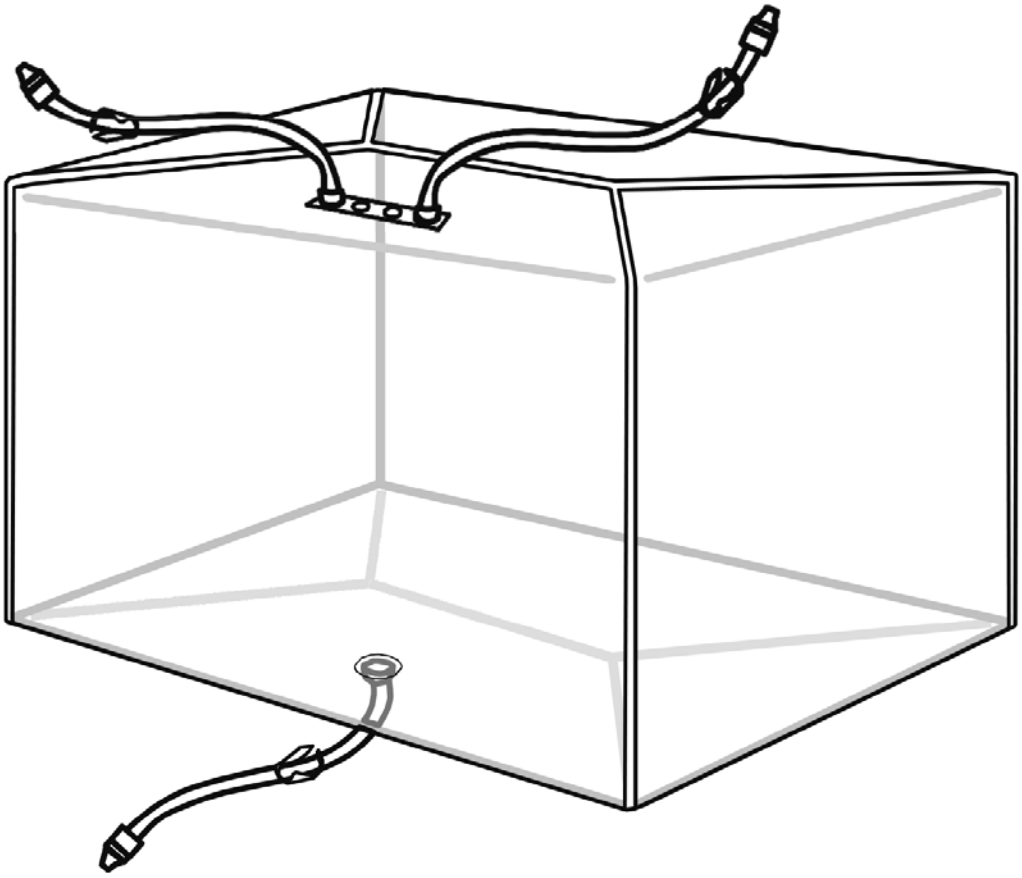
sartorius stedim biotech

User Manual

Flexsafe® 3D Bag For Palletank®

100L, 200L and 500L



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Flexsafe® 3D Bag 100L, 200L, 500L

For use with:
- Palletank® for Storage: 200L & 500L
- Palletank® for Storage (stackable): 200L & 500L
- Palletank® for In-Process Fluid Handling: 200L & 500L
- Palletank® for Shipping: 100L, 200L & 500L
- Plastic Palletank®: 200L & 500L

1. Introduction

Flexsafe® 3D standard bags are designed for processing, storage and transport of large volume biopharmaceutical solutions in Sartorius Stedim Biotech's Palletank® containers. Flexsafe® meets your requirements for outstanding robustness and ease of use for all your single-use bioprocessing needs, from cell cultivation to shipping of drug substance.

The Flexsafe® 3D System is composed of a disposable sterile bag, the Flexsafe® 3D Bag and the Palletank® rigid container constructed of stainless steel or plastic. The Palletank® supports the fluid contained within the Flexsafe® 3D Bag. The two make up the System and must be used together to ensure a robust process solution. When filling, the bottom and sides of the bag conform to the shape and dimensions of the Palletank®. The exact fit ensures bag functionality by eliminating folds or creases in the bag film.

