
Urgent Field Safety Notice

Ambu AuraGain
December 9, 2015

Details on affected devices:
Ambu® AuraGain™ - Single Use Laryngeal Mask - Sterile

Catalogue Number	Size	LOT numbers
408300000	Size 3	All lots through lot number 1790072 (including this number and lower), except lot number 1756844, 1758852, 1768981, 1771564, 1774137, 1785130, 1787754
408400000	Size 4	All lots through lot number 1810862 (including this number and lower), except lot number 1804456
408500000	Size 5	All lots through lot number 1774140 (including this number and lower), except lot number 1732626 and 1745421

Description of the problem:
Lack of Sterility Assurance.
A failure has been discovered during routine quality control at the manufacturing site. This failure may cause a small hole (approximately 0,5 mm) in the pouch of the device leading to a potential compromised sterile barrier. A leak in the sterile barrier may allow contamination of the device with the risk of causing an infection, which may require antibiotic treatment.

After the identification of failure, comprehensive investigation has shown a low prevalence of up to 3% for the affected LOTs.

Ambu has not received any complaints or other market feedback on the matter, since the products were marketed in 2014

The cause has been thoroughly investigated, and Ambu has taken immediate appropriate corrective actions to eliminate the issue.

Action to be taken by the user:

Within 1 week of receipt of this letter, please return confirmation of receipt of this Field Safety Notice (appendix 1).

Since you have purchased the AuraGain device, there may be affected devices in your stock. You should address this by either selecting action route A or B, per below:

> A: Users are always instructed to perform pre-check of the device before use, and as noted in the IFU, the device is sterile unless the packaging is damaged or opened.
> For the affected LOTs, special attention should be given to the area of the pouch where the device connector is located, please follow the instructions in appendix 2.
>
> B: Place your AuraGain devices of the affected LOTs in quarantine, for collection and replacement by Ambu.

Either course of action you choose, all affected devices are eligible for replacement by Ambu.

Please contact your Ambu representative to arrange replacement.

Within one month of receipt of this letter, please return your confirmation of actions described in Field Safety Notice Completed (appendix 3).

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 transfer this notice to other organisations 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 apologise for any inconvenience and thanking you in advance for your cooperation.
Ambu confirms that this notice has been notified the appropriate Regulatory Agency

Appendix 1:

Confirmation on
Field Safety Notice RECEIVED

The undersigned person hereby confirms that

_____

State Hospital/ Clinic/ Emergency Center Name

Has received Field Safety Notice from Ambu A/S dated December xx, 2015 regarding
Ambu AuraGain, Lack of Sterility Assurance

_____

Date

_____

Name

_____

Title

_____

Signature

Appendix 2:

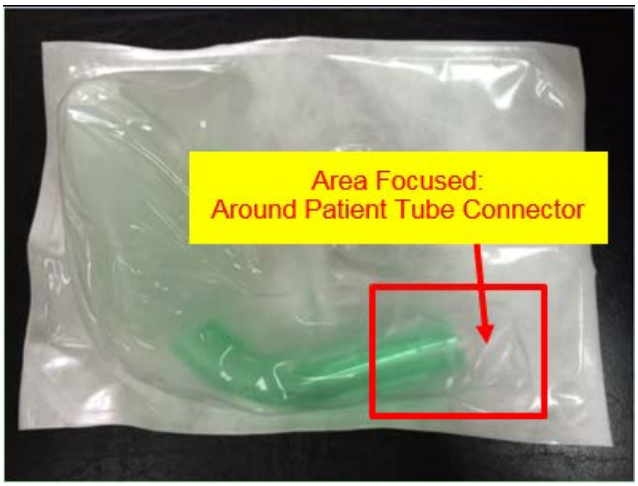
Follow these instructions to identify the AuraGain devices that may have a broken sterile barrier.

Please see picture to the right for positive identification of the device:

Note identification of device name highlighted with red box, and identification of LOT number highlighted with yellow box

Step 1:

The cause of the potentially compromised sterile barrier is a small hole in the transparent film. Please see picture to the right, for a visual specification of the area to inspect.



Step 2:

The inspection should be carried out in a setting with good light, to support best possible identification of breach. The breach is associated with a mark in the transparent film. If a device has a mark like illustrated on the picture to the right, it should be discarded. If in doubt whether a specific device has a hole, please discard.

Discarded devices should be collected and quarantined. Information on discarded devices should be kept and filled into appendix 3.

Appendix 3:

Confirmation on
Field Safety Notice Completed

The undersigned person hereby confirms that

_____

State Hospital/ Clinic/ Emergency Center Name

Has completed the actions described in Field Safety Notice from Ambu A/S dated December xx, 2015 regarding

Ambu AuraGain, Lack of Sterility Assurance

Numbers of products discarded: _____

Number of products returned to Ambu: _____

_____

Date

_____

Name

_____

Title

_____

Signature