

OSSTEM[®]
IMPLANT

Surgical Manual

Smart Guide KIT

Introduction

Welcome,

and thank you for choosing Osstem Implant products. This catalogue is designed to support dental professionals with product information, clinical workflows, and practical guidance for daily use. It is important to inform patients about the option of dental implant treatment and the potential benefits it may provide. For further information, please contact your local Osstem representative.

Important Notice

This document is provided for **informational and educational purposes only** and does not replace the applicable product label, the current product-specific Instructions for Use (IFU), formal clinical training, or independent professional judgment. All product information, specifications, and protocols are subject to change without notice. Not all products may be approved, cleared, released, licensed, or available in all markets. Product illustrations are not shown to scale. Despite careful preparation of this catalogue, typographical, editorial, translation, or printing errors may occur. **All critical information must be verified against the current product-specific IFU and product label before use.**

Electronic IFU (per (EU) 2021/2226)

- Surgical Drill & KIT System is eligible for provision of electronic instructions for use (e-IFU) under Regulation (EU) 2021/2226 for professional users.
- e-IFUs are available at [website URL: ifu.osstem.com] in the official languages required by the Member State(s) where the device is placed on the market.
- The e-IFU content is consistent with the paper version; all updates are promptly reflected in both versions.
- If requested, a paper copy of the IFU will be supplied free of charge, within 7 calendar days.
- The e-IFU website maintains historical versions for traceability of all previously applicable instructions.
- Labeling on the product/package indicates the provision of e-IFU and how to access it online.

Surgical Manual | English Edition

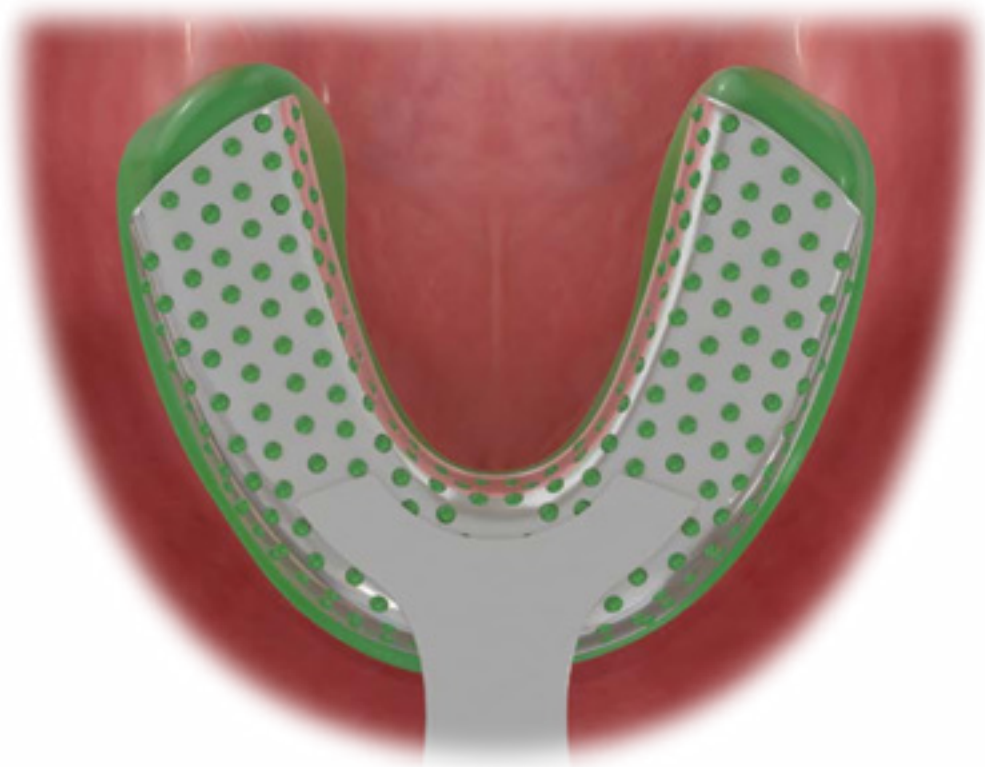
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Radlická 740/113c
158 00 Prague, Czech Republic

Note: *This brochure is based on the global 2021 Osstem Surgical Manual and has been visually revised and adapted for the European market. Product availability and specifications may vary by country and are subject to change without notice. Images are for illustrative purposes only. For professional use only.*

