

Purpose:

There have been reported instances of DMSO filter separations. Therefore a temporary corrective action is recommended.

Scope:

This technical services bulletin covers the process to affix a cable tie to the AXP processing bagset to ensure that the DMSO filter does not become detached. ThermoGenesis Corp will provide the Cable tie tool and training of this process.

Background:

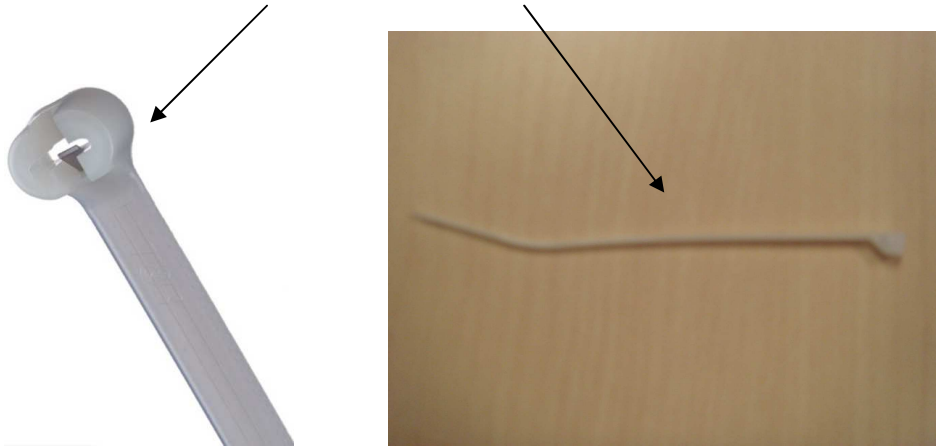
In August of 2008, a change was made in the DMSO tubing to one with a slightly larger dimension. This change has, in some instances, resulted in the loss of the required mechanical bonding between the tubing and filter stem, and ultimately in the filter separating during processing. Affixing a cable tie to the tubing at the filter stem prior to processing eliminates the potentiality of this issue.

In more than 4200 bagsets where the cable tie was affixed there have been zero (0) DMSO filter separations. In those instances prior to the use of the cable tie when the DMSO filter did separate, sterility testing after processing found no contamination of the samples.

Procedure:**1. Materials and Equipment**

- 1.1 Cable tie
 - 1.1.1 Manufacturer: TY-RAP
 - 1.1.2 Manufacturer Part Number: TY523M
 - 1.1.3 Suppliers:
 - 1.1.3.1 Grainger Part Number 3KG93
 - 1.1.3.2 Newark Part Number 31F2658

