

Innovative Treatment Solutions





Southern Implants is a leading provider of unique and innovative dental implant products with a focus on top-end professional users who want more choices. Southern's expertise in research, development and manufacturing of dental implants allows us to provide Innovative Treatment Solutions that will reduce treatment times and improve patient outcomes.

Striving for excellence and meeting customer needs, has led to our wide product range characterized by Unique and Innovative products which include;

- Multiple interfaces, to suit customer preference.
- INVERTA™ implant, featuring a body-shift design, engineered for primary stability and suitable for immediate loading.
- Co-Axis®, sub-crestal angle correcting implant, available in angulations of 12, 24 & 36° and various internal and external connections.
- MAX implant, specifically designed for immediate molar tooth replacement.
- The ZYGAN and ZYGEX implants for severely resorbed maxilla and craniofacial reconstruction.

Our product portfolio is in synchronized evolution with protocol improvements and technological advances.

 $My \, since re \, thanks \, to \, all \, specialists, dentists \, and \, technicians \, who \, put \, their \, trust \, in \, our \, company.$

Graham Blackbeard
Managing Director, Southern Implants

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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.

An innovation for immediate implant placement into a molar extraction socket

The immediate placement of a conventional dental implant into a molar extraction socket poses a number of difficulties. Most significantly, the size and shape of the multi-rooted socket is not favourable for the optimal placement of a typical implant, often resulting in compromised implant positioning, poor primary stability or the inability to place an implant at all.

Anatomical difficulties may necessitate a waiting period of 3-4 months to allow for socket healing before attempting to place an implant. Often, the healed site presents with reduced bone volume resulting in the need for bone augmentation procedures, especially in the maxilla. This leads to further lengthening of treatment time, multiple procedures and increased cost and complexity of delayed molar replacement.

An alternate approach has been to place a conventional implant into one socket of a multi-rooted site, typically the palatal socket of the upper molar. Problems associated with this approach include adverse biomechanical forces with buccal overhang of the restoration and poor prosthetic design with unfavourable emergence profile.

The **MAX** implant advances a molar specific implant design and dedicated surgical protocol which makes immediate placement of the implant into a multi-rooted socket predictably attainable, thus avoiding the multitude of potential problems highlighted above.

The MAX implant features a macro design with larger than conventional diameter and strong taper with the express benefit of achieving optimal primary stability where bone to implant contact is low, whilst maximum preservation of surrounding bone is facilitated. The flute and thread design provide for self-tapping ability of the implant.

The **MAX** implant range is manufactured from commercially pure Grade 4 Titanium. The **MAX** implants are available with the following connection types: External Hex, Internal Hex, TRI-NEX (Trilobe & Hex) and Internal Octagon. (See page 07 for available diameters and lengths).

The design of the MAX implant provides for a prosthetic platform shift in each of the available configurations.

INSTRUCTIONS FOR USE

This surgical manual serves as a reference only for the placement of Southern Implants' range of **MAX** dental implants. It is strongly recommended that clinicians, whether experienced or inexperienced implant users, always undertake device specific training before undertaking a new treatment method.

The procedures described in this manual do not cover the wide variety of possible patient conditions that could influence the treatment planning, execution and outcomes of treatment.

Indications

The **MAX** implant is indicated for immediate replacement of compromised molar teeth in the mandible or maxilla in suitable sites and is intended to provide support for a fixed or removable dental prosthesis in the form of a single tooth, partial-arch, or full-arch restorations.

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 fully functional support for a prosthesis.

MAX

(External Hex connection)







PROMAX

(Internal Hex connection)





TRI-MAX®

(Trilobe connection / Hex insertion)





$MAXIT^{TM}$

(Internal Octagon connection)





IMPLANT LENGTHS & CODES

MAX	MSc-MAX			7mm	9mm	11mm
			Ø6.0mm	MAX-6-7 MSc-MAX-6-7	MAX-6-9 MSc-MAX-6-9	MAX-6-11 MSc-MAX-6-11
			Ø7.0mm	MAX-7-7 MSc-MAX-7-7	MAX-7-9 MSc-MAX-7-9	MAX-7-11 MSc-MAX-7-11
•			Ø8.0mm	MAX-8-7 MSc-MAX-8-7	MAX-8-9 MSc-MAX-8-9	MAX-8-11 MSc-MAX-8-11
		.i.	Ø9.0mm	MAX-9-7 MSc-MAX-9-7	MAX-9-9 MSc-MAX-9-9	MAX-9-11 MSc-MAX-9-11

- NOTE: External Hex MAX implants are available in 2 configurations:

 a) Surface-roughened up to the beveled collar. The surface has a S_a-value of 1.4 microns.

 b) MSc range with a 3mm turned surface coronal area of specific roughness.
- 6mm length **MAX** implants are also available on request (**MAX6-6** and **MSc-MAX-6-6**) c)

