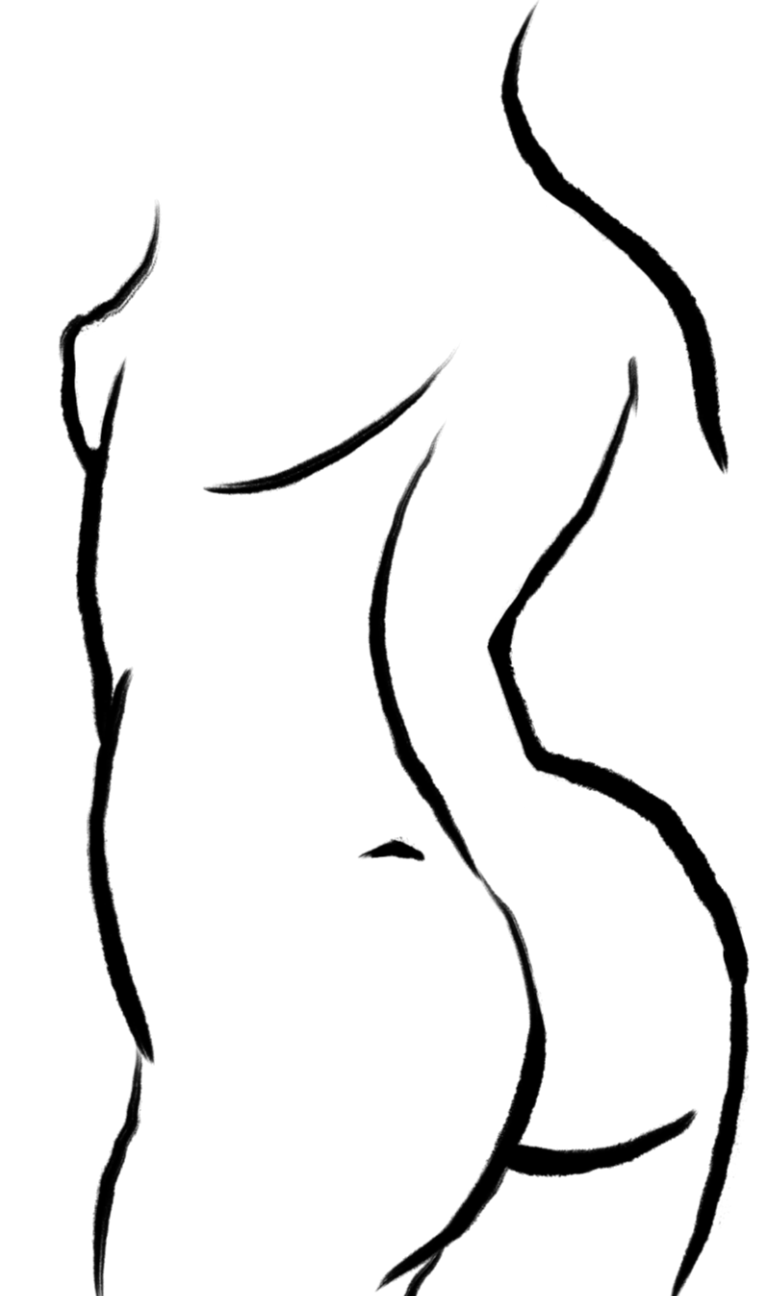


An abstract black line drawing of a human figure, possibly a woman, in profile, facing right. The lines are thick and expressive, capturing the essence of the body's form without fine detail. The figure is positioned on the left side of the slide.

# EIKONHA<sup>®</sup>

Architectural Reshaping of Body

## Contents

- 1 What is Eikonha?
- 2 Composition and Mode of Action
- 3 EIM Technology
- 4 Indications
- 5 Essential Anatomy for Body Augmentation
- 6 Planning, Preparation and Post-care
- 7 Contraindications and Adverse Events
- 8 Quiz



# What are Body Fillers?

- ▶ A Body filler is a Biocompatible product that is injected in the body to correct the deformities or augment the body part
- ▶ Cosmetic body-shaping procedures can be categorized into those that remove tissue and those that add volume.
- ▶ Body fillers are designed / produced for filling large areas

## Ideal Properties

- Biocompatible & Biodegradable
- Non-antigenic
- Non-pyrogenic
- Non-inflammatory
- Non-toxic
- Non-animal
- Stable after injection
- Non-migratory
- Long-lasting but resorbable
- Natural looking
- Cost-effective
- Ease of learning how to inject
- Easy to inject
- Easy to store



# Types of Fillers

Fillers can be classified based on different category

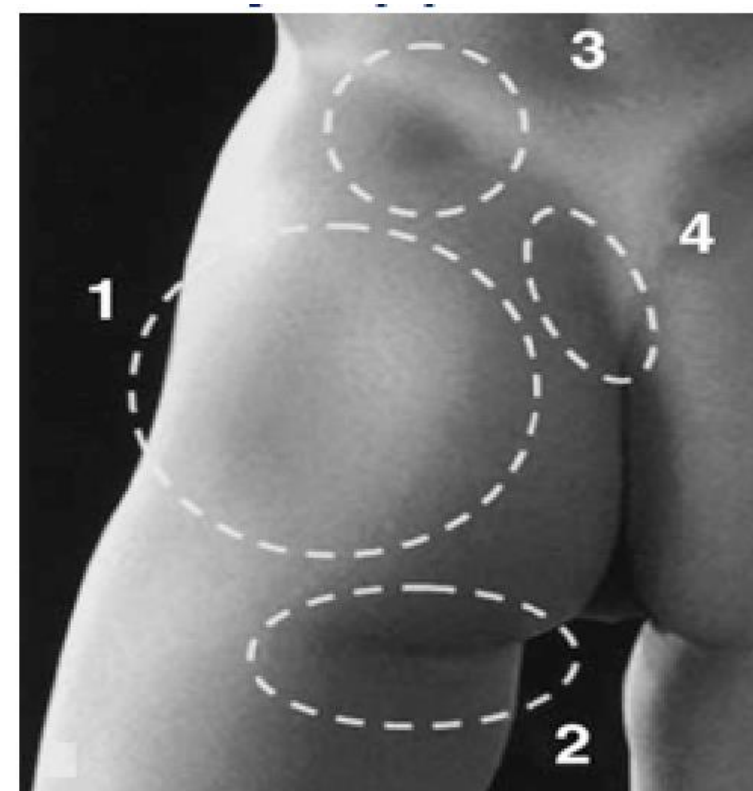
1. **Based on longevity:** Temporary, semi-permanent and permanent fillers
2. **Based on site of placement:** Dermal, Subdermal and Supraperiosteal
3. **Based on origin of filler material:** Heterograft, Allograft, Autograft, Synthetic materials

# Essential Anatomy for Body Augmentation



# Components of Beautiful Buttocks

1. **Lateral depression:** a hollow on the lateral aspect of each buttock formed in its deepest point by the greater trochanter.
2. **Infragluteal fold:** a horizontal crease arising from the median gluteal crease and runs laterally under the ischial tuberosity with a slight upward concavity.
3. **Supragluteal fossettes:** two hollows located on either side of the medial sacral crest. They are formed by the posterior superior iliac spine and medially by the multifidus muscle.
4. **V-shaped crease:** two lines arising in the upper portion of the gluteal crease toward the supragluteal fossettes.



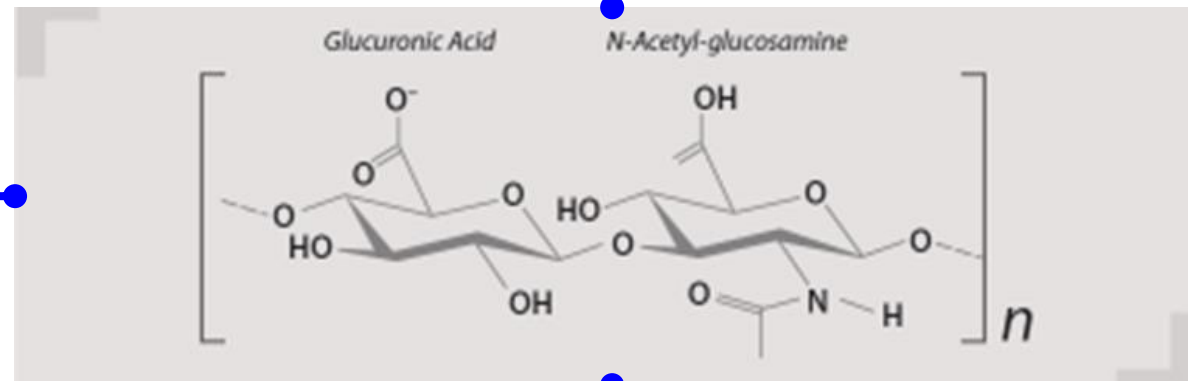
# Composition and Mode of Action



# ABOUT HYALURONIC ACID

Essential constituent of Extra  
Cellular Matrix (ECM)

