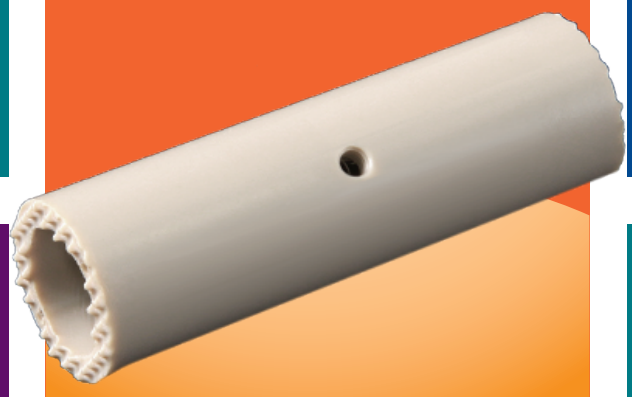
Amendia

The Elements of Healing

SAMSON

VERTEBRAL BODY REPLACEMENT SYSTEM



Amendia

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SAMSON CORPECTOMY
VERTEBRAL BODY REPLACEMENT

SURGICAL TECHNIQUE GUIDE

Samson Corpectomy Vertebral Body Replacement System

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Amendia
The Elements of Healing

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Disclaimer:
The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon before and during surgery as to the best mode of treatment for each patient. Please reference the 510K or package insert for additional information and a complete list of intended indications, warnings, precautions, and other medical information.

Features & Benefits

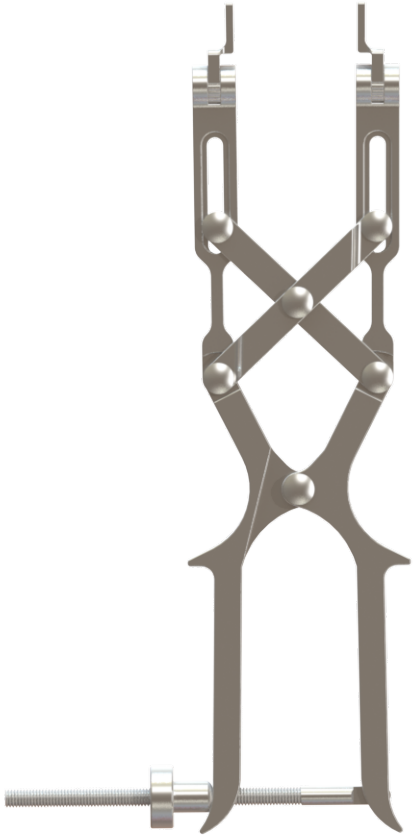
- Constructed of PEEK
- Tantalum radiopaque markers to optimize visibility and placement
- Pyramidal teeth provide multi- directional resistance to migration
- Hollow core allows for large amounts of graft material to facilitate fusion
- Cylindrical shape
- Design ensures a high degree of compressive strength and dimensional stability

Available Sizes (mm)	
14 D x 14 H	14 D x 31 H
14 D x 15 H	14 D x 32 H
14 D x 16 H	14 D x 33 H
14 D x 17 H	14 D x 34 H
14 D x 18 H	14 D x 35 H
14 D x 19 H	14 D x 36 H
14 D x 20 H	14 D x 37 H
14 D x 21 H	14 D x 38 H
14 D x 22 H	14 D x 39 H
14 D x 23 H	14 D x 40 H
14 D x 24 H	14 D x 41 H
14 D x 25 H	14 D x 42 H
14 D x 26 H	14 D x 43 H
14 D x 27 H	14 D x 44 H
14 D x 28 H	14 D x 45 H
14 D x 29 H	14 D x 46 H
14 D x 30 H	14 D x 47 H
	14 D x 48 H

