SOUTHERNIMPLANTS®
Innovative Treatment Solutions

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

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Intended use
ILZ 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.

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 fully edentulous patients in the upper or lower jaw. Restorations comprise of full and removable dentures.

Description
The ILZ implant is a self-tapping tapered one piece implant with a Ø1.8mm ball head, made of commercially pure special grade 4 titanium (UTS ≥900 Mpa). All implants are surface-roughened with Southern Implants' abraded SInergy surface. The surface has an average S_a value of 1.4 microns.
The ILZ implant is also available in the angulated Co-Axis® design. Featuring a built-in 12° angle correction above soft tissue. This facilitates optimal use of available bone. Co-Axis® versions are available with 4.8mm and a 3mm hexagonal collar height.

ILZ IMPLANT RANGE

Ø2.4 Straight Implants with 4.8mm collar height

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

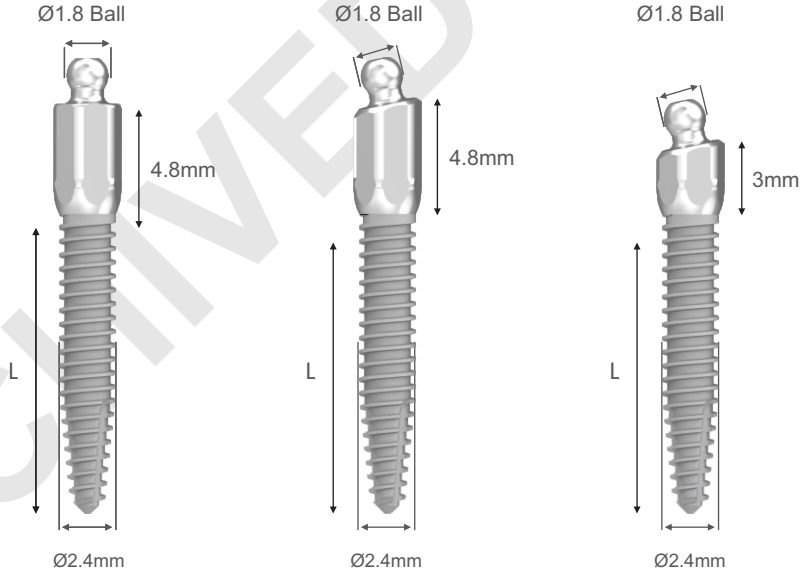
Ø2.4 Co-Axis® Implants with 4.8mm collar height

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

Ø2.4 Co-Axis® Implants with 3.0mm collar height

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

ILZ straight implant | **ILZ Co-Axis 12º implants**



Indications for use
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.
- 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.
- 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.

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.

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.

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 re-use 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 re-used 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 non-sterile gloves), remove the TYVEK lid and drop or place the sterile tube onto the sterile field. The PEEK cap is attached to the implant and serves as a carrier. Carefully remove the implant from the sterile tube. Do not touch the sterile implant.

Other sterile components are packed in a peel pouch or blister-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 bister-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.

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.

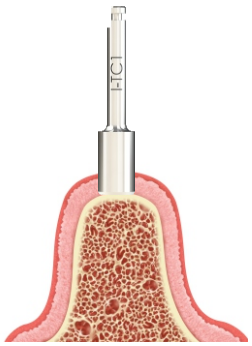
Often in the atrophic mandible, the residual ridge is lingually inclined beneath the desired prosthetic positioning of the mandibular teeth. In these cases a 12° Co-Axis design is indicated which allows for compensation of this lingual inclination in the mandible & palatal inclination in the maxilla.

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.

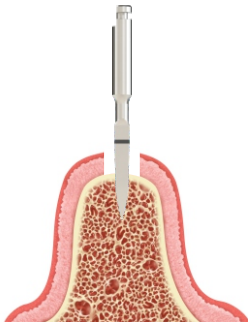
SURGICAL PROCEDURE

Step 1: Preparing the osteotomy
(*Fig. 1*)
The tissue cutter (I-TC1) is used to remove soft tissue of the required diameter.
Recommended speed: 1200rpm.

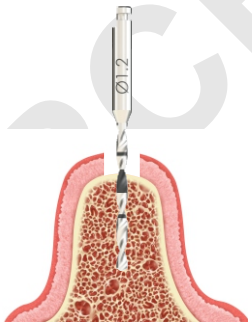


(*Fig. 1*)

Step 2: Initiate the osteotomy
(*Fig. 2*)
Initiate the osteotomy with a spade drill (D-3SPADE-1.8M) (*Fig. 4A*), 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.

