GLP REPORT

TEST FACILITY:

NAMSA
6750 Wales Road
Northwood, OH 43619

SPONSOR:

Paul Tiege
ViRexx Medical Corporation
8223 Roper Road NW
Edmonton, Alberta, T6E 6S4
Canada

CONFIDENTIAL

STUDY TITLE:

ISO Intracutaneous Study - Extract

TEST ARTICLE:

Occlusin® 500 Artificial Embolization Device

IDENTIFICATION NO.:

Batch: FL288

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Summary

The test article, Occlusin® 500 Artificial Embolization Device, Batch: FL288, was extracted in 0.9% sodium chloride USP solution and sesame oil, NF. These extracts were evaluated for intracutaneous reactivity based on the requirements of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity.

A 0.2 ml dose of the appropriate test article extract was injected by the intracutaneous route into five separate sites on the right side of the back of each rabbit. Similarly, the corresponding control was injected on the left side of the back of each rabbit. The injection sites were observed immediately after injection. Observations for erythema and edema were conducted at 24, 48, and 72 hours after injection.

Under the conditions of this study, there was no erythema and no edema from the SC extract injected intracutaneously into rabbits. There was very slight erythema and very slight edema from the SO extract injected intracutaneously into rabbits. The test article extracts met the requirements of the test since the difference between the test extracts and corresponding control mean score was 1.0 or less.

Study and Supervisory Personnel:

Colleen M. Stevenson, A.A.
Ericka N. McCalla, B.S.
Deedee M. Shoe, B.A.
Carrie A. Fetter
Shelli L. Snyder, A.A.
Nicole L. Pence, A.A.
Molly F. Corvo, B.S.
Diane L. Miller
Heather A. Huseman, B.S.

Approved by:

Michelle E. Longstreet

Michelle E. Longstreet, B.S.
Study Director

7-12-07
Date Completed

Statement of GLP Compliance

This study was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58).

There were no deviations from the protocol, standard operating procedures or the GLP Regulations which were judged to have had any significant impact on the validity or interpretation of the data.

All laboratory data has been accurately recorded and verified, as indicated by the signature below.

Study Director: Michelle E. Longstreet

Michelle E. Longstreet, B.S.

7-12-07

Date

1. Introduction

Purpose
The test article identified below was extracted and the extracts were evaluated for biocompatibility based on the requirements of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. The purpose of the study was to determine whether leachables extracted from the material would cause local dermal irritant effects following injection into rabbit skin.

Dates
The test article was received on May 30, 2007. The animals were injected on July 2, 2007, and the observations were concluded on July 5, 2007.

GLP Compliance
The study initiated by protocol signature on June 11, 2007, was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations, 21 CFR 58. A Statement of Quality Assurance Activities was issued with this report.

Duplication of Experimental Work
By signature on the protocol, the sponsor confirmed that the conduct of this study did not unnecessarily duplicate previous experiments.

2. Materials

The test article provided by the sponsor was identified and handled as follows:

Test Article:	Occlusin® 500 Artificial Embolization Device
Identification No.:	Batch: FL288
Stability Testing:	In progress (per sponsor)
Expiration Date:	Stable for duration of intended testing (per sponsor)
Strength, Purity and Composition:	The sponsor elects not to provide this information to NAMSA and takes full responsibility for this data and can supply this information if requested to do so.
Physical Description of Test Article:	Glass vials containing white beads
Storage Conditions:	Refrigerated
Vehicles:	0.9% sodium chloride USP solution (SC) Sesame oil, NF (SO)
Preparation:	The test article was prepared based on the sponsor supplied surface area of 44 cm^2 per sample. One sample was included in each preparation. Based on a ratio of 120 cm^2:20 ml, a 44.0 cm^2 portion of the test article was covered with 7.3 ml of the vehicle. A 7.3 ml portion of the extract was added to the original container in order to remove the test article from the original container, and the test article with vehicle was transferred to a sterile vial for extraction. The test article was extracted in SC and SO at 37°C for 72 hours. The extracts were agitated during extraction. The extraction vehicles without test article were similarly prepared to serve as controls.

