Surgical Manual
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Cortex Dental Implants Industries Ltd. is a developer, manufacturer and marketer of innovative, high-quality and affordable dental implants, prosthetic products and surgical kits.

The company was established in 2008 by a group of expert clinicians, maxillofacial surgeons and opinion leaders in the field of dental implantology, who have joined forces with leading business and marketing professionals to answer the market need for practical, innovative solutions for dental rehabilitation and restoration.

Cortex takes pride in being a dynamic, fast-moving company whose mission is to provide the world with top-quality, innovative products that will change people's lives.

Cortex's Vision

- To be innovative and bring patent-protected solutions.
- To achieve the greatest possible precision in fitting the components it produces.
- To produce the cleanest possible surfaces, with the best possible morphology for osseointegration.
- To provide dental professionals with easy-to-use kits which include all the components they may require for a procedure, using any chosen strategy, while meeting the strictest sterilization standards.
- To bring great value-for-money to our customers and their patients.
- To simplify patients' surgical and recovery process as much as possible.

Cortex puts great effort into sharing knowledge and experience with clinicians worldwide and invests in establishing training frameworks to reinforce the confidence of clinicians.

Cortex Implants Standards

The Cortex manufacturing plant operates in conformity with ISO QMS standards, 9001/2008 and EN ISO 13485:2012 (medical). Cortex has passed inspection of the European Notified Body (CE 0473) for approval of the design, manufacture and quality assurance systems of Cortex implants, prosthetic components and surgical tools. Cortex products are also cleared for marketing in the USA. We are currently in the process of completing registration and regulatory procedures in a large number of additional countries.
General Information

Read this manual carefully before starting treatment. The manual is intended as a reference guide to optimize the use of Cortex 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 major health risk to patients and can lead to the failure of implant procedures.

Icon Key

Internal hex and conical connections are indicated by icons

A bold icon indicates the connection shown

When both icons are in bold, both systems can be used
Cortex dental implants are made with biocompatible titanium alloy and consist of threaded, tapered and straight designs featuring a proprietary internal hex or conical connection which provide superior strength, stability and esthetics.

Conical Connection Platform is the unique interface between the fixture and the abutment. It gives it superior bending strength and elasticity and eliminates the micro-movements and micro-leakage between the two. The conical interface allows simple self-guiding seating of the abutment without the the necessity of using an extra intraoral.

The system can solve all clinical indications with a manageable range of implant components and instruments.

All Cortex implants feature the roughened surface, which extends up to the bevel of the implant where the medialized prosthetic connection begins, creating a continuous bone-to-implant surface to the apex.

For specific product description and net quantity please refer to individual product labels. Although final placement of a Cortex 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 Cortex implants available allows clinicians to weigh the advantages of each implant type, and to select the best suited based of the individual case.

Cortex implants are recommended for placement at the crest of the ridge or slightly below.
Surgical Strategies

Allows the implantologists to adopt any implant strategy during the implant procedure:

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

Cost Effective Package: 6 Elements in One

- Cover screw
- Plastic healing cap
- Titanium healing cap
- Transfer
- Abutment
- Implant

Prime Implant Set Package

- Dental Implant
- Surgical cover screw
**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**

Contraindications customary in oral surgery should be observed.

Patients with the following conditions should not be considered for implant procedures:

- Patients taking corticosteroids, anticoagulants or anticonvulsant treatment and those receiving radiation or other immunosuppressive therapy.
- Lactating or pregnant women and patients with abnormal laboratory values for BUN, creatinine or serum.
- Patients with diabetes or cardiovascular disease.
- Hypertension above 110/170 mmHg, osteoporotic crush fractures, respiratory disease, thyroid or parathyroid disease.
- 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.
- Patients with active osteolitic, inflammatory or infectious processes in the implantation site.
- Patients suffering from hemophilia, granulocytopenia or other bleeding problem.
- Osteoradionecrosis patients receiving biphosphonate treatment are in danger of bisphosphonate related osteonecrosis of the jaw (BRONG).
- Unattainable prosthodontics reconstruction.
- Psychiatric disorders that interfere with patient understanding and compliance with the necessary procedure.
- Poor patient motivation.
- Unrealistic patient expectations.
- Inability of patient to manage oral hygiene.
- Patient with 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.
**Surgical Protocol**

