

## Implantables Comparison Brochure

From bioabsorbable tubing and microporous monofilaments, to electrospun composite membranes and more, Zeus provides a host of implantable products designed to safely exist within the body and meet the growing needs of the medical device industry.



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## Long-term Implantable Non-Absorbable Applications

Zeus has developed a host of non-absorbable products that align with industry requirements across a diverse range of applications such as polymeric wraps for metallic stents, femoral closure devices, mitral valve repair, and more.



### Polymeric Wraps for Metallic Stents

Since the first bare metal coronary stent was implanted in 1986, stent design has undergone tremendous transformation and improvement. Among the numerous improvements in stent technology was the introduction of stents covered with a graft material, typically a form of PTFE, for use in various coronary and peripheral vascular applications.

Covered stents have an advantage over bare metal stents in that they can help prevent the development of restenosis, the gradual re-narrowing of the stented portion of the blood vessel. Today, Zeus helps support the continued evolution of covered stent technology through our Aeos™ ePTFE and Bioweb™ product lines.

### Aeos<sup>™</sup> ePTFE Sub-Lite-Wall<sup>™</sup> Tubing, Oriented Tubing, **Ribbon, and Membranes**

Aeos™ ePTFE is produced by mechanically expanding biocompatible PTFE to produce a microporous structure of solid nodes interconnected by fibrils. This combination of microporous structure coupled with the many PTFE qualities which are retained after stretching, make Aeos<sup>™</sup> ePTFE an extremely versatile material for stent grafts.

- Microporous
- Soft and flexible
- Ultra-thin

### Bioweb<sup>™</sup> PTFE/PU Composite Membrane

Bioweb<sup>™</sup> is a non-woven composite membrane produced by electrospinning biocompatible PTFE and PU in polymeric nanofibers. Bioweb™ PTFE/PU composite membranes provide an efficient adhesion platform for stents and scaffolds, enabling low-profile encapsulation over nitinol frames without sutures at a much lower temperature (266 °F / 130 °C) than traditional ePTFE coverings (572 °F / 300 °C). In addition to lower temperature bonding than ePTFE, Bioweb<sup>™</sup>'s PU layer combined with the PTFE layer provides isotropic mechanical properties, allowing Bioweb™ to encapsulate a wider variety of frames and unique geometries.

- Microporous & ultra-thin
- Isotropic mechanical properties



Aeos™ ePTFF membrane



Low temperature bonding (266 °F / 130 °C)

