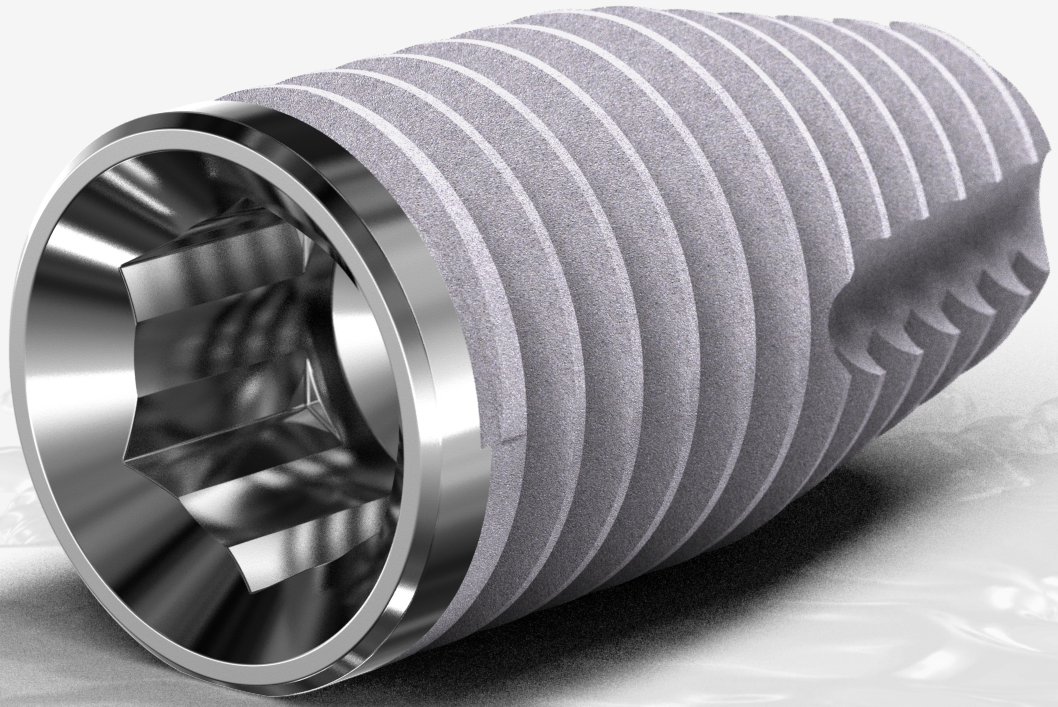
PROVATA™
SOUTHERNIMPLANTS



SURGICAL MANUAL

VERSION 1

Dental implants are now an indispensable part of dental treatment options. With the globalization of medical infrastructures and higher standards of living, implant applications continue to increase.

Southern Implants has been a manufacturer and distributor of dental implants since 1987. Today, the Southern group is a leading biomedical engineering entity, with major intellectual property and capabilities in implantable devices, arthroplasties and tissue regeneration. Top-end professional users, who want more choices, have driven our product range to enormous and exciting heights. Striving for excellence and meeting customer needs has led to our wide product range characterized by numerous unique and innovative products, which include:

- Multiple interfaces, both internal and external, to suit customer preference.
- The MAX implant, a specialised implant, specifically designed for immediate molar tooth replacement.
- Co-Axis®, the first angled-top, screw-form implant, available in angulations of 12°, 24°and 36°.
- The Zygomatic and Oncology implants, optimized for prosthetic versatility.
- Many products engineered for primary stability and suitable for immediate loading.

My sincere thanks to all specialists, dentists and technicians who give continual feedback, suggestions and input. Our products are an interpretation of your needs.

Graham Blackbeard
Managing Director, Southern Implants

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Contents

Further information available on our website
www.southernimplants.com

Please note:
- Images are for illustration purposes only and do not necessarily accurately represent the product.
- All dimensions in this catalogue are in mm, unless otherwise specified.
- **Not all products are cleared for sale in all countries.**

Introduction

This surgical manual provides instructions for placement of the Southern Implants' PROVATA™ Implant range.

Note: This surgical manual is not intended as a substitute for adequate training. For the safe and effective use of dental implants, it is strongly suggested that specialized training be undertaken, including practical training to learn proper technique, biomechanical requirements, and radiographic evaluation.

Implant Description:

- The PROVATA™ implant is a self-tapping tapered implant made of commercially pure special Grade 4 Titanium (UTS≥ 900 Mpa).
- All implants are surface-roughened using Southern Implants' proven surface. The surface has an average S_a value of 1.4 microns. For detailed information, see CAT-1116.
- Tapered implants facilitate good stability for cases involving immediate loading and/or soft bone.
- The PROVATA™ implant is also available with the 12° angulated platform Co-Axis® design. This design enables tilting of the implant without compromising the restorative emergence angle.
- Cover screws and healing abutments are supplied separately.

PROVATA™

PROVATA™ Co-Axis® 12°

MSc-PROVATA™

MSc-PROVATA™ Co-Axis® 12°

Indications and intended use

These dental implants are indicated for immediate replacement of compromised teeth in the mandible or maxilla, and intended to provide support for a fixed or removable dental prosthesis in the form of a single tooth, partial-arch or full-arch restoration.

Considerations

Bone quality and quantity

Choose an appropriate size implant for the amount of bone available, without violating the biological width, and evaluate sufficient bone volume surrounding the implant body. Take care to avoid anatomical structures such as the sinus and mental nerve.

In dense bone, use new drills and profuse irrigation. In low-density bone, it is recommended to undersize the osteotomy by drilling with a smaller final drill (i.e. if placing a diameter 4.0mm implant, final shaping drill would be 3.3mm). Preferably use soft bone drills in this bone.

Loading times

Healing period is generally 3-4 months in the mandible and 4-6 months in the maxilla; however, healing periods may vary for each patient. When a shorter healing time or immediate loading is being considered, the assessment must be based on the individual clinical situation (i.e. bone quality, bone quantity, primary stability achieved, loading conditions, design of super- structure, etc.)

Implants may be immediately temporized on single or splinted multiple-unit restorations, if good primary stability is achieved.

Immediately temporized restorations should be kept out of occlusion.

The patient should adhere to a soft diet and place minimal forces on the restoration for 6-12 weeks.

Troubleshooting

Implant mobility: If the fixture is very loose, consider removal and replacement with a wider diameter fixture, without further drilling.

Poor fixture alignment: If the angular misalignment is less than 30°, the problem can be addressed using angulated abutments. If the angle is greater than 30°, remove the implant and allow the surgical site to heal for approximately six months. Repeat surgery on the same area after the healing period, or use a Co-Axis® implant to take full advantage of available bone.

Exposed threads: If the implant threads are exposed in the coronal region, perform a bone augmentation procedure.

Over-countersinking: Over-countersinking can cause complications with primary stability in cortical bone. The countersink should not extend beyond the cortical region whenever possible. Continue with normal treatment protocol, but it is recommended to avoid immediate or early loading, and to pay special attention to the stability of the implant in the first 3-6 months after placement.

Additional Information

Prosthetic planning

The PROVATA™ prosthetic range has a broad and versatile collection, capable of solving all clinical indications. Please consult the PROVATA™ product catalogue (CAT-2060) and various "Instructions for use" documents for more information.

Instrument care & sterilization

Please consult the Southern Implants Cleaning and Sterilization Procedure Guidelines (CAT-1039) for guidance concerning the maintenance of drills, instruments and surgical trays.

Tooling
Southern Implants' Twist Drills are made of stainless steel. Tapered dedicated drills and Screw Taps are made of Titanium Alloy.

Contraindications
Do not use in patients:
- who are medically unfit for dental implant procedures.
- who are allergic or have hypersensitivity to pure titanium or titanium alloy (Ti-6AL-4V) or polyetheretherketone (PEEK).
- where adequate numbers of implants cannot be placed to achieve full functional support for a prosthesis.

Warnings:
Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures. Drilling beyond the depth intended in the mandible may potentially result in permanent numbness to the lower lip and/or chin or lead to a haemorrhage in the floor of the mouth. Besides the mandatory precautions for any surgery, such as asepsis, one must avoid damage to the nerves and arteries by referring to anatomical knowledge and preoperative radiographs.

Responsibility for proper patient selection, adequate training, experience in the placement of implants and providing appropriate information for informed consent, rests with the practitioner. Improper technique can result in implant failure and/or loss of supporting bone. Southern Implants will not accept liability for damage caused by improper implant treatment.

