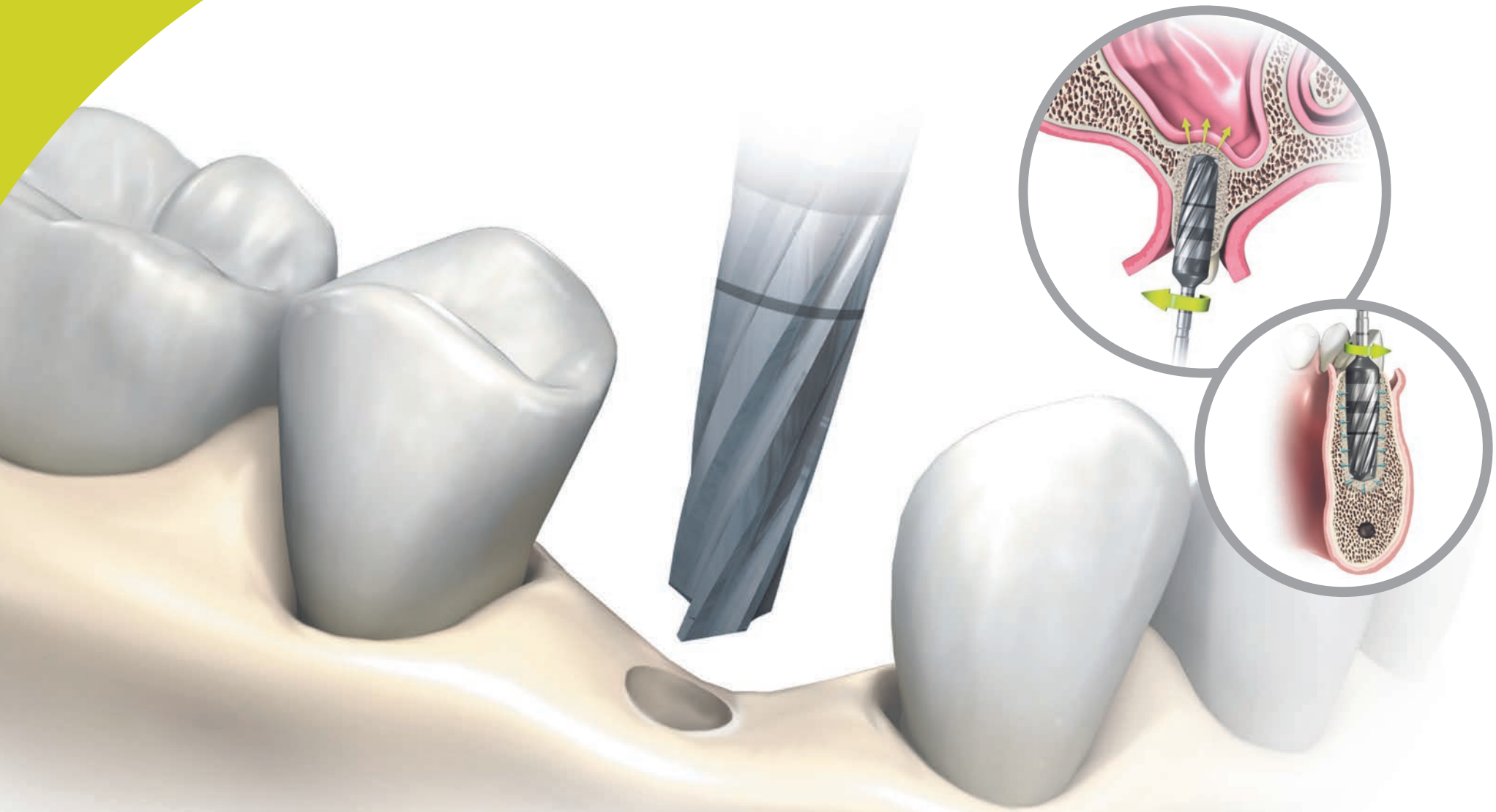


Versah®
THE OSSEODENSIFICATION COMPANY

Densah® Bur Surgical Technique Manual

Versah®
THE OSSEODENSIFICATION COMPANY

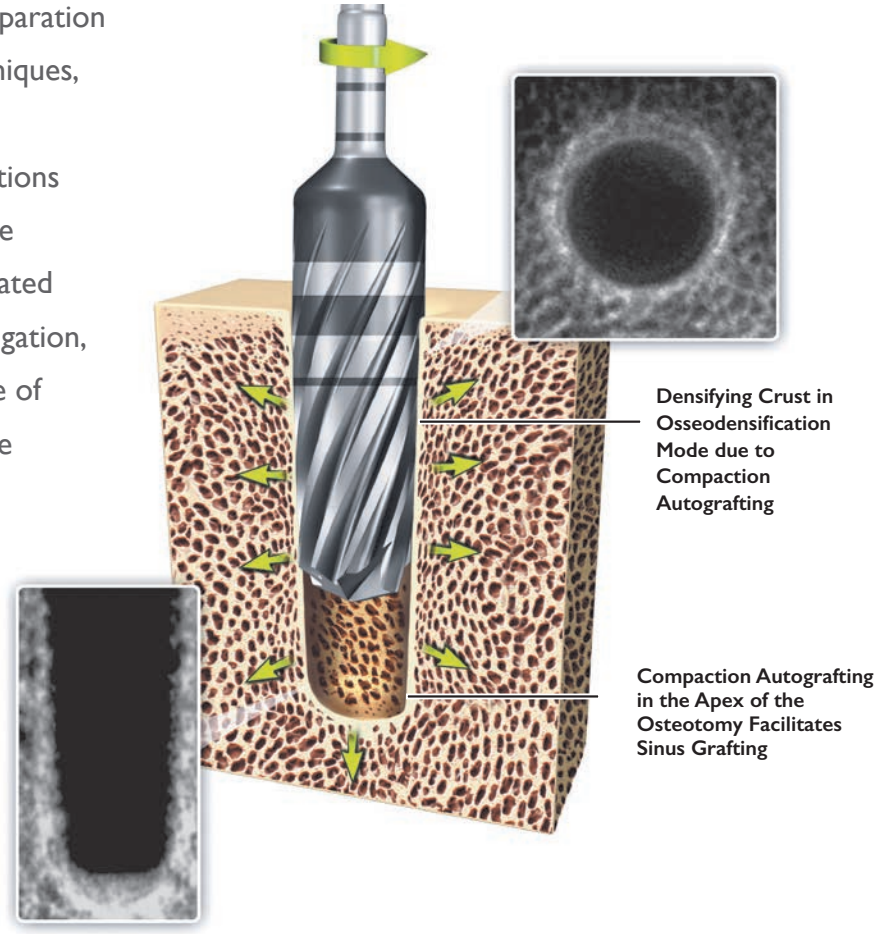
SECTIONS

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, somewhat akin to a traditional hammered osteotome but without the trauma and other limitations. 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.



A biomechanical as well as histological validation study of the osseodensification technology and the Densah® Bur was performed by the Experimental Biomechanics Laboratory at Lawrence Technological University in Southfield, Michigan, in 2013–2014. Study concluded that, in porcine tibia, osseodensification increases primary stability and creates a densification crust around the preparation site by compacting and autografting bone along the entire depth of the hole.

Click link to view PDF: www.versah.com/ltu

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

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.
03. Kold S, et al. Bone compaction enhances fixation of hydroxyapatite-coated implants in a canine gap model. *J Biomed Mater Res B Appl Biomater*. 2005;75(1):49-55.
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05. Nkenke E, et al. Histomorphometric and fluorescence microscopic analysis of bone remodelling after installation of implants using an osteotome technique. *Clin Oral Implants Res*. 2002;13(6):595-602.
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10. Kold S, et al. Compacted cancellous bone has a spring-back effect. *Acta Orthop Scand*. 2003;74(5):591-595.
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

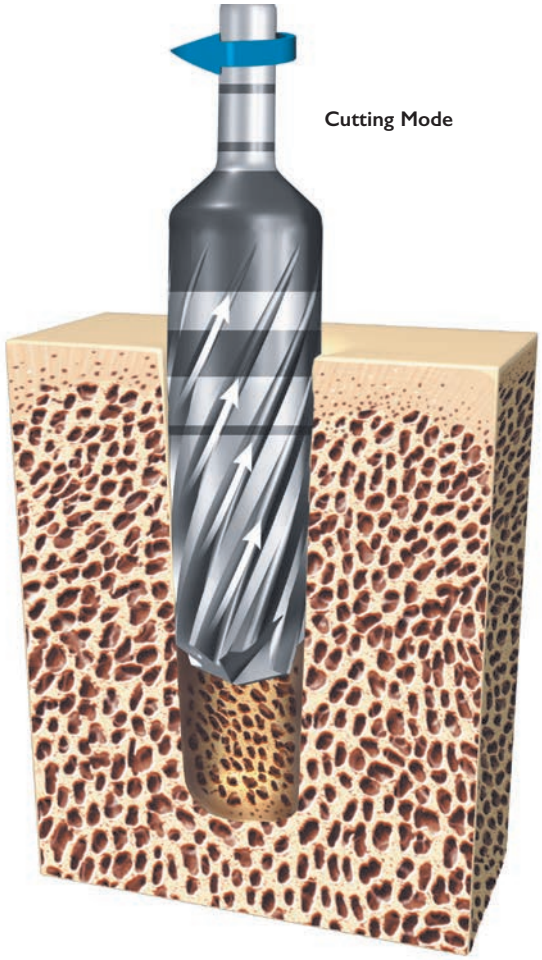
Regular twist drills or straight fluted drills have 2-4 lands to guide them through the osteotomy. Densah® Burs are designed with 4 or more lands, which precisely guide them through bone. More lands means less potential chatter. During osseodensification, Densah® Burs produce a controlled bone plastic 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 condense 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)**.

