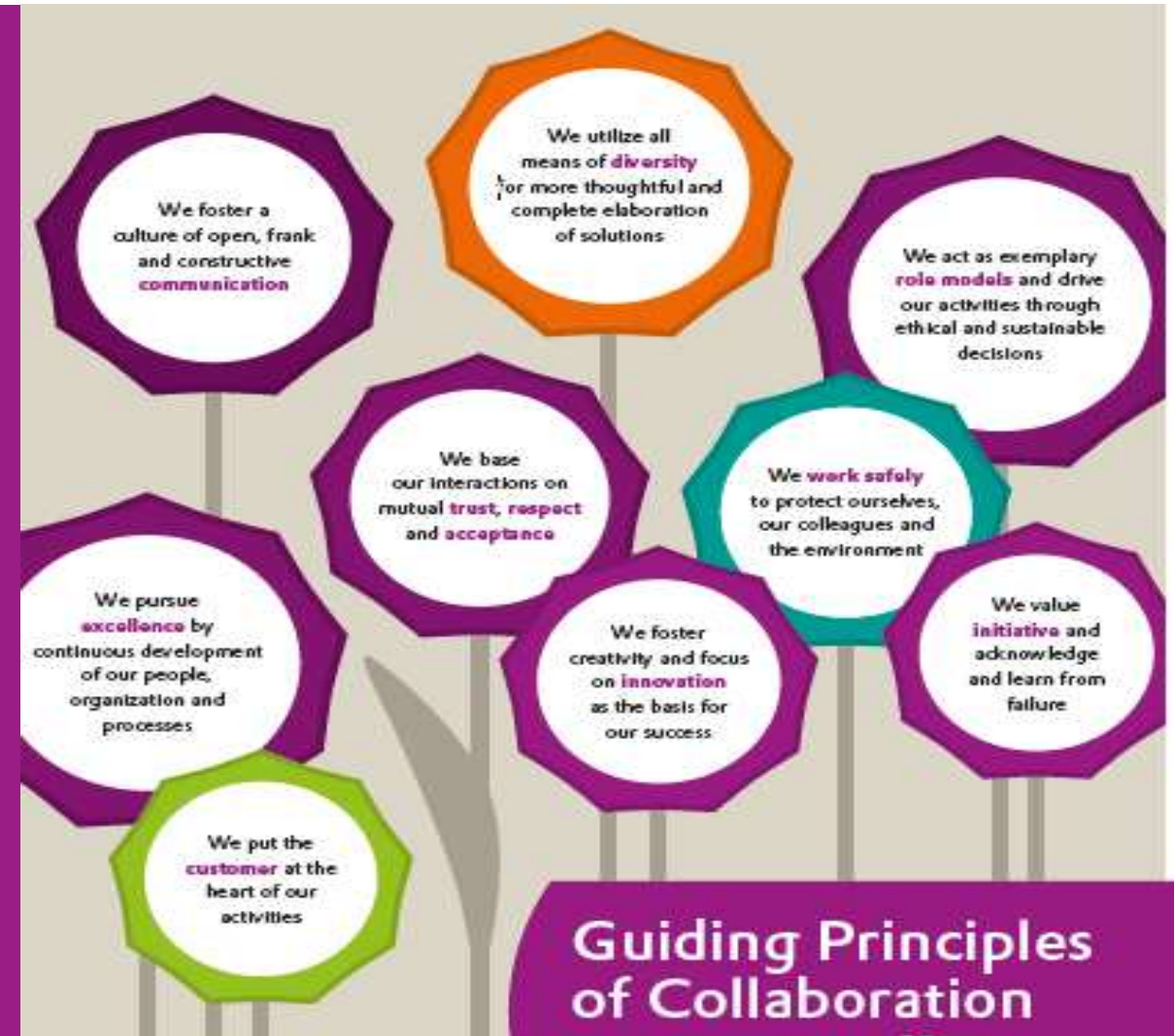


Evonik. Leading Beyond Chemistry

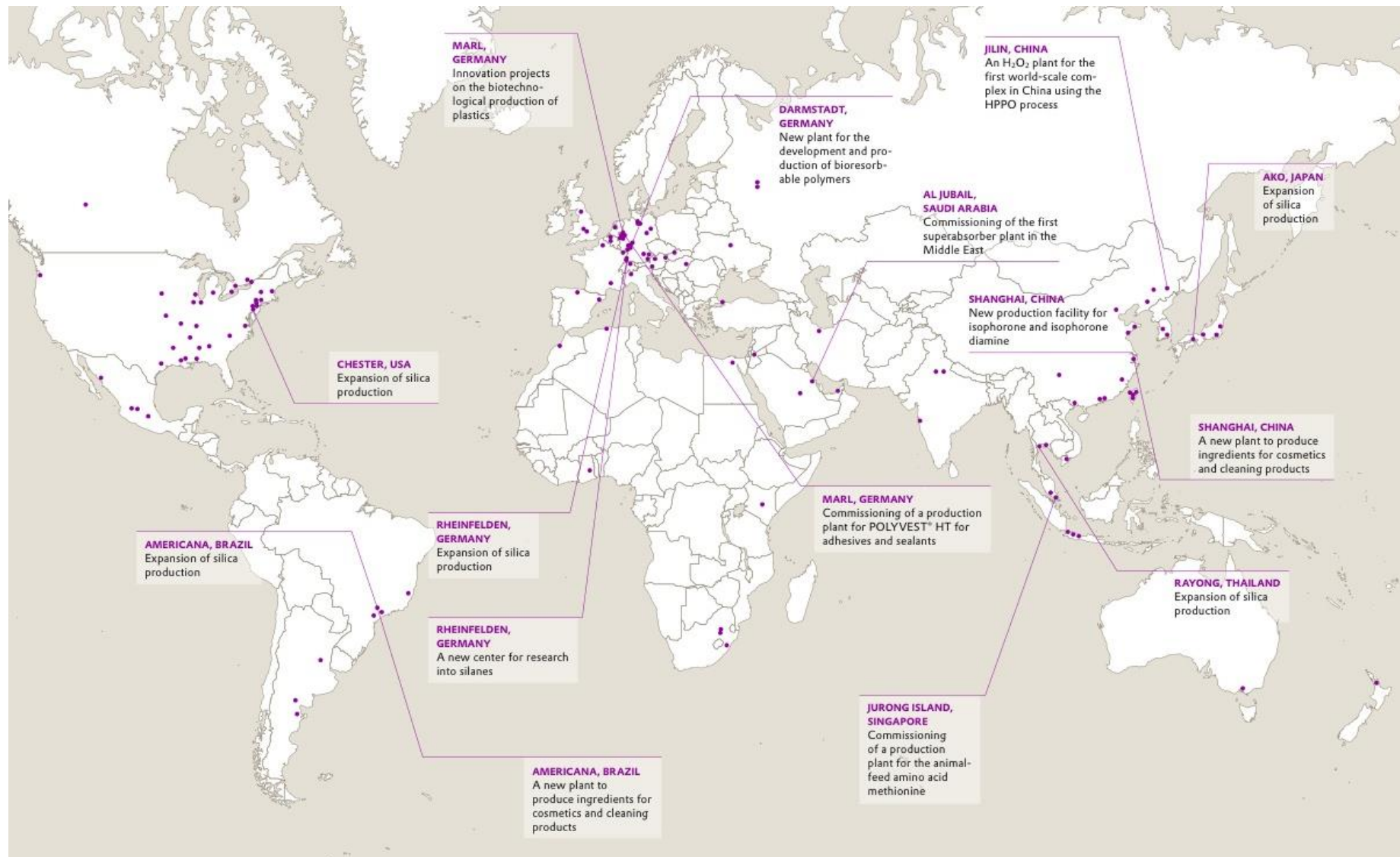
Evonik VESTAKEEP PEEK



September 12, 2024

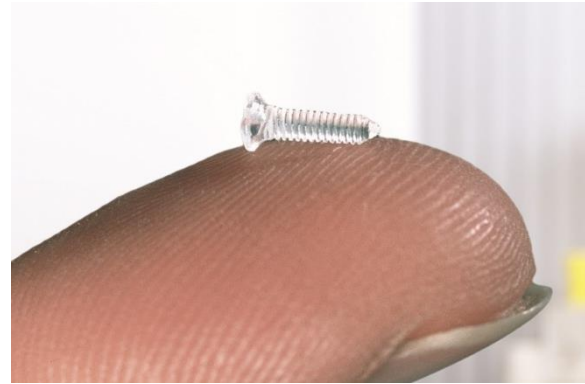
matthew.cantwell@evonik.com

Production sites in 25 countries, active in over 100 countries, worldwide investments.



