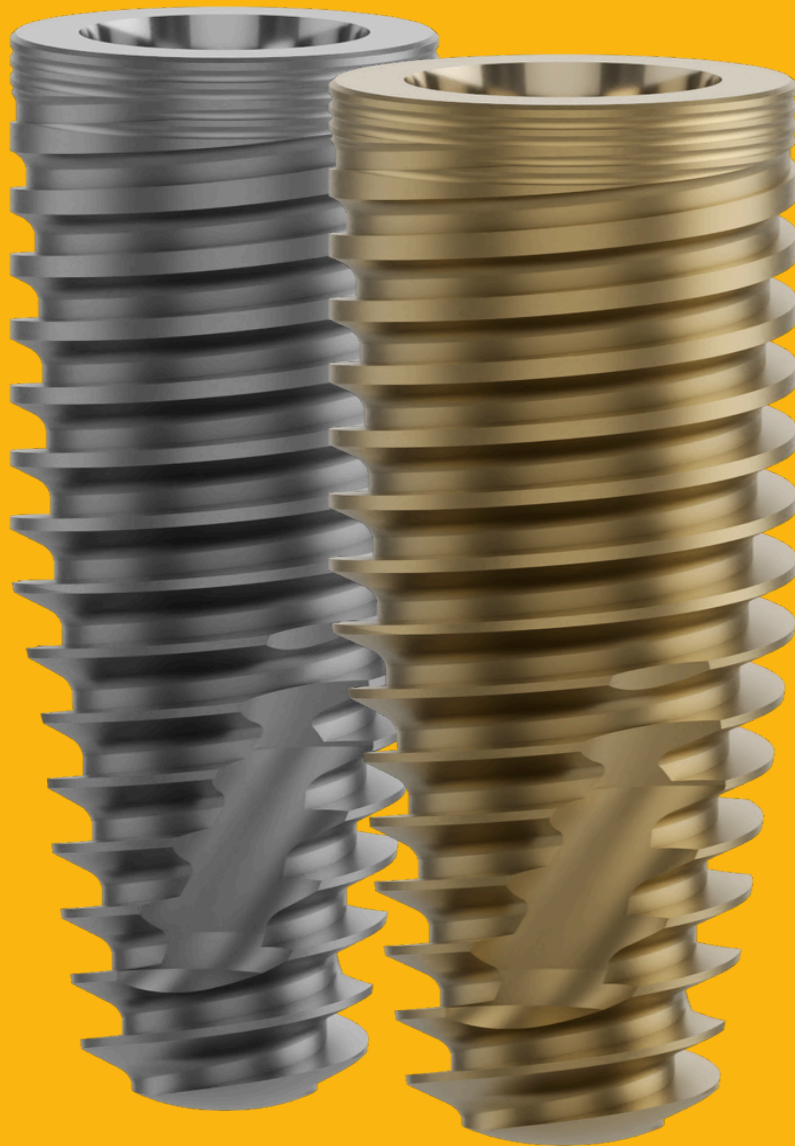
