Euronda Alle®

EN

Guide to irrigation lines

Euronda Alle®

Your surgical field
Simply perfect

Alle® is a new line of disposable products designed specifically to create a sterile and uncontaminated surgical field for dental procedures, and to prevent the risk of infection. Alle® is a comprehensive line of products aimed at providing dental clinics with the high standards of protection required in operating rooms.

Alle® is a brand by Euronda S.p.a., one of the leading manufacturer of medical devices for infection control in dental practices. With Alle®, Euronda is making an important addition to its range, which perfectly reflects its mission: total protection for dentists, staff and patients.

Implant surgery and irrigation lines

When creating an implant site, managing temperatures is essential to ensure that the implant is osseointegrated correctly. Friction created by dental drills can cause temperatures to soar and inflict considerable damage. Exceeding 47°C for more than a minute risks thermal necrosis of the bone tissue.

Euronda Alle® has developed a range of high-quality disposable irrigation systems that guarantee maximum sterility and keep your surgical area cool. For maximum safety when operating and to achieve the very best results during implant surgery, Alle® irrigation lines optimise the transfer and management of coolant flow.

Compatible

Totally compatible with the main physiodispensers and implant drills on the market.

High quality

Thanks to robust plastic materials and high-quality parts - free from phthalates - and to scrupulous manufacturing processes.

Sterile

Individually packed in sterile blister packs with labels for maximum traceability: sterility guaranteed for 5 years from the manufacturing date.

10 excellent reasons to choose the Euronda Alle® irrigation lines

1. **Versatile**
   Ideal for internal single Irrigation, with the possibility of internal and external irrigation.

2. **Compatible**
   With the most common physiodispenser models and mechanised systems.

3. **Packaging**
   Packed individually in sterile blister packs.

4. **Traceable**
   Double adhesive label provided for maximum traceability.

5. **Guaranteed**
   Alle® products guarantee you all the reliability, functionality and quality of the Euronda brand.

6. **Sterile**
   Sterilised with ethylene oxide, following a scrupulous process compliant with the regulations in force regarding residue.

7. **Free from latex and phthalates**
   For complete respect for patients' health and the environment.

8. **Five-year validity**
   The sterility of the Euronda Alle® irrigation lines is valid for 60 months.

9. **Quality**
   The Alle® line offers the highest quality standards on the market, with no compromises.

10. **Complete**
    Equipped with an "open/close" perforator with cap, air filter and silicone tip to facilitate insertion.

Best practices and guidelines for implant surgery

It is recommended that you:

- Use disposable or sterilisable surgical drills, but for a limited number of operations.
- Use a double irrigation line with liquid flowing in and out at the same time via a Y-connector, with a coolant flow rate **between 800 ml/min and 1200 ml/min** to ensure that temperatures are properly controlled.
- Use a saline solution cooled to around **4° C**.
- Adjust your dental drill to **between 800 and 1200 RPM**, adjusting speed and manual pressure based on the type of bone being treated.

Bone being treated	Speed	Pressure
Dense and compact bone	High speed	High pressure
Spongy bone	Low speed	Low pressure

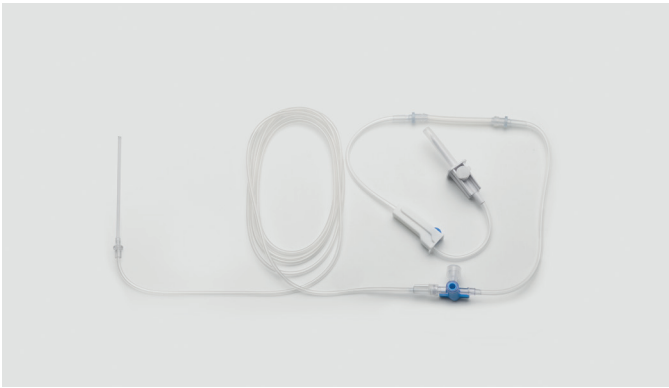
Mechanical irrigation lines

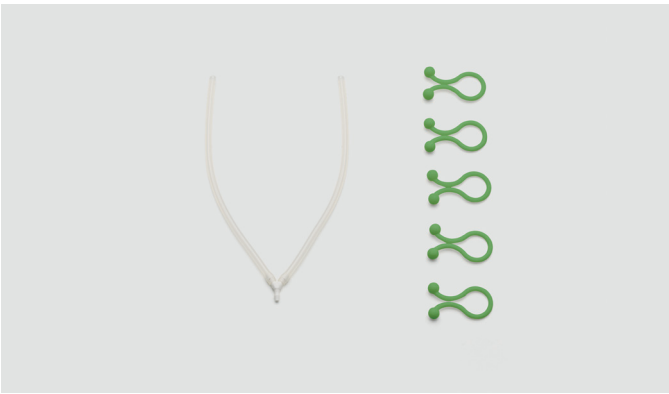
Alle® mechanical irrigation systems are designed to control coolant flow in the most effective way possible, keeping your dental drill and implant site at the right temperature.

