SCYON Orthopaedics AG

Packaging Insert (with Cleaning and Sterilization Instructions)

ENGLISH

ALPS
Advanced Locking Plate System

Manuals are subject to change;
the most current version of each
manual is always available online.
Printed on: XXXX

Version 0001
Date 2019/06/17

Basic Instructions on the Use of SCYON Implants and Instruments for Orthopedics and Osteosynthesis

Product Description
Surgical implants offer orthopedic surgeons a means of precise bone fixation. They also play a generally supportive role in treatment, healing of fractures, and reconstructive surgery (osteosynthesis and correction of degenerative diseases). However, implants are not suitable to replace normal body structures or bear the body's weight (see product-specific instructions).

Selecting an Implant/Indications
Consider the following points when treating traumatic and/or degenerative skeletal changes:

1. **Selecting the implant.** It is of paramount importance to select the proper implant. The potential for success is increased by selecting the proper implant size and shape. The characteristics of human bone and soft tissue pose restrictions on the size and strength of implants. No partial weight-bearing or non-weight-bearing product can be expected to withstand the full, unsupported weight of the body. If a strong bone union is to be achieved, the patient needs adequate external assistance. Likewise, the patient must restrict physical activities that would place stress upon the implant or allow movement at the fracture site and thus delay healing.

2. **Patient-related factors.** A series of patient-related factors have a strong influence on the success of surgery:
a Weight. An overweight or obese patient can place so much stress on the product that it will fail, perhaps even reversing the effects of surgery.
b Occupation or activity. Professional occupations pose a risk when external forces subject the body to substantial physical loads. This can cause the product to fail and even undo the achievements of surgery.
c Senility, mental illness, or alcoholism. These conditions may cause the patient to ignore certain necessary limitations and precautions, leading to the failure of the product or other complications.
d Certain degenerative diseases and smoking. In some cases, a degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the implant. In such cases, the products serve only as a means to delay or temporarily relieve the disease.
e Sensitivity to foreign bodies. Where hypersensitivity to a material is suspected, appropriate tests should be undertaken prior to selecting or implanting the material.

3. **Correct handling.** Correct handling of the implant is extremely important. If the shape of the implant must be altered, the device should not be bent sharply, bent backwards, notched, or scratched. Such manipulations, in addition to all other improper handling or use, can produce surface defects and/or concentrate stress in the core of the implant. This in turn may eventually cause the product to fail.

4. **Postoperative care is essential.** Physicians should inform their patients about the implant's load restrictions and offer a plan for postoperative behavior and increasing physical loads. Failure to do this can generate malalignment, delayed bone healing, implant failure, infections, thrombophlebitis, and/or wound hematomas.

5. **Removal of the osteosynthetic product.** While the physician makes the final decision on when to remove the implant, it is advisable – if possible and appropriate for the individual patient – to remove fixation products after the healing process is complete. This holds true particularly for young and active patients.

6. **Compatibility.** SCYON guarantees the compatibility of its different original implants and/or instruments. The product-specific instructions for use as described by SCYON must be followed. It is not advisable to mix SCYON products with those of different manufacturers, since designs, materials, mechanics, and construction are not harmonized. SCYON assumes no liability for any complications arising from mixing components or from using foreign instruments.
If not otherwise mentioned it is not recommended to mix different implant metals.
Mixing of metals may lead to galvanic corrosion and a release of ions. This may cause inflammatory response, metal sensitivity reactions, and/or long term detrimental systemic effects. In addition, the corrosion process can reduce the mechanical strength of the implant.

7. **Information and qualification.** Surgeons should be fully aware of the intended use of the products and the applicable surgical techniques, and they should be qualified by appropriate training (for example, by the Association for the Study of Internal Fixation, AO).

8. **Potential Risks:**
– Implant failure from selecting the wrong implant and/or overloading the osteosynthesis
– Allergic reactions from material incompatibility
– Delayed healing from vascular disturbances
– Pain triggered by the implant

9. **MRI – Magnetic Resonance Imaging**
MRI information can also be found in the corresponding technique guide at http://www.scyon.ch/
All measurements are based off similar implantable devices which show equivalent material specifications and similar geometry.
a Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-14 and ASTM F 2119-07: Non-clinical testing of worst case scenario in a 3 T MRI -system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.
b Radio-Frequency-(RF-)induced heating according to ASTM F 2182-11a: Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature

rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T])

Single-Use Products
Products intended for single use must not be re-used (see product-specific instructions and “Interpretation of symbols”).
Re-use or clinical processing (e.g. cleaning and re-sterilization) may compromise the structural integrity of the device and/or lead to device failure. This may result in patient injury, illness or death. Furthermore, re-use or clinical processing of single use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.
Do not reprocess soiled implants. Any SCYON implant that has been soiled by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Sterile Products
Products supplied in a sterile condition are labeled “STERILE” (see “Interpretation of symbols”). Remove products from the package in an aseptic manner. The manufacturer cannot guarantee sterility if the package seal is broken or if the package is improperly opened, and assumes no liability in such instances.

