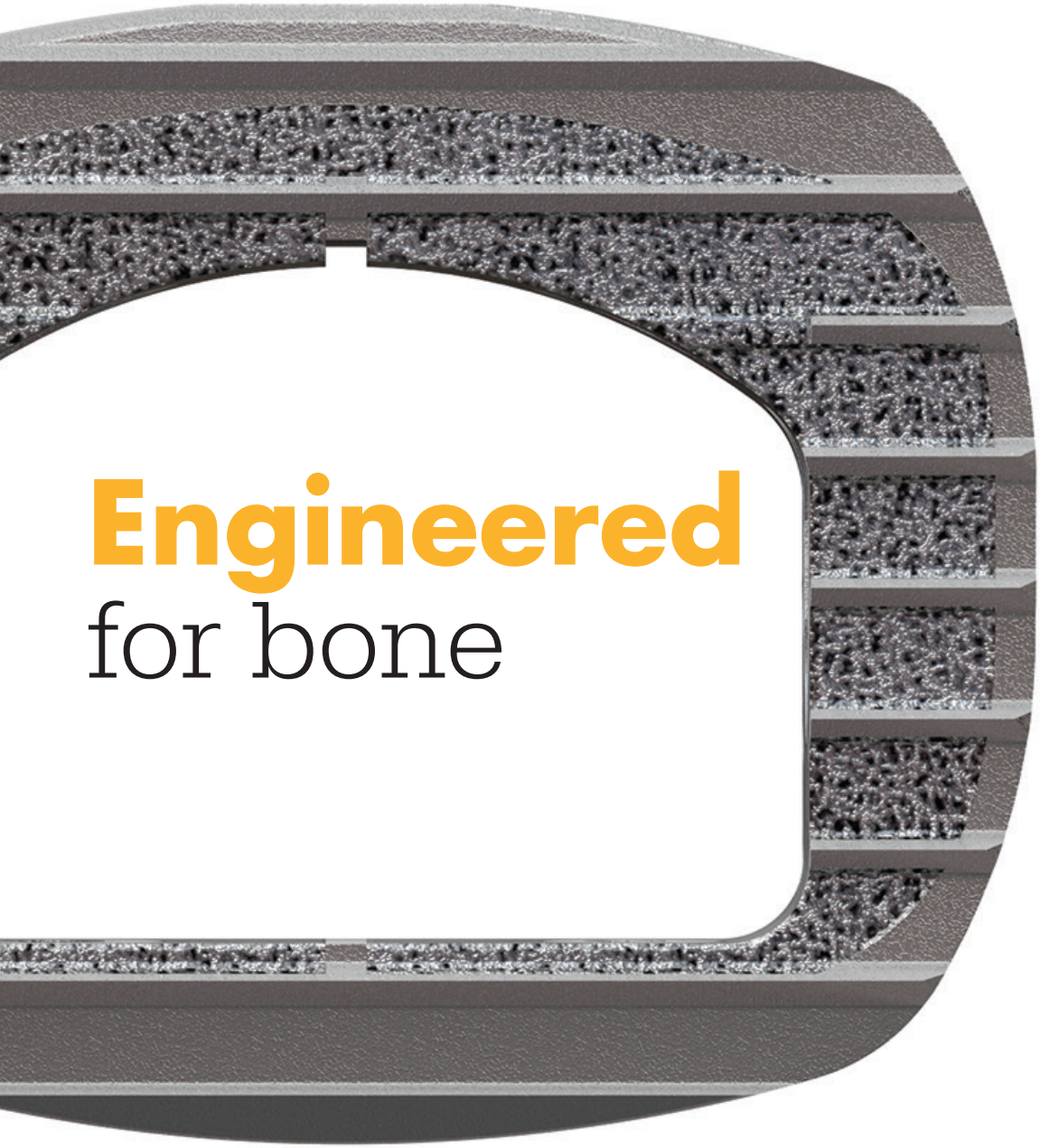
stryker

Tritanium® C
Anterior Cervical Cage



Engineered
for bone

Featuring Tritanium In-Growth Technology[1]:

Built to fuse™

Technical summary

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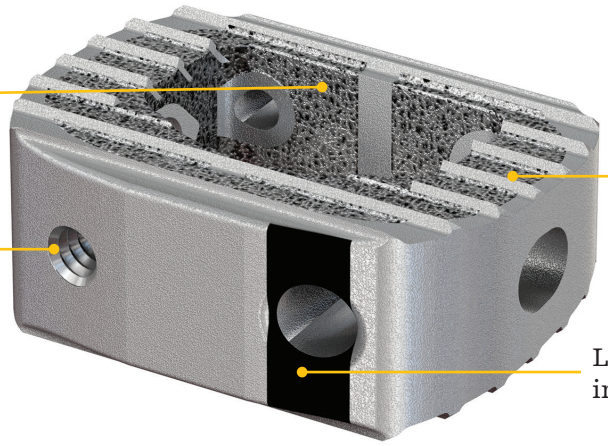
Tritanium C Cage
design overview

The Tritanium C Anterior Cervical Cages are hollow, titanium alloy (Ti-6Al-4V) interbody fusion devices intended for use as an aid in spinal fixation in the cervical spine. The Tritanium C Anterior Cervical Cages are offered in a variety of footprints, heights and lordotic angles designed to adapt to a variety of patient anatomies.

