

CERES™

A Natural, Safe and Long-lasting Product Series.

HL

CERES™

PREMIUM HYALURONIC ACID FILLER

명원국제(주) MY Korea Trade Co., Ltd.

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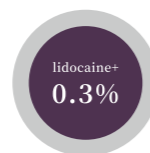
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Ceres Premium HA Filler Character



Disposable medical devices certified by the Korean Food and Drug Administration

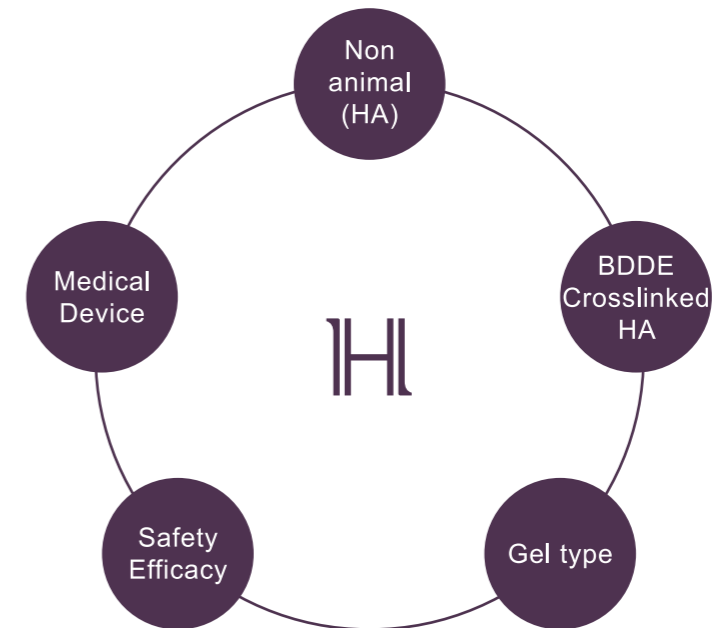


Safe, efficient and durable products containing 0.3% lidocaine

세레스 프리미엄 히알루론산 필러 Ceres Premium Hyaluronic Acid Filler

Ceres Filler can be substituted for natural skin ingredients and will improve wrinkles. It is a resorbable medical device composed of hyaluronic acid that is derived from non-animal origins.

Characteristics of Ceres Filler



Medical Device

KFDA(2013.05)
Graft/prosthesis, biomaterial B04230.01(4)

Non-animal HA

Usage of HA produced by bacterial fermentation by Streptococcus equi Biocompatibility(Non-toxic, non-immune characteristics) Biodegradability

BDDE Crosslinked HA

BDDE Crosslinked HA
Particle structure. overcome short biodegradability of HA. High persistence during infusion(6~12 months)

Gel type

HA Conc.: 20mg/ml (2%)
High Viscosity: about 2,700,000 cP. Low Inj.: about 10 N

Safety and efficacy

Through multicenter clinical trial, safety and efficacy of Ceres Filler have been proven.

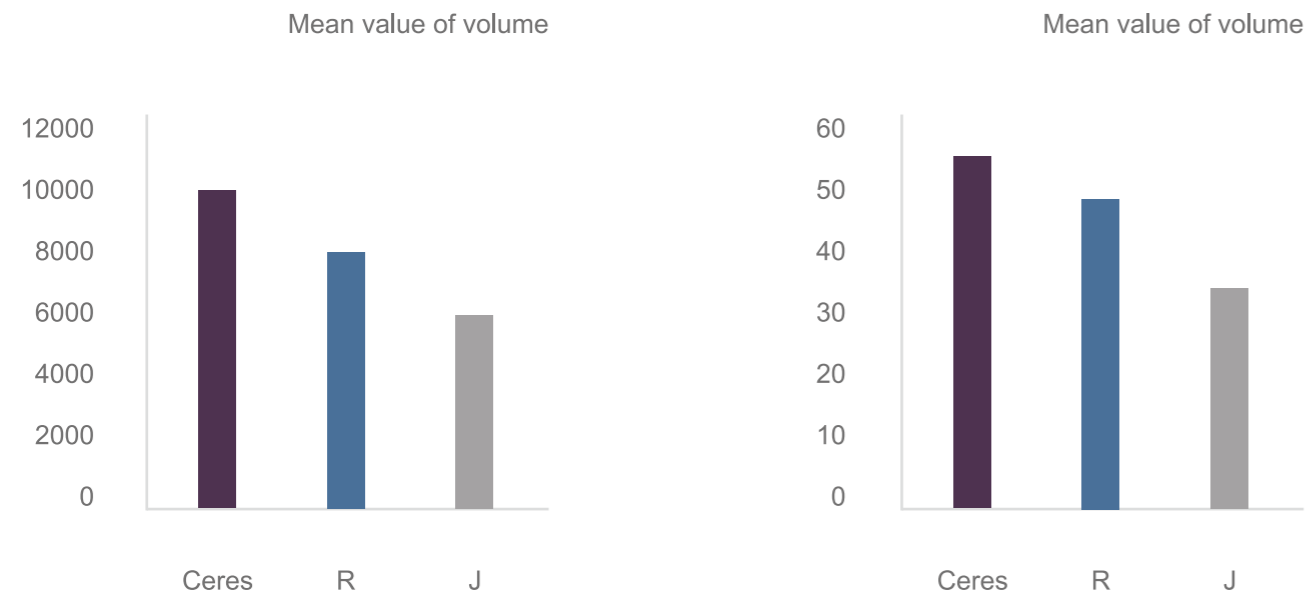
HA 필러 제품별 비교 및 효력시험 HA Filler Comparison and Efficacy Test

