IMPORTANT INFORMATION

- GENERAL INFORMATION
- INSTRUCTIONS FOR REPROCESSING AND STERILIZATION
- ASSEMBLY INSTRUCTIONS
- FUNCTIONAL CONTROL
- END-OF-LIFE CRITERIA

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This document, "Important information", provides general information and instructions on the reprocessing and sterilization of medical devices for the company *aap* Implantate AG and should be used together with the corresponding, device-specific Instructions for Use. The document also contains instructions on disassembly and criteria by which the user can determine the end of the life cycle.

1. GENERAL INFORMATION ON THE USE OF IMPLANTS

This general information relates exclusively to medical devices sold by the company *aap* Implantate AG. Devices in the above-mentioned sense are the implants and instruments that are needed for an operation.

1.1 DEVICE DESCRIPTION

The devices are used for the temporary fixation of bone fragments for bone healing until osseous consolidation. Implants are intended for single use on human bone.

Single-use devices  "Do not re-use"

All devices labeled  "Do not re-use" are intended exclusively for single use. Re-use of these devices is excluded.

If the devices are to be reprocessed, the function and integrity of the devices may be impaired and/or the device may fail. In addition, it may lead to injury, disease or death of the patient. The risk of contamination of clinically reprocessed or reused disposable products is increased, and pathogen transfer from patient to patient may occur. Even apparently undamaged, used single-use devices may not be reused as invisible signs of wear and/or contamination may be present.

⚠ Warning
- Implants and wire devices by *aap* are single-use devices. Re-use is excluded by *aap*. Processing of used implants and implants that have already come into contact with bodily fluids is strictly prohibited. Please ensure that they are disposed of appropriately (see Chapter 1.5 Disposal).

Reusable non-sterile devices

All devices that are delivered non-sterile and are <u>not</u> marked with the symbol  (see the section on single-use devices) are considered to be reusable, non-sterile devices. They must be reprocessed both before the first and each subsequent use, and before disposal or submission for damage assessment.

Reprocessing consists of several mandatory steps which are described in detail in Chapter 2. Thorough cleaning (manual and/or automated) is an important part of the reprocessing process which must be carried out before sterilization. The efficacy of the sterilization process may be reduced by organic substance residues and/or an increased number of microorganisms on the device. The person responsible for the reprocessing is responsible for ensuring that the reprocessing actually performed with the equipment, materials and personnel used achieves the desired result. To achieve this, validation and routine inspections of the process on site are required.

aap is not liable for failures to comply with this information on reprocessing the devices.

⚠ Warning
- Reusable products can wear out as a result of use and lose their function. The integrity of the devices must therefore be checked before each use (see Chapter 5.1 and Chapter 5.2). Worn out or functionally impaired devices must be disposed of immediately

⚠ Precaution
- Influences of the reprocessing which lead to damage to the product are not known. End of life of a device is normally determined by wear and damage due to use. A careful visual and functional inspection before the next use is the best way of identifying a device that is no longer functional (see Chapter 5.1 and Chapter 5.2).
- *aap* does not accept any liability for damage caused by a lack of or by irregular checks on the devices, in particular the drill.

Sterile devices

Sterile *aap* devices are sterilized with gamma radiation. The packaging system consists of a sterile barrier system (double packaging) in protective packaging. The protective packaging contains labels which can be used for patient documentation to ensure the traceability of the devices.

Storage and shipping conditions:

Type	Condition	Temperature range	Humidity	Max. duration
Sterile packed devices	Shipping	0 °C to 60 °C	< 70%	6 days
	Storage	15 °C to 23 °C	< 70%	until the expiration date*

* If the storage conditions indicated are exceeded, a time-bound upper limit equivalent to the shipping conditions applies: Temperature range 0 °C to 60 °C with maximum humidity of 70% for a maximum of 3 whole days.

Sterile packed devices must be stored in their sealed original packaging. They should be stored protected from dust and in a clean, dry place out of direct sunlight. Opening the protective packaging (breaking the seal) is deemed to be equivalent to using the contents. The expiration date must always be checked before the packaging is opened. If the expiration date has passed, the devices should not be used.

The sterile barrier must be checked for defects before opening. If defects of any kind in the sterile barrier or the device are identified, the devices should not be used. Sterility is only ensured by undamaged packaging. The sterile devices may only be unpacked in the context of the surgery using aseptic methods that take into account the relevant specifications of the clinic. After unpacking, the devices should undergo visual inspection. Devices with defects of any kind must be disposed of.

1.2 MATERIAL AND MATERIAL RESISTANCE

All implants by *aap* are made of titanium grade 4, titanium grade 2 (ASTM F67, ISO 5832-2) or a titanium alloy TiAl6V4 (ASTM F136, ISO 5832-3). The titanium materials used are corrosion-resistant and biocompatible. K-wires are made of stainless steel (ASTM F138, ISO 5832-1) or a titanium alloy TiAl6V4 (ASTM F136, ISO 5832-3). K-wires made of the titanium alloy are subsequently yellow anodized. Instruments are made of stainless steel, titanium alloy TiAl6V4 (ASTM F136, ISO 5832-3), PEEK, PEEK CA30 or propylux (black and yellow).

1.3 REMOVAL OF THE INSTRUMENT OR OF INSTRUMENT FRAGMENTS

The *aap* instruments are designed to be safe for the mechanical loads that occur for the range indicated. If an *aap* instrument breaks during use, a medical imaging device (e.g. radiation device, CT etc.) should be used to locate the components or fragments.

1.4 SERIOUS INCIDENTS

In the event of incidents with *aap* devices, these must be reported immediately via *incident@aap.de* and to the competent authorities of the member state where the user is situated. The devices involved must be secured for further testing. *aap* will not accept the return of other implants used.

1.5 DISPOSAL

The devices must be disposed of as medical devices in line with the facility's processes and the national regulations.

⚠ Warning

- It is essential that devices are reprocessed before disposal.
- Sharp and pointed devices must be disposed of in a safety container. The use of specially sealable containers and the application of protective caps is recommended.
- Sharp edges and pointed ends must be checked particularly carefully on the devices to avoid injuries and contamination.

2. REPROCESSING OF DEVICES

2.1 GENERAL PRINCIPLES

The devices are marketed by *aap* in non-sterile and sterile condition and are labeled accordingly. *aap* devices delivered non-sterile must be cleaned, disinfected, and then steam sterilized before surgical use; this also applies to the first use after delivery (after removal of the protective transport packaging).

In order to ensure that the value of the devices is maintained, this reprocessing recommendation and the relevant national laws and standards must be complied with. Any packaging elements must be removed from the device before cleaning and sterilization (cardboard packaging, packaging foam, tubular film, blister packs, protective caps, holding devices etc.).

⚠ Precaution

- Trays by *aap* are intended for the sterilization, transport and storage of devices. They are not intended for cleaning and disinfection when filled. The devices must be removed from the trays and cleaned and disinfected separately.

When removing devices from the package always check for device integrity and that implant type and size match the specifications on the printed label.

