

MIC*

Gastrostomy Tube ENFit®



Description

The MIC* Gastrostomy Feeding Tube with male ENFit® feeding port and male ENFit® medication port is available in 10 different French sizes. The tubes have a balloon content of 7-10ml except those indicated with "LV" (see table below).

Medical grade silicone gastrostomy feeding tube, silicone internal retention balloon, SECUR-LOK* External Retention Ring, tapered distal tip, recessed distal tip at recommended fill volume (Except Fr 12), barium sulphate stripe.

Available Sizes

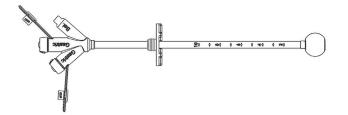
Size (OD)	Balloon volume	Item#
(xx)		
12 Fr	2 - 3 ml	8100-12LV
14 Fr	3 - 5 ml	8100-14LV
16 Fr	3 - 5 ml	8100-16LV
18 Fr	7 – 10 ml	8100-18
20 Fr	7 – 10 ml	8100-20
22 Fr	7 – 10 ml	8100-22
24 Fr	7 – 10 ml	8100-24
26 Fr	7 – 10 ml	8100-26
28 Fr	7 – 10 ml	8100-28
30 Fr	7 – 10 ml	8100-30

Main materials

Tube: Silicone, Tritan, Barium Sulphate, Not formulated with Natural Rubber Latex. Not formulated with DEHP / DBP / BBP. MR Safe

Indication

The MIC* Gastrostomy feeding tube is indicated for patients who require long term feeding, are unable to tolerate oral feeding, who are at low risk for aspiration, require gastric decompression and / or medication delivery directly into the stomach.



Counter indication

Contraindications for placement of 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 instruction for use for additional warnings and information.

Sterilisation

Products Sterilised by Gamma Radiation (R).

Packaging

Each unit of MIC* Gastrostomy feeding tube is packed in an individual Tyvek Pouch.

One pouch inside a carton box. Size: (LxWxD) 33 x 15,6 x 2,2 cm

Weight: 204 g (0,45lbs)

5 carton boxes in a shipping case.

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

carton box (sell unit).

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 (2797).

Storage

Store in a dry and cool place, away from sources of heat and radiation. Keep as much as practicably possible in its dispenser box

Shelf life

3 years, from date of manufacture.

Item#	GTIN#	Sell Unit Package
8100-12LV	00350770445007	00350770445007
8100-14LV	00350770442914	00350770442914
8100-16LV	00350770442921	00350770442921
8100-18	00350770442938	00350770442938



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8100-20	00350770442945	00350770442945
8100-22	00350770442952	00350770442952
8100-24	00350770442969	00350770442969
8100-26	00350770442976	00350770442976
8100-28	00350770442983	00350770442983
8100-30	00350770442990	00350770442990