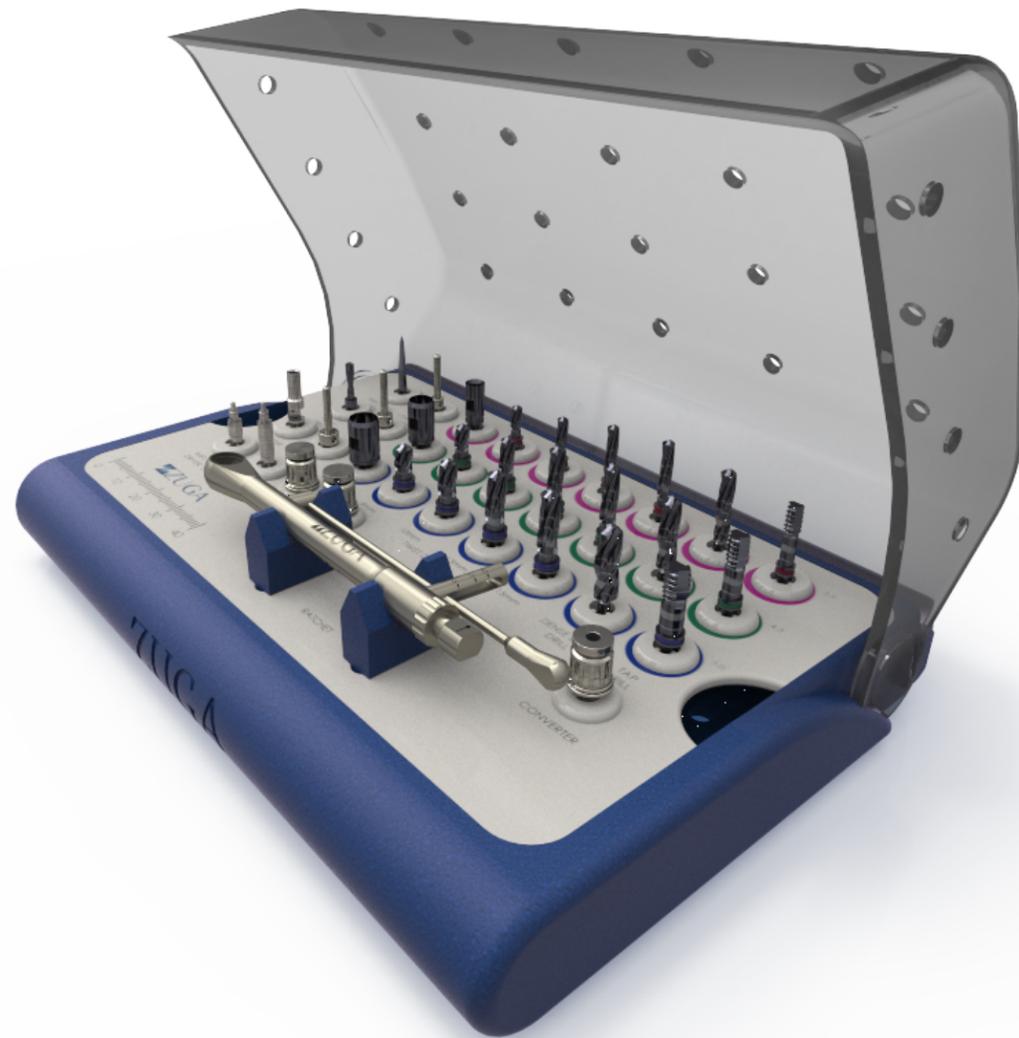




 **ZUGA**

CONVENTIONAL SURGICAL PROCEDURE MANUAL



## ABOUT ZUGA



Zuga Medical focuses on simple restoration and digital guidance during the implant process. Zuga strives for improvements in minimally invasive implanting, precision implants and restorations, and provides dentists with digital implant and restoration products and tools.

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## PRE-OPERATIVE PLANNING

### Clinical Evaluation

A clinical evaluation of the prospective implant site provides the basis for any implant procedure.

- Ensure the patient's current medical conditions or other factors do not put them at risk during the oral surgical procedure or subsequent healing period.
- Evaluate the health of the gingival tissue and other surrounding soft tissues. Prior to placing the implant, it may be necessary to perform additional oral procedures as precaution against contamination or infection from surrounding tissues.



- Confirm adequate inter-occlusal space for the prosthesis at the intended implant site.
- Recommended inter-occlusal space is 2-4mm distance between mandibular teeth and maxillary teeth.
- A minimum of 1mm bone surrounding the implant on all sides is favorable for long-term implant stability.

### Radiographic Evaluation

In addition to clinical evaluation, oral radiographic evaluations such as CT scanning, X-Ray images and implant planning software products provide information beneficial to pre-operative planning.

- Plan against inadvertent penetration of sensitive oral anatomy, such as the inferior alveolar nerve and mental foramina.
- Review location of cavernous anatomical structures such as the mandibular canal, nasal floor, and maxillary sinus, as it is important to leave a 2mm space between such structures and intended implant.
- Determine bone density and bone topography of the intended implant site, which subsequently affects drilling protocol.

