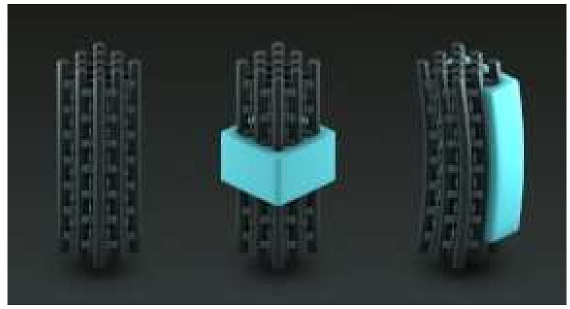
What is a Composite Material?



Composite materials are in essence a combination of two materials with different chemical properties that only mix on a macroscopic level. The individual components remain physically distinct, the resulting composite structure behaves as one with superior mechanical properties.

Many high-performance composite materials are designed by embedding continuous or fragments of carbon fibres in a host polymer matrix.

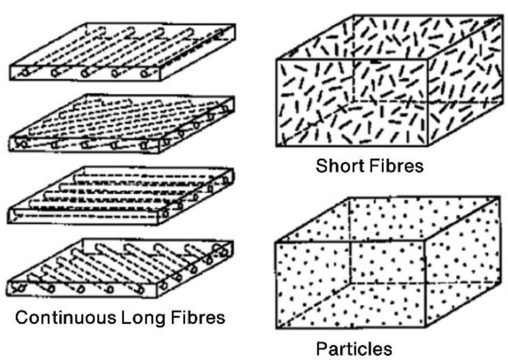
What roles do the Fibres and Matrix play?

The structural properties of composite materials depend primarily on the choice of the fibre reinforcement.

By orienting carbon fibre bundles in the direction of the primary load pathway, composites can be designed for specific mechanical properties such as strength and stability while allowing for complex load-bearing thin-wall geometries.

The resin matrix instead holds the fibres in place, transfers load between fibres, gives the composite material its outer contour and determines the surface properties.

What is ostaPek®?



ostaPek® is a Coligne proprietary carbon composite material, made up of 67% long carbon fibres embedded in a 33% high-performance polymer PEKEKK matrix.

The long carbon fibres allow for programmability of the material depending on the use case.

PEKEKK has a noticeably higher strength level and overall stability compared to PEEK.

Radiolucency

ostaPek® carbon composite material is 100% radiolucent and therefore allows for clear post-operative radiological visual assessment and treatment.

Biological Potential / Osteophilic Properties

Carbon composite spine implants show five times more cell growth compared to PEEK[1]. Human osseous cells are distributed continuously and homogeneously on the

[1] G Barbanti Brodano, C Di Bona, A Gasbarrini, M Tognon, S Boriani, P Parisini: Carbon fiber reinforced polymer (CFRP) cage induces better cells adhesion, spreading and proliferation than PolyEtherEtherKetone (PEEK) cage. European Cells and Materials. 2007; 14(Suppl.1):19

carbon composite implant surfaces compared to multi-layered discontinuous cell clusters on PEEK.

In comparison to titanium surfaces, ostaPek® implants show improved results in terms of cellular density and viability of human osseous cells, without needing a coating[2]. Moreover, osseointegration in terms of percent bone area for distances from the implant surface of 0.1mm is four times higher for carbon-fibre-reinforced composite compared to Titanium[3].

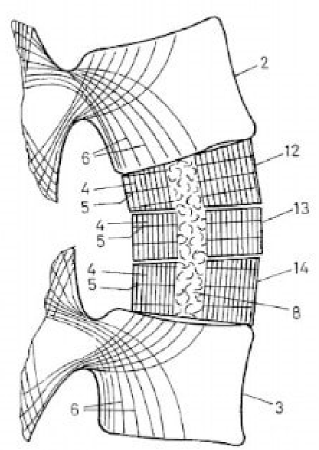
Additional info – The tests presented in the 2nd study quoted above were performed prior to release to market. They show strong scientific evidence and satisfy even the most recent regulatory requirements as proof of safety. Over and above having proven biocompatibility they also demonstrate that bone cells adhere to ostaPek® carbon composite even better than to Titanium, without any coating required.

