DISTEK | BIONE SINGLE-USE BIOREACTOR SYSTEM

CONVERT TO A SINGLE-USE BIOREACTOR IN SECONDS!

Distek, Inc. has developed a benchtop scale single-use bioreactor (SUB) for mammalian cell growth, cell therapy, insect cells, and other unique applications performed in a stirred tank bioreactor. The gamma irradiated BIOne SUB is engineered with a disposable headplate welded to a triple-layered liner that can be easily inserted into a non-sterile bioreactor glass vessel, converting it to a disposable SUB within a matter of seconds. Upon media addition, the liner expands and molds to the glass vessel, preserving the geometry of the existing bioreactor. The BIOne SUB's liner material emulates the large-scale SUBs used in pilot and commercial biopharm production facilities around the world. Performing R & D studies using the most similar material on the market streamlines your tech transfer and can de-risk your process BEFORE transferring to pilot scale.

BIOne

SINGLE-USE HEADPLATE

CUSTOMIZABLE ABOVE & BELOW THE HEADPLATE

- 2L & 5L Working Volume
- Optional Single-Use pH Probe
- Increased Throughput
- Weldable Tubing
- Flute, Micro & Open Pipe Sparging Options
- Non-Invasive DO & Optional pH Probe Ports
- USP Class VI Materials
- Repligen® ATF Perfusion Tube Compatible
- Animal Derivative-Free
- Low Antioxidant Liner Material
- Compatible with Most Manufacturers' Glass Vessels and Controllers

