EVONIK INDUSTRIES

# VESTAKEEP® PEEK

## Biomaterials for Medical Applications

VESTAKEEP®

Evonik. Power to create.

# VESTAKEEP® PEEK
# is setting new standards

Evonik, the creative industrial group from Germany, is one of the world leaders in specialty chemicals. Our activities focus on the key megatrends health, nutrition, resource efficiency and globalization.

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.

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

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-chromium. However, more and more implants are being made of PEEK, which have many advantages over metal. VESTAKEEP® i-Grades have been created to fill these needs.

From its exceptional material properties and performance capabilities, VESTAKEEP® PEEK is the material of choice for medical applications.


*Michael Smith, founder and CEO of K7 LLC attributed VESTAKEEP® PEEK's durability as a key component in gaining FDA 510(k) clearance.*

*"We could not be more pleased with the test results and material durability of VESTAKEEP® PEEK", said Smith. "The inherent strength and added ductility have created new possibilities for our PEEK implant designs."*

## Customized VESTAKEEP® PEEK for the human body

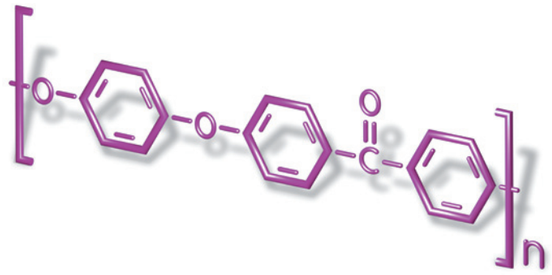
Biocompatibility, biostability and safety are all major criteria when a material is selected for a medical device or a medical implant.

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. These test results attest to VESTAKEEP®'s excellent biocompatibility and biostability, which are principally attributed to the polymers` high chemical resistance and thermal stability.

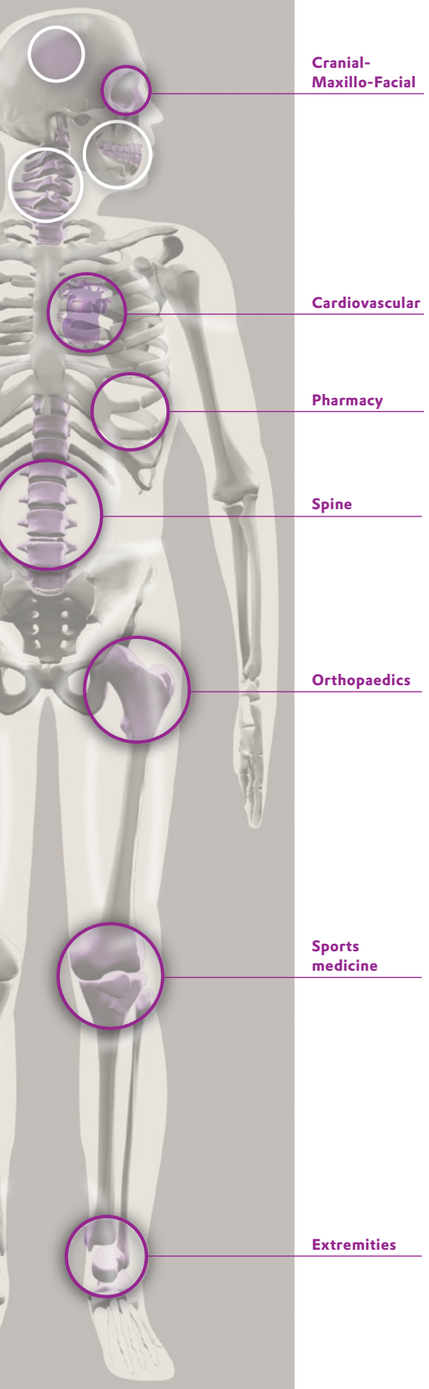
## Advantages at a glance

VESTAKEEP® PEEK provides convincing advantages like:

- biocompatibility
- biostability
- sterilization compatible
- resistant to chemicals
- modulus similar to bone
- metal-free
- wear comfort due to light weight and low thermal conductivity
- no x-ray artifacts and/or adjustable opacity
- injection molding and extrusion compatible
- low water absorption
- easy to machine
- good processability
- lower stress-shielding effect



# 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.

## X-ray transparency

Traditionally, metals have been the materials of choice for spinal cages and other implants in the human body, but recently 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 being developed.

