

Full IFU:

[Versah.com/instruction-for-use/](http://Versah.com/instruction-for-use/)



Densah® Bur, ZGO™ Densah® Bur & Versah® Universal Guided Surgery System  
Instructions for Use

## SECTIONS

1. Osteotomy Preparation .....	p04
2. Unique Characteristics and Clinical Advantages.....	p09
3. Densah® Burs Versatile Utilization .....	p12
4. The Densah® Bur Kit .....	p19
5. Indications and Contraindications for the Use of Densah® Burs .....	p28
6. Versah® Guided Surgery System.....	p44
7. The ZGO™ Densah® Bur Kit.....	p50
8. Indications and Contraindications for the Use of ZGO™ Densah® Burs.....	p58
9. Versah® ZGO™ Guided Surgery System .....	p67
10. Densah® Burs and Accessories Maintenance, Cleaning, and Storage .....	p70
VERSAH® TERMS AND CONDITIONS OF SALE .....	p76

\*Please visit [versah.com/ifu-manuals](https://versah.com/ifu-manuals) for the most current IFU

# 7. The ZGO™ Densah® Bur Kit









The ZGO™ Densah® Bur kit includes 8 burs that are designed to create osteotomies for all major zygomatic implants in the market. The 65 mm length ZGO™ Densah® Burs are marked with depth markings from 15-45 mm. The 90 mm length ZGO™ Densah® Burs are marked with depth markings from 15-60 mm. They are designed to be used in a consecutive increasing order to achieve the desired osteotomy diameter.

## **Included in the Kit:**

- 4 ZGO™ Densah® Burs - 65 mm length
- 4 ZGO™ Densah® Burs - 90 mm length
- 1 Universal ZGO™ Densah® Bur Holder
- 2 ZGO™ Densah® Tapered Pilot Drills
- 2 ZGO™ Guided Keys

## I. Included in the Kit

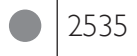
ZGO™ Densah® Burs are designed to be used for osseodensification in small increments in dense trabecular bone to allow gentle expansion of the osteotomy. **In soft bone**, the osteotomy final preparation diameter should be prepared with the ZGO™ Densah® Bur with an average diameter that measures **0.5-0.7 mm smaller** than the implant major diameter. **In hard bone**, the osteotomy final preparation diameter should be prepared with ZGO™ Densah® Bur with an average diameter that measures **0.2-0.3 mm smaller** than the implant major diameter. **With Osseodensification, bone preservation creates a spring back effect. As a rule, osteotomies must not be undersized beyond the above stated parameters.**

ZT™ 65 mm Series				ZT™ 90 mm Series			
ZT1525-65	ZT2030-65	ZT2535-65	ZT3040-65	ZT1525-90	ZT2030-90	ZT2535-90	ZT3040-90
							

## ZT™ 65 mm Series



3040



2535



2030



1525



Pilot

## ZT™ 90 mm Series



3040



2535



2030



1525



Pilot



In abundant dense bone: ZGO™ Densah® Bur to be used in Cutting Mode (800-1500 rpm) in Clockwise direction or to be used with (Densify-Preserve) after Cut (DAC) protocol (see page 59).

Please refer to ZGO™ Densah® Bur Animation for general use instruction.  
To view, visit us on the web at [www.versah.com/zgo-densah-bur](http://www.versah.com/zgo-densah-bur)

## I. Included in the Kit

The ZGO™ Densah® Burs (65 mm & 90 mm) are internally irrigated\* (as shown in figure I). The ZGO™ Tapered Pilot Drill is only externally irrigated. **The ZGO™ Tapered Pilot Drill and ZGO™ Densah® Burs are single use only.**

\*To ensure proper irrigation through the ZGO™ Densah® Burs, the handpiece must be able to supply internal irrigation.

### ZT2535-65 mm

figure I



## I. Modes

ZGO™ Densah® Burs progressively increase in diameter throughout the surgical procedure and are designed to be used with a **standard surgical motor**, to preserve and compact bone (800-1500 rpm) in a counterclockwise direction (**Densifying Mode**), and to precisely cut bone if needed (800-1500 rpm) in a clockwise direction (**Cutting Mode**).

Counterclockwise (CCW)  
Non-Cutting Direction



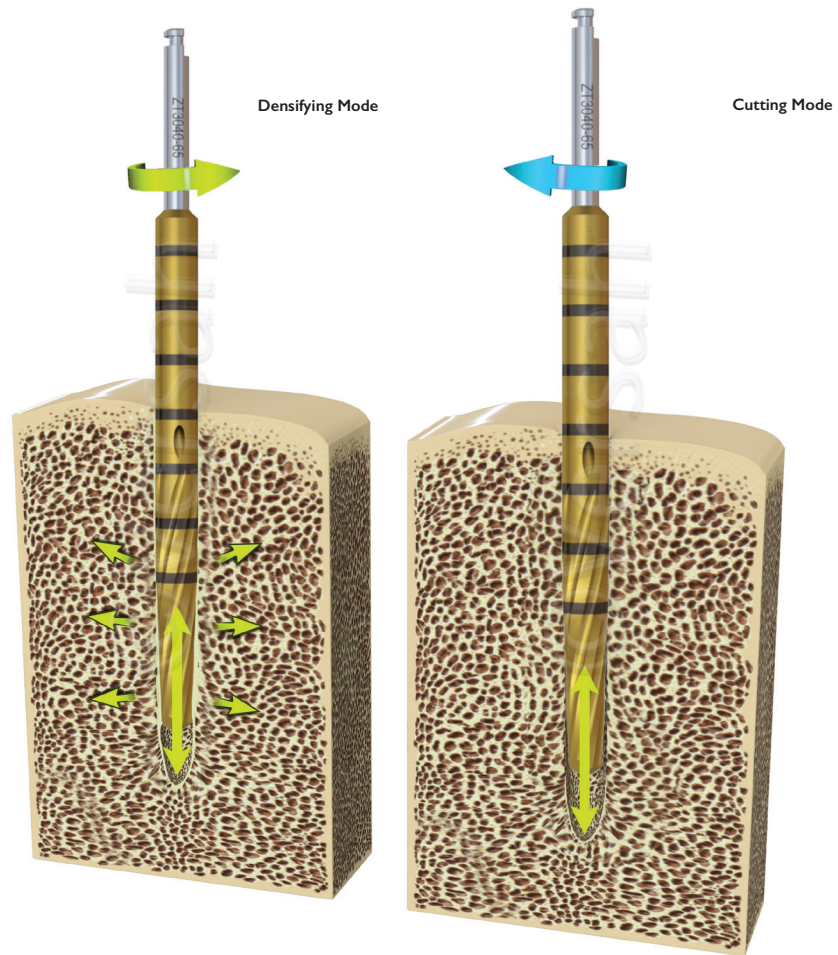
Clockwise (CW)  
Cutting Direction



## II. Motion

The ZGO™ Densah® Burs are always to be used with copious irrigation in a **Bouncing-Pumping motion** (vertical pressure to advance the drill into the osteotomy, then a minor pull out for pressure relief, then advance with vertical pressure again and so on in an in/out fashion). The duration and number of bouncing-pumping episodes (in/out) are usually dictated by bone density and desired length.

