

**SINGLE  
USE  
SUPPORT.** 

PIONEERING BIOPHARMA



# RoSS<sup>®</sup> shell: Robust storage and shipping

The secondary packaging for every single-use bag





# ONE FOR ALL: THE ROSS® SHELL

The RoSS® shell offers a **robust & safe protection for bioprocess containers** of any size and vendor **during freezing, transportation, storage & thawing**.

With more than 300,000+ RoSS® shells sold worldwide, the RoSS® shell provides a tamper-evident system with minimized risk of contamination. The perfect composition for **robust storage & shipping for all 2D single-use bags**.

## THE SETUP FOR BAG PROTECTION

The RoSS® shell is composed of a stainless-steel top and bottom lid, a robust plastic frame, and 3D foam inlays (see Figure 1). These components provide unparalleled advantages in the handling of liquids in single-use bags. The composition of elements that embed the bioprocess containers is simple, easy to recycle, validated for use in a cleanroom environment, and it offers significant cost-efficiency and process flexibility.

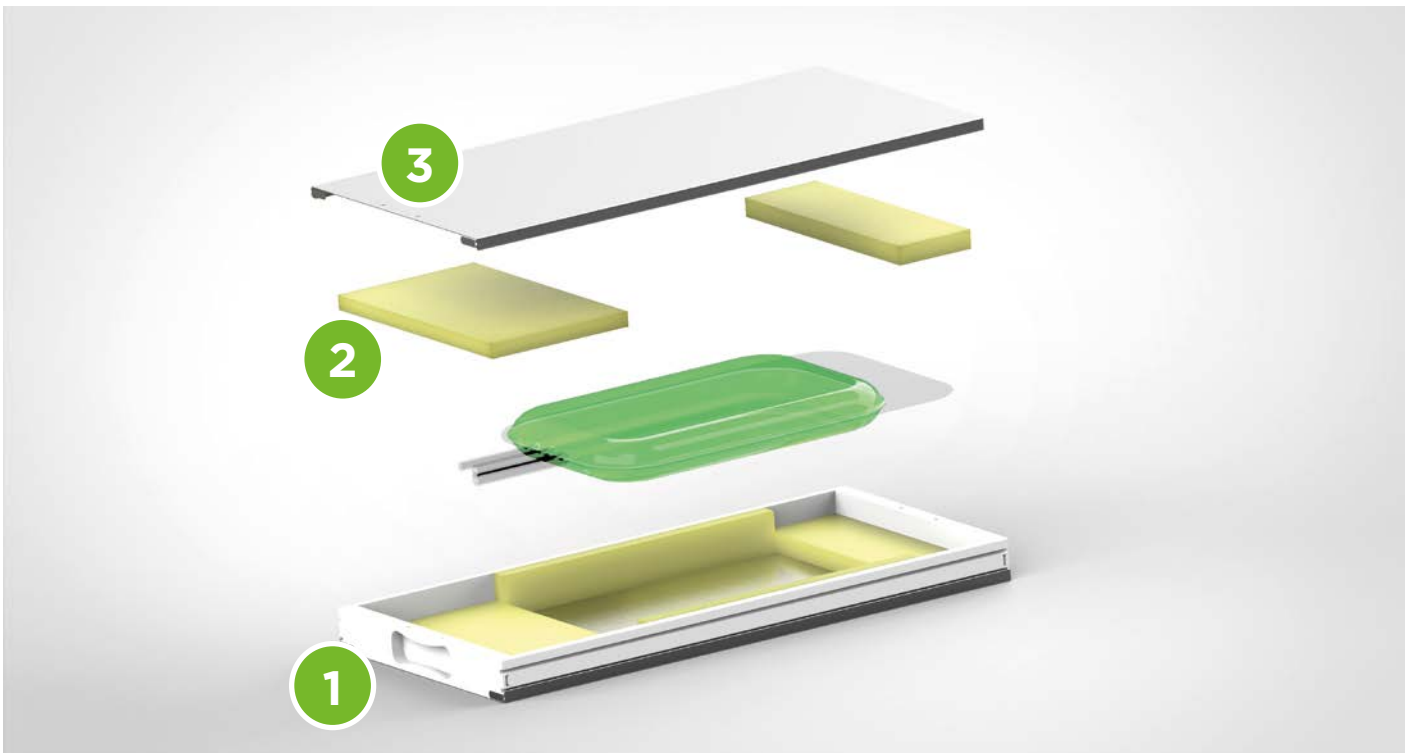


Figure 1: Components of the RoSS® shell

- 1** PE frame → **Provides robustness**
- 2** 3D foam inlays → **Ensures immobilization**
- 3** Stainless-steel lids → **Enables plate freezing**



