S . M . T . L .

subject: **Comparative Allevyn Wound Dressing Testing**

date: **24th March 2009**

from: **Victoria Baines**
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Report No: 09/2896/1

Test Report

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1. Name & Address of Client/Requesting Authority.

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2. Introduction

The SMTL were requested by the client to perform comparative testing on Allevyn and Versiva XC foam wound dressings.

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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
Smith & Nephew	Allevyn Adhesive 10 x 10 cm	66000599	520318	40	19/12/2008
Smith & Nephew	Allevyn Adhesive 10 x 10 cm	66000599	520387	20	19/12/2008
Smith & Nephew	Allevyn Non-Adhesive 10 x 10cm	66157637	0839	30	19/12/2008
Smith & Nephew	Allevyn Non-Adhesive 10 x 10cm	66157637	0846	2	19/12/2008
ConvaTec	Versiva XC Adhesive 10 x 10cm	410609	3015639	30	19/12/2008
ConvaTec	Versiva XC Adhesive 10 x 10cm	410609	2807992	1	19/12/2008
ConvaTec	Versiva XC Non-Adhesive 11 x 11cm	410607	7F30046	30	19/12/2008
ConvaTec	Versiva XC Non-Adhesive 11 x 11cm	410607	7D28335	2	19/12/2008

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

3.1 Departures/Abnormalities of Sample Condition

None

4. Date of Testing

December 2008 - February 2009

5. Testing Details

5.1 Moisture vapour permeability

The moisture vapour permeability of the dressings was determined using SMTL test method TM-8.[1]

In this test, a sample of dressing is applied to a Paddington cup to which is added 20 ml of a solution of sodium and calcium chloride containing 142 mmoles/litre of sodium ions and 2.5 mmoles/litre of calcium ions.

The cup is placed in an inverted position (with the test solution in contact with the sample) upon the pan of a top loading balance located within an incubator set at 37±2°C . The balance is connected to an electronic data logging device which records changes in the weight of the cup resulting from the loss of moisture vapour through the dressing. A tray containing 1 kg of freshly dried silica gel is placed in the bottom of the incubator to maintain a low relative humidity within the chamber.

At the end of the test the recorded data is down-loaded for examination.

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5.2 Fluid handling properties

The fluid handling properties of the dressings were examined using SMTL test method TM-390,[2] which is written in accordance with the European Standard *BS EN 13726:1:2002 - Test methods for primary wound dressings. Part 1; Aspects of absorbency. Section 3.3 - Fluid Handling Capacity (absorbency plus moisture vapour transmission rate, liquid in contact).*[3]

In this test, five samples of each dressing are applied to Paddington cups, to which are added 20 ml of a solution of sodium/calcium chloride containing 142 mmol/litre of sodium ions and 2.5 mmol/litre of calcium ions. The cups are weighed using a calibrated analytical balance and placed in a temperature and humidity controlled incubator used to maintain an environment of 37±2°C and a relative humidity level below 20% for a period of 24 hours.

At the end of the test the cups are removed from the incubator, and are allowed to equilibrate at room temperature for a period of 30 minutes prior to reweighing on the analytical balance.

From these weighings the loss in weight due to the passage of moisture vapour through the dressing is determined. The base of each cup is then removed and any remaining fluid allowed to drain.† After a period of 15±2min the cup is then reweighed once again and the weight of fluid retained by the dressing calculated by difference.
This test can be repeated over a period of 48 hours.

5.3 Foam Absorbency Testing to BP Requirements

The absorbency of the dressings is determined using SMTL test method TM-366[4] which is written in accordance with the *British Pharmacopoeia 1993 Volume II, Polyurethane Foam Dressings.*.[5]

Five dressing were sectioned into 5cm x 5cm samples. The weight of the samples were then determined using a calibrated balance. Dressings were then immersed in de-ionised water for 60 minutes, before being drained on a draining board inclined at 45° for 5 minutes. The weight of the samples after draining was then determined, and the individual increase in weight per sample calculated. The increase in weight shall be greater or equal to 7.5 times the dry weight.

† If there is an accumulation of test fluid between two components of the dressing, the inner component must be slit with a scalpel blade to allow free drainage of the entrapped fluid.

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5.4 Standards relevant to the test method.

— *BS EN 13726-1:2002: Test methods for primary wound dressings. Aspects of absorbency. Section 3.3 Fluid handling capacity (plus moisture vapour transmission rate, liquid in contact)*[3]

— *British Pharmacopoeia 1993 Volume II, Polyurethane foam dressings*[5]

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

The following deviations from the SMTL test method TM-390[2] were employed

— Tests were also performed over a 72 hour duration.

