



# The next evolution of dermal fillers

Introduction to AuroDerm's proprietary intellectual property for use of micro-Gold particles in dermal fillers for aesthetics procedures

# How are dermal fillers used?



## Enhance lips

Injectable dermal fillers can be used to add volume to the lips for a fuller, plumper look. Lip enhancement are among the most common aesthetic procedure - with over 2.6 mil procedures annually alone in the US (2019 figure).



## Enhance facial contours

Dermal fillers can be strategically injected to lift sagging skin, enhance cheekbones, strengthen the jawline, and restore facial contours.



## Fill wrinkles and folds

Dermal fillers can fill in wrinkles, folds, and lines in the skin, helping to create a smoother and more youthful appearance.



## Most commonly used filler - Hyaluronic Acid

The most widely used non-permanent dermal filler today is Hyaluronic Acid (HA), which makes up ~75% of global value<sup>1</sup>; even higher share of use in US and Europe

Dermal fillers have become increasingly popular in aesthetic procedures over the last decade and the market is expected to grow at 8.4%<sup>1</sup> CAGR over the next 10 years.

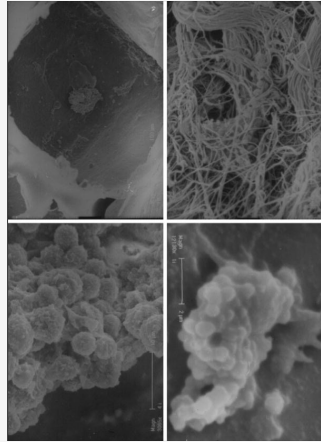
However, unwanted side effects like infections remain a challenge. There is a clinical need for innovation to improve the safety and efficacy of dermal fillers.

<sup>1</sup>Data sourced from Precedence Research report



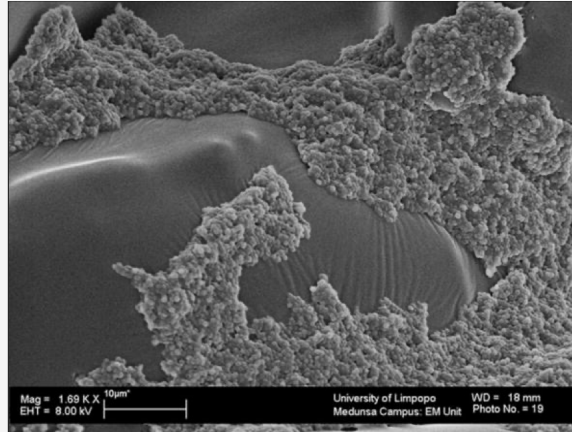
# The problem

## Biofilm formation is the most common long lasting side-effect of dermal fillers



### **Bacteria infections** can form in and/or around filler implant

Dermal fillers can be a vehicle for infection due to contamination of needles when multiple injections are administered



### An implant in combination with bacteria creates **biofilm**

Continued presence of bacteria forms biofilm on and inside of implant. Biofilm is a microbial community that has produced a polymeric matrix. It is irreversibly adherent to both living and nonliving surfaces – here seen on a silicone surface



### Inflammation can become chronic and eventually create **granulomas**

Once bacteria succeeds in forming biofilm, the infection can become untreatable and develop into a chronic state. As a result, a granuloma is formed below the skin

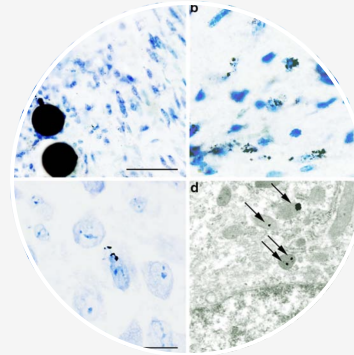
Up to 80% of long-term adverse effects from dermal fillers are related to the formation of biofilm

## The science of micro-Gold particles



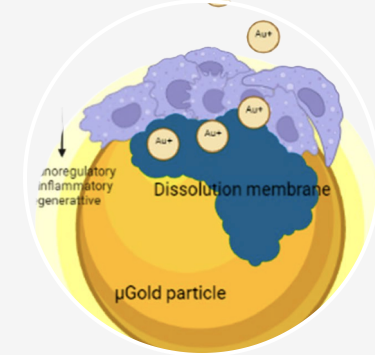
### What are micro-Gold particles?

