



No.L1538

# Test Report

## TEST ITEMS

Test for delayed-type hypersensitivity (Maximization test)

## TEST ARTICLE

Insertion Tube & Universal tube for Flexible endoscope  
(spec: BF-GIF-CF-LG)

## IDENTIFICATION No

060506

## SPONSOR

Shanghai Yanshun Scope Parts & Accessories Co., Ltd.

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SUMMARY

A guinea pig maximization test of the test article, **Insertion Tube & Universal tube for Flexible endoscope (spec: BF-GIF-CF-LG)** was conducted to evaluate the potential delayed dermal contact sensitization. This study was based on the requirements for the International Organization for Standardization ISO 10993-10-2002: Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity.


The test article was extracted in 0.9% sodium chloride solution (SC) and olive oil (OO). Each extract was injected intradermally and patched occlusively to ten test guinea pigs (per extract) in an attempt to induce sensitization. The vehicle was similarly injected and patched occlusively to five control guinea pigs (per vehicle). Following a recovery period, the test and control animals were received a challenge patch of the appropriated test article extract and the reagent control. All sites were scored at 24h and 48h after patch removal.

Under the conditions of this study, the SC and OO extracts of the test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

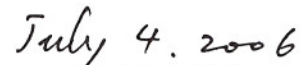
## Study and Supervisory

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Study Director:



SUN Jiao, Ph.D.



Date Completed

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## INTRODUCTION

A guinea pig maximization test of the test article identified below was conducted to evaluate the potential to cause delayed dermal contact sensitization. The test article was received on May.16, 2006. Treatment began on May.25, 2006, and the final observations were concluded on Jun.22, 2006.

This study was completed in the lab of Shanghai Biomaterials Research & Test Center (SBRTC). SBRTC 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: Insertion Tube & Universal tube for Flexible endoscope  
(spec: BF-GIF-CF-LG)

Identification №: 060506

Storage Conditions: Room temperature

Vehicles: 0.9% sodium chloride solution (SC)  
Olive oil (OO)

Test Article Preparation: For each phase of this test, a ratio of 4g: 20ml was used for each test extract. The test article was extracted in SC and OO at 70°C for 24h.

Reagent Control: The vehicles (without test article) were similarly prepared to serve as the reagent control.

Condition of extracts:	<u>SC test</u>	<u>SC Control</u>
Induction I:	Clear	Clear
Induction II:	Clear	Clear
Challenge:	Clear	Clear
	<u>OO test</u>	<u>OO Control</u>
Induction I:	Clear	Clear
Induction II:	Clear	Clear
Challenge:	Clear	Clear

Additional materials: Freund's Complete Adjuvant (FCA) was mixed 50:50 (v/v) with the vehicle.  
A 10% (w/w) sodium lauryl sulfate (SLS) suspension in petrolatum.

Sample Disposition: Any remaining sample was discarded.

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## METHODS

### Test System:

Species:	Albino guinea pig
Source:	SHANGHAI SONGLIAN LAB ANIMAL-FEILD
Sex:	Male
Body Weight Range:	300 grams to 350 grams
Age:	Young adult
Number of animals:	Thirty

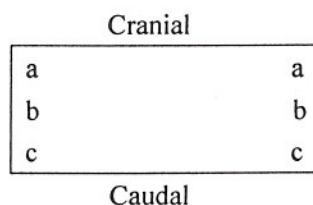
### Animal Management:

Husbandry:	Conditions conformed to “Laboratory animal-Requirements of environment and housing facilities”.
Food:	SONGLIAN’s Guinea Pig Diet was provided daily.
Housing:	Animals were housed in groups in stainless steel suspended cages identified by a card indicating the Identification No of the test article and first treatment date.
Environmental:	The room temperature was monitored daily. The temperature range for the room was 21°C to 24°C. The room humidity was monitored daily. The humidity range for the room was 40% to 70%.
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy, unused animals were selected.

### Experimental Procedure:

#### 1. Intradermal induction phase (Induction I):

The day prior to treatment, the fur was clipped on all treatment sites with an electric clipper. The following day, the test animals were injected with the extract of the test article and the control animals were injected with the reagent control. Three rows of intradermal injections (two per row) were given to each animal within an approximate 2cm×4cm boundary of the fur clipped area as illustrated below:



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**Test Animals:**

- a) 0.1ml of 50:50(v/v) mixture of FCA and the chosen vehicle
- b) 0.1ml of test extract
- c) 0.1ml of 50:50(v/v) mixture of the concentration used at site a and b

**Control Animals:**

- a) 0.1ml of 50:50(v/v) mixture of FCA and the vehicle
- b) 0.1ml of vehicle
- c) 0.1ml of 50:50(v/v) mixture of the concentration used at site a and b

**2. Topical induction phase (Induction II):**

Seven days after completion of the intradermal induction phase, the same area was clipped free of fur and treat with 10% SLS suspension in petrolatum. The suspension was massaged into the skin over the injection site to provoke a mild acute inflammation. The area was left uncovered. At 24h after the SLS administration, a 20mm×40mm section of absorbent gauze patch, saturated with freshly prepared the extract of the test article, and then was topically applied to the previously injected sites of the test animals. The control animals were similarly patched with the appropriate reagent control. Each patch was secured with an occlusive dressing. The dressings and patches were removed after 48h.

**3. Challenge phase**

At least 14 days after completion of the topical induction phase, used appropriate patches soaked the solution at the concentration of site C, and patched on the left upper flank of each animal. Then the animals were secured with an occlusive dressing. The dressings and patches were removed after 24h.

**4. Observation of animals**

The appearance of the challenge skin sites of the test and control animals was observed 24h and 48h after removal of the dressing. The skin reactions for erythema were described and graded in according with the criteria shown below:

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

**RESULTS**

No evidence of sensitization was observed, the grade of both the SC and OO extract of the test article was 0.

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, both the extracts of the test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

### 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

