Test Report

TEST ITEMS

90-Day Subchronic Toxicity Study in the Rat by subcutaneous Implantation Route

TEST ARTICLE

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

IDENTIFICATION №

150643

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

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Add: 201, Building 2, № 427 Jumen Road, Shanghai, China Zip Code: 200023
TEL: 0086-21-63034903 FAX: 00[redacted]
Web site: www.sbrtc.com E-mail: [redacted]@163.com

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SHANGHAI BIOMATERIALS RESEARCH & TEST CENTER
Add: 201, Building 2, № 427 Jumen Road, Shanghai, China Zip Code: 200023
TEL: 0086-21-63034903 FAX: 008[redacted]
Web site: www.sbrtc.com E-mail: [redacted]@163.com

SUMMARY

The test article, Non-absorbable Surgical Suture (model: PTFE), was evaluated for potential systemic toxicity following by 90-day subcutaneous implantation route in the rats. The test article was evaluated for subchronic systemic toxicity in accordance with the requirements of the 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.

Forty SD Rats with body weight range from 184.2g to 218.6g were utilized. The test sample was implanted by subcutaneous route. The blank control group received surgical insult only. The animals were observed immediately after 90-day subcutaneous implantation route for signs of behavioral change or toxicity. The determination was based upon clinical observations, animal/organ weights, evaluation of hematological, clinical chemistry, and coagulation parameters, necropsy observations, and histopathological assessment of selected tissues from animals exposed to the test sample as compared to the control animals.

Under the conditions of this study, there was no significant evidence of systemic toxicity of the test sample by the 90-day subcutaneous implantation route to the rat as compared to the control animals, except for local inflammatory reaction at the implant sites.

Study and Supervisory Personnel: FEI Yun
MA Jiadong
JIN Ruifen
JI Lina
XUE Yang
LU Hua

Study Director: Sun Jiao, Ph.D. Apr 11, 2016 Date Completed

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Add: 201, Building 2, № 427 Jumen Road, Shanghai, China Zip Code: 200023
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INTRODUCTION

The purpose of the study was to evaluate the potential of the test article to cause subchronic systemic toxicity by subcutaneous Implantation Route in the rat. 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. The animals were treated on Nov. 17, 2015, and the terminal procedures were performed on Mar. 31, 2016.

This study, initiated by protocol signature on Oct. 8, 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:	150643
Temperature Tolerance:	STERILE
Storage Conditions:	Room temperature
Test Article Preparation:	According the requirement of the sponsor, 450cm (0.72g)/ 70kg [sample amount/human weight] of clinical maximum dosage, 30 times of animal experiment amplification, 237cm of the test sample was implanted into the subcutaneous tissue per 200g of a rat, respectively.
Blank Control:	According the requirement of the sponsor, the blank control group received surgical insult only.

METHODS

Test System:

Species:	Rat
Strain:	SD
Source:	Shanghai Jiesijie Experimental Animal CO., LTD
Sex:	20 male, 20 female
Body Weight Range:	184.2g to 218.6g before injection
Number of Animals:	40

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Web site: www.sbrtc.com E-mail: [redacted]163.com

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 Pu Lu Teng Biological Technology Co. Ltd.
Water:	Pure water
Housing:	Healthy animals were acclimatized to the laboratory conditions for 5 days before the treatment, and then they were randomized and assigned to groups 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 20℃ to 24℃. The room humidity range was from 50 % to 60%. The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy, unused animals were selected.

Experimental Procedure:

Prior to dosing, each rat was weighed and identified. Forty rats (20 male, 20 female) divided into two groups. Each group (10 male, 10 female) was treated with the test sample and the blank control by the subcutaneous implantation route respectively. Rats were observed daily for general health.

Laboratory Observation:

1. Body weights were recorded for each rat prior to injection, weekly, the day prior to termination (pre-fasted weights) and the day of termination (fasted weights).
2. Animals were observed daily for general health.
3. Detailed examinations for clinical signs of disease or abnormality were conducted daily for the 90 days.

Terminal Procedures:

At the end of the workday on day 90, the animals were weighed and food was withheld for a maximum of 20 hours. On day 91, the animals were weighed. The blood specimen was collected from femoral artery and then performed a complete blood cell count with differential and clinical chemistry analyses. Then the rats were euthanatized by an intravenous bolus of a pentobarbital sodium.