Safe, versatile and practical, they are compatible with most physiodispensers and automatic systems.

Alle® mechanical irrigation systems are available in the following formats:

- Single internal irrigation
- Single external irrigation
- Double internal and external irrigation





Classification

MD class IIa

Material

Silicone, PVC, Phthalate-free ABS, Latex-free

Sterility

Sterility guaranteed for 5 years from the manufacturing date

Accessories

S-shaped pipe clamp to arrange connecting pipes and fix them in place

Y-connector to divide the flow in two and enable internal and external irrigation where necessary.

Details

Set of 10 units

Code	Type	Models*	Pieces
270601	**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	10
270602	**1/2Y**	W&H Elcomed 100 / 200, Astratech Elcomed 100	10
270604	**1**	Nouvag TCM3000 /MD8000 / MD7000 / MD10 / MD10S / MD11 / MD20 / MD30	10
270606	**1/2Y**	De Giorgi Steril Intraplant / Intrasurgery 2.0 / Intramatic 2 / Intramatic Plus	10
270607	**1/2Y**	Kavo Intrasept 905, Mectron Piezosurgery II / Piezosurgery 3 / Piezosurgery Touch	10
270609	**1/2Y**	NSK Surgic XT / Surgic XT Plus, Osseocision®, VarioSurg, Aseptico Aeu 6000-70V / 7000E-70V / 7000L-70V / 17Bv2 / 26OS / 707Av2, Bonart Piezo Surgical System	10
270610	**1/2Y T**	W&H Implantmed / Elcomed SA-310 / Piezomed, Nobel Biocare OsseoSet™	10
270613	**1/2Y**	Anthogyr Expert Unit Implanteo / Implanteo Led	10
270616	**1/2Y**	W&H Elcomed SA-200C, Frios Unit E for Dentsplay	10
270617	**1/2Y**	KaVo Intrasurg 300/500 / Intrasurg 300 PLUS / Intrasurg 1000 / Intrasurg / 1000 Air	10
270618	**1/2Y**	Bien Air Chiropro 980, BioSAFin Easy Surgery / MyTUTOR, EMS Piezon, Master Surgery®, Esacrom Surgysonic I / Surgysonic II / Surgysonic Moto	10
270621	**1**	Kavo MASTERsurg / EXPERTsurg	10
270622	**1**	Nouvag Physiodispenser 2000	10

Code	Models*	Pieces
270626	Extension line for irrigation set with luer lock connector	10

Legenda

1 - Single irrigation
1/2 -Internal and external irrigation without a Y-connector
1/2Y -Internal and external irrigation with a Y-connector
T - Tap to connect a second irrigation line to a second handpiece or to connect an irrigator

* All trademarks mentioned are registered and belong to the relevant manufacturers.

Components

Quality in every single element

ABS spike

Helps to perforate the saline bag port and is equipped with an air filter with “open/close” system to manage the flow of the liquid.

Roller clamp

Enables you to adjust flow or stop it all together in one easy move, so you can manage the flow rate of the liquid to meet your needs.

Silicone tip

Helps to connect the irrigation line with cooling needles present in the different wands available on the market.

Connecting tap

Present in certain models, this optimises the simultaneous connection of various pipes, preventing liquid and pressure loss.

Tube

Flexible and elastic, medical-grade PVC tube. Optimises connection and flow of coolant from bag to wand.

Section for peristaltic pump

The section of the tube going into the peristaltic pump is made from soft silicone for high liquid-flow accuracy, guaranteeing outstanding performance throughout surgical procedures. The length of the pump section varies based on the motor that the line is fitted to, making it adaptable to different pumps available on the market.

Details

ABS spike with “open/close” system

Roller clamp

Silicone tip

Connecting tap

Medical-grade silicone tube

Section for peristaltic pump

Manual irrigation line

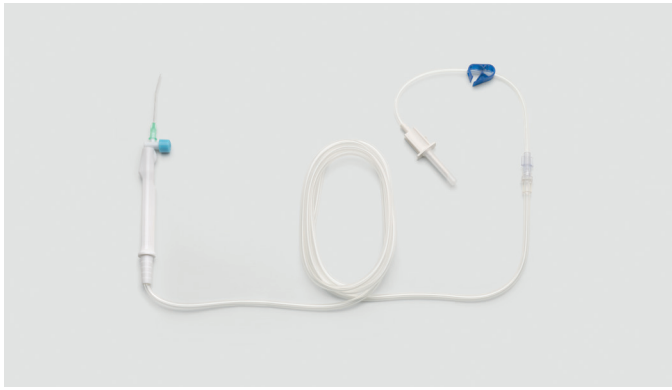
Alle® manual irrigation systems come with a button-based flow regulator that enables assistants to keep surgical fields clean and implant sites cool.

