Brief Summary Document

Overview

Product Autotome™ Pro RX Sphincterotome Family – IFU 52177896

Audience: Health Care Professional (HCP):

Rx Statement

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.*

Content

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 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.

- Only a recommended guidewire 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.
- Any use of this device, other than those indicated in these instructions is not recommended. Failure to do so may result in patient injury.
- 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 and may result in patient injury.
- 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.
    - 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.
    - 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.
    - 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 pacemaker 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.

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 so may result in a fire and/or an electrical injury to the patient or user.
    - Inappropriate use of the guidewire may result in damage to wire/tip, interfacing device and/or duct.
    - 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.
- 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.

- 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.
- 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.
- 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.
- 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.
- Always monitor sphincterotomy endoscopically to maintain device visibility and to avoid any patient injury.
- Always make sure that a good return path to the electrosurgical unit is maintained to avoid patient injury.
- Do not use a guidewire (or Sphincterotome) that has been cut, burned or damaged. Damaged insulation may cause unsafe currents in either the patient or the operator. Leakage current to the patient or user may increase at the site of the damaged insulation.
- 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.
- 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.

PRECAUTIONS

- If using an 0.025" angled guidewire post stripping with 0.035" guidewire, carefully advance the 0.025" guidewire through the sphincterotome using short, deliberate 2-3 cm movements covering the introducing channel with the thumb may help to prevent the guidewire dislodging during initial insertion.
- 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.
- 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 this Electrosurgical Accessory is 225 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.
- No modification of this equipment is allowed.
- Please review the operations and service manuals of the electrosurgical generator for proper settings and operation prior to using the Sphincterotome.
- Avoid handle extension/retraction while it is in a coiled position. Kinking of the catheter shaft may occur, rendering the device inoperable or hinder injection capability.
- Do not wipe guidewire with dry gauze as this may decrease surface lubricity or may cause damage to the wire tip.
- Inspect the guidewire for roughness or abrasion at the tip.
- Manually preforming the Sphincterotome may compromise the desired orientation of the cut wire.

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

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

POTENTIAL ADVERSE EVENTS

Possible complications include, but not 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