Instructions for Use

for

Endorectal Coil

1.5 T: O-HLE-015-01899 – GEHC part # 5772252-2
1.5 T: O-HLE-015-01946 – GEHC part # 5818916-2
3.0 T: O-HLE-030-01900 – GEHC part # 5772250-2
ZUB-01955 – GEHC part # 5772250-3

to be operated on

GE 1.5 T MR systems
GE 3.0 T MR systems

Important Document: Read Carefully and Keep in a Safe Place

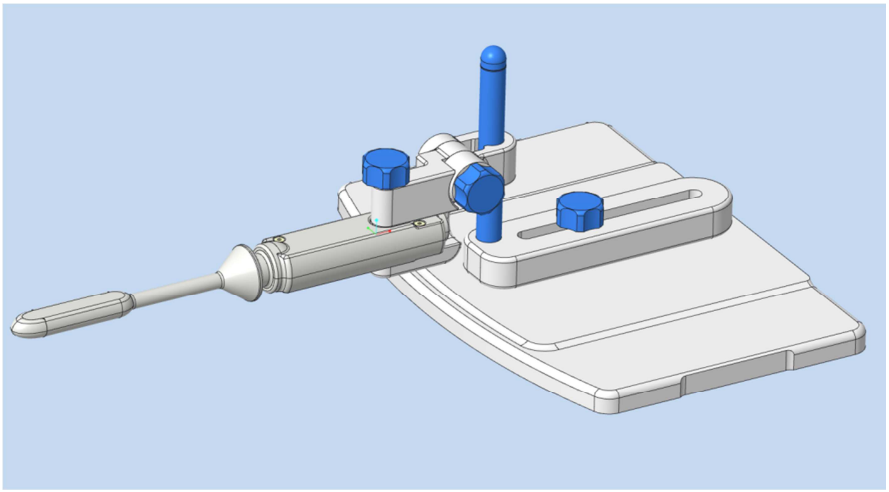

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Table of Contents

Part I General Instructions

1 Instructions for Use

1.1 Instructions for Use

The Instructions for Use are part of the above-mentioned product of RAPID Biomedical GmbH (RAPID Biomedical). It is meant for individuals who operate, install or commission this product. Before working with this product, it is essential to read the Instructions for Use carefully. Consult RAPID Biomedical in case you do not understand parts of the Instructions for Use. The Instructions for Use have to be made available to all users of the product at all times during its lifetime. The Instructions for Use have to be passed on to any subsequent owner/user of the product.

1.2 Product Safety Signs and Labels

Product Safety Signs and Labels are described as follows.

⚠CAUTION
Indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

CAUTION consists of the following elements:

Situation	*Information about the nature of a hazardous situation.*
Hazard	*Consequences of not avoiding a hazardous situation.*
Prevention	☞ *Methods of avoiding a hazardous situation.*

NOTICE
Indicates important information considered to notify people on hazards that could result in things other than personal injury.

NOTICE consists of the following elements:

Situation	*Information about the nature of a hazardous situation.*
Hazard	*Consequences of not avoiding a hazardous situation.*
Prevention	☞ *Methods of avoiding a hazardous situation.*

Indicates useful advice or recommendations.

1.3 Copyright

Unauthorized copy of the Instructions for Use in whole or in part is an infringement of RAPID Biomedical's copyright.

1.4 Limitation of Liability

The specifications and data contained in the Instructions for Use were correct at the time of going to print. RAPID Biomedical does not accept liability and is also exempted from all claims by third parties arising from damage incurred with the device due to inappropriate or unauthorized use, operational errors or disregarding the Instructions for Use, especially the safety instructions contained herein. The warranty and liability conditions contained in the Standard Terms and Conditions (AGB) of RAPID Biomedical are not affected.

1.5 Provision of Instructions for Use

- CD-ROM: A CD with electronic Instructions for Use in different languages is being delivered together with the product. For further information refer to the eIFU Leaflet.
- Download: Electronic Instructions for Use can be downloaded in different languages and all available versions from the RAPID Biomedical Website: www.rapidbiomed.de
- Instructions for Use in paper form or on CD: Instructions for Use in paper form or on CD can be ordered from RAPID Biomedical free of charge via email (see email address on page 2). Unless ordered differently, the latest version will always be delivered within 7 days after receipt of order. For available languages refer to the eIFU Leaflet.

2 Handling

2.1 Device Sensitivity

NOTICE	
Situation	Sensitive electronic device, not handled with care.
Hazard	Device can be damaged.
Prevention	☞ Handle and use with appropriate care. ☞ Avoid jolts or impacts which can affect the device. ☞ Only carry the device by its housing. ☞ Treat any attached cables and plugs with due care and do not use them for carrying the device.

⚠CAUTION	
Situation	Carrying the device by cables and/or plugs.
Hazard	Patient and/or user can be harmed, device and/or other equipment can be damaged.
Prevention	☞ Do not carry the device by its cables and/or plugs. ☞ Carry the device by its handles or by lifting the main body. ☞ Handle the device with care.

2.2 Maintenance

No maintenance is required if the device is used properly and cleaned regularly.

2.3 Storage

Store the device away from potential sources of contamination and mechanical impacts in a dry cool place which is not subject to strong variations in temperature (see 10.1 Specifications).

2.4 Disposing of Old Devices

RAPID Biomedical hereby confirms that its devices conform to the guidelines, regulations and laws of the European Union concerning the disposal of waste electrical and electronic equipment in its latest version (see 10.3 Labeling).

NOTICE	
Situation	Improper disposal.
Hazard	Environmental hazard.
Prevention	☞ This device must not be disposed of as domestic waste. Send the old device for disposal to the manufacturer (find address on page 2).

RAPID Biomedical accepts the return of packaging material and of old device.

2.5 Returning of Devices

RAPID Biomedical ships its products in dedicated packaging which can be reused several times. Returning of devices is handled by the distributor. Contact your local service representative accordingly.

NOTICE	
Situation	Inadequate packaging and/or improper means of transport.
Hazard	Device can be damaged.
Prevention	☞ The original packaging is supposed to be used for returning the product.

2.6 Environmental Protection

RAPID Biomedical assures it will observe the environmental-protection regulations of the applicable EU Directives over the entire life cycle of its devices from development through manufacturing and disposal (see also 10.3 Labeling).

3 General Safety Instructions

3.1 General Information

Proper and safe operation of the Endorectal Coil in combination with the MR system requires technical knowledge of the operating personnel and a high degree of familiarity with this Instructions for Use and the Instructions for Use of the MR system.

⚠CAUTION	
Situation	Maloperation of the device during installation, operation, service and/or repair.
Hazard	Patient and/or user can be harmed, device and/or other equipment can be damaged.
Prevention	☞ The device may only be installed by authorized personnel. ☞ The device may only be operated by trained personnel. ☞ It is mandatory to follow this Instructions for Use closely. ☞ Follow the Instructions for Use of the MR system, additional devices and facilities.

⚠CAUTION	
Situation	Defective medical device.
Hazard	Patient and/or user can be harmed, device and/or other equipment can be damaged.
Prevention	☞ The operational reliability of the device must be checked and ensured prior to each use. ☞ The device must not be used in the event of any defect. Notify your local service representative immediately.

Checking the operational reliability of the device includes checking the housing, checking the connections (cables, plugs) and checking all labels (10.3 Labeling). The same applies to all the other devices required for operation and the accessories being used.

The local service representative must be notified immediately in the event of damage or malfunction. Missing or damaged labels may only be amended or replaced by the service representative. Only a representative authorized by RAPID Biomedical is entitled to repair or alter this product. See Chapter 4 Error Case.

When initially operated and prior to first use on a live test subject, proper function of the device must be verified and documented by a test on an appropriate MR phantom (9.1 Performance / Quality Assurance).

⚠CAUTION	
Situation	Disturbed signal detection by low SNR or image artifacts.
Hazard	Patient and/or user can be harmed, device and/or other equipment can be damaged.
Prevention	☞ Proper function of the device has to be checked and ensured prior to each use. ☞ The device is not to be used if failure of proper function is detected. ☞ The device may only be operated by trained personnel.

ⓘ	For EU Member States only: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the state in which the user and/or patient is established.

Prescription Use only – "℞ only"

Country specific laws restrict this device to sale by or on the order of a physician, or with the descriptive designation of any other practitioner licensed by the law of the country in which he practices to use or order the use of the device. This device may only be distributed to persons who are licensed practitioners or to persons who have a prescription or other order from a licensed practitioner to purchase it.

3.2 Area of Use

The device has been developed for use in conjunction with the MR system indicated in 5 Device Description.

The EC Declaration according to Article 12 of Directive 93/42/EEC [Article 22 of Regulation (EU) 2017/745] stipulates that the device may only be used in combination with the specified devices. Use of the device in combination with other non-listed devices is regarded as off-label-use and disregard of the Intended Use. This leads to the loss of warranty.

⚠CAUTION	
Situation	The device is not operated according to Intended Use.
Hazard	Patient and/or user can be harmed, device and/or other equipment can be damaged.
Prevention	☞ The device is to be used according to its Intended Use only.

Follow the instructions in the manual for the MR system, as well.

3.3 Risk Factors

⚠CAUTION	
Situation	Exposure of the patient to radio frequency (RF) magnetic fields may involve the following risk factors: ○ Presence of conductive (metallic) objects or implants within the sensitivity region of the RF transmit coil ○ Presence of medicinal products in transdermal patches ○ Skin-to-skin contact of different parts of the body ○ Presents of damp clothing ○ Placement of patient body or extremities against the RF transmit coil surface ○ Contact between patient and RF receive coil cable and the routing of the RF coil cable in proximity to the RF transmit coil ○ Formation of loops with RF receive coil cables and the ECG leads ○ Use of MR conditional ECG electrodes and leads ○ MR examination of sedated or unconscious patients or patients with loss of feeling in any body parts. ○ Presence of unconnected RF receive coils or electric cables remaining in the RF transmit coil during MR examination.
Hazard	Patient may experience local excessive RF heating.
Prevention	☞ All removable conductive objects are to be removed from the patient; e.g. watches, coins, jewelry, etc. ☞ Do not perform MR examinations on patients with conductive implants. ☞ Do not perform MR examinations on patients with medicinal products in transdermal patches. ☞ Check the position and posture of the patient to avoid conductive loops; e.g. calf-to-calf, hand-to-hand, etc. ☞ Do not perform MR examinations on patients with damp clothing. ☞ Check the position of the patient to avoid contact with the RF transmit coil surface. ☞ Check the position of the patient to avoid contact between patient and RF receive coil cable when the routing of the RF coil cable is in proximity to the RF transmit coil. ☞ Check the routing of RF receive coil cables and ECG leads to avoid loops. ☞ Observe Instructions for Use of ECG electrodes and leads. Pay close attention to expiration dates. ☞ Continuously monitor sedated or unconscious patients or patients with loss of feeling in any body parts closely during MR examinations. ☞ Remove disconnected coils or cables prior to the MR examination.

4 Error Case

4.1 Indication of Error

The device has no error indicators. Operators have to rely on other means of error indication. In this regard they should:

- constantly observe the error information provided by the MR system
- regularly check on the functionality of the device (e.g. for unexpected examination results, for degraded MR image quality, etc.)

4.2 Error Condition

Ensure that the product is set up and used according to the applicable Instructions for Use. Contact your local service representative for assistance in any other case.

