ARTHREX-BUSA CONSUMABLE ACCESSORIES

BASIC UDI-DI: 00887919TD-CONSUMABLES

Instructions For Use

Description:
Arthrex-BUSA Consumable Accessories include Saw Blades. These devices are made of surgical grade stainless steel and designed to fit into a surgical jig, or power system.

Intended Use / Purpose:
Arthrex-BUSA Consumable Accessories are medical devices intended to be used on human patients to cut and resect bone or -hard tissue during surgical procedures. These devices are intended to be used by licensed medical professionals in a healthcare environment while conducting surgical procedures.

Intended Patient Population:

- Devices are intended for use in patients of all ages requiring surgical intervention where the cutting, shaping and/or resecting bone or hard tissue is necessitated.

Terminal Sterilization:

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

Product Life Cycle:

- Arthrex-BUSA cutting accessories are transient medical devices, are intended for single use only and must not be reused.

General Precautions:

- This device should only be used in compliance with its intended use.
- Do not re-use or reprocess used consumable accessories. Re-use of a single use device may lead to patient or user injury. Possible risks associated with re-use of a single use device include, but are not limited to infection, mechanical failures that lead to bone/soft tissue damage or thermal necrosis.
- 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.
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- Consumable Accessories addressed in this IFU are sharp objects and must be handled with caution and according to acceptable local and national recommendations to prevent injuries.
- Follow local and national laws and regulations and use personal protective equipment when handling contaminated consumable accessories after use as it presents a potential biohazard.

General Warnings:

- The product is intended for use only by fully trained health care professionals in their safe and effective use.
- The product is intended to be a single use device and shall not be reprocessed.
- 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 (recommended range -30°C – 60°C), and humidity (recommended range 15% - 90%).

Saw Blades:

- 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 before each use. Do not attempt to straighten or sharpen. Do not use if damaged.

Indications for Use:
Arthrex-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 and foot and ankle.

Clinical Benefits

- A multiple-sized offering of consumable accessories allows the user to precisely to cut, shape and/or resect bone or hard tissue during surgical procedures.

IFU-0051 REV C
Date of Revision: 2026-05-26
EDCO 26.0120

Contraindications:

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

Potential Adverse Events, Residual Risks:

- Thermal bone or soft tissue necrosis
- Damage to bone, nerve, vessels, and other soft tissues
- Infection
- Adverse tissue reaction, such as hypersensitivity and irritation
- Fragments or shavings may end up in the patient's body in some cases of breakage. Fragments or shavings can be poorly tolerated by the body or implant with possible cytotoxicity, genotoxicity, carcinogenicity and other toxicity implications. They should be removed when possible.
- Fragments left in the body may result in displacement, localized heating, or artifacts in an MRI environment

Substance of Concern Precaution:

- Some products contain nickel, which is suspected of causing cancer. Caution is advised when using on high-risk patients.

Glossary of Symbols:
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:

Products addressed in this IFU are considered to be sharp objects. Dispose of product using a sharps container or recycle in accordance with local laws and regulations.

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