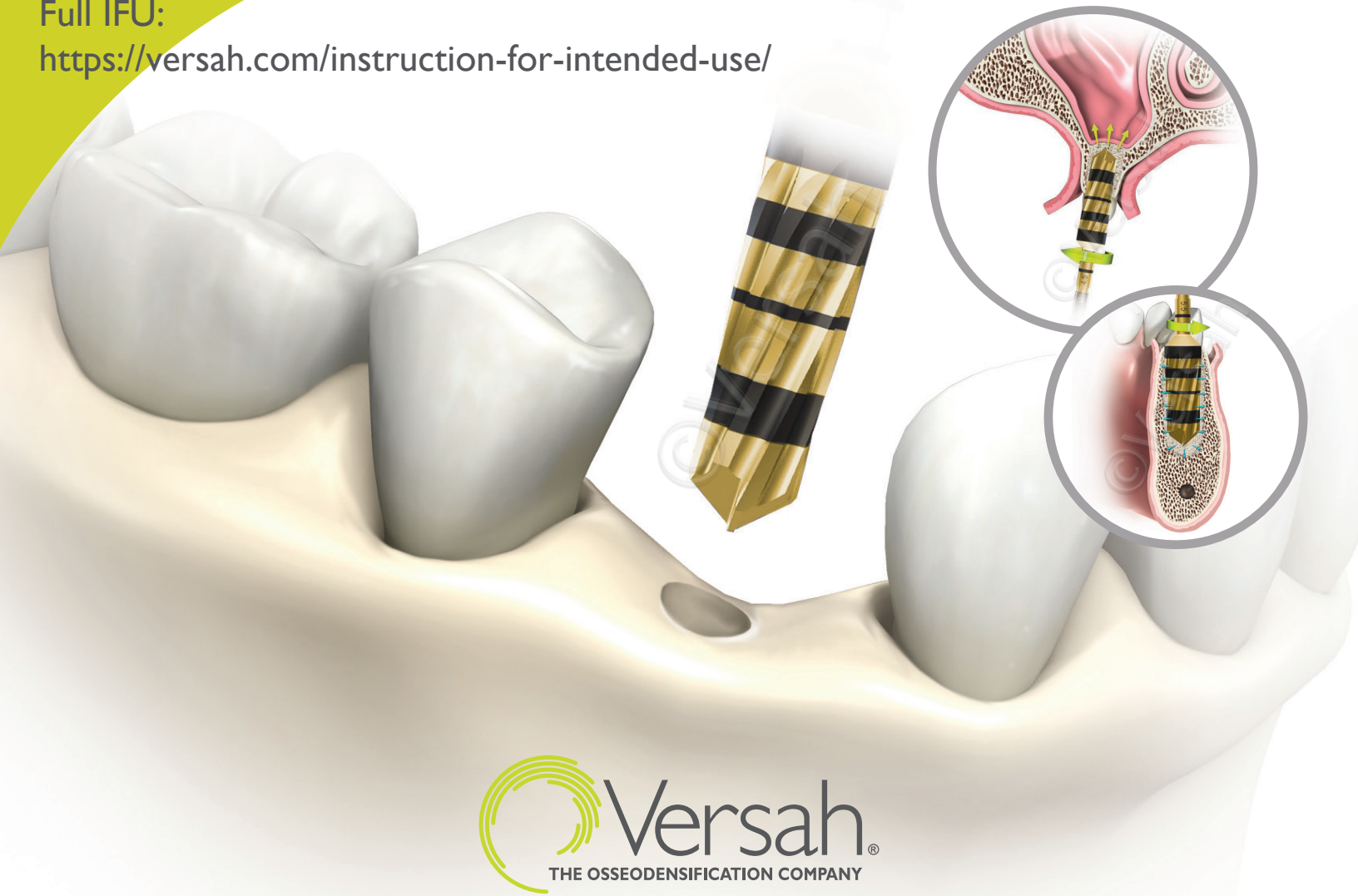
Full IFU:
https://versah.com/instruction-for-intended-use/



Versah®
THE OSSEODENSIFICATION COMPANY

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

SECTIONS

*Please visit https://versah.com/instruction-for-intended-use/ 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			
ZT1525-65	ZT2030-65	ZT2535-65	ZT3040-65
			

ZT™ 90 mm Series			
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**

*Clinician judgement and experience should be applied in conjunction with this suggestive use protocol.

