

# Tyrocore: a proprietary polymer uniquely designed for vascular scaffolds

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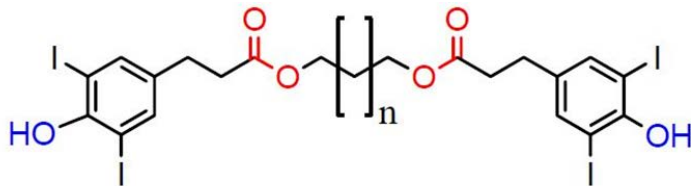
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I have the following potential conflicts of interest to report:  
Receipt of honoraria or consultation fees: REVA Medical

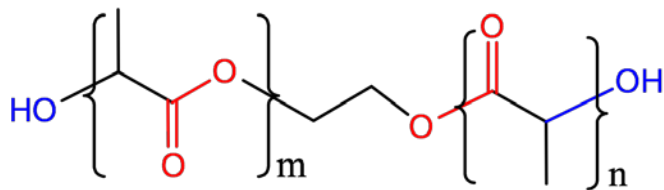
# Novel Tyrocore Polymer Overcomes First Generation BRS Limitations

- Limited use of first generation BRS due to poor **usability** and **clinical outcomes**.
- The **Tyrocore** bioresorbable polymer is **uniquely** designed for vascular scaffold applications.
- **Fantom**, a **second generation BRS** made from Tyrocore, offers substantial improvements over first generation BRS.

## Tyrocore Composition



Iodinated desamino-tyrosine polycarbonate




Poly(lactic acid) diol

## Features

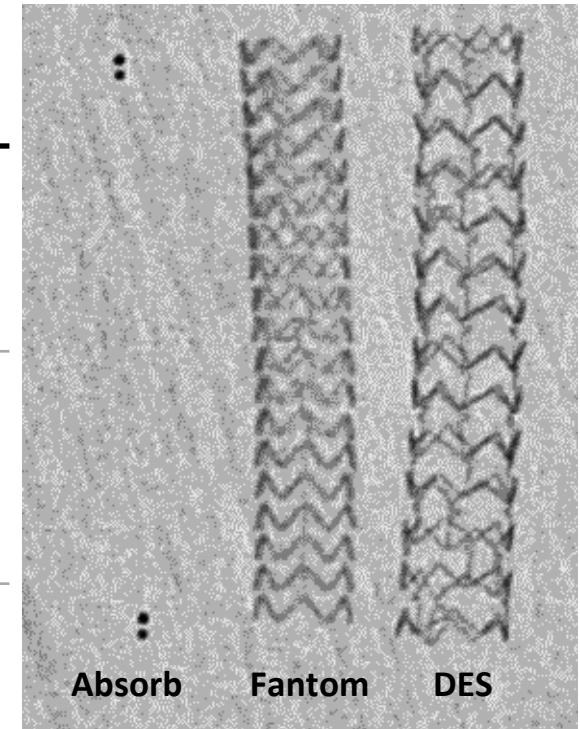
- **Biocompatibility**  
derived from tyrosine amino acid
- **Strength**  
polycarbonate phenyl ring structure (Iodinated diphenol)
- **Radiopacity**  
covalently bound iodine to polycarbonate backbone
- **Ductility**  
High molecular weight and composition provide ductility
- **Flexibility**  
Monomer molecules are linked with propane diol for flexibility