Condition of Extracts:

	Test	Control
SC:	clear with particulates*	clear
SO:	clear with particulates*	clear

*The test article had no sign of clumping at time of decant.

3. Test System

Test System

Species:	Rabbit (*Oryctolagus cuniculus*)
Breed:	New Zealand White
Source:	Myrtle's Rabbitry, Inc.
Sex:	Male
Body Weight Range:	2.3 kg to 2.4 kg at selection
Age:	Young adult
Acclimation Period:	Minimum 5 days
Number of Animals:	Two
Identification Method:	Ear tag

Justification of Test System

The intracutaneous injection test in rabbits is specified in the current ISO testing standards and has been used historically to evaluate biomaterial extracts.

4. Animal Management

Husbandry:	Conditions conformed to Standard Operating Procedures that are based on the "Guide for the Care and Use of Laboratory Animals."
Food:	A commercially available rabbit feed was provided daily.
Water:	Potable water was provided *ad libitum* through species appropriate water containers or delivered through an automatic watering system.
Contaminants:	Reasonably expected contaminants in feed or water supplies did not have the potential to influence the outcome of this test.
Housing:	Animals were individually housed in stainless steel suspended cages identified by a card indicating the lab number, animal number, test code, sex, and date dosed.
Environment:	The room temperature was monitored daily. The temperature range for the room was within a range of 61-72°F. The room humidity was monitored daily. The humidity range for the room was 30-70%. The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).
Accreditation:	NAMSA is an AAALAC International accredited facility and is registered with the United States Department of Agriculture. Additionally, NAMSA maintains an approved Animal Welfare Assurance on file with the National Institutes of Health, Office for Laboratory Animal Welfare.
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy, previously unused, thin-skinned animals free of mechanical irritation or trauma that could interfere with the test were selected.
Sedation, Analgesia or Anesthesia:	Sedation, analgesia or anesthesia was not necessary during the routine course of this procedure.
Veterinary Care:	In the unlikely event that an animal became injured, ill, or moribund, care was conducted in accordance with current veterinary medical practice. If warranted for humane reasons, euthanasia was conducted in accordance with the current report of the American Veterinary Medical Association's Panel on Euthanasia. The objective of the study will be given due consideration in any decision and the study sponsor will be advised.
IACUC:	This procedure has been approved by NAMSA Institutional Animal Care and Use Committees (IACUC), and is reviewed at least annually by the same committees. Any significant changes to this procedure were approved by the IACUC prior to conduct.

5. Methods

Each animal was weighed. Within a 4 to 18 hour period before treatment, each rabbit was clipped free of fur from the back and both sides of the spinal column to yield a sufficient injection area. Two rabbits were prepared per pair of extracts. A 0.2 ml dose of the appropriate test article extract was injected by the intracutaneous route into five separate sites on the right side of the back of each rabbit. Similarly, the corresponding control was injected on the left side of the back of each rabbit. Injections were spaced approximately 2 cm apart. The appearance of each injection site was noted immediately after injection. The animals were returned to their respective cages following the procedure.

Observations for erythema and edema were conducted at 24, 48, and 72 hours after injection. Reactions were scored on a 0 to 4 basis. Any reaction at the injection sites was also noted. The reactions were evaluated according to the following subjective rating scale:

SCORE	ERYTHEMA (ER)	EDEMA (ED)
0	No erythema	No edema
1	Very slight erythema (barely perceptible)	Very slight edema (barely perceptible)
2	Well-defined erythema	Well-defined edema (edges of area well-defined by definite raising)
3	Moderate erythema	Moderate edema (raised approximately 1 mm)
4	Severe erythema (beet redness) to eschar formation preventing grading of erythema	Severe edema (raised more than 1 mm, and extending beyond exposure area)

6. Evaluation and Statistical Analysis

The mean erythema and edema scores for the test and control extracts for each animal at each scoring interval were calculated. All mean erythema and edema scores for the test and control extracts were totaled and divided by 12 (2 animals x 3 grading periods x 2 grading categories) to determine the overall mean score for the test extract and corresponding control. The difference between the overall mean score of the test and corresponding control extracts was calculated by subtracting the overall mean score for the control from the overall mean score for the test extract.

