Low pain disposable automatic safety lancet for cross infection prevention

Youth Startup Academy alumni company EOI Incorporation



E.O.I Inc. Song, Gwang-hoon

Disposable automatic safety lancet

is used in all public places performing blood collection (The Korean Red Cross Blood Centers, domestic and foreign hospitals and clinics, nursing homes, public health centers, military hospitals and blood donation centers). It enables small amount of blood sampling and therefore is used as a disposable medical device in various diagnostics sectors for checking cholesterol, glycated hemoglobin (HbA1c), hemoglobin, types A/B/C hepatitis, HI test, etc., and its use has been on the rise significantly every year.



Project Background

Globally, cross infections caused by re-uage of disposable lancet in diagnostic tests has been continuously on the rise. The US, Europ and Japan have already legislated that all the blood collection for disease diagnosis shall be done by using a disposable safety lancet ^[1].

The	e Me	dical N	ews	검색어를 입력	검색어를 입력하세요.			
전체 정책	·행정	의원·병원	학회·학술	의료기기·IT	제약·유통	약사·약학		
속보 지난해 약	사회 불량	의약품 접수 112건	ł					
정책·행정 'Due diligence against th			gainst the re	use of medic	al devices st	rengthens'		
	홍성의	북 기자 (hongsi@	bosa.co.kr) 다른	이사 보기				
송고시간 : 2012-11	-16 1α 19		Ē	,프린트 🖂 이메일	발 🗈 기사목록 🧧	f) 💟 🚺 🏧	D	

Reuse of disposable medical devices prohibited

Congressman Jaechul Shim submitted the revision bill for the Medical Act...Violation is punishable by up to 1 year in jail

The revision of the Medical Act is now underway to prohibit the reuse of disposable medical devices such as syringes. Congressman Jaechul Shim formulated the revision bill of the Medical Act, specifying the reuse of medical devices.

This revision contains penalty provisions of up to 1 year of jail term and KRW 5 million in fine for those who reuse disposable medical devices. Congressman Shim said, "Though some medical institutions are reusing single-use medical devices and receiving insurance

coverage, there is no legal grounds to punish these people as the law does not clearly define disposable medical devices", explaining his rationale behind the revision. "By providing a clear definition of what disposable medical devices are and setting penalty rules for those who break the law, it is hopeful that infections stemming from disposable medical devices in hospitals can be minimized and the health and life of the public can be protected," said the congressman.

<Source: Hankook Ilbo, Feb 16, 2016, Bora Nam, rarara@hankookilbo.com >

A single-use automatic safety lancet that causes little pain and prevents cross infection

Phase 1: Prevent the reuse of medical devices

<Source: The Medical News Nov 16, 2012, Sung-ik Hong (hongsi@bosa.co.kr) >

복지부, 식약청-심평원간 정보연계작업 진행

Phase 2: Advance blood draw technology

Phase 3 : Making contributions to the medical health and safety of the people

1) [©]KFDA Notice in March 2009₁: It is imperative to prepare lancing devices that prevent cross infection.

Motivation for Product Development

"Since 2009, 11,592 blood donors suffered from the adverse effects after drawing blood."

Congresswoman Jeong-Lim Moon said, "Drawing blood may cause a huge medical accident...and it is necessary to review a policy to reduce blood collection"

[2014 National Assembly Audit] "Every day, at least one blood donor experiences adverse effects"

[Table 1] Blood collection related accidents over the past 5 years

Year	Number of cases	Compensation (KRW)
2010	309	70,140,357
2011	343	385,990,048
2012	379	69,377,014
2013	371	82,337,560
2014.6	210	44,033,671
Total	1,612	651,878,650

※ Source: Data submitted by the Korean Red Cross

< Source: Congresswoman Hyun-sook Kim's office, Health and Welfare Committee of the National Assembly>

Medical compensation for blood draw related adverse effects

		(Unit: Case, KRW)
	Case (Number)	Compensation (KRW)
2009	300	46,081,150
2010	309	70,140,357
2011	343	385,990,048
2012	379	69,377,014
2013.6	176	35,559,600
Total	1,507	607,148,169

• There is a difference between the date of estimating compensation for adverse effects and the date of compensation pay-out. The table shows compensation on the date of pay-out.

 Reference: Korean Red Cross Blood Service
 On 22th, Congresswoman Jong-Lim Moon of the Health and Welfare Committee reported that a total of 11.592 blood donors have experienced adverse effects during blood transfusion and the compensation for them has amounted to KRW 600 million since 2009 based on her analysis of data submitted by the Korean Red Cross.

