

TECHNICAL DATA SHEET

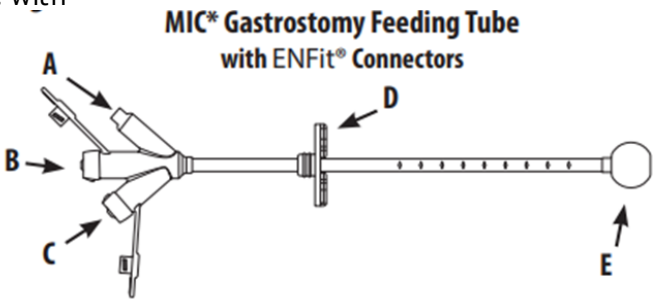
MEDICAL DEVICE REFERENCE  
8100\_xx  
MIC\* G tubes with ENFit® Connector

  
2797

DESCRIPTION

| Product Code | 8100_12                                                      | 8100_14                                                      | 8100_16                                                      | 8100_18                                                      | 8100_20                                                      | 8100_22                                                      | 8100_24                                                      | 8100_26                                                      | 8100_28                                                      | 8100_30                                                      |
|--------------|--------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|
| Description  | MIC* Gastrostomy Feeding Tube with ENFit® Connectors - 12 Fr | MIC* Gastrostomy Feeding Tube with ENFit® Connectors - 14 Fr | MIC* Gastrostomy Feeding Tube with ENFit® Connectors - 16 Fr | MIC* Gastrostomy Feeding Tube with ENFit® Connectors - 18 Fr | MIC* Gastrostomy Feeding Tube with ENFit® Connectors - 20 Fr | MIC* Gastrostomy Feeding Tube with ENFit® Connectors - 22 Fr | MIC* Gastrostomy Feeding Tube with ENFit® Connectors - 24 Fr | MIC* Gastrostomy Feeding Tube with ENFit® Connectors - 26 Fr | MIC* Gastrostomy Feeding Tube with ENFit® Connectors - 28 Fr | MIC* Gastrostomy Feeding Tube with ENFit® Connectors - 30 Fr |

The AVANOS\* MIC\* Gastrostomy Feeding tube with ENFit® Connector.



- Medical grade silicone gastrostomy feeding tube
- low profile design
- proximal Anti-reflux valve
- SECUR-LOK\* connector
- silicone internal retention balloon
- tapered distal tip
- recessed distal tip at recommended fill volume
- bariumsulphate stripe

## MAIN MATERIALS

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

| Component                  | Raw Material                        |
|----------------------------|-------------------------------------|
| Tube                       | Silicone with ink markings          |
| Balloon Inflation Port     | ABS valve with ink markings         |
| ENFit® access ports        | Silicone/ tritan copolyester insert |
| External retention bolster | Silicone                            |
| Balloon                    | Silicone                            |

## INDICATION

The AVANOS\* MIC\* Gastrostomy Feeding Tube is indicated for use in patients who require long-term feeding, who are unable to tolerate oral feeding, who are at low risk for aspiration, who require gastric decompression, and/or medication delivery directly into the stomach. The device can be used as initially placed tube or as a replacement tube in a mature tract.

## 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 GAMMA.

## PACKAGING

- Content of 1 kit is packed in an individual sterile hard tray.
- One tray inside a carton box (shipping case).
- Dimensions: Carton box (LxWxD) 15.6 x 2.23 x 33.0 cm
- Weight: 204.1g (0.45 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

3 years from the date of manufacturing.

| Product Code   | 8100_12                | 8100_14                | 8100_16                | 8100_18                | 8100_20                | 8100_22                | 8100_24            | 8100_26            | 8100_28            | 8100_30            |
|----------------|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|--------------------|--------------------|--------------------|--------------------|
| Each (EA) GTIN | 003507<br>704450<br>07 | 003507<br>704429<br>14 | 003507<br>704429<br>21 | 003507<br>704429<br>38 | 003507<br>704429<br>45 | 003507<br>704429<br>52 | 0035077<br>0442969 | 0035077<br>0442976 | 0035077<br>0442983 | 0035077<br>0442990 |
| Case GTIN      | 103507<br>704450<br>04 | 103507<br>704429<br>11 | 103507<br>704429<br>28 | 103507<br>704429<br>35 | 103507<br>704429<br>42 | 103507<br>704429<br>59 | 1035077<br>0442966 | 1035077<br>0442973 | 1035077<br>0442980 | 1035077<br>0442997 |

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.