# Tyrocore Offers Improved Properties Compared to PLLA

## Properties of Tyrocore versus PLLA

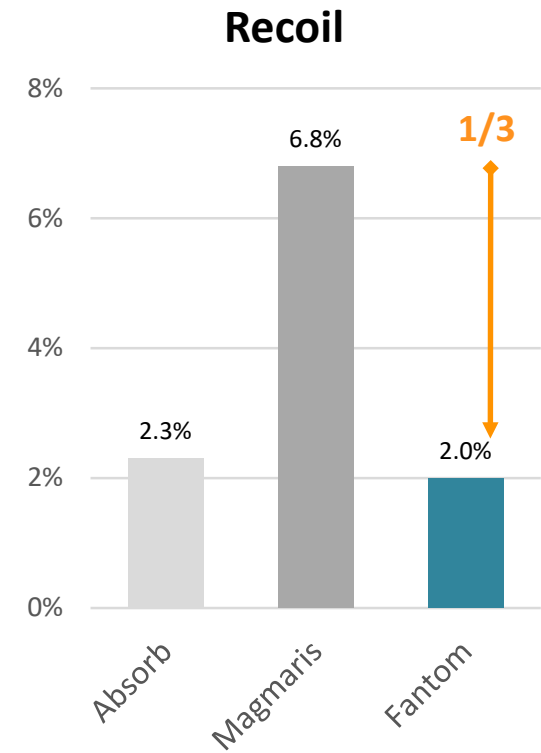
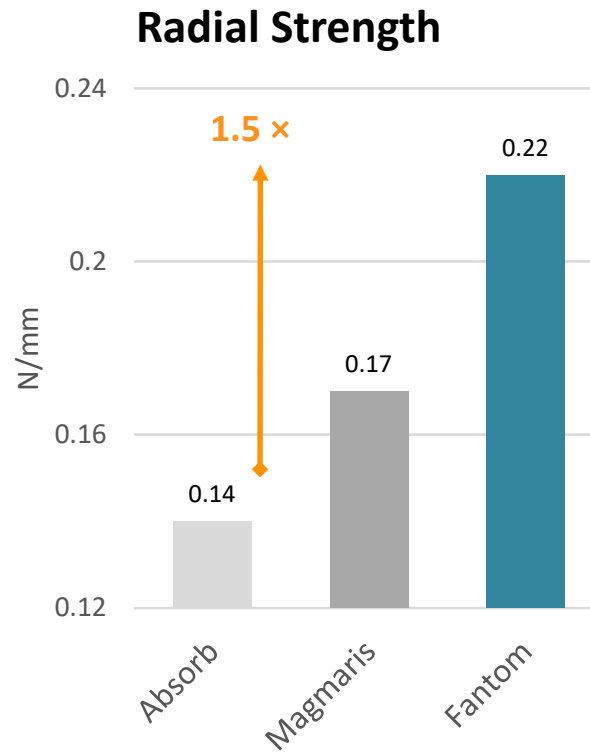
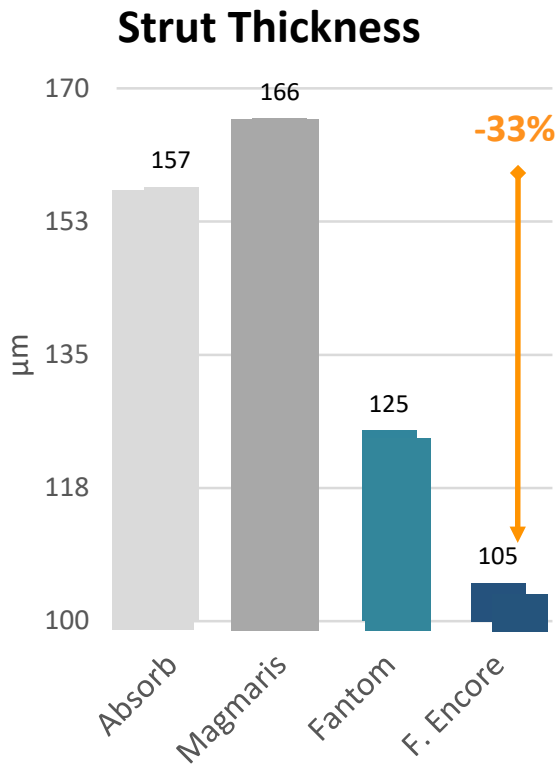
Attribute	Tyrocore	PLLA <sup>1</sup>	Benefit
Ultimate Tensile Strength	100-110 MPa <b>2x</b>	50-70 MPa	Thinner struts Radial strength Longitudinal strength
Elongation at Break (Ductility)	120-200% <b>&gt;50x</b>	2-10%	Single-step inflation Larger expansion range
X-Ray Visible	Yes 	No	Accurate placement

