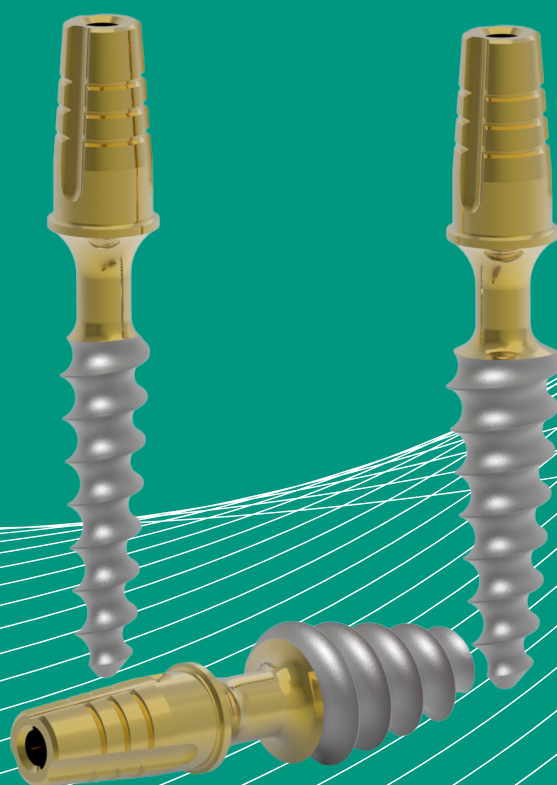


SANATSMILE

HELIX-D

BASIC SURGICAL INFORMATION

ONE-PIECE IMPLANT SYSTEM –
SURGICAL TECHNIQUE AND TECHNICAL HANDLING INFORMATION



SCOPE OF THIS DOCUMENT

This document provides basic information on the surgical use of the Sanatmetal Helix-D one-piece dental implant system. The indications, contraindications, sterile packaging requirements and reprocessing requirements must always be interpreted in conjunction with the current instructions for use.

Instructions for use: ifu.sanatmetal.hu

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1. SYSTEM OVERVIEW

The Sanatmetal Helix-D is a one-piece, tissue-level dental implant system with an integrated prosthetic component. The system is designed for the treatment of narrow edentulous alveolar ridges and to support immediate treatment protocols, provided that an insertion torque of at least 25 Ncm can be achieved for each implant.

The implants are manufactured from biocompatible, high-purity titanium and feature a treated endosseous surface. The product range is available in endosseous diameters of Ø3.3–4.7 mm and lengths of 8–16 mm, while the Ø5.5 mm version is available in lengths of 8–14 mm in the current portfolio.

1.1 KEY DESIGN FEATURES

- One-piece implant with an integrated prosthetic component – no separate implant–abutment connection.
- Compression thread geometry to support primary stability.
- Dual-tapered implant body with a narrowing apical region.
- Polished transmucosal neck surface.
- Neck design adapted to the implant diameter.
- The neck of the Ø3.3 mm version can be angulated by up to 15° to establish the final prosthetic axis.



1.2 CLINICAL APPLICATION CONCEPT

The main applications of the Helix-D system are implant-assisted stabilisation of complete removable dentures and a straightforward, direct prosthetic workflow enabled by its one-piece design. The narrow implant diameters also allow use in narrow alveolar ridges, subject to careful assessment of the anatomical conditions and available bone.

2. PREOPERATIVE PLANNING

Following patient selection and clinical and radiographic assessment, the number and positions of the implants to be placed must be determined, taking into account the available bone volume, mucosal thickness and planned prosthetic treatment.

