

 **NEW**  
with lidocaine

OPTIMAL  
**SKIN**  
INTEGRATION

**Belotero<sup>®</sup>**  
It's a part  
of me

MERZ AESTHETICS

**BELOTERO<sup>®</sup>**  
The filler you'll love

## Belotero® – It's a part of me

### It's a part of you

Belotero® offers you an extended range for smoothing and filling wrinkles, restoring facial volumes and rehydrating skin.

### It's a part of them

Belotero® integrates smoothly into an anti-ageing regimen that enhances confidence and self-assurance. It has an intelligent design for an advanced bespoke aesthetic solution with predictable and natural outcomes for optimal patient satisfaction and trust.



Belotero® Hydro is an ideal treatment option to deliver effective results when patients want deep rehydration and firmer skin.

The Belotero® range of fillers delivers predictable and harmonious results for the smoothing and filling of lines and wrinkles, lip augmentation and the restoring of facial volumes.

### Belotero® range of fillers now with lidocaine

#### Improved patient comfort

- The addition of the anesthetic, lidocaine, enhances patient comfort in more sensitive areas
- The influence of lidocaine endures after the injection procedure

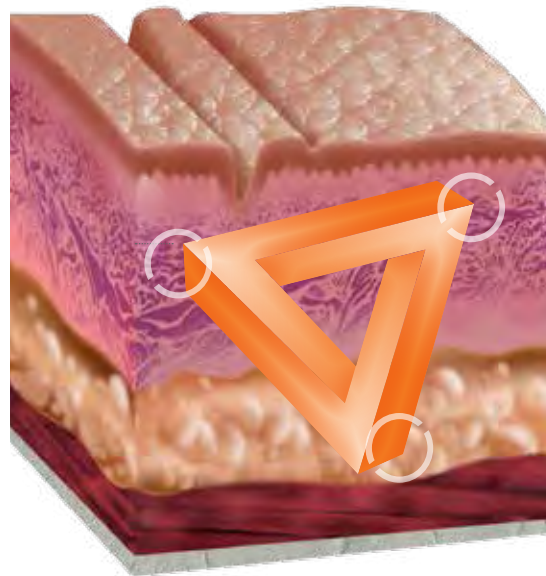
# Belotero® – Holistic solution for targeted needs

The Belotero® products can be used individually or in combination to tailor an aesthetic solution for each patient depending on the skin's structural and functional needs.

## What does the skin need?

### ELASTICITY –

for optimal tissue support



### COHESIVITY –

for excellent tissue integration

### PLASTICITY –

for excellent malleability to model and shape



**ELASTICITY –**  
the ability of a gel to return to its initial shape after being subjected to strain



**COHESIVITY –**  
the ability of a gel to stick together and thereby maintaining gel integrity



**PLASTICITY –**  
the ability of a gel to be shaped and modelled

The Cohesive Polydensified Matrix of Belotero® enables seamless dermal integration<sup>1</sup>

#### Control



#### Cohesive gel Monophasic polydensified



#### Fragemented gel Monophasic monodensified gel



#### Non cohesive gel Biphasic



By optimising the balance of these properties, the Belotero® range of fillers integrates seamlessly into the skin tissue and lets you achieve predictable and harmonious results.

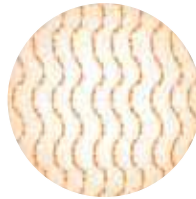
<sup>1</sup> Van Gieson elastin staining

## Intelligent design in aesthetics

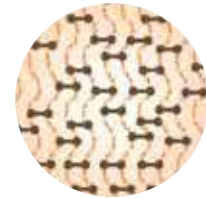
The Belotero® fillers are manufactured using a patented Dynamic Cross-Linking Technology that results among others in a monophasic Cohesive Polydensified Matrix (CPM).



**Phase 1**  
Hyaluronic acid in its original form  
(single chains, random coil structure)



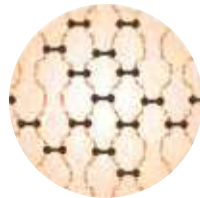
**Phase 2**  
Linearisation of the individual  
hyaluronic acid chains:  
the random coil structure untangles



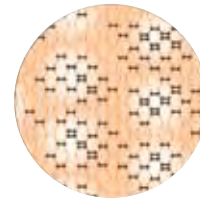
**Phase 3**  
First hyaluronic acid crosslinking  
process with BDDE:  
a cellular, monophasic gel emerges

### STANDARD CROSS-LINKING

Phase 4 to 5 constitute the innovative part of the patented DCLT technology



**Phase 4**  
Expansion of the gel that was created  
in the crosslinking process



**Phase 5**  
Second crosslinking process,  
supplemented with additional  
non-crosslinked hyaluronic acid

### PATENTED DYNAMIC CROSS-LINKING TECHNOLOGY (DCLT)<sup>2</sup>

This advanced DCLT technology provides the ideal balance of cohesivity, elasticity and plasticity to match the needs of the targeted layer of the skin.

<sup>2</sup>Patent family publication number WO2005/085329

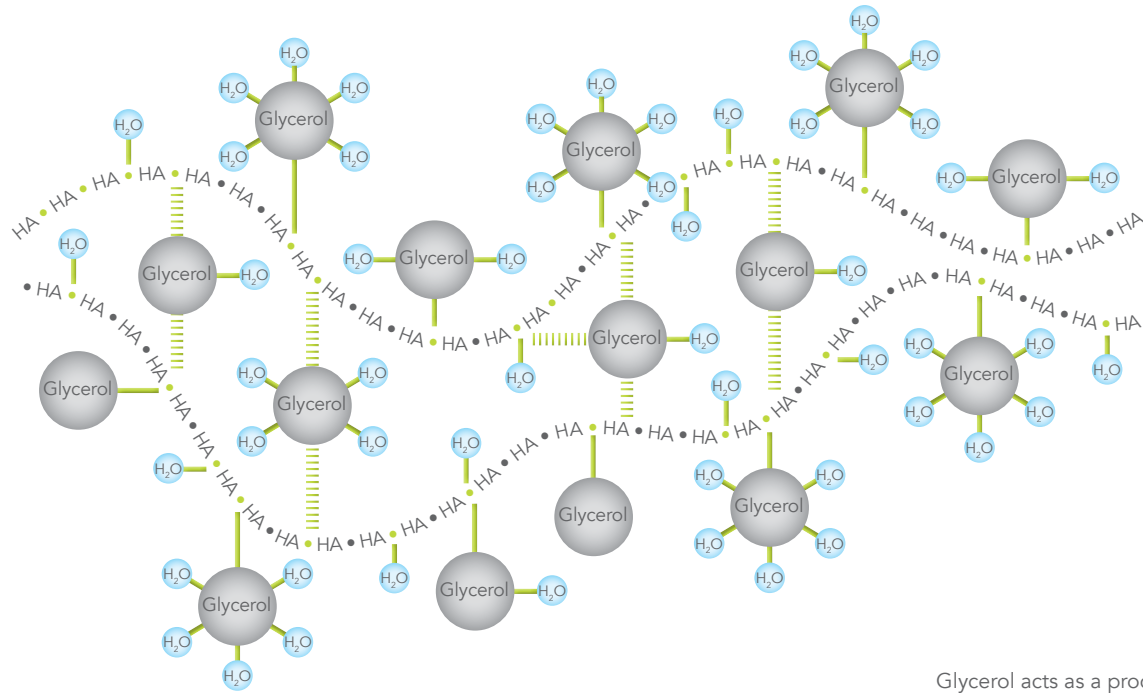
# Belotero<sup>®</sup> Hydro

Skin rehydration  
Complexion radiance



# Belotero® Hydro\* – Designed for rehydration whilst restoring skin radiance and skin elasticity

HA + Glycerol – A unique and patented combination<sup>3</sup>: Made with naturally occurring substances thus perfectly biocompatible and totally resorbable.



Glycerol acts as a protective sheath around the HA

| Composition   | Amount                | Purpose  |
|---|-----------------------|--|
| High molecular weight, non-crosslinked highly concentrated Hyaluronic Acid (HA) | 2.5 – 3 MDa, 18 mg/ml | Known as a hydrating agent and for its inhibition of matrix-metalloproteinase (MMP) which degrades collagen <sup>4</sup>                     |
| Glycerol  | 21 mg/ml              | Known for its ability to hydrate and acts as a 'protective sheath' to slow HA degradation and hence increase duration of action <sup>5</sup> |
| Phosphate-citrate buffer  | pH 7                  | To adjust and maintain a physiological pH  |

\* Belotero® Hydro is equivalent to Mesolis® +, a registered trademark of Anteis S.A.

