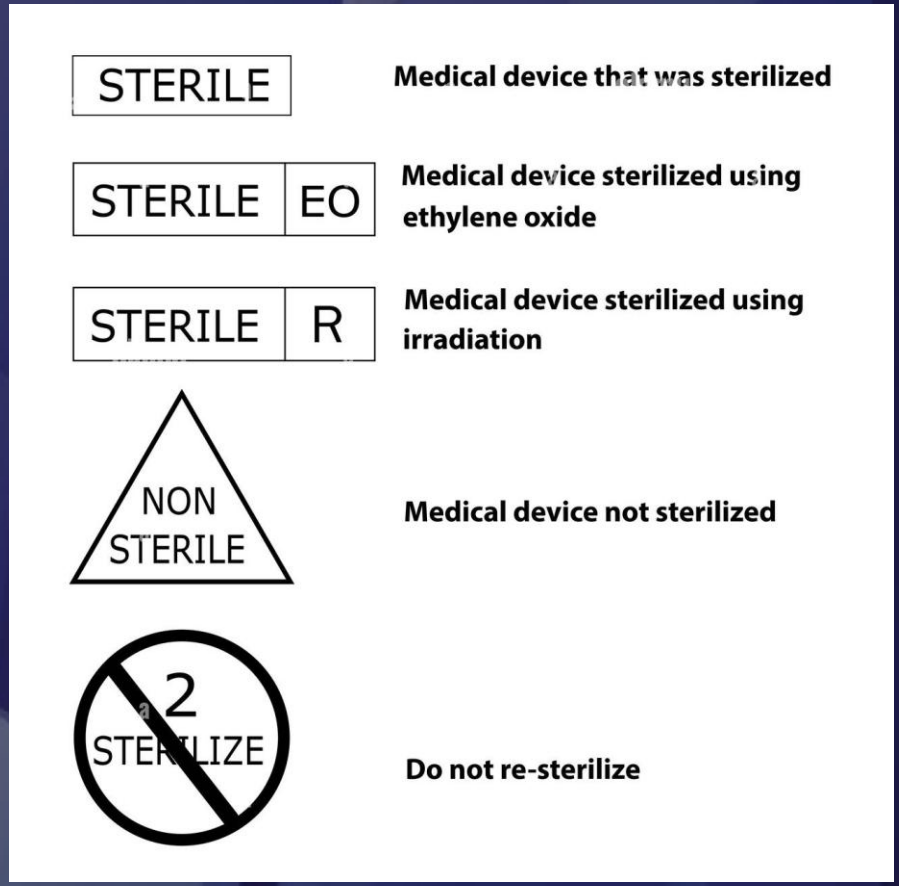
Poly-Med, Inc.

Absorbable Devices and Sterilization

August 25, 2026



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Poly-Med, Inc. Overview

Expertise	Poly-Med is a leader in the development & production of high-performance absorbable biomaterials, precision components, & implantable medical devices
Polymer Formulations	Absorbable polyester copolymers, Light-curable macromers for 3D printing, Modified hyaluronic acids
IP	250+ issued patents and applications
Employees	260+ employees; 50+ with advanced degrees (PhD's and Masters)
Certifications & Registrations	ISO 13485 compliant QMS, FDA Registered FDA Onsite Inspection 2024– No findings



