

# Post-op Accountability: Innovasis registry: HA PEEK and Why

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Innovasis Meeting, Feb 2019



# Overview

- Case
- Intro to HA PEEK
- Why registries?
- Registry details









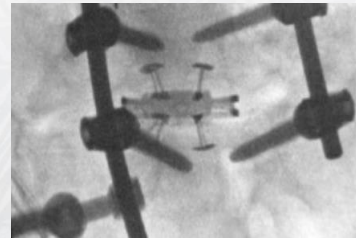
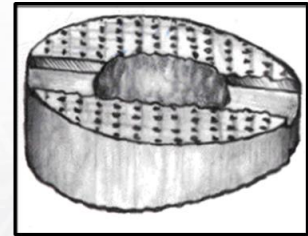


# The problem: Nonunions



# Implant Materials in Spine Surgery

- Titanium
  - Porous
  - Acid-Etched
- PEEK
- Ceramic
- Carbon Fiber
- HA Coated
- HA Infused



# The Ideal Interbody Material

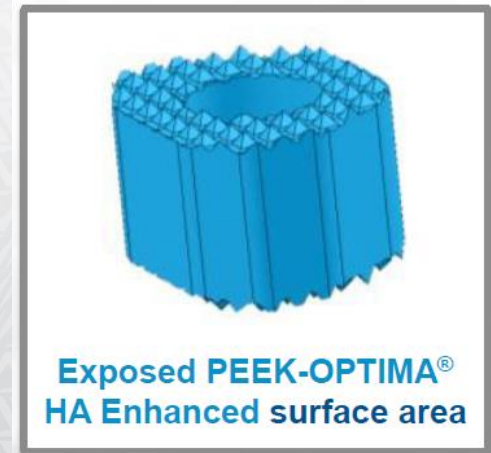
- Facilitates bone growth
- Imaging capability
- Modulus similar to bone
- Biomechanical properties
- Cost effective





## What is HA PEEK?

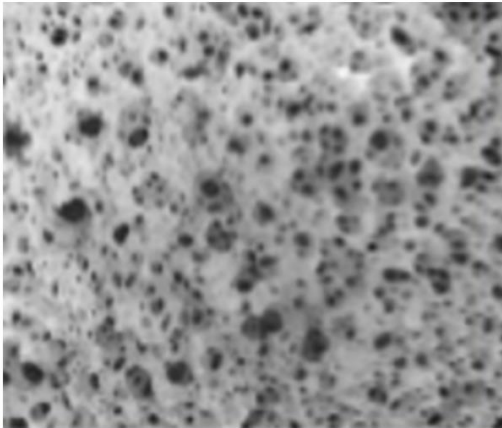
- Composite material of 80% PEEK, 20% Hydroxyapatite integration
- Structural and mechanical properties of PEEK combined with osteoconductive properties of HA
- No coatings or laminate
- Hydroxyapatite
  - Osteoconductive biomaterial used to enhance bone apposition
  - Chemical crystal structure similar to bone





# Proven HA PEEK Benefits

## BONE LIKE STRUCTURE



With a modulus closer to bone<sup>^</sup>, PEEK-OPTIMA HA Enhanced reduces stress shielding at a higher rate than titanium<sup>^^</sup>

## OSTEOCONDUCTIVE SURFACE



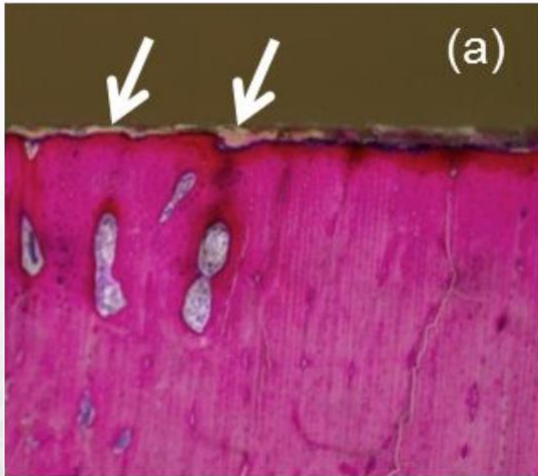
Fully integrated with hydroxyapatite on all surfaces for earlier bone ongrowth and greater new bone formation.<sup>\*,\*\*</sup>