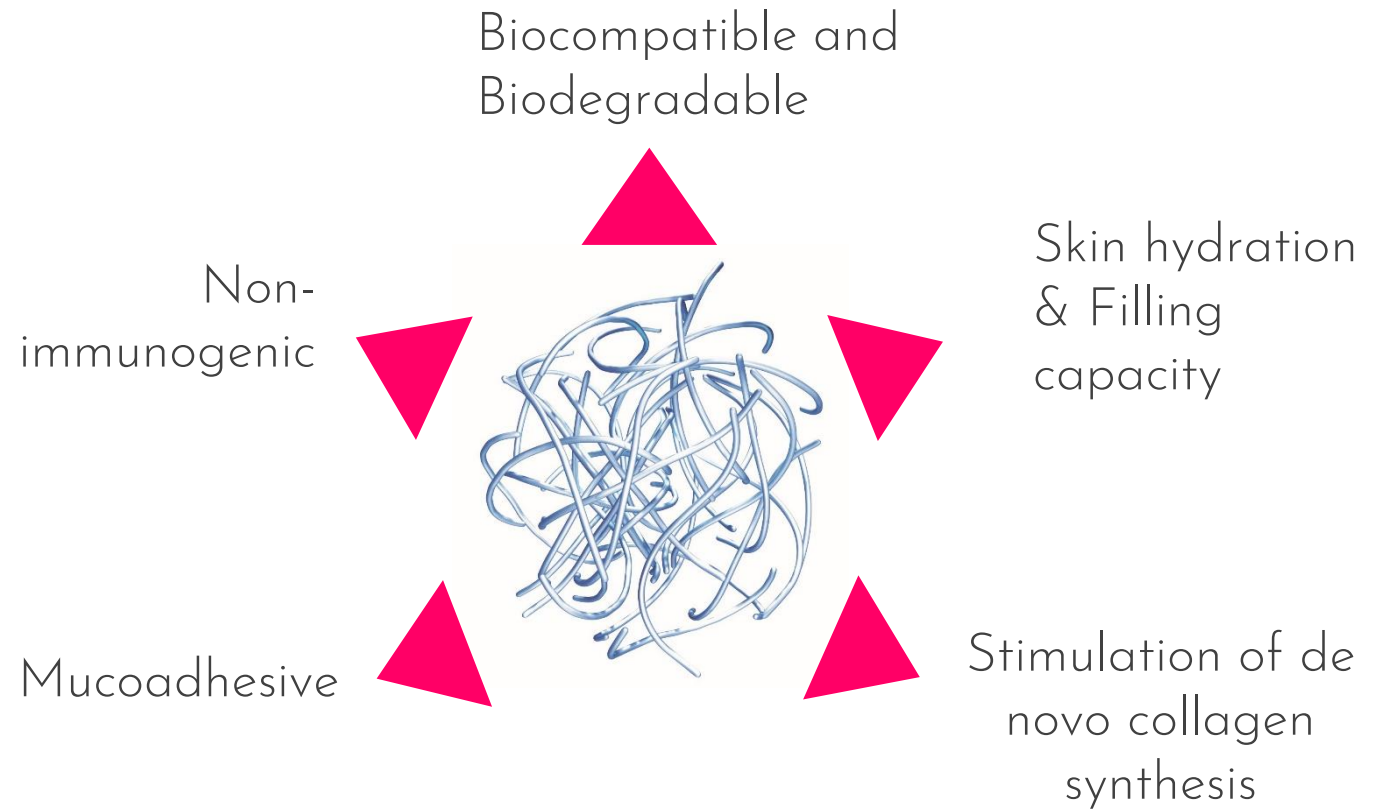
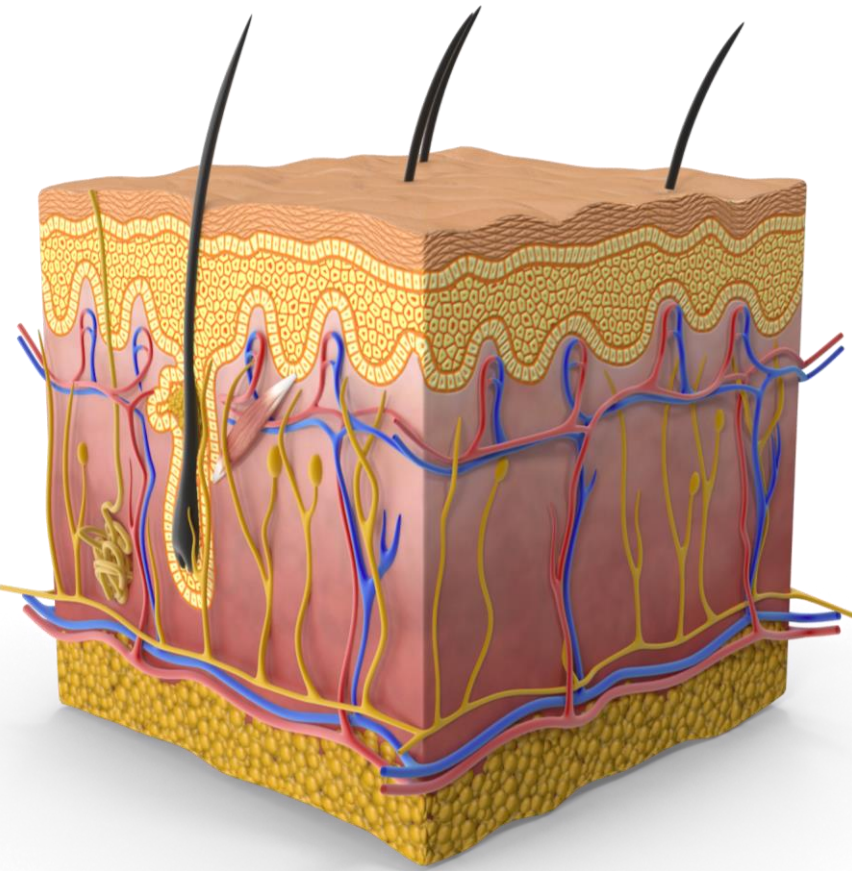
Vital component



The largest quantity resides in the skin  
(epidermis & dermis)

An abundant and  
ubiquitous substance in  
human body

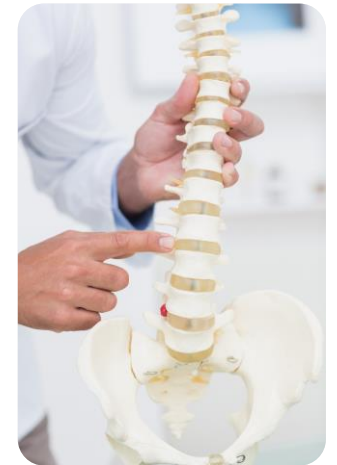
## PROPERTIES OF HYALURONIC ACID



# SAFETY OF HYALURONIC ACID

▶ Long-term use/knowledge and various applications.

| Area         | Application                     | Example                     |
|--------------|---------------------------------|-----------------------------|
| Biomedical   | Othopedic surgery               | Arthritis                   |
|              | Rheumatology                    | Osteoarthritis              |
|              | Ophthalmology                   | Eye surgery                 |
|              | Otolaryngology                  | Treatment of the vocal fold |
|              | Dermatology and plastic surgery | Dermal filler               |
|              | Wound healing and dressing      | Diabetic ulcer, skin burns  |
|              | Tissue engineering              |                             |
| Pharmacology | Drug delivery                   |                             |



## SAFETY OF HYALURONIC ACID

- The toxicity data have been described in a safety assessment report by a panel of experts and such reports include use in 223 products.
- Its safety is supported by the large amount of use worldwide.

