Dermatology Medical Devices
Nail Fungus Treatment Laser

MEDICELL HEALTHCARE

Mycosis Laser

The Future of Nail Fungus Treatment

CENTER FOR MEDICAL INNOVATION UNIVERSITY OF UTAH

University of Utah Asia Campus Industry Foundation
ASIA CAMPUS | THE UNIVERSITY OF UTAH

biohub 서울바이오허브

ITP 인천테크노파크 INCHEON TECHNOPARK

Problem (1) - What

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Q: What is Nail Fungus?

Overview

- **Nail fungus** is a common infection of the nail
  - approximately **5% of the population** [1]
  - affects **36M** people in USA
- **Nail fungus** is also called **onychomycosis**
- When fungus infects the areas between your toes and the skin of your feet, it's called **athlete's foot (tinea pedis)**.

Symptoms of nails

- Thickened
- Discolored
- Brittle, crumbly or ragged
- Misshapen
- Separated from the nail bed
- Smelly

➔ Nail fungus can affect fingernails, but it's more common in **toenails**.

[1] Onychomycosis of toenails: orthopaedic and podiatric considerations Stuart C Murray[1], Rodney P R Dawber
[2] Onychomycosis: newer insights in pathogenesis and diagnosis Chander Grover[1], Ananta Khurana

Problem (2) – Who

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Q: Who is most likely to get a Fungal Infection of the Nails?

From older adults to all family members

Nail Infections are more common among people who

- Have **diabetes**
- have a disease of **poor circulation**
- are over age 65
- wear artificial nails
- swim in a public swimming pool
- have a nail, skin injury around the nail
- have a **weakened immune system**

➢ The number of the 65 and over population in USA
: approximately **59.2 million** nationally [3]

Your family may increase your odds of contracting a fungal infection

- You are more at risk, if you live with someone who has a nail infection in your family

[3] Source : U.S. Census Bureau, Vintage 2023 Population Estimates

Problem (3) – Why

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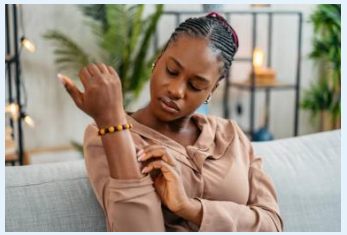
Q: Why are Fungal Infections of the Nails difficult to cure?

Continuous Treatment is neccessary

Fungal nail infection is a Never-Ending Story!

- Rates of **reinfection** are high, even with the use of strong drugs.
- To reduce the chance of reinfection, you must **continue treatment** until the nail completely grows out



Treatment of onychomycosis with antifungal agents [4]

Agent	Dose	Duration
Terbinafine	250 mg	Toenails: once per day for 12 weeks
		Fingernails: once per day for 6 weeks
Itraconazole	200 mg	Toenails: once per day for 12 weeks
	pulse therapy	Toenails: 200 mg twice per day for 1 week/no treatment for 3 weeks. Repeat for 3–4 months
		Fingernails: 200 mg twice per day for 1 week/no treatment for 3 weeks. Repeat for 2 months
Fluconazole	300–450 mg	Toenails: once/week for 9–12 months
	150–300 mg	Fingernails: once/week for 4–6 months
Ciclopirox nail lacquer	apply once per day	Remove lacquer once per week. Treat for up to 48 weeks
Amorolfine nail lacquer	apply once or twice a week	Remove lacquer before each new application. Toenails: 9–12 months. Fingernails: 6 months

[4] Reference : Fungal Nail Infections (Onychomycosis): A Never-Ending Story? Mahmoud Ghannoum [1,], Nancy Isham [1]*

Problem (4) – How

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Q: What Treatments are used for Fungal Nail Infections?