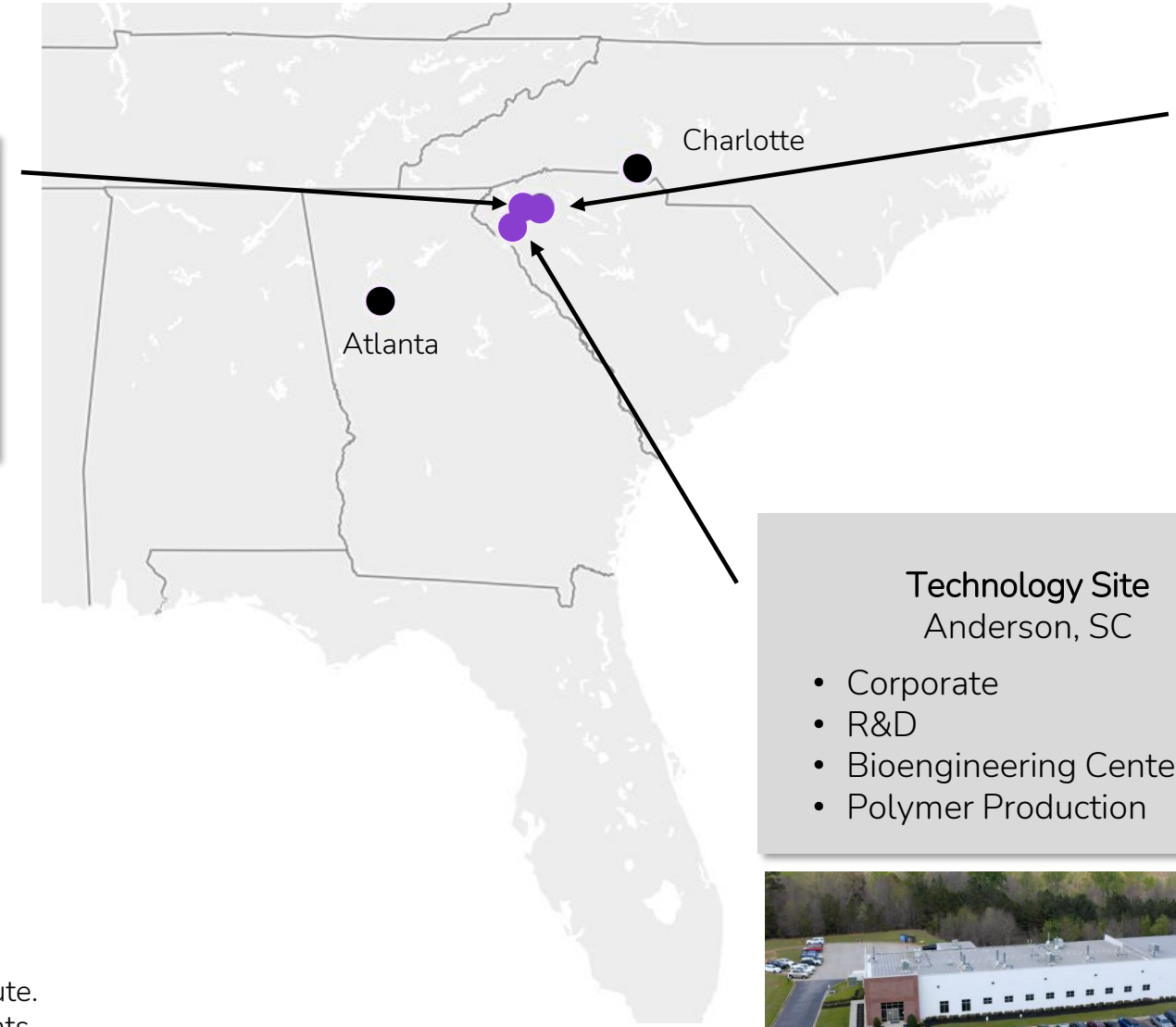
Poly-Med, Inc. was founded by Dr. Shalaby W. Shalaby in 1993.

