OSSTEM IMPLANT

Surgical Manual

EIR 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

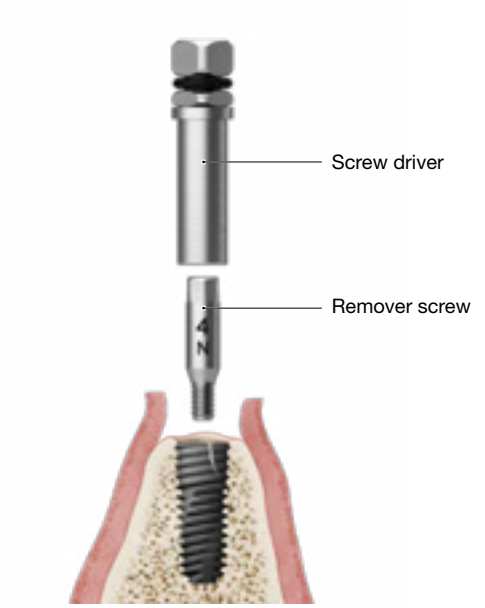
Publication date: April 2026

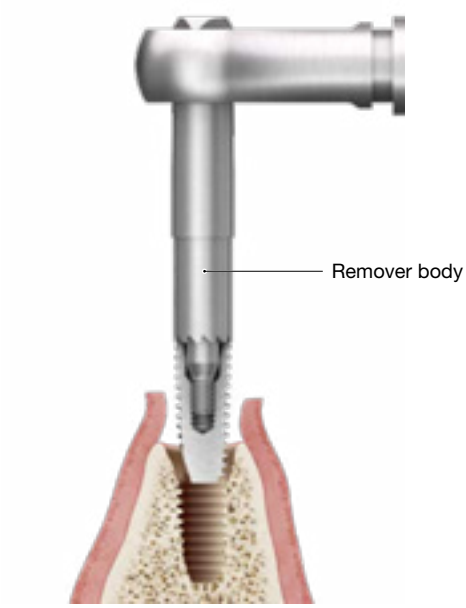
Publisher: Osstem Europe s.r.o.
Radlická 740/113c
158 00 Prague, Czech Republic

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.*

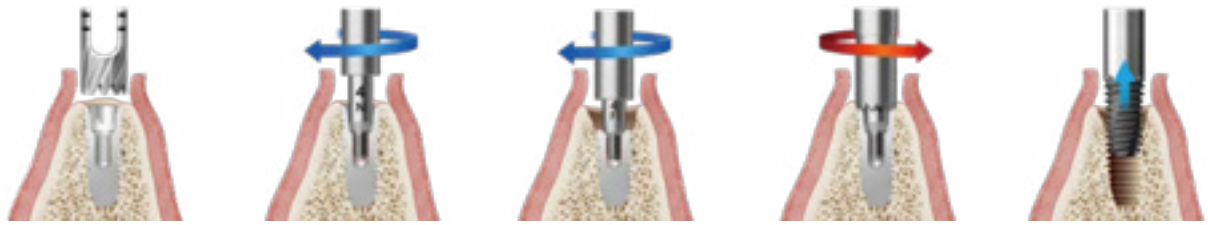
EIR KIT

**When the problematic Implant can no longer be used,
the EIR KIT can easily remove it without causing bone loss**





Simple and fast two-step removal



Trephine drill | Connect remover screw | Connect remover screw | Connect remover body | Remove Implant

case 1 Crack/partial fracture + Hard bone

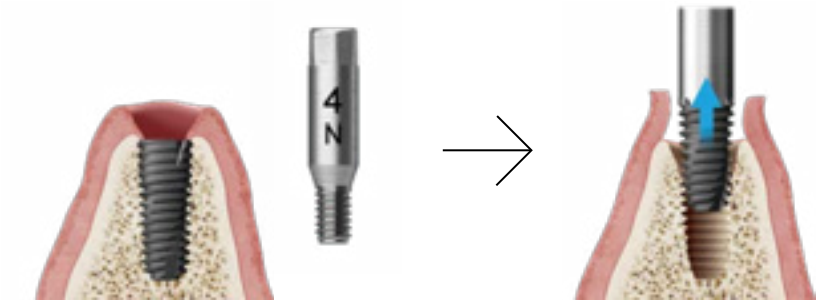
case 2 ❶ Crack/partial fracture + Normal bone / Hard bone ❷ Normal condition

case 3 Complete fracture up to the hex part (only the screw remains)

1 Indication

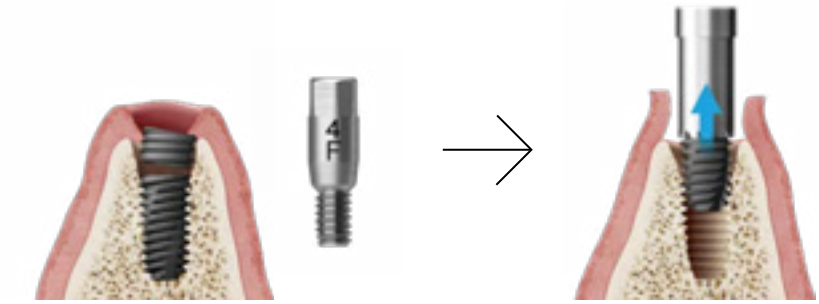
A Crack on the implant in the case of partial fracture

