EPM Mueller® Cup Extractor C2

„Knockout Tool for Cup Joint Prosthesis“
CE, ISO 13485
FDA Establishment Registration Number: 3003759646
Patented in most countries, USA Pat.Nr. 5.534.006, USA Pat.Nr. 8.603.100B2
EP 0.645.127, DE 43.32.872 C1

Technical Documentation

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Technical Documentation

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1. Description
The universal extraction device for hemispherical- and screw-acetabular cups replacement **EPM Mueller® Extractor C2** is a modern surgical instrument which addresses problems arising through the increasing number of revision surgeries in total joint replacement. It ensures secure, efficient, low cost and correct handling. Ergonomic aspects concerning the design of the grip and handling have been incorporated into manufacture as a result of ongoing feedback and development. Key part of the instrument is the patented clamping mechanism and head with exceptional clamping force ensuring a secure connection between the instrument and almost all knee implant design commercially available today. The applied force is transferred to the prosthesis axially, thereby avoiding dangerous eccentric leverage.

2. Components

Option: 6 cup osteotome, quick adapter with plate or pneumatic coupling for Woodpacker

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Option: 11c cup osteotome
3.1 Handling

Place the two pressure jaws into the opening of the body and secure it with the 2 body pin screws using the Allen key No.3.

Turn the extractor jamcase from the handle first almost completely out and then screw the guiding tube of the extractor into the thread of the body until it stops. Now you can compress or release the jaws as desired by turning the lever including jamcase into the handle. The jaws are held by your hand on the body always in the wide-open, or at the spreading jaws in the closed position.

3.2 Prosthesis knock out

a. Cup knock out with clamping jaws:

Adjust the opening of the jaws to the cup outside dimension and set the jaw tips perpendicular to the plane of the cup. Beat the jaws by the striking weight, until the jaw step abut the acetabular rim. Now turn the lever in a vertical position to extractor, with the jamcase until you pinch the cup firmly, then press the lever on the handle. Now you can extract the cup by striking movement of the hammer weight towards extractor handle.

In a press-fit cup use after the relaxation of the cup cup osteotome matching closely the size of the cup to remove bone and soft tissue contacts remains on the cup to avoid bigger tissue damages.

b. Hemispherical cup knock out with spreading jaws:

Adjust the opening of the spreading jaws to the cup inside (you have to place the jaws to catch favorable places). Now turn the extractor lever in a vertical position, including jamcase until you clamp the cup firmly, then press the lever to the handle.

Now you can extract the cup by striking movement of the striking weight towards extractor handle. In a press-fit cup use after the mobilisation cup osteotome matching closely the size of the cup to remove bone and soft tissue contacts remains on the cup to avoid bigger tissue damages.
c. **Screw-cup knock out with spreading jaws:**

First mount the body handle on the side of the body and turn the handle until it stops. Adjust the opening of the spreading jaws to the cup inside. Now turn the extractor lever in a vertical position, including jamcase until you clamp the cup firmly, (you have to place the jaws to catch favorable places), then press the lever to the handle. Now you can unscrew the cup by turning it anti-clockwise with the body handle.


**3.3 Disassembling**

The unit is disassembled by unscrewing the threaded connections without additional tools, excepting the jamcase and the jaws body, which is further decomposed into parts using a supplied Allen key.
Das Gerät wird durch Lösen der Gewindeverbindungen ohne jegliche Zusatzwerkzeuge zerlegt, bis auf Zustellgehäuse und Backen-Gehäuse, welche mit Hilfe eines mitgelieferten Inbusschlüssel 3 weiter in Einzelteile zu zerlegen sind.

**4. CLEANING and STERILIZATION**

The new instrument: has to be cleaned up and disinfected before sterilisation.

**4.1 Disassembly**

- 1. Completely unscrew (reverse clockwise) lever assembly (jamcase) of handpiece
- 2. Remove the pin screw, with the Allan key 3 delivered, than lever, thereafter bolt with plasticinset with a narrow instrument (pressure rod can be used)
- 3. Extract pressure rod
• 4. Detach handpiece by unscrewing completely from the guiding tube
• 5. Slide off the striking weight
• 6. Remove guiding tube by unscrewing completely from the instrument body
• 7. Remove the 2 body pin screws with the Allan key for removing the jaws.

4.2 Assembly

For Assembly, simply use reverse order.
The EPM Mueller® Extractor is by loosening the screw connections without any additional tools to disassemble, up to the jamcase, which is further disassembled with the supplied Allen key, into single pieces.

ATTENTION: use the bolt always with the plasticinset together!

4.3 Preparation

Brand new instruments and those returned from repair must be removed from their transportation packaging before storing and / or inclusion in the instrument usage and processing cycle.

4.4 Storage

Store it at room temperature in dry rooms. Condensate may cause subsequent corrosion damage.
Never store it near chemicals such as active chlorine which emit corrosive vapors.
To avoid mechanical damage during processing, store it from the beginning in suitable racks or retainers.

