



make  
the  
connection

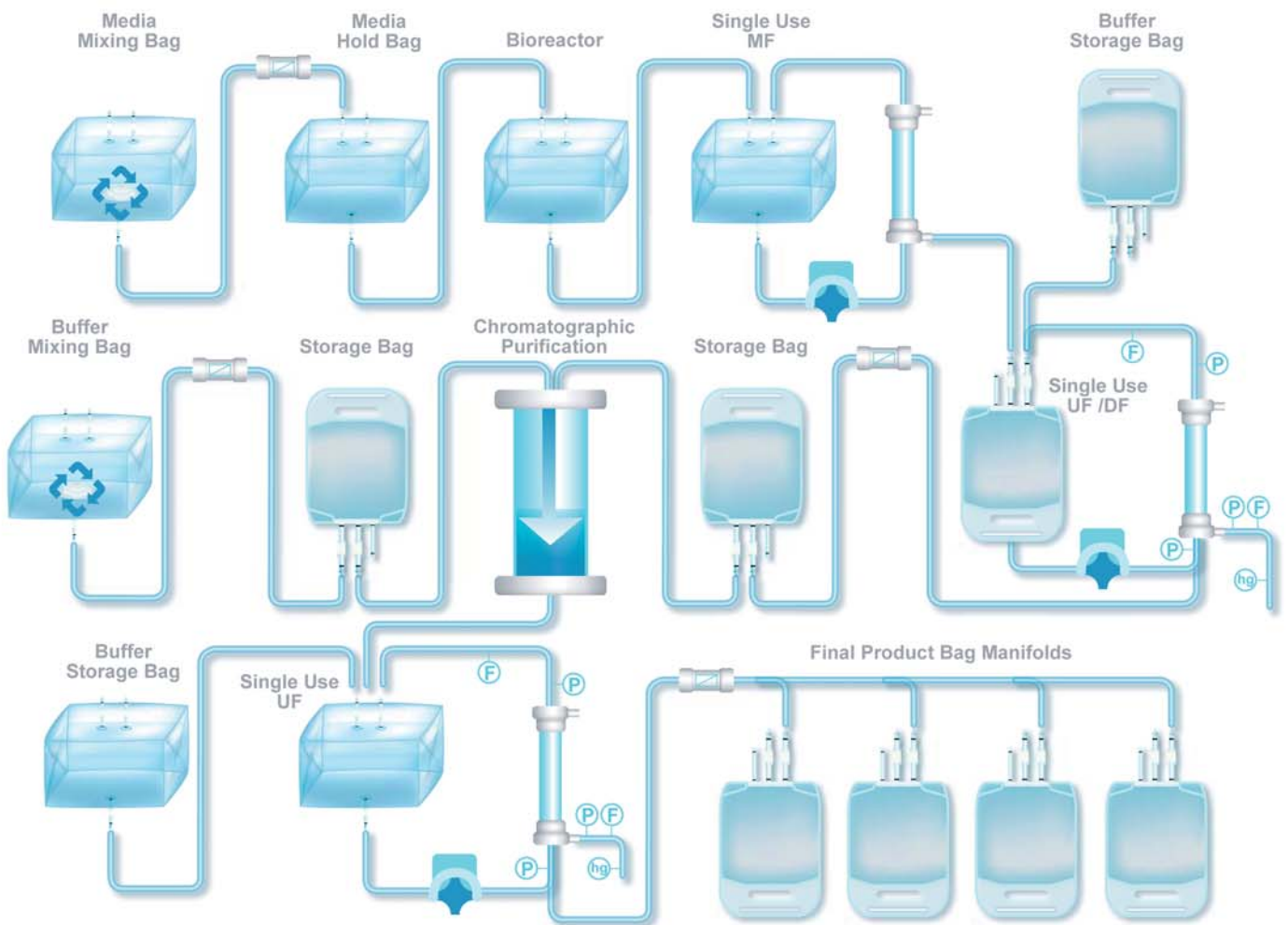


# make the connection

## JM BioConnect® – Make the Connection

JM BioConnect® mission statement is to be the upstream and downstream disposable process solution specialist for our customers in the pharmaceutical and biotech industry. This is not limited to single disposable units but within our portfolio JM BioConnect® design and manufacture complete (sterile) single-use operation units for both at the upstream as on the downstream side of your fermentation process.

