

2021 Oxygenator 2

Permission to print: Yes

Category Oxygenator

Incident type Good Catch Near Miss

Duration of incident: minutes

Description:

Leak from luer lock on the inlet side of Ref BO-HQV 141400 neonatal oxygenator Getinge group, identified during priming. It was a relatively slow leak which was not identified when the occlusion was checked, and with a crystalloid prime any small drops on the floor would have been difficult to identify. The leak was identified when albumin was added and a small drop of yellowish fluid was observed on the floor. Oxygenator changeout was performed and on examination of the 2nd oxygenator a similar crack on luer casting was noticed. This was "Bench" pressure tested and the same leak was identified, the oxygenator /reservoir were of the same batch. A 3rd oxygenator was opened with a different batch, visibly examined and looked intact. This was then placed with the primed circuit. Surgery continued without issue. Original product: Leaked during priming. Ref BO-HQV 141400, Lot 3000166932, manuf: 26/04/2021, exp 26/04/2023. Oxy lot: (blue sticker) 3000147605, reservoir lot: (silver sticker) 3000156399 BO-02950. 2nd Oxygenator (not used as crack identified before placement): Ref BO-HQV 141400, lot:3000166932, man:26/04/2021, exp 26/04/2023. Oxy lot Blue(blue sticker) 3000147605, reservoir lot:(silver sticker3000156399- not required).

GOOD CATCH - what went well Attention to detail. The leak was identified when albumin was added (small drop of yellowish fluid was observed on the floor), this could easily have been misinterpreted as condensation from the exhaust port. Further examination showed a hairline crack on the luer casting, the luer lock cap which came with the oxy was replaced with a "Braun " combi -stopper, the leak was significantly more obvious then. The vigilance of the operator and the use of a lamp positioned on the oxy. port. A thorough examination of the 2nd oxy above what would normally be expected particularly being the same batch including pressure testing using Plasmalyte 148. Good communication was made to delay anaesthesia induction until problem was sorted. (only 1 other oxygenator was available and if there had been an issue it would have meant changing to a different device with a blood prime required).

What could we do better The problem was identified in advance of any possible negative effect,

Preventive actions Thorough examination of luer castings on that particular equipment planned, both leaking oxy returned to manufacturer for examination

Type of incident: Equipment

Hospital incident filed: Yes

Ext Authority Advised Yes

Discussed with team: Yes

Rule issue No

Skill issue No

Patient outcome varianc Nil

Commentary This good catch report illustrates close attention to detail in pre CPB checks and recognition of a potential product batch issue. PIRS2 Ed

