OSSTEM IMPLANT

Surgical Manual

ESSET 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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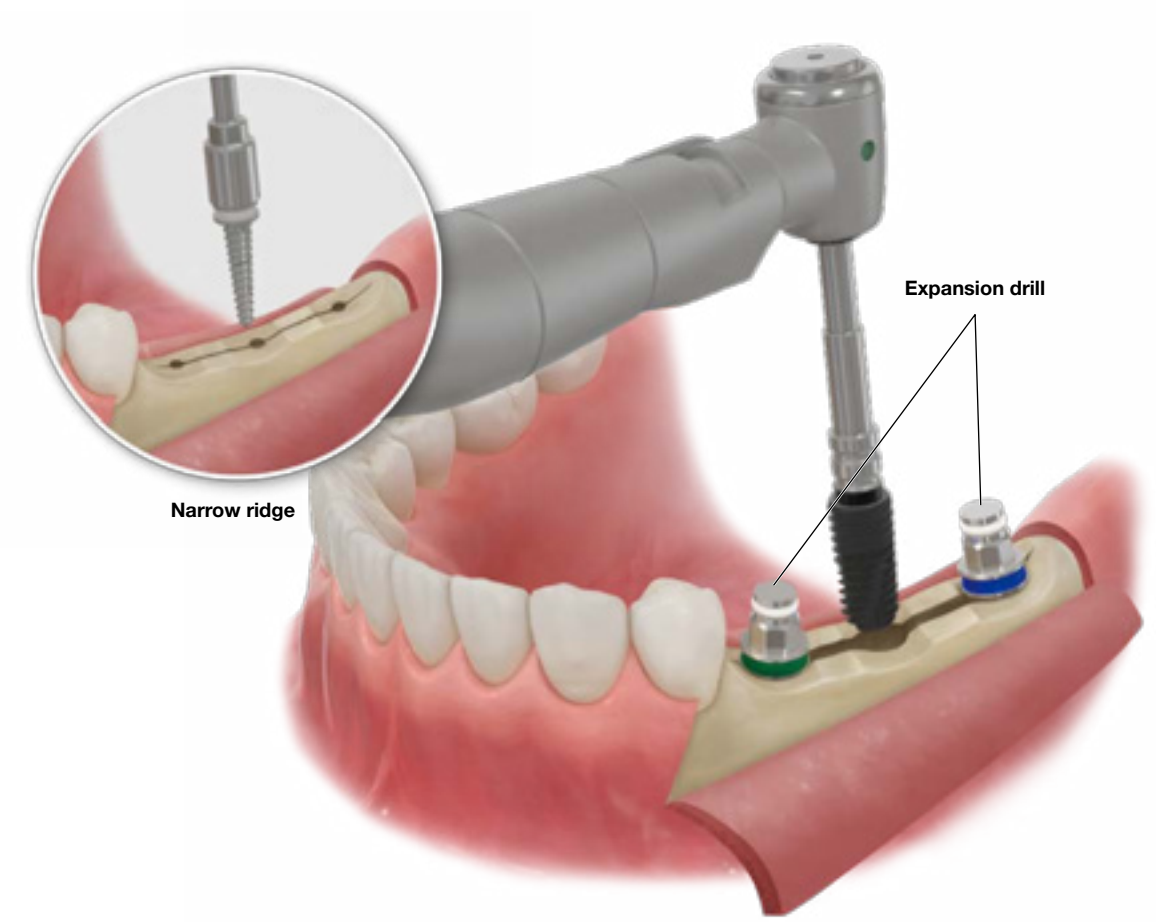
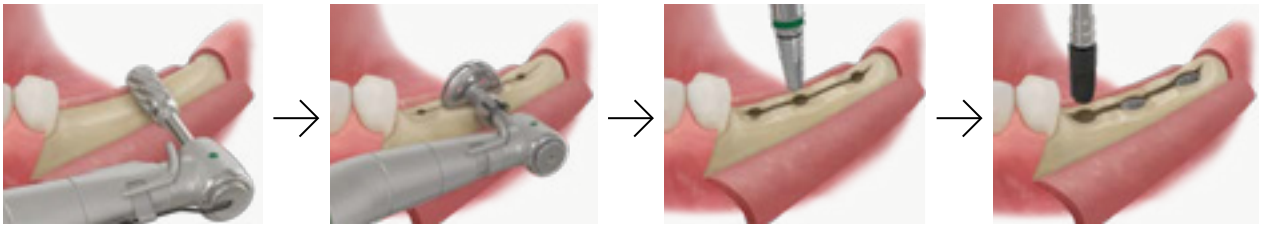
158 00 Prague, Czech Republic

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.*

ESSET KIT

KIT used to perform ridge split an expansion safely without malleting the narrowed alveolar ridge



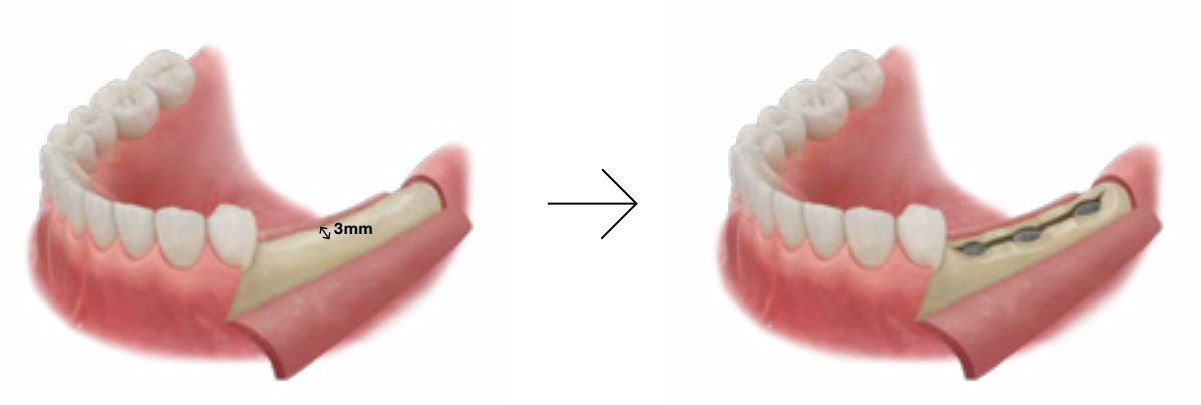


Level alveolar bone | Cut alveolar bone | Expand alveolar bone | Place implant

1 Indication

When placing Ø4.0/4.5 Implants on a narrow ridge

· Place the narrowed alveolar ridge with ridge split and expansion.



