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SAMYANG

16 LAFULLEN

LAFULLEN

Prefilled Syringe 1ea PCL(Polycaprolactone) Based Dermal Filler

LAFULLEN

LAuter(Pure) × **FULLEN**(Fill)

Fill your Beauty, Capture the Moment

- 05 Product
- 06 Samyang Holdings Corporation
- 08 LAFULLEN[®] P-PCL Technology
- 09 Pre-clinical Study
- 10 Clinical Study



Product

LAFULLEN®

Product	LAFULLEN®
Classification	Medical Device Class IV
No. of Product License*	21-941
Туре	Prefilled Syringe 1ea

* Korea MFDS (Ministry of Food and Drug Safety) No.

LAFULLEN[®] Composition



- * P-PCL : Porous Polycaprolactone * CMC : Carboxymethylcellulose * GRAS : Generally Recognized As Safe

Samyang Holdings Corporation

Business Area

Samyang Holdings' Medical Devices business has become the Global No.1 in Surgical Suture Raw material with more than 25 years of experience in biodegradable polymer manufacturing and application technology. Samyang now intends to expand its portfolio for Medical Aesthetics.



Major Achievements



Global Suture Raw Material M/S



Product Portfolio



Exporting Country



Global Partnership

Major Location



Samyang Discovery Center (Headquarter & R&D Center)

Completion 2016

Pharmaceuticals Plan

SAMYANG

Completion 1997

Product

Location

Injection. API

Daejeon, Korea

Certification

Related Department

Marketing & Sales Regulatory Affairs Planning R&D Center

Location

Seongnam-si, Gyeonggi-do, Korea

EU GMP, PMDA (Japan), GMP, KGMP (Korea)







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Medical Devices Plant

Completion 1996

Product Sutures, Hemostats, Patches

Location Daejeon, Korea

Certification

KGMP, CE Mark, ISO13485 (Medical Devices), KGMP (Pharmaceuticals)

Samyang Biopharm USA Inc.

Completion 2018

Business Model

•NRDO (No Research Development Only) •Therapeutics for Oncology and Rare Diseases •License-in / Out

Location

Cambridge, MA, USA

LAFULLEN[®] P-PCL Technology

- LAFULLEN[®] uses SEP Technology* for manufacturing highly homogeneous P-PCL microspheres which have unique pores and smooth surfaces.
- P-PCL microspheres reduce the polymer content per unit volume.
- Increased particle's homogeneity improves injection convenience and minimizes the possibility of nodule.

Particle Shape (×1,000)

LAFULLEN®



Product A



Pre-clinical Study



LAFULLEN[®] Cover

Neocollagenesis

Collagen fibers were more evenly generated compared to Product A.





LAFULLEN[®] (12 weeks)







Product A (12 weeks)

Pre-clinical study on the safety and efficacy of LAFULLEN[®] has been published in the prestigious international academic journal 'Journal of Cosmetic Dermatology(JCD),' a Scientific Citation Index (SCI) publication.

Volumizing effect

Volume retention of LAFULLEN[®] shows superior results compared to Product A.



3D Scanning Device(Primos®) picture, Hairless mice

JCD Volume 19, Issue 3 (2019) -

Full Degradation

All of the P-PCL microspheres were safely degraded in rabbits throughout 30 months observation period.



Full degradation of P-PCL microsphere, Rabbit

Clinical Study



Clinical study on the safety and improvement effect of LAFULLEN[®] has been published in the prestigious international academic journal 'Dermatologic Therapy,' a Scientific Citation Index (SCI) publication.

Dermatologic Therapy Volume 35, Number 5 (2022)

WSRS*

Efficacy for correction of wrinkles after the treatment sustained up to 12 months.



* WSRS: Wrinkle Severity Rating Scale

GAIS*

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Conception of the local division of the loca

Over 96% of patients had 'improved, much improved and very much improved' results at 6, 9, and 12 months period after LAFULLEN[®] treatment.



■ Improved ■ Much improved & Very much improved

* GAIS : Global Aesthetic Improvement Scale (3 = Very much improved, 2 = Much improved, 1 = Improved, 0 = No change, -1 = Worse)

Volumizing

Long-term volumizing effects were evaluated by analyzing volume changes using a 3D scanner (Morpheus 3D®).



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