The Flexsafe® 3D System has been designed with a bottom port that allows bottom drainage of the bag for virtually 100% fluid recovery.

Typical applications for the Flexsafe® 3D System include processing, storage and transport of large volume biopharmaceutical solutions under sterile conditions. The extended standard product range with proven application specific designs in combination with the Palletank® allow the Flexsafe® 3D System to meet your needs for a wide range of bioprocessing applications. Flexsafe® 3D bags and corresponding Palletank® for the are currently available from 100L to 1000L. The System can be moved with a pallet jack, forklift, or a dolly (up-to 1000L).

Purpose
This instruction for use describes the operations required to prepare, fill and drain a 100L, 200L or 500L Flexsafe® 3D Bag in its dedicated Palletank®.

2. Palletank® & Flexsafe® Bag Description

2.1 Palletank® Description

Sartorius Stedim Biotech currently offers 5 ranges of Palletank® for use with 100L, 200L and 500L Flexsafe® 3D Bags.

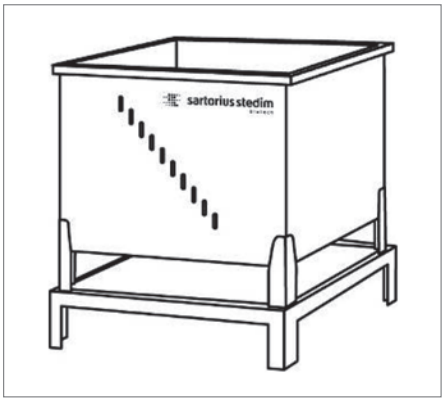


Fig. 1: Palletank® for Storage

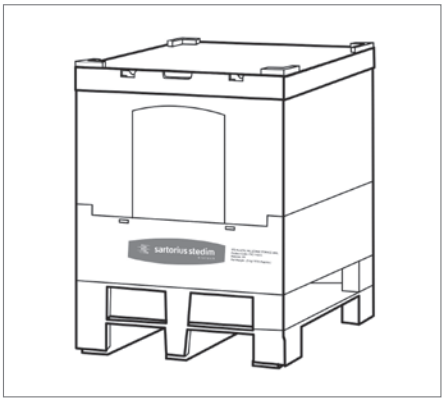


Fig. 2: Plastic Palletank® for Storage

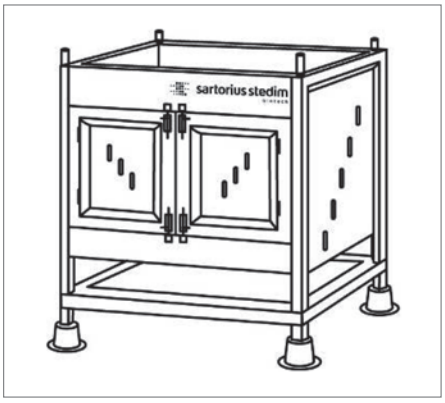


Fig. 3: Palletank® for In-Process Fluid Handling

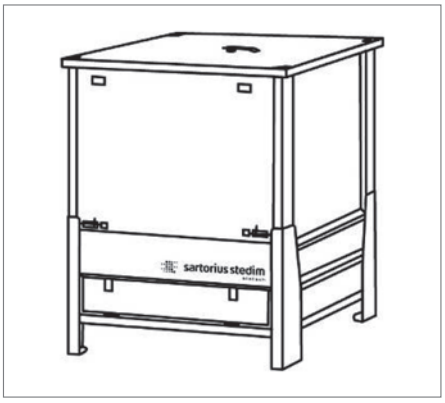


Fig. 4: Palletank® for Shipping

2.2 Flexsafe® 3D Bag Description

(see Fig. 5)