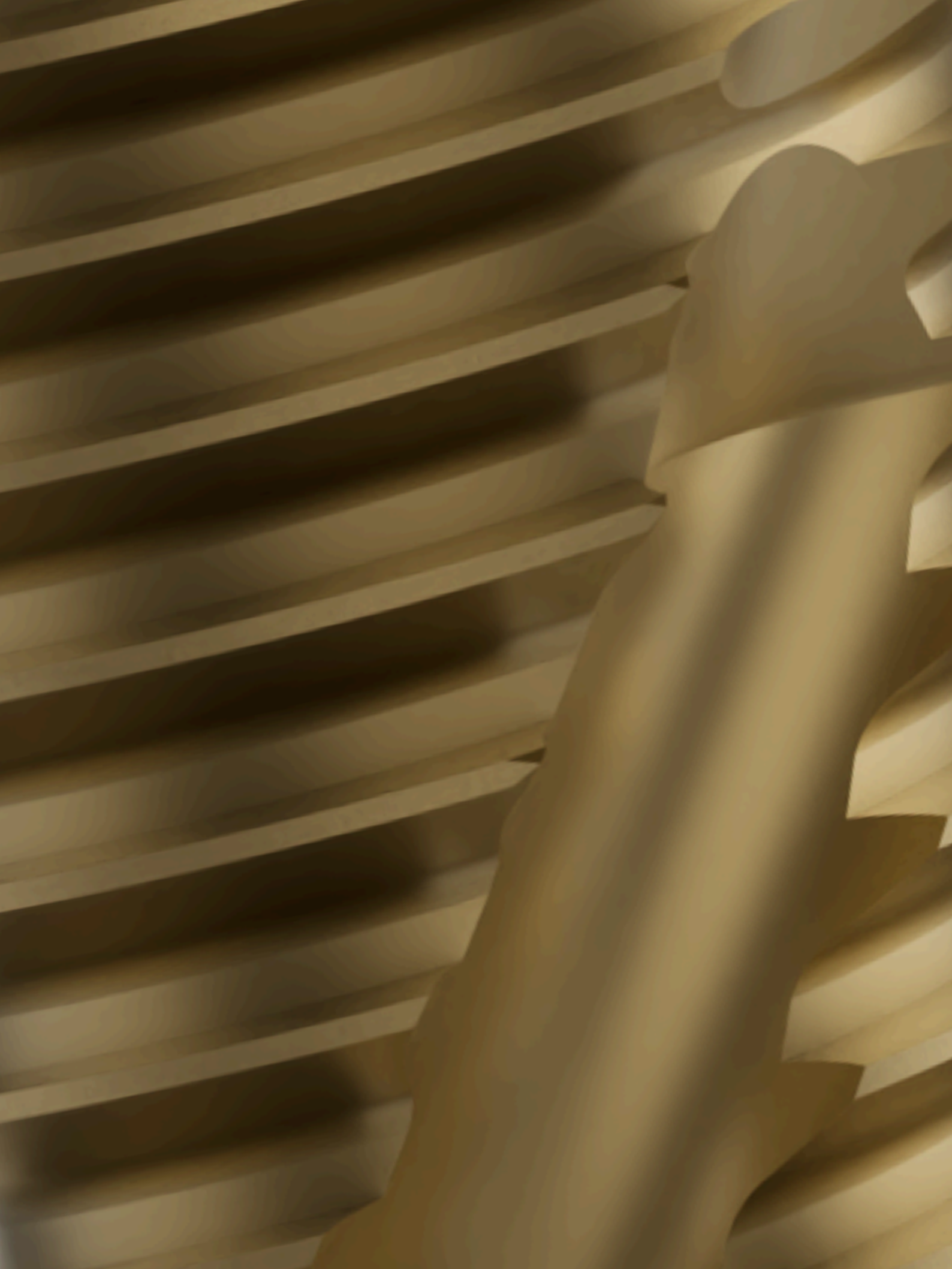