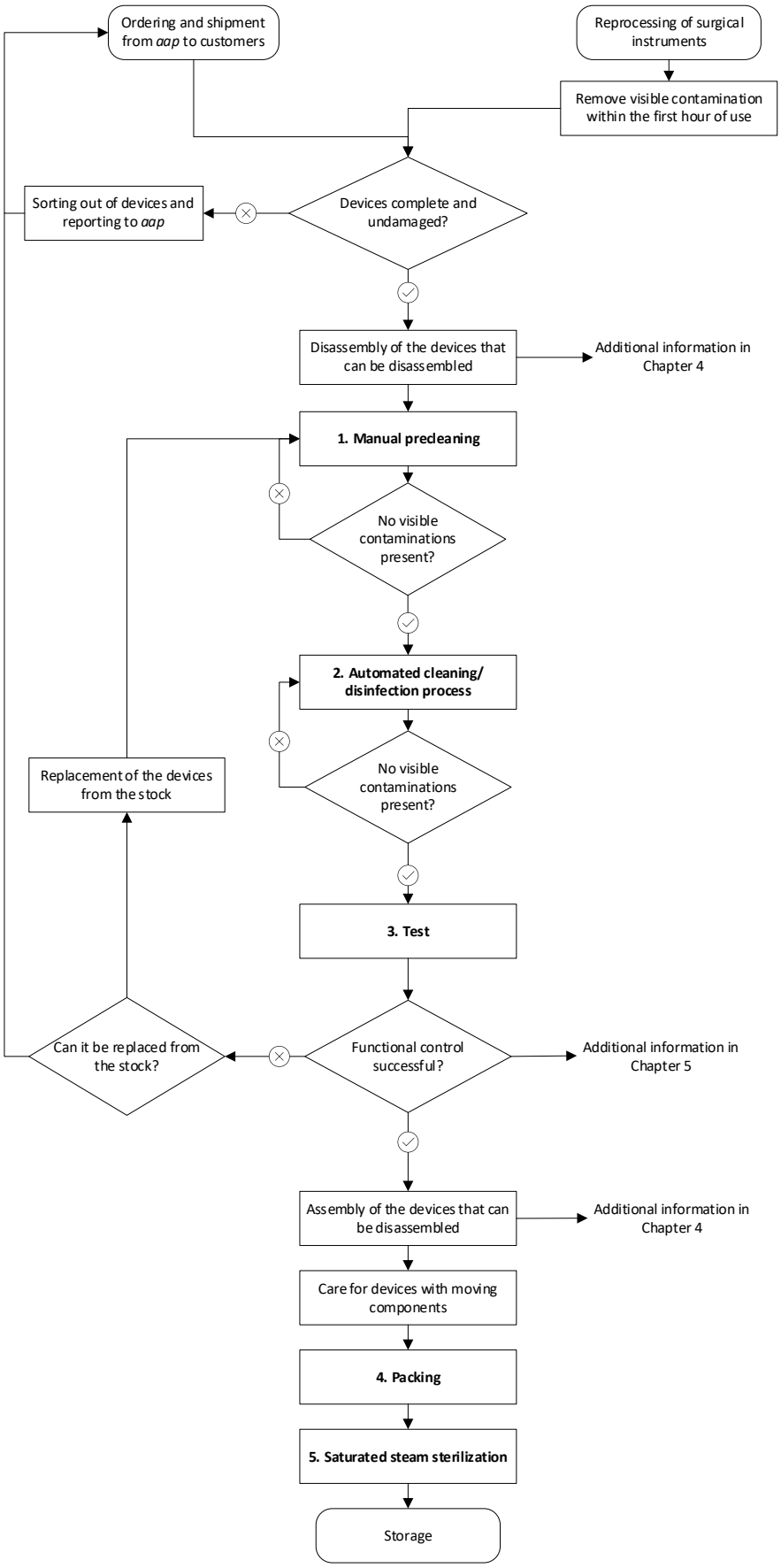
The following guidelines should be followed when selecting cleaning agents and disinfectants:

Material	Not recommended for the material:
Titanium and titanium alloy	All oxidizing acids (e.g. nitric acid, hydrogen peroxide (H2O2), oxalic acid, acidic sulfur)
Stainless steel	Hydrogen peroxide (H2O2), oxalic acid with increased chlorine concentration
Color marking	Excessive concentrations of cleaning agents and disinfectants with all oxidizing acids (e.g. nitric acid, hydrogen peroxide (H2O2), oxalic acid, acidic sulfur)

When selecting the cleaning program during an automated cleaning/disinfection process, consider the material of the medical devices to be cleaned and follow the appliance manufacturer's instructions.

2.2 REPROCESSING

aap recommends the following procedures and their parameters as well as the following sequence:



2.2.1 MANUAL PRECLEANING

- Visible contamination must be removed within the first hour of using the devices.
- Disassemble the devices that can be disassembled. Further information on disassembling multi-component instruments can be found in Chapter 4
- Sliding shaft instruments must be fully opened and scissors and forceps opened to a 90° angle in order to clean as much of the hidden surfaces as possible.
- The devices must be put into cold water and brushed under the surface of the water using a cleaning brush (e.g. Interlock, REF 09098) until the surface is visibly clean.
- Instruments with cavities must be cleaned for two minutes with a round brush that is the right size for the lumen. This step should be repeated three times.
- *aap* recommends using ultrasonic bath treatment for coarse soiling.
- In addition, a syringe or high-pressure water gun should be used to rinse cavities, blind holes, notches and channels with cold tap water for at least 30 seconds. Contact between devices and the syringe or high-pressure water gun should be avoided to rule out scratches.
- Carry out a visual inspection of the device and repeat the precleaning as required until no further visible impurities can be identified.
- Let the devices drain and go on to the next cleaning step.

2.2.2 AUTOMATED CLEANING/DISINFECTION PROCESS

It is essential that the cleaning and disinfection device has proven efficacy (FDA approval or CE mark according to ISO 15883)

- When selecting the cleaning program, it is necessary to consider the material of the medical devices to be cleaned and the appliance manufacturer's instructions.
- The disassembled instruments must remain disassembled for the subsequent cleaning and disinfection process.
- Devices must be inserted into the appliance in such a way as to ensure that they are rinsed through.
- It is necessary to rinse for at least 60 seconds in cold tap water.
- It is then necessary to clean for 10 min with "Neodisher® MediClean forte" (Dr. Weigert) at a dosage of 5 ml/l deionized water (pH >10.0 to 11.5) at 55 °C.
- It is necessary to rinse for at least 60 seconds in cold, deionized water.
- Thermal disinfection should be carried out according to the A_0 concept in accordance with DIN EN ISO 15883-1 with deionized water (according to the recommendation by the KRINKO Commission at the Robert Koch Institute the A_0 value should be 3000).
- Drying should be carried out automatically at 110 °C for at least 20 minutes.
- Carry out a visual inspection of the device and repeat the cleaning as required until no further visible impurities are present.

