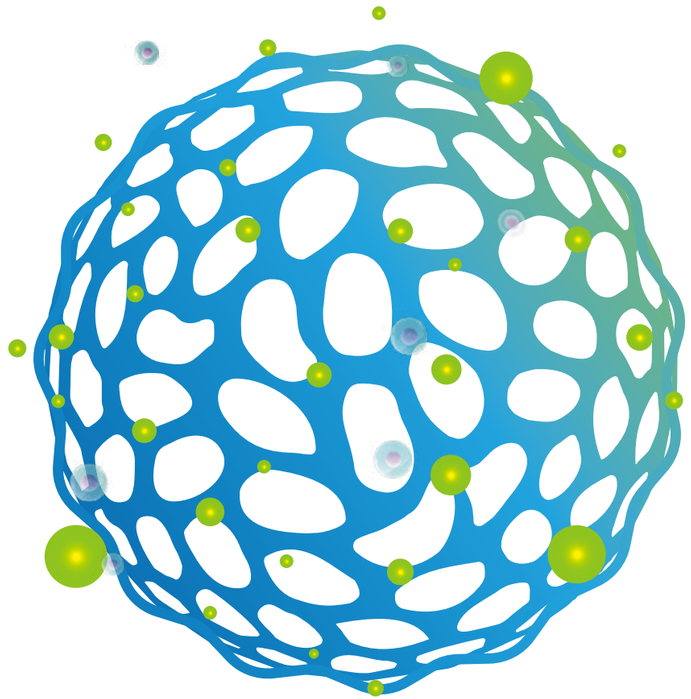
ARCHITECT FOR CELLS

EXPERT IN 3D MANUFACTURING OF HIGH-QUALITY CELLS

CytoNiche
Architects for Cells

Total Solution for Mass Manufacturing of Cells

Product Catalogue



CytoNiche
Architects for Cells

Follow Us on WeChat

Follow Us @ CytoNiche

E-mail: global_sales@cytoniche.com

Web: en.cytoniche.com

Address: No.208, Building 1, Zone B, Yiyuan Cultural and Creative Industry Base, Haidian District, Beijing, China

Address: 15th Floor, Building No.4, Maoyuan Road No.260, Fengxian, Shanghai China

Date: 2024.03

BEIJING CYTONICHE BIOTECH CO., LTD.

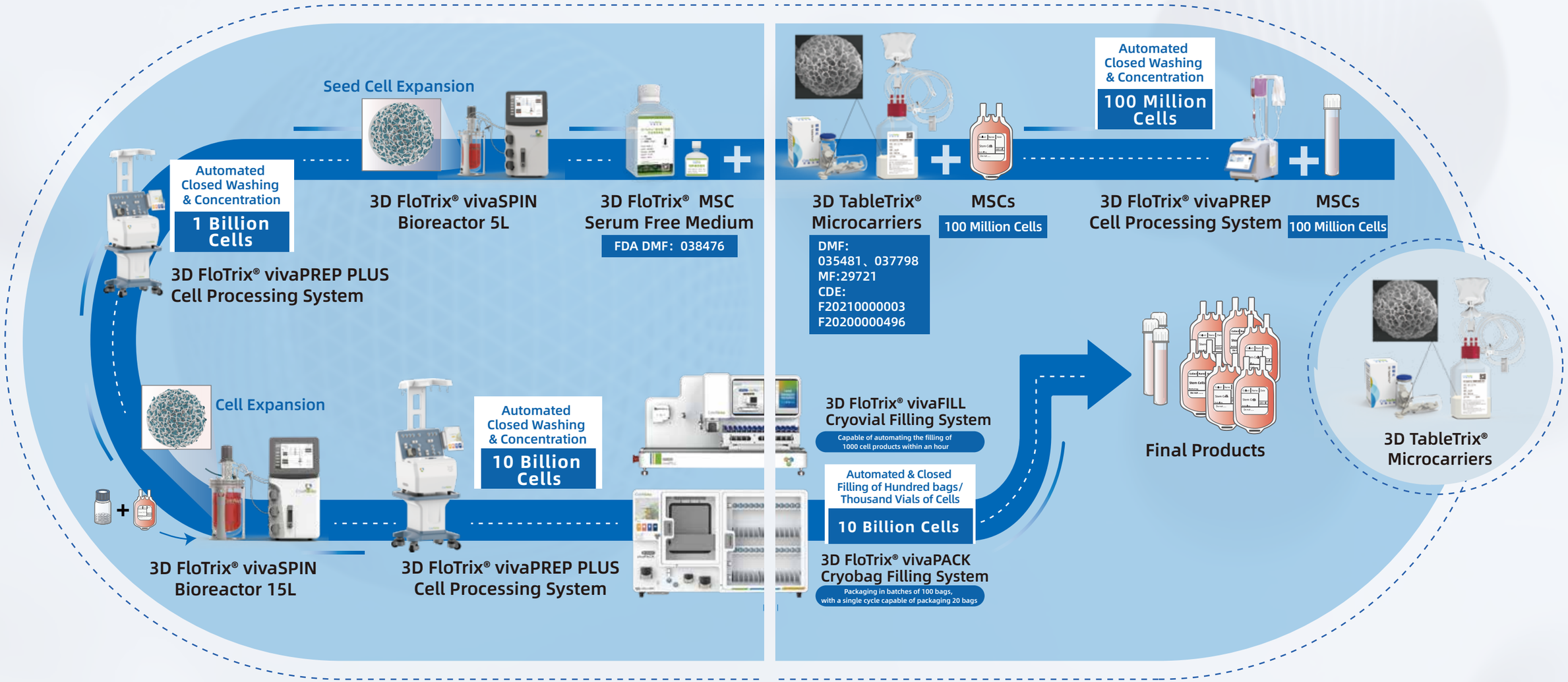
SHANGHAI CYTONICHE BIOTECH CO., LTD.


Igniting a New Era in
Industrial Cell Development
EXPERT IN 3D M
Empowering cell
3D cellular mass
Pharmaceutical Grade Microcarriers with
DMF

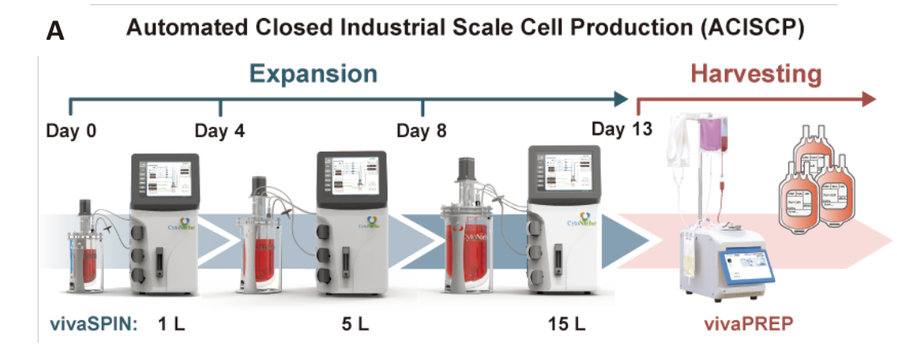

ARCHITECT FOR CELLS:
ANUFACTURING OF HIGH-QUALITY CELLS
and gene therapy advancement with intelligent
manufacturing technology to benefit more patients

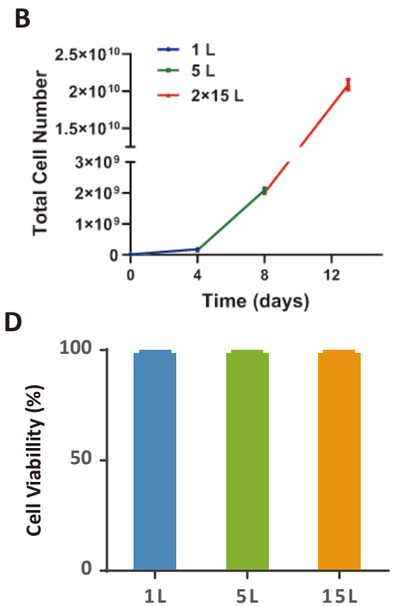
TABLE OF CONTENTS

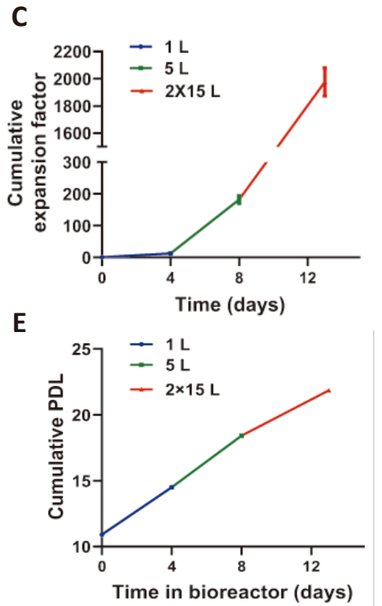
Experience Effortless Stem Cell Pro duction with 3D FloTrix® Technology



Producing Billions of Stem Cells Effortlessly







- A. ACISCP platform
- B. Cumulative number of cells harvested in the stepwise scale-up process
- C. Cumulative expansion factor in the stepwise scale-up process
- D. Cell viability of each stage in the process
- E. Cumulative cellular PDL in the stepwise scale-up process

References:
GMP-grade microcarrier and automated closed industrial scale cell production platform for culture of MSCs. J Tissue Eng Regen Med. 2022 Oct;16(10):934-944. doi: 10.1002/term.3341. Epub 2022 Aug 5. PMID: 35929499.

Production of ten billion (1×10^{10}) cells.

Units: Thousand US Dollar

Process	2D	3D	Cost difference (≈)
Rent Expenses	0.15	0.03	-80%
Energy Consumption	1.23	0.03	-98%
Reagent and Consumable Costs	24.62	23.08	-10%
Personnel Costs	1.54	0.31	-80%
Total Costs	27.69	23.08	-20%

Note: 2D production with 10-layer cell factory, 3D production with 15L bioreactor.

Efficiency meets affordability

Experience 3D FloTrix® Technology

Produce Cells of Unmatched Quality

1. **Bid farewell to the inconsistency:**
   With 3D FloTrix®, each batch yields cells of consistently high quality.
2. **Say goodbye to contamination:**
   Fully closed system safeguarding the integrity of your valuable cell cultures.
3. **Real-time monitoring:**
   Allows for precise tracking of cell growth and process parameters to provide invaluable insights into the progression of your cultures.

