ZISHÉL

PREMIUM HA FILLER

Contents

01 Brand Story

02 ZISHÉL Filler

03 ZISHEL GROUP

04 Manufacturer

Brand Story

What is your Philosophy for beauty?

EMBRACE THE ELEGANCE

Elegance is the Only Beauty that Never Fades.

'Audrey Hepburn'

EXPRESS THE ELEGANCE

I Feel that Beauty and Feminity are Ageless.

'Marilyn Monroe'

ZISHÉL Filler

[Volumizing Line]
HA Fillers
HA Fillers with Lidocaine

[Skin Vitalization Line]
AQUA SOFT Filler

FAQ

FILL | VOLUMIZING | ARCHITECT

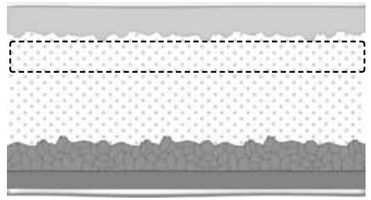
ZISHÉL HA Fillers

The premium brand for the non-animal hyaluronic acid gel fillers manufactured for effective and stable viscoelasticity. The product is composed of the tissue reconstructive material intended to be used for facial tissue augmentation. The brand demonstrates its quality and biocompatibility via proven literatures, testing reports, and efficacy evaluations- WSRS clinical data and patient's satisfaction level.

ZISHÉL HA Filler TOUCH

Is cross-linked hyaluronic acid(20mg/ml) used in the area of superficial dermis to correct superficial wrinkles: fine lines and wrinkles on thin skin. TOUCH's average grain size is 200μm and it is packed in three units: 1ml(27G,29G), 2ml(25G,27G), 3ml(25G,27G).

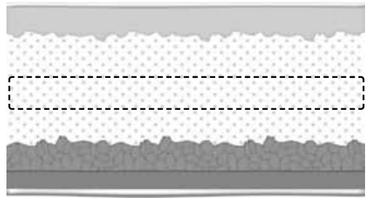
Superficial Dermis



ZISHÉL HA Filler MILD

Is cross-linked hyaluronic acid(20mg/ml) used in the area of mid dermis to fill all moderately pronounced wrinkles of the full face. MILD's average grain size is 500μm and it is packed in three units: 1ml(27G,29G), 2ml(25G,27G), 3ml(25G,27G).

