



Life Sciences

Instructions For Use

USD3194

Stainless Steel Mix Tanks

For use with the LevMixer[®] and Magnetic Mixer Single-Use Mixing Systems

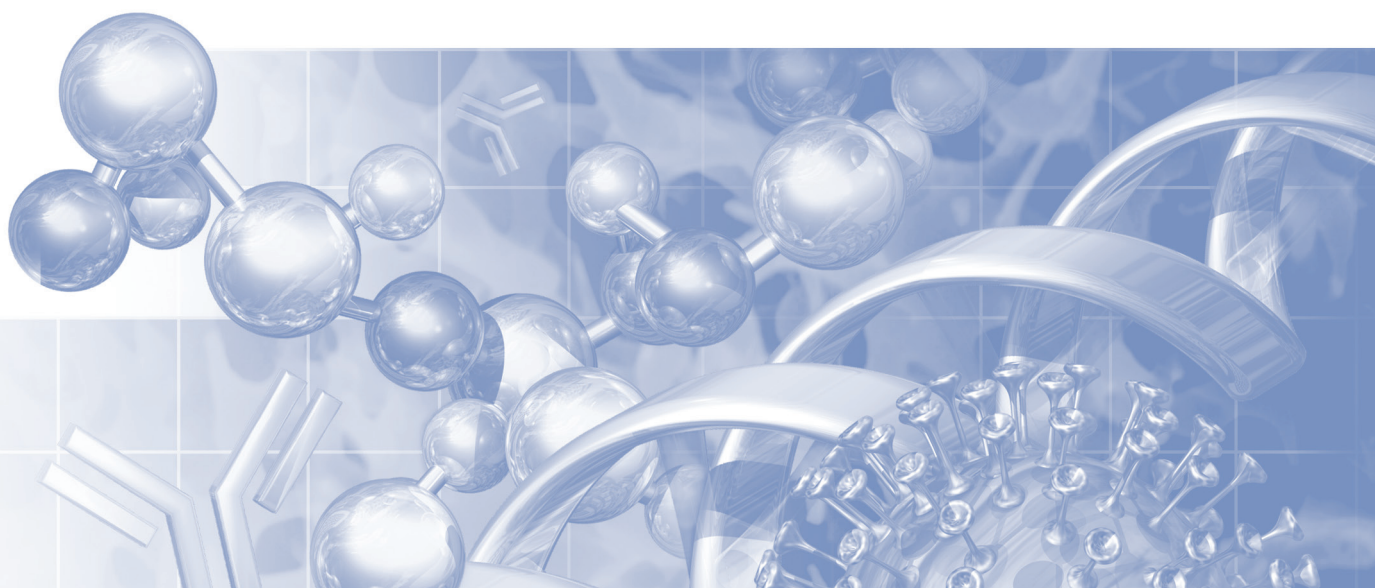


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A. Safeguards and Precautions



1. Read and follow all instructions in this manual carefully, and retain this manual for future reference
2. Do not use this equipment in any manner inconsistent with these operating instructions or under any conditions that exceed the environmental specifications stated.
3. Be sure the power supplied to this equipment matches the specifications indicated on the control box and described on the Copy of Equipment Nameplate page.
4. If the unit is transported or stored in temperatures colder than the operating environment it is necessary to wait 1-2 hours to equalize the internal temperatures of the unit before powering on.
5. Be sure all power is disconnected before opening, assembling or disassembling the control box.
6. For full compliance with CE specifications, be sure the appropriate ground connection is made.
7. For technical assistance contact the sales organization from which you purchased the product or Pall Life Sciences directly.
8. Each LevMixer and Magnetic Mixer mixing biocontainer contains a magnetic impeller, which is a source of strong magnetic field within close proximity 30.5 cm (12 in.) of the impeller. PEOPLE USING ANY ELECTRONIC MEDICAL DEVICES, SUCH AS PACEMAKERS, SHOULD NOT BE INVOLVED IN THE CLOSE HANDLING OF MAGNETIC MIXER DRIVE, LEVMIXER OR MAGNETIC MIXER MIXING BIOCONTAINERS, MAGNETIC CHARGERS, IMPELLERS OR TEST IMPELLERS.
9. Keep the supplied magnetic shields on biocontainers, magnetic chargers, and impellers when not in use.



