cm^3 (20 c) to inject the contrast and attach to the proximal luer.
11. The Sphincterotome is now ready to use.

    Precaution: Manually preforming the Sphincterotome may compromise the desired orientation of the cut wire.

Procedure

Precaution: Any use of this device, other than those indicated in these instructions, is not recommended.

Precaution: Prior to insertion and during advancing of the RX Needle Knife XL and Microknife™ XL Sphincterotome in the endoscope, ensure that the cutting wire is fully retracted.

1. Insert the Sphincterotome into the endoscope.

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Warning: The Sphincterotome should never be connected to the Active Cord prior to inserting the Sphincterotome through the endoscope to avoid injury to patient or equipment resulting from improper electrical circuit grounding.

Precaution: The Sphincterotome should be advanced through the endoscope using short, deliberate 2-3 cm movements to prevent inadvertent damage to the catheter shaft, such as kinking.

2. Direct the cutting wire position to the desired orientation. For Sphincterotomes with Rotation Feature adjust the desired orientation by rotating the handle either left or right. For RX Needle Knife XL and Microknife XL Sphincterotome ONLY - Prior to activating the cautery current determine the line of incision. Practice the endoscope movement associated with this line of incision prior to cutting. The cut wire is capable of extending up to 7 mm. Select the appropriate length upon visualizing the distal tip of the catheter in the duodenum.
3. Cannulate the CBD using the Sphincterotome.
4. Following cannulation, use X-Ray or fluoroscopy to confirm position of the Sphincterotome in the CBD by injecting contrast medium through the injection port and/or using the radiopaque distal marker.

Warning: Always monitor sphincterotomy endoscopically to maintain device visibility and to avoid any patient injuries.

5. Withdraw the Sphincterotome slightly, so that the cutting wire is in the appropriate position when viewed endoscopically.
6. If a guidewire is not used, standard endoscopic and Sphincterotome placement technique should be used. Otherwise, advance the guidewire until it is selectively positioned in the CBD.

Note: Removal of the guidewire is not necessary during sphincterotomy if a Boston Scientific Pancreatic or Biliary recommended guidewire is used and the following precautions are observed.

Warning: For RX Needle Knife XL and Microknife™ XL Sphincterotome ONLY - If a guidewire is used with the procedure, remove it from the guidewire lumen before activating cautery current. Failure to remove the guidewire may cause electrical shock to the user and/or patient. Reintroduce the guidewire after completion of cautery procedure.

Warning: Always make sure that a good return path to the electrosurgical unit is maintained.

Precaution: If the guidewire is removed during sphincterotomy, turn the electrosurgical generator power down before removal. After removal, gradually increase power until acceptable cutting effect is achieved.

Precaution: Do not remove guidewire during sphincterotomy. Removal of the guidewire during sphincterotomy may result in loss of insufflation and/or back flow of fluids.

7. Prior to performing Sphincterotomy, make sure the Sphincterotome cutting wire is in proper position when viewed endoscopically.

Warning: 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.

8. Attach the Active Cord to the connector on the Sphincterotome handle by completely inserting it until no pin is visible.

Precaution: When the handle needs to be rotated for tip adjustment, the active cord should not be connected to the Sphincterotome.

Precaution: The Sphincterotome does not need to be energized prior to performing sphincterotomy. Energizing the cutting wire prior to use will cause premature cutting wire fatigue and will compromise the cutting wire's integrity.

9. Using the appropriate power setting, energize the cutting wire to incise and cauterize the Papilla of Vater and/or the Sphincter of Oddi.

Warning: Any electrosurgical device constitutes a potential electrical hazard to the patient and operator.

Warning: Ensure that the patient is properly grounded prior to use of the monopolar electrosurgical generator and Sphincterotome to avoid patient injury.

Warning: Because the electrosurgical effect is greatly influenced by the size and configuration of the active electrode, it is impossible to determine the exact effect achieved in a given control setting. It is very important that if the proper generator setting is not known, one should set the unit at a power setting lower than the recommended range and cautiously increase the power until the desired effect is achieved. Failure to do so may result in patient injury.

Warning: It is recommended to maintain direct and constant contact with tissue when applying electrocautery current. Failure to do so may result in broken cut wire, damage to the endoscope and/or patient injury.

Precaution: For MicroKnife XL and RX Needle Knife XL Sphincterotome ONLY - When applying electrosurgical current, ensure that the cutting wire is in constant motion to avoid excessive focal coagulation and charring and to prevent breakage of the cut wire.

10. Detach the Active Cord from the connector on the Sphincterotome handle.
11. Upon successful cannulation, a recommended guidewire may be placed through the Sphincterotome to allow easy exchange with other Guidewire compatible devices.

Device Removal

The Sphincterotome may be removed with or without leaving the guidewire in place.

Prior to removal of the Sphincterotome, ensure that the handle is in the relaxed position and that the electrosurgical generator is turned OFF.

Endoscopic devices may be exchanged over the guidewire. The striped movement markers may be endoscopically monitored to help maintain access in the selected biliary duct. If the wire begins to move proximally or distally, the striped movement markers will provide endoscopic visual confirmation and allow repositioning of the wire.

If the guidewire is to remain in place while the Sphincterotome is withdrawn, utilize the following steps for RX Devices:

1. With the guidewire locked in the RX Locking Device, withdraw the Sphincterotome from the scope until the wire exit port is visible at the locking device and resistance is felt.
2. Perform standard exchange procedure over the final 5 cm of the Sphincterotome. Unlock the guidewire and retrieve the Sphincterotome. Once the distal tip of the Sphincterotome is exposed from the locking device, relock the guidewire into the locking feature of the RX Locking Device and remove the Sphincterotome completely from the guidewire.
3. Pull the Sphincterotome off the wire.

Disposal

To minimize the risk of infection or microbial hazards after use, dispose device and packaging as follows:

After use, device may contain biohazardous substances. The device and packaging should be treated and disposed of as biohazardous waste or have them treated and disposed of in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

Post-Procedure

Any serious incident that occurs in relation to this device should be reported to the manufacturer and relevant local regulatory authority.

PATIENT COUNSELING INFORMATION

Brief the patient on any relevant post-procedure instructions, contraindications, warnings, precautions and/or adverse events found within this Instructions for Use (IFU), pertaining to the patient.

REFERENCES

For recommendations on current settings for sphincterotomy, refer to the monopolar generator's recommended power setting for sphincterotomy.

WARRANTY

For device warranty information, visit (www.bostonscientific.com/warranty).

SYMBOL DEFINITIONS

Commonly used medical device symbols that appear on the labeling are defined at www.bostonscientific.com/SymbolsGlossary.

Table 1. Symbol Definitions

	Contents
GW R	Recommended Guidewire

REF

M00532810	M00545200	M00573540	M00583060
M00535900	M00545840	M00573550	M00583070
M00535910	M00573040	M00573560	M00584000
M00535920	M00573050	M00573570	M00584010
M00535930	M00573060	M00583000	M00584020
M00545150	M00573070	M00583010	M00584030
M00545160	M00573080	M00583020	M00584040
M00545170	M00573090	M00583030	M00584050
M00545180	M00573100	M00583040	M00584060
M00545190	M00573110	M00583050	M00584070

AR REP

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CE 2797

BSC (MB IFU Template 8.2677 x 11.6929 A4, 92310600) IFU, MB, Sphincterotomes, en, 52177895-01A