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PORTLAND ORTHOPAEDICS *Pty Limited*

THE MARGRON HIP REPLACEMENT SYSTEM

ABN 92 086 839 992

ATTN ROD FERRARI

Best regards

David Seker

With Compliments

THERAPEUTIC GOODS ADMINISTRATION

0 5 AUG 2002

MEDICAL DEVICES SECTION

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PROTOCOL NO. **PJ 0037/1**	AUTHOR P Priscott	ISSUE DATE 12 July 2001
TITLE Gamma Irradiation Sterilisation of Margron Hip Components	APPROVED by	PAGE **1 of 7**

1.0 PURPOSE

1.1 This plan outlines the requirements to substantiate the sterilization process of exposure to 25kGy as a means to provide a sterility assurance level (SAL) of 10^{-6} in line with requirements of the Australian Therapeutic Goods Administration, BS EN 556: 1995 and ISO 11137: 1995.

2.0 SCOPE

2.1 This validation plan is applicable to all sizes of Margron Hip Replacement components, namely necks, stems and modules.

2.2 Vimek Quality Assurance Department and AMS Laboratories Pty Ltd are qualified to carry out and interpret this plan.

3.0 DEPARTMENTS AND CONTRACTORS AFFECTED

3.1 Vimek Quality Assurance Department

3.2 Contractor: AMS Laboratories, 118 Hatersley Street, Rockdale, NSW

3.3 Contractor: ANSTO Irradiation & Dosimetry Service, Lucas Heights

4.0 DEFINITIONS

4.1 Facsimile Device – due to the high cost of manufacturing component parts, it is possible that some or all of the test devices may comprise of components that have been through all of the manufacturing stages but have some imperfections that render them unsuitable for sale. These nevertheless represent accurately the devices that are released for sale and are therefore deemed to be satisfactory for validation purposes.

4.2 Equivalence of Modules and Stems. The components named "modules" are designed as extension pieces for the stems. As such they do not have threads but are tapered and are hydroxyapetite coated as are the stems. The manufacturing process is therefore very similar to the stems and for the purposes of the validation plan are considered to be the same.

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5.2 ISO 11137: 1995. Sterilization of health care products – requirements for validation and routine control – radiation sterilization.

5.3 ISO/TR 13409. Technical Report. Sterilization of health care products - Radiation sterilization - Substantiation of 25 kGy as a sterilization dose for small or infrequent product batches.

5.4 Kowalski JB & A Tallentire (1999), Radiation Physics & Chemistry, *54*, 55 – 64. Substantiation of 25 kGy as a sterilization dose: a rational approach to establishing verification dose.

5.5 BS EN 1174-1: 1996. Sterilization of medical devices - Estimation of the population of microorganisms on product. Requirements.

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5.5 ISO 11737-2: 1998. Sterilization of medical devices – Part 2: Tests of sterility performed in the validation of a steirlization process.

6.0 PRODUCTS TO BE EVALUATED

6.1 The components of the Margron Hip Replacement System to be evaluated are as follows:

6.1.1 Necks (various sizes).

6.1.2 Stems (various sizes).

6.1.3 Modules (various sizes).

7.0 EQUIPMENT TO BE USED

7.1 ANSTO irradiation facilities

7.2 AMS Laboratories microbiology facilities

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In line with the international move towards process validation and reduction in final batch sterility testing, this validation plan sets out the path to achieve that process validation.

The BS EN 552: 1994 standard is the primary standard for validation and routine control of sterilization by irradiation in Australia. However, this document cites the technical document ANSI/AAMI ST 31 - 1990 as the source of methods to be used for dose setting, B1 and B2. These were subsequently incorporated into ISO 11137; 1995, after BS EN 552 had been published.

The application of methods B1 and B2 require a relatively large number of product items drawn from a number of separate production batches. It is recognised that many health care manufacturers produce products in much smaller batch sizes than are catered to in the BS EN 552 and ISO 11137 standards. This led to the issue of ISO/TR 13409 which gives guidance on batch sizes in increments up to 1,000, compared with the other standards which assume batch sizes of greater than 1,000.

