Miniassistant

INSTALLATION AND USE MANUAL

LUZZANI DENTAL

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MADE IN ITALY

CE
1370

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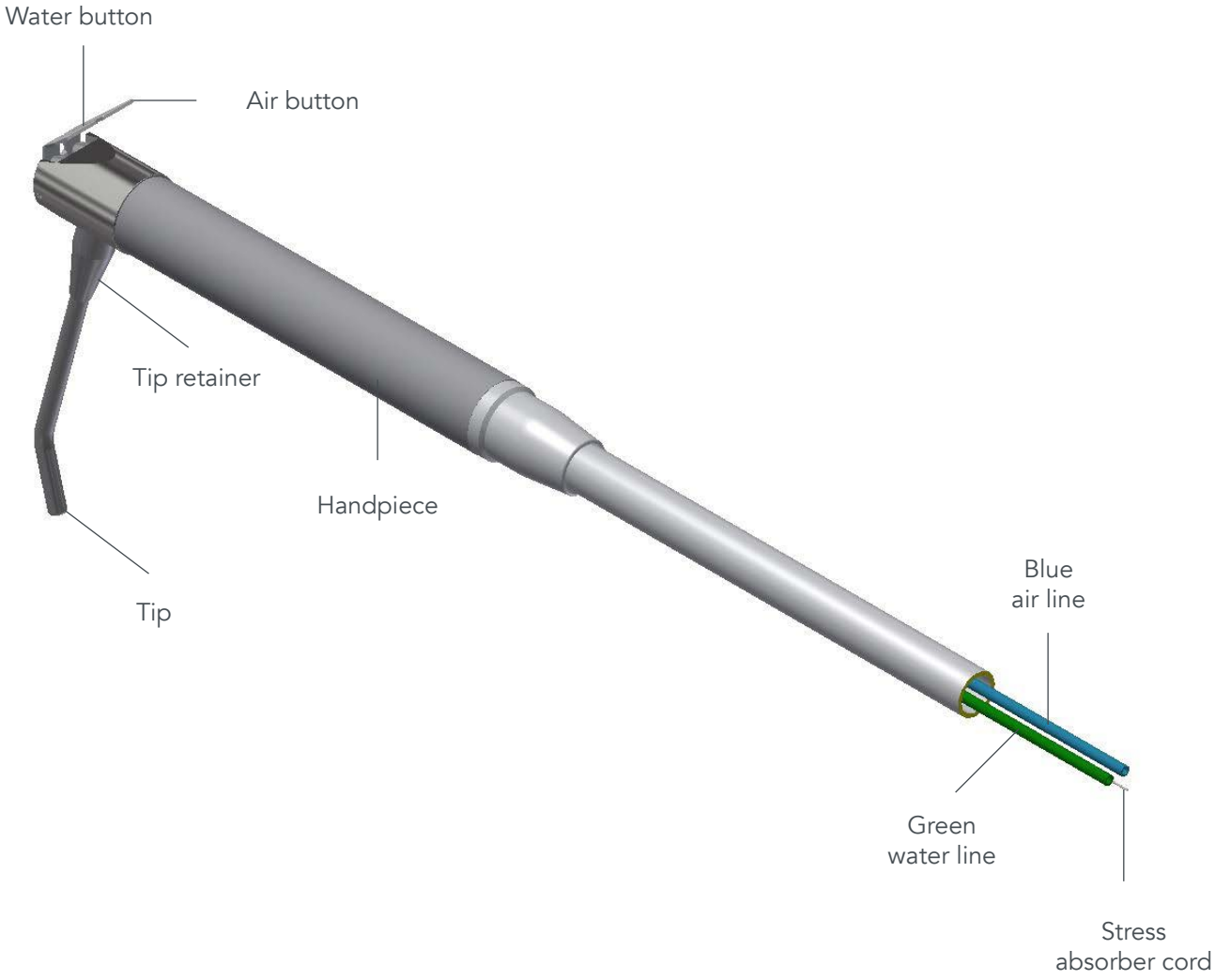
0 —— SYRINGE LEGEND



1 —— WARNINGS

1.1 — Any unauthorised tampering, modification or improper use immediately terminates the warranty and exonerates our company from all liability for injury or damage to persons, animals or property that may be caused by such interference.

1.2 — The stress absorber cord must be anchored to the dental unit. This cord is designed to absorb any strains, thus preventing abnormal traction on the electrical or air/water line connections.

1.3 — Before use, the water and air lines must be correctly connected.

1.4 — To meet the requirements of Directive 93/42/EEC, the company has established a post-marketing surveillance procedure to monitor any problems generated by the use of our products. The attached form allows you to report any faults and suggest improvements which will be considered for subsequent versions of the product.

