J DENTAL CARE

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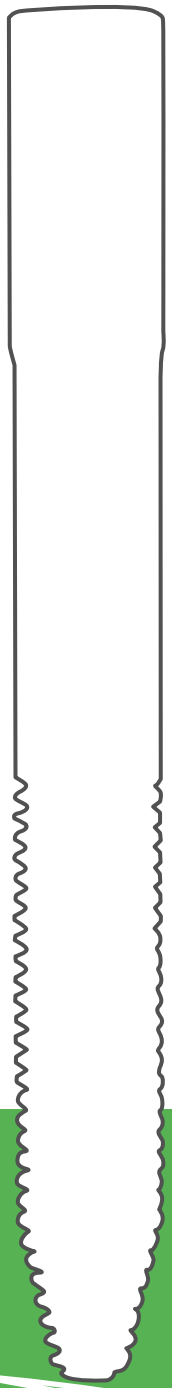


Dental Implant

JD ZYGOMA

JDZygoma surgical procedure

JD ZYGOMA

INDICATIONS FOR USE

JDZygoma dental implant is a JDentalCare implant system.

JDZygoma Dental implant System is intended to be implanted in the upper jaw arch to provide support for fixed or removable prosthetic devices in patients with partially or fully edentulous maxilla, in order to restore patient esthetics and chewing function.

The JDZygoma Implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

PRE-OPERATIVE EXAMINATION OF THE PATIENT

A thorough pre-treatment evaluation of edentulous patients or patients with failing/terminal dentitions is necessary to establish a predictable treatment outcome. The user of JDZygoma products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. To begin the evaluation of this group of patients, the following may be taken into consideration.

1. **Medical history and chief complaint**
   Any conditions that might affect the result or influence candidacy for surgery are noted here. Consideration for referral for medical clearance as indicated.

2. **Dental history**
   Ascertain the patient's expectations, past dental history with dental failure, e.g. periodontal disease, admitted or known habits including clenching and bruxing.

3. **Radiographic analysis**
   Initial radiographic evaluation may be done with the help of a panoramic radiograph (OPG). Upon the discretion of the practitioner, a full mouth periapical series (FMX/FMS) may be considered. It is recommended to perform a medical (CB)CT scan analysis prior to the final decision.

4. **Intra- and extraoral examination**
   For patients with existing non-restorable teeth, documentation of the findings for their removal is noted. A screening exam for intraoral soft tissue health is paramount. Evaluation of the temporomandibular joint (TMJ) is also recommended. Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process.

5. **Pre-surgical evaluation of maxillary sinus health**
   3D radiographic survey allows for the identification of the following in the maxillary sinus:
   - Maxillary sinus polyps
   - Thickness of the Schneiderian membrane
   - Potential air-fluid level
   - Patency of the osteomeatal complex
   - A healthy maxillary sinus is essential for the placement of zygoma implants.
   - Any pathology of the maxillary sinus must be considered a contraindication of the zygoma implant placement.

Precautions

Improper technique can lead to implant failure, loss of supporting bone, inadequate primary stability or other adverse effects, such as sinusitis, oral antral fistula or loss of implant's osseointegration. Thorough screening of implants candidates should be performed including examination to detect any maxillary sinus pathology, an evaluation of patient's capacity to maintain proper oral hygiene, patient's motivation, and the presence of parafunctional habits. Visual inspection as well as periapical radiographs is essential to determine anatomical landmarks, occlusal conditions, periodontal status and adequacy of bone. It is strongly suggested that a CAT Dental Cone Beam 3D be used for a dental scan to provide a more detailed evaluation of dimensions and quality of bone.

