



**WELCOME TO HAIZE MEDICAL**

**[www.haizemed.com](http://www.haizemed.com)**

**2017**

## Vision and Mission

US PATENT  
US8480573 B2

US PATENT  
14/579,830

US PATENT  
15/587,050



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CE  
0123



A platform of medical transformation for surgeons, clinicians and leaders in innovative medical devices.

**HAIZE**

# Company Profile – Organization Structure



Designed by **Shanghai Institute of Surgical Engineering and Technology**

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Tel: +86-(0)21-62496290  
Fax: +86-(0)21-62496290-818

Manufactured by **Jiangsu Haize Medical Scientific Development Co., Ltd.**

Add: No.99, Furongzhongsan Road, XiShan Economical Development Zone, Wuxi, Jiangsu, 214192, China.  
[www.haizemed.com](http://www.haizemed.com)  
E-mail: [haizemed@haizemed.com.cn](mailto:haizemed@haizemed.com.cn)  
Tel: +86-(0)510-82832301  
Fax: +86-(0)510-82832301

**HAIZE**

## Company Profile – Brief Introduction



HAIZE Medical, headquartered in Shanghai, is a high-tech enterprise of R&D, manufacture, sales and technical services of medical surgical instruments and disposables.

All products are registered and certified by CFDA, FDA and CE and filed patents in US, Europe and China etc.

### US, European Patents Protected Products

- |   |   |
|---|---|
| 1 | <b>ViClean<br/>Single Use Wound Potector</b>    |
| 2 | <b>ViSure<br/>Single Use Surgical Retractor</b> |
| 3 | <b>ViClear<br/>Single Use Suction Irrigator</b> |



## Brief Introduction of the Founder and Inventor Jianmin Qian MD,PhD



- Director of Liver Transplant Center, Huashan Hospital of Fudan University & General Hospital of Red Cross Society of China.
- Chief Physician of Department of General Surgery, Huashan Hospital of Fudan University & General Hospital of Red Cross Society of China.
- Professor, doctoral supervisor of Department of Surgery, Fudan University
- Fellow of IHPBA (International Hepato-Pancreato-Biliary Association)
- Fellow of Chinese Society of Organ Transplantation of CMA (Chinese Medical Association)
- National Expert with Remarkable Contributions, won 12 national Science-Technology Progress Prizes, 7 ministerial Science-Technology Progress Prizes, possesses over 40 overseas and domestic intellectual properties, published 46 papers in national core periodical and SCI.

# Certificates

US PATENT US PATENT US PATENT  
US8480573 B2 14/579,830 15/587,050



Europäisches Patentamt  
European Patent Office  
Office européen des brevets



SURGICAL INNOVATION LEADER AND PIONEER

## FDA Listing, FDA510K, CE, ISO13485.

2017013 Establishment Registration & Device Listing

**FDA**

[FDA Home](#) [Medical Devices](#) [Databases](#)  
**Establishment Registration & Device Listing**  
New Search [Back To Search Results](#)

**Proprietary Name:** VIClean  
**Classification Name:** RING (WOUND PROTECTOR), DRAPE RETENTION, INTERNAL  
**Product Code:** [K04](#)  
**Device Class:** 2  
**Regulation Number:** [878, 4370](#)  
**Medical Specialty:** General & Plastic Surgery  
**Registered Establishment Name:** [Jiangsu Haize Medical Scientific Development Co., Ltd.](#)  
**Registered Establishment Number:** 3010601984  
**Owner/Operator:** [Jiangsu Haize Medical Scientific Development Co., Ltd.](#)  
**Number:** 10045402  
**Establishment Operations:** Contract Manufacturer; Manufacturer; Complaint File Establishment

201702 510(k) Premarket Notification

**FDA**

[FDA Home](#) [Medical Devices](#) [Databases](#)  
**510(k) Premarket Notification**  
New Search [Back To Search Results](#)

