

**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<sup>2</sup> 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

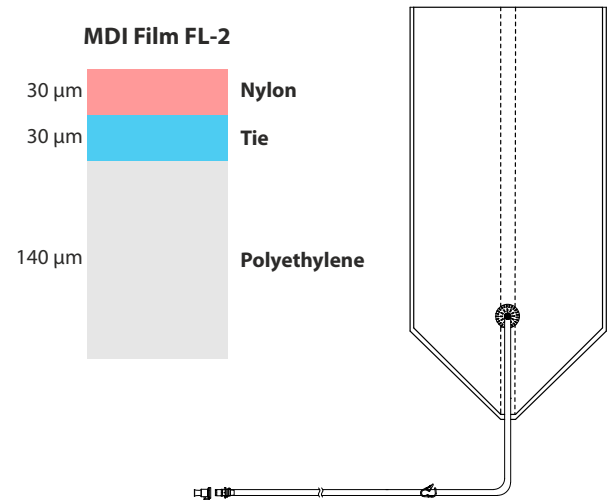
Gamma Irradiated @25 kGy

## Ordering Information (Pack of 10)

for 50 L **AseptiLiner** : AL07HXXXXXXXXS302

for 100 L **AseptiLiner** : AL08IXXXXXXXXS302

for 200 L **AseptiLiner** : AL11JXXXXXXXXS302



### 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 ANSI/AAMI/ISO 117371

for 500 L **AseptiLiner** : AL09KXXXXXXXXS302

for 1000 L **AseptiLiner** : AL10MXXXXXXXXS302