# Supplement: Temporary modification to indications for use for extracorporeal support devices

## OXY-1 System

### Background

On April 6, 2020 the United States Food and Drug Administration (FDA) published the following guidance: "Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices during the Coronavirus Disease 2019 (COVID-19) Pubic Health Emergency."

Under this guidance, the FDA is allowing temporary limited modifications to the indications of certain FDA-cleared or FDA-approved cardiopulmonary devices without prior submission of premarket notification. These modifications are allowed, in light of the public health emergency, when they do not create an undue risk. This indication modification is in effect for the duration of the public health emergency related to COVID-19, as declared by the Department of Health and Human Services (HHS).

### Indications for use

In accordance with the FDA guidance, the devices listed below have a modified indication for use during the COVID-19 public health emergency. This indication modification has not been cleared or approved by the FDA, but shall apply temporarily to the device models listed in this supplement:

**The device can be used for longer than 6 hours in an extracorporeal membrane oxygenation (ECMO) circuit to treat patients who are experiencing acute respiratory or acute cardiopulmonary failure.**

The table below shows the system part numbers, device descriptions, and FDA-cleared indications for use for the various cardiopulmonary devices granted the above modified indication.

| System Part Numbers* | Device Description | FDA-Cleared Indications for Use |
|---|---|---|
| 001-0500-100 | OXY-1 Console with accessories:<br>• Pump Driver<br>• E-Drive<br>• E-Drive pole mount<br>• Pole Mount | The Oxy-1 System is intended to be used for extracorporeal circulation cardiopulmonary bypass. The Oxy-1 System pumps, oxygenates and removes carbon dioxide from blood within the indicated flow rates for use up to six hours in duration. |

| System Part Numbers* | Device Description | FDA-Cleared Indications for Use |
|---|---|---|
| 001-0400-100 | OXY-1 PLU Disposable<br>• Pump Lung Unit<br>• Priming Kit<br>• Cable Guard<br>• Condensate Tray<br>• Console Intake Filter | The Oxy-1 System is intended to be used for extracorporeal circulation cardiopulmonary bypass. The Oxy-1 System pumps, oxygenates and removes carbon dioxide from blood within the indicated flow rates for use up to six hours in duration. |

## Device performance

There are no changes to device performance as described in the instructions for use for these devices.

## Durability testing

Abiomed has successfully conducted the following reliability testing:

- Blood Pump Reliability for 30 days
- Pump Driver Motor Reliability for 1 year
- The OXY-1 System durable component demonstrated 36-month service life

Abiomed has reviewed vendor data and concluded the following reliability:

- The OXY-1 System's internal Oxygen Concentrator has a service life of 3 years

## Animal and Clinical testing

Abiomed has successfully conducted bio-compatibility testing to required support patient contact for ≤24hr.

## Potential risks

There are risks and adverse events related to all extracorporeal life support (ECLS) procedures and anticoagulation, including: heart, vessel, or lung damage, hypoxia or hypercarbia due to inadequate gas exchange, anemia, infection, hemorrhage, liver or kidney failure, stroke, and death.

See the device IFU for device-specific risks and potential adverse effects.

## Clinical signs or observations that suggest device changeout is necessary

The blood pump should be evaluated for changeout if the clinician determines during the extracorporeal procedure that adequate patient support is not being achieved. Examples of device performance-related indications that a changeout is needed may include inadvertent trauma or evidence of cracking, an audible rattling noise caused by air bubbles in the pump head, or severe hemolysis or thrombus formation

If a changeout is deemed necessary, obtain a replacement device before discontinuing circulation

through the original device.

To change out the pump:

1. Set up all necessary equipment to change out PLU Disposable:
    a. Sterile drapes and sterile scissors
    b. Minimum of 6 tubing clamps
    c. Disinfectant solution and applicators
    d. New, primed PLU Disposable with blood tubing cut to desired length and clamped
    e. Large syringe with saline solution for de-airing connector interface
    f. 3/8" sterile hose barb connectors
2. Install 3/8" hose barbs into replacement PLU Disposable blood tubes.
3. Position replacement PLU Disposable adjacent to the PLU Disposable being changed.
4. Use aseptic technique to create a sterile field and disinfect blood tube surfaces that will be cut for implantation of the replacement PLU Disposable.
5. Clamp Return and Drainage blood lines on both sides of the tube transected locations. Set Pump RPM to 0.
6. Cut blood tube between each pair of clamps.
7. De-air and connect replacement PLU Disposable with corresponding patient line. Verify the correct line matches the corresponding blood flow direction.
8. Repeat steps 6 & 7 for other set of blood tubing.
9. Remove failed PLU Disposable from Pump Driver and insert replacement PLU Disposable.
10. Remove Cable Guard.
11. Unclamp blood tubing and increase pump speed to return blood flow to desired set point.
12. Inspect for presence of air bubbles as flow is restored.
13. At Console, change out failed PLU Disposable gas tubing with replacement PLU Disposable gas tubing.
14. Verify sweep gas flow is restored to the PLU Disposable.
15. Reattach Cable Guard.

## Use conditions

The intended users are patients who are experiencing acute respiratory failure or acute cardiopulmonary failure, and the duration of use is likely to extend beyond the labeled 6-hour indication. There are no other changes to the intended use as described in the instructions for use for these devices. There are no changes to the contraindications as described in the instructions for use for these devices.