Before using, they must be sent through the entire processing cycle in the same manner as used instruments.

The reprocessing comprises:
- Preparation (pretreatment, collecting, precleaning and taking the instrument apart.
- Cleaning, disinfecting, rinsing, drying
- Visual inspection of clearness and acceptable condition of material
- Care and repair where required
- Functional test
- Marking
- Packaging and sterilization, approval for reuse and storage

Validated cleaning, disinfecting and sterilization processes, supplemented by defined configurations for loading the washers/disinfectors and sterilizers are an indispensable prerequisite for quality assurance.
Automated reprocessing with thermal disinfection and steam sterilization should be preferred.
Use correct water quality!
When using softened water, especially when applying thermal disinfection in the final rinse, anodized aluminium surfaces might be subject to attack due to an increased pH value.
Using demineralised water for steam sterilisation, limit values for feed water quality conforming to EN 285 and ISO 17665 are required.
We recommend using demineralized water for the final rinse for the following reasons:
- No spotting
- No increase in concentration of corrosive constituents, e.g. chlorides
- No dried crystalline residues which could have a negative effect on the downstream sterilization process
- Protection and stabilization of anodized aluminium surfaces
4.5 Returned instruments

Only if the instruments have been cleaned, disinfected, dried and have been declared hygienically safe

4.6 Cleaning and Disinfecting

Any residues should be removed. Never immerse stainless steel instruments in a physiological salt (NaCl) solution, it leads to pitting and stress corrosion cracking. The passive layer of brand new instruments is necessarily still thin and so these instruments tend to critical treatment conditions than are older used instruments. Avoid long intervals between use and treatment for reuse. For manual cleaning, active non-protein-fixing cleaners with or without antimicrobial effect and/or enzymes are to be used. Regarding detergents and disinfectants, the manufacturer’s instruction concerning concentration, temperature and exposure time should always be strictly followed! Use soft, lint-free cloths or towels, plastic brushes or cleaning guns for cleaning. To prevent water spots (spotting), a final rinse using fully demineralised water is recommended. After this the instrument must be dried carefully immediately. By machine-based cleaning, only validated machine cleaning and disinfecting processes (DIN EN ISO 156883 and national guidelines) should be used.

4.6 Check and care

Instruments must be checked visually – tactile and be macroscopically clean. Maintenance means targeted application of a lubricant milk to the joints, threads or friction surfaces of instruments. This prevents metal on metal friction and therefore constitutes a preventive measure against friction corrosion. Requirements for care agents:
- Paraffin/white oil based, in accordance with the current European or United States Pharmacopeia
- Biocompatible
- Suitable for steam sterilization and vapor permeable
Instruments must not be treated with care agents containing silicone oil. The proper functioning of the instruments must be assured by testing.

Apply instrument oil to tube, rod and screws periodically to minimize wear friction.

4.7 Packaging

International standard EN ISO 11607 1 and 2 apply to packed items requiring sterilization. It must be possible to mark and identify the package with information such as:
- Sterilisation date
- Packer
- Expiry or “use before” date (if date has been defined)
- Contents

4.8 Sterilisation

It is important to use only sterilisation methods and sterilizers that allow validated sterilization processes conform national guidelines. Sterilisation accessories and packaging materials must be selected in accordance with the items to be sterilised as well as with the sterilisation method used.
Steam sterilization is the method of choice and is performed with saturated steam, usually at 134°C. Use validated steam sterilization processes in accordance with ISO 17665, EN 554 (or DIN 58946 Part 6 in Germany).

4.9 Sterile storing

To guarantee the sterility of instruments until they are used on the patient, germ-tight packaging is absolutely essential. Further requirements for the protected storage of sterile supplies and the prevention of corrosion damage include a dust-free and dry environment and the prevention of temperature fluctuations.

5. TECHNICAL DATA

- Instrument can be used for the following prosthesis dimensions: clamping 5-110 mm, spreading 18-80 mm
- Striking weight: 1.0kg (2.2 lb)
- Total weight: 2.65 kg (5.83 lb)
- Total length: 585mm (23.1 inches)
- Hitting distance: 205mm (8.1 inches)

6. ACCESSORIES

Art No.  Description

1001.15.4.C2  EPM Mueller® Cup Extractor C2

1001.15.2.3.B2  Body B2
1001.15.2.3.S  Body pin screw
1001.15.2.3.G  Body handle
1001.15.2.4.L  Cup clamping jaw left
1001.15.2.4.R  Cup clamping jaw right
1001.15.2.3-4.L  Knee and cup spreading jaw left
1001.15.2.3-4.R  Knee and cup spreading jaw right
1001.2.17.ST  Guiding tube ST
7. WARRANTY, SERVICE:

24 month Exchange warranty after invoice date.

ATTENCION: not following the use, cleaning and care instructions described, expire the Warranty!

International / European / German Sales, Hotline, Guarantee, Service, Spare parts, Repair: