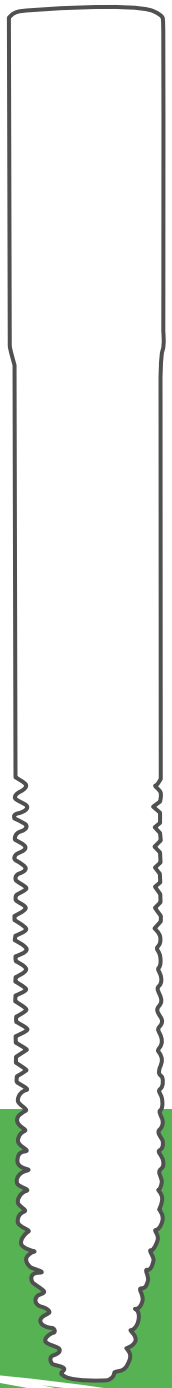
J DENTAL CARE

*just smile*

MADE IN ITALY



Dental Implant

# JD ZYGOMA

JDZygoma surgical procedure

# JD ZYGOMA

## INDICATIONS FOR USE

Dental implant JDZygoma is a JDentalCare implant system.
JDZygoma implants are dental implants intended for zygomatic bone. They are comprised of fixtures and prosthetic devices. JDentalCare zygomatic implants act as a prosthetic anchorage in the rehabilitation of partial or total edentulism, in reconstruction with dental prosthesis.
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

An appropriate planning of every aspect of the oral surgery is essential for the long-term success of a prosthesis.
The preoperative planning should be made based on the expected aesthetic and functional restorative results.
The user of JDZygoma products has the duty to determine whether or not any product is suitable
for the particular patient and circumstances. The choice of unsuitable sizes of the devices and the malposition of the implant may lead to complications, undesirable effects and to the failure of treatment. To avoid this, a detailed examination through clinical and radiographic analysis of the patient general health condition and current medical status, and an evaluation of patient motivations and expectations are necessary. Moreover, factors such as cigarette smoking, masticatory function and alcohol consumption are to be considered. Dental casts can be used to define the position and angulation of implants.
The dentist will develop the plan after gathering all the required data, because they provide important information and make possible a backward planning, with the aim to improve the safety and the results of the surgical procedure.

**Before the intervention are strongly recommended:**

- Psychological and physiological evaluation
- Examinations (e.g radiological examination and TC Cone Beam examination)
- Evaluation of general medical and dental history, medical examinations, clinical examinations (complete blood count)
- Collection of patient information, giving more attention to factors that could interfere with the success of the treatment ( e.g. cigarette smoking, poor oral hygiene, uncontrolled diabetes, active chemotherapy, bruxism)
- Performing of a session of professional teeth cleaning
- Definition of an oral hygiene program, with periodontal interventions (if any)
- Providing information to patients about contraindications and undesirable side effects
- Prescription of antibiotic prophylaxis and of an eventual pharmacological treatment, when needed,
- Prosthetic planning in collaboration with dental technician
- Evaluation of risks related to an inadequate treatment of bone and mucosal tissues
- Make the study casts and then the wax-up/set-up on it

The type, diameter and final positioning of the implants, the number of implants to be used, and consequently the appropriate prosthetic components to be used, should be chosen according to the patient's specific anatomy. The dimensions of the devices should be considered as minimum guidelines and are specified in the brochures of the relevant implant line.

### General

The clinician must attend a specific advanced training beyond the supervision of expert implantologysts about the JDZygoma implant placement.
JDZygoma implants are indicated to be surgically placed in the upper jaw , in the zygomatic bone, to support dental prostheses. They can be used to replace natural teeth in case of lost both for natural and traumatic causes. JDentalCare zygomatic fixtures are intended to be used in case of partially or fully edentulism.
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.

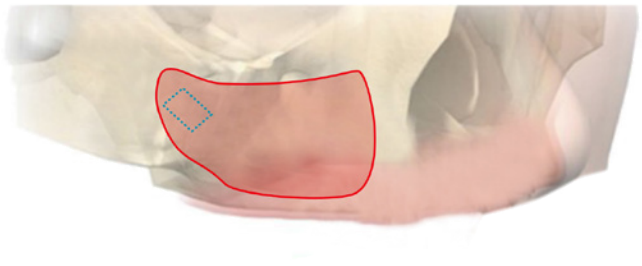
### Radiographic examination

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. It is also mandatory to check the patency of the ostiomeatal complex.
- To evaluate the volume of the zygomatic bone. Minimum bone thickness raccomended is 6mm.

