Description:
The VersaDriver Pneumatic Osteotome System is comprised of four (4) components: a hose, hand piece, slap hammer, and blades. The hand piece, slap hammer and hose come in a SteriTite reusable sealed sterilization case. The blades come pre-sterilized. The system is designed to provide the surgeon with the ability to cut bone, shape bone, separate implants from bone, separate implants from bone cement, remove bone cement and perform any other function that is typically performed by a manual osteotome.

Blades
The surgeon should select a blade with an appropriate length to match the depth they wish to drive the blade into the bone site. Curve blades should be used where more force or shaping is needed in cutting or separating the bone from the implant or cement. It is critical that the splash guard be securely in place to protect the hand piece chuck from blow back during the procedure.

Hand Piece
The blade should be attached to the hand piece by twisting the chuck in the "UNLOCK" direction while inserting the blade. The hose must also be attached to the base of the hand piece by pushing the hose into the hand piece and turning it counter clock wise. The hand piece is engaged by pulling the trigger. It can be operated in a "Safe" mode where the hand piece will not strike the blade, a "Single Strike" mode where the hand piece will strike the blade a single time and "Auto" mode where the hand piece will strike the blade continually when the trigger is depressed. This selection is made by turning the knob at the back end of the hand piece.

Hose
The hose attaches the hand piece to the source of nitrogen in the OR using a Shrader fitting. It is designed to both deliver the compressed gas to the hand piece and then exhaust the gas out of the sterile field.

Slap Hammer
The slap hammer is intended to free blades that have become stuck while driving them into a wound site. The slap hammer is designed to attach to the hole on the back end of the blade once the blade has been removed from the hand piece. By using the sliding weight on the hammer to impart a force on the blade, the slap hammer will allow the surgeon to drive the blade in a reverse direction.

General Precautions:

- Care should be taken to ensure that proper sterilization of the equipment is performed. The four filters in the tray must be replaced with hydrophobic non-woven polypropylene 7.5-inch round filters (Case Medical PN: SCF02). Additional information on use of the SteriTite case is available on our web site at www.Brasseler USAmedical.com.
- The "Expiration" date on the blade label should be checked to confirm that the product's good to use date has not expired. If expired, blade should be discarded.
- Only use nitrogen with the handpiece. Air from a compressor typically contains water and oil and will clog the handpiece.
- The pressure of the nitrogen used to power the hand piece should be adjusted to the typical operating pressure prior to surgery according to the following table.

Type of Gas	Minimum Operating Pressure	Typical Operating Pressure	Maximum Operating Pressure
Nitrogen	80 psi	100 psi	120 psi

- The pressure may be adjusted during surgery between the minimum and maximum pressure to adjust the force applied to the blade by the hand piece.
- Never immerse the handpiece in any liquid during cleaning. This will fill the internal chambers with liquid and damage the handpiece.
- Never "dry fire" the handpiece by firing it without the blade being pushed against a cutting surface. "Dry firing" will cause excessive stress to the internal components and damage the handpiece.

1. SCOPE
This instruction manual provides information on the care, cleaning, disinfection, maintenance, and sterilization of Brasseler USA Medical's VersaDriver hand piece, hose, blade extraction tool, tray, and case. The VersaDriver blades cannot be cleaned and sterilized after use.

2. PURPOSE
These instructions are recommended for the care, cleaning, maintenance, and sterilization of reusable **Brasseler USA** Medical orthopedic VersaDriver instruments. This document is intended to assist health care personnel in safe handling practices, effective reprocessing, and maintenance of **Brasseler USA** Medical reusable devices. The document is intended to assist the hospital and central supply management in developing and following procedures for safe and effective reprocessing of **Brasseler USA** Medical instrument sets. Hospital personnel, including those in receiving and central sterile supply departments (CSSD), as well as in the operating room (OR) may be directly involved in handling instruments purchased or loaned from **Brasseler USA** Medical. Hospital directors and other management in each of these departments should be informed of these instructions and recommendations to ensure safe and effective reprocessing and to prevent damage or misuse of reusable devices.

