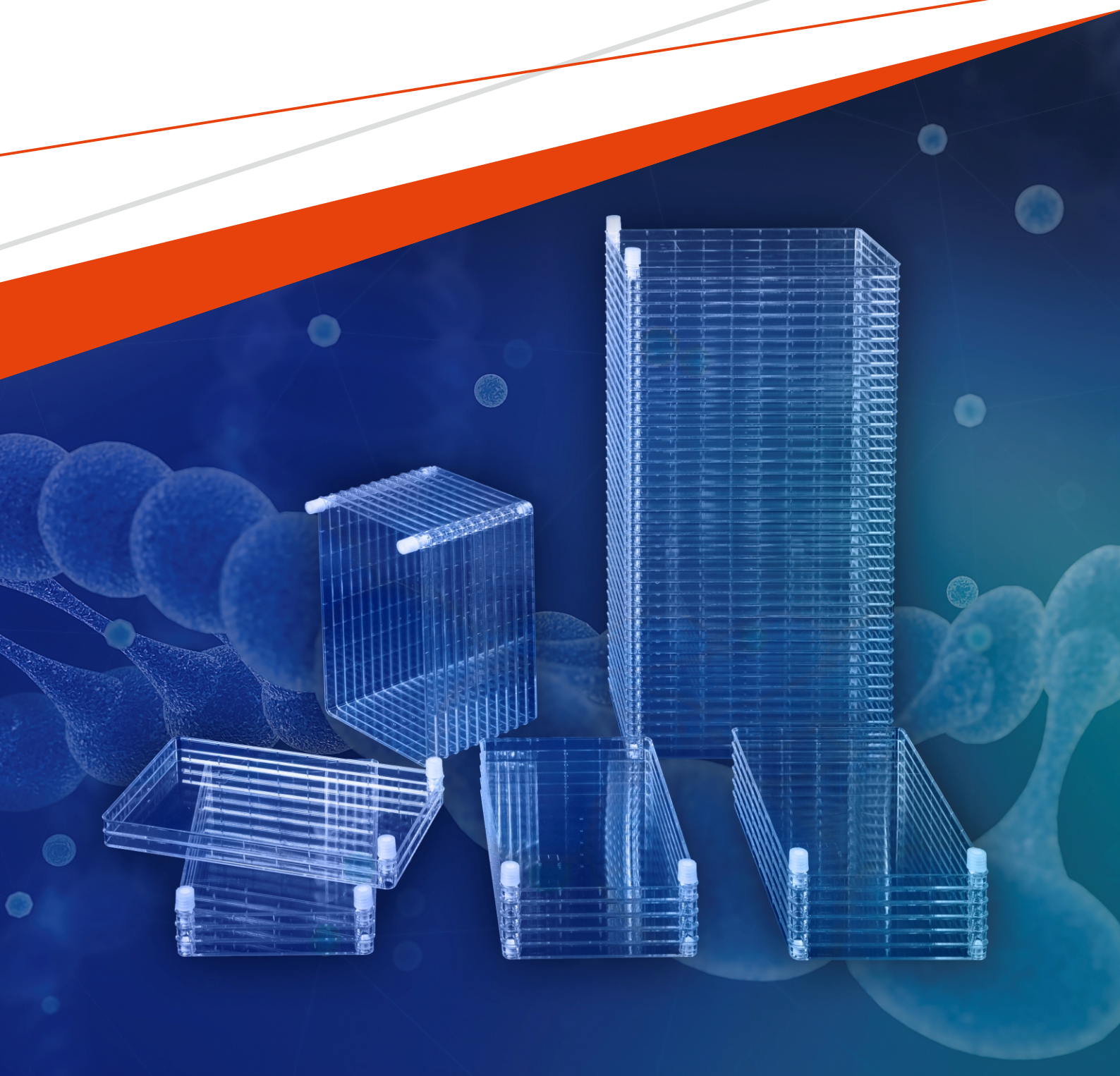
FeiFanT
APPLIED BIOTECHNOLOGY

Cell Culture Multi–layer Chambers



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About FeiFanT Applied Biotechnology

Established in 2017, FeiFanT is a professional manufacturer that is concerned with the design, development and production of biotechnology. Our team have been working with biopharmaceuticals for 20 years, and that is why we have always had a reverence fo the industries we work in and the products we produce.

