K962067

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# SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

Proprietary Device Name: CAPIOX® SX25 Hollow Fiber Oxygenator with detachable Hardshell Reservoir

Classification Name: Cardiopulmonary bypass oxygenator, heat exchanger, reservoir, defoamer, blood filter and manifold.

Intended Use:

The CAPIOX® SX25 Hollow Fiber Oxygenator is used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery. The integral heat exchanger is used to warm or cool the blood or perfusion fluid flowing through the device.

The CAPIOX SX25 Hardshell Reservoir (detachable) is used to store blood during extracorporeal circulation from both the venous line and the cardiotomy line. The reservoir contains filters to remove particulate matter and defoamers to facilitate air bubble removal.

Description

CAPIOX® SX25 Hollow Fiber Oxygenator contains an integrated heat exchanger and a detachable Hardshell Reservoir. This design permits an integrated system for ease of use as well as independent use of the oxyegnator and of the Hardshell reservoir to accommodate a variety of circuit configurations.

The SX25 oxygenator is a membrane oxygenator consisting of microporous hollow fibers with an integrated heat exchanger, consisting of stainless steel tubes.

The detachable Hardshell reservoir has a rotatable connection with the oxygenator which permits optimum positioning for connections in the circuit. The venous blood inlet port is also rotatable to permit minimizing tubing lengths which could result in lower circuit priming volumes.

The Hardshell reservoir contains a defoamer and a screen filter in the venous blood inlet section. The total capacity of the reservoir is 4,000 mL.

The cardiotomy section of the hardshell reservoir contains a defoamer and a cardiotomy filter to facilitate gas bubble removal and the removal of particulates/emboli from suctioned blood entering the reservoir.

A detachable sampling system is positioned at the top of the hardshell reservoir which contains 3 three-way stopcocks. These stopcocks can be used for sampling. The sampling system contains a one-way valve permitting withdrawal of liquid samples but prohibiting entry of air into the blood exiting the oxygenator.

## Substantial Equivalence

The CAPIOX® SX25 Oxygenator and Hardshell Reservoir are substantially equivalent to the CAPIOX SX18 Oxygenator and Hardshell Reservoir as follows:

Intended use: same

Design and Materials:

The basic device design and all materials for the SX25 and the SX18 are the same.

The CAPIOX SX25 has a larger membrane surface area than the SX18.

Both the CAPIOX SX25 and the CAPIOX SX18 have the same integrated heat exchangers and the same detachable hardshell reservoir.

## Technology and Principles of Operation

These devices (SX18 and SX25) use hollow fiber membrane technology and utilize gravity and/or external vacuum (cardiotomy) for blood collection into the reservoir. Air removal is facilitated by defoamers and the tendency of air to rise through liquid. Particulate removal is facilitated by the blood flow pathway through filters contained in the reservoirs. Some form of pumping mechanism is utilized to transfer blood from the reservoir component to the oxygenator component.

The technology and principles of operation for the SX25 and the SX18 are the same.

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Specifications

The priming volume for the SX25 is slightly higher than that for the SX18 (340 versus 270 mL, respectively) because of the increased membrane area. The membrane surface area of the SX25 is 2.5 $m^2$ and that for the SX18 is 1.8 $m^2$. This difference does not affect the substantial equivalence of the devices since both provide adequate gas exchange for clinical use.

Maximum blood flow rate for both devices is 7 LPM for venous flow and 5 LPM for cardiotomy flow.

The heat exchanger and the detachable hardshell reservoir are the same for both devices.

Performance

Comparison of the SX25 and SX18 performance was conducted. The following tests were performed:

- Gas Transfer (short term and 6-hour)
- Effect on Blood Components
- Pressure Drop

Note: The heat exchanger and the detachable hardshell reservoir are the same for both devices. Performance testing for these components was presented in K922799. Additionally, the effect on blood components of the cardiotomy section was presented.

In summary, the expected increase of gas transfer and decreased pressure drop was observed for the SX25 due to the increased surface area. Effect on blood components was substantially equivalent.

The SX25 and the SX18 are substantially equivalent in intended use, design and materials, technology/principles of operation, and specification with the exception of the increased membrane surface area. Differences as described above do not raise new issues of safety or effectiveness.

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Additional Safety Information

•Sterilization conditions have been validated to provide a Sterility Assurance Level (SAL) of $10^{-6}$.

•Ethylene oxide residuals will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal Register of June 23, 1978 (or as finalized or amended).

•Manufacturing control tests include 100% performance and leak testing.

•Blood contacting materials are acceptable in accordance with the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, " Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (External communicating devices/Circulating Blood/Limited contact duration).

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Prepared by: Sandi Hartka, M.A.S., R.A.C.
Submissions Supervisor
Regulatory Affairs

for: Terumo Medical Corporation
2100 Cottontail Lane
Somerset, NJ 08873