

**RIGGTEK**



**2016**

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*The Evolution in Dissolution Testing*

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# VORANKÜNDIGUNG

BIOne – der Einweg-Bioreaktor mit vielen Vorteilen

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The **BIOne** benchtop single-use bioreactor system for mammalian cell growth and recombinant protein production as a robust model for bioprocess development

THE SIMPLEST SINGLE-USE BIOREACTOR SYSTEM ON THE MARKET TODAY!

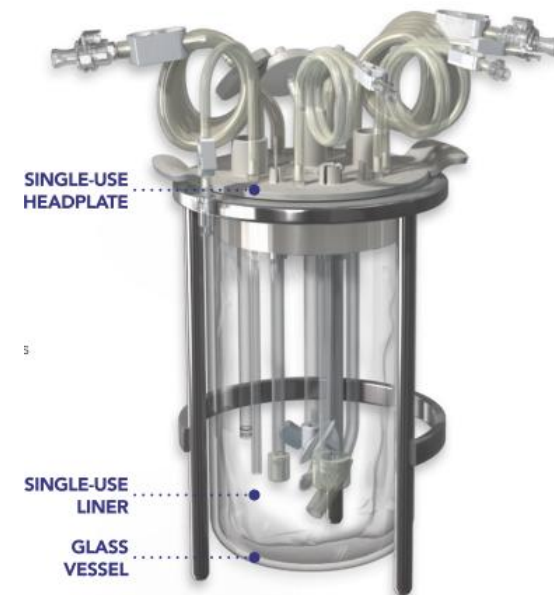
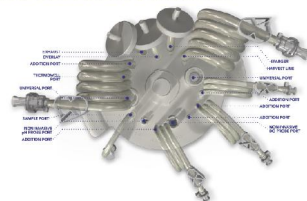


## BIONE

### SINGLE-USE BIOREACTOR SYSTEM

You don't need to make a large capital investment to **convert your existing benchtop glass bioreactor to a single-use bioreactor**. Simply remove your existing headplate and place the preassembled and sterile Distek BIOne System into the glass vessel. The "patent pending" bioreactor liner will mold to and mimic your existing glass system allowing you to continue using your existing cabinet, probes, motor, heating jacket and recipes. Since the liner is identical to the dimensions and aspect ratio of your existing vessel, there is no need to change your process. All materials are USP Class VI, animal derivative free and utilized in existing single-use products.

SINGLE-USE HEADPLATE CONFIGURATION

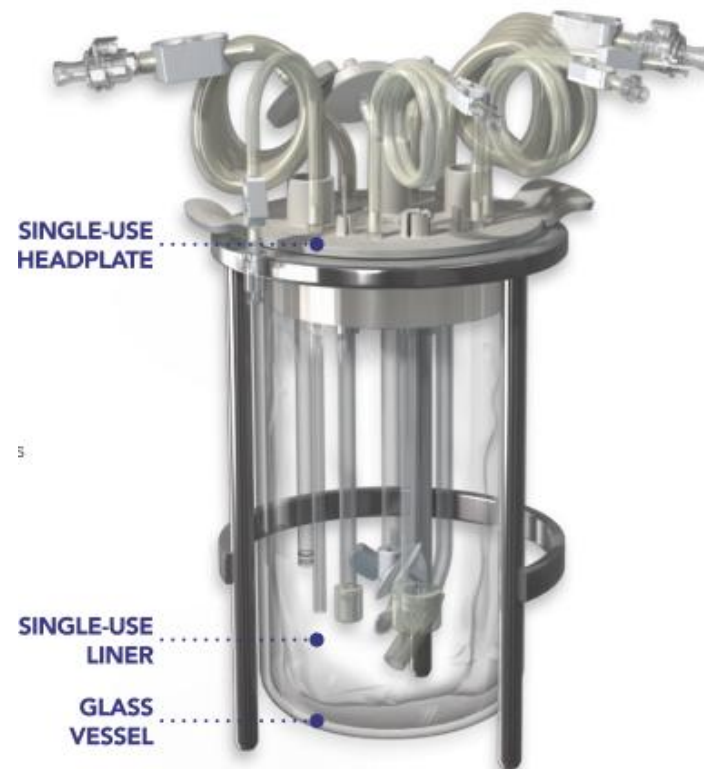


\* Image rendered without media

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\* Image rendered without media