10. DO NOT open the control box while the unit is plugged in.
11. DO NOT submerge the unit in water. The unit outer surfaces may be cleaned and sanitized by wiping with a mild detergent solution.
12. DO NOT cut the ground plug.

B. Specifications

Table1

*Specifications sheet**

Footprint, mm (in.) W x L	30 L round	889 x 813 (35 x 3)
	50 L round	889 x 813 (35 x 32)
	100 L round	889 x 813 (35 x 32)
	200 L round	1270 x 1143 (50 x 45)
	350 L round	1320 x 1270 (52 x 50)
	500 L round	1168 x 1041 (46 x 41)
	1000 L round	1397 x 1194 (55 x 47)
	2000 L round**	1778 x 1600 (70 x 63)
	2500 L round**	1778 x 1600 (70 x 63)
Tank, framing and cabinet material	304 L stainless steel	
Tank external surface finish	Brush polished	
Surface roughness	Internal: Less than 35 µin. Ra / 0.89 µm Ra External: Less than 47 µin. Ra / 1.2 µm Ra	
Welds	Polished smooth, per EN ISO 5817 – quality level D	
Casters	2 x locking swivel, 2 x fixed	
Wheel material	Polyurethane	

Jacketed Models

Jacket type	Dimpled, insulated	
Jacket rating	Max 6.2 bar @ -5/90 °C / Max 90 psig @ 23-194 °F	
Jacket connectors	Threaded female 1 in. BSPP, 1 in. NPT, ½ in. BSPP or ½ in. NPT (see applicable tank drawing for details)	

Models with Load Cells

Number of load cells	3 (mobile tanks) or 4 (fixed location tanks)	
Operator interface type	LCD display, membrane keypad	
Control box ingress rating	IP 65	
Voltage	100-230 VAC	
Maximum humidity	85%, avoid condensation	
Ambient temperature	4-40 °C	
Power cord length	600 cm (20 ft)	
Power cord plug options	US, EU, Australia, Switzerland, UK	
Signal type(s) for remote output	4-20 mA	

* For customized tanks, please refer to applicable tank drawing for exact specifications.

**Note: 2000 L and 2500 L round tanks for use with Magnetic Mixer only

Table 2*Recommended Working Volumes*

Tank Description	Minimum Working Volume *	Maximum Working Volume
30 L round	9.6 L	30 L
50 L round	14 L	50 L
100 L round	22 L	100 L
200 L round	40 L	200 L
350 L round	40 L	350 L
500 L round	40 L	500 L
1000 L round	74 L	1000 L
2000 L round	139 L	2000 L
2500 L round	139 L	2500 L

* This is the smallest volume of liquid that Pall recommends be mixed in the tank. It is defined as being the volume at which the impeller is JUST covered by the liquid; below this volume, the impeller will be at least partially exposed.

C. Overview

Standard mix tanks described in this manual are designed for use with the LevMixer and Magnetic Mixer systems and associated biocontainers.

The standard mix tanks have 4 available configurations:

1. Standard
2. Standard with load cells
3. Standard jacketed
4. Standard jacketed with load cells

Additional options include monitoring probe supports and closed-loop heater/chillers for temperature control.

The mixing system can accommodate a variety of standard and custom-designed single-use mix biocontainers available from Pall Life Sciences.

These tanks are not designed to be compatible with other mixing technologies nor with biocontainers supplied by other manufacturers. Modification of these tanks without prior authorization from Pall will immediately void the warranty.

D. Unpacking and Set Up for First Time Use

The tank ships in a wooden crate. Carefully open the crate, remove the tank, and position it in the desired working location. The crate should be retained for use in the event that the tank has to be shipped in the future.

Tanks fitted with a heating/cooling jacket may be connected to an external supply of heating/cooling fluid. Available connection types are female 1 in. BSPP, 1 in. NPT, ½ in. BSPP or ½ in. NPT (see applicable tank drawing for details).

Mobile tanks fitted with integral load cell systems incorporate three (3) load cell assemblies and a weight indicator unit. These tanks should be located on a level surface and have their casters locked prior to use.

Fixed location tanks fitted with integral load cell systems incorporate four (4) load cell assemblies and a weight indicator unit. These tanks should be securely bolted to a level surface in accordance with all local Environmental Health and Safety (EH&S), building and seismic regulatory requirements.

Each load cell assembly must be prepared and inspected to ensure correct weighing performance. The following steps are required in preparation for first use (NOTE: exact load cell and mounting kit design and orientation may vary from those shown – consult the documentation provided with your tank for details of your particular configuration):

1. Use the provided Allen wrench to remove the shipping plate from each of the load cell assemblies (Figure 1). The plates and bolts should be retained for use in the event that the tank has to be shipped in the future.

Figure 1

Removing load cell shipping plate

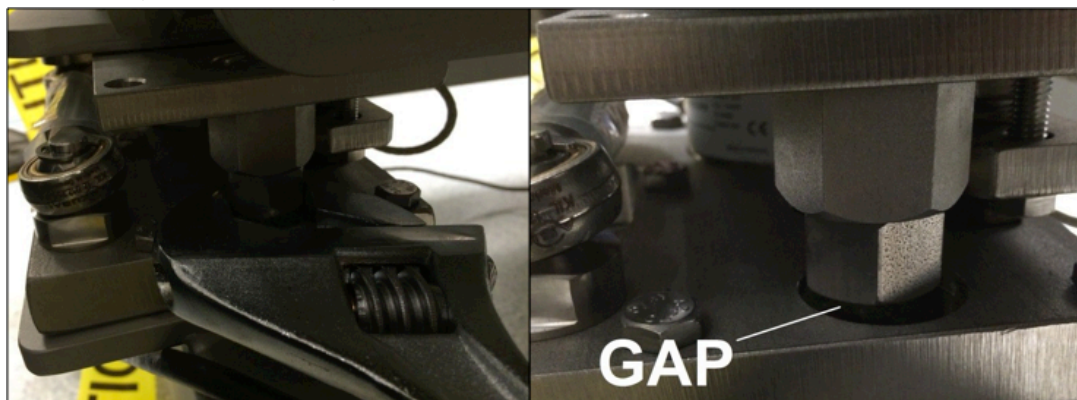


2. While holding each load cell in the correct orientation, use a wrench to fully retract the jack bolt (Figure 2, left image). Confirm that, after retraction, there is a visible gap between the head of the jack bolt and the opposing mounting plate (Figure 2, right image) and that the load cell sits securely in its recess without any looseness or play.

CAUTION: Take care to avoid trapped fingers when installing load cells.

Figure 2

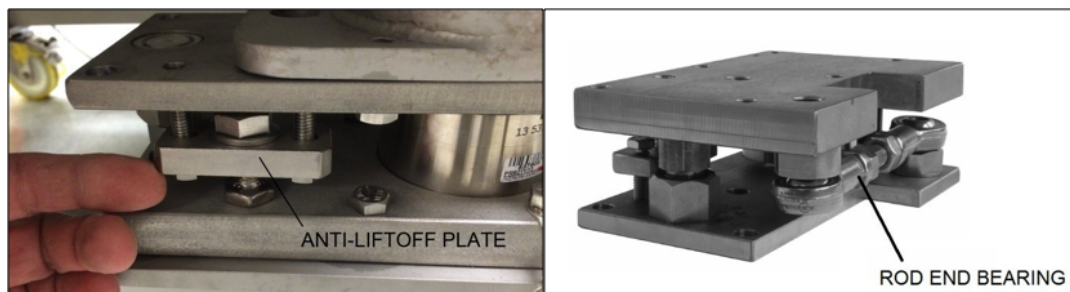
Jack bolt adjustment and inspection



3. Verify that each anti-liftoff plate and rod end bearings (heim/rose joint) move freely (Figure 3). Binding in these assemblies can cause inconsistent weight readings or problems with return to zero.

Figure 3

Anti-liftoff plate and rod end bearing



4. Connect the power cord and secure with the threaded collar (Figure 4).

Figure 4

Attaching the load cell power cord



5. Plug the power cord into the appropriate power outlet. Verify that the load cell indicator responds to applied loads as expected, and that it returns to zero consistently.
6. Each load cell is supplied pre-calibrated with a certificate. Following installation, calibration should be confirmed or repeated according to user organization requirements. Repeat calibration service is available directly from the load cell supplier. Contact Pall for details.

E. Biocontainer Installation

Note: the procedure described below is intended for LevMixer and Magnetic Mixer single-use mixing systems and biocontainers only.

