

## TECHNICAL DATA SHEET

### MEDICAL DEVICE REFERENCE

**9640\_xx, 8644\_xx, 8645\_xx, and 8630\_xx**

**MIC\* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors 2797**



### DESCRIPTION

Product Code	9640_14	9640_20	9640_24	Product Code	8644_14	8644_20	8644_24
Description	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors - 14 Fr - PULL	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors - 20 Fr - PULL	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors - 24 Fr - PULL	Description	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors - 14 Fr - PULL	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors - 20 Fr - PULL	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors - 24 Fr - PULL

Product Code	8630_14	8630_14J	8630_20	8630_20J	8630_24	8630_24J
Description	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors - 14 Fr - PUSH OTW	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connector - 14 Fr - PUSH OTW	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connector - 20 Fr - PUSH OTW	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connector - 20 Fr - PUSH OTW	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connector - 24 Fr - PUSH OTW	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connector - 24 Fr - PUSH OTW

Product Code	8645_14	8645_20	8644_24
Description	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors - 14 Fr - PULL	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors - 20 Fr - PULL	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors - 24 Fr - PULL

- Medical grade silicone construction
- ventilated SECUR-LOK\* connector multiple ports
- radiopaque stripe and bumper aid
- Internal retention bumper

#### Kit Includes:

- 1 removable Push PEG tube
- 1 5 Fr retrieval snare
- 1 universal feeding adapter
- 1 bolus feeding adapter
- 1 SECUR-LOK\* retention ring
- 1 5 ml vial 1% Lidocaine packet
- 1 Povidone-Iodine Ointment
- 1 Povidone-Iodine Swabstick Packet
- 1 18G X 1.5 in 0.5 micron blunt filter needle
- 1 25G X 1 in needle
- Fenestrated drape with adhesive tabs
- 5 ml safety syringe
- Safety scalpel with #11 blade
- 1 18G X 2.75 in safety introducer needle
- 1 guidewire
- 1 stainless steel scissors
- 1 stainless steel hemostat
- 1 tubing clamp
- 1 water soluble lubricant
- 4 gauze sponges
- 2 slit gauze sponges
- 1 suture strand

The AVANOS\* MIC\* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors.



## MAIN MATERIALS

- Not formulated with Natural Rubber Latex.
- Not formulated with DEHP.

Component	Raw Material
Tube	Silicone with ink markings
Forceps	Stainless steel
Scissors	Stainless steel
Placement wire/ guidewire	HDPE
Scalpel	Stainless steel
Snare	Stainless steel and PTFE
Suture	Polyethylene suture

## INDICATION

The AVANOS\* MIC\* Percutaneous Endoscopic Gastrostomy (PEG) Feeding Tube Kit is designed for placement convenience and comes in complete placement kits for both the Pull and Push placement methods. The comprehensive kit includes many major components including bolus and universal feeding adapters, a tubing clamp, placement wire, a SECUR-LOK\* retention ring, accompanying needles and sponges, and a traction removable Pull PEG tube. Please look below for a full list of included items. Available in 14, 20 and 24 French sizes, the MIC\* PEG is traction removable.

## COUNTER INDICATION

Contraindications for placement of a low-profile gastrostomy feeding tube include but are not limited to ascites, colonic interposition, portal hypertension, peritonitis, and morbid obesity. Do not re-use, re-process, or re-sterilize these products. Consult the instructions for use, additional warnings, and information.

## STERILIZATION

Products sterilized by Ethylene Oxide (EO).

## PACKAGING

- Content of 1 kit is packed in an individual sterile hard tray.
- One tray inside a carton box (shipping case).

For 9640\_xx and 8630\_xx:

- Dimensions: Carton box (LxWxD) 40.3 x 29.2 x 6.3 cm
- Weight: 544.3g (1.2 Ibs)
- Bar coding: GTIN symbology on carton box.

For 8644\_xx and 8645\_xx:

- Dimensions: Carton box (LxWxD) 29.8 x 23.4 x 6.7 cm
- Weight: 408.2g (0.9 Ibs)
- Bar coding: GTIN symbology on carton box.

## MANUFACTURING

Produced in Mexico.  
 The manufacturing site's quality system is ISO-13485-2016 compliant.

## REGULATORY INFORMATION

Applicable European Union directive	Applicable products are CE marked according to MDD93/42/EEC Annex IX*
DM Class	Class II
Notified Body	BSI - CE 2797

## STORAGE

Store in a clean, dry place at room temperature, away from sources of heat and radiation.

## SHELF LIFE

2 years from the date of manufacturing.

Product Code	9640_14	9640_20	9640_24
Each (EA) GTIN	00350770446448	00350770446431	00350770446295

Product Code	8644_14	8644_20	8644_24
Each (EA) GTIN	00350770446264	00350770446271	00350770446288

Product Code	8630_14	8630_14J	8630_20	8630_20J	8630_24	8630_24J
Each (EA) GTIN	00350770446516	00350770446547	00350770446523	00350770446554	00350770446530	00350770446561

Product Code	8645_14	8645_20	8644_24
Each (EA) GTIN	00350770446301	00350770446318L	00350770446325

Last Updated: July 2023

The dimensions and properties listed above can vary within pre-established specifications. This document was created using the most recent information. In the interest of continuous improvement, the characteristics of the product may change without prior notice.