Non-Sterile Products
SCYON products supplied in a non-sterile condition must be cleaned and steam sterilized prior to surgical use. Prior to cleaning, remove and dispose all original disposable packaging (e.g. silicone rubber guards, tip guards, protection caps, blisters, pouches, bags, packaging foam, card board etc.). Clean products before first and every use, and before returning for maintenance and repair. Prior to steam sterilization, place the product in an approved wrap or container.
The first and most important step in decontaminating all re-usable instruments is thorough (manual and/or mechanical) cleaning and rinsing. Thorough cleaning is a complex process whose success depends on various interrelated factors: Water quality, quantity and type of cleaning agent, cleaning method (manual, ultrasonic bath, washer/disinfector), thorough rinsing and drying, proper product preparation, time, temperature, and thoroughness of the individual responsible for cleaning.
Residual organic matter and/or a large number of microorganisms may reduce the effectiveness of the sterilization process.

Locating of the instrument or fragments of instruments
SCYON Instruments are designed and manufactured to perform safely within the scope of their inteded use.
However if a metallic instrument (e.g. steel; aluminium; titanium and its alloy etc.) breaks during use, a medical imaging device (e.g. CT, Radiation Devices etc.) can aid in locating fragments and/or components of the instrument.

Processing Non-sterile Unsoiled SCYON Implants and Reprocessing SCYON Reusable Devices – Instruments and Instrument Trays

These recommendations are for processing SCYON non-sterile implants and SCYON reusable devices. SCYON reusable devices include certain surgical instruments, instrument trays and cases. The information provided applies to unused and unsoiled implants only. Explanted SCYON implants must never be reprocessed and should be handled according to hospital protocol. Do not reprocess soiled implants. These recommendations are to be followed unless otherwise noted on specific package inserts.

Cautions	– Do not use steel wool or abrasive cleaners. – Avoid solutions containing iodine or high chlorine content. – Only place SCYON devices with items of similar metallic composition together in an ultrasonic cleaner. – Any SCYON implant that has not been used, but has become soiled with blood, tissue and/or bodily fluids/matter, should be handled according to hospital protocol. SCYON does not recommend the reprocessing of soiled implants. – SCYON implants should not be lubricated – SCYON implants should not be processed or transported with any type of soiled or contaminated materials. – Do not use a SCYON implant if the surface has been damaged. – Soiled or used SCYON instruments should not be loaded into a case for cleaning in a mechanical washer. Soiled SCYON instruments must be processed separate from trays and cases. SCYON cases are designed to be an organizational tool for the steam sterilization process, a storage tool for all medical devices and an organizational tool for surgery. – Long, narrow cannulations, blind holes and intricate parts require particular attention during cleaning. – The sterilization parameters are only valid for devices that are adequately cleaned. All devices must be thoroughly cleaned. – SCYON implants and instruments must be terminally sterilized prior to use. – The sterilization parameters are only valid for devices that are adequately cleaned. – The parameters listed are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment in accordance with ISO 15883 and ISO 17665. – Cleaning agents with a pH between 7–9.5 are recommended. Cleaning agents with a pH-value up to 11 and higher than 11 respectively should only be used considering the data regarding material compatibility according to its data sheet. Refer to Material Compatibility of SCYON Instruments and Implants in Clinical Reprocessing. – Consult national regulations and guidelines for additional information. Compliance is additionally required with internal hospital policies and procedures and recommendations of manufacturers of detergents, disinfectants, and any clinical processing equipment.
Limits on reprocessing	– Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on SCYON implants and surgical instrumentation.A discoloration has no adverse effect on titanium or titanium alloy implants. The protective oxide layer is fully maintained. – End of life of a device is normally determined by wear and damage due to use. Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, flaking, wear and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and excessively worn devices should not be used.