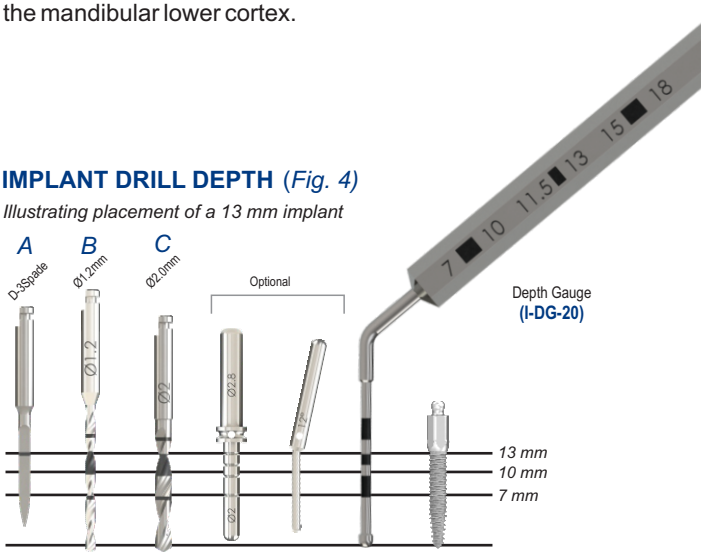

(*Fig. 2*)

Step 3: Pilot drilling – Ø1.2mm twist drill (*Fig. 3*)
In **soft** bone, drill in the planned direction with the 1.2mm (D-12T-M15) (*Fig. 4B*) 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.

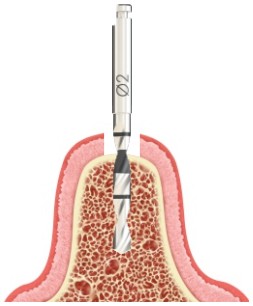


(*Fig. 3*)

IMPLANT DRILL DEPTH (*Fig. 4*)
Illustrating placement of a 13 mm implant

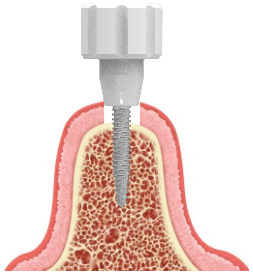


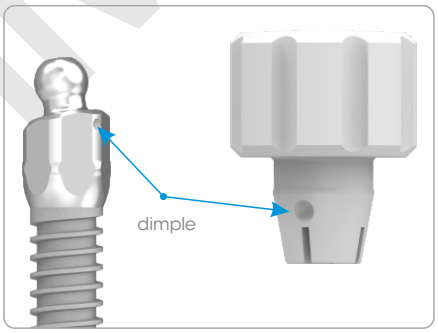
Step 4: Final drill (Optional) - Ø2.0mm twist drill (*Fig. 5*)
In **medium** bone, drill to 50-60% of the desired depth with the Ø2mm (D-20T-M15) (*Fig. 4C*) twist drill and then place the implant.
In **dense** bone, drill to 100% of the desired depth with the Ø2mm twist drill and then place the implant.



(*Fig. 5*)

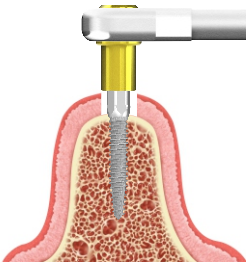
Step 5: Implant Placement
The ILZ implant is packaged with a PEEK cap which is used to carry the implant to the prepared site. The initial insertion of the implant is done by hand, using the PEEK cap. (*Fig. 6*)
When used with the Co-Axis® ILZ implant, a dimple on the PEEK cap (*Fig. 7*) indicates the 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.


(*Fig. 6*)



(*Fig. 7*)

Step 6: Fully seat the implant (*Fig. 8*)
Final insertion to the required torque is done with a torque wrench fitted with a wrench insert, (I-WI-ILZ-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.


(*Fig. 8*)

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.

Clinical benefits
Patients can expect to have their missing teeth replaced.

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, ASTM F67 and ISO5832-2, UTS≥ 900MPa).

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 10mm 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 General Dental Implants	600954403869

Related literature & catalogues

CAT-2087M - ILZ Mini Implants Product Catalogue

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.