



Densah[®] Bur & Versah[®] Guided Surgery System Instructions for Use



CE2797 Products = Densah Burs, Tapered Pilot Drill,
G-Stop Gauges, G-Stop Keys

CE Products = Parallel Pin, Parallel Pin - XL,
Universal Bur Holder, C-Guides, G-Stop Holder



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*Please visit versah.com/ifu-manuals for the most current IFU

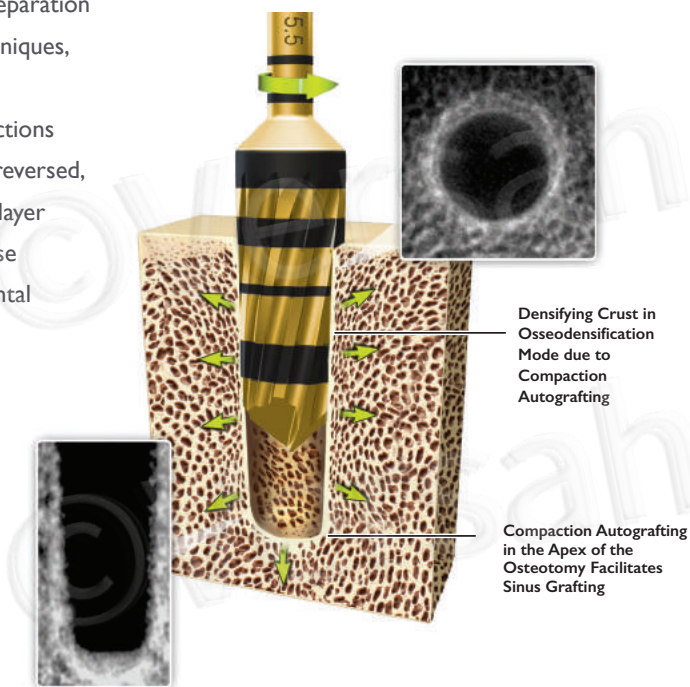
1. Osteotomy Preparation

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

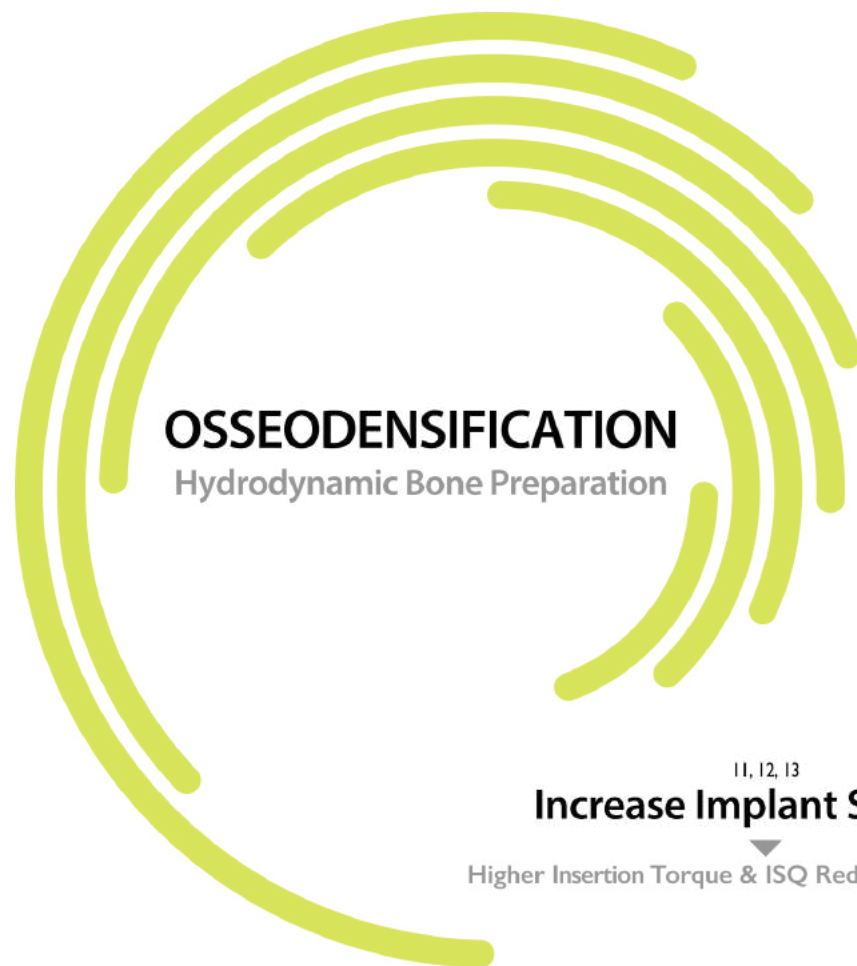
The Densah® Bur technology is based on a novel biomechanical bone preparation technique called “osseodensification.” Unlike traditional dental drilling techniques, osseodensification does not excavate bone tissue. Rather, bone tissue is simultaneously compacted and auto-grafted in outwardly expanding 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.

Biomechanical¹ 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.



1. Huwais, Salah, and Eric G. Meyer. "A Novel Osseous Densification Approach in Implant Osteotomy Preparation to Increase Biomechanical Primary Stability, Bone Mineral Density, and Bone-to-Implant Contact." *International Journal of Oral & Maxillofacial Implants* 32.1 (2017).
2. Trisi, Paolo, et al. "New osseodensification implant site preparation method to increase bone density in low-density bone: in vivo evaluation in sheep." *Implant dentistry* 25.1 (2016): 24.
3. Lahens, Bradley, et al. "Biomechanical and histologic basis of osseodensification drilling for endosteal implant placement in low density bone. An experimental study in sheep." *Journal of the Mechanical Behavior of Biomedical Materials* 63 (2016): 56-65.
4. Lopez, Christopher D., et al. "Osseodensification for enhancement of spinal surgical hardware fixation." *Journal of the mechanical behavior of biomedical materials* 69 (2017): 275-281.

* To view or to download PDF visit us on the web at www.versah.com/our-science



01. Todisco, M. and P.Trisi, Bone mineral density and bone histomorphometry are statistically related. *Int J Oral Maxillofac Implants*, 2005. 20(6): p. 898-904.
02. Frost HM. A brief review for orthopedic surgeons: fatigue damage (microdamage) in bone (its determinants and clinical implications). *J Orthop Sci*. 1998;3(5):272-281.
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09. Duncan RL, Turner CH. Mechanotransduction and the functional response of bone to mechanical strain. *Calcif Tissue Int*. 1995;57(5):344-358.
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11. Trisi P, et al. Implant micromotion is related to peak insertion torque and bone density. *Clin Oral Implants Res*. 2009;20(5):467-471.
12. Pagliani L, Sennerby L, Petersson A, et al. The relationship between resonance frequency analysis (RFA) and lateral displacement of dental implants: an in vitro study. *J Oral Rehabil*. 2013;40(3):221-227.
13. Trisi P, Colagiovanni M, Perfetti G. Implant Stability Quotient (ISQ) vs Direct in Vitro Measurement of Primary Stability (Micromotion): Effect of Bone Density and Insertion Torque. *Journal of Osteology and Biomaterials*. 2010;1(3).

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**).

Counterclockwise (CCW)
Non-Cutting Direction

Clockwise (CW)
Cutting Direction



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.