## PRE-OPERATIVE PLANNING

### Bone Type Classification

The density and orientation of trabeculae in spongy bone differs from patient to patient and from location to location. These variations can create differences in perceived resistance when preparing the implant site. Bone type is most accurately assessed using numerical values gained from CT scans, measured in Hounsfield units (HU).

Type	Description	CT Value	Visual
D1	Dense cortical bone.	>1250 HU	
D2	Dense to porous cortical bone surrounding dense trabecular bone.	850-1250 HU	
D3	Thin porous cortical bone surrounding fine trabecular bone.	350-850 HU	
D4	Fine trabecular bone.	150-350 HU	

## ZUGA IMPLANT

### Implant Features

Zuga understands the importance of an implant that is continuously stable, integrates quickly, and delivers better aesthetics for the patient. The key to success in osseointegration is achieving immobility between the implant surface and the surrounding bone. With osseointegration in mind, Zuga implants have the following features:



- **Hybrid Shape**  
The upper 2/3 of the Zuga implant is a cylindrical shape; the lower 1/3 is a gradual taper with an anti-rotation flute. As such, the implant is self-tapping while appropriately compressing the bone, which improves bone quality in the implant area.
- **Platform Switching to Reduce Alveolar Bone Loss**  
All Zuga implants connect to all Zuga abutments so that dentists can choose a wide variety of platform switching options, which can facilitate adhesion in the alveolar crest bone. The resulting contact of the gingival soft tissue and abutment surface forms a closure at the implant/abutment intersection, which prevents the loss of alveolar crestal bone, an issue that could affect the health of surrounding hard and soft tissues.
- **High Purity Etched Surface**  
Zuga's proprietary surface treatment provides a uniform rough surface while uniquely maintaining a level of purity to optimize osseointegration.
- **Increased Surface Area to Increase Stability**  
Primary stability and biological retention is proportional to the contact area: the key factor is the shape of thread. Zuga's half-circle thread provides a larger surface contact area between the bone and implant, which condenses bone and helps to establish better osseointegration.
- **Mil Specified Titanium**  
Zuga uses a proprietary melt of commercially pure titanium that increases tensile strength and crush resistance capacity to levels higher than typical medical grade, commercially pure titanium. This yields an implant that provides greater support for abutments and crowns while also optimizing osseointegration expectations.

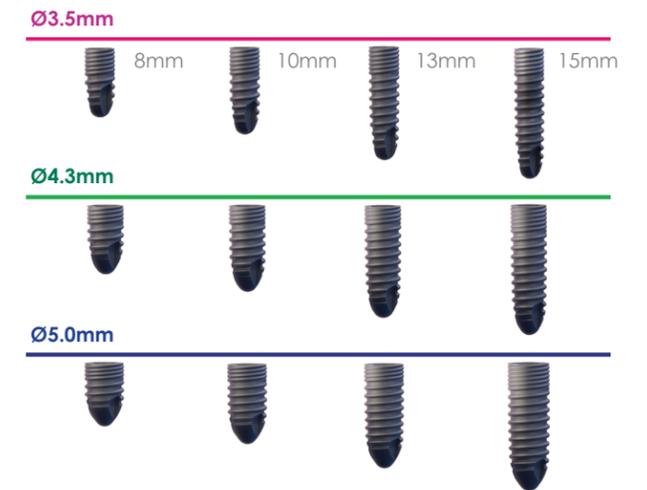
## ZUGA IMPLANT

### Implant Selection

Zuga implants are available in a versatile range of shapes, diameters and lengths for all circumstances, including situations with limited space and/or bone quantity.

- When selecting a diameter of implant, keep in mind that a minimum of 1mm bone surrounding the implant on all sides is favorable for long-term implant stability.
- When selecting a length of implant, ensure that the apex of the implant will not penetrate any unintended anatomical structures.
- A good margin of safety is keeping the apex of the implant at least 2mm from vital structures, such as the mandibular canal.
- In cases of small diameter implants and low bone volume, bone-grafting techniques may be necessary.

Implant Diameters: **Ø3.5mm**, **Ø4.3mm**, and **Ø5.0mm**  
Implant Lengths: 8mm, 10mm, 13mm, and 15mm



# SYSTEM ORGANIZATION

## Color Coding

Zuga's Tool kit organizes cutting tools both sequentially (in the recommended surgical drilling order), and by color markings that correspond to implant diameter. Color-coding the drilling tools provides an intuitive interface ideal for incremental drilling, helping to simplify the implant procedure and reduce risk.



