

NR Technology  
Dynamic Design Pharma, Inc.

US Patent 6,655,759

# Summary - NR Technology

1. NRC Canister
2. Alpha NRF System
3. NR-HP Flange

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## 350 NRC Aluminum Canister

## NRC Canister Description

The Non-Rotating Canister (NRC) is a RTP canister system that features a proprietary beta flange that, by means of a custom bearing system and seal, is free to rotate in relationship to the canister.

The NRC beta flange is designed to interface with industry standard RTP ports, including La Calhene's DPTE. It attaches to the canister by means of a circular static seal and locking hardware.

The NRC canister, in one of its forms, is a spun aluminum canister with an internal shuttle mechanism designed to hold a parts tray. It also features lifting handles and self supporting devices that permit hands free docking of the NRC onto the RTP port.

The non-rotating feature of the beta flange yields the benefit of total versatility in the design of the NRC canister body. It can be manufactured in many different shapes, sizes and materials as required by the application at hand.

## NRC Canister Features

- Aluminum or stainless steel beta flange
- Proprietary bearing and dynamic seal system that permit rotation of the beta flange in relation to the canister body.
- Standard or custom designed canister body, as required by the application.
- Self support devices that permit docking the NRC to the Alpha port without having to support the weight of the canister.
- Interface features to the transport and lift system manufactured by Dynamic Design Pharma. A totally safe method of handling the potentially heavy canisters in the manufacturing facility.
- Internal shuttle mechanism that serves the function of safely attaching a tray to the NRC canister body, ideal for safe handling of heavy machine parts in and out of isolator systems. The shuttle permit pulling the tray out of the NRC for easy reach of the components housed internally.
- Internal tray, custom designed to the application or in its standard form. Attaches to the shuttle without tools and permits safe handling of components.

## NRC Canister Specification

- Nominal beta flange size: 190mm, 270mm, 350mm and 460mm
- Length of standard canister body: as required by the application
- Material: 6061-T6 aluminum alloy or 304 stainless steel
- Shuttle stroke from retracted to extended position: As required by the application
- Leak tightness: Capable of passing ammonia leak test when pressurized to 250 pascal internal pressure.
- Interface with standard La Calhene DPTE Rapid Transfer Ports.
- The NRC is compatible with steam sterilization and VHP gas decontamination.

## NRC Canister - Advantages over existing technology

The NRC's beta flange permits applications that are impossible to implement with today's RTP canister technology.

- The shuttle and tray hardware permit the safe transfer of heavy or delicate parts into and out of isolator system.
- The canister body does not rotate. As a result, it features handling features and self supporting devices that make its transport and docking safe for the operator.
- Interface to a transport system permits handling and docking of the NRC Canister without requiring any lifting by the operator.
- The NRC's beta flange permits the customization of the canister body to the application. For example a motorized shuttle system or an air mixing module for VHP gas distribution.

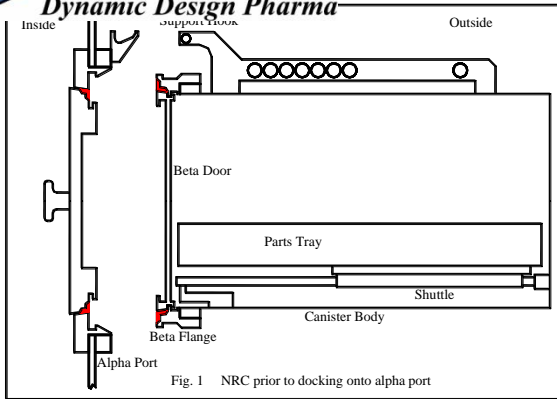


## NRC Canister Applications

Following are examples of application that benefit the most from the NRC's features.

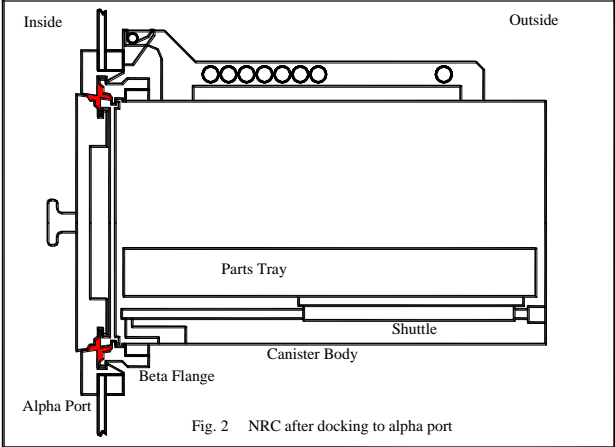
- Sterile machine parts transfer into the isolator system during the Change Over process between production lots.
- Sterile machine parts introduction and removal during campaign style production.
- Production supplies introduction such as micro supplies, environmental monitoring supplies, sanitization supplies.
- Continuous material flow such as stoppers or powder introduction and rejects removal.
- Air mixing fan module for application where additional air mixing is necessary to achieve proper VHP gas distribution.

# NRC Canister Docking Sequence



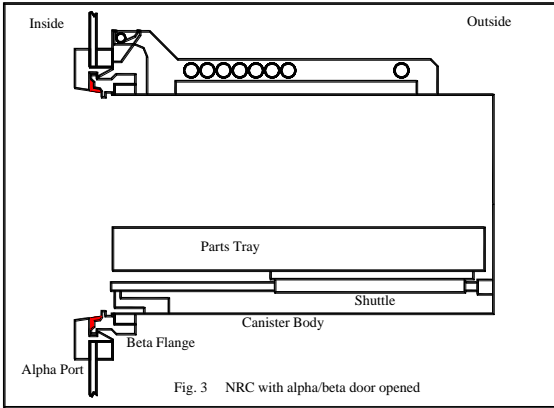
**NRC ready to dock onto RTP port**

- The NRC is moved into proximity to the alpha flange.
- The support hook engages the mating cradle of the RTP port.
- The operator does not have to support the NRC's weight during docking.



**NRC is docked to the RTP port**

- Once the alpha and beta flanges are placed into contact with each other, the beta flange is rotated to complete the docking process while the canister body does not rotate, permitting the internal components to remain stationary.

