SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	INSTRUCTIONS FOR USE: Southern Implants® MAX Implants
Español	INSTRUCCIONES DE USO: Southern Implants® MAX Implants
Italiano	ISTRUZIONI PER L'USO: Southern Implants® MAX Implants
Français	MODE D'EMPLOI : Southern Implants® MAX Implants
Deutsch	GEBRAUCHSANWEISUNG: Southern Implants® MAX Implants
Português	INSTRUÇÕES DE UTILIZAÇÃO: Southern Implants® MAX Implants

South Africa – Headquarters 1 Albert Road, Irene, RSA
T: +27-12-667-1046 | **E:** info@southernimplants.com

Subsidiaries

Australia
Southern Implants Australia
T: +61-2-8076-9337
E: info@southernimplants.com.au

Spain and Portugal
Southern Implants Ibérica
T: +34 935 053 507
E: info@southernimplants.es

EC REP
United Kingdom and Ireland
Southern Implants UK
T: +44-20-8899-6845 / 6 / 7
E: info@southernimplants.co.uk

USA and Canada
Southern Implants North America Inc.
T: +1-561-472-099
E: customercare@southernimplants.com

Intended use

The devices are intended to treat partially or fully edentulous patients eligible for placement of one or more dental implants as a means of fixing a permanent or removable single crown, partial or full-arch dental prosthesis in the upper or lower jaw. The devices allow for immediate or delayed prosthetic restoration based on the user's evaluation of the patient's eligibility.

Intended user

Maxillo-facial Surgeons, General Dentists, Orthodontists, Periodontist, Prosthodontists and other appropriately trained and experienced implant users.

Intended environment

The implants are intended to be used in a clinical environment such as an operating theater or a dentist consultation room.

Intended patient population

This device is used in the dental restoration of partially or fully edentulous patients in the upper or lower jaw. Restorations may comprise single teeth, partial or full bridges, and may be fixed or removable.

Table A

Range	Item Code	Diameter in mm *(D)*	Implant Lengths *(XX)*
MAX	MAX-*(D)*-(XX)	6 / 7 / 8 / 9	6 / 7 / 9 / 11
PROMAX	PROMAX*(D)(XX)*	6 / 7 / 8 / 9	7 / 9 / 11
TRI-MAX®	TRI-MAX*(D)-(XX)*	7 / 8 / 9	7 / 9 / 11
MAXIT™	MAXIT*(D)-(XX)*f	7 / 8 / 9	7 / 9 / 11

Indications for use of our MAX Implants

Southern Implants MAX implant system is intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications.

The MAX implant provides support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

Contraindications

Do not use in patients:

- who are medically unfit for dental implant procedures
- where adequate numbers of implants could not be placed to achieve full functional support of the prosthesis,
- who are allergic or have hypersensitivity to pure titanium or titanium alloy (Ti-6Al-4V), gold, palladium, platinum or iridium.
- who are under the age of 18, have poor bone quality, blood disorders, infected implant site, vascular impairment, uncontrolled diabetes, drug or alcohol abuse, chronic high dose steroid therapy, anti-coagulant therapy, metabolic bone disease, radiotherapy treatment.

Description

Southern Implants® MAX implants from Southern Implants are made from biocompatible, commercially pure, Grade 4 Titanium and are available in a range of lengths and diameter configurations to be used with a range of prosthetic components (see the MAX product catalogue).

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. Cover screws and healing abutments are supplied separately.

Warnings

THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING

- For the safe and effective use of dental implants, it is suggested that specialised training be undertaken, including hands-on training to learn proper technique, biomechanical requirements and radiographic evaluations.
- 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, damage to nerves/vessels and/or loss of supporting bone.
- 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, or 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 clinicians choose a short implant, then clinicians 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.

Cautions

New and experienced Implant users should do training before using a new system or attempt to do a new treatment method. Take special care when treating patients who have local or systemic factors that could affect the healing of the bone and soft tissue. (i.e. poor oral hygiene, uncontrolled diabetes, are on steroid therapy, smokers, infection in the nearby bone and patients who had oro-facial radiotherapy.)

Thorough screening of prospective implant candidates must be performed including:

- A comprehensive medical and dental history.
- Visual and radiological inspection to determine adequate bone dimensions, anatomical landmarks, occlusal conditions and periodontal health.
- Bruxism and unfavourable jaw relations must be taken into account.
- Proper pre-operative planning with a good team approach between well trained surgeons, restorative dentists and lab technicians is essential for successful implant treatment.
- Minimising the trauma to the host tissue increases the potential for successful osseointegration.
- Electro-surgery should not be attempted around metal implants, as they are conductive.