**Device Classification Name:** [Laparoscope, Stereol & Panor Surgery](#)<sup>27</sup>  
**510(k) Number:** [K161421](#)  
**Device Name:** Single Use Surgical Suction Irrigator  
**Applicant:** JIANGSU HAIZE MEDICAL SCIENTIFIC DEVELOPMENT CO., LTD. No. 95, Fuzhuoyuan Road, Nantou Economic Development Zone, Wuxi, CN 214000  
**Applicant Contact Correspondent:** Vikiun Sun  
**Correspondent Contact:** Vikiun Sun  
**Regulation Number:** [878,48007](#)  
**Classification Product Code:** [C024](#)  
**Date Received:** 05/23/2016  
**Decision Date:** 09/20/2016  
**Decision:** Substantially Equivalent (SESE)  
**Registration Medical Specialty:** General & Plastic Surgery  
**510k Review Panel Statement:** [Classified](#)<sup>28</sup>  
**Type:** [Traditional](#)<sup>29</sup>  
**Reviewed By Third Party:** No  
**Combination Product:** No

2017013 Establishment Registration & Device Listing

**FDA**

[FDA Home](#) [Medical Devices](#) [Databases](#)  
**Establishment Registration & Device Listing**  
New Search [Back To Search Results](#)

**Proprietary Name:** VISure  
**Classification Name:** RETRACTOR  
**Product Code:** [G046](#)<sup>6</sup>  
**Device Class:** 1  
**Regulation Number:** [878,48007](#)  
**Medical Specialty:** General & Plastic Surgery  
**Registered Establishment Name:** [Jiangsu Haize Medical Scientific Development Co., Ltd.](#)<sup>8</sup>  
**Registered Establishment Number:** 3010601984  
**Owner/Operator:** [Jiangsu Haize Medical Scientific Development Co., Ltd.](#)<sup>9</sup>  
**Number:** 10045402  
**Establishment Operations:** Foreign Exporter; Manufacturer; Complaint File Establishment

ZERTIFIKAT • CERTIFICATE • 认证证书 • CERTIFICATO • CERTIFICADO • CERTIFICAT

**EC Certificate**  
Full Quality Assurance System  
Directive 90/269/EEC on Medical Devices (MDD), Annex 1 (including 16) (Directive No. 90/269/EEC)  
No. 01 14 05 87905-002

**Manufacturer:** Jiangsu Haize Medical Scientific Development Co., Ltd.  
No. 95 Fuzhuoyuan Road, Nantou Economic Development Zone, Wuxi, Jiangsu Province, P.R. CHINA  
214000, CHINA

**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)  
Wilmshurststr. 10  
65462 Hattersheim  
GERMANY

**Product Category(s):** Single Use Surgical Retractor; Single Use Surgical Suction Irrigator

The Certification Body of TÜV SÜD Product Service GmbH certifies that the above-mentioned manufacturer has implemented a quality assurance system for single use surgical instruments in accordance with the requirements of the respective directive. The manufacturer is authorized with MDD Annex 1. This body certifies special certificates for the requirements of the Directive and its respective product standards. For a complete list of items it becomes available from TÜV SÜD website in Germany. See document number:

**Report No.:** 041488101  
**Valid from:** 2014-01-10  
**Valid until:** 2019-01-10

**Date:** 2014.06.17

TÜV SÜD Product Service GmbH, Leinfelden-Echterdingen • Rosenstraße 1 • 70569 Stuttgart • Germany

**CERTIFICATE**  
No. Q1N 17 03 87905 004

**Holder of Certificate:** Jiangsu Haize Medical Scientific Development Co., Ltd.  
No. 95 Fuzhuoyuan Road, Nantou Economic Development Zone, Wuxi, Jiangsu Province, P.R. CHINA  
214000, CHINA

**Facility/Plant:** Jiangsu Haize Medical Scientific Development Co., Ltd.  
No. 95 Fuzhuoyuan Road, Nantou Economic Development Zone, Wuxi, Jiangsu Province, P.R. CHINA  
214000, CHINA

