Versah® THE OSSEODENSIFICATION COMPANY

Frequently Asked Questions (FAQ)

1.

Q. Who is Versah?

A. Versah, LLC is a Michigan-based company started in 2014. The Founder, President and Chief Executive Officer of the company is Dr. Salah Huwais, DDS, a practicing periodontist in Jackson, Michigan. The mission of Versah, LLC is to market and sell to dental professionals high quality dental devices based on a new technology for drilling into bone tissue that we have coined "osseodensification."

2.

Q. Is Versah affiliated with any other surgical instrument or implant company?

A. No. We are an independent surgical tool manufacturer. Our dental burs can be used with common surgical equipment and all commercially available implants.

3.

Q. How can I contact Versah, LLC?

A. Click here to contact Versah, LLC.

---

4. PURCHASE & SHIPPING QUESTIONS

Q. Where can I buy Densah® Bur Products?

A. Click here to view Versah Shop.

5.

Q. What are the prices of the Densah® Bur products?

A. Click here to view Versah Shop.

6.

Q. I only place tapered implants, so do I need to buy the full Densah® Bur Kit (VDBK)?

A. The VT5 Densah® Bur Kit of 4 progressively larger tapered burs is sufficient for most X.5 X.7 and X.8 implant applications. (VT8 Densah® Bur Kit is used for placing X.0, X.2, X.3 implants.) In some dense bone, it may be advisable to implement a milder expansion rate by progressively alternating VT5 and VT8 Densah® Burs. For placing tapered implants in dense bone, the practitioner will want both the VT5 & VT8 Densah® Burs. The VDBK Densah® Bur Kit contains all of the burs in VT5 and VT8 kits, plus four VS finishing burs needed to place straight (non-tapered) implants.

7.

Q. I only place straight (non-tapered) implants, so do I only need to buy the VS8 Densah® Bur Kit?

A. The VS8 Densah® Bur Kit contains four "finishing" burs for placing straight (non-tapered) implants. The VS8 Densah® Bur Kit must be paired with either the VT5 or the VT8 Densah® Bur kit to accomplish all but the final osteotomy expansion steps. In dense bone, it may be advisable to implement a milder expansion rate by progressively alternating the VT5 and VT8 Densah® Burs. For placing straight implants in these dense bone, the practitioner will want the full VDBK Densah® Bur Kit, which contains all of the burs in the VT5 & VT8 plus the VS8 Densah® Burs.

---

8. TECHNICAL QUESTIONS

Q. What is Densah® Bur Technology?

A. The Densah® Bur technology is based on a new technology for osteotomy preparation that we have coined "osseodensification." Unlike traditional bone drilling technologies, osseodensification does not excavate bone tissue. Rather, bone tissue is simultaneously compacted and auto-grafted in an outwardly expanding direction to form 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, higher initial implant stability, higher initial torque values, and may facilitate faster healing.

9.

Q. How does Densah® Bur Technology work?

A. The multi-fluted Densah® Bur creates and expands a pilot hole without excavating significant amounts of bone tissue through a unique, highly controllable, fast and efficient procedure with minimal heat elevation. In the densifying mode, downward surgical pressure coupled with steady external irrigation creates a gentle hydrodynamic compression wave inside the osteotomy that works with the fluting to generate a strong, densified layer of surrounding bone while plastically expanding the bony ridge at the same time. The taper design allows the surgeon to modulate pressure and irrigation, while providing a unique real-time haptic feedback that makes the Densah® Bur intuitive for every skilled practitioner. Densah® Burs can be rotated in the clockwise cutting direction to cleanly cut bone like a traditional surgical bur. This dual use capability enables the qualified practitioner to concurrently prepare multiple osteotomy sites of different width/bone conditions by either osseodensifying or drilling each site without removing the Densah® Bur from the drill motor.

Click here to view Instructions For Use.
Click here to watch Animation Video.

10.

Q. Do I need to use special implants with the Densah® Bur?

A. No. You can use any tapered or straight anchor/implant that you would otherwise choose for a particular application. Select the correct Densah® Bur Kit based on your preferred implant type and size.

