Cleaning, sterilisation and maintenance

RAP-hip®
Hip stem extraction set

CE 0297

Legal Manufacturer:

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04.002.002.e_Cleaning Steril Maintenance-I01_EN_V3

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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” document 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 V2	March 2021	Including of EU Authorised Rep-resentative: MED-RAS GmbH

2 Validity

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

- the RAP-it® 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 Summary

3.1 Procedure

Step	*Work step*	*Section*
1	Completely dismantle instrument	5
2	Pre-clean bore holes manually, e.g. with a soft brush	6
3	Clean and disinfect automatically in a washer-disinfector	0
4	Pre-assemble and package the instrument	7 + 8
5	Steam sterilisation	10

3.2 Recommended cleaning and sterilisation method

- A thorough combined manual/automatic cleaning process is recommended.
- The recommended sterilisation method for the RAP-hip® hip stem extraction set provided by Mathys AG is autoclaving.

Step 1	Completely dismantle the instrument.
Step 2	Immerse the instrument completely in an enzymatic solution and soak it for 10 minutes. Scrub the instrument carefully with a nylon brush with very soft bristles. Pay special attention to cavities, apertures, and other difficult-to-reach areas.
Step 3	Rinse at least 1 minute with purified water. Rinse apertures and other difficult-to-reach areas thoroughly.

Step 4	Run the instrument through a **standard instrument cycle** (cleaning and disinfection) in the washer-disinfector.

Type of cycle	Temperature	Pressure	Sterilisation time	Drying time
Pre-vacuum	134° C	3 bar 28.5 psi	18 minutes	30 minutes

4 General safety and cleaning instructions

4.1 Introduction

This manual refers to the **RAP-hip®** 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

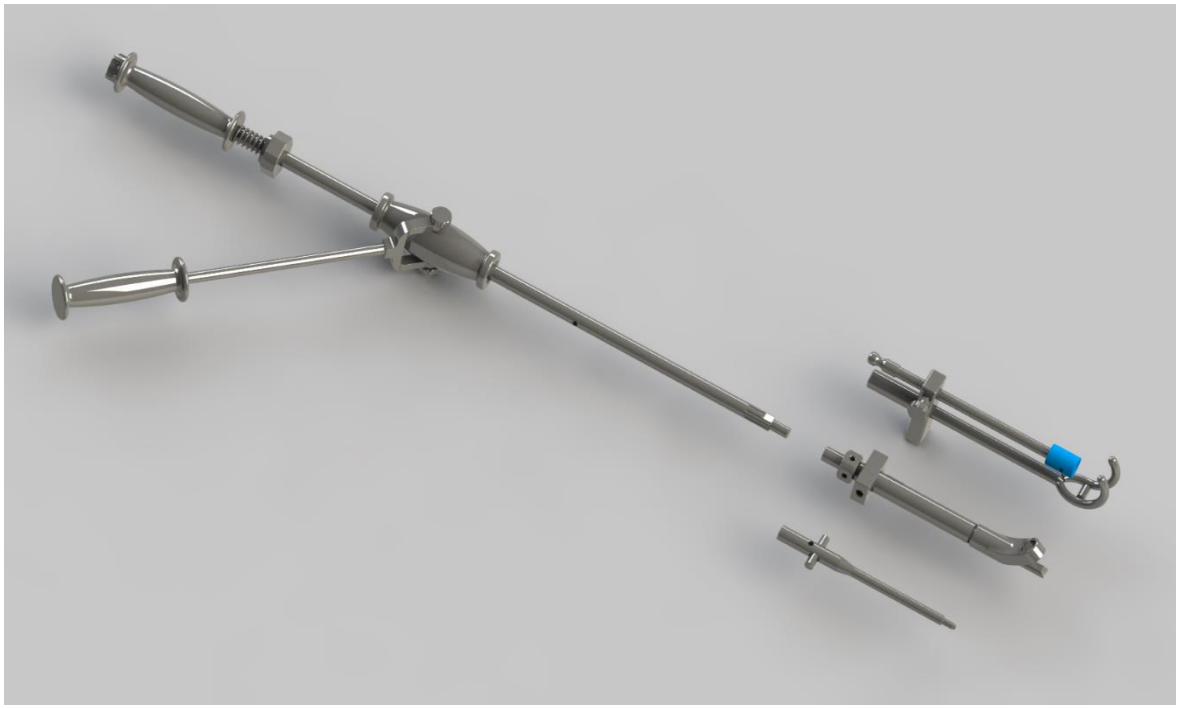

Fig. 1: The RAP-hip® hip stem extraction device consists of a basic RAP-it® set and various adapters

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.