I. Included in the Kit

The ZGO™ Densah® Burs (65 mm & 90 mm) are internally irrigated* (as shown in figure 1). 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

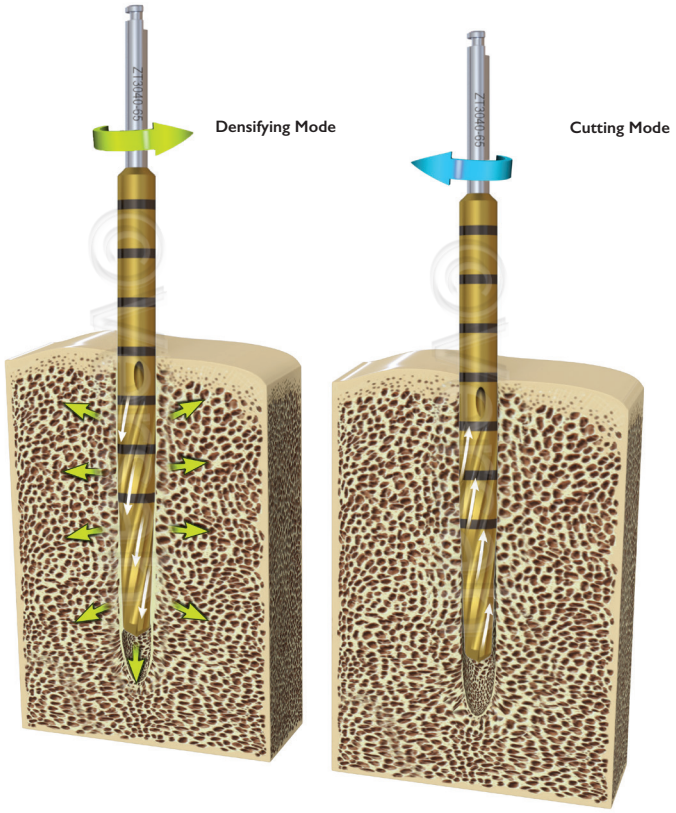
figure 1

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)**.

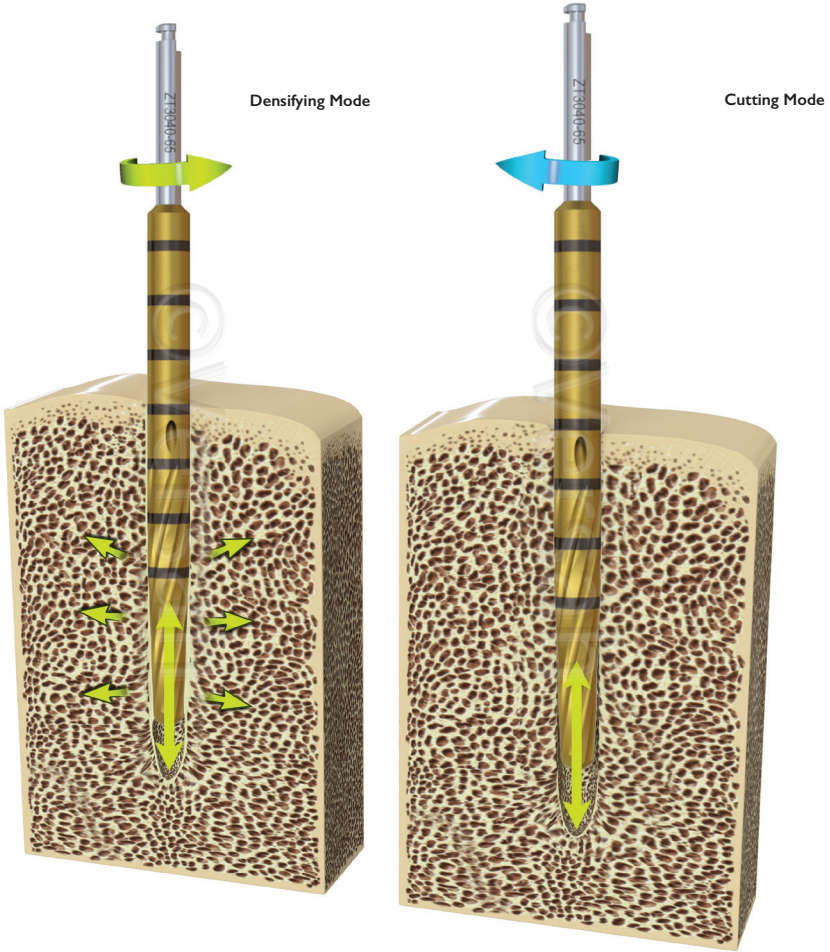
Counterclockwise (CCW) Non-Cutting Direction

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 https://versah.com/zgo-densah-burs/

