2026 Oxygenator fibre leak

Permission to print:	Yes
Category	Leak
Category 2	Oxygenator
Severity	Good Catch No Harm Incident
Type of incident:	Equipment
Description:	On 31/10/2026, a patient underwent elective coronary artery bypass grafting on cardiopulmonary bypass. All pre-bypass safety checklists were completed with no issues found. Bypass started at 09:21, and the aortic cross-clamp was applied at 09:33. At 10:29, I noticed a small pool of blood, about 20 mL (increased to 100-150) under the oxygenator. On inspection, blood was leaking from the three exhaust ports at the base (inferior aspect) of the oxygenator, the ports used for gas exhaust and CO2 sampling. Blood was dripping from all three ports at a slow but steady rate, about one drop every few seconds for a duration of 60mins. Oxygenator performance was not affected. Gas exchange stayed adequate, with sweep gas flow and FiO2 within normal ranges and unchanged for the whole case. However, blood at the gas exhaust ports suggested a possible loss of fibre integrity in the moment and a potential breach between the blood phase and the gas phase with concern for contamination. Photographs were taken during and after the case. They show blood pooling on the absorbent pad beneath the oxygenator while it was in use. After the case, the underside of the oxygenator showed blood-tinged froth in the gas-phase compartment at the base of the fibre bundle, across about half its circumference, with blood visible in the gas exhaust slots. Because of the possible contamination risk from blood-gas phase contact, the team decided to give extra prophylactic antibiotics. The patient received teicoplanin in addition to the standard cefazolin prophylaxis. Device: Medtronic Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface, Serial Number: 8114764450
GOOD CATCH - what went well	The surgical team was notified promptly once the leak was detected. Unfortunately, the case was outside normal hours (weekend call in), so no N+1 was available. However, the nursing staff were able to help by retrieving and opening a new oxygenator, which allowed me to inspect the underside and pinpoint where the blood was coming from. This helped me understand diagnostically what was happening. Overall, the team communicated well and developed a safe escalation plan in case the oxygenator became compromised, which, in this situation, it did not. The patient lost only 100–150 mL of blood, so there was no increased exposure to blood products.
What could we do better	One potential improvement would be to add a step to the pre-bypass checklist: clamping off the oxygenator and pressurising it while primed to check its integrity. The oxygenator was not returned to Medtronic for diagnostic evaluation because it was contaminated with patient blood. In future, this could be addressed by flushing it with saline to remove the blood before sending it back for evaluation.
Preventive actions	The incident has been circulated to cardiothoracic and perfusion staff, with no further action required at this stage. Medtronic was notified and confirmed that the likely cause was a fibre integrity issue, which they noted can occur during manufacturing but is very rare. An official diagnosis could not be confirmed because the oxygenator had been

	disposed of.
Manufacturer advised:	Yes
Discussed with team:	Yes
Hospital incident filed:	Yes
Ext Authority Advised	Yes
Patient outcome variance	Unknown