<sup>3</sup> Patent family publication number WO2007/077399

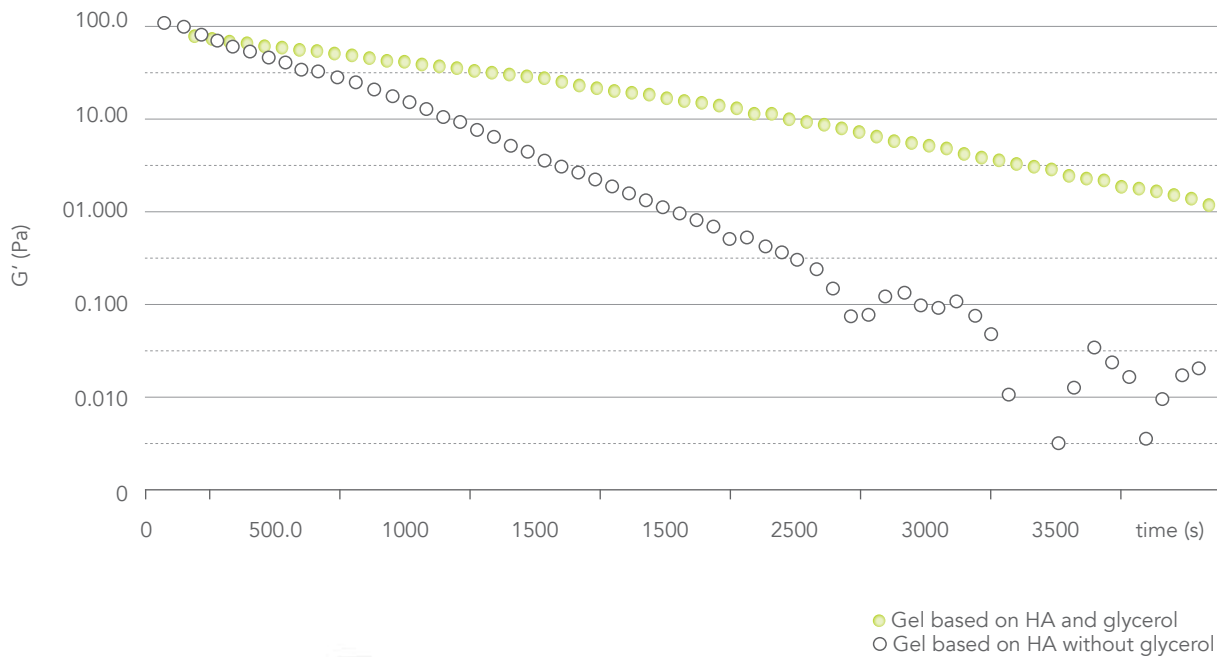
<sup>4</sup> Sasaki A et al., Tohoku J. Exp. Med., 2004, 204, 99-107.

<sup>5</sup> Fluhr J. W. et al., Br J Dermatol. 2008 Jul; 159(1): 23-34.

**BELOTERO® HYDRO**

## Additional benefit: The addition of glycerol prevents HA degradation caused by free radicals

In vitro tests show the increased resistance against free radical degradation of an HA gel combined with glycerol.<sup>6</sup>



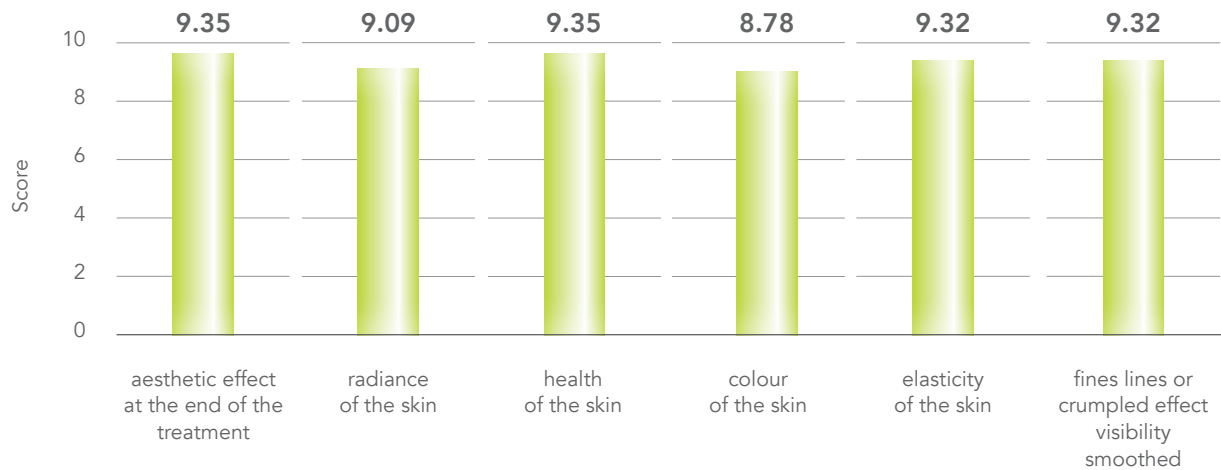
86%  
of females want  
to look radiant  
and rested<sup>7</sup>

<sup>6</sup> Data on file  
Face Value Wave I (n = 2939) – page 11 –  
internal data Merz Pharmaceuticals GmbH

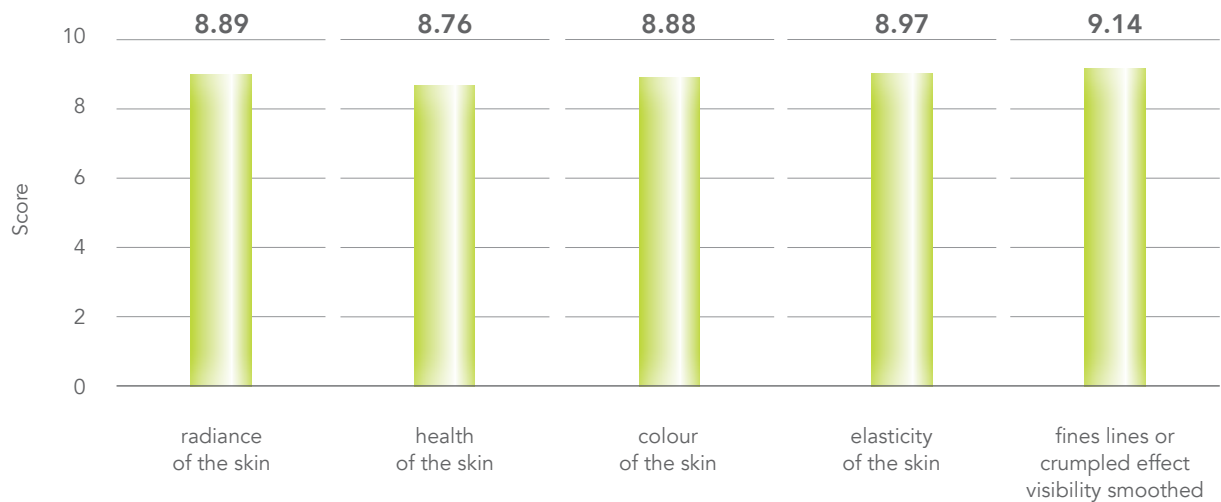
**BELOTERO<sup>®</sup> HYDRO**

# Belotero® Hydro ensures a high level of satisfaction for you and your patients<sup>8</sup>

Very high practitioner satisfaction with an average score of 9.2/10



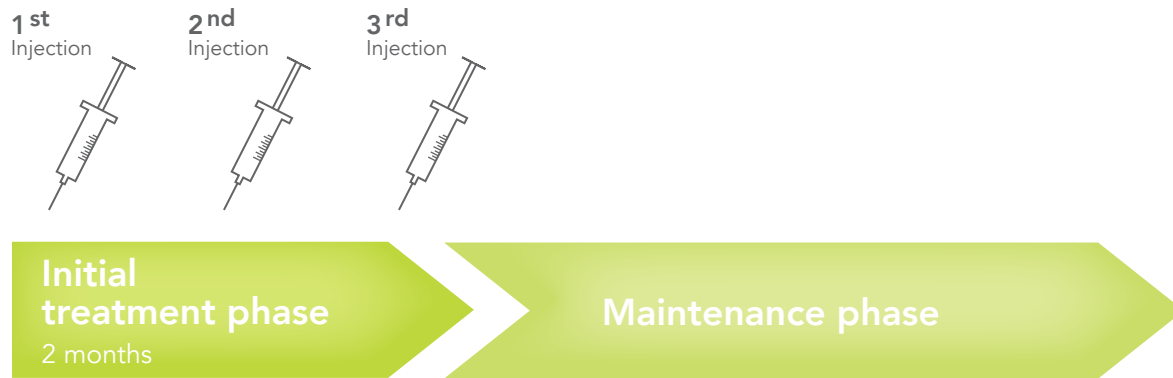
Excellent patient appreciation with an average score of 8.9/10



<sup>8</sup> In 2009 a satisfaction enquiry on Mesolis+ gel (equal to Belotero® Hydro) was conducted on an international level. During that period, 113 patients and 23 practitioners evaluated the product itself and the quality of the aesthetic outcomes.

