

# OptiMesh® HA Nano

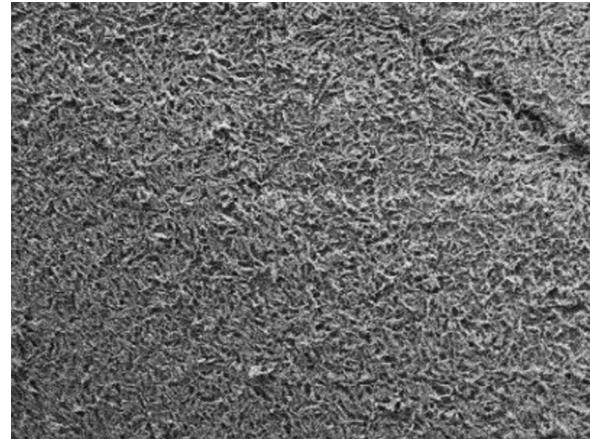
Designed to Ignite Osseointegration

# HA Nano Surface Technology

HA Nano surface technology is a 20-nanometer thin surface treatment composed of crystalline hydroxyapatite (HA)

## HA Nano Features

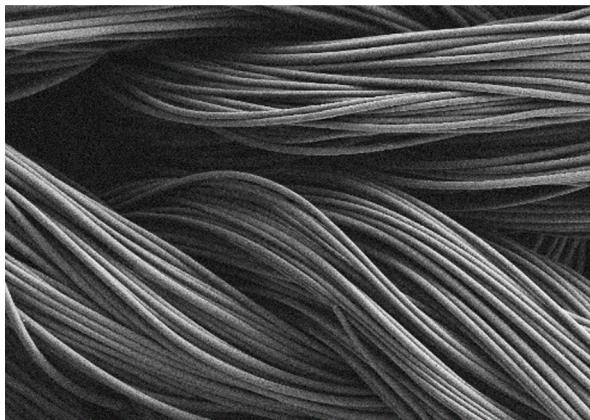
- Mimics natural bone structure
- Ultra hydrophilic
- Precisely engineered nano-roughness
- Promotes a rapid biological response and cellular activity
- Leverages an active, wet chemistry method, creating an ultra-bioactive surface



HA Nano surface (40.00 kX mag)

## Proven Technology

- 30+ pre-clinical and clinical studies validating enhanced osseointegration and superior clinical outcomes on multiple substrates.
- With over 2 million implantations, accelerated osseointegration has been demonstrated through biomechanical, histomorphological, and biological evaluations.



OptiMesh woven structure (200x magnification)



Absorption comparison at 3 seconds

## Rapid Surface Spreading

- HA Nano's combination of high wettability and optimal surface chemistry, with precisely engineered nano-roughness, facilitates rapid bioactivity and absorption of growth factors onto the implant.

# OptiMesh® HA Nano

Next generation implant combining two proven technologies

OptiMesh and OptiMesh Align™ are the first and only conforming, patient-specific expandable implants that feature HA Nano, a well studied nano-thin surface treatment. This technology is designed to create an ultra-hydrophilic absorption environment that promotes rapid cellular activity and creates a 3D bioactive surface area, all intended to accelerate osseointegration and reduce potential infection risks.

This first-of-its-kind OptiMesh HA Nano implant is designed to activate osteoblastic activity and incorporates engineered nano-roughness to deliver enhanced stability on one of the industry's largest expandable implant footprints.

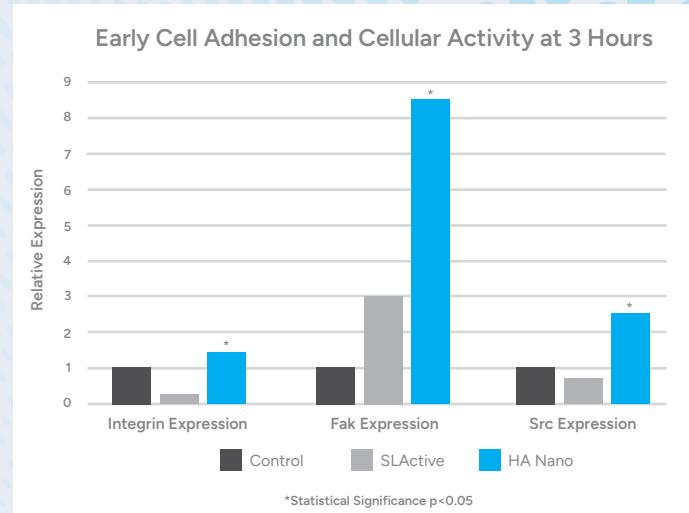
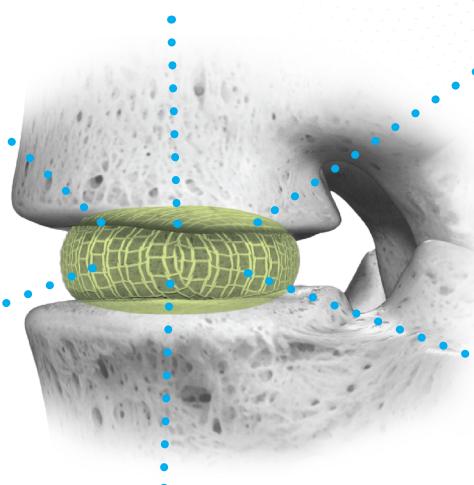


Figure 2: HA Nano promotes an environment conducive to the up-regulation of osteogenic markers which support the promotion of early cell adhesion and faster osseointegration.