General

JDZygoma implants are placed following the extramaxillary protocol. This is a modification of the traditional Branemark technique. In the Extramaxillary approach a bypass of the maxillary sinus is being made in a manner that prevents damage to the sinus membrane. JDZygoma Implants are designed to reach and make use of the zygomatic bone. JDZygoma implants are recommended for placement only in the posterior maxilla. Because placement of zygomatic implants is a complex and technique-sensitive procedure, the clinician must attend specific advanced training beyond the supervision of expert implantologysts about the JDZygoma implant placement. JDZygoma implants can be tilted up to 45 ° from the occlusal plane. When used with angulations between 30 ° and 45 ° the tilted implant must be splinted; a minimum of 4 implants must be used when supporting a fixed prosthesis in a fully edentulous arch. This device is contraindicated for use of device in bone which has been irradiated as part of therapy in the past 6 months. Implant failure increases when implants are placed in irradiated bone as radiotherapy can result in progressive fibrosis of vessels and soft tissue, leading to diminished healing capacity. Additionally, use of Zygomatic Implants in bone tissue which has been irradiated as part of cancer therapy may result in the following:

• Delayed or failed osseointegration of implants due to reduced bone vascularity, clinically expressed as osteoradionecrosis;

• Tissue dehiscence and osteoradionecrosis; and/or

• Implant failure and loss.

Implant treatment of irradiated patients is dependent upon issues like the timing of implant placement in relation to the radiation therapy, anatomic site chosen for implant placement, and radiation dosage at that site and consequent risk of osteoradionecrosis. The implant site begins with the exposure of the maxillary lateral wall, a mucoperiosteal flap and total thickness is raised by making a crest incision with bilateral distal vertical incision on the tuberosity areas. During the surgical exposure of the lateral wall of the jaw it is absolutely necessary to pay attention to the vital structures including nerves, veins and arteries. Injuries to these anatomical structures can lead to complications such as traumas of the eye, as well as extensive bleeding and dysfunctions associated with the nerves.

Radiographic examination

As with any implant patient case, a radiographic assessment is essential. As far as the Zygoma Implant protocol is concerned, the main objectives are twofold:

1. To detect the presence of any pathology in the maxillary sinuses, bearing in mind that the thickness of the antral mucosa should not exceed 6mm.
2. To evaluate the volume of the maxillary bone surrounding the Zygomatic cavity.

JD ZYGOMA

SURGICAL PROCEDURE

1. Make an incision on the crest of the edentulous maxilla with distal vertical releasing incision.

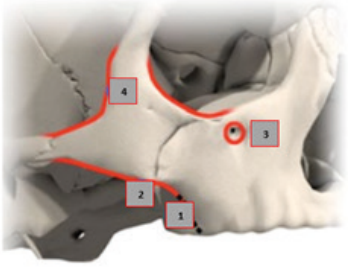
2. Reflect a full thickness mucoperiosteal flap exposing the lateral maxillary wall.

3. Expose the alveolar crest, including its palatal side.

4. Dissect carefully to the level of the infraorbital foramen. Identification of the infraorbital foramen may assist with anatomic orientation.

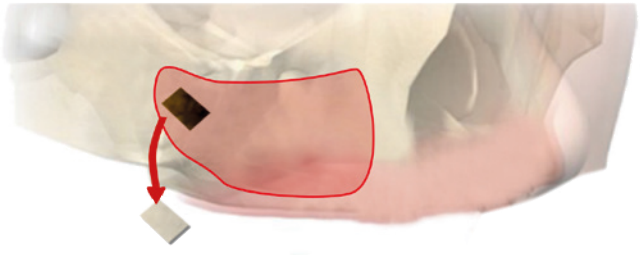
5. Reflect laterally at the level of the infraorbital nerve and expose the body of the zygomatic bone. **Caution:** it is essential to identify and protect the infraorbital nerve.

6. Place a retractor in the frontozygomatic notch to facilitate visualization of the intended apical point of the implant (with special emphasis on avoiding penetration of the orbital floor). When the dissection is complete, the landmarks 1-4 will be visible.



1 - Posterior wall of the maxillary sinus
2 - Zygomatic-maxillary buttress
3 - Infraorbital foramen
4 - Frontozygomatic notch

7. Make an approximately 10mm x 5 mm window on the lateral wall of the sinus, close to the infrazygomatic crest.



8. Carefully lift the sinus mucosa away from the area where the implant will pass following extra-sinus path, from the floor of the sinus to the roof, trying not to penetrate the membrane. Provide appropriate clinical management and treatment of any patients experiencing postsurgical sinus infection, should there be penetration of the sinus.

