SINGLE USE SUPPORT.

PIONEERING BIOPHARMA

ADVANCED FLUID & COLD CHAIN MANAGEMENT FOR BULK DRUG SUBSTANCES

Protect | Connect | Fill-Filtration
Freeze-Thaw | Store | Ship

www.susupport.com

CONTENT

THE ONE PROCESS SOLUTION FOR BULK DRUG SUBSTANCES.

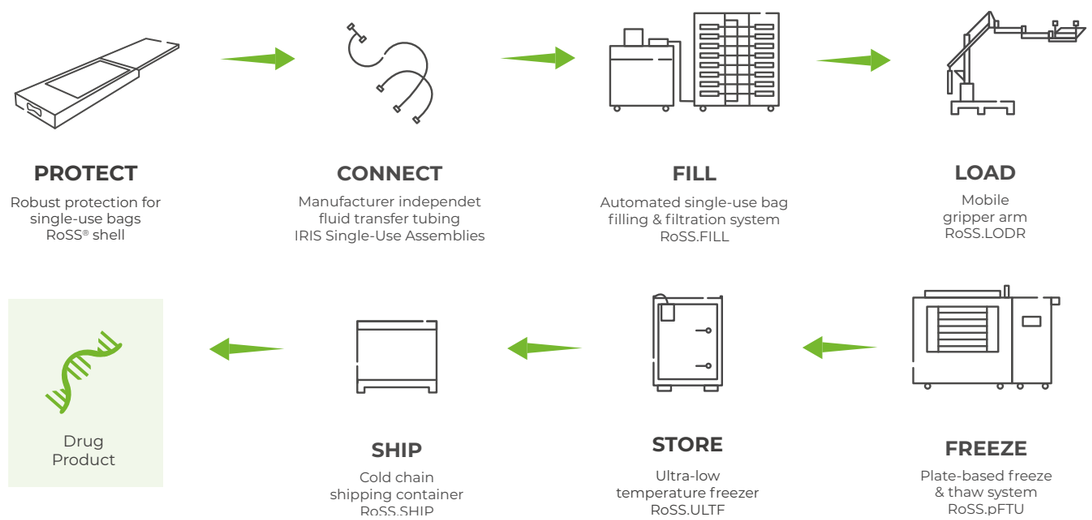
Flexible. Secure. Trusted. Simple.

Single Use Support has revolutionized the management of drug substances at sub-zero temperatures. The end-to-end process solution provider closes the gap between biopharmaceutical production interfaces, such as upstream, downstream bioprocessing and fill-finish, giving biopharma companies access to a new and **100% secure end-to-end logistics process** for liquids.

The single-use technologies based on RoSS® are a combination of integrated platform systems, sterile consumables and auxiliary services to achieve process excellence in commercial GMP handling of up to 500L of bulk drug substances or more per batch.

See all technologies and areas of application on **www.susupport.com**

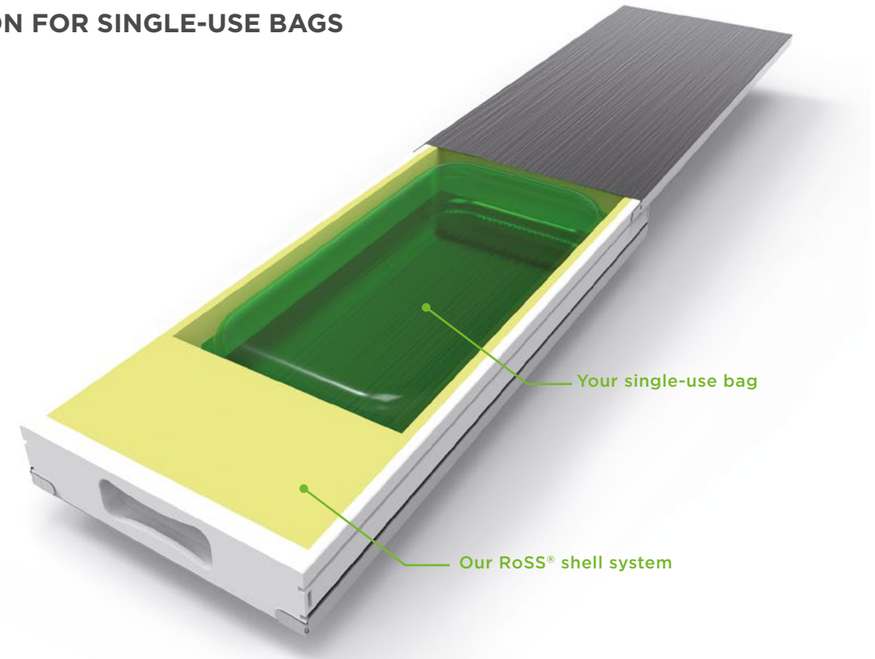
Let‘s create your end-to-end process for bulk drug substances



Fluid management & cold chain handling for bottles:
Integrated and vendor-independent fill-filtration & freeze-thaw platforms also for usage with single-use PE bottles. Contact us for more information.

RoSS® Shell

PROTECTION FOR SINGLE-USE BAGS



More than 300,000 RoSS® shells shipped worldwide and <0.001 % product loss.

