Instructions for Use and Preparation
of Medical Products of INTERCUS GmbH

Use, Cleaning, Disinfection, Sterilisation, Maintenance and Care

1 Introduction

PLEASE READ THESE INSTRUCTIONS CAREFULLY AND OBSERVE THE INSTRUCTIONS

This document titled „Instructions for Use and Preparation of INTERCUS Products" contains information on:

- The use
- The preparation (cleaning, disinfection and sterilisation) of medical products of INTERCUS GmbH before use
- The inspection and maintenance of the medical products
- The distinguishing marks with respect to wear and loss of serviceability

Other information on the products is rendered in the various product leaflets, catalogues and as part of the operating techniques. All information can be obtained from INTERCUS GmbH or our dealers at any time. Moreover, the contact data as well as additional information is available on the Internet at www.intercus.de.

The preparation of the products, which are described hereinafter, has been tested and validated by INTERCUS (cleaning, and disinfection as well as sterilisation process).

In the following text, the designation „products" shall comprise:

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

In case of different handle, the product groups are indicated explicitly.

2 Use

2.1 Implants

2.1.1 General safety instructions

(1) INTERCUS implants are packed non-sterile and are supplied non-sterile, and must be used once only.

(2) INTERCUS implants have been designed in conformity with the latest knowledge in implantation technology and the recognised rules of engineering art. However, their safety and functional efficiency can be ensured only when the general information of this sheet is observed and followed.

(3) The operator has to be acquainted with the subjects of implantation and explantations of implants, with the state of science and technology as well as with the AO principles of fracture management. As long as no other details are specified by INTERCUS, the implantation and explantation must be done in accordance with the AO principles (see for example AO "Instrumente und Implantate - Technisches Handbuch" [Eng. Instruments and Implants – Technical Handbook]; second edition; Springer-Verlag 1995).

(4) In general, the patient's doctor must explain the indications, contraindications, undesired side-effects, complications and the post-operative treatment. After the implantation, regular medical checks should be performed.

(5) When adapting the plates to the bones, please ensure that the maximum bending angle of 15° is not exceeded. Multiple bending back and forth is to be avoided, as it can weaken the plate material.

(6) When shortening (cutting) plates and wires, you have to make sure that no burrs have formed on the cutting edge, as they could injure the patient.

(7) Complications, which could be the result from faulty indications, operating techniques or asepsis, fall under the responsibility of the operator, and cannot be attributed to the manufacturer or to the supplier of the INTERCUS products.

(8) Before every use the operator shall have to convince himself of the perfect condition of the implant, especially in combination with standard implants of other manufacturers. Standard implants are implants whose geometry is described in the AO standard or prescribed by standards (for example standard screws according to ISO 5835). Which INTERCUS products can be combined with each other is described in the INTERCUS catalogs, standard implants from other manufacturers must be comparable to these.

(9) The angle-stable INTERCUS implants shall not be used together with angle-stable implants of other manufacturer.

Implants are intended only to promote healing and are no substitute material for intact tissue and bone material.

2.1.2 Compatibility

The bone plates, bone screws and flat washers, bone wires and bone nails are available in many different shapes and sized, and are made of surgical implant material – surgical stainless steel and titanium (ensuring bio-compatibility). The data are rendered on the label. The implants may be combined only with units which have been produced from the same material.

For the implantation of the implants INTERCUS instruments are available which are in conformity with the AO standard. When applying the products, the intended purpose, the size data and the type of connection (in case of screws, for example) shall have to be observed in order to ensure the intended use and the correct selection of instruments. These data are rendered in the product identification of the products.

2.1.3 Storage and treatment

Implants are highly sensitive to damage.

Due to this fact an extremely careful treatment is required:

- Products should be stored in an unopened state in the original packaging.
- The protective packaging may be removed only directly before treatment.
- Implant must neither be mechanically handled nor modified in any other way, unless the construction and the operating technique explicitly provide for this. If in doubt, ask INTERCUS for a written recommendation.
- By no means may products be implanted which are obviously damaged, scratched, treated incorrectly, or which have been worked in an unauthorised manner. These products shall have to be returned to the supplier for check-up.