⚠CAUTION	
Situation	Unauthorized repair of a defective device.
Hazard	Patient and/or user can be harmed, device and/or other equipment can be damaged.
Prevention	☞ Only a representative authorized by RAPID Biomedical is entitled to repair the device.

Part II Product Information

5 Device Description

The Endorectal Coil (1.5T Endorectal Coil O-HLE-015-01899, 1.5T Endorectal Coil O-HLE-015-01946, 3.0T Endorectal Coil O-HLE-030-01900 and ER Coil Support ZUB-01955) is designed for use with a magnetic resonance (MR) system. The coil is designed to work in unison with the Body Coil (BC) of the MR system, which will excite the hydrogen (1H) nuclei with radio frequency (RF) magnetic fields, so that the coil may receive the resultant RF signal from the excited nuclei. The coil is designed as a reusable receive-only coil for high resolution MR examination of the prostate.

The coil housing is minimally sized and drop-shaped for better patient comfort. It features a flat top to minimize the distance of the inside receive coil electronics to the prostate. The coil is receive-only (Rx) and consists of a single loop coil element with an integrated low noise preamplifier and a connector to the GE 1.5 T MR system or GE 3.0 T MR system. The coil is fixed tuned and matched to the typical loading condition of a prostate examination at the Larmor frequency of 1H at 1.5 T (63.9 MHz) or 3.0 T (127.7 MHz), respectively. Decoupling circuits are integrated in the single loop element providing a decoupling from the Body Coil of the MR system during transmission of the RF excitation pulse.

It is recommended to employ an Endorectal Coil Model in combination with the additional available ER Coil Support. The ER Coil Support is designed for use with any Endorectal Coil Model (1.5T Endorectal Coil O-HLE-015-01899, 1.5T Endorectal Coil O-HLE-015-01946 and 3.0T Endorectal Coil O-HLE-030-01900). It supports stabilizing the Endorectal Coil in any position required by each individual endorectal MR examination. The ER Coil Support features a collet for acceptance of the Endorectal Coil. The Endorectal Coil is fixated inside the collet by tightening of a knurled screw. It offers five degrees of freedom to align the position of the collet with the required spatial position of the Endorectal Coil housing. Two additional knurled screws allow to lock the ER Coil Support in the desired alignment.

5.1 Indications for Use, Contraindications, Environment

Indications for Use / Intended Purpose	The Endorectal Coil is indicated for use as diagnostic device extension for GE 1.5 T MR systems and GE 3.0 T MR systems to produce transverse, sagittal, coronal and oblique images, spectroscopic images and/or spectra, displaying the internal structure of the prostate. These images when interpreted by a trained physician yield information that may assist in diagnosis.
Contraindications	The Endorectal Coil does not alter the general contraindications for MR examinations on GE 1.5 T MR systems and GE 3.0 T MR systems. For endorectal MR examinations there are additional contraindications to be identified and considered by the medical practitioner (see also 7.1 Patient Selection).
Application	Prostate
Intended Population	Adults (greater than 21 years of age)
Applied Parts	The whole medical device
MR System	GE 1.5 T MR systems or GE 3.0 T MR systems
Field Strength B_0	1.5 T or 3.0 T respectively
Operation of 1H Body Coil	necessary (1H excitation)

5.2 Scope of Delivery

The following components are supplied with this device:
For GE 1.5 T MR systems with “P port connection”

- 1.5T Endorectal Coil (GEHC part # 5772252-2)
- eIFU Leaflet
- CD containing electronic Instructions for Use in different languages

For GE 1.5 T MR systems with “A port connection”

- 1.5T Endorectal Coil (GEHC part # 5818916-2)
- eIFU Leaflet
- CD containing electronic Instructions for Use in different languages

For GE 3.0 T MR systems

- 3.0T Endorectal Coil (GEHC part # 5772250-2)
- eIFU Leaflet
- CD containing electronic Instructions for Use in different languages

For all Endorectal Coil Models

- ER Coil Support (GEHC part # 5772250-3)

5.3 Device Overview

5.3.1 Endorectal Coil Models

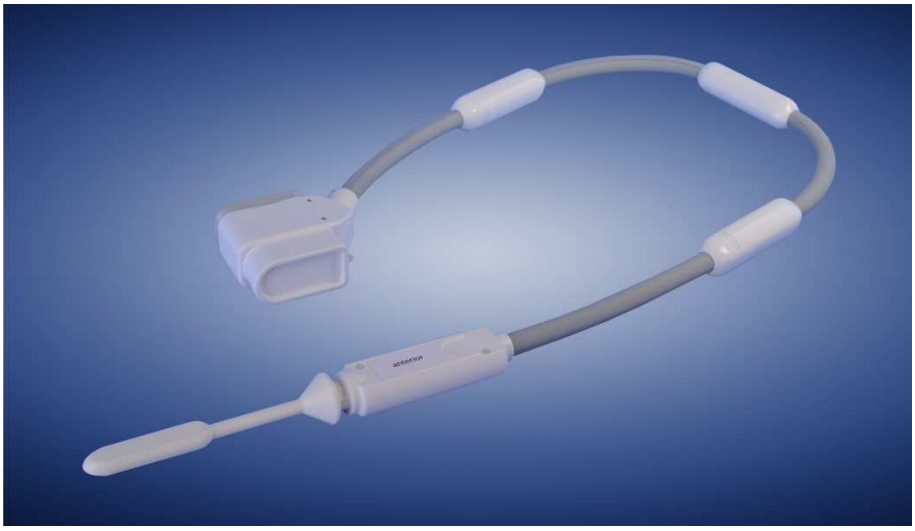

Figure 1: 1.5T Endorectal Coil - O-HLE-015-01899 (“P Port”)

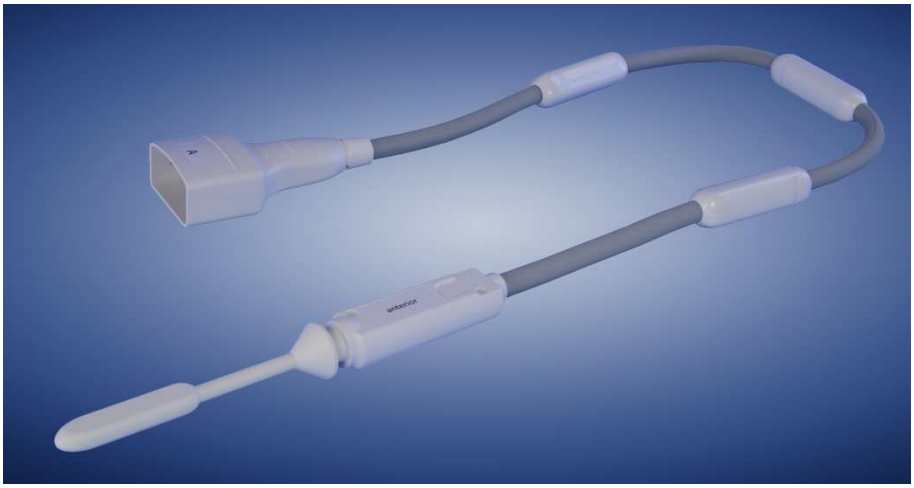

Figure 2: 1.5T Endorectal Coil - O-HLE-015-01946 (“A Port”)

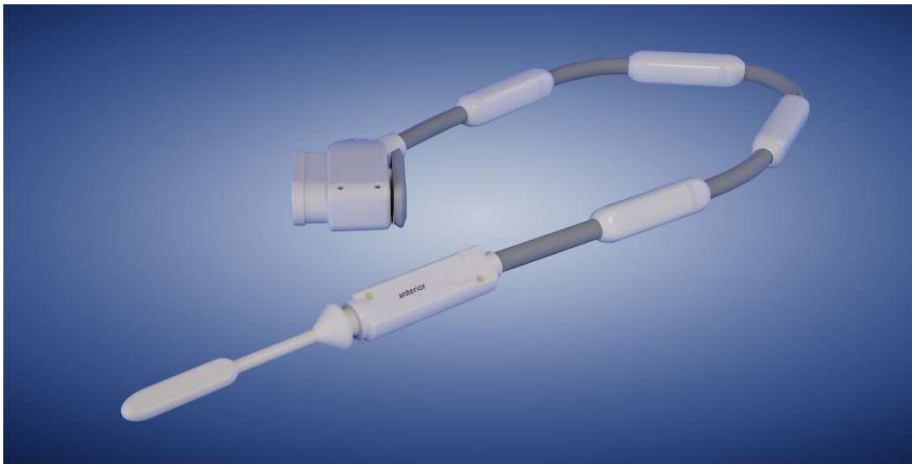

Figure 3: 3.0T Endorectal Coil - O-HLE-030-01900

5.3.2 ER Coil Support For All Models

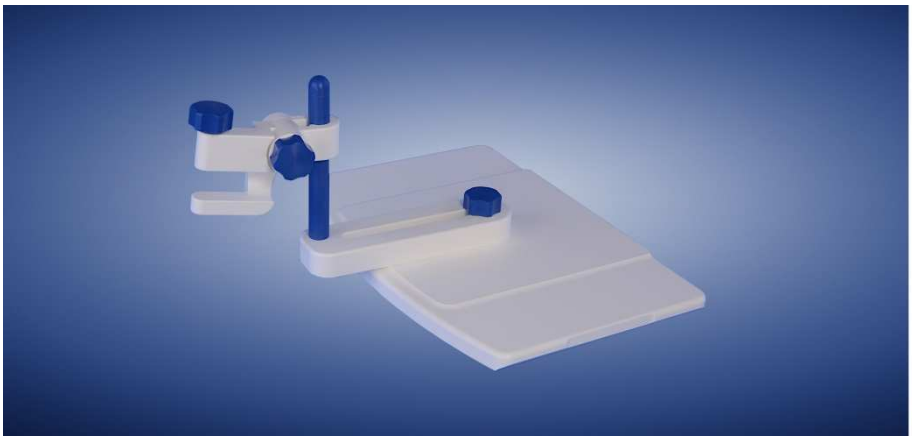

Figure 4: ER Coil Support - ZUB-01955

6 Initial Operation and Recommissioning

Before initial operation after delivery, service or repair, always check the operational reliability of the device.

NOTICE	
Situation	Device is operated before being acclimatized.
Hazard	Damage of medical device due to condensation.
Prevention	☞ Installation and initial operation of the device may only take place after a reasonable period of acclimatization. Store the unpackaged device for 24 hours before operation in the environment intended for later operation. ☞ See Attachment 10.1 Specifications for the permissible environment for operating the device.

	The device is only cleaned but not disinfected at the time of delivery. Before initial operation the device has to be preprocessed by following the instructions of chapter 8 Reprocessing.

⚠CAUTION	
Situation	Device is not preprocessed before initial use.
Hazard	Required level of disinfection not achieved resulting in danger of infection.
Prevention	☞ The device has to be preprocessed by following the instructions of chapter 8 Reprocessing.

7 Regular Use

7.1 Patient Selection

⚠CAUTION	
Situation	In addition to the general contraindications for MR examinations, additional contraindications might exist for an endorectal MR examination. Contraindications might include (note that the list below may not be complete): ○ Patients with surgically absent anus or rectum. ○ Patients with hemorrhoids (bleeding hemorrhoids). ○ Patients with previous colorectal surgery (intestine bleeding or rupture). ○ Patients with inflammatory intestinal diseases (intestine bleeding or rupture). ○ Patients with post-radiogenic increased vulnerabilty of the rectum. ○ Patients with constrictions (complications). ○ Patients with obstructive masses within the rectum (complications). ○ Patients with acute diarrhea.
Hazard	Patient can be harmed.
Prevention	☞ Each patient has to be screened for contraindications. ☞ This screening has to be assessed by the medical practitioner.

