medartis®

Instructions for Use for Medartis APTUS Plates, Screws and Instruments

Introduction

These instructions for use are for a product line of
Medartis AG, Hochbergerstrasse 60E, 4057 Basel/Switzerland
Phone +41 61 633 34 34, Fax +41 61 633 34 00, www.medartis.com.
All instructions provided in this document must be followed.

Notes Regarding the Delivered Goods

The individual parts of the system may only be accepted when the manufacturer's label and packaging are undamaged and unopened at the time of delivery. If this is not the case, the rejected goods must be returned to Medartis AG, Basel/Switzerland or to the relevant Medartis Territory Consultant or distribution partner within ten working days.
Implants are intended for single use only and are not designed to be reused. All components are delivered **NON-STERILE** and must be appropriately prepared before first use.
All packaging must be removed before preparation.

Product Materials

APTUS implants, plates and screws, are made of pure titanium (ASTM F67, ISO 5832-2) or titanium alloy (ASTM F136, ISO 5832-3). All of the titanium materials used are biocompatible, corrosion-resistant and non-toxic in a biological environment.
K-wires and staples are made of stainless steel (ASTM F138, ASTM F139); instruments in direct contact with the patient are made of stainless steel, PEEK, aluminum, Nitinol or titanium.

Color Coding Concept

System Size	Color Code
APTUS 1.2	red
APTUS 1.5	green
APTUS 1.7	turquoise
APTUS 2.0	blue
APTUS 2.2	purple
APTUS 2.3	brown
APTUS 2.5	purple
APTUS 2.8	orange
APTUS 3.0	yellow
APTUS 3.5	green
APTUS 4.0	brown
APTUS 5.0	dark blue
APTUS 7.0	turquoise

Plates, Screws and Blades
Special implant plates, screws and blades have their own color:

Implant plates gold	Fixation plates
Implant plates blue	TriLock plates (locking)
Implant screws gold	Cortical screws (fixation) and cannulated compression screws
Implant screws blue	TriLock screws (locking) Screws for blade fixation
Implant screws pink	Cancellous screws (fixation)
Implant screws silver	TriLock Express screws (locking) Transfixation screws (fixation)
Implant screws green	SpeedTip screws (self-drilling)
Implant spiral blades blue	Spiral Blades Proximal Humerus

TriLock plates (locking) are marked with the following symbol: 

Intended Use

The APTUS fixation systems are used for fractures, osteotomies and arthrodesis of the hand, forearm, shoulder and foot.
The APTUS cannulated compression screws are used for bone fractures, osteotomies and arthrodesis.

Indications

APTUS Titanium System (Hand and Radius)
- The APTUS Titanium System is intended for use in hand and forearm fractures, osteotomies and arthrodeses

APTUS 1.5 Trilock
- The APTUS 1.5 Trilock is intended for use in hand and forearm fractures, osteotomies and arthrodeses

APTUS Hand Group
- Management of the fractures of the distal, middle and proximal phalanges and metacarpals
- Management of all types of transversal fractures, spiral fractures, fractures near joints with or without joint involvement, shaft fractures, comminuted fractures, dislocated fractures, avulsion fractures
- DIP and PIP arthrodeses

APTUS CMC-I Fusion Plate System
- The APTUS CMC-I Fusion Plate System is intended to be used for fusion of the trapezium with the first metacarpal

APTUS Radius 2.5 Group
- Management via radio volar approach of extra-articular extension and flexion fractures, articular extension and flexion fractures, correction osteotomies for badly healed radius fractures
- Management via dorsal approach of rare extension fractures that cannot be adequately reduced via volar approach, procedures for which the soft tissue conditions make a volar approach very difficult or impossible, correction osteotomies requiring stabilization from the dorsal side, carporadial fusions

APTUS Wrist 2.5 System
- APTUS Wrist 2.5 System is intended for use in hand and forearm fractures, osteotomies and arthrodeses