Tritanium C Anterior Cervical Cage design

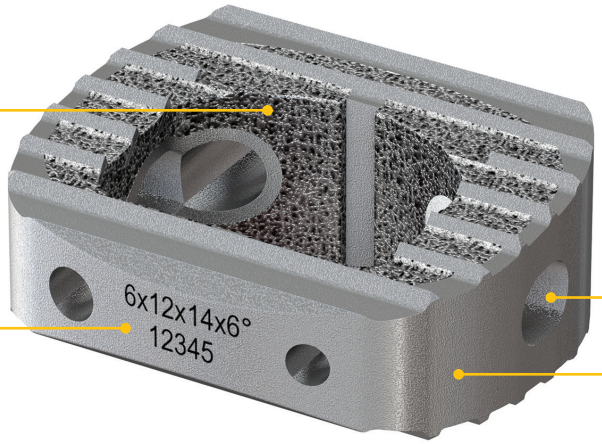


Large central graft window maximizes bone graft volume

Threaded inserter attachment for rigid inserter-to-cage connection

Solid-tipped, precisely angled serrations designed for bidirectional fixation and to maximize surface area for endplate contact with the cage

Laser marking verifies proper inserter attachment



Highly porous titanium alloy material throughout cage

Smooth posterior nose facilitates cage insertion

Lateral windows to reduce stiffness of cage and aid in visualization of fusion

Thin layer of solid material surrounding cage provides smooth insertion

Tritanium C Cage technical data

Material	Titanium alloy
Mean porosity range	55-65%
Mean pore size range	400-500µm
Pore size range	100-700µm

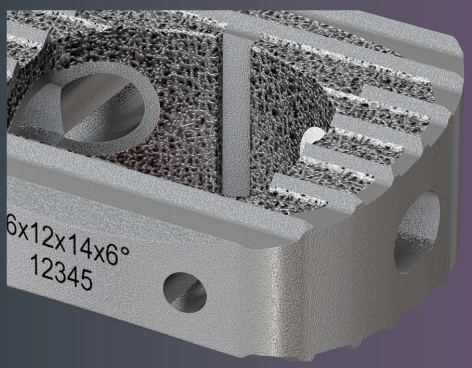
Footprint	Lordotic option	Heights
12 x 14mm	6°	5 to 9mm
14 x 17mm	6°	5 to 9mm
	10°	6 to 8mm

Open architecture

The large central and lateral windows of the Tritanium C Cage are designed to reduce the overall stiffness of the cage, helping to prevent stress-shielding. The large central graft windows allow for maximized bone graft volume inside the cage and the lateral windows allow visualization on CT and X-ray. Cages with an open architecture have also been shown to have lower rates of subsidence than closed cages[2,3].

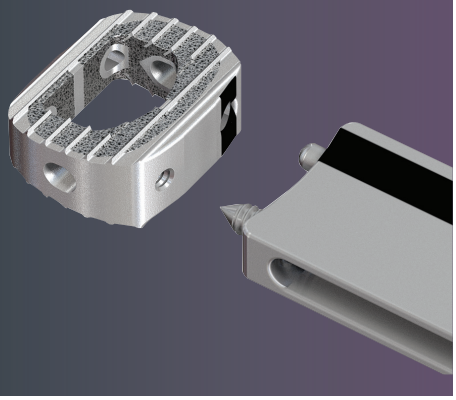
Tapered nose

The smooth tapered nose of the Tritanium C Cage is designed to facilitate insertion into the disc space, while a thin layer of solid material on the sides of the cage helps reduce the chance of the cage catching on soft tissue during insertion.

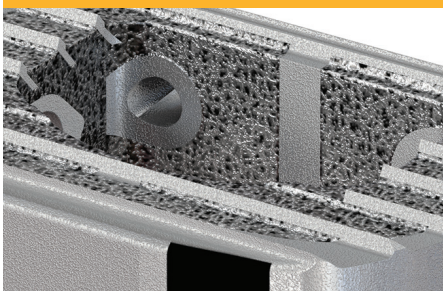


Instrumentation

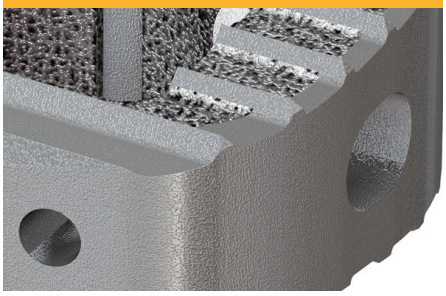
The threaded inserter connection allows for rigid engagement and control during insertion.



