Instructions for the use

of medical devices (incl. accessories) made by INTERCUS GmbH

Use, cleaning, disinfection, sterilisation, maintenance and care

1. Introduction

PLEASE READ THESE INSTRUCTIONS CAREFULLY AND FOLLOW THE INSTRUCTIONS

This document contains information on:

- use
- preparation (cleaning, disinfection and sterilisation) of non-sterile medical devices supplied by INTERCUS GmbH before use
- inspection of and care for the medical devices
- features that characterise wear and tear and loss of product serviceability

Further information on the products can be found in the various product leaflets, catalogues and surgical techniques. All information can be requested from INTERCUS GmbH or our distributors at any time. The contact details and additional information can be found online at: www.intercus.de

In the following text, the term “instrument” covers:

surgically invasive and non-invasive instruments
surgically invasive and non-invasive accessories

In the following text, the term “product” covers:

Implants (screws, plates, wires and nails)
Instruments
Rotating instruments (drills)
Storage systems / sets

If items require different handling, the product groups will be explicitly mentioned.

NON STERILE Chapters 1-4 and 6-7 of these instructions apply to non-sterile medical devices.

STERILE R Chapters 1-3 and 5-7 of these instructions apply to sterile medical devices.

It is possible to differentiate between non-sterile and sterile products which are on the market by checking the labelling on the packaging. In addition to the “non-sterile” and “radiation sterilised” symbols, a distinction can be made using the item number and lot number. There is an “S” in front of the item number and lot number of sterile products.

	Placed on the market in a non-sterile condition	Placed on the market in a sterile condition
Symbol	NON STERILE	STERILE R
Item number	987654	**S**987654
Lot number	0123456	**S**0123456

2. Use

2.1 Implants

2.1.1 General safety instructions

(1) INTERCUS implants may only be used once.

(2) INTERCUS implants have been designed in line with the latest findings in implantation technology and the recognised rules of engineering. However, the safety and functionality of the implants can only be guaranteed if the operator observes and follows the instructions contained within this document.

(3) The operator must be familiar with the topic of the implantation and explantation of implants, with the current state of science and technology and with the AO principles of fracture management. Unless otherwise specified by INTERCUS, implantation and explantation must be carried out in accordance with the AO principles (for example, see “AO-Instrumente und -Implantate - Technisches Handbuch”; second edition; Springer-Verlag 1995).

(4) As a general rule, the doctor must inform the patient about indications, contraindications, unwanted side effects, complications and post-operative treatment and record this information. Regular medical check-ups should be performed after implantation.

(5) When fitting plates to bones, make sure not to exceed a maximum bending angle of 15°. Bending the plate backwards and forwards multiple times should be avoided, as this will weaken the plate material.

(6) When shortening (cutting down) plates and wires, make sure there is no feathering on the cut edge as this could injure the patient.

(7) Complications which could arise due to incorrect indications, operating techniques or asepsis are the responsibility of the operator and cannot be blamed on the manufacturer or the supplier of the INTERCUS products.

(8) The operator must ensure that the implants are in perfect condition before each use, especially when combining them with standard implants made by other manufacturers. Standard implants are implants for which the geometry is described in the AO standard or prescribed by standards (e.g. standard screws according to ISO 5835). The INTERCUS catalogues describe which INTERCUS products can be combined; standard implants from other manufacturers must be comparable with these.

(9) The INTERCUS angle-stable implants are not to be used in conjunction with angle-stable implants made by other manufacturers.

(10) With implants with tips (e.g. wires) there is a risk of the user being injured and of damage to the user’s gloves.

(11) Contact of implants with electrically operated instruments (e.g. Cauter) must be avoided. Contact can lead to damage to the implant and thus increases the risk of implant failure.

Implants are only used to promote healing and are not a substitute for tissue and bone material.

The user and/or patient are required to report all serious incidents in connection with the product to the manufacturer and the responsible authority with jurisdiction over the area in which the user and/or patient is based.

2.1.2 Compatibility

The bone plates, bone screws and washers, bone wires and bone nails are available in many different shapes and sizes and are made from surgical implant materials, namely, surgical stainless steel and titanium (biocompatibility reference). The information is shown on the label. Only implants made from the same material may be combined.

INTERCUS instruments which comply with the AO standard are available for the implantation of the implants. When using the product, pay attention to the intended purpose, size information and the type of connection (e.g. if there are screws), for example, to ensure proper use and the right choice of instruments. This information can be found on the product label.

2.1.3 Intended purpose

INTERCUS implants are used for osteosynthesis following bone breaks, for stabilising bone fragments, for stiffening joints (arthrodesis) and for correcting misalignments (e.g. osteotomies). They comply with the AO principles and are state of the art.

