

DuPont™ Liveo™ Pharma TPE Tubing

Sterilizable, weldable/sealable TPE tubing for biopharmaceutical processing

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DuPont™ Liveo™ recently has extended its solutions portfolio to offer more supply flexibility and choices to customers with new Liveo™ Pharma TPE (thermoplastic elastomer) Tubing. This new tubing is dedicated to fluid transport and single-use bioprocessing applications. It is targeted to enable aseptic connection/disconnection of tubing without connectors and can be used in peristaltic pump applications.

Liveo™ Pharma TPE Tubing is supported by a comprehensive data package, including compliance with the required and demanding USP and ISO standards that will help customers speed up the qualification process at their respective facilities.

This poster will help you learn more about the benefits of Liveo™ Pharma TPE Tubing. A complete benchmark analysis highlights the improvement of the most stringent technical requirements enabled by this new ISO Class 7-manufactured tubing. Heat-welding to itself and unquestionable welding compatibility with any kind of TPE tubing is reviewed, among other functional properties. Not only is Liveo™ Pharma TPE Tubing weldable to other brands of TPE tubing, but it also improves the weld strength. It shows outstanding performance in terms of high tensile strength, burst resistance before and after welding, and suitable stability under different sterilization routes. Finally, Liveo™ Pharma TPE Tubing embraces similar purity claims as the rest of the Liveo™ Pharma Tubing portfolio, including minimal spallation after 24 hours of pumping, low extractables and good chemical resistance.

About DuPont™ Liveo™ Pharma TPE Tubing

Key benefits

Purity

- Manufactured in ISO Class 7 cleanroom
- Low extractables

Improved performance

- Welding and welding compatibility with other tubing
- Burst resistance before and after welding
- Low level of spallation after 24 hours of pumping
- Improved pump life

Additional features and benefits

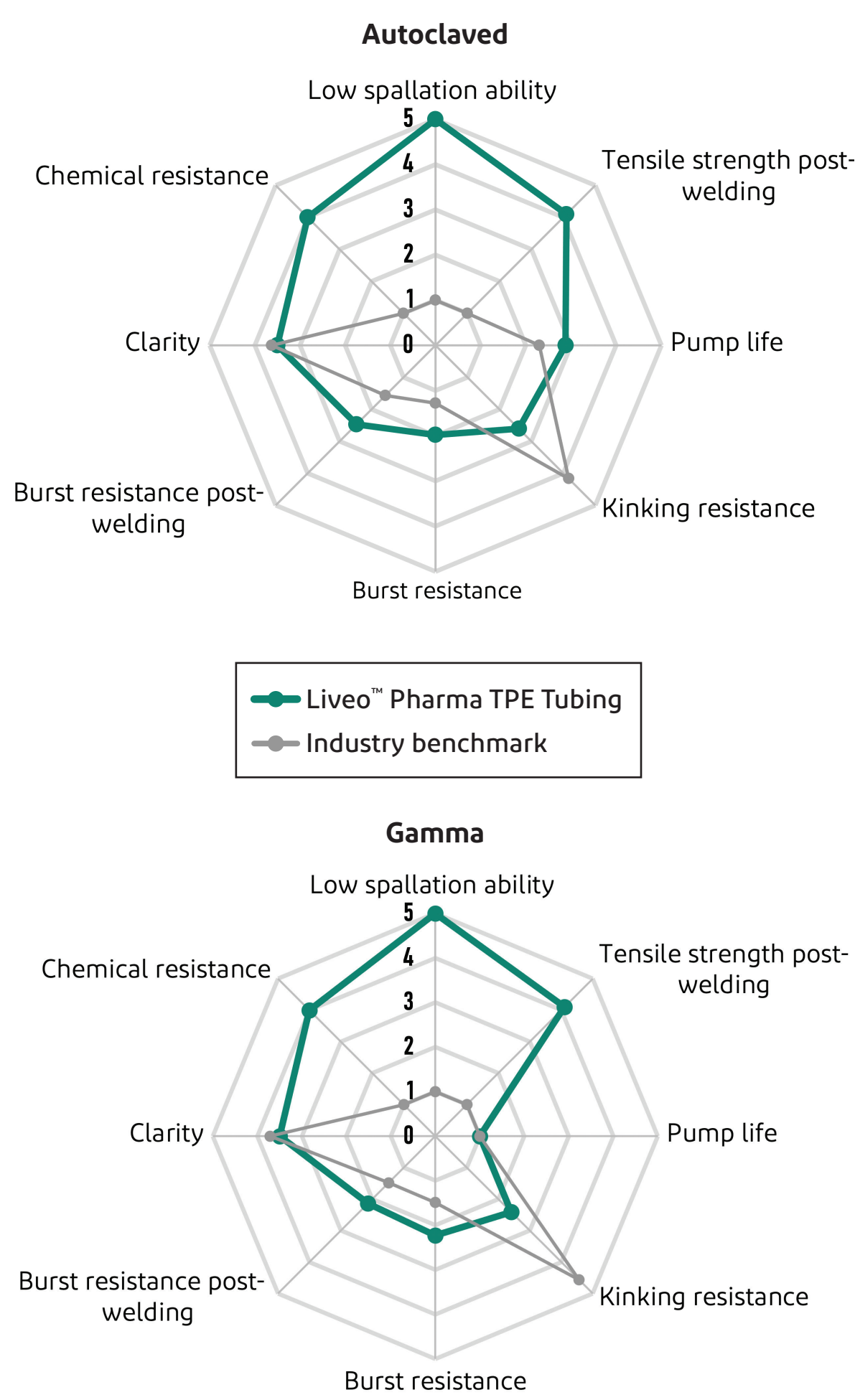
- Good chemical resistance
- Good and stable clarity after sterilization
- Comprehensive data package

