

**SPECIAL SUPPLEMENT TO DIRECTIONS FOR USE: EASYFLOW AORTIC CANNULA
TEMPORARY MODIFICATION TO INDICATIONS FOR USE TO ADDRESS COVID-19**

BACKGROUND

The United States Food and Drug Administration issued a guidance document *Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency* (Monday, April 6, 2020) to expand the availability of devices used in extracorporeal membrane oxygenation (ECMO) therapy to address the Coronavirus Disease 2019 (COVID-19) Pandemic. This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary.

COVID-19 can trigger acute respiratory failure and/or acute cardiopulmonary failure. Under such conditions, long-term extracorporeal oxygenation (i.e., extracorporeal oxygenation for greater than 6 hours) can be an important tool for treating patients and FDA recognizes the importance and utility of increased availability of extracorporeal oxygenation devices for patients during the COVID-19 public health emergency. Cardiopulmonary bypass devices, cleared or approved by FDA, are technologically capable of being used for ECMO therapy, providing extracorporeal oxygenation for longer than 6 hours. Therefore, to facilitate expanded availability of devices to perform ECMO therapy to treat COVID-19 patients, FDA is permitting manufacturers of cardiopulmonary bypass devices to modify the indications for use of their devices to include ECMO greater than 6 hours, without prior submission of a premarket notification to FDA (i.e. FDA clearance).

EasyFlow™ Aortic Cannula	
Catalogue Number	Device Description
103-200	19 French: 0.25 inch (6.3 mm)
103-300	23 French: 0.30 inch (7.7 mm)

INDICATIONS FOR USE

FDA-Cleared Indications for Use

The EasyFlow™ Aortic Cannula is intended for use in the perfusion of the aorta during cardiovascular surgery procedures requiring extracorporeal cardiopulmonary bypass for up to 6 hours.

Special Indications for Use permitted by FDA on a temporary basis to address the COVID-19 pandemic

The device can be used in an ECMO circuit to treat patients who are experiencing acute respiratory failure and/or acute cardiopulmonary failure. The device can be used in an ECMO circuit greater than 6 hours.

ADDITIONAL INFORMATION RELATED TO SPECIAL INDICATIONS FOR USE

The following information provides an addendum to the existing FDA-Cleared Directions for Use (DFU) about the device related to the Special Indications for Use.

Device Performance

Device performance is the same as that established in the DFU.

Summary of Durability Testing

The summary of durability testing is the same as that established in the DFU.

Summary of Animal Testing

There is no additional animal testing related to use for ECMO greater than 6 hours.

Summary of Clinical Testing

The summary of clinical testing is the same as that established in the DFU.



Potential Risk

Common complications of currently used peripheral cannulas are bleeding, thrombosis and hemolysis. (Svitlana Strunina, 2019)

Infection:

Per guidelines provide by the Extracorporeal Life Support Organization (ELSO): *“The cannula sites are cleaned frequently with antiseptic solution and may be covered with an antiseptic cream or ointment. Appropriate antibiotics should be given for documented infection. There is no standard policy regarding prophylactic antibiotics simply because the patient is on ExtraCorporeal Life Support (ECLS). Bacteremia during ECLS may be related to bacterial growth on a component of the circuit, but is usually related to another source in the patient. Unlike suspected “line sepsis” in the usual critically ill patient, it is usually not possible to change the access cannulas if contamination is suspected, and it may be dangerous to change the circuit. If all other sources of bacteremia have been ruled out, the entire circuit up to the cannulas can be changed expeditiously.”* (ELSO, ELSO Adult Respiratory Failure Guidelines, 2017, p. 24)

Management of the cannula and cannulation site should always be maintained using aseptic technique, and non-acetone containing cleansing agents and dressing are advised.

Decannulation:

Per guidelines provide by the Extracorporeal Life Support Organization (ELSO): *“This is the most common site of bleeding, particularly if access has been gained by direct cutdown. Bleeding at the cannulation site may be an indication that the cannula is loose or pulling out. Topical pressure will often control the bleeding, although care must be taken to avoid compressing the cannula. If bleeding persists after direct cutdown access the wound should be reexplored.”* (ELSO, ELSO Adult Respiratory Failure Guidelines, 2017, p. 25)

Improper clamping or device fixation may lead to device failure and bleeding.

Clinical Signs and Observations that suggest device change-out is required

Cannulae thrombosis is reported at rates ranging from 0.3-8.5% in the ELSO registry as a circuit thrombosis event. (ELSO, 2020) Thrombus that impedes flow through the cannulae can manifest acutely or develop over time. (Burrell, 2018) In determining if a cannula has thrombosed, it is important to troubleshoot along with other system components. Indication of cannulae thrombosis can include:

- Increasing afterload conditions in circuit without other manifestations in patient
- Decreasing preload conditions in the circuit without other manifestations in patient
- Concomitant increase/decrease in pressure gradients across the cannula
- Inability to achieve goal flow despite optimal patient and ECLS system management.

Use Conditions

Conditions of Use are addressed in the existing DFU.

References

- Burrell, e. a. (2018). *Complications of Mechanical Circulatory and Respiratory Support. In Mechanical Circulatory and Respiratory Support (pp. 498-499). Elsevier.*
- ELSO. (2020). *ELSO Registry Reports - Complications. Retrieved from https://www.else.org/Portals/0/Files/Reports/2020_January/Complication%20Trend%20Report%20January%202020.pdf*
- ELSO, *ELSO Adult Respiratory Failure Guidelines. (2017). ELSO Adult Respiratory Failure Guidelines.*
- Svitlana Strunina, J. H. (2019). *The peripheral cannulas in extracorporeal life support. Biomed. Eng.-Biomed. Tech, 64(2): 127–133.*