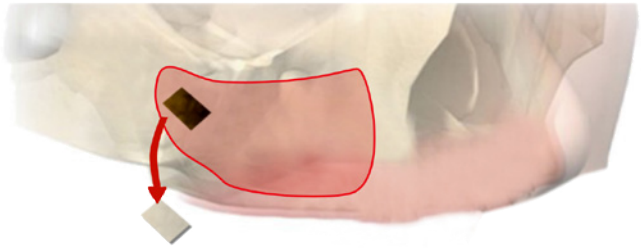
# SURGICAL PROCEDURE

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.

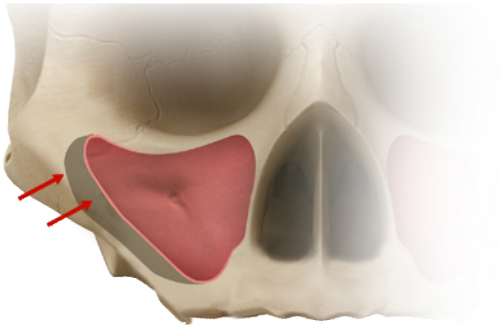


- POSTERIOR WALL OF THE MAXILLARY SINUS
- ZYGOMATIC-MAXILLARY BUTTRESS
- INFRAORBITAL FORAMEN
- FRONTOZYGOMATIC NOTCH

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 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. **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 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.



# 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 non sterile 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 laser marks for depth indications.

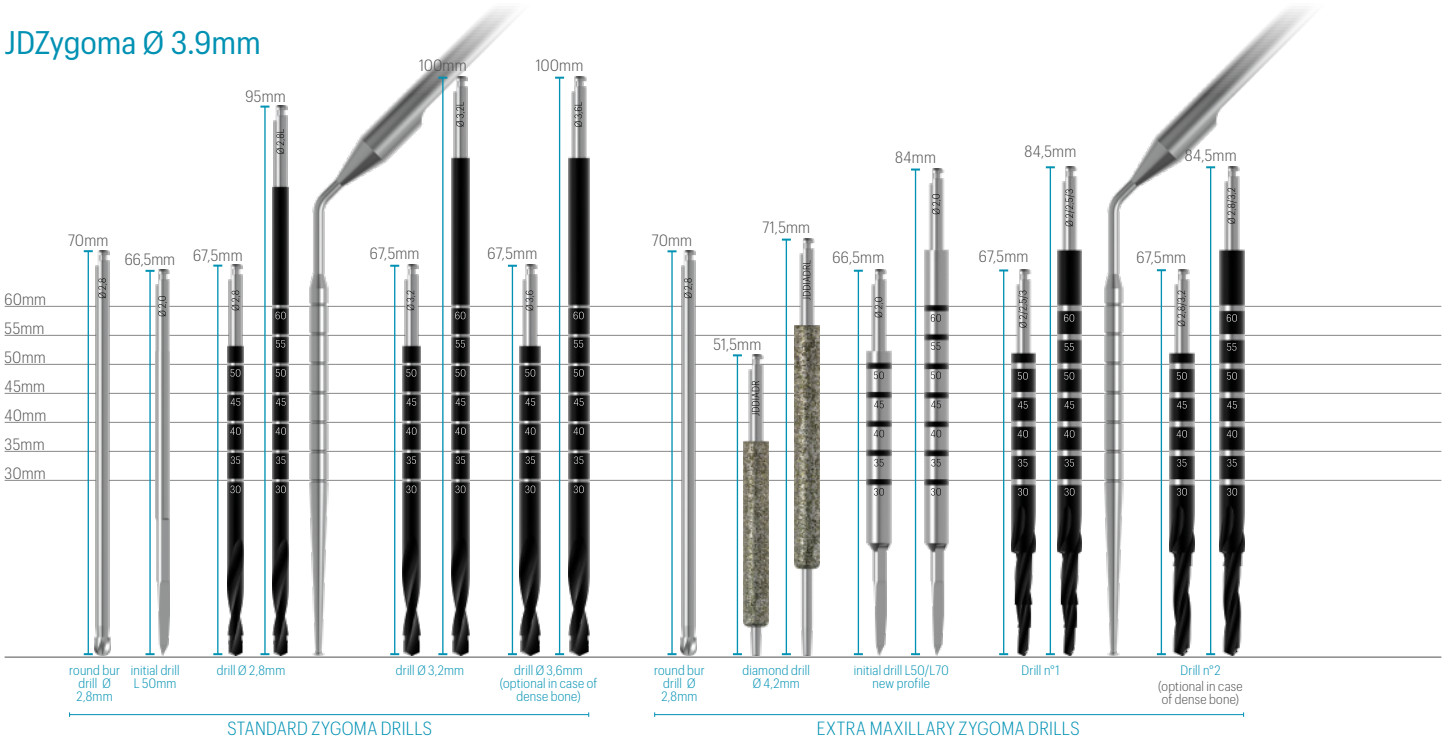
Cautions:

- 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.

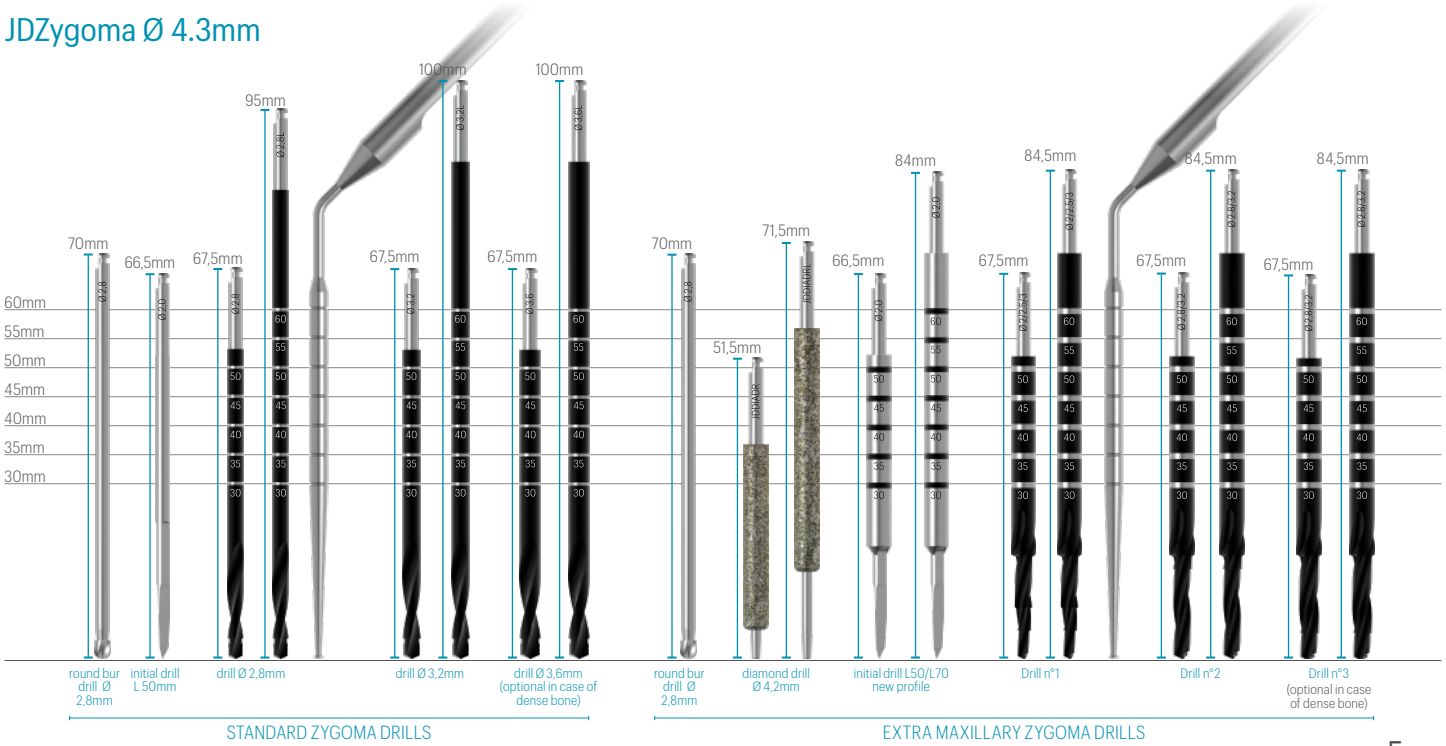
## Site preparation sequence

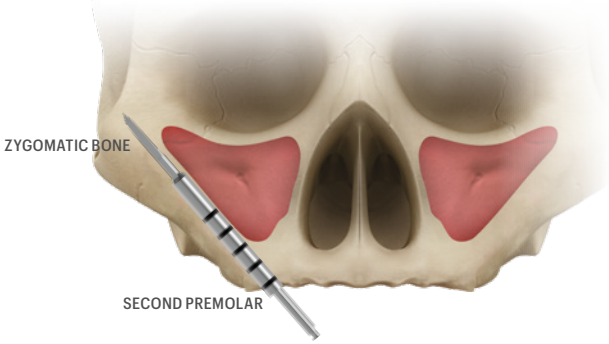
For the preparation of the implant site for the insertion of JDZygoma implants it is recommended to adhere to the following drilling sequences to ensure optimal primary stability of the implants.

### JDZygoma Ø 3.9mm

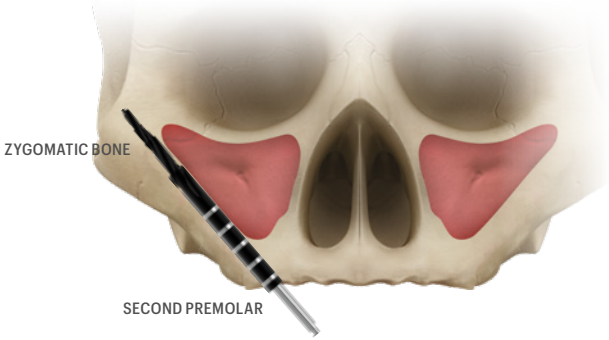



