OSSTEM IMPLANT

Surgical Manual

OneCAS 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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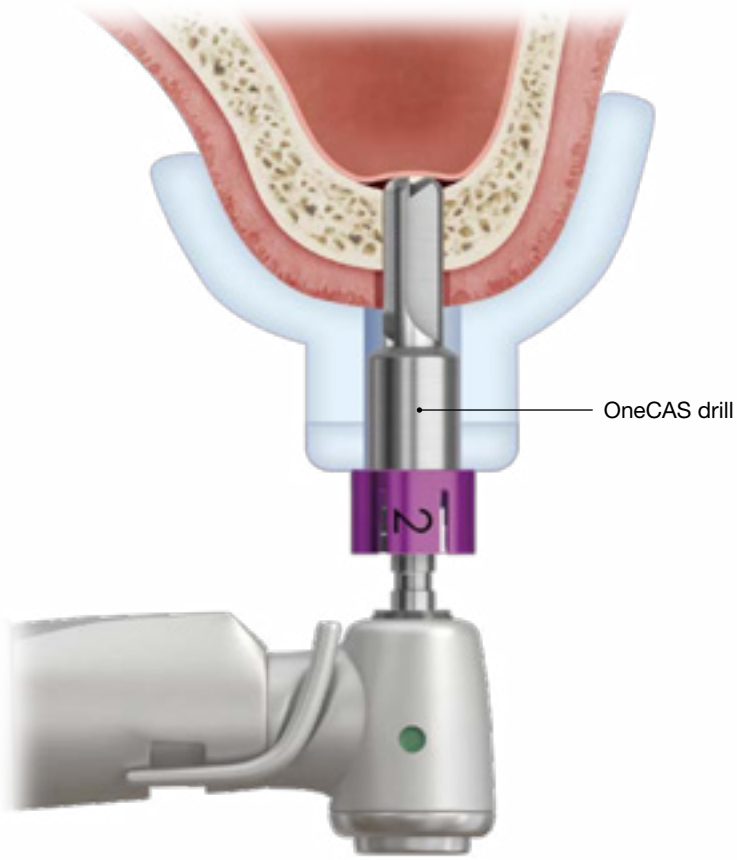
158 00 Prague, Czech Republic

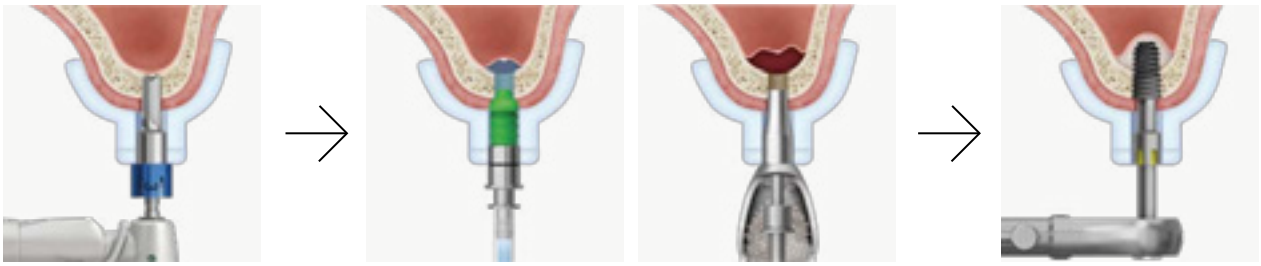
Note: *This brochure is based on the global 2021 Osstem Surgical Manual and has been visually revised and adapted for the European market. Product availability and specifications may vary by country and are subject to change without notice. Images are for illustrative purposes only. For professional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

OneCAS KIT

KIT for Digital Guided Surgery with OneGuide in maxillary Sinus Surgery cases



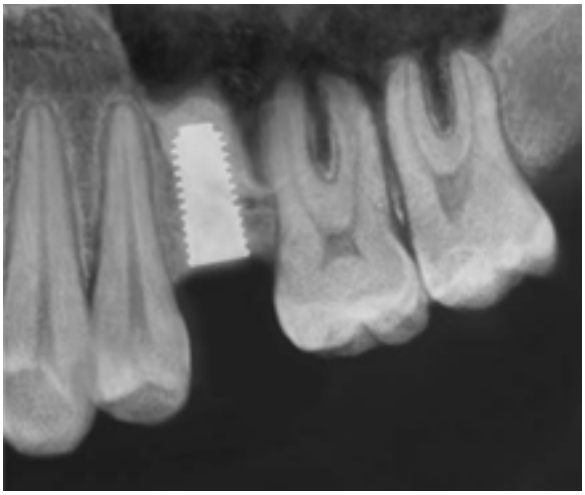
Possible to drill and placement implants after placing the OneGuide template



Drilling | Hydraulic lift | GBR | Implant placement

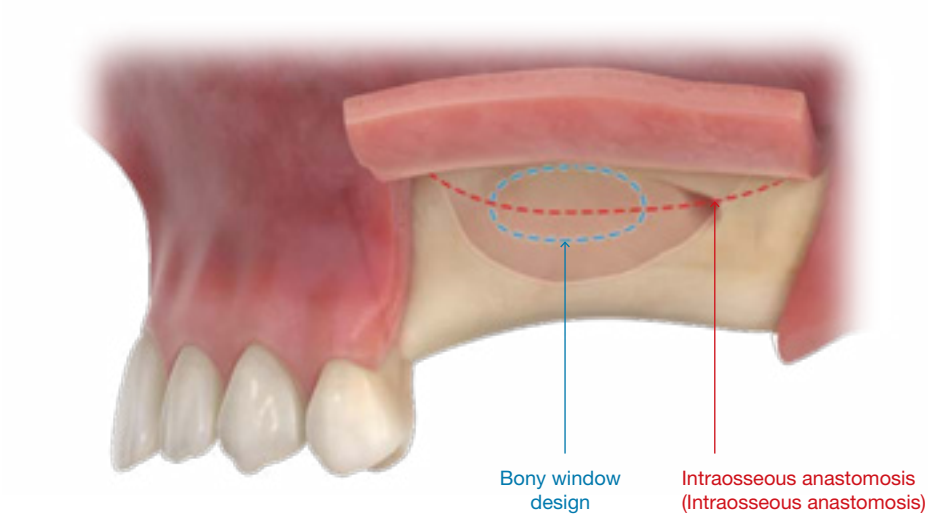
1 Indication

A When you wish to place implant at the correct position, angle and depth



B When there is an intraosseous anastomosis in the lateral wall

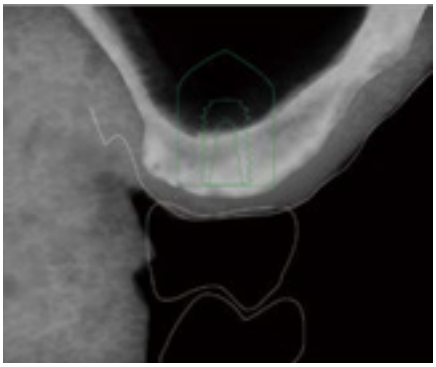
· When lateral access is not possible due to the presence of an intraosseous anastomosis in the lateral wall.



