Cross-Linked Hyaluronic Acid Filler

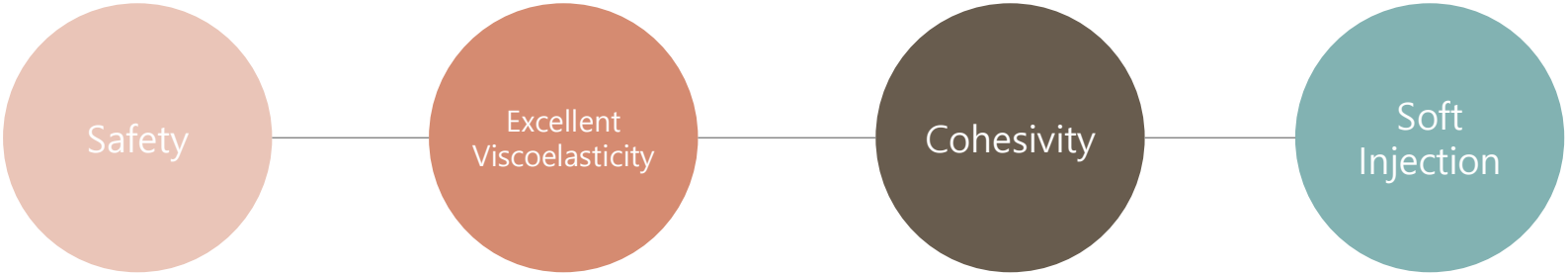
For Internal training

contents

Revitrane is..

Revitrane – Maximized advantage of HA filler

Safe monophasic type filler with minimal crosslinking agent(BDDE).



- High-quality raw material
- Minimized chemical cross-linking rate using BDDE
- Advanced residual BDDE cleaning process

- Uniform cross-linked HA structure
- Soft viscoelastic gel texture for making natural volume

- Keep initial volume for long time by cohesive gel
- Improved skin integration that blends with surrounding skin tissue

- Smooth and uniform injection
- Low extrusion force compare to the others

Revitrane is..

Monophasic type

Soft viscoelastic hyaluronic acid gel texture

REVITRANE

- *Classic*
- *Volume*
- *Premium*

CE
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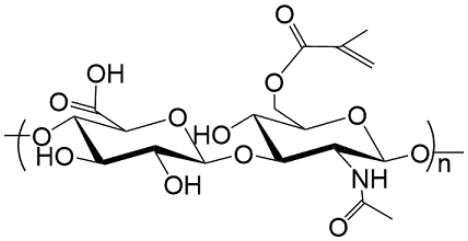
For Internal training

Revitrane is..

Skin Booster

Cross-linked gel with smooth and low cohesion gel for biorevitalization and moisturizing

Safety



Hyaluronic Acid

High Quality HA Raw materials

Approved raw material (from Shiseido, Japan)

Revitrane is manufactured using safe and qualified hyaluronic acid approved US FDA and European Directorate for the Quality of Medicines(EDQM)

Constant HA molecular structure

Stable HA structure that can endure external pressure

Purity

Safe material with lass then 10ppm of heavy metal (standards for US FDA and EDQM is 20ppm)

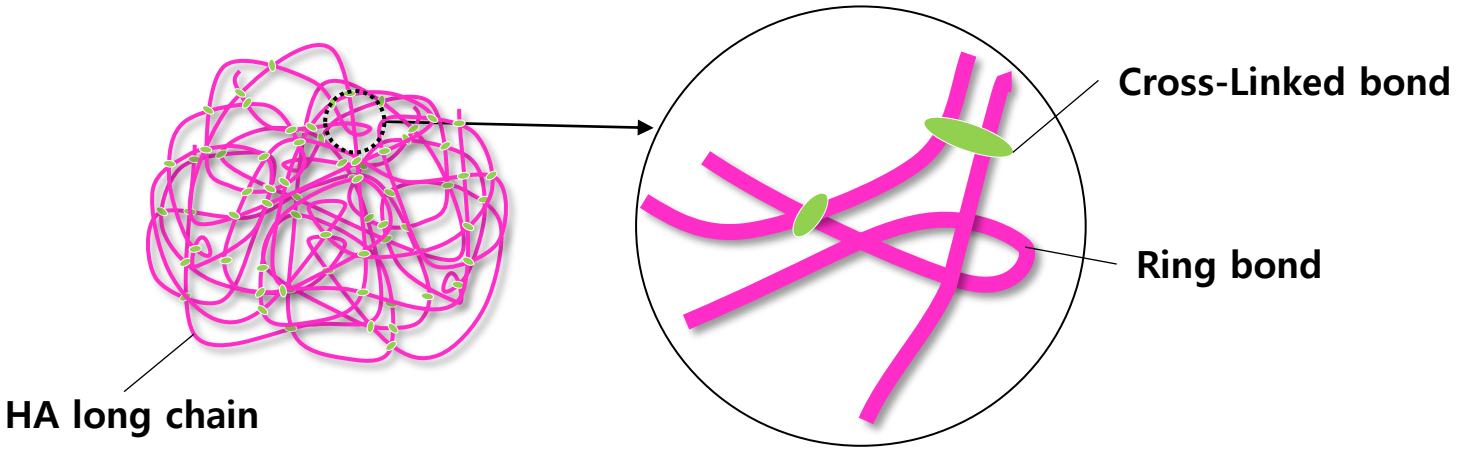
	PH. Eur	Revitrane
Residual protein	Maxium 0.3% or 0.1%	Maximum 0.1%
Endotoxin	<0.5 or 0.05IU/mg	<0.04IU/mg

Safety

BR PHARM's own HA cross-linking process

Low-chemical & **E**nhanced **D**ouble Cross-linking Method : **LED Method**

Long-time & Low-temperature cross-linking → Minimize HA deformation and increase physical crosslinking rate



Minimizes incomplete crosslinking parts(Pentant cross-linker) and increase complete cross-linking rate using long-time and low-temperature cross-linking process.

Safety

Purification Technology of Cross-Linked HA

Advanced Technique for Elimination of Residues, ATER

Unique washing technology removes residual BDDE and impurities with minimized HA deformation

Use minimum BDDE → Cross-linking ratio(MoD*) is less than 5%

Factor	J Product	Revitrane
BDDE amount	800~1000ppm	**500ppm**

Elimination tech. of residual BDDE → Complete removal of residual BDDE with unique repetitive cleaning technology

Color comparison after drying HA gel

Yellow color
For incomplete
cleaning residuals

Incomplete
washing (Yellow)

Complete
washing(White)

White color that is
original color of HA
raw material
for complete
cleaning residuals

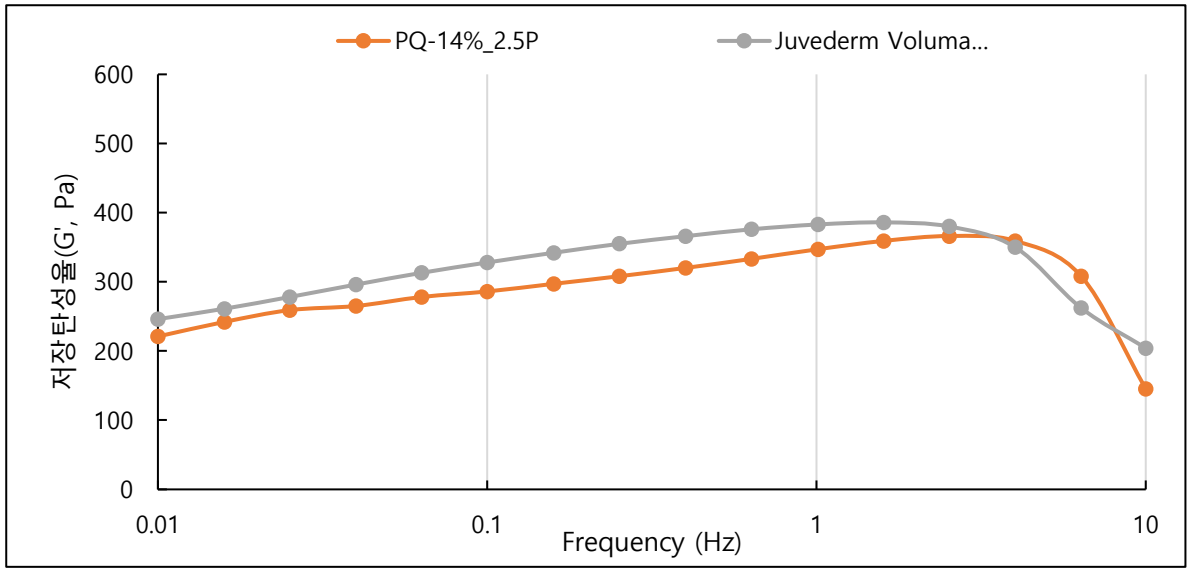
* MOD : Degree of modification

Viscoelasticity

Excellent Viscoelasticity(G')

Revitrane is soft gel type filler with very fine HA particles for optimal viscoelasticity makes natural volume. And Revitrane is easily molded and smooth injection feeling.

