# RAP-hip® Hip stem extraction set

**C** € 0297

#### Legal Manufacturer:



Effectum Medical AG Kirchgasse 11 CH-4600 Olten www.effectummedical.com

#### EU Authorised Representative:



MED-RAS GmbH Eichenallee 8H D-21521 Wohltorf

#### Marketed by:





# **Table of contents**

1	Document history	3
2	Validity	3
3	General safety and cleaning instructions	4
3.1	Introduction	4
3.2	CE certification	4
3.3	Symbols and labelling	5
3.4	General information and precautionary measures	6
3.5	Recommended methods	6
3.6	Non-recommended methods	6
3.7	Cleaning and re-sterilisation of single-use special adapters	6
4	Detailed processing instructions	7
4.1	Methods for confirming cleanliness and sterility	12
5	Dismantle the instrument	13
5.1	Disassembly	13
6	Pre-assemble the instrument	18
7	Inspection, testing, servicing and care products	18
8	Responsibilities of the hospital	19
9	Customer service information	19
10	Appendix: Overview of all possible individual RAP-hip® articles	20

# 1 Document history

New Document	Date	Old documents	
04.002.002.e_Cleaning Steril Maintenance- I01_EN V1	September 2020	The document is medically identical to the "Safrima" documen with the document number DOK-2-4-002.	
04.002.002.e_Cleaning Steril Maintenance- I01_EN V2	December 2020	Change of address of legal manufacturer	
04.002.002.e_Cleaning Steril Maintenance- I01_EN V3	March 2021	Including of EU Authorised Rep-representative: MED-RAS GmbH	
04.002.002.e_Cleaning Steril Maintenance- I01_EN V4	March 2023	Chapter 5.1 – Detailed disassembly information included  Adaptation of the cleaning proof and re-processing instructions after Effectum Medical re-processing validation meaning that various chapters have been deleted as the information has been incorporated into chapter 4	
04.002.002.e_Cleaning Steril Maintenance- I01_EN V5	May 2023	Logo replaced Small formatting corrections	

# 2 Validity

This manual refers to the complete **RAP-hip**<sup>®</sup> hip stem extraction set provided by Mathys AG, consisting of:

- the RAP-it<sup>®</sup> basic extraction set
- the universal hip stem adapters
- the special adapters for hip stems with a tapped hole in the stem shoulder
- the femoral head extractor
- other special adapters

All articles of this instrument set can be handled as described below.



# 3 General safety and cleaning instructions

#### 3.1 Introduction

This manual refers to the **RAP-hip**<sup>®</sup> hip stem extraction set provided by Mathys. Effectum Medical AG is the legal manufacturer of the product.

This set consists of:

- the RAP-it® basic extraction set
- universal hip stem adapter
- the special adapter for hip stems with tapped holes in the stem shoulder
- femoral head extraction tool
- other special adapters



Fig. 1: The RAP-hip® hip stem extraction device consists of a basic RAP-it® set and various adapters

The user must comply with local laws and ordinances in countries where reprocessing requirements are more stringent than those detailed in these instructions.

In general, new and used devices must be carefully reprocessed before and after use in compliance with these instructions irrespective of whether the products have been bought or leased.

#### 3.2 CE certification

This product consists of class 1 (multiple use) and class IIa (single use) medical devices according to guideline RL 93/42 CEE, annex IX, rule 6. The RAP-hip set is registered with the SWISSMEDIC Institute and has a CE marking.



# 3.3 Symbols and labelling

The symbols used here 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 product even when dismantled. Some of the products (as shown below) might still be labelled with Safrima AG, the former legal manufacturer.