14 mm Tall 32 mm Tall 48 mm Tall

Instrument Guide

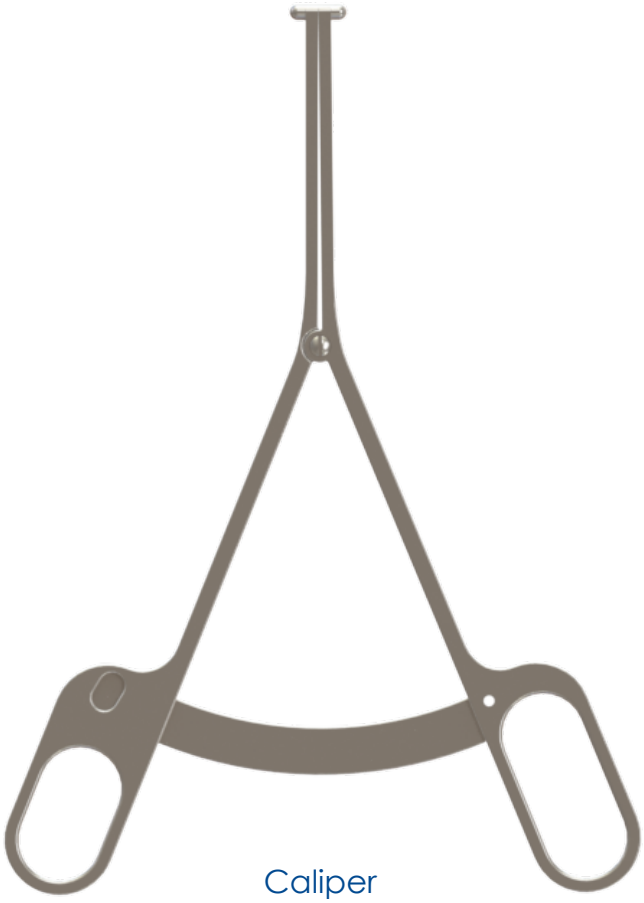
Inserter
VCINS1000



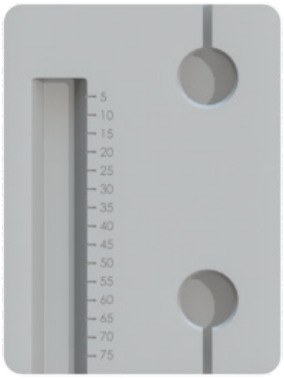
Parallel Distractor
VCPDI1001

Graft Compactor
VCGCT1003

Instrument Guide



Caliper
VCCAL1005



Graft Block
VCGBL1004

Slotted Slap Hammer
VCSSH1006

Available Sizes

Part No.	Size (mm)
13514	14 D x 14 H
13515	14 D x 15 H
13516	14 D x 16 H
13517	14 D x 17 H
13518	14 D x 18 H
13519	14 D x 19 H
13520	14 D x 20 H
13521	14 D x 21 H
13522	14 D x 22 H
13523	14 D x 23 H
13524	14 D x 24 H
13525	14 D x 25 H
13526	14 D x 26 H
13527	14 D x 27 H
13528	14 D x 28 H
13529	14 D x 29 H
13530	14 D x 30 H

Part No.	Size (mm)
13531	14 D x 31 H
13532	14 D x 32 H
13533	14 D x 33 H
13534	14 D x 34 H
13535	14 D x 35 H
13536	14 D x 36 H
13537	14 D x 37 H
13538	14 D x 38 H
13539	14 D x 39 H
13540	14 D x 40 H
13541	14 D x 41 H
13542	14 D x 42 H
13543	14 D x 43 H
13543	14 D x 44 H
13545	14 D x 45 H
13546	14 D x 46 H
13547	14 D x 47 H
13548	14 D x 48 H

STEP 1: Distraction

Obtain anterior exposure per surgeon preference.

Expose the midline of the intervertebral disc above and below the vertebrectomy site and remove the appropriate amount of disc and vertebral body.

If the **Implant** site ends at the inferior or superior endplates of the vertebral body adjacent to the replacement site, remove the superficial layers of the cartilaginous endplates to expose bleeding bone. This can be done with a variety of instruments such as osteotomes, scrapers, curettes and rasps **(Figure 1)**. Adequate preparation of the endplates is important to enhance vascular supply to the fusion site **(Figure 2)**.

Note: Aggressive cleaning of the endplate may remove excess bone and weaken the endplate.

