

Notice: As with any prescription medical device, failure to follow product instructions or changing settings and performing therapy applications without the express direction and/or supervision of a trained clinical caregiver may lead to improper product performance and the potential for serious or fatal injury.

A. Intended Use

The Axiom™ Ultrasonic Removal System is intended to be used in selective fragmentation, resection, emulsification, irrigation and/or aspiration of bone and synthetic materials (e.g., polymethyl methacrylate (PMMA) bone cement) during orthopedic revision surgeries. Its adaptive ultrasonic energy allows the user to rapidly melt, scrape, fragment and remove cement at the blade tip with minimal force, preserving the surrounding patient anatomy (bone and tissue).

B. Product Description

The Axiom™ Ultrasonic Removal System has a variety of single-use sterile blade options, varying in lengths, diameter and blade design and a dual-port generator with detachable twin foot pedal. The system has up to 10 power options 0-100% (10% increments), as well as 5 pulse modes: 0 is continuous and level 1-4 sonic pulse. Higher sonic pulses decrease the risk of bone perforation in areas with a thin cement mantle. The system enables the user to perform removal of cemented (PMMA), and non-cemented implants. The Axiom™ Ultrasonic Removal System converts standard electrical energy into mechanical energy, via the Axiom™ Ultrasonic Handpiece. This energy is transmitted through individually calibrated blades with ultrasonic frequency, causing the blades to vibrate at a controlled high speed of 25-30 kHz. This gives the user intuitive control over the blade, minimizing leverage and pressure on bone cement interface. This provides built in safety avoiding bone perforation. The high frequency softens cement into a malleable form allowing selective and rapid cement removal while preserving the surrounding patient anatomy.

C. Indications

The Axiom™ Ultrasonic Removal System and Accessories are indicated for removal of PMMA and separating a press-fit interface in arthroplasty revision surgeries. It is to be used to melt, scrape, fragment, and remove unwanted cement and bone. The system may be used as an adjunct to or substitute for manual systems.

D. Contraindications

1. The use of the generator and the attached instruments are contraindicated, when in the judgment of the surgeon, ultrasonic surgery would be contrary to the best interest of the patient.
2. It is the responsibility of the surgeon to determine whether any physical impairment of the patient would contraindicate the use of this device.
3. It is contraindicated for Central Circulatory System and Central Nervous system, for patients with systemic or local infection in area of the procedure, blood coagulation

disorders or anticoagulant use, for cardiac surgery or any procedure in the proximity of the heart, patients with electric drives (e.g., pacemaker), abdomen of pregnant women, neonatal and neurovascular patients, coagulation and dissection of vessels, contraceptive tubal occlusion or heads or eyes of patients.

E. Directions for Use

1. Ensure the installation site meets the necessary power, environmental, and space requirements. This includes verifying electrical outlets, ensuring sufficient workspace, and confirming environmental controls (e.g., temperature and humidity).
2. Connect the device to a suitable power source (US 110-120V (60Hz), UK 230-240V (50Hz)).
3. Turn on the generator.
4. Connect foot pedal and handpiece connectors to the generator.
5. Choose blade for specific surgical technique (see chart below). Individual blade calibration is stored in the console memory.

Blade Options & Usage (Benefit & Motion)	
Piercer	Creates straight relief channels; side vents evacuate melted cement. Advance → Stop (wait ≈ 15 s) → Retract
Scraper	Scoops melted debris, polishes canal walls. Start distally, pull back along cement interface
Acetabular	Curved profile frees cement 360° around cup. Circumferential sweep
Chisel	Ultra-thin blade for separation. Separate cement mantle

6. Determine if an extender is needed for procedure.
7. Thread blade of choice into the distal end of the black handle. Turn the blade until finger tight.
8. Attach sterile wrench to the flat slots on the blade, tighten by turning blade clockwise.
9. Attach the counter-wrench base to the black handle at the distal end on the flat metal slots.
10. Device will calibrate the blade when language is selected. Once system calibrations reach 100%, device ready for use. Each time a new blade is connected, the system must be recalibrated.
11. Ensure that all system components are receiving power and function as indicated on the control panel.
12. Wait until working screen appears with "Power" and "Pulse".
 - a. Power: From 0 to 100% indicates the percentage of a breakdown of watts at max 200 watts. 100% value signifies value of power at voltage of power. 1% signifies 0.8 Va value.
 - b. Blade: Related blade for the surgery type will be chosen by surgeon.
 - c. Continuous or Pulse: Predetermined 5 pulse modes are available. Depending on the tissue response, the user may opt the best pulse required for the related indication.