2 Feature

A Irregular ridges clean up possible (Crest remover)

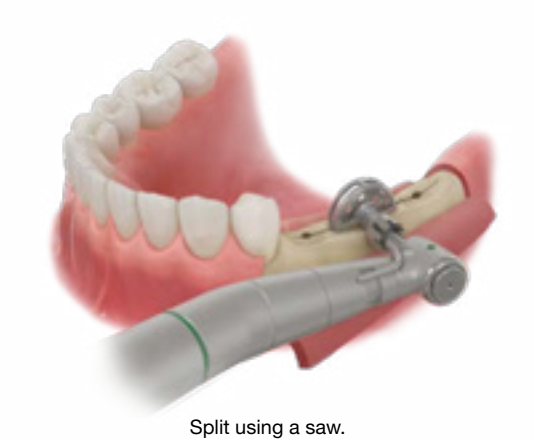
· Use the crest remover to quickly clear irregular ridges.

B Ridge split possible without malleting (Saw)

· Relieve patient discomfort caused by malleting.

Split with malleting.

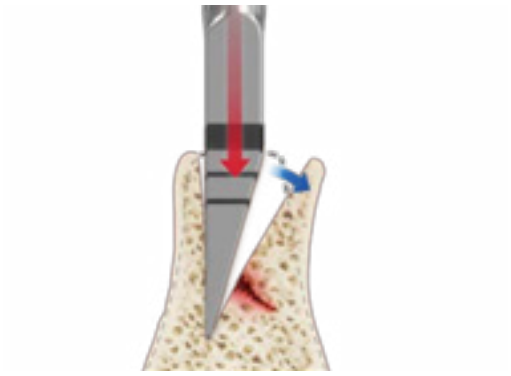
VS



Split using a saw.

C Safe expansion possible without fracturing the Buccal plate (Expansion drill)

· ·Minimize fracture by expanding split bone while self-tapping.



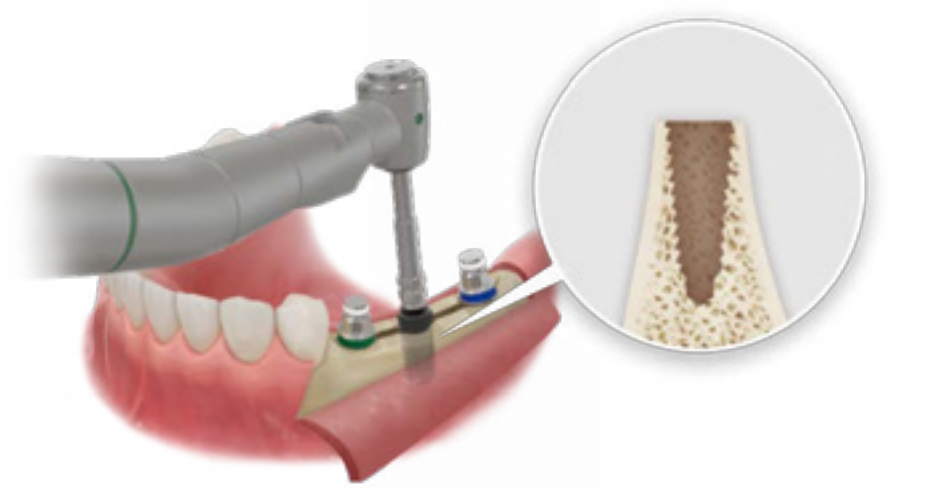
VS

Ridge split KIT / Bone spreader KIT

ESSET KIT

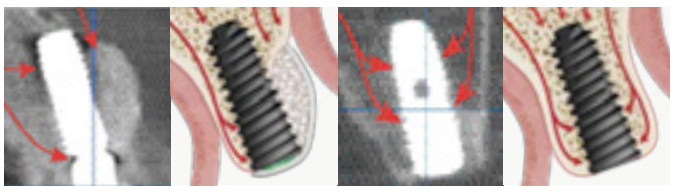
D Can be placed without torque overload

· Prevent torque overload by placing Implants in a self-tapping state of the bone with the expansion drill.



E Shorten healing period with smoother blood supply

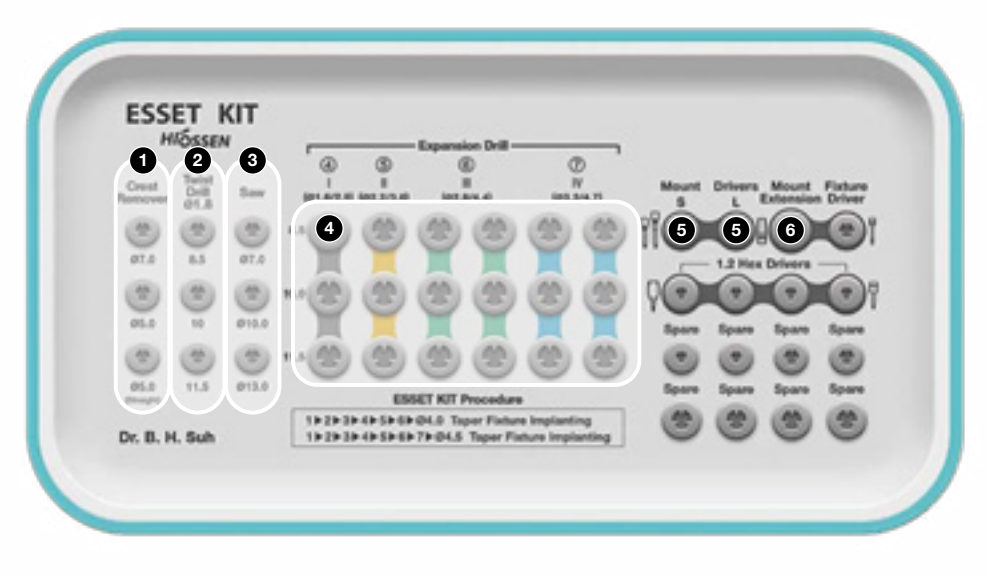
· 4 wall blood supply reduces the healing period.



