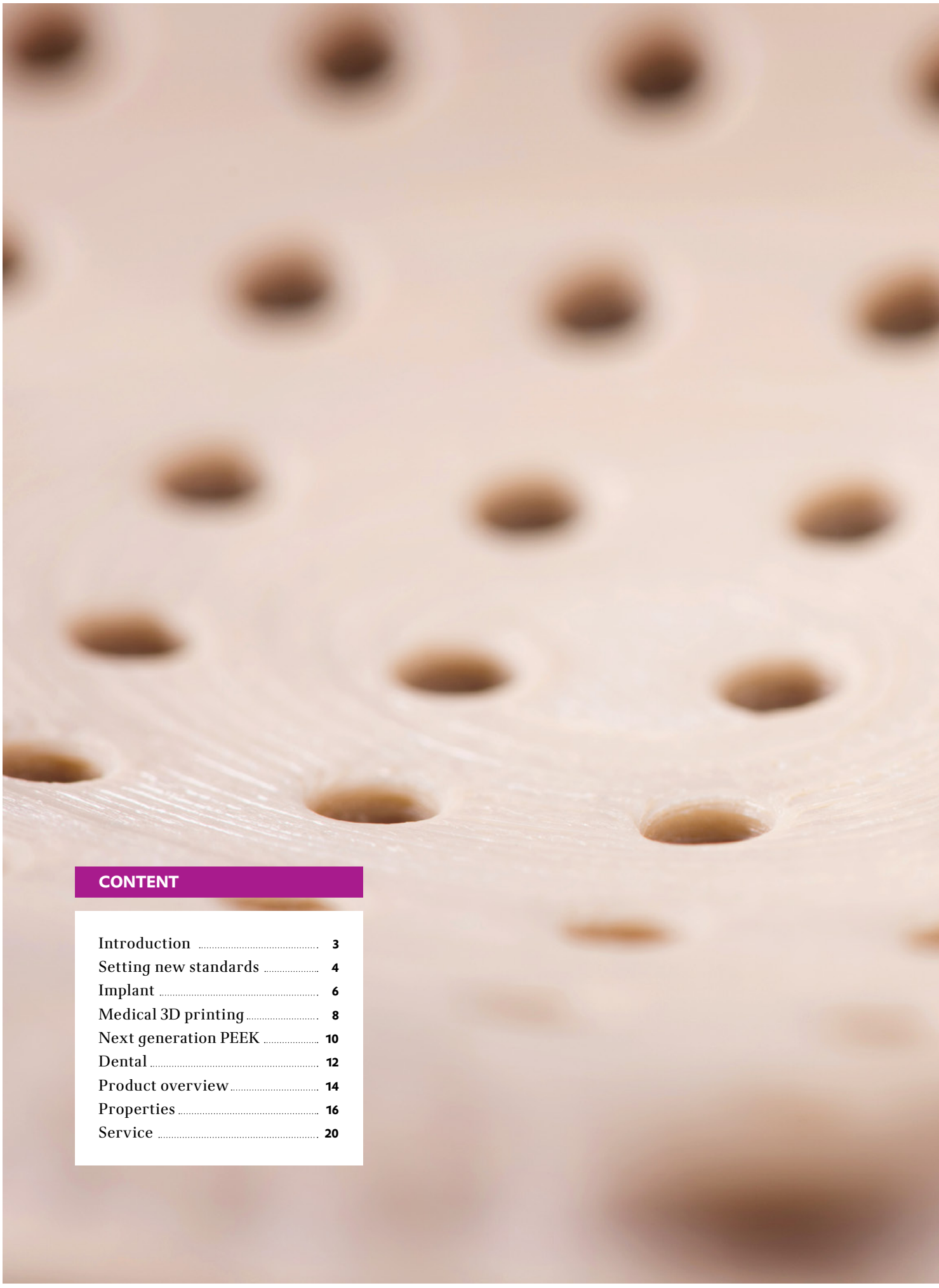
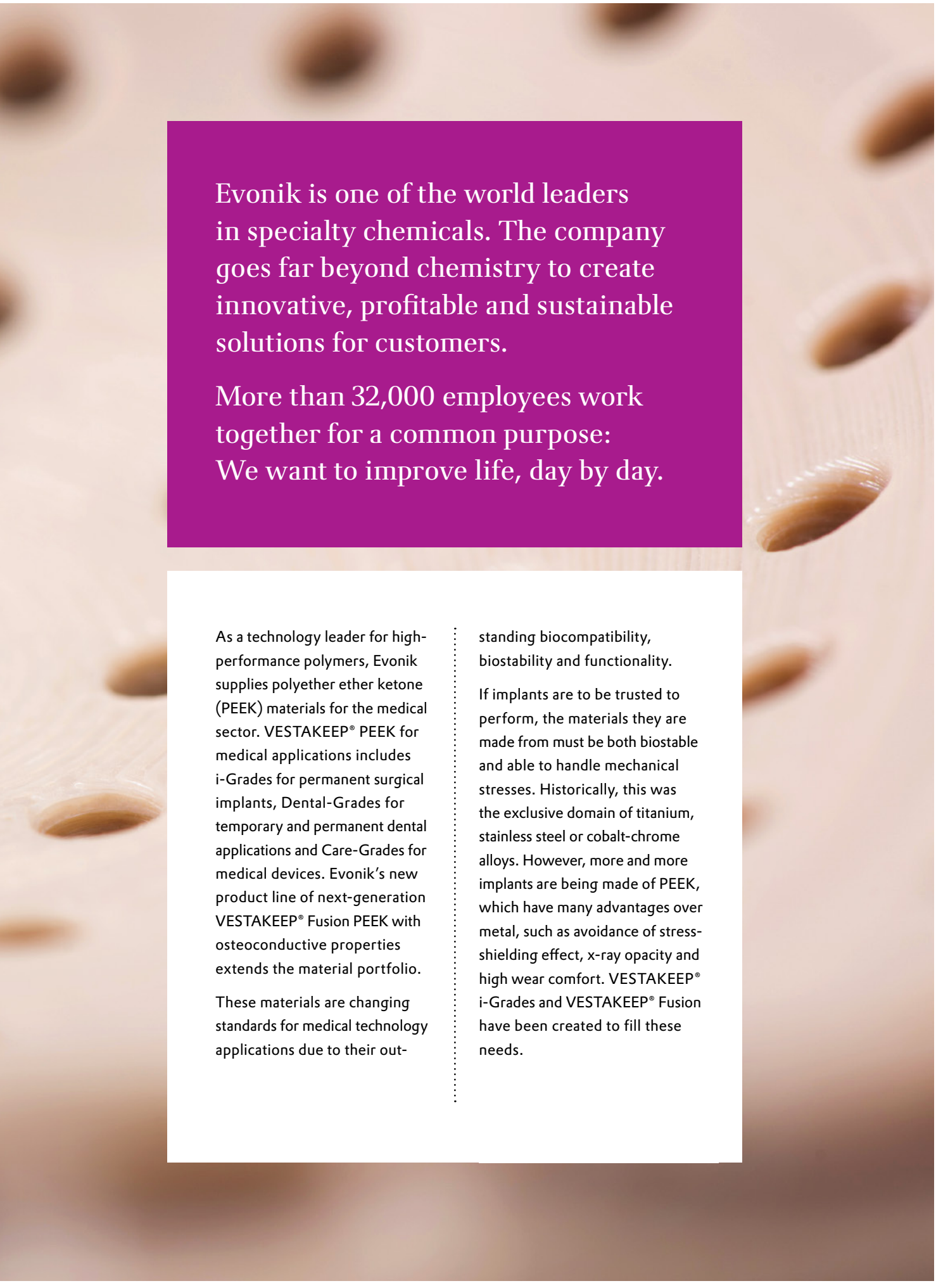
VESTAKEEP®
PEEK