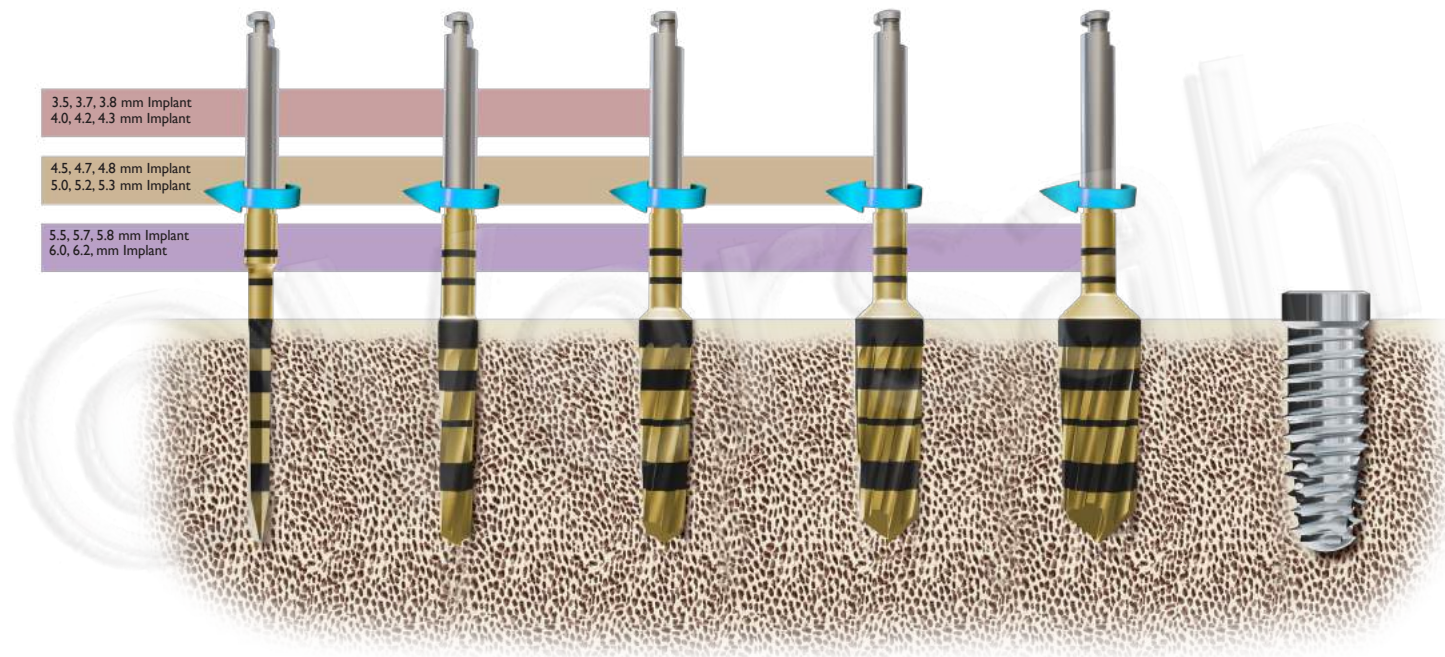


3. Densah® Burs Versatile Utilization

Site evaluation is critical to choose the drilling protocol. Bone morphology, volume and composition all influence site preparation. The Densah® Burs are designed to function in both forward and reverse 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.

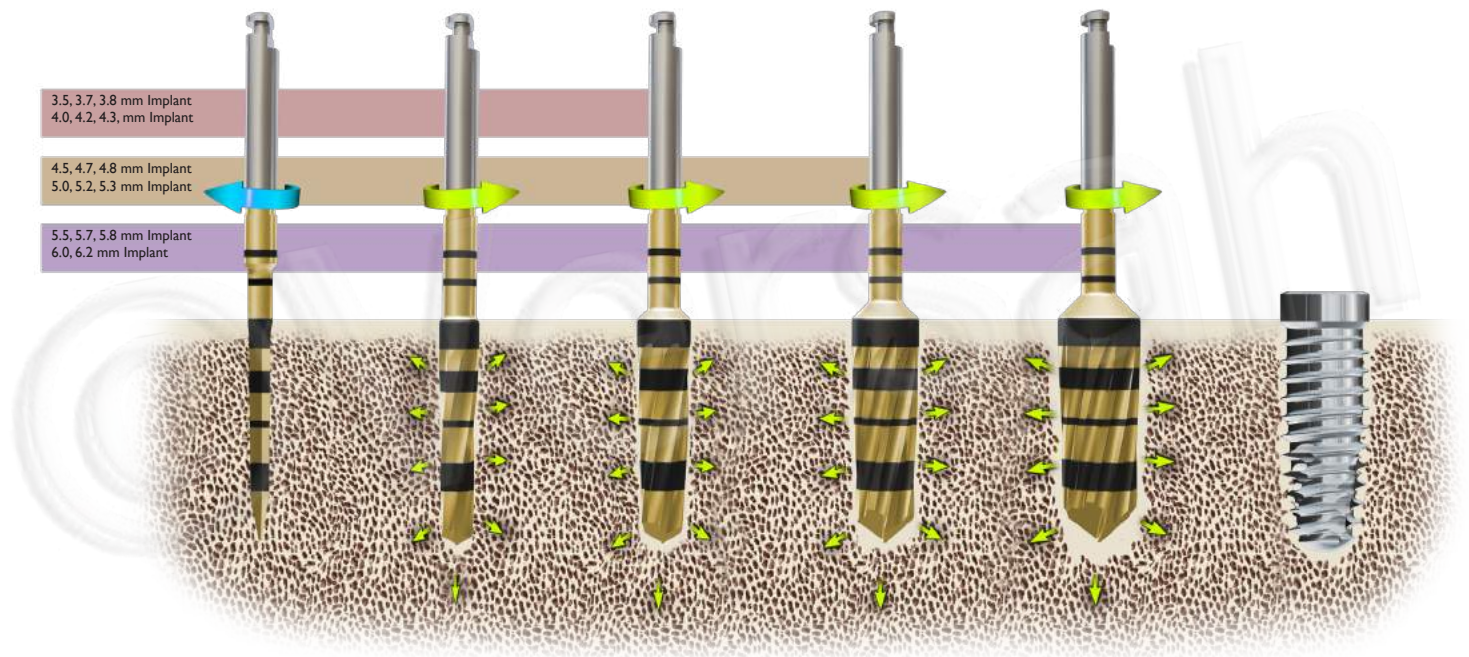
Clockwise Direction



*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

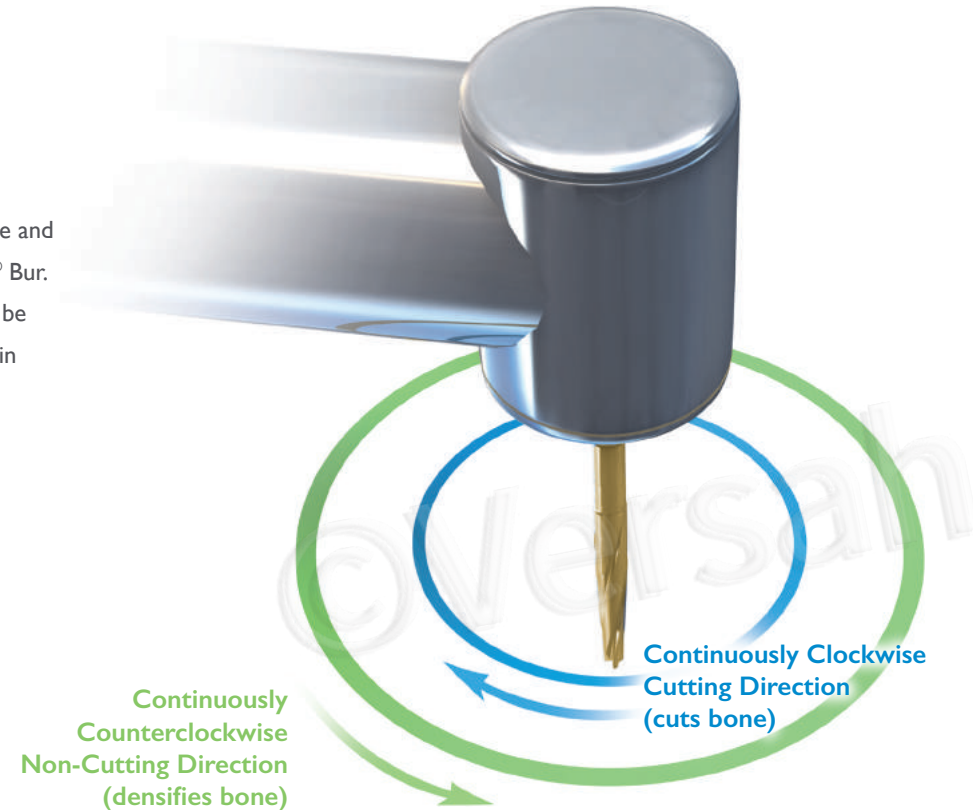
Densah® Burs can be used in both Cutting and Densifying modes within the same procedure. You can move between multiple osteotomy sites in a patient — cutting in one site and densifying in another — using the same Densah® Bur. In **hard trabecular bone**, Densah® Burs can be used in both Cutting and Densifying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

