GD Dental Implants

SURGICAL MANUAL

2-COMPONENT SYSTEMS

GDT Implants
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CONTENT

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GENERAL INFORMATION

Read this manual carefully before starting treatment.
This manual is intended to be used as a reference guide to optimizing the use of GDT implants, surgical instruments and prosthetic components. It does not replace the formal training of clinicians and dental laboratory technicians, and should not be taken as a recommendation on protocol or component selection.

IMPORTANT WARNING

Implantation procedures should not be performed without sufficient experience and adequate training at a certified institution.
Lack of training poses a significant health risk to patients and can lead to the failure of implant procedures.

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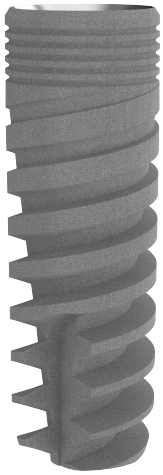
IMPLANTS

GDT dental implants are manufactured from biocompatible titanium alloy and consist of threaded and tapered designs featuring a proprietary internal hex connection which provide superior strength, stability and esthetics. The internal hexagon or internal “hex” connection implant system is one of the most widely used in a dental implant dentistry today, developed with simplicity, stability, and ease-of-use in mind.

The hex interface allows simple self-guiding and seating of the abutment without the necessity of using additional extra intraoral procedures.

GDT implants and superstructures are applicable for all clinical indications with a manageable range of implant components and instruments.



MOR SPIRAL DENTAL IMPLANTS

CFI CYLINDRICAL DENTAL IMPLANTS

GDT implants feature a roughened SLA surface, which starts up at the bevel of the implant where the medialized prosthetic connection begins, creating a continuous bone-to-implant contact surface to the apex.

For specific product description and net quantity please refer to individual product labels.

Although final placement of GDT implant is at the discretion of the implanting surgeon, we offer you our recommended guidelines. Each case should be evaluated based on placement, protocol and type of implant before the osteotomy is drilled.

Having a range of GDT implants available allows clinicians to weigh the advantages of each implant type, and to select the best suited based of the individual case.

GDT implants are recommended for placement at the crest of the ridge or slightly below.

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IMPLANT PACKAGING (TYPE 1)

Outer vial

Inner vial

Implant

Cover screw

Multi-functional carrier

Surgical Strategies:
Allows the implantologists to adopt any implantation strategy during the procedure:

- Two stages (submerge).
- One stage (Metal healing cap).
- Immediate loading.
- Immediate impression.

3 Elements in One Packaging:

- Cover screw.
- Multi use implant carrier.
- Implant.

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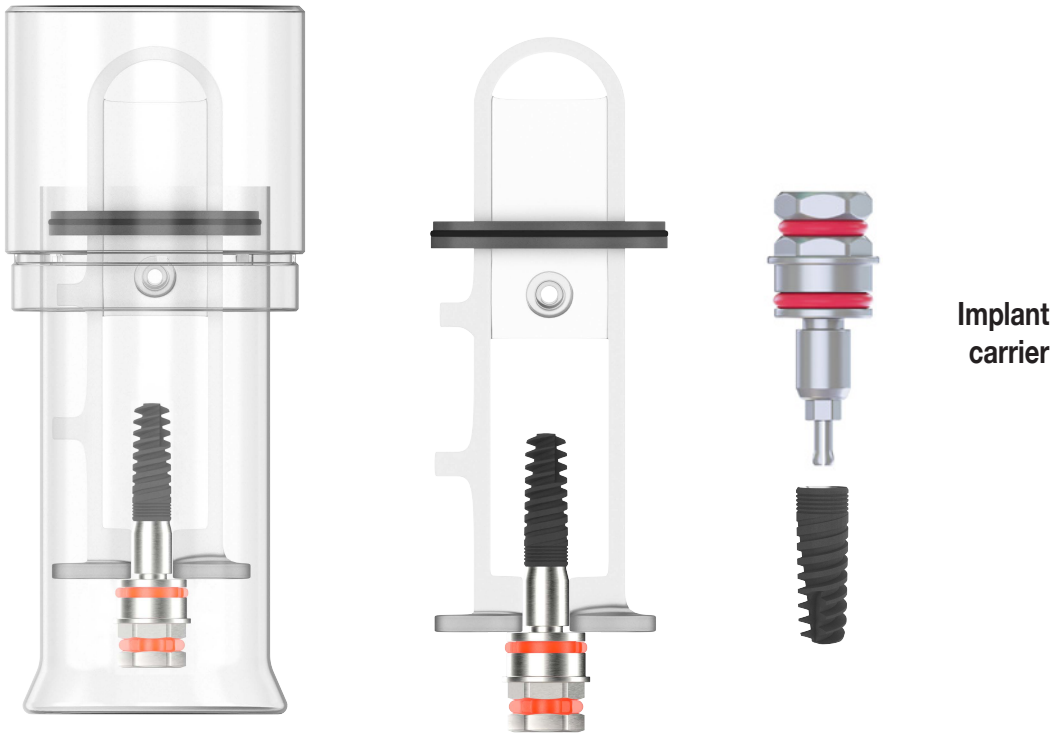
IMPLANT PACKAGING (TYPE2)



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SURGICAL PROTOCOL

Indication for Use

GDT Dental Implant System is intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multi-unit restorations, including: cement-retained, screw-retained, over denture restorations and terminal or intermediate abutment support for fixed bridgework.
The specific disease, injury, physiological condition or traumatic event leading to the loss of a tooth or to the necessity of tooth removal are manifold and inconsequential, as long they are not explicitly listed in the contraindications.
The contraindication to place implants will be evaluated by professionals on a case-by-case basis. Preoperative diagnosis is necessary to identify threats to the patient, related to the procedure of the implant placement, as well as factors that may affect the possibilities of healing of the bone and surrounding soft tissues.

