OSSTEM IMPLANT

Surgical Manual

Denture 4U 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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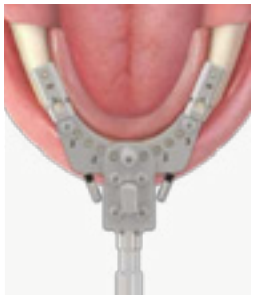
158 00 Prague, Czech Republic

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.*

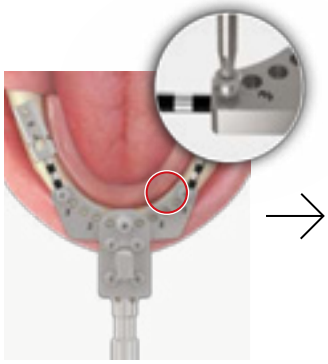
Denture 4U KIT

Osstem Fixed Denture Solution KIT that helps recover excellent masticatory force with only 4 to 6 implants

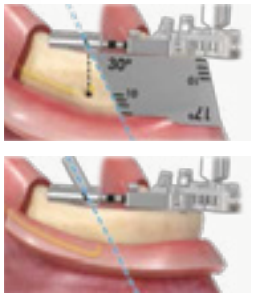
Level bone



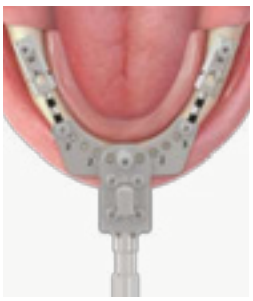
Fix anterior region



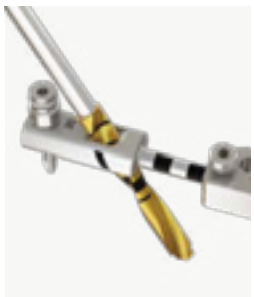
Adjust posterior guide



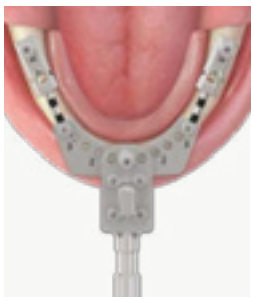
Check inferior alveolar nerve



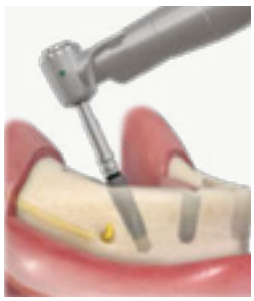
Fix posterior region



Drill posterior region



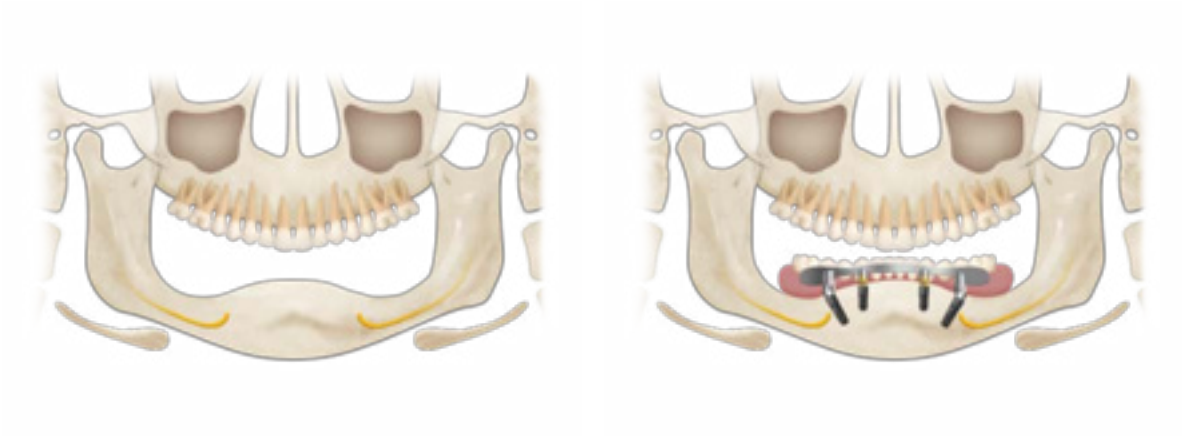
Drill anterior region



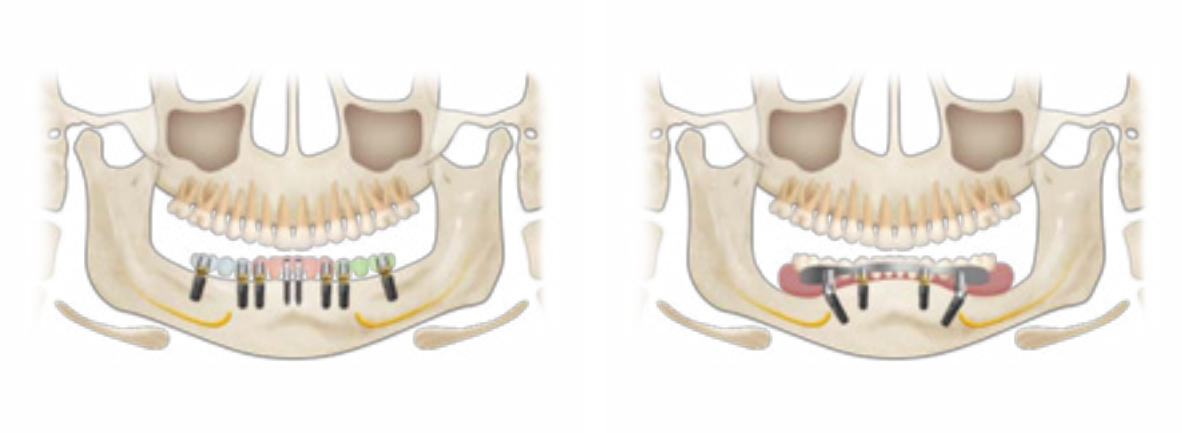
Place implant

1 Indication

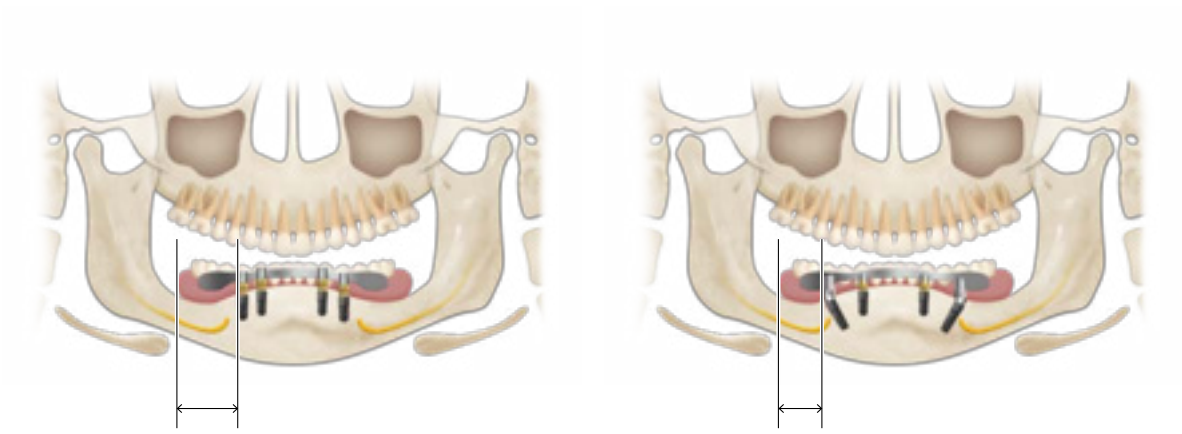
