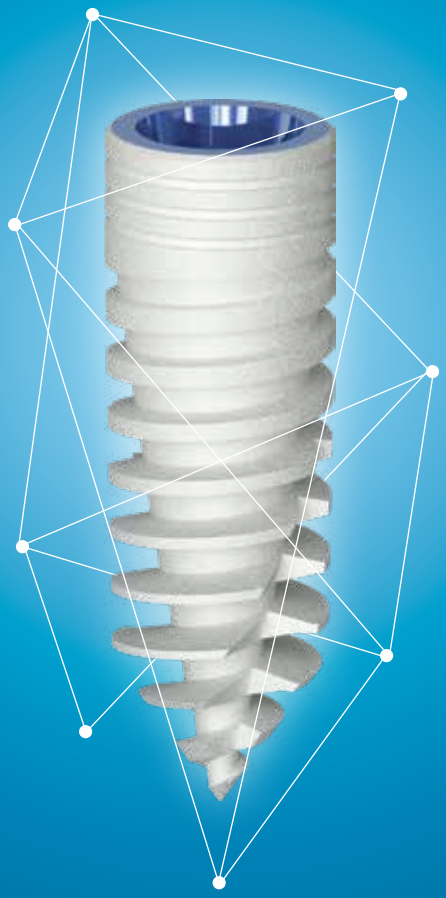


CORTEX™

The Future of Dental Implants

Surgical Manual

For Magix Dental Implant

INTRODUCTION

General Information

Read this manual carefully before starting treatment. This manual should be used as a reference guide for clinicians and dental technicians to optimize the use of Cortex implants, surgical instruments and prosthetic components.
The procedures and guidelines presented in this Manual are not intended to be a substitute for formal implant surgical or restorative training for the clinician and the dental laboratory technician. It is the responsibility of the clinician and the dental laboratory technician to determine the final protocol and component selection.

Important Warning

Lack of adequate practitioner training is a major risk factor for the success of the implant procedure and might endanger patient health. Therefore, no implantation should be performed without prior adequate training by a certified institute.

SURGICAL PROTOCOL

Indication for Use

Cortex 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.

Contraindications

The contraindications customary in oral surgery with other implant materials should be observed. These include patients on corticosteroids, anticoagulants or anticonvulsant and those receiving radiation or other immunosuppressive therapy. Lactating or pregnant women are not candidates, nor are patients with abnormal laboratory values for BUN, creatinine or serum calcium. Patients with diabetes or cardiovascular disease are contraindicated. Hypertension above 110/170 mmHg, osteoporotic crush fractures, respiratory disease, thyroid or parathyroid disease should be excluded from treatment. Patients with diagnosed malignancy in the past five years and those with nodular enlargements, tenderness or unexplained lumps or masses of the head or neck should not be treated.
Implanting procedures should not be performed on persons with active osteolitic, inflammatory or infectious processes in the implantation site.

Pregnancy, Hemophilia, Granulocytopenia or other bleeding problems, Osteoradionecrosis Patients receiving Biphosphonate treatment are in danger of bisphosphonate related osteonecrosis of the jaw (BRONG). Poor patient motivation. Psychiatric disorders that interfere with patient understanding and compliance with the necessary procedure. Unrealistic patient expectations Unattainable prosthodontic reconstruction. Inability of patient to manage oral hygiene.
Patient hypersensitivity to specific component of the procedure.

Possible Contraindications

Chronic bleeding problems, psychological impairment, treatment with chemotherapeutic agents, metabolic bone or connective tissue diseases, treatment with corticosteroids, certain cardiac and vascular diseases, diabetes (uncontrolled), tobacco usage, chronic renal disease, poor patient oral hygiene, bruxism, alcoholism.

