Supercritical CO2, the ultimate solution for tissue engineering and regenerative medicine

Supergreen 2022

The 12th International Conference on Supercritical Fluids

By Dr. DJ Hsieh, CEO

ACRO Biomedical Co., Ltd.

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www.acrobiomedical.com

October 28, 2022

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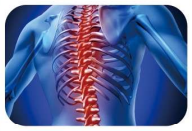
ACRO EYE

ACRO WOUND

ACRO DENTAL



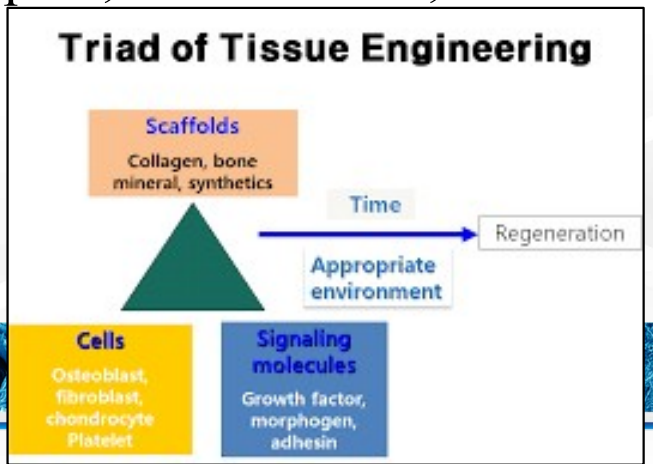
ACRO BONE

ACRO TERM

AESTHETIC MED

What are tissue engineering and regenerative medicine (TERM)?

- **Tissue engineering** evolved from the field of biomaterials development and refers to the practice of combining scaffolds, cells, and biologically active molecules into functional tissues. The goal of tissue engineering is to assemble functional constructs that restore, maintain, or improve damaged tissues or whole organs.
- **Regenerative medicine** is a broad field that includes tissue engineering but also incorporates research on self-healing – where the body uses its own systems, sometimes with help foreign biological material to recreate cells and rebuild tissues and organs. The terms "tissue engineering" and "regenerative medicine" have become largely interchangeable, as the field hopes to focus on cures instead of treatments for complex, often chronic, diseases.



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TERM -- Fast growing industry

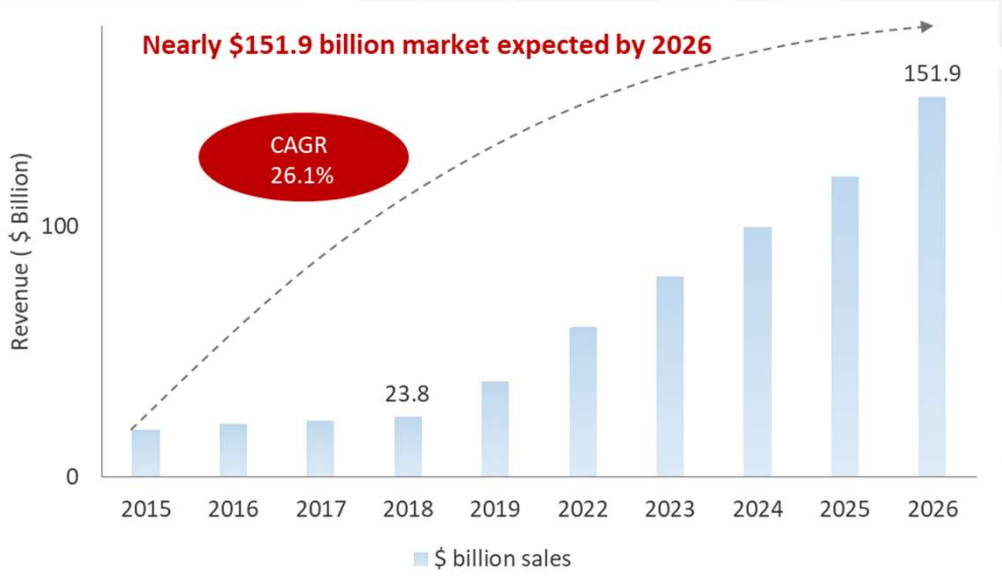
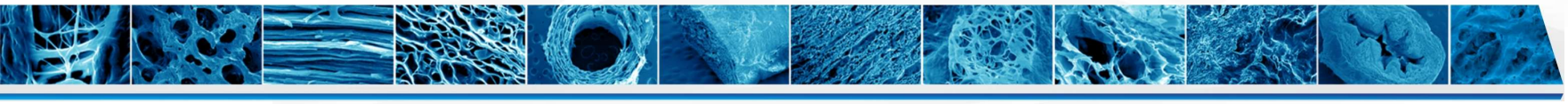


Figure 1. Regenerative medicine market size, Forecast, 2019 to 2026.
Source: Fortune Business Insights

According to Fortune Business Insights, the global regenerative medicine market size was USD $23.8 billion in 2018 and is projected to reach USD $151.9 billion by 2026, exhibiting a CAGR of 26.1% between 2019 and 2026.



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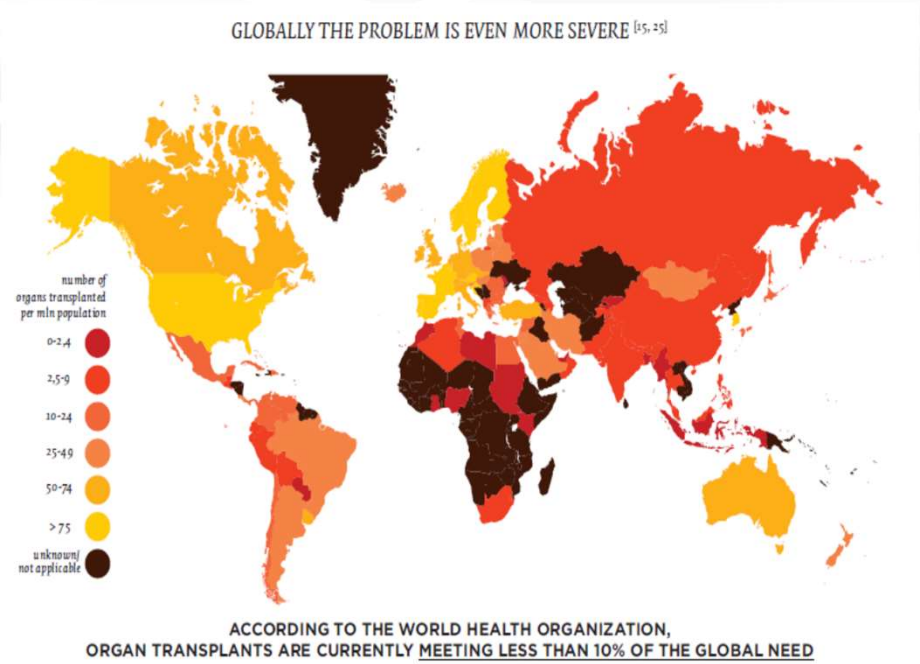
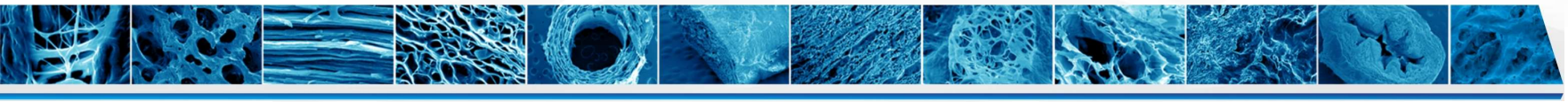
Severe shortage of donated tissues and organs



Regenerative medicine is the fastest growing field in the biotechnology and pharmaceutical industry (CAGR of 26.1%), mainly due to the severe shortage of tissues and organs in the world. According to WHO statistics, less than 10% of the demands in organ transplantation are met, and more than 90% of patients are still waiting for donated tissues and organs.



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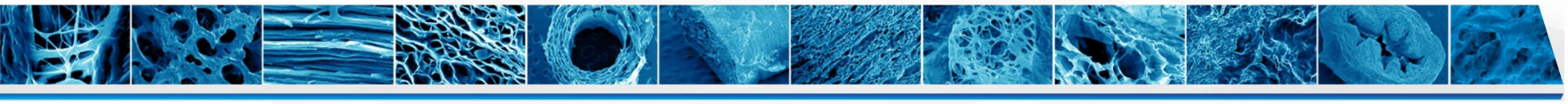
Mission and Vision

➢Mission

Our mission is to apply biomaterials from animal source to regenerate human defected tissues and organs. Ultimately becomes the global leader in tissue engineering and regenerative medicine field.

➢Vision

One day, people do not need to wait for donated tissues and organs. Tissue and organ transplantation become easily available and affordable.



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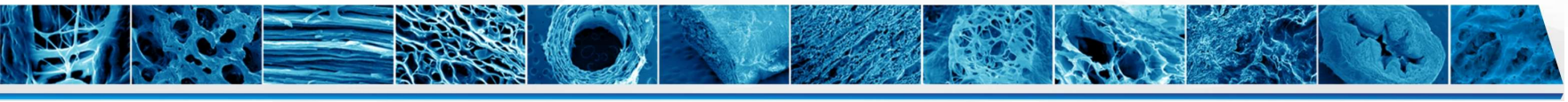
Platform technology

Porcine Tissues and Organs	Platform Technology	Class II/III Medical Devices

Porcine tissues and organs are prepared and put in the supercritical CO_2 extraction system. Other animals including cow, sheep, horse and human can also be used.

5000-5L Supercritical CO2 Extraction System

The Proprietary Technology- Supercritical CO_2 is used to remove cells, fat and other substances in animal tissues and organs, while keeping the natural collagen scaffolds as biomaterials for human tissue and organ regeneration.



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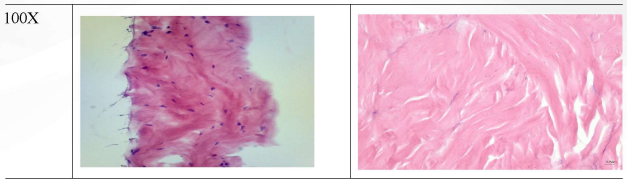
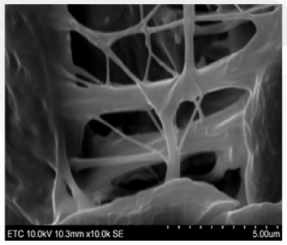
Holy Grail Technology
(Best Platform Technology, Taiwan Biopharma Excellence Awards 2022)

Advantages of $scCO_2$ Process

Untreated vs. $scCO_2$ processed

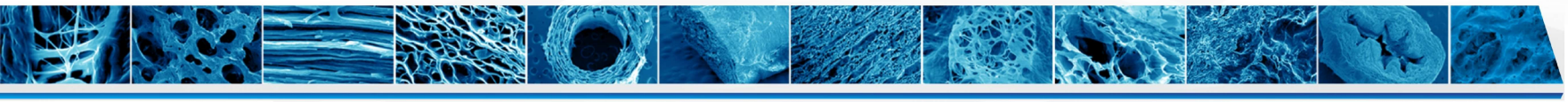




Intact collagen structures remained after scCO2 process

- ✓ Minimally manipulated process
- ✓ Does not disrupt the natural collagen scaffold structure
- ✓ No chemical solvents involved
- ✓ Bactericidal and viral inactivation process
- ✓ Environmental friendly process
- ✓ Can be applied to various tissues and organs
- ✓ Drastically reduce immune rejection

Traditional Processes	Other Processes
Purification of Atelo-collagen and reconstruction of collagen fibers into different forms of medical devices.	Using strong acids, strong alkali, SDS, or organic solvents to de-cell.
Disadvantage	
× Time, space and money consuming × Atelo-collagen can be easily degraded, thus it couldn't be long lasting in the body. × Telo-peptides are hard to be removed completely, and the residues would cause allergic reaction. × Crosslinking agents are added to extend the duration of reconstructed collagen scaffolds. Most chemical cross linking agents are carcinogens, which often cause allergic side reactions. × Collagen reconstruction by existing technology would not be able to replicate the porosity and mechanical strength of natural collagen scaffolds.	× The structure of natural collagen scaffold would be damaged by strong chemicals. × The residues of organic solvents are harmful to human body.