PROMAX			7mm	9mm	11mm
0		Ø6.0mm	PROMAX607	PROMAX609	PROMAX611
		Ø7.0mm	PROMAX707	PROMAX709	PROMAX711
		Ø8.0mm	PROMAX807	PROMAX809	PROMAX811
		Ø9.0mm	PROMAX907	PROMAX909	PROMAX911
TRI-MAX [®]			7mm	9mm	11mm
		Ø7.0mm	TRI-MAX7-7	TRI-MAX7-9	TRI-MAX7-11
•		Ø8.0mm	TRI-MAX8-7	TRI-MAX8-9	TRI-MAX8-11
•		Ø9.0mm	TRI-MAX9-7	TRI-MAX9-9	TRI-MAX9-11
//AXIT™			7mm	9mm	11mm
	6	Ø7.0mm	MAXIT7-7f	MAXIT7-9f	MAXIT7-11f
		Ø8.0mm	MAXIT8-7f	MAXIT8-9f	MAXIT8-11f
		Ø9.0mm	MAXIT9-7f	MAXIT9-9f	MAXIT9-11f

SURGICAL GUIDELINES

A thorough clinical assessment must be done to determine physical and psychological 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 (e.g. smoking, uncontrolled diabetes, radiotherapy, steroid therapy, poor oral hygiene, infection of the oral tissue, bisphosphonate therapy etc.).

PRE-OPERATIVE EVALUATION OF A MOLAR SITE

Pre-operative evaluation should include radiographic and clinical assessment of the oral cavity. It is recommended that a panoramic and/or intra-oral radiograph and/or CBCT is obtained to study the configuration of molar roots and inter-radicular bone, proximity to adjacent teeth and anatomical structures, mesio-distal and bucco-lingual dimension of teeth and bone, dimension of bone beyond the socket, bone density etc.

Three different molar socket configurations are used as a basis to describe the possible surgical techniques utilized to prepare the osteotomy for a **MAX** implant. It must be appreciated that molar socket morphology is highly variable and poses a challenging environment for implant placement, but, relating surgical technique to molar socket morphology makes this process more predictable.

Socket Type A: Extensive inter-radicular bone, i.e. divergent root configuration. In this morphology, surgical preparation by a drilling protocol can be done predictably either by extracting the tooth first, or, by drill preparation through the remaining root. Extraction before osteotomy preparation allows for visibility of the inter-radicular bone and direct selection of a pilot drill site, whereas drilling through the remaining tooth allows the dentine structure to provide drill guidance and predictable orientation of the position and axis of the site preparation. Finalization of the osteotomy preparation by means of the dedicated MAX tap is highly recommended.

Socket Type B: Thin inter-radicular bony septae, i.e. less divergent roots. This is the most frequently encountered morphology and can be very problematic to accomplish drill preparation if the tooth is removed first. Under these circumstances it is difficult to find a suitable bone site to begin pilot drilling and the drills tend to fall out of the available bone as the drill diameter is increased. This leads to the drilling preparation becoming poorly controlled and potentially destructive to the site. In these cases, it is recommended to not remove the tooth, but, to decoronate the tooth, then prepare the osteotomy through the remaining tooth to gain stability and support for the drilling process from the remaining root structure. Control of implant position and axis is made more predictable in this way. Finalization of the osteotomy preparation by means of the dedicated MAX tap is highly recommended.

Socket Type C: Absence of inter-radicular bone, i.e. convergent, fused root structure. The absence of bony septae within the socket precludes the possibility of pilot site preparation, *unless* bone height is available apical to the socket. In the latter case, apical bone will guide the drill preparation and the emphasis is placed on avoiding displacement of the implant towards the buccal plate. Finalization of the osteotomy preparation by means of the dedicated MAX tap is highly recommended.

Where no bone is available apical to the socket to establish an implant site, this morphology may best be treated by a delayed protocol where a healing period is allowed, with or without socket preservation procedures being used.

Note that divergent root anatomies associated with inter-radicular pathology may be found to have no inter-radicular bone present, in which case the same difficulties as described above may exist.

Choose the appropriate size implant for the volume of bone available.

Take care to avoid anatomical structures such as the sinus and inferior alveolar nerve. Take into consideration that the implant should be placed at least 2 mm subcrestal to allow for post-extraction bone remodeling. The implant *must not* be in contact with the buccal plate.

Type A Type B Type C

Divergent Roots





Extract then drill:

Drill through root, then extract:

Allow socket healing:







Extract then drill:

Drill through root, then extract:

Allow socket healing:

Fused Roots





Extract then drill:

Drill through root, then extract:

~

Allow socket healing:

SURGICAL PLACEMENT: ROOT AS GUIDE

Step 1: Loosen the tooth

Carefully loosen the molar by manipulation of the tooth with extraction forceps.

Do not remove the tooth from the socket. (This step will make it easier to remove the root segments later on.)