Phase	Temperature	Duration	Description
Precleaning	cold (T <40°C)	1 min	Tap water
Cleaning	55 °	10 min	Neodisher® MediClean forte (Dr. Weigert) 5 ml/l deionized water (pH >10.0 to 11.5)
Rinsing	Cold (T <40°C)	1 min	Deionized water
Thermal disinfection	>90°C	5 min	to be carried out with deionized water according to the A_0 concept in accordance with DIN EN ISO 15883-1 (According to the recommendation by the KRINKO Commission at the Robert Koch Institute the A_0 value should be 3000).
Drying	110 °	20 min	automated

2.2.3 INSPECTION

- Once the cleaning and disinfection cycle is complete, the devices must be cooled to room temperature.
- The presence of residue and residual moisture should be excluded during the visual inspection of the critical places (cavities, blind holes, notches and channels).
- Carry out a visual inspection of the device and repeat the cleaning as required until no further visible impurities are present.
- Take actions to prevent further contamination of the devices during the inspection.
- Disassembled instruments must be reassembled. For more details, see Chapter 4 Assembly and disassembly instructions.
- After reprocessing and before sterilization, check all devices for signs of end of life. Such as:
    - Damaged surfaces
    - Signs of corrosion
    - Illegible labeling and barcodes
    - Proper function. Disassembled devices must be reassembled for functional testing:

- Sharpness and damage to the cutting instruments (e.g. drill)
- Mobility of moving parts
- Bending and deformation of rotating devices (drills, K-wires).

- Damaged and defective devices should be rejected and replaced.
- Further information on functional control and signs of end of life can be found in Chapter 5 Life cycle/test catalog.

Maintenance:

- Instruments with movable components e.g. treads, joints etc. should be lubricated with medical white oil according to the pharmacopoeia after the cleaning and disinfection cycle.
- Implants and wire products may not be oiled.
- Apply the oil specifically to the joints and threads.
- Distribute the white oil evenly by moving the joints and treads.
- Remove excess white oil carefully

The following must be taken into account with care products:

- Biocompatibility
- Care products must steam sterilizable and permeable to vapor
- No care products containing silicone may be used

2.2.4 PACKING

- Devices with delicate working ends must be stored in suitable supports.
- The trays provided by *aap* should be used; otherwise, universal sterilization trays should be used in compliance with the manufacturer's instructions.
- The devices must be sufficiently well protected against mechanical damage.
- The packaging must meet the requirements of EN ISO 11607 and be suitable for steam sterilization.
- The packaging must prevent recontamination of the device during storage.

2.2.5 SATURATED STEAM STERILIZATION

For the USA: Only use FDA-approved sterilizers and FDA-approved sterilization accessories.

- The autoclave must meet the requirements of EN 285 and the sterilization process must be validated according to EN ISO 17665.
- The maximum permissible loading of the steam sterilizer must meet the manufacturer's specifications and may not be exceeded.
- Do not stack sterilization trays during sterilization.
- Cycle type: full cycle with fractionated pre-vacuum process
- Set points for the parameters:
  - Exposure temperature:
    - for the CE area: 134 °C (273 °F)
    - for the FDA area: 270 °F (132 °C)
  - Exposure time:
    - for the CE area: 5 minutes
    - for the FDA area: 4 minutes
  - Drying time: 20 minutes continuously or fractionated drying procedure

This information is provided without guarantee. The aforementioned instructions were validated by *aap* as suitable for the preparation of the devices for use to achieve an SAL value of 10^{-6} but cannot replace detailed process descriptions because it is impossible to provide a detailed description of the variety of reprocessing procedures used worldwide. The reprocessor is responsible for the desired result in the actual reprocessing using equipment, materials and personnel in the processing facility. To achieve this, validation and routine inspections of the process on site are required.

2.3 PACKAGING AND STORAGE

⚠ Precaution

- Devices with damaged packaging should not be used.
- Any elements that may affect the structure, functionality and device identification (e.g. unnecessary vibration, strain, moisture, heat and UV radiation) must be minimized by the user.

3. DEFINITION OF SYMBOLS

ISO 15223 medical devices – Symbols to be used with information to be supplied by the manufacturer

Symbol	Title/meaning of the symbols (reference number)
	Non-sterile (5.2.7)
	Date of manufacture (5.1.3)
	Manufacturer (5.1.1)
	Sterilization by gamma radiation (5.2.4)
	Do not resterilize (5.2.6)
	Use by date (5.1.4)
	Protect against moisture (5.3.4)
	Do not use if package is damaged (5.2.8)
	Number of devices
	Labeling for class Im or class IIa medical devices
	Labeling for class I and class Ir medical devices
	Do not re-use (5.4.2)
	Consult Instructions for Use (5.4.3)

 *ifu.aap.de*	Consult Instructions for Use (5.4.3) Instructions for Use available electronically
	Caution—refer to enclosed documentation (5.4.4)
	Catalogue number (5.1.6)
	Batch code (5.1.5)
	Temperature limit (5.3.7)
	Humidity limitation (5.3.8)
	Keep away from sunlight (5.3.2)
	Medical device (5.7.7)
	Double sterile barrier system (5.2.12)
	Material
	Sterilization indicator
	Caution: United States federal law restricts the sale of medical devices to sale by a physician or on prescription issued by a physician. (USA)

4. ASSEMBLY AND DISASSEMBLY INSTRUCTIONS

4.1 LIST OF DEVICES TO BE DISASSEMBLED

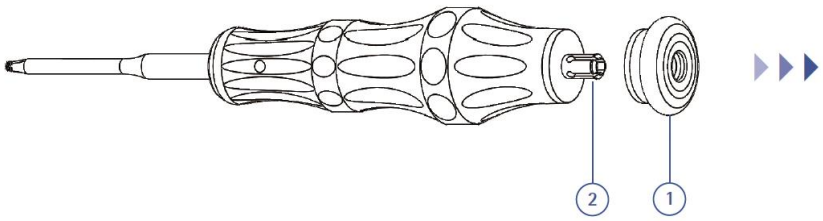
Item no.	Item name	Description of the (dis)assembly
IU 7808-00	Screwdriver T8, round handle	4.2.1 Screwdriver T8, round handle (IU 7808-00)
IS 7903-10	Depth gauge for screws ø2.7–3.5, up to L 50mm	4.2.2 Depth gauges for screws
IS 7903-20	Depth gauge for screws ø2.7, up to L 70mm	
IS 7903-30	Depth gauge for screws ø2.5, up to L 30mm	
IS 7903-40	Depth gauge for screws ø2.5, up to L 40mm	
IS 7904-20	Depth gauge for screws ø3.5–4.0, up to L 90mm	
IS 7905-20	Depth gauge for screws ø4.5–6.5, up to L 100mm	
IU 8116-50	Double drill guide ø2.5/3.5, with spring aided centering	4.2.3 Double drill guide
IU 8116-60	Double drill guide ø2.7/3.5, with spring aided centering	
IU 8117-50	Double drill guide ø3.2/4.5, with spring aided centering	
IU 8166-03	Load drill guide LOQTEQ® 3.5, adjustable up to 2mm	4.2.4 Load drill guide (IU 8166-0X)
IU 8167-03	Load drill guide LOQTEQ® 4.5, adjustable up to 2mm	
IU 8179-00	Aiming arm LOQTEQ® Distal Humerus 2.7	4.2.5 Aiming arm LOQTEQ® Distal Humerus 2.7 (IU 8179-00)
IU 7970-00	Angle gauge for closed wedge osteotomy	4.2.6 Angle gauge for closed wedge osteotomy
PA 3580-00-2	LOQTEQ® VA hinge for periprosthetics 3.5, 2 pcs. Titanium 6	4.2.7 LOQTEQ® VA hinge for periprosthetics (PA 3580-00-2)
IU 8172-10	Fixing screw for aiming device	4.2.8 Aiming device LOQTEQ®
IU 8172-11	Aiming device LOQTEQ® VA Radius 2.5, narrow R	
IU 8172-12	Aiming device LOQTEQ® VA Radius 2.5, narrow L	
IU 8172-21	Aiming device LOQTEQ® VA Radius 2.5, broad R	
IU 8172-22	Aiming device LOQTEQ® VA Radius 2.5, broad L	
IU 8172-31	Aiming device LOQTEQ® VA Radius 2.5, XL R	
IU 8172-32	Aiming device LOQTEQ® VA Radius 2.5, XL L	
IU 8173-01	Aiming device LOQTEQ® Proximal Lateral Tibia Plate 4.5, R	
IU 8173-02	Aiming device LOQTEQ® Proximal Lateral Tibia Plate 4.5, L	
IU 8174-01	Aiming device LOQTEQ® Distal Medial Tibia Plate 3.5, R	
IU 8174-02	Aiming device LOQTEQ® Distal Medial Tibia Plate 3.5, L	
IU 8174-03	Aiming device LOQTEQ® VA Distal Medial Tibia Plate 3.5, R	
IU 8174-04	Aiming device LOQTEQ® VA Distal Medial Tibia Plate 3.5, L	
IU 8176-01	Aiming device LOQTEQ® Proximal Humerus Plate 3.5	
IU 8176-03	Fixing screw aiming device LOQTEQ® SFI T15	
IU 8176-04	Fixing screw aiming device LOQTEQ® LFI T25	
IU 8177-01	Aiming device LOQTEQ® Dist. Medial Humerus Plate, R	
IU 8177-02	Aiming device LOQTEQ® Dist. Medial Humerus Plate, L	
IU 8177-03	Aiming device LOQTEQ® VA Dist. Medial Humerus Plate, R	

