

# Introduction of S-protector

September - 2017

**Wecan Medicare**

# **Content**

- 1. Introduction of S-protector**
- 2. Patent/Approvals**
- 3. Market analysis**
- 4. Marketing plan**

# Content

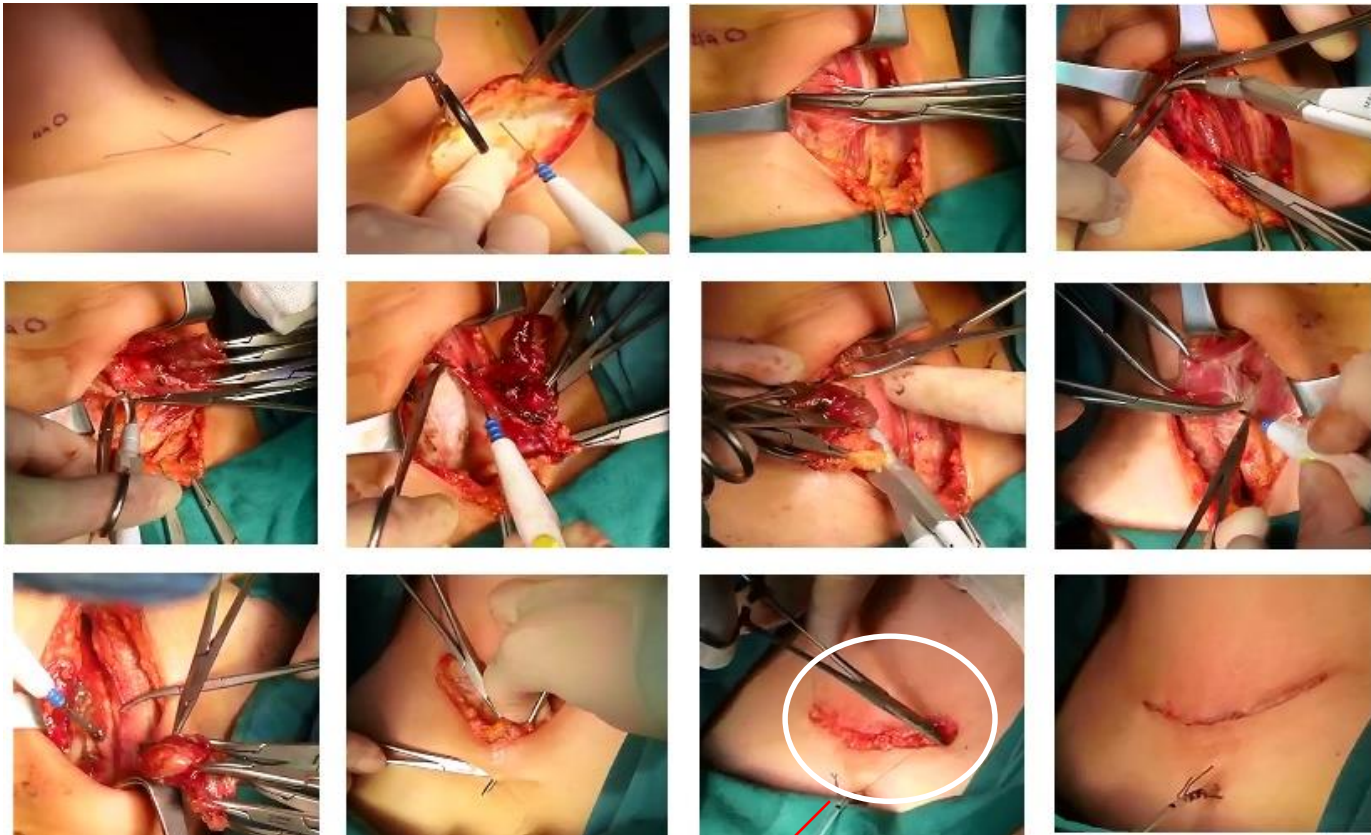
- 1. Introduction of S-protector**
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4. Marketing plan

We found unmet needs in the surgical wound protection for thyroid surgery and developed S-protector

Thyroidectomy leaves various scars on the neck and 78.8% of patients were female in Korea (National Surgical Statistics in 2014)



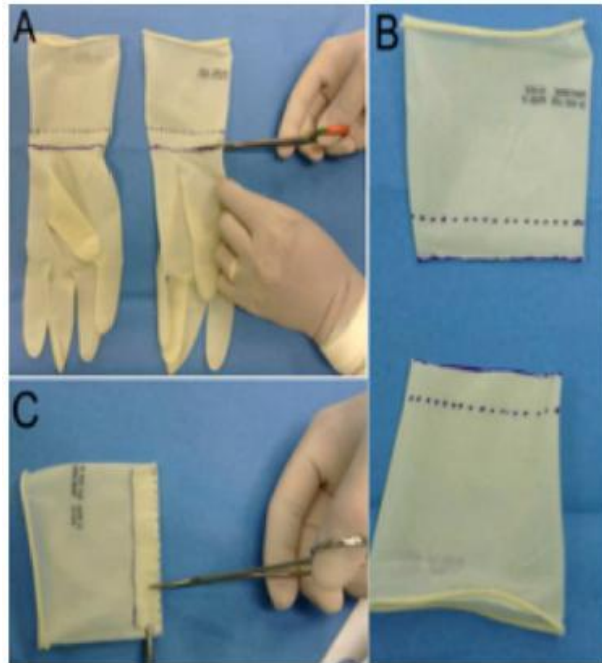
- ✓ Metal retractors that are currently used in thyroid surgery cause ischemic tissue damage and scarring as a result of uneven pressure distribution
- ✓ Energy devices are now widely used and can cause stray burns



