

DuPont™ Liveo™ Pharma Bottle Closures

High-purity overmolded assemblies to seal glass and plastic bottles and containers



Liveo™ Pharma Bottle Closures include a one-piece silicone stopper made from biomedical-grade platinum-cured silicone elastomer molded with high-purity platinum-cured silicone tubing. This makes Liveo™ Pharma Bottle Closures particularly suitable to seal threaded glass and plastic bottles and containers used for critical high-purity fluids and media in biological drug production.

Applications

Liveo™ Pharma Bottle Closures can be configured to close bottles and containers used for:

- Critical fluid transfer
- Media and buffer pooling and storage
- Sample collection
- Single-use systems
- Upstream processes
- Biopharmaceutical and biotech processes

Features and benefits

Liveo™ Pharma Bottle Closures offer customers the flexibility they desire:

- One-piece molded silicone seal part
- Produced in a strictly controlled and monitored clean manufacturing environment
- In-house compounding and extrusion of biomedical-grade silicone elastomers formulated by DuPont
- Prevention of leak risk and contamination risk
- Polypropylene screw cap
- Sterilizable (autoclave, gamma irradiation)
- Supplied in sealed polyethylene double bags
- Produced according to customer-specific designs
- Available in a choice of silicone tubing durometer formulations according to your process requirements

Regulatory and biocompatibility details

- Liveo™ Pharma Tubing products are of high purity grade and have a proven history of use in biopharmaceutical applications. The tubing is non-cytotoxic and complies with USP Class VI, USP <85> Endotoxins, USP <151> Pyrogen, USP <661> Physicochemical Tests – Plastics, USP <788> Particulate Matter for Injections, ISO 11737-1 Bioburden, ISO 10993 relevant parts, European Pharmacopoeia 3.1.9 Silicone Elastomer for Closures and Tubing, and FDA CFR 177.2600 Rubber articles for repeated use.
- Liveo™ Liquid Silicone Rubber is non-cytotoxic and complies with USP Class VI, USP <151> Pyrogen, ISO 10993 relevant parts, European Pharmacopoeia 3.1.9 Silicone Elastomer for Closures and Tubing (substances soluble in hexane, volatile matter), and FDA CFR 177.2600 Rubber articles for repeated use.
- The polypropylene cap complies with USP Class VI, USP <661> Physicochemical tests – Plastics, and USP <85> Endotoxins. The cap has no direct contact with the container fluids, media or buffers.
- All materials of construction are of animal-free origin.

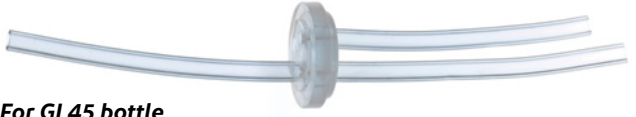



Manufacturing environment

- The DuPont™ Liveo™ Pharma Tubing and Liveo™ Liquid Silicone Rubber used to make Liveo™ Pharma Bottle Closures are the highest grade of silicone materials in the Liveo™ product range.
- Liveo™ Pharma Bottle Closures are produced at the Healthcare Industries Materials Site (HIMS) in Michigan, USA, which is dedicated to the manufacture of silicone-based materials for Pharma and Medical Devices. HIMS is FDA-registered and ISO 9001:2015-certified and is responsible for ensuring consistent product quality (e.g., change control and material traceability).

Flexibility in design: Technical specifications

- Cured silicone seal parts currently are available for GL45 and 38-430 neck bottles/containers.
- Silicone tubing is available in 50, 65 or 80 Shore A durometers. Tubing length and size are dependent upon the user's needs.
- Please note that bottles are not supplied with Liveo™ Pharma Bottle Closures.

Seal part	Platinum-cured liquid silicone rubber
Tubing	Platinum-cured silicone tubing Durometer: 50, 65 or 80 Shore A Length, size and other considerations: A range of tubing lengths and diameters can be accommodated according to the end-user's specific needs. Number and dimensions of tubing pieces molded to the seal part are determined by the closure size. Customer-specific tolerances to meet specific application requirements also are available; contact DuPont for further discussion.
Cap	Polypropylene (no fluid contact)
Closure type ¹	GL45 38-430
Sterilization	Autoclave, gamma irradiation
Customization	Contact DuPont and provide your requirements: <ul style="list-style-type: none"> • Bottleneck size: Internal diameter and thread • Tubing specifications: Number of tubes, durometer, ID/OD, length <p>Examples of customized products</p>  <p>For GL45 bottle Tubing: Two tubes of Liveo™ Pharma-50 Tubing, 3/16" x 5/16" Cap size: GL45</p>  <p>For 38-430 bottle Tubing: Two tubes of Liveo™ Pharma-50 Tubing, 1/4" x 3/8" Cap size: 38-430</p>

¹Contact DuPont for other closure types.



To learn more about DuPont™ Liveo™ Healthcare Solutions, visit liveo.dupont.com.



Smarter Healthcare.
Positive Patient Outcomes.

*DuPont™, the DuPont Oval Logo, and all trademarks and service marks denoted with ™, SM or ® are owned by affiliates of DuPont de Nemours, Inc. unless otherwise noted.
© 2021 DuPont.*

The information set forth herein is furnished free of charge and is based on technical data that DuPont believes to be reliable and falls within the normal range of properties. It is intended for use by persons having technical skill, at their own discretion and risk. This data should not be used to establish specification limits nor used alone as the basis of design. Handling precaution information is given with the understanding that those using it will satisfy themselves that their particular conditions of use present no health or safety hazards. Since conditions of product use and disposal are outside our control, we make no warranties, express or implied, and assume no liability in connection with any use of this information. As with any product, evaluation under end use conditions prior to specification is essential. Nothing herein is to be taken as a license to operate or a recommendation to infringe on patents.

Caution: Do not use DuPont materials in medical applications involving implantation in the human body or contact with internal body fluids or tissues unless the material has been provided from DuPont under a written contract that is consistent with DuPont policy regarding medical applications and expressly acknowledges the contemplated use. The customer is solely responsible to determine whether DuPont products are suited for customer's intended purpose or application and may contact DuPont technical experts for more product details prior to sourcing products. DuPont disclaims liability for any incidental or consequential damages resulting from customer's use of DuPont products. For further information, please contact your DuPont representative. You may also request a copy of DuPont POLICY Regarding Medical Applications H-50103-4 and DuPont CAUTION Regarding Medical Applications H-50102-4.

Form No. 05-1030-01-AGP0921

#16580B