SPECIAL SUPPLEMENT TO DIRECTIONS FOR USE: REVOLUTION Ph.I.S.I.O. Centrifugal Blood Pump

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).

Device model	Catalogue Number
Revolution Ph.I.S.I.O.	050300700

INDICATIONS FOR USE

FDA-Cleared Indications for Use

The REVOLUTION Ph.I.S.I.O. Centrifugal Blood Pump utilizes a rotating, vanes impeller design to move blood by centrifugal force. The pump is intended for use only with Sorin Group Deutschland Stöckert Centrifugal Pump Consoles in cardiopulmonary bypass procedures for periods of up to six 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.

ADDITIONAL INFORMATION RELATED TO SPECIAL INDICATIONS FOR USE

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

Device Performance

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

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Summary of Durability Testing

The Revolution Ph.I.S.I.O. has been tested regarding the general requirements of basic safety and essential performance in accordance with the international standard ISO 18242:2016 *Cardiovascular implants and extracorporeal systems — Centrifugal blood pumps*.

Available data confirm declared performance of the device up to 5 days use with a maximum flow rate of 5 l/min and maximum pressure of 500 mmHg.

When used for longer than 5 days, continuous monitoring is required to ensure correct device operation (refer to section ***Clinical Signs and Observations that suggest device change-out is required***).

Summary of Animal Testing

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

Summary of Clinical Performance

There is clinical evidence relevant to the current FDA guidance for extended duration of use beyond the labelled six hours duration in the DFU. Numerous publications have evaluated safety and performance outcomes with LivaNova devices or in combination with other manufacturer devices to comprise the entire ECMO circuit. These studies have demonstrated adequacy of blood flow and gas exchange with complication type and frequency in keeping with current state of the art for extracorporeal cardiorespiratory support beyond the labeled 6 hours duration of use. [1-6]

The published literature confirms safety and efficacy for the use of the REVOLUTION Ph.I.S.I.O. for a wide variety of medical conditions requiring extended extracorporeal support.

Potential Risk

The following hazardous situations may arise during the use of the device in an ECMO circuit greater than 6 hours:

- Malfunction of mechanical components resulting in interruption of flow
- Degradation and/or corrosion of the blood contacting materials (with the possibility of particles passing through the CPB circuit to the patient)
- Leaks

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

General indications are provided on DFU at paragraph "**I. BLOOD PUMP CHANGE-OUT**".

"A spare blood pump head must always be available during clinical procedure. After 5 days of use with blood or if situations arise such that, on judgment of the person responsible for perfusion, the safety condition of the patient is compromised proceed to replace the device."
Development of the following signs should be carefully monitored and pump change-out should be considered:

- Reduced pumping capability
- Blood trauma
- Leaks

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Use Conditions

Intended use relevant to the current FDA guidance are identical to those in the product DFU with the exception of duration of use which is anticipated to exceed the existing labeled indications of six hours.

There are no additional contraindications for use relevant to the current FDA guidance beyond those provided in the product DFU.

See DUF at paragraph "**C. INTENDED USE**" and "**D. CONTRAINDICATIONS**".

References

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