

Surgical Manual

123 Straight KIT

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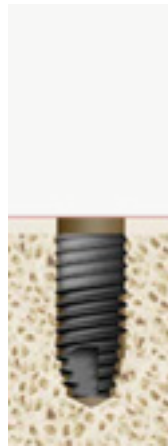
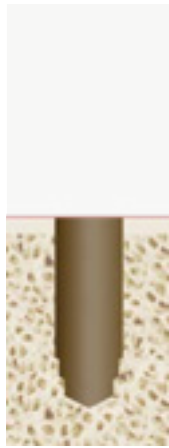
Note: *This brochure is based on the global 2021 Osstem Surgical Manual and has been visually revised and adapted for the European market. Product availability and specifications may vary by country and are subject to change without notice. Images are for illustrative purposes only. For professional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

123 Straight KIT

(123 Straight Full KIT)

Surgery KIT that enables implant placement with 3 drillings, and consisting of stopper drills instead of replaceable stoppers.

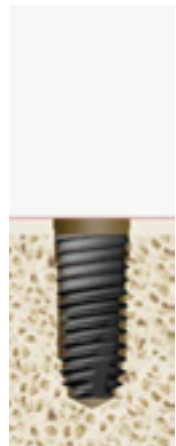
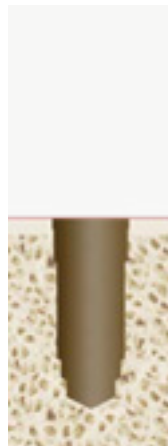
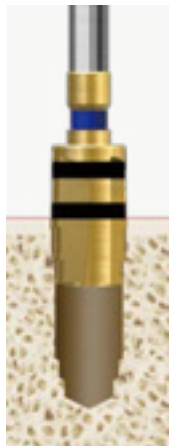
A Possible to place Straight implants



Create straight drill hole

Place straight implant

B Taper Implant 식립 가능



Create taper drill hole

Place taper implant

1 Indication

A When placing a straight implants

- Use when placing a TSII, SSII, USII implant
- Diameter: Ø3.5, Ø4.0, Ø4.5, Ø5.0



B When placing a taper implants

- Use when placing a TSIII, KSIII, SSIII, USIII , implant
- Diameter: Ø3.5, Ø4.0, Ø4.5, Ø5.0, Ø5.5



C When placing an ultra-wide taper implants

- Use when placing a TSIII/IV, KSIII, SSIII, USIII ultra-wide implant (use 123 Straight Full KIT)
- Diameter: Ø6.0, Ø7.0

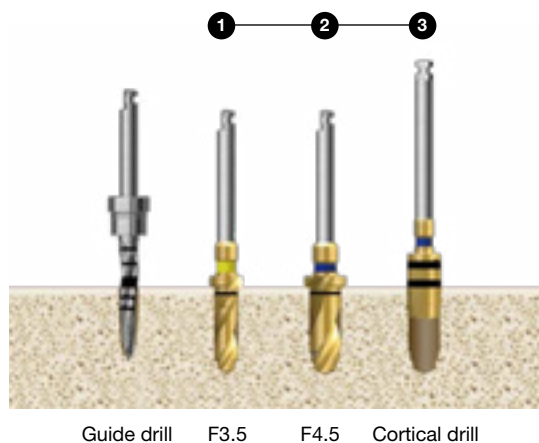


2 Feature

A Easy surgery protocol

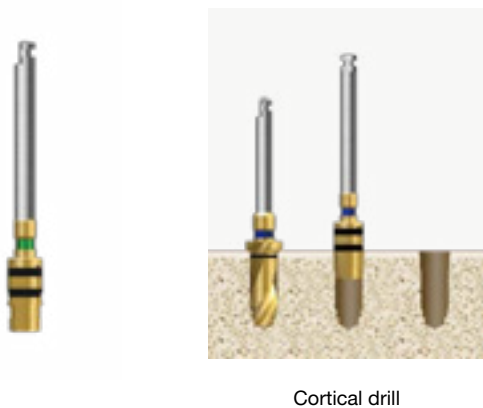
- Simple and Easy surgery protocol with 3 drillings only
- Intuitive since each implant diameter's final drill is the same regardless of Implant type

* Normal bone TSIII 4.5×10mm implant placement



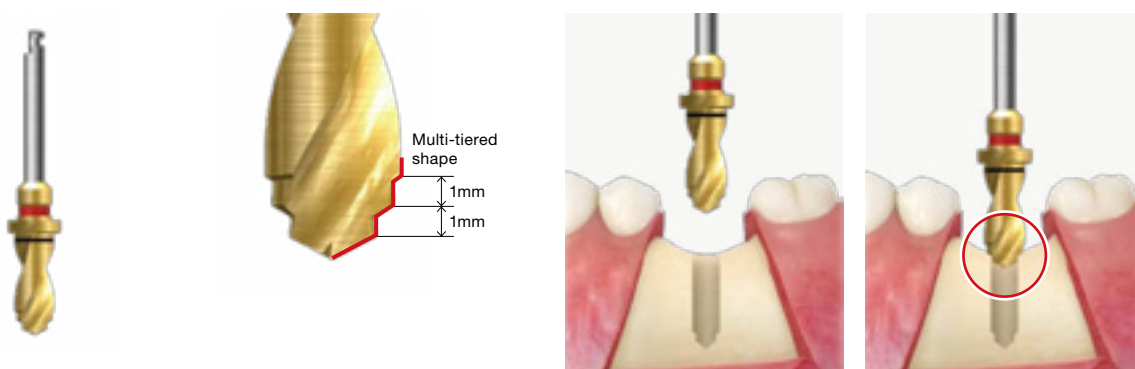
B Taper implant placement

- Exclusive Cortical drill for type III implants makes placing tapered III body type implants possible.



D Pilot drill not required

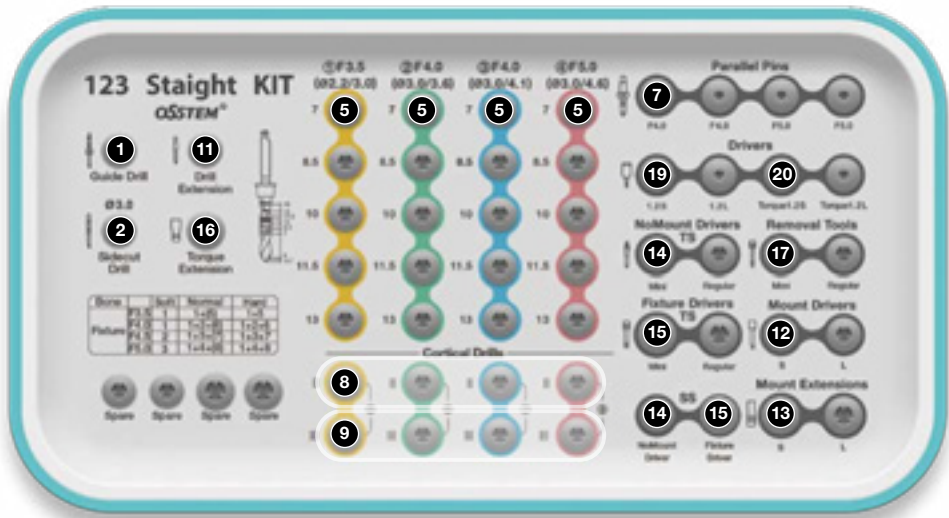
- Exclusive Cortical drill for type III implants makes placing tapered III body type implants possible.



3 Tools of KIT

123 Straight KIT

Drilling tool (1~11) Implant placement tool (12~18) Superstructure placement tool (19, 20)

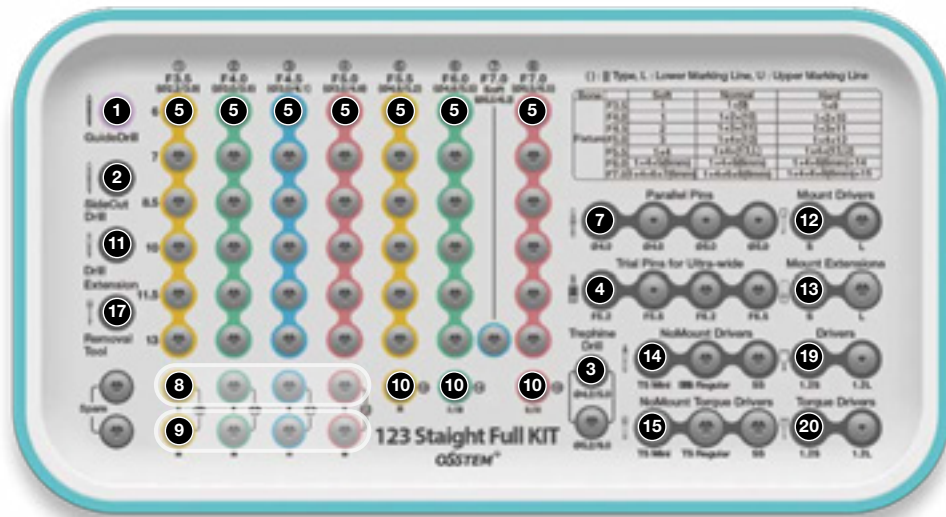


123 Straight Full KIT

Drilling tool
(1~11)

Implant placement tool
(12~18)

Superstructure placement tool
(19, 20)



4 User guide for KIT



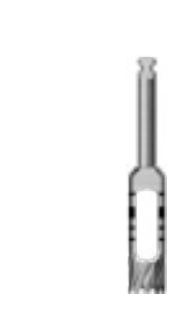
- The KIT has surgical drills for forming drill holes, a depth gauge for gauging drill depth, and parallel pins for checking placement path.
- The Full KIT has surgical drills for placing ultra-wide implants (Ø6.0, Ø7.0 diameter) and short implants (6mm long).



1 Guide drill



2 SideCut drill



3 Trephine drill
(Full KIT components)



4 Trial pin
(Full KIT components)



5 123 Twist drill



6 Depth gauge



7 Parallel pin



8 Cortical drill (II)



9 Cortical drill (III)



10 Cortical drill
(Full KIT components)



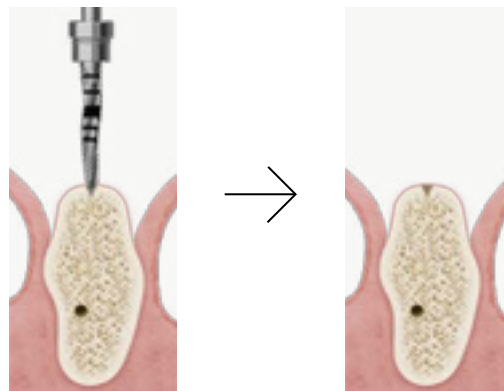
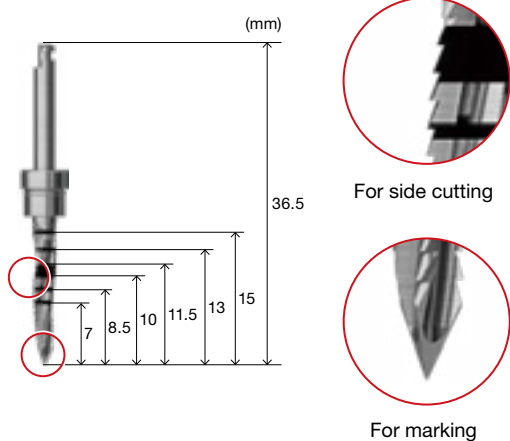
11 Drill extension

1 Guide drill

Drill used for marking the implant's placement position

User guide

- Connect the handpiece to the drill.
- Use the tip of the drill to mark the placement position.
- Drill until the marking line that corresponds with the length of the implant to be placed
- Sidecut drill is recommended in case of reaming drill hole, or correcting a path, or cutting the septal bone of extraction site.
- Recommended RPM: 1,200~1,500rpm
- Available diameters: Ø2.0



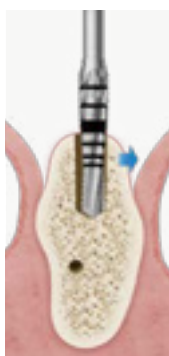
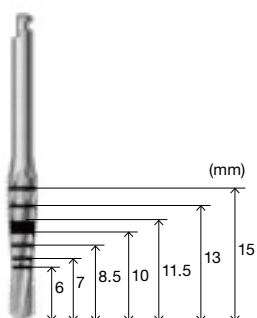
Mark the implant's placement position (marking)

2 SideCut drill

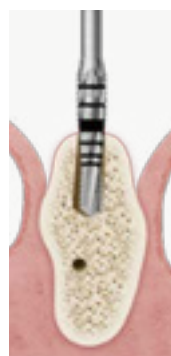
Drill used for correcting the path or ream the drilling site.