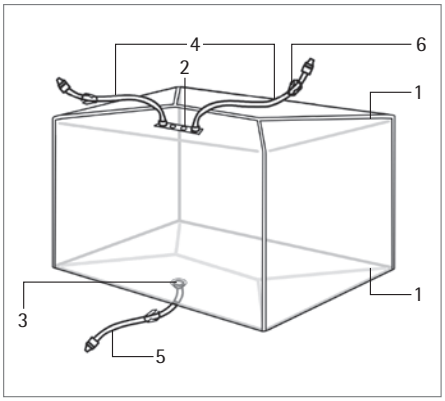


Fig. 5

1. K-seals
2. 4-port system
3. Bottom port
4. Filling tubes | Dispensing tubes
5. Filling tube | Dispensing tube
6. Clamp

3. Flexsafe® 3D System 100L, 200L, 500L Instructions for Use

3.1 Preparation of the Palletank®

1. If you use:

▷ the Palletank® for In-process Fluid Handling, open the hinged front doors by removing the four locking systems (see Fig. 6)

▷ the Palletank® for Shipping, please refer to the Palletank® for Shipping Instructions for Use delivered with the Palletank®

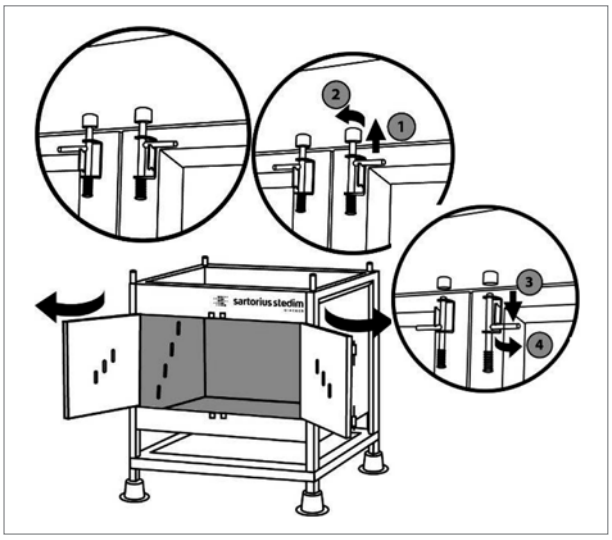
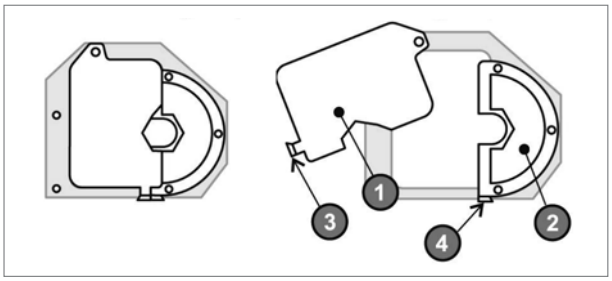


Fig. 6: Preparation of the Palletank®

2. Before installing the Flexsafe® 3D Bag in the Palletank®, check that the internal surfaces of the Palletank® are dry, smooth and free of any particles that might damage the bag surface.

3. Open the bottom gate(s) (see Fig. 7):
   - Check that the Palletank® does not contain a filled Flexsafe® 3D Bag (failure to follow this instruction may result in product loss).
   - Unlatch the retaining clip from the fastening point on the jaw of the gate.
   - Grasp the mobile side of the gate and swing the bottom gate completely open.



1. Swinging portion of bottom gate
2. Fixed portion of bottom gate
3. Retaining clip fastening point
4. Retaining clip

Fig. 7: Bottom gate closed | Bottom gate opened

3.2 Flexsafe® 3D Bag Installation, 100L, 200L, 500L

1. Obtain a packaged Flexsafe® 3D Bag of the appropriate size and position it on a smooth table with no sharp angular corners.

CAUTION

– If you are using a Palletank® for Shipping, the bag size matches Palletank® size for all bags including the 100L.
– For all other Palletank® types a 100L Flexsafe® 3D Bag should be used with a 200L Palletank® as they share the same footprint.