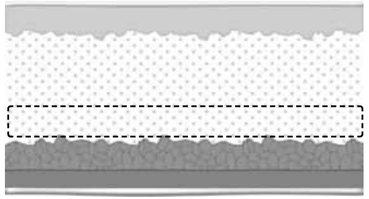
Mid Dermis



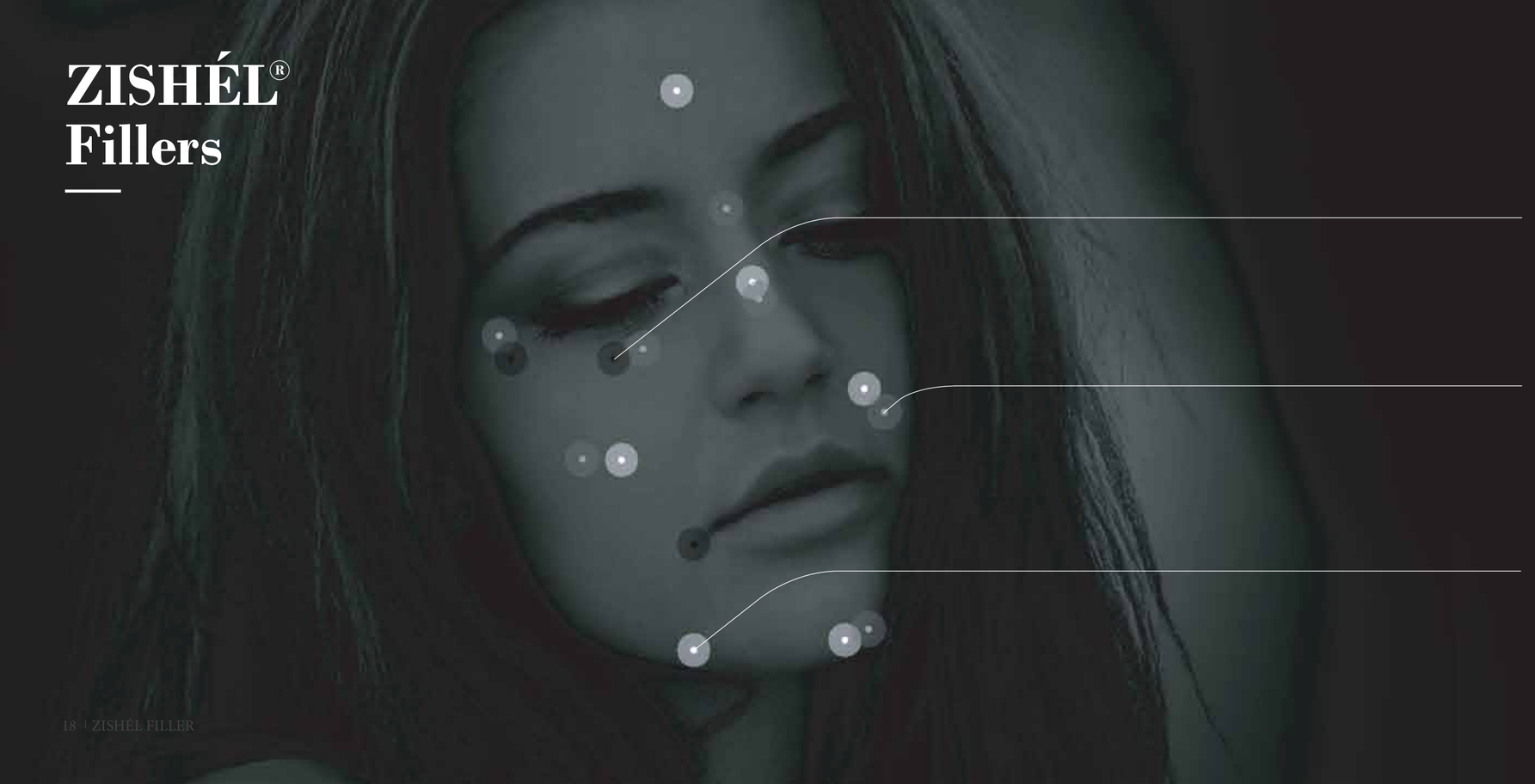
ZISHÉL HA Filler FORTE

Is cross-linked hyaluronic acid(20mg/ml) used in the area of deep dermis or subcutaneous tissue to fill the deep wrinkles. FORTE's average grain size is 1,100μm and it is packed in three units: 1ml(27G,29G), 2ml(23G,27G), 3ml(23G,27G).

