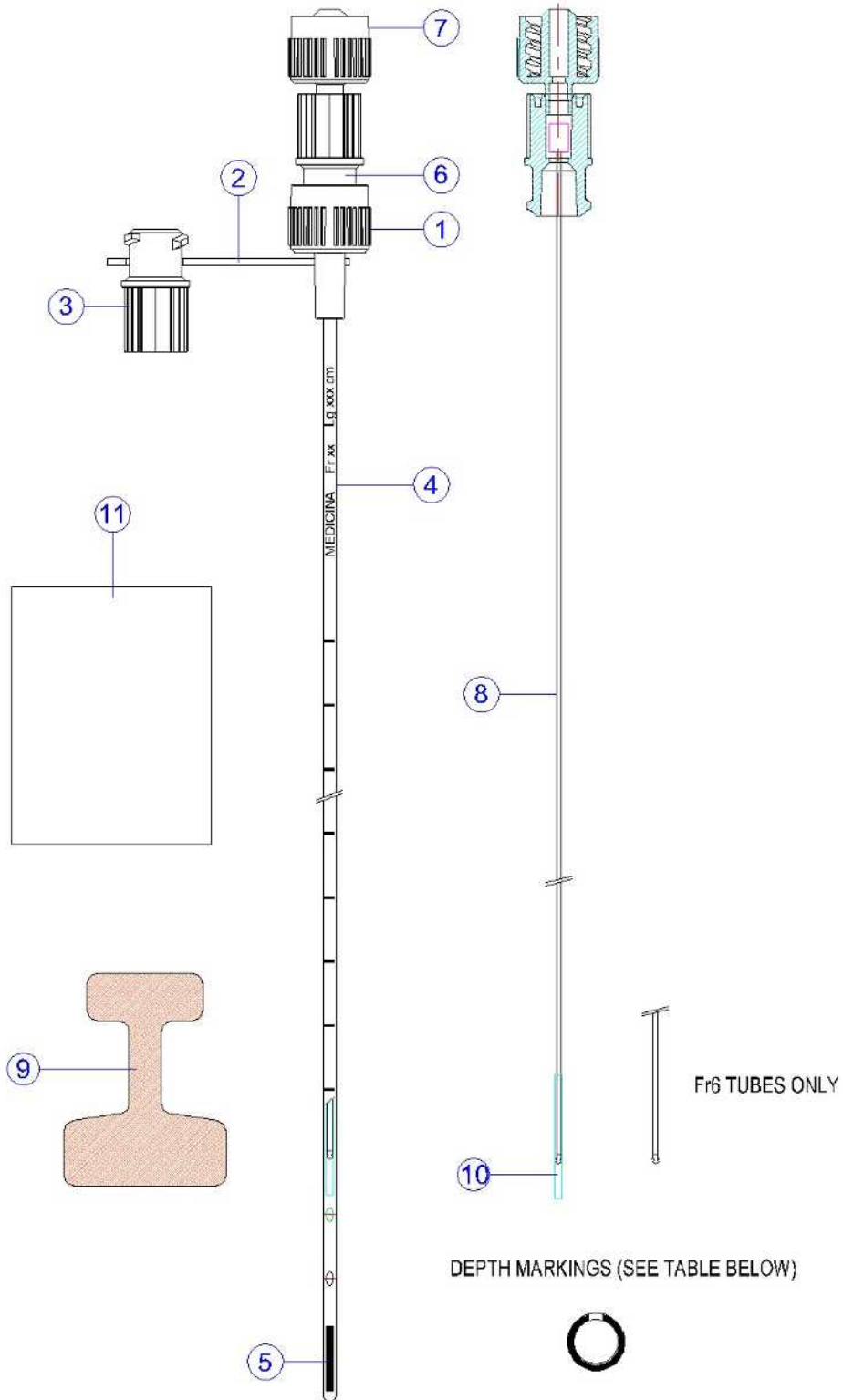


TECHNICAL DATA SHEET

ORX feeding tubes with guide and nasogastric plaster.



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) and two distal eyes.
5. Solid cord tube in **Radiopaque Polyurethane**.
6. ENFit male connector in white **ABS**, produced in compliance with norm ISO 80369-3.
7. ENFit female connector in white **DEHP FREE PVC**, produced in compliance with norm ISO 80369-3.
8. Guide in **Stainless Steel**.
9. Nasal plaster.
10. Guide end tube in blue **Radiopaque Polyurethane** (not present on NGP6/xxxL tubes).
11. Data registration label.

● INTENDED USE:

Nasogastric 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:

Standard 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 M.D. REPERTOIRE:

CND: **G02020101**

RDM: **1354315**

GMDN: **14221**

CODE	Fr	LENGTH cm	DEPTH MARKINGS cm	BOX pcs.	CARTON pcs.
NGP4/120L *	4	120	5-110	25	100
NGP5/50L *	5	50	5 - 40	25	100
NGP6/55L	6	55	5 - 45	25	100
NGP6/75L	6	75	5 - 65	25	100
NGP6/85L	6	85	5 - 75	25	100
NGP6/120L *	6	120	5 - 110	25	100
NGP8/55L	8	55	5 - 45	25	100
NGP8/75L	8	75	5 - 65	25	100
NGP8/85L	8	85	5 - 75	25	100
NGP8/120L	8	120	5 - 110	25	100
NGP10/85L	10	85	5 - 75	25	100
NGP10/120L	10	120	5 - 110	25	100
NGP12/85L *	12	85	5 - 75	25	100
NGP12/100L *	12	100	5 - 90	25	100
NGP12/120L	12	120	5 - 110	25	100
NGP14/85L *	14	85	5 - 75	25	100
NGP14/120L	14	120	5 - 110	25	100
NGP16/120L *	16	120	5 - 110	25	100

*=skaffevare

REV. Rev.	MODIFICHE Changes	DATA Date	EMESSO Issued	VERIFICATO e APPROVATO Verified and Approved
00	First issue – English language	27/06/2016	E. Benassi	D. Bosetti
01	Table updated	29/08/2016	E. Benassi	D. Bosetti
02	Table update; new code added and revised markings.	08/03/2017	E. Benassi	D. Bosetti
03	Item code NGP16/120L added.	10/10/2017	E. Benassi	D. Bosetti
04	Item code NGP6/120L added.	05/04/2018	E. Benassi	D. Bosetti
05	Item code NGP4/120L added.	20/11/2018	E. Benassi	D. Bosetti
06	pH Strip removed; packaging updated.	27/03/2019	E. Benassi	E. Benassi
07	GMDN number added	05/07/2019	E. Benassi	E. Benassi