▶ Free of significant adverse reactions

▶ Non-genotoxic

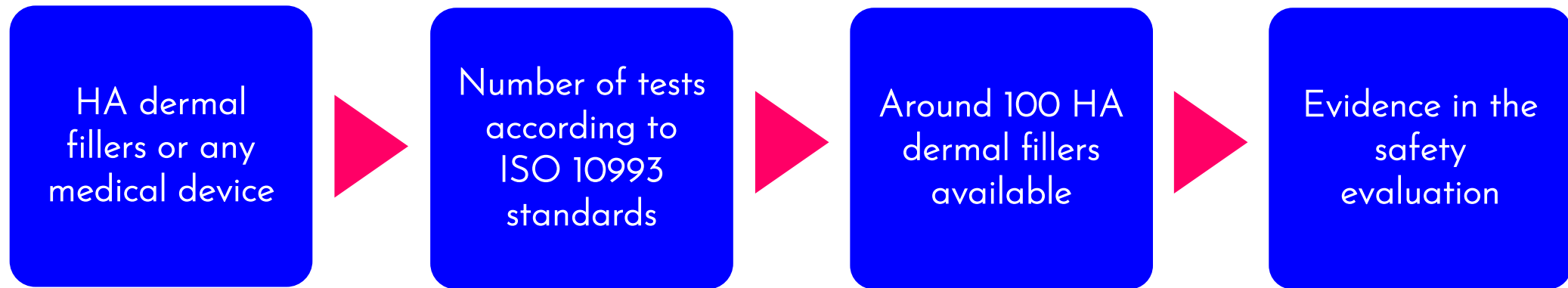
▶ Non-immunogenic

▶ Non-sensitizing

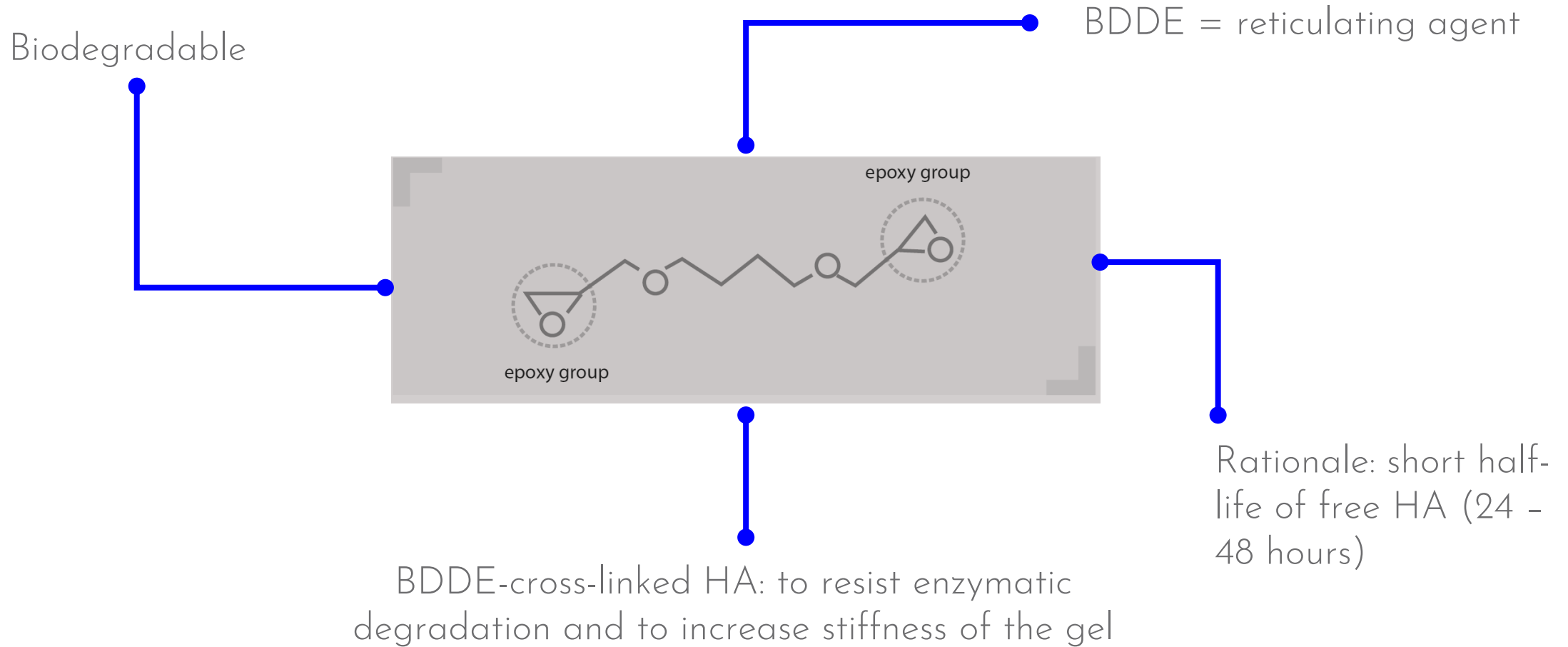


## SAFETY OF HYALURONIC ACID

▶ CE mark and registration approvals worldwide.



## ABOUT BDDE



## SAFETY OF BDDE



BDDE is biodegradable and its safety has been extensively studied through BDDE containing products and HA's in particular.

- BDDE degraded via hydrolysis in 1,4-butanediol and glycerol
- Toxicity presented in different registries
- 1,4-butanediol : non mutagenic, non sensitizing, non-carcinogenic
- Glycerol : classified as GRAS (generally recognized as safe substance) by FDA

# EIKONHA



[www.eikonha.com](http://www.eikonha.com)

# What is Eikonha?

Eikonha is next generation cross linked hyaluronic acid based dermal filler designed for architectural reshaping of body, based on *Enhanced Interlinked 3D Matrix (EIM)* technology which allows easy to inject, natural looking and long-lasting effect.



AK Pharma Inc. Miami,  
Florida, USA



CE Marked



Listed in 2020



Approved in the UAE 2020

# Certification – Homologation: AK Pharma Inc

- Since 2018: Certified ISO 13485:2016 Medical devices- Quality Management System
- Since 2018: ISO 9001:2016- Quality Management System
- Since 2018: cGMP certified
- Since 2020: FDA Registration



# Certification – Homologation: Eikonha



FDA

[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

**Establishment Registration & Device Listing**  
New Search [Back To Search Results](#)

Proprietary Name: Eikonha  
Classification Name: IMPLANT, DERMAL, FOR AESTHETIC USE  
Product Code: LMH<sup>6</sup>  
Device Class: 3  
Registered Establishment Name: [AK PHARMA, INC.](#)<sup>7</sup>  
Registered Establishment Number: 3017155434  
Owner/Operator: [AK Pharma, Inc.](#)<sup>8</sup>  
Owner/Operator Number: 10055276  
Establishment Operations: U.S. Manufacturer of Export Only Devices



**CERTIFICATE OF VERIFICATION**  
CE- Statement of Verification  
EC Design Examination Certificate

This is to certify that

**AK Pharma Inc.**  
9100 S. Dixie Blvd. Suite 100, Fort Lauderdale, Florida 33309, United States of America

Has been assessed with respect to  
Examination of the Product design as described in Annex I section 4  
Complies with the CE Marking Directive (CEC) or Medical Device as presented  
and has been found to comply therewith. Details of the Product in Annexure I attached.

Brand Name: EIKONHA  
Design, Manufacture and Distribution of EIKONHA -  
Medical Cross-linked Sodium Hyaluronate Gel - Soft Tissue Filler Product Ranges.  
Certified By: A DNY OL & NEMKO COMPANY  
CE Certificate No: 1005-2017-CE-ACC-AK-PH-01

Annexure I

| S.No | Brand         | Product Code | Medical Device Class | Product Description                                                                                |
|------|---------------|--------------|----------------------|----------------------------------------------------------------------------------------------------|
| 1    | Eikonha 10 ml | ADP001       | Class II             | Soft tissue filler gel with 10% concentration of cross-linked Sodium Hyaluronate (S-CLH) in water. |
| 2    | Eikonha 20 ml | ADP002       | Class II             | Soft tissue filler gel with 20% concentration of cross-linked Sodium Hyaluronate (S-CLH) in water. |
| 3    | Eikonha 30 ml | ADP003       | Class II             | Soft tissue filler gel with 30% concentration of cross-linked Sodium Hyaluronate (S-CLH) in water. |
| 4    | Eikonha 40 ml | ADP004       | Class II             | Soft tissue filler gel with 40% concentration of cross-linked Sodium Hyaluronate (S-CLH) in water. |
| 5    | Eikonha 50 ml | ADP005       | Class II             | Soft tissue filler gel with 50% concentration of cross-linked Sodium Hyaluronate (S-CLH) in water. |

**CERTIFICATE OF VERIFICATION**  
ANNEXURE - I  
EC Design Examination Certificate

| S.No | Brand         | Product Code | Medical Device Class | Product Description                                                                                |
|------|---------------|--------------|----------------------|----------------------------------------------------------------------------------------------------|
| 1    | Eikonha 10 ml | ADP001       | Class II             | Soft tissue filler gel with 10% concentration of cross-linked Sodium Hyaluronate (S-CLH) in water. |
| 2    | Eikonha 20 ml | ADP002       | Class II             | Soft tissue filler gel with 20% concentration of cross-linked Sodium Hyaluronate (S-CLH) in water. |
| 3    | Eikonha 30 ml | ADP003       | Class II             | Soft tissue filler gel with 30% concentration of cross-linked Sodium Hyaluronate (S-CLH) in water. |
| 4    | Eikonha 40 ml | ADP004       | Class II             | Soft tissue filler gel with 40% concentration of cross-linked Sodium Hyaluronate (S-CLH) in water. |
| 5    | Eikonha 50 ml | ADP005       | Class II             | Soft tissue filler gel with 50% concentration of cross-linked Sodium Hyaluronate (S-CLH) in water. |

**CERTIFICATE OF VERIFICATION**  
CE- Statement of Verification  
Full Quality Assurance

This is to certify that

**AK Pharma Inc.**  
9100 S. Dixie Blvd. Suite 100, Fort Lauderdale, Florida 33309, United States of America

Has been assessed with respect to  
The conformity assessment procedures as described in Annex I 11.1 a and  
Annex I 11.2 of Council Directive (CEC) or Medical Device as presented  
and has been found to comply therewith. Details of the Product in Annexure I attached.

Brand Name: EIKONHA  
Design, Manufacture and Distribution of EIKONHA -  
Medical Cross-linked Sodium Hyaluronate Gel - Soft Tissue Filler Product Ranges.  
Certified By: A DNY OL & NEMKO COMPANY  
CE Certificate No: 1005-2017-CE-ACC-AK-PH-02

**CERTIFICATE OF VERIFICATION**  
ANNEXURE - I  
EC Certificate Full Quality Assurance

| S.No | Brand         | Product Code | Medical Device Class | Product Description                                                                                |
|------|---------------|--------------|----------------------|----------------------------------------------------------------------------------------------------|
| 1    | Eikonha 10 ml | ADP001       | Class II             | Soft tissue filler gel with 10% concentration of cross-linked Sodium Hyaluronate (S-CLH) in water. |
| 2    | Eikonha 20 ml | ADP002       | Class II             | Soft tissue filler gel with 20% concentration of cross-linked Sodium Hyaluronate (S-CLH) in water. |
| 3    | Eikonha 30 ml | ADP003       | Class II             | Soft tissue filler gel with 30% concentration of cross-linked Sodium Hyaluronate (S-CLH) in water. |
| 4    | Eikonha 40 ml | ADP004       | Class II             | Soft tissue filler gel with 40% concentration of cross-linked Sodium Hyaluronate (S-CLH) in water. |
| 5    | Eikonha 50 ml | ADP005       | Class II             | Soft tissue filler gel with 50% concentration of cross-linked Sodium Hyaluronate (S-CLH) in water. |

**UNITED ARAB EMIRATES**  
MINISTRY OF HEALTH & PREVENTION  
الجمهورية العربية المتحدة  
وزارة الصحة والوقاية

**PRODUCT REGISTRATION CERTIFICATE**  
Form No: 1005  
Medical Devices for Humans - Class 4

This is to certify that the following product has been assessed by the concerned committee and approved for registration in the Ministry of Health.