**Warnings**

The implant placement procedure should be done under aseptic conditions with specifically designed sterile surgical instruments. A surgical drill system with internal or external irrigation is recommended for drilling the surgical site. The specific drilling sequences for placement of implants should be followed. The use of surgical guides, a depth probe, and parallel pins are recommended to aid in implant placement and positioning. Improper techniques can cause implant failure and loss of bone. No attempt should be made to alter or modify the implant body. The use of electrosurgical or laser instruments around metallic implants and abutments is due to the electric and/or heat conductivity of the substrate metal. Abutments are for single use only. A previously used abutment should not be sterilized and recommended reused. Reduction of the abutment intra-orally may transmit heat to the implant body and surrounding bone. 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 mount-driver interface to the implant, or stripping the walls of the osteotomy that may prevent an effective initial implant fixation. Mishandling of small components inside the patient’s 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, homecare and implant maintenance. The patient’s expectations of the final result should be clearly defined.

**Sterilization**

All Cortex 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 can not be used on another patient. The implant can not 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 sterilized 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 contamination or failure of equipment.

Surgical drills eventually become dull with use and require replacement.
Adverse Reactions

Complications that can occur include: infection, bone loss, patient discomfort, implant mobility, local soft-tissue degeneration, and unfavorable implant placement or alignment. Treatment for these reactions should follow standard dental procedures as would be indicated and applied for natural dentition. These include pain medications, antibiotics, removal from function, removal of mobile implants, and soft tissue/bone debridement and augmentation.

Implant mobility, bone loss, or chronic infection may indicate implant failure.

Any implant that appears to be failing should be treated as soon as possible. If removal of the implant is necessary, soft tissue can be curetted from the implant site and then allowed to heal in the same manner as traumatic tooth extractions.

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 positioning, 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 suide lines practitioners in the use of Cortex 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.
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 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 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 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 Cortex implants.
3. Vertical Bone Quantity

Dental implants need 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 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.

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.
Cortex Instrumentation

All Cortex surgical instruments are provided non-sterile. Always remove the instruments from the packaging prior to sterilization. Inspect the surgical instrumentation to ensure sterility and functionality.

For example, drills will become dull after many uses. Always have a backup drill sterile and available. Cortex recommends drill replacement after 20 osteotomies depending on bone density.

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. All preparation of bone tissue must be carried out under ample irrigation with saline solution and using an intermittent drilling technique.

Cortex Tapered Drills

All Cortex Tapered Drills are color-coded and externally irrigated. They are designed to achieve maximum cutting efficiency while effectively removing bone from the osteotomy during drilling. Cortex Tapered Drills are used for placement of Dynamix, Classix and Saturn implants.

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 (Enzol) for five 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 instructed 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.

**Drilling Sequence: Dense Bone - Type D1, D2**

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

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

Due to the Dynamix 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 allowing 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 accessories 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 necessary, 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.
Cortex Surgical Kits

The Cortex Surgical Kit holds all the instrumentation needed to place all diameters and lengths of implants.

Tools and drills can be purchased separately, depending on the clinician’s preference.

Drill Stoppers Kits

The stoppers kit provides a neat storage solution and allows the sterilization of stoppers. It provides an easy clip 2 mm and 2.8 mm drills without manipulation of the stoppers.