3 Manufacturing Sites, 117,000 ft^2

Financial Site
Liberty, SC

- Textile
- Electrospinning Expansion
- Finished Device Assembly & Packaging





Leader Site
Piedmont, SC

- Electrospinning
- Extrusion

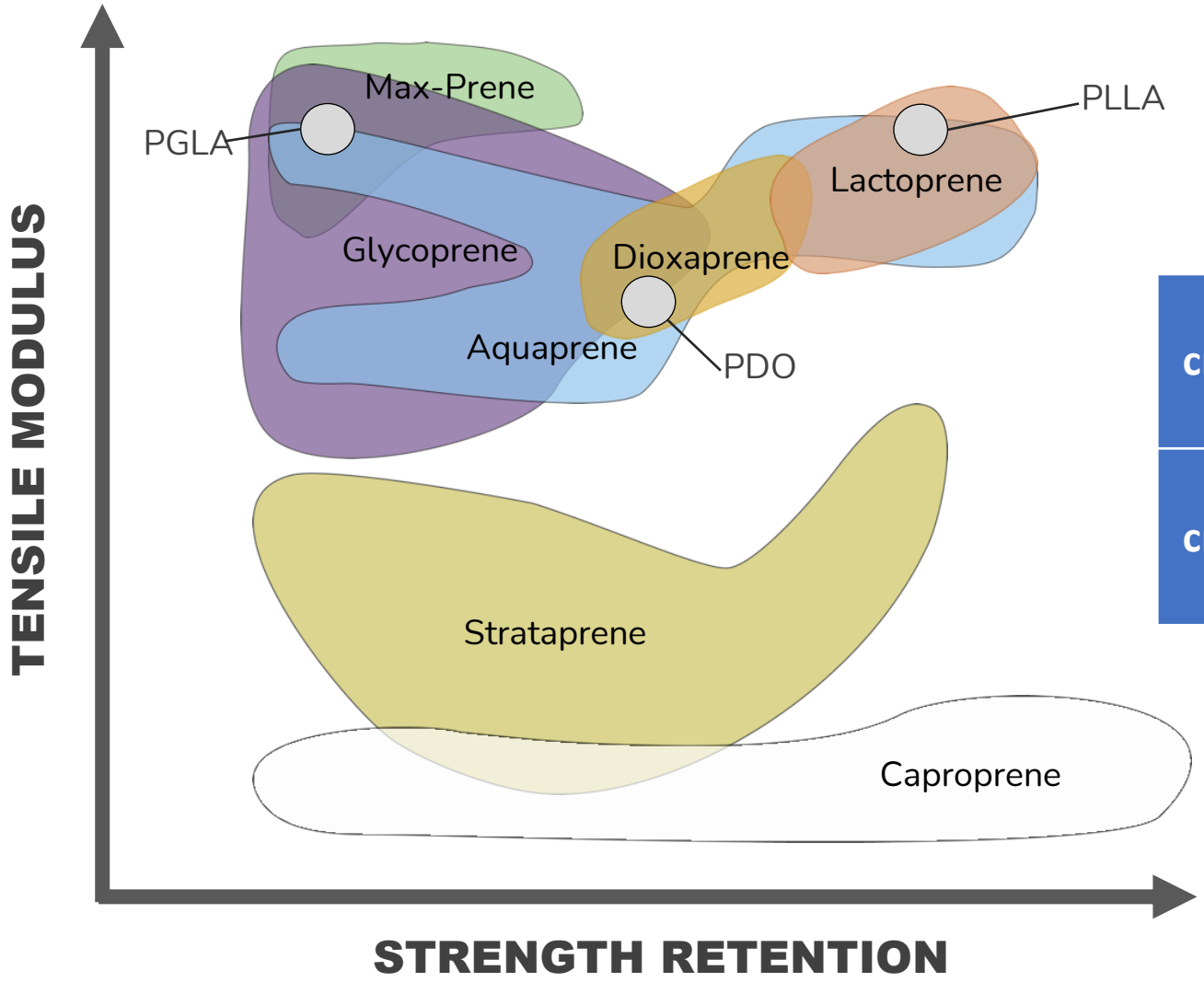


Technology Site
Anderson, SC

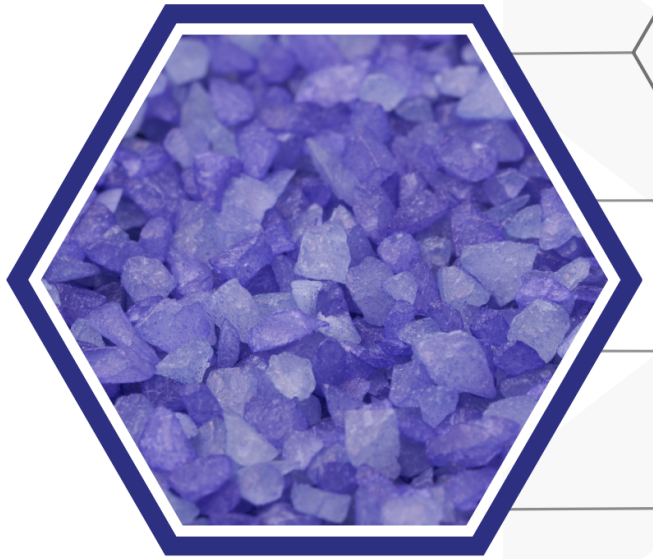
- Corporate
- R&D
- Bioengineering Center
- Polymer Production



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	Fast	Moderate	Slow
High crystallinity potential	Glycolide	p-Dioxanone	*l*-Lactide, Caprolactone
Low crystallinity potential	*d,l*-Lactide		TMC



BIOMEDICAL TEXTILES
Knitting | Braiding

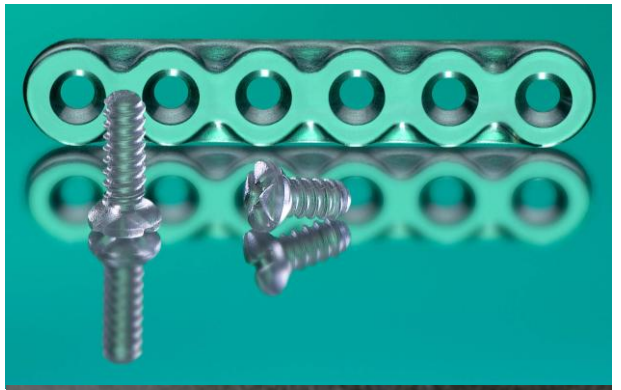
FIBERS & FILMS
Filaments | Film | Fiber Processing

