MEDESY®
ITALY

600 YEARS TRADITION®

INSTRUCTIONS FOR USE (EN)

MEDESY recommends reprocessing its medical devices according to the "instructions for use" described herein, compliant with the reference ISO 17664 standard. The reconditioning process described herein has been validated through laboratory tests, in compliance with current legislation; the application of other procedures or non-observance of what is described herein releases MEDESY from any liability and invalidates all warranty rights.

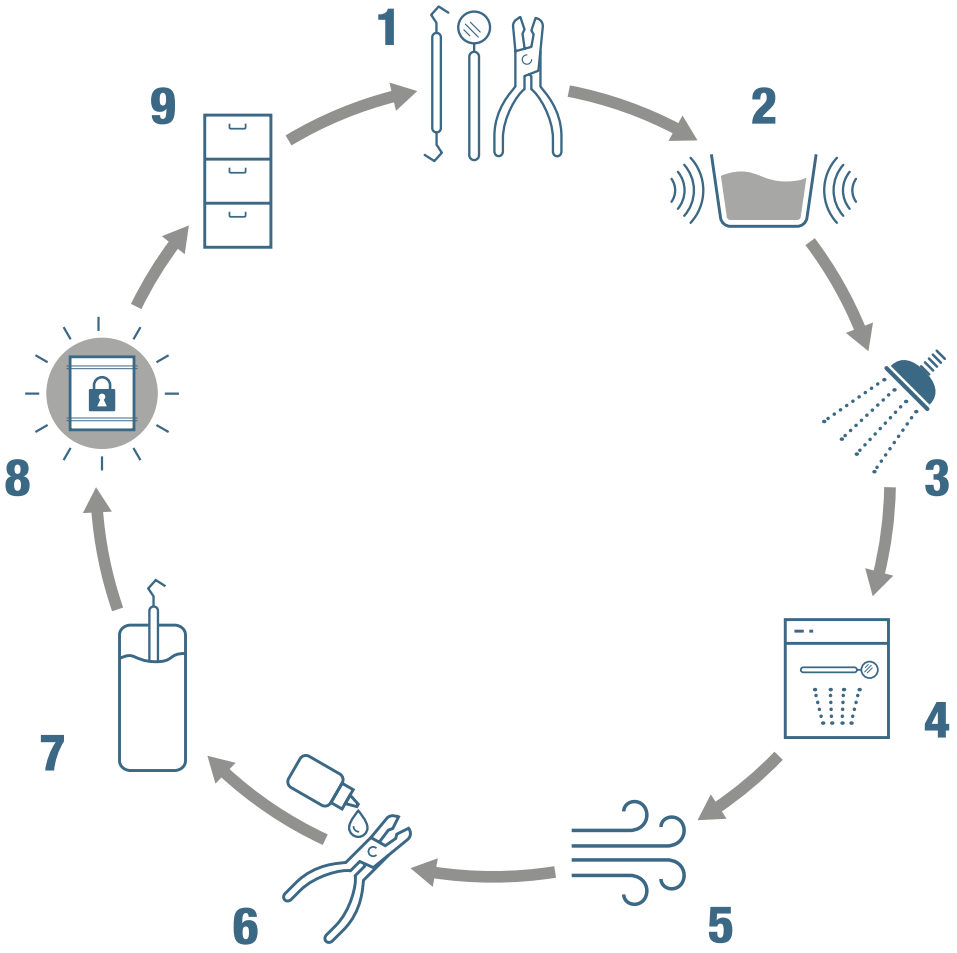
GENERAL NOTIONS

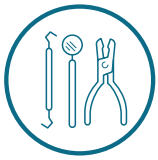
- Medical devices are intended for exclusively medical use by qualified personnel;
- Medical devices must be inspected, washed and sterilized as they are supplied non-sterile;
- Medical devices, upon first use, must be scrupulously inspected to check for any damage that occurred during transport or possible, even if remote, defects that occurred during the production processes;
- Remove the protective rubbers where provided;
- Every single device was manufactured for its specific use, so using it for purposes other than those for which it was designed and manufactured can cause serious damage and issues to both the user and the patient;
- Identify the person in charge of reprocessing who will be responsible for always and scrupulously ensuring the integrity and conformity of each individual medical device both before and after use;
- Do not use medical devices that are damaged, have altered characteristics or are unsuitable for their intended use;
- Do not carry out repairs yourself: repair or regeneration interventions on the medical device must be carried out exclusively by personnel appropriately qualified by the manufacturing company;
- It is not possible to define a maximum number of reprocessing cycles or a maximum number of uses for medical devices: it will be the designated responsible person who will evaluate whether the device is still considered compliant and safe to be used, taking into account all the information contained and described herein;
- The useful life of the medical device is determined by correct use, management and maintenance;
- Medical devices that are returned to the Manufacturer for any reason must undergo a complete sterilization cycle and be packaged in a closed sterile bag bearing the sterilization date;
- Disinfection, washing and sterilization equipment must be subjected to regular maintenance and checks according to the provisions of the relevant manufacturer;
- The quality of the water can negatively influence both the disinfection and washing results of the medical device: a high level of chlorine or other minerals present in the water can cause corrosion or stains on medical devices;
- Comply with the legal provisions in force and hygiene standards in the respective Country of use;
- Dispose of the medical device according to the legal provisions in force in the Country of use;
- In case of serious accidents related to the medical devices supplied, contact the Manufacturer and the competent national authority.

WARNINGS

- Always handle surgical devices with the utmost care and caution;
- Do not sterilize medical devices made of different materials (i.e., steel – aluminum – titanium) at the same time;
- For anodized aluminum devices, do not use products that are too alkaline or acidic as they can discolor the surface: use specific products;
- Do not cold sterilize;
- Do not sterilize with hot air or in any case at temperatures exceeding 134°C;