## Polymeric Wraps for Metallic Stents

	Aeos™ ePTFE Sub-Lite- Wall™ Tubing	Aeos™ Biaxial Oriented Tubing	Aeos™ ePTFE Membrane	Aeos™ ePTFE Ribbon	Bioweb™
Availability	Customizable	Customizable	Customizable	Customizable	Customizable
Size Classification	Ultra-Thin	Ultra-Thin	Ultra-Thin	Thicker	Ultra-Thin
Orientation	Unaxial	Biaxial	Biaxial	Uniaxial/Calendared	Random
Sintered/Unsintered	Both	Both	Both	Both	Sintered
Density Value	Low To Moderate 0.22 g/cm³ – 1.09 g/cm³	Low 0.22 g/cm <sup>3</sup> - 0.65 g/cm <sup>3</sup>	n/a	Low to High 0.22 g/cm³ - 1.52 g/cm³	n/a
Basis Weight	n/a	n/a	1.50 g/m² - 40.0 g/m²	n/a	PTFE Layer 12.27 g/m <sup>2</sup> (± 1.45 g/m <sup>2</sup> ) PU Layer 3.30 g/m <sup>2</sup> (± 1.9 g/m <sup>2</sup> )
Internodal Distance (IND)	Moderate to High 30 µm - 100 µm	Moderate to High 30 µm - 100 µm	n/a*	Low to High 10 µm – 80 µm	n/a
Porosity Value %	Moderate to High	High	Low to High	Low to High	n/a
Pore Size	n/a	n/a	Tight Pores 0.2 μm - 1.0 μm	Larger Pores 1.0 µm – 10 µm	Larger Pore Size (> 1 µm unsealed)
Microstructure SEM Image Comparison	More Uniform Unidirectional Pores 1000x	More Tortuous Path – Reduced Permeability – Pore Size 1000x	More Tortuous Path for Pores 5000x	Larger More Uniform Unidirectional Pores 1000x	Larger Pore Size 5000x
Inside Diameter (ID)	0.014" - 0.150" (0.356 mm - 3.810 mm)	0.390" - 0.866" (9.906 mm - 21.996 mm)	n/a	n/a	n/a
Inside Diameter (ID) Tolerance	± 0.003" (± 0.076 mm)	± 0.010" (± 0.254 mm)	n/a	n/a	n/a
Thickness	0.0020" - 0.0049c (0.0508 mm - 0.1245 mm) Wall Thickness	0.0020" - 0.0050" (0.0508 mm - 0.1270 mm) Wall Thickness	0.00015" - 0.00400" (0.00381 mm - 0.10160 mm) Membrane Thickness Reference Only	0.002" - 0.020" (0.051 mm - 0.508 mm)	0.002" - 0.005" 0.051 mm - 0.127 mm Membrane Thickness Reference Only
Thickness Tolerance	± 0.001" (± 0.025 mm)	± 0.002" (± 0.051 mm)	n/a	± 0.0005" (± 0.0127 mm)	n/a
Width	n/a	n/a	6" - 24" (152.4 mm - 609.6 mm)	0.05" - 4.00" (1.27 mm - 101.6 mm)	Up to 14" (355.6 mm)
Width Tolerance	n/a	n/a	n/a	± 0.020" (± 0.508 mm)	± 0.500" (± 12.7 mm)
Length	n/a	Max 12" (Max 304.8 mm) ± 0.250" (± 6.35 mm)	n/a	n/a	Min 24" (Min 609.6 mm)

\*Tighter Pore Sizes Make IND Measurement Hard to Replicate

## Tethering, Anchoring, Suturing, and Vessel Closure

Many medical procedures, especially surgeries, often require various forms of suturing or tethering to complete the operation. Procedures as diverse as valve repair, device implantation, and cosmetic surgery require specialized monofilaments and sutures that can survive a range of biological environments.

Zeus' medical monofilaments are made from USP Class VI biocompatible materials that excel in performance and not elicit unwanted biological effects including inflammation or immune response.

#### Aeos<sup>™</sup> Sutures & Monofilaments

Aeos<sup>™</sup> ePTFE suture and monofilament products deliver and maintain exceptional tensile strength and flexibility. Low surface friction allows surgeons to position knots precisely while Aeos<sup>™</sup> ePTFE high strength suture variants deliver enhanced straightpull and knot-pull strength for a stronger suture with better closure and optimized healing. All products are non-absorbable and can be permanently implanted with minimal immune response for reduced scarring.

- Can be swaged with 1:1 needle-to-suture ratio
- Soft and flexible
- High strength versions available for increased knotpull strength





#### Straight Pull and Knot Pull Strength Comparison

## Tethering, Anchoring, Suturing, and Vessel Closure

	Aeos™ Customized Monofilament	Aeos™ Suture Monofilament	Aeos™ High Strength Suture Monofilament
Availability	Customizable	Ordered as ASM/USP	Customizable
Strength Classification	Standard	Standard	Stronger
Process	Extruded	Extruded	Extruded + Drawn
Density	Moderate To High (0.65 g/cm³ - 1.85 g/cm³)	Moderate (0.56 g/cm³ – 1.09 g/cm³)	High (0.85 g/cm³ - 1.85 g/cm³)
Density Tolerance	± 0.2 g/cm³	n/a	± 0.2 g/cm³
Outside Diameter (OD)	0.010" - 0.150" (0.254 mm - 3.810 mm)	0.0080" – 0.0300" (0.2032 mm – 0.7620 mm) mean diameter	0.007" - 0.030" (0.178 mm - 0.762 mm)
Outside Diameter (OD) Tolerance	± 0.002" (±0.051 mm)	n/a	± 0.002" (±0.051 mm)

## Long-term Implantable Absorbable Applications

Zeus has developed a host of bioabsorbable products that align with industry requirements across a diverse range of applications such as absorbable stenting and scaffolding, cosmetic implants, controlled drug delivery, and more.