Deep Dermis



ZISHÉL®
Fillers



ZISHÉL TOUCH

ZISHÉL MILD

ZISHÉL FORTE

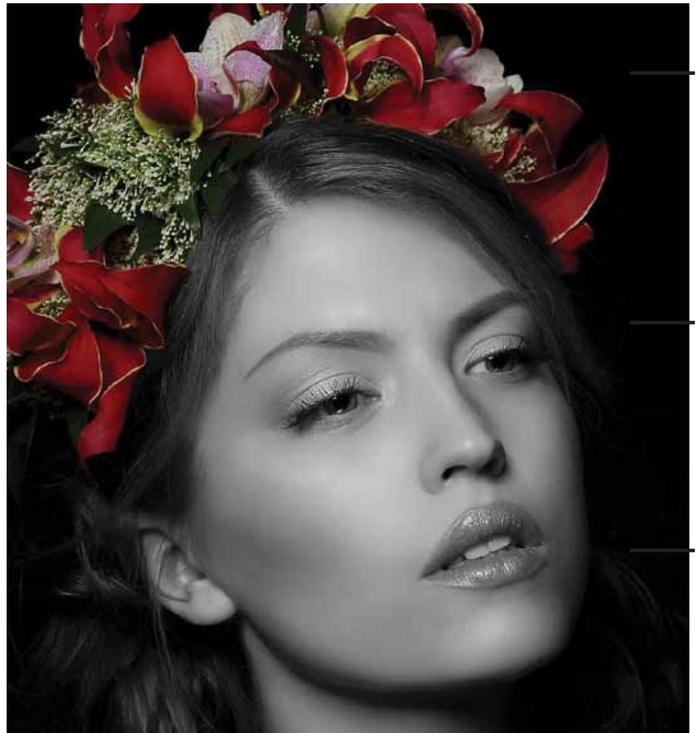
CHARACTERISTICS

Medical Device

CE Mark Approval(Fab, 2012)-Class II
KFDA Approval(May,2013)
Graft / Prosthesis, biomaterial
B04230.01(4)

Non-animal Hyaluronic Acid

Usage of HA produced by Bacterial Fermentation
(Streptococcus Equi)
Biocompatibility
Non-Toxic
Non-Immunogenic
Biodegradability



BDDE Cross-Linked HA

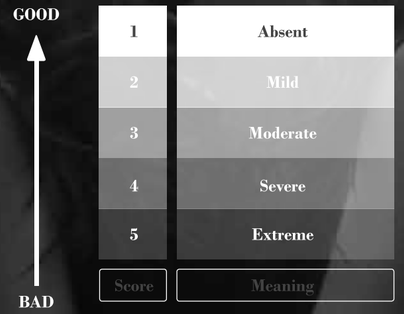
BDDE Cross-linked HA
To Enhance the Longevity of Natural HA via Decreasing the Biodegradation Rate
Biphasic Gel(Duration : 6-12 Months)

Gel Type

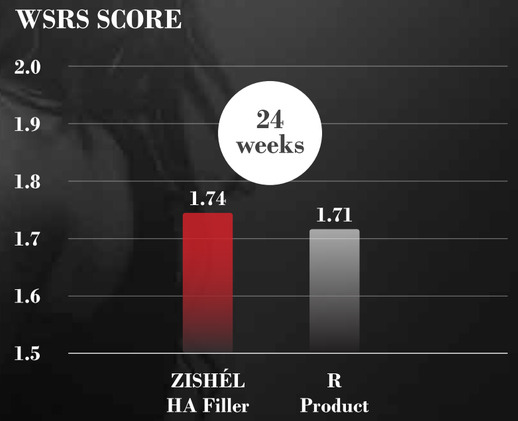
HA Cone: 20 mg/ml(2%)
High Viscosity Gel: 2,700,000 eP
Injection Forces: 10 N

Proven Safety and Efficacy

The Safety and Efficacy of ZISHÉL Filler Have Been Proven Through the Multicenter Clinical Trials.



Wrinkle Severity Rating Scale(WSRS)



Average WSRS score evaluated by the independent evaluator(FAS)

Clinical Data

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

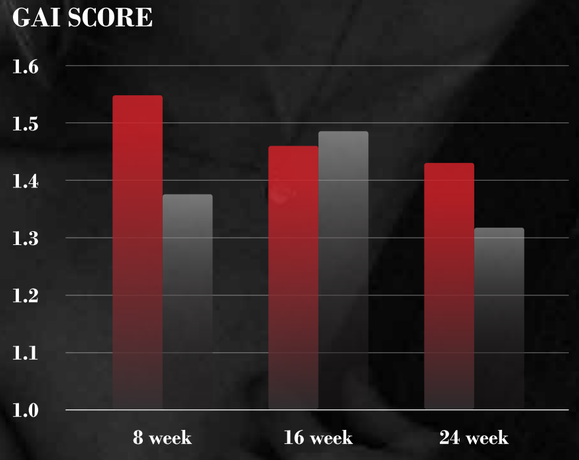
PRIMARY EFFICACY EVALUATION

ZISHÉL HA Filler is non-inferior compared to R-product.