**Certification Mark:**

**Scope of Certificate:** Design and Development, Production and Distribution of Surgical Instruments

**Applied Standards(s):** EN ISO 13485:2012 + AC:2012  
TUV SÜD Service Quality Management System  
Requirements for regulatory purposes  
ISO 13485:2012 + Cor. 1:2006  
EN ISO 9014:85:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standards. See other document(s):

**Report No.:** 041703204  
**Valid from:** 2017-06-16  
**Valid until:** 2020-06-16

**Date:** 2017-05-09  
**Page 1 of 1**

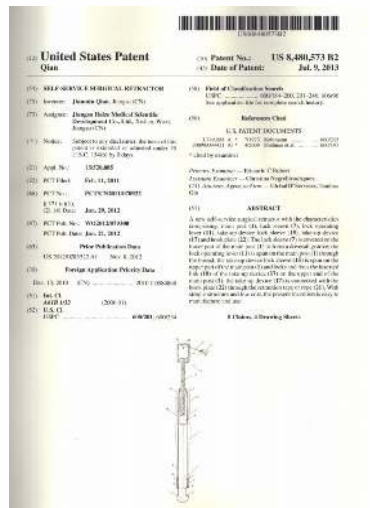
TÜV SÜD Product Service GmbH, Leinfelden-Echterdingen • Rosenstraße 1 • 70569 Stuttgart • Germany

FDA	Surgical Retractor Registered Establishment Number:3010601984.
	Surgical Suction Irrigator 510K Number: K161421.
CE	Wound Protector Registered Establishment Number:3010601984.
	No.G1 1703 87905003
ISO13485	No.Q1N 1703 87905 004

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Europäisches Patentamt  
European Patent Office  
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**US Patent**

US Patent No.: US 8,480,573 B2

US Patent No.: US 14/579,830

US Patent No.: US 15/587,050

**European Patent**

European Patent No.: 11848599.4

Patent Publication No.: PCT/CN2013/087663

Patent Publication No.: PCT/CN2011/070922

**Japan Patent**

Japan Patent No.: 5657134  
Self-Service Surgical Retractor

**India Patent**

5340/DELNP/2013  
Self-Service Surgical Retractor

**South Africa Patent**

2013/04343  
Self-Service Surgical Retractor





## China Patent

### ViSure Single Use Surgical Retractor

ZL201110140381.X

ZL201010248330.4

ZL201010288930.3

ZL201010288936.0

ZL201010584868.2

### ViClear Single Use Suction Irrigator

ZL201010053841.5

ZL201410216879.3

ZL201120057473.7

### ViClean Single Use Wound Protector

ZL201510975092.X

ZL201520634791.3



# Factory Show---Jiangsu Haize Medical Scientific Development Co.,Ltd.

PROVIDER  
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Test  
Room



Injection Workshop



Assembly Workshop



Warehouse

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## Market

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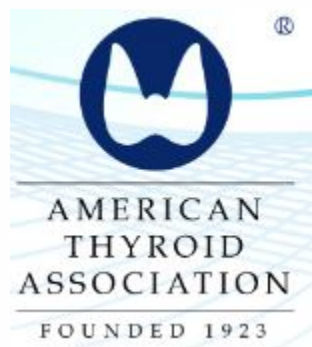
With years of experience in the medical surgical field, and strong R&D abilities, Haize Medical are able to supply the total solutions to our clients all over the world. Our main market is based on America, Europe, Middle East and ASEAN.



**HAIZE**

## HAIZE Exhibitions to meet our clients

Haize Medical participates in global main medical fairs and professional academic conference.