Storage conditions see 2.4.1 „Storage conditions"

2.1.4 Handling or non-sterile products

INTERCUS implants and complete sets are cleaned by the manufacturer in a validated cleaning plant, packed and supplied in non-sterile state in a protective packaging. This protective packaging may be removed before preparation. The implants shall have to be cleaned, disinfected and sterilised by the user.

Repeated use is not permitted in case of contact with the patient or contamination of the implant.

2.1.5 Intended purpose

INTERCUS implants are used for osteosynthesis after bone fractures, for stabilisation of bone fragments belonging together, for stiffening of joints (arthrodesis) and after osteotomies for the correction of incorrect positions, and are in conformity with the AO principles.

The product-related intended purpose is indicated on the marking (label).

2.1.6 Weight-bearing load on the implants

The implants cannot bear the full load of the treated bone segment at any time. The implants are merely intended to promote healing and do not represent a replacement for intact tissue and bone material. As a result, the patient's doctor must notify the patient about the load limits and prescribe corresponding post-operative treatment.

- All implants allow a partial load of up to 15-20 kg for 6 weeks and thereafter as per the x-ray findings, after osteosynthesis or osteotomy, provided there is acceptable bone quality and good surrounding soft tissue. This does not include comminuted fractures (AO Principles of fracture management – Thieme Verlag 2000).
- A forefoot offloading shoe is used in the foot, which is able to bear the full weight of the body.
- On the upper extremities of the body there is always stability of movement (non-load-bearing movement).
- There is no full weight-bearing load on the upper extremities like there is with the lower extremities.

2.1.7 Indication

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

2.1.8 Contra-indications

Contra-indications develop in case of acute infections, in which the healing process could be impaired by the implants placed; in case of considerably advanced osteoporosis and in case of known allergies against surgical implant materials (see the chapter on bio-compatibilities). The surgeons shall have to provide information on the risks and shall be responsible of the said.

2.1.9 Safety and service life

The service life of INTERCUS products is 50 years.
Storage conditions (see 2.4.1 "Storage conditions")
The patient, who receives this implant, shall have to be informed by the surgeon, that the safety and life of the implant depends on the following factors and risks

- Previous infections
- Overweight of the patients
- Extreme loads to be expected during work and sports
- Falling sickness or other reasons for repeated accidents with increased fracture risks
- Significant osteoporosis caused by bone softening
- Weakening of the load-bearing structures caused by tumours
- Allergies against material components in the implant

⚠ INTERCUS implants are generally made from non-magnetic surgical material, see 3 "Materials".
INTERCUS Implants has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment.
The safety of INTERCUS Implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
A MR scan should be avoided on patients who have received INTERCUS implants

2.1.10 Bio-compatibility

The materials used are indicated on the respective product label. INTERCUS implants are made of surgical implant material in keeping with:

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

In case of known allergies against implant steel, the use of steel implant shall have to be avoided, and titanium shall be used.

2.1.11 Notes with regard to pre-operative operating planning

(1) The operation shall have to be planned precisely by means of the X-ray findings.
(2) Moreover, the specific INTERCUS instruments can be used for the preparation of the bone bed as well as for the adaptation as well as insertion of the implant.
(3) Operating technique: The rules of the art and science as well as scientific publications of medical authors shall be decisive. A description of an operation can never be complete and can never comprise all risks and complications to be observed. Brochures on the operation, technical product descriptions, further-reaching information and films can be ordered from INTERCUS.
(4) Aseptic conditions in the operating theatre.
(5) When unpacking the implant, the conformity with the designation on the packaging shall have to be checked, and the qualified treatment of the implant shall have to be observed.

2.1.12 Notes concerning post-operative monitoring

- The mobilisation and post-operative monitoring are part of the responsibility of the surgeon and have to be determined patient-specifically.
- The patient shall have to be instructed that he or she shall have the implant checked after extreme falls or blows.

2.2 Instruments

2.2.1 General safety instructions

(1) INTERCUS instruments are packed and supplied in non-sterile packages, and may be used again.
(2) The INTERCUS instruments have been designed according to the knowledge in instrument technology and the rules of the art of engineering recognised. However, their safety and functionality can be guaranteed only when the instructions in this sheet are observed by the surgeon.
(3) The surgeon has to be acquainted with the entire subject when handling INTERCUS instruments as well as the state of science and technology.
(4) Complications, which arise due to faulty use, shall be the responsibility of the surgeon, and neither the manufacturer nor the supplier of the INTERCUS instruments can be blamed.
(5) The surgeon shall have to convince himself/herself of the perfect condition of the instruments prior to every use.

