OSSEOINTEGRATED FIXTURES

SOUTHERNIMPLANTS

PRODUCT CATALOGUE / SURGICAL MANUAL V.6

Osseointegrated implants are now an indispensable part of prosthetic 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 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 the Southern Implants 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.
- Products engineered for primary stability and suitable for immediate loading.

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

Graham Blackbeard
Managing Director, Southern Implants

Contents

Further information available on our website
www.southernimplants.com

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

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.

INSTRUCTIONS FOR USE

Introduction

This document contains the instructions for the use of the Southern Implants line of Osseointegrated Fixtures, which includes the implants, abutments and associated surgical, restorative and laboratory components.

Description

Southern Implants manufactures implants from biocompatible commercially pure titanium. The surface is enhanced with abrasion (grit-blasting), resulting in a pure and consistent surface. The restorative components are manufactured from titanium, titanium alloy, gold alloy and a variety of polymers.

Implant selection

The IET and IE are ultra-short pure titanium implants. The IET4 is 4.5mm in diameter and 4.1mm long. It is significantly tapered, for the purpose of achieving good primary stability. The IE is 3.75mm in diameter and available in 3, 4 and 6mm lengths. It has a wide flange to prevent intracranial penetration from trauma. The ultra-short implants can usually be used for all craniofacial defects. In large craniofacial defects bone volume can often be found for longer implants.

Intended use

The implants are placed in bone and are intended to osseointegrate to provide an attachment for an external aesthetic restoration / prosthesis. The device provides a solution for the prosthetic restoration of a cosmetic defect when other means (such as adhesives or suction) are inadequate to retain the prosthesis.

Indications

Southern Implants Osseointegrated Fixtures are indicated for the attachment of an external aesthetic restoration / prosthesis for the restoration of a physical defect when other means of attachment are inadequate. These devices are indicated for use in the maxillo-cranofacial region (including ear, nose and eye).

Contraindications

Do no use in:

- patients allergic or hypersensitive to titanium
- cases where the remaining bone is too diminished to allow implant installation
- cases where there is insufficient blood supply to the implant site
- patients with insufficient mental health precluding patient cooperation
- patients who abuse drugs or alcohol
- cases where a pre-operative screening exposes possible risks to the healing of the bone or soft-tissue
- patients who by nature of their condition, occupation or activity will be unable to keep the implant site clean

Warnings

Southern Implants osseointegrated fixtures 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 the product catalogue for interface requirements. Southern Implants will not accept liability for damage caused by improper selection of incompatible abutments and accessories.

All Southern Implants' products are intended to be used by appropriate trained and licensed professionals. For the safe and effective use of Osseointegrated Fixtures, it is strongly suggested that specialised training be undertaken, including hands-on training to learn proper technique and radiographic evaluations. THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING. 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 damage to anatomical structures during placement, implant failure and/or loss of supporting bone. Southern Implants will not accept liability for damage caused by improper implant treatment.

Do not reuse Implants, Cover screws, Temporary Abutments and Abutments. These are single-use products. Re-using these components may result in damage on the surface or critical dimensions. This may result in performance and compatibility issues. The removal of proteins from metal (such as Titanium) is extremely difficult and reuse can lead to secondary infections.
Electro-surgery should not be attempted around metal implants, as they are conductive.

PRE-OPERATIVE PROCEDURES

Planning and Precautions

Thorough screening of prospective implant candidates must be performed. Elicit and record a comprehensive medical history and consider the relevance of that information to the individual case. Visual inspection and radiographs are essential to determine anatomical landmarks and adequacy of bone. Ensure the patient has realistic expectations of the implant and the prosthetic treatment. The process of the therapy and possible morbidities should be adequately discussed.

A systematic and coordinated plan delineating the responsibilities of each member of the team should be developed and followed. During the planning phase it is important to determine if the available bone dimensions are adequate for implant placement and to confirm that the available prosthetic space is sufficient to accommodate the proposed abutment and final restoration. Minimizing the trauma to the host tissue increases the potential for successful osseointegration.

Anatomical considerations

Ears

Auricular remnants can be removed, but it is important to ensure the patient accepts this knowing it is irreversible.

Eyes, noses and other craniofacial defects

The bone encountered in these applications is irregularly shaped. The implants must be placed using the available bone, but it is also important to consider the position of the implants for the prosthetics. The implants should emerge in a

place where the attachment can be concealed within the bulk of the prosthesis, and should not make it difficult for the patient to detach.

One-stage vs two-stage surgery, healing periods and irradiation

The surgeon can decide to follow a two-stage or one-stage procedure based on various clinical factors. Healing timeframes are based on the same clinical considerations. Therefore Table 1 provides our recommendations for healing periods and the choice between one-stage and two-stage procedures.
As a precaution, implant sites that have been irradiated should follow a two-stage procedure, and thus a 4-6 month healing period.

POST-PLACEMENT PROCEDURES

Patient home-care

Patients must be instructed to clean and monitor the peri-implant area daily once the dressing is removed – it is of paramount importance to ensure soft-tissue health. This can be done during their daily bath or shower. A soft cleaning brush or alcohol free wipes can also be used. Tissue health must be reviewed at check-ups.

Table 1. Recommended healing periods

ONE-STAGE	TWO-STAGE
Healing period = 3-4 months	**Healing period = 4-6 months**
Auricular defects: Good bone quality > 3 mm thick for all implants	Auricular defects: Good bone quality < 3 mm thick for all implants
Healthy soft-tissue	Orbital, nasal and other craniofacial defects
	Compromised or soft bone
	Irradiated bone
	Compromised soft-tissue condition

Table 2. Treatment schedule

	ONE-STAGE	TWO-STAGE
SURGERY		**First**
Leave to osseointegrate with cover screw		3-5 months
SURGERY	**First**	**Second**
Apply a pressure gauze dressing	Immediately after surgery	Immediately after 2nd surgery
Check dressing, remove or reapply for another week	1-2 weeks after surgery	1-2 weeks after surgery
Clean around the implant-abutment area	Daily by patient	Daily by patient
Take impression of healed implant site	3 months after surgery	± 1 month after surgery
Total time to prosthesis fitment	3-4 months	4-6 months

Post-placement precautions

MRI

Any bar framework construction, magnetic abutments or any attachment besides the Southern Implants' implants and abutments (or cover screws) should be removed before MRI scanning. The implant and abutment may produce a small artefact in MRI scans.

This device has 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 this device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

RADIATION

If radiation treatment is scheduled after placement of an abutment it is recommended that the abutment is removed and replaced with a cover screw to allow healing before radiation is performed.

TRAUMA

Patients should be aware that implants are susceptible to traumatic loss and they should be instructed to take care when participating in rough or rigorous physical activity.

COMPLICATIONS

SOFT-TISSUE COMPLICATIONS

If infection occurs, the patient's aftercare routines should be reviewed. An antimicrobial cream can be prescribed if appropriate. The abutment can be removed if need be, to properly address soft-tissue complications. A new abutment can be placed after the appropriate healing period.