In the present case, the manufacturer's maximum sterilization batch size is approximately 200 for necks and 350 for stems/modules. Thus, the method set out in ISO/TR 13409 is the most appropriate to use while batch sizes remain at their present level. However, experience in the application of ISO/TR 13409 has shown that the method is inappropriate, particularly in cases where items have a low bioburden. This has led to situations where processes have not met the verification dose requirements even though there has been no suggestion that the delivered 25 kGy dose would not be sufficient to sterilize to an acceptable SAL. There has been a review of the method of determining the verification dose in such circumstances and these recommendations (Kowalski & Tallentire, 1999) have been adopted in this study. If the batch sizes increase in the future then the validation exercise may need to be repeated for the larger number of units per batch.

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9.0 OUTLINE OF PROCEDURE TO BE USED

9.1 The following steps will be taken to conduct the substantiation exercise.

9.1.1 Establish Test Sample Sizes.

9.1.2 Obtain Samples of Product Units.

9.1.3 Determine Average Bioburden.

9.1.4 Establish Verification Dose.

9.1.5 Perform Verification Dose Experiment.

9.1.6 Perform Test of Sterility.

9.1.6 Interpret Results and Produce Validation Report.

10.0 ESTABLISHMENT OF TEST SAMPLE SIZES

10.1 Bioburden Samples.

10.1.1 Bioburden determinations will be made from a minimum of 10 sample items from a minimum of 3 batches for each component part. Where less than 10 results are available from a batch, additional results may be used from other batches that have been tested. Thus, the overall objective will be to base verification dose decisions on the bioburden data from a minimum of 30 test results from at least 3 batches.

11.0 OBTAIN SAMPLES OF PRODUCT UNITS

11.1 Vimek will be responsible for supplying the correct number of test samples to AMS Laboratories for study.

11.2 Vimek will supply 30 items for the verification dose experiment for necks and 40 items for the stems/modules (if mixed types are used then the proportion of each will be documented). These are the required number of items for the verification dose (ISO/TR 13409) for batch sizes of 160 – 250 and 251 – 351 respectively.

11.3 AMS Laboratories will be responsible for the transfer of verification dose samples to and from ANSTO's facilities.

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12.0 DETERMINATION OF AVERAGE BIOBURDEN

12.1 Bioburden.

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12.1.2 Bioburden results will be determined by the methods according to BS EN 1174: 1996 including the application of a correction factor that takes into account the efficiency of recovery of microorganisms.

13.0 ESTABLISHMENT OF VERIFICATION DOSE

13.1 The paper by Kowalski & Tallentire (1999) demonstrates that one of two formulae should be applied in determining the appropriate the appropriate verification dose. The formula chosen will depend upon whether the average bioburden is determined to be less than 50 CFU per item or more than 50 CFU per item. These formulae are based upon the principles adopted in ISO 11137, method 1 or 2.

14.0 PERFORMANCE OF VERIFICATION DOSE

14.1 The verification dose will be delivered in the facilities of ANSTO.

14.2 The delivered dose will be verified by the use dosimeters and report issued to state the delivered dose.

14.3 The actual dose may vary from the calculated verification dose by not more than + 10 percent.

14.4 If the delivered dose is less than 90 percent of the calculated verification dose, the test may be repeated.

14.5 Once the verification dose has been successfully completed the samples will be returned to AMS Laboratories for the test of sterility to be conducted.

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15.0 PERFORM THE TEST OF STERILITY

15.1 Test of Sterility Method.

15.1.1 The method will comply with ISO 1737 – 2: 1998.

15.1.2 Additional set-up procedures will incorporate those used in currently setting up the Sterility Tests on finished products for Vimek.

15.1.3 The test of sterility will be conducted using a direct inoculation procedure whereby the entire test item will be exposed to culture medium.

15.1.4 The sample item proportion (SIP) will therefore be equal to 1.

15.1.5 For ease of use in setting up the tests (and therefore reducing the possibilities of false positive results), smaller sizes of necks and stems will be utilised in performing the validations.

