

TRUEtome™ 49, TRUEtome 44, TRUEtome 39, TRUEtome Jag 39, TRUEtome Jag 44, TRUEtome Hydra 44, TRUEtome Dreamwire™ 44 Cannulating Sphincterotome

REFER TO THE DEVICE DIRECTIONS FOR USE FOR COMPLETE INSTRUCTIONS ON DEVICE USE. RX ONLY.
CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Warning

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.

Device Description

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

Warning

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

Precautions

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: 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 overinsufflation of air, inert gas prior to high frequency surgery, etc. Endogenous gases should be sucked away if possible prior to procedure.

Patient leakage currents from endoscope, as well as energized Sphincterotome, are additive. 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. Monitoring electrodes should be placed as far from the surgical area as possible. Needle monitoring electrodes are not recommended. Avoid incidental contact between Active Cords and the patient's body, or any other electrodes. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the procedure.

Adverse Events

Possible complications include, but may not be 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.

Warning

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

Warnings

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).