BIOMATERIALS
FOR **MEDICAL**
APPLICATIONS

EVONIK
Leading Beyond Chemistry



CONTENT



Evonik is one of the world leaders in specialty chemicals. The company goes far beyond chemistry to create innovative, profitable and sustainable solutions for customers.

More than 32,000 employees work together for a common purpose: We want to improve life, day by day.

As a technology leader for high-performance polymers, Evonik supplies polyether ether ketone (PEEK) materials for the medical sector. VESTAKEEP® PEEK for medical applications includes i-Grades for permanent surgical implants, Dental-Grades for temporary and permanent dental applications and Care-Grades for medical devices. Evonik's new product line of next-generation VESTAKEEP® Fusion PEEK with osteoconductive properties extends the material portfolio.

These materials are changing standards for medical technology applications due to their outstanding biocompatibility, biostability and functionality.

If implants are to be trusted to perform, the materials they are made from must be both biostable and able to handle mechanical stresses. Historically, this was the exclusive domain of titanium, stainless steel or cobalt-chrome alloys. However, more and more implants are being made of PEEK, which have many advantages over metal, such as avoidance of stress-shielding effect, x-ray opacity and high wear comfort. VESTAKEEP® i-Grades and VESTAKEEP® Fusion have been created to fill these needs.

SETTING NEW STANDARDS

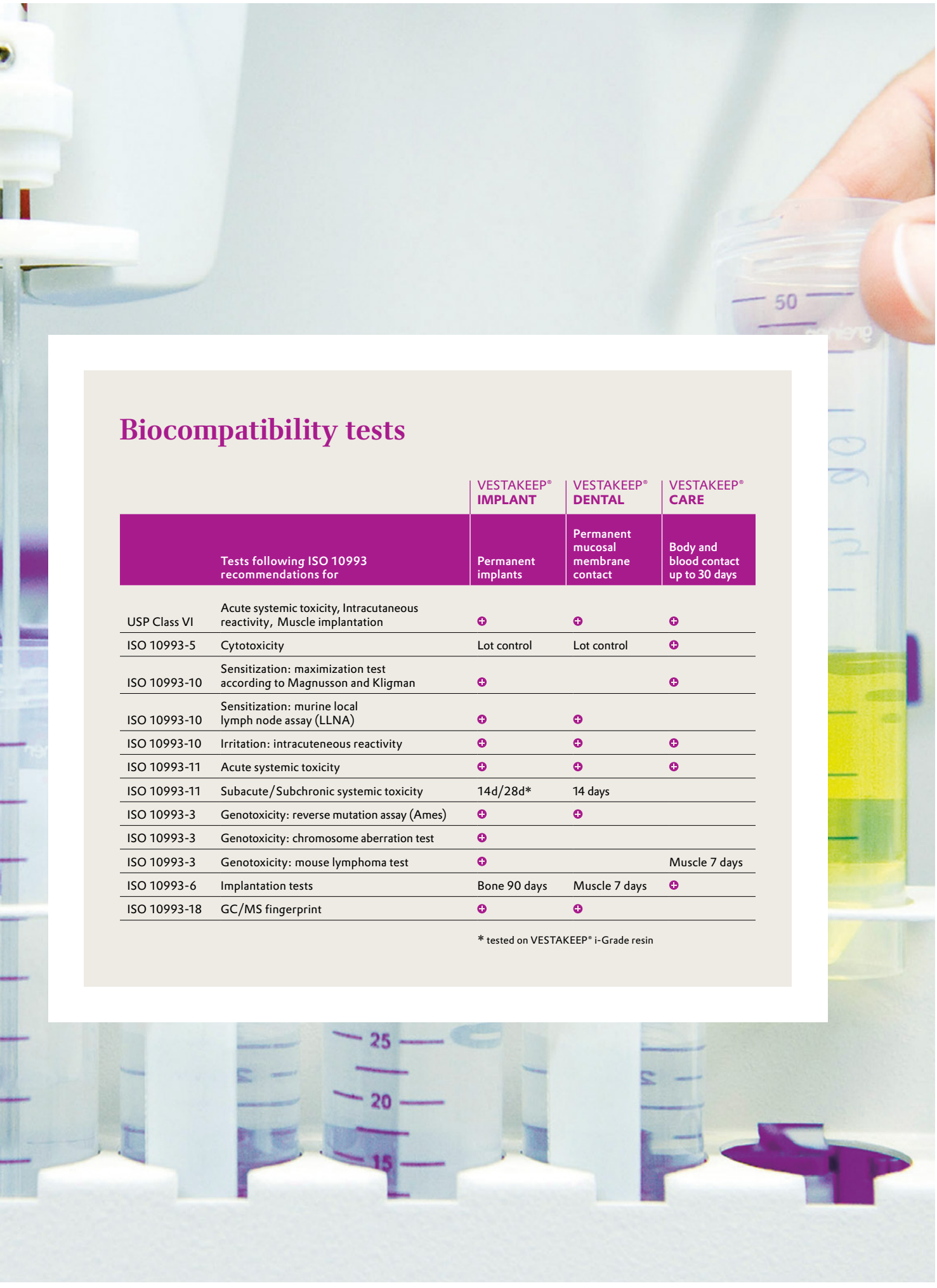
Customized for the human body

Biocompatibility, biostability and safety are all major criteria when a material is selected for a medical device or a medical implant.

In an extensive testing programme run by independent certified labs, biocompatibility has been tested according to USP <88> Class VI and following ISO 10993-1:2009 guidelines. The test results attest of VESTAKEEP® excellent biocompatibility and biostability, which are principally attributed to the polymer's high chemical resistance and thermal stability.

VESTAKEEP® PEEK provides convincing advantages like:

- → Biocompatibility
- → Biostability
- → Sterilization compatible
- → Modulus similar to bone
- → Wear comfort due to light weight and low thermal conductivity
- → Lower stress-shielding effect
- → No x-ray artifacts and/or adjustable opacity
- → Metal-free
- → Low water absorption
- → Resistant to chemicals
- → Injection molding and extrusion compatible
- → Good processability and machinability



Biocompatibility tests

		VESTAKEEP® **IMPLANT**	VESTAKEEP® **DENTAL**	VESTAKEEP® **CARE**
	Tests following ISO 10993 recommendations for	**Permanent implants**	**Permanent mucosal membrane contact**	**Body and blood contact up to 30 days**
USP Class VI	Acute systemic toxicity, Intracutaneous reactivity, Muscle implantation	⊕	⊕	⊕
ISO 10993-5	Cytotoxicity	Lot control	Lot control	⊕
ISO 10993-10	Sensitization: maximization test according to Magnusson and Kligman	⊕		⊕
ISO 10993-10	Sensitization: murine local lymph node assay (LLNA)	⊕	⊕	
ISO 10993-10	Irritation: intracuteneous reactivity	⊕	⊕	⊕
ISO 10993-11	Acute systemic toxicity	⊕	⊕	⊕
ISO 10993-11	Subacute/Subchronic systemic toxicity	14d/28d*	14 days	
ISO 10993-3	Genotoxicity: reverse mutation assay (Ames)	⊕	⊕	
ISO 10993-3	Genotoxicity: chromosome aberration test	⊕		
ISO 10993-3	Genotoxicity: mouse lymphoma test	⊕		Muscle 7 days
ISO 10993-6	Implantation tests	Bone 90 days	Muscle 7 days	⊕
ISO 10993-18	GC/MS fingerprint	⊕	⊕	

* tested on VESTAKEEP® i-Grade resin

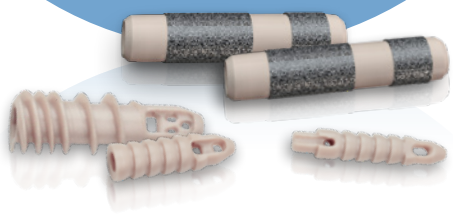
VESTAKEEP®
IMPLANT

VESTAKEEP® i-Grades are Evonik´s solution for permanent implants. They are biocompatible, have excellent mechanical properties and are extremely reliable. The extra high purity and extensive quality measures make VESTAKEEP® i-Grades an ideal material for long-term human implants.

The special combination of performance characteristics of VESTAKEEP® i-Grade PEEK polymers makes them the material of choice for implants. They are used for different fields of application such as spine, sports medicine, cardiovascular, cranial-maxillo-facial, orthopaedics, extremities or pharmacy.

