

Shanghai Shurbe Medical Technology Co., LTD

Chest seal introduction



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Advantages

A dark, atmospheric photograph of a soldier lying down, wearing a helmet and a medical device on their chest. The image is partially obscured by a dark blue circle containing the text "About Us".

About Us

Shanghai Soulbay Medical Technology Co., Ltd. is a high-tech firm that specializes in research, development, manufacturing, sales, and service of high-end medical equipment. To enhance the integration of cross-industry resources, the company invests in independent research and development of its own brand. We have partnered with Shanghai University of Technology, Shanghai Lanbao Sensing, and other universities and businesses to establish R&D laboratories and production facilities. These are located at Shanghai University of Technology, Shanghai Lanbao Science and Technology Park, Anhui Maanshan Lanbao Science and Technology Park, and Fujian Xiamen Biomedical Industrial Park. These facilities are exclusively focused on the development and manufacturing of top-tier in vitro testing equipment and molecular chemistry products. We are dedicated to developing and producing top-tier in vitro testing instruments and molecular chemistry products to establish ourselves as a medical service provider with extensive independent intellectual property rights, cutting-edge technology, and global impact. Our solutions include: The company has assembled a scientific research and technology team with top-quality R&D and innovative capabilities, leveraging the benefits of an industry-university-research integrated approach. After nearly a decade of ongoing improvements and numerous clinical validations by various enterprises and institutions, including university teams, the company has developed a non-invasive, expedient, and extremely precise solution for detecting coronary stenosis at an early stage. The company collaborated with experts and scholars from Xiamen University in the field of molecular chemistry to exchange knowledge regarding medical hydrogel. This breakthrough has allowed for pre-hospital solutions for respiratory and circulatory disorders in pre-hospital rescue and battlefield first aid, breaking technological barriers.

Part 01

Factory



Automate Factory



Part 01

Technical Team

Social titles

Main part-time jobs in social and academic groups:

Executive Director of the Chinese Society of Particuology; Deputy Director of the Particle Testing Committee; Member of the External Working Committee
Honorary Director of CHINESE SOCIETY FOR MEASUREMENT; Director of Multiphase Flow Testing Committee
Director of Chinese Society of Engineering Thermophysics; Deputy Director of Multiphase Flow Specialized Committee
Director of Chinese Society of Power Engineering
Director of International Society of Measurement and Control of Granular Materials
Director of China Electrical Engineering Society, Thermal Power Generation Branch
Member of the National Technical Committee for Particle Characterization and Separation and Screen Standardization (SAC/TC168); Member of the Particle Sub-Technical Committee (SAC/TC168/SC1)
Director of Powder Technology Branch, China Building Materials Industry Association (CBMIA)
Chairman of Shanghai Society of Particuology
Deputy Director of the Clean Energy Technology Committee of Shanghai Energy Research Association,
Deputy Director of Turbine Branch, Shanghai Mechanical Engineering Society
Member of the Ninth Committee of Shanghai Association for Science and Technology
Deputy Director of the Teaching Committee of Energy Power Engineering Discipline of the Electric Power Higher Education Committee of China Electric Power Education Association ;
Deputy Head of Power Machinery Group



Xiaoshu
Cai



Part 01

Technical Team



He has Chaired the natural Science Foundation project, as well as China's "Eighth Five-Year Plan" and "Ninth Five-Year Key Plan", the project of Education Ministry, several local enterprises' horizontal projects and cooperation projects with foreign countries. His 70 papers published primarily focus on light scattering particle measurement, two-phase flow online monitoring, and combustion diagnosis.

He has overseen over 20 national 973 programs, general program, the "Eighth Five-Year Plan" and "Ninth Five-Year Plan" of the Ministry of Education and the Ministry of Mechanical Affairs of China, and vertical program of the Shanghai Municipal Government. He has collaborated with foreign countries to execute five international programs, such as the European Community, German DFG, and U.S. Electric Power Research Institute, among other horizontal programs. The company's particle measuring instruments have gained widespread application.