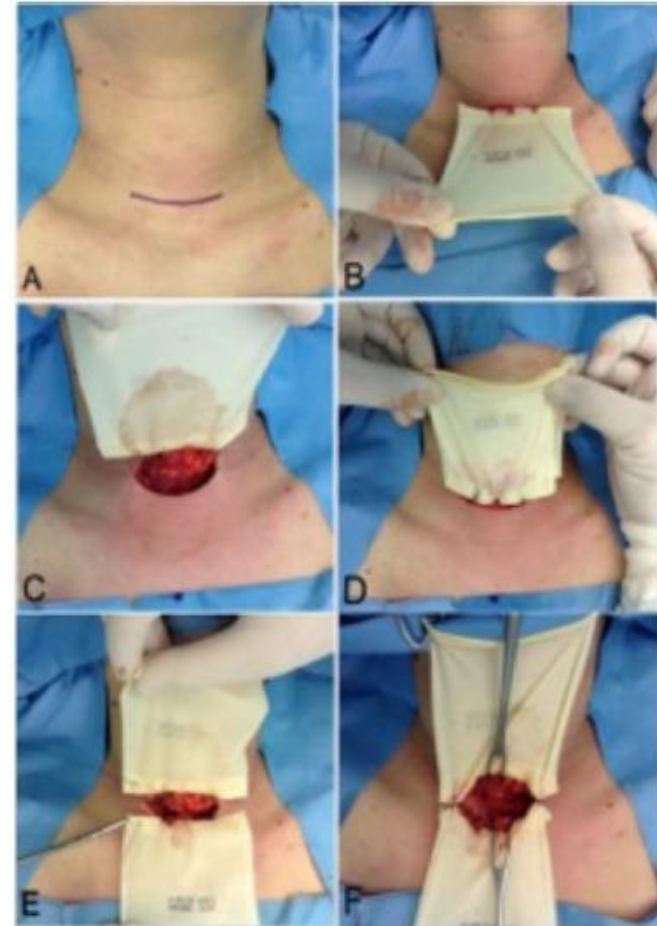
Tissue damage



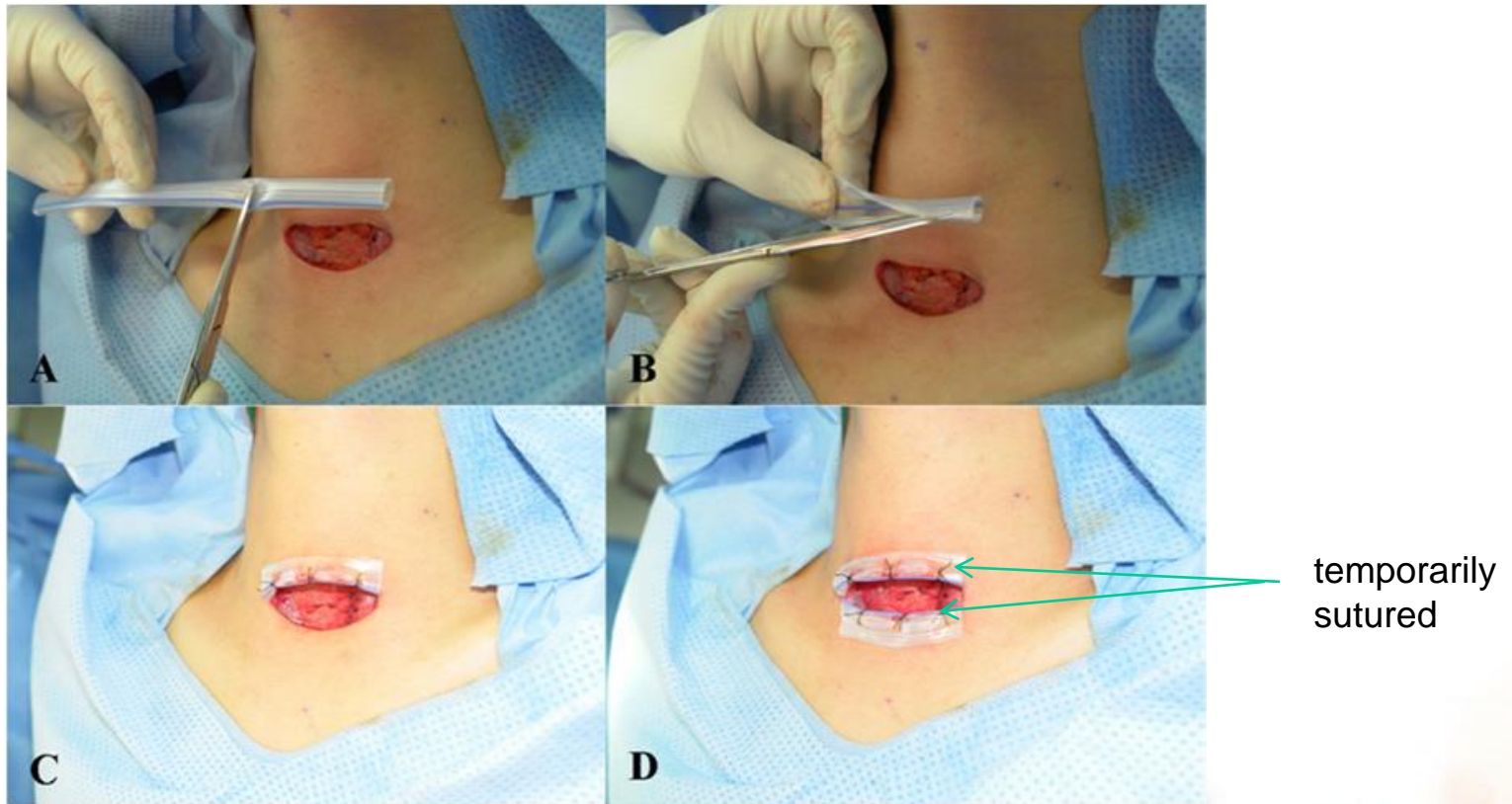
Most surgeons make homemade gadgets to protect the skin