A When bone is sufficient in the anterior region but insufficient in the posterior region



B When restoring full mouth with only a small number of implants



C When reducing cantilever by placing the implant in an inclined manner



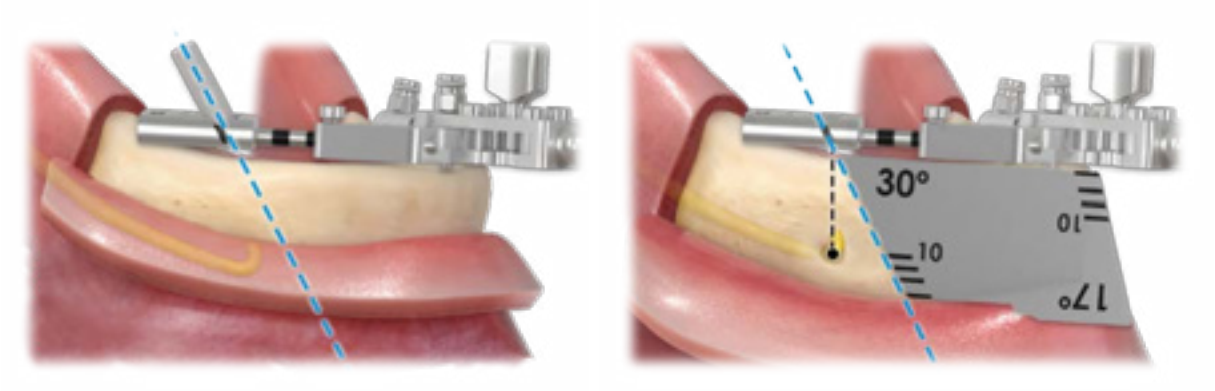
2 Feature

A 4~6 implants can be placed in a stable manner despite being tilted

· If the vertical bone mass is insufficient due to alveolar bone recession, the implant can be tilted for implantation. This Kit can be used in such cases since it provides a guide for safe drilling.

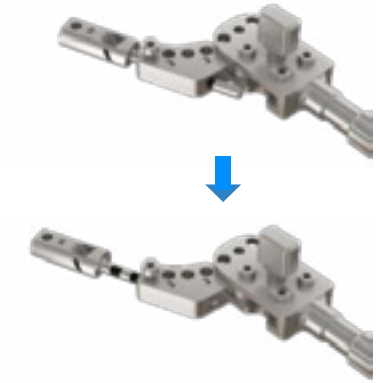
B Possible to check the position of the inferior alveolar nerve

· The position of the inferior alveolar nerve can be checked in flap or flapless surgery by using the indicator and path checker. This enables safer drilling.



C Can be placed according to the patient's arch

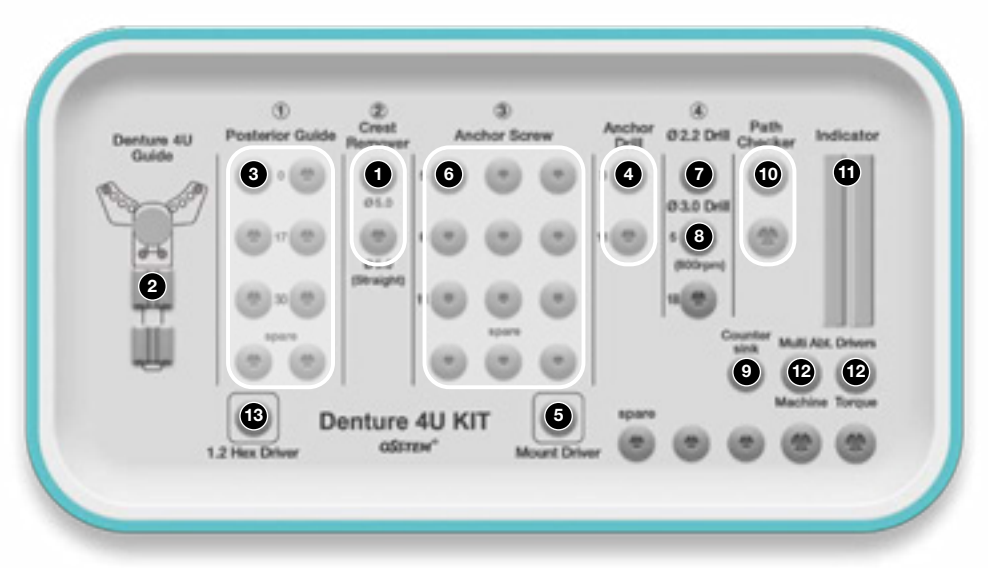
· Select/rotate guide and adjust to fit the patient's arch.



