

**Description:**

BUSA Consumable Accessories include Saw Blades, Rasps, Burs, and Twist Drills. 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:**

BUSA Consumable Accessories are medical devices intended to be used on human patients to cut, shape, resect and drill bone or soft tissue during surgical procedures. These devices are intended to be used by licensed medical professionals in a healthcare environment in the course of conducting surgical procedures.

**Intended Patient Population:**

- Devices are intended for use in patients with diseases requiring surgical intervention.

**Terminal Sterilization:**

- Devices that are sold sterile are noted on the packaging with the sterile symbol. Sterile product is sterilized by gamma radiation.

**Product Life Cycle:**

- All devices are single use devices. Re-use of a device can potentially cause bone necrosis and cross contamination.

**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.

**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.

**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.
- 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:**

BUSA consumables are indicated to be used on long, short, flat, sesamoid and irregular bones of the body. Procedures include but are not limited to orthopedic, orthopedic trauma, foot and ankle, oral maxillofacial, cardiovascular, neuro and spine procedures.

**Contraindications:**

- Devices should not be used on patients known to have metal allergies to Nickel.

**Residual Risks:**

- Risk of Thermal Osteonecrosis

**Substance of Concern Precaution:**

- Some products contain nickel, which is suspected of causing cancer. Caution is advised when using on high-risk patients.
- All of the high speed carbide burs contain cobalt. Cobalt is suspected of causing cancer and is known to damage fertility. Caution is advised when using on high-risk patients.

**Cleaning Instructions:**

- 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 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, Twist Drills 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 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 [0.977 mL per one (1) liter of warm tap water] (target lower end of the 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 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.

**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**

Steam Sterilization Type	Minimum Temperature	Minimum Exposure Time	Minimum Dry Time
Pre-Vacuum (Wrapped)	132° C	4 minutes	30 minutes
Gravity (Wrapped)	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)	134° C	3 minutes	30 minutes
Gravity (Pouch)	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.**

**Glossary of Symbols:**

[busamedical.com/resources/](http://busamedical.com/resources/)

**In Case of Injury:**

In the case of a serious incident or injury that has occurred in relation to the device, notify the manufacturer and the local regulatory authorities of the Member State in which the user or patient is established.

**Return Goods Policy:**

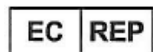
Contact your distributor regarding return goods policy.

**Product Disposal:**

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



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