# Versalis

IMPLANT SURGICAL MANUAL





# 1. SURGICAL MANUAL

The Versalis S implant is indicated for surgical procedures in the bones of the maxilla and/or mandible, providing a support platform for the installation of prosthetic components that will receive artificial teeth, thereby restoring the masticatory function of edentulous patients.

They can be used in conventional procedures (one or two surgical stages) and immediate loading (activation within 72 hours) when there is acceptable primary stability (above 45 N.cm) and proper occlusal load. They may be used in single or multiple (partial or full) rehabilitations.

The procedures illustrated and described in this manual reflect idealized presentations of patients with bone tissue of varying densities suitable for implant placement. No attempt has been made to cover the full range of real patient conditions that may negatively affect surgical and prosthetic outcomes. The clinician's judgment regarding any specific case should always prevail over any recommendations made in this or any other S.I.N. literature.

## ATTENTION

Before starting any implant surgical procedure using S.I.N. implants:

- Read and understand the Instructions for Use provided with the products.
- Clean and sterilize the surgical tray and instruments according to the Instructions for Use.
- Become thoroughly familiar with all instruments and their functions.
- Study the layout of the surgical kit and its iconography.
- Develop a surgical treatment plan that meets the prosthetic requirements of the case.
- Narrow diameter implants are intended for the anterior region of the mouth and are not intended for the posterior region due to the potential risk of implant failure.

## 2. INDICATIONS FOR USE

The Versalis S implants are intended for use in the mandible and/or maxilla as an artificial root structure for the replacement of a single tooth or for multiple prostheses (partial or full).

These dental implants can be immediately restored with a temporary prosthesis that is not in functional occlusion, or splinted for the replacement of multiple teeth, or stabilized with a screw retained full arch rehabilitation

## 3. IMPORTANT CONSIDERATIONS

Preoperative oral rinses with 0.12% Chlorhexidine Gluconate solution have been shown to significantly reduce the incidence of post-implant infectious complications. A 30-second preoperative rinse is recommended, followed by rinsing twice daily for two weeks after surgery.

Drilling should be performed under a constant flow of sterile irrigation, using manual irrigation or a peristaltic pump (available on surgical motors) to prevent bone overheating. Surgical drills must be replaced when worn out, dull, corroded, or otherwise compromised.

S.I.N. recommends replacing drills after 20 to 30 osteotomies, depending on bone density.

### ATTENTION

There is a risk of injury to the mandibular nerve associated with surgical drilling in the posterior regions of the mandible.

To minimize the risk of nerve injury, it is imperative that the clinician understands the drill depth markings in relation to the implant length to ensure correct vertical placement.

## 4. ONE STAGE PROTOCOL

An one-stage surgery can be performed by placing a healing abutment or a provisional abutment with a temporary crown that should remain in infra-occlusion, at the time of implant placement. This eliminates the need for a second procedure (re-entry).

Although the implant is not in occlusal function, some forces may be transmitted to it through the exposed transmucosal component.

Prosthetic restoration begins after the implant has osseointegrated (3 to 4 months for Versalis S Plus, which feature the HAnano surface) and the soft tissue has healed.

## 6

## 5. TWO STAGE PROTOCOL

In a two-stage surgery, the implant is placed beneath the soft tissue and protected from occlusal function and other forces during osseointegration. A low-profile cover screw is placed over the implant to protect it from soft tissue infiltration.

For Morse taper implants, placement should be 1.5 mm subcrestal.

After the osseointegration phase (3 to 4 months for Versalis S Plus implants, which feature HAnano surface) a second procedure (re-entry) exposes the implant and a transmucosal healing cap (healing abutment) is placed to allow soft tissue healing and the development of an anatomical emergence profile for the final prosthesis.

Prosthetic restoration begins after soft tissue healing.

## 6. NON - FUNCTIONAL IMMEDIATE RESTORATION

A one-stage surgery with non-functional immediate provisionalization provides the patient with a non-functional provisional prosthesis at the beginning of the treatment plan, offering immediate esthetics.

A Provisional Cylinder is placed on the implant during or shortly after surgery, and a provisional restoration is secured using temporary cement or picked up with resin material, forming a single unit with the cylinder.

The provisional crown helps shape the emergence profile, mimicking the patient's physiological soft tissue during the healing phase.

## 7. IMMEDIATE FUNCTION RESTORATION (IMMEDIATE LOADING)

One-stage surgery with immediate function is possible in good-quality bone, where multiple implants exhibiting excellent primary stability (more than 45 Ncm) can be splinted together.

Splinting the implants may provide a biomechanical advantage over individual non-splinted prostheses.

## 8. IMPLANT PLACEMENT LEVEL AND SPACING

For Morse Taper implants, placement should be performed 1.5 mm subcrestally.

## 9. IMPLANT-TO-TOOTH SPACING

The center point of the osteotomy required to maintain a specific spacing between the implant and the tooth is calculated using the following formula:  
 $\frac{1}{2}$  (implant body diameter) + desired spacing (suggested 1.5 mm).

