Guidelines
for Cleaning, Disinfection and Sterilization of reusable XCN® Leone instruments

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Introduction

General information

XCN® Leone reusable instruments are designed and manufactured using materials and technologies that allow them to be reused without compromising their functional characteristics and safety.

All reusable XCN® Leone instruments are supplied non-sterile, therefore cleaning, disinfection and sterilisation is required after removal from the package and before each subsequent use.

These guidelines for cleaning, disinfection and sterilisation of XCN® Leone reusable instruments have been developed and validated by Leone Spa according to the applicable standards (see chapter "Applicable references"). If a procedure is used that differs from the one described, it must be validated by the dental practice or hospital. The legal regulations in force in the respective countries and the hygiene regulations of the dental practice or hospital must also be observed.
Leone Spa does not assume any responsibility for possible damage, injury or anything else caused by the re-use of the products declared as single-use.

This document also provides guidelines for the inspection of reusable instruments to determine when an instrument has reached the end of its useful life and needs to be replaced.

Protective clothing and equipment

Cleaning, disinfection and sterilization staff should wear suitable personal protective clothing and equipment for their own safety; also follow the specific instructions provided by the manufacturer of the detergents and disinfectants in this respect.

Detergents and disinfectants

Use only detergents and disinfectants specifically formulated for cleaning or disinfecting medical devices and always strictly follow the instructions for use provided by the detergent/disinfectant manufacturer. The effectiveness of disinfectants must be proven in

accordance with local regulations. Leone Spa does not recommend any specific cleaning and disinfection agents. These guidelines list the detergents and disinfectants used by Leone Spa in the validation study.

When choosing detergents and disinfectants, take into account their compatibility with the material to be treated. The XCN® Leone implantology product catalogue contains information about the material of the devices. For **stainless steel** products, the use of disinfectants or detergents with a high chlorine content or containing oxalic acid, as well as physiological solutions of sodium chloride, is not recommended; for **titanium** products, the use of all oxidizing acids (such as nitric, sulphuric, oxalic or phosphoric acid) and hydrogen peroxide, is not recommended; for **aluminium** products, the use of acid or alkaline detergents with a pH value below 5 and above 9 is not recommended. Plastic materials must not be brought into contact with aggressive chemicals. For all materials, aldehyde-based disinfectants are not recommended because they have a protein-fixing effect.