Leading Beyond Chemistry :

Medical Technologies, Devices & Implants



Leading Beyond Chemistry :

Polymer technology competencies



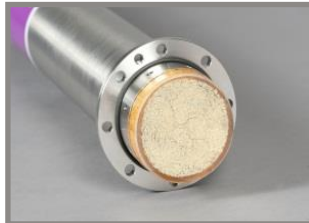
Polymer
Design



Extrusion
Technology



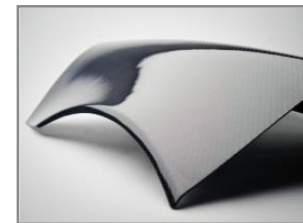
Bonding
Materials



Membrane
Technology



Fiber
Technology



Composite
Technology



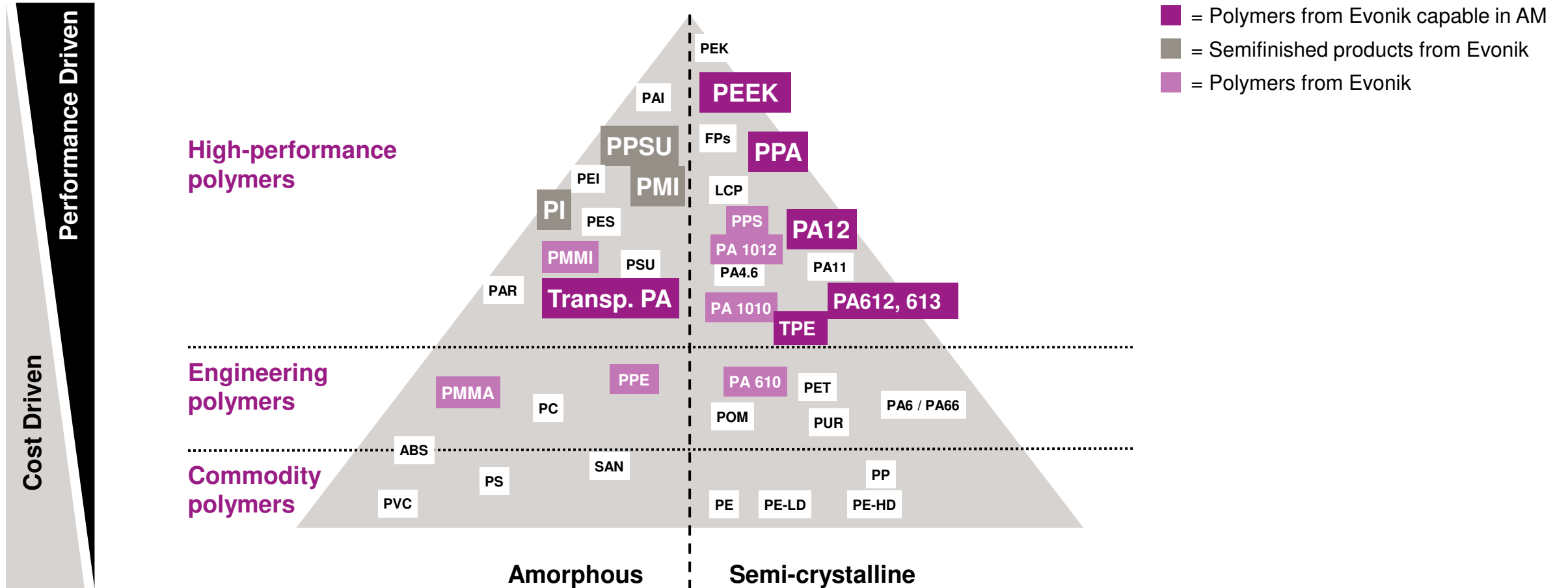
Additive
Manufacturing



Powder
Technology

Leading Beyond Chemistry :

High performance polymers



VESTAKEEP® PEEK

Manufacturing Facilities

Polymerization

ISO 9001 certified

Extruded shapes

ISO 13485 certified

Extruded in a clean room environment

Standard Rod diameters

6 mm to 50 mm

Standard Plate thicknesses

6 mm to 50 mm

Filament

1.75 mm



VESTAKEEP® PEEK

Supply Chain

Fully integrated manufacturing and processing of VESTAKEEP® ensures control of quality



