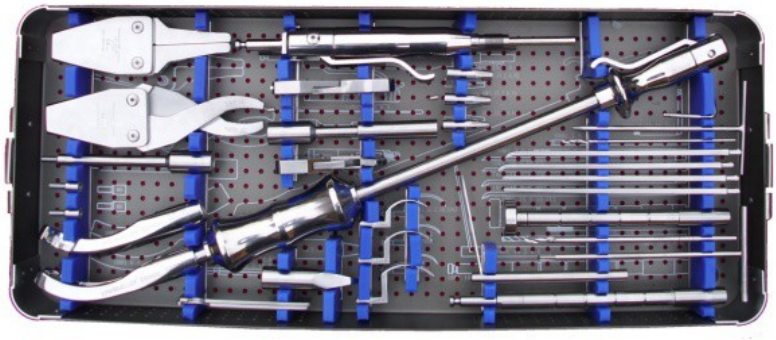
Extraction Tools for Total Joint Replacement
EPM Mueller® Hip Stem Extractor AU-S2; AU2; S2; MO;
EPM Mueller® Knee Extractor KN2, Cup Extractor C2
EPM Mueller® Modular Extractor System 2

„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® Stem Extractor AU-S2



EPM Mueller® Modular Extractor System 2 in BE box

Development of EPM Endo Plant Müller GmbH
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Technical Documentation

Content:

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) 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.

Fig. 1

Fig. 2

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

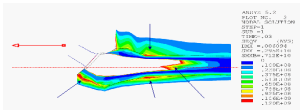


Fig. 3

3.2. Results and Discussion

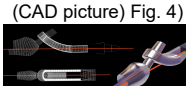
To depict the strains inside the femurs and femoral components, the von-Mises-strains (s EQV) were used. The FEA was performed in a transient mode. The diagrams 3 and 7 show the von-Mises-strains at maximal extraction forces at t=30 ms. One can notice the non-homogenous distribution of strains inside 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).

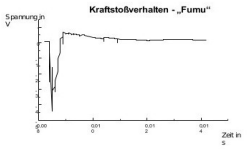


Fig. 5

Results:

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, suitable for tapers from 8 to 16 mm and also for stems with fixed heads (monobloks), with a slap hammer of 1 or 1,7 Kg.

Fig. 6a

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

Fig. 6b

EPM Mueller® Extractor CC.S2, closed head with single sliding spacer and 2,65Kg hammer(new 2019)

. 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 (new 2019)

Fig 6e

EPM Mueller® Extractor CFH.AU-S2 with a modular C frame and a 2 Kg extra hammer (new 2019)

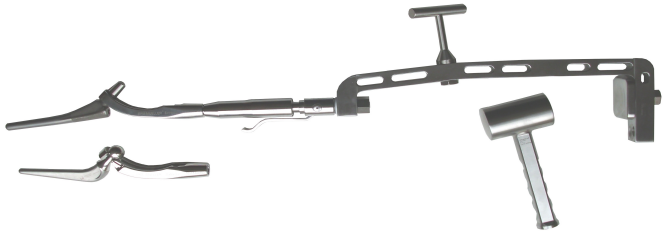


Fig 6f

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 (new 2018)

Fig.6h

EPM Mueller® Extractor CO.SA2 for Antero-access revisions with a offset link and a striking weight of 2.65 Kg (new 2019)

Fig.6i

EPM Mueller® Extractor CFH.SA2 for Antero-access revisions, with a modular C frame and a extra 2 Kg. Hammer (new 2019)

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. slap hammer (new 2019)

Fig.6l

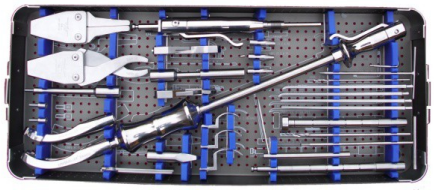
EPM Mueller® Extractor M6, for stems with M6 tread, with 1 or 1,7 Kg slap hammer

Fig.6m

EPM Mueller® Extractor C.M6 for stems with M6 tread, with 1 or 1,7 Kg slap hammer (new 2019)

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**

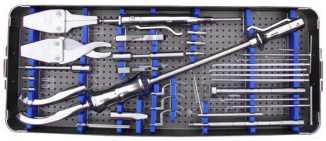


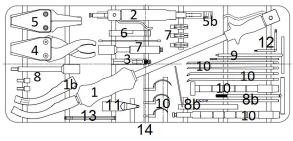
EPM Mueller® Modular Extractor System 2 in BE box.
Fig.6o

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.