— 30ml of Solution A was added to the Paddington cups for all tests.

The following deviation from the SMTL test method TM-8[1] was employed

— 30ml of Solution A was added to the Paddington cups for all tests.

5.6 Sampling Details

All samples were selected and supplied by the client.

5.7 Sample Preparation

As stated in the SMTL test method.

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6. Results

6.1 Moisture Vapour Transmission Rate

Results from MVTR experiments are presented in Tables 2 to 5. Data is also expressed graphically in Figures 1 to 4.

TABLE 2. Allevyn Adhesive Moisture Vapour Transmission Rate over 24 hours

	MVTR ($g/m^2/24Hrs$)
Run 1	7737
Run 2	6595
Run 3	7584
Mean	7305

Figure 1. Allevyn Adhesive - Moisture Vapour Transmission

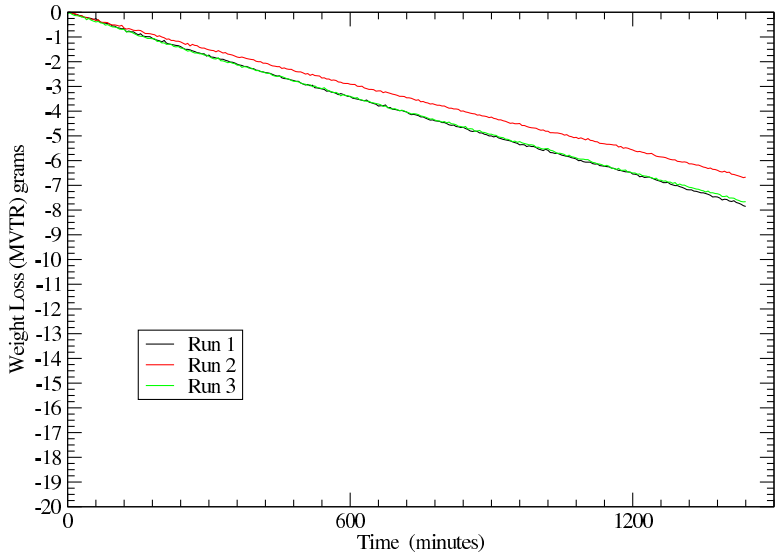

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TABLE 3. Versiva XC Adhesive Moisture Vapour Transmission Rate over 24 hours

	MVTR ($g/m^2/24Hrs$)
Run 1	1086
Run 2	814
Run 3	1262
Mean	1054

Figure 2. Versiva XC Adhesive - Moisture Vapour Transmission

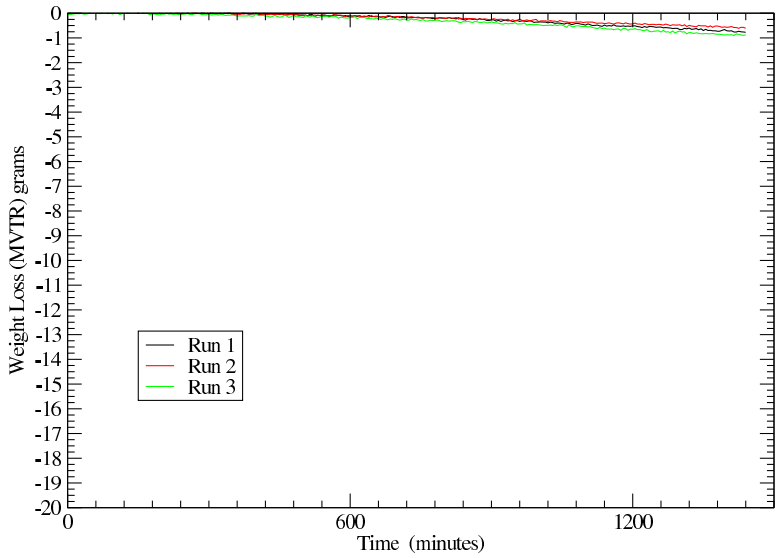

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TABLE 4. Allevyn Non-Adhesive Moisture Vapour Transmission Rate over 24 hours