Available dimensions

- 1/8" (3.18 mm) x 1/4" (6.35 mm)
- 1/4" (6.35 mm) x 7/16" (11.11 mm)
- 3/8" (9.53 mm) x 9/16" (14.30 mm)
- 3/8" (9.53 mm) x 5/8" (15.87 mm)
- 1/2" (12.70 mm) x 3/4" (19.05 mm)

Customization options

- Coil length
- I.D. x O.D.
- Multipack
- Marking
- Tolerances



Performance of Liveo™ Pharma TPE Tubing

Improved welding and sealing performance

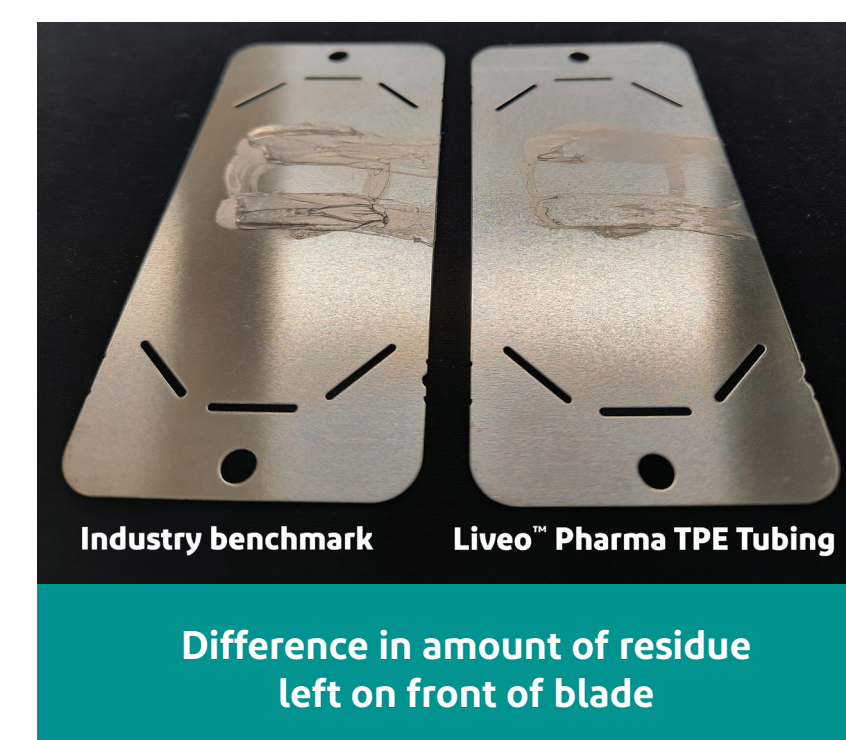