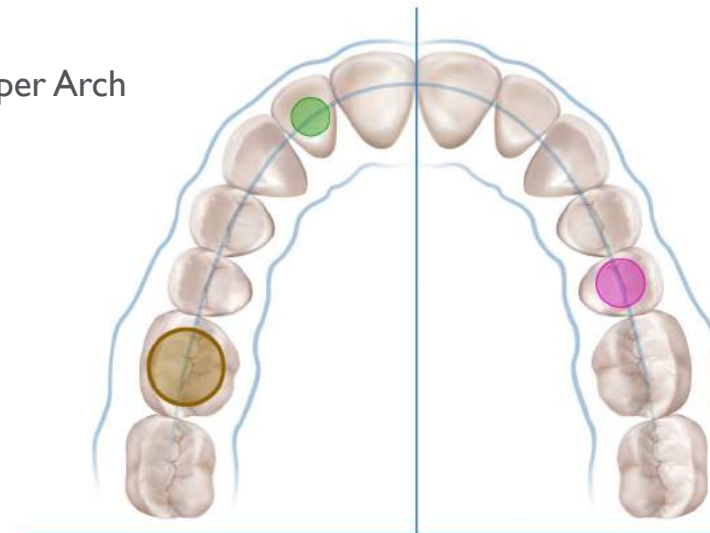


Scan this QR Code to view our Densify After Cut video

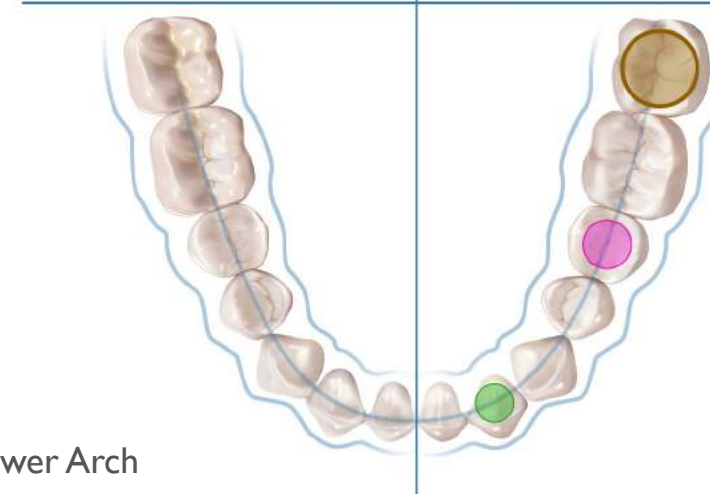


Densify or cut bone with a push of the reverse button on your implant drill console

Upper Arch



Lower Arch



- Osteotomy Site 1
- Osteotomy Site 2
- Osteotomy Site 3

Densify ↻	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cut ↺	Densify ↻	Densify ↻	<input type="checkbox"/>
Cut ↺	Cut ↺	Densify ↻	Densify ↻

*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 markings¹ 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 **(minor-diameter)** of 3.8 mm and a coronal **(major-diameter)** of 4.8 mm at 11.5 mm laser mark with an **average-diameter** of (4.3 mm) at the 8 mm laser mark which becomes the **crestal diameter for short implants length ≤ 8 mm**.

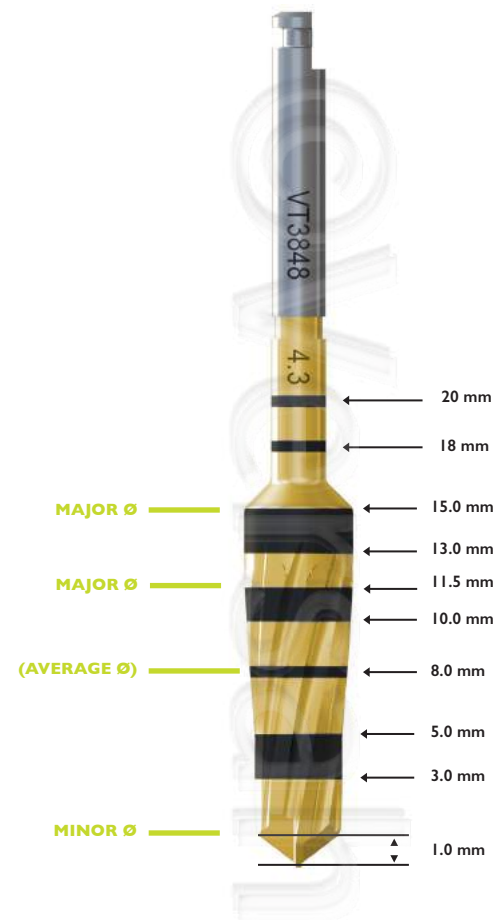
NOTE: Cutting and Densifying must be done under constant water irrigation. A pumping motion is required to prevent over heating. Surgical drills and burs should be replaced every 12-20 osteotomies² or sooner when they are dulled or worn.

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 +/- .5mm.
2. Please find details under reference 1 on page 49.

Densah® Bur Laser Lines



4. The Densah® Bur Kit

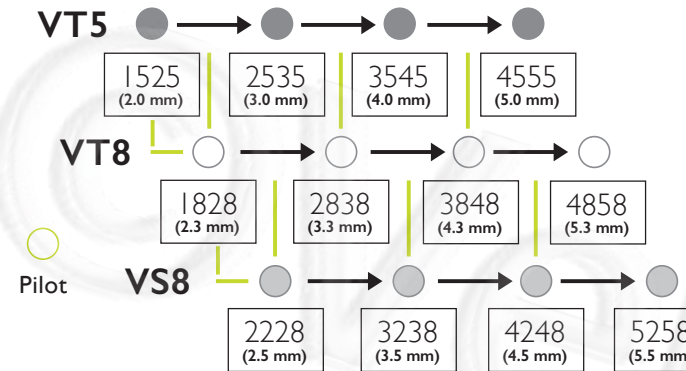
The Densah® Bur kit includes 12 burs that are designed to create osteotomies for all major dental implants in the market. Each Densah® Bur is marked with depth markings from 3-20 mm. They are designed to be used in a consecutive increasing order to achieve the desired osteotomy diameter.

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.**

VT5 Series				VT8 Series				VS8 Series			
VT1525	VT2535	VT3545	VT4555	VT1828	VT2838	VT3848	VT4858	VS2228	VS3238	VS4248	VS5258
											
(2.0 mm)	(3.0mm)	(4.0 mm)	(5.0 mm)	(2.3 mm)	(3.3 mm)	(4.3 mm)	(5.3 mm)	(2.5 mm)	(3.5 mm)	(4.5 mm)	(5.5 mm)
Average Diameter				Average Diameter				Average Diameter			

