

An Endoscopic Retrograde Cholangiopancreatography (ERCP) is performed as either an outpatient or inpatient procedure in the hospital's interventional Endoscopy or Radiology suite. Antibiotics are not routinely administered pre-procedure but are used in certain circumstances. ERCP is performed under conscious sedation, MAC (usually with Propofol) or general anesthesia. The duodenoscope is inserted into the patient's mouth and is passed through the esophagus, stomach, and into the duodenum until it reaches the papilla. A catheter is inserted through the duodenoscope and used to inject contrast dye into the biliary ducts. Fluoroscopy is used intermittently throughout the procedure to track dye injection and to follow the movements of various accessories that are applied. Still radiographs are taken to document important findings during the procedure. In the event that it is deemed that x-ray imaging is insufficient to make an adequate diagnosis or therapeutic intervention requires direct visualization, the physician may choose to perform cholangioscopy for direct visualization of the biliary tree.

The cholangioscopy procedure with the SpyGlass System is performed by a single operator with the SpyScope® Access and Delivery Catheter positioned just below the operating channel of the duodenoscope. In this configuration, the endoscopist controls both the tip deflection wheels of the duodenoscope and the knobs of the SpyScope Catheter visualization system with the same hand. The physician's other hand holds the duodenoscope to stabilize both systems. The duodenoscope is positioned in front of the papilla and a sphincterotomy is performed as necessary. The SpyGlass System is introduced into the therapeutic duodenoscope. The bile duct is cannulated, and the SpyScope Catheter guides the SpyGlass® Direct Visualization Probe into the biliary tree. The SpyScope Catheter and SpyGlass Probe are maneuvered up to the desired area of interest within the duct for direct visualization. In addition, selected ducts and branches of interest can be examined during repeated advancement and withdrawal of the system. If necessary, the SpyBite® Biopsy Forceps guided by the SpyScope Catheter are introduced and an endoscopic guided biopsy is taken.

Also, electrohydraulic lithotripsy can be utilized in the case of documented stones. A small 3 Fr electrohydraulic lithotripsy probe is passed through the working channel of the SpyScope Catheter. Under direct visualization, the lithotripsy probe is advanced until it comes in contact with the target stone. Water is infused through the dedicated irrigation channels to provide a fluid environment. Electrohydraulic lithotripsy is applied and the stone is broken into multiple fragments. Once complete, the SpyScope Catheter, SpyGlass Probe and electrohydraulic lithotripsy probe are withdrawn from the duodenoscope. A standard stone retrieval basket or large stone extraction balloon is then passed through the working channel of the duodenoscope and into the bile duct and multiple sweeps of the duct are conducted to remove any remaining stone fragments. A cholangiogram is taken to confirm that the bile duct is clear.

Refer to the Instructions for Use provided with each product for complete user information.

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