

SINGLE USE SUPPORT.

NEXT LEVEL. SCALABLE. NOW.



BULK.STREAM

The next level of drug
substance logistic

www.susupport.com

Better support for the pharma industry.

SUSupport (Single Use Support) was founded in 2015 by Johannes Kirchmair and Thomas Wurm. The headquarters are located in Kufstein/Austria and we are expanding globally at a rapid pace. You can find all subsidiaries incl. contact details on www.susupport.com

“On the basis of **single use bags**, we offer biopharma companies access to a new and 100% secure logistics process for liquids,” as Johannes Kirchmair and Thomas Wurm state.

“The technologies developed by us increase patient safety and minimize the risk of bio-contamination and product loss towards 0%.”

By using the **SUSupport** technology, **MORE** high-quality substance can be shipped internationally in a **FASTER** and **ABSOLUTELY SECURE** manner, and at a **LOWER** loading volume.

SUSupport calls this new process **BULK.STREAM®**.

SUSupport is based in Kufstein, Austria. Here, at the global headquarters, new products are developed in cooperation with international pharmaceutical companies.



We are assessed and certified as compliant with the requirements of **ISO 9001:2015**.



Scalable end-to-end solutions.

For single use bags of any size and manufacturer.

Our Mission

“We founded our company to increase patient safety by optimizing single-use technology in biopharma at the highest technological level!”

Our Vision

“We are creating a globally active company that is a technology leader in the field of liquid logistics for pharmaceutical applications, pushing the quality of life and human health to an ever-higher level worldwide.”





NEXT LEVEL. SCALABLE. NOW.

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BULK.STREAM®
The next Level of Drug Substance Logistics!

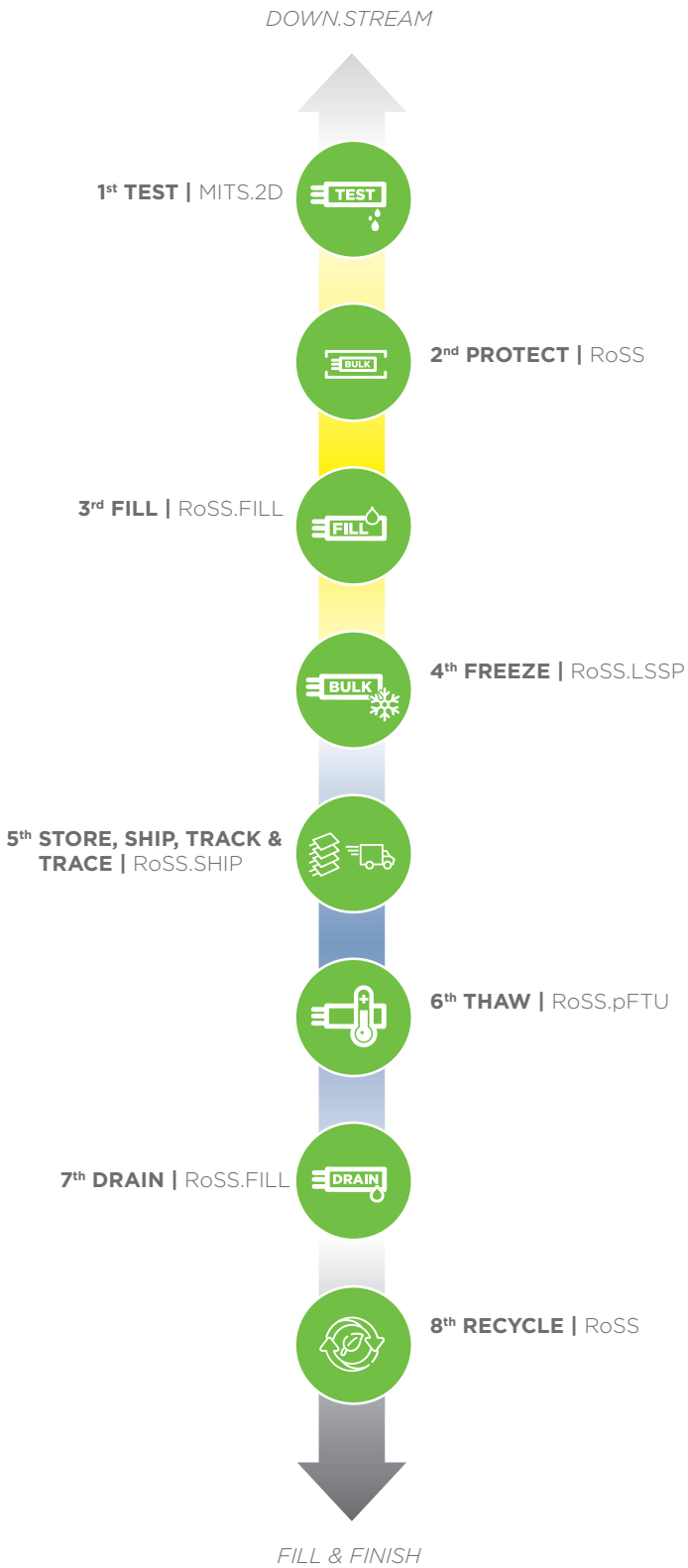
We close the gap between downstream and the fill & finish process in the biopharma industry.

