



Tissue engineering & Regenerative Medicine, Bio-Fabrication

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## Part 01 – Introduction

01. Foundation and Key Numbers

02. Core Technology Principle

03. Business Domain

04. Growth map



# 01|Foundation and key numbers

Tissue engineering & Regenerative Medicine, Bio-Fabrication



First clinical  
application





3DXPrinter  
T&R Biofab

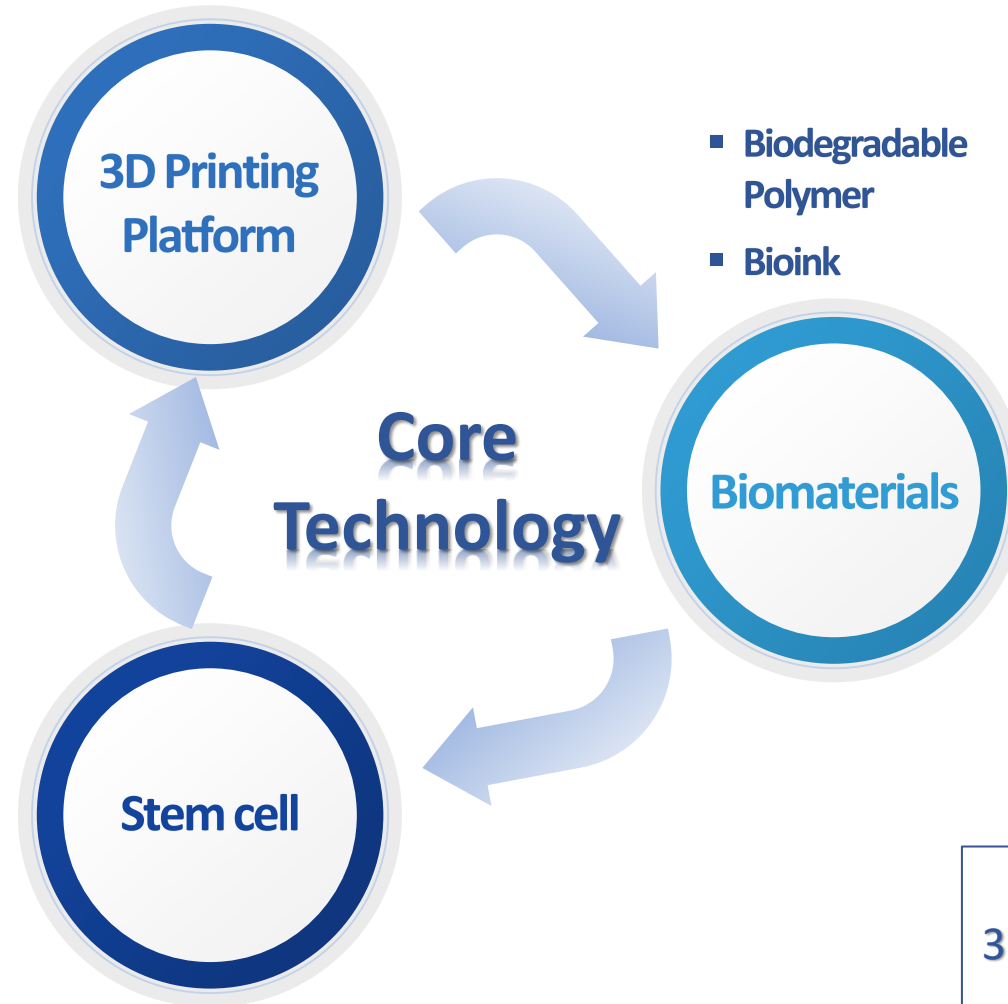
**Bioprinting Market**  
0.7B USD (2020) – 2B USD (2025)  
Ref. 3D BIOPRINTING MARKET - GROWTH, TRENDS, COVID-19 IMPACT, AND FORECASTS (2022 - 2027)



**Stem Cell Market**  
15B USD (2020) – 24B USD (2025)  
Ref. STEM CELL MARKET - GROWTH, TRENDS, COVID-19 IMPACT, AND FORECASTS (2022 - 2027)



## 3D Bioprinting System



**Biomaterial Market**  
35B USD (2020) – 50B USD (2025)  
Ref. BT1556

## “ Tissue and Organ Repair/Reconstruction/Regeneration ”

● Developing key platform technologies in manufacturing/biomaterials/cells for Tissue engineering and Regenerative medicine ●

### Scaffold for Tissue Regeneration

- ✓ Scaffold for **hard tissue regeneration**  
- Bone, Cartilage regenerative scaffolds
- ✓ Scaffold for **soft tissue regeneration**  
- Medical devices using bio-materials

### Bio Surgical Solution

- ✓ **Wound dressing**
- ✓ **ADM tissue supplement**
- ✓ Hemostatic agent
- ✓ Orthopedic tissue regeneration treatment
- ✓ Tissue regenerative drug carrier
- ✓ Tissue regenerative anti-adhesion barrier
- ✓ Nerve regeneration conduit

### Tissue and Organ

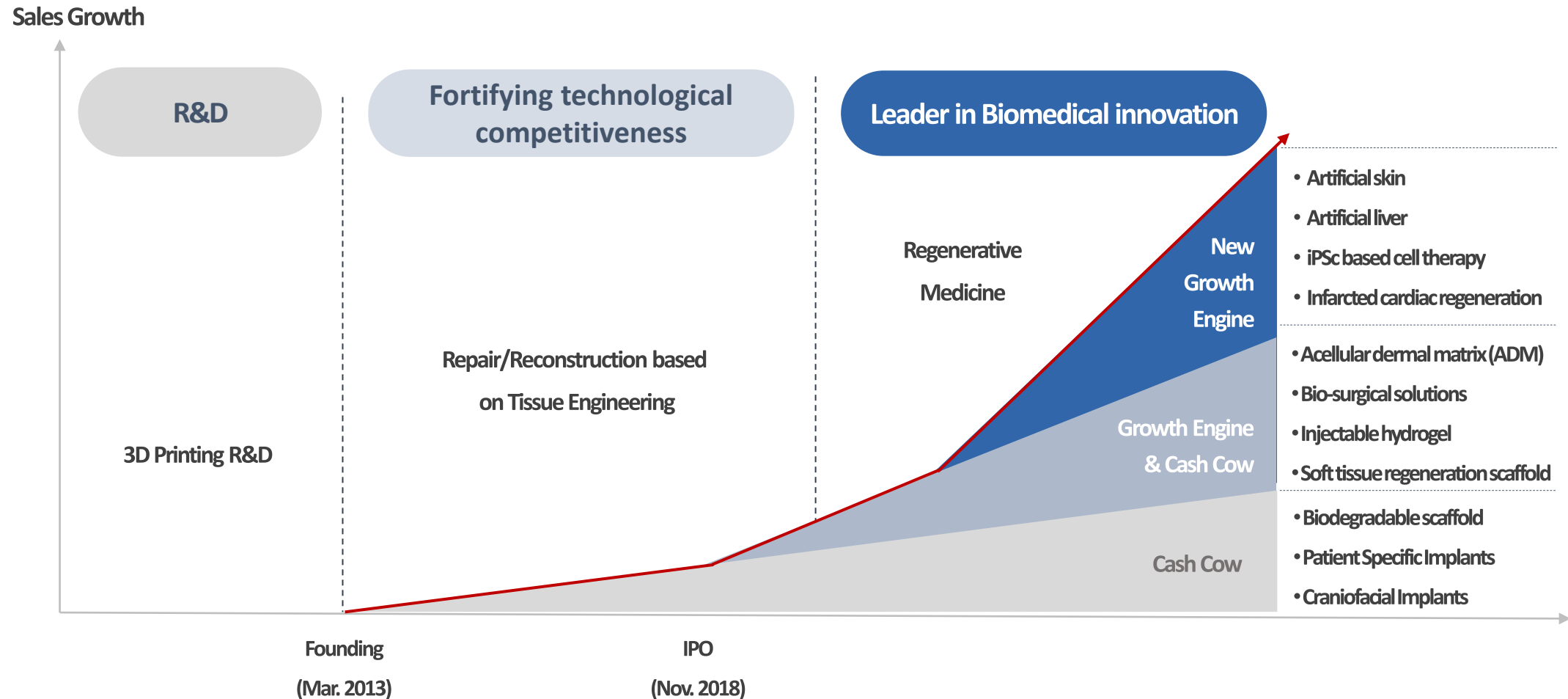
- ✓ Cardiac repair therapeutics
- ✓ Skin
- ✓ Liver
- ✓ Blood Vessel

3D Bio-  
printing

Biomaterials

Cell

## “Innovating regenerative medicine through 3D bioprinting technology”



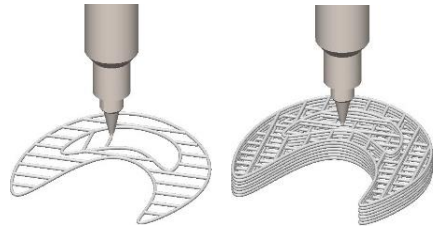




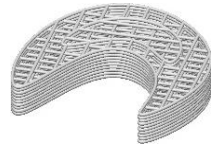
## Part 02 – Current Products & Upcoming releases

01. 3D printed medical devices

02. Bio-surgical solutions



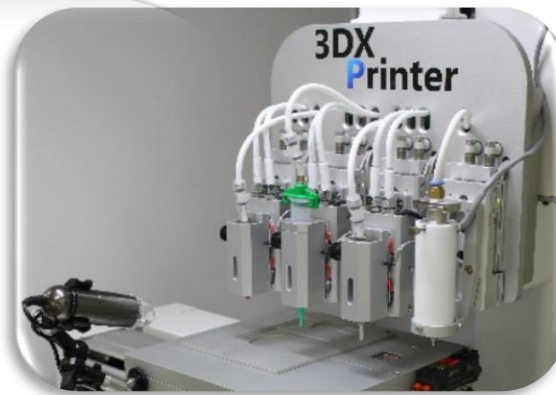
Printing FDA-approved biomaterials



Scaffold for tissue regeneration



Biocompatible materials (PCL, TCP, etc)



