

Starfill

Part of Procedure



Plus Lidocaine



Deep Plus Lidocaine



Implant Plus Lidocaine

Starfill

Product Information

No	Plus Lidocaine	Deep Plus Lidocaine	Implant Plus Lidocaine
Composition	HA 24mg/ml Lidocaine 0.3%	HA 24mg/ml Lidocaine 0.3%	HA 24mg/ml Lidocaine 0.3%
Depth of Injection	Superficial/Mid dermis	Mid / Deep dermis	Subcutaneous/ Supraperiosteal areas
Syringes	1.1ml	1.1ml	1.1ml
Needle	27G	27G	27G



[Product name] Graft/prosthesis, biomaterial <B04230.01 (4)>

[Product Authorization Number] 17-594

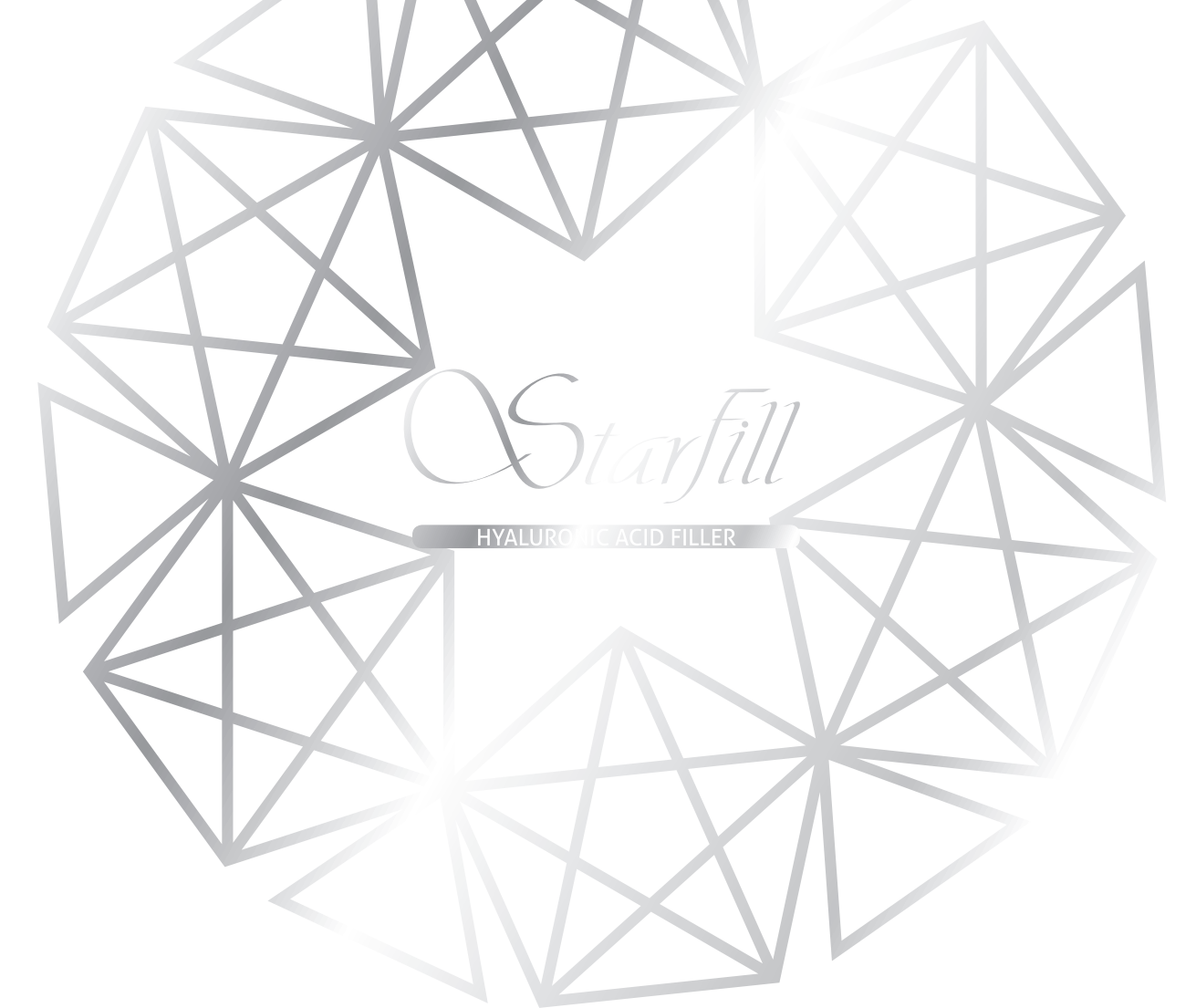
[Storage] 2°C~25°C (Do not freeze)

[Indication] Temporary improvement of face wrinkles

[Single Use / Sterile medical devices / Do not reuse] For more details, please refer to the instruction for use.



