

Product description  
&  
instructions for use

# RAP-hip<sup>®</sup> Hip stem extraction set



**Legal Manufacturer:**

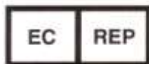


Effectum Medical AG  
Kirchgasse 11  
CH-4600 Olten  
[www.effectummedical.com](http://www.effectummedical.com)

**Marketed by:**



**EU Authorised Representative:**



MED-RAS GmbH  
Eichenallee 8H  
D-21521 Wohltorf

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## 1 Document history

New Document	Date	Old documents
04.002.001.e_Product description and IFU-I02_EN_V1	September 2020	The document is medically identical to the "Safrima" document with the document number DOK-2-4-001.
04.002.001.e_Product description and IFU-I02_EN_V2	December 2020	Change of address of the Legal Manufacturer
04.002.001.e_Product description and IFU-I02_EN_V3	March 2021	Including of EU Authorised Representative: MED-RAS GmbH
04.002.001.e_Product description and IFU-I02_EN_V4	October 2021	Chapter 2.3. update of lifetime of the instruments
04.002.001.e_Product description and IFU-I02_EN_V5	December 2021	Chapter 2.5 added warning symbol QR code moved from chapter 6 to chapter 11

## 2 Introduction

This product description and instructions for use (IFU) with document number 04.002.001.e replaces all previous versions of the RAP-hip® IFU. The document is also available for downloading online at <https://www.effectummedical.com/imprint/> and <https://www.mathysmedical.com/downloads/dokumente.html>

The RAP-hip® instrument was developed for the extraction of all common hip stems currently in the market. The instrument can be rented or purchased.

This document explains the safe use of the hip stem extraction set. The information provided here applies only to the Effectum Medical AG hip stem extraction set including the respective adapters.

This product description, instructions for use and "04.002.002.e\_Cleaning, Sterilisation, Maintenance" must be read carefully before the first cleaning, sterilisation and use.

### 2.1 Intended use

The system is intended for the removal of implant components, currently limited to the hip stem part and the femoral head of hip prostheses. The device can be used for all known patient positions and access standards in hip revision operations.

### 2.2 Indications / Contraindications

#### 2.2.1 Indications

Removal of all common **hip stems** in the left and right hips. The instrument can be used for **posterior**, **lateral** or **anterior** approach.

The device may also be used to remove only the prosthetic femoral head if the rest of the hip stem is to remain.

### 2.2.2 Contraindications

The device is not suitable for implants that do not permit fastening or handling according to the instructions for use.

This instrument set may not be used for the extraction of the acetabular cup.

The device must not be used for re-implanting new hip stems.

Monobloc stems may not be removed with the femoral head extractor. There is a special adapter for that.

The device is not suitable for perforated or reticulated hip implants through which bone tissue has developed.

The device **must not** be used if for medical and/or mechanical reasons it is impossible to be used in the position described in the surgical technique below or if the surgeon notes any discrepancies between the purpose and the use of the device.

The products must be used by trained personnel only.

### 2.3 Limitation

As for any standard operative procedure, an alternative to the RAP-it® should be included when planning an operation.

As a RAP-it® basic set and the universal adapters in the hip stem extraction set are made entirely of medical-grade steel. The instruments can be reused – in case of adequate care and if they are undamaged and clean – for 100 reprocessing cycles. The user is responsible for each further use as well as for the use of damaged and dirty instruments (no liability in case of disregard).

The special adapters are subject to extreme wear from a mechanical point of view, which is why they are declared to be “single use”.

The single use only instruments are marked accordingly on the instrument itself. Single use instruments cannot be reused.

The device may not be used to remove acetabular or resurfacing cups. Precautions must also be taken in the case of modular hip stems.


The complete device with its adapters must not be reprocessed after having been used on patients suffering from Creutzfeldt-Jakob disease or its variations. Further handling in such cases is subject to national legislation wherever the device is used. In this case, Effectum Medical AG cannot be held liable for any reuse of the device.

Individual components of the extraction set or the adapters should not be replaced by third-party products.

### 2.4 Service and spare parts

Every individual part is labelled and can be obtained from the respective country representative. See the customer service note in section 16. We also conduct service checks.

### 2.5 Warning

 All parts of the extraction sets are <b>NON-STERILE</b> when delivered!
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Cleaning and sterilisation are performed in accordance with **04.002.002.e\_Cleaning Sterilisation Maintenance**. Available for downloading online at <https://www.effectummedical.com/imprint/> and <https://www.mathysmedical.com/downloads/dokumente.html>

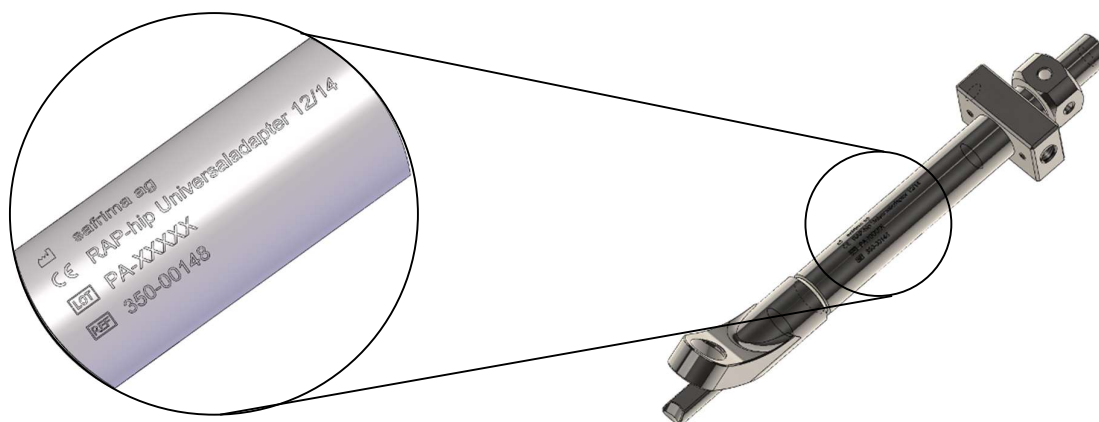
Before using the device and the adapters, these parts should be visually examined for any damage such as cracks, deformation or fractures. Worn, corroded or damaged parts of the device or adapters should not be used. They must be cleaned and sterilised before being returned to the supplier. The supplier assumes no liability for injuries, delays, or damage resulting from the failure to heed this warning. Soiled instruments must be reprocessed in the central sterile goods station.

### 2.6 Symbols and labelling

The symbols used comply with standard EN 980 and EN ISO 15223.

Each individual part is labelled as follows and can therefore be clearly identified as a Effectum Medical AG product even when disassembled. Components might be marked by "safrima ag" which is the former legal manufacturer.

 Effectum Medical AG  
 "RAP-it®" + part designation  
 LOT XXXXX  
 REF 350-00148



**Fig. 1:** Example of labelling of all RAP-hip® articles



**Fig. 2:** "Single-use" labelling <sup>1)</sup> on the special adapters

<sup>1)</sup> see also section 3.