**86th Annual Meeting of the  
American Thyroid Association**



**AMERICAN COLLEGE OF SURGEONS**  
*Inspiring Quality: Highest Standards, Better Outcomes*

**CLINICAL CONGRESS 2017**  
OCTOBER 22-26 | SAN DIEGO CONVENTION CENTER | SAN DIEGO, CA

## ViSure® Single Use Surgical Retractor

Reduce tissue damage and the risk of SSI (Surgical Site Infection)  
Revolutionary technology for the operative exposure



### Model JM-B:

Apply to bilateral epigastrium incision below costal margin and vertical hypogastrum incision.  
Gastrectomy, Liver Transplantation, Biliary Surgery, Splenectomy, Proximal Gastrectomy, Esophagus Tumor resection

### Model JM-E:

Apply to unilateral epigastrium incision below costal margin and vertical hypogastrum incision.  
Gastrectomy, Liver Transplantation, Biliary Surgery, Splenectomy, Proximal Gastrectomy, Esophagus Tumor resection

### Model JM-C:

Apply to neck and back skin muscle flap incision: Thyroid surgery, Spinal Operation.





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- Provide flexible tension, reduce injury
- Easy to install, improve operative efficiency
- Self-retaining retraction
- Relieve patient pain, prevent infection



Optional Hook Plates



Adjustable Lever Height



Controllable Retraction Direction

## Benefits

1. 1-2 minutes fast setup time
2. Quick postoperative cleanup
3. Non-dazzling Blades
4. Non-conductive macromolecular material, no electrical injury
5. Lower the incidence of SSI
6. Less medical staff required during surgery.
7. Maximum operating space available
8. Cost effective

# Clinical Application

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US PATENT  
15/587,050



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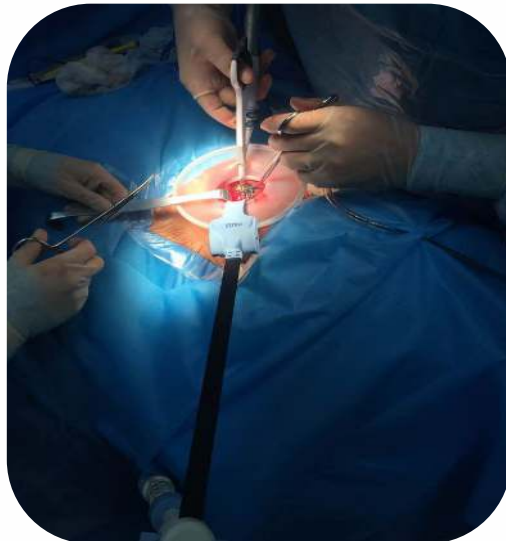
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Model JM-E is used in  
Radical Gastrectomy



Model JM-B is used in  
Hepatobiliary surgery



Model JM-C is used in  
Thyroidectomy

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## Products

US PATENT  
US8480573 B2

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14/579,830

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### Open Surgery

<b>Model JM-CX1:</b>	double-channel suction irrigator for open surgery.
<b>Model JM-CX1A:</b>	double-channel suction irrigator for open surgery.

### Laparoscopic Surgery

<b>Model JM-CX4:</b>	double-channel suction irrigator for Laparoscopic surgery.
<b>Model JM-CX4B:</b>	single-channel suction irrigator for Laparoscopic surgery

### Robotic Surgery

<b>Model JM-CX5:</b>	double-channel suction irrigator for Robotic Da Vin
<b>Model JM-CX5B:</b>	single-channel suction irrigator for Robotic Da Vinci System surgery.

# Features

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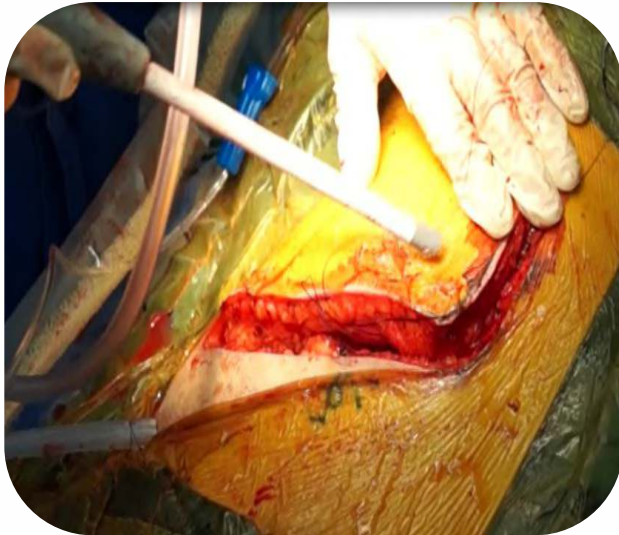