Reduce Cell Production Costs

1. **Cuts labor costs:**
   Streamline manual operations.
2. **Cuts facility maintenance costs:**
   Optimized space utilization, ideal for facilities with limited footprint.
3. **Cuts production costs:**
   Reduces reagent consumption.

Space: Save≈ 80%	Reagent and Consumables: Save: ≈ **10%**	Labor: Save≈ 80%	Total Costs: Save≈ 20%

Fulfill Large-Scale Cell Culture Demands

1. **Ideal for large-scale manufacturing:**
   Produces up to Billions of cells in a single batch.
2. **Embrace one-stop automated solution:**
   From seed train & cell cultivation, downstream processing to fill & finish.

CytoNiche Microcarrier Family

- For 3D Cell Culture

3D TableTrix® Microcarrier Series

V Series Vaccine

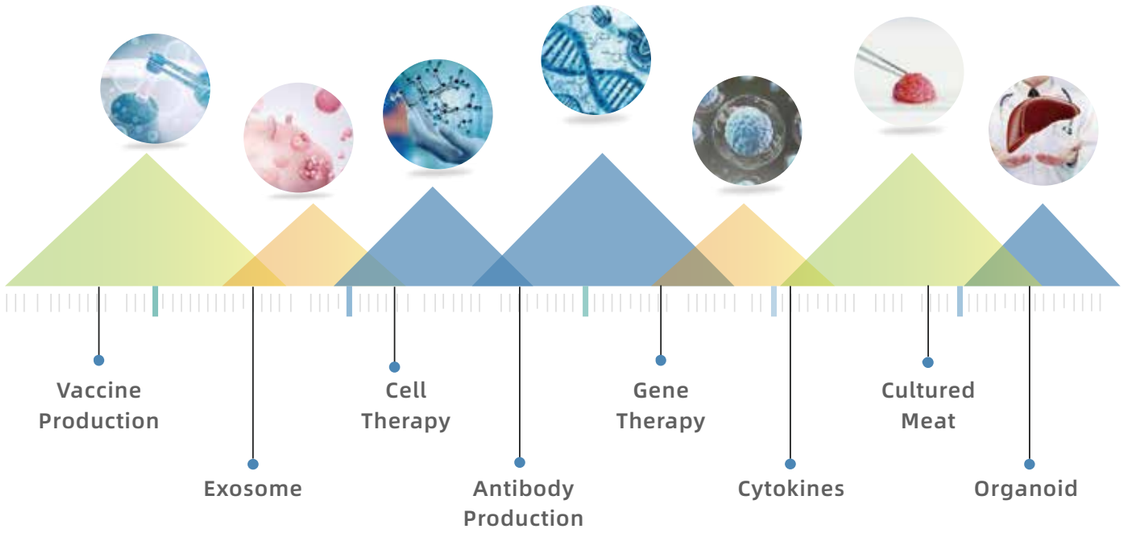
G Series Gene Therapy

W Series Stem Cells

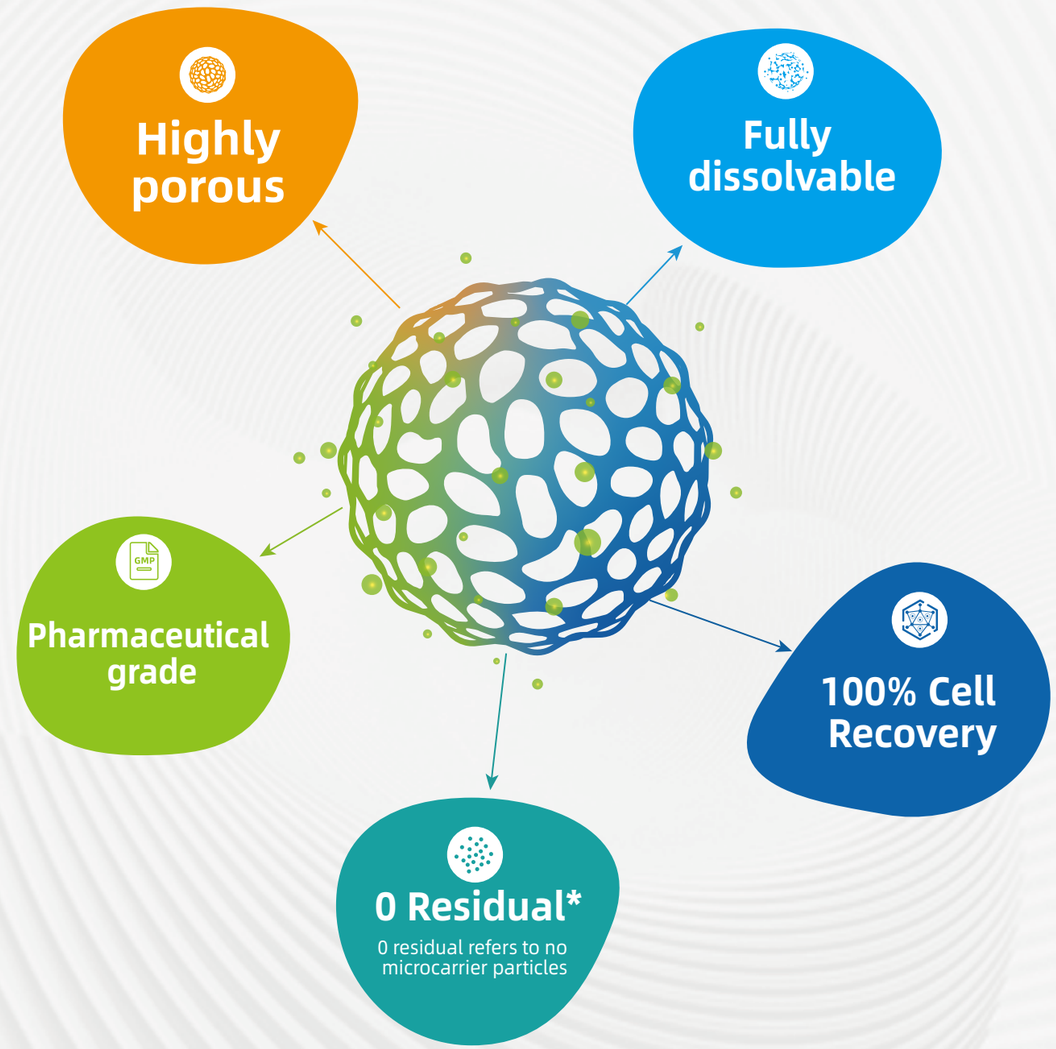
3D RecomTrix® Recombinant Collagen Microcarrier

CW Series NEW Stem Cells

- Applications of Microcarrier Technology

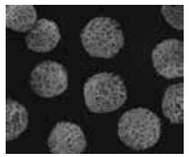


Advancing Cell & Gene Therapy with Dissolvable Microcarriers

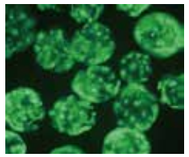


3D TableTrix® & 3D RecomTrix® Microcarriers

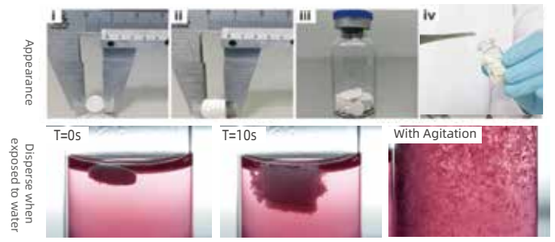
Revolutionizing cell culture with our expertise in high-quality 3D cell manufacturing, CytoNiche has developed various series of 3D microcarrier products to meet diverse application needs. Our 3D microcarriers are highly porous (>90% porosity) and elastic, mimicking cell microenvironment to enable authentic biomimetic cultivation. 3D microcarriers come in both tablet and bulk closed system packaging, suited for small scale process development and large-scale manufacturing respectively. The sterile and ready-to-use tablet packaging is proprietary innovation developed by CytoNiche to facilitated process development. These tablets are weight-defined and disperse into tens of thousands of elastic 3D porous microcarriers from each tablet upon absorption of water. Not only so, the microcarriers are fully dissolvable, ideal for harvesting cells efficiently.



Scanning Electron Microscope images show multiple uniform particles.



Viable mesenchymal stem cells (green fluorescent) grown on microcarriers.



3D TableTrix® Microcarriers are made from gelatin, and include W series, V series and G series for different applications. 3D RecomTrix® Microcarriers are made from recombinant collagen, suited for xeno-free applications.

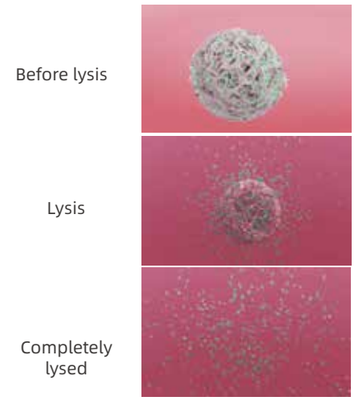
Product Specifications

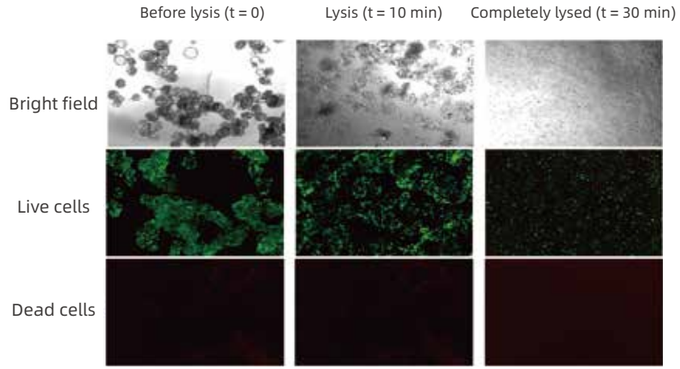
Microcarrier	Material	Structure	Dissolvable	Bead Size*(m)	Surface Area# (cm2/g)	Bead Number (particles/g)	Pore Size (m)	Packaging	Application Field
W01	Porcine Gelatin	Macroporous sphere	Yes	140-330	8300	4200	30-50	Sterile tablets sterile powder in closed system	Mesenchymal stem cells and exosomes
W02	Porcine Gelatin	Macroporous sphere	Yes	280-450	5000	1100	30-50	Sterile tablets sterile powder in closed system	Mesenchymal stem cells and exosomes
V01	Bovine Gelatin	Macroporous sphere	Yes	140-480	7500	2200	30-50	Non-sterile power	Human and animal vaccines, i.e. Vero, MDCK, MRC5
G02	Bovine Gelatin	Macroporous sphere	Yes	110-380	5900	2400	30-50	Sterile tablets sterile powder in closed system	Lenti-virus, Adeno-associatedvirus, oncolytic virus, i.e. 293T cells
CW01	Recombinant Collagen	Macroporous sphere	Yes	130-320	7700	5300	20-40	Sterile tablets sterile powder in closed system	Mesenchymal stem cells and exosomes

Bead Size: D5-D90, in DI water **#Surface Area:** $\sum_{n=0}^{100}\left(X \times \frac{n}{100} \times \pi D_n\right)$

Fully Dissolvable Microcarriers

3D TableTrix® and 3D RecomTrix® microcarriers are fully dissolvable by 3D FloTrix® Digest, to fully release cells into the supernatant for highly efficient cell harvesting. This process is gently performed at cell culture suited temperature and pH, no harsh chemicals or mechanical agitation required. As 3D FloTrix® Digest is a specific dissolution reagent that targets the microcarriers, cells remain highly viable and intact. >99.9% of dissolved microcarriers and Digest can be simply removed by centrifuge, leaving no harmful residues in your final cell products. Residual detection assays are available to support your drug quality control.





