

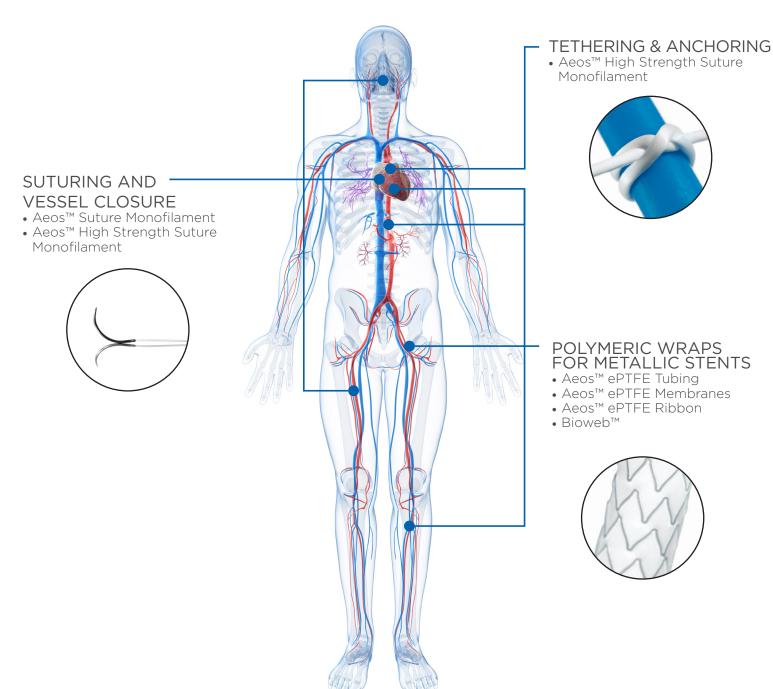
# Implantables Comparison Brochure

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.



# 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  $Aeos^{TM}$  ePTFE and  $Bioweb^{TM}$  product lines.

### Aeos™ ePTFE Sub-Lite-Wall™ Tubing, Oriented Tubing, Ribbon, and Membranes

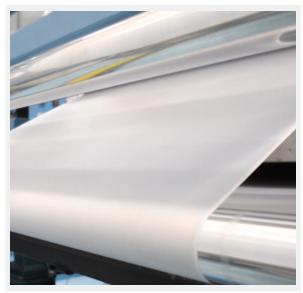
Aeos™ ePTFE is produced by mechanically expanding biocompatible PTFE to produce a microporous structure of solid nodes interconnected by fibrils. This combination of microporous structure coupled with the many PTFE qualities which are retained after stretching, make Aeos™ ePTFE an extremely versatile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

- Microporous
- Soft and flexible
- Ultra-thin

#### Bioweb™ PTFE/PU Composite Membrane

Bioweb™ 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™'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
- Low temperature bonding (266 °F / 130 °C)



Aeos™ ePTFE membrane



# 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/cm³ - 0.65 g/cm³	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)	0.050" - 1.000" (1.270 mm - 25.400 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	0.002" - 0.0049" (0.051 mm - 0.1245 mm) Wall Thickness	0.002" - 0.100" (0.051 mm - 2.540 mm) Wall Thickness	0.00015" - 0.004" (0.00381 mm - 0.102 mm) Membrane Thickness Reference Only	0.002" - 0.030" (0.051 mm - 0.762 mm)	0.002" - 0.005" 0.051 mm - 0.127 mm Membrane Thickness Reference Only	
Thickness Tolerance	± 0.0015" (± 0.0381 mm)	± 0.002" (± 0.051 mm)	n/a	± 0.001" (± 0.025 mm)	n/a	
Width	n/a	n/a	6.0" - 12.0" (152.4 mm - 304.8 mm)	0.050" - 4.000" (1.270 mm - 101.600 mm)	Up to 14" (355.6 mm)	
Width Tolerance	n/a	n/a	n/a	± 0.125" (± 3.175 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)	

<sup>\*</sup>Tighter Pore Sizes Make IND Measurement Hard to Replicate

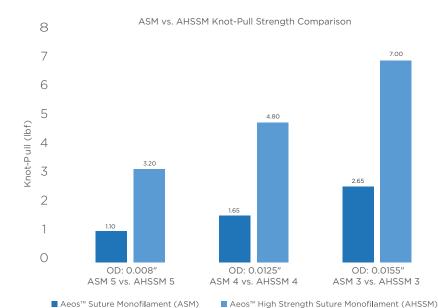
# Tethering, Anchoring, Suturing, and Vessel Closure

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 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 do not elicit unwanted biological effects including inflammation or immune response.

#### Aeos™ Sutures

Aeos™ ePTFE suture products are designed to obtain better closure, minimize the immune response, and promote optimal tissue attachment for swift patient healing. Combining a 1:1 suture-to-needle ratio with a soft feel and excellent drape, lubricious Aeos™ ePTFE suture monofilaments (ASM) help minimize patient bleeding while ensuring accurate knot placement during delicate procedures. When a step up in strength is required, Aeos™highstrengthsuturemonofilaments (AHSSM) retain the same characteristics as standard ASM, but feature nearly three times the USP knot-pull strength, helping provide superior performance for long-term loading-bearing applications.