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

DATA COLLECTION

Examination and Treatment Planning

Patient Evaluation And Selection

- Before any treatment, the patient must be informed about expected outcomes of preoperative examination and get an explanation about the treatment, including the expected results of the risks.
- Patients should sign informed consent to indicate their acceptance of treatment.
- Patient status information should be registered, such as 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 signals 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 selected, 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 radiographic 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 between the implant restoration and the adjacent natural dentition should be considered. Data collection should include dental history, restorative status and occlusion. CT scan is recommended in most cases. Radiographic examination should provide information about anatomy, pathology, quality and quantity of bone.
Due to the special abilities of Cortex implants, the implant primary stability can be achieved in very small bone volume and bone augmentation can be carried 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 therefore less bone preparation and fewer drills should be used in order to achieve high enough initial stabilization. **Primary stability is achieved by the special design of the Cortex implants.**

DATA COLLECTION

3. Vertical Bone Quantity

Dental implants needs to be stabilized in a good quality bone for successful result. 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 cortex 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 take advantage of the narrow Smart One Piece implants in order
to avoid 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 clinician's should be familiar with the cortex 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.

IMPLANT SELECTION

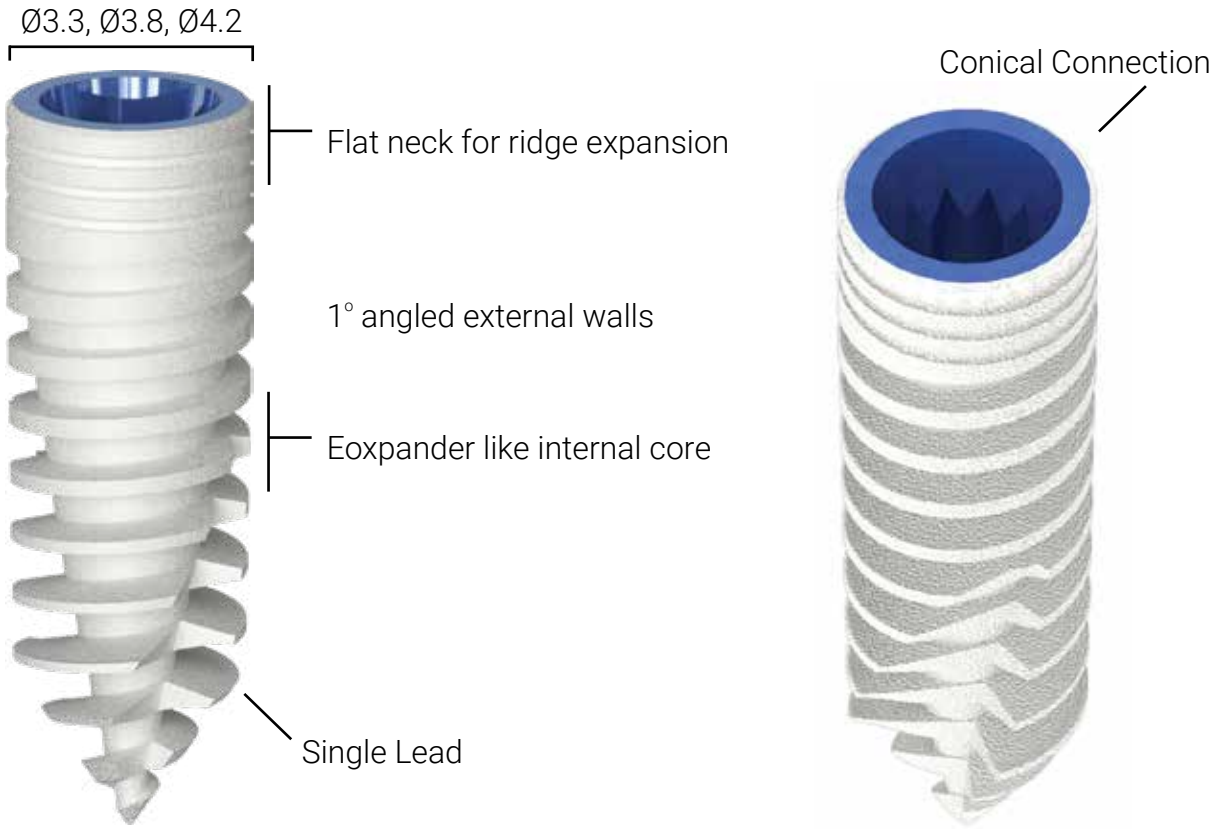
Implant is chosen according to the measurements of the ridge width and vertical length on the CT Scan. A safety zone of at least 2 mm from anatomical structures such as the mandibular canal should be maintained.
Correct treatment planning methodology will provide maximum biomechanical stability, allowing better emergence prifile 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

