Venous reservoir 2017

Permission to print: Yes

Incident type Near Miss

Type of incident: Equipment

Catagory Venous Reservoir

Description: Standard valve case, patient was heparinised, and the surgeon asked to go on

bypass. I reached over to remove the clamp from the venous line, and as I did so I spotted some blood (~5ml) on the floor under my oxygenator (inspire 6). Before this I had not seen the blood as my view of it was obstructed by the oxygenator. I informed the surgeon that I was not going on bypass as I wanted to identify the source of the blood on the floor. I found that it had leaked from the seal at the cardiotomy turret where the suckers attach (we had been using the pump sucker), and had dripped down the back of the reservoir onto the floor. I called a colleague in for a 2nd brain, and we decided to the change out

the reservoir before going on bypass.

Preventive actions Discussed with manufacturer and advsed this was a known problem related to

the gasket lubricant and reservoir molding that was undergoing a 2 stage fix (stage 1 new lubricant, stage 2 revised moulding - still in process. If recurrent then consider using a dual reservoir that has not had the same problem until

the new moulding fix is in place.

actioning reservior change out

Protocol issue No

Rule issue No

Skill issue No

Team Issue No

Violation No

Manufacturer advised: Yes

Discussed with team: Yes

Hospital incident filed: No

Ext Authority Advised No

Procedure acuity: Elective

Commentary

Monday, 30 April 2018 Page 1 of 2

Permission to print: Yes

Incident type No Harm Incident

Type of incident: Equipment

Catagory Venous Reservoir

Description: After approx. 10 mins on bypass (AVR + MVR + myectomy) I noticed that I had

blood leaking from around the cardiotomy turret (Inspire 6 - LivaNova). I called

the co-ordinating perfusionist who happened to be one of the most

experienced perfusionists in the universe. After a brief discussion of options (adding a second reservoir and rerouting the suckers) He suggested applying bone wax around the join. This worked really well, and there was no further

leaking during the case.

Preventive actions Discussed with manufacturer and advised this was a known problem related to

the gasket lubricant and reservoir moulding that was undergoing a 2 stage fix (stage 1 new lubricant, stage 2 revised moulding - still in process. If recurrent then consider using a dual reservoir that has not had the same problem until the new moulding fix is in place. Of interest was the fact that as users of the product we were unaware of this same fault having occurred elsewhere.

GOOD CATCH - what went Team collaboration to find an effective minimalist solution of applying bone

wax to a minor leak and avoiding any interruption to the procedure

Protocol issue No

Rule issue No

Skill issue No

Team Issue No

Violation No.

Manufacturer advised: Yes

Discussed with team: Yes

Hospital incident filed: No

Ext Authority Advised No

Procedure acuity: Elective

Commentary This is the second report of this problem in quick succession to PIRS. While this

was a relatively minor incident, a particular point of interest is the fact that the user was not aware of a previous rash of reports of the same issue with the same device in the same region. The explanation for not sharing this knowledge was that it was thought to be isolated to one centre. There had been no previous reports to PIRS of this gasket leak - neither from the centre where it occurred nor from the supplier. Under reporting is well known however this raises the opportunity for a closer partnership with the industry in voluntary

reporting of near miss and other product related issues. PIRS is looking to initiate a dialogue with the corporate sector on how this might be usefully

progressed - PIRS Ed

Monday, 30 April 2018 Page 2 of 2