# SYSTEM ORGANIZATION

## Instrument Label Guide

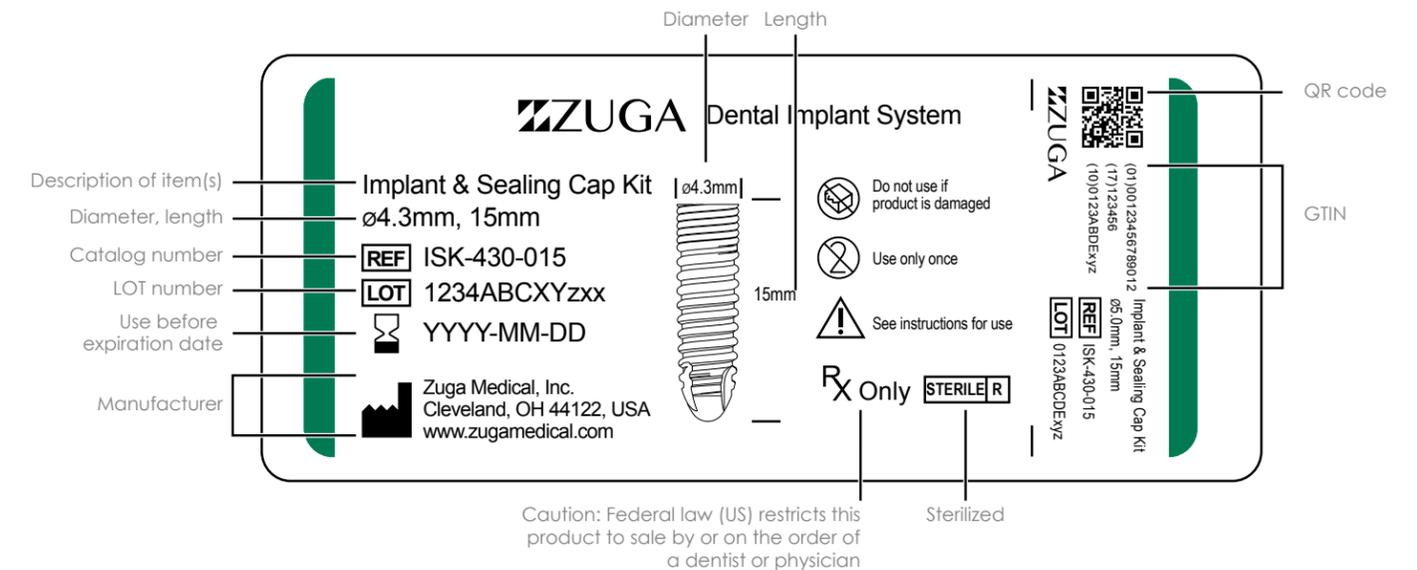
Zuga tools and accessories are color-coded to correspond to implant diameter.

- Magenta: Ø3.5mm
- Green: Ø4.3mm
- Blue: Ø5.0mm



## Implant Label Guide

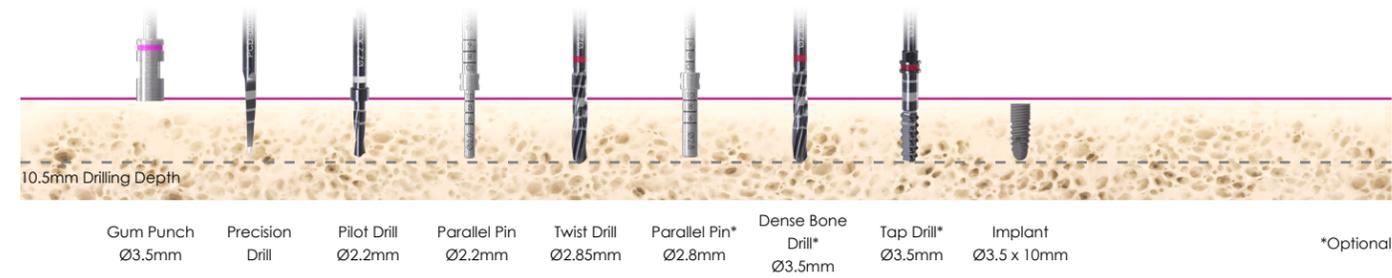
Zuga implants are color-coded by implant diameter. The color of the label corresponds to the diameter of the implant.



