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Osteotomy Preparation

Since the early days of dental implantology, osteotomies have been prepared using standard drills designed for use in industrial applications. These drill designs have proven to be functional for dental applications; implant success rates have been satisfactory over time but osteotomy preparation techniques have still been lacking for various reasons. Standard drill designs used in dental implantology are made to excavate bone to create room for the implant to be placed. Standard drill designs, in twist or fluted shapes, cut bone effectively but typically do not produce a precise circumferential osteotomy. Osteotomies may become elongated and elliptical due to chatter of the drills. In these circumstances, the implant insertion torque is reduced, leading to poor primary stability and potential lack of integration. Osteotomies drilled into narrow bone locations may produce dehiscence, buccally or lingually, which also reduces primary stability and will require an additional bone grafting procedure, which adds cost and healing time to treatment.
I. Osseodensification and the Densah® Bur Overview

The Densah® Bur technology is based on a novel biomechanical bone preparation technique called “osseodensification.” Unlike traditional dental drilling techniques, osseodensification does not excavate bone tissue. Rather, bone tissue is simultaneously compacted and auto-grafted in outwardly expanding directions from the osteotomy. When a Densah® Bur is rotated at high speed in a reversed, non-cutting direction with steady external irrigation, a strong and dense layer of bone tissue is formed along the walls and base of the osteotomy. Dense compacted bone tissue produces stronger purchase for your favorite dental implant and may facilitate faster healing.

Biomechanical\(^1\) as well as histological\(^2,3,4\) validation studies of the osseodensification and the procedure utilizing the Densah® Bur technology concluded that, in porcine tibia and Sheep Iliac Crest, osseodensification may facilitate bone expansion, increase implant stability and create a densification layer around the preparation site by compacting and autografting bone particles along the entire depth of the osteotomy.

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\(^{*}\) To view or to download PDF, visit us on the web at www.versah.com/our-science
OSSEODENSIFICATION
Hydrodynamic Bone Preparation

1, 2, 3, 4
Compaction Autografting / Condensation
Maintaining Bone Bulk Results In Higher BIC

5, 6, 7
Enhance Bone Density
Accelerates Bone Healing

8, 9, 10
Increase Residual Strain
Enhances Osteogenic Activity Through Mechanobiology

11, 12, 13
Increase Implant Stability
Higher Insertion Torque & ISQ Reduces Micromotion


NOTE: The references cited illustrate general principles of bone biomechanics and implant treatment and are not specific to the Densah® Bur.
2. Unique Characteristics and Clinical Advantages

Regular twist drills or straight fluted drills have 2-4 lands to guide them through the osteotomy. Densah® Burs are designed with 4 or more lands, which precisely guide them through bone. More lands means less potential chatter. During osseodensification, Densah® Burs produce a controlled bone plastic deformation, which allows the expansion of a cylindrical osteotomy without excavating any bone tissue.
I. Modes

Densah® Burs progressively increase in diameter throughout the surgical procedure and are designed to be used with **standard surgical engines**, 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**).
II. Motion

The 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.
Site evaluation is critical to choose the drilling protocol. Bone morphology, volume and composition all influence the site preparation. The Densah® Burs are designed to function in both clockwise (cutting mode) and counterclockwise (densifying mode) to accomplish specific objectives based on the site and bone diagnosis. One should use clinician experience and judgement in conjunction with the Densifying Reference Guide recommendation and suggested use protocols.
I. Cutting Mode; Use in the Mandible in "Type I" Bone and Abundant "Type II" Bone with Dense Trabecula.