He has collaborated with Institut Coria at the Rouen University, the Turbine Research Laboratory at the EDF Research Center; ITSM at the University of Stuttgart, Germany; the Institute of Processes and Particles at the Technical University of Cottbus; and the Institute of Gas Turbines and Steam Turbines at the Technical University of Aachen. The ENEL Research Center in Italy, the SKODA Institute of Fluid Research in the Czech Republic, the Technical University of Prague's Institute of Turbomachinery, the Electric Power Research Institute in the USA, the School of Engineering at the University of Fukui, and the University of Leeds' Institute of Particle Research. He collaborated with the American Electric Power Research Institute (AEPRI), Fukui University's Faculty of Engineering, and the Particle Research Institute at Leeds University. He also collaborated with the Coria Institute of the University of Rouen, the ITSM Institute of the University of Stuttgart, and the Institute of Processes and Particles of the Technical University of Cottbus to train doctoral students.

His research findings on measuring two-phase flow of wet steam in steam turbines and pulverized coal have been adopted by research institutes across the globe, including Germany, France, the Czech Republic, Italy, and the United States.

His expertise in particle measurement, two-phase flow measurement, and combustion spectral diagnosis is at the forefront of research in China.

He has authored over 150 papers, with over 30 of them being indexed by SCI, EI, and ISTP. Additionally, he has been granted two invention patents and seven utility model patents.



Part 01

Technical Team



Huinan Yang



Shanghai University
of
Technology, School
of Energy and
Power Engineering's
Vice Dean,
Professor, and
Doctoral Supervisor

Tianyi Cai



Shanghai University
of Technology,
School of Energy
and Power
Engineering,
Lecturer

Thoracic trauma has an incidence of about 8% in all wars, and the deaths directly resulting from it account for 25% of trauma deaths, making it the 2nd leading cause of death in the types of trauma that cause death, after craniocerebral injuries. Open thoracic trauma is the main injury leading to death in thoracic trauma, open thoracic trauma due to blast injuries is more common in wartime, land war, open thoracic trauma accounted for 7% to 12% of the total number of casualties, in the naval war, the incidence is as high as 20%. If frontline on-site treatment is possible, it will create opportunities for follow-up treatment and greatly reduce the mortality rate of open chest trauma.

The most important first aid method for open chest trauma is early rescue while judging the injury, restoring the integrity of the chest wall and negative pressure in the chest as early as possible, preventing serious respiratory and circulatory dysfunction, and how to close the chest cavity in a timely and effective manner has become the key. Open chest trauma is often combined with rib fracture or even flail chest. After the chest cavity is closed and sent to the hospital, the patient often experiences severe chest pain and dyspnea, which seriously inhibits the patient's respiratory movement. Choosing the right material to fix the chest wall can effectively relieve pain and prevent the chest wall from sinking into the chest cavity, which has become an indispensable part of the treatment of thoracic trauma patients.



Part 01

Introduction



Appearance:



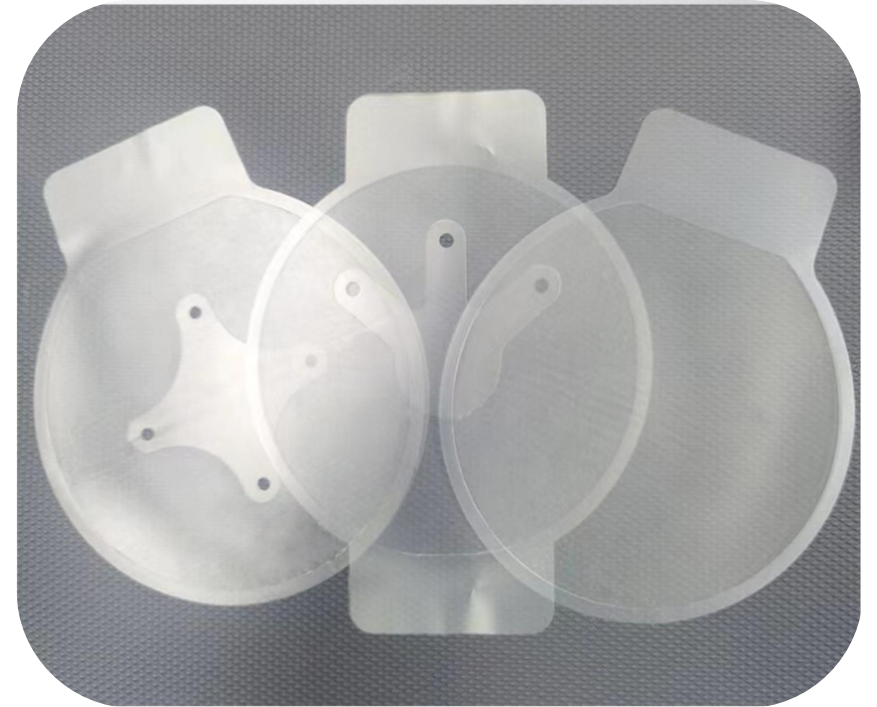
Part 01

Introduction



Chest seal

Mainly by medical hydrogel, non-woven fabric, PET film .
Products for medical or war and other traumatic situations
sealed rescue.



(SPEC):Y-D- ϕ 15.5cm

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Advantages

Part 02

Usage



Thoracic sealant is primarily used in the tactical area phase in response to penetrating thoracic trauma.






Part 02

Usage



How to use:

First, expose and open any chest wounds, expose the casualty's back for any other open chest wounds, and check for features of open or inhalation chest wounds. A casualty with an open chest wound will exhibit one or more of the following signs or symptoms:

-  Makes a sucking or hissing sound when he inhales
-  Breathlessness
-  Stabbed in the chest
-  Foam or bubbles around the wound
-  Coughing up blood



Part 02

Usage



If the wound hasn't completely penetrated the chest wall, treat it as an open chest wound. Dispose of multiple wounds in the order found. Temporarily seal the open chest wound by placing your hand or the back of your hand over it. Wipe off any dirt, blood, or fluids from the wound with 4x4 gauze or similar material. Remove the protective lining of the chest sealing patch to expose the adhesive portion of the seal. Once the casualty exhales, apply the adhesive side of the sealing patch firmly to the wound to establish a seal. Ensure that the edge of the patch extends 2 inches beyond the wound and that the adhesive side adheres to the skin. Following this, evaluate the effectiveness of the chest sealant as the casualty breathes. While inhaling, the plastic film adheres to the wound to prevent air from entering. When a casualty exhales, air from their chest can escape through the wound and venting valve. Use the "rake maneuver" to identify any additional open chest wounds, then treat their anterior flanks, back, and other affected areas in the same way. If necessary, continue to attach chest seals [2].



Part 02

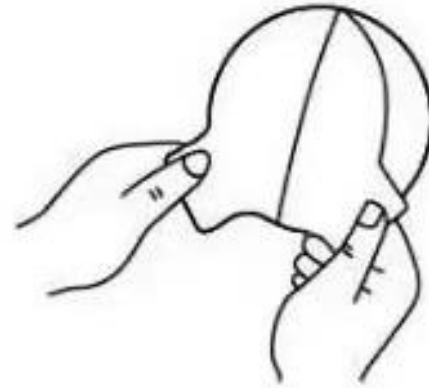
Usage



Operation Demonstration:



1、wipe away blood round the chest wound.



2、Remove the release liner.



3、Put the chest seal face up , make the adhesive side down close to the skin to ensure complete adhesion.



4、Check the back of the patients for an exit wound. Apply a second chest seal over the exit wound.

