

# Company & Product Presentation

 **innolcon**  
Share medical progress



# CONTENT



**Company Profile**



**Innolcon Products and Innovations**



**Clinical Data Comparison**

# Part 1



## Company Profile



## Innolcon Products and Innovations



## Clinical Data Comparison



# Overview



## Innolcon

is dedicated to research and development, production, sales, and services of high-end ultrasonic and ophthalmic surgical equipment.



Founded in June, 2014



Headquarters in Suzhou, China  
R&D Center in C.A, USA



First & Only Chinese ultrasonic system manufacturer with China NMPA approval for 5mm vessel sealing

# Management Team

Founder/CEO



**LUO WEI**

- Ph.D University of California, Irvine
- Profound experience in Medical device & system design, Project Management

Cofounder/Chairman



**LIU SHOUGUO**

- Entrepreneur
- Rich experience in medical industry sales & marketing

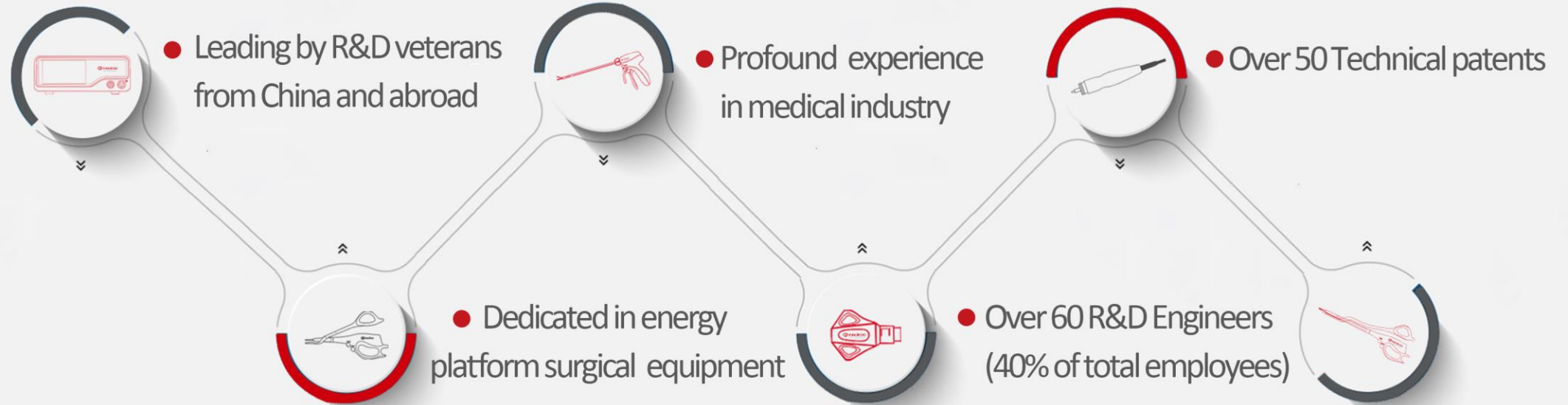
Cofounder/CTO.



**John YAN**

- Ph.D University of Cincinnati
- Dedicated to research of ultrasonic Equipment & medical device

# R&D Strength



# Manufacturing Facilities

60000m<sup>2</sup> Production Facility

## Manufacturing Building



Annual Production Capacity: 1.5m PCS of Scalpels

## Assembly Line



## Assembly Clean Room



# Quality Certificate

**EC Certificate**  
Full Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)  
No. G1 102195 0002 Rev. 00

**Manufacturer:**  
Innolcon Medical Technology (Suzhou) Co., Ltd.  
Unit 405/407/409/411, Building B2  
No. 218 Xinghu Street  
Suzhou Industrial Park  
Suzhou, Jiangsu Province  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**  
Innolcon Medical Technology (Suzhou) Co., Ltd.  
Unit 405/407/409/411, Building B2, No. 218 Xinghu Street  
Suzhou Industrial Park, 215123 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  
Innolcon Medical Technology (Suzhou) Co., Ltd.  
Unit 101, Building 13, No. 218 Sanglian Street, Suzhou Industrial Park, 215123 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies):**  
Ultrasonic Surgical System,  
Ultrasonic Surgical Scalpel

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture inspection of the respective devices / device categories in accordance with MDD Annex II assurance system conforms to the requirements of this Directive and is subject to surveillance. For marketing of class III devices an additional Annex II (4) certificate is also notes overleaf.

**Report No.:** SH19129201  
**Valid from:** 2019-08-20  
**Valid until:** 2024-05-26  
**Date:** 2019-08-20

*S. Preiß*  
Stefan Preiß  
Head of Certification/Notified Body


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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123  
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**CE**

**Certificate**  
No. Q5 102195 0001 Rev. 00

**Holder of Certificate:** Innolcon Medical Technology (Suzhou) Co., Ltd.  
Unit 405/407/409/411, Building B2  
No. 218 Xinghu Street  
Suzhou Industrial Park  
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Innolcon Medical Technology (Suzhou) Co., Ltd.  
Unit 101, Building 13, No. 218 Sanglian Street, Suzhou Industrial Park, 215123 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**  


**Scope of Certificate:** Design and Development, Production and Distribution of Ultrasonic Surgical System, Ultrasonic Surgical Scalpel

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)  
DIN EN ISO 13485:2016

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 standard(s). See also notes overleaf.

**Report No.:** SH19129201  
**Valid from:** 2019-08-20  
**Valid until:** 2022-08-19  
**Date:** 2019-08-20

*S. Preiß*  
Stefan Preiß  
Head of Certification/Notified Body

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**ISO13485**

**Test Verification of Conformity**  
Certificate No. CTC1907016101  
Issued Date: Nov 15, 2019

The sample, as described herewith, was tested pursuant to the testing standard:  
IEC 62321-5-1-2013, IEC 62321-6-2013, IEC 62321-7-1-2015, IEC 62321-7-2-2017, IEC 62321-6-2015, IEC 62321-8-2017  
and all the test results comply with the requirements of:  
RoHS Directive 2011/65/EU (EU) 2015/863  
Restriction of the use of certain hazardous substances in electrical and electronic equipment

**Applicant:** Innolcon Medical Technology (Suzhou) Co., Ltd.  
Unit 405/407/409/411, Building B2, No. 218 Xinghu Street, Suzhou Industrial Park, Suzhou, Jiangsu Province, 215123, P.R. China

**Manufacturer:** Innolcon Medical Technology (Suzhou) Co., Ltd.  
Unit 405/407/409/411, Building B2, No. 218 Xinghu Street, Suzhou Industrial Park, Suzhou, Jiangsu Province, 215123, P.R. China; Unit 101, Building 13, No. 218 Sanglian Street, Suzhou Industrial Park, Suzhou, Jiangsu Province, 215123, P.R. China

**Sample Name:** Ultrasonic Surgical System  
**Sample Model(s):** Y16-E

**Laboratory:** CCIC (Shenzhen) Environmental Service Co., Ltd.  
Floor 2, Meiliao Industrial Park, Hengsheng Industrial Zone, Nanshan District, Shenzhen, Guangdong, P.R. China  
Tel: +86-755-88630350 Fax: +86-755-88630352  
Http://www.ccc.com.cn/en/ Home E-mail: sjg@ccc.com.cn

**RoHS CE**


**For and on behalf of:** CCIC (Shenzhen) Environmental Service Co., Ltd.  
*Renfou Yang*

**RoSH**

**中华人民共和国医疗器械注册证**  
注册证编号: 国械注准20203060682

注册人名称	以诺康医疗科技(苏州)有限公司
注册人住所	苏州工业园区星湖街218号B2-409单元
生产地址	苏州工业园区星湖街218号B2-405、407、409、411单元 苏州工业园区桑田街218号苏州生物医药产业园13号楼101单元
代理人名称	/
代理人住所	/
产品名称	超声软组织切割止血手术设备
型号、规格	Y16
结构及组成	产品由发生器(Y16)、换能器(HP401、HP501)、超声刀头(SG13、SG22、SG35、SG45、SS9、SS17)、脚踏开关(FSW01)、手推手(CRT01, 选配)、刀头扳手(TWG、TWS)、测试头(TP401、TP501)、测试头扳手(TPW01)组成。
适用范围	产品在医疗机构使用,适用于需要控制出血和最小程度热损伤的软组织切割,可用于闭合直径不超过5mm的血管。
附件	产品技术要求
其他内容	/
备注	