Clockwise Direction

*Due to the geometry of the Pilot Drill do not drill too deep or use lateral pressure. This applies to all sequential pages relating to the Pilot Drill.*
II. Densifying Mode

Counterclockwise Direction

NOTE: Recommended drill speed is **800-1500 rpm** with torque range from 5-50 Ncm for both modes.
III. Versatile Utilization

Densah® Burs can be used in both Cutting and Densifying modes within the same procedure. You can move between multiple osteotomy sites in a patient — cutting in one site and densifying in another — using the same Densah® Bur. In **hard trabecular bone**, Densah® Burs can be used in both Cutting and Densifying modes within the same osteotomy. *(Densify-Preserve) after Cut Protocol.*

To view the video, visit us on the web at [www.versah.com/dac-video](http://www.versah.com/dac-video)
*Clinician experience and judgement should be used in conjunction with the Densifying Reference Guide recommendation and suggested use protocols.
IV. Densah® Bur Marking

Densah® Burs are externally irrigated and designed to be used at drill speeds of 800-1500 rpm. They are marked with laser markings from 3-20 mm depth. Densah® Burs have a tapered geometry; catalog number is a reflection of their minor and major diameter dimension. E.g., Densah® Bur VT3848 has a tip diameter of 3.8 mm and a coronal diameter of 4.8 mm with an average diameter of (4.3 mm).

NOTE: Cutting and Densifying must be done under constant water irrigation. A pumping motion is required to prevent over heating. Surgical drills and burs should be replaced every 12-20 osteotomies or sooner when they are dulled or worn.

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

1. The accuracy of laser markings are tested within +/- 0.5 mm.
2. Please find details under reference 1 on page 49.
4. The Densah® Bur Kit

The Densah® Bur kit includes 12 burs that are designed to create osteotomies for all major dental implants in the market. Each Densah® Bur is marked with depth markings from 3-20 mm. They are designed to be used in a consecutive increasing order to achieve the desired osteotomy diameter.
I. Included in the Kit

Densah® Burs are designed to be used for osseodensification in small increments (alternate between VT5 and VT8) in dense trabecular bone to allow gentle expansion of the osteotomy. In soft bone, the osteotomy final preparation diameter should be prepared with Densah® Bur with an average diameter that measures 0.5-0.7 mm smaller than the implant average diameter. In hard bone, the osteotomy final preparation diameter should be prepared with Densah® Bur with an average diameter that measures 0.2-0.5 mm smaller than the implant average diameter. With Osseodensification, bone preservation creates a spring back effect. As a rule, osteotomies must not be undersized beyond the above stated parameters.

<table>
<thead>
<tr>
<th>VT5 Burs</th>
<th>VT8 Burs</th>
<th>VS8 Burs</th>
</tr>
</thead>
<tbody>
<tr>
<td>VT1525</td>
<td>VT1828</td>
<td>VS2228</td>
</tr>
<tr>
<td>VT2535</td>
<td>VT2838</td>
<td>VS3238</td>
</tr>
<tr>
<td>VT3545</td>
<td>VT3848</td>
<td>VS4248</td>
</tr>
<tr>
<td>VT4555</td>
<td>VT4858</td>
<td>VS5258</td>
</tr>
</tbody>
</table>

Average Diameter: (2.0 mm) (2.3 mm) (2.5 mm) (3.0 mm) (3.3 mm) (3.5 mm) (4.0 mm) (4.3 mm) (4.5 mm) (5.0 mm) (5.3 mm) (5.5 mm)

Suggestive Preparation Steps for Hard Bone Osteotomy

In abundant dense bone: Densah® Bur to be used in Cutting Mode (800-1500 RPM) in Clockwise direction or to be used with Densify-Preserve after Cut protocol (see page 28).
NOTE: Case diagnosis and treatment planning should be done as normally practiced with implant patients. Care should be taken to select the appropriate Densah® Bur sequence for osteotomy preparation indicated by the implant type (tapered/straight), implant diameter and bone density (Hard/Soft). Please refer to Densah® Bur Densifying Reference Guide for specific implant placement protocol. To view or to download PDFs, visit us on the web at www.versah.com/densifying-reference-guide
II. Decision Tree for Osseodensification Protocol

