Test Report

TEST ITEMS

Test for Irritation (Intracutaneous reactivity test)

TEST ARTICLE

Non-absorbable Surgical Suture (model: PTFE)
<Specification: Z21302-60 (USP2-0/EP2.5)>

IDENTIFICATION №

150642

MANUFACTURER

Foosin Medical Supplies Inc., Ltd.

SPONSOR

TÜV SÜD Certification and Testing (China) Co., Ltd.
<Address: M Building, No.7 Wangjing Zhonghuan Nanlu, Chaoyang District, Beijing 100102, P.R.China>

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2. It will be invalid for the report without the signature of study director.
3. It will be invalid for the manual revision of the report.
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5. Please raise the objection to the Center within 15 days after the receipt of the report, otherwise it will be considered to accept the testing result.
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SUMMARY

The intracutaneous reactivity test was conducted to assess the potential of the test article, Non-absorbable Surgical Suture (model: PTFE), to produce irritation following intradermal injection of the extracts of the test article. This study was conducted to base on the requirements for the International Organization for Standardization ISO 10993-10:2010: Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization; ISO 10993-12:2012: Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

Three young adult New Zealand White Rabbits with body weight ranging from 2.3 kg to 2.4 kg were utilized. Both 0.9% sodium chloride injection (SC) and cotton seed oil (CSO) served as extraction vehicles. The test article was extracted in SC and CSO. A 0.2ml dose of the appropriate extract was injected by the intracutaneous route into five separate sites on 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. The final test extract score was obtained by subtracting the score of the reagent from the test extract score. The requirements of the test are met if the final test extract score is 1.0 or less.

Under the conditions of this study, there was no evidence of significant irritation from the SC and CSO extracts of the test article injected intracutaneously into rabbits, the difference between the test extract mean score and the reagent control mean score were all 0.0. The extract of the test article met the test requirement.

Study and Supervisory

Personnel: YANG Fan
MA Jiadong
LU Hua

Study Director: Sun Jiao — Nov 23. 2015

SUN Jiao, Ph.D. Date Completed

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INTRODUCTION

The test article identified below was extracted to determine whether the test extract would cause local dermal irritant effects following injection into rabbit skin. This test was conducted based on the requirements of ISO 10993-10:2010: Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization. The test article was received on Jun. 16, 2015. Treatment began on Oct. 16, 2015, and the final observations were concluded on Oct. 22, 2015.

This study, initiated by protocol signature on Aug. 11, 2015, was completed in the Lab of Shanghai Biomaterials Research & Test Center (SBRTC) and was conducted in accordance with the provisions of the ISO/IEC 17025-2005.

MATERIALS

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

Test Article:	Non-absorbable Surgical Suture (model: PTFE) <Specification: Z21302-60 (USP2-0/EP2.5)>
Identification No:	150642
Sterilization Status:	Sterilized
Temperature Tolerance:	-25~+55℃(declaration from the sponsor)
Vehicles:	0.9% Sodium Chloride Injection (SC)<K15062018> Cotton seed oil (CSO)< MKBS9702V>
Test Article Preparation:	Based on the ISO ratio of 6cm^2/ml [Surface area of the test sample to volume of extraction vehicle], 91.3cm^2 of the test sample were covered 15.2 ml of extraction vehicle under sterile conditions for preparing the SC or CSO test extract at 37℃ for 72 hours respectively. The extracts were used within 1 hour after extraction.
Reagent Control:	The extraction vehicles without test article were similarly prepared to serve as the test article.
Condition of extracts:	All the extract of the test and controls were clear.

METHODS

Test System:

Species:	Rabbit
Strain:	New Zealand White
Source:	SHANGHAI SONGLIAN LAB ANIMAL-FIELD
Sex:	Male
Body weight range:	2.3 kg~2.4 kg

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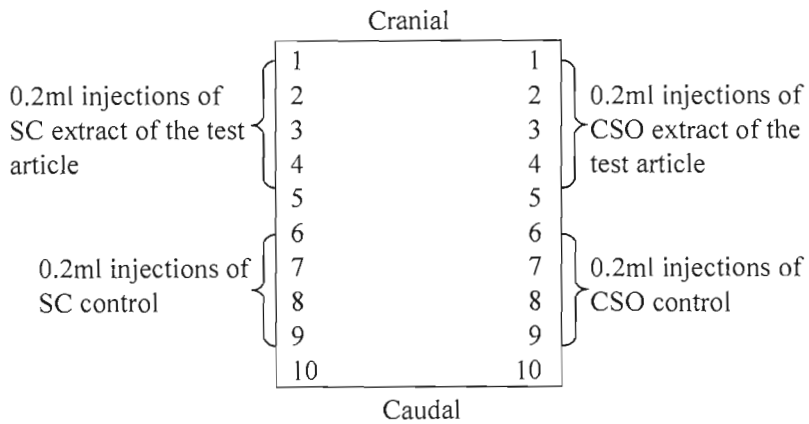
Age:	Young adult
Number of animals:	Three

Animal Management:

Husbandry:	Conditions conformed to "Laboratory animal-Requirements of environment and housing facilities"; "ISO 10993-2:2006: Biological evaluation of medical devices Part 2: Animal welfare requirements".
Food:	Diet was provided from SHANGHAI SLAC LABORATORY ANIMAL CO. LTD.
Housing:	Healthy animals were acclimatized to the laboratory conditions for 7 days before the treatment, and then they were individually housed in stainless steel suspended cages identified by a card indicating the Identification № of the test article and first treatment date.
Environmental:	The room temperature and humidity were monitored daily. The room temperature range was from 21℃ to 24℃. The room humidity range was from 56 % to 59 %.
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.