SINGLE-USE LINER

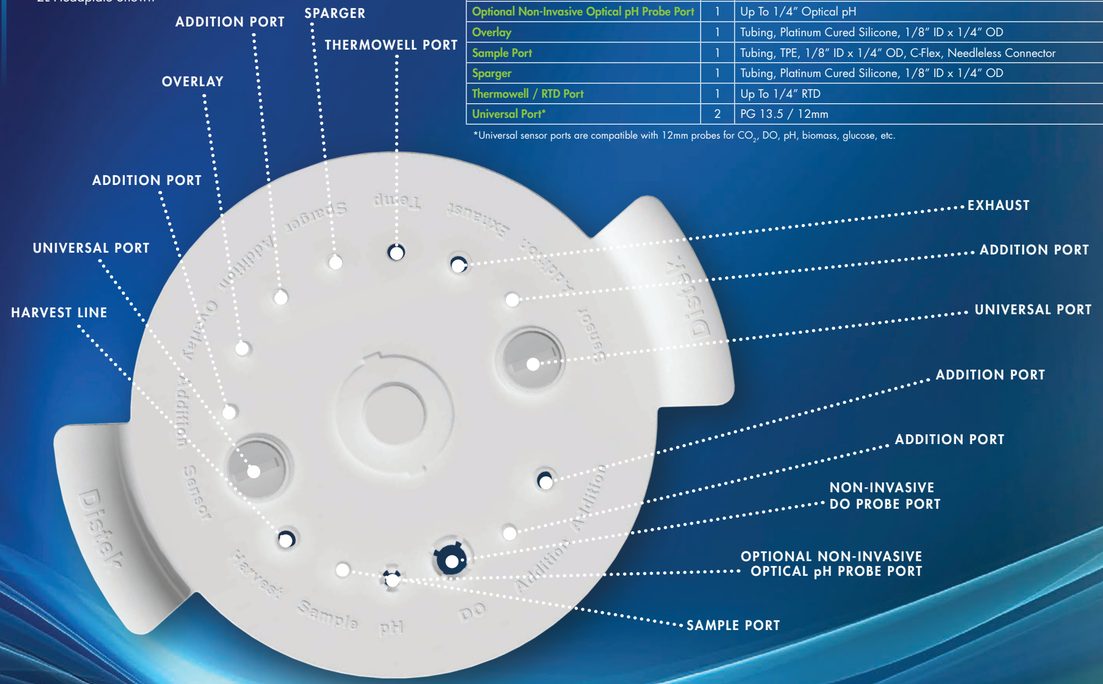
GLASS VESSEL

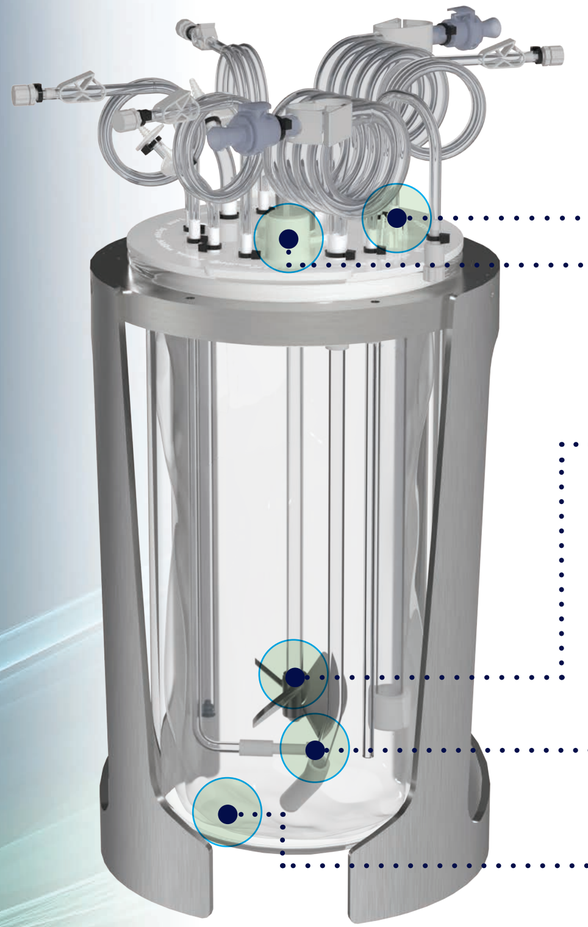
HEADPLATE CONFIGURATION

*2L Headplate Shown

ITEM	QTY	DESCRIPTION
Addition Port	5	Tubing, TPE, 1/8" ID x 1/4" OD, C-Flex, Luer Connector
Exhaust	1	Tubing, Platinum Cured Silicone, 1/4" ID x 3/8" OD
Filters (Inlet / Outlet)	3	(2) Inlet (25mm, 0.2µm PE Filter) / (1) Outlet (50mm, 0.2µm PE Filters) or (Optional 51mm Capsule Filter, 0.2µm PVDF Membrane)
Harvest Line	1	Tubing, TPE, 1/8" ID x 1/4" OD, C-Flex, Luer Connector
Non-Invasive DO Probe Port	1	12mm Standard DO Probe
Optional Non-Invasive Optical pH Probe Port	1	Up To 1/4" Optical pH
Overlay	1	Tubing, Platinum Cured Silicone, 1/8" ID x 1/4" OD
Sample Port	1	Tubing, TPE, 1/8" ID x 1/4" OD, C-Flex, Needleless Connector
Sparger	1	Tubing, Platinum Cured Silicone, 1/8" ID x 1/4" OD
Thermowell / RTD Port	1	Up To 1/4" RTD
Universal Port*	2	PG 13.5 / 12mm

*Universal sensor ports are compatible with 12mm probes for CO_2, DO, pH, biomass, glucose, etc.





HIGHLIGHTED INTERNAL FEATURES

DO & pH PROBE PORTS

- Non-Invasive (Amperometric DO/Optical pH)
- PG-13.5 (Optical DO/Electrochemical pH)
- Optional Integrated Single-Use pH Probe