For more information, visit us on the web at [www.versah.com/versah-zgo-densah-bur/](http://www.versah.com/versah-zgo-densah-bur/)



### III. ZGO™ 65 mm Densah® Bur Marking

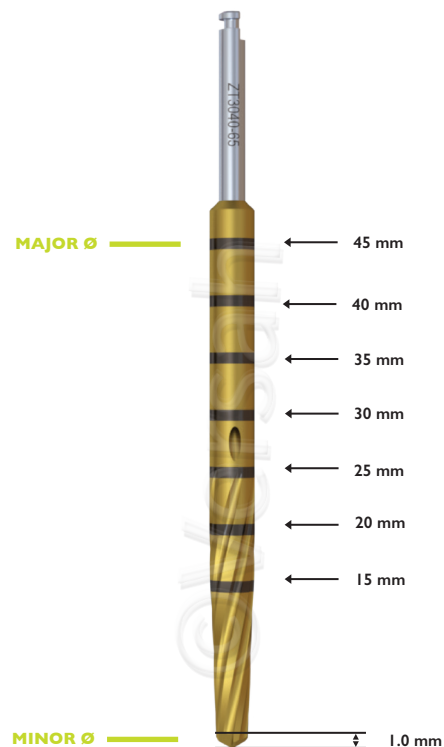
ZGO™ Densah® Burs are internally irrigated and designed to be used at drill speeds of 800-1500 rpm. They are marked with laser markings<sup>1</sup> from 15-45 mm depth. ZGO™ Densah® Burs have a tapered geometry dimension. Eg., ZGO™ Densah® Bur ZT3040-65 mm has a **(minor-diameter)** of 3.0 mm and a coronal **(major-diameter)** of 4.0 mm.

NOTE: Cutting and Densifying must be done under constant water irrigation. A pumping motion is required to prevent over heating. Surgical burs are single use and are to be replaced after every surgery.

#### Drilling Depth

Measure the drilling depth of the ZGO™ Densah® Bur from the widest part of its tip to the indication line. Regardless of the ZGO™ Densah® Bur diameter, the maximum additional tip depth is 1.0 mm.

### ZGO™ 65 mm Densah® Bur Laser Lines



1. The accuracy of laser markings are tested within +/- .5 mm.

### III. ZGO™ 90 mm Densah® Bur Marking

ZGO™ Densah® Burs are internally irrigated and designed to be used at drill speeds of 800-1500 rpm. They are marked with laser markings<sup>1</sup> from 15-60 mm depth. ZGO™ Densah® Burs have a tapered geometry dimension. Eg., ZGO™ Densah® Bur ZT3040-90 mm has a **(minor-diameter)** of 3.0 mm and a coronal **(major-diameter)** of 4.0 mm.

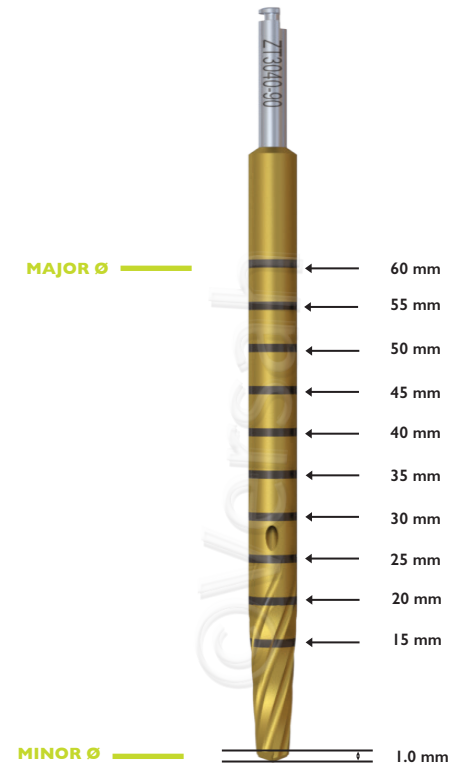
NOTE: Cutting and Densifying must be done under constant water irrigation. A pumping motion is required to prevent over heating. Surgical burs are single use and are to be replaced after every surgery.

#### Drilling Depth

Measure the drilling depth of the ZGO™ Densah® Bur from the widest part of its tip to the indication line. Regardless of the ZGO™ Densah® Bur diameter, the maximum additional tip depth is 1.0 mm.