Figure 1

Figure 2

STEP 2: Trialing

After the endplates are prepared, the **Caliper** is used to approximate the appropriate size of the **Implant** to be inserted **(Figure 3)**. The **Caliper** also provides the surgeon with tactile feedback as it relates to the distraction of the vertebral space. After the appropriate size has been determined, the comparable **Implant** is selected.

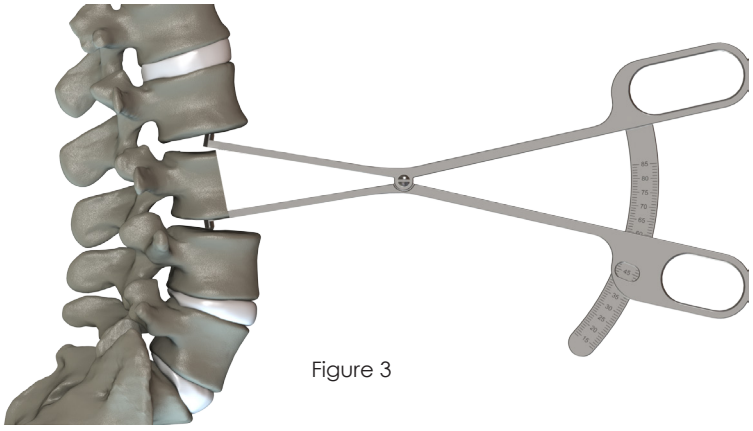


Figure 3

STEP 3: Implant Insertion

Load the **Samson Corpectomy Implant** on to the **Inserter** by placing it between the tines and threading the inner shaft to fully engage the **Implant (Figure 4)**. After attaching the **Inserter** to the **Implant**, fill the **Implant** cavity with autograft and/or allograft bone. Use the **Graft Compactor** to aid in packing the graft material into the **Implant.**

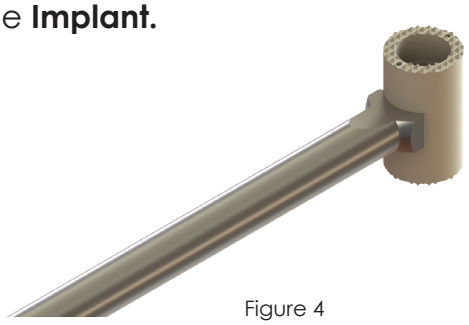


Figure 4

Introduce the **Implant** into the vertebral space using the **Inserter**. The **Implant** should be the same height or slightly larger than the size determined by the **Caliper** and should be seated securely within the disc space.

Tap the proximal tip of the **Inserter** with a mallet to gently seat the **Implant**. The **Implant** may be inserted flush with the anterior rim of the adjacent vertebral bodies or may be countersunk past the anterior rim at the physician's discretion **(Figure 5)**.

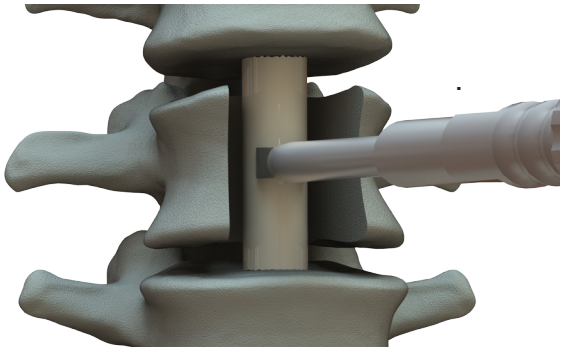


Figure 5

Disengage the **Implant** from the **Inserter** and remove the instrument. The **Inserter** may be utilized to further advance the **Implant** in the disc space by removing the threaded inner shaft. This will allow a smooth contact surface for impaction.

Final positioning of all **Implant(s)** should be confirmed using fluoroscopy. Additional autograft and/or allograft bone may be placed beside the **Implants** at the surgeon's discretion.

STEP 4: Supplemental Fixation

Because additional fixation considerably enhances the biomechanical stability of the motion segment as well as the stability of the **Cage**, the **Samson Corpectomy System** must be used in conjunction with supplemental fixation.

The final steps of the fixation procedure (e.g. rod insertion, tightening, compression) are completed after implantation of the **Cage**. Please refer to the specific system's surgical technique manual for user instructions.