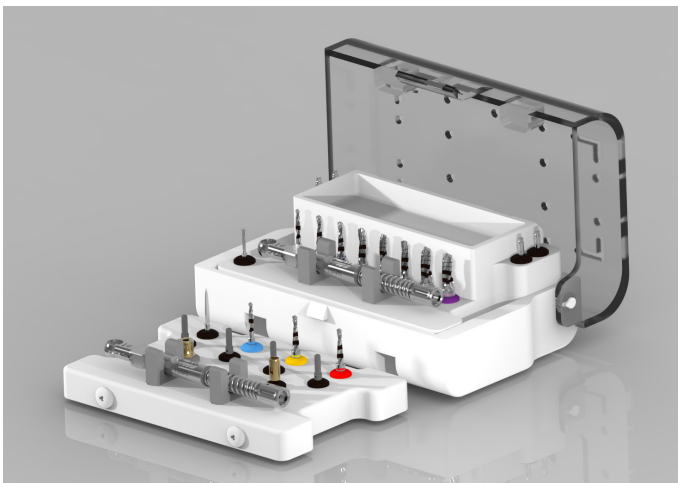
- At least 4 Helix-D implants must be used to stabilise a complete mandibular denture.
- At least 6 Helix-D implants must be used to stabilise a complete maxillary denture.
- A minimum distance of 5 mm must be maintained between implants.
- Whenever possible, the implants should be evenly distributed along the jaw arch to reduce cantilever effects and improve load distribution.
- In the mandible, the positions of the mental foramen and the inferior alveolar nerve must be taken into account. A minimum distance of 7 mm anterior to the mental foramen must be maintained.
- In the maxilla, the implant length must be selected to avoid injury to the nasal cavity and maxillary sinus.

2.1 RADIOGRAPHIC PLANNING

The available vertical bone height determines the maximum implant length that can be placed. A radiographic reference template and a reference sphere may be used to estimate the magnification factor. When three-dimensional imaging is used, the implant position can be determined within the available anatomical space in accordance with the planned prosthetic restoration.

3. SURGICAL INSTRUMENT SET

Helix-D instruments feature depth markings at 2 mm intervals to facilitate depth control in relation to the implant lengths. The system includes a dedicated Parallel guide, Driver for ratchet, Driver for handpiece and Torque wrench.



3.1 PARALLEL GUIDE

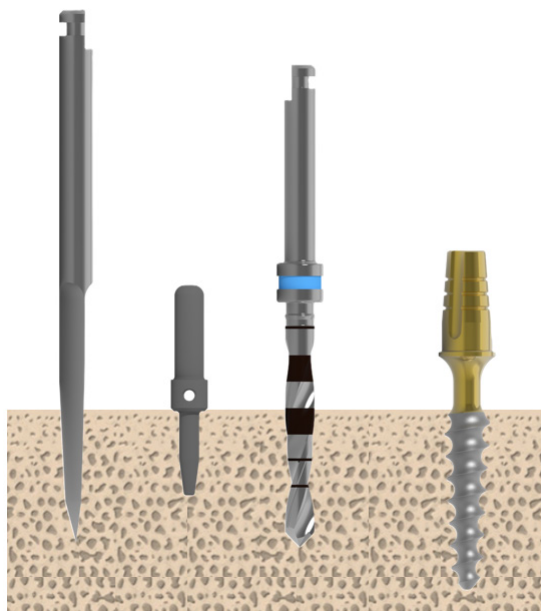
The 492096070 Parallel guide facilitates checking axial alignment and establishing parallel alignment of multiple implants during implant bed preparation. The central portion of the instrument indicates the height of the machined supragingival portion of the implant.

3.2 INSERTION INSTRUMENTS AND TORQUE CONTROL

A special adapter is required for the insertion of Helix-D implants. The implants can be inserted using the Driver for handpiece or manually using the Driver for ratchet. A Torque wrench with a range of 10–70 Ncm is available for final torque control.

ITEM CODE	DESCRIPTION	SIZE	QTY
492096069	Needle drill	–	1
492096020	Initial twist drill	2x16 mm	1
492096229	Final drill	2.9x16 mm	1
492096232	Final drill	3.2x16 mm	1
492096235	Final drill	3.55x16 mm	1
492096240	Final drill	4x16 mm	1
492096062	Driver for ratchet	–	1
492096064	Driver for handpiece	–	1
492096070	Parallel guide	–	4
1000701 / 929990432	Torque wrench	10–70 Ncm	1
492086012	Sanat Smile drill kit	–	1

4. SURGICAL WORKFLOW



4.1 STEP 1 – MARKING THE IMPLANT SITE

After planning the implant position, mark the selected insertion site with the Needle drill.