User guide

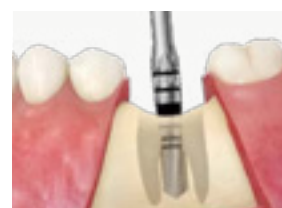
- Connect the handpiece to the drill.
- MiddleSidecut drill is recommended in case of reaming drill hole, or correcting a path, or cutting the septal bone of extraction site.
- Recommended RPM: 1,200~1,500rpm
- Available diameters: Ø3.0



Drill hole reaming



Path correction



Septal bone clean up

3 Trephine drill

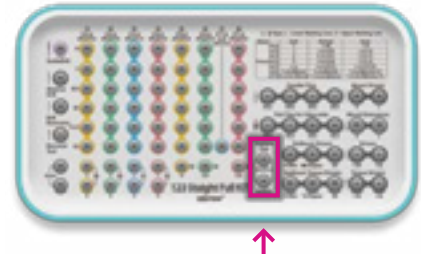
A tool used removing fractured or failed implants
(123 Straight full KIT component)

User guide

- Connect the Trephine drill to the handpiece.
- Cut the bone around the implant with the Trephine drill, and then remove fractured or failed implants.
- Available diameters: Ø4.2/Ø5.0, Ø5.2/Ø6.0



Trephine drill



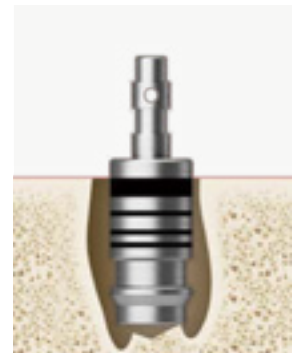
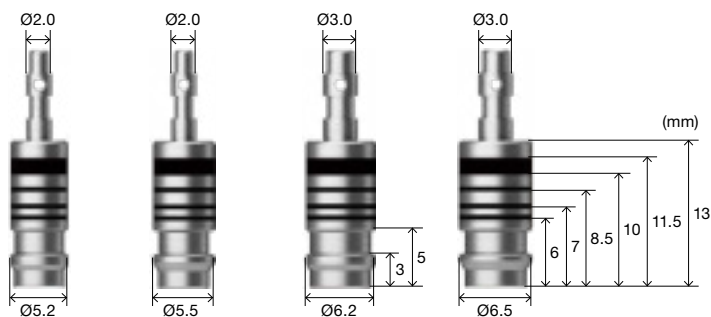
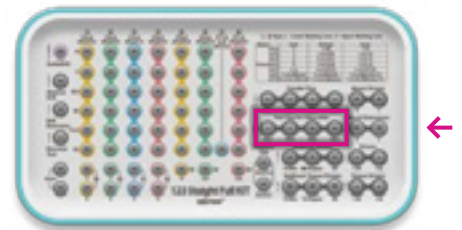
Remove implant

4 Trial pin

A tool used for checking the width and depth of the extraction socket and the failed implant socket
(123 Straight full KIT component)

User guide

- Check drilling depth of the extraction site or after using the trephine drill.
- Can be used as parallel pins.
- Diameter specifications: Ø5.2, Ø5.5, Ø6.0, Ø6.5

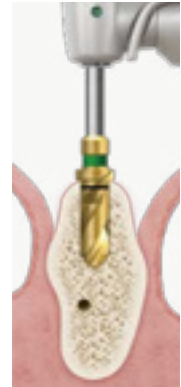
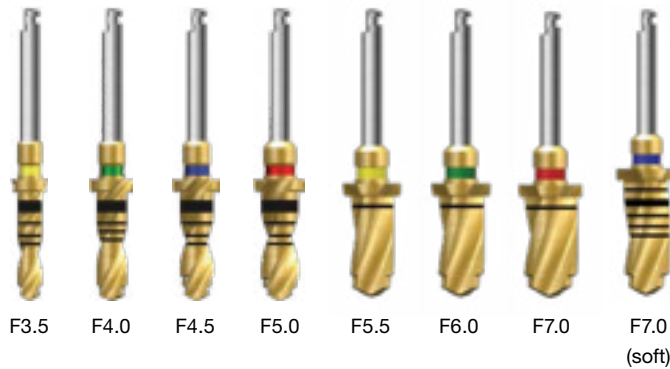
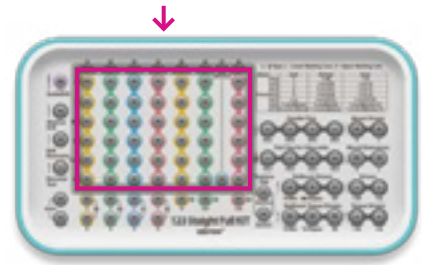


5 123 Twist drill

Used for forming drill holes

User guide

- Connect the handpiece to the drill.
- Perform full drilling until the stopper.
- Recommended RPM is 800~1,200rpm.
- Available length specifications: 6, 7, 8.5, 10, 11.5, 13mm
(123 Straight full KIT also has 6mm specifications)
- Available diameters: F3.5, F4.0, F4.5, F5.0, F5.5(123 Straight full KIT also has F5.5, F6.0, F7.0, F7.0 (soft) specifications.)

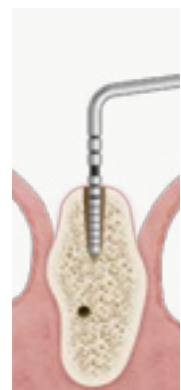
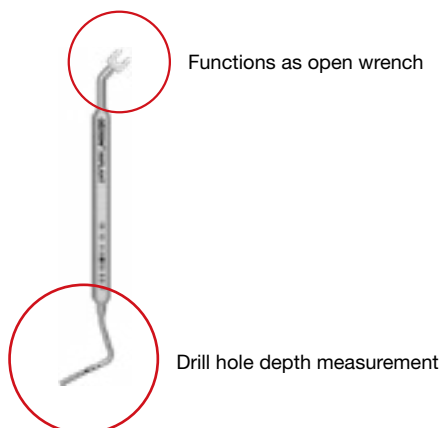
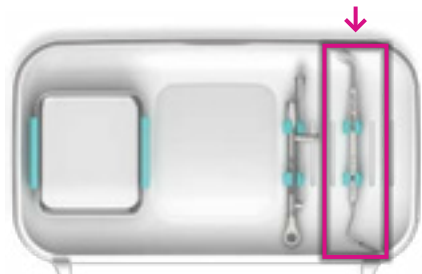


6 Depth gauge

One side of the Depth gauge is for gauging drill hole depth, and the other side is used as open wrench.

User guide

- Used when measuring drilling depth. (grooves in 1mm increments)
- Marking lines of 10mm and 11.5mm are made with one thick line to make length recognition easier.
- When removing Mount from implant, the open wrench grips the octa part of the mount in order to prevent torque application to the implant.



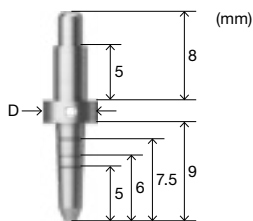
7 Parallel pin

Use to check whether the drill hole is drilled at the desired angle after initial drilling

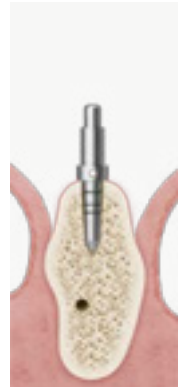
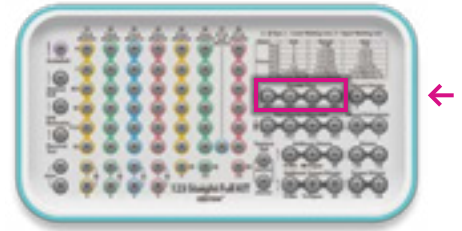
User guide

- After initial drilling and F3.5 drilling, insert it into the drill hole and check the location and path.
- The straight part can be used for checking path after initial drilling, and the taper part after F3.5 taper drilling.
- Use the specifications suitable for the drill hole size. (Standard specifications: Ø4.0, Ø5.0)
- Make the patient slightly occlude in order to check path with antagonist teeth.
- The Taper parallel pin might fall into the patient's throat, therefore it is advised to put dental floss through the hole located in the middle.
- Available diameters: F4.0 (123 Straight full KIT also includes F5.0 specifications)

After F3.5 drilling



After initial drilling

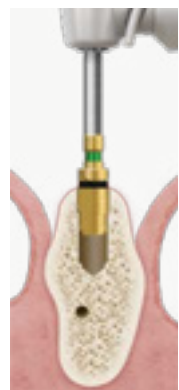
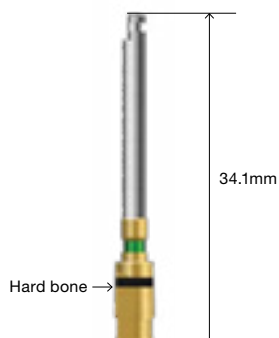
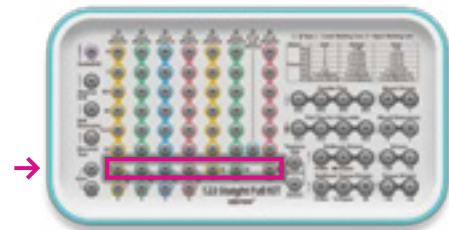


8 Cortical drill (II)

Used for cutting cortical bone to lower the torque when placing a straight implant in hard bone

User guide

- Select drill with the diameter that matches the implant to be placed.
- Connect the handpiece to the drill.
- Drill until the lower end of the laser marking line.
- Recommended RPM is 800~1,200rpm.
- Available diameters are F3.5, F4.0, F4.5, F5.0

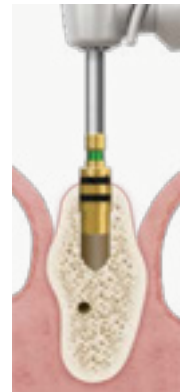
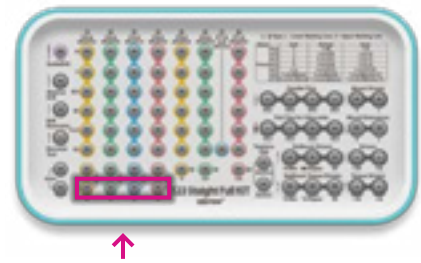
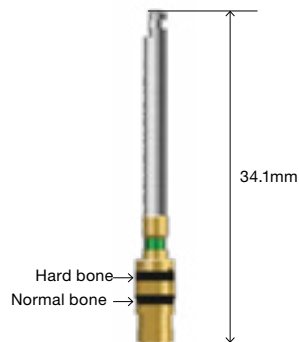


9 Cortical drill (III)

Used for cutting cortical bone to lower the torque when placing a taper implant in normal/hard bone

User guide

- Connect the handpiece to the drill.
- Drill until the lower end of the laser marking line.
- The lower laser marking line serves as a guide for drilling in normal bone, and the upper laser marking line serves as a guide for drilling in hard bone.
- Recommended RPM is 800~1,200rpm.
- Available diameters: F3.5, F4.0, F4.5, F5.0

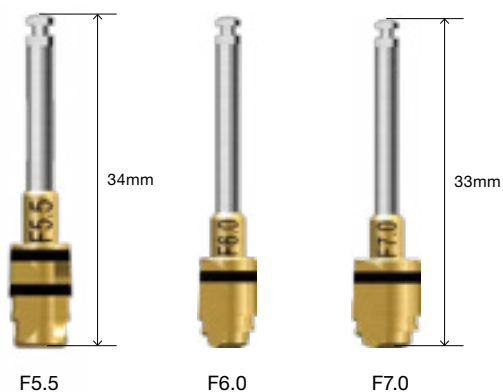
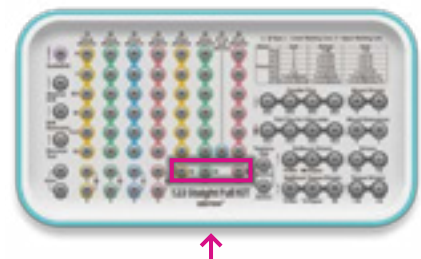


10 Cortical drill (II)

Used for cutting cortical bone to lower the torque when placing a implant in hard bone (prevent over-torque)