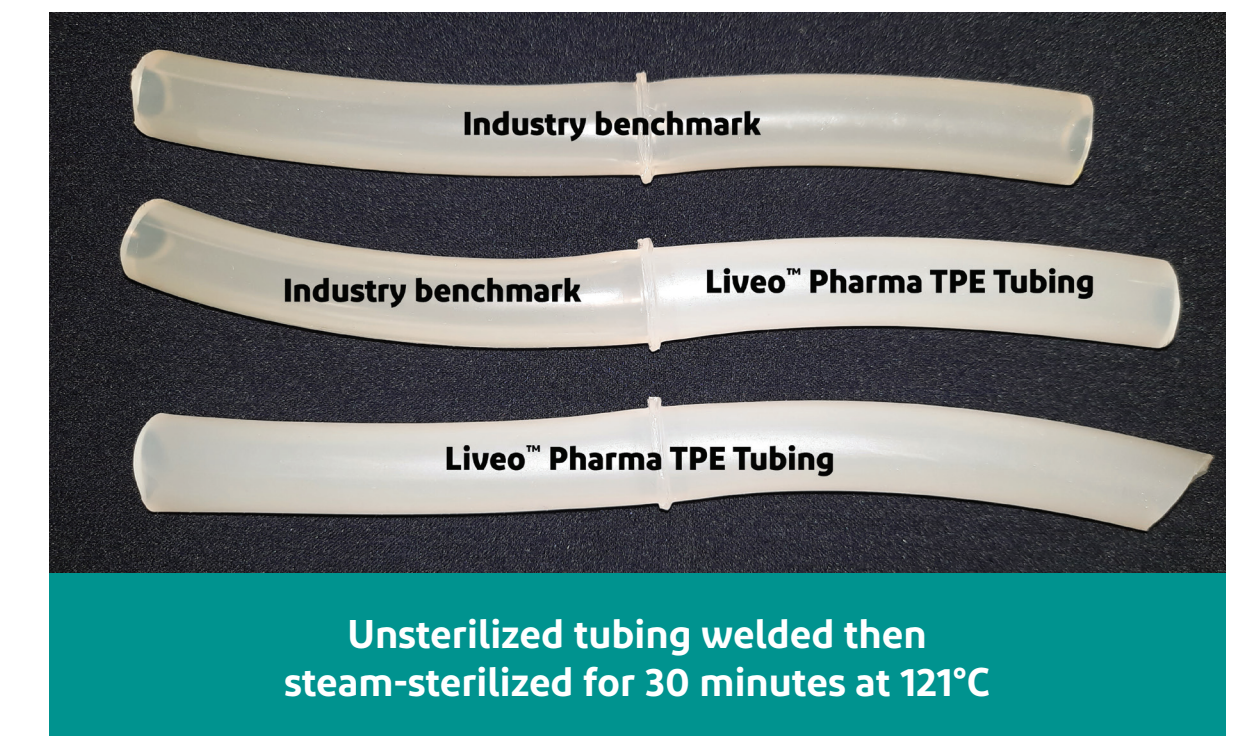
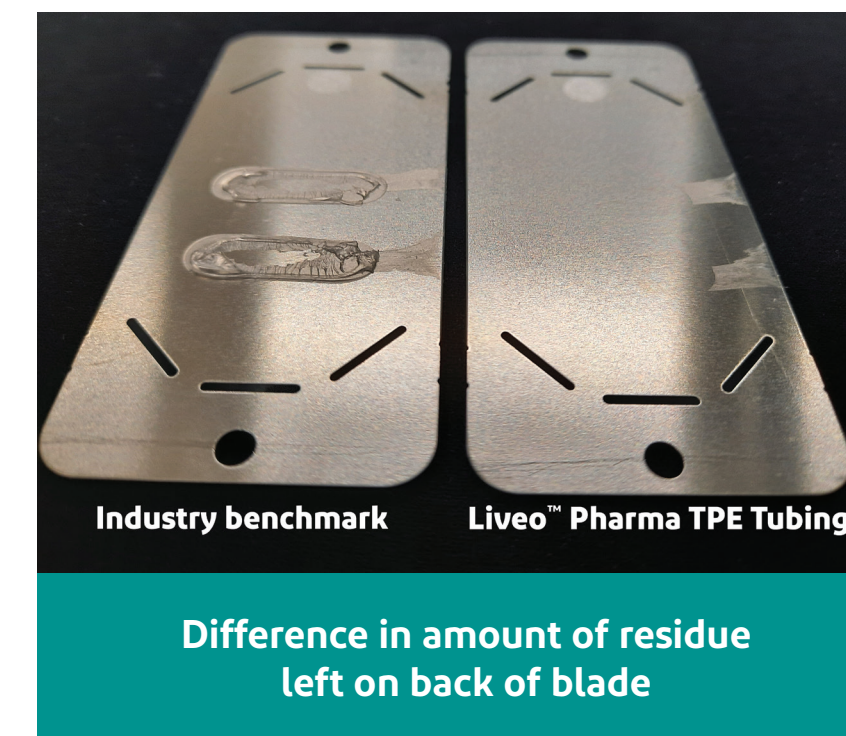
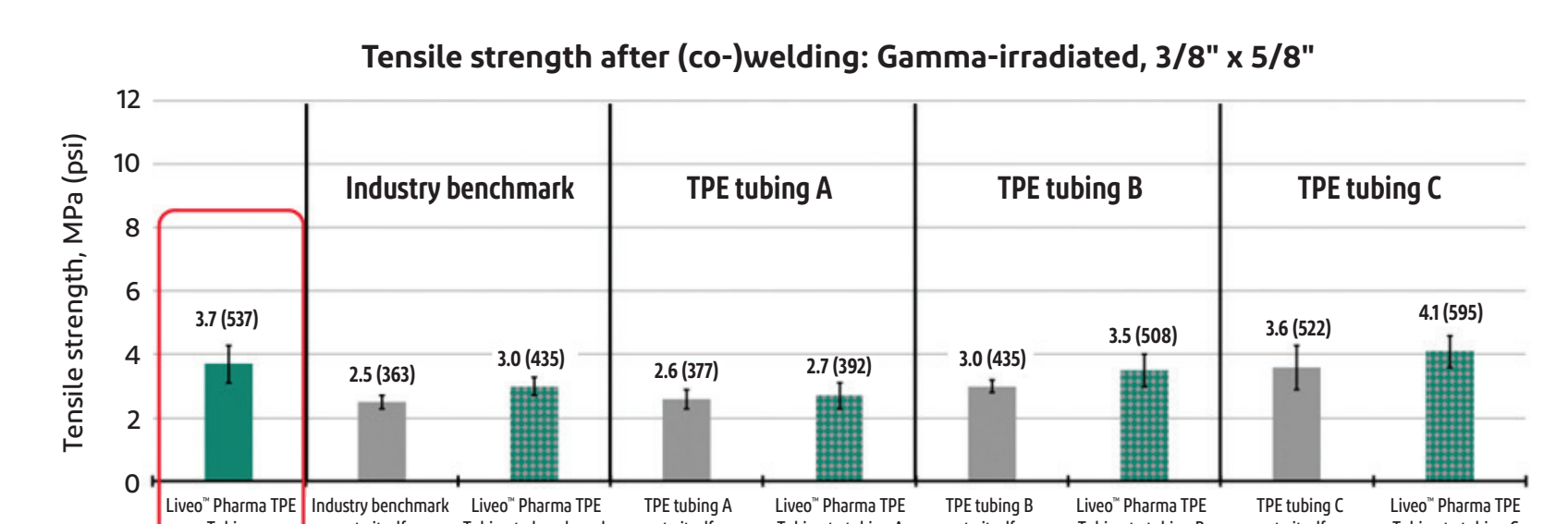
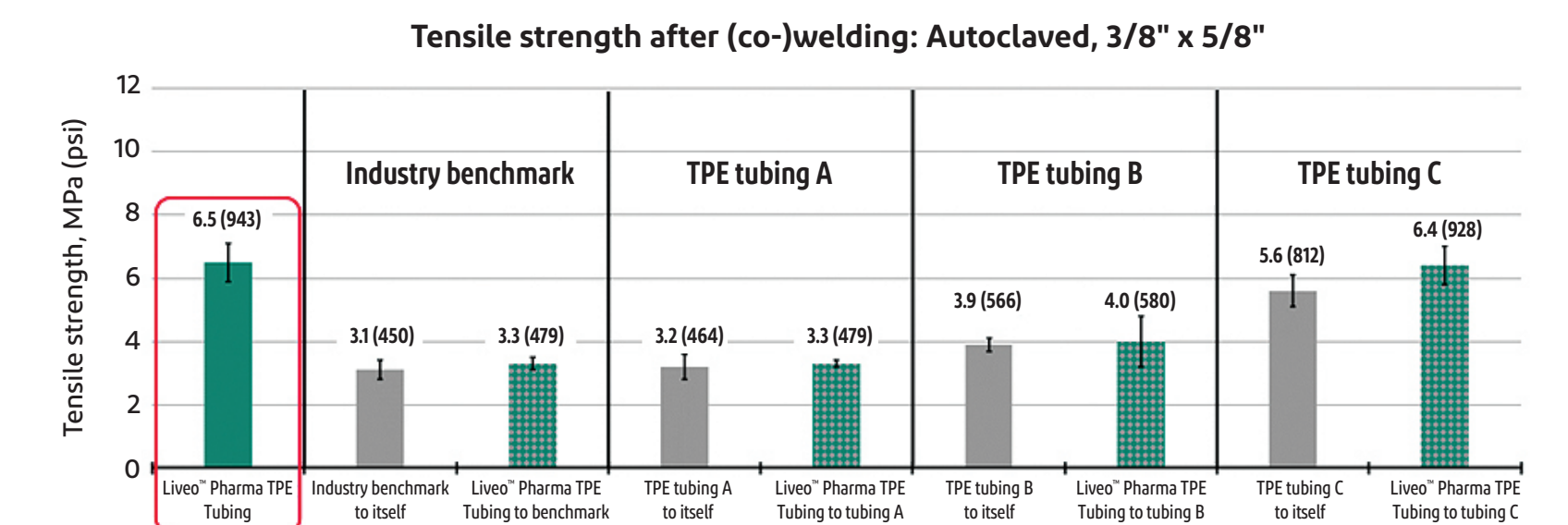
Welding evaluation

