PEEK cage with Hydroxy Apatite



Bontite®



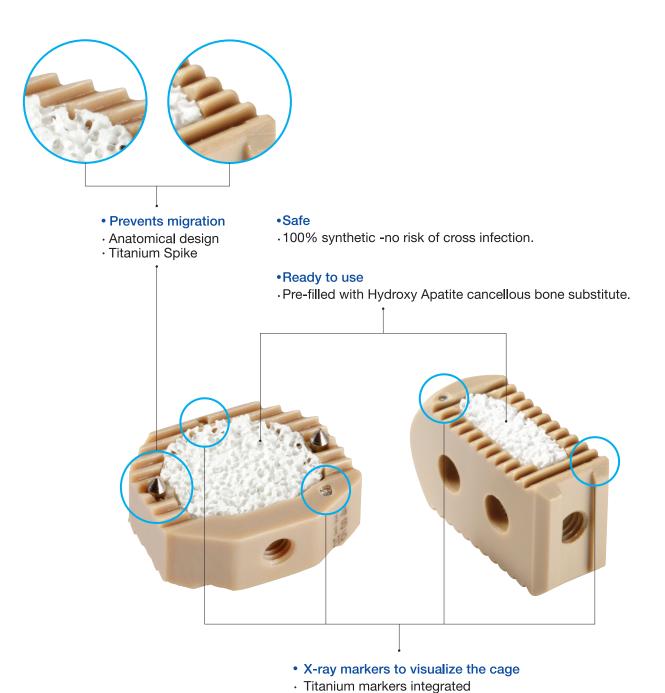


One step solution for Interbody fusion



■ PEEK cage with Hydroxy Apatite

Bontite is pre-filled with insert made of synthetic Hydroxy Apatite cancellous bone substitute. which is similar to human bone mineral component.





■ Bontite® Features

01 | Easy Handling

- Peek cage is pre-filled with a synthetic material which is identical to human cancellous bone, ready to use alone without an additional bone grafting material.
- No need for bone harvesting thus no sick of patient morbidity and potential complications, and reduce operation time.

02 | Excellent Bone Fusion

- · Bone regeneration of synthetic Hydroxy Apatite is clinically approved.
- 80% of porosity of the insert leads fast and solid bone fusion, which is identical to the 3-dimensional interconnected pore structure of human cancellous bone.

03 | Easy Identification after surgery

- Titanium markers to visualize the PEEK cage
- · Radiolucent PEEK cage allows easy identification and evaluation of the new bone growth.

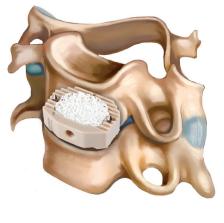
■ Bontite®Indication

Disc degeneration

Disc herniation with thining disc

Spinal stenosis

Spondylolisthesis



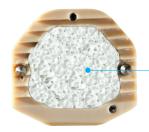




PLIF

■ Bontite® Biocompatibility

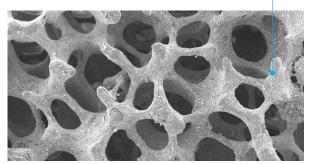
Pore Structure Comparison (SEM, Scanning Electronic Microscope)



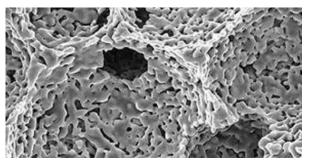
Korean Testing Laboratory,

American GLP Accreditation Institute Nelson Lab,

Passed All Biological Safety Test



Interconnected pore structure of Bontite-insert



Pore structure of B-product

300micrometer pore sized

Maximizes of bone and revascularization

Over 80% of porosity

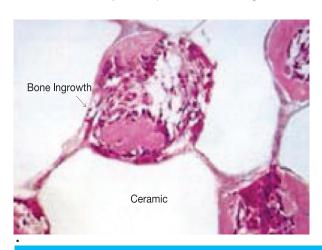
Maximum effective space for new bone formation

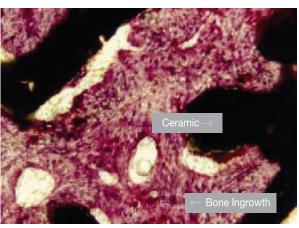
3 Dimensional interconnected structures

Solid and fast bone formation



- **Bontite** -insert has optimized 3 dimensional interconnected pore structure of 300 micrometer and 80% of porosity which is identical to human cancellous for new bone formation.
- Bontite® -insert has optimized pore structure and porosity which is easily substituted by the new bone and leads easy absorption and biodegradation.





Comparison between 2-dimentional Vs. 3-dimentional bone formation.