## VALIDATED ROBUSTNESS

All RoSS® shells manufactured by Single Use Support undergo rigorous testing and validation to ensure robustness in cold chain operations. The aim of the tests is to simulate real-life handling under standardized conditions, thereby verifying the shells' protective ability in cryogenic conditions. **Drop tests** and also **bioburden validation tests** in cleanroom environments are performed to optimize handling of single-use bags.



Figure 2: Single Use Support's in-house production of RoSS® shells

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As a result, the RoSS® shell has been proven to reduce bag rupture down to 0 %<sup>1</sup>. The robustness of this secondary packaging helps to protect frozen single-use bags when frozen down to -80 °C. Its equivalent for smaller bags, RoSS.KSET, is qualified down to -196 °C.

## FULL IMMOBILIZATION OF SINGLE-USE BAGS

While the outer shell is constructed from durable stainless steel and robust plastic elements, the interior is lined with specialized foam inlays that provide additional stabilization.



Figure 3: 3D foam insert ensuring complete immobilization of the single-use bag during freezing, ultra-cold storage and shipping

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The 3D foam offers a protective enclosure for the single-use bag and its assemblies. But it also absorbs the bag's/liquid's expanding energy caused by the density drop during freezing. At sub-zero temperatures, when the bag is already frozen, the foam hardens. The bag is fully immobilized in the hardened foam setup, making it safe to handle during storage and shipping.

## ENABLING PLATE FREEZING

The RoSS® shell enables plate-based freezing of single-use bags, which is an advanced method for cooling biologics. The stainless-steel lid enables direct, conductive freezing and thawing which ensures an efficient heat transfer between the bag and the cooling plates. **Controlled freezing from the top and bottom allows for uniform freezing** of the RoSS® shell, with a defined ice-front growth rate that minimizes the effects of cryoconcentration.



Figure 4: Frozen RoSS® shells in Single Use Support's plate freezer RoSS.pFTU Large Scale

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# ONE SHELL TO ADVANCE COLD CHAIN MANAGEMENT

Manufacturers and CDMOs can greatly benefit from using a robust secondary packaging: Robustness, full immobilization of the single-use bag and the option to perform plate-based freezing are prerequisites to equip the pharmaceutical industry to handle liquids more effectively.

The RoSS® shell provides unprecedented advantages for biomanufacturers, such as

- **Minimized product loss**
- **Maximized product integrity**
- **Free choice of type of single-use bag**
- **Limitless scalability**
- **Integration in end-to-end process**



Figure 5: RoSS® shells significantly reduce product loss when handling single-use bags in biopharmaceutical processes



## MINIMIZED PRODUCT LOSS

One of the biggest challenges faced by biotech companies is the high product loss rate, ranging from 0.5 % to 5 %, when handling single-use bags.<sup>1</sup> This loss rate is dependent on various factors, including the sensitivity of the bag at sub-zero temperatures, the type of bag used, the protection of the bag during the cold chain process, the freezing-thawing and storage process and the shipper/shipping route.

By implementing the RoSS® shell as a robust secondary packaging solution in manufacturing and logistics suites, the risk of leakage and breakage of single-use bags and assemblies can be reduced significantly. In fact, a case study demonstrated that it reduced product loss to 0 %. The results showed that minimizing product loss from 2.5 % to 0 % can result in savings of approximately \$ 700,000 per batch.<sup>1</sup>

