

mdi AseptiLiner 3D liners with drain port are specially designed for biopharmaceutical processes involving preparation and transfer of buffers, media and process intermediates.

These liners are made from robust multilayered film FL-2 with a polyethylene contact layer.

Applications

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

Specifications

Physical Properties of Film

MOC

Film : Multilayered film type FL-2
Tube : Platinum Cured Silicone

Thickness

200µm

Tensile Strength

>25 N/mm² when tested as per ASTM D-882

Elongation @ Break

>400% when tested as per ASTM D-882

Gelbo Flex Test

No pinholes after Flex durability test as per ASTM F 392

Sterilization

Gamma Irradiated @25 kGy

Bacterial Endotoxin

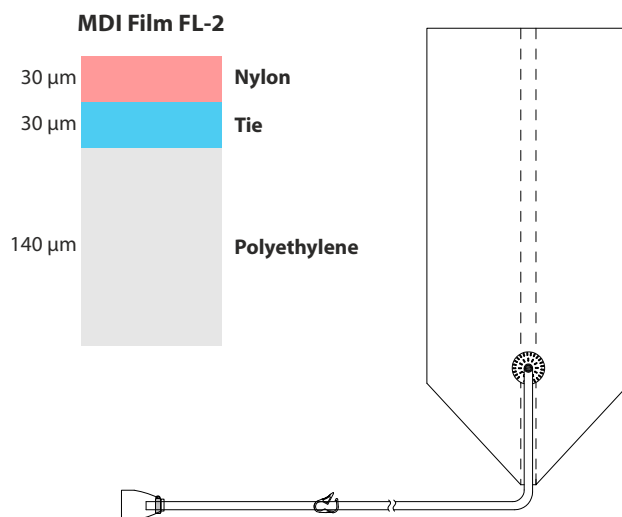
Aqueous extracts exhibit < 0.125 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

Ordering Information (Pack of 10)

for 50 L **AseptiLiner** : AL07HXXXXXXXXS302

for 100 L **AseptiLiner** : AL08IXXXXXXXXS302

for 200 L **AseptiLiner** : AL11JXXXXXXXXS302



Extractables with WFI

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

Fiber Release

Passes microscopic test for fibers

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>.

Particle Release

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

Bioburden

Bioburden level is < 1000 cfu/liner as per ANSI/AAMI/ISO 117371:1995

for 500 L **AseptiLiner** : AL09KXXXXXXXXS302

for 1000 L **AseptiLiner** : AL10MXXXXXXXXS302