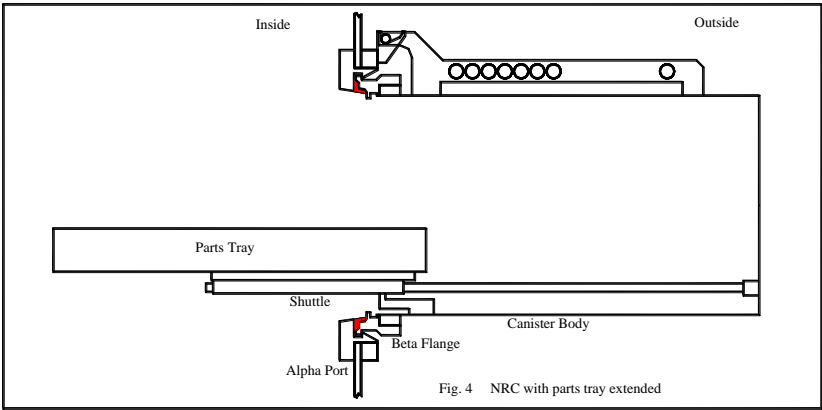


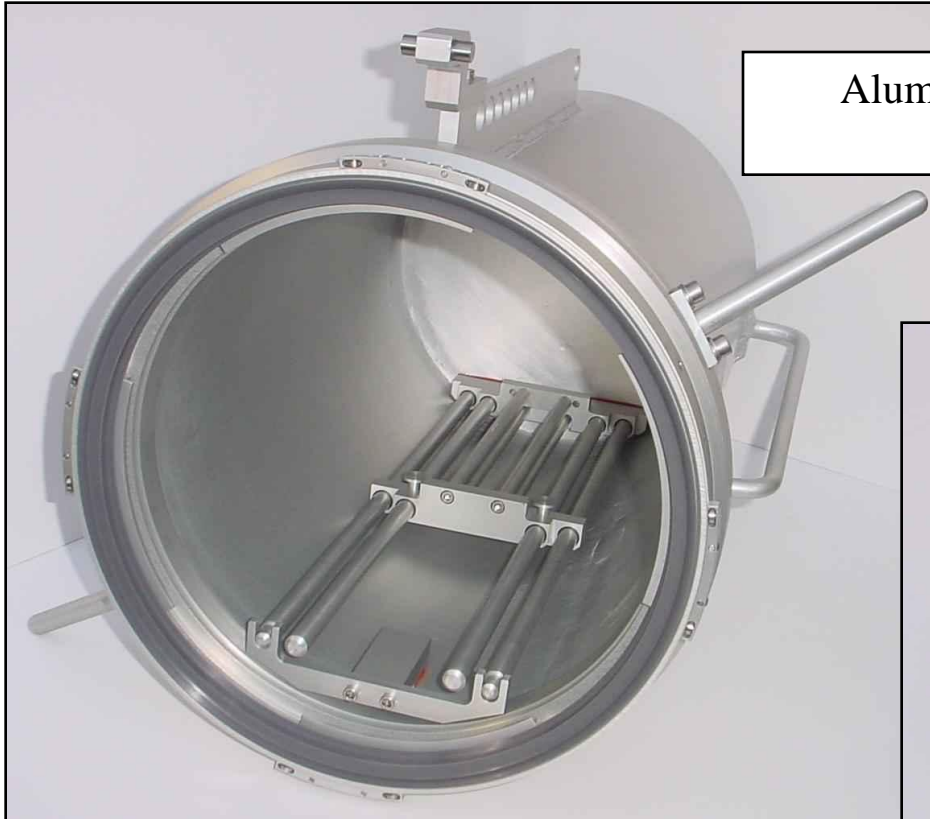
**Alpha/beta door is opened**

- Once the docking process is completed, the alpha door is opened from inside the isolator.
- The beta door is attached to the alpha door as it is swung into the isolator.
- The operator has access to the internal volume of the NRC.

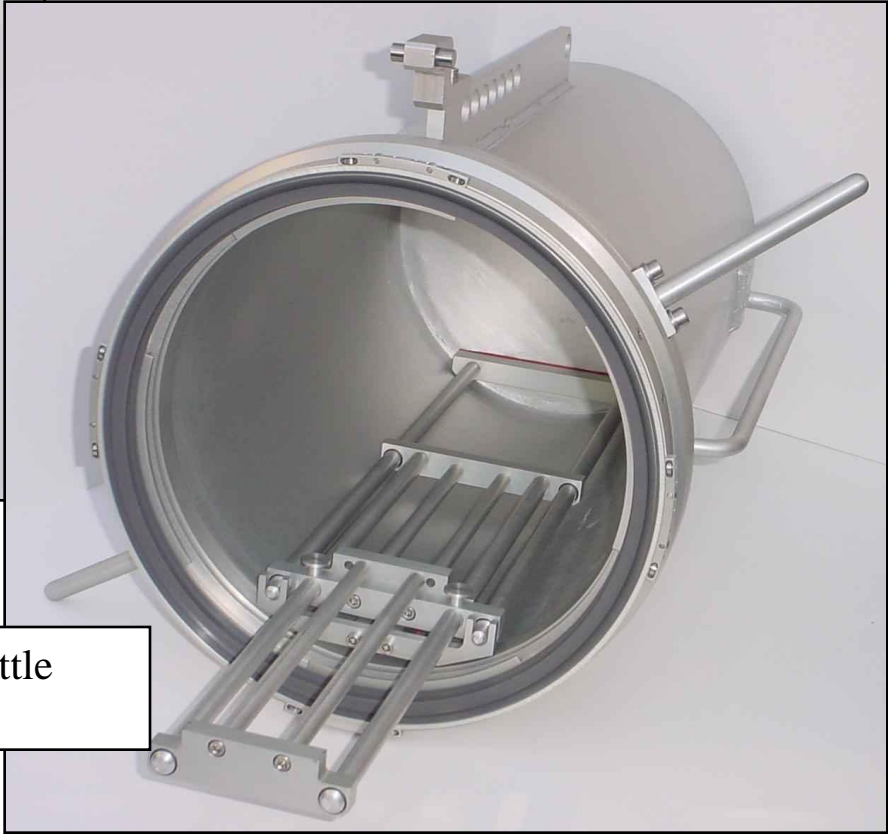
**Access to components inside**

- The components tray is pulled out of the NRC body, it is supported at all times by the NRC's internal shuttle.
- The operator has safe access to the parts held in the tray.





