

**The Versalis S implants line is a quest to optimize the daily clinical practice, bringing a more sharper macrogeometry, facilitating engagement within the bone during the implant installation and achieving high primary stability.**



Caution: U.S. federal law restricts this device to sale by, or on the order of, a licensed dentist or physician.

## PRODUCT DESCRIPTION

Versalis S implants are manufactured from unalloyed titanium conforming to ASTM F67, Grade 4, and have a double acid etched surface treatment. Versalis S dental implants with lengths of 8.5, 10, 11.5, 13, 15, 18, 20, 22, or 24mm. Versalis S implants have a 16° Morse taper (MT) connection.

Provided STERILE. Sterilized by irradiation.

## DIMENSIONAL INFORMATION

The table below provides all dimensional information for the Versalis S Implant line.

Body Ø, mm	Platform Ø,mm	Lengths, mm
3.5	3.5	8.5, 10.0, 11.5, 13.0, 15.0, 18.0
3.8	3.8	8.5, 10.0, 11.5, 13.0, 15.0, 18.0, 20.0, 22.0, 24.0
4.0	4.0	8.5, 10.0, 11.5, 13.0, 15.0, 18.0, 20.0, 22.0, 24.0
4.3	4.3	8.5, 10.0, 11.5, 13.0, 15.0, 18.0, 20.0, 22.0, 24.0
5.0	5.0	8.5, 10.0, 11.5, 13.0, 15.0, 18.0
6.0	5.2	8.5, 10.0, 11.5, 13.0
7.0	6.1	8.5, 10.0, 11.5, 13.0

Versalis S implants are for conventional 1-stage and 2-stage surgical techniques and immediate loading.

## INDICATIONS FOR USE

S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the S.I.N. dental implants are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. S.I.N. Dental Implant System implants with lengths of 20, 22 or 24mm may be tilted up to 30°. When used in the maxilla with implants with lengths of 20, 22 or 24mm at an angulation of 30°, a minimum of four implants must be used and must be splinted. When placed in the maxilla with lengths of 20, 22 or 24mm at angulations

between 0° and less than 30°, the S.I.N. Dental Implant System implants are only indicated for multiple unit restoration in splinted applications that utilize at least two implants.

## CONTRAINDICATIONS

S.I.N. dental implants are contraindicated in the following conditions:

- Insufficient bone quality and quantity to provide implant stability in the upper or lower jaw
- Inadequate bone volume, unless a bone augmentation is planned during implantation.
- When the site or systemic conditions show inadequate or poor oral hygiene;
- Acute or chronic periodontal infection;
- Chemical dependence;
- Occlusal parafunction;
- Radiation history to the implant site;
- Inappropriate patient for prolonged or complicated oral surgery;
- Inability to build a functional prosthesis;
- Rehabilitation with dental implants is also contraindicated for children, pregnant women and during breastfeeding;

## WARNINGS

Versalis S Dental Implants are intended for axial (no angulation) placement or angled placement. The maximum angulation allowed is up to 30 degrees. The surgical technique of dental implant installation is highly specialized and the surgical procedure complex, it is recommended that the professionals be technically qualified so that the application of the S.I.N. implants is safe and efficient. Failure to recognize the actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures. In lower jaw surgery, drilling beyond the depth intended may potentially result in adverse reactions and safety hazards, such as permanent numbness to the lower lip and chin, or hemorrhage in the floor of the mouth. The longer length implants (i.e., implant lengths  $\geq 20$  mm) are not intended for any specialized surgical technique or anatomic placements outside of the alveolar arches. Product is for professional use only. Product is sterilized by gamma radiation. Sterility is ensured except in cases where the package has been violated or damaged. Do not use it if the package is damaged or after the expiration date. Single use only. Do not re-sterilize. The reuse or re-sterilization of this product can cause damage to health.

