

ENEMA -FULLWASH TECHNICAL INFORMATION

Definition

- Device for gastric and smear washing with irrigator.

General features

- The enema is a device for gastric and smear washing with irrigator. It can be used for purgative or medicative aims. It is formed by a plastic bag soldered by microwaves for guaranteeing a long term use, it has a capacity of 2 litres and a graduated scale, the tube is elastic and plastic made in order to avoid rigid folds that can obstruct the correct flow; anal cannula for enemas and smear cannula for irrigation. The cannulas are packaged in thermo soldered bag. After each use carefully wash the bag and its accessories.

It's available in two models:

TRADITIONAL MODEL: with soft plastic bag, cannulas, tap and tube.

TRAVELLER MODEL: with soft plastic bag, cannulas, tap and tube, in a rigid box for guaranteeing maximum hygiene and

convenience during transport.



Mod. traditional



Applications

- It's indicated for purgative and medicative aims. Helps the intestinal evacuation increasing peristalsis for stimulating the intestinal activities.

INSTRUCTION

1. Open the pack and spread the bag, screw the tube;
2. Close the tap place at the tube bottom and screw one of the two cannulas (right for anal use, curved for smear use);
3. Fill in the bag with the desired solution;
4. Hook the enema in a point sufficient high to allow the liquid to flow with the desired pressure (higher for more pressure; less high less pressure);
5. To flow the liquid open the tap;
6. After the use, carefully wash the bag and its accessories and replace in the provided holder.

Medical device according to the directive CEE 93/42

Modified by the directive 2007/47/CE

Implementation with D.L. n°37 del 25-01-2010

Class I

- Use: Invasive device in contact with no wounded skin.



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Conformity

- DIRECTIVE CEE 93/42
- Quality Assurance System: certified according to UNI EN ISO 9001:2008.

Technical specification

ENEMA	Bag: hight 210 mm, width 110 mm
	Tube: lenght 1.400 mm, extrenal diameter 10 mm, Internal diameter 7mm
	Anal Cannula: external diameter max 15 mm, lenght 70 mm Smear Cannula: external diameter max 12 mm, lenght 143 mm
	Tap key: hight 33 mm, width 12 mm Tap body: hight 20 mm, width 15 mm, lenght 58
PACKAGE	In carton box PIC branded
	The kit is packaged in a strong plastic closed again envelope
MATERIAL	Hook PP, bag PVC phthalates free, connector PVC phthalates free, tube PVC phthalates free, connector PP, tap PP, anal cannula PP, smear cannula PE.
TYPE (gravity – pump – syringe)	gravity
USE (adult – pediatric - neonatal)	Adults
PREFILLED	No
SOLUTION	Empty, not expected

Sterile	No
Latex (in the product)	No
Latex (in the package)	No
Storage instructions	Store in a cool, dry place, away from heat and direct sunlight

Product sterilization

- No sterile product.
- It can be cold sterilized.

Biocompatibilità

- BIOCOMPATIBILITY TEST: The product has successfully undergone the biocompatibility tests for cytotoxicity, sensitization and irritation.

Disposal

- In compliance with applicable laws. The product can be integrated with the hospital waste or special waste.

Indications for use

- After each use carefully wash the device and its accessories and put it away only if total dry.



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Quality control

- The product is tested according to a sampling system presented by UNI ISO 2859.
- Each batch is controlled:
 - Bag and tap performance,
 - Tube/canulas hook,
 - Absence of faults,
 - Aesthetical visual controls

Packaging

Labels and/or packages have the following:

Product name
Manufacturer
Date and batch of production
Validity
Storage instruction
Item Bar code

Packaging material

- Packaged in single carton box with brand PIC.
- Packaged in transparent plastic envelope.

Manufacturer

- Artsana S.p.A. Via Saldarini Catelli n.1 22070 Grandate (Como) Italy.

Assortment

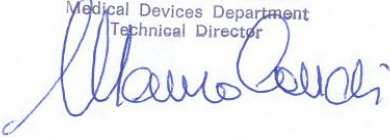
CODE	MODEL	UNIT	PACKAGE
00 002005 000 000	Traditional	1 pc	56 pcs
03 050011 000 000	Accessories Kit	1 pc	150 pcs



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Additional information

- Additional information and operating procedures are included in the technical dossiers filed with ARTSANA's Technical/Quality Assurance department.

ARTSANA S.p.A.
The Technical Department
Medical Devices Department
Technical Director


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