







# **Certifications**









ISO 9001: 2015

ISO 13485







FDA CE

# Company Profile NEST

# Let's focus on R&D and the production of consumables of cell culture : A leading manufacturer of plastic consumables in China.

Founded in 2009, Wuxi NEST Biotechnology is a worldwide manufacturer of plastic laboratory products. State-of-the-art manufacturing equipment is used on an expansive manufacturing site based in Wuxi, China. Decades of plastic-injection molding experience allows us to maintain the highest quality and performance standards expected by the hospitals, research institutions and indusrial/clinical laboratories that we serve, NEST is your best choice for laboratory consumables.

NEST has launched over 200 plastic consumable products for cell culture, molecular bislogy, immunoassays, liquid handling and storage. With stricty controlled ISO 8 grade clean rooms, exacting manufacturing standards and rigid QA procedures, the NEST brand enjoys an excellent reputation nationwide and abroad. NEST products have been exported to North America, Europe, Japan, Korea, India and other countries.

NEST is committed to innovation. We continue to research and develop new platic consumables suitable for life sciences research so that we can provide more cost-effective solutions and cutting-edge laboratory consumables for our end-users.

NEST has continually positioned itself as a brand for high end laboratory consumables.

NEST boasts of a high power laminar flow clean room meeting the ISO 8 grade with a floor space of 2,000 square meters. These facilities are equipped with a central feeding system, high precision injection machinery from Japan, robot arms with automatic conveyers, hot runner molds, and vacuum plasma and corona treatment machines from Belgium, Germany and USA. Inner room moisture content and temperature are adjustable. In 2013, NEST installed a Rhodotron TT 200 from Belgium IBA, a world leader in the E-Beam sterilization industry. NEST completes a full process chain from the sourcing of the raw materials to the in-house sterilization of the final products ready for delivery to clients.



# **NEST HISTORY**





**New Facility in Construction** 





Appear in Analytica Munich&PITTCON Explore the overseas market



NEST brand established Starting from the cell culture products

2011 **ISO9001 Certification** 



### 2013 **NEST USA Branch Estabilished**

2014

**New Facility in Operation** New facility with 27,000 square meters Rhodotron TT200 E-beam irradiation machine

imported from IBA Belgium

PCR products launched R&D of NEST Biofactory



# **2016**ISO13485 Certification Nest Biofactory validation



### 2018

# Production Capacity Enlarged by Double

Preparing for a medical device license

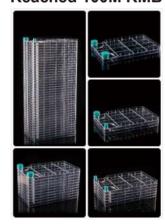








2017
Sales Revenue
Reached 100M RMB



**2019**Obtained Medical Device License



# **Quality Guarantee**

Precision Molding · Production Security · Sterilization Security

### Precision Molding NEST

### Precision Molding—Vanguard Technology (Wuxi) Co., Ltd.

Founded in 2004, Vanguard Technology (Wuxi) Co., Ltd, a brother company of Wuxi NEST Biotechnology Co., Ltd., offers design & manufacturing of precision injection molds and die-casting molds and molding production of precision injection parts and die-casting parts. The product categories cover fields including life sciences, automotive parts, communication products, electronic parts, etc.

• An operating team with experiences over 30 years.

The company has obtained certifications like IATF16949-2016 (ISO16949)/CE/FDA.

- High precision mould processing equipment imported from Germany, Japan etc.
- Professional mold flow analysis software.

#### **Representatives of Clients**

ASTON MARTIN	<b>LEAR</b> CORPORATION	u-shin	Valeo	CHINA	TRELLEBORG	SIEMENS
KONGSBERG	HILTE	TransNav Mexico	AS ONE	MASERATI	<b>TRW</b> Automotive	WEGO顧高









Class 10,000 Clean Room







# Production Security NEST

Ten thousand grade clean room.

All-electric high-speed injection molding machine imported from Japan.

Raw material which meet USP Class VI requirements. Production and quality control are performed strictly in accordance with corresponding SOP.

#### **Surface Treatment - Tissue Culture Treated**

10 years of production experience, ensures more uniform and stable cell attachment.