Southern Implants' Dental Implants have only been validated for use with the corresponding Southern Implants' abutments and accessories. Although care has been taken to create interfaces that are equivalent to similar products on the market, Southern Implants cannot guarantee outcomes obtained using components from other manufacturers. Please refer to individual product catalogues for interface requirements. Southern Implants will not accept liability for damage caused by selection of incompatible abutments and accessories.

For short implants, clinicians should closely monitor patients for any of the following conditions: peri-implant bone loss, changes to implant's response to percussion, and radiographic changes in bone to implant contact along the implant's length. If the implant shows mobility or greater than 50% bone loss, the implant should be evaluated for possible removal. If the clinician chooses a short implant, then the clinician should consider a two-stage surgical approach, splinting a short implant to an additional implant, and placement of the widest possible fixture. Allow longer periods for osseointegration and avoid immediate loading.

Caution:
Implant success cannot be 100% guaranteed.
Implant treatment may result in biologic failures i.e. bone loss or mechanical failures, including fatigue fracture of implants.

It is strongly recommended that PROVATA™ implants are used only with Southern Implants' surgical instruments and prosthetic components.

New, as well as experienced implant users, should undertake special training before using a new system or a different treatment method. Contact your local Southern Implants representative for more information.

Before surgery:
A thorough radiological and clinical assessment must be done to determine the psychological and physical health of the patient.

Take care when treating patients with local or systemic factors that could affect the healing process of the tissues or interfere with the osseointegration process (i.e., smoking, uncontrolled diabetes, radiotherapy treatment, steroid therapy, poor oral hygiene, infection of the oral tissue, systemic bi-phosphonate therapy).

Treatment planning (surgical and prosthetic design) must accommodate patient specific conditions. In cases of bruxism or unfavorable jaw relationships the treatment option may have to be reassessed and adjusted.

Implant treatment is not recommended in juvenile patients, until the mature jaw bone growth phase has been reached.

Hard or soft tissue defects may result in compromised treatment outcomes.

In cases where correction of angulation is necessary, consider a Co-Axis® implant design with a 12 degree sub-crestal angulation correction.

At surgery:
Do not place narrow implants in the posterior region. Avoid the risk of prosthetic overload, that could lead to implant failure or fracture.

All instruments and tooling used during procedures must be maintained in good condition, and care must be taken not to damage the implant or other components.

Surgical procedure:
Assess bone quality during drilling procedures and follow the appropriate drill sequence to ensure optimal primary stability.

Drill at high speed (1000 -1500 rpm for twist drills and 800 rpm for tapered drills). Use copious irrigation (saline at room temperature), and drill with a continuous intermittent motion, to avoid overheating of the bone.

The implants are ideally placed with low speed, max. 15 rpm, using a implant motor unit and handpiece.

Caution:
Never exceed insertion torque of 80 Ncm when placing these implants. Over tightening an implant may lead to damage of the implant or fracture of the bone. If a surgical driver is used to insert the implant, special care needs to be taken to avoid over torqueing.

If the implant gets stuck during implant placement or 80 Ncm of insertion torque is achieved before the implant is fully seated, rotate the implant counter clockwise (handpiece in reverse mode) and remove implant from site. Adjust the osteotomy before placing the implant again.

To prepare the site with a Tap, place the Screw Tap into prepared implant site using low speed (25 rpm) and rotate tap to appropriate depth. Switch the implant motor unit to reverse mode and remove the Screw Tap anticlockwise. Continue with implant placement until desired position is achieved using maximum 80 Ncm of insertion torque.

Depth measurement system: The marks on the Twist/Tapered shaping drills indicate actual millimeter lengths/depths and correspond to the implant length.

Final vertical positioning depends on several clinical parameters, including esthetics, tissue thickness and available vertical space.

In situations where adjacent natural teeth interfere with the contra-angle head, preventing the drill from reaching the desired depth, a drill extension shaft may be used.

Caution: The drill preparation with Twist Drills extend up to 1mm longer than the implant. Allow for this additional length when drilling near vital anatomical structures.

PACKAGING

1) Implants: The outer packaging consists of a rigid, clear box which acts as protection for the inner packaging. The inner packaging consists of a clear plastic-formed bubble-type base with a "peel-back" lid. The contents of this inner package are sterile. Labeling Information is located on the surface of the peel-back lid and on the outside of the rigid box. Within the inner packaging there is a hollow tube which contains one implant. Sterility is assured unless the container or seal is damaged or opened.
2) Other sterile components are packed in a peel pouch and sterilized by gamma irradiation. Labeling information is located on the bottom half of the pouch, inside the packet. Sterility is assured unless the pouch is damaged or opened.
3) Other non-sterile components used in the laboratory are supplied clean but not sterile. These are: laboratory analogues, some Ti abutments, CIA abutments, TIB abutments, cast waxing sleeves and gold abutments with plastic sleeves. Labeling information is located on the bottom half of the pouch, inside the packet.

STERILITY

All dental implants and some abutments are shipped sterile and intended for single use, prior to the expiration date (see packaging label). Again, sterility is assured unless the container or seal is damaged or opened. DO NOT re-sterilize or autoclave these components.

Do not reuse implants, cover screws, temporary or permanent abutments. These are single-use products. Re-using these components may result in damage on the surface or change of critical dimensions. This may result in performance and compatibility issues. The removal of proteins from the metal (such as titanium) is extremely difficult and if not removed, it can lead to secondary infections.

Products provided non-sterile must be cleaned and sterilized prior to use, according to the guidelines in CAT-1039 and the Surgical Manual.

CLEANING

- Refer to CAT-1039
- Used instruments should be soaked immediately in instrument cleaning solution to avoid the drying of blood, saliva and tissue residue.
- Used surgical trays including grommets must be cleaned with suitable disinfectants.
- Multiple-part instruments must be disassembled prior to cleaning and sterilization.
- Internal debris/residue on instruments must be removed with a soft brush.
- Instruments should be inspected, cleaned separately and discarded if damaged.
- Best results are achieved if surgical instruments are cleaned by material type.
- Instruments and trays can be cleaned and disinfected in a dedicated instrument washer or alternatively by hand, followed by an ultrasonic bath with a detergent appropriate for surgical instruments.
- Instruments and trays must be rinsed and dried thoroughly.

STERILIZATION

- Refer to CAT-1039
- Instruments and trays should be autoclaved at 121°C or 250°F for 30 minutes or at 134-137°C for 3-7 minutes with a sufficient drying cycle to avoid instruments corrosion.

POTENTIAL ADVERSE EFFECTS

Dental implant therapy has normal contradictions and risks that are extensively documented in dental implant literature.

POST-PLACEMENT PROCEDURES

The following considerations should be reviewed prior to the restorative phase:

- Quantity, quality and health of soft and hard tissues
- Implant stability
- Implant position and abutment selection
- Occlusal analysis
- Oral hygiene assessment

MAGNETIC RESONANCE (MR) SAFETY INFORMATION:

PROVATA™ implants have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artefact in the MR environment. The safety of PROVATA™ implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

STORAGE AND HANDLING

Devices should be stored at room temperature. Refer to the individual product packaging label and the corresponding manual (CAT-2060) for special handling instructions.

CAUTION: (USA ONLY)

United States Federal Law restricts this device to sale to, or on the order of, a licensed dentist or physician.