< Source: Daily Health (dailyh.co.kr) Reporter Noh Eui-guen nogija@empas.com>

A single-use automatic safety lancet that causes little pain and prevents cross infection

Phase 1: Prevent the reuse of medical devices

Phase 2: Advance blood draw technology

Phase 3 : Making contributions to the medical health and safety of the people

Preparation and history of product

Certificate of award

Excellence award

Sector : manufacturing Name : Song, Gwang-hoon

This award is presented to the person above in recognition of the excellent performance in the Gyeonggi-DKU Venture Startup Competition hosted by the Dankook University Startup Enterprise Support Foundation as part of the nationwide preliminary competition for ^rthe 2016 Kstartup League

Arpil 29th, 2016

Son, Sung U President of the Dankook University Enterprise Support Foundation

Name		Experience	
Name	Major	Period	Description
Song,	Industrial Engineering	From 2012 - today	 Participated in G&T Care's development of the prototype of a single touch automatic blood draw device (medical device). Developed and analyzed General Lancet (medical device), a disposable lancet Established a system for bverseas licensing and certification for medical devices (CE, ISO13485, GMP, FDA) Prepared technical documents and managed the quality of medical devices at the Ministry of Food and Drug Safety Completed medical device technical document course (Korea Testing & Research Institute) Completed medical device GMP training course (Medical Device Information & Technology Assistance Center/Ministry of Food and Drug Safety) Completed medical device quality manager course (Korea Testing & Research Institute) Completed Start-up Academy training (Small and Medium Business Corporation) Completed FTA and courity-of-origin manager course (Seoul Business Agency)
Gwang- hoon (Applicant)		From	 1st vender registration from Samsung, LG, SKT, Pantech, KTFT, etc Performed reliability-related functions, operated MSA (GAGE R&R) and delivered in-house quality management lectures Translated technical standards and guidelines in English/Conducted Q-COST-analysis and COPQ Conducted FMEA (DFMEA) to resolve problems at development stage Analyzed environmentally harmful materials and worked to meet international environmental standards (Eco Parter, RoHS, WEEE, REACH) Completed Samsung and LG environmental manager training course
		From 2005 to 2009	 Developed quality improvement plans for injection molding Participated in a project to verify correlations between PCB processes and the properties of plating products Provided MSA education and analysis Conducted education on quality system (ISO9001/14001) for partners

SWOT analysis of the company



- Experience and know-how in relevant fields
- Experience in quality assurance and optimal solutions
 Unique and independent technology (basic design
- completed)
- Knowledge networks in the area of medical device
- Sales networks and a pool of buyers at home and abroad
- Passion and commitment to business start-up

Strength

- Increasing importance of POCT and its market
- Increasing demands for health and welfare services as a result of population aging
- Rising awareness about the reuse of medical devices
- Declining customs duties on exports thanks to Free Trade Agreements
- Market expansion as a result of stronger regulations on disposable medical devices

Opportunity

Project name and content	Development period	Organization	Applicant's role	Supporting organization
A single touch automatic loading low pain blood- draw device	May 2, 2014 – Mar 31 2015	G&T Care	Participating researcher (R&D)	Small & Medium Business Corporation
Product manufacturing support project	Jan 2, 2013 – Sep 30, 2013	GMMC	Participating researcher (R&D)	Korea Industrial Complex Corporation
Production technology commercialization support project (Application for industrial property rights)	May 22 2013- Jul 3, 2013	GMMC	Participating researcher (R&D)	Korea Industrial Complex Corporation

d welfare services as - Price competition from low cost Chinese products

5

 Protection of intellectual properties and technological security

- Investments and financing (molding, certification)