## PRECAUTIONS

Before implant installation, to obtain a predictable long-term outcome, the professional must submit the patient to a detailed and careful medical history, examination, radiographs, laboratory tests, and study models for appropriate planning to obtain a predictable long-term outcome. Careful clinical and radiological examinations must be performed before surgery to determine the psychological and physical status of the patient. Versalis S dental implants with lengths of 20, 22 or 24mm are intended for use only in situations that allow anatomical for these implant lengths. Implant placement in soft bone is a demanding and technique-sensitive procedure that requires special care. Methods to improve the clinical situation for implant placement in soft bone include, but are not limited to splinting in a multi-unit restoration, bi-cortical bone anchorage, and using longer implants lengths (if possible) to increase the bone-to-implant contact area. For Versalis S dental implants with lengths of 20, 22, or 24mm, at least 1mm of bone is recommended beyond the length of the implant chosen.

## ADVERSE EFFECTS

Loss of the implant and prosthesis is possible for several reasons, including implant contamination, inappropriate surgical technique, poor bone quality, inappropriate oral hygiene, and parafunctional habits (tooth-grinding).

## SURGICAL COMPLICATIONS

The implant installation surgical procedure may bring risks during and after the surgery, such as: pain, edema, hemorrhage, dehiscence, paresthesia, and infection.

## SHIPMENT AND HANDLING

The S.I.N. implants are sent to professionals duly packaged, sealed and sterilized. Therefore, the package must be opened using sterile technique and must be handled only with sterilized titanium instruments.

### ATTENTION

To obtain technical support or additional information material about the product, contact: S.I.N. Implant System LTDA. Contact details are provided at the end of these instructions.

## MRI SAFETY INFORMATION



### MR Conditional

Non-clinical testing and in vitro electromagnetic simulations demonstrated that the S.I.N. devices are MR Conditional.

Warning: The patient may only be imaged by landmarking at least 30 cm from the implant or ensuring the implant is located outside of the RF coil.

A patient with this device can be scanned safely in an MR system under the following conditions:

Device Name	S.I.N. Dental Implant System
Static Magnetic Field Strength ( $B_0$ )	$\leq 3.0$ T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the coil. Extremity T/R coils permitted. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark

Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF
Artifact	image artifact can extend up to approximately 12 mm, when imaged using a gradient-echo sequence and a 3 T MR system

## INSTRUCTIONS FOR USE

Note: during all drilling to shape the implant site, avoid deflecting the drill sideways, and use continuous, copious irrigation.

The implant's transfer from the package to insertion in the surgical site shall be carried out using drivers with counter-angle fittings. **Drivers with fittings for the torque wrench cannot transport the implant and should only use it for the final insertion torque.** Versalis S implants were designed for a maximum torque of 80 N.cm. Higher torques may cause irreversible damage to the implants and surgical complications. The torque for intermediate fixation for the multifunctional abutment is 32 N.cm, and for the cemented abutment, conical abutment, or multi-unit abutment on the implant, it is 20 N.cm. For angled mini abutment 17° and 30°, the torque for intermediate fixation is 20 N.cm on the implant. The torque for component fixation on the intermediaries is 10 N.cm. **Do not install the protection screw (cover screw) with the ratchet wrench or torque meter since this may damage the implant; tighten it manually with a digital driver.**

### Full Arch Restorations

Ideally, a full arch procedure should optimize immediate loading with implant placement at minimum torque, according to the literature, and well-established fixed rehabilitation. Once full treatment planning is done and approved, the surgery and the full arch concept can be executed.