## 2.7 Units

Standard SI units are used according to ISO standard 80000.

## 2.8 Abbreviations

Abbreviations used in the text:

RAP-it®	Basic prosthesis extraction instrument (impact instrument)
RAP-hip®	Set of devices for hip stem extractions
OP	Operating theatre or operation

### 3 Description of the RAP-hip® instrument

The hip stem extraction device is a universal device intended for the removal of most current cemented or non-cemented hip-stems available on the market.

The patented instrument generates a high change in momentum by tapping a guided slip weight against a separator bolt and is therefore extremely effective at separating cancellous bone from the implant.

Due to the slim design, access is potentially possible even without a trochanter osteotomy. The instrument can be used for posterior, lateral or anterior access. The easy handling and high efficiency can shorten surgery time.

The RAP-hip® hip stem extraction device consists of:

- The **RAP-it® extraction instrument**
- **Special adapters** (below)
- **Universal adapters** (below)
- **Femoral head extraction device** (right)
- Other special adapters (not illustrated)
- Steri-Case or transport case (not illustrated)



**Fig. 3:** RAP-hip® hip stem extraction device

The instrument set is modular and can be individually assembled depending on the needs of the hospital or surgeon.

**RAP-it® extraction instrument + hip stem adapter = RAP-hip**

All parts of the RAP-it® extraction tool are made of medical-grade steel. They can be re-sterilised and reused several times. The device is sized to fit traditional sterilising boxes and baskets. It can be assembled and disassembled manually without any tools.

Adapters are instruments that form a connection to the implant.

There are:

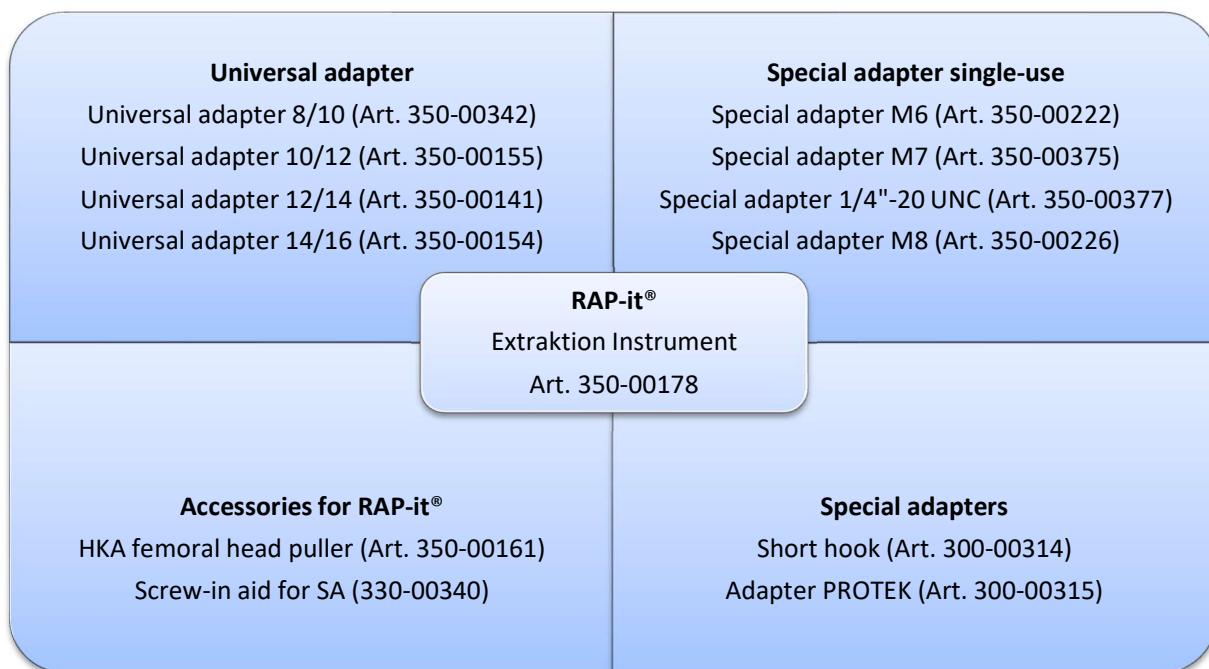
- four kinds of universal adapters for hip stems
- four kinds of special adapters with threads in the stem shoulder (e.g. Corail, some from Zweymüller, etc.)
- product or company-specific adapters.

Universal adapters are available for hip stems with a taper diameter of 8/10, 10/12, 12/14, and 14/16. They are made of medical-grade steel and can be re-sterilised and reused.

The special adapters have a thread at the distal end and are suitable for connecting to hip stems with a thread in the stem shoulder. They allow a direct connection to the implant. Thread sizes M6, M7, M8 and ¼" 20UNC are available. The special adapters are labelled "single-use" instruments for technical reasons. They are also made of medical-grade steel. If the special adapter is not needed during the operation, it can be re-sterilised until it has been used **once** for stem extraction.



The available adapters are listed below:



**Fig. 4: RAP-it® extraction instrument with range of adapters**

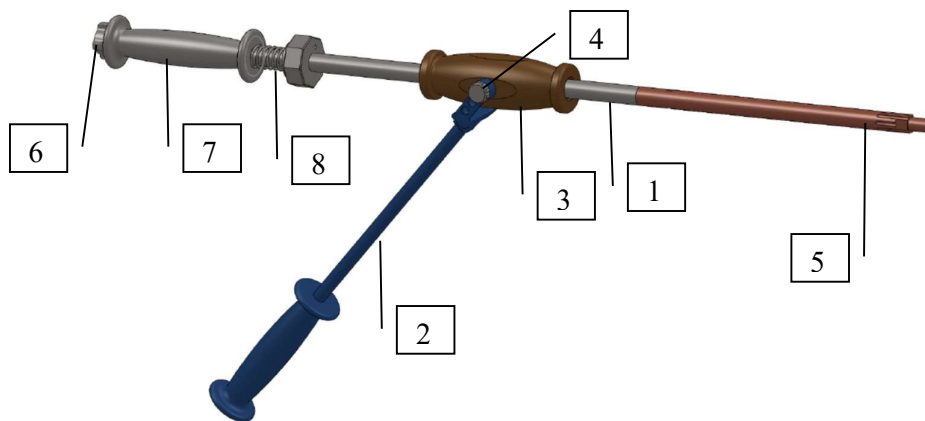
### 3.1 The RAP-it® instrument set – all articles

#### 3.1.1 RAP-it® extraction instrument

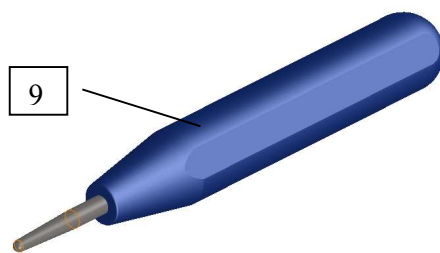
Quantity	Designation	Article no.
1	RAP-it® basic set	350-00178