Large central graft window



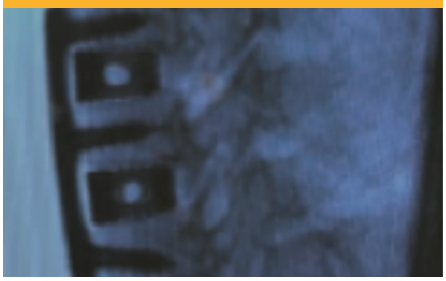
Large lateral graft windows



The Tritanium C Cage is clearly visible on CT and X-ray images

CT

X-ray

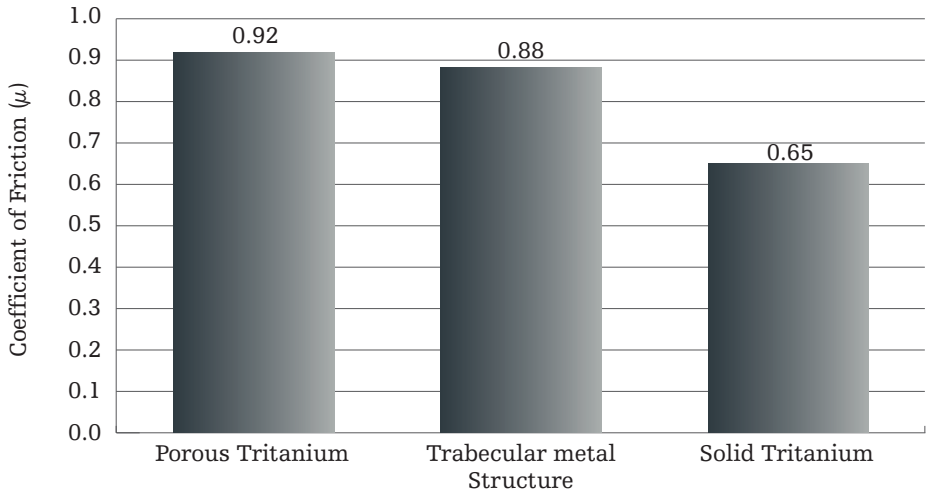


Images taken from a cadaveric study[4].

Initial stability

The unique pore structure of the Tritanium In-Growth Technology[1] gives rise to peaks and troughs at the surface of the material, meaning that the porous Tritanium C Cage has a high coefficient of friction and grips the bone to promote initial stability[6].

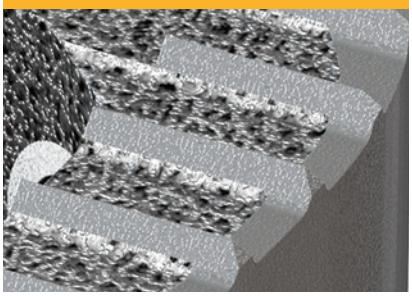
Porous Tritanium demonstrated a higher coefficient of friction than trabecular metal[5].



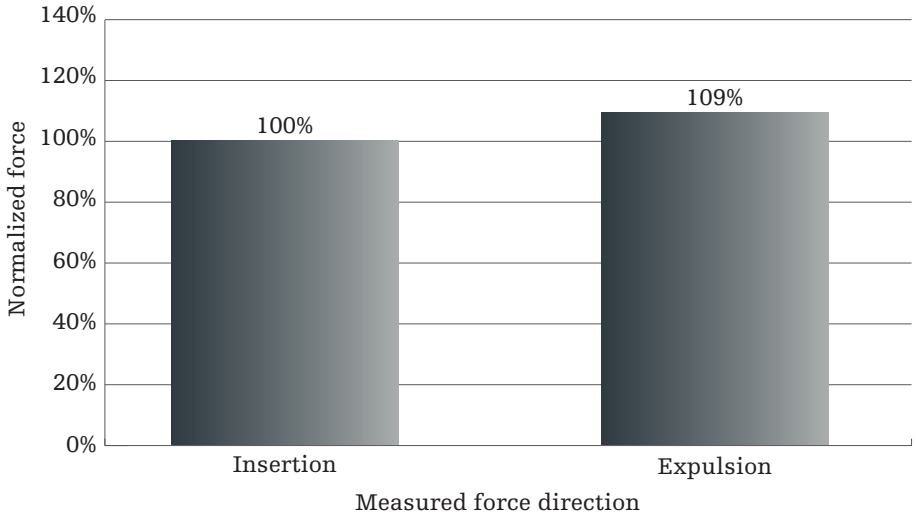
Precisely angled teeth

The precisely angled teeth of the Tritanium C Cage are designed to allow for bidirectional stability[6]. With a smooth tip designed to aid movement across the vertebral endplates, the teeth are angled such that the expulsion force is greater than the insertion force[6].

Precisely angled teeth



The expulsion force of the Tritanium C Cage was found to be 9% greater than the insertion force[6].



Insertion and expulsion testing was performed as per ASTM F04-25-02-02.

