



# BIOne Single-Use Bioreactor

Ready-To-Use Out of the Box: No Cleaning, Assembly or Autoclaving

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## A Flexible Single-Use Solution for Cell Culture & Cell-Free Reactions

The BIOne Single-Use Bioreactor (SUB) by Distek is well suited for a variety of cell culture and cell-free applications including but not limited to the production of monoclonal antibodies in CHO, AAV and Lentiviral vectors in SF9 and HEK293, adherent and aggregate stem cells, and mRNA. The BIOne SUBs have been well characterized based on  $k_L a$ , P/V, and tip speed, simplifying the tech transfer and scale up process. These customizable solutions are compatible with most bioprocessing controllers, making them easily adaptable to any lab.

### CUSTOMIZABLE

The BIOne SUB is designed for flexibility and customization. Every component above and below the headplate can be configured to address the specific requirements of a wide range of cell culture and cell-free applications.



### READY-TO-USE

The BIOne SUB, assembled in Distek's ISO 7 cleanroom with USP Class VI materials, is pressure-tested, gamma sterilized, and ready-to-use out of the box. It eliminates the need for cleaning, assembly, or autoclaving, minimizing contamination risk.



### AGNOSTIC DESIGN

With a range of motor adapters available, the BIOne Single-Use Bioreactor is compatible with many common bioprocessing controllers on the market. This allows for seamless and rapid integration into any bioprocessing laboratory.



## Designed with Adaptability in Mind

Discover our single-use bioreactor solution for cell culture and cell-free applications, specifically designed to handle a variety of needs. Key features include single or dual pitched blade impellers, flute or microsparger, along with the option for an integrated

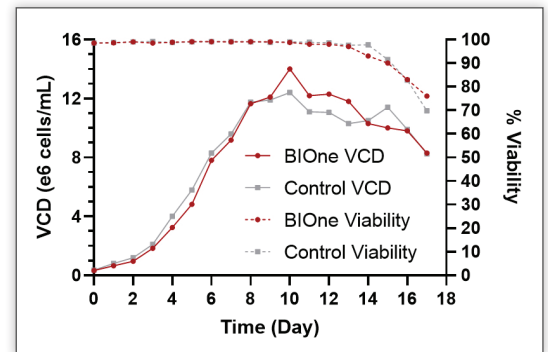
|                                     | BIOne 2L SUB             | BIOne 5L SUB | BIOne 10L SUB |
|-------------------------------------|--------------------------|--------------|---------------|
| <b>WORKING VOLUME (MAXIMUM)</b>     | 2L                       | 5L           | 10L           |
| <b>WORKING VOLUME (MINIMUM)</b>     | 0.9L                     | 1.7L         | 2.5L          |
| <b>OPERATING TEMPERATURE RANGE</b>  | 4°C to 60°C <sup>1</sup> |              |               |
| <b>OPERATING PRESSURE (MAXIMUM)</b> | 5 psig (.0345 mPa)       |              |               |
| <b>AGITATION RANGE</b>              | 15 to 450 rpm            |              |               |
| <b>IMPELLER DIAMETER</b>            | 1.78"                    | 2.36"        | 3.12"         |
| <b>IMPELLER POWER NUMBER</b>        | 1.5                      |              |               |
| <b>GAMMA IRRADIATED</b>             | 25 to 40 kGy             |              |               |

single-use pH probe. Enjoy the benefits of a non-invasive DO (polarographic or optical) port and optional optical pH port for easy integration. Our weldable TPE tubing comes in various sizes to suit your process requirements. Adaptable exhaust and inlet (sparge and overlay) filters allow for efficient oxygen transfer to the culture.

<sup>1</sup> 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 at 40°C.

### CELL CULTURE GROWTH PROFILE: BIOne SUB vs. CONTROL

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.



### STANDARD HEADPLATE CONFIGURATION

|                                   |   |  |   |   |
|-----------------------------------|---|--|---|---|
| <b>ADDITION PORT (STANDARD)</b>   | 5 | Tubing, TPE, 1/8" ID x 1/4" OD, C-Flex, Luer Connector       |   |   |
| <b>EXHAUST</b>                    | 1 | Platinum Cured Silicone, 1/4" ID x 3/8" OD                   |   |   |
| <b>FILTERS (INLET)</b>            | 2 | 50mm, 0.2µm PE Filter (2L/5L)                                | 2 | 50mm, 0.2µm PE Filter (10L)             |
| <b>FILTERS (OUTLET)</b>           | 1 | 50mm, 0.2µm PE Filter (2L/5L)                                | 1 | 200cm <sup>2</sup> Capsule Filter (10L) |
| <b>HARVEST LINE</b>               | 1 | 1/8" ID x 1/4" OD, C-Flex, Luer Connector                    |   |   |
| <b>NON-INVASIVE DO PROBE PORT</b> | 1 | 12mm Standard DO Probe                                       |   |   |
| <b>SAMPLE PORT</b>                | 1 | Tubing, TPE, 1/8" ID x 1/4" OD, C-Flex, Needleless Connector |   |   |
| <b>SPARGER</b>                    | 1 | Tubing, Platinum Cured Silicone, 1/8" ID x 1/4" OD           |   |   |
| <b>THERMOWELL / RTD PORT</b>      | 1 | Up To 1/4" RTD   |   |   |
| <b>UNIVERSAL PORT*</b>            | 2 | PG 13.5 / 12mm (2L/5L)                                       | 4 | PG 13.5 / 12mm (10L)                    |

\*One port taken when optional single-use pH is in use.