## 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 breakage. The elasticity of VESTAKEEP® i-Grade PEEK is closer to the cortical bone and has a higher elasticity than metals. This deters the stress-shielding effect on bone and allows for a longer, healthier life.



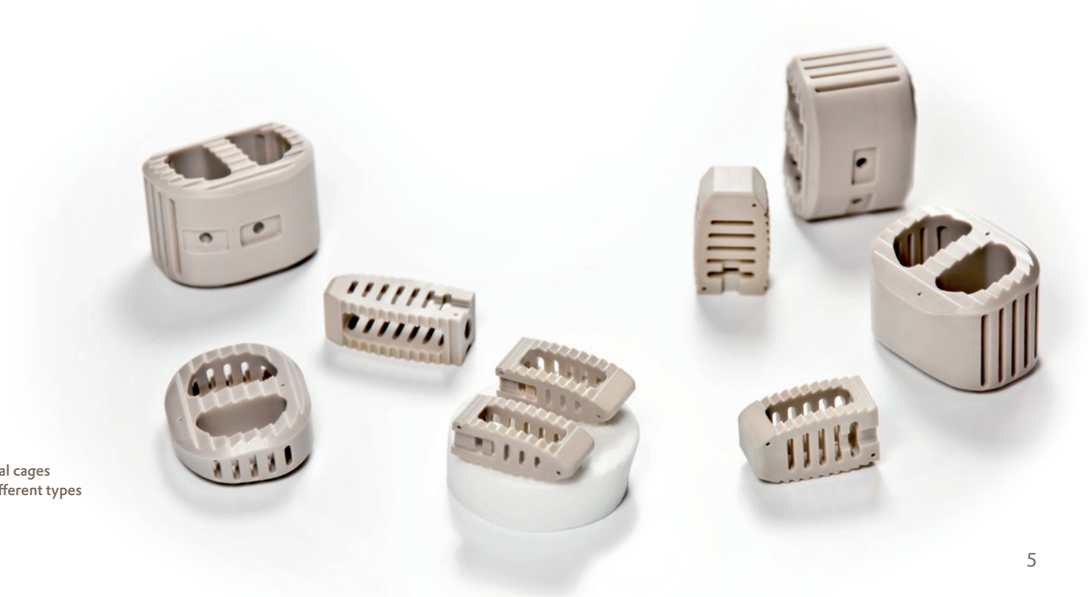
### Biocompatibility tests VESTAKEEP® i-Grade

| | | VESTAKEEP® | | |
|---|---|---|---|---|
| | Biocompatibility testing according to ISO 10993 for | i-Grade: Permanent implants | Dental-Grade: Permanent mucosal membrane contact | Care-Grade: 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 | ⊕ | | |
| ISO 10993-6 | Implantation tests | Bone 90 days | Muscle 7 days | Muscle 7 days |
| | Hemocompatibility testing | ⊕* | | ⊕ |
| ISO 10993-12 | GC/MS fingerprint | ⊕ | ⊕ | |

* tested on VESTAKEEP® i-Grade resin

## Application examples:

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



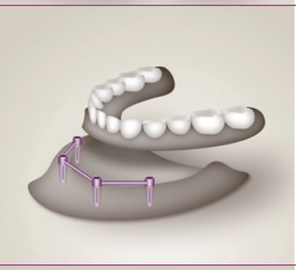
Spinal cages
in different types

Crowns

Bridges

Partial dentures

Implants, Abutments



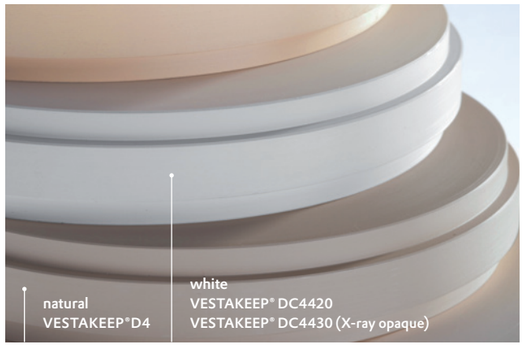
Bar restorations



# 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 products are available in a wide range of natural colors including white pigmented, tooth-colored and gingiva-colored. The selection of colors allows aesthetic solutions.