Contraindications

Contraindications can be separated into absolute and relative contraindications:

absolute and relative contraindications:
• Myocardial infAbsolute contraindications:arction: within six months of an attack,

- Cerebral infarction and cerebral apoplexy: In cases where the condition of the disease is serious and the patient is concurrently taking anticoagulants,
- Severe immunodeficiency
- Patients who are undergoing strong chemotherapy
- Severe neuropsychiatric disease, mental disability, and narcotic drug addicts
- Patients who are concurrently taking bisphosphonates
- Youths under the age of 15
- Allergies or hypersensitivities to chemical ingredients of material used: titanium alloy (Ti6Al4V).

Relative contraindications:

- Diabetes (particularly insulin-dependent).
- Angina pectoris (angina).
- Seropositivity (absolute contraindication for clinical AIDS).
- Significant consumption of tobacco.
- Radiotherapy to the neck or face (depending on the zone, quantity of radiation, localization of the cancerous lesion etc.).
- Auto-immunes diseases.
- Drug and alcohol dependency.
- Pregnancy.
- Certain diseases of the mucous membranes of the mouth.
- Bruxism.

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- Periodontal diseases (loosening of the teeth) – it is necessary to clean up the gums and stabilize the disease first.
- An unbalanced relationship between the upper and lower teeth/jaws.
- Poor hygiene of the mouth and teeth.
- An insufficient quantity of bone.
- Infections in the neigh boring teeth (pockets, cysts, granulomas), major sinusitis. Immediately after the insertion of dental implants, activities that demand considerable physical exertion should be avoided.

Temporary Contraindications:

- Systemic infection, local oral and respiratory infection.
- Anatomical or pathological contraindications.
- Insufficient alveolar bone width and height to surround the implant with at least one millimeter of bone.
- Inadequate bone height where proper implant placement would encroach within 2mm of the mandibular canal, sinus floor, etc.
- Malignancies.

GENERAL CAUTIONS / PRECAUTIONS:

Cover screw for the implant is delivered sterile and ready for use.

All other screws and prosthetic parts are delivered non-sterile and must be sterilized before use. Sterile handling is essential. Contamination may lead to infection. Dental Implants should not be re-sterilized. Any contact of the implant with foreign substances prior to use should be avoided. That's why GDT Implants are pre-mounted on a carrier. If implants not assembled any more with carrier and moving inside the vial, this implant surface is already contaminated by plastic particles. Such implant shouldn't be used and have to be replaced by the company.

The use of electrosurgical or laser instruments around metallic implants and abutments is forbidden due to the electric and/or heat conductivity of the substrate metal. Ample irrigation is necessary for cooling to prevent heat transfer.

It is very important to determine the local anatomy and suitability of the available bone for implant placement. Case planning with adequate radiographs, direct palpation and visual inspection of the prospective implant site are necessary prior to treatment and implant use.

Forcing the implant into the osteotomy deeper than the depth established by the drills can result in: stripping the driver hex interface inside the implant, stripping the driver, cold-welding of the motor mount driver interface to the implant, or stripping/breaking the walls of the osteotomy that may prevent an effective initial implant fixation. Abutments are for single use only. A previously used abutment should not be sterilized and not recommended to be reused. Mishandling of small components inside the patients mouth carries a risk of aspiration and/or swallowing.

For prevention, use rubber dam and dental floss to secure the instruments and components.

Ensure that the patient has been informed regarding implant placement and restorative procedures, home care and implant maintenance. The patient's expectations of the final result should be clearly defined.

Implants should be used according to their expiration date.

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One hundred per cent implant success cannot be guaranteed. Failure to observe the indicated limitations of use and working steps may result in failure. Implant treatment may lead to loss of bone, biologic and mechanical failures, including fatigue fracture of implants. Close cooperation between the surgeon, restorative dentist and dental laboratory technician is essential for successful implant treatment.

While being compatible with a similar prosthetic connection implant parts, it is recommended that GDT Dental Implants are used only with dedicated surgical instruments and GDT prosthetic components. A violation of this recommendation may lead to mechanical instrumental failure or unsatisfactory treatment result.

STERILIZATION

All GDT Implants are delivered in sterile, gamma-irradiated packaging with a five- year shelf life,

Implants should not be used after the expiration date, as sterility cannot be assured.

Refer to individual product labels for sterilization information; all sterile products are labeled STERILE.

The inner vial and implant body are sterile unless the outer package seal has been damaged or opened. If the implant becomes contaminated by the patient's body fluids or tissues, the implant cannot be used on another patient. The implant cannot be cleaned or re-sterilized for use in another patient.

Do not attempt to decontaminate the implant by any in-office method.

IMPORTANT NOTICE!

It is important to ensure all instrumentation, surgical hand-pieces, and equipment has been ster-ilized to prevent the possible contamination of the components, the surgical system, and the patient.

Always remove instrumentation from its packaging prior to sterilization.

Always run a system check to ensure that the surgical motor and its components are functioning properly. Backup equipment, implants and instrumentation are recommended in case of contami-nation or failure of equipment.

Surgical drills eventually become dull with use and require replacement.

Possible complications following the insertion of dental implants are:

Temporary symptoms: pain, swelling, phonetic difficulty and gingival inflammation.

More persistent symptoms: chronic pain in connection with implants, permanent paraesthesia, dysesthesia, loss of maxillary / mandibular ridge bone, localized or systemic infection, oroantral or oronasal fistula, unfavourably affected adjacent teeth, fracture of implant, jaw, bone or prosthesis, aesthetic problems, nerve damage, exfoliation, hyperplasia.

Beside the mandatory precautions for any surgery such as of asepsis, during drilling in the jaw bone, one must avoid damaging the nerves and vessels by referring to anatomical knowledge and preoperative medical imaging (e.g. radiographs). Failure to recognize actual lengths of drills rela-tive to radiographic measurements can result in permanent injury to nerves and other vital struc-tures. Drilling beyond the depth intended for lower jaw surgery may potentially result in permanent numbness to the lower lip and chin or lead to haemorrhage in the floor of the mouth.