· ·Use the normal remover screw to remove the implant



B Complete fracture up to the hex part (only the screw remains)

· Use the fracture remover screw to remove the implant

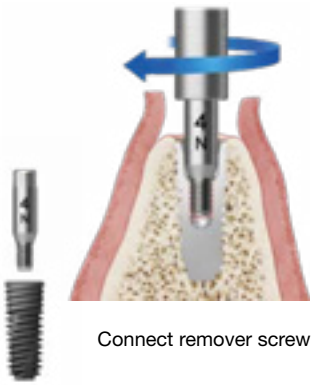


2 Feature

A How to remove implant in a simple and fast two-step

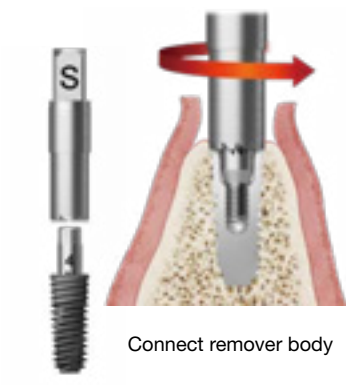
· Use the abutment removal tip-mini to remove the slipped screw hex

Step 1

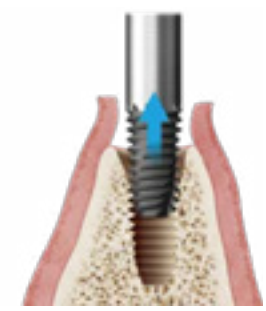


Connect remover screw

Step 2



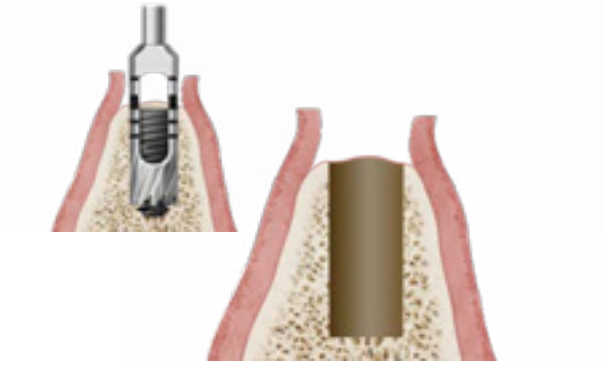
Connect remover body



Remove implant

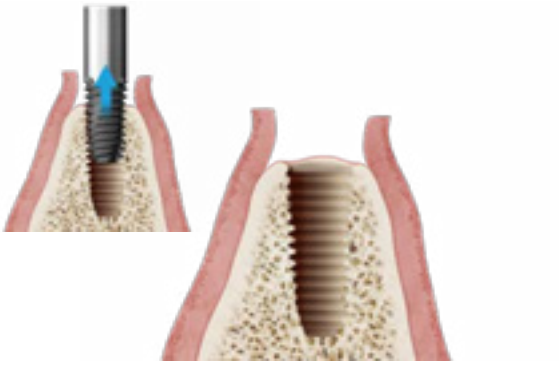
B Remove the implant without causing bone loss

When using the trephine drill



Cause bone loss as the bone is subject to removal
➡ It is not possible to place identical implant immediately after its removal

When using the EIR KIT



Does not cause bone loss because only the implant is removed
➡ It is not possible to place identical implant immediately after its removal

C Different remover screws depending on the implant condition

Check implantcon-dition

Crack Partial fracture

Hard bone

Select the remover screw

Connect the normal remover screw after using the trephine drill

Normal Crack Partial fracture

Normal / Soft bone

Connect the normal remover screw

Complete fracture up to the hex part (only the screw remains)

Connect the fracture remover screw

D Can also remove the osseointegrated implant

· The implant can be removed with the help of remover tool by applying the removal torque up to 400 Ncm

Implant diameter	Mini (Ø3.5)	Regular (Ø4.0~4.5)	Wide (above Ø5.0)
Reference removal torque	250Ncm	400Ncm	450Ncm

* In the case of exceeding reference removal torque, the cortical bone must be removed.