### Upper Arch

Upper arch cases with high pattern of bone resorption can be resolved with four implants: two (2) anterior axial implants and two (2) posterior implants tilted 30°. By tilting the two posterior implants, the bone-to-implant contact is enhanced, providing bone support even with minimum bone volume. When distributing implants, the shape and size of the maxillary sinus and areas of lesser bone availability must be considered. Make an incision that allows full access to the alveolar ridge, followed by a full-thickness flap. In the case of dental extractions, careful curettage of the alveolus and the creation of a bone platform for implant placement are necessary. Smile line transition and lip support must also be considered. Two (2) to four (4) anterior implants in a palatal position should be placed axially, and two (2) posterior implants should be placed tilted up to 30°. By tilting the two posterior implants enhances bone-to-bone implant contact, providing optimized bone support even with minimum bone volume. Additionally, tilting the implant in the maxilla allows for improved anchorage in better-quality anterior bone. For immediate loading, primary implant stability of 45 N.cm is indicated. In extraction sites, the implant placement should be between extraction sockets. For all Versalis S implants (Morse taper), it is recommended that the implant be placed 1.5 mm intra-bony (sub-crestal). The Versalis S dental implants are intended for placement in all bone types (I, II, III and IV; Lekholm and Zarb classification), with the particularity of the standard implants with diameters of 6.0 and 7.0, and the long implants, which due to their specificity are intended exclusively for type III and IV bone.

The table below lists the components compatible with the Versalis S Implant line.

Code	Compatible component	510(k) Number
CIM 3502C – 3506C	Healing Cap	K170392
CIM 4502C – 4506C	Healing Cap	K170392

TIM 0212	Cover Screw	K170392
CPTM 3501-H – 3504-H	Temporary Cylinder	K170392
CPTM 4501-H – 4504-H	Temporary Cylinder	K170392
ACM 4801C – 4804C	Conical Abutment	K170392
AIMP 3501C-H – 3505C-H	Cemented Abutment	K170392
AIMP 4501C-H – 4505C-H	Cemented Abutment	K170392
ICMT 0504 - 0506	Interface Abutment	K193096
ICMT 2004 - 2006	Interface Abutment	K193096
MAM 3301 - 3304	Micro Mini Abutment	K170392
CPCM 0504 - 0508	Healing Cap PEEK	K200992
CPCM 0504I - 0508I	Healing Cap PEEK	K200992
AIM 33401C – 33405C	Cemented Abutment	K170392
AIM 33601C – 33605C	Cemented Abutment	K170392
AIM 45401C – 45405C	Cemented Abutment	K170392
AIM 45601C – 45605C	Cemented Abutment	K170392
ICM 0804	Interface Abutment	K193096
ICM 2004	Interface Abutment	K193096
MAM 4801C – 4804C	Mini Abutment	K170392
PT 16	Fixation Screw	K170392
AORM 4801C	Overdenture Abutment	K170392
EUCLAM 3501-H – 3504-H	CrCo Abutment	K170392
EUCLAM 4501-H – 4504-H	CrCo Abutment	F170392

The table below lists the components that are compatible exclusively with the long implants (20 mm – 24 mm) of the **Versalis S Implants** line.

Code	Compatible Component	510(k) Number
AAIM 331741C – 331743C	Angled Cemented Abutment	K200992
AAIM 331761C – 331763C	Angled Cemented Abutment	K200992
AAIM 451741C – 451743C	Angled Cemented Abutment	K200992
AAIM 451761C – 451763C	Angled Cemented Abutment	K200992
AIAM 3501C-H – 3505C-H	Angled Cemented Abutment	K200992
AIAM 4501C-H – 4505C-H	Angled Cemented Abutment	K200992
MAAM 4802 - 4804	Angled Mini Abutment	K200992
MAAM 4832 - 4834	Angled Mini Abutment	K200992
MAAM 4832I – 4834I	Angled Mini Abutment	K200992

### Versalis S Implants – Body Ø 3.5 mm

#### For bone type III and IV with length implants 8.5, 10, 11.5, 13, 15 and 18mm

The lance drill (FRL 20) penetrates the cortical bone at the surgical site at a maximum speed of 1200 RPM. Prepare the surgical site with the Ø2.0mm (FRH 20) Helical drill to the depth of the mark on the previously selected implant (800 -1200 RPM). Prepare the surgical site with the Ø3.5mm tapered Helical drill (FRCV 35S) to the depth of the mark on the previously selected implant (800 RPM).