M Effectum Medical AG C "RAP-it" + part designation g PAxxxxx h 3aa-bbbbb

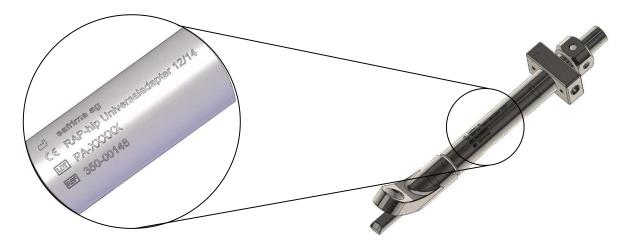


Figure 2: Sample labelling on device components



Figure 3: Labelling on single-use special adapters



#### 3.4 General information and precautionary measures

- Appropriate <u>personal protection equipment</u> must be worn when handling contaminated or potentially contaminated materials, devices or products. This includes the coats, masks, safety glasses or visors, gloves and overshoes used in operating theatres.
- Personnel in contact with contaminated or potentially contaminated medical devices must take generally accepted precautionary measures.
- <u>Do not</u> let contaminated devices <u>dry</u> before reprocessing. All stages of cleaning and sterilisation described below can be facilitated by preventing blood, body fluids, bone and tissue fragments, saline solution or disinfectant from drying on the devices used.
- Do not use metallic brushes or scouring pads when cleaning manually. These materials can
  damage the surface and coating of the hip stem extraction tool. The use of nylon brushes
  with very soft bristles and pipe-cleaners is recommended.
- Saline solutions and aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine
  or iodide-based detergents/disinfectants are corrosive and <u>must not</u> be used. Devices must
  not be immersed in Ringer's solution.
- <u>Do not</u> use mineral oil or silicone lubricants as they coat micro-organisms, preventing direct contact of steam with the surface, and are difficult to remove.
- Do not place heavy objects on any parts of the hip stem extraction set.
- Certain parts can weigh up to 1kg. Do not drop.
- Repeated reprocessing according to the instructions below has little effect on reusable devices for orthopaedic surgery unless otherwise indicated. The lifespan of stainless steel or other metal surgical devices is normally determined by wear and tear resulting from their intended surgical use and not from reprocessing.

#### 3.5 Recommended methods

- Thorough <u>cleaning combining manual and automatic</u> processes is recommended.
- <u>Autoclaving</u> is the sterilisation method recommended for Mathys AG RAP-hip<sup>®</sup> hip stem extraction set.

#### 3.6 Non-recommended methods

- Avoid using hard water. Softened tap water may be used for initial rinsing. Final rinsing must be done with purified water to eliminate mineral deposits on the devices. One of the following processes may be used to soften the water: ultrafiltration (UF), reverse osmosis, de-ionisation or equivalent methods.
- Automatic cleaning in a washer-disinfector alone is unsuitable.
- Ethylene oxide (EO), plasma gas and dry heat sterilisation methods are <u>not</u> recommended to sterilise the Rap-hip.
- The complete device with its adapters must not be reprocessed after having been used on
  patients suffering from <u>Creutzfeldt-Jakob disease</u> or its variations. Further handling in such
  cases is subject to national legislation wherever the device is used. In this case, Mathys AG
  or Effectum Medical AG cannot be held liable for any reuse of the device.

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

The special adapters are single-use articles. **However, they are not provided sterile and have to be cleaned and sterilised before use**. After use, they must be disposed of, as they are used to the limits of their capacity.





Figure 4: 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 <u>once</u> for stem extraction.

# 4 Detailed processing instructions

#### A. INTENDED USE

This document contains recommendations for the safe handling, effective care, cleaning, disinfection and sterilisation of Effectum Medical reusable surgical instruments, instrument trays and cases.

#### **B. INTRODUCTION**

All instruments must be cleaned, disinfected and sterilised before each use. This also applies particularly to the first use after delivery of the non-sterile instruments (cleaning and disinfection after removal of the protective packaging; sterilisation after wrapping). Effective cleaning and disinfection are absolutely essential for effective sterilization of the instruments.

Since you are responsible for the sterility of the instruments, you should ensure that only those procedures validated for the equipment and product are employed for cleaning, disinfection and sterilisation, that the equipment used (WD (washer/disinfector), steriliser) is checked and serviced at regular intervals, and that the validated parameters are observed during each cycle.

Please be sure to avoid any major contamination of the loaded instrument tray during use. Collect all contaminated instruments separately (without placing them in the instrument tray). Clean and disinfect the contaminated instruments and sort them only when you replace them in the instrument tray. Then sterilise the fully loaded instrument tray.

Instruments should be cleaned separately from the instrument trays and cases. The lids of the cases should be removed before cleaning. Please also comply with the current legislation in your country as well as the hygiene regulations of the hospital. This particularly applies to the differing requirements relating to effective inactivation of prions.

N.B.: Additional or deviating specifications should be observed for certain instruments (see section D. SPECIAL INSTRUCTIONS).