# Belotero® Hydro is specifically designed for deep rehydration treatments

## Practical guidance for treatment phases



**Initial treatment phase:**  
2 – 3 treatment sessions held 30 days apart are recommended in the initial treatment phase

**Maintenance phase:**  
Following this treatment trilogy, maintenance treatments should follow once or twice a year depending on the individual patient

## Tips for the initial physician – patient consultation

Belotero® Hydro may be an entry level treatment for those who have never previously considered aesthetic therapy.

The choice of when to begin a treatment is a sensitive one for patients, and helpful information prior to your recommendation can be gathered through a few quick yes/no questions.

- Is your skin often exposed to the sun?
- Does it feel as though it's lost some firmness?
- Are more fine lines noticeable of late?
- Are you a smoker?

If the answers tend to be positive, the likelihood is high that candidates will be suited to a Belotero® Hydro regimen.

## Predictable results with Belotero® Hydro\*

Face: Recovery of skin elasticity and firmness



Before



After

Neck: Recovery of skin tone and elasticity



Before



After

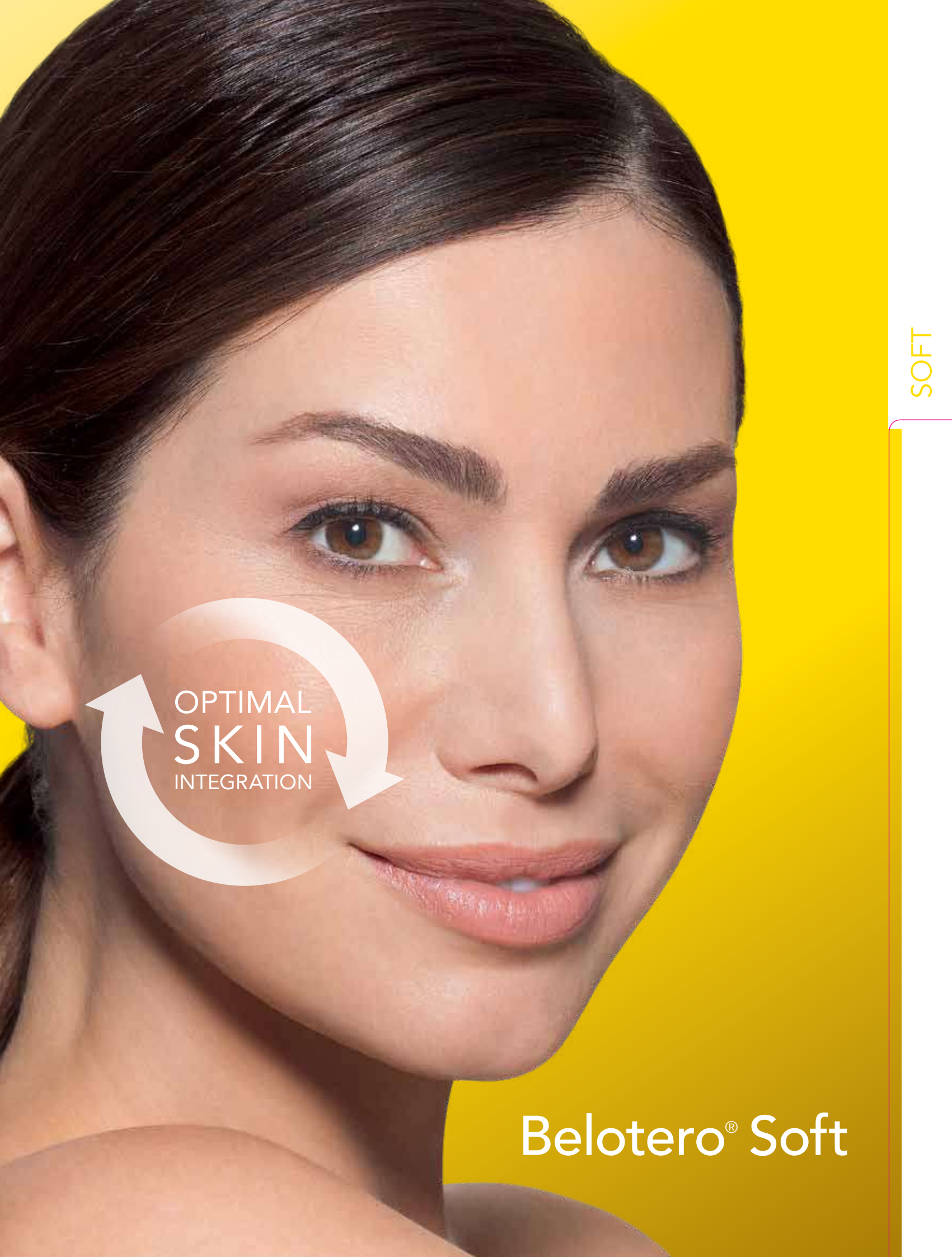
Back of hands: Improvement of skin texture and radiance



Before



After



SOFT




Belotero® Soft

## Belotero® Soft\* smoothens fine lines away

Belotero® Soft is optimal for fine line correction and deep rehydration due to its excellent cohesivity and its water binding capacity.<sup>9</sup>

Ideal for fine lines such as

- Crow's feet
- Perioral lines



Superficial  
injection for fine  
line correction

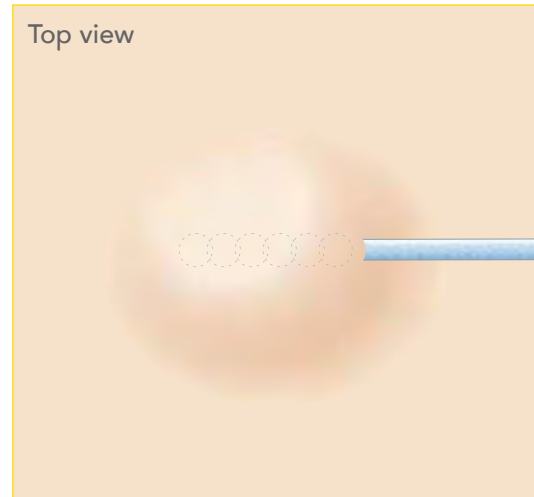
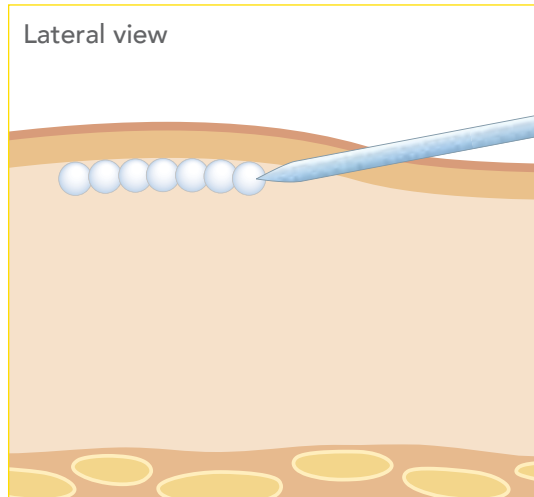
\* Belotero® Soft is equivalent to Esthéelis® Soft, a registered trademark of Anteis S.A.  
<sup>9</sup> J. Necas, L. Bartosikova, P. Branner, J. Kolar, Veterinarni Medicina, 53, 2008 (8): 397-411.

**BELOTERO® SOFT**

## A product for superficial injection techniques

### Blanching technique for natural looking results

Belotero® Soft can be administered using the blanching as well as the micro-papular injection technique for deep hydration and fine line smoothing.