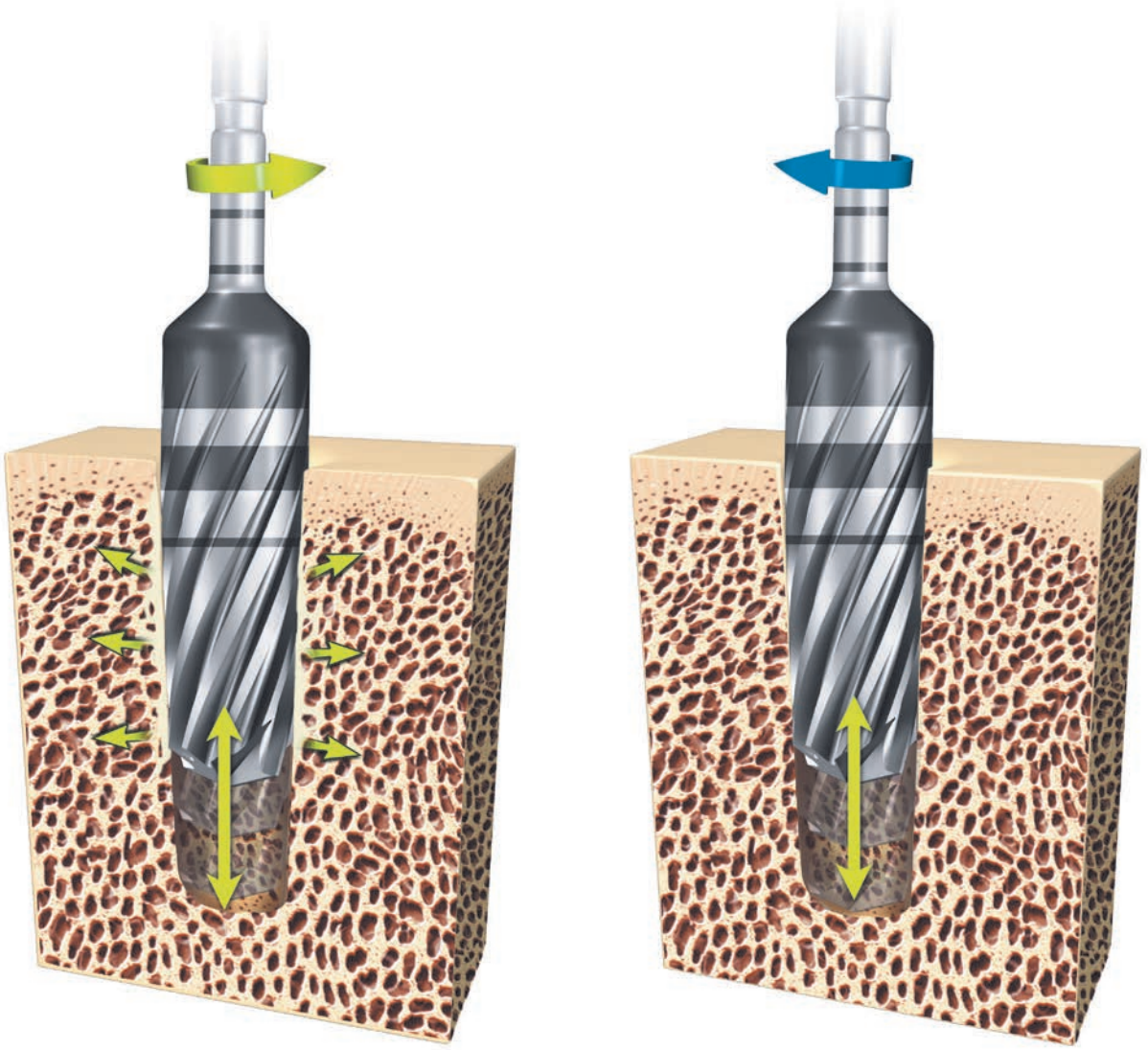
Counterclockwise (CCW) Non-Cutting Direction

Clockwise (CW) Cutting Direction



II. Motion

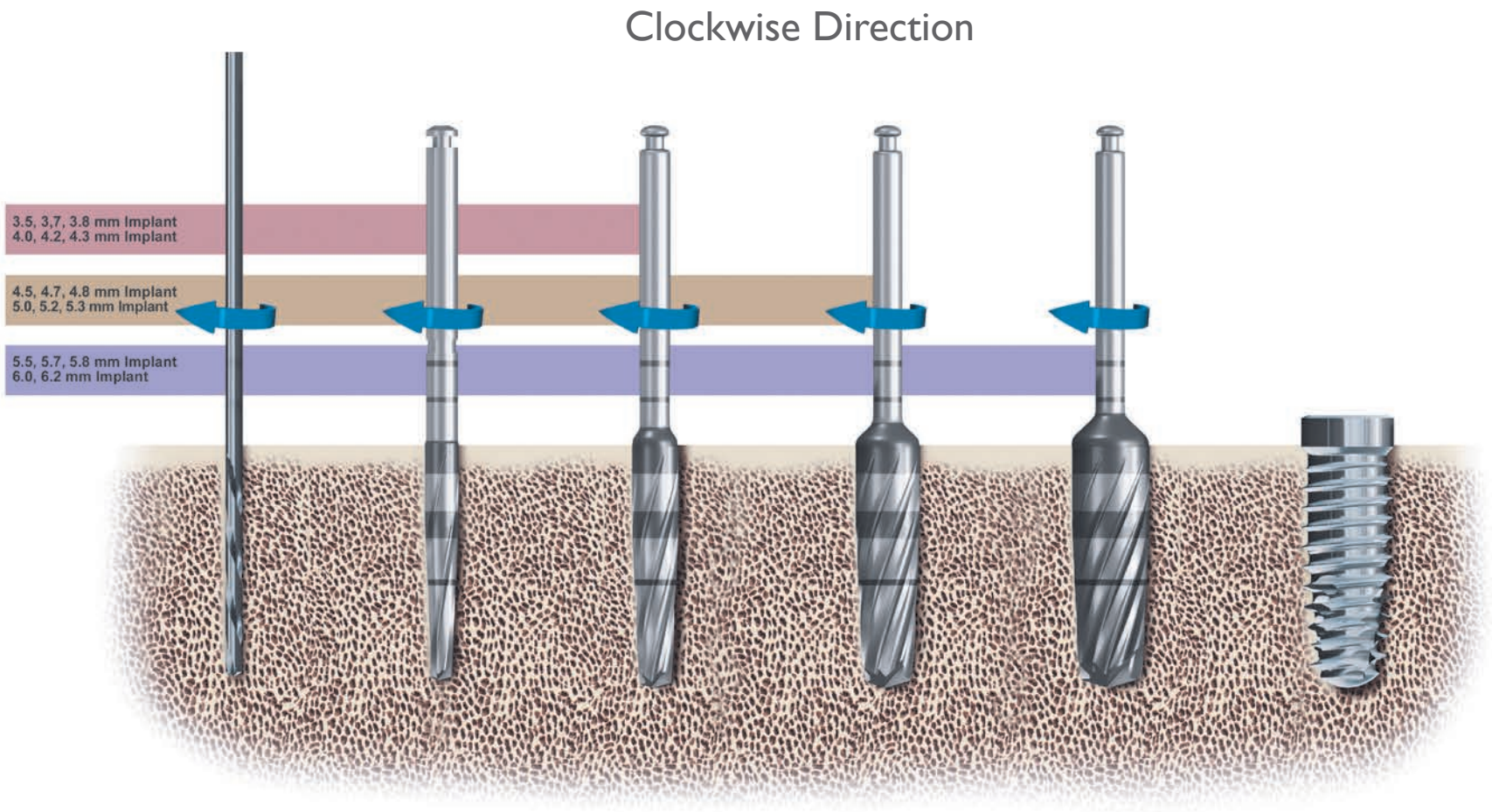
The Densah® Burs are always to be used with copious irrigation in a **Bouncing-Pumping motion** (minor vertical pressure to advance the drill into the osteotomy, then pull out for pressure relief, then advance with vertical pressure again and so on in an in/out fashion). The duration and number of bouncing-pumping episodes (in/out) are usually dictated by bone density and desired length.