1. The accuracy of laser markings are tested within +/- .5 mm.

### ZGO™ 90 mm Densah® Bur Laser Lines



# 8. Indications and Contraindications for the Use of ZGO™ Densah® Burs

## Indications

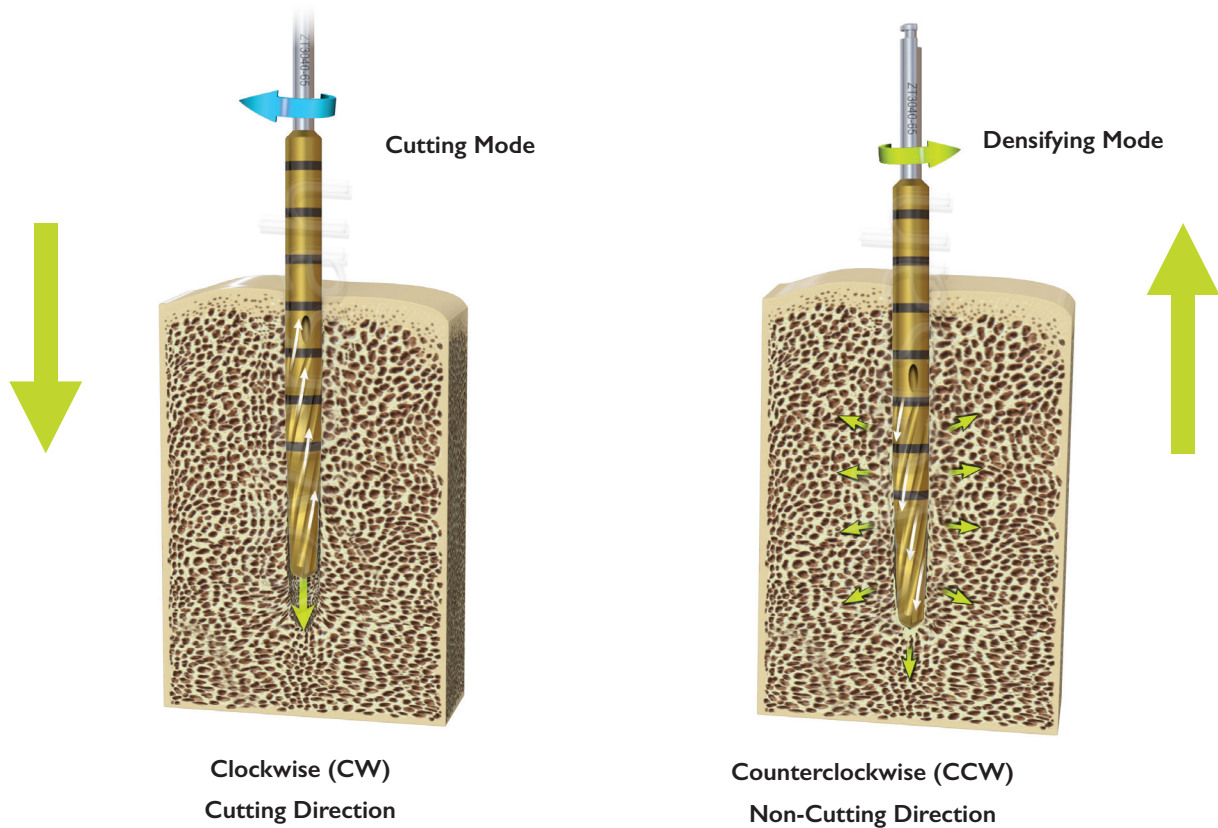
1. ZGO™ Densah® Burs are indicated for use to prepare osteotomies for implant placement in maxilla (including the zygoma and pterygoid implants).
2. The ZGO™ Tapered Pilot Drills are used to create the initial hole in bone to prepare an osteotomy for zgomatic implant placement and monitor the drilling depth.
3. The Universal ZGO™ Densah® Bur Holder is only a holder for the ZGO™ Densah® Burs, the ZGO™ Tapered Pilot Drills, and ZGO™ Guided Keys.

## Contraindications

1. Osseodensification does not work in cortical bone. In (Type I/Dense Bone); use the ZGO™ Densah® Burs in Cutting Mode (CW) and reverse-out (CCW) to re-autograft. (Densify-Preserve after Cut Protocol).
2. Traditional guided surgery may present a higher risk of implant failure due to its limitation in allowing the needed bouncing technique and adequate irrigation. Use the ZGO™ C-Guide® and Guided Keys for zygomatic guided surgery. (p68)
3. Avoid Densifying Xenograft.
4. **Do not apply lateral pressure when drilling with the ZGO™ Tapered Pilot Drill.**

The general health of dental implant patient candidates should be carefully evaluated prior to treatment. Patients with serious medical problems or in poor health should not receive dental implant treatment. Patients with medical problems such as: compromised immune system, drug or alcohol abuse, uncontrollable bleeding, endocrine disorders or titanium allergy should be carefully evaluated prior to treatment or excluded. Clinician experience and judgment should be used in conjunction with the Implant System Drilling Protocol recommendation and suggested use protocols. Do not apply lateral pressure when drilling with the pilot drill.

## (Densify - Preserve) after Cut (DAC) Protocol



\*Clinician experience and judgment should be used in conjunction with the suggested use protocols.

## I. Osseodensification in Medium and Soft Trabecular Bone Qualities

1. Reflect the soft tissue using the technique indicated for the implant position.
2. Drill to the desired depth using the ZGO™ Tapered Pilot Drill (*Drill speed 800-1500 rpm with copious irrigation*). When drilling do not apply lateral pressure, and monitor drilling depth.
3. Depending upon the implant type and diameter selected for the site, begin with the narrowest ZGO™ Densah® Bur. **Set the surgical motor to reverse** (*Counterclockwise drill speed 800-1500 rpm with copious irrigation*).
4. Begin running the bur into the osteotomy in a Densifying CCW direction. When feeling the haptic feedback of the bur pushing up out of the osteotomy, **modulate pressure with a pumping motion** until reaching the desired depth. Copious irrigation is always necessary.
5. If resistance is felt, gently increase the pressure and the number of bouncing-pumping motions to achieve desired depth.
6. Place the implant into the osteotomy. If using the surgical motor to tap the implant into place, the unit may stop when reaching the placement torque maximum. Finish placing the implant to depth with a torque indicating wrench.

\*This is a suggested protocol

## II. Osseodensification in Dense Trabecular Bone Quality

We recommend the **use of the ZGO™ Densah® Burs in small increments. Increase the number of bouncing-pumping motions** to achieve desired depth.

1. Reflect the soft tissue using the technique indicated for the Zygoma/Pterygoid implant procedure.
2. Use the ZGO™ Tapered Pilot Drill (*Drill speed 800-1500 rpm with copious irrigation*) to prepare the osteotomy either completely through the zygomatic process or 1 mm deeper than the implant length.
3. Depending upon the implant type and diameter selected for the site, begin with the narrowest ZGO™ Densah® Bur. **Set the surgical motor to reverse** (*Counterclockwise drill speed 800-1500 rpm with copious irrigation*). Begin running the bur into the osteotomy. When feeling the haptic feedback of the bur pushing up out of the osteotomy, **modulate pressure with a pumping motion** until reaching the desired depth. You may notice resistance and a gentle hammering effect while pressing down to advance the bur into the osteotomy.