Gold particles above 20 microns ( $\mu\text{m}$ ) in size made of 99.99% pure metallic gold (Au) and with particular shape of spheres, flakes or beads are considered micron-sized pure gold particles - called  **$\mu\text{Gold}$**



### Stability of micro-Gold vs. nano-Gold particles

Micro-Gold ( $\mu\text{Gold}$ ) particles will stay inside the filler and are too big for macrophages to engulf and transport away. Hence, the **effect is permanent<sup>1</sup>** as opposed to nano-Gold particles which are engulfed by macrophages and hence quickly transported away



### What are the benefits of micro-Gold particles?

As macrophages attempt to dissolve<sup>2</sup> the  $\mu\text{Gold}$  particles, gold ions are bio-released locally. Gold ions adds an **anti-inflammatory<sup>3</sup>** property to prevent, suppress and treat biofilm formation and infections. This is also often referred to as the **oligodynamic effect**

The anti-inflammatory properties of micro-Gold particles make AuroDerm dermal fillers more safe and well-tolerated than traditional fillers

<sup>1</sup>Danscher G & Rasmussen S (2023), "nanoGold and  $\mu\text{Gold}$  inhibit autoimmune inflammation: a review", Histochemistry and Cell Biology (2023) 159:225–232

<sup>2</sup>Carlander U, Midander K, Hedberg YS, et al (2019). "Macrophage-assisted dissolution of gold nanoparticles", ACS Applied Bio Material. 2019;2:1006–1016

<sup>3</sup>Larsen et al. (2008) "Gold ions bio-released from metallic gold particles reduce inflammation and apoptosis and increase the regenerative responses in focal brain injury", Histochemistry and Cell Biology (2008);130(4):681-92

# Unique properties of gold-infused dermal fillers

Leverage natural gold properties for better outcomes



## Anti-inflammatory

Gold ions released by the interaction between  $\mu$ Gold particles and macrophages suppress inflammation and kills bacteria



## Reduces side effects

Due to the inherent anti-inflammatory effect, side effects are reduced and permanently due to continued presence of  $\mu$ Gold particles



## Long-lasting softness

Due to the permanent placement of the  $\mu$ Gold particles, the anti-inflammation effect is long-lasting ensuring implant softness permanently

AuroDerm's gold-infused dermal filler technology presents a patent-protected solution to the largest long-term adverse effect of dermal fillers

# Safety and regulation

## Safety

Gold has been used in medical purposes for +150 years and is regarded as a safe, metal.

Micro-Gold particles stays within the filler and are not transported away by macrophages

The amount of gold ions bio-released from the metallic gold surfaces used in fillers are minimal so the biological effects are only local.

Unaffected by MRI

## Regulation

Dermal fillers are traditionally classified as a class III medical device by FDA (US) and in Europe as class III medical devices (MDR)



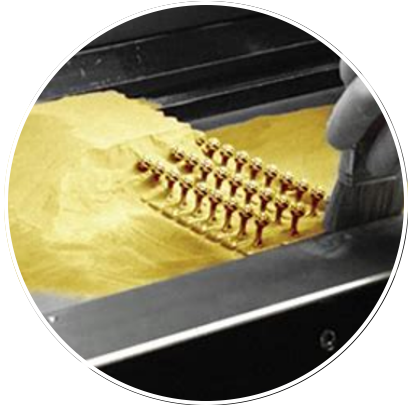
**US:** Regulatory submission requires a PMA application to the FDA. This includes information on the design of the product/filler, intended use, performance data, risk assessment, and experiences with similar products



**EU:** A class III registration and CE marking in Europe requires a notified body to conduct audit of product, intended use, production process etc.

# Production, formulation and clinical administration

of dermal fillers infused with micro-Gold particles



## Production & sourcing of micro-Gold particles

Pure metal gold (Au) of 99.99% purity is used as input in additive machining (a form of 3D printing) to create particles of 20-60  $\mu\text{m}$  gold particles shaped as spheres, flakes or beads.

The particles can be sourced from several international producers (e.g. C. Hafner & Hilderbrand, GE Additive, Cooksongold etc).