16.0 INTERPRETATION OF RESULTS AND REPORTING

16.1 Results will be accepted if the above requirements have been fulfilled. Particular attention will be directed to the following:

16.1.1 Bioburden results have had an appropriate correction factor applied to them.

16.1.2 Verification dose calculation has used the appropriate formula for the demonstrated level of average bioburden.

16.1.3 Verification dose delivered was within required dose limits.

16.1.4 Test of sterility results were valid.

16.2 If the above conditions have been met then the process will be considered validated if no positive culture media are found after 14 days of incubation at 30^0 C.

16.3 If any of the points in 16.1 and 16.2 do not meet expectations, then all results will be subjected to a formal review process and an appropriate course of action decided between Vimek, AMS Laboratories and ANSTO.

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16.4 A validation report will be written that details all results found and draws a conclusion about the efficacy of the sterilization process for the test items evaluated.

17.0 DATA RETENTION

All raw data will be stored in the archives of AMS Laboratories for a minimum period of 5 years.

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ams Laboratories Pty Ltd
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118 Hattersley St
ROCKDALE NSW 2216
Australia
Tel: 02 9567 8544 *Fax: 02 9567 8228*

VALIDATION REPORT

CLIENT:

Vimek Pty Ltd
Unit 3, 44 McCauley Street
MATRAVILLE NSW 2036

PRODUCT:

Margron Hip Replacement Components, Necks and Stems

STERILIZATION METHOD:

Gamma Irradiation

REPORT PREPARED BY:

Dr Paul Priscott

CONCLUSION:

This study confirms that the sterilization process for Margron Hip Replacement Components, Necks and Stems, has been successfully validated according to the Validation Plan, Protocol No. PJ0037/1.

Signed _____ Signed _____
Consultant Microbiologist QA Manager, Vimek Pty Ltd

8/4/02

REFERENCED DOCUMENTS (COPIES ATTACHED):

1. Validation Plan for Margron Hip Components, Protocol No. PJ 0037/1, Vimek Pty Ltd.
2. ANSTO letter dated 23/11/01, Ref No. RTP 01-787 (Stems).
3. ANSTO letter dated 26/11/01, Ref No. RTP 01-788 (Necks).
4. AMS Laboratories Pty Ltd Certificate of Analysis 0112288, Test of Sterility for Validation Study of Necks Verification Dose of 9.7 kGy, 31/12/01.
5. AMS Laboratories Pty Ltd Certificate of Analysis 0112289, Test of Sterility for Validation Study of Stems Verification Dose of 11.7 kGy, 31/12/01.

BIOBURDEN SAMPLE SIZES:

During the period 7/7/00 to 25/10/01 five batches of Stems were received and analysed for their bioburden. A total of 50 individual items were studied. This data was used to determine the appropriate verification dose to be employed.

During the period 8/6/00 to 15/3/01 five batches of Necks were received and analysed for their bioburden. A total of 44 individual items were studied. This data was used to determine the appropriate verification dose to be employed.

DETERMINATION OF THE AVERAGE BIOBURDEN:

Stems

The device was known to have a low bioburden. Accordingly, the correction factor to be applied to the actual recovered bioburden data was determined by addition of a known number of organisms to the device and from the number recovered a factor was calculated to allow for those organisms no recovered.

The correction factor was thus determined to be 1.4. All determined bioburden data were multiplied by 1.4 to obtain the estimated actual bioburden values. These were used to calculate the verification dose.

The raw data and corrected bioburdens are presented in Table 1.

The average bioburdens (with correction factor applied) for the Stems were 7, 32, 4, 11 and 10 colony forming units (CFU) per item. The maximum individual bioburden was 106 CFU per item. This being more than two times any of the average bioburdens, was used for calculating the verification dose.

