High Performance Polymers for Medical Applications

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EVONIK INDUSTRIES

1. External devices
2. Internal devices
3. Future of plastics in medicine

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Components and coatings provide added functions

Resistance against pharmaceutical agents

- Chemical resistance
- Sterilization

Transparency / Microcrystallinity

- Stress crack resistance

Joining Methods without additional materials

- Welding (heat, vibration, ultrasonic)

TROGAMID® CX – Transparency through Microcrystallinity

Semi-crystalline retains properties

Impact resistance

Good stress cracking behavior

Powder coating provides an attractive surface for medical devices

Smooth non-porous surface

Anti-bacterial properties*

Low sliding friction

VESTOSINT® - polyamide powders for coating of medical components;

- hospital furniture
- permanent installations
- Wall coverings
- Braces & supports

1. External devices
2. **Internal devices**
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High Performance Catheters using high performance polymers

Requirements:

Processability

Moisture sensitivity

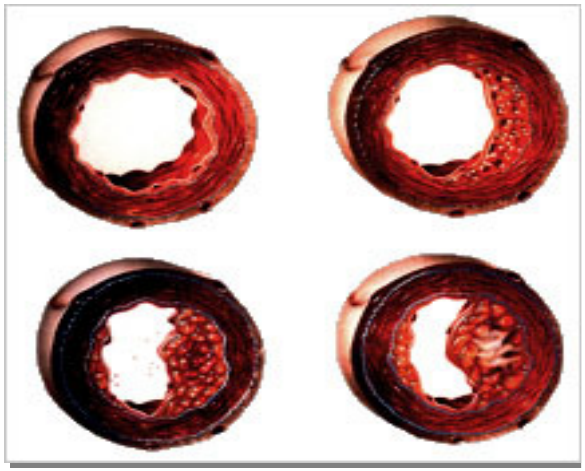
Burst pressure

Compliance

Rewrap

Puncture resistance / Hardness

Flexibility



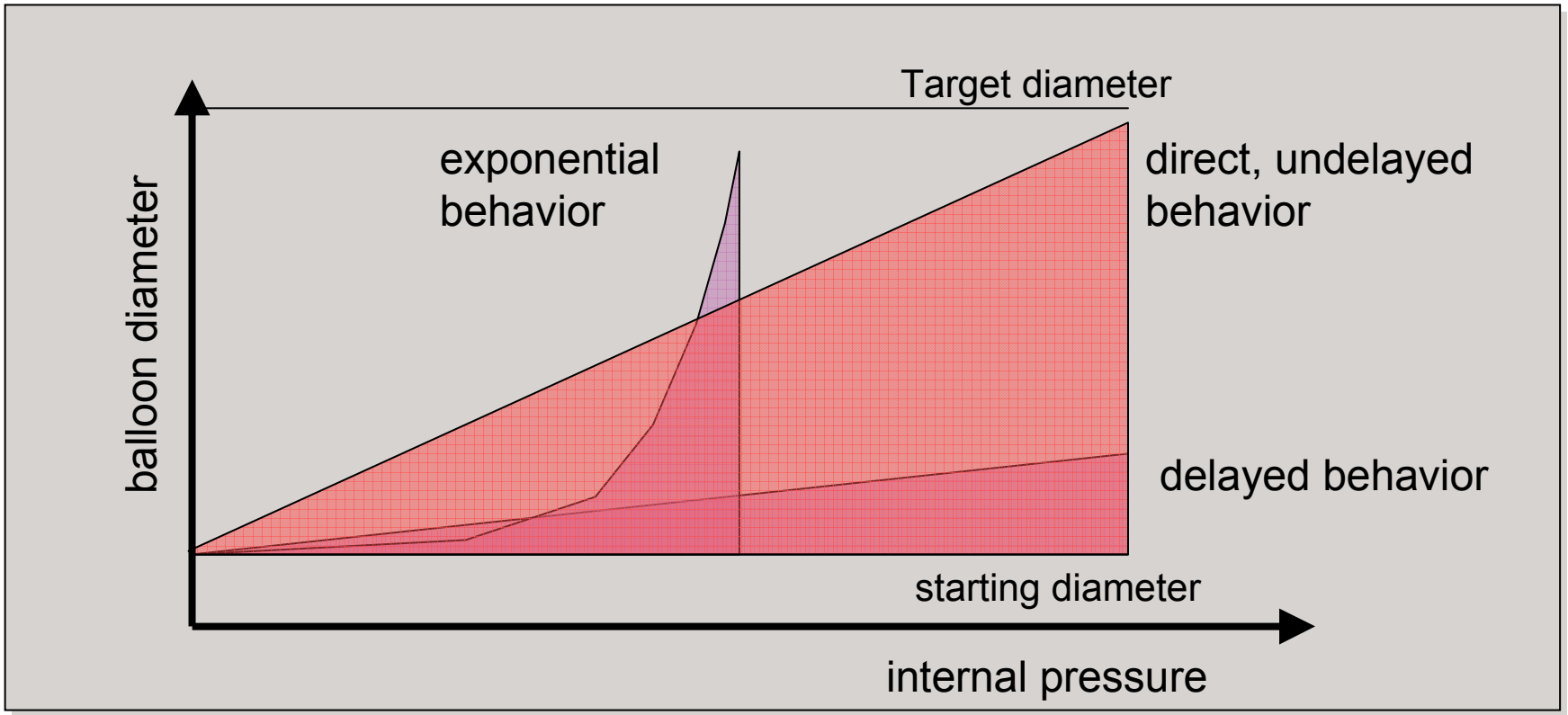
Polyamide 12 and PEBA materials fulfill these requirement and have been in use for many years.