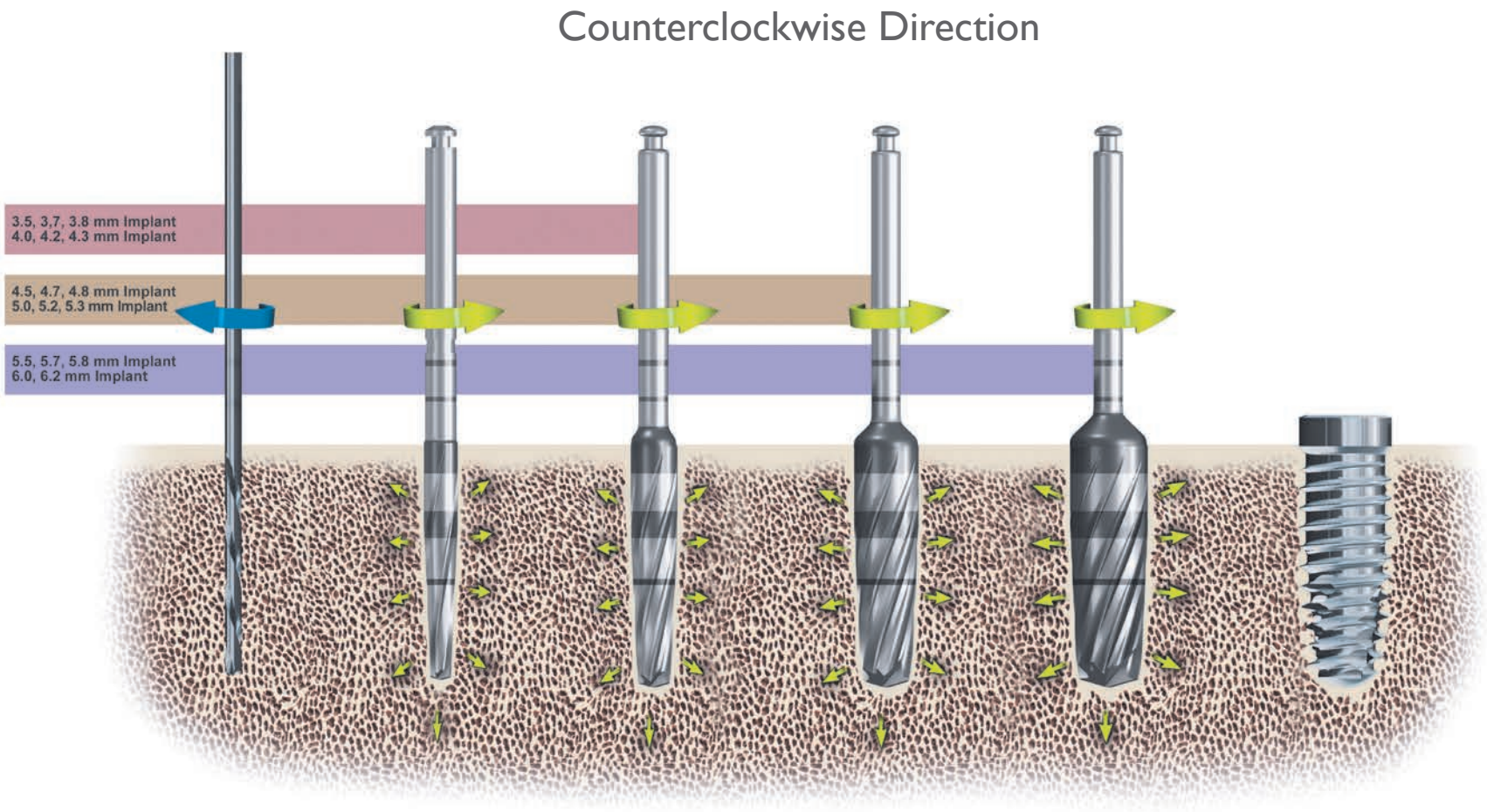
3. Densah® Burs Versatile Utilization

Densah® Burs are designed to be used in **Densifying Mode** or **Cutting Mode** if needed with a push of the reverse button on any standard surgical engine.

I. Cutting Mode



II. Densifying Mode

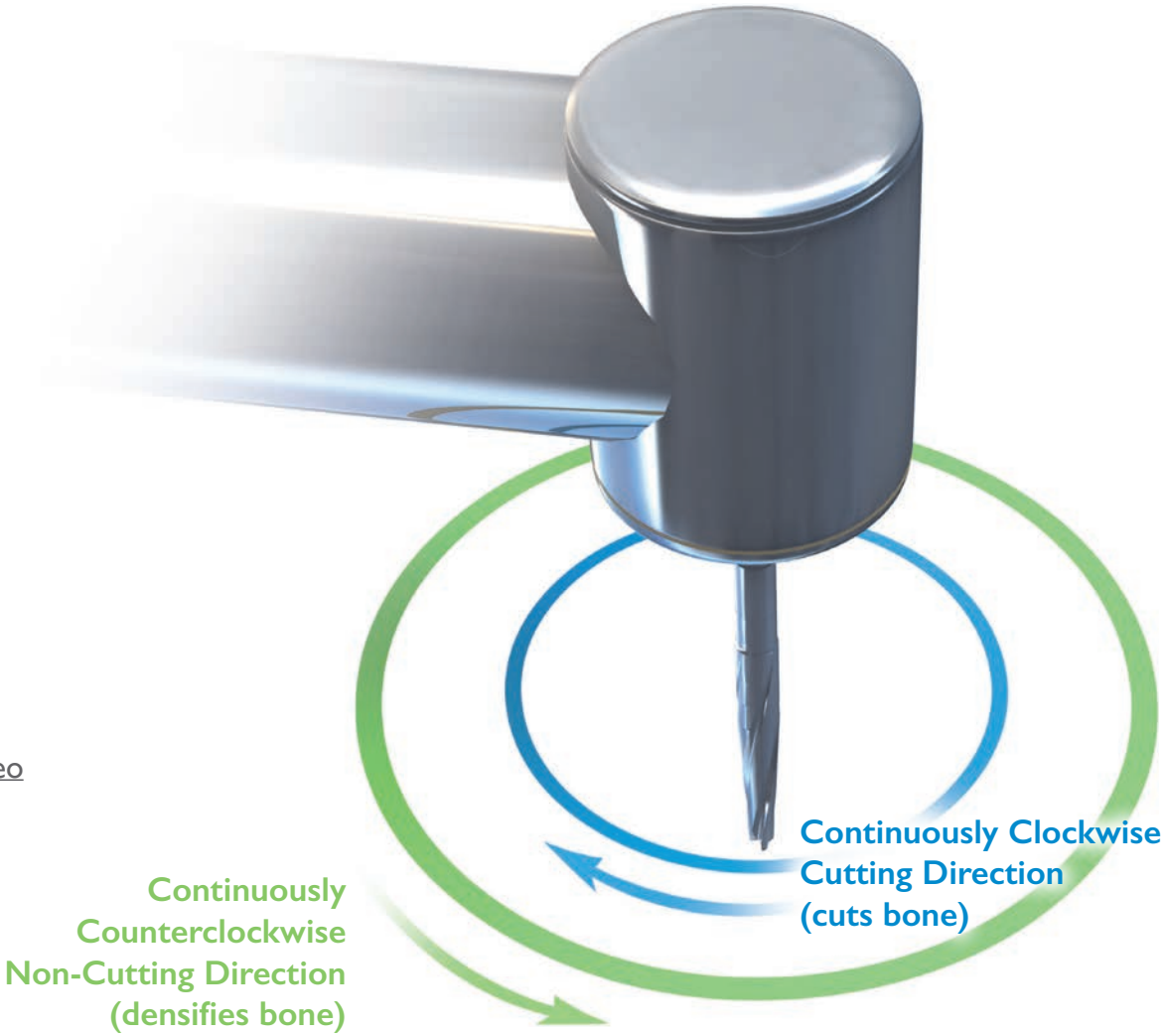


NOTE: Recommended drill speed is **800-1500 rpm** with torque range from 5-50 Ncm for both modes.

