medartis

PRECISION IN FIXATION

INSTRUCTIONS

Cleaning, Disinfection, Sterilization, Inspection and Maintenance of Medartis Products

APTUS MODUS

Cleaning, Disinfection, Sterilization, Inspection and Maintenance of Medartis Products

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For further information regarding the APTUS/MODUS product lines visit www.medartis.com

PLEASE CAREFULLY READ AND FOLLOW THESE INSTRUCTIONS

1 INTRODUCTION

This document, "Instructions for Cleaning, Disinfection, Sterilization, Inspection and Maintenance of Medartis Products" includes information about:

- the reprocessing (cleaning, disinfection and sterilization) of products from Medartis
- the inspection and maintenance of the instruments
- the identifying features relating to wear/tear and loss of usability

Additional information about the products is provided in the "Instructions for Use", individual product brochures and surgical techniques. Any information can be requested at any time from your local Medartis territory consultant or distribution partner. In addition, all relevant information can be found on the internet at:
www.medartis.com/documentation/instructions-for-use.

The reprocessing of the products (cleaning-, disinfection- and sterilization process) which is described in this document was tested and validated by Medartis.

In the following text the term "products" covers:
- implants
- instruments
- trays/containers

In case of different handling the sub-groups are explicitly mentioned.

2 GENERAL BASICS

2.1 Shipment
All components that are delivered NON-STERILE must be appropriately cleaned, disinfected and sterilized before each use. This also applies to the first use after delivery (after removal of the protective transport packaging).

2.2 Reuse of Medartis Products
Medical devices which are intended for single use are labelled with the following symbol: 

These products are intended for **one single application** in a single patient. They must be cleaned, disinfected and sterilized before use.

Repeated processing cycles as described in these instructions have negligible effects on Medartis products. Testing prior to sterilization can be required to ensure proper function, The method for the functional testing, when applicable for the implant or instrument, is provided in theses instructions.

Implants that were used in a patient and removed have to be discarded following the local requirements. They may not be reused. Re-use may compromise the structural integrity of the implants and/or lead to device failure which may result in patient injury. Furthermore, re-use of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury of the patient or user.
Implants that have come in direct contact with blood or other bodily fluids or show visual contamination must be cleaned and disinfected separately before they can be placed back into the implant tray.
Products that have not come into direct contact with a patient may be reprocessed.
Products which are not labelled with the above mentioned symbol may be reused. These products include instruments, trays/container under the prerequisite that these products are undamaged and clean. These reusable products have to be reprocessed before each use.
In case of disregarding of these instructions the manufacturer excludes any liability.

Medartis defines no maximal number of reuses for reusable products. The life-cycle of the products depends on many parameters, e.g. the way and duration of the individual usages, and/or the handling, the treatment between the usages. Careful inspections and functionality tests of the products before each usage are the best methods to affect the products' lifetime.
Medartis recommends using twist drills and reamers only for a maximum of ten times.

2.3 Assembling/Disassembling (Instruments)
To insure that instruments undergoing cleaning/disinfection can be properly assembled/disassembled, attention has to be paid to the individual "Assembly/Disassembly Instructions" provided separately at www.medartis.com/documentation/instructions-for-use.
Please keep in mind that instruments which are not represented in the "Assembly/Disassembly Instructions" are not intended to be disassembled.

2.4. Materials

Product	Material
Plates	Pure titanium, titanium alloy
Wedges	Titanium alloy
Spiral blades	Pure titanium
Washers	Pure titanium, titanium alloy
Screws	Titanium alloy
Staples	Stainless steel
K-wires	Stainless steel
Instruments	Stainless steel, PEEK, aluminum, Nitinol, silicone or titanium
Containers	Stainless steel, aluminum, PEEK, polyphenylsulfone, polyurethane, silicone

2.4.1 Material Durability
All Medartis products can be exposed to temperatures up to a maximum of 141°C (286°F). When choosing detergents and disinfectants the following warnings must be respected:

Material	Not recommended
Aluminum (anodic oxidation etc.)	► Alkaline or ingredients containing iodine or salts of heavy metal (e.g. mercury) ► Poor water quality, alkaline cleaning agents, acidic neutralizers

Color coding	► All oxidating acids (e.g. nitric acid, acid sulphur, oxalic acid), H_2O_2 (hydrogene peroxide) ► Excessive concentrations of cleaning and disinfection agents
Stainless steel	► Elevated chlorine concentration ► Oxalic acid ► H_2O_2 (hydrogene peroxide)
Titanium	► All oxidating acids (e.g. nitric acid, acid sulphur, oxalic acid), H_2O_2 (hydrogene peroxide)

3 BASICS FOR CLEANING, DISINFECTION AND STERILIZATION OF MEDARTIS PRODUCTS

The basics which are described in this chapter have to be followed for all reprocessing steps!

Thorough cleaning and disinfection are essential for an effective sterilization.

Two methods, a manual and an automatic method, are described for the cleaning/disinfection of the Medartis products. If possible an automatic procedure (disinfector) must be used. A manual procedure even with an ultrasonic bath is significantly less effective.

The pretreatment for cleaning/disinfection has to be carried out for both methods.

It is your responsibility to ensure that the components are completely sterile when used and that

- only device and product specific procedures for cleaning/disinfection and sterilization that are sufficiently validated are used
- the devices used (disinfector, sterilizer) are serviced and inspected on a regular basis
- that the validated and/or parameters recommended by the manufacturers are respected for each cycle

Please also consider the statutory regulations applicable in your country as well as the hospital's hygiene requirements. This applies in particular to the various instructions for effectively deactivating prions.

Medartis recommends that products are discarded when they came into contact with pathogens that are difficult to identify, such as variations of Creutzfeldt-Jakob's disease (confirmed or suspected pathogen).

Detergents, Disinfectants and Equipment
Observe the following aspects when choosing detergents, disinfectants and equipment for all steps:

- they must be suitable for their intended use (e.g. cleaning, disinfection or ultrasonic cleaning)
- the detergent and disinfectants must be aldehyde-free (otherwise blood residues may dry and attach firmly to surfaces)
- the disinfectant used must have a proven effectiveness (such as approval by VAH/DGHM or a CE mark)
- the detergents and disinfectants must be suitable and compatible for use with the products (please see also chapter 2.4 "Materials")
- the manufacturers' instructions, such as those regarding concentration, exposure time and temperature, must be followed

Medartis recommends the use of **freshly** produced detergent and disinfectants.

Detailed information on agents suitable in particular for a gentle cleaning and disinfection can be requested directly from the manufacturer of the detergent and disinfections. These are in Germany, Switzerland for example:

- Chemische Fabrik Dr. Weigert GmbH & Co. KG, Hamburg, Germany
- Ecolab Deutschland GmbH, Düsseldorf, Germany
- Schülke & Mayr GmbH, Norderstedt, Germany/ Zürich, Switzerland
- Johnson & Johnson MEDICAL GmbH, Norderstedt, Germany
- Bode Chemie GmbH & Co. KG, Hamburg, Germany

All our cleaning and disinfection processes have been validated using the following agents:

Manual cleaning: CIDEZYME® Enzymatic Detergent Solution, 1.6 % v/v

Manual disinfection:
CIDEX® OPA Solution (undiluted)

Automated cleaning/disinfection:
Neodisher MediClean forte (0.2 % – 1.0 %)

The manufacturer's instructions, such as those regarding concentration, exposure time and temperature, must be followed.