Potential applications

- → spinal cages
- → stents
- → suture anchors
- → access ports
- → heart valves
- → interference screws
- → small joints
- → facial implants for facial bone fractures



X-ray transparency

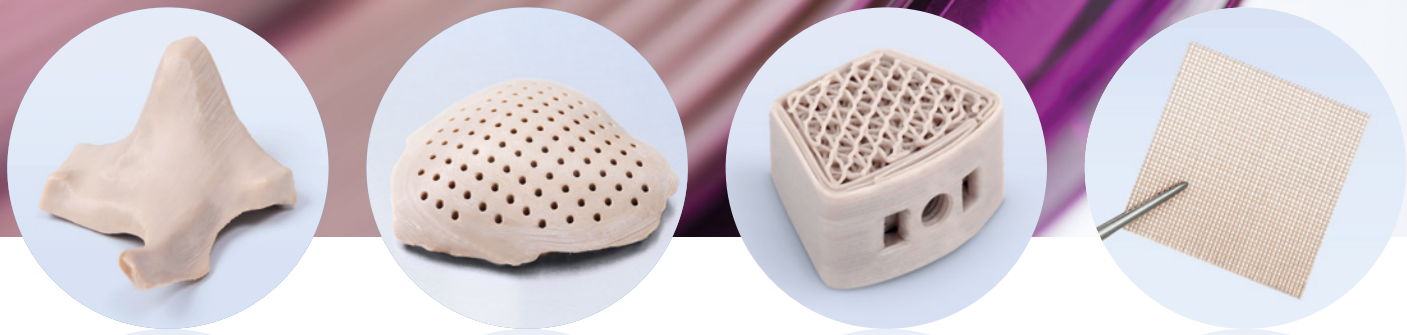
Traditionally, metals have been used in spinal cages and other implants in the human body, but over time the high-performance polymer polyether ether ketone (PEEK) has proven a serious and even more desirable alternative. Metal implants reach their limits when it comes to the imaging methods that physicians use, both during the operation, and to monitor the healing process. Because of their density, metals absorb x-rays and produce artifacts on the radiographic image. PEEK, however, is transparent to x-rays. In cases where the doctor desires to see the implant, x-ray opaque grades of VESTAKEEP® are available.

Elasticity

Another weakness of metals is the modulus of elasticity, which is much higher than that of bone.

The implant assumes a large share of the mechanical load, thereby reducing the stress on the bone. This stress-shielding effect can have far-reaching consequences: Bones need the mechanical stress to be regenerated in the healing process and also remain strong. Elimination of stress may slow down the healing process, and over the years, weaken the bone, resulting in greater susceptibility to bone deterioration and fracture. The elasticity of VESTAKEEP® i-Grade PEEK is closer to cortical bone and has a higher elasticity than metals. This deters the stress-shielding effect on bone and allows for a longer, healthier life.

VESTAKEEP® Filament for medical 3D printing



Medical 3D printing grade

VESTAKEEP® i4 3DF is perfectly suitable for additive manufacturing using fused filament fabrication (FFF) technology.

Advantages of using VESTAKEEP® Filament for additive manufacturing include:

- → Patient specific design and geometry of implants
- → New design opportunities, e.g. porous or hollow structures
- → Less material consumption

The filament is extruded from natural colored, implantable-grade VESTAKEEP® i4 G resin.

The extra high purity and extended quality measures make VESTAKEEP® i-Grade materials an excellent choice for permanent implants. The biocompatibility of VESTAKEEP® i-Grade materials has been tested following ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

Potential applications for the materials include cranio-maxillo-facial (CMF), spinal implants, trauma, and suture anchors for sports medicine.

Test & development grade

VESTAKEEP® i4 3DF-T PEEK Filaments for FFF technology are additionally offered as a cost-efficient testing grade for research and process development purposes. The testing grade i4 3DF-T and the implantable grade VESTAKEEP® i4 3DF are equivalent in terms of processing and mechanical properties. Regulatory approval of medical devices requires supporting documents like biocompatibility reports and other support which is only available for the implantable grade VESTAKEEP® i4 3DF.

More new products

Diameter & packaging

VESTAKEEP® i4 3DF and VESTAKEEP® i4 3DF-T filaments have a diameter of 1.75 mm. They are supplied on spools with 250 g or 500 g.

The spools are based on medical grade plastic TROGAMID®.

The spools are packaged in double bags to facilitate transfer into clean areas.

Ultra-fine powder

VESTAKEEP® i2 UFP10 powder is an unreinforced, medium-viscosity polyether ether ketone ultra-fine powder. The powder is supplied in 15 kg boxes with moisture-proof polyethylene liners or 5 kg buckets with moisture-proof polyethylene liners. VESTAKEEP® i2F UFP10 powder can be processed by compression molding or other technologies and is suitable for fiber composites, e.g. unidirectional carbon fiber layouts. The material is designed for long term implantable medical devices.

The biocompatibility of VESTAKEEP® i-Grade materials has been tested following ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

X-ray visible grade

VESTAKEEP® iC4506 and iC4520 for applications that need x-ray visible implants the PEEK technology offers a radiopaque plastic material based on implantable-grade VESTAKEEP® resin and pharmaceutical-grade barium sulfate.

This product type provides radiographic contrast without the disadvantage of artifact formation as can be the case with other popular materials for surgical implants.

Standard grades contain 6% barium sulfate (iC4506) and 20% barium sulfate (iC4520). Customized barium sulphate contents are available on request.

VESTAKEEP® iC4800 contains biphasic calcium phosphate (BCP) for enhanced bone integration.