Soft Trabecular Bone — Tapered Implants

<table>
<thead>
<tr>
<th>Implant Diameter</th>
<th>Bur 1</th>
<th>Bur 2</th>
<th>Bur 3</th>
<th>Bur 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5, 3.7, 3.8</td>
<td>Pilot</td>
<td>VT 1525 (2.0)</td>
<td>VT 2535* (3.0)</td>
<td>—</td>
</tr>
<tr>
<td>4.0, 4.2, 4.3</td>
<td>Pilot</td>
<td>VT 1828 (2.3)</td>
<td>VT 2838* (3.3)</td>
<td>—</td>
</tr>
<tr>
<td>4.5, 4.7, 4.8</td>
<td>Pilot</td>
<td>VT 1525 (2.0)</td>
<td>VT 2535 (3.0)</td>
<td>VT 3545* (4.0)</td>
</tr>
<tr>
<td>5.0, 5.2, 5.3</td>
<td>Pilot</td>
<td>VT 1828 (2.3)</td>
<td>VT 2838 (3.3)</td>
<td>VT 3848* (4.3)</td>
</tr>
<tr>
<td>5.5, 5.7, 5.8</td>
<td>Pilot</td>
<td>VT 1525 (2.0)</td>
<td>VT 2535 (3.0)</td>
<td>VT 3545 (4.0)</td>
</tr>
<tr>
<td>6.0, 6.2</td>
<td>Pilot</td>
<td>VT 1828 (2.3)</td>
<td>VT 2838 (3.3)</td>
<td>VT 3848 (4.3)</td>
</tr>
</tbody>
</table>

*Denotes implant placement.

**This is a generalized protocol:** Please refer to Densah® Bur Densifying Reference Guide for specific implant placement protocol. To view or to download PDFs, visit us on the web at [www.versah.com/densifying-reference-guide](http://www.versah.com/densifying-reference-guide).

In abundant dense bone: Densah® Bur to be used in Cutting Mode (800-1500 RPM) in Clockwise direction or to be used with (Densify-Preserve) after Cut protocol (see page 28).

*Clinician experience and judgement should be used in conjunction with the Densifying Reference Guide recommendation and suggested use protocols.
### II. Decision Tree for Osseodensification Protocol

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<tr>
<th>Implant Diameter</th>
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<th>Bur 4</th>
<th>Bur 5</th>
<th>Bur 6</th>
<th>Bur 7</th>
</tr>
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<tbody>
<tr>
<td>3.5, 3.8</td>
<td>Pilot</td>
<td>VT1525 (2.0)</td>
<td>VT1828 (2.3)</td>
<td>VT2535* (3.0)</td>
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<td>—</td>
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<td>VT2838 (3.3)</td>
<td>VS3238* (3.5)</td>
<td>—</td>
</tr>
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<td>Pilot</td>
<td>VT1525 (2.0)</td>
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<td>VT3545* (4.0)</td>
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<td>—</td>
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<td>VT2535 (3.0)</td>
<td>VT2838 (3.3)</td>
<td>VT3545 (4.0)</td>
<td>VT3848 (4.3)</td>
<td>VS4248* (4.5)</td>
</tr>
<tr>
<td>5.5, 5.7, 5.8</td>
<td>Pilot</td>
<td>VT1525 (2.0)</td>
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<td>VT3545 (4.0)</td>
<td>VT3848 (4.3)</td>
<td>VT4555 (5.0)</td>
<td>VT4858 (5.3)</td>
</tr>
</tbody>
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*Denotes implant placement.

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In abundant dense bone: Densah® Bur to be used in Cutting Mode (800-1500 RPM) in Clockwise direction or to be used with (Densify-Preserve) after Cut protocol (see page 28).
## II. Decision Tree for Osseodensification Protocol