Note: The tooth should remain in the socket and be minimally mobile



Step 2: Decoronate the tooth

Decoronate the tooth just above the gingival level using a high-speed handpiece.



Buccal

Lingual

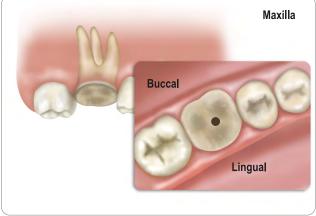
Step 3: Prepare guide hole in dentine

Initiate the pilot hole preparation into the coronal dentine surface by using a carbide bur in a high-speed handpiece. This technique allows for accurate positioning and preparation of the pilot hole.

In the maxilla, the starting point for the pilot hole should be positioned slightly to the mesial and lingual of the midpoint of the cross section of the tooth. This will avoid the implant being positioned too close to the buccal plate and will compensate for the inherent distal drifting of the subsequent drilling sequence. (Fig 1)

In the mandible, the starting point should be positioned slightly to the <u>lingual</u> of the midpoint of the cross section of the molar. This will ensure that the prepared site is kept away from the buccal danger zone. (Fig 2)

Once the correct starting point is achieved, the pilot hole can be deepened to penetrate through the tooth into the inter-radicular bone below.





Mandible

Fig 1

SURGICAL PLACEMENT: ROOT AS GUIDE

Step 4: Pilot drilling - Ø2mm Twist Drill

Pilot drilling with the 2mm twist drill should aim at establishing correct position, depth and axis of the implant site from the outset.

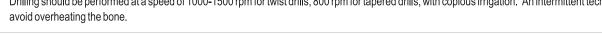
The depth of the preparation should extend minimally beyond the depth of the root apices, where anatomically safe and possible to do so. Control the drilling depth by using intra-operative radiographs to ensure that anatomical structures are respected and that the implant can be seated at least 2 mm below the margin of the most apical bone crest.

Depth marks on the drills are referenced to the cut dentine surface. NB: Expect that the lengths of drills used for preparation through the tooth, will be greater than the implant placed.

The use of intra-operative radiographs is recommended.

Control mesio-distal and bucco-lingual position, depth and axis of the osteotomy whilst pilot drilling, making corrections as needed.

Drilling should be performed at a speed of 1000-1500 rpm for twist drills, 800 rpm for tapered drills, with copious irrigation. An intermittent technique should be used to avoid overheating the bone.



Step 5: Incrementally enlarge the osteotomy

Progressively enlarge the diameter of the osteotomy by drilling through the root and inter-radicular bone with a sequence of tapered implant drills. Control the depth, axis, meso-distal and bucco-lingual positioning throughout the drilling sequence.



Follow the applicable drilling protocol for your tapered implant system, finishing with the appropriate tapered drill with the roots still in place.

Step 6: Finalize the osteotomy

Split the remnant tooth according to the root anatomy and elevate each root segment towards the central void that has been created. Remove any remnant tooth fragments. Debride and assess the site for suitability to proceed with implant placement, particularly the integrity and proximity of the buccal bone wall.

Use the MAX Tap of suitable diameter and length to finalize the preparation. A tapered drill of 6mm diameter used prior to extraction will allow access of a 7mm diameter MAX Tap post extraction.

The use of the MAX Tap is the most predictable method to properly verify final depth of implant placement, insertion torque and stability. If the bone is dense, (as typical in a mandibular site), further drilling with the dedicated MAX drill may be necessary to achieve adequate site preparation.

Achieving correct depth of placement with good primary stability is very important, but may be difficult to achieve with a greatly tapered implant where under preparation may result in the implant becoming stuck in a too shallow position. The most predictable way of finalizing the preparation is, therefore, by use of the dedicated length and diameter of MAX Tap to verify depth of placement and primary stability. By varying the selected length and/or diameter of MAX Tap, the operator will be able to determine the optimal size of implant to be placed and achieve the optimal final seating of the implant.

Use a graduated probe to measure the depth of the tap below the most apical bone crest, with a view to achieving a depth of 2mm below the most apical crest of bone.

A radiograph should be taken with the MAX Tap in site to verify the final seating of the implant to be placed, checking the apical depth relative to anatomical structures.



Optional use of MAX drill

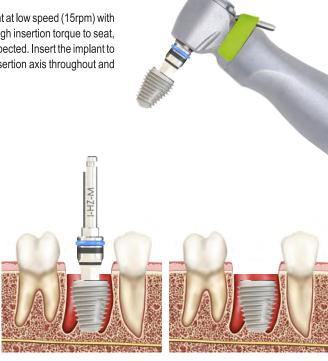


MAX Tap used for final site preparation

SURGICAL PLACEMENT: ROOT AS GUIDE

Step 7: Implant placement

Connect the insertion tool to the hand piece to carry the implant to site. Insert the implant at low speed (15rpm) with the drive unit set to a maximum torque of 40Ncm. The **MAX** implant usually requires high insertion torque to seat, therefore, the use of a hand wrench to complete the seating of the implant should be expected. Insert the implant to a depth of at least 2mm below the most apical bone crest of the socket. Control the insertion axis throughout and make corrections as needed.



