



Hose set for machinery driven irrigation system

## Irrigation in implantology

A proper irrigation during the creation of the implant site is essential for the necessary bone integration of the implant and consequently, for the success of the operation.

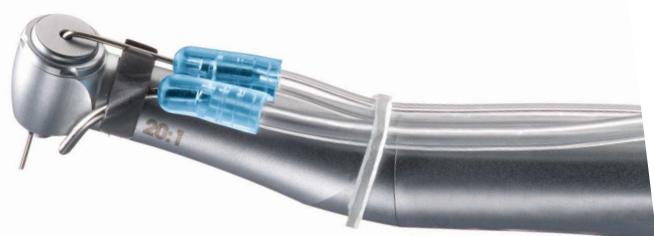
For this reason, it is very important that the surgical bur is properly cooled. An adequate, but not excessive flow of coolant liquid can be guaranteed only by an irrigation system which has been developed for a specific drilling unit.

Eriksson, in his papers, set the highest level of temperature increase at 47°C for no longer than 1 minute, in order not to induce a thermal necrosis of the bone tissue. This parameter was confirmed and analyzed in clinical operations thanks to the research made by Watanabe (1992), Gross (1995), Brisman (1996), Cordioli (1997) and Iyer (1997).

External and/or internal irrigation ensures a direct cooling on the bone surface and avoids the overheating of the bur due to friction.

Guidelines to carry out an atraumatic surgery on hard tissues:

- Usage of disposable surgical burs or usage of surgical burs on a limited number of operations
- Usage of double and simultaneous, internal and external, irrigation, by means of an Y connection and the supply of a coolant liquid between 800 ml/min and 1200 ml/min
- Number of revolutions of the bur between 800 and 1200 rpm
- Adjustment of the speed and the manual pressure on the surgical bur according to the quality of the bone (dense and compact bone: high speed, high pressure; cancellous bone: low speed, low pressure)
- Saline solution cooled at about 4°C



## Mechanical Irrigation Systems

Omnia offers a wide range of mechanical irrigation lines, specifically realised for the majority of the Physio-dispenser available on the market. Irrigation systems are supplied with a perforator, a roller for flow control, fittings and integrated peristaltic pump section.

Omnia mechanical irrigation systems offer the following options:

- a. single internal irrigation
- b. single external irrigation
- c. double internal and external irrigation

Each set for mechanical irrigation is packed in a sterile medical blister.

Each pack contains 10 pieces and each set is single use.

### Ex. Mechanical irrigation set - Ref. 32.F0139



Main features of irrigation lines are the following:

- Perforator with air filter
- Roller to adjust the flow
- Pump section in medical grade silicon
- Total length of the line, from peristaltic pump to handpiece, 230 cm
- Final tip in soft PVC

## Components

Features of Omnia irrigation lines

### Hose

The hose of the irrigation line is produced in constant section, realized to be used in medical field with characteristics of elasticity, high flexibility and transparency, so that the eventual passage of air bubbles in the water can be clearly observed. The hose is 230 cm long and its diameter is 1,5x3mm.



### Final tip

The tip is inserted in the final part of the phisioidispenser, and it comes with a practical cap which helps the connection of the irrigation line on the hand piece, allowing to connect Omnia irrigation lines with all the cooling needles used to cool the hand pieces, often having different diameters.