PITCHED BLADE IMPELLER

- Single or Dual Impeller

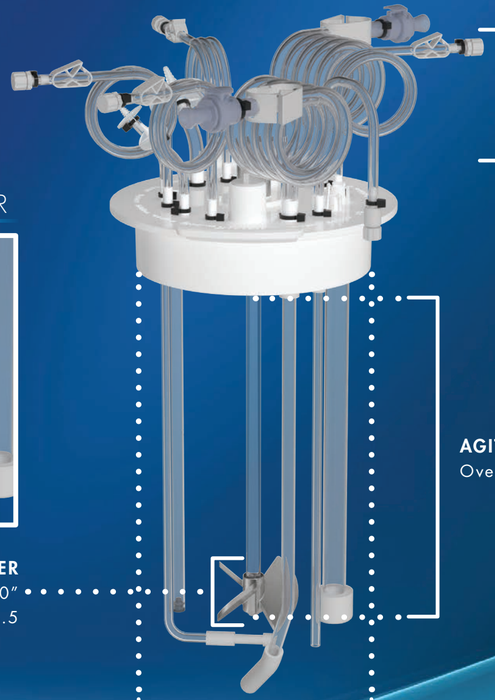
SPARGING OPTIONS

- Flute Sparger (7 x 1.5 mm hole)
- Micro Sparger (20-40 µm pore size)
- Open Pipe Sparger (1 x 3.0 mm)

LOW ANTIOXIDANT LINER MATERIAL

- Outer Layer (LDPE) – Mechanical Strength
- Middle Barrier Layer (EVOH) – Gas Barrier
- Contact Layer (ULDPE) – Cell Culture Compatible, Biologically Inert