Sartorius Biowelder® TC default settings:

- Temperature of welding step (185 to 270°C/365 to 518°F)
- Welding and cooling duration (weld 9 to 25 s; cool 30 to 50 s)
- Compatible with Cytiva Tube Sealer

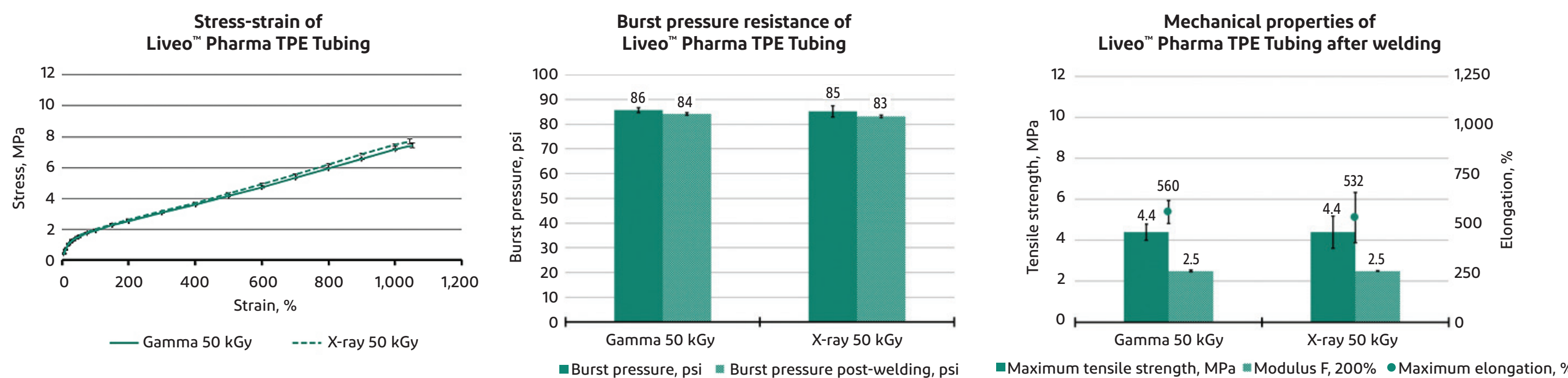
Measure

- Visual quality
- Burst pressure resistance
- Tensile strength test



Equivalency between gamma and X-ray irradiation sterilization

Liveo™ Pharma TPE Tubing sterilized by gamma and X-ray irradiation (50 kGy dose):