| Registration No. | Product Name | Manufacturer   | Class    |
|------------------|--------------|----------------|----------|
| 4488-155-1515    | EIKONHA 10ml | AK PHARMA INC. | Class II |
| 4488-155-1515    | EIKONHA 20ml | AK PHARMA INC. | Class II |
| 4488-155-1515    | EIKONHA 30ml | AK PHARMA INC. | Class II |
| 4488-155-1515    | EIKONHA 40ml | AK PHARMA INC. | Class II |
| 4488-155-1515    | EIKONHA 50ml | AK PHARMA INC. | Class II |

**GOVERNMENT OF PAKISTAN**  
Ministry of National Health Services  
Regulations & Coordination  
Drug Regulatory Authority of Pakistan

**CERTIFICATE OF ENLISTMENT, OR REGISTRATION OF A MEDICAL DEVICE OR ACCESSORY OR COMPONENT FOR IMPORT**  
Form No: 1005

This medical device is per details given below has been registered or enlisted under the DROF Act, 2012 and the rules made thereunder subject to the conditions appearing hereunder.

| Enlistment/Registration No. | Name of medical device or accessory or component    | Brand description                                                                                                                                                                                                          | Class | Shelf life |
|-----------------------------|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|------------|
| (01)                        | (02)                                                | (03)                                                                                                                                                                                                                       | (04)  | (05)       |
| MDR-2017-002                | Eikonha Cross-linked Sodium Hyaluronate (S-CLH) gel | Injectable Hyaluronic acid for cosmetic body shaping procedures. Areas for application include: Throat/Neck, Breast, Buttock, Vagina, Ankle/ankle, Eyelids, Chest shading, Body Depositions, Gluteal Shading augmentation. | C     | 36 Months  |

Concentration

20mg/ml

Volume

10ml & 20ml

Particle Size

0.5 – 1.25 mm

Duration

12 – 18 Months

# The EIM Technology

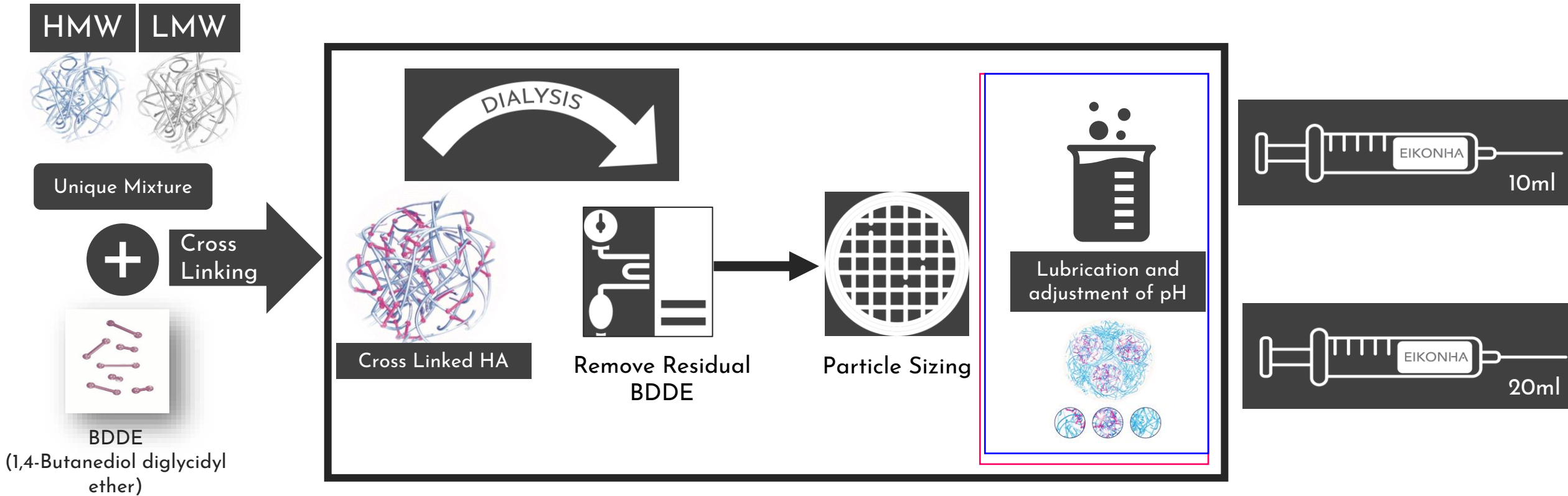
State of the Art Manufacturing Process

Enhanced Inter-linked 3D Matrix  
technology



# EIM Technology

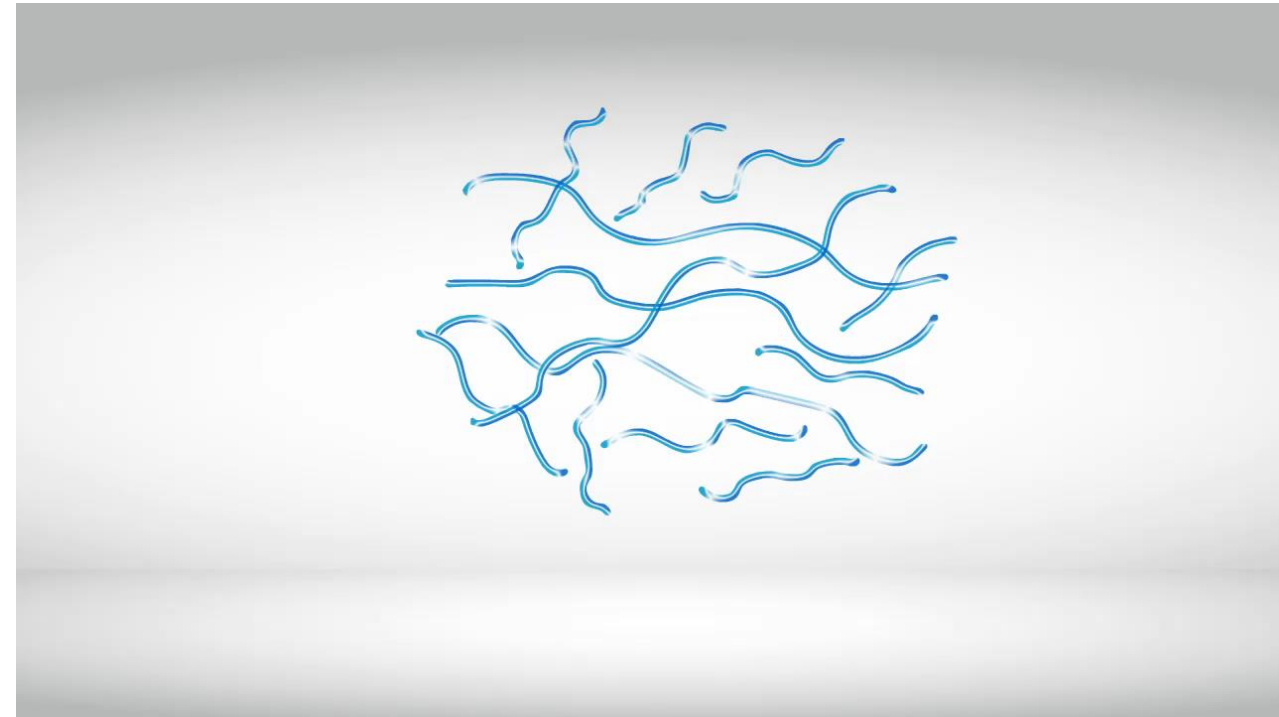
EIM (Enhanced Interlinked 3D Matrix) technology is a unique mixture of HMW and LMW Sodium Hyaluronate to have high covalent bonding among HA molecules in a polysaccharide chain.



# EIM Technology

EIM offers following benefits to EIKONHA gel:

- 3-D hydrophilic matrix network configuration which allows nutrition, oxygen and hormone to go through freely, and protect regular physiological functions of the tissue.
- Increase the surface area of HA gel
- Higher stability against natural degradation by hyaluronidase
- Good cohesivity of gel with desired syringeability
- Promising rheological properties (viscoelastic hydrated gel)





**Buttock Shaping**



**Concavities caused  
by liposuction**



**Calves**



**Reconstruction**



**Male chest Shaping**



**Body Depressions**



**Trauma/Surgical Scars**





## Breast Enhancement

- Off label since April 2012:
- Interferes with the mammogram
- Foggy images and can be difficult to analyze
- Interferes with the breast US-Scan- Cyst images with several eccos in the cyst ( looks like snowing)





# Volume Guidelines

| Indications                   | Suggested Volume for Injection                          |
|-------------------------------|---------------------------------------------------------|
| Calves Contouring             | 20-150 mL                                               |
| Buttock Shaping               | 250-350 mL                                              |
| Penile Enlargement            | For Penile girth: 18-20 mL ,    For Glans Penis: 2-3 mL |
| Depressions after Liposuction | 16-25 mL ** Depends on area to be Injected              |

