ZEEV Modular Dental Implants

ZEEV MtDI™ Implant Kit | Instructions for Use

1 Contents

The ZEEV MtDI™ Implant Kit contains the following:
1 Apex d. 3.75 mm, l. 6.5 mm (P/N APX-375-65); or
1 Apex d. 3.75 mm, l. 7.0 mm (P/N APRX-375-70
2 Rings d. 3.75 mm, l. 3.5 mm (P/N RNG-375-35)
1 Cover Screw Apex (P/N CVS-APX-00)
1 Cover Screw 1 Ring (P/N CVS-RNG-01)
1 Cover Screw 2 Rings (P/N CVS-RNG-02)

The other components (e.g., ring extractor screwdrivers, healing caps, abutments, etc.) are not part of the standard implant kit and need to be purchased separately. A detailed list of the available components can be obtained from your ZEEV Implant Ltd. local representative.

NB: ZEEV Implants does not provide any surgical tools for the implant procedure itself. You can use the standard surgical tools as per your clinic's protocol.

2 Precautions

Carefully read these instructions. The sale and use of this device is restricted to, or by the order of, a licensed dentist.

Carefully read the MtDI™ Surgical and Prosthodontics Procedure – Instructions Document on Zeev Implants' website: www.zeevimplants.com/solution

For the implant procedure you can use the standard surgical tools used in your clinic.

CAUTION: Each implant system has specific design characteristics for mating implants, abutments, prosthetic components, and instrumentation. **Do not use other implant system's components with MtDI™.** They are not configured or dimensioned for correct mating, this can lead to mechanical failure of components, damage to tissue, or unsatisfactory aesthetic results.

3 Indication for Use

The ZEEV Modular-type Dental Implant (MtDI™) is intended to replace single or multiple teeth in the fully or partially edentulous mandibular or maxillary alveolar process. The implants are appropriate for immediate loading when good primary stability with minimum 35Ncm is achieved and with appropriate occlusal loading.

4 Contraindications

Dental implants are usually less recommended for patients who have contraindicating systemic or uncontrolled local diseases such as:

Cardiovascular disorders associated with high endocarditic risk, coronary insufficiency, cancers and radiation of the facial region in the past five years, weakened immune system, uncontrolled diabetes, bone metabolism disorders, hemophilia, poor general state of health, inadequate wound healing capacity, maxillary and mandibular growth not completed, unfavorable anatomic bone conditions, periodontal disease, poor oral hygiene, bruxism, inadequate bone or blood supply, unrealistic patient expectations or poor patient motivation, psychological disorders, smoking, drug abuse or alcoholism, steroid use, allergy to titanium, aluminum, vanadium or silicone.

5 ⚠ Warnings

- Implants should be placed and restored only by practitioners who are licensed and trained to perform these procedures.
- Adequate preoperative studies should be performed to examine the anatomic structures and to assess the biomechanical, functional, and esthetic requirements of each case.
- Radiographs or other diagnostic reviews should be performed to determine position and topography of the maxillary sinus, nasal cavities, inferior alveolar nerve, mental foramen, natural tooth positions and other anatomical features that may affect implant placement or prognosis.
- Consultation between the surgeon, restorative dentist, and dental laboratory is essential for success.
- Risks of implant placement and restoration include, but are not limited to: infection, implant failure, loss of bone and soft tissue, unfavorable aesthetic result, anesthesia, dysesthesia and paresthesia in the oral and facial areas, sinus infection, dislodgement of implants and instruments in the surrounding structures, damage to adjacent teeth, non-restorable implants, fracture of implants or restorative components, and loosening of implants or restorative components.
- Each implant system has unique measuring characteristics to allow full seating of the implant to the desired depth. In some instances, drill length reference lines measure longer than the stated length of the implant.
- Please follow the below table to determine the appropriate drill length in order to insert the uppermost rim of the implant at the bone level.