Balance of properties and materials combine for desired behavior

VESTAMID® L & E (elastomeric) combines:

High elongation at yield (~50%) & break (200%)

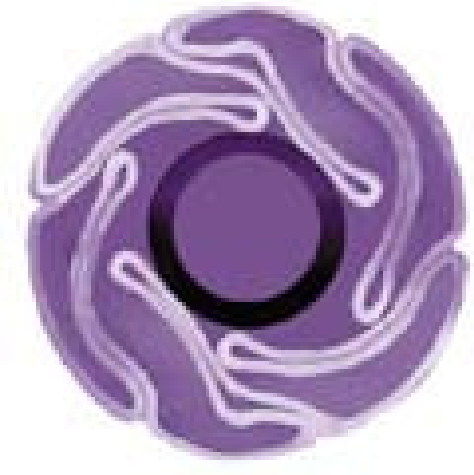
Notched resistance & flexibility (removal of catheter)

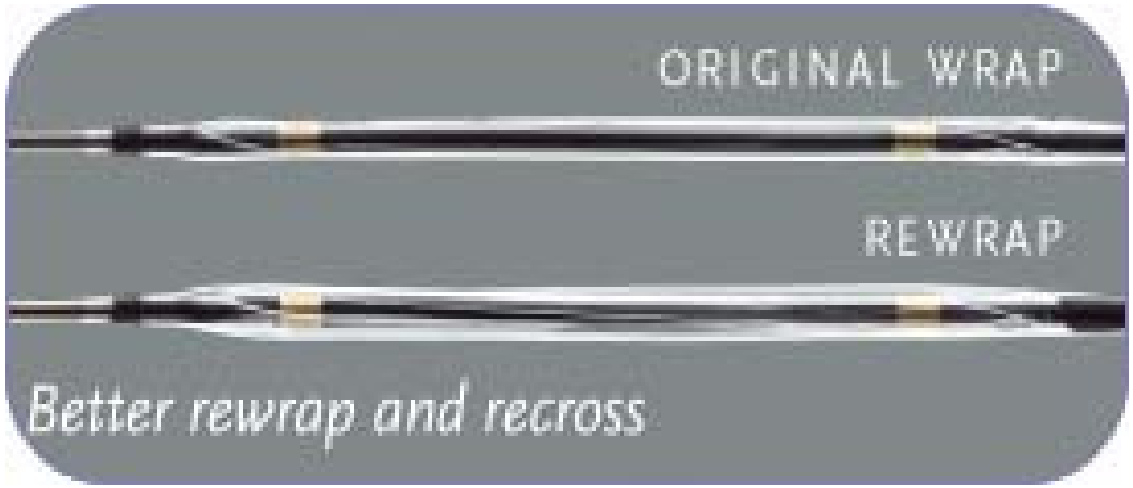


Rewrap performance determined by key material properties.

Minimal increase in deflated catheter size required

High elastic limit of VESTAMID® PA12 allows for best recovery of catheter diameter.