Registered DMF in U.S. FDA and Chinese CDE

The core product cell microcarrier series has obtained the qualification for pharmaceutical excipients from FDA DMF and 2 qualifications for pharmaceutical excipients from the National Medical Products Administration, and has passed the quality evaluation and safety evaluation qualification certification of the National Institutes for Food and Drug Control.

Registered Pharmaceutical Excipient (FDA DMF #035481)

Registered Starting Materials (FDA DMF #037798)

Registered Starting Materials (FDA CBER MF #29721)

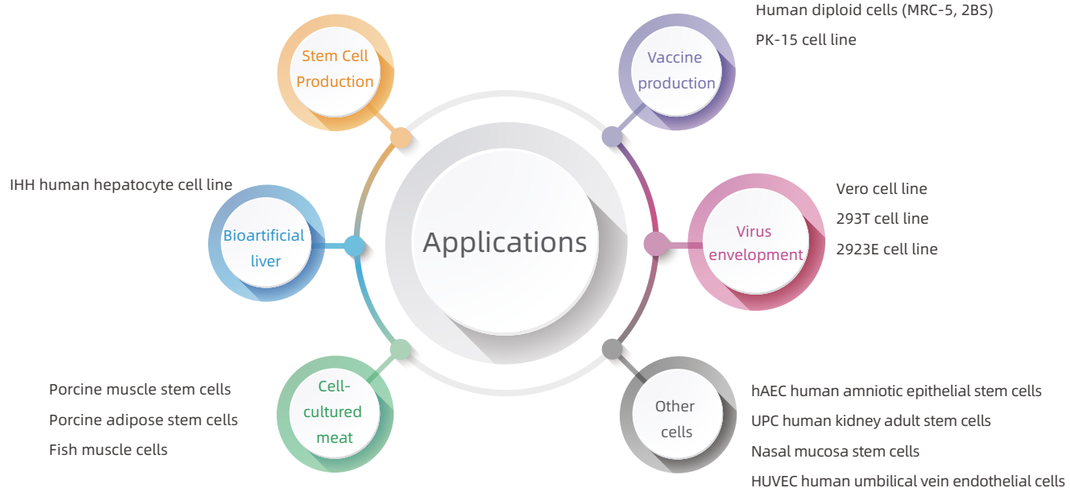
Registered Pharmaceutical Excipients
(Chinese CDE: F20200000496, F20210000003)

Quality evaluation report from National Institutes for Food and Drug Control
(Microcarrier residue assay, lysate residue assay, microcarrier stability kinetics, cytocompatibility, cytotoxicity, pyrogen reaction, genotoxicity, in vivo immunotoxicology, etc.)

Quality evaluation report issued by Jiangsu Center for Safety Evaluation of Drugs
(Microcarrier cytotoxicity, hemolysis, local irritation by subcutaneous injection, active systemic hypersensitivity, toxicity by intraperitoneal injection, etc.)

Types of Cells Tested

Human umbilical cord MSCs
Human amniotic MSCs
Human adipose MSCs
ESC-differentiated MSC
Human dental pulp MSCs
iPSC-differentiated MSC
Human bone marrow MSCs
Sheep umbilical cord MSC
Human placental MSCs
Bovine umbilical cord MSC



Vero cell line
MDCK cell line
Human diploid cells (MRC-5, 2BS)
PK-15 cell line

Vero cell line
293T cell line
2923E cell line

IHH human hepatocyte cell line

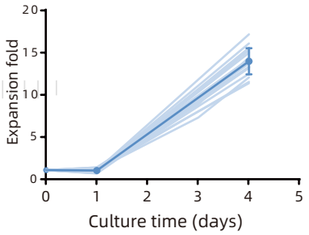
Porcine muscle stem cells
Porcine adipose stem cells
Fish muscle cells

hAEC human amniotic epithelial stem cells
UPC human kidney adult stem cells
Nasal mucosa stem cells
HUVEC human umbilical vein endothelial cells
HDF human dermal fibroblasts
3T3 cell line
Neurons

Application Cases

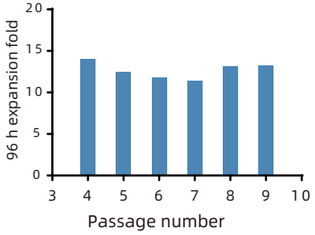
Mesenchymal Stem Cells

Expansion of human umbilical cord MSCs



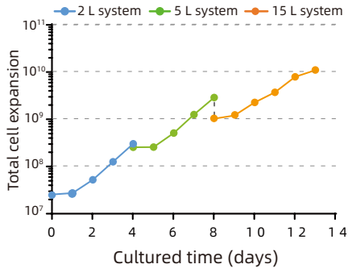
Multiple cases have shown that MSCs can expand 10-16 folds on 3D TableTrix® Microcarriers.

Continuous passage of human umbilical cord MSCs



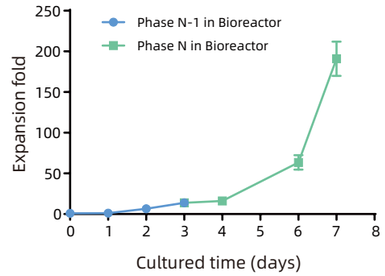
Expansion remains stable at 12-14 folds across 6 continuous subcultures.

Continuous expansion curve of human umbilical cord MSCs



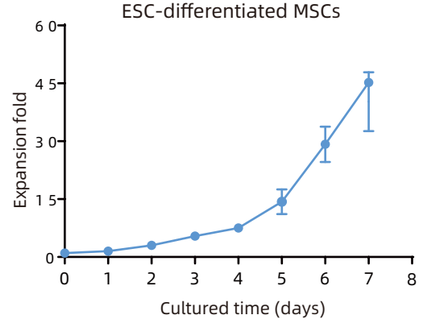
Produce 10 Billion cells per batch using 3-phase scale-up in bioreactors using 3D TableTrix® Microcarriers & 3D FloTrix® technology.

Continuous expansion curve of dental pulp MSCs (DPSC)



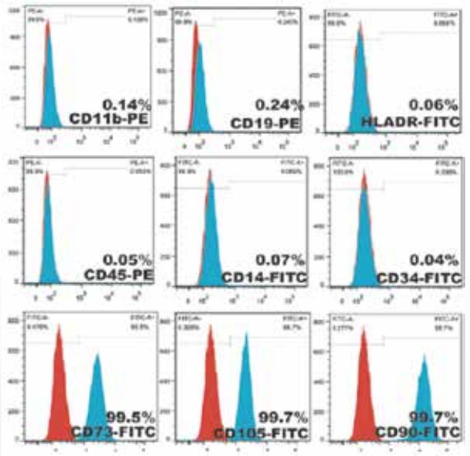
Using 3D TableTrix® Microcarriers with 3D FloTrix® technology, expand 180-200 folds of dental pulp-derived MSCs (DPSCs) in 144h.

Expansion curve of ESC-differentiated MSCs



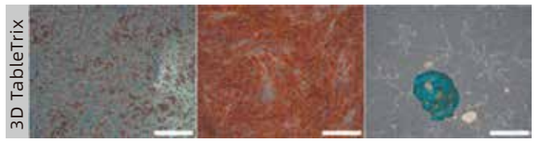
ESC-differentiated MSCs expanded 40-50 folds on 3D TableTrix® microcarriers.

01. Flow cytometry analysis



Phenotypic surface markers of MSCs harvested from 3D microcarrier culture meet quality requirement.

02. Tri-lineage differentiation



MSCs cultured and expanded by 3D microcarriers have the ability to differentiate into three lineages: osteogenic, adipogenic and chondrogenic

03. Cell safety test

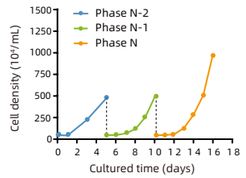
Sterility test	Should comply with regulations	Test result
Bacterial endotoxin test	<5EU/mL	< 0.25 EU/mL (10^7 cells/mL)
Mycoplasma test	Negative	Negative
Cytomegalovirus (CMV) test	Negative	Negative
EB virus (EBV) test	Negative	Negative
Human immunodeficiency virus (HIV) test	Negative	Negative
Hepatitis B virus (HBV) test	Negative	Negative
Hepatitis C virus (HCV) test	Negative	Negative
Treponema pallidum antibody (TP) test	Negative	Negative

MSCs harvested from 3D microcarrier culture meet sterility test requirements.

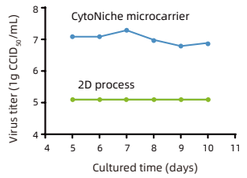
Virus production

01. Vero cells (African green monkey kidney cells)

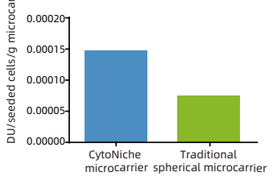
Continuous scale-up and subculture of Vero cells



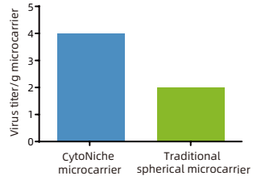
Virus A produced by Vero cells



Virus B produced by Vero cells



Virus C produced by Vero cells

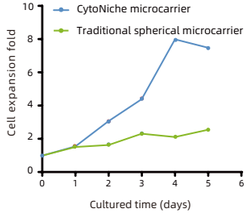


Continuous multi-stage scale-up subculture of Vero cells in a bioreactors can be enabled with 3D TableTrix® microcarrier, achieving peak cell density of 1 × 10^7 /mL.