3 Tools of KIT

Denture 4U KIT

- Guide and drilling tool (1~9)
- Metal foramen position checking tool (10, 11)
- Abutment placement tool (12, 13)



1 Crest remover

2 Denture 4U guide

3 Posterior guide

4 Anchor drill

5 Simple mount driver

6 Anchor screw

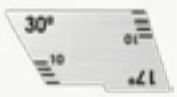
7 Guided initial drill

8 Twist drill

9 Countersink

10 Path checker

11 Indicator



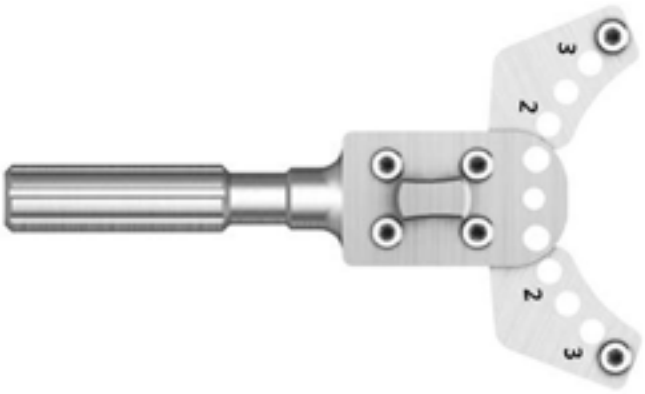
12 Multi abutment driver

13 Hand driver

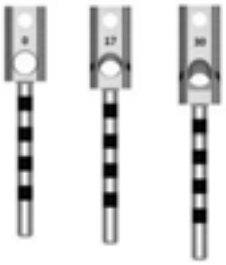
4 User guide for KIT

Includes tools for leveling the bone, a guide for deciding the placement position/direction/depth, and tools for drilling.

1 Crest remover



2 Denture 4U guide



3 Posterior guide

4 Anchor drill

5 Simple mount driver

6 Anchor screw

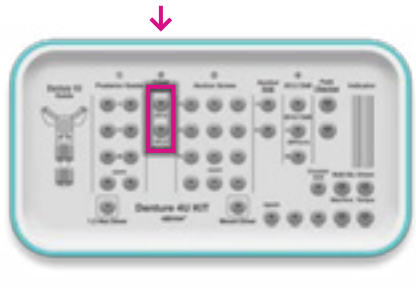
7 Guided initial drill

8 Twist drill

9 Countersink

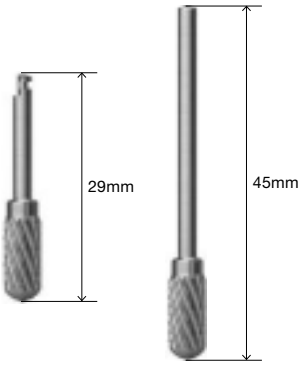
❶ Crest remover

Used for bone flattening during Denture 4U guide surgery.



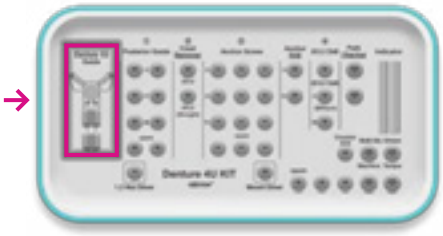
User guide

· Check narrow bone width.
· Select a handpiece.
· In case of an angle type handpiece, grind the narrow bone width at 1,200~1,500rpm.
· In case of a straight type handpiece, grind the narrow bone width at 15,000~30,000rpm.



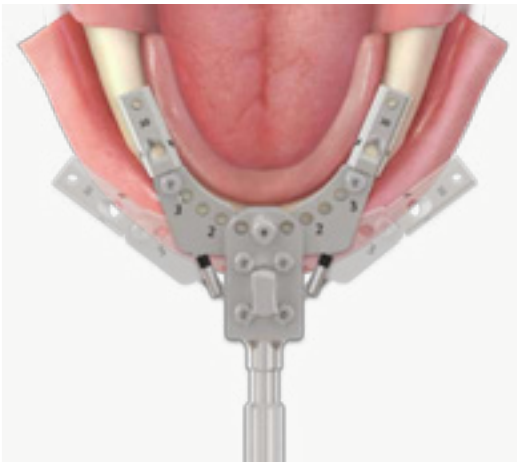
❷ Denture 4U guide

Guide for safe and accurate initial and intermediate drilling during Denture 4U surgery.

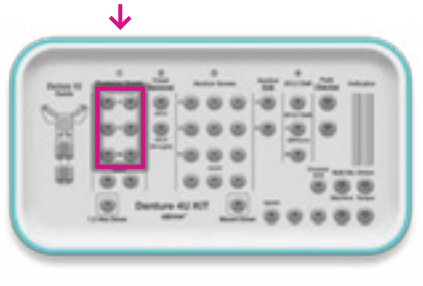


User guide

· Manually adjust the Denture 4U guide to fit the patient's arch.
· Fix the adjusted Denture 4U guide with a 1.2 hex hand driver.
· The shortest distance between the left and right first premolars is 31mm, and from that minimum distance, the guide can be rotated I outward direction up to maximum 30°.
· Left and right side can be adjusted independently.
· Denture 4U guide' handle is removable.



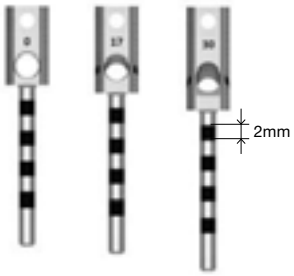
❸ Posterior guide

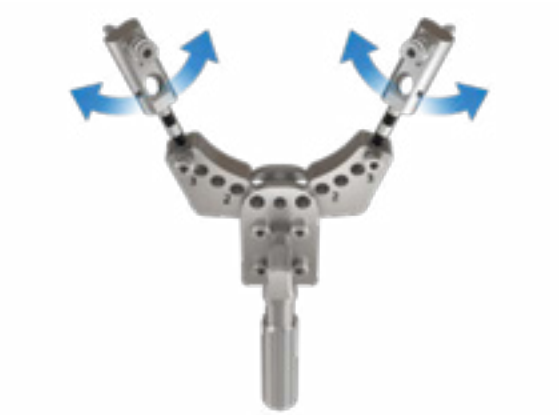


Is used for adjusting the implant placement position in
the posterior region and the angle of the buccal and lingual inclination.

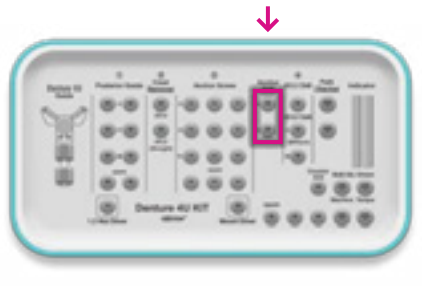
User guide

· Prior to surgery, pre-set the angle of the posterior guide using a CT scan.
· Prior to surgery, connect the anterior guide, and make sure the angle marking is visible.
· Connect the Denture 4U guide and the Posterior guide with a 1.2 hex hand driver.
· 0˚, 17˚, 30˚ specifications are available.
· The spacing of the marking lines on the rod is 2mm.
· Adjustable up to ±35˚ in the Buccal/lingual direction.