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

# Tethering, Anchoring, Suturing, and Vessel Closure

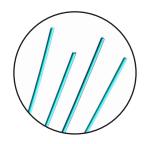
	Aeos™ ePTFE Customized Monofilament	Aeos™ ePTFE Suture Monofilament	Aeos™ ePTFE High Strength Suture Monofilament		
Availability	Customizable	Ordered as ASM/USP	Ordered as AHSSM/USP		
Strength Classification	Standard	Standard	Stronger		
Process	Extruded	Extruded	Extruded + Drawn		
Density	Moderate To High (0.65 g/cm³ - 1.85 g/cm³)	Moderate $(0.56 \text{ g/cm}^3 - 1.09 \text{ g/cm}^3)$	Moderate To High (0.85 g/cm³ – 1.75 g/cm³)		
Density Tolerance	± 0.2 g/cm³	n/a	n/a		
Outside Diameter (OD)	0.010" - 0.150" (0.254 mm - 3.810 mm)	0.008" - 0.030" (0.203 mm - 0.762 mm) mean diameter	0.008" - 0.0155" (0.203 mm - 0.3937 mm) mean diameter		
Outside Diameter (OD) Tolerance	± 0.002" (±0.051 mm)	n/a	+ 0.0015" / - 0.0005" (+ 0.0381 mm / - 0.0127 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.

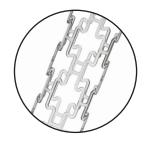
#### COSMETIC IMPLANTS

Absorv<sup>™</sup> Monofilament



#### ABSORBABLE STENTING & SCAFFOLDING

- Absorv<sup>™</sup> XSE Tubing
  Absorv<sup>™</sup> Monofilament
- Absorv™ Drawn Fiber



#### CONTROLLED DRUG **DELIVERY**

Absorv<sup>™</sup> Tubing

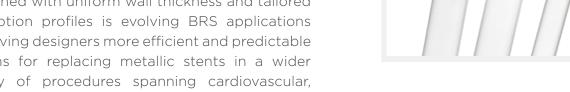


The usage of bioabsorbable polymers has grown in popularity over the last five decades, especially for applications seeking to provide an alternative to metal stents and other implantable components.

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™ XSE Tubing

Absorv™ XSE takes our Absorv™ tubing to the next level. Through improved molecular orientation, Absorv™ XSE now possesses enhanced uniformity that leads to more predictable strength and improved laser-cutting efficiency when compared to our previous generation of Absorv™ oriented tubing\*\*. Absorv™ 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")				



### Absolute Scaffold Strut Thickness Previous Generation vs. Absorv™ XSE

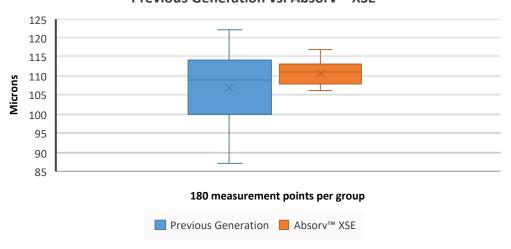


Figure 1: 30 scaffolds produced from previous generation Absorv™ oriented tubing vs. 30 scaffolds produced from new Absorv™ XSE oriented tubing. For each scaffold, strut thickness measurements were taken at three axial locations (left end, middle, and right end), wherein the minimum and maximum of four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

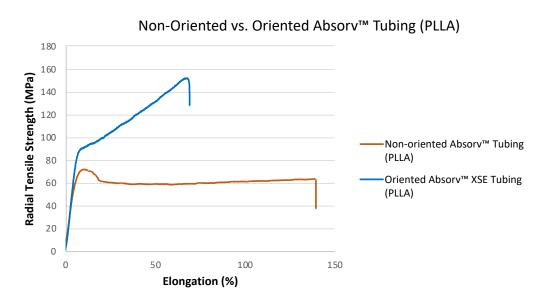


Figure 2: Absorv™ XSE oriented tubing provides more than 2x greater tensile strength over non-oriented Absorv™ tubing\*.

Disclaimer: Absorv $^{\mathbb{N}}$  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 $^{\mathbb{N}}$  tubing is free of PTFE particulates. Customers must assess the suitability and safety of using Absorv $^{\mathbb{N}}$  tubing products for medical devices.

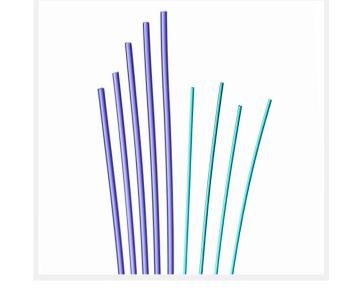
<sup>\*</sup>Based on testing of a nominal size, oriented vs. non-oriented that are not sterilized, not intended to be a specification, actual testing and economic value is subject to change with material(s), sizes, or product types.