### Versalis S Implants – Body Ø 3.8 mm

#### For bone type III and IV with length implants 8.5, 10, 11.5, 13, 15 and 18mm

The lance drill (FRL 20) penetrates the cortical bone at the surgical site at a maximum speed of 1200 RPM. Prepare the surgical site with the Ø2.0mm (FRH 20) Helical drill to the depth of the mark on the previously selected implant (800 -1200 RPM). Prepare the surgical site with the

Ø3.5mm tapered Helical drill (FRCV 35S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø3.8mm tapered Helical drill (FRCV 38S) to the depth of the mark on the previously selected implant (800 RPM). For this drilling process, if the bone is extra-soft, this step may be considered optional.

**For bone type III and IV with length implants 20, 22 and 24mm**

At the surgical site, penetrate the cortical bone with the Lance drill (FRL 20) at a maximum speed of 1200 RPM. Prepare the surgical site with the Ø2.0mm Helical drill (FRHL 20) to the depth of the mark on the previously selected implant at a maximum speed of 1200 RPM, followed by the conical drill Ø3.8mm (FRCVL 38) at 800 RPM.

1. Remove the adhesive part of the package and the inner tray containing the dental implant. Place the inner tray over a surgical tray or organizer.
2. Remove the Tyvek label and expose the implant.
3. With the drive for implant installation for Morse taper connection (CTMT 01C or CTMT 01L) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque wrench (TMECC 02) attached to the ratchet drive Morse connection (CCMT 01C or CCMT 01L).
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1224), and suture the gingiva.

**For single-stage or immediate loading, install the selected prosthetic components.**

**For bone Type I and Type II**

The lance drill (FRL 20) penetrates the cortical bone at the surgical site at a maximum speed of 1200 RPM. Prepare the surgical site with the Ø2.0mm (FRH 20) Helical drill to the depth of the mark on the previously selected implant (800 -1200 RPM). Prepare the surgical site with the Ø3.5mm tapered Helical drill (FRCV 35S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø3.8mm tapered Helical drill (FRCV 38H) to the depth of the mark on the previously selected implant (800 RPM). Prepare the cervical portion with a Ø3.8mm countersink drill (FRCTV 38) at 600-800 RPM.

1. Remove the adhesive part of the package and the inner tray containing the dental implant. Place the inner tray over a surgical tray or organizer.
2. Remove the Tyvek label and expose the implant.
3. With the drive for implant installation for Morse taper connection (CTMT 01C or CTMT 01L) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque wrench (TMECC 02) attached to the ratchet drive Morse connection (CCMT 01C or CCMT 01L).
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1224), and suture the gingiva.

**For single-stage or immediate loading, install the selected prosthetic components.**

**Versalis S Implants – Body Ø 4.0 mm**

**For bone type III and IV with length implants 8.5, 10, 11.5, 13, 15 and 18mm**



The lance drill (FRL 20) penetrates the cortical bone at the surgical site at a maximum speed of 1200 RPM. Prepare the surgical site with the Ø2.0mm (FRH 20) Helical drill to the depth of the mark on the previously selected implant (800 -1200 RPM). Prepare the surgical site with the Ø3.5mm tapered Helical drill (FRCV 35S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø3.8mm tapered Helical drill (FRCV 38S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø4.0mm tapered Helical drill (FRCV 40S) to the depth of the mark on the previously selected implant (800 RPM). For this drilling process, if the bone is extra-soft, this step may be considered optional.

#### **For bone type III and IV with length implants 20, 22 and 24mm**

At the surgical site, penetrate the cortical bone with the Lance drill (FRL 20) at a maximum speed of 1200 RPM. Prepare the surgical site with the Ø2.0mm Helical drill (FRHL 20) to the depth of the mark on the previously selected implant at a maximum speed of 1200 RPM, followed by the conical drill Ø3.8mm (FRCVL 38) at 800 RPM and the Ø4.0mm (FRCLV 40) at 800 RPM.

