OSSTEM IMPLANT

Surgical Manual

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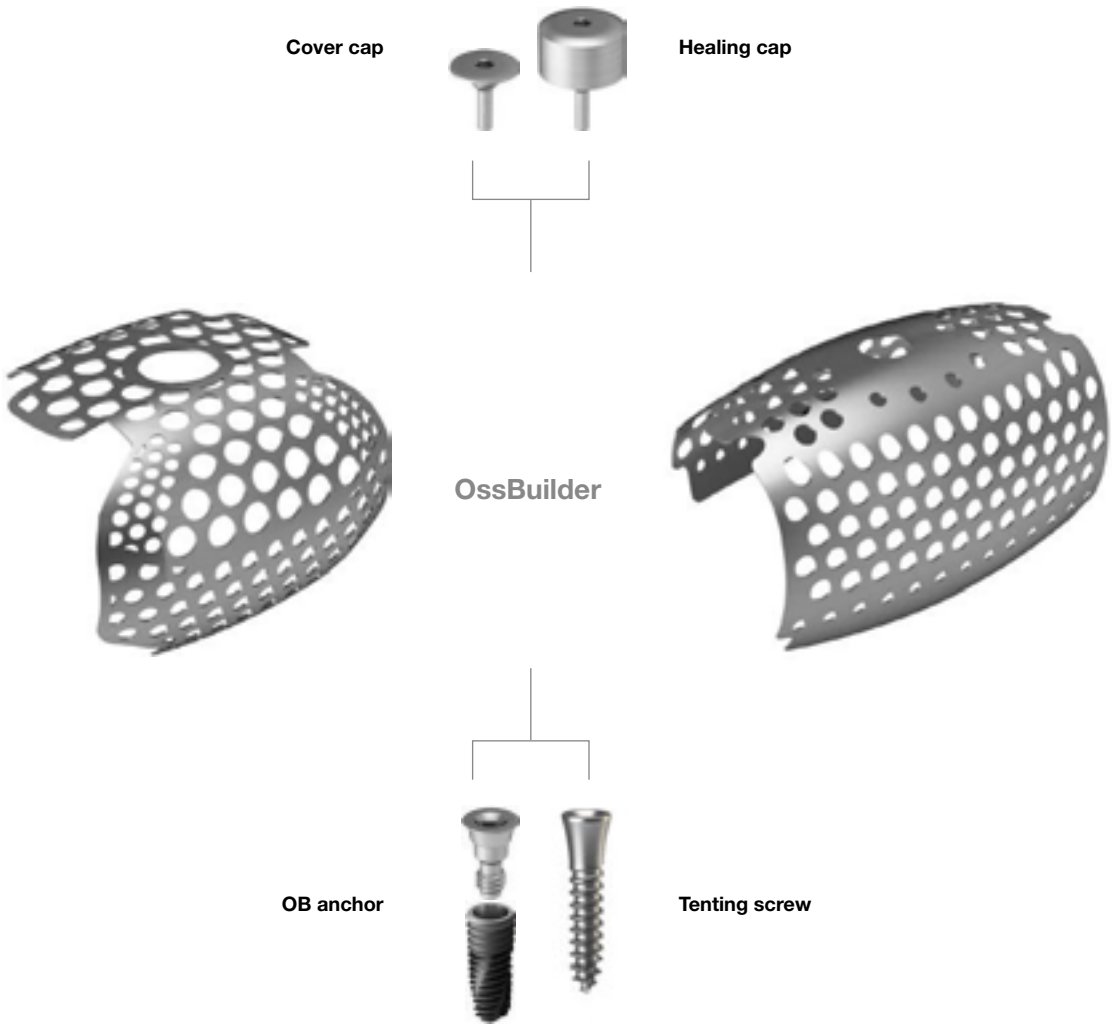
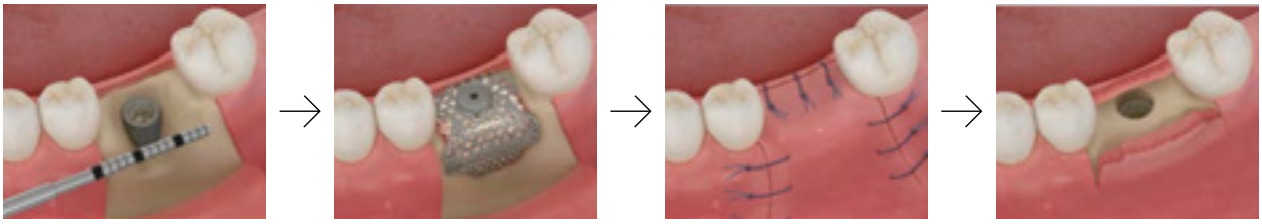
Note: *This brochure is based on the global 2021 Osstem Surgical Manual and has been visually revised and adapted for the European market. Product availability and specifications may vary by country and are subject to change without notice. Images are for illustrative purposes only. For professional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

