LG Chem | LG aesthetics

REFERENCES

1. Drug master file No. 17416, FDA.
2. Certification of Suitability of Monographs of the European Pharmacopoeia, EDQM.
3. PRIME Journal Vol.9 Issue 2, 2019, P 74-76
4. Aesthetic Plast Surg. 2017 Apr,41(2):422-428.
5. Plast Reconstr Surg Glob Open 2020;8:e2648.
6. Unpublished Clinical studies. Please request yvoire@lgchem.com
7. Plast Reconstr Surg Glob Open. 2020 Jul 23;8(7):e2975.
8. J Cosmet Dermatol. 2020 Dec;19(12):3229-3233.
9. Data on file, LG Chem. Global shipment in 2020
10. Data on file, LG Chem. Sales Data in 2022
11. HA raw material of YVOIRE has equipped more strict quality requirement (Endotoxin, Protein level and sterility test results, etc) than European Pharmacopeia 9.0.
12. US Food and Drug Administration. Executive Summary Dermal Filler Devices. November 18, 2008
13. Carbohydr Polym. 2013;91(1):410-8.
14. J Drugs Dermatol. 2011 Sep;10(9):974-80.
15. Data on file, LG Chem.
16. Galderma's patent, WO 2014/206701 A1
17. ClinicalTrials.gov Identifier: NCT02334358
18. ClinicalTrials.gov Identifier: NCT02661737
19. ClinicalTrials.gov Identifier: NCT04784299
20. ClinicalTrials.gov Identifier: NCT05106751

LG Chem

E14, LG Science Park, 70, Magokjungang 10-ro, Gangseo-gu, Seoul 07795, Korea
http://global.lgyvoire.com / yvoire@lgchem.com

These products are medical devices. Read the 'Precautions for Use' and 'How to Use' before use.

YVO-BR-B015-01-MAR22

LG Chem LG aesthetics

Science for your Dream

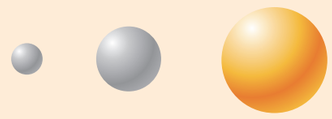
YVOIRE®

For Healthcare Professionals

Basic Information of YVOIRE®

Product Summary

YVOIRE® provides diverse product options meeting the needs of doctors and patients.

Product		YVOIRE® CLASSIC	YVOIRE® VOLUME	YVOIRE® CONTOUR	
		CLASSIC +	VOLUME +	CONTOUR 1.0	CONTOUR +
Practical uses		Smoothing and Filling Fine Wrinkles	Correcting deep wrinkles & Enhancing soft tissue volume	Restoring facial volume & Defining facial contour	
Product image					
Composition	Relative particle size	Cross-linked Hyaluronic acid 	Cross-linked Hyaluronic acid 	Cross-linked Hyaluronic acid 	
	Lidocaine	0.3% lidocaine	0.3% lidocaine	-	0.3% lidocaine
Enclosed needles		30G x ½" 1ea 27G x ½" 1ea	27G x ½" 2ea	23G x 1" 1ea	23G x 1" 1ea 23G cannula x 1" 1ea
Volume per syringe		1ml	1ml	1ml	1ml
Volumizing capacity					

YVOIRE® Product Information

YVOIRE® has natural effiacy due to delicate production.

HA raw material manufactured according to GMP-Rules and listed in US FDA DMF[1] with Certificate of suitability to the monographs. of the European Pharmacopeia by EDQM [2]

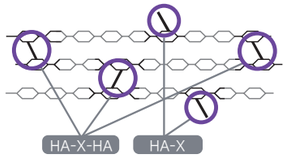
FDA DMF EDQM COS

One of few company that fully controls the quality and safety from HA raw material to end products

LG Chem

* HA: Hyaluronic acid
DMF: Drug Master File; COS: Certificates of Suitability

Improved efficacy and safety through HICE cross-linking technology [3]

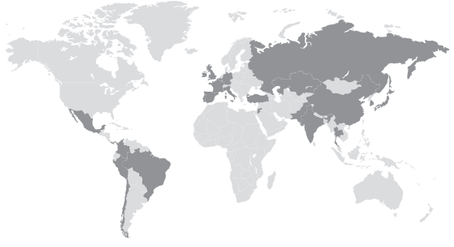


* HICE : High Concentration Equalized

Confirmed effectiveness and safety through multiple clinical trials[4,5,6,7,8]

(more than 1,500 cumulated subjects)

Global sales in over 40 countries [9]



• UK, France, Germany, China, Thailand, Brazil, Russia and other countries
• The countries shown on the map may not be accurate

More than 10 million YVOIRE injection globally.[10]

HA Features of YVOIRE®

History of LG Chem's HA research and development

HA raw material of YVOIRE® is directly manufactured by LG Chem and controlled with high standards as pharmaceutical products.[11]
The HA raw material of YVOIRE® is quality assured, identical to the ophthalmic HA fine to put in eyes.