1. Remove the adhesive part of the package and the inner tray containing the dental implant. Place the inner tray over a surgical tray or organizer.
2. Remove the Tyvek label and expose the implant.
3. With the drive for implant installation for Morse taper connection (CTMT 01C or CTMT 01L) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque wrench (TMECC 02) attached to the ratchet drive Morse connection (CCMT 01C or CCMT 01L).
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1224), and suture the gingiva.

#### **For single-stage or immediate loading, install the selected prosthetic components**

##### **For bone Type I and II**

The lance drill (FRL 20) penetrates the cortical bone at the surgical site at a maximum speed of 1200 RPM. Prepare the surgical site with the Ø2.0mm (FRH 20) Helical drill to the depth of the mark on the previously selected implant (800 -1200 RPM). Prepare the surgical site with the Ø3.5mm tapered Helical drill (FRCV 35S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø3.8mm tapered Helical drill (FRCV 38S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø4.0mm tapered Helical drill (FRCV 40H) to the depth of the mark on the previously selected implant (800 RPM). Prepare the cervical portion with a Ø4.0mm countersink drill (FRCTV 40) at 600-800 RPM.

1. Remove the adhesive part of the package and the inner tray containing the dental implant. Place the inner tray over a surgical tray or organizer.
2. Remove the Tyvek label and expose the implant.
3. With the drive for implant installation for Morse taper connection (CTMT 01C or CTMT 01L) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque wrench (TMECC 02) attached to the ratchet drive Morse connection (CCMT 01C or CCMT 01L).
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1224), and suture the gingiva.

**For single-stage or immediate loading, install the selected prosthetic components.**

#### **Versalis S Implants – Body Ø 4.3 mm**

##### **For bone type III and IV with length implants 8.5, 10, 11.5, 13, 15 and 18mm**

The lance drill (FRL 20) penetrates the cortical bone at the surgical site at a maximum speed of 1200 RPM. Prepare the surgical site with the Ø2.0mm (FRH 20) Helical drill to the depth of the mark on the previously selected implant (800 -1200 RPM). Prepare the surgical site with the Ø3.5mm tapered Helical drill (FRCV 35S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø3.8mm tapered Helical drill (FRCV 38S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø4.0mm tapered Helical drill (FRCV 40S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø4.3mm tapered Helical drill (FRCV 43S) to the depth of the mark on the previously selected implant (800 RPM). For this drilling process, if the bone is extra-soft, this step may be considered optional.

##### **For bone type III and IV with length implants 20, 22 and 24mm**

At the surgical site, penetrate the cortical bone with the Lance drill (FRL 20) at a maximum speed of 1200 RPM. Prepare the surgical site with the Ø2.0mm Helical drill (FRHL 20) to the depth of the mark on the previously selected implant at a maximum speed of 1200 RPM, followed by the conical drill Ø3.8mm (FRCVL 38) at 800 RPM, followed by the Ø4.0mm (FRCLV 40) at 800 RPM and after, the Ø4.3mm (FRCVL 43) at 800 RPM.

1. Remove the adhesive part of the package and the inner tray containing the dental implant. Place the inner tray over a surgical tray or organizer.
2. Remove the Tyvek label and expose the implant.
3. With the drive for implant installation for Morse taper connection (CTMT 01C or CTMT 01L) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque wrench (TMECC 02) attached to the ratchet drive Morse connection (CCMT 01C or CCMT 01L).
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1224), and suture the gingiva.