III. Versatile Utilization

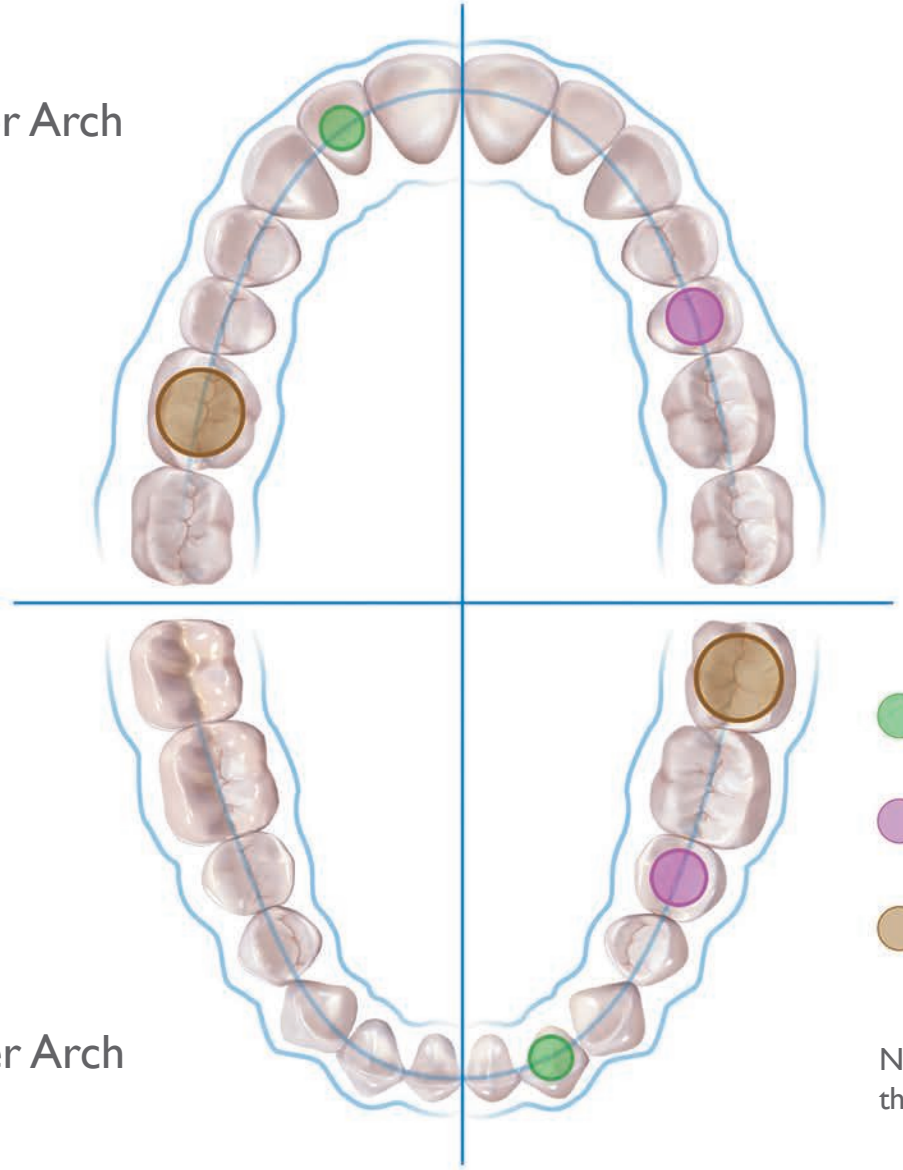
Densah® Burs can be used in both Cutting and Densifying modes within the same procedure. You can move between multiple osteotomy sites in a patient — cutting in one site and densifying in another — using the same Densah® Bur. In hard bone, the same Densah® Bur can be used to densify — cut — densify again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

Click link to view video: www.versah.com/dac-video



With a push of the reverse button of your implant drill console

Upper Arch

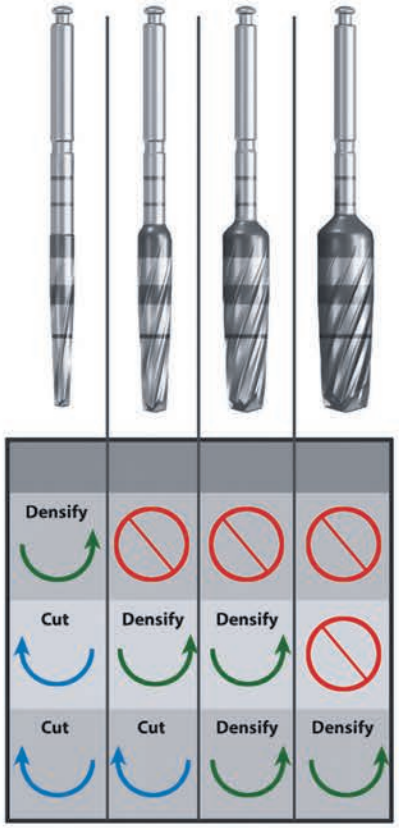


Lower Arch

Osteotomy Site 1

Osteotomy Site 2

Osteotomy Site 3



NOTE: Surgeon preference overrules this suggestive protocol

IV. Densah® Bur Marking

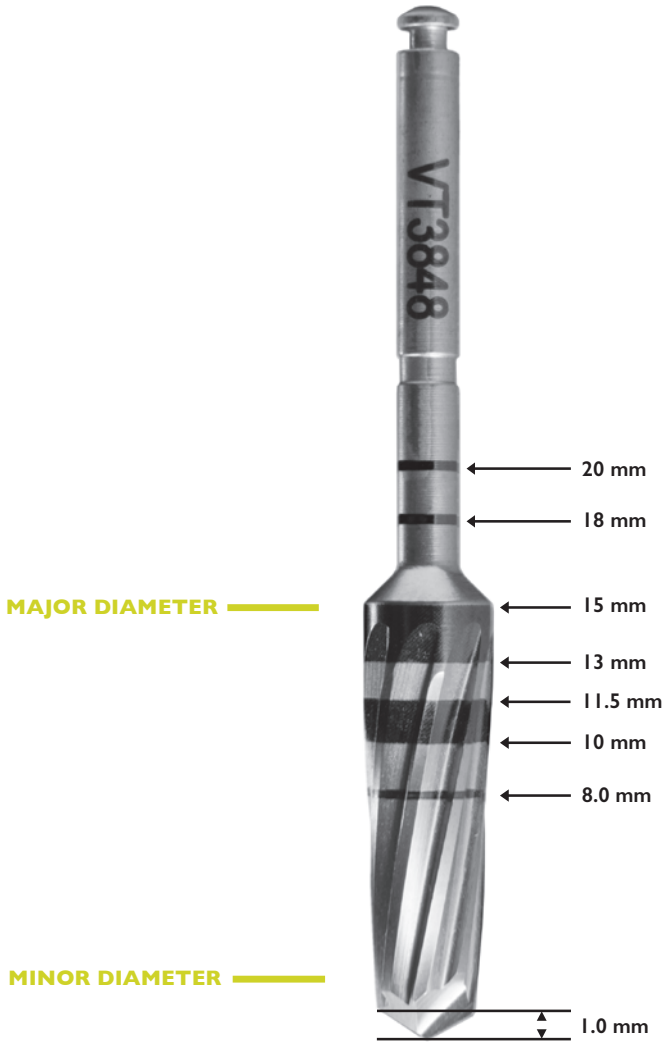
Densah® Burs are externally irrigated and designed to be used at drill speeds of 800-1500 rpm. They are marked with laser markings from 8-20 mm depth. Densah® Burs have a tapered geometry; catalog number is a reflection of their minor and major diameter dimension. E.g., Densah® Bur VT3848 has a tip diameter 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[1] or sooner when they are dulled, worn, or corroded.

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.

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 8-20 mm. They are designed to be used in a consecutive increasing order to achieve the desired osteotomy diameter.