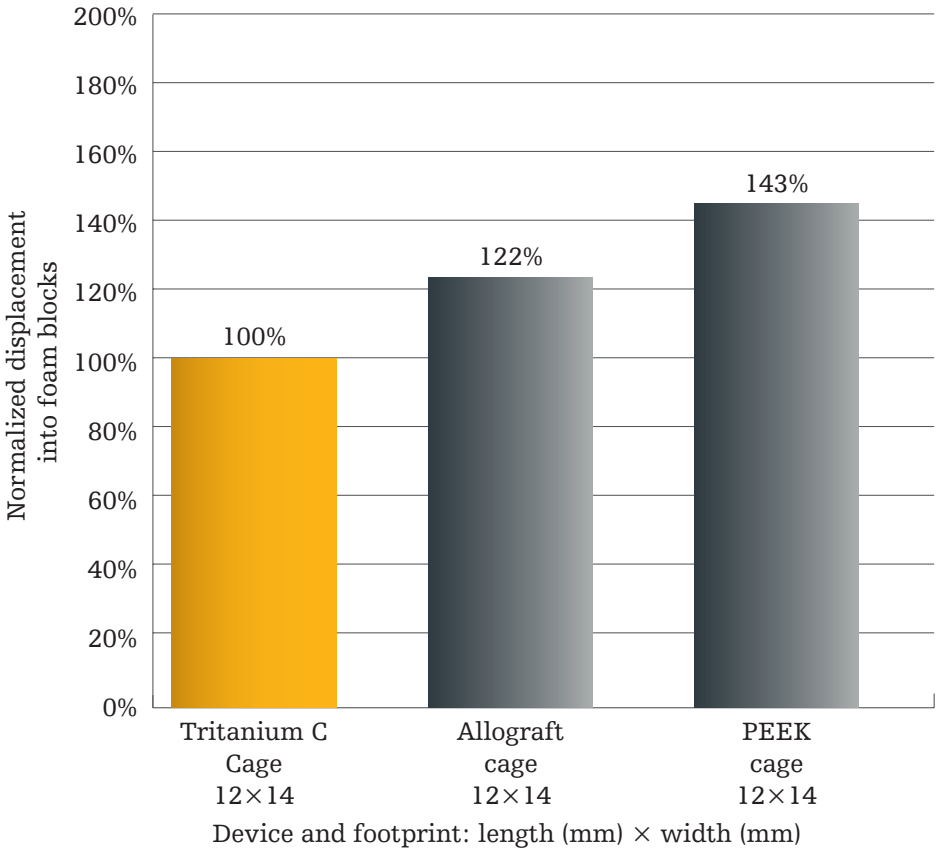
Developed to **minimize subsidence**[2]

Subsidence is a known concern with any interbody fusion device. In addition to bone quality, endplate preparation and cage position within the disc space, features of the device itself can help to minimize subsidence.

Features of the Tritanium C Cage that are designed to minimize subsidence[2]:

- Optimized cage geometry
- Maximized surface area
- Precisely engineered material modulus

The Tritanium C Cage demonstrated better resistance to subsidence than other commercially available cervical interbody cages constructed out of different materials[2].



Subsidence was measured at 100N of compressive force. Testing was performed per ASTM F2267.

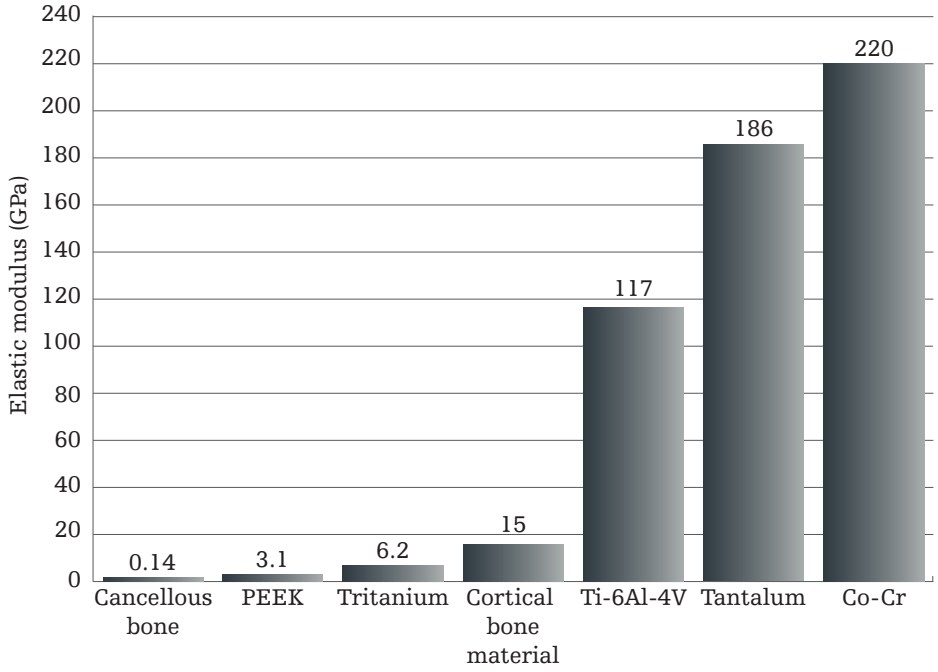
Optimized cage geometry

The Tritanium C Cage was designed with **large central** and **lateral graft windows** to reduce the overall stiffness of the cage[2] and **developed to minimize subsidence**.

Maximized surface area

The **superior and inferior teeth of the Tritanium C Cage** have been designed to maximize the total surface area of the device in contact with bone, which helps to normalize the load transmission and minimize subsidence[2,6].

Tritanium demonstrated an elastic modulus lower than that of other materials[7].