■ Clinical Studies[®]

Clinical Outcomes

Safety and Effectiveness Evaluation

: 2004.3~2005.5 Period

 Institute : Department of Orthopedic Surgery, Seoul National University Hospital

• Procedure: Posterolateral Lumbar Fusion

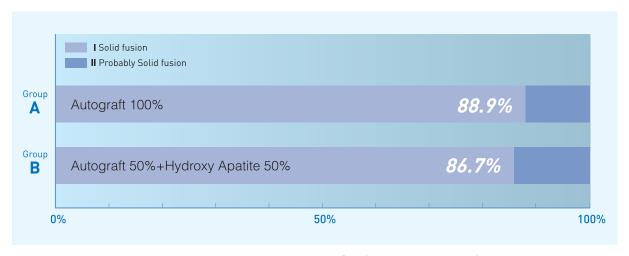
• Subjects : 32 patients, 47 levels

 Results : Safety-no complications and adverse events.

R = 97% (3D-CT)

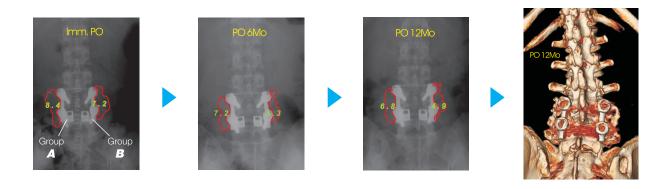
Complete Fusion Rates - Control group (A) 88.9% (Autograft 100%)

- Test group (B) 86.7% (1:1 ratio to Autograft: Hydroxyapatite)



Bony Union Rate by 3D-CT (After 12Months)

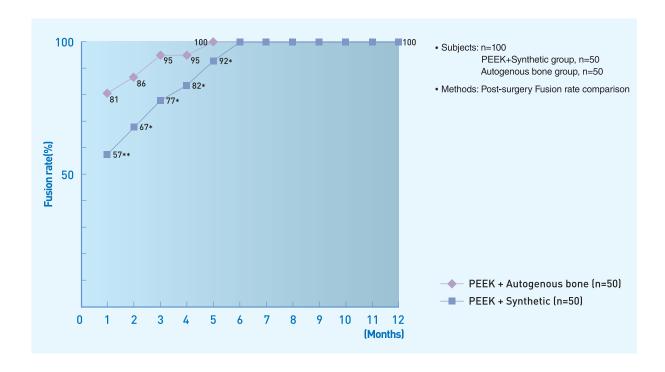
Group A: Autograft 100% Group B: Autograft 50% + Hydroxy Apatite 50%(Volume)



J.H.Lee et al, "A Prospective Consecutive Study of Instrumented" Posterolateral Lumbar Fusion Using Hydroxy Apatite as a Bone Graft Extender. Biomed. Mater. Res, 90A, 804-810, (2009)

Clinical Studies

Post 6 months, equivalent fusion rates achieved with PEEK+synthetic group and Autogenous group.



Reduced Hospital stays, Decreased blood loss and complication rates, PEEK + Synthetic is an alternative to bone harvesting.

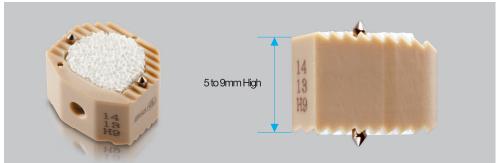
Comparison of excessive time, blood loss, complications, iliac grafting, and hospital stays in both groups

	Group A	Group B	Р
Excessive operative time(min)	0	15+_5	.0001
Excessive blood loss(mL)	0	10+_6	.0001
Donor site complications	0	6%	.0001
Hospital stay(d)	4.43+_2.36	7.00+_3.77	.002

P: Student t test



■ Bontite®c



ACDF for cervical fusion.

Art no.	W(mm)	L(mm)	H(mm)
CGAC06A05	14	13	5
CGAC06A06	14	13	6
CGAC06A07	14	13	7
CGAC06A08	14	13	8
CGAC06A09	14	13	9

■ Bontite[®]L



PLIF for lumbar fusion.

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Art no.	θ(°)	W(mm)	L(mm)	H(mm)
CGPL00A08	0	9	24	8
CGPL00A09	0	9	24	9
CGPL00A10	0	9	24	10
CGPL00A11	0	9	24	11
CGPL00A12	0	9	24	12
CGPL00A13	0	9	24	13
CGPL04A09	4	9	24	9
CGPL04A10	4	9	24	10
CGPL04A11	4	9	24	11
CGPL04A12	4	9	24	12
CGPL04A13	4	9	24	13
CGPL08A09	8	9	24	9
CGPL04A10	8	9	24	10
CGPL04A11	8	9	24	11
CGPL04A12	8	9	24	12
CGPL08A13	8	9	24	13

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