4.2 STEP 2 – MANAGEMENT OF A NARROW ALVEOLAR RIDGE

If the ridge is too narrow, the bone surface may need to be levelled using a round bur before using the Needle drill. In such cases, a conventional surgical approach with flap elevation is required.

4.3 STEP 3 – INITIAL DRILLING

Begin every procedure with the Needle drill and pre-drill to a depth equal to the length of the implant. In cases of reduced vertical bone height, radiographic verification is recommended at this stage to protect the basal portion of the mandible.

4.4 STEP 4 – CHECKING AXIAL ALIGNMENT

Use the Ø1.9 mm end of the Parallel guide to check the implant axis. When placing multiple implants, the Parallel guide may be left in position as a reference during preparation of the next osteotomy.

4.5 STEP 5 – IMPLANT BED PREPARATION

The implant bed must be prepared according to the nominal diameter and length of the implant and the bone quality. Preparation always begins with the Needle drill, followed by the additional drills specified in the table. Owing to the compression thread geometry, the osteotomy is undersized to support primary stability.

IMPLANT Ø	SOFT BONE	NORMAL BONE	HARD BONE
Ø3.3	Implant placement is not recommended	Needle drill	Needle drill
Ø3.75	Implant placement is not recommended	Needle drill, Ø2.2	Needle drill, Ø2.2, Ø2.9
Ø4.2	Implant placement is not recommended	Needle drill, Ø2.2, (Ø2.9)	Needle drill, Ø2.2, Ø2.9, (Ø3.2)
Ø4.7	Needle drill	Needle drill, Ø2.2, Ø2.9, (Ø3.2)	Needle drill, Ø2.2, Ø2.9, Ø3.2, (Ø3.55)
Ø5.5	Needle drill, (Ø2.2)	Needle drill, Ø2.2, Ø2.9, Ø3.2, (Ø3.55), (Ø4)	Needle drill, Ø2.2, Ø2.9, Ø3.2, Ø3.55, Ø4

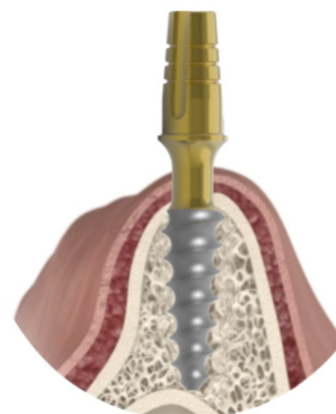
Note: The drill diameters shown in parentheses are to be used only for implants with a length of 16 mm.

4.6 STEP 6 – IMPLANT PLACEMENT

Helix-D implants are supplied in sterile packaging. When opening the sterile pack, ensure that the packaging unit containing the implant is securely positioned on a sterile surgical tray. Distribute the implants evenly, maintaining a minimum interimplant distance of 5 mm.

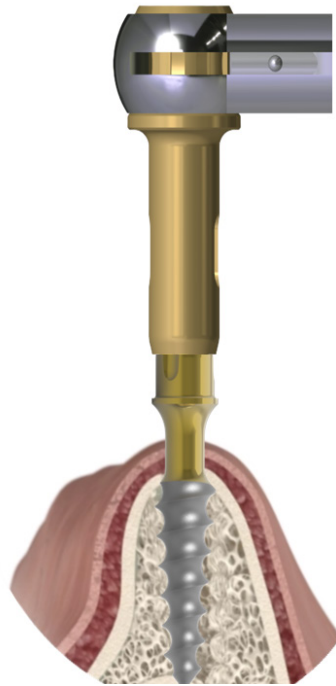
4.7 STEP 7 – FINAL POSITIONING

The Helix-D implant can be screwed clockwise into its final position using the Driver for handpiece or manually using the Driver for ratchet. The maximum recommended insertion speed is 15 rpm. The final position is correct when the entire treated endosseous surface is embedded in bone.