Product	0.1Hz	1.0Hz
Juvederm Voluma	310~330 Pa	350~400 Pa
Revitrane Premium	328 Pa	383 Pa



Revitrane Premium has similar viscoelasticity to Juvederm Voluma product

Cohesivity

High Cohesivity

Revitrane's cohesive gel texture maintains initial shape and minimizes migration under pressure

Ink diffusion testing result after 6hours for Revitrane Premium and other Korean products

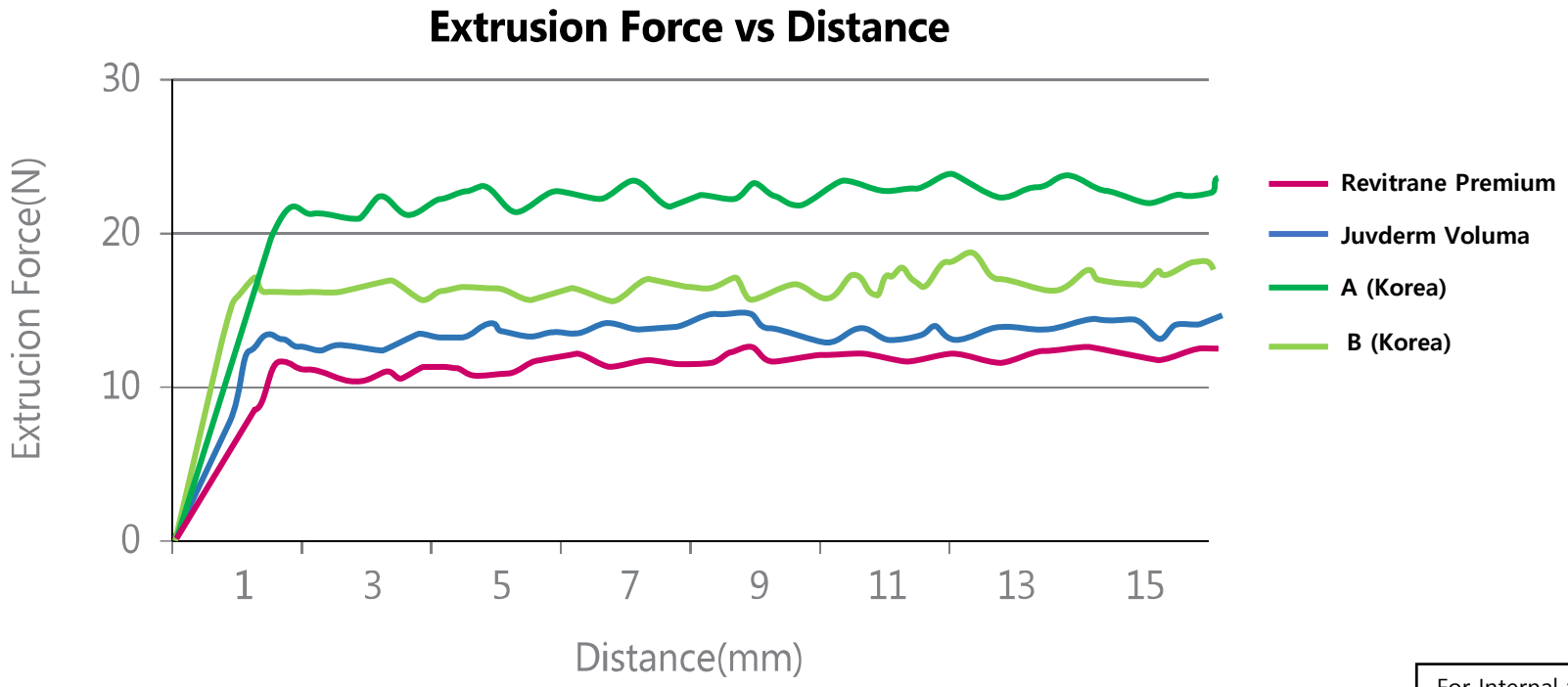
Revitrane Premium **A** **B**

Soft Injection

Low extrusion force improves treatment satisfaction

Revitrane has low and constant extrusion force though high-quality HA material and purification process for making uniform HA structure.

Product	Extrusion force(N)
Juvederm Voluma	12~15
Revitrane Premium	**10~12**

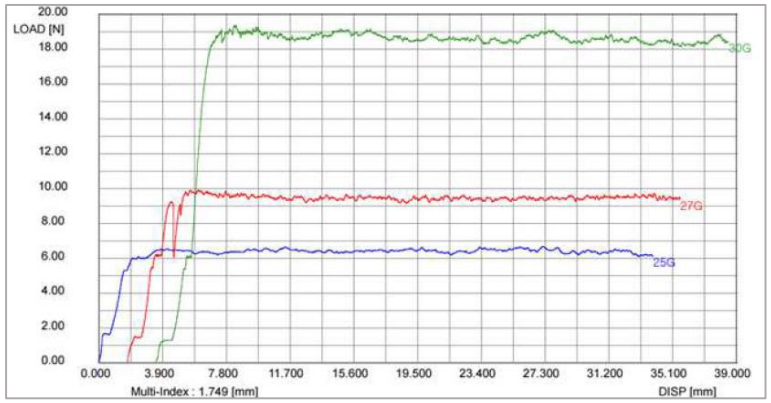


Soft Injection

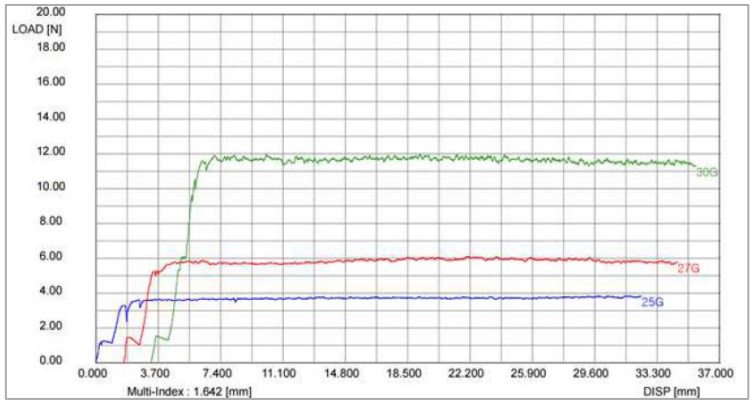
Low extrusion force improves treatment satisfaction

Revitrane Premium, Volume, Classic has an low injection pressure of 12 to 19N when using a 30G needle and an injection pressure of 3 to 7N when using a 27G needle. It is possible to select the needle according to the skill of the operator with a lower injection pressure than other filler products to perform the procedure.

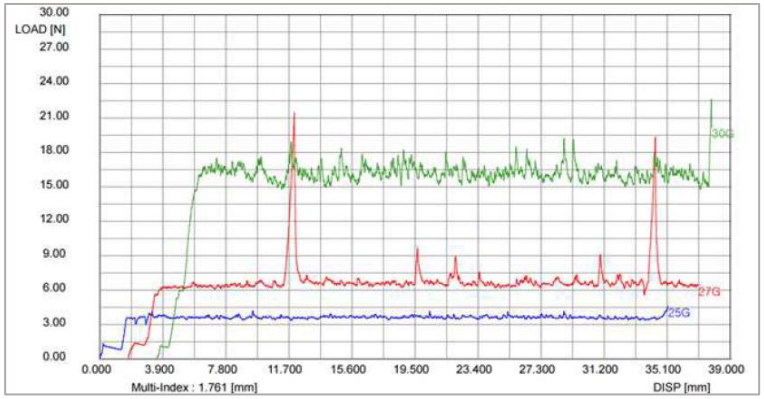
Revitrane Classic



Revitrane Volume



Revitrane Premium



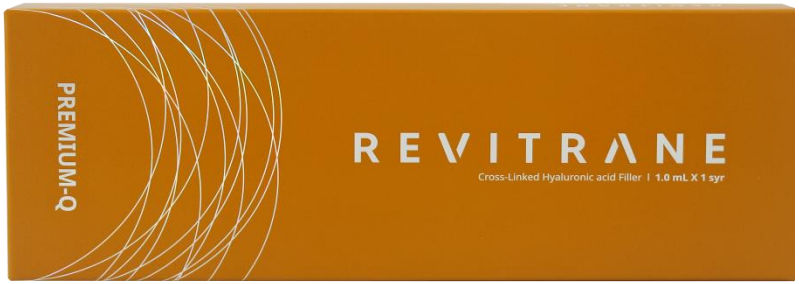
30G
27G
25G

Revitrane – Biphasic type lines

Revitrane Premium Q and Premium SUB-Q

Particle structured gel type with high elasticity for extensive facial volume augmentation

