



Local Osteo-Enhancement Procedure (LOEP)

Introduction of Bone Void Filler

ICD-10-PCS Coordination and Maintenance Meeting
September 2023

Osteoporosis: a serious burden in the U.S. with significant unmet need

A degenerative bone disease that reduces bone quality, architecture and strength resulting in increased fracture risk

\$20+ Billion spent annually in the U.S. on osteoporosis and fragility fractures

50+ million women and men are impacted by osteoporosis and are at risk of fragility fracture

Normal bone



Osteopenia



Osteoporosis



Bone fracture



The impact of fractures on patients is profound

Significant Mortality

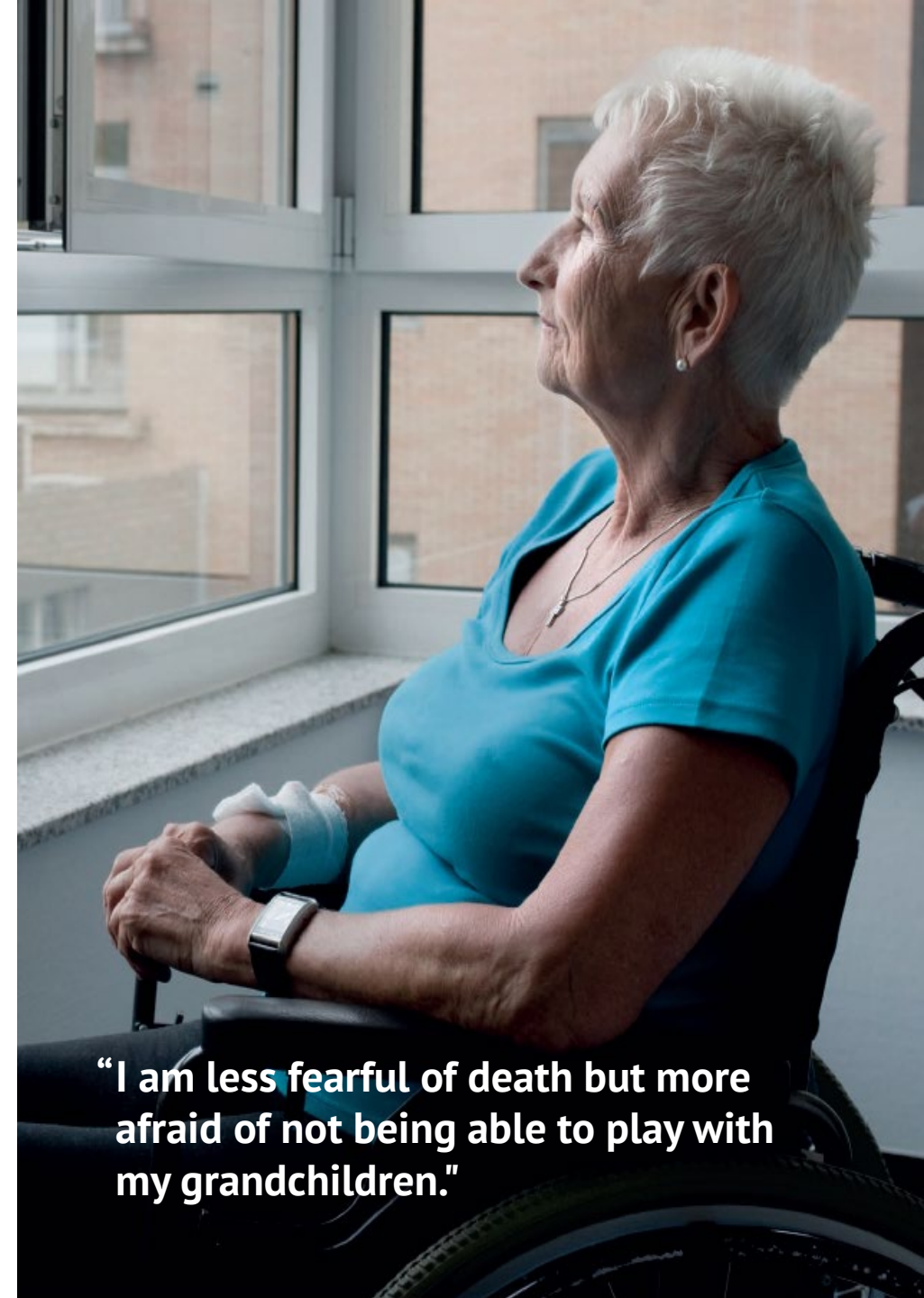
25%

25% of hip fracture patients aged 50 and over die in the year following fracture

Increased Disability and Reduced Quality of Life

40%