In-vitro study

- → Enhanced cell attachment and cell proliferation (>30%)
- → Same excellent biocompatibility as all VESTAKEEP i-Grades

Preclinical study

- → Natural image contrast in x-ray
- → Histology shows dense network of bone growth at implant interface
- → Bone histomorphometry shows ~2-fold enhanced bone apposition
- → Pull-out tests show >2-fold increased implant fixation

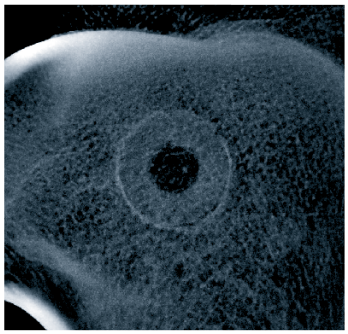
Mechanics & processing

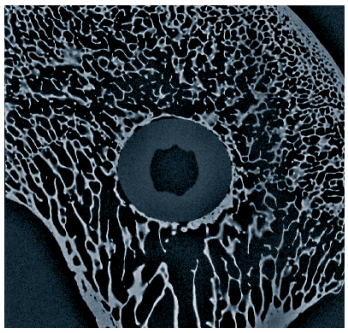
- → E-modulus similar to cortical bone
- → High ductility and impact strength
- → Versatile processing options with bioactive components presented on the surface including injection molding or 3D-printing

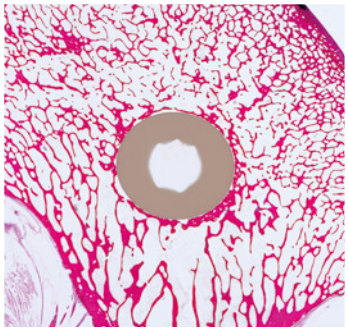
Customization

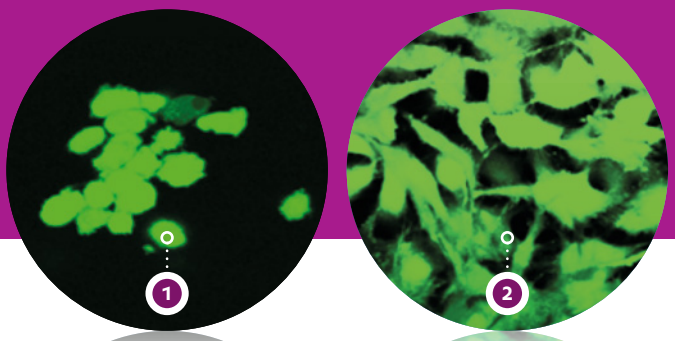
- → Calcium phosphates composition and other additives can be designed according to customer need

We boost the next generation of PEEK by introducing **VESTAKEEP® iC4800** in our new **VESTAKEEP® Fusion product line** for accelerated bone healing.



