USE AND MAINTENANCE MANUAL
Dental instrument kit:
LO RUSSO RETRACTORS

REF **141000** REF **141001** REF **141002**
REF **141003** REF **141004** REF **141005** REF **141006**

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LO RUSSO RETRACTORS

MANUFACTURER

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EN

AUTHORIZED ASSISTANCE

Assistance on medical devices can be performed only and exclusively by authorized and qualified personnel of the company ELDO Srl

PRESENTATION OF THE MANUAL

This manual contains the instructions for using the LO RUSSO RETRACTORS dental instrument kit. It contains information on the technical life of the medical device after its production and sale, and is intended for those who use the medical device or are in charge of its conservation.
This manual contains proprietary information and cannot be provided to third parties, even partially, for any use and in any form, without the manufacturer's prior written consent.
ELDO Srl declares that the information contained in this manual is congruent with the technical and safety specifications of the medical device to which the manual refers. A copy of this manual is contained in the technical file of the device, kept at ELDO Srl.
ELDO Srl does not recognize any documentation that has not been produced, issued or distributed by ELDO Srl or by its authorized representative. This manual, and the entire technical file, will be kept by the manufacturer for the period required by law. During this period, a copy of the documentation accompanying the product may be requested at the time of sale. The entire technical file remains available for this period exclusively for the control authorities, who may request a copy. After this period, it will be the responsibility and obligation of those who manage the product to ensure that both the product and the documentation comply with the laws in force, in order to be able to use it in compliance with the provisions of current legislation.

SYMBOLOGY

MD	Medical device	UDI	Unique device identification		Manufacturer		Read the manual before each use
LOT	Lot number	CE	CE mark		Manufacturing date		Protect from atmospheric agents
REF	Medical device reference		Do not dispose of in the environment		Expiration date		Protect from direct sunlight

WARRANTY

The warranty rules are listed in full in the purchase contract; they are valid only if the medical device is used under the conditions of intended use. Any repair or modification made to the device by the user or by unauthorized companies will invalidate the warranty. The warranty does not extend to damage caused by inexperience or negligence in the use of the device. The warranty that covers our devices includes the following conditions:
1. The warranty is valid for twelve or twenty-four months depending on the legal status of the purchaser.
2. The manufacturer undertakes to replace incorrectly manufactured products at its own discretion, only after careful control and verification of poor construction.
3. In case of incorrect use of the warranty terms, the transport and shipping costs are always at the buyer's expense.
4. Medical devices replaced during the warranty period become the property of the manufacturer.

5. Only the original purchaser can benefit from this warranty if the instructions for normal use contained in the manual have been followed. The manufacturer's liability and warranty expire when the original owner gives the device to others, when changes are made to the device, or when the instructions for normal use are not followed.
6. The warranty does not include damage deriving from: excessive stress (for example, using the device after ascertaining an anomaly); use of unsuitable operating methods; failure to observe the instructions for use.
7. The manufacturer assumes no responsibility for any difficulties in reselling or using the device abroad due to the provisions in force in the country where the medical device was sold.
Notice: if it is deemed necessary to use the warranty, please indicate the following data: 1. Type of medical device; 2. Date of purchase (attach the purchase document); 3. Detailed description of the problem.

DESCRIPTION OF THE MEDICAL DEVICE

Kit consisting of three instruments; the shape of each instrument is optimized to facilitate their adaptation to the anatomy of the alveolar-dental arches and facilitate their function of retraction and stabilization of the surrounding tissues. The kit includes one instrument for the upper arch and two instruments for the lower arch (one for the right side and one for the left side).
Each instrument has a handle with rounded edges and two grooves. Two arms are applied to the end of the handle. In the instruments for the lower arch, a lateral arm and an anterior arm are distinguished. The lateral arm faces outwards and serves to spread the cheek and lip. The front arm faces forward, as if it were the extension of the handle, and serves to hold and control the tongue. The scanner tip can also be placed and slid along the instrument arms. In the upper jaw instrument, the two arms face outward, to the right and left respectively, and serve to spread the cheeks and lip and to support the scanner tip.
The kit is sold in three different sizes: size 0 (the smallest size), size 1, size 2 (the largest size). The size is the only difference; their shape, their intended use and the instructions for use are identical. The tools that make up the kit cannot be sold individually, except to replace damaged or worn components of the kit. The color of the tools may differ. This is to facilitate the identification of the different sizes or provide a choice for the user. On the handle of the instruments there is a logo that identifies the manufacturer's brand. On the side opposite the logo, there are small raised indications regarding the size of the instrument (no indication: size 0; one indication: size 1; two indications: size 2).
The product is a class I invasive medical device. It does not contain latex and can be used after sterilization, which is necessary for the first use, and for each subsequent use.