PREMIUM Q



PREMIUM SUB Q

Revitrane – Biphasic type lines

Biphasic type

Uniform cross-linked hyaluronic acid particles

- **Stabilizing & Enhancing Elasticity Double-cross-linking(SEED) Technology**
- **Maximize binding ratio by our own cross-linking method for biphasic structure**
  - Chemical crosslinks and twist structure
  - Controll and make different particle size for treating purpose

- **Control the size of particles**

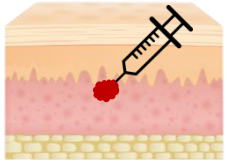
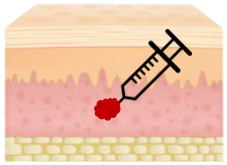
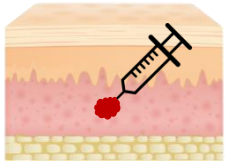
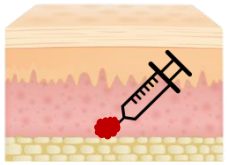
Product	Particle Size(micron)
Revitrane Premium SUB-Q	800
Revitrane Premium-Q	600

Particles (SUBQ) ▶

contents

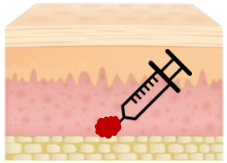
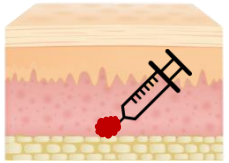
Product Specification & Treatment Area

Revitrane Series (Monophasic)

Product	Packaging	Concentration	Needle	Injection depth
 **Skinbooster**	2ml*3syr/box	20mg/ml	31G or 34G(NanoNeedle) Multi Needle Injector	
 **Classic**	1ml*1syr/box	20mg/ml	30G	
 **Volume**	1ml*1syr/box	20mg/ml	27G	
 **Premium**	1ml*1syr/box	20mg/ml	27G	

Product Specification & Treatment Area

Revitrane Premium Series(Biphasic)

Product	Packaging	Concentration	Needle	Injection depth
 **Revitrane Premium Q**	1ml*1syr/box	20mg/ml	25G	
 **Revitrane Premium SUB-Q**	1ml*1syr/box	20mg/ml	25G	

Revitrane HA20 Skin Booster

Skin Booster has lower viscosity and elasticity, and is suitable for improving fine wrinkles and overall moisturizing & elasticity of the face.

Gel Type

- Viscosity ●
- Elasticity ●
- Cohesivity ●

Needle Size

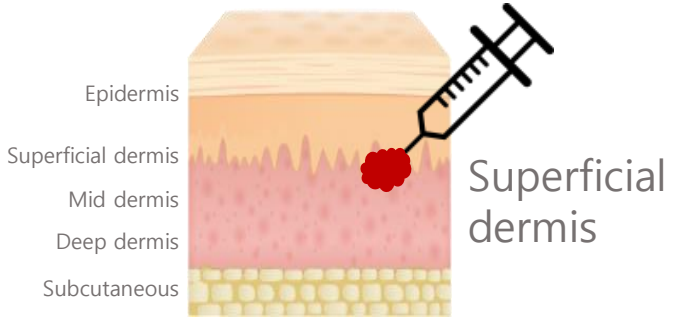
- Needle is not included
- 31G is suitable

Treatment Area

● Skin Booster

- Whole face
- Water shine treatment

Injection Depth



Revitrane Classic

Classic is designed to be treatment of the areas like lips or fine lines for expressing natural volume. It is suitable for areas that require natural volume due to less swelling.

Gel Type

- Viscosity ● ●
- Elasticity ●
- Cohesivity ●

Needle Size

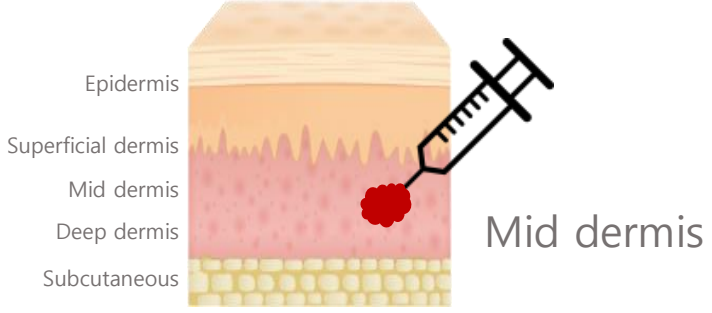
- 30G x 2 needles are included
- 30G-31G needle is suitable

Treatment Area

● Classic

- Around eyes
- Under eyes
- Smile lines
- Wrinkles around lips
- Lip volume

Injection Depth



Revitrane Volume

Volume is viscous gel texture to restore volume as it attracts and keeps moisture in the skin.
Volume has high expansion rate, so it is suitable for volumizing

Gel Type

- Viscosity ● ● ●
- Elasticity ●
- Cohesivity ● ●

Needle Size

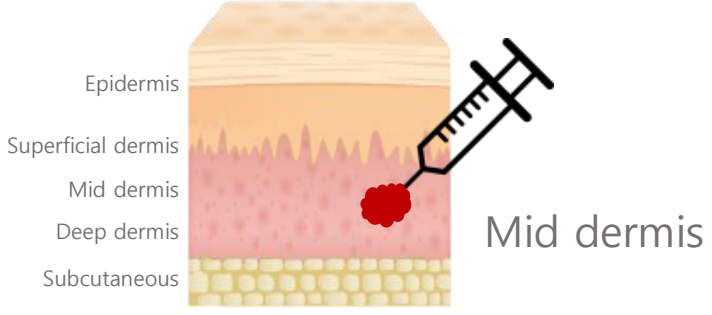
- 27G x 2 needles are included
- 27-30G needle is suitable

Treatment Area

● Volume

- Cheek
- Nasolabial folds

Injection Depth



Revitrane Premium

Premium is slightly viscous and high elastic gel type, so it is suitable for most of treatment areas for volumizing

Gel Type

- Viscosity ●
- Elasticity ● ● ●
- Cohesivity ● ● ●

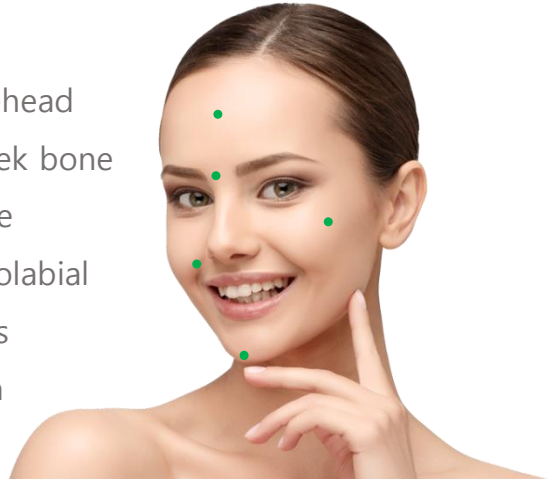
Needle Size

- 27G x 2 needles are included
- 27-30G needle is suitable

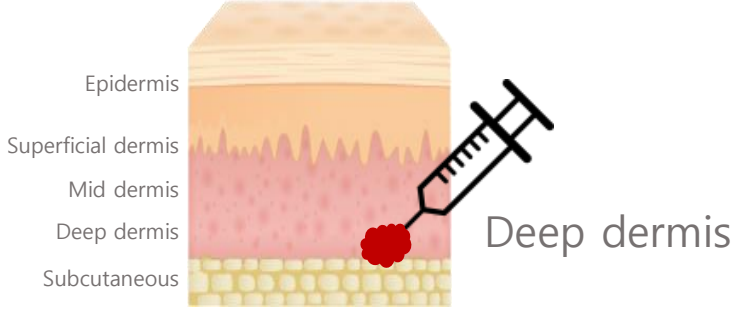
Treatment Area

● Premium

- Forehead
- Cheek bone
- Nose
- Nasolabial folds
- Chin



Injection Depth



Revitrane Premium-Q

Premium-Q's biphasic type particles provides good support to maintain structure, it is suitable for making shape of the nose area.