Typical properties of Elastomeric Polyamides (ex. VESTAMID® E62)

Density	23 °C	ISO 1183	DIN EN ISO 1183	g/cm³	1.03
Tensile test		ISO 527-1	DIN EN ISO 527-1		
Tensile strength		ISO 527-2	DIN EN ISO 527-2	MPa	42
Strain at break				%	>200
Tensile modulus		ISO 527-1	DIN EN ISO 527-1	MPa	370
		ISO 527-2	DIN EN ISO 527-2		
CHARPY impact strength		ISO 179/1eU	DIN EN ISO 179/1eU		
	23 °C			kJ/m²	N [1]
	-30 °C			kJ/m²	N [1]
CHARPY notched impact strength		ISO 179/1eA	DIN EN ISO 179/1eA		
	23 °C			kJ/m²	120 P [1]
	-30 °C			kJ/m²	8 C [1]
Shore-hardness D		ISO 868	DIN EN ISO 868		62
Temperature of deflection		ISO 75-1	DIN EN ISO 75-1		
under load		ISO 75-2	DIN EN ISO 75-2		
Method A	1.8 MPa			°C	45
Method B	0.45 MPa			°C	100

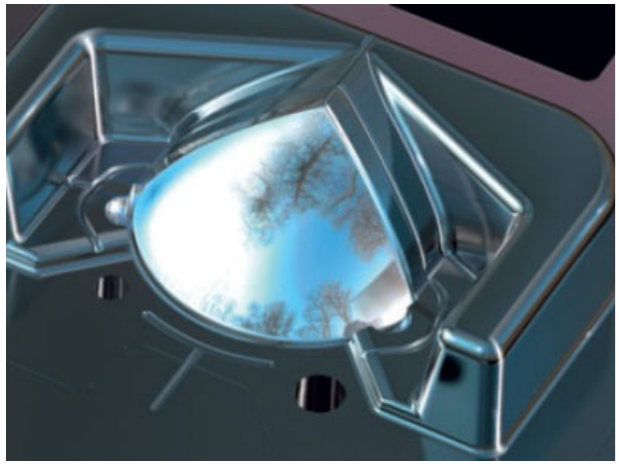
Precision processes eliminate secondary operations

Koebelin Formenbau GmbH has developed a mold with which cardiac valve flaps can be produced from PA 12 without having to undergo any subsequent finishing steps

Key Challenge: prevention of any deposits, blood clots or disruptions to blood flow from forming on the mechanical flap.

Maximum permissible parting line offset of 5 µm.

Machining the mold surfaces with a Type V33i high-precision milling machine from Makino Milling Machine Co., Ltd., Tokyo/Japan achieved the goal.



Plastics allow advances in medical technology

Spinal Cage

Metal replacement in implantable does not differ greatly from other applications:

1. Reduced complexity
2. Greater design flexibility
3. Chemical (bio-compatibility in the case of medical)

Pacemaker Encapsulation

1. Ultra thin 3-D films (25-190 microns)
2. Low stress films for precision forming.
3. Provides a custom fit in an area where real estate is at a premium

Close cooperation between material and device designer is key to successful development