I. Included in the Kit

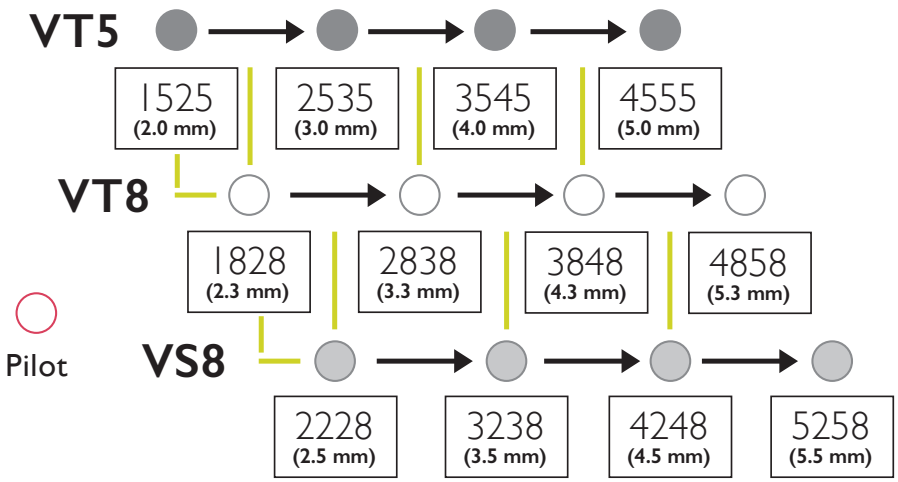
Densah® Burs are designed to be used for osseodensification in small increments (alternate between VT5 and VT8) in dense bone to allow gentle expansion of the osteotomy. In **soft bone**, the osteotomy final preparation diameter should be prepared with Densah® Bur with an average diameter that measures **0.5-0.8 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.

VT5 Burs			
VT1525	**VT2535**	**VT3545**	**VT4555**
			
(2.0 mm)	(3.0mm)	(4.0 mm)	(5.0 mm)
Average Diameter			

VT8 Burs			
VT1828	**VT2838**	**VT3848**	**VT4858**
			
(2.3 mm)	(3.3 mm)	(4.3 mm)	(5.3 mm)
Average Diameter			

VS8 Burs			
VS2228	**VS3238**	**VS4248**	**VS5258**
			
(2.5 mm)	(3.5 mm)	(4.5 mm)	(5.5 mm)
Average Diameter			

Please refer to Densah® Bur Densifying Reference Guide for specific implant placement protocol.
Click link to view PDFs: http://www.versah.com/densifying-reference-guide



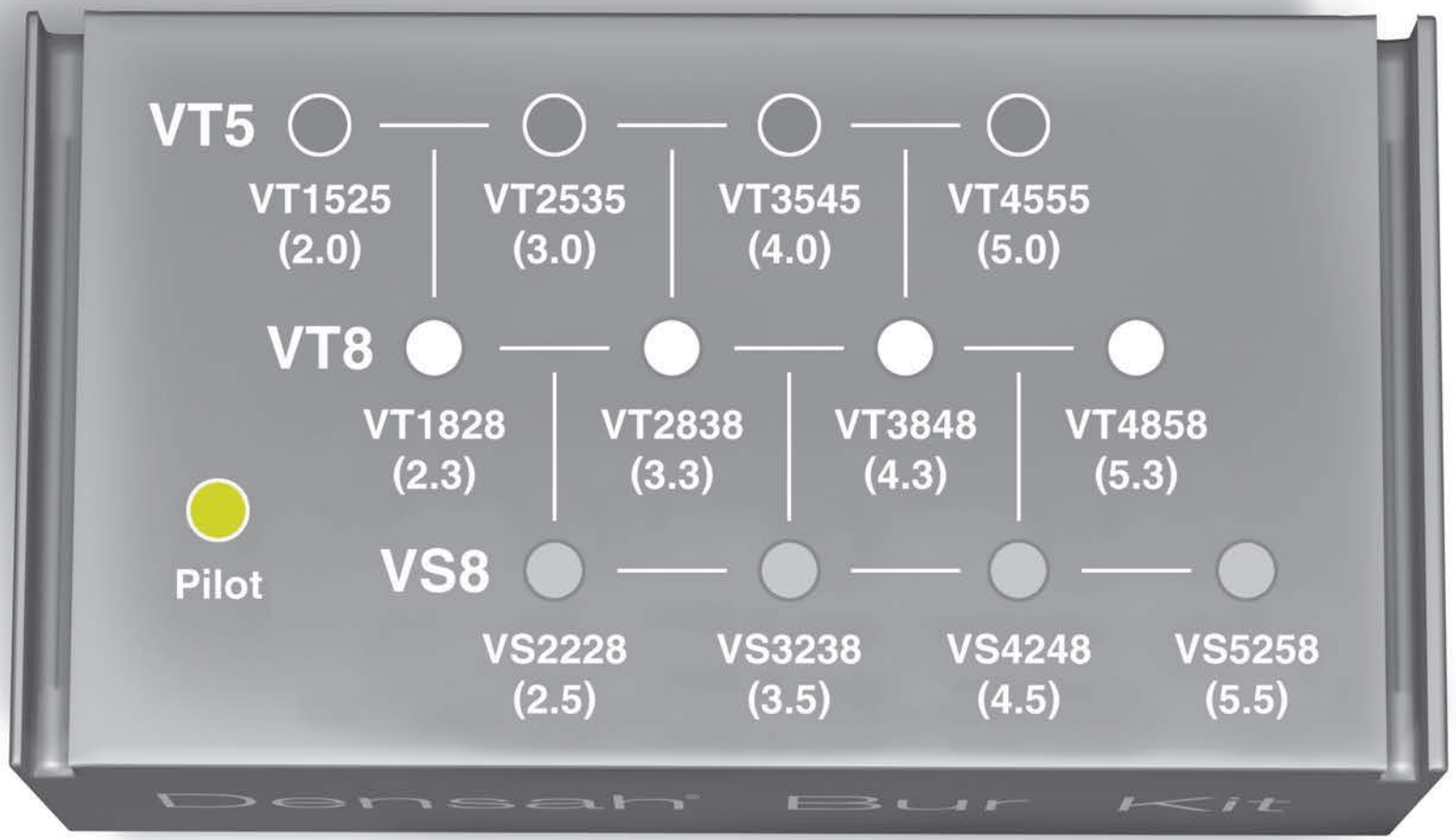
Preparation Steps for Hard Bone Osteotomy

Preparation Steps for Soft Bone Osteotomy

VT5 For Tapered Implants Placement with Diameters of X.5, X.7, X.8

VT8 For Tapered Implants Placement with Diameters of X.0, X.2, X.3

VS8 Last Step Finishers for Parallel Wall Implants



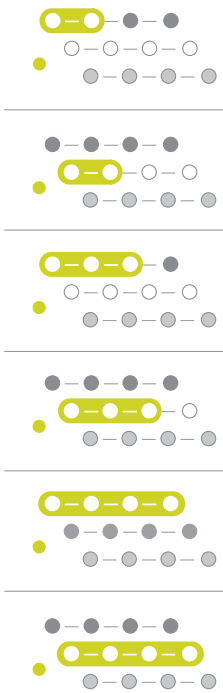
NOTE: Case diagnosis and treatment planning should be done as normally practiced with implant patients. Care should be taken to select the appropriate Densah® Bur sequence for osteotomy preparation indicated by the implant type (tapered/straight), implant diameter and bone density (Dense/Soft). Please refer to Densah® Bur Densifying Reference Guide for specific implant placement protocol. Click link to view PDFs: http://www.versah.com/densifying-reference-guide

II. Decision Tree for Osseodensification Protocol

● VT5 Set ○ VT8 Set ○ VS8 Set

Soft 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.

NOTE: Surgeon preference overrules this suggestive protocol

Continued on next page

Please refer to Densah® Bur Densifying Reference Guide for specific implant placement protocol.
Click link to view PDFs: http://www.versah.com/densifying-reference-guide

II. Decision Tree for Osseodensification Protocol

● VT5 Set ○ VT8 Set ○ VS8 Set

Hard 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.

NOTE: Surgeon preference overrules this suggestive protocol

Continued on next page

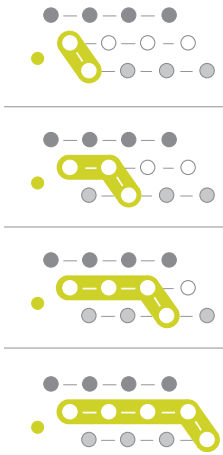
Please refer to Densah® Bur Densifying Reference Guide for specific implant placement protocol.
Click link to view PDFs: http://www.versah.com/densifying-reference-guide

II. Decision Tree for Osseodensification Protocol

● VT5 Set ○ VT8 Set ○ VS8 Set

Soft 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. NOTE: Surgeon preference overrules this suggestive protocol *Continued on next page*

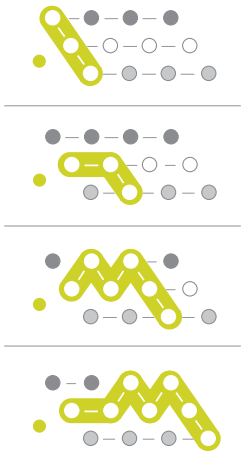
Please refer to Densah® Bur Densifying Reference Guide for specific implant placement protocol.
Click link to view PDFs: http://www.versah.com/densifying-reference-guide

II. Decision Tree for Osseodensification Protocol

● VT5 Set ○ VT8 Set ○ VS8 Set

Hard 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.