3 KIT (included components)

ESSET KIT

- Clean up crestal bone and placement position Marking tool (1, 2)
- Ridge split tool (3)
- Ridge expansion tool (4~6)
- Implant placement tool (7, 8)



1 Crest remover

2 Twist drill

3 Saw

4 Expansion drill

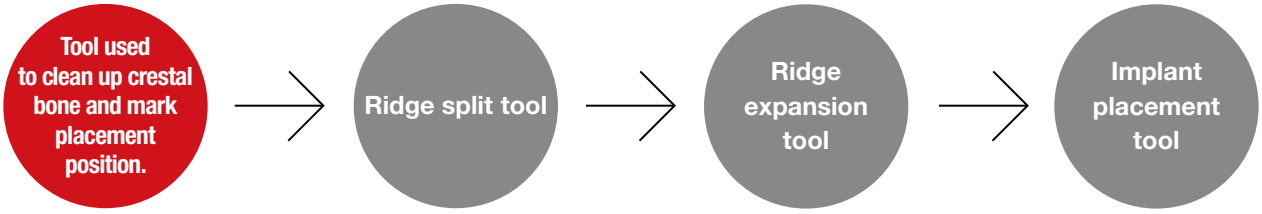
5 EXP mount driver

6 Mount extension

7 Depth gauge

8 Torque wrench

4 KIT user instructions



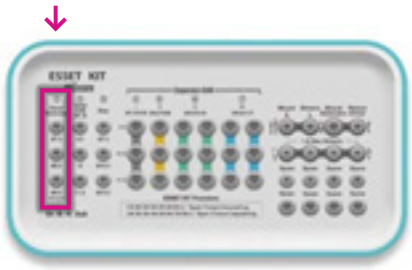
Includes a tool that cleans up the crestal bone and marks the Implant's placement position.

1 Crest remover

2 Twist drill

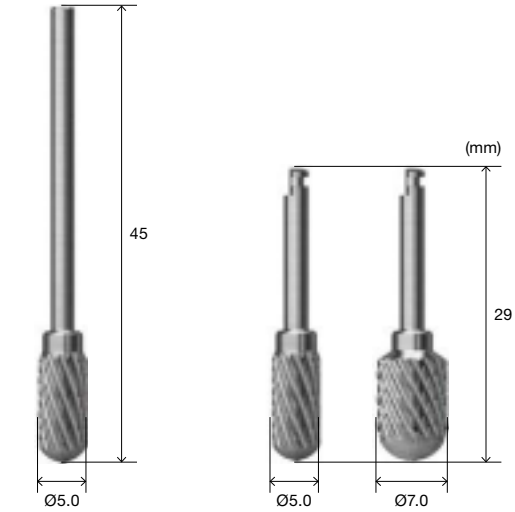
❶ Crest remover

Use to mark the Implant placement position after horizontally deleting the narrowed bone width.

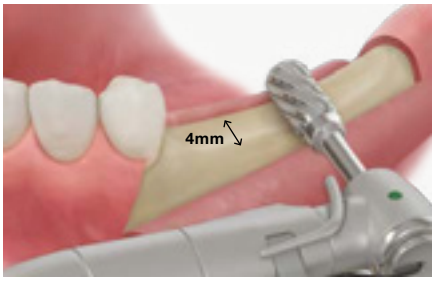


User instructions

· Assemble the crest remover to the handpiece.
· The narrowed bone width is horizontally deleted to secure a 4mm bone width.
· Mark the Implant's placement position.
· Recommended RPM: Angled: 1,200~1,500Rpm / Straight: 15,000~30,000rpm



Straight type　　Contra angle type

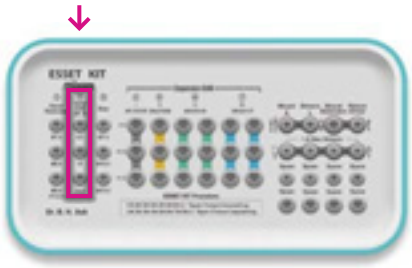


Secure 4mm in bone width

Placement position marking

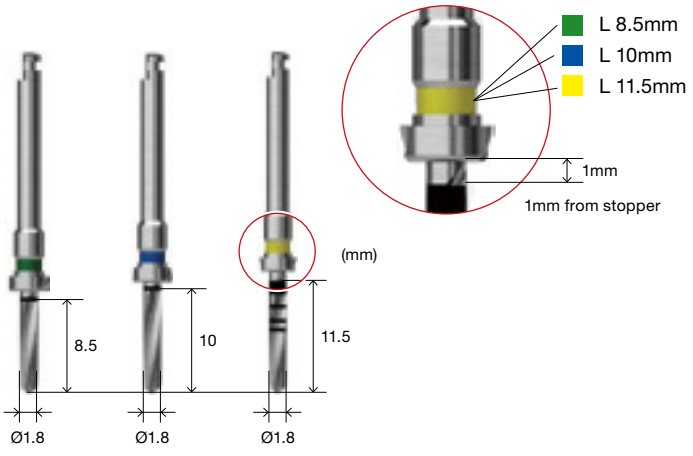
❷ Twist drill

Use to mark the Implant's placement position.

