



Spiggle & Theis Medizintechnik GmbH, Burghof 14, D-51491 Overath

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July 17th, 2014

Field Safety Notice

regarding
PTFE Ventilation Tubes of Spiggle & Theis Medizintechnik GmbH

Article-No. (REF)	Batch-No. (LOT)
104100	201308121240, 201309030100, 201311150080, A01306171000, 201311150220
104100F	201308120240
104115	201306171500, 201308081490, 201309030350, B01401281500, 201311150150, 201308120600, 201308120990, 201311150060, 201311190160, A01311150080, 201311150120, 201304421000
104115F	201308121500, 201311190020, 201311190120, 201312090900, 201312092100, 201311190130
104125	201306171000, 201311150230, 201311150430, 201308120490, 201311150110, A01311150230, 201311150390, 201308260380, A01309030100
104125F	201308120140, 201311190040
104150	201308290130, 201308260001
104200	201306140350, 201311150020, 201311150030, 201308290090
104210	201312030700, 201311150360, A01311150060, 201307120300, 201308120540, A01312030700, B01311150060
104311	201308262360, 201311193740, 201308121700

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VR-Bank Bergisch Gladbach
BLZ: 370 626 00
Kto.-Nr.: 1500 339 014
IBAN: DE58 3706 2600 1500 3390 14
BIC: GENODE33PAF

Frankfurter Sparkasse 1822

BLZ: 500 502 01
Kto.-Nr.: 306 217
IBAN: DE57 5005 0201 0000 3062 17
BIC: HELADEF1822

Kreissparkasse Köln

BLZ: 370 502 99
Kto.-Nr.: 325 550 617
IBAN: DE88 3705 0299 0325 5506 17
BIC: COXS053

Geschäftsführer: David Spiggle,
Detlef Theis, Bernd Schrieber
Amtsgericht Köln

HRB 52076
USt.-IDNr.: DE 81635072

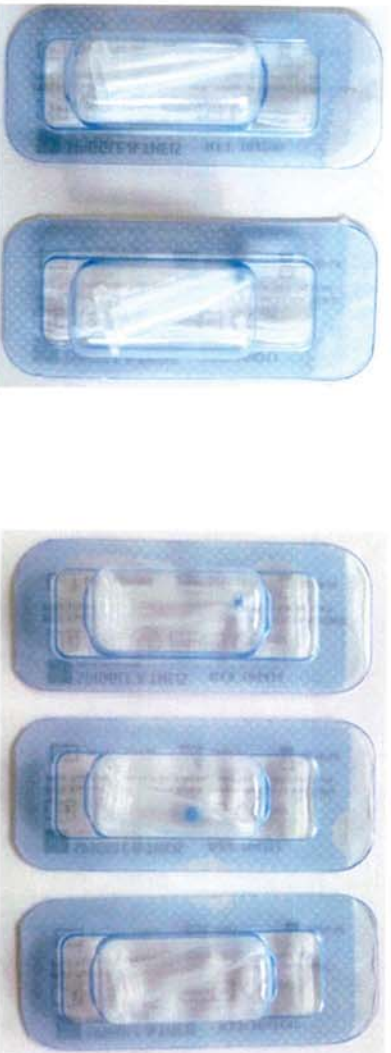




Dear Sir or Madam,

This communication is to inform you of a potentially affected weld seam of the blister packaging of the aforementioned PTFE ventilation tubes.

Within the scope of internal routine checks we discovered, that the weld seam of the blister packaging might be incomplete in the area of the pull tab. Apart from that the weld seam around the blister cavity might show a visually inconsistent blue coloring (see pictures).



No microbial contamination and thus no potential infection of patients is to be feared, since the ventilation tubes are protected by two packaging barriers – the product is within a micro container, which in turn is within a blister.

Furthermore we have not received any customer feedback regarding the above described sealing so far. However, we would still like to ask you to examine the integrity of each individual sterile package (blister), before using the above-mentioned ventilation tubes, as specified in our instructions for use:

“Any contamination of the product must be avoided. Store the product in its sealed protective packaging. Any damage to the packaging will render the product useless. Do not open the protective packaging until just before you wish to remove the product. Before opening, inspect packaging and weld seams for damage since any damage may impair the sterility of the product.”

Please withdraw blisters, where the sterile barrier appears to be impaired (see pictures above) and return them to us, we recommend you not to use these products. Of course, we will replace relevant products. Please contact our customer service in this regard (Tel.: +49 (0) 2206 90 81 0 / email: info@spiggle-theis.de).

All other products can be used safely and without restriction.



According to a risk assessment, we conclude that no additional risk is to be expected for patients who were treated with a ventilation tube that may have been packed in such a blister.

The integrity of the sterile packaging in future deliveries is secured throughout by corrective measures, already initiated and implemented by us.

Please make sure that within your organization all users of the aforementioned products and other relevant persons are aware of this **Field Safety Notice**. If you have delivered the products to third parties, please forward a copy of this information.

Please keep this information sheet at least until the action has been completed.

BfArM (German Competent Authority) has been informed of this **Field Safety Notice**.

We apologize for the inconvenience caused. However, we consider this measure necessary in the sense of general patient well-being.

Of course we are at your disposal for any questions or further information you may have.

- Our safety officer Mr. Markus Ratschinski via phone +49 (0) 2206 90 81 23 or via email m.ratschinski@spiggle-theis.de.
- Our contact person quality management Mr. Thomas Nüsse via phone +49 (0) 2206 90 81 26 or via E-Mail t.nuesse@spiggle-theis.de.
- Our customer service via phone +49 (0) 2206 90 81 0 or via E-Mail info@spiggle-theis.de in case of a replacement delivery.

Best regards

Spiggle & Theis
Medizintechnik GmbH

MARKUS RATSCHINSKI
(Managing Director/ Safety Officer)

THOMAS NUSSE
(Quality Management Representative)