SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	**INSTRUCTIONS FOR USE: Southern Implants® Bone Mill for Internal Connection Implants**
Español	**INSTRUCCIONES DE USO: Southern Implants® Molino óseo para implantes de conexión interna**
Italiano	**ISTRUZIONI PER L'USO: Southern Implants® Bone Mill per impianti di connessione interna**
Français	**MODE D'EMPLOI : Southern Implants® Broyeur à os pour implants à connexion interne**
Deutsch	**GEBRAUCHSANWEISUNG: Southern Implants® Knochenmühle für interne Verbindungsimplantate**
Português	**INSTRUÇÕES DE UTILIZAÇÃO: Southern Implants® Moinho de osso para implantes de conexão interna**

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Intended Use
Southern Implants Bone mills are intended to remove excessive bone around the implant platform.

Description
Southern Implants bone mills are cutting instruments used for bone preparation around the implant shoulder. The "handheld" versions of the bone mill have an attached handle with an idler, to hold and turn the driver by hand. The handheld bone mill is supplied non-sterile. The bone mill is a one-piece instrument and has a guide pin that enters into the internal connection of the implant to provide guidance for the bone mill, and protecting the implant shoulder from damage by the serrated cutting edge.

Indications for use
The handheld bone mills are indicated to remove excess bone around the implant platform. The removal of bone will facilitate the seating of prosthetic components.

Table 1

DC Range (Deep Conical)

For Ø3.0 DCC / DCT Implants	For Ø3.5 DCC / DCT Implants	For Ø4.0 DCC / DCT Implants	For Ø5.0 DCC / DCT Implants
			
I-HBM-DC30	**I-HBM-DC35**	**I-HBM-DC40**	**I-HBM-DC50**
Mills to Ø3.5mm	Mills to Ø4,0mm	Mills to Ø4.5mm	Mills to Ø5.5mm

TRI-NEX Range

For Ø3.5 TRI-Nex Implants	For Ø4.3 TRI-Nex Implants	For Ø5.0 TRI-Nex Implants	For Ø6.0 TRI-Nex Implants
			
I-HBML-35	**I-HBML-43**	**I-HBML-50**	**I-HBML-60**
Mills to Ø4.0mm	Mills to Ø4.9mm	Mills to Ø6,0mm	Mills to Ø6.5mm

Internal Hex Range (Provata® & M-series)

For Ø4.0 Standard restorative interface	For Ø5.0 Standard restorative interface	For Ø6.0 Wide restorative interface
		
I-HBM-M-46	**I-HBM-M-56**	**I-HBM-Z66**
Mills to Ø4,6mm	Mills to Ø5.6mm	Mills to Ø6.6mm

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.

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.
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. Care must be taken to apply the correct tightening torque of abutments and abutment screws.

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

Storage, cleaning & sterilisation
Southern Implants Handheld bone mills are supplied non- sterile and re-usable. Before re-use, it needs to be cleaned, disinfected and sterilized. The product must be stored in a dry place at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics.
Handheld bone mills are reusable and must be inspected before re-use, if there are signs of visible corrosion, dull cutting edges or expected wear, this device shall be disposed of.
If re-use seems fit:
- containment: As soon as practically possible, remove all visible residue after use (bone, blood or tissue), by immersing the

instrument in cold water (Dried soil is difficult to remove).
- pre-cleaning: Rinse with lukewarm water for 3 minutes, and remove hardened debris with a soft nylon brush. Avoid mechanical damage during cleaning.
- manual cleaning or automated cleaning: Prepare an ultrasonic bath with suitable detergent, sonicate for 20 minutes (Alternative methods can be used if proven by the end user). Rinse with purified / sterile water. Load devices into a thermo-disinfector. Run the cleaning and disinfection cycle, followed by the drying cycle.

NOTE: Always follow the instructions for use of the manufacturers of cleaning agents and disinfectants.

- Drying: dry the instruments with filtered compressed air or single use lint free wipes. Pack the instruments as quickly as possible after removal. If additional drying is necessary, dry in a clean location. Moisture on bone mills can cause corrosion and deterioration of the cutting edges.
- Inspection: do a visual inspection of the items to check for any damage/s.
- Packaging: use the correct packaging material as indicated for steam sterilisation to ensure sterility is maintained. Double packaging is recommended.

Sterilisation
Southern Implants recommends the following procedure to sterilise the instruments prior to use/re-use:

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. Place the guide pin of the handheld bone mill in the centre canal of the implant.
3. Press down slightly and rotate gently to remove any bone around the implant platform.
4. When the surrounding bone has been removed around the implant shoulder, clean the canal and platform and then seat the chosen abutment.

NOTE: Ensure that the correct handheld bone mill is used, corresponding to the Implant diameter, to avoid damage to the internal screw thread or Implant shoulder. Table A

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
Deep Conical:	Titanium Grade 5 (Ti-6AL-4V)
TRI-NEX:	Stainless Steel
Internal Hex (Provata & M-series):	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.
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.

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

Basic UDI
Product	Basic-UDI Number
Basic-UDI For Reusable Instruments	600954403876

Related literature & catalogues

CAT-2004 - Tri-Nex 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

Symbols and Warnings

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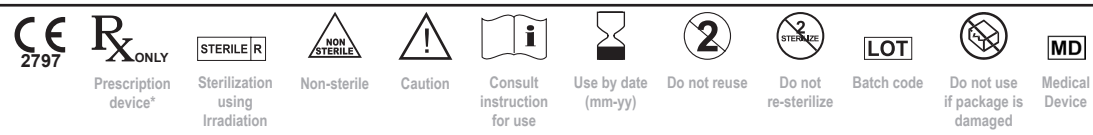

Prescription device* | Sterilization using Irradiation | Non-sterile | Caution | Consult instruction for use | Use by date (mm-yy) | Do not reuse | Do not re-sterilize | Batch code | Do not use if package is damaged | Medical Device

* 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.