Complaint Summary # SUMM-13396

Created by Angelo Zaccardo on 03-Apr-2020 08:26

Basic

SUMMARY NUMBER
SUMM-13396

SITE
Mirandola

COMPLAINT INFORMATION

COMPLAINT NUMBER
2020-00788

EXT REFERENCE

HOSPITAL/CLINIC
[redacted]

RGA / RMA #

DATE OF SUBMISSION
03-Feb-2020

EVENT DETAILED DESCRIPTION
Blood leak from around outer edge of D130 Arterial filter. This was noticed pre-bypass and under no pressure. 1 filter is available for investigation

PRODUCT INFORMATION

PRODUCT PART NUMBER
C23500

PRODUCT DESCRIPTION
[redacted]

PRODUCT LOT
1909260151

PRODUCT SN

PRODUCT PART NUMBER
03492

PRODUCT DESCRIPTION
D130 DIDECO KIDS PH SUB

PRODUCT LOT
1907030115

PRODUCT SN

INVESTIGATION

INVESTIGATION SUMMARY
The involved D130 Arterial Filter, labeled with Shop Order 488487-0067 and complained for blood leakage from side edge during pre-bypass at [redacted] was returned to Livanova facility for investigation after being subjected to gamma-rays decontamination process.
No blood residues were detected along the perimeter of the device when visually inspected.
No cracked area nor any non-conforming material were identified.

Using the setup circuit illustrated below, a leak test was performed to verify the structural integrity of the device.
The unit was filled with methylene blue solution and pressurized at increasing pressure values steps aimed at reproducing the leakage experienced by customer, monitoring the pressure value reached inside the device by pressure gauge.
In the early filling phase, blue dye solution was observed to be dripping from welding profile of tested device at internal pressure value of 169,4 mBar, as outlined in enclosed pictures.
The reported failure was reproduced during internal lab testing.
Based on collected evidences, the occurred issue was classified as leakage from welding profile.
The complaint was confirmed.
The involved device was manufactured and released conforming to specifications.
According to internal traceability, three further complaints for same issue were recorded for noticed product lot of Arterial Filter, all received from same Customer in Israel (Complaints ID 2019-07565, 2019-07857 and 2019-08264).

The present report has been reviewed as per reportability criteria described in current revision of CS_BU_GP_0023 and the review does not modify the initial reportability assessment for all applicable regulations.

ROOT CAUSES
Units from current production have been pulled from inventory and inspected.
Based on these results, further leak and burst tests have been performed.
The most probable root cause of the o-ring misplacement has been ascribed to the lack of interference between the o-ring and its housing inside the filter that might occasionally allow unexpected movements of the o-ring and then cause the leak of the filter.

CORRECTIVE ACTIONS
Non conformity report NCR-MIR-2019-0157 has been issued to address this failure.
Based on investigation root cause analysis and investigation findings, corrective actions are under evaluation in collaboration with the external supplier of the blue o-ring.

[redacted]

We will keep monitoring very carefully any possible new Customers feedback received to look into the matter.
LivaNova is committed to provide quality products and service to its customers and we apologize for any inconvenience the situation may have caused.