## Accelerated Osseointegration

### Ultra Hydrophilic

- The combination of high wettability and optimal surface chemistry, with optimized nano-roughness, mediates bioactivity and growth factor absorption to the implant.
- These absorbed growth factors serve as the foundation for new bone formation.



### Rapid Cellular Activity

- Improved osteoblast morphology and cellular attachment expedite new bone formation.

### Reduced Infection Risks

- With the accelerated cellular activity and enhanced osseointegration of OptiMesh HA Nano, there is a significantly decreased risk of bacterial growth.

### 3-D Bioactive Surface Area

- HA Nano surface treatment on OptiMesh's 3-D woven technology maximizes the bioactive surface area that participates in the fusion process.

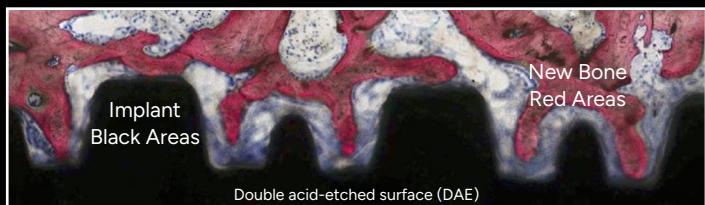
### Nano Thin Hydroxyapatite

- The nano-thin treatment layer minimizes risk of cracking or delamination as compared to traditional HA coating.
- Bone anchors directly onto the surface treated implant (compared to thick traditional HA coating.)

## Proven Advantages

- New bone formation in direct contact with the implant surface is more prominent in the HA Nano treated implants (Figures 3 & 4).
- Osteogenic nano markers are upregulated around HA Nano indicating more active, new bone formation.
- A positive effect on cells and bone tissue was confirmed in 13 in-vivo studies.

Note: Clinical studies and usage resulting from other substrates than OptiMesh.



**Figure 4:** There was a significantly higher amount of bone-to-implant growth on the HA Nano treated implants.

## Ordering Information

Catalog #	Description
500-2628	OptiMesh® HA Nano Expandable Interbody, Small
500-3032	OptiMesh® HA Nano Expandable Interbody, Medium
500-3440	OptiMesh® HA Nano Expandable Interbody, Large
700-2625	OptiMesh HA Nano Align™ Expandable Interbody, Extra-Large

Referenced effects are based on the presence of the HA Nano surface treatment as confirmed by various studies. Studies may have been performed on different base materials than OptiMesh.

\*References: Documents on File

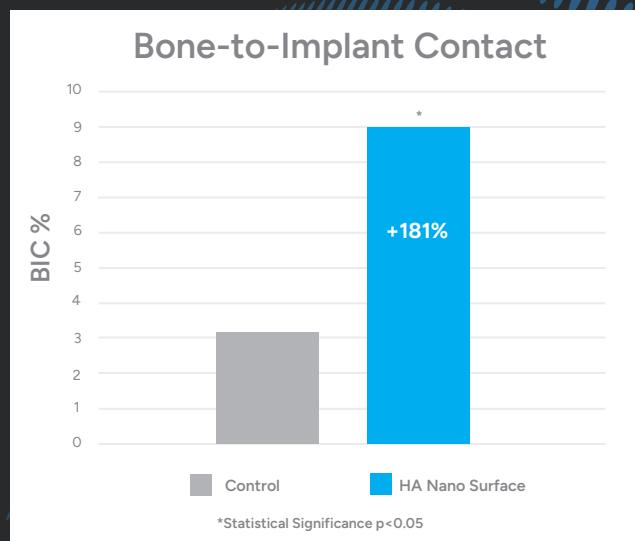
Federal law (USA) restricts this device to sale by or on the order of a physician.

The OptiMesh Multiplanar Expandable Interbody Fusion System is indicated for use as an adjunct to fusion in an intervertebral body fusion at one level in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. Eligible patients shall have undergone six (6) months of conservative (non-operative) care. The OptiMesh device, along with a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion, is intended for use with supplemental posterior fixation systems intended for use in the lumbar spine.

For a complete list of contraindications, precautions, and warnings please refer to the package insert.

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To evaluate HA Nano's effect on osseointegration, bone-to-implant contact was evaluated through histology after 4 weeks.



**Figure 3:** Results show an 181% increase in bone-to-implant contact in in-vivo studies.



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