Gel Type

- Viscosity -
- Elasticity ● ● ●
- Cohesivity ●

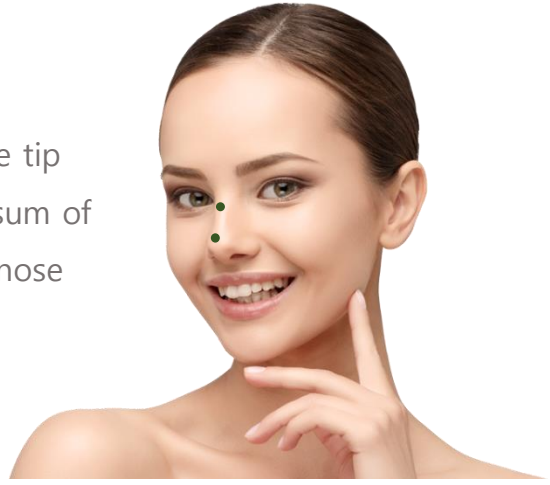
Needle Size

- 25G x 2 needles are included

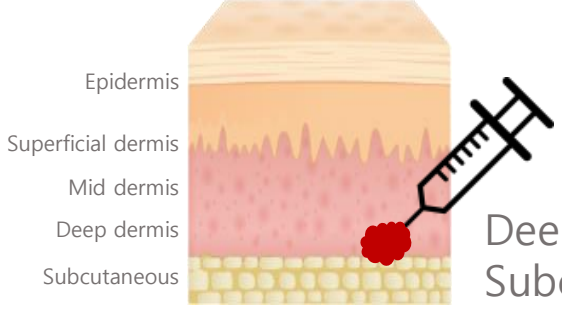
Treatment Area

● Premium

- Nose tip
- Dorsum of the nose



Injection Depth



Deep dermis/ Subcutaneous

Revitrane Premium SUB-Q

Premium SUB-Q has bigger size biphasic type particles than Premium-Q and it provides good support to maintain structure for cheek or chin area

