SOUTHERNIMPLANTS®
Innovative Treatment Solutions

Cleaning and Maintenance of Instruments

Sterilisation Guidelines

This document gives general guidance on how Southern Implants' devices, components, drills and instrumentation that are suitable for cleaning and sterilisation should be processed. These instructions are based on validated processes used to render a product free from viable microorganisms.

Southern Implants' drills and instruments are precision manufactured from high quality materials. It is vitally important that they are properly cared for and maintained. It is essential to uphold prescribed applicable cleaning and sterilisation standards to ensure the health and safety of the operators, assistants and to avoid cross-contamination between patients.

Always refer to the packaging label to determine if an instrument is sterile or not. It is essential that all instruments be cleaned, disinfected and sterilised before use.

NOTE: the final responsibility for cleaning, disinfecting and sterilisation techniques lies with the end-user (ISO17665).

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or visit

SOUTHERNIMPLANTS.COM

Please note:
- Images are for illustration purposes only and do not necessarily accurately represent the product.
- All dimensions in this catalogue are in mm, unless otherwise specified.
- Not all products are cleared for sale in all countries.

General Information

The success of implant surgery is dependent on the quality and integrity of the instruments, as per the manufacturer's instructions for use.

The process you use to clean and sterilise your instruments is one of your most important and effective tools to protect your instruments, your patients and yourself.

Not only does the instrumentation need to be cleaned and maintained, the equipment used in accordance also needs to be checked, cleaned and maintained as per their manufacturer's specifications.

1. Introduction

1.1 Materials

Southern Implants' components, drills and instrumentation are manufactured from different materials and care should be taken to clean and sterilise them according to manufacturer's instructions.

Titanium is a strong metal with low density that is relatively ductile and corrosion resistant.
Avoid using disinfectants containing the following ingredients: chlorine, oxidizing acids (hydrogen peroxide, sulfuric acid, nitric acid) and/or hydrogen peroxide. This will cause discoloration of the material.

Titanium Nitrate (TiN) is an extremely hard ceramic material, often used as a coating on titanium alloys, steel, carbide and aluminium components to improve the substrates' surface properties.
Avoid using disinfectants containing the following ingredients: chlorine, oxidising acids (hydrogen peroxide, sulfuric acid, nitric acid) and/or hydrogen peroxide (H_2O_2). This will cause discolouration of the material.

Stainless Steel instruments may include PEEK parts. Due to its special composition, it is fairly resistant to ferric oxide formation (rust), however it is still susceptible to rustl.
Hydrochloric acid and sulfuric acid damages any kind of stainless steel and should be avoided.

Aluminium is remarkable for its low density and its ability to resist corrosion through creation of an outer layer, or via a chemical reaction with the base material (anodising).
Alkaline disinfectants with a pH value higher than 5.9 will damage aluminium parts and could etch the surface, thereby destroying the shield material.

PEEK (polyetheretherketone) is a high-performance plastic with outstanding resistance to harsh chemicals.
PEEK can be sterilised at temperatures of up to 134°C (273°F). Do not clean instruments containing PEEK with tannic acid or hydrofluoric acid.

Radel is a high temperature thermoplastic material with outstanding impact resistance. Radel® R is resistant to hot water and steam and can withstand repeated cycles in a steam autoclave.
Southern Implants utilises this material for instrument trays and in some instruments. It can be sterilised at temperatures up to 134 °C (273 °F).

Aluminium Titanium Nitride (AlTiN) coating is utilised on the Deep Conical drill range which increases the service life of the drill as it increases the wear resistance of the drill cutting edges and adds corrosion resistance. Both characteristics are advantageous for multi-use tapered drills.
Ensure that the coating is undamaged before reuse.

NOTE: the use of pitted, discoloured, corroded or deformed instruments is not recommended.

1.2 Explanation of symbols on labels and documents

The following symbols are used on packaging labels and they indicate the following:

DO NOT REUSE

These devices are single use only and must not be reprocessed or resterilised.
When these devices are supplied as non-sterile, but would need to be sterilised before use, refer to the sections in this document where the appropriate guidelines apply. Please refer to any special instructions on the label or included in the packaging.

