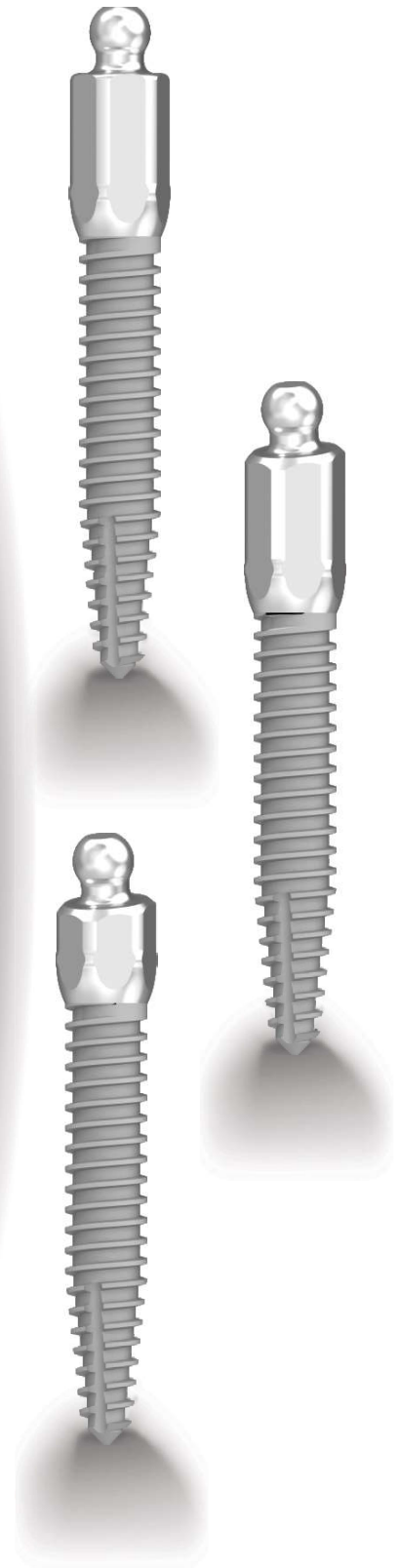
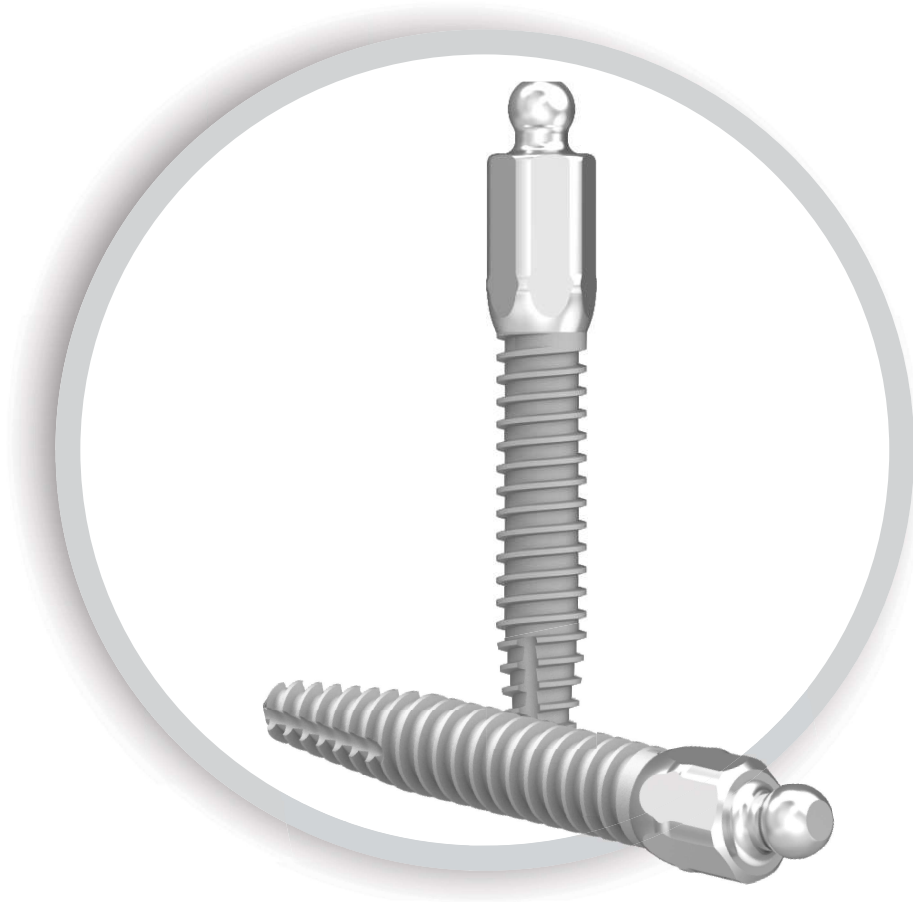




ILZ Mini Implants

Product Catalogue





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 sincere thanks to all specialists, dentists and technicians who put their trust in our company.