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Every attempt was made to account for each test sample and control. A macroscopic observation of the viscera was also conducted. The following organs were removed: Heart, Lung, Thymus, Liver, Spleen, Mesenteric Lymph Node, Kidneys, Adrenals, Thyroid gland, Esophagus, Trachea, Stomach, Duodenum, Jejunum, Ileum, Colon, Pancreas, Rectum, Bladder, Abdominal aorta, Peripheral nerve, Gonads, Bone marrow, Cecum, Eyes, Muscle, Parathyroid gland, Pituitary, Prostate, Salivary glands, Salivary gland, Spinal cord, Sternum, vagina and Tissue with visible gross lesion. The heart, lungs, liver, spleen, kidneys and adrenal glands were weighed. Paired organs were weighed together. The tissues were preserved in 10% neutral buffered formalin (NBF), until further processing. These sections were histologically processed (embedded, sectioned and stained in hematoxylin and eosin) for microscope evaluation.

Evaluations and Statistics:

The test and control groups were considered the variable for comparison. The body weight, organ weight data, organ/body weight ratio, hematology data, clinical chemistry values were analyzed statistically. Pre-fasted body weights were used to determine weight gain and the fasted body weight were used to determine anesthetic dosages at termination and organ/body weight ratio. Descriptive statistic and group comparisons of data were accomplished using a validated statistical software package. Calculations resulting in probability (P) values less than 0.05 were considered statistically signification.

DEVIATIONS

There were no deviations from the ISO 10993-11: 2006 and SBRTC-PROTOCOL-10-24.

RESULTS

A summary of body weight, organ weight, organ/body weight ratio, hematology and clinical chemistry data were presented in Table 1-5.

Clinical Observation: No behavioral changes or signs of toxicity were observed in any rat. None of the test and control animals exhibited any signs of toxicity noted at gross necropsy for either the test or control animal.

Body weight: Individual weight gain and group mean body weights for test and control rats were considered to be clinically acceptable treatment.

Necropsy: All organs appeared macroscopically normal, and there were no macroscopic changes in the viscera at necropsy that could be attributed to the test sample.

Organ Weight: Absolute organ weights and organ/body weight ratios were similar between test and control groups. There was no difference between the two groups that was considered to be related to treatment.

Hematology: Compared to the male control group, the LYM of the male test group decreased ($p<0.05$), while the GRA increased ($p<0.05$). Compared to the female control group, the MCV and PLT of the female test group increased ($p<0.05$), while the MCHC decreased ($p<0.05$).

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However, according to the historical control data in Shanghai Biomaterials Research & Test Center, the values of these indexes were mostly in the normal ranges. No other indexes showed statistically significant difference.

Clinical Chemistry: Compared to the male control group, the Ca of the male test group increased ($p<0.05$). Compared to the female control group, the BUN of the female test group increased ($p<0.05$). However, according to the historical control data in Shanghai Biomaterials Research & Test Center, the values of these indexes were mostly in the normal ranges. No other indexes showed statistically significant difference.

Histopathology: Tissue examined was within normal histomorphological limits and essentially comparable between test and control animals, except for the residual material accompanied by local inflammatory reaction at the implant sites in the test group.

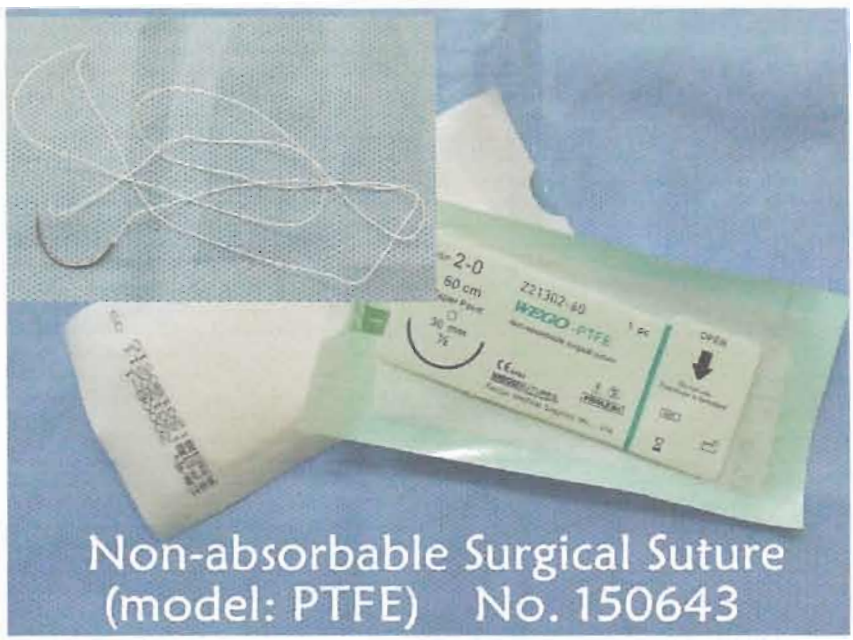
CONCLUSION

Under the conditions of this study, there was no significant evidence of systemic toxicity of the test sample by the 90-day subcutaneous implantation route to the rat as compared to the control animals, except for local inflammatory reaction at the implant sites.