3. GLOSSARY
Chemical: A formulation of compounds intended for use in reprocessing.

Cleaning: The removal of contamination from an item to the extent necessary for further processing

Contaminated: State of having been actually or potentially in contact with microorganisms

Decontamination: The use of physical or chemical means to remove, inactivate, or destroy blood borne pathogens on a surface or item to the point where they are no longer capable

rendered safe for handling or disposal

Disinfection: A process used to reduce the number of viable microorganisms on a product to a level previously specified as appropriate for its further handling or use

Manual cleaning: Cleaning without the use of an automated washer or washer/disinfector

Processing/Reprocessing: Activity including cleaning, disinfection, and sterilization, necessary to prepare a new or used medical device for its intended use

Sterilization: A validated process used to render a device free from all forms of viable microorganisms

Washer/Disinfector: A machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical, and veterinary practice

4. PROCESSING INSTRUCTIONS

These processing instructions are intended to assist the hospital and central supply management in developing procedures for safe and effective reprocessing of both hospital owned and loaned Brasseler USA Medical instrument sets.

A. WARNINGS AND PRECAUTIONS

- Universal precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges.
- Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices, and equipment. PPE includes gown, mask, goggles or face shield, gloves, and shoe covers.
- Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
- Do not place heavy instruments on top of devices.
- Do not allow contaminated devices to dry prior to reprocessing. Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover with damp cloth.
- Automated cleaning shall not be used when cleaning the hand piece and hose. Only manual cleaning process is acceptable.
- Instruments should be removed from trays and cleaned separately.
- Cleaning agents with chlorine or chloride as active ingredient are corrosive to stainless steel and must not be used. Enzymatic and cleaning agents with neutral pH are recommended.

B. POINT OF USE PREPARATION, CONTAINMENT AND TRANSPORTATION

- Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe.
- Place instruments in a tray covered with damp towels. Do not immerse instrument in liquid. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.
- Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.
- Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

C. PREPARATION OF CLEANING AGENTS

- Neutral pH enzymatic and low foaming cleaning agents are preferred and recommended by Brasseler USA.
- All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.
- Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

D. MANUAL CLEANING PROCESS

- Use the neutral pH enzyme cleaning solution that has been prepared.
- The nitrogen hose should be attached to the hand piece prior to cleaning to ensure that no liquid can enter the hand piece through the nitrogen port.
- Never submerge the hand piece or hose in any solution as this will allow liquid to enter internal workings of hand piece and cause damage. Use a soft-bristled brush to gently clean the device (particular attention shall be given to crevices, mated surfaces, and other hard-to-clean areas) until all visible soil has been removed.
- NOTE: The enzyme solution should be changed when it becomes grossly contaminated (bloody and/or turbid).
- Rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush holes and other difficult to reach areas. Continue rinsing until there is no sign of blood or soil in the rinse stream.
- Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.

E. AUTOMATED CLEANING PROCESS

- An automated washer/disinfector shall not be used.

F. INSPECTION AND MAINTENANCE

- Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning/disinfection process.
- Visually inspect for device integrity, damage and/or excessive wear NOTE: If damage or wear is noted that may compromise the function of the instrument, contact Brasseler USA Medical for a replacement.
- Check the action of moving parts (e.g., trigger, rotating parts, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.
- Never lubricate the instrument.

G. STERILIZATION INSTRUCTIONS

- Replace the four (4) 7.5” Diameter Cellulose Filters (Case Medical PN SCF01 or equivalent) in the case and close the case securely making sure the cover fits snuggly and latches are fully closed.
- Steam sterilize using a pre-vacuum cycle with an exposure time of 4 minutes at a minimum exposure temperature of 132°C (270°F) and a minimum drying time of 30 minutes. When sterilizing multiple instruments in one steam sterilization cycle, ensure that the sterilizer manufacturer’s maximum load is not exceeded. Drying times will vary according to load size and should be increased for larger loads.
- IUSS as per AAMI guidelines (“Flash” sterilization) is not recommended for the VersaDriver.