审批部门: 国家药品监督管理局  
批准日期: 2020年7月17日  
有效期至: 2025年7月17日



**China NMPA  
(5mm First & Only)**



# New Product-Phacoemulsification System



## Part 2



**Company Profile**



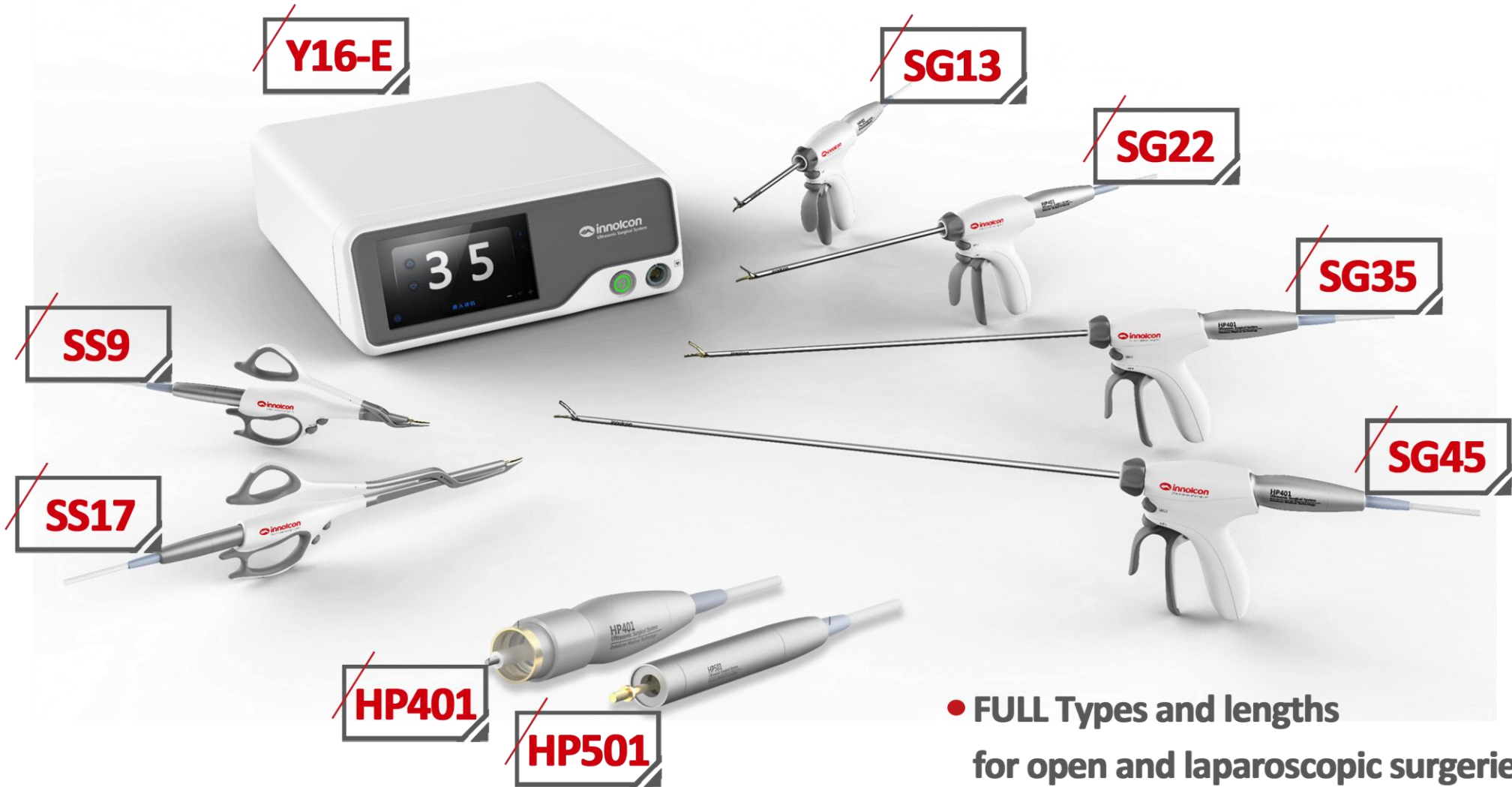
**Innolcon Products and Innovations**



**Clinical Data Comparison**



# Y16-E Ultrasonic Surgical System



- **FULL Types and lengths for open and laparoscopic surgeries.**

# INNOLCON INNOVATION

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Share medical progress



**IAT(INNOLCON Adaptive Technology)**



**Most Efficient Hand piece**

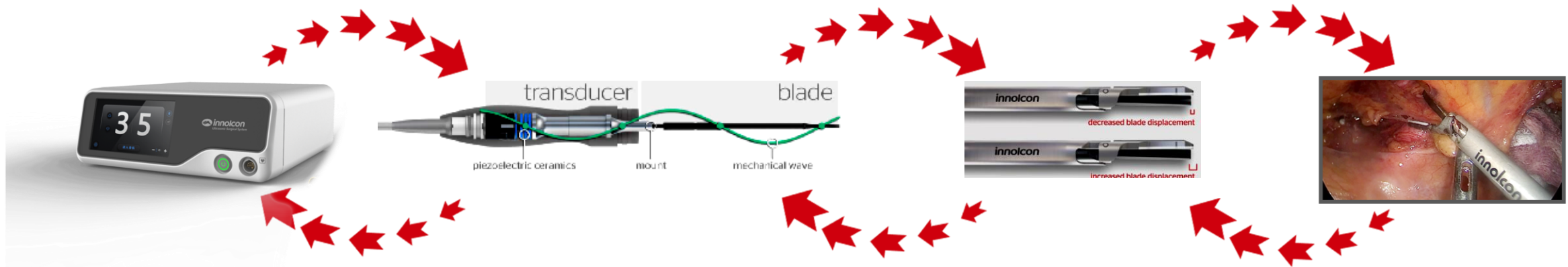


**Unique and Ergonomic Scalpel Design**



## IAT (INNOLCON Adaptive Technology)

-- Dynamic frequency auto-locking and Intelligent Response Algorithms



**Intelligently sense the tissue condition variation and respond to the system instantaneously, the generator controls energy delivery precisely**

**Benefit:**

**Reduce thermal damage effectively**

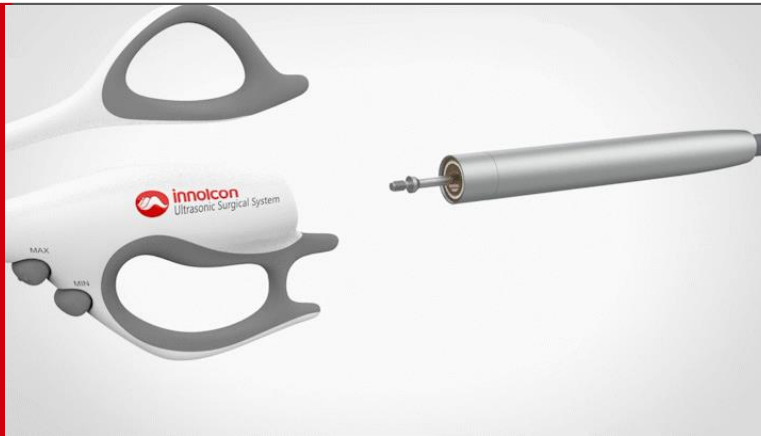
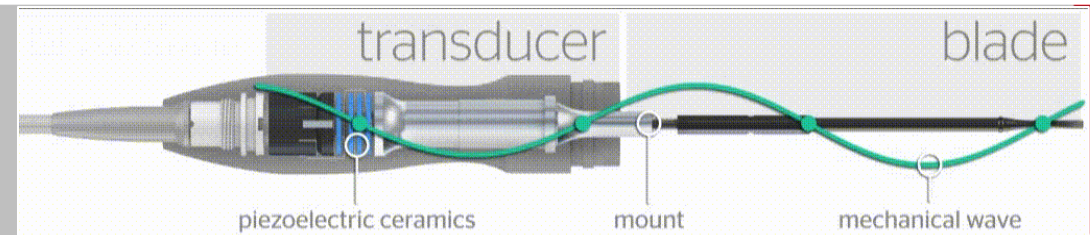
**Improve energy conversion efficiency significantly**

**Accelerate cutting speed**

**Enhance coagulating capability**

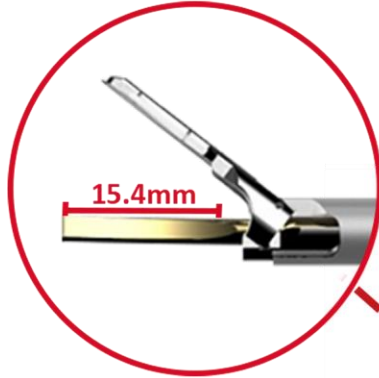
## Most Efficient Hand Piece

High Electrical-to-acoustic energy conversion efficiency.  
Same amplitude, Smaller drive current,  
Higher system efficiency (Max. output only 35W)



Scissor-type hand piece <math>< 60\text{g}</math>,  
Lightweight for dexterous and precious operation,  
reduce the fatigue of doctors and  
improve operation efficiency

## Unique and Ergonomic Scalpel Design



Super-long working blade length improves the cutting speed and enhances the safety

360° Rotation Knob for one hand operation



Ultra-low hydrogen content Titanium Alloy Blade, increases blade strength



Refined and tapered tip design ensures precision operation



## Unique and Ergonomic Scalpel Design

17mm working active blade  
and curved blade tip  
for greater visibility.