TECHNICAL DATA

Material: Polyphenylsulfone-based blend in a concentration of between 91% and 99%.
The medical device is available in three different sizes. Codes and details of the sizes are shown below:

Code	141000	141001	141002
Description	Size 0	Size 1	Size 2

Reference codes 141003, 141004, 141005, 141006 are packaging variants including, in a bundle, two or three of the above detailed sizes. In particular:

Bundle Code	141003	141004	141005	141006
Sizes included in the bundle	Size 1 + Size 2	Size 0 + Size 1	Size 0 + Size 2	Size 0 + Size 1 + Size 2

STORAGE

After purchase and until its first use, the medical device must be stored with care, if possible, inside the original packaging or one similar in size and characteristics. Before being used, the device must be sterilized. After sterilization, follow the “Storage” instructions provided in this manual in the “Cleaning, Sterilization and Maintenance” paragraph. Always respect the following general storage rules for the medical device:
- Store indoors, at a temperature between 5 ° C and 40 ° C.
- Keep away from atmospheric agents, steam jets and any material or substance capable of altering the characteristics of the device.
- Keep away from sources of heat, naked flames and direct sunlight.

HANDLING

The kit has a weight and size such as to enable its manual handling. During handling, avoid dropping or knocking. This can damage it irreversibly.

FIELD OF APPLICATION AND INTENDED USE

The kit has been designed and manufactured exclusively for professional use during dental activities. The tools that make up the kit are used to spread and stabilize the tissues (lips, tongue and cheeks) of the patient during the intraoral scan of the alveolar-dental arches. The tools can also provide support for the scanner tip.

The use of the tool kit is indicated in various odontostomatological situations. In particular, these include: the removable or fixed dental prosthesis; orthodontics; identifying the anatomy of the patient's alveolar-dental arches for clinical, anthropometric or identification purposes; intraoral scanning when the presence of involuntary movements of the mouth muscles, or poor cooperation of the patient, prevent an effective use of the intraoral scanner. The product is intended for use by:

- health personnel of the dental sector, qualified to practice dentistry and related activities;
- specialized healthcare professionals in the dental sector, qualified to practice dentistry and related activities, in private hospitals and clinics.

Unintended use

No use other than those described in the paragraph "Field of application and intended use" is envisaged. Furthermore, the following are absolutely forbidden:

- The use of the medical device by persons not authorized to practice dentistry.
- The use of the medical device by persons who have not read this manual carefully.
- The use by children, individuals with limited abilities and individuals impaired by alcohol and/or drugs.
- Use by people allergic to the material of which the medical device is made.

Limitations of the medical device

- LO RUSSO RETRACTORS do not cure any disease: they are simply instruments for dental professionals.
- The medical device can be reused, but it must be sterilized (see paragraph “Cleaning, sterilization and maintenance”) before each use.

RESIDUAL RISKS

It is absolutely forbidden to make any changes to the medical device. Any damage resulting from the use of the device, improperly modified, relieves ELDO Srl of any responsibility.Keep this manual carefully, as it is necessary for the correct and safe use of the medical device.

If the structure of the device shows deformations or damages following an accidental impact, falls, rubbing against other materials, avoid using the device. Contact the authorized assistance service and follow the instructions received.

Contraindications

In the following situations, the use of the device is contraindicated:

- Do not use in patients who are hypersensitive and/or allergic to the material of which the medical device is made.
- Do not use on injured mucosa or in the presence of alterations or lesions of the oral mucosa.

Side effects

There are no side effects to report in this manual except for those that may derive from the use of the product in subjects hypersensitive or allergic to the materials of the device. The medical device is made of hypoallergenic and non-toxic material. If it should create irritation, check for any intolerances to the materials. If there is redness of the skin, mucous membranes or other lesions, discontinue use and consult your doctor.

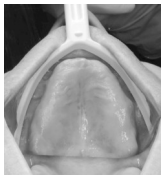
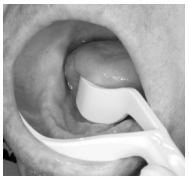
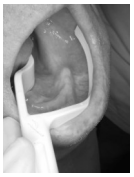
USE

Before use

- Inspect the medical device for any defects, cracks, imperfections, missing parts, and changes in shape or color.
- Sterilize the medical device following the instructions given in the “Cleaning, sterilization and maintenance” paragraph.

