

# **CRL**

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## **The Case for Rapid Transfer Ports in Nuclear and Life Science Applications**

*RTPs can be indispensable components in ensuring  
product purity and containment*

*By Rob Weber*

# Introduction

The manufacturers of high-value products in the Nuclear and Life Science industries share two common challenges as these products are moved into and out of cleanrooms, isolation chambers and gloveboxes: 1) ensure that the purity or sterility of these products are not compromised and 2) make certain that any hazardous materials that are used or waste products that are created are handled safely and securely.

Serving as an indispensable aid in meeting and overcoming these challenges are Rapid Transfer Ports (RTPs), which were developed as a way to provide safe, contained transfer of sterile or hazardous materials and waste as they are moved into and out of containment or isolation. One of the world's leading developers and providers of RTP technology is Central Research Laboratories®, Inc., (CRL), Red Wing, MN.



Over the years, CRL has created a full stable of RTP technologies that have been designed around the capabilities of the innovative Double-Door Transfer System, which allows all types of materials to be rapidly transferred into and out of cleanrooms, isolation chambers or gloveboxes without breaking containment. This capability helps ensure product purity, quality and integrity while helping to maintain an expected level of safety for operators.

Let's take a closer look at the ways that CRL RTPs can help optimize product-handling operations in the Nuclear and Life Science industries:

# Nuclear

CRL's roots actually go back to the dawn of the Atomic Age in 1945 when three recent graduates of the Massachusetts Institute of Technology – Frank G. Chesley, Demetrius Jelatis and Gordon M. Lee – pooled their resources and founded CRL. Thanks to their undergraduate experience as researchers for the U.S. War Department, CRL found immediate success as a company that designed radar-testing equipment for use by the various branches of the U.S. armed forces, as well as the U.S. Atomic Energy Commission. The company's first true breakthrough in this realm came in 1953 with the development of the Model 8 Telem manipulator, which was a safer method of handling radioactive materials.



Fast forward 44 years to 1997, when CRL introduced its first RTP model, which consisted of two main components: a stationary Alpha flange mounted to the wall of a contained environment, and the Beta assembly, a mobile container, bag or other process component that is attached to the Alpha flange. Both the Alpha flange and Beta assembly consist of a door (hence, the “double-door” designation), seal and interlock function.

The design of the RTP dictates that when the Alpha flange and Beta assembly are mated, the interlock helps protect against either of their doors accidentally opening. The doors will also not be allowed to open if the two assemblies are incorrectly docked. Specifically, the interlocks are incorporated into the flange on the Alpha assembly from where they interface with the door handle. This prevents the port door from being opened when a Beta assembly is not present; keeps the Beta assembly from being removed from the Alpha flange when the port door is open; and prevents the port-door handle from being rotated when the door is open.

The RTP has proven to be a godsend for operators in the Nuclear field who needed to optimize performance in two critical applications:

- **Research & Development (R&D)/Demolition & Decontamination (D&D):** Developing new nuclear-based products involves a great deal of R&D work, much of which requires experimentation with and handling of hazardous components, many of which cannot be allowed to come into direct contact with human beings. In this case, the capabilities of RTPs to allow the transfer of these products with no loss of containment is critical in ensuring that a fail-safe work environment is created.

D&D activities, which commonly take place at decommissioned nuclear power plants, quite often involve the removal of hazardous and radioactive materials. In all instances, processes must be put into the place that help ensure adequate protection of technicians, the public and the surrounding environment. In sum, D&D presents unique challenges for operators that must be addressed and overcome from a safety, environmental and technological standpoint. In these instances, RTPs can be an invaluable component in ensuring that all regulatory and operational requirements are met to the satisfaction of all parties involved.

- **Material Transfer:** Transferring hazardous materials in any application requires extreme protection, with all materials needing to be safely contained during transfer and storage. RTPs possess the operational capabilities to minimize the risk of contamination during all stages of hazardous-material transfer.

## Life Science

Building and maintaining a safe and secure work environment is a top-of-mind concern for all operators within the Life Science industry. This requires the creation and maintenance of highly reliable isolated environments that can protect against product contamination and exposure to potentially hazardous or dangerous materials.

Three operational areas within the Life Science realm are ideal for the use of RTPs:

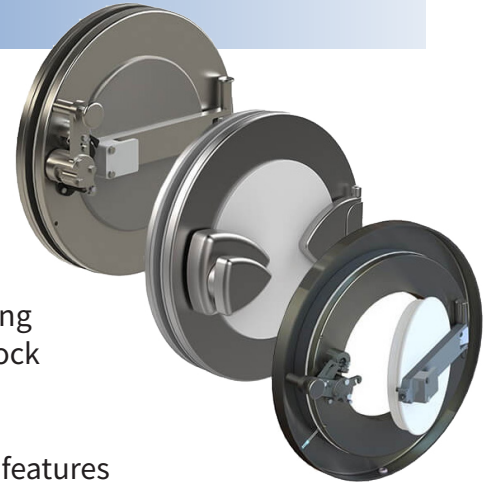
**Aseptic Manufacturing:** Keeping products free from contaminants is Job No. 1 in any aseptic-manufacturing process. From sterile Active Pharmaceutical Ingredient (API) production and product formulation to the transfer of sterile liquids/components and aseptic-filling processes, sterility must be maintained at every stage with no chance that outside contaminants can infiltrate the production process.