⚠CAUTION	
Situation	Patient with allergies, for example (note that the list below may not be complete): ○ To lubricant (e.g. lidocaine). ○ To condoms (e.g. latex, polyisoprene).
Hazard	Patient can be harmed.
Prevention	☞ Patient has to be screened for allergies. ☞ Instructions for Use of lubricants and condoms are to be observed. ☞ Selection of condoms and lubricants is the responsibility of the medical practitioner.

Recommendation

RAPID Biomedical recommends the use of Medical Condoms / Endocavity probe covers, like:

- Endocavity Probe Covers, Sterile Latex Cover with bands 3.5 x 20 cm by Protek Medical; #3230; K970891
- Ultracover® Sterile Latex Cover 40 x 300 mm by Ecolab; #86694
- NeoGuard® Narrow Width Ultrasound Probe Covers, Natural Latex free 4 x 30 cm by Civco; #610-844
- Etc.

7.2 Patient Preparation

⚠CAUTION	
Situation	Patient not prepared for endorectal MR examination, for example (note that the list below may not be complete): ○ Bowel preparation before examination.
Hazard	Patient and/or user can be harmed, device and/or other equipment can be damaged.
Prevention	☞ Patient preparation is the responsibility of the medical practitioner. ☞ The scope of patient preparation is at the discretion of the responsible medical practitioner.

7.3 Preparation of the Device

⚠CAUTION	
Situation	Device is inadequately cleaned and disinfected.
Hazard	Required level of disinfection not achieved resulting in danger of infection.
Prevention	☞ The device requires a high-level disinfection before and after each use including the initial use. ☞ The device is only to be used when covered by a double layer of condoms. ☞ The device has to be reprocessed by following the instructions of chapter 8 Reprocessing.

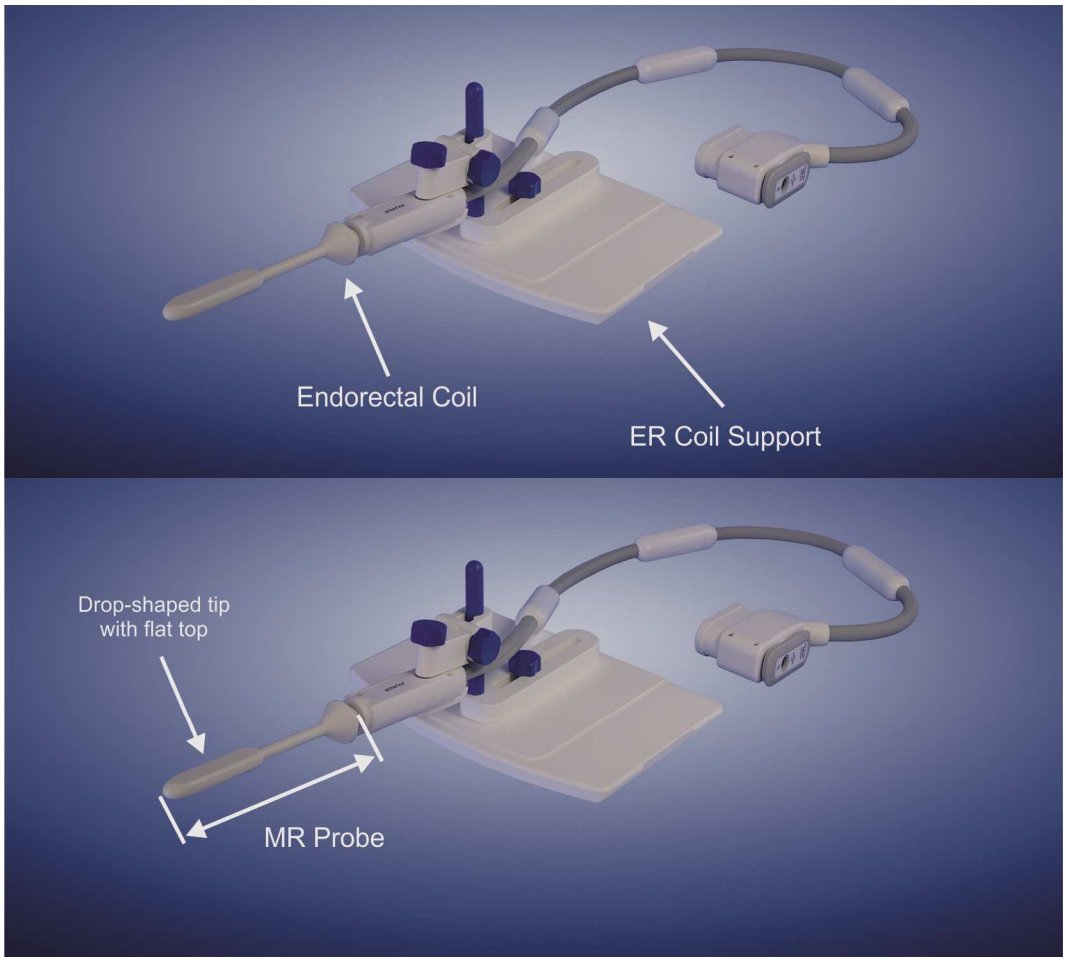

Figure 5: Endorectal Coil with ER Coil Support

The Endorectal Coil has to be prepared for MR examination according to the picture series Figure 6 to Figure 10.

Figure 6: Remove the cover from the High-Level disinfected MR Probe of the Endorectal Coil.

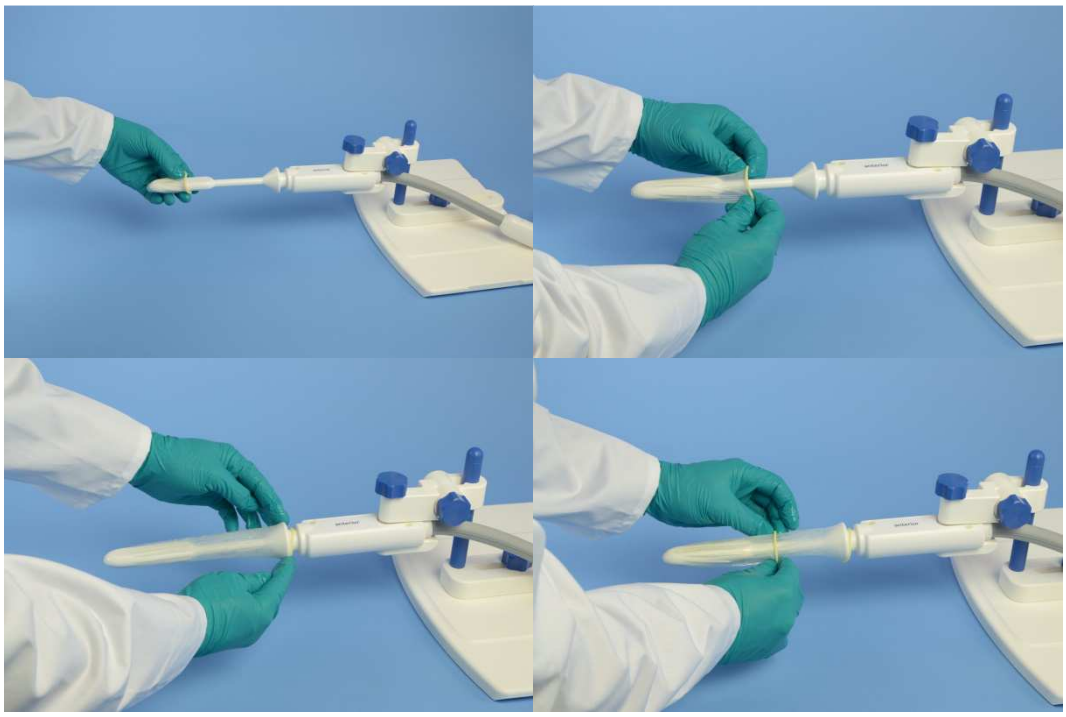

Figure 7: Cover the MR Probe of the Endorectal Coil with a double layer of condoms.

Select condoms which offer a tight grip over the cone ring for condom fixation.

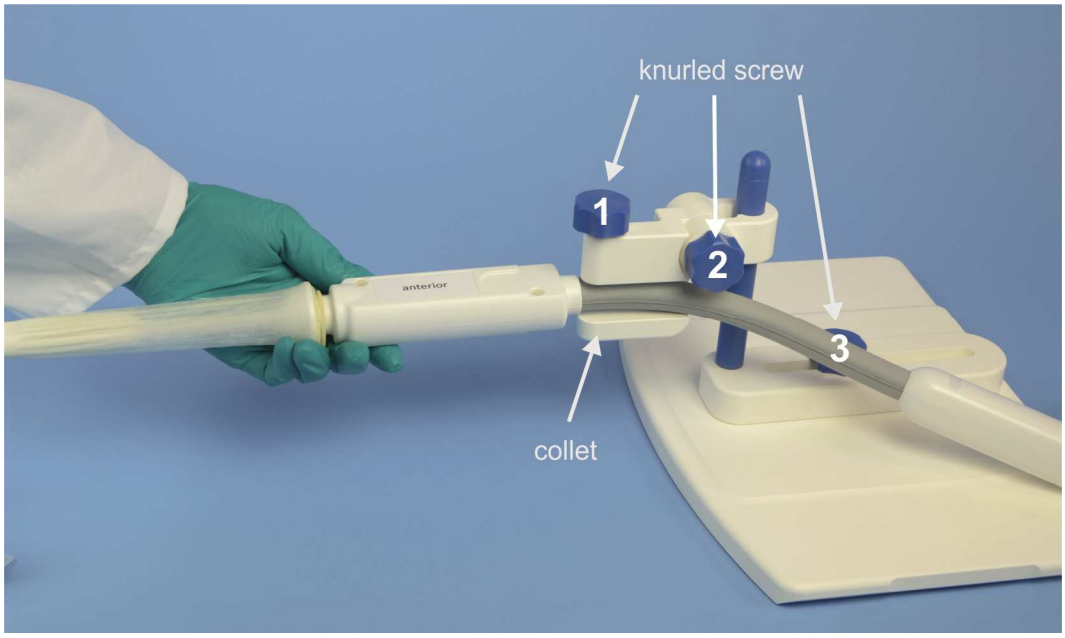

Figure 8: Prepare the ER Coil Support for mounting the Endorectal Coil by loosening knurled screw #1.

