For Doctors and Oversea Distributors

MI LINKER

PUFILLIS

PURIFIED POLYMER GEL

CONTENTS

1 Market Overview (1/4)

"The global cosmetic surgery and procedure market is projected to grow at a CAGR of 5.62% between 2020 and 2028 and is anticipated to generate revenue of $50.92 billion by 2028."

EUROPE MARKET BY REGION HIGH

NORTH AMERICA MARKET BY REGION MEDIUM

ASIA PACIFIC MARKET BY REGION VERY HIGH

REST OF WORLD MARKET BY REGION VERY LOW

SOUTH AMERICA MARKET BY REGION VERY HIGH

The factors boosting the global cosmetic surgery and procedure market growth are:

(1) Growing aging population

(2) The rapid growth of the aesthetic industry

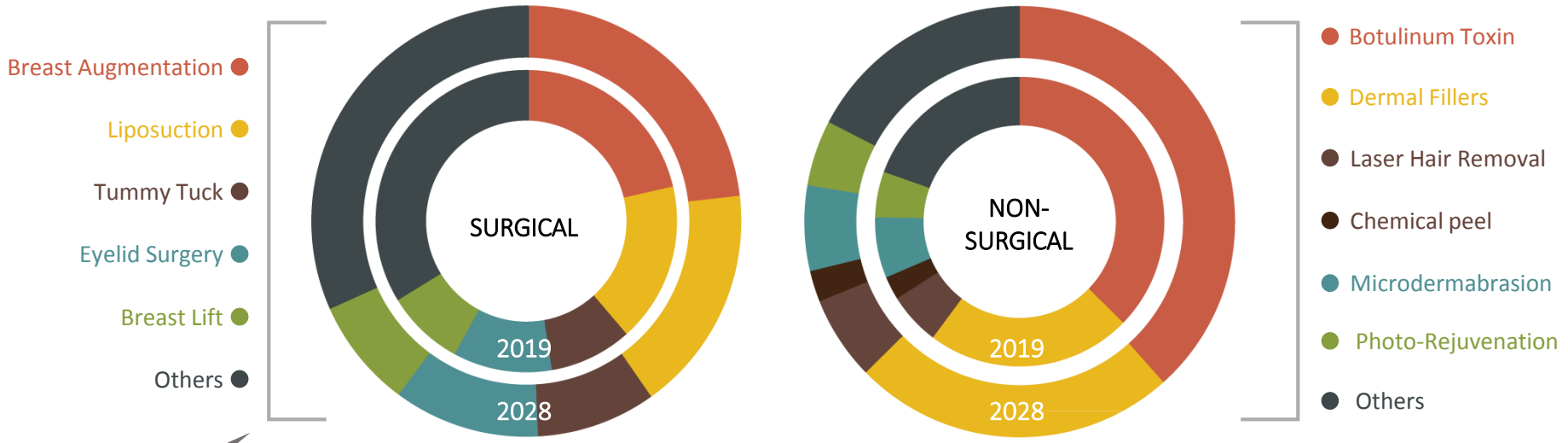
(3) Preference for non-invasive procedures and minimally invasive over invasive procedures

(4) Medical tourism in developing markets

(5) A surge in disposable income

* Source: Global cosmetic surgery and procedure market forecast 2020-2028, NKWOOD RESEARCH

1 Market Overview (2/4)



Key finding of the global cosmetic surgery and procedure market are:

(1) Botulinum toxin and Dermal fillers have the largest market share in the non-surgical type segment.

(2) Breast augmentation surgical type is dominating the surgical type segment with the largest revenue share.

(3) There are growing demands for cosmetic surgeries to enhance looks in selfies and social media platforms.

(4) There are growing demands for cosmetic surgeries to enhance looks in selfies and social media platforms.

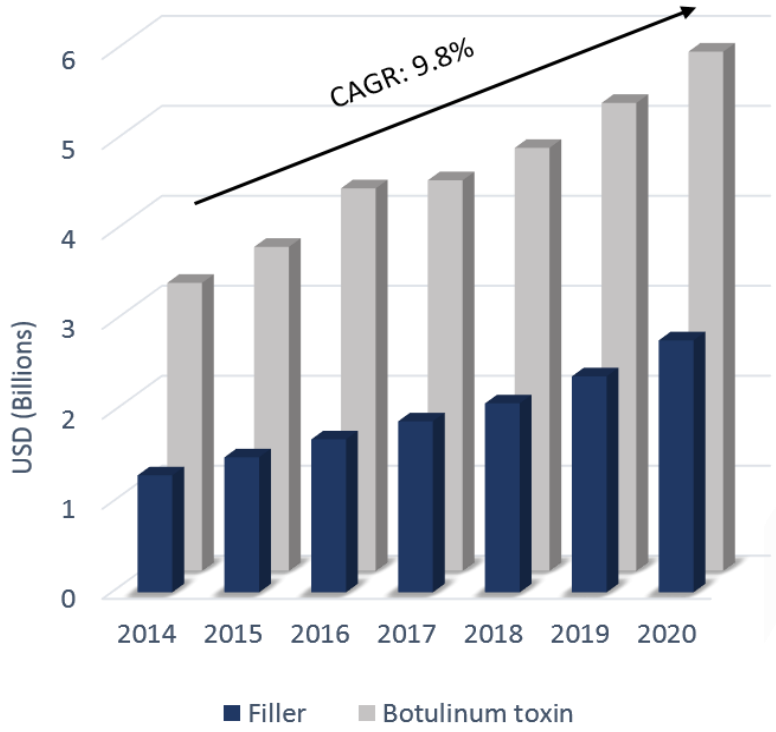
(5) Medical aesthetics are getting accepted increasingly.