### Soft Trabecular Bone — Straight Implants

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<th>Bur 4</th>
<th>Bur 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.0</td>
<td>Pilot</td>
<td>VT 1828 (2.3)</td>
<td>VS 2228* (2.5)</td>
<td>—</td>
<td>—</td>
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<tr>
<td>4.0</td>
<td>Pilot</td>
<td>VT 1828 (2.3)</td>
<td>VT 2838 (3.3)</td>
<td>VS 3238* (3.5)</td>
<td>—</td>
</tr>
<tr>
<td>5.0</td>
<td>Pilot</td>
<td>VT 1828 (2.3)</td>
<td>VT 2838 (3.3)</td>
<td>VT 3848 (4.3)</td>
<td>VS 4248* (4.5)</td>
</tr>
<tr>
<td>6.0</td>
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<td>VT 1828 (2.3)</td>
<td>VS 2228* (2.5)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>4.0</td>
<td>Pilot VT 1828 (2.3)</td>
<td>VT 2838 (3.3)</td>
<td>VS 3238* (3.5)</td>
<td>—</td>
<td>—</td>
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<td>VT 3848 (4.3)</td>
<td>VT 4555 (5.0)</td>
<td>VT 4858 (5.3)</td>
<td>VS 5258* (5.5)</td>
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In abundant dense bone: Densah® Bur to be used in Cutting Mode (800-1500 RPM) in Clockwise direction or to be used with (Densify-Preserve) after Cut protocol (see page 28).
5. Indications and Contraindications for Use

**Indications** Densah® Burs are indicated for use to prepare osteotomies for dental implant placement in the mandible or maxilla.

**Contraindications**

1. Osseodensification does not work in cortical bone.  
   In (Type I/Dense Bone); use the 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.

3. Avoid densifying xenograft.

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 judgement should be used in conjunction with the Densifying Reference Guide recommendation and suggested use protocols. Do not apply lateral pressure when drilling with the pilot drill.
I. Osseodensification in Medium and Soft Trabecular Bone Qualities

1. Flap the soft tissue using the technique indicated for the implant position.

2. Drill to the desired depth using the 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 Densah® Bur. Set the drill 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 drill 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.
II. Osseodensification in Dense Trabecular Bone Quality Especially in the Mandible

We recommend the **use of the Densah® Burs in small increments. Use the VT8 drills as intermediate alternating steps between the VT5 consecutive drills** if needed. **Increase the number of bouncing-pumping motions** to achieve desired depth.

1. Flap the soft tissue using the technique indicated for the implant position.

2. It is advised to prepare the osteotomy **1.0 mm deeper** than the final implant length, using the Pilot Drill (*Drill speed 800-1500 rpm with copious irrigation*).

3. Depending upon the implant type and diameter selected for the site, begin with the narrowest Densah® Bur. **Set the drill 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.

*Clinician experience and judgement should be used in conjunction with the Densifying Reference Guide recommendation and suggested use protocols.
II. Osseodensification in Dense Trabecular Bone Quality Especially in the Mandible

4. **(Densify - Preserve) after Cut (DAC) if needed:** When strong resistance may be felt.

   *Change the drill motor to forward-Cutting Mode* (Clockwise direction at 800-1500 rpm with copious irrigation). Begin advancing the Densah® Bur into the osteotomy until reaching the desired depth. **Stay in the osteotomy,** change the drill motor back to **reverse-Densifying Mode** 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, you will re-deposit the cut bone particles inside the boundaries of the osteotomy. (See page 29 for illustration.)

5. Place the implant into the osteotomy. If using the drill 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.

6. Osseodensification in Dense trabecular bone is only recommended to be utilized to expand a less than adequate ridge width in the Mandible.

7. In abundant dense bone: Densah Bur may be used in Cutting Mode (800-1500 RPM) in Clockwise direction or to be used with Densify-Preserve after Cut protocol.
(Densify - Preserve) after Cut (DAC) Protocol

*Clinician experience and judgement should be used in conjunction with the Densifying Reference Guide recommendation and suggested use protocols.
III. Osseodensification May Facilitate Lateral Ridge Expansion

A. Ridge Expansion Procedure

A sufficient trabecular bone thickness is needed to facilitate plastic expansion.

1. Flap the soft tissue using the technique indicated for the implant position.

2. Drill to the desired depth using the Pilot Drill (Drill speed 800-1500 rpm with copious irrigation).

3. Depending upon the implant type and diameter selected for the site, begin with the narrowest Densah® Bur. Set the drill motor to reverse–Densifying mode (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, repeatedly lift off and reapply pressure with a pumping motion until reaching the desired depth.

