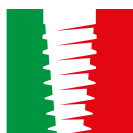




JDENTALCARE

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MADE IN ITALY

Dental Implant

JD ZYGOMA

JDZygoma surgical procedure



INDICATIONS FOR USE

Dental implant JDZygoma is a JDentalCare implant system.

JDZygoma implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arch to provide support for prosthetic devices, such as artificial teeth, 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 implant failure or loss of supporting bone or inadequate primary stability or other adverse effects. Thorough screening of implants candidates should be performed included the absence of maxillary sinus pathology, an evaluation of patient capacity to maintain a correct oral hygiene, the patient motivation, 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 TAC dental scan to provide a real evaluation of dimensions and quality of bone.

General

The clinician must attend a specific advanced training beyond the supervision of expert implantologists about the JDZygoma implant placement.

JDZygoma Implants are designed to reach and make use of the zygomatic bone.

JDZygoma implants are recommended for placement only in the posterior maxilla.

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.

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:

- 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.
- To evaluate the volume of the maxillary bone surrounding the Zygomatic cavity.

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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.



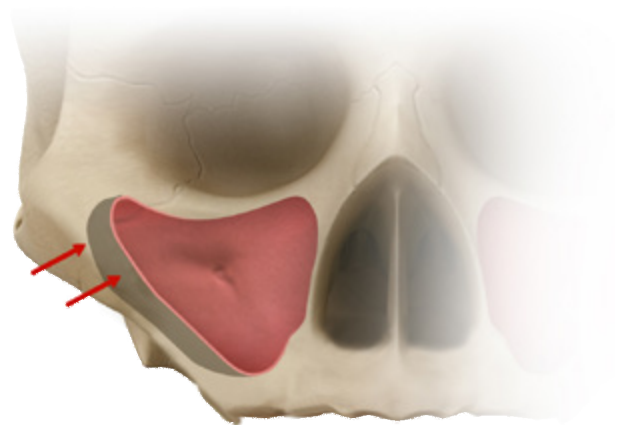
- Posterior wall of the maxillary sinus
- Zygomatic-maxillary buttress
- Infraorbital foramen
- Frontozygomatic notch

7. Make an approximately 10mm x 5mm 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 through the sinus, from the floor of the sinus to the roof, trying not to penetrate the membrane.

Caution: try to keep the sinus membrane intact during this process. However, penetration of the sinus membrane will not result in an adverse outcome.



9. Identify the trajectory of the implant by placing the round bur over the lateral wall of the maxilla:
 - The tip of the bur at the frontozygomatic notch
 - The body of the bur over the posterior lateral corner of maxillary sinus
 - The base of the bur at the crest of the ridge in the 2nd bicuspid/1st molar position.

Determine the extract point on the alveolar crest at which to start the drilling sequence, and the direction of the long axis of the implant, based on the known anatomy of the maxilla, the sinus, and the zygomatic bone. Aim for the middle of the retractor during the drilling sequence.

SITE PREPARATION SEQUENCE

- Use an in-and-out motion and drill into the bone for 1-2 seconds.
- Move the drill upwards without stopping handpiece motor. This also allows the irrigation to flush away debris.
- Proceed until desired depth is reached.
- Do not exceed 2000 rpm when drilling.
- Copious irrigation is recommended throughout the drilling sequence.

Notes:

- Drills are delivered nonsterile and need to be sterilized prior to use.
- Surgical instruments are intended for reuse. Prior to first use and each use thereafter the devices must be cleaned and sterilized by the user according to the instruction reported in the IFU of surgical instruments available at: ifu.jdentalcare.com/it/eifu. For a correct efficiency of surgical instruments, we recommend a maximum of 20-30 uses. Do not re-sterilize the same instrument for more than 30 times. The twist drills and pilot drills are made of stainless steel with an amorphous diamond coating, which gives them their black color.
- The zygomatic drills are made of stainless steel with DLC coating which gives them their black color and brings out the depth markings.