* Source: Global cosmetic surgery and procedure market forecast 2020-2028, NKWOOD RESEARCH

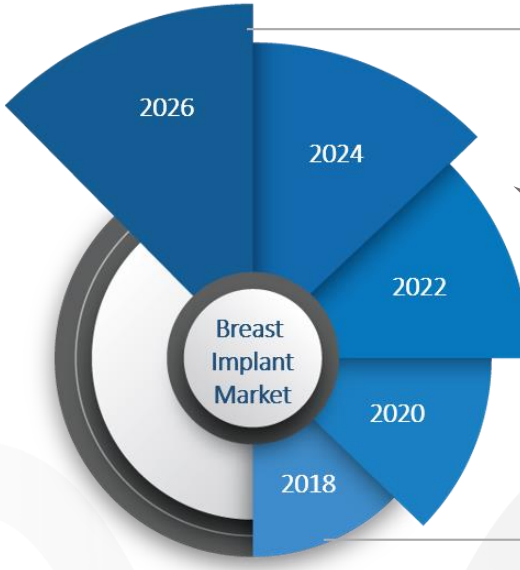
1 Market Overview (3/4)

Within the cosmetic market, the ratio of items such as botulinum toxin and filler for non-surgical procedures and breast augmentation and removal for surgical procedures is overwhelmingly high.

Botulinum Toxin & Filler Market Size



Breast Augmentation (Including reoperation) Market Forecast



However, Two major issues in recent years

(1) Harmfulness of filling materials in breast implants
– Heavy metals feeding by breakage

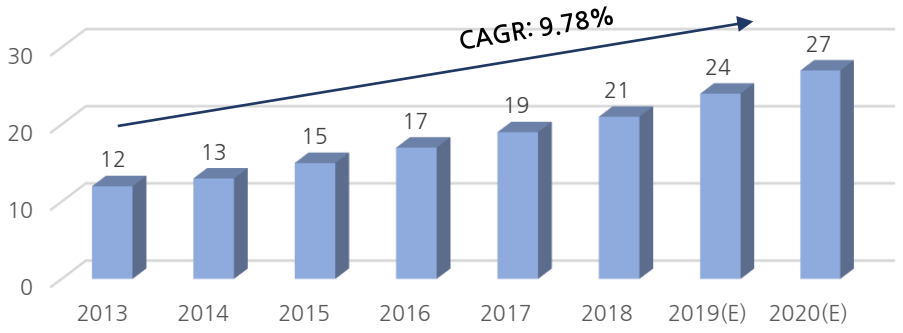
(2) Massive recall & reoperation due to rare cancer(BIA-ALCL) induction of texture type implants

* Source: Korea investor relations service report 2019-99, USB Pharmaceutical Handbook, NH Investment & securities research center, Persistence market research

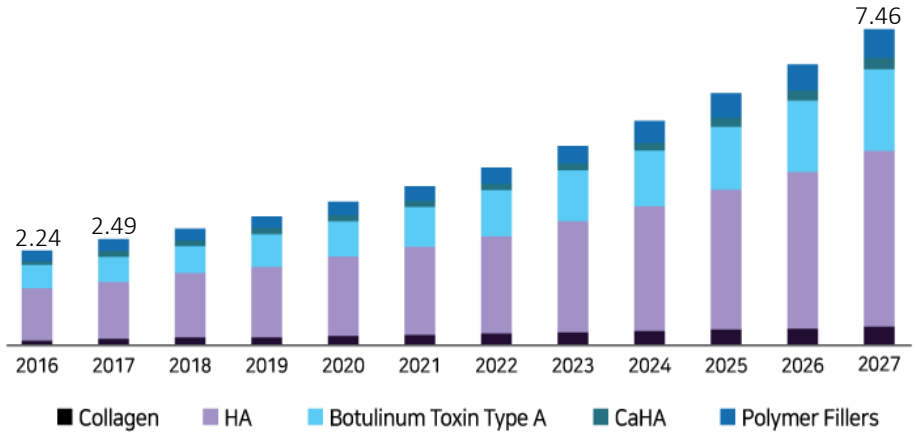
1 Market Overview (4/4)

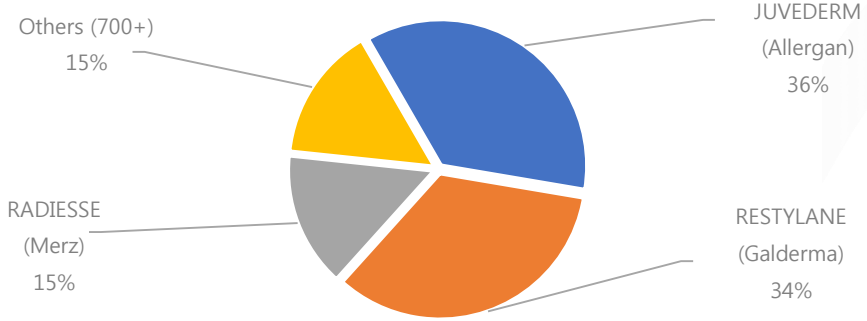
"… and the global filler market grew by an annual average of 9.78% from 2013, forming a market size of about 2.1 billion dollars in 2018"

Global Filler Market Share & Trend ($10 million)



U.S facial injectable market size, by product ($ billion)





Hyaluronic acid products based on biological have high share in the global market.

However, the interest for various raw materials, especially polymer products, is increasing due to various demands for indications, long duration and less foreign body sensation.