The right material in the right place – what we can learn from oysters.

Well protected & tamper-evident!

The validated RoSS® shell is a robust & safe protection for bioprocess containers during freezing, transportation, storage & thawing. It is a tamper-proof and contamination-free system, which can be used with all available 2D bioprocess containers, making it a vendor-independent protective shell that unifies the cold chain logistics process.

While the exterior of the shell is constructed from durable stainless steel and robust plastic elements, the interior is lined with specialized foam inlays that provide stabilization for the single-use bag and its attachments. The foam 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.

PROTECT & FREEZE YOUR BULK DRUG SUBSTANCE:

- Bag-independent
- < 0.001 % product loss
- Best freezing results

"Full immobilization of the frozen single-use bag guarantees that the bag, the tubing and all the bag accessories are immobile, preventing ruptures and breakages."

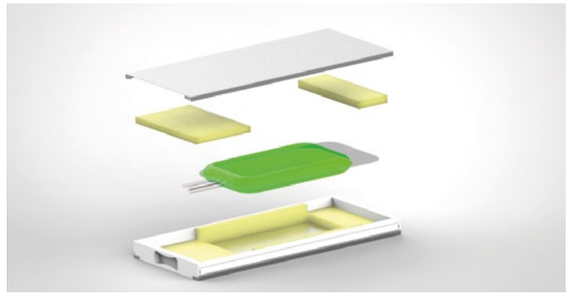
Johannes Kirchmair, Co-Founder

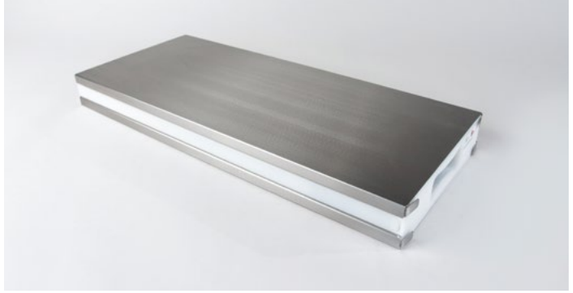
The **RoSS®** top and bottom are made of **high-quality stainless steel** that comes with the following unique features:

1. Maximum durability and strength.
2. In direct contact with the bag the stainless steel offers the ideal basis for an effective initial and ongoing **freezing process**. Furthermore, it enables a consistent and gentle **defrosting or thawing process**.
3. Thanks to the right compounds, tolerances and material strengths of the stainless-steel top and bottom, the **RoSS®** shell construction only allows for minimal vibration. It also reduces the tension in the structure of the **single-use bag** and offers **shock absorbent protection**.

Facts:

- Unique functionality and patented system
- Adjustable for all 2D single-use bioprocess containers
- Exterior: Robust, closed and tamper-proof construction
- Interior: 3D cryo foam-inlays for complete immobilization of the sensitive bag and its attachments
- Stainless-steel lids on the top and bottom for consistent and best possible freezing and defrosting performance (optimized cold and heat transfer)
- High storage density during freezing, storage and transportation
- Easy handling during the recycling process





IRIS Single-Use Assemblies

FLUID TRANSFER TUBING

Single-Use Support's **IRIS Single-Use Assemblies** are designed to optimize fluid transfer throughout the entire biopharmaceutical manufacturing process, from upstream to downstream and fill-finish.

Produced in ISO 7 cleanrooms, our assemblies ensure highest quality and GMP-compliance. Additionally, we offer the freedom to choose from a diverse range of manufacturers for each assembly component. From tubing and connectors to filters and primary packaging, our solutions provide quality, reliability and flexibility, without being constrained to a single supplier's ecosystem.

Facts:

- Highest quality standards in ISO 7 cleanrooms
- Manufacturer-independent use of components
- Experienced application engineers provide best-possible support
- Sterilization in compliance with international biopharmaceutical standards
- Lead times of no more than to 8-10 weeks depending on complexity
- Easy to install on our RoSS.FILL platforms and any desired system at your facility
- Transport validation according to ASTM 4169-16

CONNECT & FILTER WITH IRIS SINGLE-USE MANIFOLD

- 100% customizable
- Dual sourcing program
- GMP-compliant solutions

RoSS.FILL

ASEPTIC FILLING & FILTRATION

RoSS.FILL is a flexible platform for **bulk filtration and dispensing** drug substances into single-use bags.

A fully automated filling and filtration system **for 2D single-use bags from 1L up to 1000L**. Its unlimited scalability, highest throughput and modularity allow maximum process flexibility and efficiency for all higher volume applications with larger volumes, such as fermentation, mRNA, mAbs and more.

Facts:

- Fully automated filling system for single-use bags
- Flexible set-up to optionally attach multiple racks
- Ease of use in operation / recipe driven processing
- Modular system with separate control unit and pumping station
  as well as storage rack made up of RoSS trays
- Bag & connector agnostic set-up
- Suitable for cleanroom and based on international biopharmaceutical standards
- Option to take samples

FILL & FILTER YOUR DRUG SUBSTANCE

- Up to 1000L+/batch
- Highest accuracy
- Fast throughput

Product overview: Filling & filtration bulk drug substances (up to 1000L)

RoSS.FILL Bag is a fully automated single-use bag filling machine for dispensing biopharmaceuticals **from 1L up to 20L**. The fluid path is designed to be fully disposable and is able to accommodate a variety of sterile connection and disconnection options.