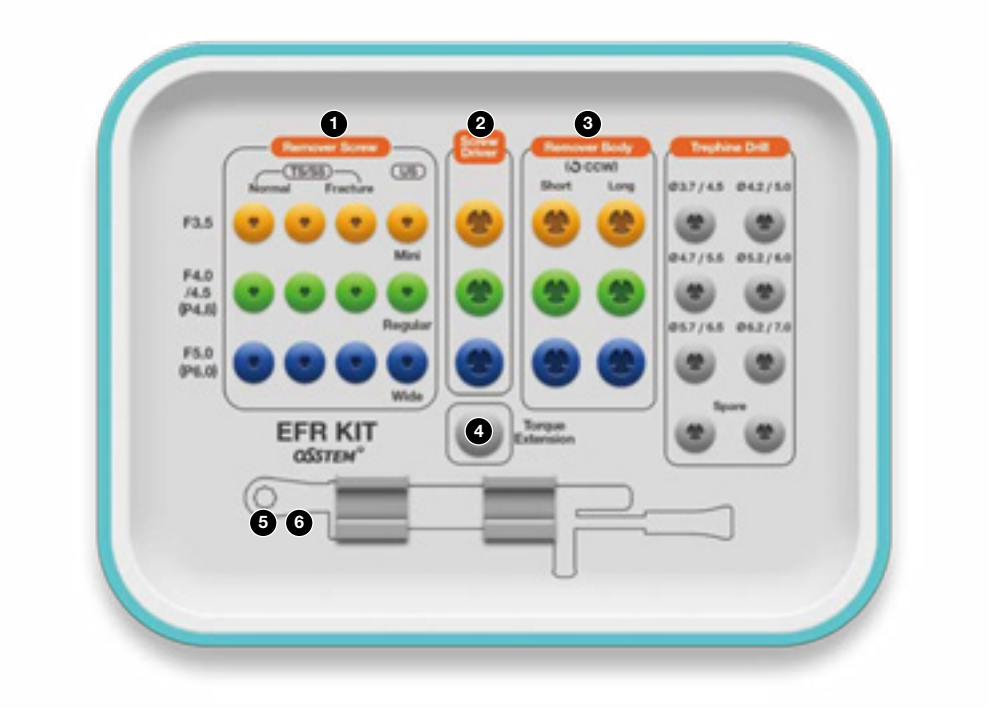
3 KIT components

EFR KIT

Select the remover screw and connecting tool (1, 2)

Select the remover body and connecting tool (3, 4)

Implant removal and separation tool (5, 6)



1 Remover screw

TS/SS

TS/SS

US

2 Screw driver

3 Remover body

4 Torque extension

5 Torque wrench

6 Implant wrench

4 A guide to using the KIT components

The KIT components consists of tools for connecting and fixing the implant and remover screw for removing the implant.

❶ **Remover screw**

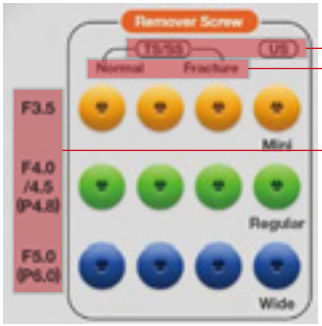
❷ **Screw driver**

❶ Remover screw

Remover screw is to rotate the remover body in counter-clockwise after connecting it to the implant

Directions for use

· Select a remover screw that matches the system (TS/SS; US), condition (normal; fracture), and diameter of the implant to be removed (EIR full KIT: compatible with products from 6 overseas companies).
· Connect to the implant .
· Reuse is prohibited because it is intended for single use.



Select system of the implant
Condition of the TS/SS implant
Select the implant diameter

Diameter of the implant
System and condition of the implant

For F4.0/4.5

[For TS/SS implant removal (normal)]
· When implanted in the incorrect direction
· When removal is necessary because of surrounding bone resorption
· When the hex part is normal but there is a crack or small fracture in the upper part

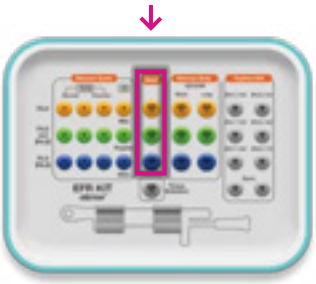
For F5.0

[For fractured TS/SS implant removal (fracture)]
· When the implant is fractured up to the inner hex part

For F3.5

[For US implant removal (US)]
· When the US implant of external type is placed in an incorrect place or problem such as cracks occurs in the upper part of the US implant

❷ Screw driver

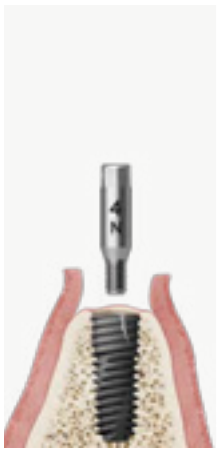


Screw driver is to fix the remover screw to the implant

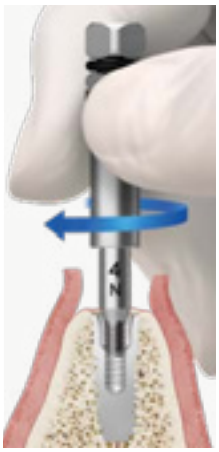
Guideline on how to use

· Select a screw driver based on the diameter of the implant to be removed.
· Connect it with the remover screw by hand and pre-tighten by rotating in clockwise.
· Apply torque in a clockwise direction using a torque wrench.
· The recommended tightening torque is as follows: regular/wide: 80 Ncm andmini: 60 Ncm.

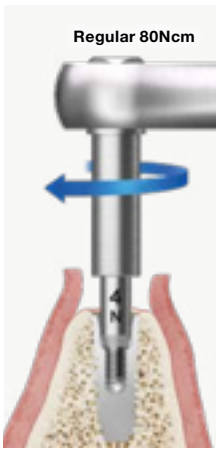
Yellow : for implant Ø3.5
Green : for implant Ø4.0–4.5
Blue : for implant 5.0 and above



Connect the remover screw to the implant



Pre-tighten using a screw driver by hand



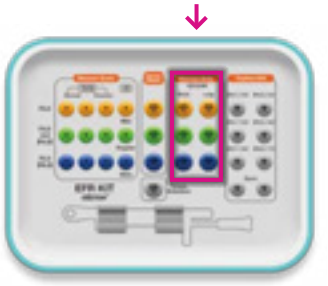
Connect using a torque wrench

The screw driver consists of tools for removing implant by connecting implant to the remover screw and applying binding force to the implant and tools for extending tool length.

