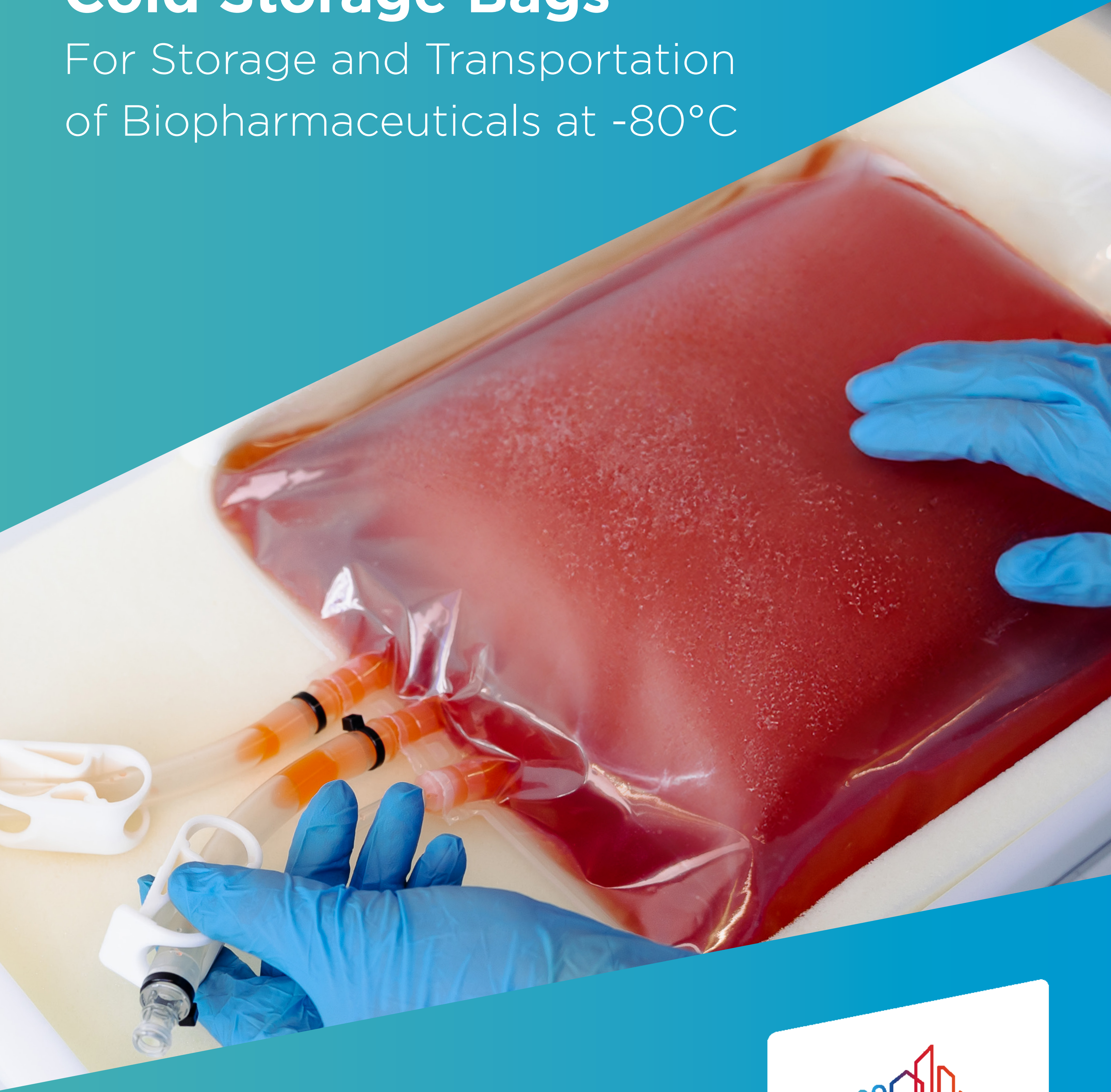
WHITE PAPER 0135

Cold Storage Bags

For Storage and Transportation of Biopharmaceuticals at -80°C



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SAINT-GOBAIN

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Cold Storage Bags deliver best-in-class robustness down to -80°C without relying on fluoropolymers (PFAS), offering a resilient and environmentally-conscious solution for cold chain applications.

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EXECUTIVE SUMMARY

Single-use containers are preferred throughout the biopharmaceutical manufacturing process to mitigate contamination risk. Cold storage is one such key process step in manufacturing many biopharmaceutical products. Large biomanufacturing operations are increasingly decentralized with different parts of the process taking place at different sites. This introduces the logistical challenge of managing cold transportation of temperature-sensitive, high value products and increases the importance of cold chain logistics in the industry. Saint-Gobain Life Sciences' cold storage bags help meet this challenge by providing a robust solution for cold storage and transportation of high-value Bulk Drug Substance (BDS) or Bulk Drug Product (BDP).

This white paper details the steps that we took in designing a solution to meet this critical challenge. We started from the ground up and extensively tested each facet of our solution. We evaluated the films, components, and tubing that we use to make our bags and, after extensive testing, developed a unique dual-film structure that bolsters the resistance to accidental damage when the bag is frozen at temperatures down to -80°C. To allow full flexibility for our customers, our cold storage bags are offered in two different tubing configurations – our industry-leading C-Flex® 374 TPE tubing, used in cold storage applications for more than 20 years, allowing aseptic welding connections and sealing disconnection and our new Sani-Tech® STHT®-LT silicone tubing, specifically designed for ultra-low temperature applications as low as -80°C. To further increase robustness, we have collaborated with Single Use Support to develop a secondary container that perfectly fits our cold storage bags.

As a result, we are pleased to showcase our cold storage bags which far exceed the performance of bags in the same material class (polyolefin - polyethylene (PE) and poly (ethylene-co-vinyl acetate) (EVA)) and show comparable cold storage performance to fluoropolymer bags on the market without using fluoropolymers which belong to the PFAS family and are under scrutiny.

1. INTRODUCTION

1.1 Cold Storage in Biopharma Applications

Cold storage is a key process step in manufacturing many biopharmaceutical products. Single-use containers are preferred by the industry to mitigate contamination risks. In a typical biomanufacturing process, cold storage bags are used at temperatures down to -80°C for frozen storage and cold chain distribution of high-value, temperature-sensitive fluids such as Bulk Drug Substance (BDS) and Bulk Drug Product (BDP).

For applications such as the manufacture of Monoclonal Antibodies (MAbs) and Vaccines, the industry has been increasingly moving away from rigid bottles and towards flexible single-use bags which enable more uniform freezing. Due to the high value of the fluid being stored, failures during cold storage and shipping can end up being very costly.