## World's largest approved 3D printed medical devices provider

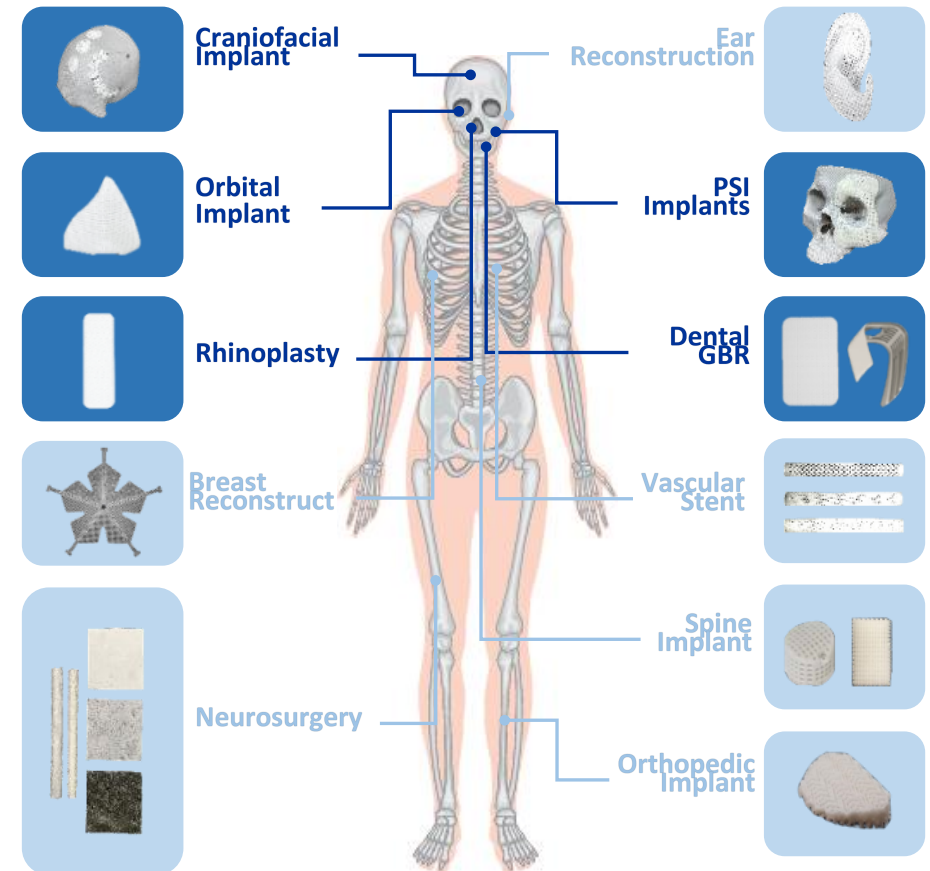
- **13 products** of class 4 medical devices (**over 13,000 specifications**)
- The largest clinical cases in the world (as of Jun. 2022 - **60,000+ cases**)
- Verified long-term follow up outcomes by **16 SCI clinical publications**

## Infrastructure in development/licensing/production/medical verification

- In the phase of **expanding indications** and **market penetration**

## Scaffolds for Tissue Regeneration

### Applications



## ► Commercialization Strategy for 3D scaffolds

### ▶ Domestic

- Securing KOLs and **clinical data. Expanding indications.**
- **Launched at over 200 general hospitals and clinics** (55 general hospitals/150 clinics)

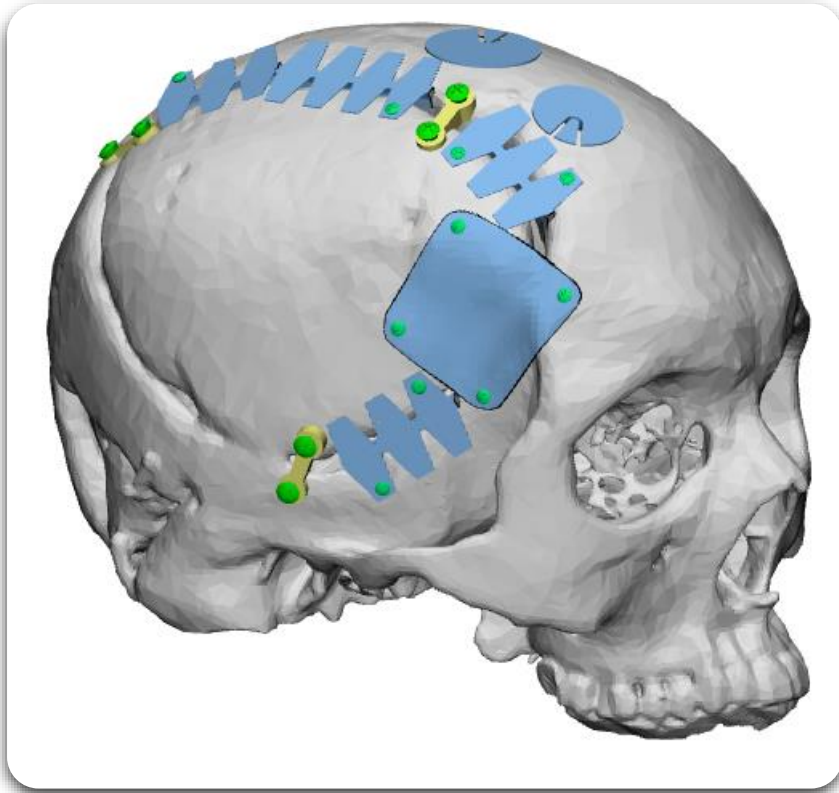
### ▶ Overseas

- Export to **5 Asian countries:** Vietnam, Thailand, Philippines, Taiwan, Japan (2018 ~)
- Achieve CE marking in 2020.04. Expanding market to Europe – starting export to Greece





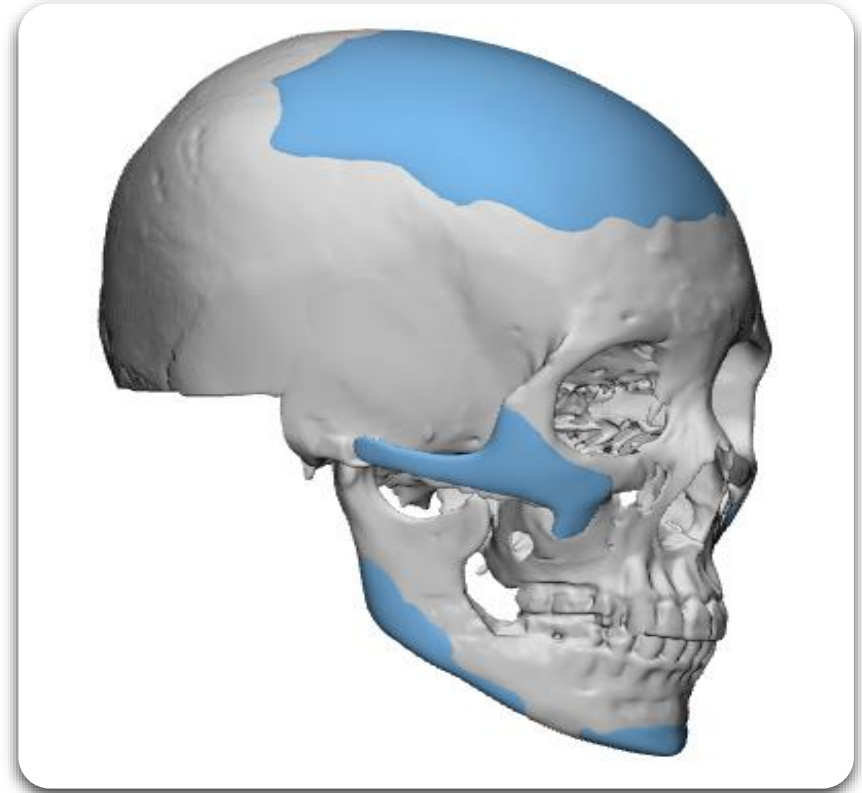
B | BRAUN



## ▶ CranioFacial Implants (CFI)

- Collaboration with **B.Braun**
- Launched in April 2021. Used in 58 hospitals (as of 22.06). Expanding market.
- **FDA** approval submitted (expected 2024)

Johnson & Johnson



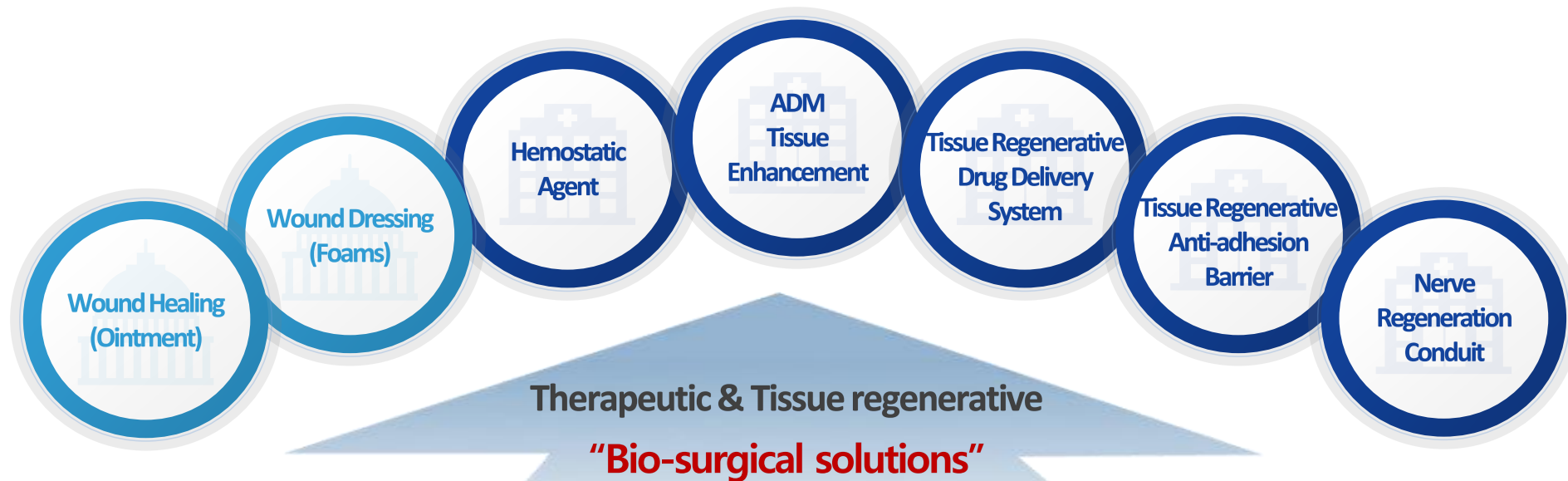
## ▶ Patient Specific Implants (PSI)

- Contract in March 2023 for Korea
- Expanding in Asia - Oceania 2023 - 2024

## "Applications of unique natural bio-material(ECM, ADM) technologies "

Patent in mass production of natural bio-materials (ADM, ECM).