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Unfavorable implant placement or alignment may be treated with either pre-angled or customized abutments. In the event that the implant is unrestorable due to unfavorable alignment or position-ing, the implant may have to be left out of function or removed/replaced.

STORAGE AND HANDLING

Devices should be stored at room temperature.

Refer to individual product labels and this manual for special storage or handling conditions.

CAUTION

U.S. Federal Law restricts this device to sale by or on the order of a licensed dentist or physician.

Treatment Planning

GENERAL INFORMATION

These instructions are guide lines practitioners in the use of GDT Implant System.
The success of any dental implant system depends upon proper use of the components and instrumentation. This manual is not intended for use as a substitute for professional training and experience.

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DATA COLLECTION

Examination and Treatment Planning

PATIENT EVALUATION AND SELECTION

- Before any treatment, the patient must be informed about expected outcomes of preoperative examination, including the expected results of the risks.
- Patients should sign a consent form to indicate their acceptance of treatment.
- Patient health status should be documented, including information regarding general medical contraindications, the surgical treatment, mental psychoses, alcohol and all of the information mentioned in instructions for use. If the patient's medical history reveals an existing condition or indicates a potential problem that may compromise treatment and/or the patient's well-being, consultation with a physician is recommended.

PREOPERATIVE PLANNING

Proper treatment planning, as well as the selection of the proper implant length and diameter, are crucial to the long- term success of the implant and restoration. Before an implant can be select-ed, the anatomical foundation available to receive the implant must be carefully assessed. Several steps should be taken to complete the evaluation:

1. Clinical Examination

Clinical examination of the oral cavity can provide important information about the health of the soft tissue at the proposed implant site. Patient examination includes a clinical and radiograph-ic examination and evaluation of general condition of the patient's health. Soft and hard tissues should be carefully examined. The patient should demonstrate an adequate dimension of attached mucosa or keratinized tissue at the site selected for implantation. In partially edentulous cases, the periodontal status of the remaining dentition should be assessed and interaction be-tween the implant restoration and the adjacent natural dentition should be considered. Data collection should include dental history, restorative status and occlusion. CT scan is rec-ommended in most cases. Radiographic examination should provide information about anatomy, pathology, quality and quantity of bone. Due to the special abilities of GDT implants, the implant primary stability can be achieved in very small bone volume and bone augmentation can be car-ried out in the same session.

2. Bone Quality

The most important factor for success is primary stability. Dense and compact bone provides high initial stability while cancellous bone provides reduced retention and it is therefore recommended that less bone preparation and fewer drills be used in order to achieve high enough initial stabilization. Primary stability is achieved by the special design of the GDT implants.

3. Vertical Bone Quantity

Dental implants need to be stabilized in a good quality bone for successful result.

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The amount of bone available for implant retention differs from site to site.

In situations where the initial stabilization is questionable, it is necessary to augment the bone volume prior to implant insertion. The unique design of GDT implants, achieves of high primary stability even in very small quantities of bone, and allows bone volume augmentation simultaneously with implant insertion, if needed.

4. Horizontal Bone Quantity

CT Scan can give us the correct data of the ridge width. The buccal and lingual surrounding bone should be at least 1 mm of the implant. 3 mm of bone between two implants should be left. In cases of less than 1 mm surrounding bone, bone augmentation procedure is needed especially in the esthetic zone.

In very narrow ridges it is recommended to consider bone augmentation procedures or to do bone augmentation simultaneously with the implantation instead of a two-stage procedure.

Type D-I Type D-II Type D-III Type D-IV

5. Pre-Operative Handling

The clinicians should be familiar with the GDT system, surgical and prosthetic protocols for efficient and accurate installation.

- Initial preparation of the patients should be done prior the implant surgery.
- Premedication of 2g of amoxicillin one hour before implant placement prophylactically and 500mg every 8 hours post treatment for one week is given based on individual indications.

Allergic patient may be given a prophylactic dose of 600 mg of clindamycin one hour before implant placement and 150 mg every 6 hours post treatment for one week.

- Proper sterilization of the room and surgical instruments should be carried out prior to the procedure.
- Local anesthesia is given by infiltration technique.
- Mouth rinsing should be carried out with 0.2% chlorhexidine solution for 1 minute.

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INSTRUMENTATION

GDT INSTRUMENTATION

All GDT surgical instruments are provided non-sterile. Always remove the instruments from the packaging prior to sterilization. Inspect the surgical instrumentation to ensure sterility and func-tionality. For example, drills may become dull after exceeding the recommended drilling cycles.so make sure you always have a sterile backup drill available.

GDT recommends drill replacement after 20 osteotomies depending on bone density. Dull drills generate more friction that causes excessive heat generation that can damage the bone and de-
prive the implantation result.

DRILLING

Implant site is prepared in a sequential procedure using drills of increasing diameter with depth indication lines that give a reading of the desired drilling depth.
Drills should be replaced when their cutting efficiency is reduced or when noticing excessive wear. All preparation of bone tissue must be carried out under ample irrigation with saline solution and using the recommended drilling technique.

SURGICAL DRILLS

We recommend using Cylindrical or Tapered Drills that are color-coded and externally irrigated. They are designed to achieve maximum cutting efficiency while effectively removing bone from the osteotomy during drilling.

CLEANING

1. After use, place drills into a beaker of plain water, mild soap or specialized cleaning solution.
2. Rinse with tap water for a minimum of two minutes while brushing with a soft bristled brush to remove visible debris. Place instruments in an ultrasonic bath containing enzymatic detergent for 5-7 minutes. Scrub the instruments again with a soft bristled brush and ream interior lumen to remove any remaining debris. Rinse and flush the instruments for one minute using tap water. Inspect visually for any remaining bone fragments or debris and scrub as necessary.