9. Identify the trajectory of the implant defined by the two points below:
   • The prosthetic connection level of the Zygomatic implant has to emerge at the position of the second premolar in proximity to the rim of the ridge.
   • The Zygomatic implant shall penetrate into the base of the Zygomatic bone as posterior as possible.

10. In order to prepare the direction of drilling the Zygomatic bone, an orientation channel should be made in the maxilla using cylindrical burs with diamond coating. At the tip of each bur there is a taper shaped ending (non-cutting) which is positioned in correspondence to the point where the zygomatic implant has to penetrate into the zygomatic bone. At this position, the bur is lowered towards the maxilla and the channel is shaped by the outer diameter of the bur. Maximum speed 1500 rpm.

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SITE PREPARATION SEQUENCE

- Use an in-and-out motion and drill into the bone for 1 to 2 seconds.
- Move the drill up without stopping handpiece motor. This also allows the irrigation to flush away debris.
- Proceed until desired depth is reached.
- Copious irrigation is recommended throughout the drilling sequence.

Notes:

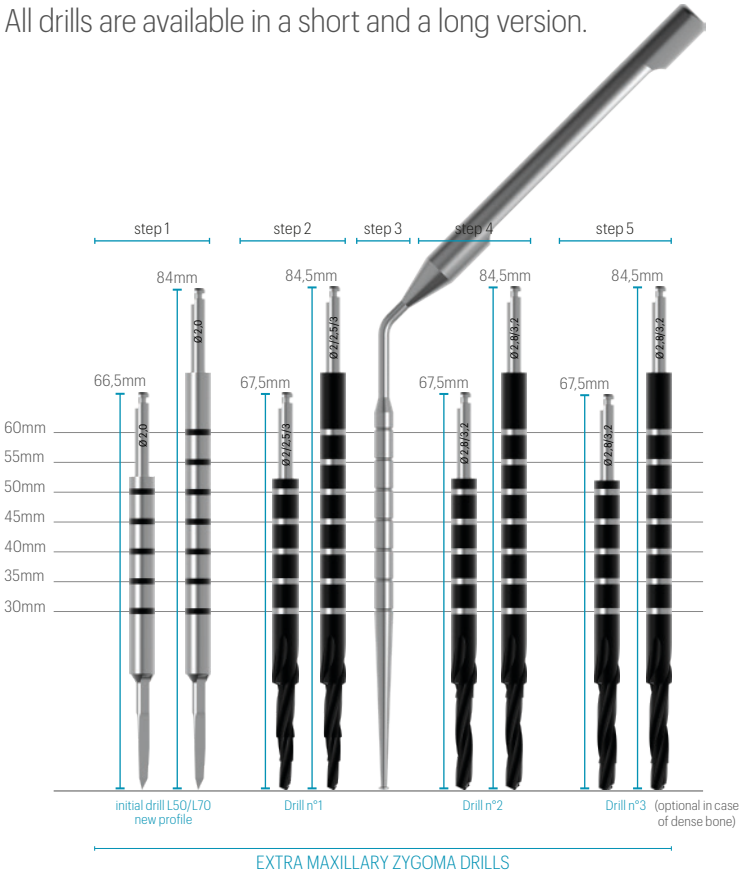
- Burs, twist drills and pilot drills are delivered nonsterile and need to be sterilized prior to use.
- Drills are disposable and should be used for one surgery only.
- The twist drills and initial drills are made of stainless steel with laser marks for depth indication.

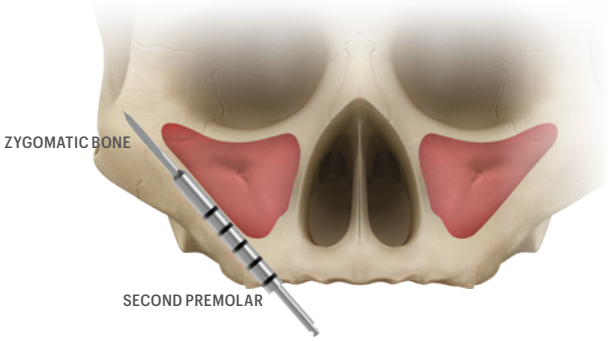
Cautions:

- Avoid lateral pressure on drills during implant-site preparation. Lateral pressure may cause drill fracture.
- Verify that drills lock in the handpiece before starting any drilling. A loose drill may accidentally harm the patient or members of the surgical team.
- Verify that all interconnecting instruments lock properly before intraoral use to prevent accidental swallowing or aspiration.

