

Osseodensification Clinical Protocols

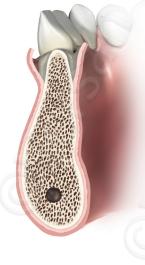


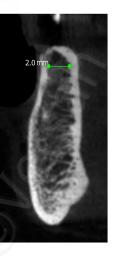
Facilitated Ridge Expansion Protocol*

Overview: 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 $\ge 1/1$ 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 + 1 mm 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.

• DIAGNOSE AND ASSESS THE AMOUNT OF THE TRABECULAR BONE USING A CBCT

- CREATE INTRA-BONY TROUGH IN NARROW RIDGE < 4 MM
- NO NEED FOR VERTICAL SIDE CUTS
- USE DENSAH® BURS IN SMALL INCREMENTS
- OVER-SIZE THE OSTEOTOMY TO BE \geq IMPLANT MAJOR DIAMETER
- OSTEOTOMY 1 MM DEEPER THAN IMPLANT LENGTH ESPECIALLY IN THE MANDIBLE
- PERFORM HARD & SOFT TISSUE VENEER CONTOUR GRAFT TO DEVELOP TISSUE THICKNESS AROUND IMPLANTS





Diagnose & assess the amount of the trabecular bone available

using a CBCT to evaluate the bone composition needed to perform a predictable plastic expansion. Flap the soft tissue using instruments and technique normally used.

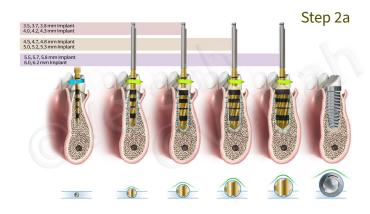
Step 1:

Create intra-bony trough in narrow ridge < 4 mm. If the ridge contains ≤ 2 mm of trabecular-bone core or high cortical bone ratio, an intrabony 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 side cuts are needed.** The ridge-split is to allow more buccal wall elasticity during the expansion procedure. **This intra-bony split is contra-indicated in resorbed ridge with a narrow base.**

Step 2:

Use the Densah® Bur in small increments, depending upon the implant type and diameter. After a narrow pilot osteotomy, change the surgical motor to Densifying Mode (counterclockwise, drill speed 800-1500 rpm with copious irrigation). Start with the narrowest Densah® Bur, in Densifying Mode, until reaching the desired depth (begin by introducing the running bur into the osteotomy. When feeling the haptic feedback of the bur pushing up out of the osteotomy, lift off and reapply pressure with a pumping motion until reaching the desired depth). As the bur diameter increases, the bone will slowly expand to the planned final diameter.





Step 2b

Clinical Versahtility of Osseodensification





Step 2 Continued...

The osteotomy may be expanded with minimal bone dehiscence, which may allow for total implant length placement in autogenous bone without thread exposure.

Step 3:

Oversize the osteotomy to be slightly wider than the implant major diameter (especially in the mandible) to prevent the implant threads from over-straining the expanded bony walls. Mandibular osteotomies need to be planned and performed to 1 mm deeper than the implant length.

Step 4:

Place an implant with a diameter that is equal or slightly larger than the initial ridge width. If using the surgical motor to tap the implant into place, the unit may stop when reaching the placement torque maximum. Finish placing the implant to depth manually with a torque indicating wrench.

Step 5:

Perform **hard and soft tissue veneer contour-graft** to augment around the implant to develop tissue thickness that may enhance long term stability.



Step 4









* Data on file, visit versah.com/our-science/ for Ridge Expansion studies



Clinician judgement and experience should be applied in conjunction with this suggestive use protocol
©2022 Versah,LC. All rights reserved. Versah, Densah, et al. are registered trademarks.10210 REV07 WWW.Versah.COM



Facilitated Densah[®] Lift Protocol I^{*}

Minimum residual bone height ≥ 6 mm. Minimum alveolar width needed = 4 mm

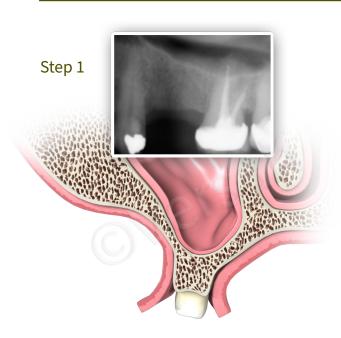
Overview: Use Densah[®] Burs in full step increments. For example: 2.0 mm, 3.0 mm, 4.0 mm, 5.0 mm.

- MEASURE BONE HEIGHT TO SINUS FLOOR
- PILOT DRILL 1 MM BELOW THE SINUS FLOOR
- DENSAH[®] BUR (2.0) IN OD MODE TO SINUS FLOOR
- ENTER WITH DENSAH[®] BUR (3.0) IN OD MODE UP TO 3MM PAST THE SINUS FLOOR
- DENSAH[®] BUR (4.0), (5.0) OD MODE UP TO 3 MM PAST THE SINUS FLOOR, IF NEEDED
- USE DENSAH® BURS IN FULL STEP INCREMENTS FOR EXAMPLE: 2.0 MM, 3.0 MM, 4.0 MM, 5.0 MM



Densifying crust in osseodensification mode due to compaction autografting

Compaction autografting in the apex of the osteotomy facilitates sinus grafting



Pilot drill 1 mm below the sinus floor.

In cases where posterior residual alveolar ridge height is \geq 6.0 mm, and additional vertical depth

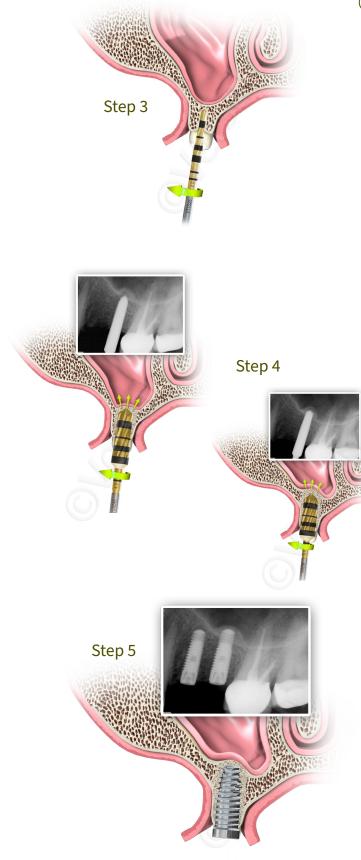
is desired, drill to the depth determined within an approximate safety zone of 1.0 mm from the sinus floor using a pilot drill (clockwise drill speed 800-1500 rpm with copious irrigation). Confirm pilot drill position with a radiograph.

Step 1:

Measure bone height to the sinus floor. Flap the soft tissue using instruments and technique normally used.



Step 2:



Clinical Versahtility of Osseodensification

Step 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 surgical 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.