APTUS Wrist Spanning Plates 2.5
- APTUS Wrist Spanning Plates 2.5 are intended for use in forearm fractures

APTUS 2.0/2.3 Four Corner Fusion Plate
- The APTUS 2.0/2.3 Four Corner Fusion Plate, an addition to the APTUS Titanium Fixation System, is designed specifically for fusion of carpal bones including: hamate, capitate, lunate, triquetrum and is for use in patients suffering pain and/or loss of function due to osteoarthritis, post-traumatic arthritis, fractures, revision of failed partial wrist fusions, carpal instability, or rheumatoid arthritis. The fusion plate is used in conjunction with locking and non-locking screws that fix the plate to the carpal bones of the hand.

APTUS Wrist Arthrodesis Plates
- APTUS Wrist Arthrodesis Plates are indicated for wrist arthrodesis

APTUS Forearm System
- APTUS Forearm Shaft Plates are intended for management of fractures and osteotomies of the radius and ulna shaft

APTUS Ulna Plates
APTUS Ulna Shortening 2.5
APTUS Coronoid 2.0
- APTUS Ulna Plates are indicated for fractures and osteotomies, in particular for the ulna

APTUS 2.0 Radial Head System
- The APTUS 2.0 Radial Head System is intended for use in proximal radial fractures and osteotomies

APTUS Foot System
- The APTUS Foot System is intended for use in small bones, in particular in fractures, osteotomies and arthrodesis of the tarsals, metatarsals and phalanges

APTUS Foot 2.8–3.5 System
- The APTUS Foot 2.8–3.5 System is intended for use in fractures, osteotomies and arthrodesis of the tarsals, metatarsals and phalanges

APTUS Foot 3.5 System
- The APTUS Foot 3.5 System is indicated for fractures and osteotomies of the calcaneus

APTUS Ankle Trauma System 2.8/3.5
- The APTUS Ankle Trauma System 2.8/3.5 is indicated for fractures, osteotomies, malunions and non-unions of the distal tibia and fibula.

APTUS Cannulated Compression Screws
APTUS headed Cannulated Compression Screws
- APTUS Cannulated Compression Screws and headed Cannulated Compression Screws are indicated for the treatment of fractures, osteotomies and arthrodesis of bones with the appropriate screw size

APTUS K-Wire System
- The APTUS K-Wire System is intended for use in fixation of bone fractures, for bone reconstruction, and as guide pins for insertion of other implants

APTUS Distal Humerus System
- The APTUS Distal Humerus System is indicated for fractures, osteotomies and non-unions of the distal humerus

APTUS Proximal Humerus System
- The APTUS Proximal Humerus System is indicated for fractures, osteotomies and non-unions of the proximal humerus

APTUS Clavicle System 2.8
- The APTUS Clavicle System 2.8 is indicated for fractures, osteotomies, malunions and non-unions of the clavicle

Contraindications

- Pre-existing or suspected infection at or near the implantation site
- Known allergies and/or hypersensitivity to foreign bodies
- Inferior or insufficient bone quality to securely anchor the implant
- Patients who are incapacitated and/or uncooperative during the treatment phase
- The treatment of at-risk groups is inadvisable

Possible Complications

In most cases, potential complications have a clinical source as opposed to arising from the implants/instruments. These include among other things:
- Loosening of the implant from insufficient fixation
- Hypersensitivity to metal or allergic reactions
- Bone necrosis, osteoporosis, insufficient revascularization, bone resorption and poor bone formation that can cause premature loss of fixation
- Soft tissue irritation and/or nerve damage through surgical trauma
- Early or late infection, both superficial and deep

- Elevated fibrotic tissue reaction around the surgical area
- Complications in implant removal from improper explantation of the implant

