TECHNICAL DATA SHEET

AVANOS* CORTRAK* 2 NASOGASTRIC/NASOINTESTINAL Feeding Tube with ENFit® connector

С€ 2797

PRODUCT DESCRIPTION

CORTRAK* 2 Nasogastric / Nasointestinal Feeding Tube with Electromagnetic Transmitting Stylet and ENFit® Connector.

FEATURES

- Polyurethane Tube
- Length, French Size, and centimeter markings printed on tube
- · Radiopaque tube and tip
- Pre-inserted braided stainless steel stylet with electromagnetic transmitting coil for use with the CORTRAK* 2 EAS.
- Distinctive YELLOW* tube design
- Anti-clog exit port
- · Y-access side port
- Water-activated lubricant on tip and internal lumen of tube
- MRI Safe (with stylet removed, MRI: ≤ 3 Tesla)

INDICATIONS FOR USE

CORTRAK* 2 EAS is designed to aid qualified operators in the placement of CORTRAK* 2 enteral feeding tubes 8 Fr or greater into the stomach or small bowel of patients requiring enteral feeding. CORTRAK* 2 EAS can be used to confirm placement of CORTRAK* 2 feeding tubes prior to commencing the delivery of enteral nutrition.

SINGLE PATIENT USE

STERILISATION

Sterile - Sterility Method: EO

COMPOSITION

- Polyurethane, stainless steel, electromagnetic transmitting stylet
- Copolyester/Thermoplastic Elastomer (ENFit Y)
- · Do not contain Natural rubber latex, BPA.

ΔVΔNOS

ENFit Connector and Tether Strap

<u>Y connector</u> is Copolyester (first shot) and Thermoplastic Elastomer (overmold) <u>Cap</u> is Polyethylene (Resin) with Compounding Solutions (Purple, PMS 2665) <u>Tether strap</u> is Polyethylene (Resin) with Chroma Colorant (Purple, PMS 2665

MANUFACTURING

COO Mexico

DATE FIRST AVAILABLE IN EU

(ENFit) - June 2015

LENGTH OF USE

The feeding tube should be monitored, regularly assessed, and replaced when clinically indicated based on functionality and patient condition.

SHELF LIFE

5 years, from date of manufacturing

REGULATORY INFORMATION

CE Certificate Number CE 711145 Notified Body BSI (2797) Class IIb Product Standards BS EN 1615:2000, BS EN 1618:1997, BS EN ISO 80369-3:2016



MRI SAFETY INFORMATION

Non-clinical testing demonstrated that the weighted CORFLO* Enteral Feeding Tubes are MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Spatial gradient magnetic field of 720-Gauss/cm or less
- MR system reported whole body averaged SAR of 3.0-W/kg

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	764-mm ²	89-mm ²	1,405-mm ²	684-mm ²
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

CORTRAK* 2 tubes are non-weighted

PACKAGING

Case Count	10
Size (Inches) (OD) (L)	11.25
Size (Inches) (OD) (W)	6.75
Size (Inches) (OD) (D)	3.5
Case Cubic Feet	0.154
Size (mm) (OD) (L)	285.75
Size (mm) (OD) (W)	171.45
Size (mm) (OD) (D)	88.9
Case Cubic Meters	0.004
Case Weight (lbs)	0.79
Stack Pattern	RB23E29
Cases per Layer	23
Layers per Unit OR Pallet	29
Cases per Unit OR Pallet	667
Other Palletizing Instructions	Various weights per code.
	Load 70206589 cases inside of Isomedix box.

ΔVΔNOS

LANGUAGES

Product	Languages
CORTRAK* 2 NG/NI	(DE) German (ES) Spanish (FR) French (IT) Italian (NL) Dutch (EN) English



BAR CODE/UNIVERSAL PRODUCT NUMBER

Type: UDI 2 dimensional datamatrix barcode on carton box and single unit

Global SKU#	Pk Lvl 1 - GTIN (EA)	Pk Lvl 3 - GTIN (CS)
42-9361TRAK2	00350770460895	10350770460892
42-9362TRAK2	00350770460901	10350770460908
42-9368TRAK2	00350770460932	10350770460939
42-9431TRAK2	00350770460949	10350770460946
42-9438TRAK2	00350770460970	10350770460977
42-9551TRAK2	00350770460987	10350770460984
42-9558TRAK2	00350770461007	10350770461004

Last Updated:

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.

