MtDI™ Surgical and Prosthodontics Procedure | Instructions

1 First Phase

1.1 Preoperative handling

Before implantation, the instrument set is checked to ensure that all the needed instruments are at hand.

All instruments that are to be used should be sterilized. Implants should not be opened until the beginning of the installation procedure.

Implantation is generally performed under local anesthesia. General measures should be taken to make the operation room and unit free of contamination.

The dentist and the chair assistant should wear sterile clothes and gloves according to correct surgical procedure.
Pre-medication is given based on individual indications. Three days before surgery the patient should begin a regiment of mouth-rinsing twice a day with 0.2% chlorhexidine solution, in order to reduce local micro-flora. Half an hour before surgery, the patient is given 1 gram of Penicillin as a prophylaxis. The penicillin should be continued after surgery according to the doctor's instructions. The areas around the mouth are cleaned with 0.2% chlorhexidine solution and the patient is covered with sterile operating sheets covering the body and the head.

1.2 The Operation

The surgical field is exposed by an incision on top of the alveolar ridge or placed remote from the crest as judged by the surgeon to be the most adequate way of performing the operation.

Mucoperiostal flaps are elevated to enable easy access to and control over the fixture sites, and to permit satisfactory registration of the jaw morphology.

All drill activities should be carried out with cooling and saline irrigation to prevent excessive heating of the bone.

The site of the implant is prepared in a step-by-step procedure using drills of different diameters with indication of the correct depths and using intermittent technique.

If the alveolar ridge is knife-edged and too narrow, the ridge has to be reduced with a drill (Crestotom drill is very suitable)

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The implant site is marked with a round drill. The ideal distance between each fixture is 3.5 to 4.0 mm, given a center to center distance of 7 to 8 mm. In partially edentulous situations the position of the fixture and their relationship to the remaining dentition must be considered, the amount of room available to the instruments should also be determined.

For pre-drilling initially prepare the fixture site with a 2.0 mm drill. By carefully positioning the drill, the correct depth and inclination of the holes will be ensured.

Direction indicators may be placed in the site to facilitate the indication of the subsequent drilling. The indicators enable the doctor to check the depth of the fixture site.

Additional drilling should be done with the twist drill of 3.2 mm. The aim of this drilling is to create a hole of 0.5 mm in diameter smaller than the fixture diameter.
In the case of 4.2 mm fixture, an additional drilling should take place with a twist drill of 3.8 mm. After further thorough suction rinsing, the implant bed should be checked again with the depth gauge.

1.1. Component Description

The MtDI™ apex fixture and connecting rings are available in the following diameters; 3.75, 4.2, 5 or 6mm. The MtDI™ is provided in its maximal length of 13.5mm; with the apex fixture of a fixed length of 6.5 mm and 2 adjustable connecting rings, each of a fixed length of 3.5 mm. The MtDI™ is also provided in length of 10 mm; with the apex fixture of a fixed length of 6.5 mm and 1 adjustable connecting ring of a fixed length of 3.5 mm. The dental surgeon can also choose the desired length of the MtDI™ by eliminating one or two of the connecting rings. The modularity of the MtDI™ enables the following dental fixture lengths; 6.5 mm (apex fixture only), 10 mm (apex + 1 ring) and 13.5 mm (apex + 2 rings). All of the MtDI™ dental fixture configurations are in range of the conventional, commercially available, dental implant lengths. The apex and connecting rings have a hexagonal internal interface and sand blasted, acid etched (SLA) outer surface morphology. Multi-Unit (MU) adaptor is connected on-top of each implant by MU tightening screw. A Mount is connected on-top of each MU adaptor by a Mount tightening screw.

A TABS™ ***Total Anti-Bacterial Leakage, Gap Sealer*** manufactured from medical ***biocompatible for implantation elastomer*** - *for* ***Peri-Implantitis Prevention*** is connected to each MtDI™ ring, Multi-Unit (MU) adaptor as-well as to MtDI™ abutments. A sealer

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made of biocompatible for implantation elastomer inserted around MU tightening screw head and abutments tightening screw head.

A schematic overview of the MtDI™ modular concept is depicted in Figure 1.

Figure 1: Schematic overview of the MtDI™ modular concept

A schematic overview of the MtDI™ implant package kit is depicted in Figure 2.

A schematic representation of the device configuration options is depicted in Figure 3.

Figure 3: Schematic overview of the MtDI™ configuration options

The Apex fixture has a conical geometry at its apical area. It is made of Titanium alloy Ti-6AI-4V. The Apex fixture has a fixed length of 6.5mm and is available in several different diameters; 3.75, 4.2, 5 and 6 mm.