Consisting of:

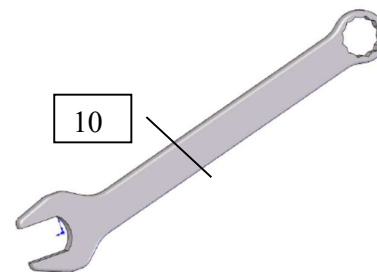
Item	Qty	Designation	Article no.
1	1	Guide rod	350-00183
2	1	Impactor	350-00145
3	1	Large impactor	300-00122
4	2	M8 screws	300-00118
5	1	Extension rod	300-00116
6	1	Nut	300-00185
7	1	Guide-rod handle	300-00180
8	1	Compression spring	500-00188
9	1	Tool for Basic instrumentation	350-00150
10	1	11mm AF open-end/ring wrench	500-00191



**Fig. 5:** RAP-it® basic set for hip stem revision operations



**Fig. 6:** RAP-it® tool (left)



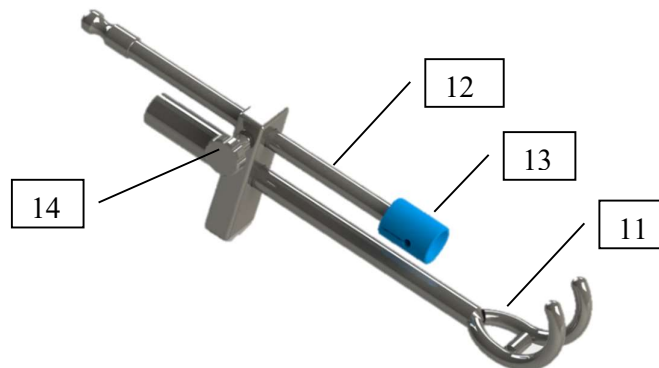
11 mm AF open-end/ring wrench (right)

### 3.1.2 Femoral head extraction tool:

Quantity	Designation	Article no.
1	Femoral head extraction tool	350-00161

Consisting of:

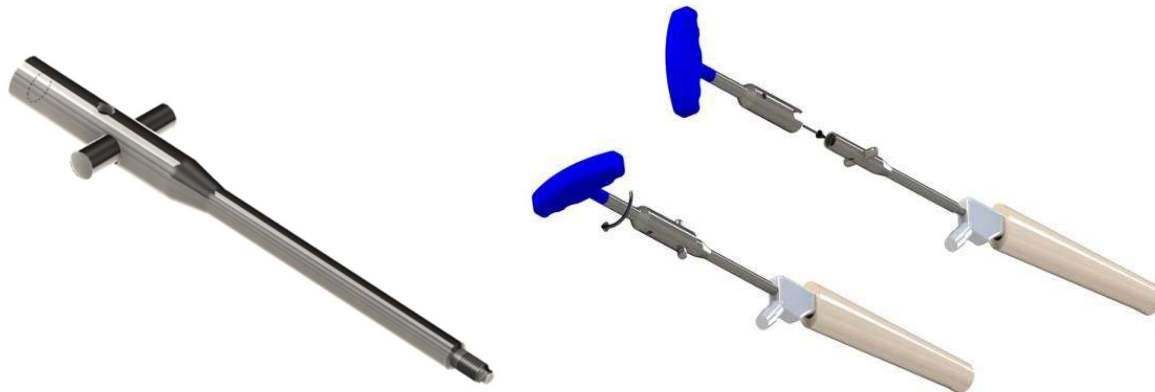
Item	Quantity	Designation	Article no.
11	1	Femoral head extraction tool fork	350-00162
12	1	Femoral head extraction tool mandrel	300-00164
13	1	Femoral head extraction tool fastener	300-00236
14	1	M8 screw	300-00118



**Fig 7:** Femoral head extraction tool

### 3.1.3 Special adapter for removing a hip stem:

Quantity	Designation	Article no.
1	Special adapter M6, e.g. Corail®	350-00222
1	Special adapter M7	350-00375
1	Special adapter M8, e.g. Zweymüller	350-00226
1	Special adapter 1/4" 20UNC (e.g. twin sys®)	350-00377
1	Optional accessory: Insertion aid	330-00340



**Fig. 8:** Special adapter (left), insertion aid as optional accessory (right)

### 3.1.4 Universal adapter for the removal of hip stems:

Quantity	Designation	Article no.
1	Universal adapter 8/10	350-00342
1	Universal adapter 10/12	350-00155
1	Universal adapter 12/14	350-00141
1	Universal adapter 14/16	350-00154

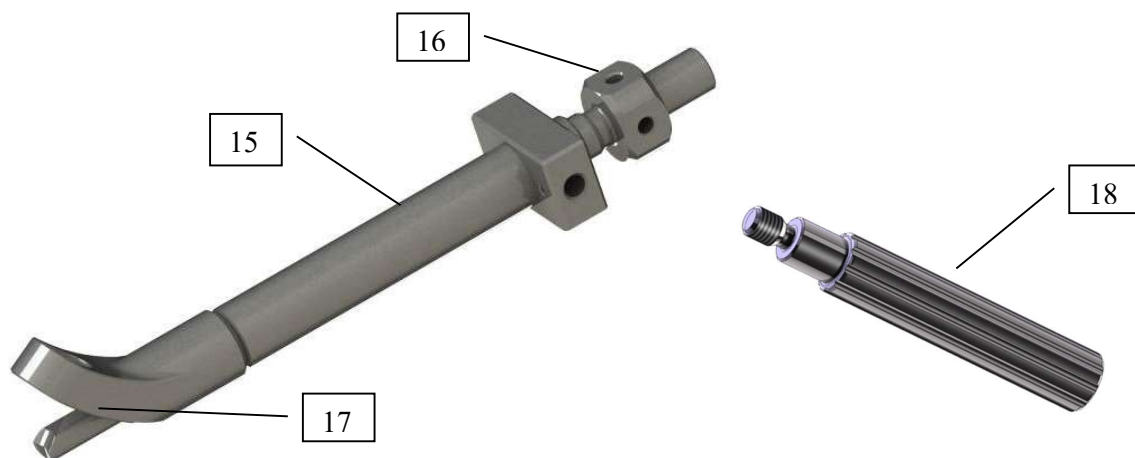
Consisting of:

Item	Quantity	Designation	Article no.
15	1	Universal adapter module 8/10	350-00344
or	1	Universal adapter module 10/12	350-00156
or	1	Universal adapter module 12/14	350-00148
or	1	Universal adapter module 14/16	350-00152

plus:

16	1	Screw	300-00137
17	1	Universal adapter mandrel	300-00138
18	1	Universal adapter handle <sup>1)</sup>	300-00190