## Radiopacity



A single Phantom scaffold contains < 1% of the iodine found in 1 ml of contrast media

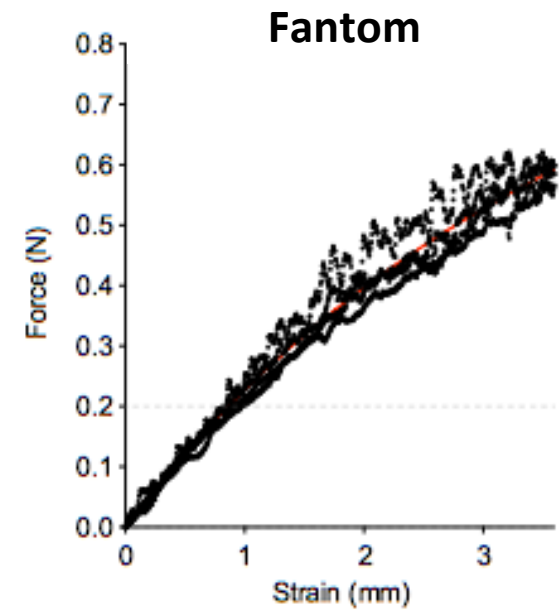
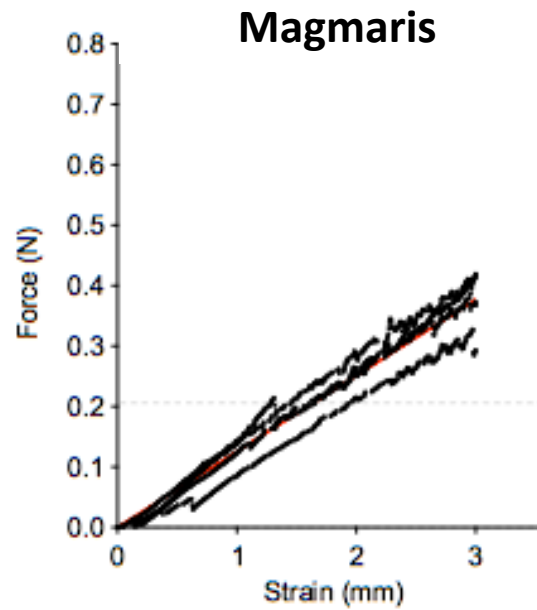
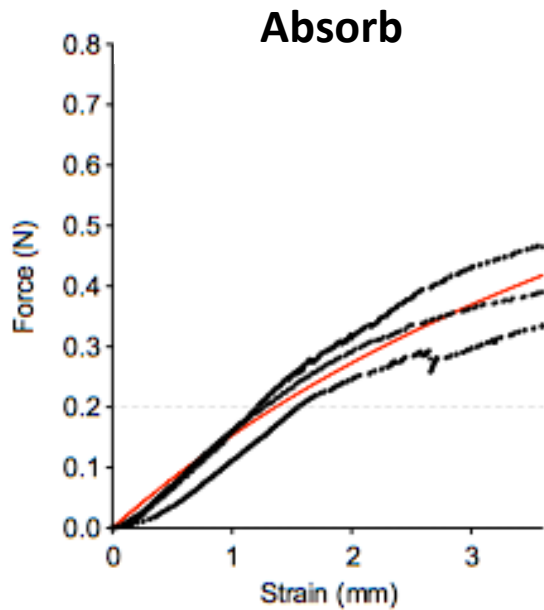
# Fantom Improved Performance



Tyrocore's high **tensile strength** enables Fantom to have **thinner struts** while **improving strength** and **reducing recoil**

1) Includes coating. Ormiston, J. New BRS Platforms. Presented EBC Rotterdam 2016.; Foin, N. Biomechanical Assessment of Bioresorbable Devices. Presented CRT 2017.  
 2) Bench testing on 3.0 mm scaffolds in water at 37°C. Radial strength measured at 15% compression. Tests performed by and data on file at REVA Medical.