Clinical Processing and Reprocessing Instructions

Point of Use Care	– Implants should remain covered until needed to avoid becoming soiled or contaminated. Only those to be implanted should be handled. – Minimal handling of implants is necessary to prevent damage to the surface. Wipe blood and/or debris from device throughout surgical procedure to prevent it from drying onto the surface. – Flush cannulated devices with sterile or purified water to prevent the drying of soil and/or debris to the inside. – Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings, – Devices should be covered with a towel dampened with sterile or purified water to prevent blood and/or debris from drying.
Containment and Transportation	– Implants should not come in contact with soiled devices and/or equipment. – Avoid cross contamination of implants with soiled instruments during transport.
Preparation for Decontamination (for all cleaning methods)	– It is recommended that devices should be reprocessed as soon as is reasonably practical following use. – Disassemble device, if device is able to be disassembled, prior to reprocessing. – Further detailed instrument Dismantling instructions are available from SCYON costumer service. – Open devices with ratchets, box locks or hinges. – Remove sharp devices for manual cleaning or place into a separate tray. – Lumens/cannula of devices should be manually processed prior to cleaning. Lumens/cannula should first be cleared of debris. Lumens/cannula should be brushed thoroughly using appropriately sized soft-bristled brushes and twisting action. Brushes should be tight-fitting. Brush size should be approximately the same diameter of the lumen/cannulation to be cleaned. Using a brush that is too big or too small for the diameter of the lumen/cannulation may not effectively clean the surface of a lumen/cannulation. – Soak and/or rinse heavily soiled devices or cannulated devices prior to cleaning to loosen any dried soil or debris. Use an enzymatic cleaner or detergent solution. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration. Use cold tap water to rinse devices. – SCYON instruments must be cleaned separately from SCYON instrument trays and SCYON cases. Lids should be removed from cases for the cleaning process, if applicable.

Cleaning	Equipment: Washer/disinfector, various sized soft-bristled brushes, lint- free cloths, syringes, pipettes and/or water jet, enzymatic cleaner or detergent solution Pre-clean method (Pre-clean method must be manually performed prior to automated cleaning method listed below.) 1. Place instruments in cold tap water for 5 minutes. 2. Brush instruments under running cold tap water until no residues are visible. Use a soft bristled brush for the outer surfaces and a bottle brush for inner surfaces. 3. Rinse instruments under running tap water. Flush lumens, channels, hinges and hard to reach areas with the aid of a water jet pistol. 4. Visually inspect the instruments, and in case of remaining soil and/or residue, repeat steps 2 and 3. Mechanical Washer process: (Pre-cleaning steps 1–4 should occur prior to this step.) *Note: The washer/disinfector should fulfill requirements specified in ISO 15883. Use MIS injector unit to process lumens and cannulations.* 5. Place instruments with care and avoid cleaning shadows. 6. Process devices using the following cycle parameters by draining between each step:

Cycle	Minimum Time (minutes)	Minimum Temperature/Water	Type of Detergent
7. Pre-wash	2	Cold tap water	N/A
8. Wash	5	55 °C desalinated water	Detergent* 0.5%
9. Neutralization	3	Cold desalinated water	N/A
10. Rinse	2	desalinated water	N/A

* see Additional Information

Inspection	SCYON instruments should be inspected after processing, prior to sterilization, for: – Cleanliness – Damage, including but not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks and wear – Proper function, including but not limited to, sharpness of cutting tools, bending of flexible devices, movement of hinges/joints/box locks and moveable features such as handles, ratcheting and couplings – Missing or removed (buffed off) part numbers, and wear – Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and worn devices should not be used. Check instruments for sound surfaces, and correct adjustment and function. Do not use severely damaged instruments, instruments with unrecognizable markings, corrosion, or blunt cutting surfaces. Further detailed function control instructions are available from SCYON costumer service. Disassembled devices should be reassembled prior to sterilization unless otherwise noted or the case is not configured for the assembled device. Further detailed instrument dismantling instructions are available from SCYON costumer service.
Packaging	Put cleaned, dry devices into the proper location in the SCYON case. Additionally, use an appropriate sterilization wrap or re-usable rigid container system for sterilization, such as a sterile barrier system according to ISO 11607. Care should be taken to protect implants, and pointed and sharp instruments from contact with other objects that may damage the surface.

Sterilization

The following are the recommendations for the sterilization of SCYON devices:

Cycle Type	Sterilization Exposure Time (minutes)	Sterilization Exposure Temperature	Minimum Dry Time*
Prevacuum *Saturated steam-forced air removal*	4 *minimum **three** pulses*	132 °C	30 minutes

* When applying dry times to SCYON cases and their accessories, dry times outside the standard healthcare prevacuum parameters may be required. The dry time is most often influenced by the presence of polymer based (plastic) materials; therefore changes such as elimination of silicone mats and/or change in sterile barrier system (i.e. heavy grade to light grade wrap) can reduce the necessary dry time. Dry times may be highly variable due to differences in packaging materials (e.g. nonwoven wraps), environmental conditions, steam quality, device materials, total mass, sterilizer performance and varying cool-down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying. Dry times generally range from 20 to 60 minutes due to differences in packaging materials (Sterile Barrier System, e.g. wraps or re-usable rigid container systems), steam quality, device materials, total mass, sterilizer performance, and varying cool-down time.

