Extraction Tools for Total Hip Replacements

EPM Mueller® Extractor AU-S2

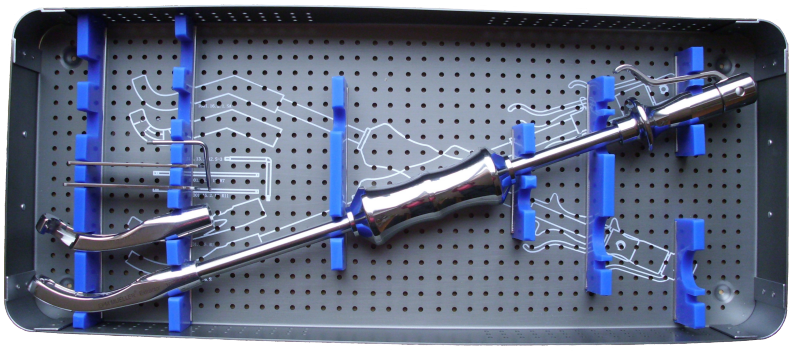
EPM Mueller® Extractor AU2

EPM Mueller® Extractor S2

„Knockout Tool for Joint Prosthesis“
CE0197, DIN EN ISO 13485/2016
FDA Establishment Registration Number: 3003759646 Aktiv
Patented , US Pat.Nr. 8.603.100B2, US Pat.Nr. 9.089.440, US Pat.Nr. 10.912.656,
EP 1.968.502, EP 2.756.825

Technical Documentation

EPM Mueller® Extractor AU-S2



EPM Mueller® Extractor AU-S2.L in box

www.epm-mueller.de

Technical Documentation

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Developed by EPM Endo Plant Müller GmbH

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1. Introduction

Since its inception in the early 60's, total hip replacement surgery has become enormously important; today it is one of the most successful surgical interventions in orthopedics.

One of the problems in total hip replacement and joint replacement surgery in general, is the limited survival time of the implants which have not reached the biomechanical qualities of the natural hip joint. Today a survival time of 10 to 15 years is considered normal if no complications occur.

After years of implantation time the devices loosen aseptically. This loosening is induced by wear particles. A loose prosthesis causes pain, which makes a revision operation necessary. (Fig. 1)

Fig. 1

Fig. 2

One of the problems during Revision Operations is the removal of the femoral component from the femora. Even if the implant is loose and micro motion is possible, they are still fixed by soft tissue and therefore hard to remove.

2. Definition of Medical and Technical Purposes

2.1. High, accurately directed forces have to be applied to the femoral component for short periods of time so that the extraction impulse only acts upon the femoral component itself. (Fig. 7)

2.2. The energy of the extraction impulse has to be so high that the connection between implant and femora (i.e. cement femora) is terminated before the energy of the impulse is transferred to the femora. (Fig. 5)

2.3. To achieve this, uniaxial force transfer is necessary as well as an extremely high connection force between instrument and femoral component. (Fig. 4)

2.4. The force vector has to be as close to the longitudinal axis of the femoral component as possible. (Fig. 4)

3. FEM-Analysis of Revision with Conventional Extraction Tools

To visualize the special relationships and magnitudes of force potentials, and to compare the loads acting upon the cortical bone of the femora in revisions of the femoral component, a finite element strain analysis of the femora while extracting a femoral component with different extraction devices was performed.

3.1. Finite-Element-Modeling (FEM), Conditions and Loads:

For the Finite-Element-Analysis (FEA), two identical femora with two identical femoral components were modeled. (Fig. 3,7). The femora were comprised of 3-D elements. The femoral component outside of the bone and heads of the extraction instruments were compiled of 2-D elements. For the calculations, the near-half symmetry of femora and femoral components were used.