1.5 — With each syringe, the package also includes a User's manual which also includes a "Fault Report Form". Since this is required by law, the user must receive this User's manual. Therefore, the syringe installer is responsible for delivering this User's manual to the dentist. Directive 93/42/EEC requires product traceability: therefore, our customers are asked to ensure that, in case of emergency, we can identify the end customer to whom the product has been sold.

1.6 — Manufacturers and/or installers of dental units are required to comply with all the prescriptions outlined in this document.

1.7 — Use the Miniassistant syringe only for the applications described in the instructions for use.

1.8 — This product must only be installed by qualified persons.

1.9 — Never modify the syringe in any way. This is strictly forbidden.

1.10 — Use only original parts produced or approved by the manufacturer. If non-OEM accessories or consumables are used, the company cannot guarantee safe operation and function. No claims can be made for damages resulting from improper use.

1.11 — Do not perform any maintenance procedures not indicated in the manual.

1.12 — Before using the syringe, make certain that the water and air supplies have been activated.

1.13 — National regulations regarding dental unit water and air quality must be met.

1.14 — The air used must be dry, clean and free of oil.

1.15 — The Miniassistant syringe meets the requirements laid out in European Council Directive 93/42/EEC: Class II A.

2 —— PRODUCT DESCRIPTION

2.1 — GENERAL

The Miniassistant syringe is a medical device designed to blow air and water (separately or together, at room temperature) to clean and/or dry the oral cavity during any dental procedure.

It has been designed for use in dentist offices and dental clinics and is built into dental units used exclusively by dentists.

Product life — under proper maintenance conditions — is 5 years.

2.2 — GENERAL CHARACTERISTICS

- The Miniassistant syringe is a medical device for dental use (class II a).
- The Miniassistant syringe has been designed using the latest ergonomic concepts for easy use and immediate cleaning and sterilisation. The tip can easily be removed for perfect autoclave disinfection and sterilisation at 134°C (see point 8).

To guarantee maximum hygiene and atoxicity, the handpieces are made of stainless steel. The devices are produced entirely in our workshop, with a tested, constantly updated work cycle using the most sophisticated machinery compliant with current quality system directives (UNI EN ISO 13485 certified).

2.3 — CONTROLS

Every syringe and all of its parts undergo duly documented, 100% complete functional and safety testing to ensure that the technical and functional design requirements are fully met.

2.4 — MARCATURA CE

All products bear CE marking both on syringe handpiece and inside. (batch number, autoclave symbol, Luzzani Dental logo, product name, CE marking with Notified Body number). The User's manual supplied with the product also includes details of our company, the main product characteristics and instructions for correct use and maintenance.

3 —— IDENTIFICATION DATA AND WARRANTY

3.1 — MANUFACTURING BATCH

A number, marked on the inside of each product, identifies the production batch; the number is printed on the central body of the syringe. This number uniquely identifies the production batch thus always guaranteeing traceability of the product and each of its components, with relative test sheets.

3.2 — WARRANTY

The product is guaranteed by our company for 12 months from the date of the delivery document. The warranty covers any device manufacturing defects (materials) and is limited solely to the replacement of defective parts, performed in our workshop. The product must be sent to our premises at the expense of the customer. For the warranty to be valid, the product must be returned intact, complete and showing with no signs of tampering.

The syringe has no functional expiration date; its expected life span is 5 years.

4 —— PACKAGING

The product is shipped in suitable packaging to prevent problems during transport. The packaging consists of a plastic bag containing the Miniassistant syringe. For added security, the syringe is inserted into a second plastic bag. The bag holds the handle, cock and tip. Several bags are placed in one box. The Miniassistant syringe comes ready for connection to the dental unit once all packaging has been removed.

⚠ IMPORTANT NOTE:

With each syringe, the package also includes a User's manual which also includes a "Fault Report Form". Since this is required by law, the user must receive this User's manual. Therefore, the syringe installer is responsible for delivering these forms to the dentist. Directive 93/42/EEC requires product traceability: therefore, our customers are asked to ensure that we can identify the end customer to whom the product has been sold.

5 —— TECHNICAL CHARACTERISTICS

Water supply pressure	Kpa	250
Max. air supply pressure	Kpa	450
Water flow rate	Cc/min	110
Air flow rate	Nl/min	10

5.1 — OPERATING CONDITIONS

Ambient temperature	10°C / +45°C
Relative air humidity	30% / 85%
Atmospheric pressure	80 Kpa - 106 Kpa

5.2 — TRANSPORT AND STORAGE CONDITIONS

Temperature	-20°C / +60°C
Relative Humidity	30% / 85%
Atmospheric Pressure	80 Kpa - 106 Kpa

6 —— INSTALLATION AND CONNECTIONS

6.1 — CONNECTION TO HYDRAULIC SYSTEM

The syringe's green line must be hooked up to the water supply.