* Source: GBI Research Proprietary database, LEADING(2019) & Greandviewresearch

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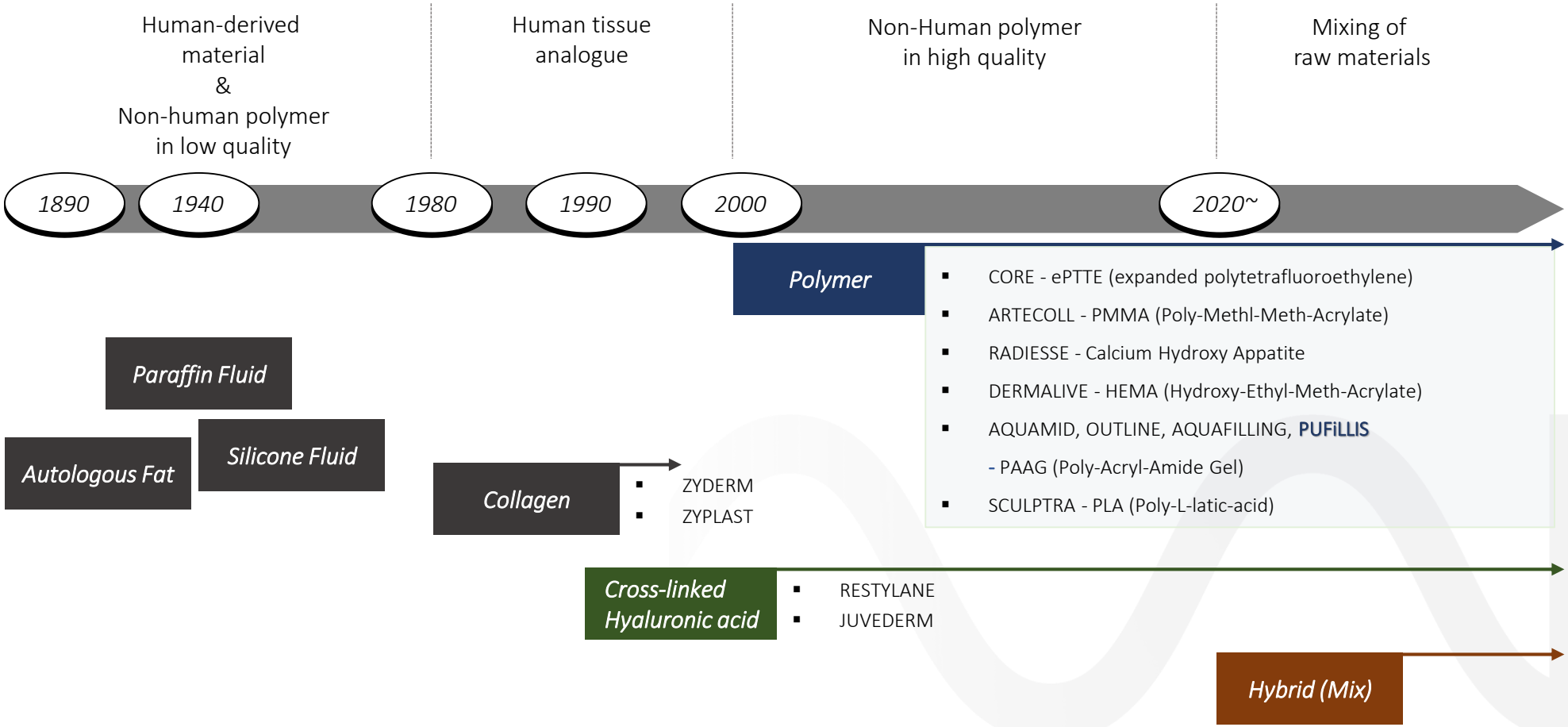
2 About a Filler

Filler acts that immediate and easy to replenish wrinkles and lack a sense of the volume of tissues arising from aging. Recently, because of the desire for beauty, products having indications for the breast and buttocks argumentation as well as the face.



3 About PUFiLLIS® (1/5)

It is hydrophilic hydrogel product consisting of 3.75% Polyacrylamide and 96.25% Sodium chloride solution. This is an absorbent mid-term filler that maintains optimal viscoelasticity and increases safety by extremely removing harmful unreacted monomers(<0.1ppm) that inevitably occur during manufacturing.

PUFiLLIS® Introduction

Residual Monomer ≒ 0

Stable Viscoelasticity

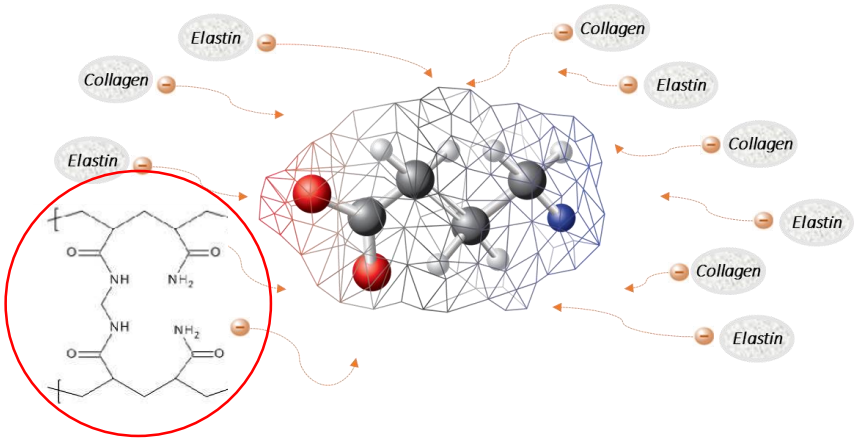
Hydrophilic Gel

	Description
Definition	Mid-term filler with monomer removed through extreme purification
Material	Hydrophilic gel of 3.75% polyacrylamide
Structure	1. 3D Matrix 2. Positive charge 3. Physiological solution
Mode of Actions	- Sponge type of high viscosity water without formation of fibrous capsulation - Substitution of ECM; Attract HA, Collagen, Elastin and GAG by positive charge
Duration	1 to 3 years
Bio absorption	Slowly absorbed by macrophages and excreted in urine
Weight	Light material (Like pure water, the specific gravity is 1)
Indication	Face & Body