Treatments Type

Conventional Treatments

- Topical Treatments (OTC)
- Home Remedies & Essential oils
- Topical Prescription (Rx) Treatments
- Oral Prescription (Rx) Treatments
- Surgical Treatments
- Essence Oils

➔ **It taskes about 6 to 12 months to be cured**

Complications

Medications and Medical Treatments increase your susceptibility to Fungal Infections

- Any medications impair the function of your **immune system** : Steroids, and chemotherapy agents decrease your immune response.
- Due to medication, **diabetes** or other conditions, other serious infections could spread beyond your feet

➔ **Laser treatment can be the best choice!!!**

Solution – Laser Treatment

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MYCOSIS LASER

405nm 635nm

Touch screen to control

- You can control the device with touch screen

Built-In-Camera

- You can monitor your treatment if the focus of laser is on the right spot of nail fungus

2-Feet-Simultaneous-Treatment

- 2 feet or hands operation possible

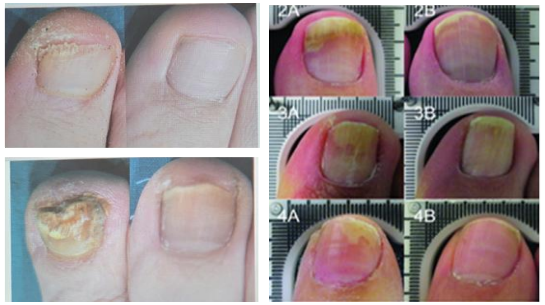
Laser output compensation function

- You can compensate the lowered laser output on a regular basis

Minimally Invasive and Low Pain

- Patients could get warm feeling in their toe and finger with low pain

You can have clean nails and toenails with Mycosis Laser



Effect Comparison

Introduction Video

Product Line-up

Dermatology Medical Devices

Medical laser irradiator - Hospital

On sale

[1] Medical Device for Hospital

- Korea : Class III
- USA : Class II

[2] Korea – On sale (July, 2024)

[3] USA-510(k) Preparation

- Utah CMI Consultation
- Feb, 2025 Submission

Medical laser irradiator - OTC

Developing

[1] Medical Device for OTC

- USA : Class II

[2] USA Target Market

- Beauty/Skin/Nail Saloon
- Home Care Product

[3] 510(k) Strategy

- Device Case Change
- Laser Power Change
- 510(k) Special Track

Regenerative Medical Device

Developing

[1] Medical Device for Skin Care

- Core Technology & Prototype Developed

[2] Product Development & 510(k) Strategy

- Korea R&D Grant : **$1.1M (USD)**
- Utah CMI Support

Why? Medicell!

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Medicell **Global Standard of Medical Device**

Faster commercialization strategy

- **(Korea) Seed Investment & Government Grant**
- Completion of product development
- GMP(QMS) and pre-clinical Test completion
- (KOR) K-FDA Certification - **Done**
- (USA) FDA-510(k) Certification – **On processing**

Global **K-Medical & Beauty's potential**

USA is the right market for Medicell!!

- **Mycosis Laser for Hospital is in medium demand**
- **Mycosis Laser for OTC is in high demand**

2020

2020.10

Establishment of Medicell

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2022

2022.05

GMP Certification (Equivalent to ISO13485)

GMP

2023

2023.04

Mycosis Laser Medical Device K-FDA Class 3

2024

2024.07

(USA) Univ. of Utah CMI FDA-510(k) Consultation

Seed Investment
$ 0.3 M (USD)