## RADIOLUCENT IMAGING

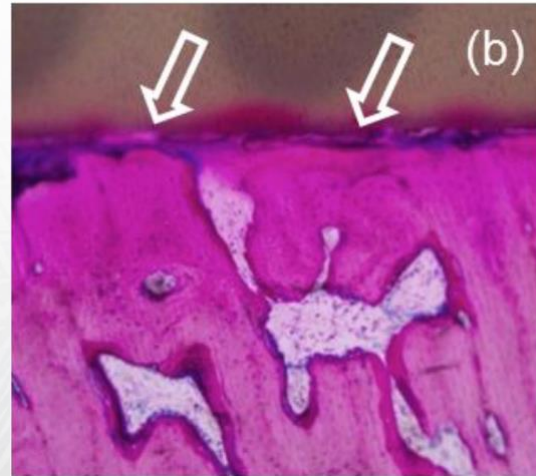


PEEK-OPTIMA HA Enhanced is radiolucent for easy monitoring of the healing site with X-rays, CT or MRI.

# Osteoconductive Surface



Natural PEEK



HA PEEK

The above images compare the two products showing a 4 week histology in sheep of (a) Natural PEEK, and (b) HA infused PEEK. Solid and open arrows show gaps and areas of direct bone contact respectively.

With the HA infused PEEK (b), a more consistent and continuous degree of direct bone contact is observed.



Jerry about to go hammer  
mode in the snackcountry

[#nosnacksleftbehind](#) [#cheeseballsFTB](#)[#powermove](#) // [@improbablereality](#)





# Why a registry?

- Analogy: Change in your life -> feedback?
  - A new diet and never weigh yourself or look in the mirror?
- Most implant companies do not do this with new technology.
  - A rep told me the other day that they didn't need to study a new technology bc they already knew it worked...



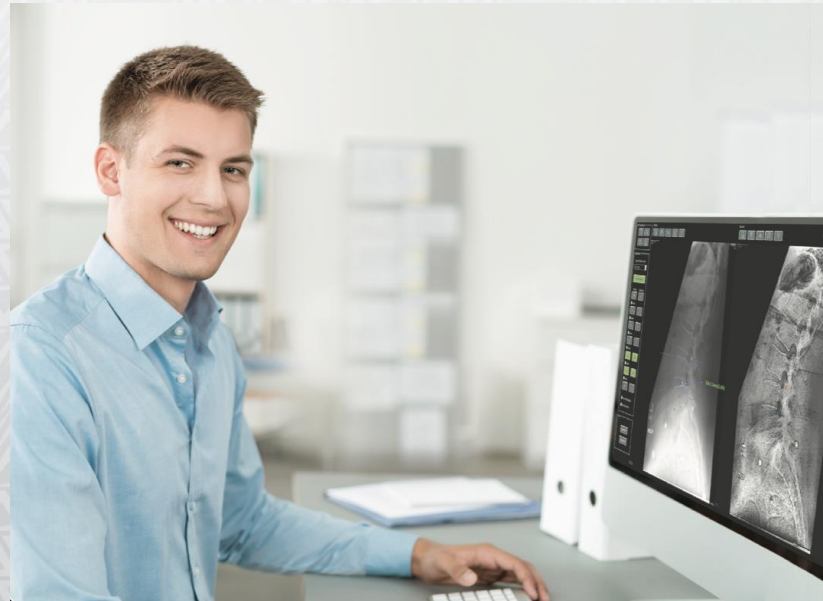
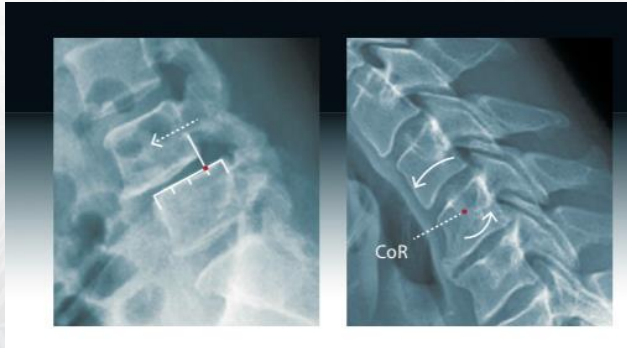
# Why a registry?

