Urgent Field Safety Notice

regarding

LT, LTSII, Gastro LT

2020-08-13

Sender:
VBM Medizintechnik GmbH
Einsteinstraße 1
72172 Sulz am Neckar
Germany

Addressee:

Customers of VBM, who received the affected products and batch-numbers of the Medical Device.

Details on affected devices:

Commercial name / brand name / make:	**Laryngeal Tube (VBM-version)**
Model number:	**LT, size 4**
Catalogue numbers (Ref):	**32-01-004**
batch / serial numbers:	0000220715
UDI-No.	Pouch: 04250105600353 Carton: 14250105600350
SRN-No.	n/a

Commercial name / brand name / make:	**Laryngeal Tube (VBM-version)**
Model number:	**LT, size 5**
Catalogue numbers (Ref):	**32-01-005**
batch / serial numbers:	0000215484
UDI-No.	Pouch: 04250105600360 Carton: 14250105600367
SRN-No.	n/a

Commercial name / brand name / make:	**Laryngeal Tube (VBM-version)**
Model number:	**LTS II, size 0**
Catalogue numbers (Ref):	**32-05-000**
batch / serial numbers:	0000213195
UDI-No.	Pouch: 04250105605235 Carton: 14250105605232
SRN-No.	n/a

Commercial name / brand name / make:	**Laryngeal Tube (VBM-version)**
Model number:	**LTS II, size 3**
Catalogue numbers (Ref):	**32-05-003**
batch / serial numbers:	0000209718 0000212108 0000216143 0000217899 0000216143 0000219118 0000201950
UDI-No.	Pouch: 04250105600377 Carton: 14250105600374
SRN-No.	n/a

Commercial name / brand name / make:	**Laryngeal Tube (VBM-version)**
Model number:	**LTS II, size 4**
Catalogue numbers (Ref):	**32-05-004**
batch / serial numbers:	0000210680 0000214356 0000218569 0000214356 0000217569 0000206283 0000205783
UDI-No.	Pouch: 04250105601282 Carton: 14250105601289
SRN-No.	n/a

Commercial name / brand name / make:	**Laryngeal Tube (VBM-version)**
Model number:	**LTS II, size 5**
Catalogue numbers (Ref):	**32-05-005**
batch / serial numbers:	0000213196 0000209847 0000216569 0000218568 0000213196 0000218568 0000207023
UDI-No.	Pouch: 04250105601299 Carton: 14250105601296
SRN-No.	n/a

Commercial name / brand name / make:	**Gastro LT (VBM-version)**
Model number:	**n/a**
Catalogue numbers (Ref):	**32-90-004**
batch / serial numbers:	0000214625 0000218320 0000212430
UDI-No.	Pouch: 04250105609271 Carton: 14250105609278
SRN-No.	n/a

Commercial name / brand name / make:	**Laryngeal Tube (SMJ-version)**
Model number:	**LT, size 3**
Catalogue numbers (Ref):	**32-01-003J**
batch / serial numbers:	0000217571 0000216210 0000214917 0000214632 0000218304 0000213525 0000214633 0000222763 0000219151 0000222523 0000218304 0000212641 0000212107 0000211967 0000211414 0000210954 0000210026
UDI-No.	Pouch: 04250105600438 Carton: 34250105600439
SRN-No.	n/a

Commercial name / brand name / make:	**Laryngeal Tube (SMJ-version)**
Model number:	**LT, size 4**
Catalogue numbers (Ref):	**32-01-004J**
batch / serial numbers:	0000222761 0000222296 0000219544 0000217573 0000219149 0000217183
UDI-No.	Pouch: 04250105600445 Carton: 34250105600446
SRN-No.	n/a

Commercial name / brand name / make:	**Laryngeal Tube (SMJ-version)**
Model number:	**LT, size 5**
Catalogue numbers (Ref):	**32-01-005J**
batch / serial numbers:	0000222762 0000219154 0000217567 0000214918 0000214631 0000213198
UDI-No.	Pouch: 04250105600452 Carton: 34250105600453
SRN-No.	n/a