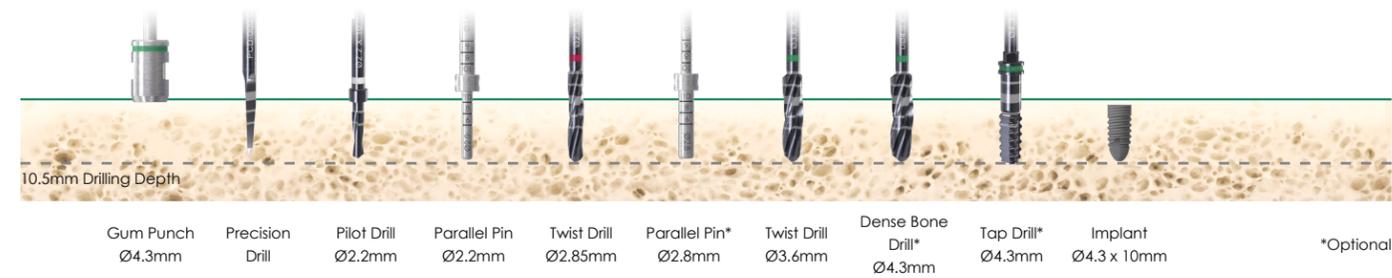
# SURGICAL PROCEDURE

## Drilling Sequence

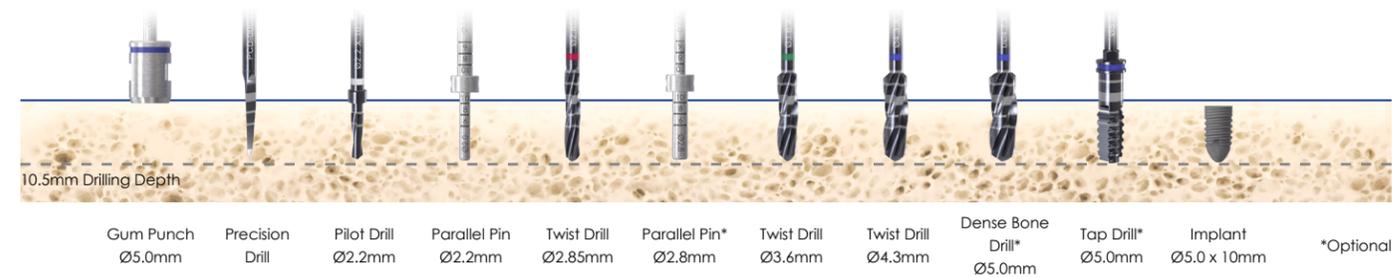
### Ø3.5mm Implant Drilling Sequence



### Ø4.3mm Implant Drilling Sequence



### Ø5.0mm Implant Drilling Sequence



# SURGICAL PROCEDURE

## Drill Protocol

RPM/Torque		Precision Drill	2.2mm Pilot Drill	3.5mm Twist Drill	3.15mm Dense Bone Drill	3.5mm Tap Drill	4.3mm Twist Drill	4.0mm Dense Bone Drill	4.3mm Tap Drill	5.0mm Twist Drill	4.7mm Dense Bone Drill	5.0mm Tap Drill
Implant	Bone Type	1600 RPM	1600 RPM	1600* RPM	1600 RPM	30 RM/45N+cm	1600* RPM	1600 RPM	30 RPM/45N+cm	1600* RPM	1600 RPM	30 RPM/45N+cm
Ø3.5mm	D4	●	●	●	○							
	D3	●	●	●	○							
	D2	●	●	●	●							
	D1	●	●	●	●							
Ø4.3mm	D4	●	●	●			●					
	D3	●	●	●			●	○				
	D2	●	●	●			●	●	●			
	D1	●	●	●			●	●	●			
Ø5.0mm	D4	●	●	●			●			●		
	D3	●	●	●			●			●	○	
	D2	●	●	●			●			●	●	●
	D1	●	●	●			●			●	●	●

● Required step

○ Optional step

\*Adjust motor to 2000 RPM in dense bone.



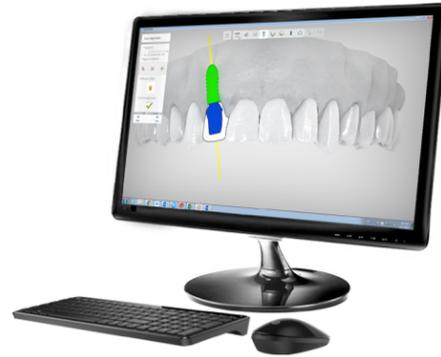
In addition to being powerful, easy-to-use, and versatile additions to any clinician's tool kit, Zuga's cutting tools have a bone-condensing effect, which improves implant stability and encourages osseointegration.

## SURGICAL PROCEDURE

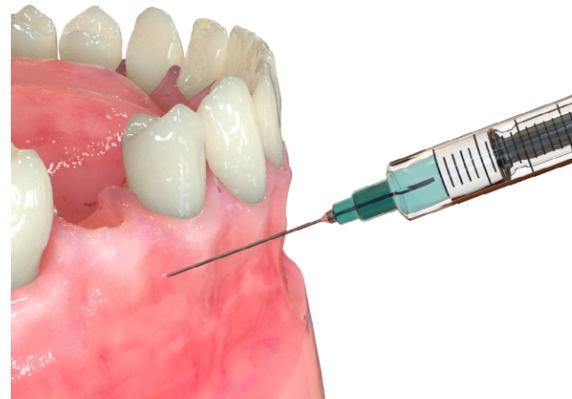
Clinical Implantation

### 1. Planning the Implant Surgery

Take CBCT or X-Ray image(s), use clinical judgment to determine appropriate implant diameter and length. Zuga recommends using one of the many implant planning software products available to help plan the surgery.

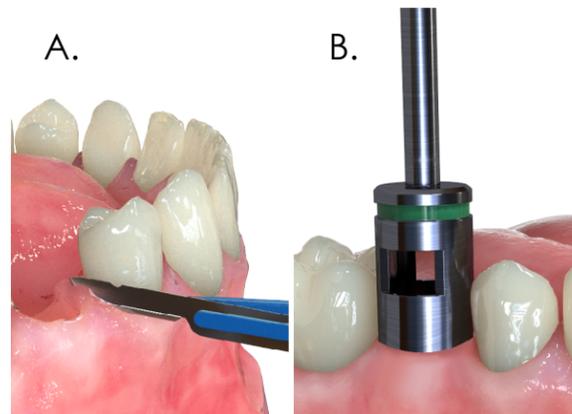


### 2. Administer Local Anesthetic at Planned Implant Site



### 3. Remove Gingiva at Planned Implant Location

- A. Use a #15 scalpel to cut a traditional trapezoidal shape incision, and then reflect the soft tissue, exposing the bone.  
OR:
- B. If choosing a flapless procedure, select the gum punch of the same diameter as the implant, place it into the handpiece, and set the motor at 1200 RPM with desired irrigation. Gently press the gum punch down, removing the gingiva and exposing the bone.