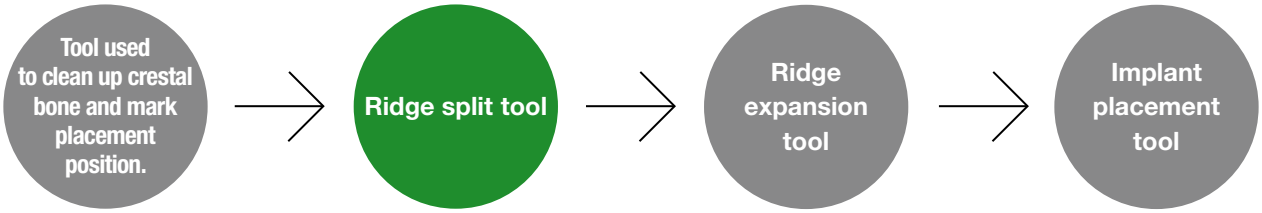


User instructions

· Select a drill suitable for the length of the Implant to be placed. (Color coding used to classify by length)
· Assemble the twist drill to the handpiece.
· Mark the Implant's placement position.
· Recommended RPM: 1,200~1,500rpm



Placement position marking

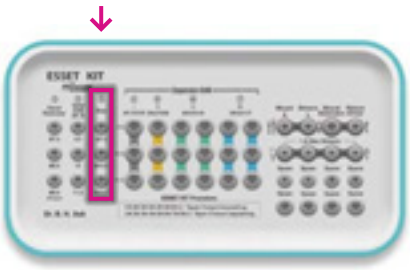


Includes a tool that cuts the width of the bone.

3 Saw

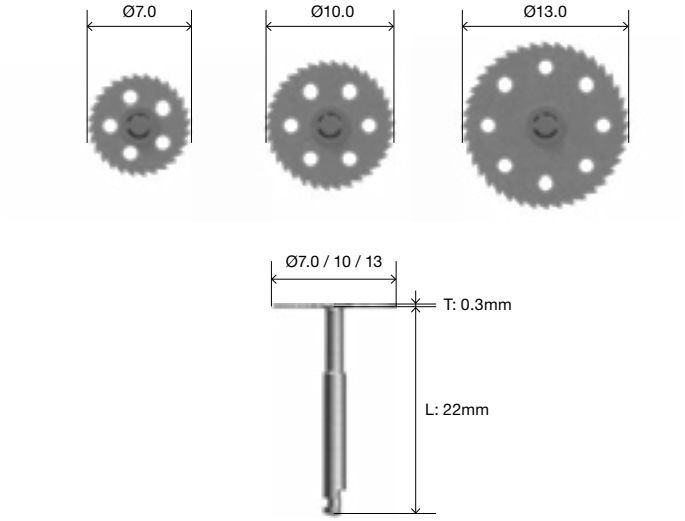
❸ Saw

Use to make incision narrowed bone width-wise.

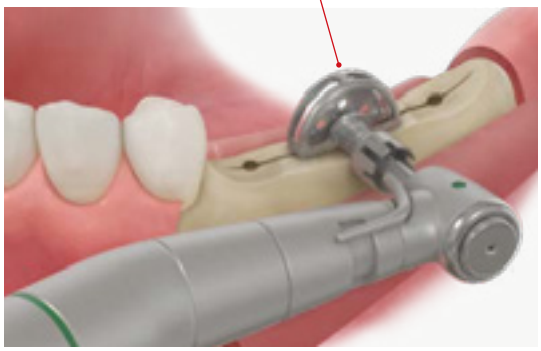


User instructions

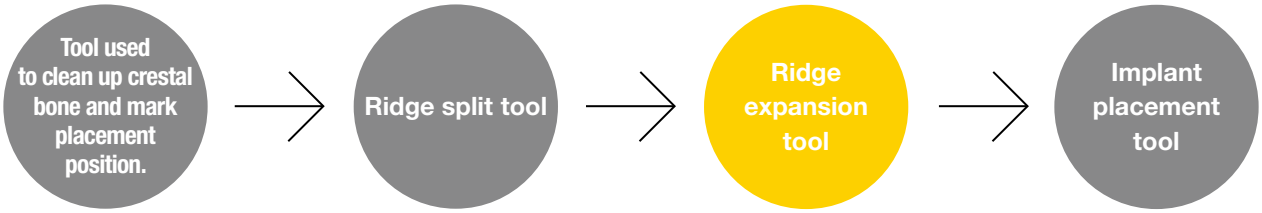
· To prevent saw fracture, start using small diameters, then expand. (Ø7.0, Ø10.0, Ø13.0)
· Assemble the saw to the handpiece. (To prevent bouncing of the saw, connect and fasten the saw protector.)
· After sawing vertically, perform horizontal sawing in the distal ⇨ mesial direction.
· Recommended RPM is 1,200~1,500rpm.



Saw protector: Window improves the visibility of the procedure.



After sawing vertically, perform horizontal sawing in the distal ⇨ mesial direction.



Includes a tool that expands the width of the incised bone.

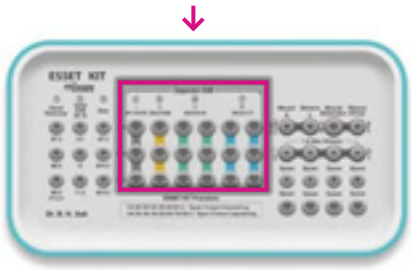
❹ **Expansion drill**

❺ **EXP mount driver**

● **Mount extension**

❹ Expansion drill

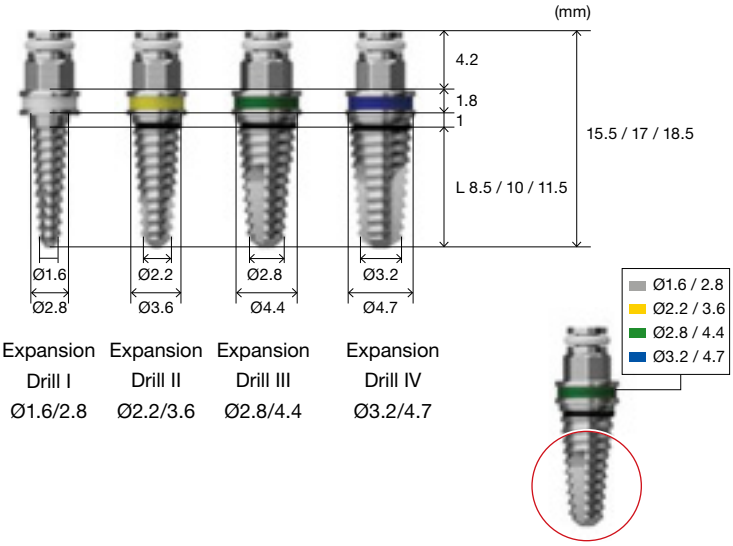
Use to expand the bone incised width-wise.



