



Complaint Number: 100341

## Report 8D

Generated By: Christine Hulme  
Generated On: 14 Jul 2011

### I. COMPLAINT INFORMATION

|                        |                         |                   |                    |
|------------------------|-------------------------|-------------------|--------------------|
| Origination Date       | 08 Jun 2011             |                   |                    |
| Sales Name             | Daniel Eng              | Sales Office      | Dunstable          |
| Telephone              | +44 (0)1636 821494      | Fax Number        | +44 (0)1582 478111 |
| Email                  | daniel.eng@scapa.com    |                   |                    |
| Customer Complaint Ref |                         |                   |                    |
| Customer Name          | Transpharma Medical Ltd |                   |                    |
| SAP Customer Number    | 124852                  | Customer Order N° |                    |
| Customer Part Number   |                         |                   |                    |

#### 1) Invoices And Items On Complaint

#### 2) Problem Description

Cotran film/Foam shrinking ref samples sent to K.Ash

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="19 May 2011"/>     |                  |                      |                   |                      |
| Process Owner         | <input type="text" value="Christine Hulme"/> |                  |                      |                   |                      |
| Team Leader           | <input type="text" value="kash"/>            |                  |                      |                   |                      |
| Is Complaint Valid?   | <input type="text" value="Yes"/>             | Return The Goods | <input type="text"/> | Dispose The Goods | <input type="text"/> |

### Comments

Please note that this complaint was entered onto the system to capture the problem which occurred on what is still a product at trial stage.

The complaint information will be used in the trial review process prior to the next run

### 1) Analysis

Sample roll rewound down from outside of customer supplied roll shows shrinkage of up to 0.30mm of shrinkage of the RX23Sv-60 foam when compared to the Cotran film.

Problem initially showed up on the first sample roll supplied to the customer, however further inspection of rolls 6 & 8 at Inglewood show up with 0.25mm of shrinkage prior to irradiation.

The specification for the pad of Cotran and Foam is 12mm +0.3mm / - 0.00mm

|        |  |      |  |
|--------|--|------|--|
| Author | <input type="text" value="Kevin Ash"/> | Date | <input type="text" value="14 Jul 2011"/> |
|--------|--|------|--|

### 2) Root Causes

1) Inherent tension within RX232V-60 and Cotran film.

2) Tension put into the lamination of the two above raw materials during the running of the pre-operation.

3) Core size that the lamination was rewound onto during the pre-operation process.

|        |  |      |  |
|--------|--|------|--|
| Author | <input type="text" value="Kevin Ash"/> | Date | <input type="text" value="14 Jul 2011"/> |
|--------|--|------|--|

### 3) Possible Solutions

|                      |  |  |  |
|----------------------|--|--|--|
| <input type="text"/> |  |  |  |
|----------------------|--|--|--|

|        |                      |      |                      |
|--------|----------------------|------|----------------------|
| Author | <input type="text"/> | Date | <input type="text"/> |
|--------|----------------------|------|----------------------|

### 4) Implemented Perm Corrective Actions

1) Core size on the final rewind of the lamination will be increased from 76mm to 152mm on the next production trial.

2) Inspection system to be put in place on next trial to monitor tension control of the lamination process.

|        |  |      |  |
|--------|--|------|--|
| Author | <input type="text" value="Kevin Ash"/> | Date | <input type="text" value="14 Jul 2011"/> |
|--------|--|------|--|

|                |  |                     |  |
|----------------|--|---------------------|--|
| Estimated Date | <input type="text" value="14 Jul 2011"/> | Implementation Date | <input type="text" value="14 Jul 2011"/> |
|----------------|--|---------------------|--|

|                 |                      |
|-----------------|----------------------|
| Validation Date | <input type="text"/> |
|-----------------|----------------------|

## 5) Corrective Actions Validation

To be validated during next production trial.

Currently there is no firm date for this trial

Author

Kevin Ash

Date

14 Jul 2011

## 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