Smart Guide KIT

**KIT for fabricating a surgical stent without using a CT
(impression required only)**

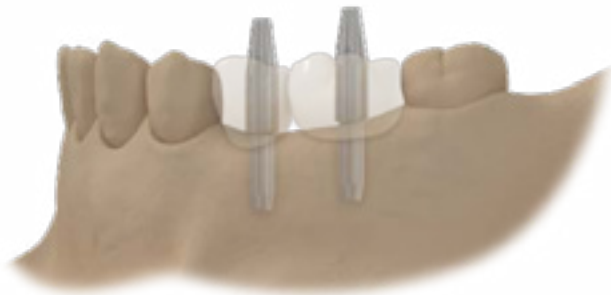


1 Indication

A When you wish to place implant in correct position



B When you wish to place implant in correct direction



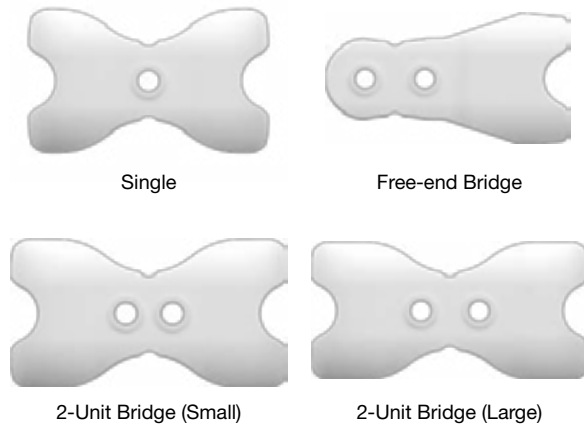
C When you wish to place an implant without a CT



2 Features

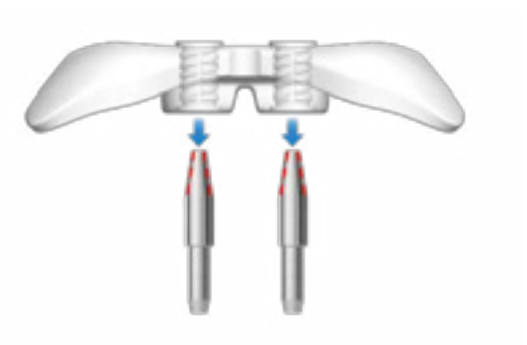
A 3D Pre-Formed Design

- SmartGuide are templates that are pre-molded in three dimensional shapes in order to make fabrication of Guides for various cases easier



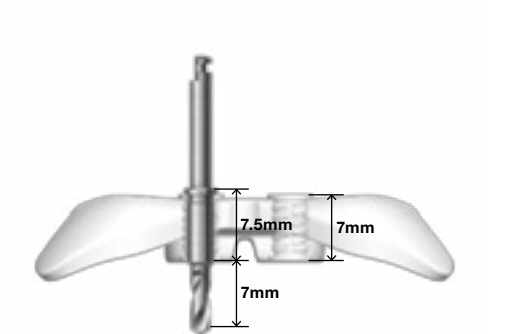
B Automatic spacing of the SmartGuide

- When the SmartGuide is connected with the the guide pins, the spacing between the two holes get automatically adjusted gap is automatically adjusted up to 1mm, thanks to its tapered shape.



