CytoNiche
Architect for Cells

3D FloTrix® vivaPACK and vivaFILL

Architect for Cells

—— Expert in 3D manufacturing of high quality cells

www.cytoniche.com

Outline

Contents

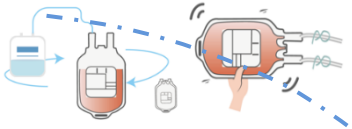
- Limitations of Current Cell Filling
- Features of vivaPACK and vivaFILL

No.1

Limitations of Current Cell Filling

Work Flow of Manual Cell Filling

Pre-Filling | **Filling Process** | **Post-Filling**



Cells preparation

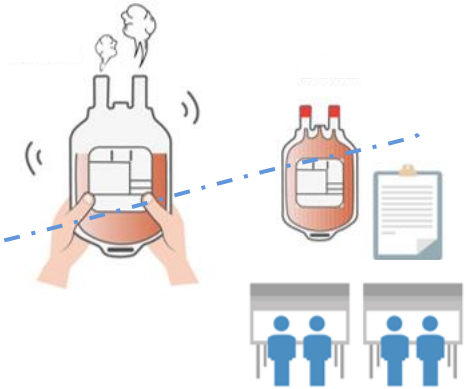
- Manual mixing
- Grade A in BSC
- Background zone: Grade B