Saint-Gobain Life Sciences' cold storage bags provide a state-of-the-art storage solution that has been extensively tested for robustness at ultra-low temperatures down to -80°C. Our unique dual-film structure enables superior performance at ultra-low temperatures compared to current films. Moreover, we have collaborated with Single Use Support to adapt their RoSS® secondary containment system to our bioprocess bags and further bolster the protection during cold storage and transportation. In this white paper, we present the results of our studies on the suitability of Saint-Gobain Life Sciences' cold storage bags for biopharmaceutical ultra-low temperature storage applications (down to -80°C).

Cold storage bags from Saint-Gobain Life Sciences are offered in two different tubing configurations – our industry-leading C-Flex® 374 TPE tubing, used in cold storage applications for more than 20 years, and our new Sani-Tech® STHT®-LT silicone tubing, which was designed from the ground up specifically for ultra-low temperature applications as low as -80°C.

1.2 Cold Storage Bag Assembly

Saint-Gobain Life Sciences' cold storage bags are manufactured under tight manufacturing controls in ISO 7 cleanrooms and are constructed using a multi-layer film specially designed for bioprocessing applications. The unique dual-film structure of our bags allows them to be robust between operating temperature extremes of +60°C and -80°C.

The outer film is the same robust multilayer film used in our bioprocess bags. It has a coextruded multi-material film construction consisting of nylon, ethylene vinyl alcohol (EVOH) and linear low-density polyethylene (LLDPE). Nylon imparts strength to the film, EVOH provides exceptional gas barrier properties and LLDPE is a fluid contact layer with a clean extractables profile.

The inner Low-Temp-LLDPE (LT-LLDPE) film is a mono-material film made from our fluid contact LLDPE and provides superior low temperature robustness to the bag.

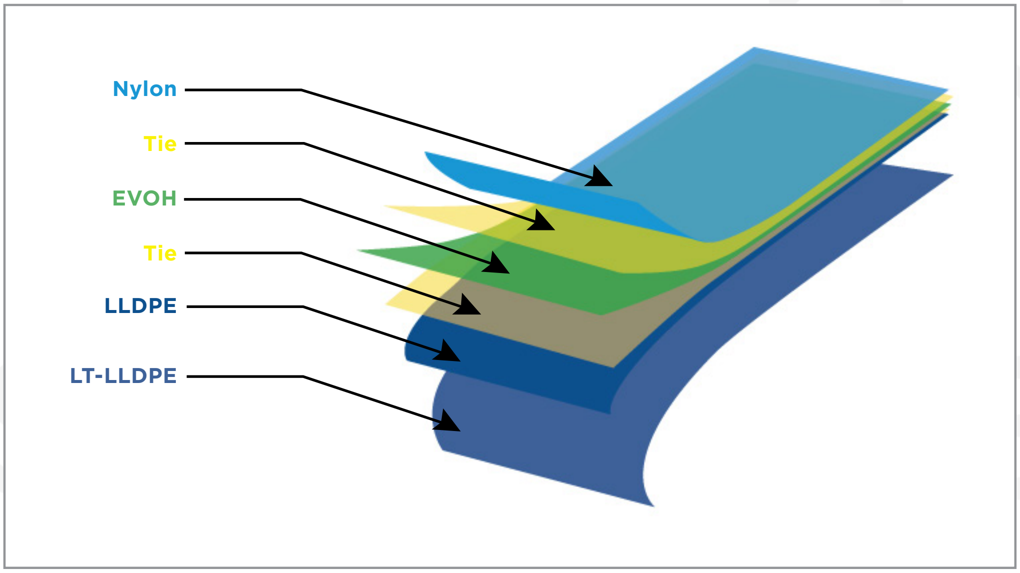


Figure 1. Dual Film Structure of Cold Storage Bags

In such cases, secondary containment is highly recommended in order to provide additional protection as well as enable ease of handling. For this purpose, we have collaborated with Single Use Support, who specializes in developing secondary containment solutions for cold-chain transportation.

RoSS® shells from Single Use Support provide robust protection for bags for cold storage and shipping. They feature stainless steel surfaces to enhance freezing performance and employ foam inserts to protect the vulnerable parts of the bag assembly such as ports, tubing, and connectors. RoSS® shells that specifically fit Saint-Gobain Life Sciences' cold storage bags in 1L, 5L, and 10L volumes were developed as a part of this collaboration.

Qualification documents for the shells are available upon request.

2. ROBUSTNESS EVALUATION

In the development of this product, we conducted extensive tests to evaluate all parts of the assembly at -80°C. We assessed critical components of the bag including the films, tubing, and connectors; we tested fully assembled and gamma-sterilized bags; and we extensively stress-tested the bag and shell assembly together.

Single Use Support provided a comprehensive validation package that included determination of fill volumes and robustness evaluation. Additionally, we also performed frozen instrumented drop tests based on the heights specified by ASTM D4169 with the help of an external testing service.

We evaluated mechanical properties of the film, weld properties and chamber integrity after subjecting water-filled bags to three temperature cycles between 25°C and -80°C. Detailed results are available upon request in the Validation Guide Summary (VGS) for our bags. Bioprocess bags for cold storage are available in 1L, 5L and 10L volumes as a starting point.

Additionally, our cold storage bags are available with C-Flex® 374 thermoplastic elastomer (TPE) tubing (allowing aseptic welding connections and sealing disconnection) as well as our Sani-Tech® STHT®-LT ultra-low temperature silicone tubing, specifically engineered for low temperature applications.