## 10. SPACING BETWEEN IMPLANTS

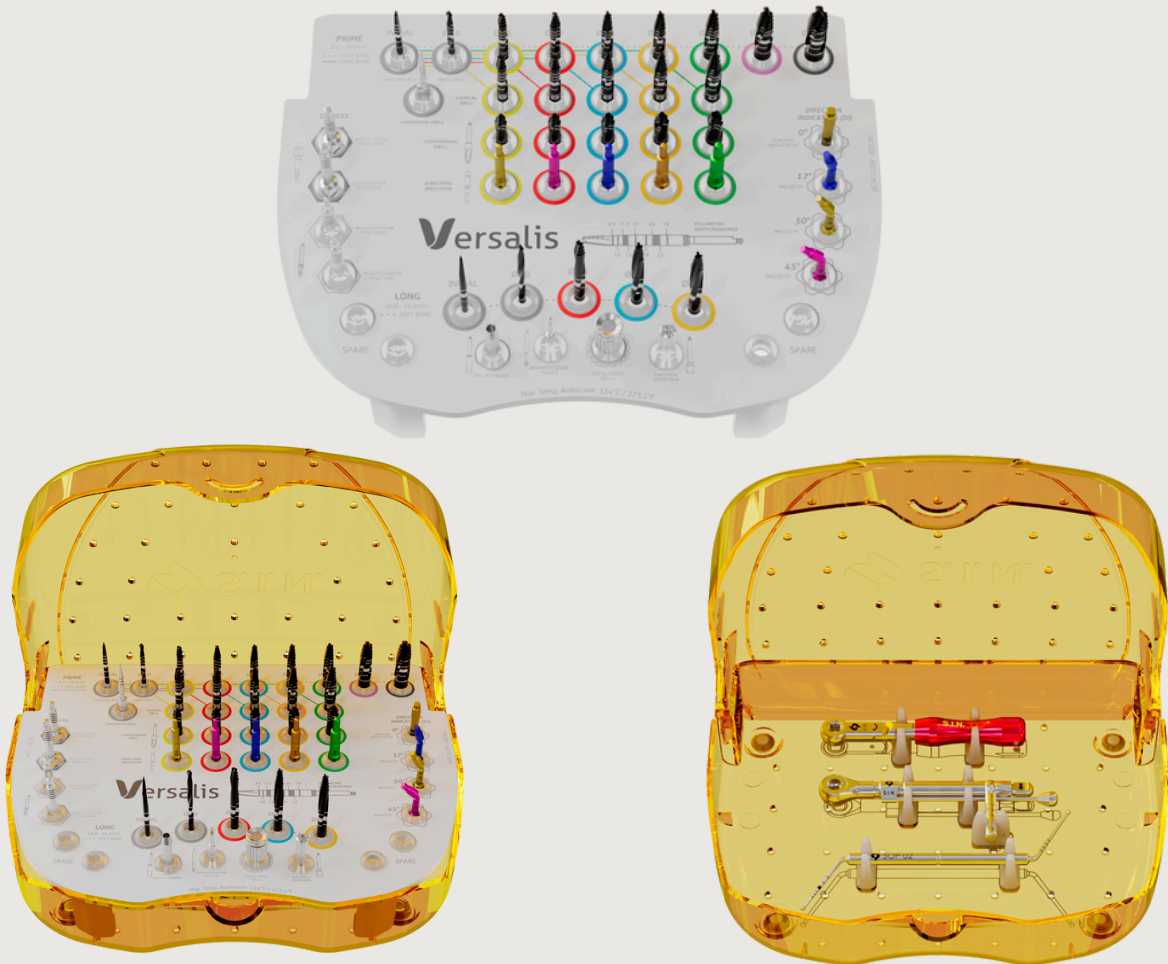
The center-to-center measurement of the osteotomy required to maintain a specific edge-to-edge spacing between two implants is calculated using the following formula:  
 $\frac{1}{2}$  (sum of the body diameters of the two implants) + desired spacing (suggested 3 mm between implants).