## SURGICAL PROCEDURE

Clinical Implantation

### 4. Flatten Exposed Bone

Once the bone is exposed, use a round bur to flatten the ridge if needed.



### 5. Precisely Define Drilling Location

Select the precision drill, insert it into the handpiece, set the motor for 50 N•cm at 1600 RPM and desired irrigation, and drill at the planned implant location and optimal angulation.



### 6. Drill Pilot Hole

Select the pilot drill, insert it into the handpiece and set the motor for 50 N•cm at 1600 RPM in soft bone, or 2000 RPM in dense bone, with desired irrigation. Drill down to the built-in automatic stop, which helps prevent over-drilling. Ensure location is sufficiently irrigated during the drilling process.



## SURGICAL PROCEDURE

Clinical Implantation

### 7. Identify Relative Location to Adjacent Teeth

Place the  $\varnothing 2.2\text{mm}$  end of the parallel pin into the osteotomy. Confirm the pin location represents optimal location and angulation for the implant based on your planning, while also comparing it to the location of adjacent teeth and/or adjacent parallel pin if multiple implants are planned. Take an X-ray with the parallel pin inserted into the osteotomy to ensure proper alignment.



### 8. Use Smallest Diameter Twist Drill to Widen Osteotomy

Select the twist drill with the length that matches the planned implant, starting with the smallest diameter twist drill, and insert it into the handpiece. Set the motor at 1600 RPM in soft bone, or 2000 RPM for dense bone with desired irrigation. Drill down to built-in automatic stop.



### 9. Identify Relative Location to Adjacent Teeth

Place the  $\varnothing 2.8\text{mm}$  end of the parallel pin into the osteotomy. Confirm the pin location represents optimal location and angulation for the implant based on your planning, while also comparing it to the location of adjacent teeth and/or adjacent parallel pin if multiple implants are planned. Take an X-ray with the parallel pin inserted into the osteotomy to ensure proper alignment. If the osteotomy is at the planned implant diameter and length, skip step 10 and move on to step 11.



## SURGICAL PROCEDURE

Clinical Implantation

### 10. Use Twist Drills to Widen Osteotomy to Planned Implant Diameter

If you are not at the planned implant diameter, repeat the step 8 drilling process, increasing in diameter, but using the same planned drill length, until the osteotomy reaches the planned implant diameter. Ensure location is sufficiently irrigated during the drilling process.



### 11. (Optional) Dense Bone Drill

If the cortical bone is too dense (type 1), use the Dense Bone Drill of the same diameter as the implant, insert it into the handpiece, set the motor at 1600 RPM with desired irrigation, and drill down while progressing through the cortical bone. Ensure location is sufficiently irrigated during the drilling process.



### 12. Thread the Implant Hole

Select the tap drill of the same diameter as the implant, insert it into the handpiece, set the motor for 45 N•cm and 30 RPM and desired irrigation. Drill slowly until reaching the desired depth. Reverse the motor at 35 RPM with 45 N•cm torque and slowly remove the drill.



## SURGICAL PROCEDURE

Clinical Implantation

### 13. Open the Implant Package

Open the implant carton and remove the tray. Remove the seal from the tray, and without touching the implant vial, drop it onto the sterilized surgical table. With surgical gloves, unscrew the vial top, and place the vial on the table for later use.



### 14. Remove the Implant from the Vial

Select the implant adapter from the tool kit. Holding the adapter top between your fingers, place the hex portion of the tool into the hex portion at the top of the implant with a gentle push, and remove the implant from the vial using the adapter.



OR:

Select the implant driver from the tool kit and attach to the handpiece. Place the hex portion of the driver into the hex portion at the top of the implant with a gentle push, and remove the implant from the vial using the driver.

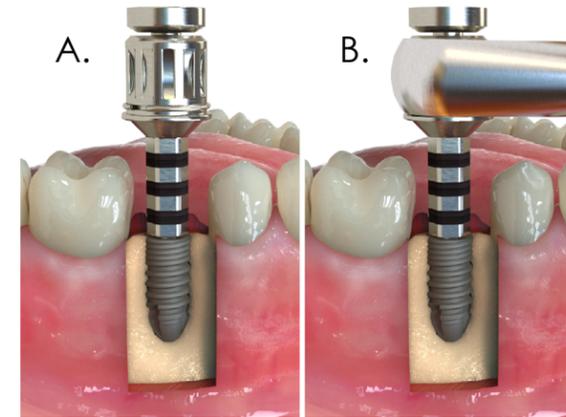


## SURGICAL PROCEDURE

Clinical Implantation

### 15. Place the Implant

- A. Place the implant into the receptor site.
- B. Use the ratchet to tighten the implant. Typical torque of  $\leq 35 \text{ N}\cdot\text{cm}$  at a speed of 15 RPM is acceptable; however, torque selection is subject to variables requiring clinical judgment and may be based on the planning process described previously.



