Evonik Corporation

High Performance Polymers for Medical Device Applications

Suneel Bandi, PhD
SPE draft, 2017
Medical Device Market

Medical Devices

Implants

- Class I, II, & III Devices
- Tubular Products
- Rigid & Clear Products
- Fixation Devices
- Dental

Non-implants

- Cardiovascular
- Fluid Delivery
- Minimally Invasive
- Drug Delivery
- Surgical Instrument
- Fixation Devices
- Imaging
- Diagnostics
- Lenses
- Instrument Housings
- Long Term Implants
HPP- Medical Portfolio

VESTAMID®
Care
PA12, PEBA and PPA

VESTAKEEP®
Care and i Grades
PEEK

TROGAMID®
Care
Transparent Polyamides

Biocompatibility Information

Sterilization Testing

Customized Solutions

Application Technology Support
High Performance Polymers for Medical Device Applications

Evonik – High Performance Polymers

VESTAMID® Care

TROGAMID® Care

VESTAKEEP® Care and i-Grades

Questions / Answers
VESTAMID® Care

PEBA – Care ME
- Minimally invasive
- Drug delivery
- Blood Management
- Pumps
- Catheters
- Balloons

PA12 – Care ML
- Components
- Minimally invasive
- Drug delivery
- Blood Management
- Pumps
- Catheters
- Balloons

VESTAMID® Care applications

PPA- Care HT Plus
- Surgical handles
- Endoscopes
- Fixation equipment
- Metal replacement
- Components
- Chemical testing
- Chromatography

Biobased - Terra
- Catheters
- Minimally Invasive
- Air Delivery
- Blood Management
- Motors

PA612 - D
- Pumps
- Guidance
- Components
- Hardware
- Motors
VESTAMID® Care ME
Polyether block amide

Flexible
Free of plasticizers
Variable hardness
Good retraction
High impact strength

Biocompatibility compliance:
USP <88> Class VI, ISO 10993-5/-10/-11, ASTM F756-08

VESTAMID® Care ME26
VESTAMID® Care ME40
VESTAMID® Care ME55
VESTAMID® Care ME62
VESTAMID® Care ME71

VESTAMID® Care ME40-B
VESTAMID® Care ME55-B
VESTAMID® Care ME65-B
VESTAMID® Care ME71-B

Adhesion to EFEP

Diagnostic & Therapeutic Catheters
Tubing

Biocompatibility compliance:
USP <88> Class VI, ISO 10993-5/-10/-11, ASTM F756-08
VESTAMID® Care ML Polyamide 12

- High impact strength
- Strong & flexible
- Puncture resistance
- Chemical & Solvent resistance
- Abrasion resistance

Diagnostic & Therapeutic Catheters and Balloons
- Flexibility
- Burst Pressure
- Compliance
- Strength

Durable Equipment

VESTAMID® Care ML16 unmodified
VESTAMID® Care ML17
VESTAMID® Care ML18
VESTAMID® Care ML19
VESTAMID® Care ML21
VESTAMID® Care ML67 stabilized
VESTAMID® Care ML94
VESTAMID® Care ML24

Biocompatibility compliance:
USP <88> Class VI, ISO 10993-5/-10/-11, ASTM F756-08
High Lubricity Multi Layer Catheters

STEP 1: Extrude Fluoropolymer over wire mandrel
STEP 2: Etch Fluoropolymer
STEP 3: Hand build successive layers of PEBA over Fluoropolymer core
STEP 4: Sleeve final layer of FEP Heat Shrink tubing
STEP 5: Heat assembly and fuse all layers together
STEP 6: Remove Heat Shrink tubing and wire mandrel for finished product

COF

<table>
<thead>
<tr>
<th>EFEP</th>
<th>PEBA</th>
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<tbody>
<tr>
<td>0.08</td>
<td>0.65</td>
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</table>
Modified PEBA Directly Bonds to Fluoropolymer EFEP to Impart Lubricity

**VESTAMID® Care ME-B**
PEBA grades which can adhere directly to fluoropolymers

VESTAMID® Care ME-B

NEOFLON™ EFEP RP-5000

Strong, adhesive-free bonding via coextrusion of VESTAMID® Care ME-B and NEOFLON™ EFEP RP-5000