NOTE: Surgeon preference overrules this suggestive protocol

Please refer to Densah® Bur Densifying Reference Guide for specific implant placement protocol.
Click link to view PDFs: http://www.versah.com/densifying-reference-guide

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 // 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.

I. Osseodensification in Medium and Soft 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 *(Clockwise 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. **Change 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 ratchet wrench.

II. Osseodensification in Dense Bone Quality Especially in the Mandible

We recommend the **use of 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 *(Clockwise 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. **Change 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

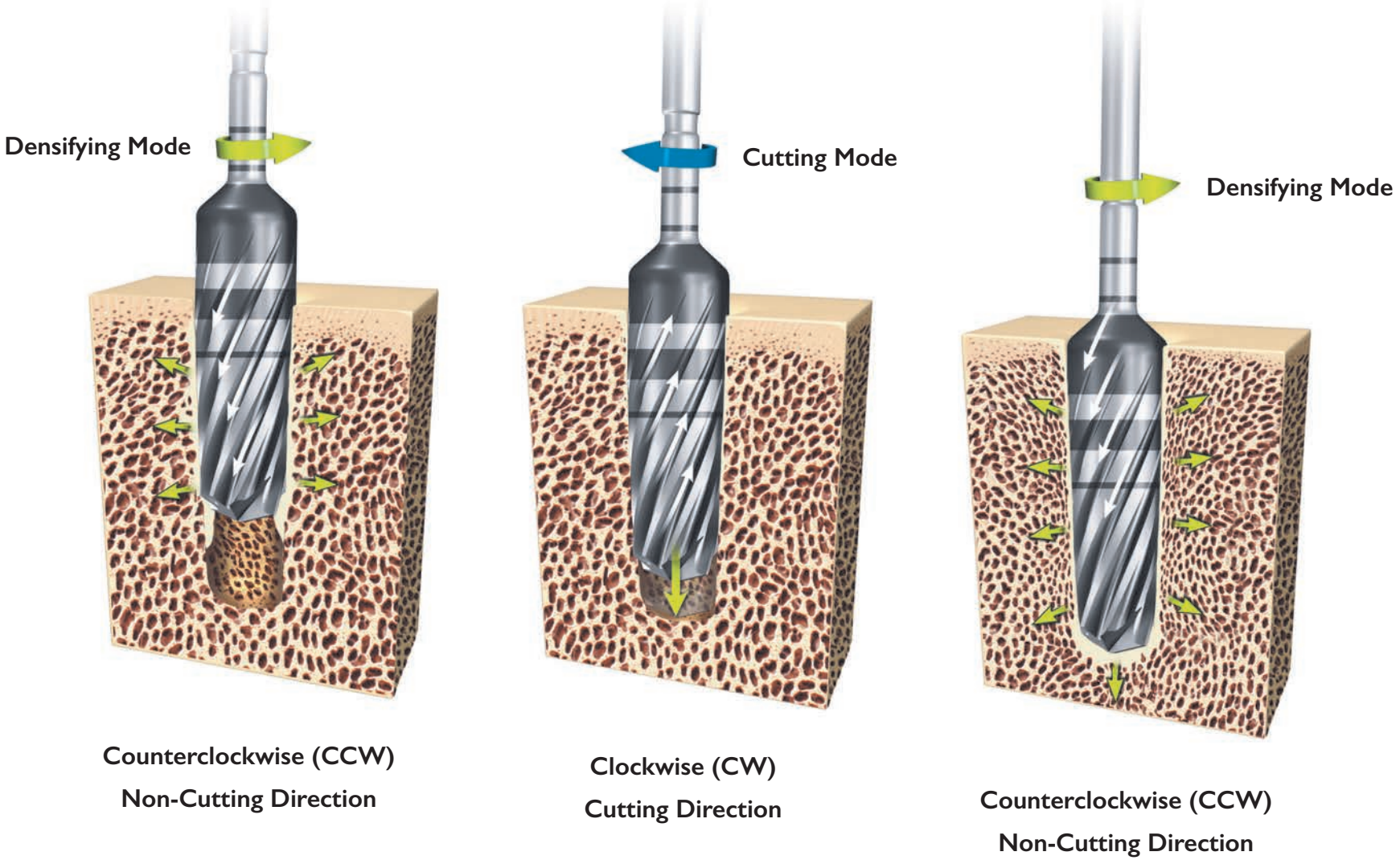
II. Osseodensification in Dense Bone Quality Especially in the Mandible

4. **Densify after Cut (DAC) if needed:** In very dense bone, 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 between cutting and densifying modes, you will re-deposit the cut bone particles inside the boundaries of the osteotomy.

   Click link to view video: www.versah.com/dac-video

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 ratchet wrench.

Densify After Cut (DAC) Protocol



Counterclockwise (CCW)
Non-Cutting Direction

Clockwise (CW)
Cutting Direction

Counterclockwise (CCW)
Non-Cutting Direction

III. Osseodensification Facilitates Lateral Ridge Expansion

A. Ridge Expansion Procedure

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

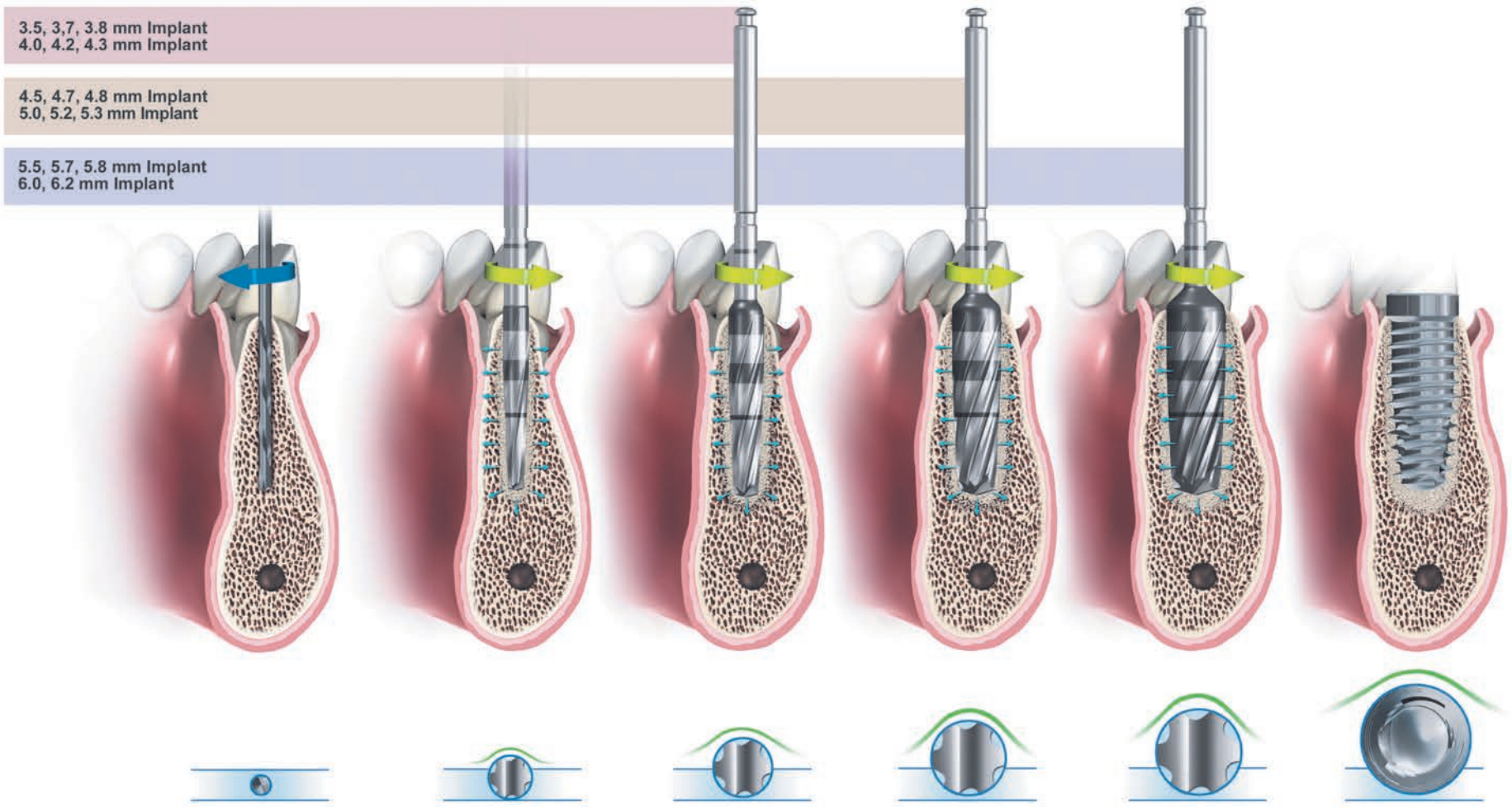
2. Drill to the desired depth using the Pilot Drill *(Clockwise drill speed 800-1500 rpm with copious irrigation)*.

