Instructions for Use for Medartis CMX APTUS Guides and Bone Models

I. General Instructions

These instructions for use do not include all of the information necessary for use of the products. Additional, case-specific information can be found in the respective documents ("Case-specific Design Freeze Document", "Statement Custom-Made Devices"), which are supplied with each case and can be viewed online on the CMX Portal in the case overview. Information on the custom-made instruments (guides and/or models) can be found in the respective case-specific design freeze document.

Additional information on the products (e.g. surgical techniques, instructions for handling of sterile products, instructions for reprocessing and maintenance, assembly/disassembly instructions, instructions for use for APTUS plates, screws and instruments) can be found on the internet at www.medartis.com/documentation/instructions-for-use. They can also be requested from the 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. Moreover, they may only be accepted when no (foreign) particles are visible 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.

The physician should always have an alternative to treatment available.

II. Scope

Guides and bone models for the following CMX systems are covered by these instructions for use:

- CMX Wrist
- CMX Forearm
- CMX Ankle

The complete list of items can be found in the corresponding surgical techniques.

III. Product Description

Product Materials

Product	Material
CMX APTUS guides and bone models	PA12 (Polyamide/Nylon 12)

The polyamide used is biocompatible for the intended type and time of application during surgery (see "Intended Purpose") and non-toxic in a biological environment.

Color Coding Concept

CMX APTUS guides and bone models are not color coded.

The color coding concept of the APTUS plates, screws and instruments to be used is described in the "Instructions for Use for Medartis APTUS Systems". You can find the current version on the internet at www.medartis.com.

Intended Purpose

Guides
CMX APTUS guides are intended for use as surgical instruments for guiding purposes when marking, drilling or sawing the bone of a specific patient.

Bone Models
CMX APTUS bone models are intended to illustrate preoperative and/or postoperative anatomical structures of a specific patient.

Risks About Which Your Patients Must Be Informed

Before using patient-specific products, inform your patients about the risks, contraindications and possible complications from the following sections ("Indications and Contraindications"; "Side Effects/Possible Complications", "Warnings" and "Cautions"). Where appropriate, particular case-specific risks are listed in the "Case-specific Design Freeze Document" and/or the "Statement Custom-Made Devices".

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.

Intended User / Patient Target Group

The products may only be used by health care professionals, e.g. surgeons, radiologists, operating room staff, and individuals involved in the preparation of the device who hold the relevant qualifications.
Medartis, as the manufacturer, recommends that the user reads all available documents (e.g. surgical techniques, instructions for reprocessing and maintenance) before first use and contacts other users who have practical experience with this type of treatment. The user must be familiar with the state of the art and the instrument and implant function.
For specific patient target groups related to each system, refer to the corresponding surgical technique of the system being used. Responsibility for proper selection of patients rests with the surgeon, based on the specific indications and contraindications of each system and on patient-related factors (e.g. activity, occupation, mental health, age, bone quality).

Intended Performance

The clinical evaluation confirms good clinical performance and safety for the different devices of CMX APTUS when they are used according to their intended purpose.

IV. Side Effects / Possible Complications

In most cases, potential complications have a clinical source as opposed to arising from the instruments. These include among other things:

- Hypersensitivity or allergic reactions
- 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
- Poor accuracy of fit due to insufficient image data (e.g. old data, insufficient resolution)

The manufacturer is not responsible for any complications arising from an 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.
- Never use products that have been damaged by transport, improper handling in the hospital, or in any other way. The physician should always have an alternative to treatment available.
- 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.
- The products are prescribed and designed specifically for the named patient only and may only be used for the treatment of the named patient. By approving the "Case-specific Design Freeze Document", the physician confirms that the custom-made product is linked to one specific patient only.
- Patient-specific products are to be used only for single use on the patient named in the "Statement Custom-Made Devices" and the indication specified there and are not to be reused under any circumstances.
- The designs of the custom-made products are based on medical image data of the patient mentioned in the "Statement Custom-Made Devices" and are therefore only applicable to this patient.
- Although the CMX APTUS guides are based on patient-specific anatomies, an optimal fit cannot always be guaranteed as this depends on the quality and currentness of the medical image data used.
- The CMX APTUS guides and bone models are designed for transient use (less than one hour).. Under no circumstances may they be implanted in whole or in part.
- Do not drill or saw into the guide. Manipulation of the guide may cause abrasion, which should not be allowed to penetrate into the tissue. Thoroughly rinse the surgical site during and after drilling and sawing and aspirate any particles that may have formed.
- Do not drill or saw into the bone model, neither preoperatively nor intraoperatively. If manipulated, the bone model is no longer representative.
- CMX APTUS guides and bone models may only be sterilized once.
- CMX APTUS guides and bone models are supplied with the "Statement Custom-Made Devices". This must always be handed over to the patient.
- Note on compatibility: CMX APTUS guides are to be used exclusively with serial products of the corresponding APTUS system (or other products specifically listed in the "Case-specific Design Freeze Document").

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.
- If the patient's anatomy has changed significantly since the medical image data were recorded, the guides shall no longer be used. Bone models are no longer representative. Ideally, this should be clarified again before surgery. The physician should always have an alternative to treatment available.

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 the patient's clinical condition and medical history, the treating physician shall ensure that the use of CMX APTUS guides and bone models 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.

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

The supplied guides and bone models are custom-made devices and are intended for SINGLE USE ONLY on a SPECIFIC PATIENT and are not designed to be reused. All components are delivered NON-STERILE and must be sterilized before first use. All packaging must be removed before preparation.
Thorough cleaning and disinfection are essential for effective sterilization.

CMX APTUS guides and bone models should be wrapped in sterilization paper or packed in double bags approved for steam sterilization and sterilized according to the state-of-the-art and approved methods.

Due to the high temperatures during the cleaning, disinfection and sterilization, the guides and bone models must not be stacked or subjected to other loads. Otherwise, the high temperature during the sterilization process in combination with the load can lead to a deformation of the products.

It is your responsibility to ensure that the products 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.
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.

After use, the CMX APTUS guides and bone models must be disposed according to local guidelines.

Detailed instructions for processing 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

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

XI. Symbols

	Consult instructions for use
	Article number / Reference number
	Lot number / Batch code
	Non-sterile
 Do not reuse	Single-use product. Do not reuse The product is intended for one single application in a single patient. Application of an already used product may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury.
	Medical device
 YYYY-MM-DD	Manufacturer Date of manufacture
	Authorized representative in the European Community / European Union
	Importer

This document is subject to continuous revision. Please verify that the current printed version is the same as the online version in your case overview in the CMX Portal (cmx.medartis.com).

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