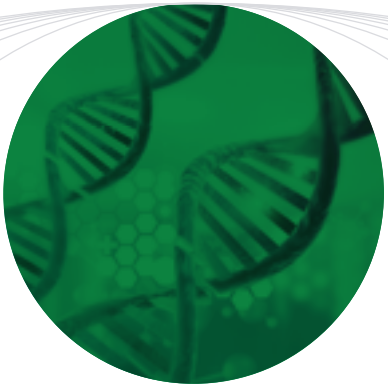
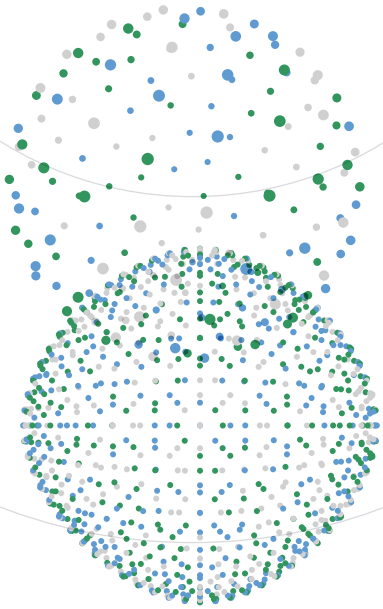
Acellular Dermal Matrix

MegaDerm®





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조직재생의학 전문 R&D기업 ㈜엘앤씨바이오는
차별화된 제품과 사업전략을 기반으로
글로벌 바이오 헬스케어 기업으로 지속 성장해나갈 것입니다.

㈜엘앤씨바이오는 인간의 삶의 질을 향상시키고, 우리 고객에게 보다 나은 가치를
선사 하자는 사명을 바탕으로 인류의 건강과 행복한 삶을 만들어가고 있습니다.

The L&C BIO Way

A research-oriented company

Unique technology

Realization of customer needs

Professional medical advisory group

Challenges to new fields

Milestone

2021. 04. 엘앤씨바이오차이나 쿤산공장 착공
01. (주)엘앤씨바이오 이에스 자회사 설립
2018. 11. (주)엘앤씨바이오 KOSDAQ 시장 상장
07. 신공장(선텍시티) 준공 및 조직은행 변경허가(식품의약품안전처)
04. (주)글로벌의학연구센터 자회사 설립
2011. 10. 공장 준공 및 조직은행 설립허가(식품의약품안전처)
08. ㈜엘앤씨바이오 법인 설립

인증리스트

제조품목허가	2021	03	유착방지피복재	MegaShield
	2020	09	생체유래흡수성창상피복재	MegaCure
		07	생체재료이식용뼈	MegaDBM S
	2019	06	콜라겐사용조직보충재	MegaDerm Intension
		04	생체골이식재	MegaBone Oss
	2018	02	생체재료이식용뼈	MegaBone Plus
	2017	11	조직수복용생체재료	MegaNuovo
		09	생체재료이식용뼈	MegaDBM
	2016	03	조직수복용생체재료	MegaDerm Plus

GMP	2019	07	품목군 추가 인증	체외용 의료용품
	2018	01	인증 획득	임상용 GMP; 체외용 의료용품
	2017	06	인증 획득	인체조직 또는 기능 대치품
	2015	12	인증 획득	인체조직 또는 기능 대치품(수출용)
ISO	2018	11	ISO 13485: 2016 인증 갱신	Non-active human tissue implant
	2015	10	ISO 13485 인증 획득	
	2012	02	ISO 9001 / 14001 인증 획득	
임상시험계획	2019	12	무릎관절 연골손상 치료재	MegaCarti
	2018	10	조직수 복용 생체 재료	MegaCartilage-E
		04	유착 방지피복재	MegaShield

Business Field

㈜엘앤씨바이오 연구소는 전문의료인과 협력하여 Tissue engineering,
Medical Devices 및 Cosmeceuticals을 비롯한 다양한 분야에서 혁신적인 Healthcare solution을
개발하고 제공함으로써 인류 삶의 질 향상에 기여하고 있습니다.