**Potent Manufacturing:** Ensuring product containment is essential when working with toxic materials, not only for the operator, but for the surrounding environment. Therefore, RTPs can play a significant role in keeping contaminants at bay during such high-value applications as High Potency Active Pharmaceutical Ingredient (HPAPI) production, the development of Potent Oral Solid Dose (POSD) pharmaceuticals, and the packaging and transport of finished APIs and POSDs.

**Aseptic/Potent Manufacturing:** This category combines the requirements of Aseptic and Potent manufacturing, with special emphasis placed on the production of Sterile High Potency Active Pharmaceutical Ingredients (SHAPI), biologics, radiopharmaceuticals and highly concentrated formulations. Again, RTPs can play a leading role in transferring these substances into and out of isolation safely through the prevention of exposure to toxic, hazardous or dangerous materials.

# Taking A Closer Look

Like all CRL innovations, over the years the company's RTPs have evolved through the diligent work of a design and engineering team that is constantly looking for ways to improve product performance. This innovative mindset has revealed itself again with CRL's recent introduction of the new E Rapid Transfer Port, or E RTP (see sidebar), which promises to make RTP operation easier than ever while maintaining the same product purity and containment capabilities that are the bedrock of Nuclear and Life Science production processes.



All RTP models feature the Double Door Transfer System, but additional features have been developed over the years that give the technology more flexibility, including:

- Handle designs that utilize minimal rotation to break the seal on the Beta container, which simplifies operation while still maintaining a high safety level
- A streamlined interlock system with interchangeable three-bayonet and four-bayonet Beta mount inserts that can be replaced without breaking containment
- Standard 316L stainless-steel body construction with three port-door options:



Stainless steel for use in strong chemical/radiation and some aseptic applications

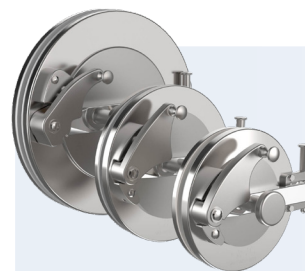


Polypropylene for use in pharmaceutical, chemical and nuclear applications



Liquid-transfer for use in sterile filling-line and fluid-transfer applications

- The elimination of pinch points on the handle, which minimizes glove damage
- The elimination of exposed fasteners that creates a smoother surface that enables easier cleaning
- Compatibility with various Beta assembly options



## A New Member Of The Family

Building on its legacy as a leading provider of Rapid Transfer Ports (RTPs) for use in critical Life Science and Nuclear applications where maintaining

cleanliness, product purity and product containment are front-of-mind concerns, CRL is pleased and proud to announce a new addition to its RTP family: the E Rapid Transfer Port, or E RTP.

The E RTP features the same standard-setting Double-Door Transfer System technology as CRL's other industry-leading RTP models, but takes their performance to a new level of efficiency, reliability, safety and ease of operation through the addition of the following enhanced features:

- An access door that can be unlatched and opened with one hand
- A 45-degree handle-turn radius that frees up valuable space inside the isolator
- Fewer moving parts for fewer maintenance concerns
- Standardized sizes for compatibility with most common beta-flange systems, including retrofits
- Easy to clean and maintain

This combination of field-proven performance and exciting new features promise to help make CRL's new E RTP a first-choice RTP technology for use in critical Life Science and Nuclear applications.

Before the introduction of the new ERTTP, CRL had already created two different iterations of its original RTP model that incorporate some, if not all, of these advanced features: the Sterile Liquid Transfer Port (SLTP) and the Sterilizable Rapid Transfer Port (SRTTP). Let's take a closer look at them:

**Sterile Liquid Transfer Port (SLTP):** The patent-pending SLTP, which builds off the proven CRTTP technology and is a component within CRL's Sterile Liquid Transfer System, helps enable efficient, safe and contamination-free transfer of aseptic liquids from sterile product devices through a barrier wall and into a cleanroom or isolator during pharmaceutical manufacturing. This design helps the SLTP satisfy Ring of Concern challenges where the Alpha door and Beta assembly meet, which is an area that is constantly at risk of becoming contaminated. The SLTP overcomes this challenge through its ability to allow the sealing surfaces to be heat sterilized.