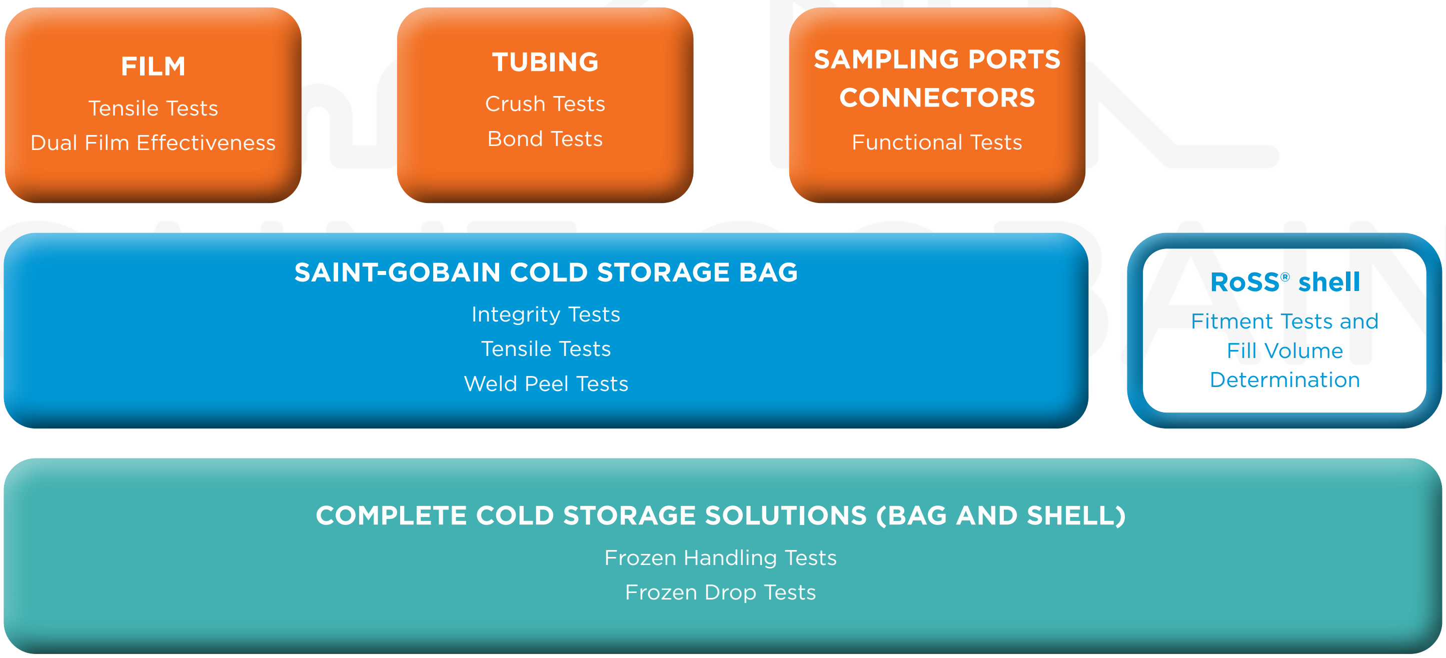


Figure 2. Robustness Evaluation Strategy (Single Use Support)

2.1 FILM TESTS

2.1.1 Film Performance at Ultra-Low Temperature

We conducted mechanical tests to compare the ultra-low temperature performance of our films to other films on the market made from materials such as polyethylene (PE), poly (ethylene-co-vinyl acetate) (EVA) and fluoropolymers. In this study, we tested various films at two temperatures, 25°C and -70°C, using a high-speed tensile test. Representative data from this study is shown below in Figures 3A, 3B, 3C and 3D.

Out of all the films tested, the Saint-Gobain Life Sciences' multilayer film, PE1, PE2 and EVA films are gas barrier films. The Saint-Gobain Life Sciences' LT-LLDPE film and the fluoropolymer film are both gas permeable films.

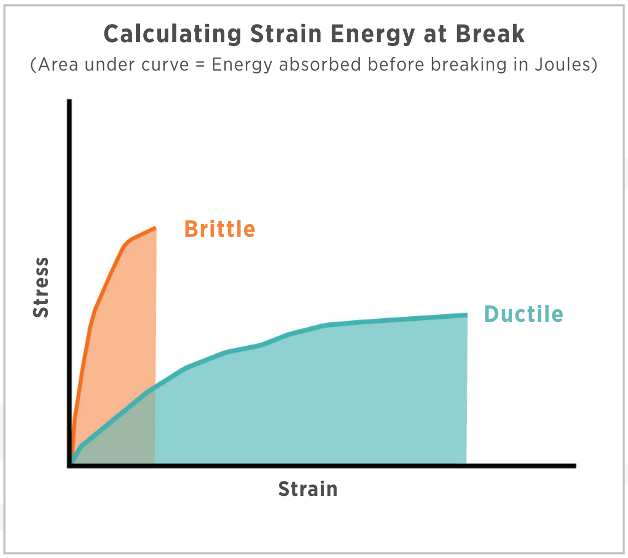


Figure 3A. Energy absorbed before breaking was calculated from the tensile curve for each film as shown in the schematic.

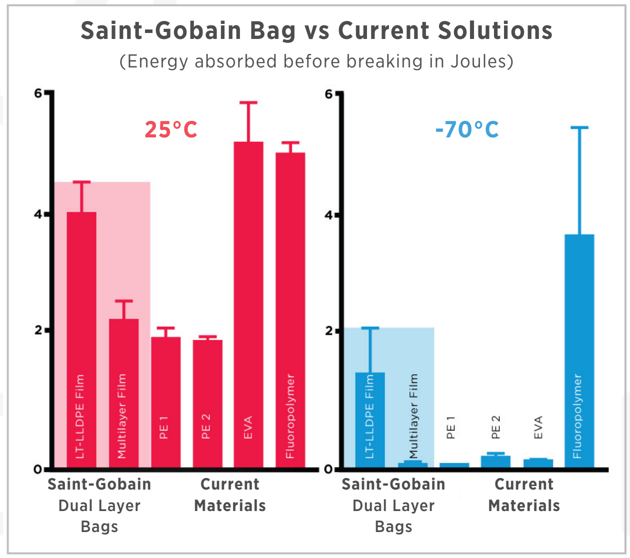


Figure 3B. Tensile test results from Saint-Gobain films and representative films (n: number of tested specimen per film category = 5). Saint Gobain bags use a unique dual-film structure that allows for a combined performance better than current films in the same material class.

- Red columns represent room temperature
- Blue columns represent ultra low temperature
- Light red and blue bars represent combined properties

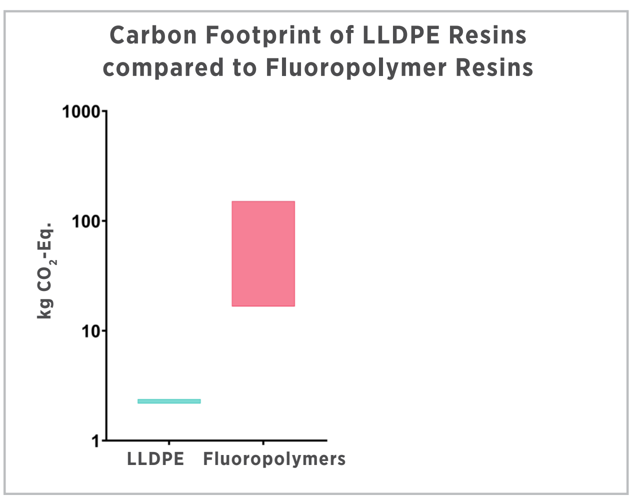


Figure 3C. Comparing carbon footprint of LLDPE resins to fluoropolymer resins. Data is shown according to ecoinvent 3.12 database for representative generic resins. Global warming potential (GWP100) calculated per IPCC 2021, climate change: total (excl. Biogenic CO2). In the LLDPE bar, the range shows GWP100 variation across regions. In the Fluoropolymers bar, the range shows variation of global GWP100 values across different fluoropolymer materials.