3 About PUFiLLIS® (2/5)

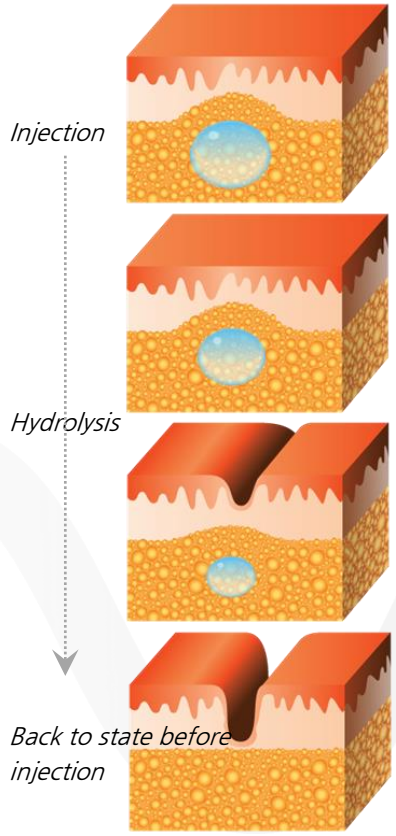
Based on the technology, know-how and patents of MI-LINKER co., Ltd., unlike existing acrylamide raw material products, despite the relatively high polyacrylamide ratio(3.75%), it maintains high biocompatibility by creating a very loose 3D bonded structure. At the same time, it exhibits absorbent properties.

3D Matrix & Positive charge



- Optimal biocompatibility (viscoelasticity) is realized at the rate of 3.75% of polyacrylamide
- A special purification method utilizing patents and know-how significantly removes monomers and maintains less than 0.1ppm
- Provides continuous elasticity and durability by attracting substances with a negative charge of the extracellular matrix

Action of PUFiLLIS®

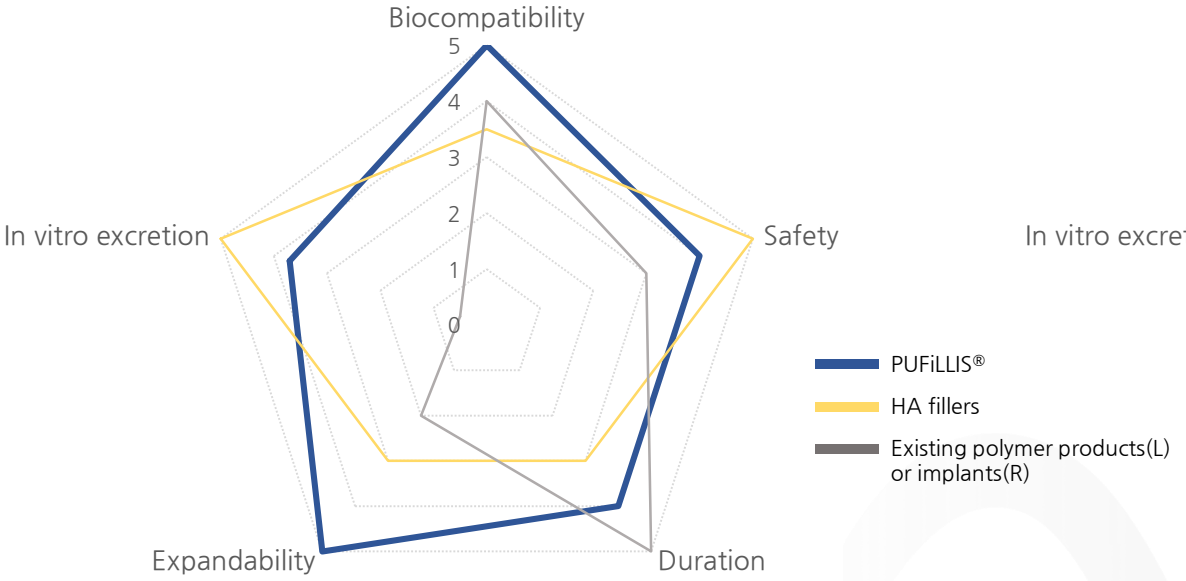


- Volume decrease as the bone begins to disintegrate from the gel surface
- Reactive monomers that were bound are integrated by macrophages
- Excretion by urine

3 About PUFiLLIS® (3/5)

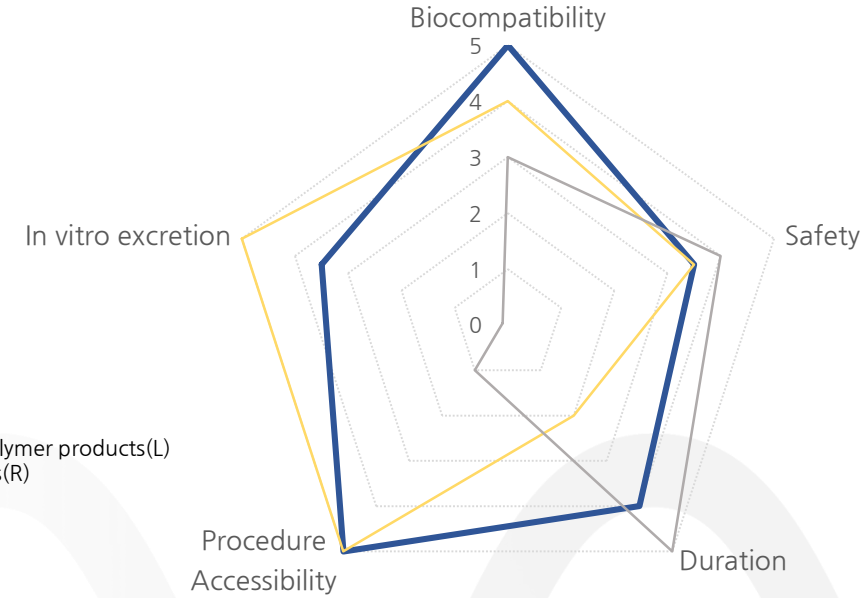
Compared to existing polymer products(for face), and implants(for body), PUFiLLIS® has advantages of high biocompatibility, easy injection procedure and removal, so it has a relatively superiority from risks such as infection and anesthesia. And it has a higher duration than HA filler. Hence, it provides high patient satisfaction.