# Safety Parameters: Eikonha

**<0.25  
UI/ml**

Low endotoxin level

Endotoxin level

**<2 µg/gm**  
Non-Detectable  
BDDE Residual  
content

BDDE

**<6 µg/ml**  
Low Protein load

Protein Load

# Physical Characteristics: Eikonha

**7.0-7.5**

pH

**570  
Pa.s**

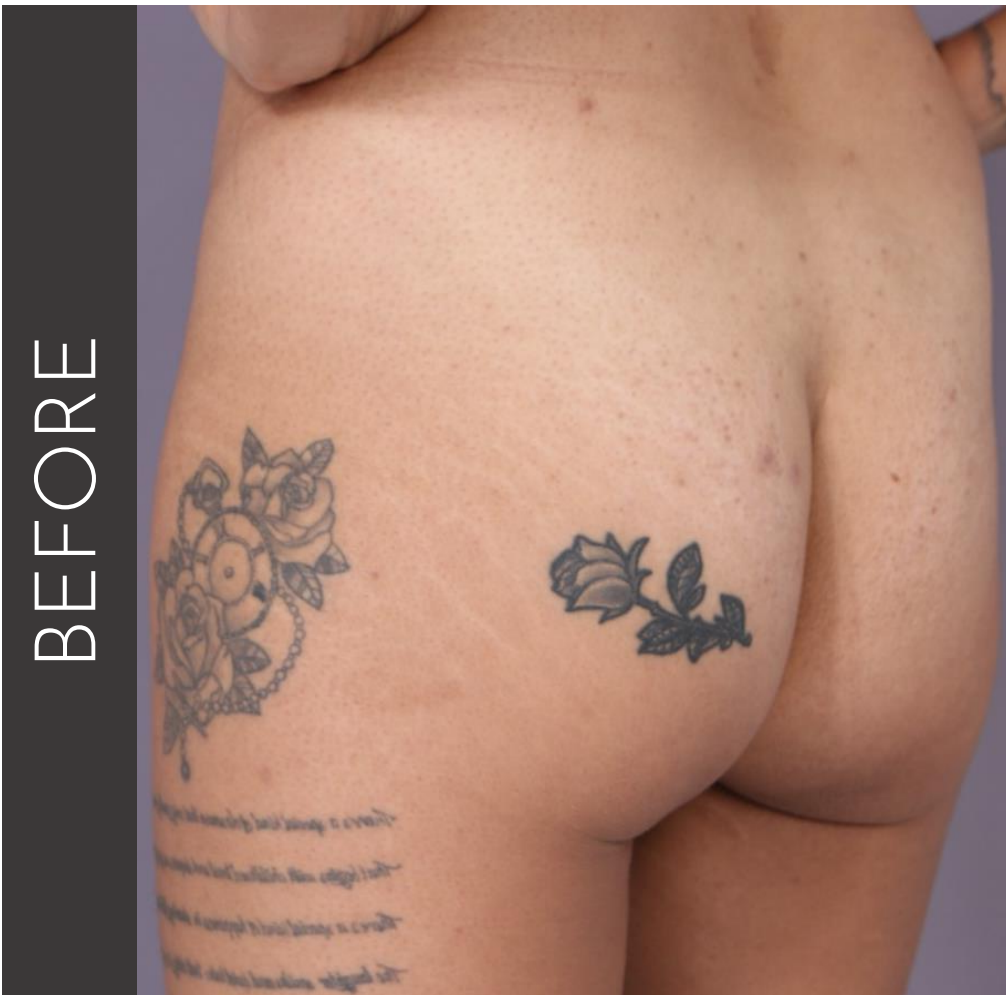
G'

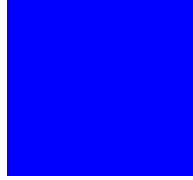
**20 N**

Extrusion Force



# Before and After





BEFORE



AFTER







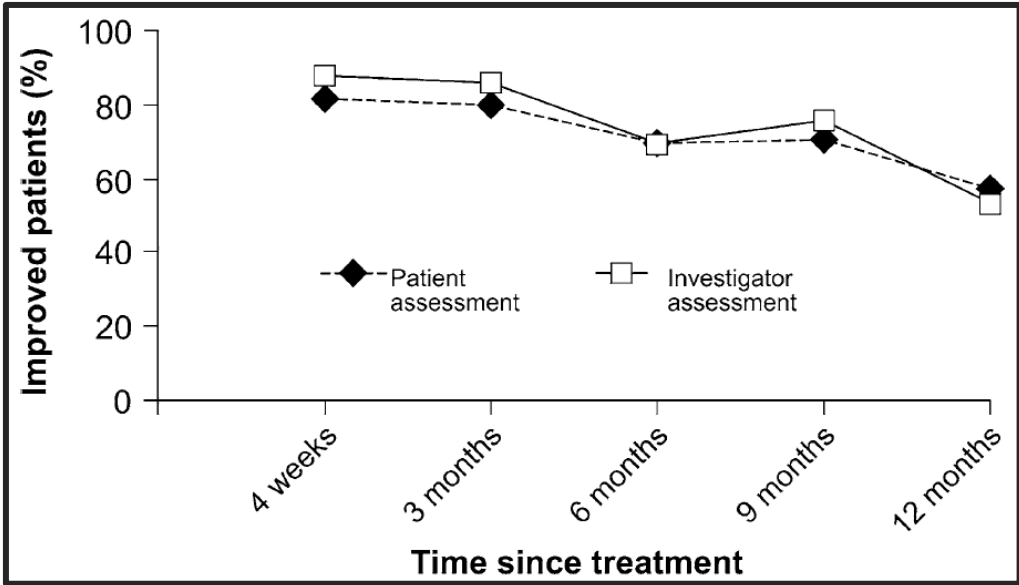






# Patient Satisfaction using HA Body Fillers

Improvement of body shape after hyaluronic acid (HA) injection, as assessed by the investigator and patients, using the Global Esthetic Improvement Scale (GEIS)



|                       | Time after HA injection | Proportion of patients (%) |                     |                    |
|-----------------------|-------------------------|----------------------------|---------------------|--------------------|
|                       |                         | Somewhat improved          | Moderately improved | Very much improved |
| Investigator-assessed | 4 weeks                 | 13.2                       | 24.5                | 49.1               |
|                       | 3 months                | 23.6                       | 36.4                | 25.5               |
|                       | 6 months                | 26.9                       | 26.9                | 15.4               |
|                       | 9 months                | 38.6                       | 25.0                | 11.4               |
|                       | 12 months               | 23.9                       | 23.9                | 4.3                |
| Patient-assessed      | 4 weeks                 | 20.8                       | 28.3                | 32.1               |
|                       | 3 months                | 29.1                       | 27.3                | 23.6               |
|                       | 6 months                | 38.5                       | 13.5                | 17.3               |
|                       | 9 months                | 38.6                       | 15.9                | 15.9               |
|                       | 12 months               | 28.3                       | 21.7                | 6.5                |

# Planning



# 3 Main Reasons - Buttock Augmentation

The main reasons why people request buttock augmentation are as follows:

1. To regain shape lost by weight loss or aging
2. To increase attractiveness and
3. To correct human immunodeficiency virus (HIV)-associated lipoatrophy

# Other Reasons - Buttock Augmentation

## **Genetic abnormality that may be one of the following:**

- Genetically absent or hypoplastic buttock
- Disproportionately large buttock
- Genetic lipodystrophies involving the gluteal region

## **Acquired abnormalities caused trauma**

- Motor vehicle accidents
- Post-tumor resection
- Animal bites
- Post-injection deformities caused by post-injection abscess or hematoma
- Depression induced by steroid injection

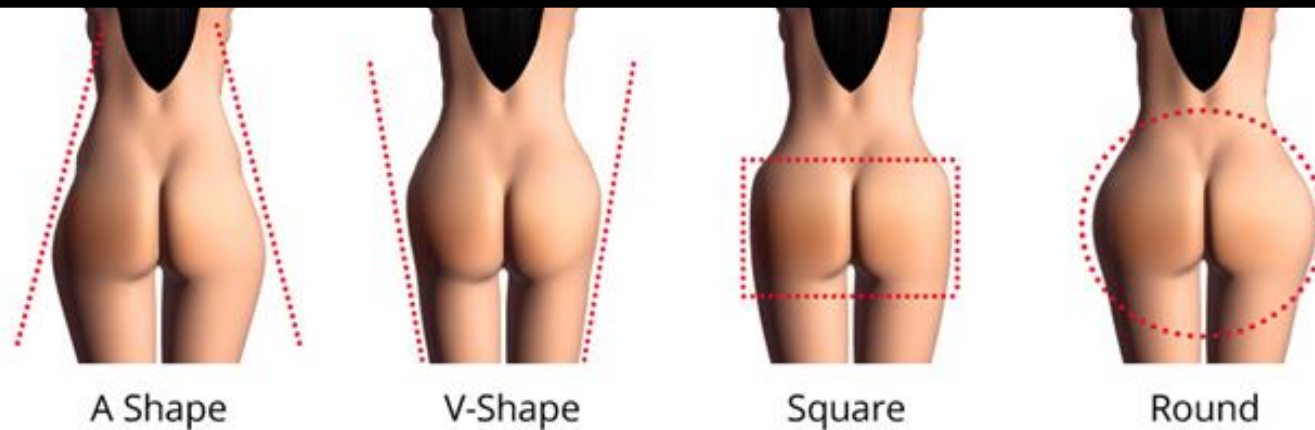
## **Acquired degenerative gluteal deformities caused by**

- Aging, sun damage and massive weight loss like post-bariatric (skin laxity)
- Obesity, menopause and skeletal deformities (diminished gluteal aesthetic)
- Loss of substance in longstanding bed-ridden state for medical diseases with atrophy of the muscle and fat and thinning of skin.
- Previous radiotherapy

## **Acquired iatrogenic abnormalities which include**

- Iatrogenic deformities after surgeries in the trochanteric or gluteal region (for tumor, bedsores or for cosmetic purposes)
- Contour irregularities after liposuction

# Planning - Desired Body Shape by Patient



4 basic shapes V-shape, A-shape, Square and Round.

**A-Type:** This resembles an upside-down heart, which being the widest part of the buttocks is at the bottom. This is the most popular type that a lot of women want, as this represents the ideal hour-glass figure.

**V-Shape:** This type is when most of the fullness is in the hips and narrows out near the bottom of the buttocks.

**Square:** This is when the buttocks are rather flat in shape, and little fat is present in the waist. This type of buttocks shape can be more difficult to sculpt than the other shapes and may require more than one fat transfer surgery.

**Round:** This type is basically full all-around, with fat distribution in the upper, mid and lower parts of the buttocks. The waist-hip ratio is equal with each other.

