

COREFILL PLUS

CE₂₂₉₂

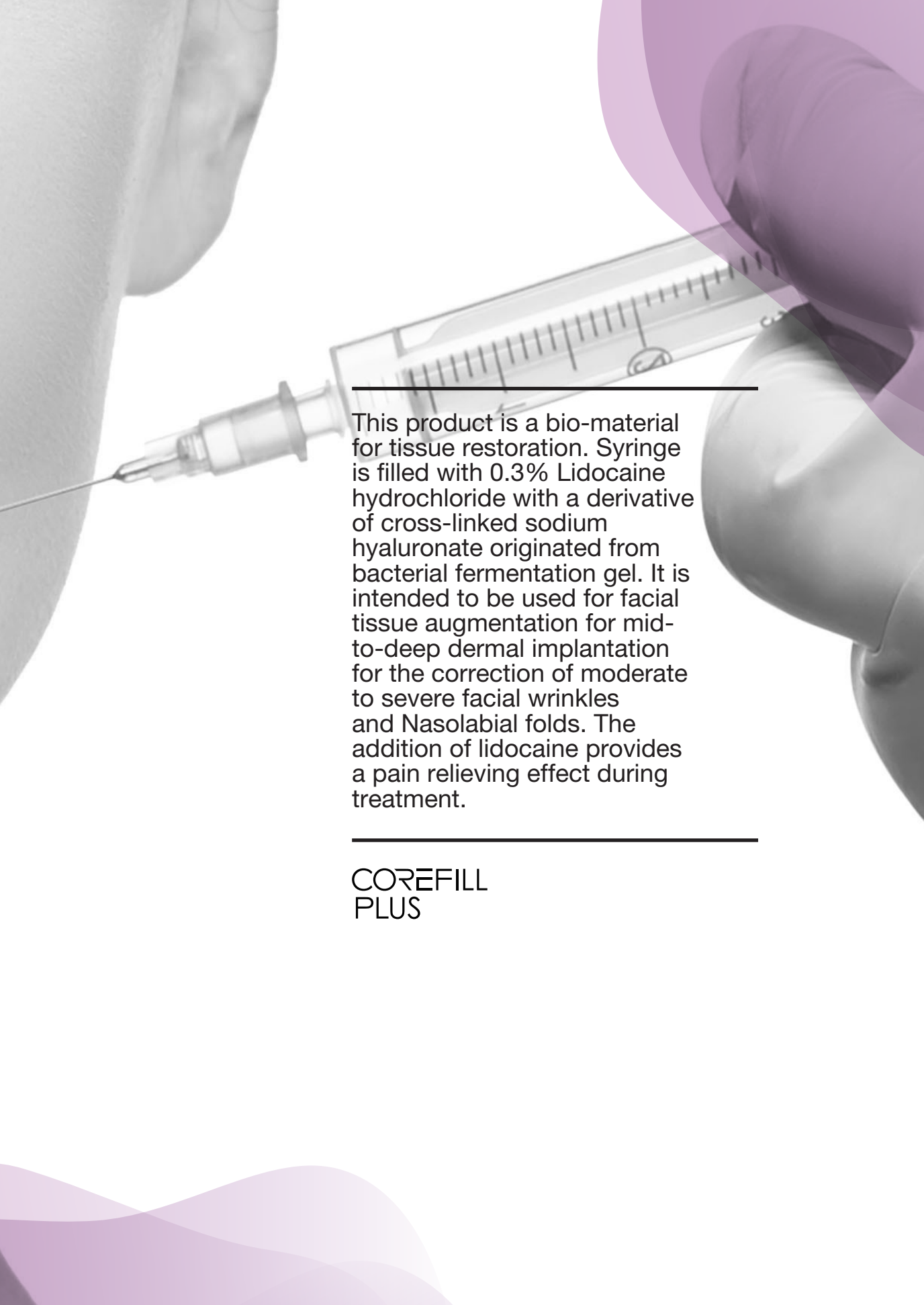
Cross-linked Hyaluronic Acid with Lidocaine