For Technical Assistance or additional product literature, please contact:

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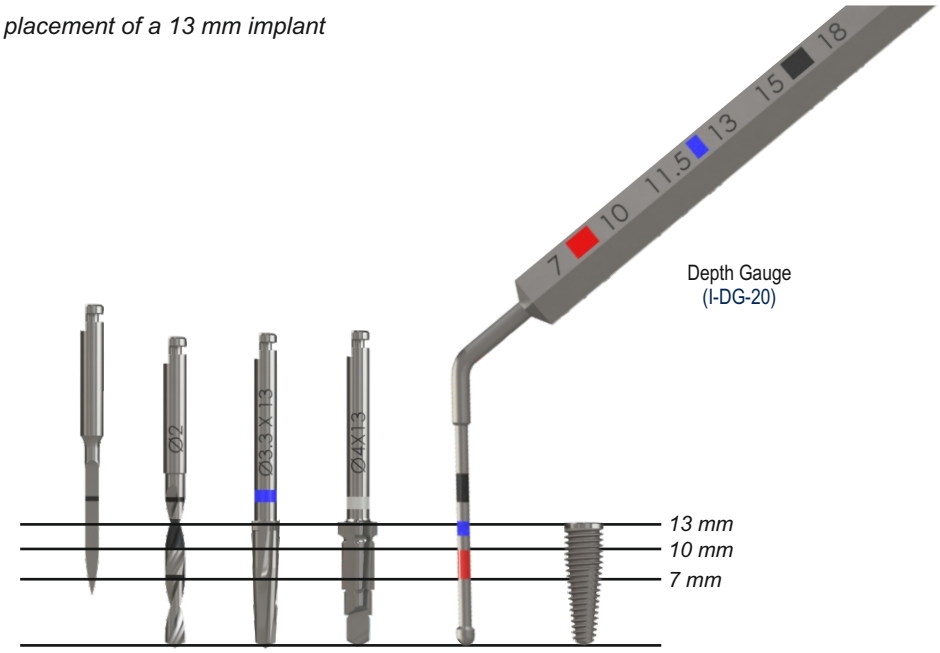
PRODUCT RANGE

	8.5mm	10mm	11.5mm	13mm	15mm	18mm
Ø4.0mm	PRO408 MSc-PRO408	PRO410 MSc-PRO410	PRO411 MSc-PRO411	PRO413 MSc-PRO413	PRO415 MSc-PRO415	PRO418 MSc-PRO418
Ø5.0mm	PRO508 MSc-PRO508	PRO510 MSc-PRO510	PRO511 MSc-PRO511	PRO513 MSc-PRO513	PRO515 MSc-PRO515	PRO518 MSc-PRO518
Ø4.0mm Co-Axis®	PRO12D408 MSc-PRO12D408	PRO12D410 MSc-PRO12D410	PRO12D411 MSc-PRO12D411	PRO12D413 MSc-PRO12D413	PRO12D415 MSc-PRO12D415	PRO12D418 MSc-PRO12D418
Ø5.0mm Co-Axis®	PRO12D508 MSc-PRO12D508	PRO12D510 MSc-PRO12D510	PRO12D511 MSc-PRO12D511	PRO12D513 MSc-PRO12D513	PRO12D515 MSc-PRO12D515	PRO12D518 MSc-PRO12D518

IMPLANT DRILL DEPTH

Illustrating placement of a 13 mm implant



PROVATA™ IMPLANTS

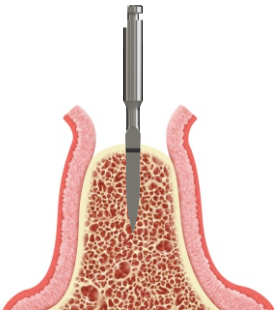
STEP-BY-STEP SURGICAL PLACEMENT

Step 1: Initiate the osteotomy

Note: It is recommended to raise a full-thickness mucoperiosteal flap.

The 3Spade drill (D-3Spade-1.8M / 1.5L) is used to initiate the osteotomy by perforating the cortical plate at the desired location.

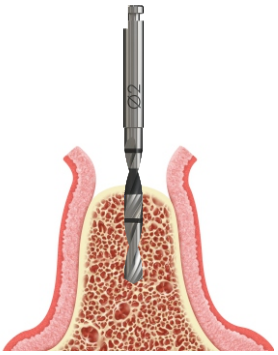
All drilling should be performed at a speed of 1000-1500 rpm with copious irrigation. An intermittent technique should be used to avoid overheating of the bone.



Step 2: Pilot drilling – Ø2mm Twist Drill

Drill in the planned direction to the appropriate depth, as indicated by the depth markings on the Ø2mm Twist Drill (D-20T-M10 / M15 / M20).

Note: Depth should allow implant to be inserted level with, or slightly submerged in surrounding marginal bone.

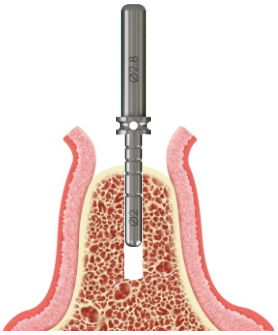


Step 3: Check alignment

Insert the Direction Indicator (I-DI) after using the Twist Drill to verify the alignment with adjacent teeth/implants and opposing arch.

A radiograph should be taken at this point to verify depth and direction.

If the drilling direction is incorrect, start a new direction with the pilot drill as in Step 2 and continue with the remaining procedures.



Step 4: Gradually enlarge the osteotomy

The PROVATA™ tapered shaping drills are length and diameter specific.

Use the length and diameter drill corresponding to the implant that is selected.

Widen the osteotomy intermittently to the desired diameter.

Step 5: Implant placement

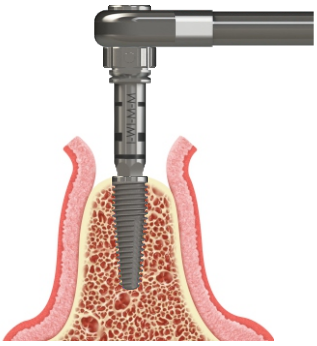
Connect the Hand-Piece insertion tool (I-HM-S / M / L) to the handpiece. Engage the internal hex of the implant with the insertion tool and carefully remove the implant from the sterile vial. (The hexagon of the insertion tool in the implant must be fully engaged before torque is applied, to prevent any damage. The hexagon is fully engaged when the straight portion of the hexagon tool is almost completely sunken in the implant.)

Alternatively, the Wrench insertion tool [I-WI-M-S / M / L] can be connected to the Ratchet Wrench (I-TWS), with wrench insert converter (I-WI-SS), and used to extract the implant from its packaging.

Insert the implant at 15-20 rpm while applying downward pressure.

Step 6: Fully seat the implant

The Ratchet & Torque Attachment Wrench (I-TWS with I-TWS-B100), in combination with the wrench insert converter (I-WI-CST) and Hand-Piece insertion tool (I-HM-S / M / L), or the wrench insertion tool (I-WI-M-S / M / L) with wrench insert converter (I-WI-SS), may be used for final manual seating of the implant.

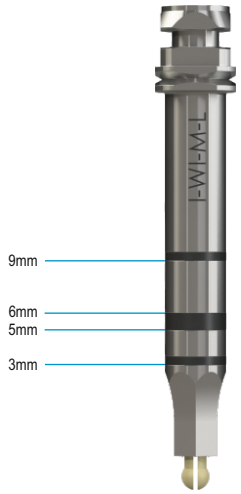


Use light finger force on the wrench when leveling the implant. Excessive torque (>80Ncm) with the wrench should be avoided, as this will cause too much compression in the bone or damage to the implant. A torque exceeding the maximum limit indicates that the implant should be retrieved and additional drilling should be performed in the site.

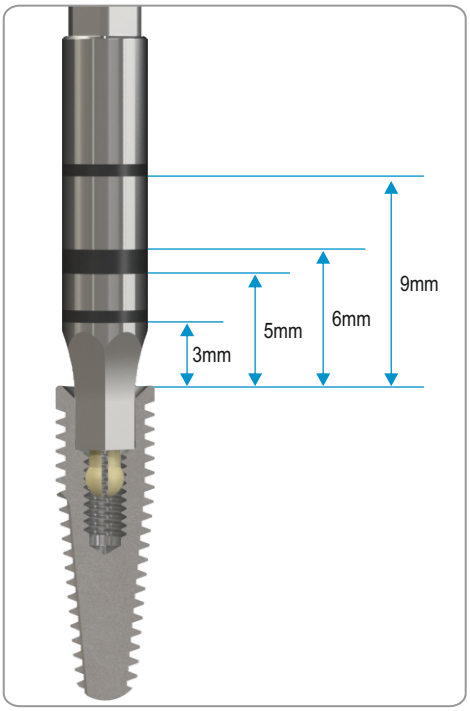
Note: Because the implants are self-tapping, it is recommended to stop rotation once the implant has reached the prepared depth. The implant may continue to advance beyond the drilled depth with further rotations, owing to the effective self-tapping thread. Care should be taken not to countersink the implant too far, especially in soft bone. There is also a risk that the implant may spin.