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Best Platform Technology, Taiwan Biopharma Excellence Awards 2022

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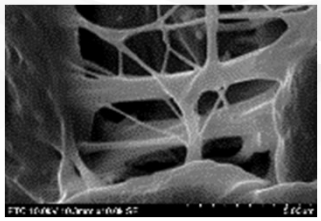
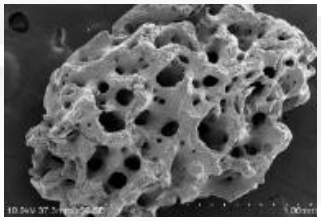
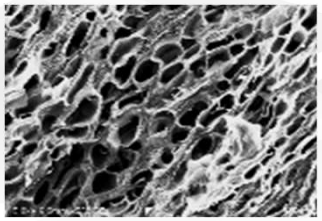
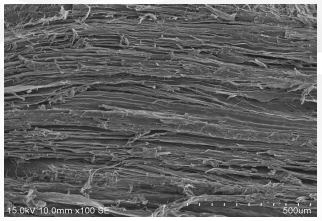
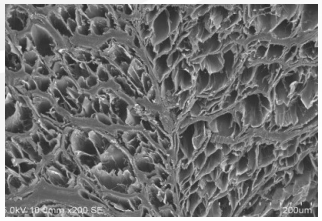
Core Technology– Supercritical CO_2 Extraction Technology

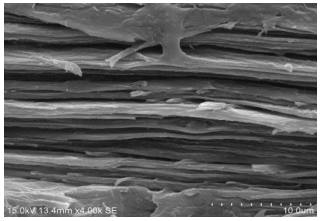

Dermis

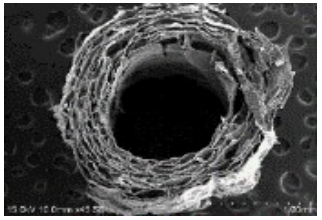

Cancelous Bone

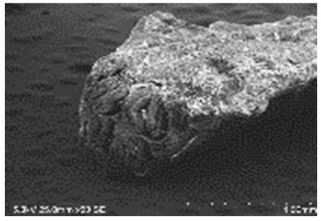

Cartilage

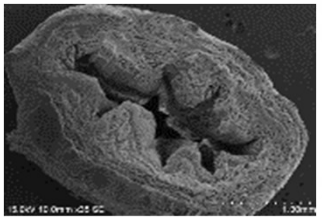

Tendon

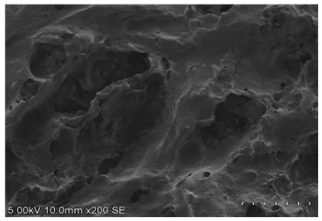

intervertebral disc

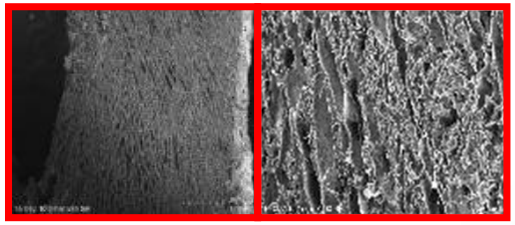

Cornea

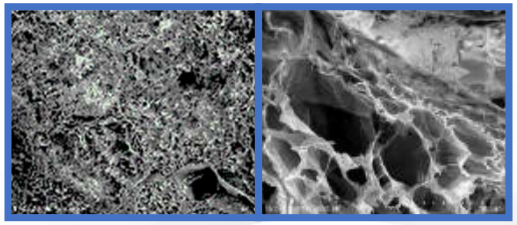

Blood Vessel

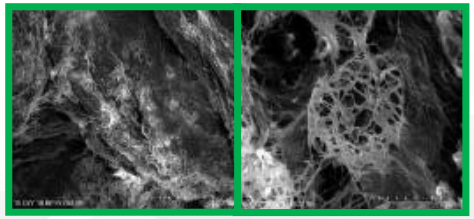

Nerve

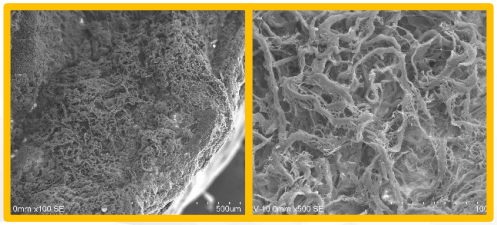

Ureter

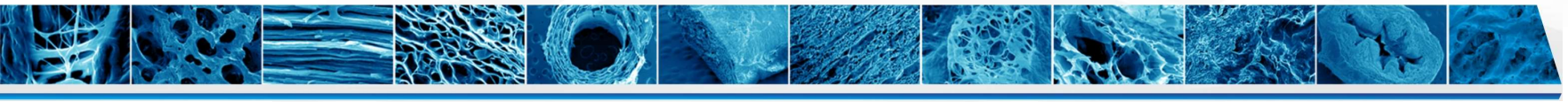

Brain


Heart


Liver


Kidney


Bladder



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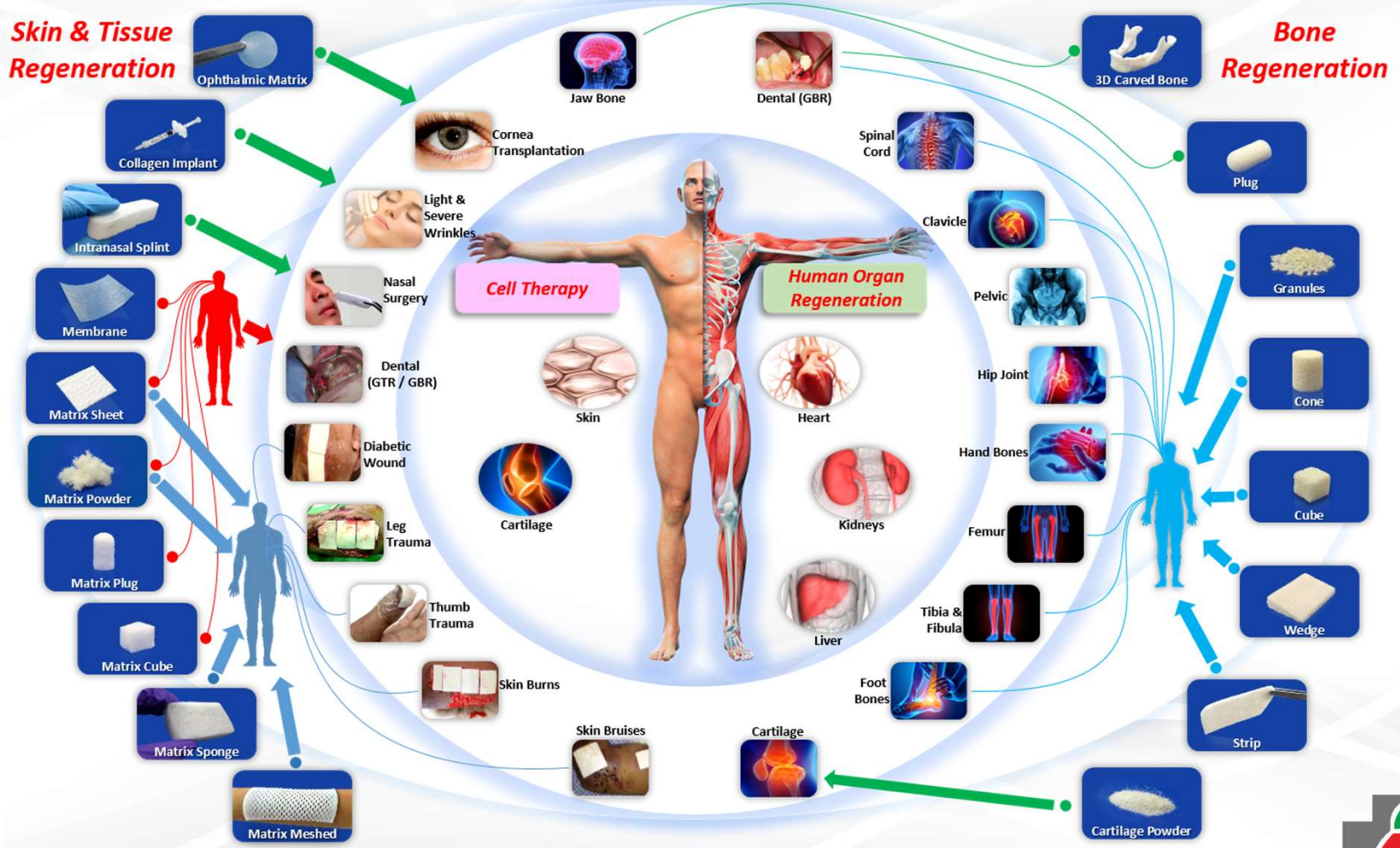
Ultimate Goals



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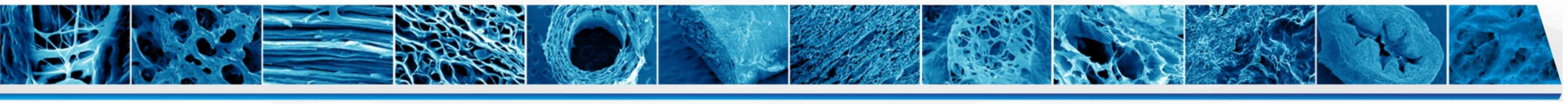
IP Protection

ACRO Patents

	Patent	Field of Application	Region(Country)							
			Taiwan	US	China	Japan	Korea	India	HK	EU
1	Acellular corneas, methods of producing the same and uses thereof	Cornea Transplantation	●	●	●	●	●	●	●	● x8
2	Preparation of acellular cartilage graft and uses thereof	Cartilage Regeneration	●	●	●	●	●	●	●	● x8
3	Preparation of high purity collagen particles and uses thereof	Aesthetic Microsurgery	●	●	●	●	●	●	●	●
4	Apparatus for treating animal skin tissue and a method for using the same	Skin Slicing	●		●				●	
5	Auxillary Slicing Device for Slicing Biological Tissue, Kits Comprising the Same and Uses Thereof	Cornea Slicing	●		●				●	
6	Acellular organ, methods of producing the same and uses thereof	Organ Regeneration	●	●	●	●	●	●	●	●
7	Acellular bone graft and artificial implant assembly comprising the same	Bone Regeneration	●							
8	Use of collagen particles in hair follicles formation or angiogenesis	Hair Regeneration	●	●	●	●	●	●	●	●

● **Granted**

● **Pending**



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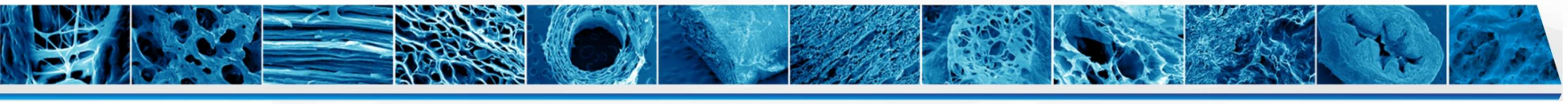
Products for Tissue Engineering



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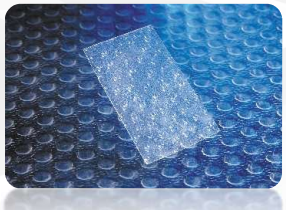
Porcine Skin Derived Products

Collagen Matrix

Collagen Matrix Powder



Collagen Membrane

ADM Particle

Dermal Filler

Atelo-Collagen

Scar Care Dressing

Scar Care Spray

Scar Care Gel

Aesthetic Prosthesis

Skin Care Series
ACRODERM

Eye Care
iMist

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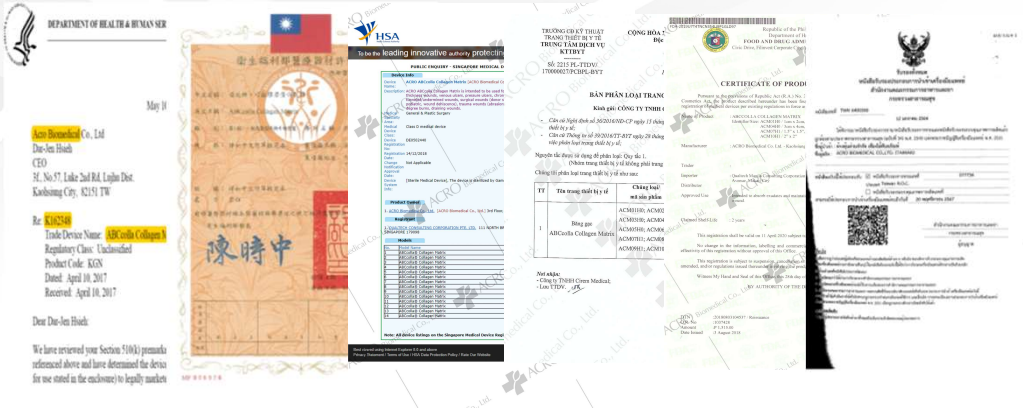
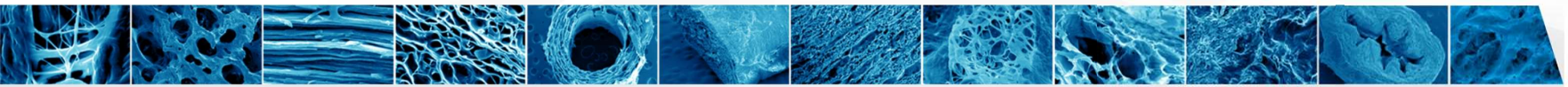
Clinical Applications for Collagen Matrix

- Burn wounds
- Diabetic ulcer wounds
- Traumatic wounds
- Surgical wounds

- Soft tissue augmentation
- Nasal operation
- Breast reconstruction
- Rotator cuff tendon repair
- Phalloplasty
- Dura mater substitute
- Hernia operation



US FDA510(k) , TFDA, HAS, PFDA, VN, TH approval



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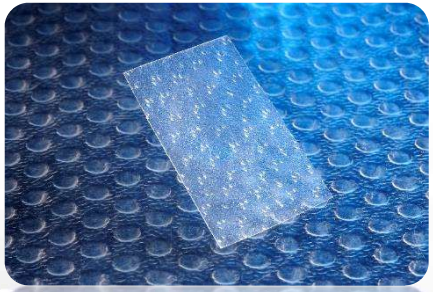
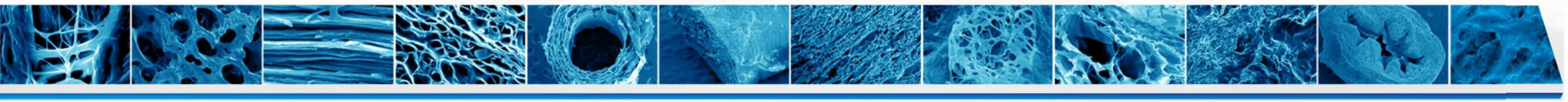
Clinical Applications for Collagen Membrane

- Dental GTR/GBR

- Anti-adhesion in Cardio-surgery(KMBiologics)
- Anti-adhesion in Tendon Repair Surgery
- Anti-adhesion in Nerve Reconstruction Surgery

TFDA, PFDA, TH approval





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Clinical Applications for Collagen ADM Scaffold

- Wound care
- Diabetes mellitus foot wound repair
- Acne scars/Skin potholes repair

- Hair growth

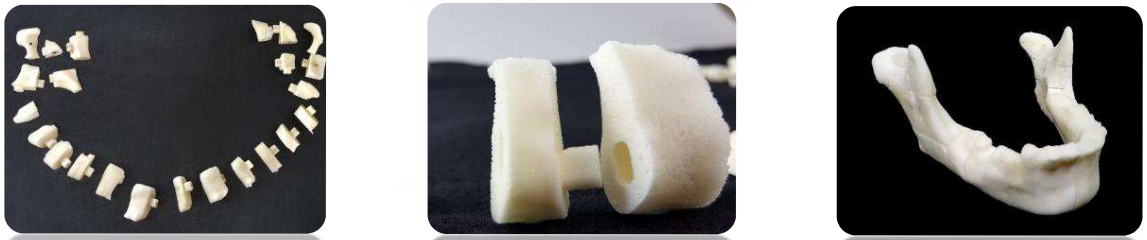
	Normal Saline	Collagen ADM Scaffold <50um	Collagen ADM Scaffold 100-150um	Sculptra	Restylane
Neo-collagen	none	***	**	*	**
Angiogenesis	none	**	**	*	*
Hair follicles	none	**	***	none	*
Inflammation	none	none	none	*	*

TFDA Approval

ACRO Biomedical Co., Ltd.

