UKAS TESTING 1492

S . M . T . L .

subject: **Testing of Allevyn AG Non-Adhesive Wound Dressing**

date: **16th December 2009**

from: **Dr Gavin Hughes**
Princess of Wales
Tel: +44-1656-752820

Report No: 09/3201/3

Test Report

09/3201/3

1. Name & Address of Client/Requesting Authority.

Alistair Bielby
Clinical Project Manager
Smith & Nephew
Healthcare House
Goulton Street
Hull
HU3 4DJ

Email: alistair.bielby@smith-nephew.com

2. Introduction

The SMTL were requested by the client to perform various physical tests on Allevyn AG Non-Adhesive Foam Wound Dressings.

This testing was originally reported in SMTL Test Reports 09/3045/1 and 09/3104/1.

3. Test Product(s)/Sample(s)

TABLE 1. Test Product(s)/Sample(s) tested by SMTL.

Manufacturer	Item	Cat No	Batch/Lot No	Quantity	Date Received	SMTL Original Report Number
Smith & Nephew	Allevyn AG Non-Adhesive 10 x 10cm	66800086	0920	7	17/7/2009	09/3045/1
			0915	10	18/8/2009	09/3104/1

NOTE: The test results in this report relate only to the test sample(s) analysed.

The information contained in this report is proprietary, and is not for circulation without the consent of the Surgical Material Testing Laboratory (S. M. T. L.), or the commissioning authority/company. This report shall not be reproduced except in full without the written approval of S. M. T. L., Princess of Wales Hospital, Coity Road, Bridgend, CF31 1RQ.

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Non-Adhesive,v 1.2 2010/02/24 11:21:10 gavin Exp $

3.1 Departures/Abnormalities of Sample Condition

None

4. Date of Testing

SMTL Project 3045 July-August 2009
SMTL Project 3104 August-November 2009

5. Testing Details

5.1 Conformability

The conformability of the dressing was determined using SMTL test method TM-16.[1]

The testing apparatus is a modification of the *Apparatus for the Measurement of Waterproofness* as originally described in the *British Pharmacopoeia 1988, Appendix XX K* and recently adopted as a European Standard *BS EN 13726-3: 2003 - Test methods for primary wound dressings; Waterproofness.* It consists of a chamber, open at one end, bearing a flange with an internal diameter of 50 mm. A retaining ring with the same internal diameter as the hole in the flange is mounted over the open end of the cylinder and this can be lowered down and clamped onto the flange, by means of a screw thread.

In use, a sample of the dressing under examination is placed on the flange and held firmly in place by means of the retaining ring.

During the course of this test, air is slowly forced into the chamber by means of a large syringe. The resultant rise in the pressure within the chamber causes the dressing to expand and form a hemisphere which gradually increases in size.

The pressure in the chamber, measured by means of a transducer and digital display unit, is increased until the upper surface of the dressing comes into contact with a marker placed 20 mm above the surface of the dressing at the start of the test. This pressure value is then recorded.

In this test, the conformability of a dressing is considered to be inversely proportional to the pressure required to distort it by a predetermined amount.

5.2 Waterproofness

The waterproofness of the outer layer of the dressing was determined using SMTL test method TM-395,[2] which is written in accordance with the European Standard *BS EN 13726:3:2003 - Section 3.2.*[3]

In this test, a specimen is cut from the dressing under test that is sufficient to completely cover the opening of the test cell (the test cell is a modified Paddington Cup as illustrated in Figure 1 of *BS EN 13726:3:2003*). The test cell is then filled completely with water at 21±2°C. The specimen is then slid horizontally over the cell with its outer facing layer in contact with the water in such a way as to avoid the inclusion of air between the surface of the water and the lower surface of the specimen.

The information contained in this report is proprietary, and is not for circulation without the consent of the Surgical Material Testing Laboratory (S. M. T. L.), or the commissioning authority/company. This report shall not be reproduced except in full without the written approval of S. M. T. L., Princess of Wales Hospital, Coity Road, Bridgend, CF31 1RQ.

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Non-Adhesive,v 1.2 2010/02/24 11:21:10 gavin Exp $

The upper surface is then covered with a dry filter paper and the upper ring of the apparatus tightened. A hydrostatic head of 500mm is then generated and maintained for 300±10sec, after which time the filter paper is examined for penetration of water and the results recorded.

The test is performed on three individual specimens, and if water penetration has occurred on any of the three specimens then the sample is deemed to have failed the test.

5.3 List of SMTL Test Methods Used.

— TM-16 - Conformability of Hydrocolloid and Film Dressings[1]

— TM-395 - Waterproofness to BS EN 13726-3:2003[2]

5.4 Standards relevant to the test method.

— The SMTL test method TM-395[2] is written in accordance with the method described in the *BS EN 13726-3: 2003: Non-active medical devices - Test methods for primary wound dressings - Part 3: Waterproofness*

5.5 Deviations/exclusions from, and additions to standard methods.

— BS EN 13726-3:2003 waterproofness has a stated non-penetration time of 5 minutes for compliance, the dressings were tested over 5 minutes as per the standard and also over an extended period of 15 minutes at the clients request.