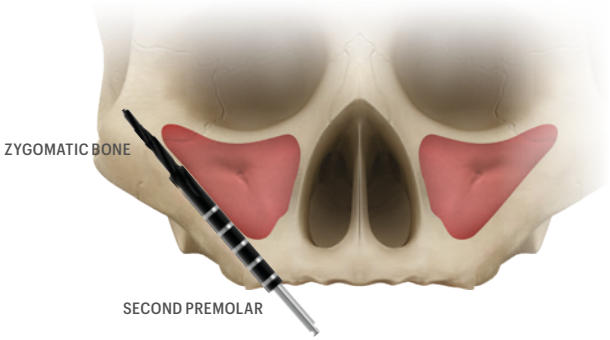
Depth measurement system

All drills are available in a short and a long version.

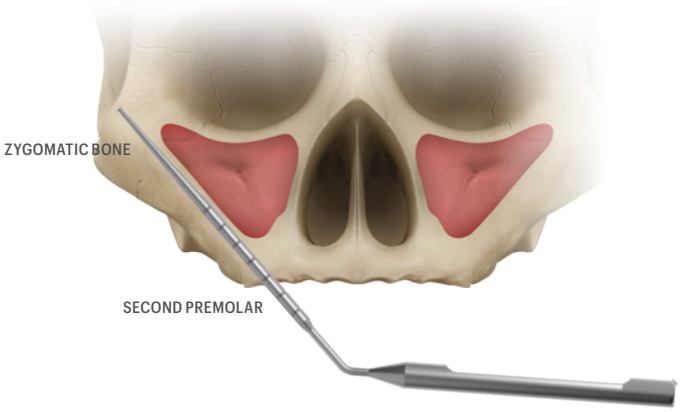




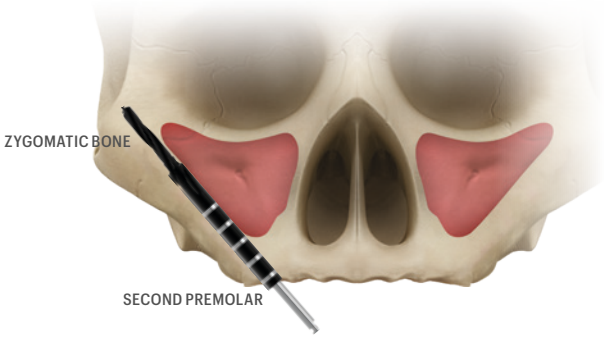
Step 1: Use the Initial Drill 2.1 mm, guided by the previously created orientation channel, to penetrate into the zygomatic bone up to the desired depth.
Maximum speed 2000 rpm.



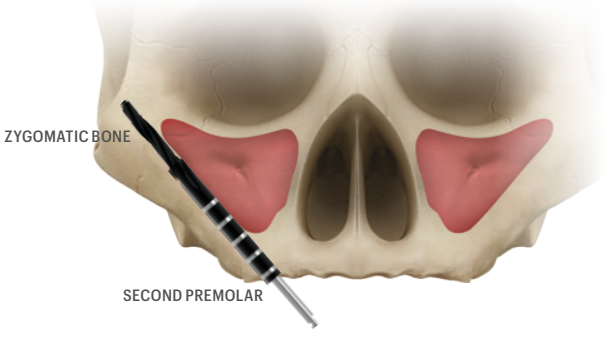
Step 2: Continue with the Drill n°1 (2.0/2.5/3.0 mm) until it penetrates the outer cortical layer of the zygomatic bone.
Maximum speed 2000 rpm.



Step 3: Verify the depth of the prepared bone site with the Angled Depth Indicator to ensure that the selected implant length will fully seat without apical bone interference.



Step 4: In case of dense bone for implant D 3.9mm and in any case for implant D 4.3 mm, widen the osteotomy with Drill n°2 (2.8/3.2 mm)
Maximum speed 2000 rpm.



