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MERZ AESTHETICS®

GPSDP Advisory Committee Meeting: Dermal Fillers

Radiesse® Injectable Implant: Overview and Use in the Décolleté

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Merz Aesthetics

Juan Daccach, MD - VP Global Product Safety



Financial Disclosure Statement

Juan Daccach, MD is an employee of Merz North America, Inc., and VP of Global Product Safety for Merz Aesthetics, which manufactures and sells dermal fillers.

Agenda

- General observations of dermal filler use trends
- Radiesse introduction
- Radiesse treatment paradigm for décolleté wrinkles
- Radiesse clinical trial experience for décolleté wrinkles
- Post-market surveillance safety data
- On going surveillance and risk mitigation
- Conclusions

General Observations of Dermal Filler Use Trends

- Fillers offer a *non-invasive* surgical alternative to achieve enhancing and rejuvenative improvements. Procedures generally offer a lower cost alternative to patients with limited-to-no recovery time.¹
- Globally, it has been estimated from 2019 that over 15 million filler treatments were performed.² The total number of dermal filler treatments globally surpassed 20 million by 2024.³
- In 2023 there were approximately 5.5 million dermal filler procedures performed globally, representing a 29% increase from the previous year, with a 4% increase in the US.³
- Fillers are consistently ranked among the most common non-surgical aesthetic procedures performed in the United States.⁴

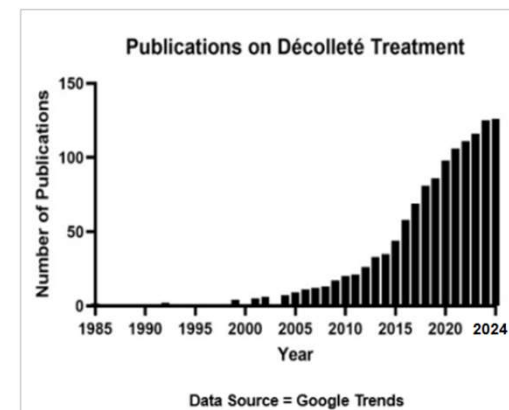
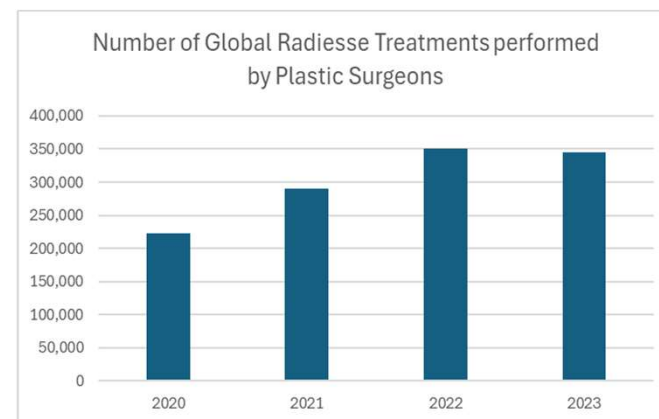
1. Funt D, Pavicic T. Clin Cosmet Investig Dermatol. 2013;6:295-316