VESTAMID® Care ME40-B on NEOFLON™ EFEP RP5000

VESTAMID® Care ME40 on NEOFLON™ EFEP RP5000
Separation Resistance Between EFEP and VESTAMID® Care ME/ME-B Grades

EVONIK-Daikin Trials

FIG. Peeling Test

Neoflon™ EFEP RP-5000 + VESTAMID® Care ME
Neoflon™ EFEP RP-5000 + VESTAMID® Care ME-B

SPE ANTEC® Anaheim 2017 / 1803
Melt Bonding Map

Melt bonding
- Co-extrusion
- Injection over molding
- Compression molding

<table>
<thead>
<tr>
<th>MATERIALS</th>
<th>OLEFINS</th>
<th>FLUORO POLYMER</th>
<th>ENGINEERING</th>
<th>Other</th>
<th>ADHESIVE</th>
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<tbody>
<tr>
<td></td>
<td>LDPE</td>
<td>HDPE</td>
<td>PP</td>
<td>EFEP</td>
<td>FEP</td>
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<td>PEBA</td>
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<td>PA 12</td>
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<td>PEBA- B</td>
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<tr>
<td>PA 12- B</td>
<td></td>
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<tr>
<td>Trogamid-B</td>
<td></td>
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</tbody>
</table>
VESTAMID® Care M30-HT
PPA High Temperature Polymers

- Durable Equipment & Instruments
- Mechanical Parts
- VESTAMID® Care M30-HT PPA

Hardness
Toughness
Dimensional stability at high temperatures
Chemical resistance
Hydrolysis resistance

Biocompatibility compliance:
USP <88> Class VI, ISO 10993-5/-10/-11, ASTM F756-08
High Performance Polymers for Medical Device Applications

Evonik – High Performance Polymers

VESTAMID® Care

TROGAMID® Care

VESTAKEEP® Care

Questions / Answers
**Microcrystalline**
- Minimally invasive
- Surgical handles
- Endoscopes
- Fixation equipment
- Dental applications

**TROGAMID® Care applications**

**Amorphous**
- Air delivery
- Drug delivery
- Blood Management
- Pumps
- Catheters
TROGAMID® Care MX & MT
Transparent Nylon

Chemical resistance
Stress-cracking resistance
Transparency

Infusion Equipment
Durable Equipment & Housings

TROGAMID® Care MX73 microcrystalline
TROGAMID® Care MX97
TROGAMID® Care MX73-L laser-absorbing
TROGAMID® Care MX73-A antibacterial
TROGAMID® Care MT50 amorphous

Biocompatibility compliance:
USP <88> Class VI, ISO 10993-5/-10/-11, ASTM F756-08
**TROGAMID® Care MX73-L**

Visible markings on transparent parts

*Nano particles absorb laser radiation but don’t interact with light in the visible range*

- Laser-welding of two transparent parts
- Surface & sub-surface laser-marking
- Preserved transparency

Absorption of laser-radiation by nano particles in TROGAMID® Care MX73-L. The generated heat welds the parts together.
Improper disinfection & maintenance of medical devices are among the key risk factors for Health-Care Associated Infections.

**TROGAMID Care MX73-A**

- Release of silver ions upon contact to water
- Biocompatibility approvals according to USP <88> class VI & ISO 10993 i.e. suitable for any body contact of ≤ 30 days

![Bacteria reduction > 99.99%](image)
High Performance Polymers for Medical Device Applications

Evonik – High Performance Polymers

VESTAMID® Care

TROGAMID® Care

VESTAKEEP® Care

Questions / Answers
VESTAKEEP® Care

Minimally invasive
Surgical tools
Chromatography
Fixation equipment
Dental applications

VESTAKEEP® Care
applications

Endoscopes
Metal replacement
Components
Chemical testing
Air & drug delivery
VESTAKEEP® Care (Non-Implant) PEEK

- Durable Equipment & Instruments
- Surgical tools
- VESTAKEEP® Care M20G PEEK
- VESTAKEEP® Care M40G PEEK
- VESTAKEEP® Care M33HP PEEK high purity
- VESTAKEEP® Care M40R PEEK rods