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 1

TABLE 1 SUMMARY OF BODY WEIGHT DATA (g)

Interval	Control (Mean±SD)		Test (Mean±SD)	
	Male	Female	Male	Female
Pretreated	200.06±10.82	197.53±10.36	197.51±8.74	197.16±10.06
28 days	338.75±36.64	258.43±22.19	335.07±31.05	257.35±16.38
56 days	420.95±43.91	310.03±27.77	431.47±35.25	305.65±19.94
Pre-fast	477.64±44.34	347.14±29.86	480.33±35.05	351.04±26.44
91 days	459.67±46.00	332.93±29.43	463.42±34.14	337.08±26.92

SD = Standard Deviation

There were no statistically significant differences between control and test groups ($p>0.05$).

TABLE 2 SUMMARY OF ORGAN WEIGHT DATA (g)

Organ	Control (Mean±SD)		Test (Mean±SD)	
	Male	Female	Male	Female
Heart	1.270±0.107	1.006±0.058	1.347±0.163	0.971±0.140
Liver	12.511±0.937	8.052±0.801	13.037±1.012	8.435±0.709
Spleen	0.719±0.067	0.546±0.082	0.758±0.069	0.593±0.111
Kidneys (2)	3.178±0.229	2.279±0.125	3.256±0.175	2.342±0.126
Adrenal glands	0.121±0.015	0.100±0.012	0.126±0.013	0.096±0.015
Gonads	7.477±0.668	0.667±0.074	7.617±0.592	0.642±0.072
Thymus gland	0.646±0.082	0.515±0.062	0.624±0.057	0.554±0.092
Brain	2.221±0.242	1.946±0.078	2.303±0.069	2.006±0.120

SD = Standard Deviation

There were no statistically significant differences between control and test groups ($p>0.05$).

TABLE 3 SUMMARY OF ORGAN/BODY WEIGHT RATIO DATA (%)

Organ	Control (Mean±SD)		Test (Mean±SD)	
	Male	Female	Male	Female
Heart	0.277±0.016	0.304±0.023	0.290±0.022	0.288±0.032
Liver	2.746±0.335	2.420±0.158	2.814±0.115	2.513±0.259
Spleen	0.158±0.023	0.164±0.020	0.164±0.015	0.177±0.035
Kidneys (2)	0.696±0.067	0.688±0.051	0.704±0.025	0.698±0.058
Adrenal glands	0.026±0.003	0.030±0.005	0.027±0.003	0.029±0.005
Gonads	1.645±0.260	0.201±0.026	1.645±0.071	0.190±0.014
Thymus gland	0.142±0.024	0.156±0.022	0.135±0.007	0.164±0.022
Brain	0.485±0.047	0.587±0.041	0.499±0.036	0.597±0.033

SD = Standard Deviation

There were no statistically significant differences between control and test groups ($p>0.05$).

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TABLE 4 SUMMARY OF HEMATOLOGY DATA

Parameter	Control (Mean±SD)		Test (Mean±SD)	
	Male	Female	Male	Female
WBC ($\times 10^9$/L)	5.67±1.07	4.83±1.12	6.35±0.91	5.46±1.81
RBC ($\times 10^{12}$/L)	8.87±1.96	7.38±0.53	8.12±0.47	7.32±0.81
HGB (g/L)	149.60±7.81	144.40±9.86	155.00±6.29	143.40±15.78
LYM (%)	68.04±4.19	63.99±7.16	61.57±6.57*	60.33±8.07
MID (%)	3.13±0.48	3.03±0.35	2.79±0.50	2.77±0.42
GRA (%)	28.83±4.21	32.98±7.18	35.64±6.54*	36.90±7.16
HCT (%)	48.75±12.25	40.86±2.66	44.63±1.84	42.18±4.56
MCV (fL)	54.79±1.60	55.51±1.86	55.10±1.71	57.72±1.68*
MCHC (g/L)	344.1±17.1	353.1±5.0	346.9±6.3	339.5±4.9*
PLT ($\times 10^9$/L)	581.1±78.7	617.8±56.8	634.2±70.7	692.6±86.6*
PT (s)	10.37±1.03	9.38±0.50	10.14±0.53	9.03±0.39
APTT (s)	15.05±2.19	14.38±1.87	14.14±1.25	13.61±1.70