Step 4:

Enter with Densah[®] Bur (3.0) OD mode up to 3 mm past the sinus floor. Use the next wider Densah[®] Bur (3.0) in densifying-mode (counterclockwise drill speed 800-1500 rpm 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.

Step 5:

Place Implant. Place the implant into the osteotomy. If using the surgical 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.



* Data on file, visit versah.com/our-science/ for Maxillary Sinus Graft studies

Clinician judgement and experience should be applied in conjunction with this suggestive use protocol
©2022 Versah,LLC. All rights reserved. Versah, Densah, et al. are registered trademarks.10307 REV08
WWW.V@C

<u>www.versah.com</u>



Facilitated Densah[®] Lift Protocol II^{*}

Minimum residual bone height 4-5 mm. Minimum alveolar width needed = 5 mm

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

- MEASURE BONE HEIGHT TO SINUS FLOOR
- AVOID USING A PILOT DRILL
- DENSAH® BUR (2.0) OD MODE TO SINUS FLOOR
- \bullet ENTER WITH DENSAH® BUR (3.0) OD MODE UP TO 3 MM PAST THE SINUS FLOOR
- DENSAH® BUR (4.0), (5.0) OD MODE UP TO 3 MM PAST THE SINUS FLOOR TO FURTHER EXPAND THE OSTEOTOMY
- USE DENSAH[®] BURS IN FULL STEP INCREMENTS FOR EXAMPLE: 2.0 MM, 3.0 MM, 4.0 MM, 5.0 MM
- USE THE LAST DENSAH® BUR IN LOW SPEED TO GENTLY PROPEL WELL HYDRATED ALLOGRAFT

Step 1:

Measure bone height to sinus floor.

Flap the soft tissue using instruments and technique normally used.

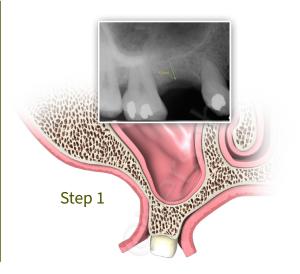
Step 2:

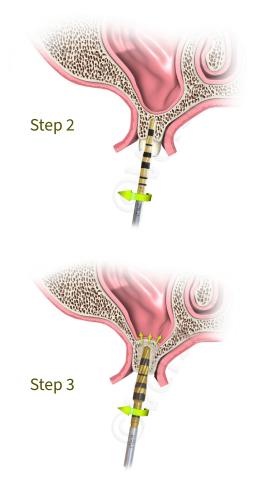
Densah® Bur (2.0) OD Mode to sinus floor. Avoid using a pilot drill. Depending upon the implant type and diameter selected for the site, begin with the narrowest Densah® Bur (2.0). Change the surgical motor to reverse (counterclockwise drill speed 800-1500 rpm–Densifying Mode with copious irrigation). Begin running the bur into the osteotomy until reaching the dense sinus floor. Confirm Bur position with a radiograph.

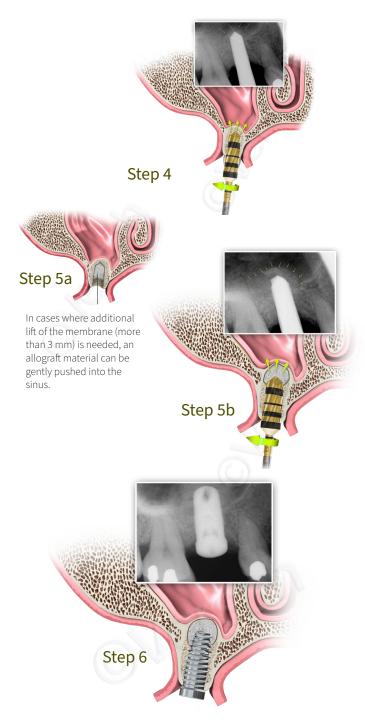
Step 3:

Enter with Densah[®] Bur (3.0) OD mode up to 3 mm 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 3 mm. **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 3 mm. Confirm the bur vertical position with a radiograph.







Clinical Versahtility of Osseodensification

Step 4:

Densah Bur (4.0), (5.0) OD mode up to 3 mm 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.

Step 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.

Step 6: Place implant.

Place the implant into the osteotomy. If using the surgical 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.





* Data on file, visit versah.com/our-science/ for Maxillary Sinus Graft studies

Clinician judgement and experience should be applied in conjunction with this suggestive use protocol ©2022 Versah, LLC. All rights reserved. Versah, Densah, et al. are registered trademarks. 10308 REV08

Immediate Implant Placement*



- ATRAUMATIC TOOTH EXTRACTION WITHOUT OR MINIMAL FLAP REFLECTION.
- CHOOSE IMPLANT DIAMETER TO BE SLIGHTLY WIDER THAN THE TOOTH APEX.
- \bullet USE DENSAH® BURS IN FULL INCREMENTS AND CCW OSSEODENSIFICATION MODE.
- FINAL DENSAH® BUR APICAL DIAMETER TO BE \geq TO THE APICAL DIAMETER OF TOOTH APEX.
- USE A WELL HYDRATED COMPOSITE ALLOGRAFT OF 70/30 CANCELLOUS//CORTICAL TO FILL THE SOCKET.
- \bullet USE DENSAH® BUR THAT IS ONE STEP SMALLER THAN THE LAST USED BUR TO DENSIFY ALLOGRAFT.
- IMPLANT STABILITY MUST BE MAINLY PROVIDED BY THE APICAL PORTION OF THE SOCKET.

Step 1:

After atraumatic tooth extraction without or minimal flap reflection and socket degranulation, use the pilot drill in clockwise mode to achieve implant trajectory.



Step 2a:

Choose implant diameter based on the tooth or its socket apical diameter. Implant needs to be slightly wider than the tooth apex. This will allow the **implant stability to be mainly provided by the apical portion of the socket.**

Step 2b:

Choose a Densah[®] Bur to be the last preparation bur based on its diameter relative to the tooth or its socket apical diameter. **Final Densah[®] Bur needs to be \geq to the apical diameter of the tooth or its socket.**

Step 3:

Use Densah® Burs in full increments, depending upon the implant type and diameter. After the pilot osteotomy, change the surgical motor to Densifying Mode (CCW, 800-1500 rpm with copious irrigation). To prep the site, start with the narrowest Densah® Bur, in OD Mode, until reaching the desired depth (begin by introducing the running bur into the osteotomy.) When feeling the haptic feedback of the bur pushing up out of the osteotomy, lift off and reapply pressure with a pumping motion until reaching the desired depth.



We believe innovative medical technology must be biologically viable and able to translate to predictable and reproducible procedures.





Use the following wider Densah® Burs until reaching the designated bur in Step 2B. As the bur diameter increases, the apical bone will slowly expand to accommodate the designated implant diameter.