2.2.2 Intended purpose

The INTERCUS instruments are in conformity with the AO standard and shall be used for implanting and/or explanting of implants on the basis of the AO principles of facture management. Among other things, the intended purpose, the size information and the type of connection (in case of screwdrivers, for example) shall have to be observed in order to guarantee the intended use. These data are rendered on the product label.

2.2.3 Storage and treatment

Storage conditions see 2.4.1 „Storage conditions"
It is recommended to carry out the re-treatment of an instrument as soon as possible of its use (see (5) "Preparation for cleaning, disinfection and sterilisation").

2.2.4 Assembly / disassembly

In case of single-part instruments, a disassembly of the instruments is not required or possible. Multi-part instruments shall have to be disassembled into their individual parts prior to cleaning.

2.2.5 Other instructions

The laser marking of the instruments may weaken partially or completely when treated by means of basic cleaners containing phosphoric acid or hydrofluoric acid, which may have a negative effect on the function. In this case the instrument is worn and has to be scrapped.

2.3 Rotating instruments

2.3.1 General information

Rotating instruments are medical products which are approved for reuse! The products are supplied in non-sterile state and have to be prepared prior to use. This product is a rotating instrument which in combination with a compatible drive system is used for abrasive removal of bony structures. The product may be used only in conformity with the information rendered here along with the corresponding drive system.
The product shall be applied by doctors trained in the special surgical discipline to be applied who have been instructed within the framework of the generally applicable training under consideration of the pertinent literature on the corresponding processes. In particular the doctor shall have to determine the extent of injury and/or change in the tissue which a surgical treatment requires, and thus shall determine the corresponding surgical-therapeutic processes. This is especially important in case of accompanying illnesses of the patients to be treated, which may limit the use of the rotating instruments.

2.3.2 Warning notice

When cleaning the cutting surfaces, special attention is required (danger of injury!). Damaged and blunt instruments must not be cleaned and reused in order to avoid high heat development on the tissue and risk for user, patient and third parties.
INTERCUS recommends applying bone drills for a maximum of ten times.

2.3.3 Intended purpose

Bone drills are used to drill open core and through holes for bone screws and to drill open medullary cavities for intramedullary bone nails.
The product-related intended purpose is rendered on the marking (label).

2.3.4 General handling

Rotating instruments shall have to be used in conformity with this information only with the corresponding drive systems. It shall have to be ensured that compatible types of connections only are used together (such as for quick couplings, triangular shanks, cylinder shanks, dental coupling).
Prior to every use, it shall have to be made sure that the rotating instruments to be used are in a technically perfect and sterile condition.
Rotating instruments with any type of damage shall have to be removed, and in general must not be used any further.
Rotating instruments shall have to be clamped up to stop in the drive. Prior to initial operation, the safe fit of the instrument shall have to be checked.
The rotating instruments are not suitable for working metal materials (such as steel alloys).

2.3.5 Pressure strength

Excessive pressure strength shall have to be avoided by all means as they may cause thermal neuroses in the tissue.
Excessive pressure strengths reduce the service life of the instrument; in an extreme case they may cause the rupture of the instrument.

2.3.6 Heat development

Basically, the development of heat cannot be prevented in case of rotating instruments, but it shall have to be kept as low as possible. The cause for a higher development of heat is, among other things, worn as well as blunt rotating instruments, an insufficient removal of the bone splinter produced, due to which the cuts can be blocked and thus cannot operate freely anymore. This will cause a prolongation of the working time on the bone. The higher heat development occurring thus may lead to irreversible damage of the bony tissue (thermal necrosis), and moreover may reduce the service life of the instruments.

2.3.7 Indications

Rotating instruments shall be used in conformity with their intended purpose and/or in keeping with the AO standards. In the process they shall fulfil the principle of abrasive removal of undesired bone substances and/or the preparation of bony implant sites.

