



The STEEN perfusate and XPS ex-vivo machine perfusion methodology permit:

- A more refined functional ex-vivo evaluation of accept/reject criteria
- Normothermic functional evaluation without oedema formation
- Permits more rational allocation and use of donor lungs

FOR RELIABLE OBJECTIVE RE-ASSESSMENT OF “MARGINAL” AND REJECTED LUNGS

Ex-vivo assessment with STEEN Solution™ can expand your donor lung pool. About four of every five lungs offered for transplantation are currently rejected by present selection criteria.^{1,2}

However, rejected lungs from marginal and extended donors have been successfully used for transplantation for well over a decade and the concept has now become routine practice.^{3,4,5,18,19,20}

The ex-vivo assessment of marginal lung function, including gaseous exchange at 37°C, was originally developed by Steen et al^{6,7,8,9,10} and has since been adopted and modified by other centres.^{12,13} The method is now an established clinical routine in most major lung transplant centres world-wide.^{11,18,19,21-24}

With EVLP, the perfusion circuit of the lung mimics in-vivo conditions; the ventilated lung is perfused with deoxygenated STEEN Solution™ with or without red cells and the critical parameters of gaseous exchange, pulmonary vascular resistance and other key variables under normothermic conditions are monitored.

The STEEN perfusate and circuitry can maintain stable lung function, without oedema formation, for up to 10 hours at 37°C.^{7,12,20-24}

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STEEN Solution™ is intended for assessment of isolated lungs after removal from the donor body for eventual transplantation into a recipient.

HOW SUPPLIED: REF 19004; 500 mL bottle.

STEEN SOLUTION™ FDA application pending in the USA.

MAINTAINS STABILITY OF ISOLATED LUNGS EX-VIVO

STEEN Solution™ is a buffered extracellular solution that includes human serum albumin to provide an optimal colloid osmotic pressure and dextran 40 to coat and protect the endothelium from excessive leucocyte interaction. STEEN Solution™ is designed to facilitate prolonged evaluation and promote stability of isolated lungs ex vivo.

STEEN SOLUTION™ CONTAINS

- Human Serum Albumin – provides normal oncotic pressure preventing oedema formation.
- Dextran – a mild scavenger which coats and protects endothelium from subsequent excessive leucocyte interaction^{14, 15} and thrombogenesis¹⁶
- Extra-cellular electrolyte composition (lowK⁺) – reduces free radical generation¹⁷ and avoids vascular spasm under normothermic conditions.

LUNG EVALUATION SET-UP

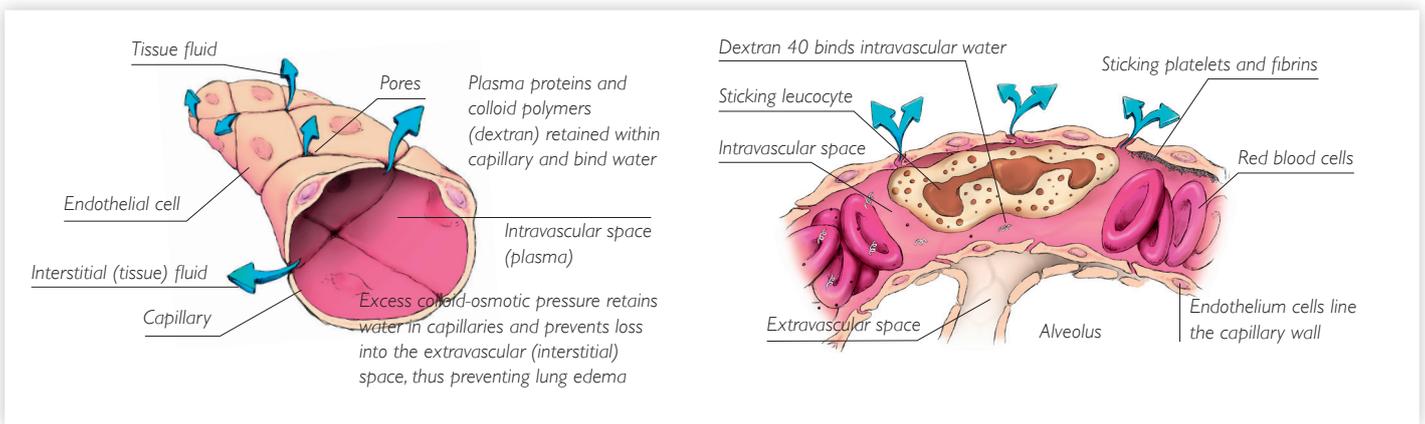
The lungs or the heart-lung block are enclosed in a transparent plastic dome-like container to maintain optimal humidity.

The "venous" afferent side of the closed circuit is connected to a pump and a heat and gas exchanger so that the perfusate – STEEN Solution™ (with or without red blood cells) – assumes physiological temperature and partial gas pressures. A leucocyte filter is connected before the inflow to prevent leucocyte-induced tissue injury. Perfusion pressure is closely monitored and should never exceed 20 mm Hg.

Since the lungs are generally cold before perfusion, initial flow rates must be very low, gradually increasing as the temperature increases. The flow should never exceed 4 l/min. Careful ventilation is

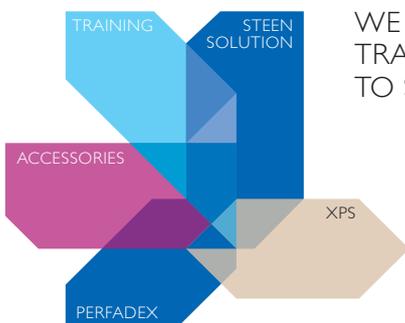
begun as the temperature of the perfusate out-flow reaches 32 °C and full ventilation is begun as it reaches 37 °C.

Functional assessment can begin when the circuit has reached the steady state described above, monitoring arterial and venous blood gases, end-tidal carbon dioxide and a range of hemodynamic parameters.



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