SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	**INSTRUCTIONS FOR USE: Southern Implants® Trephine drills**
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Português	**INSTRUÇÕES DE UTILIZAÇÃO: Southern Implants® Trefinas de trefina**

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Intended Use

Southern Implants trephine drills are intended to be used to remove a cylindrical core of bone surrounding an implant if the implant is to be explanted or to harvest cores of bone in bone augmentation procedures. The trephine drills are medical devices. The drills are intended for single use on a single patient.

Intended User

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

Intended Environment

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

Intended Patient Population

Patients that have lost one tooth or multiple teeth and are having dental implants inserted or removed.

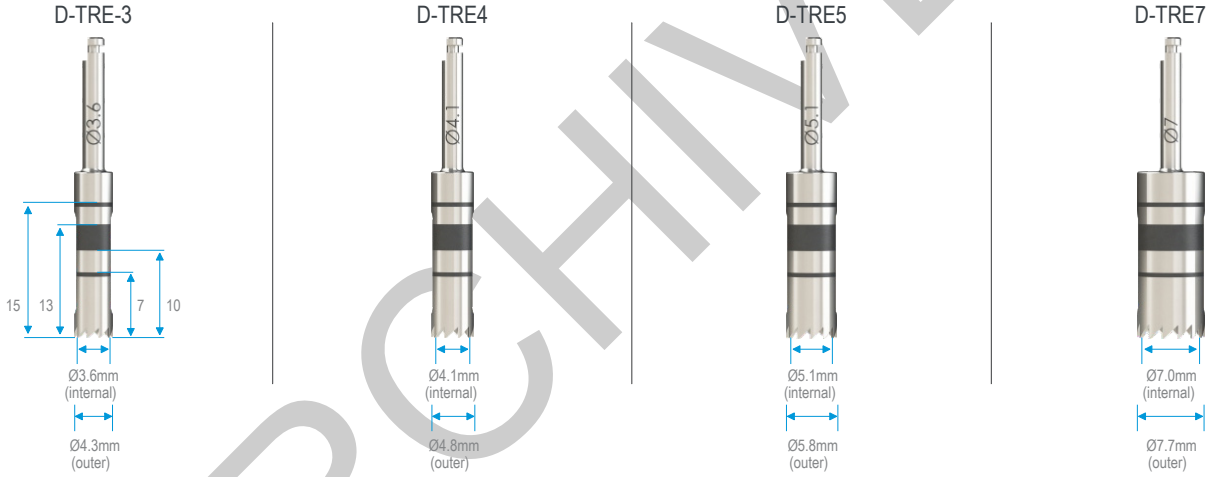
Indications for Use

Southern Implants trephine drills are indicated for removing an osseointegrated dental implant or to harvest cores of bone in bone augmentation procedures.

Description

Southern Implants trephine drills are described in table A. these devices attach to a handpiece of an implant motor unit, and has a latch compatible to ISO 1797. This is in order to connect the trephine drill to the handpiece of an implant motor unit. Trephine drills have laser marked lines at different levels in millimeters to indicate the depth of cutting. The laser marking on the shaft of the drill is to indicate the internal diameter of the device. The trephine drills have cutting edges on the end of the drill with a hollow tube in the middle of the drill. When the drill is rotated by a dental handpiece, the cutting edges remove a thin annulus of bone around an implant, separating the core of bone from the surrounding bone. This device is supplied sterile and for single patient use.

Table A



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.

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.

Surgical procedures for implant removal

1. Attach the appropriate size healing abutment to the implant. This will guide the trephine and prevent running into the side of the implant with the trephine.
2. Connect the trephine drill latch to the handpiece, if the latch is not inserted fully into the handpiece the torque is applied to the latch, resulting in possible twisting of the latch or damage to the handpiece. Consult the instructions for use of the handpiece to ensure proper engagement of the latch.
3. Do not apply more than 40-45Ncm to any latch type instrument, this could cause damage to the handpiece and/ or latch.
4. Place the trephine over the healing abutment and drill at low speed, until it grips the bone, then increase speed to 800rpm use a up and down action, with copious amounts of irrigation to prevent over heating of the bone. Drilling at low speed will improve control taking care not to touch the implant which might damage the serrated teeth of the trephine. Note: It is recommended to have more than one trephine available when using the trephine for implant removal.
5. The laser marking on the trephine will indicate the depth of drilling to assist the practitioner not to drill to deep, drill to the length of the implant being removed.

Surgical procedure for harvesting bone

1. Follow step 2 and 3 above for connecting the trephine to the handpiece.
2. Drill at low speed, until it grips the bone then increase speed to 800rpm, with an up and down technique with copious amount of irrigation to prevent over heating of the bone.
3. The volume/size of core to be removed has to be preplanned with proper radiographic imaging by the surgeon.
4. Use a instrument to push out the core of bone by inserting the instrument into the hole on the side of the trephine and pushing it out.

Storage, cleaning & sterilisation

These devices are supplied sterile (sterilised by gamma irradiation). 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. The devises must be stored in a dry place at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics.

Single use devices

Do not reuse devices indicated for single use. (Use the device prior to the expiration date).

Do not reuse implants, single use drills, cover screws, temporary abutments and abutments. Reusing 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.

Sterilisation

Southern Implants recommends the following procedure to sterilise the instruments prior to use when packed in a tray.

Methods to sterilise these devises:

1. pre-vacuum sterilisation method: Steam sterilise the instruments at 132°C (270°F) at 180-220kPa for 4 minutes. Dry for at least 20 minutes in the chamber. Only an approved wrap or pouch for steam sterilisation must be used.
2. pre-vacuum sterilisation method: Wrapped, steam sterilise at 135°C (275°F) for 3 minutes. Dry for 20 minutes in the chamber. Use a wrap or pouch that is cleared for the indicated steam sterilisation cycle.

NOTE: Users in the USA must ensure that the steriliser, wrap or pouch, and all steriliser accessories are cleared by the FDA, for the intended sterilisation cycle.

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

Trephine drill: Titanium grade 5

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 normal functional torque 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).

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 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.

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 Drills and Hand Piece Devices	600954403875

Related literature & catalogues
CAT-2004 - Tri-Nex Implants Product Catalogue
CAT-2005 - IT Implants Product Catalogue
CAT-2010 - Osseointegrated Fixtures Catalogue
CAT-2020 - External Hex Implants Product Catalogue
CAT-2042 - Deep Conical Implants Product Catalogue
CAT-2043 - Internal Hex Implants Product Catalogue
CAT-2060 - PROVATA® Implants Product Catalogue
CAT-2069 - INVERTA® Implants Product Catalogue
CAT-2070 - Zygomatic Implants Product Catalogue

Symbols and Warnings

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CE 2797 — Rx ONLY Prescription device* — STERILE R Sterilization using Irradiation — NON STERILE Non-sterile — Caution — Consult instruction for use — Use by date (mm-yy) — Do not reuse — Do not re-sterilize — LOT Batch code — Do not use if package is damaged — MD Medical Device

* 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.