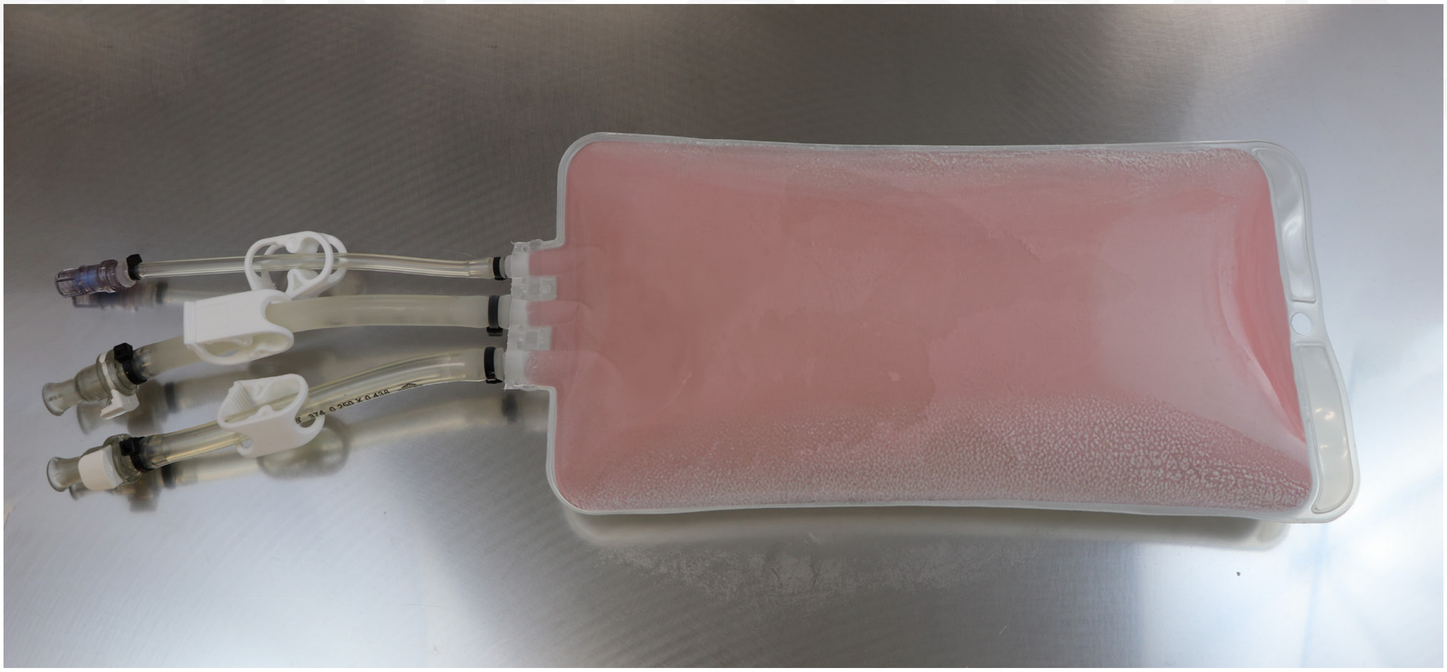
Figure 3D. Low Temperature Tensile Test In-Progress

Five specimens per film were prepared according to ASTM D638 Type IV specification. An Instron 5969 test frame with a 1kN load cell, 50kN pneumatic grips and a temperature conditioning chamber was used to conduct the test. Each specimen was mounted on the test frame to condition for one hour at the specified temperature, and tensile tests were conducted at the rate of 500mm/min. To determine how much energy the film can absorb before breaking, strain energy at break was calculated from the tensile curves. It is important to note that in cases of film breakage due to accidental drops, the shockwave from the drop may cause very high strain rates at the site where the break occurs. The exact condition could not be replicated in our setup with the required temperature conditions. However, performance of these materials at higher strain rates relative to each other is expected to follow the same trend as observed.

At room temperature conditions, all PE-based, multilayered, gas barrier films performed similar to each other. Saint-Gobain Life Sciences' LT-LLDPE film had comparable strain energy at break to EVA and fluoropolymer films. At -70°C however, all gas barrier films including the EVA absorbed much less energy before breaking increasing their vulnerability to accidental shocks. Saint-Gobain Life Sciences' LT-LLDPE film significantly outperformed the barrier films and exhibited properties comparable to the fluoropolymer film.

Fluoropolymers are known to retain their physical properties over a wide temperature range and are therefore used in ultra-low temperature applications down to -196°C. However, manufacturing processes for fluoropolymers require the use of environmentally concerning substances which has led to increased regulation globally and an industry-wide shift away from fluoropolymers. Polyethylenes typically have a relatively lower environmental impact compared to fluoropolymers. Figure 3C illustrates the differences in carbon footprint of representative LLDPE and fluoropolymer resins. LLDPE resins can have a carbon footprint 1-2 orders of magnitude lower than that of fluoropolymers.

The unique dual-film structure used in Saint-Gobain Life Sciences' cold storage bags, combining a PE-based gas barrier multi-layer film and a LT-LLDPE film, not only enables them to outperform incumbent solutions in the same class (polyolefin bags – PE and EVA), but also achieves performance levels equivalent to fluoropolymer alternatives in a non-fluoropolymer solution. In addition to testing the films independently, we also compared the performance of the finished bags with different film configurations.



2.1.2 Single vs Dual Film Structure

In order to further understand the effect of the dual film structure, we conducted frozen drop tests on 1L bags made with two different film configurations.

Film Configuration	Bag P/N	RoSS® shell P/N
Multilayer film only	BP0001L	RoSS_1070_01000000-B
Multilayer film with LT-LLDPE	BP0001-LTC	RoSS_1070_01000000-B

Table 1. Experimental Setup for Comparing Single and Dual-Film Configurations

For these tests, three bags of each configuration were filled with tap water to their nominal volume, placed in RoSS® shells and frozen in a Envirotronics ELHH-27-MR/LC Conditioning Chamber Set at -80°C ± 5°C for 24 hours. Using an MRAD 2424 Pneumatic Drop Tower and height specified by the ASTM D4169 standard, one straight drop was conducted on the largest face from a 24in height (609mm) for each specimen. The shells were opened after the drop, and a visual inspection was conducted to assess damage. The bags were then allowed to thaw, reinspected visually for leaks, emptied, and subjected to integrity testing by pressure decay.

Figure 4. Representative pictures from conditioning and drop test setup.
Left image shows conditioning chamber and right image shows drop tester.

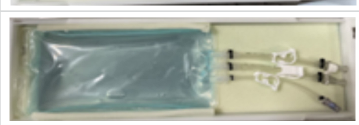
Film Configuration	Post-Drop Visual Inspection	Post-Thaw Visual Inspection	Integrity Test by Pressure Decay	Representative Pictures
Multilayer film only	0/3 Passed	-	-	
Multilayer film with LT-LLDPE	3/3 Passed	3/3 Passed	3/3 Passed	

Table 2. Summary of Results Comparing Single vs. Dual-Film Configurations

Bags with the multi-layer film all failed the first post-drop visual inspection and were not subjected to further tests. The bags with the dual film configuration passed both visual inspections as well as integrity testing, indicating the robustness of the bags. In addition to the material test results, this result further emphasizes the importance of the dual film structure.