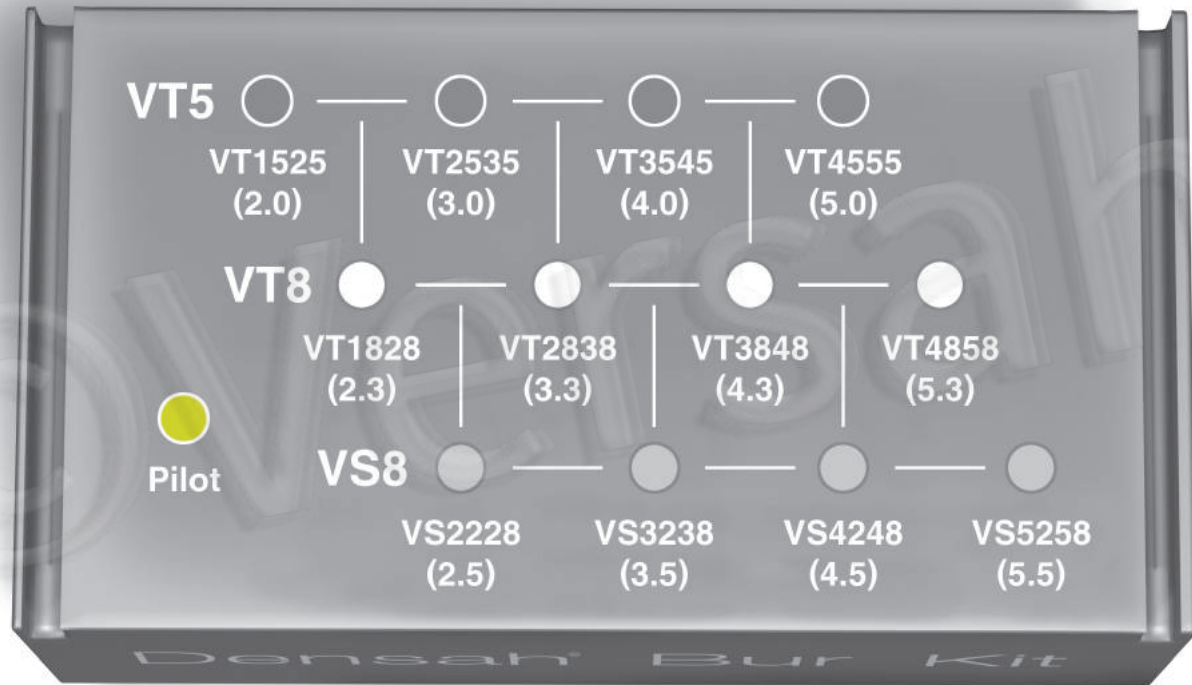
Please refer to Densah® Bur Densifying Reference Guide for specific implant placement protocol. To view or to download PDFs, visit us on the web at www.versah.com/densifying-reference-guide



— Suggestive Preparation Steps for Hard Bone Osteotomy
 → Suggestive Preparation Steps for Soft 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).

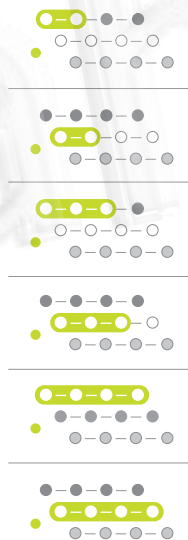


II. Decision Tree for Osseodensification Protocol

● VT5 Bur ○ VT8 Bur ● VS8 Bur

Soft Trabecular Bone — Tapered Implants

Implant Diameter		Bur 1	Bur 2	Bur 3	Bur 4
3.5, 3.7, 3.8	Pilot	VT 1525 (2.0)	VT 2535* (3.0)	—	—
4.0, 4.2, 4.3	Pilot	VT 1828 (2.3)	VT 2838* (3.3)	—	—
4.5, 4.7, 4.8	Pilot	VT 1525 (2.0)	VT 2535 (3.0)	VT 3545* (4.0)	—
5.0, 5.2, 5.3	Pilot	VT 1828 (2.3)	VT 2838 (3.3)	VT 3848* (4.3)	—
5.5, 5.7, 5.8	Pilot	VT 1525 (2.0)	VT 2535 (3.0)	VT 3545 (4.0)	VT 4555* (5.0)
6.0, 6.2	Pilot	VT 1828 (2.3)	VT 2838 (3.3)	VT 3848 (4.3)	VT 4858* (5.3)



*Denotes implant placement.

Continued on next page

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

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.

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

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II. Decision Tree for Osseodensification Protocol

● VT5 Bur ○ VT8 Bur ● VS8 Bur

Hard Trabecular Bone — Tapered Implants

Implant Diameter		Bur 1	Bur 2	Bur 3	Bur 4	Bur 5	Bur 6	Bur 7
3.5, 3.8	Pilot	VT 1525 (2.0)	VT 1828 (2.3)	VT 2535* (3.0)	—	—	—	—
4.0, 4.2, 4.3	Pilot	VT 1525 (2.0)	VT 1828 (2.3)	VT 2535 (3.0)	VT 2838 (3.3)	VS 3238* (3.5)	—	—
4.5, 4.7, 4.8	Pilot	VT 1525 (2.0)	VT 2535 (3.0)	VT 2838 (3.3)	VT 3545* (4.0)	—	—	—
5.0, 5.2, 5.3	Pilot	VT 1828 (2.3)	VT 2535 (3.0)	VT 2838 (3.3)	VT 3545 (4.0)	VT 3848 (4.3)	VS 4248* (4.5)	—
5.5, 5.7, 5.8	Pilot	VT 1525 (2.0)	VT 2535 (3.0)	VT 2838 (3.3)	VT 3545 (4.0)	VT 3848 (4.3)	VT 4555* (5.0)	—
6.0, 6.2	Pilot	VT 1828 (2.3)	VT 2838 (3.3)	VT 3545 (4.0)	VT 3848 (4.3)	VT 4555 (5.0)	VT 4858 (5.3)	VS 5258* (5.5)



*Denotes implant placement.

Continued on next page

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

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

● VT5 Bur ○ VT8 Bur ● VS8 Bur

Soft Trabecular Bone — Straight Implants

Implant Diameter		Bur 1	Bur 2	Bur 3	Bur 4	Bur 5
3.0	Pilot	VT 1828 (2.3)	VS 2228* (2.5)	—	—	—
4.0	Pilot	VT 1828 (2.3)	VT 2838 (3.3)	VS 3238* (3.5)	—	—
5.0	Pilot	VT 1828 (2.3)	VT 2838 (3.3)	VT 3848 (4.3)	VS 4248* (4.5)	—
6.0	Pilot	VT 1828 (2.3)	VT 2838 (3.3)	VT 3848 (4.3)	VT 4858 (5.3)	VS 5258* (5.5)



*Denotes implant placement.

Continued on next page

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

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).

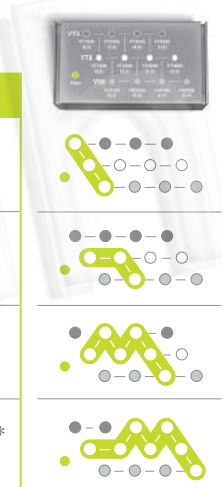
*Clinician experience and judgement should be used in conjunction with the Densifying Reference Guide recommendation and suggested use protocols.

II. Decision Tree for Osseodensification Protocol

● VT5 Bur ○ VT8 Bur ● VS8 Bur

Hard Trabecular Bone — Straight Implants

Implant Diameter		Bur 1	Bur 2	Bur 3	Bur 4	Bur 5	Bur 6	Bur 7
3.0	Pilot	VT 1525 (2.0)	VT 1828 (2.3)	VS 2228* (2.5)	—	—	—	—
4.0	Pilot	VT 1828 (2.3)	VT 2838 (3.3)	VS 3238* (3.5)	—	—	—	—
5.0	Pilot	VT 1828 (2.3)	VT 2535 (3.0)	VT 2838 (3.3)	VT 3545 (4.0)	VT 3848 (4.3)	VS 4248* (4.5)	—
6.0	Pilot	VT 1828 (2.3)	VT 2838 (3.3)	VT 3545 (4.0)	VT 3848 (4.3)	VT 4555 (5.0)	VT 4858 (5.3)	VS 5258* (5.5)



*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).

5. Indications and Contraindications for Use

Indications

1. Densah® Burs are indicated for use to prepare osteotomies for dental implant placement in the mandible or maxilla.
2. The Pilot Drill is used to create the initial hole in bone to prepare an osteotomy for dental implant placement and monitor the drilling depth.
3. The parallel pin is for use as a paralleling guide with the Densah® Burs.

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.

Continued on next page

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.