### Safe injections close to the surface without Tyndall effect<sup>10</sup>



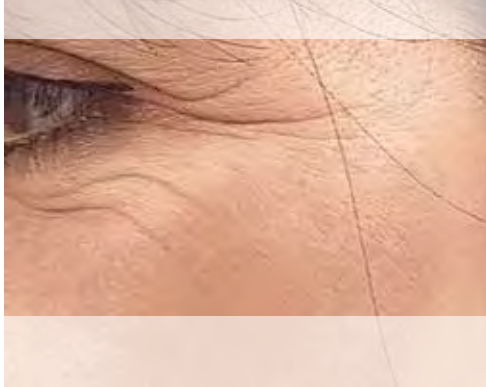
Directly after injection

- Inject at the correct depth and there is brief skin blanching at the point of injection
- The whiteness disappears after a few minutes

Picture: Courtesy P. Micheels  
<sup>10</sup> Micheels P. et al., A Blanching Technique for Intra-dermal Injection of the Hyaluronic Acid Belotero. Plastic and Reconstructive Surgery. 2013; October Supplement.

## Predictable results with Belotero® Soft\*

Crow's feet

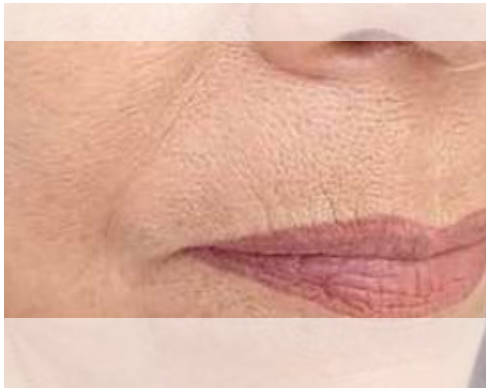


Before



After

Perioral lines



Before



After

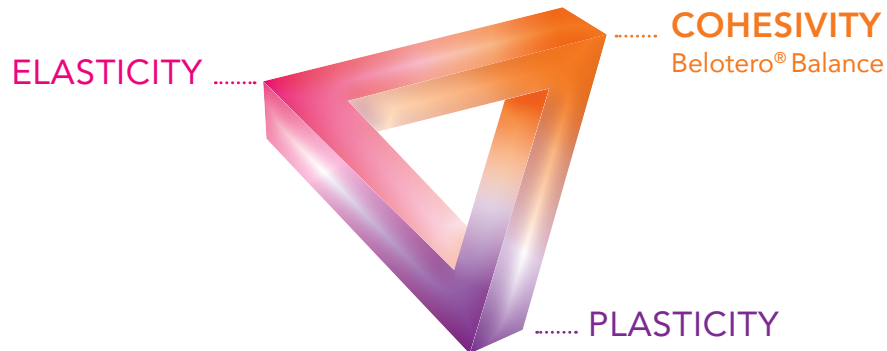


OPTIMAL  
**SKIN**  
INTEGRATION

Belotero<sup>®</sup>  
Balance

BALANCE

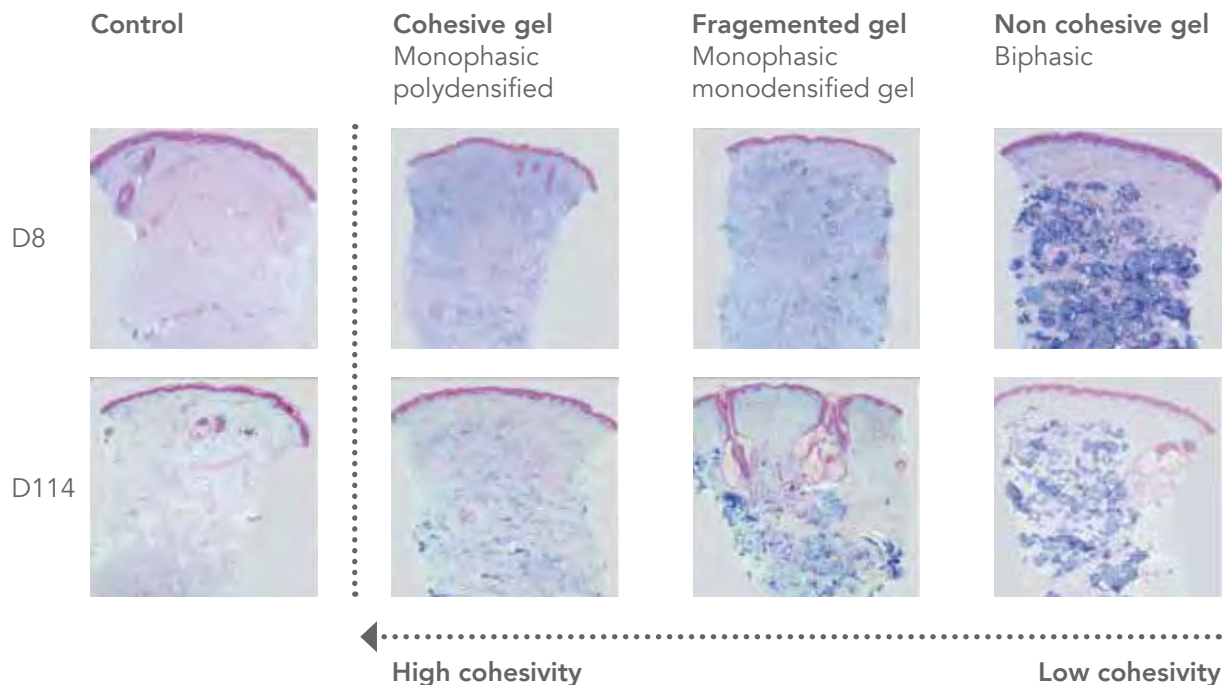
# Belotero® Balance\* becomes a part of your patients due to its seamless integration



The cohesivity of Belotero® Balance enables optimal skin integration and prevents the risk of gel migration

- Belotero® is seen to occupy the full thickness of the reticular dermis and is evenly distributed<sup>11</sup>
- No dermal trauma or structural alteration<sup>11</sup>

Cohesivity enables seamless dermal integration<sup>12</sup>



Blue areas on the images correspond to HA  
 Alcian blue staining 8 days after injection of HA fillers  
 Alcian blue staining 114 days after injection of HA fillers

\* Belotero® Balance is equivalent to Belotero® Basic as well as equivalent to Esthélis® Basic, a registered trademark by Anteis S.A.  
<sup>11</sup> Tran C, Carraux P, Micheels P, Kaya G, Salomon D: In vivo Bio-Integration of Three Hyaluronic Acid Fillers in Human Skin: A Histological Study. In press, Dermatology DOI: 10.1159/000354384  
<sup>12</sup> Van Gieson elastin staining

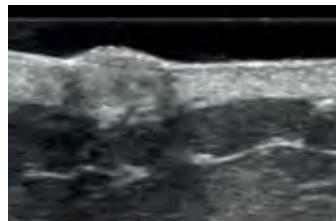
# Belotero® Balance – Good safety and tolerability

## Optimal skin integration without side effects

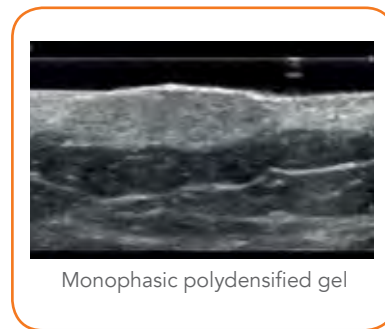
Belotero® ultrasonography images show a homogenous papule which is as dense as the surrounding tissue after injection into the superficial dermis.<sup>13</sup>



Biphasic gel



Monophasic monodensified gels



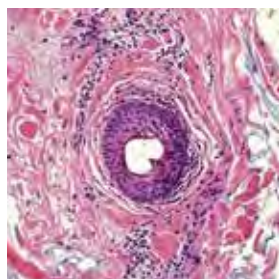
Monophasic polydensified gel

In contrast Restylane® and Juvéderm® showed a higher degree of echoes, opaqueness, and production of a cone of shadow underneath the injected papules.