Aluminum 350 NRC - Beta door removed - Shuttle mechanism retracted

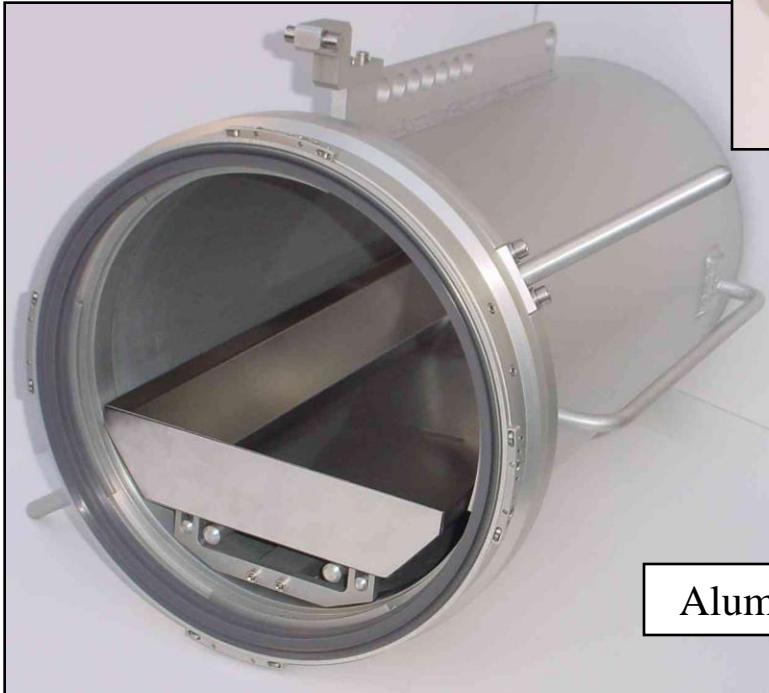


Aluminum 350 NRC - Beta door removed - Shuttle mechanism extended

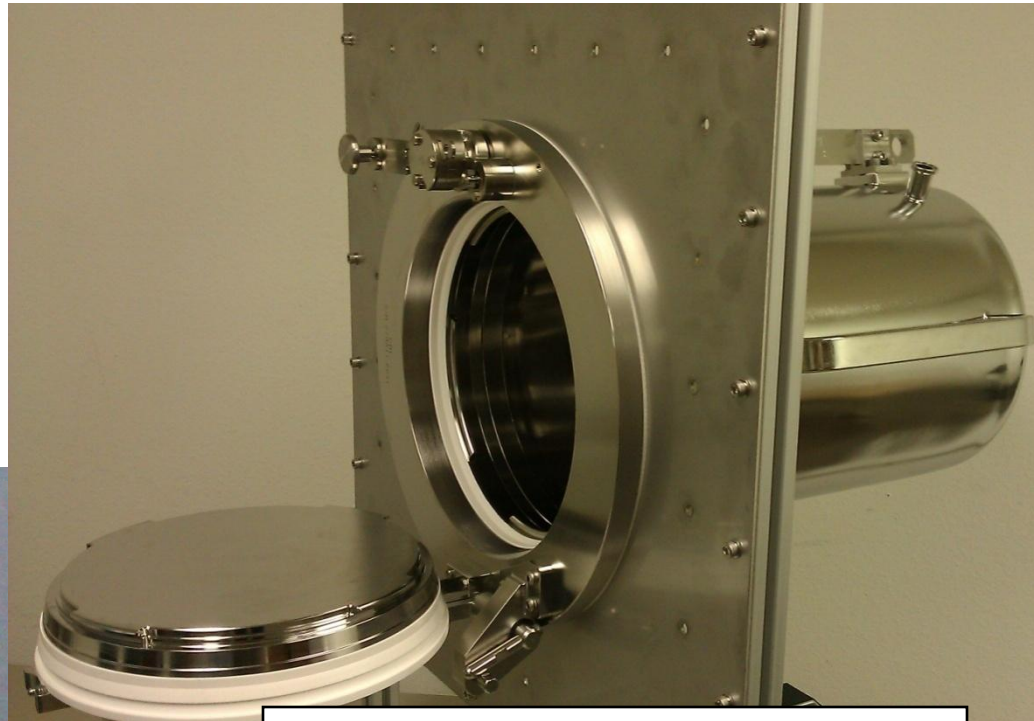
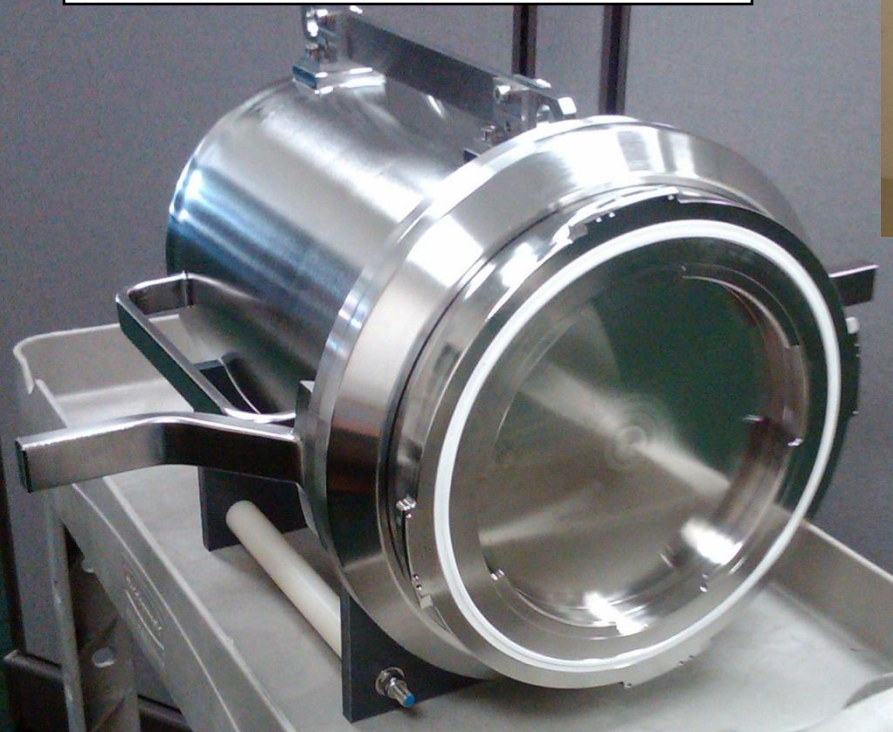
Aluminum 350 NRC – Tray extended – internal parts access