⚠ NOTE

- The water used must be potable water, filtered (<25 µm) and free of bacteria, etc.
- For the syringe to function properly, the water pressure must not be lower than indicated.

6.2 — CONNECTION TO COMPRESSED AIR SYSTEM

The syringe's blue line must be connected to the compressed air system.

⚠ NOTE

- The recommended operating pressure is around 450 kPa.

- When using the Miniassistant syringe, national regulations regarding water and air quality must also be met.
- The air must be medical grade, dry and free of oil and bacteria – a 5µm air filter is recommended.

6.3 — CONNECTION OF STRESS ABSORBER CORD

The stress absorber cord must be anchored to the dental unit. This cord is designed to absorb any strains, thus preventing abnormal traction on the electrical or air/water line connections. The manufacturer cannot be held liable for malfunctions caused by failure to anchor the stress absorber cord.

6.4 — NOTES FOR CORRECT CONNECTION

⚠
- Before carrying out functional tests, the water and air lines must be correctly connected.
- The lines must be connected carefully.

7 —— NORMAL USE

7.1 — INSUFFLATION OF COLD WATER

To blow cold water into the operating field, just press the left button on the handpiece:

7.2 — INSUFFLATION OF COLD AIR

To insufflate cold air into the operating field, just press the right button on the handpiece:

7.3 — COMBINED INSUFFLATION OF COLD WATER AND AIR (SPRAY)

To blow a combination of cold air and water (spray), press both buttons on the handpiece at the same time:

WARNING

Do not use the tip improperly. Remove and sterilise the tip after each patient.

IMPORTANT

Air and water must be able to flow freely from the tip. Do not rest the tip on the tooth or on an object. Do not press the tip against impression materials as they could cause obstruction.

7.4 — FIRST TIME USE AND USE AFTER LONG INTERVALS

⚠
- Sterilise the tip before use.
- After prolonged periods of inactivity, clean, treat and sterilise the handpiece.

⚠ BEFORE EACH PATIENT

1. Make certain the handpiece has been sterilised.
2. Adjust the supply of fluids from the dental unit (see table in point 5).
3. Press the air button and make certain that there is a clearly perceptible jet of air.
4. Check the water flow rate.
5. Use only filtered water that is free of oil and microorganisms.
6. Check the tip for any obstructions or deposits. Clean if necessary.

NOTE

- Flush out the syringe at the beginning of each work day (minimum flushing time: 2 minutes) and before each patient (minimum flushing time: 20-30 sec.).
- Immediately upstream of the syringe, install filters able to retain the microorganisms coming from the hydro-pneumatic circuit.

8 —— CLEANING AND STERILIZATION

⚠ After each use on a patient, the syringe handpiece and tip MUST be cleaned and sterilised to guarantee maximum hygiene.

To do this, proceed as follows:

Disconnect the tip by unscrewing the tip retainer

1. unscrew the tip retainer
2. withdraw the tip

Wipe with a damp cloth, removing any stains.
Set in a steam autoclave at 134°C for AT LEAST 3 minutes (in compliance with CEI EN 13060).

A — WARNINGS

- The syringe should always be sterilised, even before using it for the first time.
- Inappropriate sterilisation is hazardous for the patient and for the operators.
- Do not perform spray disinfection.
- Do not immerse in disinfectant liquids.
- Do not perform cold or hot air chemical sterilisation.
- The personnel performing the task must be skilled and specially trained.
- Use disinfectant according to the specifications on the manufacturer label.
- Do not use chlorine-based liquids.
- When simultaneously sterilising more than one item in an autoclave, check that the load does not exceed the maximum allowed.

B — PREPARATION

Eliminate surface dirt using a disposable paper towel. Clean the inside of the lines by running air and water through the syringe for about 30 seconds. Remove the stainless-steel handpiece by pressing the button on its terminal section. Unscrew the tip retainer and remove the tip.

C — MANUAL CLEANING

Use a disposable paper towel and potable water to remove any impurities or dirt that may be present.

D — AUTOMATIC CLEANING

Not envisaged

E — MANUAL DISINFECTION

Disinfect only with a disposable cloth and the permitted disinfectant (following the instructions on the label and product technical data sheet).

Recommended disinfectants:

- Incidin liquid
- FD 322 Durr
- Mikrozid AF liquid

F — AUTOMATIC DISINFECTION

Not envisaged

G — MANUAL DRYING

Dry with disposable paper towelling. Dry with clean, dry, uncontaminated compressed air, inside and out, continuing until completely dry. Do not dry with hot air.