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Application Scenarios



Pre-hospital care

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Battlefield First Aid



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Part 04

Advantages

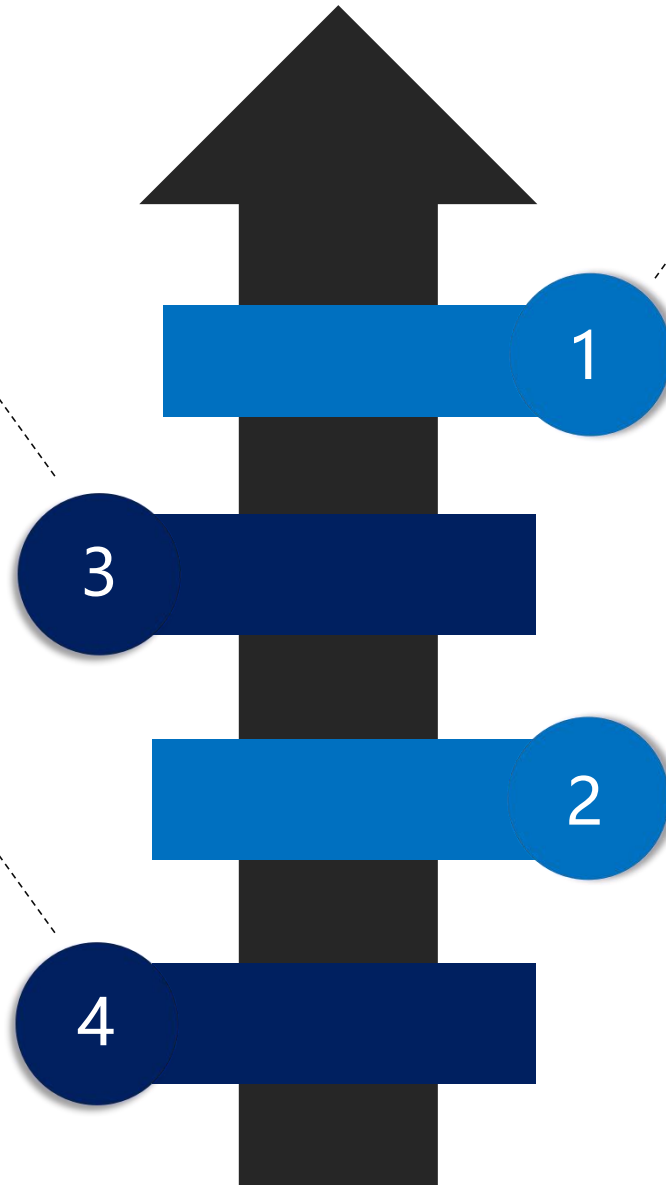
Product line

Product Process, Hydrogel
Development, Hydrogel
Testing, Technical
Advantages

Skin irritation

Cytotoxicity

Skin sensitization



Cytotoxicity

In Vitro Cytotoxicity Test of medical electrode plate (hydrogel)

According to GB/T 16886. 5—2017
MTT Method
MEM with 10%FBS extract

Test Report

1 Purpose

The purpose of the test is to determine the biological reactivity of a mammalian cell culture (mouse fibroblast L929 cells) in response to the test article.

2 Reference

GB/T 16886. 5—2017 Biological evaluation of medical devices —Part 5: Tests for *in vitro* Cytotoxicity

3 Compliance

ISO/IEC 17025: 2017 General requirements for the competence of testing and calibration laboratories (CNAS—CL01 Accreditation criteria for the competence of testing and calibration laboratories) China National Accreditation Service for Conformity Assessment LABORATORY ACCREDITATION CERTIFICATE Registration No. CNAS L2954.

RB/T 214—2017 Competence assessment for inspection body and laboratory mandatory approval—General requirements for inspection body and laboratory Certification and Accreditation Administration of the People's Republic of China INSPECTION BODY AND LABORATORY MANDATORY APPROVAL Certificate No. CMA 180015144061.