Table 1. Individual and Average Bioburden Data for Stems (Results as CFU/Item)

Date Received 7/7/00		Date Received 11/1/01		Date Received 20/7/00		Date Received 4/5/01		Date Received 25/10/01	
Lot # M330-336		Lot # notgiven		Lot # M343, 344, 345		Lot # M373,375,354		Lot # M354, 368, 373, 375, 398, 406	
Vimek Order #215		Vimek Order #375		Vimek Order #234		Vimek Order #461		Vimek Order #172	
Measured bioburden	Corrected bioburden	Measured bioburden	Corrected bioburden	Measured bioburden	Corrected bioburden	Measured bioburden	Corrected bioburden	Measured bioburden	Corrected bioburden
24	**34**	4	**6**	<2	**2**	10	**14**	6	**8**
4	**6**	<2	**2**	2	**3**	28	**39**	<2	**2**
<2	**2**	8	**11**	<2	**2**	6	**8**	8	**11**
4	**6**	<2	**2**	4	**6**	10	**14**	2	**3**
<2	**2**	10	**14**	<2	**2**	2	**3**	<2	**2**
<2	**2**	38	**53**	4	**6**	12	**17**	2	**3**
22	**31**	4	**6**	<2	**2**	20	**28**	4	**6**
8	**11**	4	**6**	<2	**2**	60	**84**	22	**31**
2	**3**	6	**8**	2	**3**	76	**106**	<2	**2**
<2	**2**	2	**3**	10	**14**	2	**3**	4	**6**
Ave.=	**10**	**Ave.=**	**11**	**Ave.=**	**4**	**Ave.=**	**32**	**Ave.=**	**7**

< = less than. For calculations of averages, results of <2 were rounded up to the detection limit, ie 2.

Necks

The device was known to have a low bioburden. Accordingly, the correction factor to be applied to the actual recovered bioburden data was determined by addition of a known number of organisms to the device and from the number recovered a factor was calculated to allow for those organisms no recovered.

The correction factor was thus determined to be 1.6. All determined bioburden data were multiplied by 1.6 to obtain the estimated actual bioburden values. These were used to calculate the verification dose.

The raw data and corrected bioburdens are presented in Table 2.

The average bioburdens (with correction factor applied) for the Necks were 9, 2, 3, 3, and 2 colony forming units (CFU) per item. The maximum individual bioburden was 24 CFU per item. This being more than two times any of the average bioburdens, was used for calculating the verification dose.

Table 2. Individual and Average Bioburden Data for Necks (Results as CFU/Item)

Date Received 8/6/00		Date Received 28/6/00		Date Received 28/9/01		Date Received 27/6/01		Date Received 15/3/01	
Lot # M307, 308, 312,313		Lot # M310, 338, 339, 340		Lot # M319, 337, 363, 364		Lot # M358, 376, 380, 388, 389, 390		Lot # not given	
Vimek Order #182		Vimek Order #202		Vimek Order #300		Vimek Order #494		Vimek Order #423	
Measured bioburden	Corrected bioburden	Measured bioburden	Corrected bioburden	Measured bioburden	Corrected bioburden	Measured bioburden	Corrected bioburden	Measured bioburden	Corrected bioburden
<2	**2**	3	**5**	<2	**2**	<2	**2**	<2	**2**
2	**3**	<2	**2**	2	**3**	<2	**2**	15	**24**
<2	**2**	<2	**2**	2	**3**	<2	**2**	3	**5**
<2	**2**	<2	**2**	<2	**2**	<2	**2**	2	**3**
<2	**2**	3	**5**	<2	**2**	<2	**2**	-	-
<2	**2**	<2	**2**	2	**3**	<2	**2**	-	-
<2	**2**	<2	**2**	<2	**2**	2	**3**	-	-
2	**3**	<2	**2**	<2	**2**	<2	**2**	-	-
<2	**2**	<2	**2**	4	**6**	<2	**2**	-	-
<2	**2**	<2	**2**	<2	**2**	<2	**2**	-	-
Ave.=	**2**	**Ave.=**	**3**	**Ave.=**	**3**	**Ave.=**	**2**	**Ave.=**	**9**

< = less than. For calculations of averages, results of <2 were rounded up to the detection limit, ie 2.

CALCULATION OF THE VERIFICATION DOSE:

Stems

Since the bioburden used for the verification dose setting was 106 CFU/item, the formula for estimating the verification dose (from Kawalski & Tallentire, Radition Phys. Chem., 54, 1999, 55-64) for bioburdens between 51 – 1,000 was used.

The $TD_{10} = 21.3 - 8.0 / 4 = 3.325$.