4. Use the Densah® Burs in small increments.

5. As the bur diameter increases, the bone will slowly expand to the final diameter.

6. Place the implant into the osteotomy. If using the drill 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.

7. If < 1.5-2.0 mm of buccal bone thickness has resulted after osseodensification, bone grafting is recommended post implant placement and complete implant coverage should be considered for 2-stage healing protocol.
*Clinician experience and judgement should be used in conjunction with the Densifying Reference Guide recommendation and suggested use protocols.
III. Osseodensification May Facilitate Lateral Ridge Expansion

B. The Plus1® Protocol

When utilizing the narrow ridge expansion technique, the implant diameter selected may be up to 0.7 mm larger in diameter than the pre-surgical narrow ridge (Plus1® Protocol). If this protocol is planned to be utilized, the proper diameter implants should be included in the treatment plan and on hand at the surgical appointment.

A minimum of 3.0 mm of alveolar ridge width is needed to place a 3.0 mm or 3.7 mm fixture.

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If < 1.5-2.0 mm buccal bone plate thickness has resulted after osseodensification, bone grafting is recommended post implant placement and complete implant coverage should be considered for 2-stage healing protocol.

In cases of initial ridge width ≤ 3mm with minimal trabecular bone, an 8-10 mm deep intrabony groove is needed prior to expansion to increase elasticity and to allow for more controlled plastic expansion with the Densah® Burs.
Clinician experience and judgement should be used in conjunction with the Densifying Reference Guide recommendation and suggested use protocols.
III. Osseodensification May Facilitate Lateral Ridge Expansion

C. Guided Expansion Graft: 2-Stage Approach

Indicated for cases with less than 3.0 mm ridge width.

1. Flap the soft tissue using the technique indicated for the implant position.

2. Drill to the desired depth using the Pilot Drill (Drill speed 800-1500 rpm with copious irrigation).

3. Begin with the narrowest Densah® Bur. Set the drill motor to reverse–Densifying mode (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, repeatedly lift off and reapply pressure with a pumping motion until reaching the desired depth.

4. Increase osteotomy diameter in small increments until reaching a final width of 3.5 – 4.0 mm. As the bur diameter increases, the bone will slowly expand to the final diameter. To view the video, visit us on the web at www.versah.com/geg.

5. Graft newly formed socket with your preferred bone allograft materials, use membrane if needed and achieve primary closer.
1. 2.0 mm

2. *Clinician experience and judgement should be used in conjunction with the Densifying Reference Guide recommendation and suggested use protocols.

3. 4.0 mm

4.
IV. Osseodensification May Facilitate Vertical Ridge Expansion

A. Maxillary Sinus Autografting - Densah® Lift Protocol I

MINIMUM RESIDUAL BONE HEIGHT ≥ 6 mm  MINIMUM ALVEOLAR WIDTH NEEDED = 4 mm

1. Flap the soft tissue using the instruments and technique normally used.

2. In cases where posterior residual alveolar ridge height is ≥ 6.0 mm and additional vertical depth is desired, drill to the depth determined within an approximate safety zone of 1.0 mm from the sinus floor using a pilot drill (Clockwise drill speed 800-1500 rpm with copious irrigation). Confirm pilot drill position with a radiograph.

3. Depending upon the implant type and diameter selected for the site, begin with the narrowest Densah® Bur (2.0). Change the drill motor to reverse – Densifying Mode (Counterclockwise drill speed 800-1500 rpm with copious irrigation). Begin running the bur to create the osteotomy. Modulate pressure with a pumping motion to reach the sinus floor. When feeling the haptic feedback of the bur reaching the dense sinus floor, stop applying any pressure.