Other advanced features and benefits of the SLTP include:

- A standard Steam In Place (SIP) cleaning process with a dedicated docking plate that enables proper Beta flange placement during sterilization activities
- Polypropylene or stainless-steel protective collar at the Ring of Concern
- An Alpha flange equipped with mechanical interlocks that help prevent improper port operation
- A product connection tube with inner surfaces polished to 15 microns and sloped to aid in drainage
- An extended polypropylene or stainless-steel Alpha port door that accommodates longer product-connection tubes
- A single- or multi-connection Beta flange with a condensate-drain connection
- Alpha and Beta flange body construction of 316L stainless steel
- Silicone gasket seals
- Tri-clover fittings on product tubes for reusable, validateable and rapid aseptic-hose connection and disconnection
- Testing and approval for use at hydrostatic pressures up to 3.4 bar (50 psi)

**Sterilizable Rapid Transfer Port (SRTP):** The SRTP offers CRL's traditional Double-Door Transfer System design and enhances it by featuring patented dry-heat sterilization technology. Unlike conventional UV-sterilization techniques, CRL's dry-heat sterilization process eliminates concerns associated with contaminated seals that may result from inconsistent aseptic wiping or the shadowing and stacking of aseptic components. This makes SRTPs ideal for the transfer of components that require high sterility-assurance levels, such as stoppers, vials and caps, into a sterile isolator or aseptic barrier system. This high sterility is achieved through the installation of an electric heater in the Alpha flange at the intersection of the seals.



This critical high-temperature zone is heated to 375°F (190°C) for a predetermined length of time after the Alpha and Beta flanges have been docked. Independent tests have shown that this dry-heat sterilization technique can result in up to a 6-log microbial reduction level at the sealing surfaces of the SRTP.

Other advanced features of the SRTP include:

- 316L stainless-steel Alpha flange with polypropylene or stainless-steel door
- Polypropylene or stainless-steel protective collar at the Ring of Concern
- Silicone gasket seals
- Automated port-door functions
- Automated protective collar
- Molded medical-grade polymer Beta flange with various bag materials
- Automated loader system for Alpha/Beta flange decking

CRL offers all of its RTPs in 105-, 190-, 270- and 350-mm sizes, with the measurement corresponding to the diameter of the Alpha/Beta assembly's opening. Those sizes are also compatible with the various ancillary components that are available, with the exception of Single-Use Beta Bags, which are currently only available in a 190-mm configuration.

# The Team Behind The Team

CRL has also always put great effort into building a Customer Service Department that is easy to navigate and offers personalized service. This capability has grown in importance in recent years as global industrial markets have felt the sting of compromised supply chains. CRL is able to cope with any supply-chain disruptions better than some others because it is a company with a worldwide footprint that features distribution partners in the United States, Canada, United Kingdom, France, Italy, India, Japan and South Korea. This network gives CRL access to resources in all corners of the globe that can help limit the negative effects of the recent supply-chain situation.

Additionally, CRL's status as a smaller company within the world of remote handling and product transfer makes it nimbler than many of its competitors. This enables the creation and use of a premier customer-service operation that has been built to meet the needs of a global client base in a timely and cost-effective way with an ironclad commitment to providing personalized service, optimized lead times and none of the "hurry up and wait" that can be inherent in larger operations.

## Conclusion

The Nuclear and Life Science industries have always been – and will continue to remain – critical ones in the global marketplace. Operators in these industries can only find true success, however, if they are able to safely and efficiently produce products that meet all standards for purity and consistency. Helping to achieve this goal are CRL Rapid Transfer Ports, which have proven for the past quarter-century to be reliable companions for those journeying through the Nuclear and Life Science industries. These RTPs have proven to provide flexibility and reliability in these critical applications as they help maintain sterile and contamination-free Nuclear and Life Science workplaces around the globe.

### About The Author:

Rob Weber is the Manager of Products & Proposals for Central Research Laboratories® (CRL), Red Wing, MN, USA, which is a DESTACO company. He can be reached at [rweber@destaco.com](mailto:rweber@destaco.com). CRL possesses more than 75 years of innovation experience in the development of remote-handling systems, including Telemanipulators, Transfer Systems, Glove Ports and Waste Drum Transfer Systems. CRL's industry-leading technology helps its customers safely and efficiently handle hazardous and sterile materials in Nuclear and Life Science applications around the world.



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*DESTACO, a Dover company, is a global leader in the design and manufacture of high-performance automation, workholding and remote-handling solutions. The company serves customers in a variety of end markets, including the automotive, life science, consumer packaged goods, aerospace, industrial and nuclear sectors. DESTACO is based in Auburn Hills, Michigan, U.S.A. The company has more than 800 employees with 13 locations, in 9 countries, across the Americas, Europe and Asia.*

*More information is available at [crlsolutions.com](http://crlsolutions.com).*