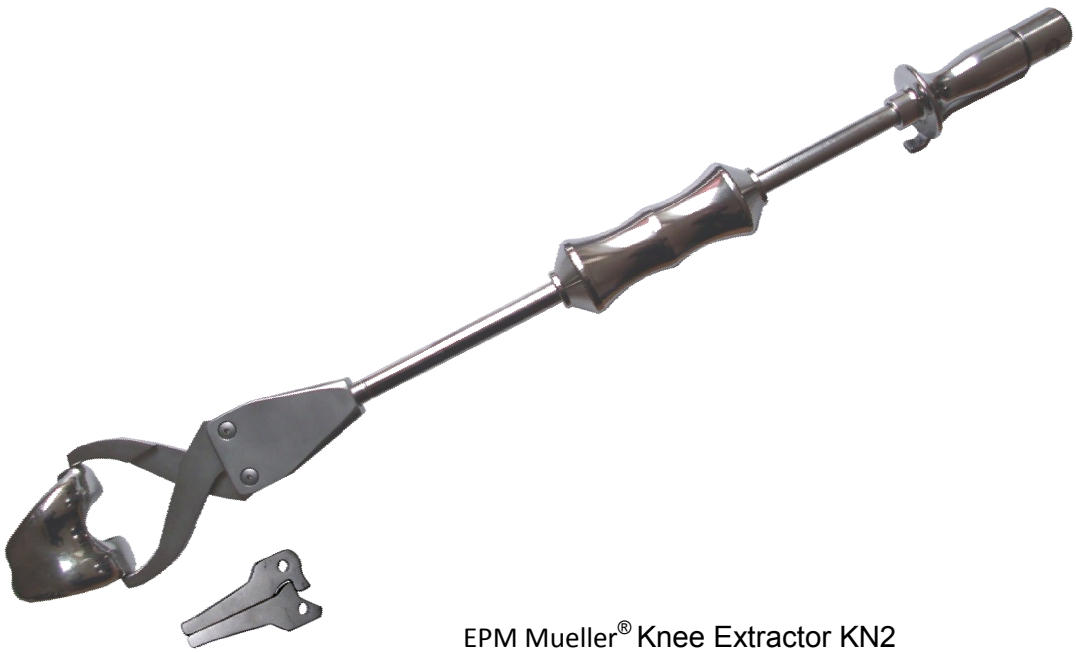
EPM Mueller® Knee Extractor KN2

„Knockout Tool for Knee 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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www.epm-mueller.de

Technical Documentation

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Developed by EPM Endo Plant Müller GmbH

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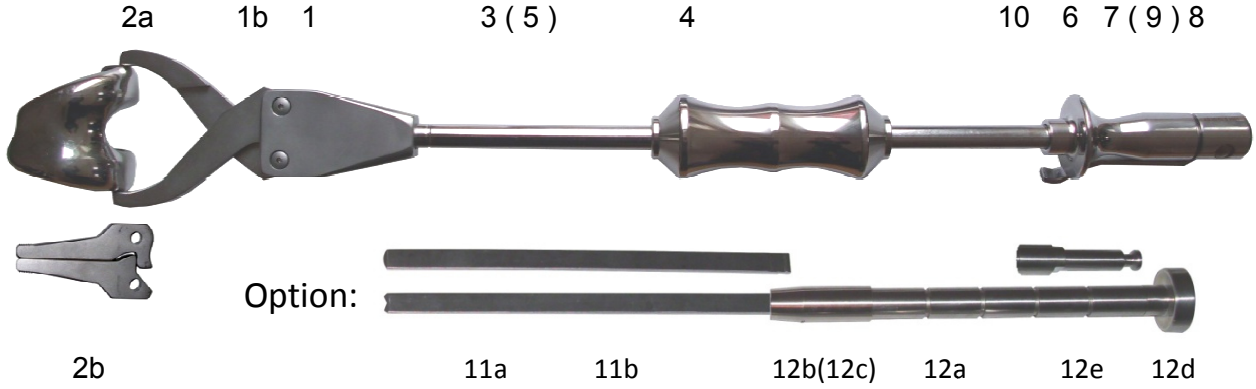
1. Description

The universal extraction device for knee artificial joint components replacement **EPM Mueller® Extractor KN2** 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



EPM Mueller® Knee Extractor KN2 with clamping and spreading jaws
+ Option: 2 chisels with quick adapter with plate or pneumatic coupling

1 jaws body	5 pressure rod	11a chisel R
1b body pin screws	6 handle	11b chisel Z
2a clamping jaws set	7 jamcase	12a Quick adapter shaft
2b spreading jaws set	8 pin screw	12b Quick adapter cover
3 guiding tube	9 bolt with plastic insert	12c Quick Adapter spring
4 striking weight	10 lever	12d Quick Adapter Plate
		12e Quick Adapter pneumatic coupling

3.