<sup>1)</sup> Only one included with order of several universal adapters



**Fig. 9:** Universal adapter (left)

universal adapter handle (right)

### 3.1.5 Other adapters:

Qty.	Designation	Article no.
1	Short hook	300-00314
1	PROTEK connector	300-00315



**Fig. 10:** Short hook (left) and PROTEK connector (centre) and Monobloc extractor (right)

## 4 Table of hip stems and use of the RAP-hip® device

Examples of non-cemented hip stems (non-exhaustive list)

Brand name	Distributor	Proposed adapter
Avenir® Müller	Zimmer	Universal adapter
Alloclassic® Zweymüller	Zimmer	Universal adapter
CLS® Spotorno®	Zimmer	Universal adapter
PROXIMA™	DePuy	Special adapter
S-ROM	DePuy	Universal adapter
Corail® AMT	DePuy	Special adapter
G2®	DePuy	Universal adapter
Summit™	DePuy	Special adapter
Balance® Microplasty™	BIOMET	Universal adapter
Aura® II	BIOMET	Universal adapter
Echo™	BIOMET	Special adapter
Taperloc®	BIOMET	Special adapter
twinSys®	Mathys	Special adapter
Stellaris	Mathys	Special adapter
MiniHip®	CORIN	Universal adapter
Nanos	smith&nephew	Universal adapter
Anthology™	smith&nephew	Universal adapter
Synergy	smith&nephew	Universal adapter
Quadra® H	Medacta	Special adapter
ABG™ II	Stryker	Universal adapter
Accolade™ TMZF®	Stryker	Universal adapter

**Table 1: Table of non-cemented hip stems (non-exhaustive list)**

Examples of cemented hip stems (non-exhaustive list)

Brand name	Distributor	Proposed adapter
M. E. Müller Straight shaft	Zimmer	Universal adapter
Optan™	Zimmer	Universal adapter
CPT®	Zimmer	Universal adapter
C-Stem™ AMT	DePuy	Special adapter
G2®	DePuy	Universal adapter
Straight shaft Autobloquante™	DePuy	Universal adapter
Corail® AMT	DePuy	Special adapter
Aura® II	BIOMET	Universal adapter
twinSys®	Mathys	Special adapter
CPCS™	smith&nephew	Universal adapter
CPS™	smith&nephew	Universal adapter
Exeter™	Stryker	Universal adapter

**Table 2: Table of current cemented hip stems (non-exhaustive list)**

## 5 Advantages of a RAP-hip®

1. This device can be used for the extraction of most standard hip stems.
2. Different adapters can be mounted at the distal end of the instrument.
3. High impact due to the impact weight accelerated with an impactor (the impact weight is no longer guided manually)
4. 53 cm acceleration pathway
5. Impact can be applied in both directions
6. Impact can be precisely dosed
7. The instrument can be completely disassembled and is thus easy to clean and re-sterilise
8. Easy to assemble thanks to screw connections
9. Manually operated, alone or with an assistant
10. No part can roll or fall from the preparation table
11. Unpleasant vibration at the wrist almost imperceptible thanks to the uncoupling of the handle
12. Various impact weights can be mounted
13. Impact weight cannot jam
14. Individual parts available as spare parts

## 6 Assembly of the instruments

### 6.1 Instructions for assembly and use on the Effectum Medical AG website

This product description & instructions for use 04.002.002 can be found on <https://www.effectummedical.com/imprint/>

### 6.2 Warnings

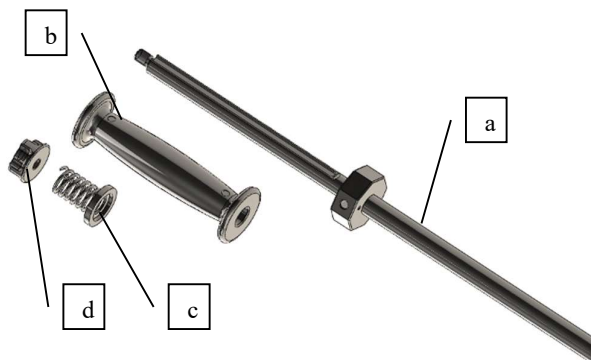
⚠ The entire set can be assembled and disassembled manually without any tools. Two tools are provided solely for the disassembly of parts that are found to be too tight during the operation.

⚠ For easier assembly and disassembly, we recommend moistening the thread. e.g. with water, before assembly. This prevents dry engagement of the threads.

⚠ Never use pliers to loosen parts – only use the tool provided.

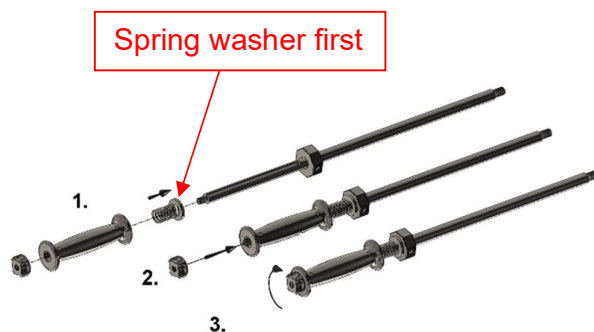
The use of pliers may cause scratches and grooves which can cause hand injuries or damage to gloves that might limit or prevent the use of the device. Metal particles and fragments must not be allowed to enter the wound. Effectum Medical AG cannot be held liable for any incidents attributable to the above-mentioned problems.

### 6.3 Preparation of the RAP-it® basic set



The patented handle of the basic set consists of the following parts:

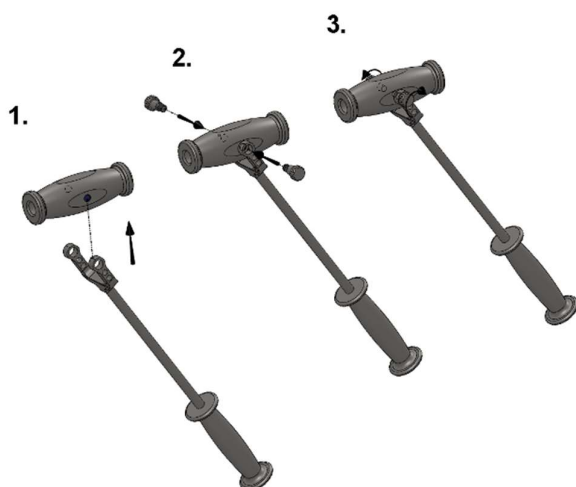
- a) Femoral head extraction tool fork
- b) Locking screw
- c) Grooved rod to secure the femoral head
- d) Femoral head fixation



Slide (1) the spring washer opening first onto the guide rod. Then fit the spring and handle. The handle must be positioned to ensure that the guide pins lie in the guide groove. Screw the nut onto the guide rod with the rounded surface facing forward (2) and tighten (3) manually.



