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CVR. nr. 63644919

30 May 2022

Urgent Field Safety Notice

Ambu® VivaSight™ 2 DLT

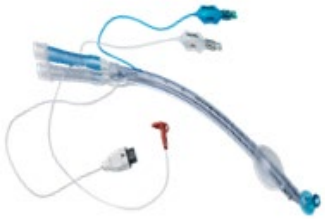
Ambu A/S - Single Registration (SRN): DK-MF-000001437

[Date] [to be filled out by Ambu Sales or Distributor]

[Attention:] [to be filled out by Ambu Sales or Distributor]

Details on affected devices:

Model	Catalog Number	Affected LOTs
Ambu® VivaSight 2 DLT Kit 35 Fr	412351000	All
Ambu® VivaSight 2 DLT Kit 37 Fr	412371000	All
Ambu® VivaSight 2 DLT Kit 39 Fr	412391000	All
Ambu® VivaSight 2 DLT Kit 41 Fr	412411000	All



Description of the problem:
Ambu has received complaints on VivaSight 2 DLT concerning leak/rupture of either the bronchial or tracheal cuff. Leakage occurred during procedure could potentially lead to loss of secure airway and will require re-intubation of the patient.

Loss of secure airway can in worst case lead to life threatening hypoxia. None of the complaints reported patient outcome affected.

Investigations have been performed to identify a possible root cause. A root cause has not yet been identified and further activities are planned in order to solve the issue.

Advise on actions to be taken by user:
Within 1 week of receipt of this letter, please return confirmation of receipt of this Field Safety Notice (appendix 1).

The traceability system at Ambu indicates that your institution has purchased the VivaSight 2 DLT products and there may be affected devices in your stock. You should address this by either discarding the products.

Customers will need to discard their VivaSight 2 DLT products. Ambu will compensate them by either replacing the units with aScope 4 Broncho Slim or providing a refund.

Within one month of receipt of this letter, please return your confirmation of actions described in Field Safety Notice Completed (appendix 2).

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the devices could have been transferred.

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

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

We sincerely apologize for any inconvenience and thanking you in advance for your cooperation. Ambu confirms that this notice has been notified the appropriate Regulatory Agency.

Contact reference person:
[Name / organisation, address, contact details Ambu Sales or Distributor]

[Signature Ambu Sales or Distributor]

Appendix 1:

Confirmation on
Field Safety Notice RECEIVED
Return to [filled in by Sales/Distributor]

The undersigned person hereby confirms that

_____

State Hospital/ Clinic/ Emergency Center Name

Has received Field Safety Notice from Ambu A/S dated [date] regarding
VivaSight 2 DLT

_____

Date

_____

Name

_____

Title

_____

Signature

Appendix 2:

Confirmation on
Field Safety Notice Completed
Return to [filled in by Sales/Distributor]

The undersigned person hereby confirms that

_____

State Hospital/ Clinic/ Emergency Center Name

Has completed the actions describes in the Field Safety Notice from Ambu A/S dated [date] regarding **VivaSight 2 DLT**

Total Number of products discarded: _____
Please fill in Table 1 if your organisation has discarded VivaSight 2 DLT

or

The organisation no longer has VivaSight 2 DLT **and all devices have been discarded:**
YES ☐ NO ☐

_____

Date

_____

Name

_____

Title

_____

Signature

Table 1 Overview of discarded affected items at your organisation

Catalogue number	Lot number	Quantity