Hardness
Toughness
Dimensional stability at high temperatures
Chemical resistance
Hydrolysis resistance

Biocompatibility compliance:
USP <88> Class VI, ISO 10993-5/-10/-11, ASTM F756-08
VESTAKEEP Implant Grades

<table>
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<tr>
<th>Resins *)</th>
<th>Stock Shapes</th>
<th>Disks</th>
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<tr>
<td>High flow for injection molding</td>
<td>Rods and Plates in various dimensions</td>
<td>Various dimensions and geometries</td>
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<tr>
<td>Low flow for extrusion</td>
<td></td>
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*) For melt processing, various viscosities are available from low to high flow
### Injection molded specimen

<table>
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<tr>
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<th>i4 G</th>
<th>iC4506 G</th>
<th>iC4515 G</th>
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<tr>
<td>BaSO4 content</td>
<td>0%</td>
<td>6%</td>
<td>15%</td>
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<tr>
<td>E-Modulus [MPa]</td>
<td>3500</td>
<td>3800</td>
<td>3800</td>
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<tr>
<td>Tensile strength [Mpa]</td>
<td>96</td>
<td>93</td>
<td>93</td>
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<tr>
<td>Charpy Impact</td>
<td>8</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>MVR [mL/10min]</td>
<td>12 (380°C/5kg)</td>
<td>10.5</td>
<td>9.0</td>
</tr>
</tbody>
</table>

- PEEK exhibits an X-ray absorption close to human tissue and is invisible in X-ray
- Barium sulphate renders VESTAKEEP® iC45xx grades X-ray opaque
- Unlike metals, the materials do not generate X-ray artifacts
- The material is MRI-compatible
Carbon Fiber Reinforced i grade Vestakeep-Injection molded

<table>
<thead>
<tr>
<th>Injection molded specimen</th>
<th>2000CF30</th>
<th>4000CF30</th>
<th>5000CF30</th>
<th>L4000G (comparison)</th>
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<tbody>
<tr>
<td>E-Modulus [MPa]</td>
<td>21</td>
<td>21</td>
<td>211</td>
<td>3500</td>
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<tr>
<td>Tensile strength [Mpa]</td>
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<td>213</td>
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<td>96</td>
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<tr>
<td>Charpy Impact</td>
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<td>9.8</td>
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<tr>
<td>MVR [mL/10min]</td>
<td>24 (400°C/5kg)</td>
<td>25.6 (400°C/21.6 kg)</td>
<td>18.9 (400°C/21.6 kg)</td>
<td>12 (380°C/5kg)</td>
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</table>
Shape memory Video
Care – Medical Portfolio

Biocompatibility Statements

CoAs

Customized Solutions

Sterilization methods

ISO 10993

Compliance

Customer specific

EtO

Gamma

Steam

ASTM F756-08

USP Class VI

Material Development

Application Technology Support

VESTAMID Care
PA12, PEBA, & PPA

TROGAMID Care
Transparent Polyamides

VESTAKEEP Care and i grades
PEEK

SPE ANTEC® Anaheim 2017 / 1818
Evonik Innovation Commitment

Major Medical Related Investment / Activity

- Corporate commitment to megatrends health / nutrition, globalization.
- Global Industry / Academic partnerships
- 70% growth in HPP business development resources in USA in last 3 years.
- Multi million investment in USA Technical Center (Lafayette, IN).
- Medical polymer portfolio and capacity expansions.
- Consideration for corporate medtech / biocompatible investment.
- Acquisition of leading bio-absorbable polymer technology.
- Acquisition of exclusive synthesis / API plant from Eli Lilly
QUESTIONS?
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High Performance Polymers
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Email: suneel.bandi@evonik.com
Biocompatibility of a material depends on the way it will be used and mainly:

**Nature of body contact**

FDA / Classification MDD 93/42/EWG
- Class 1: low risk level
- Class 2a/2b: medium risk level
- Class 3: high risk level

Classification not necessarily corresponding with contact duration time

**Duration of body contact**

ISO 10993-1 Categorization of Medical devices
- limited: ≤ 24 hours
- prolonged: > 24 hours, not to exceed 30 days
- permanent: > 30 days