



Test Report

TEST ITEMS

Test for Pyrogenicity

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>

SHANGHAI BIOMATERIALS RESEARCH & TEST CENTER

Add: 201, Building 2, № 427 Jumen Road, Shanghai, China

Zip Code: 200023

TEL: 0086-21-63034903

FAX: 0086-21-63011643

Web site: www.sbrtc.com

E-mail: biomatercenter@163.com

NOTICE

1. It will be invalid for the report without a connective seal.
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.
4. It can't be copied partly on the report without agreement, nor can be as the recorder of the order receiving and advertisement registration.
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.
6. It is only responsible for the samples received.

CSII

**SHANGHAI BIOMATERIALS RESEARCH & TEST CENTER**

Add: 201, Building 2, № 427 Jumen Road, Shanghai, China

Zip Code: 200023

TEL: 0086-21-63034903

FAX: 00

Web site: www.sbrtc.com

E-mail: [REDACTED]@163.com

TABLE OF CONTENTS

SUMMARY.....	4
INTRODUCTION.....	5
MATERIALS.....	5
METHODS.....	6~7
DEVIATIONS	7
RESULTS.....	7
CONCLUSION.....	7
RECORD STORAGE.....	7
PHOTOGRAPH OF THE TEST ARTICLE.....	8

SUMMARY

The test article, Non-absorbable Surgical Suture (model: PTFE), was extracted in 0.9% sterile nonpyrogenic sodium chloride injection (SC). The extract was evaluated in the rabbit for material mediated pyrogenicity. This study was conducted based on the requirements for ISO 10993-11:2006: Biological Evaluation of Medical Device, Part 11: Tests for Systemic Toxicity; ISO 10993-12:2012: Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

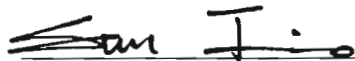
Three healthy New Zealand White rabbits with body weight ranging from 2.4 kg~2.6 kg were utilized. 0.9% sodium chloride injection (SC) was served as an extraction vehicle. The test article was extracted in 0.9% sodium chloride injection (SC). A single dose of 10ml/kg was injected intravenously via the marginal ear vein to each of three rabbits. Rectal temperatures were measured and recorded prior to injection and at 30min intervals between 1 and 3h after injection. The maximum temperature rise (as compared to baseline) for each rabbit was determined, and whether the extract of the test article induced a pyrogenic response was evaluated.

Under the conditions of this study, the total rise of rabbit temperatures during the 3h observation period was within acceptable limits. The extract of the test article was judged as non-pyrogenic.

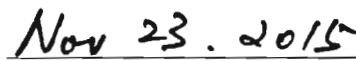
Study and Supervisory

Personnel: FEI Yun
MA Jiadong
LU Hua

Study Director:



SUN Jiao, Ph.D.



Date Completed

SHANGHAI BIOMATERIALS RESEARCH & TEST CENTER

Add: 201, Building 2, № 427 Jumen Road, Shanghai, China

Zip Code: 200023

TEL: 0086-21-63034903

FAX: 0086-21-63011643

Web site: www.sbrtc.com

E-mail: biomatercenter@163.com

INTRODUCTION

The purpose of this study was to determine whether the extract of the test article induced a pyrogenic response following intravenous injection in rabbits. *In vivo* biological reactivity was evaluated following a single injection of the extract. This test was conducted based on the requirements of ISO 10993-11:2006 Part 11: Tests for systemic toxicity. The test article was received on Jun. 16, 2015. Treatment began on Oct. 12, 2015, and the final observations were concluded on Oct. 16, 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
Storage Temperature:	-25~+55°C (declaration from the sponsor)
Vehicles:	0.9% Sterile nonpyrogenic sodium chloride injection (SC) <K15062018>
Test Article Preparation:	Based on the ISO ratio of 6cm ² /ml [Surface area of the test sample to volume of extraction vehicle], 639.1m ² of the test sample were covered 106.4ml of extraction vehicle under sterile conditions for preparing the test extract at 37°C for 72 hours respectively in each phase. The extracts were used within 1 hour after extraction. The fresh extracts was warmed in a 38°C water bath prior to injection.
Instrument Preparation:	Render the syringes, needles, and glassware free from pyrogens by heating at 180°C for 2h.
Condition of extracts:	The extract of the test was clear.

METHODS

Test System:

Species:	Rabbit
Strain:	New Zealand White
Source:	SHANGHAI SONGLIAN LAB ANIMAL-FIELD
Sex:	Male
Body weight range:	2.4 kg~2.6 kg
Age:	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 was 22°C. The room humidity was 59 %.
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy animals were selected. Prior to using, the animals in this test were conditioned for 5d by a sham test that includes all of the steps as directed under procedure except injection.

