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Your letter dated	Editor	Reiner Thiem	Direct contact	+49 (0) 92 52 / 3 59-2782
Your ref.	Our ref.	thi	Date	

Urgent Safety information

Type of action: Supplementary information on the application of RAUMEDIC NEUROVENT precision pressure catheters in magnetic resonance tomography (MRT) devices

Identification of affected medical products: see Appendix 1

Date: 18 January 2013

Reference number: F 2013_01_18

Recipients: Users of the medical products, distributors of the medical products

Dear Sir/Madam

NEUROVENT precision pressure catheter sales brochures contain a reference regarding MRT compatibility. During recent testing without patient participation it was established that the impact of electro-magnetic radiation on the catheter in certain worst-case configurations could induce isolated temperature increases of more than 10°C, which could subsequently cause tissue damage.

To ensure the continued safe use of NEUROVENT precision pressure catheters with MRT devices, please find enclosed the subsequently updated information as compiled in Appendix 2. This information is based on supplementary analysis in accordance with the pertinent ASTM standards. Safe application of the products can be effected by adhering to the directions specified in Appendix 2.

Note:

- Care should be taken to ensure that the RAUMEDIC accessory, RAUMEDIC PTO cable (Art. 095624-001) and RAUMEDIC ICP-TEMP cable (Art. 094328-001) used in the respective catheter application is **not disconnected** prior to or during the MRT examination!
- As described above, in the course of in vitro examinations during MRT 3 T in worst-case conditions, heating effects were established that could cause tissue damage. To safely prevent any such potential heating, the relevant cable must remain connected to the catheter!
- The cable should be placed in rolled-up condition (approx. 20-cm coils, which equates to approx. 3.5 winds) at the head end of the patient!

Forwarding of the safety information described here:

Please ensure that all users of the aforementioned products and any other persons who should be informed are notified of this urgent safety information. If you have passed on any of the affected products to third parties, please also forward this information to the parties in question.

Contact person:

Should you have any questions regarding this urgent safety information, please contact Reiner Thiem, Head of Regulatory Affairs, RAUMEDIC AG, either by telephone on +49 (0)9252 359 2782, by fax on +49 (0)9252 359 51 2782 or via email to Reiner.Thiem@RAUMEDIC.com

A copy of this urgent safety information has also been sent to the responsible supervisory authority in order to inform them of the action undertaken.

Thank you for your cooperation. RAUMEDIC AG always strives to provide its customers with high-quality products and services. Please accept our sincere apologies for any inconvenience that may have been caused in connection with this matter.

Yours faithfully
RAUMEDIC AG

Reiner Thiem
Head of Regulatory Affairs

Appendix 1: List of affected products
Appendix 2: User information regarding the application of RAUMEDIC NEUROVENT precision pressure catheters during 1.5 and 3 T MRT
Appendix 3: Customer response form