- Have to study new technology!
- Tremendous respect for Innovasis in setting up this registry to find out how effective HA PEEK really is.
- Helps us as surgeons to track our patients. Helps the spine community by scientifically analyzing a new technology.



# HA PEEK Registry

*A quality assessment service provided by  
Innovasis*





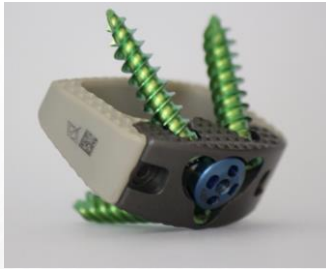
# Registry Objective

- To provide a simple, secure, confidential method for data collection and utility
- To allow investigators to access data on a real-time basis and track patient-reported outcomes and radiographic outcomes against aggregate peer data
- To provide resource to assess data for use in podiums, posters and training presentations



# Registry Product Scope

- ALIF



- PLIF



- ACDF

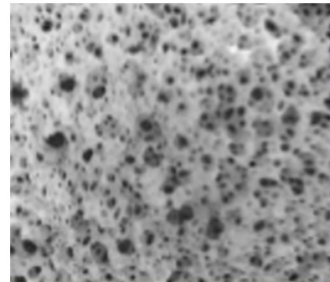


- TLIF



## HA PEEK

BONE LIKE  
STRUCTURE



With a modulus closer to bone<sup>^</sup>, PEEK-OPTIMA HA Enhanced reduces stress shielding at a higher rate than titanium<sup>^^</sup>

OSTEOCONDUCTIVE  
SURFACE



Fully integrated with hydroxyapatite on all surfaces for earlier bone ongrowth and greater new bone formation.<sup>\*,\*\*</sup>

RADIOLUCENT  
IMAGING



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



# Registry Summary

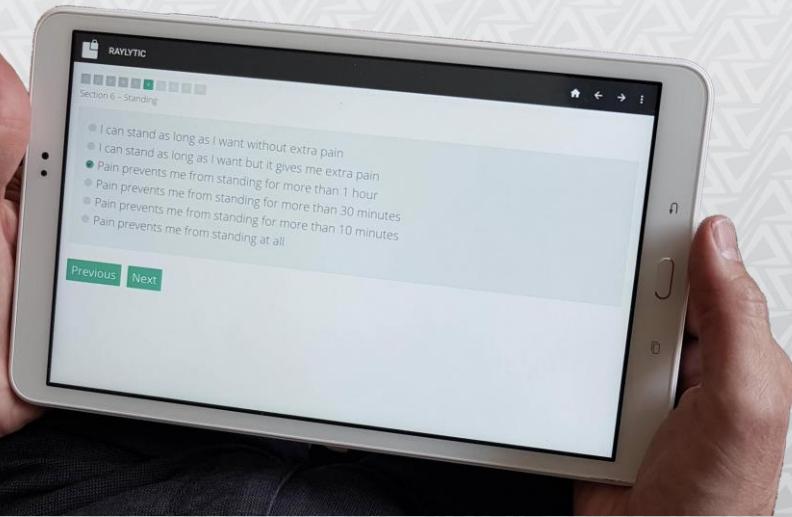
- Study type: Prospective, Observational, Patient outcome registry
- Study Population: Patients with DDD
- Inclusion Criteria: Adults receiving HA PEEK device
- Enrollment Period: 12 months
- Follow up Period: 24 months
- Patients: >100
- Sites: >10
- Data collection periods: Preop, Surgery, 6 wks, 3, 6, 12, and 24 months