#### C. CLEANING AND DISINFECTION

#### 1. BASIC PRINCIPLES

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## Cleaning, sterilisation and maintenance

If possible, an automated procedure (WD) should be used for the cleaning and disinfection of the instruments. Since a manual procedure is much less effective and reproducible – even when an ultrasonic bath is used – it should be employed only if an automated method is not available<sup>1</sup>. The pre-treatment should be carried out in both cases.

#### 2. PRE-TREATMENT

Do not allow body fluids and tissue remnants to dry on the instruments. Please remove coarse contaminants from the instruments directly after use, but at the latest within 2 hours. To avoid contamination, keep dirty instruments away from non-contaminated instruments. When selecting the cleaning agent<sup>2</sup> note the following points:

- basic suitability for the cleaning of metal or plastic instruments
- suitability of the cleaning agent for ultrasonic cleaning (no foam formation)
- compatibility of the cleaning agent with the instruments (see section C.9. MATERIAL RESISTANCE)

The concentrations, temperatures, contact times and final rinse instructions specified by the manufacturer of the cleaning agent or disinfectant must always be observed. Please use only freshly prepared solutions, sterile water or near-sterile water (max. 10 microorganisms/ml) with a low endotoxin content (max. 0.25 endotoxin units/ml), for example purified water or highly purified water, and use a soft, clean and lint-free cloth or filtered air for drying.

#### PROCEDURE:

- a) Disassemble the instruments as much as possible (see section 5. DISASSEMBLY INSTRUCTIONS).
- b) Rinse the instruments for at least 1 minute under running water (temperature < 35 °C/95 °F). Move moving parts back and forth at least three times during rinsing (see section D. SPECIAL INSTRUCTIONS).</li>
- c) Rinse all lumens of the instruments at least three times at the start of the contact time.
- d) Place the disassembled instruments for the specified contact time (but no less than 5 minutes) in the pre-cleaning solution<sup>2</sup> (ultrasonic bath without ultrasound activated) so that all instruments are sufficiently covered with the solution. Make sure that the instruments do not touch each other. Assist the pre-cleaning process by brushing with a soft brush (at the start of the contact time, for cleaning aids see section D, SPECIAL INSTRUCTIONS). During the pre-cleaning, move moving parts back and forth at least three
- e) times, if applicable (see section D. SPECIAL INSTRUCTIONS).
- f) Rinse all lumens of the instruments at least three times at the end of the contact time.
- g) Activate the ultrasound for an additional contact time (no less than 5 minutes).
- h) Next, remove the instruments from the pre-cleaning bath and rinse them thoroughly at least three times (for at least 1 minute) with water. Move moving parts back and forth at least three times during this rinsing (see section D. SPECIAL INSTRUCTIONS). Rinse all lumens of the instruments at least three times.

#### 3. AUTOMATED CLEANING/DISINFECTION

When selecting the washer/disinfector (WD) ensure that:

- the WD has been certified as effective (e.g. CE marking according to DIN EN ISO 15883 or DGHM or FDA approval/clearance/registration)
- if possible, a tested program for thermal disinfection is used (A0 value 3000 or, for older devices, at least 5 minutes at 90 °C/194 °F); chemical disinfection involves the risk of disinfectant residues on the instruments

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## Cleaning, sterilisation and maintenance

- the program used is suitable for the instruments and includes a sufficient number of rinse cycles
- only sterile or near-sterile water (max. 10 microorganisms/ml, max. 0.25 endotoxin units/ml) is used, for example purified water or highly purified water
- the air used for drying is filtered (oil-free, low contamination with microorganisms and particles)
- the WD is regularly serviced and checked/calibrated When selecting the cleaning agent ensure that:
- this is basically suitable for cleaning metal and plastic instruments
- provided thermal disinfection is not used, a suitable disinfectant of proven efficacy (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) that is compatible with the cleaning agent is used
- the chemicals used are compatible with the instruments (see section C.9. Material resistance)
- The concentrations, temperatures, contact times and final rinse instructions specified by the manufacturer of the cleaning agent or disinfectant must always be observed.