WSRS average difference between R-product applied area and ZISHÉL HA Filler 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, ZISHÉL HA Filler's non-inferiority was proved.

Score	Meaning
3	Very Much Improved
2	Much Improved
1	Improved
0	No change
-1	Worse

Global Aesthetic Improvement(GAI)



Average GAI score evaluated by the subject(FAS)

Clinical Data

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

SECONDARY EFFICACY EVALUATION

Patient's Satisfaction Level

Patient's Satisfaction Level : Among GAI average values evaluated by subject on the 8th, 16th, and 24th week, ZISHÉL Filler's satisfaction level was higher than R-product on the 8th and 24th week. However, it is not statistically significant.

Manufacturing Process

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

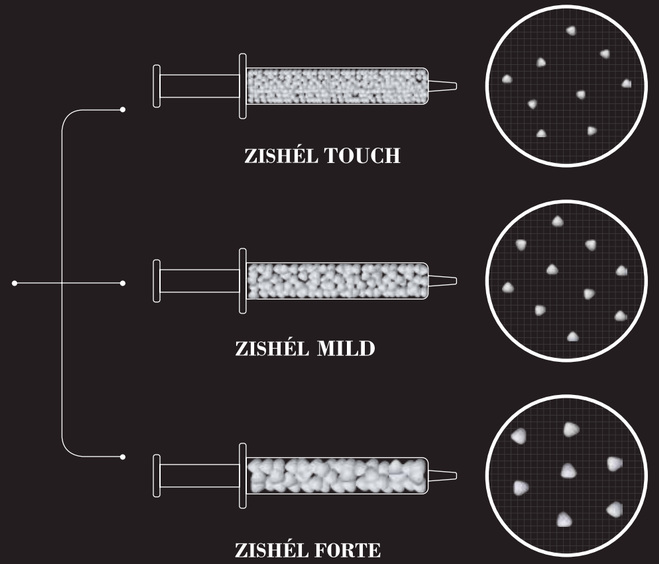
Hyaluronic Acid

1,4-Butanediol diglycidyl ether(BDDE)

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.

BDDE Cross-Linked HA

PARTICLE SIZE BASIS



COMPARISON AMONG HA FILLERS

ZISHÉL has similar chemical and physical features with the R-product and J-product, two most well-known brands in the current market.

As shown in the table, ZISHÉL outweighs the both brands' products in respect to the swelling degree and enzyme stability.