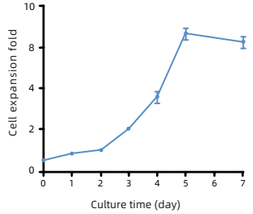
For vaccine development, titer and efficacy of viruses produced from cells cultured on 3D TableTrix® microcarrier are significantly higher than those from 2D planar culture or traditional spherical microcarriers.

02. Human diploid cells

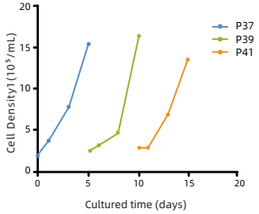
The expansion curve of human diploid cells



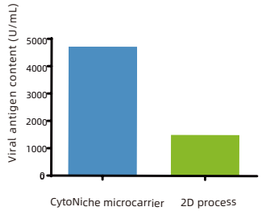
Expansion of MRC-5



Serial Passaging of MRC-5



Virus E produced by human diploid cells



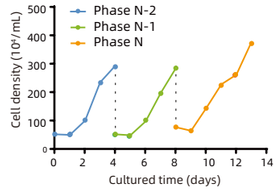
Up to 4 times more human diploid cells can be harvested from 3D TableTrix® microcarriers as compared to traditional microcarriers, and the culture density can reach over 7 × 10^6/mL. Virus titer (tested by viral antigen amount) is nearly 3 times that of 2D process.

03. MDCK cells (Madin-Darby canine kidney cells)

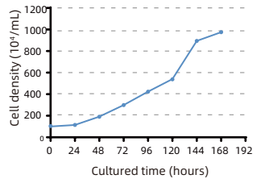
Continuous multi-stage scale-up subculture of MDCK cells in a bioreactors can be enabled with 3D TableTrix ® microcarrier, achieving peak cell density of 1 × 10^7 /mL.

For vaccine development, hemagglutination titer of virus produced from MDCK cultured on 3D TableTrix® microcarrier is nearly 4 times that of traditional spherical microcarriers.

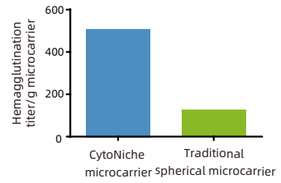
Continuous scale-up and subculture of MDCK cells



The expansion curve of MDCK cells

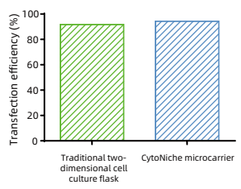


Virus D produced by MDCK cells

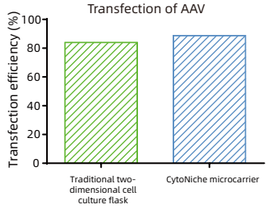


04. 293T cells

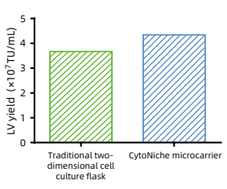
Transfection of Lenti Virus



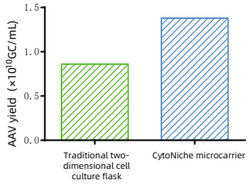
Transfection of AAV



Lenti Virus Yield*



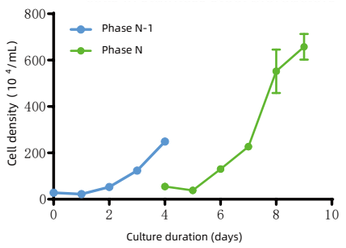
AAV Yield*



*Tested with supernatant, before concentration and purifcation

Traditional two-dimensional process parameters can easily be adapted to three-dimensional microcarrier culture process, enabling large-scale virus production.

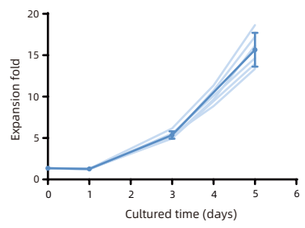
Continuous scale-up cultivation of 293T cells in stainless steel bioreactors



Continuous scale-up can be achieved with a peak cell density reaching 6.58×10^6 cells/mL.

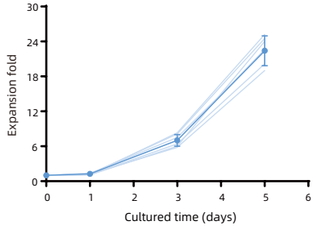
05. Other cell types

Expansion of porcine muscle stem cells



Multiple experiments have shown that porcine muscle stem cells can expand 12-18 folds on 3D TableTrix® Microcarriers.

Expansion of embryonic lung fibroblasts



Multiple experiments have shown that embryonic lung fibroblasts can expand 18-24 folds on 3D TableTrix® Microcarriers.

3D FloTrix® MSC Serum Free Medium

3D FloTrix® MSC Serum Free Medium is a xeno-free medium especially developed for cell culture on 3D microcarriers. It is also ideal for isolation and subculturing of mesenchymal stem cells on 2D planar flasks. With excellent performance, quality, and low price, this medium can help you to yield high quantity of quality stem cells for your applications, be it for research or for therapeutic purposes. This product is registered with U.S. **FDA DMF (#038476)**.

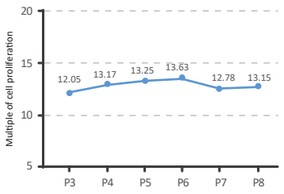
This culture medium contains two parts:

① 3D FloTrix® MSC serum-free Basal Medium (Cat. No.: RMZ112-PYJ, specification: 500 mL, storage condition 2-8°C).

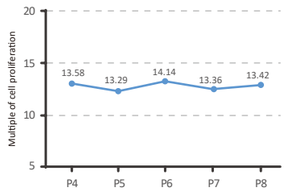
② 3D FloTrix® MSC serum-free Supplement (Cat. No.: RMZ112-B, specification: 25 mL, storage condition: -20°C and below).

Continuous subculture

Mesenchymal stem cells cultured with 3D FloTrix® MSC SFM are able to maintain stable and efficient proliferation across passages and retain MSC characteristics and tri-lineage differentiation potential.



Continuous 2D subculture of UCMSCs (P3→P8)



Continuous 3D subculture of UCMSCs (P4→P8)

Morphology of MSCs (passage 8) replated on culture flask after harvesting from continuous subculture on 2D planar flasks.

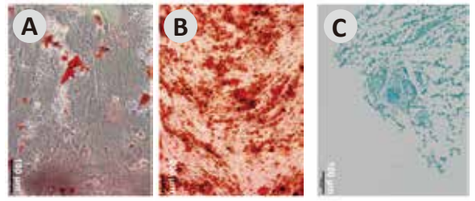
Morphology of MSCs (passage 8) replated on culture flask after harvesting from continuous subculture on 3D microcarriers.

Quality of cells

Safety Evaluation

Sterility test	Should comply with regulations.	Test result
Bacterial endotoxin test	<5EU/mL	< 0.25EU/mL (10^7 cells/mL)
Mycoplasma test	Negative	Negative
Cytomegalovirus (CMV) test	Negative	Negative
EB virus (EBV) test	Negative	Negative
Human immunodeficiency virus (HIV) test	Negative	Negative
Hepatitis B virus (HBV) test	Negative	Negative
Hepatitis C virus (HCV) test	Negative	Negative
Treponema pallidum antibody (TP) test	Negative	Negative

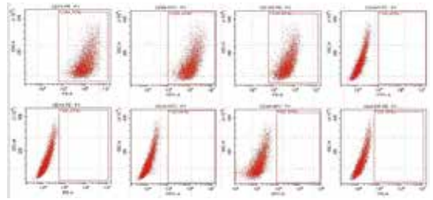
Tri-lineage differentiation potential



(A. Adipocyte B. Osteoblast C. Chondrocyte)

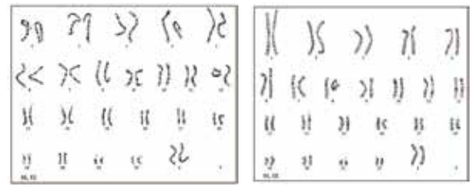
UCMSCs maintain good tri-lineage differentiation ability (3D, P5)

Phenotype Analysis



FACS analysis of UCMSCs (3D, P5)

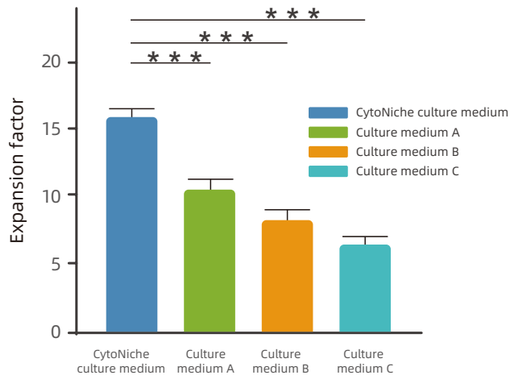
Genetic Stability

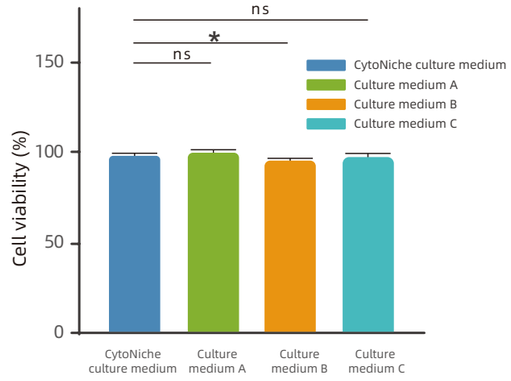


2D 3D

Chromosomal karyotype stability of UCMSCs (3D, P5)

Comparison of performance on 3D microcarriers



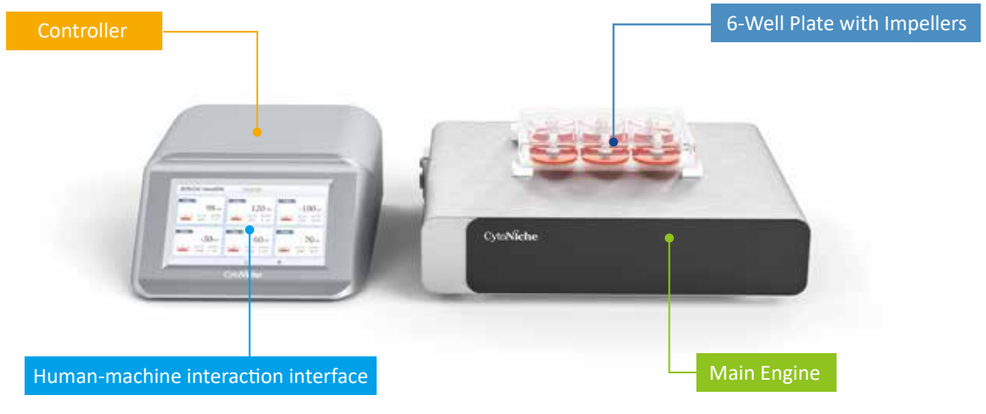


Note:

1. Data shown is for 4-day culture (triplicates) of UCMSCs on 3D microcarriers in spinner flasks at an initial density of 2.5 million cells/100 mg microcarriers.
2. One-Way ANOVA analysis used for statistical analysis.