Auxiliary equipment

- Pump
- Electrical balance
- Welder/Sealer

Filling process

- Manual operation
- Monitoring volume by electrical balance



Post Filling process

- Emptying gas inside bag manually
- Record manually

Limitations of Manual Cell Filling

Lower Efficiency/higher risk

Manual

Labour intensive

Contamination risk

Limited Capacity

Lower Quality

Hard to standardize

Unstable potency

Batch Inconsistency

Unmet GMP Guideline

Record manually

Revisable Data

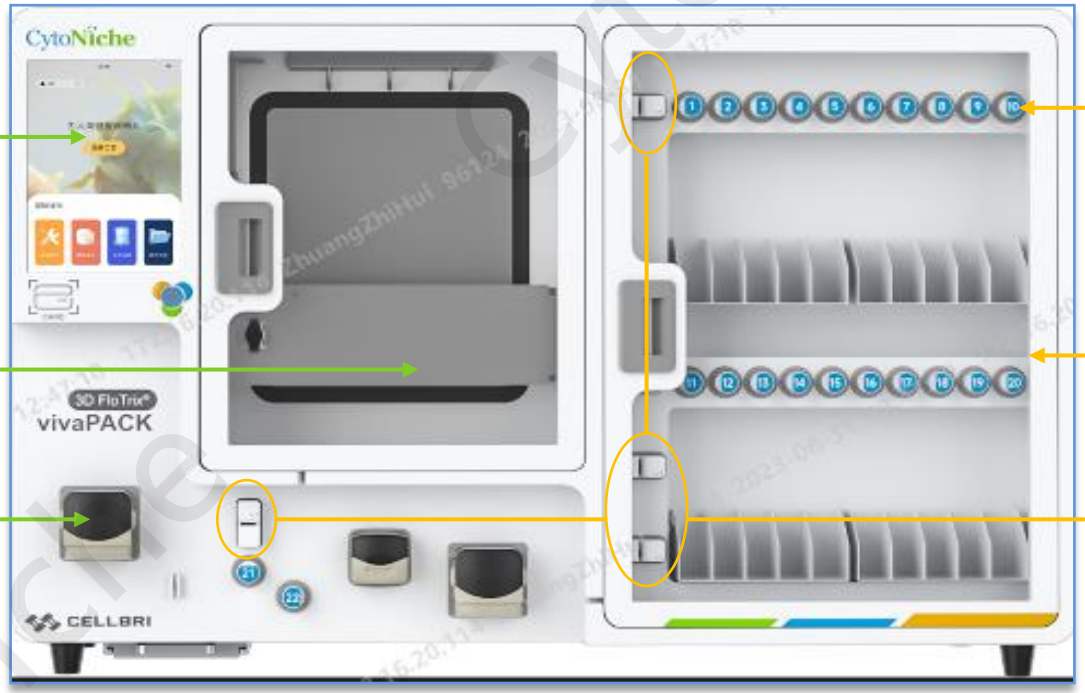
untraceable data

No.2

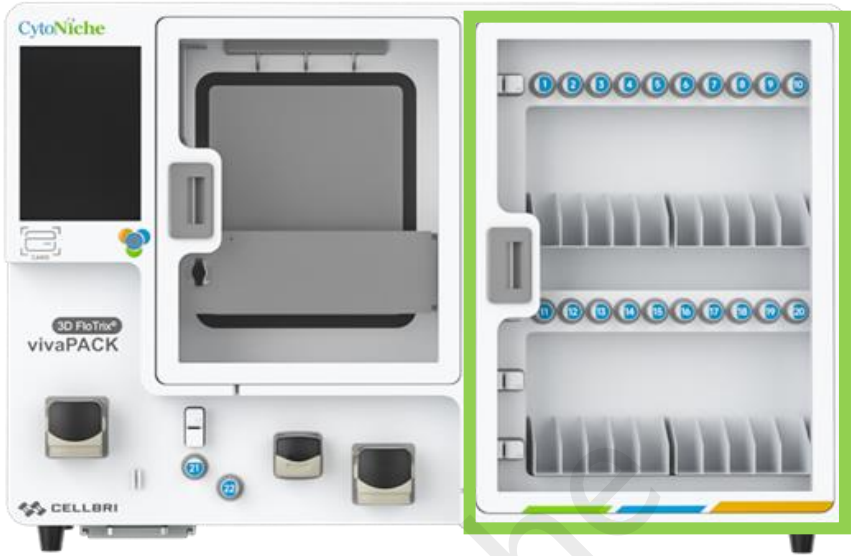
Features of vivaPACK and vivaFILL

Overview of 3D FloTrix® vivaPACK Cryobag Filling System

【Fully Closed, Automated, High-Throughput, High Precision】



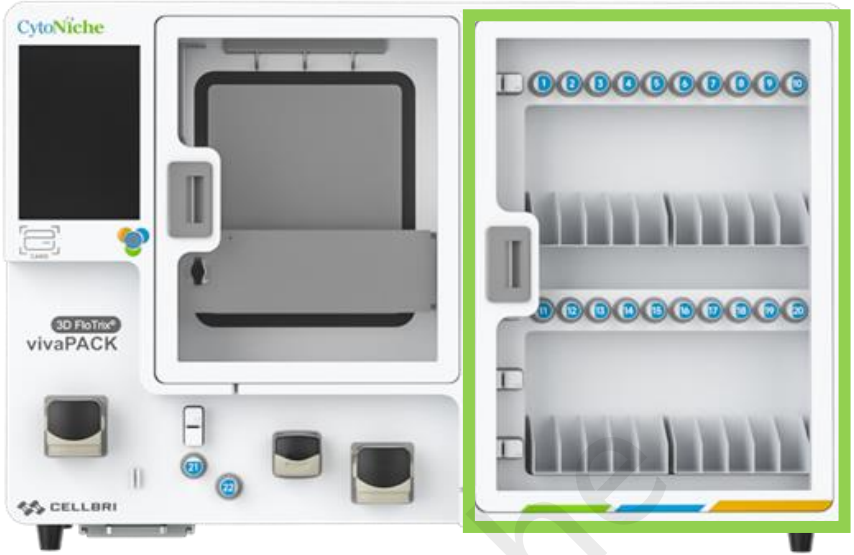
Features of vivaPACK---High Throughput



【High-Throughput Filling Bag System】

- Comprehensive system, lesser auxiliary equipment required
- 0.15-3L cells stock solution
- 20 bags per batch, 2-150mL/bag
- Maximum filling flow rate :150 mL/min → 1min/bag

Features of vivaPACK---High Throughput



【High-Precision Filling Bag System】

- Automated calibration loop by liquid sensor
- Filling Volume accuracy: < 1mL or < 2%