Comparative Pentagon Graph – for Face



- Unlike existing polymer products, it exhibits higher safety and biocompatibility due to its absorption properties, while the trouble shooting is easy
- Compared to HA products, it's possible to use various indication in the face area including long duration and deep wrinkles.

Comparative Pentagon Graph – for Body



- Compared to implants, it has high biocompatibility and excellent accessibility to procedure, and is advantages from surgical turnover and potential risks because the relatively short operation time (around 30 min.)

3 About PUFiLLIS® (4/5)

Comparative Table – for Face

	PUFiLLIS®	Existing PAAG	Cross-linked HA
Source	Co-polymer	Co-polymer	Microbial production
Bond	3D Cross link	2D Cross link	Cross link
Type	Hydrogel	Hydrogel	-
Water	Soluble	Swelling	Insoluble
Charge	Positive	No	No
Viscosity	Newton liquid	Tixotropic	Less
Biodegradable	Yes	No	Yes
Migration	No	Yes	Yes
Toxic	No	Yes(monomer)	No
Complication	Injection error	Granuloma, etc.	2~3%
Brand	-	Aquamid, etc	Restylane, etc
Weight	Light	Light	Moderate

Comparative Table – for Body

	PUFiLLIS®	Breast Bag	HA Filler
Anesthesia	GA or LA	GA	GA or LA
Operation time	0.5~2 hr*	2hr	0.5 hr
Recovery time	1~14 Days	14 Days	1 Day
Risk of procedure	-	+	-
Duration	3~10 years*	10 years	Less than 1 yr
Top up & Reduction	Both*	No	Yes
Limit of Procedure	Skill required	Skill required	Small amount only
Maintenance	Anytime* or Remove	Remove	More Sagging later
Cosmetic Result	Good	Moderate	Good
Complication	Minimum	Moderate	Minimum
Interference of Image	No	No	Yes
Satisfaction of Patient	Good	Moderate	Bad

* The result may vary depending on the surgical option using the PUFiLLIS®

3 About PUFiLLIS® (5/5)

Considering the biocompatibility due to high viscoelasticity and the characteristic of Gel, you can show its excellent effects for deep wrinkles nasolabial fold and T-zone which are difficult to contour and mold with general HA fillers. And with a specific gravity similar to water, it's lighter than any substitutes or supplement.

PUFiLLIS® Indication

- Soft tissue augmentation
- Superficial & Deep wrinkle
- Folds & Labial augmentation
- Nose augmentation, Scar & Facial remodeling
- Lip augmentation
- Breast augmentation
- Buttock augmentation
- Penile enlargement

* Due to the nature of the Hydrogel, the under eye area may not achieve the desired results.

4 Why Choose PUFiLLIS®?

1. High Safety

PUFiLLIS® is a soft tissue dermal filler, which consists of co-polyacrylamide **(3.75%)** and **normal physiologic 0.9% sodium chloride solution (96.25%)**.

The residual monomers that may occur during production with acrylamide were removed **to converge to zero**.

In addition, it is safer and compatible in human tissues because there are no side effects and discharge using macrophages.

2. Viscoelasticity

The high viscoelastic. Also, its specific gravity is almost equal to water.

So, you can expect results that are most similar to real tissue in the desired area, and it provides youthfulness.

3. Naturalness & Long-lasting effect

PUFiLLIS® is a which consist mainly of refined water.

Thanks to the special properties, this provides a naturalness and softness of the soft tissues, which saves their sensitivity. **There are no contours visible during palpation**.

It break down very slowly. It can be maintained from 1 to 10years depending on the treatment site and method.

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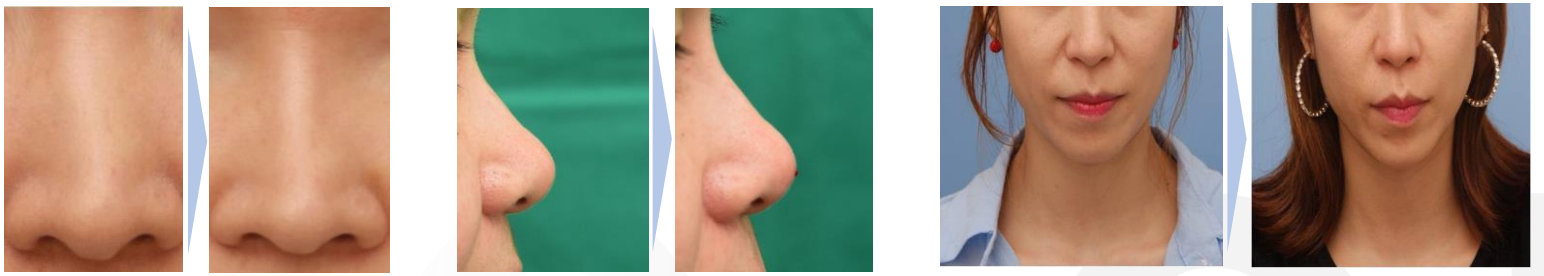
5 Result of PUFiLLIS® Application (1/2)

Facial procedure cases

Forehead contouring
(1㎖ ~ 1.5 ㎖)