Then the verification dose, $VD_{max} = 25 - [3.325 (-2 + 6)] = 25 - 13.3 =$ **11.7 kGy**.

Necks

Since the bioburden used for the verification dose setting was 24 CFU/item, the formula for estimating the verification dose (from Kawalski & Tallentire, Radition Phys. Chem., 54, 1999, 55-64) for bioburdens between 1 - 50 was used.

The $D_{lin} = 25 / 6 + 1.38 = 3.3875$

Then the verification dose, $VD_{max} = 3.388 (1.38 - -1.477) = 3.388 \times 2.857 = 9.6799$ = **9.7 kGy**.

PERFORMANCE OF VERIFICATION DOSE:

The verification doses were performed by ANSTO.

Stems

Dosimeter measurements indicated the average dose to be 11.2 kGy with maximum dose 11.7 kGy and minimum dose 10.8 kGy. These complied with requirements (see ANSTO letter 23/11/01).

Necks

Dosimeter measurements indicated the average dose to be 9.7kGy with maximum dose 10.2 kGy and minimum dose 9.2 kGy. These complied with requirements (see ANSTO letter 26/11/01).

PERFORMANCE TEST OF STERILITY:

Stems

Forty (40) Margron Hip Stems were received from ANSTO.

These were transferred to AMS Laboratories clean room and set up for the test of sterility on 11/12/01. All 40 tests showed no growth after 14 days and subsequent stasis testing confirmed no antimicrobial effects from the inoculated products (Certificate of Analysis 0112289).

Therefore all tests of sterility passed.

Necks

Thirty (30) Margron Hip Necks were received from ANSTO.

These were transferred to AMS Laboratories clean room and set up for the test of sterility on 11/12/01. All 30 tests showed no growth after 14 days and subsequent stasis testing confirmed no antimicrobial effects from the inoculated products (Certificate of Analysis 0112288).

Therefore all tests of sterility passed.

INTERPRETATION OF RESULTS:

The results referenced herein and reported in the cross-referenced documents confirm that the sterilization conditions to be applied to Vimek Hip Replacement Parts, namely Stems and Necks, comply with those required by internationally recognized standards.

The sterilization process for these products is therefore be considered validated.

ATTACHMENTS TO VIMEK VALIDATION REPORT FOR MARGRON HIP REPLACEMENT COMPONENTS, NECKS AND STEMS

Attachment	Description
1.	Validation Plan, Protocol No. PJ 0037/1
2.	ANSTO letter dated 23/11/01, Ref No. RTP 01-787 (Stems)
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12.1.1 Bioburden determinations will be made from a minimum of 10 sample items from a minimum of 3 batches for each component part. Where less than 10 results are available from a batch, additional results may be used from other batches that have been tested. Thus, the overall objective will be to base verification dose decisions on the bioburden data from a minimum of 30 test results from at least 3 batches.

12.1.2 Bioburden results will be determined by the methods according to BS EN 1174: 1996 including the application of a correction factor that takes into account the efficiency of recovery of microorganisms.

13.0 ESTABLISHMENT OF VERIFICATION DOSE

13.1 The paper by Kowalski & Tallentire (1999) demonstrates that one of two formulae should be applied in determining the appropriate the appropriate verification dose. The formula chosen will depend upon whether the average bioburden is determined to be less than 50 CFU per item or more than 50 CFU per item. These formulae are based upon the principles adopted in ISO 11137, method 1 or 2.

14.0 PERFORMANCE OF VERIFICATION DOSE

14.1 The verification dose will be delivered in the facilities of ANSTO.

14.2 The delivered dose will be verified by the use dosimeters and report issued to state the delivered dose.

14.3 The actual dose may vary from the calculated verification dose by not more than + 10 percent.

14.4 If the delivered dose is less than 90 percent of the calculated verification dose, the test may be repeated.

14.5 Once the verification dose has been successfully completed the samples will be returned to AMS Laboratories for the test of sterility to be conducted.

15.0 PERFORM THE TEST OF STERILITY

15.1 Test of Sterility Method.

15.1.1 The method will comply with ISO 1737 – 2: 1998.

15.1.2 Additional set-up procedures will incorporate those used in currently setting up the Sterility Tests on finished products for Vimek.

