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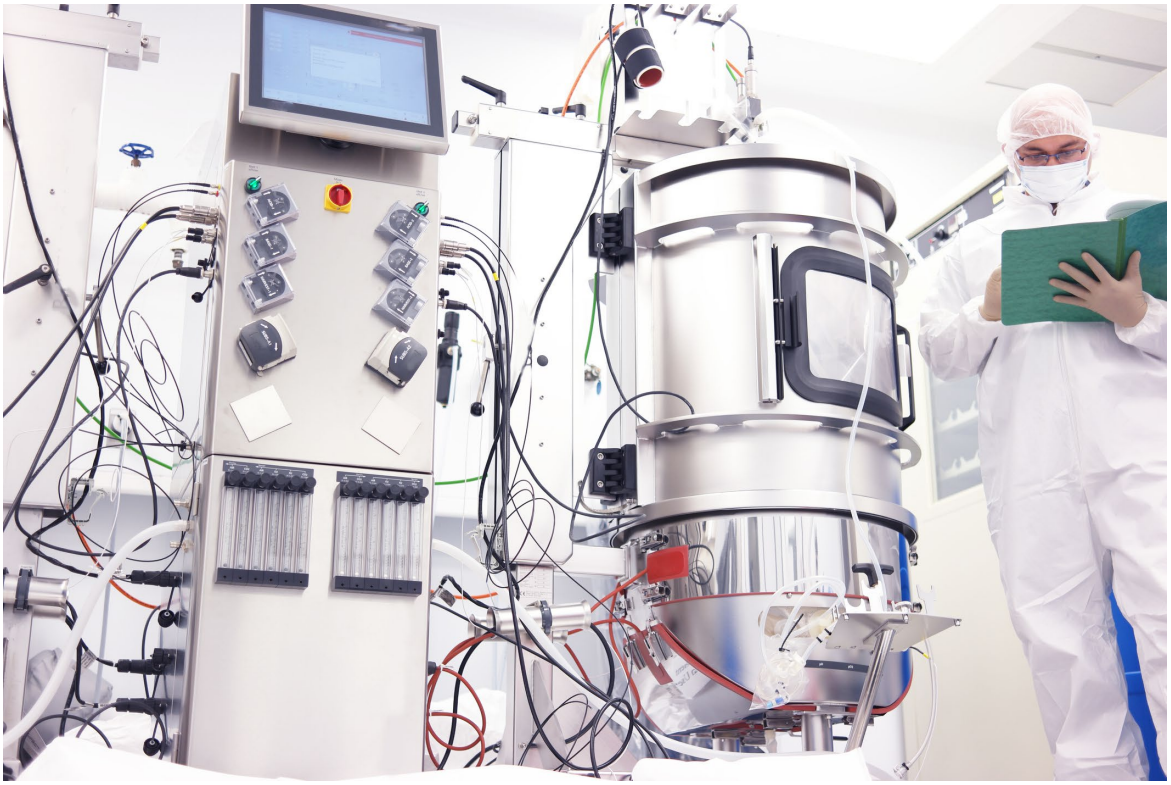
# How Can Biotechnology and Pharmaceutical Industries Better Weather This New Economy?



Biotechnology and pharmaceutical industries continue to experience increased pressure on financial performance due to several factors, including a rise in the cost of raw materials and energy, disruptions in the supply chain, and increasing consumer pressures. The need to improve overall operational efficiencies to lower the bottom line is ever-present.

In this article, Continental Disc Corporation provides insight on how pressure relief devices like rupture discs – non-reclosing safety devices also known as pressure safety discs, burst/bursting discs, or burst diaphragms that in most uses protect a pressure vessel, equipment, or system from over-pressurization or potentially damaging vacuum conditions – can have a significant impact on customer operational efficiencies.

In 2022, the world is working to recover from the COVID-19 pandemic and its after-effects. Mandatory shutdowns, illness, and cautionary restrictions like social distancing have left businesses across the globe struggling to remain open and profitable as they worked through turnover due to a retiring workforce and the Great Resignation movement, disruptions in the supply chain, and sharp inflation.

Biotechnology and pharmaceutical industries are no exception to the perils of this difficult economy as they continue to experience increased pressure on financial performance, especially wherever perfectly hygienic facilities and hermetically sealed antiseptic systems are necessary.