### JDZygoma Ø 4.3mm

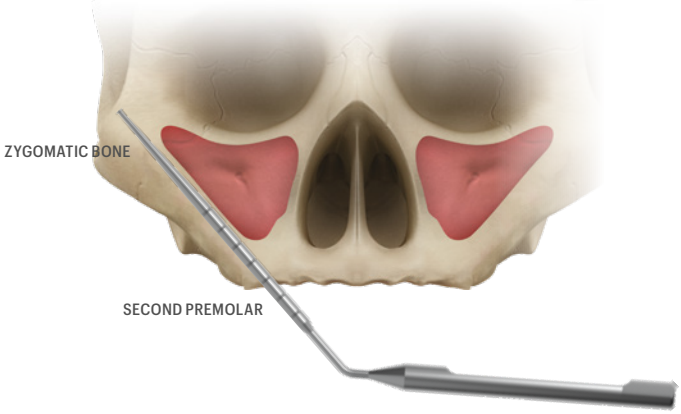




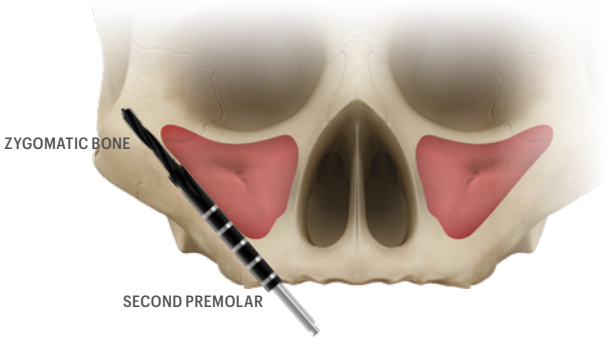

**Step 1:** Use the Initial Drill 2.1 mm, guided by the previously created orientation channel, to penetrate into the zygomatic bone up to the desired depth. Maximum speed 2000 rpm.



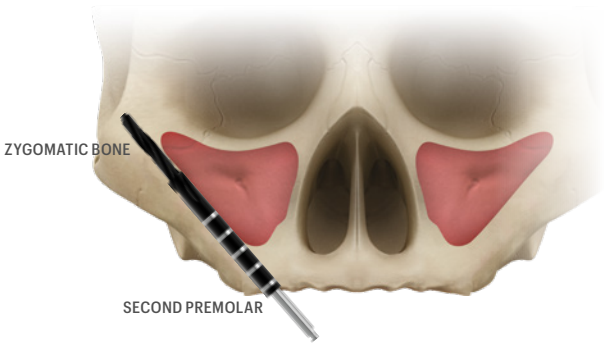

**Step 2:** Continue with the Drill n°1 (2.0/2.5/3.0 mm) until it penetrates the outer cortical layer of the zygomatic bonE. Maximum speed 2000 rpm.