	MVTR ($g/m^2/24Hrs$)
Run 1	11,645
Run 2	17,228
Run 3	18,880
Mean	15,917

Figure 3. Allevyn Non-Adhesive - Moisture Vapour Transmission

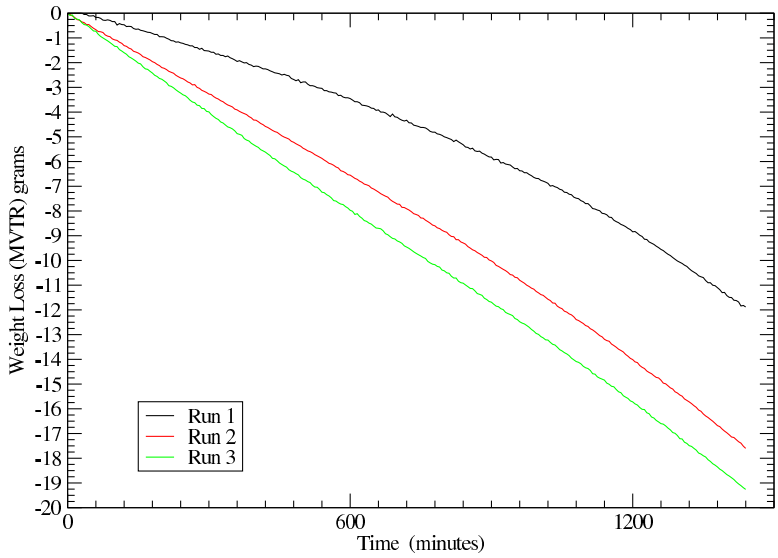

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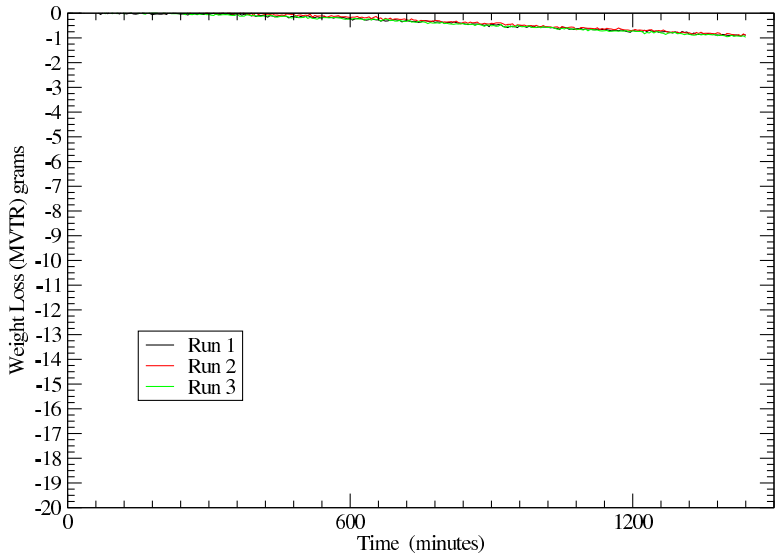
TABLE 5. Versiva XC Non-Adhesive Moisture Vapour Transmission Rate over 24 hours

	MVTR ($g/m^2/24Hrs$)
Run 1	1164
Run 2	1209
Run 3	1168
Mean	1180

Figure 4. Versiva XC Non-Adhesive - Moisture Vapour Transmission



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6.2 Fluid Handling Testing

The results of the fluid handling testing are presented in Tables 6 to 8.

TABLE 6. Fluid handling properties following 24 hours incubation

Dressing	Moisture Vapour Loss ($g/10cm^2$)	Absorbency ($g/10cm^2$)	Fluid Handling Capacity ($g/10cm^2$)
Allevyn Adhesive	10.957 (1.7401)	4.9599 (0.2179)	15.9172 (1.8875)
Versiva XC Adhesive	0.6871 (0.0928)	5.0375 (0.1331)	5.7246 (0.1930)
Allevyn Non-Adhesive	12.7836 (1.7718)	5.9149 (1.3370)	18.6985 (3.0764)
Versiva XC Non-Adhesive	0.8211 (0.0359)	5.1177 (0.0825)	5.9388 (0.1066)

Note:
- The results are the mean of 5 determinations
- Figures in brackets denote standard deviations

TABLE 7. Fluid handling properties following 48 hours incubation

Dressing	Moisture Vapour Loss ($g/10cm^2$)	Absorbency ($g/10cm^2$)	Fluid Handling Capacity ($g/10cm^2$)
Allevyn Adhesive †	26.1871 (0.9757)	3.6951 (0.8930)	29.8822 (0.1304)
Versiva XC Adhesive	1.9667 (0.1533)	5.0997 (0.1629)	7.0664 (0.2637)
Allevyn Non-Adhesive †	27.8151 (1.5081)	2.1292 (1.4073)	29.9443 (0.1053)
Versiva XC Non-Adhesive	2.0896 (0.0244)	5.2102 (0.1704)	7.2998 (0.1654)