DO NOT RESTERILISE

Indicates a medical device that is intended for single use, or for multiple use on a single patient during a single procedure.

NON-STERILE

Indicates a medical device that has not been subjected to a sterilisation process.

STERILISED USING IRRADIATION

Indicates a medical device that has been sterilised using irradiation.

MAGNETIC RESONANCE CONDITIONAL

A device or implant that may contain magnetic electrically conductive, or RF-reactive components that are safe for operations in proximity to the MRI, provided the conditions for safe operation are defined and observed.

CAUTION

This symbol is essentially a safety symbol and should be used to highlight the fact that there are specific warnings or precautions associated with the device, which are not otherwise found on the label. The symbol "Caution" is still sometimes used to have the meaning of "Attention, see instructions for use".

DO NOT USE IF PACKAGE IS DAMAGED

Indicates a medical device that should not be used if the package has been damaged or opened.

RX ONLY

Caution: (USA Only) US Federal Law restricts this device to sell to, or on the order of a licensed dentist or physician.

MANUFACTURER

Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. This symbol shall be accompanied by the name and the address of the manufacturer.

MEDICAL DEVICE

Indicates the item is a medical device.

SINGLE STERILE BARRIER SYSTEM

Indicates a single sterile barrier system.

DOUBLE STERILE BARRIER

Indicates a single sterile barrier system with protective packaging inside. The protective packaging outside the sterile barrier system prevents damage to the sterile barrier system and the contents.

USE BY

Indicates the date after which the medical device is not to be used. This symbol shall be accompanied by a date to indicate that the device should not be used after the end of the year, month or day shown.

BATCH CODE

Indicates the manufacturer's batch code so that the batch or lot can be identified.
NOTE: synonyms for "batch code" are "lot number" and "batch number".

ITEM CODE

Indicates the manufacturer's catalog number so that the medical device can be identified.
NOTE: synonyms for "catalogue number" are "reference number" and "re-order number". The manufacturer's catalogue number shall be after or below the symbol adjacent to it.

AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

This symbol shall be accompanied by the name and the address of the authorised representative in the European Community.

CE MARK (where applicable)

CE Marking is the symbol (as shown) with the Notification Body registration number.
CE Marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislations, or Product Directives (Directive 93/68/EEC).

UNIQUE DEVICE IDENTIFIER

The UDI system is intended to provide a globally recognised identification system of medical devices for distribution and use.

CONSULT INSTRUCTIONS FOR USE

Indicates the need for the user to consult the instructions for use.

For more information visit southernimplants.com/ifu

MAGNETIC RESONANCE SAFE

The device or implant is completely non-magnetic, non-electrically conductive and non-RF reactive, eliminating all of the primary potential threats during an MRI procedure.

DATE OF MANUFACTURE

To indicate the date on which a product was manufactured.

1.3 Workflow

All instrument care and maintenance procedures should be part of the practices hygiene plan and staff should be trained accordingly.

All instruments exposed to the surgical or prosthetic procedure environment are considered to be contaminated.

1. Clean

2. Disinfect

3. Thorough rinsing and drying

4. Wrapping for sterilisation

5. Sterilisation

6. Storage in sterile conditions

2. Preoperative, intraoperative and postoperative procedures

Do not place used/contaminated instruments back in the instrument tray. Keep separate and avoid contamination to other instruments in the filled tray. Handle all instruments with care and keep used instruments in a suitable holder during the operation.

2.1 Protective clothing and equipment

It is important to use protective clothing (i.e. gloves, mask and protective eyewear) while participating in the treatment of the patient (during surgical or prosthetic procedures) as well as when handling and cleaning contaminated instruments.

2.2 Cleaning agents and disinfectants

It is important to use specifically formulated cleaning agents and disinfectants. Southern Implants does not recommend any specific cleaning agent.