STEP 5: Revision Surgery (Implant Removal)

Device removal can be achieved by threading the **Inserter** into the **Implant**. Meticulous removal of all autograft and/or allograft is required prior to attempting to move the device within the vertebral space. A larger annulotomy and/or bone window may be required to accomplish this. The **Inserter** is threaded securely onto the **Implant** and a light rocking motion is used to loosen the **Implant**. Once the **Implant** is loosened, it is removed by pulling the **Inserter** in an upward motion away from the spine with care taken not to injure adjacent soft tissue structures.

Important Product Information

CAUTION: Federal law (USA) restricts these devices to the sale by or on the order of a physician. Implants and disposable instruments single use only.

Description:
The Samson Corpectomy® is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The implants have ridges or teeth in both the superior and inferior directions, which resist migration. The implants have cavities to accept packing of autograft and/or allograft. The entire structure is radiolucent so that healing can be assessed by normal radiographic methods. Additionally, radiotherapy can be performed immediately after surgery. The materials used in the implant are listed on the packages. Implants are made from PEEK per ASTM F2026. To ensure radiographic visibility for inspecting the implant position, they contain marker pins made of x-ray opaque implant material (Tantalum).

Indications for Use:
The Samson Corpectomy® is a vertebral body replacement system indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5). The Samson Corpectomy® is intended for use with supplemental fixation and is to be used with autograft and/or allograft.

Contraindications include, but are not limited to:
- Fractures
- Scoliosis
- Active infection
- Allergy to titanium, titanium alloy or PEEK
- Bone tumors in the region where the implant would have to be anchored
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Osteoporosis or similar loss of bone density
- Systemic or metabolic diseases
- Drug abuse or alcoholism
- Generally poor condition of the patient
- Morbid obesity
- Psychosocial issues; inadequate co-operation by the patient
- Fever or leukocytosis
- Any case not needing a fusion
- Patients with a know hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth
- Any case where the implant components selected for use would be too large or too small to achieve a successful result
- Any case that requires the mixing of metals from two different components or systems
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- Prior fusion at the level to be treated
- All cases that are not listed under indications

WARNINGS:
1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory anterior column support is increased by the selection of the proper size device. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION. Internal fixation appliances are load-sharing devices that are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

Precautions:
- SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
- ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be aware of the limitations of the implants. The patient should be encouraged to ambulate to tolerance as soon as possible after surgery, and instructed to limit and restrict lifting and twisting motions and any type of sports participation until the bone is healed. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration to the devices and damage to nerves or blood vessels.

Important Product Information

Possible Adverse Effects
Potential adverse effects may include, but are not limited to the following:

- Bending or fracture of implant. Loosening of the implant.
- Implant material sensitivity, or allergic reaction to a foreign body.
- Infection, early or late.
- Decrease in bone density due to stress shielding.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
- Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later postoperative period.
- Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
- Bursitis.
- Death.
- Spinal cord impingement or damage.
- Fracture of bony structures.
- Reflex sympathetic dystrophy.
- If a pseudarthrodesis occurs coupled with the Samson Corpectomy®, a mechanical grinding action could possibly occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints.
- Degenerative changes or instability in segments adjacent to fused vertebral levels.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery

Material Specification: Samson Corpectomy® is manufactured from Polyetheretherketone (PEEK) Polymers per ASTM F2026 and tantalum per ASTM F560.

Packaging: Packages for each of the components should be intact upon receipt. Damaged packages and products should not be used and should be returned to AMENDIA.

Sterilization: Products not clearly marked as sterile should be assumed non-sterile.

For Sterile Implants and Instruments:
Implants and instruments provided sterile will be clearly labeled as such in an unopened sterile package provided by AMENDIA. The contents are considered sterile unless the package is damaged, opened, or the expiration date on the device label has passed. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised. Implants supplied sterilized from AMENDIA must not be re-sterilized.

For Non-Sterile Implants and Instruments:
Implants and instruments used in surgery not clearly labeled as sterile must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization where applicable.

Only sterile products should be placed in the operative field.

