PRESCRIPTIVE INFORMATION

Habib™ EndoHPB

Bipolar Radiofrequency Catheter

Boston Scientific
Advancing science for life™

REFER TO THE DEVICE INSTRUCTIONS 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.

Intended Use/Indications for Use

The Habib EndoHPB is a radiofrequency (RF) catheter which provides bipolar energy to perform partial or complete ablation of tissue in the pancreatic and biliary tracts. The Habib EndoHPB is also intended for use to ablate malignant or benign tissue, notably to perform endoscopic biliary drainage or decompression, prior to stent placement or afterwards, to clear an occluded stent.

Contraindications

Do not use on patients with cardiac pacemakers or other active implants.

Warnings

- Consult the Instructions for Use before use.
- Do not use if the package is open or damaged as this is a Sterile Device (Ethylene Oxide).
- Only use with equipment approved in this document.
- Do not reuse this device.
- Do not use if expiry date on label is exceeded as shown by the symbol.
- Do not drive with a power exceeding power values specified in Table 1 of the IFU.
- Do not allow the electrode to come into contact with metal when activated.
- Do not pass the device through the mesh of a stent. If unavoidable, do not apply RF while passing the device through the mesh of a stent.
- Do not permit the connector to get wet.

- The device may interfere with the operation of other electronic equipment.
- Do not use needle monitoring electrodes.
- Do not use in cardiac or brain vessels.
- Smoke-plume extraction is not required for this device.
- No modification of this equipment is allowed.
- Flammable endogenous gases in the gastrointestinal tract may result in the risk of explosion to the patient. Extract the gases before performing electro surgery or irrigate with CO2.
- Do not use with type CF applied part endoscope.
- Interference may be visible on video screen during application of energy. This is temporary and causes no damage to the equipment.
- The use of the device must be by a qualified physician.

Precautions

- Do not allow the patient to come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.). The use of antistatic sheeting is recommended for this purpose.
- The device cable should not contact the patient.
- Ensure there is no pooling of fluids under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Fluids pooled in the depressions and cavities should be mopped up before the device is used.
- Exercise caution when using oxygen absorbent materials such as cotton, wool or gauze, do not become saturated with oxygen, and ignited by sparks produced by the device.
- Check the functioning of monitoring and other electronic equipment during and after use, to identify any problems caused by interference.
- Place any monitoring electrodes for physiological monitoring equipment as far as possible from the device. Monitoring systems incorporating high frequency current-limiting devices are recommended.
- Use standard endoscopic precaution and practice.

Adverse Events

The potential Adverse Events include:

- Perforation of the stomach wall
- Perforation of the bile duct
- Aneurysmal dilation of the hepatic artery
- Necrotic infection
- Abscess
- Damage to neighboring tissue, such as iatrogenic thermal injury

The effectiveness of this device for use in the treatment of pancreatic or biliary cancer or pancreatic or biliary disease (i.e. improved clinical outcomes) has not been established.