The usage of bioabsorbable polymers has grown in popularity over the last five decades, especially for applications seeking to provide an alternative to metal stents and other implantable components.

A key advantages of bioabsorbable polymers over these other materials is their ability to be absorbed naturally by the body (typically within 1-36 months), eliminating the need for permanent implantation or surgical removal at a later date. Zeus works with a number of bioabsorbable polymers including PDLGA, PLGA, PGA, PDO, PLDLLA, PLC, PLLA, and PCL, and can extrude these resins into high precision tubular geometries that can be further processed for use in bioresorbable vascular scaffolds (BRS).

#### Absorv<sup>™</sup> XSE Tubing

Absorv<sup>™</sup> XSE takes our Absorv<sup>™</sup> tubing to the next level. Through improved molecular orientation, Absorv<sup>™</sup> XSE now possesses enhanced uniformity that leads to more predictable strength and improved laser-cutting efficiency when compared to our previous generation of Absorv<sup>™</sup> oriented tubing\*\*. Absorv<sup>™</sup> XSE tubing is offered in OD sizes up to 0.295" (7.5 mm) and cut lengths up to 8.25" (209.55 mm) with wider development ranges available upon request. This unmatched sizing, combined with uniform wall thickness and tailored absorption profiles is evolving BRS applications and giving designers more efficient and predictable options for replacing metallic stents in a wider variety of procedures spanning cardiovascular, peripheral, ENT, and other fields.



- Various materials and combinations
- Optimized properties
- Controlled load transfer

See page 10 for comparison of bioabsorbable polymers.

	Absorv™ Tubing	Absorv™ XSE Tubing
Oriented/Non-Oriented	Non-Oriented	Oriented
Strength Classifcation	Standard	Stronger
Outside Diameter	0.31 mm – 6.35 mm 0.012″ – 0.250″	2.5 mm - 7.5 mm 0.098" - 0.295" Development diameters from 0.059" - 0.591" (1.5 mm - 15 mm) may be possible
Wall Thickness	25 μm - 2010 μm 0.025 mm- 2.010 mm 0.001" - 0.079"	50 μm - 250 μm (± 15% to 25%) 0.050 mm - 0.250 mm (± 15% to 25%) 0.002" - 0.010" (± 15% to 25%)
Length	up to 673 mm (± 6.4 mm) up to 26.5" (± 0.25")	up to 210 mm (± 6.4 mm) up to 8.25" (± 0.25")



Figure 1: 30 scaffolds produced from previous generation  $Absorv^{M}$  oriented tubing vs. 30 scaffolds produced from new  $Absorv^{M}$  XSE oriented tubing. For each scaffold, strut thickness measurements were taken at three axial locations (left end, middle, and right end), wherein the minimum and maximum of four equidistant circumferential strut thickness measurements were recorded. Scaffolds produced from  $Absorv^{M}$  XSE oriented tubing exhibited vastly improved strut thickness uniformity.



Figure 2: Absorv™ XSE oriented tubing provides more than 2x greater tensile strength over non-oriented Absorv™ tubing\*.

\*Based on testing of a nominal size, oriented vs. non-oriented that are not sterilized, not intended to be a specification, actual testing and economic value is subject to change with material(s), sizes, or product types.

\*\*Based on testing of a nominal size, previous generation vs new generation of oriented tubing that are not sterilized, not intended to be a specification, actual testing and economic value is subject to change with material(s), sizes, or product types.

Disclaimer: Absorv™ tubing utilizes manufacturing aids made from Class VI PTFE monofilament. As a result, embedded PTFE particulates may be present in the product. Zeus does not warrant that Absorv™ tubing is free of PTFE particulates. Customers must assess the suitability and safety of using Absorv™ tubing products for medical devices.