DRILLING SEQUENCE

The drilling protocol is adapted to the implant diameter and bone quality at the site. The in-structed drilling steps are suggested for dense/cortical bone. In softer bone fewer steps may be performed. In soft bone, 2mm or 2.8mm drills are often enough for all implant sizes. In very hard cortical bone it may necessary to drill with the next size drill only for the thickness of the cortical layer.

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DRILLING SEQUENSE: SOFT BONE – TYPE D3, D4

Marking drill	Pilot drill Ø 2.0	→	Drill Ø 2.8	Drill Ø 3.2	Implant Ø 3.75					
Marking drill	Pilot drill Ø 2.0	Drill Ø 2.5	Drill Ø 2.8	Drill Ø 3.2	Drill Ø 3.75x2.5	Implant Ø 4.2				
Marking drill	Pilot drill Ø 2.0	Drill Ø 2.5	Drill Ø 2.8	Drill Ø 3.2	Drill Ø 3.65 Drill	→	Drill Ø 4.5	Implant Ø 5.0		
Marking drill	Pilot drill Ø 2.0	Drill Ø 2.5	Drill Ø 2.8	Drill Ø 3.2	Ø 3.65	Drill Ø 4.2	Drill Ø 4.5	Drill Ø 5.2	Countersink Ø 5.0x6.0	Implant Ø 6.0

For bone types 3, you can skip the last drilling step.

When the bone is very porous, skip the last two drilling steps.

Due to the Premium Spiral special design it is possible to insert the implant into a prepared site of a much lower diameter than usual, thus allowing preservation of precious bone tissue and allow-ing the special incremental bone condensation feature of the implant to take effect.

As a result, the retention and stability are much higher without using bone condensing accesso-ries such as osteotomes. It should be noted, however, that in case of high resistance to insertion (50 Ncm), such as in a site with a substantial cortical bone layer, additional steps may be neces-sary, though usually just to penetrate the cortex.

If you feel a strong resistance at any point during implant insertion, rotate the implant counter clockwise 2-3 rounds and continue inserting the implant.

DRILLING SEQUENSE: HARD BONE – TYPE D1, D2

Marking drill	Pilot drill Ø 2.0	Drill Ø 2.5	Drill Ø 2.8	Drill Ø 3.2	Implant Ø 3.5					
Marking drill	Pilot drill Ø 2.0	Drill Ø 2.5	Drill Ø 2.8	Drill Ø 3.2	Drill Ø 3.75x2.5	Implant Ø 3.75				
Marking drill	Pilot drill Ø 2.0	Drill Ø 2.5	Drill Ø 2.8	Drill Ø 3.2	Drill Ø 3.65 Drill	Countersink Ø 3.8x4.2	Drill Ø 4.0x2.7	Implant Ø 4.2		
Marking drill	Pilot drill Ø 2.0	Drill Ø 2.5	Drill Ø 2.8	Drill Ø 3.2	Ø 3.65 Drill Ø 3.65	Drill Ø 4.5	Drill Ø 4.8	Implant Ø 5.0		
Marking drill	Pilot drill Ø 2.0	Drill Ø 2.5	Drill Ø 2.8	Drill Ø 3.2		Drill Ø 4.2	Drill Ø 4.5	Drill Ø 5.2	Countersink Ø 5.0x6.0	Implant Ø 6.0

CLEANING PROCEDURE FOR SURGICAL TRAYS AND INSTRUMENTATION

1. Disassemble the surgical kit and wash the tray using a detergent solution. Rinse the tray with water and dry thoroughly.
2. Place the instruments in a beaker of detergent solution and sonicate for approximately 10 minutes. Rinse thoroughly.
3. Remove any visible debris or bone fragments with a soft bristle brush. Rinse thoroughly.
4. Rinse the instruments with ethyl alcohol (do not use IPA isopropyl alcohol) to remove soap

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residue and minerals. This is important to help prevent corrosion and spotting.

5. Blot the instruments with a towel and allow to air dry completely.
6. Return the instruments to the appropriate locations in the surgical tray.
7. Wrap the kit in a double-layer of autoclave-wrap.
8. Sterilize the kit according to the manufacturer's instructions.

CAUTION

Do not remove the surgical kit from the autoclave until the dry cycle is complete.

The use of hydrogen peroxide or other oxidizing agents will cause damage to the surface of the instruments. Towel or air-dry all instrumentation before sterilization.

Drills and taps should be replaced when wear, a decrease in cutting performance, or signs of dis-coloration are noted.

STERILIZATION TABLE

All sterilization techniques should follow manufacturer's guidelines. If not provided,
refer to the following **Sterilization Table**:

- Autoclave 121-124° C (~250° F) 30 minute exposure / 30 minute dry time or 132-135° C (~270° 20 minute exposure / 30 minute dry time).
- Do not exceed 140° C (284° F). Always use the dry cycle.
- Each dental office is responsible for the proper, routine sterilization of instruments.
- All sterilization techniques should follow GDT guidelines.
- Place all instrumentation and implants onto the sterile work field in the order they will be used.
- This makes for a natural progression through the case sequence.
- The surgical kit is set up in this manner. Follow the drilling sequence in this guide.

SURGICAL GUIDE

The implanting surgeon, the restoring dentist, and the laboratory technician should work together to produce diagnostic wax-ups and a surgical guide. This teamwork assists the implanting sur-geon in the proper placement of the implant(s).

A surgical guide is used to indicate practical boundaries for the placement of implants and may prevent implants from being placed too buccal/lingually or mesial/distally. This process helps to ensure functional placement of implants and esthetic restorative results.

The implanting surgeon should communicate to the laboratory technician any conditions that may affect guide design (e.g., the type of incision that will be used, expected reflection of tissue, etc.).