Please do not use cleaning agents that contain one or more of the following ingredients, as it could damage, stain or deform the instruments or plastic trays:

- Organic solvents (alcohols, ethers, ketones or benzines) (minimum permissible pH value = 5).
- Strong alkalis (maximum permissible pH value = 9).
- Oxidation agents (such as hydrogen peroxide (H_2O_2) or Aldehyde).
- Halogens (such as chlorine, iodine or bromine).

Follow the instructions for use of the detergent manufacturer in terms of concentration and time allowed for instrument immersion in the cleaning agent.

2.3 Recommended water quality

It is recommended to use sterile or purified water for rinsing purposes and for diluting cleaning agents. Mineral residues from hard water can result in staining of the instruments.

2.4 Precleaning

- Heavily soiled items need to be precleaned by rinsing and flushing with water, using a nylon brush.
- Remove all visible residue as soon as possible after use (bone, blood or tissue).
- If the instruments cannot be cleaned immediately, immerse the devices in a bath of lukewarm water or suitable cleaning solution to avoid drying of debris on the instruments.
- Disassemble multi-part instruments like torque and ratchet wrenches into individual parts and then clean.
- Remove the PEEK bits from placement tools.
- Surgical kits (instrument trays) must be completely disassembled before cleaning.
- It is recommended to clean, disinfect and sterilise instruments of different materials separately.
- Scrub devices with a soft bristled nylon brush. Pay attention to features that are covered and shielded from the brushing action.
- Rinse under cold running water to remove all of the cleaning agent off the surface.

NOTE: Southern's instrument trays, manufactured by EG Medical, feature a flat silicon seat, joined to the plastic, hence a flat completely smooth surface that has been approved for washer disinfection in accordance with 93/42EEC, 90/385/EEC and DIN EN ISO/iec 17025:2005. Do not attempt to remove the silicone seat (grommet).