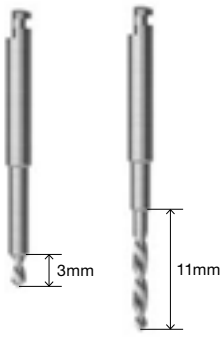
❹ Anchor drill



Used for forming a hole in the bone before fixing the anchor screw.

User guide

· Connect the Anchor drill to the handpiece.
· For soft bone, immediately place the anchor screw in the hole of
the Denture 4U guide.
· For normal and hard bone, first use a 3mm drill in the hole of
the Denture 4U guide as a guide drill, then drill with an 11mm drill.
· If the bone resorption in the posterior region is severe, drill with an 11mm drill.
· Drill at 800 rpm.

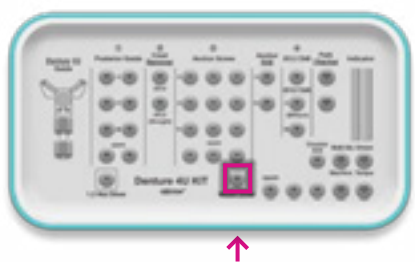


Placement with a 3mm Anchor drill

Placement with an 11mm Anchor drill

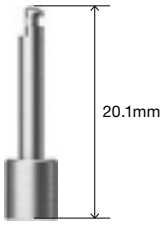
❺ Simple mount driver

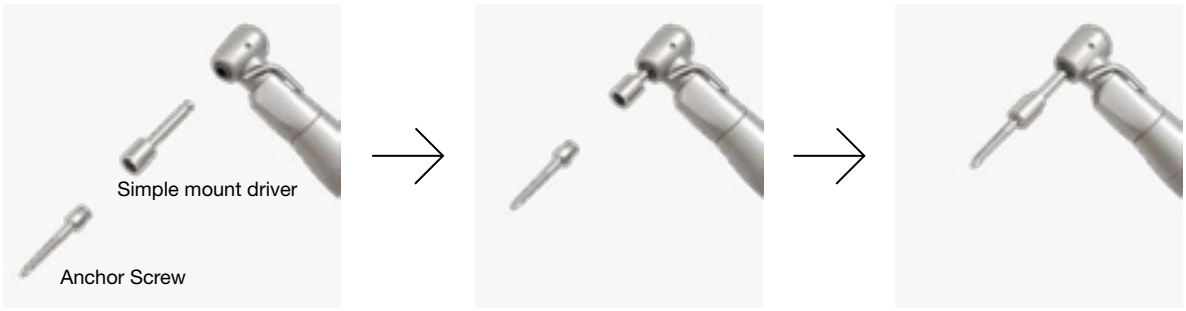
Use when placing anchor screws for stable fixation of the Denture 4U guide.



User guide

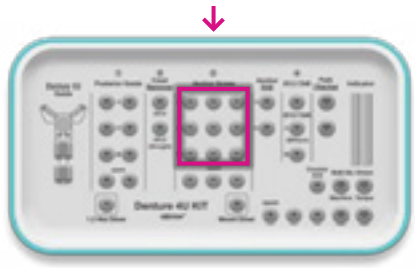
· Connect the simple mount driver to the handpiece.
· Connect the anchor screw.





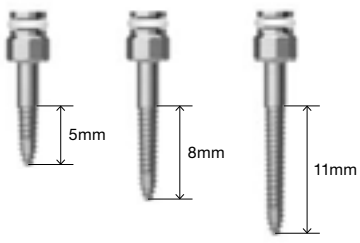
❻ Anchor screw

Used for fixing the center of the Denture 4U guide and the posterior guide to the alveolar bone in a stable manner.



User guide

· First, place an anchor screw in the midline area.
· Select an anchor screw of an appropriate length according to the degree of bone resorption in the posterior bone.
· In case the denture 4U guide is fixed in the anterior region, and the distance between the denture 4u guide and the alveolar bone in the posterior part is large, select 11mm specification.
· Be sure to stop the engine when it reaches the guide in order to prevent anchor screw from freespinning.
· Place at 50rpm.



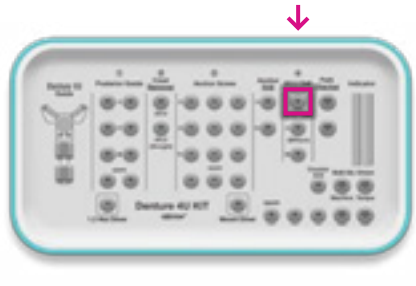
Fix in the anterior region with a 5mm anchor screw

Fix in the posterior region with a 5mm anchor screw

If alveolar bone resorption is severe in the posterior region, fix with an 11mm anchor screw.

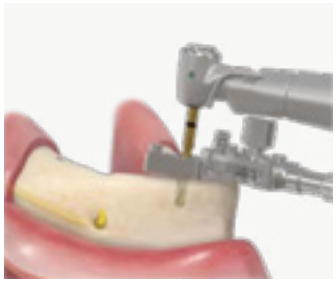
❼ Guided initial drill

Used for drilling in the anterior guide hole of the Denture 4U guide.



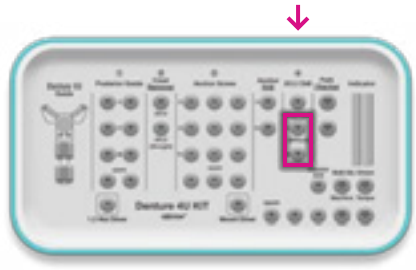
User guide

· Connect the guided initial drill to the handpiece.
· Select the anterior guide hole of the Denture 4U guide for the implant placement in the anterior region.
· Drill at 800 rpm.



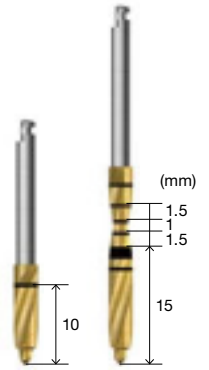
❽ Twist drill

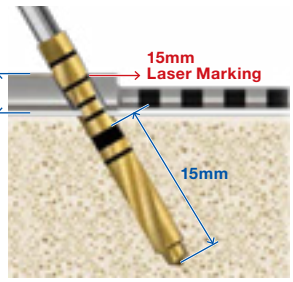
Used for drilling ierior guide hole. The angle of the twist drill and the marking line on the lateral side of the posterior guide need to be aligned when drilling.