**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

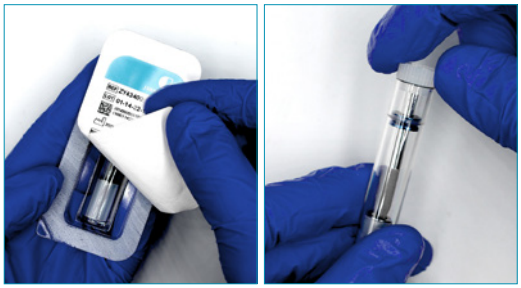
Each implant is protected by a sterile barrier with above a printed label containing variable data:

- 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:

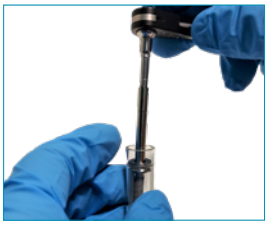
- The JDTorque dynamometric key
- The surgical engine
- The surgical driver

#### 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.

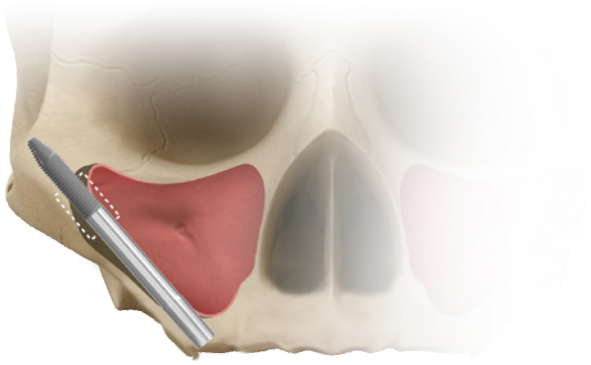
Connect the implant driver to the surgical drivers.

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 my 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 dthe 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 throught the period of using the immediately loaded provisional prosthesis. Strngly 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. (twicw 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 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.

### Re-call schedule

A re-call schedule is established, based on an individual evaluaztion 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 fell pain or anything move.

## STERILITY INFORMATION FOR IMPLANTS AND PROSTHETIC COMPONENTS

JDentalCare implants are delivered sterile. Implants have been sterilized using gamma irradiation and are single-use devices. The intact sterile packaging protects the sterilized implant from outside influences and, if stored correctly, ensures the sterility of the device up to the expiration date.
The expiration date is indicated on the labels attached on the blister and on the box. The sterile blister must be opened only at the point of use during the surgery. On the blister of implants there is a red sticker, which is a gamma sterilization indicator. It confirms that the device has been subjected to sterilization by gamma radiation.
Prosthetic components may be supplied non-sterile or sterile and are single-use devices. Please pay attention to the symbology on the label to distinguish whether the product is supplied in sterile form or not, and more specifically check which of the two symbols shown above is on the label.
In case of sterile prosthetic components, they have been sterilized using gamma irradiation. The intact sterile packaging protects the sterilized prosthetic component from outside influences and, if stored correctly, ensures the sterility of the device up to the expiration date.
The expiration date is indicated on the label attached on the cardboard case. The sterile packaging must be opened only at the point of use during the surgery. On the envelope in which the device was placed, there is a red sticker, which is a gamma sterilization indicator. It confirms that the device has been subjected to sterilization by gamma radiation.
In case of non-sterile prosthetic component, it must be sterilized by the user prior to use, through steam sterilization, as follows*:
In case of non-sterile prosthetic component, it must be sterilized by the user prior to use, through steam sterilization, as follows*:

- For US Market: Temperature: 132°C/275°F; Sterilization Time: 4 min; Dry Time: 20 min; Pressure: 3 bar; Density of worst-case load: 0,09 gr/cm$^3$
- For EU market: Temperature: 134°C/273°F; Sterilization Time: 4 min; Dry Time: 20 min; Pressure: 3 bar; Density of worst-case load: 0,14 gr/cm$^3$

