# EN INSTRUCTIONS *FOR USE — ARDS ABUTMENTS & SUPERSTRUCTURES*

**Emergency information (Commission Implementing Regulation (EU) 2021/2226, Article 5(4)):** this device requires no device-specific action in a medical emergency; read these instructions in full before the procedure, and manage any medical emergency according to standard clinical practice and the emergency protocol of the clinic.

## Indications

The product labelling and Instructions for Use (IFU) are provided in the official languages required by the Member States where the product is intended to be marketed, in accordance with Regulation (EU) 2017/745, Annex I, Chapter III, Section 23.1(d). ARDS ensures compliance with local language requirements for each country of distribution. The IFU can also be consulted on the website at https://www.ardsimplants.com/ifu.

ARDS dental implants are indicated for use in surgical and restorative applications for placement in the bone of the upper and lower jaw to provide support for prosthetic devices in order to restore the patient's chewing function. ARDS dental implants are indicated for one-stage and two-stage surgery.

## Intended Purpose

The dental abutments and restorative components are intended for use with endosseous dental implants to restore masticatory function and aesthetics in patients with partial or full edentulism. These components include:

- Healing abutments: Used temporarily during the healing phase following implant placement to allow proper tissue contouring.
- Transitional (temporary) abutments: Provide temporary prosthetic support during the osseointegration phase.
- Final abutments: Serve as a long-term connection between the implant and the final prosthesis (crown, bridge, or overdenture).

They are suitable for use in both single-stage and two-stage surgical protocols, including immediate loading depending on the clinical judgment of the dental professional. All components are single-use, to be handled and placed by qualified dental professionals in clinical or dental office settings.

## Caution

Federal law (US) restricts this device to sale by or on the order of a physician.



**Warnings:**

- ARDS Implants should be placed and restored only by practitioners who are licensed and trained to perform these procedures.
- ARDS abutments and superstructures are intended for use with ARDS dental implants only.
- Before use, please refer to applicable Instructions for Use of ARDS Dental Implants for detailed information:
  - MK-002 - ARDS Dental Implants All Types
  - Abutments and superstructures are supplied non-sterile and must be cleaned, disinfected and sterilized before use and are for single use.
  - The ARDS Abutments have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artefact in the MR environment. The safety of ARDS Abutments in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
- Small components (abutment screws, healing caps, impression copings, drivers) must be secured against aspiration or swallowing (e.g. gauze screen or throat pack, floss ligature) whenever they are handled in the patient's mouth.

## Properties of Products

The abutment and superstructure parts are constructed of a Titanium alloy or chrome cobalt. The device should not be used in patients with known allergies or hypersensitivity to any of the materials used in the implant or abutment, such as titanium or its alloys or chrome cobalt.

**Abutment and superstructure components:** The abutment or superstructure connects to the implant and allows the replacement crown, bridge or denture to be fitted on top of the implant. The abutment or superstructure is the transgingival connection from the implant to the prosthetic restoration and its basic shape is circular, which mates with the implant body surface. Various abutment or superstructure types are available with Narrow Hexagon and standard Hexagon connection and with Narrow Conical connection and Conical NP connection including Concave types: Healing Caps Abutments (1,2,3,4,5,6,7,8 mm high - Hex, conical, multi), Straight Standard Abutments (9,11,13 mm- Hex, conical, multi) and Angular 15° and 25° Standard and long, Slim Abutments (Hex, conical, multi), UCLA titanium / Chrome Cobalt base Abutment (Hex, conical, multi), CMFITAB (Hex, conical, multi), Screw type Abutments, Straight Abutments with shoulder (1,2,3,4 high- Hex, conical, multi) and Angular 15° and 25° (1,2,3,4 high), Straight Anatomic Abutments (1,2,3,4 high- Hex, conical, multi) and Angular 15° and 25° (1,2,3,4 high), Standard connectors, Ball Attachment Abutments (1,2,3,4,5,6), Straight Locator abutments (1,2,3,4,5,6,7,8) and Angular 18° and 30° (0.5,1,2,3 high), Ti-bases for CAD/CAM (0,1,2,3,4) and Straight Multi-Unit Abutment (1,2,3,4,5,6) and Angular Multi-Unit 15°,17°, 25°, 30°, 45°, 52°, 60° (1,2,3 high), Straight overdenture (0.5,1.5,2.5,3.5) and Angular Adaptor 17° and 30° Ti-UP Abutments, Ti-UP Ti-base and Ti-UP Plug-in 3.3-5.0 Abutments. The appropriate abutment type is selected in relation to the tooth position for the proposed implant.