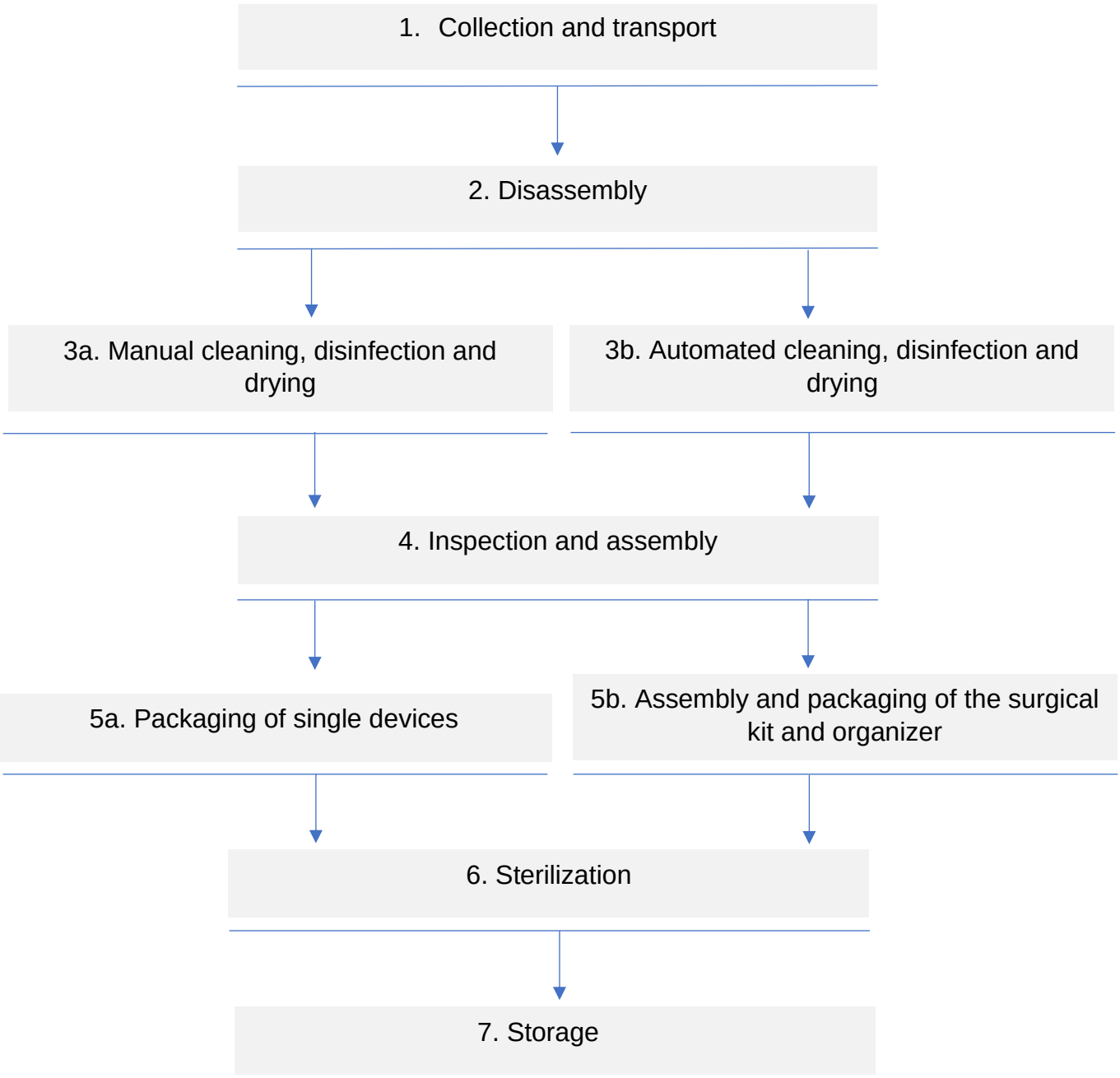
Water quality

Carefully evaluate the quality of the water used for diluting detergents and/or disinfectants and for rinsing instruments. Use at least the quality corresponding to drinking water. For the final rinse phase, we recommend the use of demineralized water or water of the same purity level.

Workflow

for cleaning, disinfection and sterilization of reusable XCN® Leone instruments

Leone Spa has validated two different methods for the cleaning and disinfection of reusable instruments, one manual and one automated with the use of a thermal washer-disinfector (washing and disinfecting device). If available, we recommend using the automated method. The following workflow shows the necessary activities for both validated methods. The following pages describe each activity in detail:



1. Collection and transport

Place used instruments in a container separately from unused instruments.

Prevent organic residues (blood, bone chips etc.) from drying on the instruments. To do this, clean highly contaminated instruments e.g. with gauze soaked in sterile distilled water and immerse them in sterile distilled water.

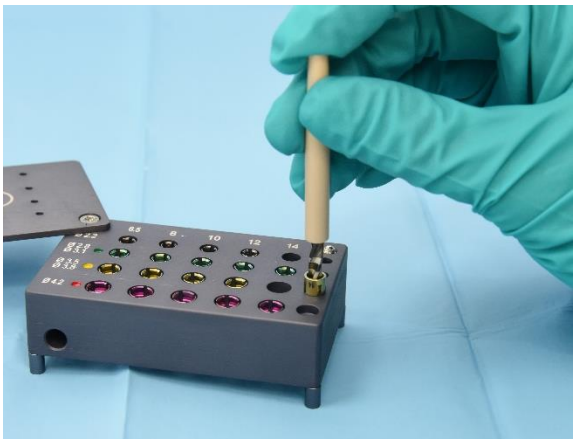
Proceed with cleaning and disinfection immediately after surgery.

