INSTRUCTIONS FOR USE
SURGICAL SAW BLADES, STERILE

FOR ADDITIONAL INFORMATION PLEASE CONTACT:

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PRODUCT DESCRIPTION

The device is a sterile, single-use surgical saw blade intended for cutting bone in orthopedic and trauma surgeries. Manufactured by newbox medical GmbH, these saw blades are designed to attach to powered surgical saw handpieces and facilitate precise osteotomies (bone cuts) during surgical procedures and fracture repair.

With the purchase of this surgical saw blade, you receive a high-quality product, the proper handling and use of which is described below.

⚠ WARNING

Read the entire instructions for use carefully, follow the inst- ructions and keep the instructions for use in order to minimize risks and burdens for the patient.

⚠ WARNING

THE PACKAGING CONTAINS STERILE PRODUCT FOR SINGLE USE ONLY

⚠ WARNING

SURGICAL INSTRUMENTS SHOULD ONLY BE USED BY TRAI- NED AND QUALIFIED MEDICAL PERSONNEL. WHEN USING ON PATIENTS' IT IS ESSENTIAL TO ENSURE THAT A SUITABLE ALTERNATIVE SYSTEM IS ON HAND AS TECHNICAL PROBLEMS CAN NEVER BE RULED OUT. NEWBOX MEDICAL GMBH SAW BLADES ARE INTENDED FOR USE ONLY ON HUMANS. NEWBOX MEDICAL GMBH SAW BLADES ARE NOT TO BE USED ON THE CENTRAL NERVOUS SYSTEM.

IDENTIFICATION

Basis-UDI: 4059216SB1BF
SRN: DE-MF-000020279

INTENDED PURPOSE

newbox medical GmbH saw blades are intended to be used by qualified surgeons for cutting and resecting bone tissue during a variety of surgical procedures.

MATERIAL INFORMATION

The saw blades are manufactured from surgical-grade stainless steel (1.4028 and 1.4310), selected for its biocompatibility, durability, and corrosion resistance. The product does not contain any natural rubber latex or phthalates.

INTENDED USER

Saw blades are intended for use by trained healthcare professionals, specifically orthopaedic surgeons and other surgical specialists.

PATIENT POPULATION

Saw blades are dedicated to sawing and separation of bones in orthopaedics and trauma patients.

EXPECTED CLINICAL PERFORMANCE

Sawing and separation of bones.

INDICATIONS

The saw blades are preferably used in surgical orthopaedics and traumatology. Their field of application lies within the following areas:

- Arthrosis
- Bone deformities
- Bone misalignments
- Bone infections
- Fractures
- Cruciate ligament rupture
- Posterior, posteromedial, and posterolateral knee instability
- Hallux valgus
- Hallux rigidus
- Bone lesions

CONTRAINDICATIONS

The saw blades should not be used under the following conditions or a risk-benefit assessment should be performed in advance:

- Prolonged blood clotting from intake of substances that cause it; may have to be withdrawn before the operation
- Serious systemic diseases that make survival after the operation unlikely
- Neurosurgical interventions
- Acute and chronic infections
- Lack of bone substance or poor bone quality
- Coagulation anomalies (haemophilia, Von Willebrand-Jürgens syndrome)
- Poor general condition of the patient which does not allow an operation
- Unacceptably high risk of anaesthesia
- Soft tissue damage
- Circulatory disorders
- Surgery before completion of growth (impairment of skeletal development)
- Existing metal allergies and all known contraindications applicable to surgical interventions

PRECAUTIONS

- The saw blade may not work properly, slip or break if excessive force (contact pressure) is applied
- In order to prevent damage due to increased temperature development during the use of the saw blade, it is strongly recommended to ensure sufficient cooling by rinsing with sterile saline
- It is strongly recommended that the fluids generated during the operation be aspirated during the procedure
- In any case of malfunctions or abnormal behaviour of the saw blade, the process should be stopped and the manufacturer contacted

WARNINGS

- Before use, please read the entire instruction manual carefully
- Use saw blades only in accordance with the information supplied with the device and the instruction for use for the motor systems / sawing machine
- Before use, make sure that the saw blades used are in perfect technical and sterile condition. Saw blades with any kind of damage or soiling are generally not to be used
- Before use check the expiration date of the saw blade. Expired saw blades are generally not to be used
- Before commissioning, check the label of the saw blade whether it is compatible with the motor system used. The saw blades may only be used with the motor system provided for this purpose

- Before commissioning, check that the saw blade is securely attached
- Use the saw blades only for their intended purpose
- Do not force the blade into incompatible systems. If resistance is encountered, discontinue use and check compatibility
- During use in the saw template, jamming or bending of the saw blade must be prevented. Do not use the saw blade as a lever under any circumstances
- Not authorized for work on metal. Do not allow instruments to come in contact with metal during use
- Make sure to provide sufficient cooling and rinsing
- Check the product and its packaging for any damage that may have occurred as a result of shipping and handling. In case of damage to the packaging, keep the package with its contents and notify the manufacturer
- You should not allow the active parts of the device to come into contact with large blood vessels to avoid possible injury
- Be extremely careful when using the saw blade, avoid using excessive force and watch out for possible damage. Unintentional movement can result in patient injury
- Do not touch the tip of the saw blades as this can result in injury

COMPLICATIONS / SIDE EFFECTS

- Nickel allergy or other immunological defence reactions; fever
- Bone healing disorders
- Extension of the operation / anaesthesia
- Nerve lesions -> short-term numbness or paralysis
- Injury of the epiphyseal plate in children
- Bleeding; haematomas
- Breaking of the saw blades

As in any moving device, in case of improper use or in case of accidental movement in the active state, the following may occur

- Injuries to surrounding tissue
- Injury to nearby blood vessels
- Necrosis of surrounding tissue if the temperature is too high due to insufficient cooling

CHECK BEFORE USE

Before surgical use, ensure the blade is fully and securely inserted into the corresponding powered handpiece. Each brand of surgical power tool features a unique interface. Improper insertion may lead to performance issues or surgical delays.

