Instructions for Disposable Activated Leukocyte Adsorber

1. Product Name

Disposable Activated Leukocyte Adsorber (hereinafter referred to as "Adsorber").

2. Model and Specifications

SYT-AICT-4: Suitable for patients weighing ≥40 kg, supplied with connecting tubing.

3. Registrant Information

Registrant / Entrusting Party: Chengdu Shangyuan Tai Biotechnology Co., Ltd.

Address: Room 1506, 15th Floor, Building 1, No.1800 Yizhou Avenue Middle Section, High-Tech Zone, Chengdu, Sichuan Pilot Free Trade Zone, China.

4. Manufacturing Information

Manufacturer / Contract Manufacturer: Sichuan Shuanglu Medical Device Co., Ltd.

Address: Xingyuan Road, Shigao Economic Development Zone, Tianfu New District, Renshou, Sichuan, China.

Manufacturing License No.: Chuan Yao Jian Xie Sheng Chan Xu 20150057.

Tel: (028) 37390389 / 37390033

Postal Code: 620564

Email: ShuangLu@SLKF.cn

Website: http://www.slkf.cn

5. Product Performance

Adsorption Performance:

Total leukocyte removal rate: ≥10% ;

CD11b+ neutrophil removal rate: ≥50% ;

Red blood cell recovery rate: ≥85% ;

Platelet recovery rate: ≥80% ;

Free hemoglobin in blood post-adsorption: ≤300 mg/L .

6.Main Components and Structure

The Adsorber consists of an external port cap, end cap, housing, flow distribution mesh, adsorption membrane, core rod, sealing ring, connecting tube, two-way connector (with connecting tube as an optional accessory), and two-way connector cap.

The connecting tube is composed of an inner port cap, inner port, catheter, external conical connector, protective sleeve, and flow clamp.

A schematic diagram of the Adsorber structure is shown in Figure 1.

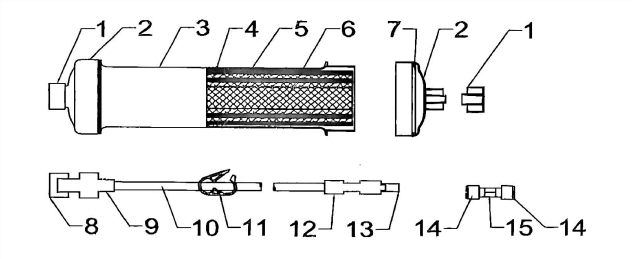

Figure 1. Structural diagram of the Adsorber

As shown in Figure 1, the Adsorber is composed of the following components: external port cap (1), end cap (2), housing (3), flow distribution mesh (4), adsorption membrane (5), core rod (6), sealing

ring (7), inner port cap (8), port (9), catheter (10), flow clamp (11), external conical connector (12), protective sleeve (13), two-way connector cap (14), and two-way connector (15).

7. Intended Use

The device is intended for the removal of activated leukocytes from blood during extracorporeal circulation.

8. Contraindications

No absolute contraindications.

Contraindicated in patients with severe thrombocytopenia, cytopenia, or coagulation disorders.

Patients must be closely monitored during use. In case of severe adverse reactions, discontinue use immediately and manage appropriately.

9. Precautions

The Adsorber is specifically designed for leukocyte removal during cardiopulmonary bypass procedures.

Blood must be anticoagulated according to physician's instructions.

Maximum inlet pressure: ≤67 kPa (≈500 mmHg).

The Adsorber must be used during rewarming in cardiopulmonary bypass surgery. Recommended use: 20 minutes; maximum use time: 1 hour.

Recommended flow rate: 250–1000 mL/min.

Extended blood contact beyond 1 hour is not advised.

10. Warnings

Improper transportation or storage may damage the device.

The Adsorber is supplied sterile. Do not use if packaging is damaged.

Do not expose to alcohol, ether, acetone, or other organic solvents.

Ensure adequate anticoagulation monitoring before, during, and after cardiopulmonary bypass surgery.

Dispose of used devices as per local medical waste regulations.

11. Instructions for Use

11.1 Compatible Devices

The Adsorber may be utilized in conjunction with any oxygenator and cardiopulmonary perfusion system once the specified conditions have been met. Connection to the blood inlet and outlet of the Adsorber shall be established using Luer connectors (Figure 2). During perfusion, the inlet pressure of the Adsorber must be continuously monitored.

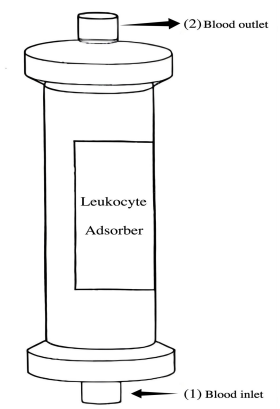

Figure 2. Illustration of Blood Inlet and Outlet

11.2 Installation （Figure 3.Illustrative Connection Diagram）

Prior to use, the appearance and integrity of the Adsorber shall be carefully inspected. During operation, the device shall be maintained in a vertical orientation. The product shall be used immediately after opening.

(1) Remove the protective caps from the blood inlet (1) and blood outlet (2). The inlet and outlet are non-directional and may be connected to the corresponding tubing.

(2) Insert the Adsorber into the holder with the blood inlet oriented downward, maintaining a vertical position.

(3) When used in conjunction with an oxygenator, the Adsorber may be connected directly via the side port.

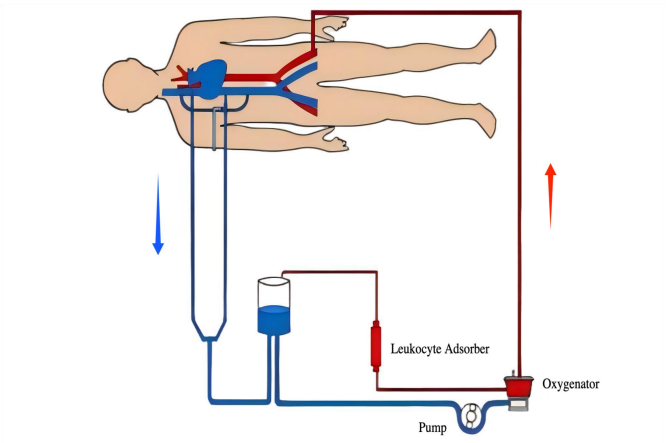

Figure 3.Illustrative Connection Diagram

11.3 Priming

The Adsorber shall be primed with 500 mL physiological saline containing anticoagulant via the two-way connector to prepare the blood-contacting surface. The outlet tubing should then be clamped to release residual microbubbles. The device may be used only after all bubbles have been completely removed.

11.4 Initiation of Adsorption

During operation, the Adsorber must be kept vertical. Both inlet and outlet valves are opened to establish flow, and blood should be introduced gradually. The inlet pressure must not exceed 67 kPa (≈500 mmHg). The system must be continuously inspected for leakage or excessive blood loss. If significant loss occurs, the blood in the Adsorber must be promptly returned to the patient and use discontinued.

11.5 Termination

At the end of adsorption, both inlet and outlet valves are closed.

12. Storage and Maintenance

The product shall be stored in a clean, well-ventilated environment, free from corrosive gases, with adequate protection.

13. Manufacturing Information

Manufacture date, expiration date, and sterilization date are indicated on the package label. Shelf life: 2 years. Sterilization method: ethylene oxide.

14. Package Contents

One complete product and one instruction manual.

15.Date of Compilation or Revision of the Instructions

Instruction Manual Version: V1.0.0; Date of Compilation: April 20, 2023.