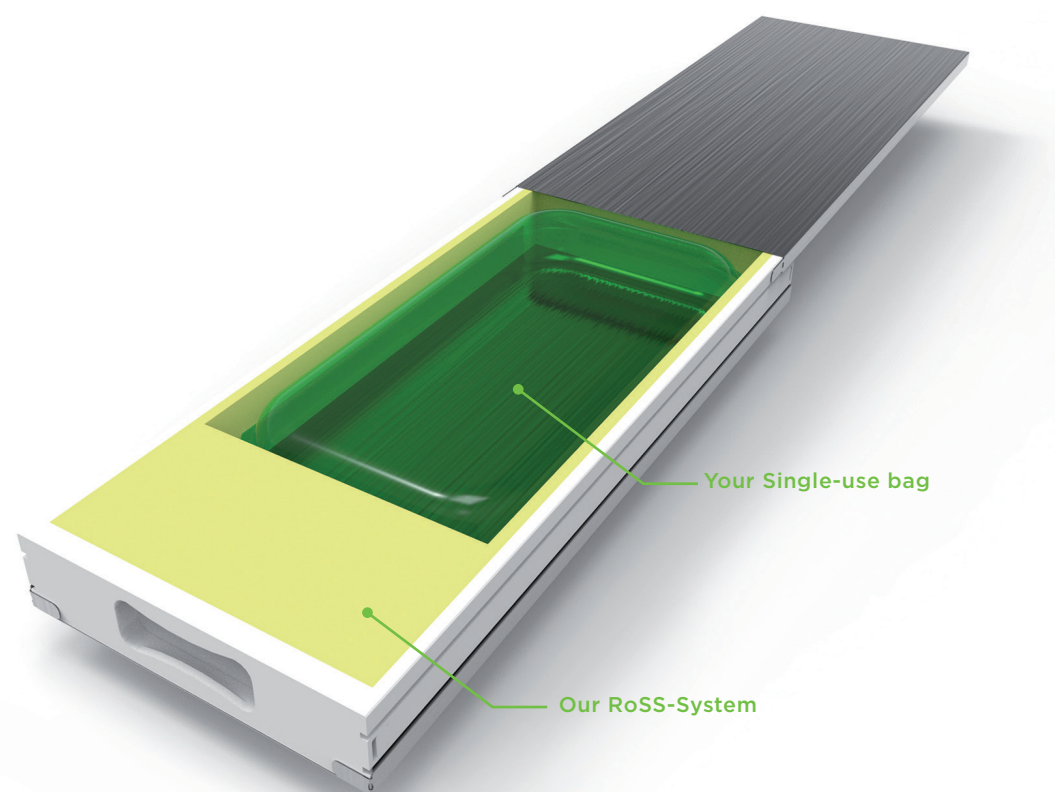
On the basis of **single use bags**, we offer biopharma companies access to a new and almost **100% secure logistics process for liquids**.

The technologies developed by us increase patient safety and minimize the risk of bio-contamination and **product loss towards 0%**.

We are able to store and ship high-quality substances in a faster and more secure manner, and at a lower loading volume than to date. We build upon standards, eliminate material deficiencies, and minimize human errors.

We call this, our new development, **BULK.STREAM®**.





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

Well protected & tamper evident!

The tried-and-tested single use bag gets its **100% secure** and compact shell. In the **first place**, the single use bag will be covered by soft **3D foam**, which provides a protective embedding as well as damping in case of vibrations. Furthermore, the volume of the bag or of the liquid contained within can be expanded during the freezing process. This allows for a perfect adaption, which in turn maximizes the protective effect.