User guide

- Select drill with the diameter that matches the implant to be placed.
- Connect the handpiece to the drill.
- The thickness of the laser marking line is 1mm.
Drill until the lower end of the laser marking line.
- Recommended RPM is 800~1,200rpm.
- Available diameters: F5.5, F6.0, F7.0

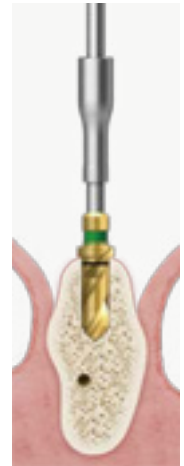
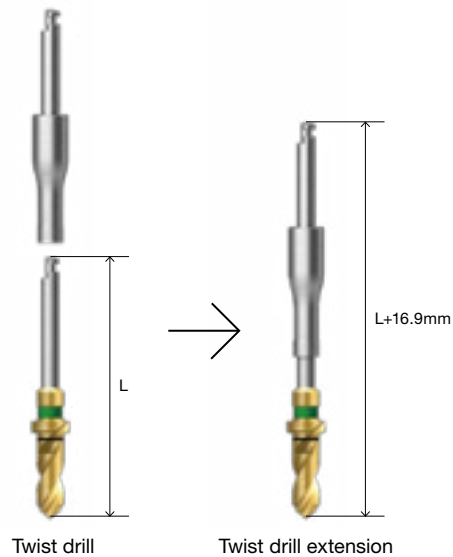
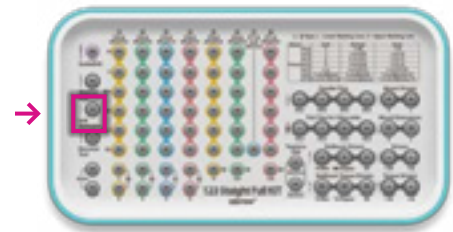


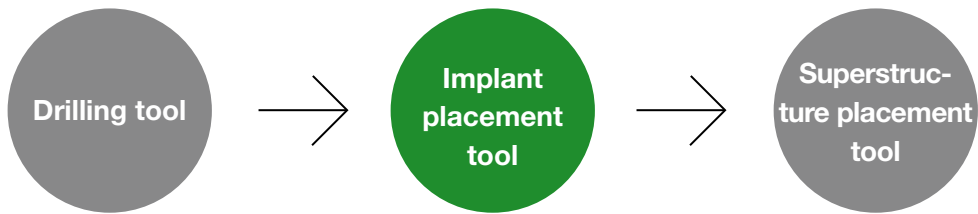
11 Drill extension

Used for extending the length of drills and other hanpiece-using tools in case there is interference from adjacent teeth.

User guide

- Connect the drill extension to the drill and connect it to the handpiece.
- The drill extension can get bent or fractured when applying strong force in case of improper connection.
- Drill at placement position.
- When using a drill extension, the length of the drill is extended by 16.9mm.





Consists of drivers for placing pre-mount implants and NoMount implants during implant placement, a torque wrench, and a removal tool used in case of mount jamming.



12 Simple mount driver



13 Simple mount extension



14 NoMount driver



15 NoMount torque driver
(Full KIT component)



16 Implant driver



17 Torque extension



18 Removal tool



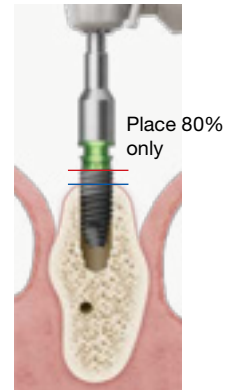
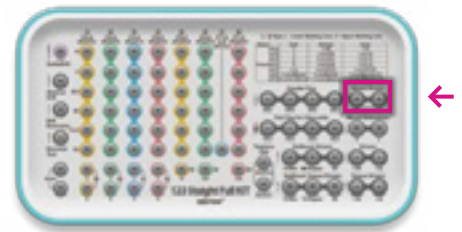
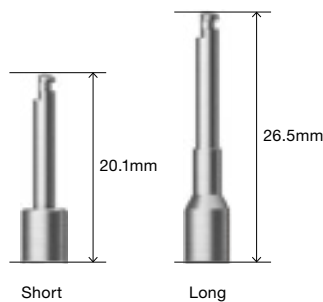
18 Torque wrench

12 Simple mount driver

Used for placing pre-mount implants with engine

User guide

- Connect the mount driver to the handpiece.
- Connect the mount driver to the the implant mount and take out the implant.
- When taking the implant into the mouth, carry it with the implant tip facing up so that it does not fall down.
- Place only approx. 80% of the implant, and adjust the additional depth with the torque wrench.
- Place the implant at a speed of only 50rpm and torque of 40Ncm.
- Short and long specifications are available.

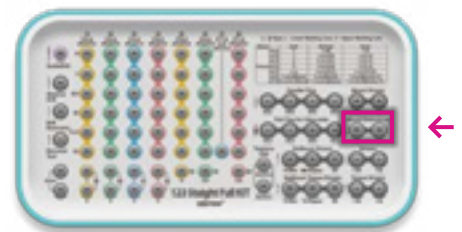


13 Simple mount extension

Tool for adjusting the additional placement depth of pre-mount implants (instrument for torque wrench)

User guide

- Connect mount extension to the torque wrench.
- Connect to the mount of the placed implant for additional depth control.
- Short and long specifications are available.



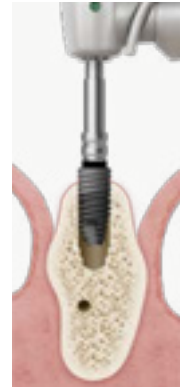
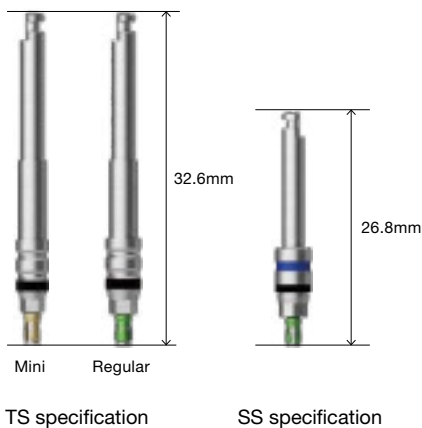
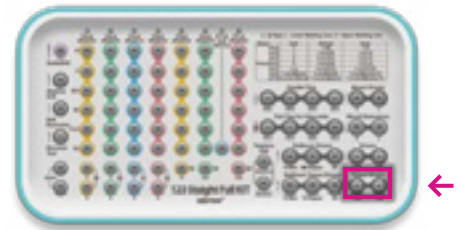
14

NoMount driver

Use when placing TS or SS NoMount implants using the engine

User guide

- Assemble the NoMount driver to the handpiece.
- Assemble the NoMount driver to the NoMount implant and take out the implant.
- When taking the implant into the mouth, carry it with the implant tip facing up so that it does not fall down.
- Place only approx. 80% of the implant, and adjust the additional depth with the torque wrench.
- Place the implant at a speed of only 50rpm and torque of 40Ncm.
- There are mini and regular (long) specifications, and SS has single regular/wide (short) specifications.



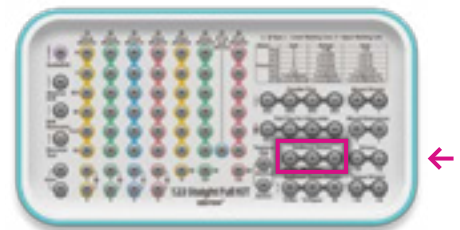
15

Implant driver / NoMount torque driver

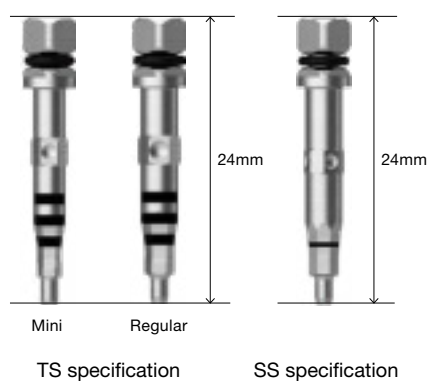
Use to adjust the additional placement depth and hex direction of the implant using a torque wrench (instrument for torque wrench)

User guide

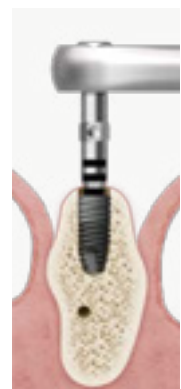
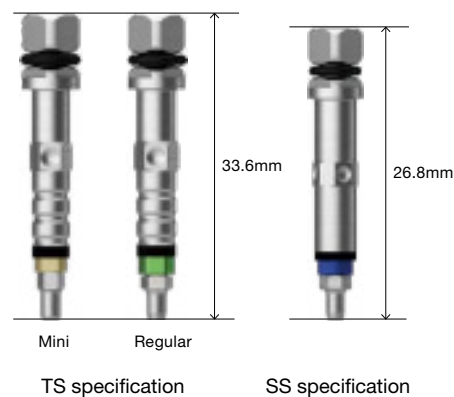
- Select a implant driver or NoMount torque driver suitable for the type of implant and connect it to the torque wrench.
- Connect to the mount of the placed implant for additional depth control.
- The NoMount torque driver is included only in the full kit and is not used for final installation.
- There are mini and regular (long) specifications, and And one single regular/wide (long) specification for SS.



Implant driver



NoMount torque driver

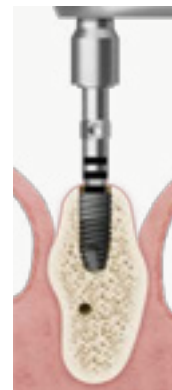
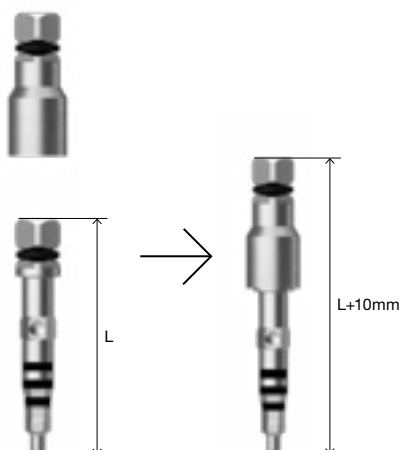
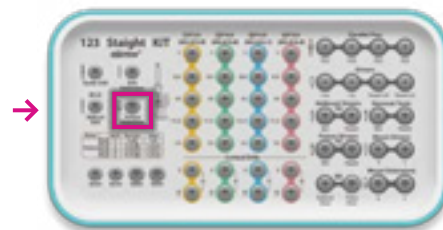


16 Torque extension

A tool that extends the length by 10mm of instruments that are used with the handpiece (Instrument used with torque wrench).

User guide

- Connect torque extension to the torque wrench.
- Then connect to tool for torque to extend their length and apply torque.
- Tool included only in the 123 Straight KIT.

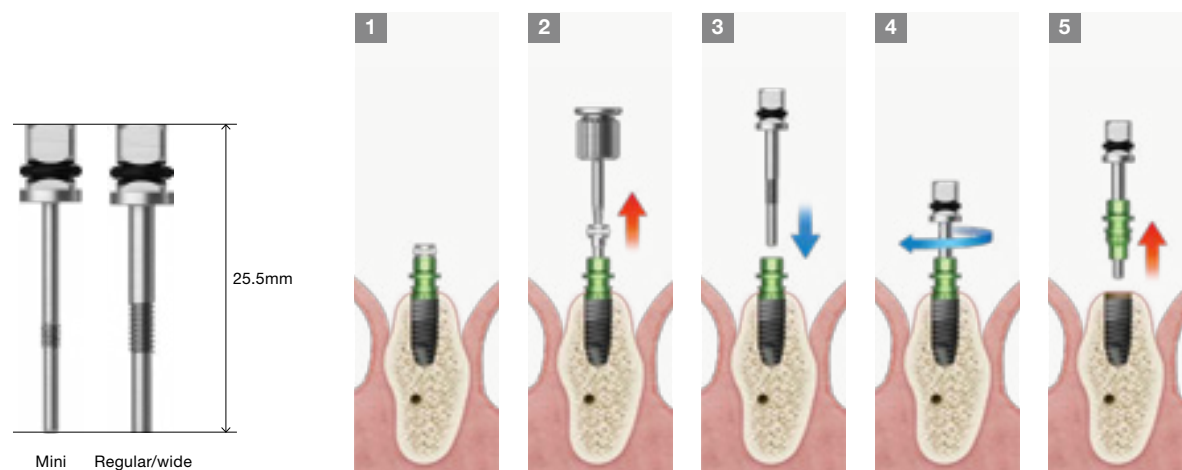


17 Removal tool

A tool that separates the mount in case of mount jamming after pre-mount implant placement

User guide

- Completely remove the mount screw with a 1.2 hex hand driver.
- Connect the Removal tool to Implant mount and rotate clockwise to separate the mount.
- Rotate the removal tool using a torque wrench.
- There are two specifications available : mini (TS, US) and regular (TS, SS, US)/wide (SS).

