



P: 517-796-3932

Toll Free: 844-711-5585

Fax: 844-571-4870



CE2797 Products = Densah® Burs, Short Densah® Burs , Short Tapered Pilot Drill, Tapered Pilot Drill, G-Stop® Vertical Gauges, G-Stop® Keys, ZGO™ Densah® Burs, ZGO™ Tapered Pilot Drill

CE Products = Parallel Pin, Parallel Pin - XL, Universal Bur Holder, C-Guide® Sleeve, G-Stop® Holder, ZGO C-Guide® Sleeve, ZGO™ Bur Holder, ZGO™ Guided Keys

****See additional information provided on www.versah.com**

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

Indications for Use: 1. Densah® Burs and Short Densah® Burs are indicated for use to prepare osteotomies for endosseous dental implant placement in the maxilla or the mandible. When a Densah® Bur is rotated at 800-1500 RPM in a reversed non-cutting direction with steady external irrigation, autogenous bone is autografted into the trabecular space along the walls and base of the osteotomy. (Data on file) 2. The Tapered Densah® Pilot Drill and the Short Tapered Densah® Pilot Drill are used to prepare the initial osteotomy in bone for endosseous dental implant placement. 3. The Parallel Pin is for use as a paralleling guide with the Densah® Burs. 4. The Universal Bur Holder is a holder for the Densah® Burs, Short Densah® Burs, Tapered Densah® Pilot Drill, Short Tapered Densah® Pilot Drill, Versah® Drill Extender, and Parallel Pins. 5. The G-Stop® Key and G-Stop® Vertical Gauge provide vertical control for drilling the osteotomy. The G-Stop® Key and G-Stop® Vertical Gauge can be used with printed guides (C-Guide® Sleeves to control the angulation of the hole). 6. The C-Guide® Sleeve is placed into a surgical guide by the dental lab as appropriate for each patient anatomy. 7. The G-Stop® Holder is a holder that holds the Densah® Burs, Short Densah® Burs, Versah® Drill Extender, Parallel Pins, Tapered Pilot Drill, Short Tapered Pilot Drill, G-Stop® Vertical Gauges, and G-Stop® Keys. 8. ZGO™ Densah® Burs are indicated for use to prepare osteotomies for implant placement in maxilla (including the zygoma and pterygoid implants). 9. 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. 10. The Universal ZGO™ Densah® Bur Holder is only a holder for the ZGO™ Densah® Burs, the ZGO™ Tapered Pilot Drills, and ZGO™ Guided Keys. 11. 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. 12. The ZGO™ C-Guide® Sleeve is placed into ZGO™ surgical guide by the dental lab as appropriate for each patient anatomy and treatment plan. 13. The Versah® Drill Extension is used to increase the length of a latch type drill, providing sufficient clearance for the dental handpiece head from the surrounding anatomical structures.

Contraindications: 1. Osseodensification does not work in cortical bone. In (Type I/Dense Bone); use the Densah® Burs/ZGO™ Densah® Bur 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. 3. Avoid Densifying Xenograft. 4. Do not apply lateral pressure when drilling with the Tapered Pilot Drill and ZGO™ Tapered Pilot Drill.

Instructions for Use and Procedure: For more information please visit versah.com.

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.

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.

Versah® Drill Extender Cleaning Instructions: 1. Pre-vacuum sterilisation method: steam sterilise the instruments at 132°C (270°F) at 180-220 kPa for 4 minutes. Dry for at least 20 minutes in the chamber. Only an approved wrap or pouch for steam sterilisation must be used. 2. Pre-vacuum sterilisation method: wrapped, steam sterilise at 135°C (275°F) for 3 minutes. Dry for 20 minutes in the chamber. Use a wrap or pouch that is cleared for the indicated steam sterilisation cycle.

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.

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 1 oz. 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. *The G-Stop® Vertical Gauge, and the C-Guide® Sleeve are single use only. ZGO™ Densah® Burs, ZGO™ Tapered Pilot Drills, ZGO™ C-Guide® Sleeves are single use only.

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.

Number of Uses: VERSAH® recommends replacing surgical burs after 12-20 osteotomies. The G-Stop® Vertical Gauge, C-Guide® Sleeve, ZGO™ Densah® Burs, ZGO™ Tapered Pilot Drills, and the ZGO™ C-Guide® Sleeves are single use only.

Guided Assembly and Disassembly Instructions: For more information please visit versah.com.

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.