Collect all instruments in a rigid, airtight container for safe transport to the reprocessing area.

Place damaged or single-use instruments (e.g. implant carrier) in an appropriate container for separate processing before disposal.

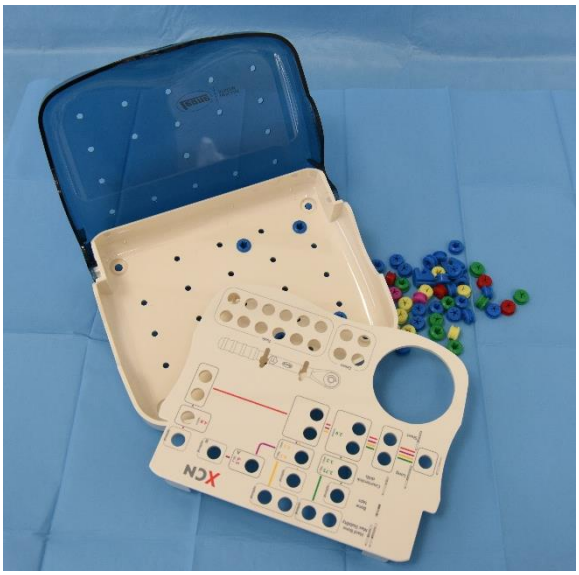
2. Disassembly

Disassemble instruments used in conjunction with other instruments before cleaning and disinfection.



Dismantle separable instruments before cleaning and disinfecting. For the prosthetic torque wrench see the Instructions for Use in the product packaging.

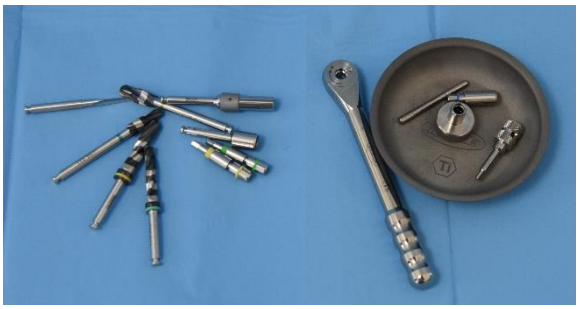
Completely **disassemble** the surgical kit, organizer and drill stop kit before cleaning and disinfection. The grommets should also be removed.



3a. Manual cleaning, disinfection and drying

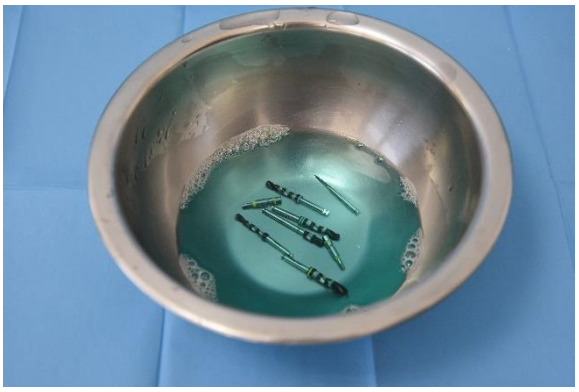
Sort instruments according to material (stainless steel, titanium, aluminium, plastics) and process them separately.

Follow the instructions at the end of this section for cleaning and disinfecting the ratchet and the abutment seater.



Immerse the instruments in lukewarm water (<40°C/104°F) to remove organic residues. Do not use fixation agents or hot water (>40°C/104°F).

Immerse the instruments in an enzymatic cleaning solution* prepared with lukewarm water.
For concentration, temperature and exposure time follow the detergent manufacturer's instructions for use.



