ENGINEERING STROKE SOLUTIONS

Acandis GmbH & Co. KG, Theodor-Fahrner-Straße 6, D-75177 Pforzheim

Acandis GmbH & Co. KG
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To affected distributors / clinical centers

April 10th, 2017

Recall of medical device:
Neurospeed Balloncatheter Article-Number 01-000601;
Batch-/Lot-Nr. 139914

Dear Sir/Madam,

Acandis GmbH & Co.KG is initiating a voluntary medical device recall of the aforementioned batch and article.

Cause for recall:

Two (2) out of 34 catheter systems of the aforementioned batch were claimed defective for a leakage on the Luerhub. Further investigation showed that the access port for application of the adhesive sealing on the Luerhub could be identified as the location for the leakage in both cases. The adhesive sealing is not sufficient on one side which causes the proximal end not to be filled correctly. The leakage only affects the lumen of the guide wire. The lumen for the balloon is not affected.
This failure is not design related but can be caused by production induced manufacturing deviations. A thorough analysis was conducted by our supplier (BAVARIA MEDIZIN TECHNOLOGIE GmbH) of the balloon catheter. The problem was bracketed to the aforementioned batch by the supplier.

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Potential hazard:

According to the product's instruction for use, the balloon catheter is to be flushed with saline solution mixed with contrast medium. In the case of both claimed system, the leakage was identified during this pre-flushing step.
In general, saline solution mixed with contrast medium may leak from the Luerhub.
The Luerhub is located outside of the patient at all times.

There is no hazard for the patient due to this potential leakage.

Immediate actions:

1. Please return the aforementioned batch at your earlies convenience.
2. Confirm via the attached form that you have received this letter. Please return this filled and signed form via fax or email to the Acandis GmbH & Co.KG.

We sincerely apologize for any inconvenience this recall may cause for you and greatly appreciate your support. Should you have any additional questions, please do not hesitate to contact your contact partner within our organization.

Pforzheim, 10th April 2017

[redacted]

[redacted]

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Pers. haftende Gesellschafterin:
Acandis Verwaltungs-GmbH
HRB 111281, Amtsgericht Mannheim
Sitz: Pforzheim
Geschäftsführer: Kirsi Schüssler,
Dr. Andreas Schüssler

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Please check applicable statement:

☐ We have located the affected article of that batch in our storage; the number of returned systems is noted below. We kept a copy of this letter for our documentation.

☐ System already used. We have used the affected article of that batch without any issues. The amount of returned systems is "ZERO". We kept a copy of this letter for our documentation.

RETRUNED ARTICLES OF THIS BATCH (incl. number) and/or comments:

_____

Clinical center / Distrubutor:_____

Name / Title:_____

Telefonnumber:_____

Date and Signature:_____

Please return this form via any of the listed options below.

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Pers. haftende Gesellschafterin:
Acandis Verwaltungs-GmbH
HRB 111281, Amtsgericht Mannheim
Sitz: Pforzheim
Geschäftsführer: Kirsi Schüssler,
Dr. Andreas Schüssler