At the ends of the heads of the extraction instruments a ramp force profile of F=0 N at time t=0s to F=10 kN at t=30 ms was imprinted in axial direction. The axial direction is parallel to the middle axis of the femora in the FEM. Therefore this represents a best case for the conventional extraction instruments. (Fig. 3)

The femora is imbedded in 2-D elements, which represent the properties of the muscle surrounding the bone. A strain-free condition is assumed at t=0. Fig. 3

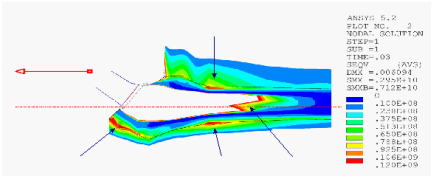


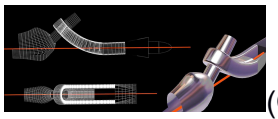
Fig. 3

3.2. Results and Discussion

To depict the strains inside the femurs and femoral components, the von-Mises-strains (s EQV) were used. The FEA was performed in a transient mode. The diagrams 3 and 7 show the von-Mises-strains at maximal extraction forces at t=30 ms.
One can notice the non-homogenous distribution of strains inside the femoral component when conventional extraction tools are used. (Fig. 3). One can deduct an asymmetrical transfer of forces to the femora from this, which can only lead to a partial disconnection of the implant from the surrounding tissue. Therefore, multiple applications of the forces have to be performed.
Looking at the distribution of the strains in the cortical bone, extraction with conventional tools causes high strains on the whole (Fig. 3, ABC) and especially high maximal strains in the middle of the prosthesis and at the lower end of the prosthesis. (Fig. 3, D)
With the conventional extraction tools, the force vector is not directed along the longitudinal axis of the femoral component - in the optimal case it is only parallel to this axis (Xp) - the femoral component therefore jams and is hard to remove. The energy impulse is conveyed laterally to the femora.
Fractures of the trochantor or the shaft of the femora can occur. (ABC). A misalignment between extraction vector and the longitudinal axis of the prosthesis can lead to injury of the bone surrounding the prosthesis, to fractures and associated lengthening of the surgical time and anesthesia, increasing of the risk of infection, etc.

4. Principle and Construction of the EPM Mueller® Extractor.

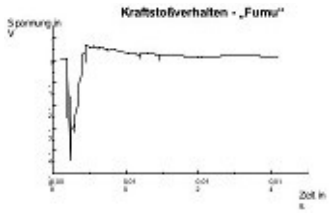
- Provide Axial force transfer and maximal clamping force.
- Ensure the necessary clamping force is transferred to the neck of the prosthesis via a curved toolhead. (Fig. 4).
- The size of the toolhead is minimized because of limited space during surgery.
- The instrument is handled outside of the surgical field.



(CAD picture) Fig.. 4

5. Measurements of Functional Prototype

The prototype was measured with a special trial set-up and a Piezo-force sensor. The profile of force application was registered to monitor change of force over time and calculate the transferred impulse.
A force was applied by hand via a weight against an infinitely hard base and registered by the Piezo-sensor. Data were acquired by an oscilloscope and stored.
The prototype of the extraction instrument is fixed and the weight (800g) is accelerated to about 10m/s. During the whole time of the experiment, the oscilloscope stores the strain delivered by the Piezo-sensor (strain proportional to force). The impulse transfer time t is calculated from the strain-time-diagram. (Fig. 5).
Results: Fig. 5



From the graph of force transfer time of t=500µs can be derived.
A peak force of 50kN can be calculated for force transfer.
This peak force corresponds to a set-up with an infinitely hard base. In practical use an elastic fixation exists and consequently the measurements stated above will not be attained.
Duration of the force: 0,5ms (=0,0005s)
Amount of force: 50Ns
The impulse is high enough to overcome the holding forces inside of the bone and loosen the prosthesis. The clamping mechanism reliably transfers the force to the implant.
Calculated clamping force at the neck of the prosthesis is 30kN.

6. The EPM Mueller® Stem Extractor

EPM Mueller® Extractor AU2 -with open head on the side and one sliding spacer, proper also for stems with fixed heads (monobloks)

Fig. 6a

EPM Mueller® Extractor S2 -closed head with single sliding spacer

Fig. 6b

EPM Mueller® Extractor CC.S2, -closed head with single sliding spacer and 2,65Kg weight

Fig. 6c

EPM Mueller® Extractor AU-S2 with 2 exchangeable heads (open **AU**+ closed **S**) and one sliding spacer

Fig. 6d

EPM Mueller® Extractor CC.AU-S2 with 2 exchangeable heads (open AU+ closed S) and one sliding spacer, with 2,65Kg weight Fig 6e