#### Biomaterials & Implantables Comparison Brochure

#### Absorv<sup>™</sup> Monofilament & Drawn Fiber

Bioabsorbable monofilaments have been utilized in the medical device industry for decades, most notably as an alternative to traditional suture materials. Absorv<sup>™</sup> monofilament continues this tradition and provides a good option for wound closure or soft tissue repair in active areas of the body when a permanent implantable material is not desirable.

When a monofilament with higher tensile strength is needed, such as in woven mesh devices, braided stents, or when seeking to form devices with unique designs and geometries, Absorv<sup>™</sup> drawn fiber is available. This high performance monofilament undergoes an additional step to elongate the fiber after the extrusion process. This extra step of drawing the fiber adds strength and uniformity to the fiber, ensuring it is optimized for your specific application needs.

- Controlled rates of degradation
- No explantation surgery
- Used in FDA-approved medical devices

	Absorv™ Monofilament (Round)	Absorv™ Profile Ex- truded	Absorv™ Drawn Fiber (Round)	Absorv™ Drawn Profile (Rectangular Profile with Aspect Ratio < 3)
Availabiality	Customizable	Customizable	Customizable	Customizable
Process	Extruded	Extruded	Extruded + Drawn	Extruded + Drawn
Oriented/ Non-Oriented	Non-Oriented	Non-Oriented	Oriented	Oriented
Strength Classification	Standard	Standard	Stronger	Stronger
Outside Diameter (OD)	0.004" - 0.080" 0.102 mm - 2.032 mm	Customer supplied drawing	0.0025" – 0.025" 0.064 mm – 0.635 mm	Height/Thickness: 0.004" - 0.030" 0.102 mm - 0.762 mm Width: 0.050" - 0.250" 1.27 mm - 6.35 mm
Outside Diameter (OD) Tolerance	± 0.0005" - 0.002" ± 0.013 mm - 0.051 mm	Customer supplied drawing	± 0.0005" - 0.002" ± 0.013 mm - 0.051 mm	Height: ± 0.001" - 0.0015" ± 0.025 mm - 0.038 mm Width: ± 0.001" - 0.003" ± 0.025 mm - 0.076 mm

### Absorv™ Monofilament & Drawn Fiber



Figure 3: Absorv™ Drawn fiber, in some sizes and materials, can provide up to 5x greater tensile strength when compared to Absorv™ Monofilament\*. Absorv™ drawn fiber also allows for heat-setting into custom shapes.



Figure 4: Controlled orientation and processing provides customizable mechanical properties such as strength, stiffness, and elongation. The fiber strength when knotted can be maximized by varying the level of orientation.



Figure 5a & 5b: Absorv™ Drawn Fibers are highly customizable and available in multiple resin options (i.e. homopolymers, copolymers, blends), as well as various shapes and sizes, allowing for tailored performance.

\*Based on testing of a nominal size, oriented vs. non-oriented that are not sterilized, not intended to be a specification, actual testing and economic value is subject to change with material(s), sizes, or product types.

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## Controlled Drug Delivery & Cosmetic Implants

From cancer treatments to tissue engineering and beyond, the novel ways in which bioabsorbable polymers can be utilized is rapidly evolving. Our Absorv<sup>™</sup> offerings help spur these innovative new applications by providing device manufacturers a versatile platform for next-generation device designs and therapies.

#### Absorv<sup>™</sup> Tubing

Like all of our bioabsorbable products, Absorv<sup>™</sup> tubing is capable of safely existing in the body for controlled lengths of time before being absorbed and eliminated naturally. Thanks to this finite functionality, Absorv<sup>™</sup> tubing is particularly well-suited for controlled drug release applications, such as in brachytherapy, where highly targeted and localized treatment is crucial.

- Various materials and combinations
- Controlled degradation rate
- No explantation surgery

#### Absorv<sup>™</sup> Ribbon

Absorv<sup>™</sup> can be produced in ribbon form, which resembles a flat sheet, albeit with notably narrower widths. Absorv<sup>™</sup> ribbons can be extruded free-form, or oriented in both the machine and transverse directions to enhance tensile properties. Unique geometries and fixtures can be later machine cut from the ribbon. The unique, high aspect ratio profile of Absorv<sup>™</sup> ribbon lends itself to a number of specialized applications that could benefit from "layers" or "patches" such as in wound closure, regenerative medicine, or tissue engineering.

