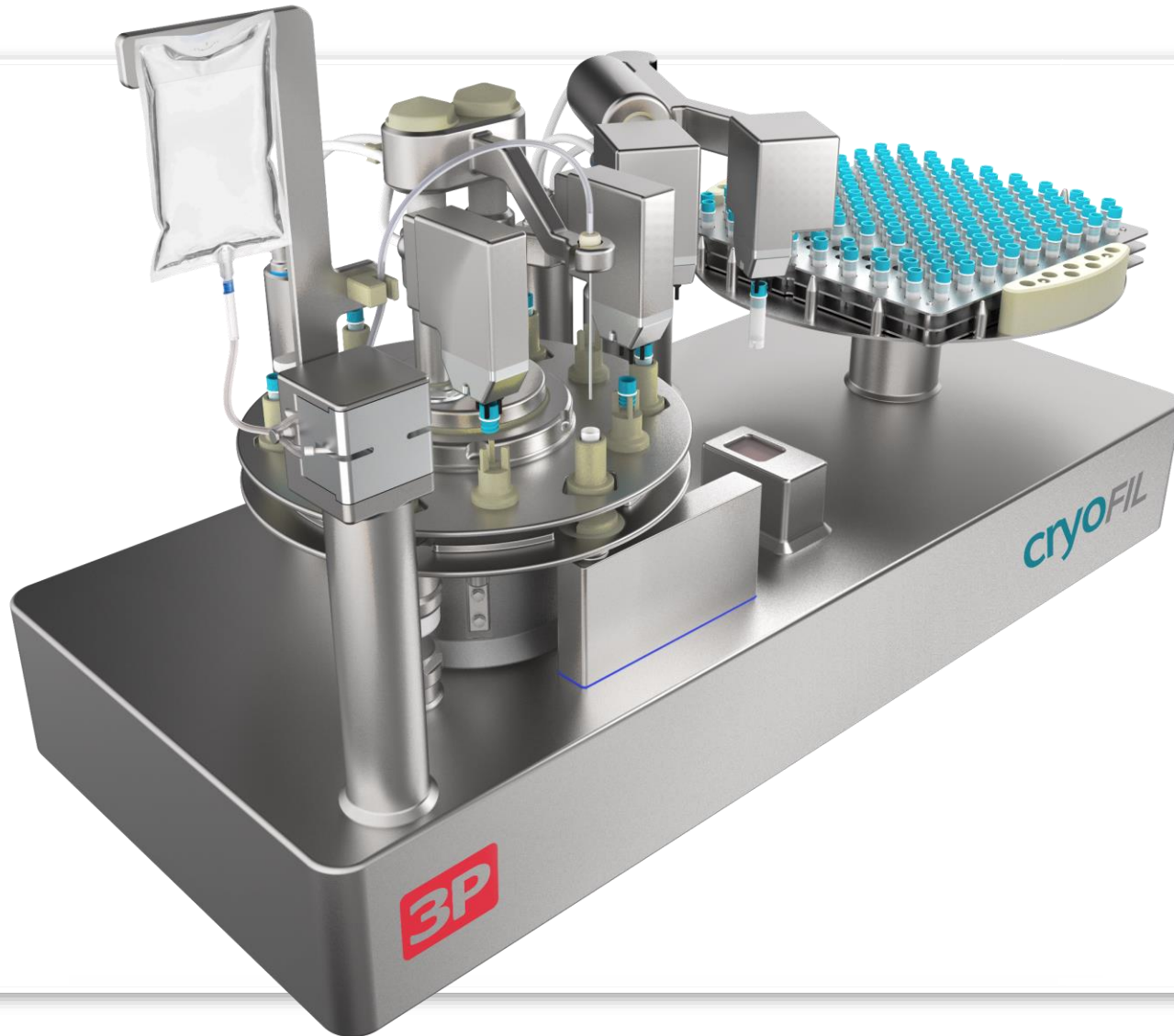




GMP Cryovial Filling Platform

Discover Range

contact

David Phasey

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Cryovial Filling Platform

The cryovial filling platform is an adaptable modular system designed to fit the needs of your application.

Key benefits:

- Up to 600 vials per hour output
- Aseptic design and cGMP compliant
- Includes 100% in-process weight verification
- Compact design fits easily into most existing isolators and bio-safety cabinets
- Minimised dead volume
- Scalable technology



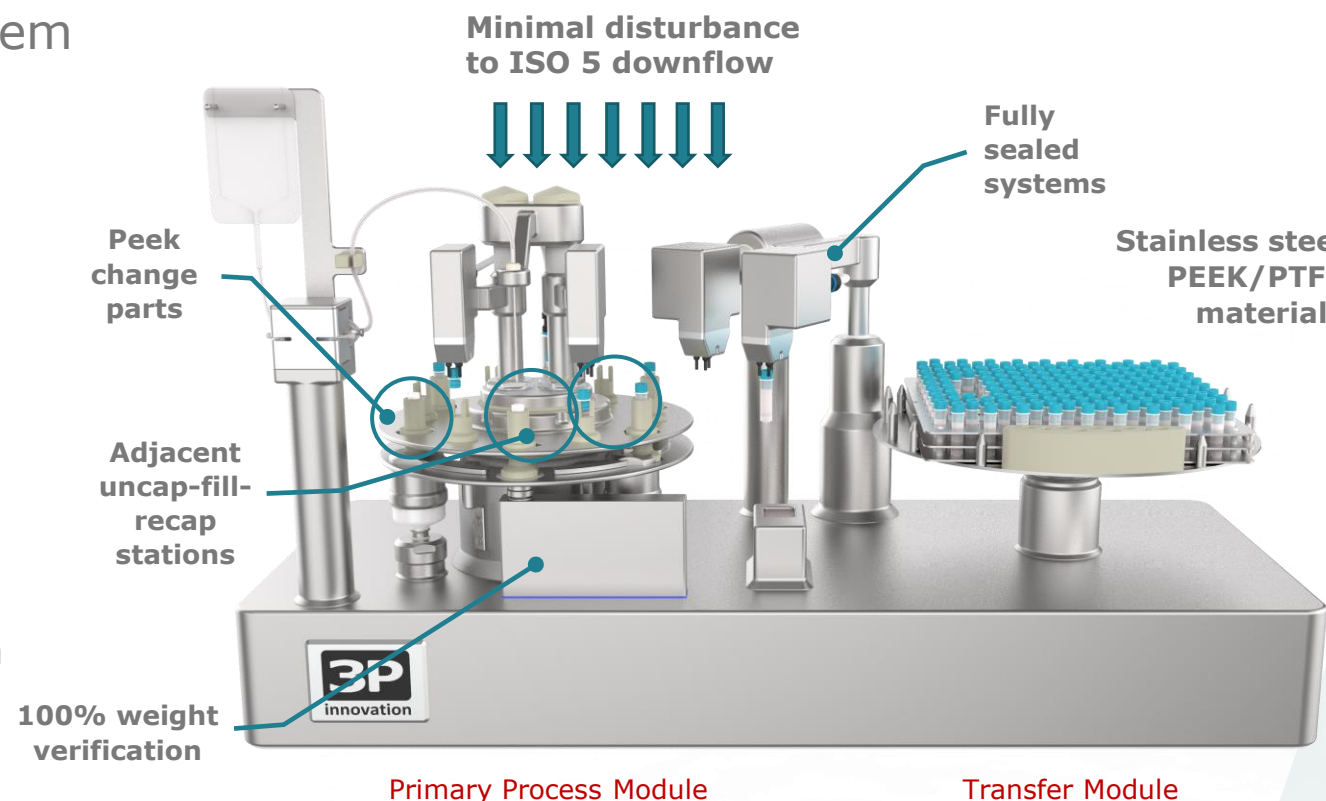
Aseptic racked cryovial filling and capping