Graham Blackbeard
Managing Director, Southern Implants

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Various Data Sheets and information are available on our website
SOUTHERNIMPLANTS.COM

Please note:

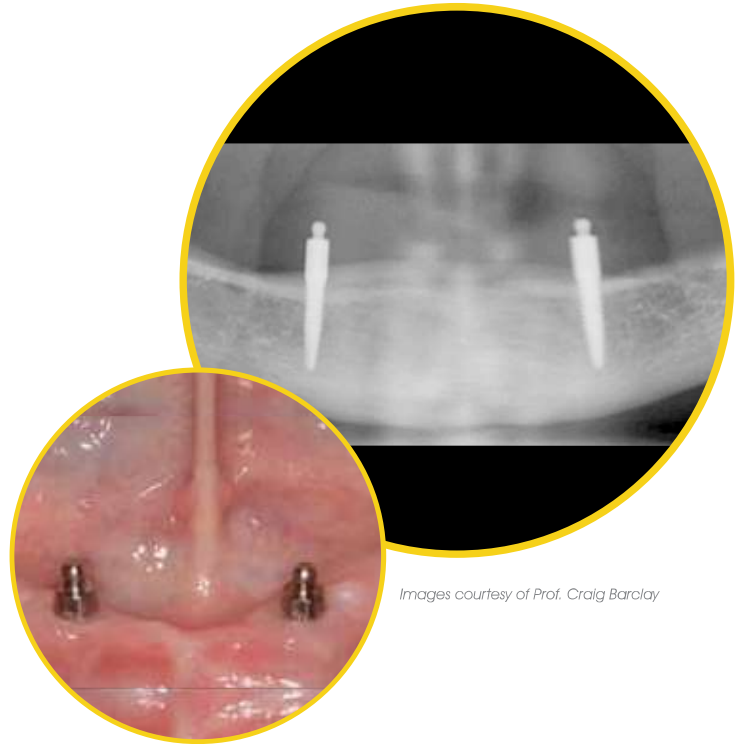
- Images are for illustration purposes only and do not necessarily accurately represent the product.
- All dimensions in this catalogue are in mm, unless otherwise specified.
- Not all products are cleared for sale in all countries.

ILZ Mini Implant

Mini dental implants in the management of the atrophic maxilla and mandible

The use of the mini dental implants to retain complete overdentures provides an alternative treatment modality for elderly patients in the management of unretentive lower dentures. Minimally invasive dentistry is of increasing importance to the modern dentist, and where appropriate can be applied to improve denture stability and function for patients.

European Journal of Prosthodontics and Restorative Dentistry (2018) 26, 190-196



Images courtesy of Prof. Craig Barclay

The Mini Dental Implant features

Popular Co-Axis®

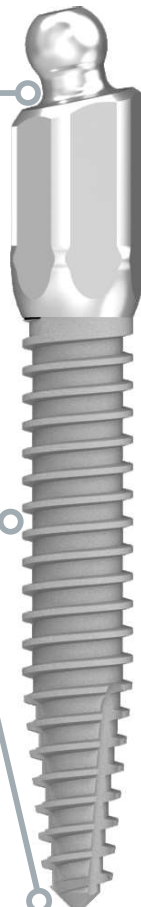
Feature with built in 12° angle correction above soft tissue. This facilitates optimal use of available bone.

High Strength Titanium

Manufactured from High Strength Grade 4 Pure Titanium (≥ 900 MpA) providing exceptional fatigue strength.

Apical Thread

Aggressive thread for maximum primary stability in trabecular bone.



One piece implant with a $\varnothing 1.8$ mm ball head.

The ILZ features a unique hexagonal collar with no sharp angles, which allows for better soft tissue adaptation around the neck of the implant.

Sinergy™ Surface

With 20 years of clinical use, the moderately rough* Southern Implants Alumina-blasted surface has shown consistently excellent results in both early osseointegration and longevity.