2 Feature

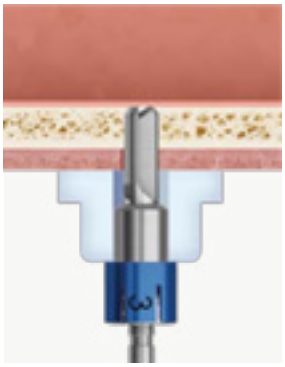
A Perform maxillary sinus surgery with pre-planned implant position

· ·Pre-plan the implant position and specifications in the maxillary sinus using CT data and surface data.



Design

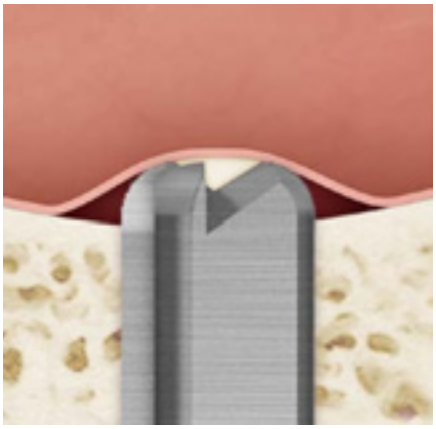
Template fabrication



Surgery

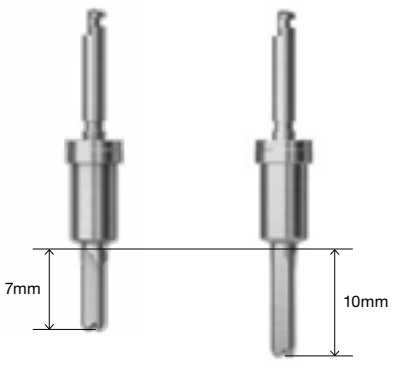
B OneCAS Drill enables sinus lifting without perforation of the maxillary sinus membrane

· The tip of the OneCAS Drill has a round shape, which prevent membrane perforation.



C Easy surgery

· Drilling depth can be adjusted with stoppers that come in 1mm increments.
· 2 length types of drills (7mm, 10mm) can be used in cases where 2~10mm of residual bone is present.

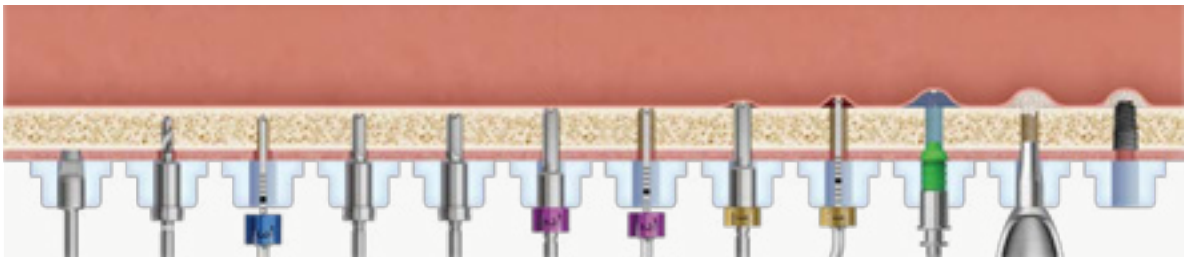


OneCAS KIT surgical procedure (recommendations)

Select drill for each surgery procedure

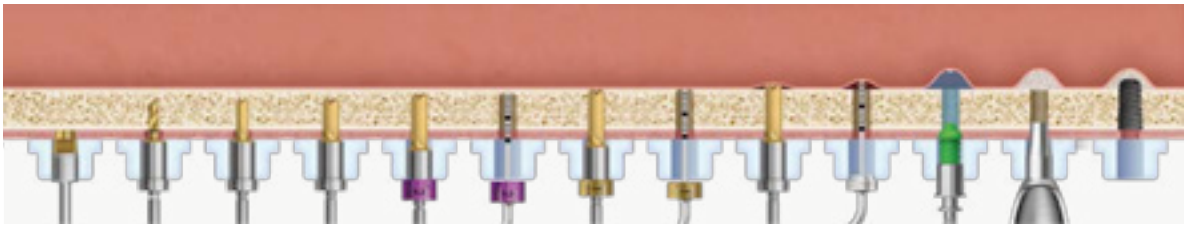
Implant		Initial	OneCAS Drill						Drilling count
		Ø2.2	Ø2.8	Ø3.1	Ø3.3	Ø3.6	Ø3.8	Ø4.1	
Diameter	Bone quality		Soft	Normal	Soft	Normal	Soft	Normal	
F Ø4.0	Soft	o	o						2
	Normal	o		o					2
F Ø4.5	Soft	o	o		o				3
	Normal	o		o		o			3
F Ø5.0	Soft	o	o				o		3
	Normal	o		o				o	3

ex) Soft bone (residual bone: 9mm), TSIII Ø4.5×10mm Implant placement case–Guide Hole: Ø5.1



Remove tissue → Initial Ø2.2×7mm → Check perforation → OneCAS Ø2.8×7mm → OneCAS Ø3.3×7mm → OneCAS Ø3.3×10mm → Check perforation → OneCAS Ø3.3×10mm → Check perforation → Hydraulic lift → GBR → Place Implant

ex) Soft bone (residual bone: 9mm), TSIII Ø5.0×10mm Implant placement case–Guide Hole: Ø5.8(W)