*Detergent used for validation by Leone Spa: Cidezyme®

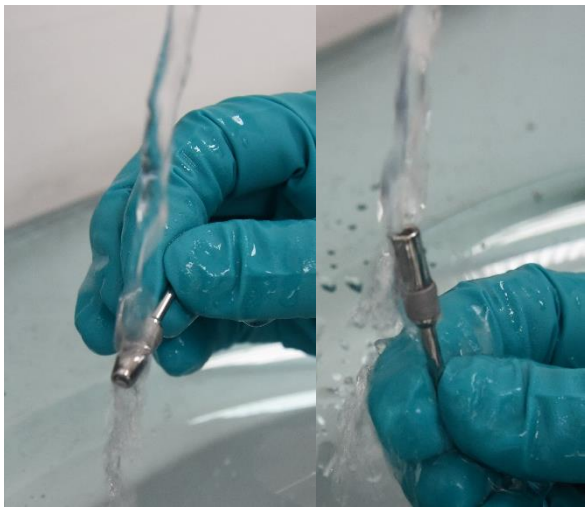
Clean each instrument with appropriate brushes and pipe cleaners with soft plastic bristles under cold running water, paying attention to critical areas of the instrument such as cavities and knurls.

Immerse the instruments in an ultrasonic bath with a cleaning solution*. For concentration, temperature and exposure time, follow the detergent manufacturer's instructions for use.

Instruments with cutting edges must not come into contact with each other during ultrasonic treatment.

*Detergent for ultrasonic bath used for validation by Leone Spa: Cidezyme®

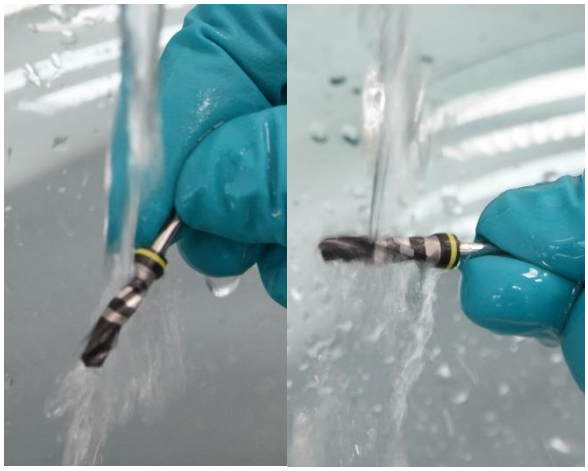
Rinse instruments thoroughly with demineralised water to remove all detergent residues.



Immerse the instruments in a disinfection solution*. The instruments must be completely covered by the solution. For concentration, temperature and exposure time follow the disinfectant manufacturer's instructions for use.

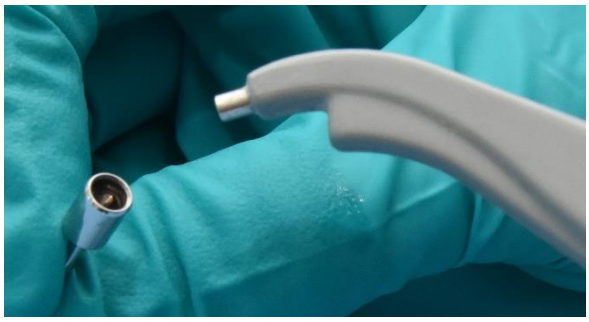
* Disinfectant used for validation by Leone Spa: Cidex® OPA

Rinse each instrument thoroughly with demineralised water for at least 1 minute or immerse the instruments for at least 1 minute in a large quantity of demineralised water. Repeat the rinsing operation at least 3 times to remove all residues of the disinfectant. Use clean water for each rinse.



Dry the instruments with compressed medical air and disposable medical wipes that do not release fibres.

If necessary, repeat the cleaning and disinfection process.



Ratchet and **abutment seater**, instruments that must not be dismantled:

Wash the ratchet head and abutment seater under running water to remove any residue.

Thoroughly **clean** the outer surface of the devices with a volatile, non-viscous disinfectant.