❸ **Remover body**

❹ **Torque extension**

❸ Remover body

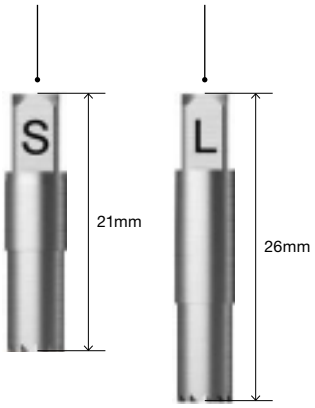


It is recommended to use to remove the implant by connecting the implant to the remover screw and applying binding force to the implant.

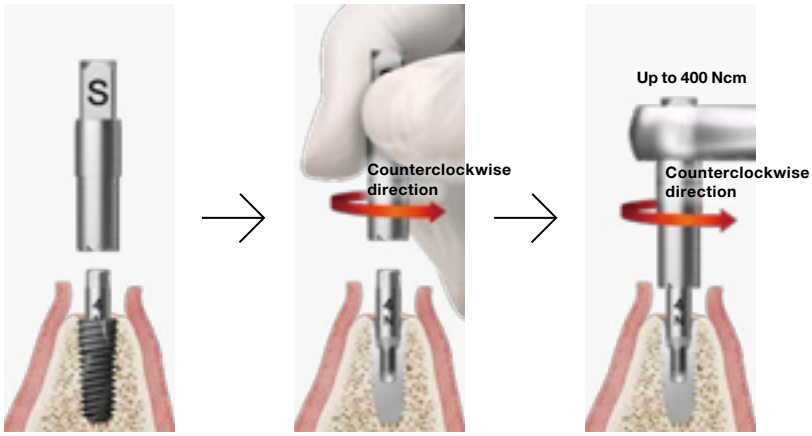
Guideline on how to use

· Select short/long specifications according to the distance from the antagonist teeth and interference with the proximal teeth.
· Select the remover body depending on the diameter of the implant to be removed.
· Connect remover body to the remover screw by hand and pre-tighten it by rotating counterclockwise.
· Apply torque in a counterclockwise direction using a torque wrench.
· Reuse is prohibited because it is intended for single use.

Yellow : for implant Ø3.5
Green : for implant Ø4.0–4.5
Blue : for implant 5.0 and above



Short Long



Connect the remover body to the remover screw

Using the remover body, pre-tighten by hand.

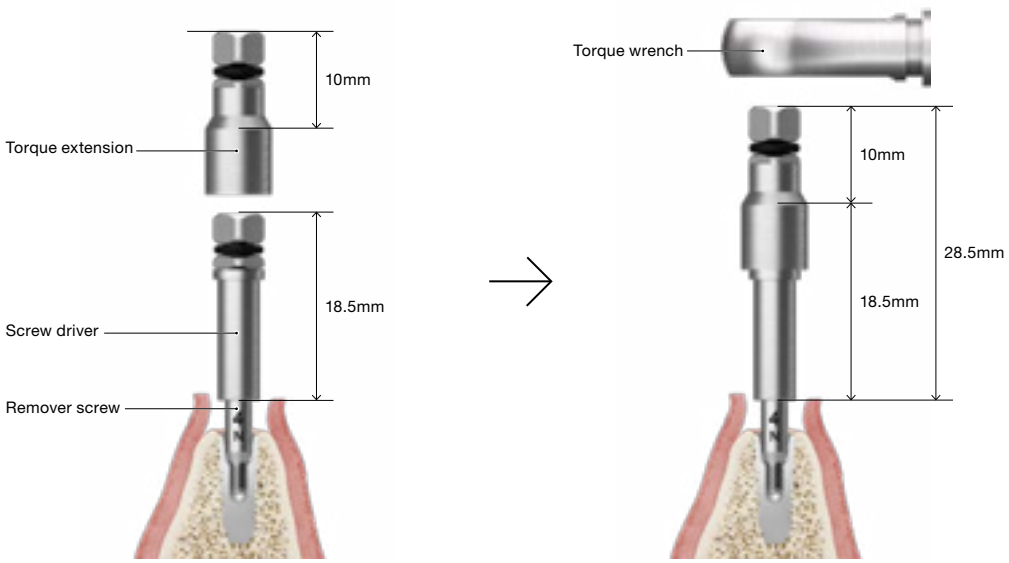
Connect using a torque wench

❹ Torque extension

Use it when extending the length of the screw driver and remover body

Guideline on how to use

· If there is interference between the torque wrench and proximal teeth, extend the height by connecting to a screw driver or remover body.
· Can extend the height by 10mm



It consists of tools for applying force in removing implant and tools for separating the removed implant.

