AseptiCel™

Single Use Bioreactors

DATASHEET

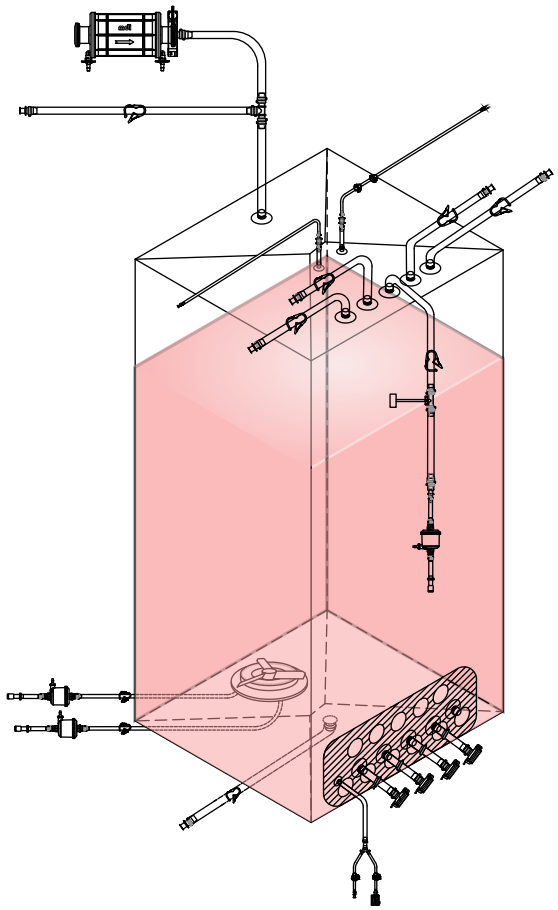
Product Description

mdi *AseptiCel*™ disposable single use bioreactors are designed for manufacture of high value monoclonal antibodies by mammalian cell culture.

These complex bioreactors with sampling systems, sparger, vent filters etc. are designed to ensure high viable cell densities and high product titre.

Mammalian cell culture is a highly critical process and the disposable bioreactor is required to be validated to provide the requisite reliability in terms of robustness and consistent performance.

mdi *AseptiCel*™ disposable single use bioreactors have been validated for various functional as well as regulatory requirement such as sterility, integrity, bioburden, bacterial endotoxin, extractables and biosafety.



Applications

Designed for your High Value
- Monoclonal Antibodies (mAbs)
- Vaccines
- Viral Vectors

Sizes Available

- 50 L
- 200 L
- 500 L
- 1000 L

DST ACSUBXX2415H

AseptiCel™

Single Use Bioreactors

DATASHEET

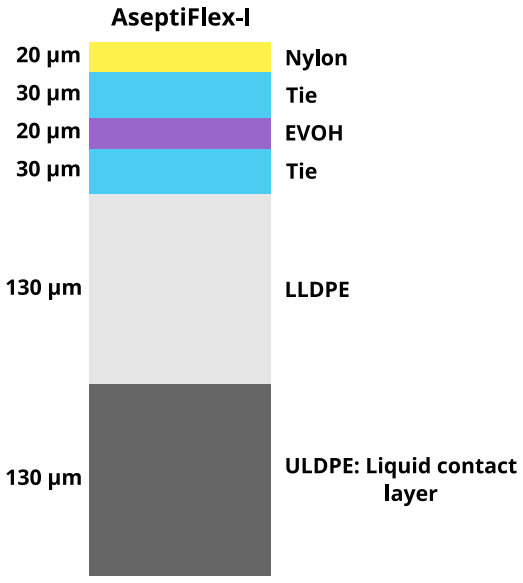
DST ACSUBXX2415H

The mdi *AseptiFlex*-I Film is a highly inert, multilayered polyethylene film specially designed for bioprocess applications.

The film is physically tough and inert to chemicals and solvents used in the biopharmaceutical industry and the various layers of the film provide an excellent barrier to Oxygen, CO_2 and moisture.

The contact layer is ultra low density Polyethylene layer without any additives.

The *AseptiFlex*-I film is produced in classified areas through validated processes to ensure consistently high quality meeting various regulatory as well as functional requirements.