## Longitudinal Stent Compression



A force of  $\sim 0.2$  N was found during recrossing with a balloon catheter

# Tyrocore Benign Degradation and Resorption

## Degradation

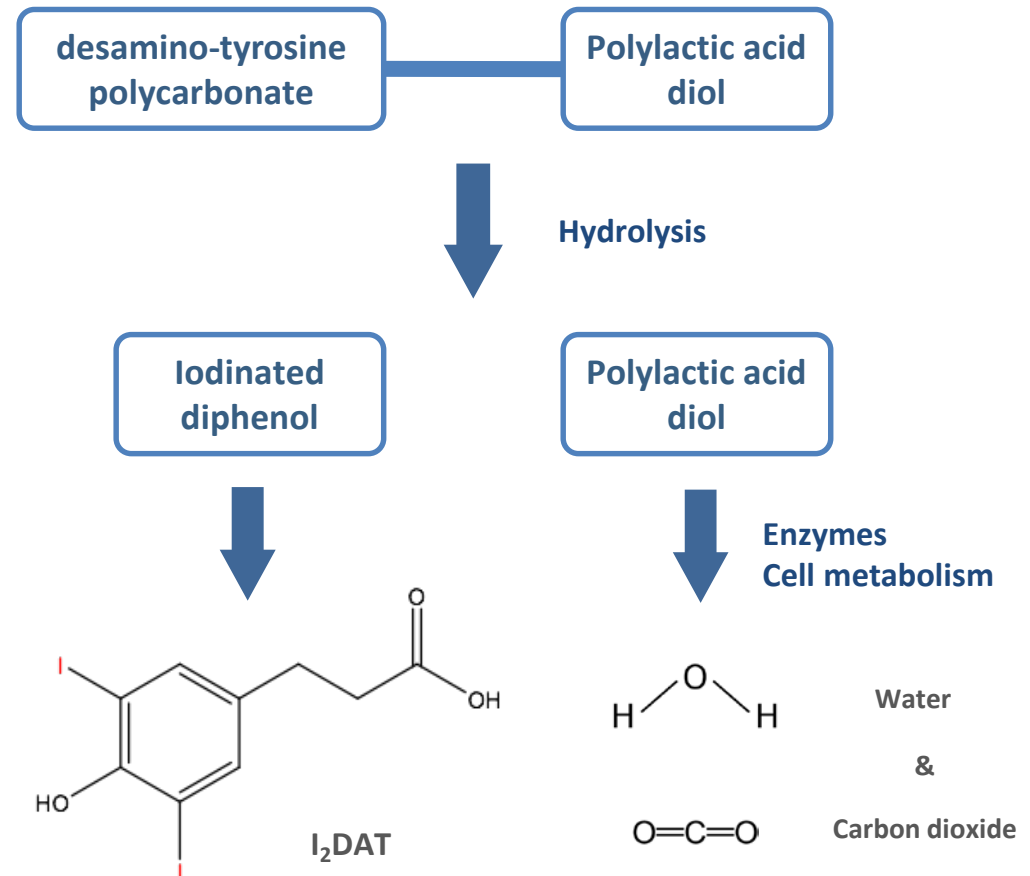
- > 80% molecular weight loss
- Vessel uncaged in 1 year