III. ZGO™ 65 mm Densah® Bur Marking

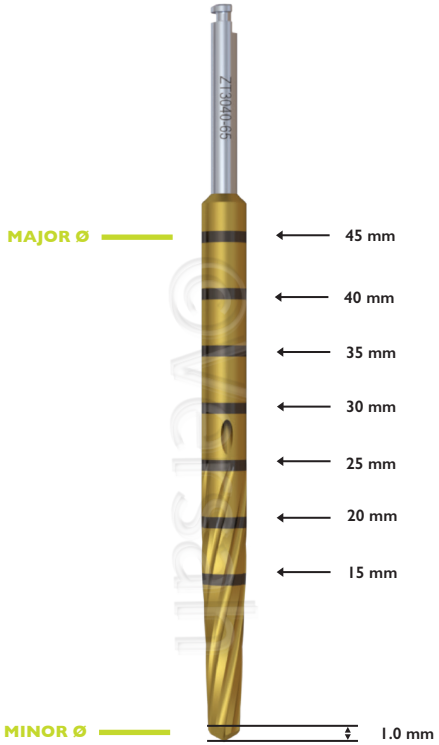
ZGO™ Densah® Burs are internally irrigated and designed to be used at drill speeds of 800-1500 rpm. They are marked with laser markings[1] from 15-45 mm depth. ZGO™ Densah® Burs have a tapered geometry dimension. Eg., ZGO™ Densah® Bur ZT3040-65 mm has a **(minor-diameter)** of 3.0 mm and a coronal **(major-diameter)**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

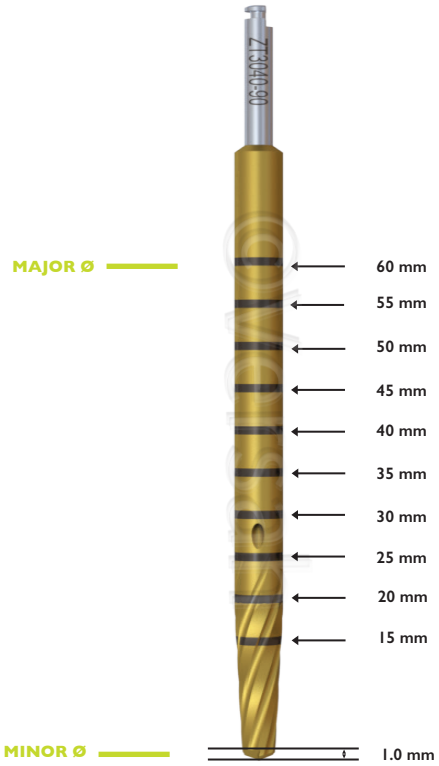
ZGO™ Densah® Burs are internally irrigated and designed to be used at drill speeds of 800-1500 rpm. They are marked with laser markings[1] from 15-60 mm depth. ZGO™ Densah® Burs have a tapered geometry dimension. Eg., ZGO™ Densah® Bur ZT3040-90 mm has a **(minor-diameter)** of 3.0 mm and a coronal **(major-diameter)**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

ZGO™ 90 mm Densah® Bur Laser Lines



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

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

Indications

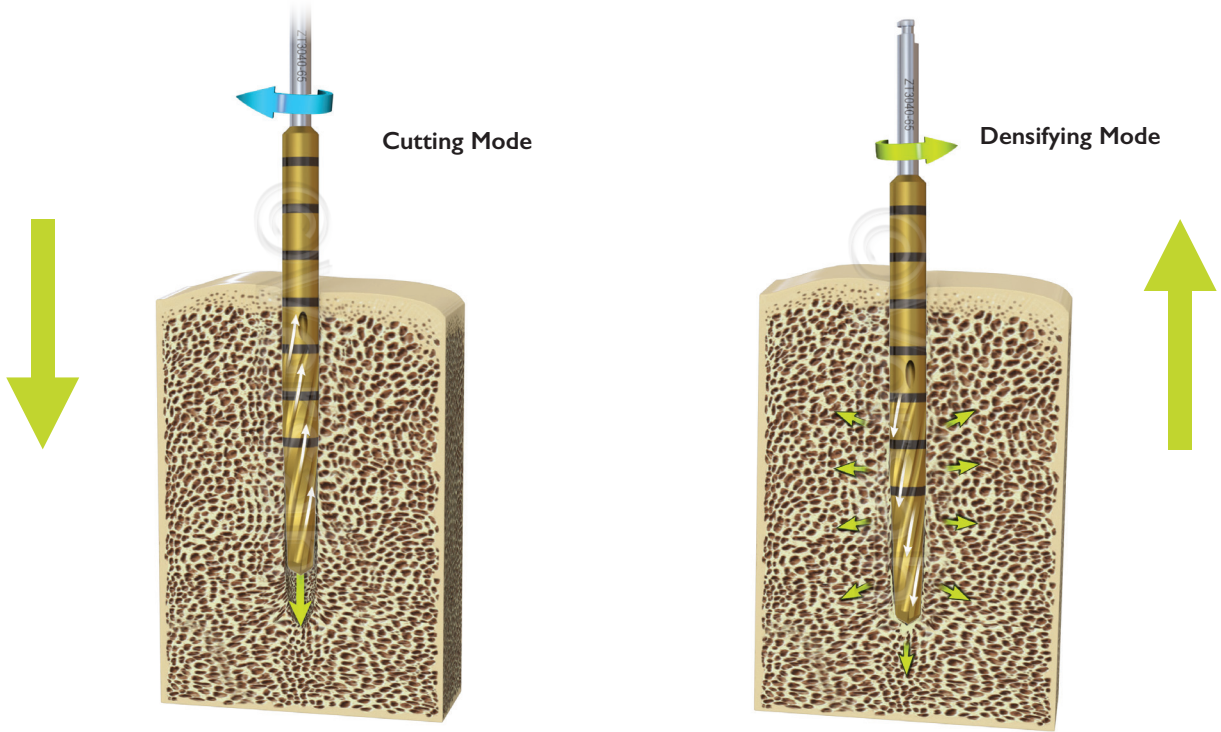
1. ZGO™ Densah® Burs are indicated for use to prepare osteotomies for implant placement in maxilla (including the zygoma and pterygoid implants).
2. The ZGO™ Tapered Pilot Drills are used to create the initial hole in bone to prepare an osteotomy for zygomatic implant placement and monitor the drilling 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 judgement and experience should be applied in conjunction with this suggestive use protocol. Do not apply lateral pressure when drilling with the pilot drill.