## Belotero® has no significant local inflammatory reaction<sup>14</sup>

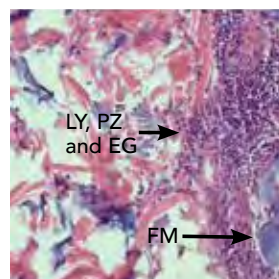
Belotero® showed an absence of an inflammatory reaction following injection intradermally.<sup>14</sup>

## Histological slides 30 days after injection



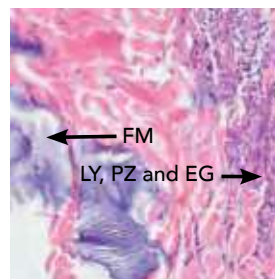
Juvéderm® 30HV

- Slight to moderate degree of chronic inflammation
- Subepidermal and perivascular increased number of lymphocytes, also plasma cells and several granulocytes



Teosyal® Deep Lines

- Severe chronic inflammation
- Dense infiltrate of inflammatory cells



Restylane® Perlane®

- Intense chronic inflammation,
- Heavy infiltration of lymphocytes, plasma cells and eosinophil granulocytes



Belotero® Balance

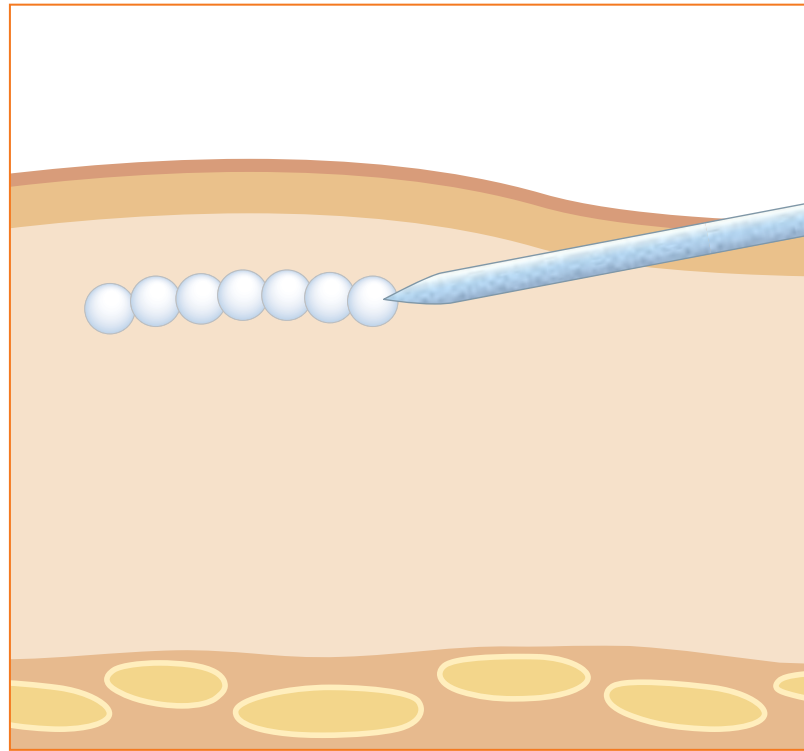
- Histomorphological normal finding free of inflammation unremarkable immune reaction

LY lymphocytes, PZ plasma cells, EG eosinophilic granulocytes, FM foreign material, E epidermis

<sup>13</sup> Micheels P et al., Dermatol Surg 2012;38:1162-1169  
 Pictures: Courtesy to Dr Micheels and Dr Besse  
<sup>14</sup> Taufig A.Z. et al., J Ästhet Chir 2009 2:29 – 36.

## Ideal for blanching

Belotero® is the only commercially available HA filler that can be administered with the blanching technique in the superficial dermis<sup>15</sup>



The multipuncture deposition of the cohesive polydensified matrix hyaluronic acid gel for the blanching technique.

**Important: 1.5 to 2 mm needle insertion**

- Injection in superficial dermis
- Injection angle of 10–12 degrees
- Multiple punctures at intervals of 0.5 cm

“Belotero® is suitable for very superficial intradermal injection using the blanching technique with little to no risk of visible product or the Tyndall effect.”

<sup>15</sup> Micheels P. et al. A Blanching Technique for Intradermal Injection of the Hyaluronic Acid Belotero. Plastic and Reconstructive Surgery. 2013; October Supplement.

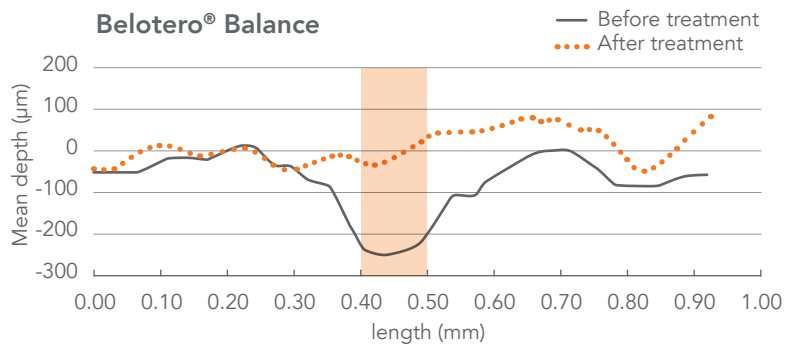
# Belotero® Balance offers smooth support of the superficial and mid dermis

The Split-Face Evenness Study showed significantly greater improvement in evenness\* of the nasolabial folds area of Belotero® Balance compared with Restylane® ( $p < 0.0001$ ).<sup>16</sup>



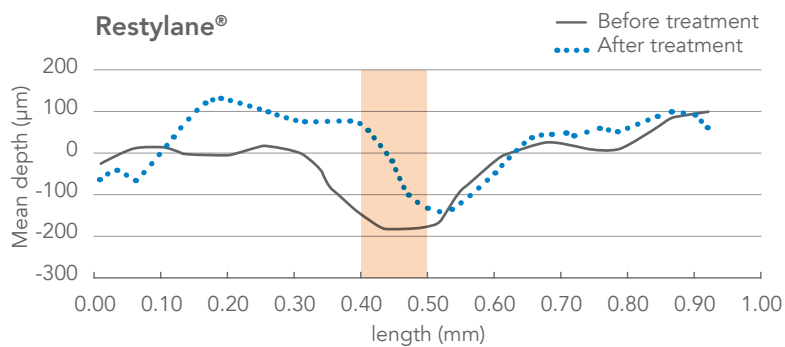
\*Evenness was measured by the mean residual depth of the nasolabial target area relative to the skin surface post treatment.

## Two-dimensional surface profiles before and 4 weeks after treatment



The total waviness of the nasolabial target area, i.e. depth and evenness was measured from the surface of the skin. Positive figures implied "bumps" in the skin and negative figures implied lines, wrinkles and folds in the skin.

At week 4, the Belotero® treatment achieved a reduction of 109.5 µm (from 248.8 µm to 139.4 µm) in the mean depth of the nasolabial fold, compared to a reduction of 71.8 µm in the Restylane® treated side.



<sup>16</sup> Prager W, Steinkraus V. A prospective, rater-blind, randomized comparison of the effectiveness and tolerability of Belotero Basic versus Restylane for correction of nasolabial folds. Eur J Dermatol 2010; 20 (6): 748-52.

## Belotero® Balance – Tried and tested

The safety of Belotero® Balance has been evaluated in 8 clinical studies<sup>17-24</sup>

In general the following were observed:

- Mild to moderate treatment-related adverse events
- No treatment-related serious adverse events
- Minimal inflammatory response
- Proven tolerability over 18 months
- Patient and physician satisfaction
- Long-term safety and patient satisfaction
- Belotero® is safe in Fitzpatrick skin types IV – VI<sup>21</sup>
- No reports of severe adverse events

### Tolerability over 18 months<sup>23</sup>

In a long-term open-label extension study for correction of nasolabial folds, Belotero® was well tolerated when repeat injections were given over an 18-month follow-up period.

Injection site bruising was the only adverse event that was considered to be related to Belotero®.

### Patients and physicians are satisfied with Belotero®<sup>17</sup>

A clinical study in 114 patients with nasolabial folds demonstrated that 81 % of patients were treated successfully for 24 weeks with the effect persisting for 36 weeks in 66% of the patients.

There was good or very good tolerability in 109 out of the 114 patients.

98% of all patients and 90% of the examiners rated the treatment success as good or very good.

<sup>17</sup> Reinmüller J et al, Dermatol News 2007; issue 11: 2-3.

<sup>18</sup> Taufig AZ, et al, J Ästhetische Chirurgie 2009; 2: 29-36.

<sup>19</sup> Prager W et al, Dermatol Surg 2012;38:1143-1150.

<sup>20</sup> Micheels P, J of cosm surg & med, VOL 4, No. 3 2009.