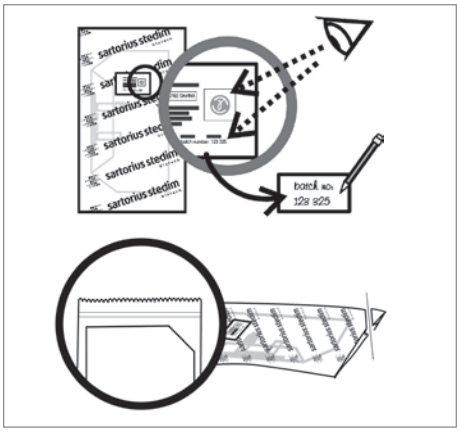


Fig. 8: Preparation of the Palletank®

2. Check that the irradiation indicator on the label is red to indicate irradiated product. Record the batch number of the bag (as seen on the product label) (see Fig. 8).

3. On a table, position the bag so that both the bottom port and the 4-port system are facing you with the bottom port underneath. This correct positioning will ensure a proper insertion of the Flexsafe® 3D Bag in the Palletank®.

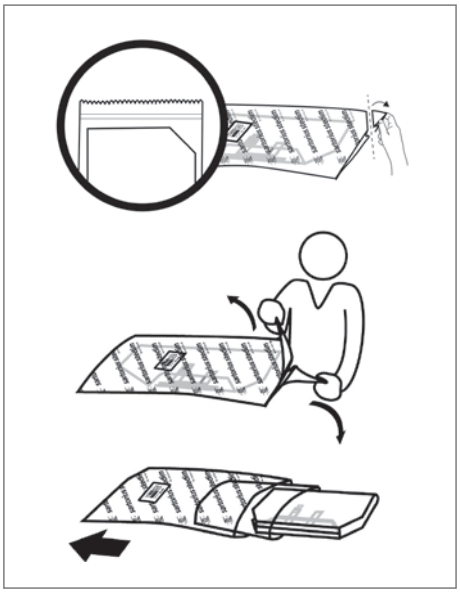


Fig. 9

4. To open and remove the secondary (external) packaging (see Fig. 9):
   – Tear open one of the corners and open completely by tearing along the weld.
   – Remove the secondary packaging by sliding it away from the Flexsafe® 3D Bag.

5. Check that the Flexsafe® 3D Bag secondary packaging is free from any damage that could compromise the sterility.

6. Repeat the 4. and 5. steps for the primary (internal) packaging.

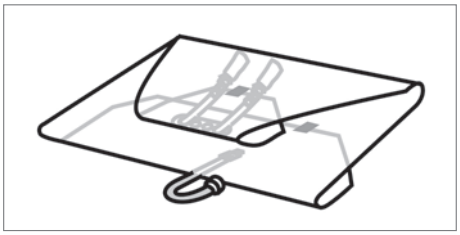


Fig. 10

7. Unfold the bag and remove any adhesive tape or protective foam from the Flexsafe® 3D Bag (see Fig. 10).

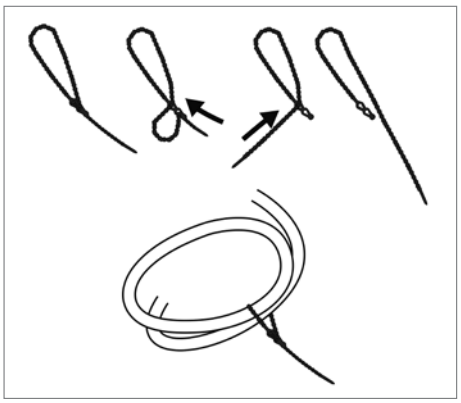


Fig. 11

8. Remove the reversible cable tie on the bottom line (see Fig. 11).

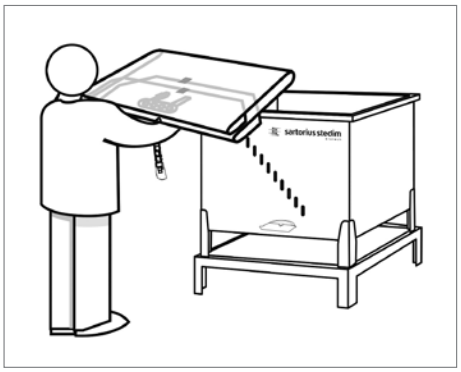


Fig. 12

9. To position the bag inside the Palletank® (see Fig. 12):
   - Hold the folded bag on both arms with the 4-port system uppermost, facing the user and the single (bottom) port underneath
   - Position yourself on the side of the Palletank® closest to the bottom gate

▷ If you are using the Palletank® for In-Process Fluid Handling
   - Insert the folded bag in the Palletank® by the front opening in such a way that the bottom port is positioned towards the bottom gate.