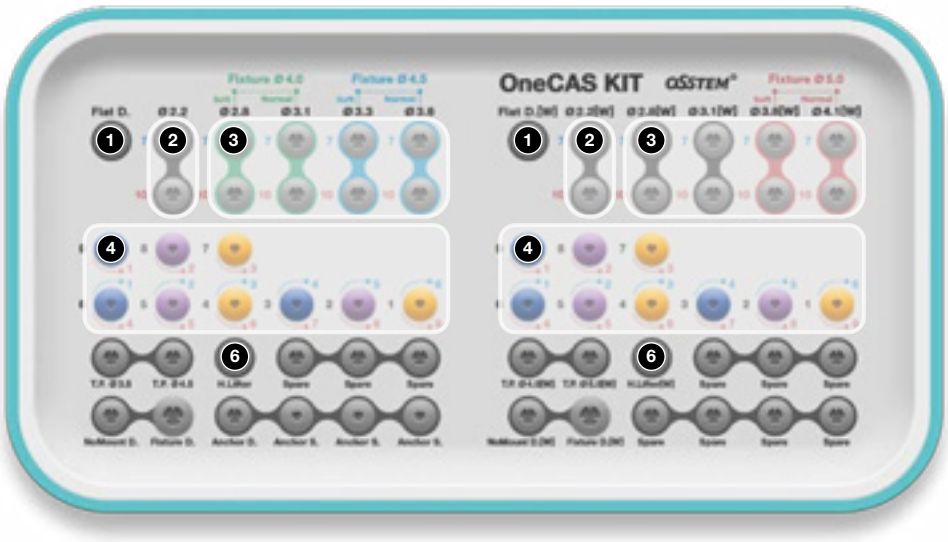


Removetissue (W) → Initial(W) Ø2.2×7mm → OneCAS(W) Ø2.8×7mm → OneCAS(W) Ø3.8×7mm → OneCAS(W) Ø3.8×10mm → Check perforation (W) → OneCAS(W) Ø3.8×10mm → Check perforation (W) → OneCAS(W) Ø3.8×10mm → Check perforation (W) → Hydraulic lift → GBR → Place Implant

3 Tools of KIT

OneCAS KIT

Drilling tool (1~5) | Hydraulic lifting tool (6) | Bone graft tool (7~8)



1 Flattening drill | **Flattening drill(W)**

2 Twist drill | **Twist drill(W)**

Ø2.2 | Ø2.2

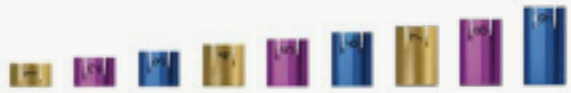
3 OneCAS drill

Ø2.8 | Ø3.1 | Ø3.3 | Ø3.6

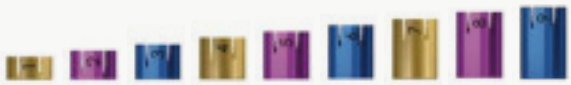
OneCAS drill(W)

Ø2.8 | Ø3.1 | Ø3.8 | Ø4.1

4 Stopper (1~9mm)



Stopper(W) (1~9mm)



5 Depth gauge (top plate component)

Depth gauge(W) (top plate component)

6 OneCAS hydraulic membrane lifter | **OneCAS hydraulic membrane lifter(W)** | **Hydraulic membrane lifter tube**

7 Bone carrier head (bottom plate component) | **Bone carrier** (bottom plate component)

8 Bone condenser (bottom plate component)

4 KIT (User guide)

Includes toolss for forming drill hole.

❶ Flattening Drill

❷ Twist Drill

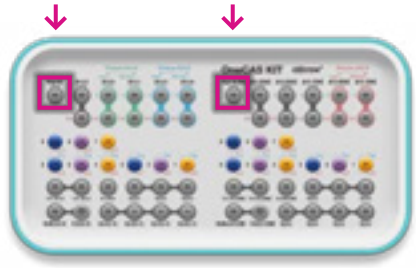
❸ OneCAS Drill

❹ Stopper

❺ Depth Gauge

❶ Flattening Drill

Used on narrow or uneven ridges.

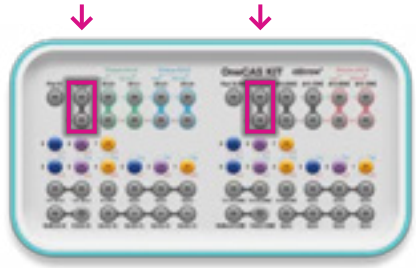


User guide

· Set drilling RPM at 800~1,200rpm.
· Drill at narrow or uneven ridges.

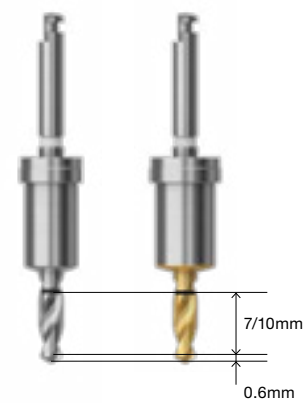
❷ Twist Drill

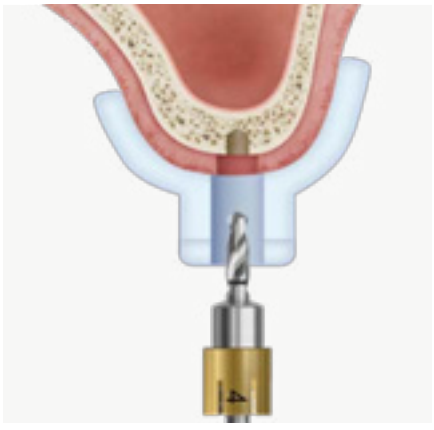
Initial Drill used before the OneCAS Drills.



User guide

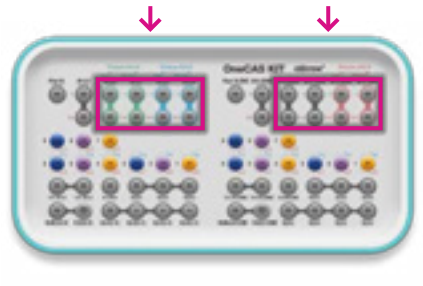
· Set drilling RPM at 800~1,200rpm.
· For safe drilling, place a stopper.
· Drill only after stopper is placed
· Drills 1mm deeper than the depth to the maxillary sinus inferior border.