VESTAKEEP® PEEK

Portfolio Overview

Dental

Resin, Rod, and Disc Product Forms
Multiple colors – Natural, White, Tooth, Gingiva
ISO 10993 Testing for Permanent Mucosal Membrane Contact



Temporary Contact

Resin, Rod and Filament Product Forms
ISO 10993 Testing for Body and Blood Contact up to 30 Days
Different Grades for Inj. Molding, Extrusion, Inj. Mold/Extrusion



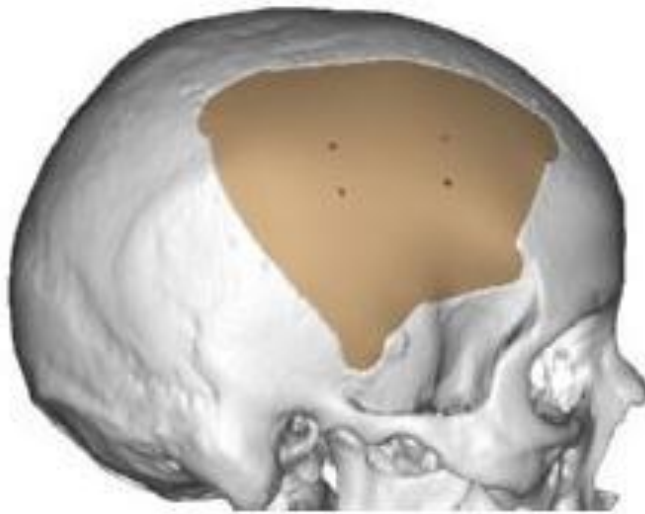
Permanent Implant

Resin, Rod, Plate, Powder and Filament Product Forms
Complete ISO 10993 Testing for Permanent Implantation
FDA Masterfile's recorded with FDA
Standard, carbon-fiber, image-contrast and Osteo Conductive



VESTAKEEP® PEEK

Permanent Implant, Temporary Contact, & Dental Biomaterials



VESTAKEEP® PEEK

For Permanent Implant Devices

Biocompatible

Complete ISO 10993 testing

Biostable

Chemically inert w/no adverse reactions in hard & soft tissue

Sterile Processing Compatible

Compatible with Steam/Autoclave, Gamma, & ETO methods

High Performance Polymer

Mechanical strength, impact strength, modulus similar to cortical bone, radiolucent or radiopaque – meets ASTM F2026

FDA Cleared

MasterFile recorded with FDA; comprehensive test results and data, ISO 13485 manufacturing



VESTAKEEP® PEEK

ISO 10993 Biocompatibility

Biocompatibility tests

Tests following ISO 10993 recommendations for		VESTAKEEP® IMPLANT	VESTAKEEP® DENTAL	VESTAKEEP® CARE
		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: intracutaneous 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® PEEK