The product-related intended purpose can be found on the label.

2.1.4 Weight-bearing load on the implants

The implants can never take on the full weight-bearing load of the treated bone segment. Implants are only used to promote healing and are not a substitute for tissue and bone material. The patient’s doctor must therefore inform them about the weight-bearing load limits and prescribe appropriate post-operative behaviour.

- After osteosynthesis or osteotomy and provided there is acceptable bone quality and good surrounding soft tissue, all implants allow a partial load of up to 15-20 kg for 6 weeks and thereafter depending on the X-ray findings. This does not include comminuted fractures (AO principles of fracture management – Thieme Verlag 2003).
- A post-operative shoe with forefoot support can be used to allow for full weight-bearing load.
- There is always stability of movement (non-load bearing movement) in the upper extremities.
- There is no full weight-bearing load on the upper extremities like there is with the lower extremities.

2.1.5 Indications

Indications for medical treatment on the basis of the AO classification.

2.1.6 Contraindications

There are contraindications to acute infections that could impair the healing process due to the implants used, advanced osteoporosis, severe circulatory disorders and known allergies to surgical implant materials (see 2.1.9 “Biocompatibility”).

INTERCUS implants may not be suitable for patients with inadequate or incomplete bone formation. Before surgery on patients with incomplete skeletal growth, the doctor must carefully evaluate bone quality and observe the AO standard.

The operator must explain the risks and bears responsibility for doing so.

2.1.7 Safety and service life

INTERCUS products have a service life of 50 years.
Storage conditions (see 2.4.1"Storage and transport conditions")
The patient receiving the implant must be informed by the operator that the safety and service life of the implant depend on the following factors and risks:

- previous infections;
- the patient being overweight;
- extreme loads expected due to work and sport;
- epilepsy or other reasons for repeated accidents with increased risk of fracture;
- significant osteoporosis or osteomalacia;
- weakening of the load-bearing structures caused by tumours;
- allergies to materials used in the implants

INTERCUS implants are generally made from non-magnetic surgical materials, see 3 "Materials".

⚠ *INTERCUS implants have not been checked for safety and compatibility in the MR environment. They have not been tested for heating, migration or image artefacts in the MR environment. The safety of INTERCUS implants in the MR environment is unknown. MR examination of a patient with INTERCUS implants could result in injury to the patient.*
Patients with INTERCUS implants should avoid undergoing MR examination. All INTERCUS implants are made from surgical implant material (ISO 5832-x series of standards). These materials are not magnetic

2.1.8 Treatment

Implants are highly sensitive to damage.
Extremely careful treatment is therefore advisable:

- Implants must not be mechanically reworked or otherwise changed in any way unless the design and surgical technique expressly allow this; if in doubt, a written recommendation from INTERCUS must be obtained;
- Under no circumstances may implants that have been obviously damaged, scratched, improperly handled or processed without authorisation be implanted into a patient. These must be returned to the supplier for inspection.

2.1.9 Biocompatibility

The materials used are indicated on the respective product label. INTERCUS implants are made from surgical implant materials in accordance with:

- ISO 5832-1/-9 stainless steel
- ISO 5832-2 unalloyed titanium
- ISO 5832-3 wrought titanium 6 aluminium 4 vanadium

alloy. If the patient is known to be allergic to implant steel, steel implants should be avoided and titanium used instead.

2.1.10 Notes regarding pre-operative surgery planning

(1) The operation should be planned precisely using the X-ray findings.
(2) The specific INTERCUS instruments/tools should also be used for the preparation of the bone bed and the adaptation and insertion of the implant.
(3) Surgical technique: the rules of art and science and findings from scientific publications by medical authors are of key importance. A surgical description can never be complete nor can it ever contain all of the risks and complications that need to be considered. Pamphlets about the operation, technical product descriptions, additional information leaflets and films can be requested from INTERCUS.
(4) Aseptic conditions in the operating theatre.
(5) When unpacking the implant, check that it matches the description on the packaging and ensure the implant is handled properly.

2.1.11 Notes regarding post-operative follow-up checks

- Mobilisation and follow-up checks are the responsibility of the operator and should be determined on a patient-specific basis.
- The patient must be instructed to have the implant checked if they experience severe falls or impacts.