- Lack of experience in business start-up and operation

Weakness

- Sustained R&D investments and stable profits

- Distribution of counterfeit products in the market

Threat

Key buying factors		Needs analysis		-6	liminate reusability
Safety	-Prevent accidents (malfunction and injuries) -Safe and simple single use			ă ă	By improving its design and structure, its reuse should be prevented. There have been claims that some of products used by Korean Red Cross blood centers can be reused.
Non-reusability	-Prevent cross infection due to reuse		Main customer needs are related to	- M	linimize fear of drawing blood by reducing pain
No pain	-Minimize pain while drawing blood		functional aspects such as safety and user convenience.		Pain caused while drawing blood provokes fear and resistance against blood collection. Patients prefer safety lancet that causes less pain even if it is disposable.
No noise	-Minimize fear associated with noise				ossible to adjust depth
Gauge	-Use needles appropriate for blood collection	_/	Individual differences exist over pain, noise and design.		By adjusting penetration and depth, the blood volumes should be collected at a level that is most appropriate for the skins of patients.
Depth	-Adjust depth and amount of blood collected	/			In some cases, penetration of needle is too deep, causing unnecessarily high volume of blood collection.
User convenience	-Easy to use				asy and simple to use Sometimes, it is hard and inconvenient for nurses and patients to utilize the
Design	-Aesthetically appealing design				device. Safety lancets that are already used should be identifiable just by looking at them.

< Source: Korea Management Association Consultants (KMAC) marketing strategy for blood draw devices>

< Korea Red Cross's needs and demands for single-use automatic safety lancets>

Technology applied to the item







II. Strength adjustment system



III. Safety sign to indicate before/after the use

Manufacturer (country)	Model (product name)	Product image	Pain mitigation (How to use)	Strength adjustment	Use/unused sign	Note
Sterilance (China)	McKesson(Xinda) SAFETY LANCET	MSKESSON	Simple blood draw (PRESS TYPE)	Adjustment unavailable	No sign (Not reusable)	
HTL (Poland)	PLUS SAFETY-LANCET	Ţ.	Simple blood draw (PRESS TYPE)	Adjustment unavailable	No sign (Not reusable)	
Arkray USA (The U.S.)	Micro-Flow Safety-Lancet		Simple blood draw (PRESS TYPE)	Adjustment unavailable	No sign (Not reusable)	
OwenMumford (England)	Unistik 2 SAFETY LANCET	, II	Simple blood draw (BUTTON TYPE)	Adjustment unavailable	No sign (Reusable)	
K Start-Up (Korea)	K-Start-Up potential start-up company SAFETY-LANCET	16.70	I. Shock- absorbing guide system (BUTTON TYPE)	II. Strength adjustment system (Weak/Safe/Strong)	III. Sign (use/unused) function (Not reusable)	
	Sterilance (China) HTL (Poland) Arkray USA (The U.S.) OwenMumford (England) K Start-Up	(country)name)Sterilance (China)McKesson(Xinda) SAFETY LANCETHTL (Poland)PLUS SAFETY-LANCETArkray USA (The U.S.)Micro-Flow Safety-LancetOwenMumford (England)Unistik 2 SAFETY LANCETOwenMumford (England)SAFETY-LancetK Start-Up (Korea)K-Start-Up potential start-up company	(country)name)Product imageSterilance (China)McKesson(Xinda) SAFETY LANCETImageHTL (Poland)PLUS SAFETY-LANCETImageArkray USA (The U.S.)Micro-Flow Safety-LancetImageOwenMumford (England)Unistik 2 SAFETY LANCETImageK Start-Up (Korea)K-Start-Up potential startup companyImage	(country)name)Product Image(How to use)Sterilance (China)McKesson(Xinda) SAFETY LANCETSimple blood draw (PRESS TYPE)Simple blood draw (PRESS TYPE)HTL (Poland)PLUS SAFETY-LANCETImageSimple blood draw (PRESS TYPE)Arkray USA (The U.S.)Micro-Flow Safety-LancetImageSimple blood draw (PRESS TYPE)OwenMumford (England)Unistik 2 SAFETY LANCETImageSimple blood draw (PRESS TYPE)OwenMumford (England)Unistik 2 SAFETY LANCETImageSimple blood draw (BUTTON TYPE)K Start-Up (Korea)K-Start-Up potential start-up company (Korea)I. Shock- absorbing guide system	(country)name)Product Image(How to use)adjustmentSterilance (China)McKesson(Xinda) SAFETY LANCETSimple blood draw (PRESS TYPE)Adjustment unavailableHTL (Poland)PLUS SAFETY-LANCETSimple blood draw (PRESS TYPE)Adjustment unavailableHTL (Poland)PLUS SAFETY-LANCETSimple blood draw (PRESS TYPE)Adjustment unavailableArkray USA (The U.S.)Micro-Flow Safety-LancetSimple blood draw (PRESS TYPE)Adjustment unavailableOwenMumford (England)Unistik 2 SAFETY LANCETSimple blood draw (BUTTON TYPE)Adjustment unavailableK Start-Up (Korea)K-Start-Up potential start-up companyI. Shock- absorbing guide systemII. Strength adjustment system	(country)name)Product image(How to use)adjustmentOse/Undset/SignSterilance (China)McKesson/Xinda) SAFETY LANCETSimple blood draw (PRESS TYPE)Adjustment unavailableNo sign (Not reusable)HTL (Poland)PLUS SAFETY-LANCETImageSimple blood draw (PRESS TYPE)Adjustment unavailableNo sign (Not reusable)HTL (Poland)PLUS SAFETY-LANCETImageSimple blood draw (PRESS TYPE)Adjustment unavailableNo sign (Not reusable)Arkray USA (The U.S.)Micro-Flow Safety-LancetImageSimple blood draw (PRESS TYPE)Adjustment unavailableNo sign (Not reusable)OwenMumford (England)Unistik 2 SAFETY LANCETImageSimple blood draw (BUTTON TYPE)Adjustment unavailableNo sign (Not reusable)K Start-Up (Korea)K-Start-Up potential start-up company SAFETY LANCETImageI. Shock- absorbing guide systemII. Strength adjustment system (Use/unused) function

