

Abutments Instructions for Use

Device description and intended use:

1. The Abutment

The abutments having a central bore and a lower mating surface that is configured to fit the mating surface of the MSDI dental implant.

MSDI abutments are configured to mate with all MSDI implants (TAF, KAF, Alef).

TP abutments are configured to mate with MSDI Til implants.

NP and RP abutments are configured to mate with Conix Implants.

MSDI abutments have a central bore, an upper portion, and a lower portion. The lower portion is configured to fit within the post-receiving section of the implant and features a 6-point hexagon or conical and a mating surface fitting the mating surface of the implant. As mentioned above, the post-receiving section includes anti-rotational features.

The abutment's upper portion is configured to lie above the top surface of the implant when the lower portion is within the implant. The upper portion forms a shoulder that follows the contours of the mating surface of the implant and has 5-8 peaks and grooves to match the contours of the patient's soft tissue.

The upper portion may be shaped in various ways for supporting various dental components such as the final restoration and/or other dental components. It has a generally cylindrical shape, and may be straight or angled in different pre-defined angles (e.g. 15°, 25°) relative to the longitudinal axis of the bore.

MSDI abutments are made of Ti6Al4V ELI, ASTM F-136 compliant alloy.



Standard Titanium Abutments



Standard Titanium Angular Abutments

2. Healing Abutment (Healing Cap)

A healing abutment, which is also configured to mate with MSDI implants, may be used to cover the bore of the dental implant so that patient's gums may be sutured around the dental implant during the healing period while leaving the implant itself uncovered, such as, for example, after a one-stage implant placement procedure. In this manner, the healing abutment may be used to prevent blood, body tissue and/or oral micro-organisms from entering the bore.

The healing abutment includes a first post that is configured to fit within the post-receiving section of the dental implant. As such, the first post includes a beveled portion that is configured to seat against the tapered portion of the post-receiving section. A second post lies below the first post. The second post is configured to fit within and to extend into the threaded section of the inner bore.

The healing abutment is secured to the implant by sharing a receiving configuration fitting within the post-receiving section of the implant.

The healing abutments are made of Ti-6Al-4V/Ti-6Al4V ELI, ASTM F-136 compliant alloy.

Indications for use:

Angular and straight abutments are designed for both single tooth and bridges (more than one tooth).

Standard and angular multi-unit abutments are intended for use to support multiple tooth prosthesis in the mandible or maxilla.

Healing caps and cover screws are intended for use with the implant system to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.

Ball attachment are designed for removable dentures.

Contraindication:

General contraindications associated with elective surgery should be observed.

Allergic or hypersensitive response to Ti-6Al-4V alloy (titanium, aluminum, vanadium).

Directions for Use:

Recommended tightening torque:

Prosthetic Device	Recommended Torque (Ncm)
Cover Screw	30
Healing Cap	15
Ball Attachment	20
Standard Multi-Unit	30
Straight Abutment	30
Angled Abutment	30

Warnings:

- All the abutments are provided cleaned and non-sterile and are intended to be sterilized prior to use.
- All the abutments are intended for single-use.
- Abutments are not intended to be further processed and used again.
- Re-use of abutments may cause cross-contamination and infection.
- Multi-Unit abutments are only intended for multi-unit restorations and are not intended for single-unit restorations.
- Small diameter implants and angled abutments are not recommended for the posterior region of the mouth.

Sterilization Instructions:

Important note: A sterilization pouch suitable for steam sterilization should be used. We recommend you to use of an FDA-cleared pouch for the intended sterilization cycle.

(e.g.: WIPAK, self-sealing sterilization pouch that was used by MSDI in the steam sterilization study).

Prior to use, abutments are to be sterilized, by steam sterilization as follows:

For Pre-vacuum process:

1. Place the abutment in the sterilization pouch.
2. Apply a fractionated pre-vacuum process – 3 pre-vacuum phases with at least 60 mill bar
3. Heat up to a minimum sterilization temperature of 132°C/270°F
4. Minimum Holding time: 4 min
5. Drying time: 30 min

For gravity process:

1. Place the abutment in the pouch.
1. Apply a fractionated with at least 60 mill bar
1. Heat up to a minimum sterilization temperature of 132°C/270°F
1. Minimum Holding time: 15 min
1. Drying time: 30 min

Explanation of Symbols:



Caution, consult accompanying documents



Lot number



Catalogue reference



Manufacturer



Date of manufacturer



Caution



Do not re-use



Non-sterile product



Authorized representative in the European Community

R_X Only

CAUTION: U.S. Federal law restricts this advice to sale by or on the order of a physician or dentist



Medical Systems and Devices International Ltd.

St. Ba'alei Malacha 26, P.O. Box 25414

Haifa 3223020, Israel

Tel: 972-54-932-0515

E-mail: Omri@msdi-ltd.com



MedNet EC-REP GmbH, Borkstraße 10

48163 Münster, Germany

Tel: +49 (0) 251 32266-0

E-mail: info@medneteuropa.com