인체조직 이식재 Line-up 구축

인체조직이식재

피부, 뼈, 연골, 근막, 건, 인대 등

MegaDerm®
동종 진피 이식재

MegaFill®
동종 진피 파우더 형태

MegaCatliage®
동종 연골 이식재

MegaSheet®
동종 근막 이식재

MegaBone®
동종 골 이식재

MegaTendon®
동종 인대 이식재

인체조직기반 재생의료, 메디컬, 미용성형 등
다양한 영역에서 활용

인체조직기반 의료기기

기존 인체조직에 고분자물질을 가교하여 효능 및 편의성 향상

MegaDBM®
동종의 탈회골

MegaDBM S®
동종 탈회골

MegaCure®
창상피복재

MegaNuovo®
조직수복용생체재료

MegaShield
유착방지피복재

MegaCarti®
(출시예정)

피부 질환 신물질 ZAG 화장품 출시
자회사를 통한 화장품 CRO영위

코스메슈티컬 및 화장품 CRO

BY THE DOCTOR

BTD MF3
재생

BTD ATO
아토피 케어

글로벌의학연구센터
Global Medical Research Center

화장품 CRO
피부 기초 및 임상

네트워크를 통하여
효율적인 의약품 제공

의약품 사업

다양한 제네릭 의약품

기존의 효율적인 네트워크 사용

제네릭으로 시작하는 효율적인 비용구조

MegaDerm®

www.lncbio.co.kr

MegaDerm®은 기증받은 인체 피부 조직을 (주)엘앤씨바이오만의
특화된 AlloClean® technology 공정을 통하여 가공한 제품으로
진피의 세포외기질(Extracelluar Matrix) 3D structure 구조로 되어 있습니다.

MegaDerm®은 피부이식뿐만 아니라 연부조직 재건의 목적으로 사용되며,
이식후 자가조직화가 진행됩니다.

- 우수한 생체 적합성
- 안정적 3차원구조
- 뛰어난 물리적 성상(인장력 및 탄성력)
- 각 질환에 적합한 크기와 형태로 제작이 가능하며, 맞춤형 주문 제작

원재료 Skin

타입

MegaDerm® FD Freeze-Dry

MegaDerm® HD Hydration

MegaDerm® Express Slit / Puncture

AlloClean® Technology

AlloClean 기술은 Pre-Screening & Testing 과정을 통해 선별된 안전한 인체조직 원재료를 이식 가능한 치료재료로 가공 처리하는 기술입니다. 본 기술의 핵심은 조직내에 함유된 세포, 미생물, 면역거부반응 인자 그리고 각종 이물질 등을 제거하는 기술로서 각각의 조직(피부, 뼈, 연골, 건/인대, 근막)의 특성을 고려하여 화학 처리와 멸균 처리를 진행 합니다.