< [Table 1] Comparisons with the products of competitors (products)>

Excellence of our item



iriy days)>

< Future of automatic safety lancet>

		2								(Unit : 10	OPCS/1BOX)
No.	Our product (A)	product		Competitor (B)		Competit or (C)			Our product (A) versus competitors' products (B)/(C)		
	Item	Cost	Share	Item	Cost	Share	Item	Cost	Share	Price comparison	Savings (%)
1	Material costs	\$6.50		Material costs	\$8.50		Material costs	\$7.50		\$1.50	23.1%
2	Assembly costs	\$4.50		Assembly costs	\$5.50		Assembly costs	\$5.50		\$1.00	22.2%
3	General expenses	\$1.50	13.6%	General expenses	\$2.50	17.9%	General expenses	\$2.00	15.4%	\$0.75	50.0%
4	Profit	\$2.00	16%	Profit	\$2.00	12.1%	Profit	\$2.00	13.3%	\$ -	<u>ية</u>
	Our price (A)		Compe	Competitor's price (B)		Competitor's price (C)		(C)	(\$3.50/14.0% price		
		\$14.	50		\$18.50			\$ 17.00		(\$2.50/14.9% price competitiveness)	

< Comparison of our product versus competitors' products in terms of costs and sales prices >

	Compe	etitors	(K Start-Up)			
Manufacturer (Country)	Medipurpose (the U.S.)	OwenMumford (England)	Start-up (Korea)			
Product name	SurgiLance Unistik 2		SAFETY-PRO (provisional)			
How to use	Press type Button type (load) <not reusable=""> <reusable)< th=""><th>Button type (strength adjustment function) <not reusable=""></not></th></reusable)<></not>		Button type (strength adjustment function) <not reusable=""></not>			
Product image			16. Ce			
Sales price	\$19.0/BOX/100PCS	\$17.0/BOX/100PCS	\$14.5/BOX/100PCS (projected price)			
Advantages of start-up	 Sustainable growth potentials based upon creative and unique technologies. Price competitiveness through efficiency in assembly and cost reduction. Diversified distribution channels in overseas markets established through participation in overseas exhibitions and fairs. Sales expansion through diversification of market channels and profit models. A profit model that taps into existing operation channels (overseas) and networks. Preparation and knowledge for medical device licensing and certification. 					

< Comparisons with the similar offerings of competitors >

Cmmercial feasibility of our item



Growth outlook for medical devices(2013-2020)

Туре	Annual average growth(%)
Medical supplies	6.3
Surgical correcting devices and prosthetic materials	6.3
Diagnostic imaging devices	4.9
Dental devices	4.3
Patient supporting devices	2.4
Others*	2.4

< The ratio and growth rate of the global medical device market by item (based on the revenue in 2014) >