The requirements of the test were met if the difference between the test extract mean score and corresponding control mean score was 1.0 or less.

7. Results

All animals appeared normal throughout the study. Results of scores for individual rabbits appear in Appendix 1. All injection sites appeared normal immediately following injection. The overall mean difference for the extracts are summarized below:

Extract	Overall Test Group Mean	Overall Control Group Mean	Overall Mean Difference (Test – Control)
SC	0.0	0.0	0.0
SO	0.8	0.9	0.0

8. Conclusion

Under the conditions of this study, there was no erythema and no edema from the SC extract injected intracutaneously into rabbits. There was very slight erythema and very slight edema from the SO extract injected intracutaneously into rabbits. The test article extracts met the requirements of the test since the difference between the test extracts and corresponding control mean score was 1.0 or less.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other samples is the sponsor's responsibility. All procedures were conducted in conformance with good manufacturing practices and ISO 13485:2003.

9. Quality Assurance

Inspections were conducted at intervals adequate to assure the integrity of the study in conformance with 21 CFR 58.35(b)(3). The final report was reviewed for conformance to Section 58.185, Subpart J, of the GLP Regulations. A Statement of Quality Assurance Activities is provided with this final report.

10. Proposed Dates

The study dates were finalized by the study director following receipt of the sponsor approved protocol and appropriate material for the study. Initiation of the study was the date on which the study director signed the GLP protocol. Projected dates for starting the study (first treatment) and for the completion of the study (final report release) were provided to the sponsor (or representative of the sponsor).

11. Records

All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSA archive files.

12. References

21 CFR 58 (GLP Regulations).

Guide for the Care and Use of Laboratory Animals, Institute for Laboratory Animal Research, National Academy of Sciences (Washington: National Academy Press, 1996).

ISO 10993-10 (2002) Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity.

OLAW, Public Health Service Policy on Humane Care and Use of Laboratory Animals.

United States Code of Federal Regulation (CFR) 9: The Animal Welfare Act.

United States Pharmacopeia (USP), General Chapter <88> Biological Reactivity Tests, In Vivo.

13. Protocol Changes

Any necessary changes to the protocol after sponsor approval or study initiation were documented and approved by the study director as protocol amendments. Copies were distributed to the sponsor, the raw data file, and the NAMSA Quality Assurance department.

Appendix 1 - ISO Intracutaneous Observations

Rabbit Number/ Gender	Body Weight (kg)	Extract	Scoring Interval											
			24 Hours				48 Hours				72 Hours			
			Test		Control		Test		Control		Test		Control	
			ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED
55060 Male	2.3	SC	0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
Mean Score			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
55188 Male	2.4	SC	0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
Mean Score			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
55060 Male	2.3	SO	1	1	1	1	1	1	1	1	0	0	1	0
			1	1	1	1	1	1	1	0	1	0	0	0
			1	1	1	1	1	1	1	1	1	0	1	0
			1	1	1	1	1	0	1	0	1	0	1	0
			1	1	1	1	1	0	1	0	1	0	1	0
Mean Score			1.0	1.0	1.0	1.0	1.0	0.6	1.0	0.4	0.8	0.0	0.8	0.0
55188 Male	2.4	SO	1	1	1	1	1	1	1	1	1	0	1	1
			1	1	1	1	1	1	1	1	1	0	1	1
			1	1	1	1	1	1	1	1	1	0	1	1
			1	1	1	1	1	1	1	1	1	0	1	1
			1	1	1	1	1	1	1	1	1	1	1	1
Mean Score			1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	0.2	1.0	1.0

ER = Erythema
ED = Edema
SC = 0.9% sodium chloride USP solution
SO = sesame oil, NF

Statement of Quality Assurance Activities

Phase Inspected	Auditor	Date
Scoring	L. M. Byrd	July 3, 2007
Final Report Review	R. J. Spino	July 12, 2007

Reports to Management and Study Director(s)	Date
Periodic Status Report	July 10, 2007

This study will be included in the next periodic status report as completed.