Cleaning Materials and Accessories for Pre-Cleaning/Cleaning
Never use metal brushes or steel wool for cleaning Medartis products; in case of disregard the material can be damaged. Use clean, lint-free cloths (e.g. Perform classic from Schülke & Mayr) and/or soft brushes (e.g. Justman Brush from VWR International). For reprocessing cannulated products and/or products with a lumen you need materials and accessories such as cleaning stylets, bottle brushes and/or syringes with corresponding cannulated attachments.

Drying Accessories
Medartis recommends lint-free single-use wipes or medical compressed air.

Water
Regarding the water quality Medartis recommends using demineralized and purified water (e.g. Aqua purificata) for cleaning, disinfection and subsequent rinsing steps. High concentrations of minerals and/or contamination with microorganism, ect. can lead to spots on the products or can even prevent an effective cleaning and decontamination.

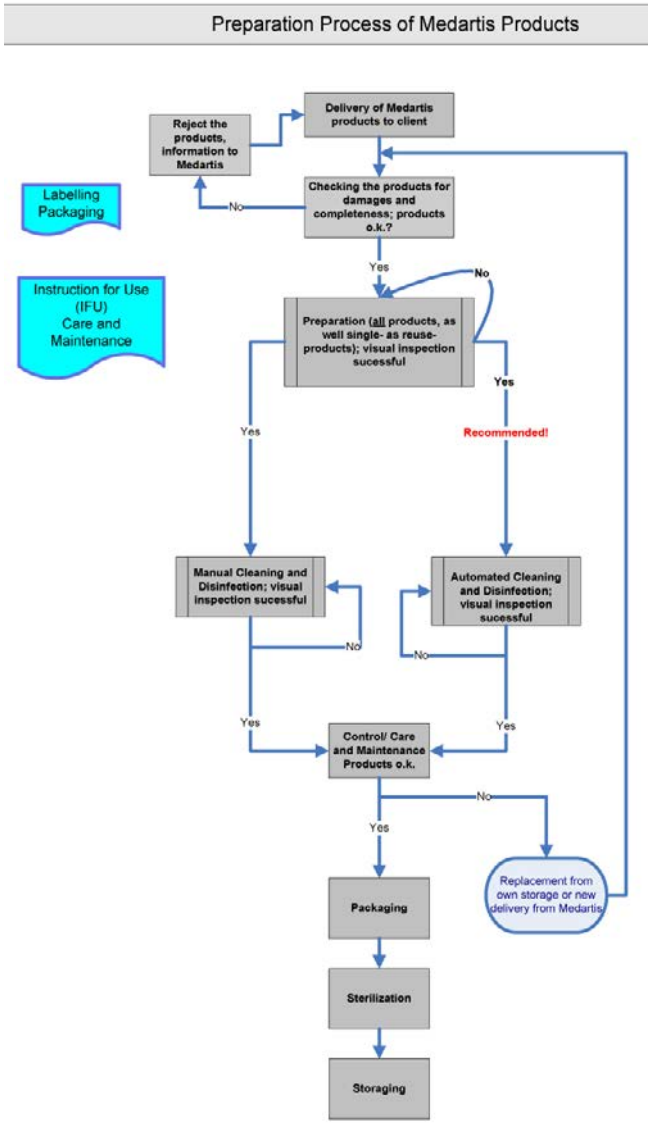
For the remainder of this document, please use the following definitions regarding water temperature:
Cold water: T < 40°C
Warm water: T > 40°C

Medartis **instrument trays** (steel or plastic) and **implant trays made from aluminum or plastic** are intended for sterilization, transportation and storage of products. They are not intended for cleaning and disinfection when loaded. The products must be removed from the trays and then cleaned and disinfected separately.

Implant trays made of steel can undergo automated cleaning and disinfection when loaded. For manual cleaning/disinfection the implants must be removed from the system and cleaned/disinfected separately.

4 FLOWCHART

The individual reprocessing steps, for single-use and reusable products, are illustrated in following flowchart. More detailed information is decribed in the subsequent text:



5 PREPARING FOR CLEANING, DISINFECTION AND STERILIZATION

5.1 Segregating and Preparation of the Instruments after Surgery

The first steps of an efficient reprocessing start in the operating room.
Major contaminants, debris of agents for haemostasis, skin disinfection, lubricants and acidic pharmaceutical products must be removed before segregating dirty instruments if possible. When segregating dirty instruments consider the following aspects: instruments can be damaged (e.g. deformation of small clamps, breakage of scissor tips) by improper technique. Therefore it has to be considered that the instruments are handled carefully and properly and the instrument trays are not overloaded.
Preferably use dry preparation for the transportation to the cleaning/sterilization department.
If a wet preparation method is used, place the instruments in a prepared solution directly after usage.

Consider that:

- multipart instruments (e.g. depth gauges, demountable handles, clamp sleeves of screwdrivers etc.) are disassembled as much as possible before the pretreatment; if needed, follow the assembly and disassembly instructions (see chapter 2.3 “assembling/disassembling”)
- articulated instruments (e.g. scissors, clamps, forceps etc.) are opened as much as possible
- all products (including grooves, holes, lumens, etc.) are sufficiently covered with solution in case of using a wet preparation method

The products have to be prepared as soon as possible to avoid drying of blood residues or debris and to avoid damage to the materials by leaving them in the solution for longer than directed.

5.2 Pretreatment for Cleaning, Disinfection and Sterilization

During manual cleaning care and attention has to be given to holes, lumens, grooves and articulated instruments!

Process of the Precleaning
Instruments
Clean the **disassembled and opened** instruments under running water and:

- remove visible contaminants with a soft plastic brush, e.g. Justman Brush from VWR International
- shift **moveable parts** under running water back and forth several times and rinse them thoroughly
- clean **large lumina** with a bottle brush by brushing them 10 times; the bottle brush has to reach the entire length of the lumen
- **cannulated devices** (products with cavities whose diameter is less than or equal to 1/6 of the device‘s length), e.g. cannulated drills, must be treated as follows:
  - cleaning by inserting the dedicated cleaning stylet into the cannulated products to remove obstructions and to achieve a flow-through; the cleaning stylet has to reach the entire length of the cannulated product

- rinse the cannulated products using a suitable cannula and disposable syringe

Instrument/Implant Trays
Instruments always have to be removed from the trays and cleaned and disinfected separately.
Clean the **instrument trays** (made from steel or plastic) as well under running water as follows:

- if applicable remove the instruments that are still in the tray; the trays have to be empty
- remove the lid if possible
- clean the individual parts under running water thoroughly

Clean the **implant trays** (made of color anodized aluminum/ plastic) as well under running water as follows:

- remove the implants from the tray; the trays have to be empty
- remove, if possible, the lid of the implant trays; handles must not be removed
- clean the individual parts under running water thoroughly

Clean the **implant trays** (made of steel) as well under running water as follows:

- first rinse the closed implant trays thoroughly
- remove the lid and rinse it separately from all sides; rinse the joints as well
- rinse the opened tray with the implants from the upper side in a way that no implants can fall out

After rinsing, all the products must be **visually inspected**; if applicable, repeat the previoulsy mentioned precleaning procedure as required until contamination is no longer visible.

In case the products are not cleaned immedialtely let them dry on an absorbent, clean and lint-free base (e.g. on lint-free disposable wipes, e.g. Perform classic from Schülke & Mayr).

6 CLEANING AND DISINFECTION

For the following cleaning and disinfection process the disassembled instruments and trays stay disassembled

6.1 Manual Cleaning and Disinfection

Important:
For manual cleaning and disinfection, the trays have to be empty. Instruments and trays must be opened and disassembled as far as possible.