**For single-stage or immediate loading, install the selected prosthetic components.**

##### **For bone Type I and II**

The lance drill (FRL 20) penetrates the cortical bone at the surgical site at a maximum speed of 1200 RPM. Prepare the surgical site with the Ø2.0mm (FRH 20) Helical drill to the depth of the mark on the previously selected implant (800 -1200 RPM). Prepare the surgical site with the Ø3.5mm tapered Helical drill (FRCV 35S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø3.8mm tapered Helical drill (FRCV 38S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø4.0mm tapered Helical drill (FRCV 40S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø4.3mm tapered Helical drill (FRCV 43H) to the depth of the mark on the previously selected implant (800 RPM). Prepare the cervical portion with a Ø4.3mm countersink drill (FRCTV 43) at 600-800 RPM.

1. Remove the adhesive part of the package and the inner tray containing the dental implant. Place the inner tray over a surgical tray or organizer.
2. Remove the Tyvek label and expose the implant.



3. With the drive for implant installation for Morse taper connection (CTMT 01C or CTMT 01L) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque wrench (TMECC 02) attached to the ratchet drive Morse connection (CCMT 01C or CCMT 01L).
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1224), and suture the gingiva.

**For single-stage or immediate loading, install the selected prosthetic components.**

### **Versalis S Implants – Body Ø 5.0 mm**

#### **For bone type III and IV with length implants 8.5, 10, 11.5, 13, 15 and 18mm**

The lance drill (FRL 20) penetrates the cortical bone at the surgical site at a maximum speed of 1200 RPM. Prepare the surgical site with the Ø2.0mm (FRH 20) Helical drill to the depth of the mark on the previously selected implant (800 -1200 RPM). Prepare the surgical site with the Ø3.5mm tapered Helical drill (FRCV 35S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø3.8mm tapered Helical drill (FRCV 38S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø4.0mm tapered Helical drill (FRCV 40S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø4.3mm tapered Helical drill (FRCV 43S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø5.0mm tapered Helical drill (FRCV 50S) to the depth of the mark on the previously selected implant (800 RPM). For this drilling process, if the bone is extra-soft, this step may be considered optional.

#### **For bone Type I and II**

The lance drill (FRL 20) penetrates the cortical bone at the surgical site at a maximum speed of 1200 RPM. Prepare the surgical site with the Ø2.0mm (FRH 20) Helical drill to the depth of the mark on the previously selected implant (800 -1200 RPM). Prepare the surgical site with the Ø3.5mm tapered Helical drill (FRCV 35S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø3.8mm tapered Helical drill (FRCV 38S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø4.0mm tapered Helical drill (FRCV 40S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø4.3mm tapered Helical drill (FRCV 43S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø5.0mm tapered Helical drill (FRCV 50H) to the depth of the mark on the previously selected implant (800 RPM). Prepare the cervical portion with a Ø5.0mm countersink drill (FRCTV 50) at 600-800 RPM.

1. Remove the adhesive part of the package and the inner tray containing the dental implant. Place the inner tray over a surgical tray or organizer.
2. Remove the Tyvek label and expose the implant.
3. With the drive for implant installation for Morse taper connection (CTMT 01C or CTMT 01L) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque wrench (TMECC 02) attached to the ratchet drive Morse connection (CCMT 01C or CCMT 01L).
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1224), and suture the gingiva.

**For single-stage or immediate loading, install the selected prosthetic components.**

#### **Versalis S Implants – Body Ø 6.0 mm**

##### **For bone type III and IV**

The lance drill (FRL 20) penetrates the cortical bone at the surgical site at a maximum speed of 1200 RPM. Prepare the surgical site with the Ø2.0mm (FRH 20) Helical drill to the depth of the mark on the previously selected implant (800 -1200 RPM). Prepare the surgical site with the Ø3.5mm tapered Helical drill (FRCV 35S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø3.8mm tapered Helical drill (FRCV 38S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø4.0mm tapered Helical drill (FRCV 40S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø4.3mm tapered Helical drill (FRCV 43S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø5.0mm tapered Helical drill (FRCV 50S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø6.0mm tapered Helical drill (FRCV 60S) to the depth of the mark on the previously selected implant (800 RPM). For this drilling process, if the bone is extra-soft, this step may be considered optional.