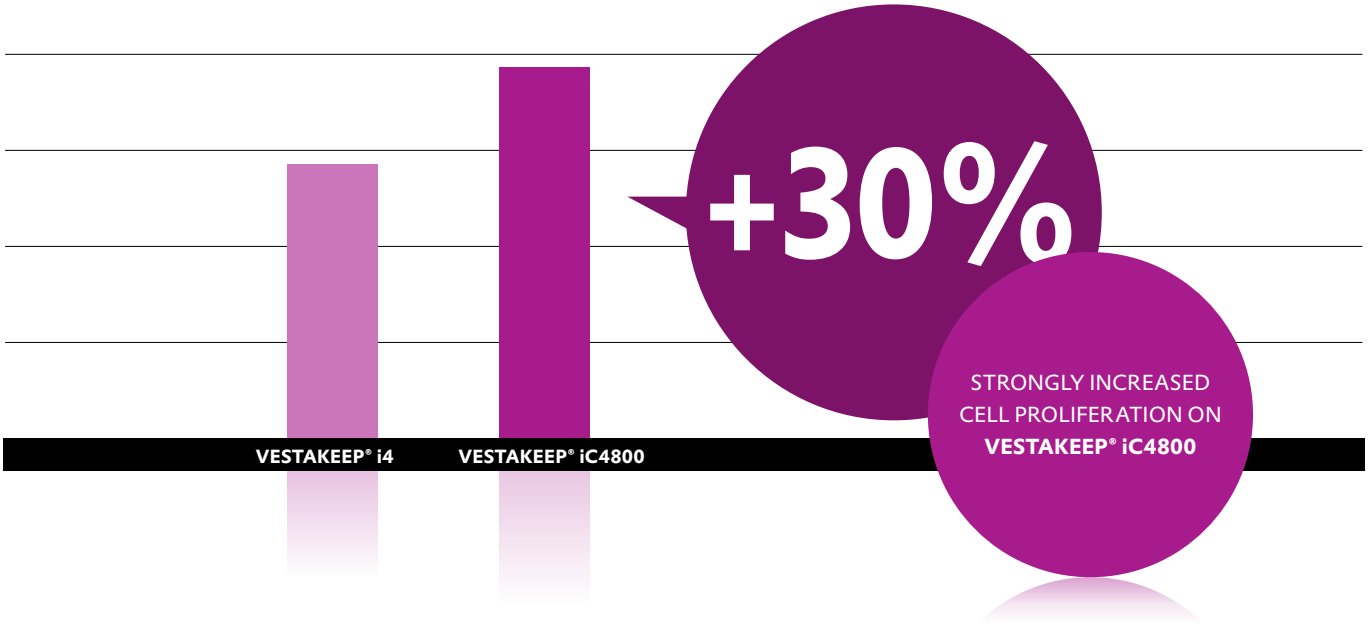




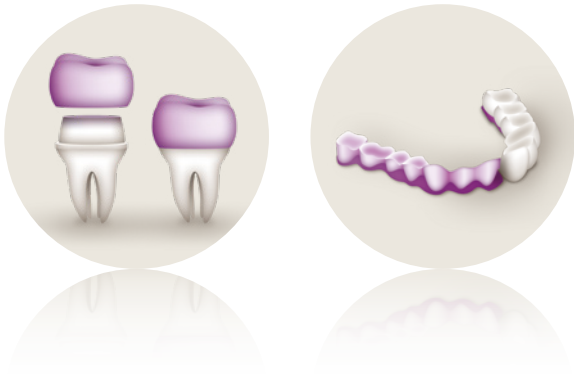


1 **VESTAKEEP® i4**
Round morphology

2 **VESTAKEEP® iC4800**
Extended cell attachment and growth



VESTAKEEP®
DENTAL



In dental technology PEEK provides a metal-free solution for outstanding wear comfort. Potential applications of **VESTAKEEP® Dental in medical devices** are for example crowns, bridges, and removable and permanent dentures alike. PEEK is one of the high level innovative materials in dental technology.

VESTAKEEP® Dental PEEK is a base material for dental products and available in a wide range of natural colors including white pigmented, tooth-colored and gingiva-colored. The selection of colors allows aesthetic solutions.

X-ray opacity

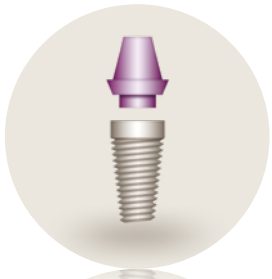
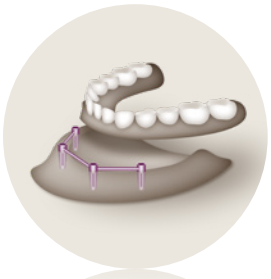
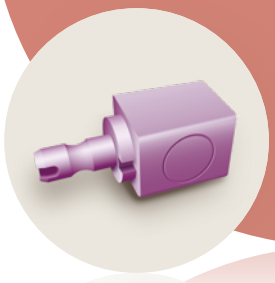
As most other plastics polyether-etherketones exhibit an x-ray absorption close to human tissue. Therefore the materials lack contrast and are invisible in x-ray examinations. Its barium sulphate content renders white VESTAKEEP® Dental DC4430 x-ray opaque. Unlike metals, the material does not generate x-ray artifacts and it is MRT-compatible.

Properties

VESTAKEEP® Dental is a strong, yet flexible material. Its flexibility provides a high wear comfort to patients and facilitates insertion of dental prostheses.

Potential applications

- → abutments
- → partial dentures
- → occlusal splints
- → inlay bridges
- → healing caps
- → dentures (basis)
- → cervical gingiva formers
- → crowns and bridges
- → attachment restorations
- → telescopic crowns
- → CAD/CAM blocks

VESTAKEEP® PRODUCTS

Grades	Resins	Color	Description	Processing
VESTAKEEP® IMPLANT	**VESTAKEEP® i2 G** **VESTAKEEP® i2 P** **VESTAKEEP® i2 UFP10**	natural	• medium viscosity	• injection molding • compounding • compression molding
	VESTAKEEP® i4 G **VESTAKEEP® i4 P**	natural	• high viscosity	• injection molding • compounding • compression molding
	VESTAKEEP® iC4506 G **VESTAKEEP® iC4520 G**	natural	• x-ray opaque • high viscosity	• injection molding
	VESTAKEEP® i4 3DF-T **VESTAKEEP® i4 3DF**	natural	• high viscosity	• additive manufacturing (FFF)