1) 원재료 안전성
Pre-Screening & Testing

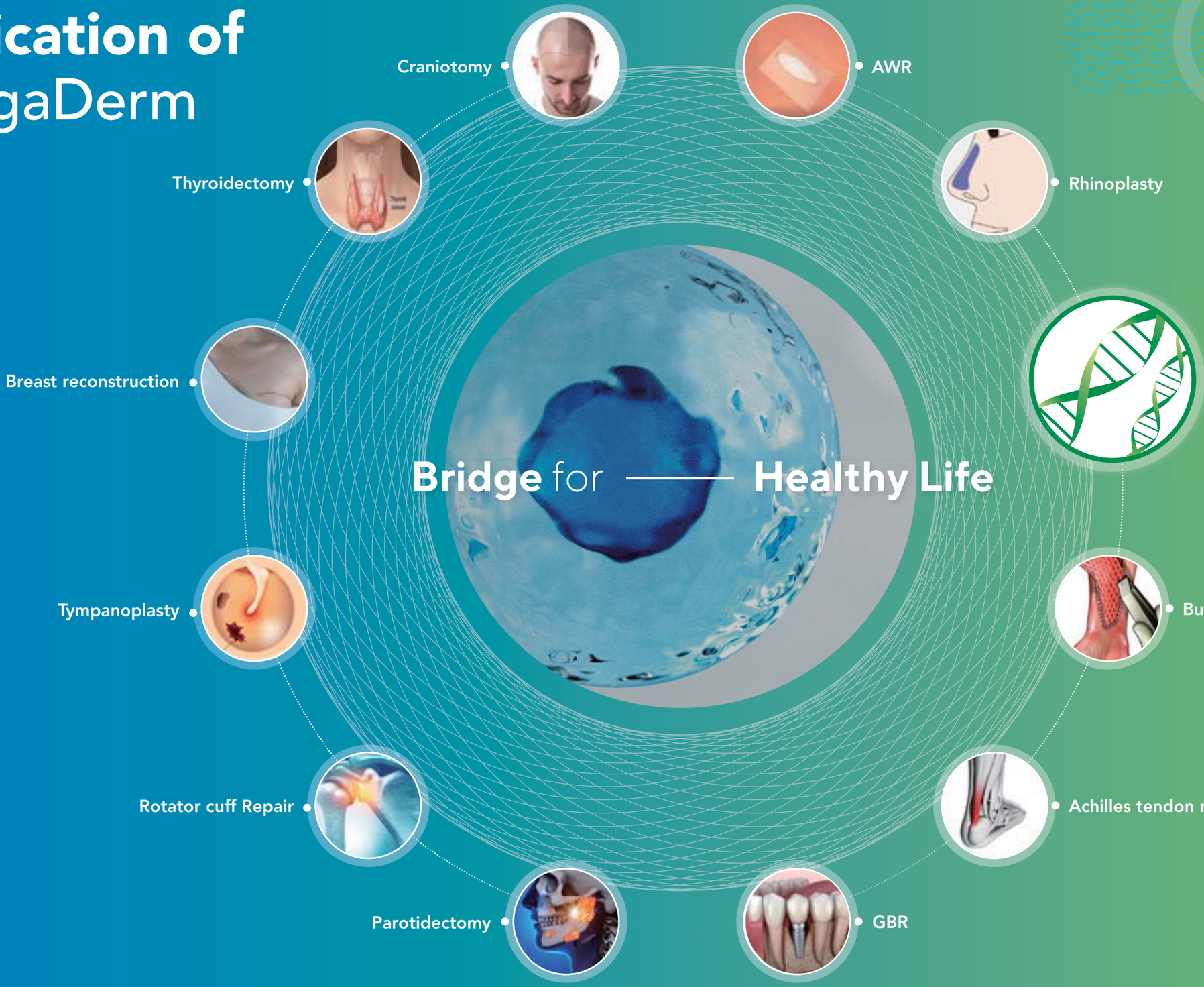
MFDS(한국식품의약품안전처) 법률 요구사항 및 AATB(미국조직은행연합회) 표준규정에 따라 인체조직 이식재 가공처리에 사용되는 원재료에 대해 혈청검사, 미생물학적 검사 등이 포함된 기증자적합성평가를 시행하여 원재료의 안전성을 확보(또는 보증)하고 있습니다.

2) 최종 멸균

Freeze/dried type products: e-beam 멸균 실시
Hydration type products: Gamma 멸균 실시

Process

Indication of MegaDerm



Life and Creativity

L&C BIO

Expansion of business field through **development of new medical devices**

MegaDerm® HD

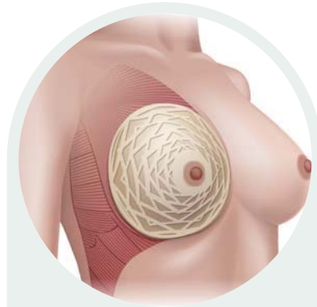
- Pre-hydrated human acellular dermal matrix

Sub-pectoral breast reconstruction with **MegaDerm® HD**

+ Pre-hydrated 제품으로 별도의 수화과정없이 바로 사용이 가능합니다.
+ Inframammary fold(IMF) definition
+ Lateral Mammary fold(LMF) definition
+ Resistance against capsular contracture
+ Avoid Rippling
+ Avoid contract between implant and native soft tissue

MegaDerm® STAR

- Pre-formed design for pre-pectoral breast reconstruction
- Pre-hydrated human acellular dermal matrix