3D FloTrix® microSPIN Multiplex System

By combining an electrically driven magnetic agitation device with the innovative 3D FloTrix® 6-Well Plate with Impellers, the 3D FloTrix® microSPIN Multiplex System facilitates simultaneous exploration and validation of various agitation process conditions in a miniaturized setting. This versatile micro system caters to a wide array of applications, including scientific research, drug development and others.



•3D FloTrix® microSPIN Multiplex System

Save up to 10 Programs

Preset 10 programs for quick start up

Customized Well Linkage

Link any wells together for parallel processing

Multiplex with 6 Conditions

Process up to 6 conditions at one time

Product Features

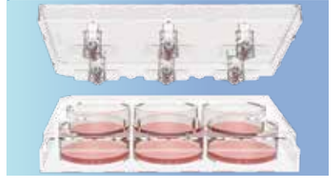
• 3D FloTrix® 6-Well Plate with Impellers

Biomechanically Mimetic

Magnetically driven impeller generates fluid dynamic to mimic biomechanics

Micro system

Perform experiments with as little as 4 mL medium to save cost



Disposable sterile consumable

Medical-grade PS with high precision manufacturing to ensure biocompatibility & ease of use

Flexible & High Precision Control

Set up any kind of agitation program, from constant to intermittent with up to 5 steps and loop up to 100 times. With a minimum steady-state error of rotation speed of ± 1 rpm, and feedback control to ensure precise execution of rotation speed, stability of experimental results is ensured.

Anti-Interference technology

Embedded with anti-magnetic interference technology to ensure each well operates independently without interference in the constrained space of a 6-well plate.

Composite heat dissipation design

Highly conductive materials and well-designed heat dissipation air ducts to help maintain a steady-state environment in the wells for cell growt.

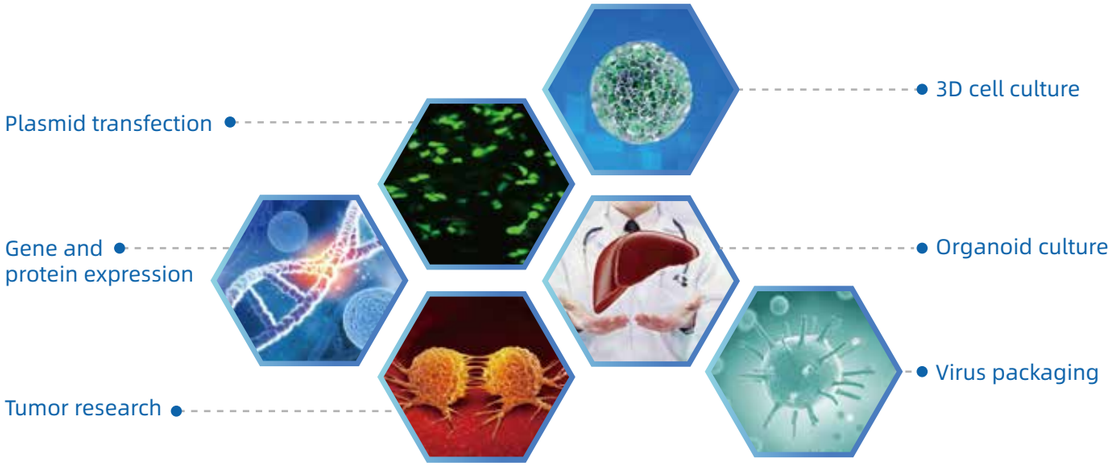
Miniaturized & Compact

As thin as 80 mm, and footprint of only 0.05 m², it can be snugged into small incubators.

User-friendly Designs

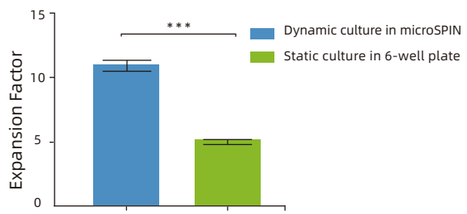
Controller with 30 degree inclination allows for easy view, and is separated from main engine so you can operate without disturbing the incubator by opening door. Linked by flat data cable to minimize pressure of incubator door.

Application

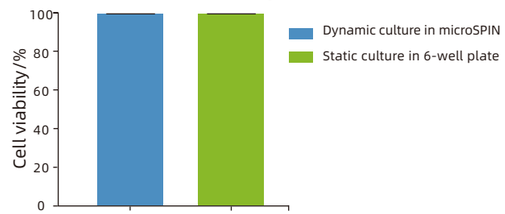


Comparing static culture & dynamic culture (UCMSCs)

Expansion of Cells



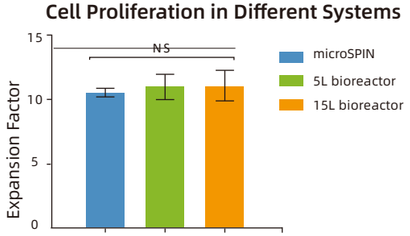
Viability of Cells



UCMSCs grow significantly better on 3D microcarriers under dynamic culture in microSPIN.

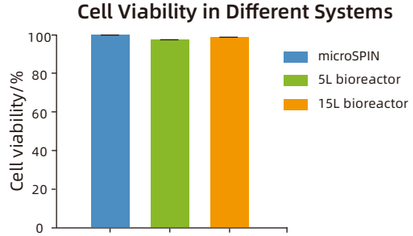
Comparing microSPIN system and 5/15L Bioreactors (UCMSCs)

Cell Proliferation in Different Systems



P value	0.7943
P value summary	ns

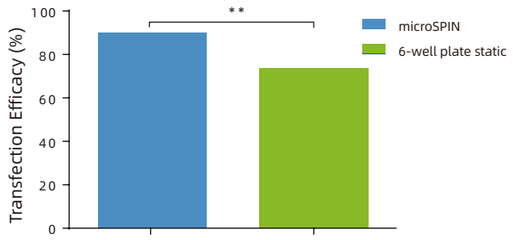
Cell Viability in Different Systems

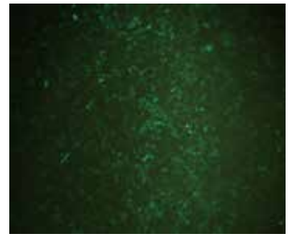


Growth of cells in microSPIN system is comparable to that in 5/15L bioreactor systems.

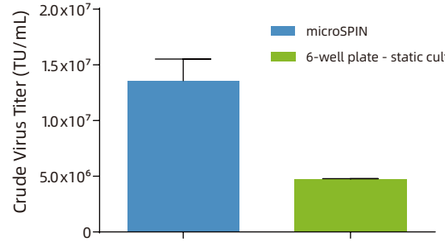
Process Development for Gene Therapy (HEK-293T Cells)

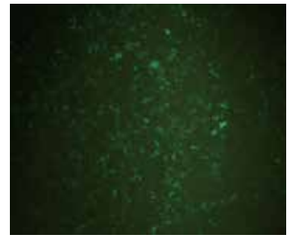
HEK-293T cells grown on 3D microcarriers are transfected under dynamic (using microSPIN) and static culture, transfection efficacy and virus titer are evaluated for comparison.





Transfection in microSPIN (72h)





Transfection in static culture (72h)

Transfection efficacy and virus titer is significantly higher under dynamic culture condition compared to static culture of HEK-293T cells on 3D microcarriers.

Product Specifications

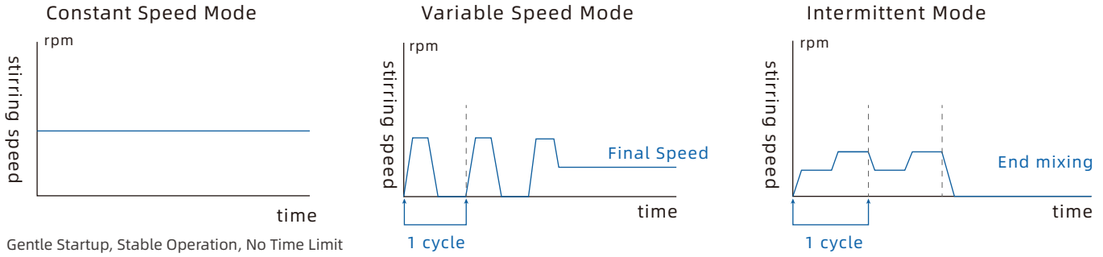
3D FloTrix® microSPIN Multiplex System	
No. of Channels	6
Channel Spacing	38.5 mm
Speed	-120 rpm to 120 rpm
Interface	5.5-inch touchscreen
Control Precision	±1rpm
Operation Environment	0℃-40℃, at 95% humidity (Main Engine); Dry, clean, oil-free, non-corrosive (Controller)
Size (LXWXH, mm)	265X210X60(Main Engine); 170X200X80(Controller)
Weight	6 kg (Main Engine); 0.6 kg (Controller)
Material(Outer Casing)	304 stainless steel (Main Engine); ABS (Controller)
Operating Voltage	12V
Operating Current	1-1.5A
Power Supply	110-220VAC, 50/60Hz

3D FloTrix® miniSPIN FLEX System

The 3D FloTrix® miniSPIN FLEX System is a magnetic stirring device meticulously engineered for the suspension culture of adherent cells. When paired with glass or disposable spinner flasks, it is ideal for scientific research, small-scale process development, validation and production. Its ultra-low-speed stirring control significantly improves the fluidity of the surrounding cell culture medium to deliver nutrients and oxygen to cells in suspension effectively. This equipment is well-suited for a range of applications including the suspension culture of adherent cells on microcarriers, fully suspension cell culture, seed cell screening, cell subculture, and optimization of associated processes.