Magix Implant - Ideal implant for Drill-Less approach

- The Magix Implant design consists of threaded,(Single lead) tapered implant with a conical connection. The implants support screw-retained, cement-retained, and over denture restorations.
- The combination of design features, enables easy and fast insertion and very high primary stability.
- The Magix Implant is self drilling, self tapping and self condensing, with outstanding advantages in medium and soft bones.
- Therefore it is exceptional solution for drill less approach or bone preservation and condensation.

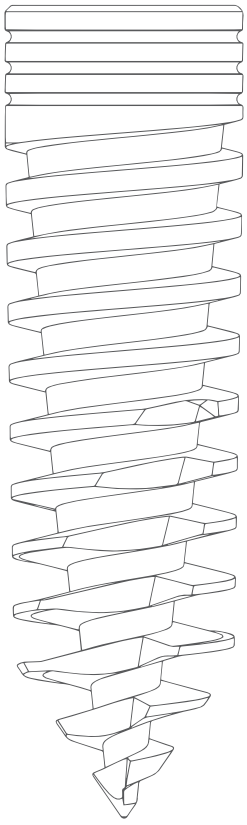


Conical Connection

- Conical Connection 12 (Compatible with Astra Tech)
- Perfect sealing in Implant abutment interface
- No micro gap
- Superior bio-mechanical strength

Advantages of drilless approach

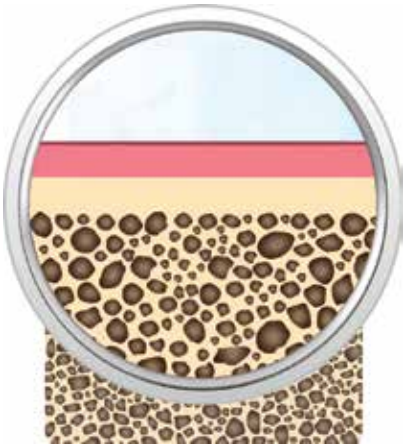
- Less risk of bone perforation or fenestration
- Bone preservation
- Bone condensation and quality improvement
- High primary stability
- More attractive approach for novice clinicians



Surgical Procedures for Cortex Implant Placement Flap Reflection Surgery

Step 1

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

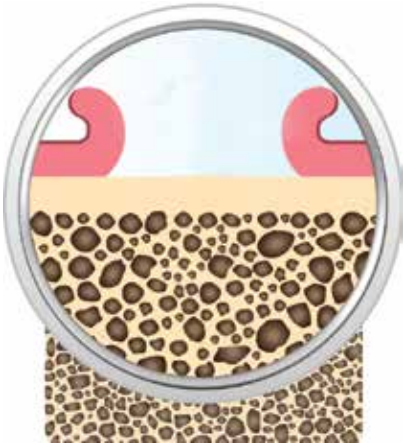


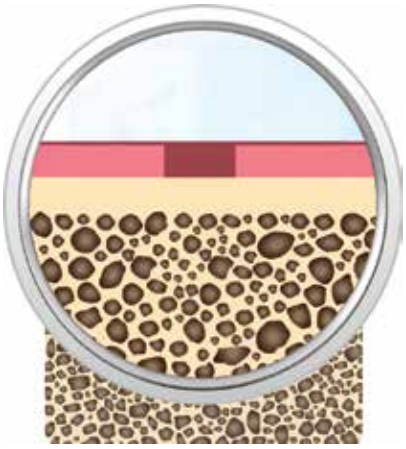
Step 2

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, locate 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 tissue punch.