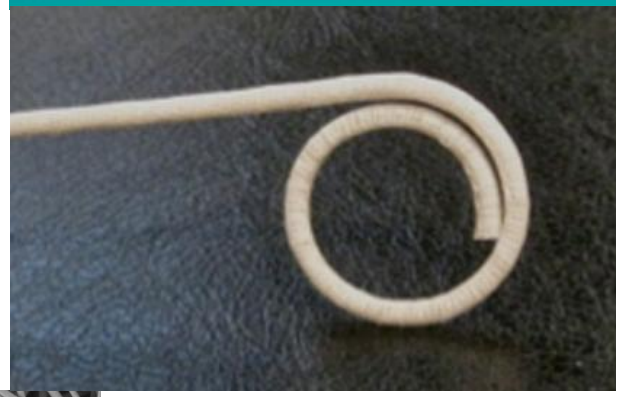
3D-PRINTING
Filament Based & Resin Based 3D-Printing

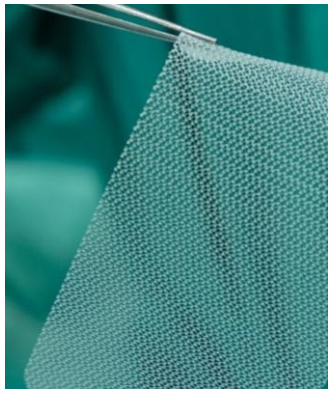
ELECTROSPINNING
Random & Non-Aligned | Fiber Size & Orientation | Coatings | Additives | Scaffold