- Steam sterilization is the preferred method for metal instrument sets. Instrument sets should be properly prepared and packaged in a case that will allow steam to penetrate and make direct contact with all surfaces.
- The following chart summarizes exposure times and temperatures that have been validated for use with the VersaDriver set in a sterile rigid container (Steritite Case) time and temperature relationships indicate holding time after the specific temperatures have been reached and do not include ramp up or ramp down times.

Cycle Type	Minimum Temperature	Pressure	Minimum Exposure Time	Minimum Dry Time
1, 2 Pre-vacuum / Pulsating Vacuum	132°C 270°F	1.86bar 27psi	4 min	30 min

1. Minimum validated steam sterilization temperature required to achieve a 10-6 sterility assurance level (SAL).
2. Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in this table.
3. AAMI/AORN steam sterilization cycles with longer times than those listed are also acceptable.
4. Drying times vary according to load size and should be increased for larger loads.

H. STORAGE INSTRUCTIONS

- Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, and temperature/humidity extremes.
- Sterile instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.

5. HOSPITAL RESPONSIBILITIES FOR BRASSELER USA MEDICAL LOANER/RENTAL SETS

- Loaner/rental sets should undergo all steps of decontamination, cleaning, disinfection, inspection, and terminal sterilization before being returned to Brasseler USA Medical. Documentation and/or evidence of decontamination should be provided with instruments being returned to Brasseler USA Medical.
- Missing or damaged instruments from loaner sets should be brought to the attention of the operating room supervisor, to the director of the central supply department, and to Brasseler USA Medical to ensure that the missing/damaged instrument (s) are backfilled and that the next hospital will receive a complete set of instruments in working condition.

INDICATIONS

VersaDriver is indicated for: hardware removal typically associated with revision surgery, general removal of plates and implants, and the cutting and/or shaping of bone.

CONTRAINDICATIONS

The VersaDriver system should not be used in spine surgery or anywhere the surgeon is working in close proximity to nerves or blood vessels and where accidently cutting them could cause serious damage.

WARNINGS

Correct selection of the blade size and shape of cutting edge is essential to optimal performance. Use of the VersaDriver system should only be undertaken after the surgeon has become thoroughly knowledgeable about anatomy and biomechanics and has had hands-on training in the use of this device. The **VersaDriver blades are for single use only** and may not be reused or re-sterilized. Blades should never be used if the splash guard is not in place.

CAUTION

Federal (USA) Law restricts this device to sale to, or on the order of, a physician who has appropriate training or experience.

ADVERSE EVENTS

No adverse events have been reported on the VersaDriver system.

HOW SUPPLIED

The VersaDriver blades are supplied sterile, in single use packaging. Contents are sterile unless the package is opened or damaged or the expiration date on the package has passed. Remove blade from packaging, using aseptic technique, only after the correct size and shaped blade has been determined. The hand piece, hose and slap hammer are supplied in a sealed surgical case. The 4 case filters should always be replaced prior to sterilization, see **Precautions**. These components should always be sterilized utilizing this case.

CONFORMANCE TO STANDARDS

The VersaDriver blades are manufactured from 410 grade stainless steel that conforms to ASTM A-240 and the splash guards are manufactured from ABS Plastic that conforms to USP Class VI or ISO 10993-1 testing protocols. All materials used in the hand piece, slap hammer and hose are approved medical grade materials.

Warranty:

Limited warranty and disclaimer: Brasseler USA Medical products 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.

Glossary of Symbols:

Brasselerusamedical.com/resources/

Return Goods Policy:

Contact your distributor regarding return goods policy.

Product Disposal:

Dispose of product or recycle in accordance with local laws and regulations.