2.2 Instruments

2.2.1 General safety instructions

(1) INTERCUS instruments have been designed in line with state-of-the-art technology and the recognised rules of engineering. However, safety and functionality can only be guaranteed if operator observes and follows the instructions contained within this document.
(2) The operator must be familiar with everything to do with handling INTERCUS instruments and the current state of the science and technology.
(3) Complications that could arise due to incorrect use are the responsibility of the operator and cannot be blamed on the manufacturer or the supplier of the INTERCUS instruments.
(4) The operator must ensure the instruments are in perfect condition before each use.
(5) Instruments or accessories with tips (e.g. trocars) or with hinges (e.g. pliers) present a risk of the user being injured as a result of pricking or crushing or of the user's gloves being damaged.

2.2.2 Intended purpose

INTERCUS instruments comply with the AO standard and are used to implant or extract implants based on the AO principles of fracture management. When using the product, pay attention to the intended purpose, size information and the type of connection (e.g. when using screwdrivers), for example, to ensure proper use. This information can be found on the product label.

2.3 Rotating instruments

2.3.1 General instructions

These products are rotating instruments which, in conjunction with a compatible drive system, are used for the abrasive removal of bony structures. The products must only be used in accordance with the information listed here and using a corresponding drive system.
Rotating instruments should only be used by doctors with training in the respective surgical discipline who have been trained in the relevant procedures as part of generally recognised training courses that take into account the relevant literature. In particular, the doctor must determine the extent of the injuries or changes to the tissue that require surgical treatment and then decide on the suitable surgical procedure. This is especially important when there are patients with comorbidities that could inhibit the use of rotating instruments.

2.3.2 Intended purpose

Bone drills are used to drill core and clearance holes for bone screws and to drill the medullary cavity for intermedullary bone nails.
The product-related purpose can be found on the label.

2.3.3 General handling

Rotating instruments must only be used in accordance with the information listed here and using a corresponding drive system. Ensure that only compatible connection types (e.g. quick coupling, triangular shank, cylindrical shank, dental coupling) are used together.
Before each use, always ensure that the rotating instruments you wish to use are in a technically perfect and sterile condition.
Rotating instruments with any kind of damage should be removed and not used in general.
Rotating instruments should be pushed into the drive until they click into place. Check that the instrument is securely in place before using it for the first time.
Rotating instruments are not suitable for use on metallic materials (e.g. steel alloys).

2.3.4 Pressure strength

Excessive pressure strength must be avoided as this can cause thermal necrosis in the tissue.
Excessive pressure reduces the service life of the instruments and in extreme cases may lead to the instrument breaking.

2.3.5 Heat development

Heat development cannot generally be avoided when using rotating instruments, but should be kept as low as possible. Causes of increased heat development include worn or blunt rotating instruments, inadequate removal of bone splinters caused by the process, which can in turn affect the cutting edges so they no longer work properly. This increases the amount of time spent working on the bone. The resultant increased heat development can lead to irreversible damage to the bone tissue (thermal necrosis) and also reduces the service life of the instrument.

2.3.6 Indications

Rotating instruments must be used in accordance with their intended purpose and in line with the AO standard. They fulfil the principle of cutting away unwanted bony substances or preparing implant sites.

2.3.7 Contraindications

In most cases, possible complications are caused not directly by the use of the instruments but rather by the incorrect choice of instrument, as well as imprecise handling and implant placement. In rare cases, patients may show over-sensitivity and allergic reaction to certain alloy elements in the material. In addition, patients with specific diseases of the bone structure (e.g. osteoporosis, bone resorption) will need customised treatment. Early or late deep and/or surface infections can occur after a procedure.

2.3.8 Check before use

Before use, every user of the instrument must check for changes, cracks or damage that could have been caused by improper transportation, storage or preparation.

2.4 General

2.4.1 Storage and transport conditions

There are no special requirements regarding the storage of non-sterile and sterile products. The products must be protected from direct sunshine and mechanical damage.
Temperature fluctuations must be avoided in order to prevent condensation from forming and causing corrosion damage.
Transport conditions should be from -20°C to +50°C and not exceed 90% RH.

2.4.2 Information

Please contact your supplier for further information.
Check the LOT no., which is marked on the label and/or on the products as follows:

LOT XXXXXX
or
LOT SXXXXXX

2.4.3 Safety and liability

It is the user's obligation to check the products for suitability and the uses for the intended purposes before using them. Use of the products is the responsibility of the user. INTERCUS GmbH assumes no liability for any resulting damages. Successful surgery is only ensured if the products are used correctly.
Transport conditions should be from -20°C to +50°C and not exceed 90% RH

2.5 Reusability of INTERCUS products

Medical devices intended for **single use** (e.g. implants, sterile products) have the following symbol on their label:

These products are intended for single use only.