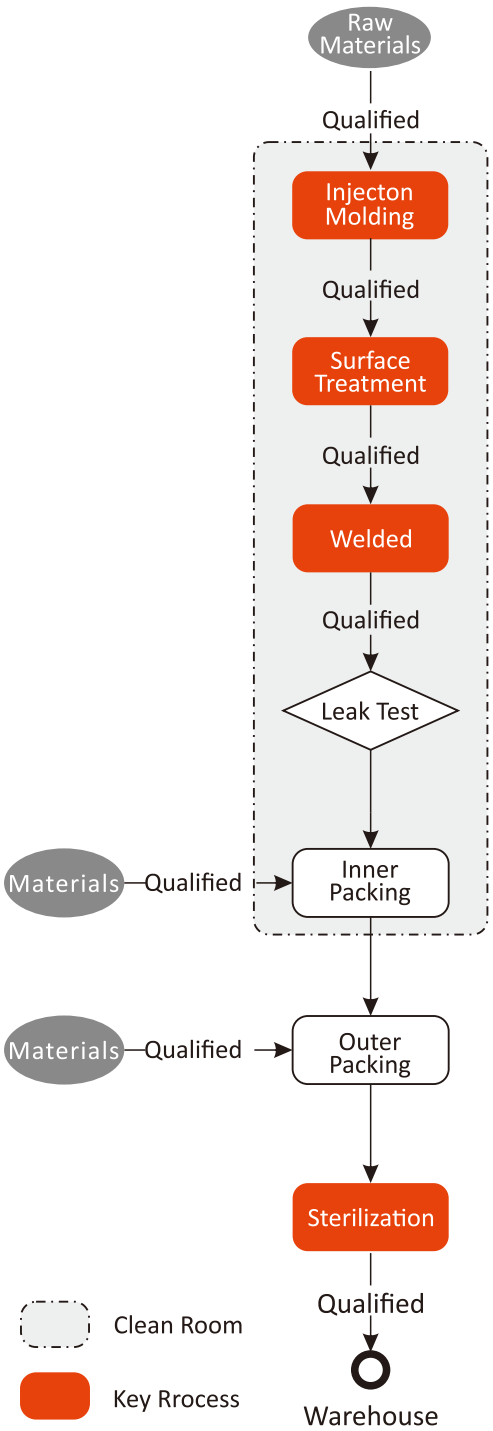
Our of reverence, we keep precise in every detail. We have always been cautious, rigorous, and truthful. We carry out production quality management in accordance with GMP principles to ensure that Man, Machine, Material, Method and Environment are all under the control. We have passed SGS certification and meet the requirements of ISO9001:2015.

We adopt a safe and mature process route, and all the processes have been rigorously validated. Nevertheless, we keep thinking about wether there are still uncontrolled quality risks all the same.

Content

FeiFanT Quality Management

FeiFanT cell culture multi-layer chambers production are ISO 9001:2015 registered.



Complies with the requirements of the USP Class VI Criteria.

Automatic appearance inspection for each tray.

TC or ultra TC surface treatment.

Ultrasonic welding process, no adhesive, no solvent, no bubbles.

100% leak tested.

The environment compliance with ISO class 7 requirements.

Packaging meets with irradiation and and customer acceptance criteria.

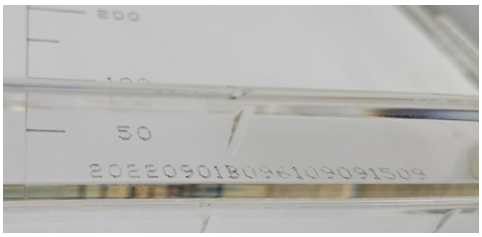
SAL 10^{-6} achieved by following ISO 11137-2 guidelines.

Barcode control for goods in and goods out.