Ability to absorb energy separates material in dental post design

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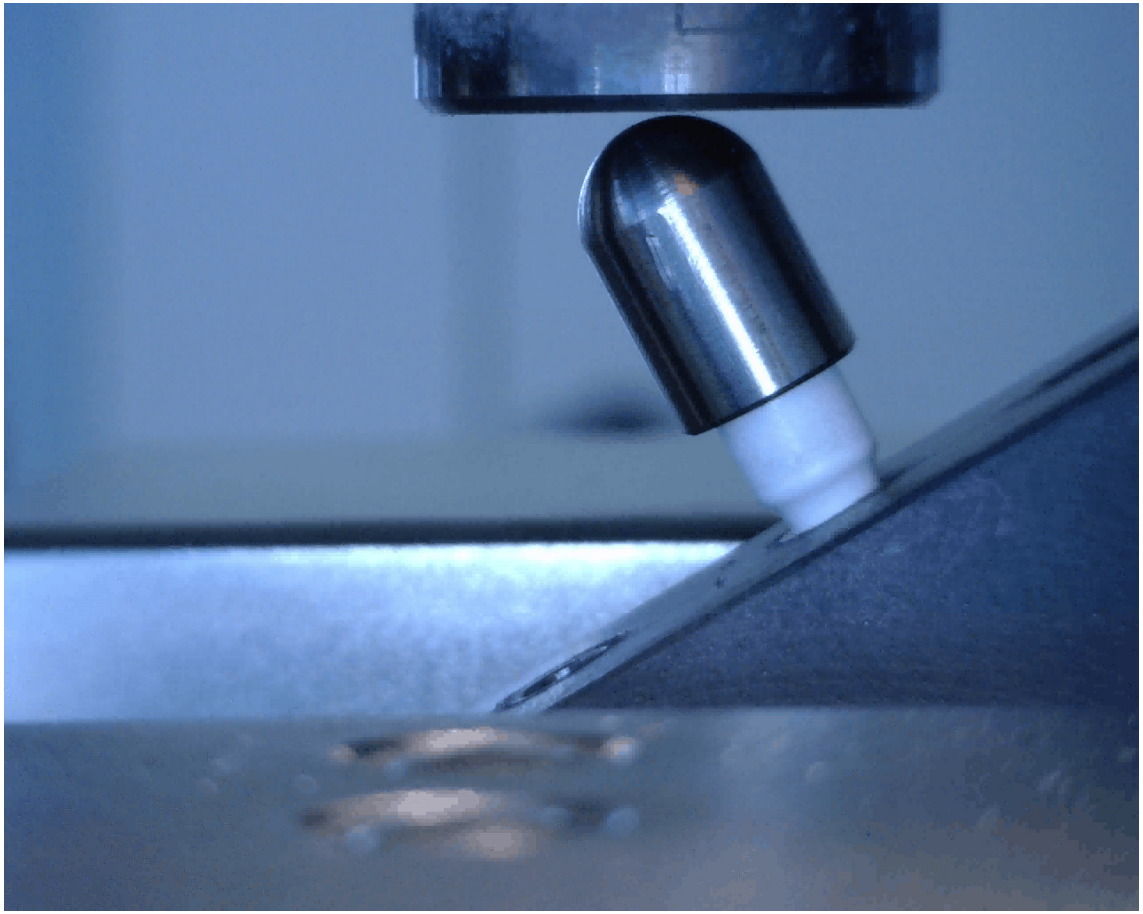

Regulatory activities critical to easy implementation

Standard testing

- USP class VI (Acute systemic toxicity, irritation, implantation)
- DIN EN ISO 10993 (Cytotoxicity, Haemocompatibility, Irritation, Sensitization)
- ASTM F 2026

EU Regulations

- VESTAKEEP® I meets the provisions of the Medical Device Directive 93/42/EEC and the Change Directive 2007/47/EG.
- (Directive is implemented in the national german law: MPG)

US Regulations

- In the USA registration of medical devices is done through the FDA (CDRH)
- The “technical documentation” is our master File for a device (reg. no. MAF – 1688).

Registration support EU

VESTAKEEP® I meets the provisions of the Medical Device Directive 93/42/EEC and the Change Directive 2007/47/EG.

(Directive is implemented in the national german law: MPG)

Full “technical documentation” for VESTAKEEP I production, covering all aspects of the medical device directive (if applicable for raw materials)

The documentation consist of 2 parts:

- part A: contains general information
- part B: contains detailed information about the product and production process

In Europe “notified bodies” are responsible for the registration process of medical devices. The technical documentation can be used for this purpose.

Registration support USA

In the USA registration of medical devices is done through the FDA (CDRH)

The “technical documentation” is our master File for a device

(reg. no. MAF – 1688).

Customers for VESTAKEEP I grades are getting a letter of authorization from us, so the FDA can use the information contained in the MAF for the registration process (510 k, PMA, …) of the medical device of our customers

How to identify your need for PEEK

	Yes
Continuous operating temperature up to 260 °C ?	
UL94 V-O rating and very low smoke density ?	
Excellent chemical resistance ?	
Need for high biocompatibility?	
Resistance against X-ray, beta – and gamma radiation ?	
Superior wear resistance ?	
Excellent creep, fatigue and modulus (metal substitution) ?	