The frames of the **RoSS®** unit are made of **heavy duty plastic** that withstands even the **lowest temperatures** and makes up the **static frame of RoSS®**. Apart from the guide rails for the **stainless steel top and bottom**, the frame contains **ergonomically shaped grip** plates for safe and intuitive handling.

PROTECT AND FREEZE YOUR BULK DRUG SUB- STANCE

- with your preferred single use bag*
- down to -90°C (-130°F)
- at any partial fill volume
- with any freezing technology

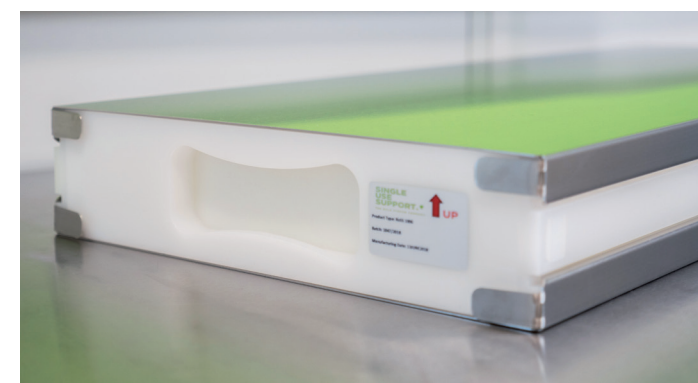
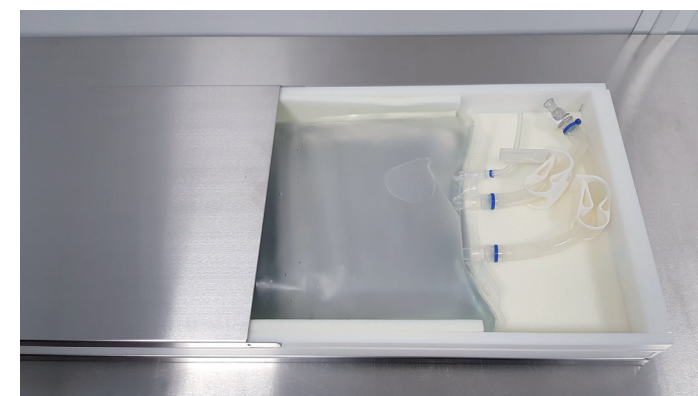
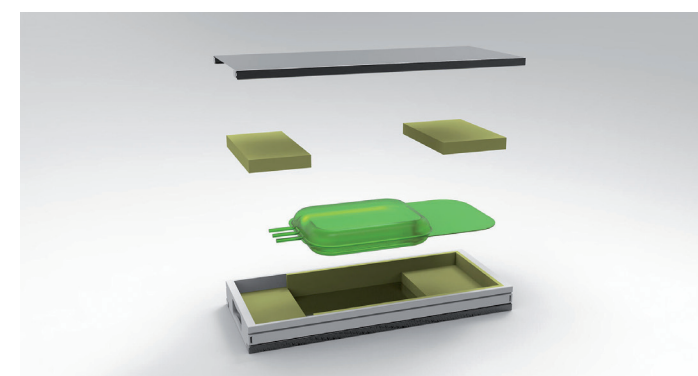
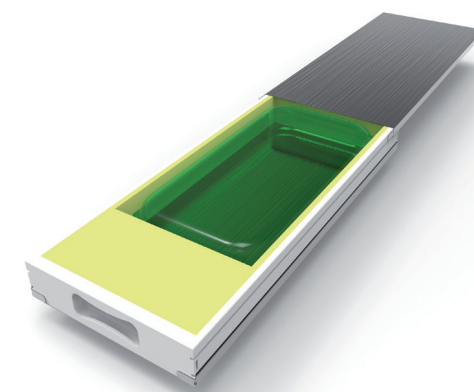
The **RoSS®** top and bottom are made of **high quality stainless steel** with the following three advantages:

1. Maximum durability and strength.
2. When in direct contact with the bag, these features offer the ideal basis for an effective initial and ongoing **freezing process**. Furthermore, they enable 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®** construction allows for only minimal vibration. It also reduces the tension in the structure of the **single use bag** and offers **shock absorbent protection**.