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Starfill

Exquisite Technology

The

<p>Raw Material</p> <p>The safety is enhanced using only high-purity raw ingredients manufactured strictly by the StarFill exclusive line, (ophthalmic pharmaceutical grade)</p>	<p>HA Concentration</p> <p>StarFill uses a syringe filled with HA 24mg/ml, cross-linked mesomolecule to pursue the ideal maintenance period and the safety of the body, including swelling prevention.</p>	<p>Viscoelasticity</p> <p>Elastic/HIVE structure, give elastic lifting maintains an ideal viscoelasticity</p>
<p>Aseptic Environment</p> <p>The Yongin plant, which was newly expanded in 2015, produces clean, pure, sterile products that have been thoroughly sterilized and removed infectious bacteria.</p>	<p>Endotoxin</p> <p>StarFill keeps endotoxin below 0.1 EU/ml minimizing various side effects that may occur after the procedure.</p>	<p>Residual BDDE</p> <p>StarFill applies for a more precise cleaning process to eliminate residual BDDE to undetectable level</p>
<p>Particle Homogenization</p> <p>StarFill produces a uniform particle size through its own Downing Process. Exquisite molding is completed with homogenized particle implementation technology.</p>	<p>pH, osmolality</p> <p>StarFill is manufactured to be based on the same pH as my body and with osmotic pressure of about 300 mOsmol/kg, which reduces the pain and discomfort of the patient after the procedure.</p>	<p>Extrusion Force</p> <p>Starfill manufactures and manages the optimized injection force for both doctor and patient's comfort.</p>

Essential

Starfill

Exquisite Molding

Maximum cross-linking efficiency
Minimized MOD Achieved by 1%

Minimized BDDE Input

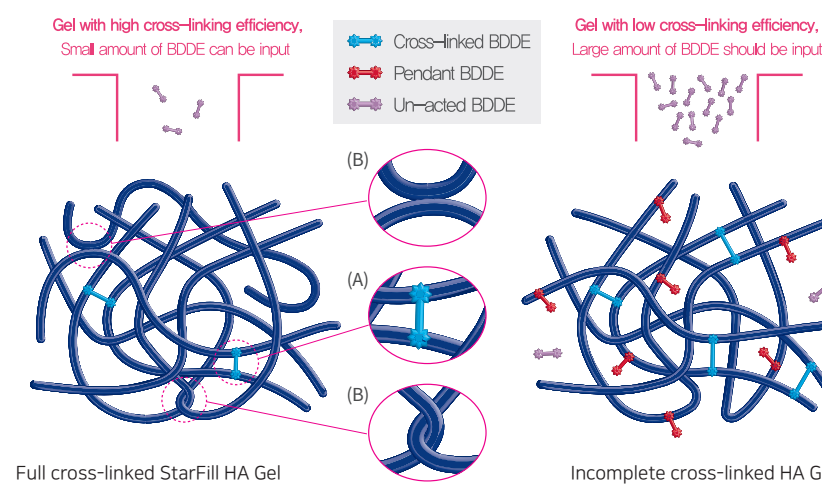
Mod(Degree of Modification)³⁾ is a safety verification requirement. 'MoD = full cross-linked BDDE + Pendant type BDDE' by checking the modification ratio of HA through measurement of total amount of BDDE present in HA Gel. MoD of StarFill is 1/6 lower than compare with other mono type filler, making it safer.

