Instructions for Use

for

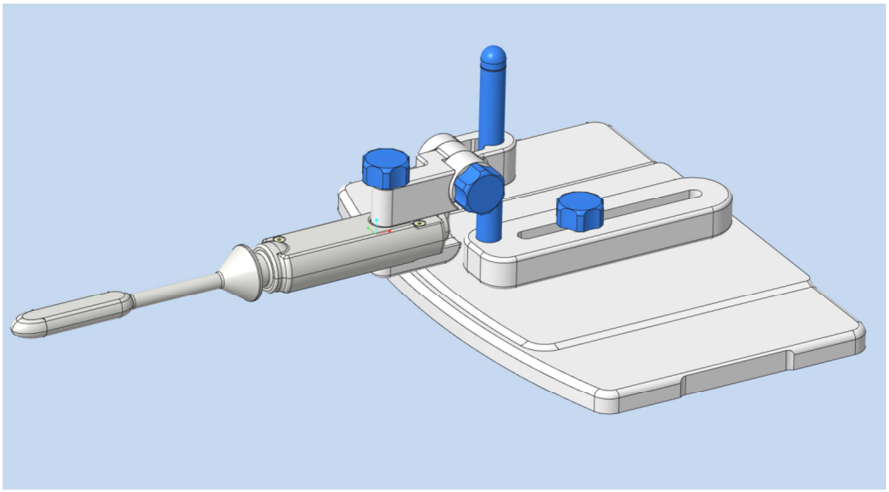
Endorectal Coil

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



CE 0197

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Document Edition: 2.0

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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 press. 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 at RAPID Biomedical free of charge via email (see email address on page 2). Unless ordered differently, always the latest version will 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 on 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	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 9.1 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 9.3 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 9.3 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. ☞ If the device is defective, it must not be used.

Checking the operational reliability of the device includes checking the housing, checking the connections (cables, plugs) and checking all labels (9.3 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 object, proper function of the device must be verified and documented by a test on an appropriate MR phantom (8.1 Performance / Quality Assurance).

⚠CAUTION	
Situation	Disturbed signal detection by low SNR or image artefacts.
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.

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 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.

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	Damaged or malfunctional device.
Hazard	Patient and/or user can be harmed, device and/or other equipment can be damaged.
Prevention	☞ The device must not be used in the event of damage and/or malfunction. Notify your local service representative immediately.

⚠CAUTION	
Situation	Unauthorized repair of a damaged or malfunctioning 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 minimum 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 the lock the ER Coil Support in the desired alignment.

5.1 Indications for Use, Contraindications, Environment

Indications for Use	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

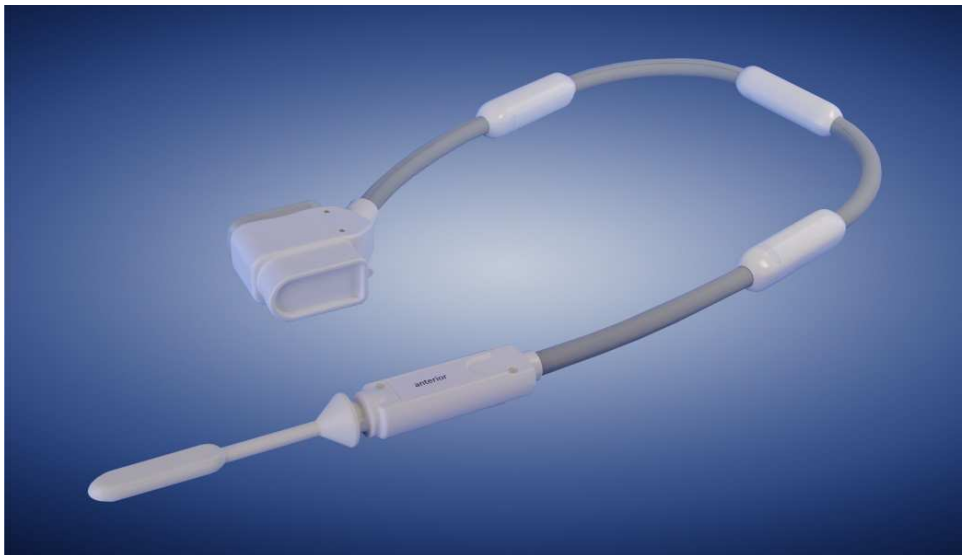

Figure 1: 1.5T Endorectal Coil - O-HLE-015-01899 (“P Port”)