Reusing implants that have come into contact with the blood or other bodily fluids of a patient is not permitted, as there is the risk of reusing contaminated implants.
If INTERCUS implants are reused, INTERCUS can no longer guarantee the product's mechanical properties due to the prior load, wear and tear or damage.
Products that are not marked with the above symbol may be reused. These are instruments, rotating instruments or storage systems/sets. The prerequisite for reusing these items is that the products are not damaged or soiled. These reusable products must be reprocessed before each use.
The manufacturer accepts no liability for this rule being disregarded.
INTERCUS does not specify a maximum number of times that reusable products can be used. The service life of products depends on many factors, such as:

- The type and duration of individual times they are used,
- How the products are handled during and between use.

Careful inspection and functional testing of the products before use are the best methods for determining the product's lifespan.

3. Materials

3.1 Implants

All INTERCUS implants are made of titanium (ISO 5832-2, ASTM F67) or titanium alloy (ISO 5832-3, ASTM B265, ASTM F136) and are anodised or made of implant steel (ISO 5832-1 ASTM F138; ASTM F139 or ISO 5832-9). All titanium and steel materials used are biocompatible, corrosion-resistant, non-toxic in a biological environment and non-ferromagnetic.

3.2 Instruments

Instruments are made of stainless steel, plastic (e.g. carbon, PEEK, PP, PPSU; silicone, Bayblend M850XF, Ixef GS-1022 WH01) or aluminium.

4. Non-sterile products on the market

4.1 General

This section of the instructions only applies to non-sterile INTERCUS products that are available on the market.
Products placed on the market in a sterile condition must NOT be processed by the user.
Non-sterile INTERCUS products which are on the market are cleaned by the manufacturer in a validated cleaning device, packaged in NON-STERILE protective packaging and then delivered. This protective packaging must be removed before processing. The products must be cleaned, disinfected and sterilised by the user.
The products should be stored unopened in their original packaging and the protective packaging should only be removed immediately before processing;

Repeated use is not permitted if a single-use product (e.g. implant) has already come in contact with a patient or has been otherwise contaminated.

4.1.1 Basics for preparing INTERCUS products

The basics described in this section must be observed in all preparation steps!
The preparation of non-sterile products, outlined here, has been tested and validated by INTERCUS (the cleaning, disinfection and sterilisation process). It is the responsibility of the person processing the item to ensure the desired result is achieved. This requires validation checks and routine monitoring of the process. Likewise, any deviation from the instructions provided should be carefully evaluated in terms of effectiveness and possible adverse consequences by the person processing the item.

Effective cleaning and disinfection is an essential prerequisite for effective sterilisation.

Solely conducting manual cleaning and disinfection of INTERCUS products is not permitted!

We recommend reprocessing instruments as soon as possible after using them (< 6 hrs).
Pre-treatment for cleaning/disinfection must be carried out.
As part of your responsibility to ensure the sterility of the individual components, please ensure that

- only sufficient device and product-specific validated processes for cleaning/disinfection and sterilisation are used.
- the devices used (cleaning device, steriliser) are serviced and checked regularly.
- the validated parameters and/or those recommended by the manufacturer are adhered to in each cycle.

Please also adhere to the valid legal regulations in your country and the hygiene regulations of the hospital. This particularly applies to the different requirements regarding effective prion deactivation. If the product comes (or is suspected to have come) into contact with elusive pathogens, such as the variant of the Creutzfeldt-Jakob disease, INTERCUS recommends disposing of the product.

Frequent reprocessing has little impact on surgical products. Product service life is usually determined by wear and tear and damage sustained during product use.

4.1.2 Cleaning and disinfection agents and devices

When choosing the cleaning and disinfection agents and devices, care should be taken in all steps to ensure that

- they are suitable for the intended application (e.g. cleaning, disinfection, ultrasonic cleaning of medical devices).
- the cleaning and disinfection agents are aldehyde-free (aldehyde fixes blood stains).
- they have proven efficacy (e.g. VAH/DGHM or FDA approval or CE marking).
- the cleaning and disinfection agents are suitable for the products and are compatible with the products (see also 3 "Materials").
- the manufacturer's information, e.g. with regard to concentration, exposure time and temperature are adhered to.

INTERCUS recommends using freshly prepared cleaning and disinfecting solutions.
More detailed information on special suitable products for gentle cleaning and disinfection can be obtained directly from the manufacturers of the cleaning and disinfecting agents. In Germany and Switzerland, these include:

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

4.1.3 Tools for pre-cleaning/cleaning

Never clean INTERCUS products with metal brushes or steel wool as doing so could damage the material.
Use clean, lint-free cloths and/or soft brushes as cleaning aids. To prepare cannulated products and/or products with hollow cavities, you will need cleaning pens, bottle brushes and/or disposable syringes with appropriate cannula attachments.