## "PATENT PENDING" SINGLE-USE LINER & HEADPLATE

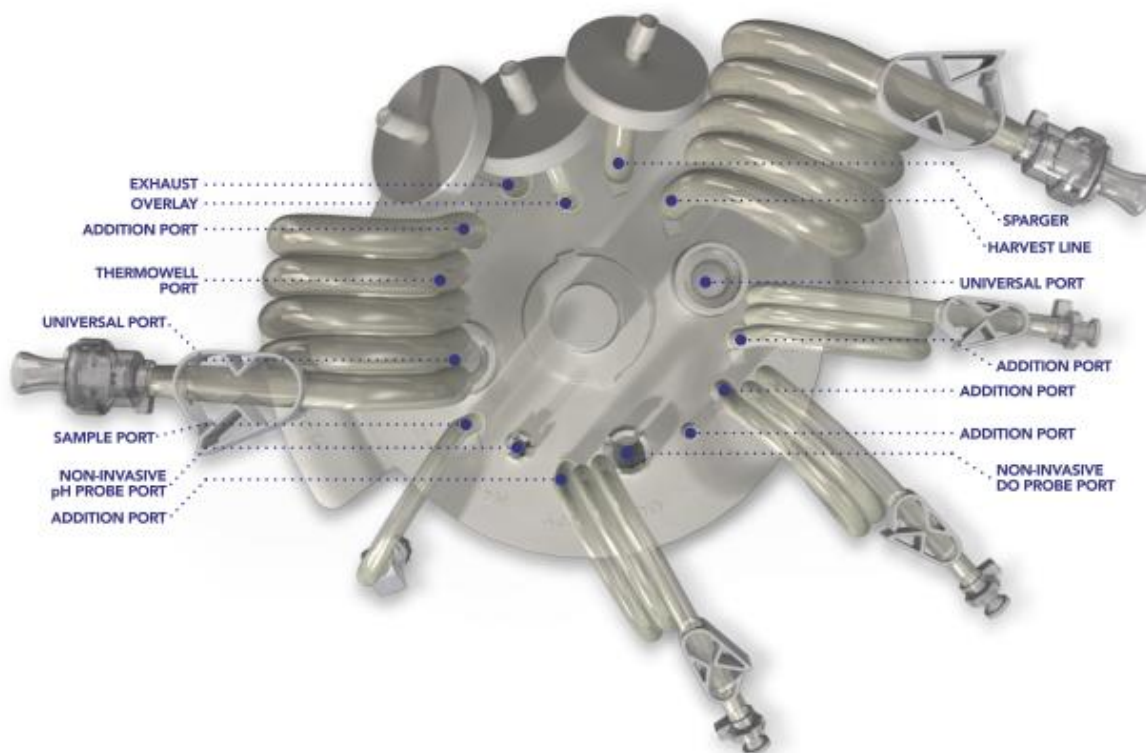
The BIOne Single-Use Bioreactor system is designed for mammalian cell culture applications. The "patent pending" design consists of a pre-sterilized assembly which fits into an existing glass vessel and contains all of the components of your existing glass system including:

- Probe Ports
- Addition Ports
- Thermowell Port
- Prefitted, Weldable TPE Tubing
- Vent Filter and Gas Inlet Filters
- Sampling Port & Harvest Line
- Microsparger or Flute Sparger
- Pitched Blade Impeller

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## MULTIPLE SENSOR PORTS

The single-use headplate contains four probe ports including:

- Non-invasive DO sensor port
- Non-invasive pH sensor port
- Two universal sensor ports which can be utilized for 12mm CO<sub>2</sub>, DO, pH, biomass, glucose, etc.

## INCREASED THROUGHPUT

Converting your existing glass bioreactor to a single-use bioreactor using Distek's BIOne system increases throughput by eliminating assembling, cleaning and autoclaving effectively reducing turn-around time between runs. Simply unpack the BIOne Single-Use Bioreactor System, place it into your glass vessel, insert your probes and you're ready to batch and inoculate!

## BIOREACTOR COMPATIBILITY

The BIOne Single-Use Bioreactor system is compatible with most manufacturers' glass vessels including: Applikon, Sartorius, Broadley James, Finesse, Infors and more.

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The **BIOne** benchtop single-use bioreactor system for mammalian cell growth and recombinant protein production as a robust model for bioprocess development

## ABSTRACT

Distek, Inc. has developed a benchtop scale single-use bioreactor (SUB) system for mammalian cell growth and recombinant protein production. The pre-sterilized BIOne system 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 sterile, disposable SUB within a matter of seconds. The Distek BIOne system significantly reduces turnaround time by allowing users to seamlessly transition to a disposable platform while utilizing their existing capital equipment, without compromising the scalability of their current process. In this study, mammalian cultures were conducted by using either the Distek BIOne system or the traditional, non-disposable bioreactor system. Comparable cell culture performance was observed supporting that the Distek BIOne system provides a robust model for bioprocess development.