3. Depending upon the implant type and diameter selected for the site, begin with the narrowest Densah® Bur. **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 pushing up out of the osteotomy, **repeatedly relax and reapply pressure with a pumping motion** until reaching the desired depth.

4. As the bur diameter increases, the bone will slowly expand to the final 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 ratchet wrench.

   Click link to view video: www.versah.com/versah-osseodensification-facilitates-ridge-expansion


3.5, 3,7, 3.8 mm Implant
4.0, 4.2, 4.3 mm Implant
4.5, 4.7, 4.8 mm Implant
5.0, 5.2, 5.3 mm Implant
5.5, 5.7, 5.8 mm Implant
6.0, 6.2 mm Implant

III. Osseodensification Facilitates Lateral Ridge Expansion

B. The Plus1™ Protocol

When utilizing the narrow ridge expansion technique, the implant diameter selected may be up to 1.0 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.

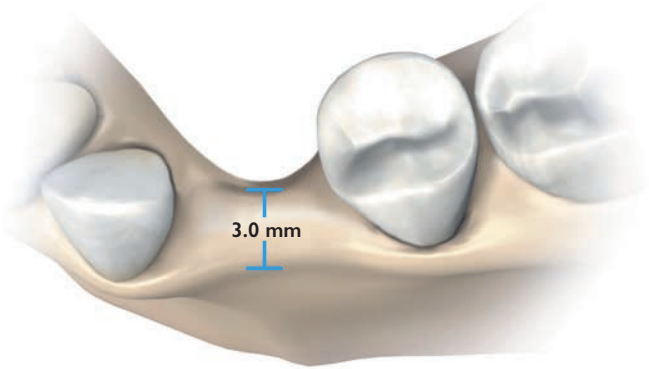
A minimum of 3.0 mm of alveolar ridge width is needed to place a 3.7 mm or 4.0 mm fixture.

A minimum of 4.0 mm of alveolar ridge width is needed to place a 4.7 mm or 5.0 mm fixture.

A minimum of 5.0 mm of alveolar ridge width is needed to place a 5.7 mm or 6.0 mm fixture.

If less than 1.0 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.

Click link to view video: www.versah.com/versah-alveolar-ridge-expansion



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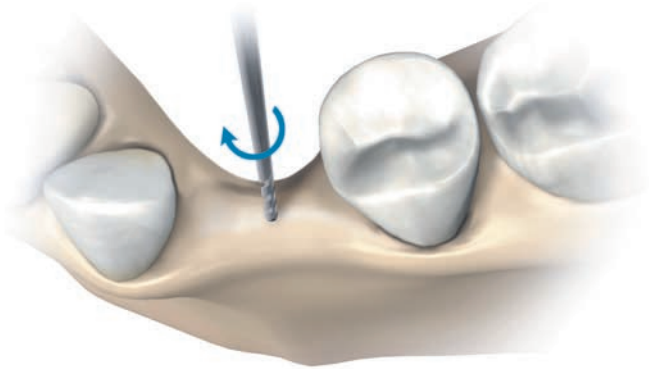

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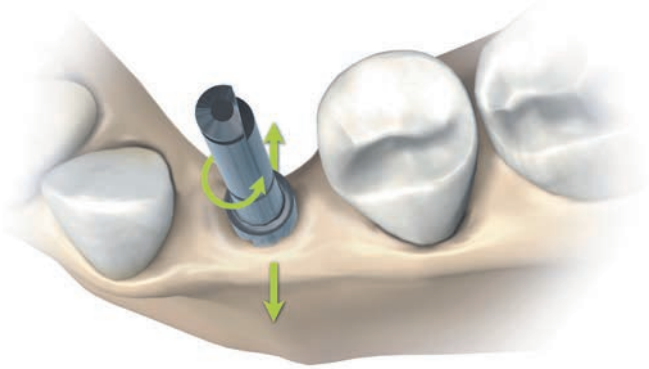

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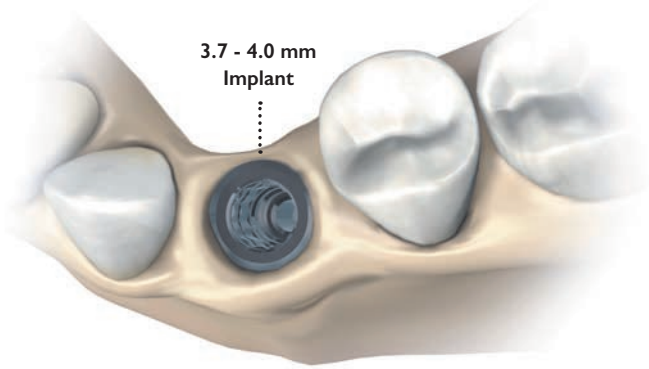


4.

III. Osseodensification Facilitates Lateral Ridge Expansion

C. Guided Expansion Graft

Indicated for cases with **less than 3.0 mm** ridge width.

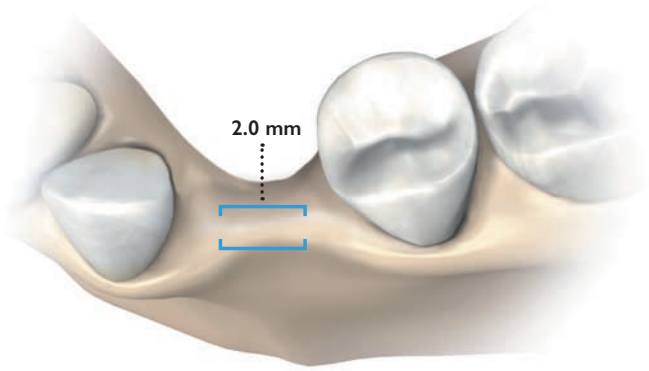
1. Flap the soft tissue using the technique indicated for the implant position.

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

3. Begin with the narrowest Densah® Bur. **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 pushing up out of the osteotomy, **repeatedly relax 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. Click link to view video: www.versah.com/geg

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



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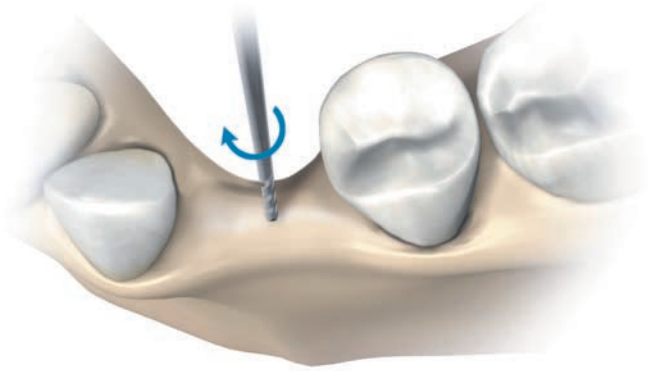

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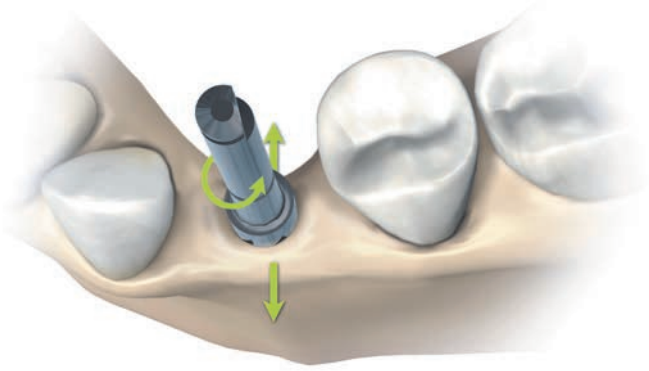

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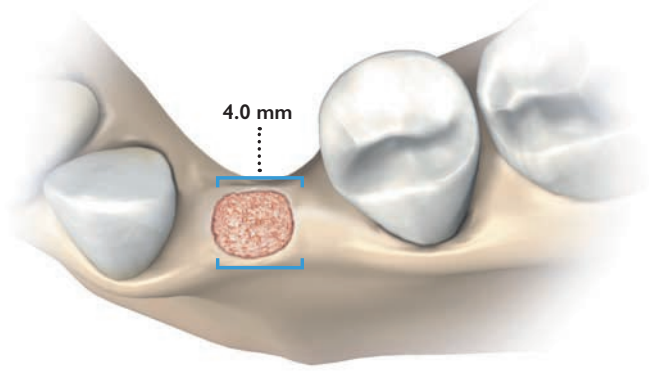


4.