Porcine Bone Derived Products

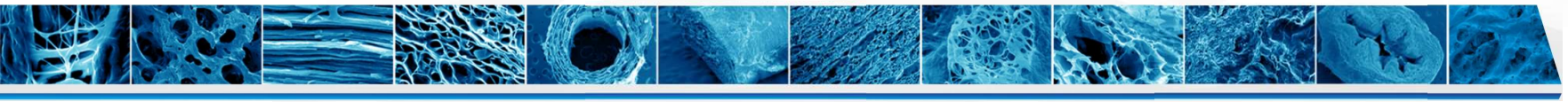
Collagen Bone Graft



"Lego" Bone Graft

Bone Graft Putty

Cartilage Graft



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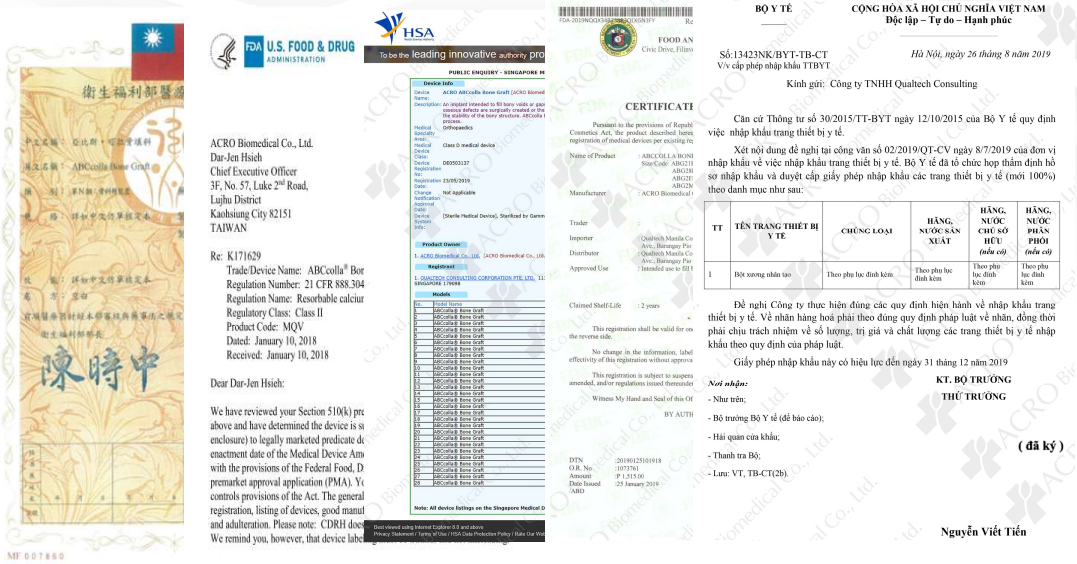
Porcine Bone Derived Products-Bone Graft



ACRO Biomedical Co., Ltd.
Dar-Jen Hsieh
Chief Executive Officer
3F, No. 57, Luke 2nd Road,
Lujhu District
Kaohsiung City 82151
TAIWAN

Re: K171629
Trade/Device Name: ABCcolla® Bor
Regulation Number: 21 CFR 888.304
Regulation Name: Resorbable calciur
Regulatory Class: Class II
Product Code: MQV
Dated: January 10, 2018
Received: January 10, 2018

Dear Dar-Jen Hsieh:

We have reviewed your Section 510(k) pre
above and have determined the device is s
enclosure) to legally marketed predicate de
enactment date of the Medical Device Amo
with the provisions of the Federal Food, D
premarket approval application (PMA). Yo
controls provisions of the Act. The general
registration, listing of devices, good manuf
and adulteration. Please note: CDRH does
We remind you, however, that device label

BỘ Y TẾ

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập – Tự do – Hạnh phúc

Số:13423NK/BYT-TB-CT
V/v cấp phép nhập khẩu TTBYT

Hà Nội, ngày 26 tháng 8 năm 2019

Kính gửi: Công ty TNHH Qualtech Consulting

Căn cứ Thông tư số 30/2015/TT-BYT ngày 12/10/2015 của Bộ Y tế quy định việc nhập khẩu trang thiết bị y tế.

Xét nội dung đề nghị tại công văn số 02/2019/QT-CV ngày 8/7/2019 của đơn vị nhập khẩu về việc nhập khẩu trang thiết bị y tế. Bộ Y tế đã tổ chức họp thẩm định hồ sơ nhập khẩu và duyệt cấp giấy phép nhập khẩu các trang thiết bị y tế (mới 100%) theo danh mục như sau:

TT	TÊN TRANG THIẾT BỊ Y TẾ	CHỦNG LOẠI	HÃNG, NƯỚC SẢN XUẤT	HÃNG, NƯỚC CHỦ SỞ HỮU *(nếu có)*	HÃNG, NƯỚC PHÂN PHỐI *(nếu có)*
1	Bột xương nhân tạo	Theo phụ lục đính kèm	Theo phụ lục đính kèm	Theo phụ lục đính kèm	Theo phụ lục đính kèm

Đề nghị Công ty thực hiện đúng các quy định hiện hành về nhập khẩu trang thiết bị y tế. Về nhãn hàng hoá phải theo đúng quy định pháp luật về nhãn, đồng thời phải chịu trách nhiệm về số lượng, trị giá và chất lượng các trang thiết bị y tế nhập khẩu theo quy định của pháp luật.

Giấy phép nhập khẩu này có hiệu lực đến ngày 31 tháng 12 năm 2019

Nơi nhận:
- Như trên;
- Bộ trưởng Bộ Y tế (để báo cáo);
- Hải quan cửa khẩu;
- Thanh tra Bộ;
- Lưu: VT, TB-CT(2b).

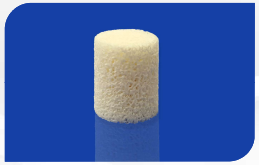
KT. BỘ TRƯỞNG
THỨ TRƯỞNG

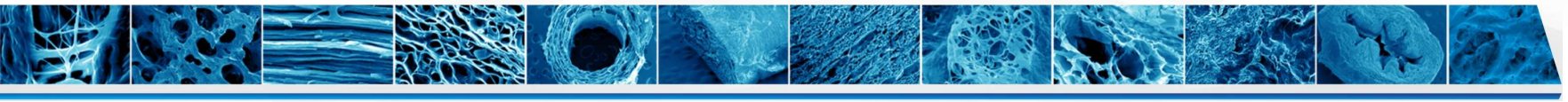
(đã ký)

Nguyễn Viết Tiến

US FDA510(k), TFDA, HAS, PFDA, VN approval for Orthopedics

TFDA, PFDA, TH approval for Dental





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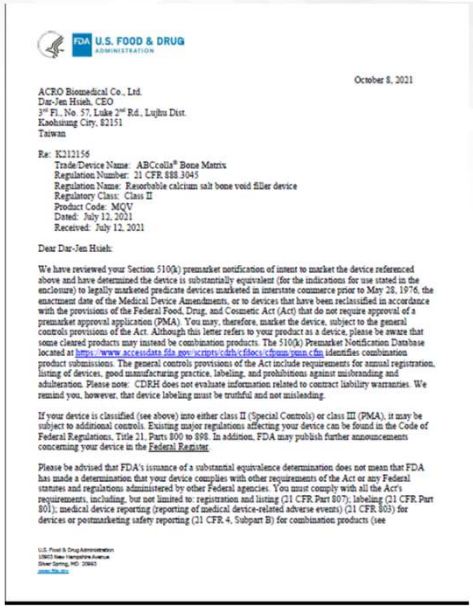
Porcine Bone Derived Products-Bone Matrix



U.S. FOOD & DRUG ADMINISTRATION

October 8, 2021

ACRO Biomedical Co., Ltd.
Dar-Jen Hsieh, CEO
3rd Fl., No. 57, Luke 2nd Rd., Lujhu Dist.
Kaohsiung City, 82151
Taiwan

Re: K212156
Trade/Device Name: ABCcolla® Bone Matrix
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: July 12, 2021
Received: July 12, 2021

Dear Dar-Jen Hsieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

www.fda.gov

US FDA510(k)

衛生福利部醫療器材許可證

衛部醫器製字第006698號

中文名稱：亞比斯可膠原骨基質

英文名稱：ABCcolla Collagen Bone Matrix

類　　別：第N類：骨科用具

規　　格：詳如中文仿單核定本

製造廠名稱：亞果生醫股份有限公司

製造廠地址：南部科學園區高雄市路竹區路科二路37號3樓

效　　能：詳如中文仿單核定本

處　　方：空白

前項醫療器材經本部審核與藥事法之規定相符准予許可特此證明

衛生福利部部長

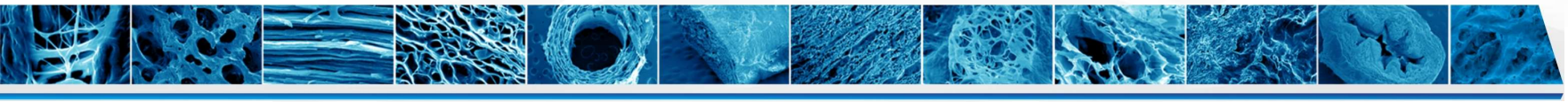
陳時中

許證日期 109 年 06 月 08 日

有效日期 114 年 06 月 08 日

MF 012533

TFDA



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Porcine Bone Derived Products-EZ Bone