IU 8177-04	Aiming device LOQTEQ® VA Dist. Medial Humerus Plate, L	
IU 8178-01	Aiming device LOQTEQ® Olecranon Plate, R	
IU 8178-02	Aiming device LOQTEQ® Olecranon Plate, L	
IU 8181-03	Aiming device LOQTEQ® VA Distal Dorsolat. Humerus Plate, R	
IU 8181-04	Aiming device LOQTEQ® VA Distal Dorsolat. Humerus Plate, L	
IU 8182-01	Aiming device LOQTEQ® Distal Lateral Humerus Plate, R	
IU 8182-02	Aiming device LOQTEQ® Distal Lateral Humerus Plate, L	
IU 8182-03	Aiming device LOQTEQ® VA Distal Lateral Humerus Plate, R	
IU 8182-04	Aiming device LOQTEQ® VA Distal Lateral Humerus Plate, L	
IU 8184-01	Aiming device LOQTEQ® HTO plate	
IU 8185-01	Aiming device LOQTEQ® DFO Plate, R	
IU 8185-02	Aiming device LOQTEQ® DFO Plate, L	
IU 8186-01	Aiming device LOQTEQ® PMT Plate 3.5, R	
IU 8186-02	Aiming device LOQTEQ® PMT Plate 3.5, L	
IU 8187-01	Aiming device LOQTEQ® PLT Plate 3.5, R	
IU 8187-02	Aiming device LOQTEQ® PLT Plate 3.5, L	
IU 8188-01	Aiming device LOQTEQ® DAT Plate 3.5, R	
IU 8188-02	Aiming device LOQTEQ® DAT Plate 3.5, L	
IU 8189-03	Fixing screw aiming device LOQTEQ® DF Plate	
IU 8191-01	Aiming device LOQTEQ® Distal Fibula Plate 3.5, R	
IU 8191-02	Aiming device LOQTEQ® Distal Fibula Plate 3.5, L	
IU 8191-03	Fixing screw aiming device LOQTEQ® Distal Fibula Plates	
IU 8192-01	Aiming device LOQTEQ® VA Distal Fibula Plate 2.7/3.5, R	
IU 8192-02	Aiming device LOQTEQ® VA Distal Fibula Plate 2.7/3.5, L	

4.2 (DIS)ASSEMBLY INSTRUCTIONS

4.2.1 SCREWDRIVER T8, ROUND HANDLE (IU 7808-00)

Disassembly:



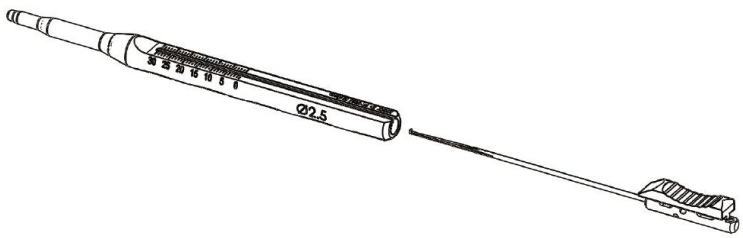
- Pulling off the head (Pos. 1)

Assembly:

- Putting on the head (Pos. 2)

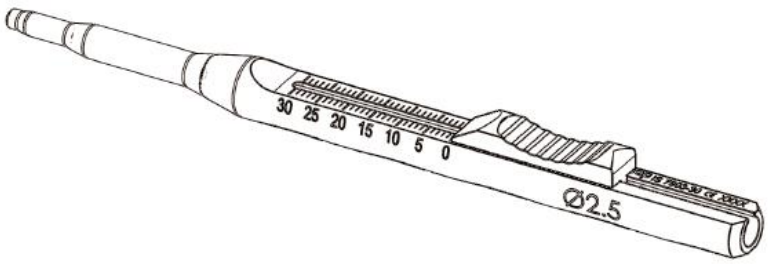
4.2.2 DEPTH GAUGES FOR SCREWS

Disassembly:



- Pull out the measurement hook

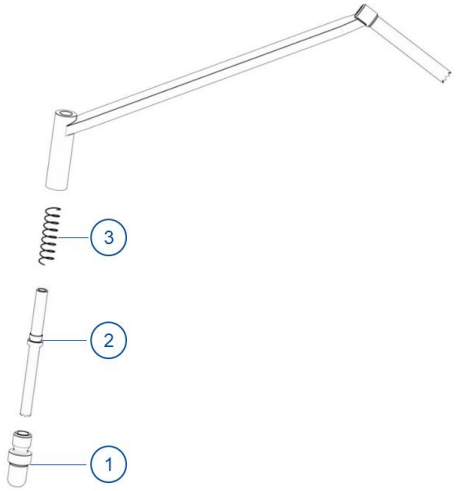
Assembly:



- Insert the measurement hook

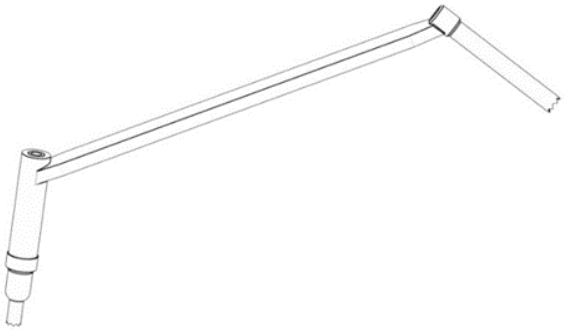
4.2.3 DOUBLE DRILL GUIDE

Disassembly:



- Unscrew the plugs in an anticlockwise direction (item 1)
- Remove the hole rod and spring from the bracket (item 2)
- Detach the spring from the hole rod before reprocessing the instrument (items 2 and 3)