### Tap

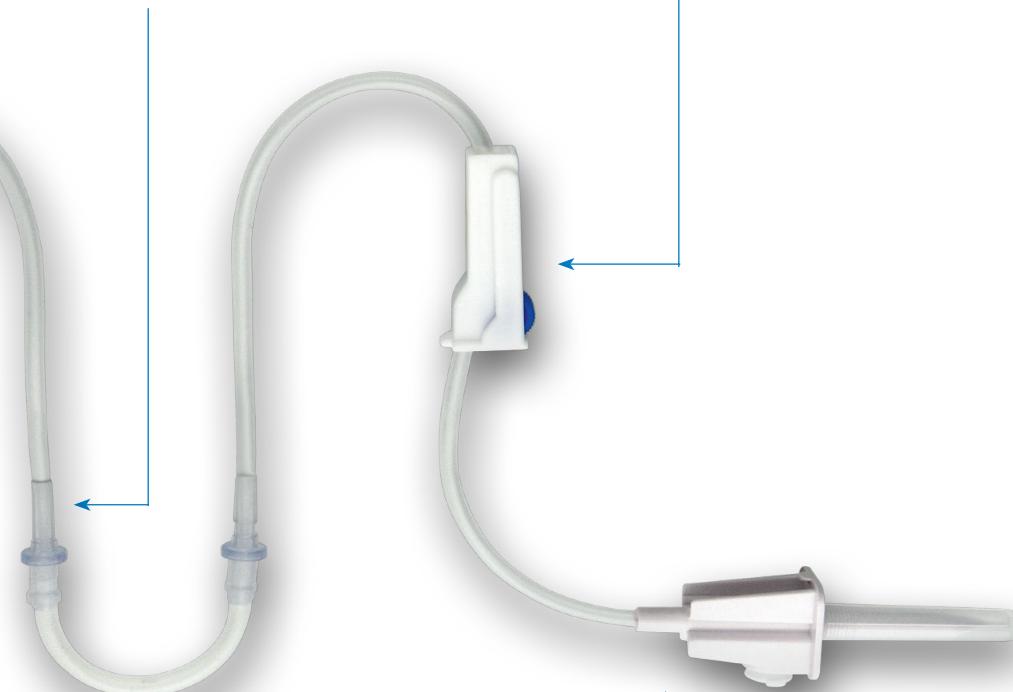
The tap is used to regulate the flow, and allows to have an optimal control on the flow of the liquid. The tap is present only in irrigation lines REF. 32.F0139, 32.F0159 and 32.F0171

### Connector

Omnia irrigation lines present a particular connector, placed after the peristaltic pump section. The connector in acetal resin acts as a reduction between the peristaltic pump section and the irrigation hose, of smaller diameter. The aim is to prevent any possible leak of water.

### Roller

The roller, a flow regulator by means of a roller, is mounted after the perforator and is used to regulate or stop the flow of the solution. The flow regulation is assured by the roller itself. When sterile liquid cooling bags of  $\frac{1}{2}$  litre are used, it is suggested to open all the roller as the flow tends to decrease with the consumption of the coolant liquid.



### Peristaltic pump hose section

The peristaltic pump hose section is in soft silicon and allows an accurate flow and long duration of usage.

The length of the peristaltic pump section varies according to the different Phisiodispenser, to adapt each irrigation line to the different peristaltic pumps available on the market.

### Perforator

The first part of the irrigation line is constituted by the perforator. The perforator is suitable to punch the cap of the coolant liquid, is supplied with an air filter, which looks like a cap to be opened and closed in order to increase the flow of the liquid.

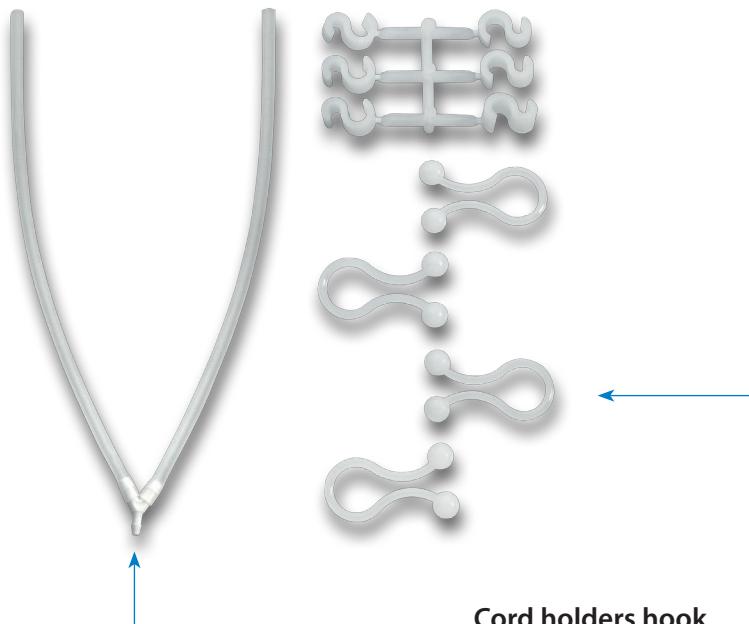
## Accessories

For those who uses the double irrigation, each blister of irrigation lines contains a bag with the following accessories:

- Y joints
- S shaped clips
- cord holders hooks

### S shaped clips

The practical S shaped clips allow to fix the irrigation hose to the cord of the micro motor.



### Y joints

In case of double irrigation, it is possible to use the useful joint, (Y connector in PVC and silicon tubings) which turns the simple irrigation into double.

### Cord holders hook

When the diameter of the cord of the phisiodispenser is very large, it is possible to use those hooks to fix it to the irrigation line.

**Suggestion for a proper usage of the irrigation line**

For a proper usage of the irrigation line we suggest to use Omnia sterile coolant liquid, whose destination of usage is registered as the cooling of surgical rotating instruments.

The sterile coolant liquid is conceived for the cooling of the surgical rotating instruments during implant surgeries or for oscillating instruments during piezoelectric surgeries. After the surgery, the sterile coolant liquid can be used to remove blood and tissue chips, to wash and irrigate the wounds. The sterile solution can be also used to wash heat sensible surgical instruments.

<b>32.E0000</b>	Sterile solution (sodium chloride 0,9%) for the cooling of rotating surgical instruments with connector for perforator in 1 litre bag (not subject to drugs regulations)	10 pcs
<b>32.E0001</b>	Sterile solution (sodium chloride 0,9%) for the cooling of rotating surgical instruments with connector for perforator and Luer Lock valve in 500 ml bag (not subject to drugs regulations)	15 pcs
<b>32.E0002</b>	Sterile solution (sodium chloride 0,9%) for the cooling of rotating surgical instruments with connector for perforator and Luer Lock valve in 250 ml bag (not subject to drugs regulations)	20 pcs



## Controls

Irrigation lines are disposable medical devices subject to 93/42/EC Directive and update 2007/47/EC and are classified in risk class IIa.

The sterilization process is validated according to EN ISO 11135-1:2007.

Irrigation lines are subject to controls and tests on the assembled product and afterwards on the final product. There are three different levels of defectiveness and related AQL (Acceptance Quality Limit), which state the limit of acceptable quality, foreseen in the provision UNI ISO 2859-1.

### **The test carried out during the production phase are the following:**

#### **1. Assembly stage**

1. Controls on critic defectiveness (for ex. Blocking up of the hose, damaged components, wrong gluing) with AQL equal to 0,25, carried out through blow test on 100% of the products. The test verifies the non obstruction of the line throw a blow of compressed air.
2. Primary defectiveness (for ex. Bend/constriction of the hose, traces of solvent) with AQL equal to 1,0
3. Secondary defectiveness (for ex. Not accurate moulding, spots or burns on the components) with AQL equal to 2,5
4. Watertight test carried out according to ISO 2859-1 charts with AQL 1, through a specific machinery, according to test specifications defined in the reference standard UNI EN ISO 8536 (test pressure not lower than 50kPa for 15 sec.)

#### **2. Packaging stage**

1. Critic defectiveness (for ex. Missing/incomplete data on the label, welding defects)
2. Primary defectiveness (for ex. Missing instructions of usage, wrong number of pieces) with AQL equal to 1,0
3. Secondary defectiveness (for ex. Damaged cartons, missing tacking tape) with AQL equal to 2,5

All the devices are tested at the end of the production in order to ensure their conformity to the technical specification stated and to the Essential Requirements defined by the Directive.

## Controls

### 3. Pre-sterilization stage

#### Analysis of the bacterial load (periodically arranged)

The analysis of the bacterial load defines the level of microbiological contamination before the sterilization and has to be in line with the parameters defined in the validation of the process of sterilisation with ETO method. References UNI EN ISO 11737-1

### 4. Post-sterilization stage

Flow test: destructive test carried out through the simulation of the functioning of the irrigation line calculating the water flow in a certain period of time (80ml/min ±10%).