❺ **Torque wrench**

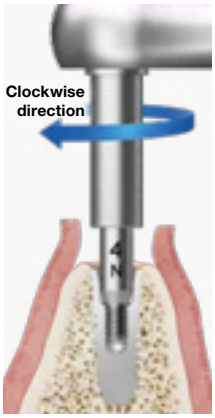
❻ **Implant wrench**

❺ Torque wrench

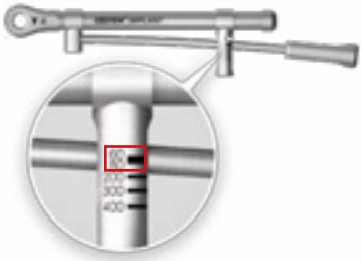
By pulling the bar, use it to apply torque to the instrument

Guideline on how to use

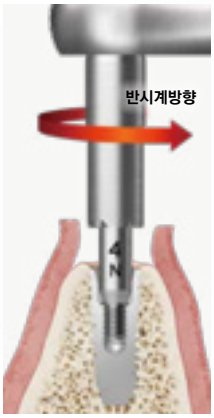
· When tightening or loosening, connect it to a screw driver or remover body.
· Apply torque by pulling the bar and aligning the center of the bar with the torque value to be applied.
· A maximum of 400-Ncm torque can be applied (60/80/200/300/400 Ncm scale displayed).
· It should be washed, sterilized, and stored after using it.

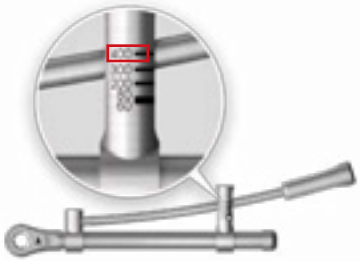


When connecting the remover screw



Tightening torque recommended for the remover screw
· Regular/wide: 80 Ncm
· Mini: 60 Ncm

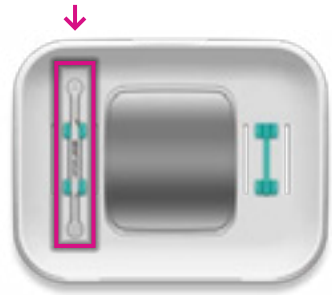




Connect the remover body; remove the implant

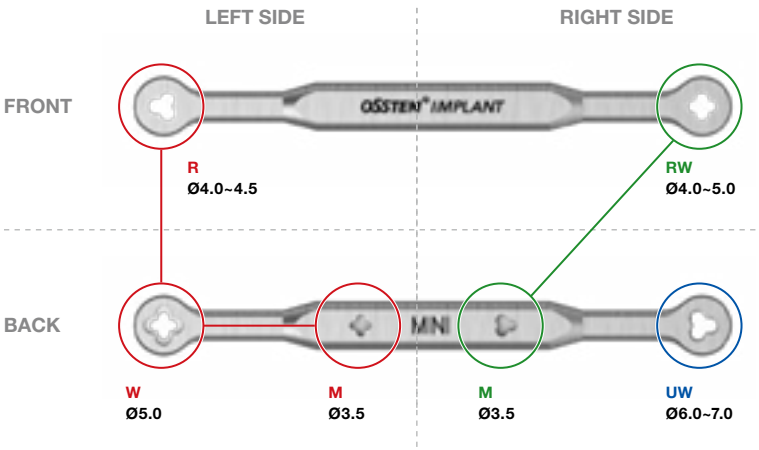
❻ Implant wrench

Implant wrench is to separate the implant from the remover tool after removing the implant.



Guideline on how to use

· Fasten the removed implant to the implant wrench hole
· Separate the remover tool from the implant.
(Refer to the following KIT sequence for the detailed sequence.)



For 3 cutting edges (M/R/W)

For 4 cutting edges (M/R/W)

For ultra wide (UW) implant

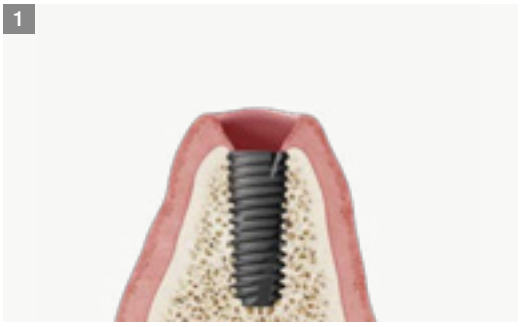
Fixed implant

5 KIT sequence

[Remove implant]

Ⓝ: Tool number

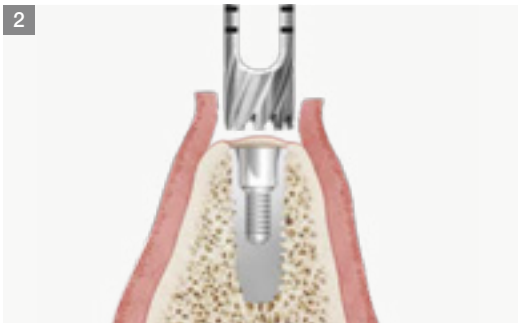
1



Check the implant condition

Normal | Crack | Partial fracture | Horizontal fracture up to the interior hex part (only the interior screw remains)

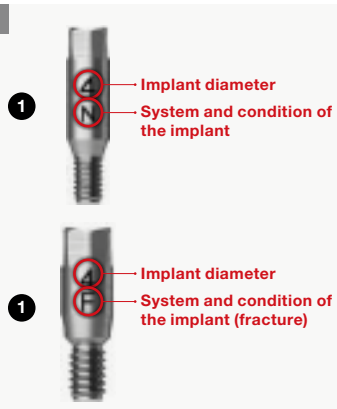
2



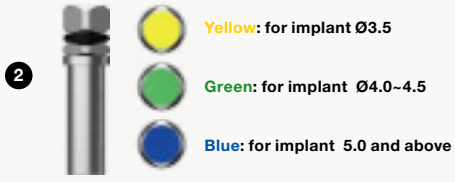
Remove the cortical bone if necessary
(trephine drill)

· Remove the cortical bone using the trephine drill to reduce the removal torque (approximately 3 mm).