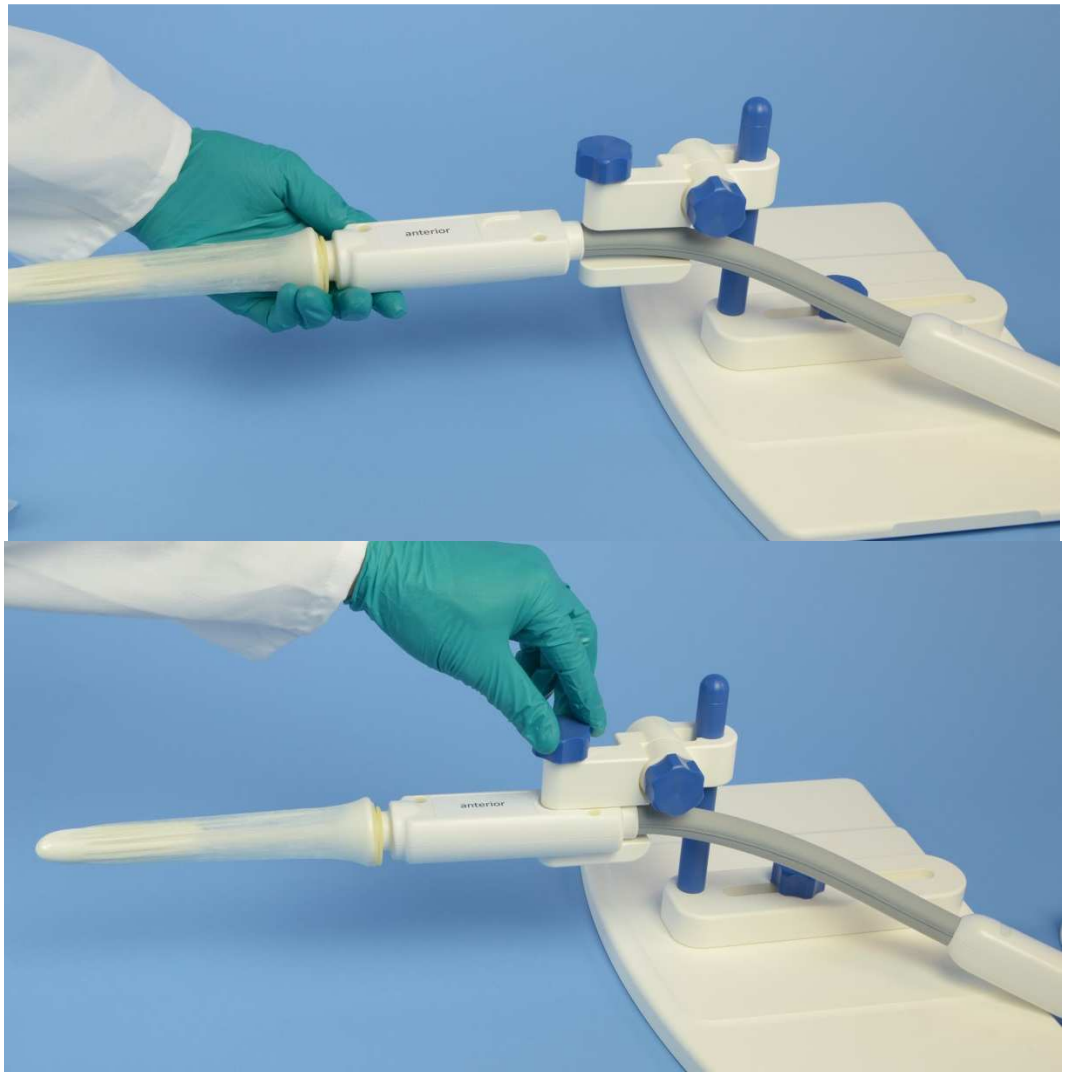

Figure 9: Insert the Endorectal Coil into the collet with the label “anterior” facing upwards. Fixate it with knurled screw #1.

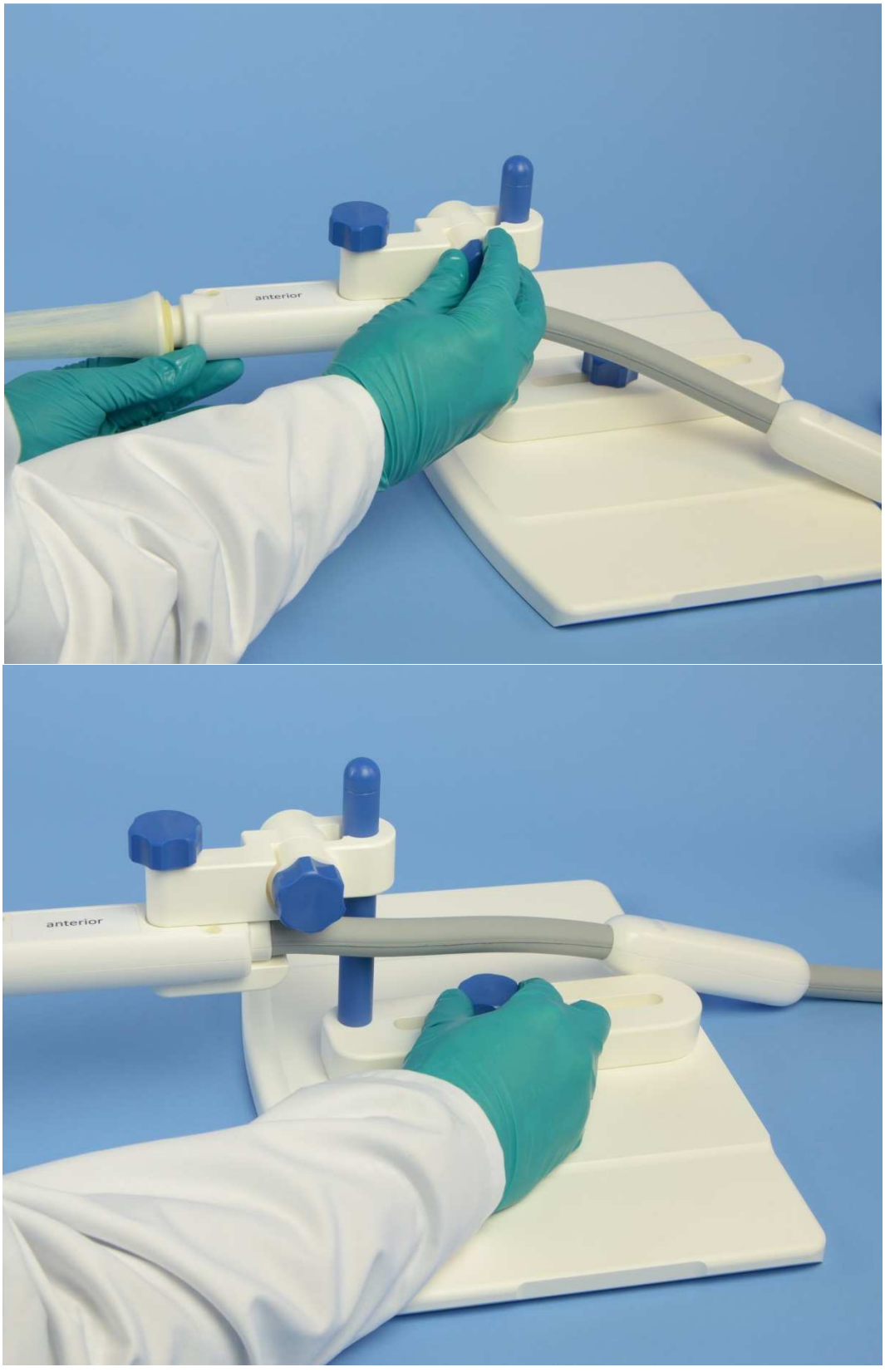

Figure 10: Each endorectal MR examination requires an individual coil positioning. The ER Coil Support can be adapted accordingly using knurled screws #2 and #3.

⚠CAUTION	
Situation	Risk of pinching during setup of the device.
Hazard	Patient and/or user can be harmed.
Prevention	☞ Setup the device with care.

⚠CAUTION	
Situation	When using in Signa PET/MR, PET signal is attenuated by the device.
Hazard	Displayed PET signal might be decreased and/or dislocated which can lead to wrong diagnostic results.
Prevention	☞ Use of an PET attenuation correction is recommendedEnsure that only the front section of the Endorectal Coil with the drop-shaped tip is located within the PET detector rings. ER Coil Support and connecting cable should not be positioned inside the PET detector.

7.4 Positioning of Patient and Coil

An exemplary workflow for positioning of patient and coil is described below. Two persons are recommended for convenient patient and device handling. This list makes no claim to completeness. Additional measures may be required; e.g. from patient contraindication analysis.

7.4.1 Exemplary Workflow Description

- The patient is positioned feet-first in lateral position facing away from the personnel.
- A digital rectal examination is performed before inserting the Endorectal Coil.
  - Examination ensures that the rectum is empty and free of obstruction.
  - Examination checks for the path of the rectum.
- The coil is removed from the ER Coil Support by loosening knurled screw #1 if the coil is mounted on the ER Coil Support.

⚠CAUTION	
Situation	Device is too large or too bulky for gentle insertion.
Hazard	Patient can be harmed.
Prevention	☞ Coating the condom-covered device with a gel lubricant could improve patient comfort for gentle insertion of the coil.

- The coil is inserted carefully.
  - With the label “anterior” facing in anterior direction (turning the flat-top of the coil housing towards the prostate; see Figure 11).
  - When the sphincter relaxes around the coil neck.
- The patient is supported when rolling back to supine position.
  - The Endorectal Coil is carefully guided during patient movement.
  - Special care is taken to provide patient comfort to the highest degree possible
- The legs of the patient are covered with a cloth in order to prevent direct contact between the device and skin of the patient.

Long lasting direct contact between the device and patient skin can lead to perspiration. Sweat is electrically conducting which means that RF power can be absorbed in usually non-conducting materials.

⚠CAUTION	
Situation	Long lasting direct contact between the device and patient skin.
Hazard	RF burning.
Prevention	☞ Avoid direct contact between the patient and the device; e.g. by using suitable pads or cloths.

⚠CAUTION	
Situation	Long lasting direct contact between the device and patient skin.
Hazard	Skin irritation.
Prevention	☞ Use the device only while the drop-shaped tip is covered by a double layer of condoms.Avoid direct contact between the other parts of the device and the patient; e.g. by using suitable pads or cloths.

- The ER Coil Support is positioned between the covered legs of the patient. Knurled screws #2 and #3 are loosened.
- The Endorectal Coil is positioned with its coil head close to the prostate in scan position
  - Special care is taken that the prostate is not exposed to too much pressure

ⓘ	Proper positioning of patient and coil is important for allowing best achievable SNR and image quality. Be careful to apply only slight pressure to the patient. Putting the patient in an uncomfortable position will increase the risk of patient movement during the examination. Decreased image quality will be the result.

Please refer to the following sample images showing proper positioning of the Endorectal Coil.

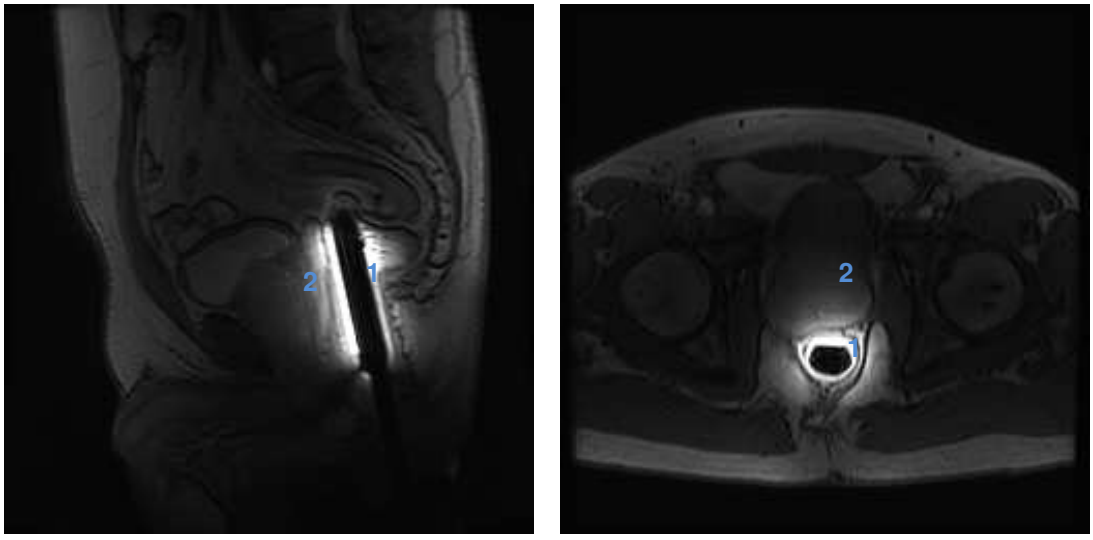

Figure 11: Localizer in vivo images in sagittal (left) and axial orientation (right) windowed / leveled to confirm the proper positioning of the coil. – Left: Sagittal view is useful to confirm that the prostate is centered with respect to coil's signal coverage. Right: Transversal view is useful to confirm the flat top (1) is facing towards the prostate gland (2) and aligned properly.