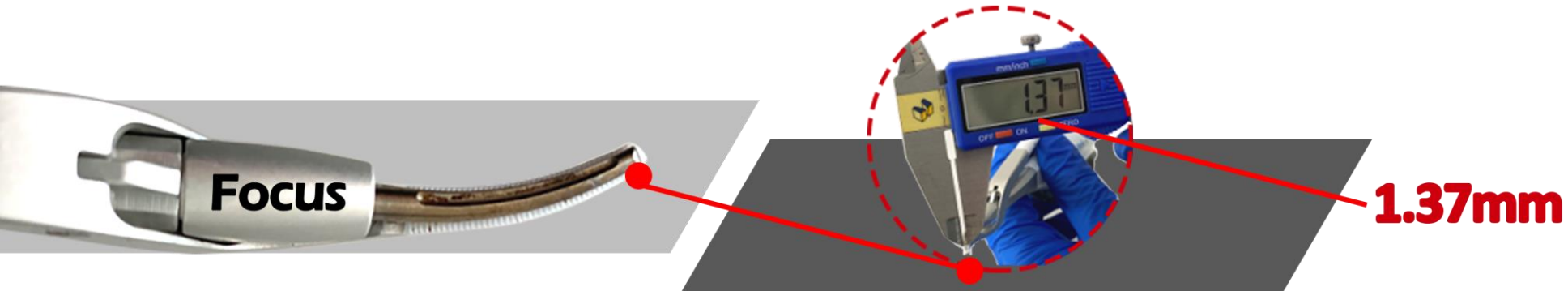
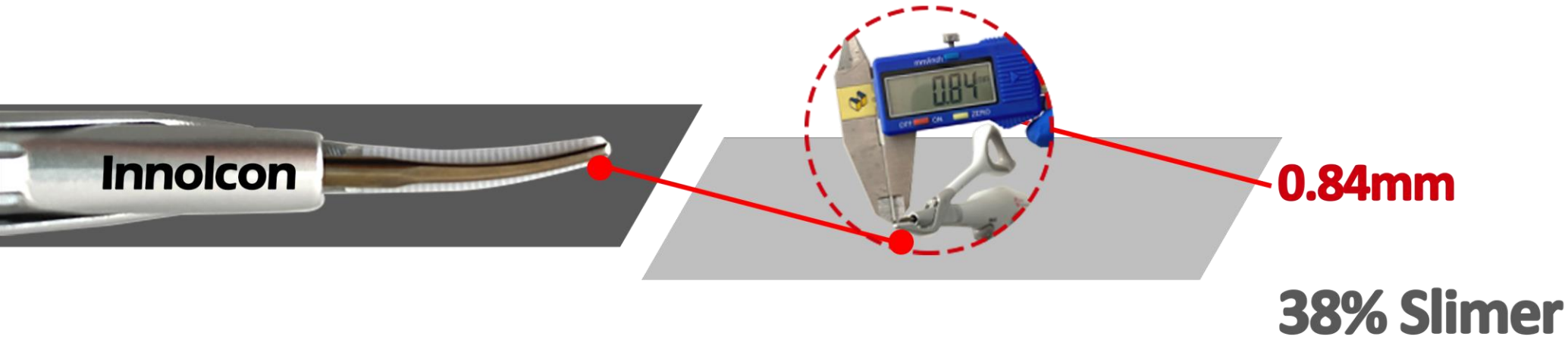
Exquisite, slimmer  
blade tip for  
precision operation  
in narrow space



Ergonomic Design  
Bigger space  
for one more finger to handle.  
More stable grasp



# Innolcon vs J&J Focus Blade Tip Size



## Part 3



**Company Profile**



**Innolcon Products and Innovations**



**Clinical Data Comparison**



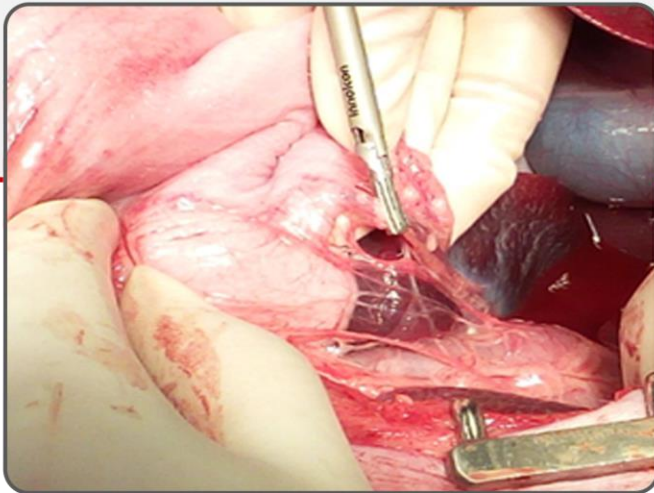
# Animal Experiment

**Experiment Model:** Swine

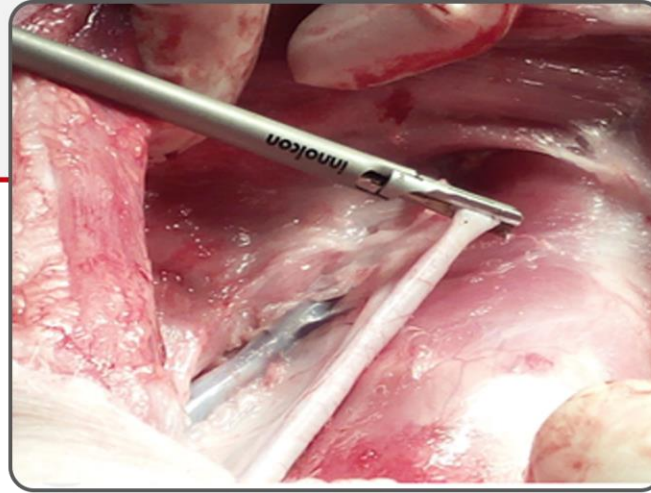
**Experiment instrument:** Innolcon SG35, SS9

**Control Group instrument:** J&J HAR36, HAR9F

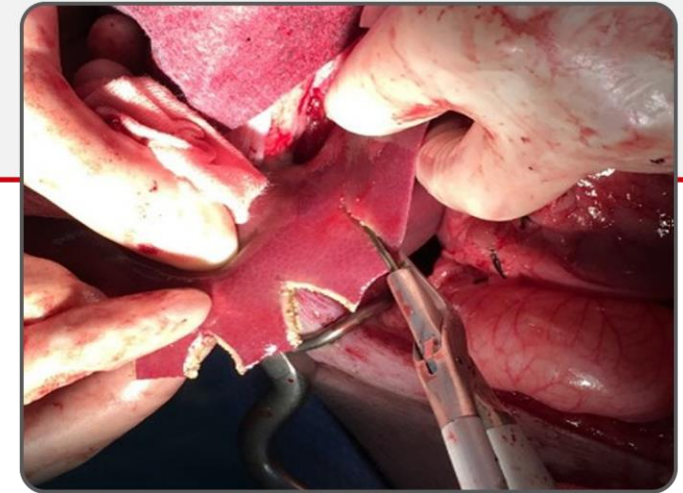
**Experiment Organization:** A third party Animal Research Center



Right Gastroepiploic Artery Sealing



Carotid Artery Sealing



Liver Dissection

# Burst Pressure Experiment

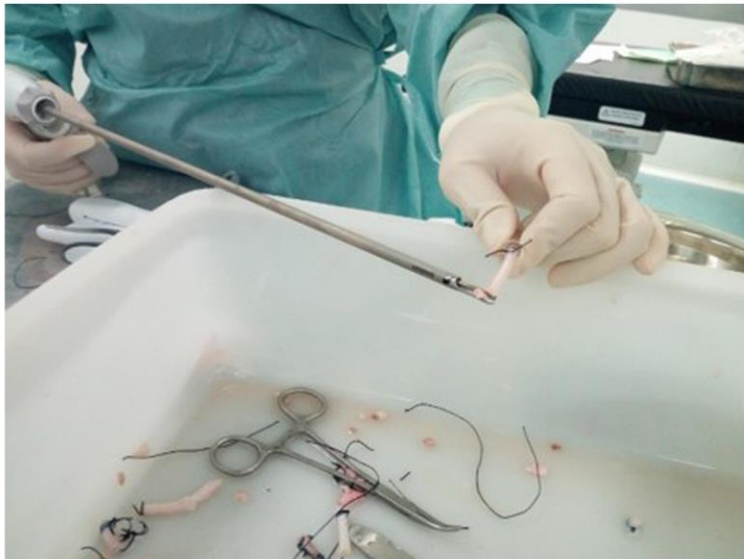
## Experiment Purpose:

To evaluate the vessel sealing quality and duration performance



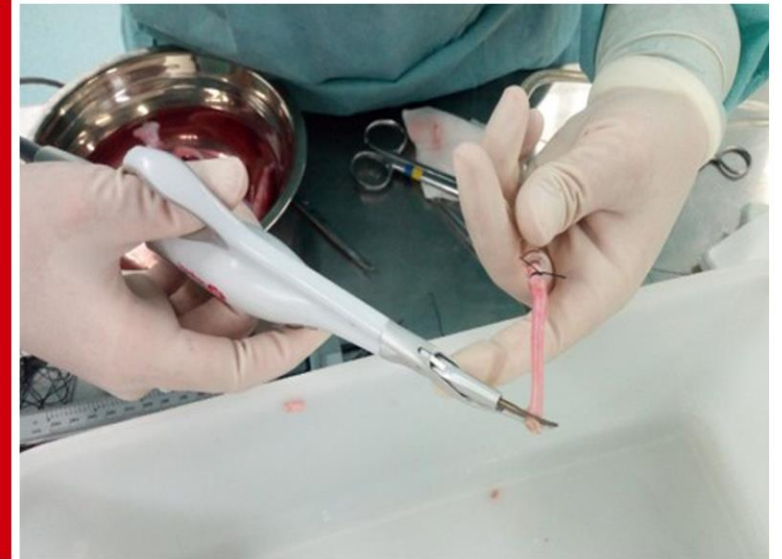
## Experiment Method:

under pressure 60-120mmHg, infuse arteries with saline and keep them in tension. Follow the IFU to seal the arteries. Then, infuse the artery with saline to max. pressure of 2000mmHg till seal bursts.



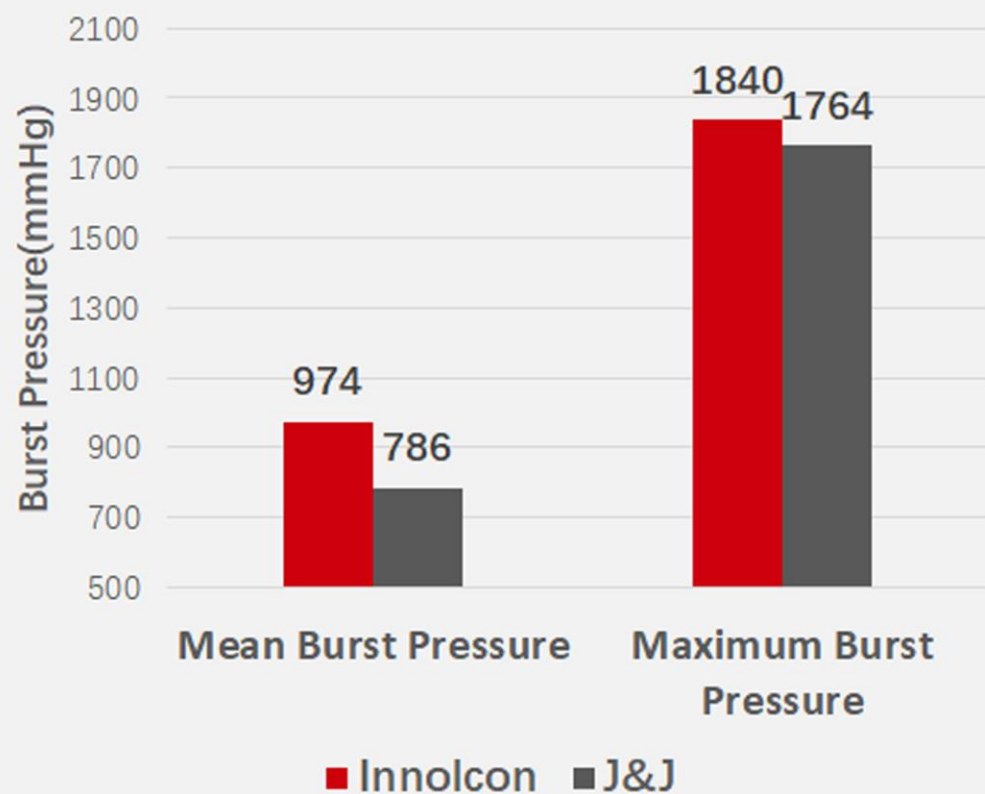
## Experiment Material:

5mm vivo porcine Carotid Artery (External Diameter)  
Experiment case: 80 cases

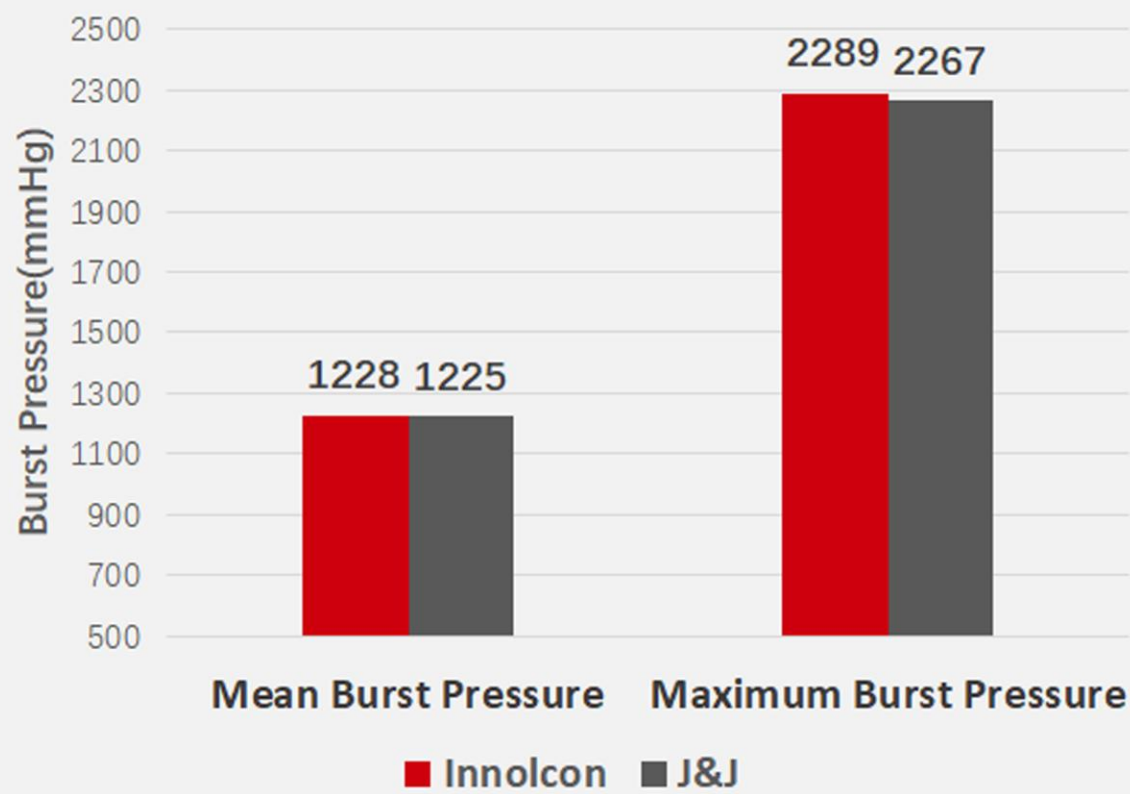


# Higher Burst Pressure

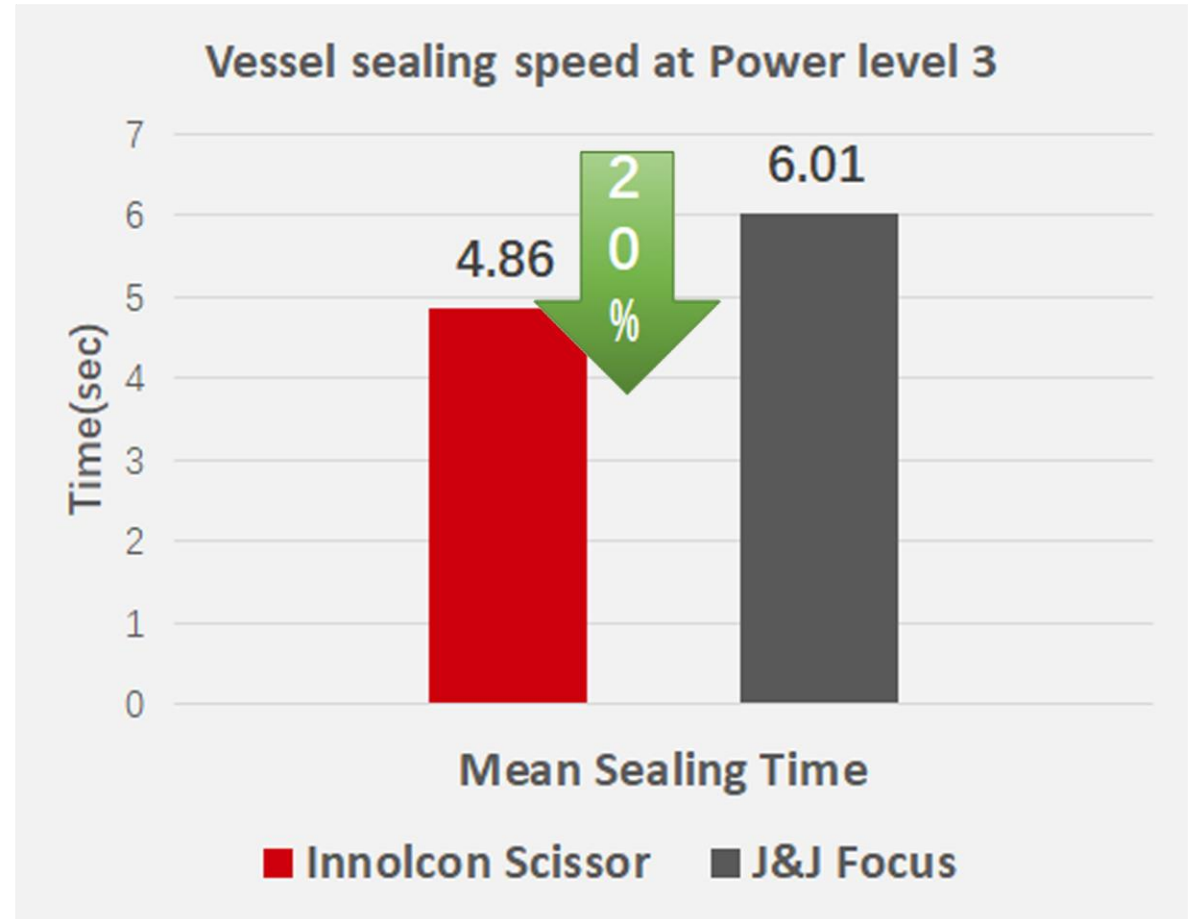
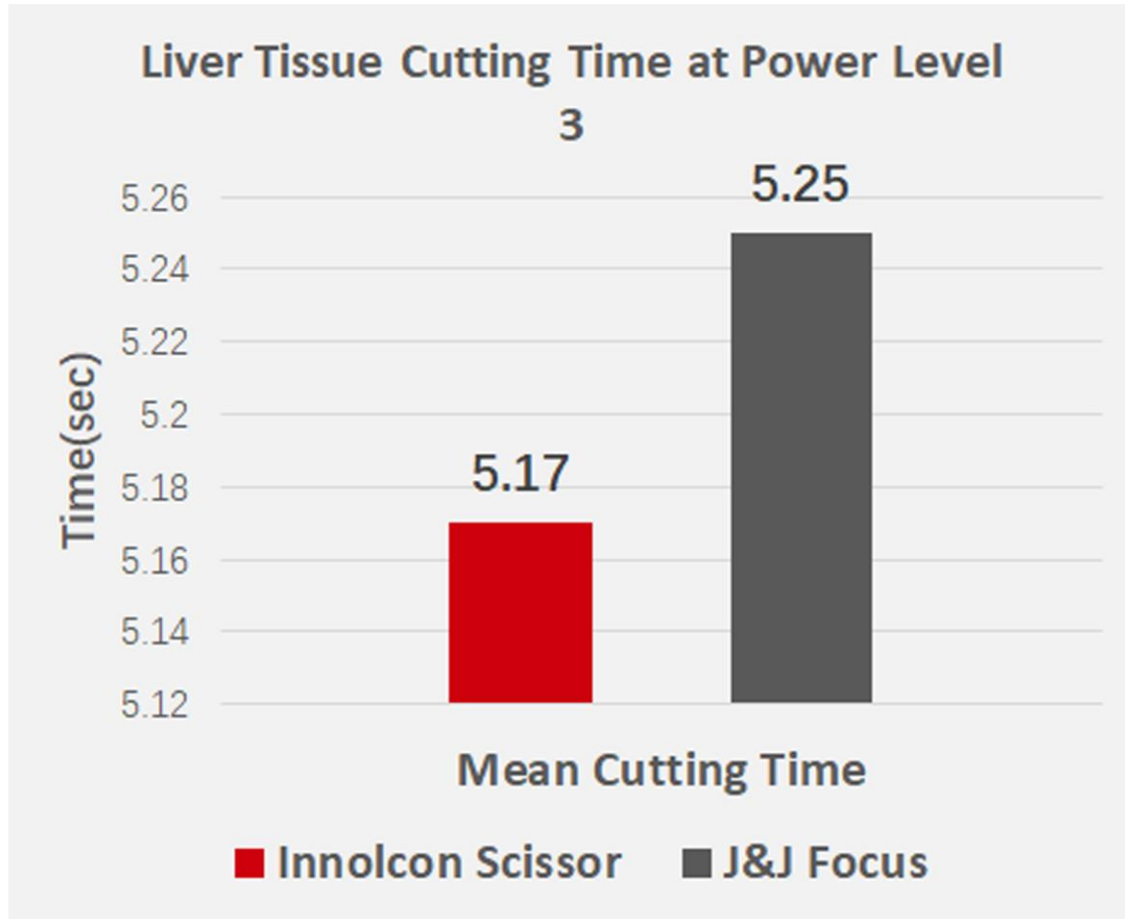
Burst Pressure in sealing vessel at 3.3-4.9mm diameter by Gun-type scalpels



Burst Pressure in sealing vessel at 2.98-5.54mm diameter by Scissor-type scalpels

