

XT System

Presented by:

Dynamic Design Pharma, Inc.

Mission Viejo, California USA

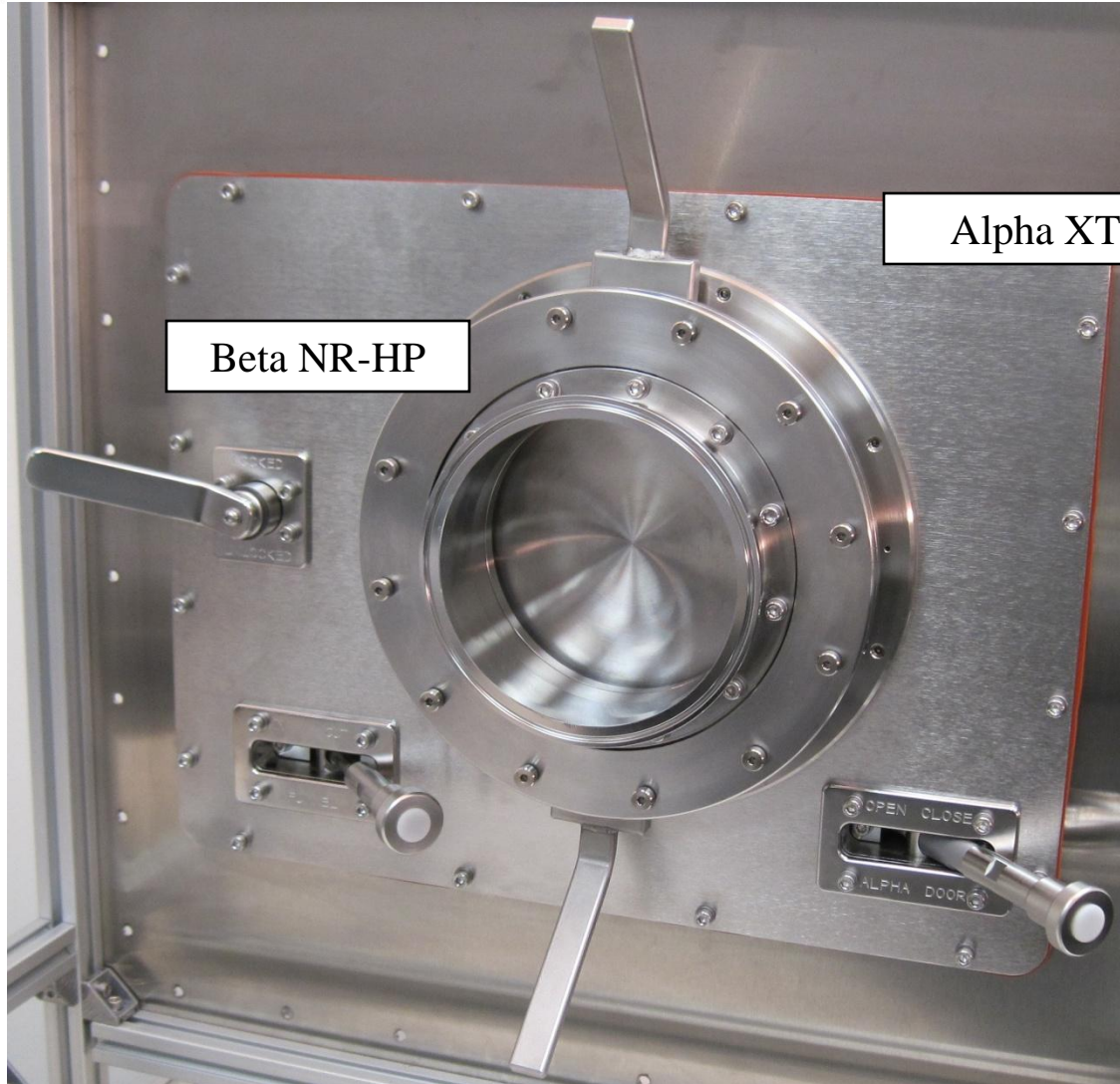
US Patent Pending

Summary – XT System

1. Description
2. Alpha XT
3. NR-HP Flange

Summary – XT System

1. Description
2. Alpha XT
3. NR-HP Flange



XT System Components - Docked

XT System Description

The XT System is composed of two systems, the Alpha XT and the Beta NR-HP, both manufactured by Dynamic Design Pharma.

The Alpha XT is the alpha side of the XT System. This alpha port is operated solely from the outside of the isolator rendering unnecessary the gloved entry into the isolator by the operator to open or close the RTP door.

The Beta NR-HP is the beta side of the XT System. It is based on Dynamic Design Pharma's proprietary NR Technology that permits rotation of the beta flange relative to its mount. The Beta NR-HP flange permits docking of a stationary system, for example a tank filled of sterile stoppers, to the alpha port without rotation.

