# Bone Dust Trap – BDT

## Instructions for Use

**Caution: Strictly following this Instructions for Use document is required to ensure safety and efficiency of the device use. Failure to follow the instructions, warnings and cautions specified in this document may result in device malfunction and compromising safety of the patient.**

### Device Description

Sterile disposable, single use surgical filter comprising a cylindrical container and a lid with integrated element of a dual stage filtrating system. Connection to the vacuum source through suction tubing is required to use the device. The Bone Dust Trap does not contain latex.

### Indications for Use

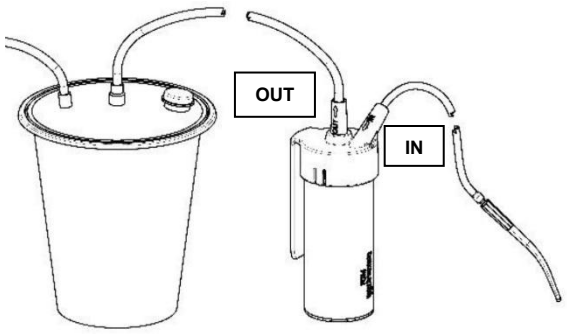
The Bone Dust Trap is intended for use as a filtration device for collecting bone dust and particles during various surgical procedures. Connected to the vacuum source in-line with suction tubing, the Bone Dust Trap separates bone particles from the surgical site fluids and captures the autogenous bone graft on the filtrating surfaces for further use in augmentation procedures.

### Directions for Use

To use the Bone Dust Trap:

1. Cut the vacuum source suction tubing, adjusting the length to keep the device within the aseptic area. Connect an outlet port marked “OUT” to the vacuum source through the suction tubing. Make sure that connection is sealed properly. Connect an inlet port marked “IN” to the suction tubing with a tip leading to the operating site as shown on Figure 1.

***Figure 1***

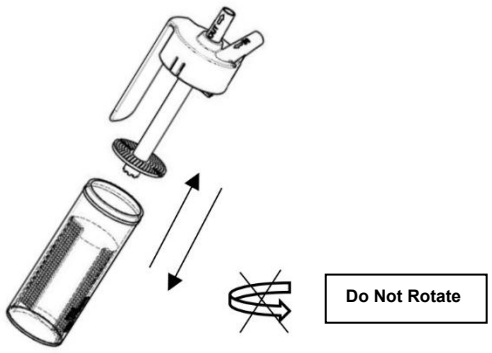



2. Place the Bone Dust Trap into a draping pouch vertically and secure with a fixation clip.

3. Once the device is filled, disconnect the outlet port of the device from the suction tubing of the vacuum source.
4. To open the device, pull the lid out holding inlet and outlet ports with your fingers. Do not rotate the lid - Figure 2.

   **Warning:** rotation of the lid may cause device damage and malfunction.

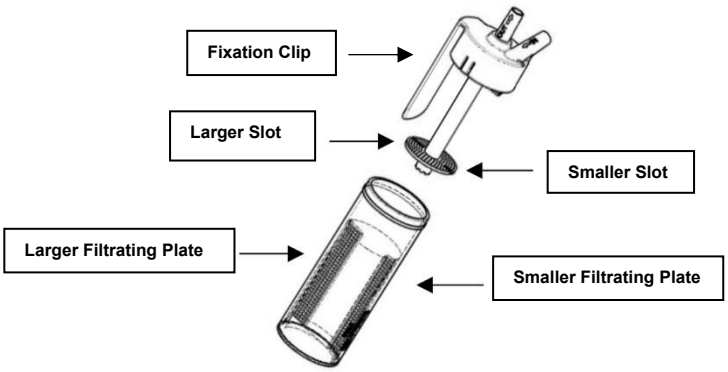
***Figure 2***




5. Remove collected bone graft. The device can be used up to 3 (three) times in total, providing three collection cycles during single operating procedure on the same patient.
6. After emptying the device, place the lid back. Make sure that the size of the slots on the filtrating membrane corresponds to the size of the filtrating plates, located along the inner walls of the cylindrical container.

   Note: The larger slot and the fixation clip are located on the same side of the device (Figure 3).

***Figure 3***



**Caution**

US Federal law restricts this device to sale by or on the order of a physician only.

To ensure maximum efficiency, the device should be positioned in the draping pouch vertically.

Instructions for use must be followed exactly to ensure the device operates as intended.

**Contraindications**

General contraindication to the surgical procedure.

Absolute contraindications include infection, sepsis, and osteomyelitis and malignant disease (risk of surgical dissemination).

**Warning**

- It is the responsibility of a surgeon and a surgical team to be trained to apply proper techniques for using the Bone Dust Trap. Improper use of the device may cause serious injury to operator or patient and/or cause damage to the device.
- The Bone Dust Trap is a single use disposable device. Re-sterilization is strictly prohibited and may cause patient contamination and device malfunction.
- Eye protection is compulsory while using the Bone Dust Trap.
- Before use, inspect the packaging and the device. Visually inspect the packaging for any signs of damage including packaging puncture, tear any other damage. Do not use the Bone Dust Trap if the packaging is compromised. Sterility is guaranteed unless the packaging is damaged or open.
- Inspect the Bone Dust Trap for any damage. Do not use if the device has any signs of damage.
- Do not connect the device to high suction units. Maximum negative pressure for the Bone Dust Trap use is 21in Hg.
- Remove the device from the patient in case of defibrillation.

**Cleaning and Sterilization**

The Bone Dust Trap is a single use only, sterile disposable device. Reuse or re-sterilization of the device is strictly prohibited.

**Disposal**

Dispose of the device according to the federal, state and local regulations.

**Warranty**

RIM Medical Technologies will not accept any returns of the devices that have been in contact with the patient blood and body fluids.

Please contact your local representative or distributor for information on return and exchange.

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## Symbols

| | | | |
|---|---|---|---|
|  | Keep Dry |  | Sterile unless Packaging is Damaged or Open |
|  | Use Before |  | Batch Code |
|  | Single Use |  | Catalog Name |
|  | Sterilized Using Irradiation |  | Consult Instructional Manual |
|  | Medical Device |  | Manufacturer |
|  | Do Not Rotate |  | Direction pointing arrows |
|  | Caution | | |

 **Manufactured for:**

**RIM Medical Technologies Incorporated**

#200, 638 - 11th Ave SW. Calgary, AB, Canada T2R 0E2
Phone: + 1 403-402-3470
Fax: + 1 587-412-5061
Emai: info@rimmedtech.com
www. rimmedtech.com
Manufactured in China



Patented – www.rimmedtech.com