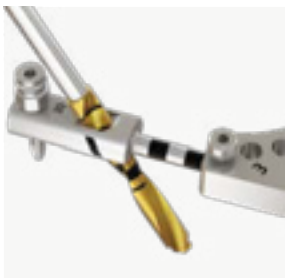


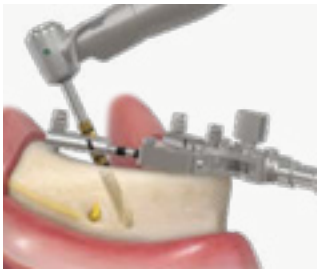
User guide

· Connect the twist drill to the handpiece.
· When drilling, slowly enter the guide hole and align the drill to the marking line on the lateral side of the posterior guide hole.
· To adjust the drilling depth, drill until the bottom part of the marking line that is visible from the mesial direction.
· When using a 0° guide or if there is interference from the antagonist teeth, drill with a 5mm drill first, then drill with the 18mm drill.
· Drill at 800 rpm.





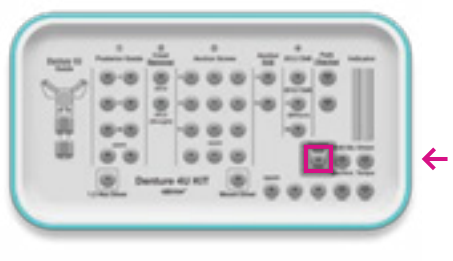




18mm drill assembled

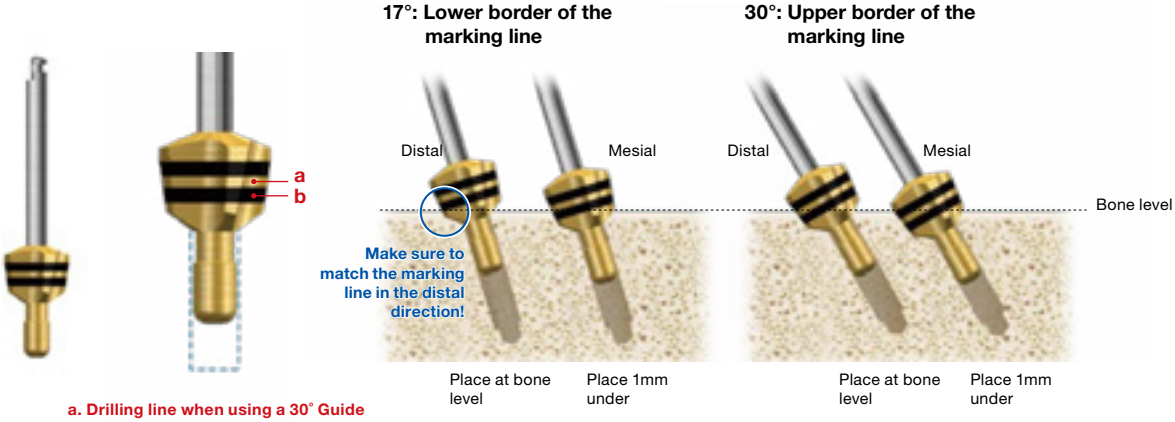
❾ Countersink

Used for preventing the Taper drills from stopping too early or for preventing interference from the prosthesis.



User guide

· Connect the countersink drill to the handpiece.
· When using the 30˚ guide, drill up to the second marking line.
· When using the 17˚ guide, drill up to the first marking line.
· When placing at bone level, drill until the bottom part of each marking line.
· When placing 1mm sub-crestal, drill until the top part of each marking line.

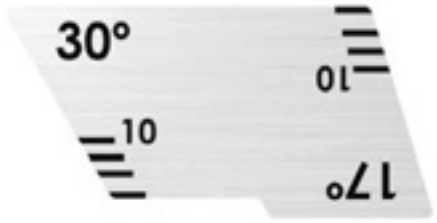


a. Drilling line when using a 30˚ Guide
b. Drilling line when using a 17˚ Guide

Guide and Drilling tool → **Metal foramen position checking tool** → Abutment placement tool

There are tools for checking the mental foramen, which is a key anatomical structure, when performing flap or flapless surgery.

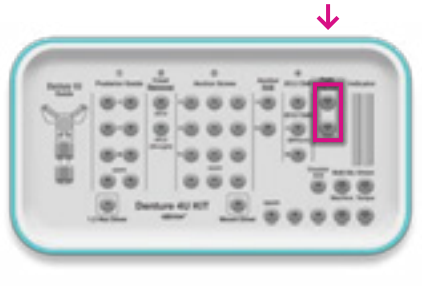
⑩ Path checker



⑪ Indicator

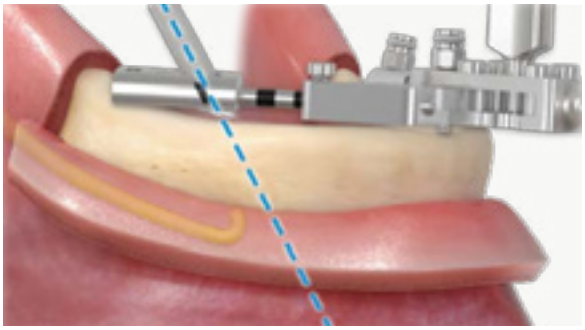
⑩ Path checker

Used for locating the mental foramen when performing a flapless surgery and use panorama or CT imaging.



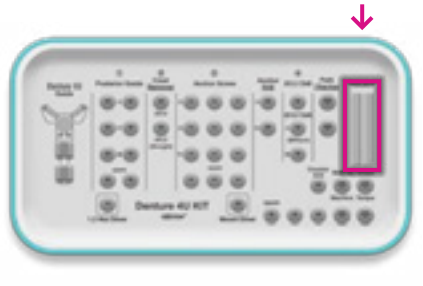
User guide

· Connect the Path checker to the drill hole.
· Check the drill path by taking a panorama or CT scan.
· If the drill path passes through the inferior alveolar nerve, readjust the position of the posterior guide.