With the offered technologies and JM BioConnect® single-use line, BioConnect® is enable to introduce complete single-use operations for the media / buffer preparation, cell harvesting or clarification, concentration and diafiltration and chromatographic processes in all vaccine, pharmaceutical proteins and monoclonal antibodies processes.



JM BioConnect® bags (*Pillow bags & Cubic bags*)  
JM BioConnect® Microcarrier Bags  
JM BioConnect® Assemblies

JM BioConnect® JetMixer™ bags  
JM BioConnect® Tubing  
JM BioConnect® Containers

## JM BioConnect® Bags

JM BioConnect® Disposable bags program consists out of the following product lines:

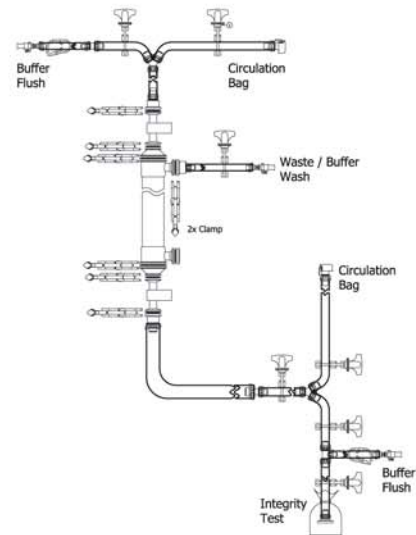
- **Pillow bags from 50 mL – 50 L**
- **3D cubic or cylindrical bags (50L-3500L)**
- **Carrier Bags**
- **Bag and tubing manifolds**
- **JetMixing Bags®**
- **Rocking / shaking cell culture bags**

All these products are manufactured by JM BioConnect® in the Netherlands in an ISO certified and FDA approved cleanroom including the sterilization by gamma radiation.

Through our flexible manufacturing organization, JM BioConnect® is able to turn-around our customer's unique specification into a custom designed and manufactured bag system. For this an unique design tool is available which funnels down customer specifications into an dedicated design

## JM BioConnect® Assemblies

JM BioConnect® Assemblies. Combining the available disposable technologies, JM BioConnect® offers complete single-use upstream and downstream processing unit operations using the existing single-use sensor technologies into JM BioConnect®'s own product-line. This results in single-use upstream media preparation systems, sampling systems and downstream systems for clarification, cell-harvesting, ultra- and diafiltration and ion-exchange and/or affinity chromatographic applications.



## JM BioConnect® JetMixer™ Bags

JM BioConnect® JetMixer™ Single-Use Mixing System is one of the lightest and most compact single-use mixing systems available on the market. JetMixer fits equally well into both product development and cGMP environments, where portability, high mixing efficiency, reliability, ease of use, and a small footprint are invaluable assets.

JM Bioconnect® JetMixer™ single use mixing system is specifically designed to give you scalable, fast, efficient, cost effective, homogeneous mixing of liquids with differing densities. The Jet-Drive system can be used for the final homogenization of product prior to the filling line, as well as for re-suspending solutions and re-homogenizing liquids after transport and storage.

**Operation Principle:** The disposable component of the JetMixer is the bag with the integrated mixing device which is an integrated magnetically impelled turbine, secured to the bottom centre of the bag. The turbine works like a centrifugal pump by drawing liquid in vertically and expelling it horizontally along the bottom through specific outlets which are pointed to the corners of the mixing bag. This internal 3D recirculation loop continually sweeps the entire volume of the bag.

- Accommodates scaling from 10L – 1000L (based on min. mix volume)
- Portable & stackable
- Footprint identical to storage bag/container
- Easy to set-up (less than one minute)
- Simple, reliable operation



## JM BioConnect® Containers

JM Separations would like to introduce to you the JM BioConnect® storage and mixing containers.

The JM BioConnect® containers are designed for the safe and robust storage & mixing of biopharmaceutical fluids contained in JM BioConnect® 3 D Bags. Those containers are available in volumes of 50 L up to 2000 L and can choose between plastic and stainless steel.