*Ma S, Towse-Smith A, De Silva RK, Alieh MA, Alsabeeha NHM, Payne AGI. Maxillary Three-Implant Overdentures Opposing Mandibular Two-Implant Overdentures: 10-Year Surgical Outcomes of a Randomized Controlled Trial. Clin Implant Dent Relat Res. 2016 Jun;18(3):527-44. (10-year prosthodontic outcomes awaiting publication)

Intended use

Mini (Ø2.4mm) dental implants are intended for stabilization of removable dentures, in patients with insufficient bone volume, for the placement of conventional implants of diameter 3.0mm or more.

The MDI is an ideal solution to overcome anatomical challenges, and avoid bone grafting procedures in the treatment of elderly patients, to improve retention and stability of their dentures.

Instructions for use

This surgical manual serves as a reference for the placement of Southern Implants range of Mini Dental Implants. It is strongly recommended that clinicians whether experienced or inexperienced implant users, always undertake device specific training before attempting a new treatment method. The procedure described in this manual does not cover all the possible patient conditions that could influence the treatment planning, executions and outcomes of the treatment.

Preoperative evaluation

A thorough clinical assessment must be done to determine the physical and psychological health of the patient. Take care when treating patients with local or systemic factors that could affect the healing of tissues or interfere with the osseointegration process. (e.g smoking, uncontrolled diabetes, radiotherapy, steroid therapy, poor oral hygiene, bisphosphonate therapy etc.)

Preoperative evaluation for Patient selection should include a radiographic and clinical assessment of the oral cavity. It is recommended that a panoramic and a cephalogram/or CBCT is obtained to study the anatomical structures, dimension of available bone, bone density etc.

Mini Dental implants are indicated for edentulous patients (generally over the age of 70), with Class V or VI ridges who do not exert the same functional load as younger edentulous patients.

Contraindications

Do not use in patients;

- Who are medically unfit for dental implant procedures.
- Who are allergic or have hypersensitivity to pure titanium.
- Where adequate numbers of implants cannot be placed to achieve full functional support for a prosthesis.
- Southern Mini Implants (Ø2.4mm) are not indicated for use as single crowns, partial bridges or fixed restorations. Immediate loading is only indicated if insertion torque of at least 35Ncm is achieved. Implant divergence of up to 35° is acceptable, and if more than that, it is contraindicated.

How to determine the number of implants:

Mandible

Two implants is the standard approach in the management of the edentulous mandible to stabilize and provide retention for the denture. The implants are ideally placed in the lower canine region of the mandible. A third implant can be placed midline for additional stability. Four implants are indicated where opposing a complete dentate upper arch.

Often in the atrophic mandible, the residual ridge is lingually inclined beneath the desired prosthetic positioning of the mandibular teeth. In these cases a 12° Co-Axis design is indicated which allows for compensation of this lingual inclination in the mandible & palatal inclination in the maxilla.

Maxilla

If bone allows, place four implants, two in the upper central region and two in the upper canine/ 1st premolar region. Implants must be placed at least 5mm apart.

Considerations

Bone quality and quantity

Choose an appropriate size implant for the amount of bone available, respecting the biological width and ensure that sufficient bone volume is surrounding the implant body. Take care to avoid anatomical structures such as the sinus and mental nerve, and the sublingual artery.

In dense bone, use new drills with profuse irrigation.

In low-density bone, it is recommended to undersize the osteotomy by drilling with a smaller final drill.

Loading times

Immediate loading (within 1 week of implant placement) is recommended, provided that all implants achieved 35Ncm insertion torque.

If immediate loading is not possible due to low primary stability then a healing period of minimum 2 months but preferably 3 months, after implant placement is indicated. During this healing phase the implants must be free-of-load in order for osseointegration and predictable healing to take place. Early loading is not allowed (between 1 week and 2 months.)

Advise patients to adhere to a soft diet for the first 6 weeks and place minimal forces on the restoration for weeks 6-12.

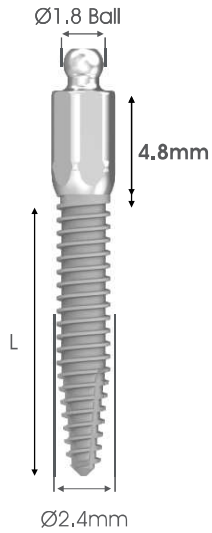
Troubleshooting

Implant mobility: If the fixture is very loose, consider removal and replacement with another fixture, in a new site. Do not immediately load unless 35Ncm insertion torque is achieved on all implants.