1. Prior to biocontainer installation, inspect the biocontainer-contact surfaces of the tank to ensure they are clean, dry and free from material or defects that might damage the biocontainer surface.
2. If a LevMixer or Magnetic Mixer drive unit is coupled to the tank, remove the drive unit before proceeding.
3. Apply the caster locks to ensure the tank will not move during biocontainer installation.
4. If appropriate, open the chamber access door(s) to allow operators access to the tank interior.

5. Ensure that a drive-biocontainer interface (Figure 5) is installed in the drive port hole on the bottom of the tank. If not, install the interface by inserting it from the bottom and securing it in place using the supplied o-ring. Ensure that the interface is fully engaged in the drive port and that the o-ring is completely installed in the corresponding o-ring channel on the side of the interface (Figure 6).

Figure 5

Drive-biocontainer interface and o-ring

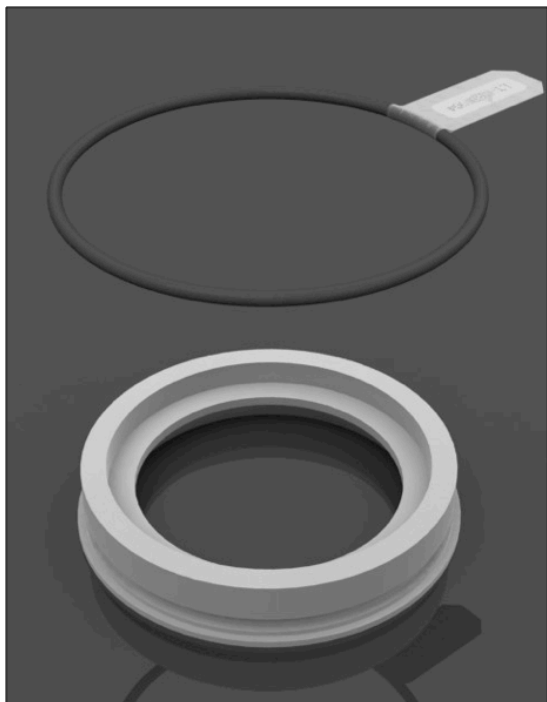
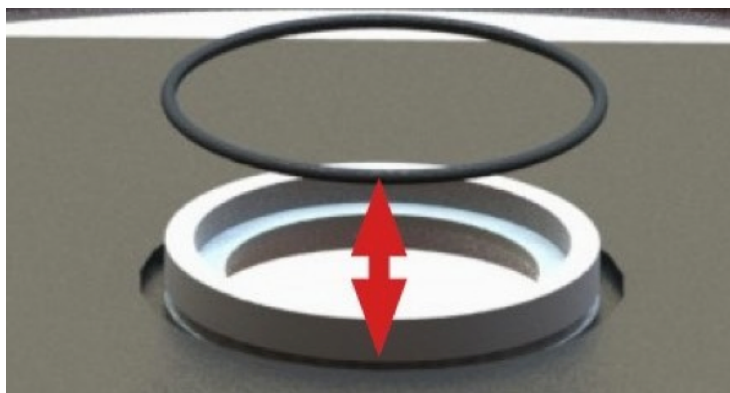


Figure 6

Interface installation in a drive port



6. Locate the magnetic clamp and centering aligner (Figure 7). These parts are required for proper biocontainer installation and alignment. Inspect the centering aligner for damage; if the center hole is deformed, torn or not concentric, discard and replace with an undamaged centering aligner. Assemble the clamp and aligner as shown in Figure 8.

Figure 7

Magnetic clamp (left) and centering aligner (right)