### **Verification for Package Strength**

Tests of multiple long-distance express transport challenges, with a breakage rate lower than 3%.

#### **Verification for Service Life of Product**

The requirements of cell growth are still met after 3-year natural aging.

### **Test for Biosafety**

In accordance with the Complication Of National Standards For Packaging Materials And Containers Directly In Contact With Drugs Of The National Medical Products Administration (Vol. Six), tests for cytotoxicity, sensitization, intra-cutaneous stimulation, acute systemic toxicity, hemolysis, etc. are all performed for the products.

### **Test for Physical and Chemical Safety**

In accordance with the Complication Of National Standards For Packaging Materials And Containers Directly In Contact With Drugs Of The National Medical Products Administration (Vol. Six), tests for insoluble particles, ignition residues, metal elements, leachables (clarity, color, pH, UV absorption, non-volatile substances, readily oxidized substances, heavy metals) are all performed for the products.

#### **Cell Growing Test**

L-929: mouse fibroblasts

VERO: renal cells of African green monkey

2BS: human embryo lung diploid cells 293T: human renal epithelial cells

# **Aseptic Security**



### Aseptic Security ——Sterilization by Electronic Beam Irradiation

- Introduce the Rhodotron TT200 electron accelerator of the Belgium company, IBA.
- Built an irradiation center at a cost of 50 millions.
- The sterilization process has been certified by the ISO 11137 quality system.

### Advantages of sterilization by electronic beams

-Less time consuming, good effects, safety and environmental protection, without chemical residues.

Sterilization by electronic beam radiation: consecutive batch irradiation processing, the sterilization can be completed within only several seconds. The method has advantages like less time consuming, good effects, safety and environment protection and no chemical residues when compared to the traditional cobalt 60 irradiation sterilization and ethylene oxide sterilization systems.

Sterilization by cobalt 60: ozone (strong oxidant) will be generated during the sterilization, which may cause damage to the product and the whole process takes a longer time (8-12 hours). Ethylene oxide sterilization: chemical residues and after sterilization, the products should be set aside for 48 hours to let the residual reagents volatilize.

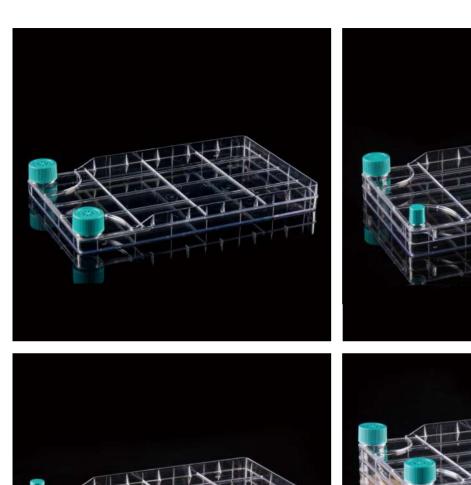
#### **Comparison of Different Sterilization Methods**

Item	Irradiation by electron accelerator	Irradiation by cobalt source	Ethylene oxide EO
Processing rate	Fast	Slow	Slow
Penetrability	Strong	Strong	Weak
Quantity of	Cycling sterilization, can meet the	Cycling sterilization,	Depends on the case body,
batch processing	needs of processing for any quantity	cannot be stopped halfway	normally less than 30 m³/time
Post treatment	Usable immediately after irradiation	Usable immediately after irradiation	Let stand for 48 hours for the residual reagents to volatilize
Safe	Controllable, no irradiation after stopping the machine	Irradiation always exists	EO is inflammable and explosive
Packaging requirements	No	No	Use of special packaging materials
Chemical residue	No	No	Yes

#### The Irradiation Process















# NEST BioFactory™ NEST

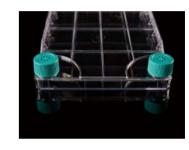
NEST BioFactory™ system is a well-designed cell culture device that utilizes the maximum culture area in a limited space, saving a large amount of space, low-cost to achieve the purpose of expanding production capacity.

