



## Hensler Bone Collector™ 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

One (1) 80cc collection container with graduations to 80 cc.  
One (1) harvest top (pre-assembled)

### HOW SUPPLIED

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

### DEVICE DESCRIPTION

The patent-pending Hensler Bone Collector™ device maximizes the collection and separation of autologous bone from surgical rongeurs.

### INDICATIONS FOR USE

The Hensler Bone Collector™ device is a sterile, single use, surgical device that is intended for to harvest autologous bone chips and tissue, generated by surgical rongeurs. The device may be used by specially qualified health care professionals including surgeons, physician assistants, first assists and certified scrub technicians.

### STORAGE, HANDLING, AND DISPOSAL

The Hensler Bone Collector™ 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 Collector™ device has undergone extensive design, development, and 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.

### PRECAUTIONS

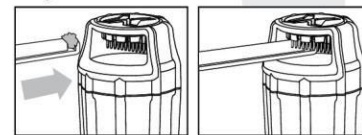
- Do not pre-soak in hot water, alcohol, disinfectants, or antiseptics to avoid coagulation of blood and/or bodily fluids.
- Do not exceed two hours in any solution and do not use solutions with pH's >9 or <5.
- Do not use steel wool, wire brushes, wire pipe cleaners, or other abrasive brushes and detergents.
- 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.

#### STEP 1:

Insert rongeur tip into HBC while holding rongeur shaft with other hand.



#### STEP 2:

Pull out and repeat as required by the surgeon.



### COMPATIBLE DEVICES AND PROCEDURE SUPPLIES

The following devices are compatible with the Hensler Bone Collector™ device:

- Universal fluid collection canisters or suction collection systems.
- Universal suction tubing.
- Kerrison™ Rongeurs.
- Leksell™ Rongeurs.

The following supplies should be assembled prior to use:

- Collection container and harvest top.

### Device Preparation

Attach harvest top to an empty collection container until ribs align.

### Collection Procedure

1. Attach the sterile collection container to the harvest top.
2. Once the ribs are aligned the HBC can be used easily and effectively to clean bone from the surgical Rongeurs multiple times, as the case allows.

### RETURN OF DEVICES

If any portion of the Hensler Bone Collector™ 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**  
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Wilmington, NC 28401, USA

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Method of sterilization using Ethylene Oxide

Do not Reuse – Single use

Use to expiration date on the package

Do not use the device if the packaging has been damaged or if sterility has been compromised

Keep away from sunlight

Keep dry.

