

Instruction for use

Notice: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Intended purpose

EZX Blade are medical device for cutting bone, tissue, etc.

Claims for clinical performance

Cutting bone, being connected with AC-powered, battery-powered, or air-powered devices.

Contraindication





















It is not indicated for long-term use or implantation.

Complications

Complications related to EZX Blade are very rare, but when they occur, they can be serious.

- Patient burn or thermal necrosis
- Paralysis by wrong operation
- Tear or puncture dura or other central nervous system
- Frostbite, hematoma in target site etc. by infection
- Injury by wrong operation or cracked chip of blade

Explanation of symbols

	Catalogue number		Keep away from sunlight
	Batch code		Keep away from rain
	Federal law restricts this device to sale by or on the order of physician		Temperature limit
	Use by date		Humidity limitation
	Caution		Manufacturer
	Consult instructions for use		Distributor
	Do not re-use		Medical Device
	Do not use if package is damaged		Unique Device Identifier
	Do not re-sterilize		Authorized representative in the European community
	Sterilized using irradiation		
	Single sterile barrier system with protective packaging inside		

Proper use

- a. Before use
 1. Read Instruction for Use of the product to understand the method of use and precautions.
 2. Identify the status of Sterilization.
 3. Remove any screws and clear away any soft tissue to ensure no interference with the blade.
- b. Size the Liner and the Blade
 1. Remove the existed acetabular liner.
 2. Measure the inner diameter of the cup by using the Liner sizing tool included in the tray.
 3. Select the 1st Liner of the same size as the inner diameter of the cup.
 4. Place the 1st Liner in the cup.
 5. Measure the outer diameter of the cup by using the Blade sizing tool included in the tray.
 6. Select the Blade which is 2~3mm larger than the outer diameter of the cup.

Cooling

Sufficient cooling should be provided when using EZX Blade. In case of insufficient cooling, the EZX Blade teeth will get clogged with bone chips, leading to increased heat generation. At the worst, this may cause irreversible damage to the bone (thermal necrosis) and reduce service life of the saw blades considerably.

Disposal

It shall be disposed or managed as an infectious medical waste. It shall be inserted into container (hospital box) with inert double plastic bag (strong, leak proof, puncture proof) after use.

Caution

- EZX Blade are to sale by or on the order of a physician.
- See instruction for use. Important information.
- See detailed handpiece user instruction manual.
- Check the package before use. If package is opened or damaged, do not use.
- Single patient use only.
- Make sure blade is locked and secure before running handpiece and protect the vibrations by handpiece.
- Monitor blade and distal handpiece temperature.
- Irrigate surgical site to reduce heat.
- Do not use excessive force.
- Blunt and damaged EZX Blade must no longer be used.
- Do not use twice. This is single use product.
- Storage conditions in dust-free, cool and away from direct sunlight.
- The user of the product is responsible for proper use the equipment during surgery.

- This is single use device not intended for resterilization and reuse. The possible outcomes from the reuse of this could be, but not limited to; insufficient or improper cleaning/ registration resulting in cross-infection of patients or degradation of physical characteristics of the device which could pose a risk to the patient. Loss of structural integrity from repeated use is also possible. Detailed examples of possible outcomes from the reuse would be as below:
- Reprocessing a single-use device may alter its characteristics so that it no longer complies with the original manufacturer's specifications and performance may be compromised.
- This device has not undergone extensive testing, validation and documentation to ensure the devices are safe to reuse. Infection is one of the greatest patient safety concerns associated with reuse. The risk of cross infection may increase due to the inability of the reprocessing system to completely remove viable micro-organisms. This may be due to design e.g. narrow lumens. Viable micro-organisms may be incompletely removed and be transferred to the next patient
- Some materials can absorb certain chemicals which can gradually leach from the material over time. For e.g. disinfectants may be absorbed by plastics and leach out during use, resulting in chemical burns or a risk of sensitization of the patient or user.
- Chemicals may cause corrosion or changes to the materials of the device. For e.g., plastics may soften, crack or become brittle.
- The material may experience stress during reuse and may fail, stretch or break.
- Inadequately cleaned device can carry bacterial endotoxins which remain after bacteria are killed.
- Don't re-start the operation when the blade is staying (remaining) in the bone or tissue, etc. Blade can be broken by unexpected force.



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