Insertion Tool Depth Markings

I-HM-L used for illustration purposes



I-WI-M-L used for illustration purposes



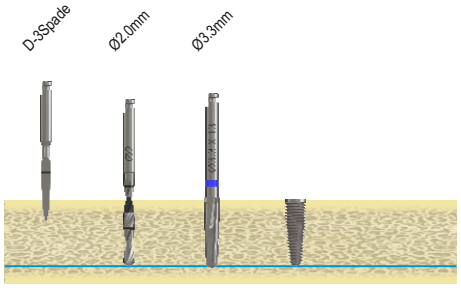
Laser markings at 3mm, 5mm, 6mm and 9mm from the implant platform.
NOTE: Number of laser markings depends on tool size (S / M / L).

Important: The PEEK bits (I-PBIT-L18) should be replaced on a regular basis. General wear & tear are to be expected with regular use (items sold separately).

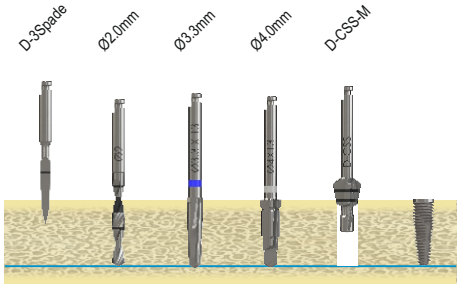
DRILL SEQUENCE

Ø4.0mm Tapered *(PRO4 / MSc-PRO4)*

Soft Bone

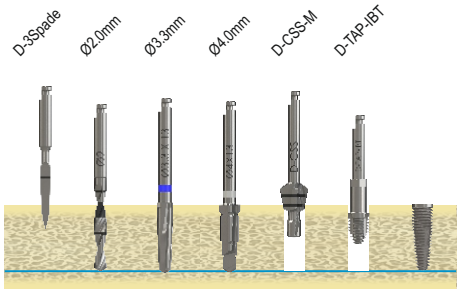


Medium Bone



(optional)

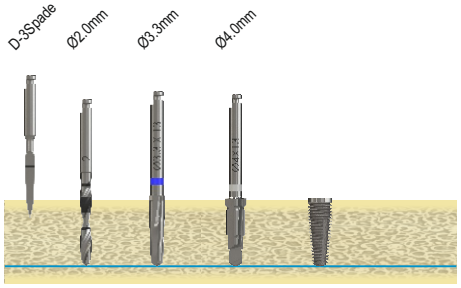
Dense Bone



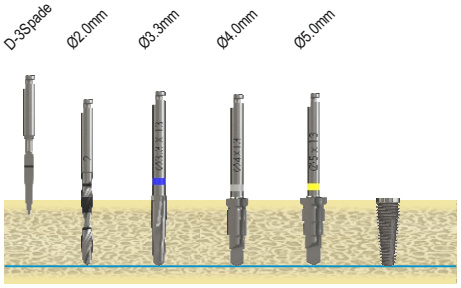
(optional)

Ø5.0mm Tapered *(PRO5 / MSc-PRO5)*

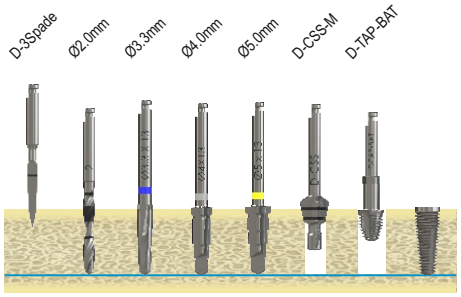
Soft Bone



Medium Bone



Dense Bone



(optional)

(illustrations are for 13mm implants)

NOTE: Site preparation sequence recommended by Southern Implants does not replace the judgement and experience of the surgeon.

PROVATA™ 12° CO-AXIS® IMPLANT

STEP-BY-STEP IMMEDIATE SURGICAL PLACEMENT

Step 1: Extraction

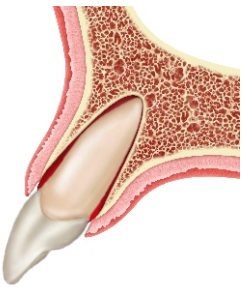
When extracting a tooth for immediate implant placement it is important to do the extraction atraumatically to keep the buccal bone plate intact. Preferably a periotome should be used to carefully loosen the tooth from the periodontium.

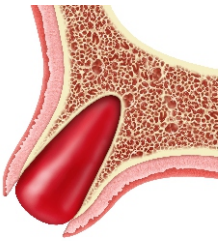
After extraction, evaluate the buccal bone plate.

If the bone is intact, evaluate the buccal soft tissue height. This will give you an indication of the vertical placement. It is recommended that the implant be placed 2-3mm sub-crestal, depending on the void between implant and buccal bone plate.

Carefully curettage the socket and remove all infected tissue where necessary.

(If the bone is not intact it is recommended to abort the procedure and let the socket heal with or without augmentation material)





Step 2: Initiate the osteotomy

The 3Spade drill (D-3Spade-1.8M / 1.5L) is used to initiate the osteotomy at the desired location. **In an extraction socket, initiate drilling on the palatal wall approximately 1/3 from the apex.**

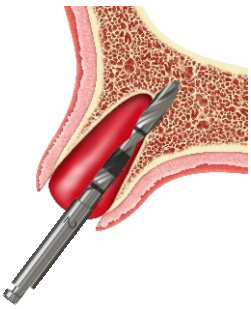
All drilling should be performed at a speed of 1000-1500 rpm with copious irrigation. An intermittent technique should be used to avoid overheating the bone.

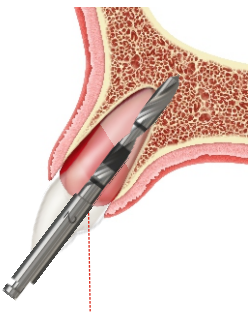
Step 3: Pilot drilling – Ø2mm Twist Drill

Drill in the planned direction to the appropriate depth, as indicated by the depth markings on the Ø2mm Twist Drill (D-20T-M10 / M15 / M20). If an anterior implant is being placed, ***align the drill to the incisal edge of the adjacent tooth.***

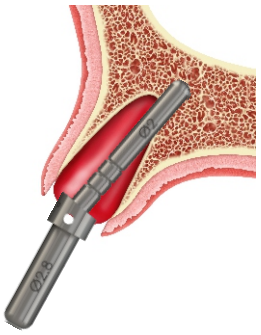
With the 12° Co-Axis® angulation, the screw access hole will come out on the palatal side in the area of the cingulum if aligned correctly. If the osteotomy is angulated too much to the palatal side (e.g. normal direction when preparing for a screw retained restoration) there is a risk of a sub-optimal restoration angle, with soft and hard tissue being compromised on the palatal side.

Note: Vertical positioning is dependent on soft tissue height and the jump gap between the buccal wall and implant.





Step 4: Check alignment

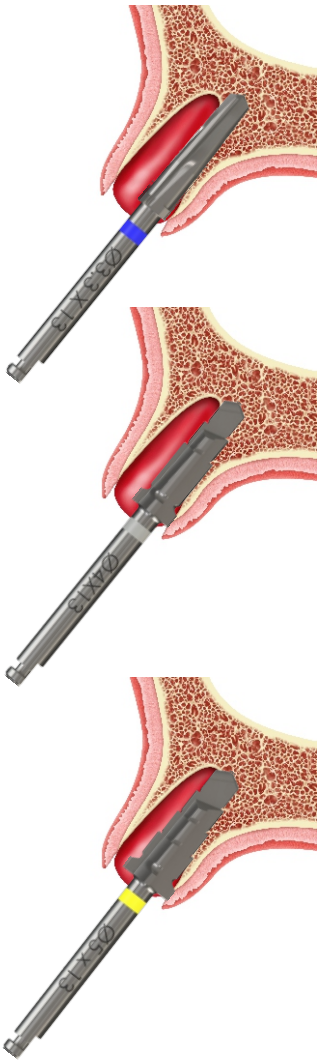


Insert the direction indicator (I-DIN-12d) after using the Twist Drill to verify the alignment with adjacent teeth/implants and opposing dentition.

A radiograph may be taken at this point to verify depth and direction.

If the drilling direction is incorrect, start a new direction with the pilot drill as in Step 2 and continue with the remaining steps.

Step 5: Gradually enlarge the osteotomy



The PROVATA™ tapered shaping drills are length and diameter specific. Use the length corresponding to the implant that is selected to be placed. Widen the osteotomy intermittently to the desired diameter.