TFDA

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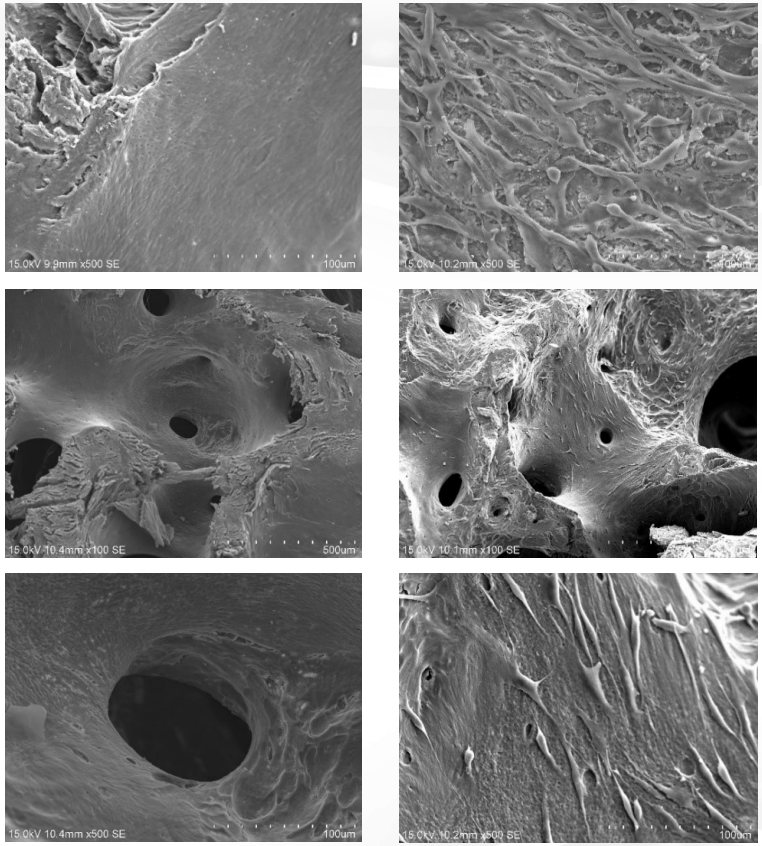
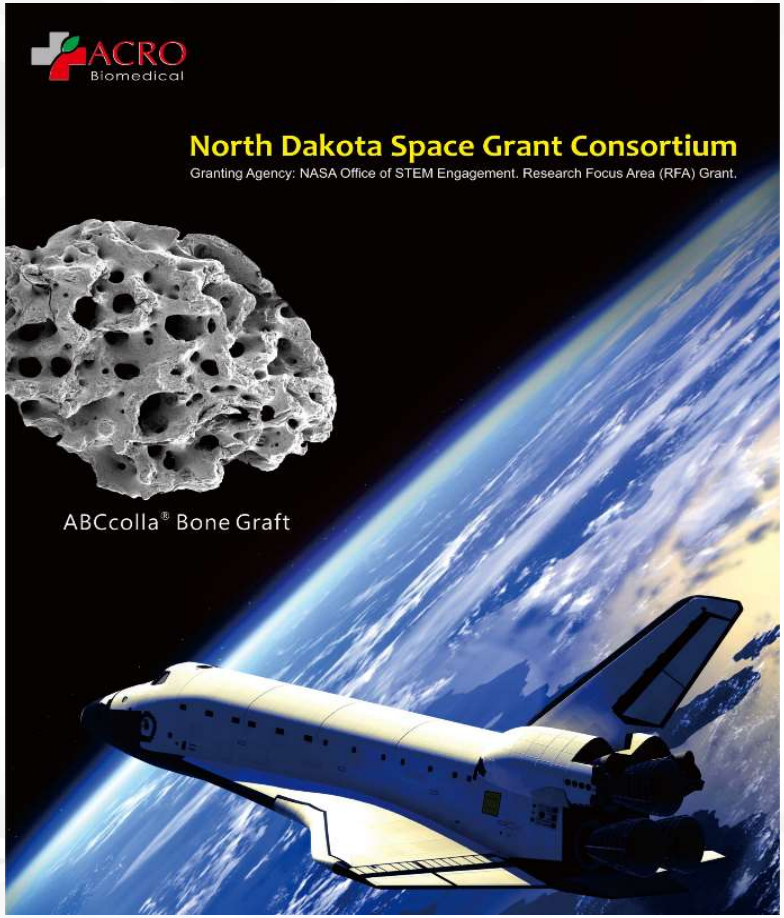
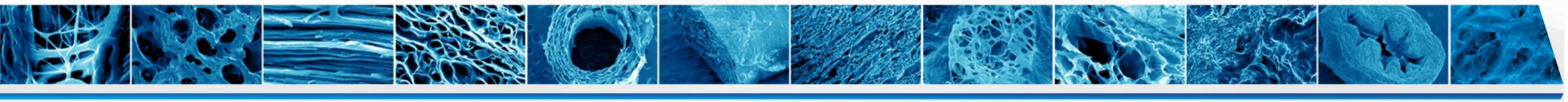
Excellent Biocompatibility



Bone graft only　　Bone graft + MG63 Cell





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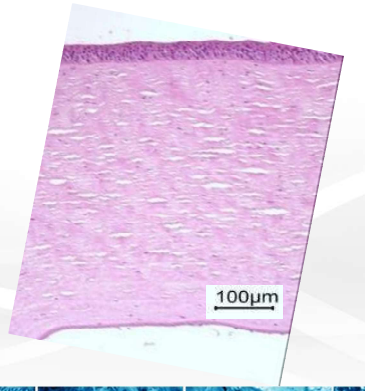
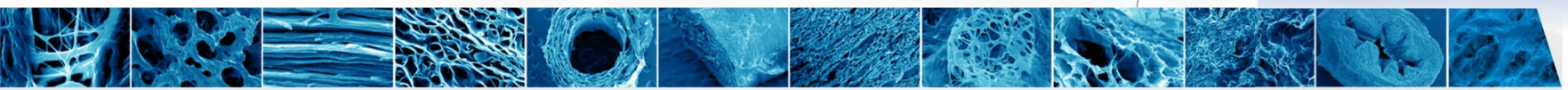
Backgrounds of Cornea Graft Development

- According to WHO statistic, there are more than 20 million people suffered from corneal blindness. 600,000 new cases add in each year but only less than 100,000 cornea transplantation is done every year. There is an extreme shortage of cornea donation.
- In Asia, donation of the cornea is not a common practice, many are waiting in line for donated cornea.
- Donated human corneas carry the cells from donor, which cause immune rejection by recipient. Immune suppressing drug is often needed for recipient for a long time.
- The eye balls are similar to human eye balls in size and the histological structures of pig cornea are the same to those of human cornea.





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Cornea Graft Manufacturing Processes

1. Harvest Cornea From Porcine Eyes

Figure (a). Porcine eyes were stored in the -20 °C freezer

Figure (b). Thawed the porcine eyes

Figure (d). The cornea is completely taken off.

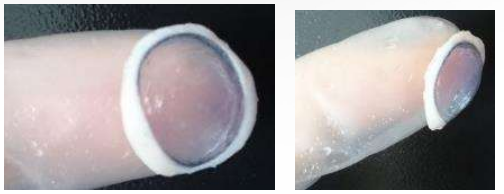

Figure (e). Cornea including sclera is removed completely from the porcine eye.

2. De-cellularization

Minimally Manipulated Process

Pretreatment

Supercritical CO_2 Process

Neutralization

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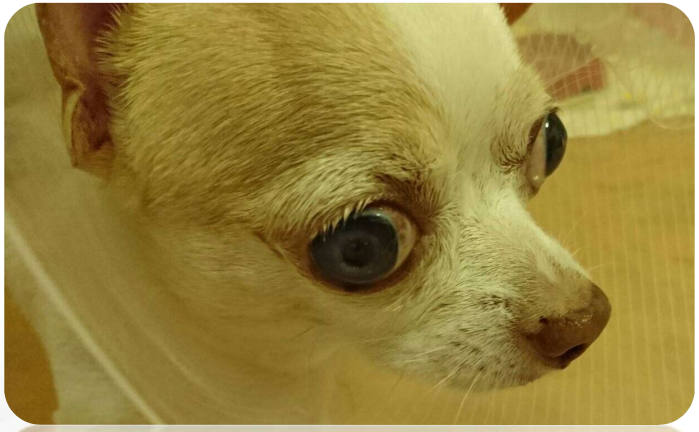
Canine Corneal Transplantation- Bunny

Penetrating Keratoplasty

Bunny before the Surgery: Damaged cornea (right eye) was turbid

Bunny after the surgery: Cornea is clear after the surgery, and showed no signs of rejection



Bunny's successful case is the FIRST in the whole world which used artificial cornea graft and showed no signs of rejection

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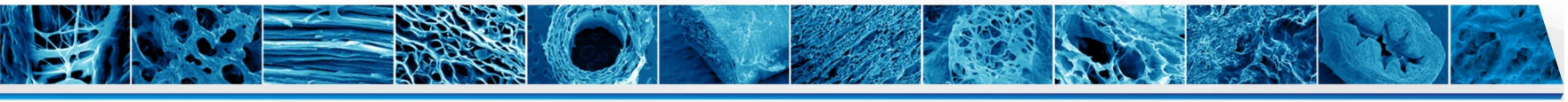
Human Clinical Trials in Taiwan

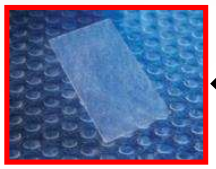
The human clinical trial was initiated for cornea transplantation in four medical centers in Taiwan.



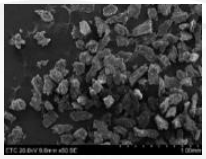
Dermal Filler Manufacturing Processes




Thin slice to 0.2-0.5mm



Collagen Membrane



50-250um particles

SEM

Homogenization

Dermal Filler

ABCcolla® Collagen Membrane

ISO-10993 Biocompatibility Tests	Result	Completion Date
Acute Systemic Toxicity Study	PASS	2016.02.08
Skin Sensitization Study	PASS	2016.02.08
Skin Irritation Test	PASS	2016.02.08
In Vitro Cytotoxicity Test	PASS	2016.08.11
Hemolysis Test	PASS	2016.05.11
Pyrogen Test	PASS	2016.03.16
Mice Erythrocyte Micronucleus Test	PASS	2016.09.26
In Vitro Mammalian Cell Gene Mutation Test	PASS	2016.10.26
Salmonella Reverse Mutation Test	PASS	2016.08.29
28 Days Repeat-Dose Subchronic Systemic Toxicity Study	PASS	2016.06.30
90 Days Muscle Implant Study 180 Days Muscle Implant Study	PASS	2017.01.20 2016.07.30

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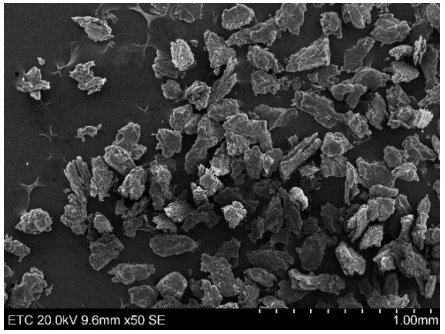
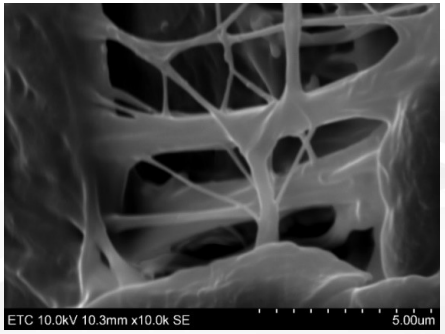
Micro-Particle Dermal Filler

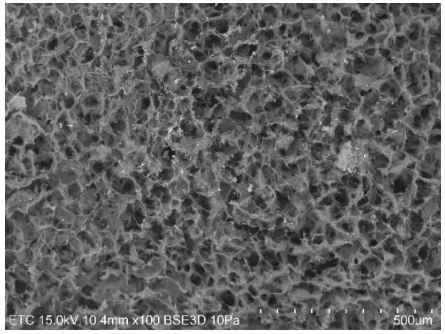
The micro-particle form collagen dermal filler developed by ACRO Biomedical is the brand new invention, which is able to last longer in the body than similar products on the market, and will not cause allergic reaction. It is predicted to occupy substantial percentage of global market share in the field of Aesthetic Microsurgery.

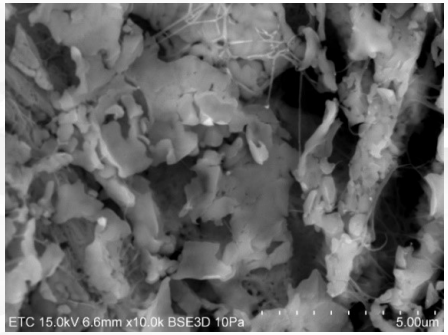
Micro-Particles by ACRO





vs. Traditional Dermal Filler





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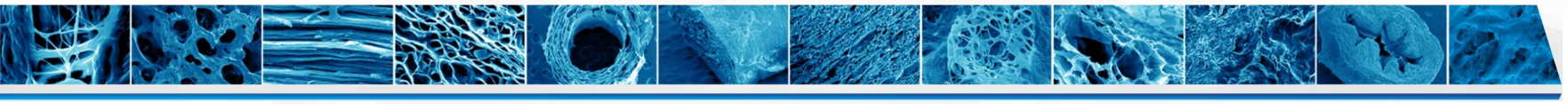
Third Generation Dermal Filler

Generation	I			II				III
Product Name	Zyderm	Cosmoderm	Sunmax I	Zyplast	Cosmoplast	Evolence	Sunmax I-plus	ABCcolla Dermal Filler
Approval Date	1991	2003	2006TFDA 2009CFDA	1985	2003	2006	2008TFDA 2011CFDA	
Non-Immunogenic		v	v		v	v	v	v
Crosslinked				v	v	v	v	
Allergic Reaction	3%	<1%	1%	>3%	<1%	1%	>1%?	<1%
Product lasts after injection	3 months	3 months	3 months	6 months	6 months	6 months	6 months	>12 months
Price/c.c.(USD)	200-400	300-600	1500	500-600	600-900	450-1000	2200	TBD
Natural Scaffold								v
Natural Mechanical Strength								v
Fibroblast Attachment								v



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ADM particles vs. other dermal fillers

ADM Particle Animal Performance Test

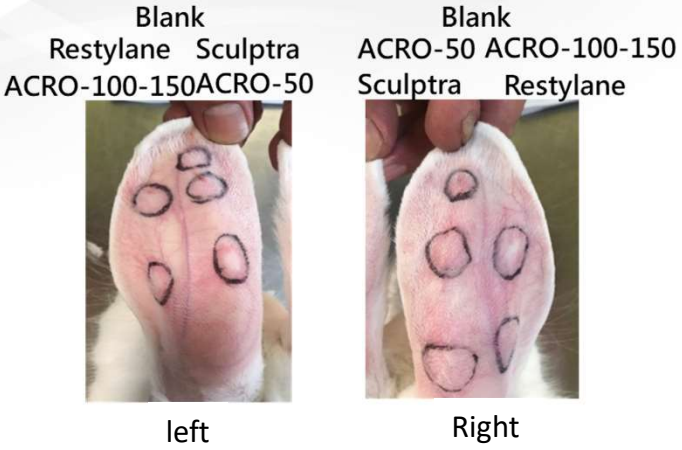
Blank

ACROGEN <50 μm　硬塊維持約2天

ACROGEN 100-150 μm　硬塊維持約2天

Sculptra　30天仍有硬塊

Restylane　30天仍有硬塊



left　Right

Day30 → Masson Trichrome staining

	Blank	ACROGEN <50 μm	ACROGEN 100-150 μm	Sculptra	Restylane
Neo-collagen	no、no	+++、+++	++、++	+、+	++、++
Angiogenesis	no、no	++、+	++、++	+、+	+、+
Inflammation	no、no	no、no	no、no	+、+	+、+
Hair follicles	no、no	++、++	+++、+++	no、no	+、+