OssBuilder KIT

KIT used to reconstruct the initial alveolar bone shape using OssBuilder (3D customized titanium membrane)





Bony defect

Bone graft and using the OssBuilder

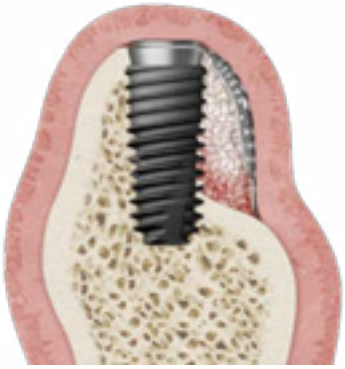
Suture

Bone generation

1 Indication

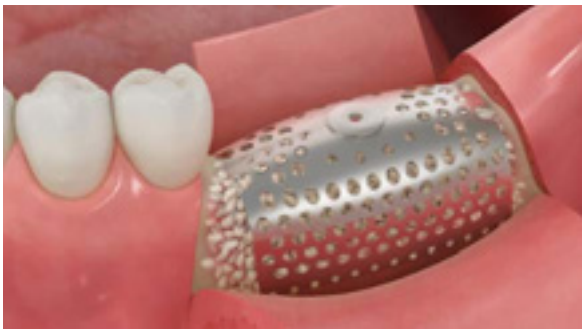
A When it is necessary to maintain space in the defective area

· Titanium material has an excellent capacity to retain volume, which helps protect the space from external pressure (narrow muscle, chewing force, tongue, etc.).



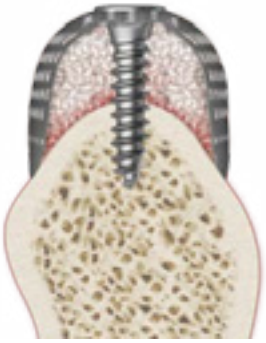
B When a significant graft is required

· Effective in cases where alveolar bone degeneration is severe and extensive alveolar bone reconstruction is required.



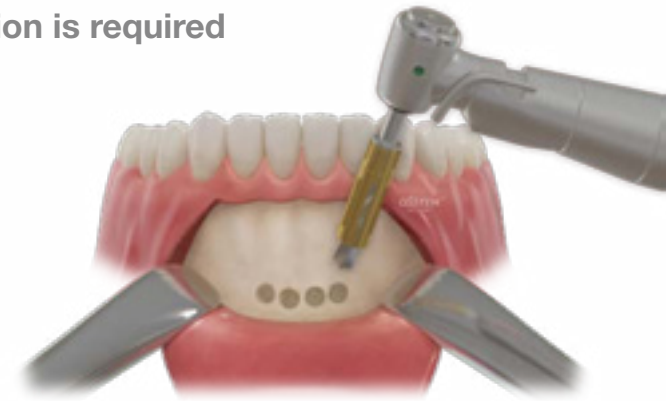
C For effective vertical bone augmentation

· Effective vertical bone augmentation is possible by using a tenting screw at the center of the alveolar bone.