4.1.4 Tools for drying

For drying, INTERCUS recommends using lint-free disposable paper towels or medical compressed air.

4.1.5 Water quality

With regard to water quality, INTERCUS recommends using demineralised and purified water (DI water) for the cleaning, disinfecting and rinsing steps. If necessary, INTERCUS recommends testing the endotoxin content in the final rinse water (thermal disinfection) to comply with national or international regulations.
High concentrations of minerals and/or contaminations with micro organisms and similar may lead to there being spots on the products or prevent effective cleaning and decontamination.

4.1.6 Material resistance

All reusable INTERCUS products may be exposed to maximum temperatures of 137 °C (278 °F).
The following warnings must be observed when choosing the cleaning agents and disinfectants:

Material	Not recommended
Aluminium (anodised etc.)	• iodine or alkaline components or salts of heavy metals (e.g. mercury) • poor water quality, alkaline cleaners, acid neutralising agents
Colour coding	• all oxidising acids (e.g. nitric acid, sulphuric acid, oxalic acid), H_2O_2 (hydrogen peroxide) • too high concentrations of cleaning agents and disinfectants
Stainless steel	• high chlorine concentrations • oxalic acid • hydrogen peroxide (H_2O_2)
Titanium / titanium alloys	• all oxidising acids (e.g. nitric acid, sulphuric acid, oxalic acid), H_2O_2 (hydrogen peroxide)

4.1.7 Assembly/disassembly

Disassembly of instruments is not required or possible if they are made of just one piece. Multi-piece instruments must be disassembled into their individual parts before cleaning.

4.1.8 Additional notes

The laser marking of products can partially or completely fade when treated with basic cleaners that contain phosphoric acid or hydrofluoric acid, which can in turn result in their functionality being impaired. In this case, the product in question is worn and must be scrapped.

4.2 Preparation for cleaning, disinfection and sterilisation

4.2.1 Gathering and preparing instruments after surgery

The first step of correct processing begins before the product even leaves the operating theatre.
Heavy soiling, residues left by haemostatic agents, skin disinfectants and lubricants, as well as corrosive pharmaceuticals should, if possible, be removed before the instrument is set aside. Please note the following when putting down the instruments: “dropping” the instruments down can damage them (e.g. by deforming or damaging the instrument, especially the tips). It is therefore important to ensure that the instruments are stored correctly and that the instrument trays are not overfilled.
Dry removal for transport to the cleaning/sterilisation department is preferable wherever possible. If using wet removal, the instruments should be placed into the appropriate cleaning solution immediately after the operation.
It is important to ensure that

- multi-piece instruments (e.g. depth gauges, removable handles, screwdriver sleeves etc.) are disassembled before pre-treatment,
- joint instruments (e.g. clamps, pliers etc.) are opened as far as possible,
- in the case of wet removal, that all surfaces (grooves, holes, lumens etc.) are sufficiently covered with solution.

The products should be processed as quickly as possible (< 6 hours) to prevent blood residues or similar from drying out and so as not to exceed the soaking time for wet removal (as this risks damaging the material).

4.3 Cleaning and disinfection

INTERCUS recommends that, if they are or could be contaminated, all instruments undergo manual pre-cleaning before machine cleaning and disinfection.

⚠ Solely conducting manual cleaning and disinfection of INTERCUS products is not permitted!

Disassembled instruments and storage systems remain in a disassembled state for the following cleaning and disinfection process.

4.3.1 Manual pre-cleaning

During manual pre-cleaning, pay particular attention to the holes, lumens, grooves and articular surfaces!

4.3.1.1 Preparation:

4.3.1.1.1 Instruments

Clean the disassembled and opened instruments under running water. While doing so, note the following:

- Remove visible contaminants with a soft plastic brush suitable for the size of the product (e.g. those made by INTERLOCK Medizintechnik GmbH www.interlockmed.com, products for the central supply of sterile goods).

4.3.1.1.2 Storage systems for implants and/or instruments

Clean the storage systems for instruments under running water as follows:

- remove any instruments that have been inserted into the storage system; the sieves must be empty
- if possible, remove the storage system lid
- clean the individual parts thoroughly under running water

Clean the storage systems under running water as follows:

- first, thoroughly rinse them while they are closed
- remove the products from the storage systems
- if possible, remove the lid of the implant storage system or, if necessary, rinse the joints; handles must not be removed
- clean the individual parts thoroughly under running water

4.3.1.2 The manual pre-cleaning process

⚠ Instruments and storage systems must be opened or disassembled for cleaning if possible!