### 5. Sterility and ETO residue

Sterility tests on the products are carried out at the end of the standard cycle in order to determine the efficiency of the process on a no. of established samples; ETO residue has to be complying with the European Farmacopea on devices at the end of the standard sterilisation cycle.

References UNI EN ISO 11737-2 and UNI EN ISO 10993-7



## Hose set for machinery driven irrigation system physiodispenser and piezoelectric surgery

### Legend

-  = single irrigation
-  = internal and external irrigation without Y joint
-  = internal and external irrigation with Y joint
-  = Tap for the connection of the second irrigation line to the second contrangle or for the connection of Omnidispenser

<b>32.F0100</b>	Tubing extension for mechanical irrigation systems		Suitable for all types of irrigation kits	10 pcs
<b>32.F0001</b>	Irrigation set	1/2Y	Suni Satelec 2000/3000, Suni Max, Surgi set basic; Surgi set pro 500, Dental Surgery Unit, Dental Unit DSC Electronic, Sweden&Martina XO Osseo, Sky unit Bredent	10 pcs
<b>32.F0006</b>	Irrigation set	1/2Y	W&H Elcomed 100/200, Astratech Elcomed 100	10 pcs
<b>32.F0016</b>	Tubing extension with Luer without piercing pin	1/2Y	W&H Elcomed 100/200, Astratech Elcomed 100	10 pcs
<b>32.F0056</b>	Extention with Luer valve and flow regulator, without perorator	1	W&H Elcomed 100/200, Astratech Elcomed 100, Hand Fuser (ref 30.E0008)	10 pcs
<b>32.F0008</b>	Irrigation set	1/2Y	ATR 3000 Plus, PhysioPlus , 3000 New , 3000 Krugg	10 pcs
<b>32.F0013</b>	Irrigation set	1/2Y	Nouvg 3000/Nouvg 7000/MD10, MD20 without tap/ Straumann model Nouvg/SM12 Sem2/SU100/CBM; Novaxa Assistant 2, Assitant I-XT, New Assistant	10 pcs
<b>32.F1023</b>	Export Irrigation set	1/2	Nouvg 3000/Nouvg 7000/MD10, MD20 without tap/ Straumann model Nouvg/SM12 Sem2/SU100/CBM; Novaxa Assistant 2, Assitant I-XT, New Assistant	10 pcs
<b>32.F0014</b>	Irrigation set	1/2Y	Nouvg Micro Dispenser 8000 with tap, MD10S, MD20 with tap	10 pcs
<b>32.F0015</b>	Irrigation set	1/2Y	Nouvg 3000/ Nouvg7000/ MD10, MD 11, MD20 without tap, MD30/ Straumann model Nouvg/ SM12 Sem2/ SU100/ CBM; Nouvg 8000 with tap, MD10S, MD20 with tap	10 pcs
<b>32.F0020</b>	Irrigation set	1/2Y	Miniuniko C, Miniuniko F Mariotti	10 pcs
<b>32.F0112</b>	Irrigation set	1/2Y	De Giorgi Steri Implant, INTRAMATIC 2	10 pcs