<sup>21</sup> Downie JP et al, Plast Reconstr Surg, 132; 41S; Oct, Suppl 2013.

<sup>22</sup> Narins RS et al, Dermatol Surg, 2010;36:730-740.

<sup>23</sup> Narins RS et al, Dermatol Surg, 2010; 36:1800-1808.

<sup>24</sup> Kühne U et al, J Drugs Dermatol 2012;11:1032-1035.

# Predictable results with Belotero® Balance\*

Nasolabial wrinkle



Before

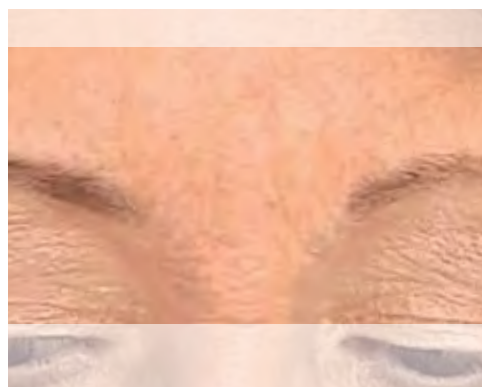


After

Glabella wrinkle



Before



After

Nasolabial wrinkle



Before



After

\* Courtesy of Dres Imhof/Kühne

## Predictable results with Belotero® Balance

Nasolabial wrinkle \*1



Before



After

Nasolabial wrinkle \*2



Before



After

\*1 Courtesy of Dr Reinmüller  
\*2 Courtesy of Merz Pharma UK Ltd.

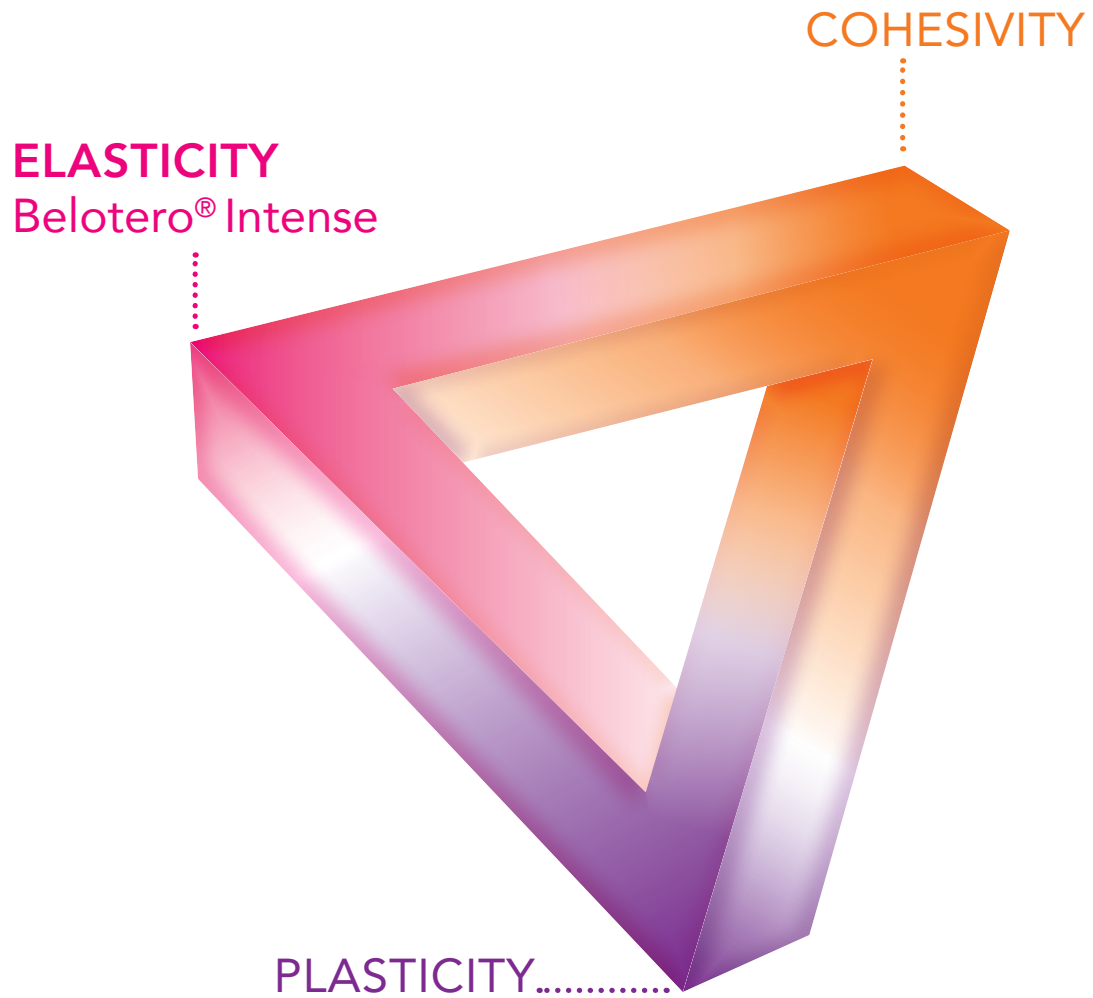
# Belotero® Intense



INTENSE

## Belotero® Intense\* offers effective filling capacity and natural looking results due to balanced elasticity

Finding the right elasticity to suit your patients' needs and expectations is a matter of balance in order to provide optimal skin support.



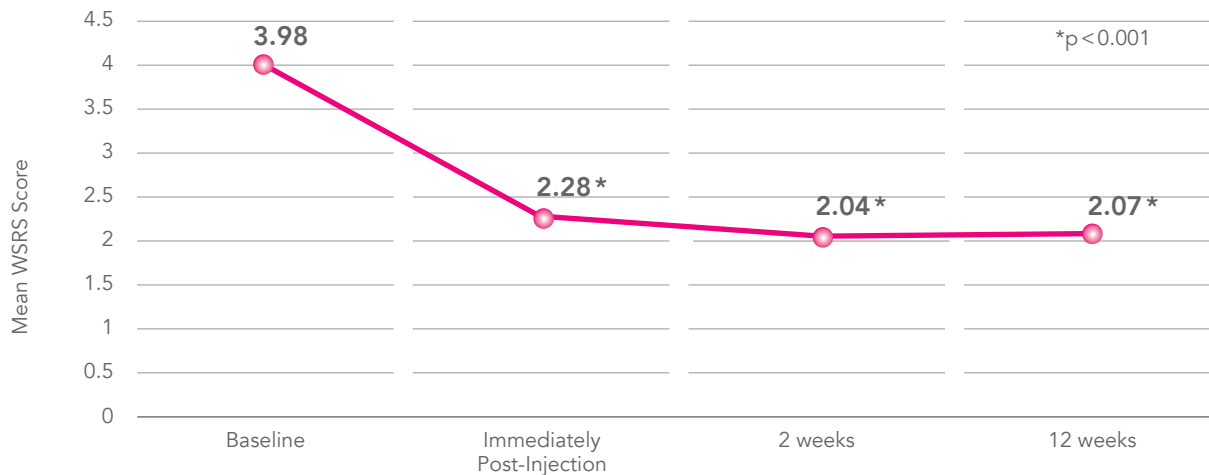
Belotero® Intense provides optimal filling capacity for predictable, natural looking results whilst maintaining excellent tissue integration to minimise lumps and bumps.

\* Belotero® Intense is equivalent to Fortélis® Extra, a registered trademark by Anteis S.A.