ZISHÉL HA Filler

R-Product

COMPOSITION
hyaluronic acid

CROSS-LINKING AGENT
BDDE

TOTAL HA CONCENTRATION
20 mg/ml

COMPLEX VISCOSITY
$2.8 * 10^6$ cP

SWELLING RATIO
2.8 ml/g

INJECTION FORCE
9 N

ENDOTOXIN
Less than 0.5 EU/ml

COMPOSITION

hyaluronic acid

CROSS-LINKING AGENT
BDDE

TOTAL HA CONCENTRATION
20 mg/ml

COMPLEX VISCOSITY
$2.7 * 10^6$ cP

SWELLING RATIO
4 ml/g

INJECTION FORCE
10 N

ENDOTOXIN
Less than 0.25 EU/ml

J-Product

COMPOSITION
hyaluronic acid

CROSS-LINKING AGENT
BDDE

TOTAL HA CONCENTRATION
22~26 mg/ml

COMPLEX VISCOSITY
$0.9 * 10^6$ cP

SWELLING RATIO
3.8 ml/g

INJECTION FORCE
13 N

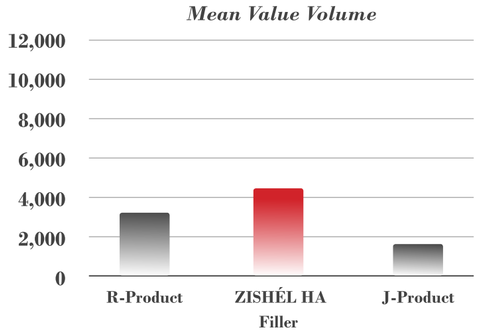
ENDOTOXIN
None

EFFICACY TEST

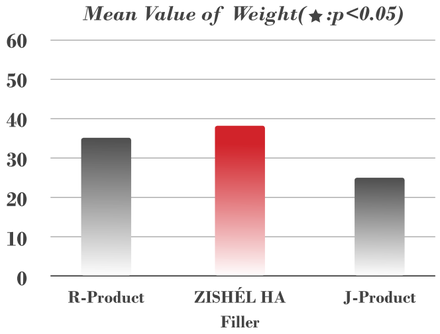
From the internal duration test using mouse, ZISHÉL had longer durability than the J-Product and similar durability with the R-Product. From the histological test, ZISHÉL shows the superior result within the material remaining for 4 months and connective tissues.

INTERNAL DURATION TEST RESULT

16 Weeks After Injection

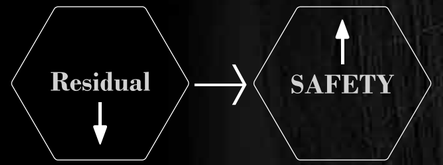


Mean Value of Weight

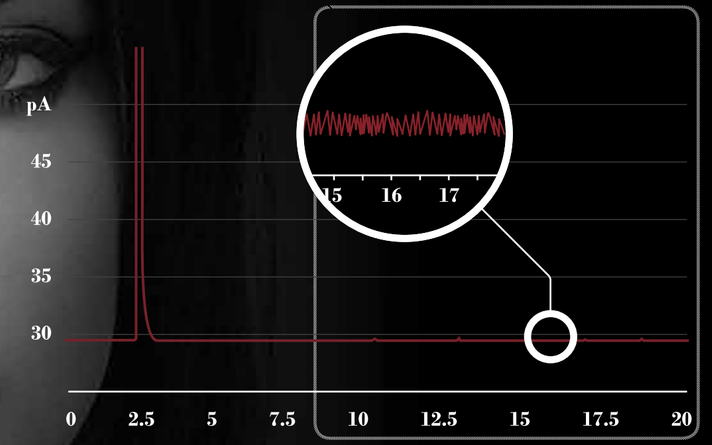


SAFETY TEST
BDDE RESIDUAL ANALYSIS

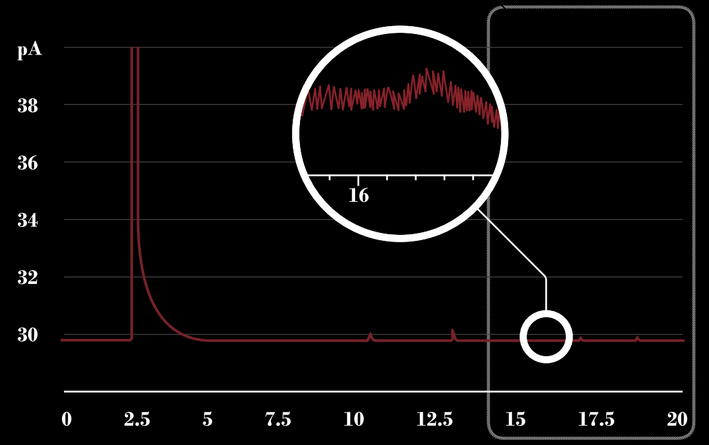
BDDE which can cause moderate skin irritation, skin sensitization, and allergic reaction is not detected in ZISHÉL. The amount of residual BDDE in ZISHÉL was confirmed through GC analysis. (The detection limit of BDDE: 1 ppm)