Quotes from selected surgeons

Spine surgeon MD, Dr. Mark L. Crawford, Norton Hospital, Paducah, Kentucky, *"With an ostaPek fusion plate, you see the formation of bone directly beneath and next to the composite implant."*

"I have been using ostaPek composite cages for a number of years. Following my patients, I have been impressed with the radiographic image quality of the fusions. There are x-rays where it seemed like white out was drawn into the cage. That was bone," says Dr. Kevin Lawson, a specialist in spinal surgery based in Saginaw Michigan.

Smart Structural Design



ostaPek® carbon composite spine cages are designed to maximise space for bone graft without compromising mechanical strength and primary stability.

This is possible by engineering specific fibre patterns that follow the direction of the longitudinal forces. ostaPek® implants reproduce the pattern of the trabeculae in the adjacent vertebral bodies to carry the physiological loads. By controlling the fibre orientation, ostaPek® implants can be designed with thin load-bearing walls and large fusion windows creating space for a significantly higher volume for bone graft.

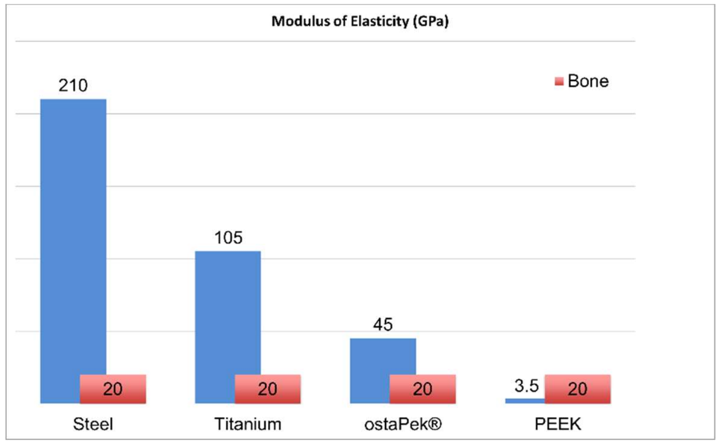
---

[2] MF Sigot-Luizard: Biological evaluation of the ostaPek (carbon PEKEKK) composite used in spinal surgery. Rachis, J Vertebral Pathology, Spinal Surgery. May 2000; 12(1)
[3] R Petersen: Carbon Fiber Biocompatibility for Implants MDPI, Fibers, Jan 2016, 4(1)

Stability & Stimulation

Biomechanical studies tell us what loads an implant must be able to sustain to guarantee both primary stability and to continue to perform until fusion is achieved.

Material sciences tell us the characteristics of the different materials under equal loading conditions[4,5]. With this data in hand, we can design our implants.



ostaPek® carbon composite modulus of elasticity is slightly higher than bone to ensure primary stability and strength throughout the bone fusion mass development, even with a light architecture of the cages.

At the same time, the stiffness of ostaPek® constructs is designed to be significantly lower than steel or titanium to ensure active stimulation of the bone cells during the development of the bone fusion mass without overloading the adjacent levels.

Fatigue Resistance

As spine surgery patients live longer and longer the utility of redundant long carbon fibres for fatigue resistance in spinal constructs is becoming more and more important. ostaPek® carbon composite material is made of 100,000 carbon fibres, fixed in space, and working interdependently.

History & Future

Now passing its 25th year of clinical history with more than 110,000 patients, ostaPek® carbon composite has demonstrated its reliability in the hands of many spinal surgeons for lumbar, thoracic, and cervical spinal fusions performed in Europe and the USA described in numerous publications[6].

ostaPek® proprietary technology has been developed in Boulder, Colorado and manufactured in Switzerland with multiple patents throughout the years[7].

---

[4] J Y Rho, R B Ashman, C H Turner: Young's modulus of trabecular and cortical bone material: ultrasonic and micro tensile measurements. J Biomech. 1993 Feb;26(2):111-9

[5] F Galbuseraa, CM Bellini, F Anasettia, CCiavarroa, A Lovia, M Brayda-Brunoa: Rigid and flexible spinal stabilization devices: A biomechanical comparison Medical Engineering & Physics. 2011; 33:490–496

[6] https://spinenuances.com/documents/publications

[7] https://spinenuances.com/documents/patents

Carbon composite implants are used more and more, the advantages related to radiological follow up and treatment for tumour patients are only starting to emerge as the patients live longer. Based on the outstanding bone fusion results we expect a similar trend for degenerative and trauma indications.

In-house fibre control enables us to tailor ostaPek® for each type of implant or spinal construct, and even potentially change mechanical properties in different regions of the spine without having to change the geometry.