




# Hensler Bone Press™ Device

## INSTRUCTIONS FOR USE

 **ATTENTION: CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.**

**CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.**

### CONTENTS

- Two (2) 80cc containers with graduations to 80 cc.
- One (1) Press top (Pre-assembled)
- One (1) Collection top with silicon tubing (pre-assembled)
- One (1) tubing elbow connector (For MAYO/drape attachment ONLY)

### HOW SUPPLIED

Components of the Hensler Bone Press™ device are supplied in a sterile package, via EtO sterilization. The Hensler Bone Press™ is intended for single use only and should not be resterilized or reused as infection or injury to the patient from damaged components may result.

### DEVICE DESCRIPTION

The patented Hensler Bone Press™ device maximizes the collection and separation of autologous bone from blood and irrigants for bone fusion applications.

### INDICATIONS FOR USE

The Hensler Bone Press™ device is intended for sterile, single-use with a surgical suction line to collect autologous bone particles that are utilized in bone fusion procedures. The device may be used by specially qualified health care professionals including surgeons, physician assistants, first assists and certified scrub technicians.

### CONTRAINDICATIONS FOR USE

The Hensler Bone Press™ device has no known contraindications.

### STORAGE, HANDLING, AND DISPOSAL

The Hensler Bone Press™ device is labeled with a Use Before Date. Do not use the device past the Use Before date on the label. Use of expired product may result in patient injury. The device is only to be handled and used by healthcare professionals. Sterile technique is always to be exercised

with the handling and use of this device. Once use of the device is complete, the device is to be discarded following all HAZMAT and biomedical waste disposal protocols per facility

### PERFORMANCE AND POTENTIAL SIDE EFFECTS

The Hensler Bone Press™ device has undergone extensive design and development testing to ensure that it achieves its intended performance. It has been designed, manufactured and packaged in a manner to achieve a safe and reliable product. The device, if not used according to these Instructions for Use, may have deleterious side effects such as compromised sterility, damage to components of the device and its packaging, and possible injury to the patient.

Please comply with all Warnings and Precautions

### WARNINGS

- Do not reuse or resterilize as infection or injury to the patient from damaged components may result.
- Do not use if package is open or damaged. If damage is observed, call Hensler Surgical Products Customer Service.
- Do not use if inner walls of clear collection tube appear or feel gouged, scratched, or chipped.
- Do not use if Filter Shaft is bent.
- Do not use if Filter does not slide easily into the collection tube or shows signs of deformity/denting.
- Do not use if Filter Screen has not been cleaned properly. All perforations should be free of debris before use.

### PRECAUTIONS

- Do not pre-soak in hot water, alcohol, disinfectants, or antiseptics to avoid coagulation of blood and/or bodily fluids.
- Do not exceed two hours in any solution and do not use solutions with pH's >9 or <5.
- Do not use steel wool, wire brushes, wire pipe cleaners, or other abrasive brushes and detergents.
- Do not allow blood, other bodily fluids, and/or tissues to dry on the instruments
- Do not use lubricants. They prevent direct contact of the surface with steam, coat microorganisms, and are difficult to remove.

### DIRECTIONS FOR USE

Refer to the following instructions and illustrations that follow.

#### COMPATIBLE DEVICES AND PROCEDURE SUPPLIES

The following devices are compatible with the Hensler Bone Press™:

- Universal fluid collection canisters or suction collection systems.
- Universal suction tubing.
- Suction tips, such as a Frazier™.

The following supplies should be assembled prior to treatment:

- Collection containers and tops with suction attached to the side port.
- Press top engaged onto the container with suction attached to the side port.
- Right angle elbow adapter attached to collection top and attached to the mayo stand. (Using the MAYO or drape attachment method).

### Device Preparation

Attach collection top to an empty container until ribs align. Attach suction tubing to side port and a suction tip to collect contents.

