

# CLEANING & STERILIZATION INSTRUCTIONS

## Cutting Accessories

- *Burs*
- *Blades*
- *K-Wires*
- *Steinman Pins*
- *Twist Drills*



## EXPLANATION OF SYMBOLS



Authorized representative in the European community.



Batch code.



Catalog number.



Conforms with the essential requirements of the European community directives.



Consult instructions for use.



Date of manufacture.



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.
- Under certain classifications of risk, the World Health Organization (WHO), or local regulatory authorities recommend special CJD (Creutzfeldt-Jakob Disease) inactivation processing procedures. Consult WHO and local regulations for further information.
- Do not clean or re-sterilize cannulated drills, tool steel, 440 steel, laser welded or brazed two piece 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 blades.
- Cutting in metal guides or accidental contact with metal retractors may damage the 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 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 pin should be removed as soon as adequate healing has occurred.

## 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 and K-Wires:

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 blades.

## PARAMETERS FOR STERILIZATION

Blades/K-Wires/Steinman 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/Blades/K-Wires/Steinman Pins/Twist Drills.



## **RETURN GOODS POLICY**

Contact your distributor regarding returned goods policy.

## **PRODUCT DISPOSAL**

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





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