6.2.1. EPM Mueller® Modular Extractor System 2





components:
1.- Hip Stem Extractor AU-S2) (1, 1b)
2.- Pneumatic Extractor Shaft
3.- Extractor attachment with spreading jaws for modular neck stems MO
4.- Knee stem Extractor attachment KN2
5.- Cup Extractor attachment with spreading jaws C2
6.- Cup Extractor clamping jaws set C2
7.- Pin and Sling Extractor attachment PS2
8.- Screw Extractor attachment M6
8b.- M6 Thread makers Set TM
9.- Damadged screw remover set SR
10.- Quick adapter with curettes, Chisels and cup osteotomes
11.- Hook Extractor attachment H2
12.- Allan key
13.- Wrence key set R7 and R11
14.-Sterilization basket with silicone lid supports and instruments

We developed 2014 EPM Mueller® Modular Extractor System 2 based on the EPM Mueller® hip stem Extractor. Newly developed attachments allows the extraction of various prostheses such as modular neckless hip, large head, knee, acetabular hemispherical or screw cups, pins, stucked drills and ruined screw.
Together with the EPM Mueller® stem Extractor AU-S2 the Modular Extractor System 2 attachments provide a complete solution for prosthesis revision problems.

6.2.2. EPM Mueller® Modular Extractor System 2 - use possibilities:

- EPM Mueller® stem Extractor S2, or AU2

- EPM Mueller® Pneumatik extractor PN2 (for pneumatic device as Woodpacker)

- EPM Mueller® Modular stem Extractor MO

- EPM Mueller® Knee shaft Extractor KN2 with extra spreading jaws, with option of chisels with quick adapter or hook

Option

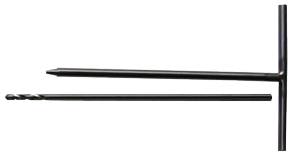
The knee shaft extractor clamping jaws can also be used for tibial component, large head hip stems, shoulder stems,modular stocked heads and stocked drills.

- EPM Mueller® hemispherical and Screwed Cup Extractor C2 with extra spreading jaws and housing handle, with option of cup osteotome and quick adapter and hook attachment

- EPM Mueller® stem Extractor M6 - **s**uitable for the extraction of stems with M6 threaded entry (such as Zimmer-shafts) or broken long shafts after made of a M6 thread with M6-thread maker set.
(with 2 extra changeble M6 screw tips)

- EPM Mueller® M6-Thread maker-Set TM

- EPM Mueller® Ruined screw remover SR



- EPM Mueller® Pin and Sling-extractor PS2 with 3 pin futter 1-2, 3-4, 5-6mm and a 120mm metal sling

- EPM Mueller® Quick-Adaptor with curette, chisels and 6 sizes cup osteotome

- EPM Mueller® Hook extractor H2

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

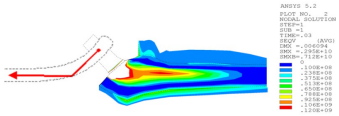


Fig. 7

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

9.1.

EPM Mueller® Stem Extractor AU-S2; AU2; S2

EPM Mueller® Stem Extractor AU-S2

9.1.1. 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.