Pre-operative examination and planning

A full medical and dental history must be taken, with emphasis on the presence of soft and or hard tissue pathology. The patient must have clinically symptom-free sinuses and no pathology in surrounding bone or soft tissue.

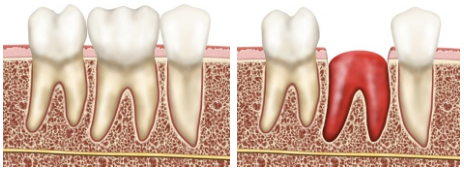
It is recommended that a CT scan and or CBCT analysis be performed as part of the planning process in order to;

- Detect the presence of any pathology in the maxillary sinuses,
- Bone volume and condition,
- Jaw relationships.
- 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. 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

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: Divergent Roots

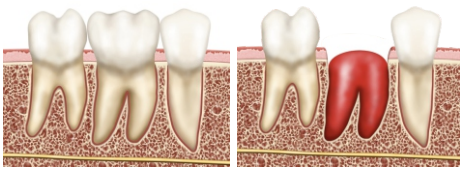
Extensive inter-radicular bone, i.e. divergent root configuration. In this morphology, surgical preparation by a drilling protocol can be done predictably either by extracting the tooth first, or, by drill preparation through the remaining root. Extraction before osteotomy preparation allows for visibility 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.



Extract then drill: ✓
Drill through root, then extract: ✓
Allow socket healing: ✓

Socket Type B: Convergent Roots

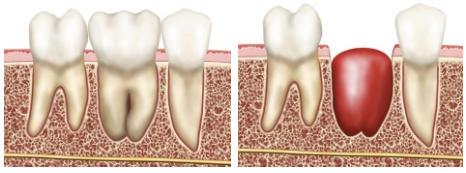
Thin inter-radicular bony septae, i.e. less divergent roots. This is the most frequently encountered morphology and can be very problematic to accomplish drill preparation if the tooth is removed first. Under these circumstances it is difficult to find a suitable bone site to begin pilot drilling and 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.



Extract then drill: ✗
Drill through root, then extract: ✓
Allow socket healing: ✓

Socket Type C: Fused Roots

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.



Extract then drill: ✗
Drill through root, then extract: ✗
Allow socket healing: ✓

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 sub-crestal to allow for post-extraction bone remodeling. The implant ***must not*** be in contact with the buccal plate.

Storage, cleaning & sterilisation

The implants, cover screws and healing abutments are supplied sterile (sterilised by gamma irradiation) 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. If packaging is damaged do not use the product and contact your Southern representative/ or return to Southern Implants. Do not reuse implants, cover screws, temporary abutments and abutments. Re-using these components may result in:

- Damage on the surface or critical dimensions, which may result in performance and compatibility degradation.
- Adds the risk of cross-patient infection and contamination if single use items are reused.

Southern Implants does not accept any responsibility for complications associated with reused components.

Packaging & Precautions to maintain the sterility of the implant

Implants are packaged as follows:

- An outer package consisting of a rigid, clear box which acts as protection for the inner package.
- The inner package consisting of a blister pack (clear plastic-formed bubble-type base with a TYVEK "peel-back" lid)
- Within the inner package there is a hollow tube which contains one implant suspended from a titanium ring, this ensures the implant never touches the inside of the plastic tube.
- Labelling information is located on the surface of the peel-back lid and on the outside of the rigid box

Care must be taken to maintain the sterility of the implant by proper opening of the packaging and handling of the implant.

- Open the implant package in the non-sterile field, with non-sterile gloves, tear the address label to open the box.
- With non-sterile gloves remove the inner blister pack. Do not place the plastic box or blister pack-lid onto the sterile field. The contents of this inner package are sterile.
- The sealed blister is to be opened by an assistant (with nonsterile gloves): remove the TYVEK lid and drop or place the sterile tube onto the sterile field, open the tube cap and attach the implant placement tool onto the implant and carefully remove from the sterile tube. Do not touch the sterile implant.

Other sterile components are packed in a peel pouch or bubble-type base with a "peel-back" lid. Labelling information is located on the bottom half of the pouch, inside the packet or on the surface of the peel-back lid. Sterility is assured unless the pouch is damaged or opened.