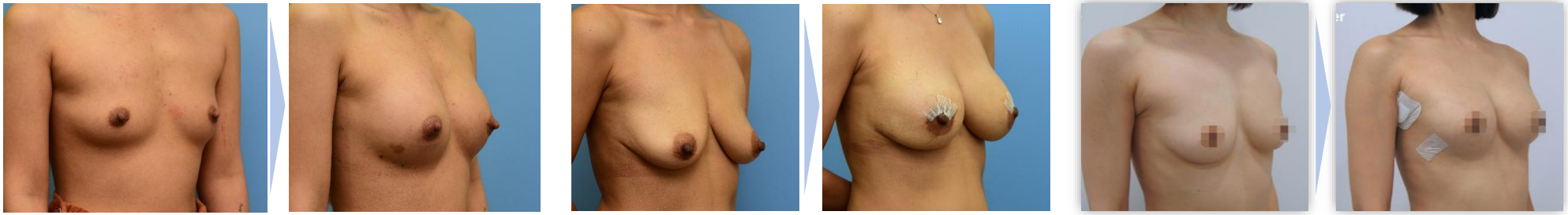
Correction of the nose
& Nasolabial folds
(1㎖ ~ 1.5 ㎖)



Chin contouring
(1.2㎖ ~ 1.5 ㎖)

5 Result of PUFiLLIS® Application (2/2)

Breast procedure cases



※ It is recommended to use after sufficient review by medical staff.

※ It can be used as a filler in combination with a silicone artificial implant (Saline Bag) as well as a direct injection procedure.

Penile procedure cases

6 Quality of PUFiLLIS® (1/2)

By constructing three dual air conditioning systems on dedicated 200m^2 scales, it is divided into [1]manufacturing and filling area (100 class), [2]other production area, and [3]QC area, medical device level 4 GMP(or ISO13485), it's designed, built, and in operation in Korea. And we has a patent for production and KFDA for export certificate.

Images of Factory






Certification

CERTIFICATE OF PATENT

Patent Number 10-2166153

Application Number 10-2020-0007151

Filing Date 2020. 01. 20.

Registration 2020. 10. 08.

Title of the Invention

Synthesis method of Polyacrylamide Hydrogel for Ti

Patentee

Patentees are filled out in a registration page.

Inventor

PARK, HYUNG JUN

This is to certify that, in accordance wit
a patent for the invention has been reg
Property Office.

2021. 04. 14.

COMMISSIONER,
KOREAN INTELLEC

특허청
Korean Intellectual
Property Office

Ministry of Food and

Certificate of Free

Institute of Global Certification

IIGIC

Management System Certification Body No. MSCB-105

CERTIFICATE

No. 21-B-0881 Rev. 0

This is to certify that the Medical Devices-Quality Management System of

MI-LINKER Co.,Ltd.

of

B-806,807, 302, Galmachi-ro, Jungwon-gu, Seongnam-si,
Gyeonggi-do, Republic of Korea

Company Reg. No.: 220-88-94925

has implemented and documented a medical devices-quality management system in compliance with the requirements of the standard

ISO 13485:2016

for

Design, Development, Production, Product Inspection, Storage and Distribution of Polymer Tissue Supplement of Graft/Prothesis

The certificate is issued on the basis of the results mentioned in the pertinent audit report. Validity of the certificate is conditionally limited by positive results of surveillance audits, which the certified company committed to undergo.

This certificate can be invalid if the certificate holder does not fulfill the conditions set out in the certification agreement.

Initial issue date: Apr. 06. 2021
Expire date: Apr. 05. 2024

G. Gilbert
Head of Certification Body

Rm. 501, Daeryung techno town, 638, Seobusaet-gil, Geumcheon-gu, Seoul, Republic of Korea
www.igcert.org

INSTITUTE OF GLOBAL CERTIFICATION

6 Quality of PUFiLLIS® (2/2)

For the past 8 years, we have researched and observed existing PAAGs from the end user's standpoint, and developed PUFiLLIS® together with experts, scientists, and professor in Korea. We have original manufacturing technology and know-how for improved PAAG, and this is where all production processes take place in Korea.

History of Related Quality

- *Aug. 2017.* Initiate a refined PAAG development project (Research and development, cross-verification completed at leading universities in Korea)
- *Feb. 2018.* Patent application for new PAAG manufacturing method
- *Sep. 2019.* Start of factory construction in Korea
- *Jul. 2020.* PUFiLLIS® acquired permission KFDA for export
- *Sep. 2020.* Patent registration for PUFiLLIS®
- *Oct. 2020.* Completed factory for PUFiLLIS® & Constructed automatic defoaming and filling system in cleanroom

Plan for Quality Verification

- *First Half 2021.* Acceptance into Product/Completed Operations Liability ($100,000) – KB Insurance Co., Ltd.

  ISO13485:2016 approved

  Philippine FDA approved (CPR in progress)
- *Second Half 2021.* Acquisition of GLP(Good Laboratory Practice) report

  CE certification preparation

7 Result of Safety Tests (1/5)

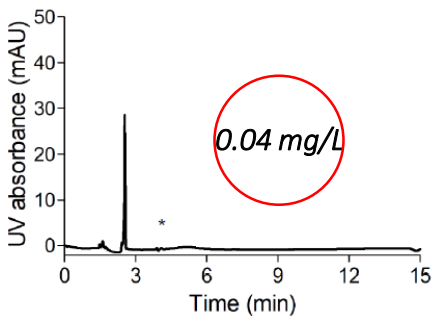
Regarding the safety, which is the weakness of products using acrylamide as raw material, before injection [1]level of unreacted monomer, after injection [2]polarized photo in the human body, [3]mechanisms excreted by rats, and [4]cytotoxicity test, etc. It has proven its superiority compared to existing PAAG products.