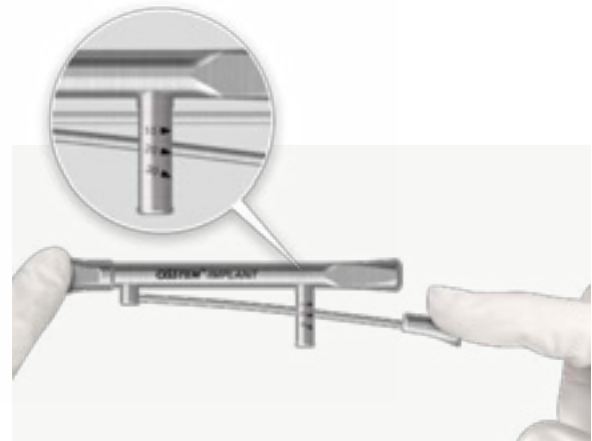
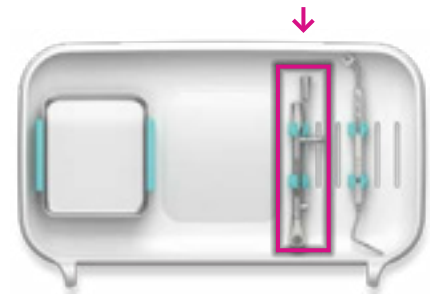


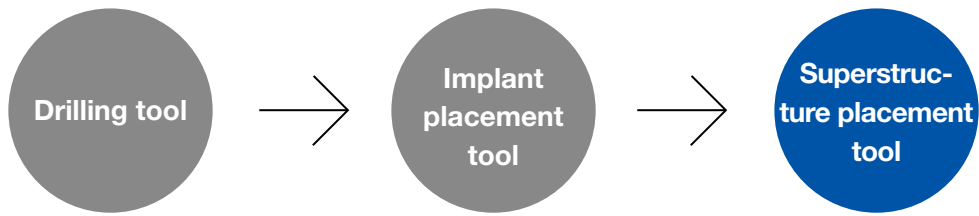
18 Torque wrench

A tool used for adjusting the implant placement depth or for applying constant torque on abutment, screw, etc.

User guide

- RotatePull the bar to match the bar with the torque value you wish to apply, and rotate clockwise for torque application.
- Torque value of 10, 20, and 30Ncm can be applied.
- Keep torque value below 30Ncm when placing the implant.





Includes tools used for placing and removing cover screw, healing Abutment, and abutment screw after implant placement.



19 Hand driver



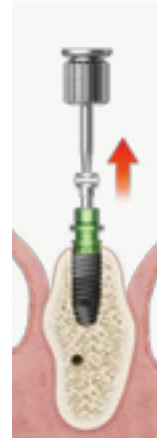
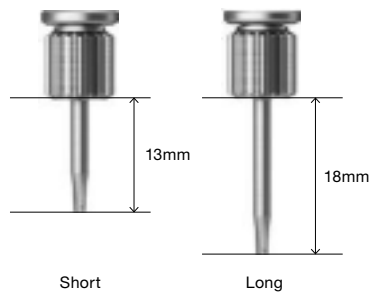
20 Torque driver

18 Hand driver

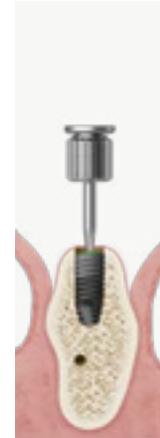
A manual driver used for tightening or loosening cover screw, healing abutment, and abutment screw after implant placement.

User guide

- Place the hand driver hex into the hex of cover screw or healing abutment.
- To tighten, turn clockwise at 5~8Ncm.
- To loosen, turn counterclockwise.
- If excessive force (above 20Ncm) is applied, hex slip may occur at the tip of the driver or the screw head. Be careful not to apply over-torque.
- When an adult male wears gloves and tightens with his fingers only, he can generate approx. 12 ~ 18Ncm of force (female: 8 to 12 Ncm).
- 1.2 hex (short, long) specifications available.



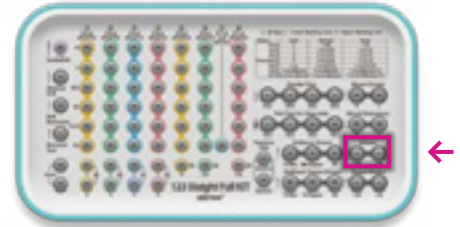
Remove mount



Assemble/remove cover screw



Assemble/remove healing abutment

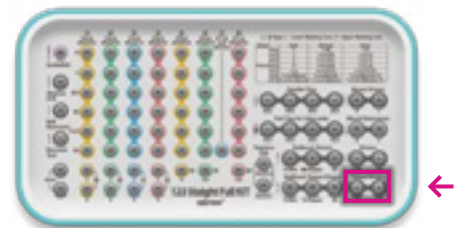
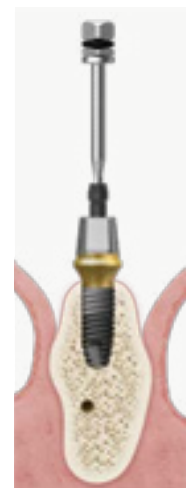
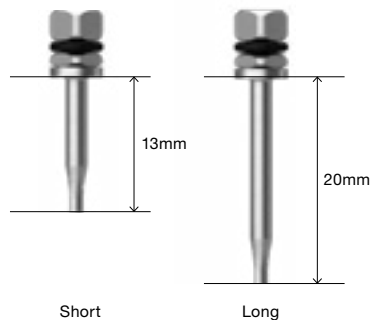


19 Torque driver

A driver used for applying torque to the abutment screw with a torque wrench (instrument for torque wrench)

User guide

- Connect the torque driver to the torque wrench.
- To fasten the abutment screw, rotate clockwise.
- To loosen the abutment screw, rotate counterclockwise.
- 1.2 hex (short, long) specifications available.



5 KIT sequence

Normal bone TSII Ø4.5 × 10mm placement

N: Tool number



Gingival incision

- Make a gingival incision and a flap in the gingiva and check the surgery region.



Mark drilling position (Guide drill)

- Mark the implant placement site by drilling 2~3mm in cortical bone with the Guide drill.
- Recommended RPM: 1,200~1,500rpm



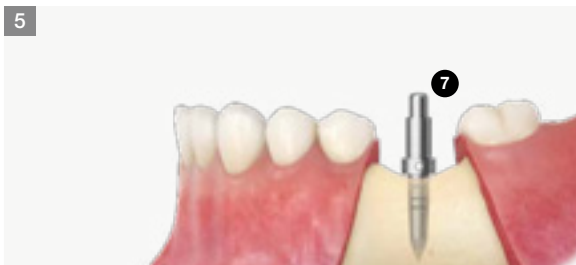
Initial drilling (Guide drill)

- Drill until the 10mm marking line with Guide drill
- Drill stopper (optional)
- The lateral blades on the side path modification easy
- Recommended RPM: 1,200~1,500 rpm



Check depth (Depth gauge)

- After initial drilling, check the depth of the hole and the status of the hole floor.
- * The lower border of the marking lines are the criteria. The single marking line for both 10 and 11.5mm together is bold for easier recognition.



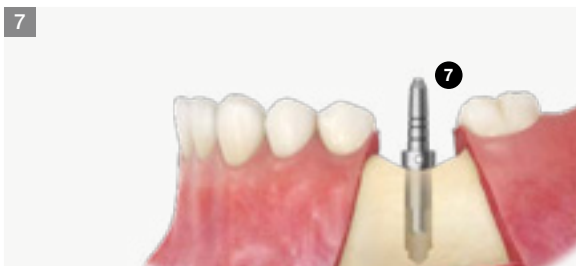
Check drilling position and path (parallel pin)

- After initial drilling, place a parallel pin into the hole to check the drilling position and path



Expand drill hole (F3.5 × 10mm 123 Twist drill)

- Full drilling up to the stopper with F3.5 123 twist drill
- Connect drill extension in case there is interference from adjacent teeth.
- If the drill gets stuck during the surgery, rotate in reverse mode to remove the drill, then resume drilling
- Recommended RPM: 800~1,200 rpm



Check drilling position and path (parallel pin)

- Check the position and path of the hole after drilling with an F3.5 drill



Perform final drilling (F4.5 × 10mm 123 Twist drill)

- Full drilling up to the stopper with F4.5 drill
- Recommended RPM: 800~1,200rpm



Place implant (Simple mount driver)

- Place only 80% of the implant by setting the maximum engine torque to 40Ncm (place implant until only two threads can be seen).
- If the implantation torque is above 55Ncm, bone necrosis might occur or the mount might get stuck.
- If a strange sound can be heard when placing implant, it must be rotated in reverse mode to remove implant.
- Recommended RPM: Max. 50rpm



Remove mount

(when placing a pre-mount implant)

- Remove the mount screw with a 1.2 hex hand driver.
- If the mount screw cannot be removed, it can be separated using a 1.2 torque driver and a torque wrench or a 1.2 machine screw driver (sold separately) and a handpiece.



- When removing the mount screw, fix the top octa part of the mount with an open wrench so that no torque is applied to the implant, then loosen the screw and remove it.



Adjust placement depth

- After connecting the implant driver with the torque wrench, rotate clockwise to place the implant 1mm below the bone level.
- Recommended torque: Max. 30Ncm



Place cover screw or healing abutment

- Consider primary stability, and fasten the cover screw or healing abutment with a 1.2 hex hand driver.

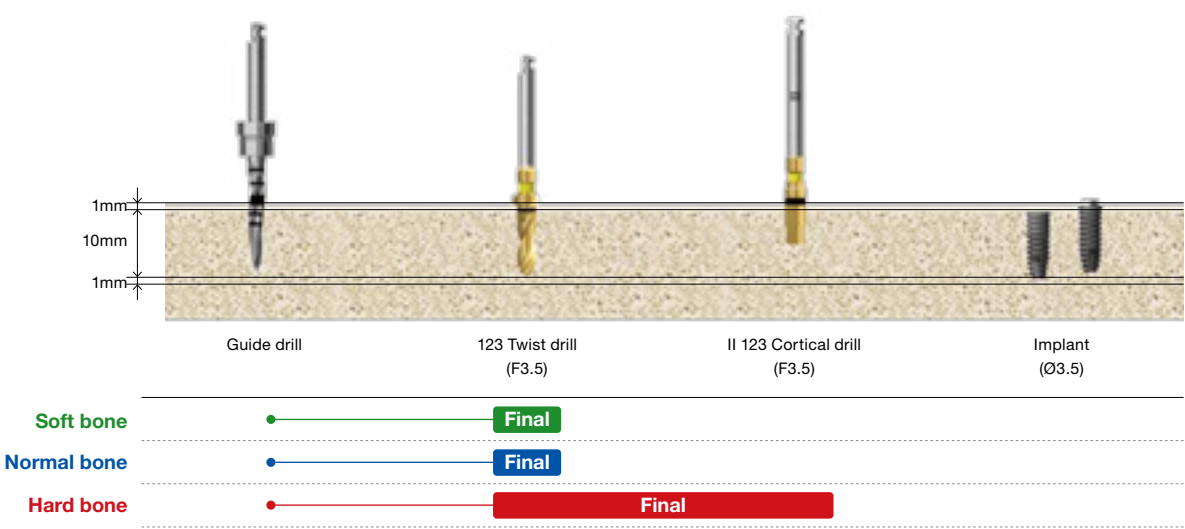


Suture

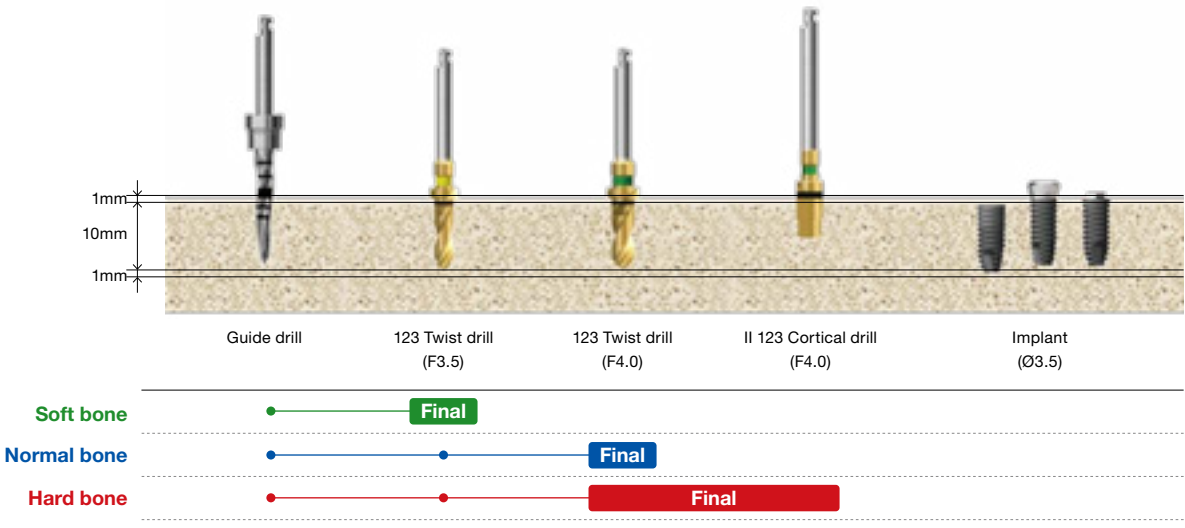
- 2-stage: Cover the cover screw with gingiva and suture so that it is not exposed.
- 1-stage: Suture with the healing abutment exposed.