Scan this QR Code to view our Densify After Cut video

(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

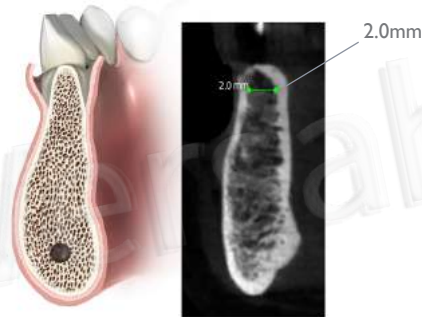
Osseodensification will not create the tissue, it may only optimize and preserve what already exists.

There is a need for ≥ 2 mm of trabecular-bone core and $\geq 1/1$ trabecular/cortical bone ratio to achieve a predictable plastic expansion. The more cortical bone there is, the more trabecular core is needed to facilitate predictable expansion. The ideal minimum ridge to expand is 4 mm (2 mm trabecular core + 1mm cortex on each side).

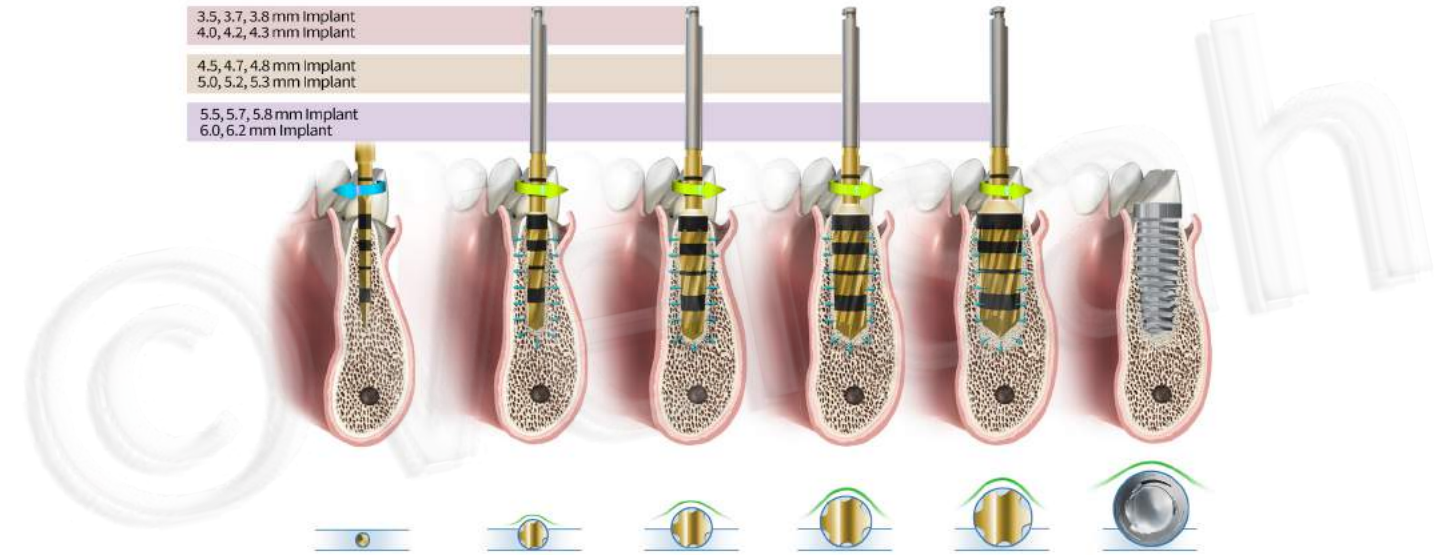
This protocol is indicated to expand a ridge with a narrow crest and wider base. It is not indicated in resorbed ridge with a narrow base.

In ridge expansion cases please oversize your osteotomy and make sure that the osteotomy crestal diameter is equal or larger than the implant major diameter.

1. **Diagnose and assess the amount of trabecular bone available using a CBCT** to evaluate bone composition needed to perform a predictable plastic expansion.
2. Flap the soft tissue using the technique indicated for the implant position.
3. Depending upon the implant type and diameter selected for the site, after a narrow pilot osteotomy, 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 lift off pressure and reapply, repeatedly lift off and reapply pressure with a pumping motion until reaching the desired depth.



Scan this QR Code to view our Ridge Expansion Procedure video



4. **Use the Densah® Burs in small increments.** As the bur diameter increases, the bone may gradually expand to the final diameter. The osteotomy may be expanded with minimal bone dehiscence, which may allow for total implant length placement in autogenous bone without thread exposure. Mandibular osteotomies need to be planned and performed to **1 mm deeper** than the implant length.
5. **Place an implant with a diameter that is equal or slightly larger than the initial ridge width** (up to 0.7 mm larger). 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. The proper diameter implants should be included in the treatment plan and on hand at the surgical appointment.
6. If < 1.5 - 2.0 mm of buccal bone thickness has resulted after osseodensification, perform hard and soft tissue veneer contour-graft to augment around the implant to develop tissue thickness that may enhance long term stability. Complete implant coverage may be considered for 2-stage healing protocol.

*Clinician experience and judgement should be used in conjunction with this suggested use protocol.

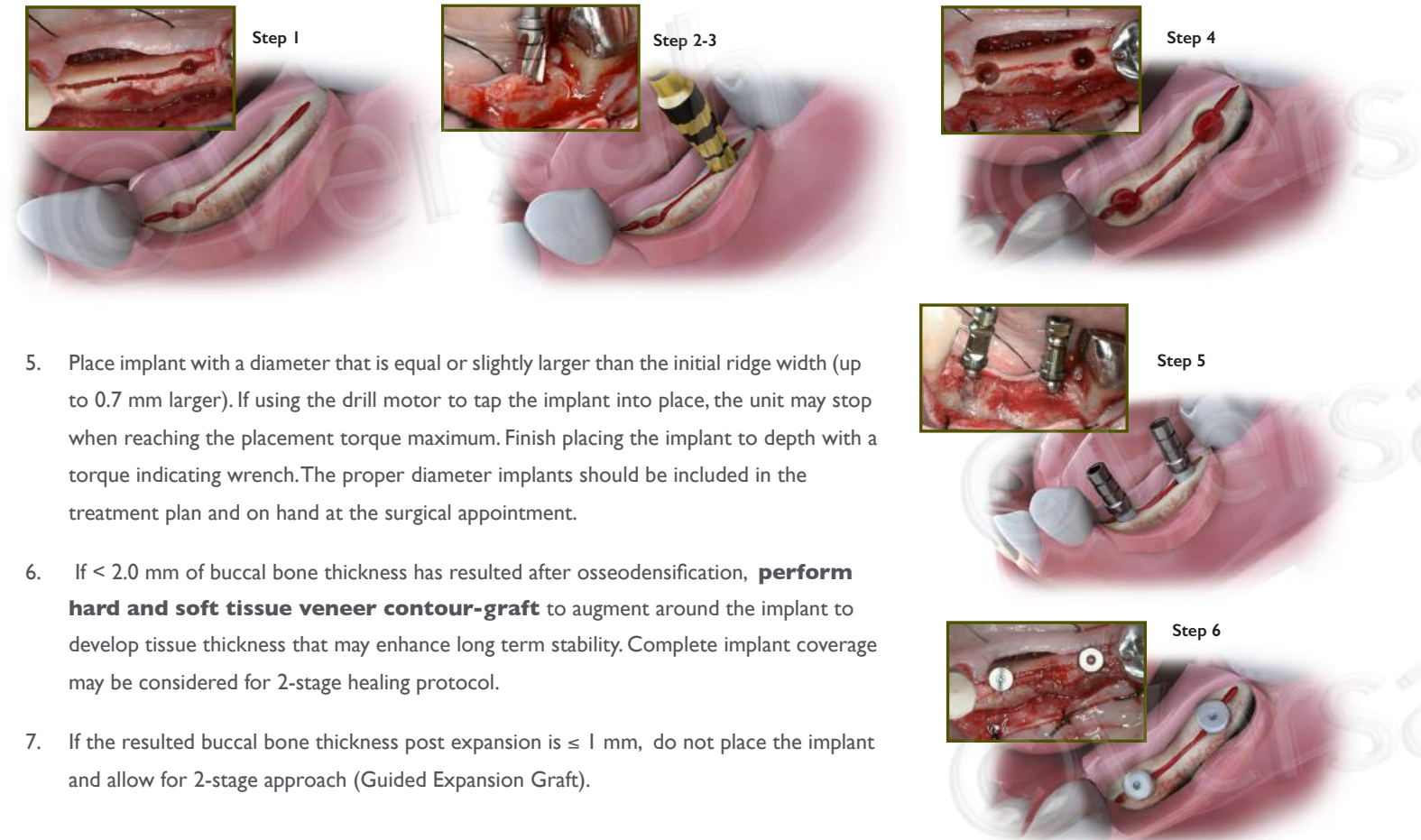
III. Osseodensification May Facilitate Lateral Ridge Expansion

B. Ridge Expansion with Modified Ridge Split:

For cases with ridge width < 4mm that contains ≤ 2mm of trabecular-bone core.