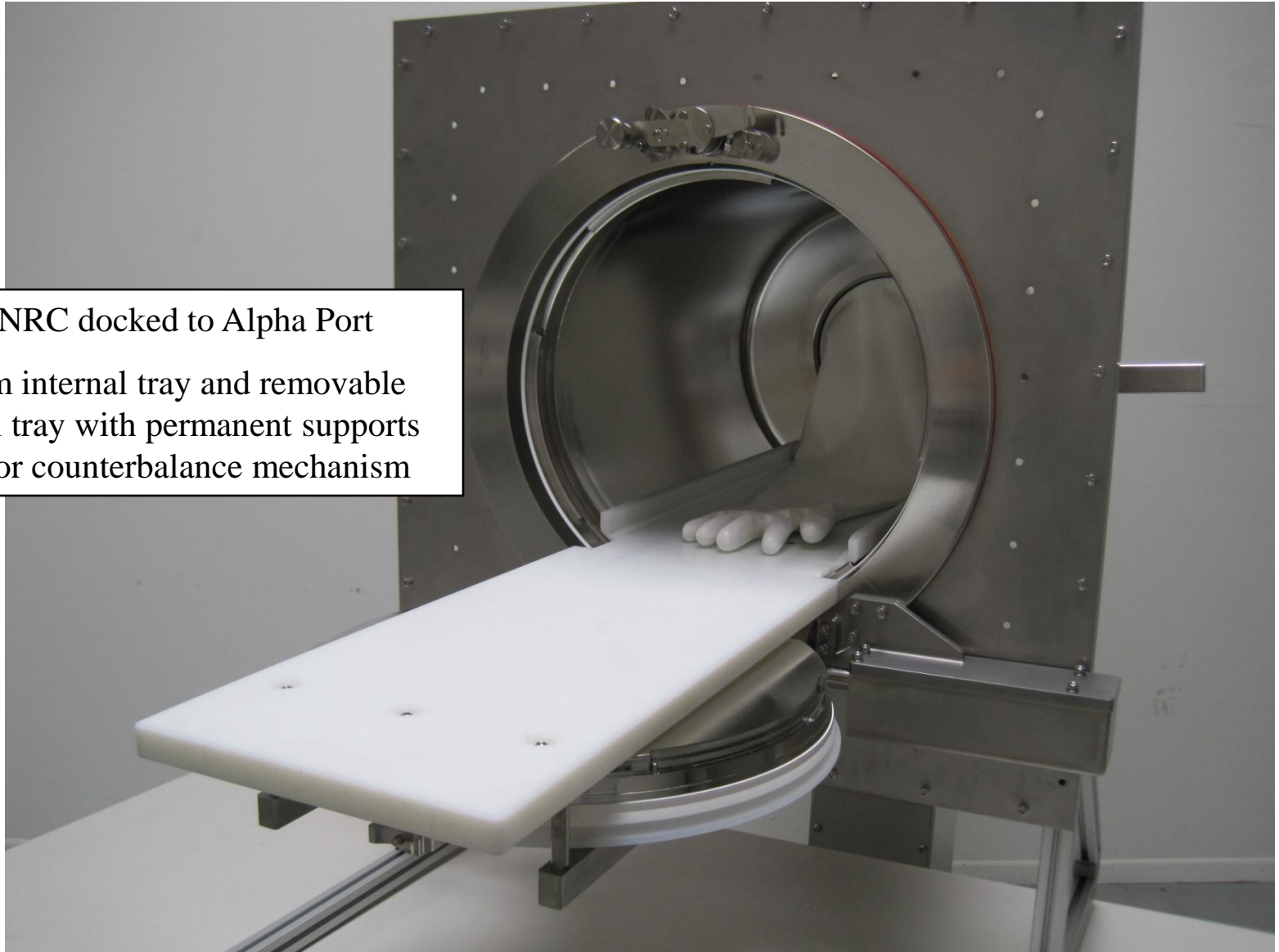
Aluminum 350 NRC - Beta door removed – Tray retracted



Stainless Steel 270 NRC Canister



Stainless Steel 270 NRC Canister  
docked to Alpha Flange

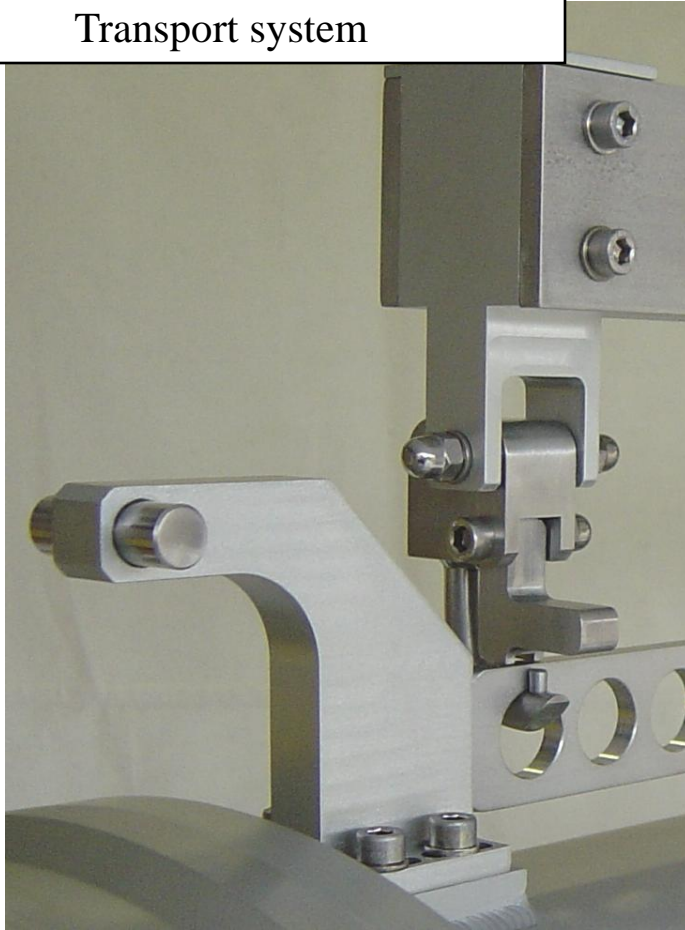


460 NRC docked to Alpha Port

Custom internal tray and removable external tray with permanent supports and door counterbalance mechanism