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IMPLANT SELECTION

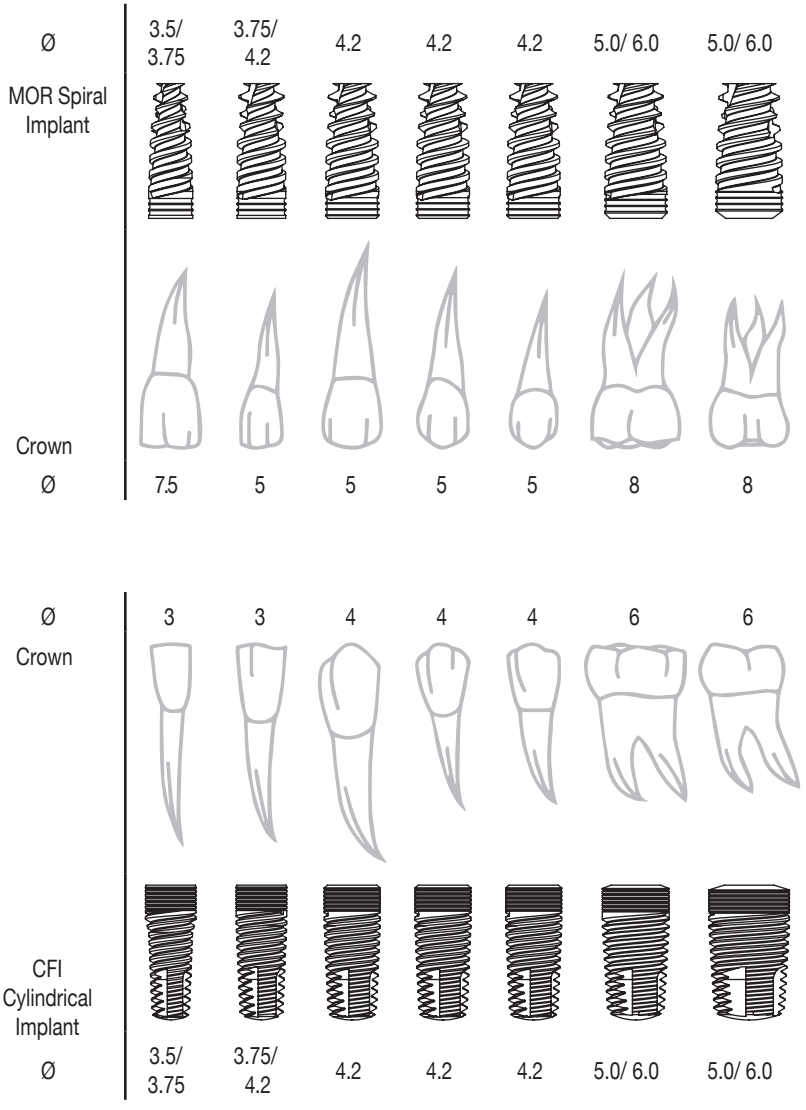
Implant is chosen according to the measurements of the ridge width and vertical length on the CT Scan. A safety zone of at least 2 mm from anatomical structures such as the mandibular canal should be maintained.

Correct treatment planning methodology will provide maximum biomechanical stability, allowing better emergence profile utilizing an implant with a prosthetic platform slightly smaller in diameter than the emergence diameter of the tooth being replaced.

Implant and healing abutment selections are based upon the relationship of several key measurements:

- The emerging dimension of the crown in relation to the diameter of the prosthetic platform of the implant.
- The height and diameter of the intended restoration at the tissue exit point.
- The bone volume at the implant site in relation to the diameter of the implant body.

GDT Implants selection according to the location in the oral cavity:



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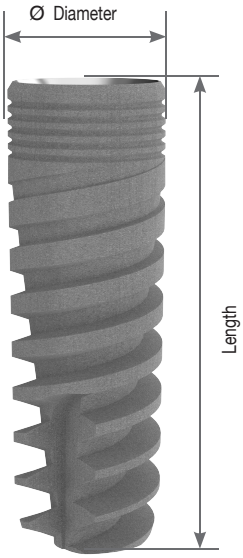
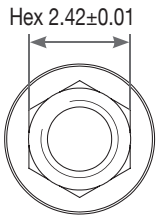
MOR SPIRAL IMPLANT

Best preservation of bone quantity and excelent initial stability.





Length / Ø	Ø 3.5	Ø 3.75	Ø 4.2	Ø 5.0	Ø 6.0
6.0 mm			M4206	M5006	M6006
8.0 mm	M3508	M3708	M4208	M5008	M6008
10.0 mm	M3510	M3710	M4210	M5010	M6010
11.5 mm	M3511	M3711	M4211	M5011	M6011
13.0 mm	M3513	M3713	M4213	M5013	M6013
16.0 mm	M3516	M3716	M4216	M5016	

Recommended for: All procedures. Positions: maxilla & posterior mandible. Not recommended for D-I bone types and sinus lifting.

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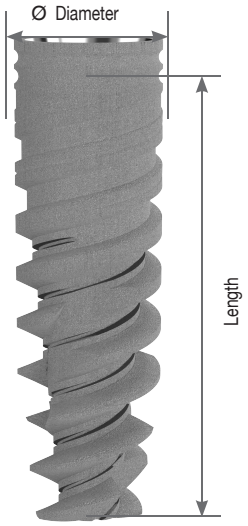
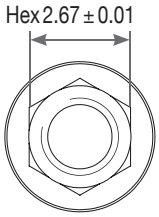
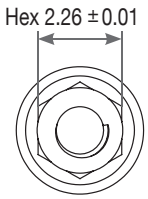
CON NP/CON RP CONICAL SPIRAL IMPLANT

The unique implant design for high primary stability and esthetic excellence.







Platform	NP	RP	
Length	Ø 3.5	Ø 4.3	Ø 5.0
6.0 mm			RP5006
8.0 mm	NP3508	RP4308	RP5008
10.0 mm	NP3510	RP4310	RP5010
11.5 mm	NP3511	RP4311	RP5011
13.0 mm	NP3513	RP4313	RP5013
16.0 mm	NP3516	RP4316	RP5016

Recommended for: All procedures.

Help to achieve high primary stability when you're dealing with soft bone, extraction sockets, or the esthetic region. Suitable for more demanding situations that require immediate implant place-ment or immediate function.