Step 4:

Loosely fill the osteotomy with well hydrated allograft in the socket. Allograft preferably to be a combination of 70/30 cancellous/cortical.



Step 5:

Densified allograft may enhance implant primary stability in the extraction socket. Use the Densah® Bur that is one step smaller than the last bur used in socket preparation. Use the bur in CCW direction, low speed 150-200 rpm with no irrigation to densify the allograft laterally into the socket walls. Follow the same implant preparation trajectory.



Step 6:

Place the implant. Using the surgical motor to tap the implant into place, the unit may stop when reaching the placement torque maximum. Finish placing the implant to depth manually with a torque indicating wrench.







Clinician judgement and experience should be applied in conjunction with this suggestive use protocol.



Molar Septum Expansion Protocol with the Densah[®] Burs^{*}

- SEPARATE MOLAR ROOTS AT THE FURCATION WITHOUT COMPROMISING THE INTEGRITY OF THE SEPTUM.
- USE PILOT DRILL IN CLOCKWISE MODE TO A DEPTH THAT IS 1 MM DEEPER THAN THE PLANNED IMPLANT LENGTH
- USE THE SUBSEQUENT DENSAH® BURS IN SMALLER INCREMENTS TO EXPAND THE OSTEOTOMY AND TO INCREASE BONE PLASTICITY
- IMPLANT PLACEMENT SHOULD BE EITHER AT THE CREST OR SUB-CREST LEVEL
- FILL THE GAP WITH A BONE GRAFT MATERIAL IF NEEDED; PREFERABLY AN ALLOGRAFT WITH A 70/30 CANCELLOUS/CORTICAL RATIO

Step 1:

Separate molar roots at the furcation without compromising the integrity of the septum. Perform atraumatic mesial and distal root extraction. Degranulate tissue to expose septum area.

Step 2:

Use a pilot drill that is 1.3 mm -1.5 mm, in clockwise mode, in the center of the septum to a depth that is 1 mm deeper than the planned implant length.

Step 3:

Depending upon the implant type and diameter, follow the corresponding Implant System Drilling Protocol starting with the smallest Densah® Bur to 1 mm deeper than the intended implant length. Run the Densah® Burs in OD mode (counterclockwise, drill speed 800-1500 rpm with copious irrigation). Use the subsequent Densah[®] Burs in smaller increments to increase bone plasticity and to expand the osteotomy. For example, use Densah® Bur (2.0) after the pilot then expand with Densah® Bur (2.3) then move to Densah[®] Bur (2.5) before introducing the Densah[®] Bur (3.0). As it is in ridge expansion cases with Osseodensification, you may over-expand the osteotomy so the last Densah[®] Bur diameter is slightly larger than the planned implant major diameter. As the bur diameter increases, the bone expands to reach the final osteotomy diameter.

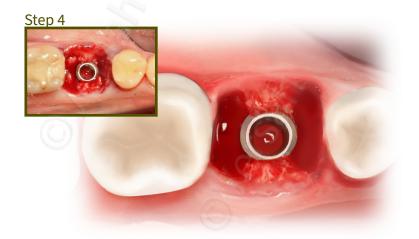






Step 3





Step 5



Step 4:

Implant placement should be either at the crest level or sub-crest level depending on its connection type.

Step 5:

Fill the gap with a bone graft material if needed; preferably an allograft with a 70/30 cancellous/cortical ratio. Seal the gap with biologics or a collagen plug and a large healing abutment and possibly place interrupted suture on top.



Step 6: Assess healing and soft tissue closure 6-8 weeks post placement.









Case courtesy of Dr. Samvel Bleyan



* Data on file, visit versah.com/our-science/ for Molar Septum Expansion studies

Clinician judgement and experience should be applied in conjunction with this suggestive use protocol ©2022 Versah,LLC. All rights reserved. Versah, Densah, et al. are registered trademarks.10310 REV07 WWW.Ve

www.versah.com



Guided Expansion Graft*

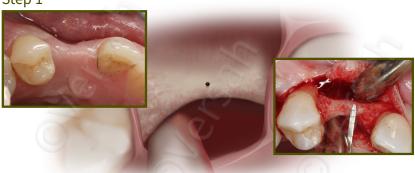
For cases with initial ridge width of \leq 3.0 mm

- USE PILOT DRILL IN (CW) MODE AND DRILL TO IMPLANT DEPTH AND ANGULATION
- USE THE SUBSEQUENT DENSAH® BURS IN SMALLER INCREMENTS TO EXPAND THE OSTEOTOMY AND TO INCREASE BONE PLASTICITY
- FINAL EXPANSION DIAMETER SHOULD NOT EXCEED THE PLUS ONE FORMULA (INITIAL RIDGE WIDTH + 1 MM)
- GRAFT THE NEWLY FORMED SOCKET WITH A 70/30 CANCELLOUS/CORTICAL COMBINATION ALLOGRAFT
- ALLOW HEALING FOR 3-6 MONTHS
- RE-ENTER THE SITE TO PREPARE FOR IMPLANT PLACEMENT USING OSSEODENSIFICATION WITH THE DENSAH® BURS

Step 1:

Flap the soft tissue using the technique indicated for the implant position. Drill to implant depth and angulation using a narrow Pilot Drill preferably 1.3 mm – 1.5 mm. (CWspeed 800-1500 rpm with copious irrigation).

Step 1



Step 2:

Depending upon the implant type and diameter, follow the corresponding Implant System Drilling Protocol starting with the smallest Densah[®] Bur to 1 mm deeper than the intended implant length. Run the Densah[®] Burs in OD mode (counterclockwise, drill speed 800-1500 rpm with copious irrigation). Use the subsequent Densah[®] Burs in smaller increments to increase bone plasticity and expand the osteotomy. For example, use Densah[®] Bur (2.0) after the pilot then expand with Densah[®] Bur (2.3) then move to Densah® Bur (2.5) before introducing the Densah[®] Bur (3.0).

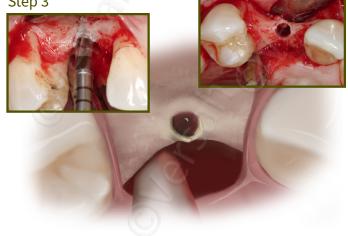
Step 2



Step 3:

Increase osteotomy diameter in small increments until reaching the intended expansion. As the bur diameter increases, the bone will slowly expand to the final expansion diameter. Final expansion diameter should not exceed the plus 1 formula (initial ridge width + **1 mm)**. For example, if you start with a 3 mm ridge, the maximum expected final osteotomy diameter is not to exceed (3+1) = 4 mm.

