

URGENT FIELD SAFETY NOTICE**WELCH ALLYN PRESSURE INFUSION CUFF
Part Number: 51-08-040 / 51-08-040DS****Lot Numbers: 100999, 101024, 101037, 101048, 101082, 101084, 101117, 101119, 101126,
101199****THIS PRODUCT IS NOT DISTRIBUTED IN UNITED STATES OR CANADA**

Action Identifier: WA10-04-01

Type of Action: Recall: Return and replacement of affected devices

Respond to This Notification within 5 Working Days

Dear Valued Customer / Distributor:

We are writing to inform you that certain Welch Allyn Pressure Infusion Cuffs are being voluntarily recalled. The recall is due to a condition that could result in a malfunction that could cause a delay in fluid resuscitation or blood transfusion, which can be life threatening in some emergency situations.

Welch Allyn is initiating this action because of the potential for a stitched seam of the outer cuff to burst when the device is inflated under normal and intended use conditions. If the seam bursts, the cuff will be unable to provide maximum pressure to fluid bags, resulting in slowed or interrupted delivery of fluids or blood.

Although no adverse events have occurred as a result of this malfunction, Welch Allyn is taking the precaution of recalling the lot numbers listed above.

The affected Pressure Infusion Cuffs are those cuffs with the lot numbers identified above in this notice. The affected lots were shipped between 2010-10-01 and 2010-10-28. Our records indicate that you purchased a Pressure Infusion Cuff from a lot affected by this potential problem. No other Pressure Infusion Cuffs besides those with the above lot numbers are subject to this recall. You will find the part number (Ref:) and lot number (LOT:) located on the box label for the Pressure Infusion Cuff. If you no longer have the device box label then refer to appendix 1 for pictures illustrating the difference between correct and incorrect seam.

With the potential for a malfunction to occur, Welch Allyn requests that you do the following:

- 1) Immediately remove the affected Pressure Infusion Cuffs from service.
- 2) Respond to this Field Safety Notice within 5 days by sending the attached completed response form to Welch Allyn to begin the process of returning your affected cuffs and arranging replacements. Contact details are provided on the Response Form.
- 3) Pass this Field Safety Notice to all those who need to be aware of it in your organization.
- 4) Create and provide to Welch Allyn a listing of the names and contact details of organisations to which affected devices have been transferred. Indicate how many

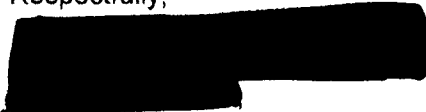
units by lot were received by each organisation. Pass a copy of the field safety notice to these organizations.

If you have any questions please e-mail Welch Allyn at fieldsafetynotice@welchallyn.com or contact +353 46 909 2135.

We have notified your National Competent Authority of our intended action.

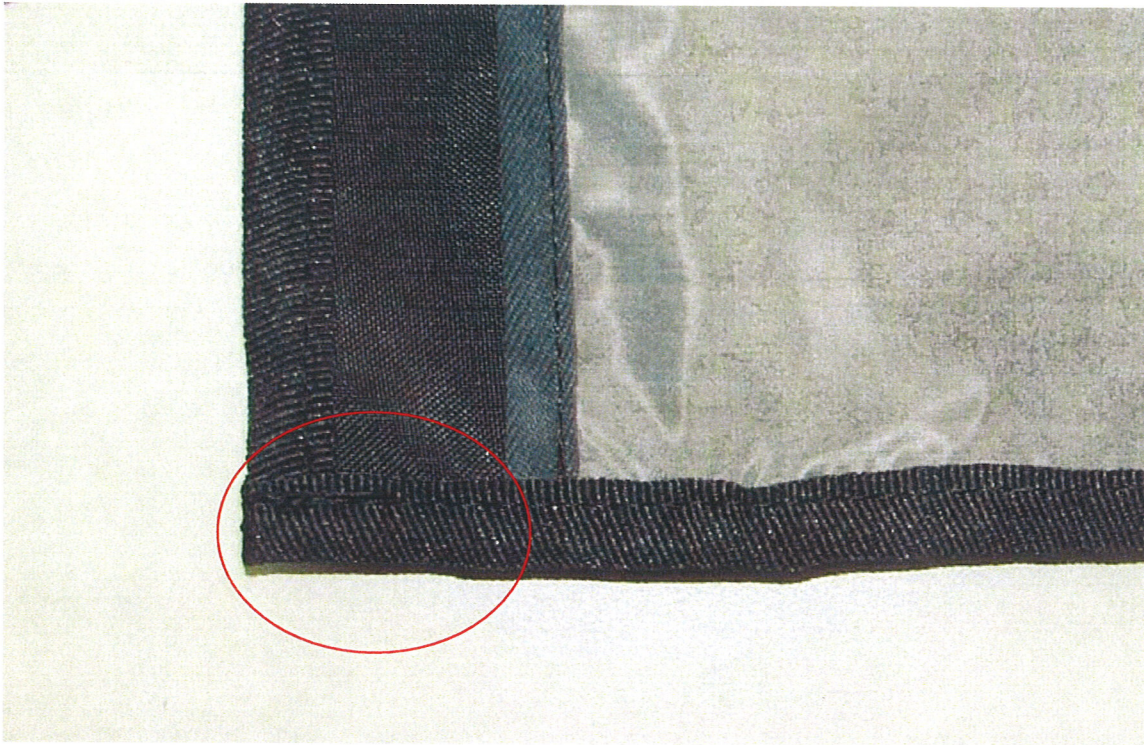
We greatly appreciate your cooperation and understanding in this matter.