Step 5: In case of dense bone for implant D 4.3 mm, widen osteotomy with Drill n°3 (2.8/3.2 mm)
Maximum speed 2000 rpm

Step 6: Plan to place the implant as posteriorly as possible, with the implant head as close to the alveolar crest as possible (typically in the 2nd premolar region). The implant must pass extra-maxillary outside of the sinus, enter the base of the zygoma bone and travel through it, exiting through the lateral cortex of the zygoma below the frontozygomatic notch.

IMPLANT INSERTION/PLACEMENT

1. Unpack the implant

Each implant is protected by a sterile barrier with above a printed label containing variable data:

- Diameters, length
- REF implant, lot number, raw materials, expiry date

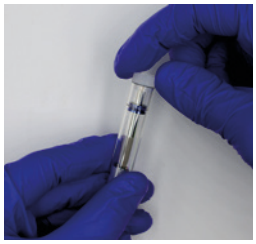
Before use check the integrity of the sterile barrier, check that the welds are intact, and the Tyvek is not damaged or cut and that there are no detachment points from the plastic laminate blister.

The blister label shows the symbol SBS indicating the "aseptic presentation" which denotes the presence of the external sterile barrier (consisting of the closed blister) which contains an additional packaging system (vial with cap) to minimize the risk of contamination after opening the single package.

Step 1: Open the blister and remove the vial

Open by pulling the peel tab located on the lower left corner of the blister. Attention: the blister guarantees the sterility of the implant. Open the blister only immediately before inserting the implant.

Step 2: Remove the cap via



2. Pick up the implant

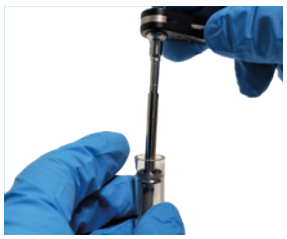
The final placement of the dental implant, depending on the clinical situation, can be carried out with one the following methods:

- The JDTorque dynamometric key
- The surgical handpiece
- The surgical driver

Use of the JDTorque® dynamometric key

Attach the surgical adapter to the JDTorque dynamometric key.

Connect the implant driver to the JDTorque® dynamometric key with the mounted surgical adapter.



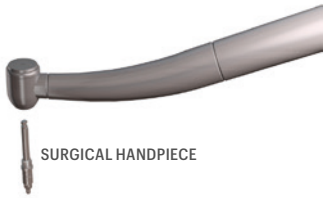
To connect the implant put light pressure on the driver.

Insert the implant in the previously made osteotomy.

Use of the surgical handpiece

Connect the implant driver to the handpiece. To connect the implant, apply light pressure on the driver.

Slowly insert the implant in the previously made osteotomy. (25 rotations/minute)



Use of the surgical drivers

It is also possible to use the surgical drivers to position the implants.

Connect the implant driver to the surgical drivers.

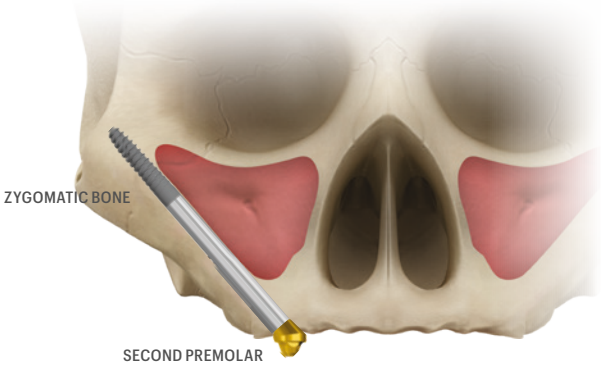
To connect the implant, apply light pressure on the driver.

Insert the implant in the osteotomy previously carried out.

Important: an excessive torque on the implant my compromise the integrity of the internal connection and put excessive pressure on the surrounding bone, negatively affecting bone integration. The implant insertion torque cannot exceed 80 Ncm.

3. Place the implant

Insert the implant into the prepared bone site. The minimal insertion torque for immediate loading is 45 Ncm.