1990	1995	2005	2011	2013
Hyaluronic acid R&D started with producer strain development	'Hyal 2000® Inj.' 1st hyaluronic acid Ophthalmic viscoelastics launched in Korea	'Hyruan Plus® Inj.' 1st 3-injection hyaluronic acid viscosupplement for osteoarthritis launched in Korea	'YVOIRE®', 1st cross-linked hyaluronic acid filler launched in Korea	'YVOIRE® plus', 1st hyaluronic acid filler with lidocaine Launched in Korea

LG Chem's Hyaluronic acid products

LG Chem's non-animal origin hyaluronic acid has been marketed in various medical fields since 1995 with confirmed safety and efficacy

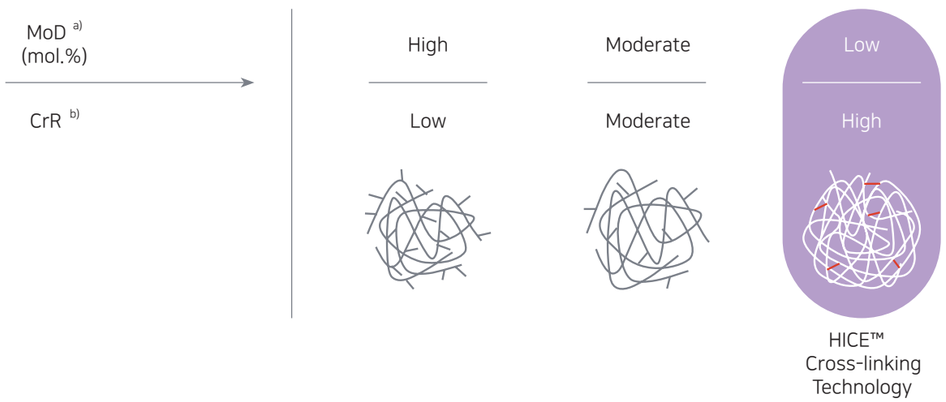
YVOIRE® is produced with HA raw material which has a high molecular weight of 3 million Daltons.[3]

YVOIRE®	3 million Daltons
Product A	1 million Daltons[12]
Product B	2.5 million Daltons[12]

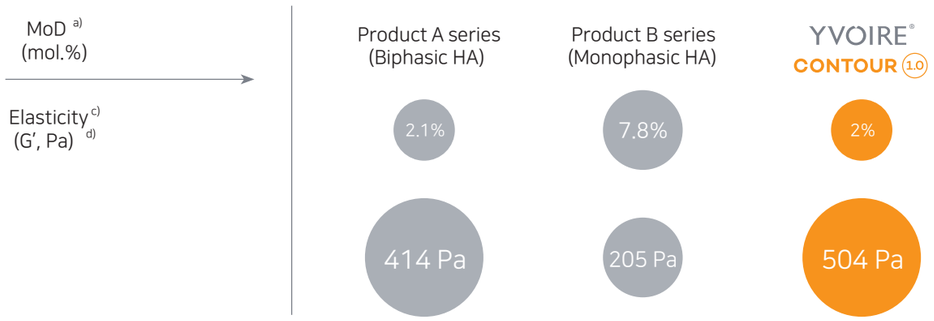
Cross-linking technology of YVOIRE®

HICE™ Cross-linking technology of YVOIRE®

HICE™ which stands for 'High Concentration Equalized' is a cross-linking technology developed by LG Chem. HICE™ cross-linking technology facilitates a higher cross-linking ratio with few amount of cross-linkers by dispersing the agents into highly concentrated hyaluronic acid during cross-linking reaction.