<https://youtu.be/CyF6dtu65II>

GMP Cryovial Fill-Finish System

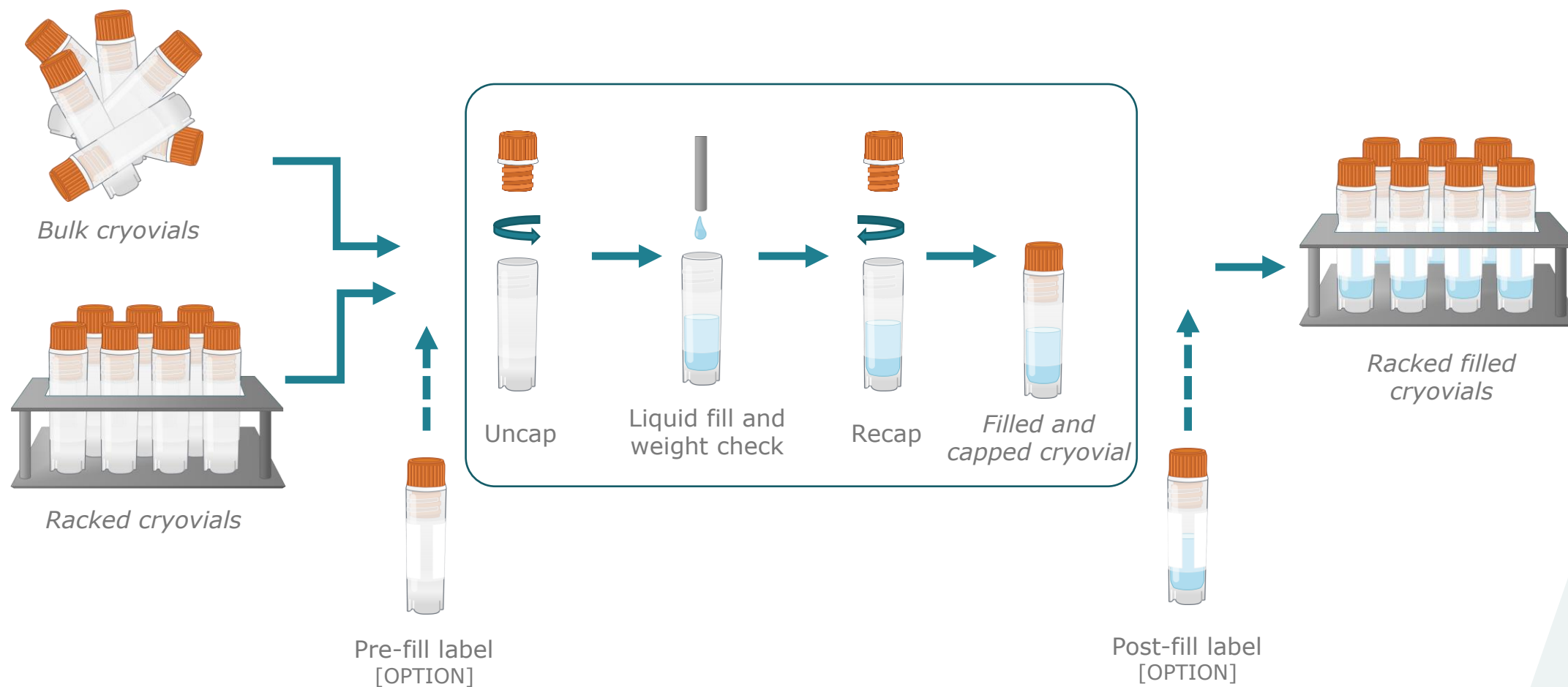
Our sterile fill-finish expertise have enabled us develop a true GMP cryovial filling system

- First air principle
- Minimal open container time
- Fully sealed systems suitable for H₂O₂ decontamination
- Stainless steel, PEEK, PTFE and other GMP materials with material traceability on critical components
- Industrial automation build, controls systems and precision
- Recipe management and CFR21 part 11 batch data compliance
 - 100% in-process weight verification
- Scalable technology



The Core Processes

There is a variety of applications which consider; sterility, in-feed format, labelling and in-process quality checks.