- Place the products in an ultrasonic bath with cleaning agent (e.g. Neodisher septo Pre Clean; 2%, Dr. Weigert; pH value max. 11) for 15 minutes.
- It is important to ensure that:
  - only fresh solutions are used,
  - a suitable cleaning or combined disinfectant and cleaning agent is used,
  - the ultrasonic bath is prepared in accordance with the manufacturer’s instructions regarding temperature, concentration etc.,
  - the ultrasonic treatment is carried out according to the manufacturer’s recommendations,
  - all components are sufficiently covered (including grooves, holes, lumens etc.),
  - the individual components do not damage each other.
- Clean the products with a soft plastic brush.
- When cleaning, move the parts backwards and forwards ten times to ensure all areas are cleaned.
- Push a round plastic brush through large lumens ten times to ensure they are clean. Make sure the plastic brush reaches the full length of the lumen.
- Rinse the products with water for at least 1 minute until all residues are removed. Note that:
  - cannulated products (e.g. cannulated drills) can also be rinsed internally using syringes and appropriate cannulas.
- Cannulated products (products with hollow cavities with a diameter of less than or equal to 1/6th the length of the product), e.g. cannulated drills, must be processed as follows:
  - If necessary, insert the appropriate cleaning brushes or wires into cannulated products to remove blockages and ensure flow. Make sure the cleaning brushes or wires reach the full length of the cannulated product.
  - Rinse the cannulated product with a suitable cannula and disposable syringe (rinse volume of at least 30 ml).

  A water pistol can be used as an additional tool for rinsing.
- After rinsing, all products must be visually inspected; if necessary, the cleaning process outlined above must be repeated until there is no visual contamination remaining.Leave the products to dry on an absorbent, clean and lint-free surface (e.g. on a lint-free disposable paper towel).

4.3.1.2.1 Warnings

Special care is required when cleaning the blades of rotating instruments (risk of injury!). Damaged and blunt instruments must not be cleaned or reused. This prevents excessive heat development in the tissue and lowers the risks for users, patients and third parties.
INTERCUS recommends using bone drills a maximum of ten times.

4.3.2 Machine cleaning and disinfection

Machine cleaning and disinfection takes place after any manual pre-cleaning. The instructions in chapters 4.1.1 and 4.1.6 must be observed when choosing

and using cleaning agents and disinfectants.
To validate the machine cleaning and disinfection process, INTERCUS used a cleaning and disinfection device (RDG) of type HO2 (Netsch-Belimed). The cleaning agent used was “Neodisher MediClean forte” in 0.8% concentration and the neutralising agent was “Neodisher MediKlar” in 0.3% – 0.1% concentration in line with the manufacturer’s instructions (Dr. Weigert instructions). Validation was carried out with the information contained in the following table.
When selecting a cleaning and disinfection device, make sure that the device meets the limits of EN ISO 15883 and that the following process steps are part of a cleaning process:

Phase	Temperature*	Duration*	Comment
Cleaning - pre-rinse	Cold	5 mins	
Cleaning - main rinse	55 °C (131 °F)	10 mins	Addition of the cleaning agent*; pH value max. 11
Neutralisation - rinse	53 °C (127.4 °F)	5 mins	neutralise with demineralised water (DI water), adding a neutralising agent if necessary *
Intermediate rinse	---	1 min	with cold DI water
Final rinse - thermal disinfection (A0 value ≥ 3000)	93 °C (199.4 °F)	5 mins	with DI water; do not add additional cleaning agent
Drying	device-specific recommendation: 90 to max. 110 °C	device-specific recommendation: 15 mins	

* the information provided refers to the use of “Neodisher MediClean forte” (0.8%) made by Dr. Weigert as the cleaning agent, “Neodisher MediKlar” (0.3% - 0.1%) as a neutralising agent and the above-mentioned cleaning and disinfection device. The times and temperatures may vary when using other process chemicals or another type of cleaning device.

4.3.2.1 The machine cleaning and disinfection process

⚠ Instruments must be opened or disassembled as described in chapter 4.3.1.2!