True HA Filler
Injectable gel with Lidocaine

1.1ml

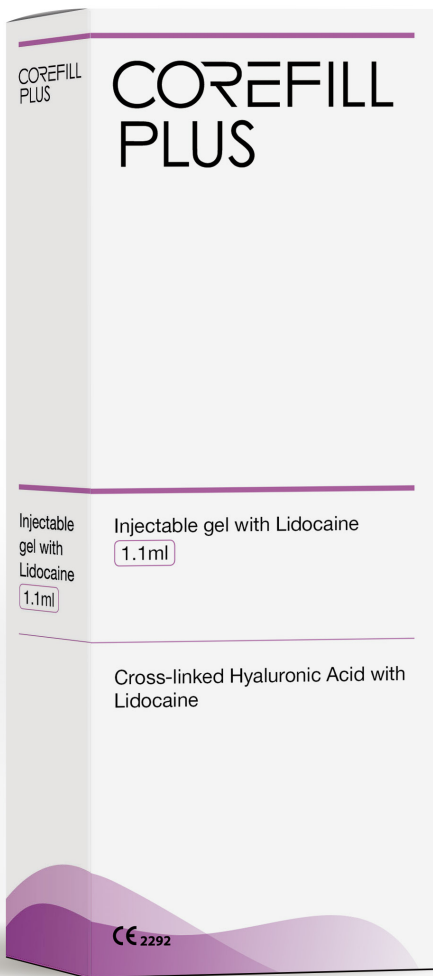






This product is a bio-material for tissue restoration. Syringe is filled with 0.3% Lidocaine hydrochloride with a derivative of cross-linked sodium hyaluronate originated from bacterial fermentation gel. It is intended to be used for facial tissue augmentation for mid-to-deep dermal implantation for the correction of moderate to severe facial wrinkles and Nasolabial folds. The addition of lidocaine provides a pain relieving effect during treatment.

COREFILL
PLUS



Product	CoreFill Plus - FINE	CoreFill Plus - DEEP	CoreFill Plus - Sub Q
Ingredient	Hyaluronic acid 24mg /ml Lidocaine 0.3%		
Package unit	1.1ml		
Purpose	Fine wrinkle correction	Deep wrinkle Correction, Volumizing	Volumizing, Contouring
Indication	Periorbital line, Lip contour	Glabella lines, Nasolabial folds, Marionette lines, Nose/forehead contour	Nasolabial folds, Chin , Body contour
Injection depth	Mid dermis	Mid, Deep dermis	Subcutaneous
Duration	3~6 months	6~12 months	Over 12 months
Complex Viscosity	100~200pa·s	200~300pa·s	300~500pa·s

Monophasic : CoreFill Plus

Soft, uniform gel type, easier to mold to achieve natural result



Biphasic Filler



Monophasic

Ideal Monophasic product manufactured by using special grinding machine,
Consistent injection (Product has uniformity)

Category	Standard	Result
Appearance	Transparent and colorless viscous liquid with no foreign substances	Satisfied
pH	6.8 ~ 7.5	7.0
BDDE Residue	Maximum 2.0ppm	detection limit
Heavy Metal	Maximum 10.0ppm	Below 10ppm
Injection Force	Maximum 30N	14.9
Osmotic Pressure	200~ 400 mmol/kg	300mmol/kg
Volume	Minimum 1.0mL	1.07~1.09mL
Aseptic/Toxic	Aseptic/Toxic	Satisfied
Endotoxin	Below 12.5EU/mL	Below 0.1EU/mL



Ingredients(HA, BDDE, Lidocaine) approved by EDQM

SHISEIDO
 SHISEIDO CO., LTD. Kakogawa Factory
 1120 Nagaya, Kakogawa-shi, Shizuoka, 436-0047, Japan
 Phone: +81-537-24-1131, Fax: +81-537-24-2252

Reference Information

Please find the molecular weight result from the following product for your reference, which is calculated by Laurent's formula.

Product name : Shiseido Sodium Hyaluronate SZE Grade -EP
 Lot No. : H03A
 Intrinsic viscosity : 2.4 m²/kg
 Molecular weight : 1.52 MDa


Date: Jan. 27, 2017
 QA manager: Kazuyuki Hosomi
 (Kazuyuki Hosomi)

Quality Assurance
 Technical Department
 SHISEIDO CO., LTD. Kakogawa Factory
 Phone: +81-537-24-1131
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 3050 Spruce Street, Saint Louis, MO 63103, USA
 Website: www.sigmaaldrich.com
 Email USA: techserv@sigmaaldrich.com
 Outside USA: eurtechserv@sigmaaldrich.com

Certificate of Analysis

Product Name: 1,4-Butanediol diglycidyl ether - ≥95%
 Product Number: 220992
 Batch Number: MKD00499
 Brand: ALDRICH
 CAS Number: 2425-78-8
 MDL Number: MFCD00005146
 Formula: C10H18O4
 Formula Weight: 202.25 g/mol
 Quality Release Date: 26 JUL 2017

Text: 