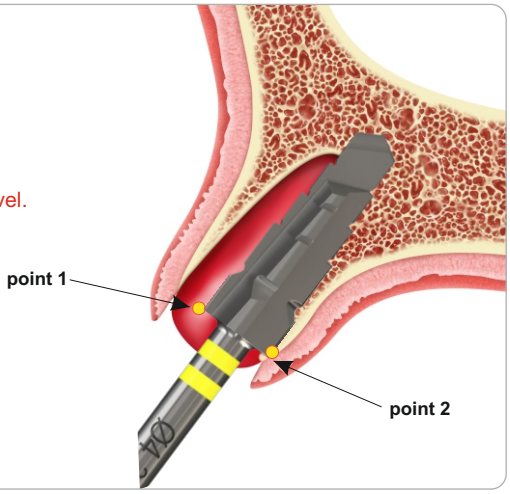
Care should be taken to drill to the planned depth. The implant should be placed at the same vertical level as the prepared osteotomy. If the implant is being forced deeper, there is a risk in soft bone that primary stability will be compromised.

Note: Caution should be taken to not over prepare the implant site, especially for shorter length implants (9mm and shorter).

Please Note: With a probe, check the soft tissue height, prepare final step at least 1 mm subcrestal.

Depending on the gap between planned implant and buccal bone plate, deeper coutersinking can be appropriate.

***Final Tapered Drill Position**



PLEASE NOTE:

Point 1
This corner of the drill is to be at bone level.

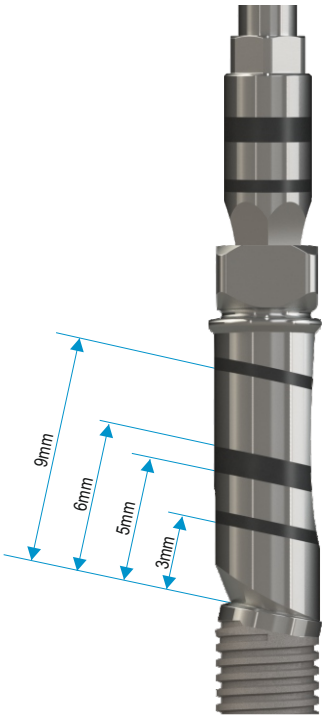
Point 2
This corner of the drill will be subcrestal.

Step 6: Implant placement

PROVATA™ Co-Axis® implants are pre-mounted and placed with an insertion tool, that fits into the hex in the Fixture Mount.

Connect the insertion tool (I-HM-S / M / L) to the handpiece.

Push the tool into the Fixture Mount. The hexagon of the insertion tool in the Fixture Mount must be fully engaged before torque is applied, to prevent any damage. The hexagon is fully engaged when the straight portion of the hexagon tool is almost completely sunken in the Fixture Mount.

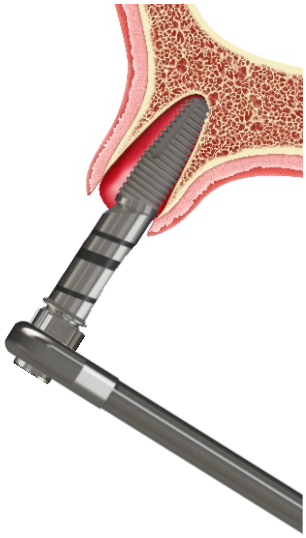


Laser marking at:
3mm, 5mm, 6mm and 9mm from the implant platform.

Insert the implant at 15-20 rpm while applying downward pressure.

Important: *The PEEK bits (I-PBIT-L18), of the insertion tools, should be replaced on a regular basis. General wear & tear are to be expected with regular use (items sold separately).*

Step 7: Fully seat the implant



The Ratchet & Torque Attachment Wrench (I-TWS with I-TWS-B100), in combination with the wrench insert converter (I-WI-SS), may also be used on the Fixture Mount for final manual seating of the implant.

Use light finger force on the wrench when leveling the implant.

Excessive torque (>80 Ncm) with the wrench should be avoided, as this will cause too much compression in the bone or damage to the implant. A torque exceeding the maximum limit indicates that the implant should be retrieved and additional drilling should be performed to increase the depth and diameter of the osteotomy site.

Note: Because the implants are self-tapping, it is recommended to stop rotation once the implant has reached the prepared depth. The implant may continue to advance beyond the drilled depth with further rotations, owing to the effective self-tapping thread. Care should be taken not to sink the implant too far, especially in soft bone. There is also a risk that the implant may spin.

Step 8: Fixture Mount Removal

Once the implant is placed and the position verified, after final X-rays have been taken, remove the Fixture Mount by unscrewing the Fixture Mount screw using a 1.27 Hex Hand-Held (I-HD-27-S / M / L) driver (fig 2).

Note: If the Fixture Mount is removed before final placement, then the implant/s can alternatively be placed with the PROVATA™ Co-Axis® Hand-Piece insertion tool (I-H-PRO12D-S / M / L).

Refer to page 24 for the PROVATA™ Co-Axis® (Hand-Piece) Insertion Tool Protocols.

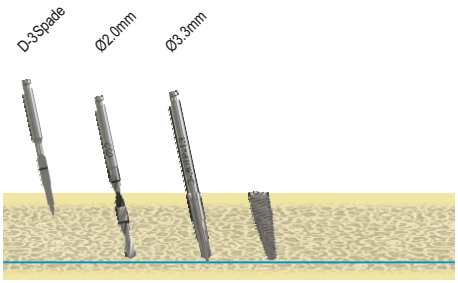
fig.1

fig.2

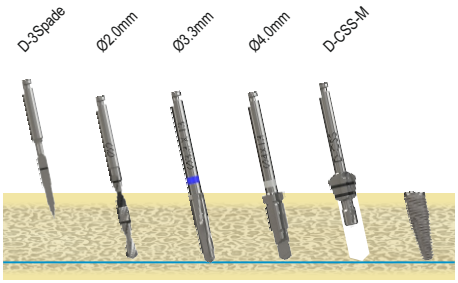
DRILL SEQUENCE

Ø4.0mm Co-Axis® Tapered (PRO12D4 / MSc-PRO12D4)

Soft Bone

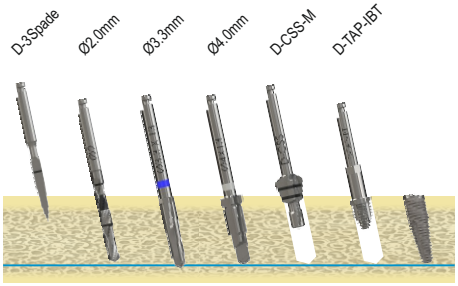


Medium Bone



(optional)

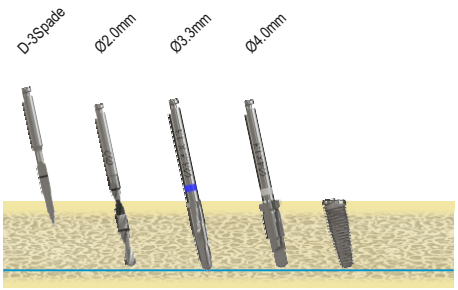
Dense Bone



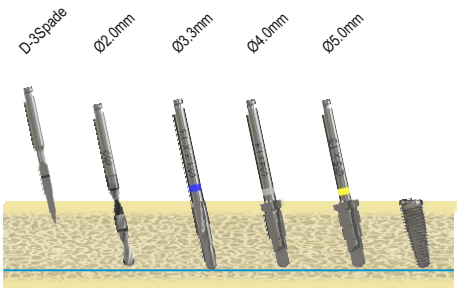
(optional)

Ø5.0mm Co-Axis® Tapered (PRO12D5 / MSc-PRO12D5)

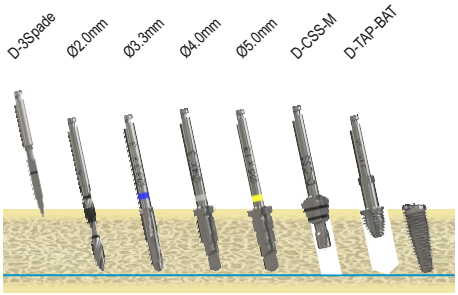
Soft Bone



Medium Bone



Dense Bone



(optional)

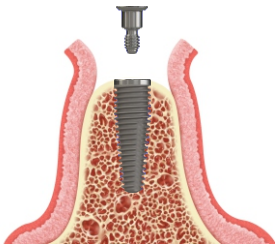
(illustrations are for 13mm implants)

NOTE: Site preparation sequence recommended by Southern Implants does not replace the judgement and experience of the surgeon.