*Continued on next page*

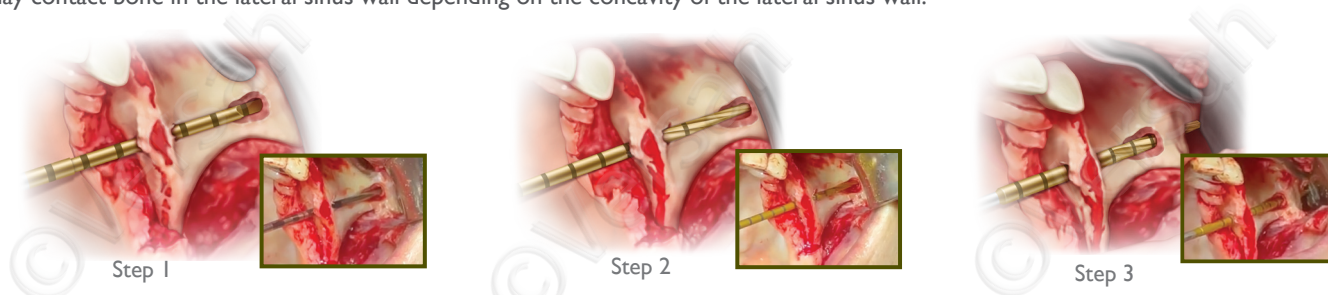
## II. Osseodensification in Dense Trabecular Bone Quality

4. **(Densify - Preserve) after Cut (DAC) if needed:** When strong resistance may be felt, approaching the zygomatic process, **change the surgical motor to forward-Cutting Mode** (Clockwise direction at 800-1500 rpm with copious irrigation). Begin advancing the ZGO™ Densah® Bur into the osteotomy until reaching the desired depth. **Stay in the osteotomy, change the surgical motor back to reverse-Densifying Mode** (CCW direction) to densify and auto-graft the cut bone back into the osteotomy walls. By not removing the bur from the osteotomy between cutting and densifying modes, bone particles would be deposited inside the boundaries of the osteotomy. (See page 59 for illustration.)
5. Place the implant into the osteotomy. If using the surgical motor to tap the implant into place, the unit may stop when reaching the maximum placement torque. Finish placing the implant to depth with a torque indicating wrench.
6. In abundant dense bone: ZGO™ Densah® Bur may be used in Cutting Mode (800-1500 rpm) in Clockwise direction or to be used with Densify-Preserve after Cut (DAC) protocol.

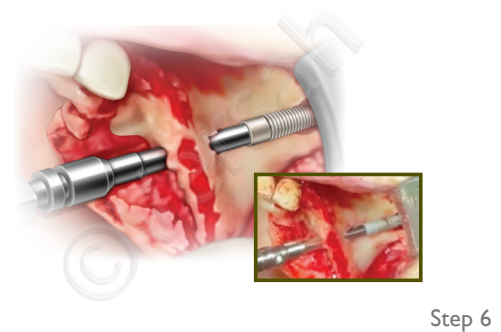
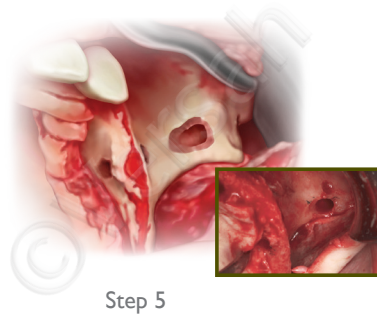
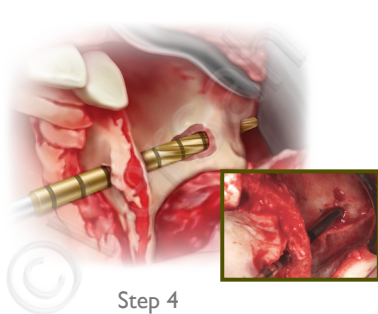
\*This is a suggested protocol

### III. Osseodensification ZAGA™ Type I-III Protocol for the Intra-maxillary - Placement\*

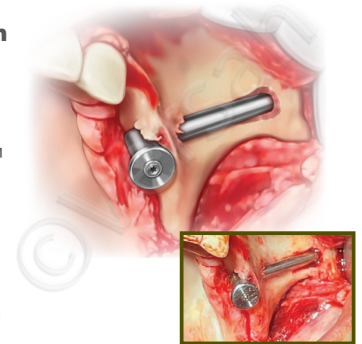
**Overview:** ZAGA™ Type I-III starts within the alveolar bone and follows predominantly the posterior – lateral sinus wall path. In these cases, the anterior maxillary wall is concave. The implant head is located within the alveolar crest and most of the body has either an intra sinus or extra sinus path. The implant contacts bone in the coronal alveolar bone and apical zygoma bone. The middle part of the implant body may contact bone in the lateral sinus wall depending on the concavity of the lateral sinus wall.



1. Use the 65 mm ZGO™ Tapered Pilot drill in CW at 800-1500 rpm to start creating a tunnel osteotomy through the alveolar crest following a trajectory that goes from the palatal into the upper buccal alveolar bone drilling into the body for the Zygoma perforating it apically through its superior lateral aspect.
2. Then use the 65 mm ZGO™ Densah® Burs in a consecutive increasing order to achieve the desired diameter of the tunnel osteotomy through the alveolar crest into the body of the Zygoma perforating apically reaching its lateral superior aspect. This is best done in CCW mode at 800-1500 rpm with copious irrigation in order to maintain and preserve the alveolar crest integrity.
3. The ZGO™ Densah® Bur exits the crestal tunnel osteotomy, glances along the lateral sinus wall and then penetrates into the zygomatic bone to create a “tunnel” osteotomy of the appropriate length and diameter just perforating apically through the superior-lateral aspect of the body of the zygoma. If necessary, use the longer 90 mm ZGO™ Densah® Burs in order to perforate apically through the body of the zygoma.



4. **Depending on the patient's anatomy and size, use the appropriate length (65 mm or 90 mm length) ZGO™ Densah® Burs** in a consecutive increasing order to achieve the desired osteotomy diameter along or within the lateral sinus wall depending on the zygomatic implant diameter and length to be placed. The zygoma bone hardness will determine the mode of the ZGO™ Densah® Bur (cutting mode (CW), densifying mode (CCW), or Densify-Preserve after Cut (DAC) protocol).
5. **The osteotomy final preparation should be prepared with the appropriate ZGO™ Densah® Bur** to be slightly undersized by an average 0.5-0.7 mm smaller than the zygomatic implant major diameter.
6. **Place the zygomatic implant.**

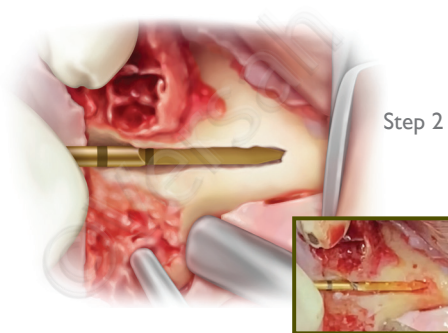
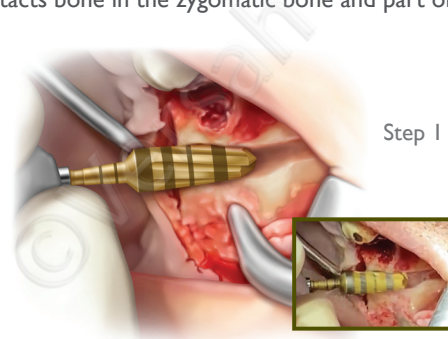