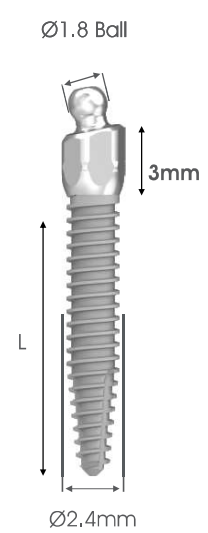
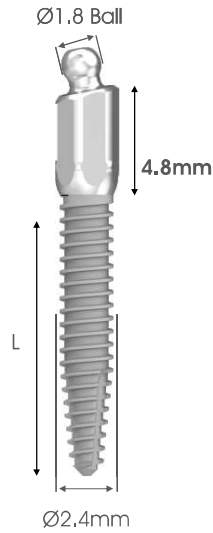
IMPLANT INFORMATION

ILZ Ø2.4mm Tapered Implants

ILZ straight implant



ILZ Co-Axis 12° implants



Implants are available in the following lengths:

ITEM CODE	IMPLANT LENGTHS (in mm)
ILZ8.5	8.5
ILZ10	10
ILZ13	13

ITEM CODE	IMPLANT LENGTHS (in mm)
ILZ12d-510	10
ILZ12d-513	13

ITEM CODE	IMPLANT LENGTHS (in mm)
ILZ12d-310	10
ILZ12d-313	13

DRILL INFORMATION

Spade Drill



D-3SPADE-1.8M

Twist Drills

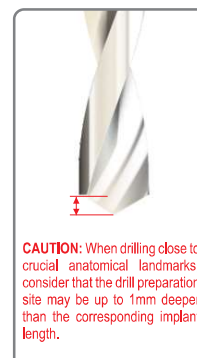
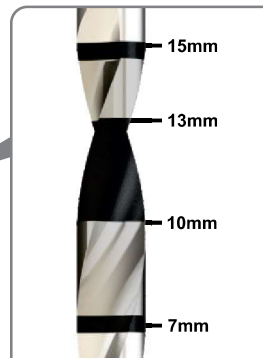


D-12T-M15

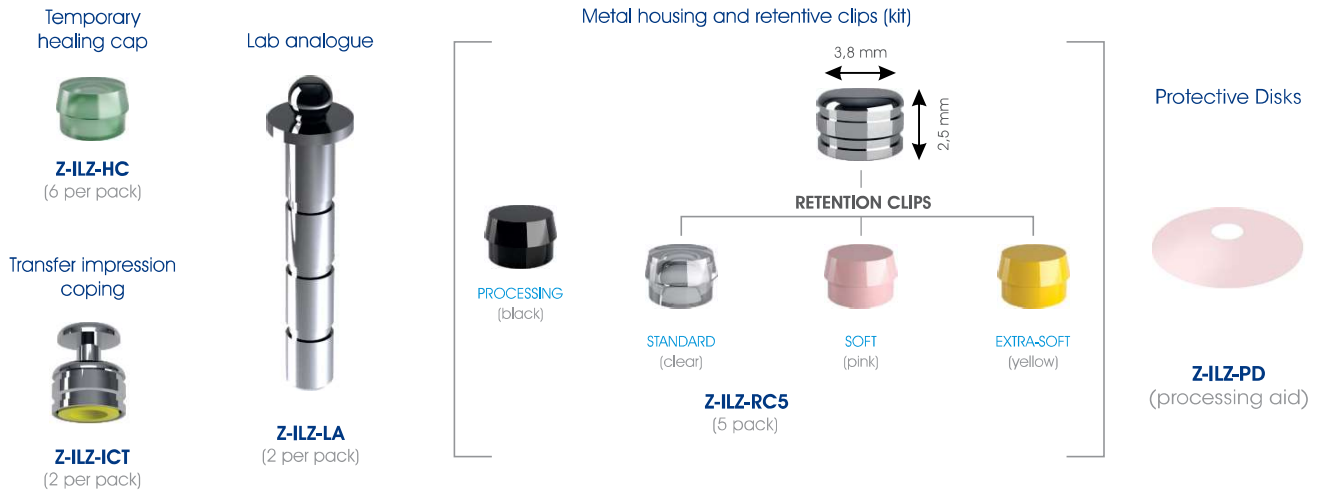


D-20T-M15

Twist drill markings



PROSTHETICS



CLIP TOOL KIT

Clip insertion tool



Clip extractor tool



Z-I-KIT-EQ

RATCHET WRENCH & TORQUE ATTACHMENT

Ratchet Wrench



I-TWS

Torque Attachment



I-TWS-B45 maximum torque 45Ncm

Converters



I-WI-CST

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



I-WI-SS

For SQUARE connection of fixture mounts and instruments

PLACEMENT TOOLS

Peek cap



(supplied attached on implant)

Wrench Insert



I-WI-ILZ-S

Handpiece Insert



I-HILZ-S/M/L

SURGICAL GUIDELINES

The vertical bone height will determine the Implant length that can be used and it is recommended that a ridge width of at least 5.5mm is available.