Inefficient  
Inconvenient  
Need a preparation time



## A pen rose drain is used to protect the incised skin edges during Thyroidectomy



'Use of a Silicone Penrose Drain to Protect Incised Skin Edges During Thyroid Surgery'  
(Hang-Seok Chang, Thyroid Cancer Center, Gangnam Severance Hospital, Yonsei University College)

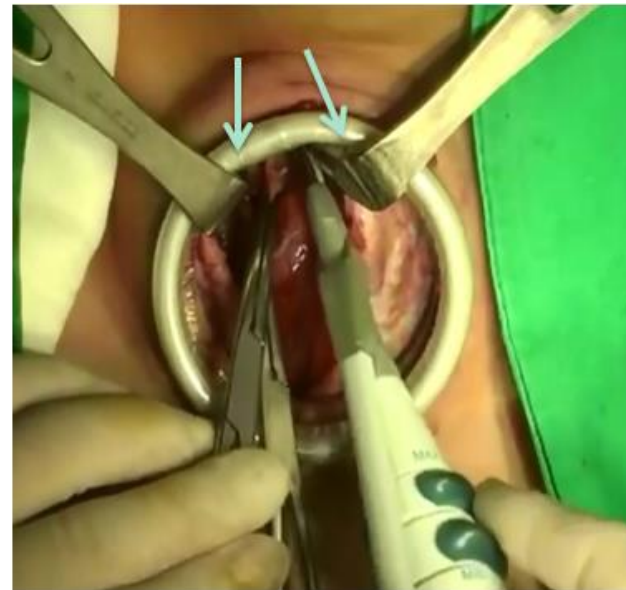


Surgical Wound Protector can alleviate the localized tension and prevent stray burns.

Without Protector



With Protector



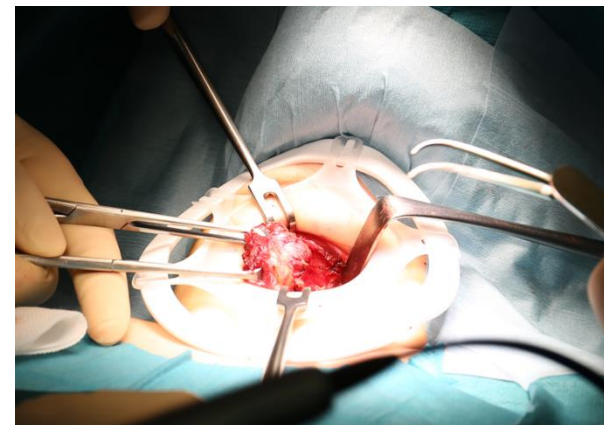
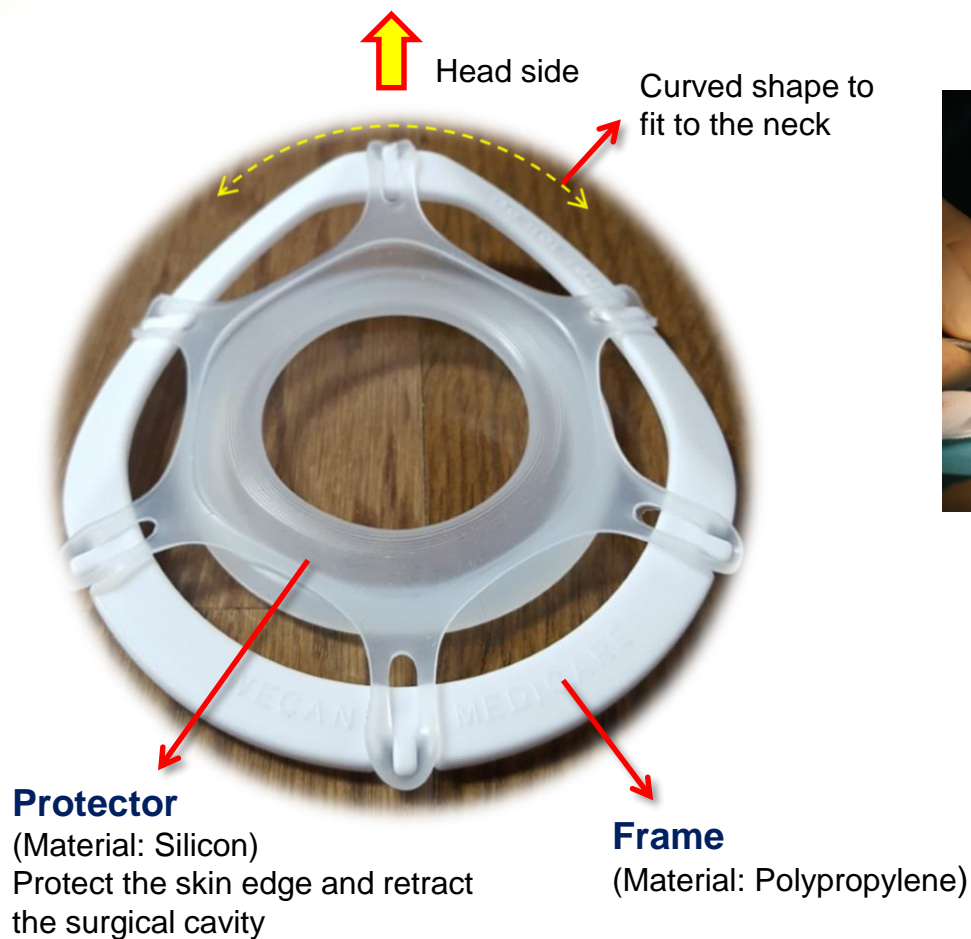
But, a ring plastic protector is hardly used because it disturbs the operation due to the thick ring  
(several devices are used in the small space)