4.2 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.

4.3 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.

- Effectum Medical AG
- CE "RAP-it" + part designation
- LOT PAxxxxx
- REF 3aa-bbbbb

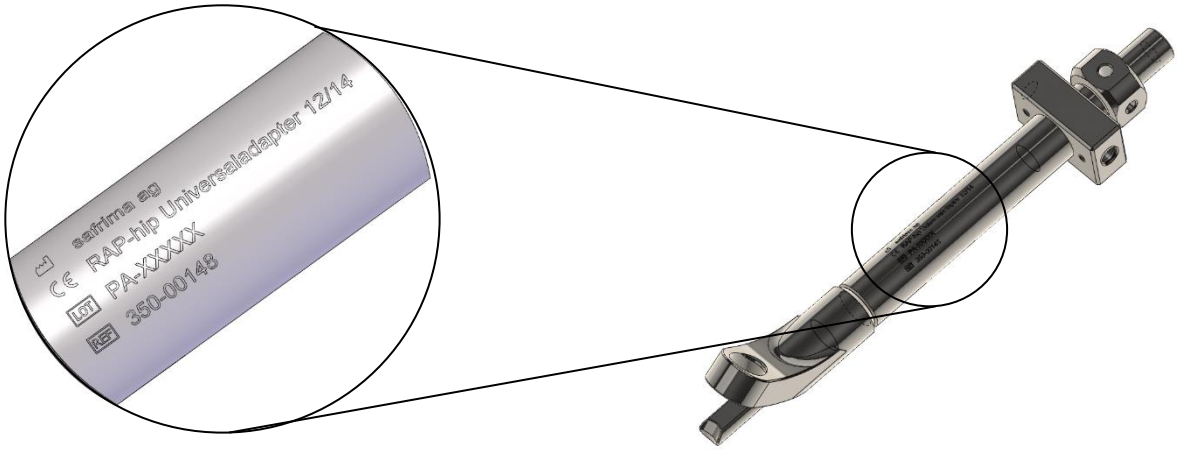

Figure 2: Sample labelling on device components

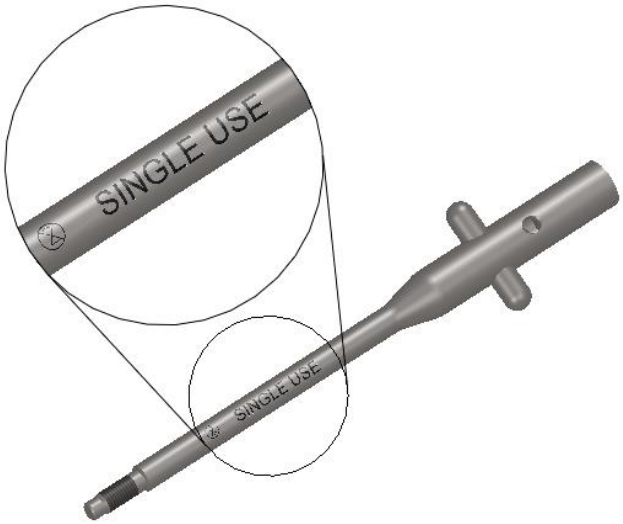

Figure 3: Labelling on single-use special adapters

4.4 General information and precautionary measures

- Appropriate personal protection equipment 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.
- Do not let contaminated devices dry 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 must not be used. Devices must not be immersed in Ringer's solution.
- Do not 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.

4.5 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.