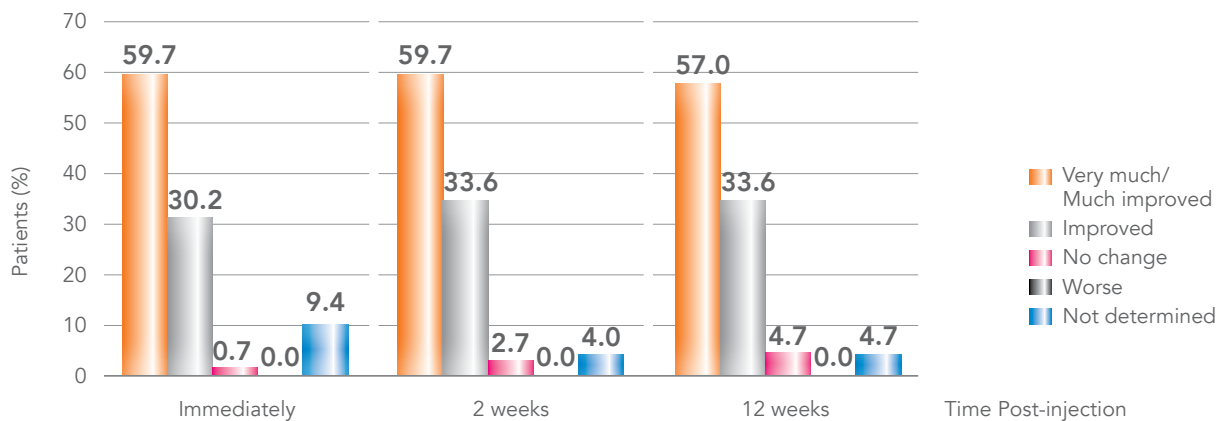
**BELOTERO® INTENSE**

## Efficacy was demonstrated in a study of 149 patients to assess the efficacy and safety of Belotero® Intense<sup>25</sup>

Mean WSRS improved significantly by 1.9 score points without any decline throughout the 12-week period.



89.9% of patients achieved improvement on the Investigator assessed Global Aesthetic Improvement Scale immediately after injection. The aesthetic effect was well maintained throughout the 3-month evaluation period.



Adverse events were localised to the injection area and occurred in 85.9% of patients immediately after injection and declined to 12.8% in week 2. None were serious.

<sup>25</sup> Pavicic T. Efficacy and Tolerability of a New Monophasic, Double-Crosslinked Hyaluronic Acid Filler for Correction of Deep Lines and Wrinkles. Journal of Drugs in Dermatology. 2011. 10(2); 134-139.

## Belotero® Intense provides lasting results and high patient satisfaction without producing lumps<sup>26</sup>

A double-blind, half-side comparison study of 20 patients with symmetric nasolabial folds who were randomised to contralateral treatment with Belotero® Intense and a biphasic HA filler (NASHA). Efficacy was assessed at baseline and after 2, 24, and 48 weeks using a wrinkle severity rating scale, subject questionnaire, and biophysical in vivo methods.

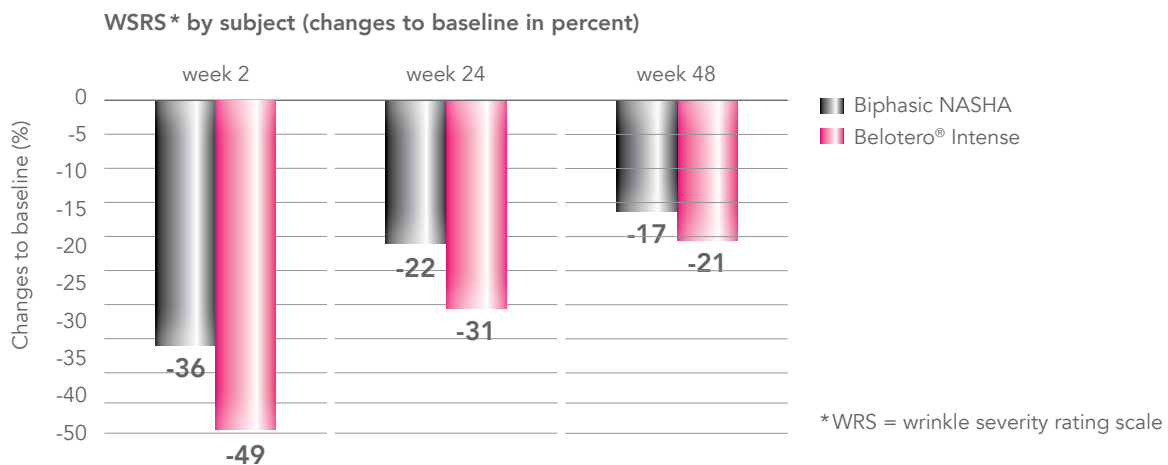
### Lasting results

All subjects showed significant improvements with both fillers up to day 365.

### Patient satisfaction

At week 24, improvement of patient satisfaction was significantly greater with Belotero® Intense,  $p < 0.001$ ; NASHA,  $p = 0.006$ ).

24 and 48 weeks after initial injection, significantly more subjects treated with Belotero® Intense judged themselves as satisfied compared with NASHA (24 weeks:  $p = 0.002$ ; 48 weeks:  $p = 0.005$ ).



After 48 weeks patient satisfaction with Belotero® Intense was significantly greater than at baseline but satisfaction on the NASHA had returned to baseline value.

Subject questionnaire confirmed that 80% of subjects treated with Belotero® Intense and 65% of subjects injected with NASHA filler stated that their expectations were met and that they would repeat the treatment course.

“These results may be due to the unique structure of Belotero® Intense which allows it to spread more regularly and fill the dermal volume defect more evenly than the biphasic product.”

<sup>26</sup> Buntrock H, Reuther T, Prager W, Kerscher M. Efficacy, safety, and patient satisfaction of a monophasic cohesive polydensified matrix versus a biphasic nonanimal stabilized hyaluronic acid filler after single injection in nasolabial folds. *Dermatol Surg.* 2013; 39(7):1097-105.

# Minimal risk of local inflammatory reaction with Belotero® Intense compared to others<sup>27</sup>

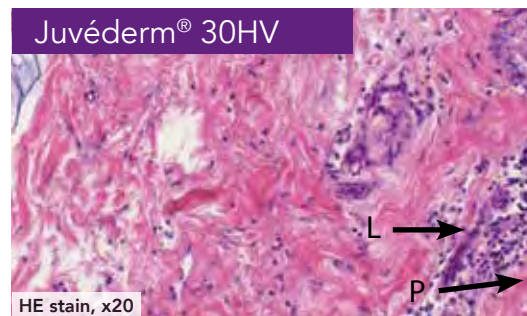
A study to assess the safety criteria of aesthetic filler materials by investigating intradermal reactions after implantation of 0.2 ml dermal filler in mapped abdominal skin areas showed no abnormality and no significant local inflammatory reaction after Belotero® injection.

## Histological slides 30 days after injection

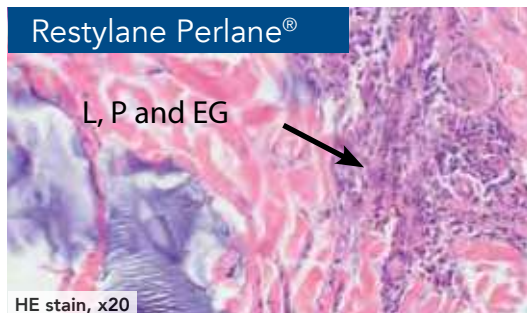
Lymphocytes (L)  
Plasma cells (P)  
Eosinophil granulocytes (EG)



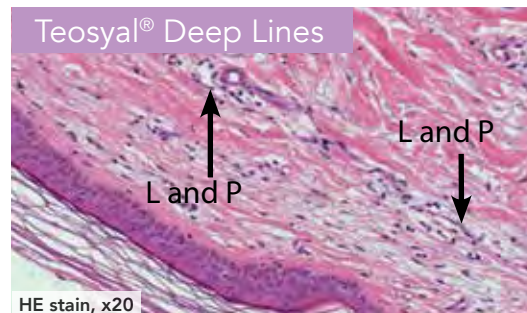
- No histomorphological inflammation reaction
- Even distribution of injection material



- Light to moderate chronic inflammation
- Increased lymphocytes, plasma cells, and eosinophil granulocytes
- Irregular distribution of injection material



- Intense chronic inflammation
- Heavy infiltration of lymphocytes, plasma cells, and eosinophil granulocytes
- Irregular distribution of injection material



- Intense chronic inflammation
- Irregular infiltration of lymphocytes and plasma cells

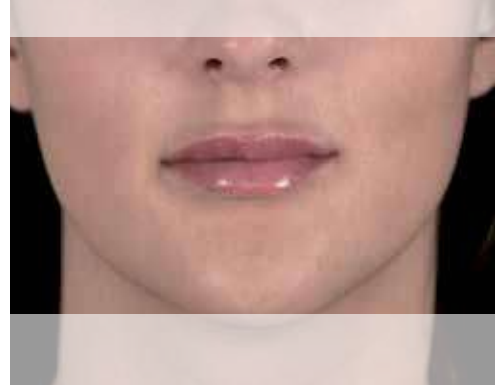
<sup>27</sup> Taufig A, et al., A new strategy to detect intradermal reactions after injection of resorbable dermal fillers. J Ästhetische Chirurgie 2009; 2: 29-36.