Dry the devices carefully using compressed medical air.

3b. Automated cleaning, disinfection and drying

Sort instruments according to material (stainless steel, titanium, aluminium, plastics) and process them separately.

Do not treat aluminium products, the ratchet and the abutment seater with automated cleaning and disinfection procedures.

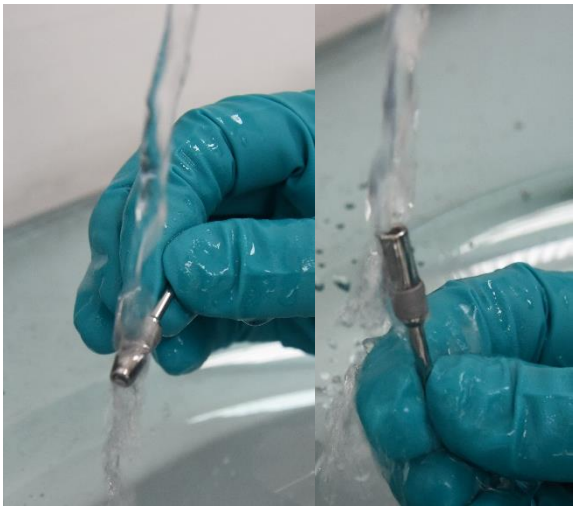
Immerse the instruments in lukewarm water (<40°C/104°F) to remove organic residues.

Immerse the instruments in an enzymatic cleaning solution* prepared with lukewarm water. For concentration, temperature and exposure time follow the detergent manufacturer's instructions for use.

Clean each instrument with appropriate brushes and pipe cleaners with soft plastic bristles under cold running water, paying attention to critical areas of the instrument such as cavities and knurls.

In case of highly contaminated instruments, **immerse** the instruments in an ultrasonic bath with a cleaning solution*. For concentration, temperature and exposure time, follow the detergent manufacturer's instructions for use. Instruments with cutting edges must not come into contact with each other during ultrasonic treatment.

*Detergent used for validation by Leone Spa: Cidezyme®



Rinse instruments thoroughly with cold running water to remove all detergent residues.

Place the instruments in a tray suitable for automated washing, close it and load it into the thermal washer-disinfector.

Place the completely disassembled surgical kit and organizer in the thermal washer-disinfector. The instruments must not come into contact with each other during automated washing.

Start the appropriate washing and disinfection program for the instruments. Regarding the individual parameters, follow the thermal washer-disinfector manufacturer's instructions.*

Start a drying cycle.

Remove instruments from the thermal washer-disinfector at the end of the program.

If necessary, finish **drying** the instruments manually with medical compressed air and disposable medical wipes that do not release fibers.

The thermal washer-disinfector shall be regularly serviced as indicated by the manufacturer in the user manual.

*The following equipment, parameters and materials were used in the Leone Spa validation study:

Thermal washer-disinfector: Miele G 7835 CD

Program: DIS.VAR.TD

Detergent: Dr. Weigert ProCare Dent 10 MA

4. Inspection and assembly

Visually **inspect** all instruments and accessories.

Where applicable, **check** if:

- the cutting edges are damaged
- signs of corrosion are visible
- marking is visible
- the DLC coating is intact
- the ISO connection is intact
- the instrument is intact.

For more details see the chapter “Useful life and replacement of reusable instruments”.

Subject the instruments to a functional test; check functioning of the ratchet and the instrument coupling devices.

Discard all instruments with signs of damage or loss of functional characteristics.

Assemble the disassembled instruments, e.g. the drill stop kit.

For mounting the prosthetic torque wrench and functional testing, see the Instructions for Use in the product packaging.

5a. Packaging of single devices

Check that the instruments are completely dry before inserting them in sterilization pouches.

Place one or more instruments in each pouch. For instruments with cutting edges, we recommend single pouching.

Close the pouch with a medical heat sealer.