Cable tie pictures



1.2 Cable tie tool

1.2.1 Manufacturer: Panduit

1.2.2 Manufacturer Part Number: GS2BL

1.2.3 Suppliers:

1.2.3.1 Newark Part Number 88F3809

1.2.3.2 DigiKey Part Number GS2BL-ND



Tension Adjuster

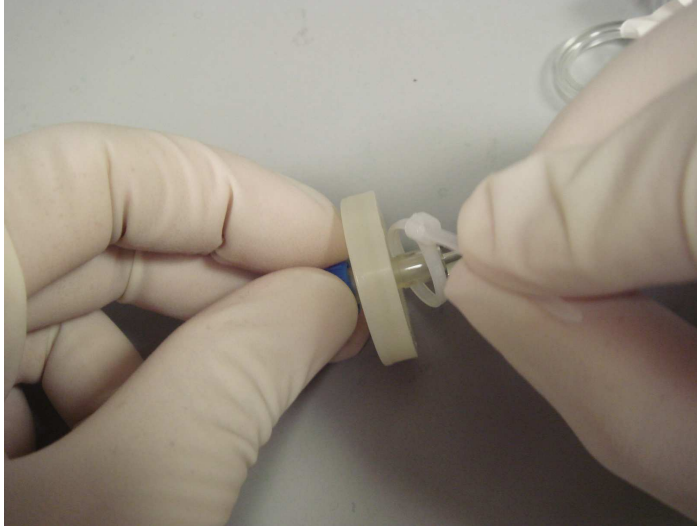
2. Set-Up

2.1 Place safety goggles over eyes.

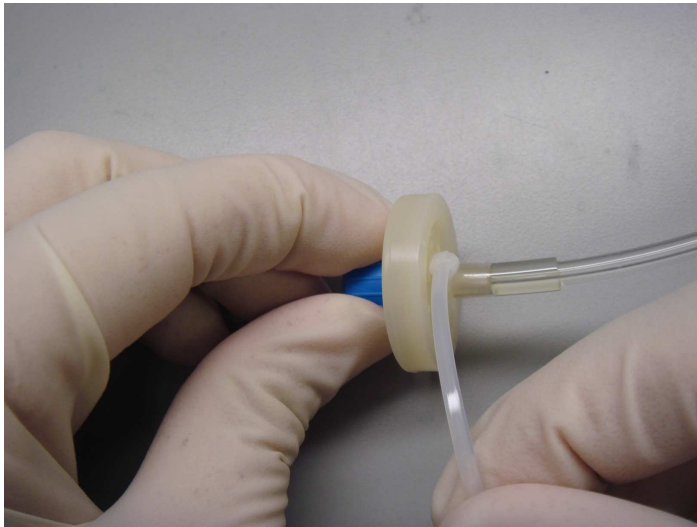
2.2 Check that the cable tie tool has the appropriate tension setting of “5” by turning the tension adjuster located on the bottom of the handle and viewed on the side of the handle. See picture above.

3. Procedure

- 3.1 Check the filter to ensure no cracking has occurred on the back surface of the filter
- 3.2 Place a cable tie around the tubing/ DMSO filter tubing connection by taking the small end and putting it through the hole on the other end of the cable tie.

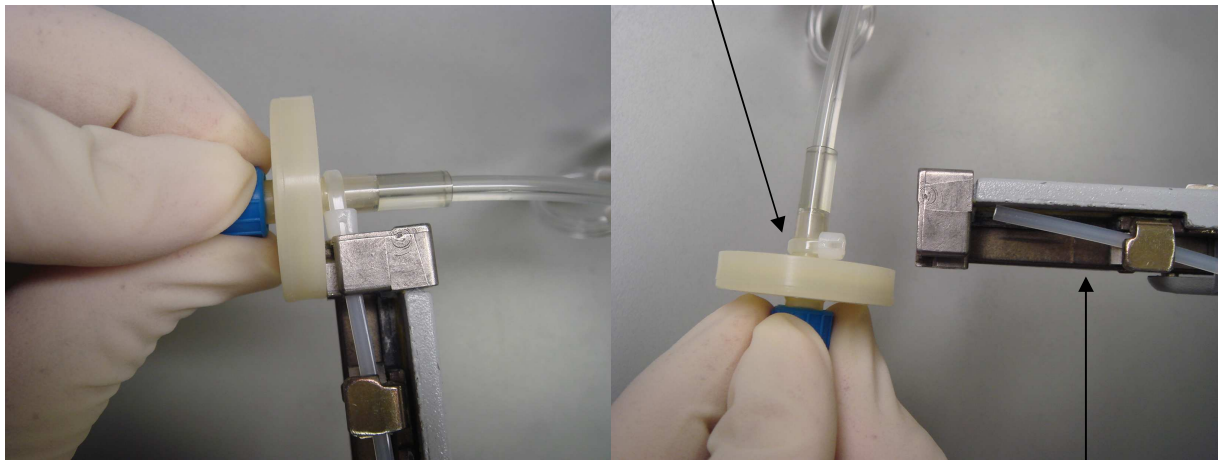


- 3.3 Close the cable tie around the outside of the tubing filter connection by pulling the thin end of the cable tie and holding the larger end until snug around the tubing.



- 3.4 Using the cable tie tool align the cable tie in the channel of the tool in picture #1 below. Close and cut the additional cable tie material around the DMSO filter male luer by pulling on the trigger handle of the cable tie tool. This will automatically cut the excess length of the cable tie shown in picture #2.

Secure cable tie



#1

#2

Cable tie tail

3.5 Once completed proceed to use the AXP processing bagset.

Contact Information:

If you have any questions, contact THERMOGENESIS CORP. Technical Service at 1-800-783-8357 (U.S. and Canada) or +1-916-858-5100 (non-U.S./Canada). You may also send a fax to +1-916-858-5199, or email at support@thermogenesis.com for assistance.