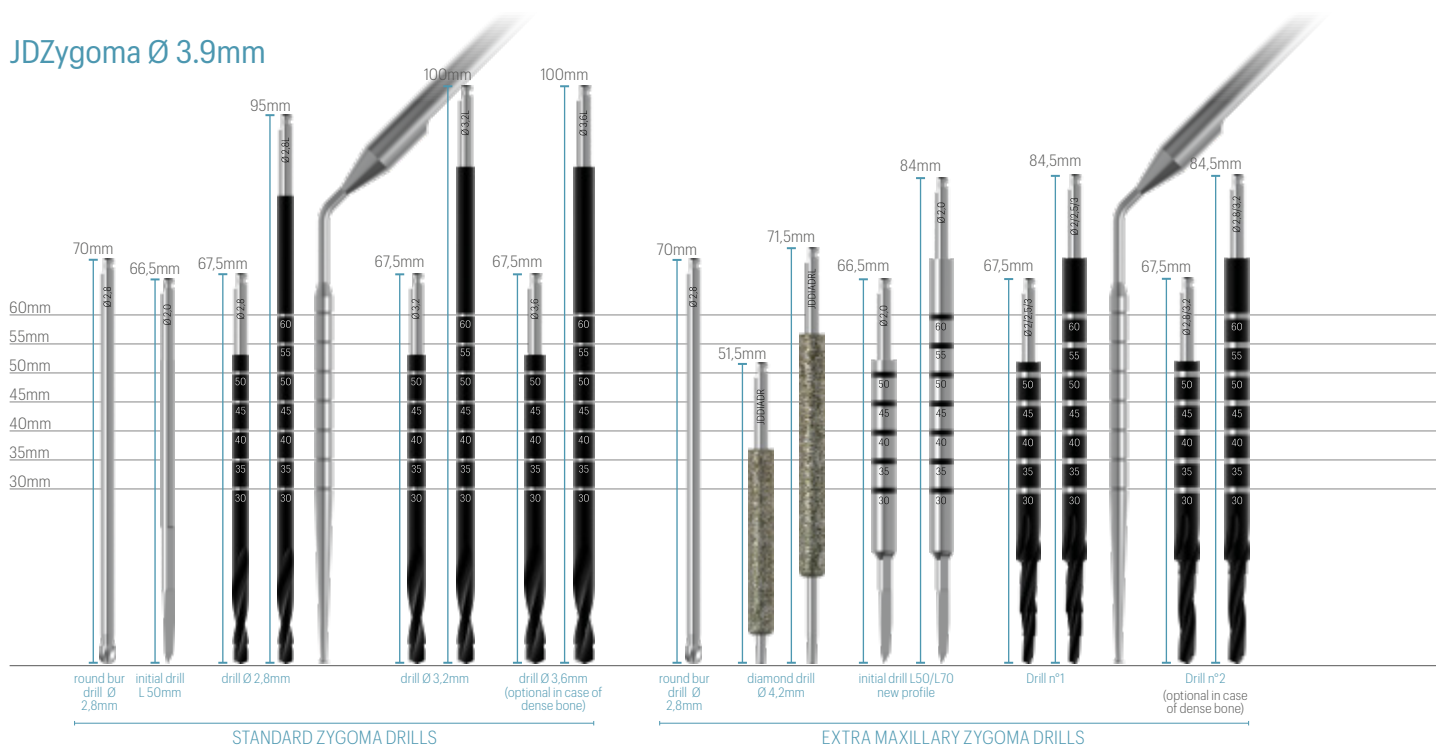
Cautions:

- 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.