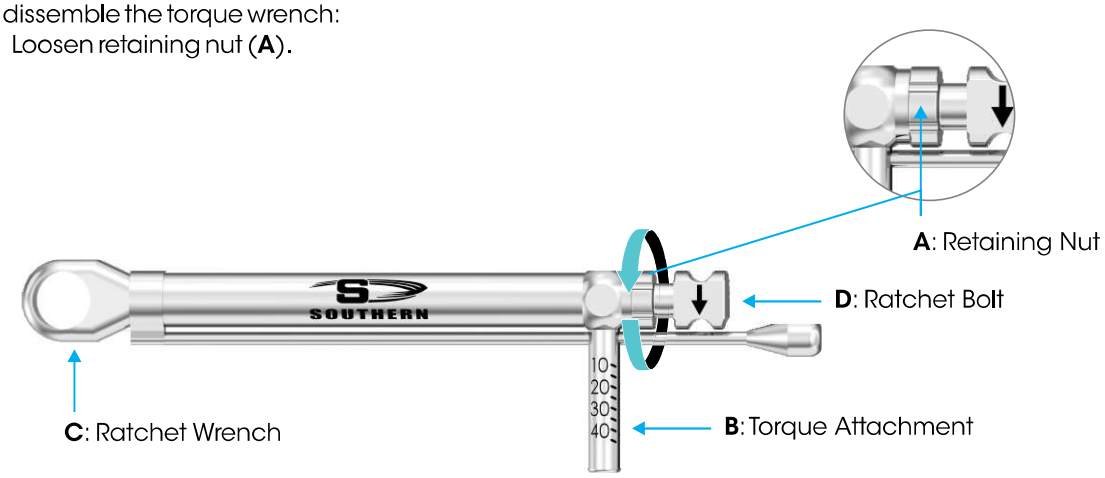
Instrument Disassembly

Disassembly of torque wrench

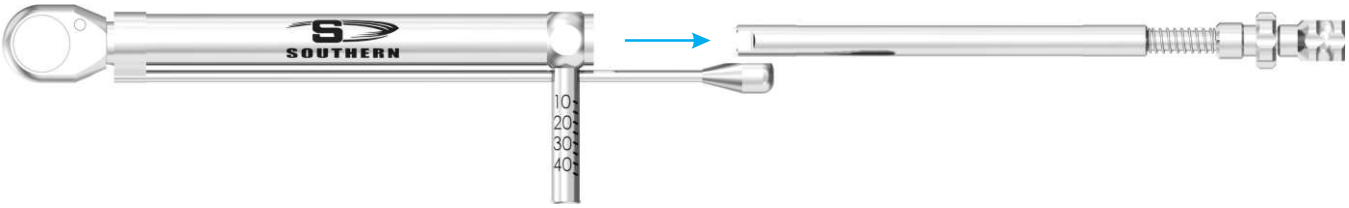
To ensure proper function of the torque wrench, it must be disassembled immediately after use and be cleaned immediately.

To dissemble the torque wrench:

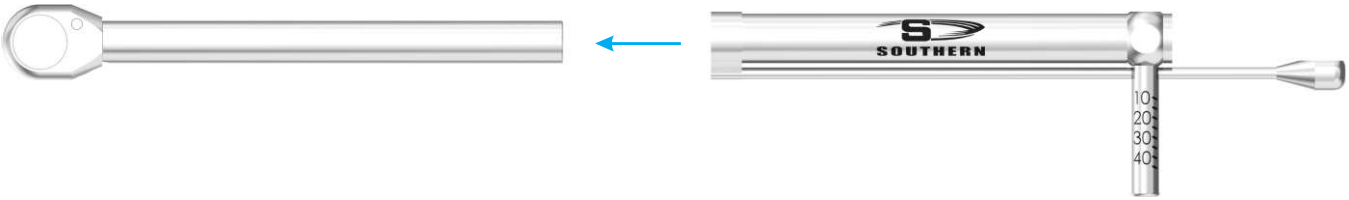
1) Loosen retaining nut (**A**).



2) Slide the ratchet bolt (**D**) out of the ratchet wrench (**C**).



3) Slide the rachet wrench (**C**) out of the torque attachment sleeve (**B**).



4) Leave the three separate components for cleaning.

Proceed with the cleaning and sterilisation procedures.

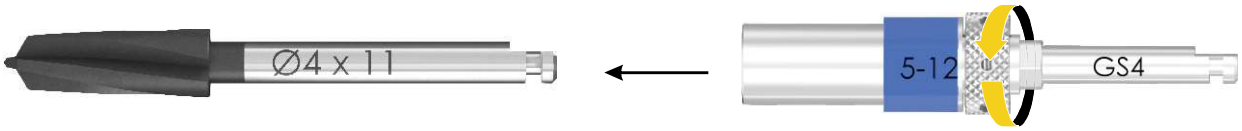
To reassemble, reverse the steps above, ensuring the torque attachment indexes the ratchet wrench correctly (**E**).

Instrument Disassembly

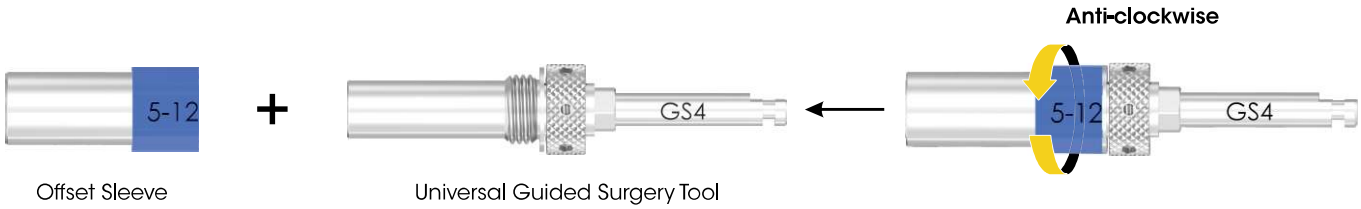
Disassembly of the SIREAL tool

To ensure proper function of the guided surgery tool, it must be disassembled immediately after use and be cleaned immediately.