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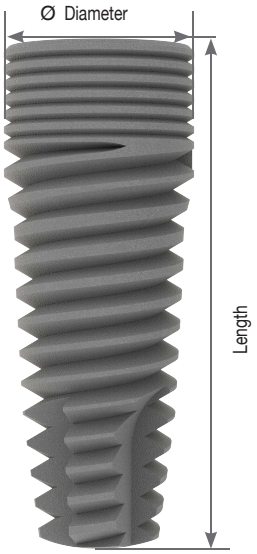
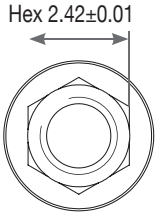
CFI CYLINDRICAL IMPLANT

Ideal bone to implant contact.





Length/Ø	Ø 3.5	Ø 3.75	Ø 4.2	Ø 5.0	Ø 6.0
6.0 mm			C4206	C5006	C6006
8.0 mm	C3508	C3708	C4208	C5008	C6008
10.0 mm	C3510	C3710	C4210	C5010	C6010
11.5 mm	C3511	C3711	C4211	C5011	C6011
13.0 mm	C3513	C3713	C4213	C5013	C6013
16.0 mm	C3516	C3716	C4216	C5016	

Recommended for: All clinical situations and more dense bone types. Not recommended for D-IV bone types.

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SURGICAL STAGE

SURGICAL PROCEDURES FOR GDT IMPLANT PLACEMENT FLAP REFLECTION SURGERY

STEP 1

If traditional flap reflection type surgery is desired, proceed with administering local anesthesia.

STEP 2

For a better visualization, make a full- thickness crestal incision and use a periosteal elevator to expose the alveolar ridge.

When working with the anterior mandible, be aware to the mental foramen and where the inferior alveolar nerve exits. Perform alveoloplasty on the crest of the ridge, if needed, to create a more even plane in which to place the implant. Irrigation should be used for all modifications of the bone. If the flapless technique is used, remove the soft tissue with a circular scalpel or with a tis-sue punch.

STEP 3

Select the appropriate implant diameter and length.

STEP 4 – MARKING DRILL (MAX. 1,200 RPM)

For optimal implant location, always use a marking drill.

With the surgical guide in place, mark the designated drilling spot on the alveolar crest using the surgical guide as a reference for proper positioning.

When using the flapless technique, punch the soft tissue before using the tissue punch.

Drill a hole on the crest with external irrigation, to the depth of 2-3 mm, until it's penetrates the cortical bone.

When placing multiple implants, proceed with the same drill for all the osteotomies before moving to the next drill in the sequence.

NOTE: It is recommended to have 1.5-2 mm of buccal bone width after the implant placement to avoid bone dehiscence.

STEP 5 – 2.0 MM PILOT DRILL (MAX. 1,200 RPM)

Select the 2mm Pilot Drill. With the surgical guide in place, drill directly through the alveolar crest using the surgical guide as a reference for proper positioning.

To continue preparing the osteotomy, use the 2.0mm drill to create a pilot hole of appropriate depth. Determine the bone density with your technical sense.

When using a flapless technique add the soft tissue thickness to the drilling depth.

If placing more than one implant and parallelism is desired, insert the Parallel Pin into the 2 mm osteotomy. Begin drilling the next site and align as the trajectory of the bone permits.

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STEP 6 – DEPTH PROBE

Check the drilling depth using the depth probe DPKOP. The marks represents drilling depths 6, 8, 10, 11.5, 13, 16 mm from the bottom of the depth probe.

STEP 7 – PARALLEL PIN

For drilling direction control, use the guide pins to determine the appropriate alignment with adja-cent teeth, other implants or opposite occlusion.

If applicable, take a radiograph to verify correct direction.

If necessary, correct the direction of the drilling. GDT Pins are dual-ended and can be used after the 2.0 and 2.8mm Initial Drills.

STEP 8 – 2.8 MM TAPERED DRILL (MAX. 1,200 RPM)

Final Drill for narrow Implant – Soft Bone

Select the 2.8mm Drill. If any change is needed in trajectory, it may be corrected at this time. Drill with copious irrigation to the appropriate depth marking on the drill.

Check the orientation of the osteotomy using the 2.8mm end of the Parallel Pin.

STEP 9 – 3.2 MM DRILL (MAX. 1,200 RPM)

Final Drill for 3.75 mm Implant – Soft Bone

Final Drill for 3.5 mm Implant – Dense Bone

Select the 3.2 Drill and proceed to enlarge the site by drilling to the desired depth line (or to the Drill Stop if installed). This is the final drill when placing either a 3.75 mm implant to D3-D4 bone type, or a 3.5 mm implant to D1-D2 type bone .

NOTE: When using Tapered Drills, drill only once to the proper depth and avoid in-and-out tech-nique since this may inadvertently over-prepare the site.

Instead, enlarge the site to the desired depth in one motion.

STEP 10 – 3.7 MM TAPERED DRILL (MAX. 1,200 RPM)

Final Drill for 4.2 mm Implant – Soft Bone

Final Drill for 3.75 mm Implant – Dense Bone

This is the final drill when placing either a 4.2 mm implant to D3-D4 bone type, or a 3.75 mm Im-plant to D1-D2 type bone. In case of a very dense bone situation, you may use the Ø3.65 cylindri-cal hard bone drill for Ø3.8 implant.

STEP 10A – 4.0X2.7 MM TAPERED DRILL (MAX. 1,200 RPM)

Final Drill for 4.2 mm Implant – Dense Bone

Select the Ø4.0 Tapered Drill. When placing either a Ø4.2 mm implant to D1 bone type, consider using countersink 3.8x4.2mm

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STEP 11 – 4.5 MM CYLINDRICAL DRILL (MAX. 1,200 RPM)

Final Drill for 5.0 mm Implant – Soft Bone

Select the Ø4.5 Cylindrical Drill. This is the final drill when placing a 5 mm Implant to D3-D4 bone type.

