

Operating Instructions  
Original Operating Instructions

# Flexsafe STR<sup>®</sup> Single-Use Bags

Volumes 50 L-2000 L



2667752-000-00



**SARTORIUS**



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# 1 About these Instructions

## 1.1 Scope

These instructions are part of the product.

These instructions apply to the product in the following versions:

- Flexsafe STR® 50 L
- Flexsafe STR® 200 L
- Flexsafe STR® 500 L
- Flexsafe STR® 1000 L
- Flexsafe STR® 2000 L

## 1.2 Accompanying Documents

- ▶ In addition to these instructions, observe the following documents:
  - Operating Instructions for Biostat STR®
  - Operating Instruction for Flexsafe STR® 2000 Lifting Device

## 1.3 Target Groups

These instructions are designed for the following target groups. These target groups must possess the knowledge listed below.

Target Group	Knowledge   Responsibilities
User	The user is responsible for operating the device and for the associated work processes. The user knows the dangers that can occur when working with the device and can avoid these dangers. The user has been trained in the operation of the device.
Electrician	A qualified electrician who has the specialized training, knowledge and experience as well as familiarity with applicable standards to evaluate the work assigned to him or her and identify possible hazards.
Operator	The operator of the device is responsible for compliance with safety requirements and workplace safety regulations. The operator must ensure that all persons who work on the device have access to the relevant information and have been instructed in work on the device.

## 1.4 Symbols Used

### 1.4.1 Warnings in Operation Descriptions

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#### **WARNING**

Denotes a hazard that may result in death or severe injury if it is **not** avoided.

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#### **CAUTION**

Denotes a hazard that may result in moderate or minor injury if it is **not** avoided.

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#### **NOTICE**

Denotes a hazard that may result in property damage if it is **not** avoided.

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## 1.5 Other Symbols

- ▶ Required action: Describes actions which must be carried out.
- ▷ Result: Describes the result of the actions carried out.
- [ ] Text inside brackets refers to control and display elements.

### **Figures in these Instructions**

Depending on the product configuration, the figures in these instructions may differ from those on the supplied product. These operating instructions show product versions that are examples.

## 2 Safety Instructions

### 2.1 Intended Use

This product is designed for use with Sartorius Biostat STR®. The scalable bioreactor family Biostat STR® is a range of stirred bioreactors in which cells can be cultivated. For this purpose, the culture medium is stirred in a single-use bag and kept under defined cultivation conditions. The bag must be disposed of after the single usage. The product must be used with a Sartorius bioreactor, e. g. Biostat STR®. The size of the single-use bag must match the size of the bag holder, e. g. 50 L.

Do **not** use the product in potentially explosive environments. The product may only be used indoors.

Do **not** carry out any processes using biological materials in Safety Classes 3 or 4.

The product may only be used with the equipment and under the operating conditions described in the Chapter "4 Technical Data," page 24. Please also consult the Chapter "Safety" in the Biostat STR® Operating Instruction.

Any further use beyond this is considered **improper** and is prohibited. These instructions are part of the product. The product is intended exclusively for use in accordance with these instructions.

#### Modifications to the product

You may not modify or repair the product or make any technical changes. Any retrofitting or technical changes to the product are only permitted with prior written permission by Sartorius Stedim Biotech.

### 2.2 Personnel Qualification

All persons working on the product must possess the necessary knowledge to use the product in for its intended purposes.

The actions described are addressed to the "user" target group. Sartorius Service personnel or other groups may be required to carry out specific actions. These actions may require specific qualifications that will be indicated in the manual.

