Instructions for Use for Medartis APTUS Systems

I. General Instructions

These instructions for use do not include all of the information necessary for use of the products. Additional information on the products (e.g. surgical techniques, instructions for handling of sterile products, instructions for reprocessing and maintenance, assembly/ disassembly instructions) can be found on the internet at www.medartis.com/documentation/instructions-for-use. They can also be requested from your local Medartis representative or the Medartis distribution partner. All instructions provided in this document and in the corresponding user information must be followed.

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 representative or distribution partner within ten working days.

II. Scope

Implants and instruments for the following APTUS systems are covered by these instructions for use:

- APTUS Hand
- APTUS Wrist
- APTUS Forearm
- APTUS Elbow
- APTUS Shoulder
- APTUS Foot
- APTUS Ankle
- APTUS CCS

The complete list of items can be found in the corresponding surgical technique(s) under www.medartis.com/documentation/instructions-for-use.

III. Product Description

Product Materials

Medartis implants and instruments are manufactured from biocompatible materials. All materials are standard implant and instrument materials for use in medical devices for orthopedics, traumatology and general surgery.

Product	Material
Plates	Pure titanium, titanium alloy
Wedges	Titanium alloy
Spiral blades	Pure titanium
Washers	Pure titanium, titanium alloy
Screws	Titanium alloy
Staples	Stainless steel
K-wires	Stainless steel
Instruments	Stainless steel, PEEK, aluminum, Nitinol, silicone or titanium
Containers	Stainless steel, aluminum, PEEK, polyphenylsulfone, polyurethane, silicone

Color Coding Concept

APTUS instruments are color coded according to the diameter of the screws being used

System Size	Color Code
1.2	Red
1.5	Green
1.7	Turquoise
2.0	Blue
2.2	Purple
2.3	Brown
2.5	Purple
2.8	Orange
3.0	Yellow
3.5	Green
4.0	Brown
5.0	Dark Blue
7.0	Turquoise

APTUS plates and screws have their own color, corresponding to a specific implant technology:

Implant plates gold	Fixation plates (fixation)
Implant plates blue	TriLock plates (locking)
Implant screws gold	Cortical screws (fixation) and CCS
Implant screws blue	TriLock screws (locking) Screws for spiral blade fixation
Implant screws pink	Cancellous screws (fixation)
Implant screws silver	TriLock Express screws (locking) and transfixation screws
Implant screws green	SpeedTip screws (self-drilling)

Intended Use

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

Indications and Contraindications

Indications and contraindications for each APTUS System can be found in the corresponding surgical technique under www.medartis.com/documentation/instructions-for-use.

IV. 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 or implant breakage
- 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 (e.g. due to bony ingrowth)

The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, or incorrectly combined implant components.

V. Warnings

- 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
- All of the implant components are intended for single use and may not be reused under any circumstances. Unless otherwise expressly stated on the label, the instruments can be reused.
- 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
- 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. The drill guide and bone should be cooled while drilling. 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. Reusable, non-sterile packaged twist drills and reamers are for single use only and may not be reused under any circumstances.
- Never use products that have been damaged by transport, improper handling in the hospital, or in any other way!
- The sterilizing cases, instrument trays and implant containers shall not be vigorously shaken or tipped over since the individual components and content may become damaged or fall out.

For application-specific warnings related to APTUS systems, it is mandatory to consult the surgical technique (www.medartis.com/documentation/instructions-for-use) of the corresponding product system being used.

VI. Cautions

- 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.
- Use the indicated screwdriver for the respective system size. Make sure that the screwdriver/screw head connection is precisely aligned in axial direction. 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.

For application-specific cautions related to APTUS systems, it is mandatory to consult the surgical technique (www.medartis.com/documentation/instructions-for-use) of the corresponding product system being used.

VII. General Important Information

Clinical Benefits

In consideration of patient's clinical condition and medical history, the treating physician shall ensure that the use of APTUS systems can be justified based on a patient-specific benefit/risk assessment. Based on the clinical evaluation and risk analysis, all residual risks are deemed acceptable when weighed against the benefits to the patient based on current knowledge/the state of the art.