9.1.2. COMPONENTS

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

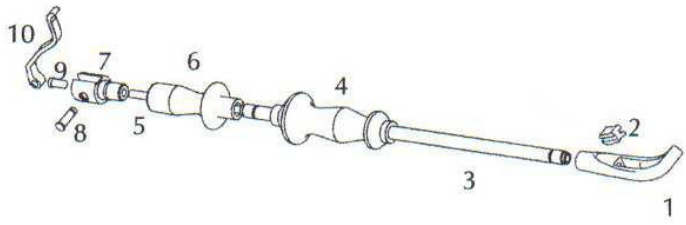


Fig. 1

9.1.3. HANDLING

The EPM Mueller HIP stem Extractor is delivered completely assembled and ready for use.
(**NON STERILE**!)
Sterilization is the responsibility of the User.

◊ **OPENING (Fig 2)**
Open lever (**1**) and thread between jamcase and handpiece (working thread) with circular movements reverse clockwise (**2**). ATTENTION: the threads at the guiding tube have to be always closed complete!
To enable clamping, move the spacer back by putting pressure on spacer (**3**).

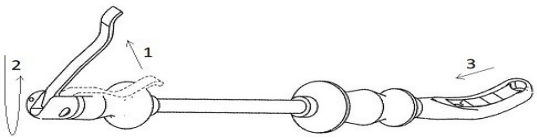


Fig. 2

◊ **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 until resistance is felt. Close (**3**) the lever to attain maximal clamping force.

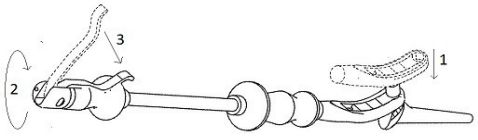
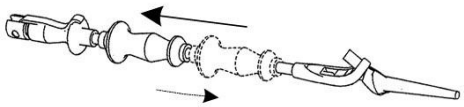


Fig. 3

◊ **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 ofthe handpiece.



Attention: Fig. 4

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

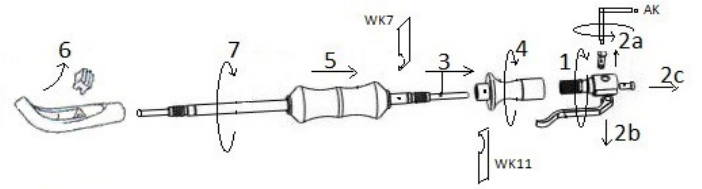
◊ **DETACHMENT**

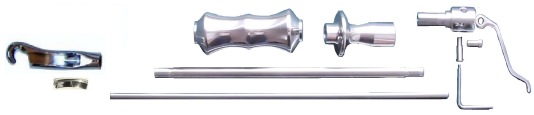
The extracted implant is removed from the tool with the reverse steps explained under OPENING of the instrument. (Fig. 2)

9.1.4 Disassembling (Fig.5a, 5b)

To disassemble look at picture 1, 5a and 5b

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 (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





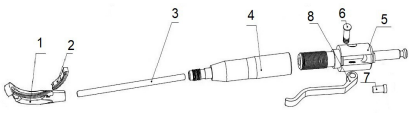
ATTENTION: use the bolt always with the plasticinset together! Fig. 5a Fig. 5b

9.2

EPM Mueller® stem extractor PN

9.2.1. Components

Abb.6a 1 2 (3) 4 8 (7) 6 5 Abb. 6B



1 Head of Tool	3 Pressure Rod PN	5 Jamcase PN	7 Bolt with plasticinset
2 Sliding Spacer	4 Handpiece	6 Pin screw	8 Lever

9.2.2 HANDLING

The EPM Mueller HIP stem Extractor is delivered completely assembled and ready for use. **(NON STERIL)**

◊ **OPENING**

Open lever (**1**) and thread between jamcase and handpiece (working thread) with circular movements reverse clockwise. ATTENTION: the thread at the tool head have to be always closed complete!

To enable clamping, move the spacer back by putting pressure on spacer (3).

◊ **APPLICATION and CLAMPING**

Slide 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 the jamcase with the opened lever(at 90° to the axis) at the distal-end clockwise until resistance is felt. Close the lever to attain maximal clamping force.

◊ **EXPLANTATION**

Through the jamcase linc shell the extractor be coupled to the pneumatic device (Woodpacker)The pneumatic force is enoufgh for explantation of old cemented HIP stems, knee stems, pins.