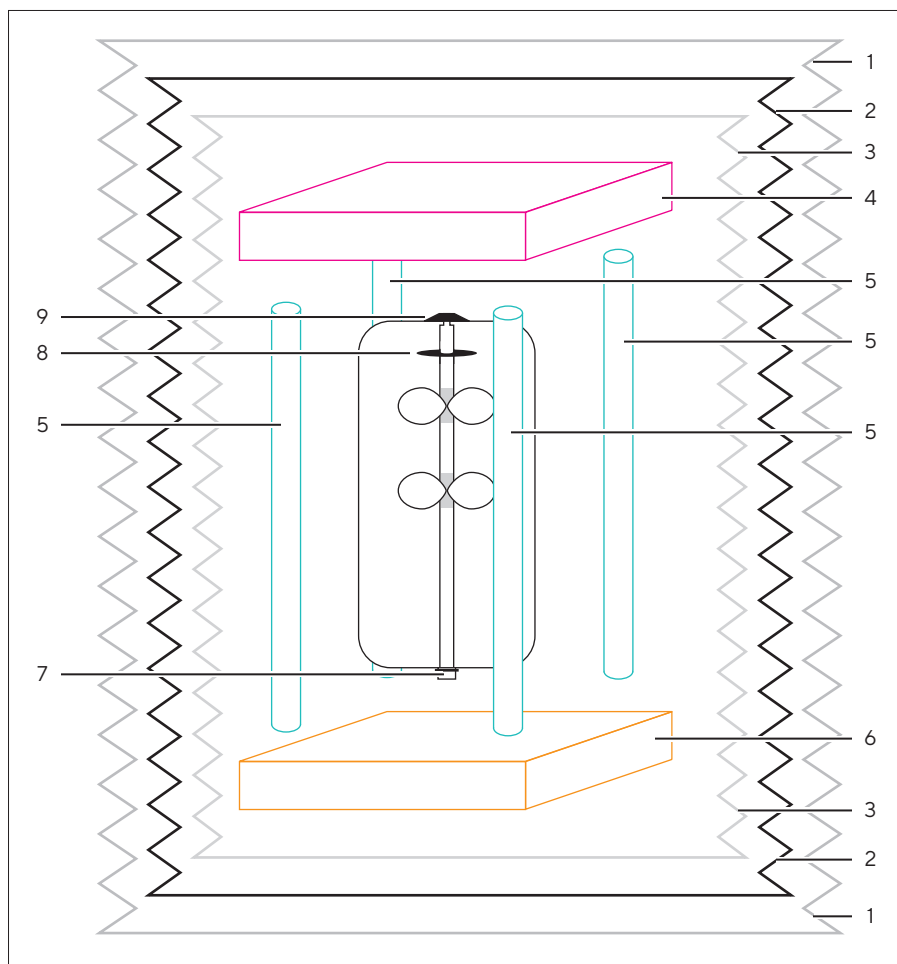
### 2.3 Significance of these Instructions

Failure to follow the instructions in this manual can have serious consequences, e. g. exposure of individuals to electrical, mechanical or chemical hazards.

- ▶ Before working with the product: Read the instructions carefully and completely.
- ▶ If the instructions are lost: Request a replacement or download the latest instructions from our website.
- ▶ The information contained in these instructions must be available to all individuals working on the product.

## 3 Unpacking

### 3.1 Packaging Materials



Pos.	Designation	Description
1	Tertiary (outer) Overpouch	<ul style="list-style-type: none"> <li>- The tertiary pouch is taped.</li> <li>- The pouch is transparent.</li> </ul>
2	Secondary Overpouch	<ul style="list-style-type: none"> <li>- The secondary overpouch is taped closed.</li> <li>- The color of the pouch is black.</li> </ul>
3	Primary (inner) Overpouch	<ul style="list-style-type: none"> <li>- The primary overpouch is sealed.</li> <li>- The pouch is transparent.</li> </ul>
4	Foam top element	
5	Plastic tube elements	
6	Foam bottom element	
7	Top Port	
8	Sparger	
9	Drain Port	

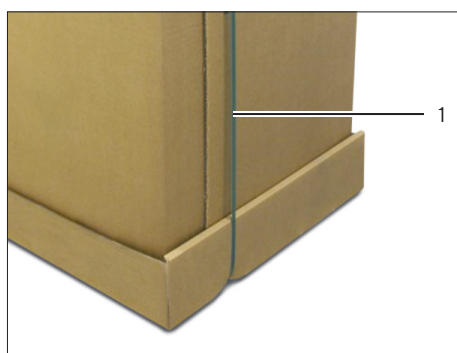






- ▶ **NOTICE** Transportation is unsafe when the bands (1) stretched around the transport packaging (2) are removed. Do **not** cut the bands.
- ▶ Cut and remove the bands (3) secured to the pallet.