Annex 1 Results

Table 1 Observation of the Cell morphology

| Group | After inoculation | Before treated with extract | 24 h after treatment |
|----------------------------|---|---|---|
| Blank control | | | Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth. |
| Negative control | | | Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth. |
| Positive control | | | Nearly complete or complete destruction of the cell layers. |
| 100% Test article extract | Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth. | Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth. | Occasional cells were round and with intracytoplasmic granules, or showed changes in morphology; occasional lysed cells were present; only slight growth inhibition observable. |
| 50%Test article extract | | | Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth. |
| 25% Test article extract | | | Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth. |
| 12.5% Test article extract | | | Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth. |

Table2 Results of the Cell Viability

| Group | Value of OD Mean±SD | Cell Viability % |
|----------------------------|---------------------|------------------|
| Blank control | 0.8610±0.032 | 100.0 |
| Negative control | 0.8720±0.021 | 101.3 |
| Positive control | 0.2008±0.011 | 23.3 |
| 100% Test article extract | 0.6650±0.051 | 77.2 |
| 50%Test article extract | 0.6964±0.070 | 80.9 |
| 25% Test article extract | 0.8112±0.021 | 94.2 |
| 12.5% Test article extract | 0.8076±0.032 | 93.8 |

Advantages

Annex 1 Test Data

Table 1 Guinea pig sensitization dermal reactions of positive control

| Group | Animal Number | (24 ± 2) h Before Phase II Patch Application | | (24 ± 2) h Following Challenge Phase | | (48 ± 2) h Following Challenge Phase | | Positive Rate after Challenge Phase |
|------------------|---------------|--|-------|--------------------------------------|---------------|--------------------------------------|---------------|-------------------------------------|
| | | Left | Right | Test Sites | Control Sites | Test Sites | Control Sites | |
| Positive Control | 1 | 2 | 2 | 1 | 0 | 2 | 0 | 100% |
| | 2 | 1 | 2 | 2 | 0 | 2 | 0 | |
| | 3 | 2 | 3 | 2 | 0 | 1 | 0 | |
| | 4 | 2 | 2 | 3 | 0 | 2 | 0 | |
| | 5 | 2 | 3 | 2 | 0 | 1 | 0 | |
| Negative Control | 6 | 0 | 0 | 0 | 0 | 0 | 0 | - |
| | 7 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 8 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 9 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 10 | 0 | 0 | 0 | 0 | 0 | 0 | |

Note: the data of positive control come from SDWH- M202102467-1 (Completed Date: 2021-06-18)

Table 2 Weigh change and clinical observation of positive control

| Group | Animal Number | Weight (g) | | Clinical Observation Except Dermal Reactions |
|------------------|---------------|------------------|------------------|--|
| | | Before Injection | After Experiment | |
| Positive Control | 1 | 316 | 392 | Normal |
| | 2 | 323 | 389 | Normal |
| | 3 | 325 | 395 | Normal |
| | 4 | 317 | 388 | Normal |
| | 5 | 319 | 393 | Normal |
| Negative Control | 6 | 328 | 387 | Normal |
| | 7 | 315 | 393 | Normal |
| | 8 | 329 | 399 | Normal |
| | 9 | 326 | 387 | Normal |
| | 10 | 320 | 394 | Normal |

Note: the data of positive control come from SDWH- M202102467-1 (Completed Date: 2021-06-18)

Skin sensitization

Skin Sensitization Test of medical electrode plate (hydrogel)

According to GB/T 16886.10-2017
Guinea Pig Maximization Test
0.9% Sodium Chloride Injection Extract

Test Report

1 Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization. The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it does not establish the actual risk of sensitization.

2 Reference

GB/T 16886.10-2017 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization

3 Compliance

ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories (CNAS—CL01 Accreditation criteria for the competence of testing and calibration laboratories) China National Accreditation Service for Conformity Assessment LABORATORY ACCREDITATION CERTIFICATE Registration No. CNAS L2954.

RB/T 214—2017 Competence assessment for inspection body and laboratory mandatory approval—General requirements for inspection body and laboratory Certification and Accreditation Administration of the People's Republic of China INSPECTION BODY AND LABORATORY MANDATORY APPROVAL Certificate No. CMA 180015144061.

Part 04

Advantages



Product line

Product Process:

The company's equipment department possesses extensive experience and is capable of designing and developing independently in the automation industry. The primary production equipment for chest seal tape comprises independently developed seven-station circular die-cutting machines and automatic buckle flat die-cutting machines. The company continuously improves the process and synchronizes equipment and technology updates with actual production needs.