*„Within the limitation of a laboratory study, the results suggest that biofilm formation on the surface of PEEK (VESTAKEEP® PEEK) is equal or lower than on the surface of conventionally applied abutment materials such as zirconia and titanium."*

Extract of the study „Biofilm formation on the surface of modern implant abutment materials" by Sebastian Hahnel (DDS, PhD, Universitätsklinikum Regensburg) et al.

Hahnel S, Wieser A, Lang R, Rosentritt M, Clin. Oral Impl. Res. 00 (2014) 1-5

## X-ray opacity

As most other plastics polyetheretherketones 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.

## Potential applications of VESTAKEEP® Dental materials in medical devices:

- crowns/bridges
- cervical gingiva formers
- temporary and permanent abutments
- attachment restorations
- partial dentures/transversal connectors
- occlusal splints
- inlay bridges
- telescopic crowns
- dentures (basis)
- healing caps



## Biocompatibility tests VESTAKEEP® Dental

| | Biocompatibility testing according to ISO 10993 for | VESTAKEEP® i-Grade: Permanent implants | VESTAKEEP® Dental-Grade: Permanent mucosal membrane contact | VESTAKEEP® Care-Grade: Body and blood contact up to 30 days |
|---|---|---|---|---|
| USP Class VI | Acute systemic toxicity / Intracutaneous reactivity / Muscle implantation | ⊕ | ⊕ | ⊕ |
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| ISO 10993-6 | Implantation tests | Bone 90 days | Muscle 7 days | Muscle 7 days |
| | Hemocompatibility testing | ⊕* | | ⊕ |
| ISO 10993-12 | GC/MS fingerprint | ⊕ | ⊕ | |

## More dental materials

Degacryl® → www.degacryl.com
Nanocryl® → www.evonik.com/hanse

# VESTAKEEP® Care

When it comes to application conditions involving high temperatures VESTAKEEP® Care grades are the materials of choice.

VESTAKEEP® Care PEEK products are available in different viscosities for processing via extrusion or injection molding.

These ductile grades offer even higher resistance to heat, chemicals, and hydrolysis. Typical areas of application for VESTAKEEP® Care include parts for housings and surgical instruments, gear wheels and other parts for functional units and durable medical equipment. Due to the material's outstanding temperature resistance, parts made out of VESTKEEP® Care grades resist steam autoclaving for an extended number of autoclaving cycles.

**Biocompatibility tests VESTAKEEP® Care-Grade**

| | | VESTAKEEP® | | |
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| ISO 10993-12 | GC/MS fingerprint | ⊕ | ⊕ | |



# Coating technologies

## Coating technologies of VESTAKEEP® PEEK

VESTAKEEP® PEEK has been validated in multiple coating technologies e.g. titanium on PEEK spinal cages.

We can provide contact information to different coating companies if interested.

Coating on VESTAKEEP® PEEK is possible for many applications

Titanium coating on VESTAKEEP® PEEK enhances bone ongrowth

# Quality and masterfiles

## Quality Management

VESTAKEEP stock shapes are produced under an ISO 13485 certified quality management system. The material is reliably supplied at a consistent and 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.

VESTAKEEP® Implant grades are ASTM F2026 compliant.

## Masterfile strength

Manufacturers require quick and predictable regulatory approval of their medical devices. Evonik filed master access files (MAF) 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.

# VESTAKEEP®
# medical product portfolio

## VESTAKEEP® for medical applications

### Delivery forms stock shapes

VESTAKEEP® medical grades are available as rod stocks and plates:

**VESTAKEEP® rods**

| diameter | standard lengths |
|---|---|
| 6 - 20 mm | 3000 mm |
| 25 - 60 mm | 2000 mm |
| 70 - 100 mm | 1000 mm |

**VESTAKEEP® plates**

available in different dimensions

- thickness up to 60 mm
- standard dimension 500 x 1000mm

VESTAKEEP® Dental grades are additionally available as discs in multiple dimensions:

**VESTAKEEP® discs**

available in different dimensions

- diameter 98.4 mm (with step)
- diameter 99.5 mm (without step)
- diameter 84.5 mm (without step)
- thickness 12 - 30 mm

Other dimensions are available on request.