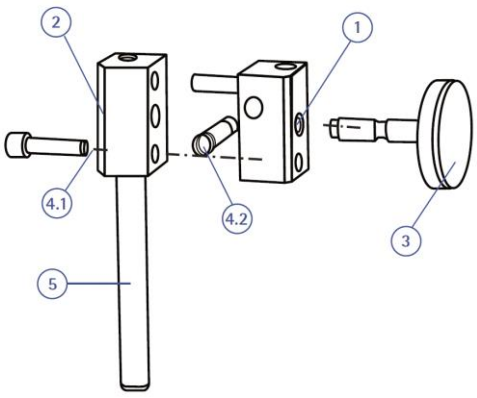
Assembly:



- Place the spring on the shorter part of the hole rod
- Insert the spring and hole rod into the bracket
- Insert the plugs in a clockwise direction

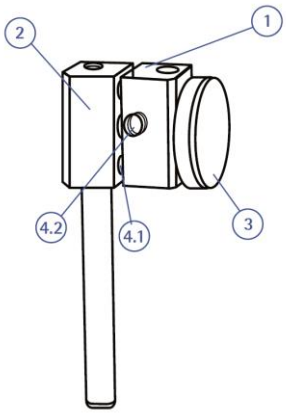
4.2.4 LOAD DRILL GUIDE (IU 8166-0X)

Disassembly:



- Remove screws (item 4) using a hex screwdriver bit SW 2.5 with quick coupling (IU 7825-00)
- Unscrew the set screw (item 3)
- Pull the compression block apart (items 1 and 2)

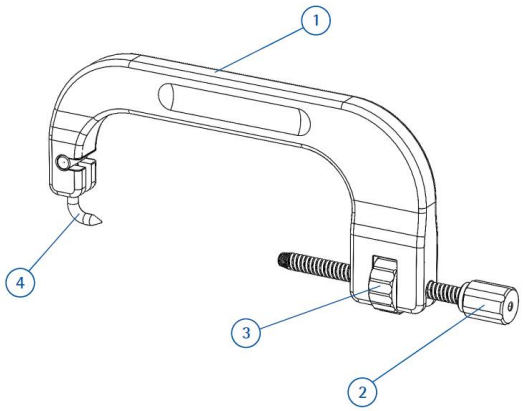
Assembly:



- Assemble the compression block (items 1 and 2)
- Insert the set screw (item 3) into the compression block, middle hole
- Screw in the holding screws (items 4.1 and 4.2) using a hex screwdriver bit SW 2.5 with quick coupling (IU 7825-00)

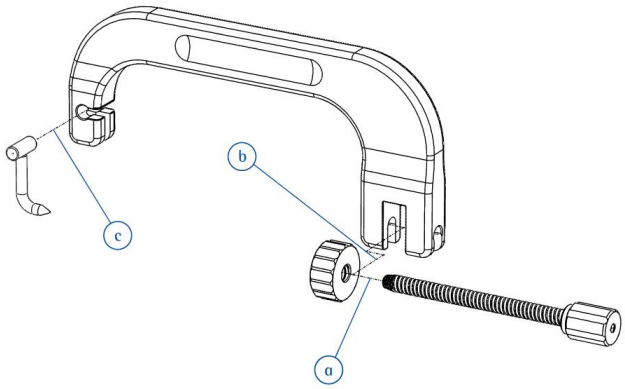
4.2.5 AIMING ARM LOQTEQ® DISTAL HUMERUS 2.7 (IU 8179-00)

Disassembly:



- The aiming arm for the distal medial humerus plate consists of four individual parts:
  1. Aiming arm made of radiolucent PEEK material
  2. Metal drill guide with external thread
  3. Metal adjusting ring with internal thread
  4. Aiming pointer
- To reduce the risk of glove perforation, care should be taken when using the aiming pointer of the aiming arm

Assembly:



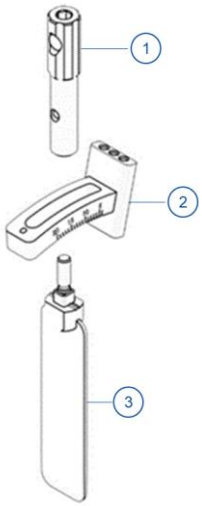
a. Screw the adjusting ring onto the guiding sleeve.

b. Click the drill guide with the assembled adjusting ring onto the PEEK aiming arm.

c. Click the aiming pointer onto the PEEK aiming arm.

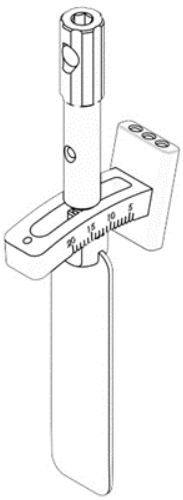
4.2.6 ANGLE GAUGE FOR CLOSED WEDGE OSTEOTOMY (IU 7970-00)

Disassembly:



- Remove the nut in an anticlockwise direction (item 1)
- Detach the angle guide (item 2) from the slider (item 3)

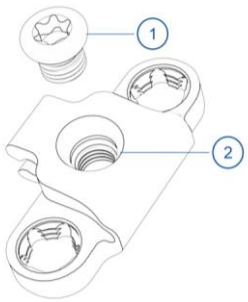
Assembly:



- Place the angle guide (item 2) on the slider (item 3)
- Place the nut on the thread of the slider and twist in a clockwise direction (item 1)

4.2.7 LOQTEQ® VA HINGE FOR PERIPROSTHETICS (PA 3580-00-2)

Disassembly:



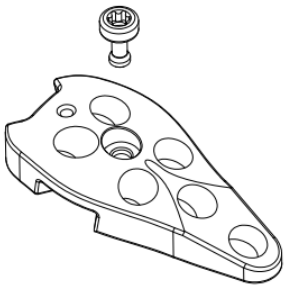
- Unscrew the fixing screw (item 1)
- Cleaning of the fixing screw in the compartment of mini strainer IC 6980-23

Assembly:

- Screw in the fixing screw (item 2)

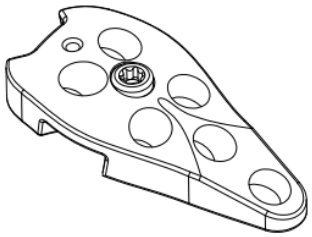
4.2.8 AIMING DEVICE LOQTEQ®

Disassembly:



- Unscrew the fixing screw

Assembly:



- Screw in the fixing screw

5. LIFE CYCLE/TEST CATALOG

PURPOSE

The aim of this test catalog is to help the user test *aap* devices for their integrity and functionality and thus to prevent further use once the end of life cycle has been reached. The optical and functional criteria provided in the test catalog that are signs of wear can be used to identify which devices have reached the end of their life cycle and may therefore no longer be used.
aap devices that are subject to multiple reprocessing should be inspected after each cleaning and disinfection process and before sterilization on the basis of this test catalog, i.e. using the criteria applicable to the device in question. They should be disposed of at the end of life cycle. Good lighting and use of a microscope are recommended for adequate testing.

STRUCTURE

End of life of a device is normally determined by wear and damage due to use. These criteria are indicated in the following test catalog and sorted by device types and groups, starting with general errors.