### Collection Procedure

1. Attach one of the sterile collection containers to the collection top.
2. Once the ribs are aligned, attach the suction tubing to the side port. This suction tubing will be provided by the individual operating rooms and is connected to the suction source in the O.R. Attach a suction tip to the distal end of the silicon tubing, projecting superior off the collection top. Examples include Frazier™ suction tips.
3. Collect the bone shavings or debris generated by the high speed electric drill.
4. It is encouraged that continuous irrigation be utilized while drilling away bone for collection and that additional irrigation be added to the container. This will increase yield and improve the texture of the harvested autologous bone.
5. Once the container is full of blood, irrigation and bone, disconnect the full container from the collection top by unscrewing the container.
6. Once detached, hand the scrub tech the full container.
7. Attach the empty container to the collection top and resume collection.

### Press Phase

1. Attach full container on to press top. Align ribs. Attach suction fully and manually deploy down.
2. Once fully depressed, tilt container to evacuate fluid through suction. Repeat if needed.
3. Unscrew container and remove the biologic material (or bone). Stage on an sterile absorbable pad. Bone will be staged to be used as the surgeon desires.




### RETURN OF DEVICES

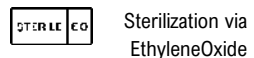
If any portion of the Hensler Bone Press™ device fails prior to or during a procedure, discontinue use. The device should be placed in a biohazard container with a Returned Material Authorization (RMA) number assigned by Hensler Surgical Products™, LLC. Please call Customer Service at +1.910.399.7380 to arrange for the return of the device for investigation

### MANUFACTURER:

**Hensler Surgical™ Products, LLC**  
2420 South 17th Street, STE C Wilmington, NC  
28401, USA 1.910.399.7380 (w)  
1.910.399.7381 (f)  
www.henslersurgical.com  
henslersurgical@gmail.com

**MADE IN THE USA**

-  Do Not Reuse - Single Use
-  Use to expiration date on the package
-  Do not use if the packaging has been damaged or if sterility has been compromised



**PROCEDURE ILLUSTRATIONS**  
**Hensler Bone Press™ Instructions**



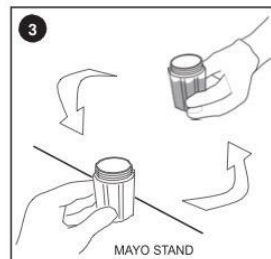
**HENSLER X<sup>®</sup>**  
**SURGICAL™**  
 HENSLER BONE PRESS™



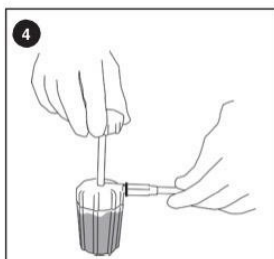
**Step 1:**  
 Attach collection top to an empty container until ribs align. Attach suction tubing to side port and a suction tip to collect contents.



**Step 2:**  
 Once container at capacity, unscrew full container.

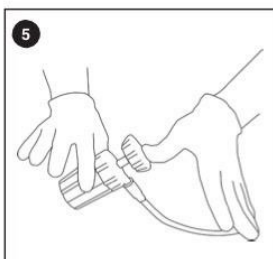


**Step 3:**  
 Pass full container to tech. Attach remaining empty container to collection top to resume surgery.

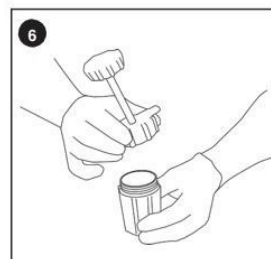


**Step 4:**  
 Screw on full container to press top. Align ribs. Attach suction fully and manually deploy down.

\*Ensure suction is operational



**Step 5:**  
 Once fully depressed, tilt container to evacuate fluid through suction. Repeat if needed.



**Step 6:**  
 Un-screw container and scoop bone out. Stage bone on a sterile, absorbable pad.

\* Repeat steps 3-6 until surgery is complete