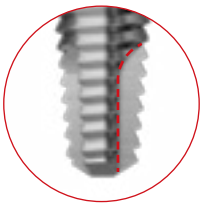
User instructions

· Select the expansion drill of the diameter and length to be used.
· Expand the bone using drills sequentially according to the diameter of the Implant. (F4.0: I ⇨ II ⇨ III, F4.5: I ⇨ II ⇨ III ⇨ IV)
· Assemble the expansion drill to the EXP mount driver and fasten it to the handpiece.
· Drill until the bottom of the black line reaches the bone level.
· Recommended RPM: 25~35rpm

Expand the incised bone width and maintain the expanded bone width



Expansion Drill I	Expansion Drill II	Expansion Drill III	Expansion Drill IV
Ø1.6/2.8	Ø2.2/3.6	Ø2.8/4.4	Ø3.2/4.7

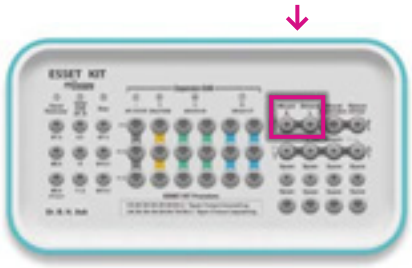


*** Self-tapping apex**
Expanding the bone without fracturing by self-tapping

Create a Cutting Edge

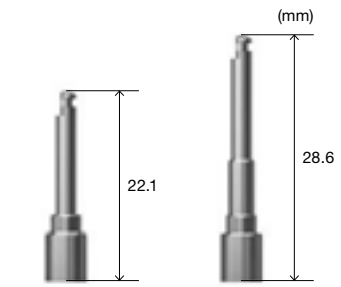
❺ EXP mount driver

Use when inserting or removing an expansion drill into bone with an engine.



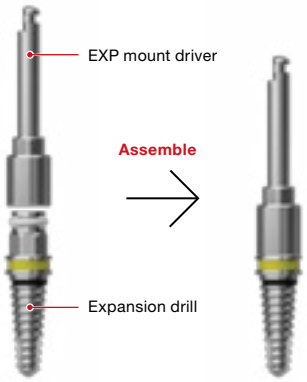
User instructions

· Assemble the expansion drill to the EXP mount driver and fasten it to the handpiece.
· Includes two specifications to prevent handpiece interference.
· Recommended RPM: 25-35 rpm



Short specification (for posterior part) available.

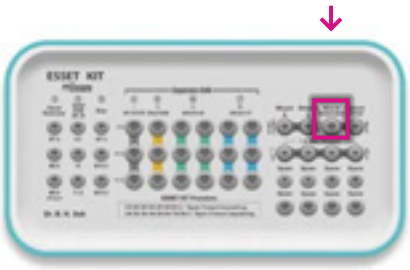
Long specification (for anterior part) available.



Assemble to the expansion drill to use

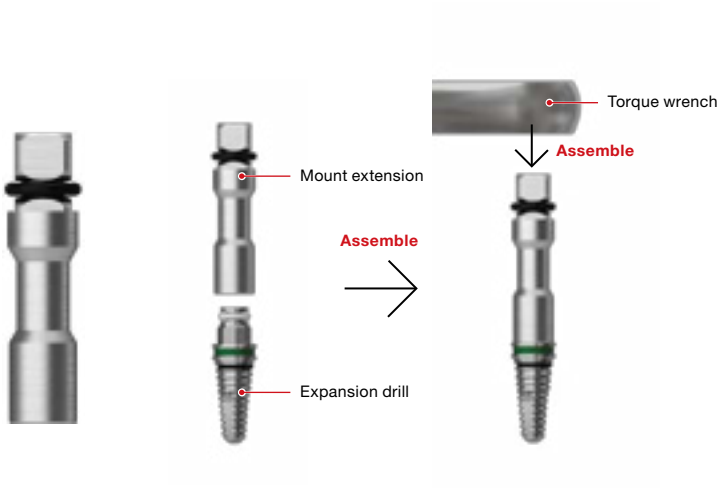
6 Mount extension

Use torque wrench to apply torque while inserting or removing the expansion drill into the bone.

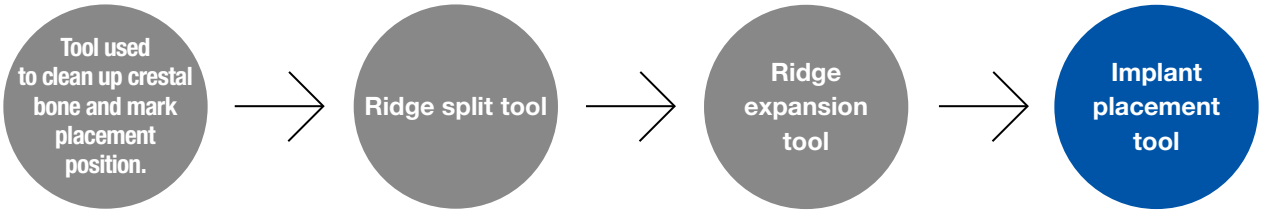


User instructions

· Assemble mount extension to an expansion drill.
· Apply torque by tightening the torque wrench.
· Recommended tightening torque: 30Ncm



Assemble to an expansion drill, then apply appropriate tightening torque.



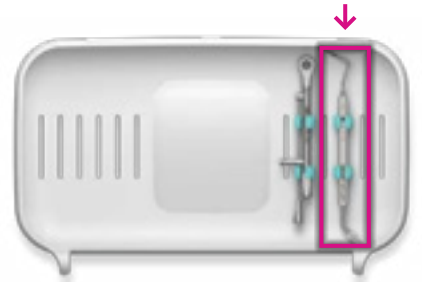
Includes tools that help place Implants.

7 Depth gauge

8 Torque wrench

❼ Depth gauge

Use for measuring drilling depth measurement and using as an open wrench.