## Hose set for machinery driven irrigation system physiodispenser and piezoelectric surgery

<b>32.F0113</b>	Irrigation set	1/2Y	Kavo Intrasept 905 - Mectron Piezosurgery II, Piezosurgery 3, Piezosurgery Touch	10 pcs
<b>32.F0118</b>	Irrigation set	1	De Giorgi ULTRASURGERY	10 pcs
<b>32.F0122</b>	Irrigation set	1/2Y	Stryker Command Instruments, Oral Max System (dental)	10 pcs
<b>32.F0134</b>	Irrigation set	1/2Y	NSK Surgic XT, Surgic XT Plus, Osseocision®, VarioSurg, Kyocera Implantor Neo, Aseptico Aeu 6000 series, Aseptico Aeu 7000 series, Bonart Piezo surgical system, Dentium iCTmotor	10 pcs
<b>32.F0139</b>	Irrigation set	1/2Y	Nobel Biocare80/ W&H Implantmed/ Implant Med new design 2005/ Implantmed SI 923/ Astratech Implant SI 923/ Surgical Motor System/Ace/Strauman/InnovaCorp. 3I/Centerpulse/Lifecore/ DU 900/ FRIOS® UNIT S/ FRIOS® UNIT S/I, Drilltech/Osseoset 100/Osseoset 200/Osseocare	10 pcs
<b>32.F0141</b>	Irrigation set	1	Anthogyr 6842 V	10 pcs
<b>32.F0142</b>	Irrigation set with Luer without piercing	1	Anthogyr 6842 A	10 pcs
<b>32.F0147</b>	Irrigation set	1/2Y	Saeshin Traus SIP10, X-Cube	10 pcs
<b>32.F0148</b>	Irrigation set	1/2Y	Anthogyr Implanteo, Implanteo LED	10 pcs
<b>32.F0150</b>	Irrigation set	1/2Y	Miniuniko Piezo, Miniuniko CL Mariotti	10 pcs
<b>32.F0151</b>	Irrigation Set	1/2Y	Sympla Proimpla; Acteon I-endo Dual, HT implant, I-Surge, I-surge plus	10 pcs
<b>32.F0159</b>	Irrigation set	1/2Y	W&H Elcomed 200 SA, Innova Corp-Strauman, Frioss Unit E	10 pcs
<b>32.F0161</b>	Irrigation set	1/2Y	KAVo Intrasurg 300/500, Intrasurg 300 PLUS, Intrasurg 1000, Intrasurg 1000 Air, SONICflex bone	10 pcs
<b>32.F0170</b>	Irrigation set	1/2Y	Bien Air Chiropro 980 / EMS PIEZON® MASTER surgery/ Esacrom Surgisonic I / UBS-Ultrasonic bone surgery/ Surgybone - Acrobone - Easybone Silfradent,BioSAFin Easy Surgery, MyTUTOR, Heracle Sweden&Martina	10 pcs
<b>32.F0171</b>	Irrigation set	1/2Y	Bien Air Chiropro 980 / PIEZON® MASTER surgery/ Piezosurgery II / Surgisonic I / UBS- Ultrasonic bone surgery/ Surgybone - Acrobone - Easybone Silfradent	10 pcs
<b>32.F0188</b>	Irrigation set	1/2Y	Silfradent	10 pcs
<b>32.F0194</b>	Irrigation set with peristaltic pump	1/2Y	Acteon Implant centre, Piezotome; Dual 2000 De Godzen; Assitant Novaxa, Suni satelec Expert	10 pcs

All the marks mentioned are **Trademarks®** belonging to the respective manufacturers.  
Visit our web site [WWW.OMNIASPA.EU](http://WWW.OMNIASPA.EU) to be always updated on the last news about our irrigation lines



Disposable Medical Devices

Headquarter **Omnia S.p.A.**

Via F. Delnevo, 190sx  
43036 Fidenza (PR) - Italy  
tel +39 0524 527453 - fax +39 0524 525230  
[www.omniaspa.eu](http://www.omniaspa.eu) / [info@omniaspa.eu](mailto:info@omniaspa.eu)

Branch **Omnia LLC**

301 Pleasant strett  
17301 Abbottstown  
Pennsylvania - USA  
Toll free (888) 323-6873 Telephone (717) 259-1633

Partner **Omnia España S.L.**

Plaza Francesc Macià , 8 - 6°D  
08029 Barcelona - España  
tel +34 93 405 31 19 - fax +34 93 439 31 42  
[www.omniaspain.com](http://www.omniaspain.com) / [pedidos@omnia-spain.com](mailto:pedidos@omnia-spain.com)



Our complete production is realized by following 93/42 CEE NORMATIVES  
Ref. 90.L0077 - Rev 02/Marzo/2014