

NUPORE[®]

BIOPAC SINGLE-USE BAGS



Medical Grade Multi-layer Film | Universal Connection Systems |
Custom Assemblies | Needle-free Sampling Ports |
100% Integrity Tested | Manufactured in ISO class 7 Clean Rooms

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BIOPAC SINGLE-USE BIOPROCESS BAGS

Nupore Single-use Bioprocess bags and assemblies are pre-sterilized customized products to meet your specific needs of storage, transfer and processing of media, buffers, intermediate fluids etc.

We produce wide range of bags from 10 mL to 1000 L, made of highest quality components and assembled in certified ISO Class 7 Cleanroom, to ensure compliance and safety. These are validated for integrity, microbial ingress, sterility, bacterial endotoxins, biosafety and extractables.

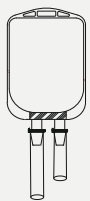


Applications

- ✓ Storage and transfer for media, buffers and drug substances
- ✓ Intermediate and Final product hold
- ✓ Cell Harvesting
- ✓ Sampling for bioreactors
- ✓ Chromatography feed
- ✓ Virus Inactivation

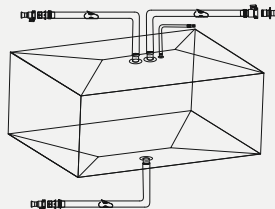
Available Formats

2D Bags



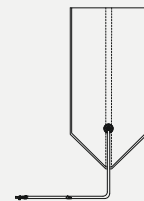
These are small volume bags typically from 10 mL to 50L designed in a 2D format. A hanging port is provided at the top of the bag to hang the bag for easy usage.

3D Bags



Large bags from 50 L to 1000 L are produced in a 3D format to handle large volume and provide greater strength. These are generally used inside a supporting tank.

Liners



A liner is an open-top bag that is placed inside a supporting vessel. These are available from 1 L to 500 L with an optional drain port at the bottom.

Features/Benefits

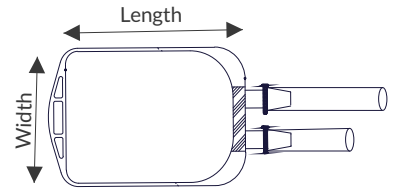
- Needle-free sampling ports
- Medical Grade Multilayer Film
- Assembled in ISO Class 7 Cleanroom
- Standard and custom assembly designs
- Wide range of bag sizes from 10 mL to 1000 L
- Exceptional barrier to O₂, CO₂ and moisture

BioPac 2D/3D Bags

BioPac 2D Bag Specifications:

These are small volume bags typically from 10 mL to 50L designed in a 2D format.

A hanging port is provided at the top of the bag to hang the bag for easy usage.

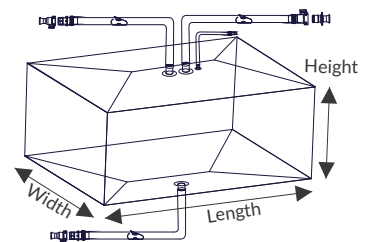


Size	Length	Width	Inlet	Outlet
10 mL	90 mm	60 mm	Female luer lock	Male luer lock
50 mL	162 mm	88 mm	Female luer lock	Male luer lock
100 mL	182 mm	95 mm	Female luer lock	Male luer lock
250 mL	188 mm	134 mm	Female luer lock	Male luer lock
500 mL	242 mm	159 mm	Female luer lock	Male luer lock
1 Ltr	273 mm	203 mm	Male quick connector	Male quick connector
2 Ltr	350 mm	203 mm	Male quick connector	Male quick connector
3 Ltr	390 mm	263 mm	Male quick connector	Male quick connector
5 Ltr	492 mm	320 mm	Male quick connector	Male quick connector
10 Ltr	710 mm	320 mm	Male quick connector	Male quick connector
20 Ltr	600 mm	584 mm	Male quick connector	Male quick connector
50 Ltr	940 mm	584 mm	Male quick connector	Male quick connector

* The dimension Tolerance is $\pm 3\text{mm}$ for bags upto 2Ltr, $\pm 5\text{mm}$ for bags for 2Ltr to 10 Ltr, $\pm 10\text{mm}$ for bags for size >10Ltr

BioPac 3D Bag Specifications:

Large bags from 50 L to 1000 L are produced in a 3D format to handle large volume and provide greater strength. These are generally used inside a supporting tank.