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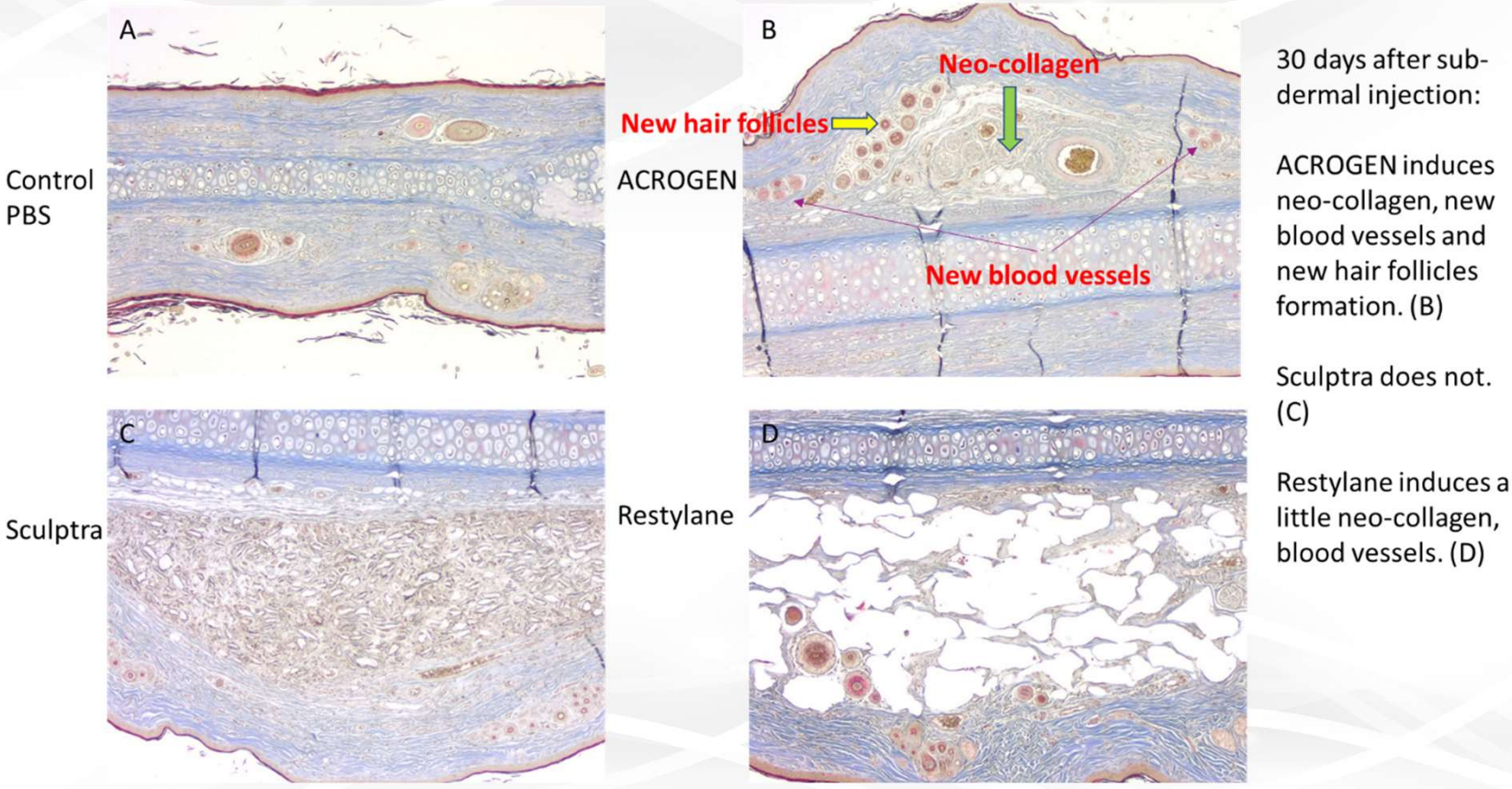
ADM particles vs. other dermal fillers

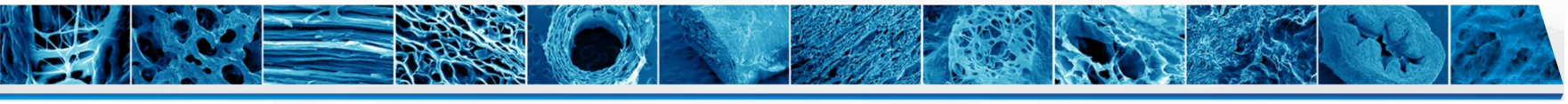


30 days after sub-dermal injection:

ACROGEN induces neo-collagen, new blood vessels and new hair follicles formation. (B)

Sculptra does not. (C)

Restylane induces a little neo-collagen, blood vessels. (D)



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ADM particles stimulate hair growth in nude mice

Day 0

Day 30

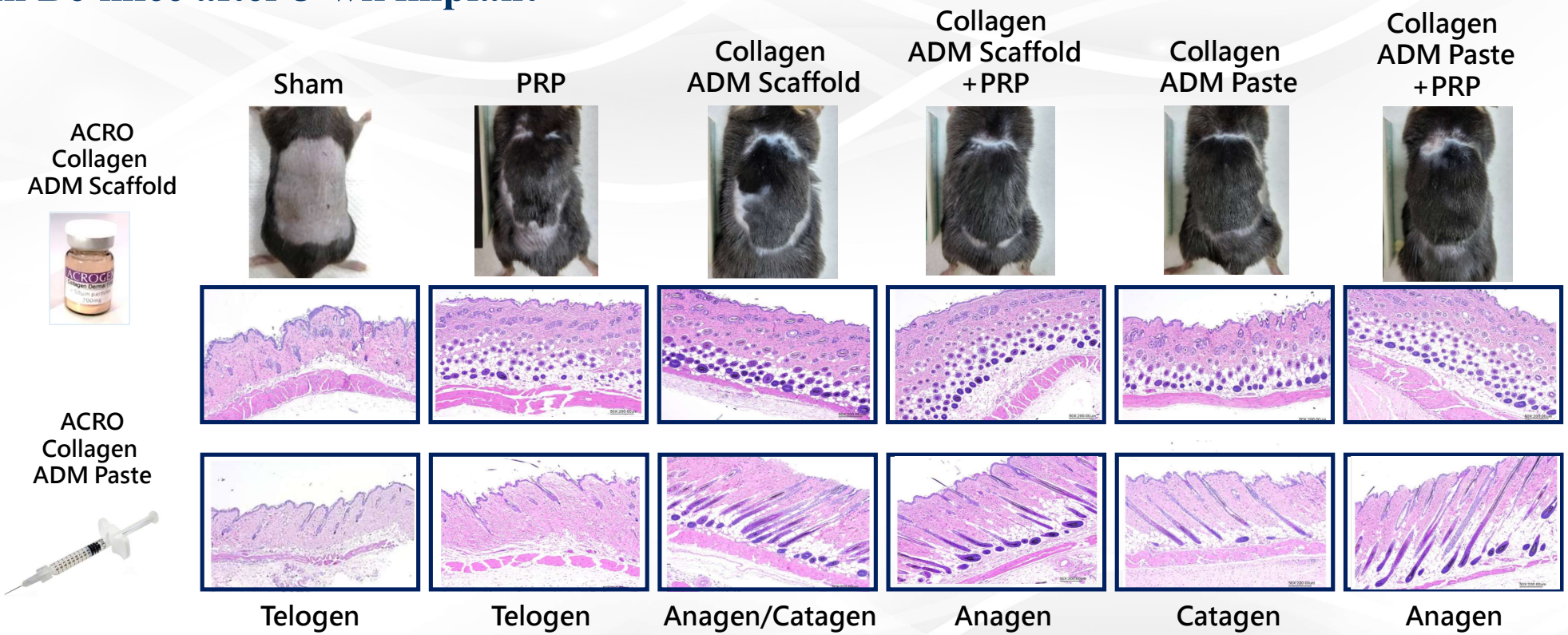
ADM particles

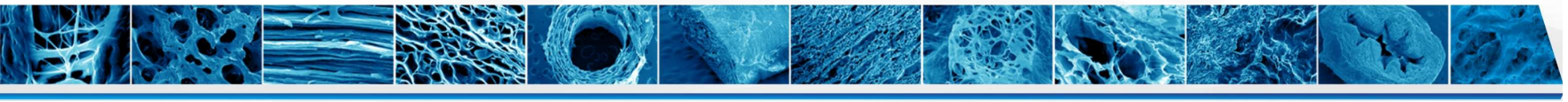
ADM particles + PRP

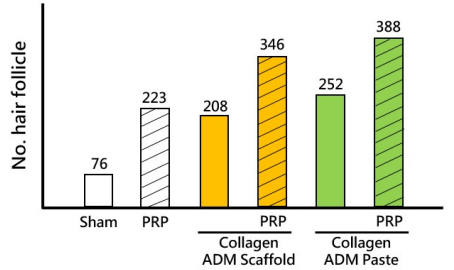
Treated every 3 days

Treated every 7 days

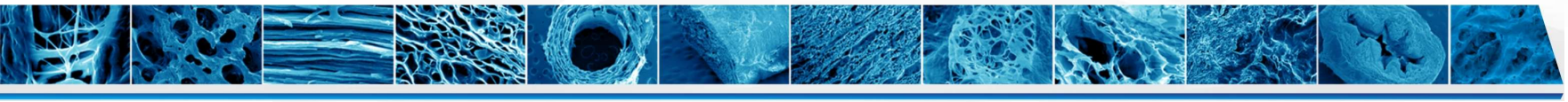
Collagen ADM Scaffold and Collagen ADM Paste induce hair follicle neo-genesis/re-activation in B6 mice after 3-wk implant







Cell therapy



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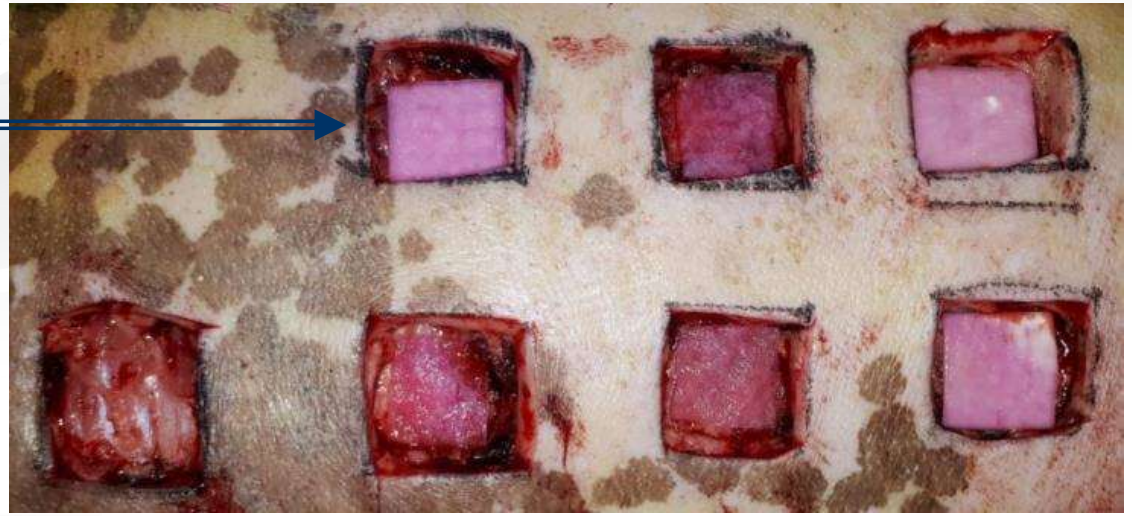
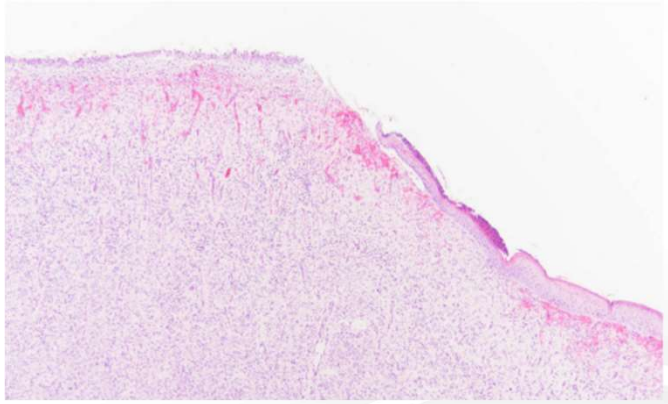
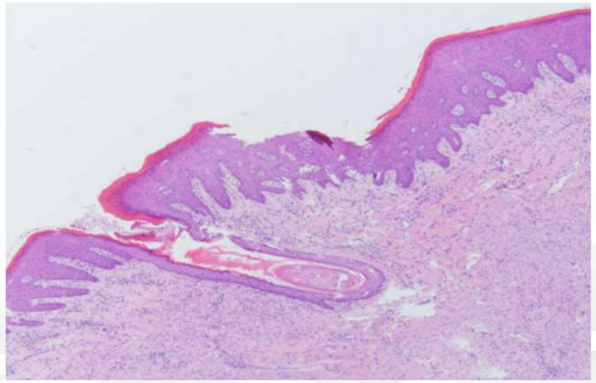
Skin Cell Therapy

Human mesenchymal stem cells(MSC) were cultured on the Collagen Matrix scaffold and then put on the wound bed.