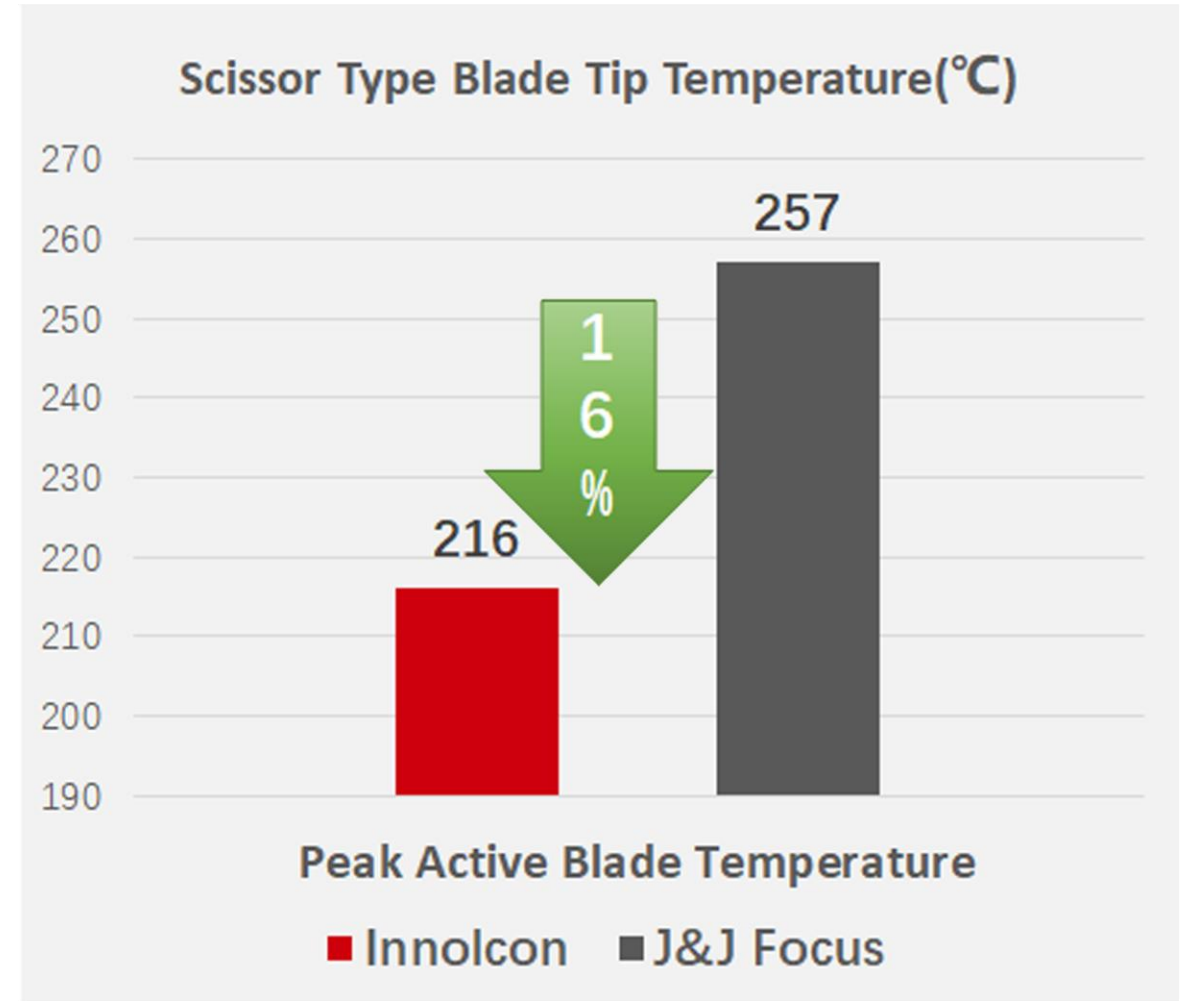
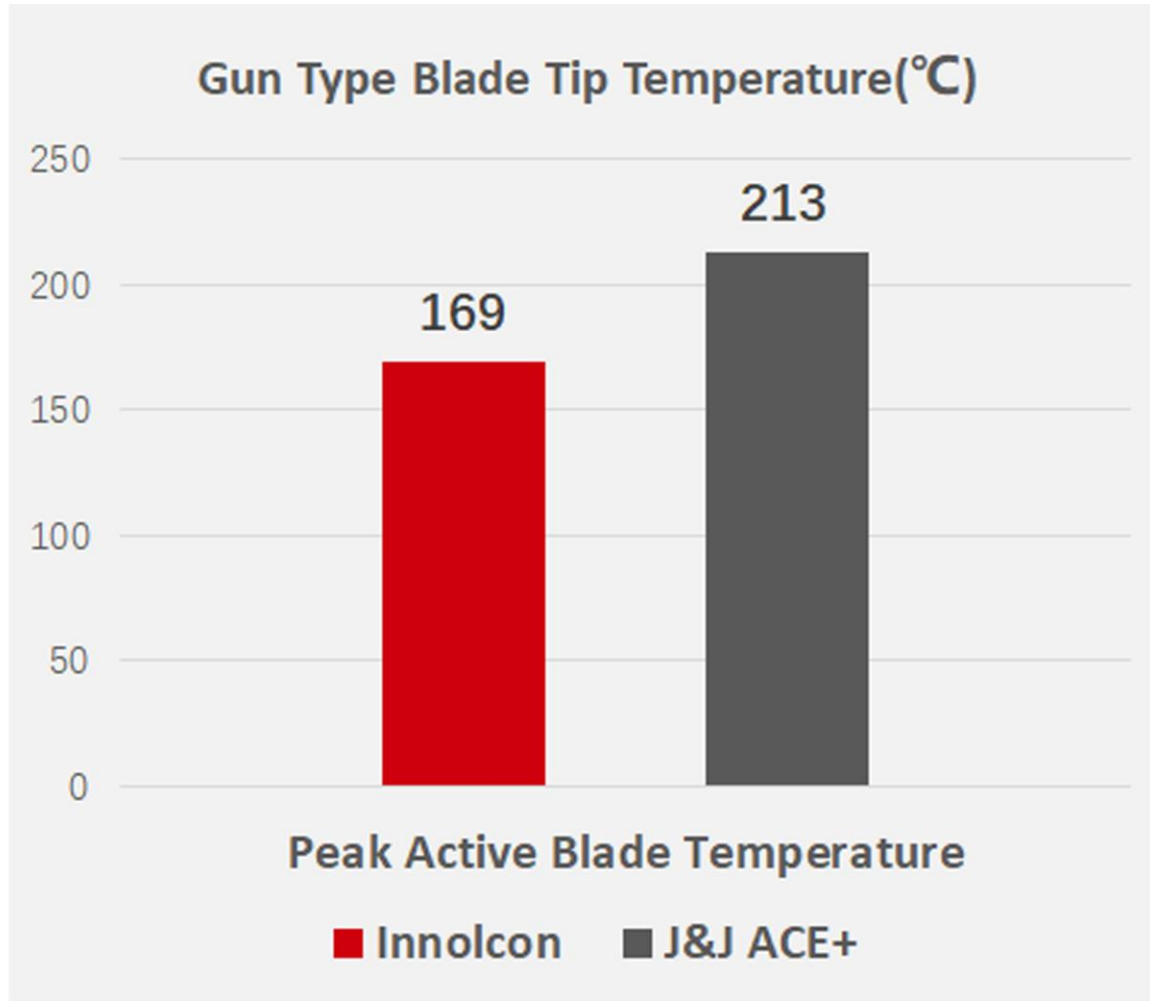


# Faster Cut Speed



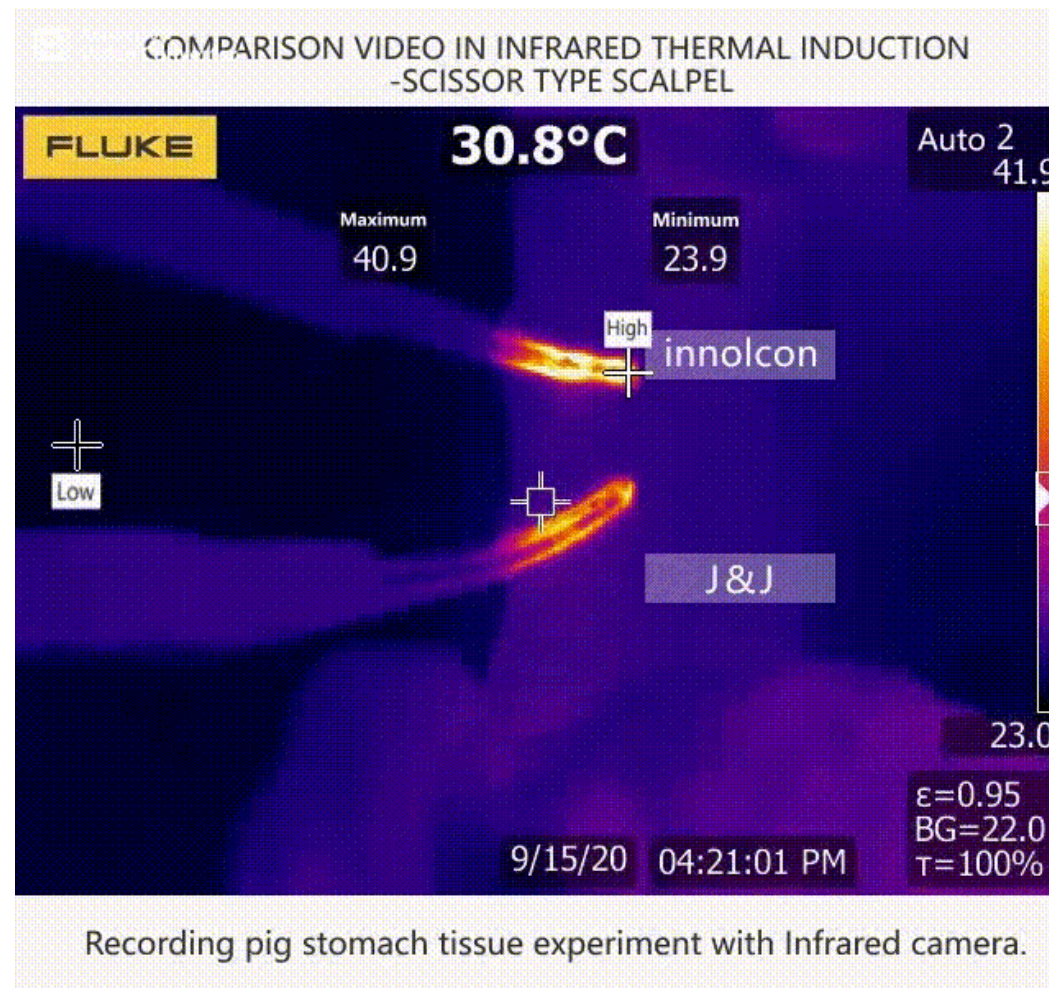
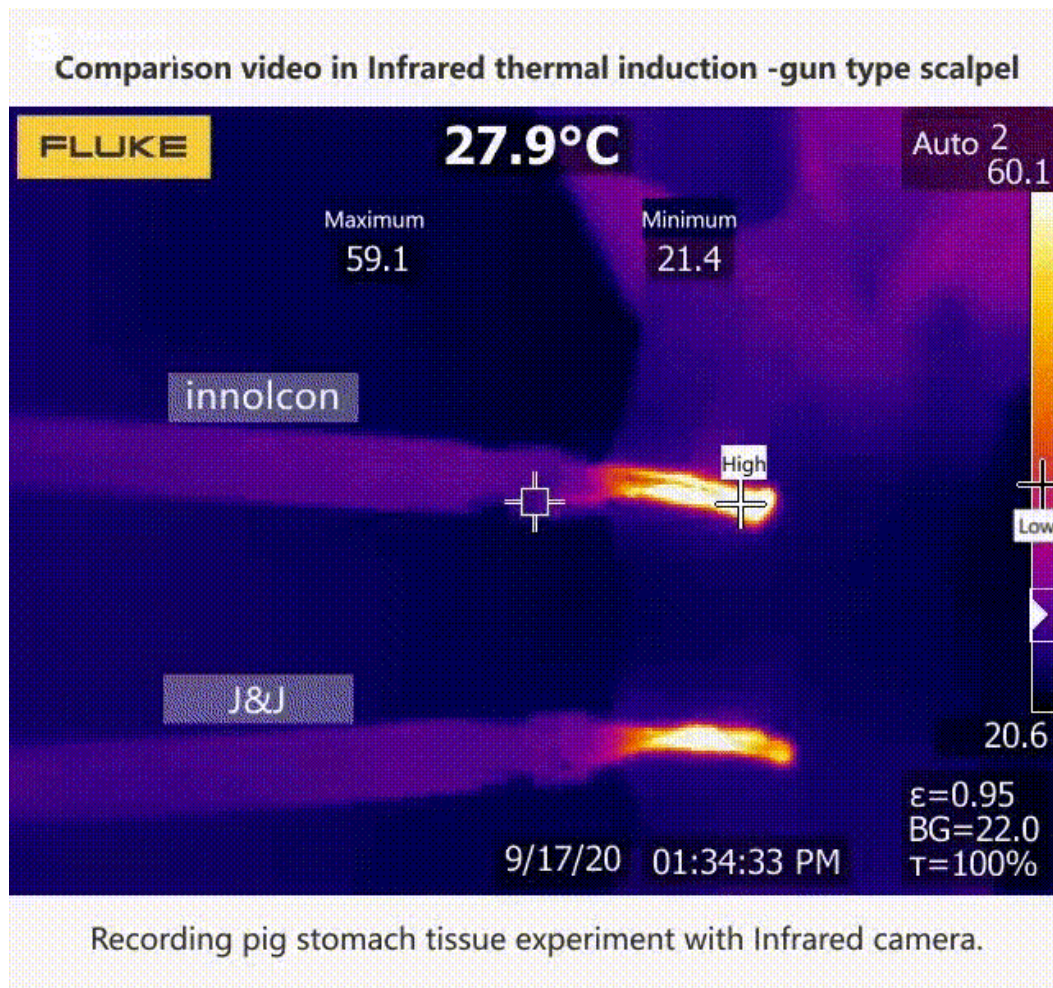
Innolcon Sealing time is 20% shorter than J&J, save 1.15sec