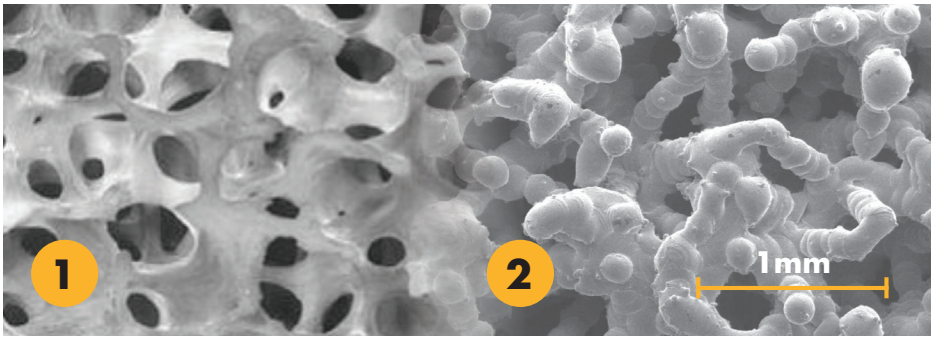
Precisely engineered material modulus

The **porous nature of Tritanium** gives it an elastic modulus that falls between cancellous and cortical bone, the two types of bone that form vertebral bodies[7].

Tritanium In-Growth Technology[1]

Stryker's proprietary Tritanium In-Growth Technology, used to build the Tritanium PL and C Cages, has been designed for bone in-growth and biological fixation[1]. The unique porous structure is designed to create a favorable environment for cell attachment and proliferation[8,9] and may be able to wick or retain fluid when compared to traditional titanium material[10]. Inspired by the microstructure of cancellous bone,[9] and enabled by AMagine, Stryker's proprietary approach to implant creation using additive manufacturing, this technology is deliberately designed for fusion.

Cancellous bone **Tritanium**



1 Cancellous bone characteristics[9]

- Average pore diameter of cancellous bone = 1mm
- Average porosity of cancellous bone = 50–90%

2 Tritanium material characteristics[11†]

- Randomized pore sizing designed to mimic cancellous bone
  - Pore size range: 100–700μm
  - Mean pore size range: 400-500μm
- Interconnected pore structure from endplate to endplate
  - Mean porosity range: 55-65%

† In spinal implants

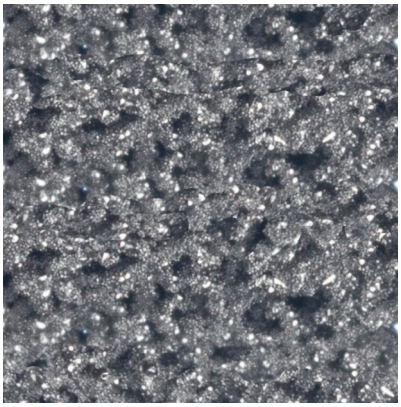
Long-term stability

Tritanium In-Growth Technology has precise and randomized pore formation, **designed to mimic cancellous bone** in order to optimize integration into surrounding tissue[9]. This technology has been created to optimize bone in-growth in spinal procedures, with a **mean pore size range of 400-500μm**. Pores greater than 300μm in size have been shown to advance capillary formation, leading to direct osteogenesis[9].

Tritanium In-Growth Technology has been engineered to have a **mean porosity range of 55-65%**. This degree of porosity leads to an interconnected porous structure that has been shown to stimulate the growth of new bone tissue into the pores[12].

Biological fixation

Investigations focused on the properties of various medical grade materials have been evolving in an effort to provide clinicians with information to assist with orthopaedic surgical procedures. Several studies that examined differences in cellular response to variations in surface roughness for titanium alloys found that roughened titanium alloy demonstrated an increase in osteoblast differentiation and a reduction in osteoclast activity[13,14]. Furthermore, the roughened titanium alloy surfaces demonstrated increased level of bone morphogenetic factors, creating an osteogenic environment that may lead to faster bone growth[14]. With this information in mind, Stryker has carefully and purposefully developed the proprietary Tritanium In-Growth Technology, which is a novel highly porous titanium alloy material.



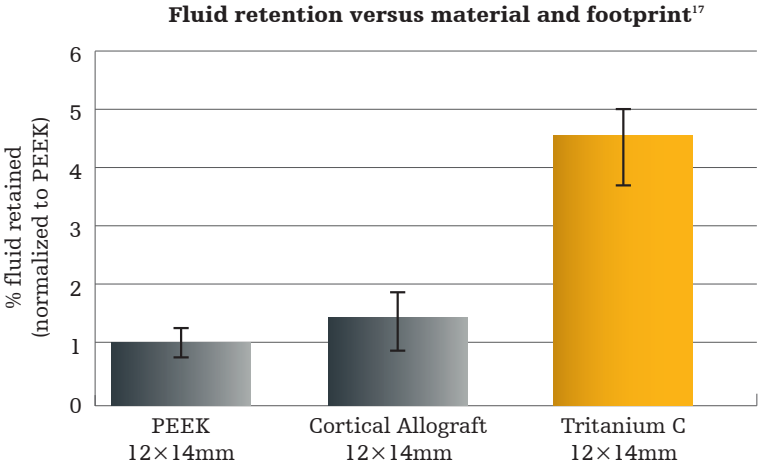
Designed to wick

Tritanium material may be able to wick or retain fluid in comparison to traditional titanium material[10]. Tritanium material demonstrated the ability to wick fluid into the porous structure under specified conditions during an experiment. It also absorbed and held fluid inside the porous structure[10].