IV. Osseodensification Facilitates Vertical Ridge Expansion

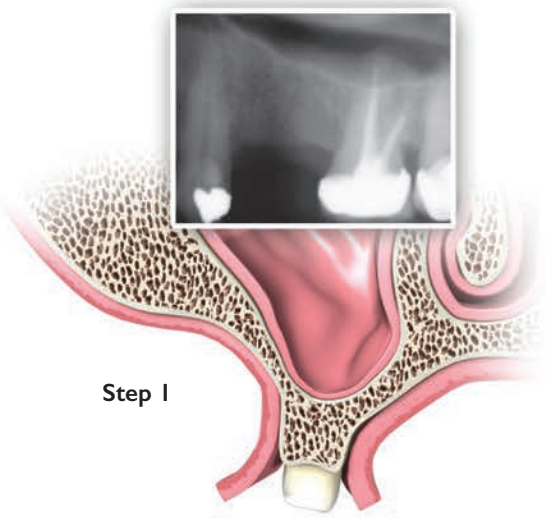
A. Maxillary Sinus Autografting

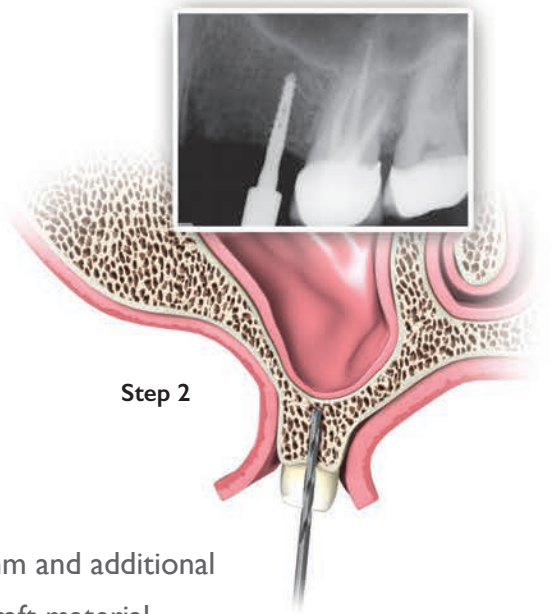
1. Flap the soft tissue using the instruments and technique normally used.

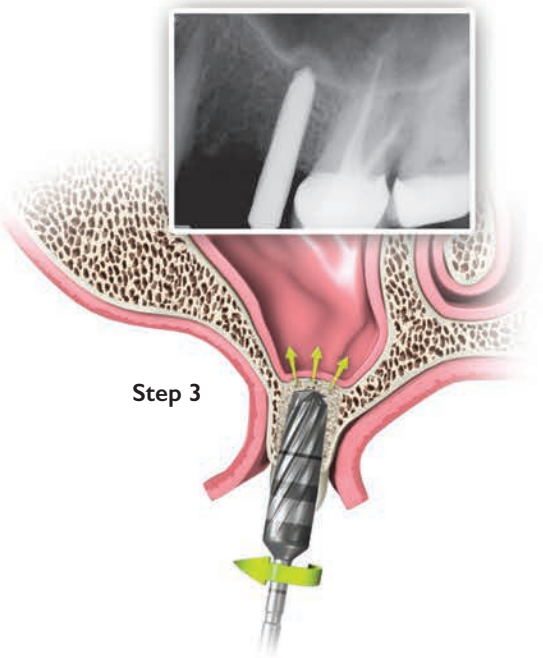
2. In cases where posterior residual alveolar ridge height is ≥ 7.0 mm and additional vertical depth is desired, drill to the depth determined within an approximate safety zone of 1.0 mm from the sinus floor using a pilot drill *(Clockwise drill speed 800-1500 rpm with copious irrigation)*. Confirm pilot drill position with a radiograph.

3. Depending upon the implant type and diameter selected for the site, begin with the narrowest Densah® Bur. 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, **modulate pressure with a gentle pumping motion** to advance past the sinus floor. Maximum advancement past the sinus floor at this stage must not exceed 1.0 mm. Confirm the first Densah® Bur vertical position with a radiograph.

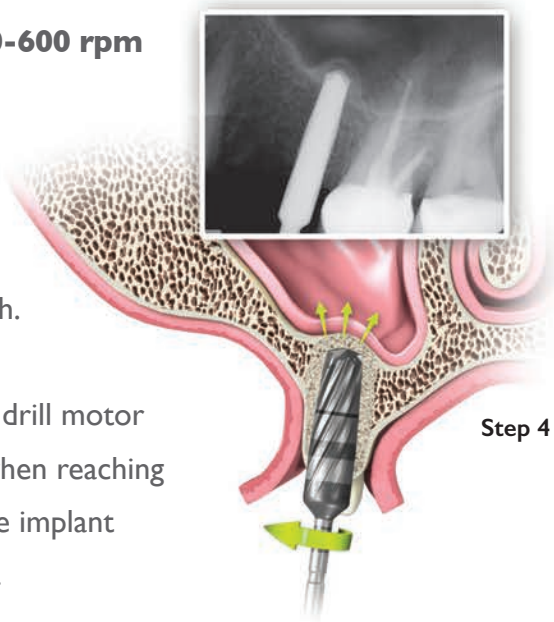
4. As the next Densah® Bur advances in the osteotomy, bone will be pushed toward the apical end and will begin to gently lift the membrane and autograft compacted bone. Use the sequential Densah® Burs in Densifying Mode *(Counterclockwise drill speed 800-1500 rpm with copious irrigation)* with **gentle pumping motion** to achieve additional vertical depth and maximum membrane lift of 3.0 mm **(in 1.0 mm increments)** and reach final desired width for implant placement.

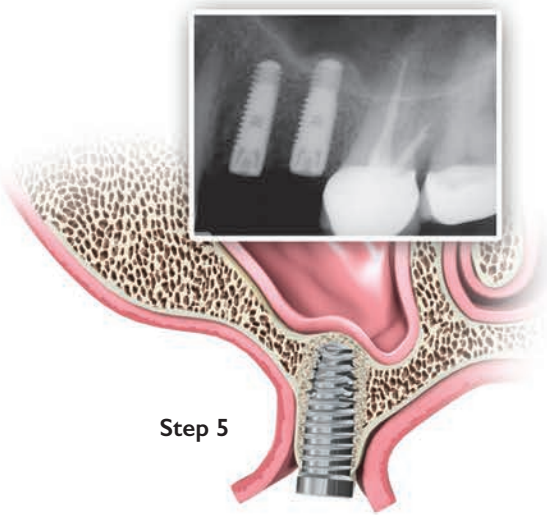






In cases where residual alveolar ridge height is less than 7.0 mm and additional lift of the membrane (more than 3.0 mm) is desired, a bone graft material can be placed into the final width osteotomy. Use the last Densah® Bur in Densifying Mode **(Counterclockwise drill speed 200-600 rpm with slow irrigation)** with **gentle pumping motion**. The Densah® Bur must only facilitate the graft material compaction to lift the sinus membrane further, and not advance beyond the sinus floor. Implant insertion will then drive the graft material into the final desired depth.





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 ratchet wrench.

Click link to view video: www.versah.com/maxillary-sinus-autograft

6. 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: 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. Do not exceed 134°C during sterilization.

STAGE 3: DURING USE — Drills should be soaked in a sterile saline solution until the cleaning stage.

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. Do not rinse or wipe burs again. *(Drills should be placed in surgical kit)*.

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. *(Do not exceed 134°C during sterilization)*.

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.

RECOMMENDATIONS: Sterilized water should be used in order to avoid surface stains.

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. VERSAH® strongly recommends completion of qualified postgraduate dental implant training and STRICT 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 ninety (90) days from the date of initial invoice.

NOTE: Surgical drills and burs should be replaced when they are dulled, worn out, or corroded. 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.

REFERENCE: 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 Click link to view Shopping Cart: 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

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, corroded, or in any way compromised. Versah® drills and burs should ordinarily be discarded and replaced after 12 to 20 osteotomies. Read and follow the "Instructions For Use."

Versah® warrants its Products to be free from defects in workmanship and materials for ninety (90) 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 ninety (90) days from the date of purchase.

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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.

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(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 ninety (90) 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.

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