To validate that the device is correctly connected and ready for use:

- Confirm full engagement of the blade within the tool's coupling mechanism
- Perform a short test activation of the power tool to verify movement is smooth and vibration-free
- Inspect for any abnormal noise, instability, or looseness

IMPORTANT INFORMATION

These Instruction for Use do not contain all the information required for the proper selection and application of this device. Prior to use, please carefully consult the Instructions for Use for the corresponding power tool system as well as any other referenced documentation to ensure safe and effective operation.
It is the responsibility of the surgeon to assess the suitability of the device for the specific clinical application. This includes consideration of factors such as power output, compatibility with attachments, and appropriate blade selection based on bone density, anatomical location, and the required cutting performance.
When used in combination with implants, the user must be familiar with the recommended surgical techniques by referring to the implant manufacturer's Instructions for Use.
The manufacturer does not assume liability for complications resulting from improper diagnosis, incorrect selection of accessories, incompatible component combinations, improper surgical techniques, or insufficient aseptic procedures.
All available product variants, including blade types, sizes, and compatible interfaces, can be found in the newbox medical product catalog.

COMBINATION WITH OTHER DEVICES

The saw blades are designed to be compatible with a wide range of surgical power tool systems available on the market. Their design ensures proper fit and function with commonly used oscillating, reciprocating, and sagittal handpieces.
Compatible with:

ConMed/Hall: Micro 100™ 5053-011, Micro Power™ 6020-022, Micro Power™ 6021-022 sagittal saws, MicroChoice, 5040-002, Micro E 5020-022
MicroAire: 1950, 1955, 2250, 6670, 6672, 6673 sagittal saw

Aesculap/B. Braun: Acculan 3Ti GA673, GA668, Acculan 4 GA331, GA336
Aesculap/B. Braun: Acculan 3Ti GB440, GA635, GA674

ConMed/Hall: M Power PRO6300, M Power2 PRO6350M, PowerPro Max PRO5300M, PowerPro + PowerPro Electric II PRO6125, PowerPro Pneumatic PRO6175, Hall Serie 4 5067-002, Hall Serie 3 5044-002, Versipower Plus 5071-002, Hall 50 PRO7300B, Hall Titan PRO9300B
ConMed/Hall: MPower™ 2 Battery, Sternum Saw Pro 6450M, 5059-006, Pneumatic Sternum Saw 5059-005, Hall 50 Sternum Saw PRO7450B

DePuy Synthes: Colibri II 532-021
DePuy Synthes: Pen Drive, Electric Pen Drive
DePuy Synthes: Compact Air Drive II + Power Drive 511.800, 511.801, Air Power Line 511.610, Battery Power Line 530.610, TRS 05.001.224, 05.001.223, 05.001.240, Battery Power Line II 530.710
Zimmer Biomet: Zimmer Universal Power System, 89-8509-450-60

Stryker: System EHD (296-98), 2000 (2108), S4 (4108), S5 (4208), S6 (6208), S7 (7208), S8 (8208)
Stryker: 4206, 4106, 2106, 296-96, 6206, 7206, 8206 reciprocating saw

Smith & Nephew Dyonics® Power Corded

Madrimed ® Vinci 300
Arthrex DrillSaw Mini 300 ™-System

These saw blades are compatible with powered surgical handpieces that provide oscillating, sagittal, or reciprocating motion. All operating parameters (e.g., speed and motion settings) must follow the respective handpiece manufacturer's instructions, as these parameters are defined by the handpiece manufacturer and are not specified or controlled by the saw blade manufacturer.

STORAGE

The sterilized saw blades have 10 years shelf life. The expire date Is indicated on the packaging. For the storage are following instructions:

- Saw blades always be stored in its original protective packaging
- Store the surgical saw blades away from direct sunlight, dry and dust-free (standard clinic environments)
- Do not remove saw blades from the package until immediately before use.

REUSABILITY

The saw blades are intended for single use only. Any liability is excluded in the event of disregard.

Symbol	Explanation
	Manufacturer
	Date of manufacture
	Use-by date
LOT	Production lot number, batch number
REF	item number
STERILE R	Sterilized using irradiation
	Do not use if package is damaged and consult instruction for use
	Keep away from sunlight
	Keep dry
	Do not re-use, single use
	Consult Instruction for use or consult electronic instruction for use
	Caution
CE 1304	CE Marking according to Medical Devices Regulation 2017/745 Notified Body: SIQ Ljubljana SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY Mašera - Spasićeva ulica 10 1000 LJUBLJANA Slovenia
MD	Medical device
UDI	Unique Device Identification
Rx Only	Medical device restricted to use by or on the order of a qualified healthcare professional.
eIFU indicator	Instructions for use are provided in electronic format: www.newbox-medical.com/ifu A paper copy can be provided upon request.



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