

Scope:

This bulletin covers changes required to prevent potential occlusion of top port during the pump-out sequences where the CS-1 removes the cryo-poor plasma from the CP-3's cryoprecipitate chamber.

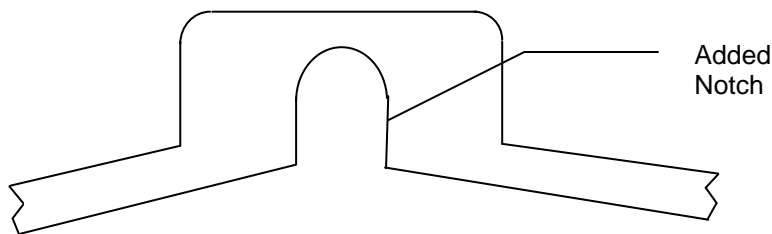
Background:

At the end of the CS-1 cycle the instrument removes the cryo-poor plasma from the CP-3's cryoprecipitate chamber leaving concentrated cryoprecipitate in the chamber for harvesting. In order for this step to be successful there must be a deep fluid channel present underneath the chamber's top port. Variations in depth of this fluid path have been found. In some CP-3s this fluid path can be very shallow and when the pump-out occurs, the thin film underneath the port can be drawn up towards the port and therefore occlude it. This leaves too much plasma in the chamber at the end of the cycle. To address this condition three modifications are required. See the following procedure.

Procedure:

1) Gasket Replacement

The CS-1 instrument currently utilizes two silicone gaskets between the blue heat transfer plate and the CP-3's cryoprecipitate chamber. The two gaskets are being consolidated into a single thicker gasket. The new gasket is equal in thickness to the two thinner gaskets, and will be easier to keep aligned on the CS-1. The new gasket also has an added notch on the top end as shown below:

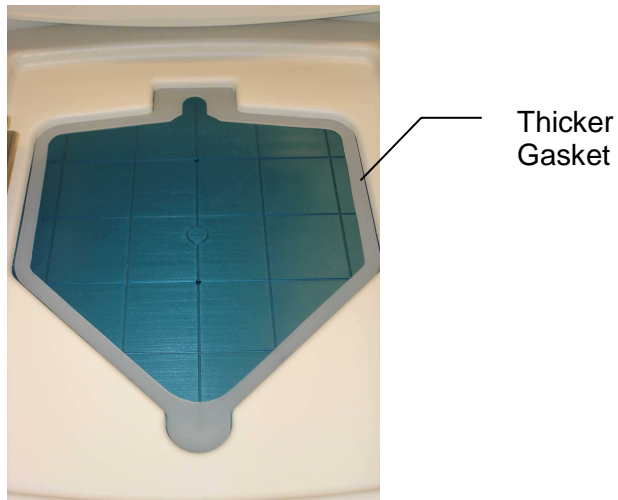


The notch is added to allow the vacuum suction from the CS-1's heat transfer plate to pull the film on the bottom of the CP-3's cryoprecipitate chamber away from the bottom of the top port. This change provides a deeper fluid path and will prevent potential occlusion upon pump-out.

- a. Remove and discard the two existing gaskets currently being used on the CS-1's heat transfer plate.

CAUTION: Dispose of replaced gaskets according to local biohazardous waste regulations.

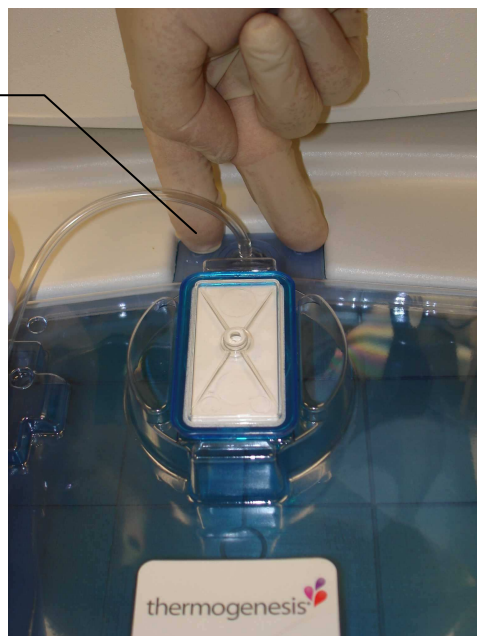
- b. Replace discarded gaskets with the supplied thicker gasket containing the notch depicted above. Align the gasket on the plate and insure it lays flat with no folds or twists.



2) Achieving Proper Vacuum Seal

To ensure proper vacuum seal when using the new gasket, an additional sealing technique will need to be performed. Upon placing the CP-3 onto the heat transfer plate, continue to press down on the top of the cryo chamber but also push down near the top edge of the plate as shown below to help achieve the vacuum seal required to begin the CS-1 cycle.

Push to help
achieve
vacuum seal



3) Final “Dry Cryo” Pump-out Technique

At the end of the CS-1 cycle when prompted to **REMOVE CRYO CHAMBER**, gently lift the cryo chamber from the heat transfer plate. The peristaltic pump will begin to pump out the final residual plasma left in the chamber. At this time push down on the chamber flange near the top port. See pictures below. The distortion of the flange will bulge the thin film under the top port, preventing the film from being drawn up and occluding the port during pump-out.



Continue to push down on the flange as long as the peristaltic pump is removing plasma from the chamber. If any residual plasma remains in the cryo chamber, open the peristaltic pump and let the excess drain by gravity.

Contact Information:

If you have any questions, contact THERMOGENESIS CORP. Technical Service at 800-783-8357 (U.S. and Canada) or 916-858-5100 (non-U.S./Canada), or fax to 916-858-5199, or email at support@thermogenesis.com for assistance.