Facts:

- Adjustable for all 2D single use bags (e.g. Thermofisher, Entegris, Sartorius, ...)
- Robust, closed and tamper-evident construction
- 3D foam offers additional space and protection for the sensitive compound of the raw bag and tubing – complete immobilization <0 °C / <32 °F
- Space for sterile connectors and long hoses
- Space for satellite samples / ID bags
- Steel plates on the top and bottom for consistent and quickest possible freezing and defrosting times
- High density, which means a reduction of required freezer space capacity
- Easy handling during the recycling process – no composite materials
- Bag can be visually checked/inspected after filling and before dispensing

Beneath its absolutely hard and robust shell, the oyster too embeds its pearl in a flexible and soft environment.



MITS.2D®

100% secure integrity test for single use bags – “at point of use” and across all manufacturers.

Single use bags offer plenty of advantages but it is not a secret that the material they are made of can be faulty.

This can cause leakage – or the penetration with bacteria, which in the **worst case** can lead to commodity loss and **bio-contamination**.

Facts:

- 100% integrity test of single use bags
- 2-micron detection limit (bacteria penetration)
- Less than 60 seconds test time per bag
- Every MITS.2D is suitable for single use bags up to 20 liters
- Bioburden reduction & avoidance of endotoxins
- Test ALL assembly groups
- Patented technology

With this, the basis for 100% secure drug substance logistics is given: A revolution.

MITS.2D®

- identifies single use systems with a lack of integrity
- fully automated point-of-use testing
- In less than 2 minutes
- Helium as tracer gas

With a patented system, MITS.2D tests single use bags with a capacity of up to 20 liters in less than 60 seconds to make sure they are 100% intact.



2 micron in 2 minutes
Real point-of-use test for single use assemblies (fully assembled)

RoSS.FILL

Fully automated bulk filling & draining.

RoSS.FILL is a flexible platform for the **allocation and distribution of bulk drug substance** in single use bags that are integrated in the **RoSS® system**. The liquid path is fully disposable and can accommodate a multitude of sterile compound- and segregation options.



With a **filling speed of 200 liters per hour**, the RoSS® units on the rack are filled in a fully automated manner. Single use bags of all established manufacturers and of different sizes and capacities are compatible. The **scalability is limitless**.

Facts:

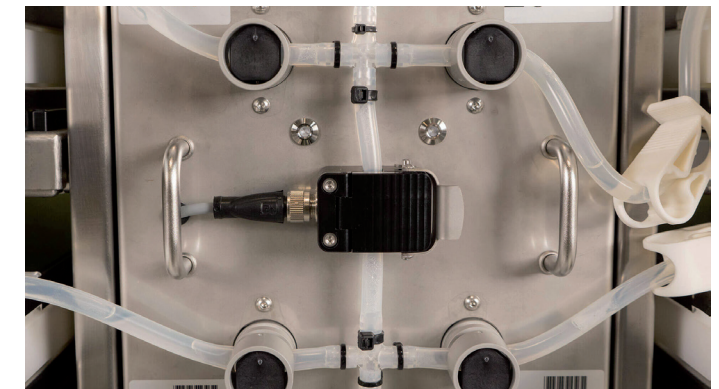
- Fully automated filling and draining system for single use bags
- Filling of up to 200 liters of substance in less than 1 hour
- Accuracy of +/-10 ml for 10 liters with individual weighing cells
- Modular system with separate control unit and pumping station as well as storage rack made up of RoSS trays filled with single use bags
- Option to take samples
- Optional MES integration

Fully automated, effective filling & draining process – what more could one wish for?

FILL YOUR BULK DRUG SUBSTANCE

- fully automated
- in less than 60 minutes
- in any single use bag*
- airless
- with highest possible filling accuracy

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



FREEZE-THAW PLATFORM
Freezing and thawing process on a new level.

