# Instructions for Use

Versah, LLC
2000 Spring Arbor Rd Suite D
Jackson, Michigan 49203 United States
P: 517-796-3932
Toll Free: 844-711-5585
Fax: 844-571-4870

CE 0297 MD Rx only Sterilize prior to use

## 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 1000 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.

**Patient Population:** Individuals receiving dental implants eligible for treatment with osteotomy as determined by the clinician.

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

| Devices<br># of Uses | Before Use<br>(Maintenance/Preparation/Sterilization) | After Use Cleaning | After Cleaning/Sterilization<br>Use Storage |
|---|---|---|---|
| Densah® Burs<br>Pilot Drills<br>Parallel Pins<br>G-Stop® Keys<br>Universal Densah® Bur Holder<br>Densah® Bur Holder X<br>G-Stop® Holder<br>ZGO™ Holder<br>Drill Extender<br><br>VERSAH® recommends replacing surgical burs after 20 osteotomies | **STAGE 1:** Light Cleaning and Rinsing — Product should be brushed and visually inspected for cleanliness, then dipped in enzymatic detergent following detergent manufacturer's instructions, rinsed, and dried.<br>**STAGE 2:** Preparation (Densah® Burs Only) — 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.<br>**STAGE 3:** Sterilization — Product should be sterilized in a prevacuum autoclave at 132°C (269.6°F) for a 4-minute duration in a standard approved sterilization wrap. Dry time 30 minutes.<br>**STAGE 4:** During Use — Densah® Burs should be soaked in a sterile water solution until the cleaning stage | **STAGE 1:** Product should be brushed and rinsed to remove any remaining blood or tissue. Complete visual inspection for cleanliness.<br>**STAGE 2:** Ultrasonic Cleaning — Product should be cleaned in an ultrasonic bath using appropriate enzymatic detergent following detergent manufacturer's instructions (During ultrasonic cleaning, contact between product should be avoided).<br>**STAGE 3:** Rinsing — Product should be rinsed with running water to completely remove detergent and then dip Densah® 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.<br>**STAGE 4:** Sterilization — Product should be sterilized in a prevacuum autoclave at 132° (269.6°) for a 4-minute duration in a standard approved sterilization wrap. Dry time 30 minutes.<br>**STAGE 5:** During Use— Product should be soaked in a sterile water solution until the cleaning stage. | After cleaning and sterilization stages, the product is ready for long-term storage; The product can be used immediately upon opening from the sterile packaging after long-term storage. |
| Zygoma (ZGO™) Burs<br>Zygoma (ZGO™) Pilot Drills<br>ZGO™ Guided Keys<br>G-Stop® Vertical Gauges<br>C-Guide® Sleeves<br><br>"Single Use Only" | **STAGE 1:** Light Cleaning and Rinsing — Product should be brushed and rinsed with an enzymatic detergent following detergent manufacturer's instructions. Brush the lumen of the article using a 1/32" lumen brush that has been wetted with the prepared detergent 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.<br>**STAGE 2:** Ultrasonic Cleaner — Product should be cleaned in an ultrasonic bath using appropriate enzymatic detergent following detergent manufacturer's instructions. (During Ultrasonic cleaning, contact between product should be avoided)<br>**STAGE 3:** Rinsing — Product should be rinsed with running water to completely remove detergent and then dip ZGO™ Densah® 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.<br>**STAGE 4:** Sterilization — Product should be sterilized in a prevacuum autoclave: Temperature at 132°C (269.6°F)<br>4-minute duration in a standard approved sterilization wrap. Dry time 30 minutes. | Not Applicable | After "initial" cleaning and sterilization stages, the product is ready for long-term storage; The product can be used immediately upon opening from the sterile packaging after long-term storage. |

**Safe Disposal: Dispose of products based on clinical practices established for disposal of reusable and single use surgical devices and per the local regulations for your area.**

**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.

EU REP — Emergo Europe B.V.
Westervoortsedijk 60;
6827 AT Arnhem;
The Netherlands

CH REP — MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug Switzerland

UKRP — U Emergo Consulting (UK) Limited
c/o Cr360 – _UL International
Compass House, Vision Park Histon
Cambridge CB24 9BZ
United Kingdom
Phone: +44(0) 1223 772 671
Email: UKRPvigilance@ul.com

AU REP — Emergo Australia
201 Sussex Street
Darling Park, Tower II, Level 20
Sydney, NSW 2000
Australia

NZ REP — Emergo NZ
24 Side Road
RD 10, Parkhill Farm
Hastings 4180

©2026 Versah, LLC. All rights reserved. Versah, Densah, et al. are registered trademarks. 10641 V6.09.26