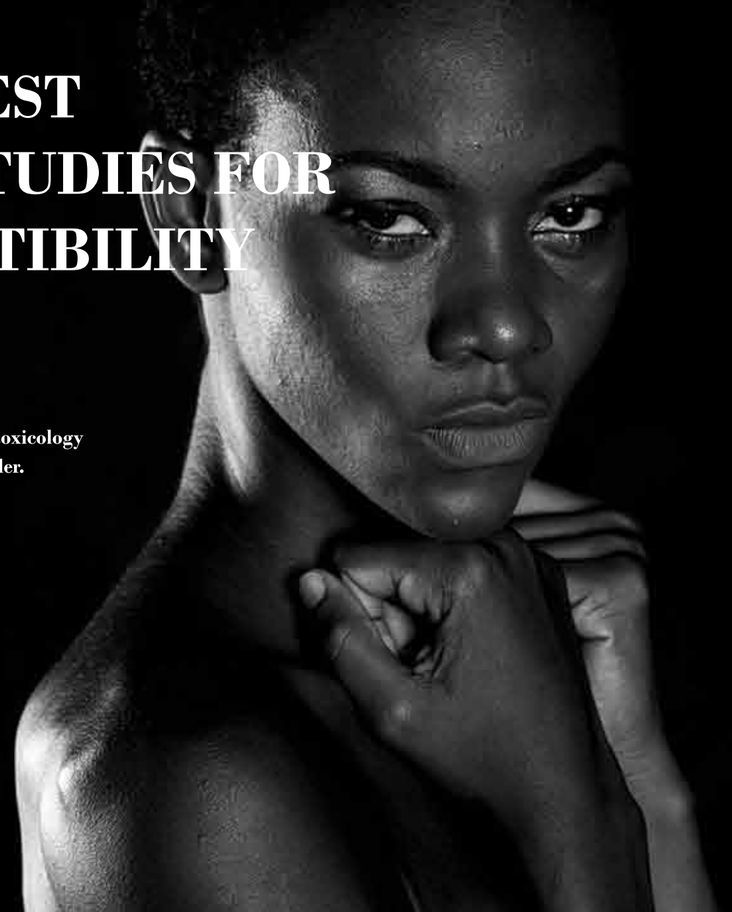
ZISHÉL GC Chromatogram



Butanediol diglycidyl ether(BDDE) Chromatogram(1ppm)



SAFETY TEST ANIMAL STUDIES FOR BIOCOMPATIBILITY



Safety

The following biocompatibility and toxicology tests were conducted on ZISHÉL Filler.

ZISHÉL FILLER

Test title	*Test Number*	*Test Standards*	*Test Results*
Acute Systemic Toxicity Test	SNUH 0800401	ISO 10993-11	**Pass**
Subchronic Subcutaneous Toxicity and Implantation in Rat -13Weeks	SNUH 0800402	ISO 10993-11 ISO 10993-6	**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	USP29	**Pass**
Bacterial Reverse Mutation Assay	SNUH 0800408	ISO 10993-3	**Pass**
In Vitro Chromosome Aberration Test	SNUH 0800409	ISO 10993-3	**Pass**
In Vivo Micronucleus Test	SNUH 0800410	ISO 10993-3	**Pass**

Teatina period - February 2009

Testing Institution Medical Device Evaluation Center, Clinical Research Institute, Seoul National University Hospital, Korea

ZISHÉL Filler With Lidocaine

ZISHÉL Filler with Lidocaine TOUCH

Cross-linked hyaluronic acid(20 mg.ml)
Average Grain Size: 200 μm
Injection Area: Superficial Wrinkles
Packaging Units
- 1ml(27G, 29G)
- 2ml(25G, 27G)
- 3ml(25G, 27G)

ZISHÉL Filler with Lidocaine MILD

Cross-linked hyaluronic acid(20 mg.ml)
Average Grain Size: 500 μm
Injection Area: All Moderately Pronounced Wrinkles on the full face
Packaging Units
- 1ml(27G, 29G)
- 2ml(25G, 27G)
- 3ml(25G, 27G)

