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OSTEOHARVESTERTM

Harvester • Morselizer • Collector • Delivery System

Instruction Manual



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I. Introduction

This manual is intended to provide the clinician with basic information for the use, installation, operation and maintenance of the OsteoMed OsteoHarvester™ System.

Read and understand the information in this manual prior to utilizing the OsteoHarvester™ system. Please pay particular attention to the **WARNINGS**, **CAUTIONS** and **NOTES** that appear throughout this manual.



WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury and may result in property damage.



CAUTION indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury and may result in property damage.



CAUTION used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may resulting property damage.

II. Indications

The OsteoHarvester™ system is indicated to aseptically and efficiently collect osseus and marrow tissue during the drilling of skeletal structures and for the collection of autogenous bone and marrow tissues.

The OsteoHarvester™ provides a one-step minimally invasive method for harvesting, morselizing and collecting cortical and cancellous bone from various sites in the body and a means for delivering harvested bone to a receptor site. The device can also be used as an In-line Suction Bone Collector.

III. Operational Requirements

The OsteoHarvester™ requires a surgical handpiece system in order to function. The OsteoHarvester™ can be used with any of the following handpiece modules:

18:1 contra-angle module of the OsteoMed OsteoPower™ Surgical Handpiece System (speed range set at 50% speed or 665 rpm),

Any contra-angle surgical handpiece system with a minimum gear reduction ratio of 18:1 and a speed range output capability of 500-700rpm.

Note: The Harvester Drill with a dental latch will fit into any dental latch contra-angle