SURGICAL PLACEMENT: EXTRACTION SITE

Step 1: Extract the tooth

The molar is carefully extracted with a view of maximum preservation of the alveolus and inter-radicular bone. This may include initial manipulation of the tooth with extraction forceps, followed by splitting of the tooth according to the root anatomy to facilitate elevation of the individual roots from the socket. Debride the site to remove any tooth fragments or infectious material, and assess the site for suitability to proceed.

The inter-radicular septum and the buccal bone-wall should be kept intact.



Step 2: Flatten inter-radicular crest

If there is a slender inter-radicular crest, use a high speed carbide bur to flatten the crest to create a wider platform.



Step 3: Initial drilling

Initiate the osteotomy by drilling into the inter-radicular bone septum, using a 20:1 handpiece with irrigation.

The 3Spade drill (D-3Spade) is used to initiate the osteotomy.

All drilling should be performed at a speed of 1000-1500rpm for twist drills, 800rpm for tapered drills, all with copious irrigation. An intermittent technique should be used to avoid overheating the bone.



Step 4: Pilot drilling - Ø2mm Twist Drill

Drill to the appropriate depth, with reference to the depth markings on the twist drill.

Control drilling depth to ensure that the implant will be seated at least 2mm below the most apical margin of the alveolar crest.



SURGICAL PLACEMENT: EXTRACTION SITE

Step 5: Incrementally enlarge the osteotomy

Progressively enlarge the diameter of the osteotomy with a sequence of tapered implant drills. Control the depth, axis, meso-distal and bucco-lingual positioning throughout.

 $Use of intra-operative intra-oral \ radio graphs \ is \ highly \ recommended.$

Follow the applicable drilling protocol for your chosen tapered implant system.



Step 6: Finalize the osteotomy

Debride and assess the site for suitability to proceed with implant placement.

If the bone is dense (as in a mandibular site), drilling with the dedicated **MAX** drill may be needed to achieve adequate preparation. Use the **MAX Tap** of suitable diameter and length to verify final depth of placement, insertion torque and stability.

Achieving correct depth of placement, 2mm below the most apical alveolar crest, with good primary stability is important.

See drill guidelines on page 24 for more detailed information.



Step 7: Implant placement

Connect the Insertion Tool to the hand piece to carry the implant to site.

Insert the implant at low speed (15rpm) with the drive unit set to a maximum torque of 40Ncm. The **MAX** implant often requires a high insertion torque, due to the large surface area and greater tapered design.

Final seating would, therefore, usually be completed using a surgical hand-wrench.

Appropriate adaptors for the hand wrench are available for the various implant connection types.





It is important that the threaded portion of the implant body is fully seated to a depth of 2mm below the most apical alveolar bone crest of the extraction socket and not in contact with the buccal wall. This will avoid possible exposure of the implant thread after healing of the socket.

Site preparation will not differ for MAX, PROMAX, MAXIT or TRI-MAX.

The seating depth of the implant may differ due to variance in design of the neck of the implant types.

In the case of the TRI-MAX and MAXIT implants which have machined coronal collars, the threaded portion of the implant should be 2mm sub-crestal while the machined coronal areas may rise above the bony crest (see Fig 1 below).

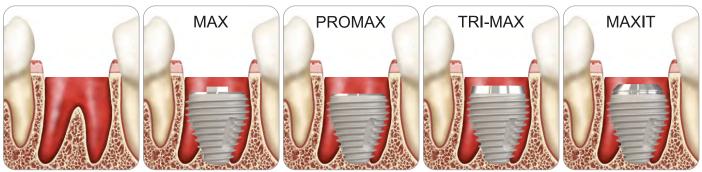


Fig. 1 (illustrations are for 9mm length implants)

TROUBLESHOOTING

Before any surgical procedure to place implants:

- read and understand the instructions for use, specific to the product
- ensure that the correct instrumentation is available (clean and sterile as per Instrument instructions for use.)
- consider patient and site specific factors that may impact the treatment plan

Implant mobility:

If the implant is mobile or has low insertion torque value, consider replacement by a wider diameter implant without further drilling, or a longer implant, if anatomy allows.

Engagement of the buccal bone plate:

Placement of the implant into contact with the buccal plate is contra-indicated. If the implant engages the buccal bone plate at insertion, remove the implant and wait for healing of the site before considering further implant therapy.