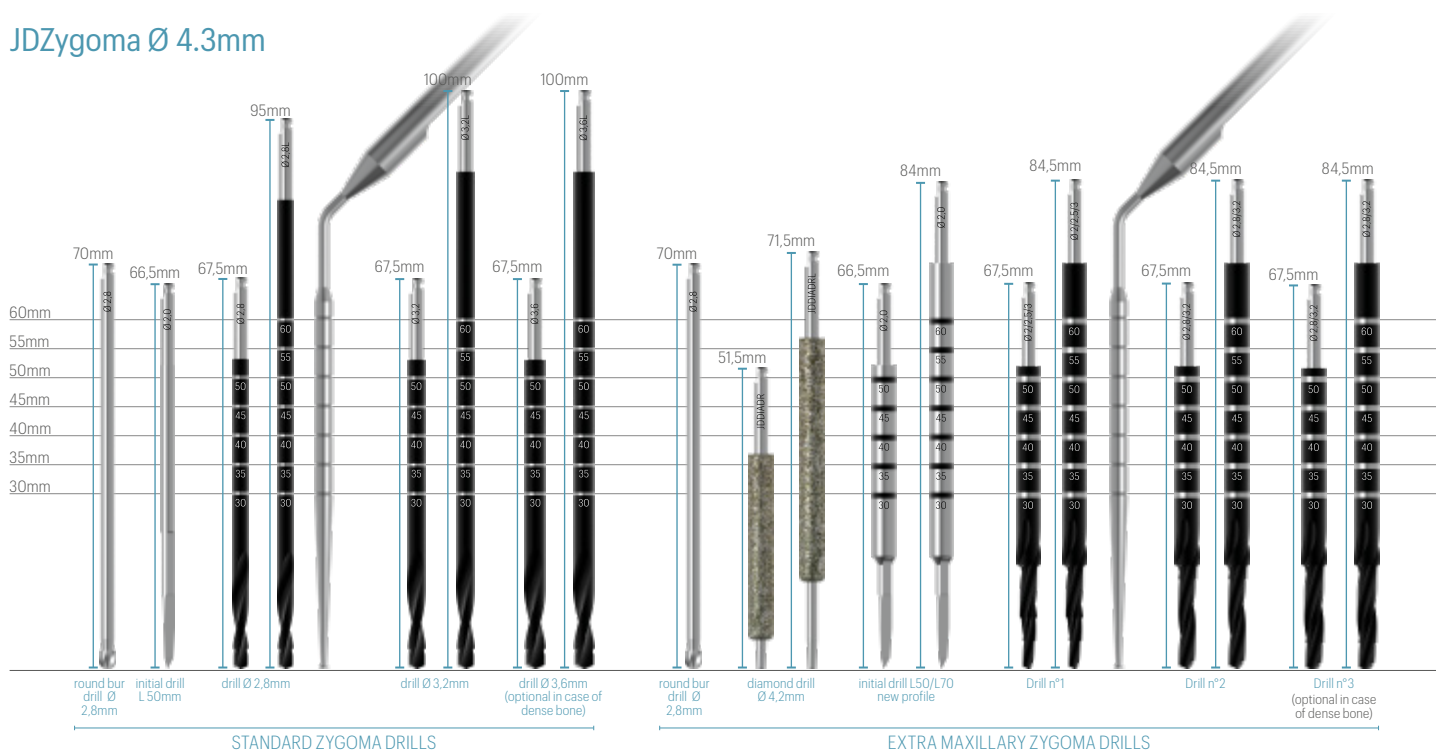
Site preparation sequence

For the preparation of the implant site for the insertion of JDZygoma implants it is recommended to adhere to the following drilling sequences to ensure optimal primary stability of the implants.

JDZygoma Ø 3.9mm



JDZygoma Ø 4.3mm

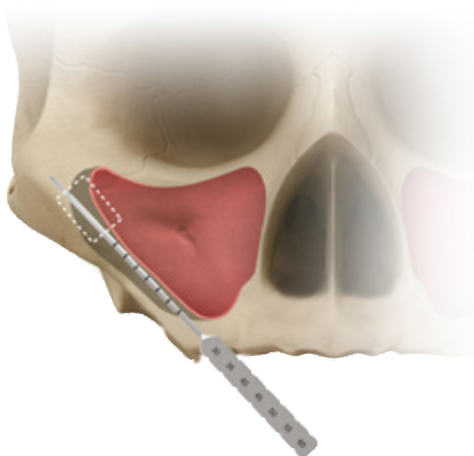




1. Make the palatal/crestal mark for the implant entrance with the round bur. Penetrate and pass the round bur through to the sinus while checking the direction of the bur through to the sinus window. The bur must be directed towards the retractor that was previously placed in the notch. Make an entrance mark in the posterior-superior roof of the sinus to allow seating of the 2.8 mm drill without chatter. Maximum speed 2000 rpm.