This protocol is indicated to expand a ridge with a narrow crest and wider base. It is not indicated in resorbed ridge with a narrow base. In ridge expansion cases please oversize your osteotomy and make sure that the crestal diameter is equal or larger than the implant major diameter.

1. In cases of an initial ridge width < 4mm that contains ≤ 2mm of trabecular-bone core, an intra-bony ridge split is needed; ridge split to be made by a Piezosurgery 0.3-0.5 mm tip. Ridge split is recommended to be as deep as the planned implant length. **No vertical cuts are needed.** Ridge split is to allow more buccal wall elasticity during the expansion procedure. **This intra-bony split is contraindicated in resorbed ridge with a narrow base.**
2. Depending upon the implant type and diameter selected for the site, after a narrow pilot osteotomy, 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 lift off pressure and reapply, repeatedly lift off and reapply pressure with a pumping motion until reaching the desired depth.
3. **Use the Densah® Burs in small increments.** As the bur diameter increases, the bone may gradually expand to the final diameter. The osteotomy may be expanded with minimal bone dehiscence, which may allow for total implant length placement in autogenous bone without thread exposure.
4. **Oversize the osteotomy** to be slightly wider than the implant major diameter (especially in the mandible) to prevent the implant thread from over-straining the expanded bony walls. Mandibular osteotomies need to be planned and performed to **1mm deeper** than the implant length.



5. Place implant with a diameter that is equal or slightly larger than the initial ridge width (up to 0.7 mm larger). 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. The proper diameter implants should be included in the treatment plan and on hand at the surgical appointment.
6. If < 2.0 mm of buccal bone thickness has resulted after osseodensification, **perform hard and soft tissue veneer contour-graft** to augment around the implant to develop tissue thickness that may enhance long term stability. Complete implant coverage may be considered for 2-stage healing protocol.
7. If the resulted buccal bone thickness post expansion is ≤ 1 mm, do not place the implant and allow for 2-stage approach (Guided Expansion Graft).

*Clinician experience and judgement should be used in conjunction with this suggested use protocol.

III. Osseodensification May Facilitate Lateral Ridge Expansion

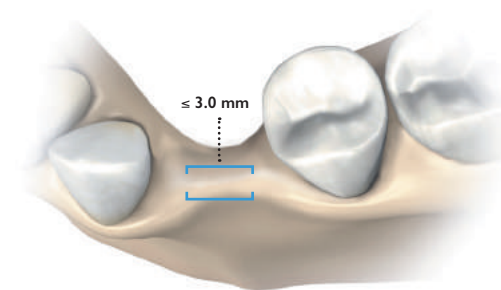
C. Guided Expansion Graft: 2-Stage Approach

For cases with initial width of ≤ 3.0 mm

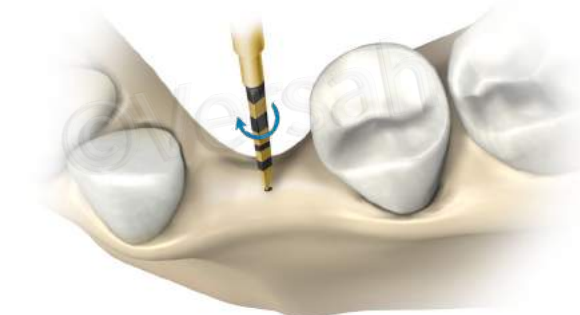
1. Flap the soft tissue using the technique indicated for the implant position.
2. Drill to the desired depth using the Pilot Drill (Drill speed 800-1500 rpm with copious irrigation).
3. Begin with the narrowest Densah® Bur. Set the drill motor to reverse—**Densifying Mode** (Counterclockwise drill speed 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 $\leq 3.5 - 4.0$ mm. As the bur diameter increases, the bone may gradually expand to the final diameter. To view the video, visit us on the web at www.versah.com/geg.
5. **Graft the newly formed socket** including surrounding area with your preferred bone allograft materials, use membrane and achieve primary closure. Allow healing for 4-6 months.
6. Perform osseodensification to facilitate further expansion if needed and place the implant. 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. The proper diameter implants should be included in the treatment plan and on hand at the surgical appointment.



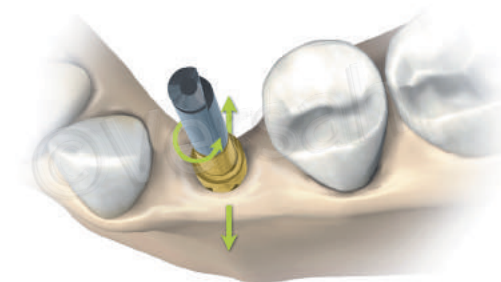
Scan this QR Code to view our Guided Expansion Graft Procedure video



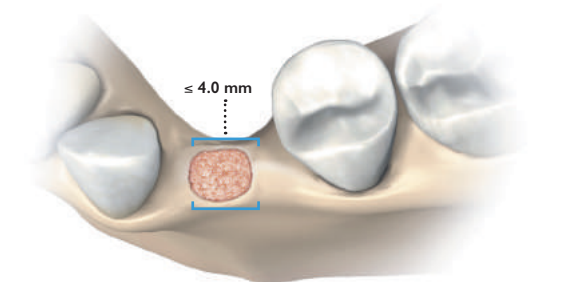
1.



2.



3.



4.

*Clinician experience and judgement should be used in conjunction with this suggested use protocol.

IV. Osseodensification May Facilitate Vertical Ridge Expansion

A. Maxillary Sinus Autografting - Densah® Lift Protocol I

MINIMUM RESIDUAL BONE HEIGHT \geq 6 mm MINIMUM ALVEOLAR WIDTH NEEDED = 4 mm



Scan this QR Code to view our Maxillary Sinus Autografting video

Overview: Use Densah® Burs in full step increments. For example: 2.0mm, 3.0mm, 4.0mm, 5.0mm.