SKIN OVERGROWTH

If the skin begins to grow over the abutment, perform skin thickness reduction surgery again. If skin regrowth persists in cases of craniofacial implants, a longer abutment can be fitted.

IMPLANT INSTABILITY AND LOSS

If the implant loses stability a cover screw can be placed and the skin closed up for osseointegration for another 3-6 months. If there is a failure to osseointegrate the implant must be removed. In craniofacial sites a suitable site for a new implant can sometimes be found in adjacent bone. All factors for case selection should be re-evaluated before proceeding with a second implant.

HANDLING, PACKAGING AND LABELLING

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. IMPLANTS MUST NOT BE TOUCHED DIRECTLY. They must be handled and placed by the instruments provided. If an implant is dropped onto a non-sterile surface, it should not be used.

PACKAGING

1. Implants: The outer package consists of a rigid, clear box which acts as protection for the inner package. The inner package consists of a clear plastic-formed bubble-type base with a "peel-back" lid. The contents of this inner package are sterile. Labelling information is located on the surface of the peel-back lid and on the outside of the rigid box. Within the inner package 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 sterilised by gamma irradiation. Labelling 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. Labelling information is located on the bottom half of the pouch inside the packet.

Cleaning and Sterilization

All implants and healing 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. Products provided non-sterile must be cleaned and sterilized according to the directions in the Cleaning & Sterilization Procedure Guidelines (CAT-1039) prior to use.

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-103
- Pre-vacuum sterilization method: Gravity Displacement, Steam sterilise the component at 132°C (270°F) at 180-220 kPa for 4 minutes, or at 135° C (275°F) at 180-220 kPa for 3 minutes. Dry for at least 20 minutes in the chamber. Only an FDA approved sterilizer and wrap or pouch for steam sterilization must be used.
- It is the responsibility of the user to establish whether or not their sterilizer is FDA approved to meet the recommended parameters.
- The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics.

CAUTION: (USA ONLY)

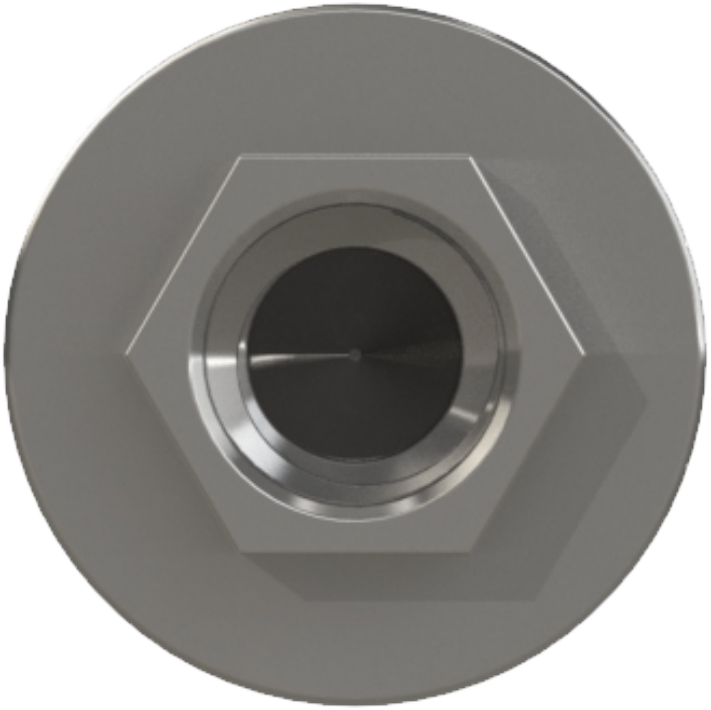
United States Federal Law restricts this device to sale to, or on the order of, a licensed dentist or physician.

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 does 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.

For Technical Assistance or additional product literature, please contact:

Southern Implants (Pty) Ltd
P O Box 605
Irene 0062
South Africa
Tel: +27 12 667 1046
www.southernimplants.com



Ø3.75mm / Ø4.5mm

Ultra-Short

External Hex Ultra-Short Ø3.75mm / Ø4.5 Implant

IE3 | **IE4** | **IE6** | **IET4** | **IETi4** (Internal Drive)

* Implant dimensions and information - page 25

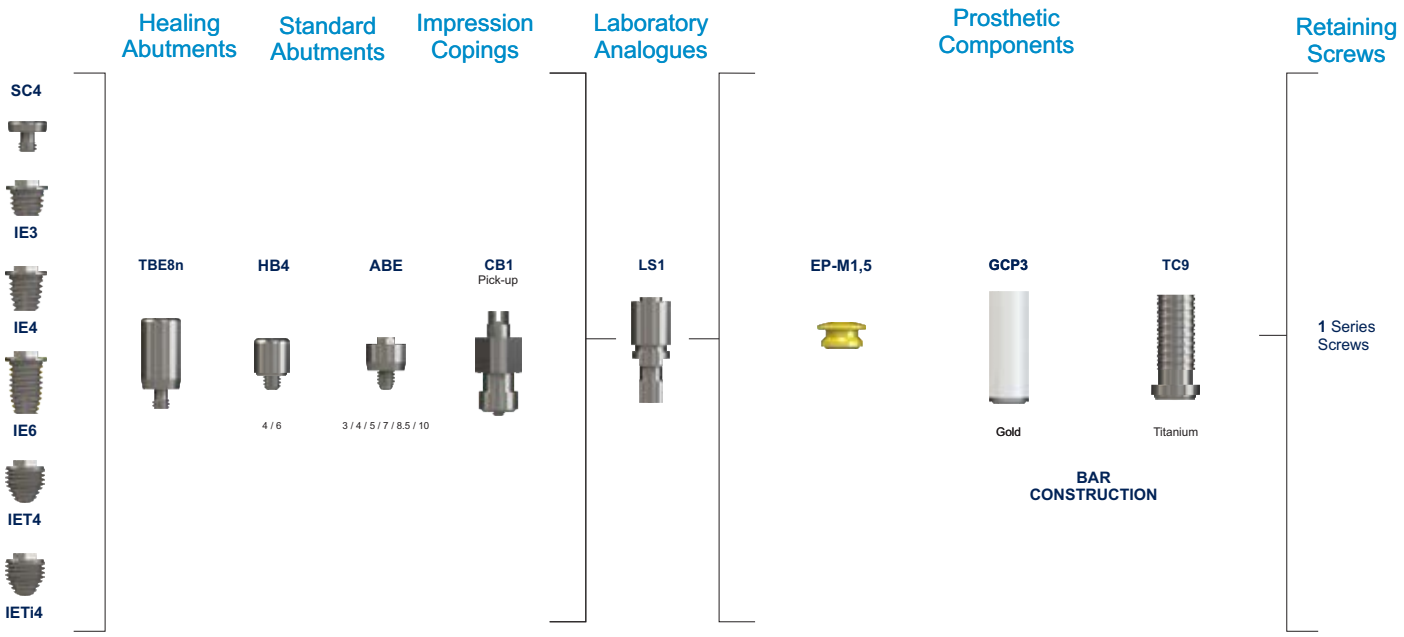
Implants are pre-mounted and available in lengths of:

IE3 / 4 / 6	
IET4	IETi4

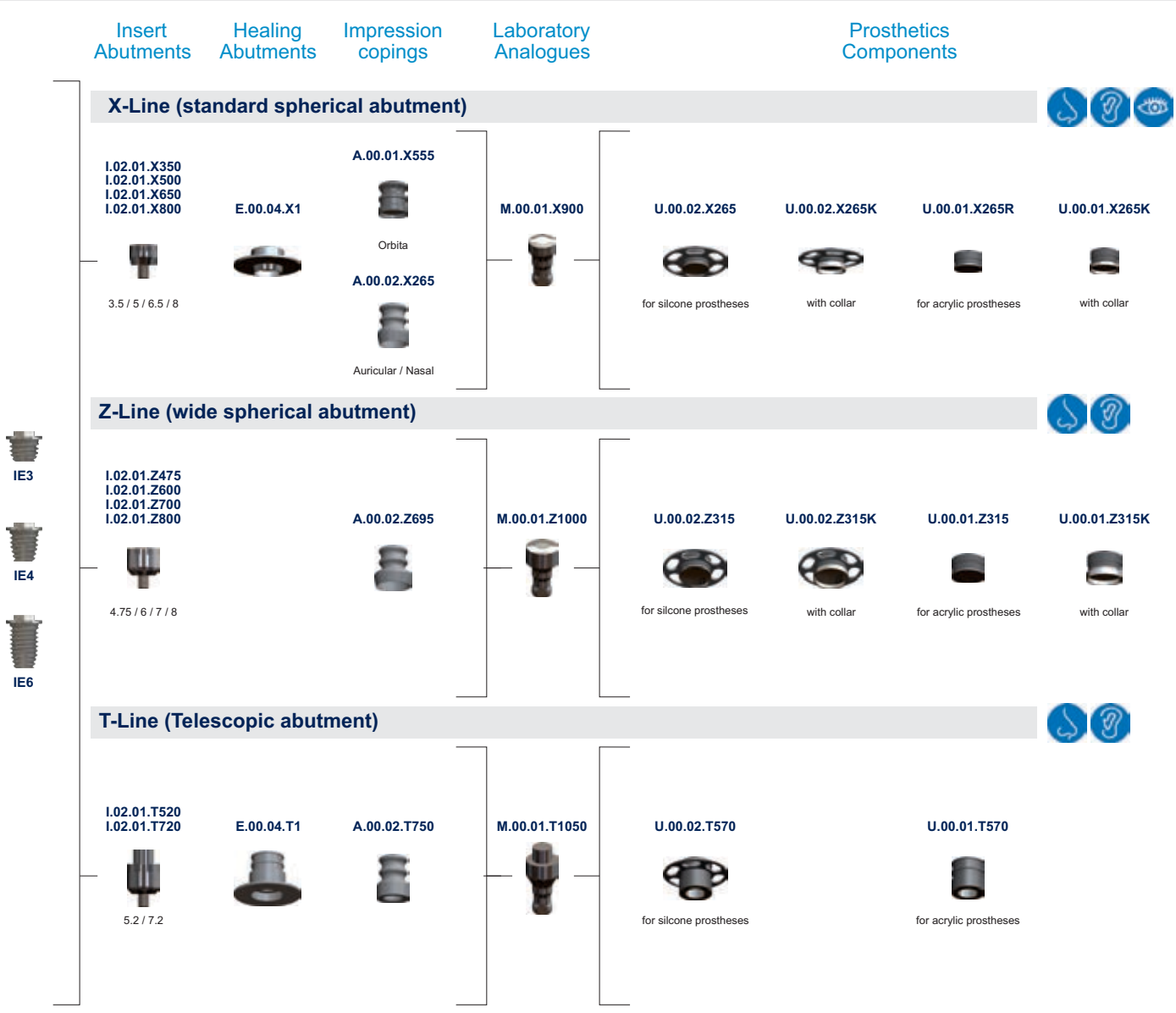
Cover Screw	Healing Abutments (one-part)		
SC4	TBE8n	TB	WB
	Ø4.5	Ø4.5	Ø5.5
	8 length	2/3/4/5/6/8 lengths	2/3/4/6/8 lengths

⚠ Not to be used on IE3 implant

Prosthetic Flowchart



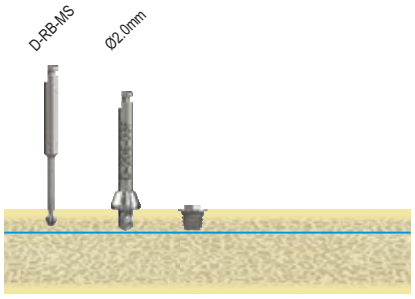
Prosthestics Flowchart: Titanmagnetics® for IE



