

FINIA[®] Fill and Finish System

Automating your final formulation
for cell and gene therapies

TERUMOBCT



You no longer have to rely on a manual method for your fill and finish step. The functionally closed, single-use Finia disposable tubing sets are designed for use with diverse cell types.

Now you can:

- Maintain a functionally closed environment
- Facilitate GMP compliance
- Reduce the variability that occurs with manual processing
- Ensure reproducible and accurate final results
- Maintain final product temperature to within 3 °C of the user-defined target

The Finia Fill and Finish System¹:

- Provides a summary report with planned and actual volumes for all material and product bags and any process alarms or flags, including user-defined tolerance thresholds for:
 - Volume
 - Material contact time
 - Temperature
- Utilizes a gamma-sterilized functionally-closed tubing set
- Automatically seals the final product and QC bags to help maintain sterility
- Maintains cell viability of greater than 95% of the inlet cell viability
- Maintains uniformity of cell concentrations to within 5% for all product bags and the QC bag
- Accurately fills product and QC bags within either 10% or 2 mL (whichever is greater) of the user-defined target
- Removes air to less than 2 mL per final product bag

¹Data on file.

GMP: Good Manufacturing Practices; QC: quality control.

SYSTEM VOLUME SPECIFICATIONS

- Volume accuracy: ± 2 mL or $\pm 10\%$ of the target volume, whichever is greater
- Product volume range: 20 mL to 174 mL
- Material volume: Product volume plus 6 mL residual volume

TUBING SET SPECIFICATIONS

Finia 50 Tubing Set:

- Quality control bag: 10 mL to 40 mL
- Product bag 1: 10 mL to 28 mL
- Product bag 2: 0 or 10 mL to 28 mL
- Product bag 3: 0 or 10 mL to 28 mL

Finia 250 Tubing Set:

- Quality control bag: 10 mL to 40 mL
- Product bag 1: 29 mL to 70 mL
- Product bag 2: 0 or 29 mL to 70 mL
- Product bag 3: 0 or 29 mL to 70 mL

EQUIPMENT SPECIFICATIONS

- Surface space required: 0.45 m² (4.8 ft²)
- Minimum clearance: 30 cm (11.8 in) around the perimeter of the device
- Device weight: 66.9 kg (147.5 lb)
- Monitor weight: 4.4 kg (9.7 lb)
- Height: 78.5 cm (30.9 in)
- Width: 88.9 cm (35.0 in)
- Depth: 49.8 cm (19.6 in)

ENVIRONMENTAL SPECIFICATIONS (device)

Particle emission:

- Fewer than 44,000 particles that measure 0.5 microns or larger per m³ of air sample
- Fewer than 366 particles that measure 5 microns or larger per m³ of air sample

ELECTRICAL SPECIFICATIONS

Safety certifications:

- IEC 61010-1 (Safety requirements for electrical equipment for measurement, control and laboratory use)
- EN 61326-1 (Electromagnetic compatibility of electrical equipment for measurement, control and laboratory use)

Electrical power requirements: 100 V AC to 240 V AC, 50/60 Hz, 10 A maximum

Installation category: II

Ethernet port: Port is electrically isolated

For more information, please visit terumobct.com/finia.

TERUMOBCT

As a global leader in blood component, therapeutic apheresis and cellular technologies, we believe in the potential of blood and cells to do even more for patients than they do today. This belief inspires our innovation and strengthens our collaboration with customers.

TERUMOBCT.COM

Terumo BCT, Inc.

10811 West Collins Ave.
Lakewood, Colorado 80215-4440
USA

USA Phone: 1.877.339.4228
Phone: +1.303.231.4357
Fax: +1.303.542.5215

Terumo BCT Europe N.V.

Europe, Middle East and Africa
Ikaroslaan 41
1930 Zaventem
Belgium

Phone: +32.2.715.0590
Fax: +32.2.721.0770

Terumo BCT Asia Pte. Ltd.

89 Science Park Drive
#04-25 (Lobby B)
The Rutherford
Singapore 118261

Phone: +65.6715.3778
Fax: +65.6774.1419

Terumo BCT Latin America S.A.

La Pampa 1517–12th Floor
C1428DZE
Buenos Aires
Argentina

Phone: +54.11.5530.5200
Fax: +54.11.5530.5201

Terumo BCT Japan, Inc.

Tokyo Opera City Tower 49F,
3-20-2, Nishi-Shinjuku,
Shinjuku-ku, Tokyo 163-1450,
Japan

Phone: +81.3.6743.7890
Fax: +81.3.6743.9800