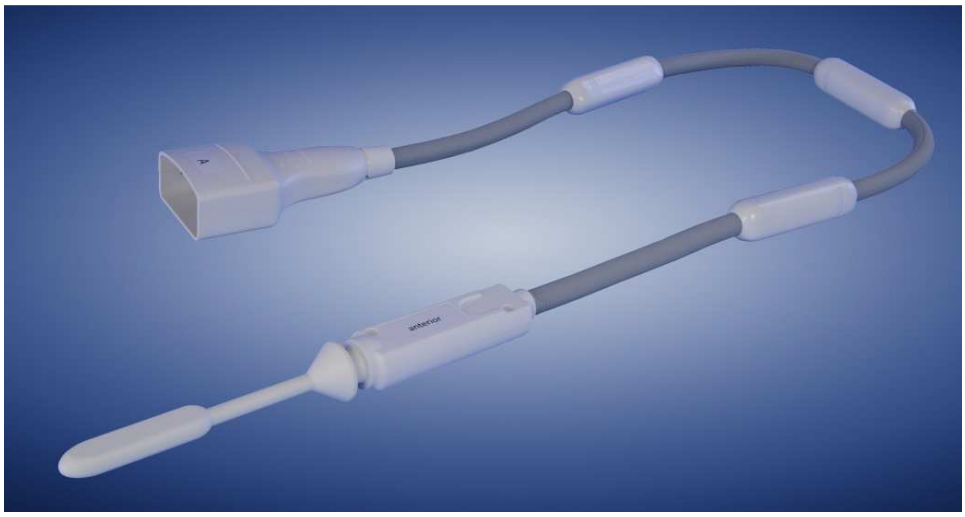

Figure 2: 1.5T Endorectal Coil - O-HLE-015-01946 (“A Port”)

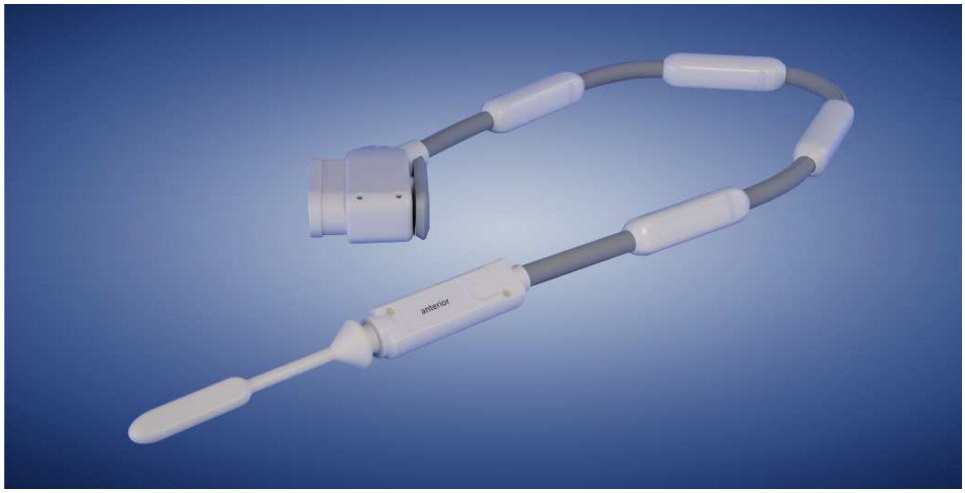

Figure 3: 3.0T Endorectal Coil - O-HLE-030-01900

5.3.2 ER Coil Support for all models

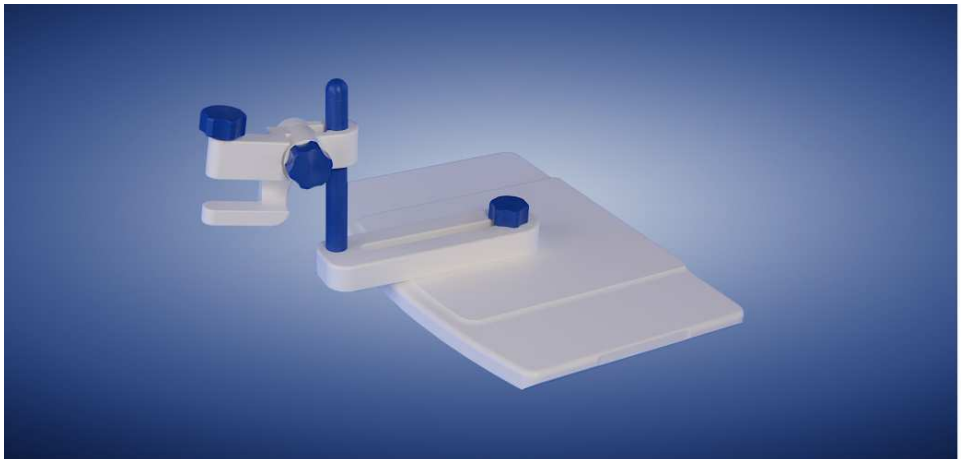

Figure 4: ER Coil Support - ZUB-01955

6 Initial Operation and Recommissioning

6.1 General Instructions

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

NOTICE	
Situation	Device is operated before acclimatised.
Hazard	Damage of medical device by condensed water.
Prevention	☞ Installation and initial operation of the device may only take place after a reasonable period of acclimatisation. Store the unpackaged device in the environment intended for later operation for 24 hours before operation. ☞ See Attachment 9.1 Specifications for the permissible environment for operating the device.