2.3.8 Contra-indications

In most cases, potentially occurring complications are in direct relationship with the use of the instruments, but are caused rather more by wrong choice of instruments as well as imprecise handling and implant placement. In rare cases, over-sensitivities and allergic reactions may develop certain alloy elements.
In addition, patients with specific diseases of the bone structure (such as osteoporosis, bone resorption) shall have to be treated individually. After an intervention, early or also late low-lying and/or surface infection may develop.

2.3.9 Test before use

Before use every user of the instrument has the obligation to check this unit for changes, fractures or damage which may have been caused by incorrect transport, storage or treatment.

2.4 General aspects

2.4.1 Storage conditions

There are not special requirements for the storage of non-sterile products. However the product should remain in the original packaging until they are processed by the user in a normal room climate (15–25 deg C, 40–65% rel. H.), protected from direct sunlight, stored and protected against mechanical damage.

2.4.2 Information

For further information, please get in touch with the supplier.
Refer to the LOT No., which is indicated on the label and/or the instrument as follows:

LOT XXXXXX

The preparer shall be responsible for the fact that the preparation really carried out produces the requested result. Validation and routine monitoring of the process shall be required for the purpose. Moreover, every deviation from the instructions rendered shall be assessed by the preparer with care for their effectiveness and the potential negative consequences.

2.4.3 Safety and liability

The user shall be obligated to check the product on his or her own authority for suitability and for possible applications for the intended purpose prior to the use of the said. The use of the product is the responsibility of the user. For any damage occurring, any liability of INTERCUS GmbH shall be excluded. Only by appropriate handling of the product is a successful operation ensured.

2.5 Reusability of INTERCUS products

Medical products which are intended for **single use** only (such as implants) have been marked on the label with the following symbol:


These products are intended for single use only.
Prior to use, they have to be prepared.

The reuse of implants which come into contact with the blood or other bodily fluids of a patient, is not permitted, as there is a hazard due to the reuse of contaminated implants.
When reusing INTERCUS implants, the mechanical characteristics of the product can no longer be guaranteed by INTERCUS due to prior stress, wear and tear.
Products which have not been provided with the symbol mentioned above may be used again. These are instruments, rotating instruments as well as storage systems/sets. The prerequisite for reuse is that the products are not damaged and soiled. These reusable products have to be prepared prior to use.
In case of disrespect the manager shall rule out any liability.

For the use of reusable products INTERCUS does not define a maximum number of reuses (exception: INTERCUS recommends using the bone drill for a maximum of ten times). The service life of products depends on many factors, such as:

- Type and manner as well as the duration of the individual applications
- Handling of the product during and between application

Careful inspection and functional tests of the products prior to use are the best methods to determine the useful life of the product.

3 Materials

3.1 Implants

All INTERCUS implants are made of titanium (ISO 5832-2, ASTM F67) and/or titanium alloys (ISO 5832-3, ASTM B265, ASTM F136) and are anodised or are produced from implant steel (ISO 5832-1, ASTM F138; ASTM F139 or ISO 5832-9). All titanium and steel materials used are bio-compatible, resistant to corrosion, non-toxic in a biological environment, and are not ferromagnetic.

3.2 Instruments

The instruments are made of stainless steel, carbon, PEEK, PP, PPSU, silicone or aluminium.

3.3 Material resistance

All INTERCUS products may be subjected to a maximum of 137 deg. C (278 deg. F).
When selecting cleaning and disinfection agents the following warning instructions shall have to be observed:

Material	Not recommended
Aluminium (anodized, etcetera)	• Iodine or alkaline component parts or salts of heavy metals (such as mercury) • Bad water quality, alkaline cleaner, acidic neutralisation agents
Colour coding	• All oxidising acids (such as nitric acid, sulphuric acid, oxalic acid), H_2O_2 (hydrogen peroxide) • Excessively high cleaning and disinfection concentrations
Stainless steel	• High chlorine concentrations • Oxalic acid • Hydrogen peroxide (H_2O_2)
Titanium/ titanium alloys	• All oxidising acids (such as nitric acid, sulphuric acid, oxalic acid), H_2O_2 (hydrogen peroxide)

4 Bases for the treatment of INTERCUS products

The basic principles described in this chapter shall have to be observed in all preparation steps!

⚠ An effective cleaning and disinfection is an indispensable pre-requisite for an effective sterilisation.