Product Portfolio & Descriptions

i2

Injection Molding grade

i4

Injection Molding & Extrusion grade
near net shape / machining compatible

i5

High ductility & fatigue resistance
injection molding & extrusion

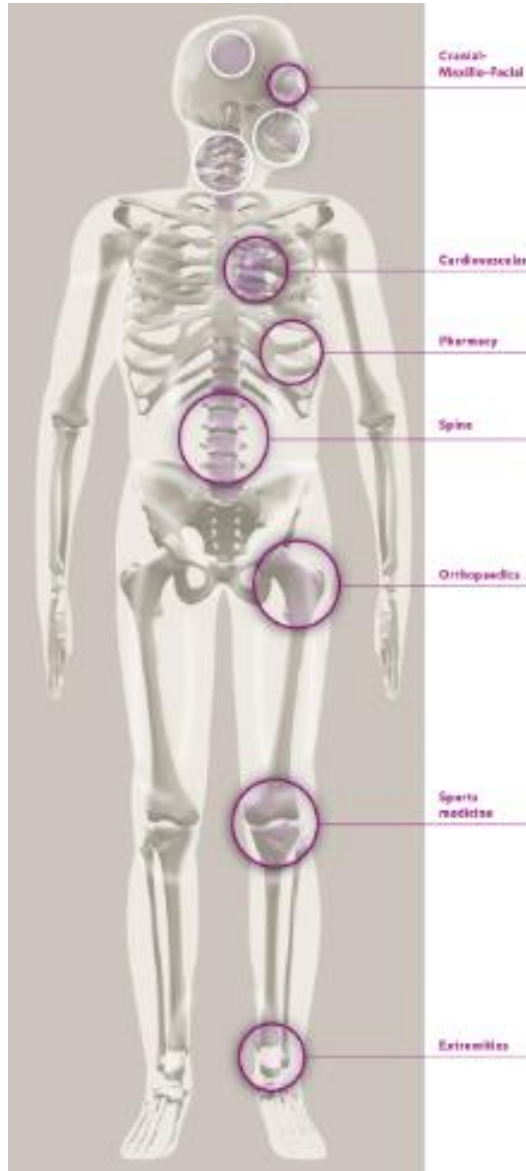
Product Portfolio

VESTAKEEP® i2G	pellets
VESTAKEEP® i4G	pellets
VESTAKEEP® i4R	rods or plates
VESTAKEEP® i5G	pellets
VESTAKEEP® i5R	rods or plates



VESTAKEEP® PEEK

Regulatory Clearances & Global Approvals



FDA 510(k) & PMA Approvals

Spine	Arthroscopy / Sports Medicine
Extremities	CMF
Cardiovascular	Oncology
Dental	

Global Region Approvals

Europe - CE Mark	India
China - CFDA	Turkey
Korea - KFDA	Israel
S. America - ANVISA	Iran
Japan - PMDA	

Innovation:

Global R&D network, regional strength

Business line projects and customer projects focused

Allentown, PA



short-term R&D

Localized Centers of Excellence

Market oriented R&D and strategic partnering

Birmingham, AL



mid-term R&D

Regional core technology
'Medical Device Competence Center'

Research areas outside our present business portfolios

Essen, Germany



long-term R&D

Corporate innovation group.
Strategic exploration and growth

Centers of Excellence: For close interaction with our customers

Global strategic locations near our customers

Develop and test custom-tailored polymers and solutions with customers and external partners to drive their success

Medical Polymers COE

Allentown, PA

Compounding

Molding

Testing



Innovation: Medical Devices Competence Center (MDCC)

Geared specifically toward developing and advancing our core polymer technologies, business lines, and markets

New Materials for Tomorrow

Implantable Polymers

PEEK

Resorbables

Additive Manufacturing

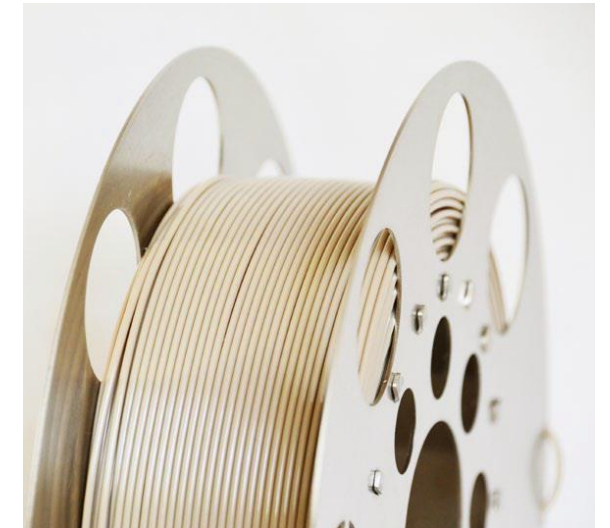
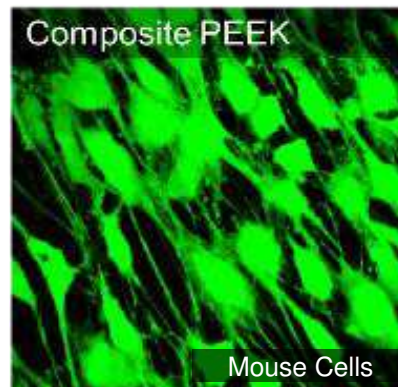
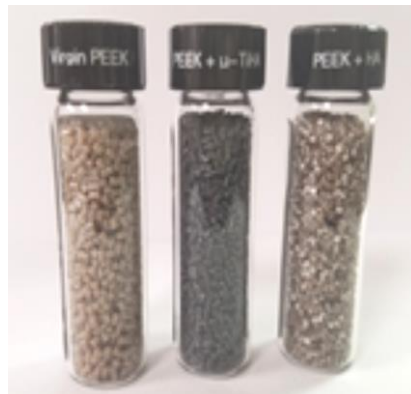
MDCC is driven by industry experienced biomedical engineers, scientists, and PhD's