4. A. Use the next wider Densah® Bur (3.0) and advance it into the previously created osteotomy with modulating pressure and a pumping motion. When feeling the haptic feedback of the bur reaching the dense sinus floor, keep modulating pressure with a pumping motion to advance past the sinus floor in 1 mm increments. Maximum possible advancement past the sinus floor at any stage must not exceed 3 mm. Confirm the first Densah® Bur vertical position with a radiograph. Bone will be pushed toward the apical end and will begin to gently lift the membrane and autograft compacted bone.
4. B. Use the sequential Densah® Burs in Densifying Mode (Counterclockwise drill speed 800-1500 rpm with copious irrigation) with pumping motion to achieve additional vertical depth and maximum membrane lift of 3 mm (in 1 mm increments) and reach final desired width for implant placement. Densah® Burs must not advance more than 3 mm past the sinus floor at all times regardless of the Densah® bur diameter.

5. Place the implant into the osteotomy. If using the drill 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 experience and judgement should be used in conjunction with the Densifying Reference Guide recommendation and suggested use protocols.
IV. Osseodensification May Facilitate Vertical Ridge Expansion

B. Maxillary Sinus Autografting - Densah® Lift Protocol II

MINIMUM RESIDUAL BONE HEIGHT = 4-5 mm  MINIMUM ALVEOLAR WIDTH NEEDED = 5 mm

Flap the soft tissue using the instruments and technique normally used. In cases where posterior residual alveolar ridge height is = 4-5 mm and additional vertical depth is desired. **Avoid using a pilot drill.**

1. Depending upon the implant type and diameter selected for the site, begin with the narrowest Densah® Bur (2.0). Change the drill motor to reverse – Densifying Mode (Counterclockwise drill speed 800-1500 rpm with copious irrigation). Begin running the bur to create the osteotomy. Modulate pressure with a pumping motion to reach the sinus floor. Stop drilling once you feel the haptic feedback of the bur reaching the dense sinus floor. Confirm Bur position with a radiograph.

2. A. Use the next wider Densah® Bur (3.0) and advance it into the previously created osteotomy with modulating pressure and a pumping motion. When feeling the haptic feedback of the bur reaching the dense sinus floor, modulate pressure with a pumping motion to advance past the sinus floor in 1 mm increments. **Maximum possible advancement past the sinus floor at any stage must not exceed 3 mm.** Confirm the first Densah® Bur vertical position with a radiograph. Bone will be pushed toward the apical end and will begin to gently lift the membrane and autograft compacted bone.

B. Use the sequential wider Densah® Burs in Densifying Mode (Counterclockwise drill speed 800-1500 rpm with copious irrigation with pumping motion to achieve additional vertical depth and maximum membrane lift of 3 mm (in 1 mm increments) and reach final desired width for implant placement. **Densah® Burs Must not advance more than 3 mm past the sinus floor at all times** regardless of the Densah® Bur diameter.
3. In cases where additional lift of the membrane (more than 3 mm) is desired, an allograft material can be placed into the final width osteotomy.

4. Use the last Densah® Bur in Densifying Mode (Counterclockwise drill speed 150-200 rpm with no irrigation) to propel the allograft into the sinus. The Densah® Bur must only facilitate the allograft material compaction to lift the sinus membrane further, and not advance beyond the sinus floor. *Repeat steps 3 & 4 to facilitate additional membrane lift.

5. Place the implant into the osteotomy. If using the drill 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 experience and judgement should be used in conjunction with the Densifying Reference Guide recommendation and suggested use protocols.
IV. Osseodensification Facilitates Vertical Ridge Expansion

C. Maxillary Sinus Autografting - Densah® Protocol III

MINIMUM RESIDUAL BONE HEIGHT = 2-3 mm  MINIMUM ALVEOLAR WIDTH NEEDED = 7 mm

This protocol will be taught and practiced during Osseodensification hands-on training courses utilizing specially designed simulation clinical models.