11.

Q. What patients make good candidates for the Densah® Bur osseodensification procedure?

A. All patients otherwise healthy enough for receiving dental implants are candidates for osseodensification. The Densah® Bur may form a stronger osteotomy in all bone types (Types I-IV) compared with traditional drilling. In addition, the Densah® system often allows for expansion of a narrow ridge to receive an implant that previously would have required a grafting procedure. Thus, more patients become candidates for safely placing an implant with fewer procedures and less "wait time."

12.

Q. Is Osseodensification biomechanically valid?

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

Click here to view Lawrence Technological University Research Poster.

13.

Q. Is the Densah® Bur osseodensification procedure more painful for my patient?

A. Patient-sensed discomfort associated with the Densah® Bur procedure is equivalent to that of traditional drilling.

14.

Q. How long does the average osseodensification procedure take?

A. Most surgical practitioners are surprised at the fast feed rates of each progressively larger Densah® Bur. Numerous videos showing actual surgical procedures have been uploaded to our website that will give you a realistic understanding of just how efficient this new technology is. For an average large dental implant (in the 5.7-6.0mm range), the pilot osteotomy is followed by four progressively larger Densah® Burs. Narrower implants typically take less time because fewer expansion steps to reach final osteotomy size are required. Osteotomies in dense bone might take slightly more time if you need to progressively alternate the VT5 and VT8 burs to reach the final osteotomy size.

Click here to view Clinical Videos.

15.

Q. What differences will I notice with the osseodensification procedure?

A. The most striking difference most dental surgeons will notice is the modulation technique. The unique design of the Densah® Bur combined with irrigation creates a gentle hydrodynamic compression wave inside the osteotomy. The surgeon will feel through their handpiece the "push-back" from this hydrodynamic compression wave and be able to control its intensity by modulating downward pressure. This real-time haptic feedback enables the skilled practitioner to intuitively find the pressure point at which the bone begins to plastically expand. The surgeon then controls (i.e., modulates) the downward pressure so that the osteotomy continues expanding at a suitable rate.

16.

Q. Do I need a pilot hole?

A. Yes. The formation of a standard 1.7mm pilot hole to the desired depth must precede the use of the first 1525 or 1828 Densah® Bur. Never use a Densah® Bur without a properly sized initial pilot hole.

17.

Q. Can I skip the recommended progression of Densah® Burs in suitably soft bone?

A. No. Even in soft bone, the recommended progression of Densah® Burs must be followed. For example: 3.5, 3.7 and 3.8 mm diameter-tapered implants, the progression following a 1.7mm pilot hole is 1525, 2535. For 4.0, 4.2 and 4.3mm diameter-tapered implants, the progression following a 1.7mm pilot hole is 1828, 2838. This sequence allows for the plastic deformation expansion and osseodensification to occur at an optimal rate.

18.

Q. Where can I receive training to effectively use the Densah® Bur procedure?

A. Training will be available at the University of Minnesota School of Dentistry. New training centers are being developed, so please periodically check our website for training opportunities coming nearest to you.

19.

Q. May I eliminate the step of ridge augmentation in narrow ridges prior to implant placement?

A. With the Densah® Bur system you may be able to place an implant utilizing the Plus1™ Protocol. This protocol may allow the placement of an implant that is up to 1mm larger in diameter than the pre-surgical narrow ridge, without augmentation. For example, The Densah® Bur system may allow placement of a 3.7-4.0mm tapered implant in a minimum ridge width of 3mm. A 5mm implant may be placed in a 4mm ridge. And a 6mm implant may be placed in a 5mm ridge.

20.

Q. What peak insertion torque values should I expect with the osseodensification process?

A. Initial clinical data has shown that implants placed with the Densah® Bur system may routinely achieve a peak insertion torque of 40-85 Ncm.

Click here to view Clinical Poster.

21.

Q. How long before the implant can be loaded?

A. Initial clinical data on file has shown an increase in total implant stability throughout healing, which may allow a shorter waiting period to loading. Observe the approved indications for use for the implant system and follow the implant manufacturers recommendation.

22.

Q. What kinds of equipment are needed for the Densah® Bur?

A. Any commercially available surgical drill motor and handpiece that are capable of operating in both forward (clockwise) and reverse (counterclockwise) directions, and can achieve at least 1200 rpm with torque 5-50 Ncm in both directions, will work with the Densah® Bur system.

23.

Q. Is it necessary to irrigate the osteotomy site during the osseodensification procedure?

A. Yes. Apply an abundant steady flow of sterile irrigating fluid to the osteotomy site throughout the procedure. Without ample irrigation, the risk of overheating and necrosis is high. Irrigation is necessary to facilitate the plastic deformation expansion of the bony tissue.

24.

Q. Is the Densah® Bur reusable?

A. The 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[01]. It is recommended that replacement Densah® Burs be on hand in the event replacement is needed during a surgery.

25.

Q. Can my Densah® Burs be re-sharpened/re-furbished?

A. Unfortunately, the manufacturing tolerances needed to achieve the requisite performance of our Densah® Burs are so precise that re-sharpening is not possible. Please dispose of used Densah® Burs that have reached the end of their useful life in a safe and responsible manner.

26.

Q. Can Densah® Burs be used with computer generated implant placement guides?

A . At this time, Densah® Burs are not compatible with any implant placement guide systems. We are, however, actively investigating adaptation of our products to accommodate computer generated implant placement guides and hope to have an offering in this category soon.

27.

Q. What is the difference between the Densah® Burs and rotatory expanders?

A . Unlike the Densah® Burs, rotatory expanders cannot be used with high-speed rotation of 800-1500 RPM. They are only to be used with low speed rotation of 20-50 RPM. In addition, rotary expanders link the expansion rate to the rotation rate, which is controlled solely by the expander threads pitch. This limits surgical control, so bone is usually manipulated either at its elastic deformation region or with slight more force it can quickly reach its fracture limit.
Densah® Burs are designed to unlink the rotation rate to the expansion rate to allow full surgical control to produce bone plasticity with a rate dependent stress to achieve a rate dependent strain. Optimizing Bone Plasticity utilizing osseodensification may reduce the risk of buccal bone fracture.

28.

Q. Can I run the standard drilling bits in my implant kit in reverse to replicate the Versah osseodensification protocol?

A . Unlike conventional drills, Densah® burs are specially designed for the Versah osseodensification protocol. Densah® burs provide smooth, chatter-less operation at high-speed reverse rotation (800-1500 RPM) to optimize bone plasticity and expand an osteotomy with virtually no risk of bone damage and with minimum patient discomfort. Furthermore, Densah® burs are uniquely engineered to autograft bone particles throughout the osteotomy. In contrast, conventional drill bits are not designed to function in reverse at high speed. There is significant risk that your conventional drill bit run in reverse will produce excessive chatter and may over-heat the bone if the surgeon applies excessive axial force. Please do not use our protocol with any conventional drill bits. Densah® Burs are the only bone drilling burs in the market designed for osseodensification.

---

29. Pressure Osteonecrosis-Fact or Fiction?

Q. Do I need to be concerned about High Insertion Torque (IT) values, achieved with osseodensification using the Densah® Bur System, causing pressure osseonecrosis during implant placement?

A. The short answer is **NO** – Bone pressure necrosis is not a concern with the high insertion torque values achieved by osseodensification using the Densah® Burs. In fact, the literature supports that higher insertion torque values and more dense surrounding bone are a combination that enhances primary stability and healing, and minimizes micro-motion of the implant [02]

The term Pressure Osseonecrosis (bone pressure necrosis), although used frequently, has never been clearly defined in the literature other than generally viewed as excessive compression (pressure) of bone created during implant insertion and it is limited to cortical dense bone. [03]

The theory is that high insertion torque values for implant placement above 40-45 Ncm may create pressure ischemia and microcirculation disturbances to osteocytes leading to bone resorption. Compression of bone beyond its physiologic limits may result in ischemia leading to osseous necrosis. [04-05] **However, no scientific data exists to support these opinions and this phenomenon has never been scientifically proven.**

On the other hand, both animal histological and human controlled clinical studies have shown that high insertion torque does not induce bone necrosis.