- Various materials and combinations
- Controlled degradation rate
- No explantation surgery





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## Controlled Drug Delivery & Cosmetic Implants

	Absorv™ Extruded Special Ribbon (Aspect Ratio > 3)	Absorv™ Drawn Ribbon (Aspect Ratio > 3)
Oriented/Non-Oriented	Non-Oriented	Oriented
Strength Classifcation	Standard	Stronger
Width	0.250" – 1.25" (± 20% to 25%) 6.35 mm – 31.75 mm (± 20% to 25%)	0.050" – 0.250" (± 20% to 25%) 1.27 mm – 6.35 mm (± 20% to 25%)
Thickness	0.004" - 0.010" (± 20% to 25%) 0.102 mm - 0.254 mm (± 20% to 25%)	0.004" - 0.030" (± 20% to 25%) 0.102 mm - 0.762 mm (± 20% to 25%)
Length	Up to 673 mm (± 6.4 mm) Up to 26.5" (± 0.25")	Up to 673 mm (± 6.4 mm) Up to 26.5" (± 0.25") Spooled Put Up Available

### **Bioabsorbable Polymers**

Zeus has extensive experience with multiple bioabsorbable polymers, including custom blends and formulations. With advanced processing capabilities, we can successfully fine-tune mechanical properties and absorption profiles to meet the unique specifications of your design.

These tables are meant to serve as a general guideline only. For some polymers, varying levels of molecular orientation and crystallinity may result in a significant deviation from these values. Users should evaluate the material to determine suitability for their own particular application. If you do not see a particular bioabsorbable polymer listed below, or would like to inquire about custom formulations, please contact us to discuss your precise requirements.

MECHANICAL	ASTM	PDLGA (50DL/50G)	PLGA (10L/90G)	PGA	PDO	PLDLLA (80L/20DL)	PLGA (82L/18G)	PLGA (85L/15G)	PLC (95L/5C)	PLLA	PCL
Total Mass Loss (months)		1-2	3 - 4	4 - 6	5 - 9	12 - 18	12 - 20	18 - 24	18 - 30	18 - 36	24 - 36
Modulus of Elasticity (GPa)	ASTM D638 / ISO 527	2.0 - 4.0	3.0 - 6.0	6.0 - 7.0	0.4 - 1.0	2.0 - 4.0	2.0 - 4.0	2.0 - 4.0	2.0 - 4.0	3.0 - 4.0	0.2 - 0.4
Ultimate Tensile Strength (MPa)	ASTM D638 / ISO 527	45	45	95	65	50	60	60	60	65	25

### Bioabsorbable Polymers Comparison

THERMAL	ASTM	PDLGA (50DL/50G)	PLGA (10L/90G)	PGA	PDO	PLDLLA (80L/20DL)	PLGA (82L/18G)	PLGA (85L/15G)	PLC (95L/5C)	PLLA	PCL
Melt Temp (°C)	ASTM D3418	amorphous	200 - 210	215 - 225	100 - 110	115 - 130	135 - 145	140 - 150	160 - 180	180 - 190	55 - 65
Glass Transition Temp (°C)	ASTM D3418	45	42	40	-10	60	50	55	55	60	-60

# Get to know Zeus.



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### PROVIDE SOLUTIONS · ENABLE INNOVATION · ENHANCE LIVES

Zeus, headquartered in Orangeburg, South Carolina, is the world's leading polymer extrusion and catheter design manufacturer. With over 55 years of experience in medical, aerospace, energy, automotive, fiber optics, and other leading industries, Zeus's mission is to provide solutions, enable innovation, and enhance lives. The company employs over 2,400 people worldwide with facilities in Aiken, Columbia, Gaston, Orangeburg, and St. Matthews, South Carolina; Branchburg, New Jersey; Chattanooga, Tennessee; San Jose, California; Arden Hills, Minnesota; Guangzhou, China; and Letterkenny, Ireland. For more information, visit *www.zeusinc.com*.



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