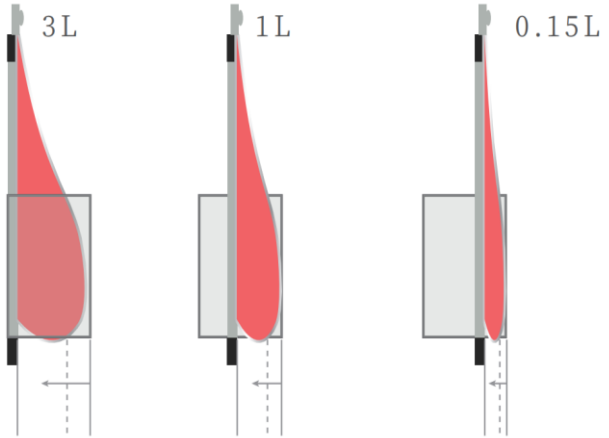
Filling volume	Matching bags	accuracy
2~3mL	1.Filling volume is below half of the total volume of freezing bag 2.Typical bag size: 10/25/50/100/250/500mL	< 0.3mL
3~10mL		< 0.5mL
10~50mL		< 1mL
50~150mL		< 2%

Features of vivaPACK--- Automated

【Automated Temp-Controlling System】

- ✓ Mixing chamber temperature controlled at 2-8℃
- ✓ Lower cell viability deviation(<5%) after completing cell filling

Features of vivaPACK--- Automated



【Automated Mixing System】

- ✓ Intelligent squeezing and mixing mode
- ✓ Mixing intervals and pressure accurately controlled