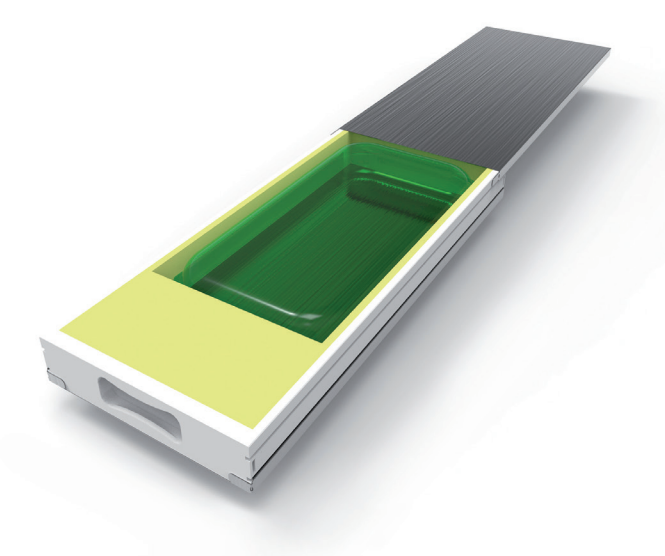
It is no secret that **SUSupport** is continuously **developing** and expanding the **Bulk.Stream®**. This is why plate-based **freezing and defrosting facilities** for stability studies as well as for **small to big batch sizes** have been developed.

RoSS.pFTU blockbuster aspires to replace **Cryovessels**, which are used for very large batch sizes, in the single use variant. Its development is currently in its final stage.

Safety and constant **freezing of high-quality substances** in an even shorter timeframe will be pushed **to a new level** – a further milestone for the biopharma industry.

- Facts:**
- Easy manual operation
 - For single use bags of any size and manufacturer
 - At highest possible speed & accuracy
 - For best product stability results
 - Fully controllable
 - Scalable end-to-end solution

Start into the future with a scalable platform!



RoSS.pFTU lab scale
RoSS.pFTU “lab scale” is the perfect solution for studies conducted in labs and, above all, if you want to start a controlled and scalable freezing process.



RoSS.pFTU large scale
RoSS.pFTU large scale is a plate-based freeze-thaw unit for any scale and batch size.

Compatible with single use bags of all manufacturers and sizes

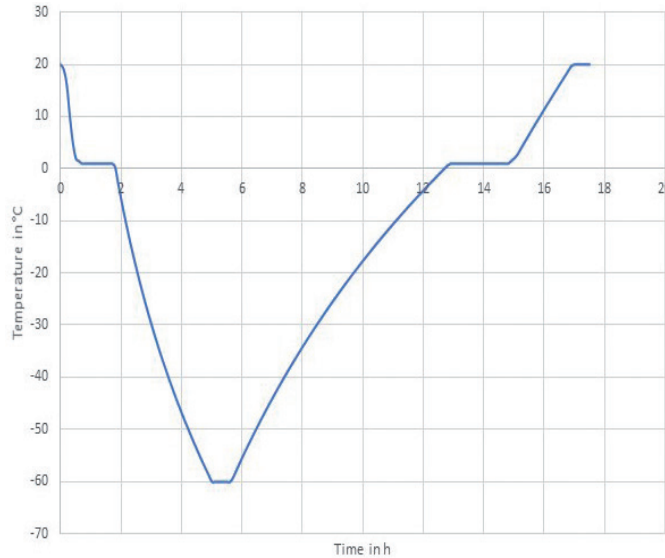


RoSS.pFTU small scale
RoSS.pFTU small scale is a plate-based freeze-thaw unit for studies and small scale batches.



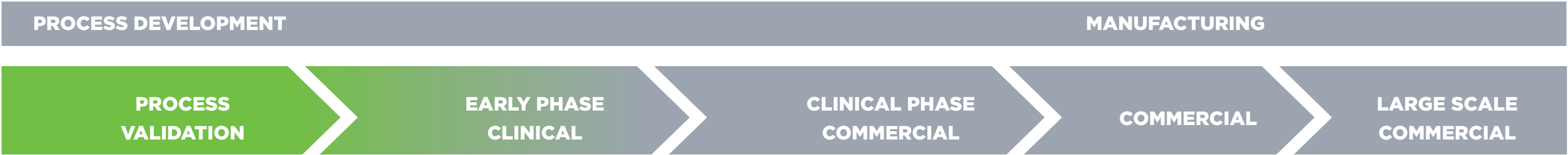
RoSS.pFTU blockbuster scale
Blockbuster scale single use platform: for bulk drug substance of up to 300 l in one fully disposable unit.