2. Continue with the Twist Drill 2.8 mm until it penetrates the outer cortical layer of the zygomatic bone at the incisura. Maximum speed 2000 rpm.



3. Use the Straight Depth Indicator to determine the required implant length.



4. Widen osteotomy with Twist Drill 3.2 mm. Maximum speed 2000 rpm.



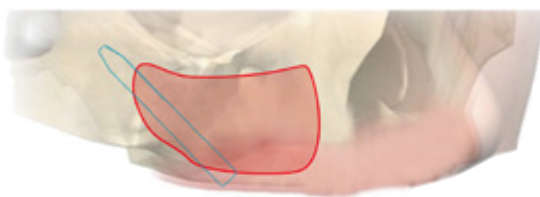
5. Finalize osteotomy with Twist Drill 3.6 mm in case of dense bone. Maximum speed 2000 rpm

Caution: Ensure correct angulation and avoid drill wobble, as this can inadvertently widen the preparation site.

Caution: If the sinus membrane cannot be kept intact during osteotomy preparation, carefully irrigate away debris when inserting the implant. Any mucosal remnants in the bone site may prevent osseointegration of the implant.



6. 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. Copious irrigation of the sinus is recommended prior to implant placement.



7. 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 simultaneously pass through the floor of the sinus and the maxillary sinus, enter the base of the zygoma bone (the posterior-lateral portion of the maxillary sinus roof) and travel through it, exiting through the lateral cortex of the zygoma below the frontozygomatic notch. Depending on the anatomy of the patient, the implant body may be positioned inside or outside the maxillary sinus.

Note: Adjustments to this implant placement may be considered due to anatomical variations in the maxilla as well as the maxillary sinus.

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IMPLANT INSERTION/PLACEMENT

1. Unpack the implant

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

- Diameter, length
- REF implant, lot number, raw materials, expiry date and UDI

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 at the point of use

Step-2

Remove the vial cap



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 engine
- The surgical driver



Use of 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 engine

Connect the implant driver to the hand piece. 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.

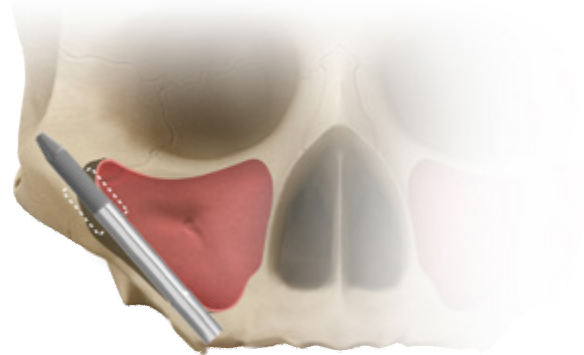
Insert the implant in the osteotomy previously carried out.

Important: an excessive torque on the implant may compromise the integrity of the internal connection and put excessive pressure on the surrounding bone, negatively affecting bone integration. The implant insertion torque shall be between 25 Ncm and 80 Ncm.



3. Place the implant

- Insert the implant into the prepared implant site with an insertion torque between 25 Ncm and 80 Ncm.
- Confirm the correct insertion angle of the implant while continuing through the sinus until the implant apex engages in the zygomatic bone.



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.

FINALISATION OF IMPLANT SURGERY

There are two options for finalizing the implant surgery.

Two-stage delayed function

Use the JD Screwdriver to connect a cover screw to the implant. Suture tissue flap using desired technique. In the delayed loading protocol, after the placement of dental implants, is required a 3-6 months load-free healing period for healing and osseointegration.

Note: be sure to relieve the surface of the tissue around the denture to avoid contact between implants and denture.

One-stage immediate Function

Provisionalize implants for immediate Function on abutment level by fabricating a provisional bridge using JD Conical Abutments in combination with JD Temporary Abutments for Conical abutments.

Note: JDZygoma connection is compatible with JDEvolution Plus implant line, so please refer to JDEvolution Plus catalogue to choose the most suitable component. The insertion torque for JDEvolution Plus prosthetic screws for conical abutment is 15 Ncm.

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 throughout 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.

Also remind patients that they are not to blow their nose until instructed.

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 first 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.

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 that they should return immediately if they feel pain or anything move.



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