Safety slide cover is designed to ensure the exact location of stoppers, to prevent errors in assembly.
INSTRUMENTATION

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 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 “Sterilization Table”

CAUTION

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

Sterilization Table

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Exposure/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>121 - 124°C</td>
<td>30 minute exposure/30 minute dry time</td>
</tr>
<tr>
<td>132 - 135°C</td>
<td>20 minute exposure/30 minute dry time</td>
</tr>
</tbody>
</table>

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 manufacturer’s 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 surgeon 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.).
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
CLASSÍX

Ideal Implant for Dense Bone

- The Classix Implant design consists of threaded, (double thread 2x1.6 mm, 4 threads at the cervical area) slightly tapered implant with an internal hexagonal connection. The implants support screw-retained, cement-retained, and over denture restorations.
- The combination of design features, enables easy and confident insertion, very high primary stability and bone to implant contact surface.
- The Classix Implant is designed to provide a confident solution for all situations, bone types and surgical protocols. The 3 milling cutting edges, makes it easy to insertion to a dense bone.
- It is an exceptional solution for single tooth to a full mouth rehabilitation. Recommended for all clinical situations and all bone types.

SATURN

Ideal Implant for Immediate Replacement with immediate loading.

The best solution for D5 bone type
Saturn Implant Design

The ultimate implant for post-extraction Immediate loading Saturn Implant Design.
- The Saturn implant design consists of threaded, (double thread 2x2.2 mm) tapered implant with an internal hexagonal connection with a circumferential wing bellow the cortical bone.
- 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 immediately after extractions and immediate loading, better stability in sinus augmentation, angled placement in tuberosity.
- The Saturn Implant is self tapping, self drilling and self condensing, with outstanding advantages in bone types DIII, DIV, DV.
- It is therefore an exceptional solution for immediate replacement and immediate loading with a better load distribution and less stress in cervical area.

Saturn reduces displacement and stress distribution at the neck of the implant which may prevent bone loss after loading.

Finite element analysis demonstrates that the added wings considerably reduce stress distribution at the implant neck, thus reducing potential for bone loss at the crest.
**IMPLANT SELECTION**

**DYNAMIX**

*Ideal Implant for Soft Bone and immediate loading*

- The Dynamix Implant design consists of threaded (double thread 2x2.2 mm, 4 threads at the cervical area) tapered implant with an internal hexagonal 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 Dynamix Implant is self tapping, self drilling and self condensing, with outstanding advantages in all bone types, especially in soft bones.
- Therefore it is exceptional solution for immediate replacement and immediate loading.

**SMART 1PIECE**

*Ideal Implant for narrow ridges and narrow spaces*

**Smart One Piece Implant Design**

The Smart One Piece Implant design consists of a threaded, tapered implant and an integrated, abutment, which is placed in a single-stage procedure.

The Smart One Piece 3.0 and 3.3 mm narrow implant is indicated for use in the treatment of missing maxillary lateral incisors or mandibular central and lateral incisors.
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, 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 tissue punch.

Step 3
Select the appropriate implant diameter and length. For this example, a 11.5 mm implant is used.
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.

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

Check the drilling depth using the depth probe CT-0710. The marks represents drilling depths 6, 8, 10, 11.5, 13, 16 mm from the bottom of the depth probe.
**SURGICAL STAGE**

**Step 7 - Parallel Pin**

For drilling direction control, use the guide pins CT-0410 or CT-0413, to determine the appropriate alignment with adjacent teeth, other implants or opposite occlusion.

If applicable, take a radiograph to verify correct direction.

If necessary, correct the direction of the drilling. Cortex Parallel Pins are dual-ended and can be used after the 2 and 2.8mm Initial Drills.

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**Smart 1 piece Implant Installation**

![Smart 1 piece Implant Installation Diagram]

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**Step 8 – 2.8 mm Tapered Drill (max. 1,200 rpm)**

**Final Drill for 3.3 mm 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.
### SURGICAL STAGE

<table>
<thead>
<tr>
<th>Step 9 - 3.2 mm Tapered Drill (max. 1,200 rpm)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Final Drill for 3.8 mm Implant – Soft Bone</strong></td>
</tr>
<tr>
<td><strong>Final Drill for 3.3 mm Implant – Dense Bone</strong></td>
</tr>
</tbody>
</table>

Select the 3.2 Tapered 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 3.8 mm implant to D3-D4 bone type, or a 3.3 mm implant to D1-D2 type bone.