Korea Government Grant
$1.1M
TIPS, Seoul Bio R&D

2025

2025.06

(USA) 510(k) Submit for Hospital

2026

2026.03

(USA) 510(k) Submit for OTC

[Phase I : Technology Development] Korea Start up Support

[Phase II : Business Scale Up] USA Market Penetration

Target Market

Nail Fungus (Onychomycosis) Market

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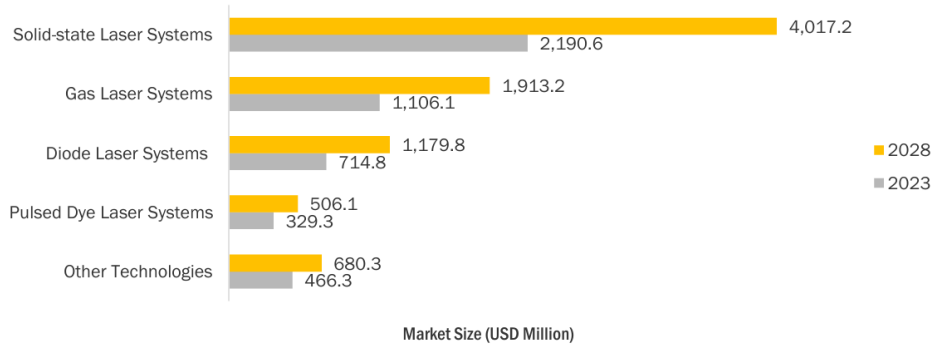
Market Size

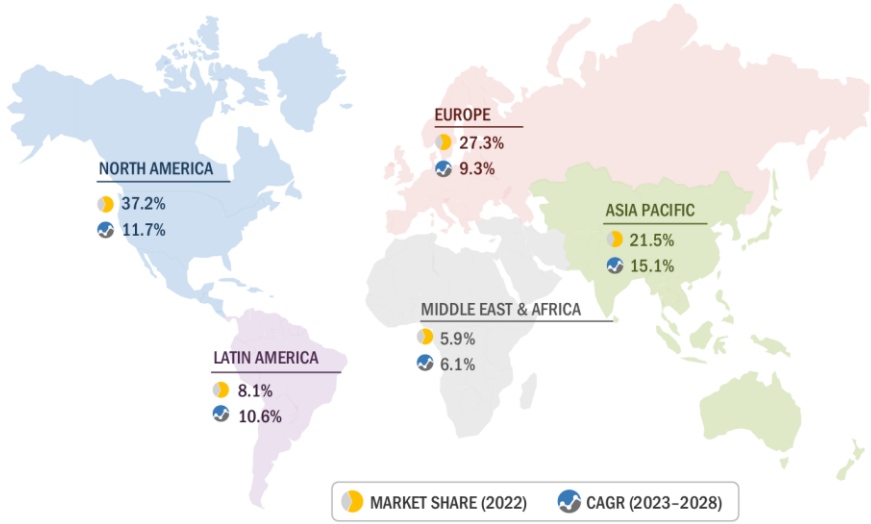
- The medical lasers market is projected to reach **USD 8,296.5 M by 2028** at a **CAGR of 11.5%** from 2023 to 2028.
- The Diode Laser Systems market size is estimated at **USD 1,1179M in 2028** and is expected to grow at a **CAGR of 4.4% by 2030**.



MEDICAL LASERS MARKET, BY TECHNOLOGY, 2023 VS. 2028 (USD MILLION)

Regional Insights

- **North America** onychomycosis market held **the largest share of about 40%** in 2024 and is expected to market size of **46.7M (USD)**
- This can be attributed to the rising prevalence of target disease and favorable government initiatives. North America is one of the developed regions with high healthcare expenditures.



GEOGRAPHICAL SNAPSHOT OF MEDICAL LASERS MARKET

Source : Markets and Markets, FORECAST to 2028

Mycosis Laser

Competitive Analysis

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1. Built-in Camera

It is convenient for doctors and patients to see the location of athlete's foot and the treatment process.

2. Laser output difference

Benchmark Lunula Laser (USA) output - 405nm, 635nm

3. Laser output compensation function

Function to correct laser output through annual A/S visit

4. 2-Feet-Simultaneous-Treatment

Save time by treating both feet at the same time

	LUNULA LASER (USA)	ONYCHO LASER (KOREA)	MYCOSIS LASER (Medicell)
Product Shape			
Wave-length	405nm/635nm (Dual Diode Laser)	405nm/635nm (Dual Diode Laser)	405nm/635nm (Dual Diode Laser)
Output	405nm : 23.00±2.00mW 635nm : 17.25±1.25mW	405nm : 19mW± 15% 635nm : 40mW± 15%	405nm : 23.00±2.00mW 635nm : 17.25±1.25mW
Built-in Camera	X	X	O
Operation time	12min	12, 15, 20min	12, 15, 20min
Advantage	1. First imported product (FDA approved) 2. Good therapeutic effect and quality	1. First product in Korea 2. 2nd largest penetration in Korea	1. Best in Class 2. Built-in camera 3. Built –in laser power compensation
Drawback	1. Single Mode: Long Time Taking 2. Difficulty and high cost of after-sales service	1. Quality issues 2. Poor performance due to laser power differences	1. Late entry to market