Difficulties placing the implant to full depth:

The MAX implant will, in most cases, require high insertion torque to achieve seating to full depth due to the greatly tapered design. The control of implant insertion torque and placement depth is greatly improved by the use of the MAX Tap as a final step in site preparation and is highly recommended in order to avoid possible difficulties of implant placement. The MAX Tap is inserted into the prepared osteotomy by handpiece drive at low speed, then hand wrenched to the correct depth. If the desired depth of placement cannot be achieved with the chosen MAX Tap, an alternate MAX Tap of smaller diameter and/or shorter length will usually allow correct placement to be achieved.

If the implant becomes stuck in a supra crestal / crestal position, remove the implant and consider whether the depth and/or width of the osteotomy needs to be increased. Use of a drill to deepen the osteotomy or use of a **MAX Tap** to widen the osteotomy can be considered. Alternately, selecting a narrower and/or shorter **MAX implant** may be the preferred solution, rather than further site preparation.

IMPLANT PICK-UP & INSERTION TOOLS

MAX and MAXIT pick-up and placement procedure

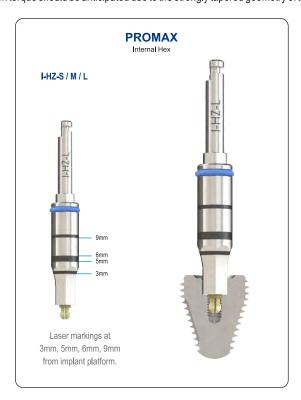


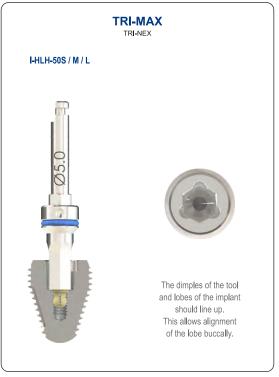


- 1. MAX and MAXIT implants are packaged with a fixture mount attached to the implant
- 2. The connector to handpiece, I-CON-X or I-CON-IT, is inserted into the hand piece and used to pick up the fixture mount with attached implant.
- 3. The implant is inserted by motor into the site at 15rpm and 40Ncm torque value, with gentle apical pressure. When the flutes are no longer visible, irrigation can begin.
- 4. After implant insertion using the motor, the cylinder wrench, I-RATCHET-2 or I-TWS, can be used to complete the insertion manually by hand wrenching. A high insertion torque should be anticipated due to the strongly tapered geometry of the implant.

PROMAX and TRI-MAX pick-up and placement procedure

- 1. The latch grip handpiece tool I-HLH or I-HZ-S/M/L is used to pick up the implant from the packaging.
- 2. The hexagon of the insertion tool must be fully engaged into the implant before torque is applied. The hexagon is fully engaged when the parallel sided portion of the hexagon tool is completely sunken into the implant.
- 3. The implant is placed into the prepared site and driven with a motor unit at 15rpm while applying gentle apical pressure.
- 4. After implant insertion using the motor, the cylinder wrench, I-RATCHET-2 or I-TWS, can be used to complete the insertion manually by hand wrenching. A high insertion torque should be anticipated due to the strongly tapered geometry of the implant.





Important: The PEEK bits which provide retention of the tool within the implant should be replaced on a regular basis. General wear & tear is to be expected with regular use. (Items sold separately.)

IMPORTANT CONSIDERATIONS

The post implantation healing period is generally 3-4 months, however, healing periods may vary for each patient. Assessment for immediate, early or delayed loading must be based on assessment of the individual clinical situation (i.e. bone quality, bone quantity, primary stability achieved, loading conditions, design of super structure, occlusal forces etc.) and other patient related factors. Note that the strongly tapered design and large diameter of the implant may allow high insertion torque to be achieved, but, implant to bone surface area contact may be low, due to the highly variable multi-rooted socket anatomy. In cases of immediate temporization, 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.

ONE-STAGE PROCEDURE

Healing abutment

The **MAX** implant will most often provide adequate primary stability to allow a one-stage surgical procedure to be adopted. This calls for the placement of a healing abutment.

Healing abutments are provided in various configurations, manufactured in either Titanium or PEEK materials. See product catalogue for applicable range of healing abutments.

Select a healing abutment of appropriate width and height for the given situation.

Place sutures to lightly approximate the soft tissue to the healing abutment, when necessary.





TWO-STAGE PROCEDURE

Cover Screw

In exceptional circumstances, where it may be necessary to perform a two-stage, submerged healing procedure, a cover screw can be placed prior to soft tissue closure.

After an appropriate healing period, expose and remove the cover screw using the appropriate driver, and place an appropriate healing abutment.

Exposure of the cover screw can be done with either 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.

Tighten all healing abutments and cover screws to 10-15 Ncm.





DRILL & INSTRUMENT INFORMATION

All surgical drills are externally irrigated and intended to be used with steady sterile irrigation. The tapered drills have highly efficient cutting flutes, even in dense bone. Recommended drill speed is 1000-1500 rpm for twist drills and 800 – 1200 for tapered drills. Reduced drill speed is recommended in soft bone or as drill diameter increases. Southern Implants Twist Drills and Screw Taps are made of stainless steel. Tapered dedicated drills are made of Titanium.