RoSS.FILL Base allows to **fill several 2D single-use bags up to 500L** and is therefore most suitable for commercial bulk filling usage. The option to attach a 3D single-use bag makes it possible to fill one batch of up to 1000L.

RoSS.pFTU

CONTROLLED FREEZING & THAWING

All Single Use Support freeze-thaw platforms offer insular solutions for the freeze/thaw processes of each clinical phase.

They are compatible with single-use bags of all established bag manufacturers, sizes and capacities and add flexibility with the option to freeze vials, bottles and single-use bags. While maintaining highest safety standards and proven product stability during safe and controlled freezing of high-value biopharmaceuticals, they offer unrestricted scalability: From 1mL up to 50L bags and a batch size of up to 500L.

Facts:

- Controlled freezing down to -90°C/-130°F
- Easy recipe-driven operation
- For single-use bags, bottles and vials
- At highest possible speed & accuracy
- For best product stability results
- Scalable from lab to blockbuster production

FREEZE & THAW YOUR DRUG SUBSTANCE

- Up to 1000L+/batch
- Highest accuracy
- Fast throughput

Comparison slow (A) vs. fast freezing (B): Increased cryoconcentration at slow freezing

The most fundamental concern when designing freeze/thaw procedures is the phenomenon of cryoconcentration. During the freezing process, the ice formation excludes solutes (including protein) from the growing ice crystal.

The picture at the top (A) illustrates cryoconcentration generated by slow freezing from all sides in a static freezer. The highest concentration is evident in the bag's center at the last point of freeze. This leads to pH shifts and potential denaturation of the protein.

The picture at the bottom (B) shows that the ice front is growing from top and bottom simultaneously and relatively quickly to meet at the bag's central horizontal line. Due to the speed of freezing, cryoconcentration is very slow and the protein's distribution in the frozen solution is very homogeneous.

(A) UNCONTROLLED
"slow freezing"
dark blue region visible at the bottom center

(B) CONTROLLED
"fast freezing"
more uniform coloring

RoSS.LODR

MOBILE GRIPPER ARM FOR ERGONOMIC WORKING

RoSS.LODR is a mobile gripper arm that ensures ergonomic handling of the RoSS® shell for any loading or unloading activity, be it from the RoSS.FILL to RoSS.RACK or RoSS.RACK to RoSS.pFTU.

The innovative supporting device for enhanced transportation of heavy loads facilitates a safe working environment and can significantly reduce work-related repetitive strain injuries.

Facts:

- Improve ergonomics, health and safety when handling single-use bags up to 50L
- Customized shovel compatible with various secondary packaging options, including RoSS® Shell and bottles
- Rotatable and lockable shovel with 8 positions for versatile handling
- Soft-start functionality for smooth and secure operation
- Hold-to-run control mechanism for precise user management
- Integrated safety clutch for added protection

RoSS.ULTF

ULTRA-LOW TEMPERATURE STORAGE FREEZER

RoSS.ULTF is an upright ultra-low storage solution for frozen drug substances. The system keeps the desired set point temperature as low as -80°C (-112°F).

The platform enables modular and easy-to-install cold room storage capacity that smartly fills a gap for the biopharmaceutical industry between small-scale low storage density lab freezers and large but expensive walk-in freezers. It offers full temperature control thanks to reliable air temperature conformity and a highly modular interior that can be equipped with shelving systems to store all available single-use bags, bottles or other primary packaging.

ULTRA-LOW STORAGE FOR FROZEN LIQUIDS

- Down to -80°C/-112°F
- Capacity for up to 300L
- Modular interior

Facts:

- Insulated container for long-term cooling of frozen drug substances
- Continuous setpoints between -20°C and -80°C (-4°F to -112°F)
- High storage density and stackability of RoSS® shells
- Customized interior with shelf systems, drawer systems or trolleys
- GMP-compliant alarm management
- Customized connections to MES
- Full stainless steel AISI 316 interieur/exterieur
- Flexible storage location

RoSS.SHIP

COLD CHAIN SHIPPING

RoSS.SHIP is a cold chain transport container for shipment of frozen 2D bioprocess containers placed within RoSS® shells. Frozen drug substances can be stored and shipped in a protected manner and in compliance with international standards. Available in single-use and multi-use, the statically, highly robust RoSS.SHIP container is designed for passive cooling with dry ice.

Optionally, the geographical location as well as the RoSS.SHIP container's inside temperature can be tracked and monitored 24/7.

Facts:

- Insulated shipping containers for passive cooling processes
- Validation based on ISTA 7D 144h summer / ASTM / D4169
- Optional temperature- / GPS- / G-Force-tracking / UV air pressure
- Adjustable to any requirements and batch sizes
- Suitable for phase change materials and dry ice
- Single-use or multi-use