The MtDI™ is provided as one apex fixture and one or two connecting rings. The apex and rings are connected to each other by the device MU adaptor and the MU adaptor tightening screw connects MU adaptor to the implants' Apex and Rings. The rings have a cylindrical outer geometry. They are made of Titanium alloy Ti-6AI-4V. Each ring has a fixed length of 3.5mm and is available different diameters, each connecting to the apex fixture of the same diameter; 3.75, 4.2, 5 or 6mm.

For Two stages implants surgery - the MtDI™ implant kit contains a set of cover screws with a diameter of Ø3.7mm, which suits the Ø3.75 mm, Ø4.2 mm, Ø5 mm and Ø6 mm implants. The cover screws are also manufactured from Titanium alloy Ti-6AI-4V. All the cover screws have a 1.25 mm internal hexagon interface, with a thread of 1-72 UNF. The cover screw is placed in the fixture during the bone integration period between the fixture and the bone. It completely occludes the internal interface keeping it free from ingrowth of bone and debris. The cover screw is supplied sterile and is provided with the MtDI™ dental implant.

The MtDI™ implant kit also includes a designated Mount connected to MU adaptor. The role of the MtDI™ MU adaptor is to maintain the apex and connecting rings in their implantable configuration until the time of implantation and during the implementation processes. The MU adaptor tightening screw connects MU adaptor to the implants' Apex and Rings. **The tightening screw should be unscrewed only after screwing the implant into its final position at the bone level and bone primary fixation of the implant has been achieved along the entire implant surface.** The mount is manufactured from medical grade stainless steel. The MtDI™ and the connecting rings are provided in the original package restrained to the designated mount. The MU adaptor, MU tightening screw and MU Healing cap are also manufactured from Titanium alloy Ti-6AI-4V.

Prior to implantation into the jaw bone the dental surgeon can decide if to disassemble some of the connecting rings utilizing the accessory ring disassembly tool, and implant a shorter implant configuration.

Two surgical managements protocols are available:

1. **One stage surgery** – MU Healing cap is screwing to MU adaptor by 20N for gingival flap adaptation and closure.

2. **Two stages surgery** - the appropriate Tightening Cover Screw is screwed into the implant head (L1 – 1 Ring; L2- 2 Rings; L0- Apex).

1.2. Intended Use

The MtDI™ Dental Implant device 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 is achieved and with appropriate occlusal loading.

1.3. Principles of Use

The Modular type Dental Implant (MtDI™) is a dental implant, which is based on a modular design consisting of up to two connecting rings that can easily connect to achieve the desired implant length. The Modular type Dental Implant (MtDI™) is surgically implanted into the

patient's upper or lower jawbone, and by a process of osseointegration become firmly integrated into the bone. Following the osseointegration process, the surgical site is reopened and the abutments, crown, bridge, or other supra-structures necessary to restore chewing function to the patient are installed.

Fixture mounting

The fixtures come in plastic tube. The fixtures and the tube, 3 cover screws and MU healing cap are packed in sterile peel-off packs. Before starting the procedure, the sterility date should be checked and care should be taken that the package is complete.

The fixture is pulled out of the plastic site with the fixture holder, and placed directly in the implant bed. Screwing the implant in by hand can be attempted. If this is unsuccessful, then one can use either a Ratchet Wrench or Handpiece Connector and drill for screwing the self-tapping fixture into the bone. In cases where the Handpiece is being used, the installation is carried out at low speed, 20 rpm, under profuse irrigation with saline and at a maximal torque of 35 Ncm. In cases where the Ratchet Wrench is being used, saline irrigation should be used. The fixture should be placed in a position slightly below the marginal bone level. The objective is to get the fixture in contact with as much cortical bone as possible. The fixture holder should be taken out of the fixture **after complete insertion of the implant for the desired length,** by screwing out the tightening screw by hexagonal screwdriver.

The fixture holder should be remaining in place and be connected to the implant by the tightening screw during all the implant insertion process. Only after complete insertion of the implant for the desired length, the fixture holder may be taken out of the fixture by screwing out the tightening screw by hexagonal screwdriver.
Every time you are screwing out the tightening screw – pull it out only after all its length it totally released.

Rings assembly and disassembly utilizing the tool kit

If the implant's length should be shortened to achieve desire clinical bone length, the surgeon may reduce rings by appropriate ring disassembly tool.
It can be done either after the fixture insertion (recommended), or before the fixture insertion and then surgeon may use special forceps to hold the fixture while reduce rings by appropriate ring disassembly tool.
There are two available ring disassembly tools each for the designated ring to be disassembled; one for the disassembly of a ring in a fixture configuration of apex and a single adjustable ring and the other for the disassembly of the upper ring in a fixture configuration of apex and two adjustable rings.