Step 3



Step 4



Step 4:

Graft the newly formed socket/osteotomy including surrounding area with your preferred bone allograft materials, preferably a 70/30 cancellous/cortical ratio. Use membrane and try to achieve tension free primary closure. Allow healing for 3-6 months.

Step 5

Step 5:

Re-enter the site and perform Osseodensification to facilitate further expansion if needed and place the implant. Use the Densah® Burs in smaller increments. Do not under-prep the osteotomy beyond 0.5 mm - 0.7 mm in the maxilla or 0.2 mm - 0.5 mm in the mandible.



Step 6:

If using the surgical 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.











Case courtesy of Dr. Salah Huwais * Data on file, visit versah.com/our-science/ for Guided Expansion Graft studies



Clinician judgement and experience should be applied in conjunction with this suggestive use protocol ©2022 Versah, LLC. All rights reserved. Versah, Densah, et al. are registered trademarks. 10216 REV07

www.versah.com

Versah[®] C-Guide[®] System Protocol

Overview: Versah[®] Guided surgery is an innovative system that allows for adequate irrigation, proper visualization of the osteotomy expansion/preparation, freedom to luxate the Densah[®] Bur and the ability to manage multiple sites with different preparation depths and diameters with precision.

Step 1:

Imaging: Obtain a CBCT scan and clinical impressions of patients designated jaw(s).

Step 2:

Treatment Planning: Contact Versah[®] certified dental lab. Send the lab the CBCT scan and clinical impressions. For a list of all Versah certified labs please visit: **versah.com/guided-surgery-system/**

Step 3:

Schedule case planning session with your

lab to decide the final implant diameter, angulation, C-Guide[®] Sleeve placement, and drilling sequence with the needed Densah[®] Burs.

Step 4:

Select the appropriate G-Stop® assembly.

Snap the vertical gauge onto the Densah[®] Bur designated groove. The gauge should spin freely. (figure 1, 2, 3)

Example:

Large (L) G-Stop [®] Vertical Gauge, (L) G-Stop[®] Key, (L) C-Guide[®] Sleeve

C-Guide® Sleeve

G-Stop®

Vertical Gauge

S4248

1-8







Versah®

Guided Surgery Protocol

Versah[®] guide is a bone level guide

Maximum distance between the C-Guide[®] Sleeve and crestal bone level is 2 mm^1 plus 1 mm C-Guide[®] Sleeve shoulder = 3 mm offset



Figure 1



Figure 3

1. Guentsch, A., An, H., & Dentino, A. R. (2022). Precision and trueness of computer-assisted implant placement using static surgical guides with open and closed sleeves: An in vitro analysis. Clinical Oral Implants Research, 00, 1–10. https://doi.org/10.1111/clr.13904

Step 5:

Follow the suggested Densah[®] Bur Implant System Drilling Protocol. Use the G-Stop[®] Keys in incremental steps, e.g., when the distance between sleeve and bone is 2 mm (see Step 3) start with the G-Stop[®] Key (5 mm) to mark your osteotomy and establish initial trajectory - Exchange (5 mm) for the (10 mm), repeat in regular intervals leading up to your final length, repeat with each Densah[®] Bur. Your G-Stop[®] Key must align with your C-Guide[®].



Figure 4 (Surgical Keys)

Example (Final length desired 13 mm):

- Tapered Pilot Drill with (5 mm key then 10 mm, 13 mm)
- VT1525 with (5 mm key then 10 mm, 13 mm)
- VT2535 with (5 mm key then 10 mm, 13 mm)

Densah[®] Bur **G-Stop®** Vertical **Available** C-Guide[®] Sleeve Gauge + Key Compatibility Sizes ID 4.40 mm 6.25 mm Placement up to 3.25 mm 1 mm Implant 0D 4.2 mm ID 5.20 mm 6.25 mm Placement up to 4.3 mm 1 mm Implant OD 6.1 mm OD 5 mm ID 6.20 mm Placement up 6.25 mm to 5.3 mm Implant 1 mm OD 6 mm OD 7.1 mm Scan for more ID 7.20 mm information Placement up 6.25 mm to 6.2 mm Implant 1 mm OD 8.1 mm OD 7 mm * Data on file, visit versah.com/our-science/ for Guided Surgery studies

Sizing the Versah® Guided Surgery System



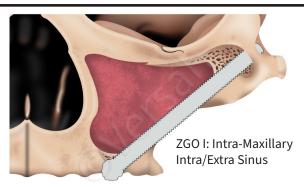
Clinician judgement and experience should be applied in conjunction with this suggestive use protocol ©2022 Versah,LLC. All rights reserved. Versah, Densah, et al. are registered trademarks. 10311 REV10

www.versah.com

Intra-Maxillary Intra/Extra Sinus Zygoma Protocol I/II



Overview: The anterior maxillary wall is slightly more concave. The pathway is **totally intra-maxillary with an intra/extra-sinus approach**. A tunnel osteotomy is created through the alveolar crest, into the sinus internal lateral wall, to slightly come out through that lateral wall and then re-enter again as a second tunnel osteotomy into the sinus to come out through the body of the zygoma.



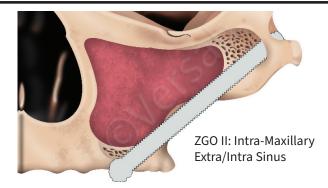
ZGO I: Intra-Maxillary Intra/Extra Sinus: The anterior maxillary wall is slightly concave. The pathway is intra-maxillary with a mostly intra-sinus path.

Step 1:

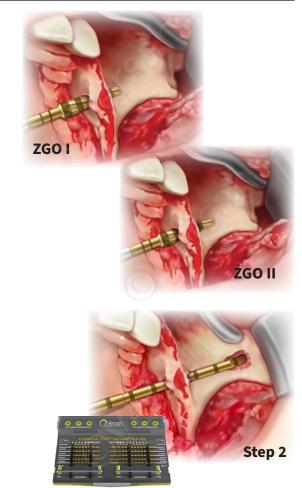
The tunnel osteotomy is initiated with the Universal Densah® pilot drill through the alveolar crest in clockwise (CW) mode to reach the floor of the sinus. Then the Universal Densah® Burs are used in a consecutive increasing order of 2mm, 2.3mm, 3mm, & 3.3mm in the counterclockwise (CCW) mode to preserve and widen the crestal osteotomy and initiate the entry into the sinus lateral wall. This would achieve preservation of the sinus membrane and Osseodensification of the alveolar bone.

