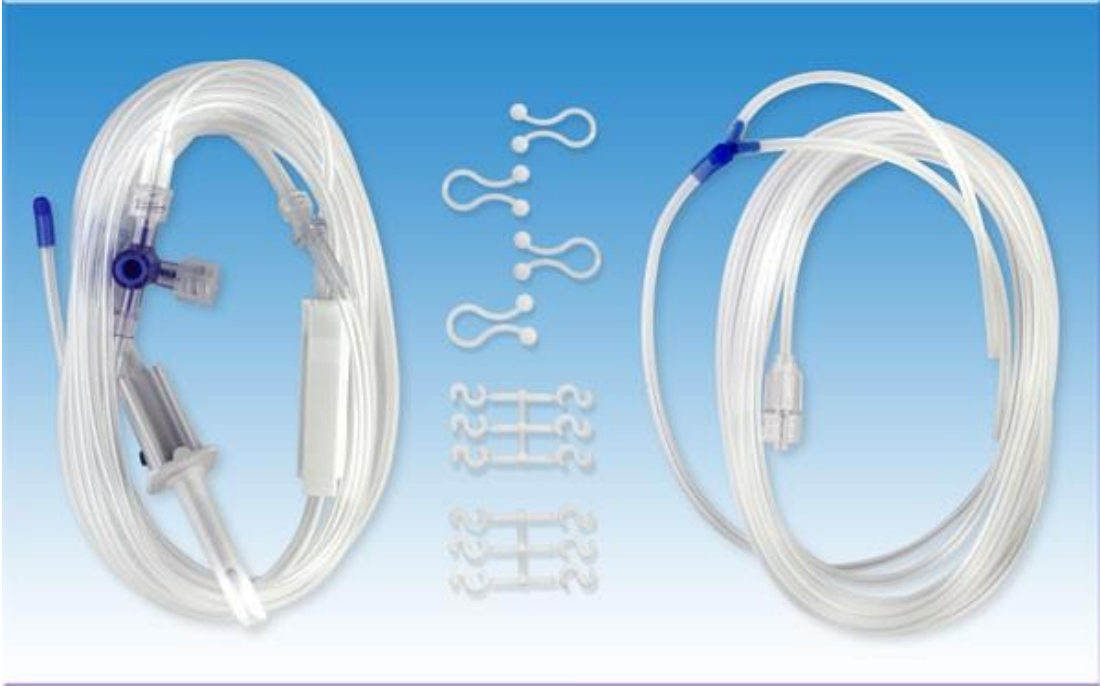


# Product Data Sheet

|                                                                                     |  |
|-------------------------------------------------------------------------------------|--|
| IRRIGATION SET                                                                      |  |
| OMNIA PART CODE: 32.F0139.00                                                        |  |
|  |  |