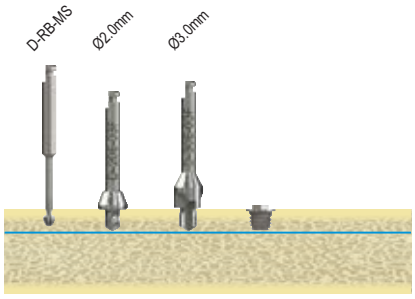
Site Preparation Sequence

Ø3.75mm Parallel Walled *(IE3)*

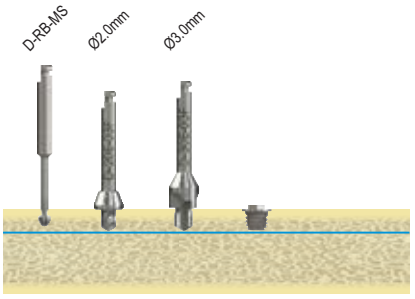
Soft Bone



Medium Bone

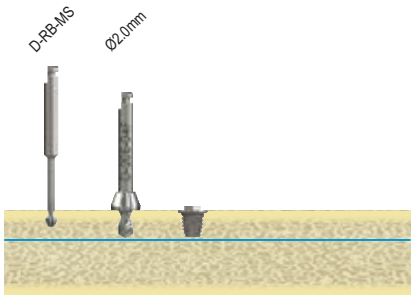


Dense Bone

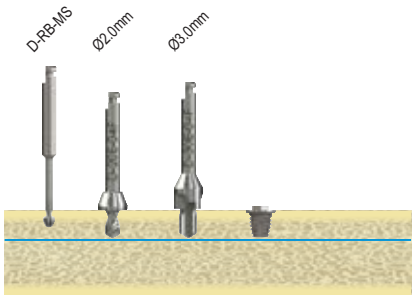


Ø3.75mm Parallel Walled *(IE4)*

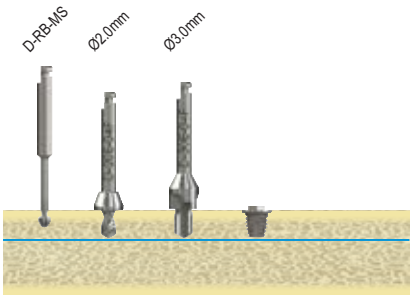
Soft Bone



Medium Bone

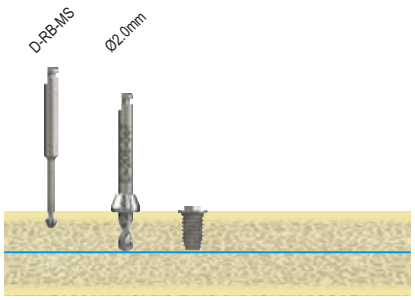


Dense Bone

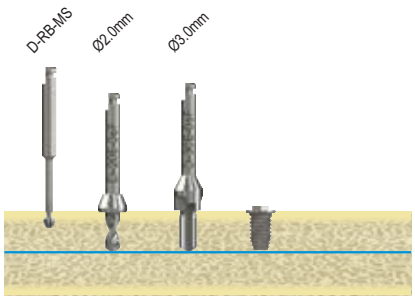


Ø3.75mm Parallel Walled *(IE6)*

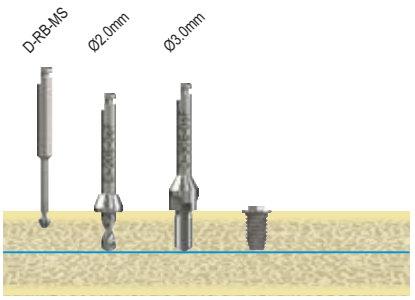
Soft Bone



Medium Bone

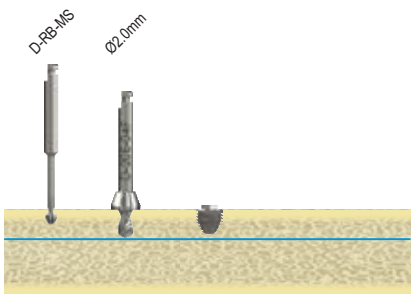


Dense Bone

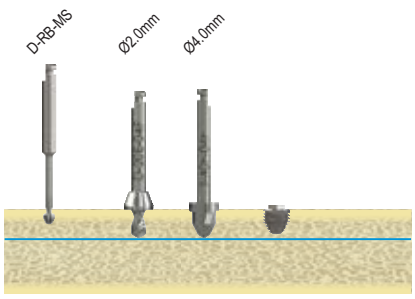


Ø4.0mm Tapered *(IET4 / IETi4)*

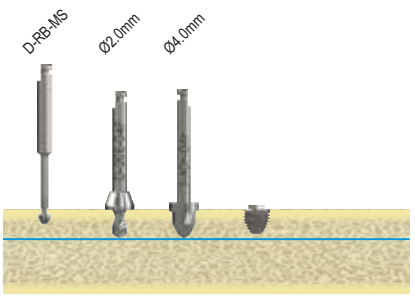
Soft Bone



Medium Bone



Dense Bone



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

Instrumentation

Ø3.75mm Parallel Walled *(IE3 / 4 / 6)*

IE3 **IE4** **IE6**

Placement Tool	Converters		Drivers	
I-CON-X / S	**I-WI-CST**	**I-WI-SH**	**I-CS-HD**	**I-HD-M**
				
Fixture Mount Driver	For Handpiece (latch-type) inserts featuring the W&H hex	Fixture Mount to Wrench	Cover Screw Driver 0.9 Hex	Hex Driver 1.22 Hex

Ø4.5mm Tapered *(IET4)*

IET4

Placement Tool	Converters		Drivers	
I-CON-X / S	**I-WI-CST**	**I-WI-SH**	**I-CS-HD**	**I-HD-M**
				
Fixture Mount Driver	For Handpiece (latch-type) inserts featuring the W&H hex	Fixture Mount to Wrench	Cover Screw Driver 0.9 Hex	Hex Driver 1.22 Hex

Ø4.5mm Tapered *(IETi4)*

IETi4
(Internal Drive)

Insertion Tools			Converters		Drivers	
I-HID-S / M / L	**I-HIDU-S / M / L**	**I-WIID-S / L**	**I-WI-CST**	**I-WI-SH**	**I-CS-HD**	**I-HD-M**
						
Handpiece Insert with W&H	Handpiece Insert Universal	Wrench Insert	For Handpiece (latch-type) inserts featuring the W&H hex	Fixture Mount to Wrench	Cover Screw Driver 0.9 Hex	Hex Driver 1.22 Hex

NOTE: Refer to page 17 and CAT-1191 for more information on wrench insert converters.

** Most instruments are available in various lengths*

SURGICAL and PROSTHETIC PROCEDURE

Implant placement planning must be done by the full team responsible for the complete treatment of the patient. A thorough examination, including etiology of the tissue, should be done. All procedures and possible morbidities must be described to the patient.
At least two implants must be used per epithesis. Avoid large cantilevers in the prosthesis. Implants should be placed at least 10mm apart. Implant positioning is important. As much as it depends on the availability of bone, it must also be appropriate for the prosthesis – implants must emerge in the bulk of the prosthesis where the attachment can be concealed.

Prosthetic ears
Two implants is usually sufficient for prosthetic ear attachment. Place implants parallel to each other. The standard abutments can be used and a bar can be constructed to fit within the anti-helix of the ear.

Prosthetic eyes, noses and other craniofacial epitheses
Other craniofacial epitheses usually require three (or more) implants for adequate support. It can be difficult to place implants in parallel, in which case magnetic abutments from Technovent can be used (see www.technovent.com).

Defect location	Implant	Abutment
Ear	IE IET	Standard abutment + Bar
Eyes or nose	IE IET	Magnetic abutment (www.technovent.com)
Large craniofacial / midfacial	IE IET	Standard abutment + Bar **or** Magnetic abutment (www.technovent.com)

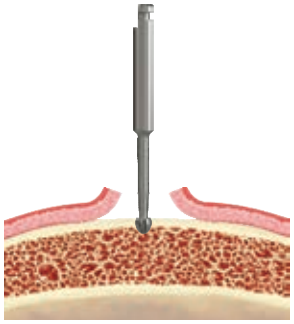
Site Preparation

Step 1: Initiate the osteotomy

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

The round burr (D-RB-MS) is used to initiate the osteotomy by perforating the cranial bone at the desired location.

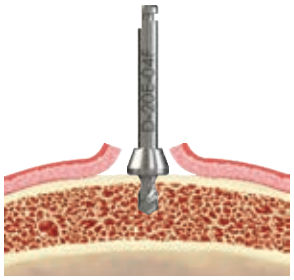
All drilling should be performed at a speed of 1000 -1500 rpm with copious irrigation. An intermittent technique should be used to avoid overheating of the bone.