	VESTAKEEP® i5 G	natural	• very high viscosity	• injection molding
	VESTAKEEP® iC4800 G	natural	• osteo-conductive • x-ray opaque • high viscosity	• injection molding
VESTAKEEP® DENTAL	**VESTAKEEP®D4 G**	natural	• high viscosity	• injection molding • extrusion
	VESTAKEEP® DC4420 G	white	• high viscosity	• injection molding • extrusion
	VESTAKEEP® DC4430 G	white	• high viscosity • x-ray opaque	• injection molding • extrusion
	VESTAKEEP® DC4450 G	tooth	• high viscosity	• injection molding • extrusion
	VESTAKEEP® DC4470 G	gingiva	• high viscosity	• injection molding • extrusion
VESTAKEEP® CARE	**VESTAKEEP® M20 G**	natural	• medium viscosity	• injection molding
	VESTAKEEP® M33 G-HP	natural	• high purity • medium viscosity	• injection molding
	VESTAKEEP® M40 G	natural	• high viscosity	• injection molding • extrusion

Delivery forms resins	Stock shapes	Delivery forms stock shapes
Granules • supplied in 1 kg, 5 kg or 10 kg hobbocks with polyethylene liners **Filaments** • supplied with 1.75 mm diameter on spools with 250 g or 500 g **Powders** • supplied in 15 kg boxes with polyethylene liners or 5kg buckets with polyethylene liners	**VESTAKEEP® i4 PL** **VESTAKEEP® i4 R** **VESTAKEEP® iC4506 R** **VESTAKEEP® iC4520 R** **VESTAKEEP® i5 R** **VESTAKEEP® iC4800 R**	**Rods** diameter / standard lengths 6 - 20 mm: 3000 mm 25 - 60 mm: 2000 mm 70 - 100 mm: 1000 mm **Plates** available in different dimensions • thickness up to 60 mm • standard dimension 500 x 1000 mm
Granules • supplied in 25 kg boxes with polyethylene liners (2 x 12.5 kg)	**VESTAKEEP® D4 R** **VESTAKEEP® DC4420 R** **VESTAKEEP® DC4430 R** **VESTAKEEP® DC4450 R** **VESTAKEEP® DC4470 R**	**Rods** diameter / standard lengths 6 mm: 3000 mm 8 mm: 3000 mm 100 mm: 1000 mm **Discs** available in different dimensions • diameter 98.4 mm (with step) • thickness 12 to 30 mm
Granules • supplied in 25 kg boxes with polyethylene liners (2 x 12.5 kg)	**VESTAKEEP® M40 R** **VESTAKEEP® M40 PL**	**Rods** diameter / standard lengths 6 - 20 mm: 3000 mm 25 - 60 mm: 2000 mm 70 - 100 mm: 1000 mm **Plates** available in different dimensions • thickness up to 60 mm • standard dimension 500 x 1000 mm