If the implant's length should be elongated to achieve desire clinical bone length, the surgeon may add rings by ring assembly tool. Ring is connected to ring assembly tool by screw. The ring should be placed at the uppermost part of the implant. The ring assembly tool should be taken out of the fixture by screwing out the tightening screw by hexagonal screw driver.

Cover screw/ Healing cap insertion.

The cover screw should be taken out of the sterile package by using a hexagonal screw driver and can be tightened with light finger pressure and by Ratchet Wrench or Handpiece to a maximal torque of 20 Ncm. In the event that more than one implant is to be inserted, the above procedure should be repeated for every implant.

If primary stability torque of >35 Ncm was achieved, appropriate healing cap* may be screwed by using a hexagonal screw driver and can be tightened with light finger pressure and by Ratchet Wrench or Handpiece to a maximal torque of 20 Ncm.

The entire operation area should be rinsed with room temperature saline.

Common bone substitutes, collagen membranes and other bone regeneration materials and technique should be selected according to their producer instructions and common surgical technique.

The mucoperiostal flap should be repositioned carefully and sutured with interrupted mattress sutures ensuring a tight seal over the fixtures. After suturing, the patient should be instructed to bite down on gauze rolls that have been placed on the flaps in order to limit hematoma formation.

The patient should be instructed to dispose of the gauze rolls after half an hour. Eating or drinking for two hours after the surgical procedure is forbidden. For the first day following surgery, the patient should avoid drinking or eating hot food and beverages.

Note:

* Has to be ordered separately:

Standard Healing caps may be used only for connecting to the implant's Apex part.

HLC-RN1-03	Healing Cap 1 Ring, l. 3mm;	HLC-RN2-03	Healing Cap 2 Rings, l. 3mm;
HLC-APX-04	Healing Cap Apex, l. 4mm;	HLC-RN1-04	Healing Cap 1 Ring, l. 4mm
HLC-RN2-04	Healing Cap 2 Rings, l. 4mm;	HLC-APX-05	Healing Cap Apex, l. 5mm
HLC-RN1-05	Healing Cap 1 Ring, l. 5mm;	HLC-RN2-05	Healing Cap 2 Rings, l. 5mm
HLC-APX-06	Healing Cap Apex, l. 6mm;	HLC-RN1-06	Healing Cap 1 Ring, l. 6mm
HLC-RN2-06	Healing Cap 2 Rings, l. 6mm		

2 The first Healing phase

One week after surgery, the old denture or other temporary provision is to be checked for any compression over the fixture areas. Dentures are relined with soft liners. The sutures can normally be removed at the same time and the operation area is checked for complete soft-tissue healing.

The healing period for osseo-integration follows the general pattern for unloaded immobile fixtures. In the mandibula a minimum of 3 months and in the maxilla at least 6 months is advocated for healing.
The patient is regularly checked during the healing phase. Attention should be given to the patient's general condition - paying close attention to infections in the mouth, especially in the areas of the fixtures where complete growth of soft tissue is desired.

3 Surgical Procedure – Second phase

The aim of this procedure is the installation of the healing abutment/cap. The procedure is carried out after infiltration of local anaesthetic. The healing abutment/cap is advocated for temporary use during the short mucosal healing phase, offering flexibility for the selection of the final abutment or other solutions.

Locating the fixtures

This is done by using radiographs along with the known treatment planning of the position of the fixtures. A stent is used for guiding towards the precise place of exploration.
A small incision is made to confirm the position of the cover screw. A tissue punch instrument may be used to remove the overlying tissue. When little or no attached mucosa is present only an incision is needed. When the mucosa is thick, it may be necessary to make a long incision with limited flap elevation.
The bone and soft tissue that might inhibit the removal of the cover screw are removed in order to gain access for the removal of the cover screw.
The cover screw is removed using the hexagonal screwdriver. The fixture is then rinsed with saline, the appropriate* healing abutment is chosen according to the mucosal height and then the healing abutment/cap is put in place.
At this stage, the fixture can be checked for immobility. When the abutment is tapped with a metallic instrument, if a metallic, ancylotic ringing sound is heard, this denotes osseo-integration.
The healing abutment/cap is recommended for intermediate use. It can be installed with the hexagonal screwdriver, using only light finger force for the seating and by Ratchet Wrench or Handpiece to a maximal torque of 20 Ncm.

4 Second healing phase

During this 7 to 10 day period the gingiva has the opportunity to heal around the healing cap. The patient can accelerate the healing process through mouth rinsing with Chlorohexidine diglucanatis 0.2% twice daily.