40% of patients no longer able to walk independently following fracture



"I am less fearful of death but more afraid of not being able to play with my grandchildren."

Current treatments are pharmaceuticals

1. **At least 12 – 18 months of compliant use needed to gain measurable protection**
2. **Low usage and compliance, even in highest-risk patients**
3. **>45% residual risk remains even with perfect drug therapy compliance**

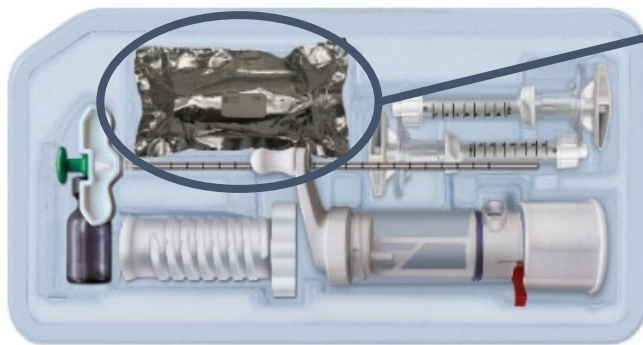
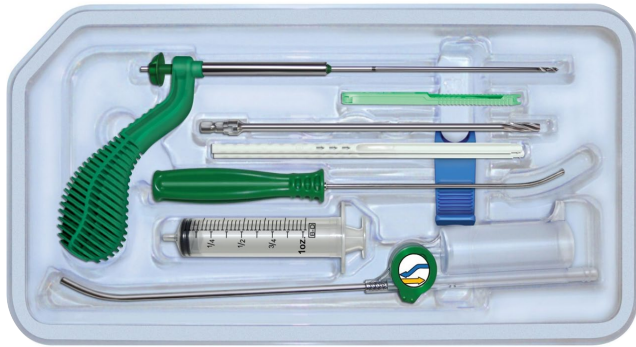


AgNovos™ Solution: Local Osteo-Enhancement Procedure is a targeted therapy designed to reduce fracture risk

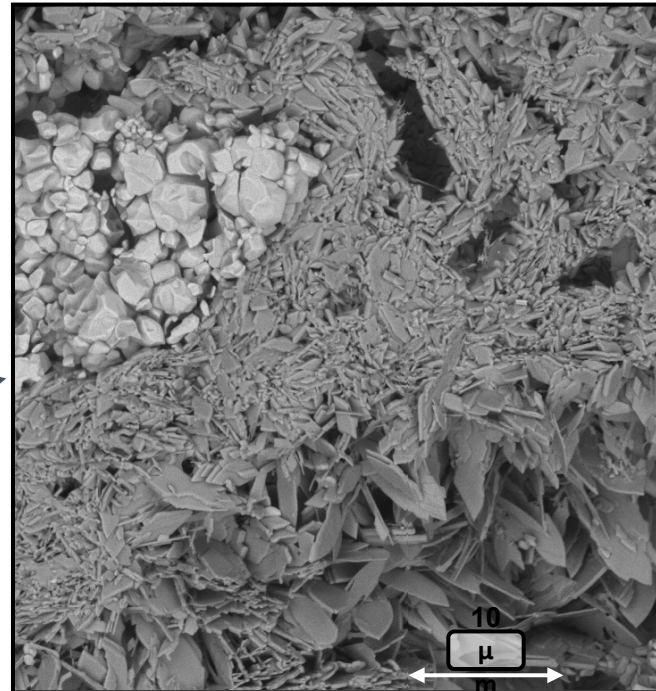


Overview of Product: AGN1 Local Osteo-Enhancement Procedure (LOEP) Kit

Single use, procedural kit containing proprietary implant material and procedural instruments