3



Remover screw



Screw driver

Select the remover screw and screw driver

· Select a remover screw matching the system (TS/SS; US), condition (normal; fracture), and diameter of the implant to be removed.

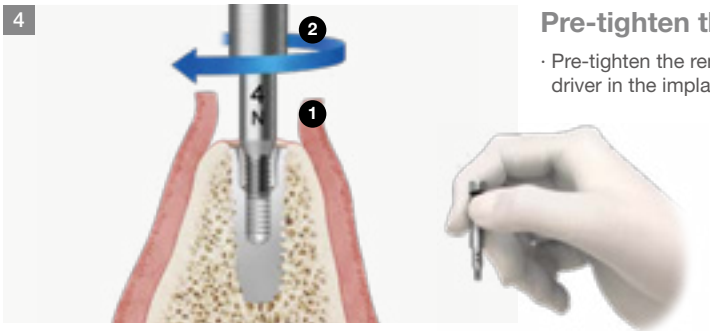
⇨ In the case of normal/crack/partial fracture: normal

In the case of a fracture up to the hex part: fracture

· Select a screw driver that matches the diameter of the implant to be removed.

· Connect the selected remover screw to the screw driver.

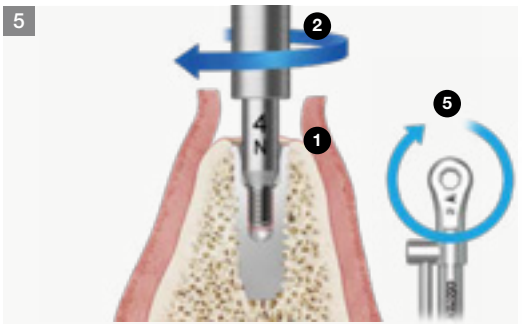
4



Pre-tighten the remover screw by hand

· Pre-tighten the remover screw by hand that is connected to the screw driver in the implant (rotate it in clockwise direction)

5

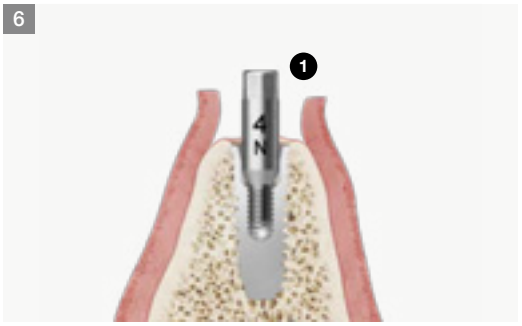


Connect the remover screw using the torque wrench

· Connect the torque wrench to the screw driver and apply force (clockwise direction).

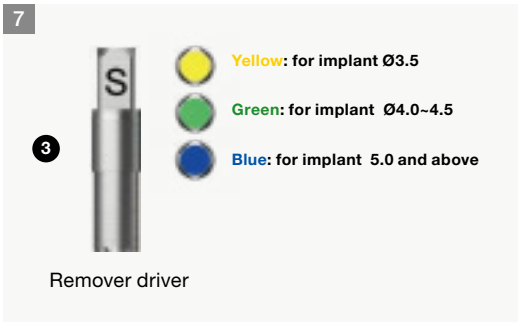
· The recommended tightening torque is 80 Ncm for Regular/Wide and 60 Ncm for Mini.

6



Remove the screw driver

7

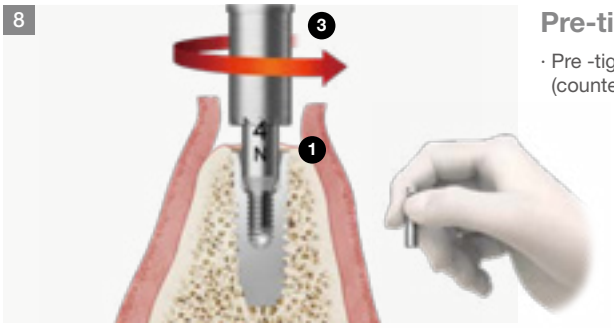


Remover driver

Select the remover body

· Select a remover body that matches the diameter of the selected implant.

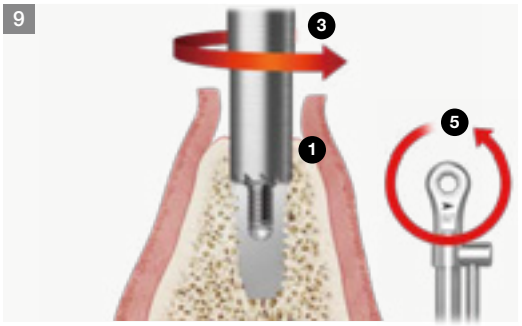
8



Pre-tighten the remover body by hand

· Pre -tighten the remover by hand to the remover screw (counterclockwise direction).

