

## IRRIGATOR – SOFT WASH TECHNICAL INFORMATION

### Definition

- Device for auricular and intestinal washing.

### General features

- The irrigator with cannula is soft and it's a device for intestinal and auricular irrigations
- Available in a wide range of different volumes.

### Applications

1. Open the pack
  2. Keep the device
  3. Fill it in with a fluid necessary for anal administration.
  4. After the use, clean and disinfect the device.
- **Medical device DIRECTIVE CEE 93/42 modified by the directive 47/2007/CE.**  
**Implementation with D.Lgs n° 37 of 25/01/2010**



### **Class I**

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

### Conformity

- DIRECTIVE CEE 93/42 modified by the directive 47/2007/CE.  
Implementation with D.Lgs n° 37 of 25/01/2010
- Quality Assurance System: certified according to UNI EN ISO 9001:2008.

### Technical specification

<b>IRRIGATOR</b>	PVC, Plastic, soy oil, Stabilizer, Colourant, Aroma Vanilla, Silicon Fluid.
<b>PACKAGE</b>	In carton box PIC branded

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

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### 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.

### Indications for use

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

### **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 1, 22070 Grandate (Como) Italy.

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### Assortment

Code	Model	Unit
00 002475 100 000	25 ml	6 pz
00 002476 100 000	35 ml	6 pz
00 002477 100 000	50 ml	6 pz
00 002478 100 000	65 ml	6 pz
00 002479 100 000	85 ml	6 pz
00 002480 100 000	155 ml	6 pz
00 002481 100 000	145 ml	6 pz
00 002482 100 000	180 ml	6 pz
00 002484 100 000	260 ml	6 pz
00 002486 100 000	340 ml	6 pz
00 002487 100 000	520 ml	6 pz
00 002488 100 000	750 ml	6 pz

### Additional information

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

#### The Technical Department

ARTSANA S.p.A.  
Dr. MAURO CASSANI  
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Technical Director

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