FeiFanT™ Quality Traceability

Tracking code:

Each Chamber has a unique, clear, permanent and unchangeable tracking code, which records the batch number and production date and manufacturing time. Base on this information, detailed production data for this chamber can be traced back, such as injection molding data, surface treatment data, welding data and leak test data.



Batch Manufacturing and Testing Records:

The key data in the production process and quality control are recorded in detail.

Batch Records can be traced back to the following information:

Personnel: Production personnel of the batch of products.

Machine: Machine state and key parameters at production time.

Material: The information on raw material and all accessories.

Testing data: Quality testing data of this batch of products.

Environment: Environmental monitoring record of this batch of products.

FeiFanT™ Summary of Validation

Resin Information:

Resin complies with the requirements of the USP Class VI Criteria.
Validated and tested reference to *Pharmaceutical Packaging Material Standard.*

Production Process:

Fully automatic production process. During the production process, the chamber will not be in contact with human hands.

Surface Treatment:

Surface treatment improves cell attachment by incorporating significantly more oxygen into the surface of cell culture, rendering it more hydrophilic (wettable) and increasing surface stability.

Biological Evaluation:

Acute systemic toxicity test
Cytotoxicity test
Intracutaneous Irritation test
Skin sensitization test
Hemolysis test

Chemical Characterization:

The qualitative and quatitative analysis of the extractables and leachables were tested reference to *Pharmaceutical Packaging Material Standard.*

Cell Culture:

293T, Vero, MRC-5, 2BS, KMB-17, PHKC, MSC

……

Evironment:

The environment compliance with ISO class 7 requirements.

Aging Test:

After 150 days accelerated aging test, the product can still meet the requirements of cell culture.

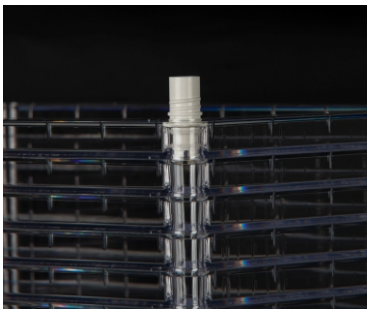
Packaging:

Test according to ISO 2248:1985.

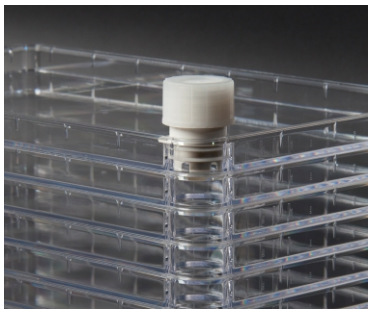
Sterile:

Carry out irradiation dose verification according to ISO 11137, and ensure product sterility level at SAL 10^{-6}.