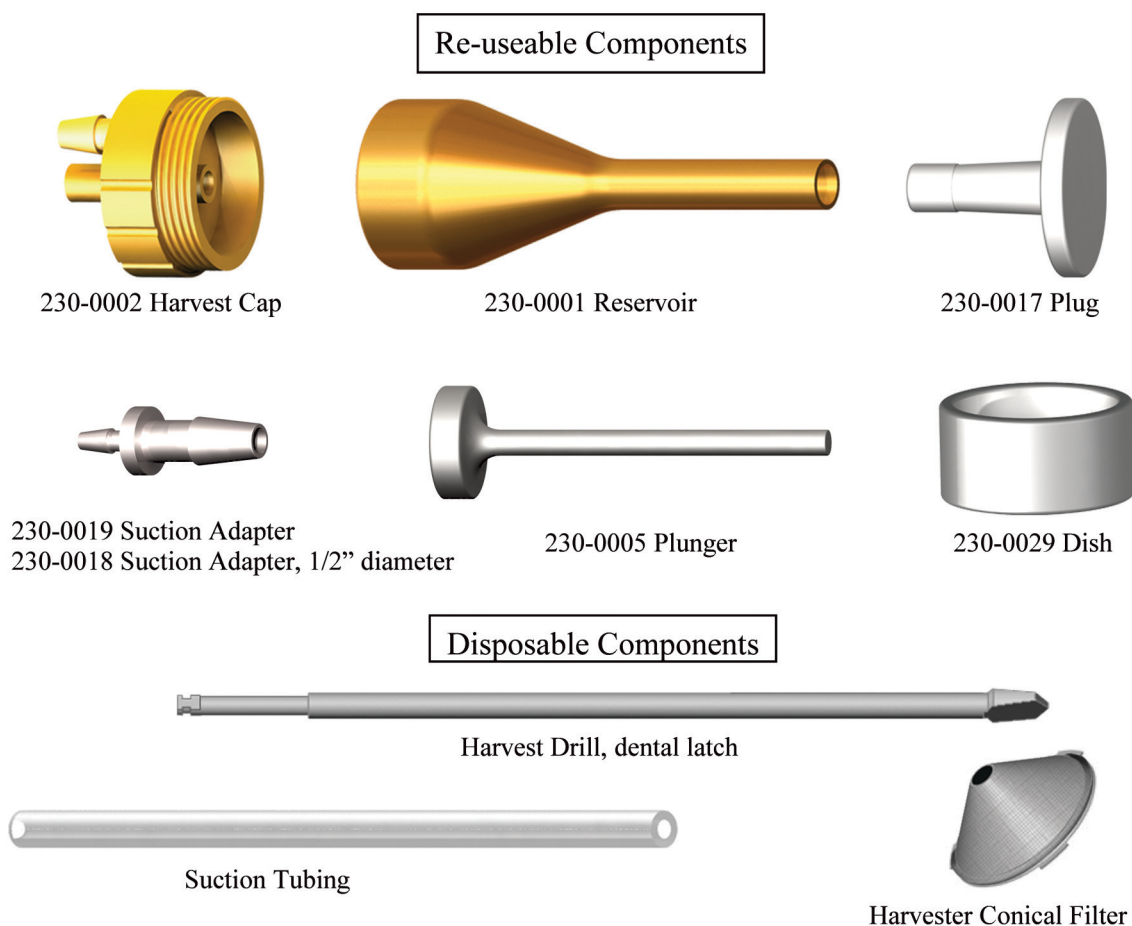


IV. Instructions for Use - Bone Harvester

The OsteoHarvester™ is primarily intended to be used as a Bone Harvester to harvest, morselize, collect autogenous bone and deliver the collected bone to a receptor site.

Bone Harvester components:

The OsteoHarvester™ is comprised of reusable components and of disposable components that are intended for single patient use only. The components are as follows:



Note: Disposable parts are delivered in autoclavable pouches, that include one each of a Harvest Drill, Harvest Conical Filter and six inch section of suction tubing. Once the autoclavable pouch has been opened, it is NOT returnable to OsteoMed.

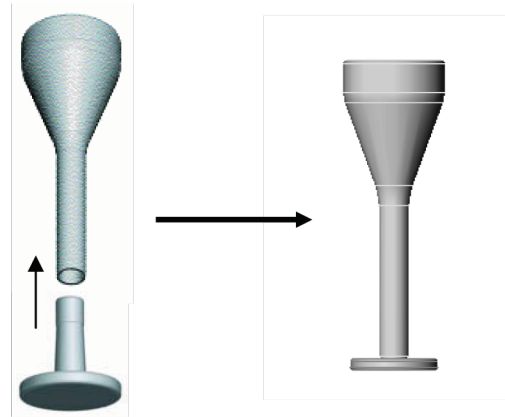
Bone Harvester Assembly



Prior to use, system components should be inspected for any damage. DO NOT USE if damage is apparent. Call OsteoMed Customer Service to report any damage or product problem at (800) 456-7779.

Step 1.

Insert the Plug into the distal end of the Reservoir. Set both parts aside.



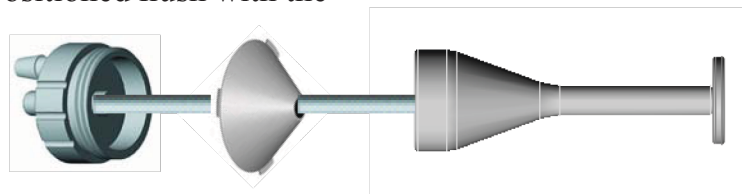
Step 2.

Slide the Harvest Filter over the proximal end of the Harvest Drill. Then slide the Harvest Cap over the proximal end of the Harvest Drill and Filter.



Step 3.

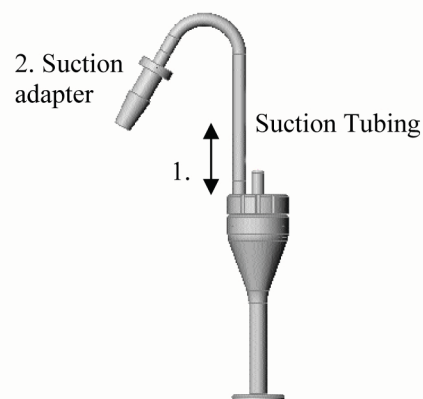
Screw the Reservoir and Plug onto the Harvest Cap. If some resistance is encountered, make sure the Harvest Conical Filter is not bent, but positioned flush with the Harvest Cap.