Those are designed to perfectly fit with the JM BioConnect® JetMixer™ bags with its integrated impeller that can be used for liquid/ liquid and powder/liquid applications.

Those containers can be supplied with suitable transport rollers for your special-size containers. Any required size of transport roller can be created.



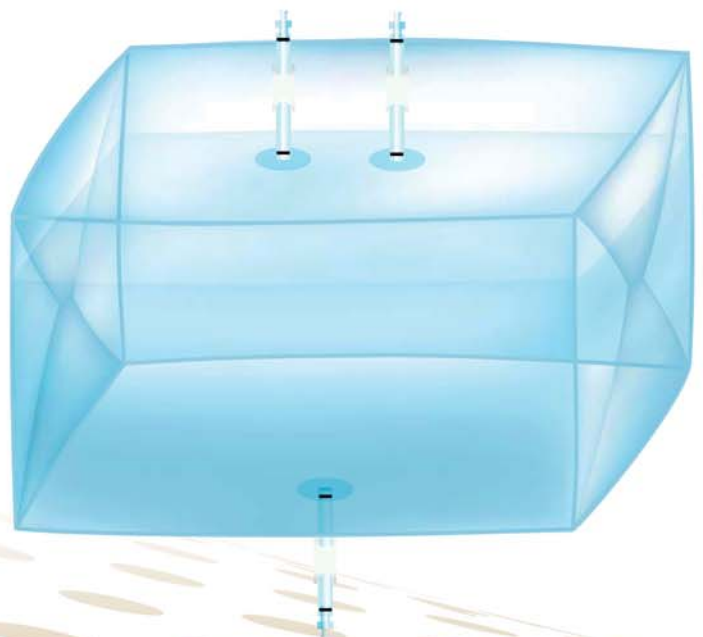
## JM BioConnect® Tubing

Based on the same type of material, JM Bioconnect® developed an unique thermoplastic tubing called Solmed® TubeFlex 4502 tubing, weldable by all commercial available tube welders and tube sealers. This Solmed® TubeFlex 4502 tubing is manufactured in a complete controlled cleanroom environment using the cleanest biological compatible material, TPE and is absolutely free of any animal derived ingredients and/or oils. A complete validation binder is available for our customers of which a summary can be downloaded here. The Solmed® TubeFlex 4502 tubing can be sterilized using autoclaving, gamma radiation, UV and/or ETO. Further it is successfully validated and tested as peristaltic pump tubing and is resistant for pressures upto 3 bar.



## JM BioConnect® Film specifications

- Produced under laminar flow conditions in an ISO class 7 clean room.
- High oxygen barrier: 0.1 cc/(m<sup>2</sup>.day.bar)
- Suitable for pillow bags and 3-D cubical bags
- Resistant to gamma sterilization
- Inert polyethylene fluid contact layer
- High clarity and flexibility
- Compatible with the PE based tubing and PE injection moulding compound
- USP Class VI
- EP 3.1.5
- Bacterial endotoxins





## **JM BioConnect® Hollow fibers** **re-usable HF membranes**

Our application specific, high-capacity, anti-fouling UF and MF hollow fiber membranes perform better, last longer, and save you money. This new proprietary membrane technology results in enhanced product yields, high capacity, and less fouling. See how WaterSep's 75 years of membrane experience can help you optimize your application and improve the economics of your cross-flow filtration processes.

The WaterSep product offering is based on 3 fluid path lengths -12"- 24" - 41"- that are consistent throughout the entire product line. This enables easy and reliable scale-up and scale-down of your process, by choosing between four different hollow fiber diameter.

## **JM BioConnect® Hollow fibers** **single-use HF membranes**

WaterSep has developed a unique line of single-use, glycerin free(GF), low extractables hollow fiber cartridges, that significantly reduce the cost of ownership and eliminate pre-rinsing of the membrane.

### **JM BioConnect®**

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- Ready to use cross-flow filtration – no pre-rinse required
- 80X reduction in extractables compared to glycerin condition membranes
- True plug-and-play at its best, connect, use and discard
- No cleaning and cleaning validation required
- Self contained HF cartridges – no hardware – no installation
- 100% integrity tested
- Very cost effective, compared to cassettes
- A complete line of UF and MF membranes available

### **Manufactured by Watersep**