Gel Type

- Viscosity -
- Elasticity ● ● ●
- Cohesivity ●

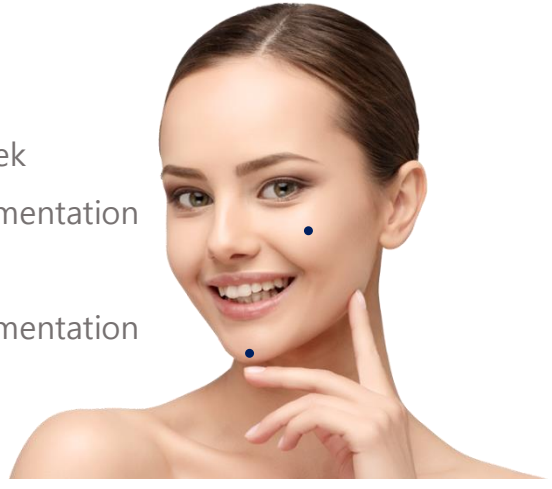
Needle Size

- 25G x 2 needles are included

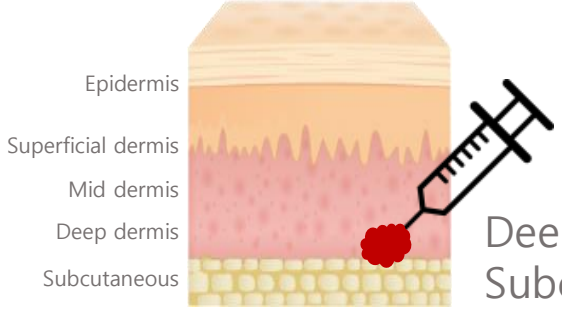
Treatment Area

● Premium SUB-Q

- Cheek augmentation
- Chin augmentation



Injection Depth



Deep dermis/ Subcutaneous

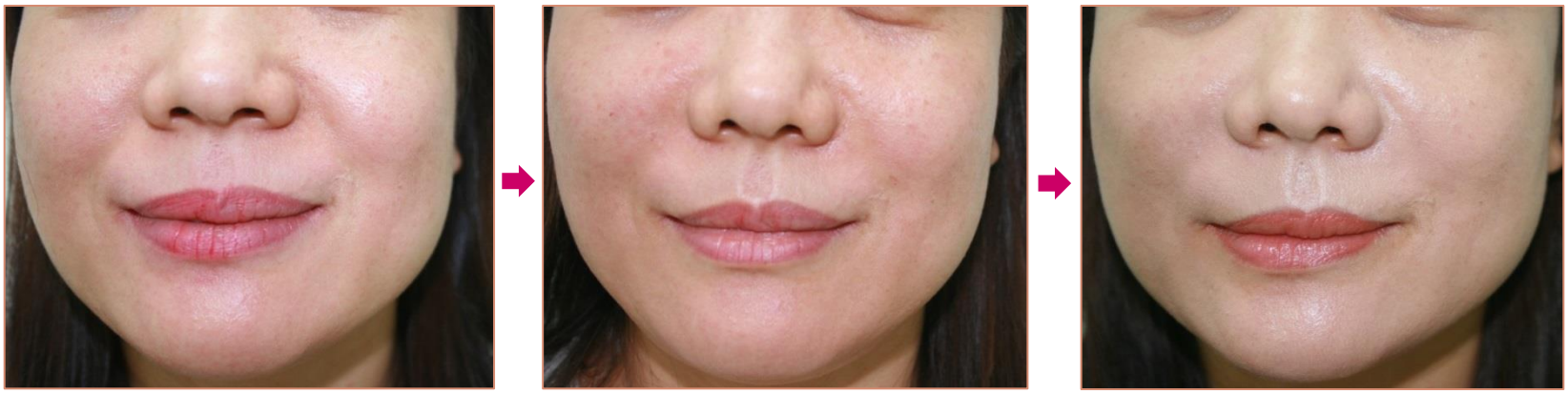
contents

Clinical data

Before & After

Revitrane Volume, Age 43, Female, Nasolabial fold Left 2cc/Right 3cc

Before **Right After** **After (7days later)**

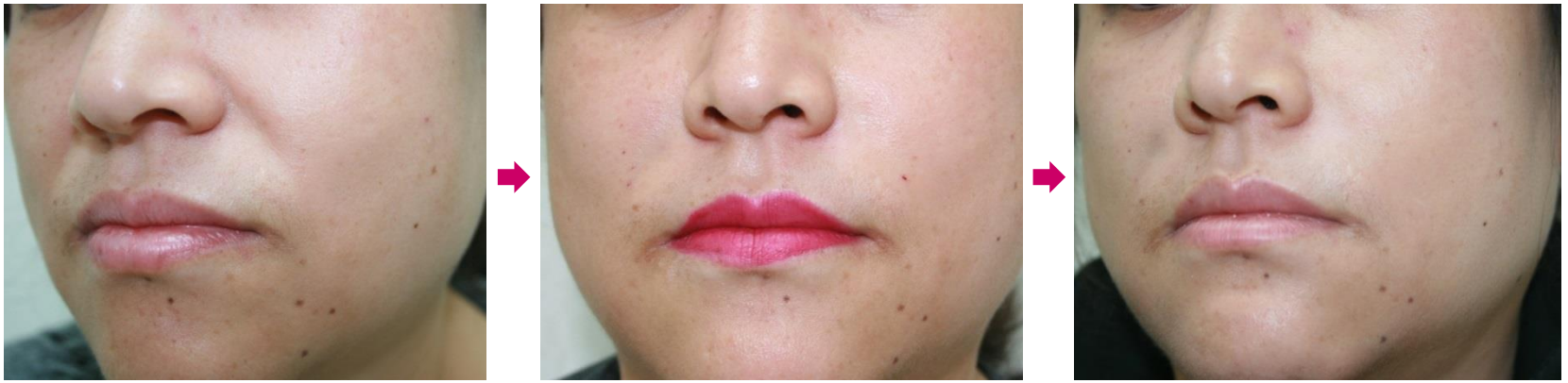


Clinical data

Before & After

Revitrane Volume, Age 40, Female, Nasolabial fold Left 3cc/Right 3cc

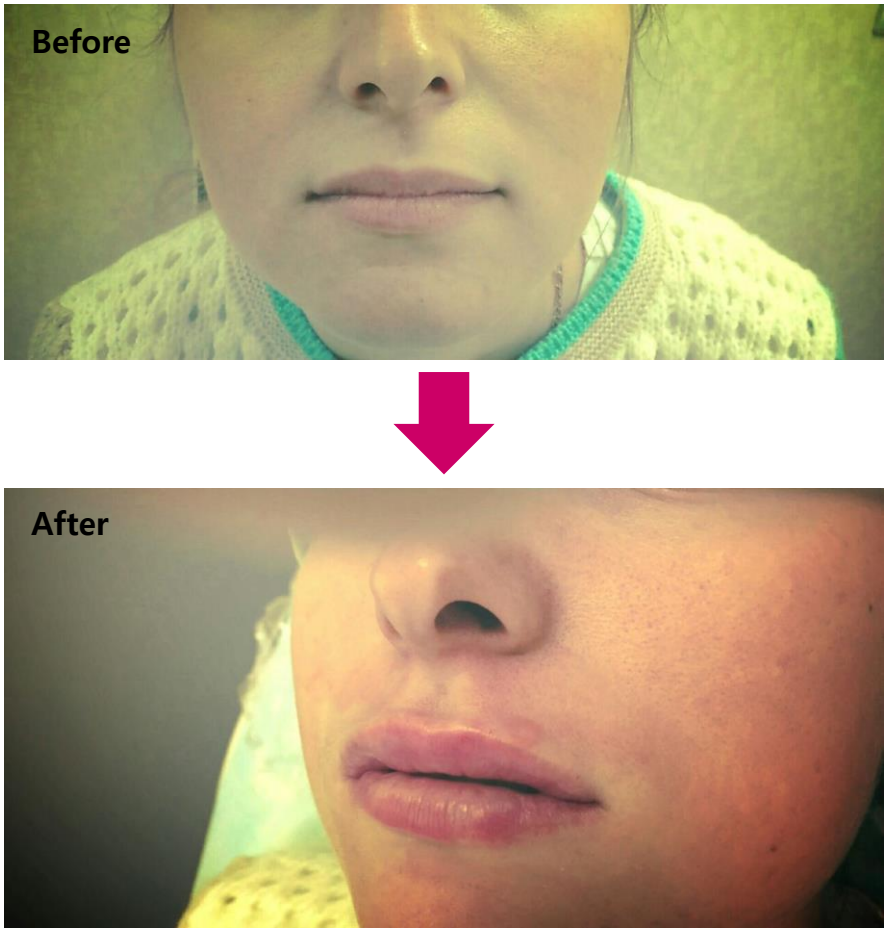
Before **Right After** **After (7days later)**



Clinical data

Before & After

Lips : **Revitrane Classic 0.8ml**



Clinical data

Before & After

1. Cheek : **Revitrane Premium SUB-Q 1cc**
2. Whole face : **Revitrane HA20 Skin Booster**

Clinical data

Before & After

1. Forehead + eyebrow
   : **Revitrane Classic 1.2ml**
2. 1st and 2nd zygomatic lines
   : **Revitrane Volume 1.0ml**
3. Nasolacrimal groove
   : **Revitrane Classic 0.6ml**
4. Nasolabial folds
   : **Revitrane Classic 1.4ml**
5. Lips
   : **Revitrane Classic 0.8ml**
6. Whole face
   : **Revitrane Skin booster 2.0ml**

contents

Study

Pre-clinical study

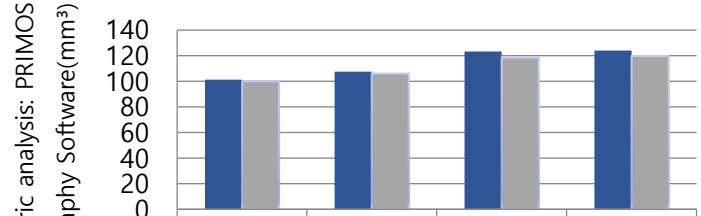
In the comparative advantage test, as a result of testing the volume of Revitrane and J Company's product in the folds, the Rebitran volume showed excellent initial volume and durability.

In a comparative study on injections between Revitrane vloume and Product J,
The result showed great efficacy and long lasting at the nasolabial folds

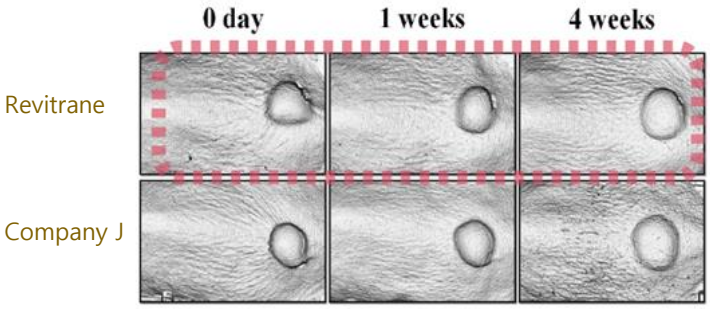
- **Efficacy assessment – Long lasting Scored by Chung Ang Univ., Korea 2018**

Volume Change after Revitrane

Volume injection



	Day0	week 1	week 4	week 8
Revitrane	101.17	107.47	123.29	124
Company J	100	106	118.52	119.7



The change of initial filler volume: Volumetric analysis; PRIMOS(LITE) topography (with software PRIMOS 5.8)

Study

Research of cross-linking #1

Study of swelling degree and elasticity according to HA molecular weight

Polymer(Korea), Vol. 39, No. 6, pp. 976-980 (2015)
http://dx.doi.org/10.7317/pk.2015.39.6.976

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ISSN 2234-8077(Online)

히알루론산 피부용 필러의 분자량에 따른 팽윤도와 탄성계수 영향

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셀루메드 생체재료의공학연구소 *㈜비앙뷰티플 레볼루션

(2015년 7월 16일 접수, 2015년 7월 23일 수정, 2015년 8월 3일 채택)

Influence of Molecular Weight on Swelling and Elastic Modulus of Hyaluronic Acid Dermal Fillers

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****R&D Laboratory, Cellumed Co., Ltd., Seoul 153-782, Korea*
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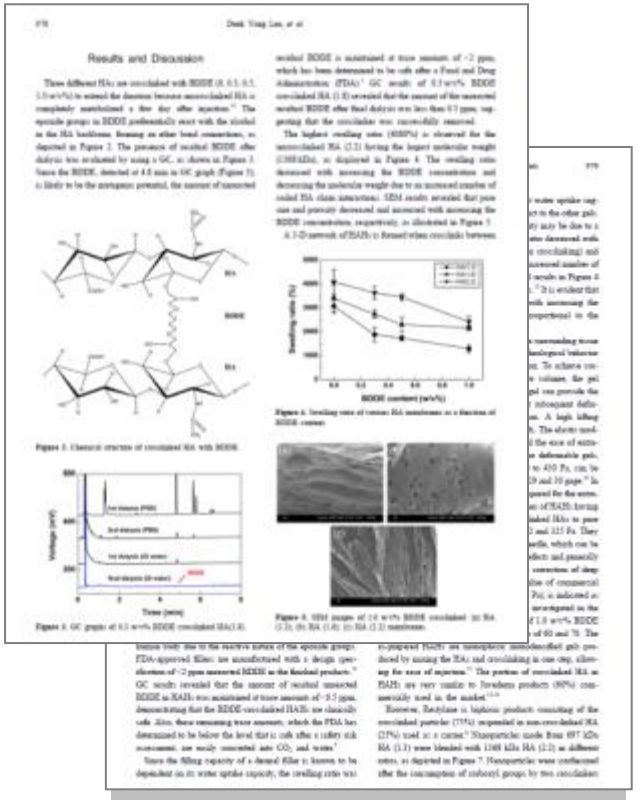
초록: 분자량이 다른 세종류 히알루론산(HA)에 1,4-butanediol diglycidyl ether(BDDE)가 가교된 HA를 첨가하여 하이드로젤을 제조하고 HA 분자량에 따른 팽윤도와 탄성계수의 효과를 조사하였다. 최종 두석 후 잔류 BDDE 양은 0.5 ppm 이하이었다. 비가교된 분자량이 큰 HA에서 최대 팽윤도가 관찰되었다. 팽윤도는 비가교 HA 양과 가교도에 각각 비례와 반비례하였다. 1.0 w/v% BDDE 가교 HA와 HA(1368 kDa)를 혼합한 monophasic 하이드로젤의 탄성계수는 152~325 Pa이었다. 15% 가교 HA(687 kDa)과 85% HA(1368 kDa)로 구성된 biphasic 하이드로젤의 탄성계수는 178 Pa이었다.