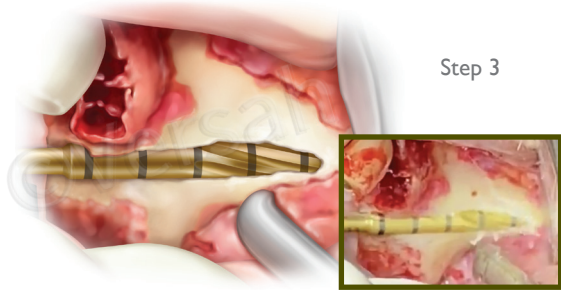
\*Clinician experience and judgment should be used in conjunction with this suggested use protocol

## IV. Osseodensification ZAGA™ Type IV Protocol for the Extra-maxillary - Placement\*

**Overview:** ZAGA™ Type IV follows an extra-maxillary path. **The maxilla and alveolar bone show extreme vertical and horizontal atrophy.** The implant head is located buccal to the alveolar crest usually in a “channel” osteotomy. There is either no osteotomy, or a minimal osteotomy in the form of a “channel” at this level. Most of the zygomatic implant body has an extra sinus/extra-maxillary path. The coronal part of the zygomatic implant is extra-maxillary usually in a “channel” whereas the apical part of the implant is surrounded by bone in a “tunnel” osteotomy in the zygomatic bone. The zygomatic implant contacts bone in the zygomatic bone and part of the external lateral sinus wall.

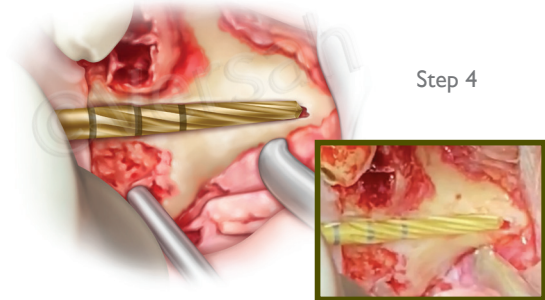
1. Create the coronal "channel" osteotomy: use the Densah® Burs in half increments starting with the VT1525 (2 mm) working up to VT3545 (4 mm) in Cutting Mode CW at 800 – 1500 rpm with copious irrigation as a “side cutter” to **create a channel in the residual alveolar ridge and lateral wall of the maxillary sinus.**
2. Then use the 65 mm/90 mm ZGO™ Tapered Pilot drill in CW at 800– 1500 rpm through the “channel” to enter the inferior aspect of the body of the zygoma in order to **prepare a “tunnel” osteotomy of the appropriate length just perforating apically through the superior-lateral aspect of the body of the Zygoma.**





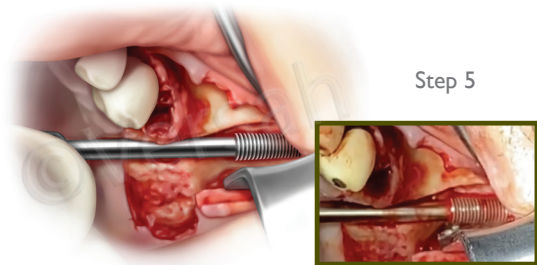
Step 3

3. Depending on the patient's anatomy and size, **use the appropriate length (65 mm or 90 mm length) ZGO™ Densah® Burs in a consecutive increasing order to achieve the desired osteotomy diameter and length** depending on the zygomatic implant diameter and length to be placed. This is done either in cutting mode (CW), densifying mode (CCW), or Densify-Preserve after Cut (DAC) protocol depending on the Zygoma bone hardness.



Step 4

4. **The osteotomy final preparation should be prepared with the appropriate ZGO™ Densah® Bur to be slightly undersized by an average 0.5–0.7 mm smaller than the zygomatic implant major diameter.**



Step 5

5. **Place the zygomatic implant.**

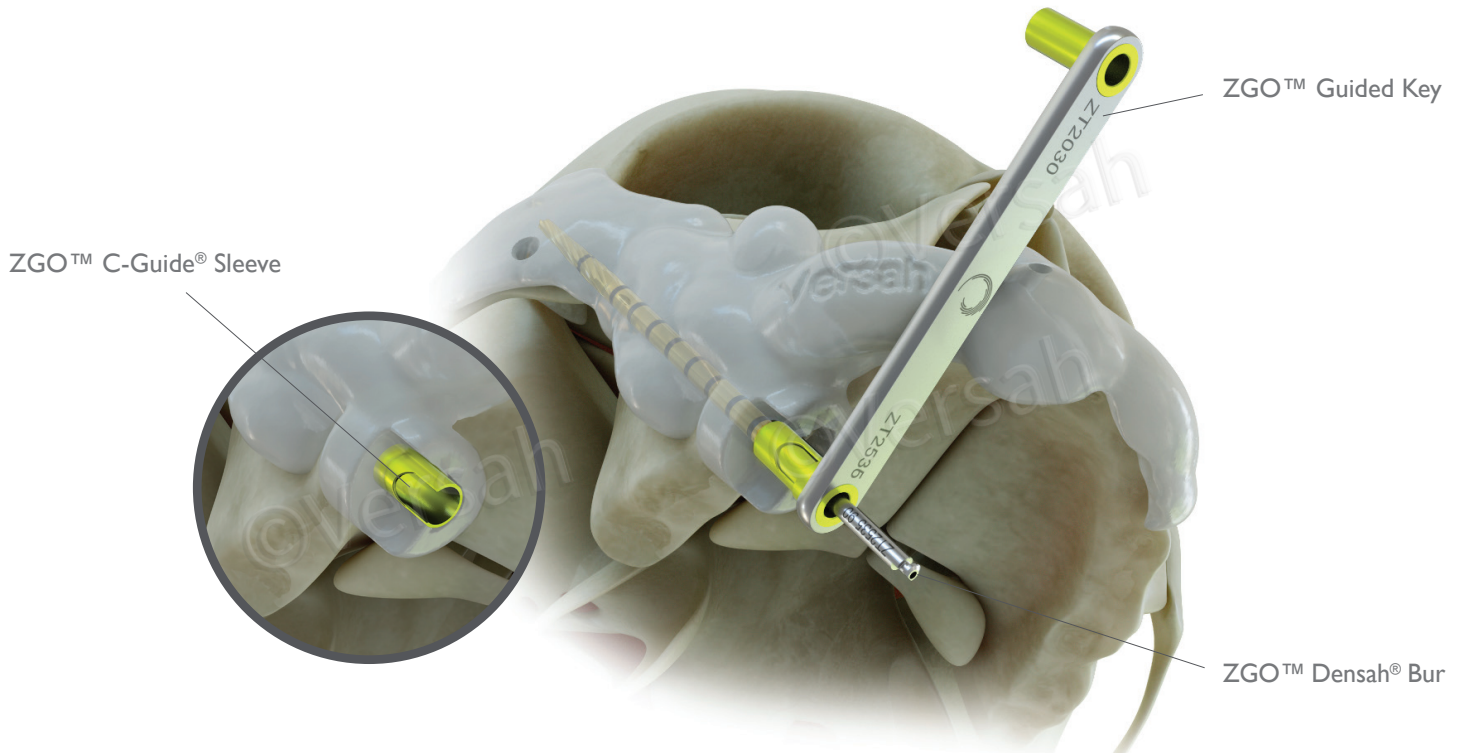
\*Clinician experience and judgment should be used in conjunction with this suggested use protocol

