

Description:

Brasseler U.S.A. Accessories include Saw Blades, Rasps, Burs, and Twist Drills, K-Wires, Steinmann Pins, Guide Wires and Orthopedic Pins. These devices are made of surgical grade stainless steel, tool steel and/or tungsten carbide, and designed to fit into a surgical jig, or power system.

Intended Use:

These accessories are intended for use by professional users to;

- Cut, shape, resect for using Saw Blades and Rasps on bone and soft tissue.
- Drill or resect using Twist Drills and Burs on bone.
- Fixate bone or soft tissue using K-Wires, Steinmann Pins, and Orthopedic Pins.
- Secure alignment of bone fragments with using

Guidewires. in a healthcare environment in the course of conducting a surgical procedure.

General Precautions:

- This device should only be used in compliance with its intended use.
- 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.
- 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.
- 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.
- Follow the instructions and warnings issued by the suppliers of any cleaning and disinfection agents and equipment used.

General Warnings:

- 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 consumable accessories from a different lot 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.
- Do not use accessories if, upon receipt, package is opened, damaged or shows any sign of tampering or debris.
- Prior to use, inspect the accessory for signs of corrosion or oxidation. Do not use the accessory if corrosion or oxidation is present.
- 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 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.
- Do not use consumable accessory with a handpiece not maintained according to the manufacturer's specifications.
- Lack of adherence to maintenance specifications, may result in possible increased blade or tooth breakage.
- Irrigation is recommended during use as necessary to prevent tissue or bone necrosis.
- Do not allow the accessory to 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.
- After use, accessories may be a potential biohazard and should be handled and disposed with acceptable medical practice and local laws, national requirements, 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.

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.

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.

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.

Orthopedic Pins:

- Care must be taken not to cut through surgical gloves when handling any sharp-edge orthopedic device.
- Pins are intended for single use only. Reuse of pins may increase the risk of product damage and patient injury.
- Do not use if the pins exhibit signs of corrosion or damage.
- Avoid placing pins into bone sections which are subject to high tensile or torsional stress moments in order to minimize the risk of stress fractures.
- Transcortical pin fixation is detrimental to bone strength and

may be associated with increased risk of bone necrosis.

- Ensure low drilling speed to avoid excessive heat generation which may result in bone necrosis. External irrigation should be applied, if possible.

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

Saw Blades and Rasps:

- Use caution when utilizing metal guides to minimize metal on metal contact as damage to saw blade may occur 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 sawblade 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.
- Always inspect for bent, dull, or damaged blades or burs before each use. Do not attempt to straighten or sharpen. Do not use if damaged.

Indications for Use: (Below is not an exhaustive list of accessory applications)

- **Large Bone Saw Blades**
Large bone saw blades are used in orthopedic surgeries in cases requiring bone cutting such as, but not limited to total knee arthroplasty, or amputation, or autopsy.
- **Sagittal**
Sagittal saw blades are ideal for cutting precise wedges and transverse osteotomies.
- **Oscillating**
Oscillating saw blades provide accurate cutting for curved and straight osteotomies in orthopaedic, oral/maxillofacial, and podiatric applications.
- **Reciprocating**
Reciprocating saw blades are outstanding for transverse osteotomies necessary in orthopedic, oral/maxillofacial, and podiatric applications.
- **Rasps**
Small bone reciprocating rasps are designed for contouring bone.
- **Twist Drills**
Twist Drills are burs used to make holes in bones or hard tissue.
- **Burs**
Surgical burs are designed for use Neurosurgical, Orthopaedic, Oral/Maxillofacial, Plastic, and Reconstructive Surgery.

- **K-Wires and Steinmann Pins**
Used for internal fixation of small and large bone fractures.
- **Guide Wires**
Guide Wires are specifically used to mark the prescribed path for Designated cannulated screw and secures alignment of the bone Fragments while the screw is being insert.
- **Orthopedic Pins**
Orthopedic Pins are to fixate cutting blocks and other devices to Bone during hip, knee, shoulder, extremity arthroplasty, and trauma surgeries.

Cleaning Instructions:

- Unused consumable accessory removed from original non-sterile package:
 1. Sterilize as directed on the table on page 3.
- 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 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 K-Wires, Steinmann Pins, Guide Wires, Orthopedic Pins, Burs, and Saw Blades:

Exclusion – Opened and Unused cannulated twist drills, high speed burs, laser welded or brazed two piece saw blades cannot be cleaned or re-sterilized as this may cause corrosion or oxidation and should be discarded.

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.



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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.
- 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, oxidation, or rusting of the product.

Cautions:

- 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.

Parameters for Sterilization:

Sawblades/Twist Drills/K-Wires/Steinmann Pins

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 / Twist Drills / K-Wires / Steinmann Pins / Guidewires / Orthopedic Pins.

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.

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