2. Dermal Fillers Market Survey, Medical Insights 2021

3. Global Survey 2023. Full report and Press release. ISAPS. 2023

4. The Aesthetic Society. Aesthetic Plastic Surgery National Databank Statistics, 2022

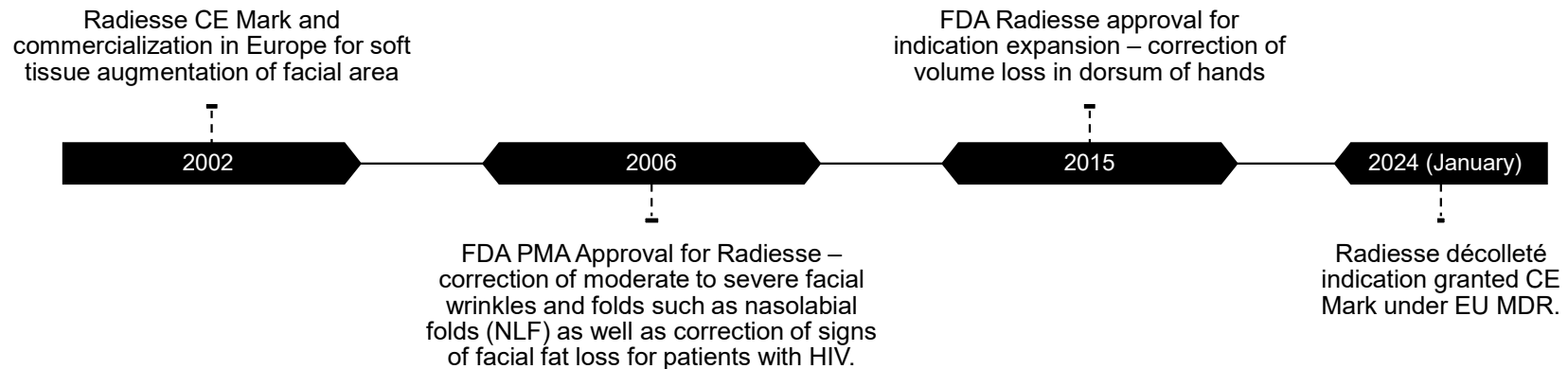
The International Society of Aesthetic Plastic Surgery ISAPS



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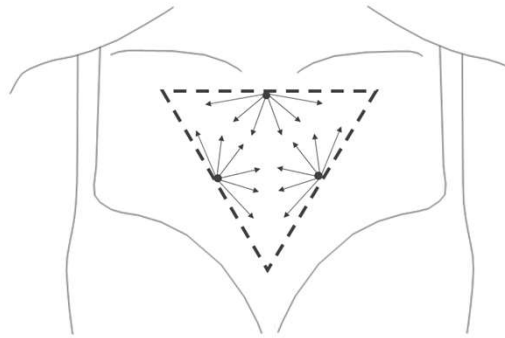
Radiesse® Introduction

- Radiesse is an opaque, white colored dermal filler made up of CaHA microspheres in a water-based gel.
- Radiesse is biodegradable, non-animal based and free from animal protein.
- Radiesse injectable implant (diluted 1:2 with 0.9% sterile saline) is intended for the treatment of wrinkles of the décolleté (note: Radiesse has not been approved by the US FDA for use in the décolleté).
- The safety profile of Radiesse has been established and proven in short- and long-term clinical trials and confirmed in almost 200 publications¹.



Radiesse® Treatment Paradigm for Décolleté Wrinkles

- The décolleté treatment region comprises approximately 100 cm², and is delineated superiorly by the sternoclavicular notch, laterally by the midclavicular line, and inferiorly by the superior point of the intermammary cleft.



- Radiesse injections are not intended for the area overlying or including breast tissue. They are performed at the dermal/subdermal junction.
–*“The risk of damaging mammary tissue is negligible, as the mammary glands are located underneath the superficial layers of the breast which should be beyond the reach of a cannula and/or needle”.*¹

1. Van Longhem, Jani. Expert treatment technique. Page 95. CRC press. 2021..

Note: Radiesse has not been approved by the US FDA for use in the décolleté

Radiesse® is Safe and Effective for Treating Décolleté Wrinkles in Clinical Trials

IIT: Prospective Clinical Trial Evaluating the Long-Term Safety and Efficacy of Calcium Hydroxylapatite (Radiesse) for Chest Rejuvenation¹ *Fabi et al.*

- Subjects showed improvement in the dynamic and resting appearance of décolleté wrinkles 6, 12, 26, and 52 weeks after injection using the Merz Décolleté Scale
- Subject satisfaction scores improved over the year (7-point scale)