The marks on the twist drills indicate actual millimeter lengths.



CAUTION: The drill preparation depth with twist drills extends up to 1mm longer than the implant. Allow for this additional length when drilling near vital anatomical structures.



In situations where adjacent natural teeth interfere with the contra-angle head of the handpiece, preventing the drill from reaching the desired depth, drills with longer shafts are available.

Do not use MAX Drills with a drill extension.



Do not use MAX Taps with a drill extension.

MAX Profile Gauges (Optional)



MAX-7-PG-7







MAX-8-PG-7







MAX-9-PG-7



MAX-9-PG-9



SITE PREPARATION: MAX, PROMAX & MAXIT IMPLANTS

Intermediate drilling for MAX, PROMAX & MAXIT implants is performed using the tapered drill sequences of the External Hex range. The length of tapered implant drill corresponds to the particular implant length planned.

External Hex intermediate drills (used for MAX, PROMAX & MAXIT implants)

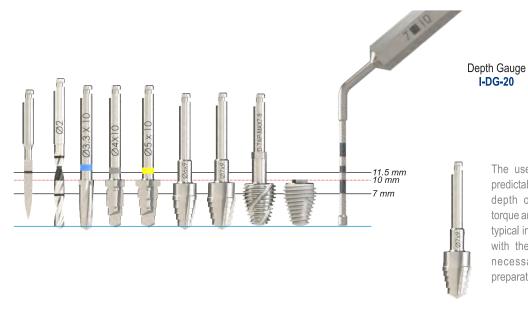


D-33TP-8.5 D-33TP-10 D-33TP-11.5 D-40TP-6 D-40TP-8.5 D-40TP-11.5 D-50TP-8.5 D-50TP-8.5 D-50TP-10 D-50TP-11.5 D-60TP-6 D-60TP-8.5 D-60TP-10 D-60TP-11.5

(Optional, but recommended for the through-the-tooth technique)

IMPLANT DRILL DEPTH

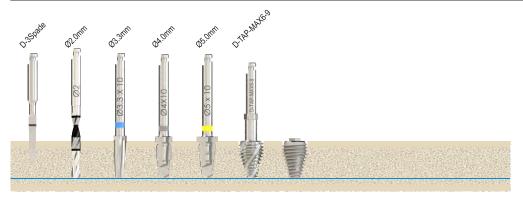
Illustrating placement of a Ø7 x 9mm MAX implant



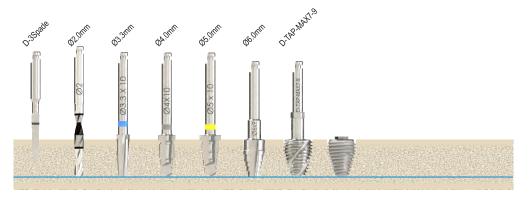
The use of the MAX Tap is the most predictable method to properly verify final depth of implant placement, insertion torque and stability. If the bone is dense, (as typical in a mandibular site), further drilling with the dedicated MAX drill may be necessary to achieve adequate site preparation.

DRILL AND INSTRUMENT INFORMATION

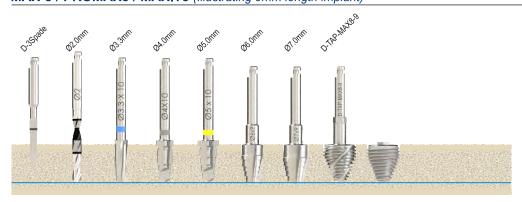
MAX-6 / PROMAX6 (Illustrating 9mm length implant)



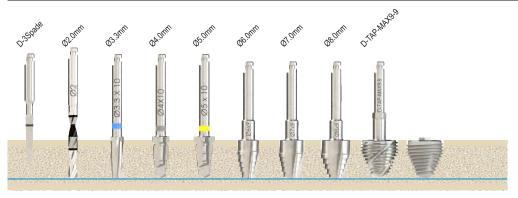
MAX-7 / PROMAX7 / MAXIT7 (Illustrating 9mm length implant)



MAX-8 / PROMAX8 / MAXIT8 (Illustrating 9mm length implant)



MAX-9 / PROMAX9 / MAXIT9 (Illustrating 9mm length implant)



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

DRILL AND INSTRUMENT INFORMATION

SITE PREPARATION: TRI-MAX IMPLANTS

Intermediate drilling for TRI-MAX implants is performed using the tapered drill sequences of the TRI-NEX range. The length of tapered implant drill corresponds to the particular implant length planned.

TRI-NEX tapered intermediate drills



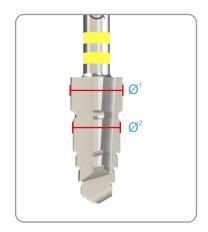
(Optional, but recommended for the through-the-tooth technique)

NOTE: - Initial drill protocol for TRI-MAX implants is recommended using the TRI-NEX tapered intermediate drills. Refer to page 18 for available dedicated MAX drills.