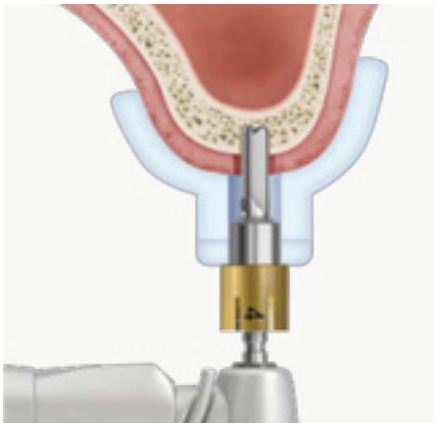
❸ OneCAS Drill

Drill usedwhen approaching the maxillary sinus membrane

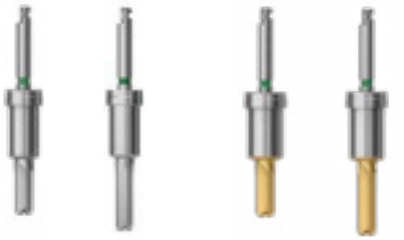


User guide

· Set the drilling RPM to 800rpm.
· For safe elevation, connect the stopper before drilling.
· Select the final drill diameter based on the bone quality.
· Possible to gain autogenous bone when drilling at low speed.
· Includes drills for regular hole (Ø5.1) and drills for wide hole (Ø5.8).
· The length specifications are 7mm and 10mm for each diameter.
· The short and long Ø3.3 and Ø3.6 drills for Wide hole (Ø5.8) can be purchased separately as option tools.specifications) are sold separately.



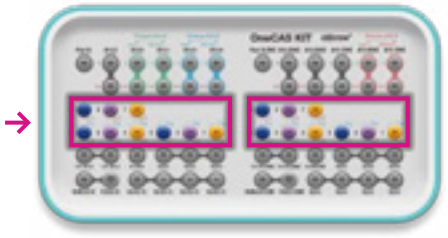
Regular Hole (Ø5.1) Wide Hole (Ø5.8)



	Regular Hole(Ø5.1)				Wide Hole(Ø5.8)					
Length \ Diameter	Ø2.8	Ø3.1	Ø3.3	Ø3.6	Ø2.8	Ø3.1	Ø3.3	Ø3.6	Ø3.8	Ø4.1
7mm	KIT included	KIT included	KIT included	KIT included	KIT included	KIT included	Sold separately	Sold separately	KIT included	KIT included
10mm	KIT included	KIT included	KIT included	KIT included	KIT included	KIT included	Sold separately	Sold separately	KIT included	KIT included

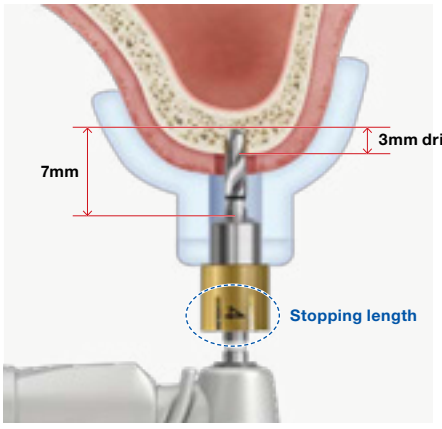
❹ Stopper

Tools for preventing membrane perforation when lifting the maxillary sinus lift.



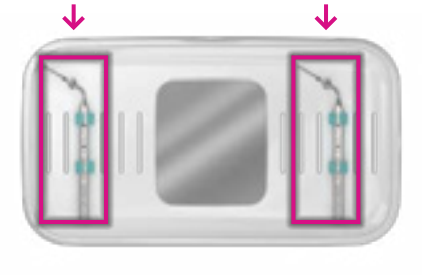
User guide

· The number written on the stopper means how much mm the drills get shorter.
· Includes a total of 9 specifications, ranging from 1 to 9 mm.
· Place the stopper on the drills.
· Includes stoppers for regular hole (Ø5.1) and stoppers for wide hole (Ø5.8).



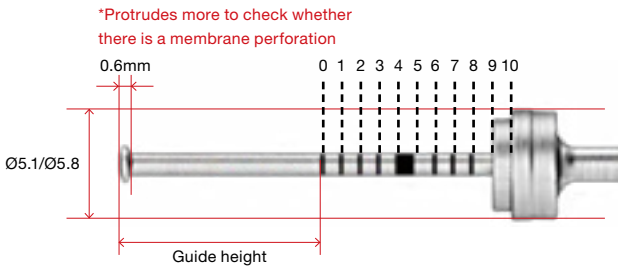
❺ Depth Gauge

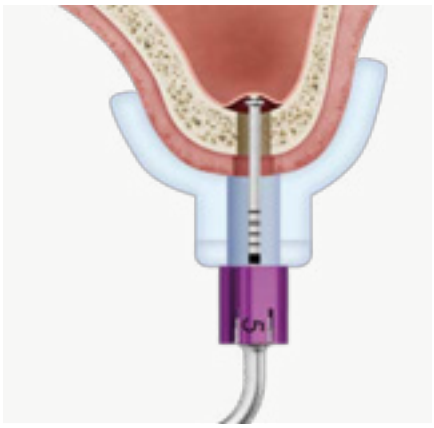
Instrument for checking whether sinus membrane is lifted.
Instrument used for measuring the depth of the residual bone.



User guide

· Includes one for regular hole (Ø5.1) and one for wide hole (Ø5.8).
· Place the stopper first before measuring the depth.



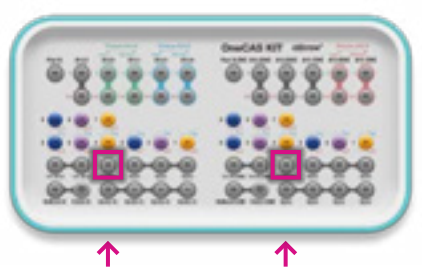


Includes maxillary sinus lifting tools for hydraulic lifting.

6 Hydraulic Membrane Lifter & Tube

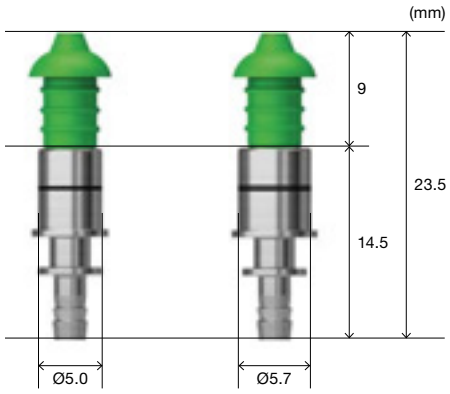
❻ Hydraulic Membrane Lifter & Tube

Maxillary sinus membrane elevation tool that operates with hydraulic lifting.
Has wing shape design, which is optimized for sealing in a flapless surgery.