Biocompatibility/high purity package

Comprehensive qualification health data for Liveo™ Pharma TPE Tubing

- USP <665>: Polymeric Components and Systems Used in the Manufacturing of Drug Products
- USP Class VI: Intracutaneous Toxicity, Systemic Toxicity, Muscle Implantation
- ISO 10993: Biocompatibility – Part 5: Cytotoxicity; Part 6: Muscle Implantation; Part 10: Irritation & Skin Sensitization; Part 11: Acute Systemic Toxicity
- USP <85>: Endotoxins
- USP <151>: Pyrogenicity
- USP <232>: Elemental Impurities
- USP <788>: Particulates
- ISO 11737-1: Bioburdens



Qualification guides for Liveo™ Pharma TPE Tubing

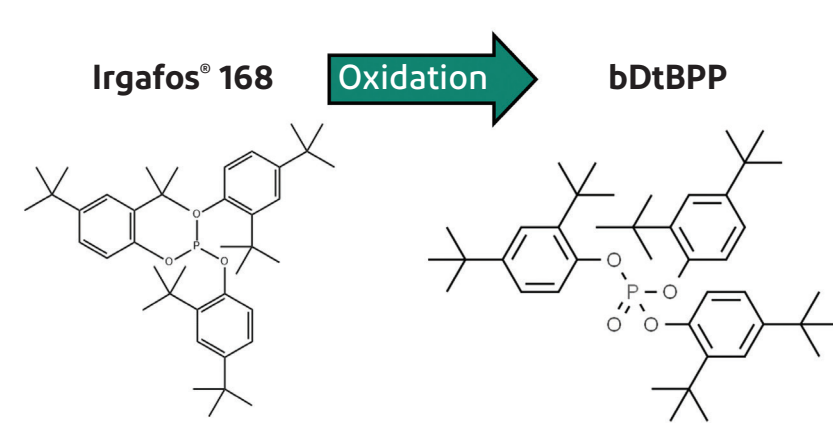
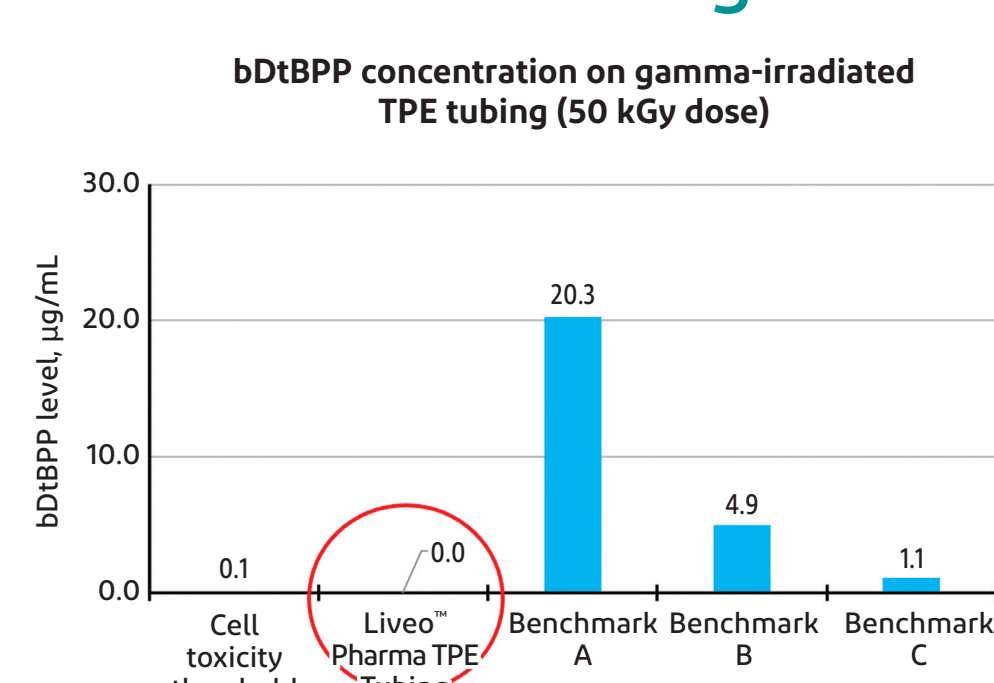
Data before and after sterilization

