

Company Brief

I. Company Overview

Company Name: RIMSCIENCE Co., Ltd.

Date of Establishment: April/09/2012

Mission:

- Overcome human's motions
- Help human's five senses
- Emulate doctors' good skills and dexterity

Business: Medical/Surgical Devices and Services

- EPIA
- Intelligent Drill
- Surgical Sewing Machine
- Intelligent surgical robot system (Natural Motion-Controlled Digital Robot)

Key Executives:

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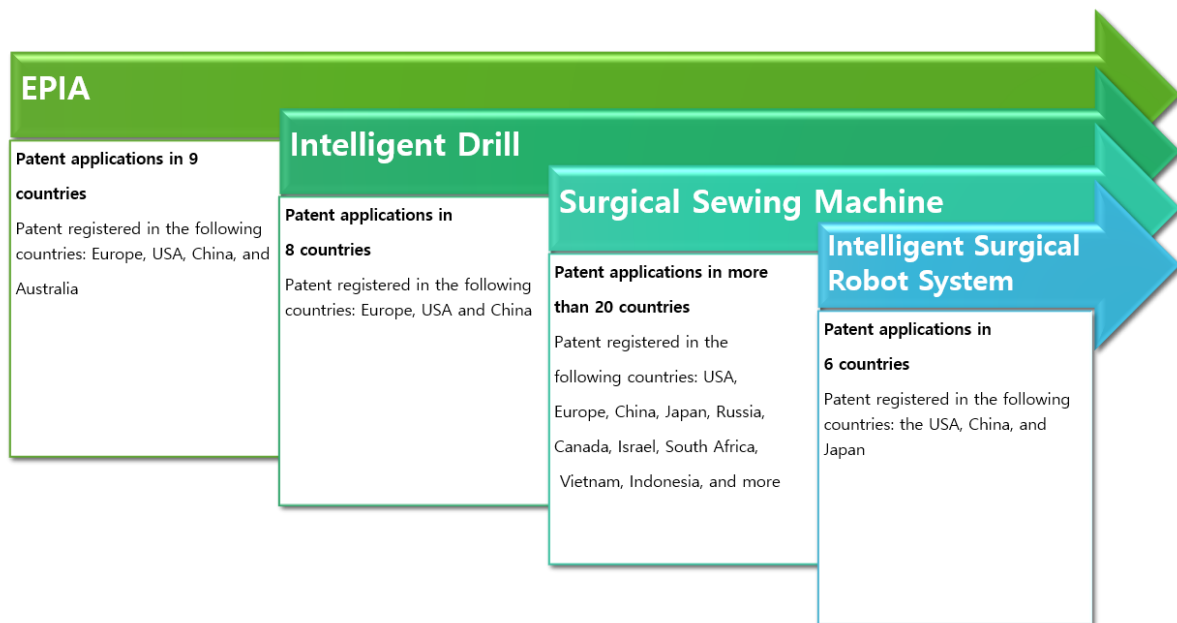
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II. History

Summary	
2021	2021 SME Direct Support Service EPIA Investigator Initiated Clinical Trial approval ISO13485 certified CE certified
2020	Veterinary medical device manufacturing business /export license VETPIA (Automatic Epidural Anesthesia Device for animal) Prototype production Certificate of GMP Registration of medical device manufacture Surgical Sewing Machine Technology grade: T4 (graded by NICE Investors Service) Selected for three R&D support tasks including One-Stop Support project from DGMIF Exhibition & Academy: Arab Health 2020, Medical Fair Asia 2020, Digital RESI (Online Pitching) Acquired government certificate for venture business
2019	Exhibition & Academy <ul style="list-style-type: none"> American Urological Association 2019 Medtec China 2019 American Society of Anesthesiology 2019 Chinese Orthopaedic Association 2019 EPIA (Epidural Anesthesia Device) prototype completed
2018	Recruited executive members Prototyped Surgical Sewing Machine
2017	Prototyped Auto-stop Drill
2015	Presented AI Needle at American Urological Association 2015 and European Association of Urology 2015
2013	Presented Surgical Sewing Machine at American Urological Association 2013
2012	Established RIMSCIENCE Co., Ltd.
2009	Submitted patents on Surgical Sewing Machine

III. Patents



IV. Detailed Product Description

Epidural anesthesia assistant device with safety function: Autostop in epidural space or bone (CE approval)

1. Introduction

EPIA is the device that finds out the epidural space automatically based on the results of an analysis of the reaction forces received as the needle progresses.