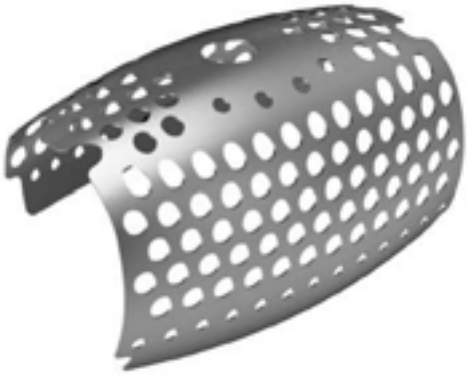
D When autogenous bone collection is required

· Includes a tool for autogenous bone collection (easier autogenous bone collection).



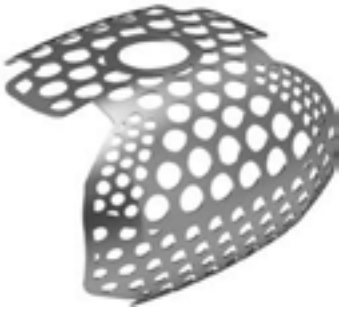
2 Feature

A KIT used for OssBuilder for quick operation without cutting or bending



3D custom titanium membrane

B KIT used for OssBuilder fabricated in various specifications according to the type of bony defect



OB 2 Lateral builder(15 types)

OB 3 Jaw builder(12 types)

C KIT used for OssBuilder equipped with autobone collector capable of autogenous bone collection

3 KIT (included components)

OssBuilder KIT

Defect measurement tool (1)

OssBuilder assembly and removal tool (2~9)

Autogenous bone collection tool (10~11)

1 Defect gauge gauge (bottom panel component)

2 Tenting screw drill

3 Stopper

4 Machine screw driver

5 Hand driver

6 Cover cap

7 Healing cap

8 OB anchor

9 Tenting screw

10 Autobone collector

11 Bone ejector (bottom panel component)

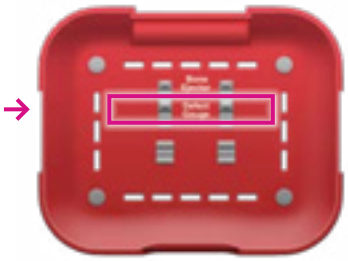
4 KIT user instructions

Includes a tool to measure the amount of bony defect.

1 **Defect gauge**

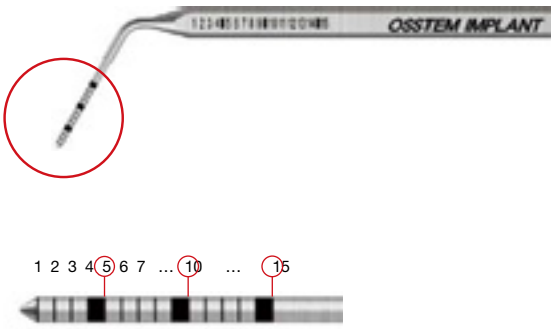
❶ Defect gauge

Use to measure the amount of vertical and horizontal defects in the bony defect.

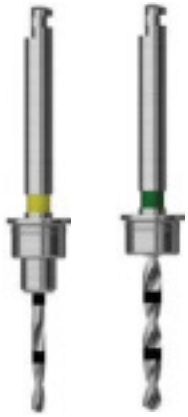


User instructions

· Check the defective area first.
· Marked in 1mm increments. Thick lines mean 4-5, 9-10, 14-15.
· Using a defect gauge, align with the defect area around the Implant.
· Accurately measure the defect amount of the defective part,
then select the appropriate OssBuilder specification.



Includes a tool used for fastening and removing a tenting screw used as a substitute for a Implant in case of insufficient bone mass or narrow bone width or OssBuilder, a titanium membrane.