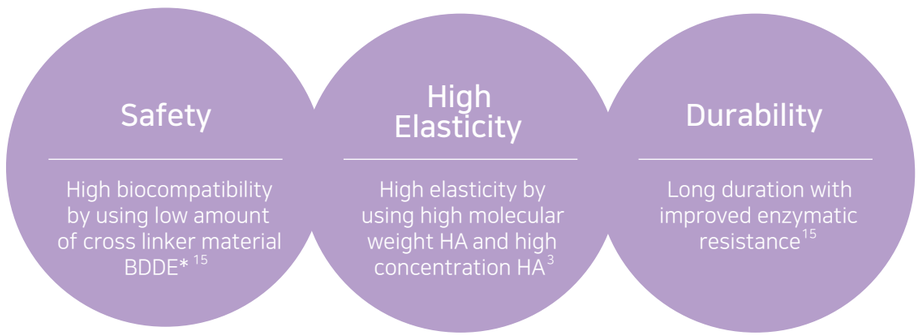
Comparison of MoD[a)] and volumizing effect[3]



The products chosen for the comparison had the highest storage modulus among its lidocaine options in the brand

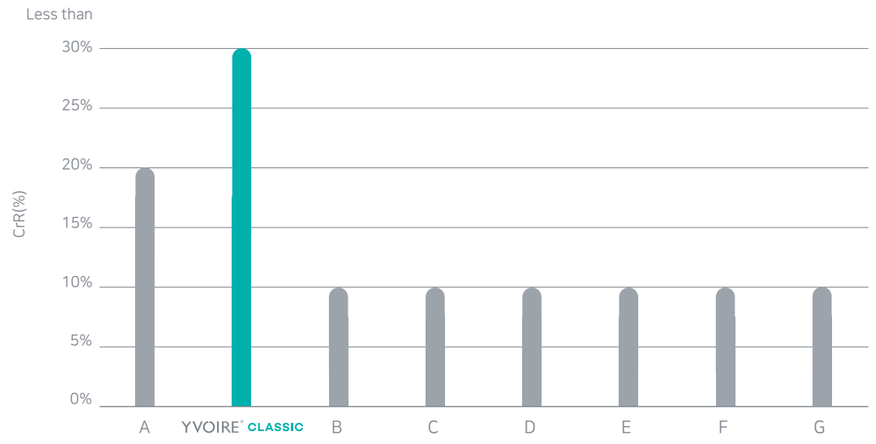
a) Modification Degree: The MoD is calculated with the following formula, (Pendent cross-linkers + cross-linked cross-linkers) / (HA units) This represents the total cross-linkers(BDDE) in the end product only [13]
b) Cross-linking Ratio: The number of cross-linked BDDE among the total BDDE
c) Storage modulus (G', Pa): Measured at 0.02Hz (Frequency sweep mode, 25℃, strain 4%), clinically indicates volume restoration effect[14]
d) Pa, Pascal, Storage modulus G'

Benefits of HICE™ Cross-linking Technology of YVOIRE®



BDDE: 1,4-Butane Diol Diglycidyl Ether

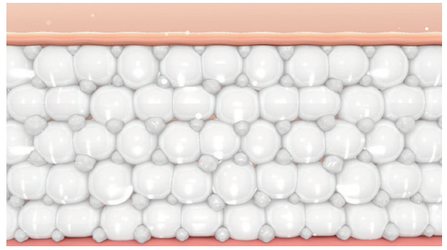
Cross-linking ratio of HA filler products[16]



CrR : The number of cross linked BDDE among the total BDDE
Diagram by LG Chem

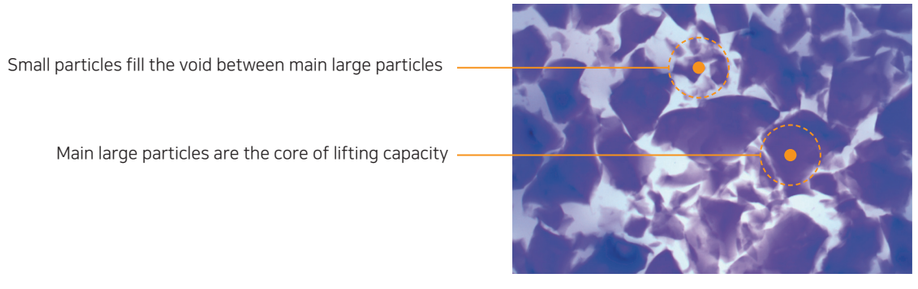
HA features of YVOIRE® CONTOUR

YVOIRE® contour shows smooth surface outlines and supporting capacity owing to its ideal multi-particle size composition.[3, 5]



YVOIRE® contour shows smooth gel surface by filling the void between main large particles with small particles, leads to high plasticity.