As an industry leader in rupture disc design, innovation, and manufacturing technology, thought leaders at Continental Disc Corporation are asking, *"How can we help our customers in the biotechnology and pharmaceutical industries weather the challenges of this new economy?"*

To address this question, we will explore the need to improve operational efficiencies by increasing productivity, including production uptime, throughput, reduction in waste, and reduction in the cost of ownership, as well as how rupture discs can positively impact a biotechnology or pharmaceutical company's bottom line.

First manufactured in the mid-20th century, a rupture disc is a sacrificial, non-reclosing pressure relief device carefully designed and manufactured to rupture or burst at a predetermined amount of pressure. The active component consists of a one-time-use membrane usually made of a thin metal diaphragm placed in a disc holder, activated to burst by the predetermined set pressure. Rupture discs are used in most applications to protect a pressure vessel, equipment, or system from over-pressurization or potentially damaging vacuum conditions, using either forward-acting (tension loaded) or reverse-acting (compression) technology.

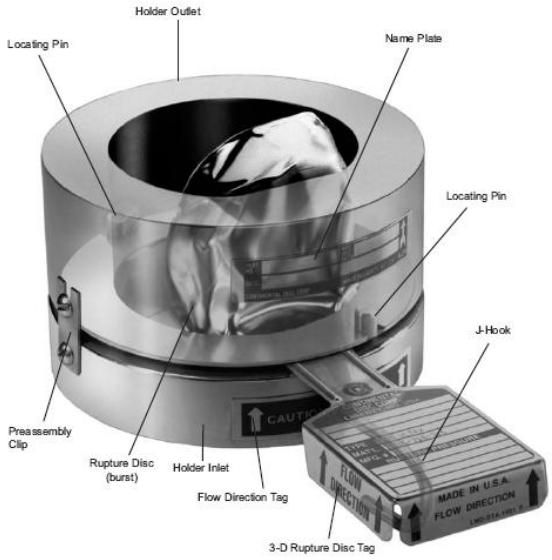



*Figure 1: Diagram of a rupture disc*

Commonly used in biotechnology and pharmaceutical facilities as a single protection device or a secondary relief device for a conventional safety valve, rupture discs provide instant response to an increase or decrease in system pressure, at times within milli- or microseconds, and provide major advantages including leak-tightness, cost, response time, size constraints, and ease of maintenance.

Over time, rupture discs evolved into modified, specialized, or completely custom designs to serve the particular needs of overpressure systems in a multitude of industries, from Aerospace and Aviation to Chemical and Food & Beverage processing to Medical & Healthcare.

Advanced technology resulted in a range of rupture disc designs, and the capability of adding a burst disc indicator (BDI) allowing a facility to instantaneously and reliably be notified the moment a rupture disc bursts. Precision-cut or laser scores were added to precisely weaken the disc at a specific point, as seen on Continental Disc's SANITRX HPX® rupture disc (right), allowing precision performance, greater uptime, and reduction in the cost of ownership. Rupture discs like this can withstand cycles from full vacuum to a high percentage, often up to 80% of its stamped rating. For example, the SANITRX HPX® is capable of withstanding cycles from full vacuum to 95% of its stamped rating.

*Figure 2: Continental Disc Corporation's SANITRX HPX rupture disc*

When properly manufactured and installed on an overpressure protection application, a rupture disc allows customers to drive improvement in operational efficiencies by reducing downtime, lowering maintenance costs, and increasing facility productivity while reliably protecting personnel, equipment, and the environment.

However, rupture discs can be prone to weaknesses. Metal fatigue caused by pressure cycling and operating conditions can spike past the disc's recommended limits, causing the disc to burst at pressures lower than the product's marked burst pressure. Also, as process pressure lowers, the disc material thickness decreases which can lead to a delicate disc material similar to the thinness of tin foil, making it highly prone to damage and generating a higher sensitivity to corrosion. Additionally, rupture discs are notoriously problematic during installation due to their torque-sensitive gasket. When improperly handled or installed incorrectly, rupture discs can be easily damaged, extending operational downtime and increasing the cost of operations.

While ensuring the safety of personnel and equipment, pressure relief devices like rupture discs can have a significant impact – either positive or negative – on consumer efficiencies including the frequency of scheduled and unscheduled process stoppages, elasticity to manufacturing process changes, resilience to process controls issues due to manufacturing process intensification, and the cost of stock required to support operations.