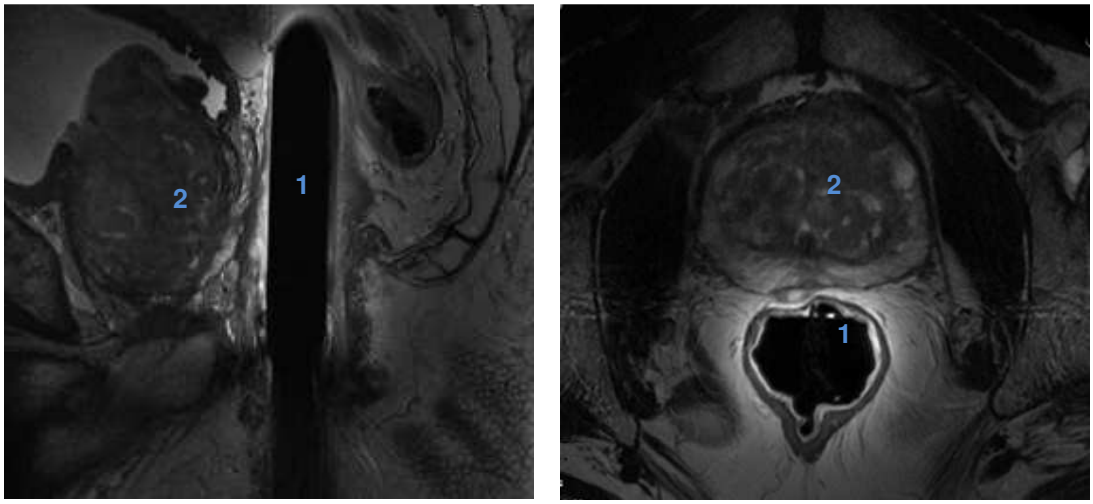

Figure 12: T2 in vivo images in sagittal (left) and transversal orientation (right) showing a well-positioned Endorectal Coil with a centered prostate gland (2) and the flat top (1) facing towards the prostate.

- The position of the Endorectal Coil is stabilized in scan position using the ER Coil Support.
  - The Endorectal Coil is carefully held in place; lateral deviations are corrected if necessary.
  - The collet is moved over the Endorectal Coil.
  - The collet is moved anteriorly on the pillar - the coil is tilted dorsally presacral in the pelvis.
    (This helps avoiding artifacts close to the coil in the prostate and deformation of the prostate.)
  - Tighten all knurled screws carefully so that the Endorectal Coil is fixated in its position.

A support of the patient's knees can help improving patient comfort.
Some lubricants may create image artifacts. Lubricant image artifacts can be reduced by minimizing the amount of lubricant used.

- The Endorectal Coil is connected to the MR system following chapter 7.5 Connecting to the MR System.
- The patient table is moved into the MR system.
  - The center of the region to be examined is matched to the iso-center of the magnet as well as possible.
  - The center of the drop-shaped tip has a distance of 150 mm to the end of the cone ring for condom fixation (see Figure 13).

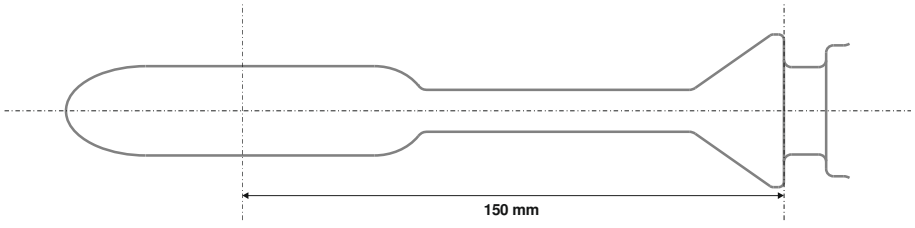

Figure 13: Distance between the center of the drop-shaped tip towards the end of the cone ring for condom fixation.

- Endorectal MR examination procedures are started (7.6 Imaging Considerations)

7.5 Connecting to the MR System

The Endorectal Coil is equipped with one connecting cable terminating in a GE connector (GE P-Port connector for 1.5T Endorectal Coil O-HLE-015-01899 and 3.0T Endorectal Coil O-HLE-030-01900; GE A-Port connector for 1.5T Endorectal Coil O-HLE-015-01946).

1.5T Endorectal Coil O-HLE-015-01899 *and 3.0T Endorectal Coil* O-HLE-030-01900*:*
The GE P-Port connector can be plugged into socket 1, 2 or 4. Ensure that GE P-Port connector is locked after being plugged into the socket.
Note that if the Endorectal Coil is used in combination with Anterior Array AA and Posterior Array PA coils, the AA coil has to be plugged into socket 1.

1.5T Endorectal Coil O-HLE-015-01946*:*
The GE A-Port connector has to be plugged into socket A.

The coils will be recognized and displayed on the MR system once connected.

Check the Coils' Tab on the user interface of the GE MR system before starting an MR examination. Select the Endorectal Coil from the Coil Components list and the desired coil configuration from the Coil Configuration list.

The coil is not correctly connected to the MR system if the coil is not shown in the Coil Components list. Any examination is prohibited in such case.

⚠CAUTION	
Situation	Examinations with the device not connected according to this Instructions for Use.
Hazard	Patient and/or user can be harmed, device and/or other equipment can be damaged.
Prevention	☞ The device has to be connected as specified in this Instructions for Use. ☞ Follow the connecting instructions given in the Instructions for Use of the MR system. ☞ Prior to examinations make sure all connections have been completed. ☞ Proper connection between the coil and the MR system needs to be checked in the user interface of the software prior to each exam. ☞ Examinations are not to be performed if the coil is inside the magnet and disconnected from the MR system.

If any auxiliary device is required to operate the product, follow the Instructions for Use of all devices used.

⚠CAUTION	
Situation	Usage of equipment which is not MR safe or which is not specifically approved for usage with the device.
Hazard	Patient and/or user can be harmed, device and/or other equipment can be damaged.
Prevention	☞ Use only equipment which is MR safe and approved for combined usage with the device.

7.6 Imaging Considerations

- Before going into diagnostic imaging, confirm with a localizer the proper positioning of the Endorectal Coil with regards to the prostate.
- Window/level the localizer images to confirm the proper positioning of the coil as shown in Figure 11.
  - Sagittal view is useful to confirm that the prostate is centered with respect to coil's signal coverage.
  - Transversal view is useful to confirm the flat top is facing towards the prostate gland and aligned properly.
- Uniformity correction algorithms such as PURE could be quiet beneficial in balancing the steep signal intensity profile from Endorectal Coil use and recommended if available.
- PROPELLER sequence deserves special attention with Endorectal Coil.
  - PROPELLER uses NEX signal averaging for two purposes: 1) SNR improvement and 2) streak artifact reduction.
  - While Endorectal Coil provides the SNR boost, streak artifact reduction would still need a reasonable number of NEX (at least a NEX of 2).

7.7 Disconnecting the Device

If not otherwise specified in the manual of the MR system or auxiliary devices, proceed as follows when removing the coil from the site of use after completing a measurement/examination.

1. Move the patient table out of the magnet bore.
2. Disconnect the Endorectal Coil from the MR system.
   a. Attach cover onto coil connector (see Figure 14).
3. Remove the ER Coil Support by:
   a. Loosen all knurled screws carefully.
   b. Detach the collet from the Endorectal Coil.
   c. Remove the ER Coil Support from the patient table.
   d. Start reprocessing immediately according to chapter 8.2 Workflow ER Coil Support.
4. Remove the Endorectal Coil from the patient carefully.
   a. Start reprocessing immediately according to chapter 8.3 Workflow Endorectal Coil.
5. Remove the cloth.
   a. Properly dispose of the cloth.
6. Help the patient off the patient table.

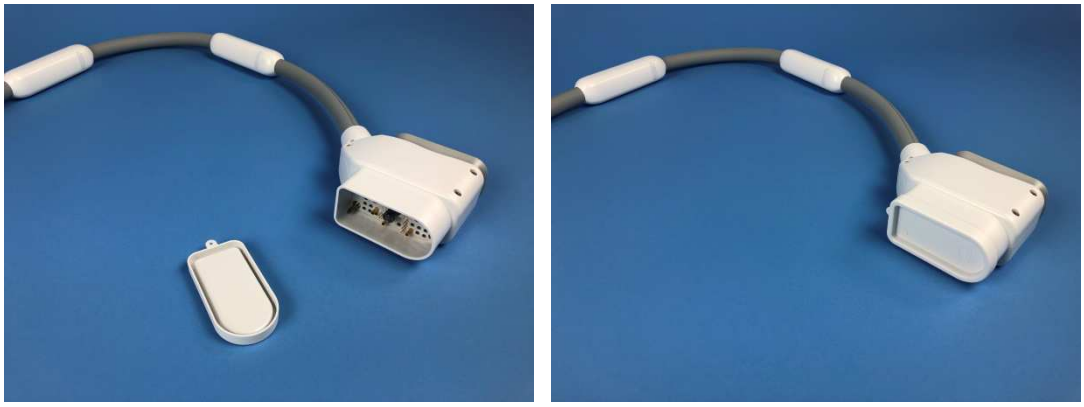

Figure 14: Attach cover onto coil connector of the Endorectal Coil.

8 Reprocessing

8.1 General Information

Cleaning and disinfection must comply with all applicable laws and regulations which have the force of law within the jurisdiction(s) in which the system is located.

⚠CAUTION	
Situation	Use of other cleaning solution, disinfectants, special accessories, and/or cleaning and disinfection procedures other than described in this Instructions for Use.
Hazard	Patient and/or user can be harmed, device and/or other equipment can be damaged.
Prevention	☞ The device may only be reprocessed by trained personnel. ☞ Only use a cleaning solution and disinfectants specified in this Instructions for Use. ☞ Only use special accessories specified in this Instructions for Use. ☞ Only use reprocessing procedures described in this Instructions for Use.

The reprocessing instructions have been validated by RAPID Biomedical as appropriate for the ability to successfully reprocess the device for its reuse. The user is responsible for the reprocessing of the device, which is actually carried out at the reprocessing facility. The user has to ensure that the device can be effectively reprocessed and safely reused over its use life, as intented. This requires verification and / or validation and routine monitoring of the reprocessing.