- For cannula-type devices, with blind holes or cavities, ensure an effective reconditioning process by removing all organic or other residues;
- All composite devices (i.e., mirror with handle) must be disassembled before reprocessing;
- Jointed devices for washing and sterilization must always be stored in an open position;
- Do not use detergents with strong alkalis (pH > 9), strong acids (pH < 4), phenols or iodophors;
- Choose detergents or disinfectants appropriately so that they comply with medical use and can be applied effectively on medical devices with CE marking;
- Scrupulously follow the instructions given by the Manufacturer of the detergent or disinfectant, with particular attention to the amount of concentration and exposure time in the solution;
- Do not implement reconditioning processes other than those listed.

REPROCESSING INSTRUCTIONS





1: COLLECTION

Collect used devices as soon as possible after their use, transport them in a suitable container to the place where the reconditioning process will take place.

2: DECONTAMINATION

Carry out decontamination (or pre-washing) by pre-soaking in special tanks to reduce the microbial load present on the devices used; it is recommended to use detergents based on 3-aminopropyl-dodecyl-1,3-propanediamine and alkyl-benzyl-dimethyl ammonium chloride (*for example, Zhermack Zeta 1 Ultra*), to respect the dilution percentages and recommended immersion times by the detergent manufacturer.

3: RINSE

The disinfected material must be rinsed thoroughly before proceeding to the washing phase.

4: WASHING

Washing can be done in two ways:

4.1: MANUAL WASHING

Remove organic, inorganic residues and microorganisms using a brush with nylon bristles, trying to reach even the difficult points and any joints of the device (do not use brushes with steel bristles to avoid ruining the surfaces and active parts of the devices). An ultrasonic tank can be used to effectively wash the devices: the devices must be completely immersed in the solution, opened or disassembled, placed so that no shadow areas remain. The cleaning solution must be renewed at regular intervals and in any case at least daily. Do not place mirrors, aluminum or titanium tools in ultrasonic tanks. At the end of washing, rinse the devices thoroughly with demineralized water in order to remove detergent residues and any deposits. Inspect the devices to verify that they are properly cleaned and have not been damaged or broken during washing.
(Detergent: Zhermack Zeta 1 Ultra)

4.2: AUTOMATIC WASHING

Place the devices in the appropriate spaces provided by the device washing machine. Follow the instructions indicated by the manufacturer for times, cycles and washing methods applicable to medical devices. The use of a cycle with thermodisinfection phase is recommended. The instructions for use may vary depending on the Country of use. Maintenance, inspection and settings of the device washer must be carried out periodically according to the frequency and recommendations given by the Manufacturer. Failure to maintain the device washer can ruin and alter the surfaces of the devices. Inspect the devices to verify that they are properly cleaned and have not been damaged or broken during washing.
(Detergent: Euronda Euroclean 120 – thermodisinfector: Euronda Eurosafe 60)

An enzymatic detergent is recommended: carefully follow the instructions indicated by the manufacturer of the detergent used, respecting the dilution percentages and immersion times.