NEST BioFactory™ system can be used for industrial scale production such as vaccine, monoclonal antibodies or biopharmaceuticals production, and they are suitable for adherent cell culture.

Specifications: Single layer, 2 layers, 5 layers, 10 layers and 40 layers.

#### Two Wide Vent Caps (with extra 16 sterile wide plug seal caps packaged separately)

Cat.No.	Layer	Cultivation area (cm²)	Length(mm)	Width(mm)	Height (mm)	/Case
771001	1	647	335	205	44	8
771101	2	1279	335	205	61	8
771204	5	3175	335	205	112	4
771302	10	6335	335	205	197	6
771403	40	25295	335	205	712	2



### 1 Narrow Vent Cap + 1Narrow Plug Seal Cap (with extra 8 sterile narrow vent caps & 8 sterile narrow plug seal caps packaged separately)

Cat.No.	Layer	Cultivation area (cm²)	Length(mm)	Width(mm)	Height (mm)	/Case
772001	1	647	335	205	44	8
772101	2	1279	335	205	61	8
772204	5	3175	335	205	112	4
772302	10	6335	335	205	197	6
772403	40	25295	335	205	712	2



### 1 Wide Vent Cap & 1 Narrow Plug Seal Cap (with extra 8 sterile wide plug seal caps & 8 sterile narrowvent caps packaged separately)

Cat.No.	Layer	Cultivation area (cm²)	Length(mm)	Width(mm)	Height (mm)	/Case
773001	1	647	335	205	44	8
773101	2	1279	335	205	61	8
773204	5	3175	335	205	112	4
773302	10	6335	335	205	197	6
773403	40	25295	335	205	712	2



# **BioFactory™ Versus Rolling Bottles**



### Advantages of BioFactory™

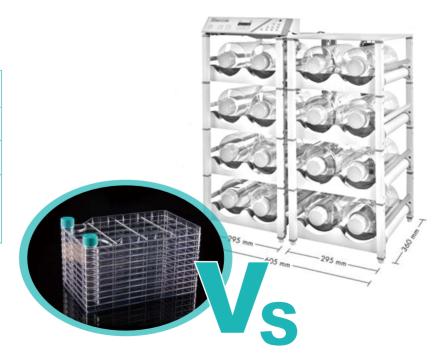
- Large culture area with less space occupied;
- Reduced manual operations to decrease contamination risk;
- Can be operated manually or combined with automated equipment for use;
- Can realize standardized operations to reduce intra-batch difference.

### **Disadvantages of Rolling Bottles**

- · Heavy workload of manual operations;
- · High risk of contamination;
- A large amount of washing and verification processes;
- Poor controllability of the production processes with large intra-bottle difference, hard to unify the quality of different batches:
- Large space occupation, hard to rapidly expend the production scale;
- Low level of automation.

### **Comparison of Utilization Rate**

Compared Items	10-layer BioFactory™	Rolling Bottle
Individual Culture Area	6,335cm²	1,800cm <sup>2</sup>
Quantity	16	50
Total Culture Area	10m²	9m²
Occupied Space	0.216m³	0.973m³



# **Design Characteristics of BioFactory™ NEST**

1

# Large-caliber Connection Channel

Large-caliber connection channel may quickly equilbrium the culture medium and shorten the liquid adding progress, to better increase cell viability.



2

### One-piece Injection Molding for Mouth and Body

Ensure better sealability and better strength.



3

#### **Strong Packaging**

Double-layer air-exhausted packaging: meet the use requirements of pharmaceutical clients.

Built-in protection layer: hard to be damaged, suitable for long-distance transportation.



4

#### **Unique Design of Cap**

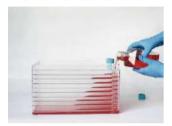
"Petal" pattern distribution of pores, to enhance gas exchange to facilitate cell culture.



### **User Manual**



#### **Cell Culture**



Pour the prepared culture medium into the cell factory (Volume suggestion: 150 - 200 mL for each layer).



Lay the cell factory on its side to balance the liquid level.



With the liquid-adding opening upward, the culture medium will be evenly distributed to each layer after standing.