Implants must be removed from the system and must be cleaned and disinfected separately.

Manual Cleaning Process

- Place the **products** in the cleaning bath with enzymatic cleaning solution for 5 minutes (e.g. CIDEZYME® Enzymatic Detergent Solution, 1.6 % v/v)
  It has to be considered that
  - the products must be adequately covered (including grooves, holes, lumens, etc.)
  - the individual components are not in a position to damage each other
  - the manufacturer‘s instructions, such as those regarding, exposure time, temperature and concentration must be followed
- Clean with a **soft plastic brush** (e.g. Justman Brush from VWR International).
- During cleaning, shift **moveable parts** back and forth 10 times so that all areas/spots are cleaned properly.
- Clean **large lumina** with a bottle brush by brushing them 10 times; the bottle brush has to reach the entire length of the lumen.
- **Cannulated devices** (products with cavities whose diameter is less than or equal to 1/6 of the device‘s length), e.g. cannulated drills, must be treated as follows:
  - insert the dedicated cleaning stylet to remove obstructions and to achieve a flow-through; the cleaning stylet has to reach the entire length of the cannulated product
  - rinse the cannulated products using a suitable cannula and disposable syringe (rinsing volume: 30 ml)
- Clean the products (if applicable the individual parts) in the **ultrasonic bath** for minimum 15 minutes; it has to be considered that
  - only freshly prepared solutions are used
  - only a suitable detergent or a combined disinfectant/ detergent is used (e.g. CIDEZYME® Enzymatic Detergent Solution, 1.6 % v/v)
  - the manufacturer‘s instructions, such as those regarding concentration, exposure time and temperature, must be followed
  - the ultrasonic bath, including rinsing and drying process of the products, is carried out corresponding to the manufacturers’ instructions
- Afterwards remove the products (if applicable individual parts) from the ultrasonic bath. The following **rinsing process** with cold or warm water must be carried out for at least 1 minute until visible contamination is no longer evident. It has to be considered that
  - lumina also are rinsed inside thoroughly
  - cannulated products (e.g. cannulated drills) also are rinsed inside using syringes and suitable cannulas

  For rinsing also hand-held water jets can be used.
- After rinsing with cold or warm water all products must be **visually inspected**; if applicable, the cleaning and disinfection process has to be repeated as required until visible contamination is no longer evident.
- Let the products dry on an absorbent, clean and lint-free base (e.g. on lint-free disposable wipes, such as e.g. Perform classic from Schülke & Mayr).

Manual Disinfection Process

- Place the **products** in the disinfection bath for at least 15 minutes (e.g. CIDEX® OPA Solution, undiluted). It has to be considered that
  - the products are adequately covered
  - the individual components are not in a position to damage each other
  - the manufacturer‘s instructions, such as those regarding

exposure time, temperature and concentration, must be followed

- During disinfection shift **moveable parts** back and forth 10 times so that all areas/spots are disinfected properly.
- **Lumina** have to be filled with disinfectant inside as well.
- **Cannulated devices** (Products with cavities whose diameter is less than or equal to 1/6 of the device's length), e.g. cannulated drills, must be treated as follows: rinse the cannulated products with disinfectant using a suitable cannula and disposable syringe (rinsing volume: 30 ml).
- Afterwards remove the products (if applicable individual parts) from the disinfection bath. The following **rinsing process** with cold or warm water must be carried out for at least 1 minute until all leftovers of the disinfection bath are removed. It has to be considered that
  - lumina also are rinsed inside thoroughly
  - cannulated products (e.g. cannulated drills) also are rinsed inside 3 to 5 times using syringes and suitable cannulas
- Visually inspect the products and repeat the cleaning and disinfection process as required until visible contamination is no longer evident.
- The products must be completely dried directly afterwards. It is recommended to dry the products using medical compressed air; this is especially gentle and effective. Otherwise lint-free disposable wipes (e.g. Perform classic from Schülke & Mayr) can be used. If applicable, the products have to be stored in a clean environment until they are **completely dry.**

Main reasons for mechanical damages during manual reprocessing are:

- metal brushes
- abrasive detergents
- applying significant forces
- "dropping products", "bumping products", "tossing products"

- Finally **inspect** the products (see chapter 7.1 "Inspection").
- **Service** the products (see chapter 7.2 "Care and Maintenance").
- **Pack** the products preferably immediately (see also chapter 8 "Packaging") or if necessary, after giving them additional time to dry in a clean environment.

6.2 Automated Cleaning and Disinfection

It is preferable to segregate dirty products using a dry method before starting the automated cleaning/disinfection process. If a wet method was used, ensure that the products have been rinsed thoroughly after pretreatment as remaining foam may reduce the rinsing pressure in washer/disinfectors and thus have a negative impact on the cleaning result. This is also valid if products are additionally processed in an ultrasonic bath. Cannulated products and lumina have to be rinsed using syringes and/or hand-held water jets.

Regarding choosing and using **detergents and disinfectants** the information in chapter 2.4.1 and chapter 3 have to be observed. In case no thermal disinfection is used while automated cleaning and disinfection, it has to be observed that the used disinfectant is compatible with the detergent.

Medartis has used "Neodisher MediClean forte" for the validation process of the automated cleaning and disinfection and has followed the instructions of the manufacturer (instruction Dr. Weigert). The validation was carried out according to table below.

When selecting the disinfector, make sure that the cleaning process includes the following phases in accordance with EN ISO 15883:

Phase	Temperature	Duration	Action
Cleaning	55°C (±2°C) (131°F; ±3.6°F)*	10 min.*	Adding detergent*
Neutralization	Cold (T < 40°C/104°F)	2 min.	Neutralize with cold water
Rinsing	Cold (T < 40°C/104°F)	1 min.	Rinse with cold water
Thermal disinfection (A_0 value > 3'000)	≥ 90°C (194°F)	5 min.	With demineralized and purified water; do not add additional detergent
Dry	Device-specific (T < 141°C / 286° F)	Device-specific	Drying process

* The information provided is based on the use of "Neodisher MediClean forte" by Dr. Weigert; validation was performed with a concentration of 0.2 % at 50°C; if a different detergent is used, exposure times, concentrations and temperatures may vary; the relevant manufacturer's instructions must be observed.

Automated Cleaning and Disinfection Process
To be considered:
For automated cleaning and disinfection, instruments have to be removed from the trays.
Instruments have to be opened and disassembled!

Implant trays made of aluminum or plastic are not intended for cleaning and disinfection when loaded. Implants must be removed from the trays and must be cleaned/disinfected separately.

Implant trays made of steel can undergo automated cleaning and disinfection when loaded. Make sure the implant trays have been properly sealed with their lid prior to automated cleaning/disinfection

7 INSPECTION AND MAINTENANCE

7.1 Inspection

In general sufficient cleanliness is the basic requirement for a successful sterilization.
Before the products are packaged for sterilization they have to be inspected visually. (Recommendation: use working place light fixtures ideally with magnifiers).

Instrument Inspection
Check **all instruments** after cleaning and disinfection for damage and function. For checking the function multi-part instruments have to be assembled ("Assembly/Disassembly Instruction"). Check the instruments for damages as e.g. for:

- corrosion
- damaged surfaces
- fissures
- chipping
- other abrasion
- contamination
- functionality

If the products are still contaminated they have to go through the entire cleaning and disinfection process again.