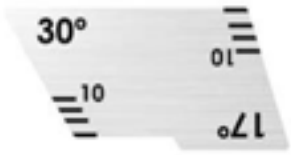
⑪ Indicator

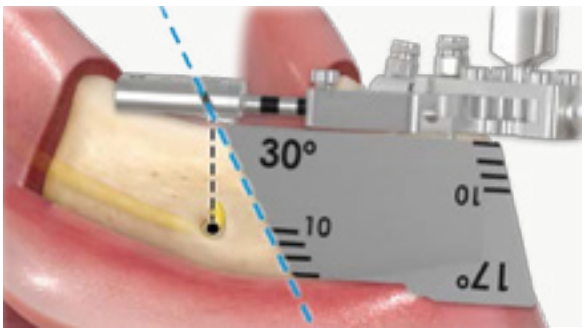
Used for checking location of the mental foramen in case the flap is opened.



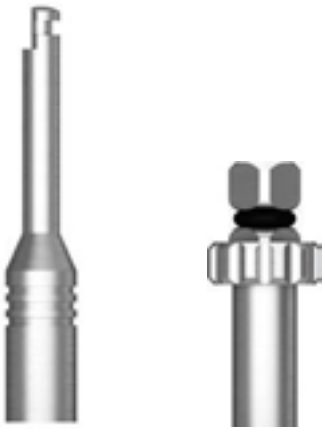
User guide

· Open the flap.
· Hold the indicator with a hemostat or needle holder.
· Put the Indicator next to the guide, and check the drill path with the correct angle specification.
· Check the drill path and change the implant placement position by adjusting the posterior guide if necessary.





Includes tools for placing multi abutments and multi angled abutments.

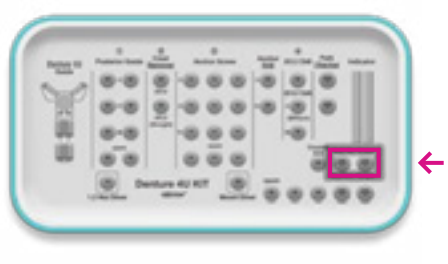


⓬ **Multi abutment driver**

⓭ **1.2 hex hand driver**

⓬ Multi abutment driver

Use to fasten multi abutment after surgery.

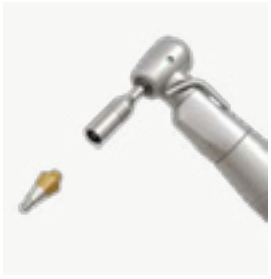


User guide

· Connect the multi abutment machine driver to the handpiece.
· Connect the multi abutment to the multi abutment machine driver.
· Place the abutment (torque: 30Ncm) in the oral cavity.
· When placing the multi abutment with the multi abutment outer driver, connect the abutment to the multi abutment outer driver and then place it with 30Ncm in the oral cavity.

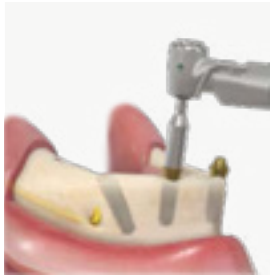
Multi abutment machine driver

Multi abutment outer driver



Multi abutment machine driver connected to the handpiece

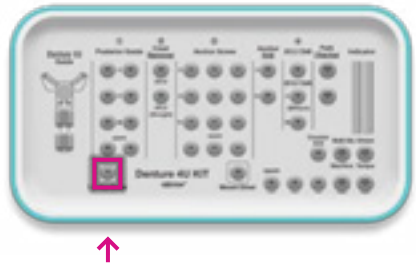
Multi abutment connected to the multi abutment machine driver



Placement in the mouth

⓭ 1.2 hex hand driver

Used for placing multi-angled abutments or cylinders after surgery, and for fixing the guide before surgery.



User guide

· Connect the multi-angled abutment to the oral cavity using a dedicated holder.
· Connect the multi-angled abutment dedicated screw to a 1.2 hex hand driver.
· Tighten at 20Ncm for Mini and 30Ncm for Regular.

5 KIT sequence

Normal bone **#33, #43 (TSIII diameter 4.0×10mm)**
#35, #45 (TSIII diameter 4.5×13mm)

Ⓝ: Tool number

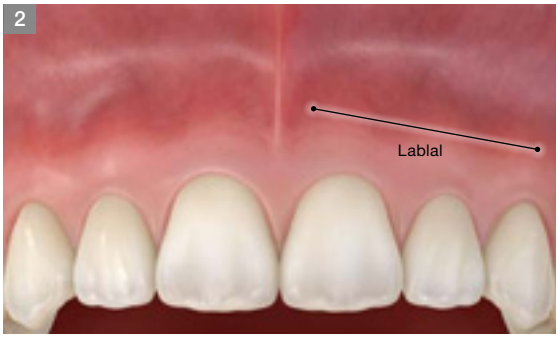
1

Bone leveler (Crest remover)

· Level bone with crest remover in order to better guide positioning

· Recommended use: Angled type: 1,200~1,500rpm
Straight type: 15,000~30,000rpm

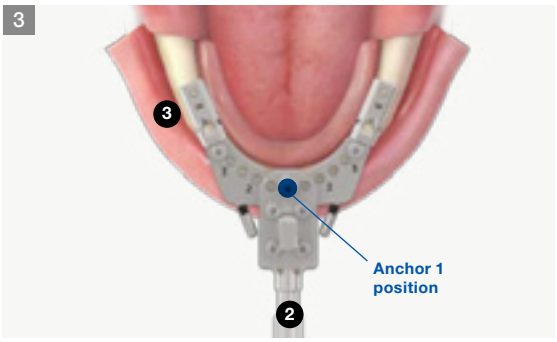
2



Set center position

· Check center position by referring to the labial frenum or midline of the nose/jaw

3



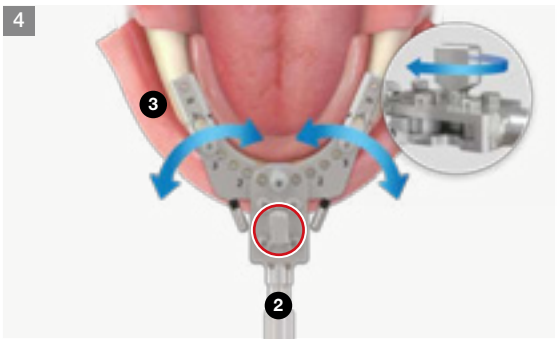
Fix at 1 point in the anterior region
(anchor drill & anchor screw)

· Fix with an anchor screw first, and then use an Anchor drill if the bone is too hard and the anchor screw cannot be placed.

· It is recommended to perform additional drilling with an 11mm drill after pre-drilling with the 3mm specification for the Anchor drill.