◊ **DETACHMENT**
The extracted implant is removed from the tool with the steps explained under OPENING of the instrument.

9.2.3 Disassembling

To disassemble look at picture 1, 5a and 5b
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 (presure rod can be used)
3. Extract presure rod
4. Remove sliding spacer through rectangular space at the instrument head
5. Detach handpiece by unscrewing completely from the tool head

9.3

EPM Mueller® Modular-stem extractor MO

9.3.1. Components

. 2a 2b 2c 1 3 (5) 4 10 6 7 (9) 8

EPM Mueller® Modular-stem Extractor MO Modular shaft spreading jaws attachment

1 body	3 guiding tube	6 lever	9 bolt with plastic insert
1b body pin screws	4 stroke weight	7 jamcase	10 handle
2a, 2b, 2c Spreading jaws Set	5 pressure rod	8 pin with screw	

9.3.2. Handling

Place the spreading jaws set in 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 jaws body until it stops. Now, by turning the lever together with the jamcase, the spreading jaws will get off and catch the modular stem.

The jaws are always hold by your hand on the body in the closed position ◊

Stem knocking out: Adjust the spreading jaws to the prosthetic modular neck cavity and insert it till stops. Turn the lever is in a vertical position to Extractor, including jamcase until you pinch the prosthesis firmly, finally press the lever to the handle. You can now extract the prosthesis by striking movement of the hammer weight towards Extractor handle.

9.3.3. 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

9.4

EPM Mueller® Knee extractor KN2

9.4.1. Components

2a 1b 1 3 (5) 4 10 6 7 (9) 8 Option: 11a 11b 12b(12c) 12a 12e 12d

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

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

9.4.2. Handling

Place the two pressure jaws into the opening of the housing and secure it with the 2 mounting screws using the Allen key. Turn first the extractor jamcase from the handle almost completely out. 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 into the handpiece. Your hand on the body holds the jaws always in the wide-open position, or at the spreading jaws in the closed position.

◊ **Prosthesis knock out:**

Adjust the opening of the jaws to the prosthesis outside dimension to be extracted (by the spreading jaws adjust to the inside dimension). The adjustable clamping jaws can clamp objects of 5-110 mm (at 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 hammer weight towards Extractor handle.

9.4.3. 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

9.5

EPM Mueller® Hemispherical- and screw-cup extractor C2

9.5.1. Components .

2a 1b 1a 3 (5) 4 10 6 7 (9) 8 Option: 11 12b(12c) 12a 12d 12e

2b 1c Hemispherical cup spreading jaws extractor Screw cup spreading jaws extractor Screw cup spreading jaws pneumatic extractor

EPM Mueller® Hemispherical and screw cup extractor C2 with clamping and spreading jaws
Option: 6 cup osteotome, quick adapter with plate or pneumatic coupling for Woodpacker

1a body	3 guiding tube	8 pin screw	12b quick adapter cover
1b body pin screw	4 striking weight	9 bolt with plastic insert	12c quick Adapter spring
1c body handle	5 pressure rod	10 lever	12d quick adapter plate
2a clamping jaws	6 Handle	11 cup osteotome	12e quick adapter pneumatic
2b spreading jaws	7 jamcase	12a quick adapter shaft	

9.5.2. 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.

◊ **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.
You can now extract the cup by striking movement of the hammer weight towards extractor handle. In case of 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.

◊ **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. You can now extract the cup by striking movement of the striking weight towards extractor handle.
In a press-fit cup use after the mobilisation of the 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.

◊ **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. You can now unscrew the cup by turning it anti-clockwise with the body handle.

9.4.3. 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.

9.6

EPM Mueller® Pin and sling extractor PS2

2 2a 3 4 6

1a 1 Pin and sling extractor PS2 Pin and Sling extractor Attachment

9.5.1. Components

1 Pin and sling extractor shaft 2 pin chuck for 1-2, 3-4 and 5-6mm diameter 3 guide tube 6 Handle
1a Cover 2a metal I sling 120mm 4 striking weight .