C Sufficient sleeve length

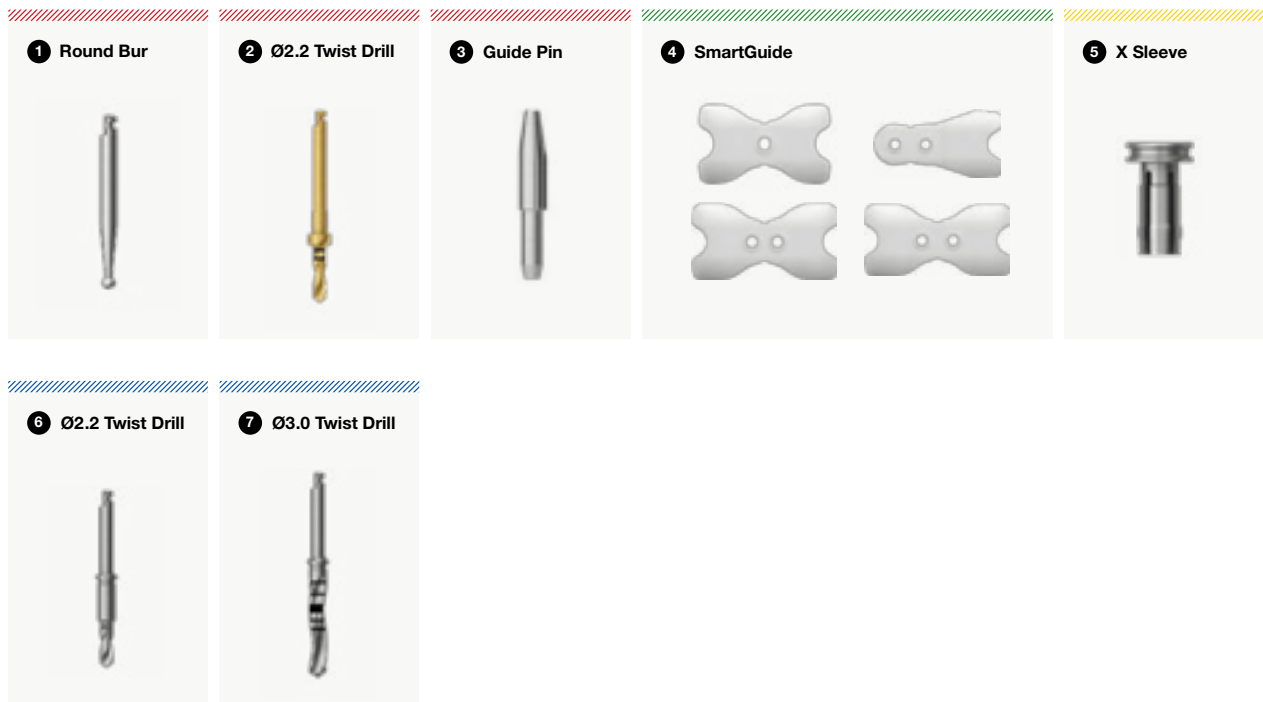
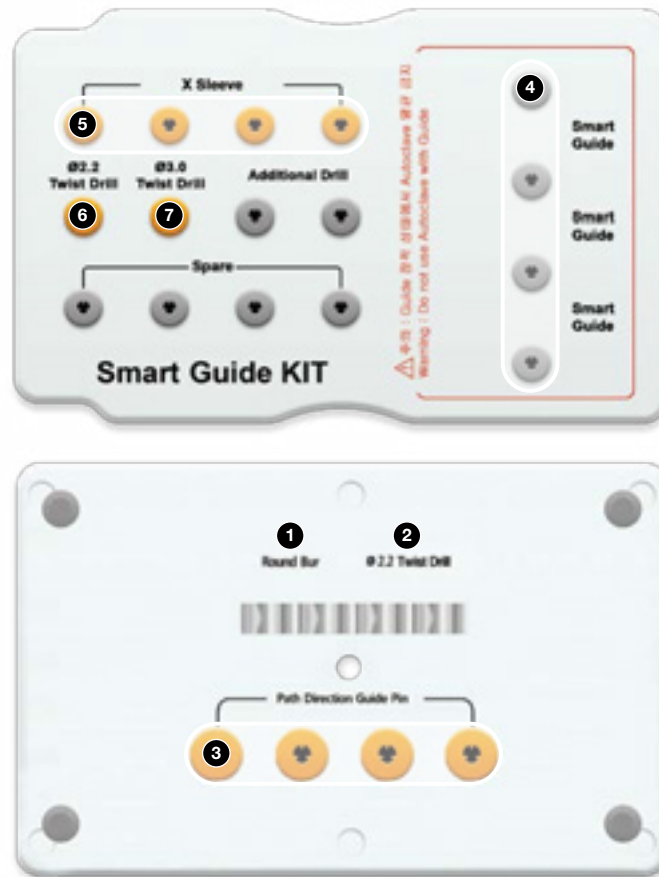
- Thanks to its long sleeves, accurate drilling path can be maintained during drilling.



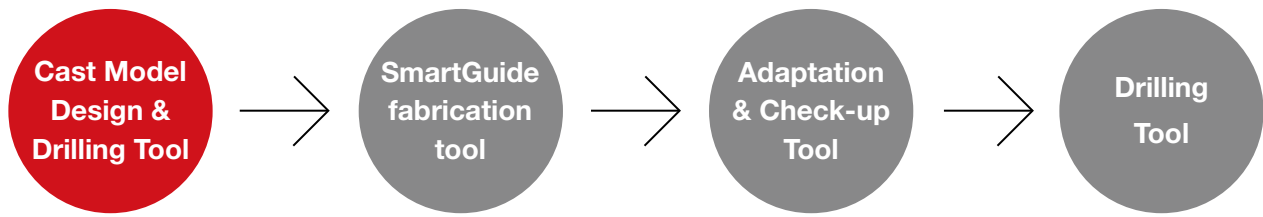
3 Tools of KIT

Positioning Guide Full KIT

- ▨ Cast Model Design & Drilling Tool (1-3)
- ▨ SmartGuide Fabrication Tool (4)
- ▨ Adaptation & Check-up Tool (5)
- ▨ Drilling Tool (6, 7)



4 User guide for KIT



Includes a tool that can drill on the plaster model and check the implantation path.



1 Round bur

2 Ø2.2 twist drill (for plaster model)

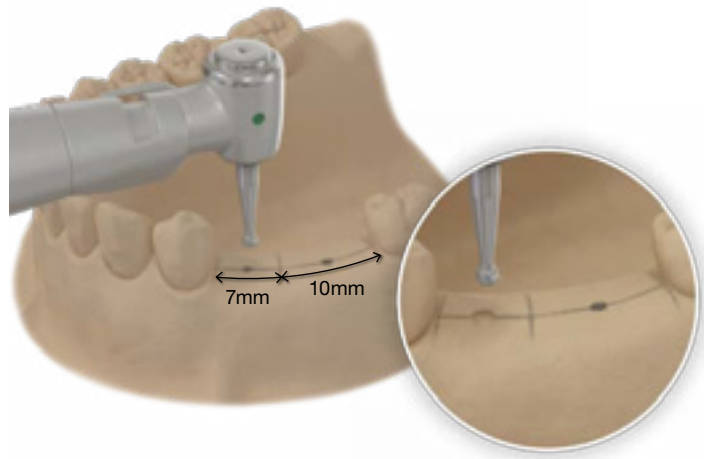
3 Guide Pin

1 Round bur

Used for marking on plaster model.

User guide

- Check the toothless region on the plaster model.
- Connect the round bur to the handpiece.
- Drill at 800 to 1,200 rpm with the round bur to mark the placement position, which is the center of the tooth-missing area.

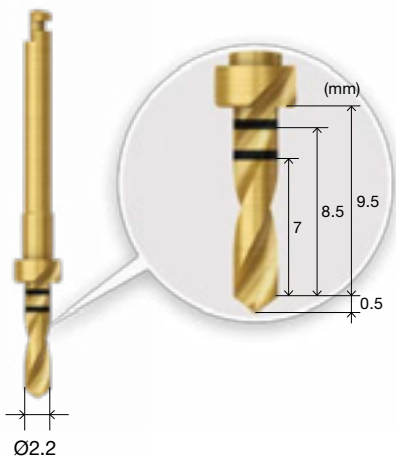
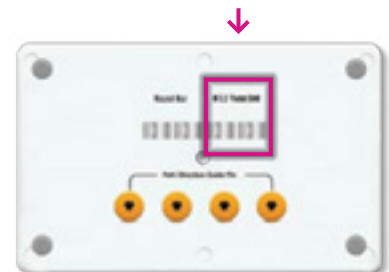


2 Ø2.2 Twist drill (for plaster model)

Used for additional drilling after using the round bur.

User guide

- Connect the Ø2.2 Twist drill to the handpiece.
- Drilling is additionally performed at the speed of 800~1,200rpm at the position marked with a round bur on the plaster model.

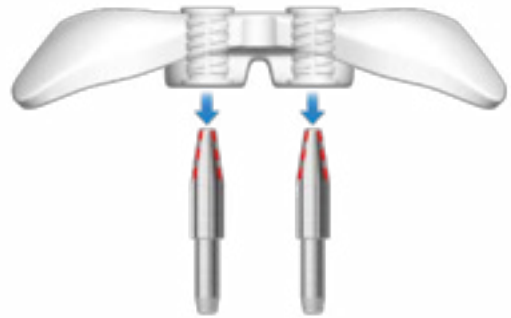
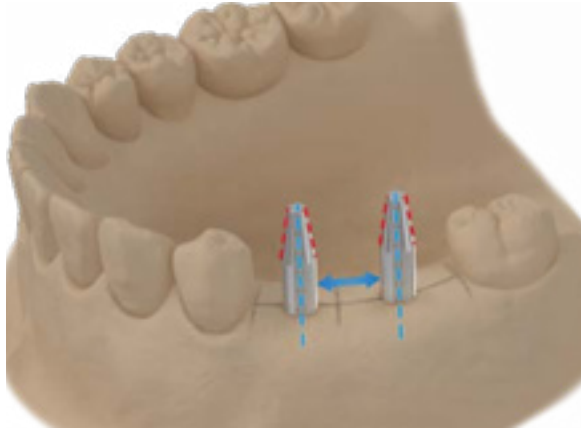


3 Guide Pin

Confirm the path by placing it in the hole on plaster model.