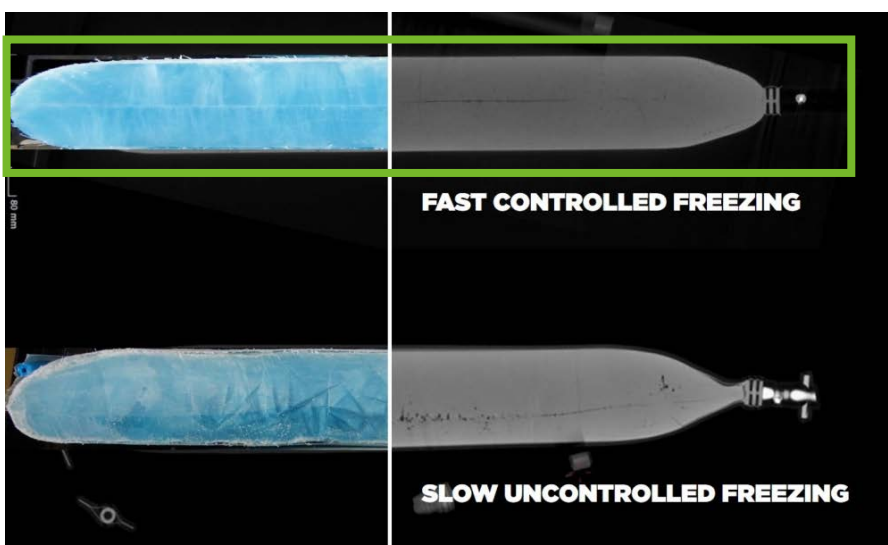


Figure 6: Case study results demonstrate that the RoSS® shell reduced product loss to 0%

## MAXIMIZED PRODUCT STABILITY

The RoSS® shell enables for advanced plate-based freezing of single-use bags with direct cold exposure between the cooling plates and the single-use bag. This allows for accelerated freezing and controlled ice front growth from the bottom and top, ultimately providing homogeneous freezing results that are game-changing for the industry.

The enhanced level of control over freezing and direct surface contact maximizes the integrity of cells, proteins and other APIs. The freezing rate for each product is adjusted based on its characteristics. Cells can now be frozen at a recommended freezing rate of -1 °C to -4 °C/min leading to maximum cell survival after cold chain storage and shipping.<sup>2</sup> This level of control over the freezing process can be applied to any API.



*Visualization of cryoconcentration using Naphthol Blue Black 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.*

Figure 7: Results of controlled and uncontrolled freezing of single-use bags



## VENDOR-AGNOSTIC PROTECTION

Various single-use bags are utilized for transferring liquids during bioprocessing. These bags vary in their film, form, structure, ports and other features, and are selected based on the content's behavior. It is important to consider that when choosing a single-use bioprocess container; CDMOs may become limited to a specific ecosystem of solutions, which may restrict access to other solution providers.



Figure 8: The RoSS® shell is suitable for all available single-use bags, including Lab-tainer® from ThermoFisher, Mobius® from Merck/Millipore, Allegro™ bags and more. Allegro™ is a registered trademark of Cytiva.

The RoSS® shell provides a solution to the inflexibility of specific 2D bioprocess containers from certain manufacturers and sizes.

**It can be used with all available 2D bioprocess containers**, making it a vendor-independent protective shell that unifies the cold chain logistics process.

By using bag-independent process solutions, CDMOs can reduce their costs for cold chain logistics utilizing single-use bags by up to 60 % and significantly improve fluid and cold chain storage and shipping processes.<sup>3</sup>

## LIMITLESS SCALABILITY

In biomanufacturing, the volumes handled can range from 1 mL to 1000 L+ per batch. The RoSS® shell is available for 2D single-use bags up to 50 L. For bags of 250 mL and below, the RoSS.KSET is the appropriate solution as a protective shell.

Scale-up and scale-out are both approaches to increase manufacturing volumes throughout commercialization. Scale-out involves increasing the quantity of same-sized single-use bags, while scale-up involves changing to larger single-use bags.

When scaling up production, one of the biggest challenges in freezing is ensuring consistent and reproducible stress on drug substances across all scales, filling volumes, and loading scenarios. Single Use Support addresses this challenge by standardizing the ice front growth speed for all possible scenarios, regardless of the filling volume, bag type, or freezing platform size<sup>4</sup>.