Warnings and Precautionary Measures

- The products may only be used by medical personnel who hold relevant qualifications.
- Medartis, as manufacturer, recommends that the user reads all available documents before first use and contacts other users who have practical experience with this type of treatment
- Never use products that have been damaged by transport, improper handling in the hospital, or in any other way!
- All of the implant components are intended for single use and may not be reused under any circumstances
- Necessary care must be observed for storage and use of the products:
  - Damages (e.g. from improper cutting or bending) to and/or scratches on the instruments/implants can substantially impair the strength of the product and lead to premature breakage
  - Repeatedly bending the plate in opposite directions may cause the plate to break during postoperative treatment
- All of the system components have been developed and manufactured for a specific purpose and are therefore precisely adapted to each other. The user may not alter any of the components or replace them with an instrument or product from another manufacturer even if the size or shape is similar or exactly corresponds to that of the original product. The use of materials from other manufacturers, structural changes resulting from the use of third-party products and/or material impurities as well as minor deviations or imprecise fit between the implants and instruments, or similar, can represent a risk for the user, patient or third parties
- The sterilizing cases, instrument trays and implant containers shall not be vigorously shaken or tipped over since the individual components may become damaged or fall out
- Unless otherwise expressly stated on the label, the instruments can be reused
- Twist drills and reamers: It is recommended not to exceed a maximum drilling speed of 1'000 revolutions per minute to avoid overheating the bone. With reamers, it is advisable to use a speed of less than 1'000 revolutions per minute, or to use a handle for controlled, manual reaming. Twist drills and reamers may only be used for a maximum of ten times
- Use the indicated screwdriver for the respective system size. Make sure that the screwdriver/screw head connection is precisely vertically aligned. If not, there is a greater risk of damage to the implant and screwdriver blade. When inserting the screw, ensure that a sufficient axial force is used between blade and screw. At the same time, the axial force should be in certain limits in order not to damage the bone structure
- Implants can cause artifacts in various imaging procedures such as CT, MR

MRI Safety Information

The APTUS products have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration or image artifact in the MR environment. The safety of the APTUS products in the MR environment is unknown. Scanning a patient who has an APTUS product may result in patient injury.

Multidirectional, Angular Stable TriLock Locking System

Correct locking (±15°) of the TriLock screws in the plate:
Visual inspection of the screw head projection provides an indicator of correct locking. Correct locking has occurred only when the screw head has locked flush with the plate surface (Fig. 1 and 3). However, if there is still a noticeable protrusion (Fig. 2 and 4), the screw head has not completely entered the plate and reached the locking position. In this case, the screw has to be retightened to obtain full penetration and proper locking. In case of poor bone quality a slight axial pressure might be necessary to achieve proper locking. Due to the system characteristics, a screw head protrusion of around 0.2 mm exists when using plates with 1.0 mm thickness.
Do not overtighten the screw, otherwise the locking function cannot be guaranteed anymore.

Correct: LOCKED

Fig. 1

Incorrect: UNLOCKED

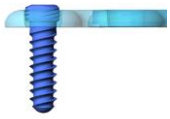

Fig. 2

Correct: LOCKED

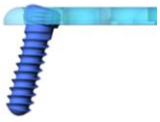

Fig. 3

Incorrect: UNLOCKED

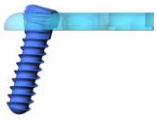

Fig. 4

Instructions for Selecting the Appropriate APTUS Products

Medartis, as manufacturer, does not recommend a specific surgical procedure for a specific patient. The operating surgeon is solely responsible for choosing the appropriate implant for the specific case. The follow-up treatment as well as the decision of whether to retain or explant the implant is the responsibility of the user.
The treating physician should beforehand become thoroughly familiarized with the procedure, for example by:

- Carefully studying all the product documentation
- Carefully reviewing the current professional literature
- Consulting with colleagues experienced in this field and with the use of this system
- Practice in handling the system and practice of the surgical procedure

Implants are generally designed to remain in the body temporarily and be removed after sufficient (osseous) healing has taken place.