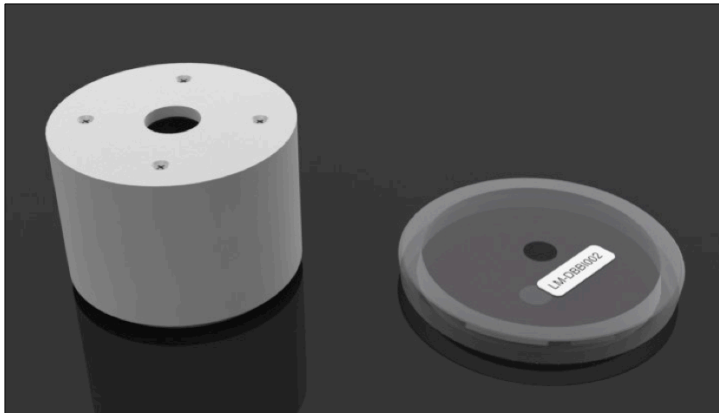
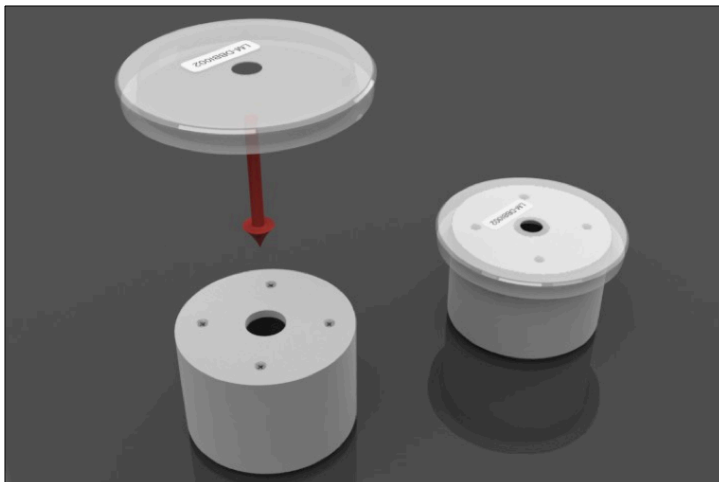


Figure 8

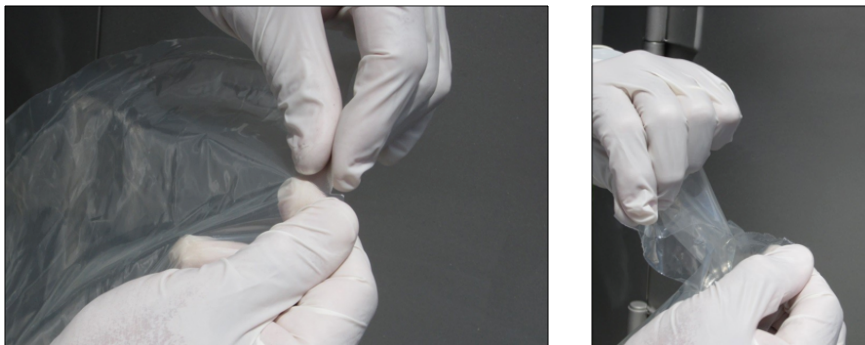
Magnetic clamp assembled with centering aligner



7. Select a LevMixer or Magnetic Mixer single-use mixing biocontainer according to the drive type you plan to use. BIOCONTAINER AND DRIVE UNITS ARE NOT INTERCHANGEABLE. Verify the correct article code and expiration data. Remove the outer and inner packaging by tearing open at the Easy Tear notch (Figure 9) - DO NOT USE SCISSORS OR OTHER CUTTING IMPLEMENTS. Retain the label from the inner packaging according to the user organization's Quality policies.

Figure 9

Opening packaging bags via the Easy Tear notch



8. Visually inspect the biocontainer for shipping damage or imperfections; cuts, tears or punctures; film cracks that are externally rough/sharp to the touch (note: white creases that are not sharp to the touch are typically not a cause for concern); impeller detached from impeller seat/post; kinked tubing that cannot be unkinked; damaged, missing or detached subcomponents. If any such imperfections are discovered, contact Pall or the user organization's Quality group for advice on whether the biocontainer should be used.
9. A blue shipping disc is magnetically attached to the outside of the biocontainer, over the impeller seat. Remove the blue shipping disc (Figure 10) (retain this item; it will be used to secure the impeller during subsequent biocontainer disposal). Place the magnetic clamp/centering aligner assembly over the impeller seat, ensuring the hole in the centering aligner lines up with the post on the seat. The clamp will be magnetically attracted to the impeller, and will secure the assembly to the impeller seat when properly installed (Figure 11).

