April 20, 2020

Dear Customer,

The United States Food and Drug Administration, on Monday April 6, 2020, issued a guidance document to expand the availability of devices used for 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.

Cardiopulmonary devices, such as the devices listed in the table below, are technologically capable of being used for ECMO therapy for greater than 6 hours. FDA is permitting manufacturers of cardiopulmonary bypass devices to temporarily modify the Indications for Use to include ECMO therapy greater than 6 hours, without prior submission of a premarket notification to FDA.

The below devices 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 > 6 hours.

<table>
<thead>
<tr>
<th>Core Part Numbers</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>45-95-02, 48-30-00, 48-40-00, 48-50-00</td>
<td>S5 Heart-Lung Machine</td>
</tr>
<tr>
<td>60-00-60</td>
<td>CP5 Centrifugal Pump Driver</td>
</tr>
<tr>
<td>050000000, 050300700</td>
<td>Revolution Centrifugal Pump</td>
</tr>
<tr>
<td>050700, 050725, 050701</td>
<td>Inspire Family of Oxygenators</td>
</tr>
<tr>
<td>050576</td>
<td>EOS PMP Oxygenator</td>
</tr>
</tbody>
</table>

*Other part numbers that include these devices in different configurations are also covered by this supplement.

Note: While some legacy LivaNova products may also meet the functional demands of this treatment type, only devices that are actively manufactured and sold by LivaNova are formally covered by this supplement.

A Special Supplement to the product package insert will be included with each associated disposable shipment. The Special Supplement contains the temporary Indications for Use statement as well as the following information related the product’s use in ECMO:

- Device Performance
- Summary of Durability Testing
- Summary of Animal Testing
- Summary of Clinical Testing
- Potential Risk
- Clinical Signs and Observations that suggest device change-out is required:
- Use Conditions

The Special Supplement to the product package inserts can be accessed by visiting the LivaNova website at www.livanova.com/coronavirus or by visiting each specific product page through the LivaNova website at www.livanova.com.

Best Regards,

LivaNova Cardiac Surgery Team