### ATTENTION

During implant placement, clinicians should apply their best judgment regarding the appropriate spacing based on the individual patient's conditions.

# 11. SURGICAL KIT AND DRILLING SEQUENCE

Before use, clean and sterilize the surgical tray and instruments according to the Instructions for Use. Study the surgical kit layout, which includes a direction indicator with precise millimeter markings for each diameter. Surgical assistants should be fully familiar with all instruments and their uses before starting the surgical procedure



Surgical Kit Versalis S - KCSV 01EN

The Versalis S surgical kit features a linear and intuitive layout that guides the surgeon through each drilling step.

The sequence begins at the upper left and progresses to the right, following the color-coded rows for each implant diameter. For every diameter, the kit includes drilling options for different bone densities (H for hard bone), ensuring clarity and efficiency during the procedure.

# DRILLING SEQUENCE VERSALIS S STANDARD

## SOFT BONE

	IMPLANT	Initial (FRL 20)	Lindemann (FRLI 01)	Helicoidal (FRH 20)	Ø3.5 (FRCV 35S)	Ø3.5 (FRCTV 35)	Ø3.8 (FRCV 38S)	Ø3.8 (FRCTV 38)	Ø4.0 (FRCV 40S)	Ø4.0 (FRCTV 40)	Ø4.3 (FRCV 43S)	Ø4.3 (FRCTV 43)	Ø5.0 (FRCV 50S)	Ø5.0 (FRCTV 50)	Ø6.0 (FRCV 60S)	Ø7.0 (FRCV 70S)
IVMT 35xx		●	●	●	●●											
IVMT 38xx		●	●	●	●		●●									
IVMT 40xx		●	●	●	●		●		●●							
IVMT 43xx		●	●	●	●		●		●	●●						
IVMT 50xx		●	●	●	●		●		●		●●					
IVMT 60xx		●	●	●	●		●		●		●		●●			
IVMT 70xx		●	●	●	●		●		●		●		●		●●	

● Optional   ● Optional in case of very soft bone   Initial Drill speed of 1200 rpm   Conical Drill speed of 800 rpm   Countersink Drill speed of 600 + 800 rpm

## HARD BONE

	IMPLANT	Initial (FRL 20)	Lindemann (FRLI 01)	Helicoidal (FRH 20)	Ø3.5 (FRCV 35H)	Ø3.5 (FRCTV 35)	Ø3.5 (FRCV 35S)	Ø3.8 (FRCV 38H)	Ø3.8 (FRCTV 38)	Ø3.8 (FRCV 38S)	Ø4.0 (FRCV 40H)	Ø4.0 (FRCTV 40)	Ø4.0 (FRCV 40S)	Ø4.3 (FRCV 43H)	Ø4.3 (FRCTV 43)	Ø4.3 (FRCV 43S)	Ø5.0 (FRCV 50H)	Ø5.0 (FRCTV 50)
IVMT 35xx		●	●	●	●	●												
IVMT 38xx		●	●	●					●									
IVMT 40xx		●	●	●							●		●					
IVMT 43xx		●	●	●								●		●	●			
IVMT 50xx		●	●	●								●				●		●

● Optional   Initial Drill speed of 1200 rpm   Conical Drill speed of 800 rpm   Countersink Drill speed of 600 + 800 rpm

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# DRILLING SEQUENCE VERSALIS S LONG

## BONE TYPES III AND IV

Ø DIAM. (mm)	Initial (FRLL 20)	Helicoidal (FRHL 20)	Ø3.8 (FRCVL 38)	Ø4.0 (FRCVL 40)	Ø4.3 (FRCVL 43)
Ø3.5	●	●	●●		
Ø3.8	●	●	●	●●	
Ø4.0	●	●	●	●	●●

● Optional   ● Optional in case of very soft bone   Initial Drill speed of 1200 rpm   Conical Drill speed of 800 rpm

## 12. DIRECTION INDICATOR



Used to assess the position and angle of the osteotomy. Supplied straight or angled at 17°, 30° and 45°.