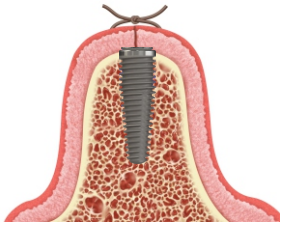
TWO-STAGE PROCEDURE

After the implant is fully seated in the osteotomy, place the Cover Screw (CS-M) with a 1.27 Hex Hand-Held (I-HD-27-S / M / L), Hand-Piece (I-HHD-27S / M / L) or Wrench Insert (I-WI-27S / M / L) driver.

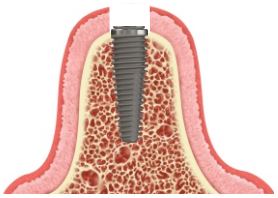
Tighten to 10-15 Ncm.



Reposition the flap margins together and suture closed.

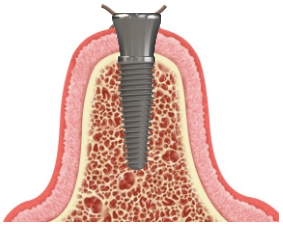


After an appropriate healing period, expose and remove the cover screw using the 1.27 Hex driver. Exposure of the cover screw can be done either with a mid-crestal incision using a scalpel, or if the keratinized mucosa is broad, a soft tissue punch (I-TC1 / I-TC5) of the appropriate diameter may be used. Locate the cover screw by probing the soft tissue.



Place the selected Healing Abutment (HA-M-xx-3 / 4 / 6) or appropriate definitive abutment.

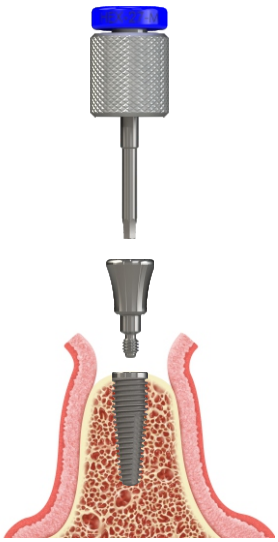
There is a range of healing abutments to select from, according to length and width. Select a length at least 2 mm supra-mucosal. Refer to the PROVATA™ Catalogue (CAT-2060) for healing abutment options.



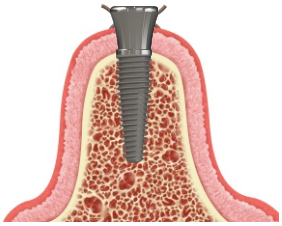
ONE-STAGE PROCEDURE

After the implant is fully seated in the osteotomy, place the selected Healing Abutment (HA-M-xx-3/4/6) or appropriate definitive abutment with a 1.27 Hex Hand-Held (I-HD-27-S / M / L), Hand-Piece (I-HHD-27S / M / L) or Wrench Insert (I-WI-27S / M / L) driver.

Tighten to 10-15 Ncm.



Arrange the flap margins around the Healing Abutment for a tight seal and suture.



IMMEDIATE LOADING PROCEDURE

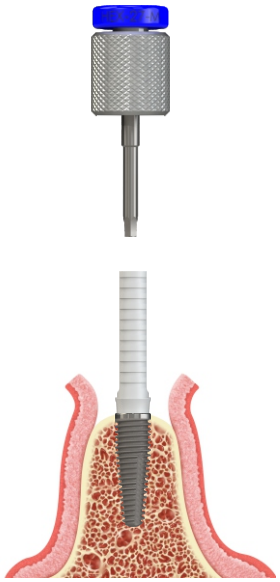
After the implant is fully seated in the osteotomy, place the Temporary Titanium (TC-M / TC-NM) or PEEK (PKC-M-2 / PKC-NM-2) Cylinder and Retaining Screw (TS-Z-18) with a 1.27 Hex Hand-Held (I-HD-27-S / M / L), Hand-Piece (I-HHD-27S / M / L) or Wrench Insert (I-WI-27S / M / L) driver.

Refer to the PROVATA™ Catalogue (CAT-2060) for alternative screw and driver options.

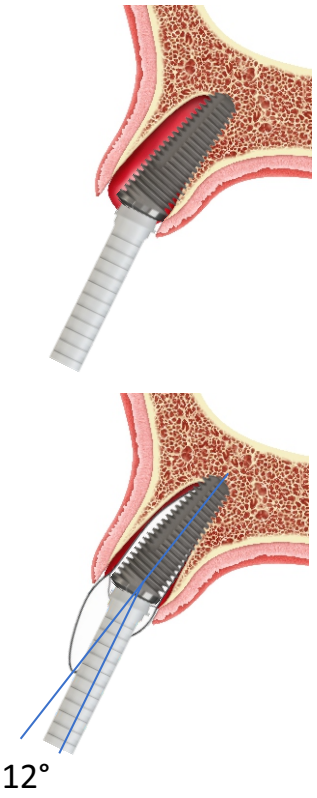
Retaining Screw Tightening torque:

Titanium Cylinders (TC-M / TC-NM)	32 Ncm
PEEK Cylinders (PKC-M-2 / PKC-NM-2)	15 Ncm

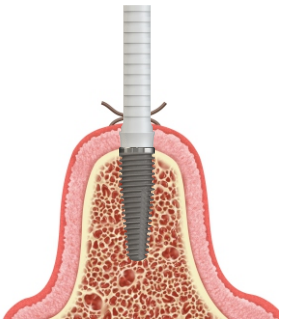
PROVATA™

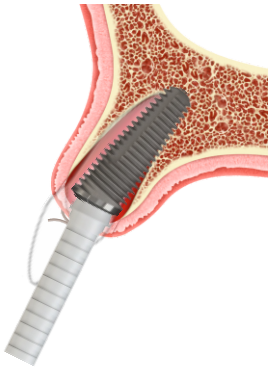


PROVATA™ Co-Axis® 12°



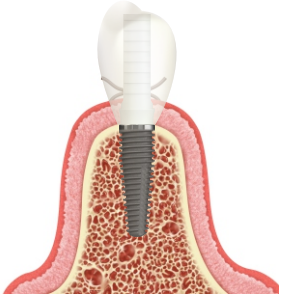
Arrange the flap margins around the Temporary Cylinder to create a tight seal and suture.





Fabricate the temporary crown in the preferred material and technique.

It is recommended that single and partial units be kept out of the occlusion during the healing phase.