6.2 SAR Monitoring

The device does neither feature separate monitoring of the specific absorption rate (patient protection) nor maximum applied rms RF power (component protection, see 9.1 Specifications). This is done by the MR System by monitoring and limiting maximum rms RF power during scans.

To ensure that both, SAR and maximum applied rms RF power control do work properly, the coil is encoded and recognized by the MR System when plugged. When plugging the coil, the MR System recognizes this incident and sets related parameters given in the corresponding configuration file. By this mechanism, patient and coil are kept safe from being harmed/ destroyed.

⚠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. Do not perform any examination with a disconnected device.

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 be (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 constrictions (complications). ○ Patients obstructive masses within the rectum (complications).
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): ○ On lubricant (e.g. lidocaine). ○ On 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 lies within the responsibility of the medical practitioner.

Recommendation

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

- Ultracover Latex 40 x 300 mm by Ecolab; #86694
- Sterile Latex Cover 3.5 x 20 cm by Protek Medical; #3230
- NeoGuard 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 at 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

ⓘ	The Endorectal Coil supplied by Rapid Biomedical is not high-level disinfected and not sterile at the point of delivery. For high-level disinfection of the device follow instructions of chapter 7.8 Cleaning and Disinfection.

⚠CAUTION	
Situation	Device is inadequately cleaned and disinfected.
Hazard	Required level of disinfection not achieved resulting in danger of infection.
Prevention	☞ The device has to be high-level disinfected before and after each use including the initial use. ☞ The device is only to be used when covered by two condoms lying upon each other.

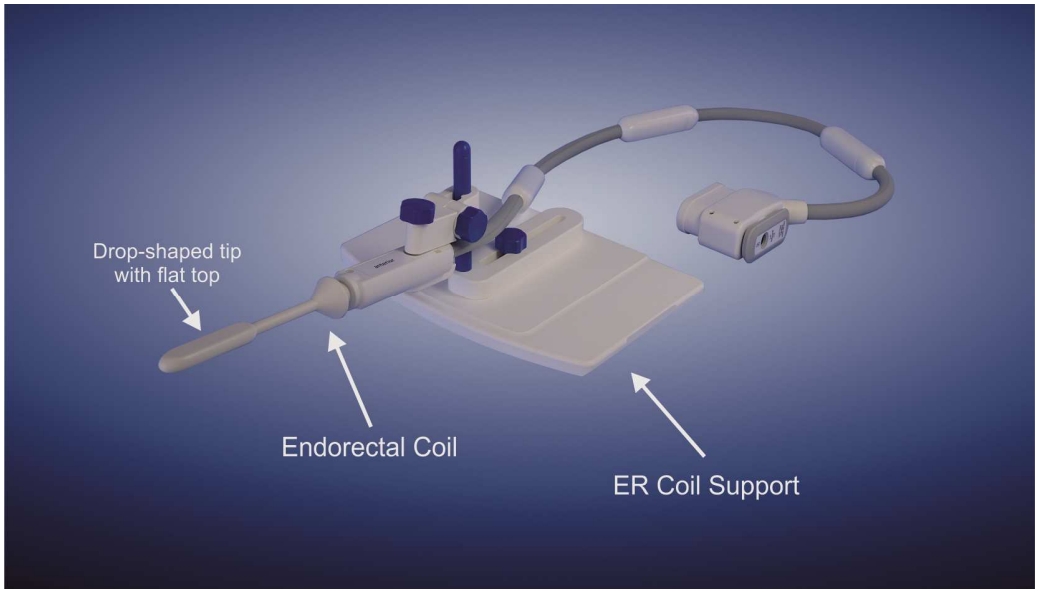

Figure 5: Endorectal Coil with ER Coil Support

The Endorectal Coil has to be prepared for MR examination according to the picture series Figure 6 to Figure 9.