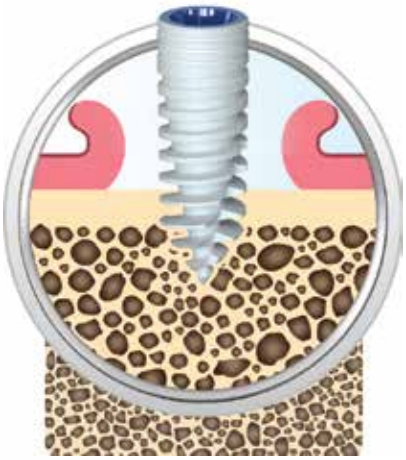


Step 3

Select the appropriate implant diameter and length.
For this example, a 11.5 mm implant is used.

Step 4

Insert Magix implant using hand piece with 30 rpm and a maximum torque of 80 Ncm or manually' using a hand driver.



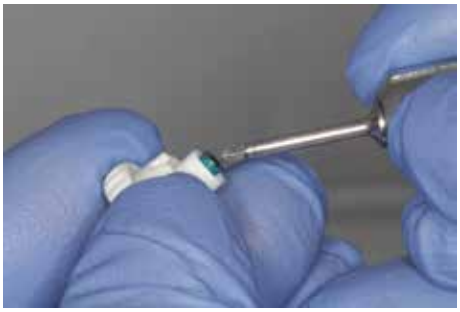
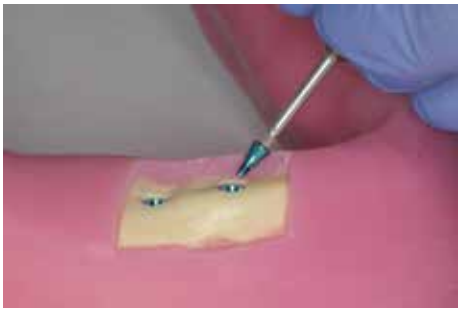
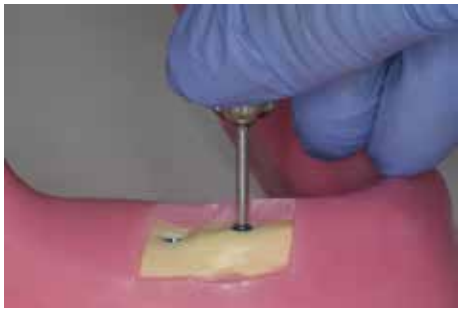
MCT-R215

CT-0510C

SURGICAL STAGE

Cover Screw Installation

Following implant placement, use the Hex Driver 1.25 to remove the Cover Screw from the implant packaging on the underside of the implant vial cap. Carry the Cover Screw to the implant and hand-tighten.

Closure and Suturing

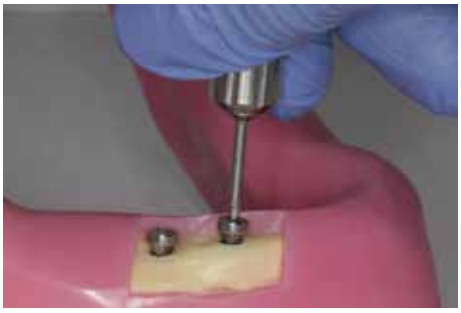
Close and suture the tissue flap utilizing the desired technique.
Take a radiograph to use as a baseline of the implant-to-bone height for future diagnosis.

Post-operative Procedures
The patient must be instructed to follow a routine post-surgical regimen that includes ice or cold packs for 24 hours 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 as well. Anti-edema 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 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.

SURGICAL STAGE

Healing cap installation

When stabilization is adequate and the One Stage Protocol is desired, a trans mucosal Healing Cap should be placed.
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.



Immediate Loading

The Cortex Implants are indicated for immediate loading when good primary stability is achieved (35Ncm and more) and with appropriate occlusal loading.
Use 30 Ncm to tight the abutment screw.