### VESTAKEEP® grades

| | stock shapes | color | resins | description | processing | Delivery forms resins |
|---|---|---|---|---|---|---|
| **VESTAKEEP® Implant** | — | natural | VESTAKEEP® i2 G<br>VESTAKEEP® i2 P | • standard viscosity | • injection molding<br>• compounding and compression molding | **granules**<br>• supplied in 1 kg, 5 kg or 10 kg hobbocks with polyethylene liners<br>**powders**<br>• supplied in 10 kg hobbocks with polyethylene liners |
| | VESTAKEEP® i4 PL<br>VESTAKEEP® i4 R | natural | VESTAKEEP® i4 G<br>VESTAKEEP® i4 P | • high viscosity | • injection molding<br>• extrusion<br>• compounding and compression molding | |
| | VESTAKEEP® i5 R | natural | VESTAKEEP® i5 G | • very high viscosity | • extrusion | |
| **VESTAKEEP® Dental** | VESTAKEEP®D4 R | natural | VESTAKEEP®D4 G | • high viscosity | • injection molding<br>• extrusion | **granules**<br>• supplied in 25 kg boxes with polyethylene liners (2 x 12.5 kg) |
| | VESTAKEEP® DC4420 R | white | VESTAKEEP® DC4420 G | • high viscosity | • injection molding<br>• extrusion | |
| | VESTAKEEP® DC4430 R | white, X-ray opaque | VESTAKEEP® DC4430 G | • high viscosity | • injection molding<br>• extrusion | |
| | VESTAKEEP® DC4450 R | tooth-colored | VESTAKEEP® DC4450 G | • high viscosity | • injection molding<br>• extrusion | |
| | VESTAKEEP® DC4470 R | gingiva-colored | VESTAKEEP® DC4470 G | • high viscosity | • injection molding<br>• extrusion | |
| **VESTAKEEP® Care** | — | natural | VESTAKEEP® M20 G | • standard viscosity | • injection molding | **granules**<br>• supplied in 25 kg boxes with polyethylene liners (1 x 25 kg) |
| | — | natural | VESTAKEEP® M33 G-HP | • melt filtrated high purity grade<br>• medium viscosity | • injection molding<br>• extrusion<br>• film extrusion<br>• small diameter tubes | |
| | VESTAKEEP® M40 R | natural | VESTAKEEP® M40 G | • high viscosity | • injection molding<br>• extrusion | |

**R** = rods **PL** = plates **G** = granules **P** = powder

VESTAKEEP® PEEK can be processed using all techniques such as injection molding, extrusion and the compression molding.

Combined, this means maximum freedom for the client and the best product for the patient for extreme mechanical, thermal and chemical requirements.

# VESTAKEEP® Service

## First-class service for manufacturers of medical products

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 customer from start to finish** in their search for new areas of innovative applications.

The service we offer includes the following:

- 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

## Customized solutions

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

### Standard

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

| | | | | |
|---|---|---|---|---|
| geometry / colors / properties | match a standard product | standard production specification | regulatory support | product delivery |

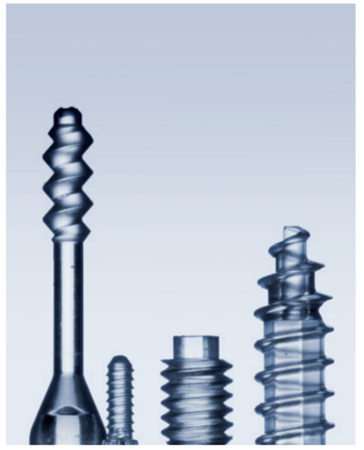
### Customized solution

customer asks for customized geometries/colors

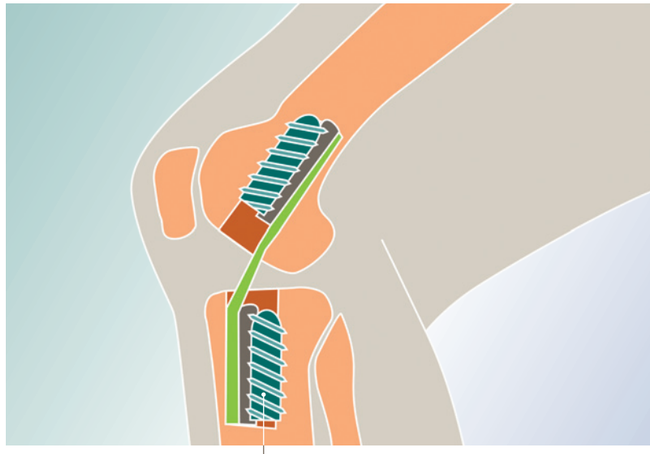
| | | | | | | |
|---|---|---|---|---|---|---|
| geometry / colors / properties | customized solution required | review requirements propose solution | provide prototype | customer specification | regulatory support | deliver customized product |