Product Complaints: Any health care professional (e.g. customer or user) who has experienced dissatisfaction in the services of AMENDIA or who has any complaints about AMENDIA products referring to quality, identity, durability, reliability, safety, effectiveness, and/or performance, should notify this to the sales representative, distributor, or AMENDIA customer service. Further, if any of the devices, instruments or components ever malfunction, (i.e. do not meet any of their performance specifications or otherwise do not perform as intended), or are suspected of doing so, the distributor should be notified immediately. If any AMENDIA product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

Manufacturer:
AMENDIA, 1755 West Oak Parkway, Marietta, GA 30062, 877-755-3329 (Toll Free), 770-575-5200 (Main), 877-420-1213 (Fax)

Recommended Sterilization Procedures for Samson Corpectomy® (VBR) System Instrumentation and Implants
Provided Non-Sterile:
Manufacturer: Amendia, Inc.
Method: Manual Cleaning and Steam Sterilization

Device(s): Trays/Implants/Instruments

Important Product Information

Cautions:	The Samson Corpectomy® (VBR) system components provided NON-STERILE should be cleaned and sterilized before use. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended. Cleaning agents with chlorine or chloride as an active ingredient are corrosive to stainless steel and should not be used. Saline solution has a corrosive effect on stainless steel and should not be used. Use only neutral pH cleaning agents and detergents. Samson Corpectomy® System IMPLANTS are single use. Therefore these guidelines are not intended for USED Samson Corpectomy® spinal implants or DISPOSABLE, single use instruments. The Samson Corpectomy® System has not been evaluated for safety and compatibility in the MR environment. The Samson Corpectomy® (VBR) System has not been tested for heating or migration in the MR environment.
Limitations on Reprocessing:	Repeated processing has limited effect on REUSABLE instruments. End of life is normally determined by wear and damage due to use.

Instructions:	
Point of Use:	Use clean flowing water and disposable wipes to remove excess soil. Reprocess instruments as soon as possible to prevent body fluid and tissue from drying on instruments prior to cleaning.
Preparation for decontamination:	Disassemble all components to provide maximum exposure for cleaning.
Cleaning -Automated	Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. An automated system may be used as a follow-up method to manual cleaning.
Cleaning-Manual	1. Disassemble all components before cleaning. 2. Completely submerge instruments in enzyme solution and allow to soak for a minimum of 20 minutes. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, and appropriately sized soft-bristled brush (e.g. pipe cleaner brush). 3. Remove the devices from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas. 4. After manual cleaning, and all visible blood, soft tissue, and bone have been removed ultra-sonic cleaning may be used. Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for a minimum of 10 minutes at 45-50kHz. 5. Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas. Use de-ionized water for final rinse of all components. 6. Repeat the sonication and rinse steps above until all visible contamination has been removed. 7. Thoroughly and promptly, remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe. Allow the tray and components to dry for a minimum of 15 minutes. The tray and components must be thoroughly dry prior to sterilization cycle.

Important Product Information

Disinfection:	Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments.
Maintenance, inspection, and testing;	Carefully inspect each device to ensure that all visible blood and soil have been removed. Inspect lumens to confirm that all foreign material has been removed. Visually inspect for damage and/or wear. Note: If any damage or wear is noted that impairs the function of the instrument, contact your Amendia representative for a replacement.
Packaging:	This set of components may be loaded into a dedicated tray, supplied by the manufacturer, for sterilization.
Sterilization:	Visually inspect all components for any remaining debris prior to sterilization. The Samson Corpectomy® system components provided NON-STERILE should be autoclave sterilized using the sterilizer manufacturer's instructions and the institution's procedures for ensuring sterility. The sterilization cycle should occur in a calibrated autoclave. Sterilize utilizing a pre-vacuum steam autoclave for a minimum of 4 minutes at 270°F (132°C.) The 4 minute, 270° pre-vacuum steam sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).
Drying:	A minimum drying time of 20 minutes, after sterilization, is recommended. Drying times may vary according to load size and should be increased for large loads. Dry, thoroughly and promptly, after both cleaning and sterilization.
Storage:	Store components in a clean, dry, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and extremes in humidity and temperature.

The instructions provided above have been validated by Amendia as being CAPABLE of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the reprocessing as actually performed, using equipment, materials, and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process. Any deviation by the re-processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

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