## Objectives of development

- How to distribute localized force evenly
- How to improve Alexis(ring wound protectors)
- What is a safer material than plastic?  
(to avoid chemical exposure to blood vessel)
- Can the protector be meaningful in ergonomics?  
(save the preparation time and reduce the number of surgical assistants)

# S-protector

(Surgical wound protector for thyroidectomy)



	Incision size
Small	3 ~ 5 cm
Medium	5 ~ 7 cm
Large	7 ~ 10 cm

Why S-protector is better than competing products?

## Competing product list

Establishment name	Country	Product	No. of approvals
Applied Medical Australia	Australia	Ring(Wound Protector), Drape Retention, Internal	3
Applied Medical Distribution Center	USA	Ring(Wound Protector), Drape Retention, Internal	14
Applied Medical Europe	Netherlands	Ring(Wound Protector), Drape Retention, Internal	4
Applied Medical Resources Corp.	USA	Ring(Wound Protector), Drape Retention, Internal	5
Applied Medical Resources Corporation	USA	Ring(Wound Protector), Drape Retention, Internal	4
Changzhou Ankang Medical Instruments Co.	China	Disposable Wound Protector(4 items)	1
Covidien	USA	SurgiSleeve™ Wound Protector, Drape, Surgical SurgiSleeve™ Extra Small Wound Protector	6
Covidien LLC	USA	SurgiSleeve™ Wound Protector - Laparoscope, General & Plastic Surgery	4
Isomedix Operations, Inc	Canada	Ring(Wound Protector), Drape Retention, Internal	1
Jiangsu JDC Medical Devices Co. Ltd	China	Wound Protector, Ring(Wound Protector), Drape Retention, Internal	1

43 products were approved by FDA(Regulation No.: 878.4370)



## FDA registration of S-protector

Regulation Number: 878. 4370

Registered Establishment Number: 3013734015

The screenshot shows the FDA's public database for medical devices. The page is titled "Establishment Registration & Device Listing" and includes a search bar and navigation links. The main content area displays the following information for the S-protector device:

<b>Proprietary Name:</b>	S PROTECTOR (WOUND PROTECTOR AND RETRACTOR); SP-T01A, SP-T01, SP-T02, SP-G01A, SP-G01, SP-G02, SP-G03, SP-G04, SP-G05
<b>Classification Name:</b>	RING (WOUND PROTECTOR), DRAPE RETENTION, INTERNAL
<b>Product Code:</b>	<a href="#">KGW</a>
<b>Device Class:</b>	2
<b>Regulation Number:</b>	<a href="#">878.4370</a>
<b>Medical Specialty:</b>	General & Plastic Surgery
<b>Registered Establishment Name:</b>	<a href="#">WECAN MEDICARE CO., LTD</a>
<b>Registered Establishment Number:</b>	3013734915
<b>Owner/Operator:</b>	<a href="#">Wecan Medicare Co., Ltd</a>
<b>Owner/Operator Number:</b>	10055423
<b>Establishment Operations:</b>	Manufacturer

Page Last Updated: 08/21/2017  
 Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.  
 Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

## Competing products (Ring plastic protectors)



**Brand: Alexis**  
Applied Medical, USA  
The 1st developer and  
market leader



**Brand: SurgiSleeve**  
Covidien/Medtronic  
The 2nd market leader with  
modified products



**Similar products**  
(Canada, China, e.t.c.)

Improved

## S-protector



**Brand: S-protector**  
Wecan Medicare, Korea  
The innovator

- Patent granted
- PCT submitted

## Improvement-1

# Safer setup and removal

### Ring wound protector

When inserted/removed, the skin is pulled and rigid ring causes a damage on the skin edge of incision

[Setup]