- (Co-)welding and sealing (various welding/sealing machines)
- Mechanical, physical and functional properties

Low extractables in Liveo™ Pharma TPE Tubing

Productivity depends on cells and media: The higher the number of cells, the more drug substance produced. The healthier the cells, the higher the drug substance quality.

Irgafos® 168 (antioxidant) easily degraded in bis(2,4-di-tert-butylphenyl) phosphate (bDtBPP); bDtBPP is known to inhibit cell growth (e.g., Chinese Hamster Ovary cell culture).



Purity testing of Liveo™ Pharma TPE Tubing

ISO 11737-1: Determination of a population of microorganisms on products
 → Bioburden counts: 0.01 CFU (limit: ≤0.10 CFU/mL)
 CFU = colony-forming unit

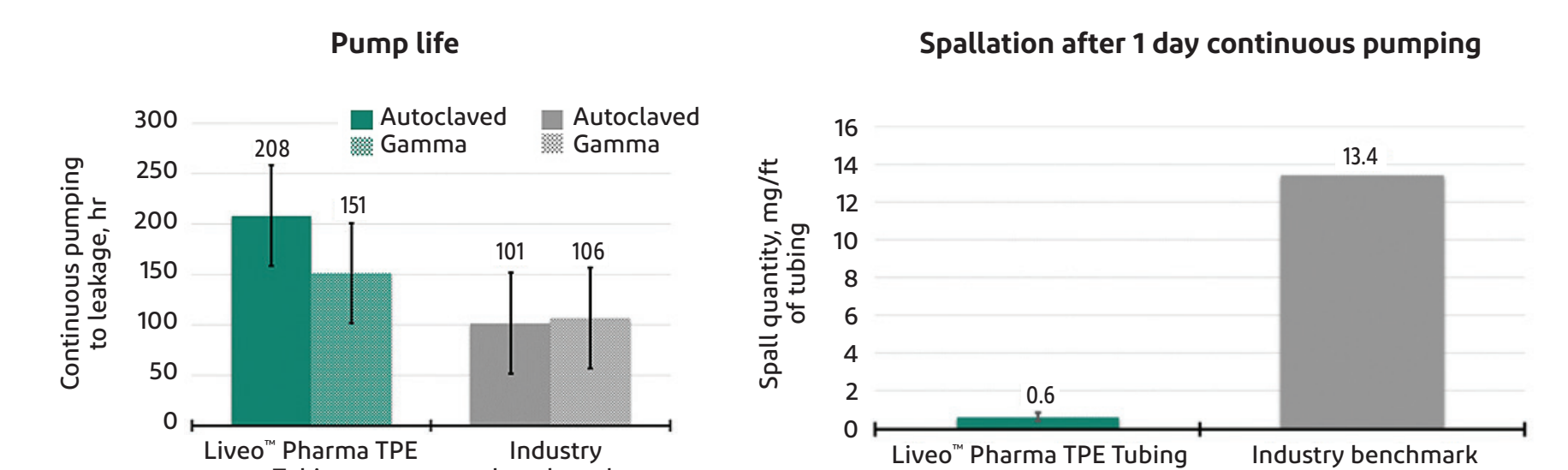
USP <788>: Particulate Matter in Injections (Method 2)
 ≤3,000 for ≥10 µm particulate size → 0.10 particulate
 ≤300 for ≥25 µm particulate size → 0.01 particulate

USP <85>: Bacterial Endotoxins Test (BET)
 → All Liveo™ Pharma TPE Tubing: <0.125 EU/mL (EMA limit: 0.250 EU/mL final drug)