· Recommended use: 800rpm

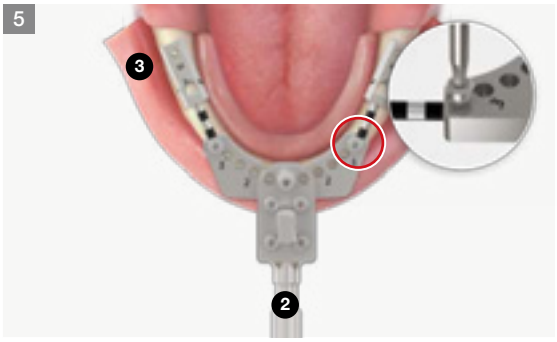
4



Adjust anterior guide (Denture 4U guide)

· After positioning the guide according to the patient's arch, fix it with a 1.2 hex hand driver.

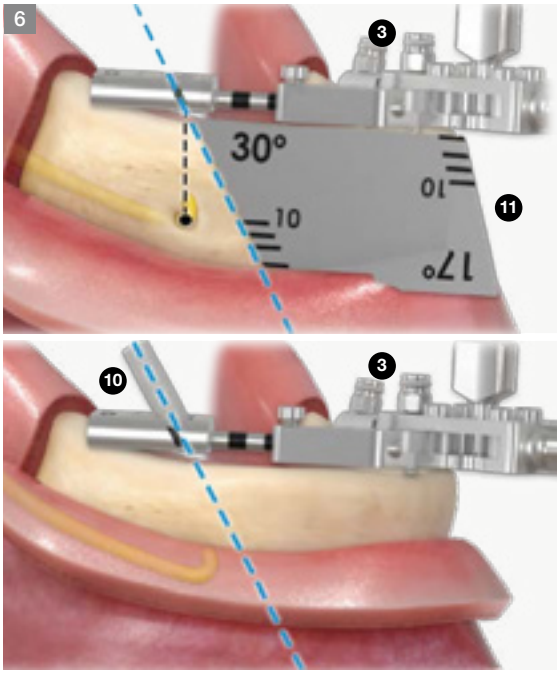
5



Adjust posterior guide (Posterior guide)

· Adjust the angle, distance, and buccal/lingual angle of the posterior guide and fix it to the Denture 4U guide with a 1.2 hex hand driver.

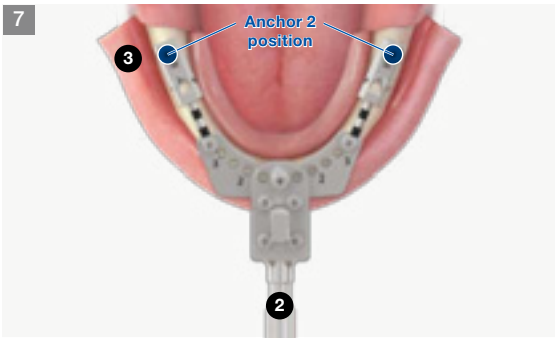
6



Check surgery safety (check inferior alveolar nerve)

· Use an indicator or path checker to identify the position of the inferior alveolar nerve for safe operation before drilling.

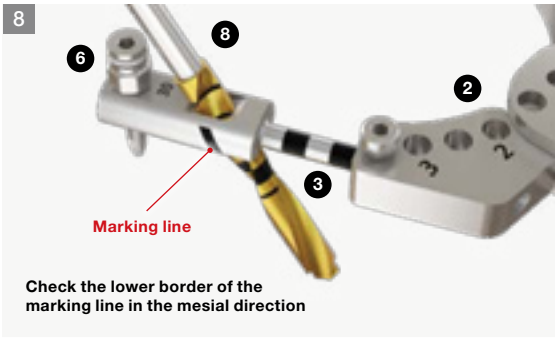
7



Fix posterior guide at 2 points in the posterior region (Anchor drill & anchor screw)

- Fix at 2 points with an anchor screw.
- Fix with an anchor screw first, then use an anchor drill if the bone is too hard and the anchor screw cannot be placed.
- It is recommended to perform additional drilling with an 11mm drill after pre-drilling with the 3mm specification for the Anchor drill.
- Recommended use: 800rpm

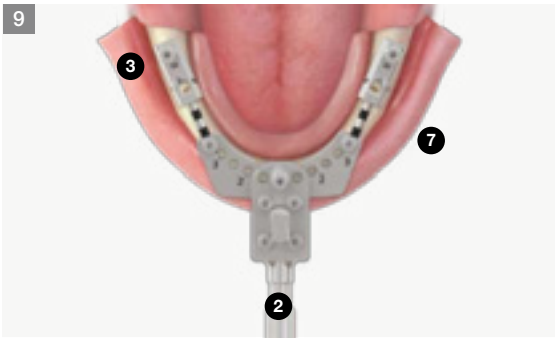
8



Posterior drilling (Twist drill)

- When drilling, slowly enter the guide hole by aligning the drill with the marking line on the side of the posterior guide hole.
- Recommended use: 800rpm

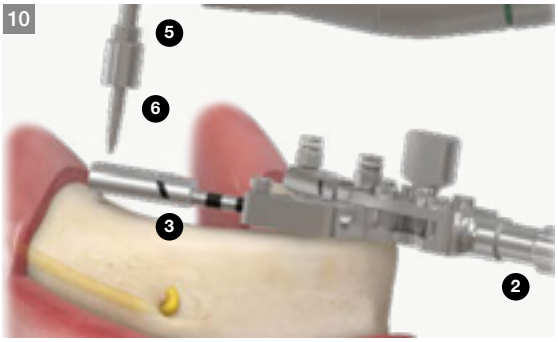
9



Anterior drilling (Guided initial drill)

- When drilling, slowly enter the guide hole by aligning the drill with to the marking line on the side of the Denture 4U guide.
- Recommended use: 800rpm

10



Remove anchor screw and Denture 4U guide

- Remove the anchor screw placed in the anterior and posterior regions by rotating them in reverse direction.