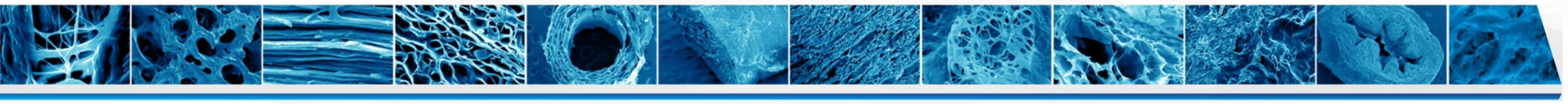


Collagen Matrix alone



Collagen Matrix + hMSC

MSC differentiated into epidermal, dermal layers and also hair follicle structure



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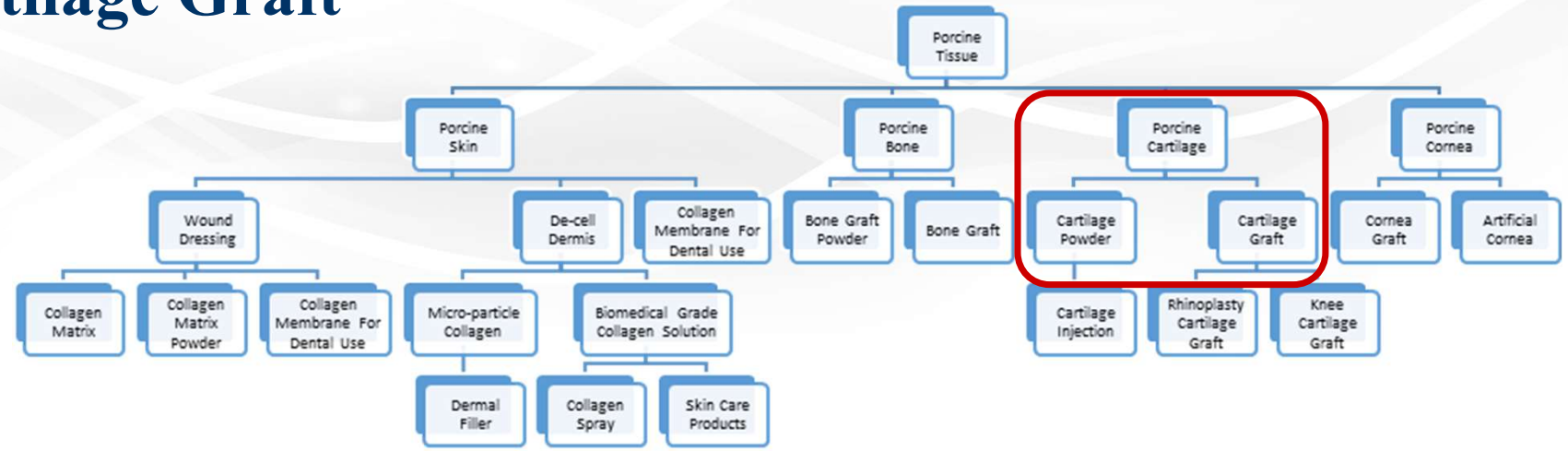
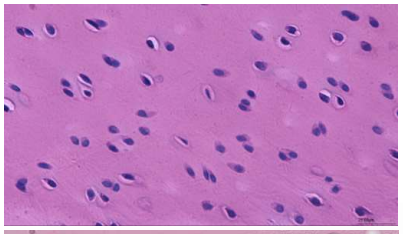
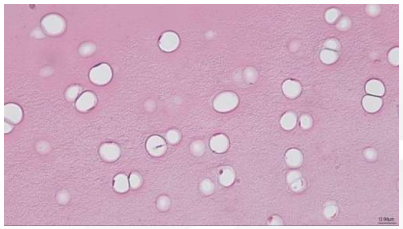
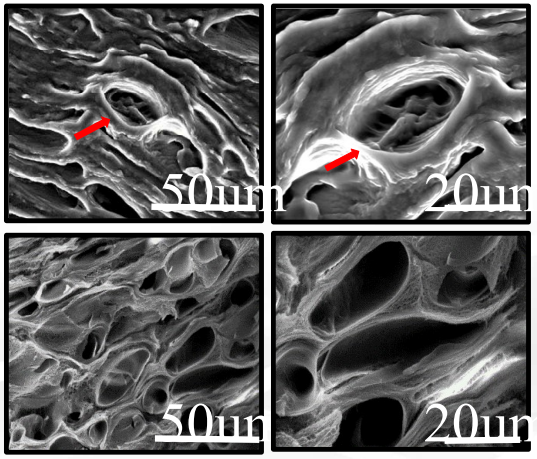
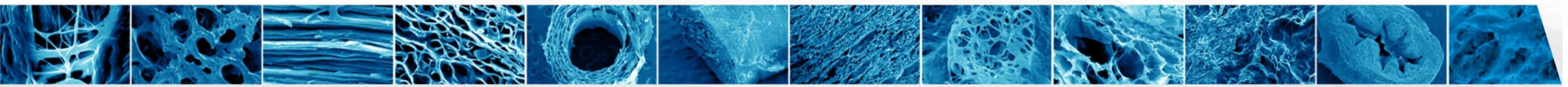
Cartilage Graft











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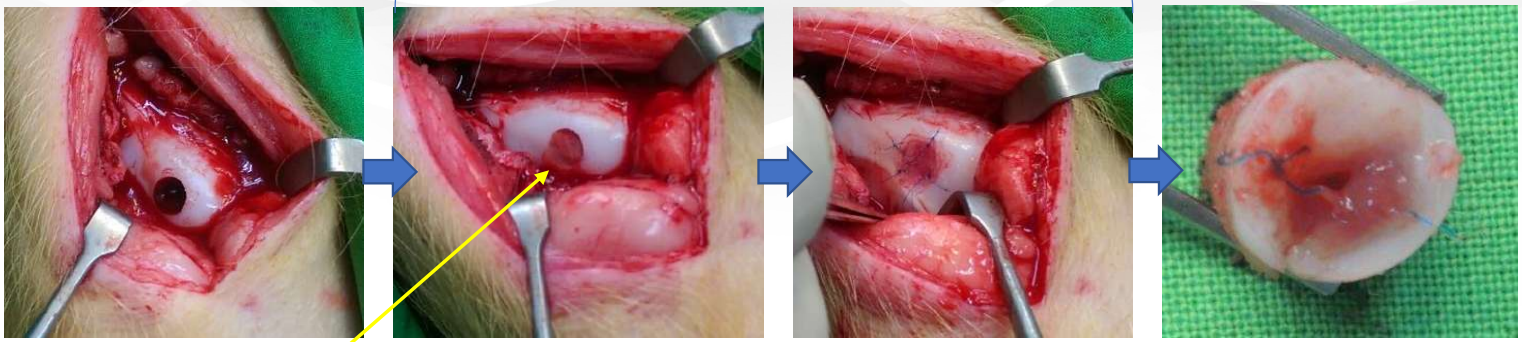
Knee Joint Cell Therapy

Created defect
(diameter:7mm)

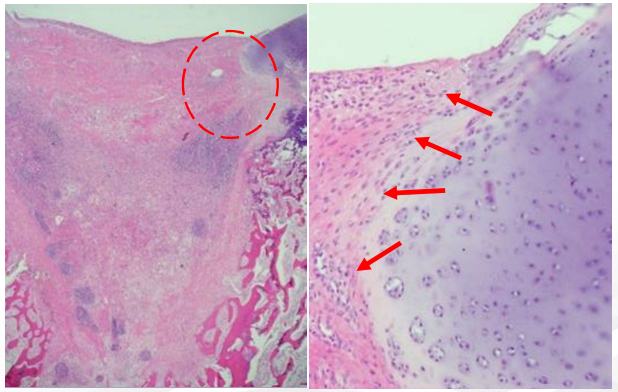
Transplant the 3D construct

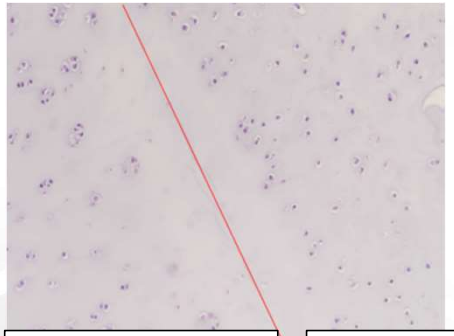
Collect tissue 1 month after
transplantation



The cartilage defect can be completely reconstructed in 30 days and restored to the same structure as the original cartilage tissue.

Cartilage Graft
+ PRP
+ Chondrocytes





Original cartilage | Transplanted cartilage

- Result: Excellent cartilage reconstruction after 1 month

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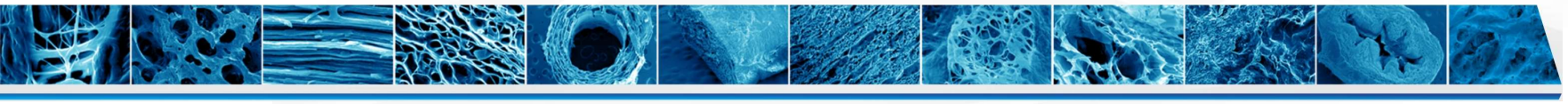
Organ engineering



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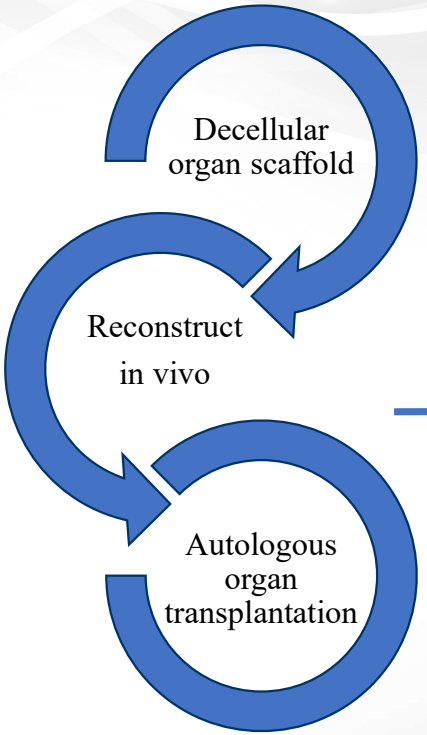
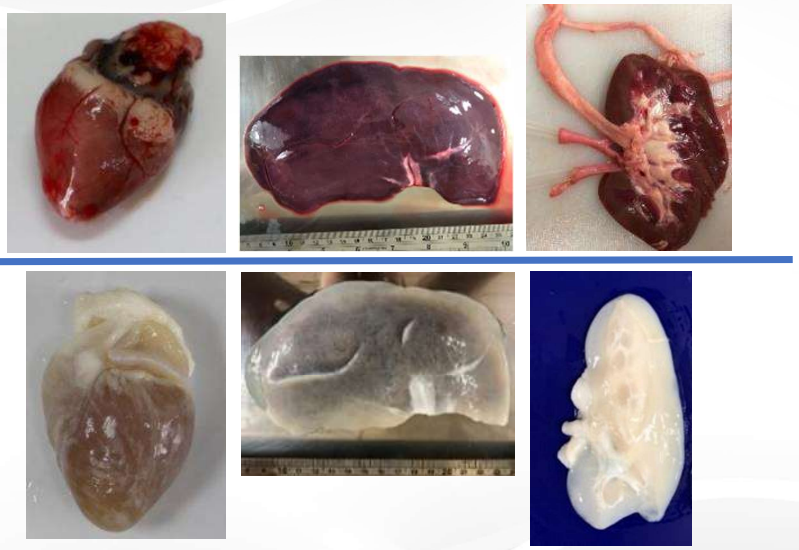
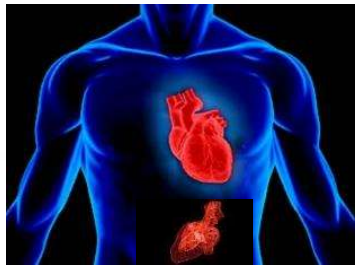
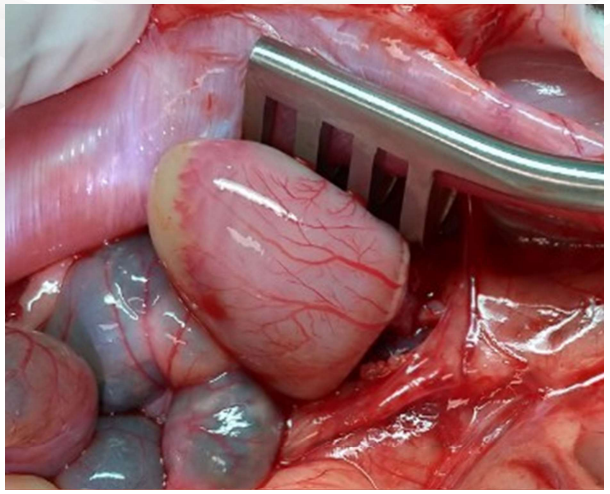
Organ Engineering