The autoclave manufacturer's operating instructions and recommended guidelines for maximum sterilization load should be followed. The autoclave must be properly installed, maintained, validated and calibrated.

Storage

Packaged products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity.

Additional Information

SCYON used the following supplies during validation of these reprocessing recommendations. These supplies are not listed in preference to other available supplies which may perform satisfactorily. Cleaning Agent Information: neodisher MediClean (Dr.Weigert, Hamburg)

The cleaning and sterilization information is provided in accordance with ANSI/AAMIST81, AAMI TIR 12, AAMI TIR 30, DIN EN 285, EN ISO 11138-3, EN ISO 11737-1, EN ISO 14937, EN ISO 15883-1, TS/ISO 15883-3, ISO 17664, ISO 17665-1, DGHK, DGSV, AKI and RKI
The recommendations provided above have been validated by the medical device manufacturer as being capable of preparing a non-sterile SCYON medical device. It remains the responsibility of the processor to ensure that the processing is actually performed using equipment, materials and personnel in the reprocessing facility, and achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any devi- ation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.

Manufacturer Contact

For further information, contact SCYON costumer service in Zurich (Switzerland).

Material Compatibility of SCYON Instruments and Implants in Clinical Processing

SCYON Instrument Materials

Knowledge of the materials used and their properties is essential for ensuring that instruments are proficiently processed and maintained.

Stainless steels

SCYON instruments are made predominantly from corrosion-resistant steels, recognizable by their shiny or dull metallic color. As a result of their high chromium and nickel content, corrosion-resistant steels form a protective chromium oxide layer, known as a passive layer, on the metal surface. This passive layer protects the instrument against corrosion and rust. Incorrect or careless handling (e.g. damage to the surface) and attacks of a chemical, electrochemical or physical nature, can adversely affect the corrosion resistance.
Two types of stainless steels are used, differentiated based on their composition and properties:

– Martensitic steels, which are corrosion resistant and whose high hardness can be influenced and adjusted by heat treatment, possess high wear resistance and high cutting edge retention. These steels are used for cutting and sharp-pointed instruments, e.g. drill bits, reamer heads, awl, burrs or cutting edges of pliers.
– Austenitic steels, which cannot be hardened by heat treatment, possess high corrosion resistance, elasticity and toughness, and are generally non-magnetic. These steels are used for non-cutting instruments, e.g. drill guides, gauges and aiming devices.
– SCYON recommends disinfectants, cleaners or detergents with pH 7–11 for all stainless steels.

Aluminum, titanium and its alloys

Titanium and titanium alloys are used as implant materials. On instruments titanium is used for only a few applications, mainly color coding of instruments. The surface of titanium alloys is also treated electrochemically (anodizing), producing a resistant oxide layer. Various color shades can be applied using this layer.
Although anodized aluminum, titanium and its alloys have good corrosion resistance, contact with strong alkaline detergents or disinfectants and solutions containing iodine or certain metal salts can lead to chemical attack and dissolution of the surface depending on the specific composition of the detergent.
Consequently, SCYON recommends disinfectants, cleaners or detergents with pH 6 – 9.5. Products with a higher pH value, especially higher than pH 11, should only be used subject to the material compatibility requirements stated on the data sheet and other information from the manufacturer of the detergent.

Plastics

Various plastics are used for certain instrument parts, e.g. handles, radiolucent parts. In addition to pure plastics composite materials are also used in some cases.
All used plastics are able to withstand correct processing. Some of the plastics can become soft during steam sterilization, but do not undergo permanent deformation at normal sterilization temperatures below 140 °C. The material can, however, be damaged, for example by repeated immersion in disinfectants outside the pH range of 4 – 9.5 and by overstressing. Also, some rinsing aids can lead to discoloration or embrittlement of plastics and composites by repeated use.

Recommended temperatures and pH levels

Material	Temperature*	pH
Stainless steel	up to 149 °C	7–11
Aluminum	up to 150 °C	6–9.5
Titanium alloys	up to 150 °C	6–9.5
Plastics	up to 140 °C	4–9.5
Nitinol	up to 149°C	6–9.5

* The recommended processing temperatures take into account material properties and internally validated parameters for processing.

Causes of Corrosion and Surface Change or Damage

The surface of the instruments can be attacked and damaged by incorrect handling or contact with various substances. Awareness of the following possible causes of corrosion and material damage can help to avoid their occurrence.