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: _____ 7-12-07

Ryan J. Spino, B.S.
Auditor, Quality Assurance

Date

STORE IN REFRIGERATOR
(+4°C)
CALIBRATION #: 7420
TECH/DATE: VS 5-30-07

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07T_37252
25447_001 25447

Required field

SPONSOR FINAL REPORT WILL BE ADDRESSED AND MAILED TO

ViRexx Medical Corp — Paul Tiege
COMPANY NAME* — **ATTN***
8223 Roper Road
ADDRESS*
Edmonton — Alberta — T6E 6S4
CITY* — **STATE*** — **ZIP***
Canada
COUNTRY*
780 989 6715
PHONE*
780 436 0068
FAX*
ptiege@virexx.com
E-MAIL*

INVOICE INFORMATION
same, Attn. Erin Horwitz
BILLING ADDRESS (include Company Name if different from mailed to)*

V0725-186PT
PURCHASE ORDER NUMBER*
T07 2708
COST ESTIMATE AND PROPOSAL NUMBER
☐ VISA ☐ MasterCard ☐ American Exp.
CARD HOLDER NAME
CREDIT CARD NUMBER — **EXPIRATION DATE**
ACCOUNTS PAYABLE PHONE* — **ACCOUNTS PAYABLE FAX***

Occlusin® 500 Artificial Embolization Device
TEST ARTICLE NAME *USE EXACT WORDING DESIRED ON FINAL REPORT* * +*

Embolotherapy
INTENDED CLINICAL USE OF TEST ARTICLE:*

X BATCH ☐ CODE ☐ LOT — FL288
CHECK ONE — **IDENTIFICATION NUMBER***

CONTROL ARTICLE NAME*

☑ BATCH ☐ CODE ☐ LOT
CHECK ONE — **IDENTIFICATION NUMBER***
NAMSA recommends only one lot, batch, or code per test article submission.

QUANTITY SUBMITTED:* 38 vials Occlusin® 500 Artificial Embolization Device , Batch FL288
(please specify quantities for each lot/batch/code provided)
PHYSICAL DESCRIPTION OF TEST ARTICLE (Chemical/Material type/Color)*
glass vials containing white beads

TEST ~~ARTICLE IS~~ CATEGORIZED AS BEING A (check all that apply):* +
MEDICAL DEVICE ☐ BIOLOGIC ☐ TISSUE
☐ PHARMACEUTICAL ☐ CHEMICAL ☐ OTHER

+ A detailed composition list and current MSDS sheet must accompany any chemical or biologic test article. A certificate of testing or reprocessing must be submitted for any human tissue derived sample or clinically used medical device

TEST ARTICLE BEING SUBMITTED IS:*
STERILIZED ☐ NOT STERILIZED
☐ **NAMSA TO STERILIZE BY:** ☐ EO (additional charge) ☐ STEAM

Mixtures of test or control articles with carriers require analysis to demonstrate proper concentration, homogeneity, and stability.*
☐ Sponsor will provide analytical methods; or
☐ Sponsor will perform analysis on representative aliquots provided by NAMSA.

STORAGE CONDITIONS*
☐ ROOM TEMPERATURE X REFRIGERATION ☐ FREEZER
☐ OTHER:

TEST AND CONTROL ARTICLE CHARACTERIZATION: The sponsor assures the above test article has been characterized for identity, strength, purity, and composition as required by FDA Good Laboratory Practice Regulations of 21 CFR Part 58.105. Stability testing is the responsibility of the sponsor and is subject to FDA audit. Characterization and stability information are also required for control articles. Please check the statement(s) applicable to the test and control articles for both Stability and Strength, Purity and Composition sections below.