# Planning - Patient Selection - Fat vs HA Body Filler

| <b>Fat</b>                                                                                        | <b>Body Filler</b>                                                                                                |
|---------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>• Donor areas</li></ul>                                     | <ul style="list-style-type: none"><li>• No donor areas</li></ul>                                                  |
| <ul style="list-style-type: none"><li>• Enough fat for the requirements</li></ul>                 | <ul style="list-style-type: none"><li>• The volume depends on the compliance</li></ul>                            |
| <ul style="list-style-type: none"><li>• More invasive procedure</li></ul>                         | <ul style="list-style-type: none"><li>• Minimally invasive procedure</li></ul>                                    |
| <ul style="list-style-type: none"><li>• Longer downtime</li></ul>                                 | <ul style="list-style-type: none"><li>• Shorter downtime</li></ul>                                                |
| <ul style="list-style-type: none"><li>• The result will be long lasting to permanent</li></ul>    | <ul style="list-style-type: none"><li>• Last for 18 to 24 months</li></ul>                                        |
| <ul style="list-style-type: none"><li>• Living tissue responding to biological stimulus</li></ul> | <ul style="list-style-type: none"><li>• Bio resorption is variable so result longevity if more accurate</li></ul> |
| <ul style="list-style-type: none"><li>• Immediate Result but ultimate result will vary</li></ul>  | <ul style="list-style-type: none"><li>• Immediate and Accurate Result; Easy to top up</li></ul>                   |

100ml of Eikonha= 150cc implant

# Procedure Planning



- Sterile technique and environment
- Anesthesia
- Technical (1.5mm Coleman type 1 cannula)
- Depth
- Distribution
- Immediate result

# Pre-Op

1. Photos
2. Prophylactic oral antibiotics and analgesics
3. Marking ( standing)
4. Local anesthesia/tumescent infiltration
5. Surgical prep and draping
6. Dressing: Steris trip and waterproof-dressings



# Post-Op Care



1. Apply ice packs
2. Avoid sun and heat exposure until D7
3. No strenuous exercise until D14
4. Oral analgesics until D5
5. No pressure over the treated areas until D7
6. Comfortable clothes ( cycling shorts, leggings)
7. 1st follow up D7

# Buttocks

## Patient Selection

## Procedure Selection

Low body fat percentage: <20%

- Implants
- Fillers

High body fat percentage: >30%

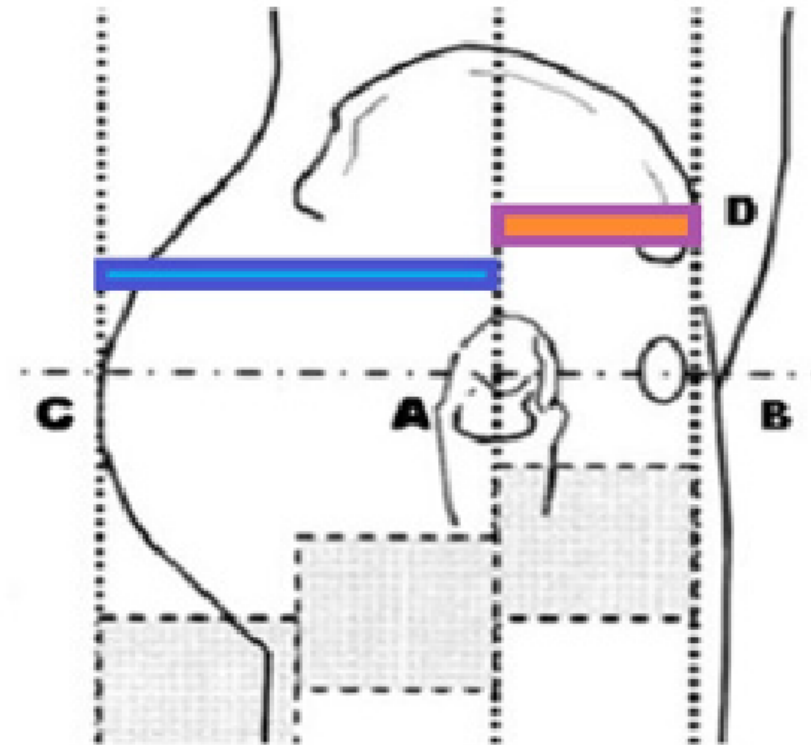
- Loose Weight

Body fat percentage: >20% & <30%

- Fat graft
- Fillers

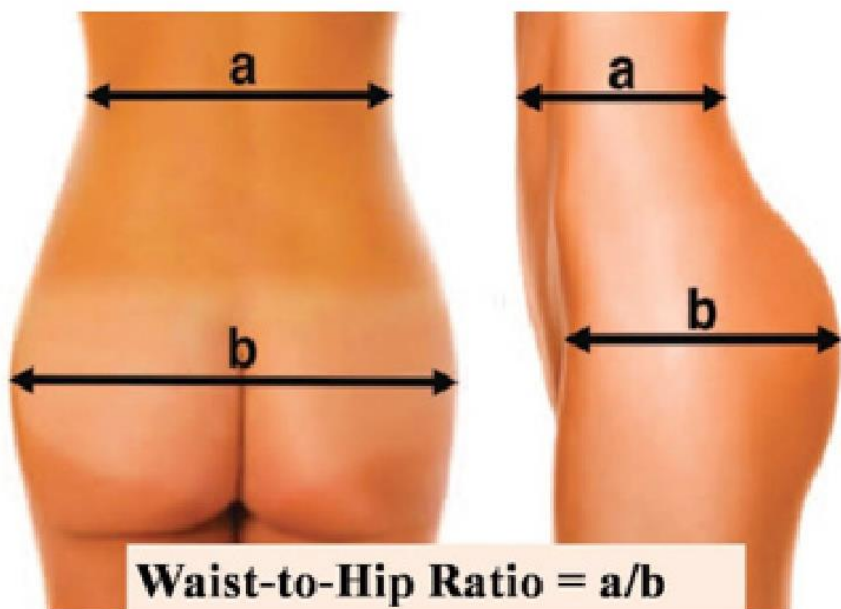
# Injection Guidelines





(A) Greater trochanter, (B) Point of maximal projection of the mons veneris, (C) Point of maximal gluteal projection, (D) Anterior superior iliac spine.

# Waist to Hip Ratio



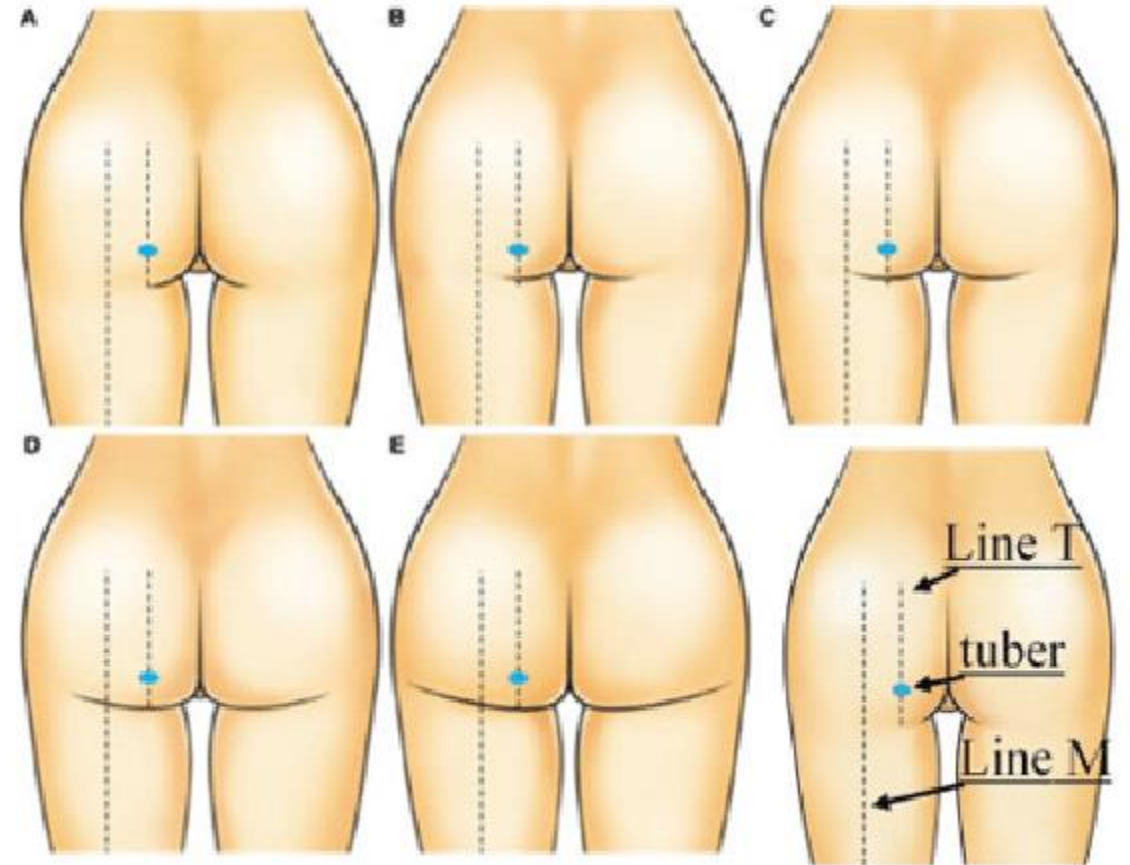
|                                          | Most Attractive<br>(Percentage of<br>Respondents) | Second Most<br>Attractive<br>(Percentage of<br>Respondents) |
|------------------------------------------|---------------------------------------------------|-------------------------------------------------------------|
| <b>Posterior View</b>                    |                                                   |                                                             |
| Waist-to-hip ratio                       | 0.64 (44.2)                                       | 0.60 (25.0)                                                 |
| vertical ratio for lateral<br>prominence | Inferior gluteal<br>convexity (26.3)              | 70:30 (23.6)                                                |
| <b>Lateral View</b>                      |                                                   |                                                             |
| Waist-to-hip ratio                       | 0.70 (29.8)                                       | 0.725 (22.4)                                                |
| vertical ratio for lateral<br>prominence | 50:50 (45.1)                                      | 40:60 (37.5)                                                |