Screw the guide rod by hand (do not use a tool!) into the relevant extension rod and tighten it by hand.



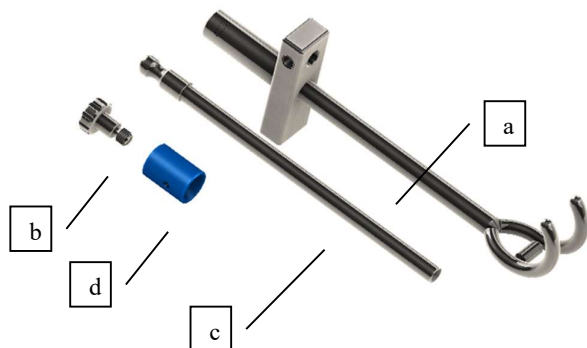
Firmly attach the impactor to the impact weight manually using the two fixation screws provided.



Slide the impactor and impact weight assembly onto the guide rod.



#### 6.4 Preparation of the femoral head extraction tool



The femoral head extraction tool consists of four parts

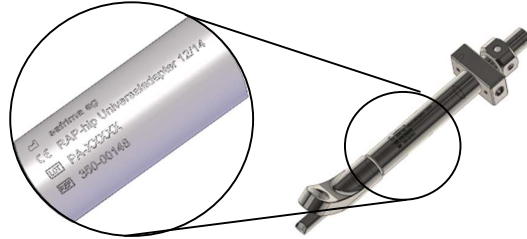
- a) Femoral head extraction tool fork
- b) Locking screw
- c) Grooved rod to fix the femoral head
- d) Femoral head fixture



Insert (1) the rod into the aperture provided for this purpose on the femoral head extraction tool, centre (2) the rod approximately and lock it (3) with the screw. Put (3) the femoral head fixture in place

## 6.5 Preparing the universal adapter

⚠ The surgeon defines the adapter to connect to the hip stem.



**Fig. 11:** Identification of the universal adapters

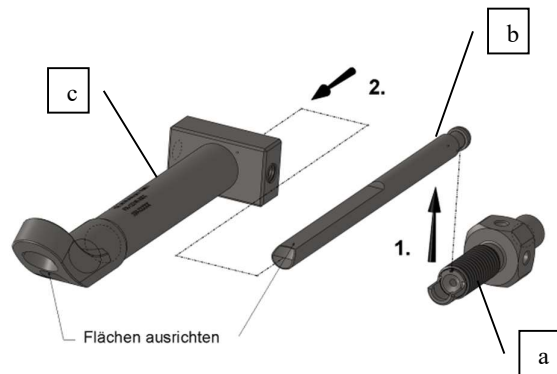
### Universal adapter

According to the diameter of the **taper of the hip stem**, choose:

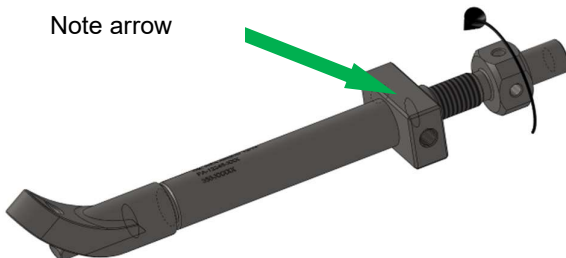
- Universal adapter UA 8/10
- Universal adapter UA 10/12

- Universal adapter UA 12/14
- Universal adapter UA 14/16

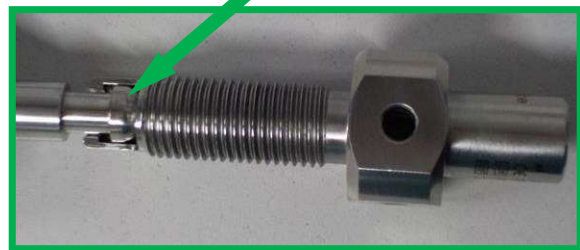
### Assembly of the universal adapter



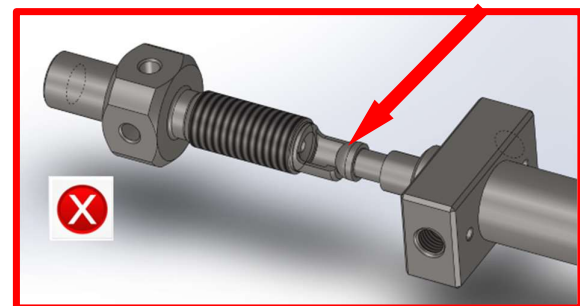
Note arrow



First **hang** the mandrel (b) into the pressure screw (a).



Then insert the pressure screw / mandrel unit into the guide tube of the adapter (c) and screw in initially with only two to three turns. Note the correct position of the surface on the mandrel; the **arrow on the adapter and the mandrel** must face each other.



## 6.6 Preparation of the special adapter

**Caution: The special adapters are single use and shall not be used multiple times.**

⚠ The surgeon defines whether to use the special adapter or the universal adapter for the connection to the hip stem.



### ***Special adapter***

No preparation work is required for the special adapter.

Depending on the thread in the neck of the stem, select:

- Special adapter SA M6
- Special adapter SA M7
- Special adapter SA M8
- Special adapter 1/4" 20UNC

## 7 Operating technique with a special adapter

⚠ Only a qualified surgeon can carry out the operation.

The operating technique described below is best carried out with the help of an assistant.

All screw connections must be tightened fully by hand before using the special adapter. During the operation, the surgeon's assistant must ensure that none of the screw connections have become loose.

<b>Operating technique</b>	<ol style="list-style-type: none"> <li>1.) Remove the femoral head</li> <li>2.) Screw in the special adapter on the implant</li> <li>3.) Screw in the RAP-it® and carefully knock out the hip stem</li> <li>4.) Constantly check the condition of the tissue and femur</li> <li>5.) Constantly check whether the stem has loosened</li> </ol>
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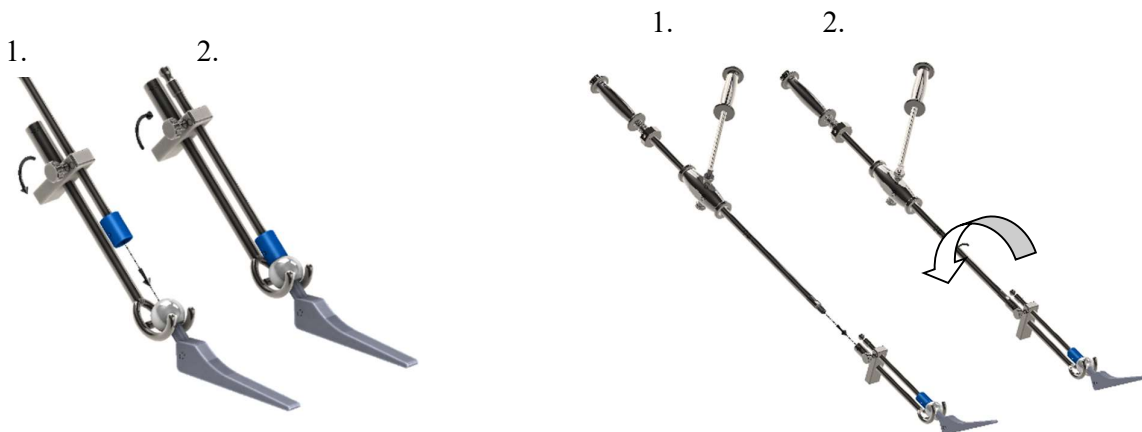
### 7.1 Important warnings for use

⚠ The impact force generated is determined by the surgeon due to manual application. Gentle, but also massive impacts can be carried out with the instrument. Effectum Medical AG points out that the femur or tissue could be damaged through improper application of force.