Epidural anesthesia also called as regional anesthesia, blocks pain in an area of the body by blocking nerve impulses into the epidural space. Epidural space, which is right outside of the membrane that protects the spinal cord. This aids in reducing the sensation of the lower part of the body. The epidural anesthetic is the most common method to reduce pain during normal or C-section delivery.

Injection is a common technique during surgery systems and is often performed depending on an individual doctor's experience and senses.

Identification of the epidural space during injection is critical, yet epidural injection is considered the most difficult technique to acquire since a success rate of it is as low as 80%. Side effects or complications include nausea, spinal cavity, low blood pressure headaches (also known as post-dural puncture headache) at the range of 0.5-3% incidence rates, and even paralysis or nerve damage in very rare cases.

The common technique for epidural injection is the loss of resistance (LOR) with saline. This technique relies on an operator's tactile sense to perceive the sudden loss of pressure on the plunger of the syringe. It is reported that the false-positive success rate of LOR is as high as 30%.

2. Characteristics

- EPIA is equipped with a sensor to detect the reaction force of the needle as the needle advances steadily and mechanically. As the needle progress through skin, subcutaneous tissue, ligamentum flavum, and epidural space, EPIA gives a real-time measurement of reaction force, which is then useful to detect an epidural space.

3. Advantages

- EPIA gives a better identification of the epidural space than the LOR technique.
- Compared to other epidural injection equipment such as CompuFlo® or Epidrum®, EPIA does not rely on pressure or LOR. Instead, it measures the change of reaction force, providing more accurate detection of epidural space.

- EPIA's software can be applied to various needle injection practices in the fields of urology, gynecology, or catheter insertions.

4. Market

The estimated global needle market size is USD 5.97 billion in 2017 and is expected to reach USD 9.96 billion in 2025 with a CAGR of 6.6% over the period

(<https://www.grandviewresearch.com/press-release/global-needles-market>).

Global Epidural Anesthesia Disposable Devices Market is estimated to reach USD 16.51 billion by 2027, growing at a CAGR of 6.3 % between 2019 and 2027.

(<https://www.profsharemarketresearch.com/epidural-anaesthesia-disposable-devices-market/>)

5. Patent:

- PCT/KR2012/007774 INTELLIGENT SURGERY SYSTEM

The patent is currently registered in the USA, China, Australia, Japan and Europe and pending in Thailand, and South Korea.

- PCT/KR2020/007866 APPARATUS FOR APPLYING PRESSURE TO A MEDICAL NEEDLE

The patent is currently pending.

6. R&D status

- EPIA has received ISO13485 certification in March 2021.
- EPIA has been approved of an investigator-initiated exploratory trial by KFDA in March 2021.
- Pre-clinical experiments collaborated with Seoul National University have been concluded in March 2021.
- Animal test of EPIA was conducted by KNOTUS in April 2020.
 - The non-clinical test for the EPIA was tested by using an 18G needle on 56kg porcine model with the 4th generation of EPIA device. Neurosurgeon, anesthesiologist and orthopedist's faculty members participated in the experiment. As a result of analyzing the X-ray and the reaction force graph results, we confirmed that the various sections of the reaction force detected by the EPIA coincide with the actual epidural space. Detection of the epidural space and auto-stop function were both successful.
- Medical Device Conformity Assessment has been conducted with Seoul National University Hospital.

Intelligent Drill

1. Introduction

Intelligent Drill is an Orthopedic power tool device that automatically stops at the distal bone based on the results of an analysis of the difference in the rotational speed of the drill bit according to the difference in strength and the density of the bone tissue.