<sup>\*\*</sup>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.

#### Absorv™ 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™ 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™ 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 & Drawn Fiber

	Absorv™ Monofilament (Round)	Absorv™ Profile Extruded	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)	er 0.004" - 0.080" Customer supplied 0.102 mm - 2.032 mm 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	Height: ± 0.001" - 0.0015" ± 0.025 mm - 0.038 mm Width: ± 0.001" - 0.003" ± 0.025 mm - 0.076 mm	

Custom sizes outside the listed capabilities may be possible upon request.

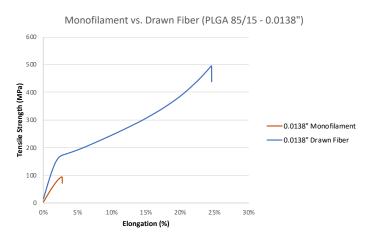


Figure 3: Absorv<sup>™</sup> Drawn fiber, in some sizes and materials, can provide up to 5x greater tensile strength when compared to Absorv<sup>™</sup> Monofilament\*. Absorv<sup>™</sup> drawn fiber also allows for heat-setting into custom shapes.

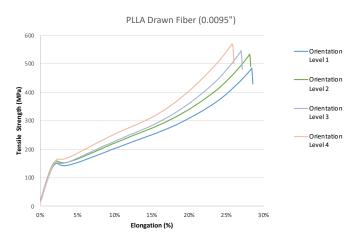
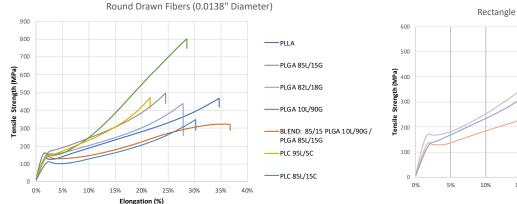


Figure 4: Controlled orientation and processing provides customizable mechanical properties such as strength, stiffness, and elongation. The fiber strength when knotted can be maximized by varying the level of orientation.



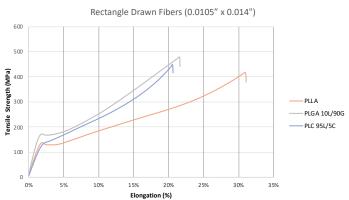


Figure 5a & 5b: Absorv<sup>M</sup> Drawn Fibers are highly customizable and available in multiple resin options (i.e. homopolymers, copolymers, blends), as well as various shapes and sizes, allowing for tailored performance.

\*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.

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.

### Controlled Drug Delivery

From cancer treatments to tissue engineering and beyond, the novel ways in which bioabsorbable polymers can be utilized is rapidly evolving. Our  $Absorv^{\mathsf{TM}}$  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,  $Absorv^{TM}$  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,  $Absorv^{TM}$  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



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## 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.

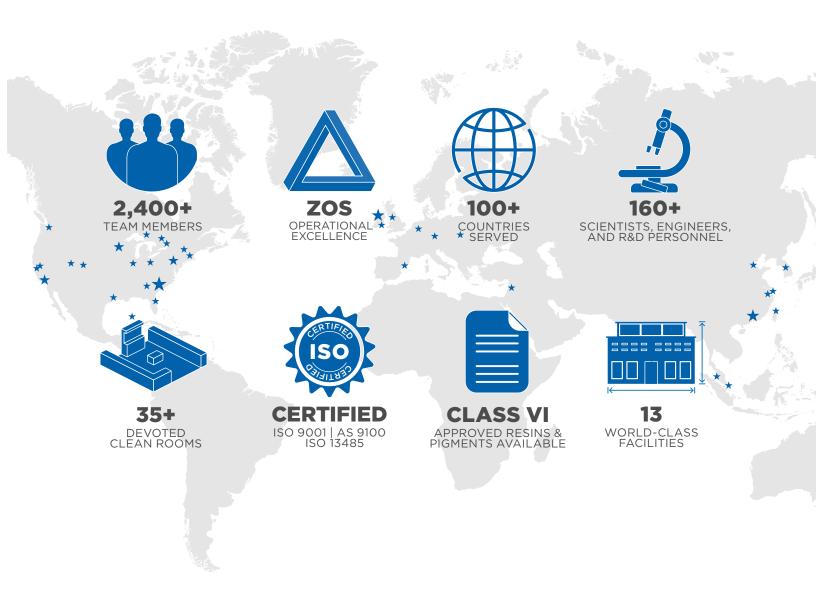
These tables are meant to serve as a general guideline only. For some polymers, varying levels of molecular orientation and crystallinity may result in a significant deviation from these values. Users should evaluate the material to determine suitability for their own particular application. If you do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

#### Bioabsorbable Polymers Comparison

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

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.



#### ——OUR MISSION ——

#### 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.