(Densify - Preserve) after Cut (DAC) Protocol



*Clinician judgement and experience should be applied in conjunction with this suggestive use protocol.

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.

*Clinician judgement and experience should be applied in conjunction with this suggestive Implant System Drill 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.)

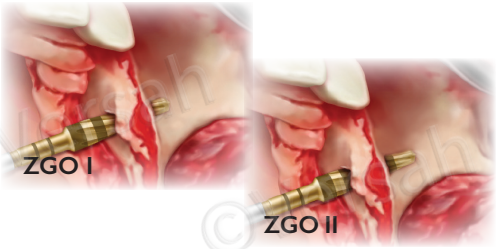
5. Place the implant into the osteotomy. If using the surgical motor to tap the implant into place, the unit may stop when reaching the maximum placement torque. Finish placing the implant to depth with a torque indicating wrench.

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.

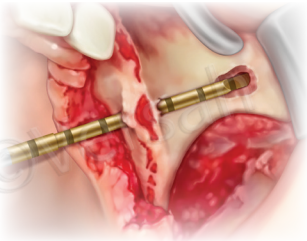
*Clinician judgement and experience should be applied in conjunction with this suggestive Implant System Drill Protocol.

III. Osseodensification ZGO™ Type I/II Protocol for the Intra-maxillary Intra/Extra Sinus Placement*

Overview: The anterior maxillary wall is slightly more concave. The pathway is **totally intra-maxillary with an intra/extra-sinus approach**. A tunnel osteotomy is created through the alveolar crest, into the sinus internal lateral wall, to slightly come out through that lateral wall and then re-enter again as a second tunnel osteotomy into the sinus to come out through the body of the zygoma.



Step 1



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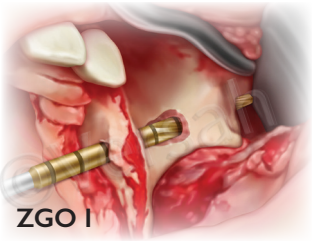
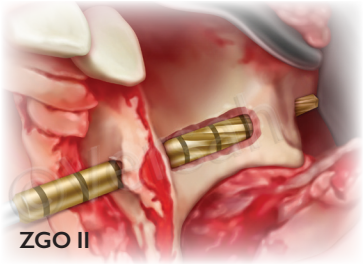
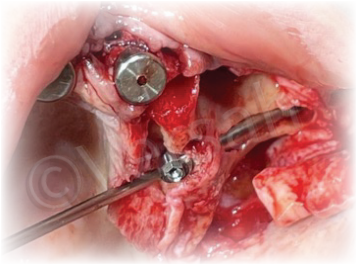