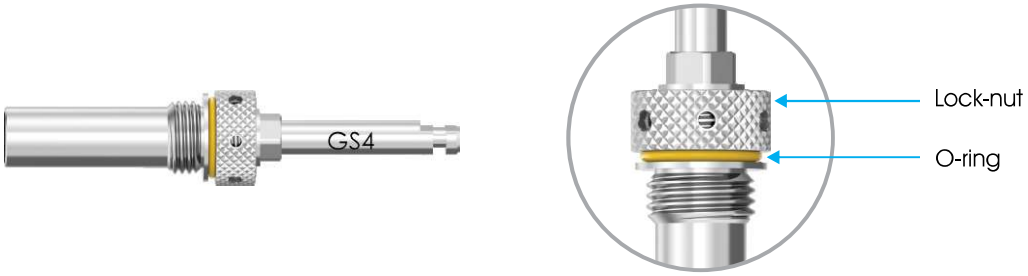
1. Rotate the twist lock in an **anti-clockwise** direction to open the slot for the drill latch and remove the drill.



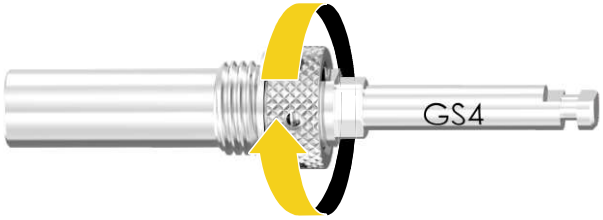
2. Unscrew the offset sleeve in an **anti-clockwise** direction from the universal guided surgery tool.



Remove the O-ring. The O-ring is placed between the lock-nut and the top of the offset sleeve stop.



Proceed with cleaning and sterilisation procedures. Ensure to rotate the latch to remove al possible debris.



Replace the O-ring after sterilisation procedures. O-rings are available separately (product code: OR-DC3).

3. Cleaning and disinfection procedures

If detergent is not a high level disinfectant, sonicate/rinse with 70% ethanol for 5 minutes.
Allow components to dry completely before sterilising.

A. Manual cleaning

Follow all steps as per precleaning.

Manual cleaning is done using cleaning accessories, water and processing chemicals. It is recommended to clean, disinfect and sterilise instruments of different materials separately. Scrub devices with a soft bristled nylon brush. Pay attention to features that are covered and shielded from the brushing action.

Prepare ultrasonic bath with a suitable cleaning solution (an enzymatic cleaning solution with a pH level between 7-10) and sonicate the instruments for 20 minutes or as per the manufacturer's instructions. Avoid instruments touching one another. This is done to protect tips and cutting edges etc.

Rinse with purified or sterile water until all cleaning solution is removed and then dry using filtered compressed air or lint free wipes.

If the product is not visibly clean, the cleaning procedure must be repeated.
The cleaned product must be handled in a manner to prevent contamination.

B. Automated cleaning procedure

Follow all steps as per precleaning and manual cleaning.

After precleaning, pack the instruments into an instrument tray or special instrument racks and load into the washer. Follow the manufacturer's instructions for the washer disinfector.

Run cleaning cycle A:
Minimum cycle parameters:

- 2 minute mixed water rinse;
- 7 minute wash with detergent at 43°C minimum temperature;
- 2 minute rinse in warm water at 45°C minimum temperature;
- 1 minute disinfection at 91°C.

If the product is not visibly clean, then the cleaning procedure must be repeated and items reinspected. If needed, use compressed air or wipes for manual additional drying.

Run cleaning cycle B:
15 minute pre-soak in 0.5% Thermosept®, 15 minutes in ultrasonic-cleaner in 0.5% Thermosept®. Thereafter, load the instruments in the washer disinfector in their tray ensuring that the instruments are securely placed in their allocated positions. Run the automatic wash cycle.

Minimum cycle parameters:

- 2 minute mixed water rinse;
- 7 minute wash with detergent at 43°C minimum temperature;
- 2 minute rinse in warm water at 45°C minimum temperature;
- 1 minute disinfection at 91°C.