NRC – Supported by Lift Transport system

Detail – NRC interface with Lift Transport system

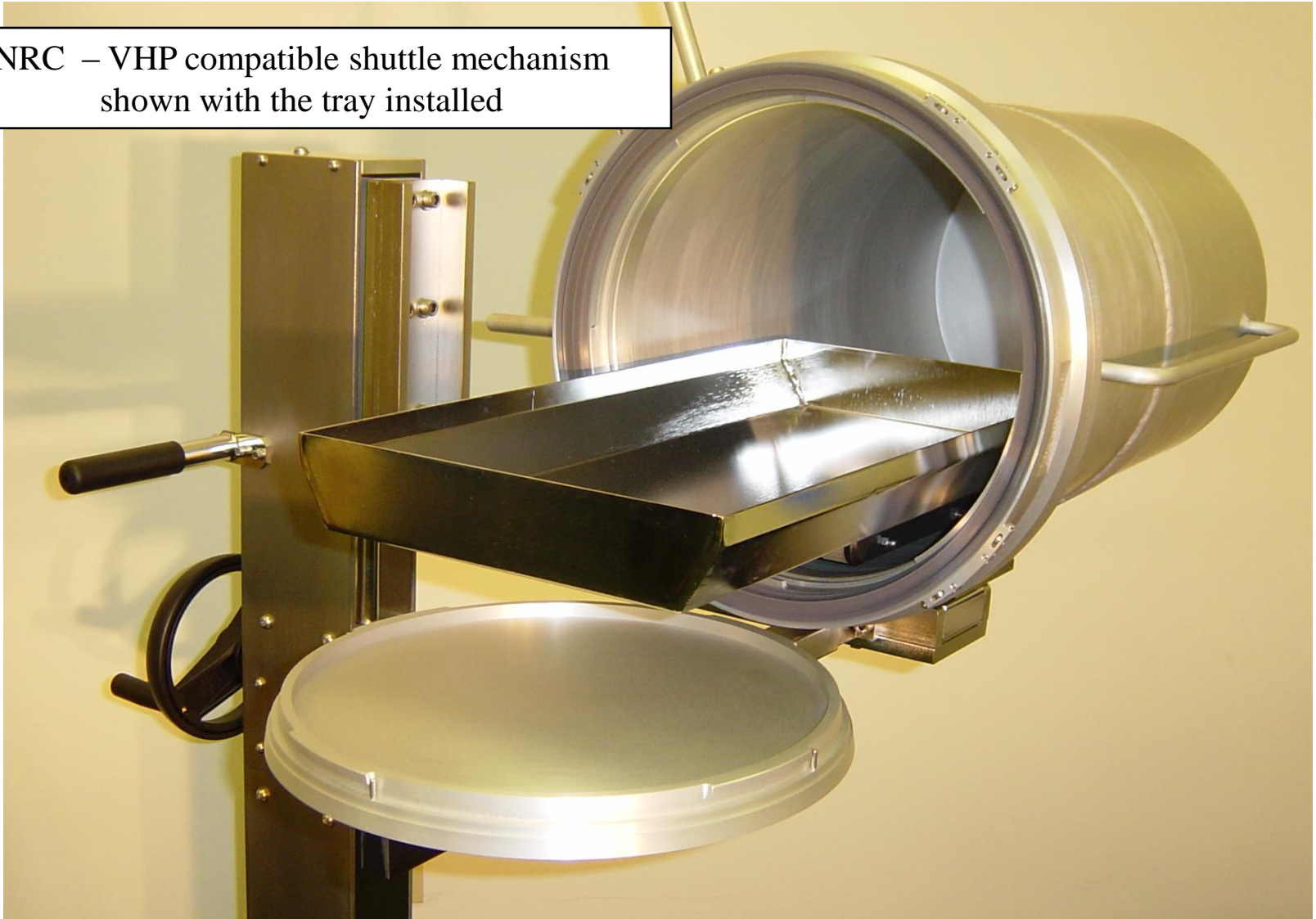


NRC – VHP compatible shuttle mechanism shown with tray removed





NRC – VHP compatible shuttle mechanism  
shown with the tray installed



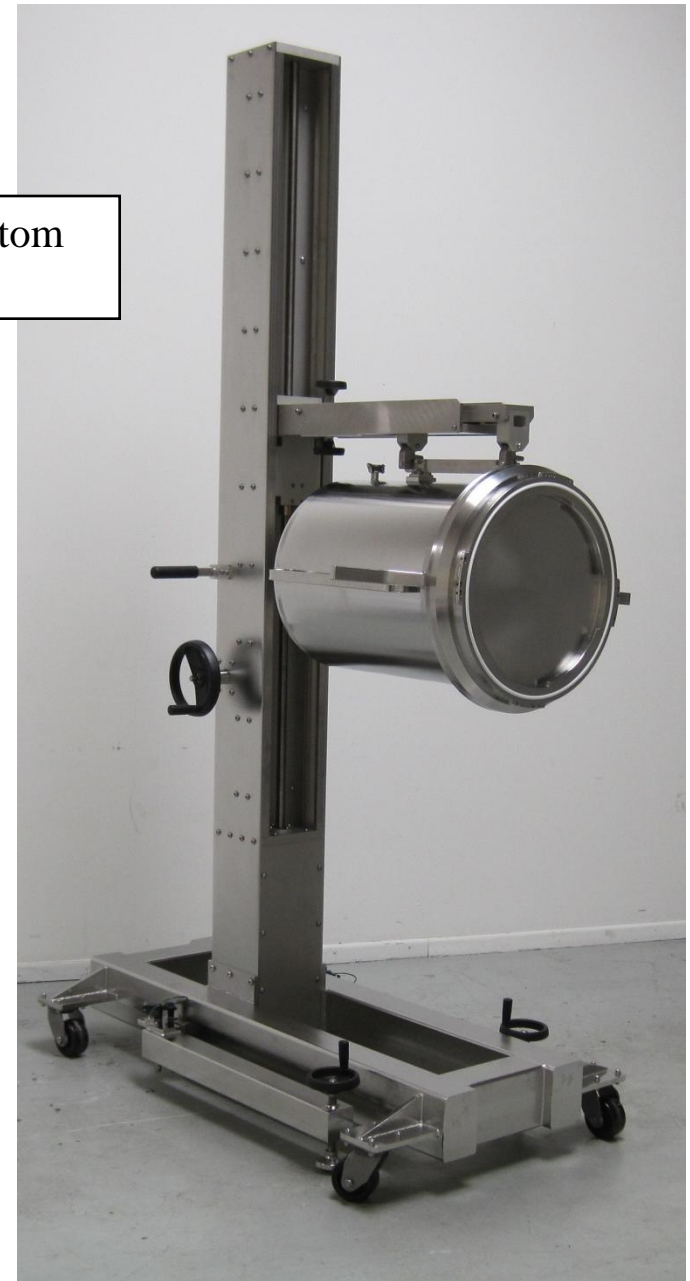
NRC – Supported by Lift/Transport system.