9.6.2. Handling

Pin extractor:

Turn the guiding tube (3) together with striking weight and handle in the Extractor attachment (1) until it stops. The cover (1a) should be placed on the attachment with the non threaded part forward and cover the pin chuck part. First, turn the cover tube back onto the shaft. Then turn the pin chuck counterclockwise to the shaft-end thread firmly.
Turn now forward the cover over the chuck. Insert the chuck opening on the pin to be extracted and turn the cover so long until you catch firmly the pin. . Now you can extract the pin by hammer striking movement direction extractor handle.

Sling extractor:

The cover tube (1a) should be placed with the thread-free part to the attachment. Turn the cover tube toward the shaft until the 2 recesses in the shaft are free. Hook one end of the sling and cover it with the cover. You can now attach the other end of the sling around the part to be removed and hook it into the second recess and cover it with the cover. Now you can extract the hooked part by hammer striking movement direction Extractor handle.

9.6.3. Disassembling

The unit is disassembled by unscrewing the threaded connections without additional tools.
A complete separation from the extractor attachment is performed in reverse order.

9.7

EPM Mueller® stem extractor M6

2 1 3 4 6

Extractor M6 with 2 M6 extractor screws Extractor M6 attachment

9.7.1. Components

1 M6 Extractor attachment 2 M6 screw 3 guiding tube 4 striking weight 6 Handle

9.7.2. Handling

Turn the guide tube of the extractor with the handle and striking weight in the thread of the M6 Extractor attachment till stop. Turn on the attachment screw one of the 2 M6 screws until they stop. (by damaging the thread at the extraction having to change only the M6 screw). Now you can turn the extractor into the thread on the shaft (or in the manufactured M6 thread with the thread maker Set TM on a broken shaft).till stop and extract the shaft or the broken shaft part by striking movement of the hammer weight direction extractor handle.

9.7.3. Disassembling

The unit is disassembled by unscrewing the threaded connections without additional tools.
A complete separation from the Extractor attachment is performed in reverse order.

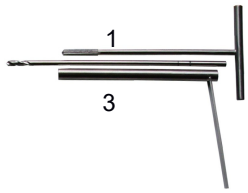
9.8

EPM Mueller® thread maker set TM

9.8.1. Components

1. M6 thread maker with T handle
2. M5 drill
3. M6 Thread makers guide with handle

.



M6 thread maker set

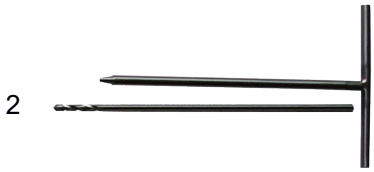
9.8.2. Handling

Place the guide to the broken shaft site. Bring the M5 drill in the guide tube up to the broken point. The first mark on the drill is now on the edge of the guide tube. Start now to drill up to the second mark reaches the edge.
The 2 markers are 10 mm apart. After removal of the drill, the guide tube and thorough rinsing, you can make the M6 thread with the thread maker. By twisting movements and repeated rinsing you create about 8 mm thread length. Now you can screw the M6 extractor and extract the stem broken part.

9.9

EPM Mueller® Ruined screw remover SR

9.9.1. Components



1. T handle with reverse conical screw
2. M3 Drill

9.9.2. Handling

Drill first 2-3 mm with the M3 drill into the damadged screw head. Than place straight the T handel screw tip inside the drilled hole. Turn now with preshure the T handel till the T handle screw tip stockt into the damadged screw.
Now turn further reverse clockwise with less preshure till you remouve the screw.