Although these implants may be placed flapless, it will require careful planning and consideration to avoid anatomic structures e.g. mental foramen, sinuses and lingual artery.

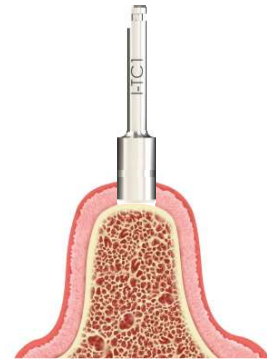
It is recommended that clinicians who use MDI's are able to carry out flap surgery.

Step 1: Preparing the osteotomy

Illustrating placement of 13mm implant

The tissue cutter (I-TC1) is used to remove soft tissue of the required diameter.

Recommended speed: 1200rpm.



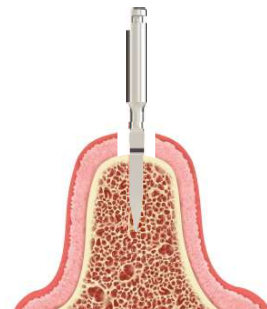
Step 2: Initiate the osteotomy

Flapless placement often makes it difficult to determine the exact middle position of the osteotomy, because of the irregular shape of the ridge.

The solution is to initiate the osteotomy with a spade drill (D-3SPADE-1.8M), to pierce the bone accurately, and to avoid drilling down the side of the ridge.

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

Always place the most distal implants first and then work towards the midline.



Step 3: Pilot drilling - Ø1.2mm twist drill

In **soft** bone; drill in the planned direction with the 1.2mm twist drill to the appropriate depth as indicated by the markings on the drill. Place and seat the implant.

In **medium** to **dense** bone; drill in the planned direction and to full depth with the Ø1.2mm drill.

Use the direction indicator (I-DIN) to check implant axis and correct if necessary. Leave the indicator in, and proceed with the next site, respecting the minimum of 5mm distance between implants.

Note: In cases of reduced vertical bone height, an x-ray should be taken to ensure that the drill did not pass through the mandibular lower cortex.

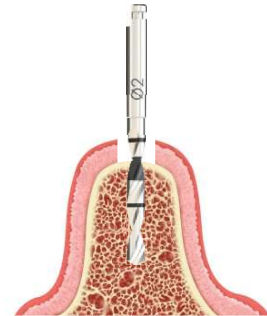


SURGICAL GUIDELINES

Step 4: Final drill (Optional) - Ø2.0mm twist drill

In **medium** bone; drill to 50-60% of the desired depth with the Ø2mm twist drill and then place the implant

In **dense** bone; drill to 100% of the desired depth with the Ø2mm twist drill and then place the implant.

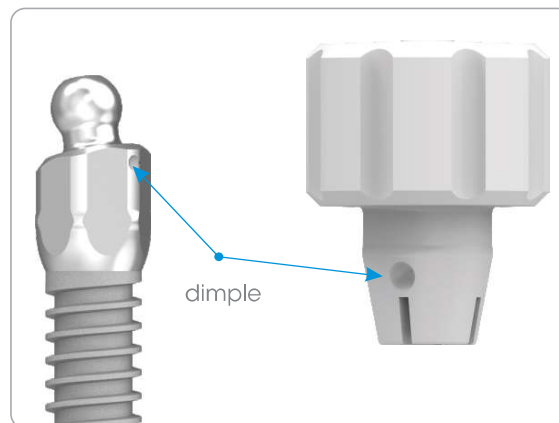
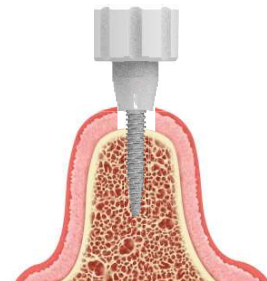


Step 5: Implant Placement

The ILZ implant is packaged with a PEEK Cap which is used to carry the implant to the prepared site. The initial insertion of the implant is done by hand, using the PEEK cap.

When used with the Co-Axis® ILZ implant, a dimple on the PEEK cap indicates the position from which the ball is angled away. When used in the upper jaw, this dimple must be facing buccal, and facing lingual in the lower jaw.

Note: Allow the implant collar to be inserted level with, or slightly submerged in surrounding marginal bone.
All implants need to be placed as parallel as possible in order to maximize the longevity of the retentive elements.