NRC on a swivel mount for a custom  
material handling application



460 NRC Supported by custom  
Lift/Transport system.

Telescoping horizontal beam for effortless  
docking process of 460 NRC canister



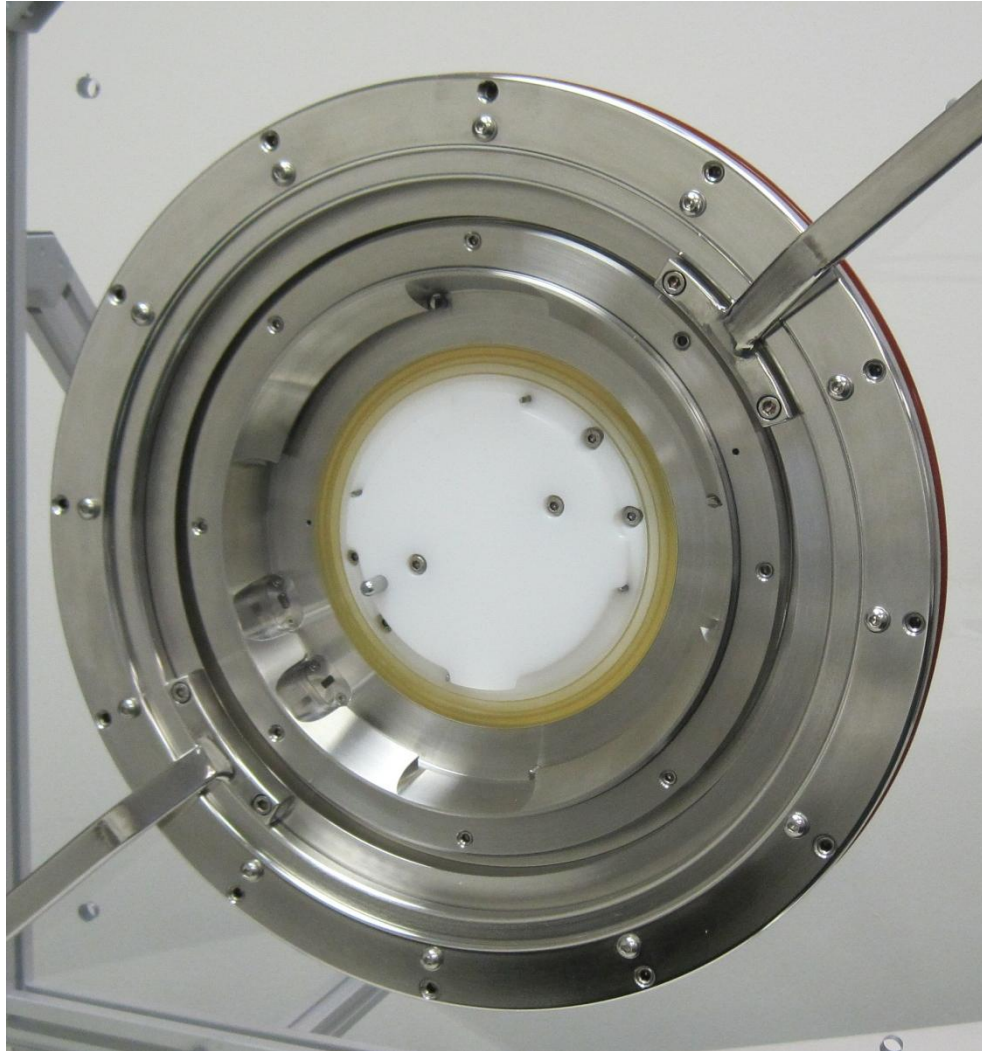
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3. NR-HP Flange