9.10

EPM Mueller® hook extractor H2

Hook extractor H2

Hook extractor attachment H2

9.10.1. Components

1. hook attachment 3. guiding tube 4. striking weight 6. handle

9.10.2. Handling

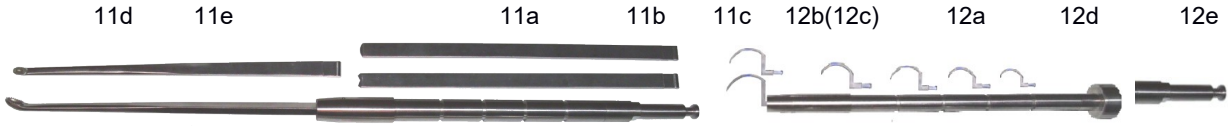
Turn the hook attachment to the extractor guiding tube with the handel and striking weight until it stops. After hooking the item, remove it by striking movement of the striking weight towards extractor handle. **Caution**: The hook-tip can break off at to strong hits

9.10.3. Disassembling

The unit is disassembled by unscrewing the threaded connections without additional tools.

9.11

EPM Mueller® Curette, chisel, 6 cup osteotome with quick adaptor with plate and with pneumatic coupling



EPM Mueller® 2 curette, 2 chisels and 6 cup osteotome, quick adapter plate or pneumatic coupling for Woodpecker

9.11.1. Components:

11a chisel R	11d curette S	12b quick adapter cover	12e quick adapter pneumatic coupling
11b chisel Z	11e curette L	12c quick adapter spring	
11c cup osteotome	12a quick adapter shaft	12d quick adapter plate	

9.11.2 Handling

Pull the cover back and put the curette, chisel or osteotome into the recess of the quick adapter shaft and let the cover off. The spring under the cover pushes it back to the closed position.

9.11.3 Disassembling

Remove the curette, chisel or osteotome from the quick connector. Pull then the cover completely until it stops, then turn it to the right and slide off the sleeve from the shaft. You can now remove the spring. At the other end of the shaft rotate the plate or the pneumatic coupling from the shaft.

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.

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

11.1. EPM Mueller® stem extractor S2, or AU2

· Tapers: Æ 8 – 16 mm
· Striking weight: 1.0 kg (2.2 lb)
· Total weight: 2,2 kg(4.84 lb)
· Total length: 550mm ()(Standard), 620mm (25 inches)(long),
· Hitting distance: 205mm (8.1 inches) standard; 275mm (8.8 inches) long

11.2. EPM Mueller pneumatic stem extractor PN

· Tapers: Æ 8 – 16 mm
· Striking: pneumatic device as Woodpacker
· Total weight: 1,2 kg (2.4 lb)
· Total length: 350mm (14.1 inches)

11.3 EPM Mueller® modular-stem extractor MO

· Inside modular neck reces : Æ 8-10mm / Æ 10-17mm
· Striking weight: 1.0 kg (2.2 lb)
· Total weight: 2,65 kg(5.83 lb), 1,35 kg (2.97 lb) (PN Variant)
· Total length: 560mm (22.1 inches)(Standard), 630mm (25 inches)(long), 360mm (PN)
· Hitting distance: 205mm (8.1 inches) standard; 275mm (8.8 inches) long

11.4 EPM Mueller® Knee Prosthesis extractor KN2

· Prosthesis dimensions : 7 - 110mm
· Striking weight: 1.0 kg (2.2 lb)
· Total weight: 2,65 kg(5.83 lb), 1,35 kg (2.97 lb) (PN Variant)
· Total length: 590mm (23.3 inches)(Standard), 660mm (26 inches)(long), 360mm (PN)
· Hitting distance: 205mm (8.1 inches) standard; 275mm (8.8 inches) long

11.5. EPM Mueller® acetabular hemispheric- and screw-cup extractor C2

· Cup outside dimension Æ 38 - Æ 74mm
· Striking weight: 1.0 kg (2.2 lb)
· Total weight: 2,65 kg(5.83 lb), 1,35 kg (2.97 lb) (PN Variant)
· Total length: 590mm (23.3 inches)(Standard), 660mm (26 inches)(long), 360mm (PN)
· Hitting distance: 205mm (8.1 inches) standard; 275mm (8.8 inches) long

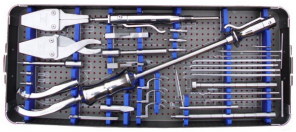
11.6. EPM Mueller® Pin and sling extractor PS2