⚠ A single manual cleaning and disinfection of INTERCUS products is not permitted!

The preliminary treatment for cleaning/disinfection shall have to be carried out. Within the framework of your responsibility, please observe for the sterility of individual components that:

- Processes sufficiently validated for the devices and products are used for the cleaning/disinfection and sterilisation
- The devices used (RDG, steriliser) are serviced and checked in regular intervals
- The parameters validated and/or recommended by the manufacturer are observed during every cycle

⚠ In addition, please observe the legal regulations applicable in your country as well as the hygiene regulations of the hospital. This shall apply in particular for the different requirements with respect to an effective inactivation of prions. In case of contact (or suspicion thereof) of the product with elusive pathogens, such as the variants of the Creutzfeldt-Jakob disease, INTERCUS recommends to discard the products.

⚠ Regular reworking has minor effects on surgical products. The product service life is normally determined by the wear and tear when using the product.

4.1 Cleaning, disinfecting agent and devices

When choosing the cleaning, disinfecting agents and devices, please observe in all steps that:

- They are suitable for the intended use (such as cleaning, disinfection, ultrasonic cleaning of medical products)
- The cleaning and disinfecting agents are free from aldehyde (otherwise fixation of blood stains)
- They have an approved efficacy (such as VAH/DGHM or FDA approval and/or CE label)
- The cleaning and disinfecting agents are suitable for the products and are compatible with the products (see also chapter 3 "Materials")
- The manufacturer's data are observer with respect to concentration, reaction time and temperature, for example

INTERCUS recommends the use of freshly prepared cleaning and disinfecting solutions.

Detailed data on the specific products suitable for gentle cleaning and disinfection can be obtained directly from the manufacturers of the cleaning and disinfecting agents. In Germany and Switzerland, these are for example:

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

4.2 Auxiliary means for preliminary cleaning/cleaning

Never clean INTERCUS products with metal brushes or steel wool; the material may be damaged in case of disregard.

Use clean, lint-free cloths and/or soft brushed. For the preparation of cannulated products and/or products with hollow cavities, you need cleaning pins, bottle brushed and/or disposable syringes with appertaining tubes as attachments.

4.3 Auxiliary means for drying

For cleaning, INTERCUS recommends lint-free single-use paper towels or medical compressed air.

4.4 Water quality

With respect to water quality, INTERCUS recommends the use of demineralised and purified water for cleaning, disinfecting as well as reflushing steps. High concentrations of minerals and/or contaminations with micro-organisms, and similar, may cause spots on the products or may prevent an effective cleaning and decontamination.

5 Preparation for cleaning, disinfection and sterilisation

5.1 Placing and preparing the instruments after the operation

The first step of correct treatment starts in the operating theatre already.

Coarse soiling, residues of haemostatic, skin disinfecting and lubricating agents as well as caustic medicinal products should be removed, if possible, before laying down the instruments. When placing the instruments, the following shall have to be observed: by improper "dropping" of the instruments, they may be damaged (such as deformation or damage of instruments, in particular the tips). For this reason, make sure that the instruments are placed correctly and the instrument baskets are not overfilled.

If possible, dry disposal should be preferred for the transport to the cleaning/sterilisation department. In case of wet disposal, the instruments shall have to be laid into the corresponding cleaning solution directly after operation. In the process, please make sure that:

- Multi-piece instruments (such as depth gauges, removable handles, tubes for screw drivers, etcetera) are disassembled before pre-treatment
- Hinge instruments (such as clamps, tongs, etcetera) are opened as widely as possible
- In case of wet disposal all surfaces (grooves, holes, lumen, etcetera) are sufficiently covered with the solution

The products should be treated as fast as possible (< 6 h) in order to be prevent blood residues and similar from drying up and to not exceed the time for wet disposal time (danger of material damage).

6 Cleaning and disinfection

For all instruments, INTERCUS recommends to manually pre-clean them before machine cleaning and disinfection, if they are or could be contaminated.

⚠ Manual cleaning and disinfection of the INTERCUS products only are not permitted!

For the following cleaning and disinfection process, the disassembled instruments and storage systems remain disassembled.

6.1 Manual pre-cleaning

During manual pre-cleaning, special attention shall be given to holes, lumen, grooves and articular surfaces!

