

**CGDerm**<sup>TM</sup>

Regenerative Tissue Matrix

*(Freeze dried Acellular Dermal Matrix)*

**CGCryoDerm**<sup>®</sup>

Regenerative Tissue Matrix

*(Cryopreserved Acellular Dermal Matrix)*

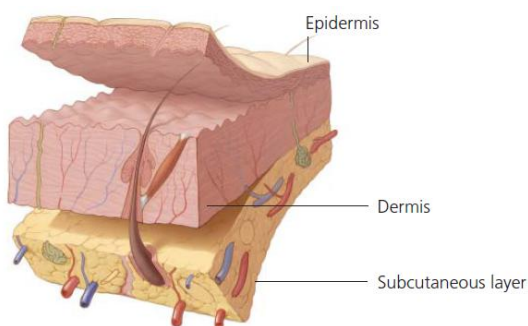


## What is CGDerm™ / CGCryoDerm™ ??

CGDerm/CGCryoDerm are processed by the CGBio co. and is available through Daewoong Bio.

CGDerm/CGCryoDerm are an allograft derived from donated human skin. The epidermis and dermis are removed from the subcutaneous layer of the skin during the recovery procedure. The tissue is then processed using a sodium chloride solution and detergent to remove the epidermis and all viable dermal cells while maintaining the original dermal collagen matrix. The cells are removed to minimize inflammation or immunorejection at the surgical site.

CGDerm/CGCryoDerm are then treated in a disinfection solution that combines detergents with acidic and antiseptic reagents to further clean the tissue so that it passed KGMP, USP<1116> for sterility. Finally, it is freeze-dried, cut to size and packaged in a terminally sterilized double pouch and envelope in CGDerm. In CGCryoDerm, it is packaged in sterilized double pouch and envelope, it is cryopreserved.



Normal Human Skin

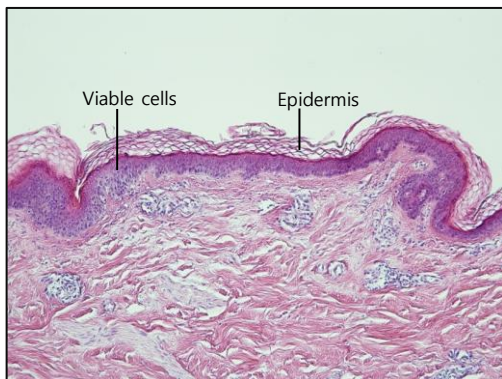


CGDerm/CGCryoDerm Collagen Matrix

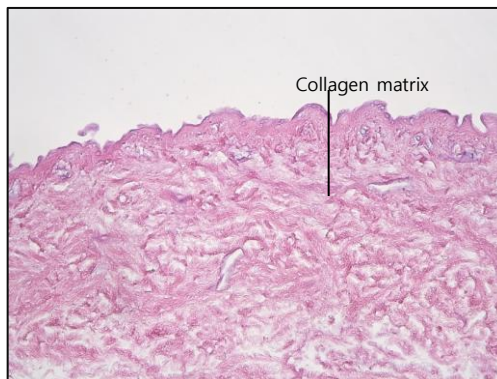
When ready for use, CGDerm should be rehydrated in at least 100ml of sterile, room temperature saline or lactated Ringer's solution. It will typically rehydrate in three minutes or less to a uniformly soft and pliable consistency. Additional rinsing to remove any residuals is not needed.

When ready for use, CGCryoDerm should be thawed in at least 100ml of warm sterile saline or lactated Ringer's solution. It will typically be thawed in five minutes or less to a uniformly soft and pliable consistency. Additional rinsing to remove any residuals is not needed.