Cleaning

Cleaning is an essential step before an effective disinfection. Cleaning is the physical removal of foreign material; e.g. dust, soil, organic material such as blood, secretions, excretions and microorganisms. Cleaning generally removes rather than kills microorganisms. Cleaning is accomplished with water, detergents and mechanical action.

Disinfection

Disinfection is the inactivation of disease causing microorganisms.

This device except the MR Probe is classified as a noncritical item with regard to reprocessing. The MR Probe is classified as a semicritical medical product with regard to reprocessing (see Figure 15). Therefore a high-level disinfection is required for the MR Probe.

The reprocessing of this device is only validated for using the hydrogen peroxide high-level disinfectant “Resert™ XL HLD High Level Disinfectant” by Steris Corporation, Mentor, OH 44060, U.S.A.

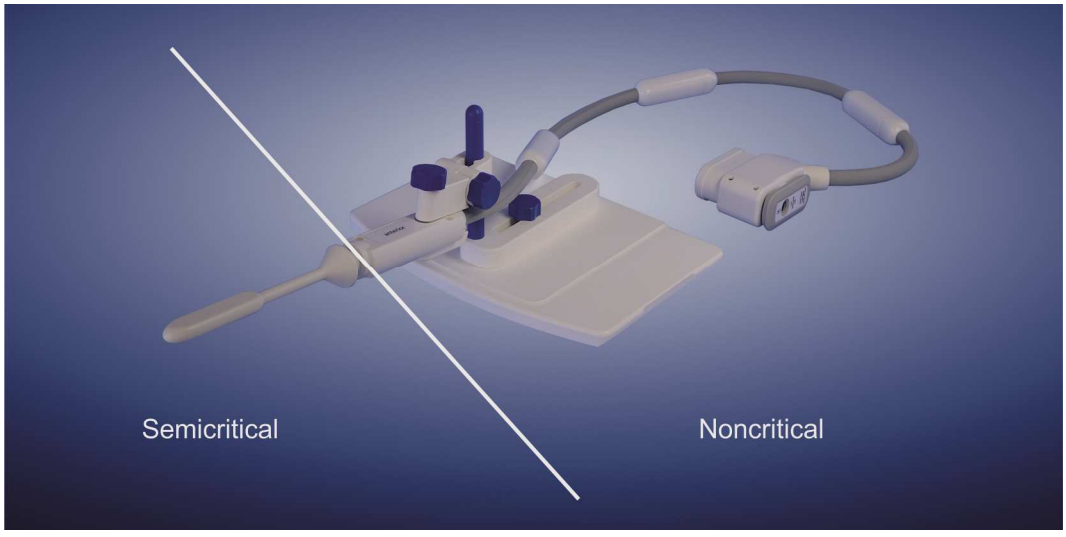

Figure 15: Classification of product parts with regard to reprocessing.

	The Instructions for Use of the Personal Protective Equipment (PPE), special accessories, cleaning agent and disinfectants are also to be observed.

⚠CAUTION	
Situation	Use of inappropriate Personal Protective Equipment (PPE).
Hazard	User can be harmed.
Prevention	☞ Use only PPE which is appropriate for the individual reprocessing step.Observe Instructions for Use of the cleaning agents and disinfectants used for the individual step.

8.1.1 Limitations and Restrictions in the Reprocessing

After extended use, the high-level disinfection (HLD) will have an effect on the device due to chemical interactions. The use life of the device is limited by these interactions.

The device is coated with a biocompatible paint. Alteration of this paint has to be monitored closely:

- A discoloration does not have an adverse effect on the biocompatibility of the paint.
- Blistering of the paint does have an adverse effect on the biocompatibility. The device is not safe to be used any longer.

End-of-use-life indicators:

- Blistering of the paint ends the use life of the device.
- The use life of the device ends after 500 reprocessing cycles.

⚠CAUTION	
Situation	Use of a device, when use life has ended.
Hazard	Patient can be harmed.
Prevention	☞ Carefully check for end-of-use-life indicators. ☞ Do not use a device when use life has ended.

8.1.2 Reprocessing Workflow

- Wear appropriate PPE when handling cleaning solutions, disinfectants and the device. PPE includes gloves, eye protection, impervious gown, face shield or simple surgical mask, etc.
- Properly discard expendable items like gloves, wipes etc.
- Automated reprocessing is not feasible for this device. Follow procedures for manual reprocessing of the device described below.

	Successful reprocessing of the device for its safe reuse requires a high degree of familiarity with this chapter (8 Reprocessing of this Instruction for Use). Ensure that all accessories are available and ready before starting reprocessing.

8.2 Workflow ER Coil Support

8.2.1 Summary of Steps

The following table shows a summary of steps necessary to properly reprocess the device.

Follow the detailed steps instructed in chapter 8.2.2 Detailed Steps.

(1) Initial Treatment	☞ Place the device in a container. ☞ Transport the device to reprocessing area immediately.
(2) Pre-Cleaning	☞ Rinse the device under running water. ☞ Disassemble the device.
(3) Cleaning	☞ Immerse parts in cleaning solution. ☞ Clean surfaces, holes and threads. ☞ Rinse the parts thoroughly. ☞ Dry surfaces, holes and threads. ☞ Visual inspection of cleanliness.
(4) Low Level Disinfection (LLD)	☞ Immerse parts in disinfectant. ☞ Rinse thoroughly.
(5) Drying	☞ Dry surfaces, holes and threads.
(6) Inspection	☞ Visual inspection for damages.
(7) Packaging	☞ Reassemble the device. ☞ Pack the device in a clean container.
(8) Storage & Transportation	☞ Store the device.

8.2.2 Detailed Steps

(1) Initial Treatment at the Point of Use	
Accessories	• Appropriate container with lid; e.g. MR compatible, size 50cm x 50cm x 21cm (length x width x height).

Steps	• Place ER Coil Support in container.
	• Label the container; e.g. with
	  ○ Device identification
	  ○ State of the device; e.g. contaminated
	  ○ Packaging date
	  ○ Signature
	• Transport to reprocessing area immediately.
	• Begin “Preparation before Cleaning” without delay.

(2) Preparation before Cleaning	
Accessories	No special accessories required.

Steps	• Rinse under running water.
	• Disassemble ER Coil Support:
	  ○ Loosen and remove all knurled screws (Part No. 1-3).
	  ○ Separate the individual components (Part No. 4-7).
	  ○ See Figure 16 for an overview.
	• Begin “Cleaning” without delay.

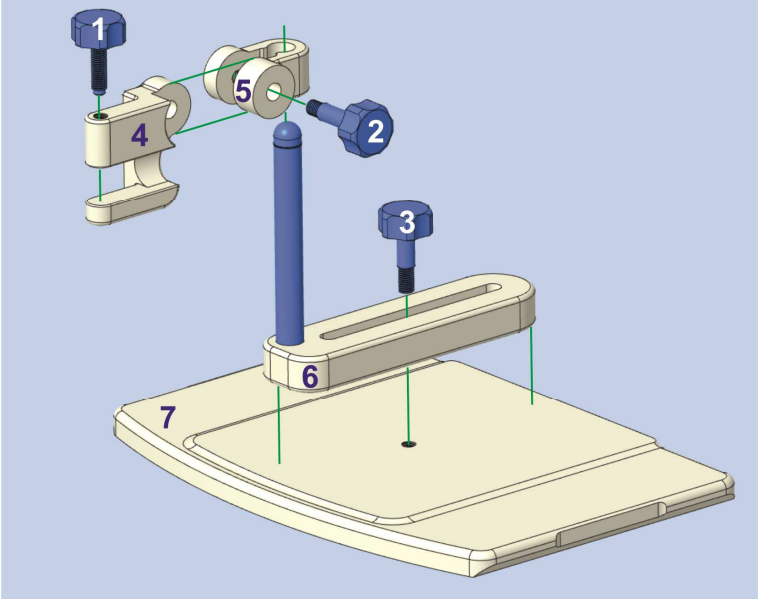

Figure 16: Disassembled ER Coil Support.

(3) CLEANING	
Accessories	• pH-neutral enzymatic cleaning detergent; e.g. B. Braun Helizyme 1% solution. • Immersion bath container filled with cleaning solution; e.g. size 50cm x 50cm x 20cm (length x width x height). • Soft, lint-free wipes soaked with cleaning solution; e.g. B. Braun Melsungen AG, B. Braun Wipes ECO. • Cleaning brush, non-abrasive, Nylon twisted brush head; e.g. size 10mm x 50mm (diameter x min. length). • Soft, lint-free wipes, dry; e.g. B. Braun Melsungen AG, B. Braun Wipes ECO.
Steps	• Immerse single parts completely for the minimum time according to IFU of cleaning solution; e.g. 5 minutes for B. Braun Helizyme 1% solution. • Clean surfaces with soaked wipes thoroughly while immersed. • Clean holes and threads using the brush thoroughly while immersed. • Rinse thoroughly with clean, fresh tap water. • Dry surfaces, holes and threads with dry wipes. • Check that the parts are visibly clean; repeat the process for parts determined not to be visibly clean.

(4) LOW LEVEL DISINFECTION (LLD)	
Accessories	• Low-level disinfectant, alcohol based, concentration 60%–80% alcoholic solution; e.g. Schülke & Mayr GmbH, mikrozid® AF liquid / mikrozid® AF wipes. • Immersion bath container filled with disinfectant; e.g. size 50cm x 50cm x 20cm (length x width x height).
Steps	• Immerse single parts completely for the minimum time according to IFU of disinfectant; e.g. 5 minutes for mikrozid® AF liquid. • Rinse thoroughly with clean, fresh tap water.

(5) DRYING	
Accessories	• Soft, lint-free wipes, dry; e.g. B. Braun Melsungen AG, B. Braun Wipes ECO.
Steps	• Dry surfaces, holes and threads with dry wipes.

(6) INSPECTION	
Accessories	No special accessories required.
Steps	• Visually inspect for damages and other signs of material deterioration. • In case of any findings see chapter 3 General Safety Instructions.

(7) PACKAGING	
Accessories	• Appropriate clean container; e.g. MR compatible, size 50cm x 50cm x 10cm (length x width x height).

Steps	• Reassemble ER Coil Support for “Application” as shown in Figure 17.
	  ○ Choose “Application” setup.
	  ○ See Figure 17 for details on component arrangement.
	  ○ Use knurled screws (Part No. 1-3) to fixate individual components (Part No. 4-7).
	• Place ER Coil Support in clean container.
	• Label the container; e.g. with
	  ○ Device identification
	  ○ State of the ER Coil Support; e.g. cleaned, low-level disinfected
	  ○ Packaging date
	  ○ Signature

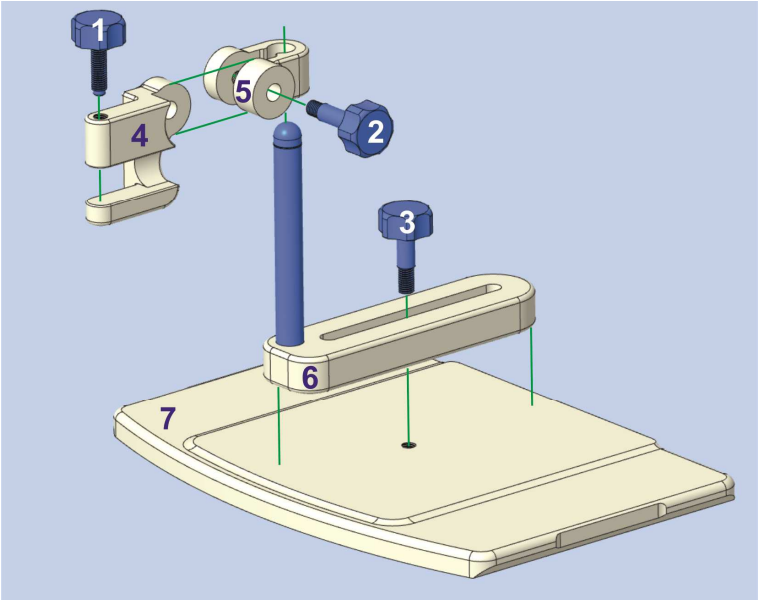

Figure 17: ER Coil Support assembly in “Application” setup.