EPM Mueller® Extractor CFH.AU-S2 with a C frame and a 2 Kg extra hammer

. Fig 6f

EPM Mueller® Extractor SA for Antero-access revisions, with closed head, one slider spacer and a slider bar

Fig 6g

EPM Mueller® Extractor SA2 for Antero-access revisions, with closed head and single slider spacer

Fig.6h

EPM Mueller® Extractor CO.SA2 for Antero-access revisions with a offset link and a striking weight of 2.65 Kg

Fig.6i

EPM Mueller® Extractor CFH.SA2 for Antero-access revisions, with a modular C frame and a extra 2 Kg. Hammer

Fig.6j

EPM Mueller® Extractor MO for modular neck stems with spreading jaws assambly

Fig.6k

EPM Mueller® Extractor C.MO for modular neck stems with spreading jaws assambly, with 2.65 Kg. Striking weight

Fig.6l

EPM Mueller® Extractor M6, for stems with M6 tread

Fig.6m

EPM Mueller® Extractor C.M6 for stems with M6 tread

Fig.6n

The **EPM Mueller® Extractor AW6** has been in clinical use since 1993, the **EPM Mueller® Extractor AE (ABC Extractor)**, the **EPM Mueller® Extractor AU** since 1999 and the **EPM Mueller® Extractor S** since 2004, the **EPM Mueller® Extractor PN** since 2007, the **EPM Mueller® Modular Extractor System 1** since 2009.
We launched 2014 the new **EPM Mueller® Extractor SA** for Anterior approach revisions, **EPM Mueller® Extractor MO** for modular stems and the **EPM Mueller® Modular Extractor System 2, EPM Mueller® Knee Extractor KN2 and EPM Mueller® Cup Extractor C2**

EPM Mueller® Modular Extractor System 2 in BE box
Fig.6o

We launched 2018 the new **EPM Mueller® Extractor SA2 f**or Anterior approach revisions and the **EPM Mueller® Knee Extractor KN3**

2019 we lauched a new extractor schaft variants **CC** and **CO** with increased slap hammer of 2.65 Kg. and the modular C frame schaft variant **CFH** with a extra 2 Kg hammer.

The EPM Mueller® Extractor is characterized by axial force transfer and exceptional clamping mechanism.
The necessary clamping force is transferred to the implant neck by a curved tool head.
The size of the tool head is adapted to space restrictions dictated by the surgical procedure.
The EPM Mueller® Extractor is handled outside of the surgical field. The EPM Mueller Extractor can be removed from the prosthesis after extraction via an easy snap-lock mechanism without additional tools. It can be disassembled and assembled easily and fits into a standard surgical tray.
Easy cleaning and sterilization are assured; the instrument is fully autoclavable.

7. FEM-Analysis of Revision with the EPM Mueller® Stem Extractor

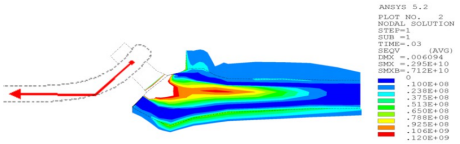


Fig. 7

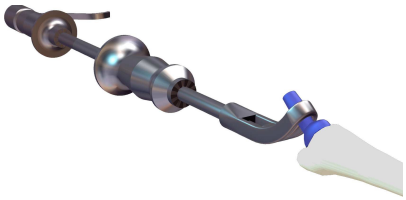
The direction of force of the EPM Mueller® Extractor (normal case) lies in the middle axis XY of the femora (Fig. 7).
The strain distribution in the prosthesis during extraction with the EPM Mueller Extractor is homogenous, which favors the detachment of the implant from spongiosa and soft tissue.
Strain in the cortical bone is low and shows no peaks.
Therefore the risk of fracture of the cortical bone is minimized.
The EPM Mueller® Extractor is optimized for practical application. The extraction forces are applied to the relevant sides, the clamping force is extremely high and dependable and the device can universally be used for the most implant necks.