❷ Tenting screw drill

❸ Stopper

❹ Machine screw driver

❺ Hand driver

❻ Cover cap

❼ Healing cap

❽ OB anchor

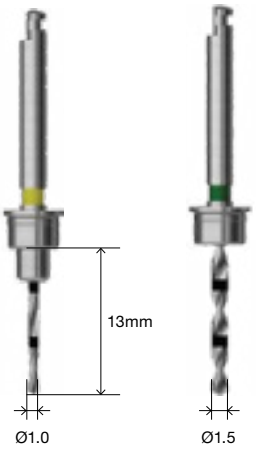
❾ Tenting screw

❷ Tenting screw drill

Use to install a tenting screw when it is difficult to install a Implant.

User instructions

· For soft/normal bone, select the Ø1.0 tenting screw drill. For hard bone, select the Ø1.5 tenting screw drill.
· Laser marking is marked with 1, 2, 3, 4, 5, 6, 7, and 8mm.
· Adjust the drilling RPM to 1,200~1,500 rpm.
· Assemble the stopper before drilling.



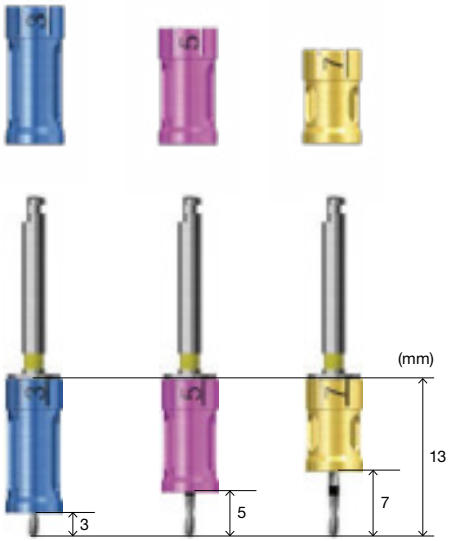
Soft / Normal bone Hard bone

❸ Stopper

Assemble with tenting screw drill

User instructions

· The number on the stopper means the length of the drill protruding when it is fastened to the drill.
· Assemble the stopper you want to use to the drill.



❹ Machine screw driver

Mainly used for installing/removing the tenting screw.

User instructions

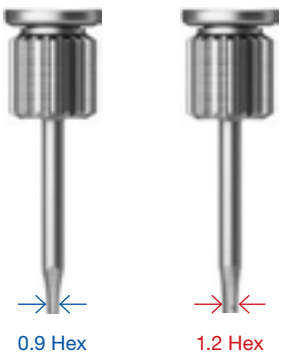
· 0.9 Hex is mainly compatible with internal type new OB components,
1.2 Hex is compatible with the old OB Components of external type.
· Set RPM to 25.
· Assemble to an engine to use.

❺ Hand driver

Use to assemble/disassemble OssBuilder accessories.

User instructions

· 0.9 Hex is mainly compatible with internal type new OB components,
1.2 Hex is compatible with the old OB Components of external type.
· Assemble by hand to use.

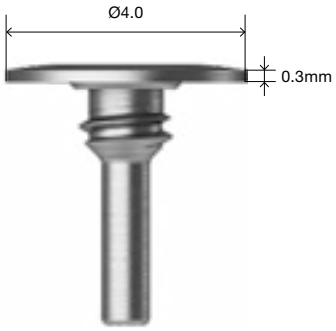


❻ Cover cap

Used to fix OssBuilder to the anchor.
Used when sufficient initial stability is required.

User instructions

· Assemble using a 0.9 hex hand driver.
· Use according to the recommended torque of 5~8Ncm.
· Disposable (reuse prohibited).