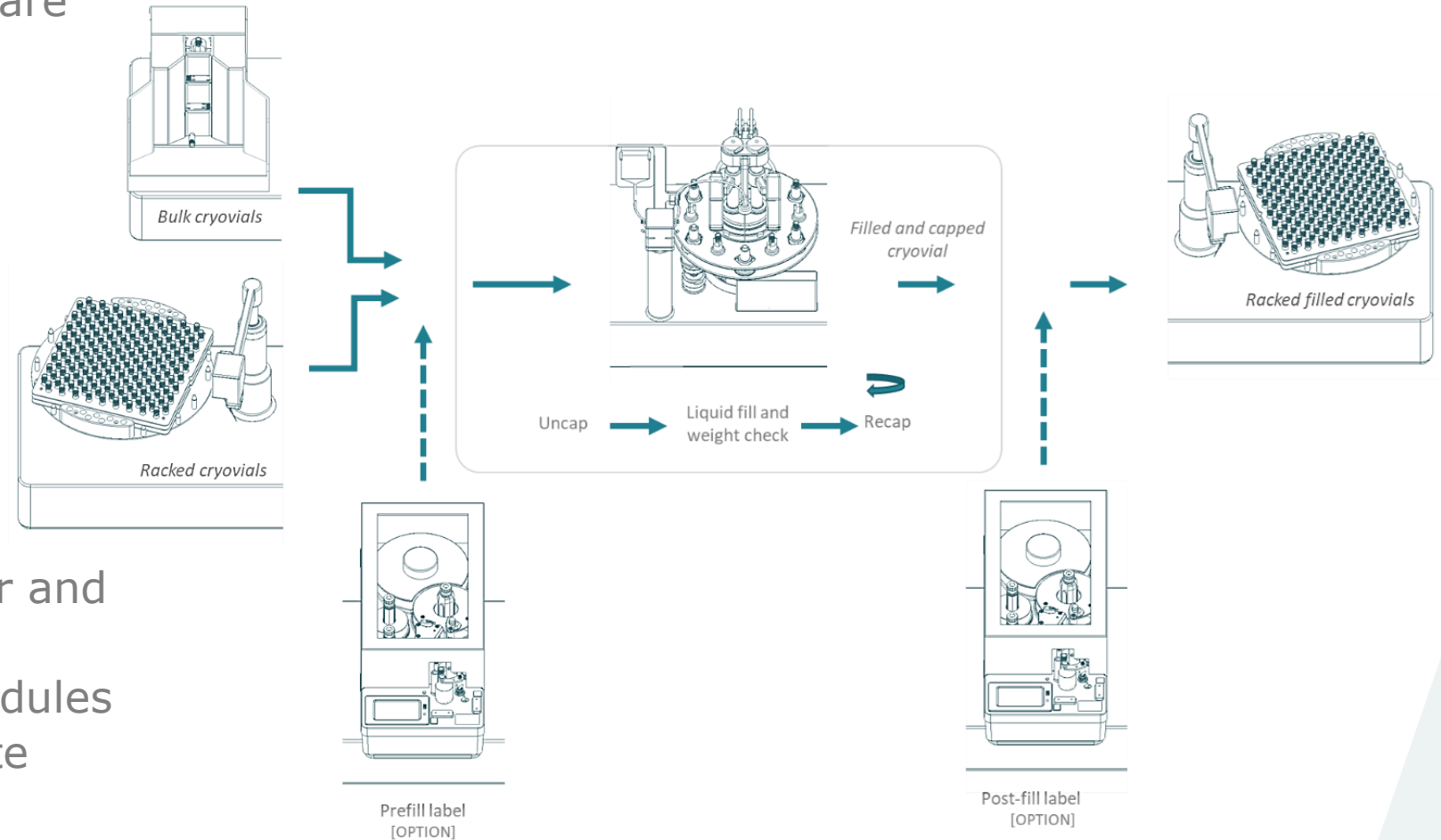


Cryovial Platform

The 4 core modules which are configured to meet a given need are:

- Filler and capper
- Rack transfer
- Bulk-feeder
- Labeller

For each process-specific solution, additional transfer and inspection modules are introduced to bring the modules together to form a complete system.



Barrier Systems

A range of integrated containment options is offered to suit varying requirements

Cleanroom

These systems are offered on an integrated lab bench. This is particularly applicable to pre-labelling or non-GMP filling.



Bio-safety Cabinet

ATMP/CGT filling is generally required in a controlled environment such as a Class II BSC.

The cryoFIL can be integrated with a 4' Baker BSC reducing footprint in your cleanroom.

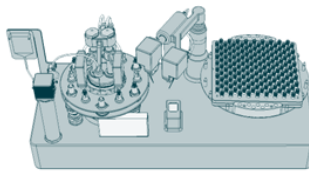
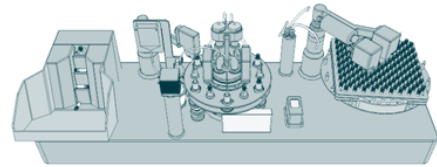
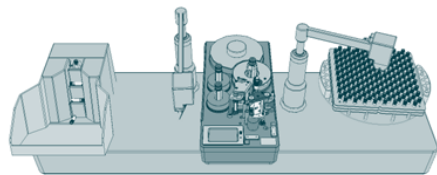
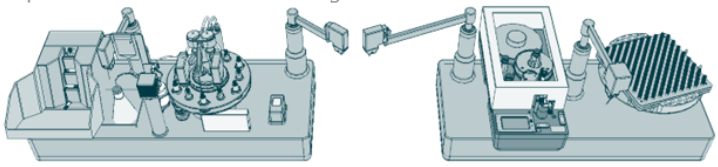


Aseptic Isolator

For the highest level of sterility assurance, Cryovial fill finish technology can be integrated into isolator barrier technology



System Configurations

Key features				Recommended Containment Configurations			MODEL	SYSTEM DESCRIPTION
BATCH SIZE	FEED	FILL	LABEL	Open Bench	Class II BSC	Isolator		
Smaller batch sizes <100	Manual Rack Load	•			•	•	CryoFill	- Manually loaded rack with empty vials - Fully automated decap, fill and recap - Can be integrated into a 4ft Baker Class II BSC 
Larger batch sizes up to 600 per unit	Automatic feed from bagged components	•			•	•	CryoFill+	- Integrated step feeder to allow bulk feeding - Fully automated decap, fill and recap - Can be integrated into a 5ft Baker Class II BSC 
			•	•	•		CryoLabel	- Integrated step feeder to allow bulk feeding - Label application using industry standard CAB systems labeller. - Direct tube marking option available - Automatic transfer to rack - Ideal for using alongside the CryoFill 
		•	•			•	CryoFill Pro	- Fully integrated system including bulk feed, decap, fill, recap, label and CRF rack. - Fill before labelling for maximise cleanliness at fill stage - Suitable for use in dedicated isolator system - Option for automated rack storage 

There are a range of configurations determined from the sterility and process required. 3P innovation has formed a variety of common systems considering:

- Production containment: Low-bioburden or sterile
- In-feed format: Bulk or pre-racked cryovials
- In-feed labelling: Labelled or blank

Label, fill and cap for low-bioburden

Labelling can be done prior to filling to remove the time constraint between filling and freezing.

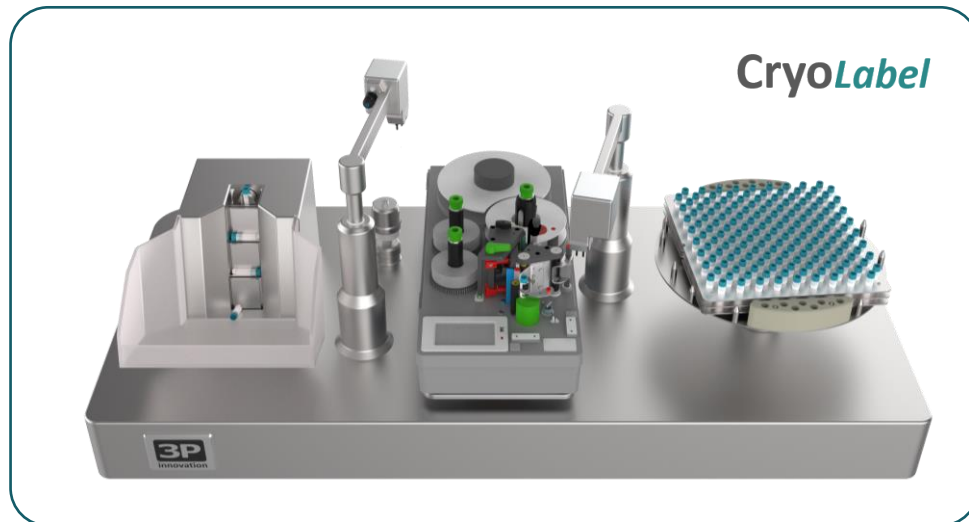
The cryovials can be manually transferred between platforms using racks suitable for cryogenic freezing