2L, SINGLE IMPELLER SPECIFICATIONS

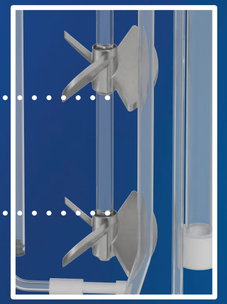


C-FLEX TUBING
Inner Diameter: 0.125″
Length: 30″

AGITATOR SHAFT
Overall Length: 6.87″

HEADPLATE INNER DIAMETER: 4.87″

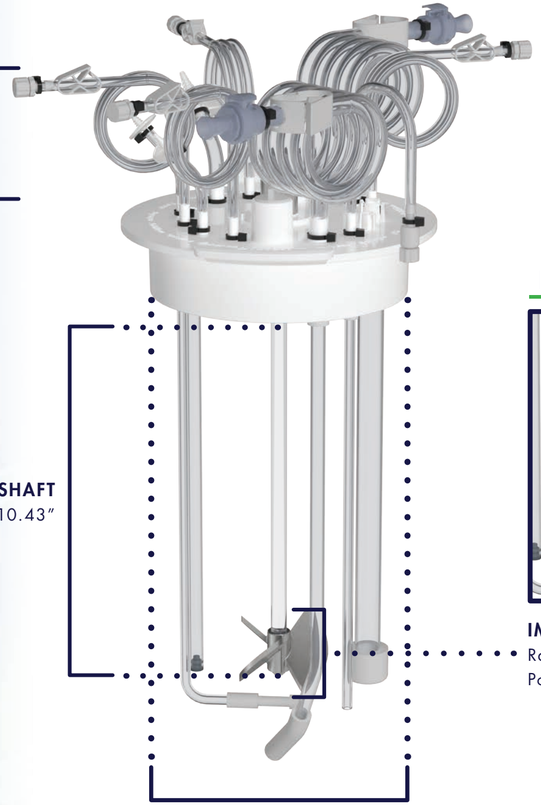
DUAL IMPELLER



AGITATOR SHAFT
Inter-Impeller
Length: 3.23″

IMPELLER
Radius: 0.950″
Power Number 1.5

5L, SINGLE IMPELLER SPECIFICATIONS



C-FLEX TUBING
Inner Diameter: 0.125″
Length: 30″

AGITATOR SHAFT
Overall Length: 10.43″

HEADPLATE INNER DIAMETER: 6.00″

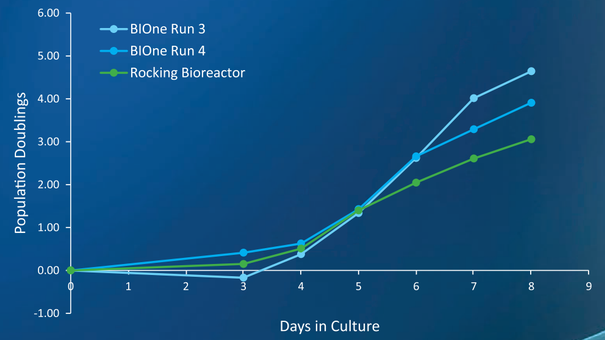
DUAL IMPELLER

AGITATOR SHAFT
Inter-Impeller
Length: 4.25″

IMPELLER
Radius: 1.250″
Power Number 1.5

T-CELLS

Comparing a single donor across the BIOne 1250 stirred tank system with a 2L BIOne single-use bioreactor and the rocking bioreactor system indicates that the BIOne enables increased cell expansion toward the later stage of the cell culture. The average increase in expansion was 1.22 population doublings. This difference in expansion shown in this experiment could correspond to a 24-48 hour reduction in total culture length depending on the target yield. Culture is typically the limiting factor in production speed and reducing the length of time required to achieve a therapeutic yield will result in faster product release.

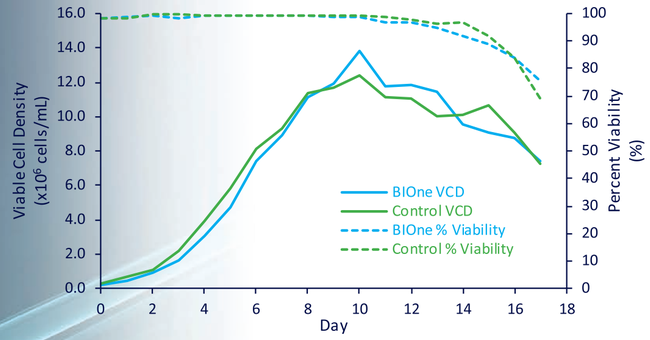


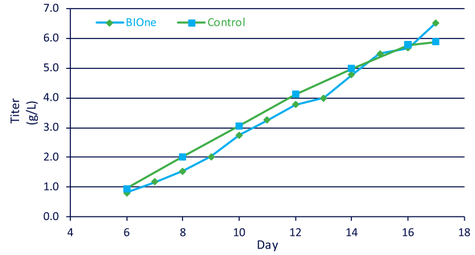
APPLICATIONS

- Process Development
- Process Optimization
- Stem Cell Cultivation
- Process Validation
- Adherent Cell Culture with Microcarriers

CHO CELLS

Cell Culture. Growth profiles and titer were evaluated with a CHO cell line in a 17 day fed-batch process. Titer was quantified starting on Day 6. Similar growth and titer were observed in the BIOne and glass vessel control. Performance results indicate that the BIOne single-use bioreactor system is a suitable bench scale SUB for mammalian cell growth and recombinant protein production.





The BIOne single-use bioreactor system effectively eliminates the time, risk, and costs associated with cleaning, assembling, and autoclaving non-disposable bioreactors. The BIOne achieved comparable growth profiles and recombinant protein production relative to a glass vessel bioreactor. Similar performance attributes in these key areas demonstrate the BIOne's utility as a robust model for bioprocess development.

121 North Center Drive
North Brunswick, NJ 08902
888.2.DISTEK
distekinc.com
bione@distekinc.com

TECHNICAL SPECIFICATIONS	BIOne 2L SUB	BIOne 5L SUB
Working Volume (Maximum)	2L	5L
Working Volume (Minimum)	0.9L	1.7L
Operating Temperature Range	4°C to 60°C[1]	4°C to 60°C[1]
Operating Pressure (Maximum)	5 psig (.0345 mPa)	5 psig (.0345 mPa)
Agitation Range	15 to 450 rpm	15 to 450 rpm
Gamma Irradiated	Gamma Irradiated between 25 and 40 kGy	

[1] BIOne SUB materials rated for use in processes at temperatures up to 60°C (exception of Hamilton Single-Use pH probe, with a maximum operational temperature definition of 50°C). Structural Integrity Testing completed for operations up to 60°C. Leachable and Extractables Testing completed for operations up to 40°C.

MADE IN USA
Rev E