Pre-pectoral breast reconstruction with **MegaDerm® STAR**

+ 수술 시 Implant를 한번에 쉽게 커버할 수 있습니다.
+ Pre-hydrated 제품으로 별도의 수화과정없이 바로 사용이 가능합니다.
+ 수술 시간과 환자의 회복 시간을 줄여줍니다.
+ Less pain
+ Inframammary fold(IMF) definition
+ Lateral Mammary fold(LMF) definition
+ Resistance against capsular contracture
+ Avoid Rippling
+ Avoid contract between implant and native soft tissue

For sub-pectoral breast reconstruction

Size (cm)	Thickness (mm)
5 x 14	1.0 - 1.5
6 x 14	
6 x 16	
7 x 18	
8 x 16	

Size (cm)	Thickness (mm)
5 x 16	1.5 - 2.3
6 x 14	
6 x 16	
7 x 18	
8 x 16	

For pre-pectoral breast reconstruction

Size (cm)	Thickness (mm)
12 x 16	1.0 - 1.5 or 1.5 - 2.3
10 x 20	
14 x 14	
16 x 16	
18 x 18	

For pre-pectoral breast reconstruction (MegaDerm Star)

Size (cm)	Thickness (mm)
16 x 16	1.0 - 1.5
18 x 18	
20 x 20	

Volume replacement with diced MegaDerm®
in breast conserving surgery

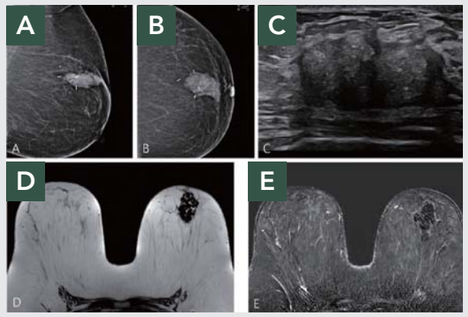
- Ref) Volume replacement with diced acellular dermal matrix in oncoplastic breastconserving surgery : a prospective single center experience, Gwak et al. World Journal of Surgical Oncology, (2020) 18:60

The excision cavity was then filled **with the diced MegaDerm® pieces.**

Diced type

Size (cm)	Thickness (mm)
5 x 6	5
3 x 6	

+ A, B) Mammography showed diced-MegaDerm as a mass with a well circumscribed margin on the left mediolateral oblique viewand left cranio-caudal view.
+ (C) The diced-MegaDerm was observed to the same echogenicity as fibroglandular parenchyma on B-mode ultrasonography.
+ (D, E) The diced-MegaDerm showed low signal intensity on T2-weighted imaging and no enhancement on contrast-enhanced magnetic resonance imaging.



Satisfaction with cosmetic and overall surgical outcomes in patients

The responses in the cosmetic and overall satisfaction questionnaire revealed that more than 90% of the patients were strongly satisfied.

+ **Patients :** 120 patients aged 20–80 years with breast cancer who desired BCS between December 2017 and August 2018
+ **Analysis :** Patient and surgeon satisfaction with the surgery outcomes 6 months postoperatively
+ **Results** : 1) Cosmetic outcome (p = 0.250)
  Patient group: 9.7 (± 0.8)
  Surgeon group: 9.7 (± 0.8)2)
  2) Overall satisfaction (p = 0.001)
  Patient group: 9.4 (± 1.0)
  Surgeon group: 9.5 (± 1.1)

Score	N (%)	Strongly satisfied		Satisfied		Neutral		Dissatisfied				Average score
		10	9	8	7	6	5	4	3	2	1	
Cosmetic outcome	Surgeon	91(77.8)	16(13.7)	8(6.8)	1(0.9)	0	0	1(0.9)	0	0	0	9.7
	Patient	92(78.6)	18(15.4)	5(4.3)	0	1(0.9)	1(0.9)	0	0	0	0	9.7
Overall outcome	Surgeon	78(66.7)	23(19.7)	9(7.7)	3(2.6)	2(1.7)	1(0.9)	1(0.9)	0	0	0	9.4
	Patient	83(70.9)	23(19.7)	6(5.1)	0	4(3.4)	1(0.9)	0	0	0	0	9.5

Postoperative complication rates in breast cancer patients after volume replacement with diced MegaDerm®

Postoperative complication rates in 117 breast cancer patients after volume replacement 6 months postoperatively