▷ If you are using any other Palletank®, insert the folded bag by the top of the Palletank® in such a way that the bottom port is positioned towards the bottom gate.

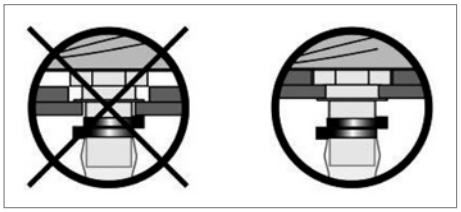


Fig. 13

10. Insertion of the bottom port tube in the bottom gate:
    - Carefully feed the bottom drain line through the Palletank® bottom gate using two hands to ensure the line does not reach the floor.
    - Maneuver the bag bottom port so that the groove in the bottom port is inserted with the fixed portion of the bottom gate. (see Fig. 13).
    - While holding the bottom port firmly, close the mobile jaw of the gate. Ensure that the groove of the bottom port is captured by both halves of the gate to prevent movement of the bottom port during filling. (see Fig. 14).
    - Latch the bottom gate to secure the bottom port within the gate.
    - The port should be snug in the gate and not have room for movement. Check that the bottom port is properly seated in the bottom gate by firmly but gently tugging on the bottom port and checking for movement. If the bottom port appears to have freedom of movement, repeat step 10.

11. Unfold the bag and drape the 4-port system and the top tubing onto the Palletank® front wall.

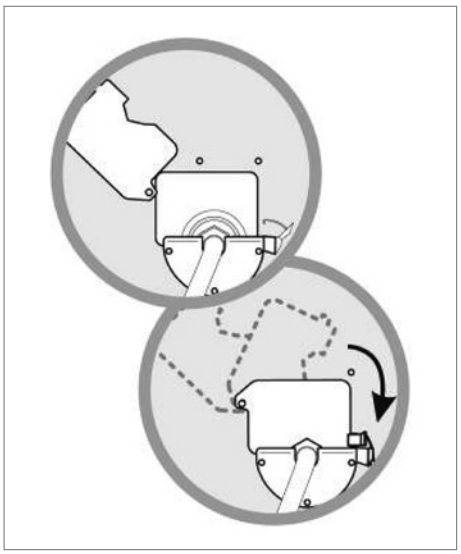


Fig. 14

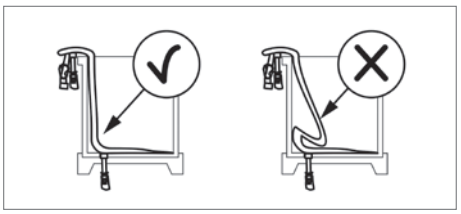


Fig. 15

12. Ensure that the corners of the bag are in contact with the front corners of the Palletank® so that the bag will take the shape of the Palletank®. (see Fig. 15).

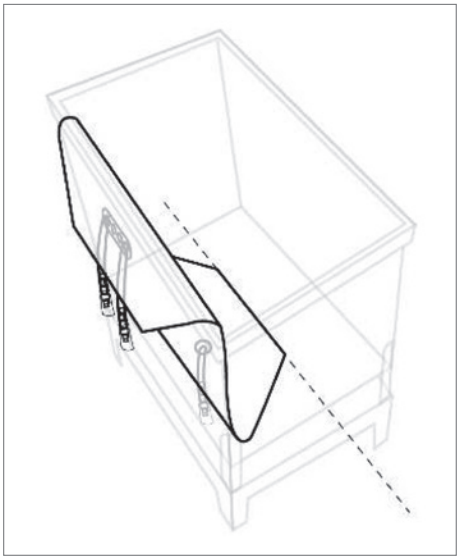


Fig. 16

13. Check that the K-seal of the Flexsafe® 3D bag is correctly positioned along the centerline of the Palletank® and parallel to the front and back of the container (see Fig. 16).