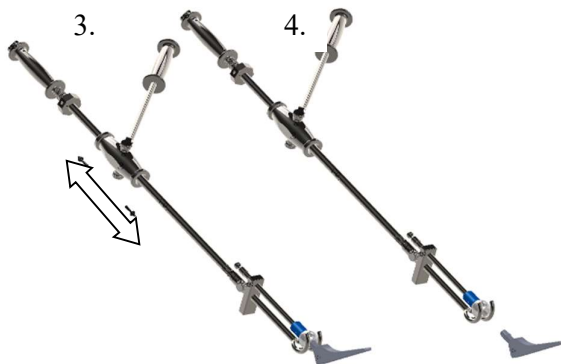
⚠ The femoral head must be removed before the hip stem is removed because the femoral head could be loosened by the strong impact and fall into the wound.

⚠ Monobloc stems, in which the femoral head is firmly connected to the hip stem, may not be removed using the femoral head extractor.

### 7.2 Removing the femoral head



Insert (1) the femoral head extraction tool around the femoral head. Position it so that the femoral head can be removed from the taper. Release the screw, lower the rod onto the femoral head and press lightly. Tighten (2) the locking screw firmly by hand.



Remove the femoral head by means of **gentle** taps with the impactor head.

⚠ Only give **gentle** taps because the strike axis is at an angle to the hip stem axis. Excessive blows can damage the femur.

⚠ Do not allow the femoral head to drop into the wound.

Unscrew the femoral head extraction tool and disassemble it for cleaning.

**Alternatively:**



The femoral head can also be easily removed by **gently** tapping the back of the extension of the femoral head extraction tool with a hammer.

The hammer is not included in the Rap-Hip® set.

**Fig. 12:** Careful use of a hammer

Screw the RAP-it® basic set into the femoral head extraction tool.

### 7.3 Screw in the special adapter up to the stop



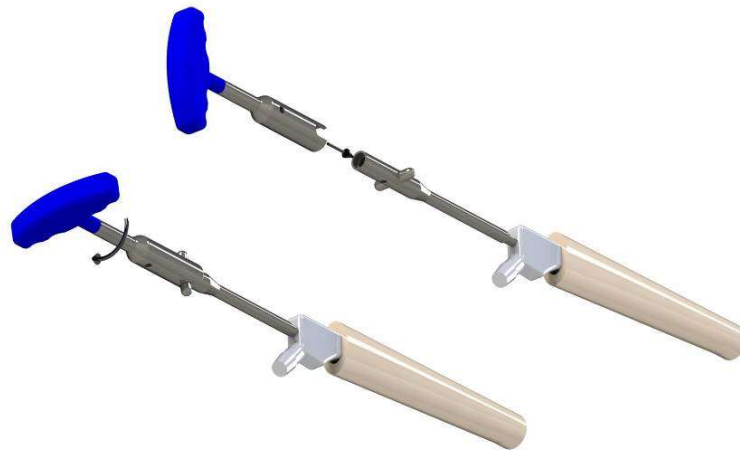
The bore hole on the hip stem must be well exposed and accessible. The bore hole must also be free of tissue. To create a good connection between the implant and the instrument, the special adapter must screw in **completely up to the end of the bore hole**. If too few threads are engaged with the implant, the special adapter may tear out.



⚠ Always screw the special adapter into the implant as far as the stop!

**Tip:**

If available, use the insertion aid (optional accessory).



**Fig. 13:** Use of the insertion aid (optional accessory)

#### 7.4 Screw in the RAP-it® set and carefully extract the hip stem



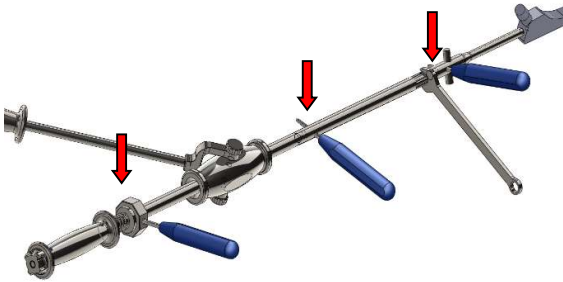
Now screw the extraction instrument to the special adapter. Hold the impactor and weight firmly and rotate the extraction instrument around its axis as illustrated (arrow).

The surgeon can now begin to tap the impact weight against the separator bolt using the impactor. It is important that the instrument vector does not deviate greatly from the longitudinal axis of the femur.

This operation is repeated until the implant is freed.

Always make sure that all screw connections on the device are tight, in particular the direct connection between the adapter and the implant.

## 7.5 Disassembly



**Fig. 14:** Using the tools for disassembly

On completion of the extraction procedure, the entire device can be unscrewed and disassembled.

If this cannot be done manually, holes (see red arrows) or grooves have been placed at the respective sites for loosening the screw connections with the enclosed tool.

**⚠** *Never use pliers to loosen the screw connections, only the enclosed tools.*

Scratches and grooves made by pliers can cause hand injuries, damage gloves and impair or prevent operation of the instrument.



## 8 Operating technique using a universal adapter

⚠ Only a qualified surgeon can carry out the operation.

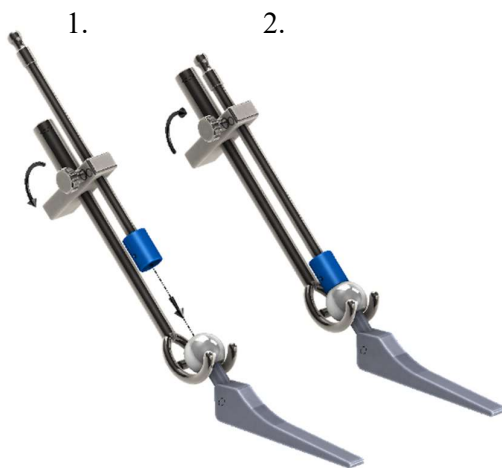
The operating technique described below is best carried out with the help of an assistant.

All screw connections on the instrument must be screwed in completely and tightened manually before use. The assistant ensures that no screw connections are loosened during the operation.

