SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	**INSTRUCTIONS FOR USE: Southern Implants® Bone Mill & Protector Caps for External Hex Implants**
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Português	**INSTRUÇÕES DE UTILIZAÇÃO: Southern Implants® Bone Mill & Protector Caps for External Hex Implants**

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Intended Use

Southern Implants® Bone mills are intended to remove excessive bone around the coronal aspect of the inserted dental implant if bone would interfere with the seating of the abutment. Bone mill Protector caps are intended to guide the bone mill towards the coronal (the platform), of the implant to remove excessive bone whilst protecting the implant.The bone mills are medical devises, and intended for single patient use.

Description

The bone mills have cutting edges on their tip that cut the bone at an angle when rotated by a dental handpiece. The core of the bone mill is hollow to allow it to fit over a protector cap that fits onto the implant to protect the implant interface while milling the bone. The bone mill is supplied with the protector cap. Protector caps are available separately and supplied non-sterile. The bone mill has a latch dimension compatible to ISO 1797. This is in order to connect the bone mill to the handpiece of an implant motor unit.

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.

Intended user

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

Table A (Description/Compatibility)

Indications for use

The Bone mills are indicated to be used with the corresponding protector cap, to remove excess bone from the and around the implant platform. The removal of bone will facilitate the seating of prosthetic components.

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, iridium, Stainless steel and Radel.
- 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, specialised training, including hands-on training to learn proper technique for placement of implants, biomechanical requirements and radiographic evaluations must be done.

Responsibility for proper patient selection, 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.

- The use of non-sterile items can lead to secondary infections of the tissue or transfer infectious diseases.

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.
- Minimizing 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.

During surgery
Care must be taken that parts are not swallowed during any of the procedures, a rubber-dam application is recommended when appropriate. All components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components or equipment.

Post-surgery
Regular patient follow-up, and proper oral hygiene must be achieved to ensure favourable long-term results.

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 container prior to surgery. And for sterilisation procedures when the protector cap is bought separately.

Methods to sterilise the surgical instruments
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.

Before Surgery
All components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

Surgical procedures
1. Remove the cover screw or healing abutment.
2. Attach (finger tighten) the protector cap to the implant using a 1.22mm hex driver or universal hex driver.
3. The bone mill is fitted to a slow or medium speed hand piece and placed over the Cap, rotate and mill at low speed (60-100rpm), using copious amounts of irrigation. Ensure no bending forces are applied when guiding the bone mill over the protector cap.
4. When the surrounding bone has been removed around the implant head, ensure that the implant platform is clean of any bone particles.
5. The chosen abutment can now be seated.

Note: Ensure that the appropriate protector cap is used, corresponding to the Implant diameter, to avoid damage to the internal screw thread or Implant shoulder.

Clinical benefits
Through this procedure 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
Bone mill: Titanium Grade 5 (Ti-6AL-4V)
Protector cap: Titanium Grade 5 (Ti-6AL-4V)

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 Handpiece Devices	600954403875

Related literature & catalogues

CAT-2020 - External Hex Implants Product Catalogue
CAT-2069 - INVERTA® Implants Product Catalogue
CAT-2070 - Zygomatic 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.