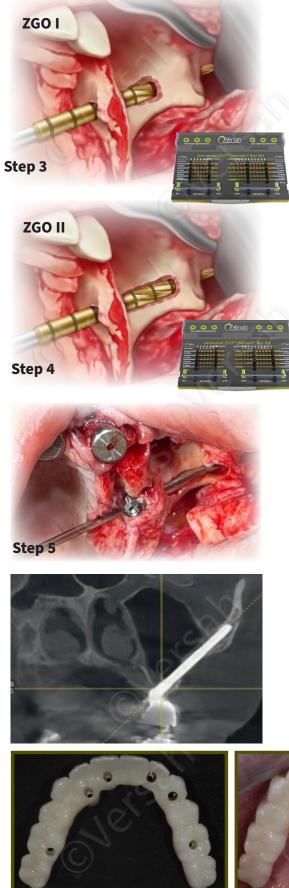
Step 2:

Using the appropriate length ZGO Densah® pilot drill (65mm or 90mm) depending on the patient's anatomy and size, in CW mode, enter the prepared crestal tunnel osteotomy to come out through the lateral sinus wall to enter again, through another tunnel osteotomy, into the inferior surface of the zygoma, then through the body of the zygoma, to exit the superolateral surface of the body of the zygoma.



ZGO II: Intra-Maxillary Extra/Intra Sinus: The anterior maxillary wall is slightly more concave than ZGO I. Therefore, it follows the same ZGO I surgical principle with pathway that is **intra-maxillary** but with a mostly **extra sinus path**.





Step 3:

After the pilot osteotomy, use the appropriate length ZGO Densah® Burs (65mm or 90mm) depending on the patient's anatomy and size. Starting with Densah® Bur ZT 1525, widen the crestal osteotomy in CCW mode entering the sinus cavity to come out through the lateral sinus wall to enter again, through another tunnel osteotomy, switch to CW mode as needed to enter into the inferior surface of the zygoma, through the body of the zygoma and exiting the superolateral surface of the body of the zygoma.

Step 4:

The zygoma hardness and implant diameter will determine the final ZGO Densah[®] Bur diameter i.e.; ZT2030, ZT2535, or ZT3040 **The ZGO Densah[®] Burs best to be utilized CW/CCW as needed based on bone density at 800-1500rpm with copious irrigation.**

 Clockwise (CW) cutting mode for denser bone
 Counterclockwise (CCW) densifying mode in softer bone
 A combination of CW & CCW using the Densify- Preserve after Cut (DAC) protocol for intermediate bone hardness

Step 5:

The zygomatic implant is then placed. Although the zygomatic implant can be seen through the anterior maxillary wall, most of the implant body has an intra-sinus path. **In ZGO I and ZGO II the implant contacts bone at:**

- 1) The alveolar crest.
- 2) The internal sinus wall.
- 3) The lateral sinus wall.
- 4) The body of the zygoma



Case courtesy of Dr. Costa Nicolopoulos



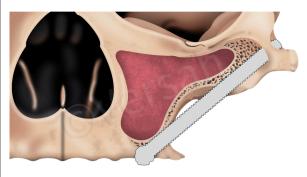
Versah. c

Clinician judgement and experience should be applied in conjunction with this suggestive use protocol
©2022 Versah,LLC. All rights reserved. Versah, Densah, et al. are registered trademarks.10377 REV05
WWW.Versah.com

Intra-Maxillary Extra Sinus Zygoma Protocol III



Overview: In these cases the anterior maxillary wall is very concave. The pathway is **intra-maxillary with a totally extra sinus path**. A tunnel osteotomy is created through the alveolar crest to come out into the external maxillary wall and then re-enter again as a second tunnel osteotomy into the body of the zygoma to come out through the superolateral aspect of the body of the zygoma. Between the two tunnel osteotomies the maxillary wall is very concave and therefore, there is no groove/channel osteotomy between the two tunnel osteotomies i.e. the middle part of the implant body would not touch the most concave part of the wall.



Step 1:

The tunnel osteotomy is initiated with the Universal Densah® pilot drill through the alveolar crest in clockwise (CW) mode to come out buccally through the maxillary buccal plate/anterior maxillary wall. Then the Universal Densah® Burs are used in a consecutive increasing order of 2mm, 2.3mm, 3mm, & 3.3mm in the counterclockwise (CCW) mode to widen the crestal osteotomy and achieve preservation and Osseodensification of the alveolar bone.

Step 2:

Using the appropriate length ZGO Densah® pilot drill (65mm or 90mm) depending on the patient's anatomy and size in CW mode, enter the previously prepared crestal tunnel osteotomy to come out glancing along the concave part of the anterior maxillary wall to penetrate and re-enter the inferior surface of the zygoma, then through the body of the zygoma to exit the superolateral surface of the body of the zygoma thereby creating a tunnel in the zygomatic bone. Step 1 Step 2







Step 3:

After the pilot osteotomy, depending on the patient's anatomy and size, use the appropriate length ZGO Densah® Burs (65mm or 90mm) Starting with ZGO Densah® Bur ZT1525, to widen the crestal tunnel crestal osteotomy in CCW mode and then glance along the concave part of the anterior maxillary wall. Switch to CW mode to penetrate and enter the inferior surface of the zygoma, through the body of the zygoma and exit the superolateral surface of the body of the zygoma, thereby widening the tunnel in the zygomatic bone. Zygoma bone hardness and implant diameter will determine the final ZGO Densah® Bur diameter.

Step 4:

The zygoma hardness and implant diameter will determine the final ZGO Densah[®] Bur diameter i.e.; ZT2535, or ZT3040 **The ZGO Densah[®] Burs best to be utilized CCW/CW as needed based on bone density at 800-1500rpm with copious irrigation.**

 Clockwise (CW) cutting mode for denser bone
 Counterclockwise (CCW) densifying mode for softer bone

3) A combination of CW & CCW using the Densify-Preserve after Cut (DAC) protocol for intermediate bone hardness

Step 5:

The zygomatic implant is then placed. The implant head is located in the alveolar crest. The middle part of the implant body does not touch the most concave part of the anterior maxillary wall. In this intra-maxillary extra sinus path the implant contacts bone at:

- 1) The alveolar crest coronally
- 2) The zygomatic bone apically



Versah.

* Data on file, visit versah.com/our-science/ for Zygomatic Implant studies

Case courtesy of Dr. Costa Nicolopoulos

Clinician judgement and experience should be applied in conjunction with this suggestive use protocol

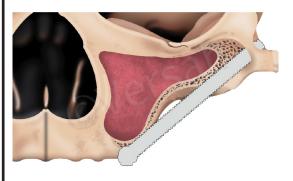
©2022 Versah,LLC. All rights reserved. Versah, Densah, et al. are registered trademarks. 10528 REV02

www.versah.com

Extra-Maxillary Extra Sinus Zygoma Protocol IV



Overview: This ZGO protocol IV follows an **extra-maxillary path**. The maxilla and alveolar bone show extreme vertical and horizontal atrophy. The pathway is **extra-maxillary with totally extra sinus path**. The implant head is located buccal to the alveolar crest usually in a shallow "channel" osteotomy. Most of the zygomatic implant body has an extra sinus/extra-maxillary path. The coronal part of the zygomatic implant is extra-maxillary usually in a **"channel" osteotomy** whereas the apical part of the implant is surrounded by bone in a **"tunnel" osteotomy** in the zygomatic bone. The zygomatic implant contacts bone in the zygomatic bone and part of the external lateral sinus wall.