Why is this important?

- Wicking, synonymous with capillary action, allows for the distribution of nutrients even against gravity[15,16].
- Wicking, synonymous with capillary action, may lead to the migration and attachment of cells[15].

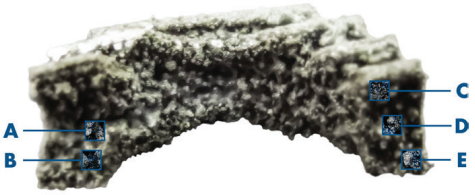
The Tritanium C Cage demonstrated it absorbed 3 times more bone marrow aspirate (BMA) than allograft and 4 times more BMA than PEEK in an in-vitro study [17]

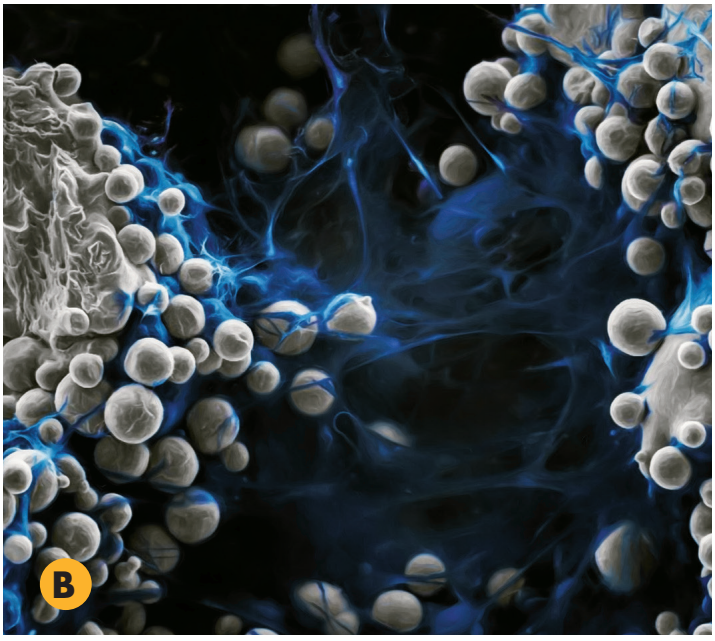


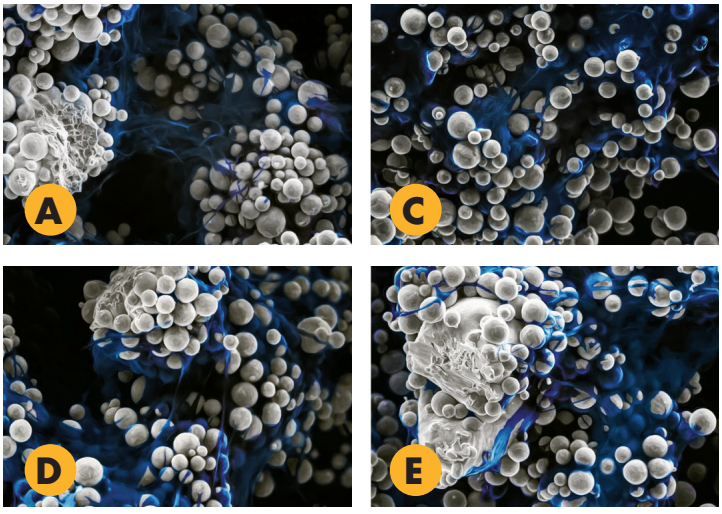
This experiment was performed using heparinized porcine bone marrow aspirate. No correlation to human clinical outcomes has been demonstrated or established.

Designed to create a favorable environment for cells[8,9]

A coupon built with Tritanium In-Growth Technology demonstrated that osteoblasts (bone cells) **infiltrated, attached** to and **proliferated** on the porosity of the Tritanium technology[8]. The unique porous structure is designed to create a favorable environment for cell attachment[8,9].







● - Osteoblasts ● - Tritanium In-Growth Technology

Normal human osteoblast cells were used for in-vitro cell studies. No correlation to human clinical outcomes has been demonstrated or established.

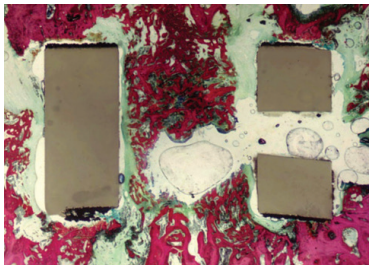
* Image depicts a sample built with Tritanium Technology used for in vitro cell studies. The sample was designed to mimic a generic interbody cage with an open graft window. This is not an implantable device.