Figure 9: The RoSS® shell is available in sizes up to 50L

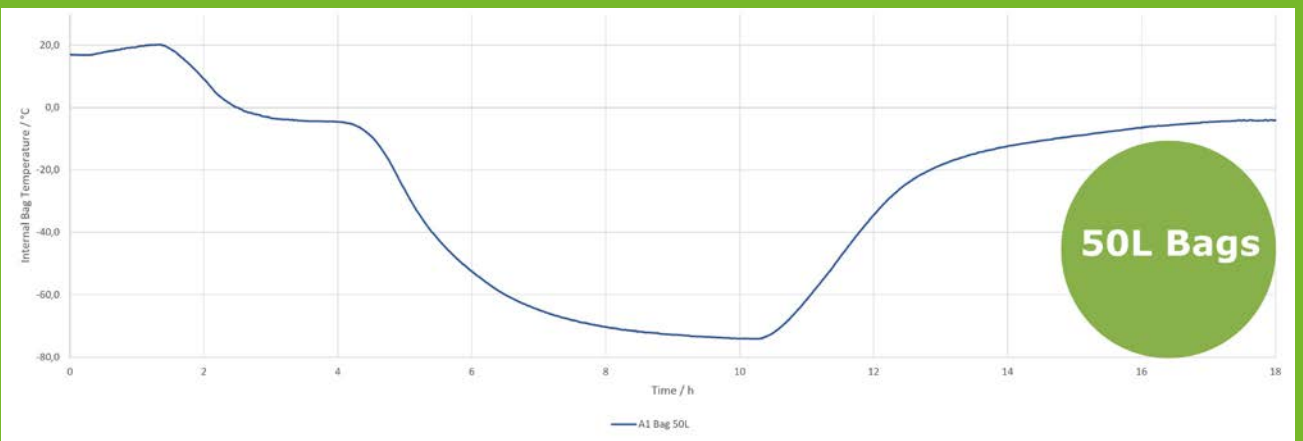
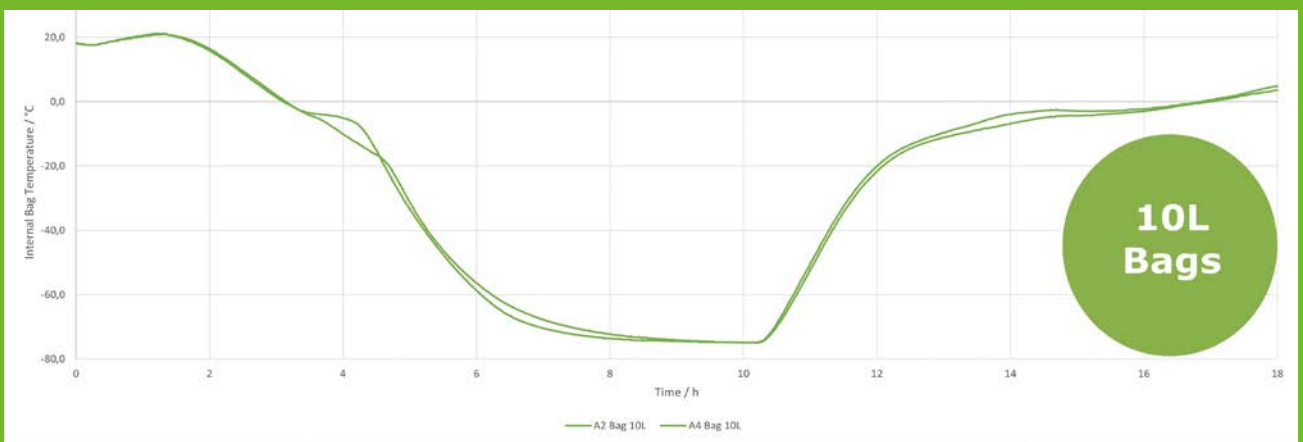
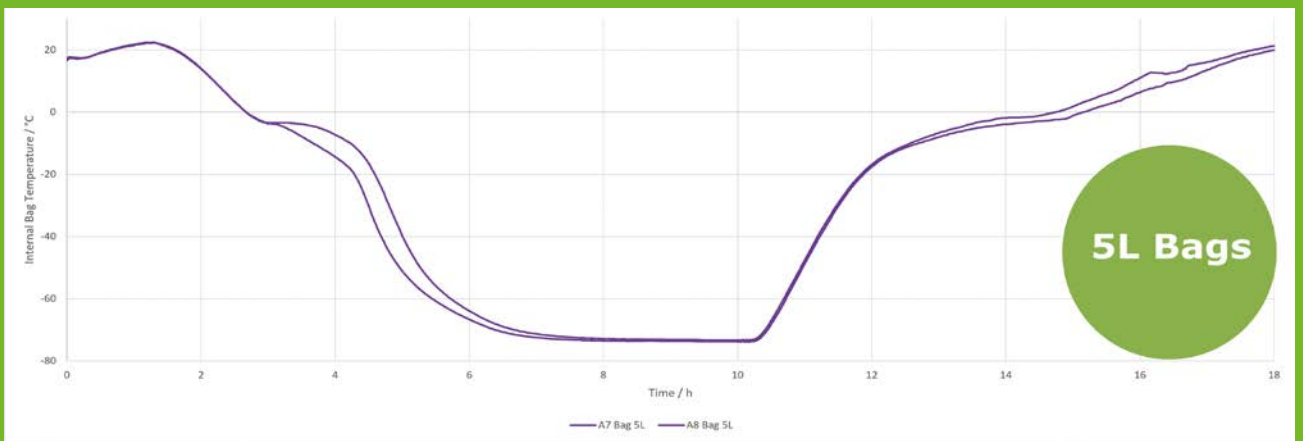
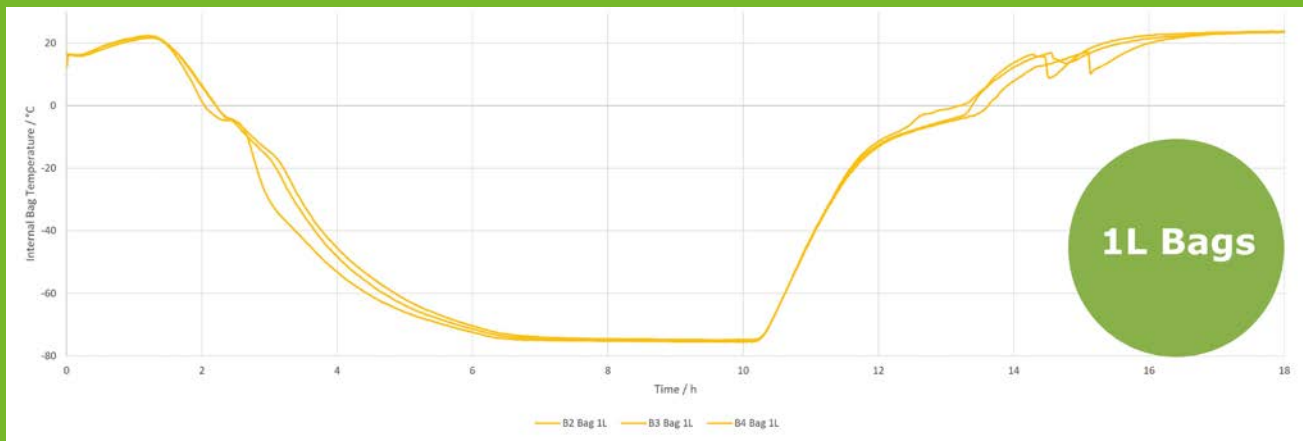