Usage

- Inspect the patient's mouth; make sure there are no mucous lesions. Before using the device, take out removable dentures, other removable equipment or any other obstacles in the patient's mouth.
- Carefully select the size of the device to be used, based on the size of the patient's alveolar-dental arches. Using a tool that is too large could create compression or provoke tissue injury.
- Hold the instrument by the handle. To ensure the correct orientation of the instruments, the logo engraved on the handle must be facing the operator.
- Insert the instrument into the mouth slowly and carefully, making a small rotating movement of the arms of the instrument, similar to how you would do with an impression tray. Do not flex the arms of the instruments during insertion into the mouth: the springback could cause injury to the patient. Once inserted in the oral cavity, the instrument must be placed in position. For the upper arch the two arms must be housed in the vestibule; for the lower arch, the anterior arm must be lateral to the tongue, while the lateral arm must be in the vestibule. Please note that for the lower arch, there are two instruments: one for the right side and one for the left side, which must be used correctly (see figures). Once it has been placed in position, the instrument must be held firmly, without letting go and without using excessive pressure.
- Once the instrument has been used, it must be removed carefully, with a reverse movement to that of insertion.
- Start the medical device used for the cleaning and sterilization procedure.

					
Upper arch tool	Lower jaw instrument, right side of the patient	Lower jaw instrument, left side of the patient	Upper arch tool in place	Lower jaw instrument, right side of the patient, in place	Lower jaw instrument, patient's left side, in place

Warnings

- Handle with care, respecting the correct positions and orientation of the different instruments of the kit. The arms of the instruments, if improperly oriented, or used carelessly, could cause trauma or injury to the patient's tissues.
- Do not exert improper pressure on the arms of the instruments: they could be damaged or broken.
- Do not try to bend or modify the shape and size of the instruments through the use of pressure, thermal or chemical agents. The resistance and safety of the instruments would be irreversibly damaged.
- The instruments inserted in the patient's mouth must be correctly and firmly held by the operator using the handle. Instruments left loose in the patient's mouth, or not properly held, could move and cause harm, trauma or injury to the patient.
- Instruments should not be placed between the teeth, nor should the patient squeeze or chew on them. The patient's teeth or tissues could be damaged or traumatized, and the instruments could be irreversibly damaged.

CLEANING, STERILIZATION AND MAINTENANCE

Attention! The product must be cleaned, disinfected and sterilized before each use (including first use after purchase) according to these instructions, in accordance with EN ISO 17664: 2017. Disinfection alone is not enough. Thorough cleaning and disinfection are the prerequisites for effective sterilization. The cleaning and sterilization procedure should be started as quickly as possible, at the latest one hour after use. Avoid exposing the product to unnecessary liquids. In addition, you must comply with the legal provisions in force in your country as well as the hygiene provisions of the dental practice or hospital. Frequently repeated sterilization has little effect on this device. The end of the useful life of the device is mainly determined by wear and tear resulting from use. When in doubt, devices should always be replaced - better sooner than later. The decision to reuse the device is the sole responsibility of the operator. In the case of too frequent use, the manufacturer assumes no responsibility for the function, performance and safety of the device.

For reasons of workplace safety, and to minimize cross-contamination/infections, suitable personal protective equipment (protective clothing, protective gloves, goggles and mask) must be used during the entire cleaning, disinfection and sterilization procedure.