While reverse-acting rupture discs like Continental Disc's SANITRX HPX® are currently utilized in sanitary processes for biotechnology and pharmaceutical facilities to protect against system overpressure, mitigating the risk of unscheduled stoppages and product contamination, many facilities have yet to fully benefit from the latest technological advances.

The number one cause of rupture disc failure is due to mishandling during installation. Accidental denting during transport, misalignment during installation, and improper torquing can alter the intended performance of the disc. Frequent installation problems like inexperience, use of sanitary clamps (not ideal), and limited available space can also lead to damage to the rupture disc, extending maintenance time and cost. Potential detrimental changes in performance or damage caused by vent-side pipework can result in unscheduled stoppages and safety issues. And integral seal deterioration requiring frequent replacement of rupture discs drives up cost.

All of these challenges have remained unaddressed in the biotechnology and pharmaceutical industries until now.

Traditionally, sanitary rupture discs are used in a wide range of sanitary and hygienic applications, and while they can withstand cycles from full vacuum to a high percentage of the stamped rating, they are easily susceptible to damage. Any amount of damage to the disc can result in an increased risk of unscheduled stoppages, product contamination, and increased cost of operations.

Today, a new innovative design is being introduced in the rupture disc market addressing the need to improve process performance, reliability, and safety within the biotechnology and pharmaceutical industries. By incorporating a rupture disc within welded tubular sanitary ferrules, i.e., sanitary ferrules, this new product reduces the risk of damage to the delicate rupture disc and minimizes safety and installation issues, resulting in better system efficiency and performance.

*Figure 3: Rupture disc in welded cartridge*

Additionally, because the rupture disc is contained within a welded housing, the entire product can be removed, inspected, and replaced from a system without disturbing and potentially damaging the disc, offering longevity of service where traditional discs cannot.


*Figure 4: Continental Disc Corporation's IntegrX-HPX™ rupture disc*

For instance, Continental Disc Corporation's model – the IntegrX-HPX™ – combines the SANITRX HPX® rupture disc with an American Society of Mechanical Engineers (ASME) Bioprocessing Equipment (BPE)-compliant crevice-free inlet design to drive durability and performance while mitigating the risk of unscheduled stoppages.

The beauty of this design lies in the coupling of the IntegrX with the HPX platform, providing the advantage of millions of cycles plus ease of installation in a singular, welded ferrule, making it difficult to make contact with and dent the disc.

By removing the need for integral seals between the disc and the system piping, the disc housing reduces the risk of damage during transport and installation, virtually eliminating improper torquing of the holder because the disc is already seated and welded into place. As such, this innovative design requires less maintenance and on-hand stock, therefore offering a positive impact on the cost of ownership.

By utilizing the durability and service life the SANITRX HPX® provides, the IntegrX-HPX™ rupture disc offers a unique opportunity to boost efficiency and safety while driving the cost of ownership down.

Of course, any rupture disc design hoping to be installed in a biotechnology and pharmaceutical facility must operate as part of a hygienic or sanitary system as well as a safety device. Its ability to be cleaned either in place or by dismantling and cleaning on site (also known as in-situ) is paramount to minimizing operational downtime. To verify product cleanliness, this new product design was tested using riboflavin test validation – the benchmark of cleanability test certification. Taking one step further, the IntegrX-HPX™ employs a gas tungsten arc welded (GTAW) design, utilizing argon to eliminate discoloration and ensure product cleanliness, delivering a clean surface perfect for pharmaceutical and biotechnology systems.

Additionally, sanitary rupture disc products must be able to be easily identified in process plants for required maintenance and safety inspections. A rupture disc installed in close quarters or a "clumped" area may obscure the marked product information found on the rupture disc body. Unfortunately, competitor rupture discs do not include an incorporated tag, extending the time needed to locate the product in the system and potentially obscuring the

product information. The integrated tag on the IntegrX-HPX™ not only allows the product to be easily located, supporting operation for ease of inspection and identification with the capability for product details to be marked on the body as well, but assists in installation to ensure correct flow direction.

*Figure 5: Pharmaceutical tanks installed in close quarters.*

Incorporating this new rupture disc design ensures the safety of equipment, throughput, personnel, and environment while virtually eliminating the risk of damage to the rupture disc, providing ease of installation and use in close quarters, and limiting the cost of unscheduled stoppage, effectively driving the cost of ownership down.

Until recently, this welded design had not grown into popularity; while rupture disc manufacturers had previously constructed welded specials products, the idea for the first standard welded product had not come to fruition or been tested.

To date, the industry standard called for the installation of gasketed rupture disc products as a sanitary solution in pharmaceutical and biotechnology applications. Recently, a trend of customers evaluating fully-welded rupture disc assemblies as sanitary solutions created an opportunity for Continental Disc to reference its experience in welded specials products for applications in other industries resulting in a best-in-class product designed and manufactured specifically for the biotechnology and pharmaceutical industries that takes advantage of the best disc in the industry housed in a welded format to ensure certified cleanability, durability, and ease of handling for safer sanitary products.

The challenge: Ensuring this new design is effectively seamless – welded together without gaps or hairline scratches that could allow product buildup or accumulation of spore-forming bacteria and other microbial contaminants, creating an opportunity for microbiome growth that would prevent effective cleaning and have a detrimental effect on the quality of the end product.

To answer this challenge, this new product design is meticulously tested using riboflavin test validation – the benchmark of cleanability test certification – by a leading bioprocess institute to ensure a crevice-free design where the disc meets the inlets ID. Continental Disc also performs additional testing above and beyond the industry benchmark to ensure the product contains no surface-breaking defects.

In the following images, two IntegrX-HPX™ rupture discs were viewed with a microscope to determine if any gaps were present. The difference between a product containing a gap and a crevice-free product can clearly be seen.

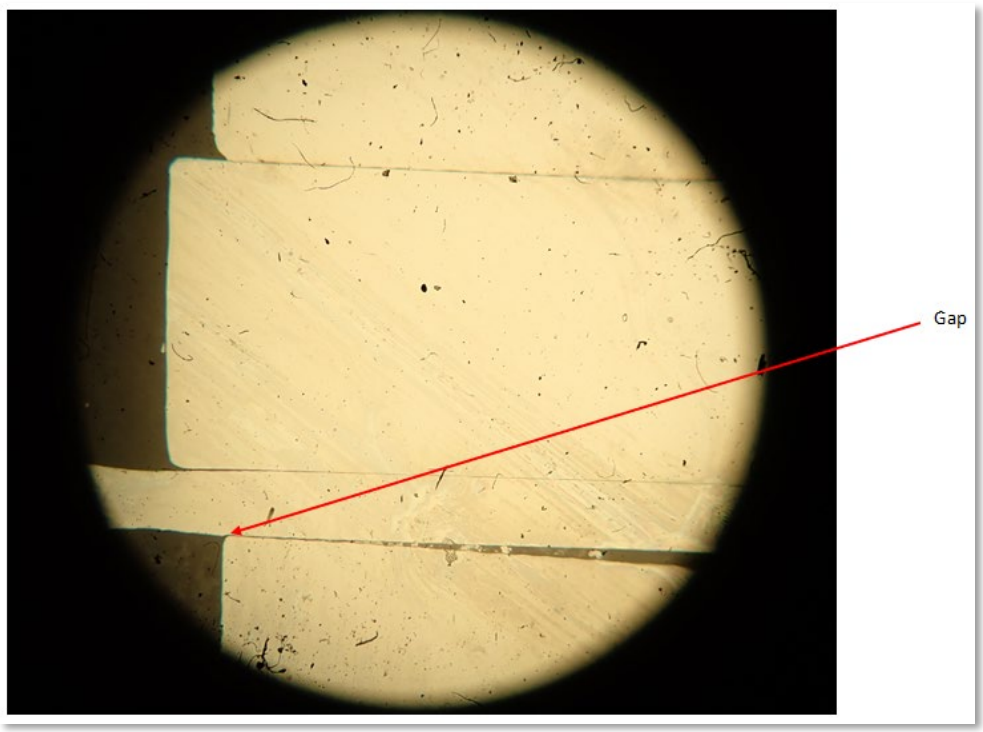



*Figure 6: Microscope image identifying a visible gap between the disc and the inlet sign ID.*