Note: The Plug will prevent the Harvest Drill from falling out of the Reservoir prior to attaching it to the handpiece module.

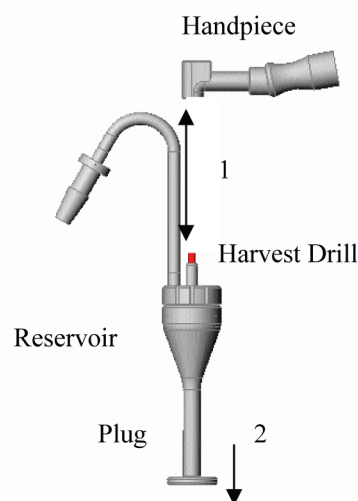
Step 4

1. Attach the suction Tubing to the Harvest Cap.
2. Insert the Suction Adapter to the source end of the suction Tubing.
3. Connect the Suction Adapter to the operatory suction tubing apparatus.



Step 5

1. Insert and lock the Harvest Drill into the handpiece module of choice.
2. Remove Plug.



Selection of Bone Harvest Site

Bone can be harvested from various sites in the body. Recommended sites include the symphysis and the ascending ramus of the mandible.

Selection of Adequate Speed Range

If using the 18:1 contra-angle module of the OsteoMed OsteoPower™ Surgical Handpiece System, the speed range button should be set at 50% (665 rpm).

If using the contra-angle module of another handpiece system, set the speed range to approximately 500-700 rpm.

Operation

Step 1

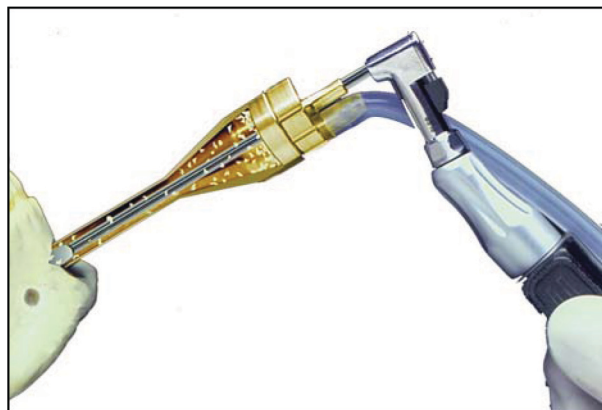
Turn on suction.

Step 2

Place the tip of the Harvest Drill onto the harvest site with the Reservoir cannula tip flush with the bony surface.

Step 3

Start actuating the Drill while maintaining constant pressure on the bone while irrigating the site. Drill as many holes as needed to obtain the desired volume of morselized bone.



Note:

Operation: It may be helpful to hold the Reservoir with one hand while holding the handpiece module with the other hand to ensure that the device is properly positioned, i.e. flush with the bone, throughout the procedure.

Built-in Safety Mechanism: The Harvest Drill bores holes approximately 4.5mm in diameter and depending on which disposable pack is used, either 7mm or 11mm in depth. A Built-in Safety Mechanism will not allow the harvest drills to plunge deeper than the 7mm or 11mm depths.

Reservoir Capacity: Each hole collects approximately .4cc. The capacity of the reservoir is approximately 3cc, corresponding to the bony content of about 8 holes.

CAUTION

Do not modify any accessory of the OsteoHarvester System. Use only OsteoMed approved accessories and replacement parts.

! CAUTION

External Irrigation is highly recommended when harvesting bone to avoid thermal necrosis.

! WARNING

When harvesting bone, care should be taken to avoid tooth roots, soft-tissue structures and any underlying nerves.

! WARNING

Use of a dull, worn or overused Harvest Drill may cause heat build-up in the bone and handpiece module. All OsteoMed Harvest Drills are intended for SINGLE PATIENT USE ONLY.

! WARNING

Suction tubing and Harvest Filter are intended for SINGLE PATIENT USE ONLY. The Harvest Drill, Harvest Filter and Suction Tubing should be discarded after every case.

Delivery of Harvested Bone to Grafting Receptor Site

Step 1

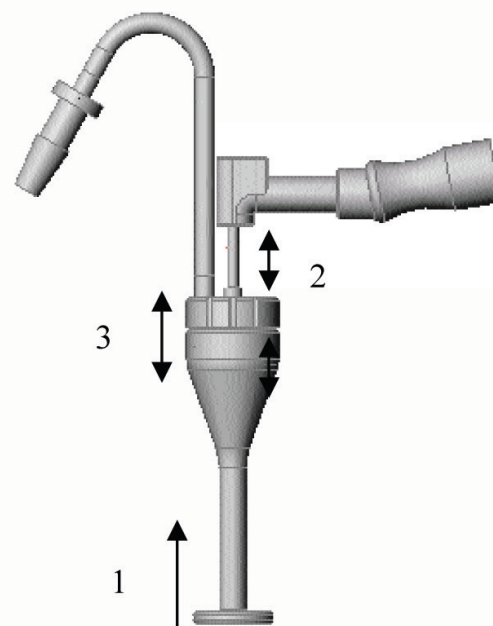
When finished harvesting, insert the Plug into the Reservoir. The Plug will prevent the bony content from coming out of the Reservoir.

Step 2

Detach the Harvest Drill from the handpiece module.

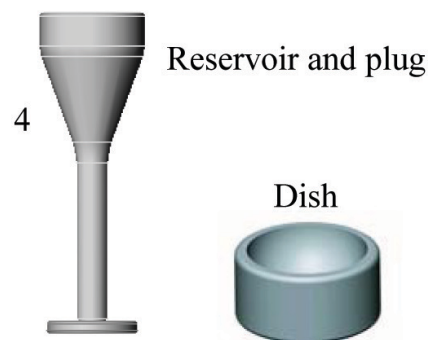
Step 3

Carefully unscrew the Harvest Cap from the Reservoir. There may be some bone accumulation on the Filter. The Filter may be scraped with a curette, elevator or similar instrument to collect this bone.



Step 4

Depending on how full the Reservoir is, either the Reservoir or the OsteoHarvester™ Dish may be used to prepare or mix the final bony mixture to be delivered to the grafting receptor site.



Step 5

The Reservoir and Plunger may be used together in a syringe-like manner to deliver the bony mixture to the site. Place the mixture back into the Reservoir. Remove the Plug. Using the Plunger, press to release the bony mixture from the Reservoir into the grafting receptor site.

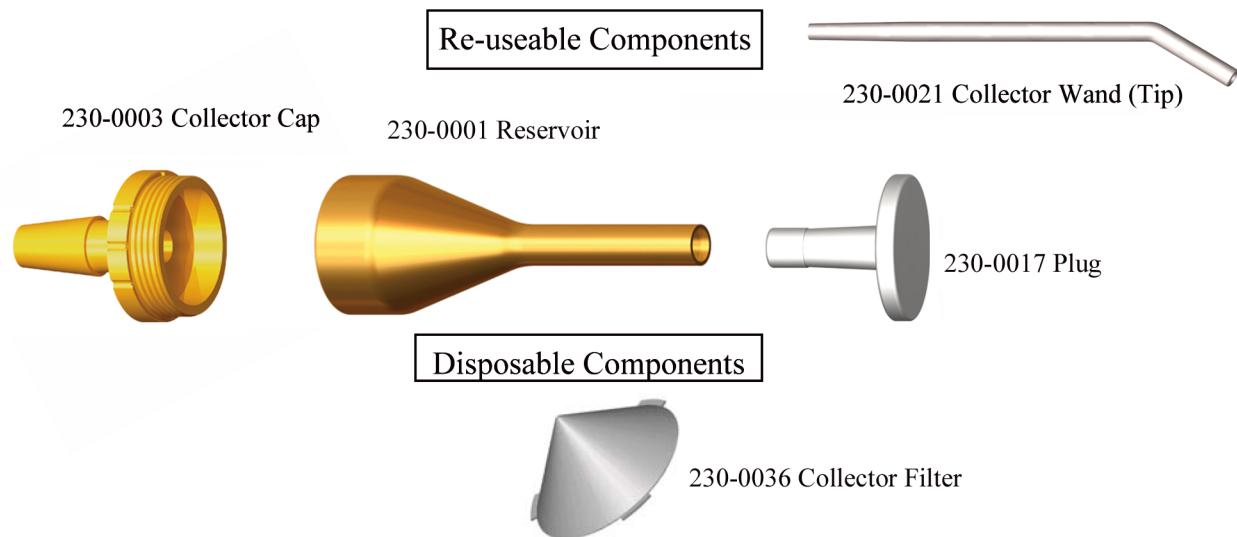


Please refer to page 8, sections VI and VII for Cleaning and Sterilization Recommendations.

V. Instructions for Use - Bone Collector

The OsteoHarvester™ may also function as a Bone Collector. The Bone Collector accessory components include the Collector Cap, Collector Filter and Collector Wand.

Bone Collector Components



Assembly and operation

Step 1 Insert the Collector Wand into the distal end of the Reservoir.

Step 2 Place the Collector Filter on top of the Reservoir flange.

Step 3 Screw the Collector Cap onto the Reservoir.

Step 4 Attach the operatory suction tubing to the Collector Cap.

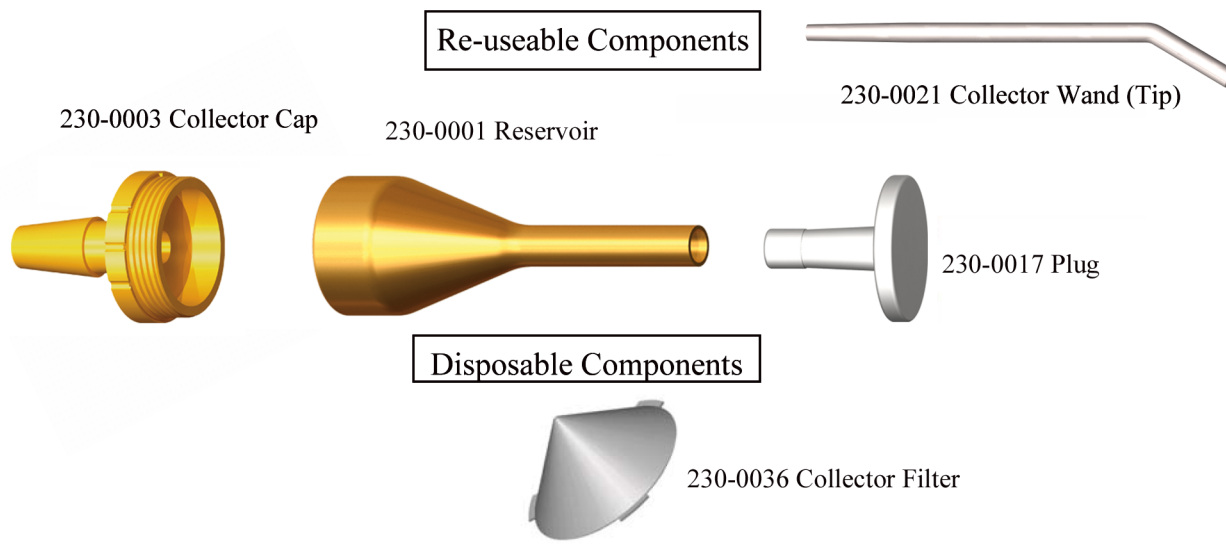
Step 5 Activate Suction.



Delivery of Harvested Bone to Site

Step 1 When finished collecting, remove the Collector Wand and insert the Plug into the Reservoir.

Step 2 Carefully unscrew the Collector Cap from the Reservoir. There may be some bone accumulation on the Filter that may be scraped and collected with a curette, elevator or similar instrument.



Delivery of Harvested Bone to Site

Step 3 Depending on how full the Reservoir is, either the Reservoir or the OsteoHarvester™ Dish may be used to prepare or mix the final bony mixture to be delivered to the grafting receptor site.