INJECTION MOLDING
Supported by Qualified Partners

CONSTRUCT OR FINISHED DEVICE
Packaging | Labeling

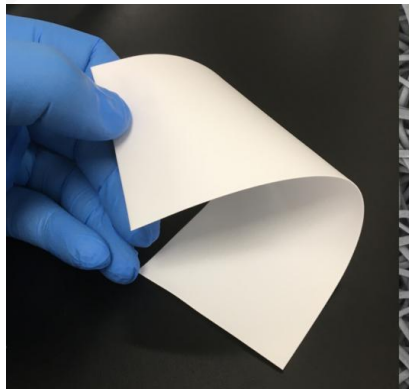


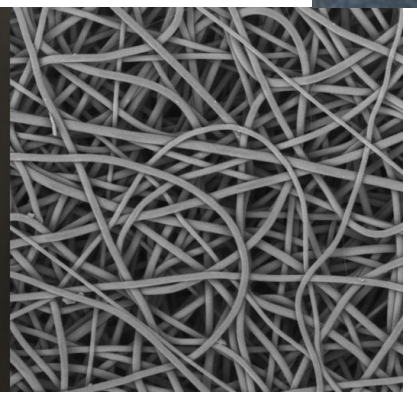












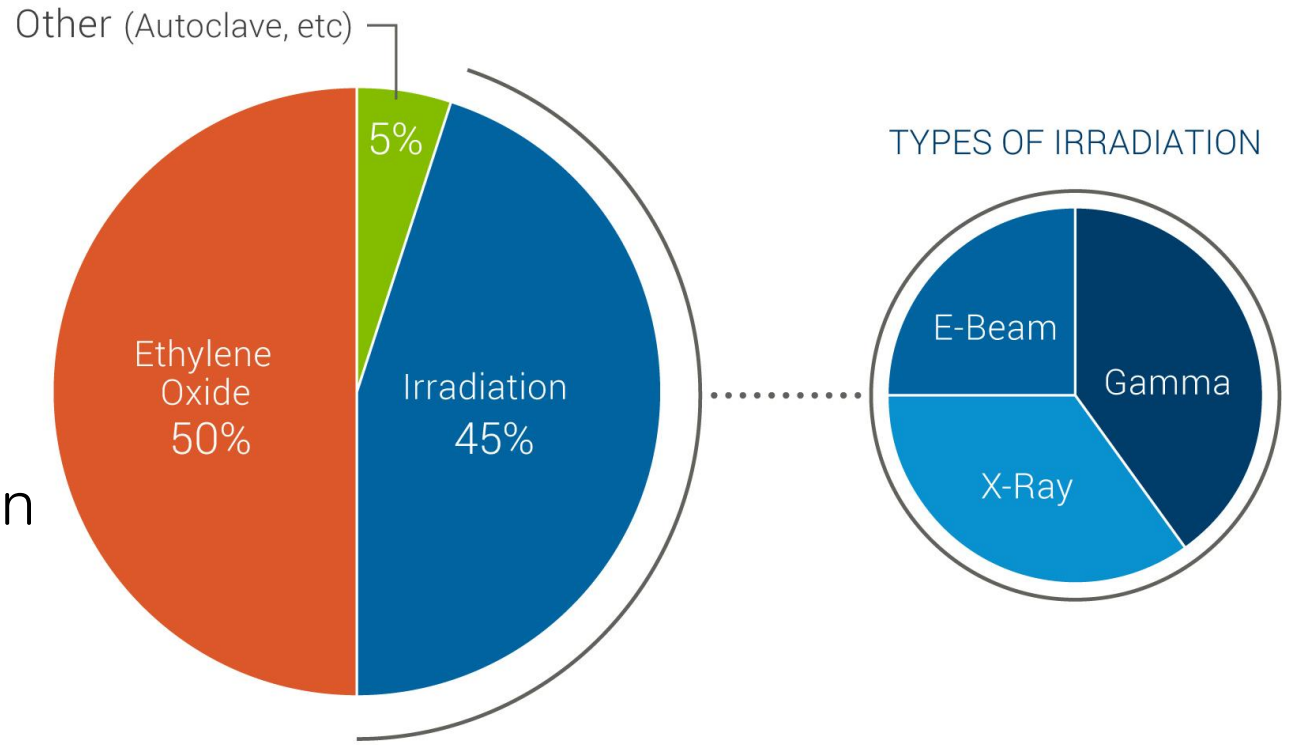


Primary modes of degradation…

- Chemical
  - Moisture – Random chain scission
  - Oxidation
  - Enzymatic
- Thermal
- Aging

Sterilization across medical devices

- Absorbable, Implantable, single use products
- Requires SAL 10^{-6}
- EO, Gamma, e-Beam
- Other techniques
  - Radiation
  - Reactive oxygen / nitrogen
  - scCO2
  - Steam, Dry Heat



Source: Approximate values per the International Irradiation Association (iia) and the FDA

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Sterilization across medical devices

- Absorbable medical device primarily sterilized through EO, ionizing radiation causes degradation through chain scission
- Surface sterilization that uses ethylene oxide, temperature, and moisture

Benefits of EO

- Successful history of use
- Less damage than ionizing radiation
- Can modulate temperature

Issues with EO

- EPA, Site closures
- More difficult validations
- Surface only, no enclosed cavities
- Process temperature
- High, prolonged humidity

Sterilization across medical devices

- Absorbable medical device primarily sterilized through EO, ionizing radiation causes degradation through chain scission
- Surface sterilization that uses ethylene oxide, temperature, and moisture

Gamma Irradiation

- Final hermetic seal
- No temperature excursions

But…

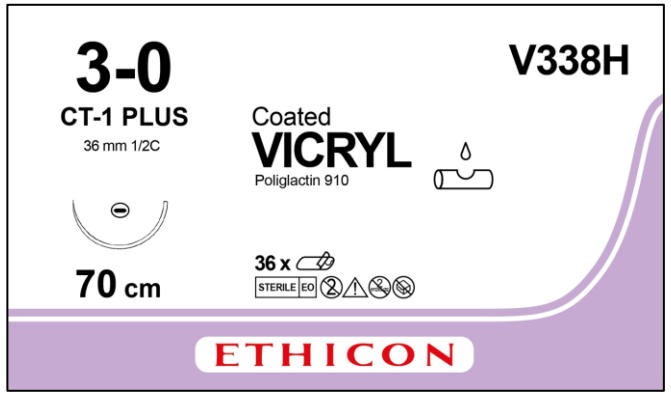
- Variability in dosage, potential device variability
- Possible color change

e-Beam

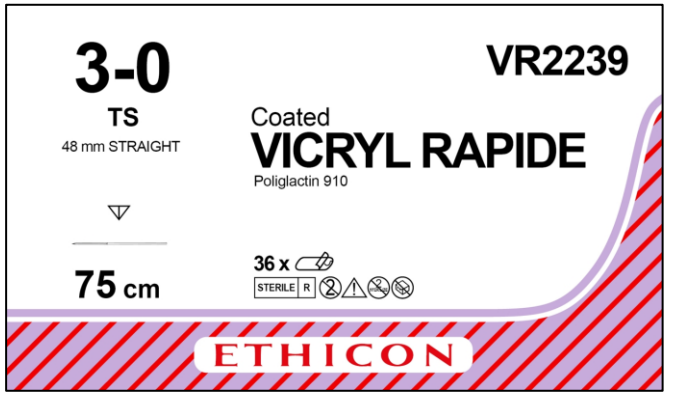
- Final hermetic seal
- No temperature excursions
- More consistent dosage

