Urgent Safety Notice

Type of Action: Information for User

with respect to

Endorectal Coils manufactured by RAPID Biomedical GmbH

FSCA Identifier: CAPA0024

2019-08-16

Sender:

RAPID Biomedical GmbH
Kettelerstraße 3-11
97222 Rimpar
Germany

Recipient:

To all Users of Endorectal Coils specified as follows

Identification of affected Medical Devices

Endorectal Coils for utilization in MR

Trade Name	REF Number	revision
13C-1H endorectal surface receive coil	O-XLE-HLE-030-01924	V01
13C-1H endorectal surface receive coil	O-XLE-HLE-030-01947	V01
1.5T Endorectal Coil	O-HLE-015-01899_A	V00
3.0T Endorectal Coil	O-HLE-030-01900_A	V00
31P-1H endorectal surface transmit coil	O-XL-HLE-030-01752	V01

Description of Issue and Source as Analyzed

The operator manual of the endorectal coils listed above requires reprocessing of a semicritical medical device without special requirements . Instructions of reprocessing are not given according to the standards (state of the art). Furthermore, the effectiveness of the procedure is not validated. Taking these facts into account, the product risk assessment was updated and shows that the product risk is still acceptable but not as low as possible. For a minimal product risk it is necessary that the user is utilizing condoms which lower the probability of contamination of the product by far. When not reprocessed appropriately, the risk of infection of the patient still remains, as well as the risk of infection of the user himself even though with a lower probability.

RAPID Biomedical has no information about any incident with regards to this situation.

Which actions are to be taken by the recipient of this notice?

The user has to obey the following rules when using one of the endorectal coils listed above.

- The measures described in the instructions for use for avoiding a contamination of the medical device are to be followed strictly.
- When judging whether the usage of the endorectal coil is medically acceptable the remaining risk has to be taken into account.
- Besides a thoroughly cleaning after each usage (according to instructions for use) a disinfection has to be performed. This disinfection process is not adequately described in the instructions for use and should, therefore, be evaluated by specialists of your institution.

In case there is any lack in clarity the user should contact RAPID Biomedical GmbH. The attending physician of patients which have already been examined by using one of the endorectal coils has to get access to this information. RAPID Biomedical GmbH is planning to provide an update of the reprocessing description by the end of year 2019.

Forwarding this Information

Please make sure within your organisation that all users of the medical devices listed above and all other persons to be involved get notice of this "Urgent Safety Information". In case you have forwarded one of these medical devices to a third party, please forward a copy of this information and inform the contact given below.

Please keep this notice until this measure is finished.

RAPID Biomedical GmbH confirms that the responsible governmental authority has been informed.

Contact:

RAPID Biomedical GmbH
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