Step 2: Pilot drilling

The pilot hole is then created using a Ø2.0mm dedicated drill. Drill in the planned direction to the appropriate depth. Drill depth is controlled by the flange on the drill.

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



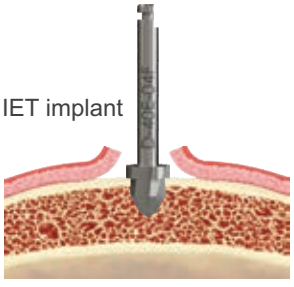
Step 3: Gradually enlarge the osteotomy

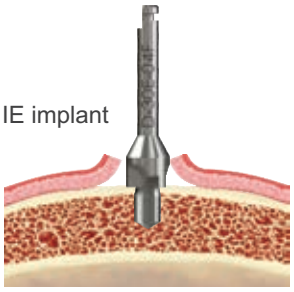
The Osseointegrated Fixtures' drills are length and diameter specific. Use the length and diameter drill corresponding to the implant that is selected.

Widen the osteotomy intermittently to the desired diameter. The final drill will then be used to prepare the site for the implant.

Note: The final drill need not be used in soft bone.

Warning: The total implant length is reached when the drill flange touches the bone surface. The drill will continue drilling (with higher resistance) and countersink the implant. This will drill deeper than the length of the implant so ensure there are no sensitive anatomical landmarks in reach of the drill.





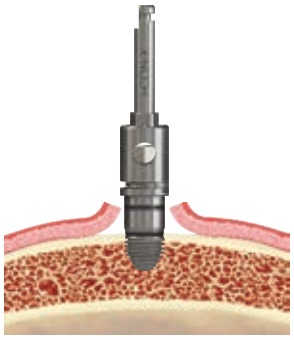
Implant Handling and Placement

Step 4: Implant Placement

A) The **IET** and **IE** implants are supplied with a Fixture Mount.

Connect the Hand-Piece Insertion Tool (I-CON-X) to the Hand-Piece. Engage the implant mount, and carefully remove the implant from the sterile vial.

Insert the implant at low speed (15-20 rpm) without irrigation.

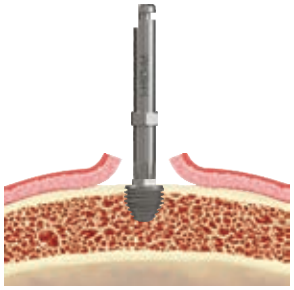


B) The **IETi** implants are placed with an insertion tool, that fits into the implant (spline in internal thread).

Connect the Insertion Tool (I-HID-S / M / L) to the Hand-Piece, and carefully remove the implant from the sterile vial. The insertion tool in the implant must be fully engaged before torque is applied, to prevent any damage.

Alternatively, the Wrench Insertion Tool (I-WIID-S / 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.

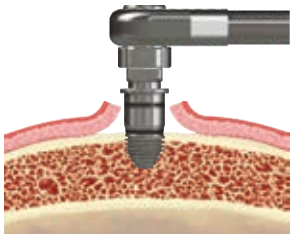
Insert the implant at low speed (15-20 rpm) without irrigation.



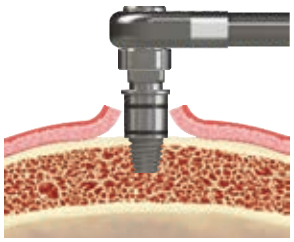
Step 6: Fully seat the implant

The implant is placed such that the platform of the IET implant, or the bottom of the flange for the IE implant, is flush with the bone.

The Ratchet & Torque Attachment Wrench (I-TWS with I-TWS-B45 / B100), in combination with the Converter (I-WI-SH) may be used for final seating of the implant. For insertion torques above 50 Ncm, this manual wrench is indicated. See table below.



Warning: Do not continue inserting the IE implants once the flange hits the bone – this can cause the screw thread in the bone to strip, reducing primary stability.



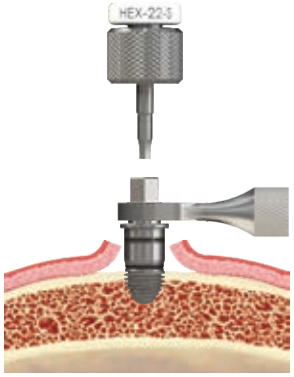
Note: If final stability is less than 10 Ncm remove implant and prepare a new implant site in adjacent bone with a lower torque setting on the motor unit.

Torque Values to seat implant

Implant	Medium-soft bone	Hard bone
IE3, IE4	10-20 Ncm	30-50Ncm
IE6	20-30 Ncm	60-70 Ncm
IET4	10-20 Ncm	40-50 Ncm

Step 7: Fixture Mount Removal

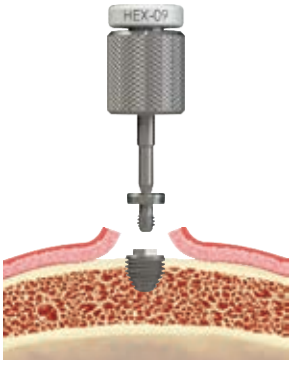
Undo the fixture mount screw (TSHZ3) with a 1.22 Hex handpiece bit (I-HHD-22M/L) or Hand-Held driver (I-HD-M/L) and remove the fixture mount. Use of the fixture mount spanner (I-SP-X) is recommended to avoid loosening the implant.



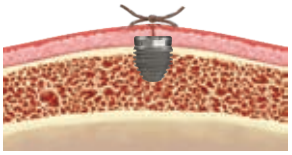
TWO-STAGE PROCEDURE

After the implant is fully seated in the osteotomy, place the cover screw (SC4) with a self-gripping 0.9 Hex cover screw driver (I-CS-HD).

Tighten to 10-15 Ncm.

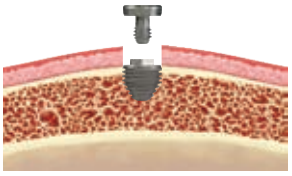


Reposition the flap margins together and suture closed.



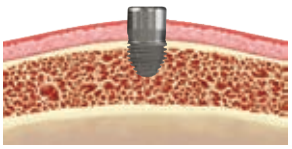
After the recommended healing period, in a second surgery, remove the cover screw.

Exposure of the cover screw can be done either with a tissue cutter (I-TC1) or a mid-crestal incision using a scalpel. Locate the cover screw by probing the soft tissue.



Place the temporary healing abutment using the1.22 Hex Hand-Held (I-HD-S / M / L) driver or the permanent abutment using the Abutment (I-AD) driver in the implant to approximately 10-15 Ncm (hand tightened). Ensure the correct abutment length is chosen such that the abutment protrudes the correct amount from the skin. The standard abutment (ABE) can be used for constructing a bar, or Titanmagnetics abutment can be used.