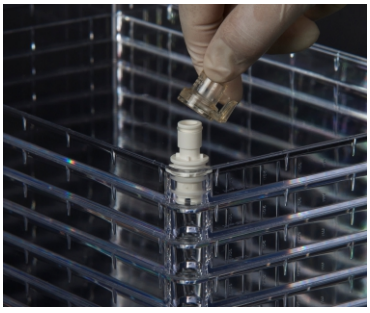
FeiFanT™ Filling Ports



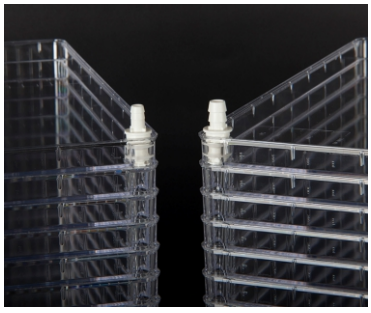
Narrow mouth



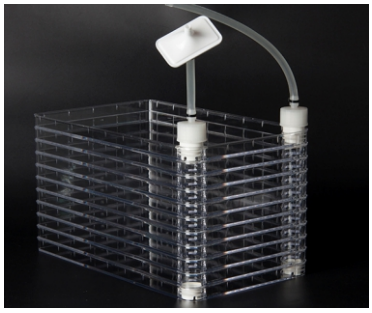
Wide mouth



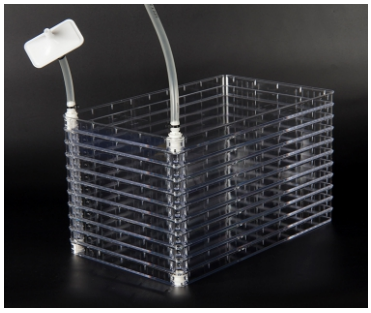
MPC Filling Port



Hose Barb Filling Port

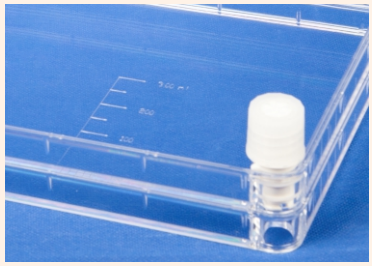


Pre-assembly Closed System



Pre-assembly Closed System

Accessories



The first tray has a clear and accurate scale

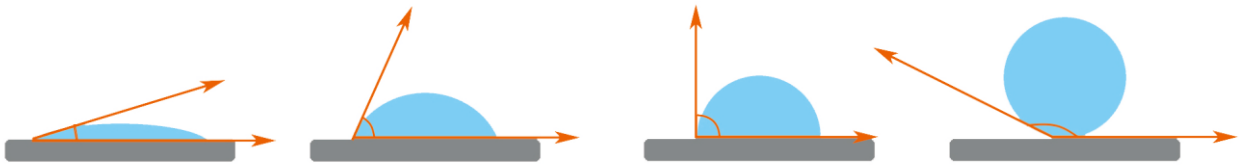
FeiFanT™ Cell Culture Surfaces

The surface of FeiFanT™ cell culture multi-layer chambers were treated to produce better surface growth of attached cells. This process improves cell attachment by incorporating significantly more oxygen into the surface of cell culture, rendering it more hydrophilic and increasing surface stability. Hydrophobicity and hydrophilicity can be defined by the water contact Angle, the smaller the contact Angle, the better the hydrophilicity. However, it is not that the better the hydrophilic, the more suitable for cell culture.

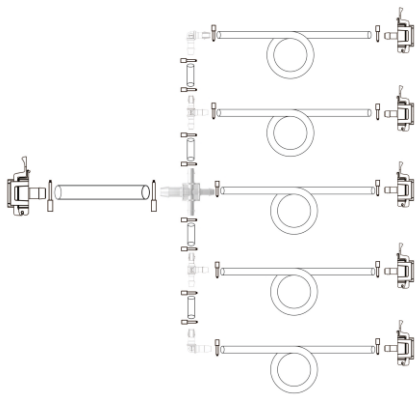
There are 2 types of surface treatment, TC or ultra TC:

TC surface treatment: Suitable for most cell culture applications.

ultra TC surfacet treatment: More hydrophilic than TC, which is suitable for low-serum or serum-free cell culture, primary cell culture, MSC culture and other difficult cell culture conditions.



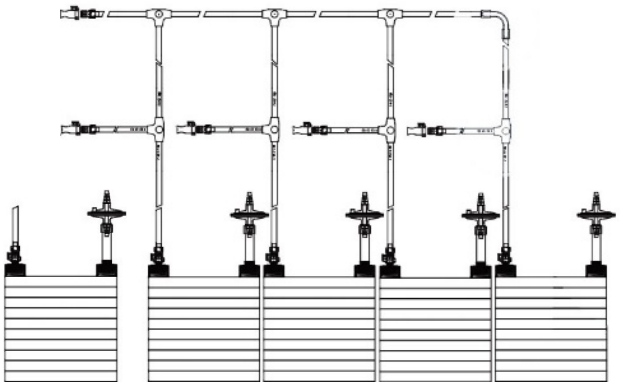
FeiFanT™ Pre–assembly Closed System



- Customized closed system with pre-assembled tubing and filters, reduces the chance of contamination.
- These specifications can be designed to suit your application such as tubing size and length, tubing connector or heat-sealed tubing ends.
- Pre-assembled high throughput air filter that can be sterilized by gamma irradiation.
- We can design, develop and integrate custom components. Designed specifically to suit your applications and specifications.