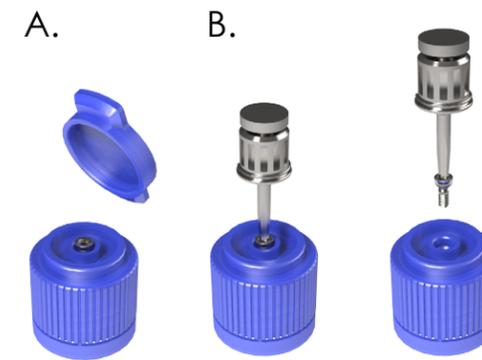
OR:

Place the implant into the receptor site using the handpiece. Install the implant with the handpiece at a low speed of 15 RPM and maximum torque set to  $35 \text{ N}\cdot\text{cm}$ .



### 16. Remove Sealing Cap from Vial Cap

- A. Wearing surgical gloves, pick up the vial top. Using the tabs, remove the vial cap cover.
- B. Use the restoration adapter to remove the sealing cap from the vial top.



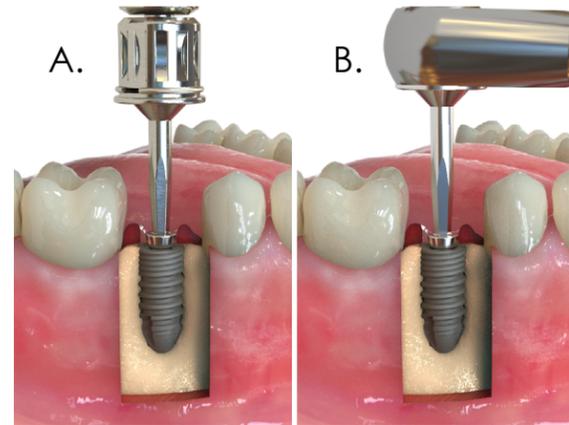
## SURGICAL PROCEDURE

### Clinical Implantation

#### 17. Place Sealing OR Healing Cap

Placing a sealing cap:

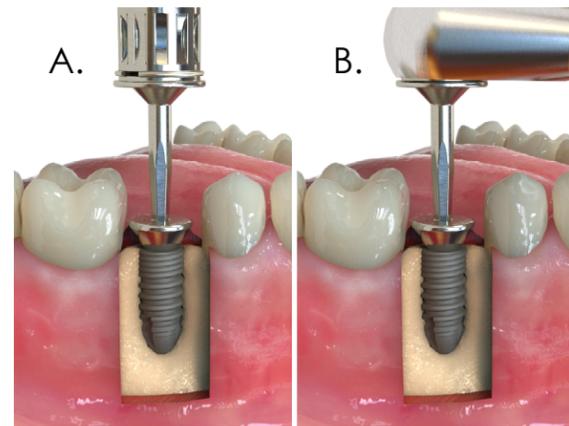
- Using the restoration adapter, gently place the sealing cap at the same angle as the implant. Rotate the restoration adapter using light finger force until the threads in the healing cap and the internal threads of the implant engage each other.
- Use the ratchet to tighten and secure the healing cap into place. Recommended torque 15 N•cm.



OR:

Placing a healing cap:

- Select the appropriate Zuga healing cap based on implant and abutment diameter and length. Using the restoration adapter, gently place the healing cap at the same angle as the implant. Rotate the restoration adapter using light finger force until the threads in the healing cap and the internal threads of the implant engage each other.
- Use the ratchet to tighten and secure the healing cap into place. Recommended torque 15 N•cm.