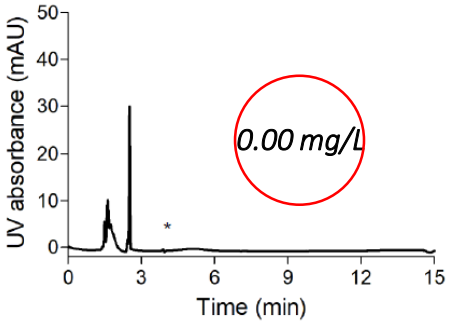
*(1) Level of Unreacted Monomer (HPLC)**

Residual monomers, which are inevitably generated when polyacrylamide gel is produced, can have a harmful effect on the human body even in small amounts. This test is a direct that can confirm how pure PUFiLLIS® is.

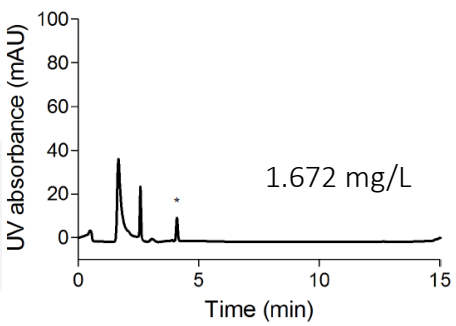
"Unreacted monomer value of PUFiLLIS® does not exceed 0.1ppm(mg/L) by utilizing the manufacturing method patent and know-how"

[PUFiLLIS®]





[Similar product]



Even on dozens of tests, PUFiLLIS® did not exceed 0.1ppm(mg/L)

* Source: Bio-function materials & tissue engineering lab in Hanyang University / The research institute of basic sciences in Seoul University

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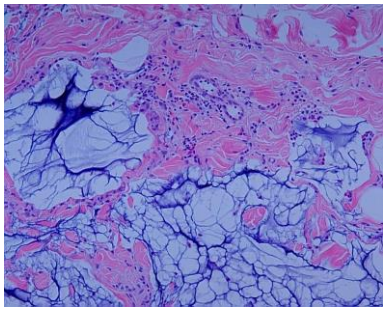
7 Result of Safety Tests (2/5)

(2) Polarization Photo in Body*

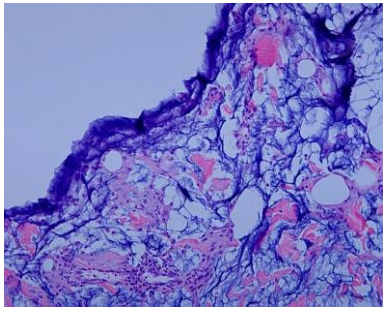
PUFiLLIS® is injection into the human body can be found represents which history. And when it injected a saline, we have observed that dissolving time & showed histological changes after dissolution.

"Confirmation of shape absorbed by macrophages"



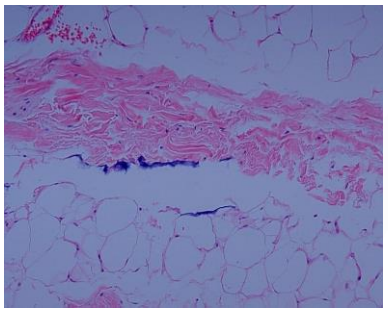
A large and variable size small spaces containing PUFiLLIS® (H&E, x400)

The biopsy status after 3 weeks of filler injection (the control group)



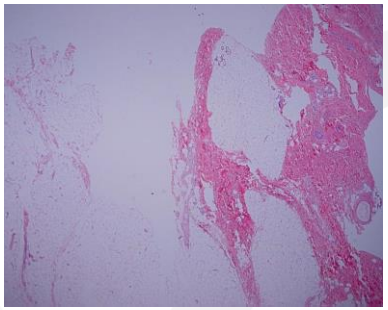
The filler is remarkably melting and condensed at the periphery (x400)

The biopsy status after 30 minutes from injected saline(1㎖)



The spaces previously occupied with filler are mostly empty and still contain small amount of filler remnant (x400)

The biopsy status after 2 hours from injected saline(1㎖)



The skin turns back to normal structure 1 day after saline injection (x20)

The biopsy status after 1 day from injected saline(1㎖)

* Source: LEE, SUN WOO MD, Ph.D / KIM, EUN KYUNG MD, Ph.D

7 Result of Safety Tests (3/5)

(3) Excretion Mechanism*

We conducted the experiments using rats to confirm the mechanisms of excretion of the PUFiLLIS®. In this experiment, we were able to obtain two results. (1)Rats also did not have any problems and (2)the metabolites were detected in the urine of rats.

"Confirmation of acrylamide metabolite (AAMA; N-acetyl-S(3-amino-3-oxopropyl)-L-cysteine) detection through urine"

Table 6. Concentration of AAMA in rat urine samples (Male)

Group	Animal No.	Time											
		1st (ng/total volume)						2nd (ng/total volume)					
		0	6	12	24	48	72	0	6	12	24	48	72
Reference	11001	NA	NA	NA	NA	NA	NA	-	-	-	-	-	-
	11002	NA	NA	NA	NA	NA	NA	-	-	-	-	-	-
	11003	NA	NA	NA	NA	NA	NA	-	-	-	-	-	-
	11004	NA	NA	NA	NA	NA	NA	-	-	-	-	-	-
	11005	NA	NA	NA	NA	NA	NA	-	-	-	-	-	-
Test substance 1	12001	NA	68.69675	539.456	NA	NA	NA	NA	NA	NA	NA	NA	NA
	12002	NA	4093.8684	2992.6635	NA	NA	NA	NA	NA	NA	NA	NA	NA
	12003	NA	1680.7812	1829.166	NA	NA	NA	NA	NA	NA	317.586	NA	NA
	12004	NA	2407.4388	767.8856	NA	NA	NA	NA	NA	NA	NA	NA	NA
	12005	NA	5667.4384	2949.8456	NA	NA	NA	NA	NA	NA	NA	NA	NA