Microscopic view of YVOIRE® contour



Clinical Data of YVOIRE®

YVOIRE® confirmed its clinical efficacy on wrinkle correction and volume restoration, durability and safety through multiple clinical trial (more than 1,500 cumulative subjects).

Indicated year means the beginning year of clinical study, and the number of subjects is based on enrollment. Comparators are different in each clinical study, corresponds to each YVOIRE® products.

2008

A randomized, multi center, single-blind, active-controlled, matched pairs design clinical study to evaluate the correction of facial wrinkles and folds and safety of Meso Glow versus IAL system in nasolabial fold intradermal injection

41 subjects, Korea

2009

A randomized, multi center, single-blind, active-controlled, matched pairs design clinical study to evaluate the correction of facial wrinkles and folds and safety of HA IDF versus Restylane® in nasolabial fold intradermal injection[7]

58 subjects, Korea

2010

A randomized, multi center, single-blind, active-controlled, matched pairs design clinical study to evaluate the correction of facial wrinkles and folds and safety of HA IDF II versus Perlane® in nasolabial fold injection[5]

57 subjects, Korea

2012

A multi center, prospective and retrospective observation study to evaluate the safety and biodegradability of YVOIRE® classic s injected in the nasolabial folds up to 12 months after injection

68 subjects, Korea

2013

Evaluation on safety and biodegradability of YVOIRE® volume injection in the nasolabial folds up to 12 months after injection

80 subjects, Korea

2013

A randomized, multi center, double-blind, active-controlled, matched pairs design clinical study to evaluate the efficacy and safety of HA IDF II plus versus HA IDF II in nasolabial fold injection[8]

62 subjects, Korea

2014

A randomized, multi center, double-blind, active-controlled, matched pairs design clinical study to evaluatae the efficacy and safety of HA IDF plus versus HA IDF in nasolabial fold injection[4]

62 subjects, Korea

2014

A multicenter, randomized, rater-blinded, active-controlled, matched pairs design clinical study to evaluate the efficacy and safety of YVOIRE® contour compared with Restylane SubQ™ injected into the anteromedial malar region[5]

83 subjects, Korea

2014

A multi-center, prospective and observational study to evaluate long-term safety and biodegradability of YVOIRE®classic s injected into the nasolabial folds[17]

503 subjects, China

2015

A multicenter, extension clinical study to evaluate the long-term efficacy and safety of repeat treatment of YVOIRE® contour injected into the anteromedial malar region in subjects who have completed the LG-HACL014 study

13 subjects, Korea
* Repeated Treatment

2015

A multi-center, prospective and observational study to evaluate long-term safety and biodegradability of modified sodium hyaluronate gel (YVOIRE® volume s) injected for correction of nasolabial folds Medical Device Final Clinical Study Report[18]

503 subjects, China

2022

Additional global clinical trials are in progress

To Evaluate the Performance and Safety of YVOIRE® Volume Plus for Improvement of Mid-face Volume[19]

103 subjects, Germany

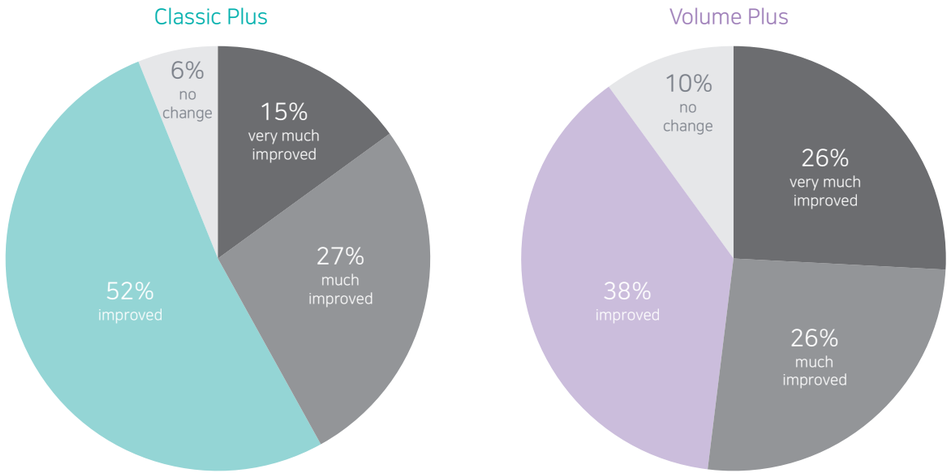
A Randomized, Multicenter, Evaluator-Blinded, Active-Controlled, Parallel-Group Investigation to Evaluate the Performance and Safety of YVOIRE® Classic Plus Versus Comparator for Temporary Correction of Nasolabial Folds[20]