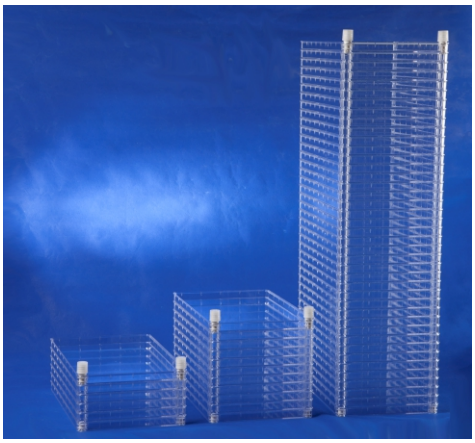
FeiFanT™ Cell Culture Multi–layer Chambers

Cell culture multi-layer chamber (Cell Factory) have been used for large-scale cell culture for more than 30 years as an alternative to the roller bottle process.



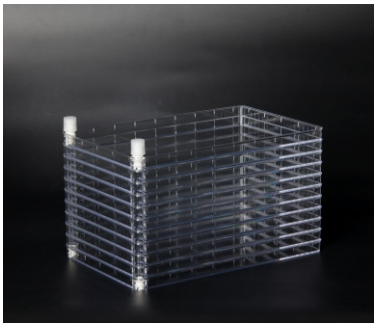
Benefits

- Sterile disposable bioreactor for large scale production of (mammalian) cells.
- TC or ultraTC surfaces treatment for growing attached cells.
- Big surface-to-volume ratio and hence space saving.
- Low contamination / cross contamination risks
- Growth kinetics is the same as that lab scale culture, easy to scale up.
- Serial No. on each chamber provides documentation for GMP compliance and traceability.
- Available in 1, 2, 4, 5, 10 and 40 tray versions for cell proliferation.
- Self-venting caps prevent pressure build-up during transport.
- Automatic production line ensures stable quality and reduces pollution risks.
- Ultrasonic welding process, no adhesive, no solvent, no bubbles.
- 100% leak tested.
- Irradiation sterilization complies with with ISO 11137 ensure SAL 10^{-6}.
- FeiFanT™ offers a variety of accessories to simplify handling and reduce contamination risks.
- Wide-mouth an narrow-mouth chambers can be fitted various applications.
- Quality audits at any time.
- Validation binders can be provided under a signed confidentiality agreement.



FeiFanT™ Cell Culture Chambers, Narrow Mouth Ports

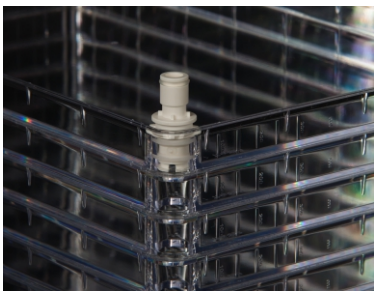
PTFE connector (ATT991301) that assembled a tubing can be inserted into the ports of narrow mouth chambers. The size of port is consistent with Nunc™ Cell Factory™, and accessories are universal.



Cat. No.	No. of Trays	Surface Treatment	Culture Area, cm²	Units per pack/case
FCB100101	1	ultra TC	632	1/6
FCB100201	2	ultra TC	1264	1/6
FCB100401	4	ultra TC	2528	1/4
FCB100501	5	ultra TC	3160	1/4
FCB101001	10	ultra TC	6320	1/6
FCB104001	40	ultra TC	25280	1/2
FCB1T0101	1	TC	632	1/6
FCB1T0201	2	TC	1264	1/6
FCB1T0401	4	TC	2528	1/4
FCB1T0501	5	TC	3160	1/4
FCB1T1001	10	TC	6320	1/6
FCB1T4001	40	TC	25280	1/2

FeiFanT™ Cell Culture Chambers, MPC Ports

MPC connector is widely used on SUS (Single use bioprocess bag). The chamber with male MPC ports is conveniently assembled with SUS.