But…

- Less penetrating, package limited
- More expensive



+ Radiation Sterilization =



Ethylene Oxide Sterilized

Strength Retention:

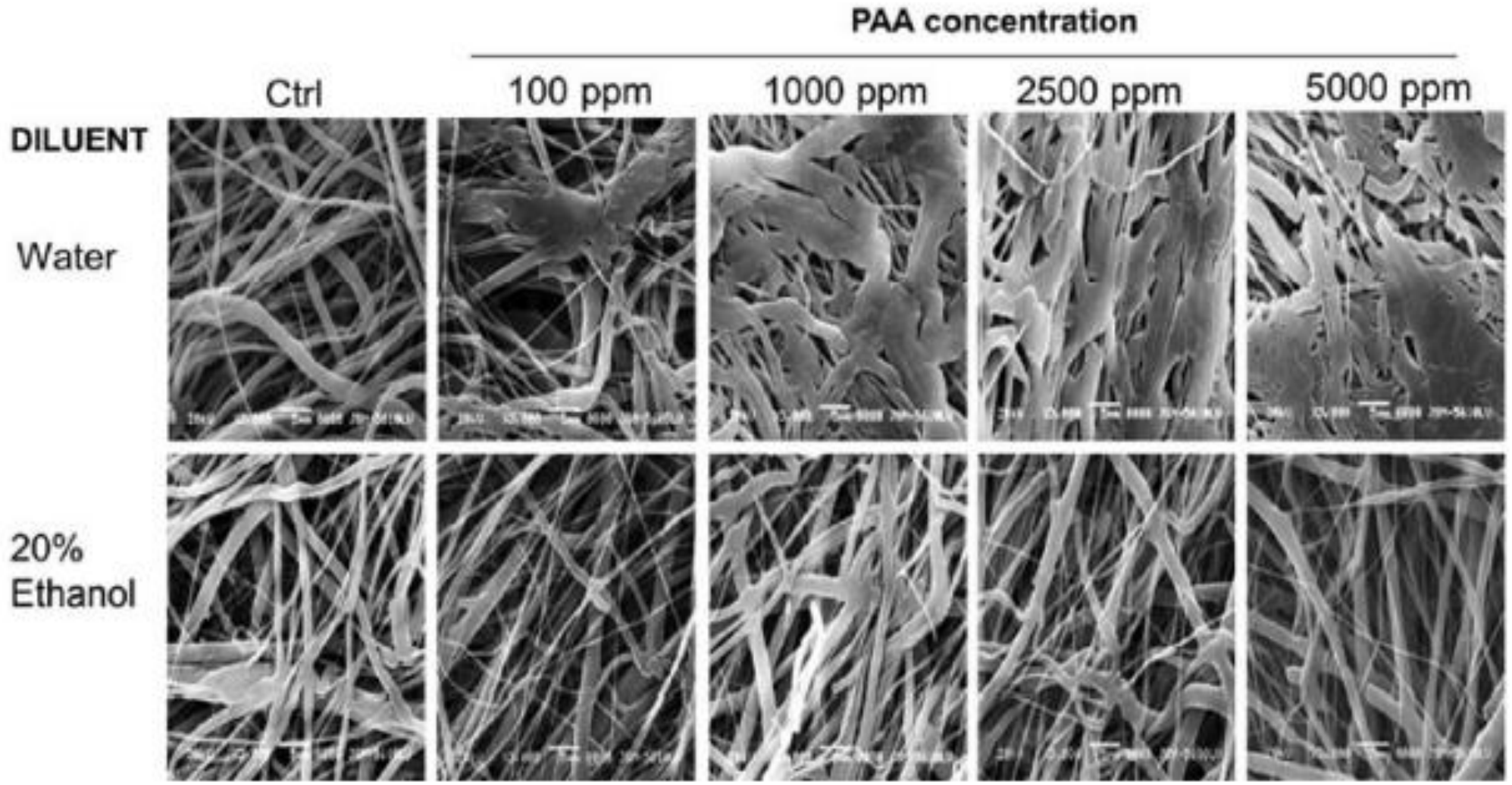
- 75% @ 14 days
- 50% @ 21 days

Radiation Sterilized

Strength Retention:

- 50% @ 5 days
- 0% @ 14 days

EO, Autoclave, Peracetic acid



Yoganarasimha, et. al. Peracetic Acid: A Practical Agent… Tissue Engineering: Part C, 2014.