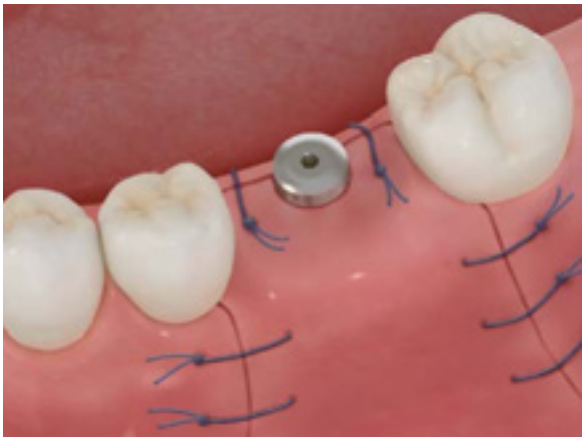


❼ Healing cap

Use to fix OssBuilder to anchor When soft tissue is insufficient / Used for gingival healing.

User instructions

· Assemble using a 0.9 hex hand driver.
· If soft tissue is insufficient, suture using a healing cap.
· Disposable (reuse prohibited).

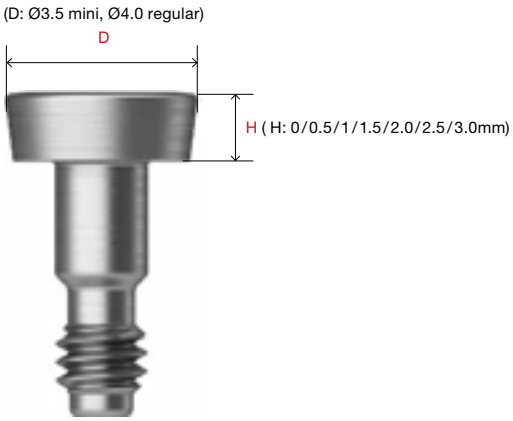


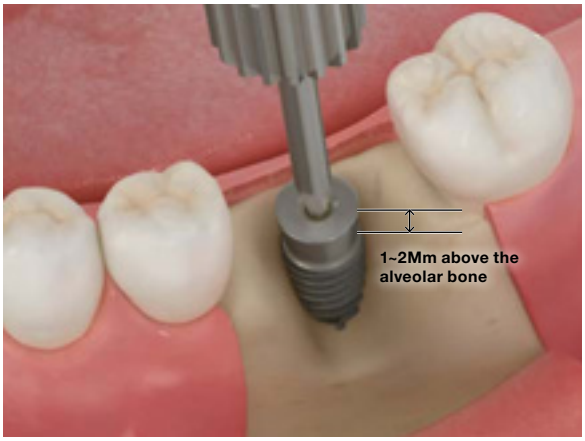
❽ OB anchor

Anchors the OssBuilder by fastening it to the Implant.

User instructions

- Depending on the type of TS Implant, choose from two types: mini/regular.
- Select according to the upper exposure height (H) of the Implant.
- If the implant is placed deep, select a specification that is 1-2 mm higher in the alveolar bone.
- Assemble the 0.9 hex hand driver to the OB anchor and then to the Implant.
- Disposable (reuse prohibited).



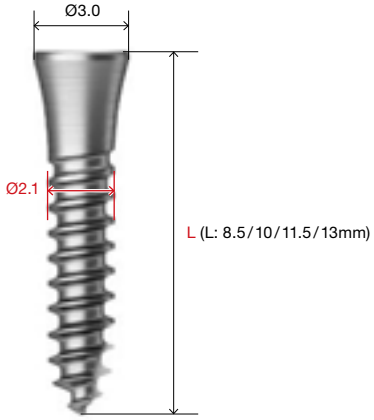


❾ Tenting screw

Use when vertical bone growth is required but Implant placement is difficult.

User instructions

- Assemble using a 0.9 hex torque driver.
- Use according to the recommended RPM is 35rpm.
- Disposable (reuse prohibited).



Includes a tool for collecting cortical bone or discharging the autogenous bone collected inside the stopper.