14. Remove the reversible cable tie(s) on the top lines (see Fig. 11).

Fig. 17

15. Position all clamps as close as possible to their bag ports, remove their protection cap and close all of them (see Fig. 17).

3.3 Filling of 100L, 200L and 500L Flexsafe® 3D Bags

Sartorius Stedim Biotech recommends filling through the top ports of bags.

1. Check that all clamps are closed (see Fig. 17).

2. Connect the bag to the supply line in accordance with the aseptic procedures used on your site.

CAUTION

If you are using the Palletank® for In-Process Fluid Handling and filling through the top, be particularly careful not to connect any tubing through the front doors.

Fig. 18

3. Open any clamps on the filling line (see Fig. 18).

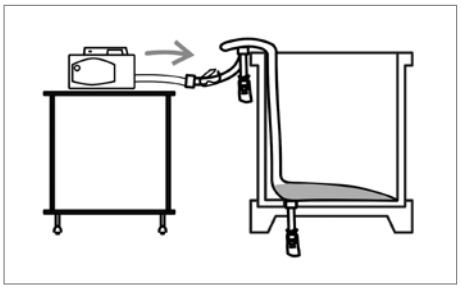


Fig. 19: Flexsafe® 3D Bag filling

4. Start to fill the Flexsafe® 3D Bag – Sartorius Stedim Biotech recommends the use of peristaltic pumps for filling and dispensing from the bag (see Fig. 19).

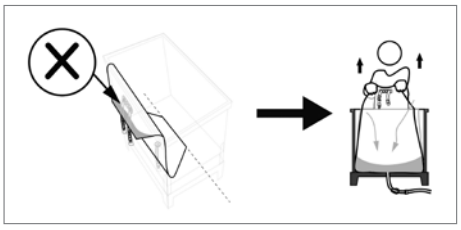


Fig. 20

CAUTION

– As the bag fills, make sure the liquid not get entrapped into the bag fold. Regularly lift the bag from the top to have the liquid falling at the bottom of the Palletank® (see Fig. 20)
– As the bag fills, make sure that no tubing becomes trapped between the bag and the Palletank®

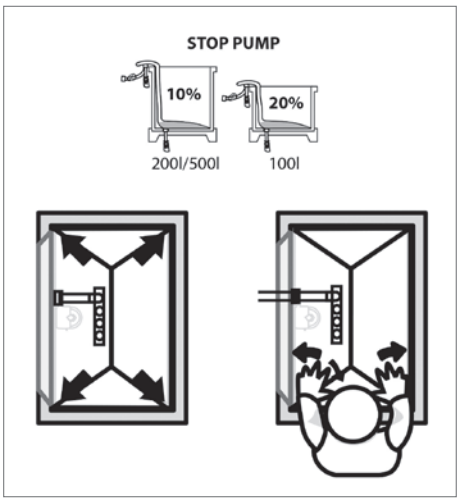


Fig. 21

5. After 10% of the bag's nominal capacity for 200L and 500L or 20% of the bag capacity for the 100L, stop the filling and perform the following steps (see Fig. 21):
   - Remove the top port of the bag from the front side of the Palletank® and allow it to sit freely within the Palletank®
   - Manually adjust each bag corner to its appropriate position
   - If you use the Palletank® for In-Process Fluid Handling, close the hinged front doors and secure the four locking systems.

Sartorius Stedim Biotech recommends the use of the Self Deploying accessory which eases the installation and the filling of the Flexsafe® bag, saves operator time and eliminates risky bag manipulations post installation. As the bag fills, the Deploying Accessory removes all tension from the top of the bag by allowing the top tubing to gradually slide along the Accessory allowing for a reproducible and effortless bag deployment to its appropriate position within the Palletank® for Storage and In-Process Fluid Handling. Please contact your sales representative for further details.