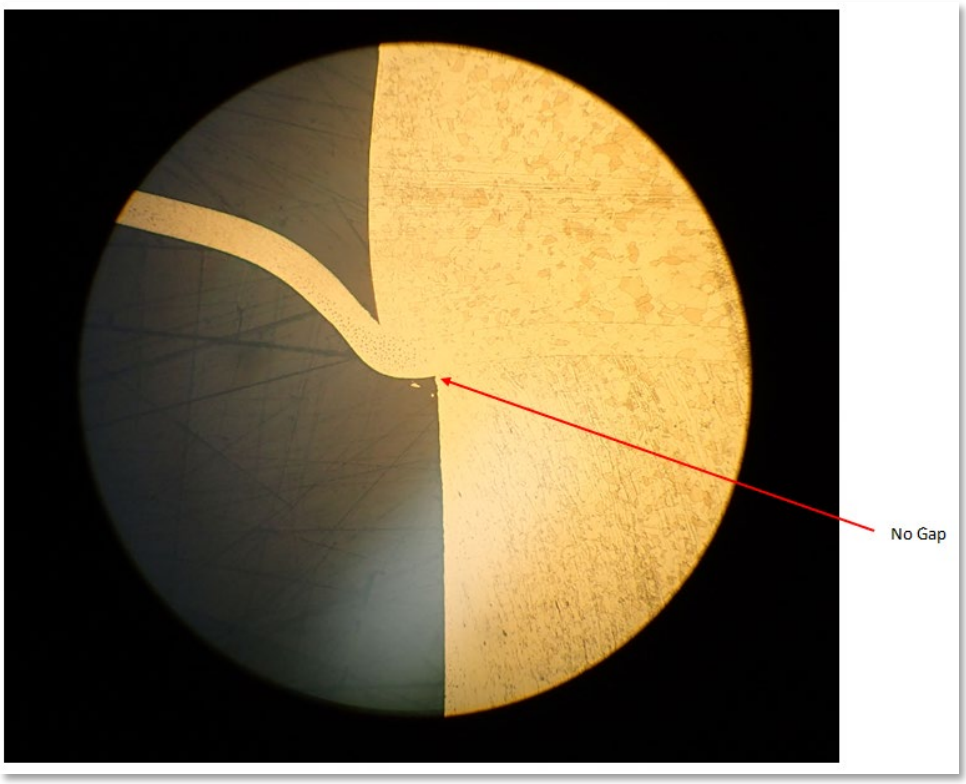



*Figure 7: Microscope image displaying no visible gap between the disc and the inlet sign ID.*

Recently, Continental Disc was able to install the first real-world application for this new product design. Customer X was experiencing high turnover with their maintenance team due to retirement and The Great Resignation movement, creating a challenging environment to keep maintenance teams properly trained. Inexperienced with rupture discs, maintenance employees would unknowingly mishandle the product, resulting in damage to the disc in transport and installation, causing a spike in problematic installations.

Rupture discs are notoriously problematic during installation due to their torque-sensitive gasket. A lack of training, hard-to-reach installations, and inexperience resulted in continued product damage due to mishandling and improper installations, increasing the customer's cost of operations.

In an attempt to resolve the issue, Competitor 1 proposed a new product similar to the IntegrX-HPX™, however, Customer X was aware of the advantages of the SANITRX HPX® and was interested in Continental Disc's ability to propose a product that not only resolved their initial problem but provided the durability of a well-known product. Additionally, Customer X was attracted to the IntegrX-HPX's™ capability to eliminate the risk of damage from transport, mishandling, and installation to the rupture disc due to its welded housing unit design, with the 3D tag to identify the disc's location within process piping, proving to be an added bonus.

While Customer X continued to experience personnel turnover, the IntegrX-HPX™ provided ease of installation, reducing the extent of experience, and therefore cost of new employee training required to successfully transport and install a rupture disc without damage. Continental Disc was able to win the order and provided the IntegrX-HPX™ as a successful patch to virtually eliminate the risk of damage as new employees are trained.

Although the IntegrX-HPX™ is not a truly unique product, it does serve as an advantage in specific situations – perfectly suited for cyclic process conditions from full vacuum to 95% of the stamped rating, thanks to the incorporation of the SANITRX HPX® rupture disc. A best-in-class product designed and manufactured specifically for the biotechnology and pharmaceutical industries, the IntegrX-HPX™ takes advantage of the best rupture disc in the industry housed in a welded format, ensuring certified cleanability, durability, and ease of handling for safer sanitary products while virtually eliminating the risk of damage.


By incorporating the IntegrX-HPX™ into their system, biotechnology and pharmaceutical facilities will not only weather the challenges of this new economy, but ensure the safety of their equipment, end product, personnel, and environment while driving down the cost of ownership.

Interested in ordering one for your biotechnology or pharmaceutical system? We'd love to help. Get in contact with one of our engineers on our website: https://www.contdisc.com/; we'll contact you with more information within one business day.

View the full list of IntegrX-HPX™ technical details, features, options, and specifications here.