STEEN SOLUTION™

For reliable objective assessment of donor lungs

Ex vivo assessment with STEEN Solution™ can expand your lung donor 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 almost two decades and the concept has now become routine practice at some centers.[3, 4, 5, 16, 17, 18]

The *ex vivo* assessment of marginal lung function, including gaseous exchange at 37°C, was 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 clinically established in many major lung transplant centers worldwide.[16, 17, 19, 20, 21, 22]

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

Clinical evidence has verified that at least six hours of EVLP is safe with an acellular perfusate and that at least two hours is safe with a cellular perfusate. In the USA, the FDA has granted approval for up to four hours of EVLP with an acellular perfusate.[18, 19, 20, 21, 22]

The STEEN Solution™ perfusate used for EVLP permits:

- Refined functional *ex vivo* evaluation of accept/ reject criteria
- Oncotic pressure preventing edema formation
- Increased usage of donated lungs

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

Humanitarian Device. Authorized by Federal law in the USA for use in flushing and temporary continuous normothermic machine perfusion of initially unacceptable excised donor lungs during which time the ex vivo function of the lungs can be reassessed for transplantation. The effectiveness of this device for this use has not been demonstrated.

XVIVO PERFUSION

STEEN SOLUTION™

Maintains stability of isolated lungs ex vivo

STEEN Solution™ is a buffered extracellular solution that includes human serum albumin to provide an optimal oncotic 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™ offers flexibility in the choice of EVLP methodology. Safe use of STEEN Solution™ in the Scandinavian and the Toronto protocols is clinically documented.

STEEN Solution™ contains:

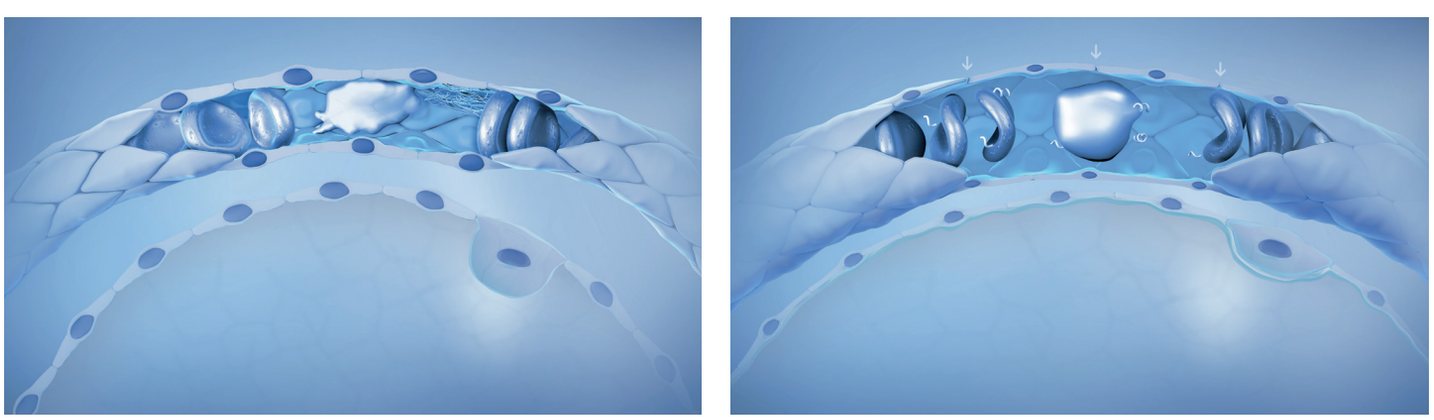
- Human Serum Albumin – provides normal oncotic pressure preventing edema formation
- Dextran 40 – a mild scavenger which coats and protects endothelium from subsequent excessive leucocyte interaction[14, 15]
- Extra-cellular electrolyte composition

Clinically evaluated EVLP protocols:

SCANDINAVIAN PROTOCOL	TORONTO PROTOCOL
Red blood cells	Acellular
Perfusion flow: 100% CO	Perfusion flow: 40% CO
Open left atrium	Closed left atrium
CE approved	FDA approved under an HDE

Supply information:

Reference:	Packaging:
19004	500 ml bottle



Plasma proteins (HSA) and colloid polymers (Dextran 40) bind and retain water within capillaries.

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