

Product Specifications

Brand : Cenaman®
Product : Gravity Set

Product description

Enteral nutrition disposable gravity feeding set with ENplus Spike and ENFit connection.

The Cenaman ENFit Gravity Set is designed to administer enteral nutrition in the absence of an enteral pump. The closed system set is equipped with a spike for connection with tube-feeding bags/ bottles with an ENPlus connection system. The set also contains a detachable screw cap for flexible use with a feeding bottle or container and a Y-port for flushing access with an ENFit syringe.

Intended use

The Cenaman ENFit Gravity Set is intended for administration of enteral nutrition and fluid by gravity, without the use of an enteral pump. For use under the guidance of a healthcare professional.

Classification

Class IIa under the Medical Devices Regulations (SI 2002 No. 618, as amended) and Class IIa under the Medical Device Directive 93/42/EEC.

Packaging & Product Reference

Product reference	Description	Piece(s)	EAN Piece	Outer carton (pcs)	EAN OC
C061013	CENAMAN GRAVITY SET W/AP	1	6973648241934	30	16973648240156

Features

- Sterile if pouch is intact
- Products are individually packed
- ENFit connector
- Purple ENPlus spike and Y connector
- Wide-neck-bottle adapter for connection with tube-feeding bags/ bottles with an ENPlus connection
- Transparent drip chamber and purple roller clamp
- 210 cm length
- Usage: 24 hours

Product Specifications

Contraindications

Do not use on:

- infants younger than 3 months;
- patients with gastrointestinal bleeding;
- patients with extensive resection of the small intestine;
- patients with jejunal fistula;
- patients with severe diarrhea, refractory vomiting, severe malabsorption syndrome and weakness;
- in severe metabolic stress patients.

Precautions

- Sterile if pouch and seal are intact, do not use if damaged.
- For enteral use only.
- For single patient use only. Device should be replaced after 24 hours.
- Re-use and use longer than 24 hours can cause serious infections.
- Store in a dry, clean place.
- Not to be used with enteral pump.
- Only suitable for ENFIT connection.
- Contains small parts which may be dangerous for young children.
- Check whether the initial packaging is intact before use.
- Don't use if there is foreign matter inside or the protective cover is detached.
- This product is a sterile product, it should be used immediately when open and be discarded after use according to laws and regulations related to medical waste.
- In case a serious incident has occurred in relation to the device: Inform manufacturer Jiangxi Hawk Medical Supplies Co.,Ltd as listed on the packaging, your local distributor and the competent authority.

Sterilization

EO sterilized

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Absence of specific components

Component	Present
Latex	No
Phthalates	No
Substances of animal origin	No
Substances of human origin	No
Blood or blood derivatives	No
Medicinal substances	No
Heavy Metals	No

Storage conditions

Store the product in a cool, dry environment away from direct sunlight, high heat, and high humidity.

Shelf life

Cenamán® Gravity set has a shelf-life of 3 years from production date, when stored under specified conditions.

Product picture



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Product Specifications

Approval	Name	Date	Signature
Associate Category Management Director - Infusion & Nutrition	Susanne van den Berg		
RA Specialist	Alexandra Maria da Silva Duarte		