Product R&D roadmap

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Nail Fungus Laser Treatment

Mycosis Laser (Medical Laser Irradiator) – On Sale

Product Development

Development Start	Medical Device
2021.01	2021.12

KFDA Clearance

Quality Management	Insurance Code Enroll	KFDA Approved	Launch
2022.05	2022.06	2023.04	2024.01

On-Process **FDA-510(k) Submission**

FDA –510 (k) for Hospital	FDA –510 (k) for OTC
2025.06	2026.03

RENEWCELL

Skin Care Medical Device

Renewcell (Dermatologic medical devices) - Developing

Phase I : Product Development

Core Technology Development

Start	Prototype for DEMO	Certified test report
2022.01	2023.01	2023.09

On-Process **Phase II : Commercialization – TIPS and Seoul Bio R&D**

Product Development		Certified by KFDA & FDA			
Prototype for Test	Stability evaluation (KCTL)	Pre-Clinical Test	Clinical trial	KFDA Approval	FDA / 510(k) submission
2025.11	2025.04	2025.07	2026.01	2026.06	2026.07

Business Milestone (1) Domestic & Overseas Business Plan

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Product	Market	2024	2025	2026
Mycosis Laser Hospital	Domestic	• Product launches, conference papers • Build sales and marketing infra	• Build a national distribution network	• Activating sales
	USA	• Univ. of Utah CMI Collaboration	• FDA 510(k) Submission • Launch a U.S. product & Investment	• Build a global sales network
Mycosis Laser II OTC	USA	• OTC product development and int'l approval strategies ➔ Univ. of Utah CMI Collaboration	• FDA 510(k) Submission • Univ. of Utah CMI Collaboration	• Launching a product in the USA
Renewcell	Domestic	• Commercial Development: Prototyping • Safety testing, preclinical trials	• Clinical Trials (Konkuk Univ Hospital) • FDA approval	• Launch Domestic Sales • Built new factory
		R&D Project by Seoul City - $ 0.4M (USD)		
	Overseas	• Visit to the University of Utah CMI, USA	• Advancing RenewCell and Commercializing • Overseas • 510(k) preparation and approval application ➔ Univ. of Utah CMI Collaboration	• (US) FDA-510(k) Approval (Japan) PMDA approval preparation
			TIPS R&D Project - $ 0.7M (USD)	

Investment Seed → (Overseas) Pre A, Series A

Marketing & Sales Strategy

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Product 1 Mycosis Laser

	Product	Market	Sales Strategy		Remarks
Entry	Mycosis Laser **Hospital**	Korea	Step 1 Basic sales	Selling to hospitals that need it (한강연세병원, 라파엘 외과)	**Monthly Sales Goals : 10 or more**
			Step 2 Foot Salon Franchise • Managing onychomycosis & Ingrown toenails • Provide additional in-hospital revenue models	Commercialize revenue model (한강연세병원, 개원닷컴) 	
			Step 3 Open a hospital and Provide basic medical equipment	Basic medical device item delivery model for hospital openings	
Expansion 1	Mycosis Laser **Hospital**	USA	Targeting the Korean community	Marketing to Korean towns in New York and New Jersey	**Going Overseas 1**
			Targeting the U.S. community	• Medical Device and Pharmaceutical Company Partnerships in Utah • Developing a collaborative model by moving into the Utah CMI	
		Japan	Obtain a Japanese approval	PMDA - Approval as a Laser Irradiator	**Going Overseas 2**
			RX Japan Collaboration Model	Start with regional cities like Osaka and Nagoya	
		ASEAN	Launching international trade shows	Utilize KOTRA-supported projects (Indonesia, Vietnam, etc.)	
			Collaborate with local companies	Collaborate with companies with local operations in SE Asia	
Expansion 2	Mycosis Laser **OTC**	USA	OTC Nail / Skincare Shop, Home Sales • Utah CMI Consulting Completed (Jul 2024) • US market exclusivity business model		**Only 1 product In USA**
			University of Utah CMI, Product Review (upcoming)		

