

mdi AseptiLiner™ 3D Liners

mdi AseptiLiner[™] 3D liners are specially designed for biopharmaceutical processes involving storage and transfer of process intermediates such as post centrifuge slurries and pellets. The easy to seal design using wire ties ensures leak proof storage and transfer.

Applications

- > Preparation of media and buffers before filtration
- > Pooling process intermediate solutions
- > Waste collection from downstream purification processes

Specifications

Materials of Construction

Film FL-1 : Ultra Low Density Polyethylene (ULDPE)

Physical Properties of Film

Tensile Strength >20 N/mm² when tested as per ASTM D-882

Elongation @ Break >280% when tested as per ASTM D-882

Sterilization Gamma Irradiated @25 kGy

Bacterial Endotoxin

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

Extractables with WFI

Does not affect the quality of Water for injection (passes test as per USP)

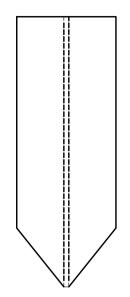
Biosafety

Passes the Biological Reactivity Tests, *In Vivo* for Class VI plastics as described in USP <88>.

Passes the Biological Reactivity Tests, *In Vitro* for Cytotoxicity as described in USP <87>.

Ordering Information (Pack of 10)

for 50 L AseptiLiner™	:	AL13HXXXXXS302
for 100 L AseptiLiner™	:	AL14IXXXXXXS302
for 200 L AseptiLiner™	:	AL15JXXXXXXS302
for 500 L AseptiLiner™	:	AL16KXXXXXXS302



Fiber Release Passes microscopic test for fibers

Particle Release

The filtrate complies with USP <788> test for particulate matter in injections

Bioburden

Bioburden level is < 1000 cfu/liner as per ISO 11737-1

Dimensions

AseptiLiner™	Drum Size		
Volume	Diameter	Depth	
50 Litre	43 cm	46.5 cm	
100 Litre	51 cm	63.5 cm	
200 Litre	59 cm	91 cm	
500 Litre	79 cm	126 cm	