Delivery Forms

F ..... Filament
G ..... Granules
P ..... Powder
UFP ..... Ultra fine powder
PL ..... Plates
R ..... Rods

Other dimensions of stock shapes are available on request.

VESTAKEEP® PROPERTIES

VESTAKEEP® grades for implants, dental applications and medical devices **are changing standards** for medical technology applications.

Delivery Forms

- F ..... Filament
- G ..... Granules
- P ..... Powder
- UFP ..... Ultra fine powder
- PL ..... Plates
- R ..... Rods

Properties		Test method	Unit
Density			
23°C		ISO 1183	g/cm³
Melt Volume-Flow Rate (MVR)			
380°C, 5kg		ISO 1133	
Tensile test			
Stress at yield	23°C,50% r.h.	ISO 527-2	MPa
Strain at yield	23°C,50% r.h.	ISO 527-2	%
Strain at break	23°C,50% r.h.	ISO 527-2	%
Tensile modulus		ISO 527-2	MPa
Charpy notched impact strength			
23°C		ISO 179/1eA	kJ/m²
-30°C		ISO 179/1eA	kJ/m²
Izod notched impact strength			
23 °C		ISO 180	kJ/m²
Flexural test			
Flexural modulus	23°C,50% r.h.	ISO 178	MPa
Flexural strength	23°C,50% r.h.	ISO 178	MPa
Thermal behaviour - DSC			
Recrystallisation temperature		ISO 11357	°C
Tg	onset, 2nd heating	ISO 11357	°C
Tg	midpoint, 2nd heating	ISO 11357	°C
Tm	2nd heating	ISO 11357	°C
Water absorption			
Saturation	23°C	ISO 62	%

VESTAKEEP® **IMPLANT**

i2 G i2 P i2 UFP 10	i4 R i4 PL	i4 G i4 P	iC4506 R	iC4506 G	iC4520 R	iC4520 G	iC4800 R	iC4800 G	i5 R	i5 G
1.30	1.30	1.30	1.35	1.35	1.50	1.50	1.46	1.46	1.30	1.30
70		12		10						7
100	109	96	109	95	110	85	105	90	105	95
5.0	4.8	5.0	4.6	5.0	4.2	4.2	4.0	4.0	4.6	5.0
>20	>20	>20	>20	>10	>10	>10	>10	>10	>20	40
3700	4000	3500	4200	3600	4800	4350	4700	4350	3900	3400
6C		8C		7C		7C		4.7C		9C
6C		8C								8C
	5.5		5.4		5.2		4.5		6.3	
	4050		4200		4700		4700		3850	
	165		170		175		165		160	
290	285	285	285	285	285	285	285	285	285	285
145	145	145	145	145	145	145	145	145	145	145
155	155	155	155	155	155	155	155	155	155	155
340	340	340	340	340	340	340	340	340	340	340
0.4	0.4		0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4

VESTAKEEP® PROPERTIES

Properties		Test method	Unit	VESTAKEEP® DENTAL				
				D4R	D4G	DC4420 R	DC4420 G	DC4430 R
Density								
23°C		ISO 1183	g/cm³	1.30	1.30	1.51	1.49	1.51
Melt Volume-Flow Rate (MVR)								
380°C, 5kg		ISO 1133			12		9.5	
Tensile test								
Stress at yield	23°C, 50% r.h.	ISO 527-2	MPa	110	96	110	95	110
Strain at yield	23°C, 50% r.h.	ISO 527-2	%	4.8	5.0	4.2	4.8	4.2
Strain at break	23°C, 50% r.h.	ISO 527-2	%	>10	>10	>10	>10	>10
Tensile modulus		ISO 527-2	MPa	4000	3500	4800	4100	4800
Charpy notched impact strength								
23°C		ISO 179/1eA	kJ/m²		8.0		6.8	
-30°C		ISO 179/1eA	kJ/m²					
Izod notched impact strength								
23 °C		ISO 180	kJ/m²	5.5		5.2		5.2
Flexural test								
Flexural modulus	23°C, 50% r.h.	ISO 178	MPa	4050		4700		4700
Flexural strength	23°C, 50% r.h.	ISO 178	MPa	175		175		175
Thermal behaviour - DSC								
Recrystallisation temperature		ISO 11357	°C	285	285	285	285	285
Tg	onset, 2nd heating	ISO 11357	°C	145	145	145	145	145
Tg	midpoint, 2nd heating	ISO 11357	°C	155	155	155	155	155
Tm	2nd heating	ISO 11357	°C	340	340	340	340	340
Water absorption								
Saturation	23°C	ISO 62	%	0.4	0.4	0.4	0.4	0.4