- 1) Insert the green distal ring into the incision
- 2) Grasp the white proximal ring and roll it in/out until the incision is retracted

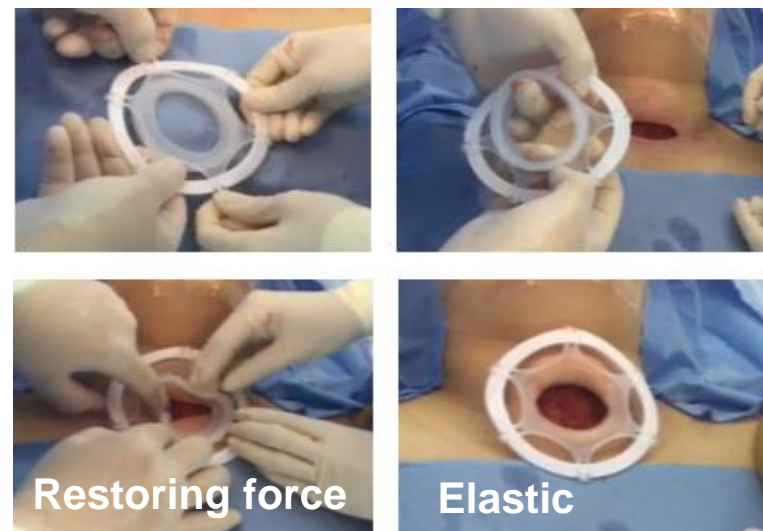


### S-protector

A silicon ring is smoothly inserted and removed without touching the incision

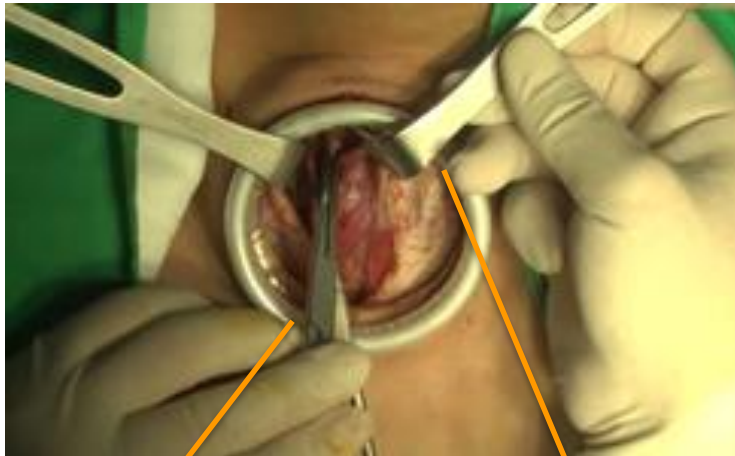
[Setup] : Faster and easier

- 1) Combine the flexible silicon protector with the white plastic frame
- 2) Flip the inside ring out and push it into incision



## Improvement-2

### More efficient surgery



Thick plastic ring      Inflexible and limited space

- The thick and rigid ring disturbs the use of surgical devices
- The surgical space is not extended even by retractors



Thin plastic frame      Flexible and expandable space

- The thin plastic frame does not disturb the use of surgical devices
- The surgical space can be flexibly extended by retractors

## Quality evaluation results

Out of 20 Endocrine surgeons in 17 major hospitals;

*100% said 'better than ring plastic protectors'*

*100% said 'efficient to reduce surgical scarring'*

*75% said 'saves the operation time'*

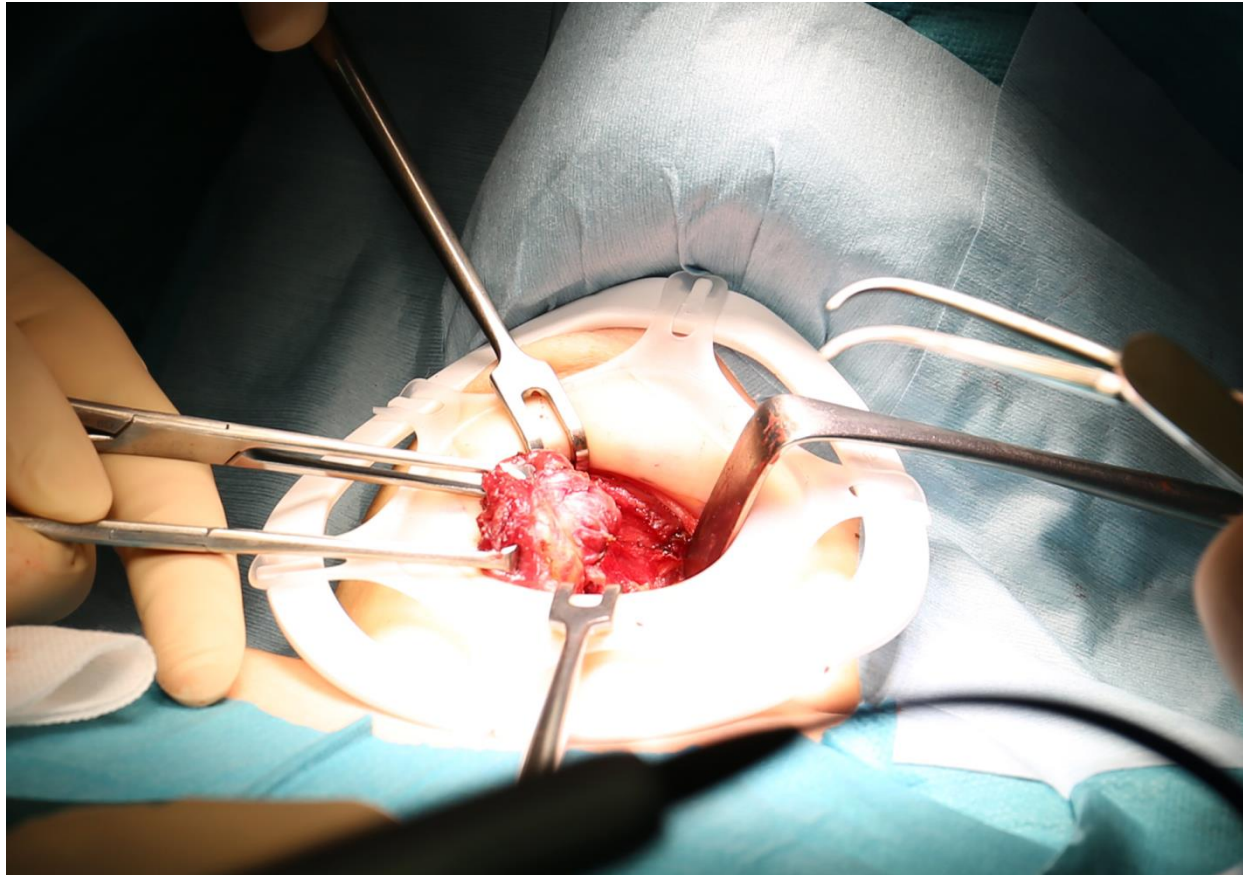
*75% said 'reduces the pain after surgery'*