EO, Autoclave, Peracetic acid

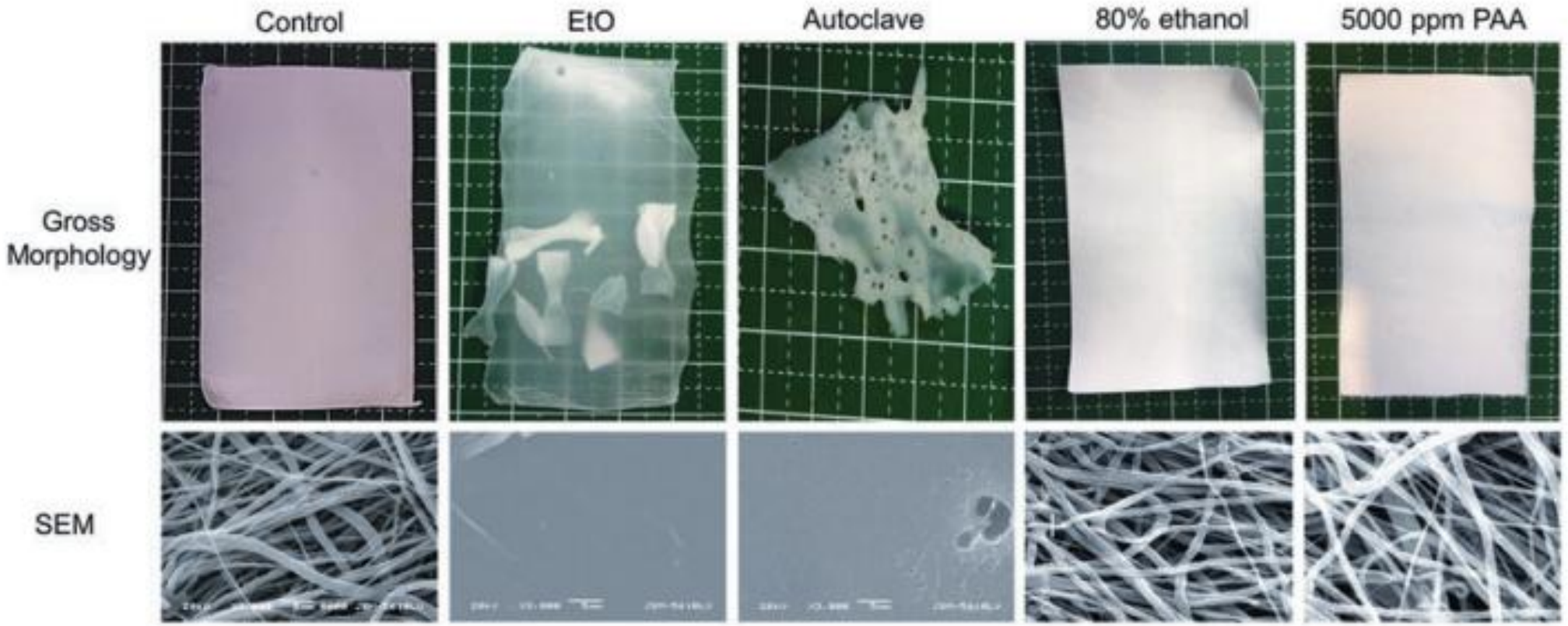
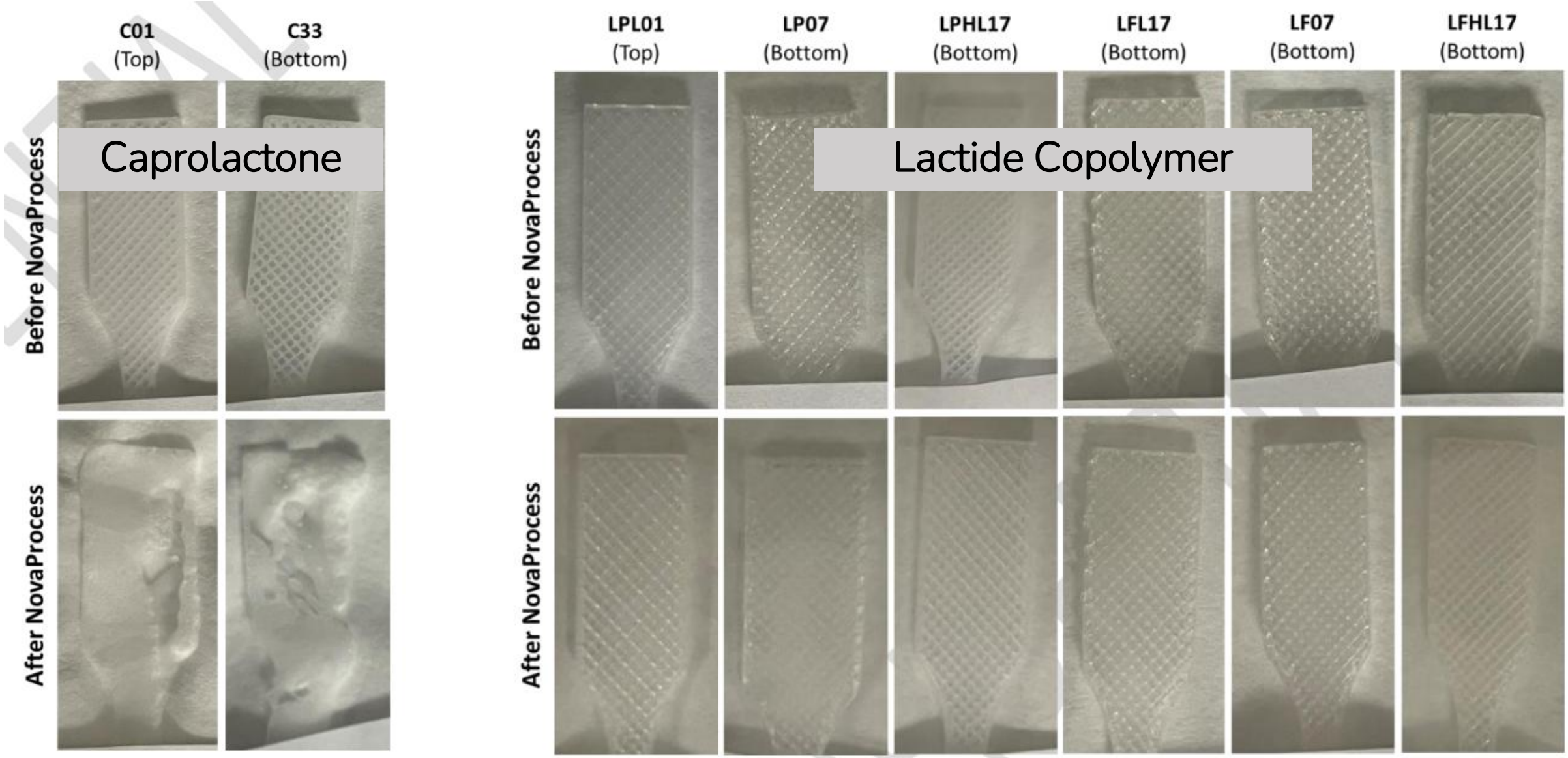