For steam sterilization use a sterilization pouch suitable for the device and in accordance with ISO 11607 and EN 868-5.

Label each pouch with:

- the expiry date of sterility
- name of the person carrying out packaging and sterilization
- name and article code of the product (if the device is not clearly visible)

5b. Assembly and packaging of the surgical kit and organizer

Check that instruments are completely dry before placing them in the surgical kit or organizer.

Place the instruments in the appropriate grommets/brackets in the surgical kit or organizer.

Close the surgical kit/organizer with the lid.

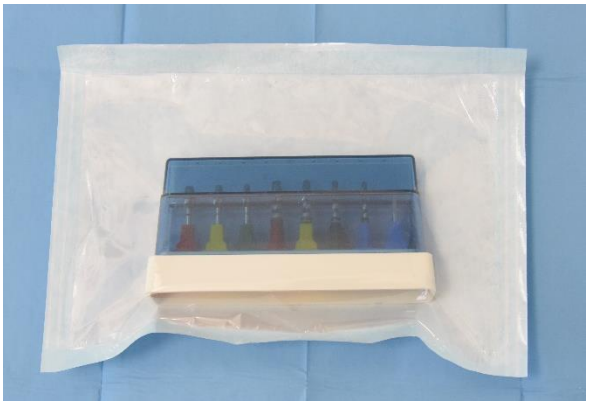
Place the surgical kit/organizer in a pouch.

Close the pouch with a medical heat sealer.

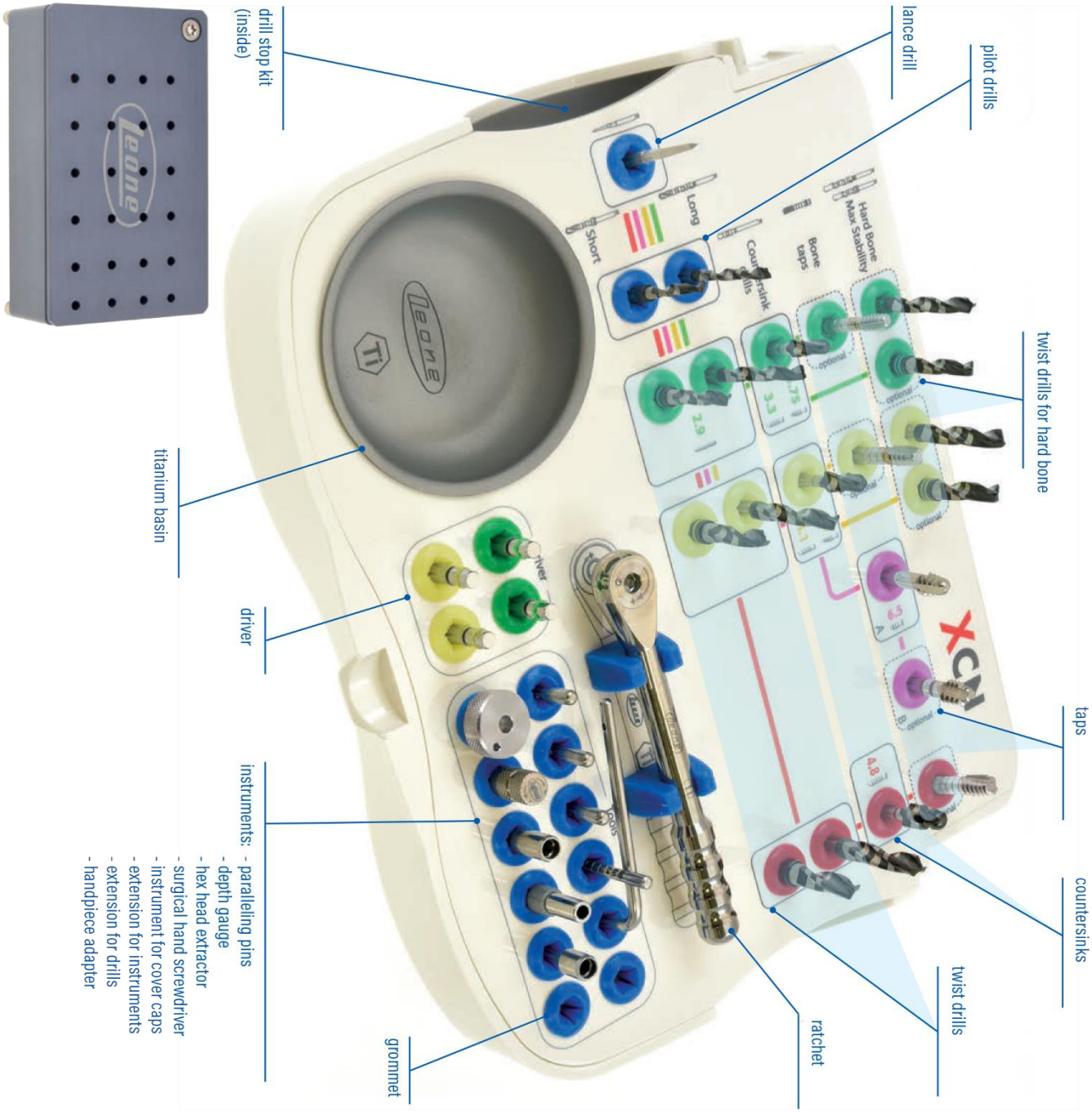
For steam sterilization use a sterilization pouch suitable for the device and in accordance with ISO 11607 and EN 868-5.