#### PROCEDURE:

- a) Disassemble the instruments as much as possible (see section E. DISASSEMBLY INSTRUCTIONS).
- b) Place the disassembled instruments in the WD (make sure that the instruments do not touch each other).
- c) If applicable, connect the instruments to the flushing adapter of the WD (see section D. SPECIAL INSTRUCTIONS)
- d) Start the program.
- e) After the program ends, if applicable disconnect the instruments from the flushing adapter and remove the instruments from the WD.
- f) Check and pack the instruments as soon as possible after removal (see section C.4. VISUAL INSPECTION / FUNCTION TEST, section E. DISASSEMBLY INSTRUCTIONS, section C.6. PACKAGING and section G. LOADING PLAN FOR STERILISATION), if applicable after additional drying, in a clean place.

#### 4. VISUAL INSPECTION / FUNCTION TEST

Carefully check reusable instruments before sterilisation for the following points:

Cleanliness: Ensure that all visible traces of blood and other contaminants have been removed. Damage or wear: Visually inspect the instruments for signs of damage including, but not limited to, corrosion, damaged surfaces, tears or wear.

Functionality: Including, but not limited to, sharpness of cutting tools, mobility of joints and couplings (see section D. SPECIAL INSTRUCTIONS)

Do not reuse damaged instruments (for restrictions on the number of reuses see section C. 10 REUSABILITY). Instruments that are still contaminated must be recleaned and disinfected.

#### 5. MAINTENANCE

Reassemble disassembled instruments (see section E. DISASSEMBLY INSTRUCTIONS). Lubricate the hinges, threads and other moving parts according to section E. DISASSEMBLY INSTRUCTIONS. Please use only instrument oils (white oil), taking account of the maximum sterilisation temperature, that are approved for steam sterilisation and are of proven biocompatibility. Please use the smallest possible amount of oil and only oil the moving parts (not the complete instrument!). Instrument oils or fats should not be used for some instruments (see section D. SPECIAL INSTRUCTIONS).

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## Cleaning, sterilisation and maintenance

#### 6. PACKAGING

Sort the cleaned and disinfected instruments into the appropriate sterilisation tray (see section G. LOADING PLAN FOR STERILISATION) and pack the sterilisation trays into sterilisation containers that satisfy the following requirements (Material/Process):

- DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilisation (temperature-resistant up to at least 142°C (288°F), adequate vapour permeability)
- the instruments / sterilisation packs are adequately protected against mechanical damage
- the sterilisation containers are regularly maintained in accordance with the manufacturer's instructions

The contents of a sterilisation container should not exceed 7.2 kg.

#### 7. STERILISATION

Only the sterilisation methods listed below should be used for sterilising Effectum Medical products. Other sterilisation methods are not permitted.

#### Steam sterilisation

- fractional vacuum method/dynamic air removal 3.4 (with adequate product drying5)
- steam steriliser according to DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated according to DIN EN ISO 17665 (valid IQ/OQ (picking) and product-specific performance qualification (PQ))
- maximum sterilisation temperature 138°C (280°F plus tolerance in accordance with DIN EN ISO 17665)
- sterilisation time (exposure time at the sterilisation temperature)

The following parameters must be employed for the sterilisation of Effectum Medical products with the fractional vacuum method and dynamic air removal:

Country	Minimum sterilisation time (minutes)	Maximum sterilisation temperature	Minimum drying time (minutes)
USA	4	132°C (270°F)	20 <sup>5</sup>
Germany	56	134°C (273°F)	
Other countries	4	132°C (270°F) / 134°C (273°F)	

The steriliser manufacturer's instructions for use must be followed. If several instruments are sterilised at the same time in a steam sterilisation cycle, make sure that the maximum sterilisation load is not exceeded. Drying times vary according to the load size and should be prolonged accordingly if the load is fairly substantial. The steriliser must be installed, calibrated, validated and maintained correctly.

N.B.: Do not use hot air sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation, flash sterilisation or plasma sterilisation!

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## Cleaning, sterilisation and maintenance

#### 8. STORAGE

After sterilisation, the packed products must be stored in a dry, dust-free environment, protected from direct sunlight, pests and extreme temperatures and humidity.

#### 9. MATERIAL RESISTANCE

When selecting the cleaning agents and disinfectants, make sure that they do not contain any of the following constituents:

- organic, mineral and oxidising acids (minimum permitted pH: 5.5)
- strong alkalis (maximum permitted pH: 10.1, neutral or slightly alkaline cleaners recommended)
- organic solvents (e.g. acetone, ether, alcohol, benzines)
- oxidising agents (e.g. peroxide)
- halogens (chlorine, iodine, bromine)
- · aromatic, halogenated hydrocarbons
- oil (only silicone parts)

When selecting the cleaning and disinfection agents, please also note that corrosion inhibitors, neutralising agents and/or rinse aids may leave behind potentially harmful residues on the instruments. Do not use acidic neutralising agents or rinse aids.