Implant length	Components	Uppermost drill line
6.5 mm	6.5 mm	Uppermost rim of 6 mm line
7.0 mm	7.0 mm	Between 6 mm and 8 mm line
10 mm	6.5 mm + 1 ring	Uppermost rim of 10 mm line
10.5 mm	7.0 mm + 1 ring	Between 10 mm and 11.5 mm line
13.5 mm	6.5 mm + 2 rings	Uppermost rim of 13 mm line
14 mm	7.0 mm + 2 rings	13 mm line + 1 mm

- It is recommended that the implant surgeon be thoroughly familiar with the specific measurement system being utilized and provide a suitable safety margin adjacent to any teeth and vital structures. Failure to recognize the difference between the actual length of the drill and radiographic measurements can result in permanent injury to the nerves or other vital structures by drilling beyond the depth intended, potentially resulting in permanent numbness to the lower lip and chin or other injuries.
- One-hundred percent success cannot be guaranteed. Lack of adequate quantity and/or quality of remaining bone, infection, inadequate surgical technique, poor patient oral hygiene, and generalized disease are some potential causes for failure of osseo-integration, both, immediately after surgery or after osseo-integration is initially achieved. Pre-operative hard tissue or soft tissue deficits may yield a compromised aesthetic result or unfavorable implant angulation.
- With respect to children, routine treatment is not recommended until completion of alveolar growth has been verified.
- The ZEEV MtDI™ and accessories have not been evaluated for safety and compatibility in the MRI environment. The ZEEV MtDI™ and accessories have not been tested for heating or migration in the MRI environment. **Do not use in MRI environment.**
- All efforts must be made to minimize damage to the host tissue. In particular, special attention must be paid to thermal and surgical trauma and to the elimination of contaminants and sources of infection.
- The surgical procedure requires a high degree of precision and care according to **MtDI™ Surgical and Prosthodontics Procedure – Instructions.** Any divergence from the principle of least possible trauma at implant installation increases the risk of failure to establish osseo-integration.
- Common drills should be selected with specific drilling speed range of 200-500 rpm.
  Special drills should be selected with their specific drilling speed range. For example - Densah® Burs progressively increase in diameter throughout the surgical procedure and are designed to be used with standard surgical engines, to preserve and condense bone (800-1500 rpm) in a counterclockwise direction (Densifying Mode), and to precisely cut bone if needed (800-1500 rpm) in a clockwise direction (Cutting Mode)
  Special care should be taken to avoid over or under preparation of the osteotomy. Implants should be inserted in such a way that they are stable and lack any mobility.
  Common bone substitutes, collagen membranes and other bone regeneration materials and technique should be selected according to their producer instructions and common surgical technique.
- All instruments used in surgery must be maintained in good condition and care must be taken that the instruments do not damage the implants or other components.
- Precautions must be taken to avoid the swallowing or aspiration of components used in implant dentistry.

- After the implant installation, the surgeon's evaluation of bone quality and initial stability will determine when implants may be loaded.
- Implants are supplied sterile and are for single use only - DO NOT RESTERILIZE.
- Reprocessing the implant may result in bio-contamination, degraded performance or loss of function.
- Do not use after the expiration date.
- Do not use an implant if it has been opened or the packaging has been damaged. If tampering or damage exists, contact your ZEEV Implant Ltd. local representative.

6 Follow Up Care

- Patients should be instructed in appropriate oral hygiene and care of the implants and restorations.
- Periodic follow up appointments should be made to confirm and maintain adequate function of the implants and the health of the surrounding tissues. We suggest the following protocol:
  - **7-10 days after placement:** stitch removal, patient maintenance instructions
  - **1 month after placement:** tissue healing evaluation
  - **4 months (mandible) / 6 months (maxilla) after placement:** implant exposure, tissue healing evaluation, osseointegration and bone quality assessment using standard intraoral dental periapical radiographs, rehabilitation by crown and bridge
  - **12, 18 and 24 months after placement:** tissue healing evaluation by: Probing Pocket Depth (PPD), Bleeding on Probing (BP), suppuration/exudate (SUPP), Periapical Radiographic Exam, patient maintenance instructions

7 Tools Cleaning

- The ZEEV MtDI™ components included in the implant kit are supplied sterile and are intended for single use.
- The surgical tools shall be cleaned according to manufacturer instructions.

8 Tools Sterilization

- The ZEEV MtDI™ components included in the implant kit are supplied sterile and are intended for single use. **Do not resterilize**.
- The surgical tools shall be sterilized according to manufacturer instructions.

9 Materials

ZEEV MtDI™ and its components are made out of medical grade titanium alloy (Ti-6AI-4V Eli). The apex and rings contain internal implantable grade silicone sealing rings.

10 Labeling Symbols

	Caution/Attention: See Instructions for Use		Do Not Use if Package is Open or Damaged
	Do Not Reuse		Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician
	Expired By		Catalog Number
	Manufacturer		Number of Units
	Lot Number		Sterile using irradiation
	Authorized Representative in the European Union		CE Mark

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