The final dermal filler solution will have a concentration of approx. 72.000 particles per ml. - or approx. 20 mg gold



## Formulation & administration of gold-infused filler

Since gold particles in a filler substance (often Hyaluronic acid) will sink; the best way is to infuse the filler is at point of care before administration of filler.

There are several options for formulation and infusion of a dermal filler with micro-Gold particles. A few options:

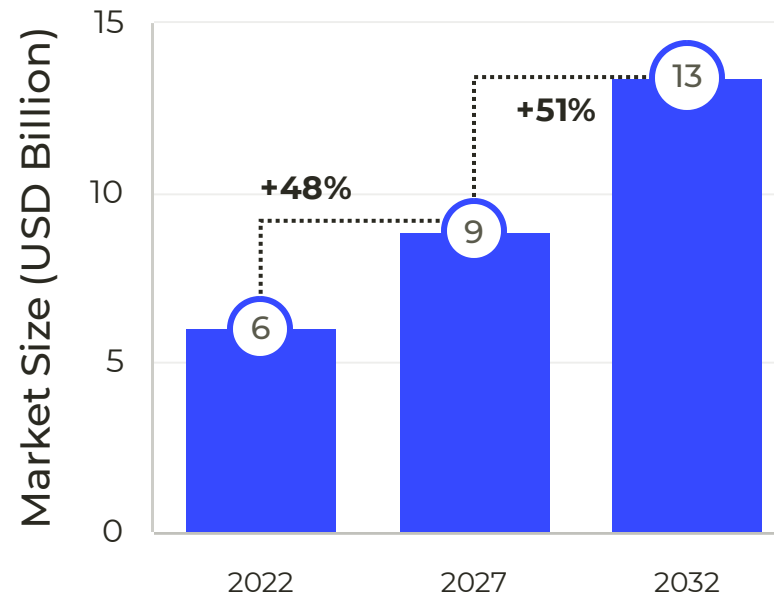
- As dry powder in empty vial that is mixed with hyaluronic acid by clinician
- Gold-particles preloaded in small volume filler that is then mixed into larger quantity
- Dual compartment vial
- Pre-filled dual chamber syringe

# The market for dermal fillers is large, growing and generic

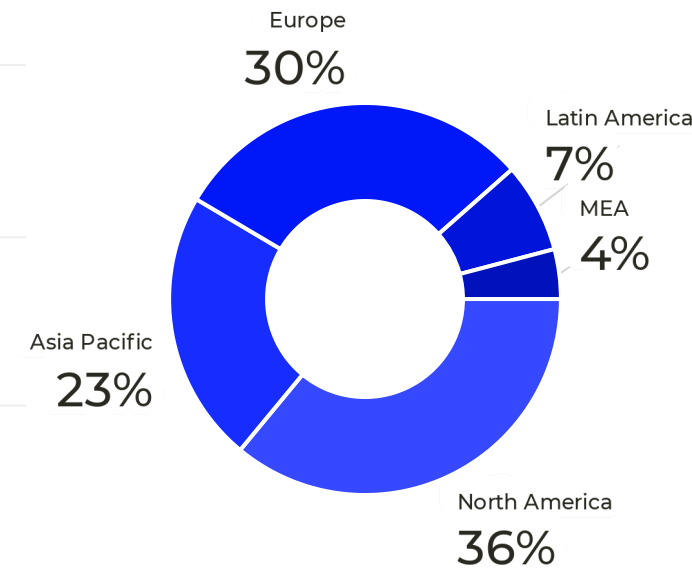
The dermal filler market is projected to grow at a CAGR of 8.4% between 2022-2032.

- Global market for dermal fillers was \$6.0 bn in 2022, expected to grow by a 8.4% CAGR over the next decade to \$13.4 bn in 2032.
- The US and Europe make up the most attractive regions, covering 2/3 of global market share.
- Dermal fillers are mostly generic products consisting of Hyaluronic Acid; making up 76% of sales in 2022.

Forecasted market development for dermal fillers (2022-2032)<sup>1</sup>



Regional-split of dermal filler market by value (2022)<sup>1</sup>



Bringing gold-infused dermal fillers to market represents a large untapped market opportunity to **differentiate** in a crowded generic landscape