Non-sterile components are supplied clean but not sterile in a peel pouch or bubble-type base with peel-back lid. Labelling information is located on the bottom half of the pouch, or on the surface of the peel-back lid.

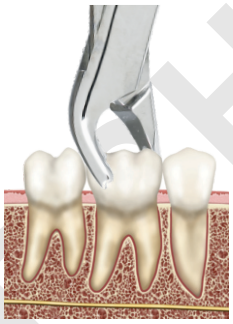
Surgical Placement: Root As Guide

Step 1: Loosen the tooth

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

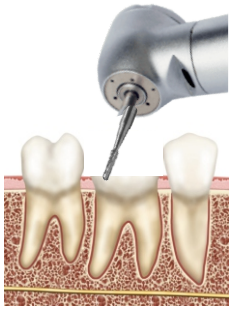
Do not remove the tooth from the socket. (This step will make it easier to remove the root segments later on.)

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.



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 lingual 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)

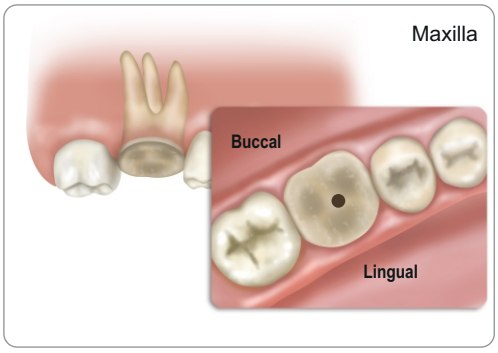


Fig 1

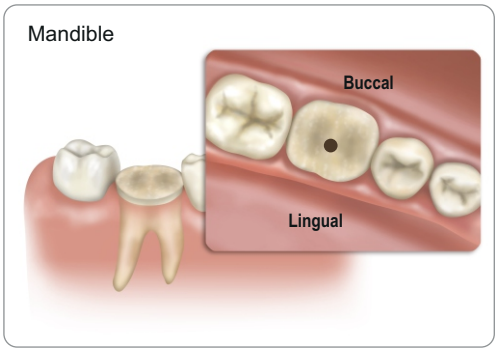


Fig 2

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

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.

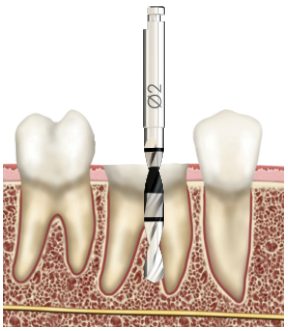
The depth of the preparation should *extend minimally beyond the depth of the root apices*, where anatomically safe and possible to do so. Control the drilling depth by using intra-operative radiographs to ensure that anatomical structures are respected and that the implant can be seated *at least 2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