In case of damage the instruments must be exchanged!

Options for parts showing signs of corrosion, annealing colors and/or water spots:
Instruments that show inacceptable signs of corrosion, annealing colors and/or water spots may be treated using an acidic cleaning concentrate for stainless steel surgical instruments such as Borer Chemie 34GR. When doing so, the instructions of the cleaning agent must be followed. Be advised that such cleaning agents can only be used on instruments that do not contain any aluminum components.

The appendix provides sample photos for damaged and/or contaminated products.

During inspection the following aspects have to be considered in particular:

- thoroughly inspect **critical parts** such as handle structures, articulated instruments, cavities, cannulated products etc. in particular
- instruments with **lumina** and cannulated products (e.g. cannulated drills) have to be checked for free passage without obstructions Products without free passage/ obstructions have to be reprocessed. Damaged instruments have to be exchanged!
- **cutting instruments** (e.g. drills) have to be checked for sharpness and damages. Worn or damaged instruments must be exchanged!
- **rotating instruments** (e.g. drills) have to be checked additionally for bending. This can easily be done by rolling the rotating instrument on a flat surface. Bent rotating instruments have to be exchanged!

Implant Inspection
Before assigning the **implants** to the implant containers or implant trays, check them **all** after cleaning and disinfection for damages and contaminations.

The appendix provides sample photos for damaged and/or contaminated implants.

Tray Inspection
Check **all the trays** after cleaning and disinfection for damages and function. For checking the function multi-part trays have to be assembled.

Check the trays for:

- corrosion
- damaged surfaces
- fissures
- chipping
- other wear
- contamination
- functionality

Where contaminations remain, the products have to go through the complete cleaning and disinfection process again.

In case of damage the products have to be exchanged!

The appendix provides sample photos for damaged and/or contaminated trays.

During inspection the following aspects have to be considered in particular:

- thoroughly inspect critical parts such as handle structures, articulated parts, cavities, cannulated parts etc. in particular
- insure the correct and safe fitting of the lid on the tray or respective container

7.2 Care and Maintenance

In general the care and maintenance procedure has to be carried out prior to functional inspection.

Assemble the disassembled instruments and trays again ("Assembly/Disassembly Instructions"). Correct assembly is an absolute requirement to avoid damages and/or compromised functionality.

Carefully apply maintenance products to the articulations, closures or threads and sliding surfaces e.g. sissors, clamps, etc. This is a preventative action to avoid fretting corrosion.

Consider the following aspects with respect to maintenance products:

- use of paraffin-based/white oil-based products
- biocompatibility
- the products are steam-sterilizable and steam-permeable
- products containing silicone must not be used (may cause stiffness)

Process

- Apply maintenance products carefully to the articulations, closures or threads and sliding surfaces.
- Disperse the maintenance products throughout by moving the articulating/sliding surfaces.
- Remove remaining maintenance products residues with a lint-free cloth.

In the case of damage or reduction of functionality of the instruments, they have to be exchanged (see also chapter 7.1 "Control").

8 PACKAGING

Medartis recommends sterilizing the products in the specially designed sterilization containers, implant containers and

instrument trays.

Also single sterilization wrapping (single or double wrapping) and/or other sterilization containers can be used.

If the total weight of the loaded module is over 10 kg, the module must not be sterilized in a sterilization container; rather, wrap it in sterilization paper and sterilize it in the latest manner using the approved methods.

The following requirements must be fulfilled:

- Accord with EN ISO 11607/EN 868-3 to 10 (so far EN 868; ANSI/AAMI/ISO 11607)
- Ability for steam sterilization
- Sufficient protection of the implants and instruments respectively the sterilization packaging from mechanical damage
- Regular maintenance of the sterilization containers according to the insructions of the manufacturer

9 STERILIZATION

For the following sterilization process the disassembled instruments and trays are assembled.

For the sterilization process the instructions of the appropriate sterilizers have to be followed.

Steam Sterilization
All NON-STERILE products can be sterilized in an autoclave. The autoclaves must be in accordance with EN285 respectively EN13060 regarding validation, servicing, maintenance and controlling.

For both initial and subsequent sterilization, the following parameters were validated by Medartis in accordance with the requirements of the current sterilization standards, EN ISO 17665 and ANSI/AAMI ST79.

Procedure	Fractionated and dynamic prevacuum process	Flow and gravitation processes
Exposure time	≥ 4 min	≥ 15 min.
Temperature	132°C/134°C	132°C/134°C
Drying time	> 20 – 30 min.	> 20 – 30 min.

Medartis recommends that sterilization is performed in accordance with the above validated processes. If the user utilizes other processes (e.g. flash sterilization), these must be validated by the user. The ultimate responsibility for validation of sterilization techniques and equipment lies with the user.

Outside the USA: the sterilization time can be extended to 18 minutes to meet the recommendations of the WHO and the Robert Koch Institut (RKI). Medartis products are designed for these sterilization cycles.

Do not use hot-air sterilization, radiation sterilization, formaldehyde sterilization, ethylene oxide sterilization or substitute procedures for sterilizing thermolabile products such as plasma or peroxide sterilization for Medartis products.

10 STORING

After sterilization, the products must be stored in a dry and dust-free environment. Temperature variations have to be avoided to prevent corrosive damages.
The maximum storage time is dependent on different factors such as packaging, methods of storing, environment and handling. The user should define a maximal storage time for sterile products until use. Within this defined time the products have to be used or reprocessed again.

11 SYMBOLS

	Consult instructions for use
	Article number / Order number
	Lot number
	Serial number
	Do not use if packaging is damaged
	Medical device
	Non-sterile
	Single-use product. Do not reuse The product is intended for one single application in a single patient. Application of an already used product may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury.
	Do not resterilize Resterilization can result in implants not being sterile, and/or not meeting performance specifications and/or altered material properties. Resterilization may also compromise their structural integrity and/or lead to failure.

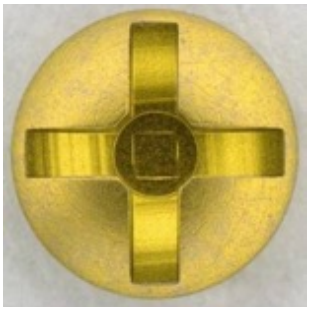
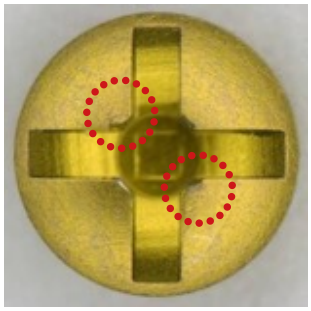
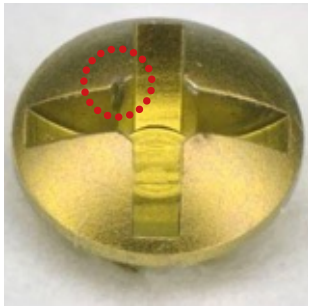
STERILE R	Sterile product. Sterilized using irradiation The product has been subjected to a validated irradiation sterilization process and is supplied in sterile packaging. Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use any product where the sterile packaging has been opened or damaged and do not remove them from the packaging until immediately before use. Once the sterile packaging has been opened, the product cannot be resterilized. Sterility of the device must be ensured at all times. The device is for single-use only and may not be reused under any circumstances. Reuse or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury.
 YYYY-MM-DD	Use by date
 YYYY-MM-DD	Manufacturer Date of manufacture
 YYYY-MM-DD	Date of manufacture
	Conditionally MR safe
EC REP	Authorized representative
	Importer
	TriLock plates (locking)
	HexaDrive
	Self-drilling screws
CE 0197	Applies only to EC risk class I devices in sterile condition, I devices with a measuring function, I reusable surgical instruments, IIa and IIb devices.
CE	Applies only to EC risk class I devices.