*70% said 'helps reduce surgical assistants'*

(Refer to 'Quality Evaluation Report of S-protector by Endocrine Surgeons in Korea' and the trial test was conducted during April -June, 2016)



## Quality evaluation test ongoing in Japan



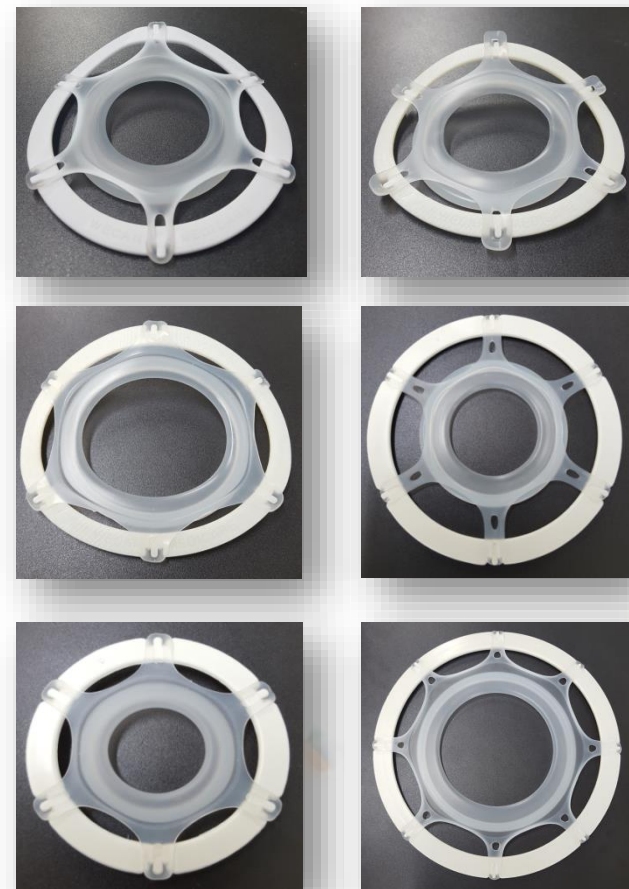
The picture was provided by Wataru Kitagawa MD. Ph. D/Chief of Department of Medical Technology & Surgery, Ito Hospital, Tokyo, Japan on March 3, 2017

# Product diversification

Core value is the design of protector by utilizing the property of silicon



Different sizes of ring, height, length, width of holder, hardness of silicon itself can make various shapes