Step 3

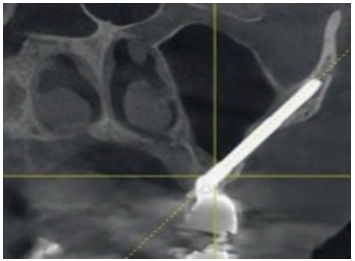
1. The tunnel osteotomy is initiated with the Universal Densah® pilot drill through the alveolar crest in clockwise (CW) mode to reach the floor of the sinus. Then the Universal Densah® Burs are used in a consecutive increasing order of 2mm, 2.3mm, 3mm, & 3.3mm in the counterclocwise (CCW) mode to preserve and widen the crestal osteotomy and initiate the entry into the sinus lateral wall. This would achieve preservation of the sinus membrane and Osseodensification of the alveolar bone.
2. Using the appropriate length ZGO Densah® pilot drill (65mm or 90mm) depending on the patient's anatomy and size, in CW mode, enter the prepared crestal tunnel osteotomy to come out through the lateral sinus wall to enter again, through another tunnel osteotomy, into the inferior surface of the zygoma, then through the body of the zygoma, to exit the superolateral surface of the body of the zygoma.
3. After the pilot osteotomy, use the appropriate length ZGO Densah® Burs (65mm or 90mm) depending on the patient's anatomy and size. Starting with Densah® Bur ZT1525, widen the crestal osteotomy in CCW mode entering the sinus cavity to come out through the lateral sinus wall to enter again, through another tunnel osteotomy, switch to CW mode as needed to enter into the inferior surface of the zygoma, through the body of the zygoma and exiting the superolateral surface of the body of the zygoma.



Step 4



Step 5



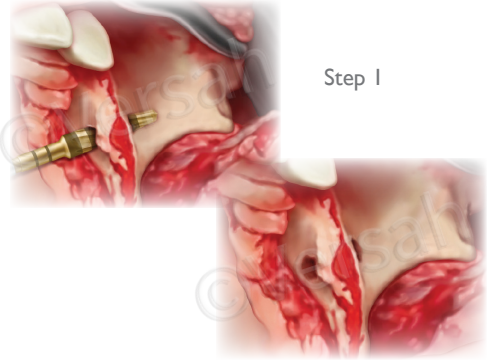
4. The zygoma hardness and implant diameter will determine the final ZGO Densah® Bur diameter i.e.; ZT2030, ZT2535, or ZT3040 **The ZGO Densah® Burs best to be utilized CW/CCW as needed based on bone density at 800-1500rpm with copious irrigation**.
   1) Clockwise (CW) cutting mode for denser bone
   2) Counterclockwise (CCW) densifying mode in softer bone
   3) A combination of CW & CCW using the Densify- Preserve after Cut (DAC) protocol for intermediate bone hardness
5. The zygomatic implant is then placed. Although the zygomatic implant can be seen through the anterior maxillary wall, most of the implant body has an intra-sinus path. **In ZGO I and ZGO II the implant contacts bone at**:
   1) The alveolar crest.
   2) The internal sinus wall.
   3) The lateral sinus wall.
   4) The body of the zygoma

*Clinician judgement and experience should be applied in conjunction with this suggestive use protocol.

IV. Osseodensification ZGO™ Type III Protocol for the Intra-maxillary Extra Sinus Placement*

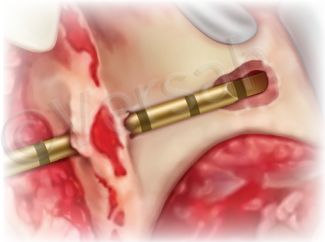
Overview: In these cases the anterior maxillary wall is very concave. The pathway is **intra-maxillary with a totally extra sinus path**. A tunnel osteotomy is created through the alveolar crest to come out into the external maxillary wall and then re-enter again as a second tunnel osteotomy into the body of the zygoma to come out through the superolateral aspect of the body of the zygoma. Between the two tunnel osteotomies the maxillary wall is very concave and therefore, there is no groove/channel osteotomy between the two tunnel osteotomies i.e. the middle part of the implant body would not touch the most concave part of the wall.

1. The tunnel osteotomy is initiated with the Universal Densah® pilot drill through the alveolar crest in clockwise (CW) mode to come out buccally through the maxillary buccal plate/anterior maxillary wall. Then the Universal Densah® Burs are used in a consecutive increasing order of 2mm, 2.3mm, 3mm, & 3.3mm in the counterclockwise (CCW) mode to widen the crestal osteotomy and achieve preservation and Osseodensification of the alveolar bone.



Step 1

2. Using the appropriate length ZGO Densah® pilot drill (65mm or 90mm) depending on the patient's anatomy and size in CW mode, enter the previously prepared crestal tunnel osteotomy to come out glancing along the concave part of the anterior maxillary wall to penetrate and re-enter the inferior surface of the zygoma, then through the body of the zygoma to exit the superolateral surface of the body of the zygoma thereby creating a tunnel in the zygomatic bone.