Selecting the Appropriate Implants

Medartis, as the 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 must 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, practice of the surgical procedure and postoperative treatment

Generally, implants are designed to remain in the body temporarily and be removed after sufficient (osseous) healing has taken place. They are not designed for long-term bone replacement. Where they are mechanically supporting the osteosynthesis, the regular operating period of the implants is expected to be between 30 days and 6 months.

Removal of Implants

In the case of complications, it might be necessary to remove the implants. For removal use the indicated screwdriver. Make sure that the screwdriver/screw head connection is precisely aligned in an axial direction.

Postoperative Care

Taking into account the individual fracture conditions and patient compliance, it is important to ensure adequate postoperative relief of the osteosynthesis in terms of adaptation or mobilization stability (e.g. splinting and/or immobilization). Postoperatively, the fixation achieved with the implants must be treated with care until the bone has fully healed. Patients must strictly observe follow-up instructions given by their physicians to avoid detrimental strain on the implants. Early load-bearing can increase the risk of loosening, migration or breakage of the implants.

MRI Safety Information

The APTUS products have not been evaluated for safety in the MR environment. They have not been tested for heating or unwanted movement in the MR environment. The safety of APTUS products in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

VIII. Cleaning, Disinfection and Sterilization of Non-Sterile Products

All implants and instruments 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. All packaging must be removed before preparation.
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 case/tray.
It is your responsibility to ensure that the implants 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.

Detailed instructions for processing/reprocessing of medical devices are described in the brochure “Instructions for Cleaning, Disinfection, Sterilization, Inspection and Maintenance of Medartis Products” and can be downloaded from www.medartis.com/documentation/instructions-for-use.

IX. Complaints and Adverse Events

Any complaint or adverse event that has occurred in relation to the device should be reported to the manufacturer and the respective national competent authority of the state in which the user and/or patient is established.

X. References

The following user documentation on the products is additionally available online and can be found under the following link www.medartis.com/documentation/instructions-for-use:
- Surgical techniques
- Instructions for handling of sterile plates, screws, staples and instruments
- Instructions for cleaning, disinfection, sterilization, inspection and maintenance
- Assembly/disassembly instructions

For additional information contact your local Medartis representative the Medartis distribution partner or the manufacturer directly under the given address.

XI. 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
STERILE R	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.
	Date of Manufacture (5.1.3)	Indicates the date when the medical device was manufactured.
NON STERILE	Non-sterile (5.2.7)	Indicates a medical device that has not been subjected to a sterilization process.
REF	Catalogue number (5.1.6)	Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT	Batch code (5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
MD	Medical device (5.7.7)	Indicates that the device in question is a medical device
EC REP	Authorized representative in the European Community / European Union (5.1.2)	Indicates the Authorized representative in the European Community / European Union
	Not listed	Indicates a single sterile barrier system with internal protective packaging
	Not listed	TriLock (locking technology)
CE 0197	Not listed	Applies only to EC risk class I devices in sterile condition, class I devices with a measuring function, class I reusable surgical instruments and class IIa and IIb devices.
CE	Not listed	Applies only to EC risk class I devices.
UK CA 0086	Not listed	Applies only to UK risk class I devices in sterile condition, class I devices with a measuring function, class IIa and IIb devices.
UK CA	Not listed	Applies only to UK risk class I devices.

This document is subject to continuous revision. The most current version is always available online at www.medartis.com/documentation/instructions-for-use.

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Disclaimer: This information is intended to demonstrate the Medartis portfolio of medical devices. A surgeon must always rely on her or his own professional clinical judgement when deciding whether

to use a particular product when treating a particular patient. Medartis is not giving any medical advice.
The devices may not be available in all countries due to registration and/or medical practices. For further questions, please contact your Medartis representative (www.medartis.com). This information contains products with CE and/or UKCA marking. All pictures shown are for illustration purposes only and may not be an exact representation of the product.
For US only: Federal law restricts this device to sale by or on the order of a physician.