8. Surgical Use in Garmisch-Partenkirchen-Hospital of the EPM Mueller® Stem Extractor

The EPM Mueller® Extractor has been in clinical use in Garmisch-Partenkirchen-Hospital since October of 1993. At the time of writing, EPM Mueller Extractor has been used during over 600 total hip revision operations in the hospital. A large number of femoral components have been successfully removed; with only a few was extraction not possible. These failures were primarily in the experimental phase, using the prototypes (AW3/4); the geometry of the instrument head has since been changed accordingly.
EPM Mueller® Extractor AU has been in clinical use since 1999.
The remaining failures were due to a maximal stability of the implant in the surrounding bone, meaning an absence of loosening. Stable implants cannot be removed by an extraction tool alone.
To date no complications, for example bone fractures, have been noted.
Handling has proven to be safe and easy. The posture approach usually favored in GarmischPartenkirchen often leads to restricted available space at the operative site; the limited size of the toolhead and the handling of the instrument outside of the surgical field have therefore proven extremely useful.
The surgical personnel have praised easy handling, cleaning and sterilization of the EPM Mueller® Extractor. All parts of the EPM Mueller® Extractor can be assembled and disassembled with ease and safety.
The space needed for storage is minimal and since the instrument can be used universally it is not necessary to maintain a large inventory of extraction devices

9. Use Instructions

EPM Mueller® Stem Extractor AU2, S2



EPM Mueller® Extractor AU-S2

Contents:

9.1. DESCRIPTION

The universal extraction device for total hip replacement femoral components **EPM Mueller® Extractor** 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 implant necks or tapers, commercially available today.
The applied force is transferred to the prosthesis' neck axially, thereby avoiding dangerous eccentric leverage.

9.2. COMPONENTS

1 Head of Tool
2 Sliding Spacer
3 Guiding Tube
4 Striking Weight
5 Pressure Rod
6 Handpiece
7 Jamcase
8 Pin screw
9 Bolt with plasticinset
10 Lever

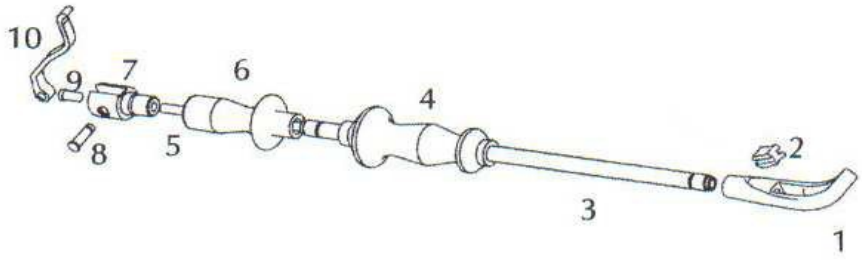


Fig. 1

9.3. HANDLING

The EPM Mueller Extractor is delivered completely assembled and ready for use.

(**NON STERILE**) Sterilization is the responsibility of the User.

9.3.1 OPENING (Fig.2)

Open lever (**1**) and thread between jamcase and handpiece (working thread) with circular movements reverse clockwise, holding then handpiece also (**2**).
ATTENTION: the threads at the guiding tube have to be always closed complete, but not tight!
To enable clamping, move the spacer back by putting pressure on spacer (**3**).

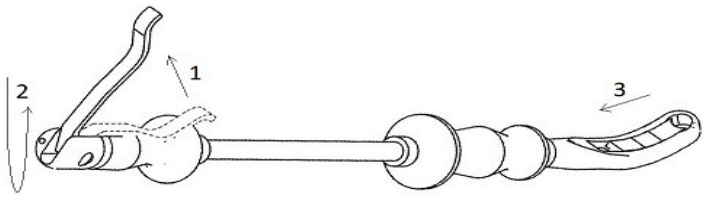


Fig. 2

9.3.2 APPLICATION and CLAMPING (Fig.3)

Slide (**1**) tool as far as possible over the neck of the prosthesis.
Note:
To use the instrument safely and effectively, the orientation of the prosthesis **has to be** analyzed carefully and the EPM Mueller® Extractor **has to be APPLIED AXIALLY**.
For clamping, rotate (**2**) the jamcase with the opened lever(at 90° to the axis), at the distal-end clockwise, holding the handpiece also, until resistance is felt. Close (**3**) the lever to attain maximal clamping force.