Step 1:

Create the coronal **"channel"** osteotomy using the regular Universal Densah® Burs starting with the VT1525 (2.0) working up to VT3545 (4.0) in Cutting Mode CW at 800 - 1500 rpm with copious irrigation as a "side cutter" to **create a channel osteotomy in the residual alveolar ridge and the lateral wall of the maxillary sinus.** Once the osteotomy gets closer to the sinus membrane, switch to CCW (OD mode) to preserve the sinus membrane integrity while defining the channel osteotomy.



Step 2:

Using the appropriate length ZGO Densah® pilot drill (65mm or 90mm) depending on the patient's anatomy and size in CW mode, follow the "channel" trajectory to enter the inferior aspect of the body of the zygoma in order to prepare a "tunnel" osteotomy of the appropriate length just perforating apically through the superior-lateral aspect of the body of the zygoma.









After the pilot channel osteotomy, depending on the patient's anatomy and size, use the appropriate length (65 mm or 90 mm length) ZGO Densah® Burs, starting with ZGO Densah® Bur ZT1525, in CW cutting mode/CCW densifying mode as needed to widen the osteotomy in a consecutive increasing order to achieve the desired osteotomy diameter and length depending on the zygomatic implant diameter and length to be placed. When getting close to the sinus membrane, drilling direction is changed to CCW in order to preserve the sinus membrane integrity.

Step 4:

Step 3:

The zygoma hardness and implant diameter will determine the final ZGO Densah® Bur diameter ie: ZT2030, ZT2535, or ZT3040. The ZGO Densah® Burs best to be utilized CCW/ CW as needed based on bone density at 800-1500rpm with copious irrigation.

 Clockwise (CW) cutting mode for denser bone.
 Counterclockwise (CCW) densifying mode for softer bone
 A combination of CW & CCW using the Densify- Preserve after Cut (DAC) protocol for intermediate bone hardness.
 Zygoma bone hardness and implant diameter will determine the final ZGO Densah[®] Bur diameter.

Step 5:

The zygomatic implant is then placed. The implant head sits on the buccal of the alveolar crest. The middle part of the implant body does not touch the most concave part of the anterior maxillary wall. In this extra-maxillary extra sinus path contacts bone at:

1)The buccal outer aspect of the crest.

2)The zygomatic bone apically



Case courtesy of Dr. Costa Nicolopoulos





Clinician judgement and experience should be applied in conjunction with this suggestive use protocol

©2022 Versah, LLC. All rights reserved. Versah, Densah, et al. are registered trademarks. 10295 REV06

Osseodensification Published Papers

Biomechanical

- **B 1.** Huwais S, Meyer EG. A Novel Osseous Densification Approach in Implant Osteotomy Preparation to Increase Biomechanical Primary Stability, Bone Mineral Density, and Bone-to-Implant Contact. Int J Oral Maxillofac Implants 2017;32:27–36.
- B 2. Cáceres F, Troncoso C, Silva R, Pinto N. Effects of osseodensification protocol on insertion, removal torques, and resonance frequency analysis of BioHorizons[®] conical implants. An ex vivo study. J Oral Biol Craniofac Res. 2020 Oct- Dec;10(4):625-628. doi: 10.1016/j.jobcr.2020.08.019.
- **B 3.** Frizzera, F., Spin-Neto, R., Padilha, V. et al. Effect of osseodensification on the increase in ridge thickness and the prevention of buccal periimplant defects: an In-vitro randomized splitmouth pilot study, BMC, Oral Health 22,233 (2022) https://doi.org/10.1186/s12903-022-02242-x

Histological

- H 1. Mullings O, Tovar N, Abreu de Bortoli JP, Parra M, Torroni A, Coelho PG, Witek L. Osseodensification Versus Subtractive Drilling Techniques in Bone Healing and Implant Osseointegration: Ex Vivo Histomorphologic/ Histomorphometric Analysis in a Low-Density Bone Ovine Model. IJOMI. 2021 Sep-Oct;36(5):903-909. doi: 10.11607/jomi.8828.
- H 2. Mello-Machado, R.C., Sartoretto, S.C., Granjeiro, J.M. et al. Osseodensification enables bone healing chambers with improved low-density bone site primary stability: an in vivo study. Sci Rep 11, 15436 (2021).
- H 3. Torroni, A, Lima Parente, PE, Witek, L, Hacquebord, JH, Coelho, PG. Osseodensification drilling vs conventional manual instrumentation technique for posterior lumbar fixation: Ex-vivo mechanical and histomorphological analysis in an ovine model. J Orthop Res. 2020; 1–7.
- H 4. Witek, Lukasz, et al. "Absence of Healing Impairment in Osteotomies Prepared via Osseodensification Drilling." The International Journal of Periodontics & Restorative Dentistry, vol. 39, no. 1, 1 Nov. 2019, pp. 65–71., doi:10.11607/prd.3504.
- H 5. Lahens B, Lopez CD, Neiva RF, Bowers MM, Jimbo R, Bonfante EA, Morcos J, Witek L, Tovar N, Coelho PG. The effect of Osseodensification drilling for endosteal implants with different surface treatments: A study in Sheep. J Biomed Mater Res B Appl Biomater. 2018 Aug 6.
- H 6. Oliveira PGFP, Bergamo ETP, Neiva R, Bonfante EA, Witek L, Tovar N, Coelho PG. Osseodensification outperforms conventional implant subtractive instrumentation: A study in sheep. Mater Sci Eng C Mater Biol Appl. 2018 Sep 1;90:300-307.