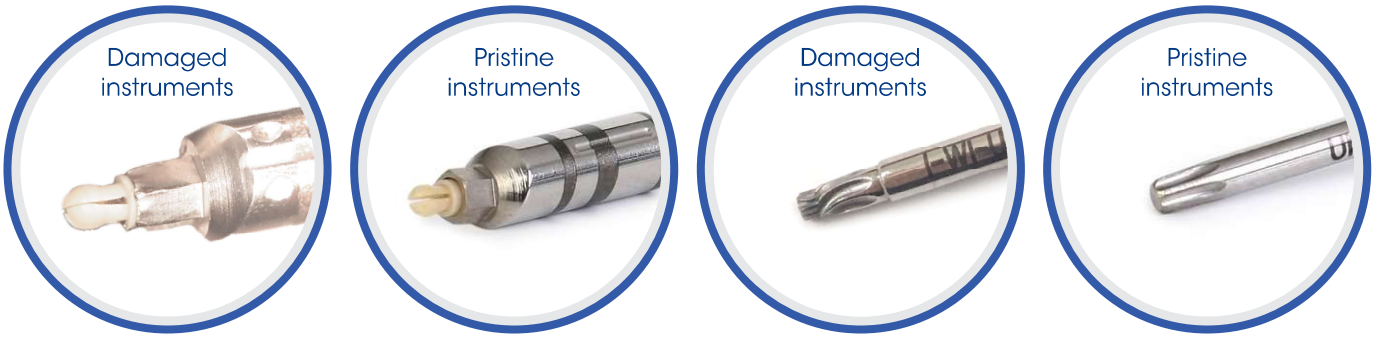
Check instruments for visible soil. Repeat cleaning if soil is visible and reinspect.
If needed, use compressed air or wipes to do manual additional drying.

NOTE: moisture on instruments can cause corrosion and deterioration of the cutting edges.

4. Inspection

Inspection, maintenance, functional testing and packaging

Check all instruments after cleaning for corrosion, damaged surfaces, chipping or dull cutting surfaces. Check all handles, joints, latch and cutting or fitting edges for visible damage or distortion. Use a magnifying glass and ensure there is enough light during inspection.



Reuseability

Discard any damaged or blunt devices. Instruments with illegible markings/labelling must also be replaced. Instruments should be disposed in containers specially designed for this purpose.

Instruments which are still contaminated must be cleaned and disinfected again. Damaged, corroded or worn instruments should not come into contact with cleaned instruments to avoid contact corrosion.

NOTE: Southern Implants does not strictly define the maximum number of uses as applicable for reusable instruments. The number of uses will be determined by the integrity of the cutting edge or fitting surfaces.

If not supplied sterile, single use devices must be cleaned, disinfected and sterilised prior to used and are not intended to be reused.

Maintenance

Reassemble the disassembled instruments (see specific instruction for use) and do a functional test with instruments with moving parts to ensure proper function (i.e. torque wrench). Avoid contamination during assembly.

Packaging

If applicable, sort the cleaned and disinfected instruments and pack into the associated sterilisation cassette. Place the instruments into a sterilisation pouch or any other approved packaging material.

Use the correct packaging material as indicated for steam sterilisation to ensure sterility is maintained. Double packaging is recommended.

Fit the instruments or the sterilisation cassettes in disposable sterilisation packaging corresponding to the following requirements: ISO11607 or DIN58953-7 (for use in the USA, ensure compliance by using a FDA cleared material).

Suitable for steam sterilisation (temperature resistance up to at least 137°C (278.6 °F), with sufficient steam permeability).

NOTE: an indicator strip with the following information should be affixed to the packaging after sterilisation:

- Date of the sterilisation.
- Expiration date.
- Name of person who cleaned and packed the instruments.
- Lot number if applicable.

5. Sterilisation

Prevacuum method: steam sterilise the components at 134-137°C (274 – 279°F), at 180-220 kPa for 3 – 7 minutes. Dry for at least 10 minutes in chamber.