Bone drilling for perforation is a common procedure in various fields of surgery including orthopedics, neurosurgery, plastics and reconstructive, craniomaxillofacial and ear nose and throat (ENT). For example, in order to fix a ruptured bone in orthopedic surgery, drilling is required to make a hole for screw insertion. According to stop the drill, it only relying on the doctor's sensation. The drill bit rotates at an average speed of 1,000 RPM, and if the drill advances a bit more after the penetration, the soft tissues surrounding the bones (blood vessels and nerves) may cause serious damage or even fatal medical malpractice.

2. Characteristics

- Drilling speed in a layer of cortical/compact bone and cancellous/spongy bone is different due to the difference in their densities.
- Intelligent Drill is equipped with a sensor that detects the change in rotational speed as it penetrates the bones.
- Drilling automatically stops after penetrating the second layer of cortical bone by sensing the sudden change of drill speed.
- Furthermore, the auto-stoppable by sensing the change in drilling speed can be set at any point of drilling. This technology is applicable to almost all drilling parts and is useful in various settings of surgery.

3. Advantages

Intelligent Drill provides a fine control of drill speed and ensures better performance during a surgical procedure. Sensitivity of drilling sensor can be modified to suit different types of orthopedic surgeries. Thereby, Intelligent Drill reduces the possibility of risk, negligence or unfavorable accident during operation.

4. Market

The estimate of global surgical drill market is USD 410 million in 2017 and is expected to grow at a CAGR of around 4.5% from 2018 to 2026.

(<https://www.transparencymarketresearch.com/surgical-drills-market.html>).

5. Patent:

- PCT/KR2014/003688 ROTATIONAL PRESSING DEVICE CAPABLE OF ELECTRICAL CONTROL AND CONTROL METHOD THEREFOR

The patent is registered in South Korea, Europe, China, Indonesia, Vietnam and USA while it is pending in the Japan and India.

6. R&D status

- A simulation experiment for testing an auto-stop function of Intelligent Drill was conducted successfully in April 2020.
- The first prototype of Intelligent Drill was produced in 2017.
- A sensor software for Intelligent Drill is currently completed.
- The prototype production of intelligent disposable drills will be proceeded with Daegu-Gyeongbuk Medical Innovation Foundation (DGMIF).

Surgical Sewing Machine

1. Introduction

During the surgical procedure, doctors manually suture the affected area or incision using a fishing needle-shaped surgical needle and a medical thread (suture). In the surgical process, suturing requires a long labor and doctors hand skills, so the deviation of the suturing result may be caused by individual doctors' experiences. Currently, there are various wound sealing methods such as medical staplers, surgical tapes, adhesives, etc. Despite the other wound sealing methods, the suture is still preferred because it has the advantage of being able to produce an elaborate and durable suture in various parts. Clothing sewing has been industrialized and automated after the invention of the automatic sewing machine, yet, medical suture still depends on manually. The RIM sewing machine is the sewing machine-type medical device that replaces the existing manual- type suturing process. It uses the knotless method using two suture threads so that high- strength auto sealing is possible. By reducing the overall surgery time, it can be very beneficial to both patients and doctors.

2. Characteristics

- Surgical Sewing Machine offers automatic suturing by using knotless method and two suture threads.
- The machine is designed to be a hand-carrying size with disposable parts.

3. Advantages

Surgical Sewing Machine has many advantages compared to the conventional suturing method.

- It shortens the overall suturing time, requiring less amount of labor.
- It produces consistent and reproducible suturing and tensile strength.
- It minimizes excessive organ/tissue damages since it doesn't require the use of a fishhook-like surgical needle.
- The surgery outcome with using the Surgical Sewing Machine is more likely to be successful and favorable to patients.

4. Market growth

The estimate of surgical suture market is USD 5.02 billion by 2023 from USD 3.68 billion in 2017

(<https://www.marketsandmarkets.com/Market-Reports/surgical-sutures-market-18374832.html>).

The global surgical staplers' market is expected to reach USD 4.78 Billion by 2022 from USD 3.38 Billion in 2017, at a CAGR of 7.2 %

(<https://www.marketsandmarkets.com/Market-Reports/surgical-stapler-market-79557149.html>).