VESTAKEEP® **CARE**

DC4430 G	DC4450 R	DC4450 G	DC4470 R	DC4470 G	M20 G	M33G-HP	M40 R	M40 G
1.50	1.52	1.51	1.36	1.36	1.30	1.30	1.30	1.30
9.5		9.5		11	70	20		12
95	110	95	110	95	100	98	110	96
4.8	4.2	4.8	4.5	5.0	5.0	5.0	4.8	5.0
>10	>10	>10	>10	>10	>20	>20	>20	>20
4100	4800	4100	4400	3600	3700	3600	4000	3500
6.8		6.8		7.5	6C	6C		7C
	5.2		5.4				5.5	
	4800		4100		7500			7500
	175		175		180			180
285	285	285	285	285	290	285	285	285
145	145	145	145	145	145	145	145	145
155	155	155	155	155	155	155	155	155
340	340	340	340	340	340	340	340	340
0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4

For more information on VESTAKEEP® resins please visit
our material database at **www.plastics-database.com**

OUR SERVICE

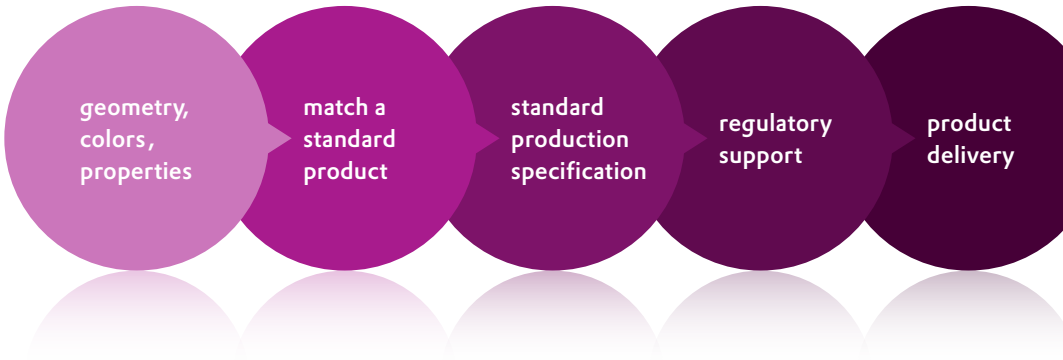
We support you from start to finish

We offer a wide standard portfolio but also help our customers with our material competence to develop the next generation medical implant applications.

In addition to the attributes of the VESTAKEEP® product, Evonik provides a comprehensive service for the development and implementation of polymer technologies. We support our customers from start to finish in their search for new areas of innovative applications.

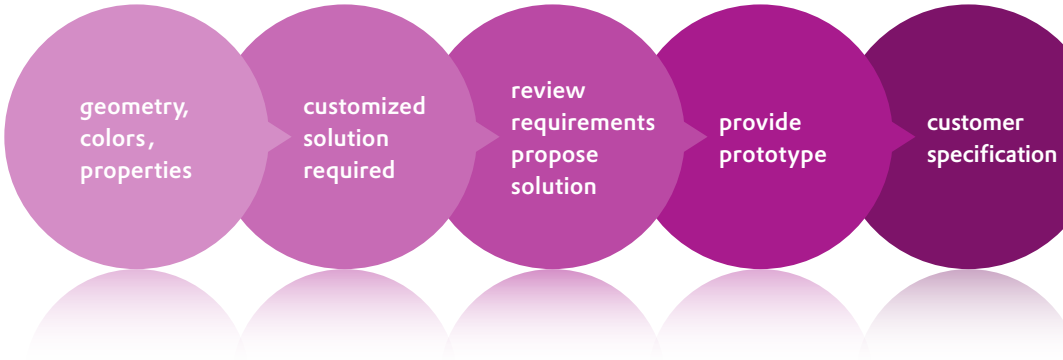
Standard

Customer uses VESTAKEEP® PEEK standard portfolio to develop e.g. spinal implant applications



Customized solution

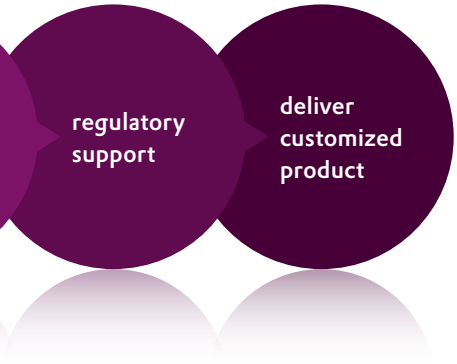
Customer asks for customized geometries/colors



Quality and masterfiles

The service we offer includes:

- → Research expertise from decades of experience
- → Advice on materials selection, new material development
- → Support and guidance in processing
- → Technical service for optimizing the manufacturing process



Quality Management

VESTAKEEP stock shapes are produced under an ISO 13485 certified quality management system. The material is reliably supplied at a consistent and high quality. All production is fully traceable all its way back to the raw materials used for the resin polymerization.

VESTAKEEP® PEEK resins and stock shapes for medical applications have thoroughly been tested for biocompatibility and toxicity based on ISO 10993 and USP <88> Class VI.

Neat VESTAKEEP® Implant grades are ASTM F2026 compliant.

Masterfile strength

Manufacturers require quick and predictable regulatory approval of their medical devices. Evonik holds master access files (MAF) at the FDA for both the VESTAKEEP® Implant grade resins and stock shapes. The MAFs contain comprehensive data generated in-house and also at independent test laboratories. MAFs are updated regularly as new products are developed and additional data on existing materials are obtained.

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