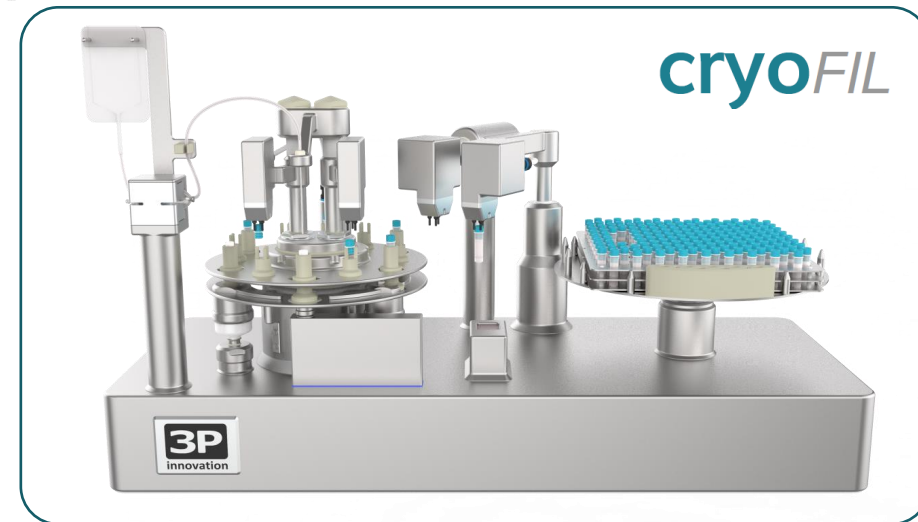
*Integrated
BSC*



*Integrated lab
bench*



Cryovial labelling from bulk, in a BSC or on a bench



Racked cryovial filling and capping in a BSC or on a bench

Fill and cap for sterile applications

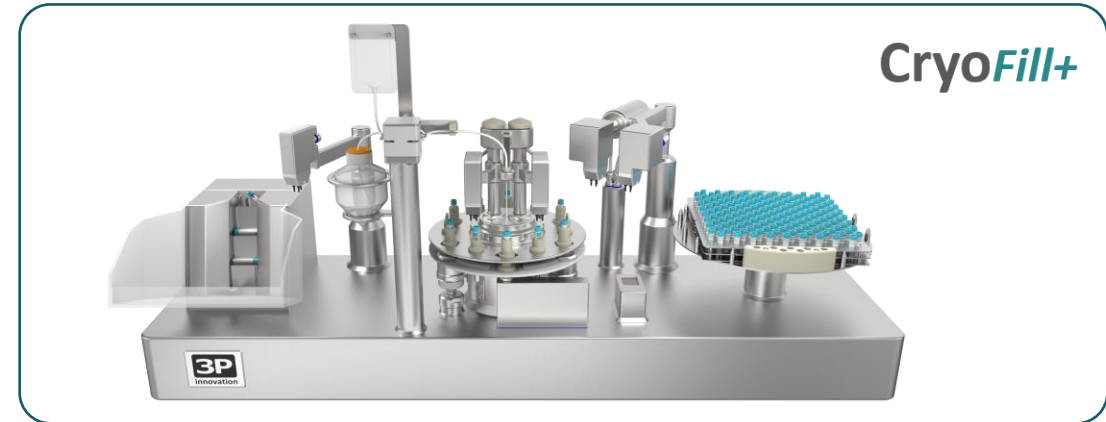
Where labelling is not required, filling solutions can be supplied for in-feeds of both rack and bulk.

These systems may only require a single chamber isolator. These systems are applicable for sterile applications.

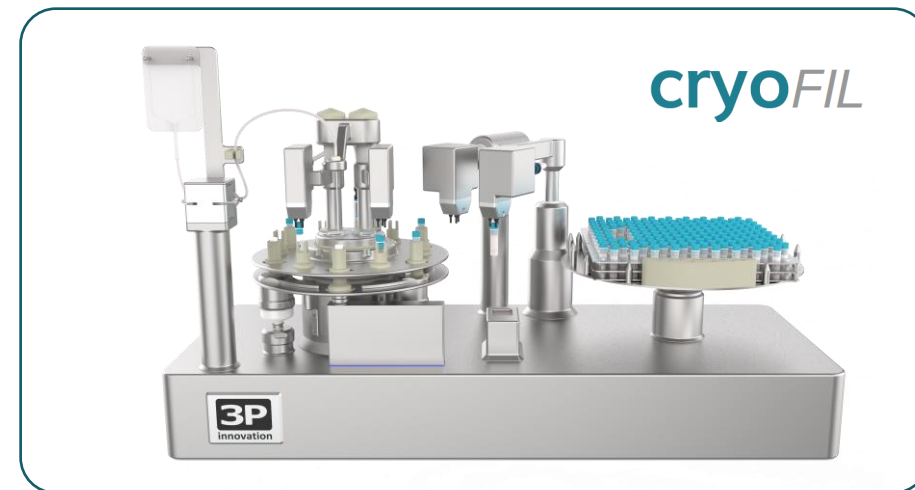


*Low cost single
chamber isolator
from SKAN*

*Integrated
biosafety cabinet*



Bulk cryovial filling and capping a Grade A isolator chamber



*Racked cryovial filling and capping a
Grade A isolator chamber*

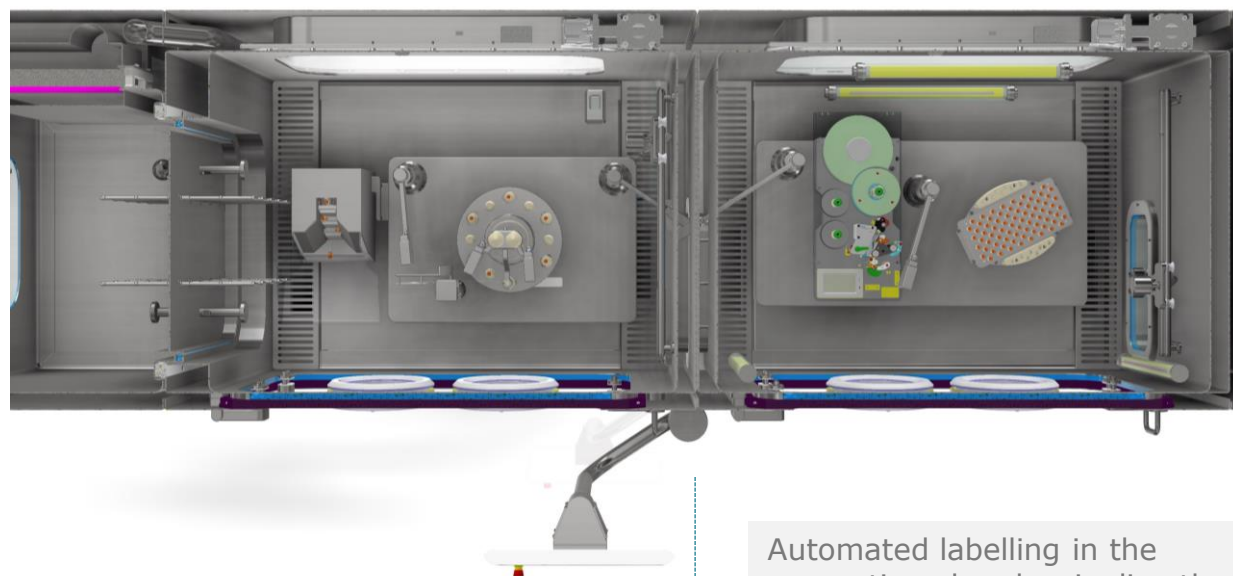
Aseptic isolator integration

CryoFill Pro

*Bulk cryovial filling and capping
a Grade A isolator chamber*

*Cryovial labelling in a supporting
lower grade chamber*

Raw materials can be introduced to aseptic processing area via pass chamber with hydrogen peroxide decontamination