There is a table with representative figures for each device type/group. Under the figures, there are symbols which indicate whether the devices can be reused (✓) or have reached the end of their service life and must therefore be disposed of (✗). Under the figures with the respective assessments, there is a description of the possible damage and a procedure recommended by *aap*. The representative figure is used only for visualizing the description. Each device must therefore be checked in line with the description of wear and damage and assessed accordingly to determine the end of its service life.

⚠ Precaution

- Surfaces can wear through repeated use and reprocessing so direct labeling on the device is no longer legible.
- If information applied to the item (e.g. catalogue number, functional label, symbols) can no longer be clearly read, the device must be replaced immediately.
- *aap* does not accept any liability for damage caused by a lack of or by irregular checks on the devices, in particular the drill.

5.1 GENERAL DAMAGE

5.1.1 SUPERFICIAL DAMAGE



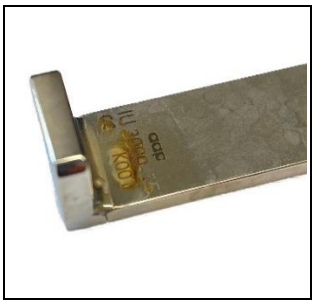
Possible damage

- Deep scratches or notches
- Flaking or chipping
- Direct marking illegible or missing
- Discoloration

Procedure

- Discoloration alone has no negative effect on the device or its function. Repeat the cleaning if necessary.
- If a device is damaged it must be discarded

5.1.2 RUST, CORROSION, PITTING CORROSION

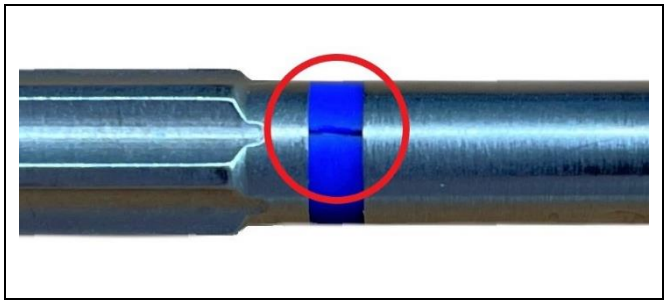

Possible damage

- Rust
- Corrosion
- Pitting corrosion

Procedure

- Repeat the cleaning
- If the areas of corrosion cannot be removed, the device must be discarded.

5.1.3 CRACKS



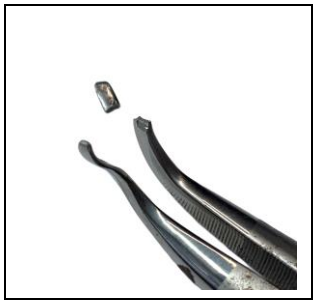
Possible damage

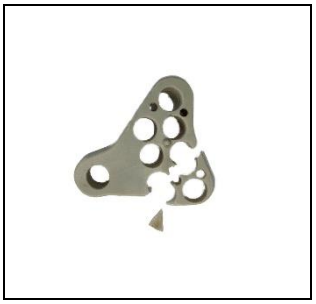
- Cracks on surfaces
- Cracks on welds
- Cracks on assembly sites
- Cracks on cannulations
- Cracks on devices with thin walls

Procedure

- If devices have cracks, they must be discarded.

5.1.4 BREAKAGE (INTO TWO OR MORE PARTS)





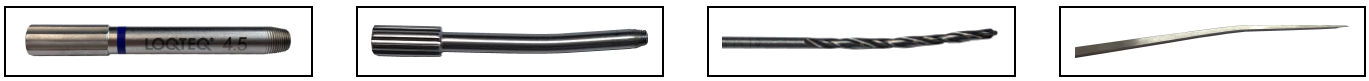
Possible damage

- Breaks at welds
- Breaks at assembly sites
- Breaks of tips
- Breaks of devices with thin walls

Procedure

- If devices are broken, they must be discarded.

5.1.5 BENT, DEFORMED, OR TWISTED



Possible damage

- Bent bodies
- Bent tips
- Bent pins
- Bent sleeves

Procedure

- Roll the device backwards and forwards on a flat surface to check it.
- If devices are bent, they must be discarded.

5.1.6 ILLEGIBLE UDI MARKING

Possible damage

- UDI marking is no longer suitable for tracking

Procedure

- Check the scanning function (must be suitable for Direct Part Marking (DPM)); clean the surface, change the scanning distance/angle, change the ambient lighting
- If the actions above still do not result in successful scanning, the device must be discarded

5.1.7 OTHER DAMAGE

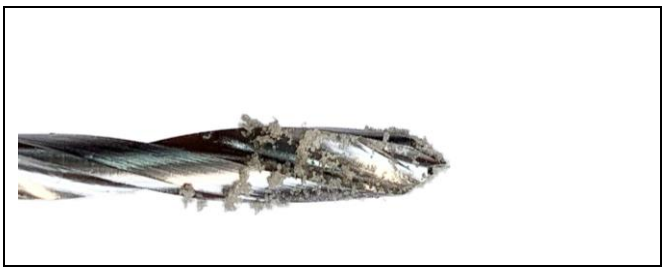
Missing components:

If individual components are missing from instruments that can be assembled, rendering correct assembly impossible, the device must be discarded

Jamming:

If instruments that can be assembled are jammed into one another, rendering correct assembly or disassembly impossible, the device must be discarded.

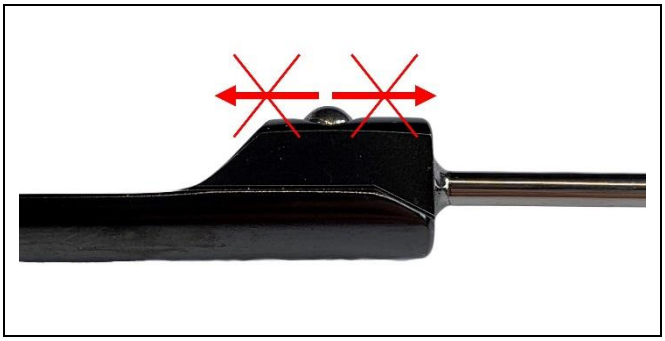
Contamination:



Possible damage	Procedure
• Blood, bones, tissue or other residue are not fully removed by cleaning	• If the surfaces are contaminated, follow the reprocessing instructions. • If the contamination cannot be removed from the surfaces, the device must be discarded.

5.2 DAMAGE BY FEATURE

5.2.1 INSTRUMENTS WITH A SPRING-LOADED BALL BEARING



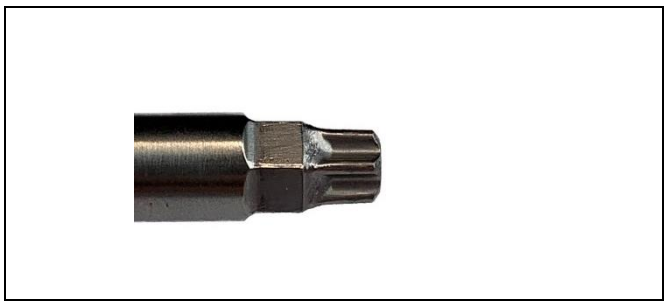
Possible damage

- Missing ball bearing
- Ball bearing jammed

Procedure

- Carefully clean the ball bearing and insertion mechanism and, if necessary, apply medical white oil according to the pharmacopoeia
- The device must be discarded if the ball bearing is missing.