After CGDerm/CGCryoDerm are transplanted into the patient, host cells begin to infiltrate into the three-dimensional collagen matrix. The patient's blood revascularize the implant and fibroblasts are incorporated into the matrix



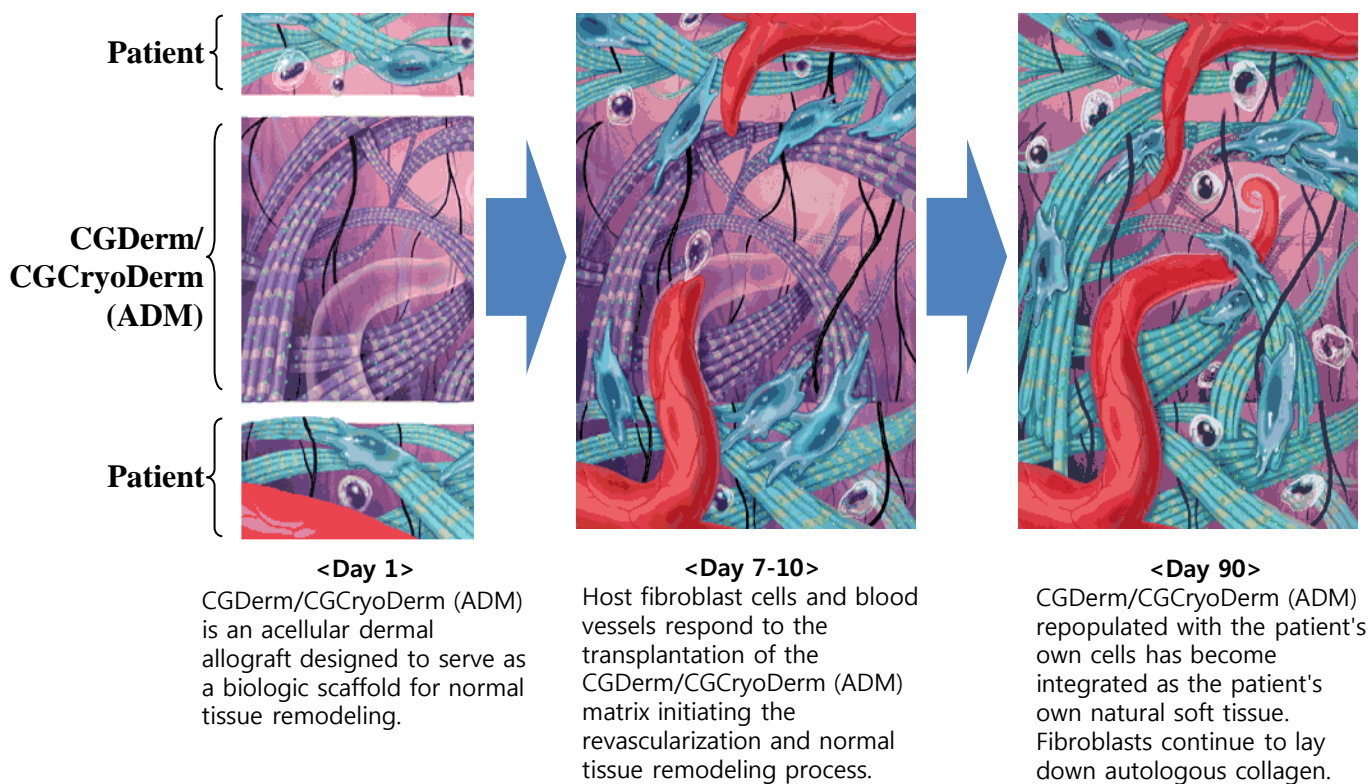
Human normal skin, with cells intact  
(200X magnification)



CGDerm, with cells removed  
(200X magnification)

## Tissue remodeling process

CGDerm/CGCryoDerm (acellular dermal matrix, ADM) is human acellular dermal allograft, which is intended for the repair or replacement of damaged soft tissue. CGDerm/CGCryoDerm (ADM) is made of donated human tissue by special process of high technology. Main purpose of this technological process is to be easily transplanted without rejection by eliminating immune response. When healing completed, CGDerm/CGCryoDerm (ADM) eventually becomes the patient's own tissue.



## Indications & Contraindications

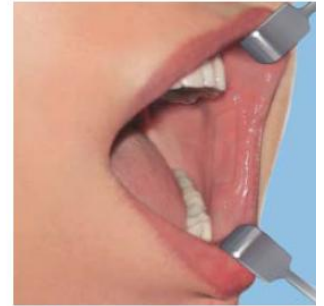
CGDerm/CGCryoDerm is for homologous use only. Homologous use as defined by the FDA is: The replacement or supplementation of a recipient's tissue with a tissue form that performs the same basic function or functions in the recipient as in the donor.