· Pin size : Æ 1-2, 3-4, 5-6mm
· Sling length 120 mm
· Striking weight: 1.0 kg (2.2 lb)
· Total weight: 1,9 kg(4.18 lb), 0,9 kg (2 lb) (PN Variant)
· Total length: 550mm (21.7 inches)(Standard), 620mm (25 inches)(long), 350mm (PN)
· Hitting distance: 205mm (8.1 inches) standard; 275mm (8.8 inches) long

11.7. EPM Mueller® Hook extractor H2

· Striking weight: 1.0 kg (2.2 lb)
· Total weight: 1,65 kg(3.63 lb), 1,2 kg (2.64 lb) (PN Variant)
· Total length: 530mm (20.9 inches)(Standard), 600mm (23.7 inches)(long), 360mm (PN)
· Hitting distance: 205mm (8.1 inches) standard; 275mm (8.8 inches) long

12. Supply Extractors and Spare parts



1001.15.AU-S2.PN.KN2.C2.MO.PS2.M6.TM.SR.QP-CUC.QH-CO.H2.BE
. EPM Mueller® Modular extractor system 2

1001.7.AU-S2	EPM Mueller® Stem Extractor AU-S2
1001.5.AU2	EPM Mueller® Stem Extractor AU2
1001.6.S2	EPM Mueller® Stem Extractor S2
1001.8.PN.AU; PN.S	EPM Mueller® Stem Extractor PN.AU, or PN.S
1001.15.3.KN2	EPM Mueller® Knee Extractor KN2
1001.15.4.C2	EPM Mueller® Hemispheric- and Screw-cup Extractor C2
1001.15.5.MO	EPM Mueller® Modular- Stem Extractor MO
1001.15.6.PS2	EPM Mueller® Pin and sling Extractor PS2
1001.15.7.M6	EPM Mueller® Extractor M6
1001.15.8.TM	EPM Mueller® Thread maker TM
1001.15.9.SR	EPM Mueller® Damaged screw remover SR
1001.15.10.QP-CUC	EPM Mueller® Quick adaptor with pneumatic coupling curettes and chisels QP-CUC
1001.15.10.QH-CO	EPM Mueller® Quick adaptor with hammer plate and 6 cup osteotomes QH-CO
1001.15.11.H2	EPM Mueller® Hook extractor H2
1015.15.12.BE	Basket with lid and silicone holder, (62/24/7) BE

Spare parts:
EPM Mueller® Modular Extractor System 2

. 1001.15.AU-S2.PN.KN2.C2.MO.PS2.M6.TM.SR.QP-CUC.QH-CO.H2.BE
Item no.:

12.1 EPM Mueller®Slap hammer HIP stem extractor 1001.7.AU-S2

1001.2.5.AU	Head AU
1001.2.6.S	Head S
1001.2.04.U	Slider spacer U
1001.2.17.ST2	Guiding tube ST2
1001.2.17.L2	Guiding tube L2 **Option**
1001.2.15.ST	Pressure rod ST
1001.2.15.L	Pressure rod Long **Option**
1001.2.09.N	Striking weight 1000g
1001.2.09.S	Striking weight 1700g **Option**
1001.2.11.2.ST	Handel 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
1001.2.14.2	Lever