FIG. 2. Optical (top) and scanning electron micrograph (bottom) images to illustrate morphology changes of electrospun polycaprolactone (e-PCL) scaffolds after sterilization treatments. Ethylene oxide (EtO) turned scaffolds into a solid, translucent film (dog-bone samples, placed in the same sterilization pouch, fused to the sheet), while autoclaving melted the scaffold. Complete loss of structure fibrous architecture can be observed with both standard sterilization methods. Chemical processing of scaffolds at room temperature (80% ethanol and PAA) did not induce any macro- or microscopic changes in scaffold morphology. Color images available online at www.liebertpub.com/tec

Yoganarasimha, et. al. Peracetic Acid: A Practical Agent… Tissue Engineering: Part C, 2014.

scCO2 Sterilization

POLY-MED, INC.



Conclusions

Ethylene oxide is the dominant mode of sterilization for absorbable devices, followed by Gamma and e-Beam

Sterilization is a critical process for creating safe and effective medical devices

Any mode of sterilization can impact absorbable polymers

Sterilization requirements should be considered early as part of product requirements, with compatible materials and design attributes going hand-in-hand with process selection

At Poly-Med, we are trusted partners dedicated to advancing patient care through the creation of high-performance absorbable biomaterials, precision components, & implantable medical devices.

By integrating cutting-edge material science with clinical insight, we design & manufacture transformative solutions that support healing, improve outcomes, & redefine the future of medical interventions.



POLY-MED, INC.

ADVANCED ABSORBABLE IMPLANTS