User guide

- Place the Guide Pin inside the drill holes in a way that the narrower part fits into the holes that were forms with the Ø2.2 twist drill.





Able to choose different Smart guides depending on the teeth missing area.



Single



Free-end Bridge



2-Unit Bridge (Small)



2-Unit Bridge (Large)

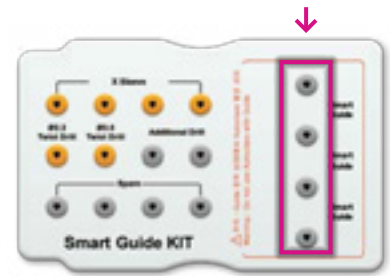
4 SmartGuide

4 SmartGuide

Can be freely shaped in hot water at 75°C, and the fabrication time can be reduced thanks to its 3D pre-formed design.

User guide

- Select the SmartGuide that matches best the location of the missing teeth.
- Immerse the selected SmartGuide in water at 75°C for approx. 1 minute.
- When the color of the SmartGuide becomes transparent, take it out of the water.
- Place the transparent SmartGuide on the guide pins that are placed in the plaster model.
- Mold the Smart guide according to the shape of adjacent teeth.
- Wait until the color changes to opaque white.





Includes a tool to check whether the SmartGuide formed on plaster model fits well in the oral cavity.



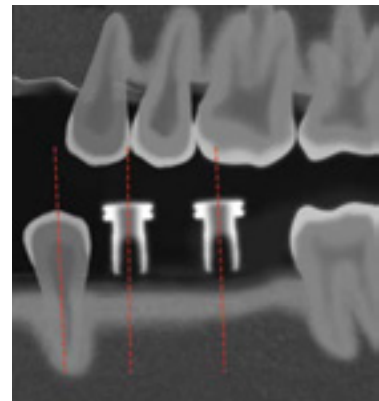
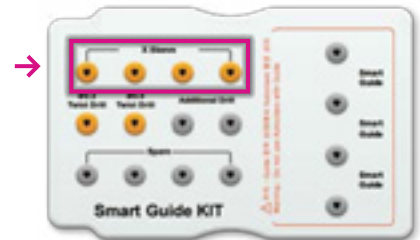
5 X Sleeve

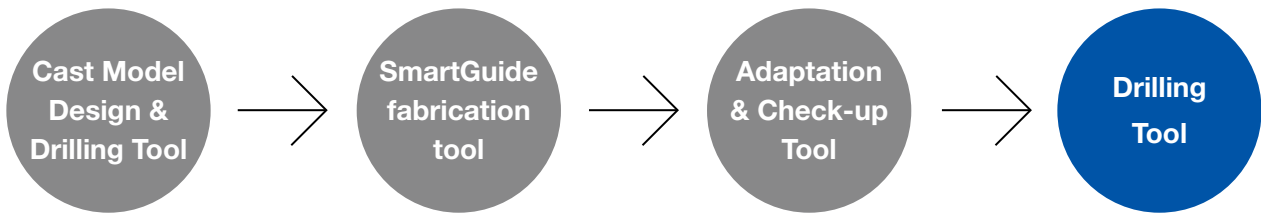
5 X Sleeve

Used for checking the path of the SmartGuide

User guide

- Place the SmartGuide, which was made on the plaster model, in the oral cavity.
- Place the X sleeve into the SmartGuide sleeves.
- Take an X-ray.
- Check whether the path is aligned with the adjacent teeth and whether the X sleeve is in correct relation with the antagonist tooth.
- If the position or path is inappropriate, start over from the first process which is model design.





There are tools for Initial drilling and middle drilling that can be used when the SmartGuide is placed in the mouth in order to place implants



6 Ø2.2 Twist Drill

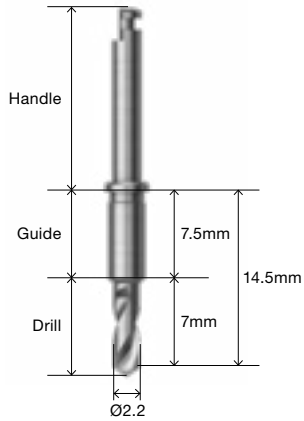
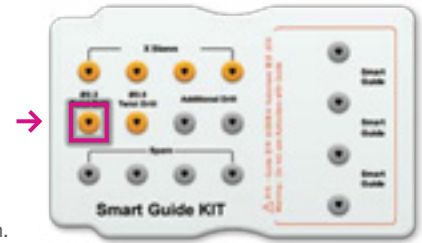
7 Ø3.0 Twist Drill

6 Ø2.2 Twist Drill

Drill used for drilling in the oral cavity with the guidance of the SmartGuide

User guide

- Remove the check up bush and connect the Ø2.2 Twist Drill to the handpiece.
- Drill through the SmartGuide hole with a Ø2.2 Twist Drill at a speed of 800~1,200rpm.