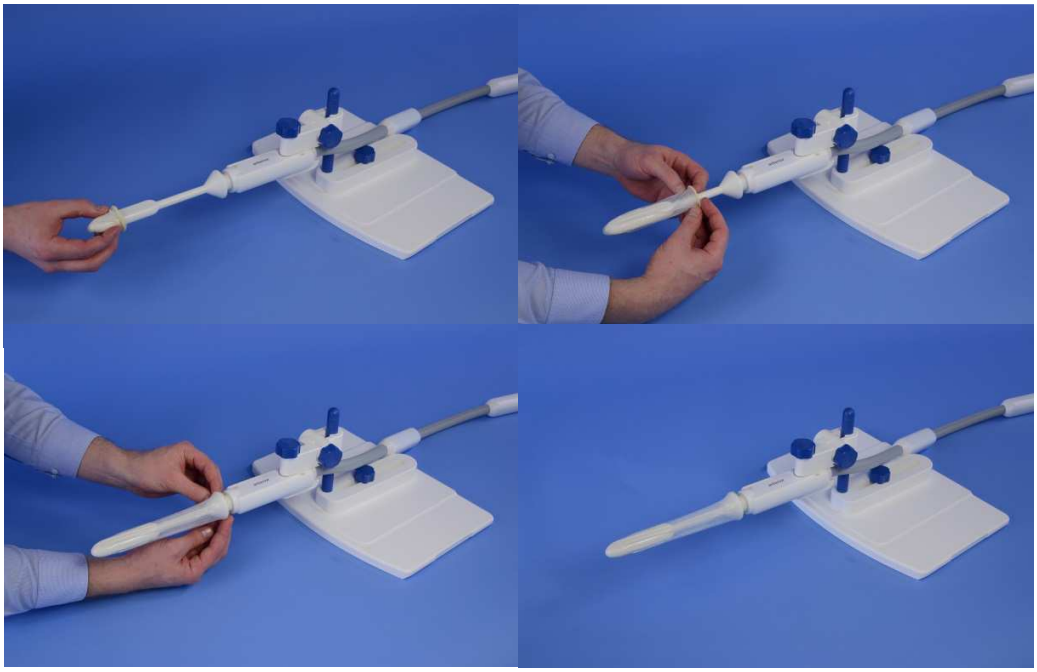

Figure 6: Cover the drop-shaped tip of the Endorectal Coil with a double layer of condoms.

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

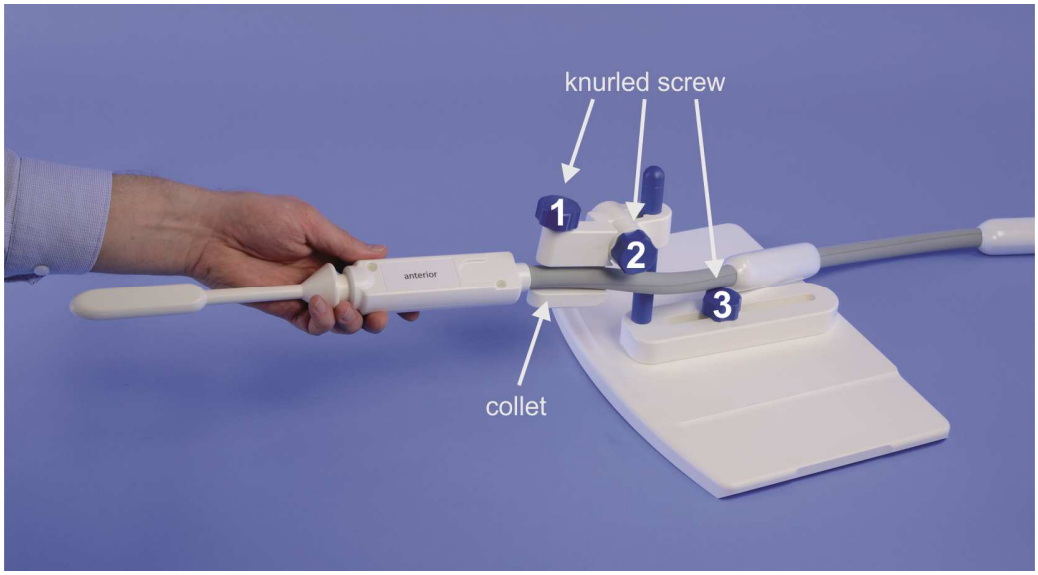

Figure 7: Prepare the ER Coil Support for mounting the Endorectal Coil by loosening knurled screw #1.