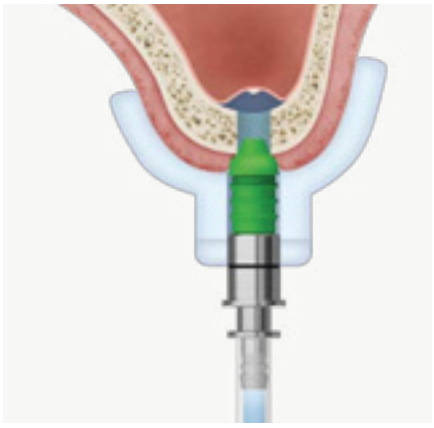
User guide

· Prepare a syringe with 3cc capacity.
· Connect Syringe, Tube and Hydraulic Membrane Lifter.
· Inject saline solution slowly into the syringe
· Inject saline by gradually increasing the injection amount 0.5cc ⇨ 1.0cc ⇨ 1.5cc.



Regular Hole
Ø5.1

Wide Hole
Ø5.8



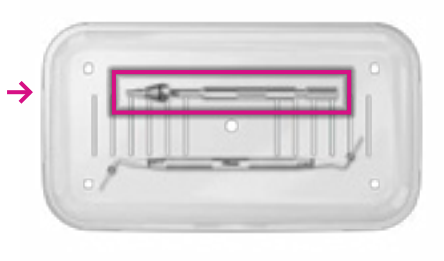
Includes toolss used for filling bone graft material into the sinus.

7 Bone Carrier

8 Bone Condenser

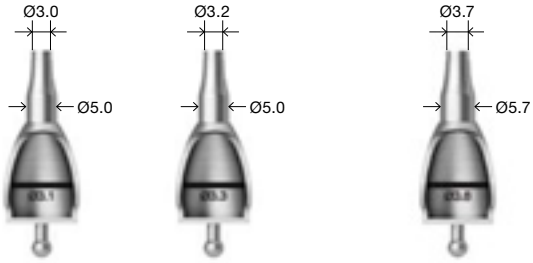
❼ Bone Carrier

Instrument used for filling bone graft material into the sinus.

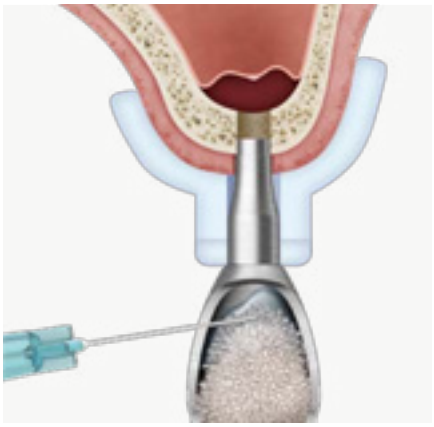


User guide

· After drilling with OneCAS Drill Ø3.1, use Bone Carrier Head Ø3.0.
· After drilling with OneCAS Drill Ø3.3/3.6, use Bone Carrier Head Ø3.2.
· After drilling with OneCAS Drill Ø3.8/4.1, use Bone Carrier Head Ø3.7.
· Tighten the handle on the back of the Bone Carrier to fix the head.
· After inserting it all the way into the OneGuide Hole, fix it for use.
· Fill the bone material behind the marking line of the head.
Then, use bone condenser to take small amounts and fill the sinus with bone graft material.

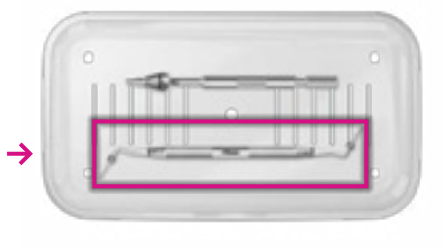


Regular Hole (Ø5.1)　　Wide Hole (Ø5.8)



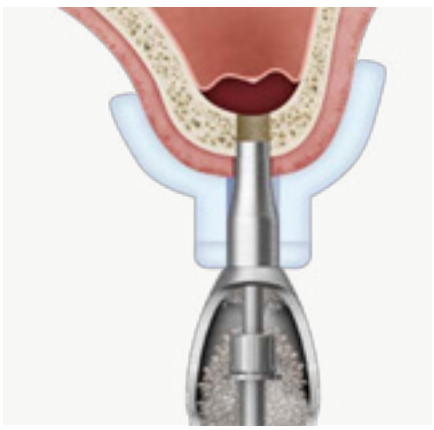
❻ Bone Condenser

Tool that pushes bone material into the sinus.



User guide

· Use the bone condenser to take small amounts of bone graft material and fill the sinus.



5 KIT sequence

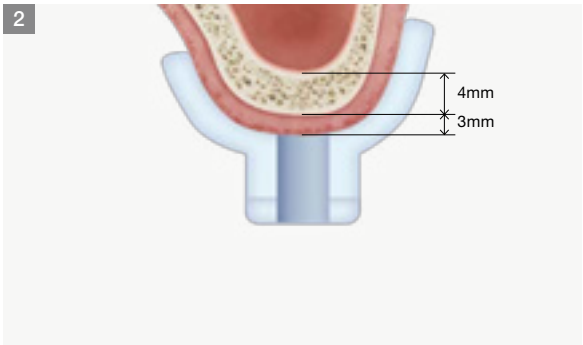
Soft bone Residual bone height 4mm / TSIII Ø4.5×8.5mm placement

1

Preparation for surgery

· Check surgical report which includes treatment plan.
· Confirm the diameter and length specifications of implants for each treatment area.
· Sterilize at low temperature before placing OneGuide Template in oral cavity.
  - Plasma sterilization
  - Immerse in 0.2% Chlorhexidine Solution (e.g. hexamidine) for 5 minutes.

2



Placement of guide

· Place the guide in the oral cavity, then check the fit through the window (tooth and gingival surface).

3

Make gingival incision (tissue punch)

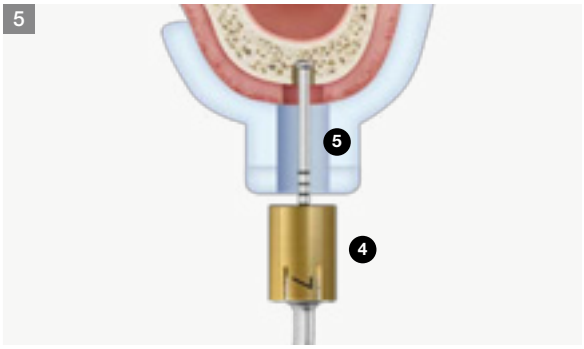
· Use a tissue punch with a Ø0.7~1.5 smaller diameter than the healing abutment.