Figure 10: Scalable freezing with single-use bags from 1 L to 50 L



## ADD-ONS FOR OPERATIONAL WORKFLOWS

Beyond robustness, immobilization, and scalability, the RoSS® shell ecosystem is complemented by accessories that further enhance protection, usability, and process control. These little extras bring big relief for operational workflows:

**Extra safe:** Tamper-evident solutions provide visible protection where process security is critical. **Adhesive seals** clearly indicate unauthorized opening, while mechanical options such as **cable ties** or **steel wires** secure lids or front panel eyelets, supporting rapid detection and investigation of any deviations.



Figure 11: Tamper-evident seal

**Extra adaptable:** For partially filled bags, dedicated **partial-fill foams** compensate for unused volume within the shell and ensure defined contact with the stainless-steel lid, maintaining reproducible freezing performance. **Cryo Control Units** further stabilize the system, in blast or static freezers, by minimizing bulging effects caused by volume expansion during freezing.



Figure 12: Cryo Control Unit

**Extra smart:** Sampling and monitoring options extend the RoSS® shell's functionality throughout the cold chain. **Sample bags** and **vial inlays** enable secure freezing and transport of reference or QC material alongside the primary bag, while **data loggers** support continuous monitoring of temperature and handling conditions.



Figure 13: Sample vial inlays in panel

**Extra efficient:** **Handle tools**, **tubing guides**, and **labeling options** simplify handling, protect assemblies, and ensure clear identification across all packaging levels.



