CE
1639

BUSA®
SURGICAL INSTRUMENTATION

# EZX

## ACETABULAR CUP REMOVAL SYSTEM

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## INSTRUCTIONS

**Note: The components are protected by cable ties and bubble wrap. Before sterilization, make sure the packaging material is removed.**

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.

### A. Product Description

EZX is an attachment of Surgical Handpiece that delivers the rotational force of Surgical Handpiece. Being attached at the head of handpiece, it is connected and used with previously reported saw.

### B. Indication for use

EZX is intended to remove hemispherical, non-cemented acetabular cups.

### C. Claims for performance

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

### D. Directions for use

a. Before use

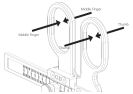
1. Read Instruction for Use of the product to understand the method of use and precautions.
2. Identify the status of Sterilization.
3. Remove any screws and clear away any soft tissue to ensure no interference with the blade.
4. Operate the device and inspect each component to identify any defects. If any damage or corrosion is found, the device should not be used.

b. Size the Liner and the Blade

1. Liner sizing tool and blade sizing tool
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.

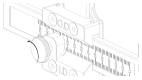
2.Sizing tool(XST2000M)

1) Remove the existed acetabular liner.
2) Grip the sizing tool as below figure.

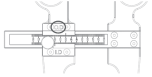


3) Press the jaw to the outer part of acetabular cup and adjust another jaw to contact with the opposite part.

4) After conforming the position of two jaws, fix the handle by rotating knob counterclockwise direction.

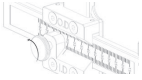


5) Measure the outer diameter of acetabular cup by reading O.D scale of indicator.

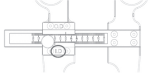


6) Press the jaw to the inner part of acetabular cup and adjust vanother jaw to contact with the opposite part.

7) After conforming the position of two jaws, fix the handle by rotating knob counterclockwise direction



8) Measure the inner diameter of acetabular cup by reading I.D scale of indicator.



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.

**Notice: How to assemble and inspect EZX liner**

1. When assembling the liner to the EZX shaft head, push the liner onto the distal end on the shaft head until you feel resistance against your hand.
2. Once the liner is assembled, hold the shaft vertically with the liner part on top. If the liner turns smoothly without moving up and down when rotated by hand, the assembly is successfully completed.
3. Do not use excessive force when assembling as it may damage the o-ring of the shaft head.

c. Removal of cup with T-handle

1. Assemble the Shaft and the Blade by inserting the connectors of the Blade into the slot.
2. Pull back the locking sleeve of the Rachet T-handle and connect with the Shaft.
3. Place the tip of the Shaft firmly to the center of the Liner.
4. Rotate and advance the Blade by turning the Rachet T-handle and pushing the side handle at the same time. Keep doing it until the Blade will create a guided pathway around the rim of the cup about 1~2mm depth.

d. Removal of cup with Power handpiece

1. Remove the 1st Liner and place the 2nd Liner of the same size
2. Disconnect the Rachet T-handle from the Shaft. Connect a Power handpiece and the Shaft using Hudson attachment.
3. Start cutting with the Power handpiece.
4. Advance the Blade by pushing the handle of the Shaft until the cup is fully extracted.

※Caution: Keep the angle of the Shaft and Cup at 90 degrees. Advance the Blade gently while checking the bone cutting. If you force to advance the Blade aggressively then there might be a chance of the cause of Blade breakage.

e. Storage after use and maintenance

1. Storage after use
   Perform external washing and cleaning after use, and store the product in a place not exposed to corrosive gas. Keep clean and be careful about moisture and dust.
2. Maintenance method
   Appropriate regular maintenance on the product and its components is required to maintain optimal performance.

Manual cleaning method

1) Rinse soiled device under running cold tap water for at least (2) minutes. Remove gross soil using a sponge, soft lint-free cloth or soft-bristled brush. For cannulations of the handpiece and attachments, the cleaning brush should be used.
2) Manipulate all moving parts under running tap water to loosen and remove gross debris.
3) Spray and wipe the device using a neutral pH enzymatic solution for a minimum of (2) minutes. Follow the enzymatic detergent manufacturer's directions for correct temperature, water quality (i.e. pH, hardness) and concentration/dilution.
4) Clean the device manually under running warm water using an enzymatic cleaner or detergent for a minimum of (5) minutes. Manipulate all moving parts under running water. Use a soft-bristled brush and/or soft lint-free cloth to remove all visible soil and debris. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct temperature, water quality and concentration/dilution.
5) Rinse the device thoroughly using cool to lukewarm running water for a minimum of (2) minutes. Use a syringe or pipette to flush lumens and channels. Actuate joints, handles and other movable device features in order to rinse thoroughly under running water.
6) If visible contamination has been remained, repeat steps 1–5. If visible contamination has been removed, final rinse for (2) minutes.
7) Final rinse with de-ionized or purified water for a minimum of (2) minutes.
8) Dry device using a clean, soft lint-free cloth or clean compressed air.