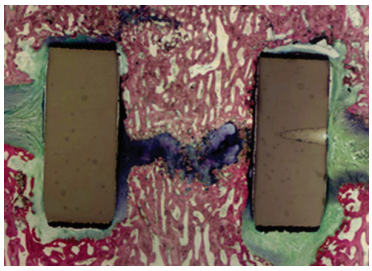
Designed for in-growth

Stryker's Tritanium In-Growth Technology has been designed for bone in-growth and biological fixation[1]. As shown in Stryker's two level lumbar interbody fusion study in an ovine model, both quantitative and qualitative image assessments confirmed that the Tritanium PL Cage resulted in bone in-growth at both the 8- and 16-week follow-up time points, however correlation to human clinical outcomes has not been demonstrated or established[18].

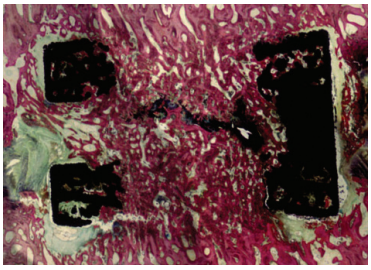
PEEK Cage

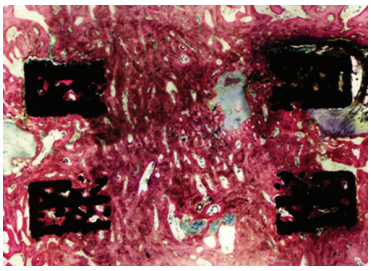
Ti Plasma Sprayed PEEK Cage





Tritanium PL Cage

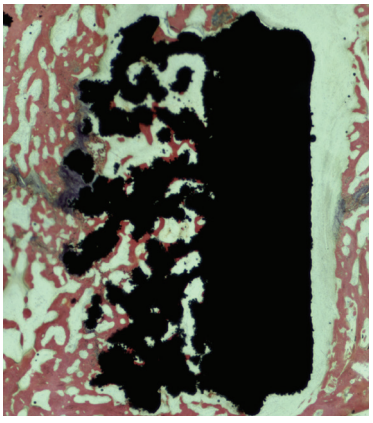




8 weeks post-op
in an ovine model[18]

16 weeks post-op
in an ovine model[18]

Tritanium C Cage



8 weeks post-op
in an ovine model[19]

Sagittal view. Correlation to human clinical outcomes has not been demonstrated or established. This report reflects interim data and is subject to change until release of the final study report.

Material characteristics for Tritanium In-Growth Technology

Material characteristics	Tritanium technology	Exhibits characteristic
Strong, stiff and biocompatible material[20]	• Made from titanium alloy	•
Highly porous material[9,21,22] Porosity> 46% Average pore diameter> 300µm	• Mean porosity range: 55-65% • Pore diameter range: 100-700µm • Mean pore size range: 400-500µm	•
Interconnected porosity[23]	• Porosity on superior and inferior surfaces and within internal walls	•
Porous architecture reflective of bone composition[9]	• Tritanium material consists of random interconnected architecture with rugged, irregular pore sizes and shapes that are designed to mimic cancellous bone	•
Roughened surface[20,24]	• Coefficient of friction = .92	•
Manufacturing process capable of reproducible randomization	• Utilizes proprietary Additive Manufacturing technique to produce completely randomized yet reproducible porous structure	•
Ability to wick and retain fluid[25]	• Tritanium material may be able to wick or retain fluid in comparison to traditional titanium material[10]. Tritanium material demonstrated the ability to wick fluid into the porous structure under specified conditions during an experiment. It also absorbed and held fluid inside the porous structure[10] • The Tritanium C Cage demonstrated it absorbed 3 times more bone marrow aspirate (BMA) than allograft and 4 times more BMA than PEEK in an in-vitro study[17]	•
Realistic environment for cell growth[26]	• A coupon built with Tritanium In-Growth Technology demonstrated that osteoblasts (bone cells) infiltrated, attached to and super proliferated on the porosity of the Tritanium technology[8]. The unique porous structure is designed to create a favorable environment for cell attachment[8,9]	•

Empowered by **AMagine**

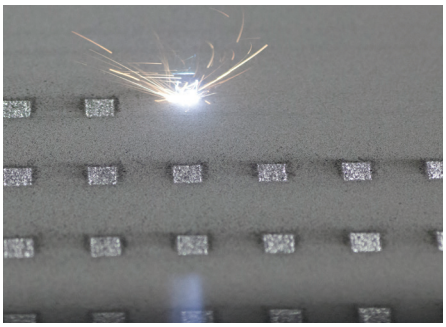
AMagine is Stryker's proprietary approach to implant creation using additive manufacturing (AM). Additive manufacturing allows us to push beyond conventional manufacturing techniques to address design complexity and achieve previously unmanufacturable geometries, but also to deliver the performance, reproducibility and quality you expect from our products.

Stryker's investment in additive manufacturing began in 2001 and, since then, Stryker has collaborated with leading universities in Ireland and the UK to industrialize 3D printing for the healthcare industry.

The AMagine Institute, Stryker's new global technology development center/hub located in Cork, Ireland, is the world's largest additive manufacturing facility for orthopaedic implants. Among the most advanced AM facilities of its kind, it is where bright ideas are transformed into exciting new implants.