⑩ Autobone collector

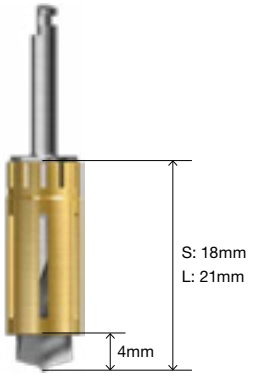
⑪ Bone ejector

⑩ Autobone collector

Autogenous bone collection tool

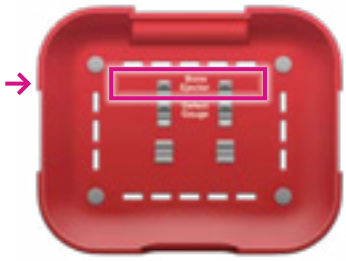
User instructions

· Assemble the autobone collector to the hand-piece.
· After fastening, insert the stopper.
· The stopper is fastened to the first-stage locking part. (recommended 300~600rpm)
· Drill by standing upright on the bone.
· Prepare the steel bowl.
· Slowly remove the stopper from the steel bowl.
· Autogenous bone is pushed out with a bone ejector.
· Acquire autologous bone.



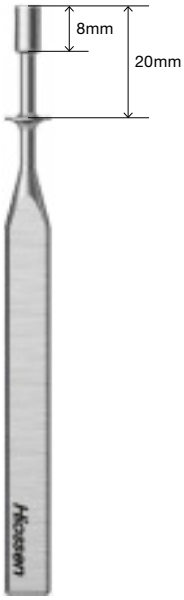
⑪ Bone ejector

A tool to help eject autogenous bone inside the autobone collector.



User instructions

· Remove the autogenous bone stored in the stopper using the bone ejector.



5 KIT sequence

[Assembly sequence] Use OssBuilder 2, 3 wall

Ⓝ: Tool number

Anesthetize after confirming the treatment site.

Drilling

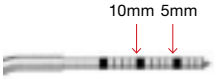
· Make an incision in the gingiva to check the bony defect, then drill according to the specifications of the Implant.

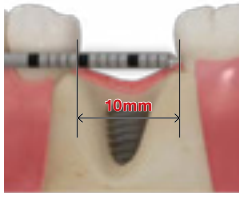
Place Implant (TSIII Ø4.5×10mm)

· Recommended RPM: 35rpm

Check proximal of the bony defect site (Defect gauge)

· Check the proximal length of the bony defect using a defect gauge.

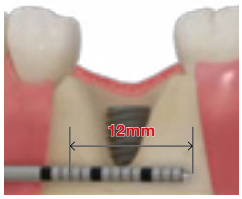




Proximal(P) 10mm

Check buccal width of the bony defect site (Defect gauge)

· Check the buccal width of the bony defect using a defect gauge.

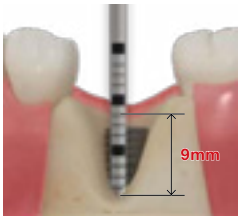


Buccal width(BW) 12mm

6

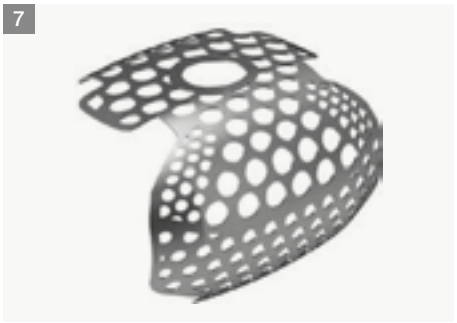
Check buccal length of the bony defect site (Defect gauge)

· Check the buccal length of the bony defect using a defect gauge.



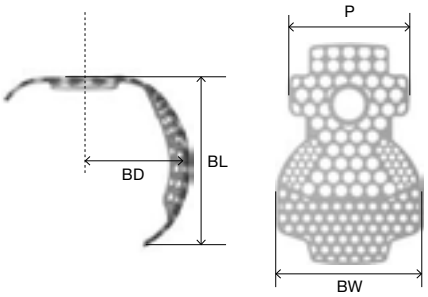
Buccal length(BL) 9mm

7



Select OssBuilder specification

· Select specifications based on measured dimensions.