## Resorption (mass loss)

- Results in reduced radiopacity over time
- Completed in ~ 4 years

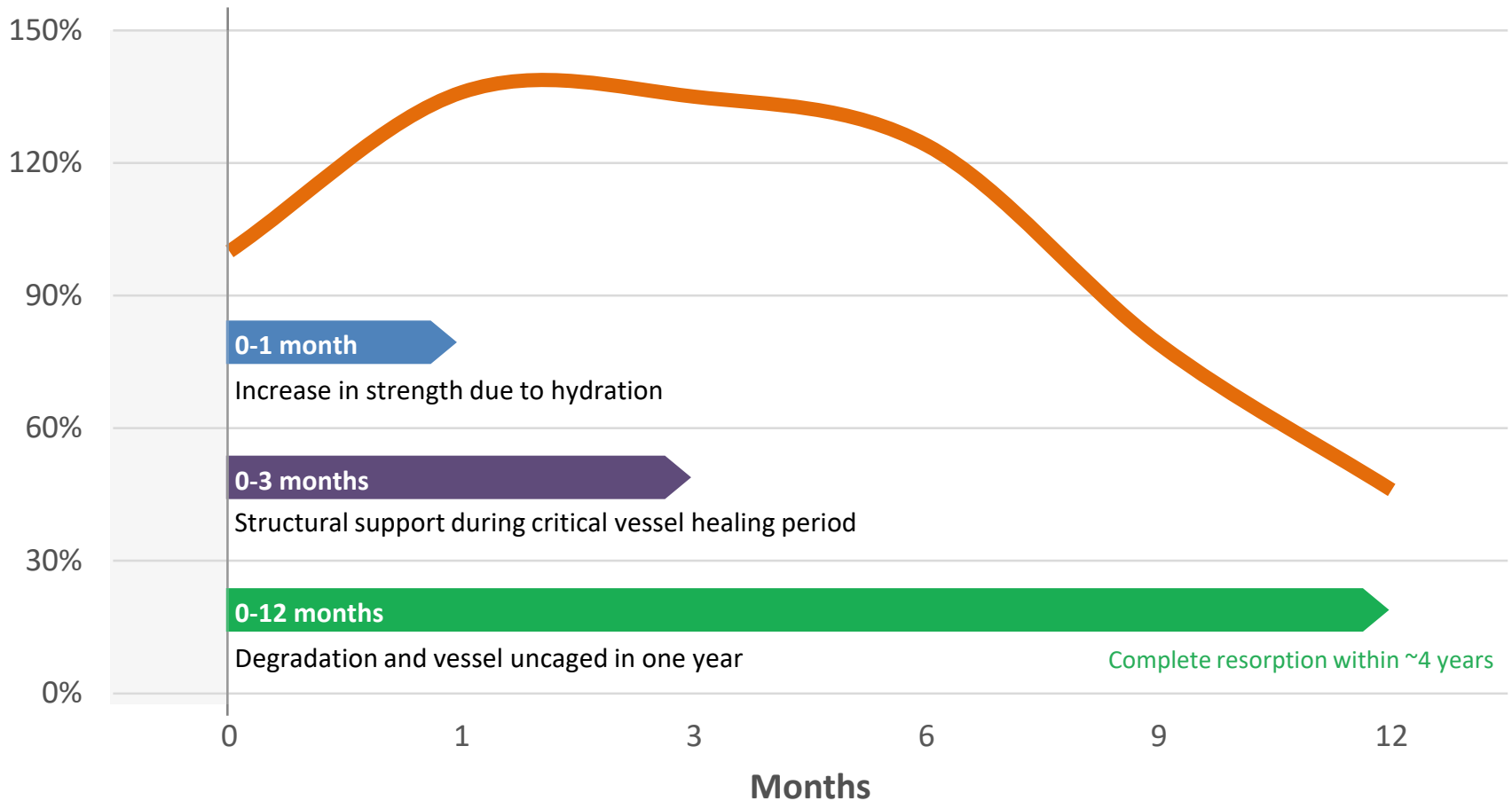
Radiolabel ADME study shows I<sub>2</sub>DAT is safely excreted

## Tyrocore Degradation





## Fantom Radial Strength During Degradation



# Tyrocore Biocompatibility for Excellent Vessel Healing

## 0-3 Months

- Fantom struts are covered with mature endothelium
  - Substantially fewer adherent platelets than the Absorb control