4.8 NECK ANGULATION ADJUSTMENT

The neck of the Ø3.3 mm Helix-D version can be angulated by up to 15° to adjust the prosthetic axis. Adjustment must be performed in a controlled manner using the instruments specified for the system.



5. COMPLETE DENTURE STABILISATION

5.1 MANDIBULAR DENTURE STABILISATION

At least 4 Helix-D implants must be placed to stabilise a complete mandibular denture. Particular attention must be paid to the inferior alveolar nerve and the sublingual artery when planning the procedure. It is advisable to begin placement with the most distal implant, positioned at least 7 mm anterior to the mental foramen.

5.2 MAXILLARY DENTURE STABILISATION

At least 6 Helix-D implants must be placed to stabilise a complete maxillary denture. The available vertical bone height and the positions of the nasal cavity and maxillary sinus must be assessed during planning.

6. PROSTHETIC WORKFLOW

The one-piece design of Helix-D enables a direct prosthetic workflow. The appropriate Impression post can be used for closed-tray impression taking, and a compatible Laboratory analogue is available for laboratory procedures.

- The appropriate Impression post must be used for closed-tray impression taking.
- A Laboratory analogue matching the Impression post is available for the dental laboratory.
- The definitive crown can be cement-retained.

ITEM CODE	DESCRIPTION	SIZE
492096067	Impression post	-
492096068	Laboratory analogue	-
492096071	Impression post - conical	-
492096072	Laboratory analogue - conical	-

7. PRODUCT LIST

7.1 IMPLANT RANGE

ITEM CODE	DESCRIPTION	SIZE
492023308	Helix-D dental root	3.3x8 mm
492023310	Helix-D dental root	3.3x10 mm
492023312	Helix-D dental root	3.3x12 mm
492023314	Helix-D dental root	3.3x14 mm
492023316	Helix-D dental root	3.3x16 mm
492023708	Helix-D dental root	3.75x8 mm
492023710	Helix-D dental root	3.75x10 mm
492023712	Helix-D dental root	3.75x12 mm
492023714	Helix-D dental root	3.75x14 mm
492023716	Helix-D dental root	3.75x16 mm
492024208	Helix-D dental root	4.2x8 mm
492024210	Helix-D dental root	4.2x10 mm
492024212	Helix-D dental root	4.2x12 mm
492024214	Helix-D dental root	4.2x14 mm
492024216	Helix-D dental root	4.2x16 mm
492024708	Helix-D dental root	4.7x8 mm
492024710	Helix-D dental root	4.7x10 mm
492024712	Helix-D dental root	4.7x12 mm
492024714	Helix-D dental root	4.7x14 mm
492024716	Helix-D dental root	4.7x16 mm
492025508	Helix-D dental root	5.5x8 mm
492025510	Helix-D dental root	5.5x10 mm
492025512	Helix-D dental root	5.5x12 mm
492025514	Helix-D dental root	5.5x14 mm

7.2 INSTRUMENTS AND FULLY EQUIPPED TRAY

ITEM CODE	DESCRIPTION	SIZE	QTY
492096069	Needle drill	-	1
492096020	Initial twist drill	2x16 mm	1
492096229	Final drill	2.9x16 mm	1
492096232	Final drill	3.2x16 mm	1
492096235	Final drill	3.55x16 mm	1
492096240	Final drill	4x16 mm	1
492096062	Driver for ratchet	-	1
492096064	Driver for handpiece	-	1
492096070	Parallel guide	-	4
1000701 / 929990432	Torque wrench	10-70 Ncm	1
492086012	Sanat Smile drill kit	-	1

8. DOCUMENTATION AND SAFETY INFORMATION

This basic surgical information does not replace the current instructions for use supplied with the product. For indications, contraindications, warnings, sterilisation/reprocessing information and limitations of use, the information provided on the label and in the instructions for use shall always take precedence.

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