Team Capabilities

CEO & Key Members

MEDICELL HEALTHCARE

C E O

Brian Lim CEO

Education & Career

◇ Korea Institute of Technology(KIST) Startup

◇ PhD. in Computer Science, Korea University

◇ M.B.A., Korea Uni Graduate School of Biz

◇ B.S. in Electronics and Electrical Engineering, Hanyang University

- AI Healthcare, DTx, EduTech Commercialization
- Global Startup World Cup Rank #2
- Global Major Account : T-mobile, NTT-Docomo, AXA etc.
- 2022, 2023 CES Innovation Award

Mr. Koo CEO

Education & Career

◇ Korea Broadcasting Corporation (KBS). R&D Center

◇ Masters of KAIST Electronics Communications

◇ B.S. in Electronics and Electrical Engineering, Hanyang University

- 30-year-enineer in Electronic Engineering
- Developed products such as stroke diagnostic equipment, medical laser irradiation equipment, and spinal surgery equipment.
- Possesses ultra-precision control circuit and software program development know-how

최강식 원장

Co-Founder / Key Doctor

- 의학박사
- 내과 전문의
- 성인병 클리닉
- 최강식 내과 대표 원장
- 메디셀 Co-Founder 및 주요 주주

도진우 원장

Key Doctor

- 서울대학교 의학박사 ,외래교수
- 강남 제이디클리닉 원장
- 한국 미용성형학회 정회원
- 의사를 교육하는 병원 제이디클리닉
- 세계에서 찾는 피부 성형 외과
- 전문의 의료진의 1:1 맞춤 솔루션

조영훈 원장

Key Doctor

- 연세대 의과대하구피부과 전문의 및 강사
- 미국 국립암센터 피부과 연수
- 을지대학교 의과대학 피부과 교수
- 카이스트 부속의원 진료부장 ,피부과장
- 대전 테크노연세 피부과 원장
- 메디셀 투자 주주

임시연 원장

Key Doctor

- 한양대학교 의학사/석사/박사
- 전 한양대학교 부속의료원 소아외과 임상교수
- 대한 외과학회 평생회원
- 대한 소아외과학회 정회원
- 현 라파엘외과 대표 원장

Global commercialization capabilities

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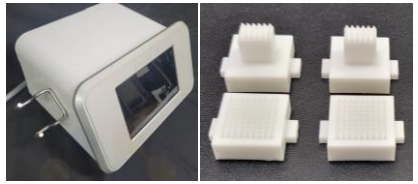
1 Commercialized product planning and development capabilities

Mycosis Laser
(KFDA- Class3 / Launched)

Godbaro –K
(KFDA-Class1 / Launched)

Renewcell
(KFDA – Class3 / Developed)



2 Domestic Ministry of Food and Drug Safety, U.S. FDA Licensing Capabilities

- Medical Device Test Certified
- GMP – Quality Management
- Pre-Clinical Test
- FDA-510(k) for each product
- Univ. of Utah CMI

3 Domestic and international Bio/ Medical Equipment networking

- (Kor) Seoul Biohub
- (Kor) Konkuk Univ. Hospital
- (USA) Univ. of Utah
- (USA) Biocom California
- (USA) Pegsus VC