STEP 11A – 4.8 MM CYLINDRICAL DRILL (MAX. 1,200 RPM)

Final Drill for 5.0 mm Implant – Dense Bone

Select the Ø4.8 Cylindrical Drill. This is the final drill when placing a 5.0 mm Implant to D1 bone type.

STEP 12 – 5.2 MM DRILL (FINAL DRILL FOR 6.0 MM IMPLANT) (MAX. 1,200 RPM)

Final Drill for 6.0 mm Implant – Soft Bone

Use the counter-sink 5.0-6.0 drill when placing a 6.0 mm Implant to D2-D4 bone type. 6.0 implants are not recommended for D1 dense bone.

STEP 13 – IMPLANT DELIVERY

Open the outer vial and place the sterile inner implant vial onto the sterile field.
The implant may now be removed from the vial, delivered to the site and placed using multi-pur-pose carrier mount which are designed to simplify the implantation process.
It enables a simple, manual removal of the implant from the vial, followed by a direct placement of the implant in the osteotomy site.

STEP 14 – IMPLANT INSERTION

Start implant insertion using the carrier mount until you feel resistance and implant stops spin-ning.
Once the Implant has stopped, remove the r mount by pulling it out manually. Continue inserting the implant with the surgical driver using the ratchet or manual handle driver.
Avoid contact between the implant and other oral tissue or saliva.

CAUTION

with any insertion tool used, avoid tightening of the implant with more than 60 Ncm.
Over tightening may compromise the integrity of internal connection and over compress the sur-rounding bone, compromising osseointegration.
It is generally recommended to place the implants using a torque lower than 80 Ncm.

STEP 15 – IMPLANT POSITIONING

If the treatment plan includes using anatomically shaped abutments such as the angled or straight esthetic contour abutments, the rotational position of the implant can be adjusted at the

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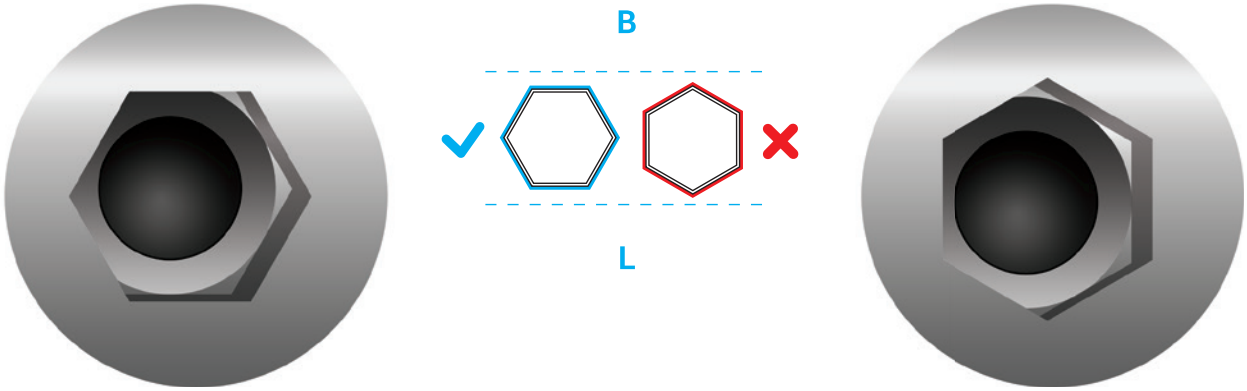
time of placement to ensure optimal positioning of the final abutment.

This will allow the restoring clinician to take full advantage of the anatomical abutment contours and minimize the need for abutment prepping.

If the clinical situation allows, adjust the final position of the implant so that any one of the six internal Hexagon walls faces the buccal or facial aspect.



MOTORIZED IMPLANT PLACEMENT (HAND-PIECE)

Attach the appropriate Motor Mount Implant Driver to the handpiece. Press lightly and rotate the driver until it engages the internal connection of the abutment or the implant. Press firmly to fully engage the connection.

With the GDT Motor Mount Implant Driver attached to the hand-piece. Thread the implant into the osteotomy at approximately 20 rpm until it is snug.

NOTE: In some clinical situations, the clinician may prefer to use the Surgical Ratchet placed to the surgical Implant driver or the Direct Handle Driver to manually tighten the last few rotations and fully seat the implant. This allows for a better tactile feel during seating.

STEP 16 – COVER SCREW INSTALLATION

Following implant placement, use the driver 1.25 to remove the cover screw from the backside of the implant multi-function carrier. Carry the cover screw to the implant and hand tighten.

STEP 16A – HEALING CAP INSTALLATION

When stabilization is adequate and the One Stage Protocol is desired, a transmucosal healing cap should be placed.

Attaching a healing abutment immediately following implant placement eliminates the need for a second stage surgery. Eliminating the second surgical procedure reduces trauma and decreases treatment time, while the two-stage implant design maintains restorative flexibility.

Following implant placement, use the hex driver 1.25 to remove the healing cap from the implant packaging on the underside of the implant vial cap. Carry the healing cap to the implant and hand-tighten.

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STEP 17 – CLOSURE AND SUTURING

Close and suture the tissue flap utilizing the desired technique. Take a radiograph to use as a baseline of the implant-to-bone height for future diagnosis.

STEP 18 – POST-OPERATIVE PROCEDURES

The patient must be instructed to follow a routine post-surgical regime that includes ice or cold packs for 2-4 hours in intervals post-implantation and to consume a soft, high-nutrient diet, if possible. According to individual surgical practice, consideration should also be given to dietary supplements with high protein, high vitamin and high mineral content for up to a month. Anti-ede-ma steroid therapy may be initiated prior to surgery and continued for a period of 24 hours to one week post-surgery.

Antibiotic treatment may be initiated one day pre-op and up to one week post-op as the patient's condition dictates. Sutures should be removed after approximately 10 days or as an individual's soft tissue healing dictates.