4

Drilling: Ø2.2 twist drill, 7mm

· Stopper: 4mm (the amount that is shortened from the drill length)
· Recommended RPM: 800~1,200rpm

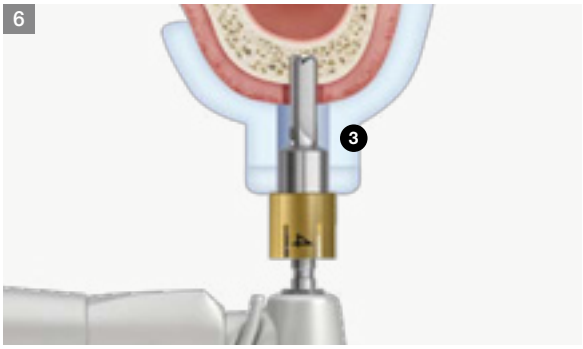
5



Dedicated depth gauge for Ø5.1 Hole

· Stopper: 7mm (the amount that is shortened from the depth gauge length)

6

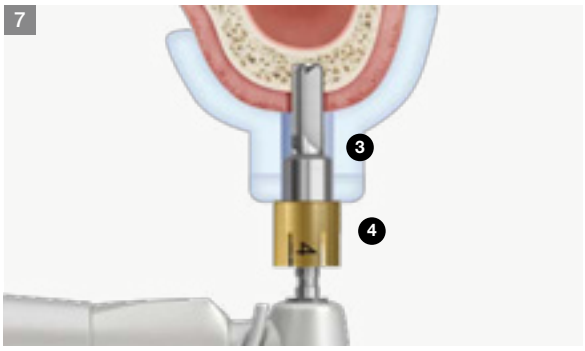


Drilling: Ø2.8 OneCAS drill, 7mm

· Stopper: 4mm (the amount that is shortened from the drill length)
· Recommended RPM: 400~800rpm

Ⓝ: Tool number

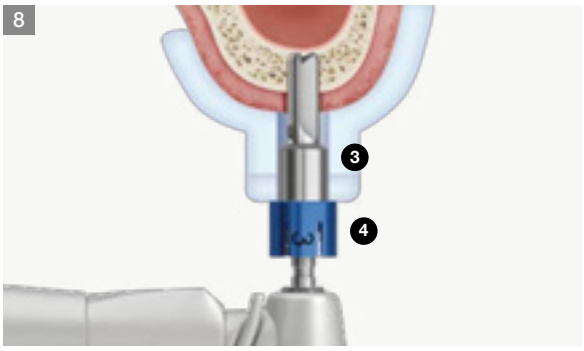
7



Drilling: Ø3.3 OneCAS drill, 7mm

· Stopper: 4mm (the amount that is shortened from the drill length)
· Recommended RPM: 800rpm

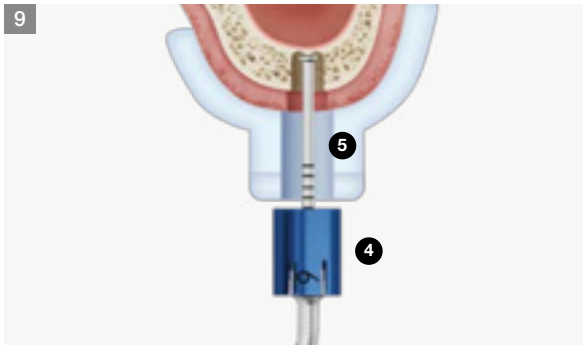
8



Drilling: Ø3.3 OneCAS drill, 7mm

· Stopper: 3mm (the amount that is shortened from the drill length)
· Recommended RPM: 800rpm

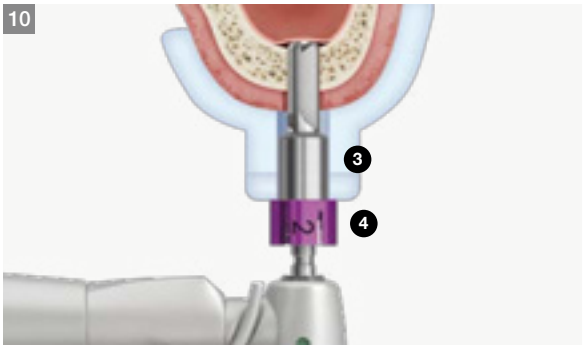
9



Dedicated depth gauge for Ø5.1 Hole

· Stopper: 6mm (the amount that is shortened from the depth gauge length)

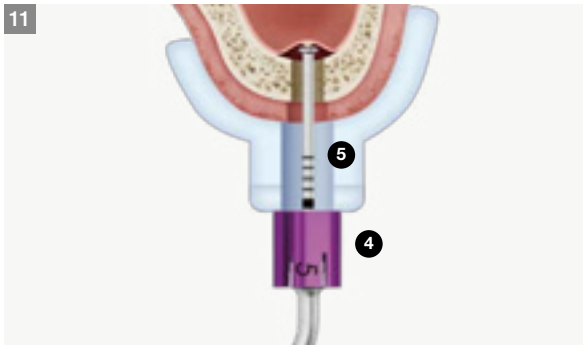
10



Drilling: Ø3.3 OneCAS drill, 7mm

· Stopper: 2mm (the amount that is shortened from the drill length)
· Recommended RPM: 800rpm

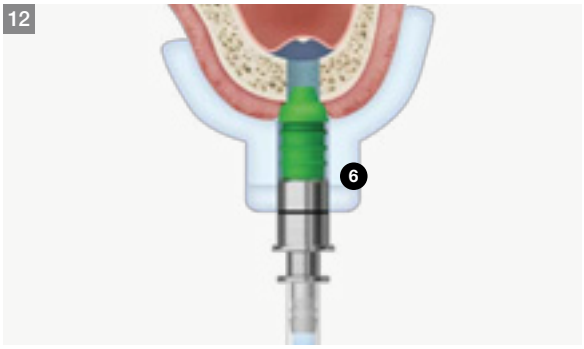
11



Dedicated depth gauge for Ø5.1 Hole

· Stopper: 5mm (the amount that is shortened from the drill length)

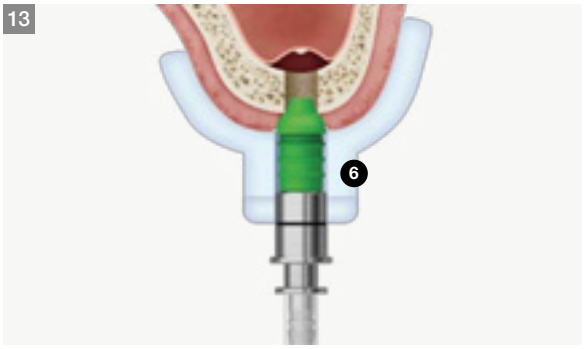
12



Inject 0.5cc of saline (push)

· Fill the 3cc Syringe with 1.5cc of saline, then connect to hydraulic lifter.
· Slowly inject approxSlowly inject saline in 0.5 increments after placing the hydraulic lifter into drill hole in a sealed manner.