9

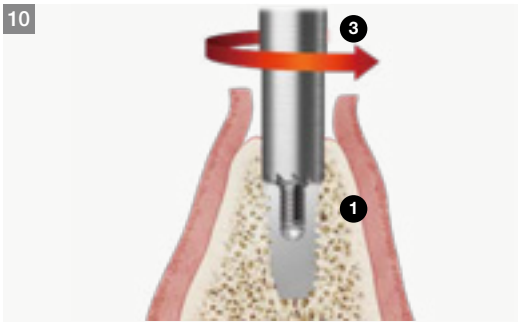


Connect the remover body using the torque wrench

· Apply torque (counterclockwise direction) after connecting the torque wrench to the remover body.

· A maximum of 400-Ncm torque can be applied.

10



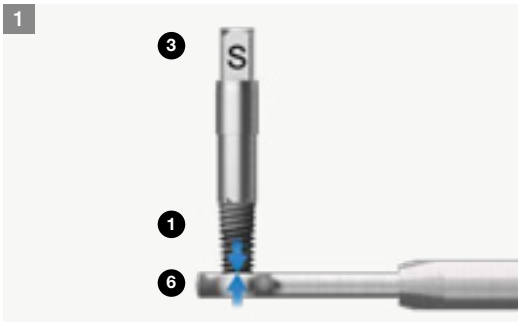
Remove the implant

· When applying torque, remove the implant using the binding force generated by the strong adherence of the implant and remover body (removed without bone loss).

[Separate the implant from the removal tool]

N: Tool number

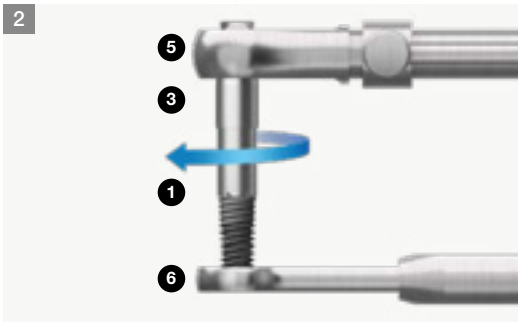
1



Fix the implant to the implant wrench hole

· Fix the removed implant to the implant wrench hole (fix to the hole that matches the number of cutting edges and diameter of theimplant).

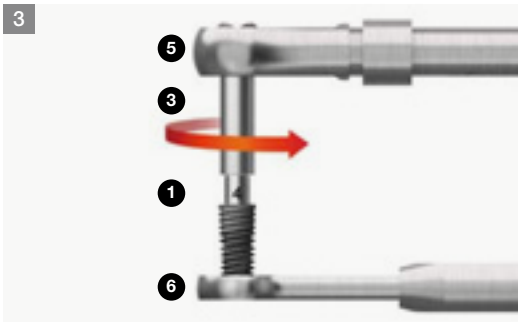
2



Separate the remover body with the torque wrench

· Separate by rotating clockwise after connecting the torque wrench to the remover body.

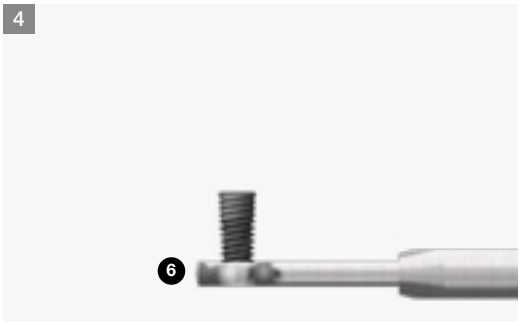
3



Separate the remover screw using the torque wrench

· Connect the torque wrench and separate by rotating counterclockwise after connecting the screw driver to the remover screw.

4



Separate the implant

· Separate the implant from the implant wrench.

· Because separation may be difficult depending on the degree of wear of the implant wrench, check the degree of wear and replace it with a new torque wrench.

Osstem

Type	Mode	Mini Ø3.5/ -	Regular Ø4.0~4.5/P4.8	Wide Ø5.0/P6.0
TS/SS	Normal	FRSM35	FRSR40	FRSW50
	Fracture	FRSM35F	FRSR40F	FRSW50F
US		FRSM35US	FRSR40US	FRSW50US
KS	Normal	KSFRSM35	KSFRSR40	KSFRSW50
	Fracture	KSFRSM35F	KSFRSR40F	KSFRSW50F

Nobel Biocare

Type	Mode	Mini Ø3.5	Regular Ø4.3	Wide Ø5.0/6.0
Active	Normal	FRSMNA35	FRSR40	FRSW50
	Fracture	FRSMNA35F	FRSR40F	FRSW50F
Replace	Normal	FRSMNR35	FRSR40	FRSW50
	Fracture	FRSMNR35F	FRSR40F	FRSW50F

Straumann

Type	Mode	Mini Ø3.3	Regular Ø4.1	Wide Ø4.8
Bone Level	Normal	FRSMS33	FRSRS41	FRSWS48
	Fracture	FRSMS33F	FRSRS41F	FRSWS48F