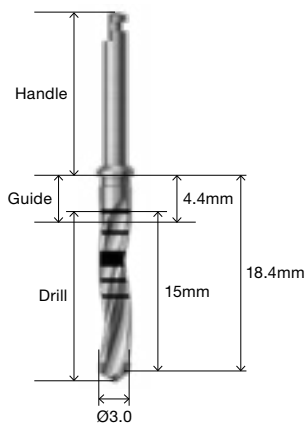
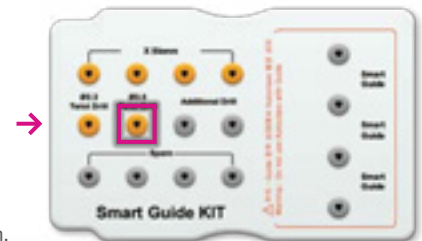


7 Ø3.0 Twist Drill

Drill used after drilling with Ø2.2 twist drill in the oral cavity.

User guide

- Connect the Ø3.0 Twist drill to the handpiece.
- Drill through the SmartGuide hole with a Ø3.0 Twist Drill at a speed of 800~1,200rpm.



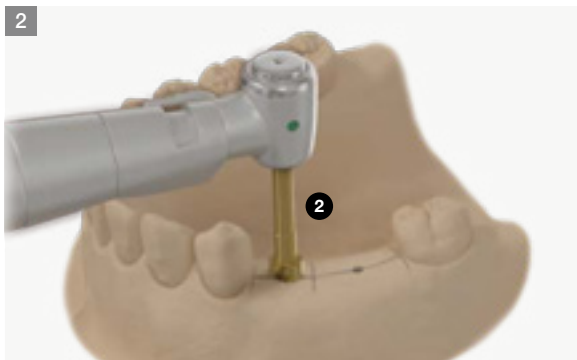
5 KIT sequence

Multiple case | #35, 36

N: Tool number



Select implant placement position on the working model



Drilling: #35, 36 (Round bur / Ø2.2 twist drill)

- Drill with a round bur and Ø2.2 twist drill on #35 and 36 of the working model
- Recommended RPM: 800~1,200rpm



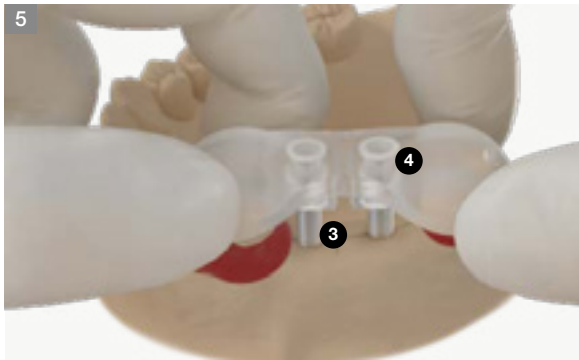
Select SmartGuide specification (Guide pin)

- Check the path by placing the guide pins into the drill holes. Then, select the appropriate SmartGuide's specification.



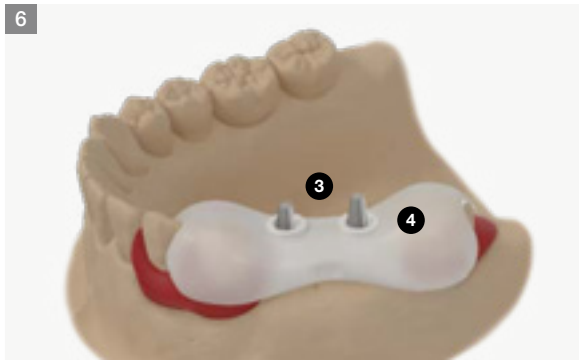
Immerse SmartGuide

- Immerse the selected SmartGuide in water at 75°C for approx. 1 minute.
- When the color of the SmartGuide becomes transparent, take it out of the water.



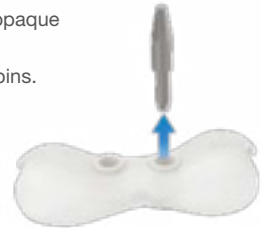
Mold SmartGuide

- Place transparent SmartGuide on the guide pins in the oral cavity.
- Mold according to the shape of adjacent teeth.
- Remove UnderCut with Wax.