6.1.1 Pre-treatment

6.1.1.1 Instruments

Clean the disassembled and open instrument under running water. In the process the following has to be observed:

- Clean the visible soiling with a soft plastic brush, that sized to the size of the product (for example from INTERLOCK Medizintechnik GmbH www.interlockmed.com, products for the central sterile supply).

6.1.1.2 Storage systems for implants and/or instruments

Clean the **storage systems for instruments** under running water as well:

- Remove instruments, which have been sorted in potentially, from the storage systems; the sieves have to be empty
- If possible, remove the lid of the storage system
- Thoroughly clean the individual parts under running water

Clean the **storage systems for implants** under running water beforehand also as follows:

- Rinse the said thoroughly in closed condition first of all
- Remove the implants from the storage systems
- If possible, remove the list of the storage systems for implants or rinse the joints, if necessary; handles must not be removed in the process
- Clean the individual parts thoroughly under running water

6.1.2 Process of manual pre-cleaning

⚠ If and when possible, instruments and storage systems must be open and/or disassembled for the cleaning process !

- Place the products in an ultrasonic bath with cleaning agents (such as Neodisher septo Pre Clean; 2 percent, Dr. Weigert) for fifteen minutes.
- In the process, it has to be made sure that:
  - fresh solutions are used only
  - a suitable cleaning or combined disinfection and cleaning agent is added
  - the ultrasonic cleaning bath is prepared according to the instructions of the manufacturer with respect to temperature, concentration, etcetera
  - the ultrasonic treatment is carried out according to the recommendations of the manufacturer
  - all components are adequately covered (including grooves, holes, lumen, etcetera)
  - the individual components do not damage each other
- Use a soft plastic brush to clean the products.
- When cleaning mobile parts move them back and forth ten times to that all parts are cleaned.
- Use a round plastic brush to clean large lumen by brushing through ten times; make sure that the plastic brush reaches the full length of the lumen.
- Rinse the products with water for at least one minute until all residues have been removed. Please observe that:
  - cannulated products (such as cannulated drills) have to be rinsed inside as well by using syringes and corresponding cannulas
- Cannulated products (products with hollow spaces, the diameter of which is small or equal 1/6 of the length of the product), such as cannulated drills, have to be treated as follows:
  - Insert the corresponding cleaning brushes or wires into the cannulated product in order to remove any potential blockages and to ensure passage. Make sure that the cleaning brushes or wires reach the full length of the cannulated product.
  - Rinse the cannulated product with a suitable cannula and disposable syringe (flushing volume at least 30 ml).

  A water pistol can be used for rinsing as another auxiliary means.
- After rinsing, all products have to be checked visually; if necessary, the cleaning process mentioned above has to be repeated until no visible soiling is left.
- Let the product dry on an absorbent, clean and lint-free pad (such as on a lint-free single-use power towel).

6.2 Machine cleaning and disinfection

After the manual pre-cleaning potentially carried out, the machine cleaning and disinfection has to be carried out.
When selecting and using the cleaning and disinfecting agents, the instructions in chapters 3.3 and 4 shall have to be observed.
For the validation of the machine cleaning and disinfection process, INTERCUS has used a cleaning and disinfecting device (RDG) of type HO2 (Netsch-Belimed) and cleaning agent „Neodisher MediClean forte" in 0.8 percent concentration and as neutralizing agent "Neodisher MediKlar" in 0.3 percent to 0.1 percent concentration in keeping with the data of the manufacturer (instruction - Dr Weigert). The validation has been carried out as rendered by the data in the following table.
When selection the RDG, please make sure that the RDGs comply with the limit values of EN ISO 15883 and that the following phases are part of a cleaning process:

Phase	Temperature*	Duration*	Action
Cleaning – pre-rinsing	Cold	5 min.	
Cleaning – main rinsing	55 deg. C (131 deg. F)	10 min.	Addition of the cleaning agent*; pH value - max. 11
Neutralisation	53 deg. C (127.4 deg. F)	5 min.	Neutralise with demineralized water (DI water), if necessary adding a neutralisation agent *
Rinsing	Cold	1 min.	Rinse with cold DI water
Thermal disinfection (A_0 value ≥ 3,000)	93 deg. C (199.4 deg. F)	5 min.	With DI water; do not add additional cleaning agent
Drying	Device-specific recommend: 90 to max. 110 deg. C	Device-specific ommend: 15 min.	Drying process

* The information rendered refer to the use of „Neodisher MediClean forte" (0.8 percent) of Dr Weigert as cleaner, „Neodisher MediKlar" (0.3 percent to 0.1 percent) as neutralisation agent and the RDG mentioned above; when using other process chemicals indicated or another RDG, times and temperatures may vary.