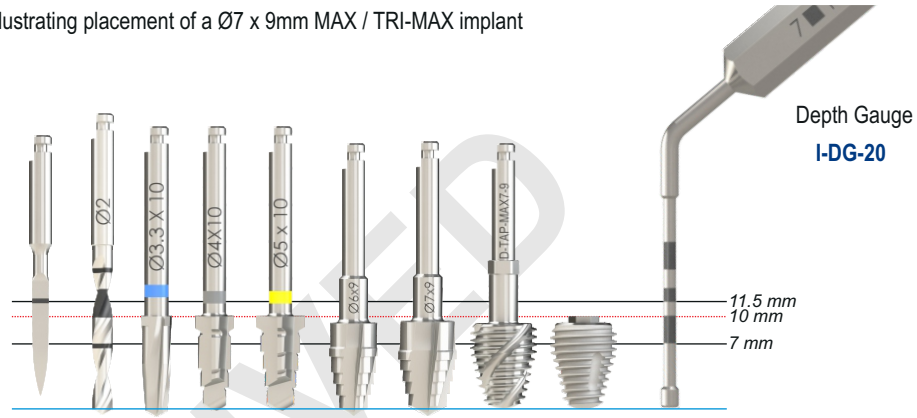


Step 5: Incrementally enlarge the osteotomy

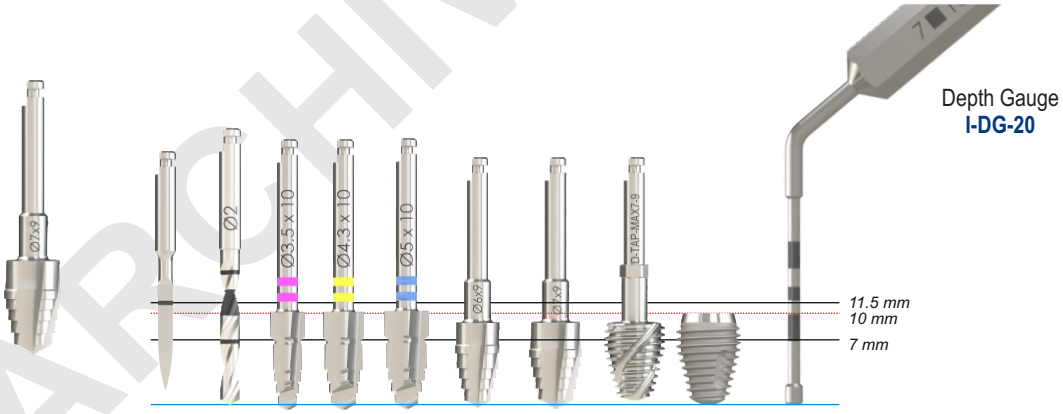
Progressively enlarge the diameter of the osteotomy by drilling through the root and inter-radicular bone with a sequence of tapered implant drills. Control the depth, axis, meso-distal and bucco-lingual positioning throughout the drilling sequence.

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

Illustrating placement of a Ø7 x 9mm MAX / TRI-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.



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.

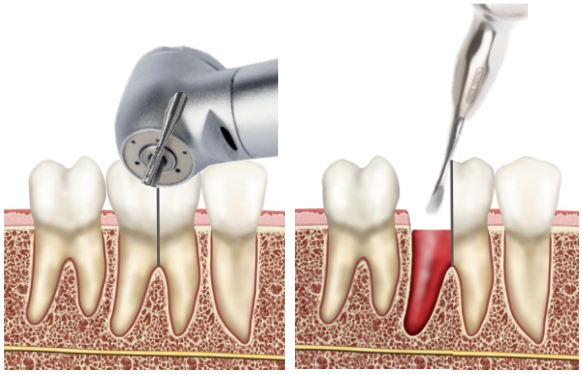
Optional use of MAX drill

MAX Tap used for final site preparation

SURGICAL PLACEMENT: EXTRACTION SITE

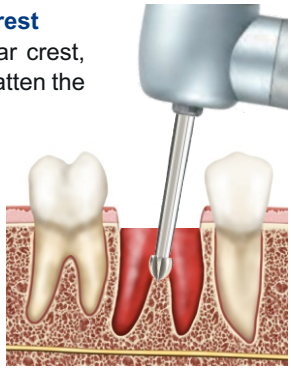
Step 1: Extract the tooth

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.

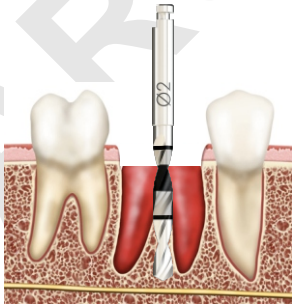


Step 3: Initial drilling

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.

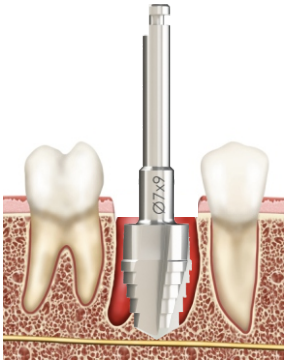
Step 4: Pilot drilling – Ø2mm Twist Drill

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.



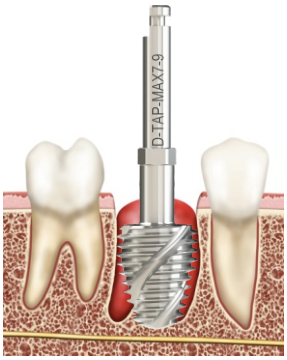
Step 5: Incrementally enlarge the osteotomy

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 radiographs is highly recommended.
Follow the applicable drilling protocol for your chosen tapered implant system.