Step 6: Fully seat the implant

Final insertion to the required torque is done with a torque wrench fitted with a wrench insert, (I-WHLZ-S), or with a handpiece fitted with a handpiece insert, (I-HILZ-S/M/L). The I-HILZ also has a dimple to assist with Co-Axis orientation (maximum speed of 15rpm).

A minimum of 35Ncm insertion torque must be achieved to consider immediate loading.

Do not exceed 45Ncm.

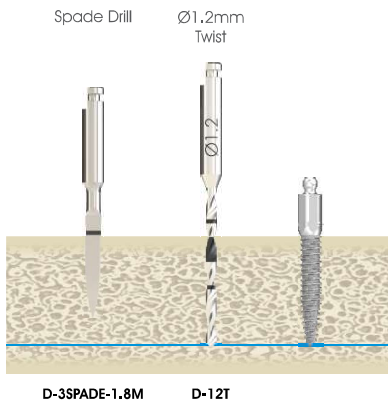


SITE PREPARATION SEQUENCE

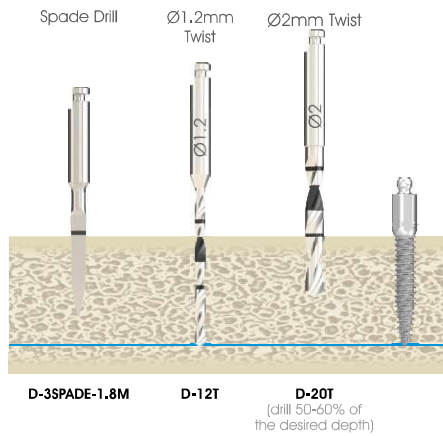
Straight Implants

(illustrations are for 13mm implants)

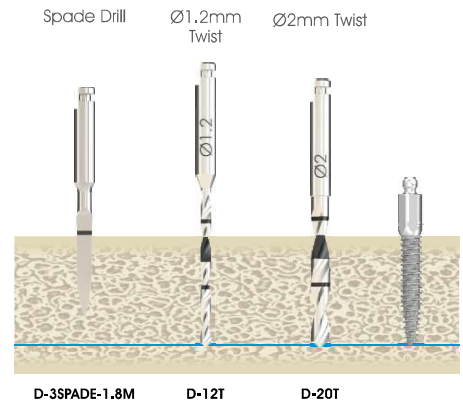
Soft Bone



Medium Bone

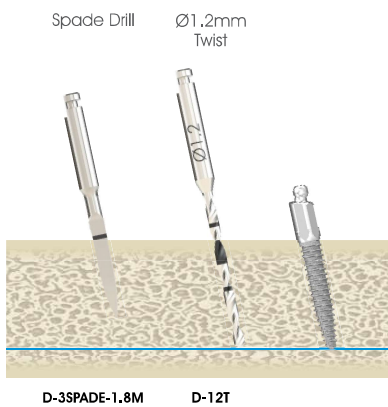


Dense Bone

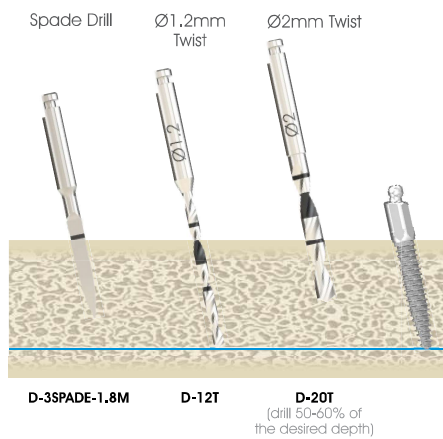


Co-Axis® Implants

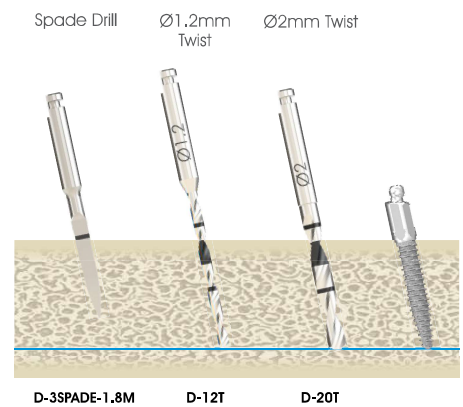
Soft Bone



Medium Bone



Dense Bone



PROSTHETIC PROCEDURE: Direct Restorative Protocol

Direct, chairside modification of an existing well-fitting and well-functioning denture, to an implant supported overdenture using ILZ retention clips:

Step 1

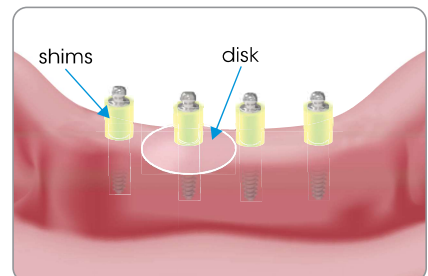
Relieve denture, create holes or a channel/trough to accommodate implants and metal housings. Allow 1mm around the housing for sufficient thickness of the self-polymerising resin.