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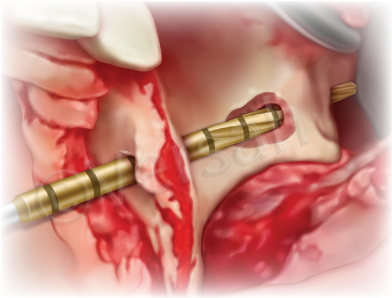

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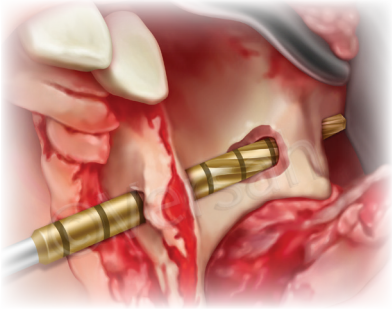
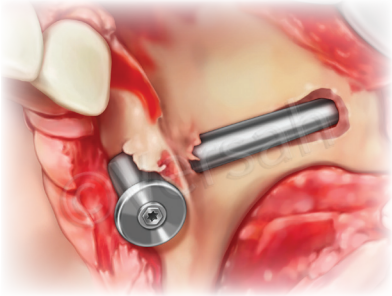


Step 4



Step 5

3. After the pilot osteotomy, depending on the patient's anatomy and size, use the appropriate length ZGO Densah® Burs (65mm or 90mm) Starting with ZGO Densah® Bur ZT1525, to widen the crestal tunnel crestal osteotomy in CCW mode and then glance along the concave part of the anterior maxillary wall. Switch to CW mode to penetrate and enter the inferior surface of the zygoma, through the body of the zygoma and exit the superolateral surface of the body of the zygoma, thereby widening the tunnel in the zygomatic bone. Zygoma bone hardness and implant diameter will determine the final ZGO Densah® Bur diameter.

4. The zygoma hardness and implant diameter will determine the final ZGO Densah® Bur diameter i.e.; ZT2535, or ZT3040 **The ZGO Densah® Burs best to be utilized CCW/CW as needed based on bone density at 800-1500rpm with copious irrigation**.
   1) Clockwise (CW) cutting mode for denser bone
   2) Counterclockwise (CCW) densifying mode for softer bone
   3) A combination of CW & CCW using the Densify-Preserve after Cut (DAC) protocol for intermediate bone hardness

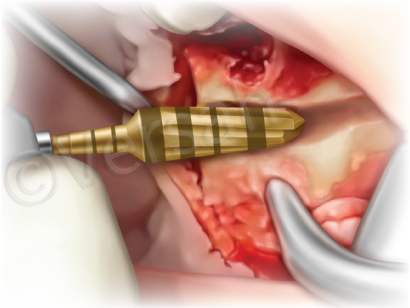
5. The zygomatic implant is then placed. The implant head is located in the alveolar crest. The middle part of the implant body does not touch the most concave part of the anterior maxillary wall. In this intra-maxillary extra sinus path the implant contacts bone at:
   1) The alveolar crest coronally
   2) The zygomatic bone apically

*Clinician judgement and experience should be applied in conjunction with this suggestive use protocol.

V. Osseodensification ZGO™ Type IV Protocol for the Extra-maxillary Extra Sinus Placement*

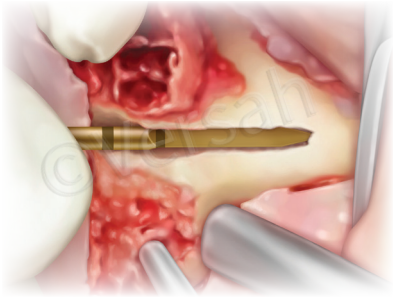
Overview: This ZGO protocol IV follows an extra-maxillary path. The maxilla and alveolar bone show extreme vertical and horizontal atrophy. The pathway is extra-maxillary with totally extra sinus path. The implant head is located buccal to the alveolar crest usually in a shallow "channel" osteotomy. 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" osteotomy 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 using the regular Universal Densah® Burs starting with the VT1525 (2.0) working up to VT3545 (4.0) in Cutting Mode CW at 800 - 1500 rpm with copious irrigation as a "side cutter" to **create a channel osteotomy in the residual alveolar ridge and the lateral wall of the maxillary sinus**. Once the osteotomy gets closer to the sinus membrane, switch to CCW (OD mode) to preserve the sinus membrane integrity while defining the channel osteotomy.