Buttock Anesthetics preferences

**Reference:**  
Abulezz T (2019) A Review of Recent Advances in Aesthetic Gluteoplasty and Buttock Contouring. Plast Surg Mod Tech 6: 147. DOI: 10.29011/2577- 1701.100047

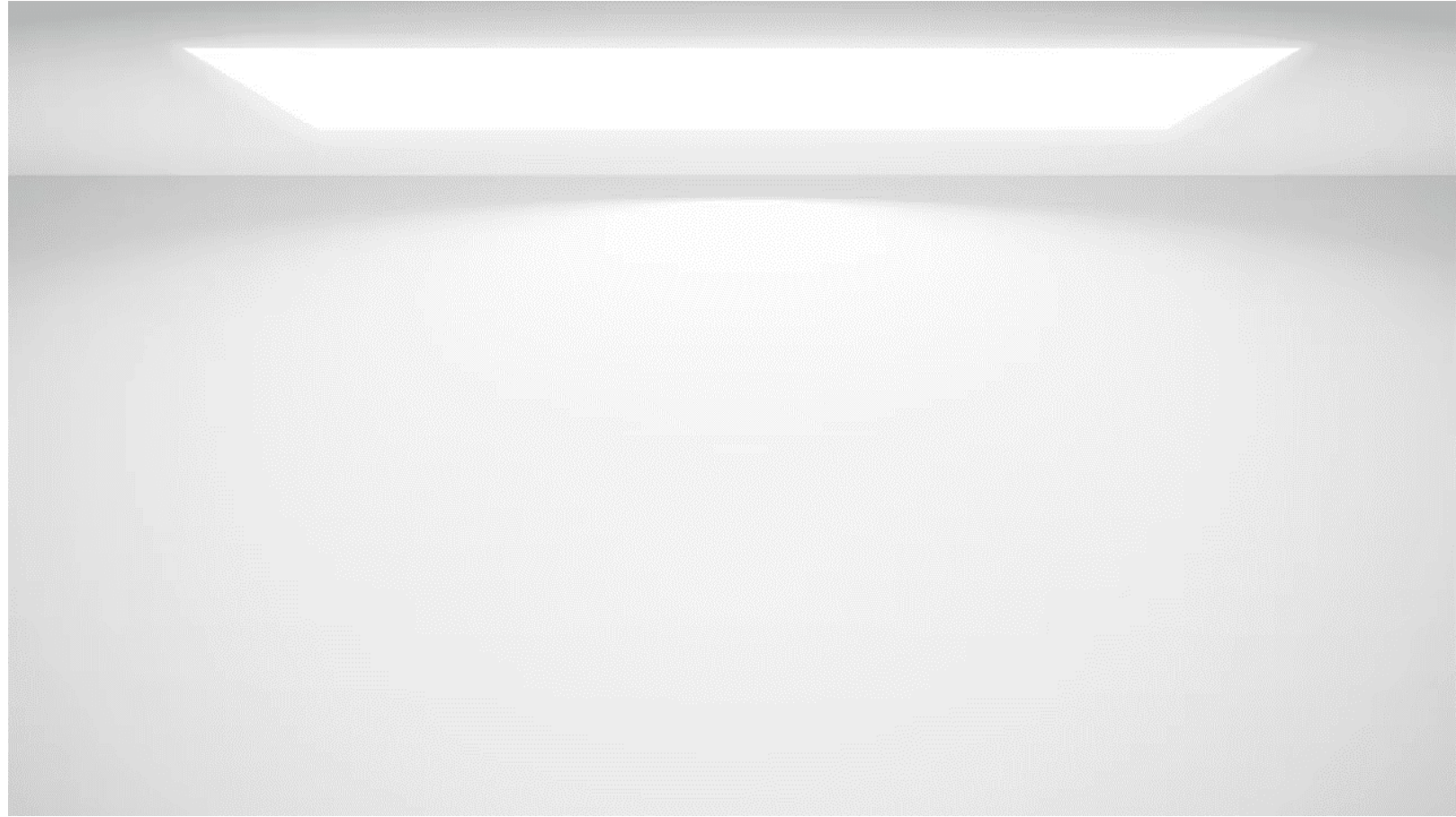
# Degree of Ptosis

- (A) **Degree zero:** the crease can reach T-line but not overpass it.
- (B) **Degree 1:** minimal pre-ptosis. The crease passes over T line, but does not reach M- line.
- (C) **Degree 2:** moderate pre-ptosis. The crease reaches M- line.
- (D) **Degree 3:** borderline pre-ptosis. The crease goes beyond M-line, with no ptotic tissue at M-line.
- (E) **True ptosis.** There is ptotic tissue at M-line

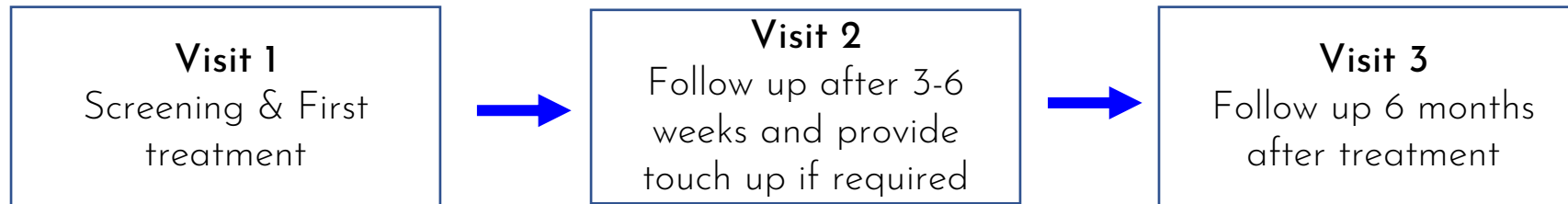


# Injection Guidelines

- Skin fold thickness can be measured using calipers over the subcutaneous layer (where possible)
- Skin laxity can be determined by measuring the distance between two points marked on the skin while the skin is relaxed, and once again when the skin is stretched.
- Skin laxity is defined as the percentage difference between these two measurements.



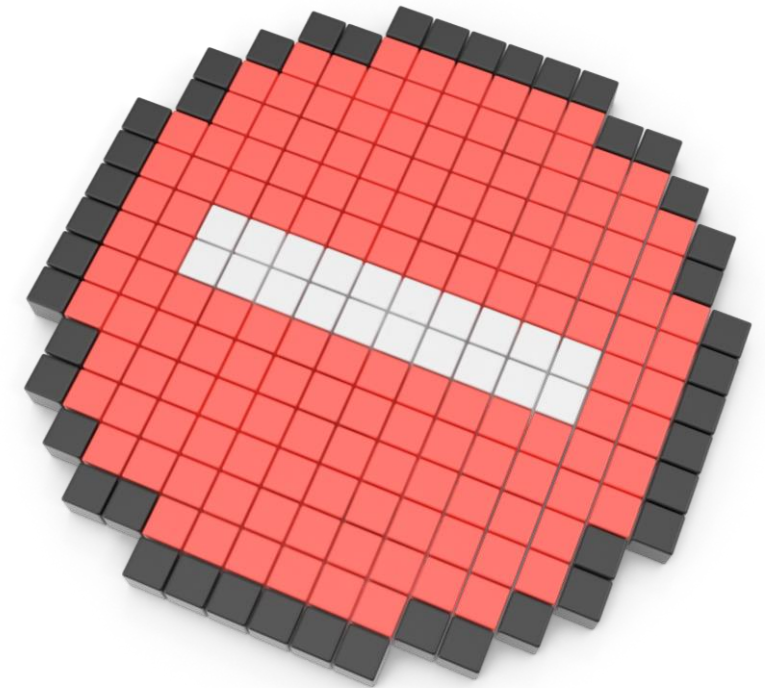
# Visit Plan



# Contraindications

---

- Permanent Fillers
- Auto Immune diseases
- Known allergies to the components
- Susceptibility to keloids (?)
- Current treatment with steroids (?)
- Pregnancy and Lactation
- Age (< 18)
- Bleeding disorders
- Anti platelets, anticoagulants, thrombolytics



# Adverse Events

---

- Related to the product:

1. Migration/mobility
2. Extrusion
3. Nodules
4. “Capsular contraction”
5. Short duration

- Related to the technique

1. Oedema and bruising
2. Pain
3. Infection
4. Asymmetry
5. Contour irregularities

# Warning

- Do not freeze ( $<2^{\circ}\text{C}$ ).
- Check the integrity of the packaging.
- Check the expiry dates stated on the labelling.
- Do not re-sterilise.
- Do not reuse.
- Never attempt to straighten a bent needle/cannula.