Additional Information

Additional information on the products (e.g. the surgical technique, handling instructions for sterile plates, screws and instruments, care, cleaning, disinfection and sterilization of non-sterile products) can be requested from your local Medartis Territory Consultant or distribution partner. In addition, all relevant information can be found on the internet at www.medartis.com.

Single-Use Device

Do not reuse

The product is intended for one single application in a single patient. Application of an already used device may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury.

Sterile Packaged Products

The product has been subjected to a validated irradiation sterilization process and is supplied in sterile packaging. Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use any product where the sterile packaging has been opened or damaged and do not remove them from the packaging until immediately before use. Once the sterile packaging has been opened, the product cannot be resterilized. Sterility of the device must be ensured at all times. The device is for single-use only and may not be re-used under any circumstances. Re-use or re-processing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury.

Sterile packaged twist drills and reamers
Single-use, sterile packaged cutting tools such as twist drills and reamers are intended for single-use and must not be re-used. Re-use or re-processing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury. All single-use cutting tools have to be discarded after the operation following the local requirements.

Non-Sterile Products

Instructions Regarding Cleaning, Disinfection and Sterilization of Non-Sterile Products

All implants, instruments and containers in the APTUS systems that are delivered **NON-STERILE** must be cleaned, disinfected and sterilized before each use. This also applies to the first use after delivery (after removal of the protective transport packaging).
Thorough cleaning and disinfection are essential for effective sterilization.
All implant components are intended for one single application in a single patient. Implants that were used in a patient and removed, have to be discarded following the local requirements. Application of an already used device may compromise the structural integrity of the implants and/or lead to device failure which may result in patient injury. Furthermore, application of an implant that has already been used may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury of the patient or user.

Implants that have not come into direct contact with a patient may be reprocessed.
Implants that have come into direct contact with blood or other bodily fluids or show visual contamination must be cleaned and disinfected separately before they can be placed back into the implant tray.
It is your responsibility to ensure that the implants and instruments are completely sterile when used, to use device- and product-specific procedures for cleaning/disinfection and sterilization that are sufficiently validated, to regularly service and inspect the employed devices (disinfector, sterilizer), and to ensure that the validated and/or manufacturer's recommended parameters are maintained for each cycle.
The statutory regulations applicable in your country and the hospital's hygiene requirements must also be observed. This applies in particular to the various instructions for effectively deactivating prions.

Basic Instructions

If possible, use an automated procedure (disinfector) for cleaning and disinfecting. Manual procedure is possible, but Medartis recommends not using a manual procedure even with an ultrasonic bath due to the significantly reduced efficiency and potential damage to implants or instruments.
Pretreatment is required in both cases.

Choosing Detergents, Disinfectants and Equipment

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

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

For **cleaning materials and accessories**, both for precleaning and manual cleaning, observe the following:

- Use only clean, lint-free cloths and/or soft brushes (never use metal brushes or steel wool)

- When necessary, use materials and accessories such as cleaning stylets, syringes, cannulas and bottle brushes for cannulated products or products with a lumen

For **drying accessories**, Medartis recommends lint-free disposable paper wipes or medical compressed air.

For **water quality**, Medartis recommends that deionized or reverse osmosis water is used for cleaning, disinfection and subsequent rinsing steps.

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

Implant trays made of steel can undergo automated cleaning and disinfection when loaded. For manual cleaning, the implants must be removed from the system and then cleaned and disinfected separately.
Remove major contaminants in the operating room before segregating dirty instruments. Preferably use dry preparation for the transportation to the cleaning/sterilization department. If a wet preparation method is used, place the instruments in a prepared solution directly after usage. The instruments must be disassembled and opened as much as possible. All products (including grooves, holes, lumens, etc.) must be sufficiently covered with solution. To avoid damage to the materials, do not leave them in the solution for longer than directed.