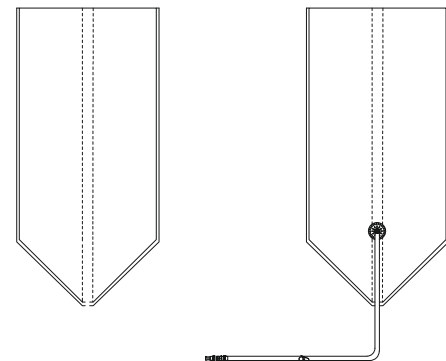
Size	Length	Width	Height
50 L	430 mm	400 mm	350 mm
100 L	480 mm	440 mm	510 mm
200 L	750 mm	580 mm	600 mm
500 L	1100 mm	720 mm	730 mm
1000 L	1100 mm	890 mm	1180 mm

*Tolerance of $\pm 10\text{mm}$ for 3D bags dimensions

TruLiner 2D/3D Tank Liners

Made of transparent and durable pharmaceutical grade PE film, Nupore tank liners are open top bags designed to perfectly fit inside the standard cylindrical drums and eliminate the need for vessel cleaning after media and buffer preparation.

These are offered with/without bottom drain and sterile/nonsterile options.



Special Features & Benefits

- ✔ Manufactured in ISO Class 7 Cleanroom
- ✔ No animal derived components
- ✔ Minimizes bioburden
- ✔ Gamma sterilized, ready-to-use
- ✔ Eliminates cleaning and reduces cross-contamination risk
- ✔ Drums and Trolleys also provided
- ✔ Very low extractable profile for low product/ patient risk

TECHNICAL SPECIFICATIONS

Make	Polyethylene
Sterilization	Gamma
Thickness	6 mil (150 µm)
Port/Tubing	Bottom port can be provided with PCS/TPE Tubing

Size	Length	Width	Height	Fits Tank OD x H
50 L	300 mm	280 mm	1000 mm	11 x 15 in
100 L	410 mm	390 mm	1100 mm	13 x 27 in
200 L	470 mm	490 mm	1200 mm	18 x 30 in
300 L	500 mm	520 mm	1500 mm	22 x 36 in
560 L	650 mm	670 mm	1500 mm	24 x 48 in

**Tolerance of ± 10mm for the dimensions*

Liner Drums & Trolleys

Liner Drums

Nupore cylindrical drum containers are ideally suited to be used with TruLiner® single-use 3D liner bags. Made of high quality LLDPE material using advanced manufacturing techniques, these are durable containers with smooth surface finishing.

The drums are available in volume 50L to 500L.



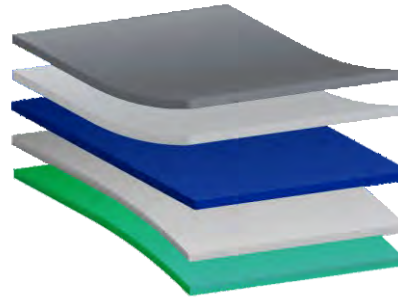
Trolleys

For easy manoeuvrability and convenience, Nupore provides specially designed SS trolleys for its cylindrical drums. These are helpful in handling of large volume liquid storage, mixing and transfer operations.

Multi-Layered Film

BioPac Single-use bags are fabricated from medical-grade, multilayer polyethylene film specially designed for bioprocess applications.

The film provides exceptional compatibility, high strength and superior barrier to Oxygen, Carbon Dioxide and moisture. The contact layer is made of ultra low density Polyethylene layer which is free of any antioxidants, plasticizers, or adhesives.