**NOTE:** When using Tapered Drills, drill only once to the proper depth and avoid in-and-out technique since this may inadvertently over-prepare the site. Instead, enlarge the site to the desired depth in one motion.

<table>
<thead>
<tr>
<th>Step 10 – 3.7 mm Tapered Drill (max. 1,200 rpm)</th>
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</thead>
<tbody>
<tr>
<td><strong>Final Drill for 4.2 mm Implant – Soft Bone</strong></td>
</tr>
<tr>
<td><strong>Final Drill for 3.8 mm Implant – Dense Bone</strong></td>
</tr>
</tbody>
</table>

Select the 3.7 Tapered Drill. This is the final drill when placing either a 4.2 mm implant to D3-D4 bone type, or a 3.8 mm implant to D1-D2 type bone.

<table>
<thead>
<tr>
<th>Step 10A – 4.0 mm Tapered Drill (max. 1,200 rpm)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Final Drill for 4.2 mm Implant – Soft Bone</strong></td>
</tr>
</tbody>
</table>

Select the 4.0 Tapered Drill. This is the final drill when placing either a 4.2 mm implant to D1-D2 bone type.
Step 11 – 4.3 mm Tapered Drill (max. 1,200 rpm)

**Final Drill for 5.0 mm Implant - Soft Bone**

Select the 4.3 Tapered Drill. This is the final drill when placing a 5 mm Implant to D3-D4 bone type.

Step 11A - 4.8 mm Tapered Drill (max. 1,200 rpm)

**Final Drill for 5.0 mm Implant - Dense Bone**

Select the 4.8 Tapered Drill. This is the final drill when placing a 5 mm Implant to D1-D2 bone type.

Step 12 – 5.4 mm Tapered Drill (Final Drill for 6 mm Implant) (max. 1,200 rpm)

**Final Drill for 6 mm Implant – Soft Bone**

Select the 5.4 Tapered Drill. This is the final drill when placing a 6 mm Implant to D2-D4 bone type. **Not recommended for dense bone.**
**SURGICAL STAGE**

**Step 13 - Choose Implant Package**

All Cortex implants are delivered in sterile double tube packaging. Choose the suitable package according to the surgical strategy you want to take.

*For two stages submerged surgery - Prime Package is recommended*
*For one stage or immediate loading - Premium Package is recommended.*

**PRIME**
- Implant
- Cover screw

**PREMIUM**
- Cover screw
- Plastic healing cap
- Titanium Healing cap
- Transfer
- Abutment
- Implant

**Step 14 – Implant delivery (Premium Package)**

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 the unique, patent pending multi purpose transfer 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 15 – Implant Insertion**

Pull the implant out manually of the via manually and start implant insertion using the multi purpose plastic transfer mount until you feel resistance and implant stops.

Once the Implant has stopped, remove the transfer mount by simply pulling it out manually.

Continue inserting the implant with the surgical driver 2.42 with the ratchet or 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 50 Ncm. Over 50Ncm, remove the abutment and continue insertion directly with the Implant.

Over tightening may compromise the integrity of the abutment, internal connection and over compress the surrounding bone, compromising osseointegration. It is recommended to place the implants using a torque lower than 60 Ncm.

**Step 15a - Implant insertion Non-Touch Delivery System**

Open the outer vial and place the sterile inner implant vial onto the sterile field.

Open the inner vial and pick up the Implant from the titanium sleeve using the 2.42 mm driver or motor mount.

The conical connection requires the use of a dedicated drivers and motor mounts that match the platform size configuration. The item numbers can be identified on the side of the driver tip. Carry the implant to the osteotomy facing upward to prevent accidental dislodging.

**FOR SMART ONE PIECE:**

Pull out the implant manually of the vial and insert the implant to the osteotomy using the driver CM-0041.

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 the abutment, internal connection and over compress the surrounding bone, compromising osseointegration.

Step 16 - 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 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 connection lobes faces the buccal or facial aspect.
The Cortex Implant Motor Mount Driver attaches directly to the abutment portion or the implant.