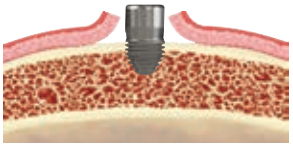
The impression can be taken at the abutment level using the appropriate impression coping.



ONE-STAGE PROCEDURE

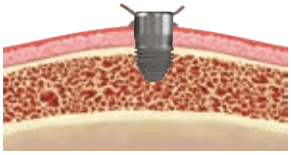
Place the selected healing abutment or appropriate definitive abutment with a 1.22 Hex Hand Held (I-HD-S / M / L), Hand-Piece (I-HHD-22S / M / L) or Wrench Insert (I-WI-22S / M / L) driver.

Tighten to 10-15 Ncm.



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

The impression can be taken at the abutment level using the appropriate impression coping.



Consult CAT-5015 for a discussion of one-stage vs two-stage.

DRILL INFORMATION

Pilot Drills

CODES

D-RB-MS

D-RB-MS

Dedicated Drills

CODES

D-20E-03F / 04F / 06F

D-30E-03F / 04F / 06F

D-40E-04F

D-30E-04F

D-40E-04F

INSTRUMENT INFORMATION

Wrenches

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-FME-XS / M / L

Fixture Mount extension (hex top)

I-WI-CST

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

I-WI-SS

Fixture Mount to Wrench (Square)

I-WI-SH

Fixture Mount to Wrench (Hex)

I-WI-SL

For handpiece (latch type) inserts without W&H hex

DRIVER INFORMATION

Drivers

COVER SCREW DRIVERS		
HANDHELD	HANDPIECE	WRENCH
		
I-CS-HD/L	I-HHD-09	I-WI-09

HEALING ABUTMENT & PROSTHETIC SCREW DRIVERS		
HANDHELD	HANDPIECE	WRENCH
		
1.22 I-HD-S/M/L	I-HHD-22S/M/L	I-WI-22S/M/L

Abutment Drivers (for straight Compact Conical and Standard Abutments)

HANDHELD	HANDPIECE	WRENCH
		
I-AD	I-HAD	I-WI-A

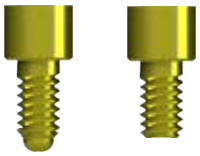
Driver Information for 1 Series Screws

	HANDHELD	HANDPIECE	WRENCH
UNIGRIP			
	I-UGI-S/M/L	I-HUG-S/M/L	I-WI-UG-S/M/L

Refer to CAT-1203 for alternative slotted 1 Series drivers

Southern Implants 1 Series Screws

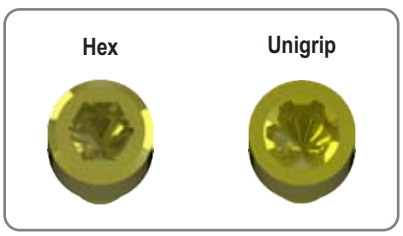
Head Diameter 2.25mm
10-15Ncm



	Titanium	Gold	Brass
Hex	TSH1	GSH1	BSH1*
Unigrip	TSU1	GSU1	

(Blackened and for laboratory use only)

Screw Head Connections



NOTE:

- *Due to design revisions and changes, screw tips may be flat or rounded.*
- *Always ensure that the correct screw is used for the relevant implant and component.*

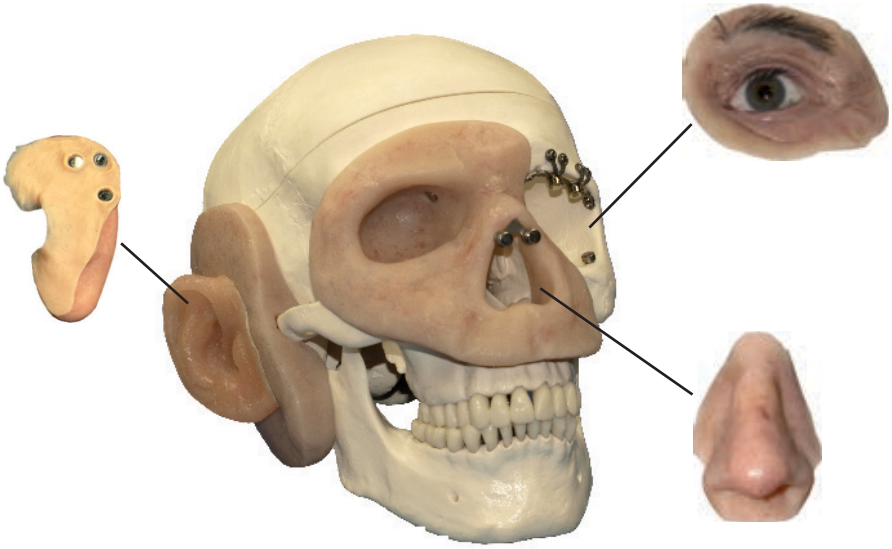
Refer to CAT-1003 for alternative slotted 1 Series screws

TITANMAGNETICS BY STECO

TITANMAGNETICS BY STECO

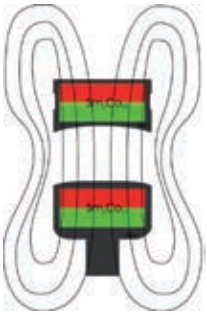
Magnetic attachments for facial prosthesis

The universal and easily manageable solution for implant-supported face prostheses and obturators.

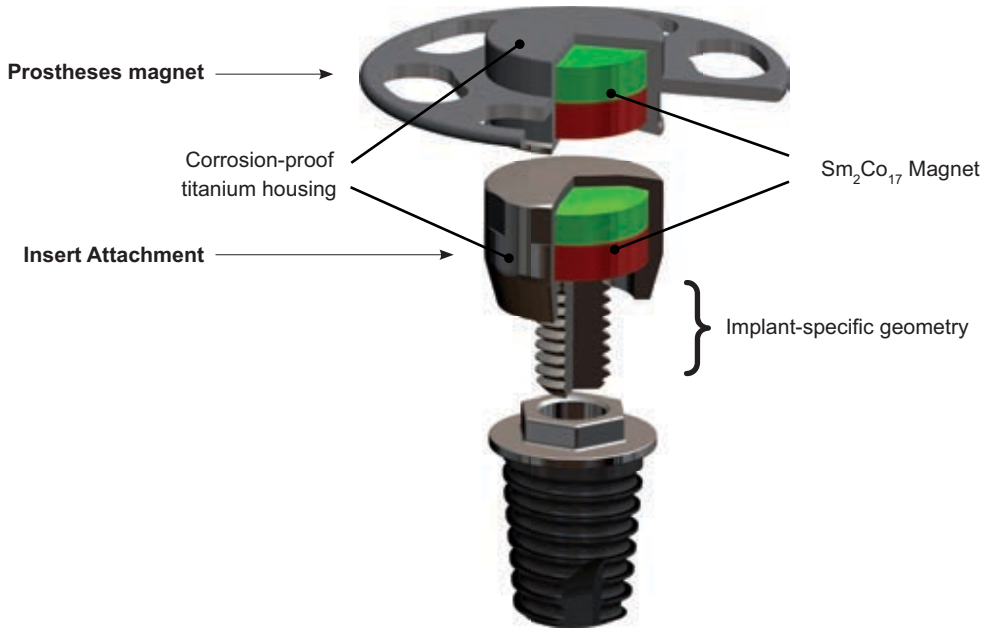


Dual magnet system

Two open magnetic fields exert a force of attraction over a longer distance than mono-magnet systems.