12.2 Pneumatic HIP stem extractor shaft PN 1001.8.PN

1001.2.11.PN2 Handel PN

1001.2.12.PN Jamcase PN

1001.2.15.PN Pressure rod PN

1001.2.07.2 Bolt with plastic inset

1001.2.13.4 Pin screw

1001.2.13.A2.5-3 Allan key

1001.2.14.2 Lever

12.3 Knee Extractor attachment 1001.15.3

1001.15.2.3.B Body

1001.15.2.3.S Pin screw

1001.15.2.3.L Knee clamping jaw left

1001.15.2.3.R Knee 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

12.4 Hemispheric-and screw cup Extractor attachment 1001.15.4

1001.15.2.3.B2 Body 2

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

12.5 Modular-shaft Extractor spreading attachment 1001.15.5

1001.15.2.5 Modular-shaft Extractor spreading jaws set

1001.15.2.5.FJ Modular fix jaw

1001.15.2.5.MJ Modular mobile jaw

1001.15.2.5.MP Modular mobile piece

1001.15.2.5.S jaw pin screw

12.6 Pin and sling attachment 1001.15.6

1001.15.2.6.B Attachment shaft

1001.15.2.6.C Shaft cover

1001.15.2.6.P2 Pin chuck 1-2mm

1001.15.2.6.P4 Pin chuck 3-4mm

1001.15.2.6.P6 Pin chuck 5-6mm

1001.15.2.6.S Metal sling 120mm

12.7 M6 Screw attachment with 2 M6 screws 1001.15.7

1001.15.2.7.M6A M6 Screw attachment

1001.15.2.7.M6 M6 Screw

12.8 M6 Thread maker set 1001.15.8.TM

1001.15.2.8.G Drill guide with handle

1001.15.2.8.D M5 drill

1001.15.2.8.TM M6 thread maker with T handle

12.9 Damaged screw remover set 1001.15.9.SR

1001.15.2.9.D M3 Drill
1001.15.2.9.R Reverse drill with T handle

12.10.1 Quick adapter with pneumatic coupling, curetten and chisels

1001.15.10.QP-CUC

1001.15.10.QP Quick adapter with pneumatic coupling
1001.15.2.10.QB Quick adapter shaft
1001.15.2.10.QP Pneumatic coupling
1001.15.2.10.QC Shaft cover
1001.15.2.10.QS Shaft spring
1001.15.2.10.CUS Curette small
1001.15.2.10.CUL Curette big
1001.15.2.10.CR Chisel round
1001.15.2.10.CZ Chisel zak

12.10.2 Quick adaptor with plate and 6 cup osteotome .

1001.15.10.QPH-CO 1001.15.10.QH Quick adaptor with plate 1001.15.2.10.QB Quick adaptor shaft 1001.15.2.10.QH Plate 1001.15.2.10.QC Quick adaptor cover 1001.15.2.10.QS Shaft spring 1001.15.2.10.CO44 Cup osteotom 44 1001.15.2.10.CO48 Cup osteotom 48 1001.15.2.10.CO52 Cup osteotom 52 1001.15.2.10.CO56 Cup osteotom 56 1001.15.2.10.CO60 Cup osteotom 60 1001.15.2.10.CO64 Cup osteotom 64

12.11 Hook attachment

1001.15.11.H Hook pointed

12.12 Wrence key set 1001.15.13

1001.15.2.13.R7 Schlüssel R7
1001.15.2.13.R11 Schlüssel R11

12.13 Sterilization basket with lid and silicone holder

1001.15.12.BE Coated aluminum basket with lid 62/24/7cm

13. Warranty, Service

24 months replacement warranty from date of invoice (not granted for non-compliance with the operating and maintenance or use instructions, or consumption parts like drills , screws, sling, osteotomes, curettes, chisel and hook)

International / European / German-
Sales, hotline, warranty, service, spare parts, repair:

EPM Endo Plant Müller GmbH
Schleusen Str. 8, 63839 Kleinwallstadt
Tel.:+49-(0)6022/25419
Fax: +49-(0)6022/ 25419
e-mail: epmmueller@aol.com

www.epm-mueller.de

14. Conformity Declaration

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 Gelenkprothesen
The medical device „EPM Mueller® Extractor“ Extraction Tool for Joint 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
. GTIN6946998813144

Art.-Nr. 1001.6. S; 1001.6.S2
Produkt Identifikation UMDNS (15-580) : 5000.E
. EPM Mueller® Extractor S/S2, 1000.1006.2000
. GTIN6946998813151

Art.-Nr. 1001.15.AU-S2.PN.KN2.C2.MO.PS2.M6.TM.SR.QP-CUC.QH-CO.H2.BE
Produkt Identifikation UMDNS (15-580) :5000.E
. EPM Mueller® Modular Extractor System 2, 1000.1015.2000
. GTIN6946998813359

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