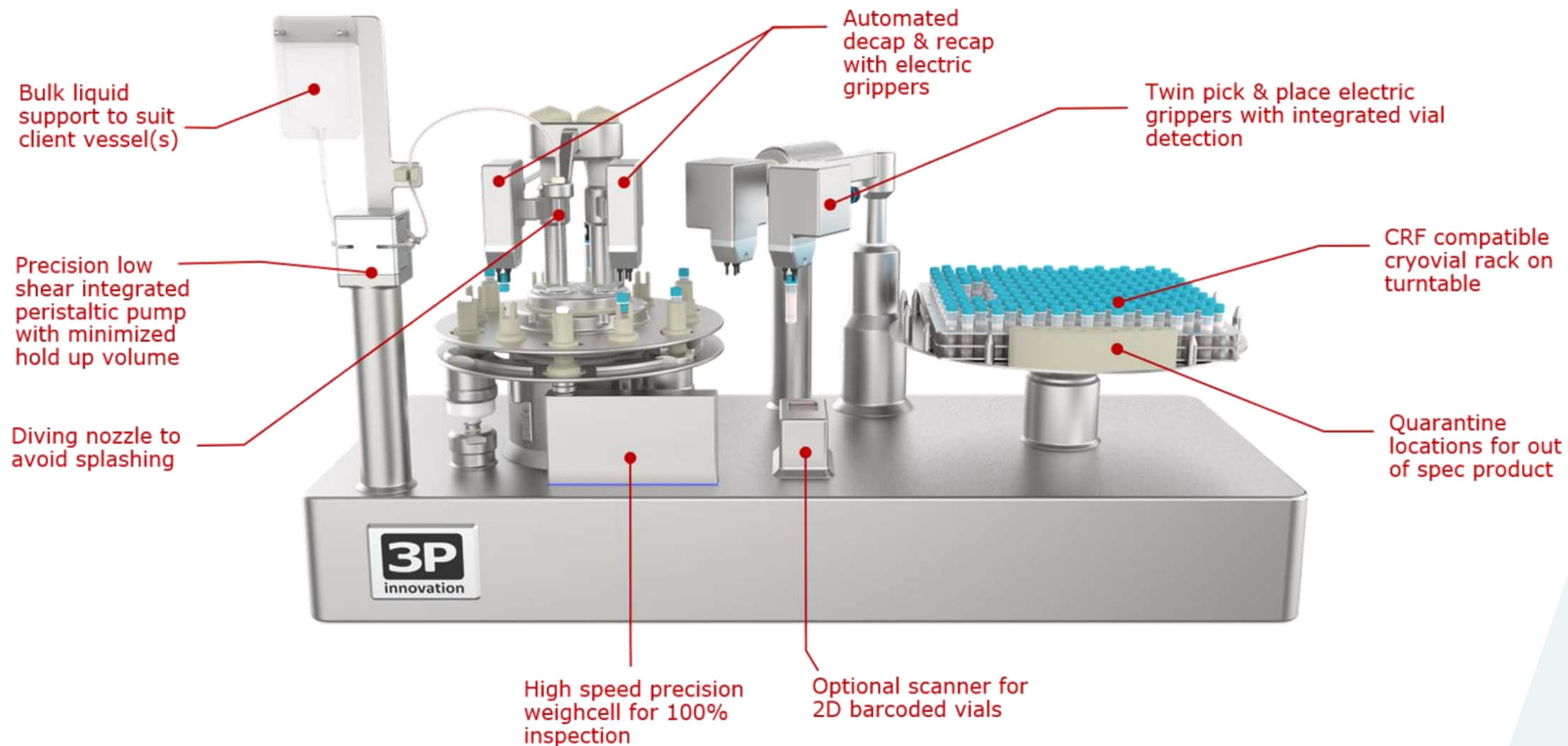
Cryovials can be filled automatically from a bulk supply of unlabelled cryovials, all within a Grade A environment, for the greatest sterility assurance

Automated labelling in the supporting chamber is directly connected to the filling process for the quickest possible time from start of filling to racked and labelled vials ready for freezing



*Fully integrated,
feed, fill and
label*

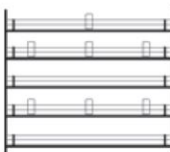
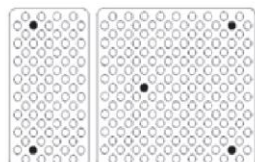
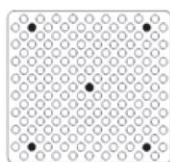
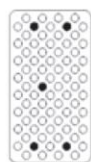
cryoFIL - Layout



Rack details

Model No. & Description	Dimensions H x W x D in. (cm)	Storage	CryoMed 0.6 cu. ft.	CryoMed 1.2 cu. ft.	CryoMed 1.7 cu. ft.	CryoMed - IVF 0.6 cu. ft.	CryoMed - IVF 1.2 cu. ft.
 4000703 1.2/2 mL freezing rack - large	1.1 x 12 x 12 (2.8 x 30.5 x 30.5)	Racks per chamber	N/A	5	5 large & 5 small	N/A	5*
		Vials per rack	N/A	161	161 & 76	N/A	161*
		Total # vials per chamber	N/A	805	1,185	N/A	805*
 4000701 1.2/2 mL freezing rack - small	1.1 x 6 x 12 (2.8 x 15.2 x 30.5)	Racks per chamber	5	N/A	5 large & 5 small	5*	N/A
		Vials per rack	76	N/A	161 & 76	76*	N/A
		Total # vials per chamber	380	N/A	1,185	380*	N/A

- Model shows a Thermofisher 4000703 sized rack (161 vials)
- Rack footprint 305 x 305mm
- Custom racks can be provided within this space envelope



0.6 cu. ft.

1.2 cu. ft.

1.7 cu. ft.

