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SECTION II  
SUMMARY AND CERTIFICATION

SAFETY AND EFFECTIVENESS  
PULL PEG TRAY SUMMARY

The Summary of Safety and Effectiveness on percutaneous endoscopic gastrostomy and the Pull PEG tray 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

Percutaneous endoscopic gastrostomy (PEG) has become the method of choice for patients, both adults and children, unable to take nutrition through normal means, yet, have a functional gastrointestinal tract. Percutaneous endoscopic gastrostomy is a less invasive and traumatic method of placement than a surgical procedure.

The placement of PEGs, via endoscopy, has been clinically acceptable for more than 10 years. Several manufacturers provide PEG units to the market.

A U.S.E. PULL PEG Tray includes all necessary products (eg. silicone feeding tube, bolster, feeding adapter, etc.) and accessory products (eg. lubricating jelly, disposable hemostat, grasping snare) to complete the endoscopic gastrostomy.

Contraindications For Utilizing a PEG

The following are contraindications for percutaneous endoscopic gastrostomy.

- (1) Patients with massive ascites, sepsis, esophageal or gastric obstructions, esophageal or gastric varices and morbid obesity.
- (2) If the patient's stomach can not be transluminated.
- (3) If the patient is combative and can not be sedated.

Manufacturing Overview

U.S.E. 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

- Mamel, J.J.: Percutaneous Endoscopic Gastrostomy: A Review. American Society of Parenteral & Enteral Nutrition 87: 65, 1987.
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- Ponsky, J.L. and Gauderer, M.: Percutaneous Endoscopic Gastrostomy: A Nonoperative Technique for Feeding Gastrostomy. Gastrointestinal Endoscopy 27: 9-11, 1981.
- Ponsky, J.L., Gauderer, M. and Stellato, T.A.: Percutaneous Endoscopic Gastrostomy in Children. Gastrointestinal Endoscopy 27: 128, May 1981.
- Ponsky, J.L., Gauderer, M. and Stellato, T.A.: Percutaneous Endoscopic Gastrostomy: Review of 150 Cases. Archives of Surgery 118: 913-914, August 1983
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## SAFETY AND EFFECTIVENESS GUIDEWIRE PEG TRAY SUMMARY

The Summary of Safety and Effectiveness on percutaneous endoscopic gastrostomy and the Guidewire PEG tray 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

Percutaneous endoscopic gastrostomy (PEG) has become the method of choice for patients, both adults and children, unable to take nutrition through normal means, yet, have a functional gastrointestinal tract. Percutaneous endoscopic gastrostomy is a less invasive and traumatic method of placement than a surgical procedure.

The placement of PEGs, via endoscopy, has been clinically acceptable for more than 10 years. Several manufacturers provide PEG units to the market.

A U.S.E. GUIDEWIRE PEG Tray includes all necessary products (eg. silicone feeding tube, bolster, feeding adapter, etc.) and accessory products (eg. lubricating jelly, disposable hemostat, grasping snare) to complete the endoscopic gastrostomy.

### Contraindications For Utilizing a PEG

The following are contraindications for percutaneous endoscopic gastrostomy.

- (1) Patients with massive ascites, sepsis, esophageal or gastric obstructions, esophageal or gastric varices and morbid obesity.
- (2) If the patient's stomach can not be transluminated.
- (3) If the patient is combative and can not be sedated.

### Manufacturing Overview

U.S.E. 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.

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- Mamel, J.J.: Percutaneous Endoscopic Gastrostomy: A Review. American Society of Parenteral & Enteral Nutrition 87: 65, 1987.
- Mellinger, J.D. and Ponsky, J.L.: Percutaneous Endoscopic Gastrostomy. Endoscopy 24: 64-67, Jan-Feb 1992.
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