Quick Guide | TSII, SSII, USII (Length: 10mm)

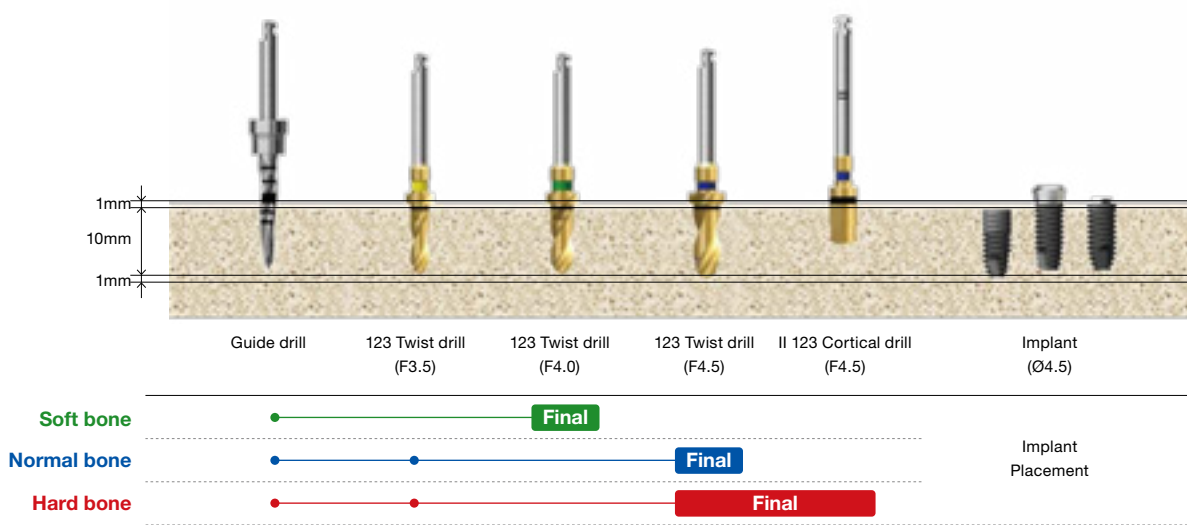
Ø3.5×10mm implant placement



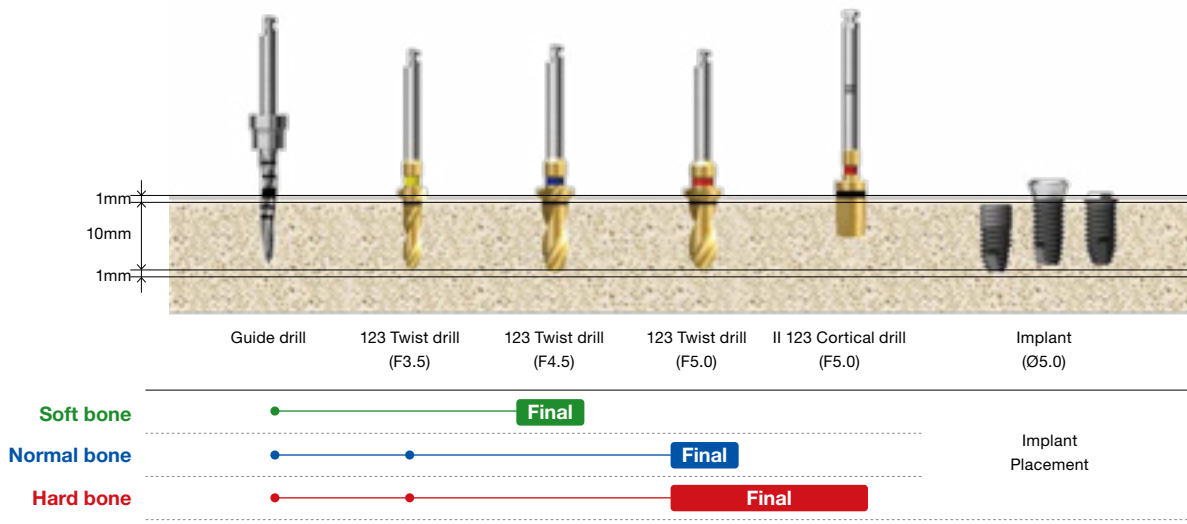
Ø4.5×10mm implant placement



Ø4.5×10mm implant placement

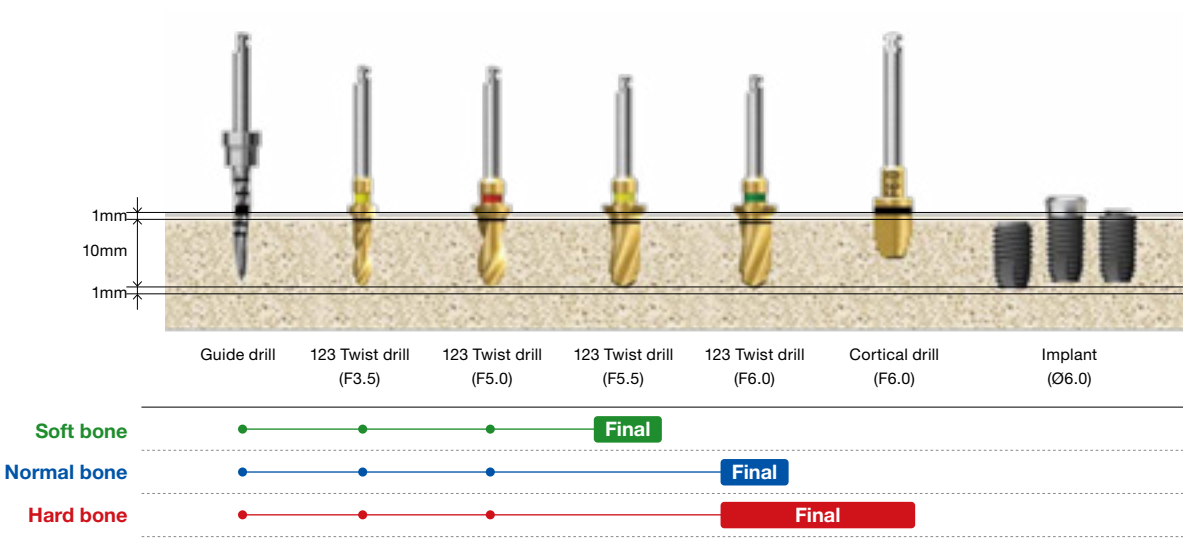


Ø5.0×10mm implant placement

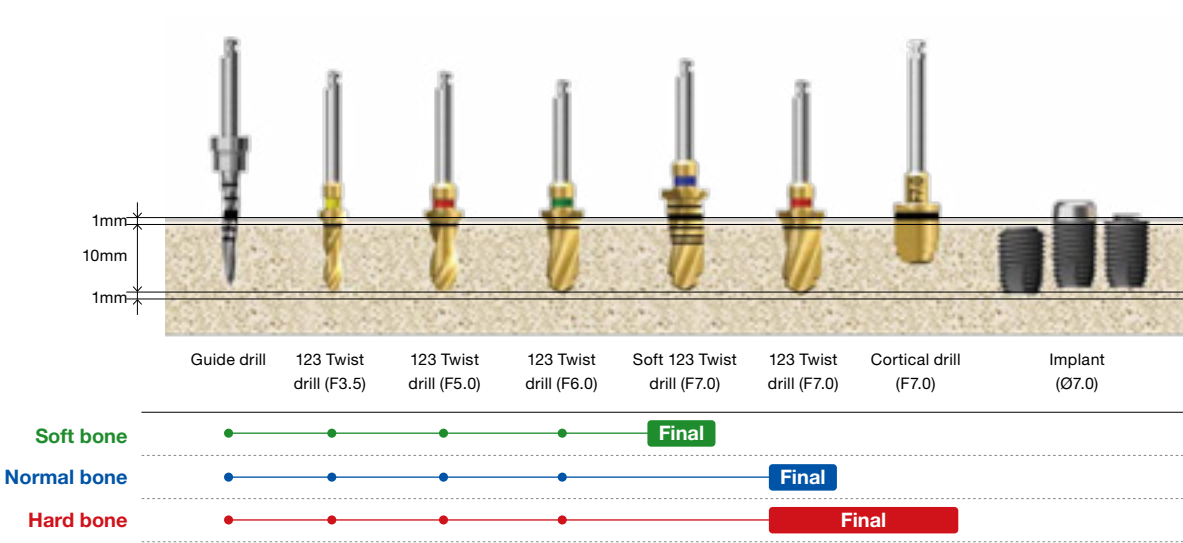


Quick Guide | Ultra-wide TSII, SSII, USII (Length: 10mm)

Ø6.0×10mm implant placement (123 Straight full KIT)



Ø7.0×10mm implant placement (123 Straight full KIT)

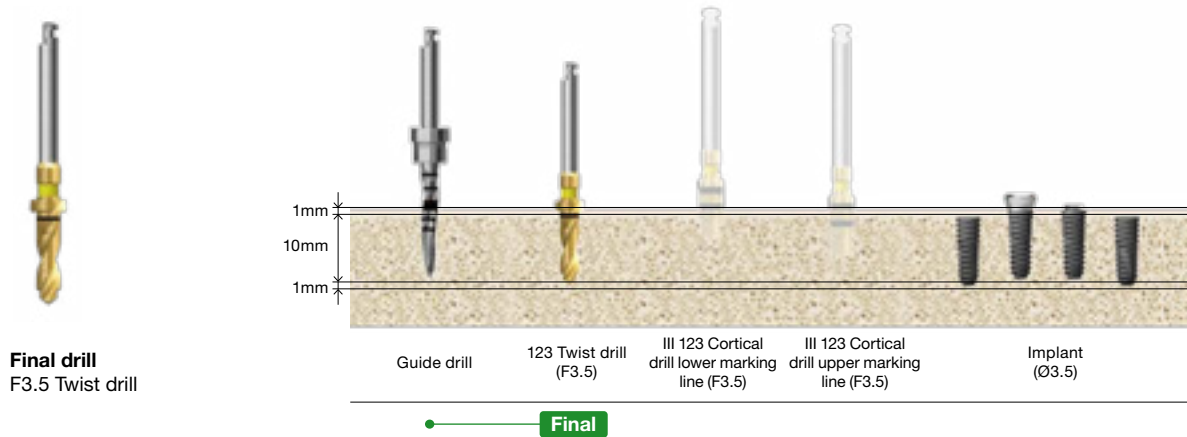


Quick Guide | TSIII, KSIII, SSIII, USIII (Length: 10mm)

Ø3.5×10mm implant placement

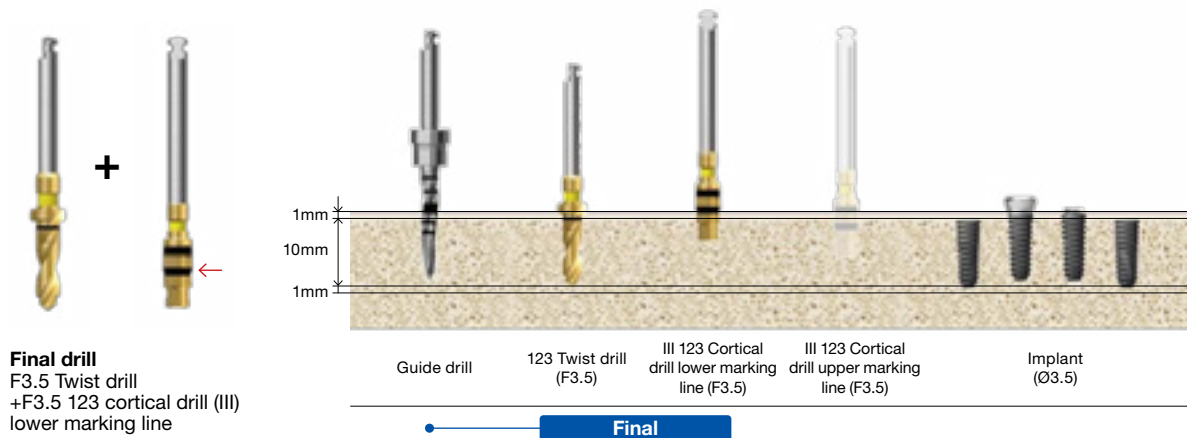
Soft bone Use a drill one size smaller than the nominal drill

Use a F3.5 twist drill as the final drill in order to increase bone interference and secure sufficient primary stability.