5: DRYING

Humidity can compromise the sterilization outcome and cause the formation of stains. Dry the devices manually preferably with disposable cloths that do not release fibers or with compressed air. The formation of surface stains can be caused by the use of non-demineralized water: the stains can be easily removed using a soft cloth and a specific product for device maintenance.

6: MAINTENANCE

Inspect the devices to ensure that the washing was effective in removing any organic residues and, if any, the entire reconditioning cycle must be repeated.
At this stage it is important to inspect and analyze the device so that it is still compliant with its use and removing any deformed, worn or corroded devices: therefore, check the entire condition of the device.
▸ Assemble the devices that had previously been disassembled;
▸ Lubricate all devices with joints or sliding guides with lubricating oil suitable for medical use and therefore suitable for use in steam sterilization (*for example, REF 4155*). It is recommended to lubricate and handle the devices cold;
▸ If necessary, sharpen the devices (*i.e., curettes*) and effectively remove any metal residues.

7: PACKAGING

After the inspection and any maintenance, carry out the packaging process in a place other than the washing one. Make sure the devices are completely dry, then proceed with their packaging. It is recommended to report: sterilization date with relevant expiry date; name of operator who executed and verified the process. The quality of the bag used can compromise the quality of sterilization and can cause the formation of surface stains in the device as it is ineffective in expelling the humidity formed inside the bag.

8: STERILIZATION

It is recommended to exclusively use class B steam sterilizers for devices and to scrupulously follow the recommendations and instructions for use given by the manufacturer, including in particular the loading method.
▸ Use the standard 134°C (273°F) / 5-minute cycle for all devices;
▸ Do not use cycle flash;
▸ Do not use temperatures higher than recommended;
Maintenance of the sterilizing machine must be carried out regularly according to the provisions given by the manufacturer. The use of demineralized water is recommended to avoid the formation of surface stains on the devices.
The use of other sterilization procedures and methods than those recommended falls under the responsibility of the user.

9: STORAGE

The bags containing the sterile devices must be stored away from lights and heat sources, in dry and dust-free environments. Avoid sudden changes in temperature and direct exposure to sunlight. Store at moderate temperatures between 5° and 40°C. Sterilization can only be maintained if the devices remain packaged or bagged according to validated standards.

MEDESY recommends using GAMMAFIX boxes to manage the surgical device reconditioning process correctly, effectively, safely and quickly.

For further information on correct reconditioning, please see the Website **www.a-k-i.org**