Immediate Implant Placement

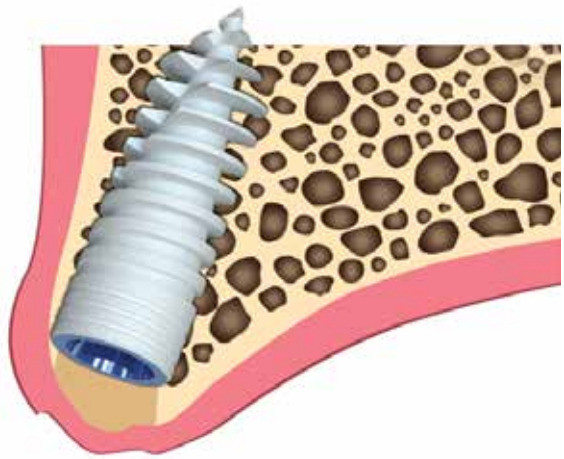
Immediate implant placement is defined by the International Congress of Oral Implantologists (ICOI) as the placement of an implant at the time of tooth extraction,
into the extraction socket.

Magix Implant can be placed immediately if the following criteria are observed:

- Seventy-five (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 prevent tissue in-growth.

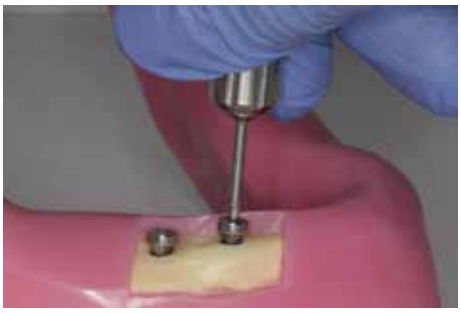
  Immediate Provisionalization, Non-occlusal Load Immediate provisionalization is defined by the International Congress of OralImplantologists (ICOI) as a clinical protocol for the placement of an interim prosthesis, with or without occlusal contact with the opposing dentition, at the same clinical visit as implant placement.

  Magix 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 contacts 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°.



Soft Tissue Healing and Temporization Procedures

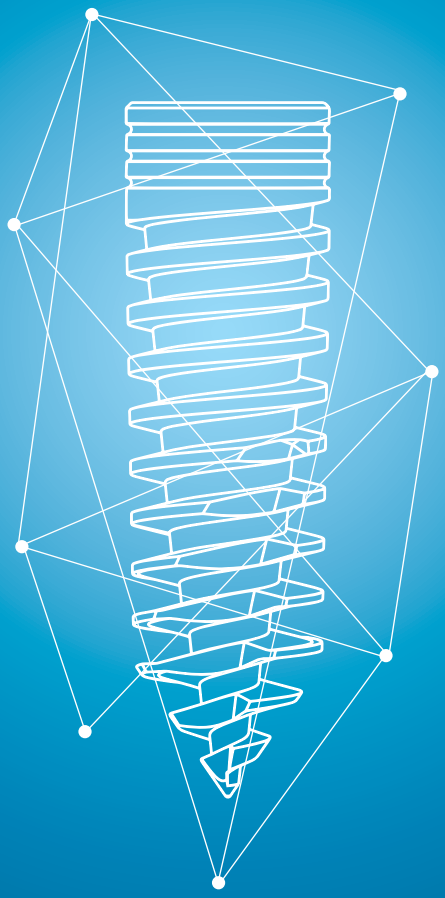
Following the placement of a Magix Implant, soft tissues can be contoured using a titanium Healing Cap or a custom fabricated temporary abutment.
Titanium Healing Abutment
A titanium Healing Abutment can be placed
at the time of implant placement (single stage surgery) to help contour soft tissues during the healing phase.
Healing Abutments are available in a variety of sizes and are placed using the Hex Driver 1.25.



Immediate Temporization

If the Immediate Provisionalization criteria were been met, temporization of the implant may be performed using Cortex PEEK Temporary Abutment, Multi Unit Abutments or Titanium Abutments . The Temporary Abutment manufactured out of PEEK (polyetheretherketone) and it's allowing the clinician to create a progressive loading of the Implant.

MAGİX



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