2.2 COMPONENT PERFORMANCE AT TEMPERATURES DOWN TO -80°C

2.2.1 C-Flex® 374 Tubing Performance Testing

C-Flex® 374 is a thermoplastic elastomer (TPE) tubing designed for biopharmaceutical fluid processing. C-Flex® 374 is weldable and sealable using commercially available tube welders and sealers.

To evaluate the welding performance of C-Flex® tubing after exposure to ultra-low temperature conditions, tube specimens with a 3/8in (9.53mm) outer diameter were cut into 20in (508mm) pieces and frozen at -80°C for approximately 47 hours and 187 hours. After conditioning, the samples were thawed, cut in half, and welded using a C-Flex® Connect-Flex TPE tubing welder. These specimens were then subjected to tensile tests at a strain rate of 20in/min (508mm/min) until failure and the tensile performance was compared to unconditioned controls. No deterioration in weld performance after freeze-thaw cycling was measured.

For more information about C-Flex® TPE tubing and its performance under various conditions, please refer to our C-Flex® white paper.

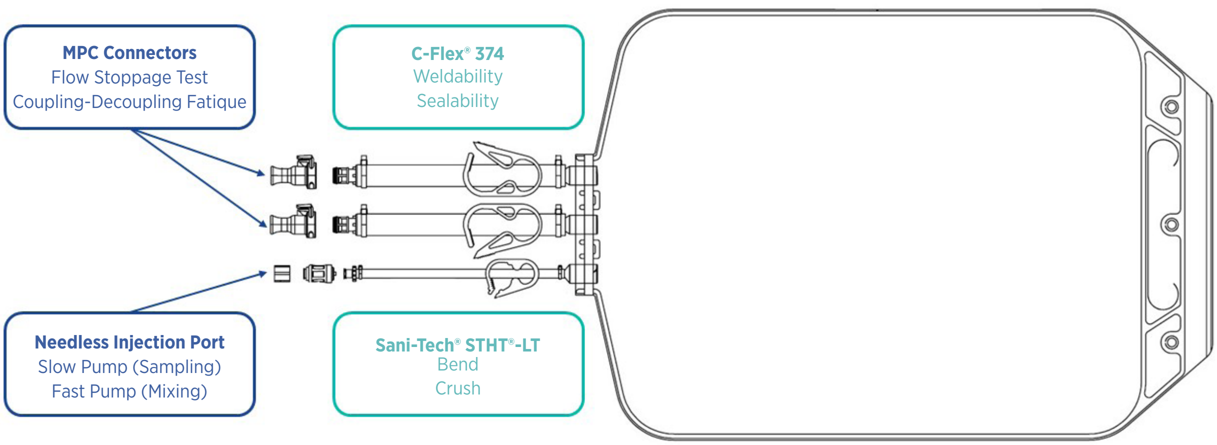


Figure 5. Schematic Diagram of Component Tests Performed

2.2.2 Sani-Tech® STHT®-LT Tubing Performance Testing

Sani-Tech® STHT®-LT is a platinum-cured silicone tubing designed specifically for applications where ultra-low temperatures are present. Where traditional silicone tubing products would become brittle and prone to damage in these conditions, this tubing has the unique ability to remain flexible and crush-resistant at temperatures as low as -80°C. STHT®-LT is produced without using any fluoropolymers and brings their unique low-temperature performance capabilities to the silicone material without any of the risks.

Traditional Silicone Tubing

Sani-Tech® STHT®-LT

Figure 6. Frozen Bend Test Performance of Sani-Tech® STHT®-LT Tubing vs Traditional Silicone Tubing

Bend tests were performed on as-manufactured samples according to ASTM D380-94, wherein the samples were conditioned at -80°C for 72 hours and tested immediately upon removal from the freezer. Crush tests were performed according to ISO 28702 wherein the samples were conditioned at -80°C for 24 hours and tested immediately upon removal from the freezer.

Tubing P/N	ID inches (mm)	OD inches (mm)	Crush Test, -80°C	Bend Test, -80°C
STHTLT-031-1	0.031 (0.8)	0.094 (2.4)	10/10 Passed	45/45 Passed
STHTLT-250-2	0.250 (6.4)	0.375 (9.5)	15/15 Passed	75/75 Passed
STHTLT-500-4	0.500 (12.7)	0.750 (19.1)	18/18 Passed	30/30 Passed

Table 3. Summary of Results for Tubing Performance at Low Temperature

Saint-Gobain Life Sciences' cold storage bags are available with two different tubing configurations: our industry leading C-Flex® 374 TPE tubing and also our Sani-Tech® STHT®-LT silicone tubing. Additional details on the bend and crush tests are available upon request.

2.2.3 Connectors

As part of our robustness testing strategy, we also extensively tested the critical components on our bags such as the sampling ports and connectors. The primary objective of this study was to identify if these components maintain their functionality after temperature cycling between room temperature and -80°C. The components were gamma-sterilized at 25-40kGy and conditioned for 3 cycles at -80°C for 72 hours followed by 24 hours at +25°C. The following functional tests were conducted for multiple freeze/thaw cycles to give a margin of safety for the most extreme expected use case:

- Visual Inspection (All Components) - Visual inspections were conducted on each component before and after each conditioning cycle and after a test was conducted. The body of the sampling port or connector being tested was observed for cracks, signs of wear and discoloration. The rubber seals, wherever present was observed for breaks, gaps, and discoloration.
- Flow Stoppage Test (MPC Connectors) - A 10L bag chamber was filled with colored water to 200% of its nominal capacity to 20L. The bag was then hanged vertically with all clamps closed. The drain tube was primed with liquid. The test port was placed on a fixture consisting of a short length of tubing and connected to the draining line. The bag clamp was opened, and the test port was allowed to bear the full weight of the liquid in the bag. The end of the fixture was placed on a white paper towel to identify any leakage of the colored water. Observations were conducted for one minute. No leakages were observed in any of the tested connectors.
- Coupling-Decoupling Fatigue (MPC Connectors) – After each freeze-thaw cycle, MPC connectors were tested, pairwise for their ability to connect securely. Each pair was connected and disconnected 10 times and marked as passing if the audible click was heard. All connectors passed.
- Slow Pump (Needleless Injection Port, Sampling) – Test port was connected to a 20mL syringe using the luer connection. Using a syringe pump, 15mL water was drawn into the syringe at 14mL per minute to simulate sampling and then ejected back into a reservoir. This process was repeated 3 times. The Flow Stoppage Test was repeated to observe any leaks.
- Fast Pump (Needleless Injection Port, Mixing) – Test port was connected to a 20mL syringe using the luer connection. Using a manual process, 15mL water was drawn into the syringe in under 5 seconds and ejected back into the reservoir under 5 seconds to simulate mixing. This process was repeated 10 times. The Flow Stoppage Test was repeated to observe leaks.

Component	Test	Results/Notes
Sampling Ports	Slow Pump (Sampling)	5/5 Passed
	Fast Pump (Mixing)	5/5 Passed
	Flow Stoppage	5/5 Passed
Connectors	Flow Stoppage	10/10 Passed
	Coupling-Decoupling Fatigue	10/10 Passed

Table 4. Summary of Component Tests. Visual inspection results are not explicitly included since all components tested passed the visual inspections at every checkpoint described above.

All components tested were able to withstand three temperature cycles between -80°C and +25°C.

2.3 BAG PERFORMANCE AT TEMPERATURES DOWN TO -80°C.

2.3.1 Operating Temperature Validation Summary

Extensive tests were conducted as a part of the validation for Saint-Gobain Life Sciences' cold storage bags to qualify the bags to be used at temperatures as low as -80°C and as high as 60°C.

As part of this validation, representative bags with similar construction to Saint-Gobain Life Sciences' cold storage bags were filled to the recommended fill volume and conditioned at 60°C and -80°C; their performance was compared to controls conditioned at ambient temperature.

For ultra-low temperature testing, 64 bags from two different production lots were conditioned at -80°C and subjected to three freeze-thaw cycles; 10 bags (5 bags from each lot) were used as ambient controls. After conditioning, the bag chambers were subjected to integrity testing by pressure decay. For this test, bags were placed in a fixture with constraining plates spaced 1 cm apart. Using the package tester, the bags were inflated with nitrogen to an internal pressure of 2psi. The pressure was continuously monitored, and a bag passed if the pressure drop was less than 0.2psi over 60 seconds.

After the integrity test was completed, three bags were randomly selected from each of the two lots to test weld peel strength compared to ambient controls. In this test, three specimens measuring 1in x 3in (25.4mm x 76.2mm) were taken from each bag according to the schematic below. The peel test specimen was placed in a Instron 33R 4465 Load Frame equipped with a 5kN load cell and1 kN pneumatic grips with an initial grip separation of 1.5in (38.1mm). The specimen was pulled apart at the rate of 20in/min (508mm/min). The mode of weld failure was visually observed and the maximum load at break was recorded for statistical comparisons. A specimen was deemed to be passing if the films yielded or broke before undergoing delamination at the weld. All tested specimen passed. Additionally, statistical comparison of means was done using one-way ANOVA to identify broader trends, if any. No significant difference was found, indicating that the weld strength is not functionally altered after three freeze-thaw cycles (Figure 7-9).

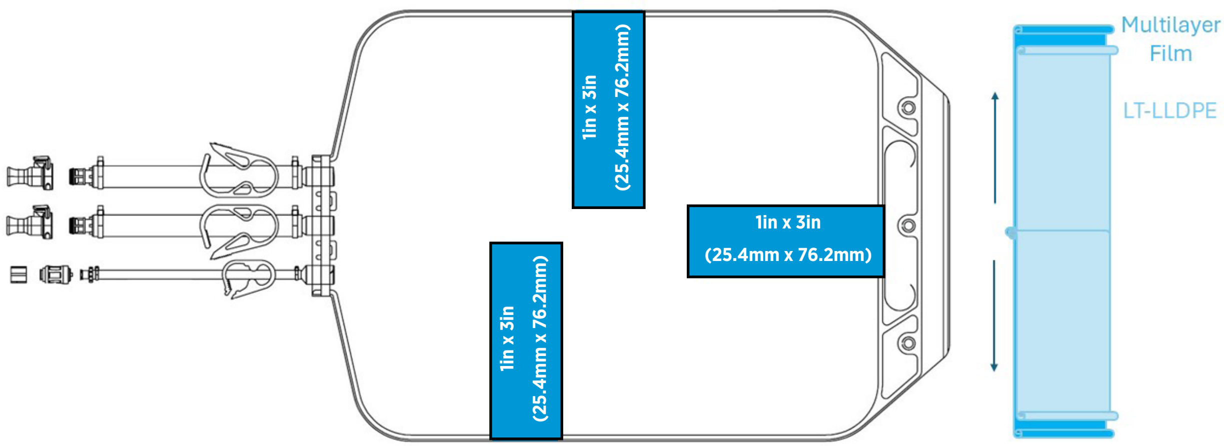


Figure 7. Schematic Sampling Diagram for Weld Peel Tests

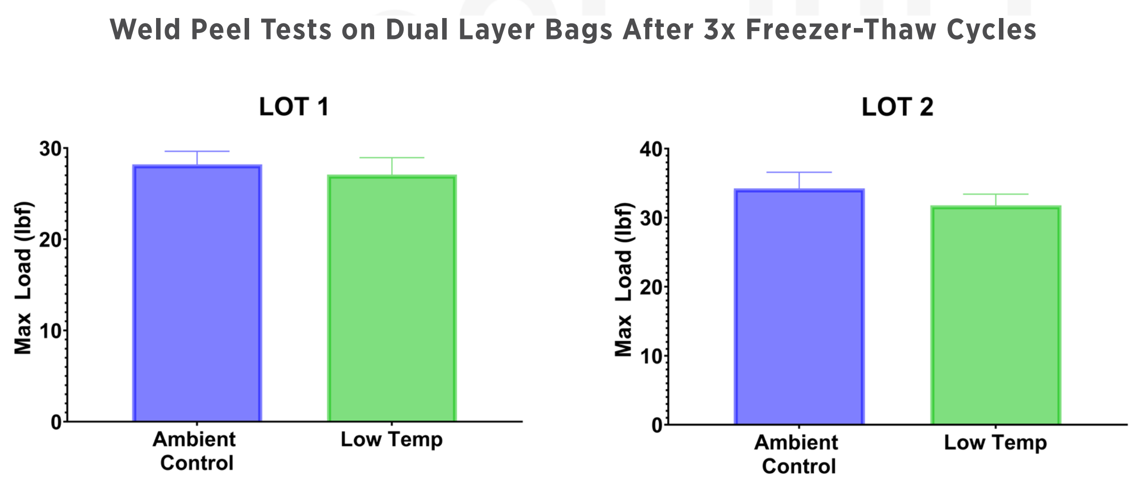


Figure 8. Comparison of samples conditioned at low temperature compared to ambient control. Each bar represents an average of 9 specimen (3 bags with 3 specimens taken from each). One-way ANOVA was used to compare means, and no significant difference was found between the ambient controls and conditioned samples.

Five 1in x 12in (25.4mm x 308.4mm) specimens of the multilayer film were taken from one randomly selected bag from each lot and subjected to tensile tests according to ASTM D882 using the same instrumentation setup as the weld peel test described above. Initial grip separation was set at 10in (254mm) and the test was conducted at a strain rate of 2in (50.8mm) per minute. Comparisons were done between ambient controls and the conditioned samples using one-way ANOVA. No significant difference was found in the yield strength of the film (Figure 9 and Table 5).

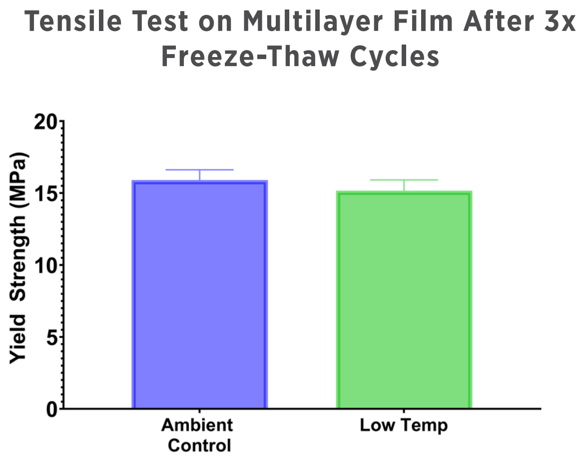


Figure 9. Yield strength of the film before and after conditioning. Each bar represents an average of 10 samples. One-way ANOVA was used to compare the means, and no statistically significant difference was found.

Test	Method	Samples Tested	Results
Pressure Decay	Internal Method	63/64 bags Insert port on one bag was damaged during handling, so chamber integrity was not tested.	All Passed
Weld Peel Strength	Internal Method	6 bags (3 selected randomly from each lot)	All Passed
Tensile Properties	ASTM D882	2 bags (1 selected randomly from each lot)	All Passed

Table 5. Summary of Test Results of Bags Subjected to 3 Freeze-Thaw Cycles

Detailed results are available upon request in the Validation Guide Summary.

2.4 BAG AND SHELL ASSEMBLY PERFORMANCE AT TEMPERATURES DOWN TO -80°C.

2.4.1 Materials

Nominal Volume	Bag P/N	Shell P/N	Target Fill Volume
1L	BP0001-LTC	RoSS_1070_01000000-B	1L
5L	BP0005-LTC	RoSS_1071_01000000-C	4.5L
10L	BP0010-LTC	RoSS_1072_01000000-E	8.5L

Table 6. Part Numbers (P/N) for Bags and Shells and Target Fill Volume

2.4.2 Fill Volume Determination

Bag films, like most materials, tend to contract and embrittle when subjected to lower temperatures. Water, on the other hand, tends to expand in volume at temperatures below 4°C. As a result of these opposing behaviors, fill volume is a critical factor that determines the robustness of a freezing bag. A widely accepted rule of thumb for freezing bags is setting the fill volume at 80% of the nominal volume, however the specific volumes can vary based on the bag-shell system used. Single Use Support conducted an evaluation of fill volume for specific Saint-Gobain Life Sciences' cold storage bag and RoSS® shell combinations and determined the Target fill volume indicated in Table 6 (above).

Smaller volumes can be handled with additional foam spacers. Detailed validation reports are available upon request.

2.4.3 Simulated Handling Tests

Polymeric materials are more susceptible to damage at ultra-low temperature than they are at room temperature. The foam inlay in the RoSS® shells protects the bags from shock damage by hardening around the ports and seams to immobilize the assembly. Frozen handling tests intended to simulate rough handling during operations were conducted independently by Single Use Support and Saint-Gobain Life Sciences.

In the Single Use Support validation, one bag of each size was filled with tap water to the target volume (Table 6) and then placed in the appropriate RoSS® shell. The shell was frozen using a Single Use Support Plate Freezer RoSS.pFTU Large Scale set to -80°C ± 5°C. The frozen shell was dropped onto a table from a height of 5cm (~2in) twice on each face amounting to a total of twelve drops. The shells were allowed to thaw, and a visual inspection was conducted to check for damage and leaks. All bags passed.

In the Saint-Gobain Life Sciences validation, three bags of each size were filled with tap water to the target volume (Table 7) and then placed in the appropriate RoSS® shell. The 1L and 5L shells were frozen for 24 hours using an Eppendorf CryoCube 570n ULT freezer set at -80°C ± 5°C. 10L Shells were frozen for 24 hours in a Envirotronics ELHH-27-MR/LC Conditioning Chamber Set at -80°C ± 5°C. The frozen shell was dropped onto a table from a height of 5cm twice on each face amounting to a total of twelve drops. Shells were opened in the frozen state and a visual inspection was conducted to assess any damage to the bags. After thawing, the bags were subjected to another round of visual inspection. Bags were then emptied and subjected to integrity test by Pressure Decay using a BT-IntegraPack integrity tester and an internal protocol. All bags passed.

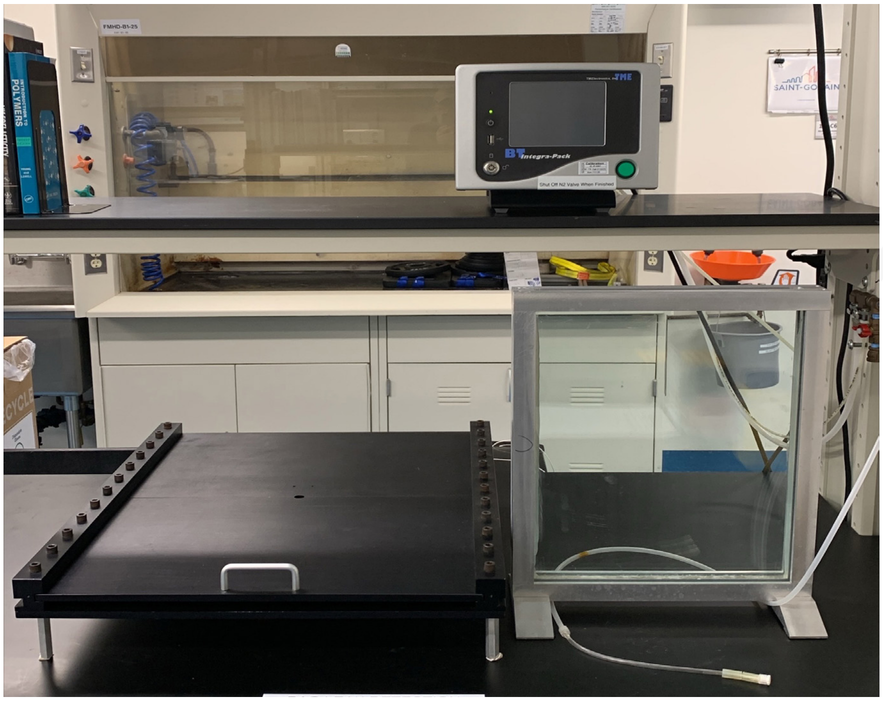


Figure 10: Integrity Test by Pressure Decay

Nominal Volume	Fill Volume	Visual Inspection (Frozen)	Visual Inspection (Thawed)	Integrity Test by Pressure Decay
1L	1L	3/3 Pass	3/3 Pass	3/3 Pass
5L	4.5L	3/3 Pass	3/3 Pass	3/3 Pass
10L	8.5L	3/3 Pass	3/3 Pass	3/3 Pass

Table 7: Saint-Gobain Simulated Handling Tests Summary

2.4.4 Instrumented Drop Tests Based on ASTM D4169

The ASTM D4169 standard provides guidance on performance testing shipping systems' ability to withstand distribution environments. This standard is typically applied to the shipped package, which in this case, would include the bag encased in a shell and then placed in a tertiary container such as a shipping box or a pallet box. While this doesn't apply specifically to primary (bags) or secondary containers (protective cassettes/shells), which are not shipped as-is, the standard lays out drop test parameters intended to simulate extreme conditions that may be experienced by packages during shipping. As such, instrumented drop tests were performed at the highest assurance level laid out by the ASTM D4169 standard (Level 1) to evaluate the robustness of the bag-shell assembly to extreme shocks experienced during shipping. This testing was conducted at an independent lab outside of Saint-Gobain Life Sciences. Post-test evaluations were conducted at Saint-Gobain Life Sciences.