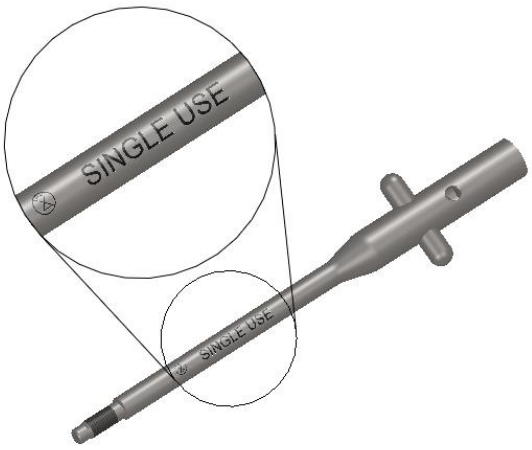

Figure 4: Labelling on the single-use special adapters

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

4.6 Recommended methods

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

4.7 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 not recommended to sterilise the Rap-hip.
- 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, Mathys AG or Effectum Medical AG cannot be held liable for any reuse of the device.

4.8 Methods of validation

The following methods are used for validation of the cleaning, disinfection, and sterilisation process. Any methods/systems deviating from this must be revalidated.

4.8.1 Cleaning and disinfection

- Automatic reprocessing in the Miele Lab G7733 (Rinse programme 1)
- Hot water disinfection at 75°C for 1.5 minutes
- Drying at 60°C

4.8.2 Sterility

- Sterilisation of the test objects at 134°C for 9 minutes (half-cycle test for validation!)

5 Dismantle the instrument

⚠ Always dismantle the instrument **completely**.

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

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

⚠ 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.

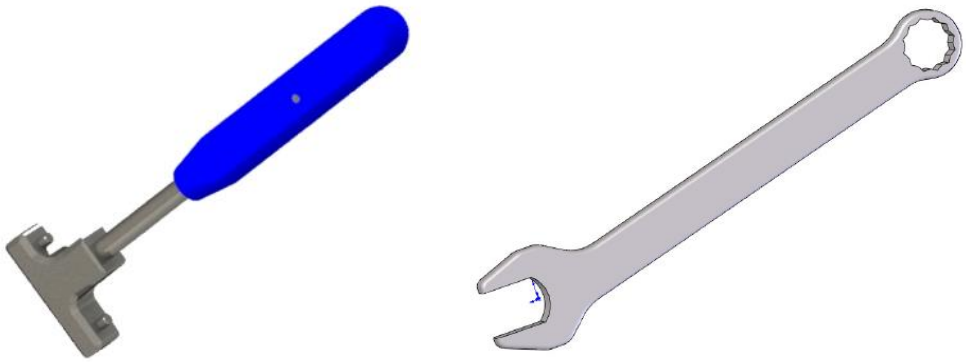

Figure 5: Tool (left), open-end spanner size 11 (right)

5.1 Disassembly

After the extraction, the entire extraction set can be dismantled. If this cannot be done manually, holes or grooves have been placed at the respective sites for loosening the screw connections with the enclosed tool or an open-end spanner.

⚠ *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.

6 Cleaning instructions

6.1 Preparation

6.1.1 On delivery and before use in the operation theatre

- Inspect the equipment: the set must be complete.
- Carry out a visual and manual inspection as described in section 9.
- Cleaning must comply with the following instructions in this section.
- Sterilisation must be carried out as described in section 10.

6.1.2 During or immediately after use in the operation theatre

- The hip stem extraction tool must be wiped with a single-use, lint-free cloth to remove any body fluids and tissues. Place the device in a basin of distilled water or cover with a damp cloth.
- The device must be cleaned within 30 minutes of use to minimise the risk of drying before it is cleaned.
- The devices used must be taken to the central sterilisation and reprocessing service in closed or covered containers to avoid any risk of unnecessary contamination.

6.1.3 Preparation for cleaning

- Devices must be removed from the metal or polymer baskets for cleaning. Device baskets, boxes and lids must be cleaned separately.
- The RAP-hip® hip stem extraction set consists of several components. The device must be dismantled if it is to be cleaned effectively.
- Be careful not to lose any components. Each component is labelled and can thus be attributed to the device.
- The symbols or specific instructions engraved on the devices must be meticulously followed, in particular the “single use” indication on special adapters (⊗; symbol according to EN standard 980 and 1041).