Test Article	Control Article	Stability (Choose One)
X	☐	Stability testing is in progress; article is stable for duration of intended testing.
☐	☐	Stability testing is complete and on file with sponsor. Expiration date (test): Expiration date (control):
☐	☐	Marketed product stability characterized by its labeling.

Test Article	Control Article	Strength, Purity, and Composition (Choose One)
☐	☐	Sponsor provided data in a Certificate of Analysis or other appropriate documentation and results will be reflected in the final report.
X	☐	Sponsor elects not to provide this information to NAMSA and takes full responsibility for this data and can supply this information if requested to do so.

If requesting to return sample, please check the courier and include your:
☐ UPS ☐ Federal Express ☐ Other: Account Number:

T053007_017
FEDEX VIREXX 5-30-07 Requires Ice Packs

AUTHORIZED BY SPONSOR — DATE 28 MAY 07
NAMSA STUDY DIRECTOR — DATE 6-11-07

REV040207

GLP PROTOCOL

TEST FACILITY:

NAMSA
6750 Wales Road
Northwood, OH 43619-1011

SPONSOR:

Paul Tiege
ViRexx Medical Corporation
8223 Roper Road NW
Edmonton, Alberta,
Canada

STUDY TITLE:

ISO Intracutaneous Study, Extract

Approvals

Sponsor Representative (Sponsor): [signature]

Date Approved: 28MAY07

Study Director (NAMSA): Michelle E. Longstaff

Date Initiated: 6-11-07

Special Laboratory Instructions:

Control Article
Controls (extraction vehicle without test material) will be prepared in the same way and at the same time as the test extracts.

3. Test System

Test System

Species:	Rabbit (*Oryctolagus cuniculus*)
Breed:	New Zealand White
Source:	Single USDA licensed supplier
Sex:	No particular gender is prescribed in this test
Body Weight Range:	2.0 kg or greater at selection
Age:	Young adults
Acclimation Period:	Minimum 5 days
Number of Animals:	Two per extract or pair of extracts
Identification Method:	Ear tag

Justification of Test System
The intracutaneous injection test in rabbits is specified in the current ISO testing standards and has been used historically to evaluate biomaterial extracts.

4. Animal Management

Husbandry:	Conditions will conform to Standard Operating Procedures that are based on the "Guide for the Care and Use of Laboratory Animals."
Food:	A commercially available rabbit feed will be provided daily.
Water:	Potable water will be provided *ad libitum* through species appropriate water containers or delivered through an automatic watering system.
Contaminants:	Reasonably expected contaminants in feed or water supplies should not have the potential to influence the outcome of this test.
Housing:	Animals will be individually housed in stainless steel suspended cages identified by a card indicating the lab number, animal number, test code, sex, and date dosed.
Environment:	The room temperature will be monitored daily. The recommended temperature range for the room is 61-72°F. The room humidity will be monitored daily. The humidity range for the room is 30-70%. The light cycle will be controlled using an automatic timer (12 hours light, 12 hours dark).
Accreditation:	NAMSA is an AAALAC International accredited facility and is registered with the United States Department of Agriculture. Additionally, NAMSA maintains an approved Animal Welfare Assurance on file with the National Institutes of Health, Office for Laboratory Animal Welfare.
Personnel:	Associates involved will be appropriately qualified and trained.
Selection:	Only healthy, thin-skinned animals free of mechanical irritation or trauma that could interfere with the test will be selected. To reduce the number of animals used for testing, and to comply with the directives of the NAMSA Institutional Animal Care and Use Committee (IACUC), rabbits on this study may have been used previously in an unrelated test model. Any previously evaluated test or control articles did not cause a response in the animals. Complete history of animal usage is traceable in laboratory records. Animals used for previous evaluations will be identified in the report.

