

MIC-KEY*

Gastro-Jejunal Feeding Tube ENFit®



Description

MIC* Gastro-Jejunal Feeding Tube (MIC* GJ-Tube) is a double lumen balloon tube with male ENFit® gastric drainage (C) and jejunal feeding port (B), intended for endoscopic or fluoroscopic initial placement or as a replacement in an existing stoma tract.

It's made of medical grade silicone, silicone internal retention balloon (E), SECUR-LOK* External Retention Ring (D), tapered distal tip.

Multiple gastric and jejunal exit ports

Tungsten weighted jejunal portion: indicated jejunal length is measured from the distal aspect of the retention balloon to the catheter tip

Bariumsulphate stripe along the gastric part of the tube.

Available Sizes

Code	French	Jejunal length	Balloon volume
8650-16-15	16	15 cm	7-10 ml
8650-16-22	16	22 cm	7-10 ml
8650-16-30	16	30 cm	7-10 ml
8650-16	16	45 cm	7-10 ml
8650-18-22	18	22 cm	7-10 ml
8650-18-30	18	30 cm	7-10 ml
8650-18	18	45cm	7-10 ml
8650-22	22	45 cm	7-10 ml

One kit contains:

1- MIC* GJ-Tube with ENFit® connection

1- Stainless steel, teflon coated guidewire

1- Patient Care Guidelines

Main materials

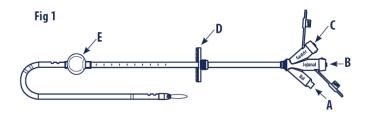
Tube: Silicone, Tritan, Tungsten (Radiopaque filler)

Polypropylene, Barium Sulphate

Guide wire: stainless steel and Teflon coating
Not formulated with Natural Rubber Latex.
Not formulated with DEHP / DBP /BBP.

Indication

The MIC* GJ-Tube is indicated for use in patients who cannot absorb adequate nutrition through the stomach, who have intestinal motility problems, gastric outlet obstruction, severe gastroesophageal reflux, are at risk of aspiration, or in those who have had previous esophagectomy or gastrectomy.



Counter indication

Contraindications for placement of a GJ-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 instruction for use for additional information and warnings.

Sterilisation

Products Sterilised by Gamma Radiation (R).

Packaging

Each unit of MIC* GJ-Tube and guide wire are packed in a Tyvek

One pouch inside a carton box.

Box size: 6,3 x 29,2 x 40,3 cm (LxWxD)

Box weight: 544 g (1,2lbs)

Bar coding: GTIM symbology, linear, on unit packaging and

carton box.

Manufacturing

Manufactured in Mexico.

The manufacturing site's quality system is ISO13485 compliant.

Regulatory information

Product CE marked as per 93/42/EEC Directive. Class of the device: IIb. Notified body: BSI (0086).

Storage

Store in a dry and cool place, away from sources of heat and radiation.

Shelf life

2 years, from date of manufacture.

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©2020 Avanos Medical BVBA. All rights reserved. Created Febr 08-2021, version 3, LVA, Page 1 of 2 The dimensions and properties listed above can vary within preestablished 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.



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Code	Inner Package	Sell Unit Package
8650-16-15	00350770445731	00350770445731
8650-16-22	00350770445748	00350770445748
8650-16-30	00350770445755	00350770445755
8650-16	00350770445762	00350770445762
8650-18-22	00350770445779	00350770445779
8650-18-30	00350770445786	00350770445786
8650-18	00350770445793	00350770445793
8650-22	00350770445809	00350770445809