Respectfully,

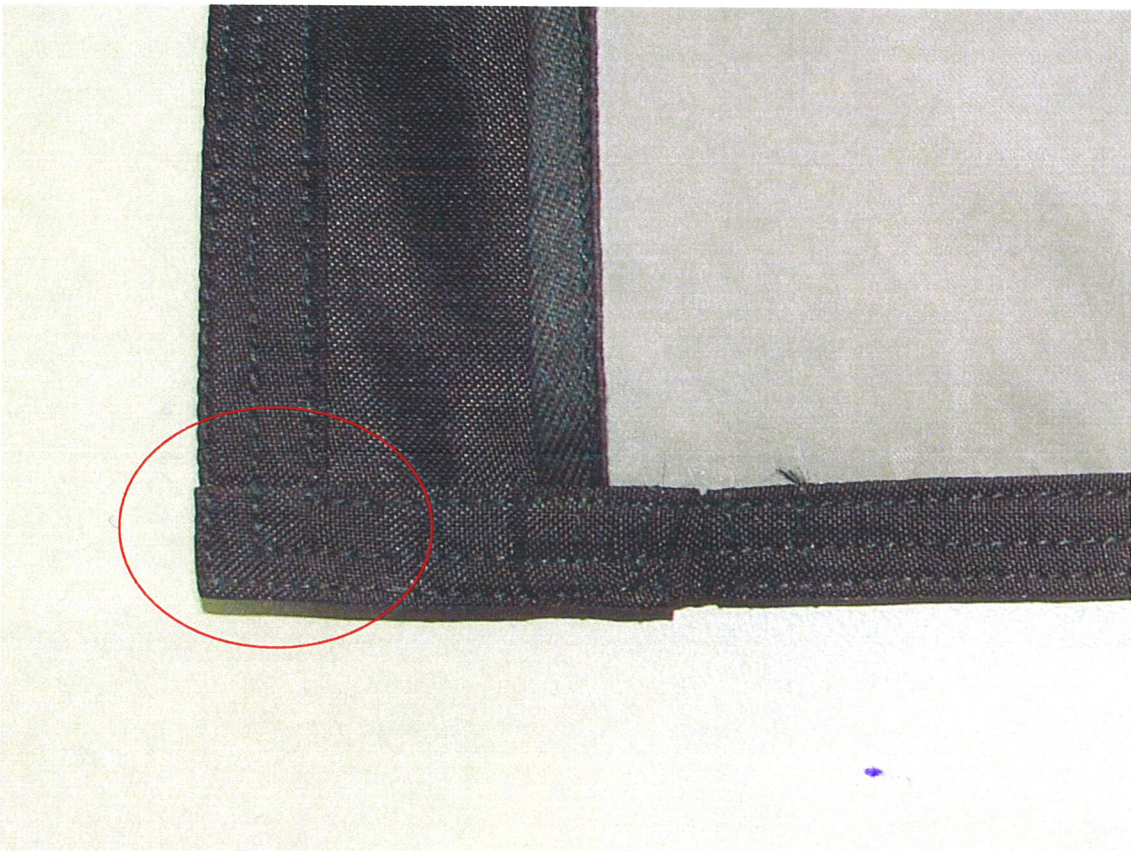
A large black rectangular redaction box covering the signature of the Director.

Director, International Quality & Regulatory Affairs
Welch Allyn

APPENDIX 1



Incorrect Seam (Single Stitch)



Correct Seam (Triple Stitch)

PLEASE SEND COMPLETED RESPONSE FORM WITHIN (5) WORKING DAYS

WELCH ALLYN PRESSURE INFUSION CUFF - Part Number: 51-08-040 / 51-08-040DS

We have read and understand the instructions provided in the field safety notice:

Name (please print):			
Signature/Date			
Title:			
Telephone No.			
Email Address:			
Organisation / Firm			
Street		Post Code	
City		Country	

Quantity of Affected Cuffs of Each Lot in Your Possession

Lot	Quantity	Lot	Quantity
100999		101084	
101024		101117	
101037		101119	
101048		101126	
101082		101199	

UNKNOWN LOT:	Quantity
Quantity of Cuffs for which you do not have lot number but which visually match the "Incorrect Seam" photo in appendix 1:	

QUANTITY OF CUFFS PASSED TO OTHER ORGANISATIONS: Provide a separate listing in addition to this response form. List Organisations, Contact Details, Lots and quantities.

WELCH ALLYN CONTACT DETAILS

PLEASE SEND COMPLETED RESPONSE FORM WITHIN (5) WORKING DAYS TO:

E-MAIL	FAX	POST
fieldsafetynotice@welchallyn.com	00353 4690 67755	Regulatory Department Welch Allyn Ltd. IDA Business Park, Dublin Road Navan, Co. Meath Ireland.