- The use of the MAX Tap is the most predictable method to properly verify final depth of implant placement, insertion torque and stability. If the bone is dense, (as typical in a mandibular site), further drilling with the dedicated MAX drill may be necessary to achieve adequate site preparation.

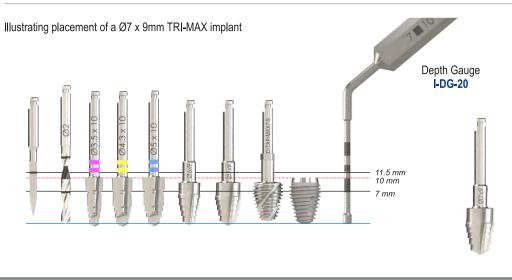
DRILL MARKINGS

The TRI-NEX tapered drills are recommended for medium to hard bone. The different collar markings stand proud of the tray to ensure easy selection.



CODES	Ø'	ز
D-L-35	3.9	3.2
D-L-43	4.6	4.2
D-L-50	5.1	4.5
D-L-60	6.1	5.5

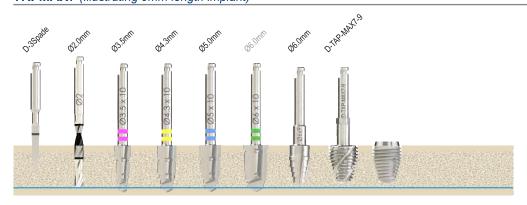
IMPLANT DRILL DEPTH



The use of the MAX Tap is the most predictable method to properly verify final depth of implant placement, insertion torque and stability. If the bone is dense, (as typical in a mandibular site), further drilling with the dedicated MAX drill may be necessary to achieve adequate site preparation.

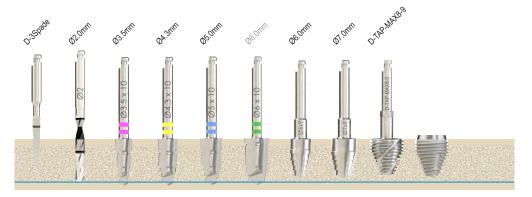
TRI-MAX IMPLANTS

TRI-MAX7 (Illustrating 9mm length implant)

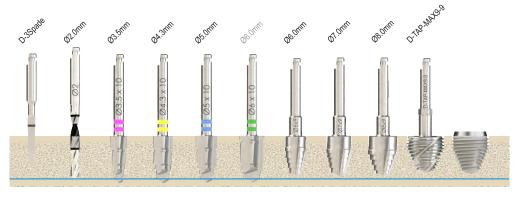


TRI-MAX8 (Illustrating 9mm length implant)

NOTE: Drill length of intermediate drills may differ from the length of definitive drills.



TRI-MAX9 (Illustrating 9mm length implant)



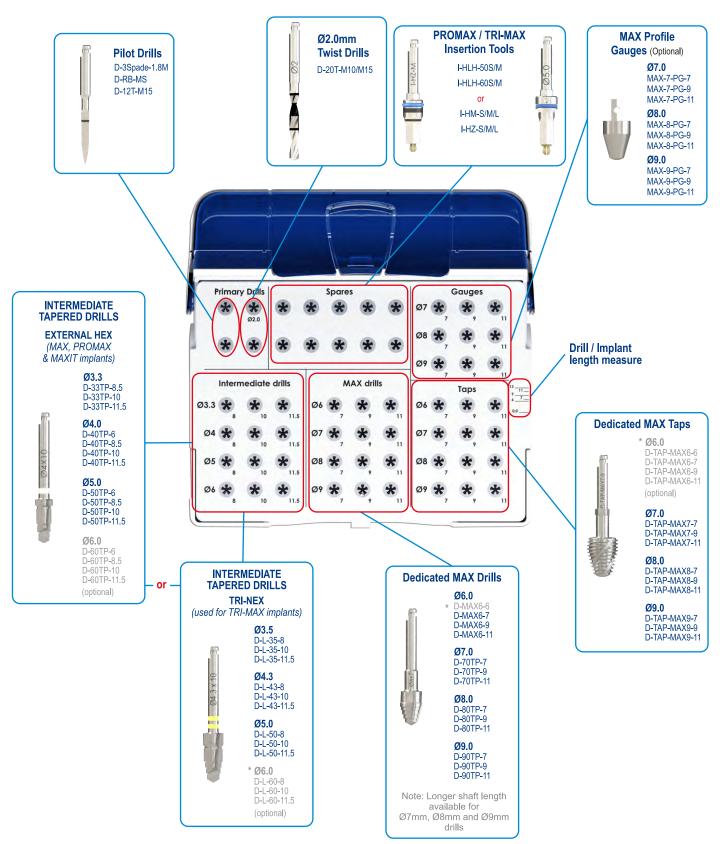
(illustrations are for 9mm length implants)