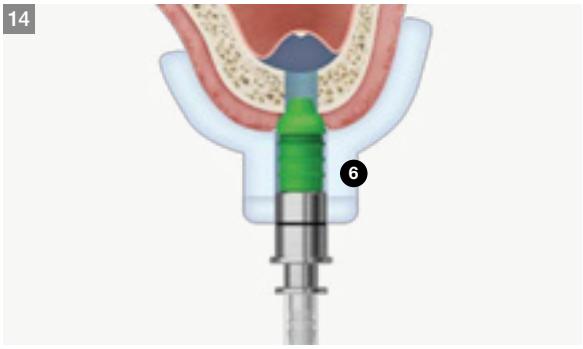
13



Withdraw 0.5cc of saline (pull)

· Slowly withdraw approx. 0.5cc

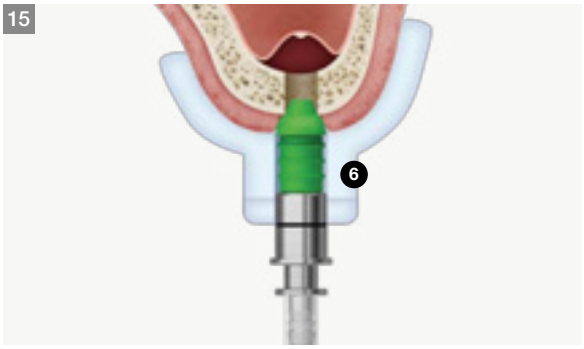
14



Inject 1.0cc of saline (push)

· Slowly inject approx. 1.0cc

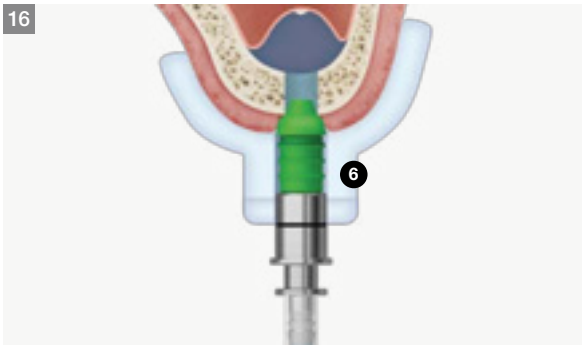
15



Withdraw 1.0cc of saline (pull)

· Slowly withdraw approx. 1.0cc

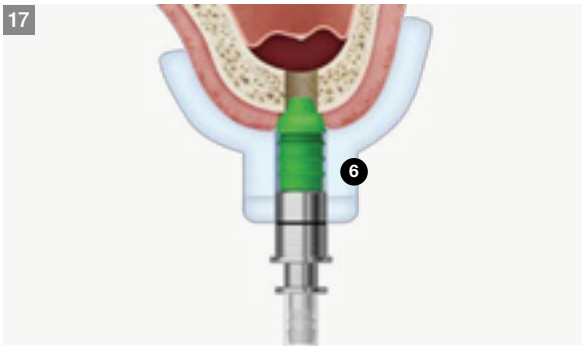
16



Inject 1.5cc of saline (push)

· Slowly inject approx. 1.5cc

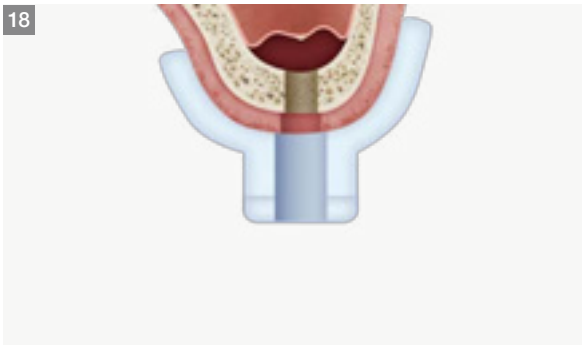
17



Withdraw 1.5cc of saline (pull)

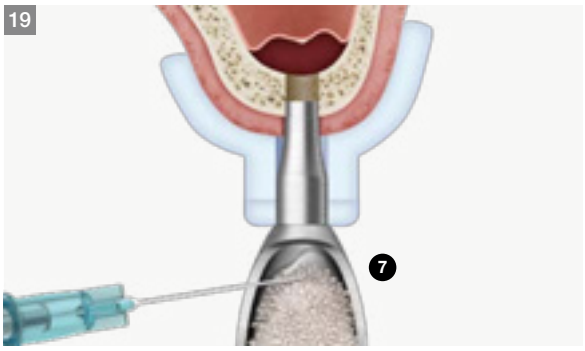
· Slowly withdraw approx. 1.5cc

18



Finish lifting

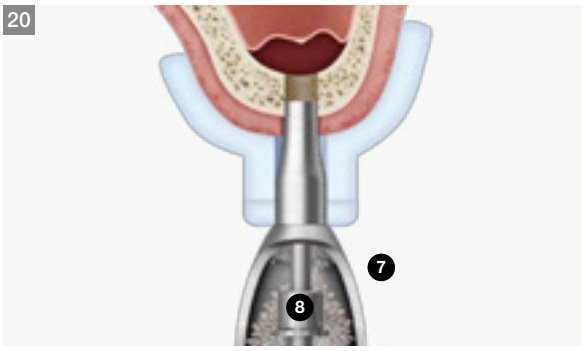
19



Fill bone graft material (bone carrier)

· Put bone graft material behind the marking line of the bone carrier. Then, inject saline into the bone carrier hole.
· Put approx. 0.15cc behind the head's making line.