Clinical applications include, but are not limited to, the following;

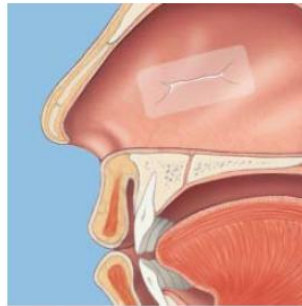
- Parotidectomy
- Tympanoplasty
- Facial soft tissue defects
- Facial sling
- Lower eyelid reconstruction
- Nasal reconstruction
- Nasal septal perforation
- Cleft palate repair
- Oral resurfacing
- Vestibuloplasty
- Radial forearm freeflap repair
- Breast reconstruction postmastectomy
- Abdominal wall repair



Breast reconstruction  
postmastectomy



Oral cavity repair



Nasal septal perforation



Abdominal wall repair

### Indications

CGDerm/CGCryoDerm are processed to remove cells while maintaining the integrity of the matrix with the intent to address the issues of the specific and nonspecific inflammatory responses. It is used for the replacement of damaged or inadequate integumental tissue or for the repair, reinforcement or supplemental support of soft tissue defects.

### Contraindications

Use of CGDerm/CGCryoDerm in patients exhibiting autoimmune connective tissue disease is not recommended.

- Specific or nonspecific immune response to some component of the graft

Please refer to the package insert for additional precautions and adverse effects.

## Production Information

| Graftable            | 10                                      | 20                                       |
|----------------------|---|--|
| CGDerm<br>CGCryoDerm | 9/1000~13/1000 (inch)<br>0.23~0.36 (mm) | 14/1000~20/1000 (inch)<br>0.36~0.51 (mm) |

| Breast reconstruction | SIZE         | Thickness                                |
|-----------------------|--------------|--|
| CGDerm<br>CGCryoDerm  | 4 cm X 12 cm | 31/1000~90/1000 (inch)<br>0.80~2.28 (mm) |

| Nipple reconstruction | SIZE       | Thickness                                |
|-----------------------|------------|--|
| CGDerm                | 1.2 $\Phi$ | 31/1000~90/1000 (inch)<br>0.80~2.28 (mm) |

| Dental | SIZE                                      | Thickness                               |
|--------|---|---|
| CGDerm | 1 cm X 2 cm<br>1 cm X 4 cm<br>2 cm X 4 cm | 9/1000~35/1000 (inch)<br>0.23~0.90 (mm) |

| Thick implantable | SIZE                       | Thickness  |
|-------------------|----------------------------|--|
| CGDerm            | 4 cm X 7 cm<br>5 cm X 7 cm | X-Thick 41/1000~90/1000 (inch)<br>1.04~2.29 (mm)     |
|                   |                            | XX-Thick 91/1000~130/1000 (inch)<br>2.30~3.29 (mm)   |
|                   |                            | XXX-Thick 131/1000~170/1000 (inch)<br>3.30~4.29 (mm) |
|                   |                            | XXXX-Thick over 171/1000 (inch)<br>over 4.30 (mm)    |

## Feature

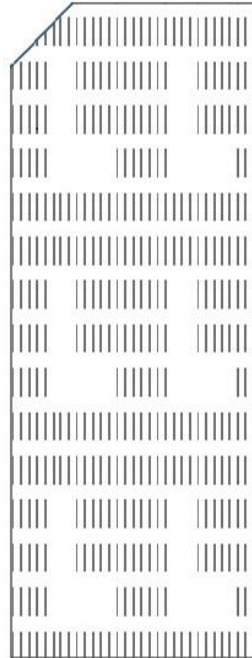
- Rehydrated/thawed quickly
- Is aseptically processed and passes KGMP, USP<1116> for sterility.