Step 6: Finalize the osteotomy

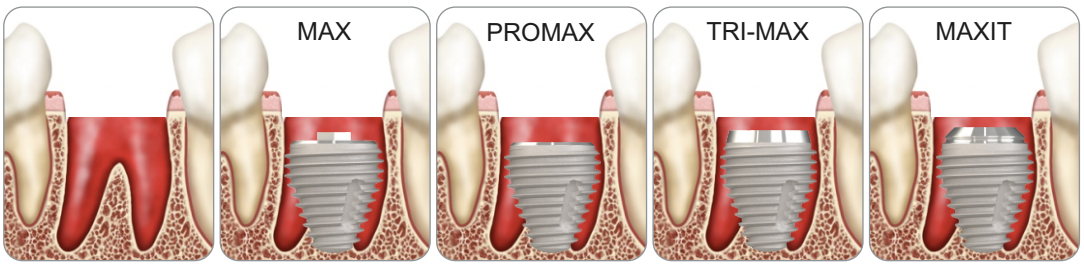
Debride and assess the site for suitability to proceed with implant placement.
If the bone is dense (as in a mandibular site), drilling with the dedicated MAX drill may be needed to achieve adequate preparation. Use the MAX Tap of suitable diameter and length to verify final depth of placement, insertion torque and stability.
Achieving correct depth of placement, 2mm below the most apical alveolar crest, with good primary stability is important.



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).

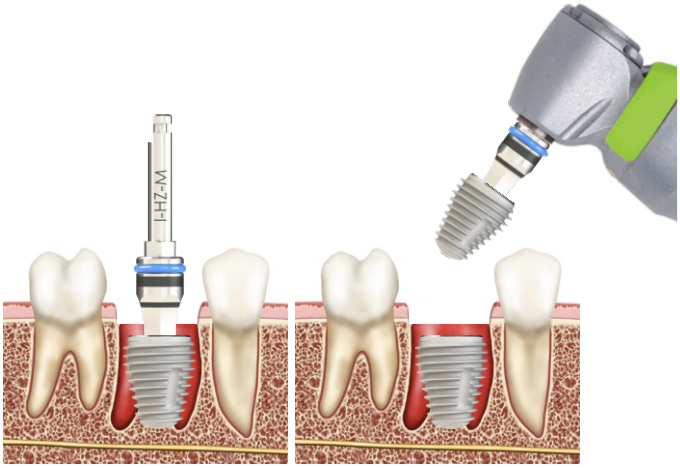
Fig. 1



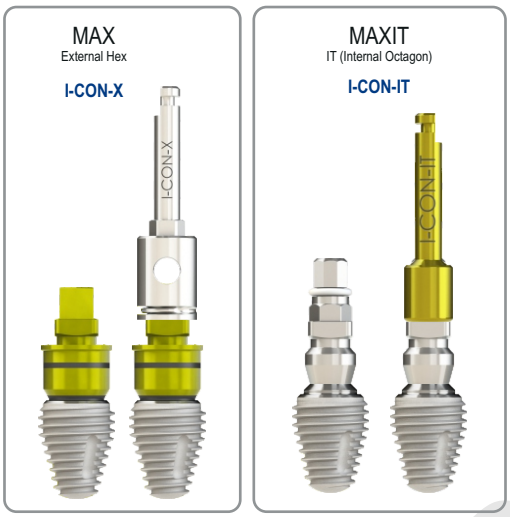
(illustrations are for 9mm length implants)

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.

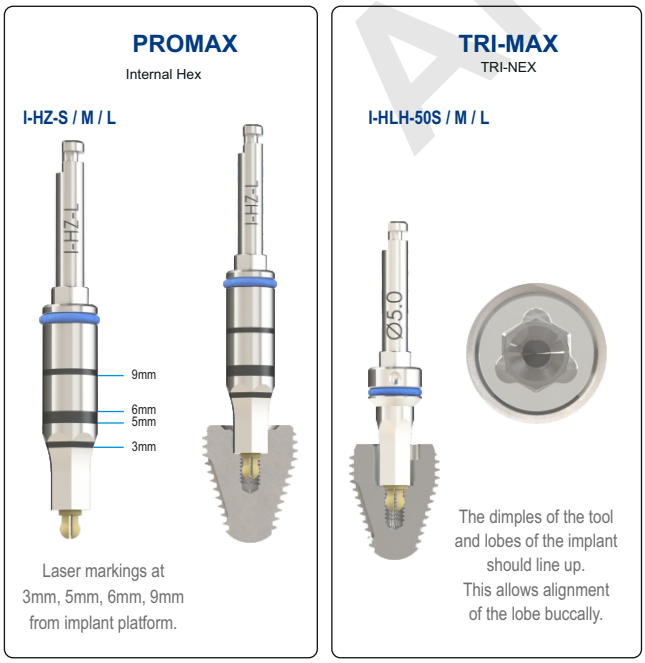


MAX and MAXIT pick-up and placement procedure



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.