Text	Specification	Result
Appearance (Color)	Colorless	Colorless
Appearance (Form)	Liquid	Liquid
Infrared Spectrum	Conforms to Structure	Conforms
Purity (GC)	> 95.0 %	96.1 %

Michael Grady, Manager
 Quality Control
 Milwaukee, WI US

Sigma-Aldrich warrants, that at the time of the quality release or subsequent retail date this product conformed to the information provided in this specification. This product specification does not be available at Sigma-Aldrich.com. For further inquiries, please contact

MOEHS CATALANA, S.L.
 Polgono Puig Sur
 C/Carre Masnou (Spain), UA - 08191 Rubí (Barcelona - SPAIN)
 Tel: (34) 93 586 05 29
 Fax: (34) 93 588 85 13

MOEHS PRODUCTOS QUÍMICOS

CERTIFICATE OF ANALYSIS

Product: **LIDOCAINE HYDROCHLORIDE Ph. Eur. 9 / USP 36** Code: 74850
 Batch No: 731 Manufacture: 02/2017 Re-test Date: 02/2022
 Customer: **MUN FOUNG PHARM. CO., LTD**
 Shipment (kg): 30,00 Packs: 6

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS		
Appearance	Crystalline powder	Conforms
Colour	White or almost white	Conforms
SOLUBILITY		
In Water	Very Soluble	Conforms
In Ethanol (96)	Finely Soluble	Conforms
In Chloroform	Soluble	Conforms
In Ether	Insoluble	Conforms
IDENTIFICATION		
IR Spectrum	Conforms to Std.	Conforms
IRSC	Conforms to Std.	Conforms
Chloride reaction	Positive	Conforms
SPECIFIC TESTS		
Water (5%)	5.5% to 7.0%	6.21 %
Aspect of solution 5	Clear (Max. Ref. 1 opal)	Conforms
Colour of solution 5	Colourless (Max. Ref. 0-9)	Conforms
pH (0.5% Sol.)	4,0 to 5,5	4,82

We hereby certify that the above information is authentic and accurate. This batch has been manufactured, including packaging and quality control, in the above mentioned site in full compliance with the GMP requirements. The batch processing, packaging and analysis records were reviewed and found to be in compliance with ICH Q7, EU GMP Part II and 21 CFR Parts 210 & 211.

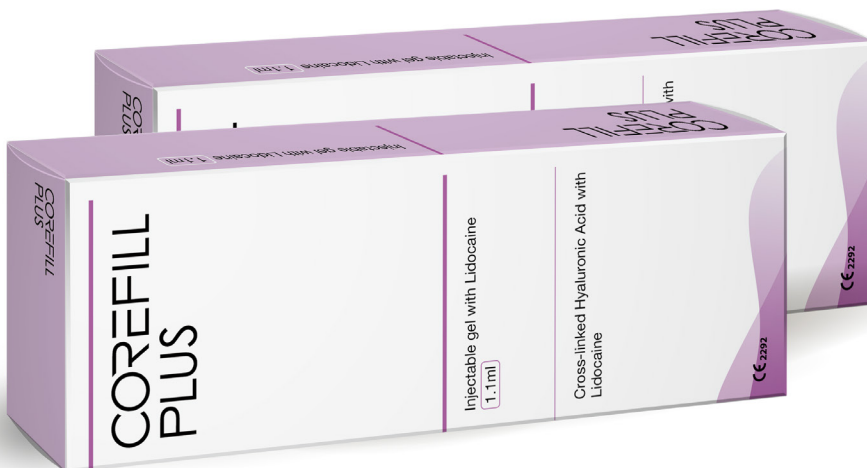
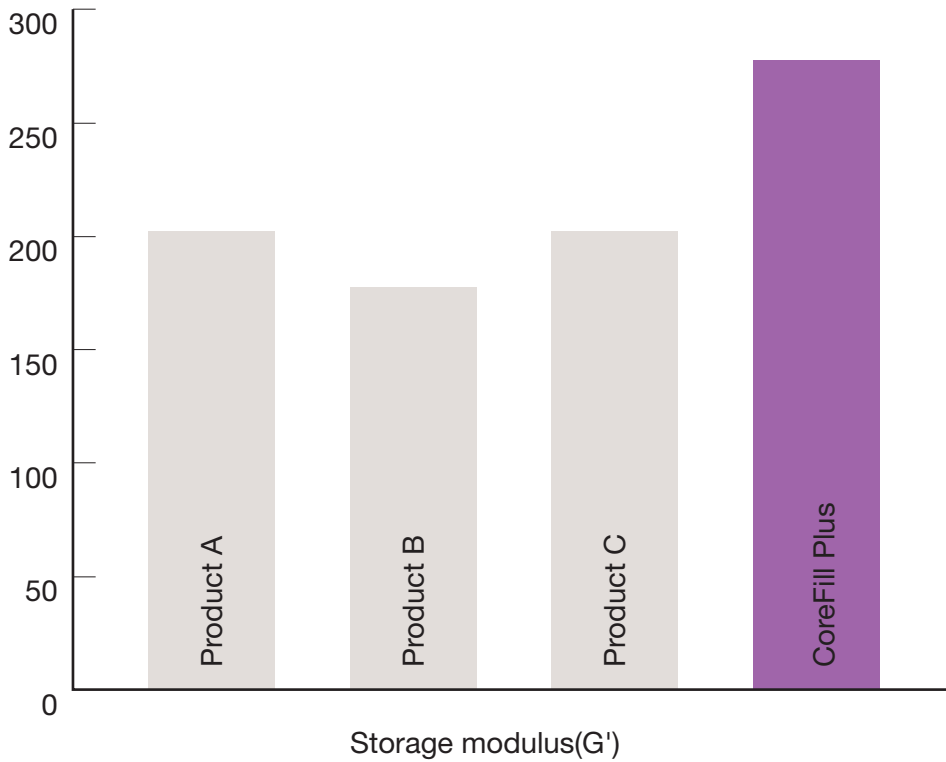
Released by: Ch. Ho on: 02/02/2017
 CMA Issued by: 02/02/2017
 Signed by: Quality Control