Slowly place the cell factory in a horizontal position.



Incubate in a cell incubator.

#### **Precautions**

- 1. Please pre-heat the cell factory and culture medium to the culture temperature: since it takes a long time for a large incubator to reach the set culture temperature, pre-heating the cell factory and culture medium to the culture temperature before starting the experiment may speed up cell attachment and significantly increase cell recovery.
- 2. Slow operating is required to avoid occurrence of air bubbles caused by sharp shaking: air bubbles may lead to flowing the medium from an upper layer to a lower layer.
- 3. Avoid spraying the alcohol onto the breathable cover, since alcohol may wet the hydrophobic membrane filter and make it impermeable and consequently affect the gas exchange or causes pressure imbalance during operations.

#### **Cell Harvest**

- 1. After the culture is completed, pour the culture medium out.
- 2. Wash the factory with the calcium- and magnesium-free phosphate buffer solution (CMF-PBS) (40-50 ml/layer) and if necessary, repeat the washing process.
- 3. Digestion: pre-heat the digestion solution (10-40 ml/layer) in advance.
- 4. Collection: centrifuge for 5 min at 1000 rpm, remove the digestion solution and collect cells.
- 5. Washing: wash the incubator with CMF-PBS or culture medium after digestion.

#### **Precautions**

- 1. Ensure that the culture surface of each layer is completely immersed in the CMF-PBS, and gently shake the cell factory forward and backward to wash off the residual culture medium.
- 2. Distribute the digestion solution evenly to each layer; gently tilt the incubator forward and backward, left and right to ensure that the digestion solution has completely covered the culture surface; gently tap the incubator to help the cells detach from the surface.
- 3. Since it is unable to clearly observe the digestion status of the cells in the middle layers of a cell factory, it is recommended to refer to the digestion status of a culture flask or a single-layer cell factory under exactly the same culture conditions. Or, use a dedicated observation platform for multiple-layer cell incubators to observe the growth status of cells in each layer.
- 4. If there are numerous cells present in the washing solution or the culture layers of the cell factory, it is necessary to wash for multiple times or adjust the procedure of cell digestion.
- 5. Even a slight deviation of the culture temperature may affect the cell harvest rate, so it is required to pay close attention as to whether or not the culture temperature is exactly the set temperature.

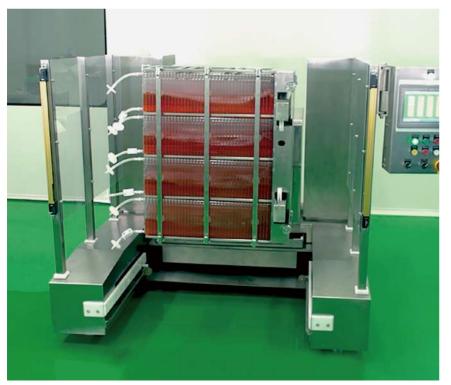




# BioFactory™ Automatic Shaker NEST

Achieve automated and high-efficiency operating of liquid adding, shaking, digesting and liquid pouring-out, etc. for BioFactory<sup>™</sup> during large-scale culturing, to reduce heavy manual workload and the errors introduced by human factors.

- The whole device is fully made of stainless steel materials, without rubber transmission parts.
- The device is fully electricity-powered; the ACFM is strictly in accordance with the requirements of EU directives; all parts comply with relevant regulations, no compressed gas source required.
- Use a complete set of imported servo motors and imported reducers, with high operating safety factors.
- Noiseless operation is achieved by using imported linear guides and ball screws.



Loading



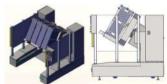


Lean Forward: 0-20°

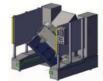




Lean Back: 0-35°



Left Rotation, Right Rotation It's available to lean back or forward while rotating.