ZISHÉL Filler with Lidocaine FORTE

Cross-linked hyaluronic acid(20 mg.ml)
Average Grain Size: 1,100 μm
Injection Area: Deep Wrinkles
Packaging Units
- 1ml(25G, 27G)
- 2ml(23G, 27G)
- 3ml(23G, 27G)

BRIGHTENING | SKIN VITALIZATION | HYDRATION

ZISHÉL AQUA SOFT

It is targeted at the universal range of treatment areas including the face, neck, decolletage (the area between the neck and breasts) and hands; designed to replenish the hyaluronic acid loss through aging, hence hydrating the skin and improving its elasticity and tone. the natural hydration properties of ZISHÉL AQUA SOFT also make it well suited to all skin types, whether the skin is dry or oily.

ZISHÉL
AQUA SOFT

ZISHÉL AQUA SOFT restores the hydro balance of the skin to improve roughness, elasticity, brightness, moistu -rization of skin surface and fine wrinkles to create a fresh and natural look.

ZISHÉL AQUA SOFT Information

It has low concentration rate and is injected to skin dermis upper level. Cross-linked with HA that enables longer duration of the product.

INFORMATION

Composition	Cross-linked HA 15mg/ml One syringe contains 3ml of ZISHÉL AQUA Three 3 ml syringes in a package
Intended Usage	Temporary improvement of facial wrinkles
Duration of effect	This depends upon your age and lifestyle as well as the correct placement of the product by a practitioner. Generally, two to three treatments every fourth week are recommended initially, followed with maintenance treatments approximately every four to six months.
Storage conditions	To be stored at room temperature(1-30celsius) away from direct sunlight
Shelf life	36 months(Refer to the product label)

FAQ

How long will it take for me to see the result?

You will see results immediately after treatment. You can even look in the mirror after one side of your face has been treated in order to compare the treated and untreated sides of your face.

What are the side effects of ZISHÉL?

The most common side effects are swelling, bruising, redness, or tenderness at the injection site immediately after treatment. In order to learn more, simply contact your qualified facial plastic surgeon.

Where can I use ZISHÉL?

It is recommended that the product is used for the correction of moderate to severe facial wrinkles, folds, and acne scars such as the nasolabial folds, marionette lines, and vertical wrinkles.

Is ZISHÉL safe?

ZISHÉL is manufactured and clinically proved to be safe by CHA Group(Top leader in pharma and stem cell research and has 26 units of hospitals, medical universities, stem cell banks, and research labs located in the United States, Japan, and South Korea)

ZISHEL Group

Embracing Elegance
Expressing Elegance

ZISHEL GROUP

was established to R&D, market, and distribute the novel medical technologies for Plastic, Reconstruction and Aesthetics. In connection with more than 23 international medical chains and +11450 private clinics, we have the mega-size distribution channels in over 52 countries covered by +35 blockbuster distributors worldwide. The majority of our executives were both educated and trained in the United States. They lead with excellence via unique leadership styles over our staffs and have propitious relationships with internationally recognized professors, physicians, and healthcare professionals worldwide. Our key differentiator is our continual investments for R&D activities under variety of applications. In the fast-changing healthcare environment, we challenge ourselves to adapt to new trends and lead developments for novel solutions tailored to our clients' needs.