3. Sterilization

Warning and precaution

1) Using a disinfectant to wipe the exterior does not help sterilization and is not recommended.
2) Always separate components from the product before sterilization.
3) Recommended minimum drying time must be permitted whenever attachment are sterilized. Failure to do so may reduce performance of the product and induce early failure.

Sterilization method

Steam sterilization is a safe and effective method, and there are no restrictions in sterilizing the product.

<Method of steam sterilization>

| Method | Status | Cycle | Min. Temp | Max. Temp | Min. Exposure Time | Max. Exposure Time | Min. Drying Time | Max. Drying Time |
|---|---|---|---|---|---|---|---|---|
| Steam | Wrapped<br>Unwrapped<br>Tray | Pre-vacuum | 121°C | - | 30 minutes | - | 15 minutes | Unlimited |

1) Sterilize according to the recommended method described in the table below.

**E. Precautions for Use**

a. Restrictions

There are no known restrictions.

b. Warning

1. Protective glasses are recommended when using the product.
2. The medical staff is responsible to have thorough understanding on the method of using the product and accessories connected to it prior to using the product.
3. Since the attachment is provided as unsterilized, it must be cleaned and sterilized before use.
4. Do not contact the attachment and its moving part during use. They can injure the user.
5. Do not attach, insert or remove components during operation of the handpiece. Place the mode lever on Safe position before inserting or removing the product.
6. Do not contact the cut surface when blade is attached to the handpiece. Sharp surface can cause injury.
7. After use, properly dispose the blade used together according to the regulation and procedure of the hospital.

8. Do not re-sterilize and reuse disposable blade. Re-sterilization standard for disposable products has not been established, and reusing such products can reduce performance, safety and sterility of the product.

c. Precautions

If the device is used in disregard of the warnings, it may lead to soft tissue burns, bone loss and/or infection of the procedural area due to metal debris or splatter resulting from high speed.

1. During a cutting procedure, stem dislocation should be performed enough not to interfere with the rotation of EZX shaft.
   If the device repeatedly makes abnormal noise or friction during the procedure, stop the procedure immediately and check the affected area and the device.
2. Remove soft tissues around the cup before performing the procedure. If possible, remove soft tissues until the edge of the targeted cup is clearly shown.
3. During the procedure, maintain a 90° angle between the shaft and the liner.
4. This device cannot be used on the cup where pins and spikes are also used. If pins, spikes, or screws cannot be removed in the cup, do not use this device.
5. Do not use for removing cups that are non-hemispheric.
6. Do not use the blade to cut cups, pins, or screws.
7. Do not subject the device to strong impact such as bending, breaking, or twisting as it may bend or break blades or connectors.
8. Always be careful when removing blades as they are very hot after use.
9. This product must be used according to the intended purpose.
10. Be careful in handling the device. When the device is dropped on the floor or damaged, immediately return it to the place of purchase for service.
11. The product must be used with equipment and accessories tested and approved according to the medical device standards of the manufacturer. The product may not function properly with other products or violate the medical device standards.
12. When the product, its components and other products used together are not used, stored and managed as described in Instruction for use, or repaired and altered by a person not authorized by the manufacturer, they are excluded from free warranty service.
13. Do not arbitrarily alter the product since none of its parts can be repaired by the user.
14. Check whether all components are accurately and safety attached and perform function test before use.
15. Wash and sterilize all equipment and components as described in Instruction for use.
16. Do not disassemble the product or apply lubricant since the product is provided with complete sealing. The product can be excluded from free warranty service.
17. Check whether blade is bent, blunt or otherwise damaged before use. When it is damaged, dispose it instead of trying to straighten or sharpen it.
18. Completely wash and inspect the components as described in User Manual after use.
19. Since the product can be damaged, components must be attached as designated.
20. Do not let blade to contact other surgical instruments. Blade and instruments can be damaged.

**F. Contraindication**

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

**G. Complications**

Complications related to EZX are very rare, but when they occur, they can be serious. Most complications are related to surgery techniques and possible complications would be, not limited to;

- Patient burn or thermal necrosis
- Paralysis by wrong operation
- Frostbite, hematoma in target site etc. by infection
- Injury by wrong operation or cracked chip of blade

**H. Storage conditions and method**

a. Perform washing and cleaning of the exterior after use.
b. When a problem occurs in the product, appropriately indicate the problem and contact a nearby office or service center.

c. Regular inspection must be conducted as prescribed to preserve the product in its optimal status.
d. Do not arbitrarily adjust or alter the product.
e. Please return devices and attachments no longer in use to your local representative of IMEDICOM for disposal.

**I. Expiration**

Semi-permanent

**J. Caution**

Use and selling of this product are limited to medical specialists.

**K. Symbols**

Catalog number


Manufacturer


General Warning


Refer to instruction manual/booklet

Authorized representative


Distributor

Serial Number

Unique Device Identifier


Keep dry


Date of manufacture

Medical device


Keep away from sunlight

Federal law restricts this device to sale by or on the order of a physician


Use by date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