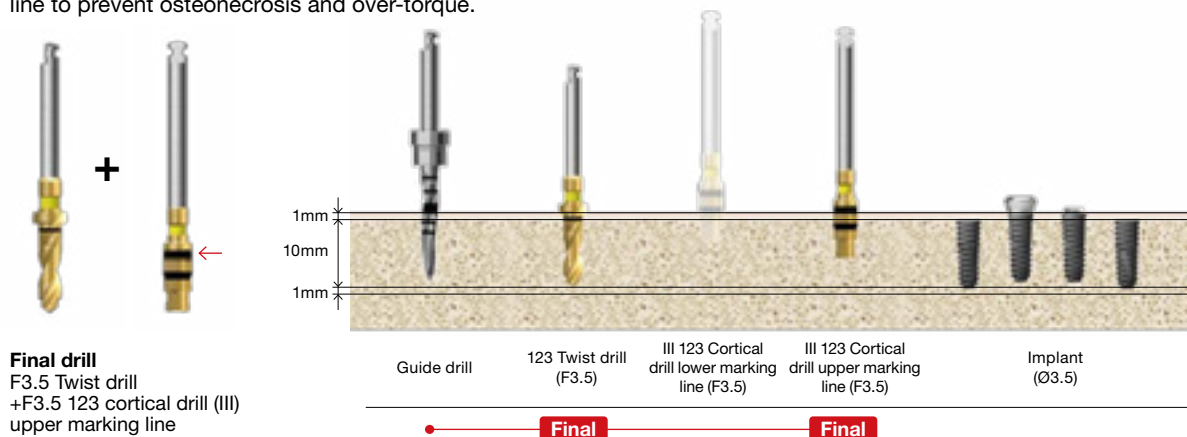
Normal bone Use nominal drill

Use F3.5 123 Twist drill and F3.5 123 cortical drill (III), and drill until the lower marking line to create a drill hole



Hard bone Use nominal drill and cortical drill

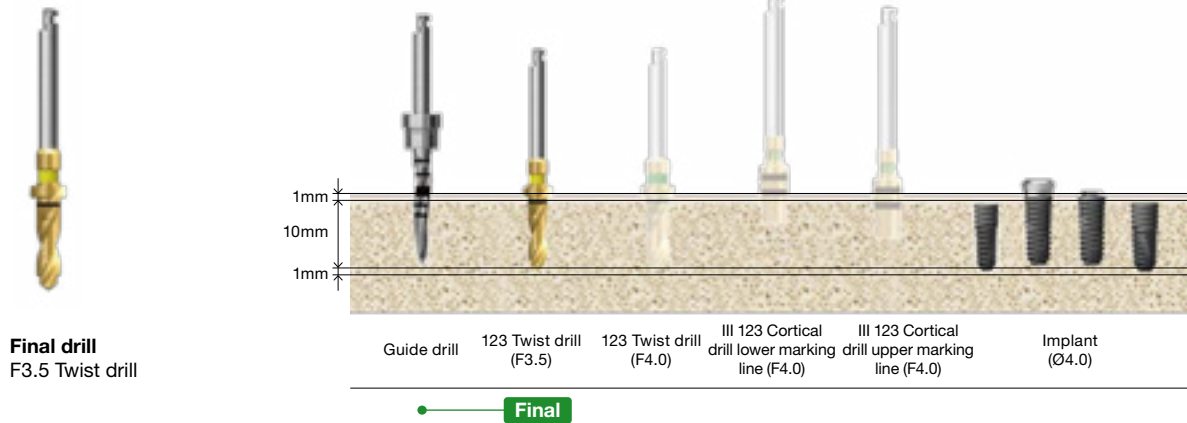
Since bone quality is hard, use a F3.5 123 Twist drill and F3.5 123 cortical drill (III) and drill until the upper marking line to prevent osteonecrosis and over-torque.



Ø4.0×10mm implant placement

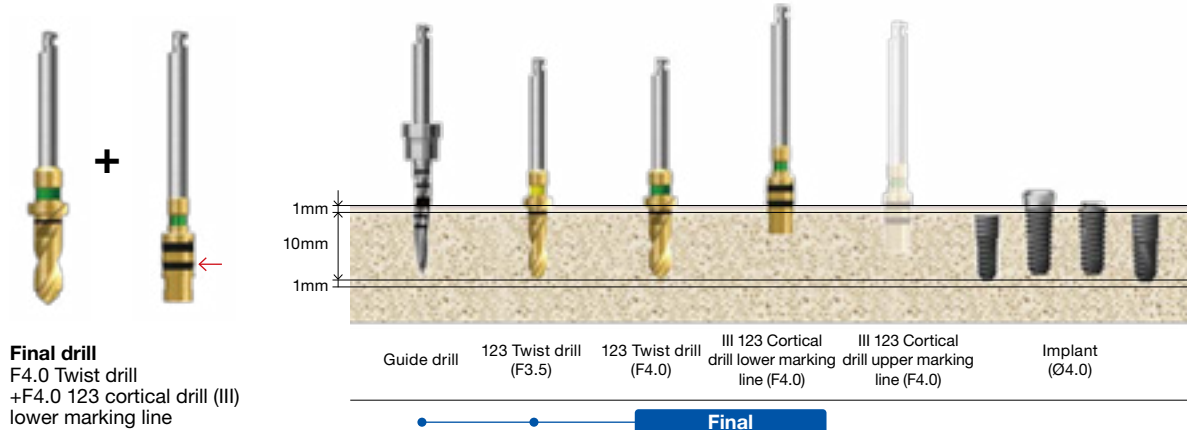
Soft bone Use a drill one size smaller than the nominal drill

Since bone quality is soft, use a F3.5 twist drill which is smaller than the implant's diameter as the final drill in order to increase bone interference and secure sufficient primary stability.



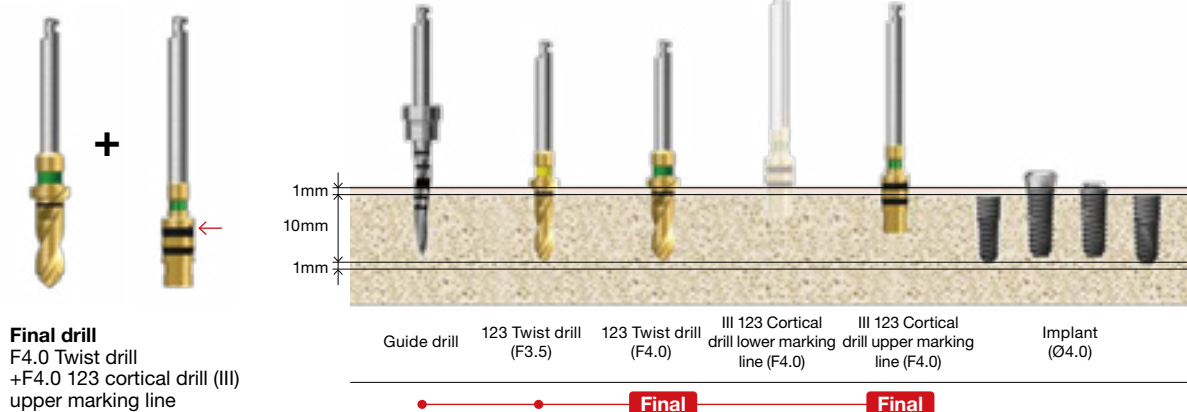
Normal bone Use nominal drill

Since bone quality is good, use a F3.5 123 twist drill and F4.0 123 cortical drill (III) that matches the implant's diameter and drill until the lower marking line.



Hard bone Use nominal drill and cortical drill

Since bone quality is hard, use a F4.0 123 Twist drill and F4.0 123 cortical drill (III) and drill until the upper marking line to prevent osteonecrosis and over-torque.

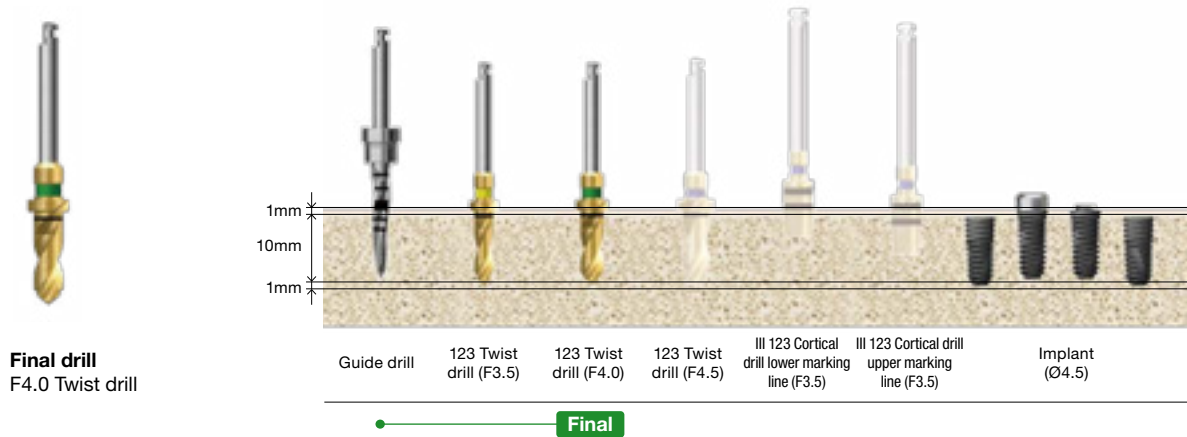


Quick Guide | TSIII, KSIII, SSIII, USIII (Length: 10mm)

Ø4.5×10mm implant placement

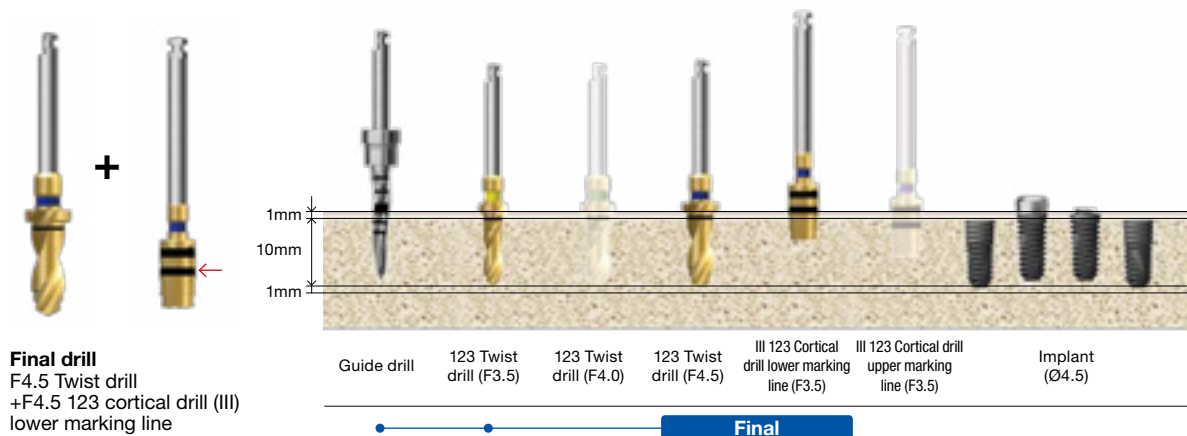
Soft bone

Since bone quality is soft, use a F4.0 twist drill which is smaller than the implant's diameter as the final drill in order to increase bone interference and secure sufficient primary stability.