Astra

Type	Mode	Mini Ø3.5	Regular Ø4.0	Regular Ø4.5	Wide Ø5.0
Osseo Speed TX	Normal	FRSMNA35	FRSRA40	FRSR40	FRSW50
	Fracture	FRSMNA35F	FRSRA40F	FRSR40F	FRSW50F

3i

Type	Mode	Mini Ø3.25	Regular Ø4.0	Wide Ø5.0/P6.0
Full Osseotite Tapered Certain	Normal	FRSMI325	FRSRI40	FRSWI50
	Fracture	FRSMI325F	FRSRI40F	FRSWI50F

Zimmer

Type	Mode	Mini Ø3.7	Regular Ø4.1	Wide Ø4.7	Ultra-wide Ø6.0
Tapered	Normal	FRSMZ37	FRSRZ41	FRSWZ47	FRSWZ60
	Fracture	FRSMZ37F	FRSRZ41F	FRSWZ47F	FRSWZ47F

Biohorizons

Type	Mode	Mini Ø3.8	Regular Ø4.6	Wide Ø5.8
Internal	Normal	FRSRZ41	FRSWZ47	FRSWZ60
	Fracture	FRSRZ41F	FRSWB46F	FRSWB46F

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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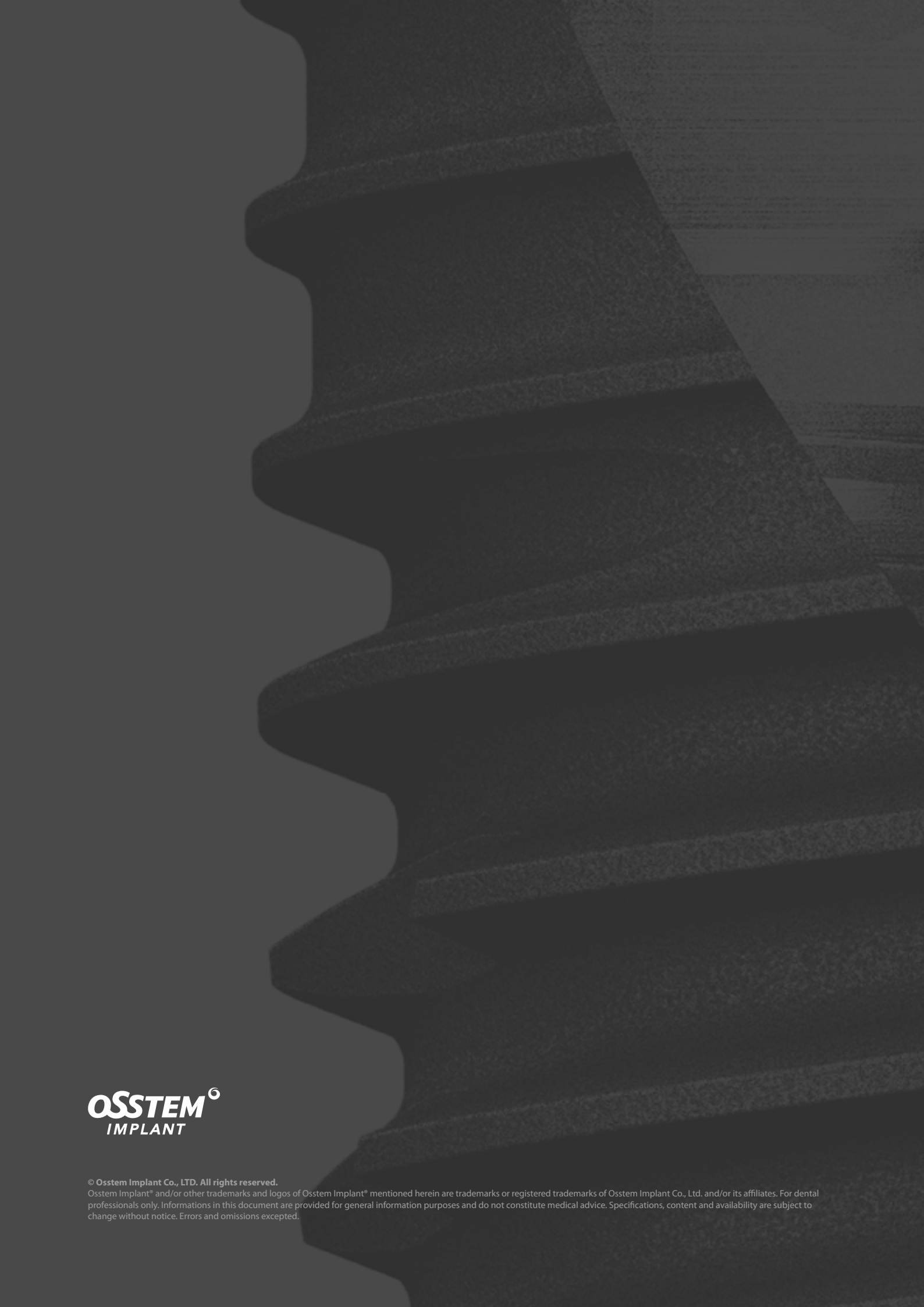

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