Experimental Procedure:

Not more than 30min prior to injection, the temperature of each animal was measured by ZRY-2D Pyrogen Tester. This temperature was recorded as the control temperature for the study. Each rabbit was received a single intravenous injection of the extract via the marginal ear vein at 10ml/kg of body weight. Rectal temperatures were measured and recorded at 30min intervals between 1 and 3h after injection. The maximum temperature rise (as compared to baseline) for each rabbit was determined.

Consider any temperature decreases as zero rises. If no rabbit showed an individual temperature rise of 0.5°C or more above the baseline temperature, the extract of the test article met the requirements for the absence of pyrogens. If any rabbit showed an individual temperature rise of 0.5°C or more, a retest was conducted using five other rabbits. If not more than three of the eight rabbits showed individual rises in temperature of 0.5°C or more, and if the sum of the eight individual maximum temperature rises did not exceed 3.3°C, the test article met the requirements for the absence of pyrogens.

DEVIATIONS

There were no deviations from the ISO 10993-11:2006 and SBRTC-PROTOCOL-9-37.

RESULTS

No single rabbit showed a temperature increased of 0.5°C or more above its baseline temperature. Individual temperatures are presented below:

№	Weight (kg)	Sex	Dose volume (ml)	Baseline (°C)	Hours after Injection						Maximum Rise
					1	2	3	4	5	6	
1	2.6	♂	26	39.4	39.3	39.3	39.3	39.4	39.3	39.3	0.0
2	2.5	♂	25	39.0	39.1	39.0	39.1	39.1	39.0	39.1	0.1
3	2.4	♂	24	38.8	38.9	38.8	38.9	38.8	38.9	38.8	0.1

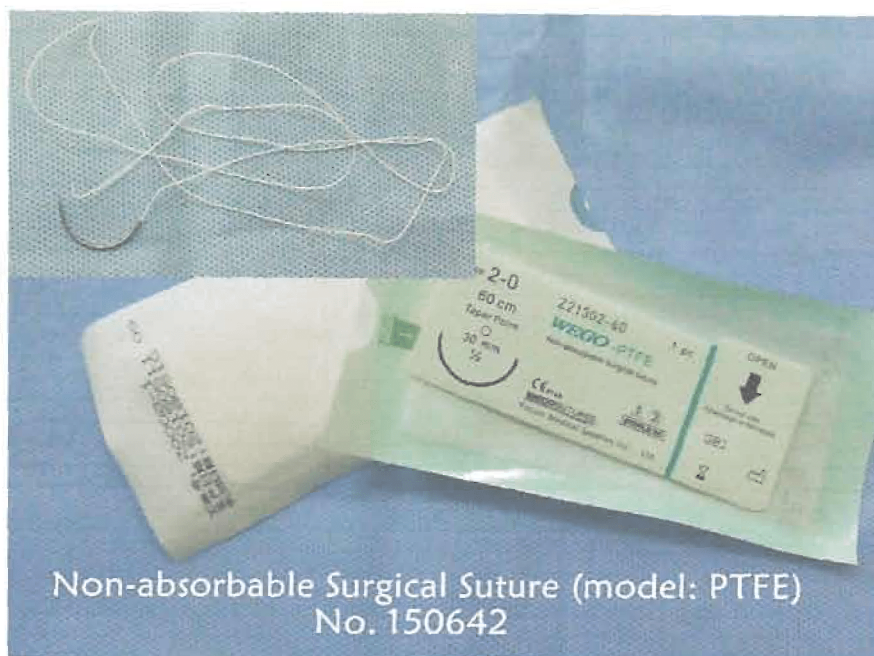
Results and conclusions apply only to the test article tested. No further evaluation of these results is made by Shanghai Biomaterials Research & Test Center.

CONCLUSION

Under the conditions of this study, the total rise of rabbit temperatures during the 3h observation period was within acceptable limits. No evidence of material-mediated pyrogenicity was observed. The extract of the test article was judged as nonpyrogenic.

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**SHANGHAI BIOMATERIALS RESEARCH & TEST CENTER**

Page 8 of 8

Add: 201, Building 2, No 427 Jumen Road, Shanghai, China

Zip Code: 200023

TEL: 0086-21-63034903

FAX: 0086-21-63034903

Web site: www.sbrtc.comE-mail: sbrtc@163.com