Study

Research of cross-linking #2

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가교된 히알루론산 구슬로 제조한 피부용 필러의 점탄성 특성

전철병 · 김예나 · 손시원 · 이득용† · 김진태 · 권미경* · 김영주** · 김석순***
대림대학교 의공융합과, *네오바이오텍 치과재료연구소, **베리콤 기술연구소, ***㈜비알뷰티플 레볼루션
(2016년 2월 2일 접수, 2016년 2월 26일 수정, 2016년 3월 7일 채택)

Viscoelasticity of Hyaluronic Acid Dermal Fillers Prepared by Crosslinked HA Microspheres

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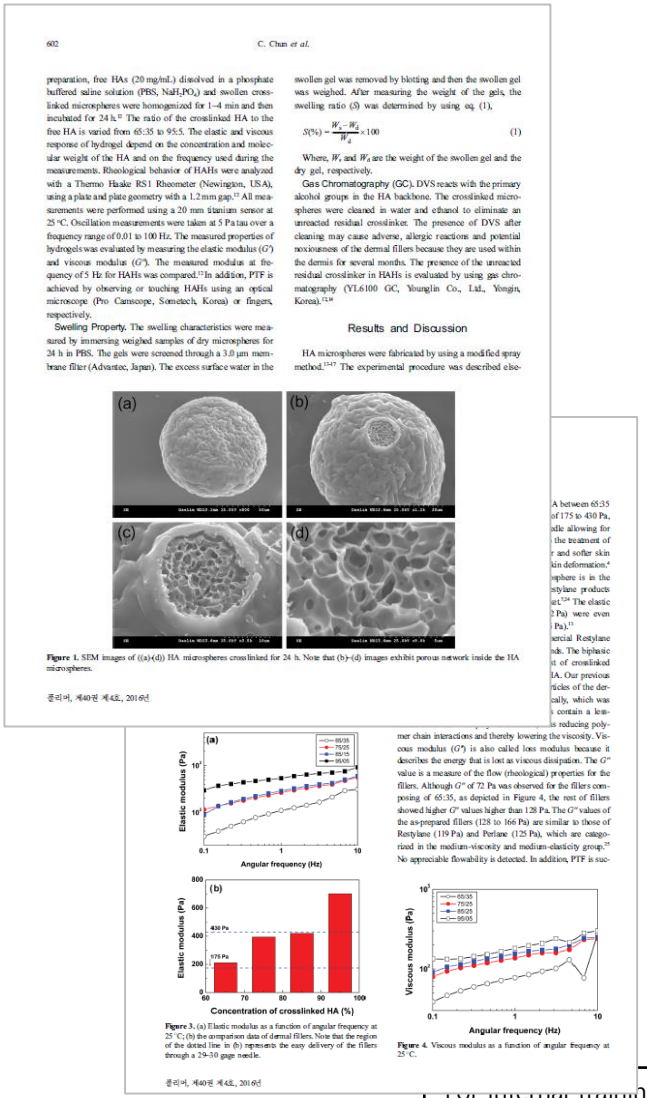
초록: 디비닐 설폰 가교제로 가교한 히알루론산(HA) 구슬과 비가교된 HA의 부피비가 65/35~95/5로 다른 피부용 HA 필러를 제조하여 가교된 HA 구슬이 필러의 탄성계수와 입자감에 대한 효과를 조사하였다. 구슬 내 2~4±0.5 μm 내부기공을 가진 HA 구슬의 평균 입도는 60~100±4 μm이었다. HA 필러의 가교된 젤 입자 크기는 300±30 μm이었다. 가교된 HA 미세구슬의 부피비가 65에서 95%로 증가함에 따라 필러의 탄성계수는 211에서 700 Pa로 증가하였다. 29~30 게이지 주사바늘을 통과할 수 있는 175~420 Pa 탄성계수를 가진 필러의 가교된 구슬의 부피함량은 65~85%이었다. 실험결과, 모든 필러들은 가교된 HA 구슬의 부피비가 증가할수록 젤 입자 밀도 증가로 인하여 입자감도 증가하였다. 본 연구에서 injectability와 입자감이 우수한 피부용 필러를 성공적으로 제조하였다.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preparation, free HAs (20 mg/mL) dissolved in a phosphate buffered saline solution (PBS, NaH_2PO_4) and swollen cross-linked microspheres were homogenized for 1~4 min and then incubated for 24 h.[32] The ratio of the crosslinked HA to the free HA is varied from 65:35 to 95:5. The elastic and viscous response of hydrogel depend on the concentration and molecular weight of the HA and on the frequency used during the measurements. Rheological behavior of HAHs were analyzed with a Thermo Haake RS1 Rheometer (Newington, USA), using a plate and plate geometry with a 1.2 mm gap.[33] All measurements were performed using a 20 mm titanium sensor at 25 °C. Oscillation measurements were taken at 5 Pa tau over a frequency range of 0.01 to 100 Hz. The measured properties of hydrogels was evaluated by measuring the elastic modulus (G') and viscous modulus (G''). The measured modulus at frequency of 5 Hz for HAHs was compared.[32] In addition, PTF is achieved by observing or touching HAHs using an optical microscope (Pro Camscope, Sometech, Korea) or fingers, respectively.

Swelling Property. The swelling characteristics were measured by immersing weighed samples of dry microspheres for 24 h in PBS. The gels were screened through a 3.0 μm membrane filter (Advantec, Japan). The excess surface water in the swollen gel was removed by blotting and then the swollen gel was weighed. After measuring the weight of the gels, the swelling ratio (S) was determined by using eq. (1),

$$S(\%) = \frac{W_s - W_d}{W_d} \times 100 \quad (1)$$

Where, W_s and W_d are the weight of the swollen gel and the dry gel, respectively.

Gas Chromatography (GC). DVS reacts with the primary alcohol groups in the HA backbone. The crosslinked microspheres were cleaned in water and ethanol to eliminate an unreacted residual crosslinker. The presence of DVS after cleaning may cause adverse, allergic reactions and potential noxiousness of the dermal fillers because they are used within the dermis for several months. The presence of the unreacted residual crosslinker in HAHs is evaluated by using gas chromatography (YL6100 GC, Younglin Co., Ltd., Yongin, Korea).[32,34]

Results and Discussion

HA microspheres were fabricated by using a modified spray method.[13-17] The experimental procedure was described else-

Figure 1. SEM images of ((a)-(d)) HA microspheres crosslinked for 24 h. Note that (b)-(d) images exhibit porous network inside the HA microspheres.

Figure 3. (a) Elastic modulus as a function of angular frequency at 25 °C; (b) the comparison data of dermal fillers. Note that the region of the dotted line in (b) represents the easy delivery of the fillers through a 29-30 gage needle.

Figure 4. Viscous modulus as a function of angular frequency at 25 °C.

Certificates

CE

EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II

M.2017.106.9100-I Design Examination Certificate Was Prepared for Class Ⅲ Products Defined in This Certificate.

Company Name	: BR Pharm Co., Ltd
Company Address	: 1-807, 185, Jiraesil-ro, Jijeong-myeon, Wonju-si, Gangwon-do, KOREA
Related Directives and Annex	: MDD 93/42/EEC Medical Devices Directive – Annex Ⅱ (Excluding Section 4)
Product	: Cross-linked Hyaluronic Acid Gel filler - Class Ⅲ
GMDN	: 59131
Certificate Number	: M.2017.106.9100
Report Number	: MD.3242.K.IB
Initial Assessment Date	: 12.10.2017
Registration Date	: 20.12.2017
Revision Date /No	: -
Expiry Date	: 19.12.2022

UDEM hereby declares that the requirements of Annex Ⅱ excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex Ⅱ, section 3 of the forementioned directive. According to Annex Ⅱ, section 4 an EC design examination certificate is required for placing the Class Ⅲ devices on the market. This certificate remains as the property of UDEM and must be returned to UDEM on request. The above named company and UDEM must keep a copy of the certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of the certificate in question, the certificate becomes invalid and the product on the market. The currency of the certificate can be checked through www.udem.com.tr

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Uludağ Applied Certification Training Trade Industry and Commerce Co.