Step 2

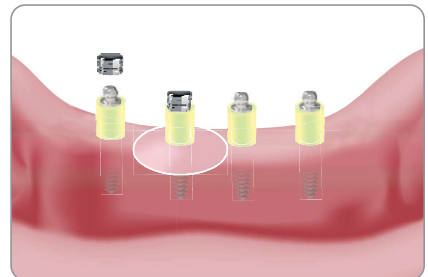
Insert the protective disk on all the implant necks to protect the gingiva. Create block-out shims around each implant to block-out undercuts and prevent acrylic from locking onto implants.

Note: Shims are tubes that fits over the implants, and can be created with dental tubing or similar products.



Step 3

Place Metal housings with the black processing clip onto the ball abutment, check alignment and ensure that there is no interference with the prosthesis.



Step 4

Apply a thin layer of adhesive (monomer) to the denture. Protect areas to remain resin free with a thin layer of petroleum jelly.



Step 5

Fill the hollowed area with self-curing resin and apply a small amount of acrylic resin to the recess of the denture base and around the metal housings. Insert the denture into the patients' mouth and have patient apply a normal bite pressure in centric occlusion. Allow 7-9 minutes for the material to set.



Step 6

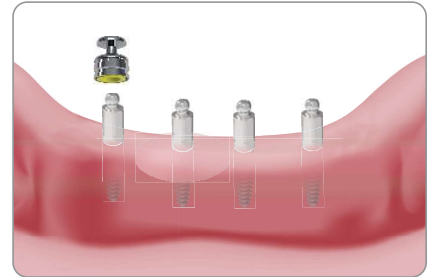
Once the resin has cured, remove the denture and block out shims, excess acrylic and finish the denture. Remove the black processing clip with the extractor tool and replace with low retention clip. Seat the final denture and advise the patient to keep in place for the first 48 hours to allow tissue healing.

PROSTHETIC PROCEDURE: Indirect Restorative Protocol

Step 1

Place the transfer Impression copings on the ball-head of the implants

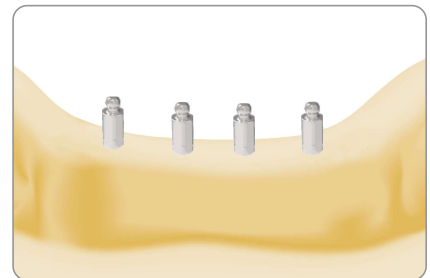
Use Vinyl poly-siloxane or polyether rubber and take an impression. The impression copings are picked up in the impression material.



Step 2

Send the impression to the dental lab who will pour a model using the ILZ laboratory analogues.

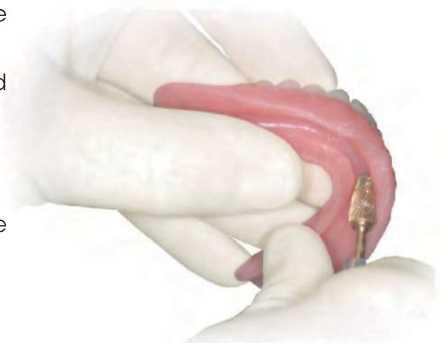
Place the metal housing on the analogue and manufacture the overdenture using conventional methods.



SECURE SOFT RELINE PROTOCOL

In the event of lack of primary stability, a soft reline is indicated, as a soft load.

- Grind down denture base at least 1 mm and relieve denture to accommodate the prosthetic heads of each implant.
- Roughen the tissue-contact surface of the denture with an acrylic bur and degrease the surface with isopropyl alcohol.
- Apply a thin coat of adhesive.
- Extrude Secure Soft Reline material onto the tissue-contact surface of the denture.
- Place the denture in the patient's mouth and ask patient to apply normal bite pressure in centric occlusion.
- Allow seven minutes for Secure Soft Reline material to set.
- Remove denture and trim excess material with fine scissors or a surgical blade.
- Mix equal drops of glazing base and catalyst.
- Use a brush to apply the mixture to the corresponding margins.
- DO NOT remove the palate of a maxillary denture during this stage.
- Ask the patient to keep the denture in place for the first 48 hours after placement to prevent tissue overgrowth.
- **Four to six months after soft load, the soft liner is replaced with Metal Housings and retention clips to increase the level of retention.**
- After osseointegration the palatal plate in a maxillary denture can be progressively removed, if desired.