5.2.2 INSTRUMENTS WITH HEX OR TORX CONNECTIONS



Possible damage

- Connection twisted around
- Connection broken

Procedure

- If a connection is damaged, the device must be discarded

5.2.3 INSTRUMENTS WITH A SHAFT OR SLEEVE

✓ ✗ ✗

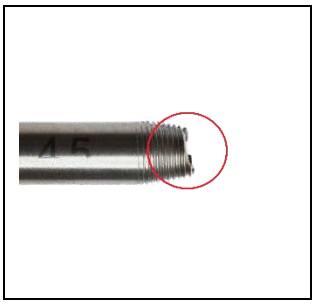
Possible damage

- Shaft or sleeve bent
- Shaft or sleeve (inside) chipped or scratched
- Shaft cracked
- Shaft broken

Procedure

- If a shaft or a sleeve is damaged, the device must be discarded

5.2.4 INSTRUMENTS WITH A THREAD



✓ ✗

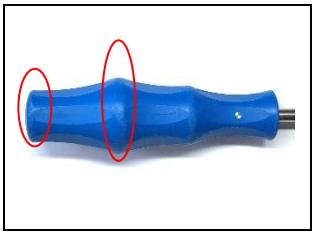
Possible damage

- Instrument is impossible or difficult to screw in or unscrew
- Thread is damaged

Procedure

- If the function of the thread is impaired or the thread is damaged, the device must be discarded.

5.2.5 INSTRUMENTS WITH PLASTIC HANDLES

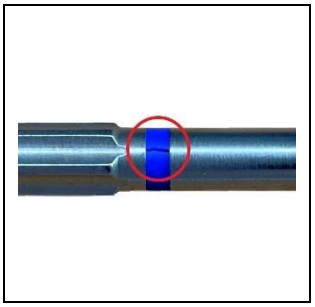

Possible damage

- Handle broken
- Surface is brittle
- Surface is flaking off
- Cracks/scratches in the surface

Procedure

- If the surface is damaged, the device must be discarded.

5.2.6 INSTRUMENTS WITH COLORED RINGS



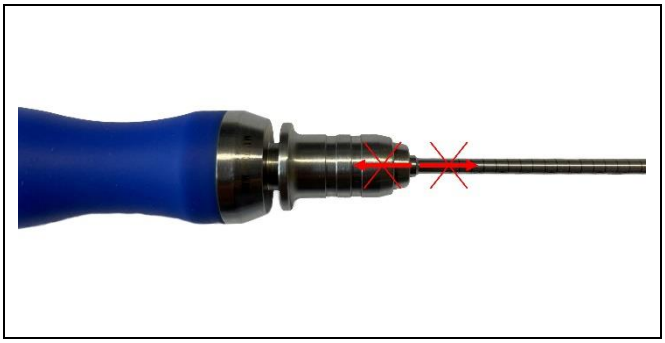
Possible damage

- Colored ring cracked (partially/longitudinally/transversely)
- Colored ring no longer present

Procedure

- If a colored ring is damaged or missing, the device must be discarded.

5.2.7 INSTRUMENTS WITH COUPLING



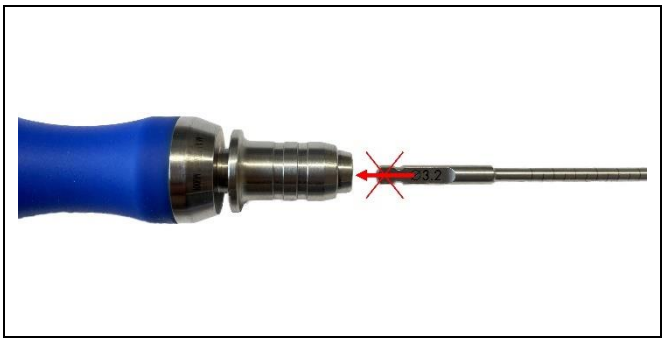
Possible damage

- Coupling cannot be detached
- Coupling does not stay connected

Procedure

- Functional test 1:
  - Engage the coupling and ensure that the assembly is held securely
- Functional test 2:
  - Engage the coupling then detach it again and ensure that the assembly can be detached easily
- If any function of the coupling is impaired, the device must be discarded.
- Maintenance:
  - Apply medical white oil to the coupling according to the pharmacopoeia as required

5.2.8 INSTRUMENTS WITH A COUPLING CONNECTION



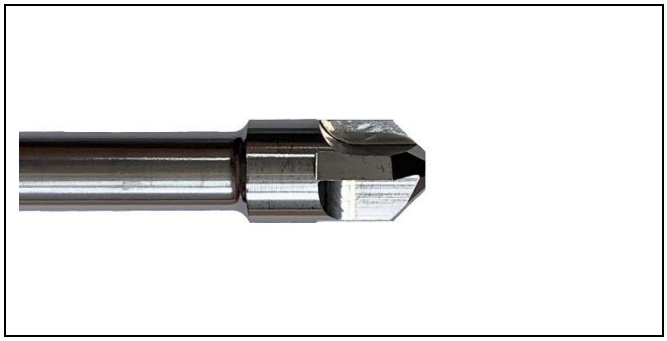
Possible damage

- Connection does not connect to the coupling
- Connection damaged

Procedure

- If the connection cannot be inserted into the coupling, check the source of the error with another coupling and another connection.
- If the assembly cannot be assembled because of the connection, the device must be discarded.

5.2.9 INSTRUMENTS WITH A CUTTING EDGE



Possible damage

- Cutting edge blunt
- Cutting edge uneven
- Cracks in the cutting edge

Procedure

- If a cutting edge is damaged, the device must be discarded.

5.3 DAMAGE BY DEVICE TYPE

5.3.1 SCREWS




Possible damage

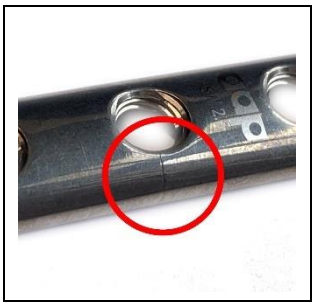
- Shaft thread damaged
- Head thread damaged
- Ridges on the thread
- Splinter formation on the thread
- Screw head shape damaged

Procedure

- If a screw is damaged, the device must be discarded.

5.3.2 PLATES






Possible damage

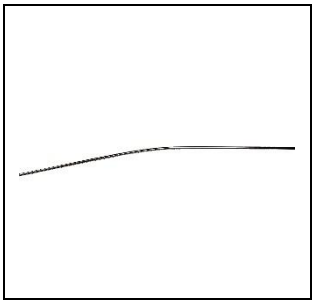
- Plate hole deformed
- Thread damaged
- Plate bent
- Plate broken
- Direct marking illegible

Procedure

- If the direct marking on the device is no longer legible, it must be disposed of
- Damaged plates must be discarded

5.3.3 K-WIRES





Possible damage

- K-wire tip blunt
- K-wire bent

Procedure

- If a K-wire is damaged it must be discarded.

5.3.4 INSTRUMENTS

Drills




Possible damage

- Cutting edge or tip of the drill blunt or chipped
- Drills bent
- Spiral coil damaged
- Spiral coil untwisted
- Coupling connection damaged
- AO coupling not functional

Procedure

- If a drill is damaged, it must be discarded.