Commercial name / brand name / make:	**Laryngeal Tube (SMJ-version)**
Model number:	**LTS II, size 0**
Catalogue numbers (Ref):	**32-05-000SMJ**
batch / serial numbers:	0000214910
UDI-No.	Pouch: 04250105608908 Carton: 34250105608909
SRN-No.	n/a

Commercial name / brand name / make:	**Laryngeal Tube (SMJ-version)**
Model number:	**LTS II, size 3**
Catalogue numbers (Ref):	**32-05-003SMJ**
batch / serial numbers:	0000210298 0000211249 0000206285 0000215176 0000212038 0000211249 0000220425 0000222781 0000205467
UDI-No.	Pouch: 04250105600278 Carton: 34250105600279
SRN-No.	n/a

Commercial name / brand name / make:	**Laryngeal Tube (SMJ-version)**
Model number:	**LTS II, size 4**
Catalogue numbers (Ref):	**32-05-004SMJ**
batch / serial numbers:	0000212563 0000213524 0000211580 0000210785 0000211116 0000217900 0000215177 0000220426 0000223477 0000222298 0000220426 0000206284
UDI-No.	Pouch: 04250105600254 Carton: 34250105600255
SRN-No.	n/a

Commercial name / brand name / make:	**Laryngeal Tube (SMJ-version)**
Model number:	**LTS II, size 5**
Catalogue numbers (Ref):	**32-05-005SMJ**
batch / serial numbers:	0000211251 0000206286
UDI-No.	Pouch: 04250105600292 Carton: 34250105600293
SRN-No.	n/a

Description of the problem:

We received several complaints from the field that the valve opener of the above-mentioned products melted during the autoclaving procedure.

After a detailed failure investigation in collaboration with our supplier we examined that the material of the valve opener was changed by mistake during a regular change of the material supplier.
The affected "wrong" material is "High Density Polyethylen" (HDPE) instead of the correct material "Polypropylen" (PP).

The HDPE material is not as heat resistant as the PP material and therefore melted during the autoclaving procedure at temperatures of 134°C.
The HDPE material is only heat resistant up to temperatures of 124°C.

As within one batch of the complete product several batches of the valve opener can be used, not all indicated products must be affected necessarily.

A risk for patients, users or other persons can be excluded, as the products must be controlled and checked on any visual damages after the autoclaving procedure. The melted valve opener is an obvious damage. Therefore, the product is not released for further use.

The risk for patients, users or other persons was evaluated as "no harm to health" with the help of a Health Hazard Evaluation.

Advice on action to be taken by the user:

As the melting valve opener is only induced at temperatures of 134°C during the autoclaving procedure, tubes, which are manually or automatically cleaned and disinfected, are not concerned. If these procedures are used for reprocessing, no further measures need to be taken from the user.

Users, who autoclave the products at temperatures of 134°C and still store the indicated products in original packaging, receive a replacement.

Users, who do not store the products in original packaging anymore, receive the valve opener as replacement part or a replacement of the complete product if required.
If the product was autoclaved at temperatures of 134°C already in the past without the appearance of the mentioned problem, no further measures need to be taken from the user.

Please make sure to take care of the indicated measures right after receipt of this Urgent Field Safety Notice and get back to us with the attached response form if needed.

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.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The German competent authority has received a copy of this Urgent Field Safety Notice.

If you have any questions, please contact:

VBM Medizintechnik GmbH
Nathalie Staiger
Phone: +49 7454 95 96 0
Fax: +49 7454 95 96 99560
Email: fieldsafetynotice@vbm-medical.de