Ref. Data from Laboratory, 2018-2019

Mono-phasic Filler	StarFill Lidocaine			A	B
	Plus	Deep Plus	Implant Plus	J-V	N-V
MoD(%) ³⁾	1.18	1.53	1.89	7.68	11.23
Complex viscosity (Pa·s, 0.1 Hz) ¹⁾	82.9	304.2	478.3	457.9	448.7
Cohesiveness ²⁾ (N)	0.4184	0.6102	0.8776	0.0443	0.8003

Maximization of Cross-linking Efficiency

StarFill through the "2-crosslinking method" that improved B) physical and A) chemical cross-link process to achieve a complete cross-linking level while minimizing the amount of BDDE as a chemical catalyst material, thereby manufacturing a gel with high viscoelastic properties.



High Viscoelasticity and Cohesiveness

Compare result of StarFill Implant Plus and representative filler products, StarFill's complex viscosity³⁾ and cohesiveness²⁾ are equivalent with foreign A products which has more BDDE input and more outstanding compare with domestic B products, can make best clinical results.

Starfill

Clinical Results

Safe HA filler StarFill increases the satisfaction of the operator and patient.

Efficacy Assessment

From the WSRS(Wrinkle Severity Rating Scale) results evaluated by independent expert panels and blinded investigators, we were able to see the wrinkle improvement of the group. This result came from compare data between Starfill and representative filler in the market.

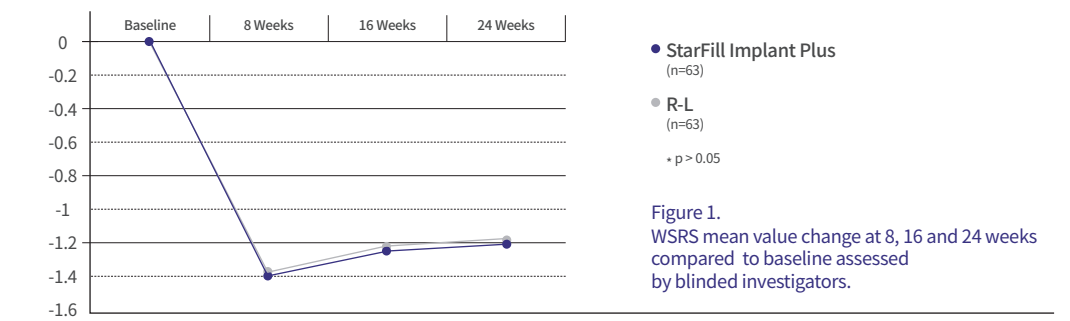


Figure 1. WSRS mean value change at 8, 16 and 24 weeks compared to baseline assessed by blinded investigators.

Participant Self-Satisfaction Assessment

Although there was no statistically significant difference in evaluating the satisfaction of the treatment with the tester and the subject's GAIS(Global Aesthetic Improvement Scale), in general, the satisfaction level of the test group was similar or slightly higher than that of the control group.

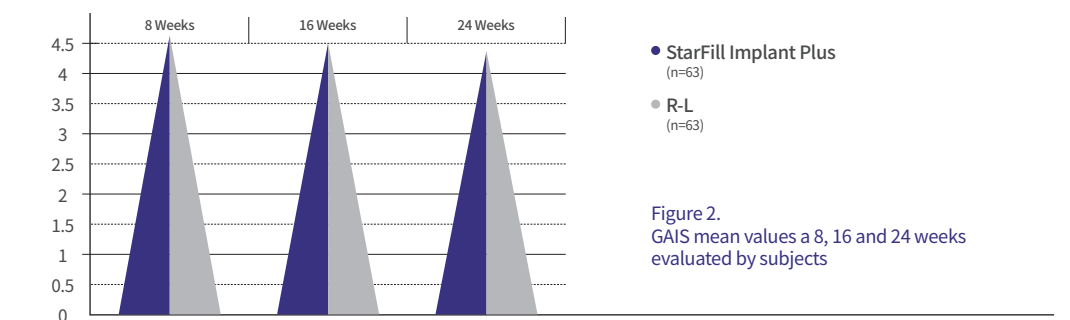


Figure 2. GAIS mean values at 8, 16 and 24 weeks evaluated by subjects

Safety Assessment

No major abnormalities were reported, and slight abnormal responses from medical devices, such as slight swelling and pain for 2-3 days, were all recovered without any special treatment. There were no signs of abnormal vital signs, physical examinations, or blood tests. StarFill has been reported to be a safe medical device due to its proven safety in the body.

Ref. Clinical Study Result, Department of Dermatology, Chung-Ang University Hospital, Korea 2016