Classification	Ceres	R Product	J Product
Composition Crosslinked agent Concentration	Hyaluronic acid BDDE 20mg/ml	Hyaluronic acid BDDE 20mg/ml	Hyaluronic acid BDDE 20mg/ml
Complex viscosity	~ 2.7x10 ⁶ cP	~ 2.8x10 ⁶ cP	~ 0.9x10 ⁶ cP
Swelling ratio	~ 4ml/g	~ 2.8ml/g	~ 3.8ml/g
Injection force	10N	9N	13N
Endotoxin(EU/ml)	Less than 0.25	Less than 0.25	-

Ceres filler has similar chemical and physical features with R product and J product which are currently dominating and filler market. However, in the aspect of its swelling degree and enzyme stability, Ceres filler outweighs other products.

Internal Duration Test Result

16 weeks after injection



세레스 프리미엄 필러 안전성 시험 Ceres Premium HA Filler Safety Test



Confirmed the amount of residual BDDE in Ceres through GC analysis

Biological safety test

The following biocompatibility and toxicology tests were conducted on Ceres.

Test Title	Test Number	Test Standards	Test Results
Acute Systemic Toxicity Test	SNUH 0800401	ISO 10993-11	Pass
Subchronic Subcutaneous Toxicity	SNUH 0800402	ISO 10993-11	Pass
Cytotoxicity Test	SNUH 0800403	ISO 10993-5	Pass
The Guinea Pig Maximization Test	SNUH 0800404	ISO 10993-10	Pass
Hemolysis Test	SNUH 0800405	ISO 10993-4	Pass
Intracutaneous Reactivity Test	SNUH 0800406	ISO 10993-10	Pass
Pyrogen Test	SNUH 0800407	USP 29	Pass
Bacterial Reverse Mutation Assay	SNUH 0800408	ISO 10993-3	Pass
In vitro Chromosome Aberration Test	SNUH 0800409	ISO 10993-3	Pass
In vitro Micronucleus Test	SNUH 0800410	ISO 10993-3	Pass

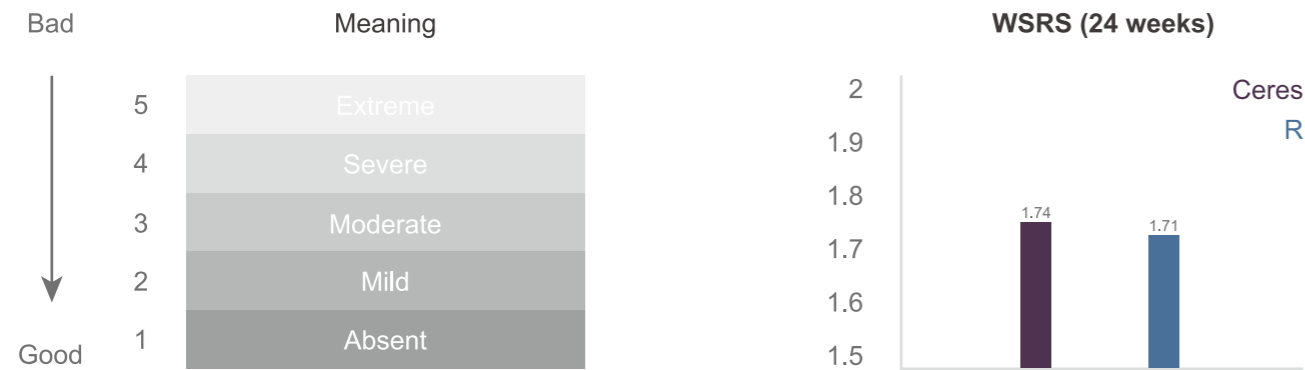
*Medical Device Evaluation Center, Clinical Research Institute, Seoul National University Hospital (2009.02)

