



## APPLICATION NOTE

# RoSS<sup>®</sup> shell for Repligen ProConnex<sup>®</sup> 2D bag

Engineered for superior mechanical protection  
of Repligen ProConnex<sup>®</sup> 2D bags

# RoSS® shell for Repligen ProConnex® 2D bag

## ABSTRACT

The RoSS® shell is a proven secondary packaging and protection platform for single-use bag assemblies throughout freezing, frozen storage, transport, and thawing. Available in dedicated configurations for Repligen ProConnex® 2D bags, it provides a reliable solution for safeguarding of frozen biopharmaceutical liquids, intermediates, and drug substances while integrating seamlessly into existing single-use and cold chain workflows.

This application note presents the RoSS® shell as a process-oriented solution for ProConnex® 2D bags. It describes how the shell provides mechanical stabilization, precise positioning, and immobilization to support controlled low-temperature handling while preserving the inherent performance characteristics of the selected Repligen bag.



**Figure 1:** RoSS® shell supporting robust handling of single-use bags in biopharmaceutical cold chain processes

## 1. ROSS® SHELL WITH PROCONNEX® 2D BAG

Single-use bags are widely used in biopharmaceutical processing, however their use under frozen storage conditions requires careful consideration. At subzero temperatures, polymeric components, including bag films, tubing, connectors, and weld or seal joints, exhibit reduced flexibility and increased brittleness. Furthermore, expansion and movement of frozen bulk fluids can generate additional mechanical stresses during freezing, storage, transport, and handling, potentially affecting the structural integrity of single-use systems.

The RoSS® shell was developed to address these challenges. It provides a robust and reusable protection concept around the single-use bag assembly, combining mechanical stabilization, defined positioning and reliable immobilization in frozen state. This makes the RoSS® shell a valuable solution for customers aiming to improve robustness and overall system performance in cold chain handling.

For ProConnex® 2D bag users, the RoSS® shell offers an established protection platform for frozen biopharmaceutical liquids, intermediates and drug substances within existing single-use and cold chain workflows. Dedicated RoSS® shell configurations are available for selected Repligen ProConnex® 2D bag sizes, providing a robust platform for freezing, frozen storage, transport, and thawing applications (Figure 1).

## 2. DESIGNED FOR SUPERIOR BAG PROTECTION

- 1** PE frame  
**Provides robustness**
- 2** 3D foam inlays  
**Ensures immobilization**
- 3** Stainless-steel top and bottom  
**Enables plate freezing**

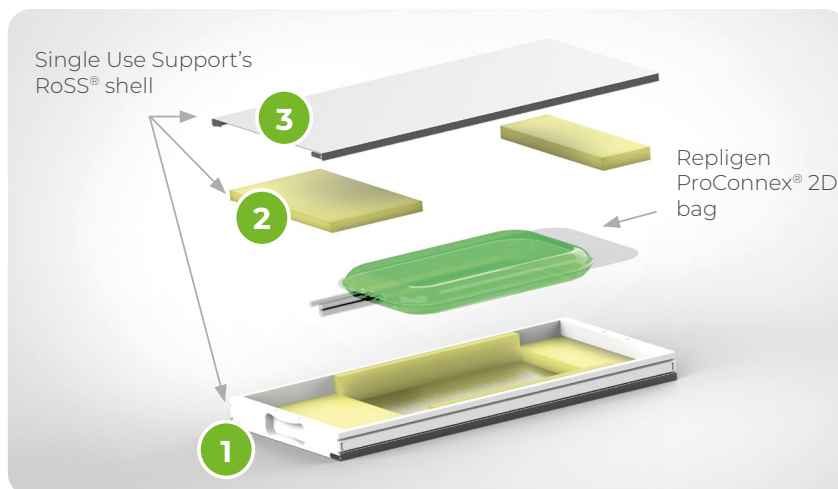


Figure 2: Components of the RoSS® shell

The RoSS® shell combines a rigid outer structure, stainless-steel top and bottom, and dedicated foam inlays to create a protective secondary packaging system for ProConnex® 2D bag assemblies (Figure 2). The robust shell enhances mechanical stability, while the foam inlays securely position the bag, tubing, connectors, and clamps within the system.



Figure 3: 3D foam inlay supporting immobilization of the ProConnex® 2D bag assembly

During freezing, the liquid expands and the bag assembly is pressed into the foam. At low temperatures, the foam hardens and contributes to immobilization of the complete assembly.