- ▶ **⚠ CAUTION** Cuts from sharp edges on the bands!  
Do **not** lift the transport packaging by the bands.
- ▶ Lift the transport packaging and set it down on the ground.
- ▶ Cut and remove the bands (1).



- ▶ In order to remove the lid (1) from the transport packaging:
  - ▶ Flexsafe STR® 50 L | 200 L:  
Take the lid off of the transport packaging.
  - ▶ Flexsafe STR® 500 L | 1000 L:  
Remove the lid from the transport packaging with a second person.

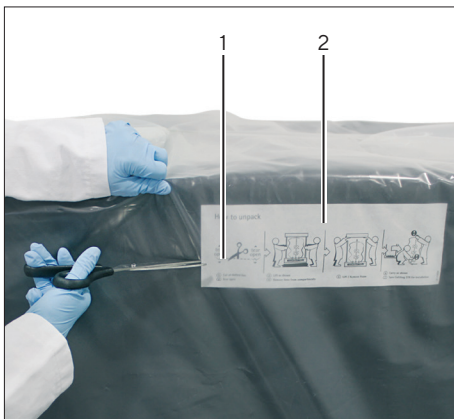




- ▶ To remove the lateral packaging (1):
  - ▶ Flexsafe STR® 50 L | 200 L:  
Lift and remove the lateral packaging out from the bottom of the transport packaging.
  - ▶ Flexsafe STR® 500 L | 1000 L:  
Lift and remove the lateral packaging from the bottom of the transport packaging with a second person.



- ▶ To remove the lower part of the transport packaging: Lift the packaged bag at the 4 plastic tube elements (1).
- ▶ Set the packaged bag down next to the transport packaging.
- ▶ On the black bag of the packaging, there is a pictogram (2) showing additional information on how to proceed.



- ▶ Dispose of the transport packaging and the transport pallet.
- ▶ Carefully cut the tertiary overpouch along the mark (1) shown on the pictogram (2).
- ▶ **⚠ CAUTION** Be careful to cut only the tertiary overpouch without damaging the secondary (black) overpouch.



- ▶ Pull the lower part of tertiary overpouch (1) downwards.
- ▶ Remove the upper part of the tertiary overpouch (2).
- ▶ In order to remove the lower portion of the tertiary overpouch: Lift the packaged bag at the 4 plastic tube elements.
- ▶ Set down the packaged bag.
- ▶ Discard the tertiary overpouch.



- ▶ Carefully cut the black secondary overpouch and the primary overpouch underneath it along the mark (1) shown on the pictogram (2).



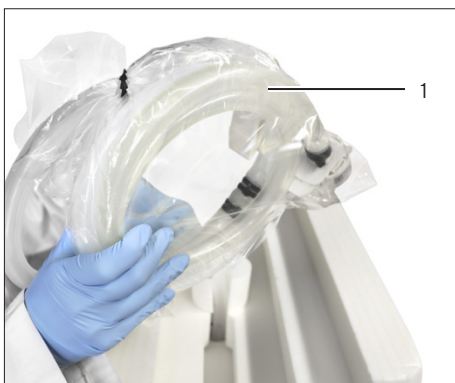
- ▶ Pull the lower part of the secondary and primary overpouches (1) downwards.
- ▶ Remove the upper parts of the secondary and primary overpouches (2).