Never clean any instruments or sterilisation trays with wire brushes or steel wool.

Do not expose any instruments or sterilisation trays to temperatures higher than 142 °C (288 °F)!

#### 10. REUSABILITY

Unless otherwise specified in section D. SPECIAL INSTRUCTIONS, the instruments can be reused for 100 processing cycles, provided they are handled with the appropriate care and are undamaged. The user is responsible for any further reuse. The same also applies to the use of damaged or contaminated instruments (any liability is excluded if such instruments are used).

- 1) In the event of manual cleaning and disinfection, any method- and product-specific validation is the sole responsibility of the user.
- 2) If you use a cleaning agent or disinfectant for this purpose (e.g. to protect the maintenance personnel), please note that this

should be aldehyde-free (otherwise there is a risk of blood contaminant fixation), of proven efficacy (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), suitable for the disinfection of metal or plastic instruments and compatible with the instruments (see section C.9. Material resistance). Please note that the disinfectant used during pre-treatment serves only to protect the maintenance personnel and cannot replace the subsequent disinfection step performed after cleaning

- 3) At least three vacuum steps
- 4) The use of the less effective gravitational method is permitted only if the fractional vacuum method is not available and requires a steriliser, a program and parameters whose product-specific validation is the sole responsibility of the user.
- 5) The actual drying time required depends directly on parameters that are the sole responsibility of the user (load configuration and

density, steriliser condition,...) and must therefore be determined by the user. Nevertheless, drying times should not be shorter than 20 minutes.



6) or for 18 minutes (prion inactivation, not relevant for USA)

## 4.1 Methods for confirming cleanliness and sterility

The instructions listed above were validated by Effectum Medical as suitable for the preparation of reusable surgical instruments.

An independent, officially accredited and recognised (§ 15 (5) MPG [Medical Devices Act]) test laboratory has provided evidence of the basic suitability of the instruments for the following methods:

- EFFECTIVE AUTOMATED CLEANING AND DISINFECTION using the WD G 7836 CD, Miele & Cie. GmbH & Co., Gütersloh, (thermal disinfection) and pre-cleaning with the cleaning agent Neodisher Mediclean (Dr. Weigert GmbH & Co. KG, Hamburg), taking the specified method into account.
- EFFECTIVE STEAM STERILISATION using the steam steriliser HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and using the fractional vacuum method of dynamic air removal.

Typical conditions prevailing in clinics and the method described above were taken into account. The user is responsible for ensuring that the processing is carried out with the suitable equipment and materials and that the personnel are trained appropriately in the reprocessing facility so that the desired result is achieved. Validation and routine monitoring of the method are normally required for this purpose. Any deviation from the procedure described here should be checked for its efficacy in order to rule out possible adverse consequences.

Please ensure that the latest version of the Care & Maintenance Instructions is always used. This can be downloaded from https://www.effectummedical.com/imprint/ and https://www.mathysmedical.com/downloads/dokumente.html



#### 5 Dismantle the instrument

Y Always dismantle the instrument **completely**.

Y The instrument should be able to be unscrewed manually. Otherwise, the tools depicted below can be used

Y Do not use other tools such as pliers or the like.

Y Sensitise the operating room personnel to the fact that according to "04.002.001.e Product description & instructions for use", the threads must always be moistened with a fluid (e.g. water) before assembly to prevent dry contact of the threads. This facilitates dismantling.

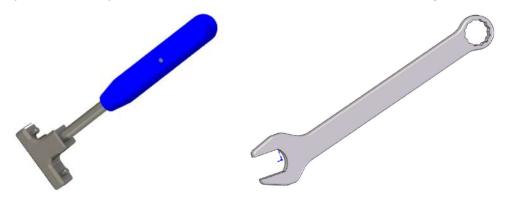


Figure 5: Tool (left), open-end spanner size 11 (right)

#### 5.1 Disassembly

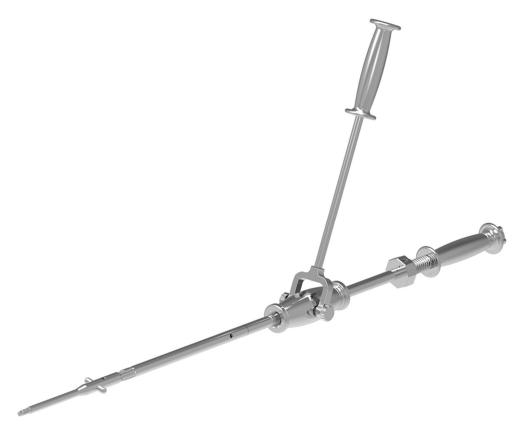
On completion of the extraction procedure, the whole extraction system must be disassembled before reprocessing.