*The tissue is bacterially inactivated by the disinfection process, which reduces the level of bacteria, spores, fungi, mold and yeast*

- Minimizes the amount of autograft needed
- Allows revascularization and cell repopulation in the three-dimensional collagen matrix for normal tissue remodeling.
- Minimizes inflammation or rejection at the surgical site, as a result of the tissue processing which removes viable cells and antigens.
- Available 1stage operation
- Protect the tissue matrix against ice crystal damage by soaking in cryoprotectant

*Optimized Cryoprotectant process forms amorphous ice and avoids tissue damage*

- Soft tissue replacement without autograft harvesting(Dental)



CGDerm/CGCryoDerm are cut and are meshed so that when positioned as shown (with the **cut** in the upper left corner; "**L**" letter mesh pattern), the epidermal side of the tissue (basement membrane) is facing up

## Case



DM foot, M/53 (CGDerm)



DM foot, M/71 (CGDerm with CuraVac)



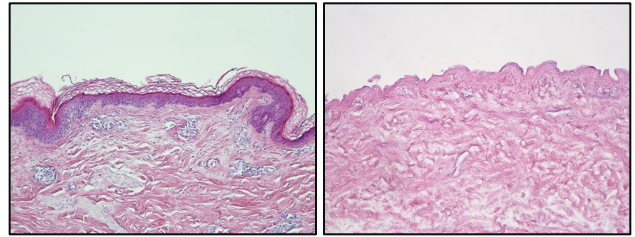
Electronic burn, M/50 (CGCryoDerm)



Electronic burn, M/44 (CGCryoDerm)

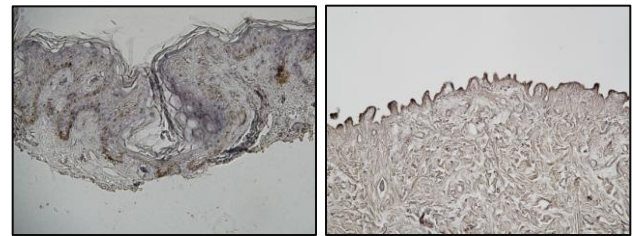
## Histological Profile

CGDerm/CGCryoDerm have been processed to remove cells while maintaining histomorphological integrity. Standard histology and immunohistochemical methods have been used to assess the dermal matrix structure and its components. Hematoxylin and eosin staining of normal human skin and CGDerm/CGCryoDerm show that the matrix is preserved during processing and demonstrates an absence of the epidermis and cells in the resulting matrix.



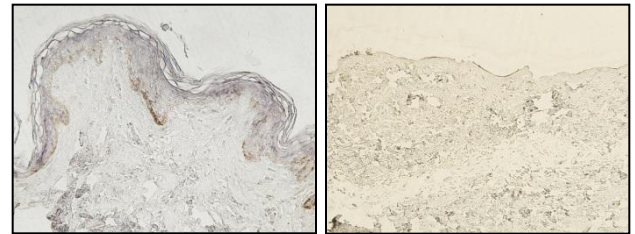
Hematoxylin and eosin staining of normal skin(left) and CGDerm(right) from the same donor. Note absence of cells and preservation of matrix structure processing

Using immunohistochemical staining methods, Type IV collagen was evaluated in CGDerm/CGCryoDerm. The collagen component is not affected during processing, demonstrated by consistent staining throughout the matrix.

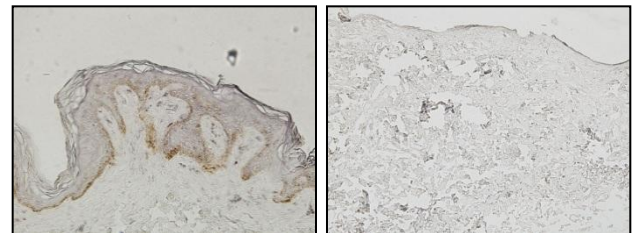


Immunohistochemical staining shows Type IV collagen in normal skin(left) and staining in basement membrane of CGDerm

Immunohistochemical evaluation of acellular dermal matrix confirm that extracellular matrix are preserved after processing except to immunogenic protein such as MHC I, II.



Immunohistochemical staining shows MHC I collagen in normal skin(left) and not staining in CGDerm



Immunohistochemical staining shows MHC II collagen in normal skin(left) and not staining in CGDerm



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