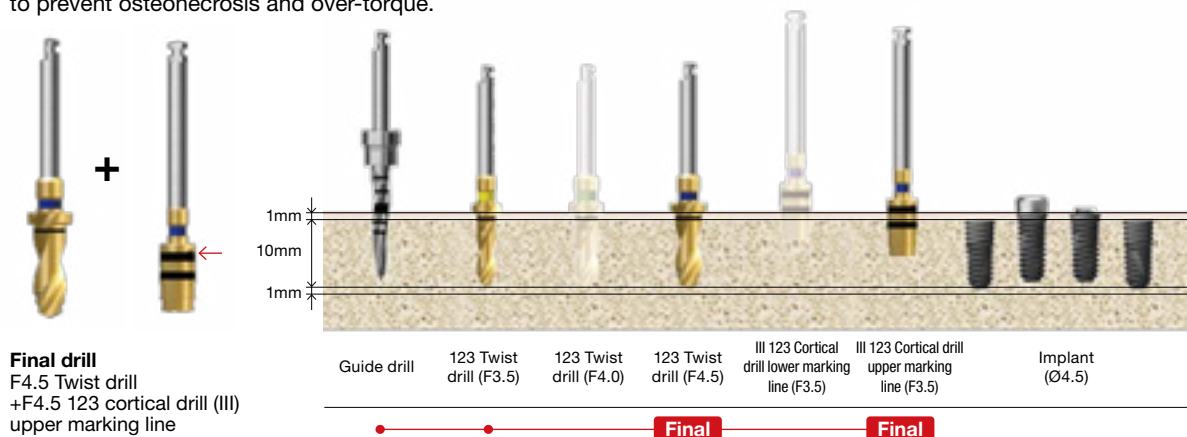
Normal bone

Since bone quality is good, use a F4.5 123 twist drill and F4.5 123 cortical drill (III) that matches the implant's diameter and drill until the lower marking line and create a drill hole.



Hard bone

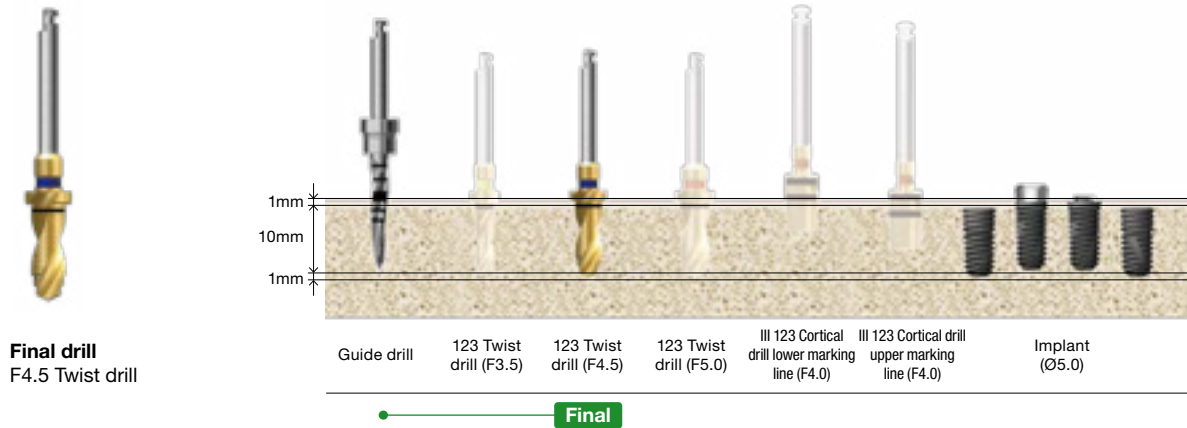
Since bone quality is hard, use a F4.5 123 Twist drill and F4.5 123 cortical drill (III) and drill until the upper marking line to prevent osteonecrosis and over-torque.



Ø5.0×10mm implant placement

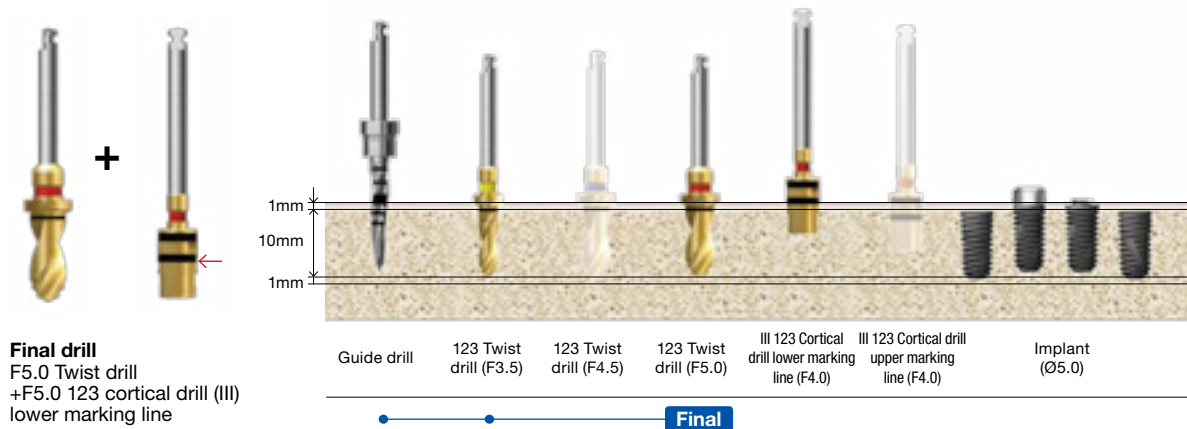
Soft bone

Since bone quality is soft, use a F4.5 twist drill which is smaller than the implant's diameter as the final drill in order to increase bone interference and secure sufficient primary stability.



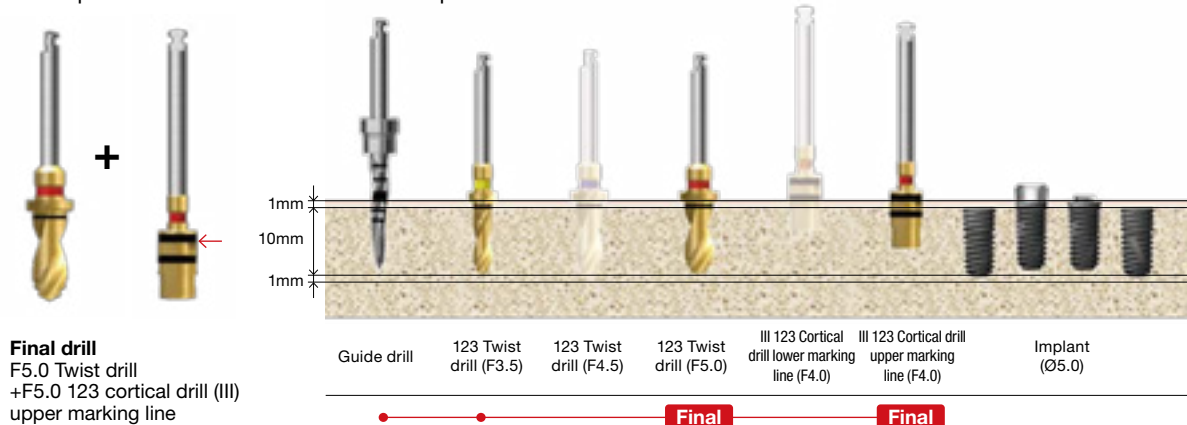
Normal bone

Since bone quality is good, use a F5.0 123 twist drill and F5.0 123 cortical drill (III) that matches the implant's diameter, and drill until the lower marking line and create a drill hole.



Hard bone

Since bone quality is hard, use a F5.0 123 Twist drill and F5.0 123 cortical drill (III) and drill until the upper marking line to prevent osteonecrosis and over-torque.

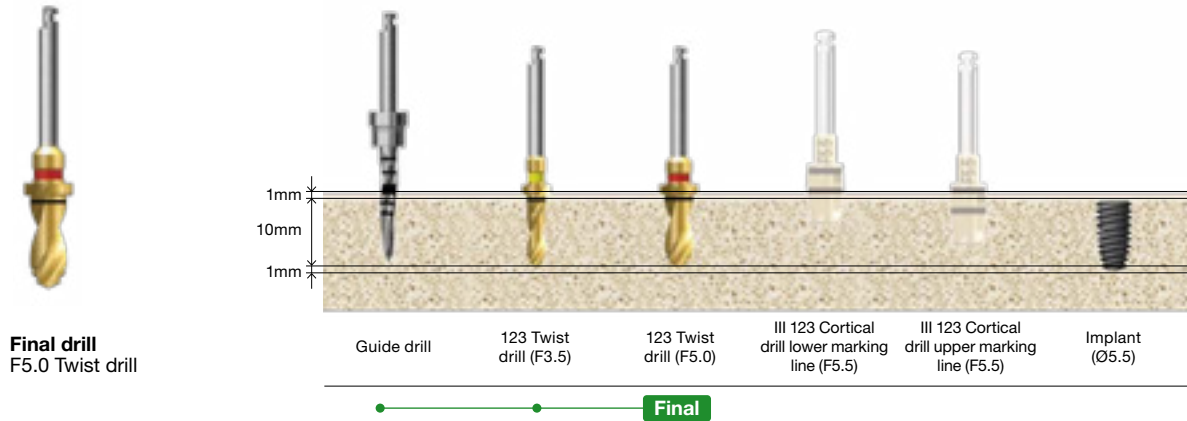


Quick Guide | TSIII, KSIII, SSIII, USIII (Length: 10mm)

Ø5.5×10mm implant placement (123 Straight full KIT)

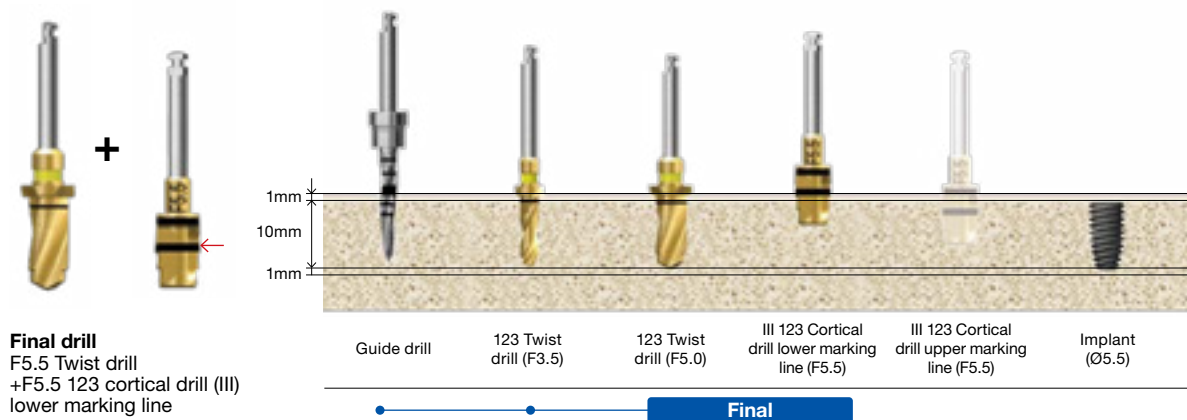
Soft bone

Since bone quality is soft, use a F5.5 twist drill which is smaller than the implant's diameter as the final drill in order to increase bone interference and secure sufficient primary stability.