11

Countersink drilling (countersink drill)

· When using the 30˚ guide, drill up to the second marking line.
· When using the 17˚ guide, drill up to the first marking line.
· When placing at bone level, drill to the bottom of each marking line.
· When placing 1mm subcrestal, drill up to the top of each marking line.
· Recommended use: 800rpm

12

Drilling: #33, #43 (F3.5 taper drill)

· Recommended use: 1,200~1,500rpm

13

Final Drilling: #33, #43 (F4.0 taper drill)

· Recommended use: 1,200~1,500rpm

14

Drilling: #35, #45 (F3.5 taper drill)

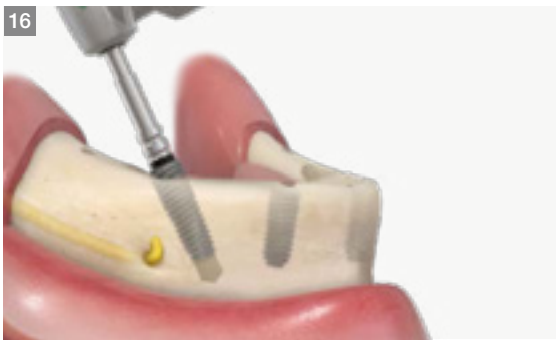
· Recommended use: 1,200~1,500rpm

15

Final Drilling: #35, #45 (F4.5 taper drill)

· Recommended use: 1,200~1,500rpm

16

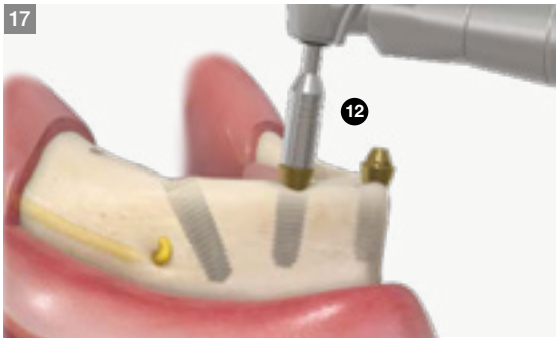


Place implant: #33, #43, #35, #45
(Nomount driver)

· Place up to 80% of the planned implant placement depth.

· Recommended placement torque: Max. 35Ncm

17

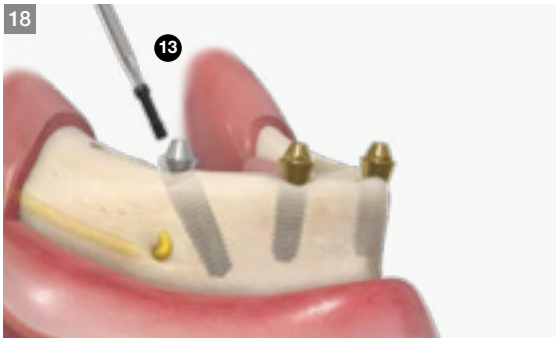


Assemble abutment (Multi abutment driver)

· Connect the multi abutment to the multi abutment machine driver.

· Recommended torque: Mini(20Ncm), Regular(30Ncm)

18



Assemble abutment (1.2 hex hand driver)

· Connect the multi-angled abutment dedicated screw to a 1.2 hex hand driver.

· Recommended torque: Regular (30Ncm)

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

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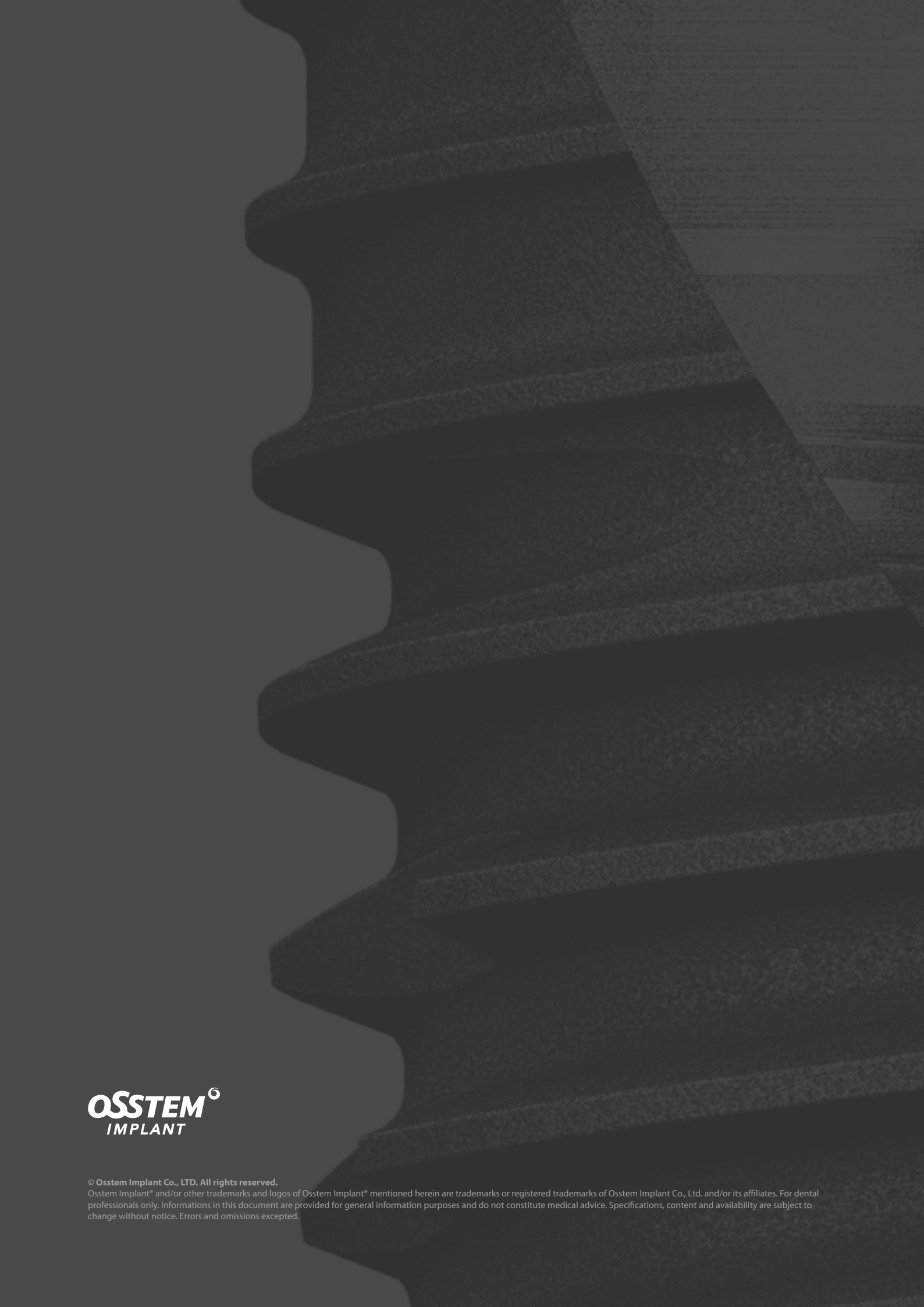

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