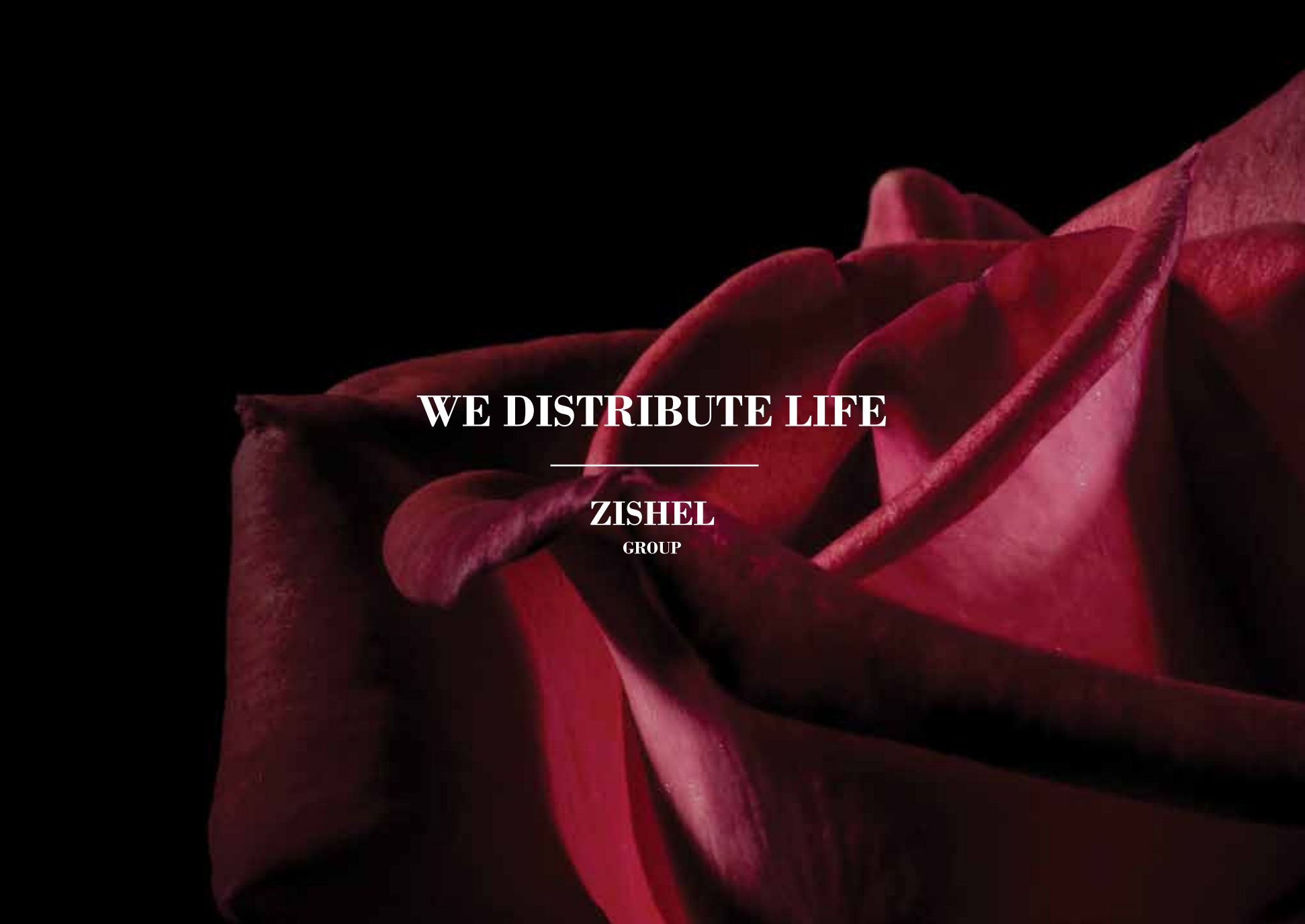
"TOP 50 PHARMA LEADER AND STEM CELL COMPANIES"

-COMTEX REPORT, LONDON-

MANUFACTURER

A Dermal Filler Made by the Global Stem Cell Leader and No.1 Women's Hospital

ZISHÉL is manufactured by the CHA Group(Top leader in pharma and stem cell research and has 26 units of hospitals, medical universities, stem cell banks, and research labs located in the Unites States, Japan, and South Korea). The CHA Group also has its own premium aesthetic medical facility well-known as the luxurious anti-aging treatment center for many celebrities. Based on its expert technology and knowledge in women's medical-care and anti-aging field, the CHA Group manufactures the most premium, biocompatible, and effective hyaluronic acid dermal filler.


WE DISTRIBUTE LIFE
ZISHEL
GROUP