TYPE	RECOMMENDATIONS	REF
MOUTH OPENER	Secure the mouth opener with safety wire using the central hole.	825/xx, 826/xx
ALUMINUM	For all aluminum devices, do not use products that are too alkaline or acidic as they could discolor the surface: use products compatible with aluminum. Do not put ultrasound or device cleaner in the tank. The devices are identifiable by the abbreviation "**Al**" on the label.	—
CANNULAE	Make sure the reconditioning is effective; there must be no organic or other residues left inside. Use the internal shaft of the Frazier to clean effectively by performing circular rotations with the shaft.	910/xx 911/xx
CURETTES AND SCALERS	With wear and reconditioning processes, they lose cutting performance and are less efficient in removing tartar deposits. It will therefore be necessary to restore the cut with the appropriate sharpening stones carried out by trained and authorized personnel. If this activity is not possible, we suggest returning the devices to the manufacturer where the devices will be reconditioned in a professional and guaranteed manner.	—
CURETTES AND SCALERS IN TITANIUM	They are specific for cleaning implants in cases of peri-implantitis. The tips are made of pure titanium; therefore, it is recommended to apply light pressure and more delicate movements compared to traditional curettes or scalers. The blue color is purely identifying to facilitate identification; if sharpened, the color fades. Do not use products that are too alkaline or acidic as they could discolor the surface: use products compatible with titanium. Do not put in ultrasonic cleaner or device cleaner.	626/2Ti.HL8, 627/4Ti.HK8, 669/1-2Ti.HL8, 669/5-6Ti.HL8, 669/7-8Ti.HL8, 669/11-12Ti.HL8, 669/13-14Ti.HL8, 640/1Ti.HL8, 640/5Ti.HL8, 651/11Ti.HL8
SPREADERS	Remove rubber protectors for each reconditioning process for a thorough and deep cleaning.	899, 900
DEVICES WITH GRADUATED SCALE	The devices may have a tolerance threshold in reading the measurement with respect to the graduated scale as they provide purely indicative data.	1301, 4578, 4987/xx, 4995/xx, 546/xx, 548/xx, 549/xx, 567/xx, 568/1, 569/xx, 570/xx, 6150, 6160/xx, 6170
MANUAL EXTRACTORS	They are considered disposable; tie the safety thread in the loop provided at the top.	7500/20, 7500/22
ROOT LEVERS	It is recommended to choose and then use the size of the lever proportionally to the portion and size of the root to be removed.	—
SCALPEL HANDLES AND BLADES	The scalpel handles (or blade holders) are compatible with #3 attachment blades with the exception of the REF 3634 which is compatible with #4 attachment blades. To insert and remove the blades from the handle after use, it is recommended to use the appropriate tools such as. REF 3636 or 3642; this important precaution can avoid the occurrence of dangerous and unpleasant accidents. View the dedicated video tutorials on **www.medesy.it**	3629, 3630, 3631, 3631/xx, 3632, 3633, 3634, 3635/xx, 3637/xx, 3640/xx
HANDLES FOR MICROBLADES AND MICROBLADES	The microblade handles are compatible with blades with a thickness of 0.65mm. Do not use for thicknesses other than the standard one. To insert and remove the blades from the handle after use, it is recommended to use the appropriate tools such as. REF 3636 or 3642; this important precaution can avoid the occurrence of dangerous and unpleasant accidents. View the dedicated video tutorials on **www.medesy.it**	3638, 3638/xx
OSTEOTOMES	They are equipped with a depth and safety stop: this stop can be adjusted and positioned to the desired size, along the graduated scale; the latter respects the following progression 8 10 12 14 16 18mm. Use the supplied screwdriver to adjust and set the depth stop.	1321/xx, 1322/xx
PERIOTOME	The periotome is a cutting device and must absolutely not be used for a lever function. Do not force or pry the portion to be extracted. Disassemble the blades for an effective reconditioning process.	867/xx, 868/xx

