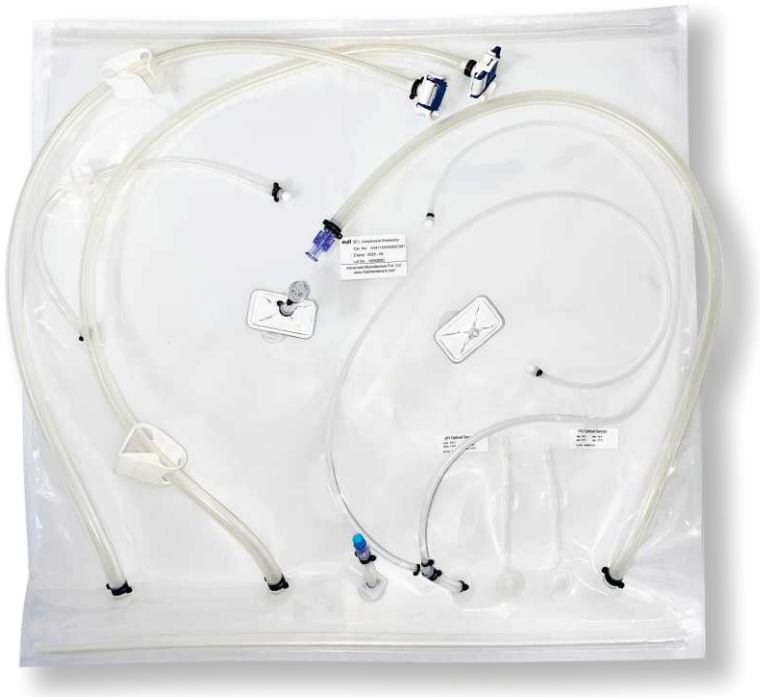
Membrane Technologies



AseptiWave™
Bioreactors

mdi AseptiWave™ single use bioreactors are designed for efficient culture of different type of cells including Mammalian cells, Plant cells, Insect cells, Microbial cells, Stem cells etc.

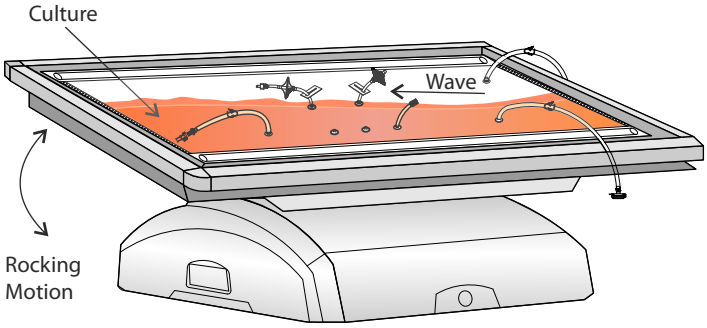
These are available gamma sterilized, in multiple sizes ranging from 2 liters for clone selection and media optimization labs, up to 50 liters, for process development as well as GMP production of biopharmaceuticals.

Applications

- Cell Culture
- Expansion of anchorage dependent cells such as epidermal and connective tissue cells
- Small scale expansion of stem cells
- Inoculum propagation
- Development and manufacture of:
  - Therapeutic protein
  - Monoclonal Antibodies (mAbs)
- Expansion of CART cells for cell therapy

Mechanism

AseptiWave™ Bioreactors require a rocking platform to induce rocking motion for optimal mixing and gas transfer required for efficient cell growth.



AseptiWave™

Bioreactors

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Materials of Construction

AseptiWave™ Bioreactor Film
Multilayered film FBG-1

BioVent Gas Filter
Hydrophobic Filter Media

Types Available

AseptiWave™ bioreactors are avilable with and without pH and DO sensors**.**

***AseptiWave*™ OS** bioreactors integrate pre-calibrated optochemical pH and DO sensors, for monitoring pH and dissolved oxygen in the culture, allowing efficient cell cultivation. The calibration data for the optical sensors is provided along with the bioreactors.