3 wall augmentation

P (mm)	BW (mm)	BL (mm)	BD (mm)
7	9	7	5.5
7	9	9	5.5
10	12	7	5.5
10	12	9	5.5
12	12	7	5.5
12	12	9	5.5

P: Proximal
BW: Buccal width
BL: Buccal length
BD: Buccal distance
(space filled with bony material)

8

Assemble OB anchor (OB anchor)

· If the Implant is placed deeper than the adjacent bone, it is recommended to select a specification with a height (H) of the OB anchor that is 1-2 mm higher in consideration of bone resorption and tissue thickness.

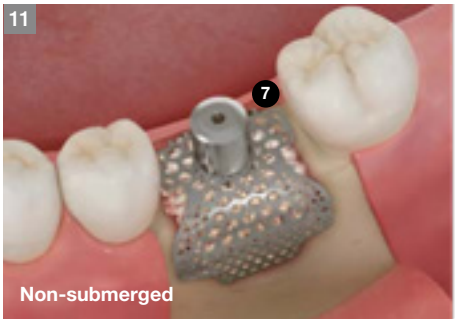
9

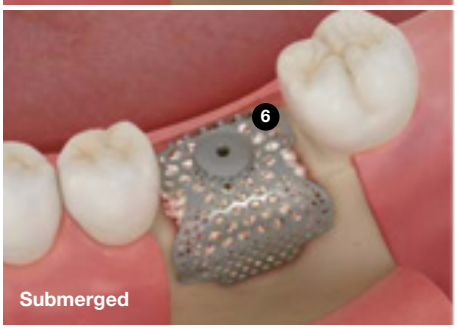
Bone graft in bony defect site

· Select a bone planting material according to the indication, then use it after soaking it in blood or saline sufficiently.
· Exercise caution not to let the corrugated material go into the OB anchor.

Assemble OssBuilder

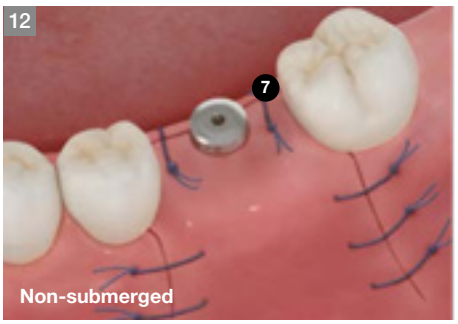
· Assemble OssBuilder on top of the OB anchor.

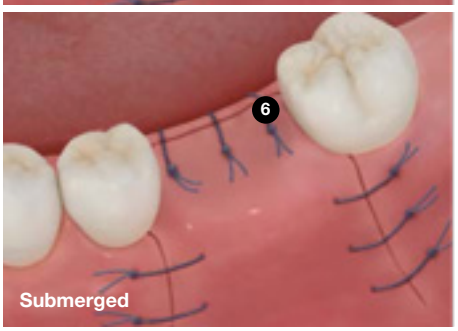




Anchor OssBuilder

· Non-submerged: Assemble healing cap
· Submerged: Assemble cover cap
· Use healing cap when primary closure is difficult due to lack of gingiva.



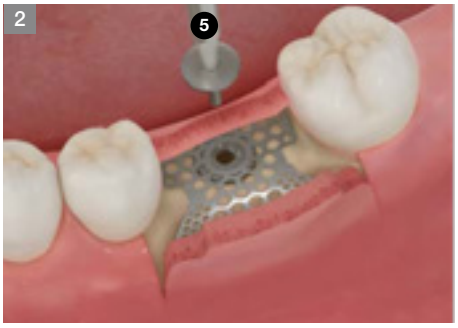


Suture

[Removal sequence] Remove OssBuilder

Ⓝ: Tool number

Make incision



Remove cover cap or healing cap

· Use a 0.9 hex hand driver.

