

mdi AseptiLiner™ 3D Liners with Drain Port

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/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

Tube Length

18 inch

Drain Port

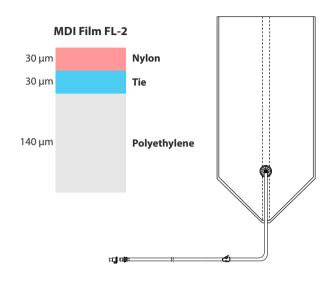
1/2" HB male quick connector with female plug

Sterilization

Gamma Irradiated @25 kGy

Ordering Information (Pack of 10)

for 50 L AseptiLiner™ : AL07HXXXXXXS302 for 100 L AseptiLiner™ : AL08IXXXXXXS302 for 200 L AseptiLiner™ : AL11JXXXXXXS302



Bacterial Endotoxin

Aqueous extracts exhibit < 0.125 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

for 500 L AseptiLiner[™] : AL09KXXXXXXS302 **for 1000 L AseptiLiner**[™] : AL10MXXXXXXS302