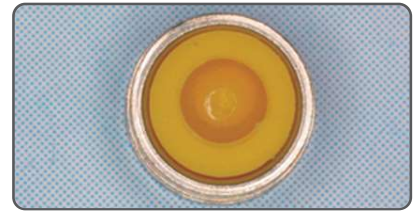


PROSTHETIC PROCEDURES: Replacement of Clips

Rhein83 recommends that clips be replaced every 12 months. The longevity of the clip is affected by many variables including: original case design, patient hygiene and general maintenance of the prosthesis.

The Rhein83 clips are manufactured with a high elasticity, which creates both mechanical and frictional retention resulting in a larger contact zone between the clip and the lower portion of the sphere.

A small space between the metal housing and the clip allows the clip to expand as it passes over the equator of the sphere. Once completely engaged, the clip returns to its original form.



How to replace the clips

In a prosthesis with metal housings, the clip can be removed by using a blunt rotary instrument operated at low RPM. Be careful not to damage the metal housing during this procedure. The clip extractor tool can also be used.



Clip insertion tool

When using retention clips, it is recommended to insert them chairside onto the attachment using the clip insertion tool.






Prosthesis with multiple attachments

In order to balance the retentive levels of a prosthesis with multiple attachments, it is possible to use clips with different levels of retention in the final case design.



Clips

-  • Yellow clip - extra soft 0.6kg
-  • Pink clip - soft retention 1.2kg
-  • Transparent clip - standard retention 1.8Kg

NOTE: The Equator overdenture abutments are produced under license by Southern Implants

GENERAL INFORMATION AND WARNINGS

Sterility

All dental implants 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. 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.

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

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

Validity: Upon publication of this manual, all previous versions are superceded.

Magnetic Resonance (MR) safety information

ILZ implants have not been evaluated for safety and compatibility in the MR environment. ILZs' have not been tested for heating, migration or image artefact in the MR environment. The safety of ILZ 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.

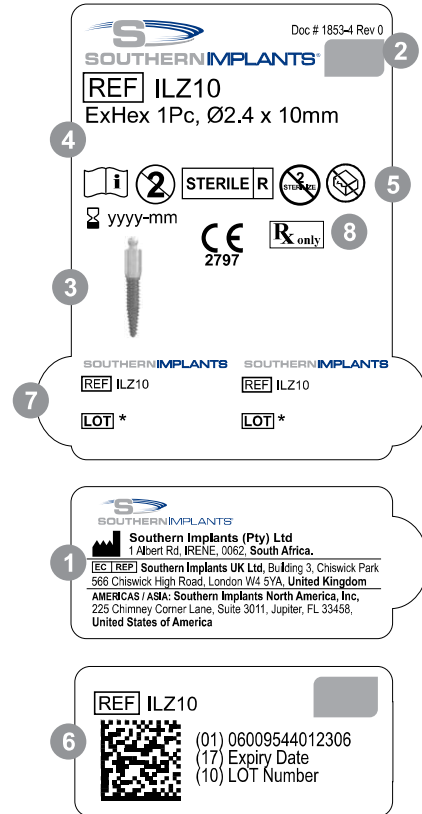
WARRANTEE: The product is guaranteed to be free of manufacturing defects. There is no warrantee replacement program for cases of non-integration/implant removal.

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

EXPLANATION OF LABELING SYMBOLS

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

- 1  **Manufacturer**
- 2  **Colour code indicating implant interface**
- 3 **Implant image**
- 4 **Implant details and size**
- 5  Sterilization using Irradiation
-  Do not Resterilize
-  Consult instruction for use
-  Do not reuse
-  CE mark and notified body number
-  Expiry date
-  Sterile unless package is opened or damaged
- 6 **2D Bar coding**
Contains the GTIN, Expiry Date and LOT Number
- 7 **Patient sticker for documentation purposes**
(to be used by health care provider on patient file)
- 8  **Prescription device**
CAUTION: FEDERAL LAW RESTRICTS THE DEVICE TO SALE BY OR ON THE ORDER OF A LICENCED HEALTH CARE PROVIDER.



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