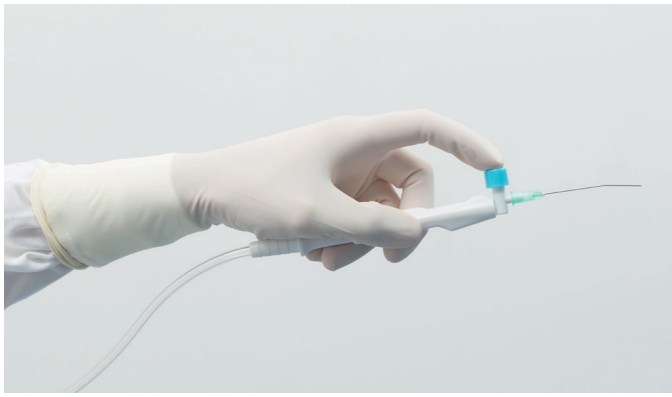
The system is also suitable for irrigation during the final fixation of implants using a torque wrench.

Classification
MD class IIa

Material
Transparent PVC

Sterility
Sterility guaranteed for 5 years from the manufacturing date





Code	Pieces
270630	5

Checks carried out on Alle® irrigation lines

The irrigation lines are class IIa medical devices that conform with Directive **93/42/EEC** and amendment **2007/47/CE.**

The irrigation lines are subject to inspections and tests. These are carried out on the assembled product and, subsequently, the final product. Our devices are biocompatible in line with **ISO 10993-1/4/7** standards. A medical device or material that comes in contact with a patient's body is expected to perform its intended function without resulting in any adverse effect to the patient. These may range from short-term (acute) to long-term (chronic) issues with adverse effects on the body. For this reason, medical devices are typically subject to biological evaluation and **biocompatibility testing** to assess the interaction between a device and the tissue, cells or bodily fluids of the patient.

The primary purpose of a device biocompatibility assessment is to protect the patient from potential biological risks.

The product has been tested for biocompatibility in accordance with **ISO 10993-1**.
This includes:

- In vitro hemocompatibility + hemolysis, in accordance with **EN ISO 10993–4**.
- Chemical toxicity, in accordance with **EN ISO 8536–4.**

Sterilisation

Ethylene oxide sterilisation in accordance with standards **EN ISO 11135** and **EN ISO 11138-1/2**

Traceability

Our medical devices are traceable, from the components and raw materials used. Coding and lotting systems, together with clearly specified manufacturing and expiry dates, enable us to trace medical devices from their origin to final destination.

Quality

There are three levels of defects and related **AQLs** (Acceptable Quality Limits) which establish acceptable quality limits, as provided for by standard **UNI ISO 2859-1.**

The following tests are carried out during the manufacturing phase:

1. **Assembly phase**

- Checks for critical defects (e.g. blocked tubes, damaged components, faulty bonding) with **AQL of 0.25**, performed by way of a blow test on 100% of the products. By forcing compressed air through the line, this test is carried out to ensure that there are no blockages.

- Checks for primary defects (e.g. bending/shrinking/narrowing of flexible tubes, traces of solvent) with **AQL of 1.0.**
- Checks for secondary defects (e.g. moulding errors, stains or burns on components) with **AQL of 2.5.**

2. **Packaging phase**

- Checks for critical defects (e.g. missing/incomplete information on labels, welding defects) with **AQL of 0.25.**
- Checks for primary defects (e.g. missing instructions, incorrect number of parts) with **AQL of 1.0.**
- Checks for secondary defects (e.g. damaged boxes, adhesive tape missing) with **AQL of 2.5.**

All devices are tested when manufacturing is complete to ensure that they comply with established technical specifications and essential requirements laid down by the Directive.

3. **Pre-sterilisation phase**

- Bacterial load analysis (arranged periodically - checked on a quarterly basis). Bacterial load analysis establishes the level of microbiological contamination prior to sterilisation, and must be in line with the parameters set out when validating the ETO sterilisation process.

Refer to **UNI EN ISO 11737-1.**

4. **Analytical checks**

- Tests for checking technological parameters and chemical-physical characteristics are carried out based on quarterly control plans, in accordance with standards **ISO 8536-4 and 8536-8**.

5. **Sterility, endotoxins and ETO residue**

- Sterility tests to ensure that the standard cycle is complied with are carried out quarterly to determine the efficiency of the process.
- The LAL test used to determine the level of bacterial endotoxins is carried out quarterly, with an acceptable limit of 5EU per device.
- ETO residue left on devices at the end of the standard sterilisation cycle is determined during the validation stage, and checked by way of sampling on a quarterly basis.

Refer to **UNI EN ISO 11737-2** and **UNI EN ISO 10993-7**.

Euronda S.p.a.
Via Chizzalunga, 1
36066 Sandrigo
Vicenza, Italy

t (+39) 0444 656111
f (+39) 0444 656199
m info@euronda.com
www.euronda.com

Euronda®