First treatment after use: Immediately after using the device, remove the surface dirt with a disposable tissue or a sheet of paper. Rinse the device with running water within one hour to prevent residues or impurities of any kind from drying on the device. In this first step, do not use substances containing aldehyde or alcohol, as these can lead to protein fixation.
Preparation for sterilization: Keep the individual instruments that make up the device separate. Visually inspect for wear and tear each instrument.
Cleaning and Disinfection: Make sure that the detergent and disinfectant used are compatible with each other and with the device. The pH value of detergents and disinfectants should be between 5.5 and 8.5. Do not use organic solvents (e.g. alcohols, ether, ketone, gasoline), oxidants (e.g. peroxide), halogens (chlorine, iodine, bromine) or aromatic / halogenated hydrocarbons in any of the cleaning and disinfection steps. Cleaning and disinfection can be performed either with a suitable machine or with a manual procedure.
Using a washer-disinfector
Only equipment authorized for cleaning and disinfection, which is clean, tested, calibrated and compliant with the applicable regulations (EN ISO 15883) can be used. Pay attention to the fact that when cleaning and disinfecting multiple instruments in a special machine, the cleaning equipment is not too full and that the instruments are not in contact with each other. It is necessary to carry out the cleaning and disinfection cycle according to the instructions of the manufacturer of the equipment and of the manufacturer of the detergent/disinfectant. Dr Weigert neodisher MA/Dr Weigert neodisher Z could be used. Respect the instructions for use of the equipment manufacturer and the manufacturer of the detergent/disinfectant, especially with regard to times of action, concentration and temperature.
Pre-cleaning should take place in a water bath, preferably without additional detergent additives, with a non-metallic cleaning brush. The duration should depend on the amount of dirt present, and in any case not be less than 1 minute. Then insert the instruments into the washer-disinfector according to the manufacturer's instructions. Indications for cleaning and disinfection of equipment: Type: Miele G7881; Cleaning temperature: 50.1 - 56.1 °C, Duration: 10:32 min; Disinfection temperature: 65.2 - 94.3 ° C, Duration: 09:55 min; Cleaning technique: clean water / demineralised water system.
Manual procedure
use only authorized disinfectants with proven effectiveness. Remove surface impurities with a disposable tissue; brush the device with a non-metallic cleaning brush for at least 1 minute in a water bath (temperature not exceeding 40 ° C) containing a detergent (ID213 by Durr Dental, at a concentration of 2%). Rinse for 20 s with water and dry at room temperature. Immerse the device in the disinfectant bath; pay attention that the instruments are sufficiently covered and are not in contact with each other. Strictly follow the instructions for use of the disinfectant manufacturer, especially with regard to concentrations, times of action and any temperature indications. We recommend the use of: ID213 from Durr Dental, at a concentration of 2%, for a time of action of 5 min. Rinse for 20 s with water and dry at room temperature.
Where impurities are still visible after the cleaning and disinfection process (either by machine or by hand), cleaning and disinfection must be repeated. The medical device must be free of any residue and dry before continuing with sterilization.
Drying: Once manual cleaning and disinfection has taken place, the instruments can be dried with a blow of filtered, oil-free compressed air, according to DIN ISO 8573-1 (purity class for medical use), or at room temperature. If a washer-disinfector is used, drying should be done with hot air, directly through this equipment.
Packaging: The device must be packaged and sealed in a transparent sterile package (sterilization bag) suitable and compliant with the standards. Follow the manufacturer's instructions for the sterilization pouches and sealing machines and the applicable regulatory requirements.
Sterilization: The recommended sterilization method is based on the use of vacuum steam autoclaves. Pay attention when sterilizing several instruments that the autoclave is not too full and that the instruments do not come into contact with each other. The following sterilization cycles can be carried out: saturated steam sterilization, 121 ° C, duration of 20 minutes; or saturated steam sterilization, 134 ° C, duration of 5 minutes. Use the autoclave drying cycle for instrument drying. Follow the instructions for use of the autoclave manufacturer. The operator must make sure within the quality management system that the sterilization cycle has not been passed.
Alternatively, the material of which the instruments are made also tolerate sterilization by other physical or chemical means. However, these are not recommended as they could quickly degrade the properties of the instruments.
Storage: To preserve sterility, instruments must be stored until use in standard-compliant sterilization

pouches in a clean, dry place. In case of damaged sterile packages, instruments must be re-sterilized before use. Mark the sterilized products in accordance with legal and national requirements. The recommended storage time for sterile medical devices is described in DIN 58953-8. The unwrapped sterilized device must be used immediately.
The above instructions have been validated as suitable for preparing a medical device for its reuse. The person in charge of carrying out the process is responsible for obtaining the desired sterilization and check for appropriate equipment, materials, personnel, and results. In order to ensure this is done, routine checks and/or validations and monitoring of the procedure are necessary.
Maintenance, checks, inspection: The medical device does not have any particular maintenance requirements. A visual inspection must always be carried out for impurities, damage, wear and deformation before and after the individual work steps. Damaged or worn devices must not be reused. If in doubt, do not use the device. All serious accidents occurring in connection with the device must be reported immediately to the manufacturer and the competent authorities of your country.
Extraordinary maintenance: Extraordinary maintenance is required in case of breakages, unforeseeable accidents or due to inappropriate use of the medical device. The situations that may arise from time to time are completely unpredictable and therefore it is not possible to describe appropriate intervention procedures. If necessary, consult the ELDO Srl technical service to receive the appropriate instructions for the situation.

DISPOSAL

The possibility of reusing the medical device is subject to the total responsibility of the user. Before discarding the device, it should be sterilized. The construction material of the device does not require special disposal procedures. However, it is necessary to refer to the local regulations for waste disposal. Therefore, at the end of the useful life of the device, ask your competent disposal facility for instructions that comply with the regulations currently in force in your region. Dispose of the packaging in the separate collection for cardboard/plastic. Do not dispose of or abandon the device or its packaging in the environment for any reason.

Please, read this manual carefully and keep it as a reference for using the device!
Periodically, check for updates on the manufacturer's website (www.lorussoretractors.com).

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