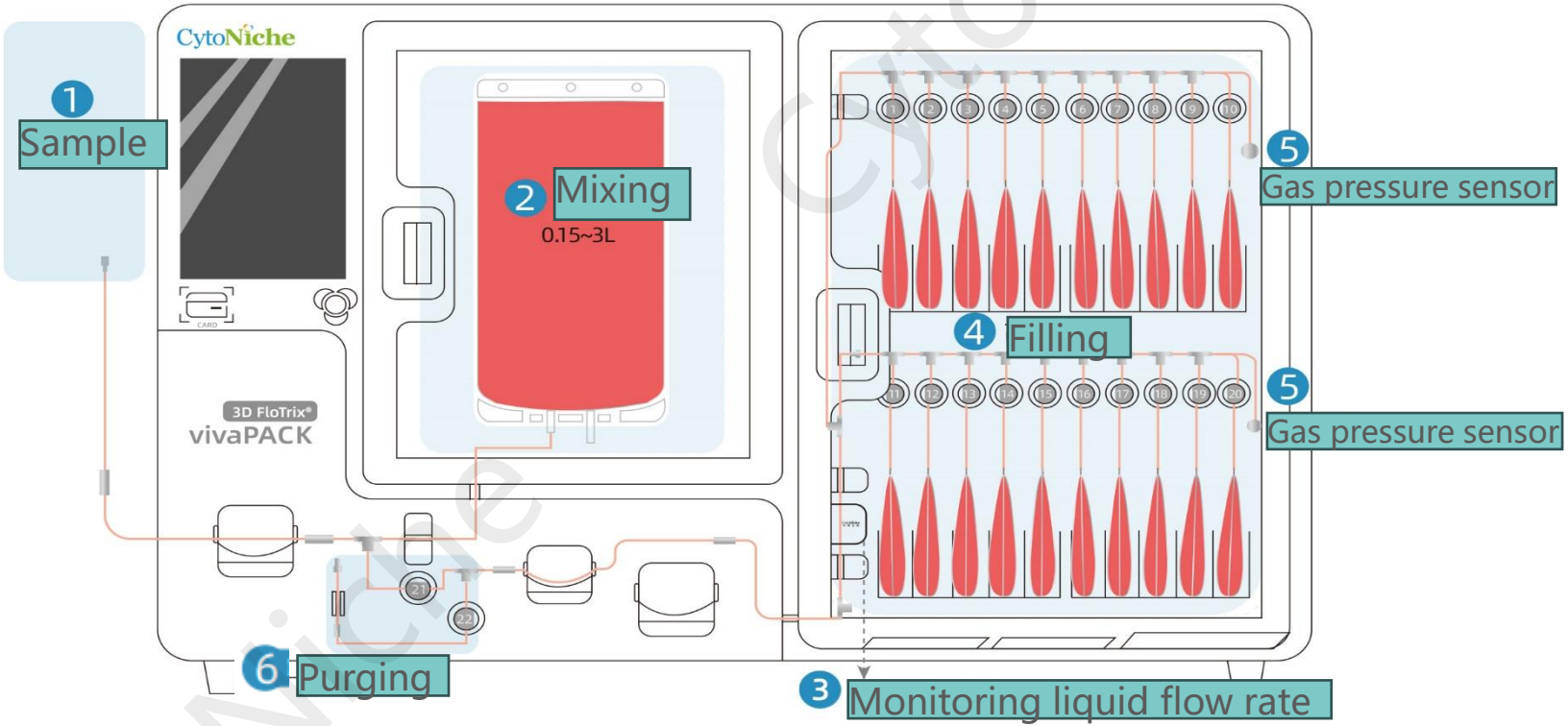
Features of vivaPACK--- Consumables

【Safe and fully closed consumables】

- ✓ Medical-grade PVC material for tubes
- ✓ Fully closed process by welding and sealing

Working Principle

【Fully Closed Process】

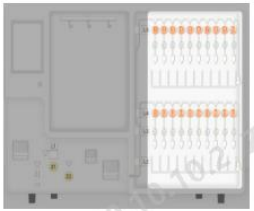


Parameters of vivaPACK

	Basic Parameters	
Characteristics	Dimensions (mm)	1184×480×795
	Weight (kg)	80
	Stock solution volume (L)	0.15-3.0
	Filling efficiency	20 bags/per batch
	Filling volume(mL)/bag	2-150
	Volume accuracy	＜1mL or ＜2%
	Maximum filling flow rate	150mL/min
	Automated purging, benchtop, with touchscreen, with barcode scanner	
	Temp：1-25℃(Cooling Plate)，accuracy：±1℃	
Cells quality	Cell density deviation among different bags	＜5%
	Cell viability deviation after filling	＜5%

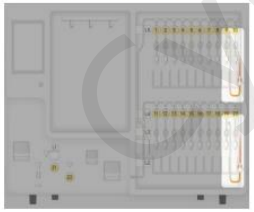
Features of vivaPACK--- User Friendly Operation

① Open the consumable, sleeve it into the large clamping plate, and only install the tubings at the No. 1-20 tube clamp valves.

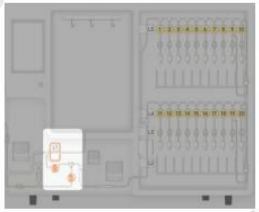


② Install the tubings at the positions of "L2-L5 sensors" as shown in the figure, and insert the lower tubing into the tubing groove.

③ Connect the "exhaust valves" at the end of the two rows of tubings to the equipment's own tubings.

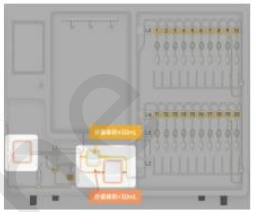


④ Sleeve it into the small clamping plate, and install it on the tubings at the positions of No. 21-22 tube clamp valves and "L1 sensor".

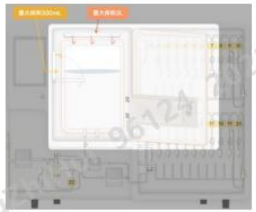


⑤ Install the "funnel" in reverse on the L1 sensor and close the two "white tube clamps".

⑥ Install the tubing at the position of "peristaltic pump" shown in the figure, and turn off the peristaltic pump.



⑦ Open the mixing compartment to connect the "mixing bag", and hang it in the mixing compartment.