# Resomer® biomaterial for bioresorbable implants



Resorbable implants made of RESOMER®



Resorbable interference screws for ACL fixation

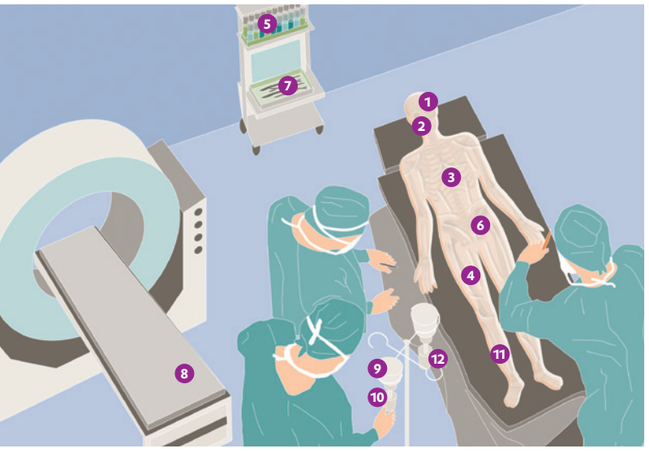
RESOMER® is the state of the art polymer for the manufacturing of biodegradable medical devices. Unique polymers made of lactide, glycolide, caprolactone or trimethylene carbonate will provide superior properties to your device for applications like: Sports medicine, trauma, CMF, coronary stents, drug depots, regenerative medicine and medical coatings.

→ www.resomer.com

## Advantages at a glance

- high biocompatibility
- x-ray transparent
- diversified product portfolio
- custom synthesis capability

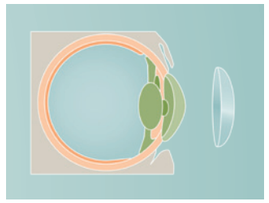
# Product overview for medical devices




### 1 VISIOMER®

VISIOMER® UHP HEMA, MMA, HEMATMDI, EGDMA, TRGDMA:
As one of the leaders in the production of Methacrylate monomers, Evonik offers highly purified hydroxyester and multifunctional methacrylates for the production of diverse medical products.

Typical applications include:
Contact lenses, IOL, bone cements, dental fillings and dentures.



### 2 POLYMER and NANOCRYL®

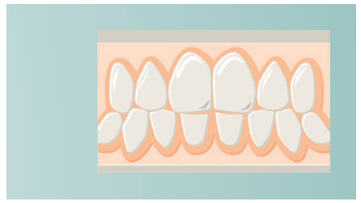
POLYMER VS, RV, MV and NANOCRYL®: Evonik Hanse GmbH offers a wide ange of silicone and acrylic based materials which can be used in formulations for different medical products.

Typical applications include:
dental impression, bite registrations, composite fillers, exoprothetics and cushionings.

### 2 DEGACRYL®

Products of the DEGACRYL® range are PMMA polymers and copolymers distin guished by consistent quality with narrow specifications and superior free flowing properties. A broad portfolio allows choosing the suitable type for applications as in the dental and medical fields.

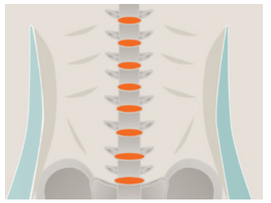
Typical applications include:
Dentures, artificial teeth, bone cement.



### 3 VESTAKEEP® PEEK

Implants from VESTAKEEP® PEEK provide a new level of quality in medicine: our PEEK polymers are used especially because of their outstanding biocompatibility and biostability.

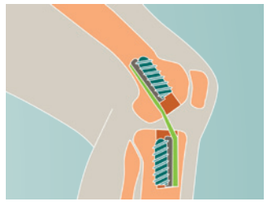
Typical applications include:
Spine, sports medicine, trauma, CMF, cardiovascular, drug ports, dental, medical textiles, ophthalmic, surgical instruments, housings.