Attach the appropriate Motor Mount Implant Driver to the hand-piece. 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 Cortex Motor Mount Implant Driver attached to the hand-piece, thread the implant into the osteotomy at approximately 20 rpm until it is snug.

The conical connection requires the use of a dedicated drivers and motor mounts that match the platform size configuration. The item numbers can be identified on the side of the driver tip.

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.

Following implant placement, use the 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.

When stabilization is adequate and the One Stage Protocol is desired, a trans-mucosal 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.
When using a Premium Package, you may leave the abutment at place. A plastic healing cap from the implant packaging on the underside of the implant vial cap, may be used to cover the abutment in the short term while the healing process takes place. Place the healing cap using a minimal amount of temporary cement. Care must be taken to avoid contaminating the surgical site with cement.

**Step 18 - 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 19 - 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-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 (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**

The Cortex Implants are designed for immediate loading when good primary stability is achieved (35Ncm and more) and with appropriate occlusal loading.

Use 30Ncm 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.

Cortex 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 prevent tissue in-growth.

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.

Cortex 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 Cortex Saturn Implants are indicated for Immediate replacement after extraction and immediate loading.

Saturn’s “wings” provide substantial initial stability, reducing stress distribution at the alveolar cortex and optimize esthetic restoration.

Saturn, with its wings, enhances considerably bone to Implant contact, mechanical torsional support and overall stability.
**Step 1**

Select the appropriate Cortex Saturn Implant diameter and length. In this example 11.5 mm is used.

![Cortex Saturn Implant](image)

**Step 2 - Tooth Extraction**

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

![Tooth Extraction](image)

**Step 3 – 2 mm Pilot Drill (max. 1,200 rpm)**

Select the 2mm 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 mm osteotomy. Begin drilling the next site and align as the trajectory of the bone permits.

![Pilot Drill](image)
**SURGICAL STAGE**

**Step 4**
Use sequential drills for desired diameter:
- 3.2 mm drill for 3.8 mm implant (red)
- 3.7 mm drill for 4.2 mm implant (blue)
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 consideration.

**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.
Restorative Procedures

Temporary/Healing Caps

Sterile temporary healing caps are available for all Cortex Premium Package implants and are manufactured out of Acetal. Temporary healing caps can be used either as a foundation for a temporary crown or as a healing cap.

NOTE: Temporary healing caps may not be re-sterilized.

NOTE: The temporary healing cap has a dual function. When used as a substructure for a temporary crown, it is referred to as a “temporary cap” and when used by itself, it is referred to as a “healing cap”.

Healing Cap

If a temporary restoration is not being fabricated, a healing cap may be used to cover the abutment portion of the implant in the short term while the healing process takes place.

Place the healing cap using a minimal amount of temporary cement. Care must be taken to avoid contaminating the surgical site with cement.

Soft Tissue Healing and Temporization Procedures

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 diameters and are placed using the hex driver 1.25.

Immediate Temporization

If the immediate provisionalization criteria have been met, temporization of the implant may be performed using the Cortex PEEK temporary abutment.

The temporary abutment made out of PEEK (polyetheretherketone) allows the clinician to create a progressive loading of the implant.
PROSTHETIC STAGE

Immediate Impressions

Lab work

Lab work

Final restoration is installed
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, use holding key CT-0242 to hold the abutment CO-8036 and open the screw with driver 1.25 mm through the holding key.

In case there is no holding key CT-0242, hold the abutment with needle holder.

Removing the Abutment from the Implant if it stuck

If excessive insertion torque was applied on the abutment CO-8036 during the installation of the implant with premium package, the abutment might be stuck.

In this case remove the abutment screw and apply a gentle counter clockwise movement.

If it is still stuck, insert the abutment extractor key CT-0262 by screwing it into the implant until it pulls out the abutment.
DRILLING SEQUENCE

**DYNAMIX / CLASSIX**

The drilling protocol is adapted to the fixture diameter and the local bone quality. In general the mandible and the symphosis area in particular, require additional steps. See table below.

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**4.3mm Drill**

- 4.3mm Drill
- 4.8mm Drill

**5.4mm Drill**
Surgical Manual