5 Prosthetic procedure

A short description of these phase is as follows:

At the beginning of the prosthetic procedure a selection of the abutment takes place, by using a pocket depth indicator to measure the gingiva thickness.

We recommend using a screwed prostatic abutment in order to facilitate unscrewing the crown if necessary.

5. 1 Installation of the abutment

The healing abutment is removed with the hexagonal screwdriver.
- Attach the abutments onto the implants and adjust for height and clearance if necessary
- Fasten the abutments with the appropriate abutment screw**:
** ABS-RNG-01 -Abutment screw for 1 Ring (implant length 10 mm)
** ABS-RNG-02 -Abutment screw for 2 Rings (implant length 13.5-14 mm)

Note:
** Has to be ordered separately.
Abutment screw that is included with the abutment may be used only for connecting the abutment to the implant's Apex part.

5.2 Connect abutment to implant

- Attach the abutment onto the implant and tighten to 35Ncm with the Screwriver Machine and Manual Torque Wrench Prosthetic.
- If the implant rotates while tightening the abutment, re-evaluate primary stability of the implant and consider a submerged approach.

5.3 Temporary restorations

5.3.1 Temporary multiple-unit restoration, screw-retained (Chair-side procedure)

Use temporary Abutment :
For individual implants - use engaging (Hexagonal connection) abutments.
For multiple splinted restorations- use non-engaging (non – hexagonal connection) abutments.
Provisionalization must be done in immediate function cases and is a common option for altering the soft tissue after a healing abutment has been used (Soft tissue management).

5.3.2 Make ac template

- Fabricate acrylic template for chair-side temporalization.
- Make access holes to allow Abutment screws to protrude.
- If the laboratory has made a prefabricated provisional bridge, make access holes to allow Abutment screws to protrude (if not already done) and adjust it to the abutments.

- Fill template with acrylic or Composite and seat over temporary abutments.

5.3.3 Adjust temporary restoration

-After seating, loosen the Abutment screws to remove the restoration.
-Trim and polish the restoration. It is important to have a smooth surface adjacent to the surrounding soft tissue.

5.3.4 Connect temporary restoration

-Connect the provisional restoration with the appropriate** abutment screws.
- Tighten to 35 Ncm using Manual Torque Wrench Prosthetic and Screwdriver Machine.
-Fill screw access holes with suitable material.

Note:

** Has to be ordered separately.
Abutment screw that is included with the abutment may be used only for connecting the abutment to the implant's Apex part.
** ABS-RNG-01 -Abutment screw for 1 Ring (implant length 10 mm)
** ABS-RNG-02 -Abutment screw for 2 Rings (implant length 13.5-14 mm)

5.4 Final restorations

5.4.1 Impression

High viscosity elastic impression material or a digital intra-oral scanner are recommended for the prosthodontics procedures.
Depending on the impression technic and the material to be used, open or closed-tray impression copings are selected.
For open tray impression, tray is prepared so that each guide pin can penetrate the tray without interfering with it.
Place the impression coping over the implant. Use the Screwdriver to tighten the screw.
A radiograph may be taken to verify proper seating of the impression coping.
The tray is placed carefully over the jaw so that the guide pins can find their way through it.
-Remove the impression.
-Place the impression coping implant replica assembly into its corresponding location in the impression and send it to the dental laboratory for model fabrication.
Total impression and total registration of occlusion and articulation will follow according to the prosthodontics principles.

5.4.2 Laboratory procedures

A final restoration is fabricated using conventional procedures.

5.4.3 Connect restoration

-Place the abutment onto the implant.

-Tighten to 35 Ncm using Manual Torque Wrench Prosthetic and Screwdriver Machine.
-For cemented restoration - remove excess cement in accordance with normal procedures

-**Check occlusion:**
Reflective contacts, crossover interferences, working and balancing interferences that are destructive should be removed as soon as possible and centric contacts should not be heavier than adjacent teeth.

Note: A radiograph can help to confirm accurate seating of the abutment.

6 Continued care and maintenance

The patient should be instructed on how to keep the fixture site and gingiva in good condition.
Patients should be instructed for daily brushing and flossing twice a day, at a minimum for keeping the implants clean and plaque-free. Using Dental floss for cleaning around abutments; Antimicrobial mouth rinses (if recommended) ; Inter-dental brushes or aids for removing food between implants/teeth and Regular professional cleanings
The dental hygienist has an important role to play in keeping dental implants infection-free.

Maintenance Period. After the implant was restored and monitored, follow-up check-ups every six months is recommended.
Occlusion should be monitored and checked by the dentist annually at the very least.
Reflective contacts, crossover interferences, working and balancing interferences that are destructive should be removed as soon as possible and centric contacts should not be heavier than adjacent teeth.