

saypha®

croma



# CONTOURING WITH PRECISION

MDR\* approved, aesthetic dermal filler

\*Medical Device Regulation

Product information for  
healthcare professionals

# saypha<sup>®</sup> volume plus

Lidocaine



saypha<sup>®</sup> volume plus Lidocaine is a cross-linked hyaluronic acid dermal filler indicated to correct moderate to severe midface volume deficit. The intended purpose is to restore facial volume.<sup>1</sup> The incorporated Lidocaine, facilitates enhanced treatment comfort for patients.<sup>1,2</sup>

## Product specifications<sup>1</sup>

<b>Concentration HA</b>	2.5 %
<b>Crosslinking agent</b>	BDDE (concentration $\leq 2$ ppm)
<b>Additional ingredients</b>	0.79% sodium chloride, 0.23% disodium phosphate dodecahydrate, 0.05% sodium dihydrogen phosphate dihydrate, 0.3% lidocaine HCL (as anaesthetic), pH of 6.7-7.3
<b>Crosslinking degree</b>	1.0-2.0 %
<b>Particle size</b>	$\sim 320 \mu\text{m}$
<b>Injection depth</b>	Deep subcutaneous and/or supraperiosteal
<b>Needle</b>	27 G x 1/2" thin wall Terumo <sup>™</sup> needle (CE 0197)
<b>Packaging unit</b>	1 box of 1 mL syringe
<b>Indication</b>	The viscoelastic implant is indicated to correct moderate to severe midface volume deficit.

## Comfort Flow syringe

Designed for optimal and reliable handling.<sup>3</sup>

**PREMIUM GLASS SYRINGE**

**NEW PRIMARY LABEL:  
EASY READABLE SCALE**

**CLEAR DIFFERENTIATION:  
NEW COLOUR CODING FOR EVERY  
PRODUCT**

**DEVELOPED AND TESTED TOGETHER  
WITH HEALTHCARE PROFESSIONALS<sup>3</sup>**



# Extrusion force

With a keen focus on every detail, the optimised HA fillers manufacturing process and meticulously designed syringe, ensure reliable extrusion force of saypha® products. saypha® volume plus Lidocaine shows **lower extrusion force among other highly crosslinked products** in the market.<sup>4</sup> Low extrusion force aims to contribute to a more precise dosing during injection.<sup>5</sup>

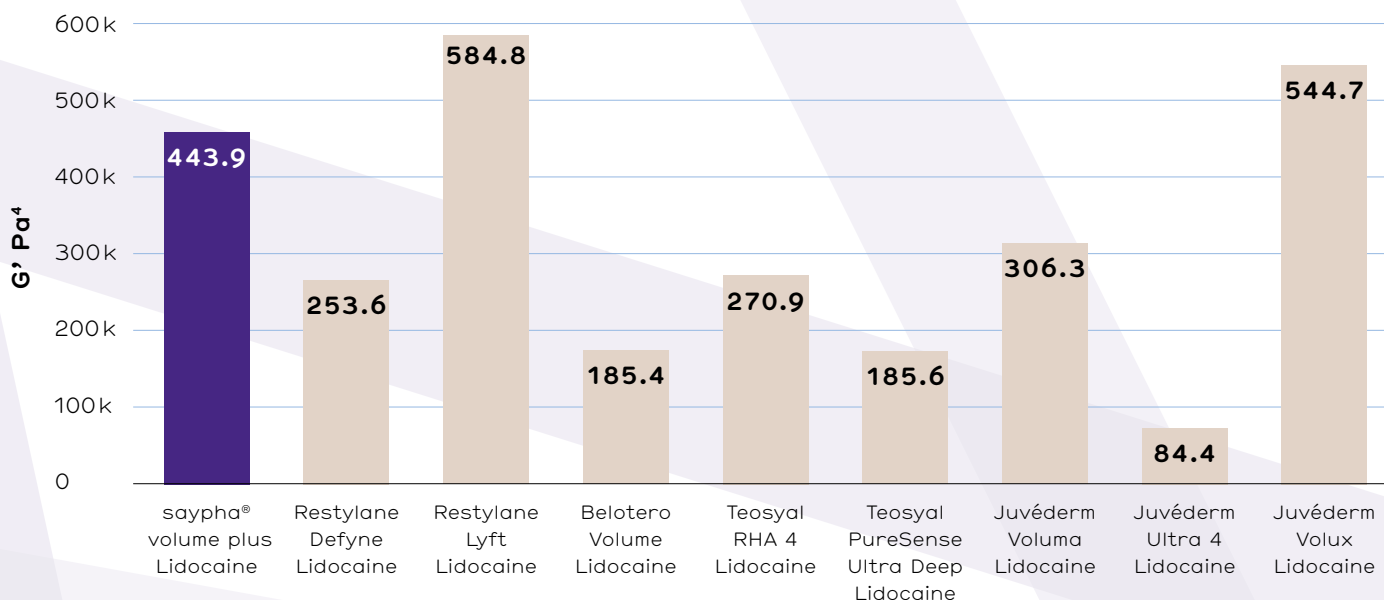
Product	IF [N]
saypha® volume plus Lidocaine	13
Restylane Defyne Lidocaine	16
Restylane Lyft Lidocaine	14
Belotero Volume Lidocaine	11
Teosyal RHA 4 Lidocaine	11
Teosyal PureSense Ultra Deep Lidocaine	20
Juvéderm Voluma Lidocaine	10
Juvéderm Ultra 4 Lidocaine	20
Juvéderm Volux Lidocaine	14