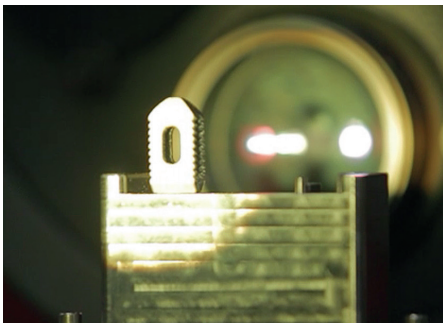
AMagine, which incorporates hundreds of quality checks per batch, enables us to design and build the Tritanium C and PL Cages with pinpoint precision, optimizing every property of the device, from pore size and porosity to shape and surgical features, for use in spinal surgery[27].

Originally launched for hip and knee implants, Stryker's Tritanium technology has been proven in over 10 years of clinical experience with more than 300,000 orthopaedic devices implanted[27].



Built with laser precision, layer by layer[27]

AMagine Institute



Hundreds of quality checks are utilized to ensure precise design in every batch

12

References

[1] PROJ 43909 | Tritanium technology claim support memo
[2] PROJ0000054457 | Tritanium C subsidence marketing memo
[3] Abbushi A, Cabraja M, Thomale UW et al. The influence of cage positioning and cage type on cage migration and fusion rates in patients with monosegmental posterior lumbar interbody fusion and posterior fixation. Eur Spine J. 2009;18(11):1621–8
[4] PROJ0000054459 | Tritanium C implant imaging marketing memo
[5] Coefficient of friction memo PROJ 44960
[6] PROJ0000054458 | Tritanium C insertion and expulsion marketing memo
[7] PROJ42624 | Tritanium PL subsidence memo
[8] RD0000053710 | Tritanium cell infiltration and attachment experiment
[9] Karageorgiou V, Kaplan D. Porosity of 3D biomaterial scaffolds and osteogenesis. Biomaterials 2005;26:5474–91
[10] RD0000050927 | Tritanium material capillary evaluation
[11] DHF0000053171
[12] Nouri A, Hodgson PD, Wen C. Biomimetic Porous Titanium Scaffolds for Orthopedic and Dental Applications. In: Mukerjee A, ed. Biomimetics Learning from Nature. Croatia: InTech; 2010
[13] Olivares-Navarrete R, Hyzy SL, Slosar PJ et al. Implant materials generate different peri-implant inflammatory factors: polyether-ether-ketone promotes fibrosis and microtextured titanium promotes osteogenic factors. Spine. 2015;40(6):399–404
[14] Navarrete R, Hyzy SL, Gittens RA, et al. Rough titanium alloys regulate osteoblast production of angiogenic factors. Spine J. 2013;13(11):1563–70
[15] Hong, M.H.; Kim, Y.H.; Ganbat, D.; Kim, D.G.; Bae, C.S.; Oh, D.S. Capillary action: enrichment of retention and habitation of cells via micro-channeled scaffolds for massive bone defect regeneration. J Mater Sci: Mater Med (2014) 25:1991–2001
[16] Oh, D.S.; Koch, A.; Eisig, S.; Kim, S.G.; Kim, Y.H.; Kim, D.G.; Shim, J.H. Distinctive Capillary Action by Micro-channels in Bone-like Templates can Enhance Recruitment of Cells for Restoration of Large Bony Defect. Journal of Visualized Experiments (2015) 103, e52947
[17] RD0000053906 | Tritanium cervical competitive wicking comparison
[18] Pre-clinical study final report, SRL 15-02 / Stryker -02-15
[19] RD0000054287 Tritanium-C Sheep Study 8-week Interim Report
[20] Carlos Oldani and Alejandro Dominguez (2012). Titanium as a Biomaterial for Implants. Recent Advances in Arthroplasty. Dr. Samo Fokter (Ed.). ISBN: 978-953-307-990-5. InTech
[21] Kujala S, Ryhänen J, Danilov A et al. Effect of porosity on the osteointegration and bone ingrowth of a weight-bearing nickel–titanium bone graft substitute. Biomaterials. 2003;24(25):4691–7
[22] Bobyn JD, Pilliar RM, Cameron HU et al. The optimum pore size for the fixation of porous-surfaced metal implants by the ingrowth of bone. Clin Orthop Relat Res. 1980;150:263–70
[23] Simon JL, Roy TD, Parsons JR et al. Engineered cellular response to scaffold architecture in a rabbit trephine defect. J Biomed Mater Res A. 2003;66(2):275–82
[24] Deligianni DD, Katsala N, Ladas S et al. Effect of surface roughness of the titanium alloy Ti-6Al-4V on human bone marrow cell response and on protein adsorption. Biomaterials. 2001;22(11):1241–51
[25] Functional and biocompatible intervertebral disc spacer containing elastomeric material of varying hardness
[26] M. J. Cooke; Enhanced cell attachment using a novel cell culture surface presenting functional domains from extracellular matrix proteins. Cytotechnology. 2008 Feb; 56(2): 71–79
[27] Data on file, Stryker's Spine division

Spine Division

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. The products depicted are CE marked according to the Medical Device Directive 93/42/EEC. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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