# Lower Blade Tip Temperature



Innolcon Blade Tip Temperature is 16% lower than J&J

# Blade Tip Temperature under Infrared Camera

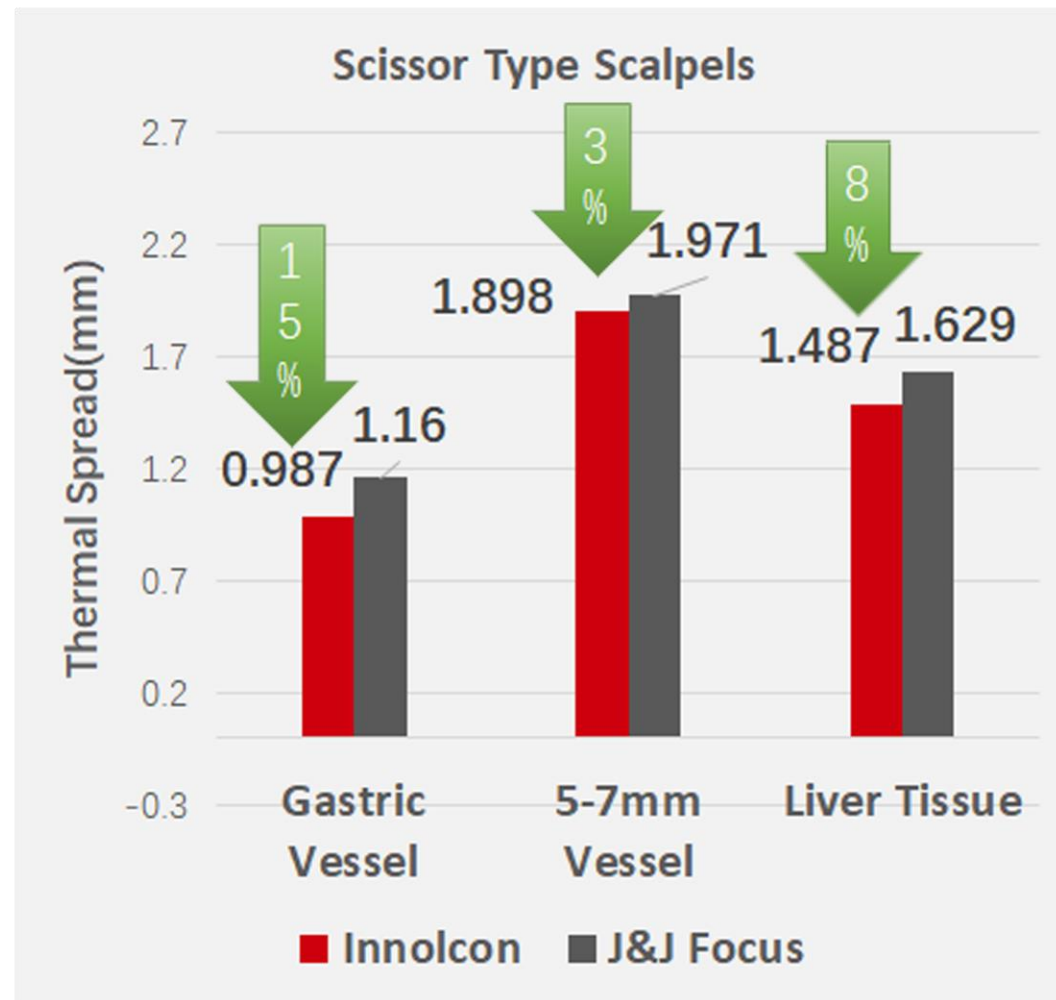
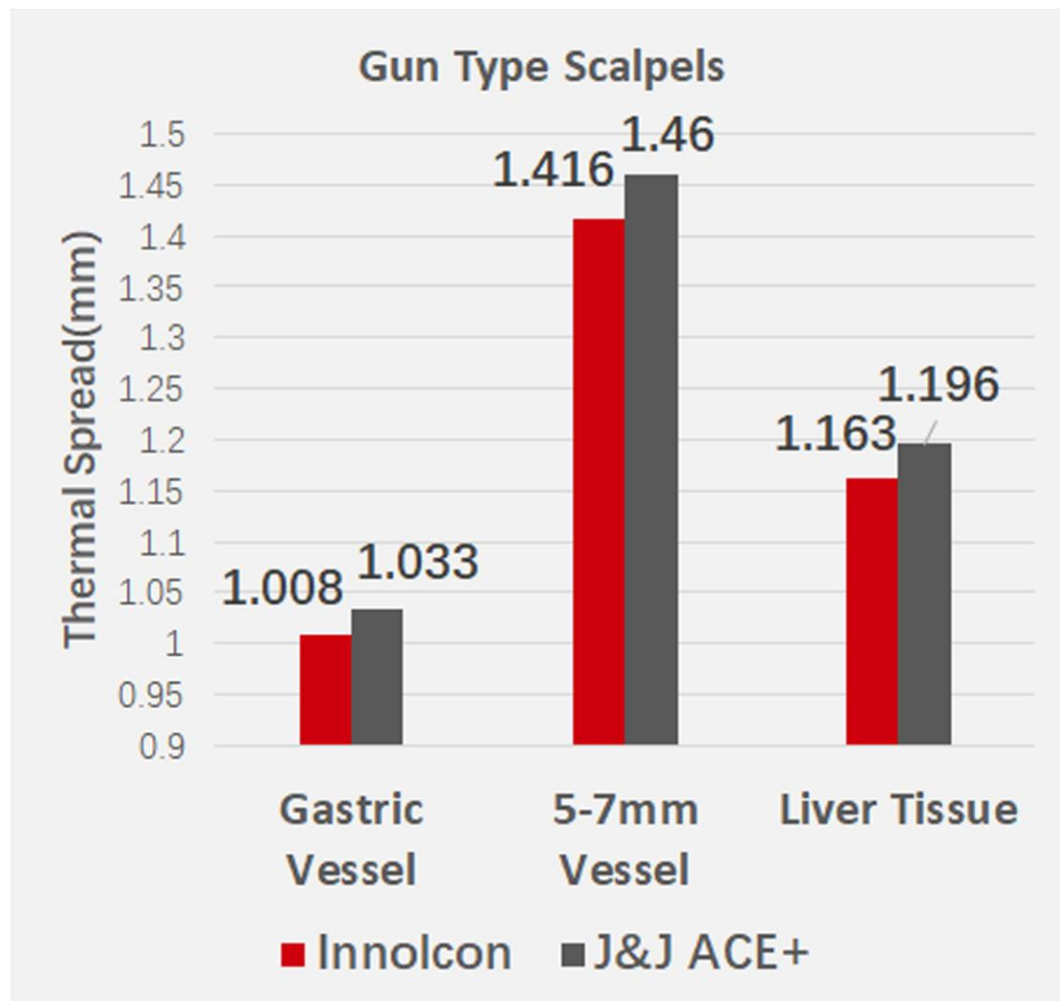


**Lower Temperature, Smaller thermal damage**



# Smaller Lateral Thermal Spread

## Lateral Thermal Spread at power level 3



# Clinical Test

## Test Purpose:

To evaluate the effectiveness and safety of Innolcon scalpels in bleeding control, minimizing thermal damage and sealing 5mm vessel in open and endoscopic surgeries.