APPENDIX

Contents

1 Screws

1.1 Picked-up or used (cross recess)

			
✓	✓	✗	✗

Possible damage

– Screws which have already been picked up show deformation on the self-locking contour (red circle)

Measures

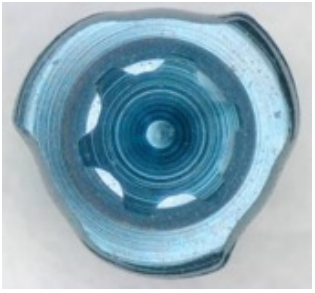
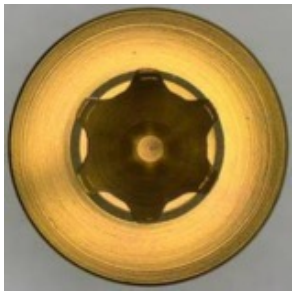
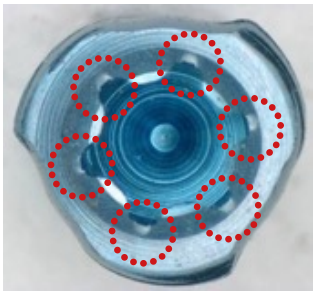
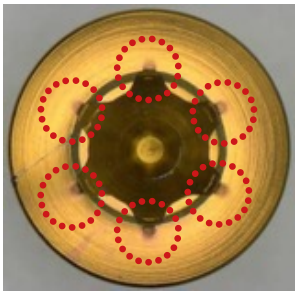
– Never place screws back in the set which show deformation either on the screw head or thread. They may not perform as intended

– At inspection of the sets take out screws that show deformation

Unacceptable screws

							
✗	✗	✗	✗	✗	✗	✗	✗

1.2 Picked-up or used (HexaDrive)

			
✓	✓	✗	✗

Possible damage

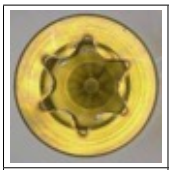
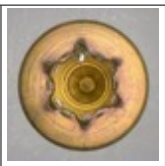
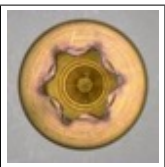
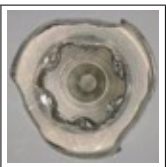
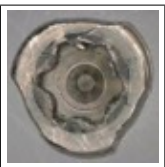
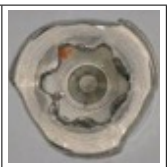
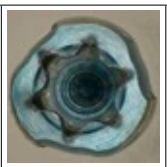
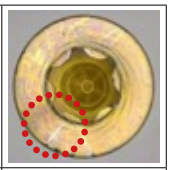
– Screws which have already been picked up show deformation on the self-locking contour (red circle)

Measures

– Never place screws back in the set which show deformation either on the screw head or thread. They may not perform as intended

– At inspection of the sets take out screws that show deformation

Unacceptable screws

							
✗	✗	✗	✗	✗	✗	✗	✗

1.3 Locking contour screw head

			
✓	✗	✗	✗

Possible damage

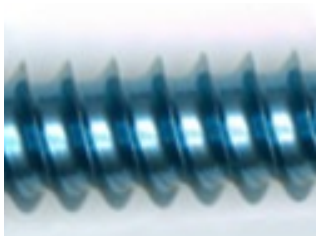
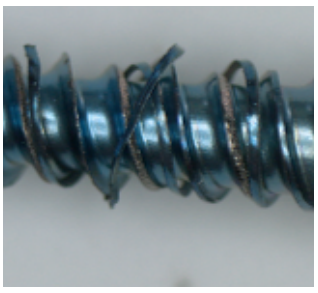
– Screws which have already been placed into a plate hole show deformation on the outer screw head. In general the lead-in grooves are damaged, show deformation and the anodization at that area is no longer existing

Measures

– Never place screws back in the set which show deformation either on the screw head or thread. They may not perform as intended

– At inspection of the sets take out screws that show deformation

1.4 Thread

			
✓	✗	✗	✗

Possible damage

– Burr formation at threads

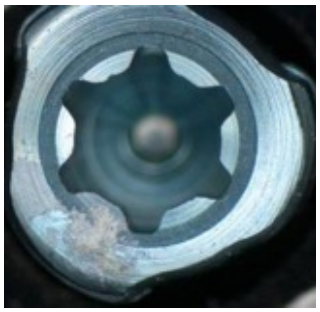
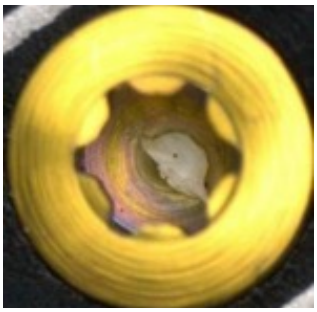
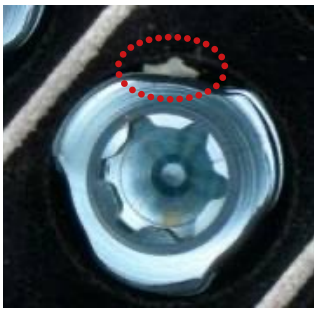
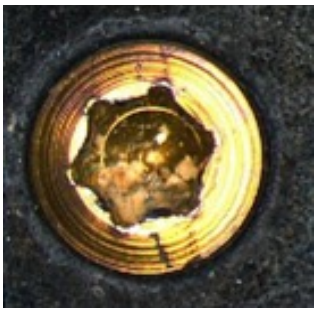
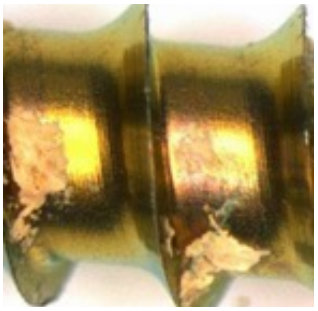
– Chip formation

Measures

– Never place screws back in the set which show deformation either on the screw head or thread. They may not perform as intended

– At inspection of the sets take out screws that show deformation

1.5 Contamination/residues

			
✗	✗	✗	✗
			
✓	✗	✗	✗

Possible damage

Screw is contaminated with:

– Blood

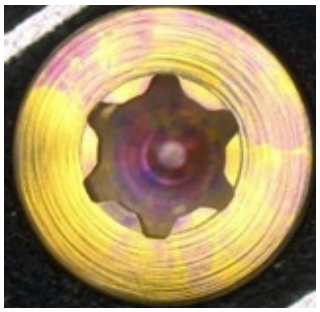
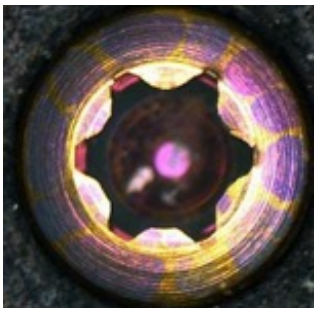
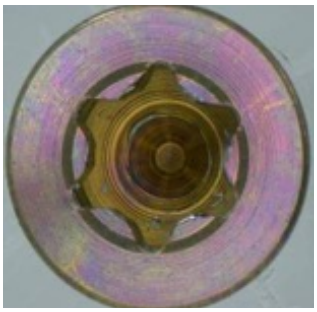
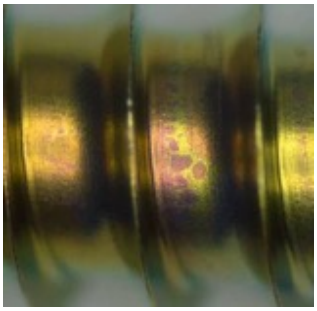
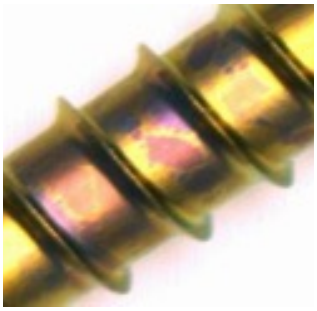
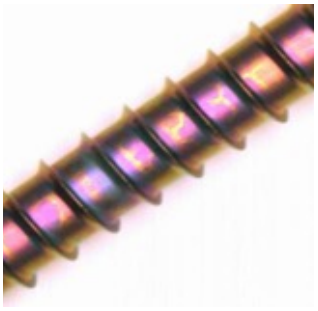
– Bone

– Other residues

Measures

– At inspection of the sets take out screws that show contamination

1.6 Discoloration

			
✓	✓	✓	✓
			
✓	✓	✓	✓

Possible damage

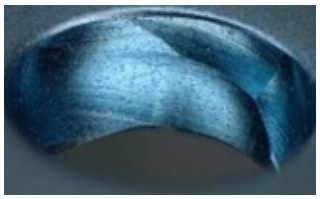
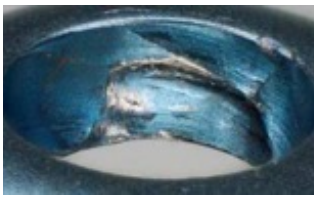
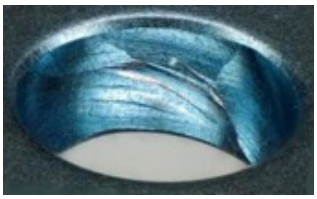
– None

Measures

– A discoloration or color change has no adverse effects on the implant or its function. The protective oxide layer is fully maintained

2 Plates

2.1 Locking contour plate hole

			
✓	✗	✗	✗

Possible damage

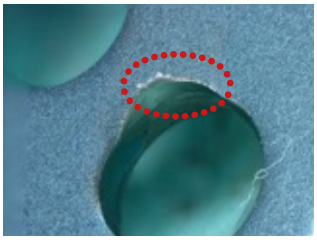
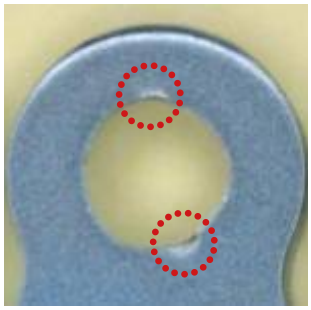
– Plate hole shows scratches, deformation and/or blank areas

Measures

– At inspection of the sets take out plates that show deformation

– Inspection recommendation: position the plate in a slightly inclined position under the microscope in order to achieve an optimal view into the locking contour of the plate hole

2.2 Surface bottom of plate

			
✓	✓	✗	✗

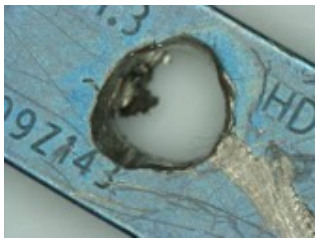
Possible damage

– Bottom of the plate hole shows deformation (red circle)

Measures

– At inspection of the sets take out plates that show deformation

2.3 Modification of product shape/form by user

	
✘	✘

Possible damage

Non compliant change of the plate design:

– Milling off the plate surface

– Drilling additional hole(s)

– Other changes to design

Measures

– At inspection of the sets take out plates that show deformation or other customer specific changes

2.4 Decoloration due to bending

		
✘	✘	✘

Possible damage

– Additional bending of an anatomically pre-shaped plate

Measures

– At inspection of the sets take out plates that show deformation

– A discoloration or color change has no adverse effects on the implant or its function. The protective oxide layer is fully maintained

2.5 Decoloration due to cleaning

		
✓	✓	✓

Possible damage

– None

Measures

– A decoloration or color change has no adverse effects on the implant or its function. The protective oxide layer is fully maintained

2.6 Discoloration

		
✓	✓	✓

Possible damage

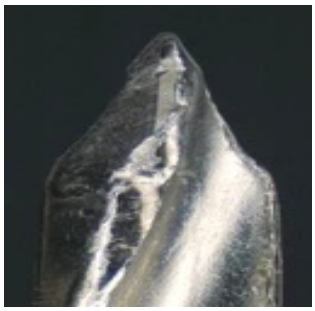
– None

Measures

– A discoloration or color change has no adverse effects on the implant or its function. The protective oxide layer is fully maintained

3 Drills

3.1 Tear and wear of the cutting edges

			
✓	✗	✗	✗

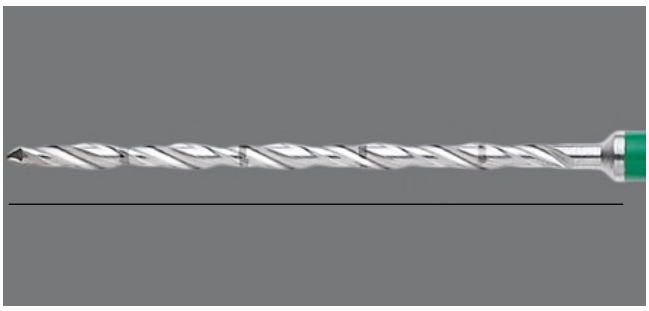
Possible damage

– Drill is blunt

Measures

– At inspection of the sets take out damaged/blunt drill bits

3.2 Bent spiral

	
✓	✗

Possible damage

– Bent spiral

Measures

– At inspection of the sets take out damaged/bent drill bits

3.3 Damaged spiral

			
✓	✗	✗	✗

Possible damage

– Damages to the spiral

Measures

– At inspection of the sets take out damaged/bent drill bits

3.4 Untwisted spiral

			
✓	✗	✗	✗

Possible damage

– Untwisted spiral

Measures

– At inspection of the sets take out damaged/untwisted drill bits

3.5 Contamination/residues

		
✓	✗	✗

Possible damage

Drills are contaminated with:

– Blood

– Bone

– Other residues

Measures

– At inspection of the sets take out damaged/contaminated drill bits

3.6 Color coding

			
✓	✗	✗	✗

Possible damage

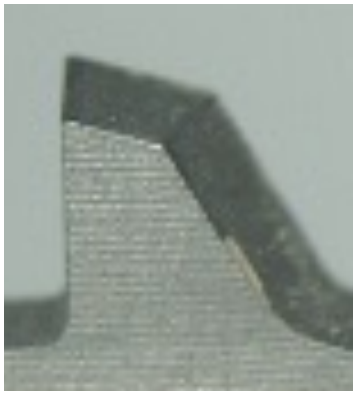
– Color coding damaged or lost

Measures

– At inspection of the sets take out drill bits with damaged color coding

4 MTP Reamers

4.1 Tear and wear of the cutting edges

	
	