BioFactory™ Handcart









### **BioFactory™ Accessories**





**744001 SPT-50 Hose**Inner Dia# 3/8 Inches (9.5 mm) ,
Outer Dia# 5/8 Inches (15.9 mm)
50 Inches/ 15 meters
1 pcs / pack



746001 C-Flex Welding Hose Inner Dia# 3/8 Inches (9.5 mm) , Outer Dia# 5/8 Inches (15.9 mm) 50 Inches/ 15 meters 1 pcs / pack



**743001 Hose Clamp** Hose clamp for 12-18 mm diameter hose 10 pcs / pack



741001 Adaptor Connector Adaptor Connector to 3/8 Inches (9.5 mm)Hose 1 pcs / pack



**751001** Y Shape Connector Y Shape CPC Connector for Inner Dia #3/8 Hose 1 pcs / pack, 5 pcs / cs



749001 T Shape Connector T Shape CPC Connector for Inner Dia #3/8 Hose 1 pcs / pack, 5 pcs / cs



742001 Vent Filter
0.22 μm, 50 mm diameter
1 pcs / pack, 5 pcs / cs
742011 Vent Filter
0.22 μm, 45 mm diameter
1 pcs / pack, 5 pcs / cs



747001 Connector CPC & PC (Inner Dia #3/8) for Hose to Hose Connecting 1 pcs / pack, 5 pcs / cs



740001 Wide Mouth Seal cap 740011 Wide Mouth Vent cap 740101 Narrow Mouth Seal cap 740111 Narrow Mouth Vent cap HDPE,1 pcs/pack, 10 pcs/cs



740201 Adaptor Cap Wide Mouth to Narrow Mouth HDPE, Spec(mm): 11.8/14.3 1 pcs / pack, 10 pcs / cs



740301 Adaptor Cap Wide Mouth to 3/8 Inches (9.5 mm)hose HDPE, Spec(mm): 7.3/11.4 1 pcs / pack, 10 pcs / cs



745001 Accessory Lite Package Hose Clamp\*1 50 mm Vent Filter\*1 15 cm SPT-50 Hose\*1 Silicone Ring\*2 1/pk, 2/cs



745011 Accessory Basic Package
Hose Clamp\*1
50 mm Vent Filter
15 cm SPT-50 Hose\*1
Adaptor Connector\*1
Silicone Ring\*2
1/pk, 2/cs



745021 Accessory Premium Package 2 different Adaptor Caps\*1 Hose Clamp\*1 Adaptor Connector\*1 50 mm Vent Filter\*1 Hose Clamp\*1 15 m SPT-50 Hose\*1



### How to use a microscope to observe the cell growth in a BioFactory™?

- 1. Use an inverted microscope to observe directly, however, it's only suitable for observing a BioFactory™ with 1-10 layers. The growth status in the bottom layers 1 and 2 can be observed, but only for the cell growth uniformity. It is not suitable for a 40-layer BioFactory™. Please contact the microscope manufacturer for more details.
- 2. Observe with a microscope dedicated for BioFactory™ observation, which has a lens in two directions for side observation and bottom observation, respectively; the cell size and growth density can be calculated using a size measurement system by observing cell status with a microscope. This model of microscope is suitable for BioFactory™ with any number of layers.
- 3. Since the cell growth conditions (surface-capability relationship) of NEST BioFactory™ are the same as those of NEST cell culture flasks, the cell culture flask can be used simultaneously to replace BioFactory™ for observation, or use a 1-layer BioFactory™ for reference.

### How many cells may be inoculated in each type of BioFactory™?

NEST BioFactory™ are made of the same raw materials using same production processes as those of NEST cell culture flasks and the cell surface and growth status are basically the same as that of cell culture flasks. Since each kind of cells have different growth characteristics and different requirements for surface density and environment, for the number of cells that can be inoculated in each type of BioFactory™, it cannot be simply generalized. Users are recommended to determine the number by multiplying the inoculation density per unit area in the cell culture flask with the used culture area of BioFactory™.

#### Volumes of various working solutions used in the cell culture.

The BioFactory™ allows large-scare cell culture in a compact space using its multiple-layer stacked structure. How much culture medium should be added in during use? And how much trypsin solution should be added in for cell digestion?

