

Permission to print: Yes

Near Miss or Accident Accident

Type of incident: Equipment

Catagory Coagulation

Knowledge Error No

Protocol issue No

Rule Error No

Skill Error No

Team Issue No

Violation No

Description:

High Trans Membrane pressure during By Pass, leading to a change out of the oxygenator We have experienced 3 different incidents of high TMP [in 2 procedures] all using Medtronic Fusion Balance coated oxygenators. All happened after being on Bypass for about 10 mins. The TMP has started to rise and the flow rate has decreased. We use a centrifugal pump. [In the first procedure we noticed decreasing flow, with increasing RPM and with no increase in the line pressure. The second procedure required two oxygenators to be changed out ].

Contributing factors:

No , ACT were all over 500 sec and there was not a common batch number. Patuient blood results were all within normal limits. We are advised that there have been at least 4 other reports of this problem all with Balance coating which may be a factor.

Corrective action:

[After the first instance initiated pre oxygenator pressure measurement]. Changed out all oxygenators without any problems. There was no adverse effects to patients

Preventative action plan:

All faulty Oxygenators were returned to the manufacturer . We have not had a report back yet . We have changed from Balance coating to Carmeda coating without a recurrence of the problem

Manufacturer advised: Yes

Discussed with team: Yes

Ext Authority Advised Yes

Patient outcome variance f Nil