3.1 Handling

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

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

3.2 Prosthesis knock out:

Adjust the opening of the jaws to the prosthesis outside dimension to be extracted (by the spreading jaws adjust it to the inside dimension). The adjustable clamping jaws can clamp objects of 5-110 mm (at the spreading jaws of 18 – 80 mm).
Turn the lever, which is in a vertical position for Extractor, to clamp firmly the prosthesis, then press the lever to the handle. Now you can extract the prosthesis by striking movement of the weight towards extractor handle.
Attention:
Do not use additional instruments with the EPM Mueller Extractor! (as HAMMER)

3.3. Dismantling

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

4. CLEANING and STERILIZATION

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

4.1 Disassembly

- 1. Completely unscrew (reverce 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 sterilissation, 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 spoting
- 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 declarated 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 withaut antimicrobial effect and/or enzymes are to be used.
Regarding detergents and desinfectants, 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 desinfecting 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.
Maintance 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

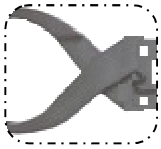
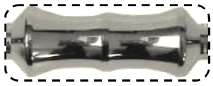
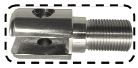
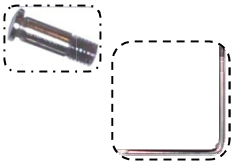
- Instrument can be used for the following prosthesis dimensions: clamping 5-110 mm, spreading 18-80 mm

- 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	
1001.15.3.KN2	EPM Mueller® Knie Extractor KN2	
1001.15.2.3.B	Body	
1001.15.2.3.S	Body pin screw	
1001.15.2.3.L	Clamping jaw left	
1001.15.2.3.R	Clamping jaw right	
1001.15.2.3-4.L	Spreading jaw left	
1001.15.2.3-4.R	Spreading jaw right	
1001.2.17.ST	Guiding Tube ST	
1001.2.15.ST	Pressure Rod ST	
1001.2.09.N	Striking Weight N (1kg/2.2 lb)	
1001.2.11.ST1	Handpiece ST1	
1001.2.12.ST2	Jamcase ST2	
1001.2.07.2	Bolt with plasticinset	
1001.2.13.2	Pin screw	
1001.2.13.A2.5-3	Allan key 2.5-3	
1001.2.14.	Lever	

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:

EPM Endo Plant Müller GmbH

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Fax: +49(0)6022-25419

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E-Mail: epmmueller@aol.com

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8. Declaration of conformity EG/CE

F	Konformitätserklärung
321	Declaration of Conformity
10001	

Wir / We EPM Endo Plant Müller GmbH
. Schleusen Str.8 , D- 63839 Kleinwallstadt

Erklären in alleinige Verantwortung, dass
Declare on our own responsibility that

Das Medizinprodukt „EPM Mueller® Extractor“ KN2 Ausschlagwerkzeug für Kniegelenkprothesen
The medical device „EPM Mueller® Extractor“ KN2 Extraction Tool for Knee Prosthesis

Art.-Nr. 1001.15. KN2
Produkt Identifikation UMDNS (15-580) : 5000.E . .
. EPM Mueller® Extractor KN“, 1000.1015.2000

Allen Anforderungen der Richtlinie 93/42/EWG entspricht.
Meets all the provisions of the directive 93/42/EEC witch apply to him.

Angewandte harmonisierte Normen:
Applied harmonized standards DIN EN ISO 9001:2000, DIN EN ISO 13485:2003

Andere normative Dokumente: GHTF (SG1) DOC No. N029R11, 02.02.2002
Other normative documents GHTF (SG3) DOC No. N 99.10, 29.06.1999

Angewandte nationale Normen: MPG, MPV
Applied national standards

Konformitätsbewertungverfahren:
Conformity assesment procedure:

Medizinprodukt der Klasse I im Sinne der EG-Richtlinie 93/42/EWG, Anhang IX.
Medical device class I, 93/42/EEC, Annex IX

CE

Kleinwallstadt, den 15.11.2014
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E.J.Müller
Dr.med.,Dr.med.stom.IMFKL.
Geschäftsführer