Step 4 The Reservoir and Plunger may be used together in a syringe-like manner to deliver the bony mixture to the site. Place the mixture back into the Reservoir. Remove the Plug. Using the Plunger, press to release the bony mixture from the Reservoir into the grafting receptor site.



VI. Cleaning and Maintenance Recommendations

The following steps are recommended after each use of the OsteoHarvester™ system:

- Completely disassemble the OsteoHarvester™ System prior to cleaning.
- Dispose of the Filter, Tubing and Harvest Drill.
- Flush all system components with mild detergent or a surgical instrument cleaning solution and water. A soft brush may be used to remove debris.
- An ultrasonic cleaning device may also be used.
- Flush with sterile water after cleaning.
- Dry with a lint-free towel. If available, forced air drying is preferred.
- Refer to “STERILIZATION RECOMMENDATIONS” (section VII) for sterilization details.

VII. Sterilization Recommendations

The Harvest and Collector Filters, Suction Tubing and Harvest Drills are intended for SINGLE PATIENT USE ONLY. They are pre-packaged non-sterile in autoclavable pouches.

The Reservoir, Harvest and Collector Caps, Collector Wand, Plug, Plunger, Suction Adapter and Dish are provided non-sterile.

Since OsteoMed is not familiar with individual hospital handling methods, cleaning methods and bio-burden, OsteoMed cannot assume responsibility for sterility even though the guideline is followed. Recommended sterilization procedures are: steam autoclave, pre-vacuum cycle, 270°F (132°C) 15 minutes exposure time.



Tubing, Filters and Harvest Drills are intended for SINGLE PATIENT USE ONLY. All parts should be discarded after each case.

VIII. Specifications

Material

Harvest Cap, Reservoir, Collector Cap, Dish: Titanium Alloy

Harvest and Collector Filter: Commercially Pure Titanium

Harvest Drill, Collector Wand, Suction Adapter, Plug, Plunger: Stainless Steel

Tubing: Silicone

Physical Specifications

Reservoir Capacity: 3cc

Dish Capacity: 6cc

Filter Pore Size: approximately .2mm

Harvest Drill Diameter: 4.5mm

Harvest Drill Plunge Depth: either 7mm or 11mm (dependent on set chosen).

Performance Specifications

Device creates and retains bone particulate 300-1000 microns in size.

Stop on drill allows for a maximum drill depth of 7mm or 11mm (dependent on set chosen).

IX. System Components List

Reusable Components

230-0001 Reservoir, 230-0002 Harvest Cap, 230-0003 Collector Cap, 230-0005 Plunger, 230-0017 Plug, 230-0019 Suction Adapter, 230-0021 Collector Wand, 230-0029 Dish

Disposable Components

230-0032 7mm Contra-Angle Disposable Set (3 pieces each of a Harvest Drill, Harvest Filter and 6" section of suction Tubing)

230-0034 11mm Contra-Angle Disposable Set (3 pieces each of a Harvest Drill, Harvest Filter and 6" section of suction Tubing)

230-0036 Collector Filter

X. Warranty and Service

The OsteoHarvester™ system components (excluding the Drills, Filters and Tubing which have no warranty) are warranted to the original purchaser to be free from defects in materials and workmanship for a period of six months from the date of purchase. This warranty is limited to the repair or replacement of the product without charge. This warranty is void in the event of abuse, unreasonable wear, misuse, or any disassembly, alteration, or repair not authorized by OsteoMed.

The reusable components of the OsteoHarvester™ system may be returned for credit within 90 days of the initial purchase. Disposable components may not be returned. Please contact Customer Service at (800) 456-7779 for additional information and assistance with this matter.

For any questions or assistance, please contact your local OsteoMed Representative or Customer Service at (800) 456-7779.



U.S. Customer Service: 800.456.7779

3885 Arapaho Road | Addison, TX 75001 | Phone: 972.677.4600 | Fax: 800.390.2620
www.osteomed.com



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