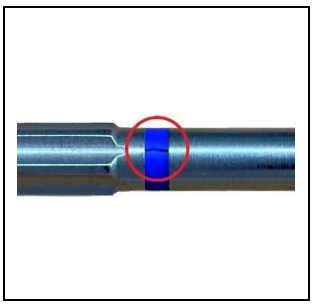
Milling tools




Possible damage	Procedure
• Cutting edge or tip of the drill blunt or chipped • Milling tools bent • Coupling connection damaged • AO coupling not functional	• If a milling tool is damaged it must be discarded.

Drilling guides, reduction sleeves, tissue protection sleeves



Possible damage	Procedure
• Thread damaged • Drill guide (inside) damaged or scratched • Colored ring damaged • Sleeve bent • Tips broken	• If there is damage, the device must be discarded.

Aiming instruments



Possible damage

- Aiming holes damaged
- Aiming instrument broken

Procedure

- If the aiming instrument is damaged, it must be discarded.

Depth gauge and aiming arm



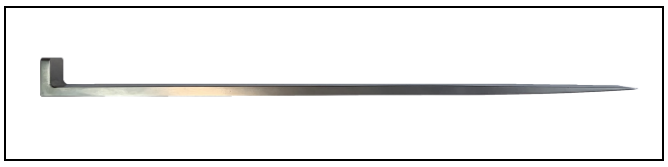
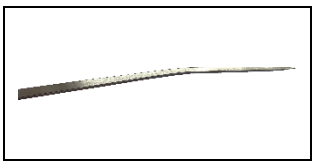

Possible damage

- Needle tip (feeler) bent
- Insertion and removal mechanism defective
- Ball bearing missing

Procedure

- If there is damage, the device must be discarded

Chisel


Possible damage

- Weld broken
- Edges chipped
- Labeling illegible
- Bent

Procedure

- If there is damage, the device must be discarded.

Angle gauge



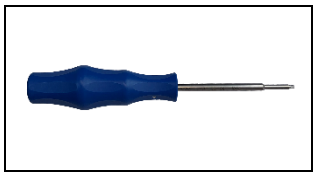
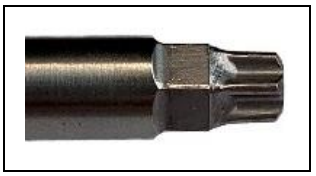
Possible damage

- Plate on the angle gauge bent
- Labeling illegible

Procedure

- If there is damage, the device must be discarded.

Screwdriver

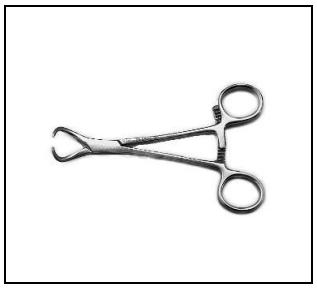
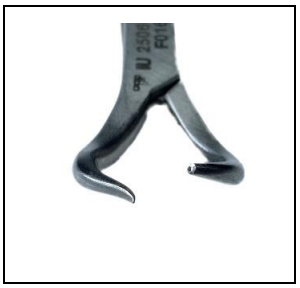
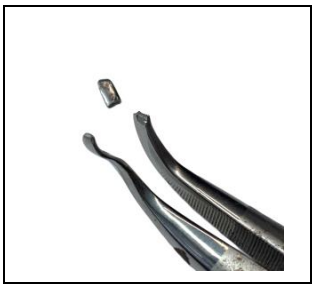
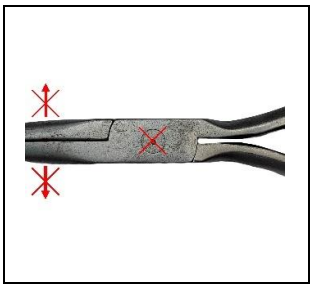
Possible damage

- Tip deformed
- Tip twisted around
- Tip broken
- Coupling piece damaged (if present)
- Handle chipped (if present)
- Shaft cracked
- Shaft broken

Procedure

- If there is damage, the device must be discarded.

Repositioning and bone spreading forceps

Possible damage

- Forceps tip is bent or damaged
- Joint is blocked or difficult to open and close
- Contamination on the joint
- Rust on the joint

Procedure

- Maintenance: Clean the joint carefully and, if necessary, apply medical white oil according to the pharmacopoeia
- If there is damage, the device must be discarded.

Bending iron

Possible damage	Procedure
• Plate hole recess chipped • Bending iron bent	• If there is damage, the device must be discarded.

Other device types

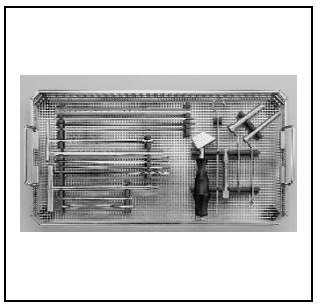
There are no specific criteria for defining the end of life cycle for the following device groups. All general criteria and respective criteria by feature apply.

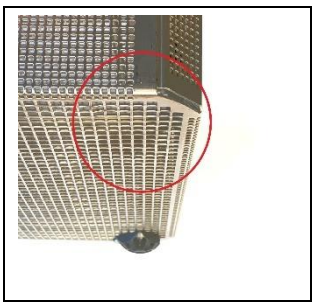
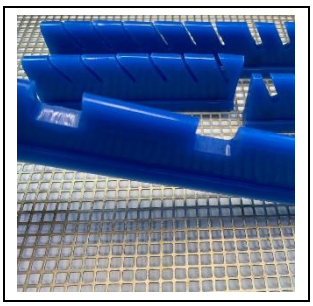
- Aiming arm
- Handles and torque limiters*
- Elevatorium and retractor
- Saw gauge
- Dissector and test hooks
- Ring stop
- Saw guide
- External aligner
- Cleaning wires

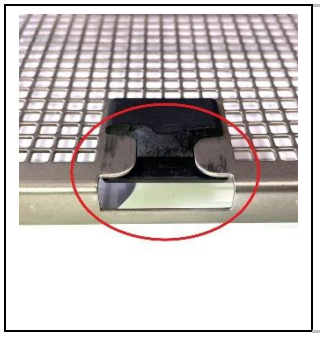
If devices have the function of torque limitation, special requirements apply which can be found in the relevant Instructions for Use. Torque limiters are intended for temporary use. Their life cycle ends after 3 years, approximately 6,000 clicks or 250 reprocessing cycles. The user is responsible for taking into account the life cycle and disposing of torque limiters after the end of their life cycle.

5.3.5 STORAGE AIDS

Trays






Possible damage	Procedure
• Surface damaged • Weld damaged • Foot broken or missing • Holding pins are loose • Holding pins are missing • Silicone strips are loose • Lid bent • Lid clip bent • Lid clip broken • Lid clip missing	• If there is damage, the device must be discarded.

Screw banks

Possible damage	Procedure
• Cover missing • Screw holes deformed or damaged • Labeling illegible	• If there is damage, the device must be discarded.

Other device types

There are no specific criteria for defining the end of life cycle for the following device groups. All general criteria and respective criteria by feature apply.

- K-wire container*
- Pyxidis plastic inserter*
- Staple for washers*

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Website: www.aap.de