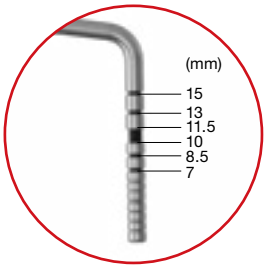


User instructions

· Used when measuring drilling depth. (grooves in 1mm increments)
· Grip the upper octa part of the mount with an open wrench so that no torque is applied to the Implant when removing the Implant mount.

Measure drilling hole depth.

Functions as open wrench.

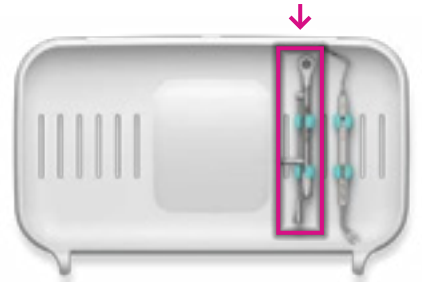


1mm groove

Mount grip for octa part on top of the mount

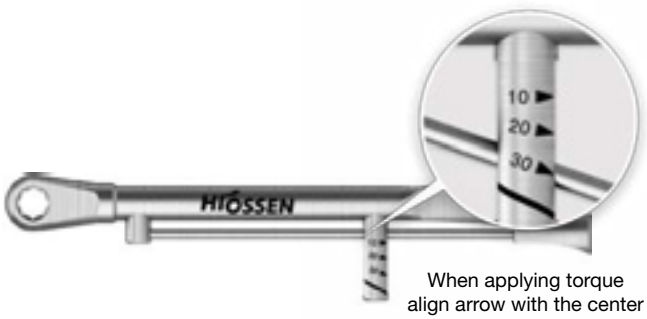
❽ Torque wrench

Use for early use with a constant torque when installing a Implant.



User instructions

· Pull the bar and adjust the center of the bar to the torque value to be applied and turn it clockwise to apply the torque.
· Torque of 10, 20, and 30Ncm can be applied.
(Last Line is approximately 40Ncm)



When applying torque align arrow with the center of the bar.

Place Implant, then apply appropriate torque value.

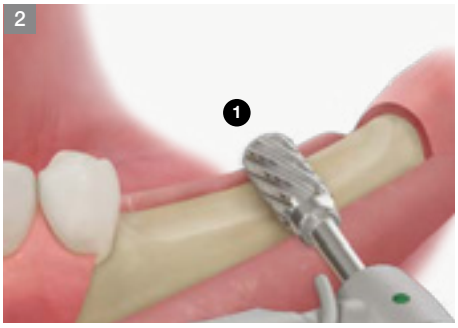
5 KIT sequence

Normal bone #35 (TSIII Ø4.0 × 10mm), #36, 37 (TSIII Ø4.5 × 10mm)

Select Implant placement position

· Check edentulous sites (#35, #36, #37).

· Consider the width of adjacent teeth and the prosthesis before the procedure when planning the placement position.

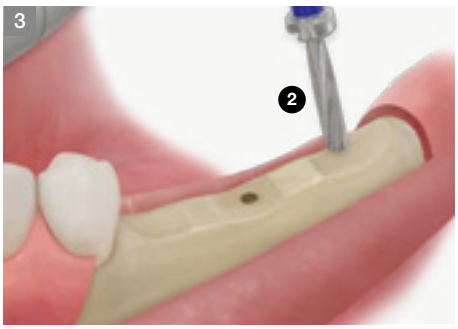


Level alveolar bone (Crest remover)

· Horizontally delete the upper surface of narrow alveolar bone with crest remover (to secure 4mm bone width).

· Mark the Implant's placement position.

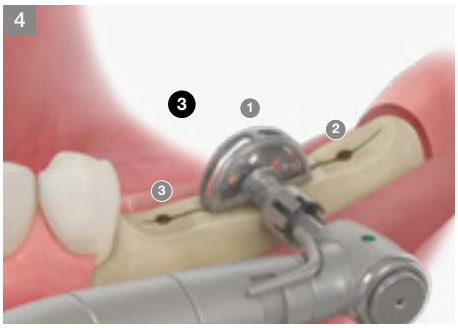
· Recommended RPM: Angled 1,200~1,500rpm / Straight 15,000~30,000rpm



Initial drilling (Ø1.8 twist drill)

· Full drilling using a Ø1.8 x 10mm twist drill up to the stopper at the marked position. (Create drilling hole to prevent saw unseating)

· Recommended RPM: 1,200~1,500rpm



Cut alveolar bone (Saw)

· Randomly divide the saw area into 2~3 parts.
Saw vertically in order: ❶ (Middle) ❷ (Distal) ❷ (Mesial). Then, link sawn part in order: ❷ (Distal) ❶ (Middle) ❸ (Mesial) to saw.

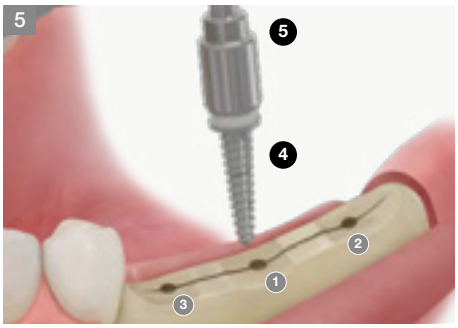
· Start with a small diameter saw, then move onto a larger diameter saw (Contra angle type configuration: Ø7.0, Ø10.0, Ø13.0).

· Approach area around adjacent teeth safely and saw (additional sawing) using a Ø7.0 saw.