Flora Guzmán
 QC Manager

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High viscoelasticity allows to maintain good volume for a lone duration



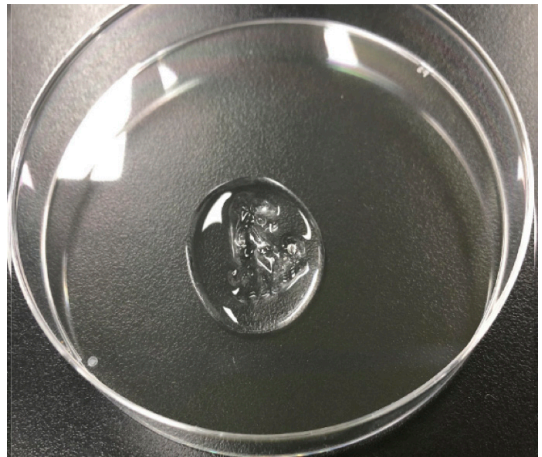
Observed changes after injecting 1ml of Hyaluronidase 750IU into 0.5ml of CoreFill Plus

12 hours after Hyaluronidase injection

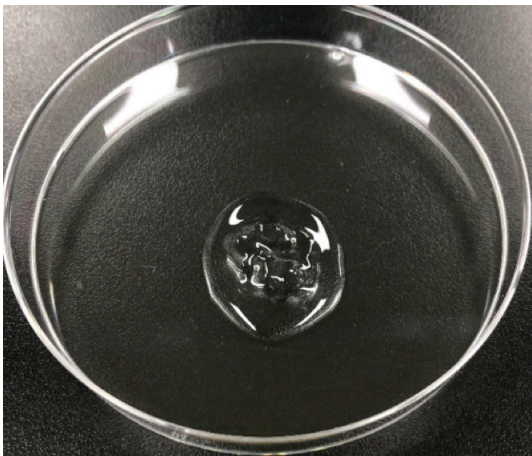
CoreFill Plus



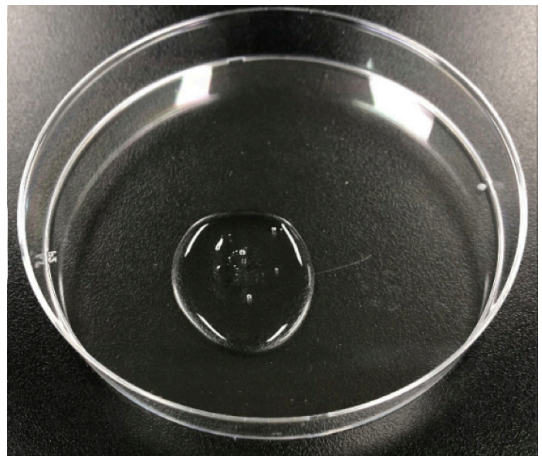
Company A



Company B



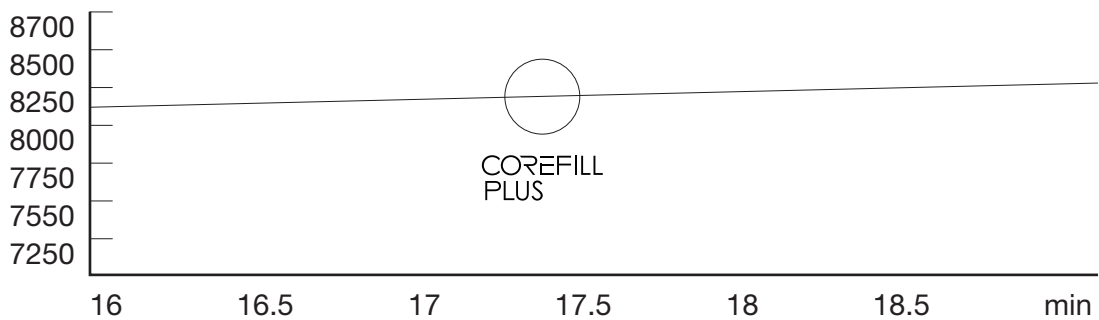