Part 04

Advantages



Product Line

product process:

Chest seal tape production process and efficiency: The company has built a fully automated circular die-cutter and automatic buckling flat die-cutter production line, utilizing full servo motor control, a complete PLC control system, and a portable integrated operating panel. The precision and speed of our equipment ensure premium quality and timely delivery. Production efficiency significantly exceeds that of traditional semi-automatic or punching and cutting machines, leading the industry's overall level. Among them, the single die-cutting machine can produce up to 100,000 pieces per day. The automatic buckling flat die-cutting process is cutting-edge, allowing for mold flexibility to produce special product specifications and one-time completion of chest sealing paste production, significantly enhancing production efficiency.

Part 04

Advantages



Product line

Hydrogel development:

As the most important part of the production process of chest seal tape, the production process and raw material formula of hydrogel. Following nearly a decade of research, development and market testing, SOULBAY's hydrogel commands a leading position in China's market. The production of hydrogel in the United States and Japan yields results comparable to those produced elsewhere, with similar performance properties and cost advantages compared to imported hydrogel. Our collaboration with Xiamen University School of Chemistry has further enhanced our expertise in this field. The company has invested significant material and manpower resources in conducting scientific and technological research and development to enhance the toughness, initial adhesion, adhesion, peel strength, biocompatibility, and other related indicators of hydrogel products. The company has invested significant material and manpower resources in conducting scientific and technological research and development to enhance the toughness, initial adhesion, adhesion, peel strength, biocompatibility, and other related indicators of hydrogel products. As a result, these indices have now achieved an impressive level of improvement. Quality of the imported Japanese hydrogel exceeds that of domestic counterparts.

Part 04

Advantages

CTI 华测检测



Hydrogel Testing:

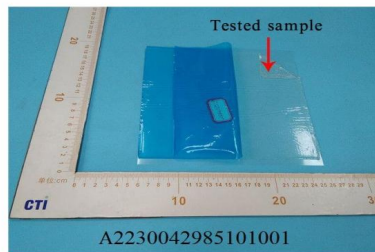
CTI 华测检测

Test Report

Report No. A2230042985101001

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Photo(s) of the sample(s)



Statement:

1. This report is considered invalid without approved signature, special seal and the seal on the perforation;
2. The Company Name shown on Report and Address, the sample(s) and sample information was/were provided by the applicant who should be responsible for the authenticity which CTI hasn't verified;
3. The result(s) shown in this report refer(s) only to the sample(s) tested;
4. Without written approval of CTI, this report can't be reproduced except in full;
5. In case of any discrepancy between the English version and Chinese version of the testing reports (if generated), the Chinese version shall prevail.



Test Report

Report No. A2230042985101001

Page 2 of 3

Test Method

| Test Item(s) | Test Method | Measured Equipment(s) |
|--------------|--|-----------------------|
| Formaldehyde | Refer to GB 30982-2014 | HPLC |
| Acetaldehyde | Refer to GB 30982-2014 | HPLC |
| Methanol | Refer to US EPA 3550C:2007 & US EPA 8260D:2018 | GC-MS |
| Acetone | Refer to US EPA 3550C:2007 & US EPA 8260D:2018 | GC-MS |

Test Result(s)

| Tested Item(s) | Result | MDL |
|----------------|----------|-----------|
| | 001 | |
| Formaldehyde | N.D. | 0.01 g/kg |
| Tested Item(s) | Result | MDL |
| | 001 | |
| Acetaldehyde | N.D. | 0.01 g/kg |
| Tested Item(s) | Result | MDL |
| | 001 | |
| Methanol | 47 mg/kg | 10 mg/kg |
| Acetone | N.D. | 10 mg/kg |

Sample/Part Description

| No. | CTI Sample ID | Description |
|-----|---------------|----------------------------|
| 1 | 001 | Transparent adhesive paste |

Remark: -MDL = Method Detection Limit
-N.D. = Not Detected (<MDL)
-mg/kg = ppm = parts per million

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GROUP

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Testing Se

Part 04

Advantages



Product Line

Technical support:

Advisor *Yiting Xu* :

Professor/Doctoral Supervisor at Xiamen University, research area research focuses on functional polymer materials, multi-element organic/inorganic nanohybrid materials, design synthesis and application of 2D nanomaterials. Responsible for directing the process tuning of hydrogels.