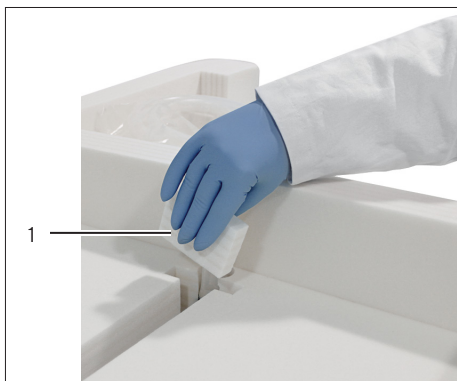
- ▶ To remove the lower portions of the secondary and primary overpouches: Lift the bag in the foam elements at the 4 plastic tube elements (1).
- ▶ Set down the bag in the foam elements (2) next to the black and the transparent bag.
- ▶ Discard the secondary and primary overpouches.



- ▶ Remove the tubes (1) from the bottom foam element.



- ▶ Flexsafe STR® 50 L | 200 L: Remove the drain line (1).



- ▶ Flexsafe STR® 500 L | 1000 L:  
Remove the fixing element (1) that is holding the drain line in place.

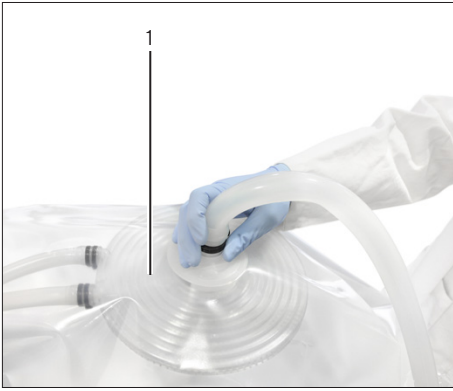


- ▶ Flexsafe STR® 500 L | 1000 L: Remove the drain line (1).



- ▶ **NOTICE** The shaft should be vertical.
- ▶ To remove the top foam element:
  - ▶ Take off and remove the top foam element with a second person (1).
  - ▶ Operator 1: Take off and remove the top foam element.
  - ▶ Operator 2: Hold the drain port.

- ▶ Unpack the drain line and remove the clamp around the drain line.  
This point is only relevant for STR® 500 and STR® 1000 bags.



- ▶ To remove the 4 tube elements:
  - ▶ Operator 2: Hold the bag at the drain port (1).
  - ▶ Operator 1: Remove the 4 plastic tube elements from the recesses in the bottom foam element (2).



#### For further steps

- ▶ Please refer to Operating Instruction Biostat STR®, Chapter "6.3 Installing Bag in Bag Holder for Biostat STR® 50 L-200 L" and Chapter "6.4 Installing Bag in Bag Holder for Biostat STR® 500 L-1000 L".
- ▶ Please make an integrity test according to the leak test instruction.

### 3.3 Unpacking the Flexsafe STR® 2000 L Bag

Personnel:

- Flexsafe STR® 2000 L bag                      3 persons

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#### NOTICE

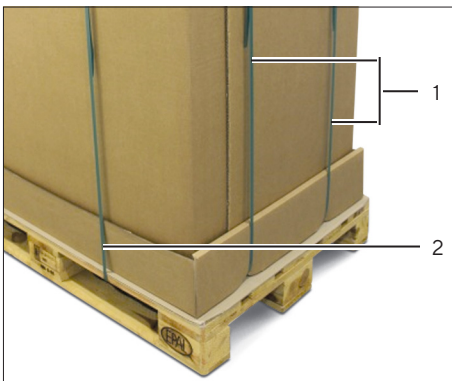
##### **Danger of damage to the bag due to improper unpacking!**

A damaged bag can lead to functional and operational disturbances.

- ▶ Carry out all steps carefully when unpacking the bag.
  - ▶ Use the installation and lifting device.
- 

#### Procedure

- ▶ Check the expiration date of the bag.
- ▶ If it has expired: Use a new bag.
- ▶ Remove the protective wrapping (1).



- ▶ **NOTICE** Transportation is unsafe when the bands stretched around the transport packaging (1) are removed. Do **not** cut the bands.
- ▶ Cut and remove the bands (2) secured to the pallet.