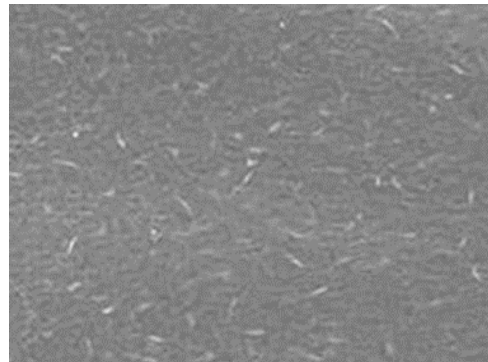
## 4-12 Months

- Fantom shows no adverse reactions as vessel uncages
  - No calcification at the interface between the tissue and the scaffold, which is observed with Absorb

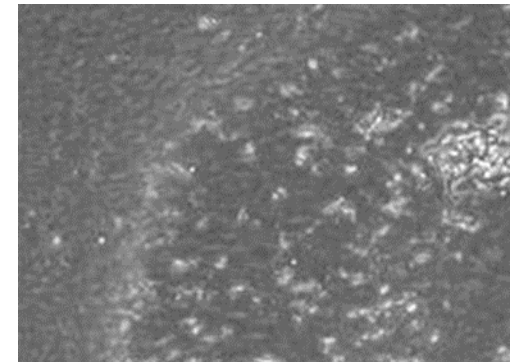
## 12-42 Months

- Fantom final degradation and benign resorption

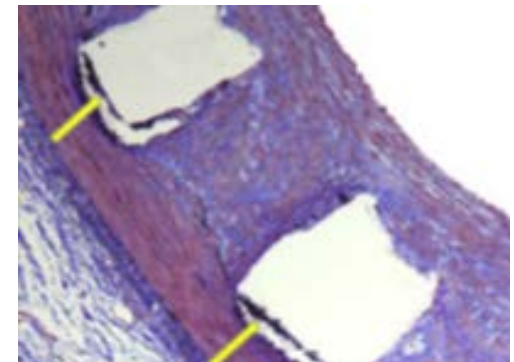
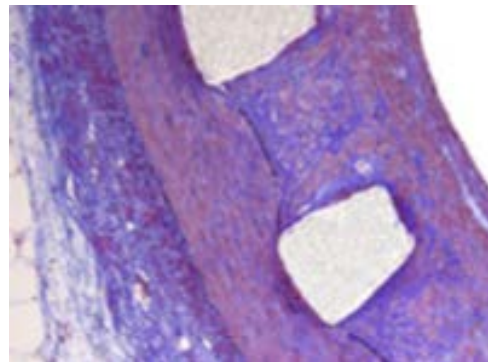
Fantom



Absorb



3-month endothelialization in rabbit artery



6-month degradation in porcine artery

# Tyrocore versus PLLA Degradation and Resorption

## 0-12 Months - Degradation

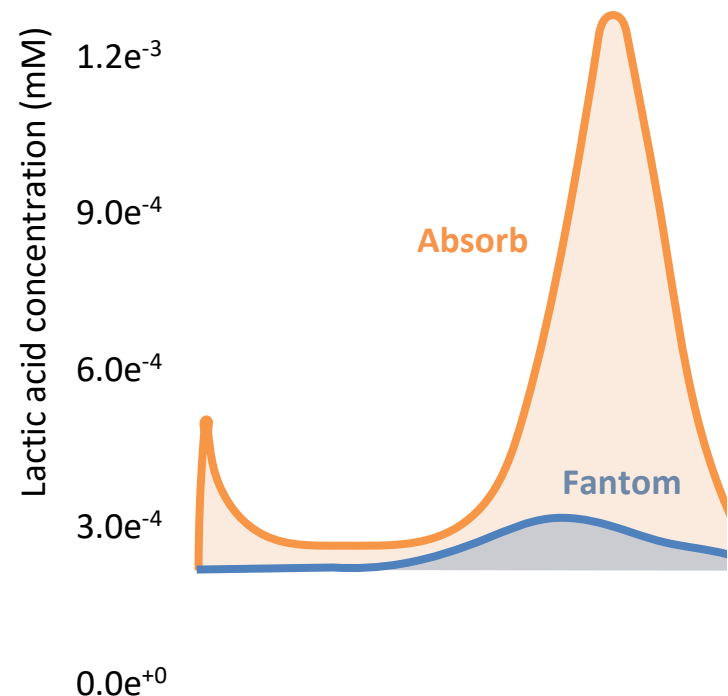
- Absorb has an early peak of lactic acid associated with coating degradation
- Fantom has minimal lactic acid