✓	✗

Possible damage

– Reamer is blunt

Measures

– At inspection of the sets take out damaged/blunt MTP reamers

5 Screwdriver

5.1 Screwdriver blade tip

			
✓	✓	✗	✗

Possible damage

– Tip deformed

– Tip broken

Measures

– At inspection of the sets take out damaged blades

5.2 Damaged screwdriver blades

			
✓	✗	✗	✗

Possible damage

– Crack in shaft

– Broken shaft

Measures

– At inspection of the sets take out damaged blades

5.3 Compromised screwdriver blade/handle connection

	
✓	✗

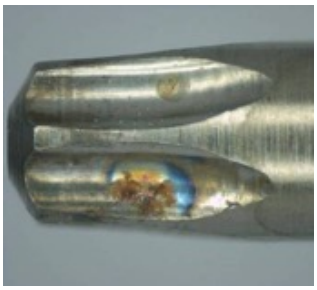
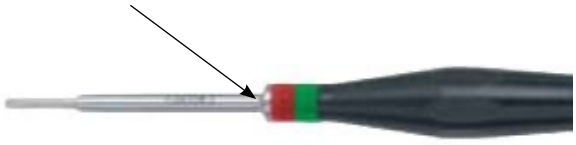
Possible damage

– Connection between handle and blade is damaged

Measures

– At inspection of the sets take out damaged products

5.4 Contamination/residues

		
✓	✗	✗
		
✓	✗	✗

Possible damage

Screwdriver blade is contaminated with:

– Blood

– Bone

– Other residues

Measures

– At inspection of the sets take out contaminated screwdrivers and blades

5.5 Damaged quick coupling handles

		
✓	✗	✗

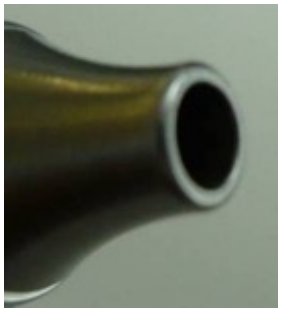
Possible damage

– Flexibility of coupling piece impaired or restricted

Measures

– At inspection of the sets take out damaged handles

5.6 Damaged quick coupling instruments

			
✓	✓	✗	✗

Possible damage

– Deformation of blade coupling

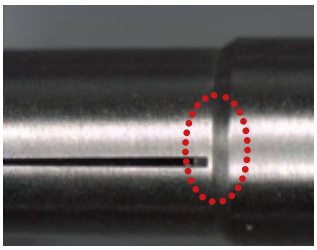
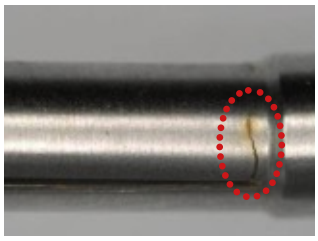
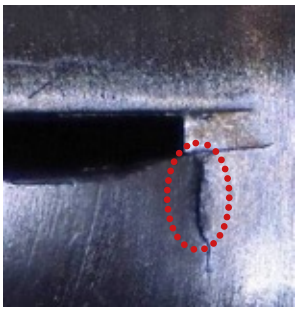
– Blade may not be inserted into handle

Measures

– At inspection of the sets take out damaged handles

6 Tension Pliers

6.1 Lamella broken, bent or cracked

			
✓	✓	✗	✗

Possible damage

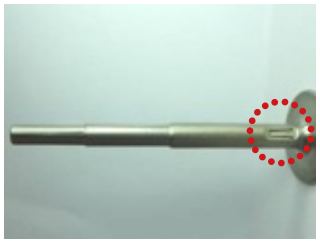
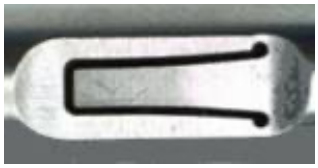
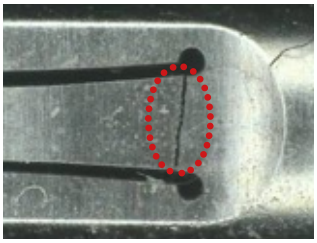
– Crack on lamella

– Lamella broken

Measures

– At inspection of the sets take out damaged products

6.2 Clip broken, bent or cracked

			
✓	✓	✗	✗

Possible damage

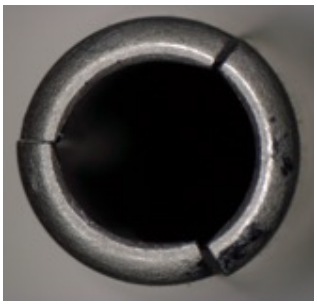
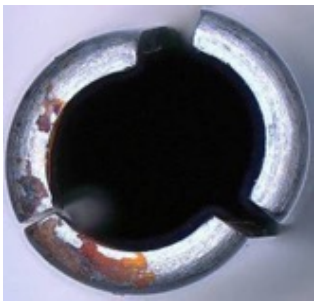
– Crack on clip

– Clip broken

Measures

– At inspection of the sets take out damaged products

6.3 Bent and/or contaminated lamella

	
✓	✗

Possible damage

– Lamella bent outwards

Lamellas contaminated with:

– Blood

– Bone

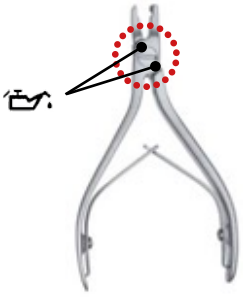
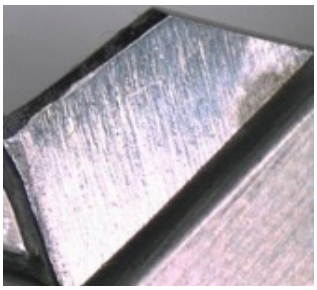
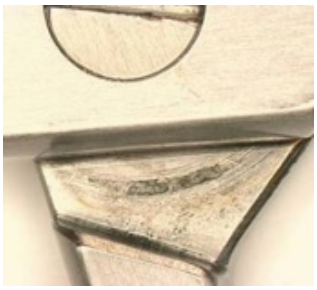
– Other residues

Measures

– At inspection of the sets take out damaged and/or contaminated products

7 Pliers

7.1 Blocked joint

			
✓	✓	✗	✗

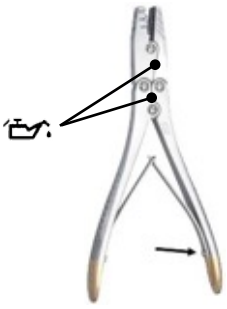
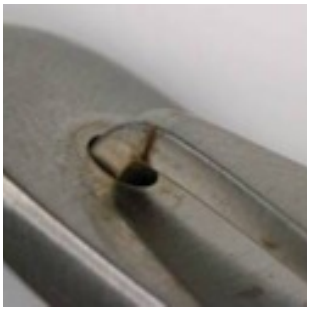
Possible damage