Used after the lance or 2.0 mm helical drill.

Each subsequent drill has its own direction indicator compatible with its diameter.

## 13. DEPTH PROBE



Assess the depth of the drilling and the integrity of vital tissues and structures, assisting in the correct preparation of the surgical socket by checking the socket walls and identifying possible fenestrations.

The depth probe features two ends, one designed for standard-length implants and the other for extra-long implants, offering versatility and precision in a single instrument.

## 14. GENGIVAL HEIGHT MT 16°



Its purpose is to assist in the selection of the prosthetic component. The gauge is fitted onto the installed implant to verify the height of the mucosal or transmucosal profile.

Color coding (anodization) facilitates visualization and differentiation during the use of the component.

## 15. USE OF DRILLS ACCORDING TO BONE TYPE

The Versalis S kit features two clear visual guides: the dotted line for soft bone and the solid line for dense bone. Just follow the line that matches your case.

DLC (Diamond-Like Carbon) coating provides less bone heating, increased durability, high cutting efficiency, sharper angle, and improved visibility under surgical lights.

Drills with progressive taper following the implant's macrogeometry.

800 RPM.

## 16. VERSALIS S IMPLANT INSTALLATION KEYS

Contra-angle driver key used to carry and initiate implant placement into the prepared surgical socket; a ratchet key and surgical torque wrench may be used to complete the installation.

Versalis S Morse taper implant keys feature laser markings every 1 mm of depth.

On the surgical motor, use a maximum torque of 40 N.cm and rotation speed between 20–40 RPM.

Maximum installation torque of 80 N.cm must not be exceeded.

## 17. IMPLANT RETENTION

To remove the implant from its packaging, align the driver with the implant, ensure the driver is fully seated inside the implant, and press firmly to engage the O-ring inside the implant.

## 18. IMPLANT INSTALLATION

Insert the implant apex into the surgical socket and activate the contra-angle for rotation. Upon achieving initial stability, remove the contra-angle driver and begin using the ratchet key.

If there is excessive resistance during insertion, reverse the direction of the implant rotation to relieve pressure and reinsert it into the surgical socket. If high torque persists, remove the implant and revise the osteotomy using the next drill in the sequence.

It is recommended to use both hands when installing the implant. One hand should stabilize the head of the torque wrench, while the other hand installs the implant by turning the torque wrench clockwise, monitoring the torque.

## 19. POSTOPERATIVE INSTRUCTIONS

A healing period (4 to 6 months for Versalis S DAE implants, and 3 to 4 months for Versalis S Plus implants with HAnano surface) without loading is often recommended to allow integration between the bone and the implant surface. This depends on the individual healing rates and the bone quality at the implant site. Each case should be evaluated independently.

The patient should be instructed to follow a post-surgical regimen, at the surgeon's discretion, including cold compresses for 24 hours after implantation. The patient's diet should consist of soft foods. Pharmacological therapy should be considered according to the patient's systemic condition.

If a removable prosthesis is used during the initial healing phase, a soft reline material should be applied to prevent pressure on the surgical site. Relieve the prosthesis over the implant site before applying the soft reline. Periodically check the healing of the patient's soft tissue and bone using clinical and radiographic evaluations. Continuous hygiene is vital for patients rehabilitated with implants.

## 20. PACKAGING OPENING

- Remove the adhesive seal from the outer packaging and take out the inner tray containing the implant.
- Peel off the Tyvek label to expose the inner packaging that contains the implant.
- Remove the cap of the primary packaging exposing the implant.
- Using the appropriate installation driver for Morse Taper connection (CTMT 01C or CTMT 01L) attached to the contra-angle, engage the driver on the implant internal connexion.
- Transfer the implant to the prepared surgical site and begin insertion at low speed (approximately 20 RPM).
- If necessary, complete the installation using the surgical torque wrench (TMECC 02) connected to the manual driver (CCMT 01C or CCMT 01L).
- After implant placement, carefully remove the installation driver.
- For delayed loading procedures, place the Cover Screw using the 1.2 mm hexagonal driver (CDH 1224), and proceed with mucosal suturing.