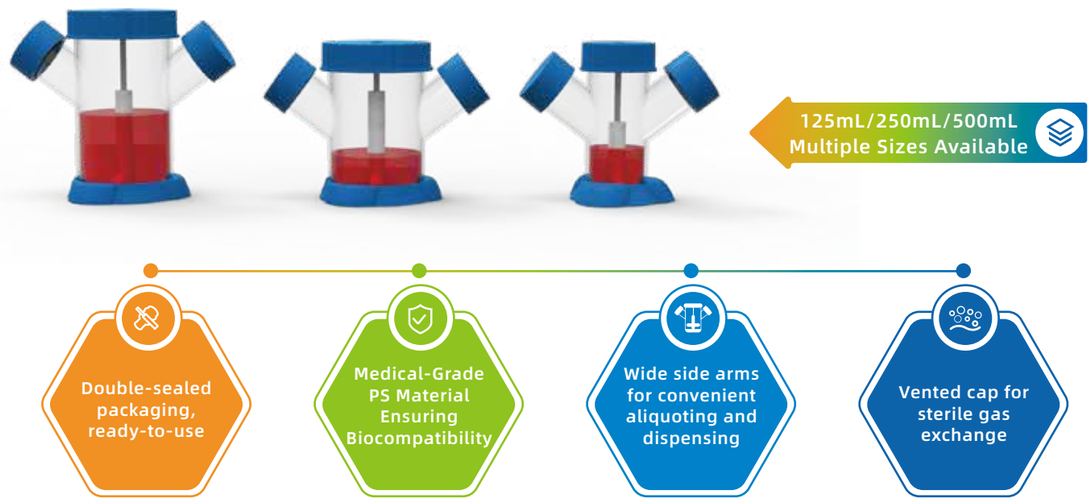
Product Features

Various Operating Modes



Explore your process conditions with freely definable parameters. Set up any kind of agitation program, from constant to varying or intermittent stirring, and loop your program as needed.

Disposable Spinner Flasks



Product Specifications

3D FloTrix® miniSPIN FLEX System	
Interface	5.5-inch touchscreen
No. of Channels	4
Channel Spacing	150mm
Speed	-120 rpm to 120 rpm
Operation Environment	125mL、250mL、500mL
Size (LXWXH, mm)	335X340X48 (Main Engine)；170X200X80 (Controller)
Weight	6.67kg (Main Engine；0.6kg (Controller)
Material(Outer Casing)	304 stainless steel (Main Engine)；ABS (Controller)
Power Supply	110-220VAC, 50/60Hz

3D FloTrix® vivaSPIN Bioreactor

The 3D FloTrix® vivaSPIN Bioreactor is an automated, and scalable stirring bioreactor developed for achieving high-quality scale-up cultivation of adherent cells, especially mesenchymal stem cells. Taken into full consideration of the fluid mechanics, process flow and control parameters, vivaSPIN is not only structurally optimized for CytoNiche's 3D macroporous, elastic and dissolvable microcarriers, its PECALS® controlling system is especially designed to accommodate the 3D FloTrix® technology for adherent cell expansion.

Product Features

1. **PECALS® Control System**
   Precise execution & real-time monitoring of process parameters, supports remote control and data logging
2. **3D FloTrix® Cell Pro System**
   Online monitoring of viable cell mass and automated growth curve plotting
3. **Enhanced air-tightness & minimized agitation blind-spot**
   Featuring multiple unique designs to achieve reliable closed-system cultivation under grade C+A environments
4. **Meets GMP Requirement**
   Traceable and complete data logging to meet audit requirement and for data analysis

Product Specifications

	Controller			
Dimension (LxWxH, mm)	636X356X703 (including footpads)			
Weight	28kg			
Control system	PECALS® compatible for GMP auditing			
Interface	12-inch color touchscreen, 1024 x 600 resolution			
Peristaltic Pump	3 pumps, speed range: ≤ 300 rpm			
Motor	0.4 kW/1.27 N.m/0-400 rpm, accuracy: ±1 rpm			
Mass Flow Meter	Air,O_2, N_2: 5-25mL/min; CO_2: 10-500mL/min			
Heat Mat	300W			
Temperature sensor	Pt100, control accuracy: ± 0.2℃			
Dissolved Oxygen (DO)	Range: 0-200%; accuracy: ±5%; it is connected with special impedance VP interfaces to shield interference.			
pH	Range: 0-12; accuracy: ±0.2; it is connected with special impedance VP interfaces to shield interference.			
Vessels				
Material	Single wall high borosilicate glass vessel with 316L SS top plate & tubing and 304 SS frame			
Sterilization	Offline high pressure steam sterilization			
Model	FTVS02	FTVS05	FTVS10	FTVS15
Vessel Volume	3.2L	7.5L	13L	19L
Max. Working Volume	2L	5L	10L	15L
Vessel Dimension（DXH, mm）	205x420mm	245x555mm	290x575mm	310x645mm
Others				
Input power	220V/50Hz			
Operation Power	1500W			
Gas	Four gases: Air_2, O_2, N_2: purity ≥ 99%, dry, oil-free, dust-free			
Minimum space for installation (LXWXH, mm)	1000X700X1000			

3D FloTrix® vivaROCK Bioreactor

Introducing the 3D FloTrix® vivaROCK Bioreactor System: Designed for high-quality scalable cultivation of cells in disposable culture bags. This system provides a gentle, low-shear, high-oxygen cell culture microenvironment, suitable for suspension cell culture, or couple with our 3D TableTrix® Microcarriers to comprehensively enhance quality and yield of adherent cells.

• Product Features

1 Sterile & Closed Single-Use System

◉ Utilizing pyrogen-free cell culture bags suitable for closed operation, eliminating cleaning and sterilization for contamination-free operation.

2 Non-invasive Agitation Mode

◉ Employing a wave-based non-invasive motion with low shear force for gentle yet efficient process.

3 Precise, Convenient, Stable

◉ Integrated weighing sensor for accurate mass measurement.

4 Options Available to Meet Every Need

◉ Various types of culture bags available, ranging from most basic bags for a quick start to bags with sensors for process monitoring, and even with perfusion if required.

5 Fast and Flexible

◉ Suitable for scalable cultivation of various cell types.

3D FloTrix® megaSPIN Single-Use Bioreactor

Designed for large scale manufacturing of cells using 3D TableTrix® & RecomTrix® Microcarriers.

• Product Features

1 PRECISION

Rigorous monitoring, and precise control of critical process parameters.

2 EFFICACY

Intricate energy transmission, heat transfer, and venting designs ensure scale-up consistency, enhancing our mass manufacturing solution.

3 SAFETY

Single-use culture bags for closed system operation to minimize contamination.

4 OPERABILITY

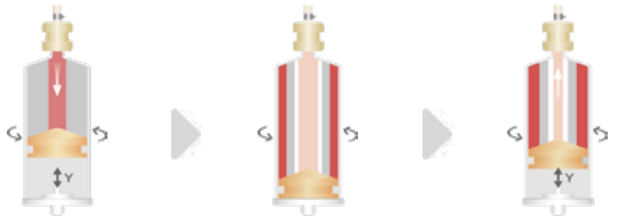
Fast deployment and switch-over between batches, suitable for high-frequency, large-scale production.

5 COMPLIANCE

Compliant with FDA 21 CFR Part 11 and GAMP5 requirements.

3D FloTrix® vivaPREP Cell Processing System

3D FloTrix® vivaPREP utilizes the principle of gradient centrifugation, coupled with a disposable closed system, to complete various cell processing steps, including cell resuscitation, washing, and concentration. This system is recommended for processing ≤ 1 billion (mesenchymal stem) cells.

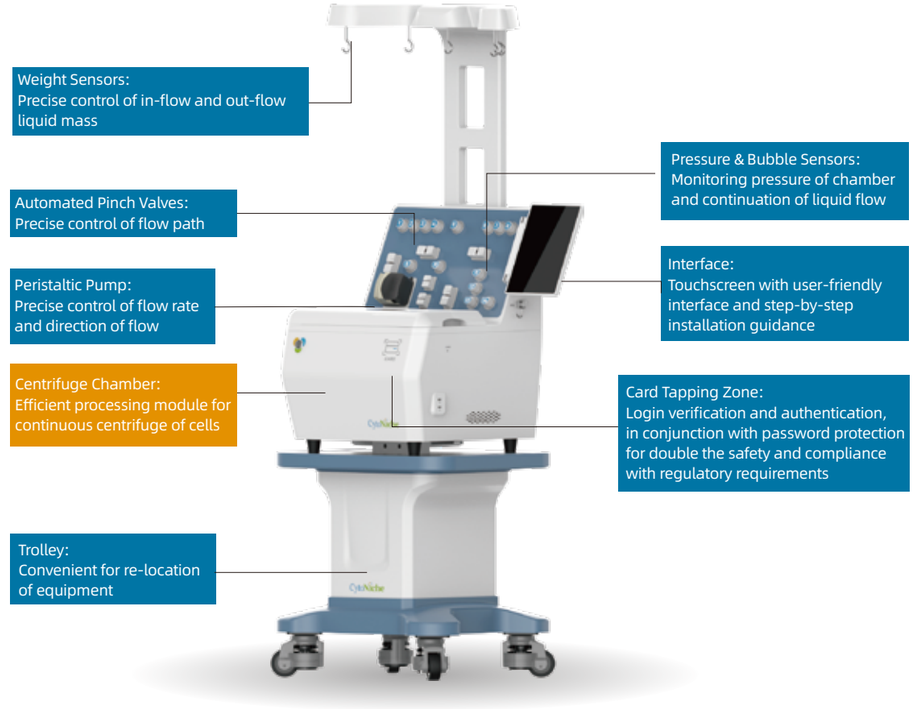


• Product Specifications

Dimension (LXWXH, mm)	260X480X900
Weight	18kg
Interface	10.1 inch touchscreen
Operating System	Linux
Separation System	Piston-based centrifuge chamber
Max RCF	6000rpm/1149g
Input Power	220V/50Hz
Operation Environment	10°C-30°C

3D FloTrix® vivaPREP PLUS Cell Processing System

3D FloTrix® vivaPREP PLUS is a fully automated and closed cell processing system specifically designed for cell therapy. Utilizing the principle of continuous flow centrifugation, together with single-use processing kit, it is suitable to concentrate and wash cells at a large scale. This system is recommended for processing 10 billion (mesenchymal stem) cells.