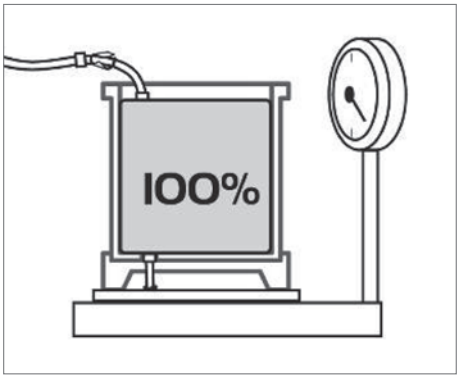


Fig. 22

6. Fill the bag to its nominal capacity (see Fig. 22) and stop the filling.

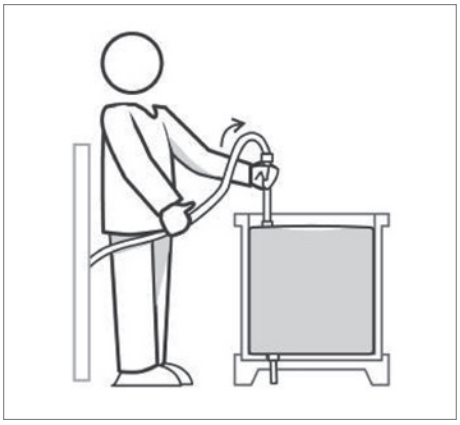


Fig. 23

7. If you have chosen to fill through the top, empty the liquid contained in the filling line into the bag by raising the tube vertically over the bag (see Fig. 23).

8. Close the clamps (see Fig. 17) and disconnect the filling line.

3.4 Emptying Flexsafe® 3D Bags 100L, 200L and 500L

Sartorius Stedim Biotech recommends dispensing through the bottom.

1. Connect bottom tubing line to receiving system according to standard procedures for your site.

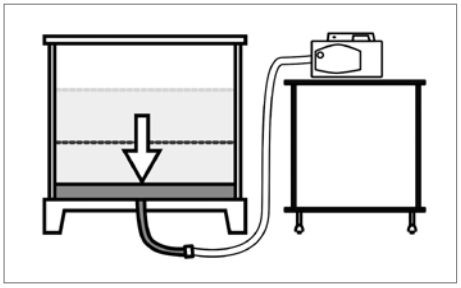


Fig. 24

2. Open any clamps on the draining line (see Fig. 18). Drain the bag – gravity can be used, but for faster draining and maximum product recovery, Sartorius Stedim Biotech recommends the use of a peristaltic pump (see Fig. 24).

3. The bag collapses as it is drained. The sloped bottom of the Palletank® and the position of the drain hole provide nearly 100% fluid recovery. This efficiency can be improved by lifting the bag at the end of the operation (see Fig. 25).

4. Once dispensing is completed, clamp the line (see Fig. 17) and disconnect the Flexsafe® 3D Bag from the receiving system.

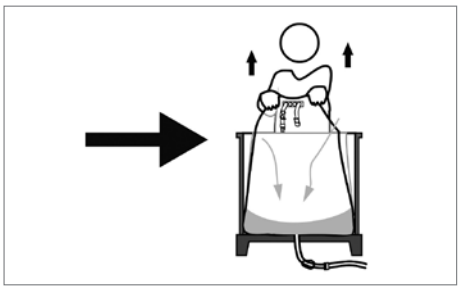


Fig. 25

5. Unlatch and open the bottom gate (see Fig. 7).

6. Lift the collapsed bag and remove it from the Palletank®.

7. Discard the Flexsafe® 3D Bag in accordance with the procedures used on your site.

4. Troubleshooting Guide

The bag will not fill.

▷ Check that any clamps on the filling line are open and that the tubing is not pinched.

When filling through the bottom, the bag comes out of the bottom gate.

▷ The edge of the jaw is not closed inside the groove of the bottom port. Position it correctly in the groove as described in step 10 of the installation procedure.

The bag looks very full before reaching the nominal volume:
The bag is most likely inserted backwards into the Palletank®.

▷ If possible given the volume in the bag, open the bottom gate, spin the bag 180° around the bottom gate and close the bottom gate. Examine Figures 15 & 16 for proper bag positioning. It is critical that the bottom seam of the bag be along the centerline of the Palletank® for proper deployment.

The bottom of the bag is incorrectly positioned.

▷ Place the corners of the bag in the corners of the Palletank® (make sure that only 10% of nominal capacity for 200L | 500L and 20% of nominal capacity for 100L is filled before adjusting; otherwise bag failure may occur).