Pump life

Testing conditions

- 24 h at 650 RPM
- Cole-Parmer® Masterflex® I/P®
- Room temperature/purified water
- Autoclaved and gamma-sterilized



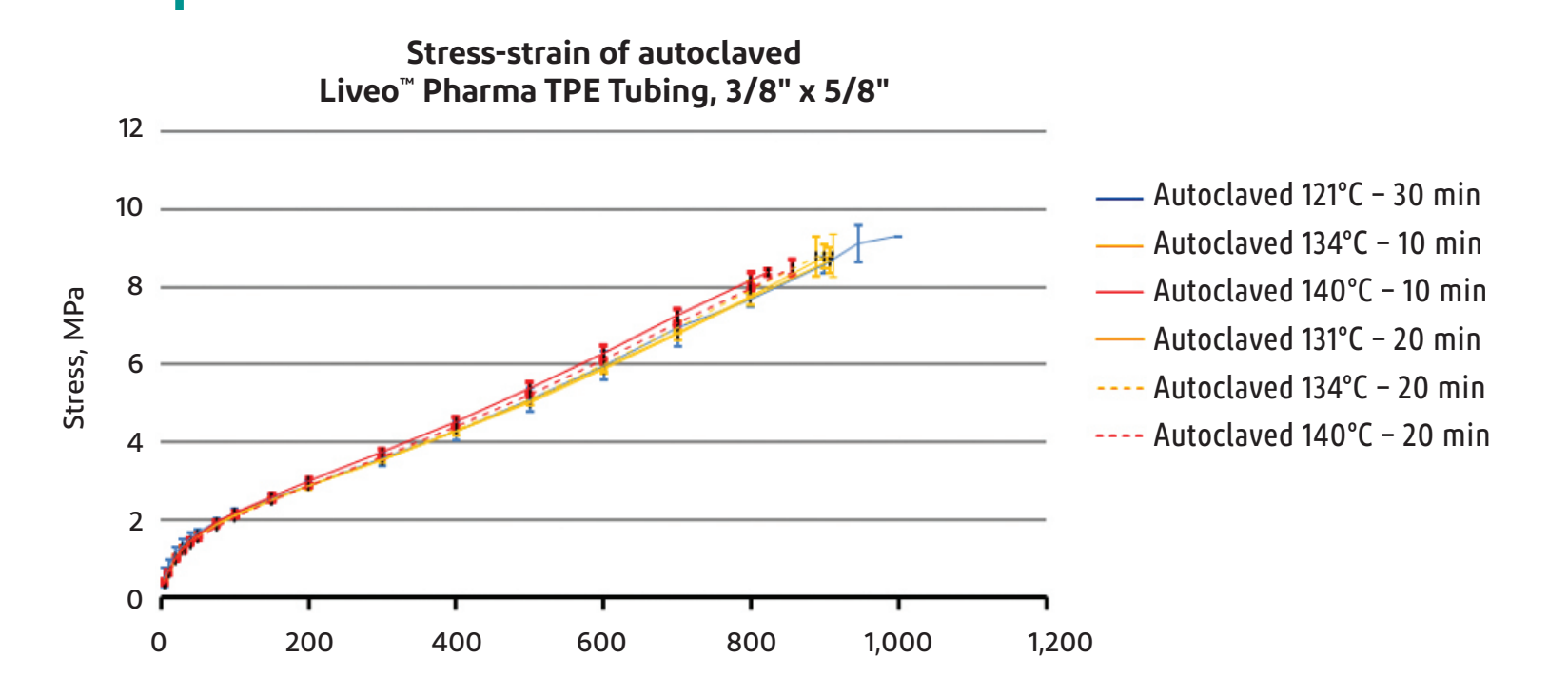
Autoclaving resistance at high temperatures

Testing conditions

- Steam sterilization via autoclaving:
- From 121 to 140°C
- From 10 to 30 min

Results

- No deformation/color change
- No change of durometer
- No change of functional properties



Good chemical resistance

Gavimetric test

- Surface-to-volume ratio 4:1
- Room temperature for 24 h
- Solvent exposed:
 - 20% (v/v) DMSO
 - NaOH 5M
 - KOH 5M
 - HCl 5M
 - Propan-2-ol
 - Ethanol