· Recommended RPM: 1,200~1,500rpm

* Saw protector can improve safety when sawing

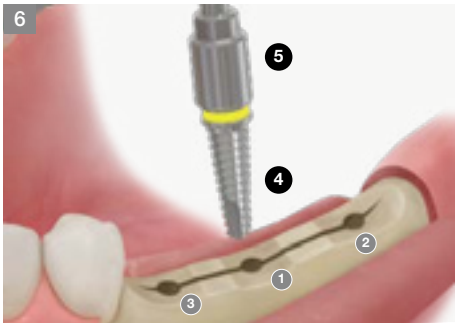
Ⓝ: Tool number



Expand alveolar bone: Step-1 (Ø1.6/2.8 expansion drill)

· Assemble expansion drill I on the expansion mount driver, and drill in order: ❶ (Middle) ⇨ ❷ (Distal) ⇨ ❸ (Mesial)

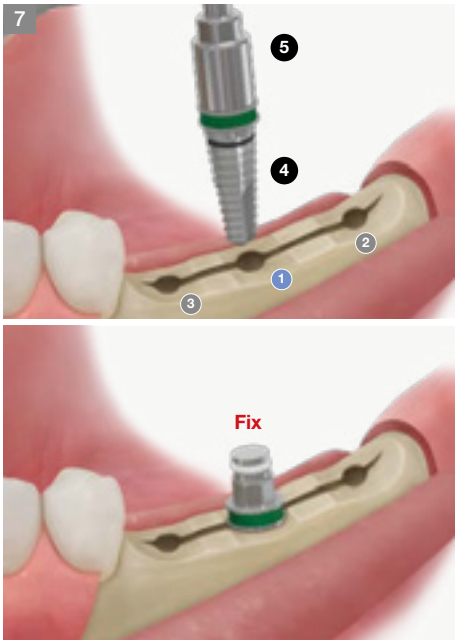
· Recommended RPM: 25~35rpm



Expand alveolar bone (additional expansion): Step-2 (Ø2.2/3.6 expansion drill)

· Assemble expansion drill II on the expansion mount driver, and drill in order: ❶ (Middle) ⇨ ❷ (Distal) ⇨ ❸ (Mesial)

· Recommended RPM: 25~35rpm



#36: Expand (additional expansion) and anchor alveolar bone: Step-3 (Ø2.8/4.4 expansion drill)

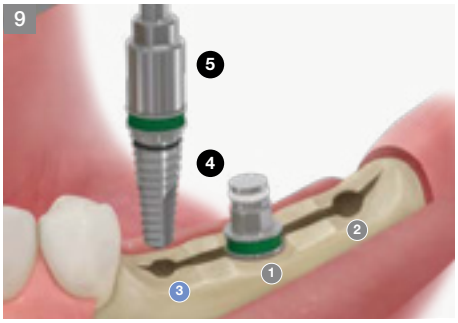
· Assemble the expansion drill III to the expansion mount driver after drilling in ❶ (Middle).

· Recommended RPM: 25~35rpm

#37: Expand (additional expansion) alveolar bone: Step-3 (Ø2.8/4.4 expansion drill)

· Assemble the expansion drill III to the expansion mount driver after drilling in ❷ (Middle). Remove after drilling.

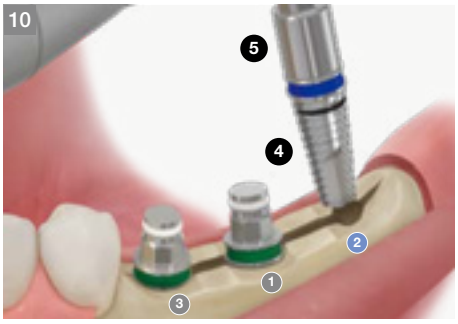
· Recommended RPM: 25~35rpm



#35: Expand (final expansion) and anchor alveolar bone: Step-3 (Ø2.8/4.4 expansion drill)

· Assemble the expansion drill III to the expansion mount driver after drilling in 3 (Mesial).

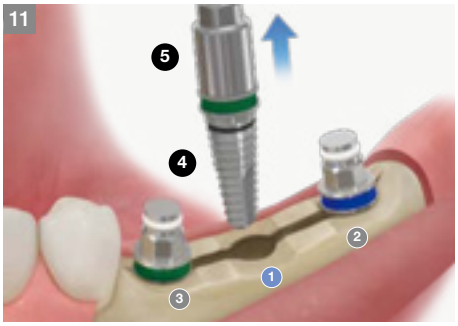
· Recommended RPM: 25~35rpm



Expand (final expansion) and anchor #37 alveolar bone: Step-4 (Ø3.2/4.7 expansion drill)

· Assemble the expansion drill IV to the expansion mount driver after drilling in 2 (Distal).

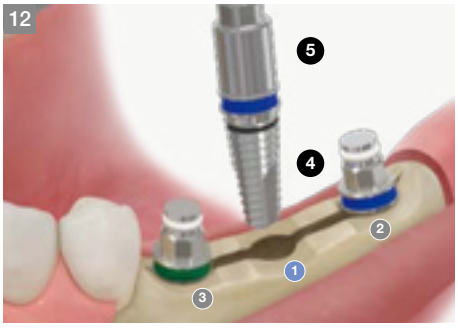
· Recommended RPM: 25~35rpm



#36: Remove anchored step-3 expansion drill

· Remove the step-3 drill anchored to the 1 (Middle) with an expansion mount driver.

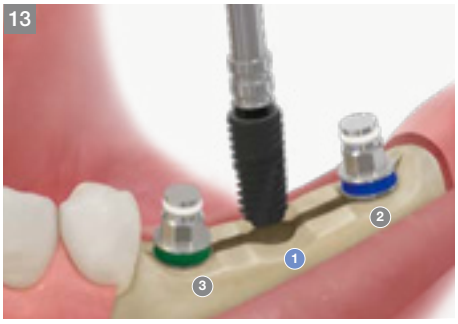
· Recommended RPM: 25~35rpm



#36: Expand (final expansion) alveolar bone: Step-4 (Ø3.2/4.7 expansion drill)

· Assemble the expansion drill IV to the expansion mount driver after drilling in 1 (Middle). Remove after drilling.