(8) STORAGE AND TRANSPORTATION	
Accessories	No special accessories required.
Steps	• Transport to defined storage location. • Store under specified conditions (see 10.1 Specifications).

8.3 Workflow Endorectal Coil

8.3.1 Summary of Steps

The following table shows a summary of steps necessary to properly reprocess the device.

Follow the detailed steps instructed in chapter 8.3.2 Detailed Steps.

(1) Initial Treatment	☞ Remove condoms. ☞ Place the device in a container. ☞ Transport the device to reprocessing area immediately.
(2) Pre-Cleaning	☞ No actions required.
(3) Cleaning	☞ Clean device with rotating movements from connector up to tip of the housing. ☞ Rinse with wipes moistened with water. ☞ Dry with dry wipes. ☞ Visual inspection of cleanliness.
(4) Low Level Disinfection (LLD)	☞ Use disinfectant wipes to disinfect all areas of the device. ☞ Rinse thoroughly with wipes moistened with water.
(5) Drying	☞ Dry with dry wipes.
(6) High Level Disinfection (HLD)	☞ Immerse MR Probe in disinfectant. ☞ Rinse thoroughly.
(7) Drying	☞ Dry with dry wipes.
(8) Inspection	☞ Visual inspection for damages. ☞ Check for end-of-use-life indicators. ☞ Check covered connector.
(9) Packaging	☞ Protect MR Probe with cover. ☞ Label the probe cover. ☞ Pack the device in a clean container.
(10) Storage & Transportation	☞ Store the device.

8.3.2 Detailed Steps

(1) Initial Treatment at the Point of Use	
Accessories	• Appropriate container with lid; e.g. MR compatible, size 50cm x 50cm x 10cm (length x width x height).

Steps	• Remove double layer of condoms from MR Probe.
	• Dispose of condoms properly.
	• Place Endorectal Coil in container.
	• Label the container; e.g. with
	  ○ Device identification
	  ○ State of the Endorectal Coil; e.g. contaminated
	  ○ Packaging date
	  ○ Signature
	• Transport to reprocessing area immediately.
	• Begin “Preparation before Cleaning” without delay.

(2) Preparation before Cleaning	
Accessories	No special accessories required.
Steps	• No actions required. • Begin “Cleaning” without delay.

(3) Cleaning	
Accessories	• pH-neutral enzymatic cleaning detergent; e.g. B. Braun Helizyme 1% solution. • Soft, lint-free wipes soaked with cleaning solution; e.g. B. Braun Melsungen AG, B. Braun Wipes ECO. • Soft, lint-free wipes, dry; e.g. B. Braun Melsungen AG, B. Braun Wipes ECO.
Steps	• Wring a wipe soaked with cleaning solution. • Clean cable area with rotating movements. Avoid back and forth movements. Move from connector up to coil housing. • Clean coil area starting at the cable and move upwards to the tip of the housing. Avoid back and forth movements. • Ensure that all areas of the device come into contact with the wipe. • Allow the cleaning solution to take effect for the minimum time according to IFU; e.g. 5 minutes for B. Braun Helizyme 1% solution. • Rinse thoroughly with moistened wipes soaked with clean, fresh tap water. • Dry with dry wipes. • Check that the device is visibly clean. Repeat the process if the device is determined not to be visibly clean.

(4) Low Level Disinfection (LLD)	
Accessories	• Low-level disinfectant wipes, alcohol based, concentration 60%–80% alcoholic solution; e.g. Schülke & Mayr GmbH, mikrozid® AF wipes. • Soft, lint-free wipes, dry; e.g. B. Braun Melsungen AG, B. Braun Wipes ECO
Steps	• Use disinfectant wipes to disinfect all surfaces of the device. • Wipe cable area with rotating movements. Avoid back and forth movements. Move from connector up to coil housing. • Wipe coil area starting at the cable inlet and move upwards to the tip of the housing. Avoid back and forth movements. • Ensure that all areas of the device come into contact with the wipe. • Allow the disinfectant to take effect for the minimum time according to IFU; e.g. 5 minutes for mikrozid® AF wipes. • Rinse thoroughly with moistened wipes soaked with clean, fresh tap water.

(5) Drying	
Accessories	• Soft, lint-free wipes, dry; e.g. B. Braun Melsungen AG, B. Braun Wipes ECO.
Steps	• Dry the device with dry wipes.

(6) High Level Disinfection (HLD)	
Accessories	• High-level disinfectant; required: Steris Corporation, Resert™ XL HLD High Level Disinfectant. • Dip tank, minimum size 12cm x 12cm x 25cm (length x width x depth) filled with High Level disinfectant. • Dip tank, minimum size 12cm x 12cm x 25cm (length x width x depth) filled with sterile, fresh tap-water. • Lab stand for mounting the device in HLD position (see Figure 19); e.g. ER Coil Support in “Coil HLD” setup.
Steps	• Attach coil to lab stand. • Immerse MR Probe in dip tank “HLD” to dedicated level as shown in Figure 19. • Expose the MR Probe to the disinfectant for 8 minutes within a temperature range of 20°C - 24°C. • Rinse MR Probe thoroughly by immersing MR Probe in dip tank “water”. • Expose the MR Probe to the sterile water rinse for 1 minute within a temperature range of 20°C - 24°C. • Detach coil from lab stand.

Assembly of ER Coil Support in "Coil HLD" setup:

- See Figure 18 for details on component arrangement.
- Use knurled screws (Part No. 1-3) to fixate individual components (Part No. 4-7).

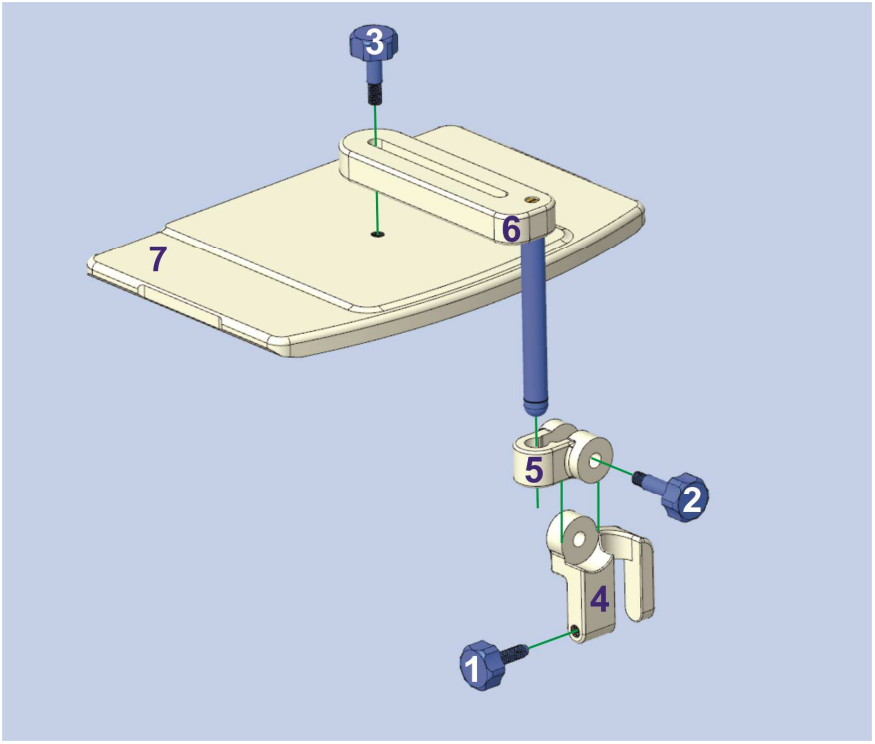

Figure 18: ER Coil Support assembly in "Coil HLD" setup.

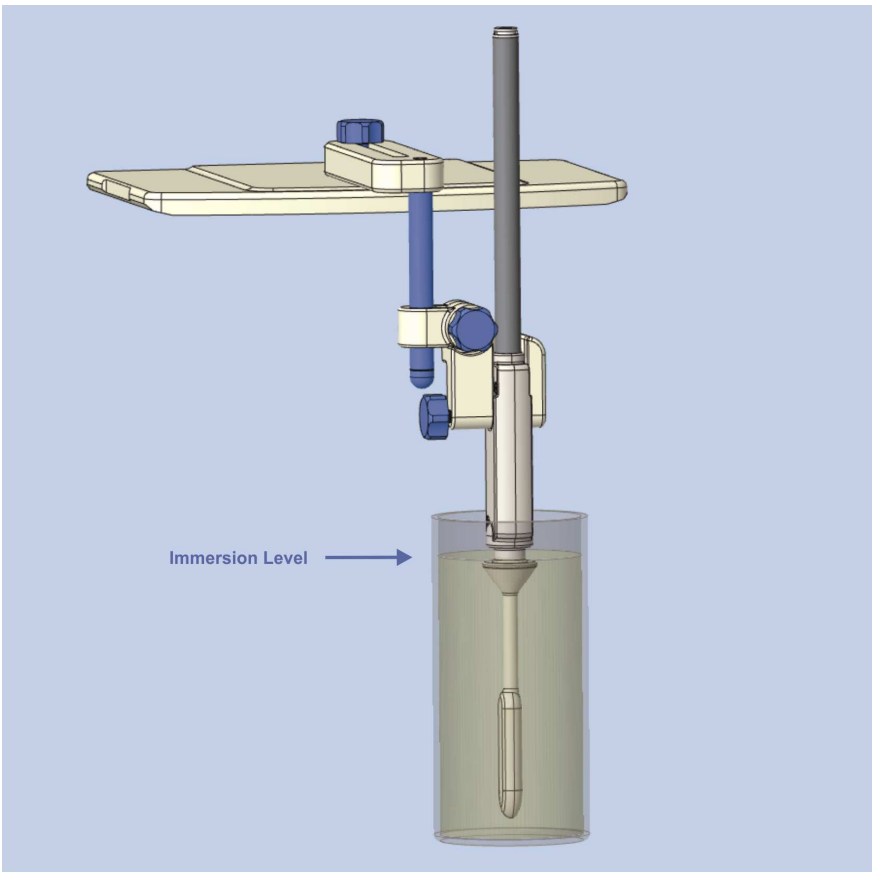

Figure 19: Probe Immersion Level.

(7) Drying	
Accessories	• Sterile, soft, lint-free, dry wipes; e.g. Schülke & Mayr GmbH, perform® sterile dry wipes.
Steps	• Dry the MR Probe with sterile dry wipes.

(8) Inspection	
Accessories	No special accessories required.
Steps	• Visually inspect for damages and other signs of material deterioration. • Ascertain that no end-of-use-life indicators are visible (see 8.1.1 Limitations and Restrictions in the Reprocessing). • Open cover of coil connector and ensure that no fluid has penetrated. • In case of any findings see chapter 3 General Safety Instructions.