$p<0.05$

White Blood Cell (WBC); Red Blood Cell (RBC); Hemoglobin (HGB);
Lymphocytes (LYM); Granulocyte (GRA); Hematocrit (HCT);
Mean Corpuscular Volume (MCV); Mean Corpuscular Hemoglobin Concentration (MCHC);
Platelet (PLT);
Prothrombin Time (PT); Activated Partial Thromboplastin Time (APTT)
SD = Standard Deviation

Compared to the male control group, the LYM of the male test group decreased ($p<0.05$), while the GRA increased ($p<0.05$). Compared to the female control group, the MCV and PLT of the female test group increased ($p<0.01$), while the MCHC decreased ($p<0.05$). However, according to the historical control data in Shanghai Biomaterials Research & Test Center, the values of these indexes were mostly in the normal ranges. No other indexes showed statistically significant difference.

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Web site: www.sbrtc.com E-mail: biomatercenter@163.com

TABLE 5 SUMMARY OF CLINICAL CHEMISTRY DATA

Parameter	Control (Mean±SD)		Test (Mean±SD)	
	Male	Female	Male	Female
GLU (mmol/L)	7.00±0.49	6.67±0.74	6.83±0.91	6.49±1.17
TOT PRO (g/L)	67.9±3.2	71.4±5.5	71.2±5.0	74.6±9.3
ALB (g/L)	37.8±1.6	40.8±3.7	39.5±2.5	42.1±5.4
GLO (g/L)	30.10±2.02	30.60±2.72	31.70±3.20	32.50±4.33
ALB/GLOB	1.30±0.08	1.38±0.15	1.30±0.11	1.37±0.11
GGT (U/L)	1.0±0.0	1.0±0.0	1.0±0.0	1.0±0.0
ALT (U/L)	50.5±7.4	46.0±7.0	49.2±5.6	54.1±20.5
AST (U/L)	196.8±34.6	165.6±22.4	176.9±22.6	209.4±73.8
ALP (U/L)	100.60±25.38	71.40±19.08	98.20±13.69	75.30±34.34
TOT BIL (umol/L)	1.0±0.0	1.0±0.0	1.0±0.0	1.0±0.0
BUN (mmol/L)	5.95±0.97	6.77±0.61	6.07±0.89	7.83±1.42*
UA (umol/L)	92.9±13.7	77.9±11.1	85.3±31.8	82.0±19.2
CR (umol/L)	53.7±6.8	56.3±3.8	51.2±6.1	57.9±5.3
LDH (U/L)	729.0±313.2	640.0±249.6	637.0±204.0	734.5±303.4
CH (mmol/L)	1.27±0.24	1.73±0.19	1.35±0.17	1.98±0.50
TG (mmol/L)	0.348±0.100	0.413±0.057	0.372±0.136	0.442±0.089
K (mmol/L)	7.213±0.374	6.808±0.300	7.133±0.383	7.035±0.538
Na (mmol/L)	147.8±1.5	146.1±2.0	149.0±2.7	147.0±2.4
Cl (mmol/L)	106.1±1.7	105.0±1.9	106.4±1.4	105.7±1.6
Ca (mmol/L)	2.481±0.080	2.554±0.079	2.613±0.074*	2.611±0.109
P (mmol/L)	2.44±0.27	2.05±0.19	2.57±0.41	2.13±0.17
AMY (U/L)	542.0±90.4	436.0±115.8	596.5±125.9	565.5±164.4

$p<0.05$

Bilirubin, total (TOT BIL); Total protein (TOT PRO); Albumin (ALB);
Globulin (GLO); γ -glutamy transferase (GGT); Alanme aminotransferase (ALT);
Aspartate aminotransferase (AST); Alkaline Phosphatase (ALP); Blood Urea Nitrogen (BUN);
Uric Acid (UA); Creatinine, serum (CR); Glucose, serum (GLU);
Lactate Dehydrogenase (LDH); Cholesterol (CH); Triglyeride (TG);
Potassium (K); Sodium (Na); Chloride (Cl);
Phosphorus (P); Calcium (Ca); Amylase (AMY)

SD = Standard Deviation

Compared to the male control group, the Ca of the male test group increased ($p<0.05$). Compared to the female control group, the BUN of the female test group increased ($p<0.01$). However, according to the historical control data in Shanghai Biomaterials Research & Test Center, the values of these indexes were mostly in the normal ranges. No other indexes showed statistically significant difference.