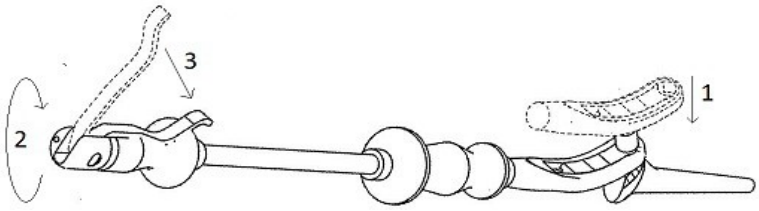


Fig. 3

9.3.3.EXPLANTATION Fig.4

The weight is placed at the end of the guidance tube closest to the prosthesis, and is then moved forcefully towards the distal end of the tool, impacting on the base of the handpiece.

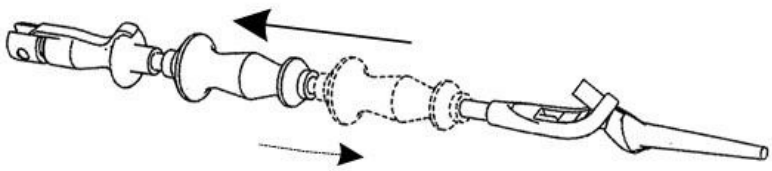


Fig. 4

Attention:
Do not use additional instruments with the EPM Mueller Extractor! (as HAMMER)

9.3.4 DETACHMENT (Fig.5)

The extracted implant is removed from the tool with the same steps explained under OPENING of the instrument. (Fig. 2)

DISASSEMBLY

To disassemble look at picture 1 and 5.

- 1. Completely unscrew (reverce clockwise) lever assembly (jamcase) of handpiece
- 2. Remove pinscrew, with the Allan key delivered (2a), than lever (2 b), thereafter bolt with plasticinset (2 c) with a narrow instrument (presure rod can be used)
- 3. Extract presure rod
- 4. Detach handpiece by unscrewing completely from the guiding tube
- 5. Slide off the striking weight
- 6. Remove sliding spacer through rectangular space at the instrument head
- 7. Remove guiding tube by unscrewing completely from the instrument head

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Further in case of stocked guiding tube in the handpiece, for exampel after deshidratation of the blood or overtighting, can be used the wrence keys R7 and R11 as help only for disassambling.

Fig. 5

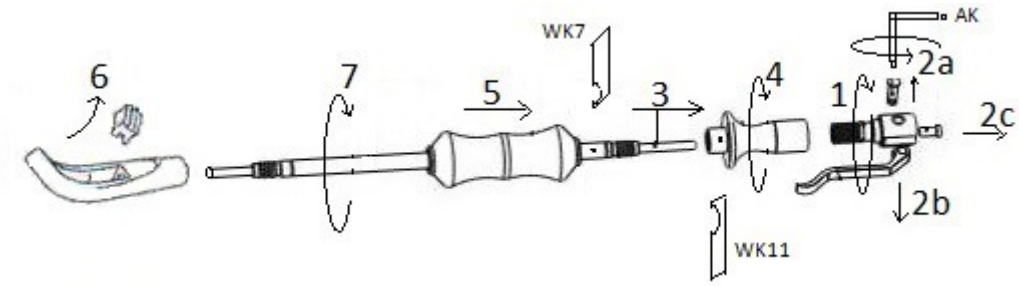


Fig. 6

Assemble

For Assamble, simply use reverse order.
The EPM Mueller® Extractor is by loosening the screw connections without any additional tools to disassemble or assemble, 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!

10. CLEANING, DISINFECTING and STERILIZATION

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

10.1 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.

10.2 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

10.3 Returned instruments

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

10.4 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.

10.5 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. The Instrument have to be cooled down to room temperature.

10.6 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, Packers name, Expiry or “use before” date (if date has been defined), Contents

10.7 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.
Use validated steam sterilization processes in accordance with ISO 17665, EN 554 (or DIN 58946 Part 6 in Germany)
Steam sterilization is performed with saturated steam, usually at 134 °c.
In the case of an application of the fractional vacuum procedure, the sterilization with the 134 ° C/2-program is to be performed with a min. holding of 5 minutes.

10.8 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.