Prosthetic components should be sterilized in sterilization pouches that must be in medical grade paper and plastic film suitable for steam sterilization and must comply with the requirements of the EN ISO 11607: 1-2 and UNI EN 868-5 standards
Note: For a correct efficiency of sterilization process, it is recommended to use B-Autoclave compliant with ISO 13060, and to regularly perform control tests suggested in the manufacturer Manual. We recommend to keep and archive all records in a specific document easy to consult in the workplace.
*Validated sterilization parameters to achieve a Sterility Assurance Level (SAL) of 10-6 in accordance to EN ISO 17665-1. Please refer to product labels for information related to devices sterilization and reusability
Warning: The devices are SINGLE USE. Do not re-use the devices (both implants and prosthetic components). Used or explanted devices cannot be reused/resterilized and must be disposed. If they are reused on another patient, there

is a risk of cross-contamination and loss of the performance and functional characteristics of the device.
Warning: Do not use sterile devices after the expiration date.
Warning: Do not use fixtures and the prosthetic components when supplied sterile if the gamma sterilization indicator is colored differently from red. Previously used or non-sterile implants must not be used under any circumstances.
Warning: The fixtures must not be cleaned, disinfected and/or re-sterilized by the users prior to use, since otherwise the main material and design features may be compromised, leading to device failure.
Warning: The device (both implants and prosthetic components) can be used only if the package is intact, closed and undamaged. Don't use the devices (both implants and prosthetic components) if the package has been damaged or previously opened. It is recommended to have a replacement implant at hand.
Any behavior different from the above may lead to infections, implant loss and to the failure of the treatment. JDentalCare disclaims any liability and shall have no responsibility for re-sterilized implants, regardless of who has carried out re-sterilization or by what method.

### Sterility information for Surgical instruments and Kits

Surgical instruments are intended for reuse. Prior to first use and each use thereafter the devices must be cleaned and disinfected by the user according to the instruction reported below(with manual or automatic process), then must be sealed, individually or within surgical kit, in a sterilization pouch and sterilized.
Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.
Warning: The device can be used only if the package is intact, closed and undamaged. Do not use the devices if the packaging has been damaged or previously opened.
Warning: In the event of suspected prion contamination, do not reuse the device, but safely dispose of it in accordance with applicable laws and regulations.
Warning: JDentalCare has validated the sterilization process to ensure sterile instruments for 6 months inside the SBS. Do not use sterile devices after this period.
Warning: Failure to follow manufacturer directions may expose the patient to infection

### Cleaning and sterilization instruction

The following cleaning and sterilization process have been validated according to international standards and guidelines, the main are reported as follow:

| Cleaning and disinfection | Steam Sterilization |
|---|---|
| ISO 17644<br>ASTM E 2314-03<br>ISO 11737<br>ISO 15883-5<br>ANSI/AAMI ST98:2022 | ISO 17665-1<br>ISO/TS 17665-2<br>UNI EN ISO 11138-1 |

According to EN ISO 17664, it is the responsibility of the user/processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.
NOTE: the manufacturer's instruction for use for any detergent/cleaning solution must be strictly followed where applicable, it is recommended to use the same/ simile products and materials as indicated by JDentalCare.
NOTE: the recommended water used for diluting cleaning agents and/ or disinfectants are purified water-PW/ or highly purified water-HPW with less than 0,25 U.I/ ml of bacterial endotoxins and maximum 10 CFU/ml for HPW and WFI.

## Initial treatment and pre-cleaning instruction for surgical instruments and kits:

Initial treatment at the point of use

The device is supplied in a NON-STERILE state and before first use it must undergo the cleaning, disinfection and sterilization procedures indicated in this instruction sheet. Before use, always examine the device in order to verify its integrity, the absence of stains, damage or wear. Start cleaning the surgical instruments immediately after use to ensure the efficacy of the reprocessing

### Pre-Cleaning

Surgical instruments

To avoid contamination of the kit box (mainly the instrument tray) and damage of sterile gloves by sharp drills it is recommended to pick up devices using a pair of tweezers. Directly after use of reusable tools remove gross soiling using a specific absorbent paper wipe. If needed rinse with running water.

- Get the medical devices to the point where cleaning is to be performed as soon as practical using specific containment for safe transportation
- Soak the instruments in 2% of disinfecting solution (Ex. ID 212- DURR DENTAL) for minimum 5 min to guarantee a safe handling by the personnel in the next steps of the process. Soaking time not less than specified in the disinfecting agent manufacturer's instructions*
- Surgical tools must be disassembled into several parts before brushing: when using twist drills with stops remove them before brushing step. When using drill extension remove it before brushing step
- After disassembly, use a soft nylon-bristled brush to gentle scrub the devices, particular attention must be given to critical area as crevices, serrations, joints and lumen. Lumen should be clean with an appropriate pipe cleaner. Brush the devices for a minimum of 30 second until all visible soils is removed.
- After brushing, rinse with running water for a minimum 1 minute to remove any residue of soil and traces of disinfecting agent

In case of highly contaminated medical devices to be subjected to an automatic cleaning process, perform a final pre-cleaning step in an ultrasonic bath: Immerse the devices in an ultrasonic bath containing 2% of disinfecting solution (Ex. ID 212- DURR DENTAL) for 5 min at room temperature ( 25 °C /77 °F)

NOTE: Maximum soaking time for IDI 212 agents is 12 hours. For different cleaning/disinfectant agents please consult manufacturer's instruction for use.

The solution used for cleaning and rinsing must be replaced after each use.

*Pre-Cleaning and Cleaning phase has been validated by JDentalCare using commercial product ID 212 by DURR DENTAL.

Kit boxes

In case of suspect contamination of the autoclavable container with biological material, it is advisable to proceed with the disassembly of the silicone rubber and support from the tray. Remove the larger impurity from the plastic parts under a jet of water at room temperature using also a brush. If the silicon supports have been removed, dry the container before reassembly. A visual inspection can verify the integral state of the container.

NOTE: The solution used for cleaning and rinsing must be replaced after each use.

*Pre-Cleaning and Cleaning phase has been validated by JDentalCare using commercial product HI CARE 2.0 PERACETIX DROX of Negri sas

### Manual Cleaning

Surgical instruments

Start cleaning the reusable surgical instruments immediately after pre-cleaning.

- Immerse the devices in an ultrasonic bath containing 2% of cleaning solution (Ex. ID 212- DURR DENTAL) for minimum 5 min at room temperature (25 °C /77 °F)

• After cleaning steps rinse in purified running water for a minimum 1 minute to remove any residue of soil and traces of cleaning solution.

Refer to the detergent manufacturer's instruction for use for additional rinsing instruction

NOTE: Maximum soaking time for IDI 212 agents is 12 hours. For different cleaning/disinfectant agents please consult manufacturer's instruction for use.

The solution used for cleaning and rinsing must be replaced after each use.

*Pre-Cleaning and Cleaning phase has been validated by JDentalCare using commercial product ID 212 BY DURR DENTAL.

Kit boxes

Start cleaning the kit boxes immediately after pre-cleaning.

- Immerse the container in a detergent solution in an ultrasonic bath for 10 min
- Rinse the container with tap water at room temperature for 1 minute to eliminate residual traces of detergent
- Place maximum attention to the dosages of the products used and to the treatment times indicated by the manufacturer

NOTE: The solution used for cleaning and rinsing must be replaced after each use.

*Pre-Cleaning and Cleaning phase has been validated by JDentalCare using commercial product HI CARE 2.0 PERACETIX DROX of Negri sas

### Manual Disinfection

Surgical instruments

- Immerge the devices in an ultrasonic bath containing 0.55% of disinfecting solution (Ex. CIDEX OPA By ASP) for a minimum of 5 minutes at minimum 20 °C / 65°F.
- After disinfection steps rinse in purified running water for a minimum 1 minute to remove traces of disinfecting agent

NOTE: The solution used for cleaning and rinsing must be replaced after each use.

*Disinfection phase has been validated by JDentalCare using commercial product CIDEX OPA By ASP

Kit boxes

- Immerse the container in a disinfectant solution in an ultrasonic batch for 10 min
- Rinse the container with tap water at room temperature for 1 minute to eliminate residual traces of disinfectant
- Place maximum attention to the dosages of the products used and to the treatment times indicated by the manufacturer

NOTE: The solution used for disinfection and rinsing must be replaced after each use.

*Pre-Cleaning and Cleaning phase has been validated by JDentalCare using commercial product HI CARE 2.0 PERACETIX DROX of Negri sas

Caution: For a correct efficiency of surgical instruments, we advise 20-30 uses maximum.

### Automatic Cleaning

The following washer was used in the JDentalCare validation: Smeg Instruments WD2145 with the following P7 custom program.

1- Place the device in a suitable instruments rack (E.g metal sieve basket) and load them into the washer/disinfector. Ensure the rack or load carrier is oriented in a horizontal position.

2- Performed automatic cleaning. The following parameters are based on the P7 TD program 90° x 5 minutes (A0= 3.000) on the SMEG WD2145 washer disinfector:

- 3 minutes of prewashing with cold filtered water
- Washing with mildly alkaline detergent, dosage 4 ml/l (0.4%), filtered water
  - step 1: 5 minutes at 50°C

• steps 2: 5 minutes at 55°C
- 3 minutes of neutralization with cold water
- 3 minutes of rinsing with deionized water
- 5 minutes of disinfection at 90° with deionized water
- Draining

NOTE: Automatic washing steps have been validated by JDentalCare using commercial product Neodisher MediClean Forte.