## S-Protector for thyroid surgery



Frame	Curved type
Protector	Small size
Diameter	3.7cm
Commercially available	



Frame	Curved type
Protector	Medium size
Diameter	4.4cm
Commercially available	



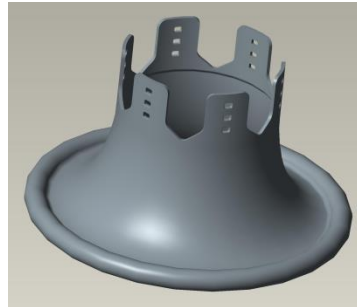
# S-protector for general surgeries



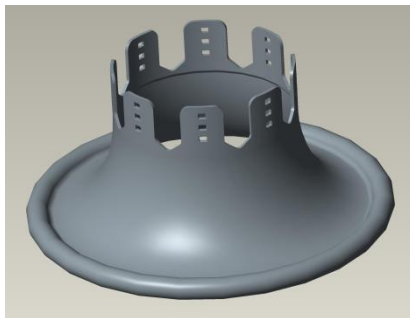
Silicon-B



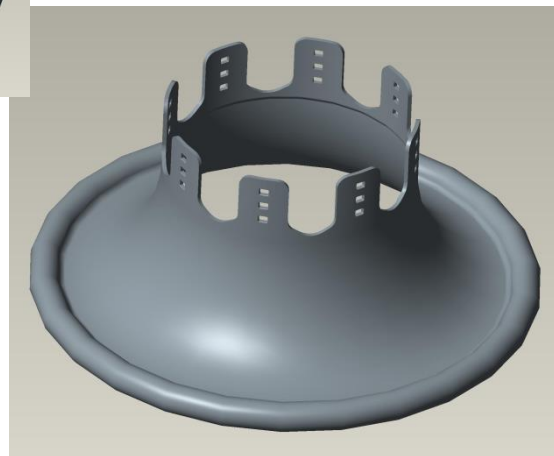
Silicon-C1



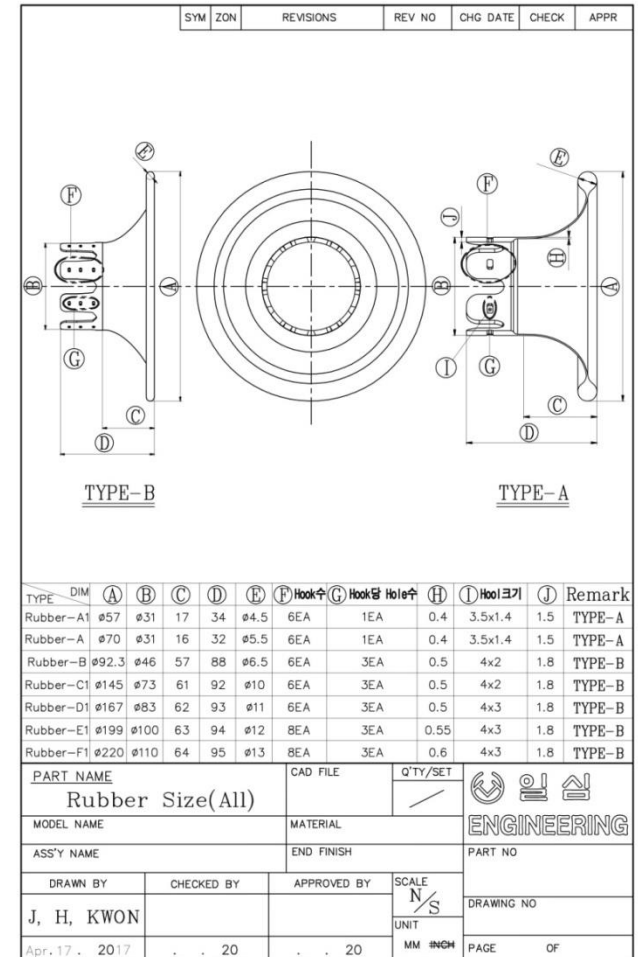
Silicon-D1



Silicon-E1



Silicon-F1




## Efficacy of S-protector

- ✓ **Prevents stray burns**  
Prevents stray energy burns caused by energy device
- ✓ **Reduces the localized tension on the skin**  
Protects the skin edge and reduces localized tension caused by metal retractors
- ✓ **Provides flexible space**  
Retracts skin gently and provides flexible(round or oval) space for more efficient surgery
- ✓ **Improves surgical results**  
Reduces the pain after surgery, results in less scarring  
Staves off the contamination of microbial or tumor cell



# Content

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The design of S-protector can be easily imitated  
so the intellectual protection should be critical

# Patent

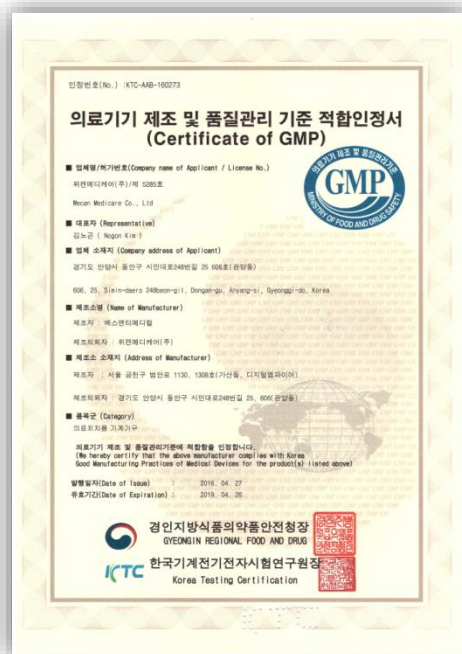
- Patent was approved on Feb. 2, 2016
- PCT(PCT/KR2016/002968) submitted on Mar. 24, 2016
- Defense patents submitted to prevent imitation