Three bags of each size were filled with tap water to the target volume (Table 8) and then placed in the appropriate RoSS® shell. The shells were frozen for 24 hours in an Envirotronics ELHH-27-MR/LC Conditioning Chamber Set at -80°C ± 5°C. Using an MRAD 2424 Pneumatic Drop Tower and heights determined by the ASTM D4169 standard, one straight drop was conducted for each specimen on the largest face. The 1L shells were dropped from a 24in (609mm) height; 5L and 10L shells were dropped from a 21in (533mm) height.

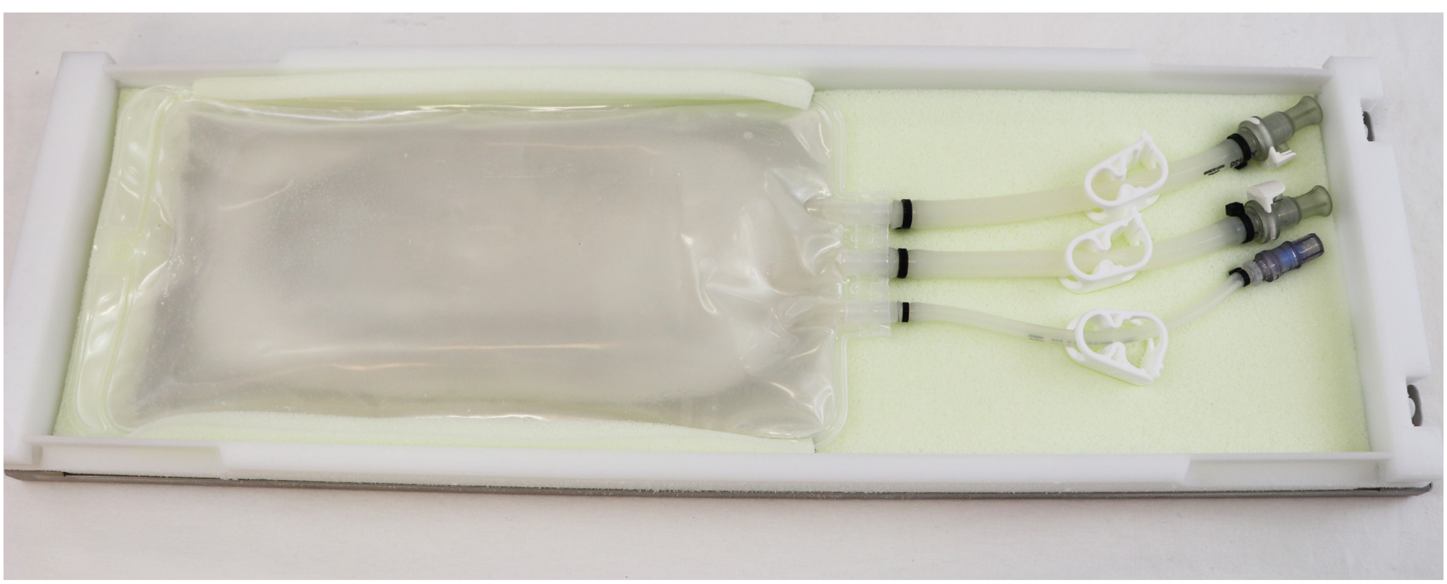
Shells were opened in the frozen state, and a visual inspection was conducted to assess damage to the bags, if any. After thawing, the bags were subjected to another round of visual inspection.

Bags were then emptied, and integrity testing by pressure decay was performed with a BT-IntegraPack integrity tester using an internal protocol. All bags passed.

Nominal Volume	Fill Volume	Drop Height	Visual Inspection (Frozen)	Visual Inspection (Thawed)	Integrity Test by Pressure Decay
1L	1L	24in (609mm)	3/3 Pass	3/3 Pass	3/3 Pass
5L	4.5L	21in (533mm)	3/3 Pass	3/3 Pass	3/3 Pass
10L	8.5L	21in (533mm)	3/3 Pass	3/3 Pass	3/3 Pass

Table 8: Frozen Instrumented Drop Test Summary

In summary, independently conducted frozen drop tests indicated the robustness of the Saint-Gobain Life Sciences' cold storage bag and RoSS® shell assembly to shipping and distribution stresses.



3. CONCLUSION

We extensively tested our Saint-Gobain Life Sciences' cold storage bags starting from the component level to the assembly level. With our unique dual-film structure, our bags offer best-in-class robustness at ultra-low temperatures down to -80°C in comparison with other polyolefin bags (PE or EVA based). Additionally, our bags demonstrate robustness on par with fluoropolymer films without using fluoropolymer films. While fluoropolymers exhibit excellent properties for cold storage applications, the manufacturing processes for fluoropolymers have environmental concerns and have been increasingly subjected to regulatory scrutiny.

Extreme test cases considered in our evaluation as well as robustness provided by combining our bags with Single Use Support's RoSS® shells can provide customers with confidence that our solution is resilient to the physical and thermal stresses experienced in day-to-day cold storage and transportation applications.

In addition, our cold storage bags are offered in two different tubing configurations – our industry-leading C-Flex® 374 TPE tubing, used in cold storage applications for more than 20 years and allowing aseptic welding connections and sealing disconnection, and our new Sani-Tech® STHT®-LT silicone tubing, specifically designed for ultra-low temperature applications as low as -80°C.

About

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Ninad has a Ph.D. in Chemical Engineering from Northeastern University, an M.Eng. in Biomedical Engineering from Cornell University and a B.E. (Hons.) in Chemical Engineering from BITS Pilani. He joined Saint-Gobain R&D in 2022 and works on New Product Development projects in Biopharmaceutical Cold Storage and Cryopreservation of Advanced Therapies.

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Saint-Gobain Life Sciences

The Bioprocess Solutions business of Saint-Gobain Life Sciences is an industry-leading provider of materials science-based solutions for single-use fluid management, including TPE and silicone tubing, connection and flow control components, bioprocess and cell culture bags, filtration products, sensors, and over-molded technology, all available in customized assemblies that are produced in 19 manufacturing facilities located around the world.