

### FDA Recall – Ventec Life Systems

#### Purpose of this communication:

- We are writing to inform you that effective immediately the FDA has issued a Class 1 recall of Ventec Life Systems VOCSN Patient Breathing Package Model #220922 distributed from December 14, 2022 to September 20, 2023. The recall is due to a manufacturing issue which causes the bonded spiral wrap to detach before or during ventilation. If the spiral wrap detaches, it can compromise the structural integrity, functionality, or cause blockage, stoppage, or leaks in the breathing circuit. The use of the affected breathing package may cause serious injuries, such as failure to ventilate, incomplete ventilation, failure to oxygenate, complete or partial airway obstruction.

#### What do I need to do?

- Please review the following recall notice: [Ventec Life Systems Recalls VOCSN Patient Breathing Package \(Pediatric, Active, Oxygen, Blue\) for Manufacturing Issue with Bonded Spiral Wrap | FDA](#)
- Notify impacted patients and facilitate the repair, replacement and/or 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.