Deeply characterized and validated

AseptiFlex-I has been extensively characterized after gamma irradiation at 50 kGy to deliver high performance:

High strength and flexibility: for safety and integrity during handling, storage and transport

Test	Reference Standard	Average Values
Tensile Strength (MD)	ASTMD-882	24 N/mm²
Flex Durability Test (Gelbo)	ASTM F-392	Passes

Protection of stored liquids from oxidation, change in pH and change in concentration of critical components: with high barrier properties for Oxygen (O_2), Carbon dioxide (CO_2) and water vapour (WV)

Test	Reference Standard	Average Values
O_2 Transmission Rate	ASTMD3985-05	0.055 cc/m²/day
CO_2 Transmission Rate	ASTMF2476	<1.0 cc/m²/day
WV Transmission Rate	ASTMF1249-13	1.135 g/m²/day

Biocompatibility for media storage and cell growth: *AseptiFlex* film is made of plastics of Non Animal Origin and is validated for Biological Reactivity tests as per USP

Test	Reference Standard	Result
Intracutaneous Toxicity	Biological Reactivity Tests, *In Vivo*, as per USP <88>	Passes
Acute Systemic Toxicity		Passes
Muscle Implantation		Passes
Cytoxicity	Biological Reactivity Tests, *In Vitro*, USP <87>	Passes

No impact on purity of process fluids: Very low extractable profile

Test	Reference Standard	Result
Non Volatile Residue	as per USP <661>	Passes
Heavy Metals	as per USP <661>	Passes
Buffering Capacity	as per USP <661>	Passes
Effect on WFI	as per USP <1231>	Passes

AseptiCel™

Single Use Bioreactors

DATASHEET

DST ACSUBXX2415H

Sepcifications

Film Material
AseptiFlex™-I

Impeller
Polypropylene

Sparger Disc
High Density Polyethylene (HDPE)

Spargers
SS 316L

Adapter for Sensors
Silicone

Biosafety
Passes Biological Reactivity test, In-Vivo, as per USP<88> for Class VI plastics.

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

Sterilization
mdi *AseptiCel*™ bioreactors are Gamma Sterilizable upto 50 kGy.

Sterility
The gamma sterilization process has been validated as per ISO 11137 to ensure a sterility assurance level (SAL) of 10^{-6}.

Bioburden Testing
Bioburden level is < 1000 cfu/device as per ISO 11737-1:2018.

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

Particle Release
Complies with USP <788> test for particulate matter in injections and USP <790> for visible particulates in injections.

Extractables
The Extractable profile of all the components used in AseptiCel™ is available as per **BioPhorum Best Practices Guide for Extractable Testing of Polyemric Single Use Components used in Biopharmaceutical Manufacturing**.

AseptiCel™

Single Use Bioreactors

DATASHEET

DST ACSUBXX2415H

Quality Management System

mdi *AseptiCel*™ bioreactors are well designed products with in-built quality assurance. ISO 9001:2015 Certified Quality Management System, careful selection of raw materials, validated production processes and testing procedures based on international standards and guidelines such as CFR, PDA, and ASTM, ensures manufacture of consistently high quality products.

Manufacturing Facilities

These are manufactured in clean rooms certified by external agencies and monitored in-house for viable and non viable particles. Employee hygiene, change rooms, gowning and de-gowning procedures and continuous monitoring of the areas is an essential part of these facilities. These facilities have been designed for unidirectional work flow with appropriate change rooms for personnel and pass boxes for material movement.

Product Realization Flow Chart

User Specified AseptiCel™ Design Specifications

User process flow requirements such as working environment, volume range, temperature conditions, fluid pressure, transfer lengths, sampling needs etc. are established

↓

Technical feasibility

Based on the above information and available components a technical feasibility of the AseptiCel™ is done and an initial drawing of same is submitted for user approval

↓

Design approval

- User approval of AseptiCel™ drawing
- Changes to finalize drawing, if required

↓

Finalized AseptiCel™ Bioreactors

CORPORATE OFFICE

Advanced Microdevices
20-21, Industrial Area, Ambala Cantt
133 006, India
E-mail: info@mdimembrane.com
Website: www.mdimembrane.com

US OFFICE

MDI Membrane Technologies INC
75 Utley Drive STE 103
Camp Hill, Pennsylvania 17011
United States of America
Website: www.mdimembranetech.com