INSTRUCTIONS FOR USE: Bone Mill for Internal Connection Implants

TRI-NEX

Internal Hex
(Provata & M-series)

DC (Deep Conical)

Intended use:
Southern Implants bone mills are intended to be used to remove excessive bone around the implant.

Description:
Hand-held bone mills are cutting instruments used for bone preparation around the implant shoulder. The bone mill has a guide pin that is inserted into the internal connection canal of the implant to provide guidance for the bone mill. This centers the cutting part to protect the implant shoulder from damage by the serrated cutting edge of the bone mill.
Bone mills are supplied non-sterile and are reusable for up to 10 uses, or when cutting efficiency deteriorates.

The full range of Bone Mills:

Bone Mill	For Implant Interface	Mills bone to:
DC (Deep Conical)		
I-HBM-DC30	DC3	Ø3.5mm
I-HBM-DC35	DC4	Ø4.0mm
I-HBM-DC40	DC4	Ø4.5mm
I-HBM-DC50	DC5	Ø5.5mm
TRI-NEX		
I-HBML-35	Ø3.5mm	Ø4.0mm
I-HBML-43	Ø4.3mm	Ø4.9mm
I-HBML-50	Ø5.0mm	Ø6.0mm
I-HBML-60	Ø6.0mm	Ø6.5mm
Internal Hex (Provata & M-series)		
I-HBM-M-46	Standard Interface implants	Ø4.6mm
I-HBM-M-56	Standard Interface implants	Ø5.6mm
I-HBM-Z66	Wide Interface implants	Ø6.6mm

Indications for use of Our implant systems:

Southern Implants' Dental Implants are intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses or full-arch prostheses. It further adds the option for immediate placement and function on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

Indications for use of Our bone mills:

Bone mills are used to remove any excessive bone or soft tissue around the implant shoulder. This will facilitate the proper fit of prosthetic components, and allow improved emergence profiles.

Contraindications:

Do not use in patients:

- who are medically unfit for dental implant procedures (e.g. uncontrolled diabetes and infection in nearby bone).
- who are allergic or have hypersensitivity to pure titanium or titanium alloy (Ti-6AL-4V), or stainless steel.

Warnings:

- **THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING**
- For the safe and effective use of dental implants it is strongly 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.
- The use of non-sterile items can lead to secondary infections of the tissue or transfer infectious diseases.
- Blunt drills may cause damage to the bone which could compromise osseointegration.

Cautions:

- New and experienced implant users should do training before using a new system or attempt to do a new treatment method.
- 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.
- Care must be taken that parts are not swallowed or aspirated during any of the procedures.

Procedure for use:

1. Remove the cover screw.
2. Place the guide pin of the hand-held bone mill in the center 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.

Materials:

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

Magnetic Resonance (MR) safety information:

This device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artefact in the MR environment. The safety of this device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Storage, Cleaning & sterilization:

These bone mills are supplied clean, but not sterile and can be re-used, provided it is maintained in a good condition, with no visible damage to the cutting edge of the bone mill or the guide pin. Bone mills must always be cleaned and sterilized before use.

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.
- **Note:** Moisture on drills 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 sterilization to ensure sterility is maintained. Double packaging is recommended.
- **Pre-vacuum sterilization:** Steam sterilize the components at 132°C (270°F), at 180 - 220 kPa for 4 minutes, or at 135°C (275°F), at 180 - 220 kPa for 3 minutes.

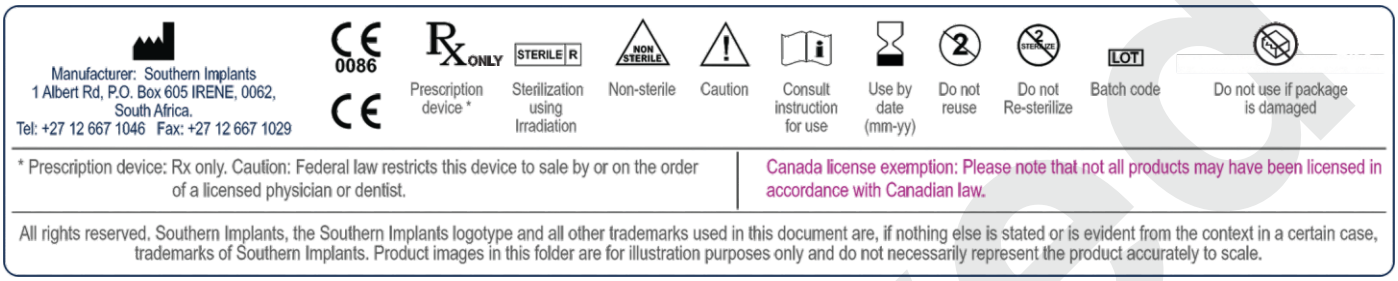
Dry for at least 20 minutes in the chamber.

- **Note:** Only an FDA or appropriate regulatory authority approved wrap or pouch for steam sterilization must be used. It is the responsibility of the user to establish whether or not their sterilizer is approved by an appropriate regulatory authority to meet recommended parameters.
- **Storage:** Maintain packaging integrity to ensure sterility in storage. Packaging should be dry before storage to avoid corrosion and degration of cutting edges. Device should be stored at room temperature and not exposed to direct sunlight.

Disposal:

Disposal of the device and its packaging shall follow local regulations and environmental requirements, taking different contamination levels into account.

Symbols & Warnings:



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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.