Cat. No.	No. of Trays	Surface Treatment	Culture Area, cm²	Units per pack/case
FCB100102	1	ultra TC	632	1/6
FCB100202	2	ultra TC	1264	1/6
FCB100402	4	ultra TC	2528	1/4
FCB100502	5	ultra TC	3160	1/4
FCB101002	10	ultra TC	6320	1/6
FCB104002	40	ultra TC	25280	1/2
FCB1T0102	1	TC	632	1/6
FCB1T0202	2	TC	1264	1/6
FCB1T0402	4	TC	2528	1/4
FCB1T0502	5	TC	3160	1/4
FCB1T1002	10	TC	6320	1/6
FCB1T4002	40	TC	25280	1/2

FeiFanT™ Cell Culture Chambers, Barbed Ports

3/8" OD barbed ports of chambers is conveniently assembled with tubing. FeiFanT™ available 1/4" OD barbed ports alternative.

Cat. No.	No. of Trays	Surface Treatment	Culture Area, cm²	Units per pack/case
FCB100103	1	ultra TC	632	1/6
FCB100203	2	ultra TC	1264	1/6
FCB100403	4	ultra TC	2528	1/4
FCB100503	5	ultra TC	3160	1/4
FCB101003	10	ultra TC	6320	1/6
FCB104003	40	ultra TC	25280	1/2
FCB1T0103	1	TC	632	1/6
FCB1T0203	2	TC	1264	1/6
FCB1T0403	4	TC	2528	1/4
FCB1T0503	5	TC	3160	1/4
FCB1T1003	10	TC	6320	1/6
FCB1T4003	40	TC	25280	1/2

FeiFanT™ Cell Culture Chambers, Wide Mouth Ports

The wide mouth port of chambers are conveninent for direct pouring and harvesting the culture medium in a laminar air flow cabinet. Culture medium or trypsin solution will faster level out between the trays during filling. FeiFanT™ offer a variety of filling caps to assemble with tubing conveniently.

Cat. No.	No. of Trays	Surface Treatment	Culture Area, cm²	Units per pack/case
FCB100111	1	ultra TC	623	1/6
FCB100211	2	ultra TC	1246	1/6
FCB100411	4	ultra TC	2492	1/4
FCB100511	5	ultra TC	3115	1/4
FCB101011	10	ultra TC	6230	1/6
FCB104011	40	ultra TC	24920	1/2
FCB1T0111	1	TC	623	1/6
FCB1T0211	2	TC	1246	1/6
FCB1T0411	4	TC	2492	1/4
FCB1T0511	5	TC	3115	1/4
FCB1T1011	10	TC	6230	1/6
FCB1T4011	40	TC	24920	1/2

Accessories of FeiFanT™ Cell Culture Chambers

FeiFanT™ offers a variety of accessories to simplify handling and reduce contamination risks. These accessories are available to allow direct aseptic transfer of media and cells via pumping or gravity feeding. Optional filling caps with attached filters with hydrophobic membranes provide for gas exchange and faster aseptic venting during liquid transfer.

Connector of Cell Culture Chambers

It is easily inserted into the ports of narrow mouth chambers, connect with 5/16" or 1/4" ID silicone tubing. Autoclavable, non-tytotoxic.

Cat. No.	Material	Gamma irradiated	Qty/Pk
ATT991301	PTFE	No	10

Filling Caps

For wide mouth chambers, FeiFanT™ offers a variety of filling caps to assemble with tubing conveniently to allow direct aseptic transfer of media and cells.