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

INSTRUMENT TRAY INFORMATION

I-MAX-EG For surgical placement of MAX Implants

Upper Tray



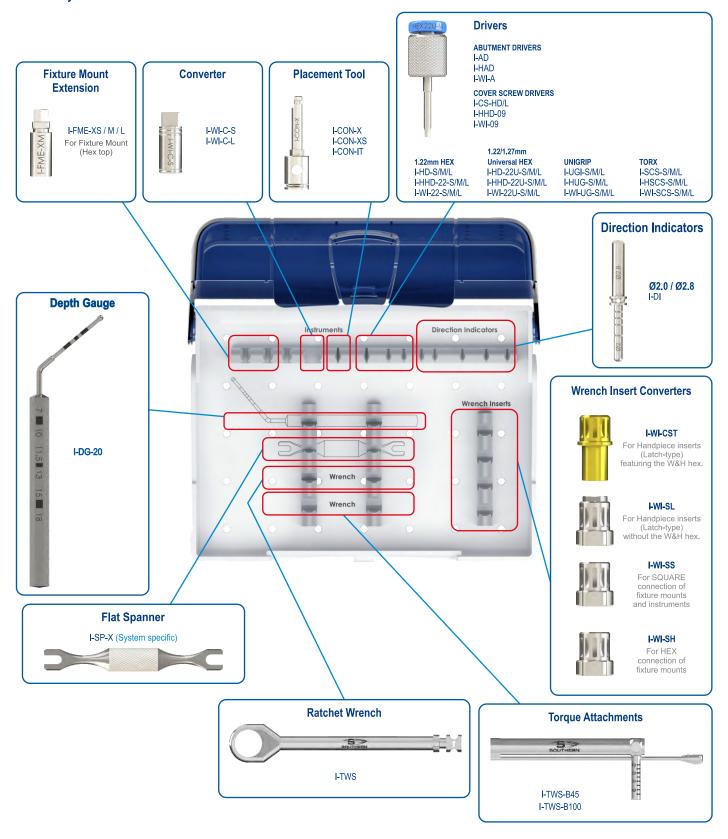
Note: Most Instruments available in Short / Medium / Long.

The surgical kit has an intuitive layout to guide the surgeon through the drill sequence.

All instruments and tooling used during the procedure must be maintained in good condition, and cleaned and sterilized prior to to use. Please consult the Southern Implants Cleaning and Sterilization Procedure Guidelines (CAT-1039) for guidance concerning the maintenance of drills, instruments, and surgical trays.

^{*} Connection system dependant

Lower Tray



EXPLANATION OF SYMBOLS

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



Manufacturer

2

Colour code indicating platform diameter

3 Implant image

4 Implant details and size

5 STERILE R Sterilization using Irradiation

STEE SEE

Do not Resterilize

[i

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

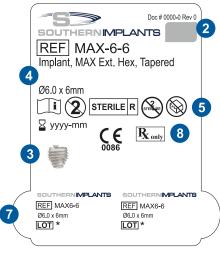
7 Patient sticker for documentation purposes (to be used by health care provider on patient file)

8 J

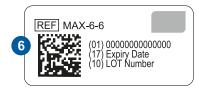


Prescription device

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







Sterility

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

Do not re-use Implants, Cover screws, Temporary Abutments and Abutments. These are single-use products. Re-using these components may result in damage on the surface 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, may lead to secondary infections.

Products provided non-sterile must be cleaned and sterilized prior to use, according to the guidelines in CAT1039 and the Surgical Manual.

Cautions

One hundred percent implant success cannot be guaranteed. Non-observance of the indicated limitations of use and working steps may result in failure. Implant treatment may lead to loss of bone, biologic or mechanical failures including fatigue fracture of implants or components.

Treatment planning, (surgical and prosthetic design) must accommodate patient specific conditions. In case 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 bone growth maturity has been reached.

Disclaimer of liability

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 hemorrhage 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 and experience in the placement of implants and providing appropriate information for informed consent, rests with the practitioner.

GENERAL INFORMATION AND WARNINGS

It is strongly recommended that **MAX** implants are used only with Southern Implants surgical instruments and prosthetic components, as combining components that are not dimensioned for correct mating, can lead to mechanical and/or instrument failure and damage to tissue or unsatisfactory esthetic results.

Southern Implants cannot guarantee outcomes obtained using components from other manufacturers. Southern Implants will not accept liability for damage caused by improper implant treatment.

Availability

Not all products shown or described in this literature are available in all countries.

Images are for illustration purposes only and do not necessarily accurately represent the product. All dimensions in this catalogue is in mm, unless otherwise specified

Magnetic Resonance (MR) safety information

MAX 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 **MAX** 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 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 more information, please call your Southern Implants Representative or visit southernimplants.com

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