Gravity method: steam sterilise the components at 121°C (250°F) for 30 minutes. Dry for at least 10 minutes in the chamber.

NOTE: follow the operating instructions of the steriliser/autoclave with regards to loading weight, size and operating time.

6. Storage

Maintain packaging integrity to ensure sterility in storage. Packaging should be completely dry before storage to avoid corrosion and degradation of cutting edges and should be stored in a dry and dark place.

Sterilisation pouch manufacturers have instructions on the storage conditions and expiration dates of sterilised items which should be followed.

Take care:

Instruments	Use instruments for their intended use only as per the specific IFU.
	Do not let surgical debris dry on instruments or drills. Soak in lukewarm water during operation and clean as soon as possible after surgery.
	Never use steel wool or other metal brushes to remove the debris.
	Do not clean/disinfect or sterilise instruments made of different materials together.
	Must be dried after sterilisation and then stored.
Instrument trays	Do not remove the silicone grommets in the Southern Implants EG trays.
	Do not expose trays to temperatures above 134° C (273° F).
Drills	Use drills for their intended use only (as per the IFU's).
	Twist drills: single use only and to be disposed off after use.
	Tapered drills and taps: indicated for 10 uses. Record number of uses on a drill usage chart.
	Do not clean/disinfect or sterilise drills made of different materials together.
Sterilisation	Flash sterilisation is not allowed. Do not use hot-air, radiation, plasma, formaldehyde or ethylene sterilisation.
	Corroded instruments will contaminate the water circuit with rust particles. Clean and inspect the unit regularly.

All autoclaves/sterilisers should comply with the requirements of and be validated, maintained and checked in accordance with SN EN 1360, EN 285, EN ISO 17665-1, AAMI ST79 or your national standard.

For more information on
Instructions for Use of our products,
please scan the below,

or visit our website
southernimplants.com/ifu

8. Warnings

Sterility

All dental implants are shipped sterile and intended for single use prior to the expiration date (see packaging label). Sterility is assured unless the container or seal is damaged or opened. DO NOT resterilise or autoclave these components.

Do not reuse implants. These are single use products. Reusing these components may result in damage on the surface of critical dimensions. This may result in performance and compatibility issues. The removal of proteins from the metal (such as titanium) is extremely difficult and if not removed, may lead to secondary infections.

Products provided non-sterile must be cleaned and sterilised prior to use, according to the guidelines as stated in the relevant 'Instructions for Use' and this 'Cleaning and Sterilisation Manual'.

Disclaimer of liability

These products are part of the Southern Implants product range and should only be used with the associated original products and according to the recommendations as in the individual product catalogues.

The user of these products has to study the development of the Southern Implants product range and take full responsibility for the correct indications and use of these products. Southern Implants does not assume liability for damage due to incorrect use.

Please note that some Southern Implants products may not be cleared or released for sale in all markets.

Storage and handling

Devices should be stored at room temperature. Refer to the individual product packaging label and the corresponding manual for special handling instructions.

Limitations on reusable instruments

A direct value for reuseable instruments can not be given. Frequent processing may have minor effects on the instruments.

The product life is normally determined by wear and damage during use, thus instruments if properly cared for and inspected after each use, can be reused many times.

Maintain a checklist for these instruments, recording the number of uses. Prior to reprocessing the device it should be thoroughly inspected and tested to determine its suitability for reuse. Drill usage charts are available on the Southern Implants' website.

Disposal

Disposal of the device and its packaging: follow local regulations and environmental requirements, taking different contamination levels into account. Be careful and avoid injury when disposing sharp instruments or drills.

Sufficient PPE must be used at all times.

Notice regarding serious incidents

Any serious incident that has occurred in relation with the device must be reported to the manufacturer of the device and the competent authority in the member state in which the user and/or patient is established.

The contact information of the manufacturer of this device to report a serious incident is as follows:
sicomplaints@southernimplants.com

For more information on Instructions for use of our products, scan the below,

or visit our website
southernimplants.com/ifu

For more information scan the below

to contact your Southern Implants Representative
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