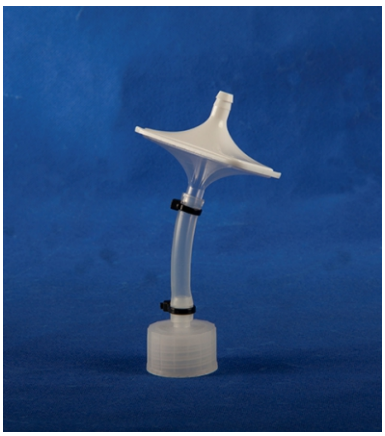
Cat. No.	Description	Gamma irradiated	Qty/Pk
ACD9926F3	Filling cap, narrow port with vented overcaps	YES	60
ACD992603	Filling cap, narrow port with close overcaps	YES	60
ACD992613P	Filling cap, Autoclavable	No	60

Replacement Caps

Cat. No.	Description	Gamma irradiated	Qty/Pk
ACD9913S0	Close cap for narrow ports	YES	60
ACD9926S0	Close cap for wide mouth ports	YES	60

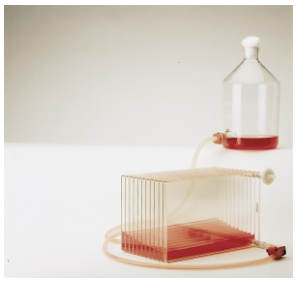
Air Vent Filter Assembly

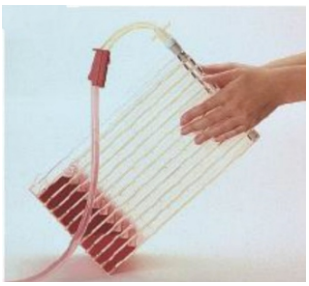
Filling cap with barbed port, assembled with TPE tubing and high throughput vent filter.



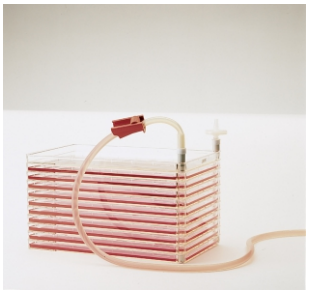
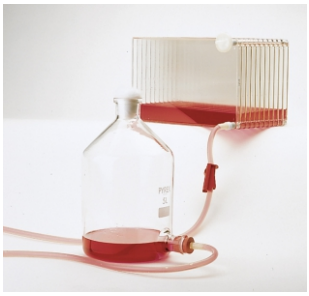
Cat. No.	Description	Gamma irradiated	Qty/Pk
AFG050FTC	Air vent filter assembly	YES	6

Instrucions for Use



- For 10-layers and 40-layers chambers, prewarming the chamber and the medium is especially important due to the middle chamber takes longer the reach the desired incubation temperature than the sides of chamber.
- Unpack the chamber, and place it inside a laminar flow hood or clean room environment to carry out aseptic connections.
- Replace a vent cap with an air vent filter assembly. Connect the tubing set of the cell suspension container to another port of the chamber. Place the chamber on side with air filter up. Open clamp to start filling. The cell suspension will level out between the trays during filling.
- After the cell suspension is completely leveled at the previous position, turn the chamber on the short side with the ports upright.
- Close the clamp to seal the tubing, or heat seal the tubing, or replace the filling tubing with an air vent filter assembly cap or vent cap.
- Gently lower the chamber to its normal horizontal incubation position, and gently tilt the chamber back and forth until the surface of each chamber is completely covered with medium. This will ensure an even distribution of cells across each of the growing surfaces.
- Place the chamber in an incubator or warm room. Due to pressure build-up during incubation, the chamber must be vented during incubation.
- Replace one of the vented caps with a filling tubing to empty the chamber. Place the chamber on side with air filter up. Ensure the chamber is located above the sterile collection vessel if emptying by gravity. Tilt the chamber to drain completely.

Harvesting Cells

1. Remove and discard the culture medium.

2. Rinse monolayer.

a. Add the recommended volume of CMF-PBS (40 to 50 ml per layer) to the chamber. Recap tightly and distribute the CMF-PBS equally to each chamber layer by laying the chamber on its longest side.

b. Once the liquid has equilibrated, stand up the vessel to separate the layers, then slowly set chamber down to incubation position. Tilt the chamber back and forth in both directions to thoroughly rinse each layer and remove all traces of the old medium.

c. Remove and discard the washing solution. A second rinse with CMF-PBS is highly recommended for cells that are difficult to harvest.