5.6 Sampling Details

All samples were selected and supplied by the client.

5.7 Sample Preparation

As per the relevant SMTL Test Method.

The information contained in this report is proprietary, and is not for circulation without the consent of the Surgical Material Testing Laboratory (S. M. T. L.), or the commissioning authority/company. This report shall not be reproduced except in full without the written approval of S. M. T. L., Princess of Wales Hospital, Coity Road, Bridgend, CF31 1RQ.

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Non-Adhesive,v 1.2 2010/02/24 11:21:10 gavin Exp $

6. Results

6.1 Conformability

The results of the conformability tests are presented in Table 2.

TABLE 2. Conformability Properties - Allevyn AG Non-Adhesive

Dressing	Inflation Pressure (mm Hg)
Allevyn AG Non-Adhesive	123
	103
	124
	117
	124
Mean	118.20 (8.983)

Note:
- Figures in brackets denote standard deviations.

6.2 Waterproofness

The results of the waterproofness testing are presented in Table 3.

TABLE 3. Waterproofness - Allevyn AG Non-Adhesive

Dressing	Water Penetration/ Time Period		BS EN 13726-3 Compliance
	5 Minutes	15 Minutes	
Allevyn AG Non-Adhesive	None	None	**Complies**

Note:
- 3 replicates tested.
- No water penetration was observed during the testing on any of the samples tested, therefore exhibiting compliance with the BS EN 13726-3:2003.

The information contained in this report is proprietary, and is not for circulation without the consent of the Surgical Material Testing Laboratory (S. M. T. L.), or the commissioning authority/company. This report shall not be reproduced except in full without the written approval of S. M. T. L., Princess of Wales Hospital, Coity Road, Bridgend, CF31 1RQ.

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Non-Adhesive,v 1.2 2010/02/24 11:21:10 gavin Exp $

Peter Phillips, Director, SMTL. Date: 8th March 2010

The information contained in this report is proprietary, and is not for circulation without the consent of the Surgical Material Testing Laboratory (S. M. T. L.), or the commissioning authority/company. This report shall not be reproduced except in full without the written approval of S. M. T. L., Princess of Wales Hospital, Coity Road, Bridgend, CF31 1RQ.

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Non-Adhesive,v 1.2 2010/02/24 11:21:10 gavin Exp $

References

1. Surgical Materials Testing Lab., "Conformability of Hydrocolloid and Film Dressings," TM-16 ().
2. Surgical Materials Testing Lab., "Waterproofness to BS EN 13726-3:2003," TM-395 ().
3. "Test methods for primary wound dressings. Part 3; Waterproofness," *BS EN 13726-3*, British Standards Institution, (2003).

The information contained in this report is proprietary, and is not for circulation without the consent of the Surgical Material Testing Laboratory (S. M. T. L.), or the commissioning authority/company. This report shall not be reproduced except in full without the written approval of S. M. T. L., Princess of Wales Hospital, Coity Road, Bridgend, CF31 1RQ.

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Non-Adhesive,v 1.2 2010/02/24 11:21:10 gavin Exp $

CONTENTS

The information contained in this report is proprietary, and is not for circulation without the consent of the Surgical Material Testing Laboratory (S. M. T. L.), or the commissioning authority/company. This report shall not be reproduced except in full without the written approval of S. M. T. L., Princess of Wales Hospital, Coity Road, Bridgend, CF31 1RQ.

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Non-Adhesive,v 1.2 2010/02/24 11:21:10 gavin Exp $

LIST OF TABLES

The information contained in this report is proprietary, and is not for circulation without the consent of the Surgical Material Testing Laboratory (S. M. T. L.), or the commissioning authority/company. This report shall not be reproduced except in full without the written approval of S. M. T. L., Princess of Wales Hospital, Coity Road, Bridgend, CF31 1RQ.

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Non-Adhesive,v 1.2 2010/02/24 11:21:10 gavin Exp $

S. M. T. L. Cover Sheet for Test Report

The information contained herein is for the use of employees and clients of S. M. T. L. and is not for publication. The report shall not be reproduced except in full without the written approval of S. M. T. L. (see BS 7501:1989)

Title: **Testing of Allevyn AG Non-Adhesive Wound Dressing**

Date: **16th December 2009**

Other Keywords:

Report No: **09/3201/3**

Author(s)	Location	Extension	Charging\ Case:
Dr Gavin Hughes	**Princess of Wales**		**09/3201/3**
			Filing\ Case:

Pages Text: 8	Other: 0	Total: 8
No. Figures: 0	No. Tables: 3	No. Refs.: 0

SURGICAL MATERIAL TESTING LABORATORY, PRINCESS OF WALES HOSPITAL, COITY ROAD, BRIDGEND. TEL: 01656-752820 FAX:01656-752830