SINGLE USE SUPPORT.

PIONEERING BIOPHARMA

ADVANCED FLUID & COLD CHAIN MANAGEMENT FOR SMALL VOLUMES

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

www.susupport.com

CONTENT

THE ONE PROCESS SOLUTION FOR SMALL VOLUMES.

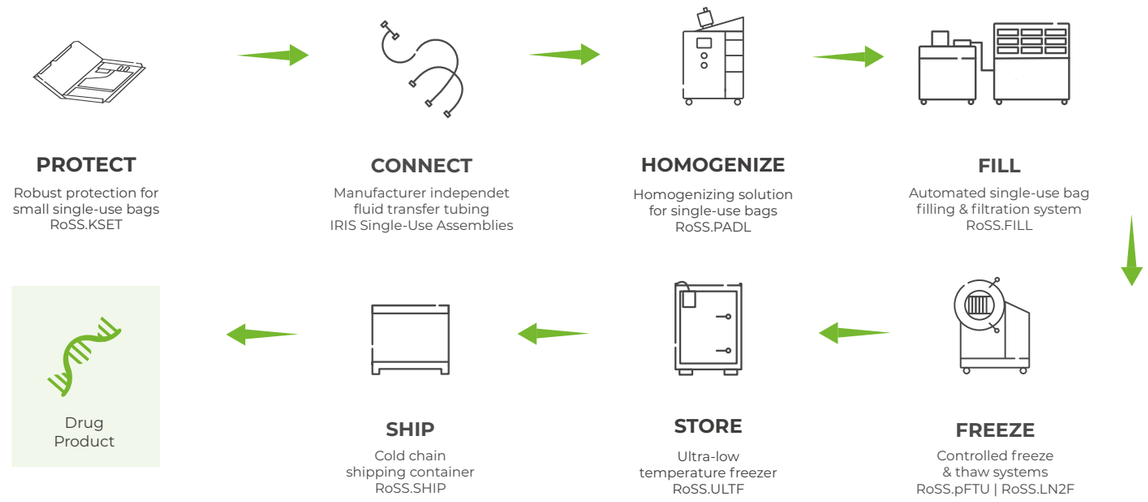
Accurate. Flexible. Secure. Trusted.

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.

Our single-use technologies and sterile consumables come with the flexibility required for fast turnaround times in advanced therapeutic approches & the handling of small volumes down to 1mL. This includes the areas of aliquotation & filtration, controlled freezing & thawing and all required logistic steps.

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

Let‘s create your end-to-end process for small volumes



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

RoSS.KSET

PROTECTION FOR SMALL SINGLE-USE BAGS

The tried-and-tested **RoSS.KSET** is the ideal secondary packaging for for single-use bags with volumes **less than 250 mL in cell and gene therapy or clinical studies**.

The shell is made of **high-density stainless steel** and can be locked and tamper-evidence sealed. This guarantees absolute protection against manipulation as well as intuitive handling at the same time.

In RoSS.KSET, single use bags are covered with one layer of soft 3D foam. This offers protection and dampens shocks. Furthermore it allows for an expansion of the liquid volume and the bag in the freezing process and immobilizes the frozen bag in the hardened foam.

PROTECT & FREEZE YOUR BULK DRUG SUBSTANCE:

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

Facts:

- Suitable for any 2D single-use bag less than 250mL
- Stainless steel for maximum durability and strength
- Fast and uniform freezing down to -196°C/-320°F
- 3D foam for immobilization of the bag and its assemblies
- Sealable locking system for tamper-evidence

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.

CONNECT & FILTER WITH IRIS SINGLE-USE MANIFOLD

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

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

RoSS.PADL

HOMOGENIZING SOLUTION

RoSS.PADL is used for homogenizing liquids during aliquotation. 2D single-use bags from any manufacturer and in sizes ranging from 500mL to 20L are kneaded by an automated mechanism to ensure the homogeneity of the liquids inside the bioprocess container. The cooling/ heating mechanism ensures maintenance of the correct temperature.