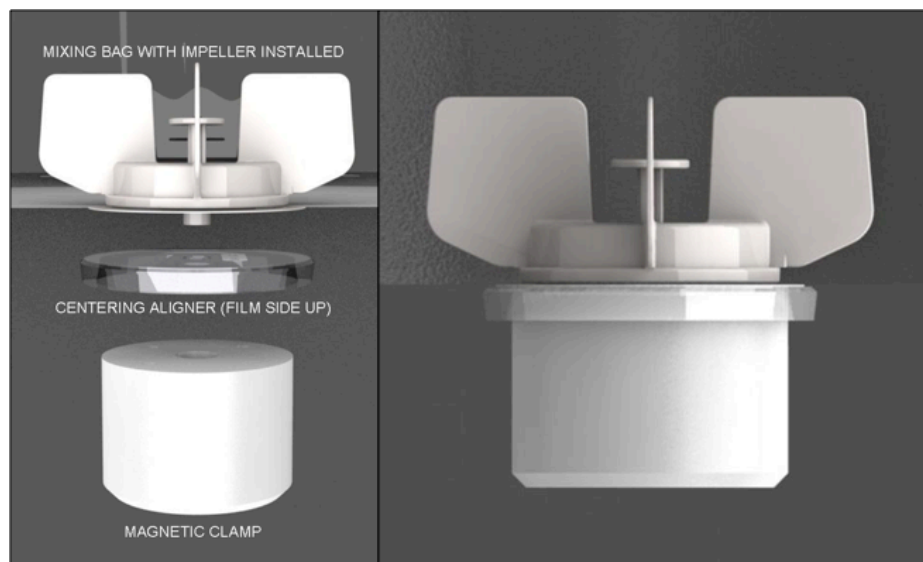
Figure 10

Removing the shipping disc



Figure 11

Assembly of biocontainer with magnetic clamp/aligner assembly



10. Place the biocontainer into the tank, ensuring the magnetic clamp/centering aligner are inserted through the drive-biocontainer interface at the bottom of the tank (Figure 12).

Figure 12

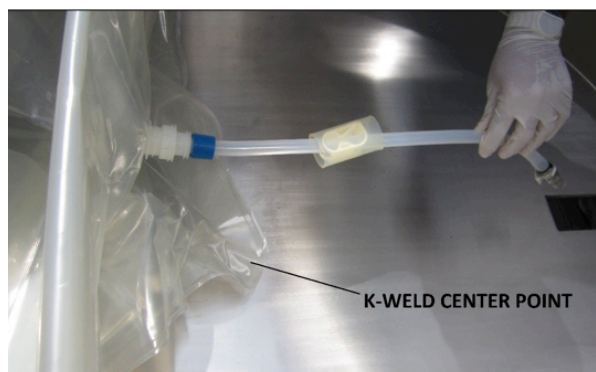
Aligning magnetic clamp with drive-biocontainer interface



11. Locate the bottom drain hose (if fitted) and orient it towards the drain port cutout of the tank (Figure 13). In the case of biocontainers 350 L and larger, position the biocontainer so that the center point of the “K-weld” is aligned with the center of the tank. Do not pull on the drain line if it is too short to reach – it will deploy naturally and align with the cutout as the biocontainer is filled.

Figure 13

Orienting the biocontainer K-weld and drain hose



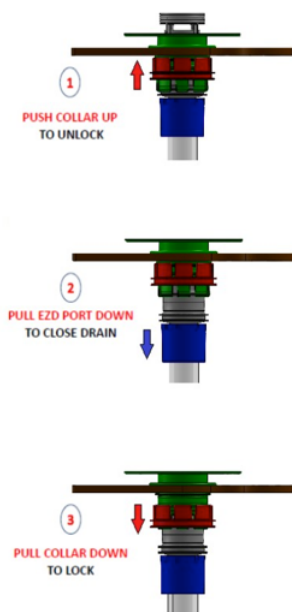
12. Align any side sample ports, sensors and/or tubing with the corresponding port cutout on the side of the tank, and pull the tubing through the cutout. Ensure the ports, sensors and/or tubing are properly aligned for clear access, and that the tubing is not pinched or kinked.
13. Before filling the biocontainer, ensure that all tubing clamps on the bottom and side biocontainer outlets are securely closed.
14. If the biocontainer incorporates an EZ Drain fitment, confirm that the drain is fully closed (slide the locking collar up, pull down firmly on the blue BarbLock[®], then slide the locking collar down). Position the EZ Drain fitment in the drain port cutout, then snap the EZ Drain clip over the fitment OUTSIDE the tank (Figure 14). NOTE: In the case of biocontainers being installed in tanks larger than 200 L, the drain fitment may not initially align fully with the drain port cutout; in such circumstances, carefully guide the drain fitment into position during the filling/inflation step.