- **B 4.** Bonfante, Estevam A, et al. "Biomaterial and Biomechanical Considerations to Prevent Risks in Implant Therapy." Periodontology 2000. 2019 Sep;81:139-151.
- **B 5.** Soldatos, N.; Pham, H.; Fakhouri,W.D.; Ngo, B.; Lampropoulos, P.; Tran, T.;Weltman, R. Temperature Changes during Implant Osteotomy Preparations in Human Cadaver Tibiae Comparing MIS[®] Straight Drills with Densah[®] Burs. Genes 2022, 13, 1716.
- **B 6.** Seo, Dong-Jun, Seong-Yong Moon, Jae-Seek You, Won-Pyo Lee, and Ji-Su Oh. 2022. "The Effect of Under-Drilling and Osseodensification Drilling on Low-Density Bone: A Comparative Ex Vivo Study" Applied Sciences 12, no. 3: 1163.
- H 7. Alifarag AM, Lopez CD, Neiva RF, Tovar N, Witek L, Coelho PG. Temporal Osseointegration: Early Biomechanical Stability through Osseodensification. J Orthop Res. 2018 Sep;36(9):2516-2523.
- H 8. Tian J, Neiva R, Paulo G, Coelho P, et al. Alveolar Ridge Expansion: Comparison of Osseodensification and Conventional Osteotome Techniques. J. Craniofac Surg 2018;00:00-00.
- H 9. Slete FB, Olin P, Prasad H. Histomorphometric Comparison of 3 Osteotomy Techniques. Implant Dent. 2018 Aug;27(4):424-428.
- H 10.Neiva, R., Tanello, B., Duarte, W., Coelho, P., Witek, L. and Silva, F. (2018), Effects of osseodensification on Astra TX and EV implant systems. Clin Oral Impl Res, 29: 444-444.
- H 11. Lopez, Christopher D, Adham Alifarag, Andrea Torroni, Nick Tovar, Jesus Rodrigo Diaz-Siso, Lukasz Witek, Eduardo D Rodriguez and Paulo G. Coelho. Osseodensification for Enhancement of Spinal Surgical Hardware Fixation. Journal of the mechanical behavior of biomedical materials 69 (2017): 275-281.
- H 12. Trisi P, Berardini M, Falco A, Vulpiani MP. New Osseodensification Implant Site Preparation Method to Increase Bone Density in Low-Density Bone: _In Vivo Evaluation in Sheep. Implant Dent 2016; 25:24–31.
- H 13.Lahens B, Neiva R, Tovar N, Alifarag AM, Jimbo R, Bonfante EA, Bowers MM, Cuppini M, Freitas H, Witek L, Coelho PG. Biomechanical and histologic basis of osseodensification drilling for endosteal implant placement in low density bone. An experimental study in sheep. J Mech Behav Biomed Mater. 2016 Oct; 63:56-65.
- H 14.Gendy, Fady G., Gregory D Kurgansky, Leyla Y. Cavdar, Christopher D Lopez, Lukasz Witek, Paulo G. Coelho and Andrea Torroni. "Mechanical properties of Ossedensification drilling as compared to Regular drilling." (2017).

Clinical

- **C 1.** Bergamo, ETP, Zahoui, A, Barrera, RB, et al. Osseodensification effect on implants primary and secondary stability: Multicenter controlled clinical trial. Clin Implant Dent Relat Res. 2021; 1–12.
- **C 2.** Tanello B, Huwais S, Tawil I, Rosen P., Neiva R. Osseodensification protocols for enhancement of primary and secondary implant stability – A retrospective 5-year follow-up multi-center study. Clinical Oral Implants Research, 2019; 30, (S19), 414–414.
- **C 3.** Mello-Machado, R.C.; Maurao, C.F.d.A.B.; Javid, K.; Ferreira, H. T.; Montemezzi, P.; Calasans-Maia, M.D.; Senna, P.M. Clinical Assessment of Dental Implants Placed in Low-Quality Bone Sites Prepared for the Healing Chamber with Osseodensification Concept: A Double Blind, Randomized Clinical Trial. Appl. Sci. 2021, 11, 640.
- C 4. Bleyan S, Gaspar J, Huwais S, Schwimer C, Mazor Z, Mendes JJ, Neiva R. Molar Septum Expansion with Osseodensification for Immediate Implant Placement, Retrospective Multicenter Study with Upto-5-Year Follow-Up, Introducing a New Molar Socket Classification. Journal of Functional Biomaterials. 2021; 12(4):66.
- C 5. Formiga, M.d.C.; Grzech-Lesniak, K.; Moraschini, V.; Shibli, J.A.; Neiva, R. Effects of Osseodensification on Immediate Implant Placement: Retrospective Analysis of 211 Implants. Materials 2022, 15, 3539. https://doi.org/10.3390/ma15103539
- C 6. Guentsch, A., An, H., & Dentino, A. R. (2022). Precision and trueness of computer-assisted implant placement using static surgical guides with open and closed sleeves: An in vitro analysis. Clinical Oral Implants Research, 00, 1–10. https://doi.org/10.1111/ clr.13904
- C 7. Huwais S, Mazor Z, Ioannou AL, Gluckman H, Neiva R. A Multicenter Retrospective Clinical Study with Upto-5-Year Follow-up Utilizing a Method that Enhances Bone Density and Allows for Transcrestal Sinus Augmentation Through Compaction Grafting. Int J Oral Maxillofac Implants. 2018 Nov/Dec; 33(6):1305-1311.
- **C 8.** Gaspar, J., Esteves, T., Gaspar, R., Rua, J. and João Mendes, J. (2018), Osseodensification for implant site preparation in the maxilla – a prospective study of 97 implants. Clin Oral Impl Res, 29: 163-163.
- C 9. Alhayati JZ, AL-Anee AM. Evaluation of crestal sinus floor elevations using versah burs with simultaneous implant placement at residual bone height ≥ 2.0 _<6.0 mm. A prospective clinical study. Oral Maxillofac Surg. 2022; doi:10.1007/s10006-022-01071-0

- C 10. Kumar, Baron Tarun, and Venkatraman Narayan, Minimally Invasive Crestal Approach Sinus Floor Elevation using Densah Burs, and Hydraulic Lift Utilizing Putty Graft in Cartridge Delivery. Clin Oral Impl Res. 2017;28(Supp 14)203-203.
- C 11. Neiva, Tanello, Huwais, et al. "Osseodensification Crestal Sinus Floor Elevation with or without Synthetic and Resorbable Calcium Phosphosilicate Putty". European Association for Osseointegration
- C 12. Nilesh Salgar; Osseodensified Crestal Sinus Window Augmentation: An Alternative Procedure to the Lateral Window Technique. J Oral Implant 1 February 2021; 47 (1): 45–55.
- C 13. Shereen W Arafat; Mohamed A Elbaz. "Clinical and radiographic evaluation of Osseodensification versus osteotome for Sinus floor elevation in partially atrophic maxilla: A prospective long term study" Egyptian Dental Journal, 65, issue 1-January (Oral Surgery), 2019, 189-195. Doi: 1021608/edj.2015.71261
- C 14. Koutouzis, Theofilos DDS, MS*; Huwais, Salah DDS†; Hasan, Fadi DDS, MSD‡; Trahan, William DMD, MSD§; Waldrop, Thomas DDS, MS¶; Neiva, Rodrigo DDS, MS∥ Alveolar Ridge Expansion by Osseodensification-Mediated Plastic Deformation and Compaction Autografting, Implant Dentistry: August 2019 -Volume 28 - Issue 4 - p 349-355.
- C 15. Stepan Jarikian, Mohamad Hassan Jaafo, Zuhair Al-Nerabieah. Clinical Evaluation of Two Techniques for Narrow Alveolar Ridge Expansion: Clinical Study. Int J Dentistry Oral Sci. 2021;8(1):1047-1052.
- C 16. Aloorker S, Shetty M, Hegde C. Effect of Osseodensification on Bone Density and Crestal Bone Levels: A Split-mouth Study. J Contemp Dent Pract 2022; 23 (2):162-168. DOI: 10.5005/jpjournals-10024-3303
- C 17. Aparicio C, López-Píriz R, Peñarrocha M. Preoperative Evaluation and Treatment Planning. Zygomatic Implant Critical Zone (ZICZ) Location. Atlas Oral Maxillofac Surg Clin North Am. 2021 Sep;29(2):185-202. doi: 10.1016/j.cxom.2021.05.003. Epub 2021 Jul 2. PMID: 34325808.
- **C 18.** Aparicio, C., Olivo, A., de Paz, V. et al. The zygoma anatomy-guided approach (ZAGA) for rehabilitation of the atrophic maxilla. Clin Dent Rev 6, 2 (2022). https://doi.org/10.1007/s41894-022-00116-7
- C 19. da Rosa JCM, Pértile de Oliveira Rosa AC, Huwais S. Use of the Immediate Dentoalveolar Restoration Technique Combined with Osseodensification in Periodontally Compromised Extraction Sites. Int J Periodontics Restorative Dent. 2019 Jul/ Aug;39(4):527-534. doi: 10.11607/prd.3883. PMID: 31226191.