	No.	Туре	Market share	Share of domestic sales	Share of export
9	1	Radiographic imaging devices	22.5	14.5	38.7
	2	Bio-Signal measurement devices	7.6	6.4	9.1
	3	ND devices	6.5	2.8	10.4
	4	Diagnostic devices	1.6	2.2	0.9
	5	Anesthesia & respiratory devices	0.6	0.6	0.5
	6	Electronic surgery and treatment devices	7.0	5.0	9.0
3	7	Non-electronic surgery and treatment devices	1.2	1.9	0.5
mber)	8	Orthopedic materials	2.9	3.9	1.8
7	9	Artificial internal organ apparatus	0.9	1.3	0.4
	10	Medical scopes	1.4	1.9	0.9
	11	Medical supplies	25.0	31.4	18.5
1	12	Dental devices	5.4	6.2	4.6
	13	Dental Materials	9.5	13.8	5.0
-	14	Home medical devices	4,4	3.5	5.4
3	15	Rehabilitation devices	2.1	3.5	0.7
	16	IVD Reagents	1.4	1.5	1.2
0		Total	(Total) 5.888.838	(Sales) 2,981,403	(Export) 2,907,432

Aging society

A rapid increase in the share of over-65 population (Unit: as a share (%) of total population)

· Growth of "healthcare industry", with heightened interest in health (Unit: KRW 100 billion)



- Korea is in the stage of aging society and is anticipated to become a super-aged society in a relatively short period of time.

- With accelerating aging of population, the incidence of diabetes is trending upward while the market for diabetes monitoring system is expanding.

[Source] KBS WORLD RADIO

<U-Health market in Korea>



- The healthcare industry is being expanded as people's interests in health and well-being are generating demands for healthcare services.

- The healthcare industry is a broad market concept that encompasses all health management services, including treatment, medical care and diseases prevention and management.

- Recently, "u-Healthcare" is catching on, with the convergence of healthcare industry with ICT and the Internet of Things (IoT).

- Growing interest in health is leading to a corresponding increase in demand for medical devices as well as the growth of the healthcare industry.

[Source] Hana Financial Investment

Analysis

Commercialization plan & marketing strategy



Commercialization plan & marketing strategy





Classificati on	Name of exhibition	Schedule	Promotional plan	Hosting country/city
	Arab Health	January 2018	Visiting the booths of existing business partners and discussing plans, market research and finding new partners(finding clients in the Middle East)	UAE, Dubai
	MedTrade	April 2017	Having meeting with new US partners, market research and finding new business partners	The US , Las Vegas
	ExpoMed	April 2017	Eastern European market research and discovering new business partners	Turkey, Istanbul
Overseas	Africa Health	May 2017	African market research, having meetings with existing business partners and finding new partners	South Africa, Johannesburg
exhibition	AACC	July 2017	Having meetings with existing US partners, market research and finding new business partners	The US, LA
	MedTrade	October 2017	Having meetings with existing US partners, market research and finding new business partners	The US, Atlanta
	Medica	November 2017	Visiting the booths of existing business partners, account settling, discussing plans and finding new business partners	Germany, Dusseldorf

Classificati on	Online	Schedule	Promotional plan	Others
Advertisem ent	Google search words Alibaba Lab Medica	Year round Year round Twice ~ three times a year	Making product keywords on new website Maintaining the golden supplier status Advertisement in January, advertisement through media and during the exhibition period in the US in November	-

< Establishment of overseas online distribution network>

<Overseas distribution network & global base >

Business growth and employment plan by phase

Production plan & job creation plan by phase



▶ 2016 Production Capability

Discrition	Workers of Line.	Daily(8 hours) capability	Line	Total daily capability	Work day	Monthly Capability
SAFETY LANCET	4	7,200	1	7,200	20	144,000

2018 SAFETY LANCET ROAD MAP								
자재투입 조립 및 포장 검사							공정	
자재투입	스프링조	- - -	이스조립	포장직 <u>순</u> 〇		감마멸균	출하 검사	
NO	1공정	2공정	3공정	4공정	5공정	TOTAL		
공정명	스프링조립	케이스조립	포장작업	출하검사	감마멸균	라인수 : 2리	<mark>사인</mark>	
인원수	2.5	2.5	2	1	-	2.0		

▶ 2015 Production Capability

Discrition	Workers of Line.	Daily(8 hours) capability	Line	Line daily capability	Work day	Monthly Capability
LANCING DEVICE	7	12,600	2	6,300	20	252,000

Create 7 jobs

2019 SAFETY LANCET ROAD MAP								
정								
돌하 넘사								
5								

▶ 2016 Production Capability

Discrition	Workers of Line.	Daily(8 hours) capability	Line	Total daily capability	Work day	Monthly Capability
LANCING DEVICE	11	19,800	3	6,600	20	396,000



Create 4 jobs

Profit & loss plans by business growth phase



Revenue growth and profit & loss plan by phase



• Thank you

World's first low-pain disposable automatic safety lancet designed to prevent cross-infection