INVESTIGATION INFORMATION

INVESTIGATION NUMBER
INV-010008

CONFIRMATION OF REPORTED FAILURE
Confirmed on Involved Device

dye solution dripping from top portion area.jpg

leakage from welding profile reproduced.jpg

leakage reproduced at internal pressure value of 169,4 mBar.jpg

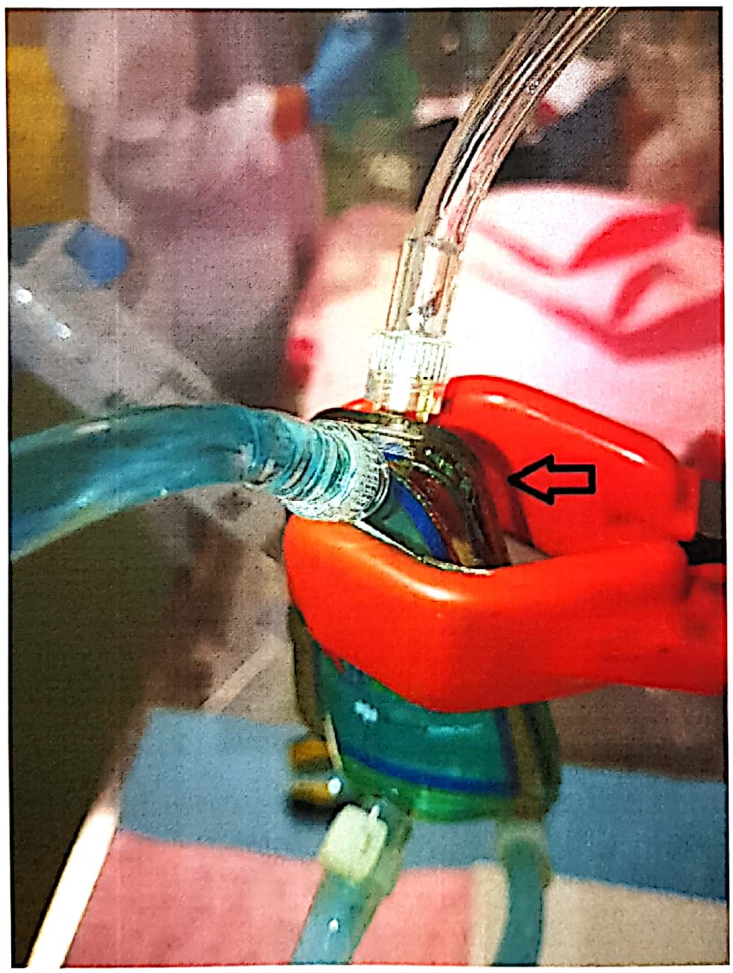
no blood residues along device perimeter (2).jpg

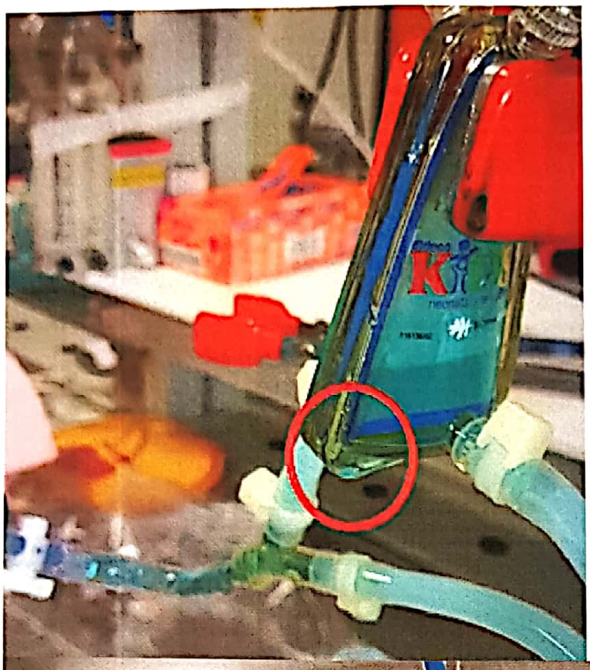
no blood residues along device perimeter.jpg

