

FDA Recall – Hamilton Medical Breathing Circuit Set

Purpose of this communication:

We are writing to inform you that Hamilton Medical has recalled certain Breathing Circuit Sets after identifying that some coaxial circuit sets with preassembled expiratory valves may not function as intended. In affected units, the expiratory valve membrane may adhere to the sealing ring, restricting valve opening and expiratory gas flow. This issue may not be detected during routine ventilator pre-operative testing unless a test lung is being actively ventilated and typically becomes apparent shortly after ventilation begins.

Restricted expiratory flow can trigger an "Exhalation Obstructed" alarm and may result in elevated end-expiratory pressure, inadequate ventilation, impaired gas exchange, and oxygen desaturation (hypoxemia).

As of July 2, Hamilton Medical has reported four serious injuries and no deaths associated with this issue.

What do I need to do?

- Please review the following recall notice: [Breathing Circuit Set Recall: Hamilton Medical Removes Breathing Circuit Set | FDA](#)
- Notify impacted patients and facilitate the resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.