
Urgent Field Safety Notice

Ambu® SPUR® II for Demand Valve

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	Catalogue number	Affected LOTs
Ambu® SPUR® II Adult for Demand Valve	32502300	▪ From LOT 1000000280 up to and including LOT 1000212707 ▪ From LOT 1717211 up to and including LOT 2034478
Ambu® SPUR® II Pediatric for Demand Valve	330023000	▪ From LOT 1000000284 up to and including LOT 1000214620 ▪ From LOT 1719493 up to and including LOT 2034479
Reservoir for Demand Valve version	325000530	▪ From LOT 1000007889 up to and including LOT 1000275049 ▪ From LOT 1726850 up to and including LOT 2012892

Ambu® SPUR® II for Demand Valve

Reservoir for Demand Valve

Ambu2021FA00001

Description of the problem:

Ambu has received an incident report following use of Ambu® SPUR II for demand valve from a German hospital, where the oxygen connector was found collapsed during use.

The oxygen connector on the Ambu SPUR II for demand valve can in very rare cases deteriorate during storage and present as collapsed. If a SPUR II for Demand Valve version with a collapsed oxygen connector is put into use, it will not be possible to provide the patient with additional oxygen from the oxygen reservoir. Additional oxygen can still be provided through the demand valve and ventilation with ambient air is still possible.

No complaints have been received in which a patient has been reported to have been harmed. The fault can be detected during preparation and testing before the resuscitator is being placed ready on the wall/hospital bed. In addition, the IFU, the relevant products standard (ISO 10651-4) and normal practice require a pre-use check that would always result in the detection of the defect and prevent the use of the device.

In February 2019 Ambu implemented a design change that eliminated the already low risk of a collapsed oxygen connector, and no issue has been detected since. This FSN therefore only impacts SPUR II for demand valve variants produced between December 2014 and February 2019. This FSN does not impact other SPUR IIs variants Ambu have provided to the market.

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 SPUR II for Demand Valve device produced between December 2014 and February 2019 and there may be affected devices in your stock. You should address this by discarding affected LOTs of the Ambu SPUR II for Demand Valve devices according to local regulations.

Within one month of receipt of this letter, please return your confirmation of actions described in Field Safety Notice Completed (appendix 2). If you would like a replacement of the discarded SPUR II for Demand Valve devices, please indicate this in appendix 2.

This field safety notice does not relate to any SPUR II for Demand Valve devices produced after February 2019 and therefore no action should be taken for them.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the devices could 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.

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
[product]

_____

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 described in Field Safety Notice from Ambu A/S dated MM DD, 2021 regarding Ambu® SPUR II for Demand Valve.

Total Number of products discarded: _____
Please fill in Table 1 if your organisation has discarded Ambu® SPUR II for Demand Valve

Organisation would like to request replacement of the discarded SPUR II for Demand Valve devices
YES ☐ NO ☐

Or

The organisation no longer has Ambu® SPUR II for Demand Valve produced between December 2014 and February 2019 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