VESTAKEEP® PEEK

New Product Developments

We're advancing the material science for medical implant applications by developing new PEEK biomaterials to meet the evolving challenges of the medical device industry



VESTAKEEP® PEEK

for Image Contrast

Image contrast VESTAKEEP® PEEK

Developed to allow for visibility of the implant under X-ray, CT, or MRI, as well as post-operative healing assessment of the surgical site.

VESTAKEEP® iC4506 & VESTAKEEP® iC4520

BaSO₄ used for radiopaque properties

Provided in Granule and Rod form

Available in 6% and 20% BaSO₄

Available in other fill rates upon request



VESTAKEEP® PEEK

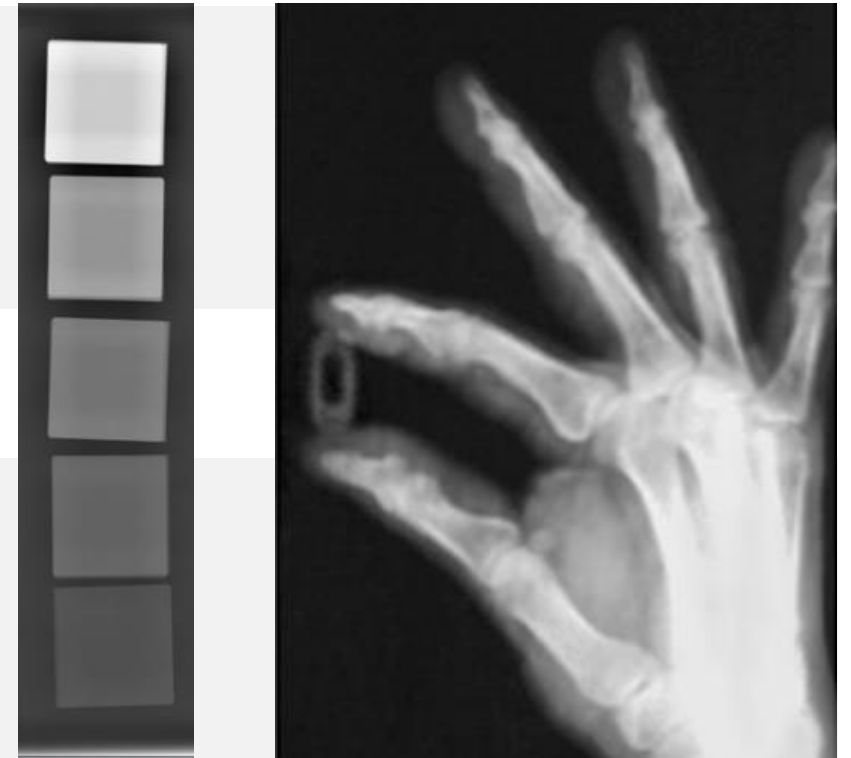
for Image Contrast

VESTAKEEP® iC4506 G & iC4520 G (granule)

Implant grade of VESTAKEEP®

VESTAKEEP® iC4506 R & iC4520 R (rod stock)