This immobilization is a key feature of the RoSS® shell concept. By reducing movement of the frozen assembly, the shell helps to protect sensitive areas such as tubing, connectors and joints during storage, transport and handling (Figure 3).

The stainless-steel top and bottom facilitate efficient heat transfer in plate-based freezing systems (Figure 4).

In combination with the optimized RoSS® shell geometry, they promote controlled and reproducible freezing, supporting robust process performance under defined operating conditions.



Figure 4: Frozen RoSS® shells in a plate-based freezing system

### 3. DEMONSTRATED MECHANICAL ROBUSTNESS UNDER DEFINED LOW-TEMPERATURE HANDLING CONDITIONS

The RoSS® shell concept is supported by internal low-temperature performance testing. These tests demonstrate how a defined shell configuration provides mechanical protection for the selected single-use bag assembly under standardized and representative cold chain conditions, including frozen-state handling stress.

For the evaluated ProConnex® configuration, the bag assembly was filled with a defined test liquid, placed inside the corresponding RoSS® shell and frozen in a plate freezer. The frozen assembly was then subjected to defined handling and drop-test scenarios to simulate challenging post-freezing handling situations (Figure 5).



Figure 5: Low-temperature performance testing of the RoSS® shell with ProConnex® 2D bag assembly

The test sequence included freezing to low-temperature conditions, controlled handling in frozen state, visual inspection, thawing to ambient temperature and repeated freeze-thaw cycles. This approach supports a practical assessment of how the shell protects the bag assembly during typical cold chain process steps.

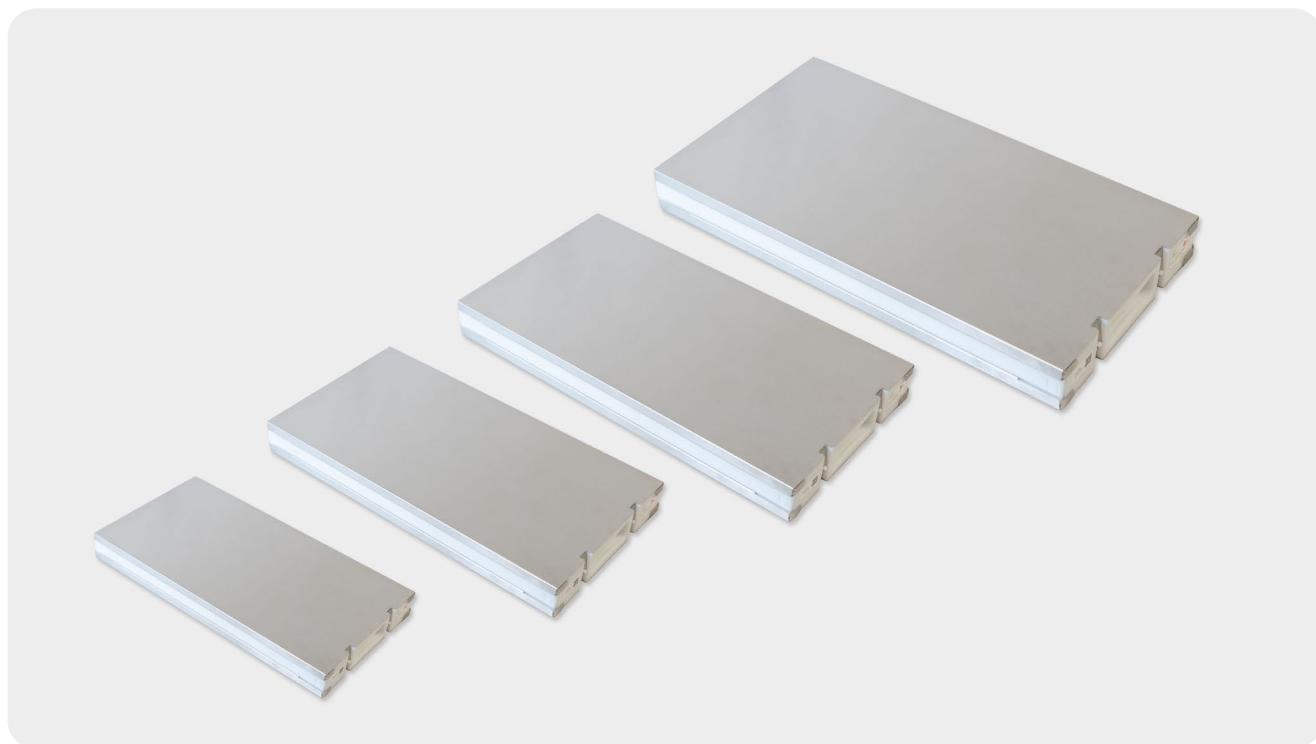
The acceptance criterion was mechanical protection, defined as no damage of bag or tubing. Under the applied test conditions, the evaluated RoSS® shell configuration fulfilled the defined acceptance criterion, with no visible damage of the bag or tubing and no liquid leakage observed after thawing.