Cure and finish SmartGuide

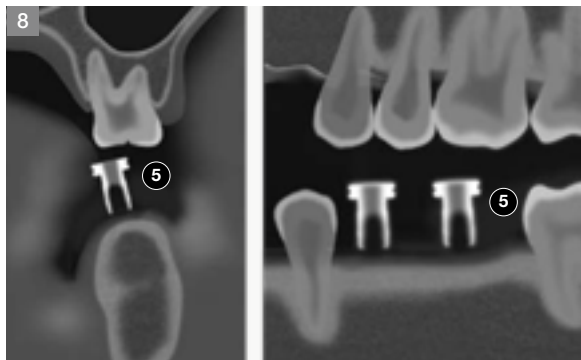
- Let the SmartGuide harden for approx. 1 minute with the SmartGuide placed in mouth
- When the color changes to an opaque white color, curing is complete.
- After curing, remove the guide pins.



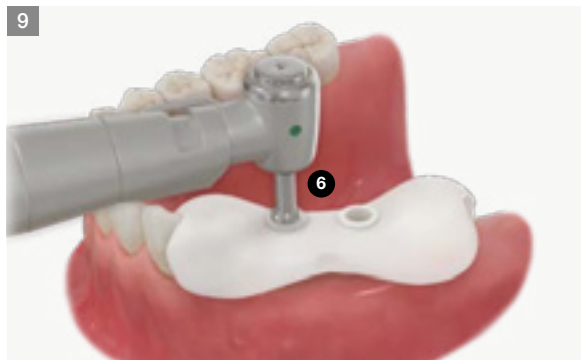
Place SmartGuide in the mouth

- Disinfect the Smart Guide at low temperature (hexamidine, alcohol)
- After placing the SmartGuide in the mouth, check the fit.
- Take the SmartGuide out of the oral cavity, fasten the X sleeve, and re-place it in the oral cavity.
- The X sleeve must be placed outside the oral cavity.





Check position and direction
(X-ray / CT)



Initial drilling: #35, 36 (Ø2.2 twist drill)

- Remove the X sleeve, then drill with a Ø2.2 twist drill at positions #35 and 36
- Recommended RPM: 800~1,200rpm



Drilling: #35, 36 (Ø3.0 twist drill)

- Recommended RPM: 800~1,200rpm

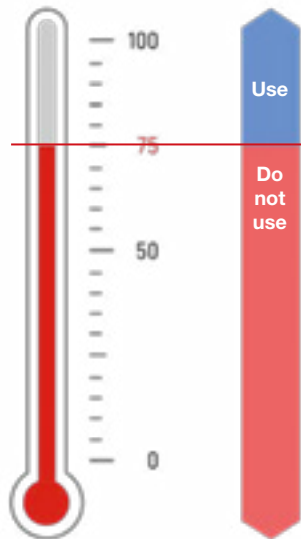


Final drilling

- Remove the SmartGuide, then perform final drilling according to the specifications of the implant to be placed.
- Then, follow ordinary implant procedure.



Water purifier hot water instructions



Min. 75°C

Use hot water when the hot water indicator is showing the maximum temperature

Under 75°C

Dispensing hot water can lower the temperature. Wait until maximum temperature is restored (min. 10 minute)

How to take care of the KITS

1



Soak (saline/distilled water)

- Soak the surgical instruments in saline or distilled water

2



Drying (remove moisture)

- Completely dry all drills, drivers, tools, etc by using a towel or fan.

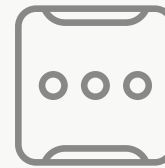
3



First wash

- After surgery, immediately separate and wash all the used instruments.

4



Organize instruments in the KIT

- Place the completely dried instruments in the KIT
- Make sure they are properly placed in the correct location
- Refer to the color coding for reference

5



Second wash

- Thoroughly wash with distilled water or running water to avoid remnants of blood or foreign debris.

6



Sterilization and storage at room temperature

- Wrap clean kit in a sterilization wrap or pouch and place into sterilizer.
- Sterilize temperature - 121°C to 132°C, time duration 15 - 30 minutes, dried and stored at room temperature.
- KIT re-sterilization is recommended immediately before surgery.
- Before and after sterilization, thoroughly dry (the drills will corrode if not fully dried after sterilization)

Important Information and Legal Notices 2026.03 ver.1.1

1. IMPORTANT NOTICE

This catalogue is intended solely as an informational and educational guide for trained dental professionals. It does not replace the applicable Instructions for Use (IFU), product labelling, formal clinical training, treatment planning, or independent professional judgment.