104 subjects, Germany

Clinical Data of YVOIRE®

Efficacy on wrinkle correction

YVOIRE® Classic Plus and Volume Plus received satisfying responses from overall subjects after 26 weeks from injection



* Evaluation scale : Evaluate the degree of wrinkle correction by GAIS (global aesthetic improvement scale, -1~3 score) at 26 weeks after the injection
** above graph shows the number of subjects evaluated on each GAIS score (%)

Study design

Classic Plus

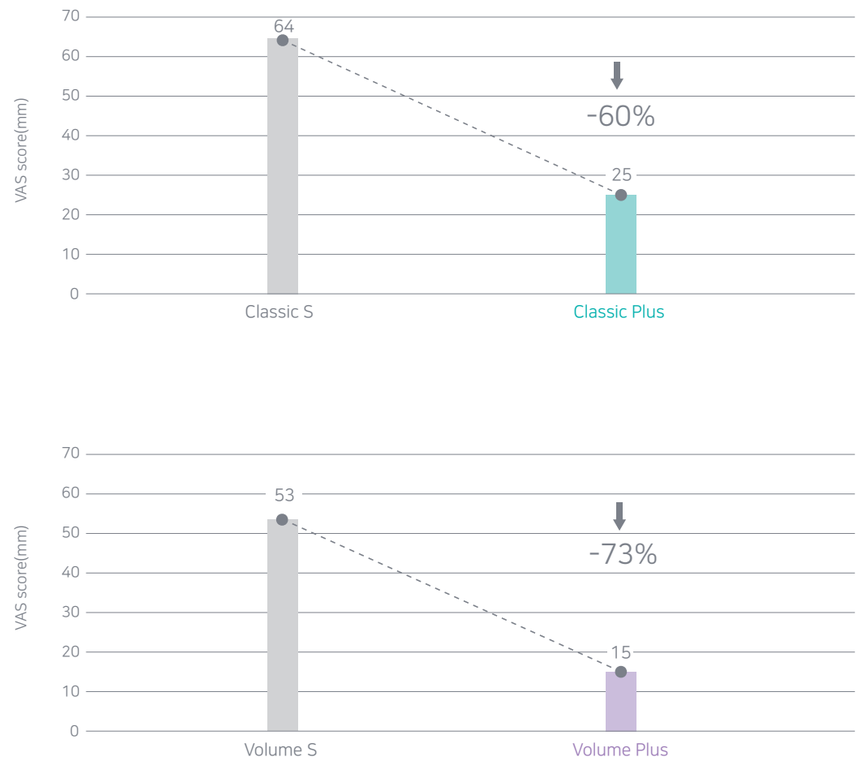
- A randomized, multicenter, double-blind, split-face study
- Total 62 subjects
- To evaluate the pain relief, efficacy of 26-weeks, and safety of 52-weeks after injecting YVOIRE® classic s and YVOIRE® classic plus for correction of nasolabial folds (50% linear threading technique, 50% serial puncture technique)[4]

Volume Plus

- A randomized, multicenter, double-blind, split-face study
- Total 62 subjects
- To evaluate the pain relief, efficacy of 26-weeks, and safety of 52-weeks after injecting YVOIRE® volume s and YVOIRE® volume plus for correction of nasolabial folds (100% linear threading technique)[8]

Pain relief

YVOIRE® Classic Plus and Volume Plus significantly reduced the patient's pain[4, 8]



Subjects evaluated the pain using the VAS (Visual analogue scale) immediately after injection. The score ranges from 0–100 and a higher score indicates greater pain intensity.

