



Intended use:

Southern Implants Bone mills are intended to be used together with the Protector cap, to remove excessive bone around the implant.

Description:

Bone mills are cutting instruments used for bone preparation around the implant shoulder. It is supplied with a Protector cap, screwed onto the implant it will provide guidance for the bone mill, while protecting the implant shoulder from damage by the serrated cutting edge of the bone mill. Bone mills and protector caps are supplied sterile and are reusable.

The full range of Bone Mills and their corresponding Bone Mill Protector Caps:

Bone Mill	Protector Caps	For Implant	
I-BPM-55	I-BPM-CAP	IP; Ext Hex Ø3.3 Implants	Mills bone to Ø5.5mm
I-BNM-45	I-BNM-CAP	IBN / IBNT; Ext Hex Ø3.25 Implants	Mills bone to Ø4.5mm
I-BNM-55			Mills bone to Ø5.5mm
I-BM-57	I-BM-CAP	IB / IBT; Ext Hex Ø3.75 Implants	Mills bone to Ø5.7mm
I-BM-67			Mills bone to Ø6.7mm
I-BAM-62	I-BAM-CAP	BA / BAT; Ext Hex Ø5.0 Implants	Mills bone to Ø6.2mm
I-BAM-77			Mills bone to Ø7.7mm
I-BBBM-77	I-BBBM-CAP	BBB / BBBT; Ext Hex Ø6.0 Implants	Mills bone to Ø7.7mm

Indications for use:

During second stage surgery, there are occasions where abutments or prostheses do not want to seat due to contact with bone adjacent to the head of the implant. Time is wasted in trying to remove the impinging bone with chisels or round burs, and potentially damaging the head of the implant during these procedures. The advent of bone mills resolves this problem: Bone mills are indicated to remove bone coronally in situations where the bone walls interfere with the seating of abutment, or the emergence profile of the prosthesis.

Contraindications:

Do not use in patients:

- who are medically unfit for dental implant procedures.

Images are for illustration purposes only and do not necessarily accurately represent the product.

- 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.
- 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.
- 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 or healing abutment.
2. Attach the protector cap to the implant using a 1.22mm 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.
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.
6. Ensure that the appropriate protector cap is used, corresponding to the Implant diameter, to avoid damage to the internal screw thread or Implant shoulder.

Materials:

Bone Mill:	Titanium Grade 5 (Ti-6AL-4V)
Protector cap:	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 and protector caps are delivered sterile and can be re-used, provided it is maintained in a good condition, with no visible damage to the cap, or cutting edge of the mill:

Containment. As soon as practically possible, remove all visible residue after use (blood, bone 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 or Automated cleaning: Prepare an ultrasonic bath with suitable detergent, sonicate for 20 minutes. (Alternative methods can be used if proven by end user) Rinse with purified/sterile water. Or load devices into a thermos-disinfector. Run the cleaning and disinfection cycle, followed by the drying cycle. Note: Always follow the instructions for use of the manufacturer of cleaning agents and disinfectants.

Drying: Dry the instruments with 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 etc.

Inspection: Do a visual inspection of the items to check for damages.

Packaging: Use correct packaging material as indicated for steam sterilization to ensure sterility is maintained. Double packaging is recommended.

Sterilization: Pre-vacuum method: Steam sterilize the components at 134-137°C (274-279°F) at 180-220kPA for 3-7 minutes. Dry for at least 10 minutes in the chamber.

Gravity method: Steam sterilize the components at 121°C (250°F) for 30 minutes. Dry for at least 10 minutes in the chamber.

Storage: Maintain packaging integrity to ensure sterility in storage. Packaging should be dry before storage to avoid corrosion and degradation of cutting edges. Devices should be stored at room temperature. Refer to the individual product packaging label and for special handling instructions. As per: CAT-1039.

Disposal:

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

Symbols & Warnings

 Manufacturer: Southern Implants 1 Albert Rd, P.O. Box 605 IRENE, 0062, South Africa. Tel: +27 12 667 1046 Fax: +27 12 667 1029	 	 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
* Prescription device: Rx only. Caution: Federal law restricts this device to sale by or on the order of a licensed physician or dentist.						Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.					
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For Technical Assistance or additional product literature, please contact Southern Implants.

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Disclaimer of liability:

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