The tool for basic set (REF-350-00150) and the 11mm AF open-end/ring wrench (REF 500-00191) can be used as a disassembly aid for unscrewing threaded components of the extraction system. The components can also be unscrewed by hand.

The following pictures depict a typical disassembly sequence using the disassembly aids. In this example, the prosthesis is removed from the prosthesis retaining adapter.

Do not use pliers to loosen the screw connections, but only use the tools provided, tool for basic set (REF 350-00150) and the 11mm AF open-end/ring wrench (REF 500-00191).

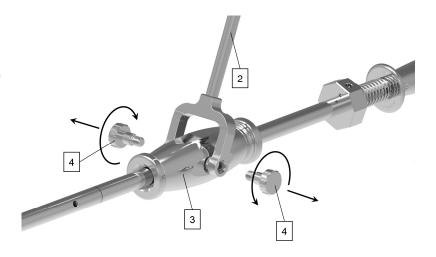




Scratches and grooves caused by the use of pliers can lead to hand injuries or glove damage and may interfere with, or prevent, operation of the device.

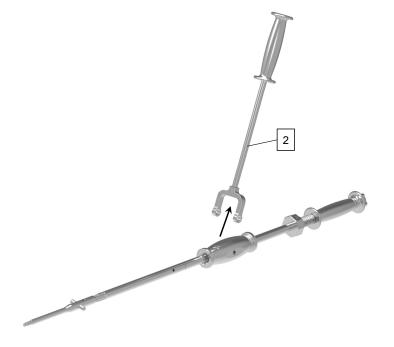
Step 1.

Loosen the M8 screws (4) that connect the impactor (2) to the large impact piece (3).



Step 2.

After loosening the M8 screws, remove the impactor (2).

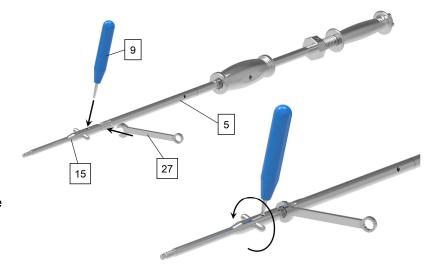


Step 3.

Insert the tool for basic set (9) into the disassembly opening of a corresponding adapter (special adapter M8 (15) is shown as an example).

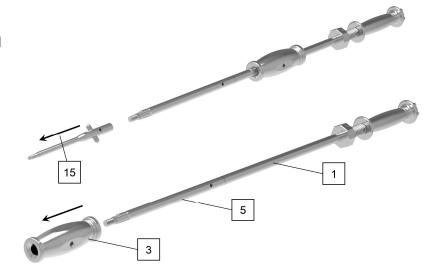
Secure the 11mm AF openend/ring wrench (27) onto the corresponding surfaces of the extension rod (5).

Turn the adapter (15) counterclockwise in order to loosen the adapter (15).



#### Step 4:

Remove the adapter (15) and slide the large impact piece (3) off the guide rod (1) and extension rod (5).

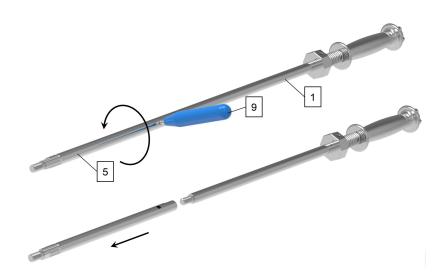


#### Step 5:

Insert the tool for basic set (9) into the disassembly hole of the extension rod (5).

Turn the extension rod (5) counterclockwise in order to loosen the extension rod (5) from the guide rod (1).

Remove the guide rod (1).