Layer	Culture Area (m²)	Volume (mL)	Washing Solution (1XPBS) mL	Digestion solution EDTA (mL)	Digestion Stop Solution (mL)
1	647	150-200	30-40	20	25
2	1279	300-400	60-80	40	50
5	3175	750-1000	150-200	100	125
10	6335	1500-2000	300-400	200	250
40	25295	6000-8000	1200-1600	800	1000

# The BioFactory<sup>™</sup> are divided into large-caliber ones and small-caliber ones, what are their respective characteristics?

- 1. After years of research and development, the NEST BioFactory™ now have a complete product selection and clients may freely choose from BioFactory™ with of two wide caps, with two narrow caps or with one wide cap and one narrow cap according to their operating and use needs.
- 2. Characteristics of two wide caps: suitable for manual operations of adding and removing liquid, can also be connected with tubing; generally used during the phase of laboratory research
- 3. Characteristics two narrow caps: suitable for being connected with tubing to facilitate subsequent process scale-up; generally used for scale production.

  Characteristics of one wide cap and one narrow cap: suitable for tubing connection and manual operations; used for scale production and laboratory research.

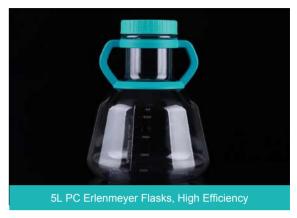
  Breathable cap: the inner is covered with a 0.22um hydrophobic film, which is air penetrable and can block bacteria and water, as well as avoid gas bloating caused by adding liquid.



# High Efficiency Erlenmeyer Flask NEST







#### Introduction

High-efficiency, large-volume culture flasks allow cells to show strong viability with large expression amount of proteins in the culture of mammalian cells and insect cells. During the culturing process, the use rate of the shaker is significantly increased, and the survival rate and viability of cells are both dramatically elevated. NEST culture flasks also provide high repeatability, which allows highly inter-batch consistency of cell growth and yield.

#### **Feature**

- The imported medical-grade polycarbonate (PC) that meets with the requirements of ISO10993 USP<661> is chosen as the raw materials, which has high transparency, great impact resistance, oxidation resistance and can withstand a high temperature of up to 121°C.
- The scale is clear and accurate when looked at from the outside, which facilitates the observation of the volume of culture medium.
- The vent cap is equipped with a 0.22-µm breathable film which is air-permeable and water-proof to efficiently prevent the passing of micro-organisms and contamination and to ensure gas exchange for good growth of cells or bacteria.
- The products have undergone the tightness test, drop test, high-temperature and high-voltage tests, flatness test, tensile test, endotoxin test, sterilization test, DNA/RNA enzyme-free tests and cell culture test, all the results of which meet the corresponding quality standards.
- Sterile individual package, easy to use.

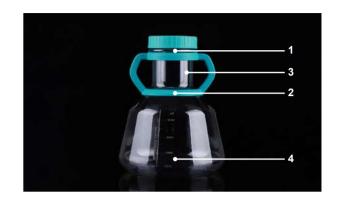
Cat.No. Volume ( L )	_ ) Cap Style	Size(mm)			/Casa	
		Height	Bottleneck Diameter	Bottom Diameter	/Case	
785101	2	Seal Cap	213.5	67	162	6
785111	2	Vent Filter Cap	213.5	67	162	6
786101	3	Seal Cap	253.5	67	162	4
786111	3	Vent Filter Cap	253.5	67	162	4
787001	5	Seal Cap	285.5	90	230	4
787011	5	Vent Filter Cap	285.5	90	230	4

# **High Efficiency Erlenmeyer Flask**



### **Design Characteristics of High Efficiency Erlenmeyer Flask**

- 1. The lower edge of the cover is thickened and widened for better leak proofing.
- 2. The 5L high efficiency erlenmeyer flask is designed with an detachable handle to solve the problem that liquid enters the cavity of the one-piece infected handle as residue. The handle is detachable for flexible application.
- 3. The designs of 2/3 L flasks are optimized with lengthened neck convenient for customers to grip and can avoid that the hand of the customer is too close to the flask mouth when pouring liquid or holding the flask. Meet the aseptic operating practices of pharmaceutical companies.
- 4. The bottom area and opening size of the NEST high efficiency erlenmeyer flask are exactly the same as those of the Thomson.