1. **Measure bone height to the sinus floor.**

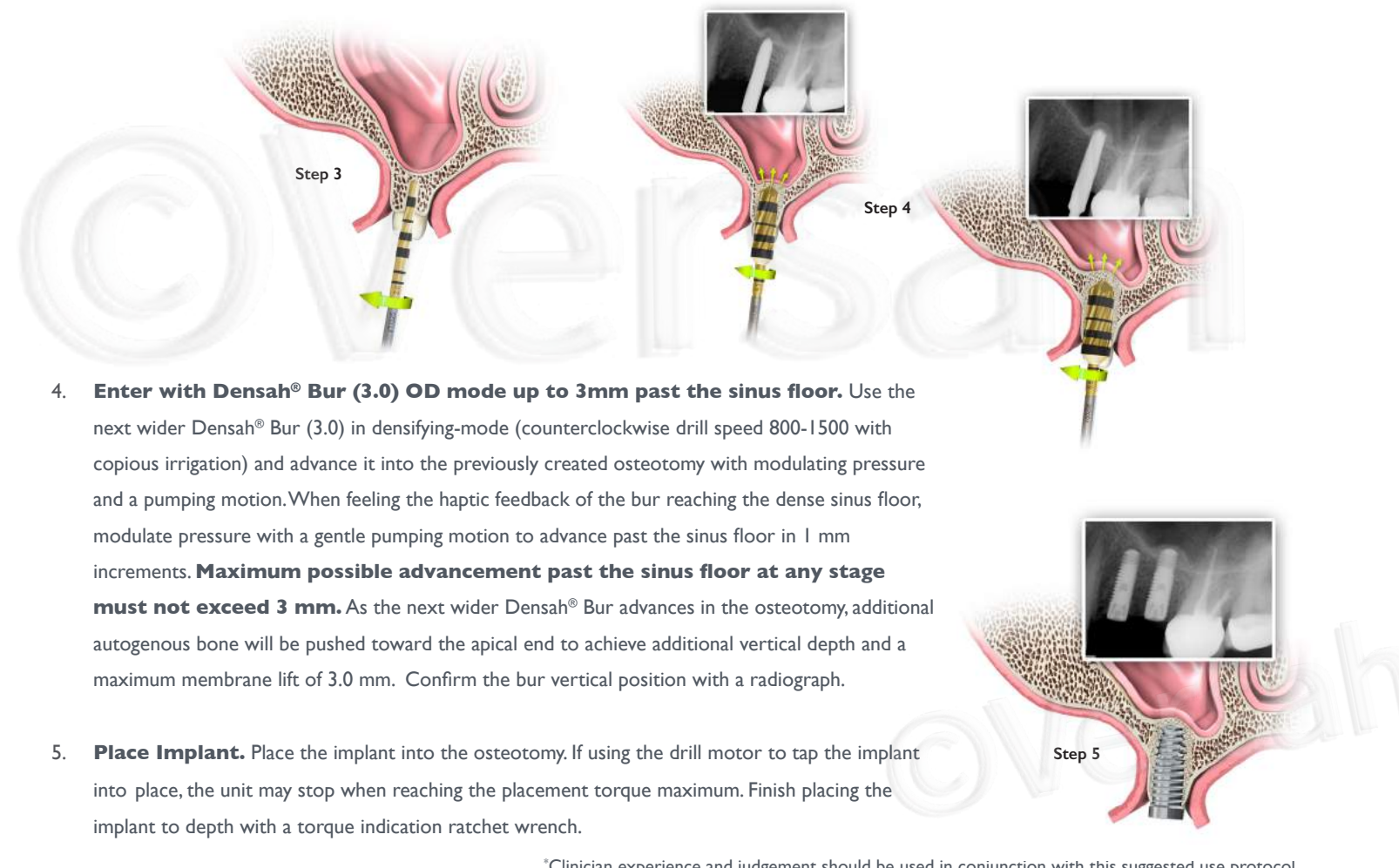
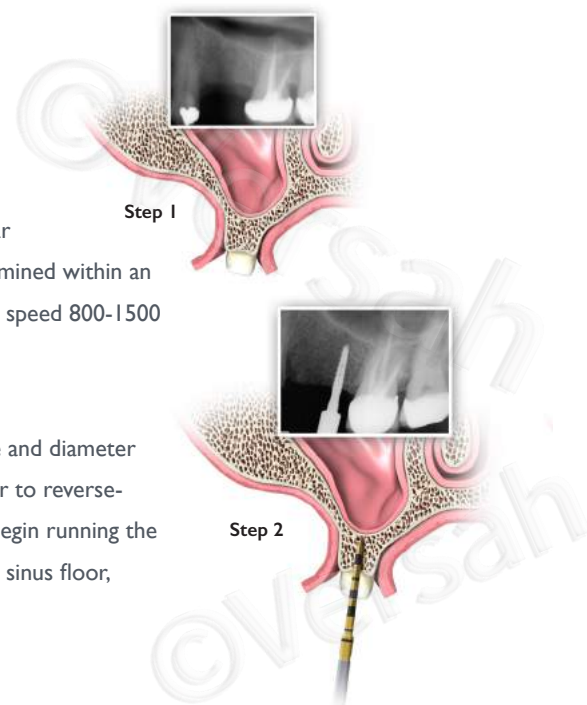
Flap the soft tissue using instruments and technique normally used.

2. **Pilot drill 1 mm below the sinus floor.**

In cases where posterior residual alveolar ridge height is \geq 6.0mm, and additional vertical depth is desired, drill to the depth determined within an approximate safety zone of 1.0mm 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. **Densah® Bur (2.0) OD mode to sinus floor.**

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 into the osteotomy. When feeling the haptic feedback of the bur reaching the dense sinus floor, stop and confirm the first Densah® Bur vertical position with a radiograph.



4. **Enter with Densah® Bur (3.0) OD mode up to 3mm past the sinus floor.**

Use the next wider Densah® Bur (3.0) in densifying-mode (counterclockwise drill speed 800-1500 with copious irrigation) 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 gentle 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.** As the next wider Densah® Bur advances in the osteotomy, additional autogenous bone will be pushed toward the apical end to achieve additional vertical depth and a maximum membrane lift of 3.0 mm. Confirm the bur vertical position with a radiograph.

5. **Place Implant.** 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 indication ratchet wrench.

*Clinician experience and judgement should be used in conjunction with this suggested use protocol.

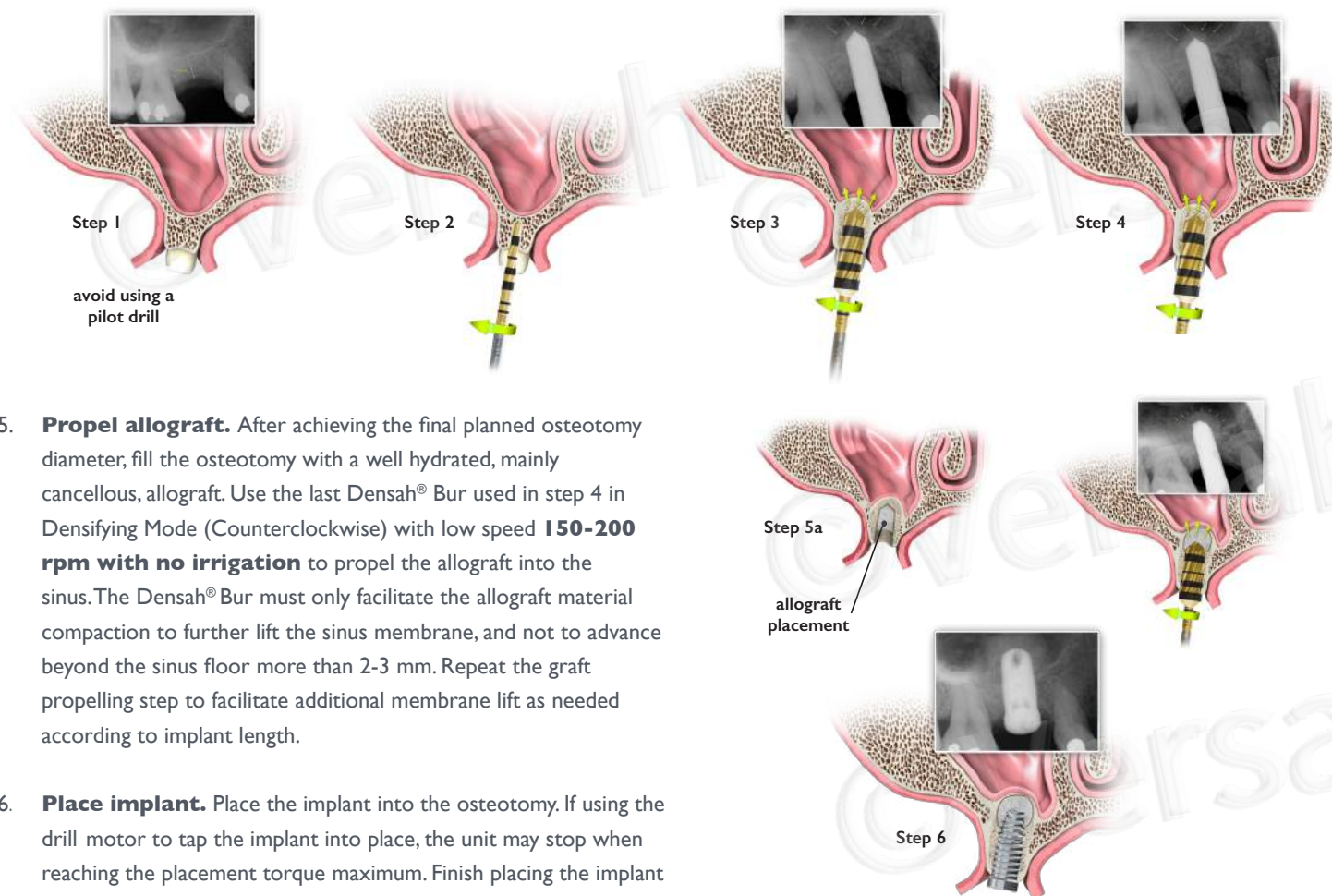
IV. Osseodensification May Facilitate Vertical Ridge Expansion