H — AUTOMATIC DRYING

Not envisaged

I — MAINTENANCE AND CONTROL

No special maintenance is necessary.

L — CONFEZIONAMENTO

Use heat sealable film-paper sterilisation pouches of appropriate size.

M - STERILISATION

The tip can be sterilised.

Sterilise in a class B steam autoclave in compliance with EN 13060 ISO 17665-1. 3-phase sterilisation with fractional vacuum system at 134°C +/- 1°C at a pressure of 2.13 bar, applying a 4-minute delay. Never exceed 134°C. The autoclave must be validated.

N — STORAGE

No particular requirements apart from storage in the sealed, sterilised pouches. Store in a suitable place that is dry, out of direct sunlight and possibly with low bioburden.

9 —— MAINTENANCE

The instrument requires no specific maintenance apart from normal cleaning and sterilisation as described in the previous paragraph.

10 —— DISPOSAL AND SCRAPPING

The product does not contain dangerous or toxic-hazardous components. Separate waste collection is required. Follow the regulations in force in your country.

11 —— INFORMATION FOR THE DENTIST

⚠ The dental unit manufacturer is required to deliver the Luzzani Dental syringe User's manual to the end user.

12 —— FAULT REPORT FORM

To meet the requirements of Directive 93/42/CEE as amended, the company has established a post-marketing surveillance procedure to monitor any problems generated by the use of our products. This commitment includes the requirement that both user and manufacturer inform the competent authorities of any incident caused to patient or user by malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use. We kindly ask you to inform us of any anomalies by sending us the sheet attached to the last page of this manual.

13 —— SYMBOLS

SYMBOLS

 Do not overturn

 Fragile

 Keep dry

 General warnings

 Separate collection for electrical and electronic equipment

 Manufacturer

Batch number

Sterilise

 Consult User's manual

INSTRUCTIONS FOR CLEANING AND STERILIZATION OF MINILIGHT, MINIMATE, MINIBRIGHT SYRINGES IN ACCORDANCE WITH UNI EN ISO 17665 REQUIREMENTS

Warning 	• Sterilization must be performed even when using the syringe for the first time. • Inappropriate sterilization is dangerous for patients and operators. • Do not perform spray sterilization. Do not place in any disinfectant liquids. • Do not perform cold chemical or hot air sterilization. • The appointed staff must be specialized and trained. • Use the disinfectant in accordance with the specifications set by the manufacturer indicated on the label. • Do not use chlorine-based solutions. • When sterilizing more than one piece in one autoclave do not exceed its maximum load capacity.
Preparation	Remove dirt from the surface using a disposable paper tissue. Let air and water flow from the syringe for about 30 seconds in order to clean the internal channels. Press the button locateci at the bottom of the sleeve and slide the stainless steel sleeve off the syringe body. Unscrew the ferrule and remove the tip.
Manual cleansing	Wipe with a disposable paper tissue and with the aid of drinking water to remove any impurities and dirt
Automatic cleansing 	Not available
Manual disinfection	Perform disinfection only with a disposable tissue and with compatible disinfectants (in accordance with the instructions included in the product label and technical data sheet). Recommended disinfectants: • Incidin liquid • FD 322 Durr • Mikrozid AF Liquid
Automatic disinfection 	Not available
Manual drying	Dry with disposable paper tissue. Dry with dry, clean and uncontaminated compressed air both internally and externally until completely dry. Do not dry with hot air.
Automatic drying	Not available
Maintenance and checking	No particular maintenance is required. There is no objective term limiting the usage life of the sleeve: check to see if there are if any damages or signs of wear and tear, replace the part if necessary.
Packaging	Use appropriately sized sterilization packages made of thermoweldable film.
Sterilization 	The sleeve and tip are autoclavable. Sterilize using EN 13060 ISO 17665-1 compliant class-B steam autoclave. Sterilize with 3 phases fractionated vacuum 134° C +/- 1 °C with 2.13 bar pressure, 4 minutes wait. Never exceed 135° C. The autoclave must be validated.
Preservation	No particular requirements other than keeping them in their sealed and sterilized package. Keep them in an appropriate environment and out of direct sunlight and in a dry place, which should have low bioburden where possible.

FAULT REPORT FORM

PRODUCT _____

TYPE _____ BATCH _____

REPORTED BY _____

COMPANY _____

_____

_____

TYPE OF REPORT

☐ ANOMALY ☐ SUGGESTIONS ☐ _____

DESCRIPTION

_____

_____

_____

_____

_____

NOTES

_____

_____

_____

_____

_____

DATE _____ SIGNATURE _____

SEND TO:

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