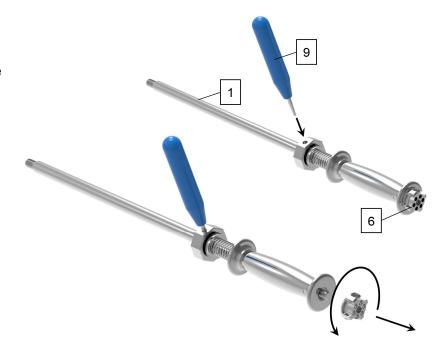


#### Step 6:

Insert the tool for basic set (9) into the disassembly hole of the guide rod (1).

Turn the nut (6) by hand counterclockwise in order to loosen the nut (6) on the guide rod (1).

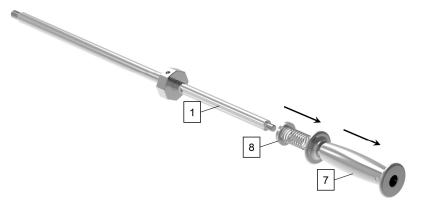
Remove the nut (6).



#### Step 7:

Slide the handle for guide rod (7) and the compression spring with washer (8) onto the guide rod (1).

The extraction system is now completely disassembled



#### 6 Pre-assemble the instrument

Due to the dimensions of the instrument, the components not assembled until use are stored in the sieve tray or a sterile container. Instructions for assembly of the instruments can be found in the product description and instructions for use (IFU) with the document number 04.002.001.e.

This cleaning, sterilisation and maintenance instruction (04.002.002.e) and the product description & instructions for use (04.002.001.e) are available at your Mathys partner. The documents are also available for downloading online at <a href="https://www.effectummedical.com/imprint/">https://www.effectummedical.com/imprint/</a> and <a href="https://www.mathysmedical.com/downloads/dokumente.html">https://www.mathysmedical.com/downloads/dokumente.html</a>

# 7 Inspection, testing, servicing and care products

- Hip stem extraction tools must be carefully examined after cleaning and disinfection to ensure that all visible soiling has been removed. Repeat the cleaning and disinfection process if any soiling is discovered.
- Check the parts and their freedom of movement to ensure that the intended sequence for use can be carried out in full.
- Proper implementation of care measures: 1)
  - The instruments are cooled to room temperature
  - Apply the cleaning agent manually and specifically to all internal and external threads
  - Apply the cleaning agent manually and specifically to the guide rod (item 350-00183) and the extension rod (art. 300-00116)
- Requirements for surgical instruments:
  - Paraffin / white oil based on the valid European and US pharmacopoeia
  - Biocompatible
  - Steam sterilization and steam permeable
- Assemble the parts making sure that this is easy to do.
- Ensure that rods and elongated parts are not deformed. Check for sharp edges, deep scratches, etc. all over the device.
- In principle, the use of disinfectant spray for medical devices is permitted and is left to the discretion of the hospital involved.
- Literature: "Instrumenten Aufbereitung", 10. Ausgabe (2016), Arbeitskreis Instrumentenaufbereitung, <a href="https://www.a-k-i.org/">www.a-k-i.org/</a>
- Remark: If faults or damage are noted, the device must be returned to the agent or supplier and not used under any circumstances.

# 8 Responsibilities of the hospital

- Effectum Medical AG orthopaedic surgery devices are generally characterised by their long service life. Nevertheless, incorrect use or insufficient protection may rapidly reduce their lifespan. Devices that no longer function properly due to wear, incorrect use or inappropriate maintenance must be returned to Effectum Medical AG or Mathys for disposal.
- Inform your local Mathys representative of any problems with the hip stem extraction tool.
- Hospitals are responsible for ensuring that reprocessing is carried out using suitable
  equipment and materials and that the staff involved has been properly trained to obtain the
  required results. Equipment and processes must be generally validated and regularly
  monitored. Any deviation from the procedure described must be validated for effectiveness
  to avoid any undesirable consequences.

#### **Rental devices**

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- Rented devices must undergo cleaning, disinfection, inspection and final sterilisation and may be returned to the rental outlet only on completion of all these decontamination steps.
- Devices returned to the rental outlet MUST be accompanied by full documentation of the sterilisation procedure.

#### 9 Customer service information

Please contact your Mathys agent directly if you have any questions. Individual parts are available. We also carry out service inspections.

# 10 Appendix: Overview of all possible 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 screws	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 basic set	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	1/4"-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