Development of products through platform technologies in ADM, ECM-based medical devices and therapy



## 1. Wound Healing

- Wound-dressing ointment containing proprietary ECM (VdECM)
- Perform dual functions of ‘Enhancing wound-healing & Scar tissue reduction’
- **22. 03** Approved by MFDS(non-antibiotics). **22. 06** Benefit assessment (non-benefits). **22. 07** Launch. **22. 09** FDA Class I listing
- **Distributorship agreement** with **Juthis International (general hospital)** and N company(scheduled)



## “Contain VdECM, component specializing in Tissue Regeneration”



## “Wound healing + Scar tissue reduction”

- **VdECM (patent pending)**
  - VdECM is obtained by eliminating cellular components of specific porcine tissue (cell, DNA, virus, etc) that can trigger immune response to extract and generate ECM components consisting of 40% collagen and **60% elastin**.

Global	Domestic
\$11 B	\$120 M
(CAGR 5.2%)	(CAGR 6%)

- 2020 Market Size -

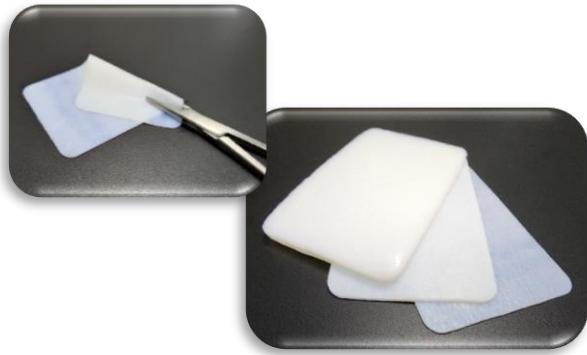
\*Global market source: Medical equipment market size & growth-wound care management market, global 2013~2020

\*Domestic market source: Production, Export, Import report on Medical Devices (2009~2013, Ministry of Food and Drug Safety)



## 2. ADM Tissue Enhancement

- Xenogeneic ADM products with similar properties to allogeneic ADM produced by patented Opti-SdECM manufacturing technology
- Degradation rate increased by 5 times (non-cross linking)
- Properties and biodegradability customized to each indication
- Possess solid technologies on hydration packing, sterilization, and ensuring packing safety
- MFDS approval **23.04**

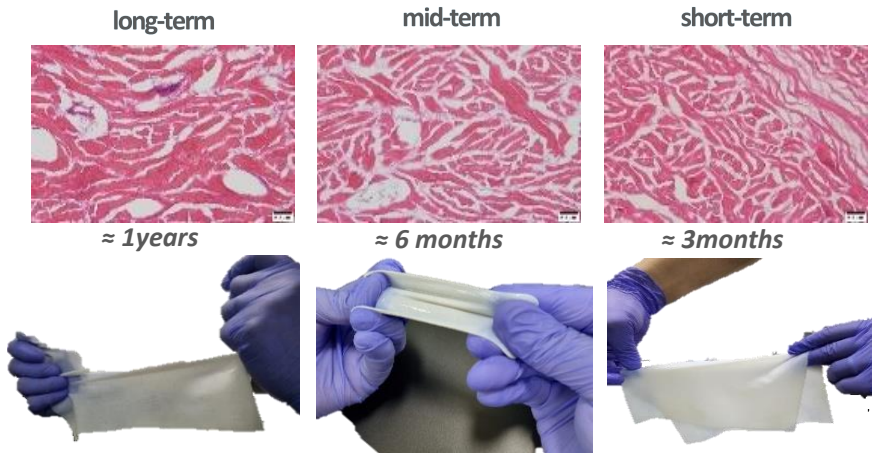
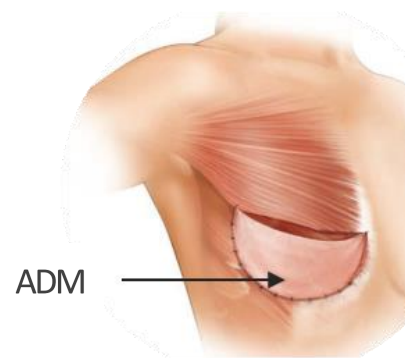


**Global**  
**Xeno \$3.4 B**  
**Human \$4.4 B**

**Domestic**  
**\$120 M**  
(CAGR 20%)

- 2024 Estimates -

Controllable with similar properties to allogeneic ADM  
Adjustable biodegradation rates

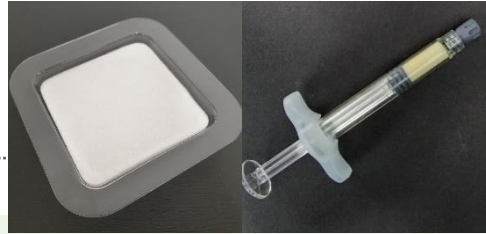


\*Global market source: Coherent MARKET INSIGHTS, Primary and Secondary Analysis

\*Domestic market source: market research report

## 3. Hemostatic Agent

- Tissue adhesive technology and 3D modeling technology
- **Power type / Matrix type**
- Superior effect on hemostasis and tissue regeneration



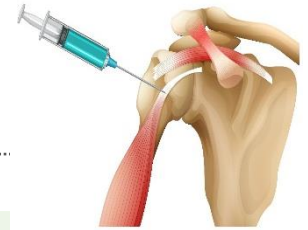
➤ **ADM** (Acellular Dermal Matrix)

➤ **ECM** (Extracellular Matrix)

➤ **Bioprinting**



➤ **Functional materials  
by each indication**



## 5. Tissue Regenerative Drug Carrier

- Sustained-release drug delivery and thermosensitive gel technology
- Enhanced gel stability
- **Applicable to various types of drugs**
- Injectable, Biodegradable within 2 weeks



## 6. Tissue Regenerative Anti-adhesion Barrier

- **Superior anti-adhesion effect (containing antibiotics)**
- Enhanced gel stability
- Reversible thermosensitive gel technology
- Injectable, Biodegradable within 2 weeks

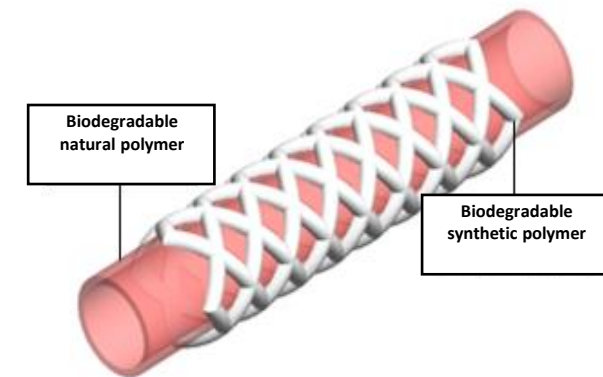


## 7. Nerve Regeneration Conduit

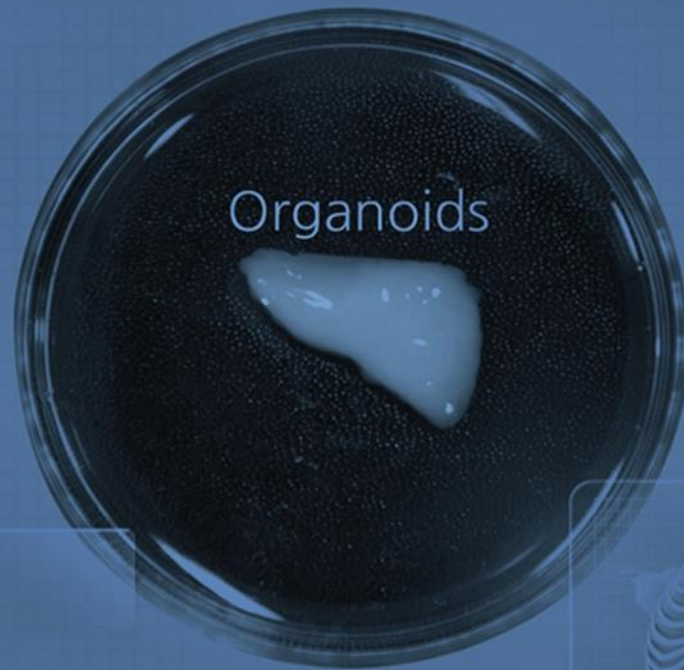
- The Global Nerve Repair and Regeneration Market size was valued at \$ 590 Million in 2017 and is forecasted to reach **\$ 1.3 Billion by 2023**
- Allogeneic nerve graft is traded at **\$ 8k** per 50mm (length)  
(in domestic all import-dependent)
- **Development of hybrid nerve conduits through ECM/3D printing technologies**
- **\$3.5M research fund from the Korea Medical Device Development Fund**
  - Project name: **"Development of complex nerve grafting techniques based on xenogeneic materials using 3D bioprinters"**
  - (Duration: 2022.04~2025.12)