세레스 프리미엄 필러 임상 시험 Ceres Premium Filler Clinical Date

Primary Efficacy Evaluation

Ceres is non-inferior compared to R product

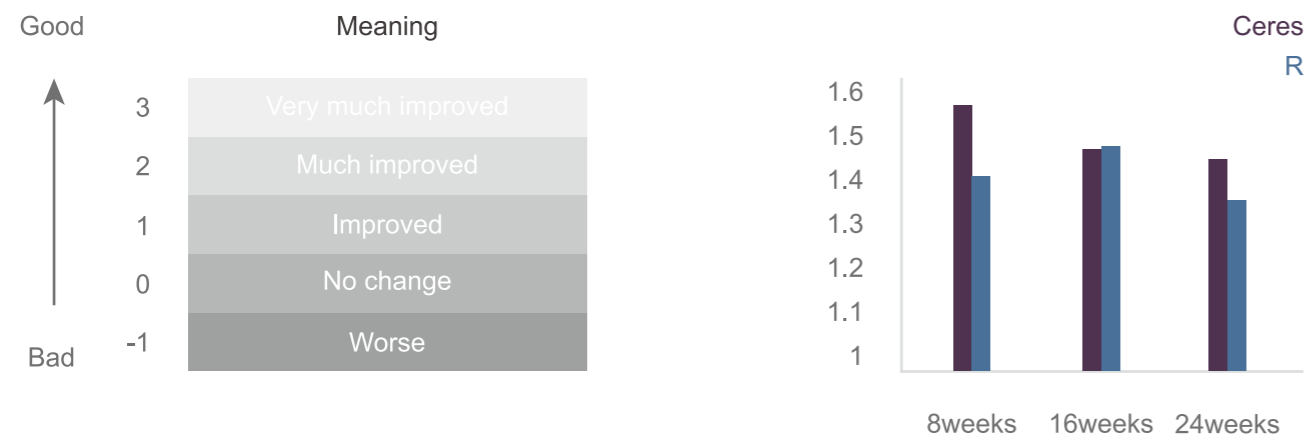
WSRS average difference between R product applied area and Ceres applied area was -0.03 ± 0.75 . The lowest value of single one-sided 97.5% confidence interval regarding WSRS result was -0.22 . As this was bigger value than -0.29 which was the non-inferiority limit in this trial. Ceres is non-inferiority was proved.



Secondary Efficacy Evaluation

Patient's Satisfaction Level

Among GAI average value evaluated by subject on the 8th, 16th and 24th weeks. Ceres satisfaction level was higher than R product on the 8th and 24th weeks. However, it is not statistically significant.



Global Aesthetic Improvement (GAI)

Average GAI score evaluated by the subject (FAS)

Ceres used to improve nasolabial fold is considered as an effective and safe medical device.

세레스 프리미엄 필러 시리즈 세분화 정보 Ceres Premium HA Filler Series Information

Hyaluronic acid (HA)



The half-life of natural HA administered in the body is very short, so it has to be modified in order to increase the stability in vivo.

1,4-Butanediol diglycidyl ether (BDDE)

BDDE Cross-linked HA



120'



240'



360'



Type	Ceres 120'	Ceres 240'	Ceres 360'
Composition	BDDE Cross-linked HA (20mg/ml)	BDDE Cross-linked HA (20mg/ml)	BDDE Cross-linked HA (20mg/ml)
Average grain	S (200 μm)	M (500 μm)	L (1,100 μm)
Indications	Shallow wrinkles	Medium wrinkles	Deep wrinkles
Inj. area	Superficial dermis	Mid dermis	Deep dermis or subcutaneous tissue
Unit	Ceres Premium Filler 120' 1.1ml (27G, 29G)	Ceres Premium Filler 240' 1.1ml (27G, 29G)	Ceres Premium Filler 360' 1.1ml (25G, 27G)
Storage	To be stored at room temperature (1~30°C) away from direct sunlight.		
Shelf life	36 months		