Models

Models

Models

7450/7451

7452/7453

7454/7455

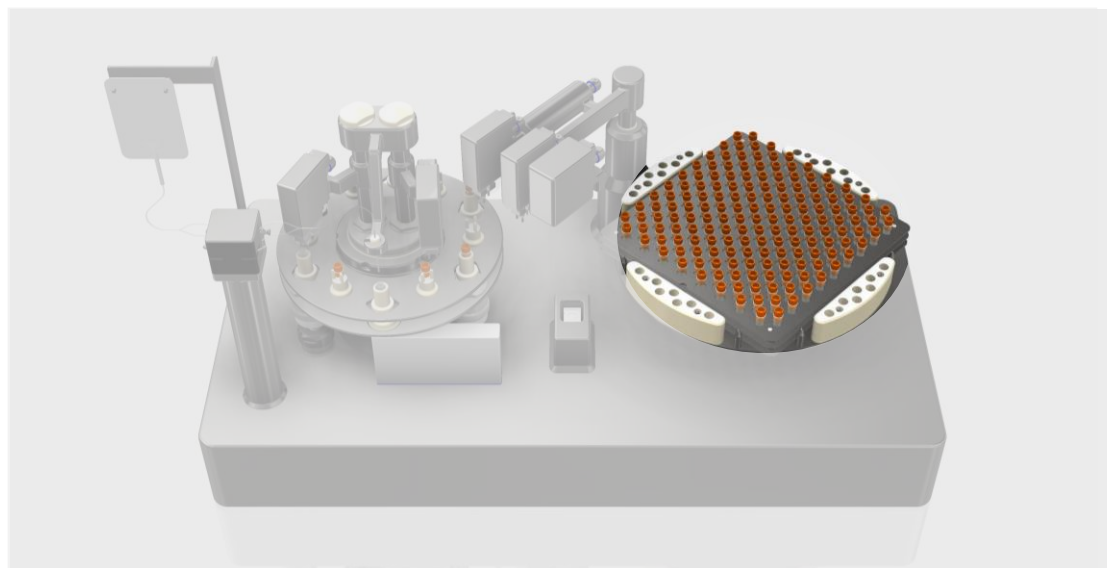
7456/7457

7458/7459

7474

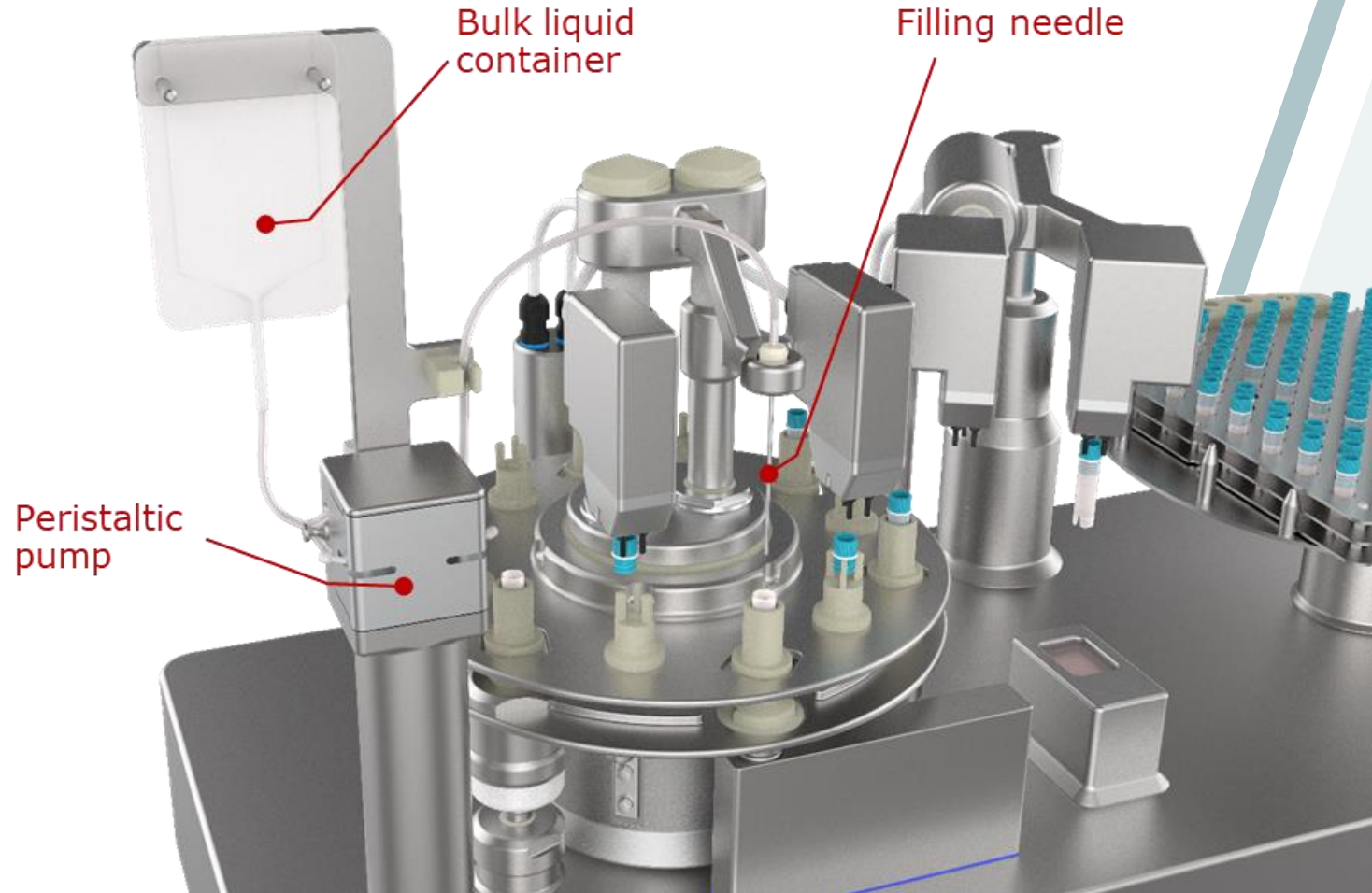
7472, 7475

7473, 7476

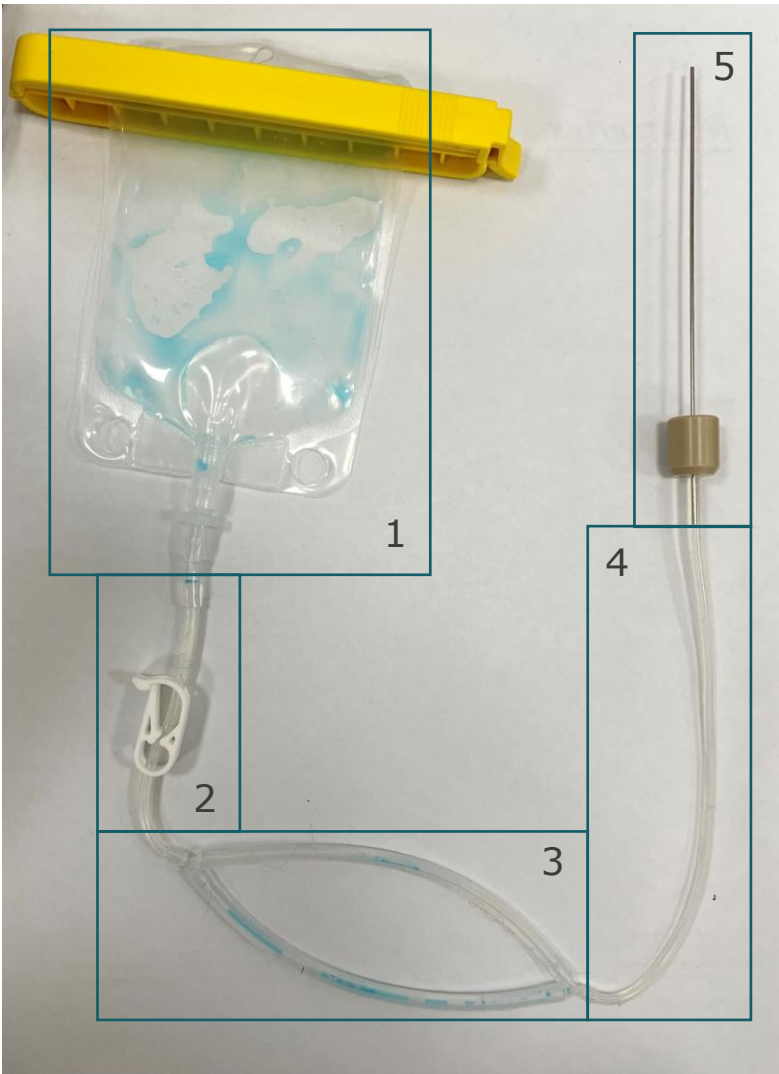


Fluid path considerations

- Product yield and product quality, are of the utmost importance
 - Maximal volume of fluid must be dispensed from the fluid path
 - Pumping must be delicate on the cells
 - Source cells must remain homogenous
- Pump/tubing sizes and types can be adjusted to suit the dose volume and balance yield and process speed
- The system design enables a range of liquid vessels to be used, including flasks and bags
- The liquid vessel can be mounted either on an elevated support or shaker/rocker to keep the fluid path as short as possible