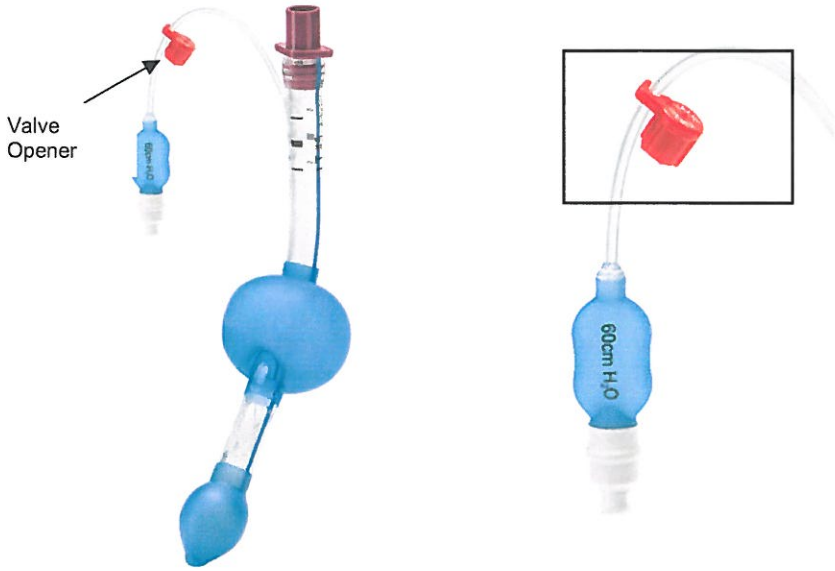
We regret the caused inconveniences

Yours sincerely
VBM Medizintechnik GmbH.

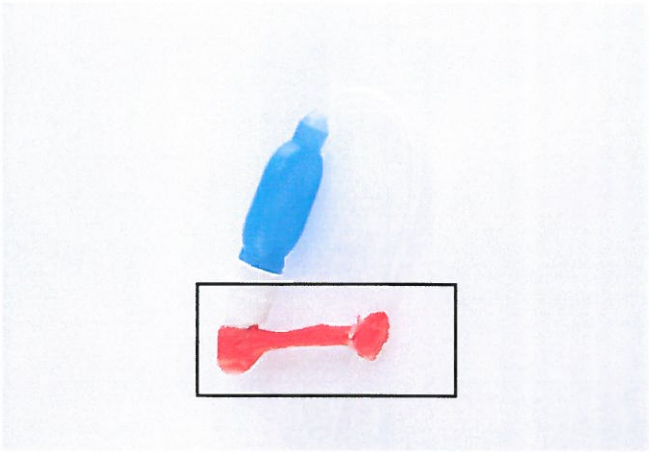
Nathalie Staiger
Vigilance Manager / Person of Regulatory Compliance

Illustration / information of the issue or of the corrective action (Appendix 1)

Example of a Laryngeal Tube with <u>functional</u> valve opener:



Example of a melted valve opener after the autoclaving procedure at temperatures of 134°C:



RESPONSE FORM

Date: *2020-08-13*

VBM Medizintechnik

Please send the completed response form within 2 working days back

LT, LTS II, Gastro LT

We have read and understand the instructions provided in the Field Safety Notice:

Name (please print)			
Signature / Date			
Title:			
Telephone No.			
E-Mail Address:			
Organisation/Firm			
Street		**Post Code**	
City		**Country**	

Quantity of <*LT's*> of each Lot in your possession:			
Lot / Batch No	**Quantity**	**Lot / Batch No**	**Quantity**

Quantity of <*LTS II*> of each Lot in your possession:			
Lot / Batch No	**Quantity**	**Lot / Batch No**	**Quantity**

Quantity of <Gastro *LT's*> of each Lot in your possession:			
Lot / Batch No	**Quantity**	**Lot / Batch No**	**Quantity**

Quantity of <*affected devices*> of each Lot in your possession:	
Quantity of ***<LT, LTS II, Gastro LT>*** for which you don't have Lot / Batch No. but which visually match the Photo in annex 1:	

Quantity of <*LT's*> passed to other organizations:

Lot / Batch No	Quantity	Lot / Batch No	Quantity

If more data needs to be indicated, please add a separate list.

Quantity of <*LTS II*> passed to other organizations:

Lot / Batch No	Quantity	Lot / Batch No	Quantity

If more data needs to be indicated, please add a separate list.

Quantity of <*Gastro LT's*> passed to other organizations:

Lot / Batch No	Quantity	Lot / Batch No	Quantity

If more data needs to be indicated, please add a separate list.

VBM Contact Details

Please send the completed response form within 2 working days back to:

E-Mail	Fax	Mail
fieldsafetynotice@vbm-medical.de	+49 (0) 7454 / 95 96 99560	VBM Medizintechnik GmbH -Complaint Handling/Service- Einsteinstraße 1 70172 Sulz a. N.