Label each pouch with:

- the expiry date of sterility
- name of the person carrying out packaging and sterilization
- name and article code of the product (if the device is not clearly visible)



Assembly of the surgical kit



6. Sterilization

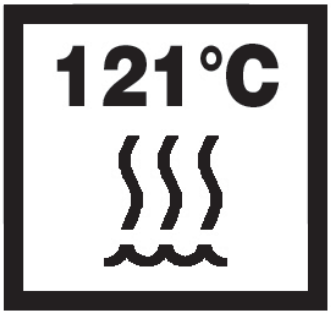
Check that the autoclave is class B, in accordance with EN 13060 and EN 285.

Place the packed devices in the autoclave.

Follow the autoclave manufacturer's instructions regarding placement of devices within the autoclave, paying particular attention to not overloading the autoclave and avoiding contact of the sterilization pouches with the interior walls of the autoclave and the filter area.

Sterilize surgical instruments in an autoclave using the following parameters**:**

- **temperature of 121°C (250°F)**
- **pressure of 1 atm**
- **minimum exposure time of 20 minutes.**



Remove the packed devices from the autoclave at the end of the program.

Place the packed devices on a dry, clean surface protected from air movement and cover with a clean, dry cloth for at least 10 minutes.

Sterilization must be performed according to a validated procedure that is continuously monitored and complies with ISO 17665-1 "Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices". The autoclave shall be regularly serviced as indicated by the manufacturer in the user manual.

7. Storage

Store the instruments in the sterile package in a dry and closed place, such as a cart or drawer, and avoid all actions that may damage them: shocks, dropping the packages, rubbing.

Follow pouch manufacturer's instructions regarding storage conditions and expiry date of sterilized products.

Useful life and replacement of reusable instruments

With regard to the useful life and need for replacement of reusable instruments, Leone Spa provides the following indications in the Instructions for Use, where the word "1 time use" is equivalent to the placement of 1 implant:

- Cutting instruments used more than 20 times or with worn out cutting edges must be replaced.
- The High Torque driver must be replaced after a maximum of 50 uses.

The useful life of a reusable instrument depends on many factors, such as the type of bone, treatment during cleaning and disinfection, etc.

Therefore, a thorough inspection of the instrument is the best method to determine the need for replacement.

The following pages show examples of signs of wear on instruments that require replacement.

Lance drill

O.K.

