

INNOVATION

INNOVATE / INVOLVE / INVENT

HA PEEK DATA REGISTRY

TECHNOLOGY BACKED BY CLINICAL DATA

The HA PEEK Registry is a multicenter, observational, quality-assessment repository sponsored by Innovasis as part of our commitment to quality and patient outcomes. It allows surgeons to collect patient outcomes and fusion data in a secure, HIPAA-compliant database that can be accessed on a real-time basis.

DATA THAT BENEFITS SURGEONS & PATIENTS

- Web-based portal, HIPAA-compliant, de-identified data
- Core Lab assessment of fusion rates for HA PEEK at 6 weeks and 3, 6, 12, and 24 months post op.
- Track outcomes against aggregate peer data
- Analyze patient satisfaction and patient-reported outcomes

DEMOGRAPHICS

- Age, Sex, BMI, etc.
- Comorbidities
- Employment Status
- Diagnosis
- Treatment
- Complications

RADIOGRAPHIC ASSESSMENT BY AN INDEPENDENT CORE LAB

- Absence of lucencies around device
- Absence of graft subsidence or migration
- Segmental ROM
- Absence of translational AP-motion or instability

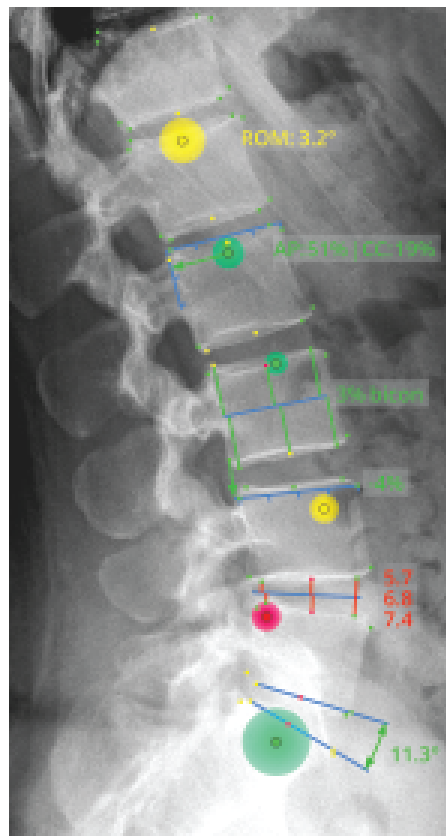
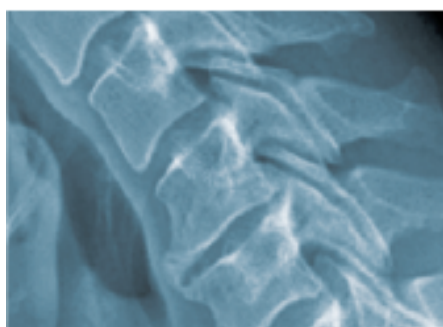
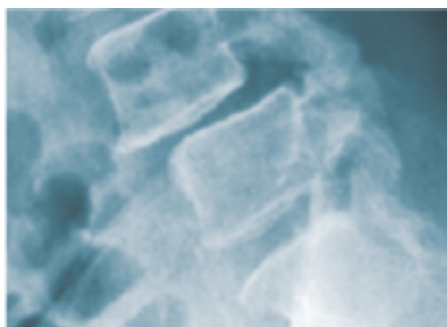
PATIENT REPORTED OUTCOME MEASURES

- Oswestry disability index (ODI), Neck Disability Index (NDI)
- Visual Analogue Scale (VAS)
- EQ-5D™
- Patient-Reported Outcome Measurement Information System (PROMIS)
- Patient Satisfaction
- Preop, surgery and postop CRFs



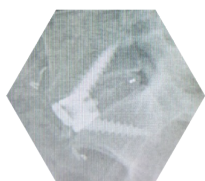
SITE AND REGISTRY SUPPORT

Innovasis staff is available to assist with registry set-up, software training, and database support. A radiographic core lab, Raylytic provides imaging assessment and database support. To learn more about participation in **The Innovasis HA PEEK Data Registry**, please contact marketing@innovasis.com or **(801)261-2236**



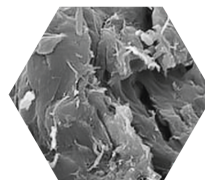
BENEFITS OF HA PEEK

Hydroxyapatite PEEK (HA PEEK) is a composite material of 80% PEEK and 20% hydroxyapatite integration. With zero coatings or laminate, structural and mechanical properties of PEEK combined with the osteoconductive properties of HA makes it an ideal material for interbody fusion.



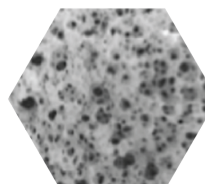
RADIOLUCENT IMAGING

PEEK-OPTIMA HA Enhanced is radiolucent for easy monitoring of the healing site with X-rays, CT or MRI.



OSTEOCONDUCTIVE SURFACE

Fully integrated with hydroxyapatite on all surfaces for earlier bone ongrowth and greater new bone formation.*,**



BONE-LIKE STRUCTURE

With a modulus closer to bone[^], PEEK-OPTIMA HA Enhanced reduces stress shielding at a higher rate than titanium^{^^}

References:

Study evaluated the bone ongrowth of PEEK-OPTIMA and PEEK-OPTIMA HA Enhanced in a bone defect model in sheep. Data on file at Invibio. This has not been correlated with human clinical experience.
** Study evaluated the in vivo response to PEEK-OPTIMA Natural, PEEK-OPTIMA HA Enhanced and allograft in a cervical spine fusion model in sheep. Data on file at Invibio. This has not been correlated with human clinical experience.
[^] J. Henkel, M. A. Woodruff, D. R. Epari, R. Steck, V. Glatt, I. C. Dickinson, P. F. M. Choong, M. A. Schuetz, D. W. Hutmacher. Bone Regeneration Based on Tissue Engineering Conceptions – A 21st Century Perspective. *Bone Research* (2013) 1, 216-248.
^{^^} Comparison of the Strength and Stiffness of Polymers with Titanium based on typical values.