Blood, pus, secretions etc.
Most human body fluids and residues contain chlorine ions, which can lead to corrosion if left to adhere to, or dry on, the instrument for prolonged periods. Instruments should therefore be cleaned and dried immediately after every use.

Saline solutions, iodine tinctures, water
The chlorine and iodine ions in these solutions cause pitting corrosion. Keep any contact with these ions to a minimum. Rinse instruments thoroughly with distilled water* to remove all residues.
Normal tap water often also contains chlorides, as well as high concentrations of other minerals, which can form marks with sharply defined edges on the instrument surface. These can usually be removed with distilled water* and non-abrasive stainless steel cleaners. Never leave wet instruments lying around; always dry them immediately. Condensation moisture produced during sterilization can be avoided by prolonging the drying phase.

Detergents, disinfectants, rinsing aids and other additives
Excessive concentrations of these products or strongly acidic or alkaline detergents can attack the protective oxide layer of stainless steel, titanium and aluminum and lead to corrosion, discoloration or other changes of the materials, properties and surface conditions. When using such products, always follow the manufacturer's recommendations in respect of concentrations, contact times, temperatures and material compatibility. Products with pH levels between 7 and 9.5 are recommended. During repeated and prolonged use some rinsing aids can attack certain plastics and lead to discoloration or embrittlement. If the instruments are cleaned in an automated washer-disinfector, follow the directions of the manufacturers of the washer-disinfector, detergents, rinsing aids and other additives.

Steel wool, steel brushes, files and other abrasive cleaning tools
Never use extra fine or normal steel wool, steel brushes, files or other cleaning tools with abrasive effect on metals to clean surgical instruments, as this will result in mechanical damage to the passive layer, leading to corrosion and malfunction.

Contact between instruments made from different metals
If stainless steel instruments are left in contact for long periods with surface-damaged instruments and are simultaneously moistened with an electrolyte, rust can form at the points of contact. Steam, water, ultrasonic cleaning solutions or other liquids and solutions can act as electrolytes. Such phenomena are occasionally observed during automated cleaning. Corrosion products that have already formed can also be transferred to other instruments by electrolytes, thereby producing surface rust. If possible, instruments made from differing materials should be cleaned and sterilized separately. Consequently, instruments with corrosion or rust spots must always be excluded and exchanged for unblemished ones. Instruments should be cleaned in their opened and dismantled state in order to avoid not only insufficient cleaning but also crevice and fretting corrosion. The passive layer in crevices or joint gaps can be damaged by chemical or mechanical action, leading to corrosion.

Inadequate lubrication
Moving instrument parts, e.g. joints, sliding parts, dismantable threaded connections etc. must be regularly lubricated. Constant metallic abrasion increases the damage to the passive layer and thus greatly increases the risk of corrosion.

Detergent residues in packing cloths
Cloths used to pack the devices must be free of detergent or other residues. Such residues can be transferred to the device surface via steam and can interact with the surface.

Overstressing of instruments
Instruments are designed only for a specific purpose and must be used accordingly. Inappropriate use can lead to mechanical overstressing, malfunction and permanent instrument damage, and this in turn increases their susceptibility to corrosion.

Note on latex
Because SCYON instruments do not contain any latex, they can safely used for patients with a latex allergy.

Repair of SCYON Instruments and ordering of spare parts.

Defective instruments can be sent to SCYON customer service for repair. Customer service will assess whether the instrument can be repaired. Make sure that you enclose a delivery note with the defective instrument containing the following information:
– Hospital address, contact person and telephone number
– Article number of the defective instrument being returned and a description of the problem

SCYON Orthopaedics AG, Hardturmstrasse 103,
CH-8005 Switzerland, +41 43 833 0311

* A conductivity of < 0.5 µS is recommended for distilled water.

Reference number

Serial number

Authorized representative


2008-12
Expiration date

Sterile

Sterilized using ethylene oxide


Do not re-sterilize

Contains or presence of natural rubber latex


Caution, see instructions for use


Consult instructions for use


Limit of temperature


Lower limit of temperature


Temperature Indicator


Sterilization Indicator

Lot or batch number


Manufacturer


2008-12
Manufacturing date

Non-sterile

Sterilized using irradiation


Do not re-use


Do not use if packaging is damaged

Notified body


European Conformity


Keep away from sunlight


Keep dry


Upper limit of temperature

MR Conditional

Quantity

SSt
Stainless steel

TiCP
Pure titanium

TAN (Ti6Al7Nb)
Titanium-aluminium-niobium alloy

SCYON Orthopaedics AG

Hardturmstrasse 103 | CH-8005 Zürich | Switzerland