CE 2292 UDEM

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Phone: +90 0312 443 03 90 Fax: +90 0312 443 03 76
E-mail: info@udemtr.com.tr www.udem.com.tr

ISO 13485

CERTIFICATE

No. 820216

LL-C Certification

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

BR Pharm Co., Ltd.
13, Sinpyeong-ro, Jijeong-myeon
Wonju-si, Gangwon-do
Republic of Korea

#807 Medical device complex, Gieopdosi-ro 200, Jijeong-myeon, Wonju-si, Gangwon-do, Republic of Korea

has been assessed and found to be in compliance with the standard

EN ISO 13485:2016

applicable to

Development, Manufacture of Hyaluronic Acid Gel, PDRN (Polydeoxyribonucleotide) Gel.

The certificate has been issued under No. **820216** for the registration period from 7th December 2018 to 14th November 2020. The first certificate date of issue is 15th November 2017.

Approved by Printed by

validity codes: **A47EF381-7DS**
Check the validity of this certificate using this code at www.ll-c.info

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GMP

인정번호(No.) : KTC-AA6-160080

의료기기 제조 및 품질관리 기준 적합인정서

(Certificate of GMP)

GMP

■ 업체명 / 허가번호 (Company name of Applicant / License No.)
(주)비알팜 / 제 4647호
BRPHARM CO., LTD

■ 대표자 (Representative)
서평순 (Pyeong Soon, Seo)

■ 업체 소재지 (Company address of Applicant)
강원도 원주시 지정면 기업도시로 200 , 807호(가곡리,의료기기종합지원센터)
807, 200, Gieopdosi-ro, Jijeong-myeon, Wonju-si, Gangwon-do, 26354, Rep. of KOREA

■ 제조소명 (Name of Manufacturer)
(주)비알팜
BRPHARM CO., LTD

■ 제조소 소재지 (Address of Manufacturer)
강원도 원주시 지정면 기업도시로 200 , 807호(가곡리,의료기기종합지원센터)
807, 200, Gieopdosi-ro, Jijeong-myeon, Wonju-si, Gangwon-do, 26354, Rep. of KOREA

■ 품목군 (Category)
인체조직 또는 기능 대치품

의료기기 제조 및 품질관리기준에 적합함을 인정합니다.
(We hereby certify that the above manufacturer complies with Korea Good Manufacturing Practices of Medical Devices for the product(s) listed above)

발행일자(Date of Issue) : 2018. 02. 04

유효기간(Date of Expiration) : 2019. 02. 03

서울지방식품의약품안전청
SEOUL REGIONAL OFFICE OF FOOD AND DRUG SAFETY

KTC 한국기계전기전자시험연구원
Korea Testing Certification

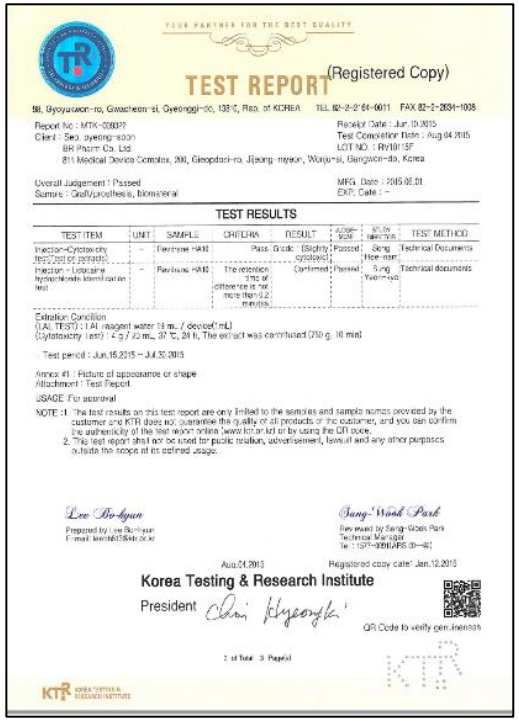
✓ CE : Cross-Linked Hyaluronic acid Gel filler (Class III)
Expiry Date : 19.DEC.2022

✓ ISO 13485

✓ GMP

Test reports

Pre-clinical test reports



TEST REPORT (Registered Copy)

98, Gyoyuk-ro, Gwacheon-si, Gyeonggi-do, 13810, Rep. of KOREA TEL 82-2-2184-0011 FAX 82-2-2634-1038

Report No : MTK-026972
Client : Seo, gyeong-soon
BR Pharm Co. Ltd
811 Medical Device Complex, 200, Gieopdaci-ro, Jijeong-myeon, Wonju-si, Gangwon-do, Korea

Receipt Date : Jun.10.2015
Test Completion Date : Aug.04.2015
LOT NO. : RV1011F

Overall Judgement : Passed
Sample : Graft/prosthesis, biomaterial

MFG. Date : 2015.06.01.
EXP. Date : -

TEST RESULTS

TEST ITEM	UNIT	SAMPLE	CRITERIA	RESULT	JUDGEMENT	STUDY DIRECTOR	TEST METHOD
Injection-Cytotoxicity Test(Test on animals)	-	Revitane HA10	Pass: Grade 2(Slightly cytotoxic)	Passed	Song Hee-nam	Technical Documents
Injection - Lidocaine hydrochloride sterilization test	-	Revitane HA10	The retention time of difference is not more than 0.2 minutes	Confirmed	Passed	Song Yeon-ho	Technical documents

Extraction Condition
(LAL TEST) : LAL reagent water 10 mL / device(1 mL)
(Cytotoxicity test) : 4 g / 20 mL, 37 °C, 24 h, The extract was centrifused (750 g, 10 min)

- Test period : Jun.15.2015 ~ Jul.30.2015

Annex #1 : Picture of appearance or shape
Attachment : Test Report

USAGE: For approval

NOTE : 1. The test results on this test report are only limited to the samples and sample names provided by the customer and KTR does not guarantee the quality of all products of the customer, and you can confirm the authenticity of the test report online (www.ktr.or.kr) or by using the QR code.
2. This test report shall not be used for public relation, advertisement, lawsuit and any other purposes outside the scope of its defined usage.

Lee Bo-hyun
Prepared by Lee Bo-hyun
E-mail: leebh0158@ktr.or.kr

Sang-Wook Park
Reviewed by Sang-Wook Park
Technical Manager
Tel : 1577-0280(ARS 0~4)

Aug.04.2015 Registered copy date: Jan.12.2016

Korea Testing & Research Institute
President Choi Hyeongki

QR Code to verify genuineness

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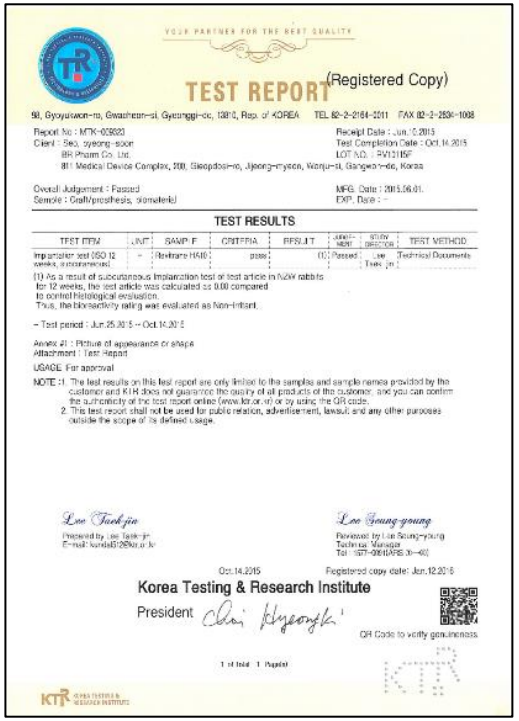
KTR KOREA TESTING & RESEARCH INSTITUTE



TEST REPORT (Registered Copy)

98, Gyoyuk-ro, Gwacheon-si, Gyeonggi-do, 13810, Rep. of KOREA TEL 82-2-2184-0011 FAX 82-2-2634-1038

Report No : MTK-026933
Client : Seo, gyeong-soon
BR Pharm Co. Ltd
811 Medical Device Complex, 200, Gieopdaci-ro, Jijeong-myeon, Wonju-si, Gangwon-do, Korea

Receipt Date : Jun.10.2015
Test Completion Date : Oct.14.2015
LOT NO. : RV1011F

Overall Judgement : Passed
Sample : Graft/prosthesis, biomaterial

MFG. Date : 2015.06.01.
EXP. Date : -

TEST RESULTS

TEST ITEM	UNIT	SAMPLE	CRITERIA	RESULT	JUDGEMENT	STUDY DIRECTOR	TEST METHOD
Implantation test (ISO 10 weeks, subcutaneous)	-	Revitane HA10	pass	(1)	Passed	Lee Tae-jin	Technical Documents

(1) As a result of subcutaneous implantation test of test article in NZW rabbits for 12 weeks, the test article was calculated as 0.00 compared to control histological evaluation.
Thus, the biocompatibility rating was evaluated as Non-Irritant.