B. Maxillary Sinus Autografting - Densah® Lift Protocol II

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

Overview: Use Densah® Burs in full step increments. For example: 2.0mm, 3.0mm, 4.0mm, 5.0mm. **Avoid using a pilot drill.**

1. **Measure bone height to sinus floor.** Flap the soft tissue using instruments and technique normally used.
2. **Densah Bur (2.0) OD Mode to sinus floor.** Avoid using a pilot drill. 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 (counterclockwise drill speed 800-1500 rpm—Densifying Mode with copious irrigation). Begin running the bur into the osteotomy until reaching the dense sinus floor. Confirm bur position with a radiograph.
3. **Enter with Densah® Bur (3.0) OD mode up to 3mm past the sinus floor.** 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, up to 3mm. **Maximum bur advancement past the sinus floor, at any stage, must not exceed 3 mm.** Bone will be pushed toward the apical end and will begin to gently lift the membrane and autograft compacted bone up to 3mm. Confirm bur vertical position with a radiograph.
4. **Densah Bur (4.0), (5.0) OD mode up to 3mm past the sinus floor.** Use the sequential wider Densah® Burs in Densifying Mode (Counterclockwise drill speed 800-1500 rpm) with copious irrigation with pumping motion to achieve additional width with maximum membrane lift of 3 mm (in 1 mm increments) to 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. **Propel allograft.** After achieving the final planned osteotomy diameter, fill the osteotomy with a well hydrated, mainly cancellous, allograft. Use the last Densah® Bur used in step 4 in Densifying Mode (Counterclockwise) with low 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 further lift the sinus membrane, and not to advance beyond the sinus floor more than 2-3 mm. Repeat the graft propelling step to facilitate additional membrane lift as needed according to implant length.
6. **Place implant.** 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 this suggested use protocol.

IV. Osseodensification Facilitates Vertical Ridge Expansion

C. Maxillary Sinus Autografting - Densah® Lift 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>

*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 STRICT ADHERENCE to established traditional surgical protocol. 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. Versah® Guided Surgery System

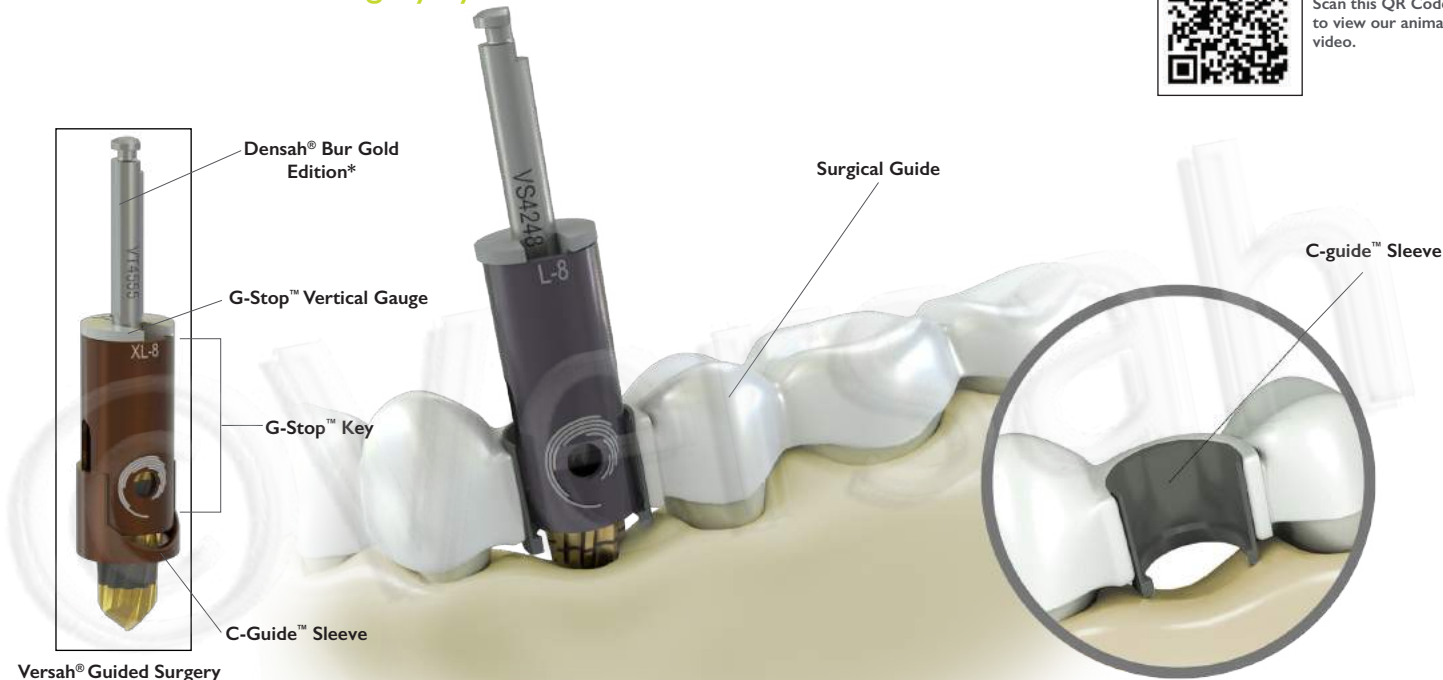
Indications for Use

1. The G-Stop™ Key and Gauge provide vertical control for drilling the osteotomy. The G-Stop™ Key and Gauge can be used with printed guides (C-Guide™ Sleeves to control the angulation of the hole.
2. The C-Guide™ Sleeve is placed into a surgical guide by the dental lab as appropriate for each patient anatomy.

I. Universal Guided Surgery System Overview



Scan this QR Code to view our animation video.



Versah® Guided Surgery System Assembly

The Versah® 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 bouncing) preparation needed for the Densah® Bur Technology. The open slots of the G-Stop™ key is designed to allow adequate irrigation. The Versah® G-Stop™ provides a keyless guided surgery operation with the ability to manage multiple sites with precision and ease.

*New and Improved Titanium Nitride Coating

II. G-Stop™ Vertical Gauge + Key Sizes & Its Compatibility



III. G-Stop™ Vertical Gauge & Key: Assembly



G-Stop™ Vertical Gauge & Key: Disassembly



IV. Size Chart



7 • Densah® Burs and Accessories Maintenance, Cleaning, and Storage

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

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

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

STAGE 3: Sterilization — Drills 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 — 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 Drills After Use

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

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 drills in Surgical Milk solution or 70% Isopropyl Alcohol for approximately 30 seconds, remove, let drain to dry. Do not rinse or wipe drills again.

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

STAGE 6: STORAGE/USE — At this stage, drills are ready for long-term storage; drills 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.**

I. Instructions for First-Time Surgical Use and Maintenance of Accessories

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.

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

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 and accessories are the responsibility of each individual clinician. **Surgeon preference and clinical judgment 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 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.

NOTE: Surgical drills should be replaced when they are dulled or worn out. VERSAH® recommends replacing surgical drills 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.

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

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

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.

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.

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.

Please find details under reference I on page 49.





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Jackson, MI 49203 USA



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



Sterilize prior to use



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October 2019

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