To be replaced

Worn out cutting edge

Rounded tip

Mucosa Punch

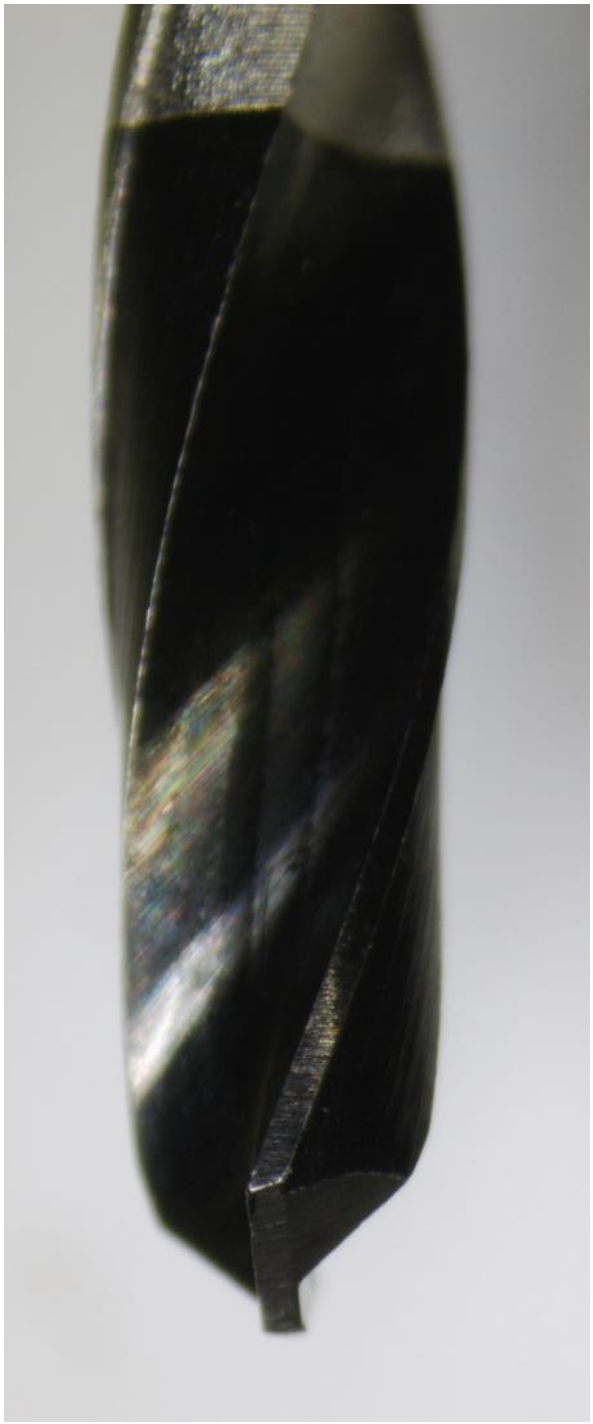
O.K.

To be replaced

Flattened cutting edge

Pilot drill

O.K.



To be replaced

Peeled off DLC coating

Rounded cutting edge

Flat abutment seater tip

O.K.

To be replaced

Dented and rounded tip

Applicable references

ISO 17664 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

ISO 15883 series on Washer Disinfectors

EN 868-5 Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods

EN ISO 11607-1 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

ISO 17665-1 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 7153-1 Surgical instruments - Materials - Part 1: Metals

ISO 21850-1 Dentistry - Materials for dental instruments

ISO 13504 Dentistry - General requirements for instruments and related accessories used in dental implant placement and treatment

Regulation (EU) 2017/745 of the European parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Instrument Reprocessing Working Group, Instrument reprocessing in dental practices - How to do it right, 4a Ed. 2016, www.a-k-i.org

ISPESL, Linee guida sull'attivitá di sterilizzazione quale protezione collettiva da agenti biologici per l'operatore nelle strutture sanitarie (D.Lgs. 81/2008 e s.m.i.)

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