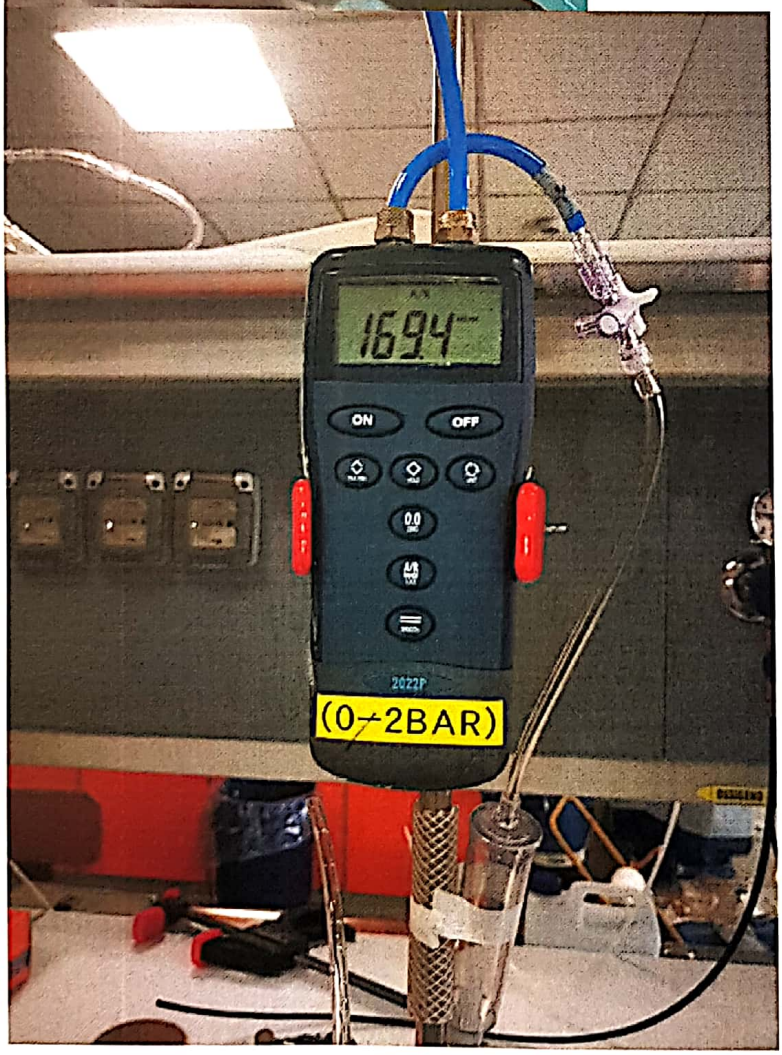
PTS traceability.jpg

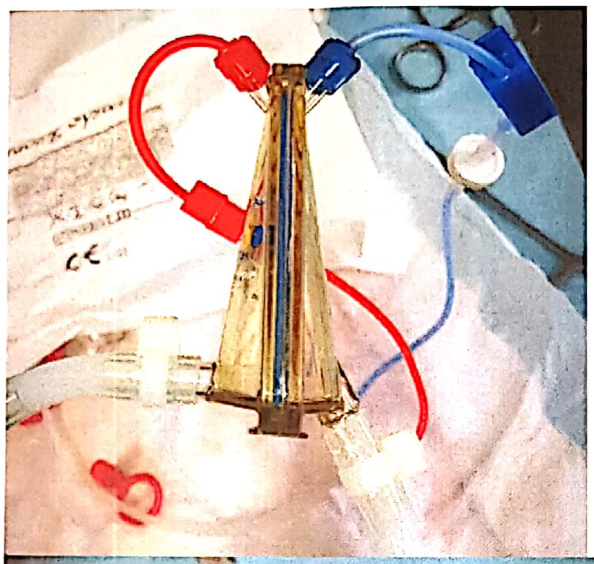
Serial number D130.jpg

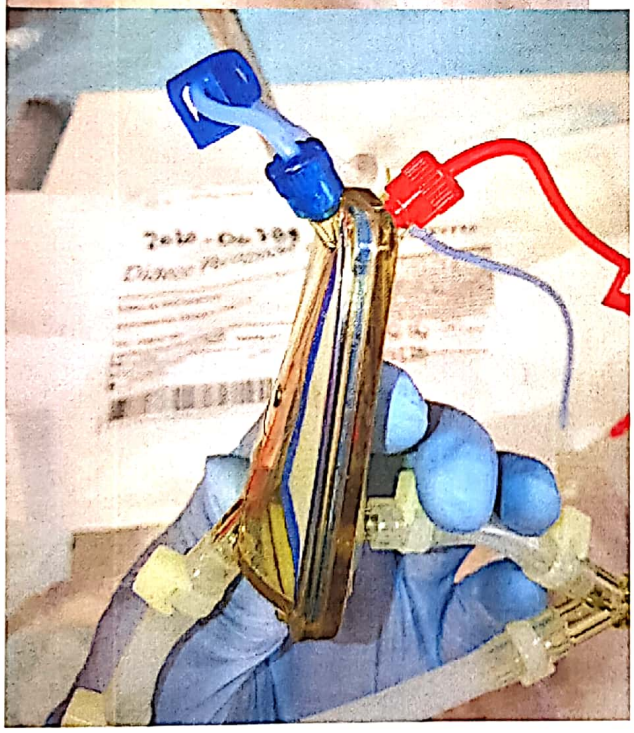
Setup circuit leak test.jpg

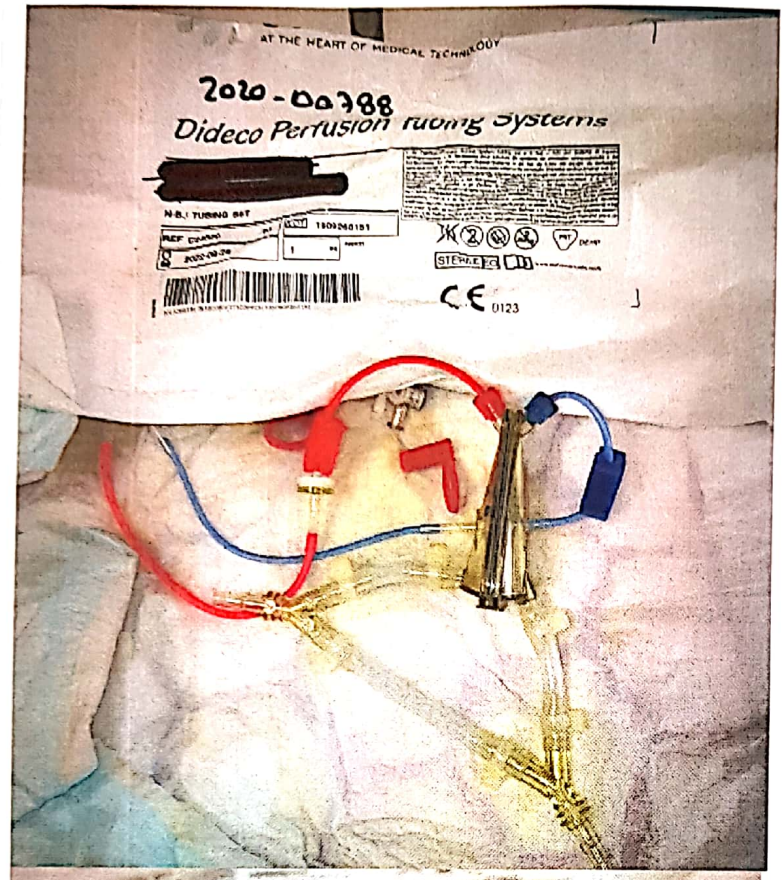


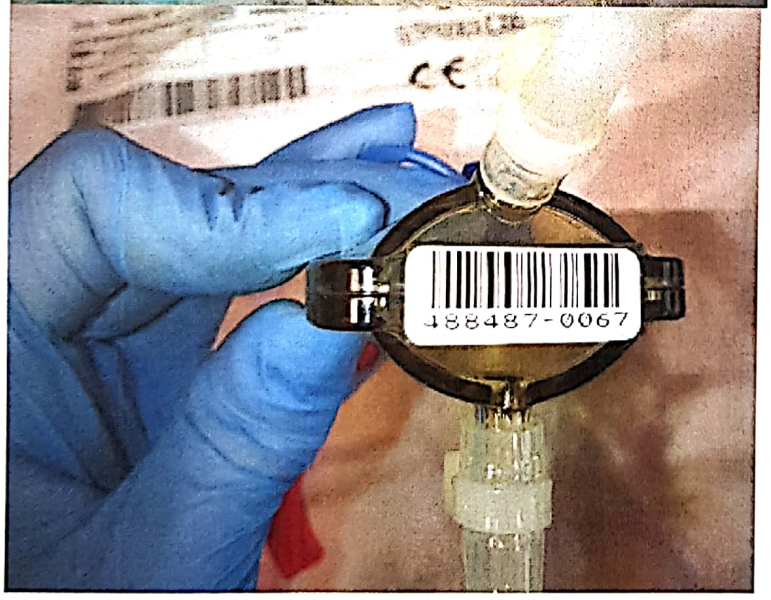


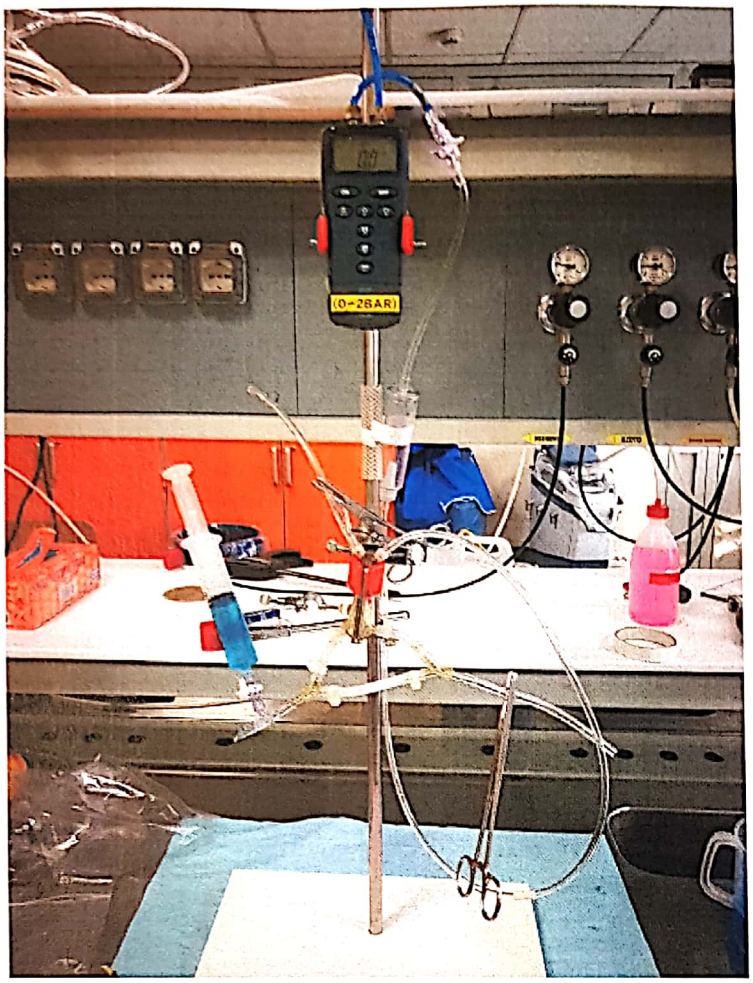












CONCLUSION

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Thank you for contacting Livanova about the issue you experienced. We have completed our investigation and this report provides the root causes and the corrective actions we have taken.

By partnering with us to provide the information about the event, together we can achieve improved product quality for patients around the world. If you have any questions, please contact your sales person.

MAIL ACTIVITY

SEND MAIL TO

SEND MAIL TO EMAILS

[redacted]

Send Mail

Angelo Zaccardo, Email: Investigation complete for Complaint 2020-00788, 03-Apr-2020 08:27

SUMMARY ATTACHMENTS

OI ATTACHMENTS

FINAL SUMMARY ATTACHMENTS

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Last Edited by Angelo Zaccardo on 03-Apr-2020 08:30