Experimental Procedure:

On the day before the test, each rabbit was closely clipped free of fur from the back and both sides of the spinal column to yield a sufficient injection area. Just before injection, the clipped area of the back was wiped with 75% alcohol soaked absorbent cotton and allowed to dry. A 0.2ml dose of the fresh extracts of test article and control were injected intracutaneouly into five separate sites as illustrated below:



The appearance of each injection site was noted immediately after injection. Observations for erythema and oedema were conducted at 24, 48 and 72 hours after injection.

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The tissue reaction for erythema and oedema was graded according to the classification system given below for each injection site and at each time interval observed, and recorded the results:

Reaction	Numerical grading
Erythema and eschar formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet-redness) to eschar formation preventing grading of erythema	4
Oedema formation	
No oedema	0
Very slight oedema (barely perceptible)	1
Well-defined oedema (edges of area well-define by definite raising)	2
Moderate oedema (raised approximately 1mm)	3
Severe oedema (raised more than 1mm and extending beyond exposure area)	4

After the 72h grading, all erythema plus oedema grades 24h, 48h and 72h were totalled separately for each test extract or reagent control for each individual animal. The score of a test extract or reagent control on each individual animal were calculated and divided the totals by 15 (3 scoring time points ×5 test or reagent injection sires). The over mean score for each test sample and each corresponding reagent were determined, the scores for the three animals were added and divide by three. The final test extract score was obtained by subtracting the score of the reagent from the test extract score. The requirements of the test are met if the final test extract score is 1.0 or less.

DEVIATIONS

There were no deviations from the ISO 10993-10:2010 and SBRTC-PROTOCOL-4-109.

RESULTS

All animals appeared clinically normal throughout the study. SC injection sites appeared normal immediately following injection; a little of CSO extract solution was expelled following injection. All the grades of SC and CSO extract of the test article of each rabbit were 0. Individual results of dermal scoring appear in Appendix.

Results and conclusions apply only to the test article tested. No further evaluation of these results is made by Shanghai Biomaterials Research & Test Center.

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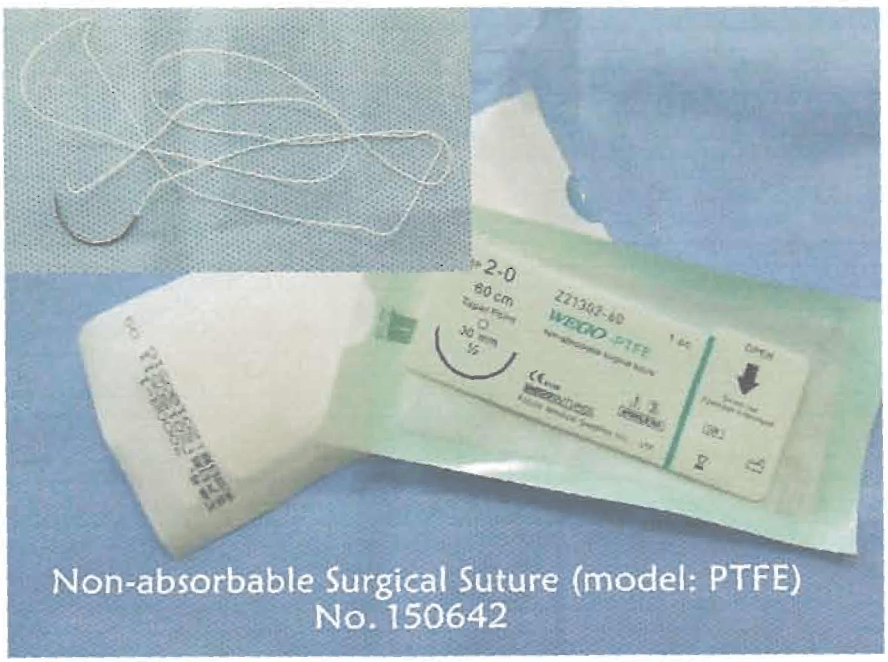
CONCLUSION

Under the conditions of this study, there was no evidence of significant irritation from the SC and CSO extracts of the test article injected intracutaneously into rabbits. The extract of the test article met the test requirement.

RECORD STORAGE

All raw data pertaining to this study and a copy of the final report are to be stored in the designated archive files at Shanghai Biomaterials Research & Test Center.

PHOTOGRAPH OF THE TEST ARTICLE



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APPENDIX

Individual results of dermal scoring were shown below:

	Rabbit № / Injection site		Scoring Interval (Hours)															
			24						48				72					
			Erythema			Oedema			Erythema			Oedema	Erythema			Oedema		
			1	2	3	1	2	3	1	2	3	1 2 3	1	2	3	1	2	3
SC	Test extract	1	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
		2	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
		3	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
		4	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
		5	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
	Reagent Control	6	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
		7	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
		8	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
		9	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
		10	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
CSO	Test extract	1	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
		2	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
		3	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
		4	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
		5	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
	Reagent Control	6	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
		7	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
		8	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
		9	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0
		10	0	0	0	0	0	0	0	0	0	0 0 0	0	0	0	0	0	0

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