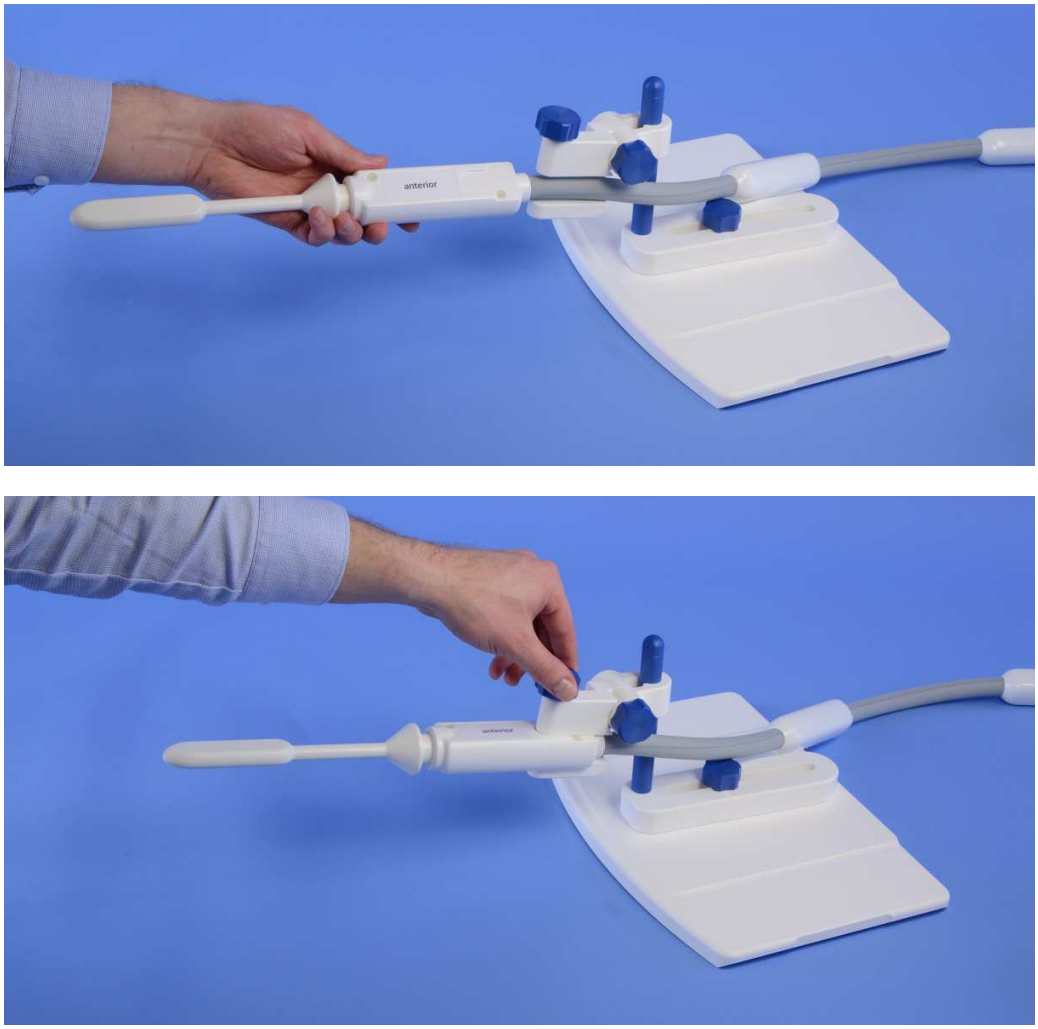

Figure 8: Insert the Endorectal Coil into the collet with the label “anterior” facing upwards. Fixate it with knurled screw #1.