\* all products were tested with 27G x ½" needles

# Rheology Data

## G' (G prime)

G' reflects the ability of the gel to regain its original shape after deformation.<sup>6</sup> It is an indicator for the lifting and volumising capacities of HA fillers.<sup>6,7,8</sup> saypha® volume plus Lidocaine has one of the highest G' on the market among highly crosslinked products, which underpins its lifting capacity.<sup>4,6,9</sup>



# saypha<sup>®</sup> volume plus

Lidocaine

## Clinically proven effectiveness & safety

for correction of **midface volume deficiency**.<sup>10</sup>

A prospective, open-label, multicentre, post-market study to evaluate safety and efficacy of saypha<sup>®</sup> volume plus Lidocaine over **36 months** in **91 subjects** with moderate to severe **midface volume deficiency**.<sup>a,10</sup>

### Month 1

**100%** of the subjects demonstrated improvement<sup>b,10</sup>

### Month 13

**77%** of the subjects had still a visible effect<sup>c,10</sup>

**78%** of the patients were satisfied with the results<sup>10</sup>

The effect lasts longer in severe cases (volume deficiency).<sup>d</sup>



**No serious side effects related to the product.**<sup>e,10</sup>

a. grades 2 or 3 on the five-point Midface Volume Deficit Severity Scale (MVDSS). b.  $\geq 1$  grade based on MDVSS (Midface Volume Deficit Severity Scale) assessed by the investigator. c. at least 1 grade based on MDVSS assessed by the investigator. d. which seemed to be independent of the volume injected at baseline. e. observed in this clinical study.

# Clinical benefits

WITH SAYPHA® VOLUME PLUS LIDOCAINE OVER **96%** OF THE PARTICIPANTS WERE PLEASED WITH THE TREATMENT RESULT AFTER 4 WEEKS.<sup>10</sup>

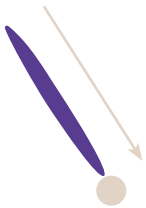
**78%** OF THE PARTICIPANTS SUSTAINED PATIENT SATISFACTION EVEN AFTER 1 YEAR.<sup>10</sup>

WITH SAYPHA® VOLUME PLUS LIDOCAINE FACIAL CONTOURING<sup>11,12,13</sup> IS POSSIBLE, DUE TO EFFECTIVE VOLUMISATION<sup>1,10</sup> OF THE MIDFACE AREA.

# Artful Accuracy

Injection techniques to correct moderate to severe midface volume deficit.<sup>1</sup>

## • Tunneling technique



- » The needle enters the skin, bevel up, at a 30° to 45° angle and is fully inserted to the hub at the appropriate depth, dictated by the nature of the defect and the dermal filler selected. The filler is then uniformly distributed, in a retrograde fashion, into the created tunnel, as the needle is slowly withdrawn from the skin. According to Sherman, it is best to stop the injection for all dermal fillers before needle withdrawal to avoid leakage and wasted product or superficial implantation that may lead to papule or nodule formation.<sup>14</sup>

» Deep subcutaneous and/or supraperiosteal injection.<sup>1</sup>

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## • Linear threading technique

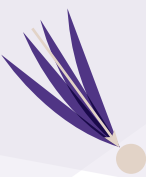


- » The needle enters the skin, bevel up, at a 30° to 45° angle and is fully inserted to the hub at the appropriate depth, dictated by the nature of the defect and the dermal filler selected. The filler is delivered as the needle is advanced using an anterograde injection technique.<sup>14</sup>

Deep subcutaneous and/or supraperiosteal injection.<sup>1</sup>

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## • Fanning technique



- » The needle is inserted, bevel up, through a single entry point and then pivoted to create a series of linear tunnels in a fanlike pattern. A retrograde thread of the volumising agent is placed within each tunnel, and the volume is tapered as the needle approaches the pivot point to avoid excess accumulation and possible nodule formation at the pivot point.<sup>14</sup>

» Deep subcutaneous and/or supraperiosteal injection.<sup>1</sup>

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## • Serial-puncture technique



- » The injection is performed slowly and at a low pressure, inserting the needle bevel-down with a 90° angle to the skin surface until touching the bone.<sup>15</sup> Once the needle is inserted into the appropriate depth, a small aliquot of product is delivered, and the needle is withdrawn. The process is repeated along the entire length of defect.<sup>14</sup>

» Deep subcutaneous and/or supraperiosteal injection.<sup>1</sup>

# Real Results



Patient received saypha® volume plus lidocaine for the correction of midface volume deficiency. The product was injected by using the bolus technique into the deep subcutis, with 1.5mL in total for both sides.



Patient treated with saypha® volume plus lidocaine for the correction of midface volume deficiency. The product was injected by using the bolus technique into the deep subcutis, with 1.5mL in total for both sides.



saypha® rich



saypha® filler



saypha® filler Lidocaine



saypha® volume



saypha® volume Lidocaine



saypha® volume plus Lidocaine

#### References

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