#### 18. Adapt Gingiva

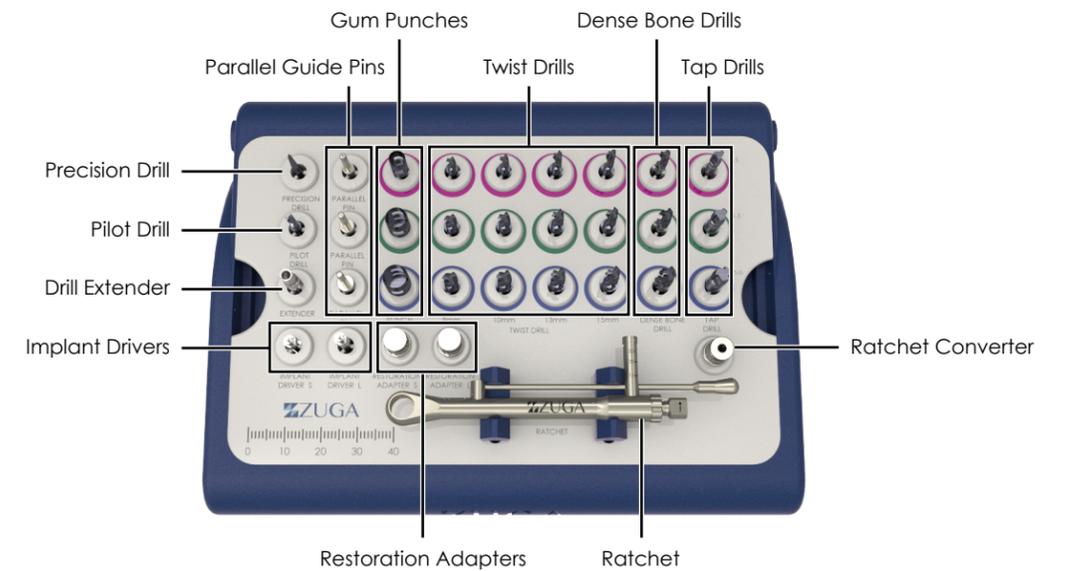
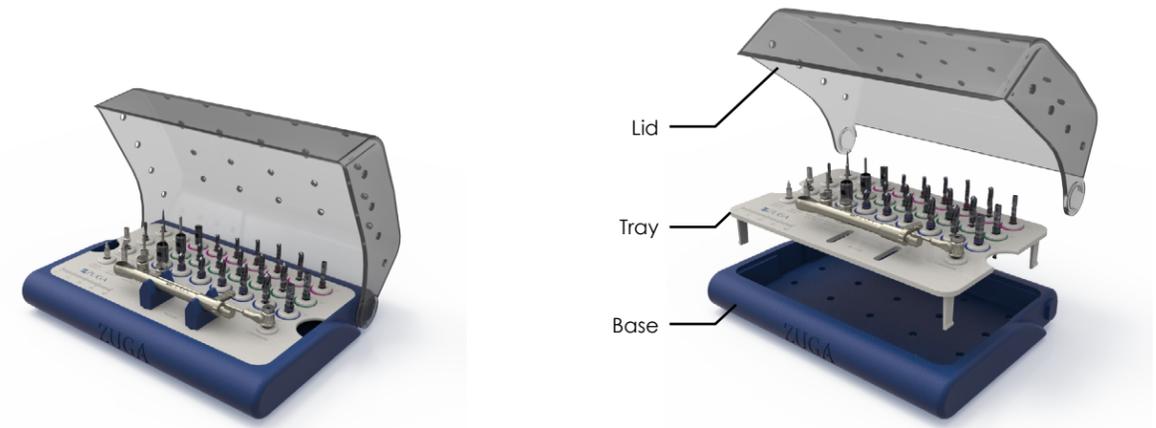
In the case of an implant site previously opened with a flap technique, adapt and suture gingiva to surround the healing or sealing cap. Allow an adequate healing period (recommended 3 months in the mandible and 6 months in the maxilla) for osseointegration.



## PRODUCT INFORMATION

### Standard Tool Kit Overview

Zuga optimizes the implant placement process by providing clinicians a tool kit that is powerful, versatile, easy to clean, and easy to understand. Zuga's tool kit features the highest quality, corrosion-resistant, surgical stainless steel instruments designed to accommodate any surgical or restorative implant procedure.



## PRODUCT INFORMATION

### Tool Details

#### Precision Drill

Precisely defines the entry point for subsequent drills.

Product Number:	PCD-000-000
Drilling Length:	15.5mm
Markings:	6.5mm, 8.5mm, 10.5mm



#### Round Bur

Used to flatten and smooth any irregularities in the patient's osteotomy once the ridge is exposed.

Drilling Diameter	Part Number
1.4mm	RBT-000-002
2.3mm	RBT-001-002
3.1mm	RBT-002-002



#### Pilot Drill

Provides an entry hole for subsequent drills. Includes automatic stop to prevent over-drilling.

Product Number:	PDT-000-008
Diameter:	2.2mm
Drilling Length:	8.5mm



#### Gum Punch

The minimally-invasive Zuga gum punch removes a small section of gingival tissue at the implant site when performing a flapless procedure.

Drilling Diameter	Part Number
4.9mm	GST-350-000
5.7mm	GST-430-000
6.4mm	GST-500-000



## PRODUCT INFORMATION

### Tool Details

#### Parallel Guide Pin

Measures the depth of the implant entry site. Equipped with a hole that, when a suture is fed through it, ensures the pin is easily retrievable from the implant site.

Waist Diameter (D <sup>1</sup> )	Pin Diameter (D <sup>2</sup> )	Pin Diameter (D <sup>3</sup> )	Part Number
3.5mm			PGP-350-000
4.3mm	2.0mm	2.8mm	PGP-350-000
5.0mm			PGP-350-000



#### Standard Twist Drill

Expands the diameter of the receptor site. The large variety of lengths and diameters allows for safer incremental drilling. Includes automatic stop to prevent over-drilling.

Diameter	Drilling Length	Markings (mm)	Part Number
3.5mm	8.5mm	6.5	TWD-350-008
	10.5mm	6.5, 8.5	TWD-350-010
	13.5mm	6.5, 8.5, 10.5-12.0	TWD-350-013
4.3mm	15.5mm	6.5, 8.5, 10.5-12.0, 13.5	TWD-350-015
	8.5mm	6.5	TWD-430-008
	10.5mm	6.5, 8.5	TWD-430-010
5.0mm	13.5mm	6.5, 8.5, 10.5-12.0	TWD-430-013
	15.5mm	6.5, 8.5, 10.5-12.0, 13.5	TWD-430-015
	8.5mm	6.5	TWD-500-008
5.0mm	10.5mm	6.5, 8.5	TWD-500-010
	13.5mm	6.5, 8.5, 10.5-12.0	TWD-500-013
	15.5mm	6.5, 8.5, 10.5-12.0, 13.5	TWD-500-015



#### Dense Bone Drill

Modifies the shape of the receptor site to be comparable to the shape of the implant at the cortical level.