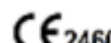

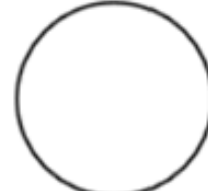

## 21. TRACEABILITY LABELS

Versalis S line implants provided by S.I.N. come with 3 (three) labels containing product information. The labels should be used as follows:

**Tax Documentation:** The dentist should reserve one label to attach to the implant's fiscal documentation.

**Medical Record:** The dentist should attach one label to the patient's record to maintain traceability of the products used.

**Implant Card:** The dentist should attach one label to the implant card to indicate which products were used.

<b>REF</b> XXXXX XXXXXX XXXXXX Reg. ANVISA: XXXXX	<b>LOT</b> XXXX  
<b>REF</b> XXXXX XXXXXXXX XXXXXXXX Reg. ANVISA: XXXXX	<b>LOT</b> XXXX  
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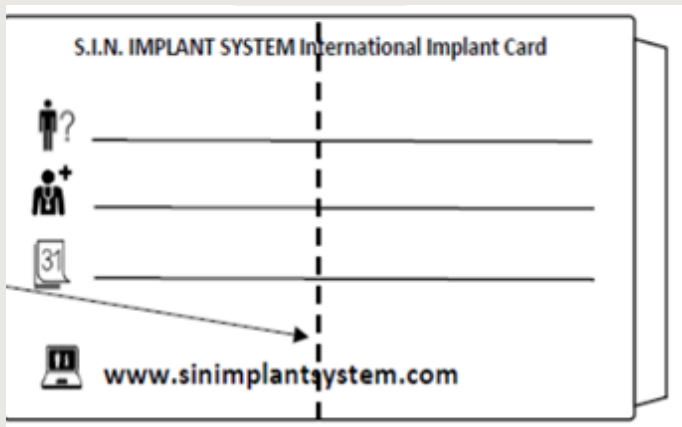
**TAX  
DOCUMENTATION**

**MEDICAL RECORD**

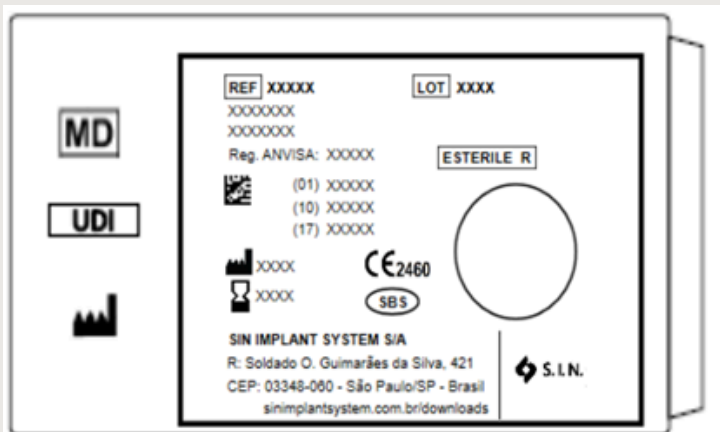
**IMPLANT CARD**

## 22. IMPLANT CARD

S.I.N. provides Versalis S line implants with an implant card. This card should be given to the patient, who should be instructed on how to store and maintain this information.



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## 23. MARKETING MATERIALS



Commercial Folder



Comparison with competitors



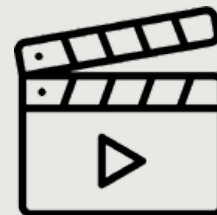
Presentation Slides



Technical Catalog



Surgical Manual



Animated Video Institutional



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