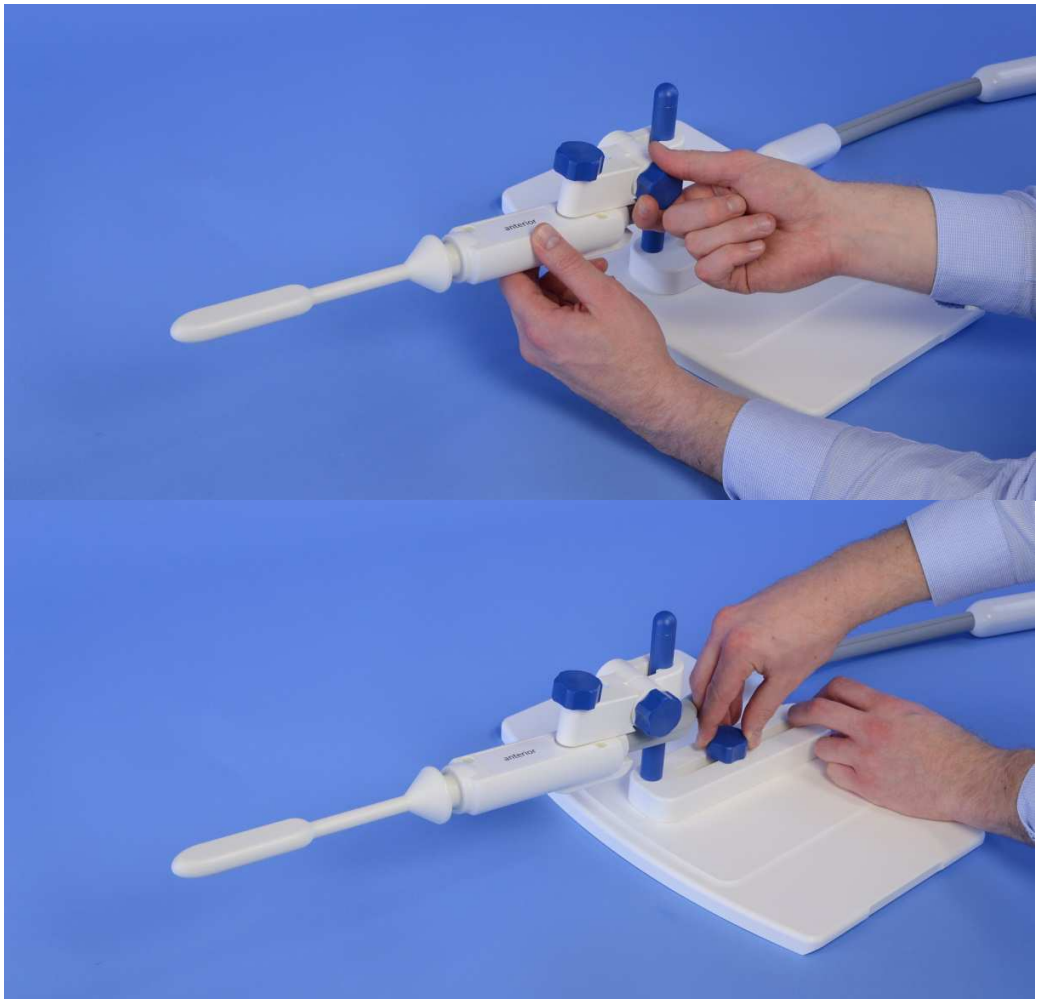

Figure 9: Each endorectal MR examination requires an individual coil positioning. The ER Coil Support can be adapted accordingly using knurled screws #2 and #3.

⚠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 recommendedTake care 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

A potential workflow for positioning of patient and coil is described below. Two persons are recommended for convenient patient and device handling. This list does not necessarily contain all measures as derived from e.g. a contraindication analysis as being conducted for each patient separately. Such measures will have to be integrated into this exemplary workflow.

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.
  - It is made sure that the rectum is empty and free of obstruction.
  - It is checked 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. ☞ Instructions for Use of lubricants have to be observed. ☞ Selection of lubricants lies within the responsibility of the medical practitioner.

- 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 Fig. 10).
  - Until 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 two condoms lying upon each other.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
  - It is taken care 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.

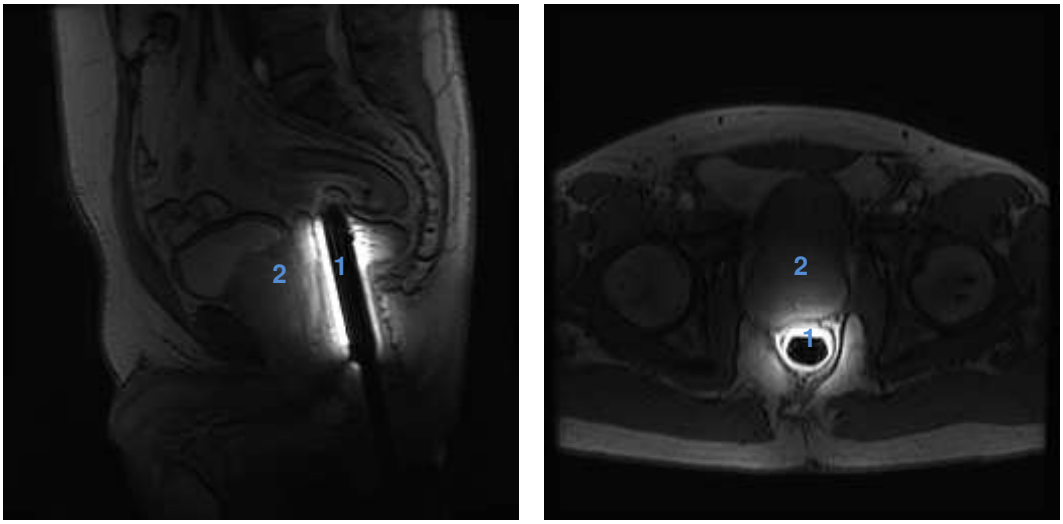

Figure 10: Localizer in vivo images in sagittal (left) and axial orientation (right) windowed / leveled to confirm the proper positioning of the coil. – Left: Sagittal view is useful to confirm that the prostate is centered with respect to coil's signal coverage. Right: Transversal view is useful to confirm the flat top (1) is facing towards the prostate gland (2) and aligned properly.