6.2.1 Process of machine cleaning and disinfection

⚠ The instruments have to be opened and/or disassembled as described in chapter 5.1!

- Place the products in the RDG.
  In doing so, please make sure that:
  - loading of storage systems, inserts, holding systems, etcetera, is suitable for rinsing
  - instruments are disassembled or joint instruments are place in open condition
  - storage systems are not overloaded (good wash around of the instruments, implants and storage systems)
  - loading patterns determined during validation are always observed
  - large products are placed on the sieve bowls in such a way that they do not obstruct cleaning of other products due to "rinsing shadows"
  - products with hollow spaces (lumen, cannulas) are always rinsed completely. For these products, suitable inserts have to be used
  - the machine is loaded in such a way that products with lumen and cannulated products are not placed horizontally and covered hollow spaces point down in order to support the flushing processes
  - products are placed according to their sensitivity in such a way that a damage is ruled out
- Start the program.
- Remove the products from the RDG after the end of the program.
- Subsequently inspect the products (see chapter 7.1 „Control").
- Maintain the products (see chapter 7.2 „Maintenance and care").
- Pack the products immediately, if possible (see chapter 8 "Packaging"), at a clean location, after additional drying, if and when necessary.

7 Control and maintenance

7.1 Control

Basically, adequate cleanliness shall be the basic conditions for the success of sterilisation. Before the products can be packed for sterilisation, they have to be checked. The check is done visually (recommendation: Use work lamps with magnifying glasses).

7.1.1 Control of instruments

After cleaning and disinfection, check all instruments for damage and function. For the functional control, multi-part instruments shall have to be assembled again.

Check the instructions for damage, such as:

- Corrosion
- Damaged surfaces
- Hairline fractures
- Breakaways
- Other wear
- Soiling
- Functionality

If some contamination is still found, the instruments shall have to pass through the complete cleaning and disinfection process once again.
In case of damage, the instruments have to be replaced!
During the check, special attention shall be given to:

- Critical areas, such as handle structures, joints, hollow spaces, cannulations, etcetera, shall have to be checked especially careful.
- Instruments with lumen and cannulated products (such as cannulated drills) have to be checked for pass-through. Products which does not open or are damaged must be retreated or replaced, if and when necessary!
- Cutting instruments (such as drills) have to be checked for sharpness and damage.
- Worn or damaged instruments must be replaced!
- Rotating instruments (such as drills) must be checked for bending in addition. This can be checked easily by simply rolling the rotating instruments on a flat surface.
- Bent rotating instruments must be replaced!

7.1.2 Control of the implants

After cleaning and disinfection, check all implants for damage and dirt. If some contamination is still found, the implants shall have to pass through the complete cleaning and disinfection process once again.
In case of damage, the implants have to be replaced (in this case, please observe the reusability – see chapter 2.5).

7.1.3 Control of the storage systems

After cleaning and disinfection check, all storage systems have to be checked for damage and function. For functional check, the multi-part storage systems have to be combined again.

Check the storage systems for:

- Corrosion
- Damaged surfaces
- Hairline fractures
- Breakaways
- Other wear
- Soiling
- Functionality

If some contamination is still found, the products shall have to pass through the complete cleaning and disinfection process once again
In case of damage, the products have to be replaced!
During the check, special attention shall be given to:

- Critical areas, such as handle structures, joints, hollow spaces, etcetera, shall have to be checked especially careful.
- The correct seat and safe hold of the cover on the shell has to be checked.

