S. M. T. L.

Cover Sheet for Test Report

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Author(s)	Location	Extension	Charging\ Case:
Pamela McCubbin	**Princess of Wales**		Filing\ Case:
Paul Hay	**Princess of Wales**		

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subject: **Investigation of Sterilisation Under Marking Tape**

date: **18th November 2003**

from: **Pamela McCubbin**
Princess of Wales
Tel: +44-1656-752820

Paul Hay
Princess of Wales
Tel: +44-1656-752820

Report No: 03/1653/1

Test Report

1. Name & Address of Client/Requesting Authority.

Mr John R. White
Clinipak Ltd
Unit B
Wessex Road
Bourne End
Buckinghamshire
SL8 5DT

Email:john@clinipak.co.uk

2. Introduction

The document reports the test results to investigate whether micro-organisms remain viable on the surface of sterile surgical instruments covered with marking tape.

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

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

Manufacturer	Item	Batch/Lot No	Quantity	Date Received
Clinipak	Instrument Marking Tape	5234	5 sheets	17/7/2003

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

3.1 Departures/Abnormalities of Sample Condition

None.

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4. Date of Testing

October - November 2003.

5. Testing Details

The investigation consisted of two separate studies. The first study validated the test method which was to be used to detect microbial growth on surgical instruments under the area covered with marking tape whilst in the second study a sterility test was performed on surgical instruments which had been inoculated with *Bacillus stearothermophilus* and covered with tape prior to sterilisation.

5.1 Validation of Test Method

Nine sterile surgical instruments were supplied by the Hospital sterile services department. These were divided into three separate groups each of which consisted of three instruments (2 scissors and 1 dissecting forceps).

A small area of each of the nine instruments was swabbed with a 24-hour broth culture of *Bacillus stearothermophilus** and allowed to dry overnight inside a laminar airflow cabinet.

After this time all of the instruments in the first group were transferred separately into sterile plastic bags containing 100ml of nutrient broth.

A strip of marking tape was then used to cover the area on each of the three instruments in the second group which had been swabbed with broth culture. The taped instruments were each aseptically transferred into sterile plastic bags containing 100ml of nutrient broth as for group 1.
All of the bags containing instruments in groups one and two were heat-sealed and incubated for 24 hours at 55 +/-2°C after which the nutrient broth in each of the bags was examined for the presence or absence of *Bacillus stearothermophilus*.

The remaining instruments (Group 3) were covered with marking tape in the same way as for the second group described above. Each strip of tape was removed from the instrument after four hours and transferred into a sterile plastic bag containing nutrient broth. Each of the instruments were also transfered into a separate bag containing nutrient broth. All bags containing tape or instrument were sealed, incubated at 55 +/-2°C and finally examined after 24 hours for the presence or absence of *Bacillus stearothermophilus*.

The results are shown in Table 2.

* *Bacillus stearothermophilus* ATCC 7953 strain is used as a biological indicator for steam sterilisation and sterility assurance studies.

5.2 Sterility Testing

A small area on each of ten sterile instruments was swabbed with a broth culture of *Bacillus stearothermophilus* and allowed to dry overnight. Each area was covered with a single strip of marking tape and the instruments placed inside a CSSD paper pouch. The packages were sealed and sent to the hospital sterile services department for sterilisation. After sterilisation five of the taped instruments were transferred directly into sterile plastic bags containing 100ml of nutrient broth. The tape was removed from the

remaining five instruments and both tape and instrument transferred into separate bags containing broth. All bags were sealed and incubated for 14 days at 55 +/-2°C after which the nutrient broth was examined for the absence of *Bacillus stearothermophilus.* The results are shown in Tables 3 - 5.

5.3 Sampling Details

All Test samples were supplied by the client.

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6. Results

6.1 Validation of Test Method

The results of the validation study is shown in Table 2 below.

TABLE 2. Detection of *B.stearothermophilus* on Surgical Instruments and Marking Tape

Test Group	Test Sample Description	*B.stearothermophilus* +/-
1	Instruments (No Tape)	+
2	Instruments (with Tape)	+
3a	Instruments (Tape Removed)	+
3b	Tape after removal from Instruments	+

NOTE
Each of the above results represents three test samples.

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6.2 Sterility Test Results

The results for the sterility testing are shown in Tables 3, 4 & 5 below.

TABLE 3. Sterility Test Results for Instruments with Tape

Sample No	*B.stearothermophilus* +/-
1	-
2	-
3	-
4	-
5	-

TABLE 4. Sterility Test Results for Instruments (Tape Removed)

Sample No	*B.stearothermophilus* +/-
1	-
2	-
3	-
4	-
5	-

TABLE 5. Sterility Test Results for Tape Removed from Instruments

Sample No	*B.stearothermophilus* +/-
1	-
2	-
3	-
4	-
5	-

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6.3 SUMMARY

The validation results in table 2 showed the test method to be appropriate for detecting the presence of *B.stearothermophilus* on the surface of contaminated surgical instruments with and without marking tape before sterilisation.

From the results in Tables 3-5 all test samples passed the test for sterility. *B. stearothermophilus* was not detected in any of the test samples after sterilisation. This indicates that there is no impairement in the killing effect during sterilisation when marking tape is used on surgical instruments.

APPROVED:

Peter Phillips, Deputy Director, SMTL. Date 18/12/03

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