## "Hybrid Nerve Regeneration Conduit"



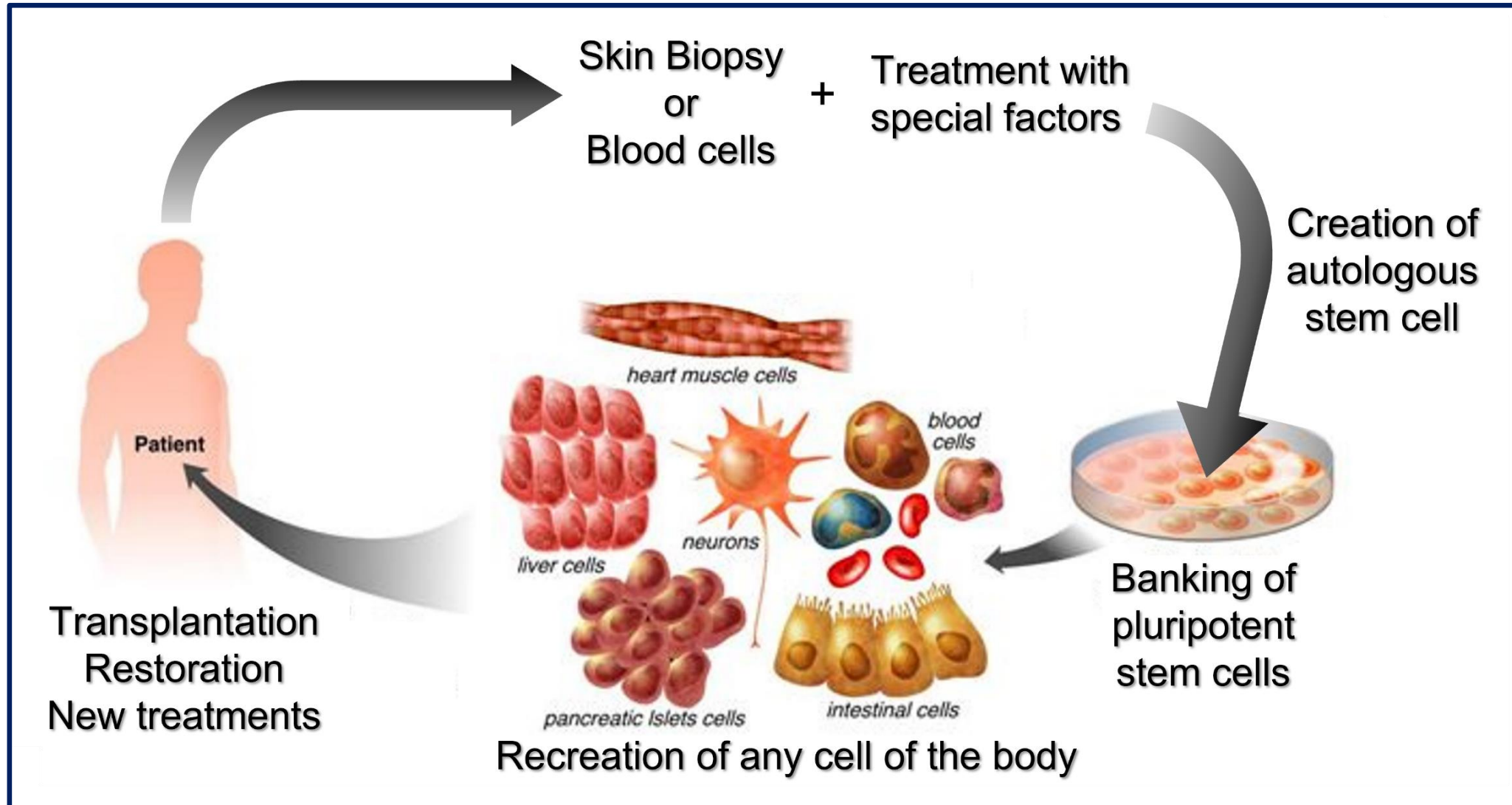




## Part 03 – Platform technology

01. iPSC and its applications

02. Artificial tissue/Organ



## “Establishment of clinical iPSC and specific cell production system”

—● Securing donor agreement & Production of cardiomyocyte, endothelial cell, and hepatocyte using virus-free iPSC ●—

### “T&R commercial cell bank”

- Cell bank based on FDA Standard Operating Procedures
- Right to commercialize

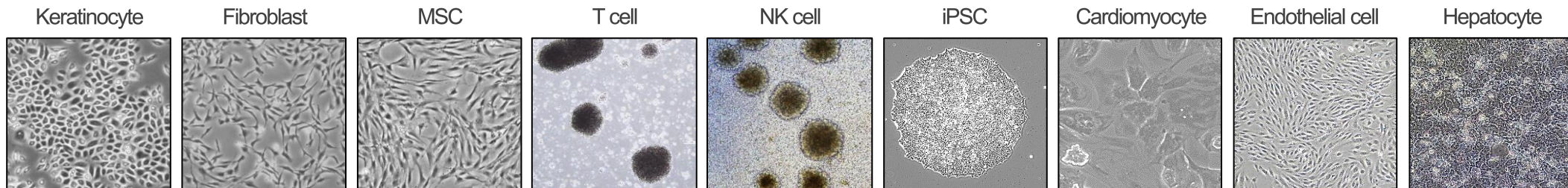
### “Clinical iPSC Banking”

- Establishing RCBs - GMP compliant
- Virus-free iPSC -> Safety
- Relationship with iPS Academia Japan

### “iPSC Differentiation technologies”

- Cardiomyocyte
- Hepatocyte
- Endothelial cell

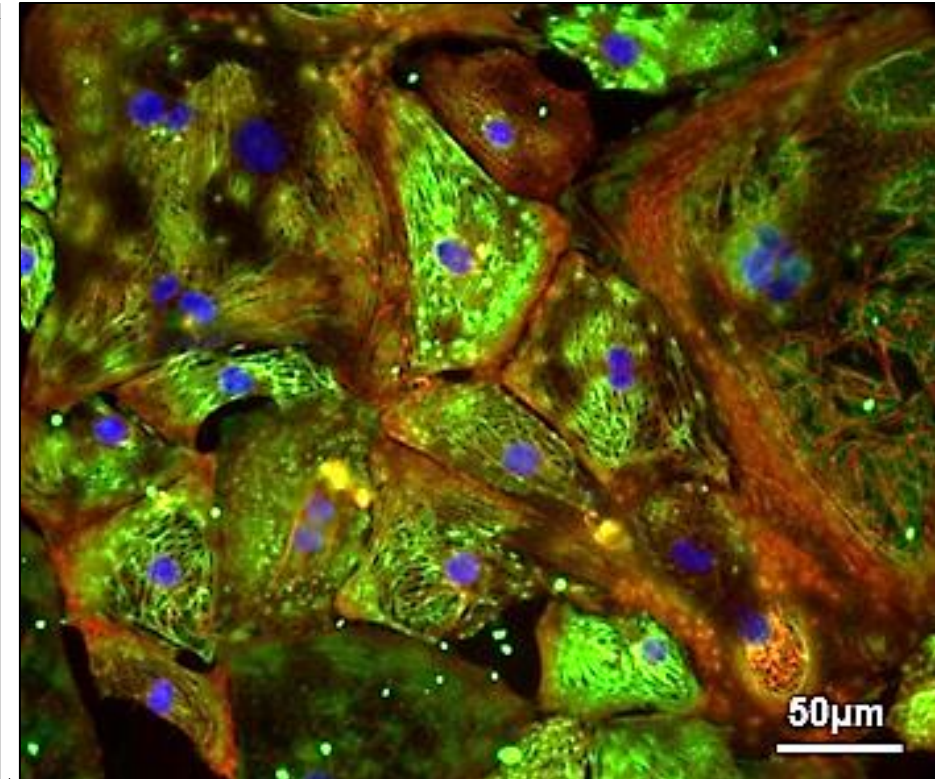
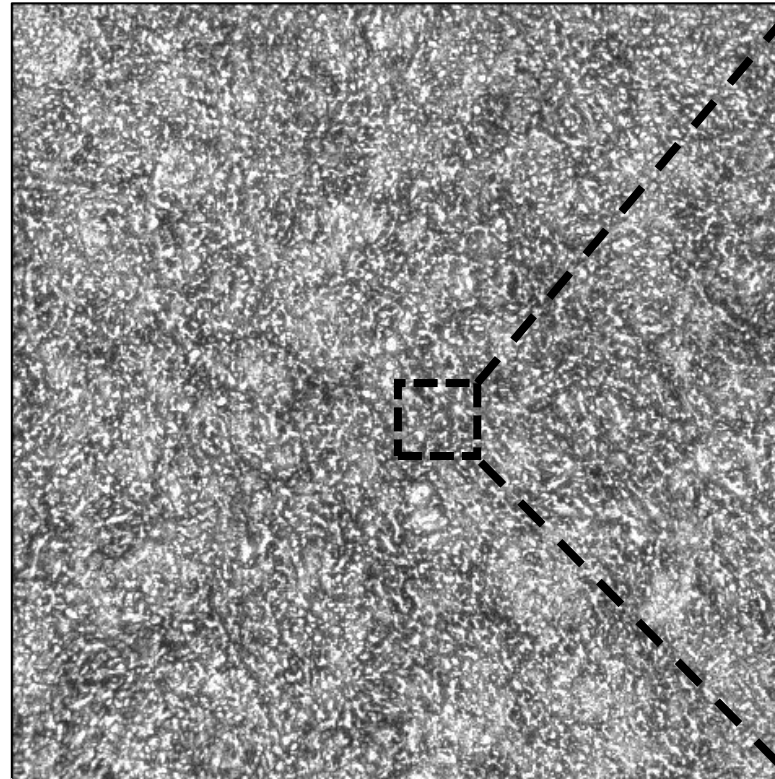
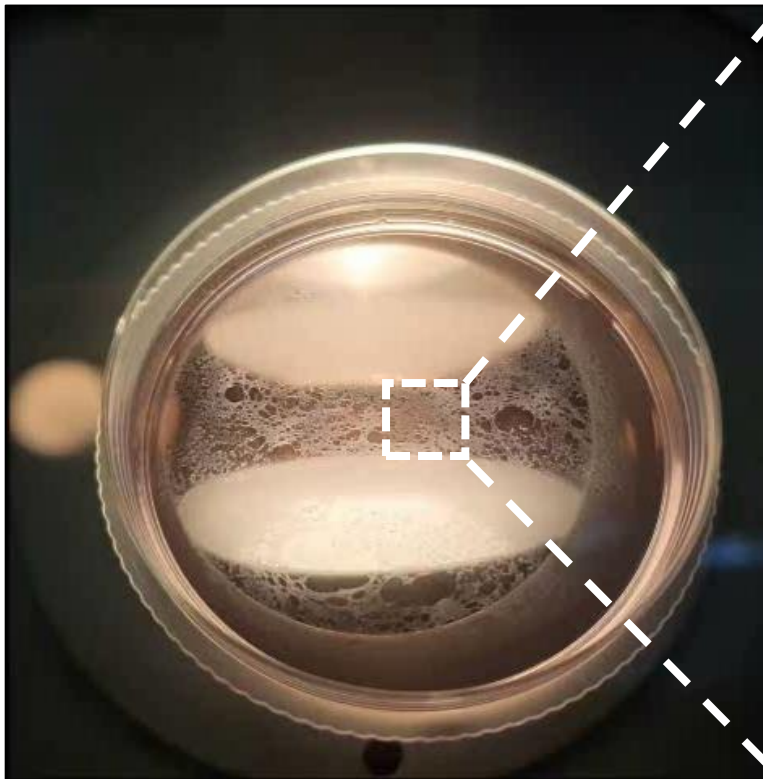
## “Building up iPSC-based treatments and platforms”





## “Clinical cardiomyocyte production and analysis”

- Production and documentation of 10 types of iPSC from cGMP facilities through CMO contract
- iPSC system using mRNA based Virus- / Vector-free products
- Completed production and analysis of **10 types of clinical iPSC cardiomyocytes**