특 허 협 령 조 약 (PATENT COOPERATION TREATY)			PCT/KR2016/002968
발신:수리관청 수신: 박기원 대한민국 431-813 경기도 안양시 동안구 시민대 로 273 로성인빌딩 2층 224호 박기원특허법률 사무소		PCT 국제출원인 및 국제출원인 통지서 (PCT 규칙 28.2(c))	
출원일 (일부 불일) 2015년 03월 29일 (29.03.2015)		중요통지사항	
출원인 또는 대리인의 서명장소 K2016-181	국제출원인 PCT/KR2016/002968	국제출원일 (일부 불일) 2016년 03월 24일 (24.03.2016)	주인일 (일부 불일) 2015년 08월 30일 (19.08.2015)
출원인 최안제디제이 주식회사			
발명의 명칭 외과수술용 견인장치			
<p>1. 이 국제출원은 위에 기재된 바와 같이 국제출원번호와 국제출원일이 부여되었습니다.</p> <p>2. 이 국제출원의 기록원본은:</p> <p><input type="checkbox"/> _____ 에도 국제사무국에 송부되었습니다.</p> <p><input type="checkbox"/> 아래의 사유로 인하여 아직 국제사무국에 송부되지 않았으며,이 통지서의 사본은 국제사무 국에 송부되었습니다:</p> <p><input type="checkbox"/> 국가안전보장에 필요한 처가를 받지 못했음</p> <p><input type="checkbox"/> 기타 (여유분 상함):</p> <p>* 국제사무국은 수리관청에 의한 기록원본의 송달을 장려하고 그 접수사실을 출원인에게 통지합니다. (이서 PCT/IB/3081). 국제사무국은 주인일부 14월이 경과할 때까지 기록원본을 수령하지 않은 해제는 출원인에게 이를 통지합니다. (규칙 22.1a)(2)</p>			
수리관청장 및 수리관 대한민국 특허청 청무대법정 팩스번호: +82 42 472 3473 이서 PCT/BO/105 (2008년 7월)		특허청장 전화번호: 82-42-481-5762	

# Approvals

- KGMP approved on Apr. 27, 2016
- ISO 13485 approved on Jan. 18, 2016
- CE approval on Mar. 21, 2017
- US FDA registration on July 31, 2017



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# Market analysis

## Premise and assumption

There is no world market data of applicable surgeries for surgical wound protectors

We obtained reliable data for Korean market and assumed the number of world market

All numbers, CAGR and other factors should be revised when accurate and reliable data are available

This is a rough draft to study the feasibility

# Number of applicable surgeries in Korea

Surgery	Male	Female	Total
Thyroid surgery	7,860	29,302	37,162
Appendectomy	48,976	44,519	93,495
Artificial cardiac pacemakers	5,003	4,918	9,921
Cholecystectomy	30,232	31,222	61,454
Inguinal and Femoral Hernia	30,470	4,484	34,954
Hysterectomy		44,087	44,087
Caesarean section		165,608	165,608
Hip replacement	9,936	16,100	26,036
Breast conserving surgery	88	19,942	20,030
Mastectomy	2,470	18,543	21,013
Gastrectomy	12,531	6,501	19,032
Partial Hepatectomy	5,006	2,386	7,392
Hepatic embolization	26,118	9,671	35,789
Cardiac surgery	3,531	3,226	6,757
General spinal surgery	70,765	93,412	164,177
<b>Total</b>	<b>252,986</b>	<b>493,921</b>	<b>746,907</b>

Thyroid surgery: 37,162 cases

General surgery(except thyroid): 709,745 cases

## Forecast of surgeries(2017-2023) - World

	2017	2018	2019	2020	2021	2022	2023	CAGR
Thyroid surgery	800,000	824,000	848,720	874,181	900,407	927,419	955,241	3%
General surgery	35,487,250	36,551,867	37,648,423	38,777,876	39,941,212	41,139,448	42,373,632	3%
Total	36,287,250	37,375,867	38,497,143	39,652,057	40,841,619	42,066,867	43,328,873	3%

### Assumption

#### 1. Thyroid surgery

- World market is estimated to be 800,000 cases  
(reliable data: China(400,000), USA(80,000), Korea(37,000))

#### 2. General surgery

- All kinds of surgeries are estimated to be 232 million(world data)
- Number of applicable surgeries is assumed as **36 million cases(16%)**  
(Assumption: world market is 50 times bigger than Korean market  
based on GDP(Korea: 2% of world GDP),  $709,745 \times 50 = 35$  million)

World market potential is about 36 mil. cases

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## Value development status

Key value	Importance	Mkt. status
Function as a retractor	medium	partially developed
Prevention of SSI*	High	partially developed
Improvement of scarring**	High	To be developed
Ergonomics (save preparation time, surgical assistants)	High	To be developed

\*SSI(Surgical Site Infection)

***\*\*How to motivate the cosmesis desire?***

(neck/breast surgery, women, young people, pediatrics, expandable to all surgeries)



# Hypertrophic scar

*Would you like to leave this for life?*



*'S-protector could have made it better'*

# Marketing plan of WM

Value to be developed	How to
Reduce post-surgery pain, scarring, risk of Contamination and stray burns	Clinical trials
Save surgical preparation, surgical assistants	Hospital survey
Unexplored market	Seminar, education, Tradeshow/exhibition

## Promotion schedule - 2017

- Mar. 16-19: KIMES(Korea Int'l Medical & Hospital Equipment Show)
- April 2-4: ENDO 2017, The American Association of Endocrine Surgeons, FL, USA
- May 18-19: JAES, Japanese Association of Endocrine Surgeons
- Aug. 13-17: WCS(The World Congress of Surgery 2017), Basel, Switzerland
- Nov. 13-16: MEDICA, Dusseldorf, Germany



Global Best Protector in 2020

Thank you !!!