Figure 14
EZ Drain clip



15. Tanks of 1000 L and larger capacity may be provided with a biocontainer hoist system (consult the documentation provided with your tank for details of your particular configuration). Hoist systems work only with biocontainers featuring grommet lift points. To use, lower the hoist gantry to its lowest position, attach to grommets using provided clips, then raise the hoist gantry to deploy the biocontainer.
16. OPTIONAL: Prior to filling with liquid, an inert gas or air may be introduced through one of the top ports (hose or powder port) to pre-inflate the biocontainer for easier handling – this can be particularly beneficial for process scales above 200 L. Pre-inflation for a contained or sterile application should be done only via a sterilizing-grade vent filter integral to the biocontainer.
17. OPTIONAL: A tank-specific powder port support device (available from Pall – see Section I) may be used to secure the biocontainer in position during the biocontainer deployment and filling process.
18. OPTIONAL: Any sensors (pH, temperature probe etc.) should be installed before filling the biocontainer.
19. Start filling the biocontainer per process requirements. If the biocontainer has been pre-inflated with gas or air, make sure that at least one top port is open to act as a vent for the displaced air to avoid the risk of over-pressurization. Venting for a contained or sterile application should be done only via an adequately sized sterilizing-grade vent filter integral to the biocontainer.
20. During the filling process, gentle adjustments to the biocontainer orientation may be made until 20% of maximum volume or 50 L (whichever is smaller) of liquid has been added. Avoid using excessive force during biocontainer adjustment to prevent inadvertently damaging the biocontainer assembly. Minor wrinkles generally do not impact mixer performance.
21. In the case of larger tanks with access doors, the doors should be securely latched closed before the liquid level reaches their sills. Appropriate precautions should be taken to ensure the tank doors are not opened while the biocontainer is full.
22. Continue filling the biocontainer to the desired level. **DO NOT EXCEED RECOMMENDED BIOCONTAINER CAPACITY** (see Table 2). Stop filling the biocontainer once its top is flush with the top of the tank, or if it appears close to fully inflated. Take care not to over-inflate the biocontainer.
23. Once filled, the tank should not be moved.
24. When the EZ Drain is part of the single-use mixer biocontainer design, follow the instructions below to operate the valve correctly:

Figure 15
EZ Drain operation



25. For drainage and disposal guidelines, see section H.

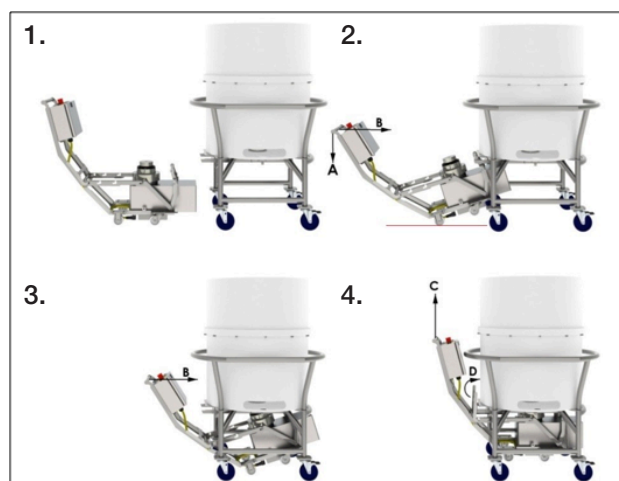
F. Coupling the Drive Unit to the Tank

Coupling of the drive unit to the tank should be performed only when the installed biocontainer is filled with fluid to at least the minimum working volume. No coupling should be attempted with an empty or dry biocontainer as the impeller may damage the biocontainer.

1. Remove the magnetic clamp (Figure 11) from the biocontainer-tank assembly before coupling the drive. To remove the magnetic clamp, reach underneath the drive port and carefully pull the magnetic clamp downwards until it is free from the biocontainer-tank assembly.
2. Make sure that the drive unit has a latch installed in the correct position to match the rail port intended for connection. See the drive user manual for corresponding latch and port positions.
3. Carefully press down on the drive handle and raise the front wheels off the ground (as shown on the second step of Figure 16)
4. Align the guide bearings on the drive port with the tank guide rails.
5. Roll the drive unit along the rails all the way until the bearings rest in the notch located at the end of the rails.
6. Using the drive unit handle, lift the drive unit to a horizontal position. While holding the drive unit in this position, pivot the latch toward the tank so that the cross bar rests on the hooks in the guide rails (as shown in the fourth step of Figure 16).