- ▶ Press the 8 perforated carrying handles of the transport packaging inwards.
- ▶ **⚠ CAUTION** Cuts from sharp edges on the bands!
  - ▶ Do **not** lift the transport packaging by the bands.
  - ▶ Lift the transport packaging by the carrying handles.
- ▶ Lift the transport packaging off of the pallet and set it down on the ground.



- ▶ Turn the transport packaging 180°.



- ▶ The bottom side of the transport packaging is facing upwards.



- ▶ Cut and remove the bands from the transport packaging.





- ▶ Remove the lid (1) from the transport packaging with a second person.



- ▶ Lift and remove the side walls (1) of the transport packaging from the bottom of the transport packaging with a second person.



- ▶ To remove the lower part of the transport packaging: Lift the packaged bag at the 4 plastic tube elements (1).
- ▶ Set the packaged bag down next to the transport packaging.
- ▷ On the black bag of the packaging, there is a pictogram (2) showing additional information on how to proceed. Follow the indications on the pictogram.



- ▶ Dispose of the transport packaging and the transport pallet.
- ▶ Carefully cut the tertiary overpouch along the mark (1) with scissors shown on the pictogram.
- ▶ Carefully tear open the tertiary overpouch vertically.



- ▶ Remove the upper part of the tertiary overpouch.
- ▶ In order to remove the lower portion of the tertiary overpouch: Lift the packaged bag at the 4 plastic tube elements.
- ▶ Set down the packaged bag.
- ▶ Discard the tertiary overpouch.



- ▶ Carefully cut the black secondary and the transparent primary overpouches with scissors underneath it along the mark (1) shown on the pictogram.
- ▶ Slightly tear open the secondary and primary overpouches underneath vertically.



- ▶ Remove the upper parts of the secondary and primary overpouches.
- ▶ Discard the secondary and primary overpouches.



- ▶ Take the tubes (1) out of the bottom foam element.



- ▶ Remove the vacuum-packed bag with hose clamps (1) from the bottom foam element, and clamp tubing lines if desired.



- ▶ To remove the upper foam element:
  - ▶ Operator 1: Hold the bag at the top port (1) in a vertical position.
  - ▶ Operators 2 and 3: Take off and remove the bottom foam element (2).



- ▶ Move the gripper of the installation and lifting device into the recesses of the lower foam part.



- ▶ **NOTICE** Danger of damage to the bag from the Tri-Clamp! If the bag is jammed by the Tri-Clamp, the bag film can be damaged and render the bag unusable. Do **not** clamp the bag film between the Tri-Clamp and the top port.
- ▶ Position the Tri-Clamp of the installation and lifting device around the top port and close (see Instructions for Installation & Lifting Device). Position the bag so that the vertical weld on the bag without dip tube lines are aligned with the lift arm. This weld will be positioned down the center of the bag holder door.

A belt is attached to the drain port of the bag and rolled up. The use of the belt prevents extension of the telescopic shaft during installation in the bag holder.



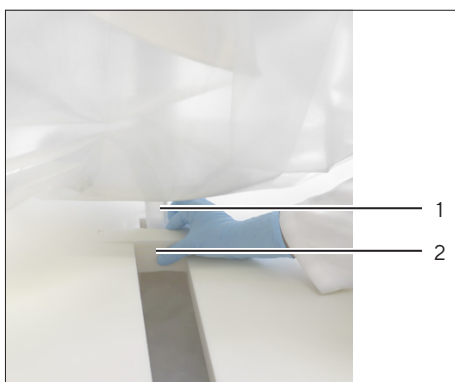
- ▶ Remove the two white strips of adhesive tape from the belt.
- ▶ Unroll both ends of the belt.



- ▶ Hang holes on both ends of the belt on the hook (1) of the installation and lifting device.