Business Milestone (2) Investment & Exit

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	2020~2024	2024	2025	2026	2027
Milestone	Planning and development of pain-free skin beauty medical devices • Launch of Mycosis Laser (hospital use) product	• FDA 510(k) approval in progress • Univ. of Utah CMI Collaboration	• Mycosis Laser II (OTC) – 510(k) approved • Renewcell product development and domestic and overseas licensing completed		• (USA) Launch of AI digital healthcare service
R&D Project	**Government R&D Grant (2020~2024)** Development of Renew Cell prototype Stepping Stone Challenge : 0.1M(USD)	**R&D Grant for Development** Mycosis Laser II (OTC) & Renewcell R&D Grant(TBD) • SBA MedicalBio Commercialization : 0.4M (USD) • TIPS R&D : 0.7M (USD)		**AI digital healthcare service collaboration and marketing(2026~)** AI healthcare service expands overseas	
Investment	**Capital : 715M (KRW)** Co-CEO : 59.18% Co-Founder : 26.73% Employees : 5% Investors : 9.09%	**Seed** **$0.3M (USD)** **Pre Value : $3M (USD)** ▪ Mycosis Laser	**Pre A** **(Overseas) $1.5M (USD)** **Pre Value :$15M (USD)** ▪ Mycosis Laser for Hospital 510(k)	**Series A** **(Overseas) $5M (USD)** **Pre Value : $50M (USD)** ▪ Mycosis Laser for OTC ▪ Renewcell KFDA & FDA	**M&A / IPO**
	2020~2024	2024	2025	2026	2027

Continuous growth strategy

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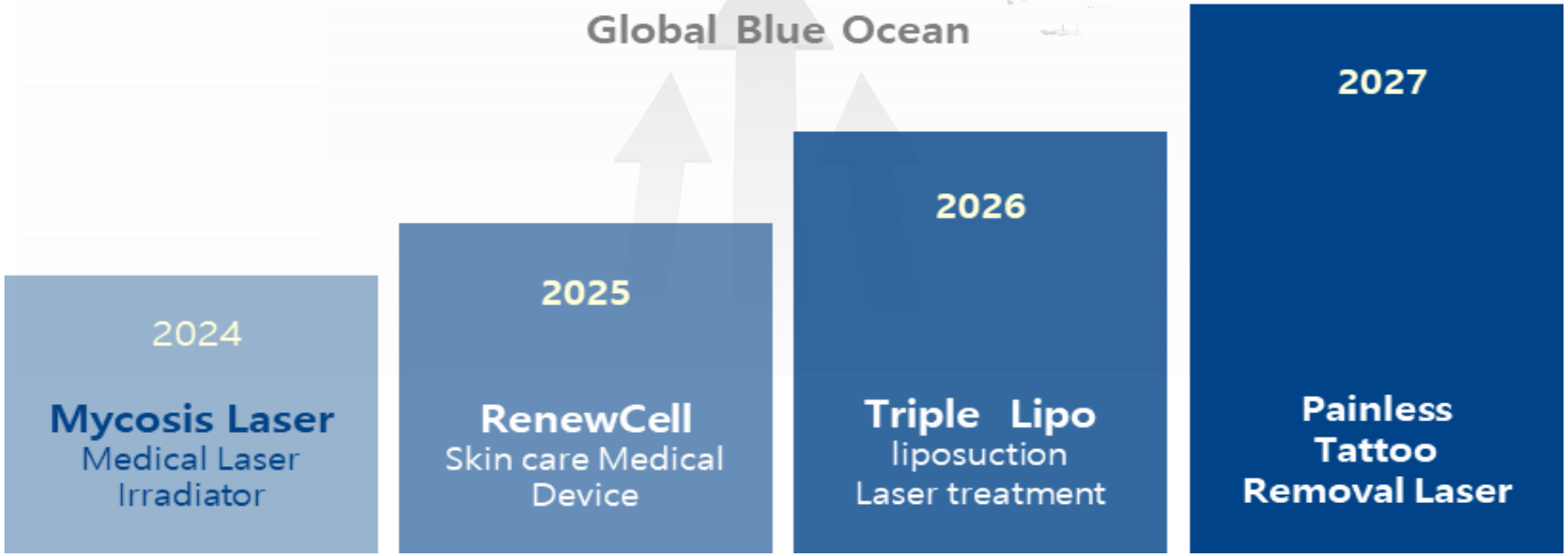
Aiming to become a pain-free skin care Global No. 1 company

VISION

GLOBAL No.1 Painless Medical Devices



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Thank you

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