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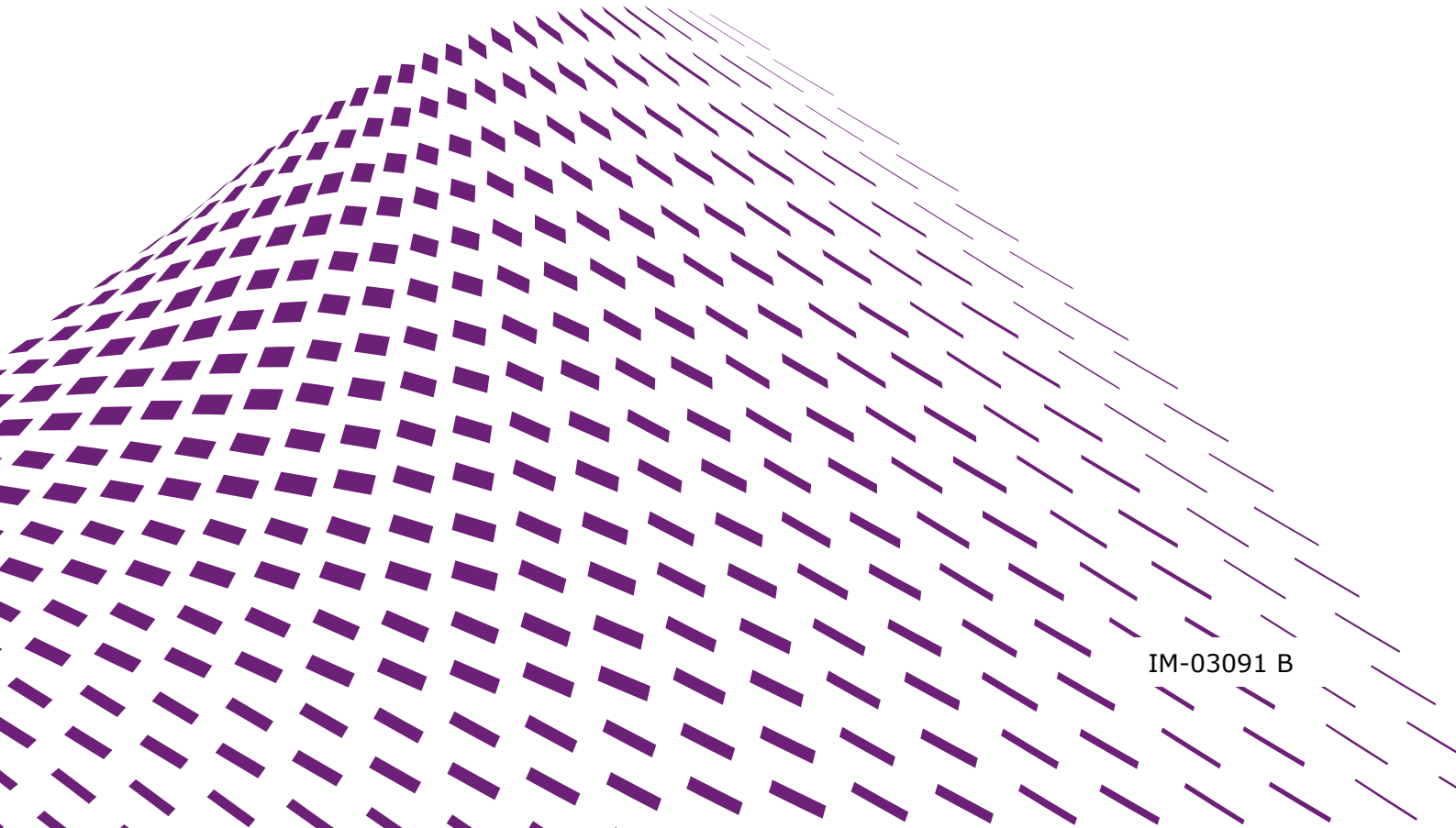
Use of LivaNova ECMO/CPB Devices for Respiratory Support during the COVID-19/SARS-CoV-2 positive patients FAQs

April 20 2020



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1. Purpose

This document is intended to support health care providers during COVID-19/SARS–CoV2 pandemic with respect to several questions that have arisen regarding the use of oxygenators and cardiopulmonary products with COVID-19 patients.

The information provided in this communication is based on the scientific and technical information available at the time of publication in response to specific questions, and therefore subject to change. COVID 19/SARS – CoV2 is a new viral disease, and LivaNova does not currently have test data to support the topics addressed in the present communication. The Q&A has been developed according to LivaNova technical and theoretical knowledge.

2. Disclaimer

This information does not replace or alter current Indications or Instructions for Use of any device distributed by LivaNova. Users of devices distributed by LivaNova shall follow all applicable Instructions for Use. This information does not constitute a legal, medical or professional advice and the responsibility for deciding whether and how to use an oxygenator rests solely with the attending physician or healthcare provider.

3. When treating COVID-19 patients, is it possible for SARS – CoV2 virus to migrate to the gas side of ECMO Oxygenators?

ELSO (Extracorporeal Life Support Organization) has issued a guidance document with indications on ECMO treatment for COVID 19/SARS – CoV2 patients with Severe Cardiopulmonary Failure (1).

The current COVID 19/SARS – CoV2 outbreak may make ECMO support necessary in certain patients treated in the intensive care unit (ICU). Several questions have arisen regarding the transmission of respiratory viruses (H1N1, SARS, MERS and COVID-19) through the hollow fibers of Extracorporeal Membrane Oxygenation (ECMO) oxygenators and the consequent cross-contamination of Intensive Care Units (ICUs) and Operating Rooms (OR) environment by aerosolization of exhaled gas exiting the oxygenator gas outlet port.