### Operating technique

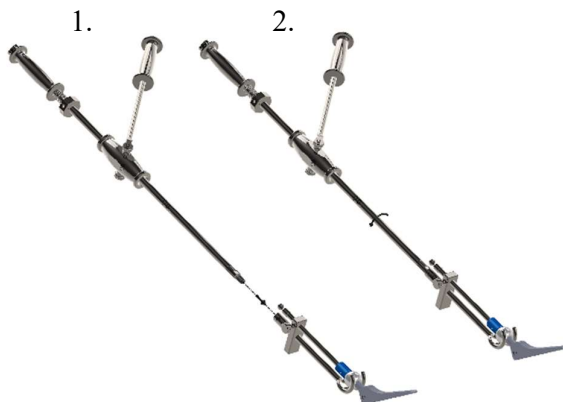
- 1.) Remove the femoral head
- 2.) Attach the universal adapter to the implant
- 3.) Screw in the RAP-it® set and carefully tap out the hip stem
- 4.) Constantly check the condition of the tissue and femur
- 5.) Constantly check whether the stem has loosened

### 8.1 Removing the femoral head



Hook (1) the femoral head extraction tool round the femoral head.

Position it so that the femoral head can be removed from the taper. Release the screw, lower the rod onto the femoral head and press lightly. Tighten (2) the locking screw by hand.



Screw the RAP-it® basic set onto the femoral head extractor and remove the femoral head by gentle taps with the impactor/impact weight.



Remove the femoral head by **gently** tapping it with the impactor/impact weight.

⚠ Do not allow the femoral head to drop into the wound.

⚠ Only give **gentle** taps because the strike axis is at an angle to the hip stem axis. Excessive force may damage the femur.

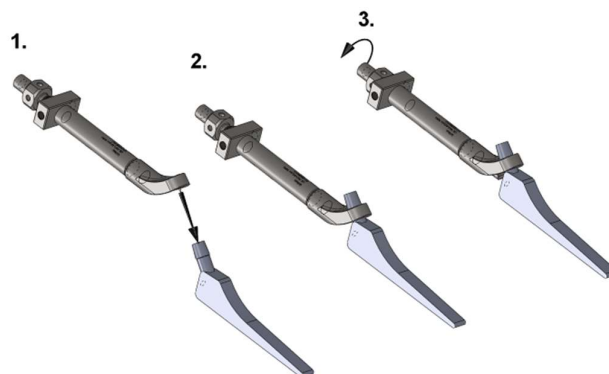
Unscrew the femoral head extraction tool and disassemble it for cleaning.



Alternative:

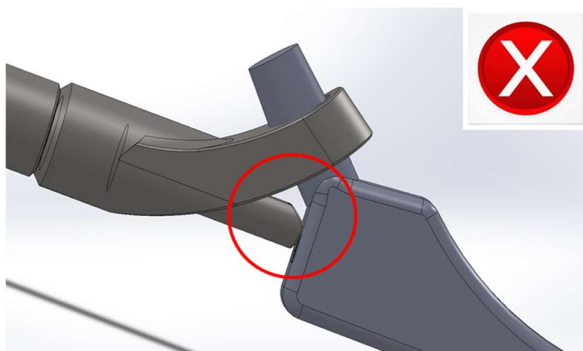
The femoral head can also be easily removed by **gently** tapping the back of the extension of the femoral head extraction tool.

## 8.2 Attaching the universal adapter to the implant

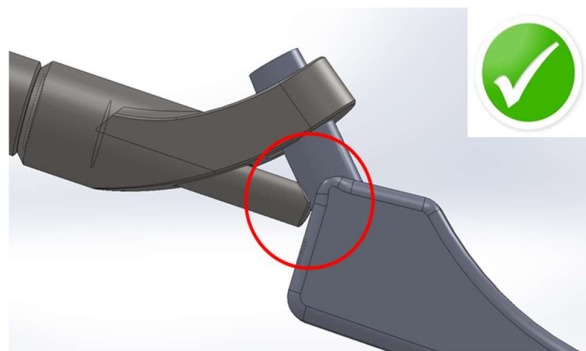


Introduce (1) the universal adapter allowing the taper of the implant to enter the aperture. The pressure screw is now screwed into the end of the adapter until the distal end of the mandrel is stably attached to the **neck of the stem** (2). Tighten (3) the pressure screw firmly by hand (do not use a tool!).

### ⚠ Important remark on fitting the universal adapter to the stem:

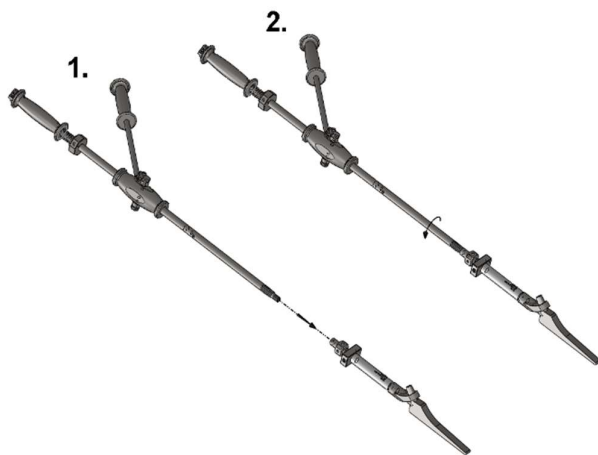


**Fig. 15:** Wrong: the mandrel is resting against the shoulder



Correct: the mandrel is jammed against the neck

### 8.3 Screw in the RAP-it®



With the help of the assistant who holds the impactor and impact weight, the guide rod is now screwed onto the proximal end of the universal adapter up to the stop.

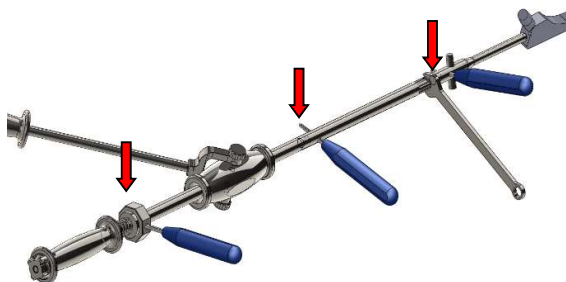
### 8.4 Tap the hip stem carefully



The surgeon can now start to tap the impact weight against the separator bolt using the impactor. Care must also be taken to keep the guide rod in line with the longitudinal axis of the femur and the implant.

This operation is repeated until the implant is freed. Always make sure that all screw connections on the device are tight, in particular the direct connection between the adapter and the implant.

## 8.5 Disassembly



**Fig. 16:** Using the tools for disassembly

On completion of the extraction procedure, the entire extraction system can be unscrewed and disassembled. If this cannot be done manually, holes (see red arrows) or grooves have been placed at the respective sites for loosening the screw connections with the enclosed tool.