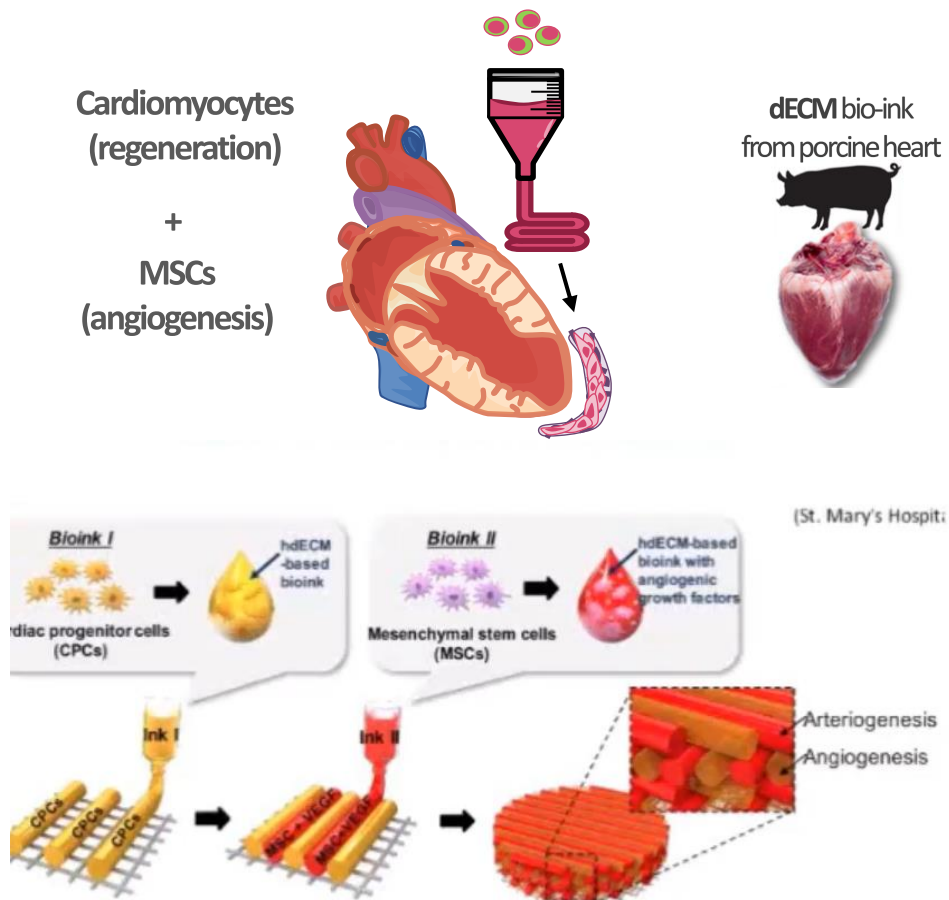


- Secured ₩2.13 Billion research fund from ‘Korea Medical Device Development Fund’
  - Project name: “**Commercial iPSC-derived Ventricle Cardiomyocyte Production Technology and Commercialization**” (Duration: 2021.08~2025.12)

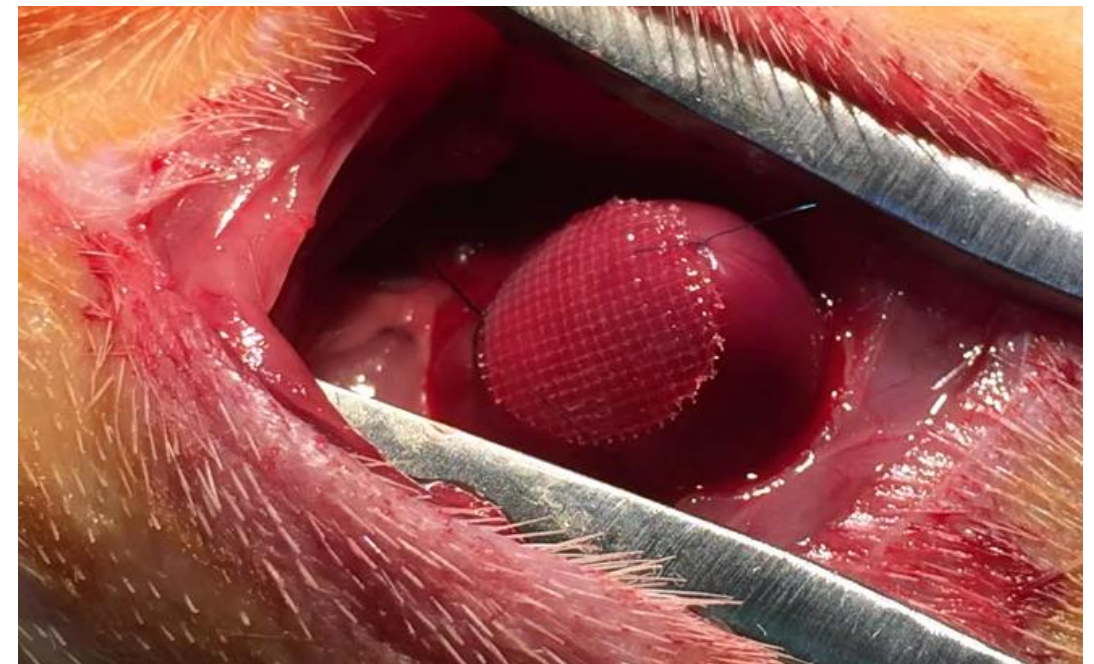


## “Development of 3D cell therapeutics for cardiac tissue regeneration”

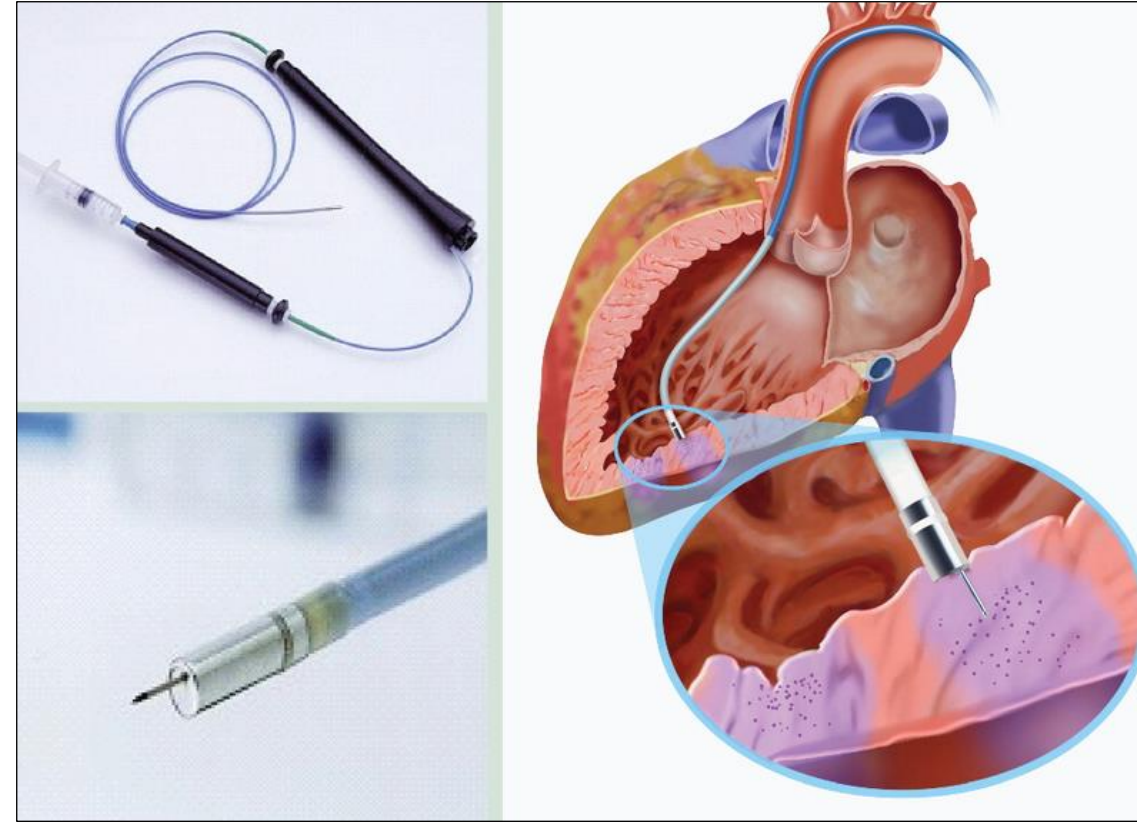
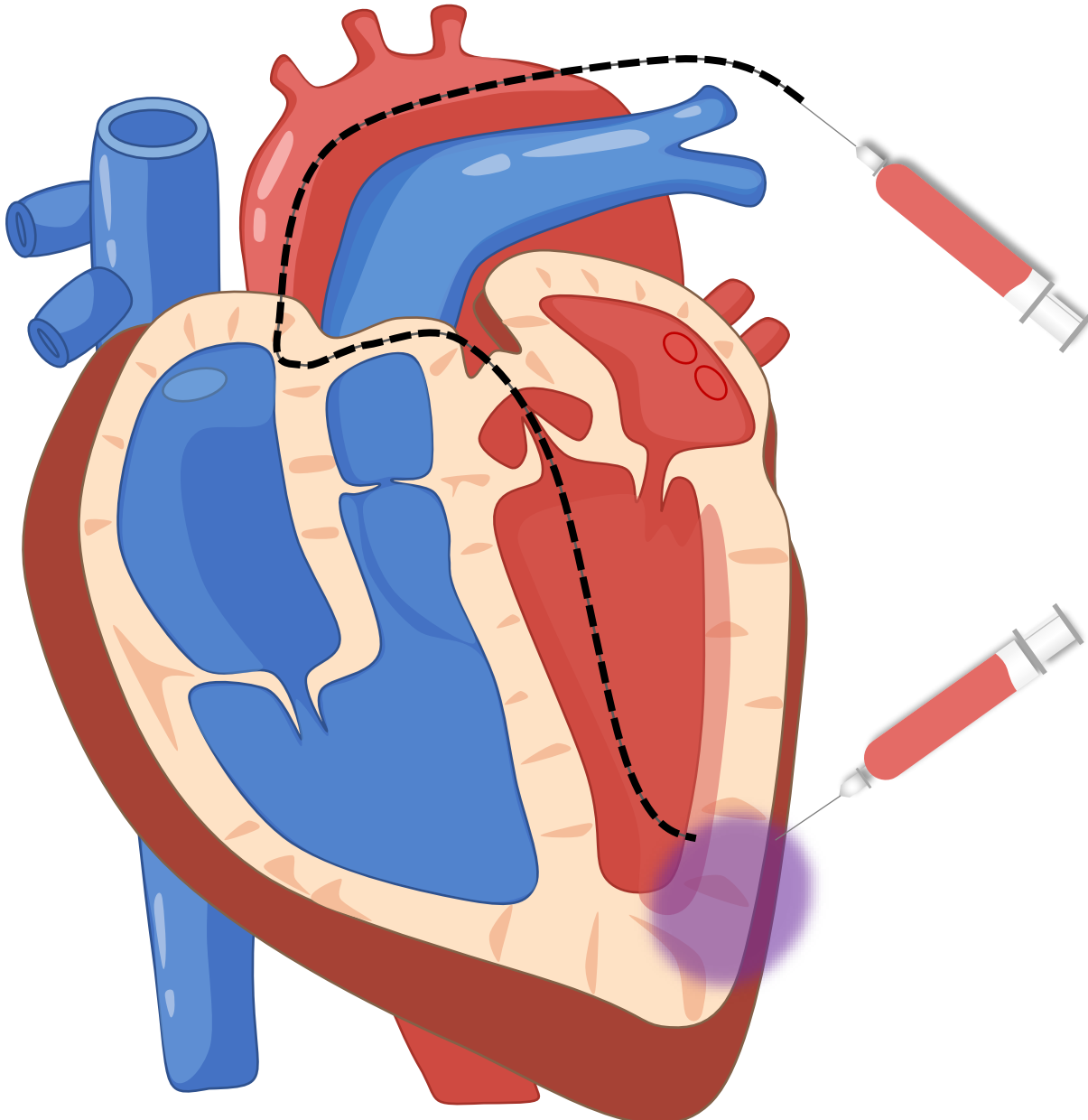
Therapeutics targeting both angiogenesis and cardiac tissue regeneration by fusing cell-printing techniques with 2 types of stem cells