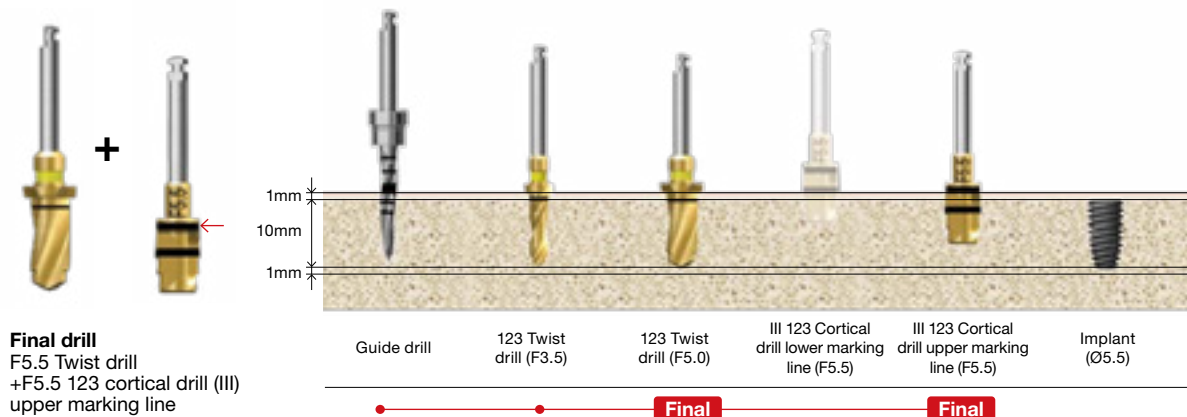
Normal bone

Since bone quality is good, use a F5.5 123 twist drill and F5.5 123 cortical drill (III) that matches the implant's diameter and drill until the lower marking line and create a drill hole.



Hard bone

Since bone quality is hard, use a F5.5 123 Twist drill and F5.5 123 cortical drill (III) and drill until the upper marking line to prevent osteonecrosis and over-torque.



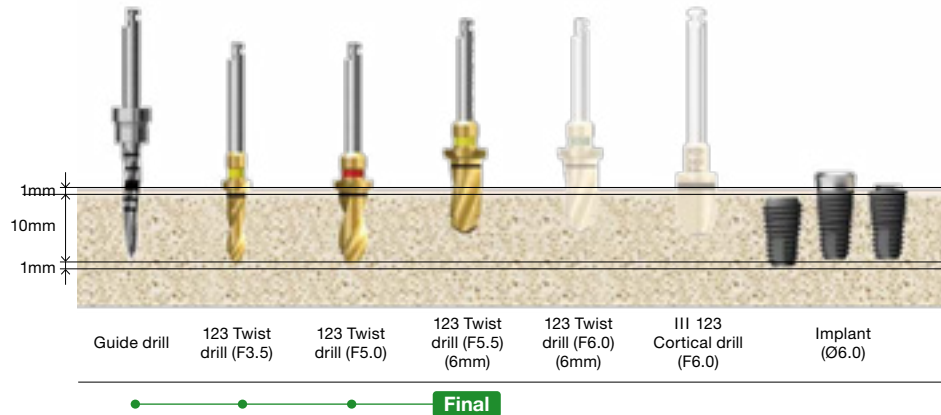
Ø6.0×10mm implant placement (123 Straight full KIT)

Soft bone

Since bone quality is soft, use a F4.5 twist drill which is smaller than the implant's diameter as the final drill to increase bone interference and secure sufficient primary stability.



Final drill
F5.5 Twist drill (6mm)

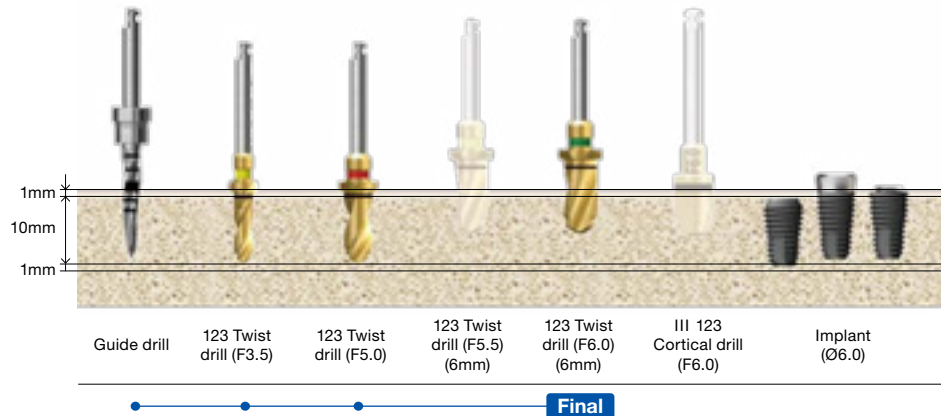


Normal bone

Since bone quality is good, use a F5.0 123 twist drill and F5.0 123 cortical drill (III) that matches the implant's diameter and drill until the lower marking line and create a drill hole.

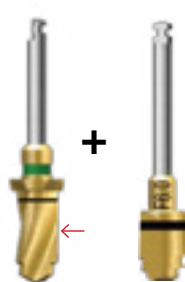


Final drill
F6.0 Twist drill (6mm)

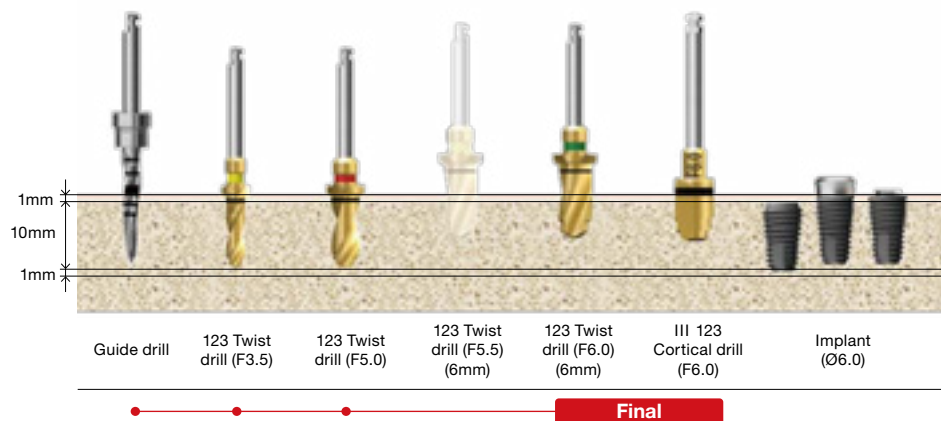


Hard bone

Since bone quality is hard, use a F5.0 123 Twist drill and F5.0 123 cortical drill (III) and drill until the upper marking line to prevent osteonecrosis and over-torque.



Final drill
F6.0 Twist drill (6mm)
+ F6.0 cortical drill

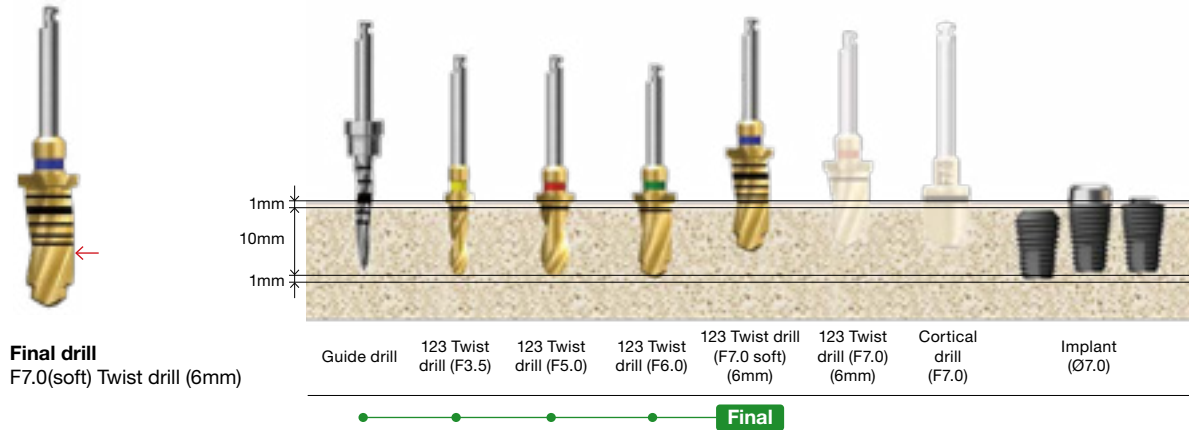


Quick Guide | Ultra-wideTSIII, KSIII, SSIII, USIII (Length: 10mm)

Ø7.0×10mm implant placement (123 Straight full KIT)

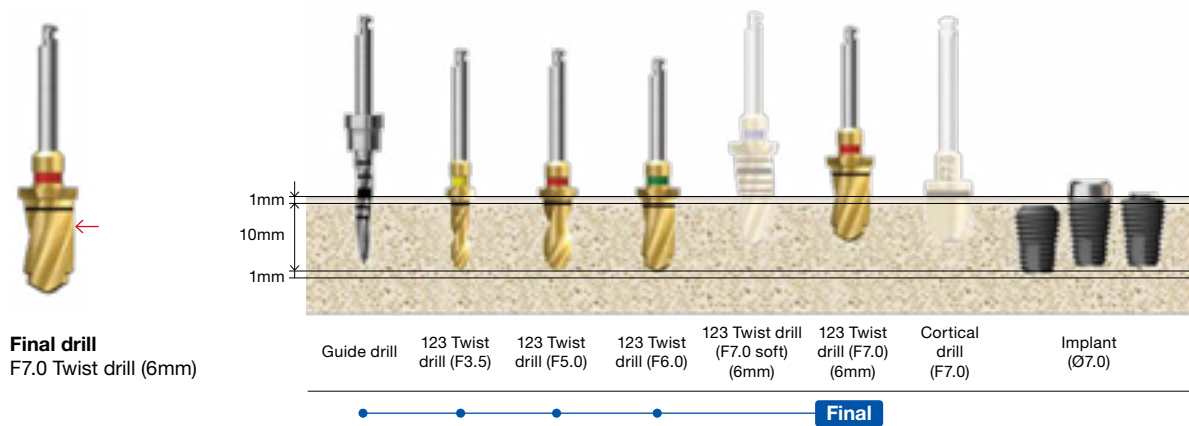
Soft bone

Since bone quality is soft, drill approx. 6mm with an F7.0 (soft) twist drill that is smaller than the implant's diameter to increase bone interference and secure sufficient primary stability.



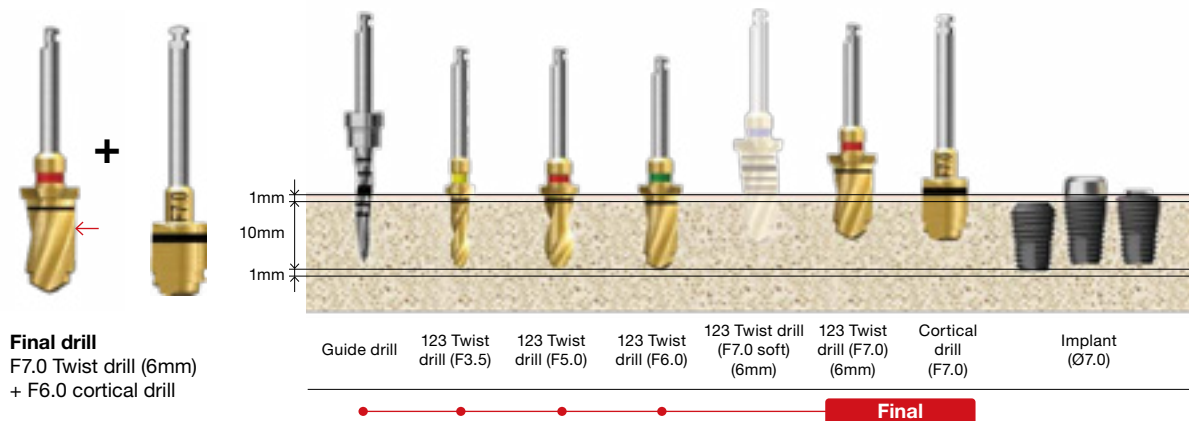
Normal bone

Since bone quality is good, drill approx. 6mm using a F7.0 twist drill that matches the implant's diameter as the final drill to create a drill hole.



Hard bone

Since bone quality is hard, use a F5.5 123 Twist drill and F5.5 123 cortical drill (III) and drill until the upper marking line to prevent osteonecrosis and over-torque.



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.

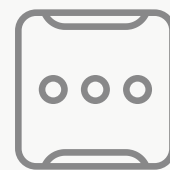
3



First wash

- After surgery, immediately separate and wash all the used instruments.

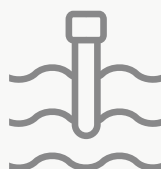
4



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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