Clinical Data of YVOIRE®

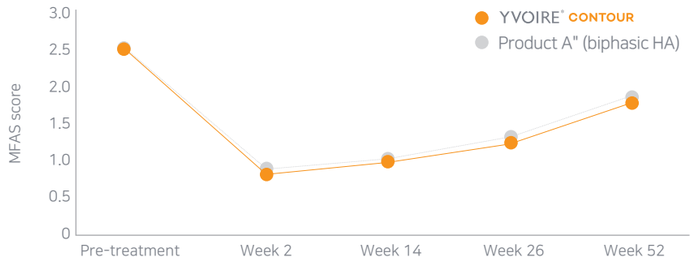
Long-term Efficacy of YVOIRE®

YVOIRE®contour confirmed the clinical efficacy and safety of volume augmentation in mid-face for up to 1 year.[5]

Phase IV - YVOIRE® CONTOUR

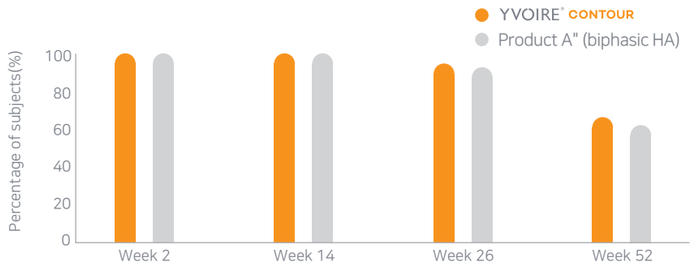
Amulticenter, randomized, rater-blinded, active-controlled, Split-Face Design clinical study to evaluate the efficacy and safety of YVOIRE® contour (test device) compared with Product A" (Biphasic HA, control device) injected into the anteromedial malar region (n=83).

MFAS score



MFAS responder rates

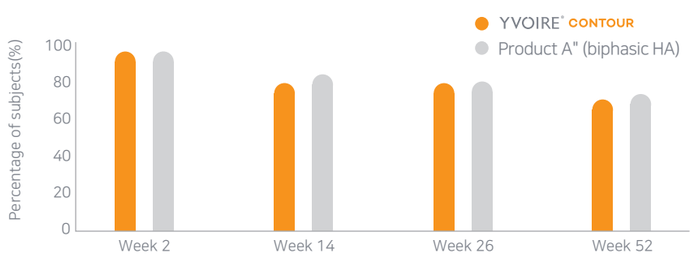
MFAS(Mid Face Aesthetic Scale) : A validated 5 Point Reference scale with photographs that classifies the fullness and volume in the mid-face area (0 : Full volume ~ 4 : Very severely sunken)



· MFAS responder rate : percentage of the subjects with improvement in MFAS score by at least 1 grade from baseline

GAIS responder rates

GAIS (Global Aesthetic Improvement Scale): A measure of the relative overall improvement after HA filler injection compared th the pre-injection. (-1: Worse ~ 3: Very much improved)



· GAIS responder rate : percentage of the subjects with improvement in GAIS score by at least 1 grade from baseline

Long-term Safety of YVOIRE®

YVOIRE®classic s and YVOIRE® volume s confirmed the long term safety and biodegradability.[17,18]

Phase IV - YVOIRE® CLASSIC Ⓢ

A multi-center, prospective and observational study to evaluate long-term safety and biodegradability of YVOIRE®classic s for 24 months after the initial injection into nasolabial folds.

- Target population : Chinese subjects whose WSRS grade is equal or greater than 2
- No. of subject : Total 503
- All the serious adverse events(1.99%) were unrelated to the investigational medical device.

The complete biodegradation was observed in all the subjects within 78 weeks after last treatment.

Phase IV - YVOIRE® VOLUME Ⓢ

A multi-center, prospective and observational study to evaluate long-term safety and biodegradability of YVOIRE® volume s for 24 months after the initial injection into nasolabial fold.

- Target population : Chinese subjects whose WSRS grade is equal or greater than 2
- No. of subject : Total 503
- All of the serious adverse events(3.98%) are unrelated with the study device.
- The complete biodegradation was observed in all the subjects within 78 weeks after last treatment.

AE: adverse events

Injection Area of YVOIRE®

YVOIRE® CLASSIC S
YVOIRE® CLASSIC +

Glabella Line
Tear Trough
Crow's feet
Barcode Lines
Upper Eyelid

YVOIRE® VOLUME S
YVOIRE® VOLUME +

Forehead Augmentation
Lip Contouring
Lip Augmentation
Cheek
Nasolabial folds
Temple
Nose Augmentation
Marionette Line

YVOIRE® CONTOUR 1.0
YVOIRE® CONTOUR +

Cheekbones
Chin Augmentation
Jaw Line

These are for your information only, the injection areas and the appropriate products for it must be chosen according to the judgement of a trained physician.
'Indication' and 'Precautions for Use' may vary from countries.
* Specific regions such as periobital and lips are not recommended for some countries(China,etc)

Science for your Dream

YVOIRE®

LG Chem LG aesthetics