- Place the products into the cleaning device.
  It is important to ensure that
  - the loading of storage systems, inserts, holders etc. is suitable for rinsing,
  - instruments are disassembled and those with joints/hinges are opened out,
  - storage systems are not overloaded (to ensure good rinsing of the instruments, implants and storage systems),
  - the loading patterns defined during validation are always observed,
  - large products are placed on the sieve trays in such a way that they do not obstruct the cleaning of other products,
  - products with hollow cavities (lumens, cannulations) can be fully rinsed out inside too. These products require suitable inserts with flushing devices,
  - the machine is loaded in such a way that products with lumens and cannulated products do not lie horizontally and that hidden cavities point downwards to aid the rinsing process,
  - the products are placed in a way that suits their level of sensitivity so as to avoid damage.
- Start the programme
- Remove the products from the device at the end of the programme
- Then inspect the products (see chapter 4.4.1 “Inspection”)
- Maintain the products (see chapter 4.4.2 “Maintenance and care”)
- Pack up the products as quickly as possible (see chapter 4.5 “Packaging”) in a clean place and after additional drying if this has been deemed necessary

4.4 Inspection and maintenance

4.4.1 Inspection

Adequate cleanliness is the basic prerequisite for successful sterilisation. Before products can be packed away for sterilisation, they must be inspected. This inspection is done visually (recommendation: use work lights with magnifying lenses).

4.4.1.1 Instrument inspection

After cleaning and disinfection, check all of the instruments for damage and functionality. Multi-piece instruments must be reassembled to check their functionality.
Check the instruments for damage, such as:

- Corrosion
- Damaged surfaces
- Hairline cracks
- Chipping
- Other wear and tear
- Contamination
- Functionality

If contaminants are still present, the instrument must go through the entire cleaning and disinfection process again.
If damaged, the instrument must be replaced!
During inspection, special attention must be paid to the following:

- Critical areas such as handle structures, joints/hinges, hollow cavities, cannulations etc. must be checked particularly carefully.
- Instruments with lumens and cannulated products (e.g. cannulated drills) must have clear passage. Products that do not have clear passage through them or that are damaged must be reprocessed or replaced if necessary!
- Cutting instruments (e.g. drills) must be checked for sharpness and damage.
- Worn or damaged instruments must be replaced!
- Rotating instruments (e.g. drills) must also be checked for deformation. This is easy to check by simply rolling the rotating instrument on a flat surface.
- Bent rotating instruments must be replaced!

4.4.1.2 Implant inspection

After cleaning and disinfection, check all implants for damage and soiling.
If contaminants are still present, the implant must go through the entire cleaning and disinfection process again.
If damaged, the implant must be replaced (please note the instructions on reusability, see chapter 2.5).

4.4.1.3 Storage system inspection

After cleaning and disinfection, check all storage systems for damage and functionality. Multi-piece storage systems must be reassembled to check their functionality.
Check the storage systems for:

- Corrosion
- Damaged surfaces
- Damaged product mounts
- Hairline cracks
- Chipping
- Other wear and tear
- Contamination
- Functionality (e.g. closures/seals)
- Completeness

If contaminants are still present, the products must go through the entire cleaning and disinfection process again.
If damaged, the products must be replaced!
During inspection, special attention must be paid to the following:

- critical areas such as handle structures, joints and hinges, cavities etc. must be checked particularly carefully,
- the correct fit and secure hold of the lid on the tray must be checked.

4.4.2 Maintenance and care

Maintenance measures are generally carried out before the functional checks.
Reassemble the disassembled instruments and storage systems. It is essential that products are assembled correctly in order to prevent damage and/or functional limitations.
Care means the targeted application of care products to joints, threads and sliding surfaces, e.g. on screw gauges, forceps etc. This is a preventive measure against fretting corrosion.
The following should be noted when dealing with care products (e.g. AESCULAP STERILIT I):

- Use paraffin/white oil-based products
- Biocompatibility
- They must be suitable for steam sterilisation and vapour-permeable
- No care products containing silicone may be used (these can lead to stiffness)

Process:

- apply the care product to the joints, threads and sliding surfaces
- distribute the care product evenly by moving the joint/sliding surface
- remove excess care product residue using a lint-free cloth

If instruments and/or storage systems show signs of damage or functional limitation, they must be replaced (see also chapter 4.4.1"Inspection").

4.5 Packaging

INTERCUS recommends sterilising in the sterilisation containers, implant containers, implant or instrument trays provided for this purpose.
However, disposable sterilisation packaging (single or double packaging) and/or other sterilisation containers can also be used.
A loaded module weighing a total of over 10 kg must not be sterilised in a sterilisation container. This must be wrapped in sterilisation paper in line with the latest technology and sterilised using an approved method.
The following requirements must be met:

- Compliance with EN ISO 11607/EN 868-3 to -10 (formerly EN 868)
- Suitability for steam sterilisation
- Sufficient protection for the implants and instruments or sterilisation packaging to prevent mechanical damage
- Regular maintenance of the sterilisation containers in line with the manufacturer's specifications

4.6 Sterilisation

⚠ The disassembled products must be reassembled and fitted for the following sterilisation process.
During sterilisation, the instructions of the corresponding steriliser must be followed.
Do not use hot air sterilisation, any formaldehyde or ethylene oxide sterilisation and do not use substitute procedures for the sterilisation of thermolabile goods such as plasma or peroxide sterilisation for your INTERCUS products.

