



Complaint Number: 101243

Report 8D

Generated By: Jayne Jamieson
Generated On: 20 Jun 2012

I. COMPLAINT INFORMATION

Origination Date	15 Sep 2011		
Sales Name		Sales Office	Dunstable
Telephone		Fax Number	+44 1582 478111
Email			
Customer Complaint Ref			
Customer Name	Lohmann & Rauscher GmbH & Co KG		
SAP Customer Number	125204	Customer Order N°	
Customer Part Number			

1) Invoices And Items On Complaint

2) Problem Description

adhesive: a large number of produced dressings showed a mass of glue at the adhesive edge, when the silicone paper is removed this is leaving a residue of adhesive on the wound pad.

Damages on the PU membrane: defects to the material.

Joints: Joints cannot be detected easily as the adhesive film is transparent (could we use a coloured one). The material could hardly be removed from the release liner in the area of the joint-adhesive-tape which lead to a burst of the membrane & resulted in interrupted production.

Batch number 2029848 GE Date 07.06.2011

Actions Requested From The Customer

3) Containment Actions

II. EVALUATION AND ACTION

Sample/photo Received	<input type="text" value="Yes"/>		
Date	<input type="text" value="08 Sep 2011"/>		
Process Owner	<input type="text" value="Christine Hulme"/>		
Team Leader	<input type="text" value="tobrien"/>		
Is Complaint Valid?	<input type="text" value="Yes"/>	Return The Goods	<input type="text"/>
		Dispose The Goods	<input type="text"/>
Comments	<input type="text"/>		

1) Analysis

3 distinct areas of complaint.

1. Elongated hole in PU foam backing ~ 3.5mm x 9mm

2. Apparent build up of adhesive around 'key hole' end of Sacral dressing. This area coincides where there is no direct contact with the protective release paper between the foam island and the foam backing and could be considered purely cosmetic.

3. Makers join in paper clear and release too tight. Need an easier release and coloured (red) to stand out more.

Author	<input type="text"/>	Date	<input type="text"/>
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2) Root Causes

1. the elongated hole appears to be made by a person or machine picking at the foam. I can not guess at what stage in the manufacturing process this would have occurred. It is not possible to identify root cause at this stage.

3. The splicing tape is a makers join from the paper supplier and when contacted the supplier has responded that the tape should be siliconised to enable adhesive release. This particular splice appears to be incorrect and is considered to be an isolated case. The paper supplier will investigate the use of a coloured tape (red?) and will respond in due course.

Author	<input type="text" value="Terry O'Brien"/>	Date	<input type="text" value="09 Nov 2011"/>
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3) Possible Solutions

3. Paper supplier to advise.

Author	<input type="text" value="Terry O'Brien"/>	Date	<input type="text"/>
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4) Implemented Perm Corrective Actions

<input type="text"/>			
Author	<input type="text"/>	Date	<input type="text"/>
Estimated Date	<input type="text"/>	Implementation Date	<input type="text"/>
Validation Date	<input type="text"/>		

5) Corrective Actions Validation

Author		Date	

6) Preventive Actions

Author		Date	
Estimated Date		Implementation Date	
Validation Date			

7) Review Of Documentation

(a) MSR

Reviewed?	No		
Reference		Date	

(b) Flow chart, control plan, work inspection instructions

Reviewed?	No		
Reference		Date	

(c) FMEA

Reviewed?	No		
Reference		Date	

(d) Customer specification

Reviewed?	No		
Reference		Date	

8) Congratulate The Team