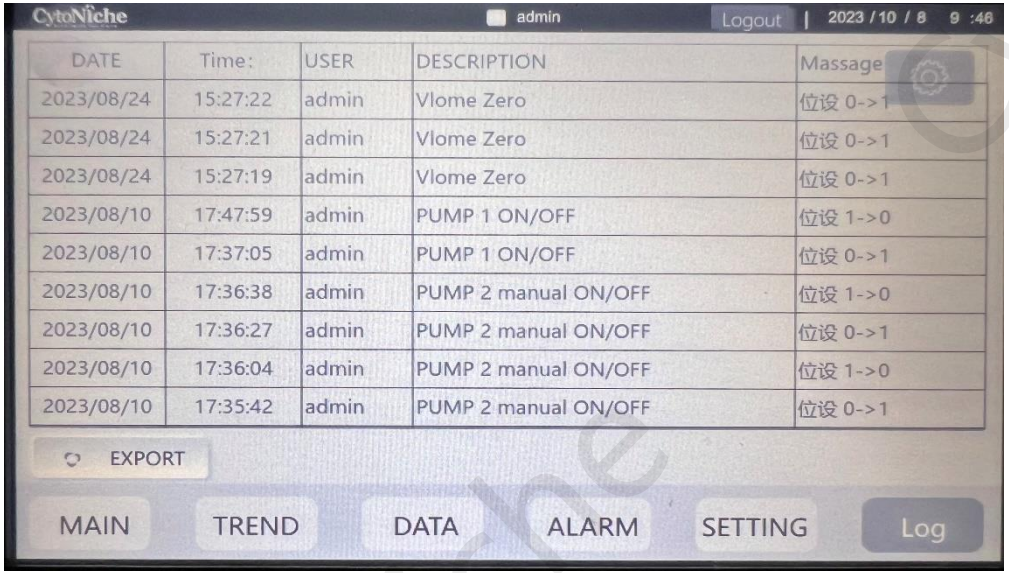


⑧ Connect the "sample bag" and hang it on the left side, and open the white tube clamp.

【User Friendly Operation】

- ✓ Diagram-guided step-by-step instructions

Features of vivaPACK--- Compliance



【Data Log】

- ✓ User management
- ✓ Traceable operational process and integrated data
- ✓ Complete and protected records
- ✓ Exportable data
- ✓ Comply with 21 CFR PART 11 and GMP requirements

Analysis of competitive product

Key parameters	CytoNiche	Terumo
Price (USD)	******	200,000
Cells stock solution	3 L	20~174 mL
Filling efficiency	20bags /per batch	4bags /per batch
Filling volume(mL)/bag	2~150	10 -28
Volume accuracy	< 2% or < 2 ml	< 10% or 2 ml
Temp-control	±1℃	±3℃
Auto-gas emission	YES	YES
Cell density deviation among different bags	< 5%	< 5%
Cell viability deviation	5%	10%

【Our Strength】

- ✓ **Higher filling efficiency**
- ✓ **More precise control system**

Overview of 3D FloTrix® vivaFILL Cryovial Filling System

3D FloTrix® vivaFILL

【Application and capacity】

- ✓ Live cells and exosome
- ✓ 1000 vials/h

Parameters of vivaFILL Cryovial Filling System

Parameters	Spec
Dimension（mm）	W*D*H：750x435x480
Weight（Kg）	50 Kg
Material	ABS&SUS304
Filling efficiency	8 vials /one time
Opening cap	16 caps/one time
Matching vial	2/5ml vial，length< 80mm
Capacity	1000 vial/h
Filling deviation	≤±0.1mL

Features of vivaFILL Cryovial Filling System

【Higher Efficiency and Friendly Operation】

- ✓ A single unit : 96 vials/batch, 8 vials in one time
- ✓ Real-time monitor uncapping and capping process by optical sensor

Features of vivaFILL Cryovial Filling System

【High-Precision Filling Vial System】

Vial volume accuracy < ±0.1mL

- ✓ High-precision pump system
- ✓ Coaxial control for 8 channels

Features of vivaFILL Cryovial Filling System

【Requirements for compatible vials】

Lid Features

Lid cap can be opened with a screwdriver.

As shown in the picture, the lid has threads.

