

# POWERFILL® Product Specifications

# PowerFill®

FIRST CHOICE FOR MICROPENIS



## POWERFILL PRODUCT INFORMATION

Product Name	PowerFill				
Component	PDLLA(Poly-D, L-Lactic Acid)				
Packaging Unit	1 vial / BOX				
Treatment Frequency	One or two times				
Lasting Effect	Over 24 months				
Manufacturer	REGEN Biotech, Inc.				

#### WHAT IS POWERFILL (POLY-D, L-LACTIC ACID)?

- Prominent, fast and safe treatment material for penis enlargement
- KFDA-approved injectable filler
- Patented technology: (biodegradable micro-particle polymer and manufacturing methods)
- Long lasting effect (2-3 years)
- Natural feeling (Collagen regeneration) & Adequate stiffness
- High safety (biodegradability and bioresorbability)
- Raw material of PowerFill (PDLLA) approved by the U.S. FDA



#### **LONG-LASTING EFFECT**

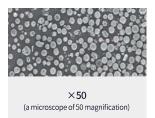
Natural volume lasting for a long time

Main Component	Time							
PLA(PowerFill)	• • •	••••	• • • • •	••••	• • • • •	• • • • •	••••	•••••
Hydroxylapatite	• • •	••••	• • • • •	• • • • •				
Hyaluronic Acid	• • •	• • • •	• • • • •	• • • • •				
Collagen	• • •	••••	• • • • •					
	3 M	6 M	9 M	12M	15M	18M	21M	24M

Different from other fillers, PowerFill, the next generation filler, keeps more natural volume for a long time as time goes by.

#### **PowerFill Microparticle Structure**

Porous PDLLA Microsphere

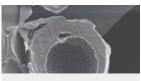




imes **1,000** (a microscope of 1,000 magnification)



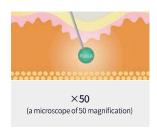
Surface Structure high density



Inner Structure Empty ※ Ref> Data on file\_Regen Biotech, Inc.

#### Mechanism of PowerFill

[Mechanism 1] Formation of new tissues and collagen with cell inflow between PDLLA particles

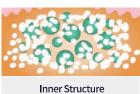








Surface Structure high density



Empty

\*\* Ref> Data on file\_Regen Biotech, Inc.

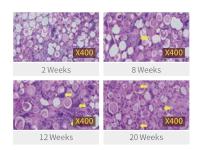
#### **Efficacy of PowerFill**

#### 1) Stimulation of new tissues and collagen production

(Production of new tissues confirmed by histological analysis)

#### Histological analysis- H&E Staining

- · Pink(cytoplasm): Dark pink or Blue(nucleus)
- · Arrows: Cells migrated into inside PLA particles



- At Week 2 after injection, cells have been growing attached to the surface of PDLLA particles and to spaces between particles.
   The empty spaces between particles have been filled with cells.
- At Week 8, there are no empty spaces between PDLLA particles, by being filled with cells which start to migrate into porous PDLLA particles.(yellow arrows).
- At Week 12 and 20, cells have migrated into the inner parts of PDLLA particles, and fill the inside of and spaces between the particles.

#### 2) Verified regeneration of new dermal tissues by histological examination



The formation of collagen is to form new tissues. From Week 4, new collagen production has been generated by the cells settled in the PDLLA.

 At Week 12 and 20, collagen expression has been increased between porous PDLLA particles and inside the particles (yellow arrows).

## SAFETY EVALUATION OF POWERFILL

### 1) PLA is safe as registered in the U.S. FDA's GRAS since 1984

#### GRAS (Generally recognized as safe)?

a U.S. FDA designation that a chemical or substance added to food is considered safe by experts

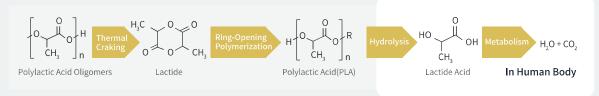
· GRAS-NO (U.S. FDA): 184.1061 (registered on Sept. 7, 1984)

#### 2) Biodegradability Completely gone after hydrolysis

PLA, the main component of PowerFill, is a biodegradable, biocompatible polymer used for medical devices for decades.

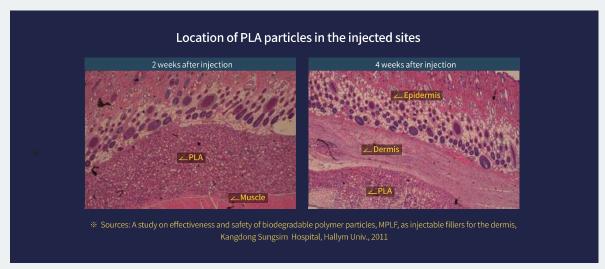
Safe and nontoxic PLA: PLA is degraded in the body through hydrolysis to lactic acid and glycogen. Then by metabolizing, PLA is decomposed into carbon dioxide and water, and is excreted outside the body.





#### 3) No migration into other tissues

No migration of PLA particles to correct folds and keep volume in the injected areas



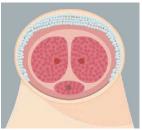
#### **PENIS**

#### Volume effect after injection

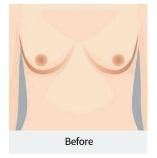
#### Powerfill treatment

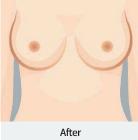
- 1. Non-incisional and Non-invasive procedures
- 2. Effective Injection for penis enlargement
- 3. Only 10 minutes of treatment
- 4. Local anesthesia
- 5. Ideal for day surgery
- 6. No stitch out
- 7. No internal hospitalization required





#### **BUTT & BREASTS**









# How to Use PowerFill

#### 01) How to Use: Reconstitution

Ten to thirty minutes prior to treatment, make a total of 10cc suspension by adding 8cc Sterile Water For Injection (SWFI) and 2cc 2% lidocaine into the PowerFill 1 vial.

#### 02) How to Use: Injection

Ten to thirty minutes prior to treatment, make a total of 10cc suspension by adding 8cc Sterile Water For Injection (SWFI) and 2cc 2% lidocaine into the PowerFill 1 vial.

#### 03) Protocol

PowerFill 2% Lidocaine 2cc

PowerFill 1 vial 17cc

SWFI 15cc