# Predictable results with Belotero® Intense\*

## Lip augmentation



Before



After

## Face contours, nasolabial folds and lip enhancement



Before



After

## Nasolabial folds and lip enhancement



Before



After

\* Courtesy of Dr Micheels

**BELOTERO® INTENSE**



OPTIMAL  
MODELLING  
CAPACITY

Belotero<sup>®</sup>  
Volume

VOLUME

# Belotero® Volume\* models and restores facial volumes due to its tailored plasticity



The intelligent and well-balanced design offers 3 advantages:

**Excellent malleability** to model and shape as desired maintaining a natural look



**Powerful volumising effect** for reliable and predictable results:

100 % of practitioners considered Belotero® Volume as superior or equivalent to competitors<sup>28</sup>

**High plasticity** facilitates easy placement of the gel after injection.

Very **low ejection force** that gives you the respective freedom to operate<sup>29</sup>

|                                   | Ejection force (N) 25G1 Terumo needle** | Ejection force (N) 22G 50 mm Softfil cannula** |
|-----------------------------------|---|--|
| Belotero® Volume (25G1, 22G 50mm) | 24.0                                    | 21.8   |
| Juvéderm Voluma (23G1", 18G 70mm) | 50.6                                    | 42.9   |
| Restylane Sub-Q (21G)             | 37.1                                    | 30.6   |

\* Belotero® Volume is equivalent to Modélis®Shape, a registered trademark bei Anteis S.A.

\*\* 1 ml of product was injected with the 25G1 Terumo needle and 1 ml with the 22G 50mm Softfil cannula.

<sup>28</sup> Clinical Evaluation Report VP1-1001: An open label and multi-centre clinical evaluation assessing the efficacy and safety of Modélis in facial depressions (9 injectors from France, Switzerland, Thailand, Germany and Belgium), February 2012.

<sup>29</sup> Data on file, Belotero® Volume US product information page 6.

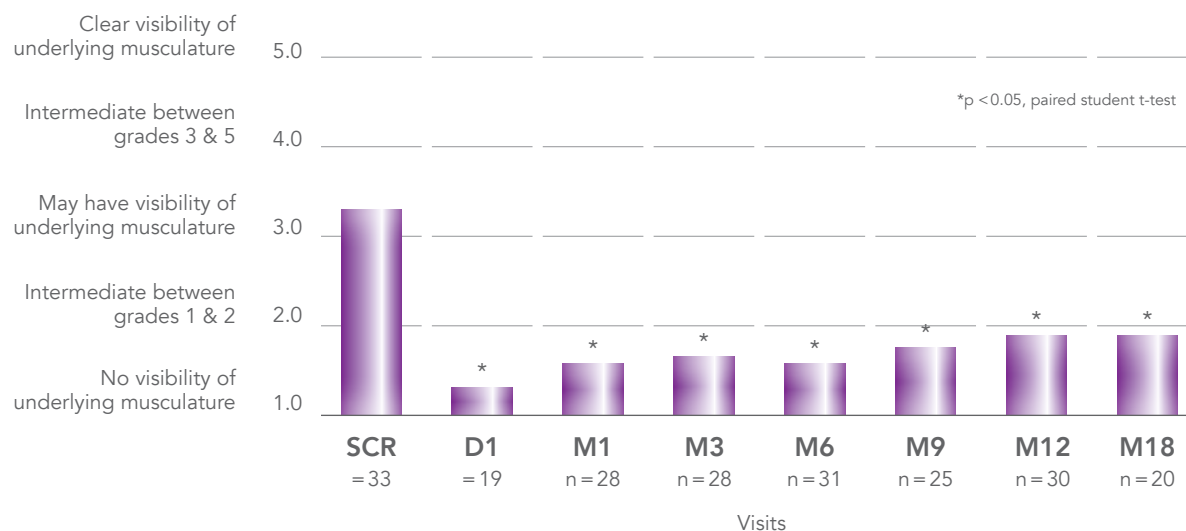
## BELOTERO® VOLUME

# Clinically proven efficacy and safety with high patient satisfaction

In a post-marketing clinical follow-up of 33 patients to assess the efficacy and safety of Belotero® Volume (2ml syringe) in the treatment of volume loss over 18 months after injection, the mean face volume loss score (FVLS) at each follow-up visit was significantly lower than mean FVLS baseline score.<sup>30</sup>

Although there was a slight increase in FVLS over time, the effectiveness of Belotero® Volume was still significant at month 12 and month 18.

## Facial volume score



At month 12 and month 18, the mean Global Aesthetic Improvement Scale score is still “Much improved”, supporting the FVLS results.

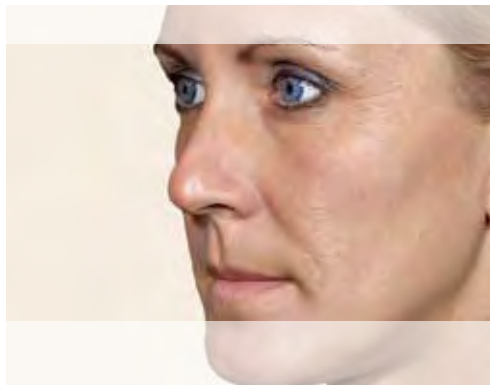
13 patients experienced at least one injection site reaction during the evaluation. Main site reactions were redness and pain of mild intensity which disappeared before the next follow-up visit.

Most patients [93 % (n=28) at month 12 and 90 % (n=18) at month 18] were satisfied with their results and were intending to repeat the treatment and recommend it to their friends.

\* SCR=screening visit, corresponds to D1 before injection  
<sup>30</sup> Data on file. Clinical Evaluation Report. Section VI

# Predictable results with Belotero® Volume\*

## Cheekbones

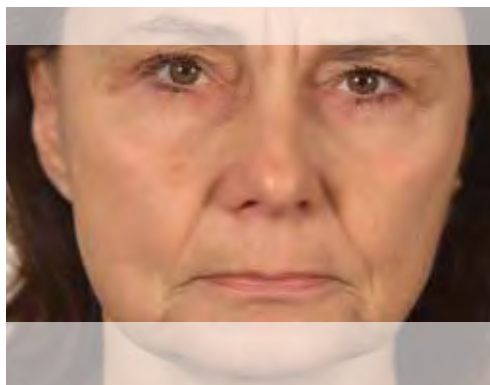


Before



After

## Cheekbones



Before



After

## Temples



Before



After



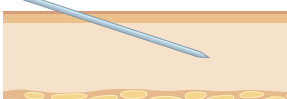
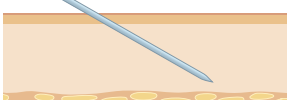
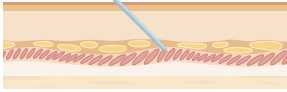
\* Courtesy of Dr Vandeputte





## The Belotero® family – It's a part of you



| Belotero® product | Indications  | HA concentration | Needle size                                 | Injection site and angle   |
|-------------------|--|------------------|---|--|
| <b>HYDRO</b>      | Skin rehydration, e.g.: face, neck, décolletage, back of hands   | 18 mg/1ml        | 30G   | Dermal/epidermal junction (nappage technique) or superficial dermis (micro-papular technique)<br> |
| <b>SOFT</b>       | Correction of fine lines, e.g.: crow's feet, perioral lines, fine forehead lines   | 20 mg/1ml        | 30G   | Superficial dermis<br>Approx 10°<br>  |
| <b>BALANCE</b>    | Correction of moderate lines, e.g.: moderate nasolabial wrinkle, glabellar lines, moderate perioral wrinkles, lip contouring, philtrum | 22.5 mg/1ml      | 27 G  | Superficial to mid dermis<br>Approx 15°<br>   |
| <b>INTENSE</b>    | Correction of deeper lines, e.g.: severe nasolabial fold, lip volume, oral commissures, marionette folds                               | 25.5 mg/1ml      | 27 G  | Mid and deep dermis<br>Approx 30°<br>   |
| <b>VOLUME</b>     | Restoration of facial volumes, e.g.: cheeks, temples, facial volume loss   | 26 mg/1ml        | 30 G +<br>27 G<br>Needle<br>27 G<br>Cannula | Deep dermis,<br>subcutaneously<br>  |

# MERZ AESTHETICS



Belotero® is a registered trademark of Merz Pharma GmbH & Co. KGaA.  
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