# Patient Outcome Measures

- ✓ CRF
  - Web-Portal based electronic questionnaires
- ✓ ODI/NDI
  - Secure, password protected access
- ✓ VAS
  - Desktop computer- and tablet-friendly app
- ✓ EQ-5D
  - Electronically stored and accessible files
  - Customizable follow-up notifications
- ✓ Patient Satisfaction



# Radiographic Outcome Measures

- Radiographs will be analyzed by an independent core lab (Raylytic Inc.) assessing fusion:
  - Radiolucency around device
  - Segmental ROM
  - Segmental translational motion or instability
  - Disc Height
  - Device migration or subsidence



# Real Time Registry: Adding a Pt

**Add Patient**

**Add a new Patient**  
The new Patient will be generated for the chosen Clinic

Clinic

**PatientID**

**Birth date (DD-MM-YYYY)**

**Gender**  
Unknown

**Surgery date (DD-MM-YYYY)**  
01.01.1970

**Treated Anatomical Structure 1**  
Select...

**Treatment / Procedure**  
Select...

**Preferred Languages**  
English (United States)

Close **Add new patient**

QDICOM  
Martina Geroldt Grace  
User Manual

Studies

Study Administration  
Questionnaire Designer  
Assign Questionnaire  
Add/Tab OCT Plots/View

Upload & Import  
Upload and Measure  
Images  
Upload Overview

Patients  
Start ePROCRP  
Add Patient

Study Overview  
Image Files  
Patients

Documentation  
Rayline Dicom Viewer  
User Manual

Private Policy | Copyright Analytic Genetix © 2018

QDICOM dev-branch-5.1.8 (PPO4182)





# Real Time Registry: Outcomes



1. How satisfied were you with your treatment?

- Satisfied
- Somewhat satisfied
- Somewhat dissatisfied
- Dissatisfied

Previous

Next



# Real Time Registry: Xray Upload

The screenshot displays the Rayview Dicom Viewer software interface. The main window shows a large X-ray image of a spine in a reclinated position, with a circled 'R' and the text 'Reklination' overlaid. To the left, a sidebar contains a menu with 'Upload and Measure' and 'Upload Overview' options, both highlighted with a dashed yellow box. A yellow arrow points from the 'Upload Overview' option to the main X-ray image. The top of the interface features a toolbar with icons for 'Load Folder', 'Load Files', 'Info', 'Clear List', and 'More'. The right side of the interface contains a patient information form with fields for 'Date' (set to 'Demo Clinic 01 0113'), 'Patient' (set to '001'), 'Surgery Date' (set to '06.09.2018'), 'Treated Anatomical Structure' (set to 'L4/5'), and 'Procedure's Position'. Below the form is a 'New Patient' button. The bottom of the interface shows a copyright notice: 'Copyright 2018, Innovasis GmbH'.



# Real Time Registry: Tracking Xrays

**QDICOM**  
Mariana Geraldi Graca  
User Menu ▾

- Studies
- Study Administration
  - Questionnaire Designer
  - Assign Questionnaire
  - Add/Edit QCT Phantom
- Upload & Import
  - Upload and Measure Images
  - Upload Overview
- Study Overview
  - Image Files
  - Patients
  - Download All DICOM Files
- Documentation
  - Rayview Dicom Viewer User Manual

**Example Study: Image Data Overview** System Instance: dev [Database: usr\_web24\_1] [Log out](#)

Image data available for evaluation [ [Show Image Preview](#) ]

Show  entries Search:  [Copy](#) [CSV](#) [Excel](#) [Print](#)

