
Field Safety Notice

Wrong assembly and labeling of LTS-D, #4

2016-04-22

Sender:

VBM Medizintechnik GmbH
Einsteinstraße 1
72172 Sulz am Neckar
Germany

Address:

Customer

Dear Sir or Madam,

Herewith we would like to inform you kindly about a possible failure in following delivered articles:

Commercial name / brand name / make:	Laryngeal-Tube LTS-D / size 4, single use, sterile
Model number:	LTS-D; #4
Catalogue numbers (Ref):	32-06-004-1
batch / serial numbers:	May 15-03
Commercial name / brand name / make:	Laryngeal-Tube LTS-D / size 2, single use, sterile
Model number:	LTS-D; #2
Catalogue numbers (Ref):	32-06-002-1
batch / serial numbers:	Oct 15-03

In the affected lot of article 32-06-004-1 size 4, a tube size 5 was mounted. The label states size 4. Therefore it could happen that the user takes a tube one size higher as intended.

In the affected lot of article 32-06-002-1 size 2, a tube size 2.5 was mounted. The label states size 2. Therefore it could happen that the user takes a tube one size higher as intended.

Detected failures did not affect the whole batch and were detected after shipment.

Detailed health hazard evaluation was conducted by VBM. As a result of this, the overall risk for patient has been evaluated as low. This can be rationalized due to following facts:

- The mounted tubes vary in their length minimally and can be used without any issues after examination resistance free ventilation and possible correction of the position. The overlapping of the graduating on the teeth marking scale on the tubes, on each of the two affected sizes, ensures proper handling like described in the instruction for use.
- The used cuffs of wrong mounted tubes are identical.

Corrective action to prevent reoccurrence of this failure has been undertaken by VBM.

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.

In case you detect a failed product, please send it back for exchange.

Please transfer this notice to other organisations on which this action has an impact.

This notice is also sent to the appropriate Regulatory Agency.

If you have any questions please contact:

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Email: fieldsafetynotice@vbm-medical.de

We regret the caused inconveniences.

Yours sincerely
VBM Medizintechnik GmbH

Joern Kelch
Safety Officer Medical devices

Illustration / information of the issue

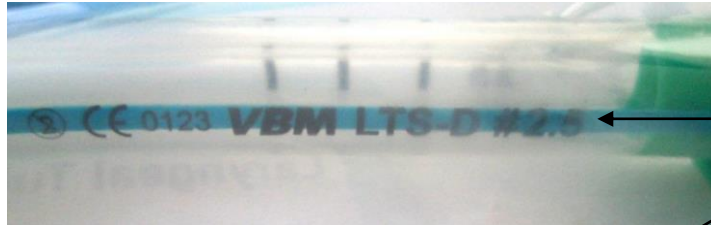
Size 4



Length Tube: 5



Size 2



Length Tube: 2.5