## “Preclinical trials - 3D cell-printed patch using 2 types of stem cells and dECM”



# 01-3| Myocardial Infarction Treatment (Cell Aggregation – Regulatory friendly)

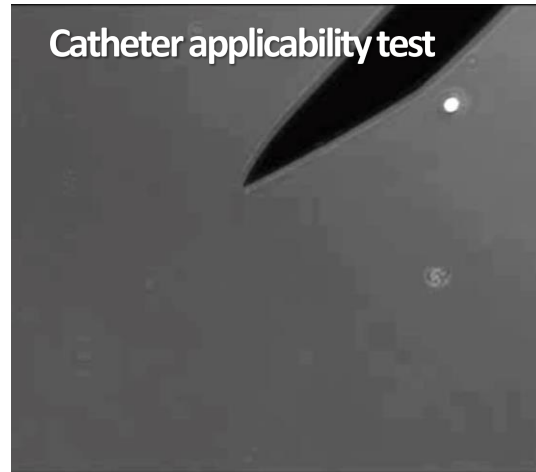
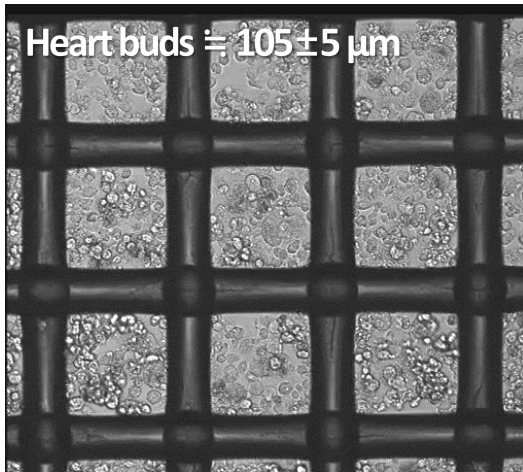




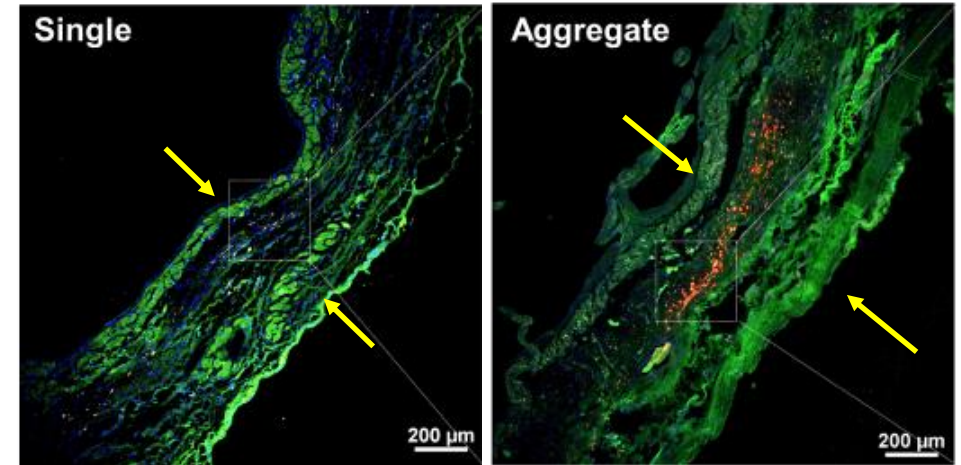
## “Development of clinically applicable FROZEN cardiomyocyte aggregates”

Completed patent registration in Korea/Japan. PCT application (on-going patent examination in USA, Europe, China)

➤ Cell aggregation technology applicable to clinically approved catheters

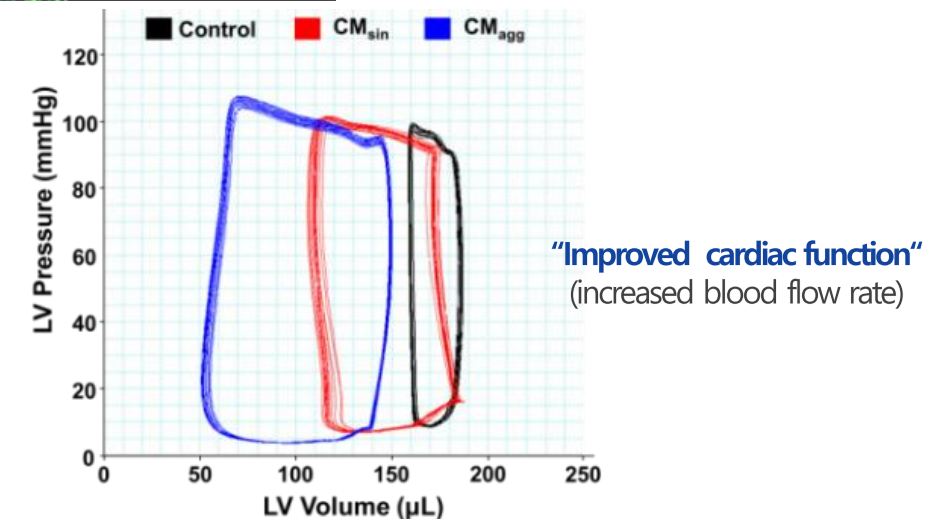


➤ Pre-clinical trials – Confirmed regenerative effects of damaged cardiac tissue after transplantation



### Cardiomyocyte aggregates [ $\sim 100 \mu\text{m}$ ]

1. Enhanced clinical performance and engraftability
2. Long-term cryopreservation (off the shelf therapy)
3. Applicable to clinical catheters (FDA friendly)



# 01-3 Myocardial Infarction Treatment – Deal Potential



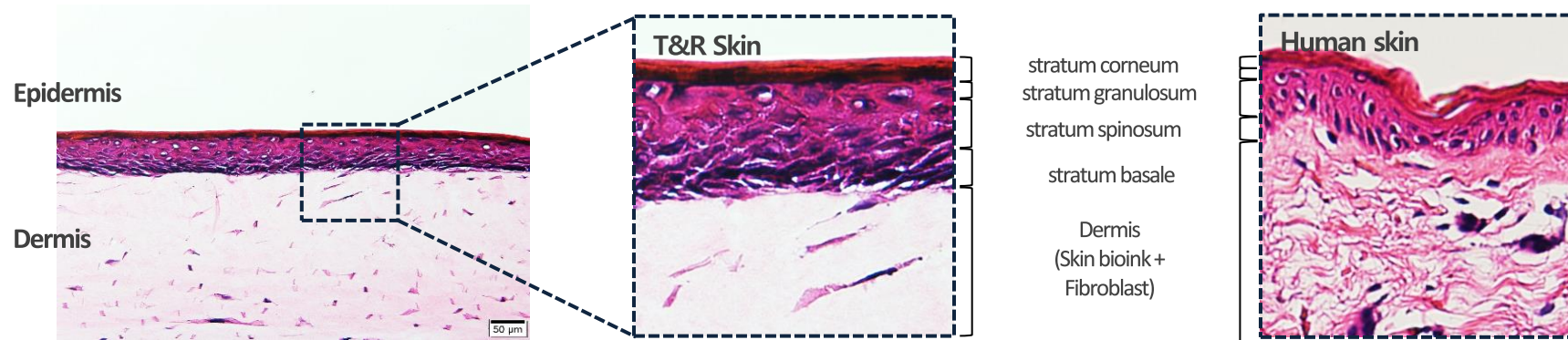
[L/O]...\$598M deal with “**Novo Nordisk**”, a Japanese stem cell company (Heartseed)...ENDPOINTS NEWS (June 11, 2021).