7.2 Maintenance and care

The maintenance measures are carried out by the functional control department as a rule.
Reassemble the disassembled instruments and storage systems. The correct installation of the products is indispensable in order to prevent damage and/or functional limitations.
Care is considered to mean the purposeful application of care products in joints, threads and sliding surface, such as screw measuring devices, tongs, etcetera. This is a preventive measure in order to prevent frictional corrosion.
With respect to care products (e.g. AESCULAP STERILIT I), the following shall have to be observed:

- Use of agents on the basis of paraffin/white oil
- Biocompatibility
- They shall have to be suitable for steam sterilisation and permeable for steam
- Do not use any silicone-containing treatment agents (may lead to stiffness)

7.2.1 Process

- Apply the care product purposefully into joints, threads and sliding surfaces.
- Spread the care product by moving the joints/sliding surfaces evenly.
- Use a lint-free cloth to remove excessive residues of the care product.
- If instruments and/or storage systems have any damage or functional limitations, they have to be replaced (see also chapter 7.1 "Control").

8 Packaging

INTERCUS recommends carrying out the sterilisation in the sterilisation vessels, implanting containers, implanting or instrument bowl intended for the purpose. However, one-time sterilisation packings (single or double packaging) and/or other sterilisation vessels can be employed.
Given an overall weight of the loaded module of over 10 kg, the said must not be sterilised in a sterilisation container, but has to be wrapped in sterilisation paper for sterilisation in conformity with the state of the art and an approved method.
The following requirements shall have to be fulfilled:

- Conformity with EN ISO 11607/EN 868-3 to 10 (previously EN 868)
- Suitability for steam sterilisation
- Sufficient protection of the implants and instruments and/or sterilisation packaging against damage
- Regular maintenance of the sterilisation vessels in conformity with the instructions of the manufacturer

9 Sterilisation

⚠ For the sterilisation process now following, the disassembled instruments and storage systems are assembled and fitted.

The instructions of the corresponding sterilisers shall have to be observed.
Do not use hot air sterilisation, no formaldehyde or ethylene oxide sterilisation, and do not apply any substitute processes for the sterilisation of thermolabile products, such as plasma or peroxide sterilisation, for the INTERCUS products.

9.1 Steam sterilisation

All non-sterile products can be sterilised in an autoclave using steam. With respect to validation, maintenance and check the autoclaves shall have to be in conformity with EN 285 and/or EN 13060.
For the first or follow-up sterilisation, the parameters mentioned hereinafter have been validated by INTERCUS in conformity with the sterilisation standards, i.e. EN ISO 17665.

Process	Fractioned and/or dynamic pre-vacuum process	Flow, gravitation process
Duration of exposition	≥ 3 min recommended: 5 min.	≥ 3 min recommended: 5 min.
Temperature	134 deg. C (273 deg. F)	134 deg. C (273 deg. F)
Drying time	> 20–35 min.	> 20–35 min.

INTERCUS recommends sterilisation in conformity with the validated procedure mentioned above. If other processed are applied by the user, they have to be validated by the user in conformity with EN ISO 17665-1.
The final responsibility for the validation of the sterilisation techniques and sterilisation equipment shall be with the user.

10 Storage of sterilised products

After the sterilisation, the sterile material has to be stored in a dry and dust-free environment in a bacteria-proof sterile material bag. Temperature variations shall have to be avoided in order to prevent condensate formation and thus corrosion damage.
The maximum storage time is dependent on various factors, such as packaging, storage methods, environmental conditions and handling. The user shall have to define a maximum storage time for sterile products until use. Within this period of time, the products have to be used or, if necessary, have to be treated (sterilised) again.

11 Disposal

No special or unusual hazards exist when disposing of INTERCUS implants and instruments. From the perspective of preventing infections, they can be disposed of as normal, contaminated operating waste.
If the disposal is performed by a disposal company as non-contaminated operating waste, the INTERCUS products are to be separately prepared (not together with other medicinal products) before any other disposal (e.g. handing over of explanted implants to patients)! It is not permitted to reuse explanted implants!

12 Marking (symbols used)

Symbol used	Significance
	(manufacturer) INTERCUS GmbH Zu den Pfarreichen 5 07422 Bad Blankenburg Germany
	batch number of the manufacturer
	(article number)
	non-sterile
	observe instructions for use
	caution
	do not re-use
CE	Conformity mark for medical products of class I (non-sterile and without measuring function)
CE 0197	Conformity mark for medical products of class IIa and higher Production date as from 18th October 2014
CE 1275	Conformity mark for medical products of class IIa and higher Production date up to 17th October 2014