DRILL INFORMATION

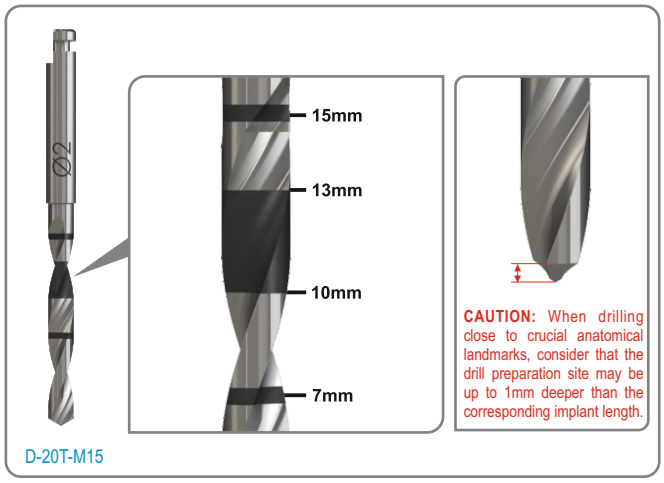
Twist Drills

D-3Spade D-20T-M10 D-20T-M15 D-20T-M20 D-29T-M15 D-29T-M20 D-30T-M10 D-30T-M15 D-30T-M20

Dedicated Taps

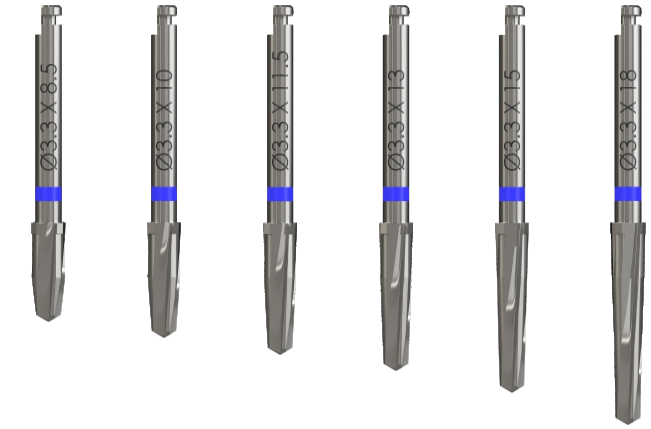
D-TAP-IBT D-TAP-BAT

Twist Drill Markings



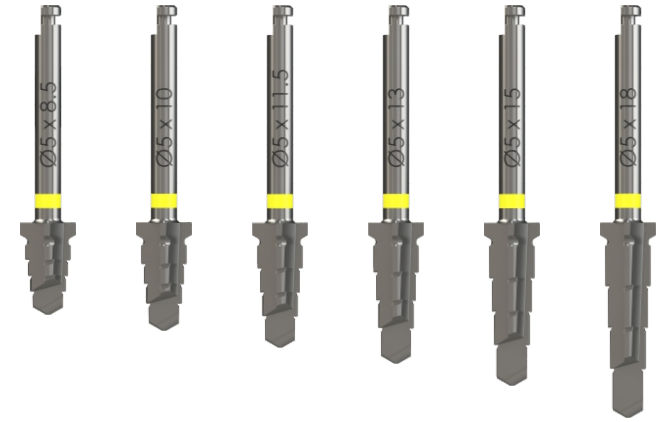
D-20T-M15

Dedicated Tapered Drills



D-33TP-8.5 D-33TP-10 D-33TP-11.5 D-33TP-13 D-33TP-15 D-33TP-18

D-40TP-8.5 D-40TP-10 D-40TP-11.5 D-40TP-13 D-40TP-15 D-40TP-18



D-50TP-8.5 D-50TP-10 D-50TP-11.5 D-50TP-13 D-50TP-15 D-50TP-18

INSTRUMENT INFORMATION

Ratchet & Torque Attachment Wrench

I-TWS

I-TWS-B45 maximum torque 45Ncm

I-TWS-B100 maximum torque 100Ncm

Refer to CAT-1051 & CAT-1186 for alternative torque wrenches.

Wrench Insert Converters

I-WI-CST

For Hand-Piece (latch-type) inserts featuring the W&H hex

I-WI-SS

Wrench insert converter to Southern Implants Square

I-WI-SL

For Hand-Piece (latch type) inserts without W&H hex

Bone Mills

I-HBM-M-46

CODES

I-HBM-M-46
I-HBM-M-56

NOTE: Bone mill recommended with placement of flared prosthetic components.

Direction Indicator

CODE

I-DI

I-DI

Angled Direction Indicators

CODE

I-DI-12d

I-DI-12d

CODE

I-DIN-12d

I-DIN-12d

Angled Profile Gauges (PROVATA™)

CODES

I-DI12D-4T-10
I-DI12D-4T-13
I-DI12D-4T-15

I-DI12D-4T-10

CODES

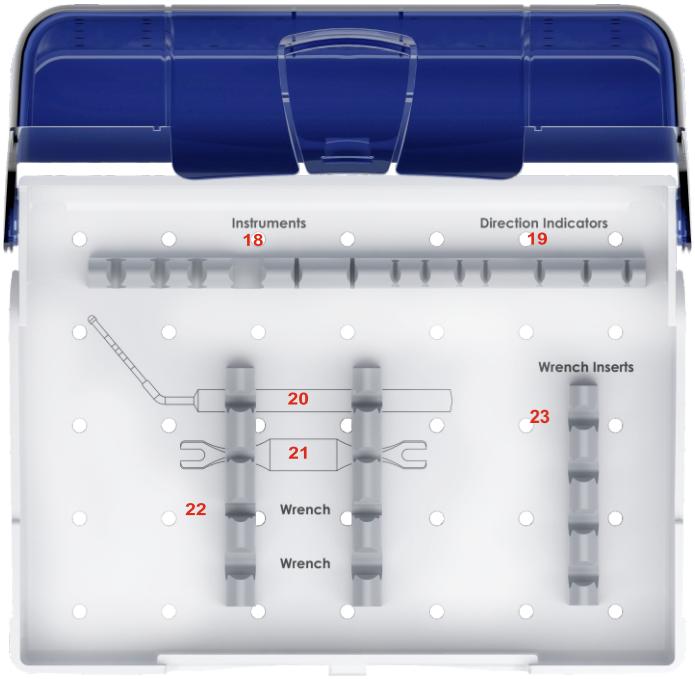
I-DI12D-5T-10
I-DI12D-5T-13
I-DI12D-5T-15

I-DI12D-5T-10

INSTRUMENT TRAY

I-HEX-EG For surgical placement of PROVATA™ Implants

(for Cleaning & Sterilization instructions see CAT-1039)



1	D-3Spade-1.8M / 1.5L	3-Spade Drill Ø1.8 / Ø1.5
2	D-20T-M10 / M15 / M20	Ø2.0 Twist Drill
3	D-CB	Counter Bore*
4	D-CSS-M	Counter Sink
5	D-29T-M15 / M20	Ø2.85 Twist Drill
6	D-30T-M10 / M15 / M20	Ø3.07 Twist Drill
7	D-33T-M10 / M15 / M20	Ø3.25 Twist Drill**
8	D-43T- M10 / M20	Ø4.3 Twist Drill**
9	D-53T-M13	Ø5.3 Twist Drill**
10	Additional drills. Refer to site preparation sequence.	
11	D-30TP-8.5 / 10 / 11.5 / 13 / 15**	
	Ø3.0mm Tapered Drills	
12	D-33TP-8.5 / 10 / 11.5 / 13 / 15 / 18 / D-TAP-IBNT**	
	Ø3.3mm Tapered Drills	** Optional TAP to replace 18mm drill
13	D-40TP-6** / 8.5 / 10 / 11.5 / 13 / 15 / 18 / D-TAP-IBT	
	Ø4.0mm Tapered Drills	Optional TAP to replace 18mm drill
14	D-50TP-6** / 8.5 / 10 / 11.5 / 13 / 15 / 18 / D-TAP-BAT	
	Ø5.0mm Tapered Drills	Optional TAP to replace 18mm drill
15	D-60TP-6 / 8.5 / 10 / 11.5 / 13 / 15 / 18 D-TAP-BBBT**	
	Ø6.0mm Tapered Drills	** Optional TAP to replace 18mm drill

16	I-FME-X	Fixture Mount Extension **
	I-CON-X	Connector to Handpiece **
	I-HM-S / M / L	Insertion Tool
	I-H-PRO12D-S / M / L	Insertion Tool *
	I-WI-M-S / M / L	Wrench Insertion Tool
17	I-CS-HD	Hand Held, Cover Screw Hex Driver (0.9 Hex) **
	I-HD-S / M / L	Hand Held Hex Driver (1.22 Hex)
	I-WI-22S / M / L	Wrench Insert Hex Driver (1.22 Hex)
	I-HHD-22S / M / L	Handpiece Hex Driver (1.22 Hex)
	I-QDI-S / M / L	Driver, Quad
	I-HD-27-S / M / L	Hand Held Hex Driver (1.27 Hex)
	I-HHD-27S / M / L	Handpiece Hex Driver (1.27 Hex)
	I-WI-27S / M / L	Wrench Insert Hex Driver (1.27 Hex)
18	I-DE-K / G	Drill Extension
19	I-DI	Direction Indicator
	I-DI-12d	Direction Indicator 12°
20	I-DG-20	Depth Gauge
21	I-SP-X	Flat Spanner
22	I-TWS	Torque Wrench Surgical
	I-TWS-B45/B100	Torque gauge attachment for I-TWS
23	I-WI-CST	Wrench to Latch Converter (W&H Hex)
	I-WI-SL	Wrench to Latch Converter
	I-WI-SS	Wrench to Square Converter
	I-WI-C-S / L	Converter from Handpiece to Wrench*

* Optional drills/instruments available.

** Optional, used with External Hex only.

Note: Most Instruments available in Short / Medium / Long.