Remove OssBuilder

Remove OB anchor

· Use a 0.9 hex hand driver

Suture

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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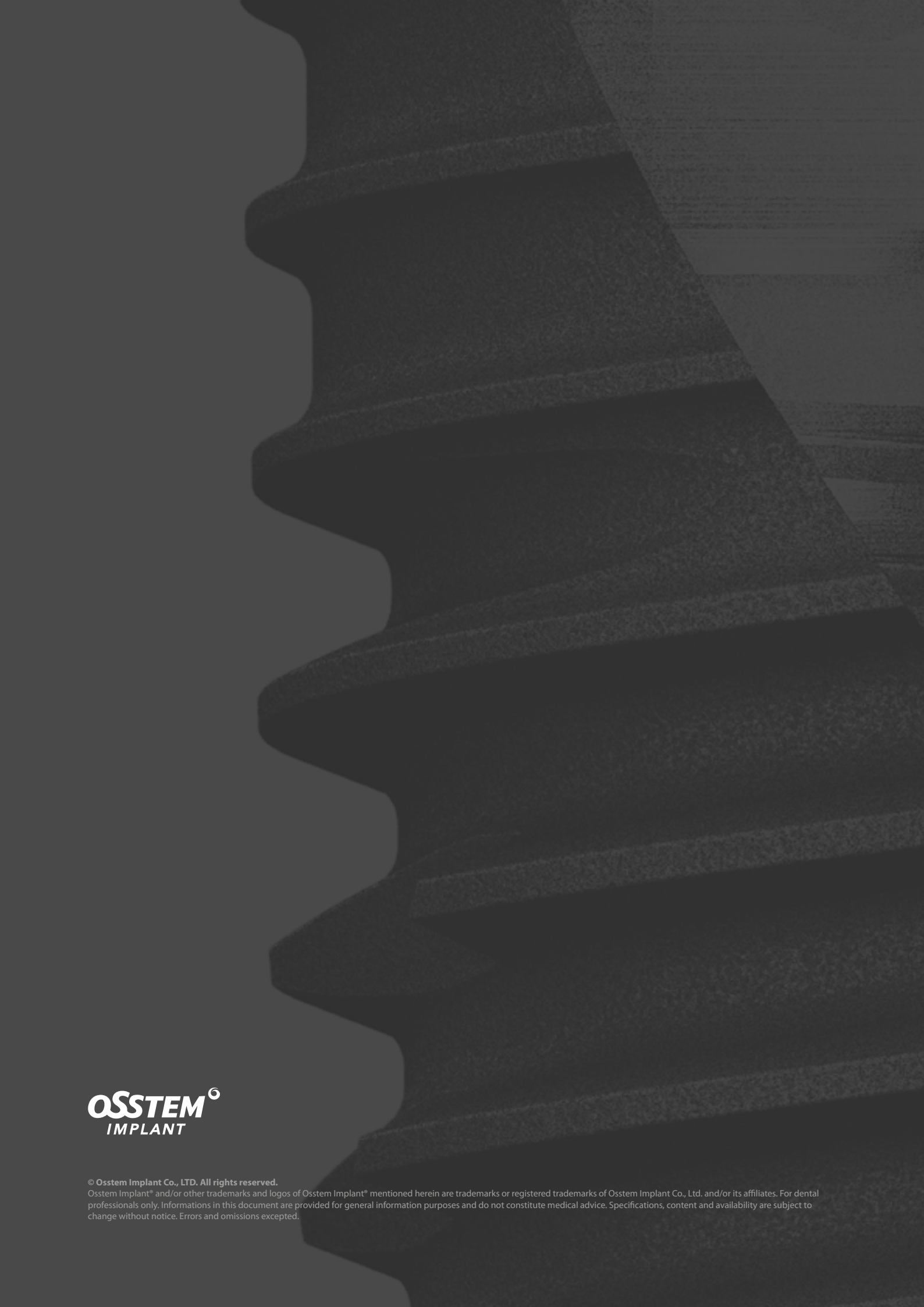

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