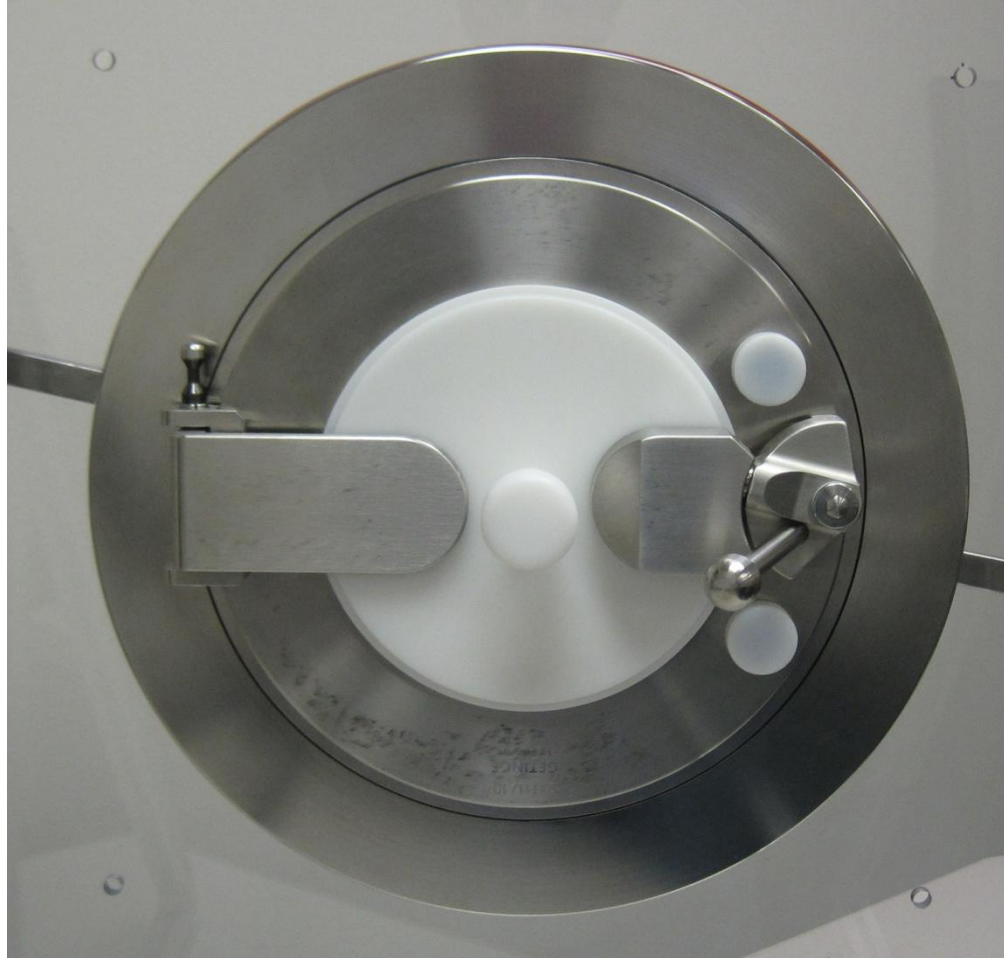
## Alpha NR Description

The Alpha NR flange is a standard alpha port with an added NR technology flange that permits the alpha rotation during the docking process.

The Alpha NR flange, by means of a custom bearing system and seal, permits the alpha port to rotate while maintaining a tight seal against the isolator wall. This rotation allows docking the beta flange without its rotation.



190 Alpha NR – Non-Sterile Side



190 Alpha NR – Sterile side

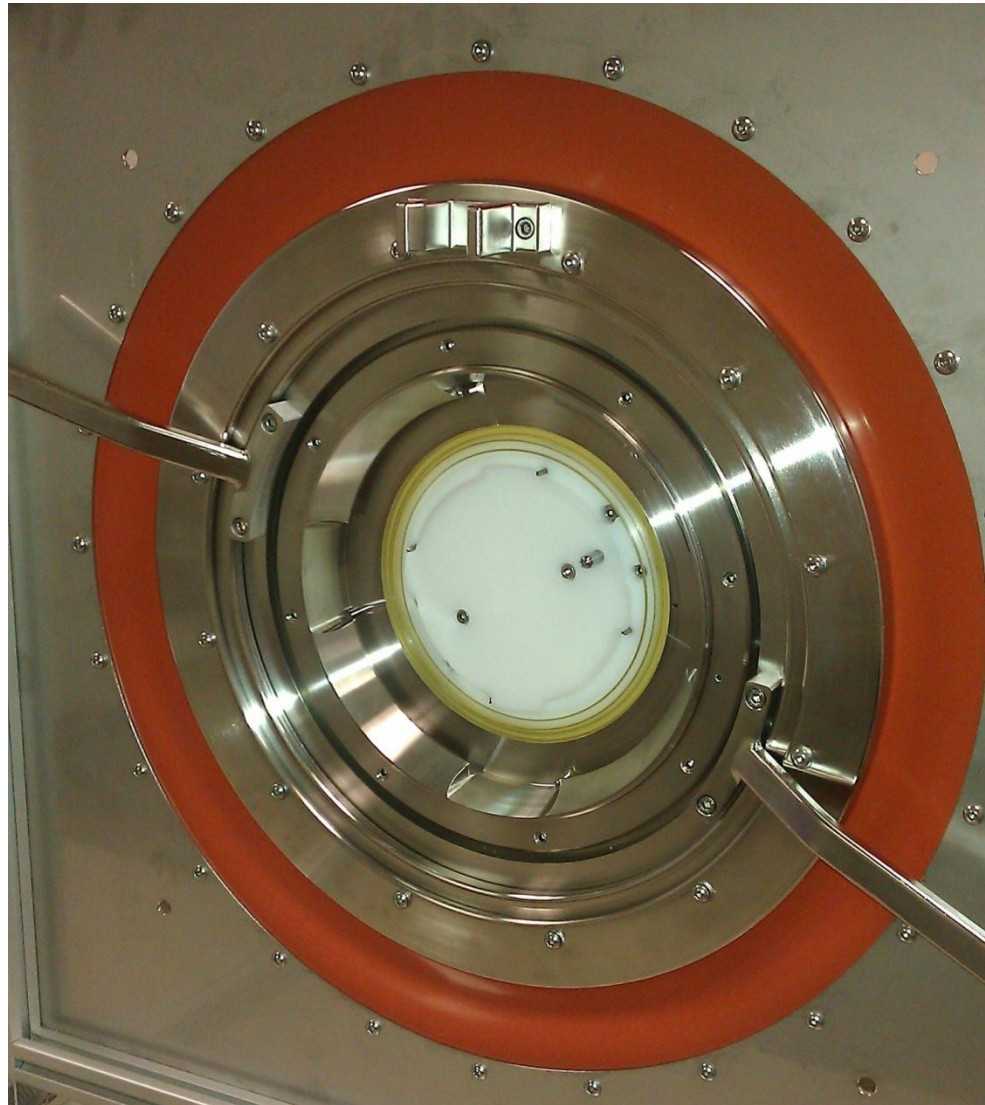
## Alpha NRF Description

The Alpha NRF flange is a standard alpha port with an added NR technology flange that permits the alpha rotation during the docking process.

The Alpha NRF flange, by means of a custom bearing system and seal, permits the alpha port to rotate while maintaining a tight seal against the isolator wall. This rotation allows docking the beta flange without its rotation.