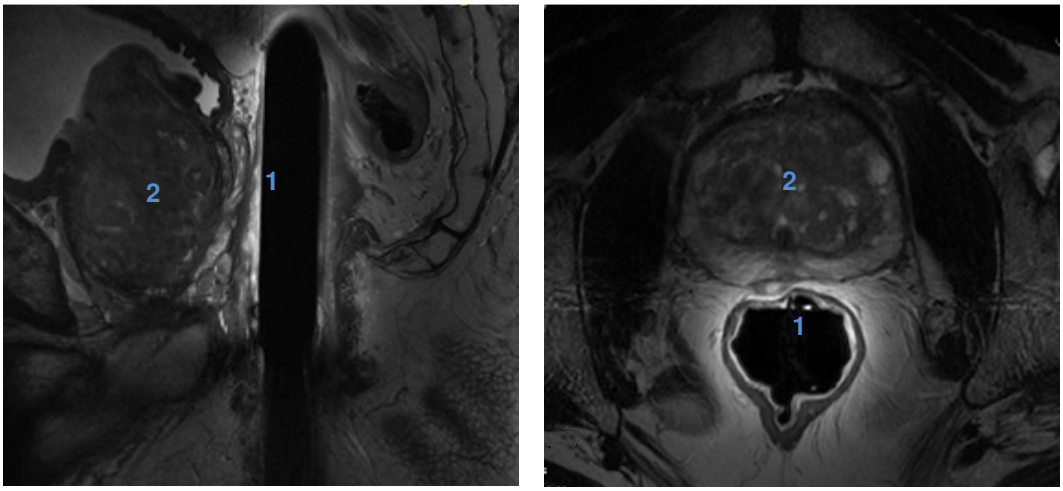

Figure 11: T2 in vivo images in sagittal (left) and transversal orientation (right) showing a well-positioned Endorectal Coil with a centered prostate gland (2) and the flat top (1) facing towards the prostate.

- 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 artefacts 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 artefacts. Lubricant image artefacts 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 Fig. 12).

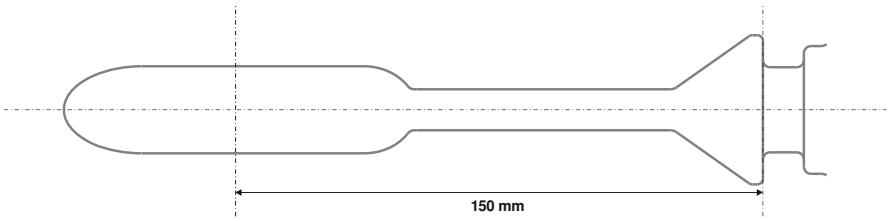

Figure 12: Distance between the center of the drop-shaped tip towards the end of the cone ring for condom fixation.

- 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.
Please 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 in socket 1.

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

The coil will be recognized and displayed on the MR system after connection.

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.

⚠CAUTION	
Situation	Squeeze patient when moving into magnet bore.
Hazard	Patient can be harmed, device and/or other equipment can be damaged.
Prevention	☞ Move, position and fix parts of coil with care.Move patient table with care at low speed.

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 10.
  - 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 reasonable number of NEX.

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.
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. Move it directly to a dedicated place for immediate reprocessing.
4. Remove the cloth.
   a. Properly dispose the cloth.
5. Remove the Endorectal Coil from the patient carefully and move it directly to a dedicated place for immediate reprocessing.
6. Help the patient of the patient table.
7. Reprocess the device.
   a. Remove the two condoms, one at a time and properly dispose the condoms.
   b. Disassemble the ER Coil Support according to Figure 13.
   c. Follow the instructions of chapter 7.8 Cleaning and Disinfection.

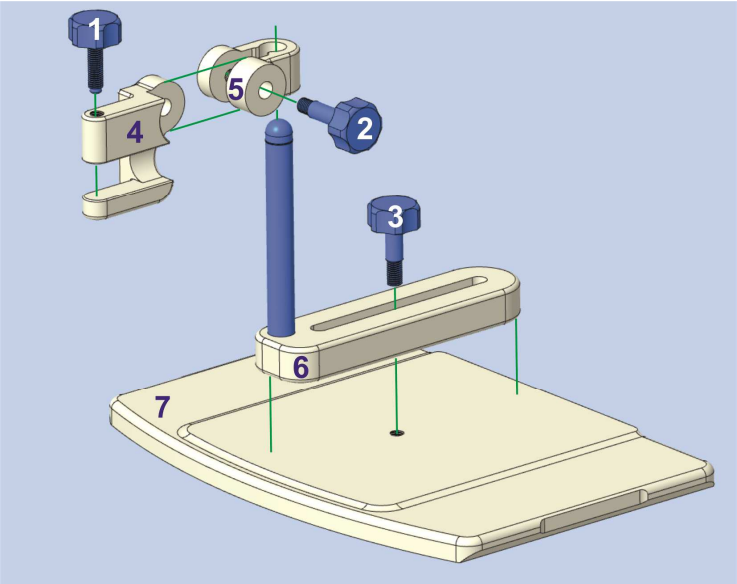

Figure 13: Disassembled ER Coil Support.