- 0.05 mm LDPE
Outer layer
- 0.01 mm TIE
Bonding layer
- 0.02 mm EVOH
Gas barrier layer
- 0.01 mm TIE
Bonding layer
- 0.23 mm ULDPE
Fluid contact layer

Special Features & Benefits

- ✓ Bio-safe for highly sensitive mammalian cells
- ✓ High strength and flexibility
- ✓ Safe against product oxidation, concentration and change in pH
- ✓ Very low extractable profile for low product/ patient risk
- ✓ No animal derived components
- ✓ Pharmacopoeia and Biocompatibility compliant

TECHNICAL SPECIFICATIONS

Test	Reference Standard	Values	Property
Oxygen Transmission Rate	ASTMD3985-05	<0.05 cc/m ² /day	Biosafety
Carbon Dioxide Transmission Rate	ASTMF2476	<0.2 cc/m ² /day	Biosafety
Water Vapour Transmission Rate	ASTMF1249-13	0.32 g/m ² /day	Biosafety
Tensile Strength at break	ASTM D-882	13 N/mm ²	Physical
Elastic Modulus	ASTM D-882	270 N/mm ²	Physical
Elongation at break, MD/TD	ASTM D-882	350 %	Physical
Density	ASTM D-792	0.9 g/cc	Physical
Haze	ASTM D-1003	7 %	Physical
Clarity	ASTM D-1003	97 %	Physical
Transmittance	ASTM D-1003	93 %	Physical

Compliance and Biocompatibility:

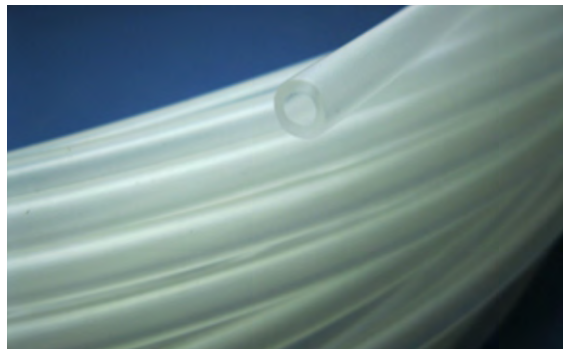
- ISO 10993-10 Irritation & Sensitization
- ISO 10993-11 Acute Systemic Toxicity
- ISO 10993-4 Hemolysis
- ISO 10993-6 Implantation test
- USP <88> Biological reactivity testing, in vivo, class VI
- USP <85> Bacterial Endotoxins – LAL
- ISO 10993-5 Cytotoxicity
- European Pharmacopoeia tests 3.1.5
- USP <87> Biological Reactivity in vitro
- USP <661.1> Polyethylene Physicochemical Tests, Extractable Metals

Single-Use Assembly Components

Tubing

Nupore provides Thermoplastic elastomers (TPE) and Platinum cured silicone tubes with wide range of internal and outer diameters and lengths, as per user and process requirements.

TPE is heat sealable and weldable and therefore makes fitment easier while braided silicone tubing is an excellent choice for high pressure and temperature resistance.



Sterilizing Grade Capsule Filters

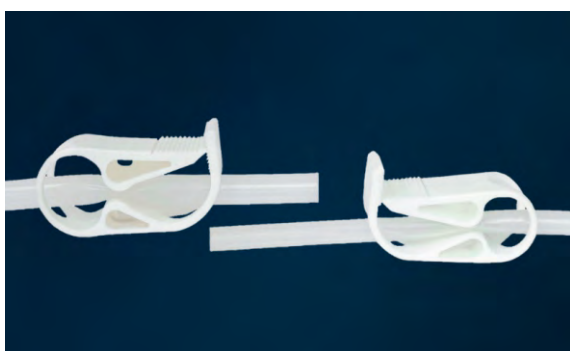
Nupore PoreCap® capsule filters are available from size 1" to 10" with multiple media options of PES, PVDF and Nylon 66 membrane in pore size 0.2 µm and 0.45 µm and various end connections.

These are compatible with ETO, Gamma and autoclave methods of sterilization.

