

CLEANING & STERILIZATION INSTRUCTIONS

Cutting Accessories

- *Burs*
- *Saw Blades*
- *K-Wires*
- *Steinmann Pins*
- *Twist Drills*



EXPLANATION OF SYMBOLS



Batch code.



Catalog number.



Consult instructions for use.



Date of manufacture.



Do not discard. Dispose of product or recycle in accordance with local laws and regulations.



Do not re-sterilize.



Do not reuse.



Do not use if package is damaged.



Manufacturer.



Non-sterile.



Sterilized using irradiation.



Use by.

CLEANING RECOMMENDATIONS

CAUTIONS & WARNINGS:

- Do not re-use or reprocess used cutting accessories.
- Follow the instructions and warnings issued by the suppliers of any cleaning and disinfection agents and equipment used.
- Follow universal precautions and protective apparel when handling and cleaning contaminated cutting accessories.
- Dispose of all cutting accessories properly after each use.
- Do not clean or re-sterilize cannulated drills, tool steel, 440 steel, laser welded or brazed two piece saw blades.
- Do not process accessories in automated washer-sterilizer.

General to all Cutting Accessories:

- Only use with appropriate power system. See applicable power system instructions for use.
- Do not use cutting accessory at speeds exceeding the handpiece manufacturer's specifications.
- Dispose of product or recycle in accordance with local laws and regulations.

Burs, Rasps and Twist Drills:

- Avoid applications of excessive lateral force.
- Use proper bur guard with bur per the handpiece manufacturer's specifications.
- Do not use carbide burs for twisting or bending cuts, breakage may occur.

Saw Blades:

- Do not use excessive force to twist or bend saw blades.
- Cutting in metal guides or accidental contact with metal retractors may damage the saw blade and may necessitate its replacement.
- Insert saw blade into alignment guide or cutting fixture prior to activating handpiece.
- Saw blades become hot from friction. Irrigation of saw blades is recommended during use and is required when using an alignment guide or cutting fixture.

K-Wires and Pins:

- Immobilize the patient's area of fixation to prevent excessive forces on the K-Wire or pin.
- Excessive forces on the K-Wire or pin may cause loosening or metal fatigue and subsequent device fracture.
- K-Wires or pins should be removed as soon as adequate healing has occurred.

Note: The effects of the Magnetic Resonance environment on the K-Wires and Steinmann Pins have not been determined. These medical devices have not been tested for magnetic field/migration, artifacts or heating in the MRI environment.

CLEANING PROCEDURES:

- It is always recommended to use unused sterile cutting accessories in each procedure.
- Unused cutting accessory removed from original non-sterile package:
 1. Sterilize as directed on the table on page 8.
- Unused cutting accessory contaminated during surgery:
 1. Remove cutting accessories from handpiece and or attachment.
 2. Clean cutting accessories as soon as possible to avoid drying of contaminants. Disinfecting the cutting accessories may be needed to protect personnel handling the instrument before cleaning and sterilization. If cleaning must be delayed, immerse the cutting accessory in a neutral-pH cleaning solution to prevent drying of contaminants on the instrument.

Saw Blades, K-Wires and Pins:

1. Rinse soiled cutting accessory thoroughly with a large amount of lukewarm (target lower end of the 72-110°F/22-43°C temperature range) running tap water for a minimum of one (1) minute.
2. Make an enzymatic cleaning solution such as STERIS® Prolystica™ 2x Concentrate Enzymatic Presoak and Cleaner [1/8 ounce per one (1) gallon of warm tap water] (target lower end of the 91-109°F/33-43°C temperature range).
3. Soak the cutting accessory in the enzymatic cleaning solution for two (2) minutes, making sure the cutting accessory is completely immersed to prevent aerosolization of contaminants.
4. Manually clean the cutting accessory using a soft-bristled brush for one (1) minute to remove soil and debris.
5. Rinse soiled cutting accessory by immersing the cutting accessory in a sufficient volume (enough to cover the device) of lukewarm, tap water (target lower end of the 72-110°F/22-43°C temperature range) for one (1) minute.
6. Repeat Step 5 two (2) more times for a total of three (3) rinses. Visually inspect cutting accessories for the presence or absence of residual soil and/or cleaner.
7. Dry immediately with a clean lint-free soft cloth.
8. Inspect for damage and replace with new cutting accessory if damaged.
9. Sterilize as directed on the table on page 8.