Implant grade of VESTAKEEP®



VESTAKEEP® Fusion

Next Generation - for Improved osteoconductivity

Broaden the application of PEEK's benefits for use in Orthopedic devices

Improve the osteoconductive properties of PEEK

Better mechanical properties

VESTAKEEP® iC4800

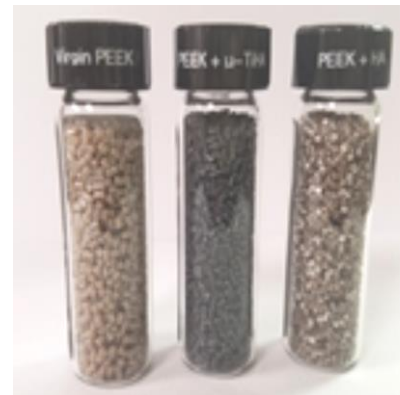
Biostable PEEK composite formulas

Addition of bone-mimetic additives with superior interface bonding with PEEK

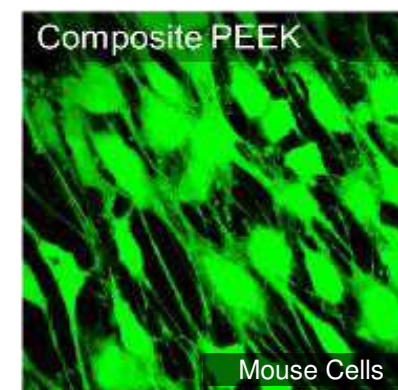
Develop extrusion processes to produce semifinished bar stocks or granules

Large animal study completed

Composite Pellets



Cellular Activity



Developed for Ortho



VESTAKEEP® 3DF PEEK Filament

Implant Grade Biomaterial for Fused Filament Fabrication (FFF)

VESTAKEEP® 3DF Filament

Implant grade PEEK filament Based on VESTAKEEP® PEEK i4G

Developed specifically for the Fused Filament Fabrication (FFF) process

VESTAKEEP® 3DF-T Filament

A technical grade of VESTAKEEP® 3DF Filament for testing and early evaluation of printing behavior and results

Product Details

Filament diameter: 1.75mm

Provided in Spool form

Filament spool lengths:
66m or 166m



Evonik's PEEK filament portfolio: VESTAKEEP® i4 3DF

VESTAKEEP® i4 3DF

- Extruded from natural colored, high viscosity VESTAKEEP® i4 G polyether ether ketone resin
- VESTAKEEP® i4 3DF filaments are compliant to ASTM F2026 “Standard Specification for Polyether ether ketone (PEEK) Polymers for Surgical Implant Applications”
- Production of filament in a clean room environment
- Supplied on medical grade TROGAMID® spools with 250g or 500g; filament diameter: 1.75 mm +/- 0.02 mm
- Double bagged for transfer into clean areas
- Biocompatibility testing documentation of base resin available

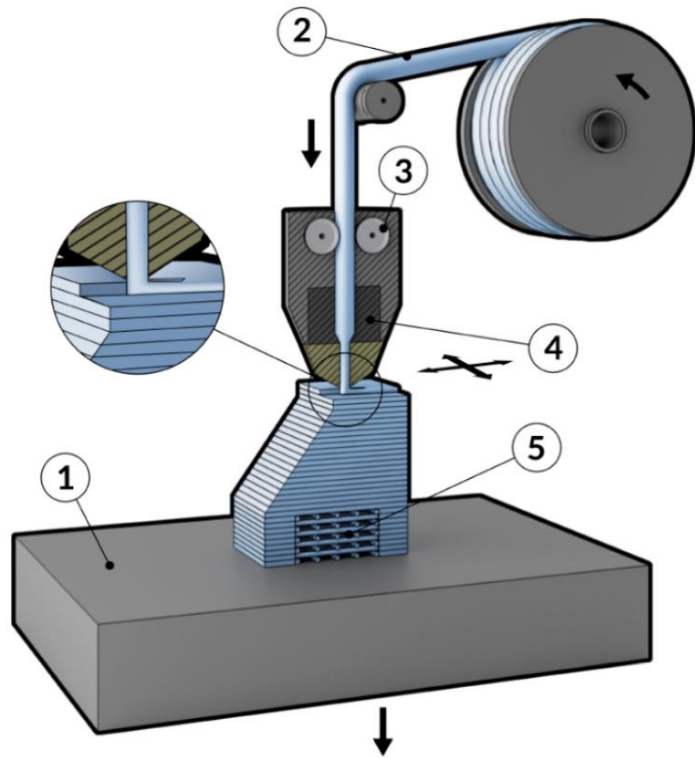


- ✓ Implantable grade PEEK-filament for permanent implantable medical devices
- ✓ Full support equivalent to all Evonik implantable grade PEEK materials

FFF / FDM Technology For The Medical Sector

Technology

- Material extrusion



Material

- Filament product family designed for development of medical devices.
- Evonik is closely working together with leading global additive manufacturing companies for FFF in the medical sector.
- Filament made of implantable VESTAKEEP® i-grade available since Q4 2019.



LEADING BEYOND CHEMISTRY TO IMPROVE LIFE, TODAY AND TOMORROW