(9) Packaging	
Accessories	• Appropriate cover for the High Level disinfected MR Probe of the Endorectal Coil; e.g. probe cover, transparent, germ-free inside, inscribable, minimum size 30cm x 10cm (length x width). • Appropriate clean container; e.g. MR compatible, size 50cm x 50cm x 10cm (length x width x height).

Steps	• Use clean probe cover to protect MR Probe from recontamination.
	• Label the probe cover; e.g. with:
	  ○ Device identification
	  ○ State of the MR Probe; e.g. cleaned, high level disinfected
	  ○ Packaging date
	  ○ Signature
	• Place the Endorectal Coil in clean container.
	• Label the container; e.g. with:
	  ○ Device identification
	  ○ State of the MR Probe, e.g. cleaned, low level disinfected
	  ○ Packaging date
	  ○ Signature

(10) Storage and Transportation	
Accessories	No special accessories required.
Steps	• Transport to defined storage location. • Store under specified conditions (see 10.1 Specifications).

9 Special Technical Instructions for Using the Device

9.1 Performance / Quality Assurance

We recommend regular verification of the device's proper function by performing the Coil Quality Assurance test.

Coil Quality Assurance tests should be run by a GE Service Representative or a third party service provider. To have a Coil Quality Assurance test run on a coil, please call your GE Service Representative or your third party service provider.

Please contact GE Healthcare at 800-582-2145 with any questions or concerns.

10 Appendix

10.1 Specifications

Device Name	1.5T Endorectal Coil	1.5T Endorectal Coil	3.0T Endorectal Coil
Device Number (RAPID)	O-HLE-015-01899	O-HLE-015-01946	O-HLE-030-01900
MR Nuclei	1H		
Operating Frequencies	63.9 MHz		127.7 MHz
MR System	GE 1.5 T MR systems		GE 3.0 T MR systems
Field Strength of MR System	1.5 T		3.0 T
RF Polarisation	linear		
Dimensions of Coil Housing	Length: 360 mm	Width: 44 mm	Height: 39 mm
Dimensions of drop-shaped tip	Length: 97 mm	Width: 25 mm	Height: 17 mm
Dimensions of Coil housings neck	Length: 75 mm	Diameter: 12 mm	
Resonator length (sensitive area)	80 mm		
Resonator width (sensitive area)	16,5 mm		
Length of Connecting Cable	130 cm		110 cm
Weight Endorectal Coil	1.0 kg		
Weight ER Coil Support	2.0 kg		
Maximum allowed Patient Weight	Only restricted by the maximum load allowed for the patient table		
Application Environment		Indoor use only	
Operating Conditions: Temperature Range		+15°C to +24°C / +59°F to +75.2°F	
Relative Humidity		30 % to 80 % RH	
Air Pressure		70 kPa - 107 kPa	
Transport & Storage Conditions: Temperature Range		-25°C to +60°C / -13°F to +140°F	
Relative Humidity		5 % to 95 % RH	

Table 10-1: Product Specifications

⚠CAUTION	
Situation	Device is not operated within the limits of specified Operating Conditions.
Hazard	Patient and/or user can be harmed and the device and/or other equipment can be damaged.
Prevention	☞ Ensure that ambient conditions of the examination room (Temperature, Relative Humidity, Air Pressure) are within limits of defined Operating Condition specifications.

10.2 Regulatory Information

Subject	Data
Manufacturer	RAPID Biomedical GmbH Kettelerstrasse 3-11 97222 Rimpar, Germany Tel.: +49 (0)9365-8826-0 Fax: +49 (0)9365-8826-99 info@rapidbiomed.de www.rapidbiomed.de
Distributed by	GE Healthcare, LLC 3200 N Grandview Boulevard Waukesha, WI 53188 USA
European Union	
Device Class	Class IIa - MDD Annex IX / MDR Annex VIII, Rule 5
Initial CE marking	2019
USA	
Device Class Device Code Premarket Submission No. Device Listing No. Manufacturer FEI Importer/Distributor FEI	Class II - 21 CFR 892.1000 MOS K191539 D371077 3005049692 2183553
Canada	
Device Class Device Licence No. Manufacturer ID Importer/Distributor ID	Class II - CMDR - SOR/98-282, Rule 2 103012 140730 117707
Turkey Importer Details/Türkiye İthalatçı Bilgileri:	
Importer/İthalatçı	GE Medical Systems Türkiye Ltd. Şti. Esentepe Mah. Harman Sok. No: 8 34394 Şişli-İstanbul Türkiye

Table 10-2: Regulatory Information

10.3 Labeling

If labels are missing or have become illegible, the device must not be operated. The labelling may only be renewed or amended by RAPID Biomedical or by a representative of RAPID Biomedical.

Item		Symbol	Device Marking/Remarks
Manufacturer			RAPID Biomedical GmbH Kettelerstr. 3-11 97222 Rimpar, Germany
Distributed by			GE Medical Systems, LLC
Device Trade Names	1.5 T – 01899	n/a	1.5T Endorectal Coil
	1.5 T – 01946		1.5T Endorectal Coil
	3.0 T – 01900		3.0T Endorectal Coil
	01955		ER Coil Support
Device Reference Number	1.5 T “P Port”	REF	O-HLE-015-01899
	1.5 T “A Port”		O-HLE-015-01946
	3.0 T		O-HLE-030-01900
	ER Coil Support		ZUB-01955
Device Serial Number		SN	n/a
Medical Device		MD	
Unique Device Identifier		UDI	
GE Healthcare part #	1.5 T – 01899	n/a	5772252-2
	1.5 T – 01946		5818916-2
	3.0 T – 01900		5772250-2
	01955		5772250-3
Device Revision		REV.	xx
Country and Date of Manufacture (YEAR-MONTH-DAY)		DE	YYYY-MM-DD
UDI Code (Sample)			(01)xxxxxxxxxxx (21)xxx
Device Type (T/R)			Receive-only Coil
CE Label (Conforms to the essential requirements of Council Directive 93/42/EEC concerning Medical Devices).		CE 0197	0197 = Number of the Notified Body
Type Examination Canada / US			

Item		Symbol	Device Marking/Remarks
Follow the Instructions for Use			
Consult the Instructions for Use for Additional Relevant Safety Issues.			
Application Part Type BF.			
Class II according to IEC 61140.			
Separate Collection of Waste Electrical and Electronic Equipment (WEEE Directive 2012/19/EU)			
Electronic Instructions for Use (eIFU)			
System side connectors allowed	1.5 T – 01899		
	1.5 T – 01946		
	3.0 T – 01900		
Notice on coil (sticker)		n/a	anterior
Notice on coil connector (sticker)		n/a	never leave unplugged inside the bore

Table 10-3: Device Labeling

10.4 Symbols Glossary

Symbol	Source	Ref. No.	Symbol Title & Definition
	ISO 7000	5957	For indoor use only. To identify electrical equipment designed primarily for indoor use.
	ISO 7000	0632	Temperature limit. To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used.
	ISO 7000	2620	Humidity limitation. To indicate the acceptable upper and lower limits of relative humidity for transport and storage.
	ISO 7000	2621	Atmospheric pressure limitation. To indicate the acceptable upper and lower limits of relative humidity for transport and storage.
	ISO 7000	3082	Manufacturer. To identify the manufacturer of a product.
	ISO 7000	2497	Date of manufacture. The date can be a year, year and month, or year, month, day. The date shall be placed adjacent to the symbol. The date may for example be given as follows: 1996-06-12.
	IEC 60417	6049	Country of manufacture. To identify the country of manufacture of products. In the application of this symbol, the "CC" shall be replaced by either the two letter country code or the three letter country code defined in ISO 3166-1 (for Germany “DE”). Name of manufacturer and date of manufacture may be added adjacent to this symbol.
	ISO 7000	2493	Catlogue number. To identify the manufacturer's catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol
	ISO 7000	2498	Serial number. To identify the manufacturer's serial number, for example on a medical device or its packaging. The serial number shall be placed adjacent to the symbol.
	IEC 60417	6191	RF coil, transmit. To identify the radio frequency (RF) coil for transmit only.
	IEC 60417	6192	RF coil, transmit and receive. To identify the radio frequency (RF) coil for both transmit and receive.
	IEC 60417	6193	RF coil, receive. To identify the radio frequency (RF) coil for receive only.
	ISO 7010	M002	Refer to instruction manual/booklet. To signify that the instruction manual/booklet must be read.
	ISO 7000	0434A	Caution. To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	IEC 60417	5840	Type B applied part. To identify a type B applied part complying with IEC 60601-1.
	IEC 60417	5333	Type BF applied part. To identify a type BF applied part complying with IEC 60601-1.
	IEC 60417	5172	Class II equipment. To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.

Symbol	Source	Ref. No.	Symbol Title & Definition
	Directive 2002/96/EC	Annex IV	Symbol for the marking of electrical and electronic equipment. The symbol indicating separate collection for electrical and electronic equipment consists of the crossed-out wheeled bin. The symbol must be printed visibly, legibly and indelibly.
	SJ/T 11364-2014	Chapter 5	People's Republic of China Electronic Standard: Marking and labeling standard for the environmental protection characteristic of a product, namely that the product does not contain any hazardous substances.
	ISO 7000	1135	General symbol for recovery/recyclable. To indicate that the marked item or its material is part of a recovery or recycling process.
	ISO 7000	0621	Fragile, handle with care. To indicate that the contents of the transport package are fragile and the package shall be handled with care.
	ISO 7000	0623	This way up. To indicate correct upright position of the transport package.
	ISO 7000	0626	Keep away from rain. To indicate that the transport package shall be kept away from rain and in dry conditions.
	Directive 93/42/EEC	Annex XII	CE marking of Conformity for Medical Devices Class I
	Regulation (EU) 2017/745	Annex V	
	Directive 93/42/EEC	Annex XII	CE marking of Conformity with the number of the Notified Body to the right of the symbol for Medical Devices ≠ Class I
	Regulation (EU) 2017/745	Annex V	
	ISO 15223-1	5.7.7	Medical Device. Indicates the item is a medical device.
	ISO 15223-1	5.7.10	Unique Device Identifier. Indicates a carrier that contains Unique Device Identifier information.

Table 10-4: Symbols Glossary

10.5 List of Acronyms

Acronym	Explanation
AGB	Standard Terms and Conditions
C	Carbon
CD	Compact Disk
CFR	Code of Federal Regulations (USA)
CMDR	Canadian Medical Devices Regulations
EC	European Community
ECG	Electrocardiogram
EEC	European Economic Community
eIFU	Electronic Instructions for Use
EU	European Union
FID	Free Induction Decay
IEC	International Electrotechnical Commission
MDD	Council Directive 93/42/EEC
MDR	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
MR	Magnetic Resonance
Na	Sodium
O-HLE-015	Surface coil; 1H; for field strength 1.5 T
O-HLE-030	Surface coil; 1H; for field strength 3.0 T
P	Phosphorus
PN	Part Number
QA	Quality Assurance
REF	Reference Number (Part Number)
RF	Radio Frequency
RoHS	Restriction of Hazardous Substances
ROI	Region of Interest
Rx	Receive Function
SAR	Specific Absorption Rate
SN	Serial Number
SNR	Signal-to-Noise-Ratio
Tx/Rx	Transmit/Receive
Tx	Transmit Function
UDI	Unique Device Identification
WEEE	Waste of Electronical and Electrical Equipment

Table 10-5: List of Acronyms