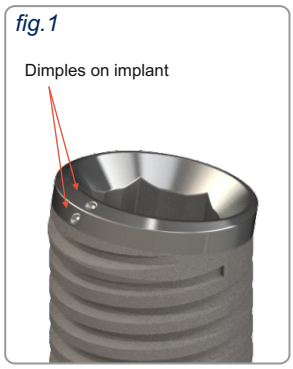
CO-AXIS® INSERTION TOOLS

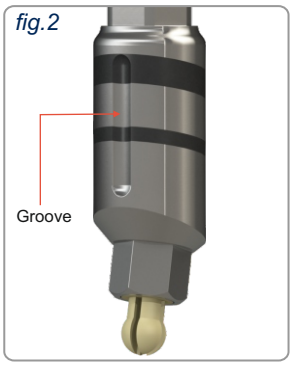
INSERTION TOOL PROTOCOL

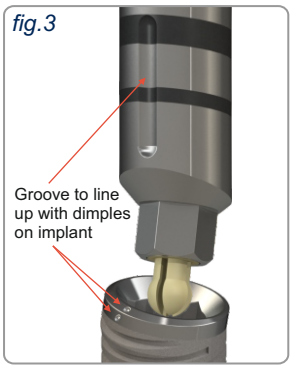
The PROVATA™ Co-Axis® implants can also be placed with a special insertion tool, **without** the Fixture Mount.

Connect the Insertion Tool (I-H-PRO12D-S / M / L) to the handpiece. Identify the dimples on the implant platform (fig.1). This side lines up with the groove on insertion tool. Identify the groove on the tool (fig.2). Line up the groove on the insertion tool with the dimples on the implant (fig.3). Push the tool into the implant until the insertion tool fits flush with the implant.

Insert the implant at 15-20 rpm while applying downward pressure.



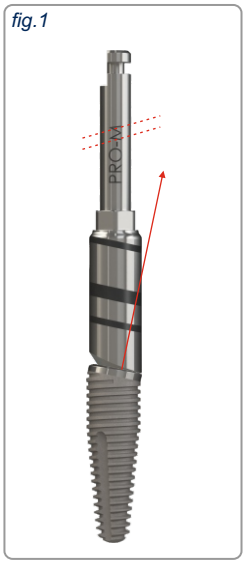


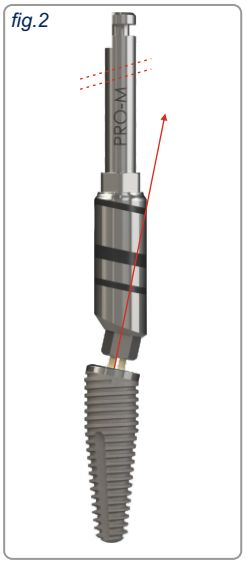


INSERTION TOOL REMOVAL PROTOCOL

1. To remove the insertion tool from the implant, pull the insertion tool in the direction perpindicular to restorative platform and parallel to prosthetic axis (fig.1).
2. The insertion tool will be removed in the direction of the pulling force (fig.2).

NOTE: Do not detach the insertion tool from implant before final placement is confirmed, after final X-rays are taken. Detach the insertion tool from the handpiece only.





Important: The PEEK bits (I-PBIT-L18) should be replaced on a regular basis. General wear & tear are to be expected with regular use (items sold separately).

IMPRESSION COPING INFORMATION

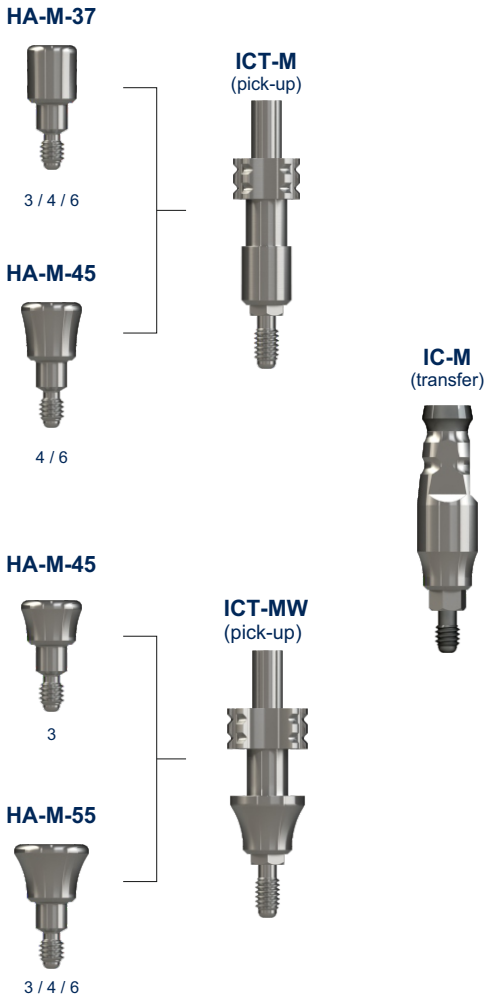
The selected Healing Abutment (HA-M-xx-3 / 4 / 6) will determine the Pick-up Impression Coping (ICT-M / ICT-MW) to be used for the impression taking process, as shown in the PROVATA™ Catalogue extract (fig. 1).

A transfer-type impression coping (IC-M) is also available in the PROVATA™ range.

Note: Due to the availability of only one transfer coping for all healing abutment sizes, some tissue impingement and discomfort may be expected with the use of smaller width and/or longer length healing abutments. The transfer coping is only recommended in compromised cases.

Refer to the Internal-Hex Range Pick-up Impression Coping information sheet (CAT-1190) for instructions on using these components.

fig.1



Extract from PROVATA™ Catalogue (CAT-2060)

PROVATA™ AND EXTERNAL HEX COMBINATION

Provata™ and External Hex implants have the same implant body configuration.

This gives flexibility in treating challenging cases, where greater than 12 degree subcrestal angulation is needed, or a narrow body implant is needed, e.g. less than a Ø4.0 mm implant.

With the same surgical instrument tray one is able to place implants ranging from Ø3.0 to Ø6.0mm and Co-Axis® implants with 12°, 24° and 36° angulations.

	Straight				Co-Axis® 12°				Co-Axis® 24°			Co-Axis® 36°
	Ø3.0	Ø3.25	Ø4.0	Ø5.0	Ø3.25	Ø4.0	Ø5.0	Ø6.0	Ø4.0	Ø5.0	Ø6.0	Ø5.0
PROVATA™			✓	✓		✓	✓					
External Hex	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

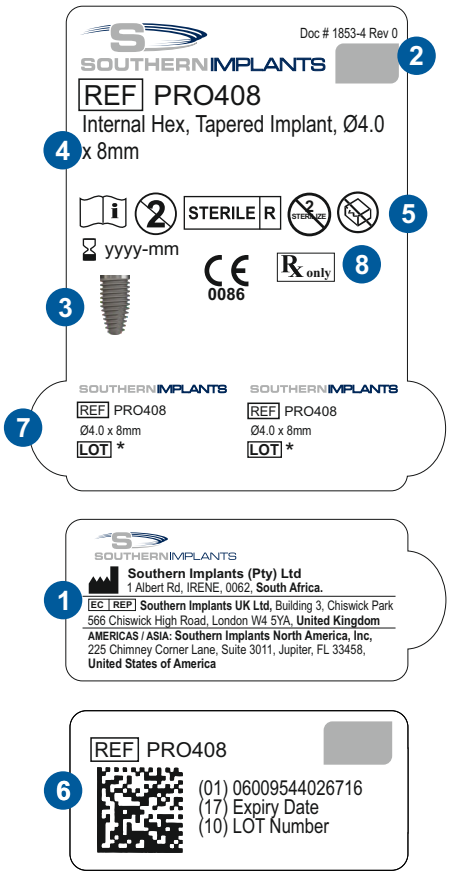
NOTE: Tapered implants only

EXPLANATION OF SYMBOLS

The following symbols are used on our packaging labels and they indicate the following:

1. **Manufacturer**
2. **Colour code indicating implant interface**
3. **Implant image**
4. **Implant details and size**
5. **Sterilization using Irradiation**
   - **Do not Resterilize**
   - **Consult instruction for use**
   - **Do not reuse**
   - **CE mark and notified body number**
   - **Expiry date**
   - **Sterile unless package is opened or damaged**
6. **2D Bar coding**
   Contains the GTIN, Expiry Date and LOT Number
7. **Patient sticker for documentation purposes**
   (to be used by health care provider on patient file)
8. **Prescription device**

CAUTION: FEDERAL LAW RESTRICTS THE DEVICE TO SALE BY OR ON THE ORDER OF A LICENCED HEALTH CARE PROVIDER.



Platform Interface

- **Ø4.0**
- **Ø5.0**

Images are for illustration purposes only and do not necessarily accurately represent the product.

For contact information on your nearest distributor,
visit www.southernimplants.com

CAT-8030-00 (C972)