+ Reoperation rate 8.5%, Removal case: 2case
+ Hematoma 5.1%, Seroma 6.0%, Fat necrosis 3.4%

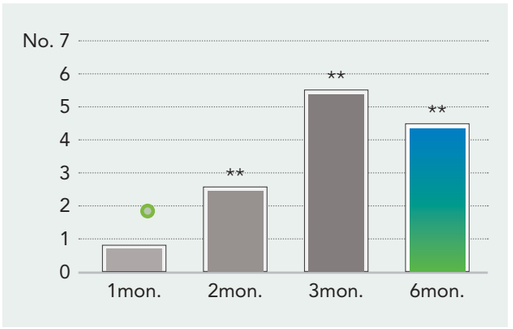
Score	Seroma	Red breast syndrome	Infection	Hematoma	Wound edge necrosis	Fat necrosis	Total
Incidence	7(6.0%)	3(2.5%)	3(2.5%)	6(5.1%)	1(0.9%)	4(3.4%)	24(20.5%)
Reoperation	0	1(0.9%)	0	4(3.4%)	1(0.9%)	4(3.4%)	10(8.5%)
ADM Removal	0	1(0.9%)	0	1(0.9%)	1(0.9%)	0	2(1.7%)

MegaDerm®: Cross-linked human acellular dermal matrix

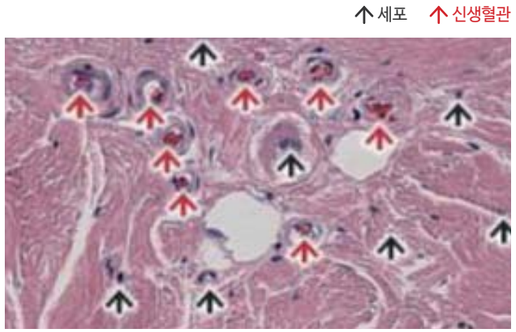
MegaDerm® 은 자연스러운 결과를 보여줍니다.

+ MegaDerm은 이식 후 자가조직화(자가 세포의 유입 및 신생혈관 형성)가 되어 자연스러운 결과를 보여줍니다.
+ 피부가 얇은 경우에도 강한 조명이나 햇빛으로 인한 이식재료의 비침 현상이 없습니다.

● Angiogenesis: 6 months after implantation



● Angiogenesis: 6 months after implantation



* Ref) Lee, Ju Hee, Hyung Goo Kim, and Won Jai Lee. "Characterization and tissue incorporation of cross-linked human acellular dermal matrix." Biomaterials 44 : 195-205.

MegaDerm® 은 흡수율이 매우 낮습니다.

+ MegaDerm은 콜라겐이 cross-linking되어 있는 제품으로, 체내 이식 후 분해가 거의 발생하지 않습니다.
+ 따라서 일관성 있고 예상 가능한 수술의 결과를 얻을 수 있으며, 환자의 만족도 또한 매우 높습니다.

MegaDerm® 은 안전합니다.

+ 알레르기 반응, 염증 반응 등이 없어 피부테스트가 필요 없습니다.
+ 실리콘 등의 합성물질 이식에서 발생하는 구형구축현상이 발생하지 않아 안전합니다.
+ 이식 이후 주변 조직에 잘 고정되어 이동성이 없습니다.

Products of MegaDerm in Rhinoplasty

Camouflaging of silicon

Dorsum (block type)

Dorsum (carving type)

Tip

Type	Size (cm)	Thickness (mm)
Camouflaging of silicon	1 x 5	0.7 - 0.9
Dorsum (block type)	1 x 5	1.8 - 2.3
		2.3 - 3.0
		3.0 - 4.0
		4.0 - 5.0
Dorsum (carving type)	1 x 5	3.0 (W3)
		4.0 (W4)
		5.0 (W5)
Tip	1 x 1	1.5 - 2.3
		2.5 - 3.0
		3.0 - 3.5
		3.5 - 4.0
		4.5 - 5.0
		5.0 - 6.0

Clinical Study

Comparative skin evaluation after split-thickness skin grafts using 2 different acellular dermal matrices to cover composite forearm defects.