Osseodensification Published Papers

- C 20. Machado, Rafael & Gama, CristianeSantos & Batista, SandroHenrique & Rizzo, Denise & Valiense, Helder & Moreira, RudaF. (2018). Tomographic and clinical findings, pre-, trans-, and post-operative, of osseodensification in immediate loading. International Journal of Growth Factors and Stem Cells in Dentistry. 10.4103/GFSC.GFSC_22_18.
- C 21. Ahmed M Ibrahim; Sherif S Ayad; Adham Elashwah. "The effect of Osseodensification Technique on Implant stability (Clinical Trial). Alexandria Dental Journal, 45,2,2020, 1-7. Doi: 10.21608/ adjalexu.2020.86758
- C 22. Gaspar J, Proença L, Botelho J, Machado V, Chambrone L, Neiva R, Mendes JJ. Implant Stability of Osseodensification Drilling Versus Conventional Surgical Technique: A Systematic Review. Int J Oral Maxillofac Implants. 2021 Nov-Dec;36(6):1104-1110. doi: 10.11607/jomi.9132. PMID: 34919606.
- C 23. Rahimzadeh S, Rolf D, Carroll A, Parashar V, Mitchell JC. Osseodensification Burs – Impact on Implant Insertion and Removal Torque. AADR/ CADR General Session, Poster ID 1028. 10.13140/ RG.2.2.31470.72002. 2018

- C 24. Pai UY, Rodrigues SJ, Talreja KS, Mundathaje M. Osseodensification – A novel approach in implant dentistry. J Indian Prosthodont Soc. 2018 Jul-Sep;18(3):196-200.
- C 25. Tretto PHW, Fabris V, Cericato GO, Sarkis-Onofre R, Bacchi A. Does the instrument used for the implant site preparation influence the boneimplant interface? A systematic review of clinical and animal studies. Int J Oral Maxillofac Surg. 2018 Apr 24.
- C 26. Kanathila H, Pangi A, An insight into the concept of osseodensification-enhancing the implant stability and success. July 2018. Journal of Clinical and Diagnostic Research 12(7): ZE01-ZE03.
- C 27. Hofbauer, Huwais. "Osseodensification Facilitates Ridge Expansion with Enhanced Implant Stability in the Maxilla: Part II Case Report with 2-Year Follow-Up". Implant Practice, April 2015
- C 28. Huwais. "Biomechanics in Implant Osteotomy Preparations". Published by Inside Dentistry, Volume 10, December 2014
- C 29. Mele, Kurtzman. "Feline Dental Implants: New Paradigm Shift in Maxillary Alveolar Osteitis Treatment Planning with Osseodensification." Journal of Osseointegration. 2019, September 11.





Preserve • Simplify • Optimize

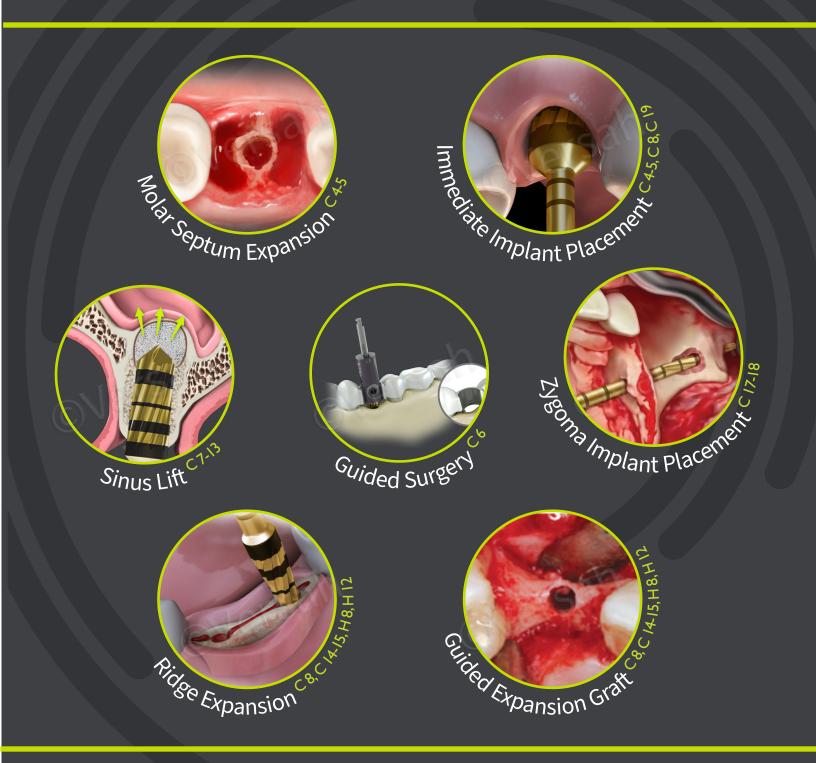
Notes	



Preserve • Simplify • Optimize

Notes	

Densah® Bur Versahtility Optimize the Site • Optimize the Outcome



* Data on file, visit versah.com/our-science/ for studies details



Versah, LLC

2000 Spring Arbor Road • Suite D • Jackson, MI 49203

Ph: 517-796-3932

Web: www.versah.com



©2022 Versah,LLC. All rights reserved. Versah, Densah, et al. are registered trademarks. 10731 REV00