No.	Description	Quantity	Illustration
1	Knurled screw (pre-amp housing)	1	
2	Knurled screw (pivot)	1	
3	Knurled screw (horizontal adjustment)	1	
4	Pivot joint	1	
5	Joint height adjustment	1	
6	Horizontal bar with pillar	1	
7	Base plate	1	

Table 7-1: ER Coil Support Components

7.8 Cleaning and Disinfection

	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. The device may only be cleaned and disinfected by authorized personnel. The adequate cleaning and disinfection of the medical device is the responsibility of the user.

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.

⚠CAUTION	
Situation	Wrong cleaning methods.
Hazard	Defective medical device.
Prevention	☞ Use only commercially available mild household cleaning detergents, diluted in water following the guidelines of the manufacturer. ☞ Use a soft damp cloth. The device must not be immersed into liquids. Make sure no liquids can infiltrate. ☞ Do not use any rough or abrasive cleansing agents, which might damage the painting or the housing material.

Disinfection

Disinfection is the inactivation of disease producing microorganisms.

This device is classified as a semi-critical medical product with regard to disinfection. Therefore a high-level disinfection is required.

The Endorectal Coil by RAPID Biomedical is cleaned but not high-level disinfected and not sterile at the point of delivery.

The Endorectal Coil has to be high-level disinfected before and after each use including the first use.

	**Recommendation** RAPID Biomedical recommends the use of a high-level disinfectant with a scope of bactericide (including Mycobacterium), fungicide and virucide. (e.g. Meliseptol® HBV tissues by B Braun, Meliseptol® rapid by B Braun or disinfectants listed by “Verbund für angewandte Hygiene e.V. (VAH)”, “Robert Koch Institut (RKI)” or “Centers for Disease Control and Prevention (CDC)” suitable for this application).

⚠CAUTION	
Situation	Non-recommended disinfectant and/or inadequate cleaning and disinfection procedures.
Hazard	Required level of disinfection not achieved, infection.
Prevention	☞ The scope of the disinfectant has to be bactericide (including Mycobacterium), fungicide and virucide.

⚠CAUTION	
Situation	Usage of an inadequate disinfection technique.
Hazard	Damage of medical device.
Prevention	☞ The disinfectant has to be an alcohol–based solution. ☞ Do not use any aldehyde- or phenol-based disinfectant solutions. ☞ The device must not be sterilized.

8 Special Technical Instructions for Using the Device

8.1 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.

9 Appendix

9.1 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 Relative Humidity Air Pressure		+15°C to +24°C / +59°F to +75.2°F	
		30 % to 80 % RH	
		70 kPa - 107 kPa	
Transport & Storage Conditions: Temperature Range Relative Humidity		-25°C to +60°C / -13°F to +140°F	
		5 % to 95 % RH	

Table 9-1: 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.

9.2 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
UMDNS Code Universal Medical Device Nomenclature System	17-542
Commercial Regulatory Authority	DE/CA59/5752/2016-R/Hd
European Union	
Device Class	**Class IIa** - according to MDD Annex IX, Chapter III, Clause 3, Paragraph 3.2, Rule 5
USA	
Device Class Device Code Premarket Submission No. Device Listing No. Manufacturer FEI Importer/Distributor FEI	**Class II** - according to 21 CFR 892.1000 **MOS** pending pending 3005049692 2183553
Canada	
Device Class Device Licence No. Manufacturer ID Importer/Distributor ID	**Class II** - according to CMDR - SOR/98-282, Schedule 1, Section 6, Part 1, Rules 2 and 12 pending 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 9-2: Regulatory Information

9.3 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
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
Date of Manufacture (YEAR-MONTH-DAY)			YYYY-MM-DD
UDI Code (Sample)			(01)xxxxxxxxxxxx (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			**pending**
Follow the Instructions for Use			

Item		Symbol	Device Marking/Remarks
Consult the Instructions for Use for Additional Relevant Safety Issues.			
Application Part Type BF.			
Class II according to IEC 61140.			
Separate Collection of **W**aste **E**lectrical and **E**lectronic **E**quipment (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 9-3: Device Labeling

9.4 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.
	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: The logo is demonstrating 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.
CE	Directive 93/42/EEC	Annex XII	CE marking of Conformity for Medical Devices Class **I**
CE 0197	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**

Table 9-4: Symbols Glossary

9.5 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	Medical Device Directive (EC)
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 9-5: List of Acronyms