Burs - *Recommended Manual Cleaning Procedure (Rotary Instruments):*

1. Rinse the burs in running cool tap water for one (1) minute.
2. Prepare a fresh neutral-pH, enzymatic cleaning solution (such as Enzol) per Manufacturer's worst-case instructions by using one (1) ounce per gallon of warm (86-109°F/30-43°C) tap water.
3. Immerse the burs in the cleaning solution and soak in the prepared solution for ten (10) minutes.
4. Using a stiff-bristled brush, clean each bur individually for a minimum of one (1) minute to remove contaminants. Care should be taken to clean crevices and other hard to reach areas thoroughly.
5. Thoroughly rinse the burs under running warm tap water (temperature to not exceed 113°F/45°C) for a minimum of one (1) minute and until visibly clean.
6. Prepare a fresh neutral pH enzymatic solution (see Step 3) in a sonicator bath. Completely submerge the burs in the solution and sonicate for fifteen (15) minutes. Separate burs from contacting and damaging each other.
7. Rinse device using running tap water (temperature to not exceed 113°F/45°C) for a minimum of one (1) minute.
8. Visually inspect devices for residual soil.
9. Dry immediately with a clean lint-free soft cloth.
10. Inspect for damage and replace with new cutting accessory if damaged.
11. Sterilize as directed on the table on page 8.

STERILIZATION RECOMMENDATIONS

WARNINGS:

- The use of disinfecting solutions for an exterior instrument wipe will not sterilize the cutting accessory.
- Inspect sterilized cutting accessories. If discoloration or rust is visible do not use.

CAUTIONS:

- Do not process in automated washer-sterilizer.
- Do not re-use or reprocess used cutting accessories.
- Do not use cold sterilization solutions as these contain oxidizing agents which may cause damage to the device.
- Do not sterilize while connected to handpiece and or attachment.
- Wrap the instruments per AAMI recognized guidelines.
- Follow the sterilizer manufacturer's written instructions for cycle parameters, load configuration and AAMI guidelines for steam sterilization.
- Do not clean or re-sterilize cannulated drills, tool steel, 440 steel, laser welded or brazed two piece saw blades.

PARAMETERS FOR STERILIZATION

Saw Blades/K-Wires/Steinmann Pins/Twist Drills

Steam Sterilization Type	Minimum Temperature	Minimum Exposure Time	Minimum Dry Time
Pre-Vacuum (Wrapped)	270° F (132° C)	4 minutes	30 minutes
Gravity (Wrapped)	270° F (132° C)	15 minutes	30 minutes

Burs – Stainless Steel, Carbide and Diamond

Steam Sterilization Type	Minimum Temperature	Minimum Exposure Time	Minimum Dry Time
Pre-Vacuum (Pouch)	273° F (134° C)	3 minutes	30 minutes
Gravity (Pouch)	275° F (135° C)	10 minutes	30 minutes

Note: These processes have been validated for a one-time sterilization as being capable of cleaning and sterilizing Burs/Saw Blades/K-Wires/Steinmann Pins/Twist Drills.

RETURN GOODS POLICY

If product needs to be returned, the following applies:

Consumable/Disposable Product:

Any unused consumable/disposable product may be returned for credit within ninety (90) days of invoice date if it qualifies for resale (unopened and unmarked package). Products may be subject to a restocking fee. Credit will not be issued for products that do not qualify for resale.

Capital Equipment:

Any unused capital equipment may be returned for credit within thirty (30) days of invoice date if it qualifies for resale (unopened and unmarked package). Products may be subject to a restocking fee. Credit will not be issued for products that do not qualify for resale.

Packaging and Shipping:

Returned items should be packaged in original packaging. Credit will not be issued for items damaged in return shipment due to packaging inadequacy.

Note: It is unlawful to ship contaminated non-sterilized products.

Contact a Customer Service Representative at Brasseler USA® Surgical Power & Accessories at 800.535.6638 to obtain a "Return Merchandise Authorization" (RMA) number.

Please include the following information with the returned product(s):

- Catalog number, serial number and lot number (if applicable) of device.
- Return Merchandise Authorization (RMA) number noted with the return.
- Original invoice number or copy of original invoice.
- Original invoice date.
- Customer name, address and account number.
- Itemized packing list.
- Brief statement describing reason for product return.

Return to:

Brasseler USA® Surgical Power & Accessories
4837 McGrath Street
Ventura, CA 93003

PRODUCT DISPOSAL

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



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