Showing 51 to 81 of 81 entries

SiteID	Site Name	PatientID	CombinedID	06M, 06M, Xray, AP	06M, X-ray, Lateral, Neutral	12M, X-ray, Extension	12M, X-ray, Flexion	12M, X-ray, AP	12M, X-ray, Lateral, Neutral	24M, MRT	24M, Exte
015	Example Clinic 5	12 ✓	01512	missing ✓	missing ✓	missing ✓	missing ✓	missing ✓	missing ✓	f/u 2019-02-23 to 2019-06-23	f/u to
016	Example Clinic 7	01 ✓	01601	+5M_23D ⬇	+5M_23D ⬇	not taken ✓	not taken ✓	+1Y_0M_00 ⬇	+1Y_0M_00 ⬇	f/u 2019-03-18 to 2019-07-16	f/u to
016	Example Clinic 7	02 ✓	01602	withdrawn	withdrawn	withdrawn	withdrawn	withdrawn	withdrawn	f/u 2019-04-01 to 2019-07-30	f/u to
016	Example Clinic 7	03 ✓	01603	+5M_21D ⬇	+5M_21D ⬇	not taken ✓	not taken ✓	+1Y_0M_12D ⬇	+1Y_0M_12D ⬇	f/u 2019-04-17 to 2019-08-15	f/u to
016	Example Clinic 7	04 ✓	01604	+5M_21D ⬇	+5M_21D ⬇	not taken ✓	not taken ✓	+11M_29D ⬇	+11M_29D ⬇	f/u 2019-04-24 to 2019-08-22	f/u to
016	Example Clinic 7	05 ✓	01605	+5M_24D ⬇	+5M_24D ⬇	f/u ends on 2018-09-28 (01M 15D left) ✓	f/u ends on 2018-09-28 (01M 15D left) ✓	f/u ends on 2018-09-28 (01M 15D left) ✓	f/u ends on 2018-09-28 (01M 15D left) ✓	f/u 2019-06-30 to 2019-10-28	f/u to
016	Example Clinic 7	06 ✓	01606	+6M_3D ⬇	+6M_3D ⬇	f/u ends on 2018-10-05	f/u ends on 2018-10-05	f/u ends on 2018-10-05	f/u ends on 2018-10-05	f/u 2019-07-07 to 2019-11-04	f/u to





# Assessment Schedule

		Preop (0M-2M/+0M)	Surgery (0M 0M+12D)	6 Weeks (42D -7D/+7D)	3 Months (3M -14D/+14D)	6 Months (6M -1M/+1M)	12 Months (12M -1M/+1M)	24 Months (24M -2M/+2M)
<b>ID</b>	<b>Outcome Measure Type</b>	<b>Assessment Procedure</b>						
1	Lateral Neutral	X		X	X	X	X	X
2	AP Neutral	X		X	X	X	X	X
3	Flexion	X				X	X	X
4	Extension	X				X	X	X
5	Patient Survey and Op Report*	X	X	X	X	X	X	X
	<b>Outcome Assessment</b>	<b>Assessment Period</b>						
	Radiolucency around device (device loosening)					1	1	1
	Range of motion (degrees)	3, 4				3, 4	3, 4	3, 4
	Translational AP-motion or instability	3, 4				3, 4	3, 4	3, 4
	Fusion in disc space anterior to device			1, 2	1, 2	1, 2	1, 2	1, 2
	Fusion in disc space posterior to device			1, 2	1, 2	1, 2	1, 2	1, 2
	Absence of graft subsidence or migration			1		1	1	1
	eCRF	5	5	5	5	5	5	5
	Visual Analogue Scale (VAS)	5		5	5	5	5	5
	NDI or ODI	5		5	5	5	5	5
	EQ-5D	5		5	5	5	5	5
	PROMIS	5		5	5	5	5	5
	Patient Satisfaction			5	5	5	5	5

\*Patient reported outcome measures will be determined by Participant and Innovasis.



# Thank you