Type	pH and DO Optical Sesnor
AseptiWave™	No
AseptiWave™ *OS*	Yes

Sizes Available

Size	Minimum Working Volume (L)	Maximum Working Volume (L)	Surface Area (cm^2)
2L	0.2	1	1452
10L	0.5	5	3430
20L	1.0	10	6272
50L	5.0	25	9344

Sepcifications

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 *AseptiWave*™ 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>.

Fiber Release
Passes test as per USP and comply with USFDA Title 21 CFR Part 210.3(b)(6) for fiber release.

Particle Release
Complies with USP <788> test for particulate matter in injections.

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

AseptiWave™

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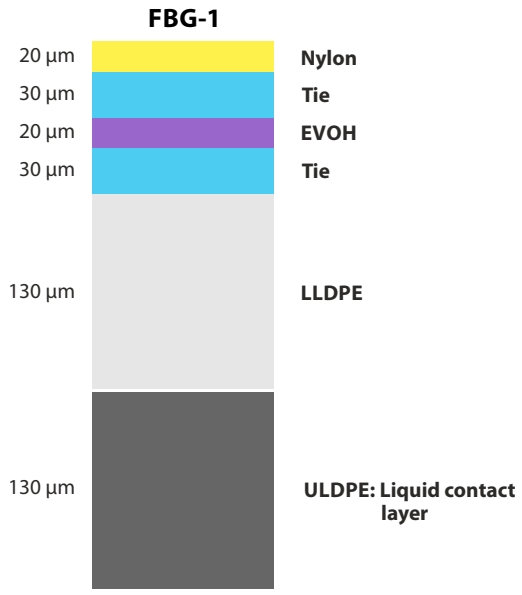
mdi AseptiFlex-D Multilayered Film type FBG-1 is a highly inert, specially designed for bioprocess applications.

The film is physically tough and inert to chemicals and solvents used in the biopharmaceutical industry.

The ultra low density Polyethylene (ULDPE) contact layer is without any additives and ensure very low extractables.

The 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

The film 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
Tear strength	TD	ASTM D1938	25.556 N
	MD		17.873 N
Puncture Resistance		EN14477	10.9578 N
Tensile Strength (MD)		ASTM D-882	27.0298 N/mm^2
Flex Durability Test (Gelbo)		ASTM F-392	Passes

Biocompatibility for cell growth: FBG-1 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

AseptiWave™

Bioreactors

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Quality Management System

mdi *AseptiWave*™ 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.

Product Realization Flow Chart

User Specified AseptiWave™ Design Specifications

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

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Technical feasibility

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

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Design approval

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

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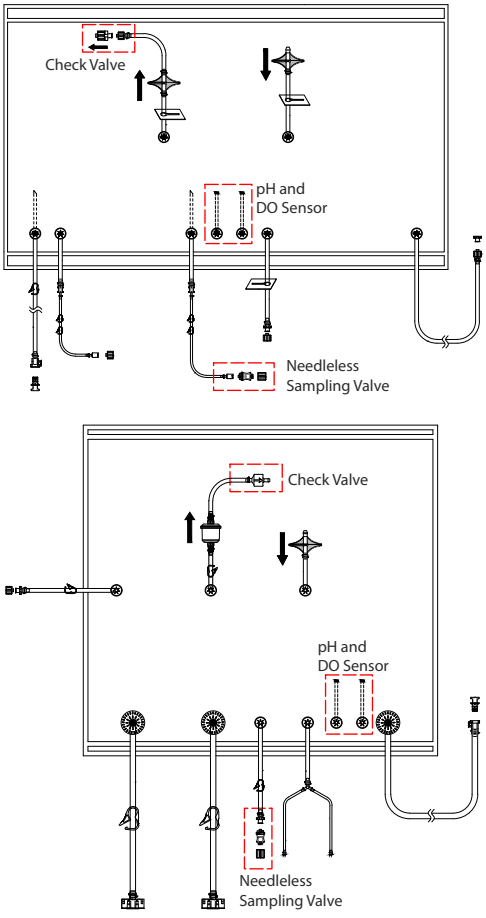
Finalized AseptiWave™ Bioreactors

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.

Below are some example of different type of Wave bioreactors produced by **mdi**. Customization can be done according to customer needs.



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