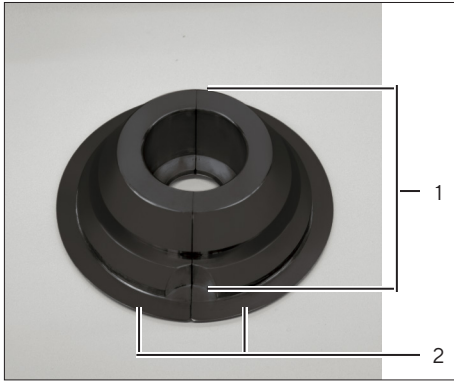


- ▶ Raise the arm of the installation and lifting device approx. 20 cm upwards to slightly lift the bag out of the top foam element.



- ▶ To remove the drain line (1) from the top foam element:
  - ▶ Remove the small fixating foam element (2).
  - ▶ Remove the top foam element with the help of a second person.
  - ▶ Lift the bioreactor to a height that allows access to the drain port of the bag.

- ▶ **⚠ CAUTION** Danger of crushing the fingers when securing the fitting cone on the drain port! The contact surfaces of the fitting cone elements are magnetic and join together abruptly when assembled. Grasp the conical elements using the handle recesses (1) and place them around the drain port.



- ▶ To prepare the fitting cone for the installation:
  - ▶ Place the fingers of your right and left hands in the recessed grips (1) provided on the fitting cone.
  - ▶ Pull the two fitting cone elements (2) apart.



- ▶ **NOTICE** Risk of damage to the bag if the cone is in the wrong position! Check the position of the cone.
- ▶ Place the cone around the drain port. The fitting cone collar (1) must be located below the drain port ring.

- ▶ Push the two cone elements together.
- ▶ Unpack the drain line.

#### For further steps

- ▶ Please refer to Operating Instruction Biostat STR®, Chapter “6.5 Installing Bag in Bag Holder for Biostat STR® 2000 L” and Lifting Device.
- ▶ Please make an integrity test according to the leak test instruction.

### 3.4 Expelling Liquid from Aeration Tubes and Combi Sparger

When filling the bag, culture medium gets into the combi sparger and the aeration tubes. To prevent damage during aeration, e.g. the aeration tubes bursting, the culture medium must be expelled from the combi sparger and the aeration tubes after filling.

#### Requirement

- The bag filling process is complete.

#### Procedure

- Start ring sparger aeration and micro sparger aeration.
- When the aeration period is complete: Switch off ring sparger aeration and micro sparger aeration.

At the following approximately gas flow rates for the different STR® sizes the gas will come out of all holes of each sparger part.

<b>STR® 50</b>	- ring sparger part: 1.50 lpm - micro sparger part: 1.50 lpm
<b>STR® 200</b>	- ring sparger part: 6.00 lpm - micro sparger part: 6.00 lpm
<b>STR® 500</b>	- ring sparger part: 25 lpm - micro sparger part: 15 lpm
<b>STR® 1000</b>	- ring sparger part: 30 lpm - micro sparger part: 15 lpm
<b>STR® 2000</b>	- ring sparger part: 80 lpm - micro sparger part: 20 lpm

For the larger system it is correct that higher gassing rates are needed for the ring sparger part because of several reasons:

- more liquid will be enter the ring sparger part compared to the micro sparger part
- higher pressure will be needed to remove the liquid
- hydrostatic pressure increased

## 4 Technical Data

### 4.1 Exterior Package Dimensions (for details check table)

Flexsafe STR®	Width [mm]	Depth [mm]	Height [mm]	Bags   Pallet*
50 L	395	395	1170	6
200 L	395	595	1445	4
500 L	765	1155	1320	1
1000 L	765	1155	1445	1
2000 L	995	1195	1715	1

\* Number may vary depending on bag reference.

The bag stored on the pallet has a higher total height of additional 145 mm to the values listed in the table above.



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The information and figures contained in these instructions correspond to the version date specified below.

Sartorius reserves the right to make changes to the technology, features, specifications and design of the equipment without notice.

Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote all genders.

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