



OPERATIV SAWBLADE INSTRUCTIONS FOR USE (IFU)

STERILE PRODUCTS

PRODUCTS

Part Number	Description
011201-90	12.5MM x 90MM x 1.27MM Sagittal Blade, Stryker Replacement
011202-90	19MM x 90MM x 1.27MM Sagittal Blade, Stryker Replacement
011203-20	9MM x 20MM x 0.79MM Sagittal Blade, Stryker Replacement
011204-90	23MM x 90MM x 1.27MM Sagittal Blade, Stryker Replacement
011291-90	MIS 12.5MM x 90MM x 1.27MM Sagittal Blade, Stryker Replacement
011300-80	11MM x 80MM x 0.76MM Reciprocating Blade, Stryker Replacement
011201-91	12.5MM x 90MM x 1.27MM Sagittal Blade, ConMed Hall Replacement
011202-91	19MM x 90MM x 1.27MM Sagittal Blade, ConMed Hall Replacement
011203-21	9MM x 20MM x 0.79MM Sagittal Blade, ConMed Hall Replacement
011204-91	23MM x 90MM x 1.27MM Sagittal Blade, ConMed Hall Replacement
011291-91	MIS 12.5MM x 90MM x 1.27MM Sagittal Blade, ConMed Hall Replacement
011300-81	11MM x 80MM x 0.76MM Reciprocating Blade, ConMed Hall Replacement

PRODUCT DESCRIPTION

All parts listed above are supplied as single use sterile. If sterile barrier is compromised consider the product not sterile. They must be cleaned and sterilized according to the guidelines below.

Operativ sawblades are manual instruments that are used to cut bone during surgery.

MATERIAL SPECIFICATIONS

Stainless steel per ASTM F899

INTENDED USE/INDICATIONS FOR USE

Sawblades are used in conjunction with a powered handpiece that is used in orthopedic surgical procedures.

INSTRUCTIONS

General

1. All items are strictly intended to be used and handled only by appropriately trained medical professionals who are familiar with their use and application in a normal hospital, clinic or ASC environment.
2. It is the user's responsibility to become familiar with the instructions for use, cautions and warnings prior to the use of these items.
3. Eye protection for operating room personnel is recommended at all times.
4. Inspect instruments and accessories prior to use.
5. Never use a damaged instrument or accessory.
6. Ensure proper insertion and tightening of the accessory into the instrument prior to use.
7. Use the require attachment and guard.
8. Protect patient tissue at all times.
9. Observe accessory during use to ensure proper operation and avoid damage to the accessory or instrument.
10. Contact with metal parts, fixtures, retractors or parts may cause damage to the accessory which could result in the replacement of the accessory.
11. A new accessory is recommended for each procedure.
12. Do not reuse, reprocess or sharpen used cutting accessories.
13. If sterilization is required, observe the manufacturers guidelines for steam sterilization equipment.
14. Observe the safe and proper disposal of accessories after use.

Sawblades

1. Only use with appropriate power system. See applicable power system instructions for use.
2. Avoid using excessive force and twisting or bending of the sawblade in any unnatural or unintended way.
3. When using a slotted fixture or capture, never start the instrument without the sawblade being first inserted properly into the slot.
4. Irrigation of the sawblade during use is always recommended and necessary when used with an alignment guide, capture or slotted fixture as the sawblade could become warm from friction.

CONTRAINDICATIONS

1. Foreign body sensitivity, known or suspected allergies to implant and/or sawblade materials.
2. Active sepsis or infection.
3. Conditions that tend to limit the patient's ability or willingness to restrict activities or to follow directions during the healing and rehabilitation period.

WARNINGS

1. The sawblades are extremely sharp. Improper handling may result in injury.

2. Patient should be advised that product materials might cause allergic reactions, including without limitation foreign body reaction, tissue irritation and inflammation, or other allergic reactions. Where material sensitivity is suspected, appropriate test should be made and sensitivity ruled out prior to use.
3. Additional warnings include those applicable to any surgical procedure. In general, careful attention must be paid to asepsis and avoidance to anatomical hazards.
4. Do not apply side or bending loads. Application of side or bending loads may result in breakage of the sawblades and risk of tissue damage or debris.
5. Beyond a single use, the precision and integrity of the sawblade could be compromised and cause breakage.

ADVERSE EFFECTS

1. Deep and superficial infections.
2. Allergies, tissue irritation and inflammation, and other reactions to materials.
3. Transient local fluid accumulation or sinus formation, arthritis pain or deformity and stiffness.
4. Bone fracture.

CLEANING AND STERILIZATION GUIDELINES

Sawblades are single use and should not be reprocessed.

CLEANING (for rare occurrence of when the sterility barrier is compromised)

1. Follow universal precautions for protective apparel when handling and cleaning non-sterile products.
2. Place the sawblades in a basin with distilled water.
NOTE: Saline solution is not recommended, as it has a corrosive effect on certain metals.
3. The sawblades should be cleaned using a neutral pH cleaning solution and a non-abrasive brush.
4. Rinse the sawblades under running water followed by a rinse in distilled water.
5. Dry the sawblades completely using a clean, lint-free towel.

STEAM STERILIZATION (for rare occurrence of when the sterility barrier is compromised)

WARNINGS

1. Do not use EtO or gamma sterilization.
2. Do not use disinfecting solutions to sterilize the sawblades.

Follow AAMI Guidelines. For sterilization of sawblades in a tray, consult guidelines provided with the specific sterilization tray.

CAUTION

Federal law (USA) restricts this sawblade to sale, distribution, or use by or on the order of a licensed healthcare practitioner.

STERILITY

The sawblades are sterilized by exposure to gamma radiation. Do not re-sterilize after use. Do not use past expiration date.

DISCLAIMER

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CONTACT INFORMATION

For more information or a product demonstration, contact your Operativ sales representative, or call 1-425-284-7262 in the United States.



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