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SPEAKER: The Habib EndoHPB is a radio frequency catheter which provides bipolar energy to perform partial or complete ablation of tissue in the pancreatic and biliary tracks. 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 occluded stent.

The Habib EndoHPB is an 8F 2.7 millimeter RF bipolar catheter with a working length of 1.8 meters. Radio frequency power is applied to the two electrodes at the tip of the catheter, so that heat is applied to the tissues surrounding the catheter. The device is compatible with endoscopes with a working channel of 3.2 millimeters or greater, and a 0.035 inch guide wire. Consult DFU for additional compatible devices.

The following describes the steps for operation of the Habib EndoHPB. Switch on the generator and put into Standby mode. Some generators default to a much higher power setting, which is not recommended for this device and its use.

Connect the adapter cable to the compatible generator. The adapter cable should remain outside the sterile clean field. Remove the pouch from the outer carton. The instructions for use are between the inside of the outer carton and the pouch containing the sterile Habib EndoHPB, and should be removed for consultation.

Open the inner pouch and remove the dispensing coil. Remove the Habib EndoHPB from the dispensing coil.

Connect the adapter cable to the electrosurgical generator cable. Introduce the endoscope and maneuver to the desired region of the gastrointestinal tract. Insert a 0.35 inch guide wire through the working channel of the endoscope into the selected duct of the hepatic, pancreatic, or biliary system. Flush the Habib EndoHPB with saline or similar and introduce over the guide wire through the working channel of the endoscope.

Under endoscopic or fluoroscopic visualization, insert the distal portion of the Habib EndoHPB catheter into the selected duct until it is in the desired position. The most distal tissue should be treated first. Ensure the target tissue lies between the electrodes.

The Habib EndoHPB bipolar radio frequency catheter provides bipolar energy to perform partial or complete ablation of tissue in the pancreatic and biliary tracts. Powered by radio frequency energy from an electrosurgical generator, this bipolar device is used by gastroenterologists during the ERCP procedure. Using fluoroscopic visualization, the catheter is placed over a guide wire, positioning its two electrodes at the site of a stricture.

Energy is applied to ablate malignant or benign tissue, notably, to perform endoscopic biliary drainage or decompression causing tissue necrosis or cell death at the target site. When the stricture is cleared, bile flows once again. Reposition and repeat as needed to cover the full stricture, distal to proximal, from the scope tip.

Another application of the device is to clear biliary metal stents that have become blocked by overgrown tissue. Ablation is performed in the same way. But this time, an inflated balloon is passed afterwards, performing debridement to clear away the dead tissue.

Bipolar heating parameters. Below the biliary bifurcation, do not exceed 10 watts. At the ampulla and above the biliary bifurcation, do not exceed 7 watts. Apply the power for a maximum of 90 to 120 seconds, depending on the generator used, table 1 and directions for use. And wait 60 seconds before removing or repositioning. Put the generator into standby mode or turn off and wait one minute with the catheter in this position.

If further tissue is to be treated, withdraw the Habib EndoHPB by 1 centimeter and repeat the procedure from step 9. Do not exceed recommended power and time settings. When the procedure is completed, remove the catheter carefully from the endoscope.

SpyGlass DS direct visualization system can be used to map the margins pre-ablation. SpyGlass DS direct visualization system can also be used to verify the lesion state post-ablation. It is recommended to perform a second endoscopy at four weeks to observe if further ablation of tissue is required.