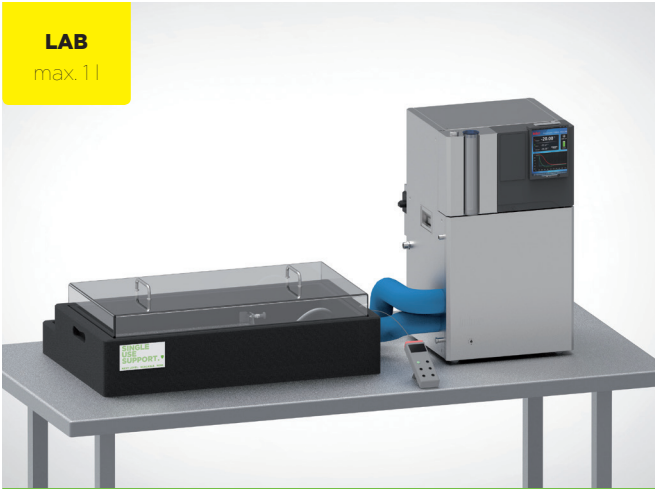



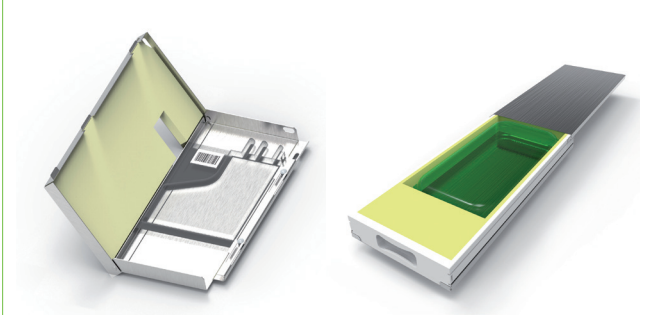
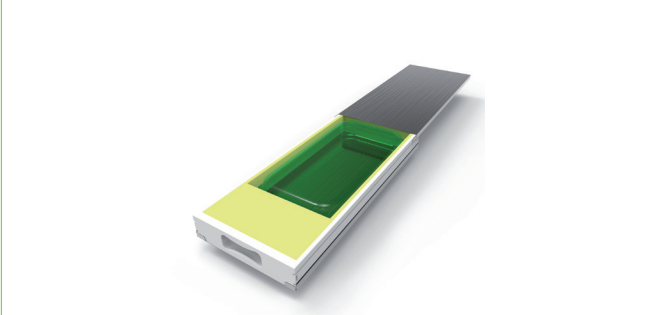
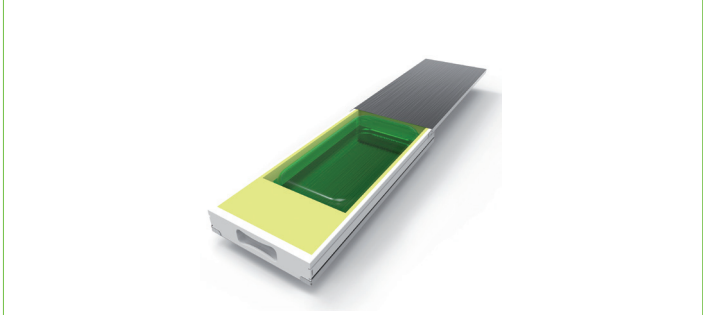

Science - freezing and thawing temperature trend



Freezing and thawing from 8 to 200 l (up to 24 RoSS® Shells)

Conclusion:
The freezing curves and kinetics are very similar and independent of the RoSS® shells loading (min. or full load) as long the individual RoSS® shells are identical in their setup (bag size and filling volume). That's one of the advantages and differentiators of the RoSS® shell that is achieved thanks to the design and combination of polyethylene sidewalls and stainless steel on top and bottom.



HARDWARE	<div>LAB max. 1 l</div>  <div>LAB SCALE</div>	<div>SMALL max. 4 l</div>  <div>SMALL SCALE</div>	<div>LARGE max. 200 l</div>  <div>LARGE SCALE</div>	<div>BLOCK-BUSTER max. 300 l</div>  <div>BLOCKBUSTER SCALE</div>
	filling volume of 10 ml to 1 l per bag	filling volume of up to 1 l per bag/RoSS®	filling volume of up to 20 l per bag/RoSS®	filling volume of up to 300 l in 50 l steps
				
	Lab system for evaluation	System for small batches and process validation	Routine batch freezing	Replaces stainless steel Cryovessel
CONSUMABLE	Preclinical & testing for BDS & CGT	Low-volume freezing of up to 4 RoSS® containers (10 ml - 1 l each)	Flexible system for up to 24 RoSS® containers (1 l - 20 l each)	Large-scale bulk drug substance processes

Highly robust, stackable, coolable and compact – Fort Knox for high-quality substances!