8. Quality Assurance

Inspections will be conducted at intervals adequate to assure the integrity of the study in conformance with 21 CFR 58.35(b)(3). The final report will also be reviewed for conformance to Section 58.185, Subpart J, of the GLP Regulations. A Statement of Quality Assurance Activities will be provided with the final report.

9. Proposed Dates

The study dates will be finalized by the study director following receipt of the sponsor-approved protocol and appropriate material for the study. Initiation of the study will be the date on which the study director signs the GLP protocol. Projected dates for starting the study (first treatment) and for the completion of the study (final report release) will be provided to the sponsor (or representative of the sponsor).

10. Records

Test article and control preparation data, dates of relevant activities (such as the study initiation and completion), the appearance of each injection site immediately after injection, individual dermal scores at 24, 48, and 72 hours.

All raw data pertaining to this study and a copy of the final report will be retained in designated NAMSA archive files.

11. References

21 CFR 58 (GLP Regulations).

Guide for the Care and Use of Laboratory Animals, Institute for Laboratory Animal Research, National Academy of Sciences (Washington: National Academy Press, 1996).

ISO 10993-10 (2002) Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

OLAW, Public Health Service Policy on Humane Care and Use of Laboratory Animals.

United States Code of Federal Regulation (CFR) 9: The Animal Welfare Act.

United States Pharmacopeia (USP), General Chapter <88> Biological Reactivity Tests, In Vivo.

12. Protocol Changes

Any necessary changes to the protocol after sponsor approval or study initiation will be documented and approved by the study director as protocol amendments. Copies will be distributed to the sponsor, the raw data file, and the NAMSA Quality Assurance department.

NAMSA

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June 12, 2007

Paul Tiege
ViRexx Medical Corporation
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Edmonton, Alberta, T6E 6S4 Canada

PROTOCOL AMENDMENT I

Test Article: Occlusin® 500 Artificial Embolization Device

Identification: Batch: FL288

NAMSA Submission ID.: 07T_37252

We have received appropriate test article and approved protocol(s) for the program to be conducted in accordance with the Good Laboratory Practice (GLP) Regulations on the material described above. Below is a projected schedule for the work to be performed.

NAMSA Code	NAMSA Lab Number	Study	Estimated Start Date:	Estimated Report Release Date:
TI261_300	07T_37252_02	ISO Maximization Sensitization Study - Extract - 0.9% SC Extract	June 25, 2007	August 24, 2007
TI261_300	07T_37252_03	ISO Maximization Sensitization Study - Extract - SO Extract	June 25, 2007	August 24, 2007
TI251_800	07T_37252_04	ISO Intracutaneous Study - Extract - 0.9% SC Extract	June 18, 2007	July 12, 2007
TI251_800	07T_37252_05	ISO Intracutaneous Study - Extract - SO Extract	June 18, 2007	July 12, 2007
TS200_901	07T_37252_06	Two Week Rat Study, Repeated Parenteral Administration of Two Extracts - 0.9% SC Extract	June 25, 2007	September 21, 2007
TS200_901	07T_37252_07	Two Week Rat Study, Repeated Parenteral Administration of Two Extracts - SO Extract	June 25, 2007	September 21, 2007

Michelle E. Longstreet

Michelle E. Longstreet, B.S.
Study Director

6-12-07
Date

cc: QA (NAMSA)
GLP study file

NAMSA

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June 26, 2007

Paul Tiege
ViRexx Medical Corporation
8223 Roper Road NW
Edmonton, Alberta, T6E 6S4 Canada

PROTOCOL AMENDMENT II

Test Article:	Occlusin® 500 Artificial Embolization Device
Identification:	Batch: FL288
Protocol:	TI251_800 ISO Intracutaneous Study – 0.9% SC, SO Extract
NAMSA Lab No.:	07T_37252_04, 05

This amendment has been written to correct the Preparation section of the study protocol:

- One vial may be used for the preparation of each the SC and SO extract.

This amendment was written prior to testing.

Michelle E. Longstreet

Michelle E. Longstreet, B.S.
Study Director

6-27-07
Date

cc: QA (NAMSA)
GLP study file