Description:
The Brasseler USA VersaDriver System includes Blades, Handpiece, Hose, Sterilization Case, Sterilization Cap, and Slap Hammer. The handpiece, slap hammer, cap, and hose come in a reusable, sealed sterilization case; it is recommended that this case alone be used for sterilization. The blades come pre-sterilized.

Intended Use:
The system is designed to provide the surgeon with the ability to cut and shape bone, separate implants from bone, separate implants from bone cement, remove bone cement and perform any other function that is typically completed by a manual osteotome.

General Precautions:

- This device shall only be used in compliance with its intended use.
- Do not re-use or reprocess blades. If a blade is re-used, there is a potential for bone necrosis and cross contamination. Failure to follow these instructions may result in corrosion, oxidization, or rusting of the product as well as the deformation of the splash guard.
- Prior to each use, perform the following:
  - Ensure all accessories are correctly and completely attached.
  - Perform the required pre-operative functional tests for handpieces/equipment and accessories.
  - Follow universal precautions and use protective apparel when handling contaminated consumable accessories.
- Blades shall never be used if the splash guard is not in place.

Follow the instructions and warnings issued by the suppliers of any cleaning and disinfection agents and equipment used.

- 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 handpiece shall 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 handpiece.
- **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. This will cause excessive stress to the internal components and damage the handpiece.
- Do not lubricate – the system is self-lubricating.
- These components shall always be sterilized utilizing the recommended case.
- The product is intended for use only by fully- trained health care professionals in their safe and effective use.
- In case of unexpected product anomaly, it is recommended to have back-up accessories from a different lot to reduce any surgical delays and to prevent prolonged or additional anesthesia exposure.
- Do not use blades if, upon receipt, package is opened, damaged, or shows any sign of tampering or debris.
- Prior to use, inspect the blade for signs of corrosion or oxidation. Do not use the blade if corrosion or oxidation is present or if splash guard is deformed.
- Always verify sterile product is within its labeled expiration date to ensure sterility prior to use. Sterility of the product cannot be assured beyond the expiration date.
- Only use blades with the VersaDriver power system.
- Do not use blade with a handpiece not maintained according to the manufacturer's specifications.
- Lack of adherence to maintenance specifications may result in possible increased blade breakage.
- Do not allow the accessory to come into contact with other metallic objects such as retractors during use to prevent blade failure and/or patient injury. Failure to do so may result in excessive heat generation or metal shavings in the surgical site.
- Do not use excessive lateral, twisting, or bending forces to prevent blade failure such as bending or breakage. Exercise extra caution when using with alignment guides or cutting fixtures.
- After use, accessories may be a potential biohazard and shall be handled and disposed within acceptable medical practice and local laws, national requirements, and regulations.
- All product shall be stored in an environment that prevents premature degradation. The product shall be protected from prolonged exposure to direct UV light, excessive heat, and humidity.

Blades
The surgeon shall select a blade with an appropriate length to match the depth they wish to drive the blade into the bone site. Curved blades shall 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 handpiece chuck from blow back during the procedure.

- Use caution when utilizing metal guides to minimize metal-on-metal contact as damage to saw blade may occur and may necessitate its replacement.
- Blades may become hot from friction. Irrigation of blades is recommended during use to prevent bone or tissue necrosis and is required when using an alignment guide or cutting fixture.
- Do not clean or re-sterilize blades. Failure to follow these instructions may result in corrosion, oxidization, or rusting of the product.
- Always inspect for bent, dull, or damaged blades before each use. Do not attempt to straighten or

sharpen. Do not use if damaged and/or missing splash guard.

WARNING: This product contains nickel, a chemical known to the state of California to cause cancer, birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

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

Hose
The hose attaches the handpiece to the source of nitrogen in the OR using a Shrader fitting. It is designed to both deliver the compressed gas to the handpiece 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 handpiece. 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.

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 shall 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.

PROCESSING INSTRUCTIONS
A. WARNINGS AND PRECAUTIONS
- Universal precautions shall be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices. Caution shall be exercised when handling devices with sharp points or cutting edges.
- Personal Protective Equipment (PPE) shall 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 shall 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 a damp cloth.
- Automated cleaning shall not be used when cleaning the handpiece and hose. Only manual cleaning process is acceptable.
- Instruments shall be removed from trays and cleaned separately.
- Cleaning agents with chlorine or chloride as the 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 shall be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.
- Used instruments must be transported 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 shall 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 shall 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 shall be attached to the handpiece prior to cleaning to ensure that no liquid can enter the handpiece through the nitrogen port.
- Prior to cleaning, set to the handpiece to "safe" mode to ensure all ports are locked and will prevent liquid from entering the system.
- **Never** submerge the handpiece or hose in any solution as this will allow liquid to enter internal workings of handpiece 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.
- Rinse in purified water (from one or any combination of the following processes: ultra-filter, reverse osmosis, deionized 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 scratches. 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 in the case and close the case securely making sure the cover fits snuggly and latches are fully closed.
- Set to the handpiece to "safe" mode to ensure all ports are locked and will prevent steam from entering the system.
- The hose must be removed from the handpiece, and the respective sterilization cap must be latched onto the airport prior to steam sterilization to prevent steam from entering the system.
- Steam sterilize using a pre-vacuum cycle with an exposure time of four (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 shall be increased for larger loads.
- As per AAMI guidelines, IUSS (Immediate use steam sterilization) or "Flash" sterilization is not recommended for the VersaDriver.
- Instrument sets shall 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 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 shall 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 shall be increased for larger loads.

Warranty:

Limited warranty and disclaimer: Brasseler VersaDriver Handpieces 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.

Authorized Brasseler Service Partners:

Brasseler USA Repairs Department
One Brasseler Blvd.
Savannah, GA 31419 USA
Telephone 1-800-841-4522

Brasseler U.S.A. Medical, LLC
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