RoSS.SHIP integrates **20 ROSS® trays** and more in a compact volume. Most **frozen substances** can be stored and shipped in a protected manner and in compliance with international standards. The statically highly solid **RoSS.SHIP** stainless steel container is designed for **passive cooling** with dry ice or “**phase change materials**” (PCM).

Optionally, the geographical location as well as the interior temperature of the **RoSS-SHIP** container can be tracked and monitored **24/7 via GPS or G-Force tracking**.

Facts:

- Isolated shipping containers for passive cooling processes
- Validation based on ISTA / ASTM 4169
- Optional temperature- / GPS- / G-Force tracking
- Adjustable to all requirements and batch sizes
- Suitable for phase change materials and dry ice
- Single use or multi use

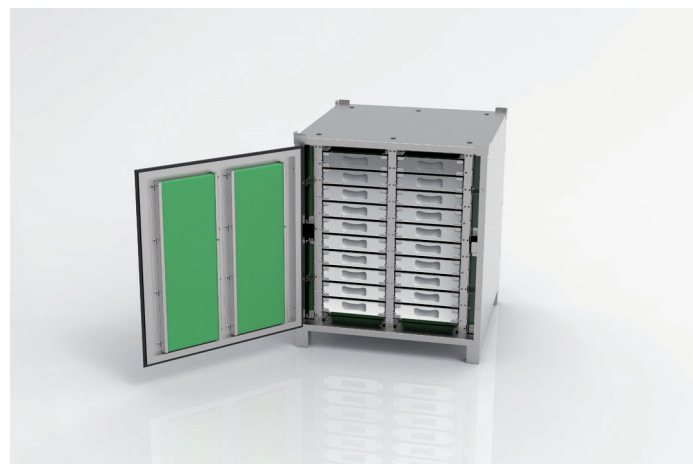
RoSS.SHIP is the best friend of anyone responsible for biopharma logistics processes – that’s for sure!

Accessories for the Bulk.Stream

Furthermore, Single Use Support provides all required **ACCESSORIES** for the **BULK.STREAM®**

Find further information on:

<https://www.susupport.com/en/bulk-stream/accessoires/>



We solve scalability issues for the Cell & Gene Therapy Industry

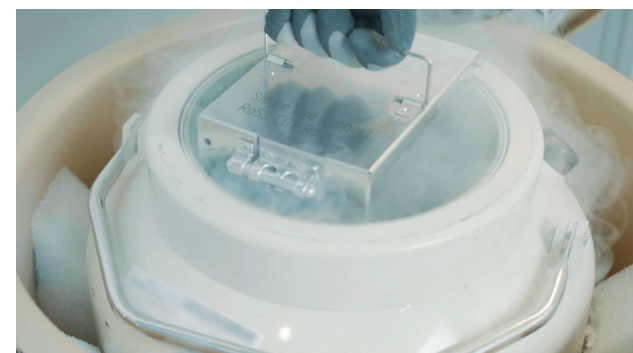
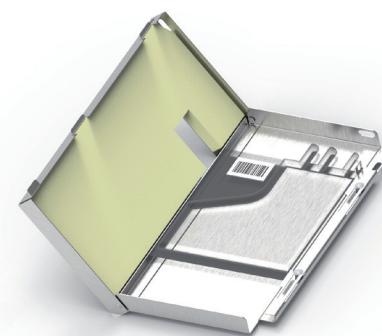
Our focus is absolute patient safety – now more than ever!!

With the use of our technology, biopharmaceutical companies active in the area of Cell and Gene Therapy can **minimize** the risk of **bio-contamination, manipulation** or **product loss** towards **0%**.

This process builds upon industry standards like **single use bags** of all sizes and manufacturers. Furthermore, we offer a framework of **preventive** and **protective measures** for this standard that reach a new and unrivaled quality level.

Our development features all **strengths of single use bags**. **Potential weaknesses and risks**, like material deficiencies or sensitive outer shells, are 100% compensated by our developments.

We call our process **CGT.STREAM**.



CGT.STREAM

1. TEST | MITS.2D



2. PROTECT | RoSS.KSET



3. FREEZE | RoSS.pFTU



4. STORE, SHIP, TRACK & TRACE | CGT.RACK | SHIPPER



5. THAW | RoSS.pFTU



6. RECYCLE | RoSS.KSET



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