- d. Foot Pedal: You can manage the operation.
 - e. Return: Screen goes back to start position.
 - f. Calibrate: You can recalibrate the blade once a new blade is required.
13. Use foot pedal to ensure blade is functioning.
 14. Choose energy level. The generator will present to the last energy level adjusted.
 15. Step on foot pedal and follow techniques for blades selected.
 16. Upon activation, the ultrasonic blade provides distinct audible feedback based on the density of the material encountered. When interacting with PMMA cement, the blade produces a low-pitched ultrasonic sound. Conversely, interaction with cortical bone generates a high-pitched audible ultrasonic sound, offering the end user real-time tactile feedback and enhanced procedural guidance.
 17. The melted cement can then be lifted out in larger, consolidated pieces for efficient canal clearance.

F. Packaging & Labeling

The single-use blades come individually packaged in sterile double Tyvek pouch packs. Inspect the product and the packaging for damage prior to use. Confirm that the device is consistent with the package label. Discard and replace any damaged devices. Store the products in a clean, dry place in accordance with the storage conditions.

G. Storage, Transport & Operating Conditions

Store sterile packaged instruments and devices in a manner that provides protection from dust, moisture, insects, vermin, and extremes in temperature and humidity.

H. Cleaning Instructions

All reusable handpiece parts and accessories must be properly decontaminated, cleaned and sterilized before each use as per instructions. Failure to do so may lead to infections. Prior to cleaning, separate all detachable components. Be certain to clear debris from all internal passages by brushing. All ultrasonic handpieces are provided clean but not sterile. Use enzymatic cleaning solution (e.g., Gigazyme Plus) according to manufacturer's instructions.

Warning:

1. Do not immerse ultrasonic console, handpiece, remote foot pedal or electric cables. These items are not sealed against liquids and damage to equipment will result.
2. Do not use ultrasonic cleaners or automated washers to clean the Handpiece as both methods could damage handpiece.
3. Do not use ULTRASONIC WASHING or CYDEX.
4. Do not sterilize the Axiom™ generator console.
5. Care should be taken to remove debris that may collect on the Axiom™ generator
6. End life is generally determined by wear or damage in surgical case.
7. Carefully inspect instruments between uses to verify proper functioning.

8. Immediately after use wipe down all components and remove any surplus body fluids and debris.

The following items are considered reusable items and should be cleaned as recommended: Generator Console, Ultrasonic Handpiece and Foot Pedal.

Manual Cleaning of Ultrasonic Handpiece:

1. Prepare detergent bath at the manufacturer's recommendation (e.g., Gigazyme Plus).
2. Pre-Treat contaminated device by soaking in an enzymatic cleaning solution for at least 5 minutes. Contaminated devices should be pre-treated within one hour of use.
3. Remove the device from the cleaning solution and remove any remaining debris or deposits using a soft brush. Do not use any brush with metal bristles or steel wool.
4. Rinse under running water for 2 minutes. Ensure that blind holes and recesses are repeatedly filled and emptied with running water.
5. Inspect the device to make certain that all residue, debris, and residual cleaning solutions are removed and that the device is free of defects and safe to use
6. Thoroughly dry the device before packaging for sterilization using lint-free cloths.

Steam Sterilization (Autoclave) of Ultrasonic Handpiece:

Wrap the instruments by AAMI recognized guidelines. Follow the sterilizer manufacturer's written instructions for cycle parameters, load configuration and AAMI guidelines for steam sterilization.

Minimum Cycle Times for Dynamic-Air-Removal Steam Sterilization Cycles	
Min. Temperature	273°F (134°C)
Exposure Time	6 min
Min. Dry Time	30 min
Sample Configuration	Wrapped

I. Product Disposal

The medical device or its components, packaging material and accessories must be disposed of in accordance with any applicable country-specific regulations and laws.

J. Inspection & Handling

1. Reuse of Sterile products, including after reprocessing and/or re-sterilization may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information, all of which present a potential risk to patient safety.
2. Do not use if the package is opened or damaged. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.
3. Store in a cool, dark, dry place.
4. Use the system prior to the "Use By" date specified on the package.
5. Do not expose the delivery system to organic solvents.

6. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

K. Caution

1. The Axiom™ System is an electro-mechanical device, which under certain circumstances could present an electrical shock hazard to the operator and/or patient when not used correctly.
2. The Axiom™ system is intended to be used in various types of invasive, surgical procedures. There may be indirect danger to the patient should the device fail during the procedure. It is recommended that the facility follows its back-up equipment protocols.
3. Use only Axiom™ accessories to assure compatibility. The use of accessories and cables other than those specified, with the exception of accessories and cables, sold by Brasseler USA Surgical Inc. as replacement parts for internal components, may result in increased emissions or decreased immunity of the ultrasonic console.
4. Carefully read all instructions for use prior to use and follow the hospital's clinical practice guidelines for ultrasonic surgery, ultrasonic, gynecology and laparoscopic procedures. Observe all warnings and cautions noted throughout these instructions. Failure to do so may result in complications. See product labels for recommended power settings.
5. The operation area must be free of explosive gases or inflammable fluids and materials.
6. To avoid unwanted procedural delays, assure the system is fully operational prior to administration of anesthesia.
7. This device must only be used by surgeons or medical staff who are trained in the types of surgical procedures that are to be carried out and trained in the specific use of ultrasonic surgical instruments.
8. The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to performing surgery.
9. As with all surgical procedures, the system operator and other clinical personnel should follow the universal precautions for infection control.
10. The devices are not to be repurposed in any way to be used for operations they are not intended for any non-medical use. No modification of this equipment is allowed.
11. Single use devices are for single patient use and one procedure only. Do not reprocess, re-use or re-sterilize products. Once used, devices must be disposed of in accordance with hospital policies.
12. Prior to use, carefully examine the unit to verify that the sterile package and contents have not been damaged. Do not use if package is opened or damaged, or if seal is broken. Replace the handle if it becomes damaged or deformed in any way either prior to or during use.
13. Do not re-sterilize sterile products.
14. Ensure all connections and mating surfaces of handle, extension and ultrasonic blades are clean and dry before assembly.
15. Ensure that electrical insulation or grounding is not compromised to avoid the risk of electric shock. This equipment must only be connected to a supply main.
16. Removal of outer covers may result in electrical shock.
17. Do not immerse ultrasonic console, handle, irrigation pump, remote foot pedal or electric cables. These items are not sealed against liquids and damage to equipment will result.
18. The system should not be used adjacent to or stacked with other equipment, and if adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.
19. This device may cause electromagnetic interference with other devices when in use. Do not place console near sensitive equipment when operating.
20. Ignoring alarms on the device while continuing to use the system may result in injury to the patient and/or surgical personnel, or equipment damage.
21. Do not attempt to manipulate or re-shape blade configurations. If the blade becomes bent do not attempt to straighten it. Dispose of the device and open a new one.
22. The audible buzzer signal sounds as loud as 65 dB while the device is engaged as a part of device operation as a warning.
23. The expiration date is printed on the package. Do not use products if their shelf life is exceeded.
24. Touching the blade of the handle by the operator, while the handle is powered on can result in personal injury.
25. Do not allow the device to contact tissue while not in use in case accidental activation should occur.
26. When you test the handle, do not allow the handle blade to contact anyone or anything during blade activation. Contact may result in patient injury, user injury, or handle blade damage.
27. Care should be taken when operating in the vicinity of nerves.
28. When using the ultrasonic handle and other instruments together, blades and accessories into the human body part must be checked if there are safety hazards caused by the rough surface, sharp edges or protrusions.
29. As with all energy sources (Electro-surgery, Laser or Ultrasound) there are concerns over carcinogenic and infectious potential of the procedure by-products e.g. tissue smoke plume and aerosols. Effective protective equipment should be used during procedures.
30. Do not force tool blades. Tools are to be guided, not forced. If the instrument meets resistance, do not force the tool. The tool may have contacted cortical bone. The application of force can cause damage to the cutting blade, the system and unnecessary damage to bone.
31. If the blade touches metal while activated sparks may be produced. Therefore, use caution when using in the presence of flammable gases or liquids.
32. After significant activation, the distal end of the device may become hot. Do not allow the blade to contact soft tissue immediately following activation. Remove any visible tissue build up from the device to prevent the

increased risk of burn injury.

33. Do not attempt removal of a bone plug with the handle.
 The jolting force often required for removal of a bone plug can cause unrepairable, permanent damage to the handle.
34. Regularly check for software updates provided by the manufacturer. Install these updates to ensure the device runs with the latest features.

L. Warranty:

Limited warranty and disclaimer: Brasseler Axiom™ Ultrasonic Removal System are sold with a limited 1-year warranty to the original purchaser against defects in workmanship and materials during normal use. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

J. Return Goods Policy:

Contact your distributor regarding return goods policy.

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K. Symbols Glossary

	Distributed By		Manufactured Date & Country of Origin
	Lot number		Keep Dry
	Catalogue number		Keep away from sunlight
	Serial number		Use by date
	Medical device		Double sterile barrier system
	Unique device identifier		Type BF applied part
	Sterilized using ethylene oxide		Do not use if box is damaged
	Caution		Federal USA law restricts this device to sale by or on the order of a physician
	Risk of electric shock		See instruction manual
	Single use only		Consult instruction for use
	Do not re-sterilize		Quantity