15.1.3 The test of sterility will be conducted using a direct inoculation procedure whereby the entire test item will be exposed to culture medium.

15.1.4 The sample item proportion (SIP) will therefore be equal to 1.

15.1.5 For ease of use in setting up the tests (and therefore reducing the possibilities of false positive results), smaller sizes of necks and stems will be utilised in performing the validations.

16.0 INTERPRETATION OF RESULTS AND REPORTING

16.1 Results will be accepted if the above requirements have been fulfilled. Particular attention will be directed to the following:

16.1.1 Bioburden results have had an appropriate correction factor applied to them.

16.1.2 Verification dose calculation has used the appropriate formula for the demonstrated level of average bioburden.

16.1.3 Verification dose delivered was within required dose limits.

16.1.4 Test of sterility results were valid.

16.2 If the above conditions have been met then the process will be considered validated if no positive culture media are found after 14 days of incubation at 30^0 C.

16.3 If any of the points in 16.1 and 16.2 do not meet expectations, then all results will be subjected to a formal review process and an appropriate course of action decided between Vimek, AMS Laboratories and ANSTO.

16.4 A validation report will be written that details all results found and draws a conclusion about the efficacy of the sterilization process for the test items evaluated.

17.0 DATA RETENTION

All raw data will be stored in the archives of AMS Laboratories for a minimum period of 5 years.

Recd
23/11
3:00 pm

Attachment 2

AUSTRALIAN NUCLEAR SCIENCE
& TECHNOLOGY ORGANISATION

ansto

LUCAS HEIGHTS SCIENCE & TECHNOLOGY CENTRE, NEW ILLAWARRA RD, LUCAS HEIGHTS, NSW, AUSTRALIA

PRIVATE MAIL BAG 1 MENAI, NSW 2234
General telephone (61 2) 9717 3111
General facsimile (61 2) 9543 5097

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23 November 2001

Dr Paul Priscott
AMS Laboratories Pty Ltd
118 Hattersley Street
ROCKDALE NSW 2216

Ref. No. RTP 01-787

40 Vimek hip replacement stems were irradiated to a target dose of 11.7 kGy ± 10% according to the ISO 11137 requirements for sterilisation dose validation.

The goods were repackaged into boxes and mounted onto stands for processing. High-dose ceric-cerous dosimeters were sited throughout the array at the expected maximum and minimum dose zones. ANSTO's dosimeters have measurement traceability to the Australian and UK Standards for Absorbed Dose. The goods were then irradiated in ANSTO's GATRI facility for a time calculated to give the required dose.

Dosimeter measurements indicate the following -

* maximum dose	11.7 kGy
* minimum dose	10.8 kGy
*average dose	11.2 kGy

The dose absorbed by the product and the uniformity ratio comply with the required specifications.

An invoice will follow.

0112.289

Best regards

Gavin J Gant
Radiation Services Officer
Radiation Technology

AUSTRALIAN NUCLEAR SCIENCE
& TECHNOLOGY ORGANISATION

LUCAS HEIGHTS SCIENCE & TECHNOLOGY CENTRE, NEW ILLAWARRA RD, LUCAS HEIGHTS, NSW, AUSTRALIA

PRIVATE MAIL BAG 1 MENAI, NSW 2234
General telephone (61 2) 9717 3111
General facsimile (61 2) 9543 5097

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26 November 2001

Dr Paul Priscott
AMS Laboratories Pty Ltd
118 Hattersley Street
ROCKDALE NSW 2216

Ref. No. RTP 01-788

30 Vimek hip replacement necks were irradiated to a target dose of 9.7 kGy ± 10% according to the ISO 11137 requirements for sterilisation dose validation.

The goods were repackaged into boxes and mounted onto stands for processing. Low-dose ceric-cerous dosimeters were sited throughout the array at the expected maximum and minimum dose zones. ANSTO's dosimeters have measurement traceability to the Australian and UK Standards for Absorbed Dose. The goods were then irradiated in ANSTO's GATRI facility for a time calculated to give the required dose.

