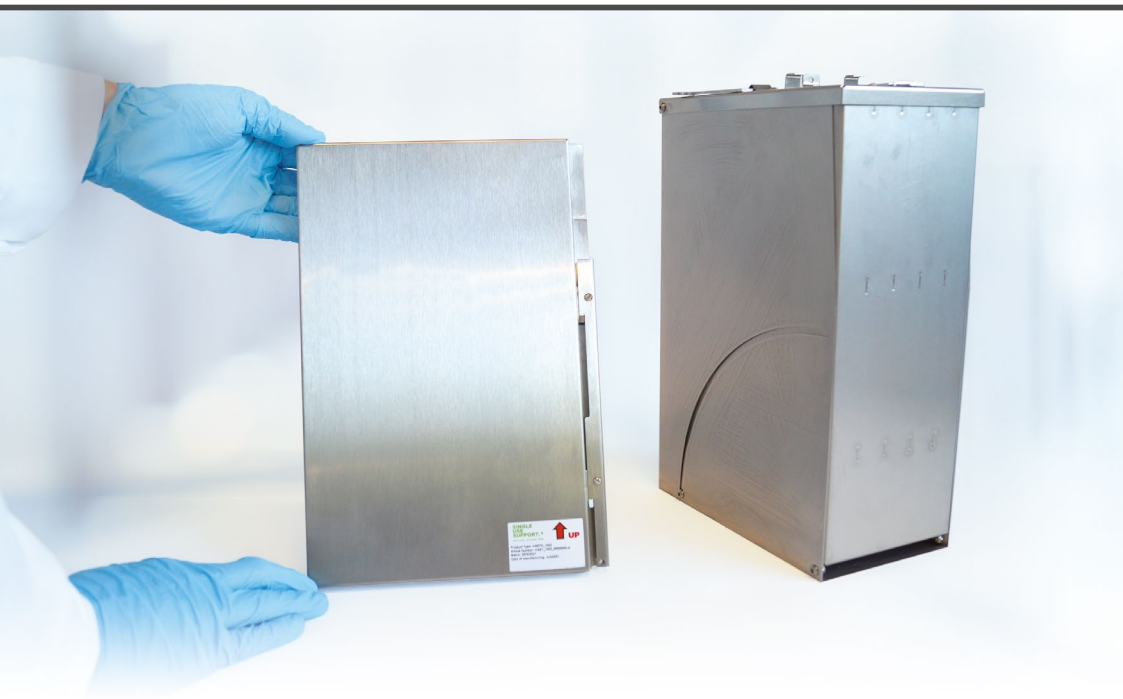


SINGLE USE SUPPORT.

PIONEERING BIOPHARMA



RoSS.KSET®

Instruction for Use

RoSS.KSET

ROBUST PROTECTION FOR YOUR DRUG SUBSTANCE AT SMALL SCALE:

- Protection of highly valued liquids
- For single-use bags up to 250mL
- Down to -200°C (-328°F)

... to ensure 0% product loss during freezing, storing and transportation!

Warning Notices

Attention: The stainless steel surface is protected with an intact passive layer prior to use. Handle carefully and avoid scratches as they may cause corrosion.

Only use moist wipes with water or 70% IPA for cleaning RoSS.KSET.

Acidic or alkaline cleaning agents can harm the surface of the stainless steel lid.

Do not store RoSS.KSET in direct contact with or near non-stainless-steel metals. Contact with other metals can destroy the passive layer and cause the stainless steel to corrode.

Protect RoSS.KSET from sunlight (UV) at any time.

Storage temperature: 5 - 25 °C / 41 - 77 °F

Remove the PE packaging as late as possible in order to protect the RoSS System.

Only use RoSS.KSET with the dedicated single-use bag.

Do not disassemble RoSS.KSET before use.

Do not jam your fingers when closing the lid.

Always wear gloves when handling with RoSS.KSET.

For storing and shipping multiple RoSS.KSET we recommend the use of storage and shipping solutions from Single Use Support GmbH or dedicated certified products.

Do not use RoSS.KSET if the packaging is damaged.

Do not reuse RoSS.KSET.

Do not open RoSS.KSET when frozen.

This product may only be handled by trained staff; for training, please contact Single Use Support GmbH.

RoSS.KSET

Directions for Use

Step 1



Place RoSS.KSET carefully on a clean surface. The label marks the upper side of RoSS.KSET. If the packaging is undamaged, remove the PE foil carefully. If the foil is faulty or seems to have been tampered, check RoSS.KSET for damages.

Step 2



Slide the lock on the right side up to open RoSS.KSET. Prepare your single-use bag to place it into RoSS.KSET.

Step 3



Remove the 3D foam inlay and put it aside. Now place the single-use bag inside the stainless-steel shell RoSS.KSET. Make sure that the tubings and connectors are inside the shell.

Step 4



Place the upper 3D tubing foam on top of the single-use bag including its tubings.

Step 5



Now close the lid of RoSS.KSET all the way back into the closing position.

Step 6



To lock RoSS.KSET for freezing, push down the lid and slide the lock down.

RoSS.pFTU or KSET.RACK



RoSS.KSET can now either be frozen in RoSS.pFTU (down to -80°C) or in combination with KSET-Rack in a LN2 freezer (-200°C)

RoSS.KSET RACK

Directions for Use with KSET.RACK

Up to 8 RoSS.KSET can be placed into special designed KSET.RACKs.

KSET.RACK is a highly robust and compact standard handling and storage system. It can withstand temperatures down to -200°C -328°F).

The main construction material is high-graded stainless steel, it is lockable, safe to freeze and protects against any manipulation.

RoSS.KSET & RoSS.KSET RACK -

Some areas of application:

- Early Clinical Phase
- Cell and Gene Industry
- Cell Banking
- Upstream Seed Train Intensification

Step 1



Place KSET.RACK carefully on a clean surface. The label marks the upper side of KSET.RACK.

Step 2



Push down the lock, as shown, in order to unlock the upright handle.

Step 3



Slide the lock of the Rack back to open top lid.

Step 4



Open the top lid.

Step 5



Open the side lid by sliding it down.

Step 6



Place RoSS.KSET inside the rack at its predefined position.

Step 7



Once KSET.RACK is filled, pull the side lid upwards again.

Step 8



Then, close the top lid again.

Step 9



Slide the lock back into the front.

Step 10



Put up the handle to lock and transport KSET.RACK.

Step 11



To secure tamper-evidence of the Rack you can optionally put cable ties into its predefined position of the handle as shown.

Disclaimer of Warranties: Single Use Support GmbH warrants that reasonable care has been used in the manufacture of this device and that it was free from defects in workmanship or materials at the time of shipment from Single Use Support GmbH. Single Use Support GmbH sole obligation shall therefore be to repair or replace any device that it determines was defective at the time of shipment. Because no product is 100% effective under all circumstances and because the actual use and handling of this device are beyond our control, Single Use Support GmbH cannot warrant for/against good/bad effects in the application and use of this device. The buyer therefore assumes all liability arising from any damages resulting from use, misuse, use other than intended. Single Use Support GmbH therefore assumes no liability of merchantability or fitness for a purpose. Single Use Support GmbH shall not be liable for incidental or consequential loss, damage or expense resulting from the use or application of this product. This warranty is in lieu of all other warranties, whether implied, express, oral or written, and no individual has the authority to vary the terms of this warranty.

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