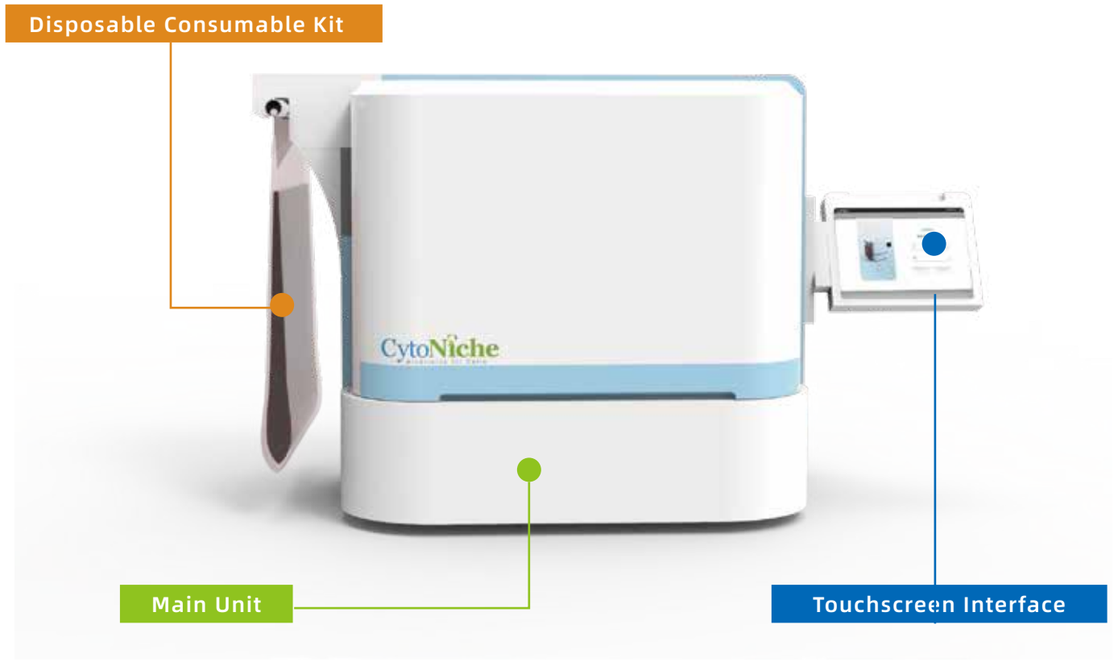


• Product Specifications

Cell Recovery Rate	≥90 %
Processing Volume	0.1-10 L
Final Volume	10-250 mL (±2 mL)
Max. Flow Rate	18L/h
Max RCF	2800rpm/400g
Separation System	Continuous centrifuge
Dimension (LXWXH, mm)	620X530X1170 (Main Unit); 732X632X672 (Trolley)
Weight	70.5kg + 35kg (Trolley)
Interface	10.1 inch TFT touchscreen
System	Linux
Input Power	110-220V/50-60Hz

3D FloTrix® vivaEXO Exosome Harvesting System

The 3D FloTrix® vivaEXO Exosome Harvesting System is an automated solution for large-scale concentration and enrichment of exosomes using multi-stage separation technology. Designed to meet modern medical and hygiene standards, this system's main unit and disposable consumable kits adhere to GMP requirements. It enables real-time parameter recording and precise control, all presented through a user-friendly human-computer interaction interface.



Product Features

Efficient Processing

Takes only slightly more than 2 hours to process 10L stock solution.

Easy Operations

Disposable ready-to-use consumable kit with preparation required.

Automated Processing

Multi-stage processing programmable to start automatically.

High Concentration

Concentrate more than 20 times, yield <500mL for 10L stock solution.

Process Monitoring

Precise monitoring of volume changes and process progress for automated processing of samples. Monitoring and control of liquid pressure for a balance of exosome quality and processing time.

Compliance with GMP Audit Requirements

System comes with user management with definable permissions authorization. Full data logging, records of parameter abnormality with alarm prompts, which cannot be modified or deleted. Records are exportable.

Product Specifications

Dimension (LXWXH, mm)	865X386X695 (excluding footpads)
Weight	40kg
Installation Space Requirement (LXWXH, mm)	1500X800X1000
Interface	7-inch color touchscreen, 800 x 480 resolution
Peristaltic Pump	Speed range: ≤ 600 rp
Weight Sensor	ange: 0-30 kg, sensitivity: 1.0-2.0±1.0 mv/V
Consumable	Single-use, 10-30L/kit
Input power	220V/50Hz
Operation Power	500W
Working Environment	10-45°C

3D FloTrix® vivaFILL Cryovial Filling System

The 3D FloTrix® vivaFILL Cryovial Filling System addresses key challenges in the filling process of cells, including large filling volumes, complex intra-batch quality control, and high costs. This system enhances the accuracy, consistency, stability, and repeatability of cell/strain banks or final products, ensuring compliance with quality control standards for enterprises engaged in cell production.

• Product Features

Efficient & Precise

1
- Up to 1000 vials per hour with automated uncapping and capping
- Volume RSD < ±0.1mL or ±5%
- Cell viability RSD < ±5% of initial viability

High Compatibility

2
- Flexible to adapt to various brands of SBS cryovials
- Compatible for both 2mL and 5mL cryovials

Flexible Configuration

3
- Compact design to fit into biosafety cabinets or isolators
- Tolerant to various sterilization chemicals, such as alcohol, UV, ozone, EO and VHP

Compliance

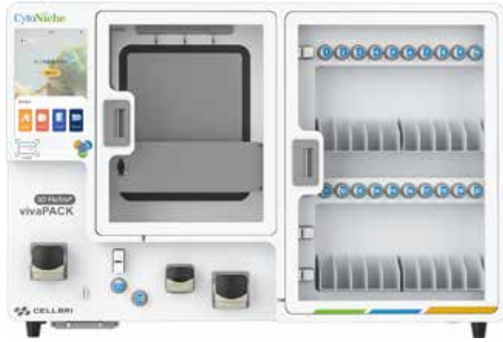
4
- Compliant with FDA 21 CFR Part 11 and GAMP5 guidelines

Specs

5
- Dimension: 750X430X476.5 mm (LXHXW)
- Weight: 50kg

3D FloTrix® vivaPACK Cryobag Filling System

Revolutionize your cell therapy production with the 3D FloTrix® vivaPACK Cryobag Filling System! This cutting-edge, high-throughput automated equipment is tailor-made for the preparation and production of cell therapy products. Paired with closed & sterile disposable tubing kit, it enables seamless, fully closed formulation filling processes, handling over a hundred bags with ease.



• Product Features

High Throughput

1
- Fills 20 bags a run, at a flow rate of up to 150mL/min
- Expandable kit for multiple runs, easily filling a hundred bags

Superior Performance

2
- Cell density RSD < ±5%
- Cell viability RSD < ±5% of initial viability

Automated & Controlled

3
- Intelligent continuous mixing of cell stock to ensure uniformity
- Temperature-controlled mixing chamber: 2-8 °C
- Automated purging of gas from bags

Flexible & Convenient

4
- Fully closed & disposable
- Flexibility to weld cryobags of your choice at your discretion

Software & Compliance

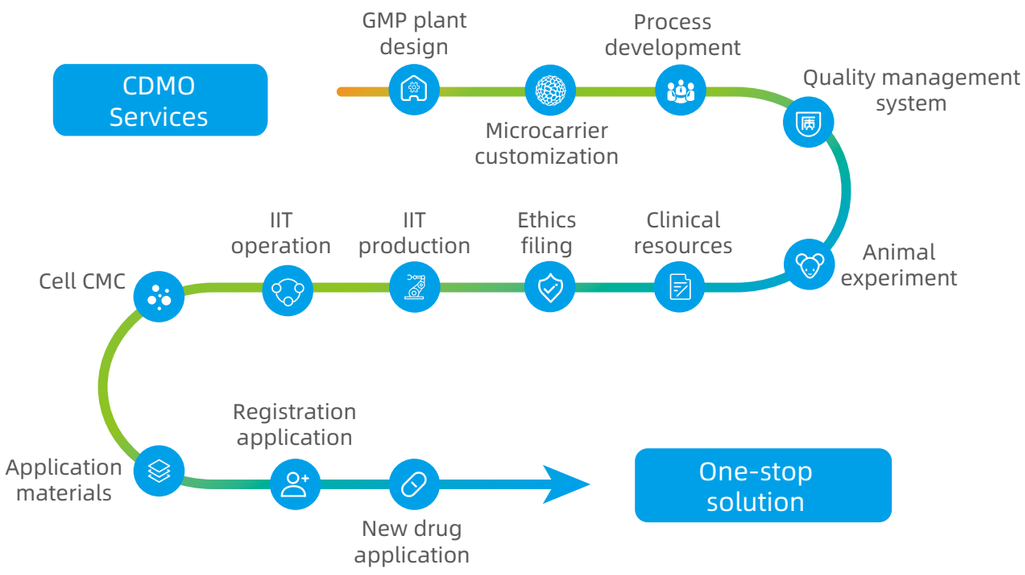
5
- Pre-set Process Software Pack
- Compliant with FDA 21 CFR Part 11 and GAMP5 guidelines

Specs

6
- Dimension: 1184X480X795 mm (LXHXW)
- Weight: 80kg

CDMO Service

Leveraging our cutting-edge and proprietary 3D FloTrix® technology, we offer comprehensive CDMO services that revolutionize the conventional CGT cell preparation process. Our services encompass technical research, process development, and GMP production, including large-scale manufacturing and preparation of mesenchymal stem cells (MSCs) from diverse tissue sources, exosomes, and viruses. Our aim is to facilitate product transformation and drive clinical application through innovative advancements.



Solution

1. Proprietary 3D FloTrix® technology revolving around patented star product 3D macroporous, elastic and dissolvable microcarriers.

2. Experience high quality 3D TableTrix® & 3D RecomTrix® Microcarriers: Made from GMP-grade raw materials, either pharmaceutical-grade or xeno-free, these microcarriers have registered Drug Master Files as excipients and starting materials with U.S FDA and Chinese National Medical Products Administration.

3. 3D FloTrix® technology is designed for customized, large-scale, intelligent and standardized production and preparation of cells at a scale of million to 10 billions.