of AAMA in rat urine samples (Femae)

	nal No.	1st (ng/total volu											
		0	6	12	2								
	001	NA	NA	NA	N								
	002	NA	NA	NA	N								
Reference	21003	NA	NA	NA	NA			-	-	-	-	-	-
	21004	NA	NA	NA	NA	NA	NA	-	-	-	-	-	-
	21005	NA	NA	NA	NA	NA	NA	-	-	-	-	-	-
Test substance 1	22001	NA	1793.0772	9173.7139	1601.055	1132.04	NA	NA	NA	555.4868	NA	NA	NA
	22002	NA	5290.362	6740.5248	766.8972	NA	NA	NA	NA	158.3796	NA	NA	NA
	22003	NA	3997.098	NA	NA	NA	NA	NA	NA	210.192	1573.513	NA	NA
	22004	NA	7040.7392	147.66925	1628.892	NA	NA	NA	NA	137.4456	NA	NA	NA
	22005	NA	-	8369.4006	574.4585	NA	NA	NA	NA	NA	3258.645	NA	NA

* Source: Genetic toxicity team in MEDVILL co., ltd. & Hoseo Analytical Research Institute of Medical Science

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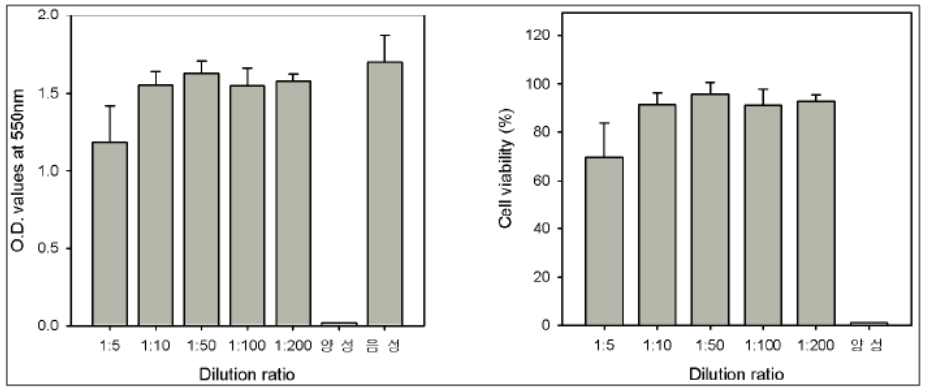
7 Result of Safety Tests (4/5)

(4) Cytotoxicity Test*

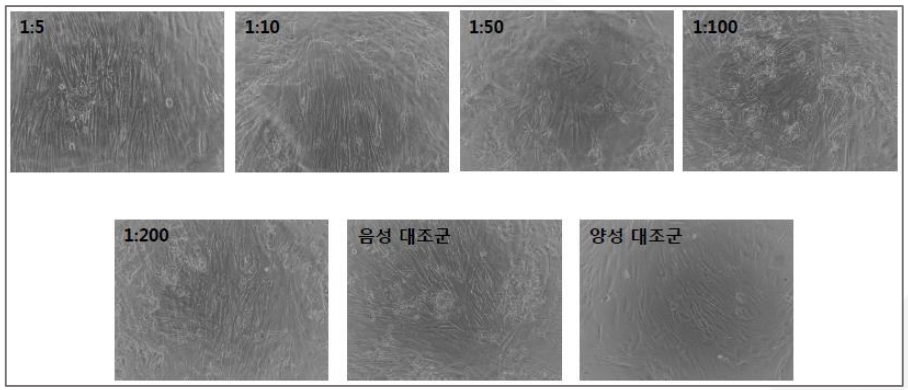
Toxicity of PUFiLLIS® & Cytotoxicity evaluation of the degradation products produced from the decomposition process and eluted material (Compliance with ISO10993-5)

[MTT assay (Evaluation of the number of cells)]



"1:5 or more, the dilution ratio was not detected at all, the toxicity of the cell"

[Cytomorphologic evaluation]



"Cell morphology was confirmed also that the eluted degradation products had no toxicity within the concentration range"

* Source: Bio-function materials & tissue engineering lab in Hanyang University

7 Result of Safety Tests (5/5)

*(5) Specific Gravity & Poorly Water-Soluble Test**

"Confirmed that it is almost the same as the specific gravity of water"

Check specific gravity though density comparison with pure H_2O

	Material Weight (2㎖)	Value of SG
DI Water	1.97	1
PUFiLLIS®	2.01	1.020305

"A Significant differences from existing PAAG products"

Poorly water-soluble test using 100% Et-OH

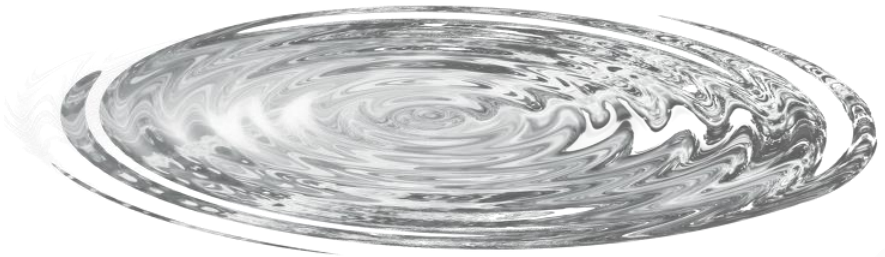
[PUFiLLIS®] [Similar product]

Determine the difference from existing PAAGs by measuring the viscosity of 10% N/S diluted solution

Normal Saline	PUFiLLIS®	Similar Product
80±10	85±15	540±60

* Source: Korea Pharmaceutical test & research institute / Bio-function materials & tissue engineering lab in Hanyang University / College of life resources and sciences in Donga University

Another New Generation Filler



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by removing even one factor that can harm

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