

USE, CARE & STERILIZATION INSTRUCTIONS







Consumable Accessories









- *Burs*
- *Saw Blades*
- *K-Wires*
- *Steinmann Pins*
- *Twist Drills*
- *Rasps*
- *Ortho Pins/Drills*
- *Guide Wires*



BRASSLER
USA[®] SURGICAL INSTRUMENTATION

EXPLANATION OF SYMBOLS

Symbol	Meaning	Standard
	Caution.	ISO 15223-1
<i>Rx Only</i>	Federal law restricts this device to sale by or on the order of a “dentist/physician” licensed by the law of the state in which he/she practices to use or order the use of the device.	<i>FDA 21 CFR Part 801.109 (b)(1)</i>
	Manufacturer.	ISO 15223-1
	Date of manufacture.	ISO 15223-1
	Authorized representative in the EC.	ISO 15223-1
	Catalog number.	ISO 15223-1
	Batch code.	ISO 15223-1

Symbol	Meaning	Standard
	Quantity.	N/A
	Sterile using irradiation.	ISO 15223-1
	Use by date.	ISO 15223-1
	Do not re-use.	ISO 15223-1
	Non-sterile.	ISO 15223-1
	Do not use if package is damaged.	ISO 15223-1
	Consult instructions for use.	ISO 15223-1
	Do not re-sterilize.	ISO 15223-1

CAUTIONS & WARNINGS

- Do not re-use or reprocess used consumable accessories. If a consumable is to be re-used, there is a potential for bone necrosis and cross contamination.
- 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 consumable accessories.
- Do not clean or re-sterilize cannulated twist drills, high speed burs, laser welded or brazed two piece saw blades. Failure to follow these instructions may result in corrosion, oxidization, or rusting of the product. Excessive corrosion, oxidization, or rusting in the cannula of the cannulated twist drills may result in interference with consumable accessories running through the cannula during use.
- Consumable Accessories manufactured from stainless steel contain nickel and should not be used on individuals with known allergic sensitivity to this metal as it may cause hypersensitivity.
- Do not process consumable accessories in automated washer-sterilizer.

General to all Consumable Accessories:

- The product is intended for use only by authorized persons fully trained in their safe and effective use.
- In case of unexpected product anomaly, it is recommended to have back-up consumable accessories to reduce any surgical delays and to prevent prolonged or additional anesthesia exposure.
- Consider potential patient reactions to contact with a particular metal to avoid possible allergic reaction.
- Inspect product package for any damage that may affect sterility prior to use.
- Inspect for debris on product in pouch prior to use. If contaminants can be seen do not use.
- Always verify sterile product is within its labeled expiration date to ensure sterility prior to use.
- Only use with appropriate power system. See applicable power system instructions for use.
- Do not use consumable accessory at speeds exceeding the handpiece manufacturer's specifications. Lack of adherence to recommended speed specifications, may result in possible increased vibration, chatter and/or damage to handpiece.

- Irrigation is recommended during use as necessary to prevent tissue or bone necrosis.
- Do not come into contact with other metallic objects such as retractors during use to prevent consumable accessory 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 consumable accessory failure such as bending or breakage. Exercise extra caution when used with alignment guides or cutting fixtures.
- Dispose of product or recycle in accordance with local laws and regulations.
- All product should be stored in an environment that prevents premature degradation. The product should be protected from prolonged exposure to direct UV light, excessive heat, and humidity.

Burs, Rasps and Twist Drills:

- Use proper bur guard with bur per the handpiece manufacturer's specifications. Failure to follow manufacturer's guidelines may result in breakage and/or patient injury.
- Do not use bur/twist drill to bend, pry or come into contact with metallic objects. Failure to do so can lead to breakage or metal shavings in the surgical site.
- Do not re-sterilize cannulated twist drills.

Saw Blades and Rasps:

- 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. Failure to do so may result in damage to the cutting end of the saw blade. Damage to the saw blade may create difficulty in inserting saw blade through alignment guide.
- Saw blades may become hot from friction. Irrigation of saw 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 laser welded or brazed two piece saw blades. Failure to follow these instructions may result in corrosion, oxidization, or rusting of the product.

K-Wires, Steinmann Pins and Guide Wires:

- 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. Failure to remove K-Wires, may result in infection, breakage and/or bending and/or loss of fixation due to the potential migration of the K-Wire.

Magnetic Resonance Imaging (MRI) Safety Statement: 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 INSTRUCTIONS:

- Do not re-use or reprocess used consumable accessories. If a consumable is to be re-used, there is a potential for bone necrosis and cross contamination.
- Unused consumable accessory removed from original non-sterile package:
 1. Sterilize as directed on the table on page 8.
- Unused consumable accessory contaminated during surgery:
 1. Remove consumable accessories from handpiece and or attachment.
 2. Clean consumable accessories as soon as possible to avoid drying of contaminants. Disinfecting the consumable accessories may be needed to protect personnel handling of the instrument before cleaning and sterilization. If cleaning must be delayed, immerse the consumable accessory in a neutral-pH cleaning solution to prevent drying of contaminants on the instrument.

Opened and Unused Burs, Saw Blades, K-Wires, Steinmann Pins and Guide Wires:

1. Rinse soiled consumable 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 consumable accessory in the enzymatic cleaning solution for two (2) minutes, making sure the consumable accessory is completely immersed to prevent aerosolization of contaminants.
4. Manually clean the consumable accessory using a soft-bristled brush for one (1) minute to remove soil and debris.
5. Rinse soiled consumable accessory by immersing the consumable 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 consumable 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 consumable accessory if damaged.
9. Sterilize as directed on the table on page 8.

STERILIZATION INSTRUCTIONS

WARNINGS:

- The use of disinfecting solutions for an exterior instrument wipe will not sterilize the consumable accessory.
- Inspect sterilized consumable accessories. If discoloration or rust is visible do not use to avoid potential patient toxicological and/or allergic reaction.

CAUTIONS:

- Do not re-use or reprocess used consumable accessories. If a consumable is to be re-used, there is a potential for bone necrosis and cross contamination.
- Do not use cold sterilization solutions as these contain oxidizing agents which may cause damage to the device.
- Do not sterilize the consumable while connected to handpiece and/or attachment as this may result in the product not being properly sterilized.
- 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 laser welded or brazed two piece saw blades. Failure to follow these instructions may result in corrosion, oxidization, or rusting of the product.

PARAMETERS FOR STERILIZATION

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

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/Guide Wires.

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.

Canadian customers contact your distributor for return policies.

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

Contact a Customer Service Representative at Brasseler USA® Surgical Instrumentation 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 Instrumentation
4837 McGrath Street
Ventura, CA 93003

Canadian customers contact your distributor for return policies.



PRODUCT DISPOSAL

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



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