# Comparison of Various Procedures used to create volume in the Body

|                        | Advantages                                                                                                                                                                                                                                                                                                                  | Disadvantages                                                                                                                                                                                                                                                                                                               |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Injectable Fat         | <ul style="list-style-type: none"><li>• Potential for lasting durability</li><li>• Versatile (can be used for a wide variety of indications)</li><li>• Can be used in combination with liposuction to sculpt body</li><li>• Filler completely biocompatible</li><li>• Potential to regenerate surrounding tissues</li></ul> | <ul style="list-style-type: none"><li>• Unpredictability of cosmetic results</li><li>• Unpredictability of fat survival</li><li>• Donor site morbidity</li><li>• Time consuming process</li></ul>                                                                                                                           |
| Segmental fat transfer | <ul style="list-style-type: none"><li>• Long-lasting graft survival</li></ul>                                                                                                                                                                                                                                               | <ul style="list-style-type: none"><li>• Requires appropriate donor site, so not suitable for many indications</li><li>• Donor site subject to considerable morbidity and scarring</li><li>• Time-consuming, complex procedure</li><li>• Requires general anesthesia</li><li>• Extensive downtime</li><li>• Costly</li></ul> |
| Flap surgery           | <ul style="list-style-type: none"><li>• Long-lasting graft survival</li></ul>                                                                                                                                                                                                                                               | <ul style="list-style-type: none"><li>• Requires appropriate donor site, so not suitable for many indications</li><li>• Donor site subject to considerable morbidity and scarring</li><li>• Time-consuming, complex procedure</li><li>• Requires general anesthesia</li><li>• Extensive downtime</li><li>• Costly</li></ul> |

|                                         | Advantages                                                                                                                                                                                                                                                                                                       | Disadvantages                                                                                                                                                                                                                                                                                   |
|-----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Silicone implants                       | <ul style="list-style-type: none"> <li>• Very long-lasting correction</li> <li>• No donor site required</li> <li>• Can be used to create substantial volume</li> <li>• Less downtime involved compared with flap surgery</li> <li>• Less complex and time-consuming compared with flap surgery</li> </ul>        | <ul style="list-style-type: none"> <li>• Risk of rupture and other serious side effects</li> <li>• Not suitable to correct small concavities</li> <li>• More downtime required compared with minimally invasive procedures</li> <li>• More costly than minimally invasive procedures</li> </ul> |
| Polyalkylimide Gel / Polyacrylamide gel | <ul style="list-style-type: none"> <li>• Long-lasting correction</li> <li>• Requires no donor site</li> <li>• Minimally invasive: little downtime, use of general anaesthetic not required</li> <li>• can be carried out in an office environment, quick, relatively inexpensive</li> <li>• Versatile</li> </ul> | <ul style="list-style-type: none"> <li>• Questionable long-term safety</li> <li>• Little empirical evidence regarding safety and efficacy in the peer-reviewed literature</li> </ul>                                                                                                            |
| Eikonha                                 | <ul style="list-style-type: none"> <li>• Requires no donor site</li> <li>• Minimally invasive: little downtime, use of general anesthetic not required, can be carried out in an office environment, quick, relatively inexpensive</li> <li>• Versatile</li> </ul>                                               | <ul style="list-style-type: none"> <li>• Correction is not permanent</li> </ul>                                                                                                                                                                                                                 |

# Comparison of Body Fillers

|                      | <b>Eikonha</b> | <b>Hyacorp</b> | <b>Macrolane</b> | <b>Benefits</b>                                                                                                 |
|----------------------|----------------|----------------|------------------|-----------------------------------------------------------------------------------------------------------------|
| HA Concentration     | 20mg/ml        | 20mg/ml        | 20mg/ml          | In body HA concentration is 20mg/ml                                                                             |
| Packaging            | 10ml/20ml      | 10ml           | 10ml/20ml        | 20ml packing provides a cost benefit to Doctors                                                                 |
| G' (Elastic Modulus) | 570pa          | 460            | 560              | Retains shape, maintains volume, less migration                                                                 |
| pH Value (Range)     | 7.0 - 7.5      | 7.0 - 7.2      | 7.0 - 7.5        | Human body pH value is 7.4. Neutral pH, identical to body pH, low risk of reaction                              |
| Cross linking agent  | BDDE           | BDDE           | BDDE             | Stable and safe cross-linking agent                                                                             |
| BDDE Residues        | <0.002 mg/ml   | <0.002 mg/ml   | <0.002 mg/ml     | Zero risk of allergic reaction                                                                                  |
| Particle Size        | 500 -1250 µm   | 300 -500 µm    | 300 to 700 µm    | Larger Particle size creates more resistance to degradation and increases volumizing                            |
| Endotoxin level      | <0.025 EU/ml   | <0.025 EU/ml   | <0.025 EU/ml     | Safer to use                                                                                                    |
| Gel Characteristics  | Biphasic       | Monophasic     | Biphasic         | Biphasic Products have uniform particle distribution, have higher stability and it also has uniform degradation |
| Duration of Results  | 12-18 Months   | 6-12 months    | 12-18 months     | Long lasting results increases patient satisfaction                                                             |

Studies & References for Body

Augmentation with HA



# Buttock Augmentation

Aesth Plast Surg (2014) 38:404–412  
DOI 10.1007/s00266-013-0251-9



ORIGINAL ARTICLE

NON-SURGICAL AESTHETIC

## Stabilized Hyaluronic Acid Gel for Volume Restoration and Contouring of the Buttocks: 24-Month Efficacy and Safety

Bruno De Meyere · Sebastian Mir-Mir ·  
Juan Peñas · Colette C. Camenisch ·  
Per Hedén



Received: 1 May 2013 / Accepted: 20 November 2013 / Published online: 24 January 2014  
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### Abstract

**Background** Stabilized hyaluronic acid (HA) of nonanimal origin manufactured using the patented NASHA® technology has been developed for use in body shaping. This study was performed to assess the safety and efficacy of stabilized HA gel when used for volume restoration and contouring of the buttocks.

**Methods** Subjects 20 years of age or older seeking buttock augmentation were recruited to this noncomparative

the time points, with a peak of 70 % of the subjects satisfied 1 month after treatment. During the 24 months, no unexpected or serious treatment-related AEs occurred. One subject experienced gel dislocation to the sacral area.

**Conclusions** The data show that stabilized HA gel is a safe and effective treatment for temporary aesthetic augmentation of the buttocks. Although the substance degrades over time, a good proportion of the subjects still rated their buttocks as improved (40 %) and expressed satisfaction



# Buttock Augmentation

Format: Abstract ▾

Send to ▾

*Aesthetic Plast Surg.* 2014 Apr;38(2):404-12. doi: 10.1007/s00266-013-0251-9. Epub 2014 Jan 24.

## Stabilized hyaluronic acid gel for volume restoration and contouring of the buttocks: 24-month efficacy and safety.

De Meyere B<sup>1</sup>, Mir-Mir S, Peñas J, Camenisch CC, Hedén P.

⊕ Author information

### Abstract

**BACKGROUND:** Stabilized hyaluronic acid (HA) of nonanimal origin manufactured using the patented NASHA® technology has been developed for use in body shaping. This study was performed to assess the safety and efficacy of stabilized HA gel when used for volume restoration and contouring of the buttocks.

**METHODS:** Subjects 20 years of age or older seeking buttock augmentation were recruited to this noncomparative multicenter study (NCT01331408). Gel at a maximum volume of 400 mL per subject was injected during one or two treatment visits. Safety and efficacy assessments (24-month follow-up evaluation) included adverse event (AE) reporting, aesthetic improvement (Global Aesthetic Improvement Scale [GAIS]), and subject satisfaction.

**RESULTS:** In this study, 61 subjects received a mean total volume of 340 mL (range 200-420 mL) of stabilized HA gel. According to subject GAIS assessment, buttock appearance was rated as "improved," "much improved," or "very much improved" by 80, 68, 42, and 40% of subjects after 6, 12, 18, and 24 months, respectively. Subject satisfaction with buttock size, shape, firmness, and general appearance was higher than before treatment at all the time points, with a peak of 70% of the subjects satisfied 1 month after treatment. During the 24 months, no unexpected or serious treatment-related AEs occurred. One subject experienced gel dislocation to the sacral area.

*Aesthet Surg J.* 2017 May 1;37(5):560-569. doi: 10.1093/asj/sjw240.

## Gluteal Augmentation Techniques: A Comprehensive Literature Review.

Oranges CM<sup>1</sup>, Tremp M<sup>1</sup>, di Summa PG<sup>1</sup>, Haug M<sup>1</sup>, Kalbermatten DF<sup>1</sup>, Harder Y<sup>2</sup>, Schaefer DJ<sup>1</sup>.

⊕ Author information

### Abstract

**BACKGROUND:** Many studies of gluteal augmentation techniques have been published in recent decades, including case reports, retrospective and prospective case series, and multicenter survey reviews. However, to date, there has been no study of the overall complications or satisfaction rates associated with the broad spectrum of techniques.

**OBJECTIVES:** The authors performed a comprehensive literature review to determine outcomes and complications of gluteoplasty techniques, including patient satisfaction.

**METHODS:** A search on PubMed/Medline was performed for clinical studies involving gluteal augmentation techniques. A priori criteria were used to review the resulting articles.

**RESULTS:** Fifty-two studies, published from 1969 through 2015, were included - representing 7834 treated patients. Five gluteal augmentation techniques were identified from these studies: gluteal augmentation with implants (n = 4781), autologous fat grafting (n = 2609), local flaps (n = 369), hyaluronic acid gel injection (n = 69), and local tissue rearrangement (n = 6). The overall complication rates of the most commonly utilized techniques were: 30.5% for gluteal augmentation with implants, 10.5% for autologous fat grafting, and 22% for local flaps. Patients' satisfaction was reported as consistently high for all the five techniques.

# Calves Augmentation

Aesth Plast Surg (2009) 33:274–282  
DOI 10.1007/s00266-008-9303-y

REVIEW

## Body Shaping and Volume Restoration: The Role of Hyaluronic Acid

Per Hedén · Gabriella Sellman · Mats von Wachenfeldt · Michael Olenius · Dan Fagrell

Original Article

Plastic and Aesthetic Research

## Hyaluronic acid in calves defects correction

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*Thank  
You*