4.6.1 Steam sterilisation

All NON-STERILE products can be sterilised with steam in an autoclave. Autoclaves must comply with EN285 and EN13060 with regard to their validation, maintenance and control.
For the first and follow-up sterilisation, the below parameters were validated by INTERCUS in line with the requirements of the sterilisation standards of EN ISO 17665.

Process	Fractional or dynamic pre-vacuum procedure	Flow, gravitation process
Exposure time	≥ 3 mins recommendation: 5 mins	≥ 3 mins recommendation: 5 mins
Temperature	134 °C (273 °F)	134 °C (273 °F)
Drying time	> 20–35 mins	> 20–35 mins

INTERCUS recommends sterilisation in line with the abovementioned process. If the user chooses to use other methods, these must be validated by the user in accordance with EN ISO 17665-1.
It is ultimately the user's responsibility to ensure validation of sterilisation techniques and equipment.

4.7 Storage of sterilised products

After sterilisation, the sterile goods must be stored in a dry and dust-free environment in a bacteria-proof sterile goods bag. Temperature fluctuations must be avoided in order to prevent condensation from forming and causing corrosion damage.
Maximum storage time depends on various factors such as packaging, storage methods, environmental conditions and handling. The user must set a maximum storage time until use for sterile goods. The products must be used or, if necessary, reprocessed (sterilised) within this time period.

5. Sterile products on the market

5.1 General

STERILE R INTERCUS products marked with STERILE R have been sterilised in a validated process using gamma radiation. The red dot on the undamaged packaging serves as an indicator for the sterile product.
Products are packed in a **double** sterile barrier with protective packaging (cardboard box) and must be stored this way. If necessary, the products are also protected with protective caps within the sterile barrier. The protective packaging (cardboard box) is not part of the sterile barrier. When using sterile packaged products, care must be taken to ensure the sterility of the product right up until the point at which it is used.
The user is **not permitted** to prepare and sterilise INTERCUS products that have been marketed in a sterile condition again.

5.2 Checking the packaging

The packaging must be checked for possible damage before the product is stored and used. If the packaging is damaged, the sterility of the product cannot be guaranteed as the sterile barrier may have been damaged. INTERCUS does not guarantee the sterility of products that come out of damaged or improperly opened packaging and assumes no liability in these cases.

5.3 Handling

⚠ The protective or sterile packaging must only be removed immediately before the product is used. Any protective caps must be removed before use. Asepsis requirements must be observed when removing the product from its sterile packaging. Products that have been removed from their sterile packaging and not used may not be re-sterilised and must be disposed of.

⚠ Products marketed as sterile should be used in order of their expiry date. Check the expiry date before opening the packaging. Products that have passed their expiry date must not be used and should be disposed of.

6. Disposal

There are no special or unusual hazards linked to the disposal of INTERCUS implants and instruments. From the perspective of preventing infection, they can be disposed of as normal, contaminated surgical waste.
If not disposed of as contaminated surgical waste by an appropriate waste disposal company, INTERCUS products must be prepared separately (not together with other medical products) before other disposal (e.g. handing over explanted implants to patients)! Reusing explanted implants is not permitted!

7. Labelling (symbols used)

In preparation for or during the introduction of Regulation (EU) 2017/745 (MDR), INTERCUS product labels will be adapted. During the transition period, the symbols marked in the following overview will be added step by step.

Symbol used	Meaning
YYYY-MM	(Manufacturer incl. date of manufacture) INTERCUS GmbH Zu den Pfarreichen 5 07422 Bad Blankenburg Germany
DE *1)	(Country of manufacture) Germany
LOT	Manufacturer's batch number
REF	(Item number / Catalogue number)
NON STERILE	Non-sterile
STERILE R	Radiation sterilised
*1)	Double sterile barrier

Symbol used	Meaning
	Do not reuse
	Do not use if the packaging is damaged
	Caution
	Follow the instructions for the use in the printed or electronic instructions for the use
CE	Conformity mark for Class I medical devices (non-sterile and without measuring function)
CE 0197	Conformity mark for medical devices in Class IIa and above Date of manufacture from 18th October 2014
CE 1275	Conformity mark for medical devices in Class IIa and above Date of manufacture up to 17th October 2014
	Shows the date after which the medical product may no longer be used
MD *1)	Medical device
UDI *1)	Unique device identifier
QTY *1)	(Number / quantity)

*1) Step by step introduction of the symbols in preparation for Regulation (EU) 2017/745