	Heartseed (cardiac spheroids)	T&R (cryopreserved 3D microcardiac spheroids)
Period	13 days	10 days
Animal	Rat, Pig, Monkey	Rat
Purity	99% cTnT (MLC2v)	>95% cTnT
Purpose	Improving contraction function / Survival	Improving survival in hypoxic environment / Maturation
Size (Cell NO)	~ 200 µm	~ 100 µm
Injection	Multi needle (self-developed) + Gelatin Hydrogel	FDA approved delivery systems
Storage	Single cells / Spheroid formation after thawing	Cryopreservation as aggregates
Hospital Usage	Tissue need to be generated	Off the shelf therapy

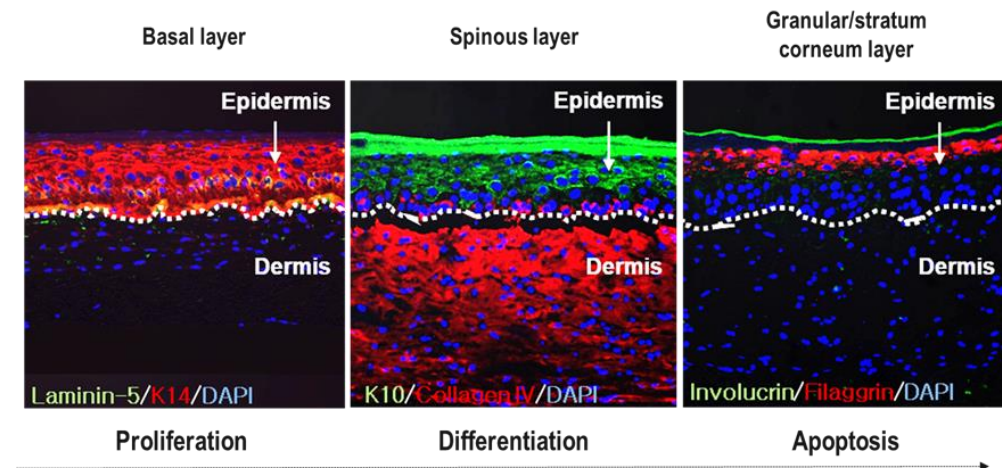


## “Development of artificial skin model based on 3D hybrid bioprinting technology”

—●— Evaluation of drugs and functional materials using 3D bio-printed artificial skin —●—



- 3D printing a full-thickness skin model
- In-vivo like skin model consisting of both epidermis and dermis
- Printing dermal fibroblasts and epidermal keratinocytes



- Expression of early and late differentiation markers (day 11)
- Very similar to native full-thickness skin

## “Advance in development through extensive collaboration”

Validation of novel materials – Model applications – Advanced new model development



- Self-developed SdECM used to create skin model
- Superior performance verses natural collagen
- Published in Acta Biomaterialia 2022 (with L’Oreal)

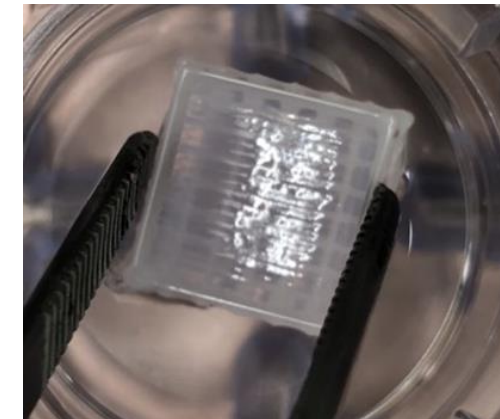
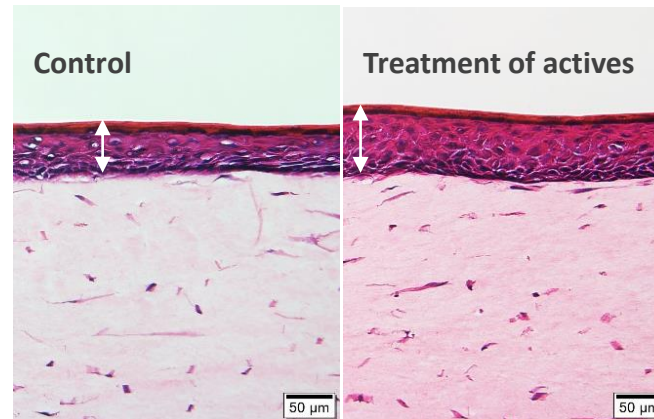
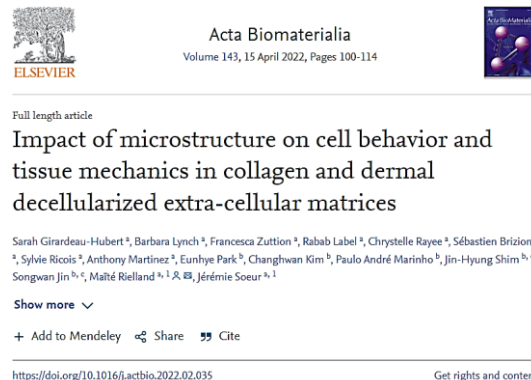
- New material evaluation using T&R skin model with HK inno.N,C company

- Therapeutic Bio skin
- In-vivo relevance

L’ORÉAL

inno.N

COSMAX  
THE SCIENCE OF KOREAN BEAUTY

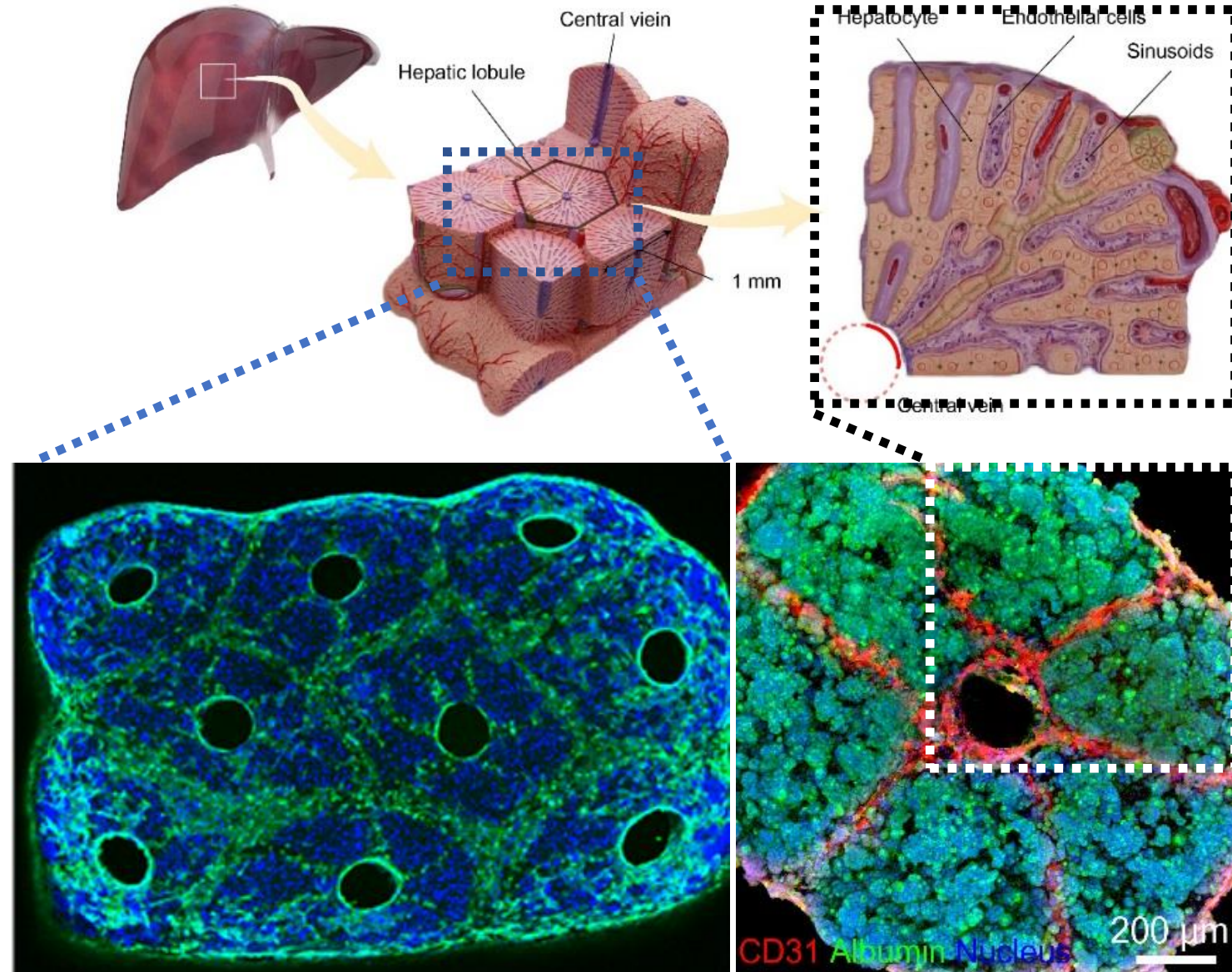
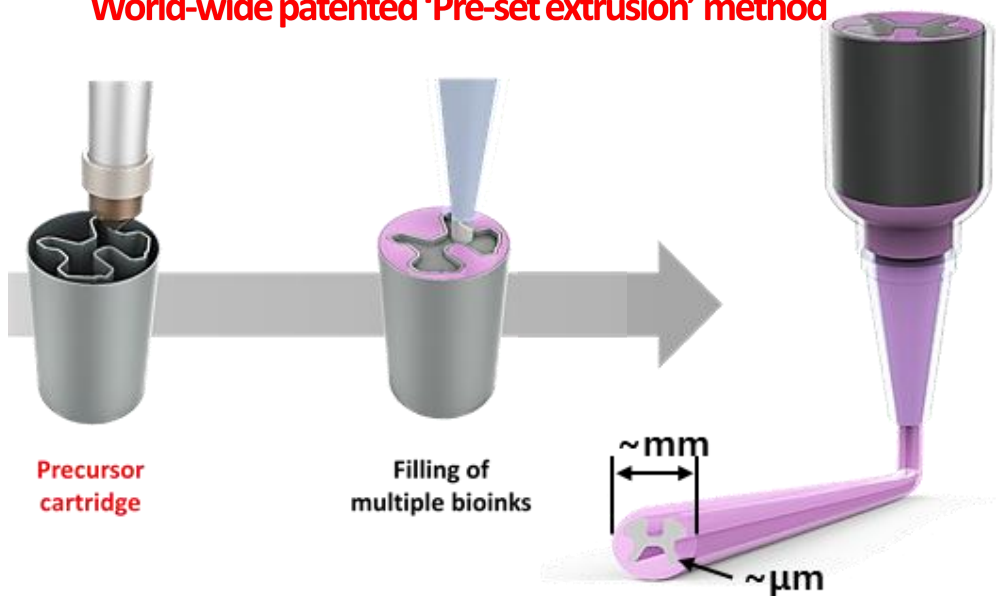