4. Tighten manually the implant with the JD torque wrench

5. Verify the correct position of the implant

6. Perform copious irrigation of the apical portion of the implant (the subperiosteal portion of the zygomatic bone) prior to the removal of the retractor from the frontozygomatic notch

7. The anterior maxillary implants are placed according to their surgical protocol

8. Close and suture tissue flap around the implant using desired technique

POST-OPERATIVE INSTRUCTIONS

Medication
Appropriate antibiotics as well as analgesis for pain management are prescribed for one week following the surgical procedure.

Diet
A soft diet is to be maintained throught the period of using the immediately loaded provisional prosthesis. Strongly recommend that "tearing" forces and hard food (e.g. raw vegetables and fruit, nuts) are to be avoided.

Oral hygiene
Encourage the use of salt water rinses for the first week and prescribe 2% Chlorhexadine rinse b.i.d. (twice daily) for one month following surgery. In addition, ensure that the use of pulsating mechanical hygiene monitored by the surgical team on an individual patient basis.

Follow-up appointments
The patients are seen one week post-operatively by the surgical as well as the prosthetic team. The need for more frequent surgical or prosthetic monitoring is determined by each team on an individual basis.

For immediate loading cases: post- insertion visit
At each visit, the stability of the restoration is checked, and a general evaluation of function, phonetics and esthetics is made. The stability of the prosthetic screws is also tested and, if necessary, the screws are retightened. The screw-access holes can be sealed by placing a soft, easily removable material over the screw head and a temporary or more permanent filling material of choice, such as composite resin, on top. The immediately loaded provisional prosthesis is normally left undisturbed for the 1first six months of the osseointegration.

Appointment for final prosthesis
After an osseointegration period of six months, the surgical team determines the integrity of all implants. The patients are then referred back to their prosthetic team for the fabrication of the final prosthesis.
Note: when connecting the final restoration be sure to verify the following.
- Verify the passive fit of the final restoration intraorally
- Tighten the prosthetic screws to 15Ncm using the JD Screwdriver and JD Torque
- Block out screw access and fill holes with suitable material
- Check the occlusion

Re-call schedule
A re-call schedule is established, based on an individual evaluation of each patient's needs and circumstances. Annual clinical check-ups are recommended, with intraoral radiographic examinations after 1, 3 and 5 years. Encourage patients to return immediately if they feel pain or anything move in the surgical site.

INSTRUMENTS AND ACCESSORIES

MANUAL CLEANING, DISINFECTION AND DRYING

The following instructions should be used for cleaning multiple-use medical devices supplied by JDentalCare including drills, surgical kits, temporary and final prosthetic components such as abutments and screws.

1. Remove debris in lukewarm water and soak devices in cleaning solution.
   Remove residual tissue or bone debris by immersing the used instruments in lukewarm water (<40°C /104°F). Do not use fixation agents or hot water (>40°C/104°F) as this could influence subsequent cleaning results. Instruments should be kept in wet environment until next step is initiated. Soak the instruments in a cleaning solution prepared with lukewarm tap water. Soaking time not less than specified in the detergent manufacturer's instructions.

2. Scrub devices with soft bristled nylon brush.
   Scrub the instruments with a soft bristled nylon brush until all visible soil and/or debris is removed. Pay particular attention to features that may be shielded from the brushing action.

3. Soak in ultrasonic bath.
   Prepare an ultrasonic bath with cleaning solution at the concentration and temperature specified in the detergent manufacturer's instructions. Immerse the devise completely and activate the bath for at least the time specified in the detergent manufacturer's instructions.

4. Rinse with purified or sterile water.
   Rinse for at least 1 minute with freshly prepared purified water or sterile water until traces of cleaning solution are removed.

5. Soak in disinfection solution.
   Prepare a bath with a disinfection solution at the concentration and temperature specified in the detergent manufacturer's instruction. Immerse the devise completely for at least the time specified in the detergent manufacturer's instructions.

6. Rinse with purified or sterile water.
   Rinse for at least 1 minute with freshly prepared purified water or sterile water until traces of cleaning solution are removed.

7. Dry with compressed air or wipes.
   Dry the devices using medical compressed air and clean lint-free single-use wipes.

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