Figure 14: Tubing guide inside RoSS® shell

These extras enable biomanufacturers to adapt the RoSS® shell to specific operational and regulatory requirements for 2D single-use bags and vials throughout the cold chain.



Figure 15: RoSS® shell with vial inlays



## INTEGRATION IN END-TO-END PROCESS

Functionally isolated platform systems were identified as the biggest cost drivers. Limited process flexibility, inhibited process flows, and slowed speed-to-market all result from the lack of compatibility of single-use bags and the lack of interconnectedness among different platform systems from multiple suppliers.

With the RoSS® shell serving as a tamper-evident centerpiece for liquid transfer of biologics, customers can freely select any 2D single-use bag as well as compatible single-use technologies to establish an end-to-end process that supports aseptic fluid handling and cold chain management in an automated and controlled manner.

Designed for responsible end-of-life handling, the RoSS® shell is made of up to 95% fully recyclable materials, including stainless steel and HDPE components that can be efficiently separated and recycled. This approach supports sustainable bioprocessing without compromising product integrity, process reliability, or regulatory compliance.

Single Use Support’s modular process solutions embrace all types and sizes of single-use containers, unifying the bioprocess containers and standardizing the process steps in biomanufacturing throughout aseptic aliquoting, controlled freezing and thawing, and ultra-cold storage and shipping.

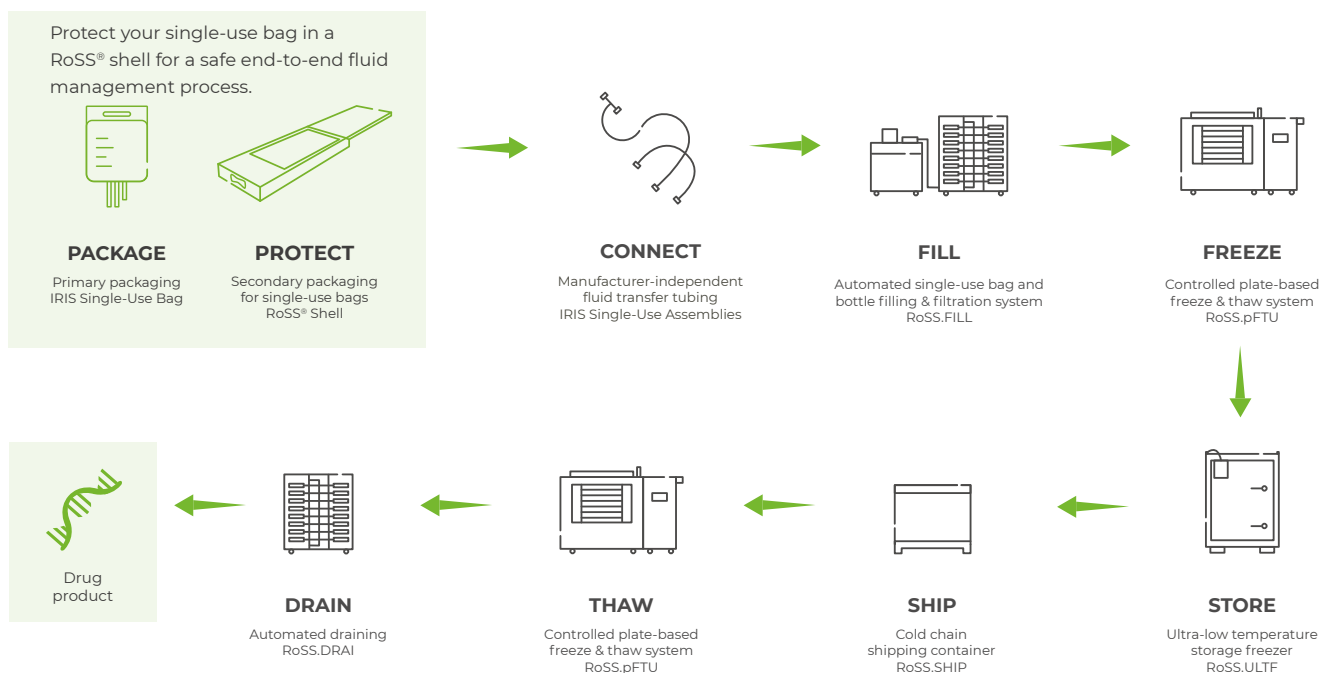


Figure 16: Single Use Support’s fluid and cold chain management process for single-use bags

## References

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