- Test period : Jun.25.2015 ~ Oct.14.2015

Annex #1 : Picture of appearance or shape
Attachment : Test Report

USAGE: For approval

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2. This test report shall not be used for public relation, advertisement, lawsuit and any other purposes outside the scope of its defined usage.

Lee Taek-jin
Prepared by Lee Taek-jin
E-mail: tvxdad0728@ktr.or.kr

Lee Seung-young
Reviewed by Lee Seung-young
Technical Manager
Tel : 1577-0280(ARS 0~4)

Oct.14.2015 Registered copy date: Jan.12.2016

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President Choi Hyeongki

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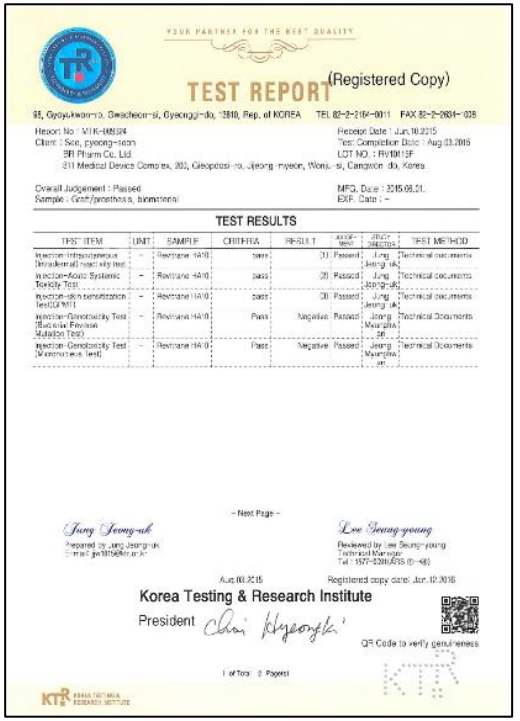

TEST REPORT (Registered Copy)

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Report No : MTK-026924
Client : Seo, gyeong-soon
BR Pharm Co. Ltd
811 Medical Device Complex, 200, Gieopdaci-ro, Jijeong-myeon, Wonju-si, Gangwon-do, Korea

Receipt Date : Jun.10.2015
Test Completion Date : Aug.03.2015
LOT NO. : RV1011F

Overall Judgement : Passed
Sample : Graft/prosthesis, biomaterial

MFG. Date : 2015.06.01.
EXP. Date : -

TEST RESULTS

TEST ITEM	UNIT	SAMPLE	CRITERIA	RESULT	JUDGEMENT	STUDY DIRECTOR	TEST METHOD
Injection-Intracutaneous (Intradermal) reactivity test	-	Revitane HA10	pass	(1)	Passed	Jung Jeong-uk	Technical documents
Injection-Acute Systemic Toxicity Test	-	Revitane HA10	pass	(2)	Passed	Jung Jeong-uk	Technical documents
Injection-skin sensitization Test(GPMT)	-	Revitane HA10	pass	(3)	Passed	Jung Jeong-uk	Technical documents
Injection-Genotoxicity Test (Bacterial Reverse Mutation Test)	-	Revitane HA10	Pass	Negative	Passed	Jeong Myeong-ja	Technical Documents
Injection-Genotoxicity Test (Micronucleus test)	-	Revitane HA10	Pass	Negative	Passed	Jeong Myeong-ja	Technical Documents

- Next Page -

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Aug.03.2015 Registered copy date: Jan.12.2016

Korea Testing & Research Institute
President Choi Hyeongki

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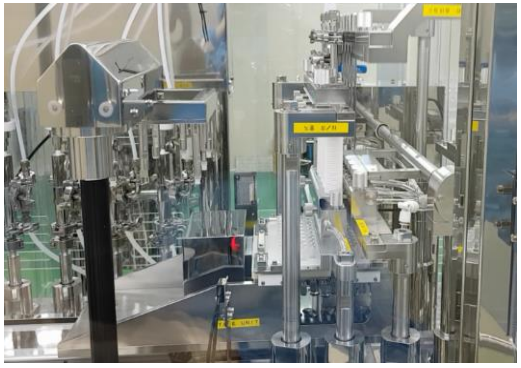
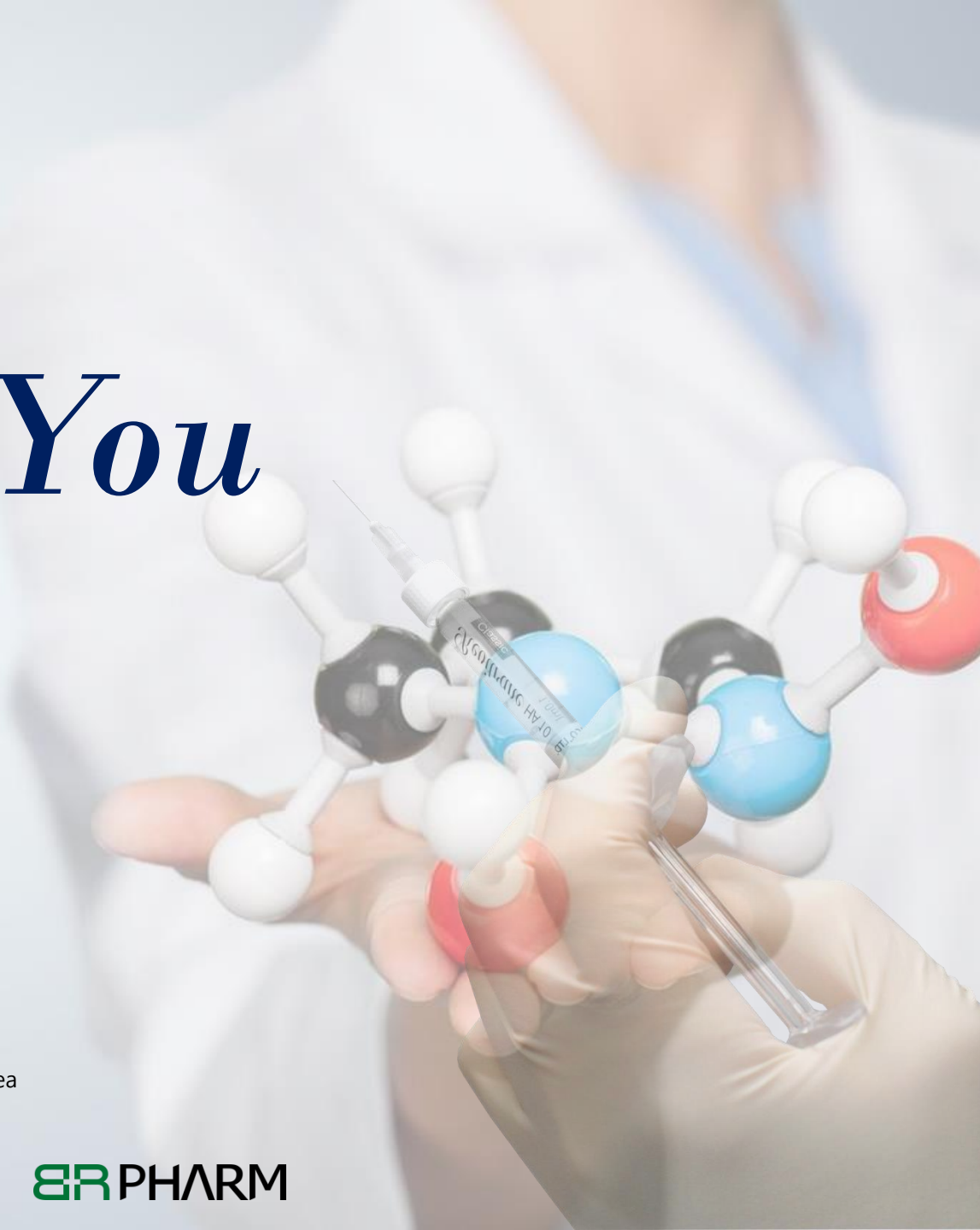
Compliant with GMP & ISO13485 production process

- ✓ Clean room condition
  - controlled by ISO14644-1
- ✓ 15,000 ~ 20,000 syr/day production capacity
- ✓ GMP & ISO13485



Thank You



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