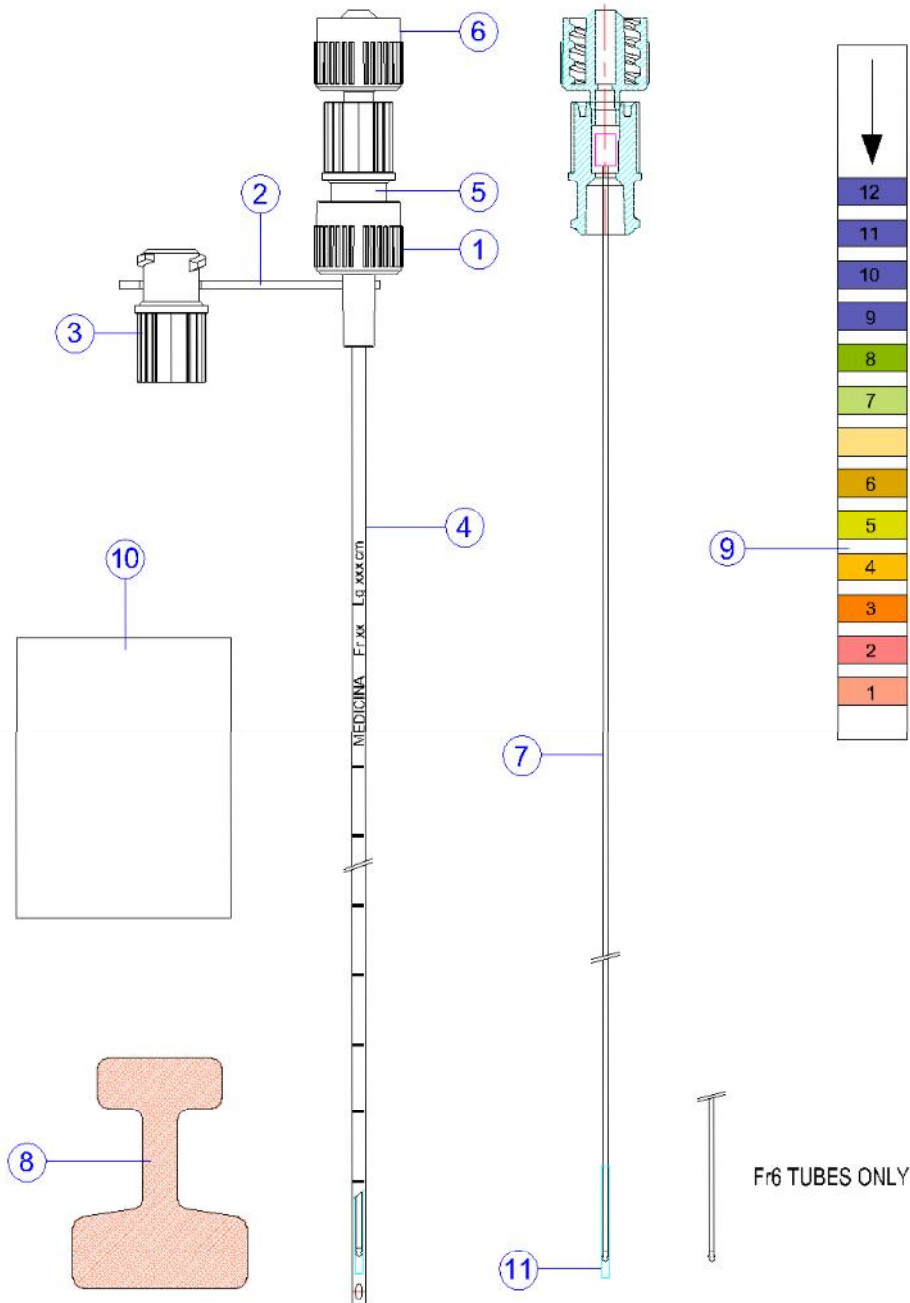


TECHNICAL DATA SHEET

ENFit Naso-Jejunal feeding tubes, ORX, with guide, Nasogastric plaster and pH indicator strip.



DEPTH MARKINGS (SEE TABLE BELOW)



Fr6 TUBES ONLY

DEHP FREE



● **PRODUCT COMPOSITION:**

1. ENFit male connector in purple **ABS**, produced in compliance with norm ISO 80369-3.
2. Strap in **DEHP FREE PVC**.
3. ENFit closed cap in white **DEHP FREE PVC**, produced in compliance with norm ISO 80369-3.
4. Tube in **Radiopaque Polyurethane** with clear stripe, with variable Fr and length (see table below), one distal eye and open tip.
5. ENFit female connector in white **DEHP FREE PVC**, produced in compliance with norm ISO 80369-3.
6. ENFit male connector in white **ABS**, produced in compliance with norm ISO 80369-3.
7. Guide in **Stainless Steel**.
8. Pediatric nasal plaster.
9. PH indicator strip.
10. Data registration label.
11. Guide end tube in blue **Radiopaque Polyurethane** (not present on 6 Fr tubes).

● **INTENDED USE:**

Naso-jejunal feeding tube for continuous or intermittent enteral nutrition.

● **PACKAGING:**

Single package in double envelope: internal PE bag + Paper/PP-PE film Blister. Multiple package (see table below).

● **PRODUCTION PROCESS:**

The device is manufactured in accordance with HMC Premedical S.p.A. Quality System and in compliance with the requirements of the standard EN ISO 13485.

● **CONTROL ON THE PRODUCT:**

In all stages of processing, according to internal procedures and to sampling plans defined by norm ISO 2859-1.

● **CLASSIFICATION:**

Class IIA sterile.

● **STERILIZATION:**

Product sterilized by ethylene oxide according to a validated course of treatment in accordance with current regulations. Shelf life 5 years from the date of sterilization. For single-use only and Non re-sterilizable.

● **STORAGE:**

Normal storage procedures and conditions.

● **DISPOSAL:**

The user must follow the legal regulations regarding disposal of hospital waste.

● **WARNINGS:**

The device must be used exclusively by healthcare professionals.

● **REGISTRATION TO ITALIAN REPERTOIRE:**

no. CND: **G02020101** – no. Repertoire: **1354315**

CODE	Fr	LENGTH cm	DEPTH MARKINGS cm	BOX pcs.
NJP6/120L	6	120	5-110	10
NJP8/120L	8	120	5-110	10
NJP8/130L	8	130	5-120	10
NJP10/120L *	10	120	5-110	10
NJP10/130L	10	130	5-120	10
NJP12/120L *	12	120	5-110	10
NJP12/130L *	12	130	5-120	10
NJP14/120L *	14	120	5-110	10
NJP14/130L *	14	130	5-120	10
NJP16/120L *	16	120	5-110	10
NJP18/120L *	18	120	5-110	10

*=skaffevare

REV. Rev.	MODIFICHE Changes	DATA Date	EMESSO Issued	VERIFICATO e APPROVATO Verified and Approved
00	First Issue – English language	04/11/2016	E. Benassi	D. Bosetti
01	Data sheet revision; depth markings update	07/09/2017	E. Benassi	D. Bosetti