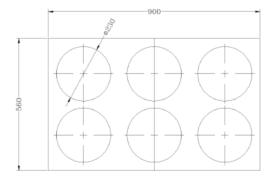
### High Efficiency Erlenmeyer Flask Versus Normal Erlenmeyer Flask

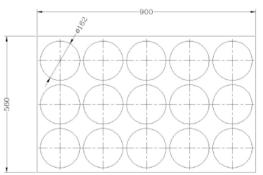
#### High Efficiency Erlenmeyer Flask Advantage

- 1. The bottom area of 3L high efficiency erlenmeyer flask is smaller than normal erlenmeyer flask. For a same shaker, more 3L high efficiency erlenmeyer flask can be placed on to which greatly reduce the usage rate of the shaker to save the client's R&D costs.
- 2. Low sheer force born by cells. The amount of foam can be efficiently controlled.









3L Normal Erlenmeyer Flask

3L High Efficiency Erlenmeyer Flask

**3L Normal Erlenmeyer Flask** 

3L High Efficiency Erlenmeyer Flask

# Transfer Cap NEST

#### **Inverted Liquid Transfer Cap**

The inverted transfer cap is used along with a 2L, 3L or 5L Erlenmeyer Flask to connect a liquid inlet tubing with the required device. When liquid transfer is required, the liquid is transferred under gravity with the inverted erlenmeyer flask.

### **Multifunctional Liquid Transfer Cap**

Unlike the two-way liquid transfer cap, the multifunctional transfer cap can be directly placed in an incubator for culture after the liquid transfer is completed. It can reach a large air flux. The sampling part is composed of a sampling nozzle and a one-way valve, which can prevent the liquid from flowing backwards during the sampling process and ensure the aseptic sampling. The liquid inlet tubing is provided with a PTFE needle filter, which solves the issue of liquid remaining in the tubing during the feeding process.

### **Two-way Liquid Transfer Cap**

The two-way transfer cap is used along with a 2L, 3L or 5L shake flask to connect a liquid inlet tubing with the required device. The liquid transfer is achieved by connection of a peristaltic pump between the erlenmeyer flask and the device. Upon completion of the transfer, the transfer cap can be replaced with a vent cap for culture.

#### **Feature**

- · Closed system reduces the risks of contamination during liquid transfer.
- The cap is molded and connected in an integrated manner, reducing the risks of leakage and media residues.
- A variety of tubing diameters are available and aseptic welding of liquid inlet tubing under normal conditions is supported.
- · High-quality materials and smooth inner wall of the tubing provide an excellent transfer performance.
- Sterility level (SAL) is maintained at 10<sup>-6</sup>.
- Endotoxin-free, and no ingredients of animal origin.

#### **Application**

• It is applicable to liquid transfer and culture during mass proliferation of bacteria and suspension cells.

Cat.No.	Name	Description of Hoses	Hoses' Length (cm)	/Case
785931	Multi-Function Liquid Transfer Cap System for 2L Erlenmeyer Flasks		50 cm	4
786931	Multi-Function Liquid Transfer Cap System for 3L Erlenmeyer Flasks		50 cm	4
787931	Multi-Function Liquid Transfer Cap System for 5L Erlenmeyer Flasks		92 cm	4
785921	Bi-directional Liquid Transfer Cap System for 2L Erlenmeyer Flasks		50 cm	4
786921	Bi-directional Liquid Transfer Cap System for 3L Erlenmeyer Flasks	Thermoplastic Hose.	50 cm	4
787921	Bi-directional Liquid Transfer Cap System for 5L Erlenmeyer Flasks	Diameter: 1/8" ID, 1/4" OD	92 cm	4
785941	Inverted Liquid Transfer Cap System for 2L Erlenmeyer Flasks		50 cm	4
786941	Inverted Liquid Transfer Cap System for 3L Erlenmeyer Flasks		50 cm	4
787941	Inverted Liquid Transfer Cap System for 5L Erlenmeyer Flasks		92 cm	4









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