# 9. Versah<sup>®</sup> ZGO<sup>™</sup> Guided Surgery System

## Indications

1. The ZGO<sup>™</sup> Guided Keys provide drilling control of the osteotomy. The ZGO<sup>™</sup> Key can be used with printed guides with C-Guide<sup>®</sup> Sleeves to control the angulation of the osteotomy.
2. The ZGO<sup>™</sup> C-Guide<sup>®</sup> Sleeve is placed into ZGO<sup>™</sup> surgical guide by the dental lab as appropriate for each patient anatomy and treatment plan.
3. The Universal ZGO<sup>™</sup> Densah<sup>®</sup> Bur Holder is a holder for the ZGO<sup>™</sup> Densah<sup>®</sup> Burs and ZGO<sup>™</sup> Guided Keys, ZGO<sup>™</sup> Tapered Pilot Drill

## I. Universal ZGO™ Guided Surgery Key System Overview



The Versah® ZGO™ C-Guide® System is an innovative instrumentation guide. Its C-shape may allow for optimum operation to give surgeons the needed freedom to modulate (in and out) preparation needed for the ZGO™ Densah® Bur Technology. The Versah® ZGO™ Guided Keys are used in conjunction with the ZGO™ C-Guide® Sleeve to assist in guiding each specific ZGO™ Densah® Bur and ZGO™ Tapered Pilot Drill.

## II. ZGO™ Guided Key & ZGO™ C-Guide® Sleeve Sizes & Its Compatibility with ZGO™ Densah® Burs



To be used with the ZGO™ Tapered Pilot Drill and ZGO™ Densah® Bur ZT1525 (both 65 mm & 90 mm long).



To be used with the ZGO™ Densah® Bur ZT2030 and ZGO™ Densah® Bur ZT2535 (both 65 mm & 90 mm long.)

The Versah® ZGO™ C-Guide® System has corresponding keys to use in conjunction with the ZGO™ Densah® Burs. Use each ZGO™ Guided Key in sequential width order until the desired osteotomy width is achieved. ZT3040-65 mm & ZT3040-90 mm fit into the ZGO™ C-Guide® Sleeve without the need of "space adaptor key" used to fit other Versah® ZGO™ Densah® Bur diameters.

# 10. Densah<sup>®</sup> Burs and Accessories

## • Maintenance, Cleaning, and Storage

NOTE: Surgical burs should be replaced when they are dulled or worn out. Versah<sup>®</sup> recommends replacing surgical burs after 12-20 osteotomies<sup>1</sup>. It is recommended to keep a spare set of ZGO<sup>™</sup> Densah<sup>®</sup> Burs on hand in the event replacement is needed during a surgery.

The G-Stop<sup>®</sup> Vertical Gauge, and the C-Guide<sup>®</sup> Sleeve are single use only. Reuse of this device may lead to patient injury, infection and/or device failure.

The G-Stop<sup>®</sup> Key recommends replacing after 12-20 osteotomies.

ZGO<sup>™</sup> Densah<sup>®</sup> Burs and ZGO<sup>™</sup> Tapered Pilot Drill are single use only. Reuse of this device may lead to patient injury, infection and/or device failure.

1. Chacon GE, Bower DL, Larsen PE, et al. Heat production by three implant drill systems after repeated drilling and sterilization. J Oral Maxillofac Surg. 2006;64(2):265-269.

## I. Instructions for Maintenance of Burs Prior to First-Time Surgical Use for Burs

**STAGE 1:** Light Cleaning and Rinsing — Burs should be brushed and visually inspected for cleanliness, then dipped in detergent, rinsed, and dried.

**STAGE 2:** Preparation — Dip burs in Surgical Milk solution or 70% Isopropyl Alcohol for approximately 30 seconds, remove, let drain to dry. Do not rinse or wipe burs again.

**STAGE 3:** Sterilization — Burs should be sterilized in an autoclave at 132°C (269.6°F) for a 4-minute duration in a standard approved sterilization wrap. Dry time 30 minutes.

**STAGE 4:** During Use — Burs should be soaked in a sterile water solution until the cleaning stage.

**\*To minimize staining residue, we strongly recommend not using any solution with glutaraldehyde.**

## II. Instructions for Cleaning and Storage of Burs After Use for Burs

**STAGE 1:** Cleaning — Burs should be brushed and rinsed with detergent to remove any remaining blood or tissue. Complete visual inspection for cleanliness.

**STAGE 2:** Ultrasonic Cleaning — Burs should be cleaned in an ultrasonic bath using appropriate enzymatic detergent (10% solution) following detergent manufacturer's instructions (*During ultrasonic cleaning, contact between burs should be avoided*).

**STAGE 3:** Rinsing — Burs should be rinsed with running water to completely remove detergent and then dip burs in Surgical Milk solution or 70% Isopropyl Alcohol for approximately 30 seconds, remove, let drain to dry. Do not rinse or wipe burs again.

**STAGE 4:** Sterilization — Burs should be sterilized in an autoclave at 132°C (269.6°F) for a 4-minute duration in a standard approved sterilization wrap. Dry time 30 minutes.