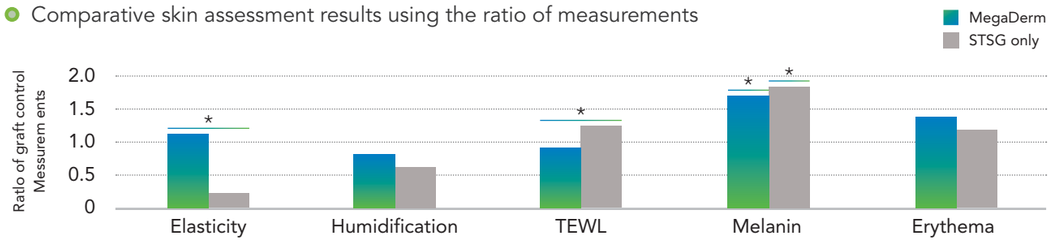
* Lee, Myung Chul, et al., The Journal of hand surgery 42.4 : 297-e1.

● Functional Skin Assessment in MegaDerm

AU, arbitrary unit. The MegaDerm grafted area and adjacent normal skin had comparable elasticity and transepidermal water loss but the MegaDerm area was less moist, darker, and redder (mean SD). *P< .05

Variable	MegaDerm Graft Area	Control Area	P Value
Elasticity	0.60 ± 0.15	0.61 ± 0.16	.22
Humidification	24.64 ± 13.48	39.90 ± 14.78	<.05*
Transepidermal water loss, g/h/m^2	10.93 ± 6.38	12.89 ± 6.22	.15
Melanin value (AU)	228.00 ± 86.50	154.00 ± 59.15	<.05*
Erythema value (AU)	324.00 ± 91.00	259.00 ± 81.06	<.05*

● Comparative skin assessment results using the ratio of measurements



● Aesthetic Evaluation Based on Patient's Point of View

Aesthetic Grade	MegaDerm®	STSG only
Excellent	8	3
Good	15	6
Fair	6	12
Poor	0	2
Total	29	23

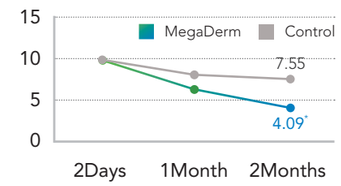
Clinical Study

Preventive Effect of Human Acellular Dermal Matrix on Post-thyroidectomy Scars and Adhesions: A Randomized, Double-Blinded, Controlled Trial.

* Kang Sang-Wook, et al. Dermatologic Surgery 41.7: 812-820.

● MegaDerm® 군은 대조군 대비 흉터 예방 효과를 보였으며, 흉터지수 및 흉터 양상의 유의한 개선을 나타내었습니다.

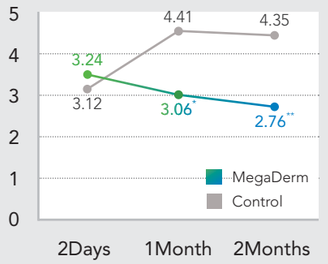
Swallowing impairment score



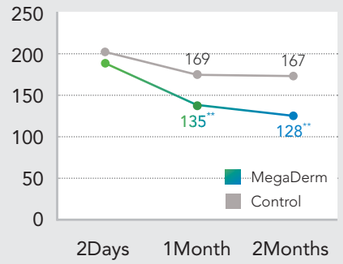
Sheet type

Size (cm)	Thickness (mm)
4 x 5	0.6 - 0.8
4 x 8	
3 x 7	

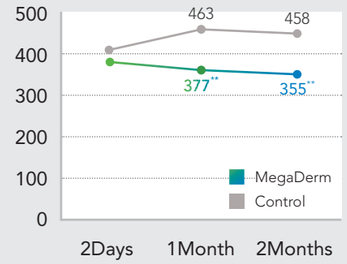
Vancouver scar scale



Melanin index(AUs)



Erythema index(AUs)



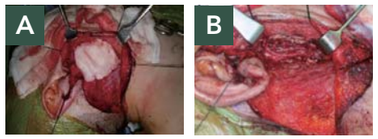
Clinical Study

Effect of human acellular dermal matrix (MegaDerm®) on infraauricular depressed deformities, Frey's syndrome, and first bite syndrome following parotidectomy: a multi-center prospective study.

