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SECTION II
SAFETY AND EFFECTIVENESS
U.S.E. REUSABLE HANDLE SUMMARY

The Summary of Safety and Effectiveness on the Reusable Endoscopic Accessory Handle used reflects data available and present at the time the summary was prepared, but, caution should be exercised in interpreting the data. The results of future studies may require alteration for the conclusions or recommendations set forth.

Procedure/Product Overview

The Reusable Endoscopic Accessory Handle can be used with various types of endoscopic accessories including biopsy forceps and polypectomy snares.

Contraindications

The Reusable handle is contraindicated for use in any contraindication to performing any type of endoscopic procedure.

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

Manufacturing Overview

U.S.E. designs, manufactures and tests 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.

Bibliography

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