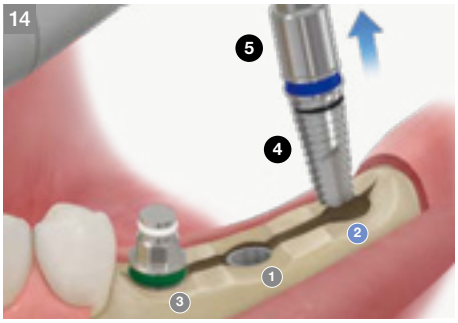
· Recommended RPM: 25~35rpm



#36: Place Implant (Ø4.5 x 10mm)

· Place Implant in 1 (Middle)

· Recommended RPM: Max. 50rpm



#37: Remove anchored step-4 expansion drill

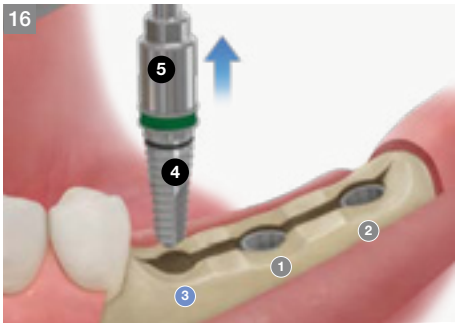
· Remove the step-4 drill anchored to the 2 (Distal) with an expansion mount driver.

· Recommended RPM: 25~35rpm

#37: Place Implant (Ø4.5×10mm)

· Place Implant in 2 (Distal)

· Recommended RPM: Max. 50rpm



#35: Remove anchored step-3 expansion drill

· Remove the step-3 drill anchored to the 3 (Mesial) with an expansion mount driver.

· Recommended RPM: 25~35rpm

#35: Place Implant (Ø4.0×10mm)

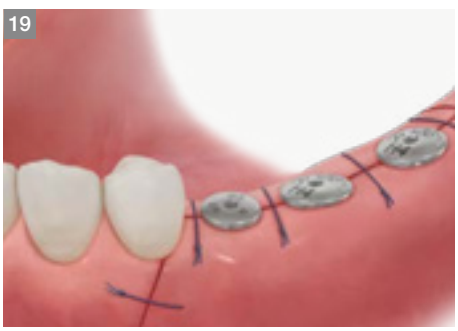
· Place Implant in 3 (Mesial)

· Recommended RPM: Max. 50rpm

Assemble healing Abutment

· Consider the type of Abutment to be fastened, then select the diameter and height of the healing Abutment and use a 1.2 hex hand driver to tighten it.

· Recommended tightening torque: 5~8Ncm



Suture

· Suture so that soft tissue is not exposed to strong tension.

· In some cases, suture after releasing incision or GBR.

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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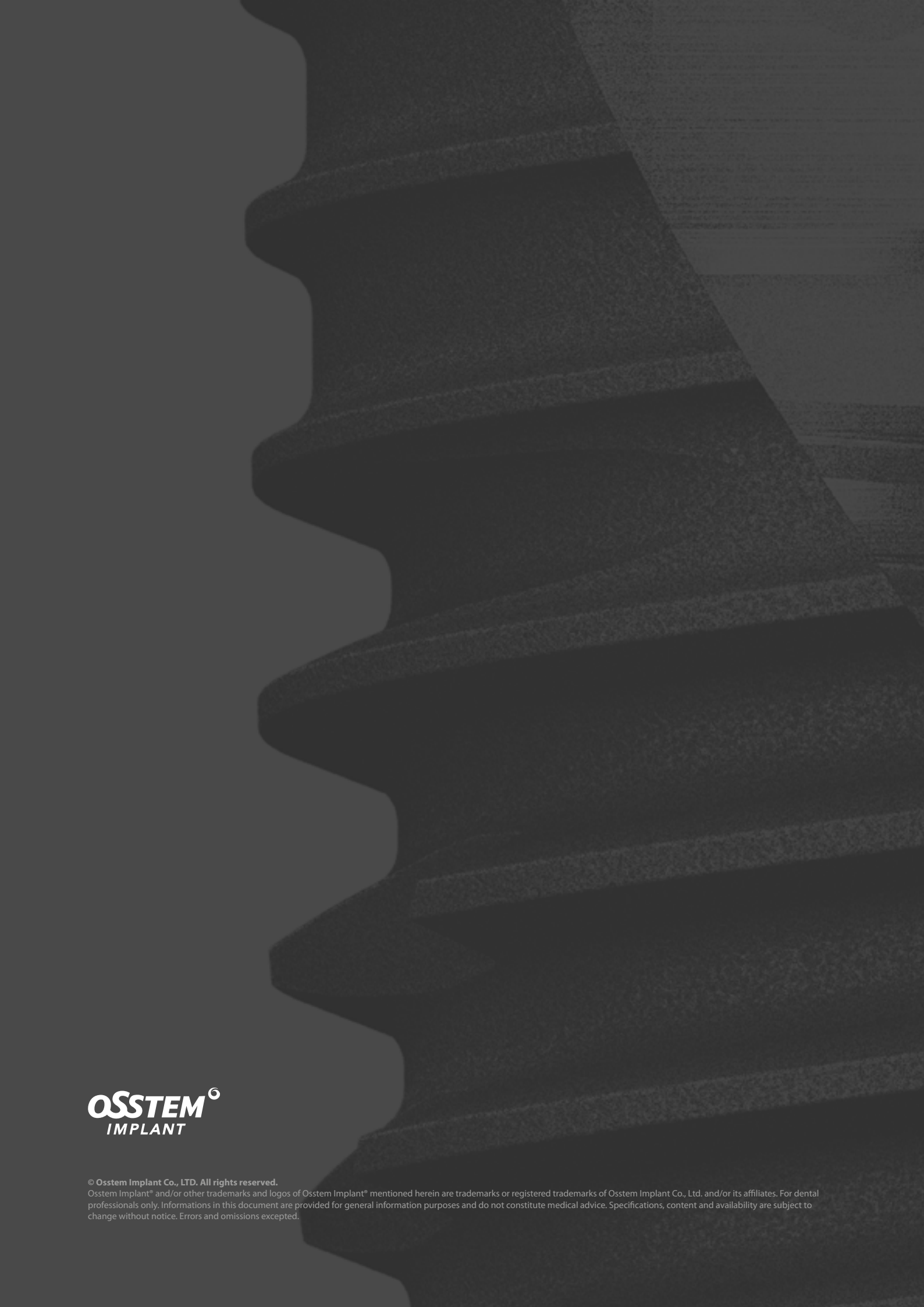

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