**STAGE 5:** During Use— Burs should be soaked in a sterile water solution until the cleaning stage.

**STAGE 6:** Storage/use — At this stage, burs are ready for long-term storage; burs can be used immediately upon opening after long-term storage.

**\*To minimize staining residue, we strongly recommend not using any solution with glutaraldehyde.**

**\* ZGO™ Densah® Burs are Single Use Only. Reuse of this device may lead to patient injury, infection and/or device failure.**

### III. Cleaning and Sterilization Instructions for the ZGO™ Densah® Burs

**STAGE 1:** Light Cleaning and Rinsing — Burs should be brushed and rinsed with Palmolive Dish liquid at 1 tbsp per gallon of cold tap water. Brush the lumen of the article using a 1/32" lumen brush that has been wetted with the prepared Palmolive solution in the irrigation hole. Rinse the parts under cold running water to aid in the removal of the residual detergent.

**Complete visual inspection for cleanliness.**

**STAGE 2:** Ultrasonic Cleaner — Burs should be cleaned in an ultrasonic bath using appropriate enzymatic detergent (10% solution) following detergent manufacturer's instructions. (During Ultrasonic cleaning, contact between burs should be avoided)

**STAGE 3:** Rinsing — Burs should be rinsed with running water to completely remove detergent and then dip burs in Surgical Milk solution or 70% Isopropyl Alcohol for approximately 30 seconds, remove, let drain to dry. Do not rinse or wipe burs again.

**STAGE 4:** Sterilization — Burs should be sterilized in a Prevacuum autoclave: Temperature at 132°C (269.6°F) 4-minute duration in a standard approved sterilization pouch. Dry time 30 minutes.

**\* ZGO™ Densah® Burs are Single Use Only. Reuse of this device may lead to patient injury, infection and/or device failure.**

## IV. Instructions for First-Time Surgical Use and Maintenance of Accessories: Parallel Pins, C-Guide® Sleeves, G-Stop® Vertical Gauges, G-Stop® Keys, Universal Bur Holder, ZGO™ Guided Keys, G-Stop® Holder

**STAGE 1:** Light Cleaning and Rinsing — Accessories should be rinsed under cold running tap water. During the rinse, use an appropriately sized lumen brush to brush the lumen of the article and use a soft-bristled brush to brush the exterior surface of the article.

**STAGE 2:** Preparation — Prepare a detergent solution using Palmolive Dish detergent or comparative brand, using 1 tbsp (table spoon) per gallon of tap water. Brush the lumen of the article using appropriately sized lumen brush that has been wetted with the prepared Palmolive or comparative brand solution. Brush the exterior surface of the article using a soft-bristled brush that has been wetted with the prepared Palmolive or comparative brand solution.

**STAGE 3:** Ultrasonic Cleaning — Prepare a detergent solution using Enzol or comparative brand in an ultrasonic unit, following the manufacturer's recommendation of 1oz. per gallon using warm tap water. Immerse the articles in the prepared Enzol or comparative brand solution and allow them to sonicate for 5 minutes. While sonicating, ensure that there is no contact between articles. Rinse the articles under running cold tap water. Allow the articles to air dry completely.

**STAGE 4:** Sterilization — Accessories should be sterilized in an autoclave at 132°C (269.6°F) for a 4-minute duration in a standard approved sterilization wrap. Dry time 30 minutes.

**\* G-Stop® Holder Lid is for storage use only. Non-Autoclavable.**

**\* The G-Stop® Vertical Gauge, and the C-Guide® Sleeve are single use only.**

## V. Cleaning and Sterilization Instructions for the ZGO™ Holder

**STAGE 1:** Clean holder with a germicidal cleaner.

**STAGE 2:** Always check for damage of the holder after rinsing and drying.

**STAGE 3:** Functional Testing, Maintenance — Make a visual inspection for cleanliness with magnifying glasses. If necessary, perform the cleaning process again until the instruments are visibly clean.

**STAGE 4:** Packaging — Place holder in sterilization packets or pouch.

**STAGE 5:** Sterilization — Sterilize the holder by applying a fractionated pre-vacuum process (according to ISO 17665) under consideration of the respective country requirements.

**STAGE 6:** Parameter for the pre-vacuum cycle — 3 pre-vacuum phases with at least 60 mbar.

**STAGE 7:** Sterilization Cycle — Heat up to a minimum sterilization temperature of 132°C-134°C/ 269.6°F-273.2°F; maximum temperature 135°C/ 274°F. Minimum holding time: 3 min. Drying time: minimum 10 min.

**STAGE 8:** In case of more than 149°C (300.2°F), the kit case may get deformed, so be careful.

**STAGE 9:** Make sure the holder will not be placed touching the inside wall of autoclave during sterilization to avoid deforming of the case.

**STAGE 10:** Manufacturer is not responsible for any damage to the product from sterilization or improper handling other than the high pressure steam sterilization method suggested by.

**STAGE 11:** Storage — Store the sterilized holder in a dry, clean and dust free environment at modest temperatures of 5°C-40°C / 41°F-104°F.

**\* ZGO™ Densah® Burs are Single Use Only. Reuse of this device may lead to patient injury, infection and/or device failure.**

## VERSAH® TERMS AND CONDITIONS OF SALE

### DENTAL DRILLS AND BURS (“Products”)

- A. **ORDER PLACING** — Orders may be placed by telephone at (844) 711-5585 or via internet at <https://shop.versah.com>. Our products may also be available through selected manufacturers’ sales representatives. When ordering by phone, please specify:
1. Customer name and contact information, including shipping information (or customer account number if returning customer)
  2. Purchase order number
  3. How items will ship including special shipping instructions, if any
  4. Product item numbers
  5. Quantities desired
  6. Dental license number
- B. **SHIPPING, TAXES** — All orders are shipped freight prepaid to destination. Customer shall pay any applicable taxes related to purchase.
- C. **PAYMENT TERMS** — Payment for Products, including any applicable tax, shipping, and handling, is ordinarily due at time of order via credit card.
- D. **PRICES ARE SUBJECT TO CHANGE WITHOUT NOTICE** — Versah® may discontinue Products or change specifications, designs, prices, or the terms and conditions of sale at any time.
- E. **LIMITED WARRANTY; LIMITATION OF LIABILITY** — Drills and burs wear with repeated use. They should be replaced when they become dull, worn, or in any way compromised. Versah® drills and burs should ordinarily be discarded and replaced after 12 to 20 osteotomies (I). Read and follow the “Instructions For Use.”