Figure 16

Coupling of drive unit to tank (LevMixer drive unit shown)



CAUTION: Do not attempt to move the tank by pulling/pushing the handle of the installed drive unit as this action may damage the drive unit. The tank should only be moved using the tank handle, and only with the tank/biocontainer empty and the drive detached.

G. Biocontainer Drainage and Disposal

After the mixing process is completed, the biocontainer's content may be drained and the empty biocontainer responsibly disposed of. The following general guidelines apply, and should be used in conjunction with all safety and environmental regulations appropriate for the process and location.

1. To discharge the biocontainer, connect the drain hose to an appropriate receptacle then open the drain tubing clamp. If fitted, the EZ Drain valve should be opened by sliding the locking collar upwards until it clicks, then pushing up on the blue BarbLock.
2. After the biocontainer has drained, any residual liquid can be recovered by gently lifting the biocontainer so as to direct the residual liquid to the drain.
3. Close all clamps and detach the biocontainer from all external connections, detach the mixer drive, remove the EZ Drain clip (if used) then carefully lift the empty biocontainer out of the tank.
4. Place the shipping shell/disc (removed during biocontainer installation) over the impeller fitment to secure the impeller and prevent it from being attracted to external steel objects.
5. Dispose of the biocontainer according to applicable EH&S policies and regulations. Incineration is a popular method of disposal because the temperatures involved will de-magnetize the impeller and shipping disc.

H. Maintenance and Care

Mixing tanks are designed to operate with minimal maintenance.

To clean, wipe down the tank surfaces using water and a mild detergent solution. Standard tanks are constructed from 304-alloy stainless steel, which may be vulnerable to corrosion if exposed to corrosive chemicals or if left in persistent contact with moisture. Appropriate precautions should be taken to prevent such corrosion. If corrosive conditions are routinely anticipated, end users should consider opting for tank systems constructed from 316-alloy stainless steel (available from Pall upon request).

It is recommended that heating/cooling fluid be drained completely from the jacket (if fitted) before transporting or storing the tank for long periods of time.

Tanks with integral load cell systems should be periodically checked for correct operation in accordance with the user organization's Quality policies.

Return the tank to its original crate, with supplied bracing in place, prior to shipping.

Periodic maintenance is recommended to keep the tank in reliable working condition. Recommended preventive maintenance procedures are listed in Table 3.

Table 3

Preventive maintenance procedures

Description	Frequency	Spare parts involved	Who performs
Load cell calibration	At least annually	None	Service or Metrology

I. Spare Parts and Standard Accessories

Table 4

Spare parts and accessories

Description	Catalog number
Drive-biocontainer interface	LT-DBBI009
Interface o-ring	LT-DBBI004
Centering aligner	LT-SVSP304
Magnetic clamp type 2	LT-SVSP309
Power cord:	
US	LT-SVSP365
EU	LT-SVSP366
AU	LT-SVSP367
SW	LT-SVSP368
UK	LT-SVSP369
Powder bag support:	
750 mm (29.5 in.) ID round	LM-SVSP039
1400 mm (55 in.) ID round	LM-SVSP040
Powder port support:	
445 mm (17.5 in.) ID round	LM-SVSP057
545 mm (21.5 in.) ID round	LM-SVSP058
750 mm (29.5 in.) ID round	LM-SVSP032
1015 mm (40 in.) ID round	LM-SVSP060
1400 mm (55 in.) ID round	LM-SVSP041

J. Service

The mixing tank was developed exclusively for mixing fluids, and solids in fluids, in specially designed disposable biocontainers. The tank should only be used for this purpose to ensure a long service life.

In the event that servicing is required for your mixer tank, Pall can provide this option through our Pall Advanced Separation Systems (PASS) Service team. Please contact your Pall representative to arrange for a service quotation if required.

K. Scientific and Laboratory Services

Pall operates a technical service to assist in the application of all of its products. This service is readily available to you and we welcome your questions so that we can help. In addition, a full network of technical representatives is available throughout the world.

L. Warranty

Pall warrants that the Allegro™ systems manufactured by Pall, when properly stored and installed, and operated as per the specifications and design conditions stated in this document will be free from defects in material and workmanship during their shelf life. Pall liability under any warranty is limited solely to replacing, or issuing credit for the Allegro systems that may become defective during the Warranty Period.

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