Pretreatment Prior to Cleaning, Disinfection and Sterilization

Pretreatment Process
- Disassemble and open the instruments as far as possible. When doing so, follow the assembly and disassembly instructions, which can be found at www.medartis.com
- Empty the instrument trays completely and remove the lid if necessary
- Empty the aluminum or plastic implant trays completely and remove the lid if necessary
- For steel implant trays, the implants can be left in the tray but the lid must be removed during the rinsing process and rinsed separately
- Clean products and individual parts under running water using soft brushes (shift moveable parts back and forth, use cleaning wire, syringes and cannulas for cannulated products; for larger lumina, use a bottle brush if necessary)
- Visually inspect the products and repeat pretreatment as required until visible contamination is no longer evident

The disassembled instruments and trays should remain dismantled for the following cleaning and disinfection process.

Manual Cleaning and Disinfection

For manual cleaning and disinfection, the trays have to be empty.
Instruments and trays must be opened and disassembled as far as possible.
Implants must be removed from the system and must be cleaned and disinfected separately.

Manual Cleaning Process
- Place the (disassembled) products in the cleaning bath with enzymatic cleaning solution for 5 minutes (the products must be adequately covered and the individual components should not be in a position to damage each other)
- Clean with a soft plastic brush
- Shift moveable parts back and forth several times
- Clean large lumina with a bottle brush
- Cannulated products (with cavities whose diameter is less than or equal to 1/6 of the device's length), e.g. cannulated drills, must be cleaned by inserting the dedicated cleaning stylet and rinsed using a suitable cannula and disposable syringe (rinsing volume: 30 ml)
- Clean the products in the ultrasonic bath for 15 minutes using a suitable detergent
- Rinse with water for at least one minute (lumina and cannulated products must also be rinsed inside using syringes and suitable cannulas); hand-held water jets can also be used
- Visually inspect the products and repeat the cleaning process as required until visible contamination is no longer evident
- Inspect the products (see the section «Inspection»)

Manual Disinfection Process
- Place the (disassembled), cleaned and inspected products in the disinfection bath for 15 minutes (the products must be adequately covered and the individual components should not be in a position to damage each other)
- Shift moveable parts back and forth several times
- Large lumina must also be filled on the inside
- Cannulated products (with cavities whose diameter is less than or equal to 1/6 of the device's length), e.g. cannulated drills, must be filled with disinfectant and rinsed using a syringe and suitable cannula (rinsing volume: 30 ml)
- Rinse with water for at least one minute (lumina and cannulated products must also be rinsed inside using syringes and suitable cannulas); hand-held water jets can also be used
- Visually inspect the products and repeat the cleaning and disinfection process as required until visible contamination is no longer evident
- The products must be completely dried directly afterwards (it is recommendable to dry them using medical compressed air)
- Inspect the products (see the section «Inspection») and service them (see the section «Product Care»)
- Pack the products preferably immediately or if necessary after giving them additional time to dry

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

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

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

The above recommendations must also be followed when choosing detergents and disinfectants for this process.

For automated cleaning, ensure that the products have been rinsed thoroughly and that there is no remaining foam.

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

Phase	Temperature	Duration	Action
Cleaning	55°C (± 2°C) (131°F; ± 3.6°F)*	10 min.*	Adding detergent*
Neutralization	Cold	2 min.	Neutralize with cold water
Rinsing	Cold	1 min.	Rinse with cold water
Thermal disinfection (Ao value > 3'000)	≥ 90°C (194°F)	5 min.	With deionized or reverse osmosis water; do not add additional detergent
Dry	Device-specific	Device-specific	Drying process

* The information provided is based on the use of «Neodisher MediClean forte» by Dr. Weigert; times and temperatures may vary if a different detergent is used; follow the applicable information provided by the manufacturer.

When loading the disinfector, use the loading layouts provided by the manufacturer; also follow the detailed information provided in «Instructions for Cleaning, Disinfection and Sterilization» at www.medartis.com.