Versah® warrants its Products to be free from defects in workmanship and materials for thirty (30) days from the date of payment or initial invoice, whichever comes first, when used and handled according to “Instructions For Use.” Versah’s only liability, and Customer’s exclusive remedy in the event of any defect, is that Versah® provide at its option, either (1) a full refund or credit in the amount of the purchase price, or (2) the repair or replacement of the Product. Versah® will not be liable for any direct or indirect, consequential, incidental, punitive, special, exemplary, or contingent loss or damage (including without limitation lost or anticipated profits, or damage to goodwill) arising from or in connection with the purchase, use of, or inability to use, the Products. Customer must return the defective Product within thirty (30) days from the date of purchase.

This warranty excludes injury or damage resulting from negligent or improper use, including use that is inconsistent with best practices, and specifically including, but not limited to, any use of the Products contrary to the Instructions For Use. Any negligent or improper use shall void this warranty. This warranty is given in lieu of all other warranties, written or oral, express or implied. Versah® does not warrant the Products’ merchantability or fitness for a purpose, excepting those expressly described in the Instructions for Use.

Please find details under reference I on page 70.

THE EXPRESS WARRANTY SET FORTH IN SECTION E IS THE ONLY WARRANTY MADE BY VERSAH®. VERSAH® DISCLAIMS ANY OTHER WARRANTIES OF ANY KIND OR DESCRIPTION WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR IMPLIED WARRANTIES ARISING FROM A COURSE OF DEALING OR COURSE OF PERFORMANCE. NO ORAL OR WRITTEN INFORMATION GIVEN BY VERSAH®, ITS EMPLOYEES, LICENSORS OR THE LIKE WILL CREATE A WARRANTY.

- F. **VERSAH® RETURN GOODS POLICY** —Versah® strives to make excellent products and hopes that you will be fully satisfied with your purchase. However, if you wish to return your purchase, we ask that you contact customer service at 1-844-711-5585 or at [info@versah.com](mailto:info@versah.com) prior to returning your goods.
- (a) **RETURN AUTHORIZATION** — Any product returned requires authorization in advance from Versah®. Customers must complete a Return Authorization Form and be issued a Return Authorization Number. The Form may be obtained from Versah® Customer Service. At this time, **Versah® cannot accept returns without a completed Return Authorization Form and correct Return Authorization Number**, which must accompany any returned product.
  - (b) **STANDARD RETURNS** — Versah® will not authorize returns of Product more than thirty (30) days after purchase. Versah® will not accept returned Product which is obsolete, damaged, or sterile merchandise which has been opened or the packaging compromised unless such product is defective. Versah® will issue a refund for the returned Product to Customer's method of payment once the purchase has been received at its office and processed by its staff. Versah® is unable to refund postage costs for returns. Returns are subject to a 20% restocking charge, which will be deducted from any funds to be credited back to Customer's method of payment. Merchandise shipped in error will receive full credit if returned in unopened package, postage prepaid.
  - (c) **WARRANTY CLAIMS** — Prior authorization is required for products returned for warranty based reasons. Versah® will not authorize returns of Product after the expiration of the thirty (30) day warranty period. Refunds or replacements will be processed in accordance with Section E of these Terms and Conditions of Sale. Product returned for warranty reasons is not subject to a restocking charge.
  - (d) **INSPECTIONS AND LOST RETURNS** — Versah® reserves the right to inspect all returned items and decline to accept the return upon inspection. Versah® cannot issue a refund or a replacement for a purchase not received by Versah®. Customer shall bear all risk of lost returns and Customer may, at its discretion, purchase insurance.
  - (e) **CHANGE OF RETURN POLICY** — Versah® and Customer agree that Versah® may, from time to time, adjust the return policy set forth in this Section F without any prior notice to Customer. Any such adjustment shall only be effective on purchases made as of the date the new policy is posted or otherwise made available to Customer.

## Caution

Federal law restricts the sale of this device to or on the order of a licensed dentist.

Treatment planning and clinical use of the Densah® Burs and accessories are the responsibility of each individual clinician. **Surgeon preference and clinical judgment overrules the suggestive Implant System Drilling Protocol and any clinical protocol.** VERSAH® strongly recommends completion of qualified postgraduate dental implant training and ADHERENCE to this IFU manual. VERSAH® is not responsible for incidental or consequential damages or liability relating to the use of the Densah® Burs and accessories alone or in conjunction with other products other than replacement under warranty.

Densah® Burs and accessories are warranted for a period of thirty (30) days from the date of initial invoice.

Any serious incident resulting from the use of the device, please report the incident to us, physician and your local health competent authority.

## Densah® Bur Tracking Log



	VPLTT	VPLTT-S	VT1525	VT1525-S	VT1828	VT1828-S	VS2228	VT2535	VT2535-S	VT2838	VT2838-S	VS3238	VT3545	VT3545-S	VT3848	VT3848-S	VS4248	VT4555	VT4858	VS5258
1																				
2																				
3																				
4																				
5																				
6																				
7																				
8																				
9																				
10																				
11																				
12																				
13																				
14																				
15																				
16																				
17																				
18																				
19																				
20																				

10078 REV 03

NOTE: Surgical burs should be replaced when they are dulled or worn out. VERSAH® recommends replacing surgical burs after 12-20 osteotomies<sup>1</sup>. It is recommended to keep a spare set of Densah® Burs on hand in the event replacement is needed during a surgery.

The G-Stop® Vertical Gauge, and the C-Guide® Sleeve are single use only.

The G-Stop® Key recommends replacing after 12-20 osteotomies.

ZGO™ Densah® Burs and ZGO™ Tapered Pilot Drill are single use only. Reuse of this device may lead to patient injury, infection and/or device failure.

ZGO™ C-Guide® Sleeve is single use.

1. Chacon GE, Bower DL, Larsen PE, et al. Heat production by three implant drill systems after repeated drilling and sterilization. J Oral Maxillofac Surg. 2006;64(2):265-269.

## Notes:

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

## Notes:

[illegible]

## Notes:

[illegible]





P: 517-796-3932 | Toll Free: 844-711-5585 | Fax: 844-571-4870



Versah, LLC  
2000 Spring Arbor Rd. Suite D  
Jackson, MI 49203 USA



See instructions for use:  
[www.versah.com/ifu](http://www.versah.com/ifu)



Sterilize prior to use



2797



ULG



**EMERGO EUROPE**  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands

©2022 Versah, LLC. All rights reserved. Versah, Densah, et al. are registered trademarks.

February 2022

10408 REV22