Dosimeter measurements indicate the following -

* maximum dose	10.2 kGy
* minimum dose	9.2 kGy
*average dose	9.7 kGy

The dose absorbed by the product and the uniformity ratio comply with the required specifications.

An invoice will follow.

Best regards

G112238

Gavin J Gant
Radiation Services Officer
Radiation Technology

ams Laboratories Pty Ltd
ACN 075 467 757
118 Hattersley St
ROCKDALE NSW 2216
Australia
Tel: 02 9567 8544 *Fax: 02 9567 8228*

Certificate of Analysis

Dated: 31/12/01

CLIENT: Vimek Pty Limited
Unit 3, 44 McCauley Street,
MATRAVILLE NSW 2036

ATTN: Ewen Laird

OUR REF: 0112288

ORDER NO: Not Given

SAMPLE DESCRIPTION: 30 x Vimek Hip Replacement Necks, set up individually.

DATE RECEIVED: 28/11/01

DATE COMMENCED: 11/12/01

EXAMINATION: Validation Study of Verification Dose of 9.7 kGy.

METHOD: Followed guidance given in ISO/FDIS 11737 Part 2 "Tests of sterility performed in the validation of a sterilization process".
Notes: (1) Each sample was directly inoculated into T05 (Tryptone Soy broth with 0.5% Tween 80)
(2) Culture medium was incubated at 30^{o}C for 14 days.

RESULTS:

CONTROLS

ISO 11737-2 Paragraph	Recommended Control	Result	Notes
A.6.2.2	Growth promoting qualities of medium	Pass	Media supplier: Amyl B# 6476 AMSL B/N T05 Exp.10/01/01 and Exp.20/02/02 Also confirmed sterile.
A.6.2.3	Test for microbicidal &/or microbistatic substances	Pass	Adequate recovery of low numbers of *C.albicans* & *B.subtilis*.

TEST OF STERILITY

Number of product units (kits) evaluated	RESULT (Number showing growth)
30	0

INTERPRETATION

None of the tested Hip Replacement Necks showed growth indicating that they passed the test of sterility. The stasis part of the test showed no presence of inhibitory substances that may have interfered with the test.

Signed : Jane Sherack

Jane Sherack B.Sc., Grad.Dip. App.Sc., MASM

ams Laboratories Pty Ltd

ACN 075 467 757

118 Hattersley St

ROCKDALE NSW 2216

Australia

Tel: 02 9567 8544 *Fax: 02 9567 8228*

Certificate of Analysis

Dated: 31/12/01

CLIENT: Vimek Pty Limited
Unit 3, 44 McCauley Street,
MATRAVILLE NSW 2036

ATTN: Ewen Laird

OUR REF: 0112289

ORDER NO: Not Given

SAMPLE DESCRIPTION: 40 x Vimek Hip Replacement Stems, set up individually.

DATE RECEIVED: 28/11/01

DATE COMMENCED: 11/12/01

EXAMINATION: Validation Study of Verification Dose of 11.7 kGy.

METHOD: Followed guidance given in ISO/FDIS 11737 Part 2 "Tests of sterility performed in the validation of a sterilization process".

Notes: (1) Each sample was directly inoculated into T05 (Tryptone Soy broth with 0.5% Tween 80)

(2) Culture medium was incubated at 30°C for 14 days.

RESULTS:

CONTROLS

ISO 11737-2 Paragraph	Recommended Control	Result	Notes
A.6.2.2	Growth promoting qualities of medium	Pass	Media supplier: Amyl B# 6476 AMSL B/N T05 exp. 21/02/02 Also confirmed sterile.
A.6.2.3	Test for microbicidal &/or microbistatic substances	Pass	Adequate recovery of low numbers of *C.albicans* & *B.subtilis*.

TEST OF STERILITY

Number of product units (kits) evaluated	RESULT (Number showing growth)
40	0

INTERPRETATION

None of the tested Hip Replacement Stems showed growth indicating that they passed the test of sterility. The stasis part of the test showed no presence of inhibitory substances that may have interfered with the test.

Signed : Jane Sherack

Jane Sherack B.Sc., Grad.Dip. App.Sc., MASM