TYPE	RECOMMENDATIONS	REF
ORTHODONTIC PLIERS	Follow the measurements given regarding maximum and minimum cutting and bending capacity shown inside each pliers. Do not cut or bend wires and metal arches having different sizes than those indicated for each pliers. Do not use pliers for roles other than the nature for which they were conceived and manufactured. Do not cold sterilize. The nippers can be resharpened through the after-sales service: only traditional nippers can be resharpened, but distal nippers cannot, due to the particular anatomy of the tip.	3000/xx
NEEDLE HOLDER	For each model, it is recommended to use the suture sizes as clearly indicated in the general catalogue; in this way, damage to the device which irremediably compromises its operation and use is avoided. **Castroviejo – Barraquer models:** To adjust the closing wings, return them to a linear and perpendicular position along the axis of the device with light pressure. View the dedicated video tutorials on **www.medesy.it**	1910/xx, 1922/xx, 2000/xx, 2010, 2012
PERIODONTAL PROBES	The tips can be attached to all mirror handles with an M2.5 metric thread. The tips are reusable as long as the scale remains legible and/or the tip does not warp.	549/xx
PHOTOGRAPHIC MIRRORS AND CONTRAST BLADES	They can only be reconditioned by chemical disinfection. Do not put in ultrasonic cleaner or device cleaner. Do not rub with any type of bristle, only use a soft cloth to dry and remove streaks.	4915/xx, 4918/xx
MIRRORS	Mirrors should not be sterilized together with other metal products; this is to prevent other sharp devices from scratching or ruining the reflective part; it is recommended not to use an ultrasonic cleaner or device cleaner for the mirrors. All mirrors produced by Medesy have a metric thread with a pitch of M2.5.	4903/xx, 4912/xx
MIRRORS, HANDLES	The mirror handles produced by Medesy have metric threads with an M2.5 pitch. They will therefore not be compatible with Inch pitch threads, called "Cone-Socket".	4900, 4905/xx, 4902, 4904 4906/xx, 4907/xx
PLASTIC POLYMER TOOLS AND ACCESSORIES	It is recommended not to use an ultrasonic tank or thermodisinfector.	201 202 205 206 214 4559 4871 4916/1 4916/2 4916/6 4916/7 4990 549/1 549/2 549/4 549/5 572 599/1 599/2 599/3 599/4 599/5 6007/xx 6008/24 6210 976/Bl 979/xx
DEVICES FOR AMALGAM AND CEMENT	Make sure to remove any residual material immediately after use to prevent it from compromising the operation of the device once hardened.	4856, 4857, 4862/xx, 4864, 4865, 4866, 4869, 4880, 4890/xx, 4891/xx
COMPOSITE TOOLS	Be sure to remove any residual material immediately after use. Do not expose to any heat source or deform the tips. Do not use hard brushes or abrasive tools to clean the yellow (TiN) or black (Nerissimo) coated tips as they may ruin the special surface coating.	473/xx 484/xx, 485/xx, 490/xx, 491/xx, 492/xx, 494/xx, 497/xx, 499/xx, 507/xx, 509/xx, 518/xx, 578/xx, 579/xx, 580/xx,
POINTED AND SHARP DEVICES	Make sure they are managed during the entire reconditioning cycle so as not to alter or modify the shape, bend or sharpness of the device.	—
JOINTED TOOLS	All hinged devices must be reconditioned in the open position; make sure to clean and remove any residue inside the joint; lubricate with lubricating oil suitable for medical use and therefore suitable for use in steam sterilization (for example, REF 4155). It is recommended to lubricate and handle the tools cold.	—
SYNDESMOTOME	The syndesmotome is a cutting tool and must absolutely not be used for a lever function. Do not force or pry the portion to be extracted. Disassemble the tips for an effective reconditioning process (1651/xx only).	1650/xx, 1651/xx

TYPE	RECOMMENDATIONS	REF
SYRINGES	Attach the needle with the correct thread chosen (EU with metric pitch / AM with inch pitch). It is possible to visually distinguish EU tips from AM tips: EU tips have a circular mark while AM tips are completely smooth. The anesthetic vial can be inserted parallel or perpendicular to the axis of the syringe, thus distinguishing between the R (Revolver) and F (Folding) models. For the reconditioning process: completely disassemble and effectively wash all components. To avoid the risk of accidents, it is recommended to use the container for used needles REF 6164 after the injection. View the dedicated video tutorials on **www.medesy.it**	4940/xx, 4941/xx, 4942/xx, 4953/xx, 4957/xx, 4962/xx, 4963/xx Siringhe tradizionali: 4956, 4958/xx, 4959/xx, 4960, 4961 Siringhe intraligamentari: 4962/xx, 4963/xx, 4965/xx
TITANIUM	For titanium devices, do not use products that are too alkaline or acidic as they could discolor the surface: use products compatible with titanium. Do not put in ultrasonic cleaner or device cleaner.	1140, 1141, 1970, 1971, 2010, 2012
HOOKS FOR DAM	Secure the hook with safety wire before using it. Do not spread the hook too much to avoid breaking it. Carefully choose the size of the hook based on the tooth to be anchored.	5595/xx

SYMBOLS

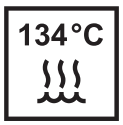
CE 0051
REUSABLE SURGICAL DEVICE

CE
ACCESSORY FOR MEDICAL DEVICE

MD
MEDICAL DEVICE


ULTRASONIC BATH (ALLOWED)


WASHER DISINFECTOR (ALLOWED)



STEAM STERILIZER (ALLOWED)

Al
ALUMINUM

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