### 4. DEDICATED ROSS® SHELL CONFIGURATIONS FOR PROCONNEX® BAGS

The RoSS® shell platform includes dedicated configurations for selected Repligen ProConnex® 2D bag sizes. The evaluated configurations are summarized below.

| Nominal bag volume | Single Use Support article number for RoSS® shell | Repligen article number for ProConnex® 2D bag | Evaluated target freezing volume range* |
|--------------------|---------------------------------------------------|-----------------------------------------------|-----------------------------------------|
| 1 L                | RoSS_1092                                         | FP2B204609                                    | 0.9 – 1.0 L                             |
| 5 L                | RoSS_1091                                         | FP2B204611                                    | 4.3 – 4.6 L                             |
| 10 L               | RoSS_1087                                         | FP2B204165                                    | 8.0 – 8.4 L                             |
| 20 L               | RoSS_1090                                         | FP2B204612                                    | 15.0 – 15.5 L                           |

\* Partial Fill Foams are available for all RoSS® shell configurations, enabling freezing across the entire working volume range from near-empty fill conditions up to the maximum qualified target freezing volume.



**Figure 6:** Dedicated RoSS® shell configurations for multiple ProConnex® 2D bag volumes.

The evaluated shell-bag setup confirmed sufficient space for the bag, tubing, connectors and clamps. The foam inlay supported immobilization and protection of the bag assembly components under the applied test conditions.

Additional technical information on freezing performance and application-specific evaluation can be provided by Single Use Support or Repligen upon request.

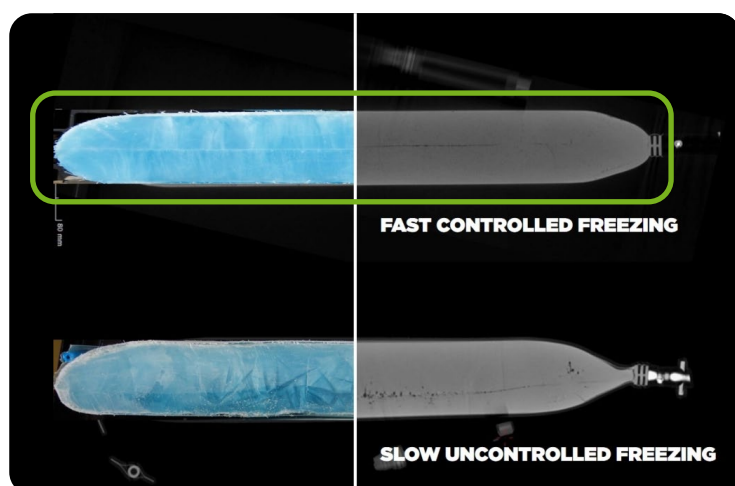
For other bag and shell sizes please contact Single Use Support or Repligen customer support.

Please find contacts on the last page.

## 5. INTEGRATION INTO END-TO-END PROCESSES

The RoSS® shell can be integrated into broader fluid and cold chain management workflows, where it acts as a protective barrier around the single-use bag during critical low-temperature process steps. When used in conjunction with plate-based freezing systems, the stainless-steel top and bottom of the RoSS® shell facilitate direct heat transfer between the shell and the cooling plates.