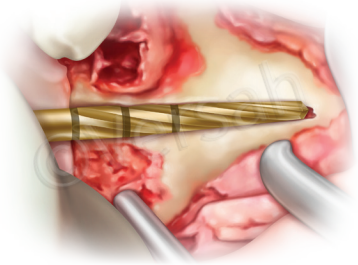


Step 1

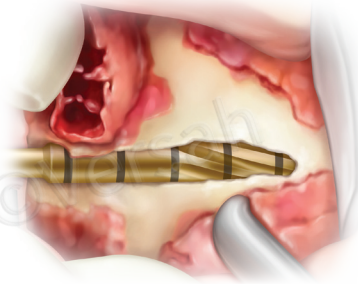
2. Using the appropriate length ZGO Densah® pilot drill (65mm or 90mm) depending on the patient's anatomy and size in CW mode, follow the "channel" trajectory to enter the inferior aspect of the body of the zygoma in order to prepare a "tunnel" osteotomy of the appropriate length just perforating apically through the superior-lateral aspect of the body of the zygoma.



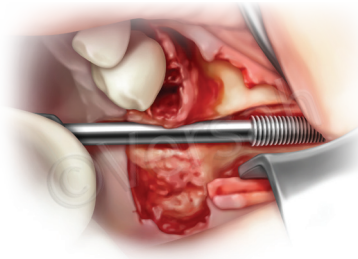
Step 2



Step 3



Step 4



Step 5

3. After the pilot channel osteotomy, depending on the patient's anatomy and size, use the appropriate length (65mm or 90 mm length) ZGO Densah® Burs, starting with ZGO Densah® Bur ZT1525, in CW cutting mode/CCW densifying mode as needed to widen the osteotomy in a consecutive increasing order to achieve the desired osteotomy diameter and length depending on the zygomatic implant diameter and length to be placed. **When getting close to the sinus membrane, drilling direction is changed to CCW in order to preserve the sinus membrane integrity.**

4. The zygoma hardness and implant diameter will determine the final ZGO Densah® Bur diameter ie: ZT2030, ZT2535, or ZT3040. The ZGO Densah® Burs best to be utilized CCW/ CW as needed based on bone density at 800-1500rpm with copious irrigation.
   1)Clockwise (CW) cutting mode for denser bone.
   2)Counterclockwise (CCW) densifying mode for softer bone
   3)A combination of CW & CCW using the Densify- Preserve after Cut (DAC) protocol for intermediate bone hardness.
   Zygoma bone hardness and implant diameter will determine the final ZGO Densah® Bur diameter.

5. The zygomatic implant is then placed. The implant head sits on the buccal of the alveolar crest. The middle part of the implant body does not touch the most concave part of the anterior maxillary wall. In this extra-maxillary extra sinus path contacts bone at:
   1)The buccal outer aspect of the crest.
   2)The zygomatic bone apically

*Clinician judgement and experience should be applied in conjunction with this suggestive use protocol.