Hold up volume

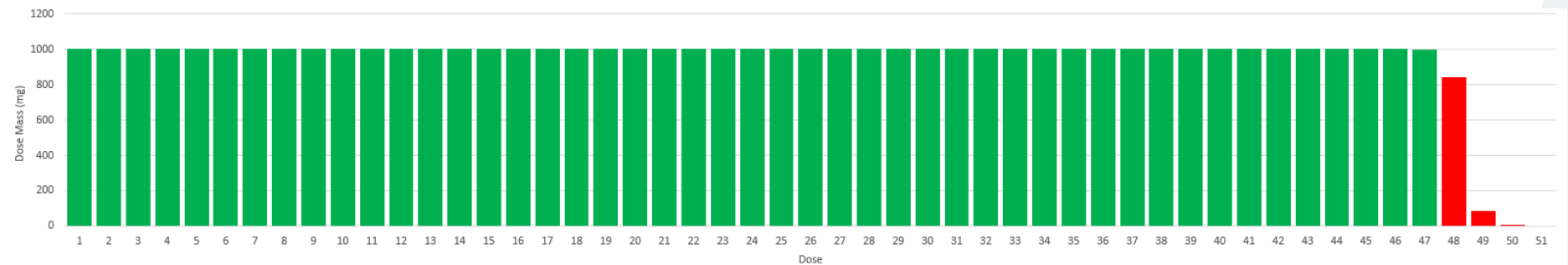


Zone	Component	Specifications	Average hold up Volume (ml)
1	Source bag	Maximum volume = 50ml	0.32
2	Bag to pump tube	0.89mm ID, 72mm fluid path length	0.003
3	Pump tube, dual channel	0.8mm ID twin	0.037
4	pump tube to dispensing nozzle	0.89mm ID, 152mm fluid path	0.013
5	Dispensing nozzle	0.6mm ID, 120mm Length	0.0005

Average of 0.068ml/metre

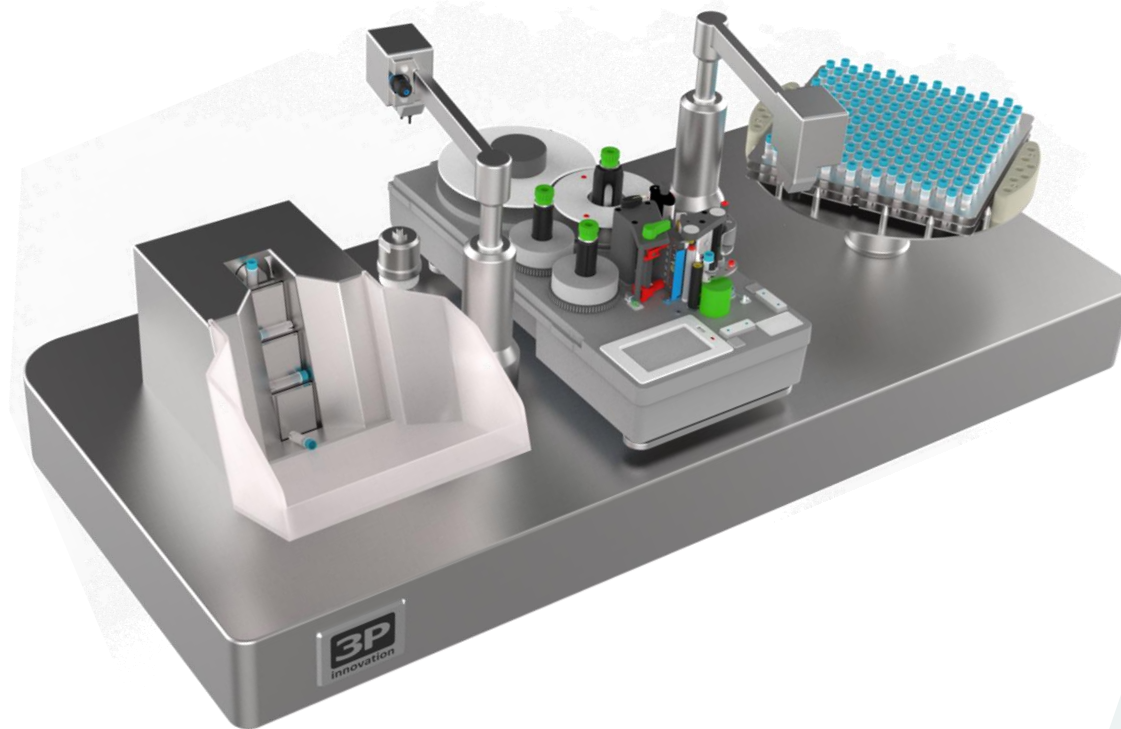
Liquid dosing and hold up volume

- Showed liquid utilisation 95%+ in a 50ml bag config
- Hold up volume - <0.5ml left in system
- 0.89mm ID tubing set
- Within dose – weight feedback to maximise in spec fills.
- The system is self purging and the first fill is in spec.