## 3D printed mini-liver tissue(hepatic lobule\*)

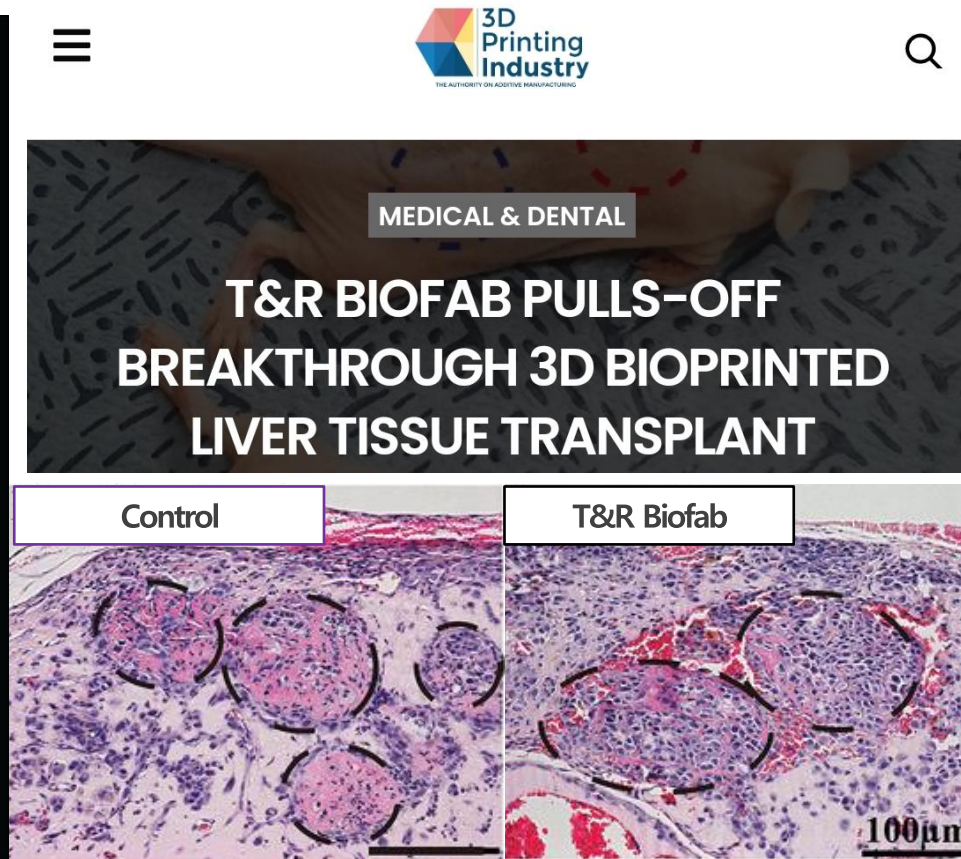
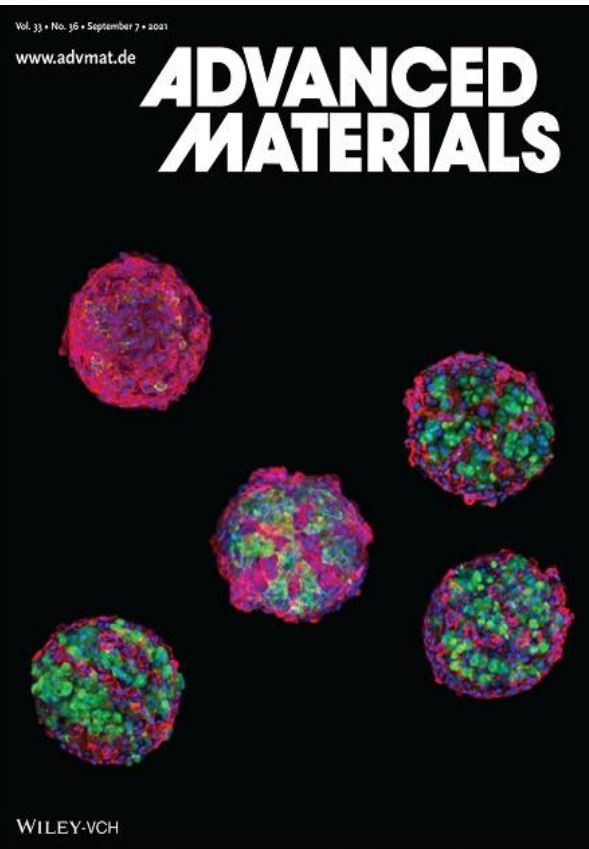
- Unheard precision of bioprinting **world-wide patented 'Pre-set extrusion' method**
- Simultaneous printing of multiple materials or cells with single head to expedite the printing process
- Marked improvement in printing resolution (10s micrometer level resolution)
- Published in *Biofabrication* (IF 10.2), *Small* (IF 13.2), *Advanced Materials* (IF 30.8)

### World-wide patented 'Pre-set extrusion' method

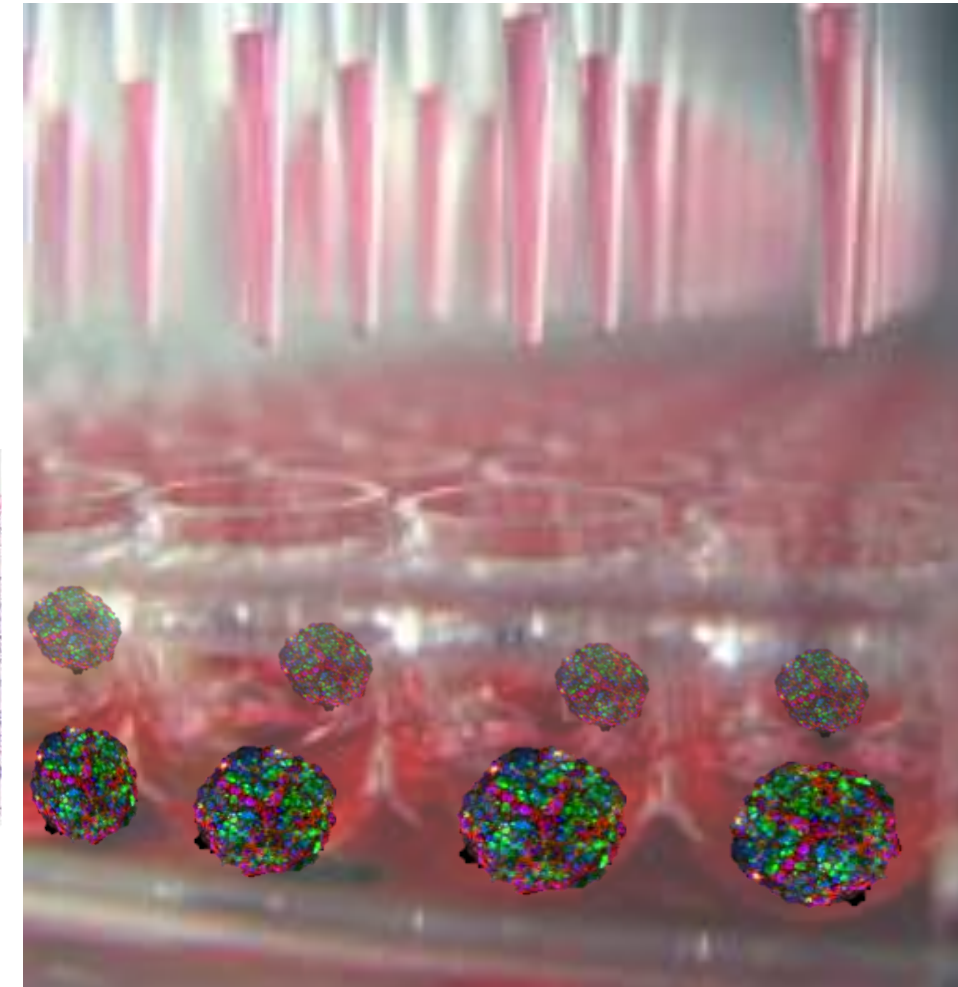




“Mass production of hepatic-lobule-like microtissue spheroids”



The next generation platform HTS



T&R spheroids exhibited unique hepatic-lobule-like structure lasted over 10 days

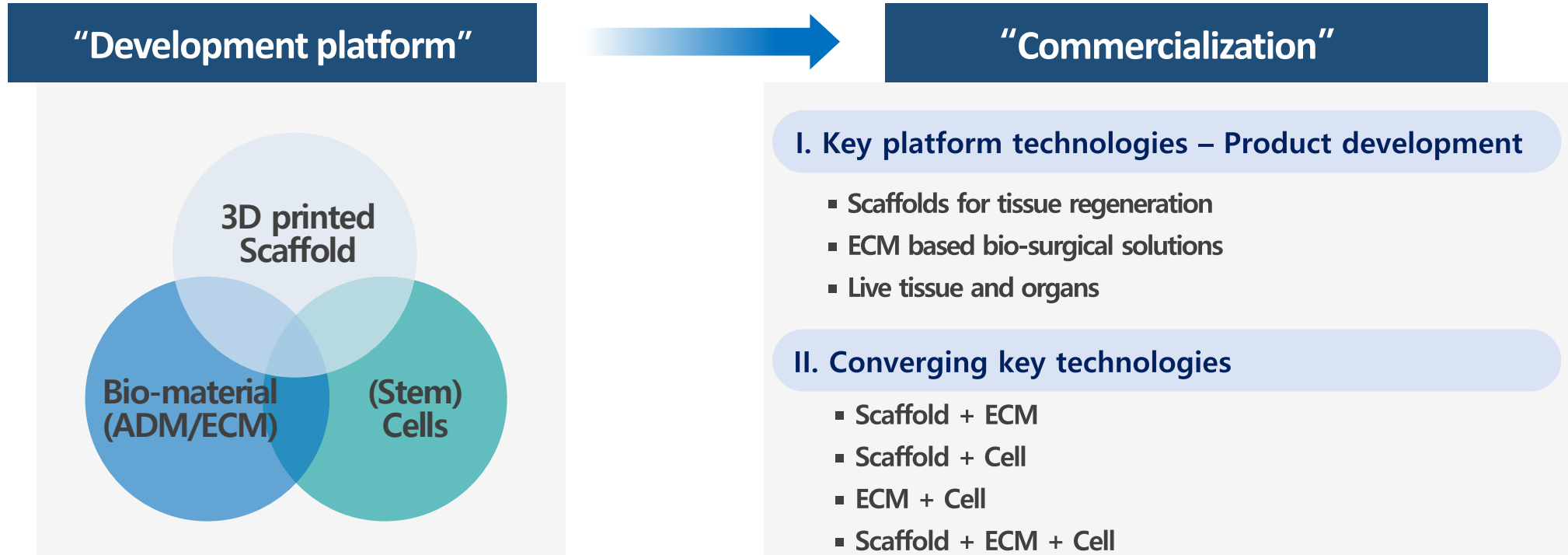




Aspect Biosystems and Novo Nordisk enter partnership  
to develop **bioprinted tissue therapeutics**  
for diabetes and obesity

**Aspect Biosystems Strikes \$2.6B Bioprinted Tissue Deal with Novo Nordisk**

# Key Competitiveness of T&R Biofab



“With self-developed platform technologies (scaffold/biomaterial/cell) in regenerative medicine, T&R Biofab possess unique competitive advantage in developing/providing various technologies and products”