3. Dissociate the monolayer.

a. Add the recommended volume (20 to 30 ml per layer) of prewarmed dissociation solution to the chamber and distribute equally to each chamber by following rinsing steps. Prewarming of the dissociation solution will reduce the incubation time required.

b. Tapping the sides of the chamber helps the cells detach from the surface.

4. Gently tilt the chamber side to side and end to end to distribute the dissociation solution evenly across each layer. Tapping the sides of the chamber helps the cells detach from the surface. Because it is impossible to directly monitor the action of the dissociation solution on the cells in the chamber, we recommend growing the same cells under identical conditions (relative cell density and medium amounts) in a companion vessel. This companion vessel (usually a flask or 1-layer chamber) can be processed in parallel to monitor the progress of the cell growth and harvestng procedure.

5. Collect the dissociation solution containing the resuspended cells into a centrifuge tubes or a plastic or glass storage bottle. Neutralize the dissociating agent (if possible) and place the cells on ice. To recover additional detached cells that have been left behind in the chamber, one or more additional rinses are recommended:

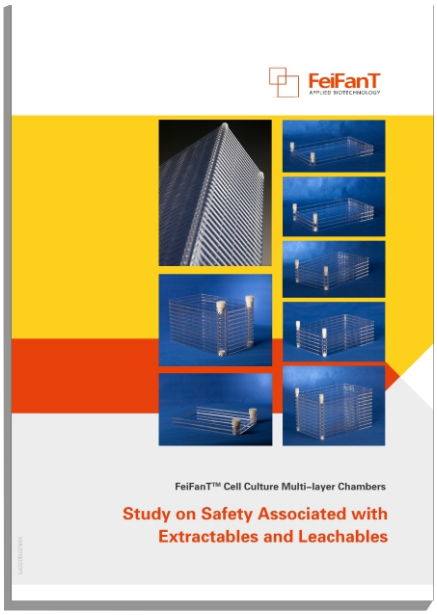
a. For cells that are easily removed, the rinse step can be done with CMF-PBS or medium and added to the cell suspension with the first dissociation solution. If a substantial number of viable cells are found in the rinsing solution, then a second rinse should be done or the dissociation solution or harvesting procedure may need to be adjusted. (See step b below.) If the rinsing solution contains few viable cells, then this step can be omitted in the future.

b. For cells that are difficult to remove, rinse step should use an additional prewarmed dissociation solution. It may be necessary to incubate the cells for a few minutes to give the solution time to act on the remaining attached cells. If a substantial number of viable cells are found in the second harvest, then the original dissociation solution or harvesting procedure may need to be adjusted. If the second harvest contains few viable cells, then this step can be omitted in the future.

6. Inactivate or remove the dissociating agents. Some dissociating agents should be immediately removed by centrifugation to prevent residue which can cause poor cell attachment or toxicity, especially in combination with serum-free medium. However, other dissociating agents, such as trypsin, can be inactivated by adding chilled medium with serum or a trypsin inhibitor and do not need to be removed. If removal is desired, spin the cell suspension at 100 x g for 5 minutes. Then remove the medium containing the dissociating agent and replace with fresh medium.

7. Count the cells to determine cell yield and viability.

Validation Binder



Validation Binder

Validation Binder is provided to you under a signed Confidentiality Agreement. The content of validation binder include below information:

Company Profile, Product Specifications, Resin Information, Chemical Characterization of Materials, Extractables and Leachables, Biological Evaluation (Acute systemic toxicity test, Cytotoxicity test, intracutaneous Irritation test, Skin sensitization test, Hemolysis test), Bacterial Endotoxin Tesing, Validation of Sterility, Validation of Manufacturing Process, Cleanroom Performance, Validation of Packaging, Quality Control.

Study on Safey Associated with Extractables and Leachables

Leachables test according to the *CSFDA Standards for Contact with Pharmaceutical Packaging Material.*

Extractables and leachables tests according to the *Guiding Principle of Compatibility of Pharmaceutical Products and Contact Materials*.

Extractables and leachables compare consistency with Corning™ CellSTACK™ and Nunc™ Cell Factory™.

FeiFanT
APPLIED BIOTECHNOLOGY

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