- No serious adverse events reported

Two Merz Aesthetics-sponsored clinical trials
Over 265 female patients enrolled (US and EU)
Combined follow up between 52 and 84 weeks

Two Pivotal, Prospective, Multicenter, Evaluator-Blinded, Randomized Studies of Diluted Calcium Hydroxylapatite (Radiesse) to Treat Décolleté Wrinkles

- Over 70% of subjects showed at least a 1-point improvement according to the Merz Aesthetics Scale (MAS) Décolleté Wrinkles
- Patients with severe baseline wrinkles showed the highest response
- A high percentage of investigators and subjects were satisfied with their results

- No treatment-related serious adverse events reported
- AEs were mostly mild and localized (i.e., injection site hematoma, pain, erythema, discoloration, and swelling)

Ongoing Safety Surveillance

- **Merz Aesthetics (Merz) complies with FDA regulations requiring routine device surveillance and ongoing adverse event reporting.**
- **Specifically, Merz reviews any reports received including but not limited to:**
 - Clinical Trials: All AEs with special focus on Serious Adverse Events (SAEs) from company-sponsored clinical studies
 - Offer insights from a controlled-setting, where intense training and monitoring occur, where clinical event details and outcomes can be verified
 - Spontaneous: Adverse events or cases from solicited and unsolicited sources including spontaneous, literature, and non-company sponsored clinical studies
 - Offer insights from a "usual care" or "real world" setting. Such reports are made voluntarily, and often lack medical details, clinical details, diagnoses, and outcomes

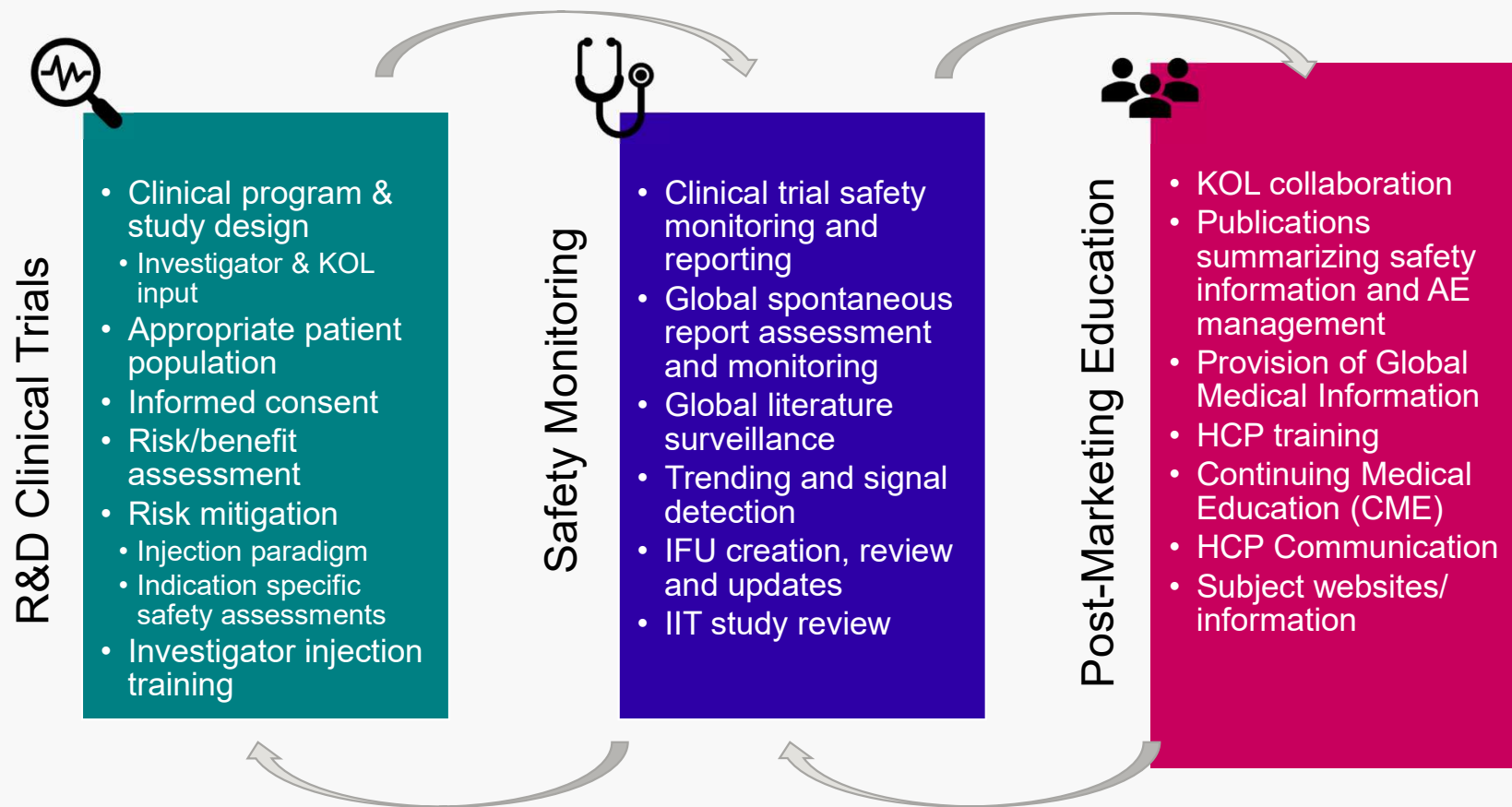
Radiesse® Post Market Surveillance Data for the Décolleté¹