If a removable prosthesis is used (only with submerged technique) during this initial healing phase, it is recommended that the underside of the prosthesis be relieved.

This area may be relined with a soft tissue conditioner to prevent pressure on the surgical site.

The patient should be examined periodically using radiographic evaluations to monitor healing of the soft tissues and bone.

IMMEDIATE LOADING

All GDT Implants are designed for immediate loading when good primary stability is achieved (35Ncm and more) and with appropriate occlusal loading. Use 30 Ncm torque to tight the abut-
ment screw.

IMMEDIATE IMPLANT PLACEMENT

Immediate implant placement is defined by the International Congress of Oral Implantologists (ICOI) as the placement of an implant at the time of tooth extraction, into the extraction socket.

GDT Implants can be placed immediately if the following criteria are observed:

- 75 percent of the implant engages freshly prepared bone.
- The implant supports the buccal or labial bone.
- All existing pathology in the socket must be removed and there is no acute infection.
- If infection is present, it must be treated appropriately and the site cleaned and allowed to heal for four to six weeks before the implant is placed.
- Labial plate is intact.
- Crown does not exceed the recommended crown-to-root ratio (1:1).
- Diameter of the implant at the crest of the extraction site should be as wide as possible to pre-vent tissue in-growth.

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Immediate provisionalization, and non-occlusal load immediate provisionalization are defined by the International Congress of Oral Implantologists (ICOI) as a clinical protocol for the placement of an interim prosthesis, with or without occlusal contact with the opposing dentition, at the same clinical visit as implant placement.

GDT Implants can be fitted with a temporary restoration at the time of implant placement if the following criteria are observed:

- Final implant tightening has a torque resistance of 35-45Ncm.
- No occlusal in excursive movements and only light contact in centric occlusion.
- Good bone volume and density (recommended in Types I, II and III).
- Angulation of implant does not exceed 15.

IMMEDIATE REPLACEMENT WITH IMMEDIATE LOADING

The GDT Premium Implants are suitable for Immediate replacement after extraction and immediate loading:

STEP 1

Select the appropriate GDT Implant diameter and length. In this example 3.75x11.5 mm is used.

STEP 2 – TOOTH EXTRACTION

Extract the tooth with conventional technique, trying to maintain integrity of the marginal bone.

STEP 3 – 1.5 MM LANCE DRILL (MAX. 1,200 RPM)

Select the 2.0mm pilot drill. To continue preparing the osteotomy, use the 2.0mm drill to create a pilot hole of appropriate depth. Drill directly through the lingual wall of the socket 3 mm above the apical region. Determine the bone density with your technical sense.

When using a flapless technique add the soft tissue thickness to the drilling depth.

If placing more than one implant and parallelism is desired, insert the Parallel Pin into the 2.0mm osteotomy. Begin drilling the next site and align as the trajectory of the bone permits.

STEP 4

Use sequential drills for desired diameter:

- 3.2 mm drill for 3.75 mm implant (blue).
- 3.7 mm drill for 4.2 mm implant (green).

Place the implant 2 mm below the crestal bone level.

If the remaining gap is more than 2 mm, the use of bone substitutes should be taken into consid-eration.

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STEP 5 – TEMPORIZATION AND PREPARING THE ABUTMENT

If the abutment requires modification, the soft tissue surgical site should be protected.

Place a rubber dam over the abutment using a lower anterior-sized rubber dam clamp.

Grind the abutment following the same requirements as conventional crown and bridge dentistry.

CAUTION

When preparing the abutment, use ample amounts of irrigation and short contacts to avoid heat transfer to the bone through the implant.

PROSTHETIC STAGE

RESTORATIVE PROCEDURES

SOFT TISSUE HEALING AND TEMPORIZATION PROCEDURES

Titanium Healing Abutment

A titanium healing abutment can be placed at the time of implant placement (single-stage sur-gery) to help contour soft tissues during the healing phase.

Healing abutments are available in a variety of sizes and diameters and are placed using the standard hex driver 1.25.

Immediate Temporization

If the immediate provisionalization criteria have been met, temporization of the implant may be performed using the GDT PEEK temporary abutments.
The temporary abutment made out of PEEK (polyetheretherketone) allows the clinician to create a progressive loading of the implant.

REMOVING THE ABUTMENT FROM THE IMPLANT IN SOFT BONE

To avoid unscrewing movements of the implant during the removal of the abutment immediately after implantation in a soft bone, hold the abutment with needle holder and open the screw with driver 1.25 mm threw the holding key.

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TABLE OF SCREW SETTING TORQUE (N-CM) AND RECOMMENDED DRILL SPEED

Prosthesis	Torque (N-cm)
Healing Cap	15
Abutments	25
Multi-Unit Abutments	30-35
Loc-In Abutments	30-35
Ball Abutments	30-35
Multi-Unit Screw	20-25

	Lance Drill	Marking / Pilot drill	Cylindrical Drill							
Ø	**1.2/1.5**	**1.9**	**2.0**	**2.5**	**2.8**	**3.2**	**3.65**	**4.0**	**4.5**	**5.2**
Code	LD120 / LD150	PD190	PD200	TD250	TD280	TD320	TD365	TD400	TD450	TD520
Speed RPM	1200-1500		900-1200	800-1000	500-700	400-700	400-600	400-600	300-500	200-400

	Lance Drill	Marking / Pilot drill	Tapered Drill							
Ø	**1.2/1.5**	**1.9**	**2.2 / 1.6**	**2.4 / 1.8**	**2.7 / 1.6**	**3.2 / 2.0**	**3.7 / 2.5**	**4.0 / 2.7**	**4.5 / 2.7**	**5.5 / 3.1**
Code	LD120 / LD150	PD190	TDC220	TDC240	TDC270	TDC320	TDC370	TDC400	TDC450	TDC550
Speed RPM	1200-1500		900-1100	700-900	500-700	400-600	400-600	300-500	300-500	200-400