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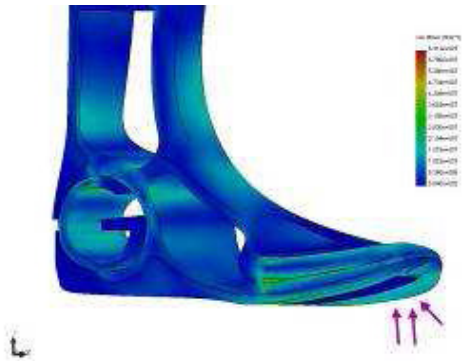
Polymers hold the potential for truly custom medical devices

Custom Orthotics

•High resolution body scanning technologies

•Utilizing the strength and compatibility of VESATMID® PA12 with additive manufacturing technologies

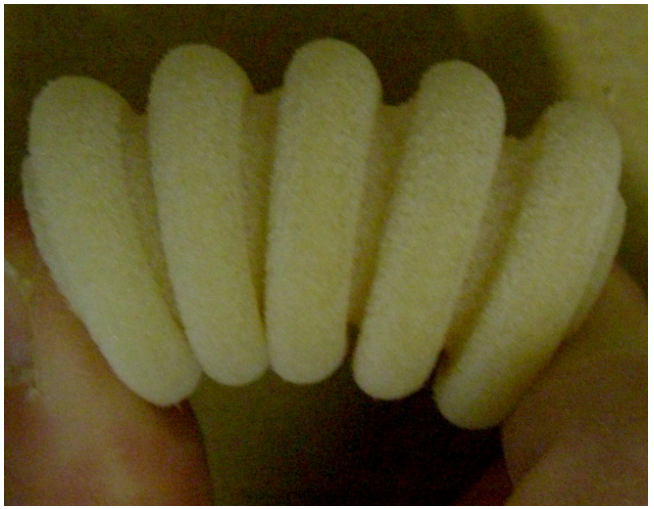
Achieves “Fits right the first time” goal



New products for SLS
Flexible material

Comparison of material properties

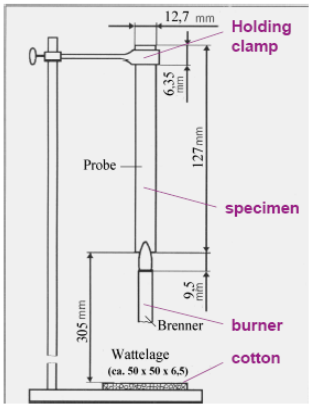
	standard grade	new flexible material
E modulus	1700 MPa (246.500 psi)	100 - 250 MPa (14.500 – 36.200 psi)
Elongation at break	15 %	>100 %
Tensile strength	45 MPa (6.250 psi)	8 MPa (1.160 psi)
Notched impact strength	3,5 KJ/m^2	No break
Melting point	186 °C (366 F)	150 °C (302 F)
Common refreshing rate	50 %	Not necessary
		Shore A 90 Shore D 40



New products for SLS
Flame retardant material

Comparison of material properties

	standard FR material	FR material 2nd generation
E modulus	2300 MPa (333.500 psi)	1000 MPa (145.000 psi)
Elongation at break	4 %	15 %
Tensile strength	45 MPa (6.250 psi)	40 MPa (5.800 psi)
Melting point	186 °C (366 F)	182 °C (360 F)
UL 94	V0 (1.6 and 3.2mm)	V0 (0.8 , 1.6 and 3.2mm)
Smoke density / toxicity	passed	passed



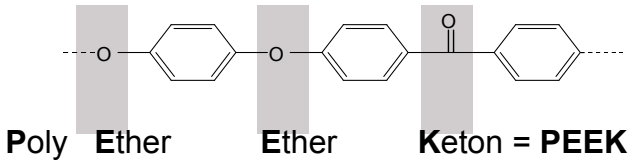
Test criterias	94 V-0
Total flaming combustion for each specimen	≤ 10 s
Total flaming combustion for all 5 specimens of any set	≤ 50 s
Cotton ignited by flaming drips from any specimen	no
Glowing or flaming combustion of any specimen to holding clamp	no
Flaming and glowing combustion for each specimen after 2 nd. Burner flame application	≤ 30 s

Vertical burning test

New products for SLS
VESTAKEEP® AR1064

Material properties

	VESTAKEEP AR1064
E modulus	> 3000 MPa (> 435.113 psi)
Elongation at break	2 %
Tensile strength	60 MPa (8700 psi)
Melting point	340 °C (644 F)
Continuous operating temperature	280 °C (536 F)



Poly **E**ther **E**ther **K**eton = **PEEK**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