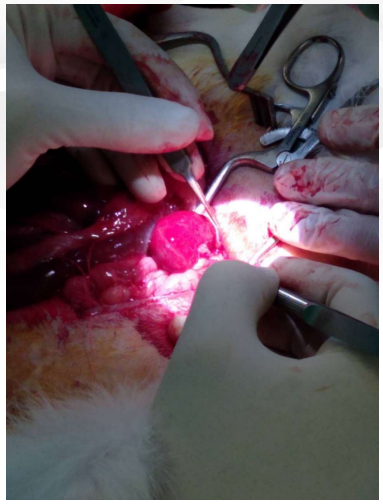


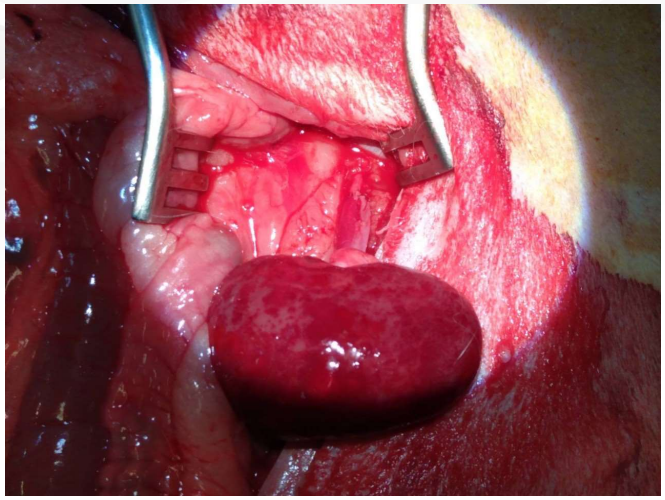


Organ Engineering-Rabbit Heart Reconstruction

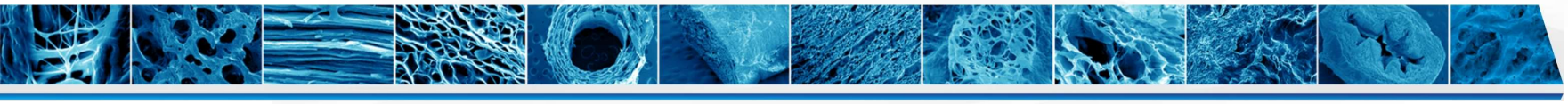


Organ Engineering-Rabbit Kidney Reconstruction





Products for Research Use Only

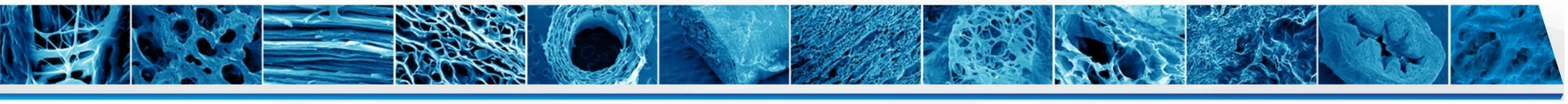


ACRO Biomedical Co., Ltd.

Tissue and Organ Collagen Scaffolds

- Cell Culture Plate

Brain, Kidney, Liver, Pancreas, Heart, Whole Skin, Dermis, Cancellous Bone, Cornea, Cartilage



ACRO Biomedical Co., Ltd.

Tissue and Organ Collagen Scaffold Powders

Native collagen scaffold powders derived from porcine tissues and organs, decellularized by supercritical CO2 extraction technology and then cryo-grinded into fine particles. All scaffold particles retain their native ECM structures, suitable for 3D bioprinting to generate all kinds of tissues and organoids for research purposes.


Dermis Scaffold Powder


Corneal Scaffold Powder


Cancellous Bone Scaffold Powder

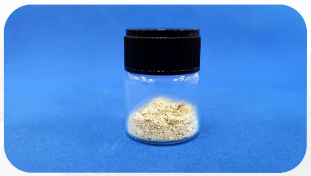

Cartilage Scaffold Powder

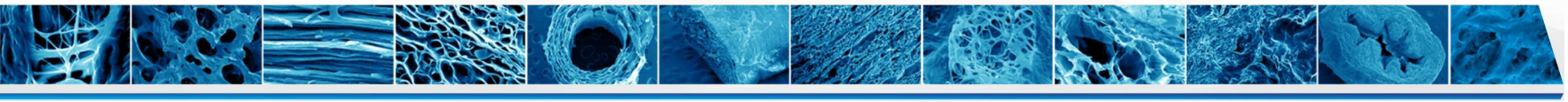

Liver Scaffold Powder


Kidney Scaffold Powder


Brain Scaffold Powder


Pancreas Scaffold Powder


Heart Scaffold Powder



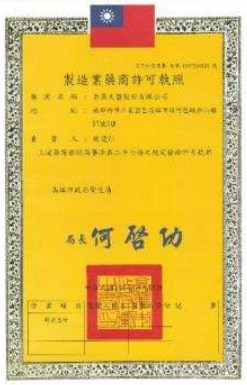
ACRO Biomedical Co., Ltd.

Publications

Read full articles here: http://www.acrobiomedical.com/index.php?option=module&lang=en&task=showlist&id=616&index=3

Product	Content	Title	Journal	IF	Status	Corresponding Author
Cornea	lamellar keratoplasty	Preparation of acellular scaffold for corneal tissue engineering by supercritical carbon dioxide extraction technology	Acta Biomaterialia 2017	8.947	Published	Dr. Ming-Long Yeh
Collagen matrix	Diabetic wound healing	Supercritical Carbon Dioxide–decellularized Porcine Acellular Dermal Matrix combined with Autologous Adipose-derived Stem Cells: Its Role in Accelerated Diabetic Wound Healing.	International journal of medical sciences 2020	3.738	Published	Dr. Shu-Hung Huang
Collagen matrix	Wound healing	Regenerative porcine dermal collagen matrix developed by supercritical carbon dioxide extraction technology: Role in accelerated wound healing.	Materialia (Acta Biomaterialia Inc.) 2020	8.947	Published	Dr. Yih-Wen Tarng
Atelo-collagen	Production and purification	Protocols for accelerated production and purification of collagen scaffold and atelo-collagen from animal tissues.	Bio Technique 2020	1.993	Published	Dr. Dar-Jen Hsieh
Organ scaffold	Organ scaffold	Protocols for the preparation of natural tissue and organ scaffolds for stem cell research and 3D bioprinting.	Bio Technique 2020	1.993	Published	Dr. Dar-Jen Hsieh/ Dr.Yih-Wen Tarng
Bone graft	Part – I-Production and characterization	Development of a regenerative decellularized porcine bone xenograft by supercritical carbon dioxide extraction technology for bone reconstruction therapy.	Journal of tissue engineering and regenerative medicine 2020	3.963	Published	Dr. Hua-Hong Chien
Bone graft	Part – II-Efficacy in tooth extraction socket	Evaluating the bone-regenerative role of the decellularized porcine bone xenograft in a canine extraction socket model.	Clinical and Experimental Dental Research 2021	Ranked #73/111	Published	Dr. Hua-Hong Chien
Cartilage	*In vitro* and *in vivo* efficacy	3D composite engineered using supercritical CO2 decellularized porcine cartilage scaffold, chondrocytes and PRP: Role in articular cartilage regeneration	Journal of tissue engineering and regenerative medicine 2021	3.963	Published	Dr. Yih-Wen Tarng
Cartilage	*In vitro* -ADSC	Novel 3D composite-chondrocyte cultured with supercritical carbon dioxide decellularized porcine nasal cartilage graft	International journal of medical sciences 2021	3.738	Published	Dr.Yun-Nan Lin
Ophthalmic matrix	Biocompatibility	Acellular porcine cornea produced by supercritical carbon dioxide extraction, a potential substitute for human corneal regeneration	Cornea 2021	2.651	Published	Dr. Ming-Cheng Tai
Cartilage	ACLT-rat model	Supercritical carbon dioxide decellularized porcine cartilage graft with PRP attenuated OA progression and regenerated articular cartilage in ACLT-induced OA rats.	Journal of tissue engineering and regenerative medicine 2021	3.963	Published	Dr. Dar-Jen Hsieh
Bone graft	Orbital bone reconstruction	Reconstruction of the orbital floor using supercritical CO2 decellularized porcine bone graft	International journal of medical sciences 2021	3.738	Published	Dr. Su-Shin Lee
Bone matrix	Bone matrix-ADSC	Supercritical Carbon Dioxide Decellularized Bone Matrix Seeded with Adipose-Derived Mesenchymal Stem Cells Accelerated Bone Regeneration	Biomedicine 2021	6.081	Published	Dr. Yur-Ren Kuo
3D Carved Bone	Personalized bone repair	Supercritical Carbon Dioxide Decellularized Xenograft 3D CAD/CAM Carved Bone Matrix Personalized for Human Bone Defect Repair	Genes 2022	4.339	Published	Dr. Dar-Jen Hsieh

Certificates



Pharmacist manufacturing license

ISO13485

GMP

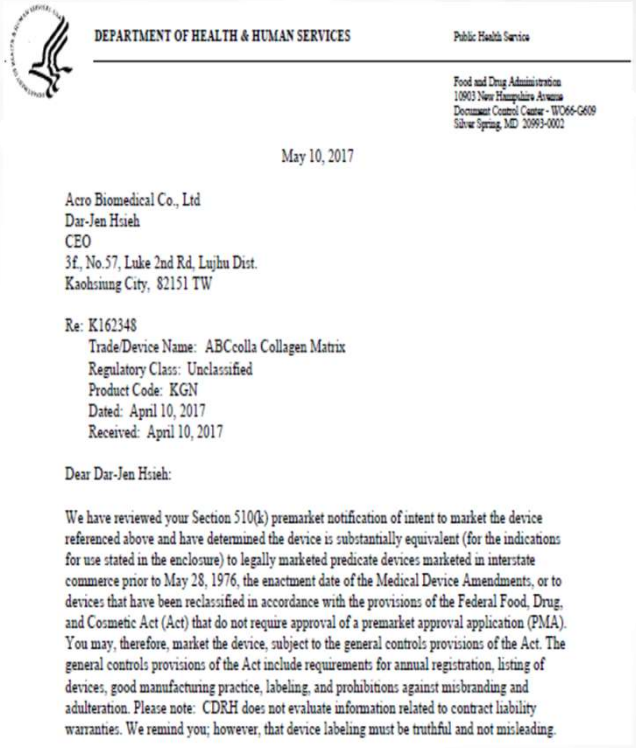
FDA MAF2771

Class I Medical Devices TFDA/CE Mark/US FDA

ACRO Biomedical Co., Ltd.

Certificates

FDA 510(K) Collagen Matrix



DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 10, 2017

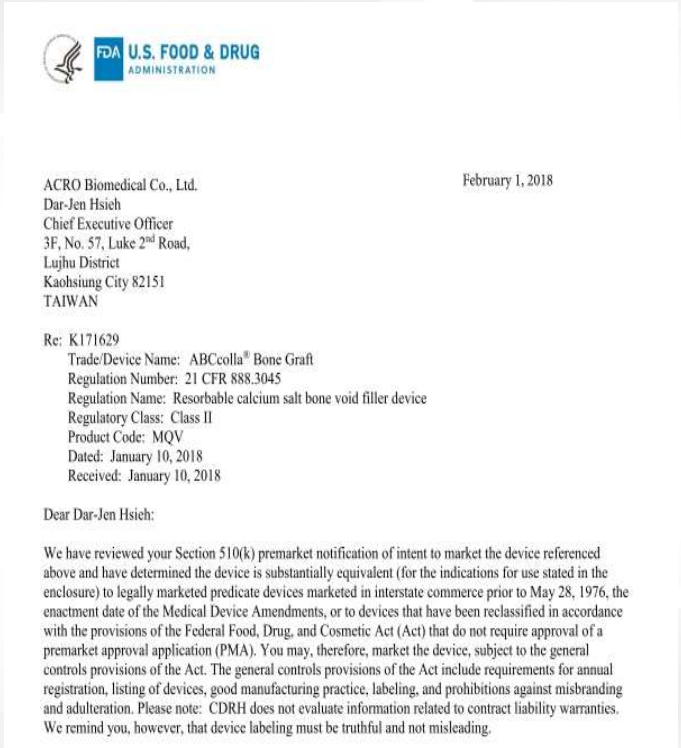
Acro Biomedical Co., Ltd
Dar-Jen Hsieh
CEO
3f., No.57, Luke 2nd Rd, Lujhu Dist.
Kaohsiung City, 82151 TW

Re: K162348
Trade/Device Name: ABCcolla Collagen Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: April 10, 2017
Received: April 10, 2017

Dear Dar-Jen Hsieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

FDA 510(K) Bone Graft



FDA U.S. FOOD & DRUG ADMINISTRATION

February 1, 2018

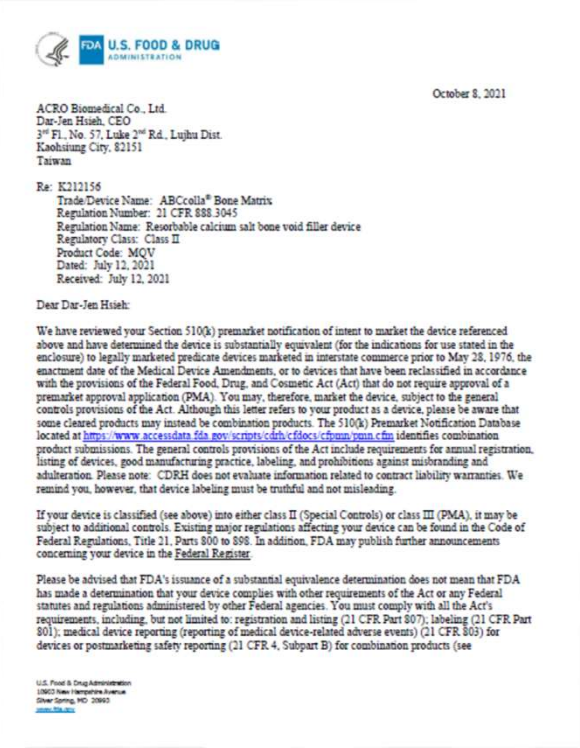
ACRO Biomedical Co., Ltd.
Dar-Jen Hsieh
Chief Executive Officer
3F, No. 57, Luke 2nd Road,
Lujhu District
Kaohsiung City 82151
TAIWAN