All clinical protocols, drilling sequences, cleaning instructions, sterilization requirements, torque recommendations, indications, contraindications, warnings, and procedural steps must be verified against the current product-specific IFU and the applicable product label for the relevant REF/product code prior to use.

In the event of any discrepancy between this catalogue and the applicable IFU, product labelling, or other official Osstem documentation, the IFU, labelling, and official product documentation shall prevail.

2. PRODUCT INFORMATION, CHANGES, AND AVAILABILITY

All products, specifications, protocols, recommendations, illustrations, and other information contained in this catalogue are subject to change without prior notice.

Not all products may be approved, cleared, released, licensed, or otherwise available in all markets. Product availability, indications, and regulatory status may vary by country. For information on the current product portfolio, approved indications, and local availability, please contact your local Osstem representative or Customer Service and consult the current official Osstem documentation.

3. PROFESSIONAL USE ONLY

Osstem Implant products are intended for use by appropriately trained dental professionals only. Dental implant treatment involves complex professional procedures and requires appropriate education, clinical training, patient selection, treatment planning, and radiographic as well as clinical evaluation.

The suitability of any procedure must be assessed individually for each patient, taking into account anatomy, bone quality and quantity, occlusion, systemic conditions, oral hygiene, compliance, and any other relevant clinical factors.

4. PRODUCT DESCRIPTION AND COMPATIBILITY

Osstem Implant offers implant fixtures, prosthetic components, surgical instruments, and related materials for dental implant treatment. Product codes, specifications, lot numbers, dates of manufacture, and expiration dates, where applicable, must be checked on the product label before use.

Unless expressly stated otherwise in the applicable product documentation, Osstem Implant abutments, prosthetic components, instruments, and related accessories are intended to be used only with compatible Osstem Implant fixtures and components. Use in combination with components or instruments from other manufacturers may result in improper fit, incomplete locking, loosening, fracture, reduced performance, or other clinical complications.

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Sterile products supplied in sterile packaging must be used only if the packaging is intact and the expiration date has not passed. If sterile packaging has been opened, damaged, or has expired, the product must not be used.

Single-use products must not be reused, reprocessed, or resterilized.

Reusable instruments must be cleaned, disinfected, inspected, maintained, and sterilized strictly in accordance with the applicable Osstem IFU before reuse.

Products must be stored in accordance with the applicable labelled

storage conditions and protected from moisture, contamination, direct sunlight, and other adverse environmental conditions.

6. CLINICAL PROTOCOLS AND PROCEDURAL GUIDANCE

Any surgical, prosthetic, drilling, insertion, loading, cleaning, maintenance, or other procedural guidance shown in this catalogue is provided for general informational purposes only and must be adapted to the individual patient, the specific product, and the current approved IFU.

Clinicians remain solely responsible for selecting the appropriate treatment protocol and for determining whether the intended procedure, component selection, loading protocol, and clinical application are appropriate for the individual case and within the approved indications for the relevant product.

7. WARNINGS, CONTRAINDICATIONS, AND POSSIBLE COMPLICATIONS

Improper patient selection, inadequate treatment planning, non-compliance with the applicable IFU, improper use, off-label use, product modification, poor oral hygiene, infection, insufficient bone quality or quantity, excessive occlusal loading, or other unfavorable clinical conditions may result in complications or treatment failure.

Possible complications and adverse events may include, without limitation, implant instability or failure, loosening, fracture, bone loss, infection, soft- or hard-tissue complications, prosthetic complications, delayed healing, or the need for revision or removal.

Contraindications and precautions must always be assessed in accordance with the applicable Osstem product documentation and accepted professional standards of care.

8. INTENDED PURPOSE

The products are tools and instruments for surgical placement of Osstem implant fixtures. The drill is used to make implant sites. The cortical drill and tap removes cortical bones or forms threads on bone for the purpose of preventing excessive torque generated when implanting a fixture on hard bone. The drivers are for the placement of the fixture, and the prosthesis is used for setting. In addition, other instruments and tools will be used as aids in the implant procedure.

The applicable product-specific IFU must always be consulted to confirm the intended purpose, indications, limitations, and approved clinical applications of the relevant product.

9. ACCURACY OF INFORMATION

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No representation is made that this catalogue is complete, current, or error-free in every respect. Users must verify all critical information against the current IFU, product labels, and other official Osstem documentation before clinical use.

10. ILLUSTRATIONS AND EXAMPLES

Product illustrations, diagrams, radiographic examples, case images, and step-by-step demonstrations are for illustrative purposes only. Unless expressly stated otherwise, they are not shown to scale and do not guarantee any clinical outcome.

Example cases do not constitute a promise or representation of treatment success in any individual case.

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