### 4 RESOMER®

RESOMER® is the state of the art polymer for the manufacturing of bio-degradable medical devices. Unique polymers made of lactide, glycolide, caprolactone or trimethylene carbonate will provide superior properties to your device for applications like:

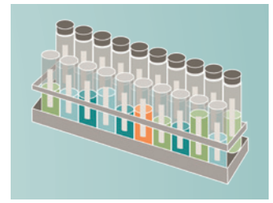
Sports medicine, trauma, CMF, coronary stents, drug depots, regenerative medicine, medical coatings.

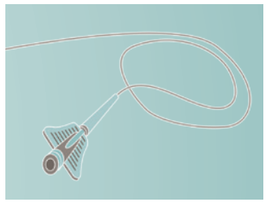


### 5 CYROLITE® MD PMMA

Acrylic Polymers for medical diagnostics applications requiring exceptional light transmittance and optical clarity. High flow for fast processing and multicavity tooling.

Typical application include:
Diagnostic cuvettes, diagnostic test packs, optical sensor view ports, crystallography trays, microfluidics, rotors.

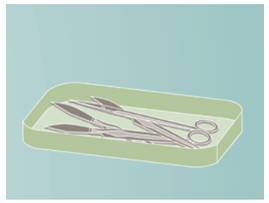




### 6 VESTAMID® Care

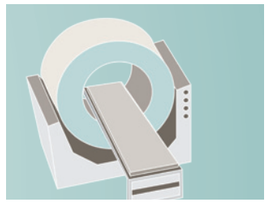
PA (polyamide)/PEBA (polyether block amide) is used successfully as a catheter material because of its high bursting resistance. This is provided by the combination of flexibility and pliability, toughness and hardness.

Typical applications include:
Catheters, housings, surgical instruments.



### 7 EUROPLEX® PPSU sheets and VESTAKEEP® PEEK films

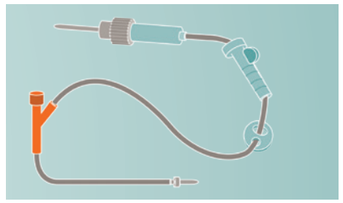
Our EUROPLEX® sheet materials are especially suitable for sterilizable containers and orthopedic applications. VESTAKEEP® films may be used as a sliding layer or electrical insulator in chemically demanding environments.



### 8 ROHACELL®

Medical table tops using ROHACELL® polymethacrylimide foam as the structural core are not only lighter, but much thinner. Their reduced mass means radiation levels required for radioscopy can be kept at a minimum, thereby exposing the patient to much less radiation and lowering health risks. Thinner table tops also reduce scatter radiation and provide x-ray images of much higher quality.

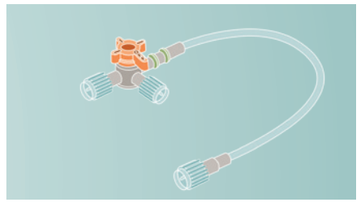
Typical applications include:
table and couch tops for x-ray and CT scan machines, operating tables, mammography plates, fixation devices for x-ray therapy.



### 9 CYROLITE®, CYREX® and XT®

Acrylic based multi-polymer compounds for medical devices and packaging delivering excellent chemical and lipid resistance. Sterilizable, bondable, BPA free and antimicrobial grades are available.

Typical applications include:
medical consumables like e.g., luer locks, dialyzer housings, protection caps and covers, blood- and plasma-separators, collection and specimen vessels, connectors and injection ports, catheter accessories.



### 10 TROGAMID® Care

TROGAMID® Care is a highly transparent PA that is resistant to stress cracking. Because of its outstanding chemical resistance it is used especially in applications that come into contact with drugs and body fluids.

Typical applications include:
Stopcocks, catheters, hearing aids, housings

### 11 DEGAPLAST®

Orthopedic exoprostheses provide high mobility and freedom of movement to disabled people. Besides metals, polymers play an important role here, too, with DEGAPLAST® based lamination systems occupying a prominent position, particularly in the handcrafting industry. DEGAPLAST® resins are methacrylate formulations based on MMA, solved PMMA, and special modifiers. The cured parts are thermoplastic and not brittle.

### 12 VESTODUR®

Specialty VESTODUR® are polybutylene terephthalate compounds. They are easy to process and the moldings made of them are dimensionally stable.

Typical application include:
Blood filters.

® registered trademark



VESTAKEEP® materials are no medical devices and do not carry CE marks. It is in the sole responsibility of the purchaser to obtain regulatory approval.

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