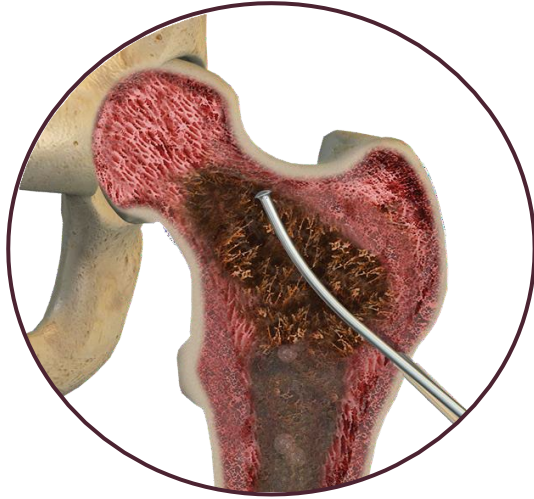
AGN1, a calcium based, resorbable, triphasic, osteoconductive implant material



Two synergistic chemical reactions form AGN1, a unique, resorbable, triphasic biomaterial that maintains mechanical integrity while being transformed to bone

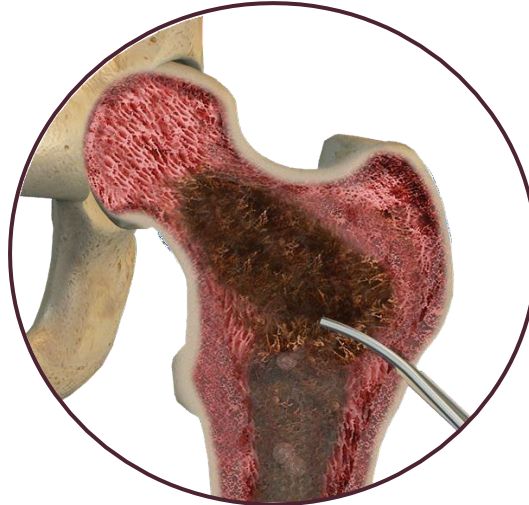
The resorption process creates a microenvironment that facilitates cellular infiltration, neovascularization, collagen deposition, mineralization and rapid bone formation

Overview of the LOEP Procedure



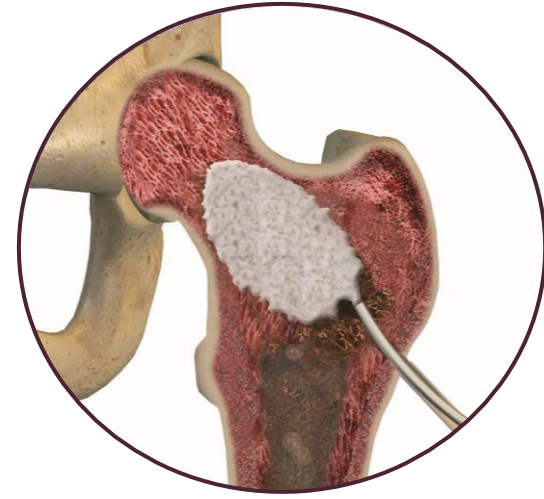
Prepare

Site
Boundaries



Clear

Site for Low
Pressure Fill



Fill

Site with AGN1
Material

- Minimally-invasive procedure
- Fills trabecular bone voids caused by local bone loss
- Proximal femur enhancement site is accessed and prepared
- Osteo-enhancement material is injected
- Provides immediate strength (hardens in ~20 minutes)

FDA Status and Medical Record Documentation

FDA Status

1. FDA pivotal trial, RESTORE, actively enrolling

Anticipate study completion mid-2025

2. FDA PMA modular process underway

Completion/closure of module 1 and module 2

3. Anticipate FDA PMA approval in 2026

Anticipate study completion mid-2025

Documentation

Documentation of the femur osteo-enhancement procedure will be contained in the operative report and may be referred to by the following terms:

- Local Osteo-enhancement Procedure (LOEP)
- Osteo-enhancement
- Osteo-Enhancement LOEP
- Femoral augmentation
- AGN1 implant material



Thank you