## Test Group instrument:

Innolcon SG13/SG22/  
SG35/SG45, SS9/SS17

## Control Group Instrument:

J&J HAR23/HAR36, HAR9F

## Test Institutions:

Shanghai Huashan Hospital,  
Fudan University Shanghai  
Cancer Center,  
Shanghai General Hospital.

**Test Group:**160 Patients

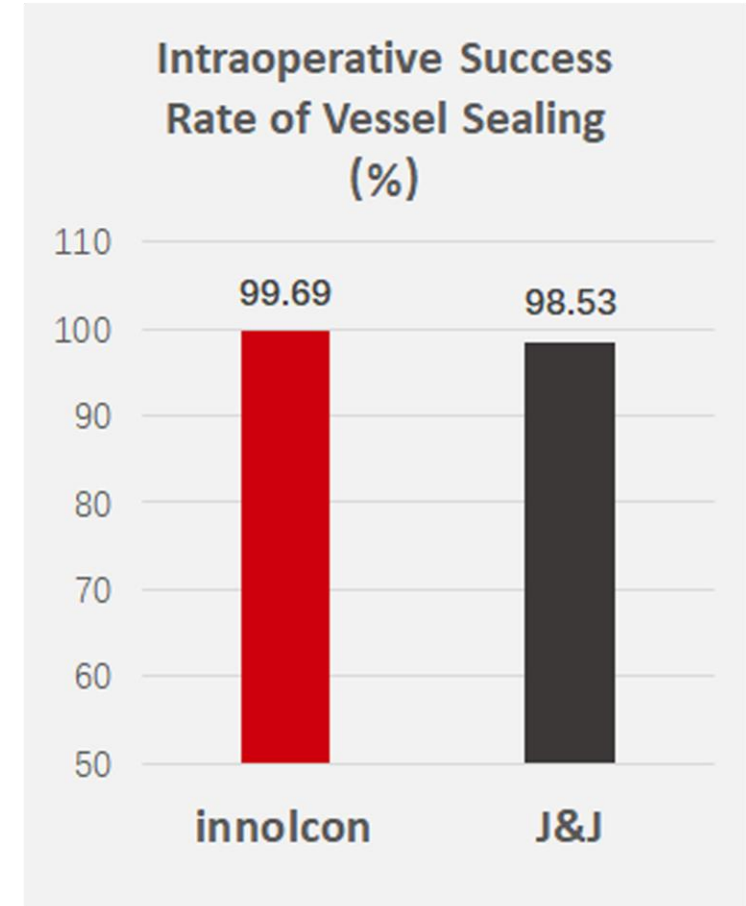
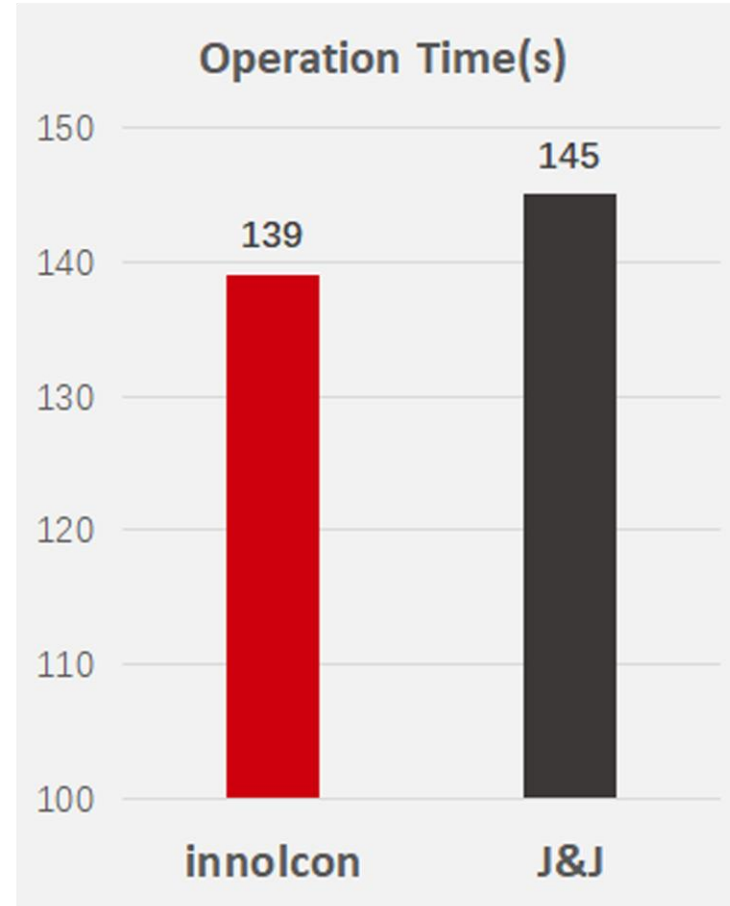
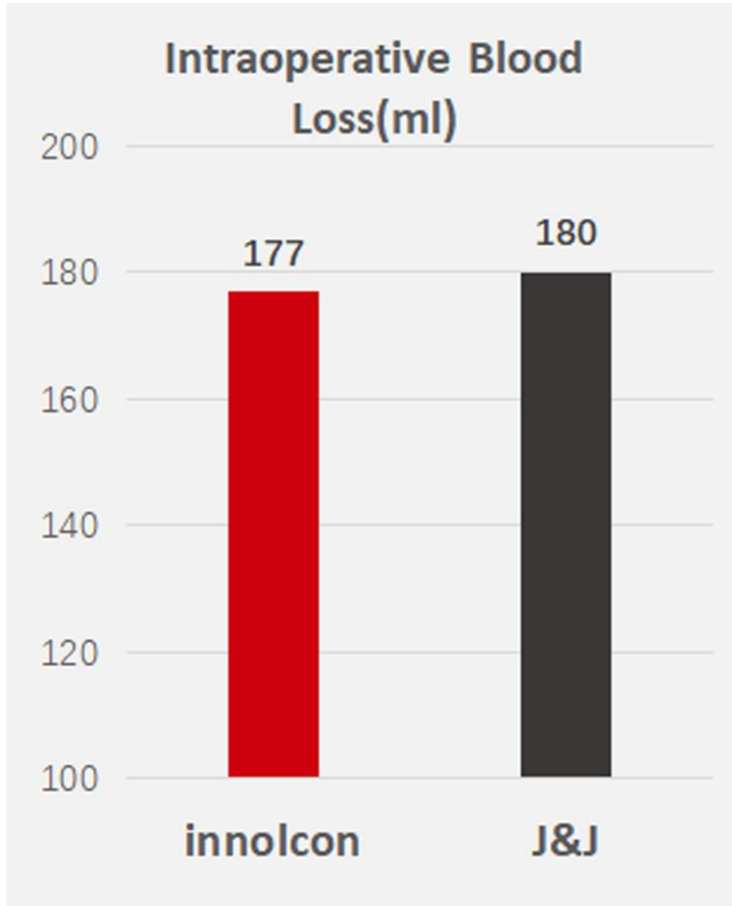
**Control Group:** 168 Patients

**Finished Surgery:** 314

(open surgery:166,  
Endoscopic surgery: 148)



# Cilincal Tests Result



**Innolcon Vs Innolcon shows consistent results in Clinical efficacy and safety.**

# Conclusion

## Innolcon Y16-E ultrasonic surgical system delivers:



**Faster dissection speed**



**Minimized thermal damage**



**Reliable coagulation**



**Higher vessel burst pressure**





**Thank you**

**Innolcon Medical Technology Suzhou Co., Ltd**  
Website: [www.innolcon.com](http://www.innolcon.com)