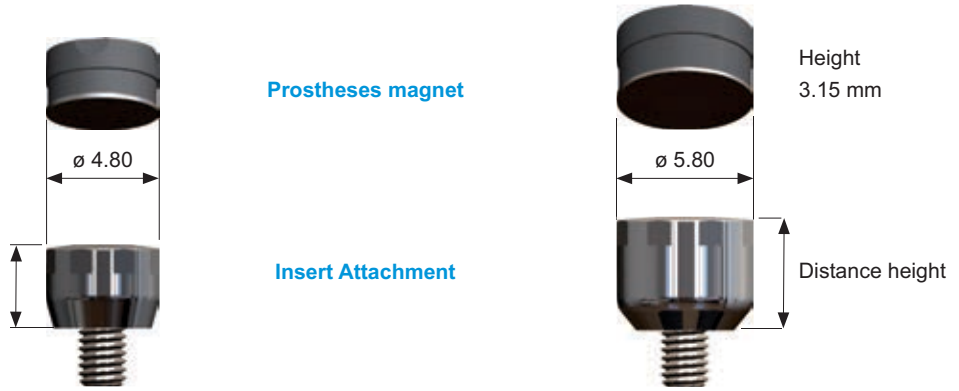
The construction principle



Spherical magnets

The slightly curved surface of the spherical StecoTitanmagnetics® X-Line and the Z-Line facilitates self centering and has the lowest lateral force introduction into the implant. X-Line and Z-Line are therefore particularly suitable for short implants. Due to the absence of lateral steering, they are also indicated for highly divergent implants.

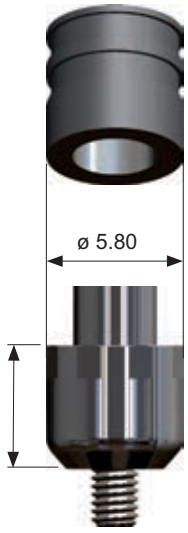
X-Line		Z-Line
Height 2.65 mm	Prostheses magnet	Height 3.15 mm
ø 4.80		ø 5.80
Distance height	Insert Attachment	Distance height
1.6 N (163 g)	Withdrawal force	3.0 N (300 g)



Telescopic magnets

The StecoTitanmagnetics® T-Line was developed exclusively for extraoral use. The telescopic bearing of 2.5 mm gives the facial prosthesis secure fixation on the tissue. The design allows a certain amount of rotation and axial movement, without losing the withdrawal force.

T-Line	
Height 5.7 mm	Prosthesis magnet
ø 5.80	
Distance height	Insert Attachment
1.4 N (143 g)	Withdrawal force



Prosthetic Components

In **X-Line** and **Z-Line** there are prostheses magnets for acrylic and, with additional retention, for silicone. For more lateral support there are prostheses magnets with extended collars available.

For silicone

with retention ring

with collar and retention ring

For acrylic

with rotation protection

with collar

In the **T-Line** there are also prostheses magnets for acrylic and with additional retention for silicone.

For silicone

with retention ring

For acrylic

Universal

Accessories

To make a new prostheses, each product line has its own compatible impression copings and laboratory analogues.

Impression Copings

- magnetic impression without screws
- lock magnetically to the insert
- the external geometry ensures the impression material is securely fixed

X-Line

Z-Line

T-Line

Laboratory Analogues

- for making models quickly and hygienically.
- the original implant does not have to be used on the insert.
- there is no need for time-consuming cleaning.
- a length of 16 mm is also available on request.

X-Line

Z-Line

T-Line

Healing Abutments

The Healing-Flange is placed on the insert to stabilize the bandage on fresh skin perforation tissue, after application of the insert. This minimizes excessive tissue proliferation. The Healing-Flange has its own magnet core and is made off tissue friendly Titanium.

X-Line

T-Line

Insertion standard tools

X-Line

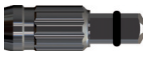
H.00.04.X2

Connector to handpiece

H.00.04.X4

Connector to .... ratchet

H.00.04.X1



Connector to I-Ratchet-2

Z-Line & T-Line

H.00.04.T2

Connector to handpiece

H.00.04.T4

Connector to .... ratchet

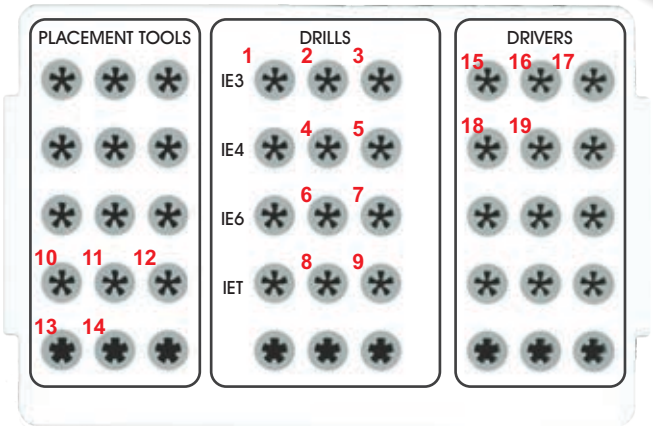
H.00.04.T1

Connector to I-Ratchet-2

INSTRUMENT TRAYS

I-EO-EG For surgical placement of Extraoral Implants

(for Cleaning & Sterilization instructions see CAT-1039)



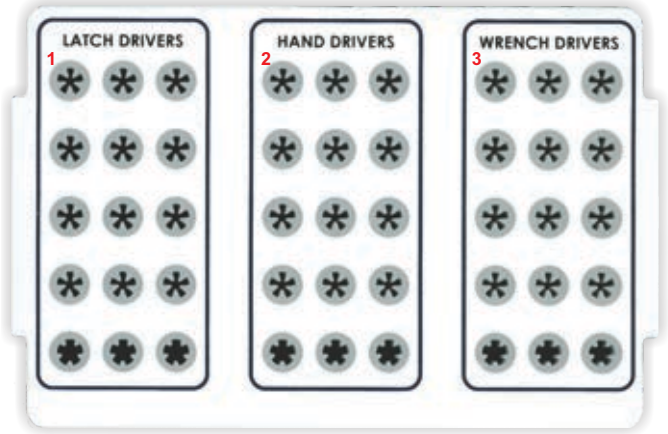
1	D-RB-MS	Round Burr
2	D-20E-03F	Ø2.0 Pilot Drill
3	D-30E-03F	Ø2.0 Pilot Drill
4	D-20E-04F	Ø2.0 Pilot Drill
5	D-30E-04F	Ø3.0 Final Drill
6	D-20E-06F	Ø3.0 Final Drill
7	D-30E-06F	Ø3.0 Final Drill
8	D-40E-04F	Ø4.0 Final Drill
9	D-TAP-IBS	Bone Tap (Optional)
10	I-CON-X	Connector to Handpiece
11	I-HID-M/L	Insertion Tool, Int. Drive, Handpiece Insert
12	I-WIID-S	Insertion Tool, Int. Drive, Wrench Insert
13	I-WI-A	Abutment Driver, Wrench Insert, Hex