5. Patents

- PCT/KR2009/003419 SURGICAL SUTURE APPARATUS HAVING SEWING FUNCTION
- PCT/KR2010/005851 SUTURING INSTRUMENT CAPABLE OF SELECTING AND SUPPLYING A SUTURING THREAD
- PCT/KR2010/005852 SUTURING INSTRUMENT HAVING A FIXING MEANS
- PCT/KR2010/006448 SUTURE APPARATUS HAVING SEWING FUNCTION

The patents related to Surgical Sewing Machine are registered in ~20 countries including the USA, Europe, China, Japan/DIV, Russia, Canada, Israel, South Africa, Ukraine, Vietnam, Indonesia, Nigeria and South Korea.

6. R&D status

- First versions of prototypes were developed by SEAWON Meditech and Keumyong.
- 1st animal test was conducted in affiliation with Samsung Seoul Hospital.
 - Surgical Sewing Machine (prototype) was used to suture internal organs and blood vessels of pigs. There was no ischemic change with minimal bleeding in the small bowels of 3 pigs during the operation. The three pigs were fed on a normal diet starting POD 1 and remained healthy until they were sacrificed. At autopsy, there was no leakage around the suture lines in the small bowels of three animals.
- Surgical Sewing Machine was presented at AUA2013: Video presentation V10-Robotics, Single Port Surgery, LESS, NOTES.
- Surgical Sewing Machine was presented at AUA2019: booth exhibition and video presentation V09-MISC GU Oncology, Complications&Techniques.
- Further prototyping of Surgical Sewing Machine will be processed by domestic and international company.

Intelligent Surgical Robotic System (Natural Motion-Controlled Digital Robot)

1. Introduction

Surgeries often rely on doctors' senses. Human mistakes, negligence or malpractices are inevitable and could result in unfavorable or harmful effects on both patients and doctors. Nowadays, robot surgery systems have emerged in the goal of ensuring safety and better surgical performance. For example, da Vinci® is one of the robotic surgical systems in the market, yet da Vinci® or other robotic surgery systems also demand direct manipulations of a doctor, and they do not produce comprehensible, automated surgical procedures by itself.

2. Characteristics

- Through intelligent surgical robotic system, movements of doctor's hands or dexterity is digitalized and stored. Using gesture recognition system and sophisticated robotic movements, such procedures can be effectively reproduced.
- Intelligent surgical robotic system does not require direct manipulation and labor of an operator.
- The surgical procedure is automatically initiated by the robot after combining and analysis of obtained, digitalized experiences and data.

*It is almost impossible for us to repeat the action once we play hole-in-one in screen golf. However, if we digitize our actions and then save them, we will be able to make hole-in-one every time.

3. Advantages

	Intelligent Surgical Robotic System	Other Surgical Robot	Reference
Pre-simulation capability	O	X	
Repeatability of successful operation	O	X	
Technical reproducibility	O	X	
Accuracy of operation	High	Low	
Speed of operation	High	Low	
Possibility of a doctor's mistake or negligence	Low	High	

4. Market

The global surgical robotics market is at USD 3.9 billion in 2018 and is expected to reach USD 6.5 billion by 2023 at a CAGR of 10.4% during the forecast period (<https://www.zionmarketresearch.com/report/surgical-robots-market>).

5. Patent:

- PCT/KR2012/00767 SURGICAL ROBOT SYSTEM FOR PERFORMING SURGERY BASED ON DISPLACEMENT INFORMATION DETERMINED BY THE SPECIFICATION OF THE USER, AND METHOD FOR CONTROLLING SAME

The patent is registered in the USA, China, Japan and South Korea while is pending in Europe and India.

6. R&D status

- Future development will be initiated after or along with completion of the medical devices described above.

V. Conclusion

For more information, please visit <http://www.rimscience.com> or watch our promotional video at <https://youtu.be/kIK6eQNp4SM>.

More importantly, we are looking forward to establishing a domestic/international business partnership, cooperation, strategic alliance or capital investment. We have patents, both registered and pending, over ~50 countries such as the USA, Europe, China, Japan, and South Korea. We would be happy to discuss your insights on our R&D, global partnership, business and further connections. Contact us at sales@rimscience.com for any advice, concerns or inquiries.