

Description

The OsteoMed OsteoHarvester™ System is comprised of a bone collection reservoir, various lids, bone drills, filters, suction tubing, and suction tips, for harvesting, morselizing, collecting, and delivering autogenous harvested bone to a defect site.

Material

The harvest collection reservoir and caps are made from Titanium Alloy (ASTM F-136). The filter is made from commercially pure Titanium (ASTM F-67). The suction tips and instrumentation are made from various grades of stainless steel, titanium, and medical grade silicone.

Clinical Indications

The OsteoMed OsteoHarvester™ System is indicated to aseptically and efficiently collect osseous and marrow tissue during the drilling of skeletal structures and for the collection of autogenous bone and marrow tissues. The bone collection filter and drills are intended for single use only. OsteoMed single use devices/instruments cannot be reused and/or reprocessed. The product has been labeled as single use only for patient safety. The design of the device and the intricacies of the surfaces may not facilitate cleaning and sterilization after contact with body tissues or fluids, so there is an increased risk of contamination if reused. This may lead to potential risks of cross infection/contamination associated with using inadequately cleaned and sterilized devices. For cutting instruments the cutting efficacy may be reduced requiring the surgeon to use increased force that might cause patient harm and/or increase the risk of thermal necrosis. Because these products have not been validated for multiple use, OsteoMed cannot guarantee the safety and effectiveness of the device if it is used on more than one patient.

Contraindications:

None Known.

Maintaining Device Effectiveness

- The operating instructions and maintenance manual should be read prior to operating any component of the OsteoMed OsteoHarvester™ System. The manual is enclosed with shipment of systems and can be obtained from customer service. Refer to part number 030-1190.
- All OsteoMed implants and instrumentation may be required for each surgery. Failure to use dedicated, unique OsteoMed instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the OsteoMed implants and instrument prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating conditions. Instruments which are faulty, damaged, or suspect should not be used. They should be replaced or sent to OsteoMed for disposition and repair.
- OsteoMed recommends the use of OsteoMed products in a sterile environment.

Instructions for Use: Bone Harvester Assembly

- Insert the plug into the distal end of the reservoir. Set both parts aside.
 - 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.
 - 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.
- Attach the suction tubing to the harvest cap. Insert the suction adapter to the source end of the suction tubing. Connect the suction adapter to the operatory suction tubing apparatus.
 - Insert and lock the harvest drill into the handpiece module of choice. Remove plug.

Instructions for Use: Bone Harvester Operation

- Turn on suction.
- Place the tip of the harvest drill onto the harvest site with the reservoir cannula tip flush with the bony surface.
- Start articulating 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.

Note: 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.

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

Instructions for Use: Delivery of Harvested Bone to Grafting Receptor Site:

- When finished harvesting, insert the Plug into the reservoir. The plug will prevent the bony content from coming out of the reservoir.
- Detach the harvest drill from the handpiece module.
- 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.
- 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.
- 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.

Instructions for Use: Bone Collector

- Insert the collector wand into the distal end of the reservoir
- Place the collector filter on top of the reservoir flange.
- Screw the collector cap onto the reservoir
- Attach the operatory suction tubing to the collector cap.
- Activate suction.

Instructions for Use: Delivery of Harvested Bone to site:

- When finished collecting, remove the collector wand and insert the plug into the reservoir.
- 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.
- 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.

- 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.

Instructions for Use: 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 guidelines.

Sterility

- Product is supplied **NON-STERILE unless expressly labeled as STERILE.**
- Note: BONE COLLECTION FILTER AND DRILLS ARE INTENDED FOR SINGLE USE ONLY.
- Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
- The user facility must clean and disinfect devices prior to sterilization per standard hospital procedures.
- Non-sterile devices are sterilizable by steam sterilization (autoclaving). For sterilization of **OSTEOMED** implant systems, the following parameters should be used.

Pre-Vacuum Steam Sterilization:

Temperature: 273°F (134°C)

Time: 30 minutes

Dry Time: 55 minutes

Configuration: Wrapped tray

Wrapping Technique: Wrapped tray in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554).

Do not exceed 275°F (135°C), to avoid compromising functions of polymeric instrumentation.

Note: Biological indicator of *G. stearothermophilus* was used in sterilization validation.

Caution

- Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so
- Do not attempt a surgical procedure with faulty, damaged, or suspect OsteoMed instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.



OSTEOMED
3885 Arapaho Road
Addison, Texas 75001 USA
Customer Service: 800/456-7779
Outside USA: 972/677-4600



Shotwell & Carr, LLC
2 St. Paul's Road
Clifton Bristol
BS8 1LT, U.K.
Tel: +44 (0) 117 9738944



Symbols and Definitions



Single Use Only

REF

Catalogue Number



Use By (Date)



Do not use if sterile package is damaged



Batch Code (Lot Number)

SN

Serial Number



Date of Manufacture



Manufacturer



Attention, See Instructions for Use



Authorized Representative in the European Community



Consult Instructions for Use



Sterile, Method of Sterilization Using Irradiation



Federal Law (U.S.A) Restricts this device to sale by or on the order of a physician.