Note:
- The results are the mean of 5 determinations
- Figures in brackets denote standard deviations

† Little fluid remained in the Allevyn Adhesive and Non-Adhesive Paddington cups at the end of the testing period. There was no evidence of leakage during the test period and the dressings appear to handle nearly all of the fluid during the test. These results are an indication of the amount of fluid applied and not necessarily the fluid handling capacity of the dressing.

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TABLE 8. Fluid handling properties following 72 hours incubation

Dressing	Moisture Vapour Loss ($g/10cm^2$)	Absorbency ($g/10cm^2$)	Fluid Handling Capacity ($g/10cm^2$)
Allevyn Adhesive ‡	-	-	-
Versiva XC Adhesive	3.1758 (0.1167)	5.3867 (0.1441)	8.56248 (0.1045)
Allevyn Non-Adhesive ‡	-	-	-
Versiva XC Non-Adhesive	3.1668 (0.0383)	5.3881 (0.1688)	8.5550 (0.1522)

Note:
- The results are the mean of 5 determinations
- Figures in brackets denote standard deviations

‡ As presented in the 48 hour test data (Table 7) the Allevyn Adhesive and Non-Adhesive dressings handle the maximum capacity of test fluid the Paddington cups can hold within 48 hours of incubation, and therefore the dressings were not subjected to the 72 hour testing.

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6.3 BP Foam Absorbency

The results from the absorbency determination are presented in Tables 9 and 12.

TABLE 9. Absorbency of Allevyn Adhesive dressings

Sample No.	Sample weight (g)	Final Weight (g)	Weight increase Factor	Complies/ Does not comply †
1	1.30	14.54	10.18	Complies
2	1.28	15.44	11.06	Complies
3	1.39	14.69	9.57	Complies
4	1.42	15.55	9.95	Complies
5	1.47	16.97	10.54	Complies

Note:
† For compliance weight increase factor shall be greater or equal to 7.5.

TABLE 10. Absorbency of Versiva XC Adhesive dressings

Sample No.	Sample weight (g)	Final Weight (g)	Weight increase Factor	Complies/ Does not comply †
1	2.69	11.34	3.22	Does not comply
2	2.53	11.36	3.49	Does not comply
3	2.60	11.53	3.43	Does not comply
4	2.51	11.70	3.66	Does not comply
5	2.43	11.53	3.74	Does not comply

Note:
† For compliance weight increase factor shall be greater or equal to 7.5.

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TABLE 11. Absorbency of Allevyn Non-Adhesive dressings

Sample No.	Sample weight (g)	Final Weight (g)	Weight increase Factor	Complies/ Does not comply †
1	1.64	22.20	12.54	Complies
2	1.79	23.89	12.35	Complies
3	1.71	21.87	11.79	Complies
4	1.64	22.31	12.60	Complies
5	1.60	23.81	13.88	Complies

Note:
† For compliance weight increase factor shall be greater or equal to 7.5.

TABLE 12. Absorbency of Versiva XC Non- Adhesive dressings

Sample No.	Sample weight (g)	Final Weight (g)	Weight increase Factor	Complies/ Does not comply †
1	2.57	12.02	3.68	Does not comply
2	2.52	13.04	4.17	Does not comply
3	2.52	12.75	4.06	Does not comply
4	2.56	13.34	4.21	Does not comply
5	2.59	13.17	4.08	Does not comply

Note:
† For compliance weight increase factor shall be greater or equal to 7.5.

Peter Phillips, Director, SMTL. Date: 26th March 2009

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References

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2. Surgical Materials Testing Lab., "Fluid Handling Capacity BS EN 13726-1:2002," TM-390 ().
3. "Test methods for primary wound dressings. Part 1; Aspects of absorbency. Section 3.3 - Fluid Handling Capacity (absorbency plus moisture vapour transmission rate, liquid in contact).," *BS EN 13726-1 Section 3.3*, British Standards Institution, (2002).
4. Surgical Materials Testing Lab., , "Foam Absorbency Testing to BP Requirements," TM-366 ().
5. "Surgical Dressings: Polyurethan Foam Dressings.," *BP 1993 Volume II*, British Pharmacopoeia, (1993 Vol II).

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Location
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