The Alpha NRF flange is similar to the Alpha NR flange except for the added silicone floating diaphragm that permits easy alignment of the flange to fixed system such as a stopper tank or a transfer isolator





## 190 Alpha NRF – Non-Sterile Side



190 Alpha NRF – Sterile Side

## Alpha NR and NRF Features

- Bearing and dynamic seal system that permit rotation of alpha flange in relation to the canister body.
- Turning handles with resulting low turning force
- Floating mount to compensate for misalignment between the alpha and the beta flanges during docking process (Alpha NRF only).
- Interface with standard La Calhene DPTE ports.
- Anti-rotation adapter that engages the beta being docked, as required by the application, to aid the docking process

## Alpha NR and NRF Specification

- Nominal beta flange size: 190mm
- Float at isolator mount (Alpha NRF only): +/- 10.0 mm
- Material: 316L stainless steel
- Leak tightness: Capable of passing ammonia leak test when pressurized to 250 pascal internal pressure
- Interface with standard La Calhene DPTE Rapid Transfer Port
- VHP gas decontamination compatible

## Alpha NR and NRF Applications

- Sterile stoppers transfer into the isolator system from the sterilizing tank. Typically, the sterilization tanks are too bulky to be rotated. The Alpha NRF system permits docking such systems without requiring their rotation
- Docking between two isolators, one having the Alpha NRF system (alpha side) and one having a standard, hard mounted, beta flange.

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## 190 NR-HP Beta Flange Description

The 190 NR-HP beta flange is a standard La Calhene DPTE beta flange connected to Dynamic Design Pharma's proprietary NR flange that functions as the interface between the beta flange and the system or device to be connected.

The NR flange, by means of a custom bearing system and seal, permits rotation of the beta flange during the docking process without the rotation of the system being docked.

An additional static seal system actuated by an external clamping system permits sealing the NR-HP flange system during internal steam sterilization processes.



## 190 NR-HP Beta Flange





190 NR-HP Beta Flange – tank connection



190 NR-HP Beta Flange with steam sterilization clamp installed

## 190 NR-HP Beta Flange Features

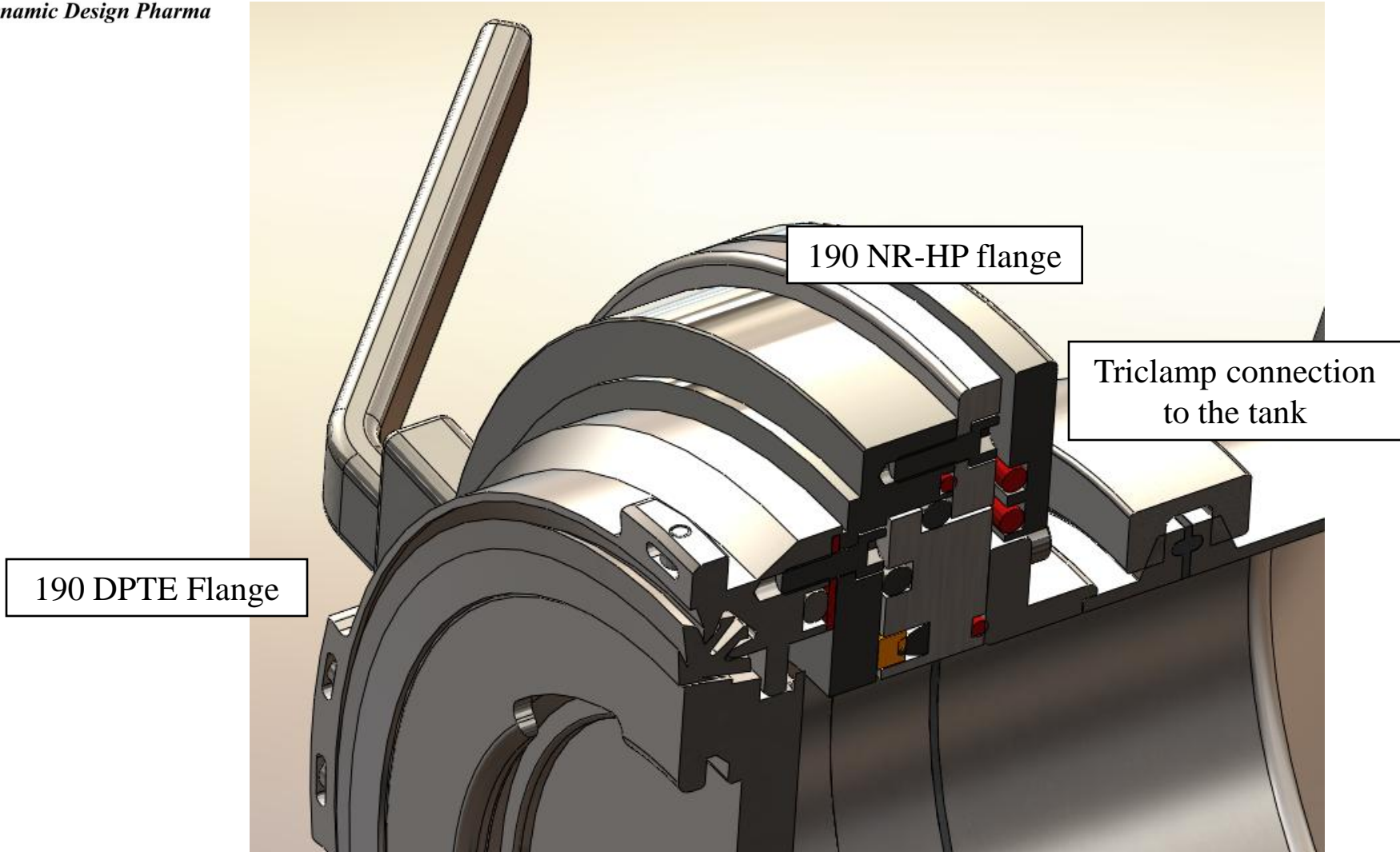
- Bearing and dynamic seal system that permit rotation of beta flange in relation to the canister/tank body
- Turning handles with low turning force
- Sealing interface to La Calhene's standard beta flange
- 6 inch triclamp interface to the system to be docked
- High pressure sealing system for steam sterilization processes

## 190 NR-HP Beta Flange Specification

- Nominal beta flange size: 190mm
- Material: 316L stainless steel
- Leak tightness (during operation): Capable of passing ammonia leak test when pressurized to 250 pascal internal pressure
- Leak tightness (during steam sterilization): Capable of withstanding 30 psi internal pressure.
- Interface with standard La Calhene DPTE Rapid Transfer Port

## 190 NR-HP Beta Flange Application

- Sterile stoppers transfer into the isolator system from the sterilizing tank. Typically, the sterilization tanks are too bulky to be rotated. The beta flange is rotated during docking while the tank remains stationary.



## 190 NR-HP Beta Flange Cross Section

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