* Joo Hyun Kim, et al. Gland Surg 2021;10(2):670-677.

The implantation of MegaDerm following total parotidectomy.

+ A. Surgical field after total parotidectomy with preservation of the facial nerve.
+ B. MegaDerm was designed and inserted between flap in parotid bed and residual parotid tissue.



Evaluation of Frey's syndrome of parotidectomy patients in the MegaDerm-use group and control group

	Month 3		Month 6		Month 12	
	ADM	Control	ADM	Control	ADM	Control
Patients (%)	3 (4.9%)	14(25.9%)	4 (6.5%)	12(22. 2%)	4 (6.5%)	8 (14.8%)
Total score (0-10)	0.23±1.2	3.48±1.54	0.36±1.31	3.57±1.1	4 (6.5%)	3.64±0.85
Frey Qx (1-4)	1.05 ± 0.34	2.13±0.48	1.25±0.24	2.36±0.78	1.32±1.15	1.41±0.78
P-value	0.032 / 0.027 / 0.095		0.037 / 0.024 / 0.315		0.018 / 0.024 / 0.287	

Visual analogue scale for the contouring deformity and subjective satisfaction score of parotidectomy patients in the MegaDerm-used group and control group.

Countouring deformity	Month 3		Month 6		Month 12	
	MegaDerm	Control	MegaDerm	Control	MegaDerm	Control
Not detectable deformity	31	8	25	5	22	4
Mild deformity	26	23	32	22	34	23
Moderate deformity	4	15	4	16	5	16
Severe deformity	0	7	0	10	0	10
Extremely severe deformity	0	1	0	1	0	1
Subjective satisfaction score	4.26±0.51	3.78±0.97	4.16±0.32	3.63±0.92	3.96±0.54	3.57±0.86
P-value (VAS/SSS)	0.001 / 0.001		0.001 / 0		0.001 / 0	

Clinical Study

Surgical Outcomes of Tympanoplasty Using Acellular Dermal Allograft: A Randomized Controlled Study.

* Kim, Sung Huhn et al. ACTA OTORHINOLARYNGOLOGICA ITALICA 2018;38:554-562;

Compared to autologous graft materials, MegaDerm is an effective alternative as a TM graft material with similar graft success rates and postoperative hearing results

* TM: tympanic membrane

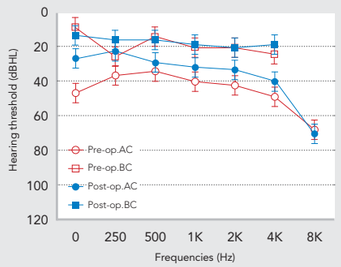
Representative tympanic membrane

+ A. Perforation of the tympanic membrane(TM)
+ B. The use of MegaDerm as a TM graft
+ C. Otoscopic views of the TM at 6 months postoperatively with complete TM closure

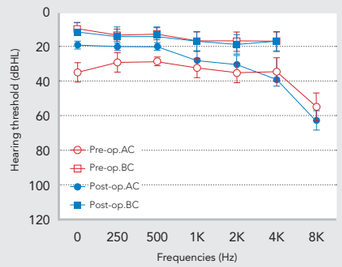
Hearing results: air-conduction, bone-conduction, air-bone gap

+ Fig A, B) Preoperative and postoperative hearing results of the perichondrium group and MegaDerm group measured at 6 months (A: perichondrium group, B: MegaDerm group) postoperatively. The air-conduction thresholds significantly improved in both groups, whereas the bone-conduction thresholds remained stable.
+ Fig C) Changes in air-bone gaps (ABGs) after tympanoplasty at 6 months postoperatively. Significant reductions in ABGs were observed in both groups, and the amount of reduction of ABGs and postoperative ABGs were not significantly different between the two groups.