4. Adopts continuous and closed production process.

5. Mesenchymal stem cells prepared by 3D FloTrix® technology have met clinical quality standards, independently verified by National Institutes for Food and Drug Control.

6. 3D FloTrix® technology saves about 80% space and labor, 10% of reagents and consumables, and 60% production time, compared to conventional methods.

7. 6 production pipelines available in GMP facility with Grade B+A and Grade C+A for manufacturing cells for clinical trials or commercialization.

Product list

Catalogue No.	Product Name	Spec
	Microcarriers	
V01-100-10g	3D TableTrix® Microcarriers V01-10g	10g/pc, 10 pc/cas
V01-100g	3D TableTrix® Microcarriers V01-100g	100g/pc, 1pc/cas
V01-500g	3D TableTrix® Microcarriers V01-500g	500g/pc, 1pc/cas
W01-10-10g	3D TableTrix® Microcarriers W01 (Powder, closed system, 10g)	10g/pc
W01-6-6g	3D TableTrix® Microcarriers W01 (Powder, closed system, 6g)	6g/pc
W01-200	3D TableTrix® Microcarriers W01(Tablets)	1g/pc, 2 pc/cas
W02-10-10g	3D TableTrix® Microcarriers W02 (Powder, closed system, 10g)	10g/pc
W02-200	3D TableTrix® Microcarriers W02(Tablets)	1g/pc, 2 pc/cas
G02-100-10g	3D TableTrix® Microcarriers G02(Bulk)	10g/pc, 10 pc/cas
G02-200	3D TableTrix® Microcarriers G02(Tablets)	1g/pc, 2 pc/cas
CW01-200	3D RecomTrix® Microcarriers CW01(Tablets)	1g/pc, 2 pc/cas
CW02-200	3D RecomTrix® Microcarriers CW02(Tablets)	1g/pc, 2 pc/cas
	Reagents	
R001-500	3D FloTrix® Digest	0.5g/pc
RMZ112-PYJ	3D FloTrix® MSC Serum Free Basal Medium	500mL basal medium
RMZ112-B	3D FloTrix® MSC Serum Free Supplement	25mL supplement
RMZ99S	3D FloTrix® Additives for 3D Culture of MSC	5mL/tube
	Equipment	
FTUS-16-01	3D FloTrix® microSPIN Multiplex System	1 stirrer+1 controller
FTMS1F01	3D FloTrix® miniSPIN FLEX System	1 stirrer+1 controllers
FTVS02	3D FloTrix® vivaSPIN Bioreactor 2L	1 controller, 1 stirred tank vessel, PECALS control system
FTVS05	3D FloTrix® vivaSPIN Bioreactor 5L	1 controller, 1 stirred tank vessel, PECALS control system
FTVS10	3D FloTrix® vivaSPIN Bioreactor 10L	1 controller, 1 stirred tank vessel, PECALS control system
FTVS15	3D FloTrix® vivaSPIN Bioreactor 15L	1 controller, 1 stirred tank vessel, PECALS control system
FTVR10	3D FloTrix® vivaROCK Bioreactor System	1 controller, 1 10L Rocker, 1 software system
FTVE10	3D FloTrix® vivaEXO Exosome Harvesting System	1 unit
vivaPREP	3D FloTrix® vivaPREP Cell Processing System	1 unit
vivaPREP PLUS	3D FloTrix® vivaPREP PLUS Cell Processing System	1 unit
vivaPACK	3D FloTrix® vivaPACK Cryobag Filling System	1 unit
vivaFILL	3D FloTrix® vivaFILL Cryovial Filling System	1 unit
R020-100	3D FloTrix® Storage Trolley (100L)	1 unit
VSTT-05-01	3D FloTrix® CELL PRO Online Cell Count System (for 5L)	1 unit
VSTT-10-01	3D FloTrix® CELL PRO Online Cell Count System (for 10\15L)	1 unit

Catalogue No.	Product Name	Spec
	Consumables for Equipment	
R013-05-01	3D FloTrix® 6-Well Plate with Impellers	5pc/cas
R009-05-01	Disposable Spinner Flasks 125mL	5pc/cas
R014-05-01	Disposable Spinner Flasks 500mL	5pc/cas
R015-05-01	Disposable Spinner Flasks 250mL	5pc/cas
R005-05-10	3D FloTrix® vivaSPIN Culture Processing 5L Full Kit	2 pc/cas, Silicone tubings with luer connectors
R005-05-11	3D FloTrix® vivaSPIN Culture Processing 5L Kit A	4set/cas, Silicone tubings with luer connectors
R005-10-10	3D FloTrix® vivaSPIN Culture Processing 10/15L Full Kit	2set/cas, Silicone tubings with luer connectors
R005-10-11	3D FloTrix® vivaSPIN Culture Processing 10/15L Kit A	4set/cas, Silicone tubings with luer connectors
R020-05-10	3D FloTrix® vivaSPIN Culture Fully Closed Processing Kit 5L	2set/cas, Silicone & C-Flex
R020-10-10	3D FloTrix® vivaSPIN Culture Fully Closed Processing Kit 10/15L	2set/cas, Silicone & C-Flex
R021-01-01	3D FloTrix® vivaROCK Cell Culture Bag (1L Basic)	Bag volume: 1L
R021-03-01	3D FloTrix® vivaROCK Cell Culture Bag (3L Basic)	Bag volume: 3L
R021-10-01	3D FloTrix® vivaROCK Cell Culture Bag (10L Basic)	Bag volume: 10L
R021-03-02	3D FloTrix® vivaROCK Cell Culture Bag (3L Monitor)	Bag volume: 3L, with single-use pH and DO sensors
R021-10-02	3D FloTrix® vivaROCK Cell Culture Bag (10L Monitor)	Bag volume: 10L, with single-use pH and DO sensors
R021-03-03	3D FloTrix® vivaROCK Cell Culture Bag (3L Perfusion)	Bag volume: 3L, with single-use pH and DO sensors, 1.2um perfusion filter
R021-10-03	3D FloTrix® vivaROCK Cell Culture Bag (10L Perfusion)	Bag volume: 10L, withsingle-use pH and DO sensors, 1.2um perfusion filter
R010-CLR-01	3D FloTrix® vivaEXO Exosome CLR Processing Kit	2set of CLR module /cas
R011-PUR-02	3D FloTrix® vivaEXO Exosome PUR02 Processing Kit	1set of PUR /cas, small MWCO
R011-PUR-03	3D FloTrix® vivaEXO Exosome PUR03 Processing Kit	1set of PUR /cas, medium MWCO
PREP-PP-05	3D FloTrix® vivaPREP Disposable Processing Kit	5 pc/cas
PREP-PLUS-00	3D FloTrix® vivaPREP PLUS Disposable Cell Processing Kit	1 pc/cas
PACK-01-01	3D FloTrix® vivaPACK Cryobag Filling Process Kit	1set/cas, PVC, male luer connector
PACK-01-02	3D FloTrix® vivaPACK Cryobag Filling Process Supplement Kit	1set/cas, PVC, male luer connector
FILL-01-01	3D FloTrix® vivaFILL Cryovial Filling Tubing Kit	1set/cas, silicone & pvc & male luer
R020-00-01	3D FloTrix® Single-Use Storage Bag (3L)	1set/cas, 1 pvc & female luer, 1 C-Flex & male luer
R020-00-03	3D FloTrix® Single-Use Storage Bag (10L)	1set/cas, 2 C-Flex & male/female luer
R020-00-04	3D FloTrix® Single-Use Storage Bag (50L)	1set/cas, 3D bag, 4 ports, C-Flex, 3 male/1 female luer
R020-00-11	3D FloTrix® Single-Use Filtration Module(5")	1set/cas, C-Flex with female/male luer
R020-00-12	3D FloTrix® Single-Use Filtration Module(1.5")	1set/cas, C-Flex with female/male luer
R020-00-05	3D FloTrix® Single-Use Storage Bag (50mL)	1set/cas, 2 ports, male/female luer
VP-PVC-01	3D FloTrix® Single-Use Storage Bag (500mL)	1set/cas, PVC, female luer
VP-PVC-02	3D FloTrix® Single-Use Storage Bag with PVC tube (3L)	1set/cas, PVC, male luer

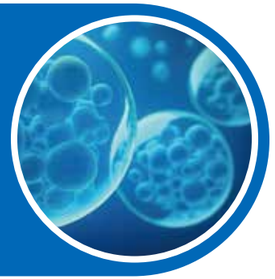
CORPORATE CULTURE

Architect for cells:
Expert in 3D manufacturing of high-quality cells

Our mission

Empowering cell and gene therapy advancement with intelligent 3D cellular mass manufacturing technology to benefit more patients

以3D细胞规模化智造技术，赋能细胞与基因治疗产业发展，惠及更多患者。



Our vision

Igniting a new era in industrial cell development

开启细胞产业化发展新时代

Our values

Win-win, Integrity, Innovation, Dedicated, Quality

共赢 诚信 创新 专注 品质

ABOUT US

CytoNiche, founded in 2018 under the leadership of Professor Yanan Du's esteemed research team from Tsinghua University's School of Medicine, boasts a distinguished pedigree with Tsinghua University as a stakeholder. Our core technology, born from the fertile grounds of Tsinghua University's research, has been heralded as a pioneering force in "Science and Technology Innovation in China" by the esteemed China Association for Science and Technology. Acknowledged as a national-level high-tech enterprise, a flagship "Little Giant" enterprise in specialized and emerging technologies, and a potential unicorn enterprise, CytoNiche has garnered essential support from the Chinese Ministry of Science and Technology for its pivotal research and development initiatives.

Specializing in high-quality three-dimensional cell manufacturing, CytoNiche offers comprehensive, tailor-made solutions for cell scale-up utilizing cutting-edge 3D microcarriers. Our proprietary 3D cell smart manufacturing platform stands at the forefront, enabling large-scale, automated, intelligent, and closed-cell drug and derivative production. This innovative approach empowers global clientele to establish state-of-the-art cell drug production lines. Having blazed trails in pioneering the production process pipeline for "billion-level" stem cells, CytoNiche is now accelerating towards the ambitious "hundred billion-level," steadfast in our commitment to revolutionize the cell and gene therapy industry with intelligent 3D cellular mass manufacturing technology to benefit more patients.

Shanghai Cytoniche Biotechnology Co., Ltd.

Beijing Cytoniche Biotechnology Co., Ltd.

Tianjin Cytoniche Biotechnology Co., Ltd.