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BELMONTMEDTECH.COM

URGENT MEDICAL DEVICE CORRECTION

Hyperthermia Pump™ Disposable Sets

April 23, 2025

Dear Partner,

Belmont Medical Technologies has initiated a voluntary recall on the following disposable products used with Hyperthermia Pump™ (HP)

Product Name	Part Number	UDI
HP Procedure Kit	902-00045	00896128002589

Description of the Problem and Health Hazard(s):

An investigation of reported failures related to leaks observed on a female quick connector identified a defect in some disposable sets. The root cause was determined to be a manufacturing issue which caused a crack in the female quick connector located on the Heat Exchanger included in the sets. The defect will lead to a fluid leak through the crack in the female connector during priming of the Rapid Infuser.

The health hazards associated with this defect may lead to a potential delay in treatment since the set will need to be replaced by another set. To date, Belmont Medical Technologies has received zero (0) reports of death, and zero (0) reports of serious injuries related to this issue. The frequency of the defect occurring on the Hyperthermia Disposable Sets is estimated to be approximately 16%.

Affected Products:

Our records indicate that you may have one or more of these affected products, which were distributed in the United States between November 06, 2024, and February 25, 2025. The Lot Numbers of the affected disposable sets are:

Affected Lot Numbers	
P/N 902-00045	20241005 20251108

Required Actions:

1. Locate the Disposable Sets (P/N 903-00045) in your possession and check their lot numbers against the lot number listed above.
2. If the affected Disposable Sets were distributed to customers, please forward the Notification of the field action to customers who received the affected products.
3. Please complete the attached form and return the completed form to Belmont Medical Technologies per the instructions provided on the form.
4. Please complete regulatory reporting to the appropriate regulatory bodies if required by your country's regulations.

Actions Taken by Belmont Medical Technologies:

1. We have corrected the issue and are manufacturing products that are free of the defects listed above.
2. We will replace any product found defective and any affected products that have not yet been used.

Contact Information:

For any questions regarding this action, technical assistance, or to report an adverse event or product complaint, please contact your in-country representative or Belmont Medical Technologies directly:

1-855-387-4547
TECHSUPPORT@BELMONTMEDTECH.COM

Report any adverse event(s) related to the use of these devices to Belmont Medical Technologies. Events may also be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program either online, by regular mail, or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm
- Phone: Call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit it by fax to 1-800-FDA-0178

This recall is being issued with the knowledge of the Food and Drug Administration.

Belmont Medical Technologies is committed to patient and user safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Respectfully,

Lida Reed
Director, Quality Assurance and Regulatory Affairs

Customer Response Form

Hyperthermia Pump™

Disposable Sets (902-00045)

Please assist Belmont Medical Technologies by acknowledging this field action.

Return the completed form to the Email listed below:

Email: HPdisposableFA@belmontmedtech.com

Please check all that apply:

☐ The listed lots have been consumed and are no longer in the inventory

☐ The product is fully or partially in our inventory

Please identify the number of units in inventory

☐ I have read and understood the attached notice.

☐ I agree to notify customers and provide customers with the Customer Notification Letter provided by Belmont Medical Technologies

☐ I agree to execute required regulatory submissions per applicable regulatory requirements.

Distributor: _____

Completed By:

Print Name	Signature	Date
Title	Phone Number	e-mail

Appendix 1

URGENT MEDICAL DEVICE CORRECTION

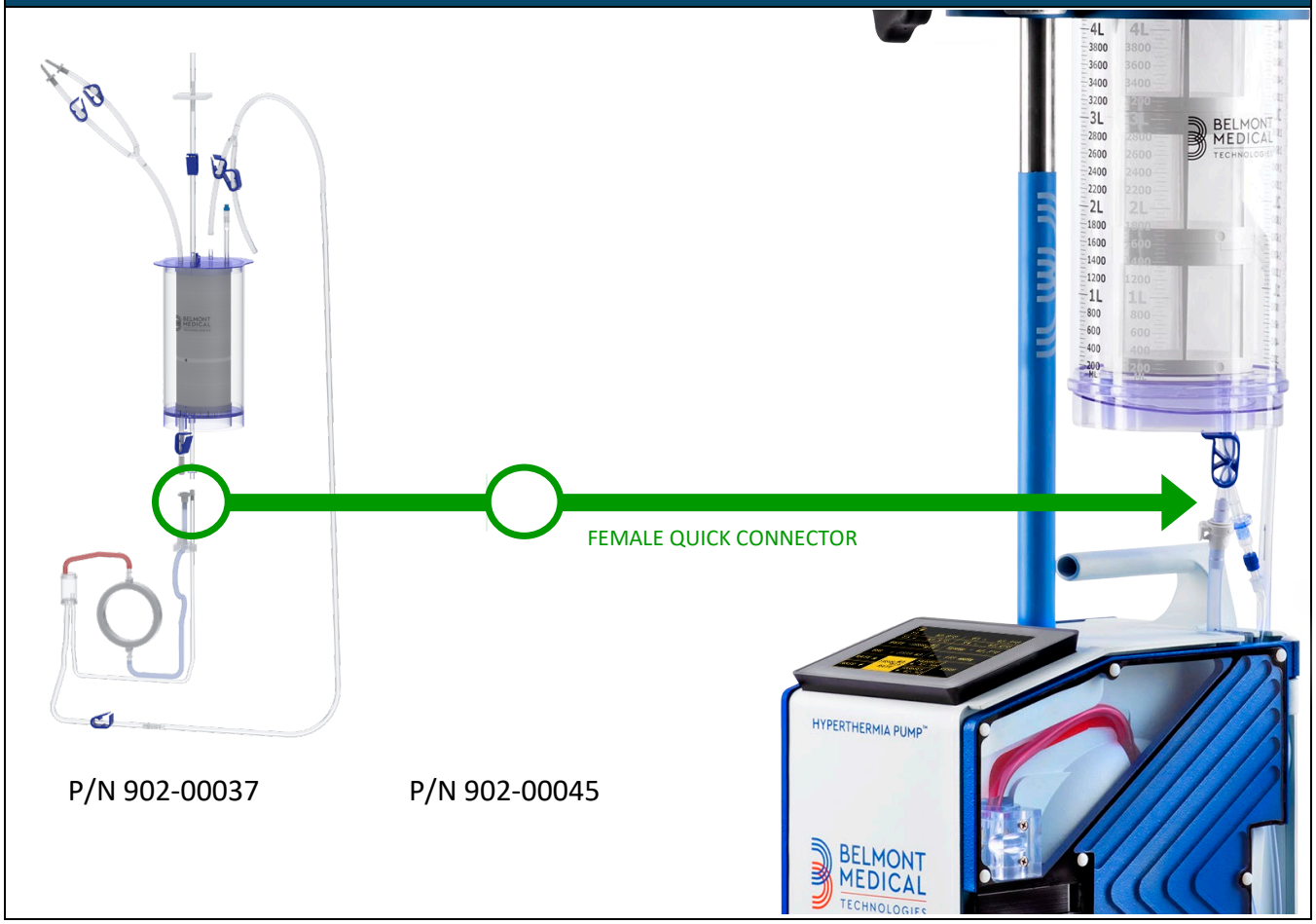
Hyperthermia Pump™

Affected Part Numbers and Lot Numbers	
P/N 902-00038	20241013

Instructions for Users of the Disposable Sets to Perform Immediately Prior to Use

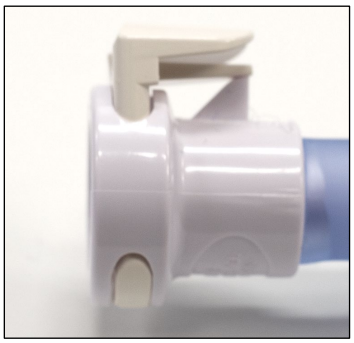
1. Verify the lot number. If the lot number on the package matches one of the lot numbers listed above, proceed with the inspection.
2. Remove the set from the packaging and visually inspect the female quick connector.