Steamable Valve and Quick Connectors

Nupore offers Steamable valve connector to provide sterile connection between steamable hard pipes with single-use systems.

Quick connectors made of Polycarbonate are ideal for connection in critical aseptic processes in pharmaceutical and biopharmaceutical manufacturing.



Tubing Connections and Other Fittings

We provide Gamma stable fittings such as T connections, Y connections, straight connections, cross connections and reducers for easy connectivity and sterile fluid pathways.

Other essential components including clamps, luer locks, plugs, valves and caps are also provided for complete assembly.

QUALITY ASSURANCE

Manufacturing Facility

BioPac Single-use assemblies are produced in our ISO class 7 certified cleanroom facility following ISO 9001:2015 Quality management systems to ensure product consistency and lot to lot reproducibility.

We have end-to-end capabilities from bag manufacturing and components assembling to testing, packaging and labelling. This helps us in maintaining stringent control over the quality and provide both standard and customized assemblies to our customers in a short lead time.

Testing

Nupore *BioPac* Single-use systems are tested and validated according to international standards and guidelines such as ASTM, PDA and USP.



100% Integrity Tested

Each *BioPac* Single-use system is tested for integrity to comply with acceptable integrity test specifications.



Pressure and Temperature Testing

SUS encounter varying pressure and temperature conditions during storage, transport and use. *BioPac* single-use systems are validated for operational suitability in wide pressure and temperature ranges.



Extractables

Nupore single-use components and assemblies are deeply characterized for non-volatile, semi-volatile and volatile extractables with different time frame and extraction media.



Endotoxin Testing

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



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 $<87>$

QUALITY ASSURANCE

Sterilization



Nupore *BioPac* Single-use systems are sterilized by gamma irradiation with a dose of 25kGy to provide the sterility assurance^a level of 10^{-6} . The sterilization process has been validated as per ISO 11137-2 which includes dose verification, dose mapping and quarterly dose audits.

Certificate of Quality



Certificate of Quality is provided with each lot and the lot number is mentioned on the packaging of each Single Use System to ensure complete traceability at the user's end.



Our Other Products



NuCart® Cartridge Filters



PoreCap® Capsule Filters



TruVent® Filters



Nupore Membrane Filters



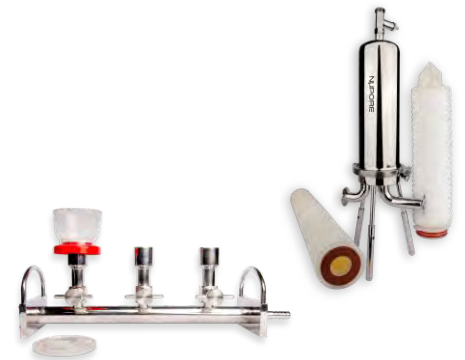
PureChrom™ Syringe Filters



Sterifunnel®



Rapid Test Membrane



Manifolds, Cartridge Housings and Pressure Vessels

ABOUT US

Nupore is a global provider of Nitrocellulose Membranes for the development of Rapid Test Kits and Membrane Filtration Devices for critical filtration applications. Founded in 1989, our expertise lies in Membrane Filtration Technology and we cater to Industries such as Immunodiagnostics, Life Sciences Research, Pharmaceutical, Microbiology and Food & Beverage.

3 Decades of Filtration

We have been at the forefront of membrane filtration technology since 1989. Our experienced team helps you choose the right filtration solution at the right place.

Committed to Quality

Carefully selected raw materials, controlled manufacturing processes, stringent quality checks and commitment to continuous improvement help us maintain the highest quality standards.

Customized Solutions

We design & engineer solutions after carefully understanding your technological & regulatory requirements to provide the optimum bespoke solution to any application.

Accredited Infrastructure

Certified manufacturing & assembling facilities and ISO class 7 clean rooms help us meet global standards as required by the critical applications in the Pharma and Diagnostics markets.



Our Customers and Distribution Partners are spread across 16 Countries Globally.



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