Diameter	Drilling Length	Markings	Part Number
3.5mm			DBD-350-000
4.3mm	7.8mm	5.3mm, 6.3mm	DBD-430-000
5.0mm			DBD-500-000



## PRODUCT INFORMATION

Tool Details

### Tap Drill

Threads the implant receptor site to match the external threads of the implant. In D1 and D2 density bone, be cautious creating large amounts of torque.

Diameter	Drilling Length	Markings	Part Number
3.5mm			TPT-350-000
4.3mm	8.5mm	10.5mm, 13.5mm	TPT-430-000
5.0mm			TPT-500-000

### Implant Drill Extender

Extends the default length of any drill shaft. Do not use the implant drill extender to extend torque-transferring instruments such as the implant driver.

Product Number: IDE-000-000

### Implant Driver

Used in conjunction with the handpiece to transport an implant and install in the osteotomy. Transfers torque from the handpiece to the implant in the receptor site.

Length	Markings (mm)	Part Number
25.0mm	5.3	PPT-000-100
33.0mm	5.3, 7.3, 9.3	PPT-000-200

### Implant Adapter

Used to manually transport an implant and install in the osteotomy. When used in conjunction with the ratchet, the implant adapter transfers torque from the ratchet to the implant.

Length	Markings (mm)	Part Number
24.3mm		RIA-000-100
29.3mm	5.3, 7.3, 9.3	RIA-000-200



## PRODUCT INFORMATION

Tool Details

### Restoration Adapter

Used to manually transport and install restoration components such as the sealing cap or healing cap. Kit includes two length options.

Length	Part Number
23.3mm	RSA-000-100
29.3mm	RSA-000-200

### Ratchet Converter

Enables any drill-based Zuga instrument to connect to the ratchet. Once connected to the ratchet, the ratchet converter allows for the transfer of torque from the ratchet to any drill-based Zuga instrument.

Product Number: RAT-000-000

### Torque Ratchet

Provides and transfers torque to secure implants or other components.

Product Number: TRK-000-000

Torque Markings: 15 N•cm, 35 N•cm, 50 N•cm



## PRODUCT INFORMATION

### Torque Guide

Procedure Type	Recommended Torque	Visual
Implant installation	>35 N•cm, if possible	
Temporary restorations on all levels	15 N•cm	
Final (non-edentulous) restorations on implant level	30-35 N•cm	
Healing components	Manual/light finger pressure (5-10 N•cm)	

## CLEANING & STORAGE

### Restoration Component Sterilization

Zuga abutments and most restoration components are supplied non-sterile and must be sterilized before use.

To sterilize abutments and other non-sterile healing components:

- Remove the items from the packaging.
- Place each item in a separate autoclave sterilization pouch.
- Steam gravity sterilize (Autoclave) for fifteen (15) minutes at a temperature of 270°F (132°C).
- Dry for 30 minutes minimum.

### Instrumentation & Kit Sterilization

Before tool kit sterilization, please thoroughly wash using the following procedure:

- Remove the tool kit tray from the case/box.
- Scrub all surfaces of the tool kit tray and case with mild soap using a soft-bristled brush.
- Rinse both the tray and case with running tap water to remove all soap.
- Inspect and ensure both items are clean. Allow to dry.
- Insert toolkit tray back into the case. Insert the cleaned tools and instruments back into the tray.

Reusable drills/burs, and instrumentation are supplied non-sterile and must be sterilized prior to use.

To sterilize the Zuga tool kit or reusable instrumentation:

- Put the entire Zuga Tool Kit in its tray into an autoclave sterilization pouch after washing, using ultrasonic, and drying.
- If you are sterilizing a single instrument, place it in an autoclave sterilization pouch.
- Steam gravity sterilize (Autoclave) for fifteen (15) minutes at a temperature of 270°F (132°C).
- Dry for 30 minutes minimum.

Tools and instruments with rust will contaminate the water circulation system in the autoclave. This will then cause rust to appear on all tools and instruments in the future. Please check and clean your tools and instruments regularly after the implant procedure is completed.

All drills can be used approximately twenty times. If drills are not reused, dispose them in a sharps container immediately.

### Storage

Restoration components should be completely dried and stored in a moisture-free environment at room temperature. Failure to do so might result in corrosion of the stainless steel tools and instruments. Inspect the sterilized bag/pouch prior to each use to ensure it is still properly sealed. If there is any question as to whether it is properly sealed, the tool kit should not be used. It should be cleaned and sterilized per the guidelines above. Check the manufacturer's instructions to determine for how long the sterilized bags/pouches are good. If the maximum storage time has been exceeded, the tools and instruments must be re-sterilized.

The validated procedures require the use of FDA cleared sterilizers, sterilization trays, sterilization wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. Follow general rules and guidance of dental surgery, sterilization, and maintenance in handling and storing the Zuga Dental Implant System Tool Kit.

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 **ZUGA**