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 estoration for 6-12 weeks.

Troubleshooting
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.

Clinical benefits
Patients can expect to have their missing teeth replaced and/ or crowns restored.

Healing
The healing time required for osseointegration depends on the individual and treatment protocol. It is the responsibility of the practitioner to decide when the implant can be restored. Good primary stability will govern if immediate loading can be done.

Implant care and maintenance
Potential implant patients should establish an adequate oral hygiene regime prior to Implant therapy. Proper post-operative, oral hygiene and implant maintenance instructions must be discussed with the patient, as this will determine the longevity and health of the Implants. The patient should maintain regular prophylaxis and evaluation appointments.

Materials
Implant: Commercially pure titanium (grade 4)

Side effects
Potential Side Effects and Temporary symptoms: Pain, swelling, phonetic difficulties, gingival inflammation. More persistent symptoms: The risks and complications with implants include, but are not limited to: (1) allergic reaction(s) to implant and/or abutment material; (2) breakage of the implant and/or abutment; (3) loosening of the abutment screw and/or retaining screw; (4) infection requiring revision of the dental implant; (5) nerve damage that could cause permanent weakness, numbness, or pain; (6) histologic responses possibly involving macrophages and/or fibroblasts; (7)formation of fat emboli; (8) loosening of the implant requiring revision surgery; (9) perforation of the maxillary sinus; (10) perforation of the labial and lingual plates; and (11) bone loss possibly resulting in revision or removal.

Breakage
Implant and abutment fractures can occur when applied loads exceed the tensile or compressive strength of the material. Potential overloading conditions may result from; deficiencies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 30 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g., bruxing, clenching), loss or changes in dentition or functionality, inadequate prosthesis fit, and physical trauma. Additional treatment may be necessary when any of the above conditions are present to reduce the possibility of hardware complications or failure.

Changes in performance
It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as well as the need to seek the services of a trained dental professional if there are any changes in the performance of the implant (e.g., looseness of the prosthesis, infection or exudate around the implant, pain, or any other unusual symptoms that the patient has not been told to expect).

MR Conditional
“Non-clinical testing and MRI simulations were performed to evaluate the dental implant system offered by Southern Implants. Non-clinical testing demonstrates that these products are MR Conditional. A patient with an implant from a Southern Implants System can be scanned safely in an MR system under the following conditions:
Static magnetic field of 1.5 Tesla and 3 Tesla only
Maximum special gradient magnetic field of 4,000 gauss/cm (40T/m)
Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg and head average SAR of 3.2 W/kg, for 15 minutes of scanning (i.e., per pulse sequence) in the normal operating mode
The scanning conditions defined above will produce a maximum temperature increase of 4.9 °C in implants from Southern Implants systems after 15 minutes of continuous scanning (i.e., per pulse sequence).
In non-clinical testing, the image artifact caused by implants from Southern Implant System extends approximately 10 mm from this

device when imaged with a gradient echo pulse sequence and a 3 Tesla MR system."

Disposal

Disposal of the device and its packaging; Follow local regulations and environmental requirements, taking different contamination levels into account. When disposing of spent items, take care of sharp drills and instruments. Sufficient PPE must be used at all times.

Disclaimer of liability

This product is part of the Southern Implants product range and should only be used with the associated original products and according to the recommendations as in the individual product catalogues. The user of this product has to study the development of the Southern Implants product range and take full responsibility for the correct indications and use of this product. Southern implants do not assume liability for damage due to incorrect use. Please note that some Southern Implants products may not be cleared or released for sale in all markets.

Notice regarding serious incidents

Any serious incident that has occurred in relation with the device must be reported to the manufacturer of the device and the competent authority in the member state in which the user and / or patient is established.
The contact information for the manufacturer of this device to report a serious incident is as follows:
sicomplaints@southernimplants.com

Basic UDI

Product	Basic-UDI Number
Basic-UDI for Max Dental Implants	600954403870

Related literature & catalogues

CAT-8028 - MAX Surgical Manual

Symbols and Warnings

* Prescription device: Rx only. Caution: Federal Law restricts this device to sale by or on the order of a licenced physician or dentist.

Canada licence exemption: Please note that not all products may have been licensed in accordance with Canadian law.