**⚠** *Never use pliers to loosen the screw connections, only the enclosed tools.*

Scratches and grooves made by pliers can cause hand injuries, damage gloves and impair or prevent operation of the instrument.

## 9 Operation technique with the "short hook"

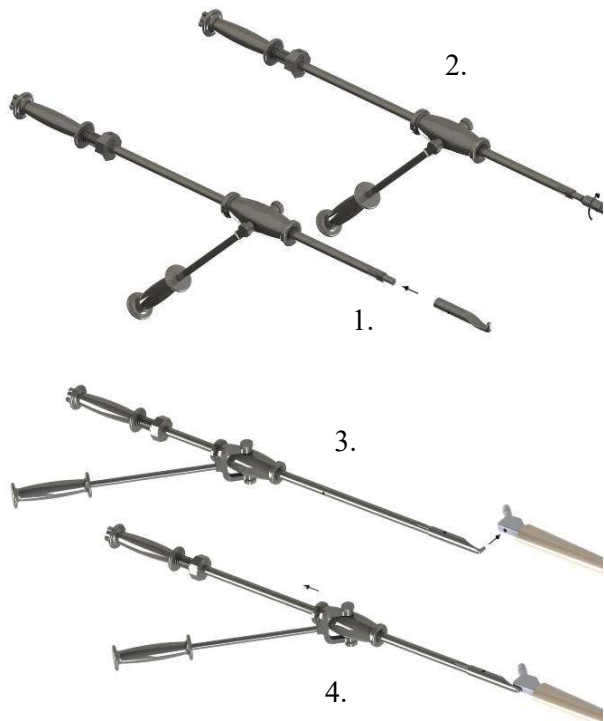
⚠ The operation may be performed only by an experienced surgeon.

The operation technique described below is best performed with the aid of an assistant.

All screw connections on the instrument must be screwed in completely and tightened manually before use.  
The assistant ensures that no screw connections are loosened during the operation.

### Operation technique

- 1.) Femoral head extraction
- 2.) Screw the "short hook" onto the RAP-it®. The extension rod, article 300-00116, may NOT be used.
- 3.) Hang the "short hook" into the recess at the back of the stem and tap the stem carefully to remove it.
- 4.) Constantly check the condition of tissue and femur.
- 5.) Constantly check whether the "short hook" is loosened from the hip stem head or slides down. Check whether the bore hole in the stem is deformed or the hip stem is at risk of failing.
- 6.) Constantly check whether the stem is loosened and whether the hook is firmly attached at the implant.




Screw the "short hook" into the RAP-it® completely.

Hang the "short hook" at the back of the hip stem and remove the implant with carefully dosed taps.

**Tip:**

Broken stems may also possibly be removed with the hook if a bore hole of  $\varnothing 6 \text{ mm}$  can be placed in the stem.

**10 Operation technique with the PROTEK connector**

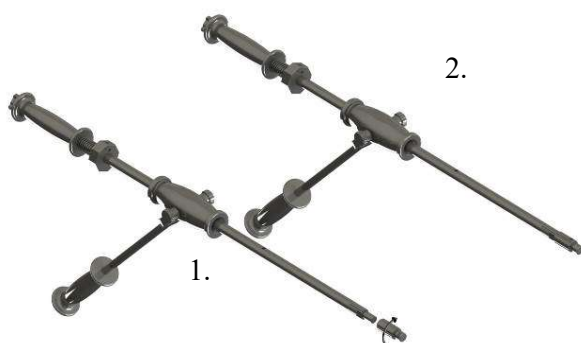
 The operation may be performed only by an experienced surgeon.

The operation technique described below is best performed with the aid of an assistant.

All screw connections on the instrument must be screwed in completely and tightened manually before use. The assistant ensures that no screw connections are loosened during the operation.


**Operation technique**

- 1.) Screw the PROTEK connector onto the front/distal end of the RAP-it®.
- 2.) Attach the desired PROTEK adapter to the taper of the hip stem.
- 3.) Screw RAP-it® onto the adapter and carefully tap out the hip stem.



Screw the PROTEK connector into the RAP-it® completely (1).

RAP-it® can now be used with the PROTEK adapters. Always follow the instructions for the PROTEK adapters (2).

 **No warranties can be assumed when using third party products**

## 11 Cleaning, sterilisation and maintenance

### 11.1 Cleaning and re-sterilisation of the extraction instrument, universal adapter, etc.

See document "04.002.002.e\_Cleaning, Sterilisation, Maintenance"

The instructions for cleaning, sterilisation and maintenance are available for downloading at <https://www.effectummedical.com/imprint/> and <https://www.mathysmedical.com/downloads/dokumente.html>



### 11.2 Cleaning and re-sterilisation of single-use special adapters

The special adapters have been declared single-use articles. They are cleaned and sterilised before use. After use, they must be disposed.

**⚠ Caution: The single use adaptors are not delivered sterile and have to be sterilized before use!**



**Fig. 17:** Labelling on the single-use special adapters

If the special adapter is not needed during the operation, it can be re-sterilised until it has been used once for stem extraction.

## 12 Disposal

Defective parts of the device or any parts no longer used must be cleaned and sterilised very carefully prior to disposal. These procedures are described in the **04.002.002.e\_Cleaning, Sterilisation, Maintenance** manual.

## 13 The products shall be disposed in compliance with hospital practice



### **Obligation to declare an incident**

Both the distributor and the users are obligated to report serious adverse events in connection with the use of RAP-hip® pursuant to MEDDEV 2.12-1 to a competent authority or Swissmedic.

Mathys AG Bettlach  
Robert Mathys Strasse 5  
2544 Bettlach  
Switzerland  
<https://www.mathysmedical.com>

### **14 Customer service information**

Individual parts are available. Please contact Mathys directly or your local service partner.

## 15 Appendix: Overview of all individual RAP-hip® articles

No.	Designation	Article no.
1	Guide rod	350-00183
2	Impactor	350-00145
3	Large impact piece	300-00122
4	M8 screw	300-00118
5	Extension rod	300-00116
6	Nut	300-00185
7	Handle for guide rod	300-00180
8	Compression spring with washer	350-00193
9	Tool for instrument	350-00150
10	Femoral head extractor fork	350-00162
11	Femoral head extractor mandrel	300-00164
12	Femoral head extractor fixation	300-00236
13	M6 special adapter	350-00222
14	M7 special adapter	350-00375
15	M8 special adapter	350-00226
16	¼" 20UNC special adapter	350-00377
17	Insertion aid	330-00340
18	Universal adapter module 8/10	350-00344
19	Universal adapter module 10/12	350-00156
20	Universal adapter module 12/14	350-00148
21	Universal adapter module 14/16	350-00152
22	Pressure screw	300-00137
23	Universal adapter mandrel	300-00138
24	Universal adapter handle	300-00190
25	Short hook	300-00314
26	PROTEK connector	300-00315
27	11mm AF open-end/ring wrench	500-00191