14	I-WI-C-S/L	Converter from Handpiece to Wrench
15	I-CS-HD	Cover Screw Hex Driver (0.9mm)
16	I-HD-S	Hex Driver (1.22mm)
17	I-AD	Handpiece Abutment Driver (optional)
18	I-HHD-22-x	Handpiece Hex Driver (1.22mm)
19	I-DE-K / G	Drill Extension
20	I-SP-X	Flat Spanner
21	I-TWA	Torque Wrench Surgical
22	I-TWS-B45	Bending attachment for I-TWS
23	I-WI-CST	Wrench Converter (W&H Hex)
24	I-WI-SH	Fixture Mount Converter
	I-WI-SL	Latch Converter
	I-WI-SS	Square Converter

* Most Instruments available in Short / Medium / Long.

I-PROS-EG Prosthetic Instrument Tray

(for Cleaning & Sterilization instructions see CAT-1039)



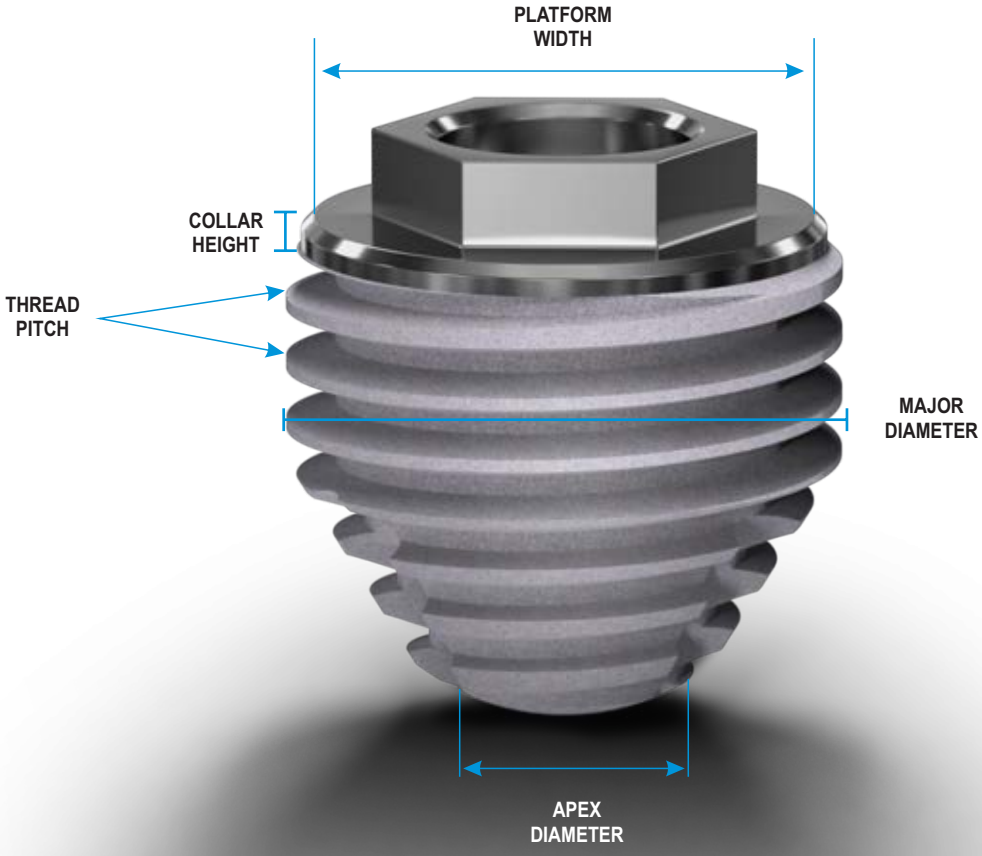
1	Dedicated space for Latch Drivers
2	Dedicated space for Hand Drivers
3	Dedicated space for Wrench Drivers
4	Dedicated space for Additional Items
5	Dedicated space for Torque Wrench and Adaptors

Please Note:
This instrumentation tray is to be ***customised by the user*** to be suitable for use with the preferred implant system and its surgical or prosthetic items.

* Most Instruments available in Short / Medium / Long.

IMPLANT DIMENSIONS AND INFORMATION

RANGE		MAJOR DIAMETER	PLATFORM WIDTH	Prosthetics	HEX WIDTH	HEX HEIGHT	COLLAR HEIGHT	THREAD PITCH	APEX DIAMETER	Cylindrical or Tapered C/T	IMPLANT LENGTHS		
											3	4	6
IE	Ø3.75mm	3.75	4.80		2.73	0.7	0.40	0.6	2.80	C	√	√	√
IET	Ø4.5mm	4.5	4.07		2.73	0.7	0.25	0.5	2.45	T		√	

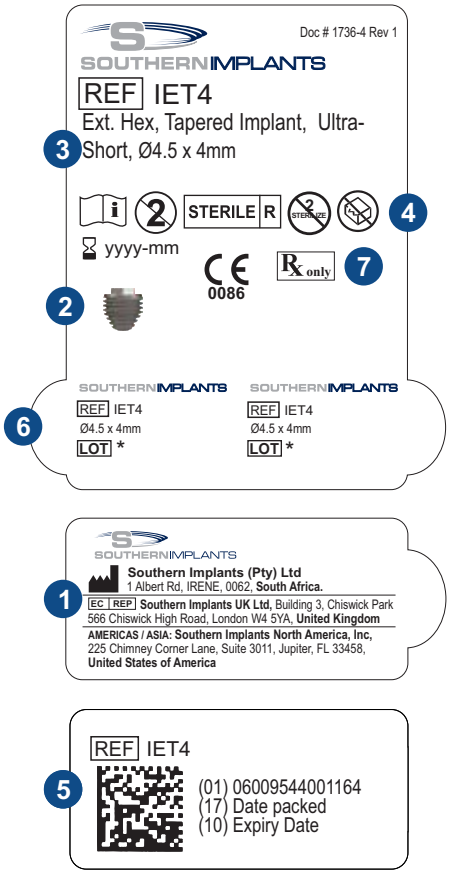


EXPLANATION OF SYMBOLS

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

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

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



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-2010-06 (C828)