Inspection (Implants and Instruments)
Before assigning the implants to the implant containers/trays, check them after cleaning and disinfection for damage and contaminants, and remove damaged and contaminated implants.

After the instruments are cleaned and disinfected, check them all for damage (e.g. corrosion, damage to surfaces, chipping, etc.), contaminants and function. Remove damaged instruments. In addition, instruments with lumina (e.g. cannulated drills) have to be checked for free passage without obstructions, cutting instruments must be checked for sharpness and rotating instruments must be checked for bending. Instruments that are still soiled must be cleaned and disinfected again.
You can find further details at www.medartis.com in «Instructions for Cleaning, Disinfection and Sterilization».

Product Care
Carefully apply maintenance products (paraffin-based/white oil-based, biocompatible, steam-sterilizable and steam-permeable) to the articulations, closures or threads and sliding surfaces.
Do not use maintenance products containing silicone.

The disassembled instruments and trays should be reassembled for the following sterilization process.

Sterilization
Medartis recommends sterilizing the products in the implant containers and instrument trays either in an FDA cleared sterilization container using only the fractionated vacuum cycle indicated below, or using the gravity displacement cycle indicated below, double wrapped with a wrap that is FDA cleared for the indicated gravity displacement cycle.

If the total weight of the loaded module is over 25 pounds, the module must not be sterilized in a sterilization container; rather, double wrap it in a FDA cleared wrap and sterilize using the gravity displacement cycle below.

Steam Sterilization
All **NON-STERILE** products can be sterilized in an autoclave (EN 13060 and EN 285). For both initial and subsequent sterilization, the following parameters were validated by Medartis in accordance with the requirements of the current sterilization standards, EN ISO 17665 and ANSI/AAMI ST79:

Procedure	Fractionated Vacuum Method (= Pre-Vacuum or Dynamic Air Removal)	Gravity Displacement Method
Exposure time	4 min.	15 min.
Temperature	132°C (270°F)	132°C (270°F)
Drying time	> 20 – 30 min.	> 20 – 30 min.

Medartis recommends that sterilization is performed in accordance with the above validated processes.
Do not use hot-air sterilization, radiation sterilization, formaldehyde sterilization, ethylene oxide sterilization or substitute procedures for sterilizing thermolabile products such as plasma or peroxide sterilization for Medartis products.

After sterilization, the products must be stored in a dry and dust-free environment.

Reusability (Implants and Instruments)
Implants that were used in a patient and removed, have to be discarded. They are not allowed to be reprocessed. Please note that a single use device (SUD) which comes into contact with the patient should not be re-used and should be returned to the manufacturer or properly disposed. No liability is assumed by the manufacturer in case of non-observance.
Medartis recommends: if products come in contact with pathogens that are difficult to identify (confirmed or suspected pathogen), they must be discarded.

Manufacturer and Headquarters
Medartis AG
Hochbergerstrasse 60E
4057 Basel/Switzerland

Symbols Glossary
ANSI/AAMI/ ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.

Symbol	Title of Symbol (Reference Number)	Meaning of Symbol
	Sterilized using irradiation (5.2.4)	Indicates a medical device that has been sterilized using irradiation.
	Do not use if package damaged (5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened.
	Do not re-use (5.4.2)	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Do not resterilize (5.2.6)	Indicates a medical device that is not to be resterilized.
	Consult instructions for use (5.4.3)	Indicates the need for the user to consult the instructions for use.
	Use-by date (5.1.4)	Indicates the date after which the medical device is not to be used.
	Manufacturer (5.1.1) and Date of Manufacture (5.1.3)	Indicates the medical device manufacturer, and Indicates the date when the medical device was manufactured.
	Non-sterile (5.2.7)	Indicates a medical device that has not been subjected to a sterilization process.
	Catalogue number (5.1.6)	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Batch code (5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified.

This document is subject to continuous revision. Please verify that the current printed version is identical to the one at www.medartis.com.

Caution: Federal law restricts this device to sale by or on the order of a physician.