## 12-42 Months - Resorption

- Absorb has a large lactic acid peak between 18 and 42 months associated with scaffold resorption
- Fantom lactic acid concentration is two orders of magnitude lower than Absorb during scaffold resorption

## Arterial Wall Lactic Acid Concentration during Scaffold Degradation

Computational Model

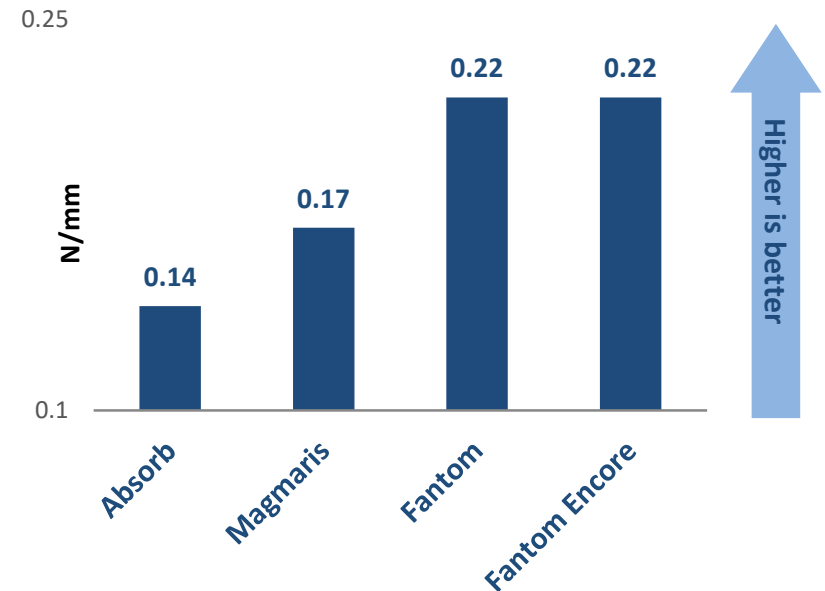


## Thinner Struts (again) without Compromising Radial Strength

Strut Thickness ( $\mu\text{m}$ )

	Absorb <sup>1</sup>	Magmaris <sup>1</sup>	Fantom	Fantom Encore
<b>2.5 mm</b>	157 $\mu\text{m}$	n/a	125 $\mu\text{m}$	<b>95 <math>\mu\text{m}</math></b>
<b>3.0 mm</b>	157 $\mu\text{m}$	166 $\mu\text{m}$	125 $\mu\text{m}$	<b>105 <math>\mu\text{m}</math></b>
<b>3.5 mm</b>	157 $\mu\text{m}$	166 $\mu\text{m}$	125 $\mu\text{m}$	<b>115 <math>\mu\text{m}</math></b>

Radial Strength<sup>2</sup>



- No changes to Tyrocore polymer composition or scaffold design
- Improved polymer processing and manufacturing techniques

1) Includes coating. Ormiston, J. New BRS Platforms. Presented EBC Rotterdam 2016.; Foin, N. Biomechanical Assessment of Bioresorbable Devices. Presented CRT 2017. 2) Bench testing on 3.0 mm scaffolds in water at 37°C. Radial strength measured at 15% compression. Tests performed by and data on file at REVA Medical.

- Tyrocore is a new and differentiated polymer for vascular scaffolds.
- Fantom offers substantial improvements over first generation BRS:
  - Reduced strut thickness
  - Increased radial strength
  - Larger expansion range
  - Radiopacity
  - Improved vessel healing
- Fantom Encore has the thinnest struts of any bioresorbable scaffold<sup>1</sup> without compromising radial strength or radiopacity.
- Tyrocore's strength, biocompatibility, and safety profile has been demonstrated in pre-clinical and clinical studies.

1) 95 µm strut thickness in the 2.5 mm diameter size