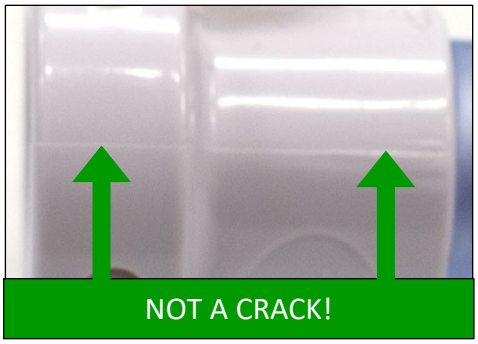
Location of Quick Connector



P/N 902-00037 P/N 902-00045

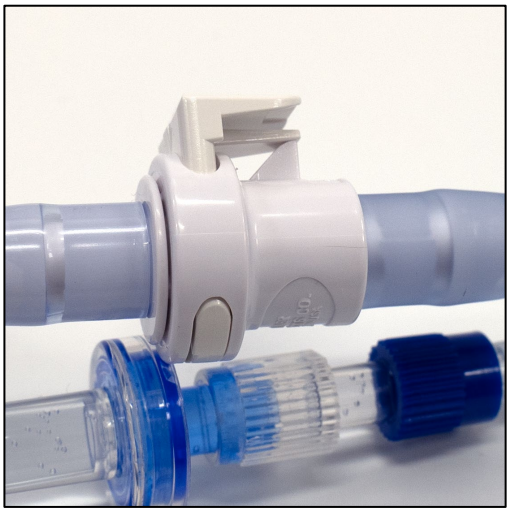
Acceptable Connector Examples

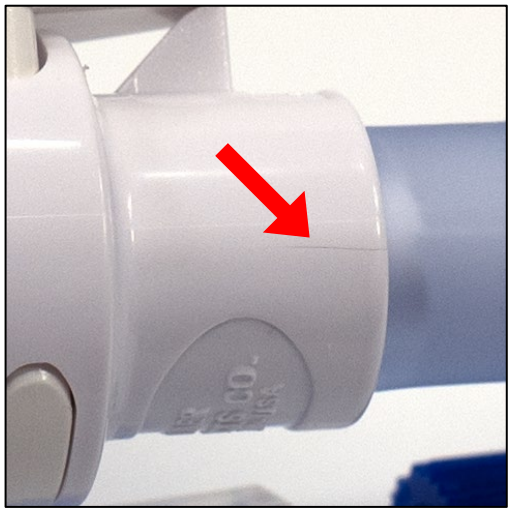




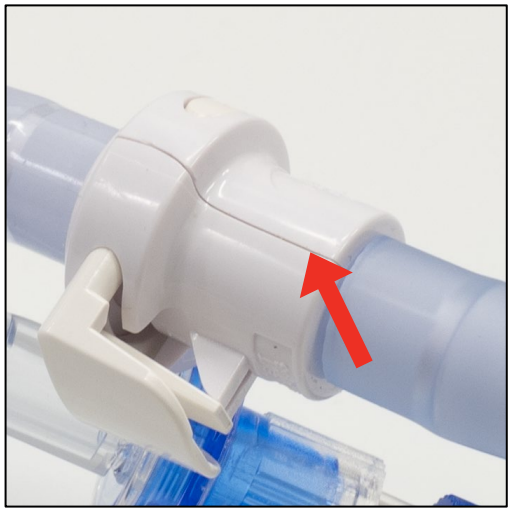
Cracked Connector Examples

Example 1 – Cracked Quick Connector

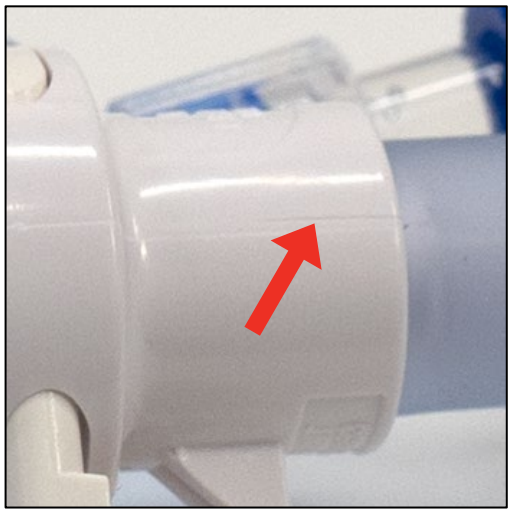




Example 2 – Cracked Quick Connector



Example 3 – Cracked Quick Connector



3. If a crack is observed, do not use the set and note the lot number. Defective sets should be discarded.
4. If no cracks are observed, install the disposable in the Hyperthermia Pump per the normal procedure described in the user manual (702-00058, Manual, Operator's, Hyperthermia Pump), chapter 2, Installing the Disposable Set.
5. Continue to prime the disposable with saline per instructions in chapter 2. Observe the female quick connector for leaks of fluid.
6. If a leak is observed, do not proceed with infusion. Remove the set, note the lot number and discard.
7. Replace the defective set with another set and repeat steps 1-5 above.
8. Proceed with Infusion if no leaks are observed during priming.
9. Note lot number of any defective set and report to Belmont using the following contact information:

1-855-387-4547
TECHSUPPORT@BELMONTMEDTECH.COM