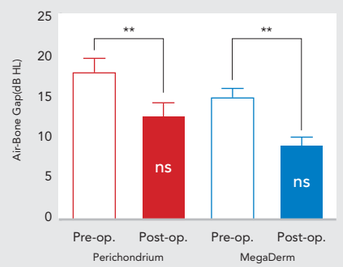
Perichondrium group



MegaDerm group



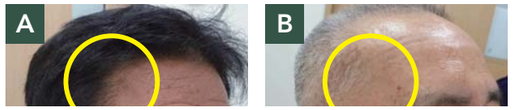
Perichondrium & MegaDerm



Replacement of pericranium:
Wound depression protectant after craniotomy

Clinical case:
protectant of depression after mini-craniotomy

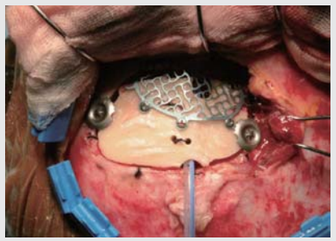
+ A) Frontoremporal Depression :
  Pterional Craniotomy without MegaDerm
+ B) No Frontoremporal Depression :
  Pterional Craniotomy with MegaDerm



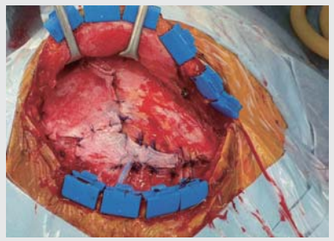
Size (cm)	Thickness (mm)
4 x 5	0.6 - 0.8
	1.0 - 1.5
6 x 8	0.6 - 0.8
	1.0 - 1.5

Pterional mini-Craniotomy

Intraoperative photograph
after pterional mini-craniotomy



Intraoperative photograph
after MegaDerm® insertion

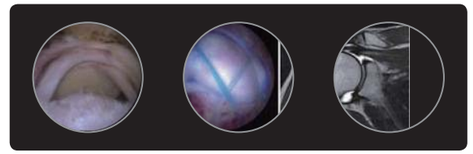


Arthroscopic rotator cuff repair with MegaDerm®

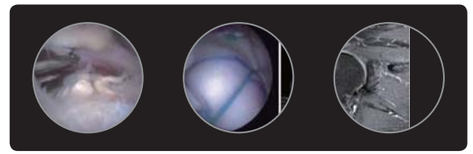
Clinical Benefits

+ Augmentation of soft tissue repairs
+ Biologically versatile scaffold for ready
  incorporation to support regeneration
+ Protects delicate tissue with
  a durable and safe matrix

1. Massive tear case : Augmentation

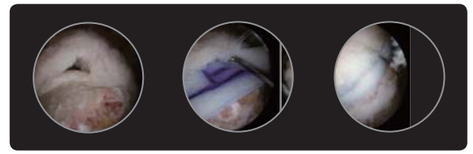


2. Retear case



Case	Size (cm)	Thickness (mm)
Massive tear case : Augmentation	4x5, 3x4, 3x3	2.0
Ratear case	4x5, 3x4, 3x3	2.0
Small tear case	1x3	0.7 - 0.9

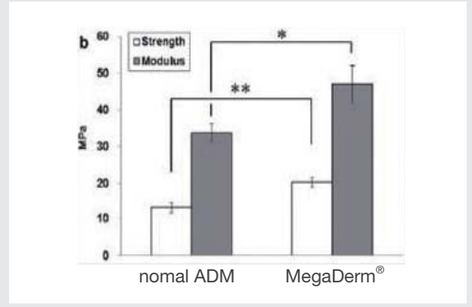
3. small tear case: interposition



Biomaechanical

Tensille strength & modulus testing.
MegaDerm은 콜라겐이 가교화되어 일반
ADM 제품 대비 tensile strength가 1.6배,
tensile modulus가 1.4배 높습니다.

Ref) Characterization and tissue incorporation
of cross-linked human acellular dermal matrix,
Biomaterials 44 : 195-205.



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㈜엘앤씨바이오 연구소는 전문의료인과 협력하여 Tissue engineering,
Medical Devices 및 Cosmeceuticals을 비롯한 다양한 분야에서 혁신적인 Healthcare solution을
개발하고 제공함으로써 인류 삶의 질 향상에 기여하고 있습니다.

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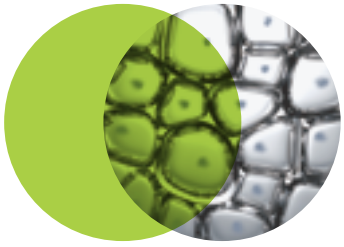

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