Many folds appear in the bag during filling.

▷ The bag is too big for the Palletank®, verify the bag size from the outer packaging and use the bag suitable for the size of the Palletank®.

The bag does not reach the walls of the Palletank®.

▷ The bag is too small for the Palletank®. Verify the bag size from the outer packaging and use the bag suitable for the size of the Palletank®.

The bag will not drain.

▷ Check that any clamps on the drain line are open and that the tubing is not pinched.

5. Precautions for Use

- To ensure trouble-free operation, the Sartorius Stedim Biotech Flexsafe® 3D Bag must be used with the Sartorius Stedim Biotech Palletank®.
- The Palletank® must be clean and dry before inserting the Flexsafe® 3D Bag. Traces of cleaning agents left on the Palletank® can potentially damage the Flexsafe® 3D Bag.
- It is the user's responsibility to verify the compatibility of the Flexsafe® 3D Bag materials with the solutions used in his | her process. Sartorius Stedim Biotech can provide guidelines for chemical compatibility, biocompatibility and extractables.
- Avoid the use of sharp objects (scissors, cutters, scalpels, etc.) in the vicinity of the Flexsafe® 3D Bag.
- The Flexsafe® 3D Bag should never be handled or carried by its connections (i.e. tubing).
- Avoid folding the Flexsafe® 3D Bag other than using the original folds provided.
- When positioning the Flexsafe® 3D Bag in the Palletank® and during any adjustments after the initial fill, handle the bag with care and use appropriate force. Avoid pulling with your full strength. If such strength is required, it is likely inappropriate to adjust the bag at this time due to the fill volume.
- The Flexsafe® 3D Bag is designed for single-use and should not be re-used.

6. Flexsafe® 3D Bag Storage Conditions

Flexsafe® 3D Bags should be stored in their original primary packaging at room temperature (5°C to 40°C), in a dry environment.

7. Shelf Life of a Flexsafe® 3D Bag

The shelf life after gamma sterilization has been validated as indicated on the labelling (product packaging and case) and in the specifications. Details are available from Sartorius Stedim Biotech upon request.

8. Product Complaint

When is a complaint justified?
When a deficiency related to the safety, quality, identity or purity or a deficiency in providing a service is identified on a marketed product.

To whom should the complaint be sent?
To your Sartorius Stedim Biotech commercial contact or distributor.

How and which information should be conveyed?
A complaint form will be provided by your Sartorius Stedim Biotech commercial contact and should be returned by e-mail, fax or letter with the following information:

- the bag or bag system product part number and lot number
- the description of the issue
- the description of the process in which the issue was detected
- the amount of products affected
- samples (or pictures if no samples are available)

If samples are returned, they must be empty, rinsed and decontaminated (if applicable). They must be returned with the signed the Health and Safety part of the complaint form.

9. Disclaimers

1. Sartorius Stedim Biotech Flexsafe® 3D Bag is for single-use only. Sartorius Stedim Biotech will not assume any responsibility of any kind if the Flexsafe® 3D Bag has been re-used.

2. Sartorius Stedim Biotech will accept no responsibility for the use of Flexsafe® 3D Bags with any containers other than Sartorius Stedim Biotech Palletank®.

3. Sartorius Stedim Biotech will not assume any responsibility if the Flexsafe® 3D Bag instructions for use as described in this document are not strictly followed and the above mentioned Precautions for Use are ignored. Upon request, Sartorius Stedim Biotech Application Specialist can provide training to any interested end users.

4. Sartorius Stedim Biotech will not be responsible for any special, incidental or consequential damages resulting from any legal theory, including lost profits, downtime, goodwill, damage to or replacement of equipment or property.

10. Warranty

Sartorius Stedim Biotech warrants that the Flexsafe® 3D Bag is produced according to specifications. Unless otherwise provided for in specifications that are individually agreed upon, the general Sartorius Stedim Biotech specifications will apply. In the case of a defective bag, please follow the above-mentioned Product Complaint Procedure.

11. Trademark

Flexsafe® and Palletank® are registered trademarks of Sartorius Stedim Biotech.

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