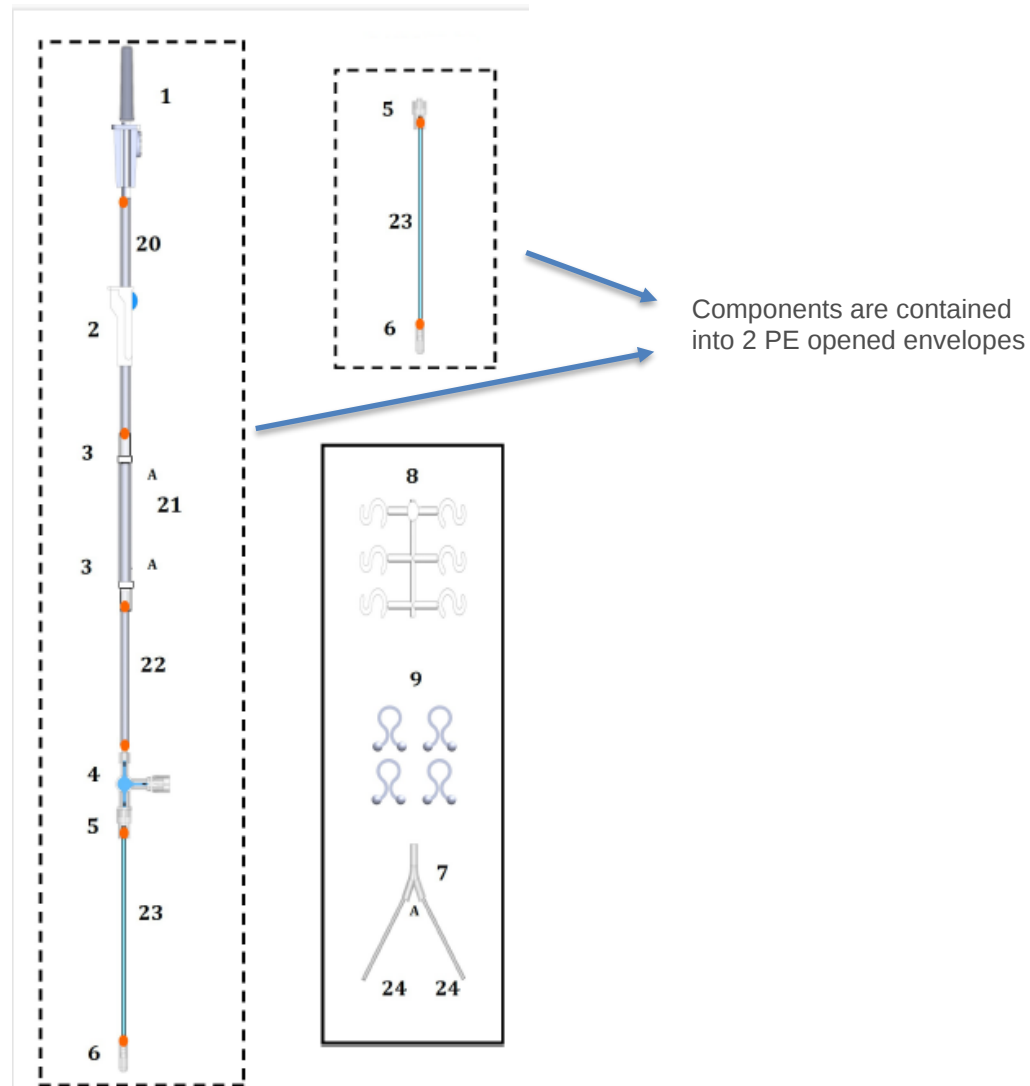
| Product Information                                                                                                                                         |                            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Manufacturer information:<br><b>Omnia Srl</b><br>Via F. Delnevo, 190<br>43036 Fidenza (PR)<br>Italy<br><a href="http://www.omniaspa.eu">www.omniaspa.eu</a> |                            |
| Description                                                                                                                                                 | Mechanical Irrigation Line |
| Contains                                                                                                                                                    | 10 pcs                     |
| Sterilization Information                                                                                                                                   | ETO – validity 5 years     |
| Shelf Life                                                                                                                                                  | 5 years                    |
| Country of Origin                                                                                                                                           | Italy                      |



| Regulatory Information - EU |                                                                                                                         |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------|
| Medical Device Status       | Yes                                                                                                                     |
| Classification              | Ila                                                                                                                     |
| Basic UDI-DI                | 805664650TF06EU                                                                                                         |
| GMDN Term                   | 47890                                                                                                                   |
| EMDN Term                   | A0304099                                                                                                                |
| Registration Number         | 84094                                                                                                                   |
| Custom code                 | 90184990                                                                                                                |
| Intended Use                | Sterile systems for irrigation, washing or cooling of surgical areas, intended to be connected to the peristaltic pump. |

| Certificate CE | Declaration of conformity         | IFU | MSDS |
|----------------|-----------------------------------|-----|------|
| OMNIA CE0546   | Yes<br><i>at each lot release</i> | Yes | No   |

## Material Information



| N. | Component description            | Material                  |
|----|----------------------------------|---------------------------|
| 1  | 2 ways vented spike              | PolyEthylene (PE) and ABS |
| 2  | Roller                           | Polystyrene               |
| 3  | Connector                        | ABS                       |
| 4  | 4 ways tap with female luer lock | Polycarbonate and PE      |
| 5  | Male luer lock                   | ABS                       |
| 6  | Terminal pin                     | PVC                       |
| 7  | Y connector                      | Nylon                     |
| 8  | 6 blue clips S shaped            | PolyPropylene             |
| 9  | 4 blue heparine hooks            | HDPE                      |
| 20 | Irrigation tube 35 cm            | PVC DEHP free             |
| 21 | Tube for peristaltic pump 9,4 cm | Silicone                  |
| 22 | Irrigation tube 20 cm            | PVC DEHP free             |
| 23 | Irrigation tube 230 cm (blue)    | PVC DEHP free             |
| 24 | Irrigation tube 12 cm            | Silicone                  |