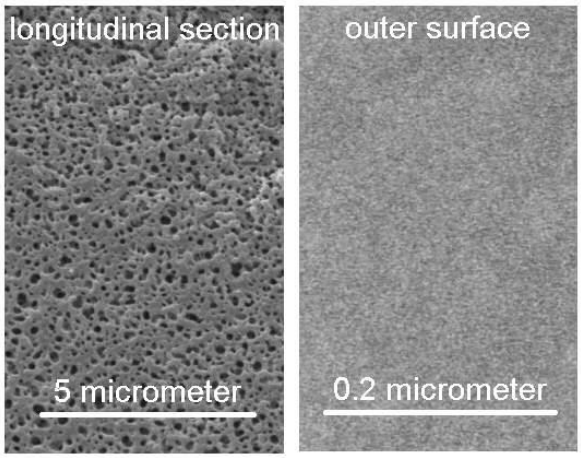

Figure 1 - SEMs of PMP fiber

The membrane material of LivaNova ECMO oxygenators is made of polymethyl pentene (PMP). These fibers have an even pore distribution throughout the whole wall thickness and are covered by a high-density polymeric skin of about 1 µm thickness. Membrane pores are of non-measurable dimension (see SEM images of Figure 1), which is designed to make the fibers impervious to plasma transmission. The dense outer skin provides an additional barrier against migration of liquids preventing the wetting of the capillaries and avoiding the passage of liquids

(like plasma or water) across the pores and into the fiber lumen. More specifically, the outer skin allows oxygen and carbon dioxide transfer across the fiber wall but avoids direct contact between blood and gas. Gases can diffuse through the membrane fiber wall thickness by mass transfer driven by the partial pressure positive gradient present between the gas compartment and the blood path. LivaNova performs leak testing during manufacturing on 100% of all ECMO devices and discards all units showing any evidence of leak.

As of today, LivaNova has no clinical evidence that the COVID 19/SARS – CoV2 penetrates or diffuses through the PMP membrane used in ECMO oxygenators that we manufacture. At this time, no case of COVID 19/SARS – CoV2 virus transmission has been reported associated with the use of LivaNova ECMO devices. Adherence to World Health Organization, national and local health organizations recommendations for healthcare providers regarding use of standard protective measures during surgeries and procedures should be observed. (2) (3) (4).

This assumes that the PMP membrane barrier remains intact and the oxygenators are used in accordance with the recommended Instructions for Use.

4. When treating COVID-19 patients, is it possible for SARS – CoV2 virus to migrate to the gas side of Polypropylene (PP) CPB Oxygenators?

Unlike the ECMO membrane oxygenators, the membrane used to produce oxygenators designed for cardiopulmonary bypass (CPB) is a porous Polypropylene (PP) membrane. This membrane, in intact conditions and within the limits of use described in the instructions for use for CPB applications, is waterproof. LivaNova tests 100% of its CPB oxygenators to determine the presence of leaks.

As of today, LivaNova has no clinical evidence that the COVID 19/SARS – CoV2 penetrates or diffuses through the PP membrane and into the gas side of PP CPB oxygenators manufactured by LivaNova. This assumes that the PP CPB oxygenator is used according to the instructions for CPB use including the time limits specified.

5. Is there any existing clinical/scientific evidence regarding the transmission of respiratory viruses (H1N1, SARS, MERS and COVID-19) through ECMO or CPB oxygenators?

This is an evolving area of study and we are not aware of any published papers on this topic. In patients with viremia there is the theoretical possibility of passage of virus from blood through the fiber membrane into the exhaled gas from oxygenators, particularly in the presence of plasma leakage across the membrane (5) (6). LivaNova has not performed specific testing of oxygenators to evaluate the likelihood of this occurrence and the available clinical evidence to this date is insufficient to quantify any associated risks. Use of polymethylpentene (PMP) membrane oxygenators may mitigate the risk of virus passage across the oxygenator membrane (ref. answer to question 3). Local Standard Operating Procedure (SOP) of the institution for dealing with infectious patients should be followed throughout device operation.

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6. Is it necessary to modify the current LivaNova devices disinfection procedure to deal with SARS – CoV2 Virus?

LivaNova has not tested the disinfection and cleaning processes specifically for the SARS – CoV2 Virus; however, the risk of cross-contamination is already contemplated in the design of our devices and at present there is no clinical evidence to suggest any changes are necessary.

When operating LivaNova equipment, LivaNova recommends that users should always follow disinfection recommendations included in the Instructions for Use, and as appropriate, supplement such disinfection procedures with any other recommendations coming from your organization or competent health authorities (e.g. use of common alcohol-based disinfectant have demonstrated effectiveness in eliminating SARS – CoV2 Virus (7) (8)).

7. Conclusions

COVID 19/SARS – CoV2 is a new viral disease that can contribute to severe respiratory failure and acute respiratory distress syndrome. Any additional clinical or other scientific information that becomes available from the medical community in relation to the use of our oxygenators and cardiopulmonary products with COVID-19 patients will be carefully analyzed. LivaNova will endeavor to share with customers and business partners any relevant information or data that becomes available. Given the rapidly evolving situation, LivaNova strongly recommends that health care providers carefully monitor new guidance and research from relevant authorities and medical societies.

References

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For professional use. Please contact us through our website to receive instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Not approved in all geographies. Consult your labeling

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