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APPENDIX 2

HISTOPATHOLOGY REPORT

The tissues samples from forty rats (twenty males and twenty females) received were fixed with formalin. Tissue received were Heart, Lung, Thymus, Liver, Spleen, Mesenteric Lymph Node, Kidneys, Adrenals, Thyroid gland, Esophagus, Trachea, Stomach, Duodenum, Jejunum, Ileum, Colon, Pancreas, Rectum, Bladder, Abdominal aorta, Peripheral nerve, Gonads, bone marrow, cecum, eyes, muscle, parathyroid gland, pituitary, prostate, salivary glands, salivary gland, skin, spinal cord, sternum, vagina and tissue with visible gross lesion. They are trimmed, embedded, sectioned and stained for routine HE histopathological evaluation.
The summary of histopathological findings was showed as follow:

SUMMARY OF HISTOPATHOLOGICAL FINDINGS

Group	Control		Test	
Sex	Male	Female	Male	Female
№ of Animals	10	10	10	10
Heart				
No significant findings	10	10	10	10
Hyperplasy of interstitial cell				
Thymus				
No significant findings	10	10	10	10
Liver				
No significant findings	9	9	6	8
Infiltrate of inflammatory cell			1	1
Hyperplasy of lymphatic tissue	1	1	3	1
Atrophy, degeneration and necrosis			1	1
Spleen				
No significant findings	10	10	10	10
Lung				
No significant findings	10	10	9	8
Hyperplasy of lymphatic tissue			1	3
Kidneys				
No significant findings	10	10	10	10
Adrenals				
No significant findings	10	10	10	10

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TEL: 0086-21-63034903 FAX: 008[redacted]3
Web site: www.sbrtc.com E-mail: [redacted]@163.com

Group	Control		Test	
Sex	Male	Female	Male	Female
№ of Animals	10	10	10	10
Stomach				
No significant findings	10	10	9	10
Infiltrate of eosinophile granulocyte			1	
Pancreas				
No significant findings	8	10	10	10
Hyperplasy of lymphatic tissue	2			
Bladder				
No significant findings	10	10	10	10
Abdominal aorta				
No significant findings	10	10	10	10
Mesenteric Lymph Node				
No significant findings	10	10	10	10
Trachea				
No significant findings	8	10	8	8
Lymphocytic infiltrate			2	1
Infiltrate of plasma cells				1
Granular leukocyte			2	
Gland hyperplasia	2			
Hyperplasy of lymphatic tissue			1	1
Thyroid gland				
No significant findings	10	10	10	10
Esophagus				
No significant findings	10	10	10	10
Duodenum				
No significant findings	10	10	10	10
Jejunum				
No significant findings	10	10	10	10
Ileum				
No significant findings	10	10	10	10
Colon				
No significant findings	10	10	10	10
Rectum				
No significant findings	10	10	10	10

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Group	Control		Test	
Sex	Male	Female	Male	Female
№ of Animals	10	10	10	10
Testes				
No significant findings	10		10	
Ovaries				
No significant findings		10		10
Uterus (including cervix and oviducts)				
No significant findings		10		8
Infiltrate of eosinophile granulocyte				2
Peripheral nerve				
No significant findings	10	10	10	10
Brain	[redacted]			
No significant findings				
All gross lesions of treatment sites				
No significant findings	10	10	0	0
Implant material			10	10
Lymphocytic infiltrate			10	10
Granular leukocyte			2	1
Infiltrate of plasma cells			1	1
Monocyte infiltration			1	1
Bone marrow of sternum				
No significant findings	10	10	10	10
Sternum				
No significant findings	10	10	10	10
Cecum				
No significant findings	10	10	10	10
Epididymides				
No significant findings	10		10	
Eyes				
No significant findings	10	10	10	10
Mammary gland (female)				
No significant findings		10		10

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Group	Control		Test	
Sex	Male	Female	Male	Female
№ of Animals	10	10	10	10
Skeletal muscle				
No significant findings	10	10	10	10
Parathyroid				
No significant findings	10	10	10	10
Pituitary				
No significant findings	10	10	10	10
Prostate				
No significant findings	10		10	
Salivary glands				
No significant findings	10	10	10	10
Seminal vesicles				
No significant findings	10		10	
Skin				
No significant findings	10	10	10	10
Spinal cord				
No significant findings	10	10	10	10
Vagina				
No significant findings		10		10

Tissue examined was within normal histomorphological limits and essentially comparable between test and control animals, except for the residual material accompanied by local inflammatory reaction at the implant sites in the test group.

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Add: 201, Building 2, № 427 Jumen Road, Shanghai, China Zip Code: 200023
TEL: 0086-21-63034903 FAX: 00[redacted]
Web site: www.sbrtc.com E-mail: [redacted]@163.com