

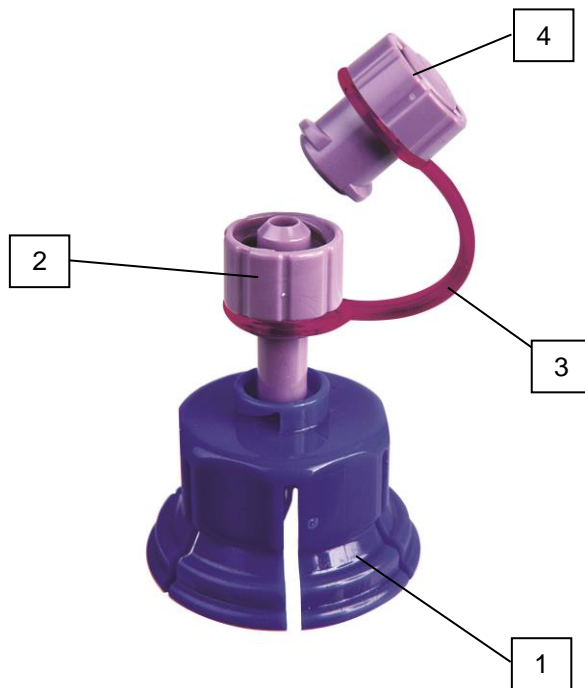
NUTRICAIR™ SAMPLING DEVICE FOR ENTERAL NUTRITION WITH ENFit FOR BOTTLE Ø 20 MM

RANGE: NUTRITION - NUTRICAIR™ ENTERAL
INTENDED USE: ENTERAL NUTRITION

REGULATORY INFORMATION

Sterile single use medical device
 CE mark Class IIa
 Notified Body : G-MED, number 0459
 GMDN Nomenclature:

DEVICE DESCRIPTION:



MAIN COMPONENTS

1. Spike for bottle in PC (blue)
2. Male ENFit nutrition tip in ABS (purple)
3. Link in TPU (purple)
4. Female ENFit nutrition cap in PP (purple)

DEHP (DOP), BBP, DBP, DIBP AND DHP are not part of composition of our products.
The residual levels of these substance conforms to REACH regulation
ABSENCE OF LATEX

TECHNICAL FEATURES:

We recommend to replace extension lines and accessories at every meal (for example: every 3 to 4 hours, especially on neonatology), or every 24 hours maximum.
 Observe the applicable rinsing protocols within the establishment.
 Nutricair™ enteral with ENFit satisfies the criteria for safe and non-interconnectable connectors from ISO 80369-3 standard.

PRECAUTIONS FOR USE:

- Sterile unless package has been opened or damaged
- Do not re-sterilize
- Discard after single use

COMPATIBILITY OF MATERIALS:

NA

PRODUCTION:

- Injection and extrusion of components
- Automatic and manual assembly

QUALITY CONTROL:

- Visual control: Absence of scratches, smudges, breaks, tasks, deformations
- Dimensional control
- Functional control (pressure, water-tightness)

STERILIZATION:

Sterilization mode: **Ethylene oxide**

Validation and control of routine of the sterilization according to the International Standard ISO 11135.

CAIR LGL did not design this device to be reprocessed or reused, and therefore cannot verify that reprocessing can clean and/or sterilize or maintain the structural integrity of the device to ensure patient and/or user safety.

PRESERVATION

Expiry date: 59 months.

STORAGE

In a clean and dry zone, shielded from the light, the temperature of which is between +5 and +40°C.

ELIMINATION

Elimination in a specialized container consisting of contaminated waste for incineration.

UNIT OF USE:

- Blister: 1 face paper, 1 face transparent.
- Packaging: 40 per carton.

ABBREVIATIONS: ABS: Acrylonitrile butadiene styrene ; ASA: Acrylonitrile Styrene Acrylate ; PA: Polyamide ; PC: Polycarbonate ; PE: Polyethylene ; PI: Polyisoprene ; POM: Polyacetale ; PP: Polypropylene ; PS: Polystyrene ; PU: Polyurethane ; PVC: Polyvinyl chloride ; SAN: Acrylonitrile styrene ; SI: Silicone ; SB: Styrene butadiene.
REACH: European regulation concerning the registration, evaluation, authorization and restriction of chemicals. Communication of information about concerned substances is mandatory if greater than 0,1% weight/weight.