9. Versah® ZGO™ Guided Surgery System

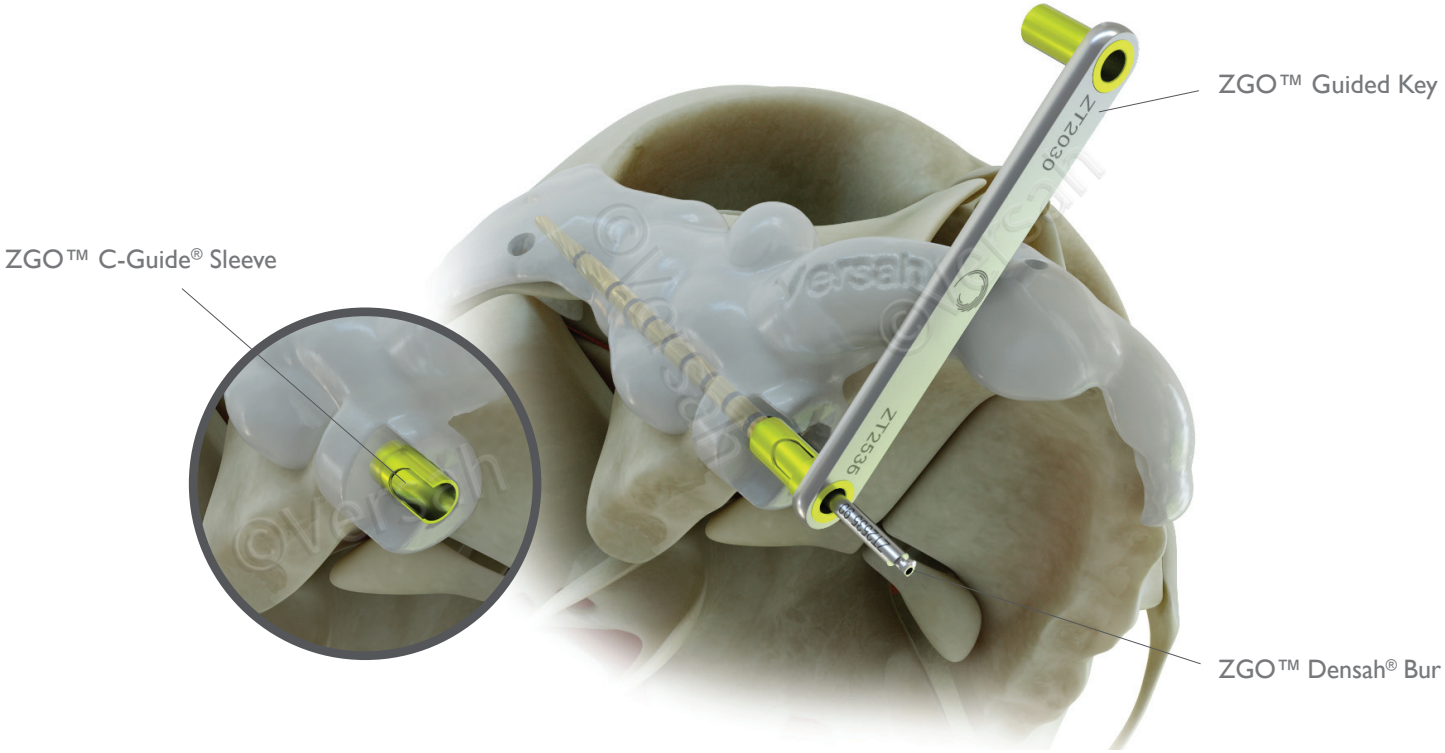
Indications

1. The ZGO™ Guided Keys provide drilling control of the osteotomy. The ZGO™ Key can be used with printed guides with C-Guide® Sleeves to control the angulation of the osteotomy.

2. The ZGO™ C-Guide® Sleeve is placed into ZGO™ surgical guide by the dental lab as appropriate for each patient anatomy and treatment plan.

3. The Universal ZGO™ Densah® Bur Holder is a holder for the ZGO™ Densah® Burs and ZGO™ Guided Keys, ZGO™ 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® Burs and Accessories Maintenance, Cleaning, and Storage

NOTE: Surgical burs should be replaced when they are dulled or worn out. Versah® recommends replacing surgical burs after 12-20 osteotomies[1]. It is recommended to keep a spare set of ZGO™ 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. Reuse of this device may lead to patient injury, infection and/or device failure.

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.

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 (1). 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 1 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 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

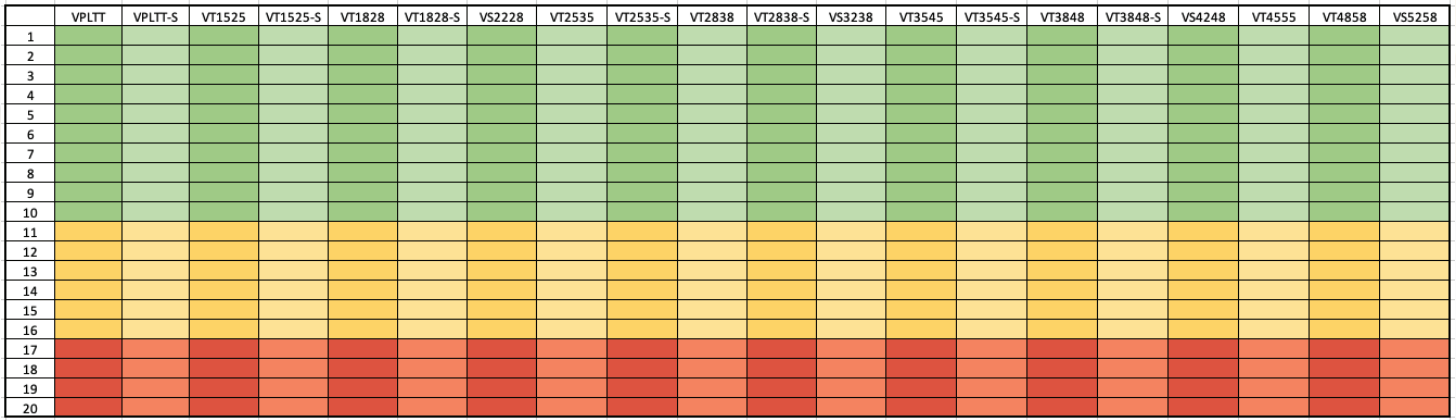
Federal law restricts the sale of this device to or on the order of a licensed dentist.

Treatment planning and clinical use of the Densah® Burs and accessories are the responsibility of each individual clinician's judgement. **Clinician judgement and experience should be applied in conjunction with this suggestive use 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
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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.

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MD

See instructions for use:
www.versah.com/ifu

Rx only

Sterilize prior to use

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July 2022

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