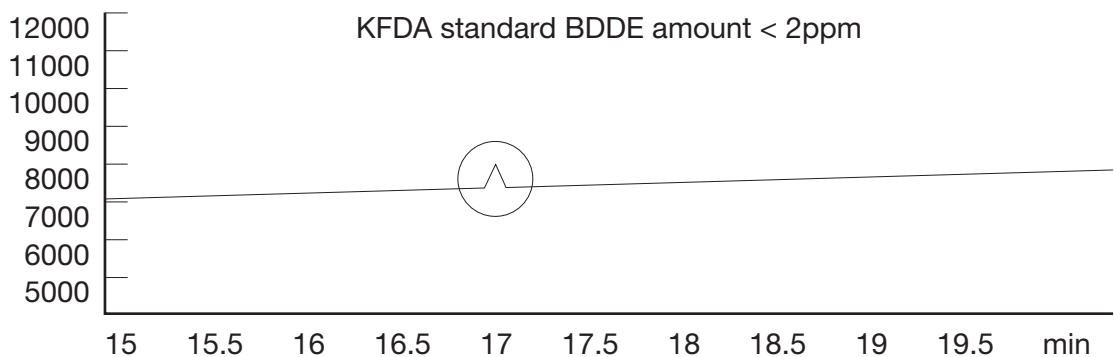
Company C



Safety_Purification(Data)

Reduces side effects such as redness, fever, erythema

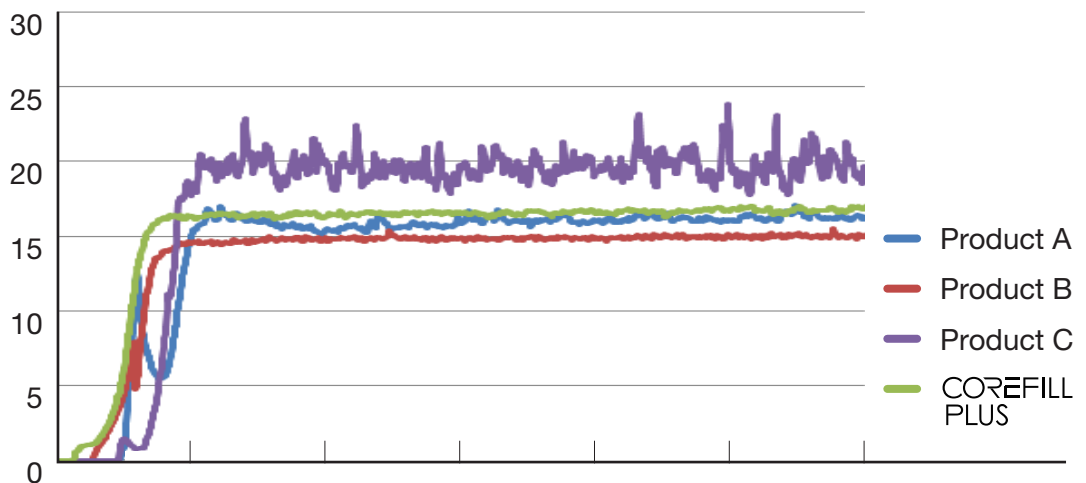
BDDE ↓ Endotoxin ↓ Protein ↓ pH ↓



Category	Standard	Result
Endotoxin	12.5EU/mL	0.95EU/mL
Osmotic	200~400mmo	318mmol/kg
pH	6.5~7.5	7.0

Convenience_Extrusion force

Consistent extrusion force allows smooth injection, therefore, increased convenience.



Ref. Manufacturer research institute



DEEP

DEEP

DEEP
Sub-Q

FINE

DEEP

Sub-Q