

Recombinant Human Interleukin-2 (rHu IL-2) Closed System Solutions™ (CSS)

General:

Akron's Recombinant Human Interleukin-2 (rHu IL-2) Closed System Solutions[™] (CSS) is packaged in sterile fluoropolymer bags with multiple closed-connection options, allowing for sterile docking into modern closed-system cell culture bioprocessing protocols. The liquid formulation and closed-system packaging of Akron's rHu IL-2 CSS increase safety and ease of use by eliminating the reconstitution step during manufacture and allows for the introduction of cytokine material into culture media in a fully contained manner.

A clean space and proper aseptic technique are recommended when handling Akron's rHu IL-2 CSS. Do not place heavy objects directly on top of the rHu IL-2 CSS bag, as too much pressure can jeopardize the integrity of the packaging. Ensure the pinch-clamp on the outlet tube is not released before a closed connection is made using the method described below. Each unit comes with a poly bag over-pouch and is packed in an individualized protective shipping cassette.

Connection Method – Weldable Tubing:

The main outlet tube that comes attached to the bag has two different sections, each made from a different weldable material to choose from. The top portion is made from weldable TPE AdvantaFlex[®] (1/8" ID x 1/4" OD) and is about 6" long. An in-line barb connector joins this to the bottom portion, which is made from standard weldable PVC (3/32" ID x 5/32" OD) and is about 6" long.

The other short sealed tube connected to the bag was used as the inlet tube and is not recommended for material removal. To make a weldable connection to rHu IL-2 CSS, follow the proceeding steps:

- Place chosen tube material section (TPE proximal, PVC distal) into tube welding machine along with process line and run standard aseptic welding protocol.
- Release the pinch-clamp on the outlet tube now welded to the process line.
- Allow solution from rHu IL-2 CSS bag to flow into your process line.
 - User can facilitate transfer by hand compressing the bag to expunge the rHu IL-2 CSS material.
 - User can allow for reverse flow to ensure full mixing of rHu IL-2 solution with culture media.



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