## Tightening torque:

Finger-tighten the Healing Cap, then tighten to 20 Ncm with a calibrated torque wrench.

Finger-tighten the abutment screw, then tighten to 30 Ncm with a calibrated torque wrench.

## Recommendations for device selection

Select the abutment/superstructure according to the implant connection (internal hex, conical NP, or one-piece), the inter-arch space and emergence profile, the angulation correction required, and whether the restoration is screw- or cement-retained. Use healing abutments during healing, transitional abutments for temporary support, and final abutments (straight/angled, MUA, Ti-base/CAD-CAM) for the definitive restoration.

## Mode of action

The abutment connects to the osseointegrated implant and serves as the interface that supports and retains the prosthetic restoration (crown, bridge or overdenture), transmitting functional loads from the prosthesis to the implant and bone.

## Description of the clinical benefit

The abutment/superstructure enables a stable, functional and esthetic prosthetic restoration on the implant, restoring masticatory function, speech and appearance, and supporting fixed or removable prostheses.

## Clinical aspects of combinations with other devices

Abutments and superstructures are intended to be used only with compatible ARDS implants and components sharing the same connection geometry and titanium alloy. Tighten the healing cap to 20 Ncm and the abutment screw to 30 Ncm with a calibrated torque wrench. Do not combine with components of other manufacturers, as compatibility and performance have not been established.

Disclaimer: these instructions provide the information necessary to use the device in a safe and efficient manner. Please read these instructions thoroughly and make sure you understand them before using the system. If any part of this manual is not clear, contact ARDS for clarifications.

Clean by rinsing under running water while brushing the outer and inner surfaces (if applicable) with soft nylon/suitable brushes. The pre-treated product can be cleaned and disinfected either manually with ultrasonic support or by using an automated cleaning and disinfection method.

## Manual cleaning

1. Choose an appropriate cleaning detergent (e.g. neodisher® Mediclean or equivalent).
2. Run an ultrasonic cleaning cycle (frequency 35 kHz) in a bath using deionized water supplemented with cleaning solution following the manufacturer's instructions.
3. Remove the instruments from the ultrasonic bath. Rinse out all cavities of the instrument parts three times (3x) under running deionized water at room temperature (20 ± 5 °C) for at least 10 seconds or until no dirt residues are visible.
4. Wipe the instruments with 70% IPA alcohol using a soft, disposable lint-free wiper.

## Manual disinfection

1. Choose an appropriate disinfection solution (e.g. CIDEX® OPA or equivalent).
2. Place the disassembled and cleaned instruments in the disinfection bath. Ensure that the instruments are covered by the disinfection solution, filling all lumens and eliminating air pockets.
3. Follow the disinfection solution manufacturer's instructions (15-20 min).
4. Rinse out all cavities of the instruments three times with disinfection solution at the beginning and at the end of the action time using a disposable syringe (minimum syringe volume 20 ml).
5. Remove the instruments from the disinfection bath.

## Rinsing

1. Immerse instruments completely in a large volume of water for a minimum of 1 minute.
2. Rinse instruments thoroughly with water at least three times. Rinse out all cavities and lumens of the instruments with water three times using a disposable syringe (minimum syringe volume 20 ml).
3. Remove the instruments and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose.
4. Repeat step 3 for a total of three rinses, with large volumes of fresh water to remove the disinfection solution residues. Residues may cause serious side effects.

## Drying

1. Dry the instruments inside/out with filtered compressed air or for 30 min at room temperature.
2. Pack the instruments as quickly as possible after removal.
3. Make sure instruments are dry before packing them for sterilization. If additional drying is necessary, dry in a clean location.