Trisi et al, demonstrated that high IT in dense bone does not induce bone necrosis or implant failure. In fact, histologically, high IT increased initial BIC (bone to implant contact) and promoted primary healing and remodeling for weeks 1-6 when compared to low IT placed implants. Implant placed with 110 Ncm showed primary bone healing with no dip at 3 weeks and 40% bone remodeling at 6 weeks. [06]

Clinical study by Ottoni et al, has correlated High IT with increased survival rate of single tooth implants under functional loading. He concluded that for every 9.8 Ncm of torque added; the risk of implant failure was reduced by 20%. [07]

Khayat et al, concluded that the use of high IT up to 176 Ncm did not prevent or inhibit osseointegration. [08]

Perren et al inserted compression plates in the tibia of sheep and observed that pressure at the screw sites of about 40 MPa did not result in pressure necrosis but rather a gradual decrease in pressure due to bone viscoelasticity [09]. Transient ischemia may be an important factor in initiating fracture healing. Ischemia in the rat tibia for 4.5 h was found to cause periosteal proliferation instead of bone death. [10]

In Summery, there is a slow gradual decline in bone stress produced at implant insertion. This decline is a result of:

1. Viscoelastic relaxation of bone.

2. Normal remodeling by basic multicellular units whereby pre-stressed bone is replaced by new bone through internal remodeling rather than surface resorption. [11-12]

Higher insertion torque combined with the enhanced osseodensification of the implant site is highly desired.

References:

[01] Heat Production by 3 implant drill systems after repeated drilling and sterilization. Chacon GE, Bower DL, Larsen PE, McGlumphy EA, Beck FM. J Oral Maxillofac Surg. 2006 Feb:64(2):265-9.

[02] Trisi, P., et al., Implant micromotion is related to peak insertion torque and bone density. Clin Oral Implants Res, 2009. 20(5): p. 467-71.

[03] Winwood, K., et al., The importance of the elastic and plastic components of strain in tensile and compressive fatigue of human cortical bone in relation to orthopaedic biomechanics. J Musculoskelet Neuronal Interact, 2006. 6(2): p. 134-41.

[04] Bashutski JD, D.S.N., Wang HL, Implant pressure necrosis: Current understanding and case report. J Periodontal 2009; 80:700-704., 2009(80): p. 700-704.

[05] Haider R, e.a., Histomorphometric analysis of bone healing after insertion of IMZ-1 implants independent of bone structure and drilling method. Stomatol, 1991(88): p. 507-521.

[06] Trisi, P., et al., High versus low implant insertion torque: a histologic, histomorphometric, and biomechanical study in the sheep mandible. Int J Oral Maxillofac Implants, 2011. 26(4): p. 837-49.

[07] Ottoni, J.M., et al., Correlation between placement torque and survival of single-tooth implants. Int J Oral Maxillofac Implants, 2005. 20(5): p. 769-76.

[08] Khayat PG1, A.H., Tourbah BI, Sennerby L., Clinical outcome of dental implants placed with high insertion torques (up to 176 Ncm). Clin Implant Dent Relat Res. , 2013. 15(2): p. 227-33.

[09] Perren, S.M., et al., The reaction of cortical bone to compression. Acta Orthop Scand Suppl, 1969. 125: p. 19-29.

[10] Svindland, A.D., et al., Periosteal response to transient ischemia. Histological studies on the rat tibia. Acta Orthop Scand, 1995. 66(5): p. 468-72.

[12] Halldin, A., et al., The effect of static bone strain on implant stability and bone remodeling. Bone, 2011. 49(4): p. 783-9.

[12] Perren, S.M., Evolution of the internal fixation of long bone fractures. The scientific basis of biological internal fixation: choosing a new balance between stability and biology. J Bone Joint Surg Br, 2002. 84(8): p. 1093-110.