

Avanços e inovação em aplicações Single Use

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Connecting People, Science and Regulation®



What's new?





11 Years ago we launched the SUB...





We have launched a SU Heat Exchanger







Keep pushing boundaries

- Find new opportunities
- Listen to the customers
- Customize
- Open architecture



Microcarrier Separation





A bag within a bag









Single-Use Fermentor





What's new



S.U.F. drilled Hole Sparge designed for high O₂ transfer with strong mixing

- 30L 1xDHS 25 holes at 0.062"dia (1.58mm)
- 300L 2xDHS 25 holes at 0.062"dia (1.58mm)





5:1 SUB

best performance, reliable scale-up



consistent O2 transfer & CO2 removal







Freezing Applications: Current Situation



Situation

- Many BioProduction processes require freezing for stability in the manufacturing process.
- Industry reports indicate as high as 50% of biologics are frozen in some step within the manufacturing process.
- Problem
 - Single-use systems currently available in the market are not reliable and have high failure rates.
 - Feedback from the market is a failure rate is as high as 20%.
- Implications
 - Customers are limiting their use of SUT in freezing application.
 - High cost and value product is being destroyed.
- Payoff
 - Provided a integrated cost competitive solution that can provide higher reliability with validated shipping and handling solutions will address many of the unmet needs of the freezing market today.





Acclimate: Frozen Handling System

Active Ingredients

- •Highly valuable
- •Frozen
- Reduce degradation
- Transportation
 - •Kept frozen
 - •Kept safe
- •Time to Freeze
- •Time to Thaw





CX5-14 Glass Transition Temperature ≈ -34.4 C



 The glass transition temperature (Tg) is the temperature at which a polymeric material changes from a viscous or rubbery state to a brittle or glassy state.



Bag inside a hard protective shell







Acclimate features

- Hard shell
- Grooves
 - to lock in place
 - to promote heath transfer
- Stackable





Knuckle design





Does it Freeze/Thaw quickly?



 Freeze and thaw test was performed on 5 of the single trays from each size and film type.
 No damage was observed on any of the bags due to Freeze and thaw test. **Freeze/Thaw**



16-0119 THERMOFISHER SCIENTIFIC FREEZE AND THAW TEST 2L CX5-14 TRAYS RUN # 161207102

REVIEWED BY: AP 19 DEC 2016



Freeze/Thaw



16-0119 THERMOFISHER SCIENTIFIC FREEZE AND THAW TEST 16L CX5-14 TRAYS RUN # 161206TFS1

REVIEWED BY: AP 19 DEC 2016





Qualify a Shipper

• CX5-14 or Aegis5-14 films in Acclimate Systems (2, 6, 12, and 16 L sizes) by:

Specimen Number(s)	Test Specs
5 Trays (all sizes)	Freeze and Thaw Test (-70°C to Room Temp)
3 Pallets (2X4, 2X3 & 1X1 Configurations)	ISTA 3B
3 Pallets (2X4, 2X3 & 1X1 Configurations)	Modified ISTA 7D – 120 Hours

• ISTA International Safe Transit Association

Shipping while frozen



The Acclimate shipping container is an optional solution for users who need to safely transport the frozen applications between separate locations.

The Acclimate shipping container has been tested by a third party test house to:

- ISTA 3B
- ISTA 7D







Does it stay Frozen?

96 hour test

- Maintains below -70C \pm 10C for 96+ hours.
- 30 of each size per frozen shipper system at 100% fill (10 Aegis, 10 CX5-14, 10 EVA 1028).





Does it stay Frozen?

120 hour test

- Maintains below -40°C±5C for 120+ hours.
- 30 of each size per frozen shipper system at 100% fill (10 Aegis, 10 CX5-14, 10 EVA 1028).



Impact Testing-ISTA 3B



Tip/tip over test:

Orientation	Pass / Fail
22 ⁰ on Edge 3 - 5	Pass
22º on Edge 3 - 5	Pass

Rotational edge and corner drop:

Drop Height	Impact Orientation
6 or 9 Inches with	Edge (3 – 6)
the opposite end supported by 3.5"	Opposite Corner (3 – 4 – 5)

Vehicle vibration:

Frequency (Hz)	PSD (g²/Hz)	Frequency (Hz)	PSD (g²/Hz)
1.0	0.00072	25.0	0.0036
3.0	0.018	30.0	0.00072
4.0	0.018	40.0	0.0036
6.0	0.00072	80.0	0.0036
12.0	0.00072	100.0	0.00036
16.0	0.0036	200.0	0.000018
Over-all g	Irms: 0.54	Duration: 1	20 Minutes

- Shock rotational edge and corner drop.
- Shock concentrated impact.
- Shock forklift truck handling.
- Shock mechanical handling.
- Shock impact test.





Acclimate: Frozen Handling System







Acclimate specifications



Nominal volume	2 L	6 L	12 L	16 L
Shell dimensions (L x W x D)	58.4 x 38.1 x 10.9 cm	78.7 x 43.2 x 10.7 cm	74.9 x 52.3 x 10.9 cm	78.7 x 58.4 x 10.7 cm
BPC dimensions (L x W)	32 x 32 cm	57.2 x 38.1 cm	54.6 x 50.8 cm	62.9 x 55.9 cm
Shell and BPC weight (empty BPC)	2.9 kg	4.1 kg	5.32 kg	5.6 kg
Knuckle design quantity	2 (one on each shell)	4 (two on each shell)	2 (one on each shell)	2 (one on each shell)
Shell and clip material	High density polyet	hylene (HDPE)		
BPC material	Aegis™5-14 film: fiv layer is a polyester layer and an ultra-lo	ve-layer, 14 mil cast fi elastomer coextrude ow density polyethyle	Im produced in a cGM d with an ethyl vinyl al ene product contact lay	P facility. The outer cohol (EVOH) barrier yer.
Port specifications	MPC quick-coupling Flex™ 374 tubing	g (polycarbonate with	silicone o-ring) inlet a	nd outlet ports, C-
Cleaning agent compatibility	The container and s room–grade cleane including: isopropy peroxide)	side clip material of co rs l alcohol and Spor-Kle	onstruction are compa enz sterilant (acetic aci	tible with clean d and hydrogen

Acclimate Individual Shipping Systems



The Acclimate shipping container has been designed with durability and environmental control in mind. The Acclimate shipping container is made of mostly recyclable materials. It is constructed with a heavy duty double-walled outer packaging box to provide strength for stacking and built to withstand shipping conditions.

Specifications

Nominal volume	2 L	6 L	12 L	16 L
Dimensions (L x W x D)	76.84 x 56.52 x 39.94 cm	97.16 x 61.59 x 39.94 cm	89.54 x 70.74 x 39.94 cm	97.16 x 76.52 x 39.94 cm
Dry ice requirement	27—29 kg	32—34 kg	39—41 kg	43—45 kg
Insulation materials	 Double-walle EPS panels: T Foil liner Cardboard box 	d cardboard box hickness: 8.89 cm (ox divider	3.5 in.)	