11.TECHNICAL DATA

Variants:

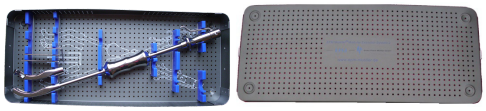
-

- Standard :1001.5.AU2; 1001.6.S2; 1001.7.AU-S2 (550 mm lang)
- **S** (with 1,7 Kg. slap hammer) 1001.5.AU2.S; 1001.6.S2.S; 1001.1.AA-S2.S
- **L** (7 cm longer as standard):1001.5.AU2.L; 1001.6.S2.L; 1001.7.AU-S2.L (620 mm long)
- **L.S** (long with 1,7 Kg. slap hammer):1001.5.AU2.LS; 1001.6.S2.LS; 1001.7.AU-S2.LS

- Instrument can be used for the following tapers: Æ 8 – Æ 16,
- Striking weight: 1.0kg (2,2 lb) standard; 1,7kg (3,74 lb)
- Total weight: 2,2 kg (4.84 lb) with 1,0kg Striking weight, (AU2 or S2)
- Total length: 550mm (21,7 inches) standard; 635mm (25 inches) long
- Hitting distance: 205mm (8.1 inches) standard; 275mm (8.08 inches) long

12. ACCESSORIES

Art No.	Description			
Variant: standard;		Long L;	Heavy S;	Long and Heavy LS
1001.7.AU-S2	EPM Mueller® Schaft Extractor AU-S2	(AU-S2.L;	AU-S2.S;	AU-S2.L.S)
1001.6.S2	EPM Mueller® Stem Extractor S2	(S2.L;	S2.S;	S2.L.S)
1001.5.AU2	EPM Mueller® Stem Extractor AU2	(AU2.L;	AU2.S;	AU2.L.S)
1001.2.5.AU	Head of tool AU			
1001.2.6.S	Head of the tool S			

1001.2.04U	Sliding Spacer	
1001.2.17.2.ST	Guiding Tube ST2	
1001.2.17.2.L	Guiding Tube L2 Option	
1001.2.15.ST	Pressure Rod ST	
1001.2.15.L	Pressure Rod L Option	
1001.2.09.N	Striking Weight N (1kg/2.2 lb)	
1001.2.09.S	Striking Weight S (1,7kg/3.74 lb) Option	
1001.2.11.2.ST	Handpiece ST2	
1001.2.12.2.ST	Jamcase ST2	
1001.2.07.2	Bolt with plasticinset	
1001.2.13.4	Pin screw	
1001.2.13.A2.5-3	Allan key 2.5-3	
1001.2.14.2	Lever	
1001.15.2.13.R7	Wrence Key R7	
1001.15.2.13.R11	Wrence Key R11	
1015.15.12.BS with 62/24/7cm	Coated aluminum basket . lid	

13. WARRANTY, SERVICE:

24 month Exchange warranty after invoice date.

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

Sales, Hotline, Guarantee, Service:

International / European / German

EPM Endo Plant Müller GmbH
Fon: +49(0)6022-25419
Fax: +49(0)6022-25419
Schleusen Str.8, 63839 Kleinwallstadt
E-Mail: epmmueller@aol.com
www.epm-mueller.de

14. 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“ Ausschlagwerkzeug für Hüftgelenkprothesen
The medical device „EPM Mueller® Extractor“ Extraction Tool for HIP Prosthesis

Art.-Nr. 1001.7. AU-S; 1001.7.AU-S2
Produkt Identifikation UMDNS (15-580) : 5000.E
. EPM Mueller® Extractor AU-S/AU-S2, 1000.1007.2000
. GTIN code 6946998813168

Art.-Nr. 1001.5. AU; 1001.5.AU2
Produkt Identifikation UMDNS (15-580) : 5000.E
. EPM Mueller® Extractor AU/AU2, 1000.1005.2000
. GTIN code 6946998813144

Art.-Nr. 1001.6. S; 1001.6.S2
Produkt Identifikation UMDNS (15-580) : 5000.E
. EPM Mueller® Extractor S/S2, 1000.1006.2000
. GTIN code 6946998813151

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 9001:2012, DIN EN ISO 13485:2016

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

CE0197

Kleinwallstadt, den 01.03.2021
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E.J.Müller
Dr.med.,Dr.med.stom.IMFKL.
Geschäftsführer