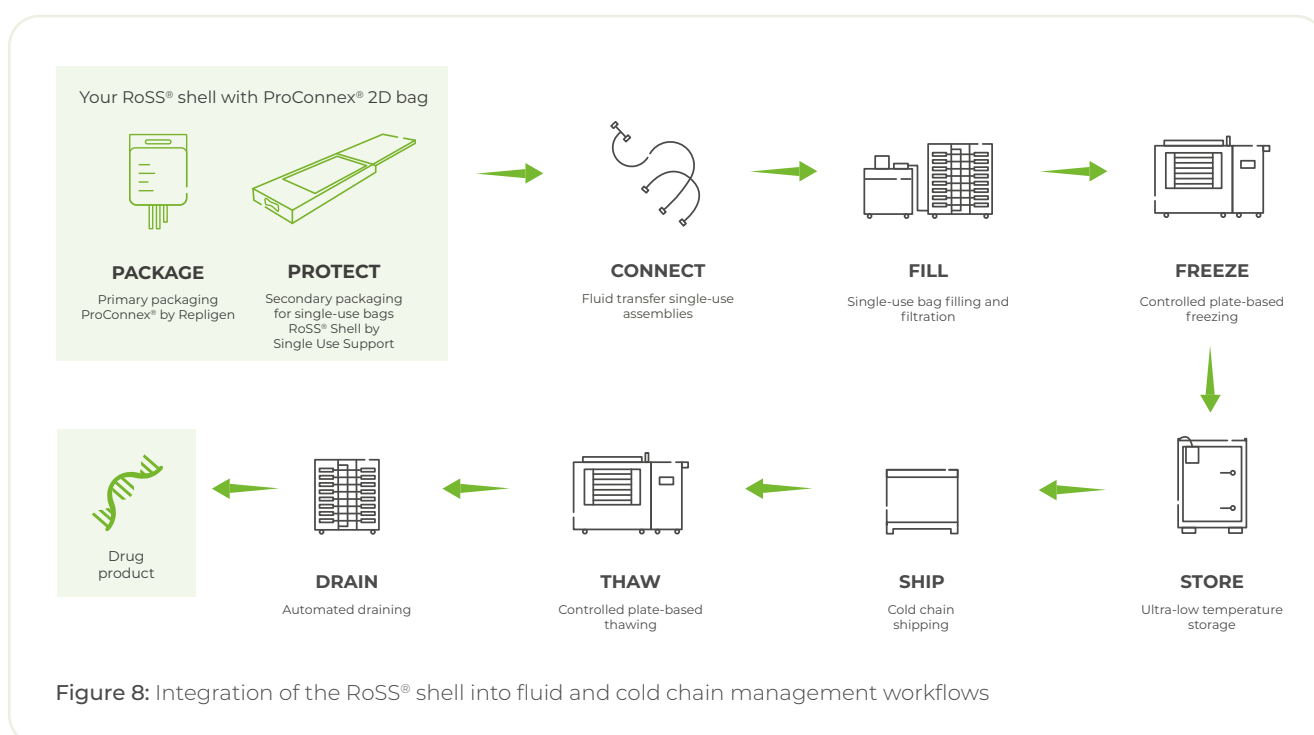
Combined with the geometry of the shell, this supports controlled freezing behavior, stable ice-front growth, and reproducible process conditions when operated within defined parameters (Figure 7).



**Figure 7:** Controlled plate-based freezing compared with uncontrolled freezing behavior

Visualization of cryoconcentration using NaphtholBlueBlack as a tracer dye. Darker blue regions indicate higher local solute concentrations as ice excludes dissolved components. During plate freezing, the bag shows uniform coloration; the thin white line marks the meeting plane of ice fronts from the top and bottom plates, indicating symmetric freezing and minimal solute accumulation. In contrast, static freezing produces darker regions – particularly in the lower area – reflecting strong concentration gradients caused by slower, less controlled solidification.

For ProConnex® 2D bags, this provides established protection that can be integrated into fluid and cold chain management workflows, including filling, freezing, cold storage, shipping, thawing, and draining (Figure 8).



**Figure 8:** Integration of the RoSS® shell into fluid and cold chain management workflows

## CONCLUSION

The RoSS® shell provides superior mechanical protection for Repligen ProConnex® 2D bag assemblies through its robust outer structure, stainless-steel top and bottom, and dedicated foam inlays, supporting defined positioning and immobilization during freezing, frozen storage, transport, and thawing.

Internal low-temperature performance testing further supports the suitability of the evaluated RoSS® shell configuration for mechanical protection under defined conditions. As overall system performance depends on the interaction between the bag, shell, and process conditions, application-specific evaluation is recommended to confirm suitability for individual customer processes.

## CUSTOMER COMMITMENT

Single Use Support and Repligen are dedicated to customer success, providing the expertise and support needed to evaluate, qualify, and implement RoSS® shell solutions with ProConnex® bags for reliable performance throughout the cold chain process.

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