Vial Features

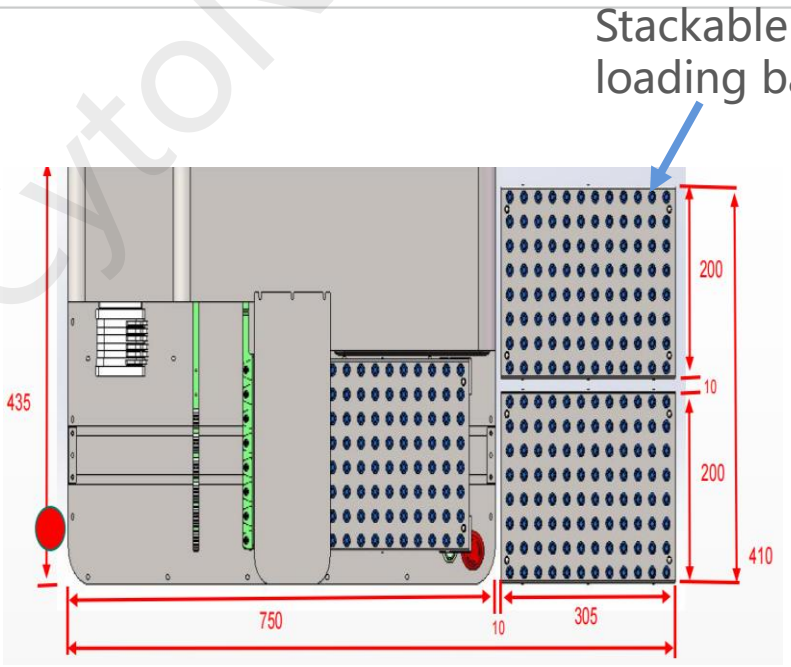
There are threads at the vial to hold it in place.

Compatible with various brand vials

- ✓ Corning、AZENTA、NEST
- ✓ 2ml/5ml

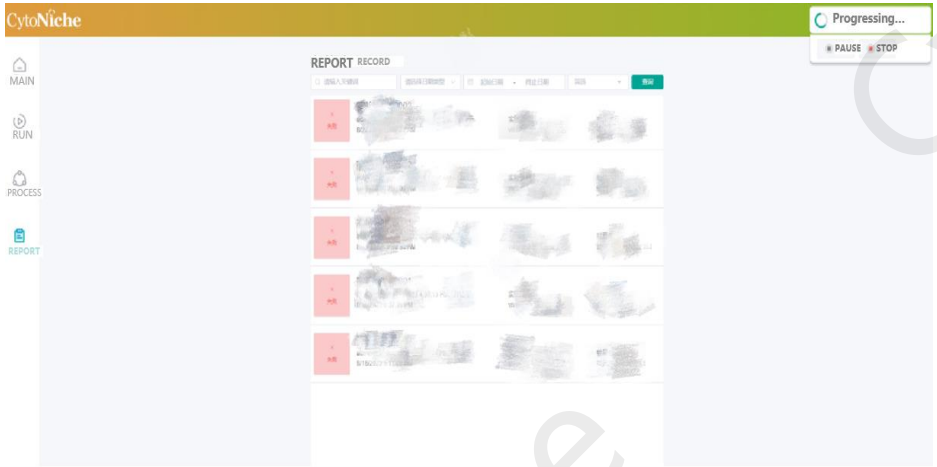
Features of vivaFILL Cryovial Filling System

【Flexible Installation】



- ✓ Installation in BSC (size requirement: L1200xW500xH500mm)
- ✓ Sterilization methods: alcohol, irradiation, ozone, ethylene oxide

【Data compliance】



- ✓ User management
- ✓ Traceable operational process and integrated data
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Product Bundles

Category No.	Product Name	Qty	Spec
vivaPACK	3D FloTrix® vivaPACK Cryobag Filling System	1 unit	NA
vivaFILL	3D FloTrix® vivaFILL Cryovial Filling System	1 unit	NA
PACK-01-01	3D FloTrix® vivaPACK Cryobag Filling Process Kit	1 cas	1set/cas, PVC, male luer connector
PACK-01-02	3D FloTrix® vivaPACK Cryobag Filling Process Supplement Kit	1 cas	1set/cas, PVC, male luer connector
FILL-01-01	3D FloTrix® vivaFILL Cryovial Filling Tubing Kit	1 cas	1set/cas, silicone & pvc & male luer

vivaFILL and vivaPACK video

Thank you

Launching a new era for industrialising cell manufacturing

CytoNiche
华 | 龛 | 生 | 物

Headquarter

B1-208 Yiyuan Culture & Innovation Base, Haidian, Beijing, P.R.China

86-010-6286 8280

marketing@cytoniche.com

en.cytoniche.com

Collaboration & Support Center

Blk 4, 260 Maoyuan Road, Fengxian District, Shanghai, P.R.China

GMP Production Center

402, Plant 6, 1 Xinxing Road, Wuqing District, Tianjin, P.R.China