## Automated cleaning and disinfection

Ensure that the washer-disinfector is validated and suitable for dental surgical instruments. Choose an appropriate cleaning and disinfection detergent (e.g. neodisher® Mediclean or equivalent) and follow the manufacturer's instructions.

1. Place the instruments in the disinfector so that joints are opened, and water can flow out of cannulas and blind holes.
2. Make sure that the instruments do not touch each other.
3. Start the appropriate program suitable for instruments.
4. Perform thermal disinfection at 90 °C for 5 minutes.
5. Inspect and pack the instruments as quickly as possible after removal.
6. Ensure the instruments are dry before packaging them for sterilization. If additional drying is necessary, dry them in a clean location.

## Sterilization

ARDS devices delivered non-sterile must be sterilized prior to use. Users should ensure that the sterilizer and all sterilization accessories (sterilization wraps, pouches, sterilization trays, biological indicators and chemical indicators) are cleared for the intended sterilization cycle.

| Cycle Type | Temperature | Exposure Time (Minimum) | Dry Time (Minimum) |
|---|---|---|---|
| **Gravity Displacement** | 135°C / 275°F | 10 min | 30 min |
| **Pre-vacuum** | 132°C / 270°F | 3 min | 20 min |

In case of storage, strictly follow the manufacturer's instructions for the sterilization accessories and storage containers. If visible signs of moisture are present (damp spots on sterile packaging, pooled water in the load) at the end of the sterilization cycle, repackage and re-sterilize using a longer drying time.

## On-the-Device Labeling

**The IFU contain information about substances that are subject to labelling requirements according to Annex I, Section 10.4.5 of the EU MDR.**

| | | | |
|---|---|---|---|
| REF | Catalogue number | CE | Regulatory compliance |
| LOT | Batch code / Lot number | eIFU Indicator | Consult instructions for use or consult electronic instructions for use (www.ai-ifu.com) |
| QTY | Quantity | | Manufactured by |
| MR | MR Unsafe | | Do not use if package is damaged and consult instructions for use |
| | Do not re-use | EU REP | Authorized representative in the European Community |
| | Importer | | Distributor |
| UDI | Unique Device Identifier | NON STERILE | Non-sterile |
| CC | Date of manufacture and country of manufacture | | Caution |

## Storage

Make sure to properly dry the products after cleaning. Keep in sterile bags.

Sterilized items must be kept in a sterilized bag in a dry area.

The user must avoid all effects that could affect the product marking or shelf life of the products, the product surface or the product geometry, such as unnecessary mechanical shock, strain, heat, UV radiation, moisture, etc.

**Disposal:** dispose of components removed from the patient, damaged components and opened unused components as potentially infectious clinical waste, in accordance with local regulations.

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## Implant card uses

An FRM-7.5.3.00.02 Implant Card (IC) is supplied with this product as required by Regulation (EU) 2017/745.

After implantation, the healthcare provider must complete the card with the relevant patient and product information, and provide it to the patient.

The patient should be instructed to retain the card and present it during any future medical consultations or procedures.

## Important warning

Lack of adequate training of practitioner is a major risk factor for the failure of the implant/restoration procedure and might endanger patient health.

Reuse can cause infections, bone resorption, hard and soft tissue damage and/or implant failure, broken screws and parts.

**Possible complications and measures to be taken:** loosening or fracture of an abutment screw or component, aspiration or swallowing of a small component, injury of the soft tissues by a fractured or sharp edge, and hypersensitivity or allergic reaction may occur. If a screw or component fractures, stop tightening, protect the airway and remove the fragment with suitable retrieval instruments, or refer the patient; do not continue to use a fractured component. Refer any suspected aspiration or ingestion of a component for radiographic examination. Instruct the patient to contact the clinic if a restoration or component becomes loose, and to

seek emergency medical care at once if a component may have been swallowed or inhaled and there is coughing, chest pain or difficulty breathing.

Reportable Events: Any serious incident that has occurred in relation to the dental abutments or superstructures should be reported to the Company and the competent authority of the Member State in which the user and/or patient is established.

In accordance with Article 32 of the EU MDR, the Summary of Safety and Clinical Performance (SSCP) is available on the EUDAMED website or from the ARDS office by email.

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