

Commercial name of the affected product:

Telemetric pressure catheter 096504-001 NEUROVENT - P- tel

Identifier: FSN 001/21
Type of action: Safety Information
Date: 2021-06-10

Sender: RAUMEDIC AG
Hermann-Staudinger-Straße 2
95233 Hembrechts
Germany

Recipients:

Clinical end users of the medical device mentioned hereafter.

Details on affected devices:

Serial numbers from serial number SN T10518 until SN T11706.

Description of the problem including root cause:

Based on several hundred implantations, RAUMEDIC has uncovered a 3.1% likelihood the beforementioned catheter generation may suffer from unidirectional negative drift. Typically, such drift events appear to be irreversible and not congruent with other typically assessed clinical parameters plus were typically uncovered in later measurements or even control measurements before the scheduled explant procedure.

Root cause analysis has been performed and returned products were thoroughly tested. Such tests revealed a risk of moisture absorption by the product. In the beforementioned number of cases condensed moisture could be identified on the electronic circuit board. Whilst the incompatibility of moisture and electronic circuits needs no further explanation, only components with analogue functionality were concerned. In contrast to digital elements analogue circuit components steadily deteriorate prior to their final failure what resulted in the drift as described.

To date, there were no reports of any serious deterioration of any patient's health status or worse. However, and very much based on the product's indication and appropriateness also for acute trauma, SAH or any other scenario suggesting an unconscious or otherwise compromised patient, correct ICP assessment can acquire more relevance due to the lack of other feedback as could be provided by an awake and conscious patient typical for the mainly pursued indication of a manifest Hydrocephalus.

To prevent even the slightest chance of creating an unfavorable user experience or patient complication, RAUMEDIC decided to suggest the return of any sterile and shelved implants remaining and built to the current specs. RAUMEDIC also warrants particular care should be applied to ICP measurements performed with any currently implanted device.

Advise on action to be taken by the user:

1. Sterile product remaining on stock:

Any NEUROVENT-P-tel product in the serial number range SN T10518 – T11706 and remaining at the customer's premises should be identified, quarantined and returned to RAUMEDIC for a full refund of the purchase price.

2. Product currently implanted on or after 2021-02-27:

Any NEUROVENT-P-tel product in the serial number range SN T10518 – T11706 and currently implanted and residing within its 90 days approved clinical use should be considered with care. Its ICP measurements should be assessed and considered only when in line with other clinical findings and the patient's response. Customers should consider challenging the product's correct response via their clinical routines as appropriate and adequate.

If such functionality tests cannot be recommended or performed without risk and particularly in unconscious or otherwise compromised patients as may occur in a trauma population, SAH or any other complication developing after the implantation, the product's reading should not solely be used to guide therapy due to the reported 3.1% likelihood of false or false static readings.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Contact reference persons:

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Reachability: Monday through Friday 8am to 5pm (GMT+1)

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

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Reiner Thiem
Head of Regulatory Affairs