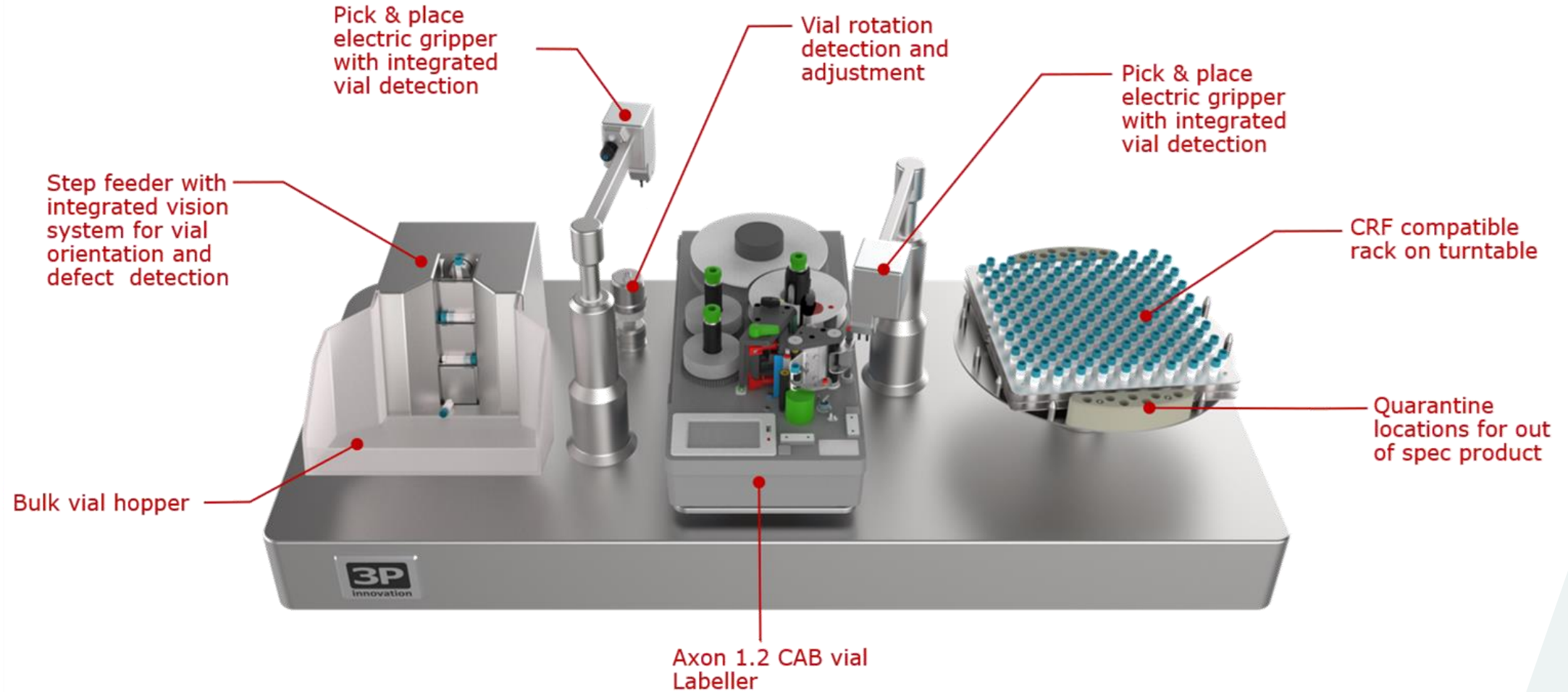


Features and Benefits

- Reduce opportunity for operator error with automatic label printing
- Minimise handling time by filling racks ready to transfer directly to a cryoFIL system
- GMP compatible design
- Manual top up of vial hopper without stopping processing
- Automatic detection of vial rotational orientation to enable repeatable label placement (avoiding obscuring the pre-printed graduations)
- Cycle time of 10 vials per minute
- Compact footprint to minimise space taken up in your cleanroom



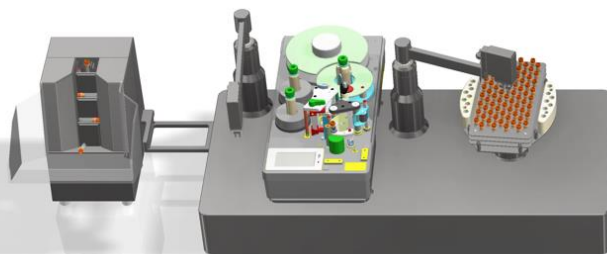
cryoLABEL - Layout



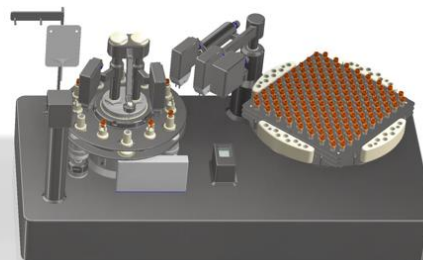
System Configurations

Low-bioburden

System 1
Bulk, Label, Rack



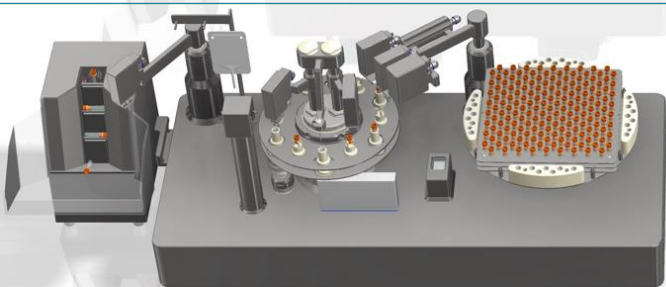
System 2
Rack, Fill, Re-rack



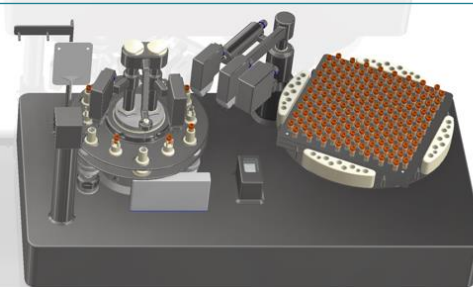
1 x BSC per system

Sterile

System 3
Bulk, Fill, Rack



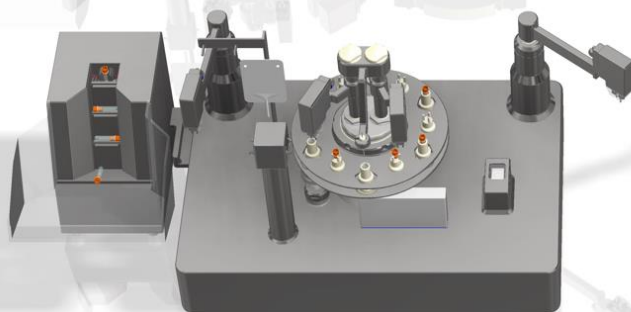
System 4
Rack, Fill, Re-rack



1 x isolator per system

Sterile

System 5
Bulk, Fill, Transfer



System 6
Transfer, Label, Rack



Fully integrated isolator system

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