CharterMedical

Freeze-Pak™ STS Bio-Containers and STS Shippers
A New Single-Use Solution for Frozen Storage & Transport to -80°C

Dominic Clarke, Bradley Bennett and Lexan Lhu
Charter Medical, 3948-A Westpoint Blvd, Winston-Salem, NC 27103 – www.chartermedical.com

Abstract


Film Not Optimized

Frozen storage is commonly performed and enables manufacturing process flexibility, long-term product stability and minimizes logistics challenges. While single-use containers are available for storage and transport of frozen products, some require a significant investment while others don't offer the necessary support and protection. Using films and bags not designed for frozen storage applications can be detrimental.

Charter Medical recently developed a new family of single-use frozen storage and transport solutions . The **Freeze-Pak™ STS** (FP-STS) bio-containers and supporting secondary single-use STS shipping containers were engineered specifically for frozen storage applications. The bags and secondary containers are both tested to support frozen storage and transport to -80°C. The **Freeze-Pak™ STS** freezing solution products have been designed to provide a simple solution while delivering the flexibility and durability required for frozen storage and transport.

The purpose of the study was to test the new **Freeze-Pak™ STS** single-use bags and secondary shipping containers for both storage and transport. The results herein demonstrate that the **Freeze-Pak™ STS** bags and secondary containers can be used effectively for storage and transport to temperatures as low as -80°C.

Freeze-Pak™ STS Frozen Storage And Transport Solutions

Results

Freeze-Pak™ STS Bags

Prior to building a bag intended for storing products frozen, a robust, flexible film designed for freezing is necessary.

Film

Unique 12mil polyolefin structure combining both durable (resistance to tearing, hardness) and flexibility (elongation, elastic modulus) features along with a low glass transition (Tg = -50°C) temperature.

Integrity and Robustness

To ensure bags are suitable for freezing applications, validation testing was performed (Fig. 1). Bags initially tested for leaks were then filled and hung for at least 72 hours to confirm bag seal, port and tubing integrity pre-freeze. Bags were subjected to freeze/thaw integrity and robustness testing. As a final test, bag ports and handles were folded over and then frozen. All bags passed.

Freeze-Pak™ STS Secondary Containers

Testing performed to support the efficacy of the secondary shipper and FP-STS bags intended for frozen storage and transport applications.

Handling and Transport

5L bags and shippers were frozen in a -80°C freezer followed by a 3 foot drop on 2 sides (Fig. 2). The frozen FP-STS bags remained completely intact and free of any damage. STS shippers were also evaluated for use in a typical transportation setting (modified ASTM). No damage to the frozen FP-STS bags was observed (Fig. 2).

Freeze-Pak™ STS Bag Testing and Validation (Figure 1)

Property	Test Protocol	Result
Integrity	2L, 20L unconstrained pressure leak test	Pass
Integrity	Nominal fill vol. (2L, 20L); hang 72 hours	Pass
Freeze/Thaw	20L bag freeze, thaw (hanging), repeat	Pass
Robustness	1L, 5L, 20L freeze, thaw, drop	Pass

Summary

A Single-Use Frozen Storage and Transport Solution

The **Freeze-Pak™ STS** disposable freezing bags and secondary shippers are designed to support frozen storage product needs. The studies conducted support the efficacy and durability for storage and transport to temperatures as low as -80°C.

- Single-use bags and storage /transport containers
- Robust film designed for freezing applications
- Support frozen storage and transport to -80°C
- Custom designs for process flexibility available

Freeze-Pak™ STS single-use primary and secondary containers from Charter Medical, Ltd. offer a new durable yet flexible freezing, storage and transport solution.

STS Secondary Container Handling and Transport Test (Figure 2)

Drop Type	Drop Height	Result
Bottom Face	3 Feet	Pass
Top Face	3 Feet	Pass

Frequency (Hz)	Assurance Level 1
1	0.0001
4	0.02
16	0.02
40	0.002
80	0.002
200	0.00002
Overall (grms)	0.72
Duation (min)	180

Modified

Frequency (Hz)	PSD (g2/Hz)
5	0.005
10	0.02
16	0.02
40	0.002
80	0.002
200	0.00002
Overall (grms)	0.675
Duation (min)	360