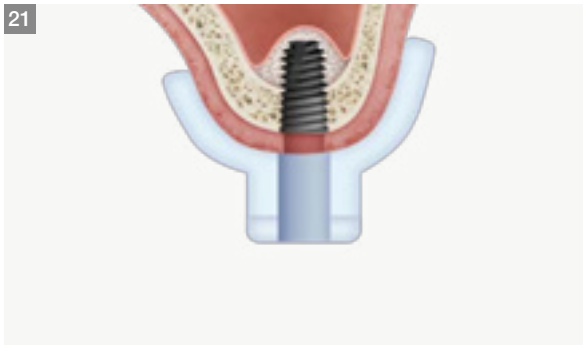
20



Push in bone graft material (bone condenser)

· Push in bone graft material little by little with the bone condenser.
· Repeat this process 4 to 5 times.

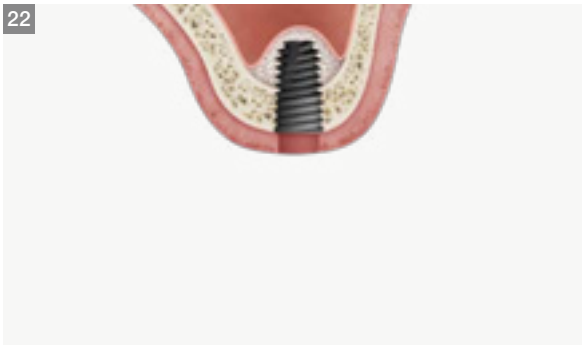
21



Implant placement (TSIII Ø4.5×8.5mm)

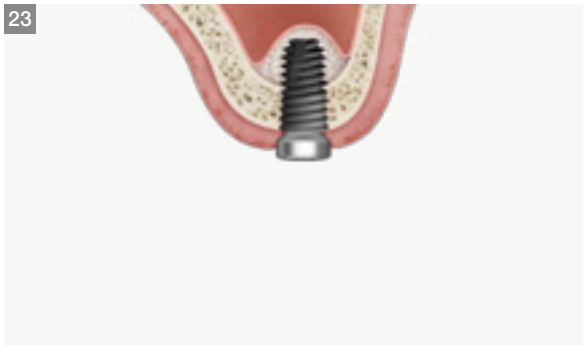
· Place implant 80% with a NoMount driver.
· Place 100% with a implant driver.

22



Remove template

23



Finish surgery

· Immediate loading: place Transfer abutment or Custom abutment, then seat provisional prosthesis.
· Delayed loading: place cover screw or healing abutment

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.

5. STERILITY, CLEANING, REPROCESSING, AND STORAGE

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

Although reasonable care has been taken in preparing this catalogue, typographical, editorial, translation, printing, and formatting errors may occur. Information may also become outdated as a result of product updates, regulatory changes, technical revisions, or clinical developments.

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.

11. TRADEMARKS AND COMPANY NAMES

All trademarks, trade names, product names, brand names, and company names are the property of their respective owners.

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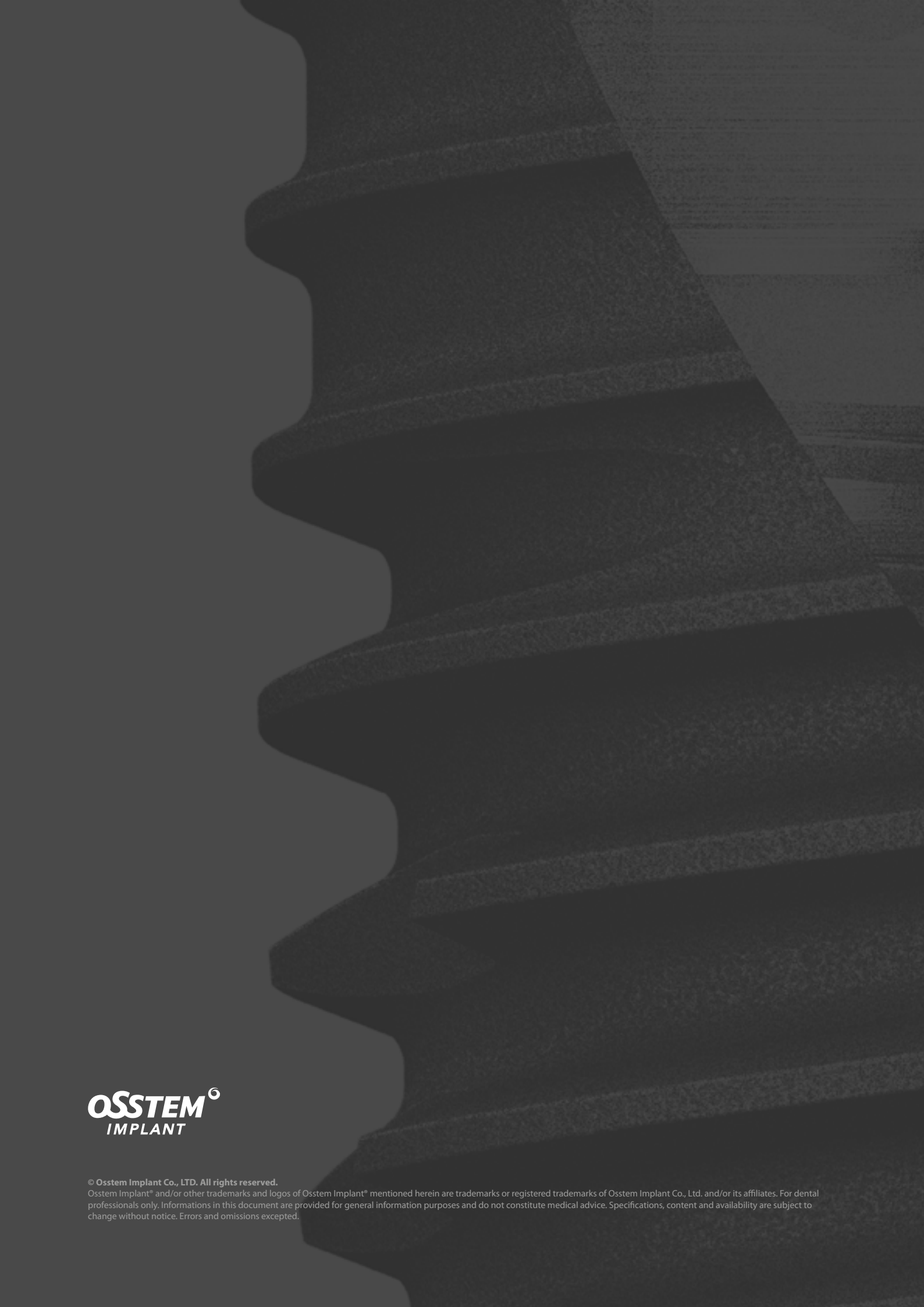

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