Osseodensification training courses are available at:

https://versah.com/training

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*Treatment planning and clinical use of the Densah® Burs are the responsibility of each individual clinician. VERSAH® strongly recommends completion of qualified Osseodensification Hands-On Training and ADHERENCE to the established traditional surgical protocols. VERSAH® is not responsible for incidental or consequential damages or liability relating to use of the Densah® Burs alone or in conjunction with other products other than replacement under warranty.
6. C-Guide System
The Versah C-Guide™ System is an innovative Universal Guided Surgery System. Its C-shape allows the clinician better irrigation, as well as full access to see and manage the osteotomy expansion with complete freedom to the modulation (in and out bouncing) preparation need for the Densah® Bur Technology. The open slots of the TeleStop™ key allow adequate irrigation. The Versah® TeleStop™ gauge provides a telescopic keyless guided surgery operation with the ability to manage multiple sites with different preparation depths with precision and ease.

*Not compatible with Nouvag, Saeyang Handpieces*
II. TeleStop™ Sizes & Its Compatibility

- **S**
  - For Placement
  - Up to 3.25mm Implant
  - VT1525 (2.0)
  - VS2228 (2.5)
  - VT2835 (3.0)
  - VT3545 (4.0)
  - VT4555 (5.0)

- **M**
  - For Placement
  - Up to 4.3mm Implant
  - VT1828 (2.3)
  - VT2535 (3.0)
  - VT3848 (4.3)
  - VT4858 (5.3)
  - VS3238 (3.5)
  - VT4258 (4.5)
  - VS5258 (5.5)

- **L**
  - For Placement
  - Up to 5.3mm Implant
  - VT2535 (3.0)
  - VT3238 (3.5)
  - VT3545 (4.0)
  - VT4555 (5.0)
  - VT4858 (5.3)
  - VS4238 (4.5)
  - VS5258 (5.5)

- **XL**
  - For Placement
  - Up to 6.2mm Implant
  - VT2835 (3.0)
  - VT3238 (3.5)
  - VT3545 (4.0)
  - VT4555 (5.0)
  - VT4858 (5.3)
  - VS4238 (4.5)
  - VS5258 (5.5)

*Not compatible with Nouvag, Saeyang Handpieces*
III. TeleStop™ Gauge & Key Assembly

Assembly Track

Teeth aligned with Assembly Track.

TeleStop™ Key & Vertical Gauge in locked position

TeleStop™ Gauge Disassembly

Prongs of TeleStop™ Gauge Removal Tool in slots of TeleStop™ Gauge to relieve tension.
IV. Size Chart

TeleStop™ Vertical Gauge

TeleStop™ Key

Engaged in locked position

C-Guide™

For placement
Up to 3.25mm Implant

For placement
Up to 4.3mm Implant

For placement
Up to 5.3mm Implant

For placement
Up to 6.2mm Implant
7. Densah® Burs Maintenance, Cleaning, and Storage
I. Instructions for Maintenance of Burs Prior to First-Time Surgical Use

**STAGE 1:** Light Cleaning and Rinsing — Drills should be 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 — Drills should be sterilized in an autoclave at 132°C (269.6°F) at a pressure of 315 Kpa for a 4-minute duration in a standard approved sterilization wrap.

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

*To minimize staining residue, we strongly recommend the use of sterile water surgical irrigation instead of sodium chloride irrigation.*
II. Instructions for Cleaning and Storage of Burs After Use

**STAGE 1:** CLEANING — Drills should be brushed and rinsed with detergent to remove any remaining blood or tissue.

**STAGE 2:** ULTRASONIC CLEANING — Drills 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 — Drills 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 — Drills should be sterilized in an autoclave at 132°C (269.6°F) at a pressure of 315 Kpa for a 4-minute duration in a standard approved sterilization wrap.

**STAGE 5:** STORAGE/USE — At this stage, kits are ready for long-term storage; burs can be used immediately upon opening after long-term storage.

*To minimize staining residue, we strongly recommend the use of sterile water surgical irrigation instead of sodium chloride irrigation.*
III. 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 are the responsibility of each individual clinician. Surgeon preference and clinical judgement overrules the suggestive Densifying Reference Guide 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 use of the Densah® Burs alone or in conjunction with other products other than replacement under warranty.

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

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

VERSAR® 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 or worn out, 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 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 49.
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.