1. Remove the adhesive part of the package and the inner tray containing the dental implant. Place the inner tray over a surgical tray or organizer.
2. Remove the Tyvek label and expose the implant.
3. With the drive for implant installation for Morse taper connection (CTMT 01C or CTMT 01L) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque wrench (TMECC 02) attached to the ratchet drive Morse connection (CCMT 01C or CCMT 01L).
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1224), and suture the gingiva.

**For single-stage or immediate loading, install the selected prosthetic components.**

#### **Versalis S Implants – Body Ø 7.0 mm**

##### **For bone type III and IV**

The lance drill (FRL 20) penetrates the cortical bone at the surgical site at a maximum speed of 1200 RPM. Prepare the surgical site with the Ø2.0mm (FRH 20) Helical drill to the depth of the mark on the previously selected implant (800 -1200 RPM). Prepare the surgical site with the Ø3.5mm tapered Helical drill (FRCV 35S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø3.8mm tapered Helical drill (FRCV 38S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø4.0mm tapered Helical drill (FRCV 40S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø4.3mm tapered Helical drill (FRCV 43S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø5.0mm tapered Helical drill (FRCV 50S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø6.0mm tapered Helical drill (FRCV 60S) to the depth of the mark on the previously selected implant (800 RPM). Prepare the surgical site with the Ø7.0mm tapered Helical drill (FRCV 70S) to the depth of the mark on the previously selected implant (800 RPM). For this drilling process, if the bone is extra-soft, this step may be considered optional.












1. Remove the adhesive part of the package and the inner tray containing the dental implant. Place the inner tray over a surgical tray or organizer.
2. Remove the Tyvek label and expose the implant.
3. With the drive for implant installation for Morse taper connection (CTMT 01C or CTMT 01L) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque wrench (TMECC 02) attached to the ratchet drive Morse connection (CCMT 01C or CCMT 01L).
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1224), and suture the gingiva.





**For single-stage or immediate loading, install the selected prosthetic components.**

**For all implants in the Versalis line, the maximum insertion torque is 80 N·cm, ensuring complete safety for both the implants and the installation drivers.**

### Symbols Glossary

ANSI/AAMI/ ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.

Symbol	Title of Symbol (Reference Number)	Meaning of Symbol
	Caution (5.4.4)	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Keep away from sunlight (5.3.2)	Indicates a medical device that needs protection from light sources.
	Upper limit of temperature (5.3.6)	Indicates the upper limit of temperature to which the medical device can be safely exposed.
	Sterilized using irradiation (5.2.4)	It indicates a medical device that has been sterilized using irradiation.
	Keep dry (5.3.4)	Indicates a medical device that needs to be protected from moisture.
	Do not use it if package damaged (5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened.
	Do not reuse (5.4.2)	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Do not re-sterilize (5.2.6)	Indicates a medical device that is not to be re-sterilized.
	Consult instructions for use (5.4.3)	Indicates the need for the user to consult the instructions for use.
	Use-by date (5.1.4)	Indicates the date after which the medical device is not to be used.
	Date of manufacture (5.1.3)	Indicates the date when the medical device was manufactured

	Manufacturer (5.1.1)	Indicates the medical device manufacturer.
	Catalogue number (5.1.6)	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Batch code (5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	MR Conditional (n/a)	Conditions under which a medical device can safely enter the MR environment

**CAUTION: Federal law restricts this device to sale by or on the order of a licensed dentist or physician.**

**MANUFACTURED BY****S.I.N. Implant System LTDA.**

CNPJ [Corporate Taxpayer's Registry]: 04.298.106/0001-74

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**PRODUCT**

Versalis S Implant

**FDA CLEARENCE 510k**

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