6.1.4 Preparation of cleaning agents

- It is recommended to use enzymatic or other pH-neutral cleaning agents to clean its reusable devices. Alkaline agents with a pH of < 12 may be used to clean stainless steel and certain polymer devices in countries following required by national legislation or local ordinances. Alkaline cleaning agents MUST be completely and thoroughly neutralised and rinsed off the devices.
- All cleaning agents must be prepared to the required dilution and at the temperature recommended by the manufacturer. Softened tap water can be used to prepare cleaning agents. Recommended temperatures must be adhered to if cleaning agents are to perform as desired.
- Note: Fresh cleaning solution must be prepared if existing solutions become contaminated (blood and/or opacities).

6.1.5 Automatic cleaning and disinfection process in Cleaning and Disinfection Devices

Step 1	Completely dismantle the device
Step 2	Completely immerse the device in an enzymatic solution and allow to soak for 10 minutes. Gently scrub the device with a nylon brush with very soft bristles until all visible soiling has been removed. Pay particular attention to cavities, apertures, mating surfaces, connectors and other inaccessible areas. Use a long narrow nylon brush with soft bristles to clean apertures.
Step 3	Remove devices from the enzymatic solution and rinse in purified water for at least 1 minute. Rinse apertures and other inaccessible areas thoroughly.
Step 4	Place the device in a suitable washer-disinfector basket and run the standard device cycle (washing and disinfection) in a washer-disinfector.

Table 1: Combined manual/automatic cleaning steps

- Note: Use of a 45-50kHz ultrasonic washer will ensure the thorough cleaning of a device.
- Note: Use of a water jet will improve the rinsing of inaccessible areas or mating surfaces.

7 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 https://www.effectummedical.com/imprint/ and https://www.mathysmedical.com/downloads/dokumente.html

8 Packing a set of devices in a sieve tray and a sterile container

- The total package must not exceed 16 kg when placed in a sterilisation container fitted with a sealed lid.
- Sieves and containers with lids can be packed in double-thickness, non-woven medical sterilisation material according to AAMI guidelines or an equivalent method.

9 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.

[1)] Literature: "Instrumenten Aufbereitung", 10. Ausgabe (2016), Arbeitskreis Instrumentenaufbereitung, www.a-k-i.org/

- ***Remark***: If faults or damage are noted, the device must be returned to the agent or supplier and not used under any circumstances.

9.1 Non-recommended methods

- Do not use mineral oil or silicone lubricants for care and maintenance because they coat micro-organisms, prevent direct contact of the surface with steam and are hard to remove.

10 Sterilisation

10.1 General Information

- Arrange all parts to ensure that steam contacts all surfaces of the device. The parts of the device must not be stacked or in contact with each other.
- Users must ensure that the device box is not tipped or the contents slip when the device is placed in the box. Silicone mats may be used to prevent the device from slipping (ensure steam penetration).

10.2 Recommended sterilisation process

- Steam sterilisation (autoclaving) is the preferred and recommended method for the hip stem extraction tool.
- Disinfection of the reusable hip stem extraction tool is only acceptable as a preparation for complete sterilisation. Table 5 contains the minimum recommended sterilisation parameters validated by Mathys AG for a sterility assurance level (SAL) of 10^{-6}.
- The steriliser manufacturer's recommendations must also be complied with. When sterilising several sets of devices in a sterilisation cycle, ensure that the maximum load of the machine indicated by the manufacturer is not exceeded.
- The set must be correctly prepared and packed in baskets and/or boxes to allow steam to diffuse and penetrate thereby coming into contact with all surfaces.

Type of cycle	Temperature	Pressure	Sterilisation time	Drying time
Pre-vacuum	134°C	3 bars 28.5 psi	18 minutes	30 minutes

Table 2: Recommended autoclaving parameters[1, 2)]

1) Local or national regulations must be followed wherever autoclaving requirements are stricter.
2) Autoclaving/disinfection parameters recommended by the World Health Organisation (WHO) for reprocessing devices if the risk of BSE/CJD contamination is suspected.

10.3 Non-recommended sterilisation methods

- Sterilisation with ethylene oxide or plasma is not recommended.
- Gravity-displacement sterilisation cycles are not recommended.

11 Storage

- Sterile and wrapped hip stem extraction tools must be dismantled and stored in an appropriate place where they are accessible only to authorised personnel.
- Protect the device from dust, humidity, contact with biological material and extreme temperatures.

12 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

- 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.

13 Customer service information

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

14 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	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