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- Simultaneous suction and irrigation.
- Adjustable flow control.
- Maintain stable pneumoperitoneum.
- Improve operative efficiency.

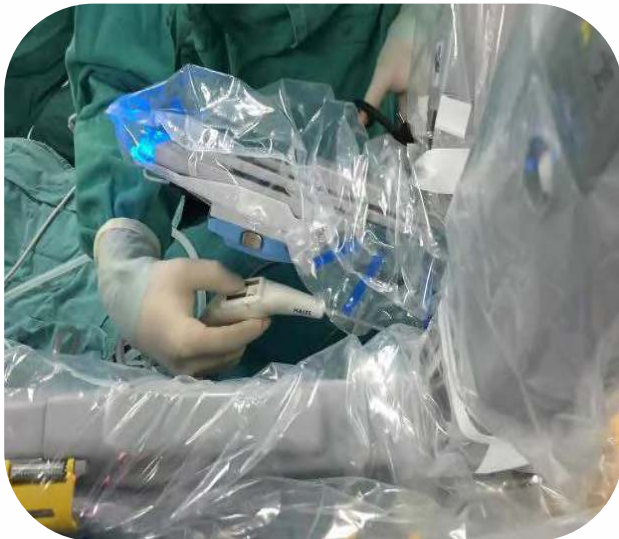




Model JM-CX1A is used in  
Hepato-Pancreato-Biliary Surgery



Model JM-CX4B is used in  
Endoscope-assisted  
thyroidectomy



Model JM-CX5B is used in  
Robotic Da Vinci System

## Products

US PATENT  
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14/579,830

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15/587,050



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ViClean Wound Protector, with unique protection feature, avoids backflow of waste fluid, protects surgical wound, surface, surgeons and operation room from contamination.

### Height-adjustable Type

Model WPB	Size: M,L,XL,XXL	Gastrointestinal Surgery, Hepatopancreatobiliary Surgery, Obstetrics & Gynecologic Surgery
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### Height-fixed Type

Model WPC	Size: L, XL	Thyroid surgery, Breast surgery and thoracic surgery.
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# Clinical Applications

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US PATENT 15/587,050



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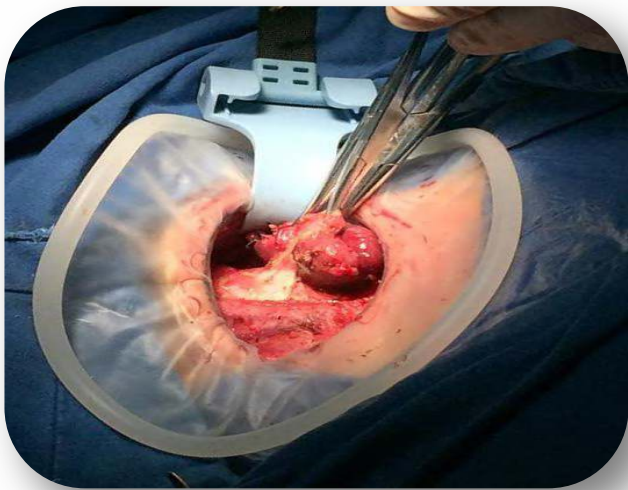
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Endoscopic Colon Carcinoma Radical Resection



Model WPB-XL is used in Hepato-Pancreato-Biliary Surgery



Model WPC is used in Thyroid Surgery



Model WPB-XL is used in Obstetrics & Gynecologic Surgery

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# THANKS FOR WATCHING

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