Skin irritation



Annex 1 Test Data

Table 3 Positive control

| Extract | Rabbit No. | Group | Reaction | Interval (hours): score=left site/right site | | |
|---------|------------|------------------|----------|--|-------|-------|
| | | | | 24±2h | 48±2h | 72±2h |
| SC | 1 | Positive Control | Erythema | 3/3 | 3/3 | 3/3 |
| | | | Oedema | 3/3 | 4/4 | 4/4 |
| | | Negative Control | Erythema | 0/0 | 0/0 | 0/0 |
| | | | Oedema | 0/0 | 0/0 | 0/0 |
| SC | 2 | Positive Control | Erythema | 3/3 | 3/3 | 3/3 |
| | | | Oedema | 3/3 | 3/4 | 4/4 |
| | | Negative Control | Erythema | 0/0 | 0/0 | 0/0 |
| | | | Oedema | 0/0 | 0/0 | 0/0 |
| SC | 3 | Positive Control | Erythema | 3/3 | 3/3 | 3/3 |
| | | | Oedema | 3/3 | 4/3 | 4/4 |
| | | Negative Control | Erythema | 0/0 | 0/0 | 0/0 |
| | | | Oedema | 0/0 | 0/0 | 0/0 |

The primary irritation score. 6.6

Note: Positive control performed once every six months, see SDWH-M202103118-1(Completed Date: 2021-06-25).

Table 4 Test Results of Dermal Observations

| Extract | Rabbit No. | Group | Reaction | Interval (hours): score=left site/right site | | |
|---------|------------|------------------|----------|--|-------|-------|
| | | | | 24±2h | 48±2h | 72±2h |
| SC | 1 | Test Article | Erythema | 0/0 | 0/0 | 0/0 |
| | | | Oedema | 0/0 | 0/0 | 0/0 |
| | | Negative Control | Erythema | 0/0 | 0/0 | 0/0 |
| | | | Oedema | 0/0 | 0/0 | 0/0 |
| SC | 2 | Test Article | Erythema | 0/0 | 0/0 | 0/0 |
| | | | Oedema | 0/0 | 0/0 | 0/0 |
| | | Negative Control | Erythema | 0/0 | 0/0 | 0/0 |
| | | | Oedema | 0/0 | 0/0 | 0/0 |
| SC | 3 | Test Article | Erythema | 0/0 | 0/0 | 0/0 |
| | | | Oedema | 0/0 | 0/0 | 0/0 |
| | | Negative Control | Erythema | 0/0 | 0/0 | 0/0 |
| | | | Oedema | 0/0 | 0/0 | 0/0 |

The primary irritation score. 0

Skin Irritation Test of medical electrode plate (hydrogel)

According to GB/T 16886.10-2017
0.9% Sodium Chloride Injection Extract

Test Report

1 Purpose

The extract of test article was evaluated for skin irritation and extrapolating the results to humans, but it does not establish the actual risk of irritation.

2 Reference

GB/T 16886.10-2017 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization

3 Compliance

ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories (CNAS—CL01 Accreditation criteria for the competence of testing and calibration laboratories) China National Accreditation Service for Conformity Assessment LABORATORY ACCREDITATION CERTIFICATE Registration No. CNAS L2954.

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太哲浩
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上海舒尔倍医疗科技有限公司
Shanghai Soulbay Medical Technology Co., LTD

Phone& Wechat&WhatsApp: 0086 13764301124

Email: william@soulbaymedical.com

Add: 上海市松江区干帆路288弄6-709

Shanghai Songjiang District Qianfan Road 288 Lane 6-709