Neutralization steps have been performed with Acidglass C2

3- Inspection and maintenance
- Visually inspect all devices for signs of damage and wear. Cutting edges should be free of defects and drills should be free from distortion. Visually inspect kit box for signs of damage and wear.
- Re-assemble the surgical kit (tray) and place the tools to be sterilized in their proper supports which will hold them still during the sterilization cycle
- Laboratory tools should be inserted into the silicon support by their stems, leaving the area to be sterilized uncovered. Surgical tools should be inserted handle first and not by their working end. The tray with utensils should be placed inside the container which can then be closed
- Only devices manufactured should be included in JDentalCare instrument tray. These validated reprocessing instructions are not applicable to trays that include devices that are not manufactured by JDC.
- These validated reprocessing instructions are not applicable to trays that include devices that are not manufactured by JDentalCare.

Caution: For a correct efficiency of surgical instruments, we advise 20-30 uses maximum.

## Drying

Surgical instruments

Dry the tools with a clean, absorbent and non-shedding wipe until completely dry. Carefully inspect each device to ensure that all visible contamination (soil or debris) has been removed. If necessary, repeat cleaning and disinfections steps.

Kit boxes

Dry the container with clean and soft cloth. Carefully inspect the kit box to ensure that all visible contamination (soil or debris) has been removed. If necessary, repeat manual cleaning and disinfection. After cleaning steps rinse in purified water for a minimum 1 minute to remove any residue of soil and traces of cleaning solution

## Inspection and maintenance

Visually inspect all devices for signs of damage and wear. Cutting edges should be free of defects and drills should be free from distortion.

Visually inspect kit box for signs of damage and wear

- Re-assemble the surgical kit (tray) and place the tools to be sterilized in their proper supports which will hold them still during the sterilization cycle
- Laboratory tools should be inserted into the silicon support by their stems, leaving the area to be sterilized uncovered. Surgical tools should be inserted handle first and not by their working end. The tray with utensils should be placed inside the container which can then be closed
- Only devices manufactured should be included in JDentalCare instrument tray. These validated reprocessing instructions are not applicable to trays that include devices that are not manufactured by JDentalCare

## Packaging

- Surgical instruments should be sterilized individually in sterilization pouches or within surgical kit in sterilization pouches. The pouches must be in medical grade paper and plastic film suitable for steam sterilization and must comply with the requirements of the EN ISO 11607: 1-2 and UNI EN 868-5 standards
- The packaging should be reported variable data as number of sterilization cycle, packaging and expiry date

JDentalCare has validated the sterilization process to ensure sterile instruments for 6 months inside the SBS.

## Sterilization

For steam sterilization of the JDentalCare reusable instruments and surgical kit sterilize as follow*:

- For US Market: Temperature: 132°C/270°F; Sterilization Time: 4 min; Dry Time: 20 min; Pressure: 3 bar; Density of worst-case load: 0,09 gr/$cm^3$
- For EU market: Temperature: 134°C/273°F; Sterilization Time: 4 min; Dry Time: 20 min; Pressure: 3 bar; Density of worst-case load: 0,14 gr/$cm^3$

Caution: do not re-sterilize the same instrument for more than 30 times.

Note: For a correct efficiency of sterilization process, it is recommended to use B-Autoclave compliant with ISO 13060, and to regularly perform control tests suggested in the manufacturer Manual. We recommend to keep and archive all records in a specific document easy to consult in the workplace.

*Validated sterilization parameters to achieve a Sterility Assurance Level (SAL) of 10-6 in accordance to EN ISO 17665-1

## Storage and Transportation

After sterilization, sterile kit with devices should be stored in a limited access area away from dust, moisture, vermin and temperature humidity extremes. Packaging should be carefully examined prior to opening to ensure the integrity.

Maximum storage time: 6 months

Warning: do not use device if the packaging has been damaged or previously opened.

Note: It is recommended to implemented a traceability system including all sterilization phases in order to identify the operator responsible of the process. The following information shall be reported on the pouches:

- Initials of the operator responsible for the sterilization cycle
- Number of sterilization cycle
- Packaging and expiry date

## Disposal

Disposal of the device shall follow local regulations and environmental requirements taking different contamination levels into account.

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