Re: K171629
Trade/Device Name: ABCcolla® Bone Graft
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: January 10, 2018
Received: January 10, 2018

Dear Dar-Jen Hsieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

FDA 510(K) Bone Matrix



FDA U.S. FOOD & DRUG ADMINISTRATION

October 8, 2021

ACRO Biomedical Co., Ltd.
Dar-Jen Hsieh, CEO
3rd Fl., No. 57, Luke 2nd Rd., Lujhu Dist.
Kaohsiung City, 82151
Taiwan

Re: K212156
Trade/Device Name: ABCcolla® Bone Matrix
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: July 12, 2021
Received: July 12, 2021

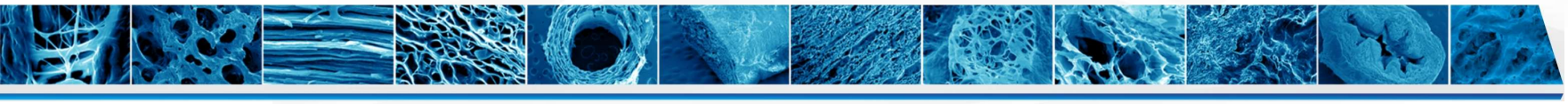
Dear Dar-Jen Hsieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993



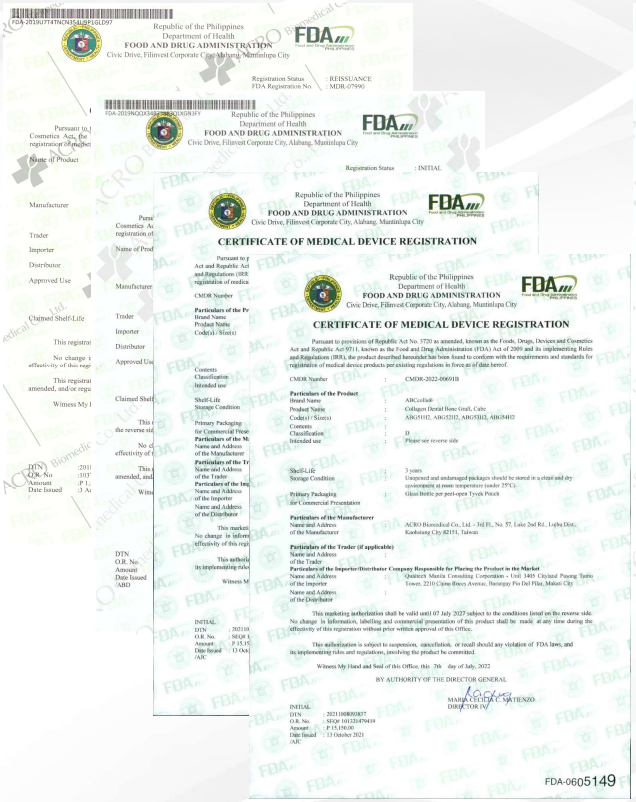
ACRO Biomedical Co., Ltd.

Certificates

Collagen Matrix/ Collagen Bone Graft/ Dental Bone Graft/ Collagen Membrane/ Collagen Bone Matrix/EZ Bone/ADM Scaffold

ACRO Biomedical Co., Ltd.

Certificates From Singapore/Philippines/Vietnam/Thailand



TRƯỜNG CĐ KỸ THUẬT TRANG THIẾT BỊ Y TẾ
TRUNG TÂM DỊCH VỤ KT TBYT
Số: 2215 PL-TTDV/ 170000027/PCBPL-BYT

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc

Hà Nội, ngày 10 tháng 10 năm 2018

BẢN PHÂN LOẠI TRANG THIẾT BỊ Y TẾ

Kính gửi: CÔNG TY TNHH CIREM MEDICAL

- *Căn cứ Nghị định số 36/2016/NĐ-CP ngày 15 tháng 5 năm 2016 của Chính phủ về quản lý trang thiết bị y tế;*
- *Căn cứ Thông tư số 39/2016/TT-BYT ngày 28 tháng 10 năm 2016 của Bộ trưởng Bộ Y tế quy định việc p*

Nguyên tắc

Chúng tôi p

TT	Tê
1	ABC

Nơi nhận:
- Công ty T
- Lưu TTD

BỘ Y TẾ
CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập – Tự do – Hạnh phúc

Số:13423NK/BYT-TB-CT
V/v cấp phép nhập khẩu TTBYT

Hà Nội, ngày 26 tháng 8 năm 2019

Kính gửi: Công ty TNHH Qualtech Consulting

Căn cứ Thông tư số 30/2015/TT-BYT ngày 12/10/2015 của Bộ Y tế quy định việc nhập khẩu trang thiết bị y tế.

Xét nội dung đề nghị tại công văn số 02/2019/QT-CV ngày 8/7/2019 của đơn vị nhập khẩu về việc nhập khẩu trang thiết bị y tế. Bộ Y tế đã tổ chức họp thẩm định hồ sơ nhập khẩu và duyệt cấp giấy phép nhập khẩu các trang thiết bị y tế (mới 100%) theo danh mục như sau:

TT	TÊN TRANG THIẾT BỊ Y TẾ	CHỦNG LOẠI	HÃNG, NƯỚC SẢN XUẤT	HÃNG, NƯỚC CHỦ SỞ HỮU *(nếu có)*	HÃNG, NƯỚC PHÂN PHỐI *(nếu có)*
1	Bột xương nhân tạo	Theo phụ lục đính kèm	Theo phụ lục đính kèm	Theo phụ lục đính kèm	Theo phụ lục đính kèm

Đề nghị Công ty thực hiện đúng các quy định hiện hành về nhập khẩu trang thiết bị y tế. Về nhãn hàng hoá phải theo đúng quy định pháp luật về nhãn, đồng thời phải chịu trách nhiệm về số lượng, trị giá và chất lượng các trang thiết bị y tế nhập khẩu theo quy định của pháp luật.

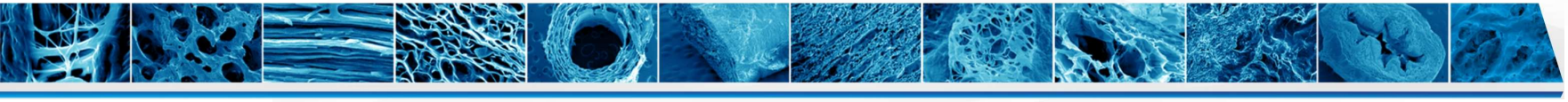
Giấy phép nhập khẩu này có hiệu lực đến ngày 31 tháng 12 năm 2019

Nơi nhận:
- Như trên;
- Bộ trường Bộ Y tế (để báo cáo);
- Hải quan cửa khẩu;
- Thanh tra Bộ;
- Lưu: VT, TB-CT(2b).

KT. BỘ TRƯỞNG
THỨ TRƯỞNG

(đã ký)

Nguyễn Viết Tiến



ACRO Biomedical Co., Ltd.

Awards

2017 National Innovation Award
(Collagen Ophthalmic Matrix)

2018 Taiwan Golden Root Award

2018 ASPA Excellence Prize

2019 Hangzhou Innovation Award
2nd Prize

2021 National Brand Yushan Award

2021 National Innovation Award
(Tissue and Organ Regeneration Technology)

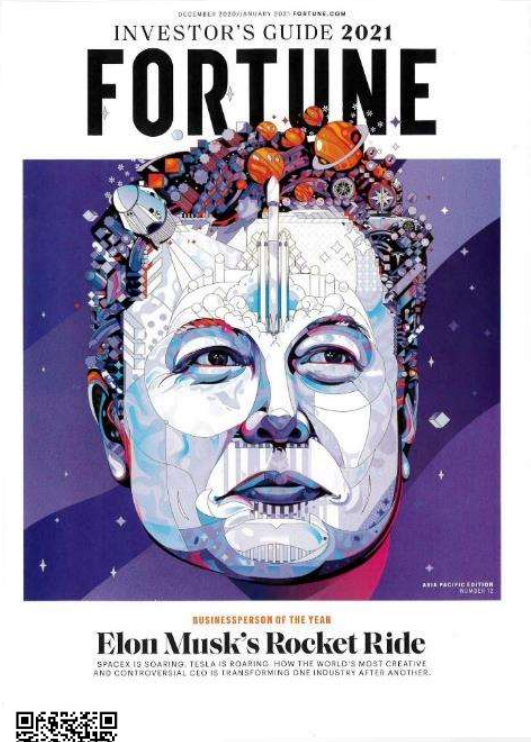
Innovation Bronze Medal Award
2022 Taipei Biotech Awards

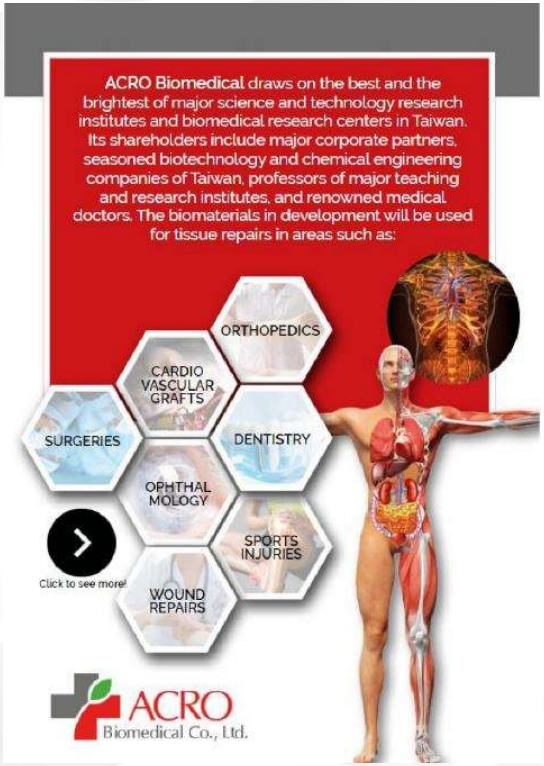
Discovery Channel

Scan to watch the video on YouTube.
https://www.youtube.com/watch?v=VQ7LrxW5oSY&t=22s

ACRO Biomedical Co., Ltd.

FORTUNE Investor's Guide 2021





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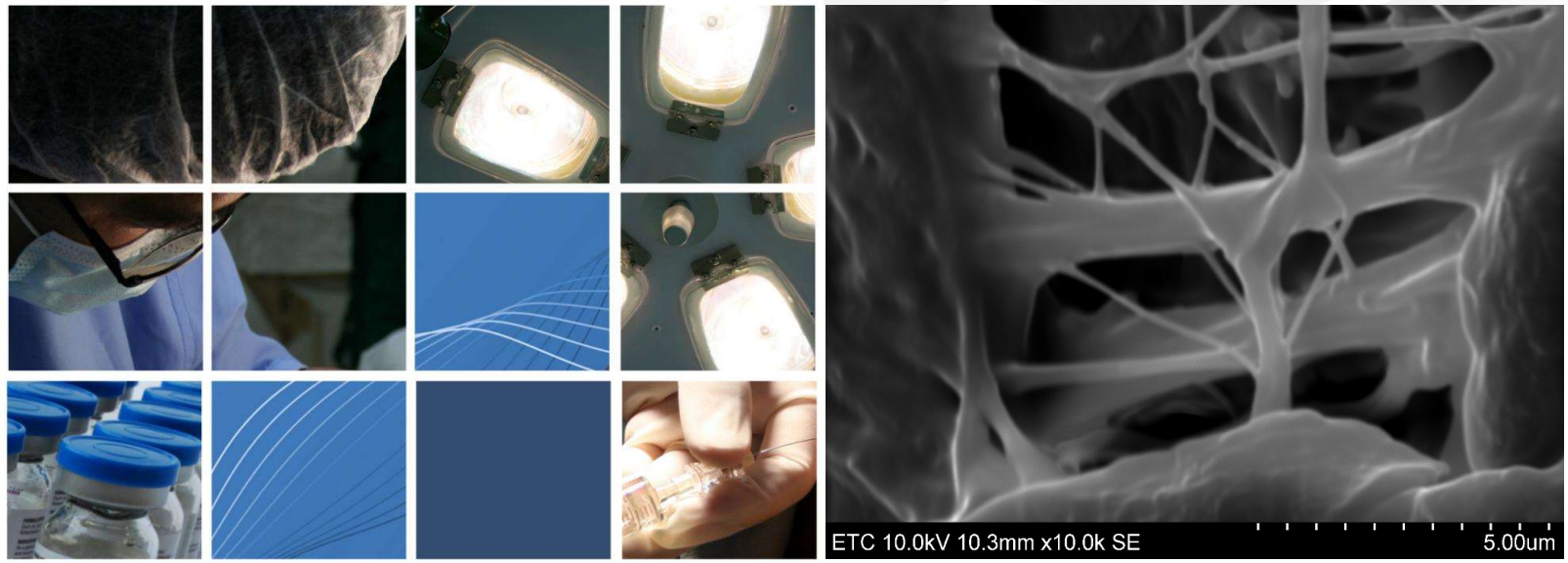
http://www.acrobiomedical.com/index.php?option=module&lang=en&task=pageinfo&id=643&index=1

ACRO Biomedical Co., Ltd.



We continue to make the IMPOSSIBLE possible.

THANK YOU

ACRO Biomedical Co., Ltd.