Where normally an operator would massage the bag, this process can be automated to increase process efficiency and reduce the risk of inconstistent product quality. The omission of human intervention enables a scalable process for one or more bioprocess containers in parallel and the reduced risk of human error in bag handling.

Facts:

- Standalone or controllable via RoSS.FILL HMI
- Suitable for all 2D single-use bags of up to 20L
- Integrated cooling and heating function
- Automated stroke depth depending on the bag
- Adjustable stroke frequency (30 to 60 strokes/minute)
- Suitable for cleanroom and GMP-compliant construction

COOL & GENTLE HOMOGENIZATION

- Bag-independent
- Consistent homogeneity
- Temperature control

RoSS.FILL

ASEPTIC FILLING & FILTRATION

RoSS.FILL is a fully **automated filling system**, specially designed for the use in cell & gene therapies with batch sizes at low volumes.

The platform allows to fill serveral small single-use bags **from 1mL to 1000mL** and is therefore most suitable for early-stage research and development of cell therapies, viral vectors, pDNA, and more.

Facts:

- Most accurate filling technology for highly precise filling
- Flexible set-up to optionally attach multiple racks
- Integrated sealer pinch valves for fluid control and aseptic decoupling
- Ease of use in operation / recipe driven processing
- 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 72L+/batch
- Highest accuracy
- Fast throughput

Product overview: Filling & filtration small volumes (1mL-1000mL)

RoSS.FILL Lab Scale is an automated filling platform at smallest footprint with state-of-the-art technology for highest accuracy to fill **up to 12 single-use bags** in standard configuration.

RoSS.FILL CGT is an automated cell and gene filling machine system for aseptic filling of **up to 36+ single-use bags** with one rack. Special designed for use in cell & gene therapies with batch sizes at low volumes.

RoSS.pFTU

PLATE-BASED FREEZING & THAWING

The **RoSS.pFTU** is an **automated plate-based freeze-thaw unit** for small batches in biomanufacturing, like cell banking, gene therapies utilizing viral vectors, lipid nanoparticles, and fill & finish procedures.

It enables the freezing and thawing of different individual volumes of drug substance **from 1mL up to 100L** with ease. Based on plates, the freezing and thawing is controlled, rapid and homogeneous.

The system is fully scalable and compatible with all batch sizes and bags from all established manufacturers.

Facts:

- Fully automated & controlled
- At highest possible speed & accuracy
- Capacity of up to 100L load with different sizes of single-use bags
- Usage for stability studies in labs & small batch sizes
- Single-use bag independent: any bag vendor, any size
- Best product stability results for mABs and BDS
- GMP-compliant, automated, at highest possible speed and accuracy

STATIC FREEZER
“slow freezing”
dark blue region visible at the bottom center

PLATE FREEZER
“fast freezing”
more uniform coloring

The picture at the top 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 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.

Product overview: Freezing & thawing small volumes (1mL-100L)

RoSS.pFTU Lab Scale is the perfect solution for clinical studies conducted in labs and, above all, if you want to start a controlled, cGMP-compliant and scalable freezing process **for small batches up to 10L**.

RoSS.pFTU Mid Scale is designed for aboratory work and lower volume freezing of AAVs, as it can be used to freeze small single-use bags (volumes less than 250mL) as well as several large single-use bags **up to 20L**.

RoSS.LN2F

CRYOGENIC CONTROLLED-RATE FREEZER

RoSS.LN2F is a powerful cryogenic controlled-rate freezer for temperatures as low as -170°C/-274°F.

It is an enclosed system that uses fast chamber cooling and continuous LN2 injection for adjustable cooling rates, enhancing cell viability and recovery. Fully scalable, the system operates with high speed and accuracy, ensuring optimal product stability.

Facts:

- Freeze your drug substance of high value in any single-use bioprocess container*
- Fully automated & controlled
- Fully scalable
- Any freeze recipe of your choice
- For best product stability results

** protected by RoSS.KSET and designed to your preferred bag*

CRYOGENIC CONTROLLED-RATE FREEZING

- Increased cell viability
- Down to -170°C/-274°F
- Down to < 250mL/bag

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