| Packaging Information               |                |                        |         |
|-------------------------------------|----------------|------------------------|---------|
| Primary Packaging (no selling unit) |                |                        |         |
| Blister                             | 250x116 mm     | 1 pcs                  | 0,08 kg |
| Secondary Packaging (selling unit)  |                |                        |         |
| Box                                 | 200x280x120 mm | 10 pcs                 | 0,8 kg  |
| Outer Packaging                     |                |                        |         |
| Carton box                          | 375x280x410 mm | 6 x 10 pcs = 60 pcs    | 4,8 kg  |
| Pallettization                      |                |                        |         |
| 40 carton boxes                     |                | 40 x 60 pcs= 2.400 pcs | 192 kg  |

| Labeling Information                                                                                  |                                                                                                                                               |
|-------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| Primary Label                                                                                         |                                                                                                                                               |
|                    | <p>Variable data (Ref code, Lot number and expiry date) added also on removable adhesive traceability labels (not printed on the blister)</p> |
| <p>Variable data (Ref. code, lot number and expiry date) printed on the right part of the blister</p> |                                                                                                                                               |

## Secondary Label



Manufacturer  
**OMNIA Srl**  
Via F. Delnevo 190  
Fidenza (PR) - Italy  
tel +39 0524.527453  
www.omniaspa.eu - info@omniaspa.eu

rev. 04/2019

**REF 32.F0139.00**

Set d'irrigazione per pompa peristaltica per l'erogazione  
dei liquidi di raffreddamento nella chirurgia orale

Set for machinery irrigation system to be used with  
dispensing liquid coolants in oral surgery

**BOX 10 pcs**

(17)220128(10)12345678(91)32.F0139.00(30)10

**LOT 12345678****2022-01-28****CE 0546****STERILE EO**

## Outer Label



Manufacturer  
**OMNIA Srl**  
Via F. Delnevo 190  
Fidenza (PR) - Italy  
tel +39 0524.527453  
www.omniaspa.eu - info@omniaspa.eu

rev. 04/2019

**REF 32.F0139.00**

Set d'irrigazione per pompa peristaltica per l'erogazione  
dei liquidi di raffreddamento nella chirurgia orale

Set for machinery irrigation system to be used with  
dispensing liquid coolants in oral surgery

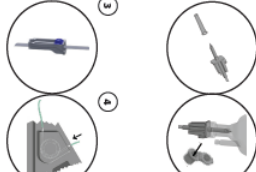
**CARTON = 6 BOXES/10 pcs**

(17)220128(10)12345678(91)32.F0139.00(30)60

**LOT 12345678****2022-01-28****CE 0546****STERILE EO**

[illegible]

# OMNIA

[illegible]

### Sterilization Parameters

The validation process to determine the lethality of the cycle is the overkill method. It has been chosen between the procedures suggested by referring standard UNI EN ISO 11135-2014. This approach, substantially conservative, is based on the inactivation of referring microorganisms in conditions more critical than the used in routinely sterilization cycles. Practically the method furnished an overkill, considering that the conditions that are lethal the referring microbial charge are stronger than the conditions necessary to destroy the bioburden of product. The procedure uses half time cycles, cycle with an half exposure than normal full time. As established by SterilVerona, the biological performance qualification consists in:

- products bioburden evaluation;
- sterilization efficacy verification using referring biological indicators;
- sterility test of the products.
- test of gas residual.

The S.A.L. (Sterility Assurance Level) obtained after the sterilization is equal to 10<sup>-6</sup>.

The validation of the Sterilization is performed according to the standards:

- EN ISO 11135:2014+A1:2019 Sterilization of health care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
- EN ISO 11737-2:2020 Sterilization of health care products - Microbiological methods Part 2: Tests of sterility performed in the validation of a sterilization process.
- EN ISO 11138-1:2017 Sterilization of healthcare products - Biological indicators - Part 1: General requirements
- EN ISO 11138-2:2017 Sterilization of healthcare products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
- EN ISO 10993-7:2008 +A1:2019 Biological evaluation of medical devices - part 7: Ethylene Oxide sterilization residuals

### Disposal information

| N.          | Disposal                                  |
|-------------|-------------------------------------------|
| 32.F0139.00 | Dispose of according to local regulations |

| Rev | Date       | Modify      | Em. | Ap. |
|-----|------------|-------------|-----|-----|
| 00  | 19.05.2023 | First issue | QA  | GM  |



AC

 Ho esaminato il documento,  
 19-mag-2023 | 7:57:29 AM CDT

126E5B3CCAB6443B87E74F00FE754E92

DocuSigned by LUIG

 Approvo il d  
 19-mag-202