– Pliers are blocked

Measures

– At inspection of the sets take out damaged and/or contaminated products

7.2 Spring broken

			
✓	✓	✗	✗

Possible damage

– Pliers are blocked

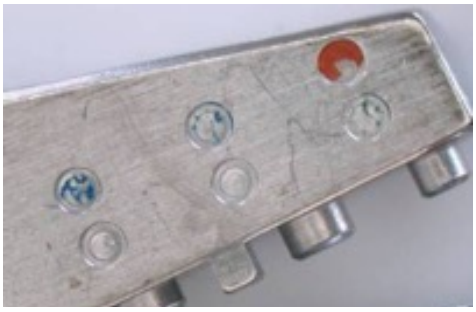
– Spring with cracks

– Spring has broken

Measures

– At inspection of the sets take out damaged and/or contaminated products

7.3 Lost color coding

	
✓	✗

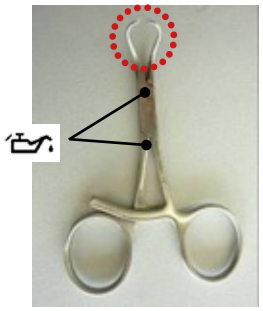
Possible damage

– Color coding damaged or lost

Measures

– At inspection of the sets take out damaged and/or contaminated products

7.4 Deformed forceps tips

			
✓	✓	✗	✗

Possible damage

– Tips deformed or damaged

Measures

– At inspection of the sets take out damaged and/or contaminated products

8 K-Wire Dispenser

8.1 Contamination/residues

		
✓	✗	✗
		
✓	✗	✗

Possible damage

K-wire dispenser is contaminated with:

– Blood

– Bone

– Other residues

Measures

– At inspection of the sets take out damaged and/or contaminated products

9 Depth Gauge

9.1 Needle broken, bent or damaged

			
✓	✗	✗	✗

Possible damage

– Needle bent or broken

– Instrument bent, distorted

Measures

– At inspection of the sets take out damaged and/or contaminated products

9.2 Contamination/residues

	
✓	✗

Possible damage

Depth gauge is contaminated with:

– Blood

– Bone

– Other residues

Measures

– At inspection of the sets take out damaged and/or contaminated products

10 Saw Guide

10.1 Damaged saw guide

			
✓	✗	✗	✗

Possible damage

– Damaged or contaminated screw guidance and/or incision

– Saw guide is contaminated with:
  - Blood
  - Bone
  - Rust
  - Other residues

Measures

– At inspection of the sets take out damaged and/or contaminated saw guides

11 Orbital Retractors

11.1 Shaped and/or used

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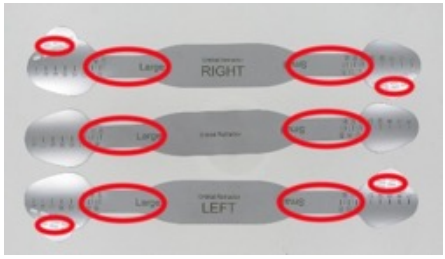
<td rowspan="2"> 
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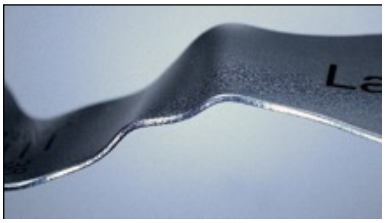
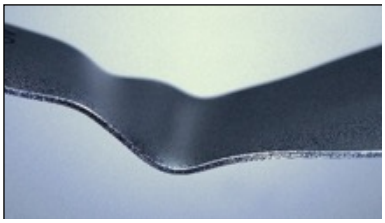
<td>  </td>
<td>  </td>
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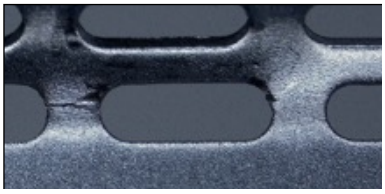
<td>  </td>
</tr>
<tr>
<td>✓</td>
<td>✗</td>
<td>✗</td>
</tr>
</table>

Possible damage

– The bar of the retractor shows deformations

– The perforated areas (shaped areas) of the retractor show cracks and/or are broken

Measures

– At inspection of the sets take out damaged retractors and/or retractors showing deformations

12 Temporary Locking Stopper for TriLock Screws

12.1 Bent and/or used

<table>
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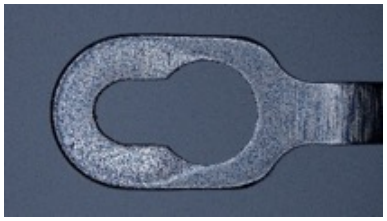
<td> 
 

 
</td>
<td> 
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<td>  </td>
</tr>
<tr>
<td>✓</td>
<td>✘</td>
<td>✘</td>
</tr>
</table>

Possible damage

– Cracks in the bend of the handle

– Deformations on the surface for tightening

Measures

– At inspection of the sets take out damaged products

13 Instruments in General

13.1 Decoloration/surface damages

			
✓	✗	✗	✗

Possible damage

– Anodized surface decolored

– Surface scratched

Measures

– At inspection of the sets take out damaged and/or contaminated products

13.2 Corrosion spots

		
Corrosion spots before cleaning	✓ After cleaning	✗ Aggressive cleaning

Possible damage

– Superficial corrosion spots on instruments

Measures

– Superficial corrosion on instruments can be removed by careful cleaining with abrasive pads (very fine/super fine 3M Scotch-Brite) or using an acidic cleaning concentrate for stainless steel surgical instruments such as Borer Chemie 34GR

– No cleaning of the instruments with abrasive or aggressive cleaning agents. They will merely damage the surfaces and possibly remove important information

14 Container

14.1 Decoloration/surface damage

			
✓	✗	✗	✗

Possible damage

– Surfaces decolored, damaged or scratched

– Marking no longer readable

Measures

– At inspection of the sets take out damaged and/or contaminated products

14.2 Damaged/broken welding seams

		
✓	✓	✗

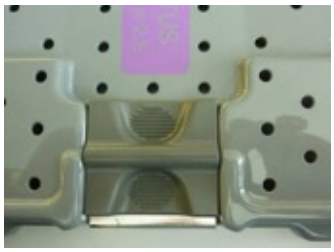
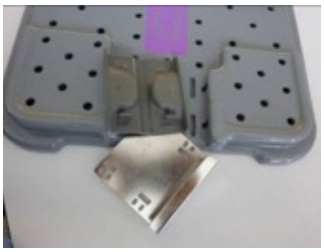
Possible damage

– Welding seams of the container are damaged/broken

Measures

– At inspection of the sets take out damaged and/or contaminated products

14.3 Damaged/broken lids

		
✓	✓	✗

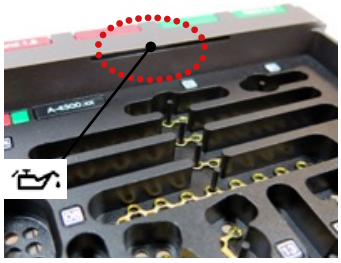
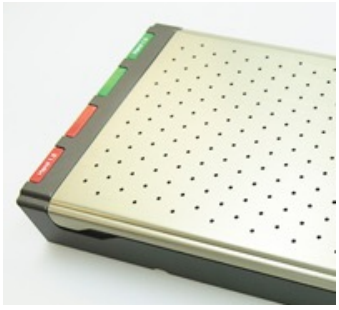
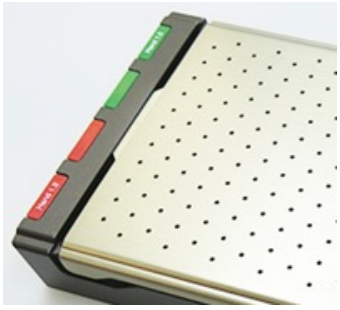
Possible damage

– Broken handles

Measures

– At inspection of the sets take out damaged and/or contaminated products

14.4 Jamming/blocked lids

		
✓	✓	✗

Possible damage

– Lids cannot be mounted on the container

Measures

– Lubricate spherical pressure piece

15 Symbol Annotation

 Instruments must be lubricated during reprocessing, refer to Instructions for Use

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