- **Search period: July 2018 – May 2025**
- Search filter: Therapy Site term “décolleté”, Therapy Site “other”
 - Keywords in case narrative: Chest, breast, image, interference, migration, ultrasound, mammography, mammogram, décolletage, décolleté
- Post Market Surveillance found 44 hits for anatomical region "décolleté" with zero cases reporting migration and/or radiological interference
- Less than 10 cases (therapy site "décolleté") per year since 2018

1. Merz In-house Data (PMS Safety Database)

Note: Radiesse has not been approved by the US FDA for use in the décolleté. However, the device is CE marked in the EU and holds other global marketing authorizations. Post market data herein is not market specific.

Risk Management & Mitigation is a Continual Process



Benefits to Patients with Radiesse®

- Patient satisfaction in facial areas: 97-98%¹⁻²
- Patient reported facial aesthetic improvement: 89%¹
- Investigator reported improvement: 92%¹

- Patient satisfaction in non-facial areas (inclusive of the chest): 90%¹
- Patient reported improvement in non-facial areas (inclusive of the chest): 94%¹
- Investigator reported improvement in non-facial areas (inclusive of the chest): 95%¹

- Patients more pleased with appearance: 96%³
- Patients that feel more attractive: 80%³

- Likelihood to return for future treatment: 80-93%⁴⁻⁵
- Would recommend to others: 94%⁵

1. Amiri et al. Plastic and Reconstructive Surgery – Global Open- 2024

2. Amiri et al. Journal of Clinical Medicine – 2024

3. Fried, Richard. The Journal of Clinical and Aesthetic Dermatology, 2011

4. Moers-Carpi et al. Dermatologic Surgery, 2012

5. Moers-Carpi et al. Dermatologic Surgery, 2007

Conclusions

- Radiesse® has been commercially approved for use since 2002 and was approved for décolleté wrinkles in Europe in January 2024.
- The safety of Radiesse is established and has been proven in short- and long-term trials; and, confirmed within the literature in almost 200 publications.
- Given the characteristics of the product, and with proper injection technique (away from the breast and in the subdermal plane) migration is unlikely.
- No reports of migration or interference in décolleté have been received.
- Global post market data does not show any signals or trends of potential concerns.
- High percentage of beneficial patient outcomes after the use of Radiesse
- Merz is committed to training activities and continuous monitoring of AEs.

Thank you

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