## INTRODUCTION

Benchtop scale bioreactor provides a cost efficient model for process development and characterization that can be readily scaled-up or scaled-down from production scale. Given that upstream process development and characterization are rigorous and complicated, high throughput is vital to ensure efficiency and avoid delays. Thus, many have utilized the single-use platform to significantly reduce turnaround time by eliminating cleaning, assembling and autoclaving. Distek, Inc. has developed the BIOne benchtop single-use bioreactor system with an innovative liner technology that inserts into existing glass vessel to easily convert the existing non-disposable platform to a disposable, single-use platform. Upon media addition, the triple-layered liner expands and molds to the glass vessel, preserving the geometry of the existing bioreactor. The BIOne is fully compatible with the existing equipment including controller, probes and agitator, thus, no new capital investment required.

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## WORKFLOW - Time Breakdown: BIOne versus Non-disposable Bioreactors

Figure 1. Workflow comparison for 24 x 2L bioreactors: BIOne versus non-disposable bioreactors. Timeline depicts individual activities and projected time involved in preparation, operation, and turnaround. A 48 hour reduction in workflow was observed.

**BIOne = 34½ Hours**    **Non-Disposable = 82½ Hours**



**48 Hour Reduction in Workflow !**

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### METHOD AND RESULTS

This study evaluated Chinese Hamster Ovary (CHO) cell culture performance and protein production in BIOne. To minimize variability, identical process parameters and equipment were used for both the BIOne system and control (non-disposable bioreactor) during this study. Additionally, normalized titer results were calculated from total protein produced in the BIOne system or the control when culture viability was  $\geq 80\%$ .

#### PROCESS CONTROL

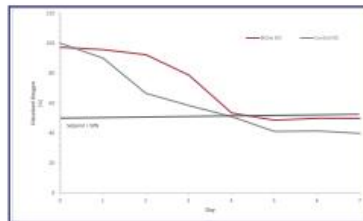


Figure 2. Dissolved Oxygen

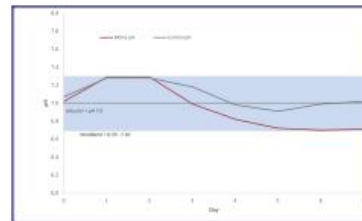


Figure 3. pH

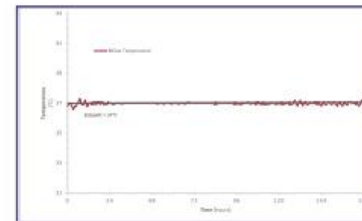


Figure 4. BIOne Temperature

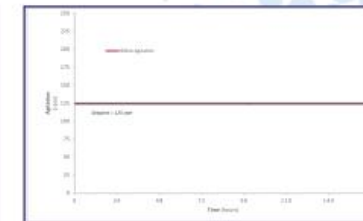


Figure 5. BIOne Agitation

Figures 2 thru 5 - Process control. Similar % dissolved oxygen (%DO) and pH were observed between BIOne and control. BIOne effectively maintained temperature and agitation setpoints. Utilizing BIOne does not affect process control capabilities for the duration of the culture run.

#### GROWTH KINETICS & TITER

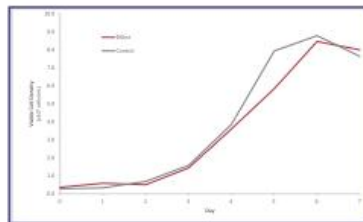


Figure 6. Viable Cell Density

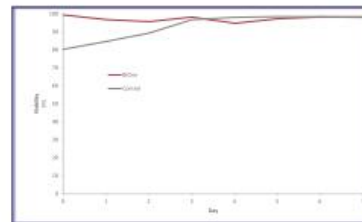


Figure 7. Viability

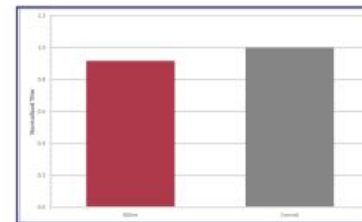


Figure 8. Normalized Titer

Figures 6 thru 8 - CHO growth and protein production. Similar growth profiles and protein production were observed between BIOne and control. Performance results indicate that the BIOne system is a suitable benchtop-scale SUB for CHO growth and protein production.

#### CONCLUSION

1. The BIOne system is a suitable benchtop-scale SUB for mammalian cell growth and recombinant protein production, effectively eliminating the time and costs associated with cleaning and autoclaving non-disposable bioreactor vessels.
2. Utilizing BIOne does not affect process control capabilities (%DO, pH, temperature, and agitation) for the duration of the culture run.
3. Reproducible cell growth profile was achieved in the BIOne system compared to control (non-disposable bioreactor).
4. Similar protein production was observed between the BIOne system and control.

We would like to thank Dr. Sarwat Khattak and her team at BTEC of NC State University for their cell culture data.  
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- Schreiben Sie uns an [info@riggtek.de](mailto:info@riggtek.de)

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*Wir sind für Sie da!*  
Ihr RIGGTEK-Team

