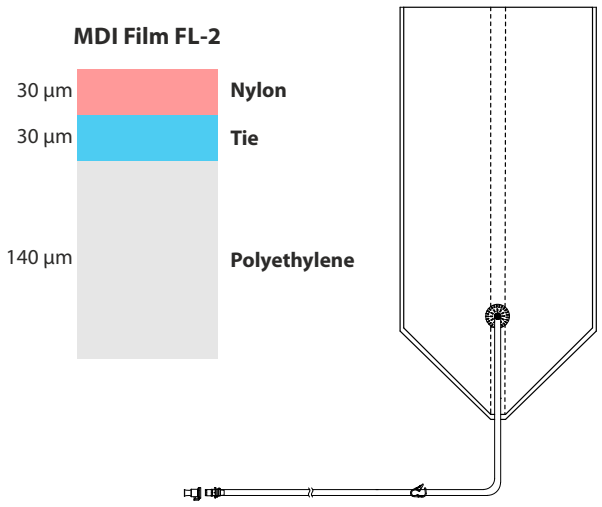
Membrane Technologies

mdi *AseptiLiner*™
3D Liners with Drain Port

DATASHEET

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

Film Thickness
200µm

Tensile Strength
>25 N/mm^2 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

Tube Length
18 inch

Drain Port
1/2" HB male quick connector with female plug

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)

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 ISO 11737-1

Ordering Information (Pack of 10)

for 50 L *AseptiLiner*™ : AL07HXXXXXXS302
for 100 L *AseptiLiner*™ : AL08IXXXXXXS302
for 200 L *AseptiLiner*™ : AL11JXXXXXXS302
for 500 L *AseptiLiner*™ : AL09KXXXXXXS302
for 1000 L AseptiLiner™ : AL10MXXXXXXS302

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