

SECTION II
SUMMARY AND CERTIFICATION

ENDOSCOPIC RETROGRADE CHOLANGOPANCREATOGRAPHY (ERCP) SUMMARY

The Summary of Safety and Effectiveness on the endoscopic procedure for bile duct pathology and the ERCP cannulas used reflects data available and presented at the time the submission was prepared, but, caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

Procedure/Product Overview

ERCP is a diagnostic procedure for suspected biliary tract obstruction such as strictures or stones. The ERCP cannula serves as the pathway by which contrast media is injected for the purpose of identifying the reason for blockage. Patients with diagnosed biliary tract calculi or strictures can then be treated with an assortment of therapeutic modalities.

Contraindications for ERCP Procedure

ERCP is contraindicated in patients with/or:

- 1) Acute pancreatitis, unless clinical situation necessitates procedure
- 2) Recent myocardial infarction, unless surgical intervention is required
- 3) Presence of barium in the GI tract
- 4) Pregnancy
- 5) Severe pulmonary disease
- 6) Allergy to contrast media
- 7) Uncooperative or unable to tolerate procedure

The physician will determine patient's appropriateness for the procedure.

Manufacturing Overview

U.S.E. manufactured and tested the product to performance specifications based on predicate and/or substantially equivalent devices.

U.S.E. manufacturing processes and procedures are based on good manufacturing practices. Quality assurance methods and procedures based on MIL-STD-9858 are utilized to assure conformance to design specifications.

Materials used in the manufacturing process are certified to standards appropriate for their use.