The XT System is built on the Getinge-La Calhene's DPTE platform but it can be adapted to any RTP port product of the type that requires rotation of the beta flange relative to the alpha flange to perform the docking process.

Summary – XT System

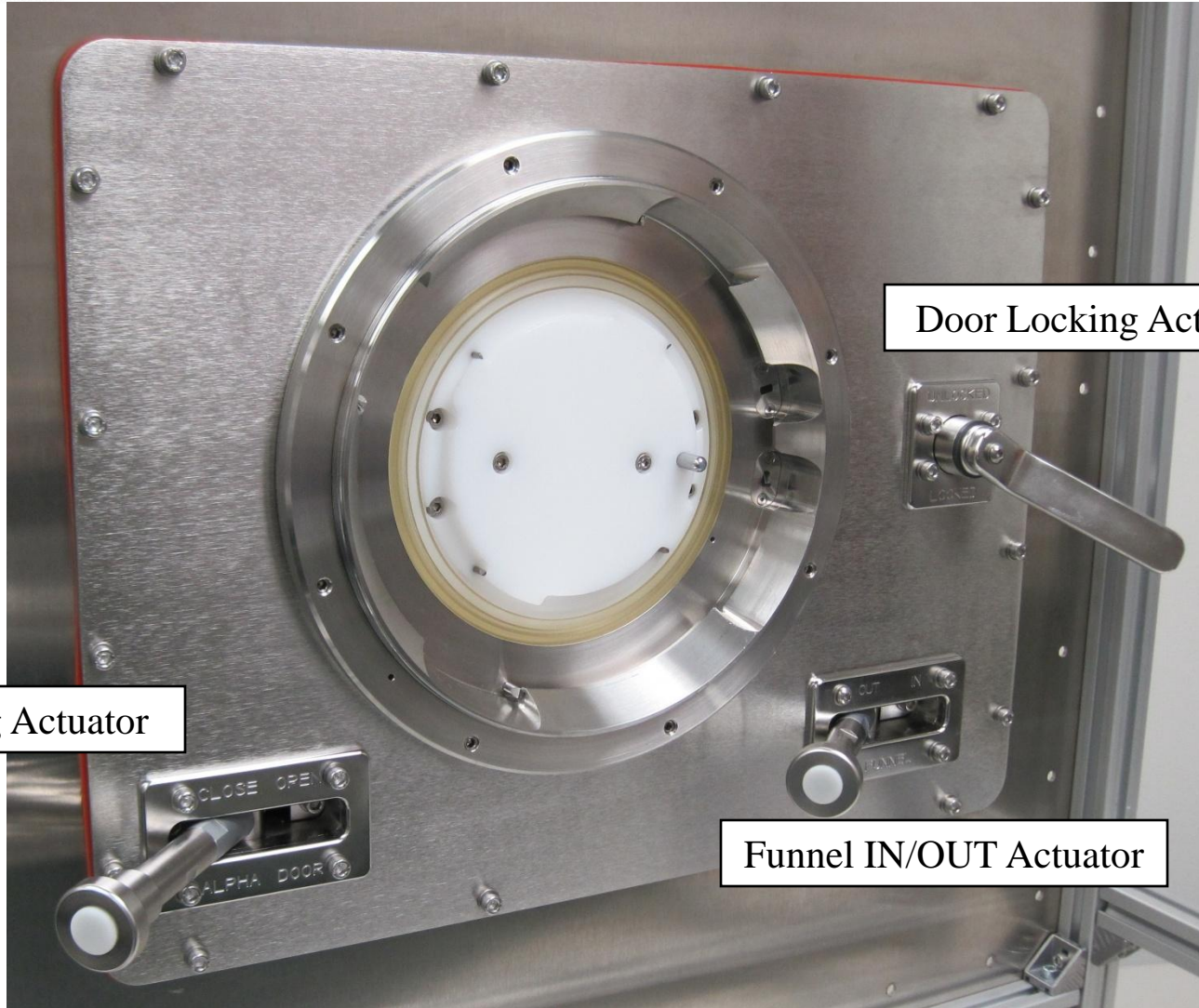
1. Description
2. Alpha XT
3. NR-HP Flange

Alpha XT Description

The Alpha XT is the alpha side of the XT System. It is built on La Calhene's DPTE alpha port platform and includes a number of mechanisms and features that permit unlocking, opening, closing and locking of the alpha door from outside the isolator.

The functionality of the standard alpha port, such as the interlock features and the alpha/beta seal and locking system are unaffected by the integration of the flange into the Alpha XT.

In one of its configurations, the Alpha XT includes a funnel that, similarly to the door actuator, is moved into the operating position from outside the isolator chamber

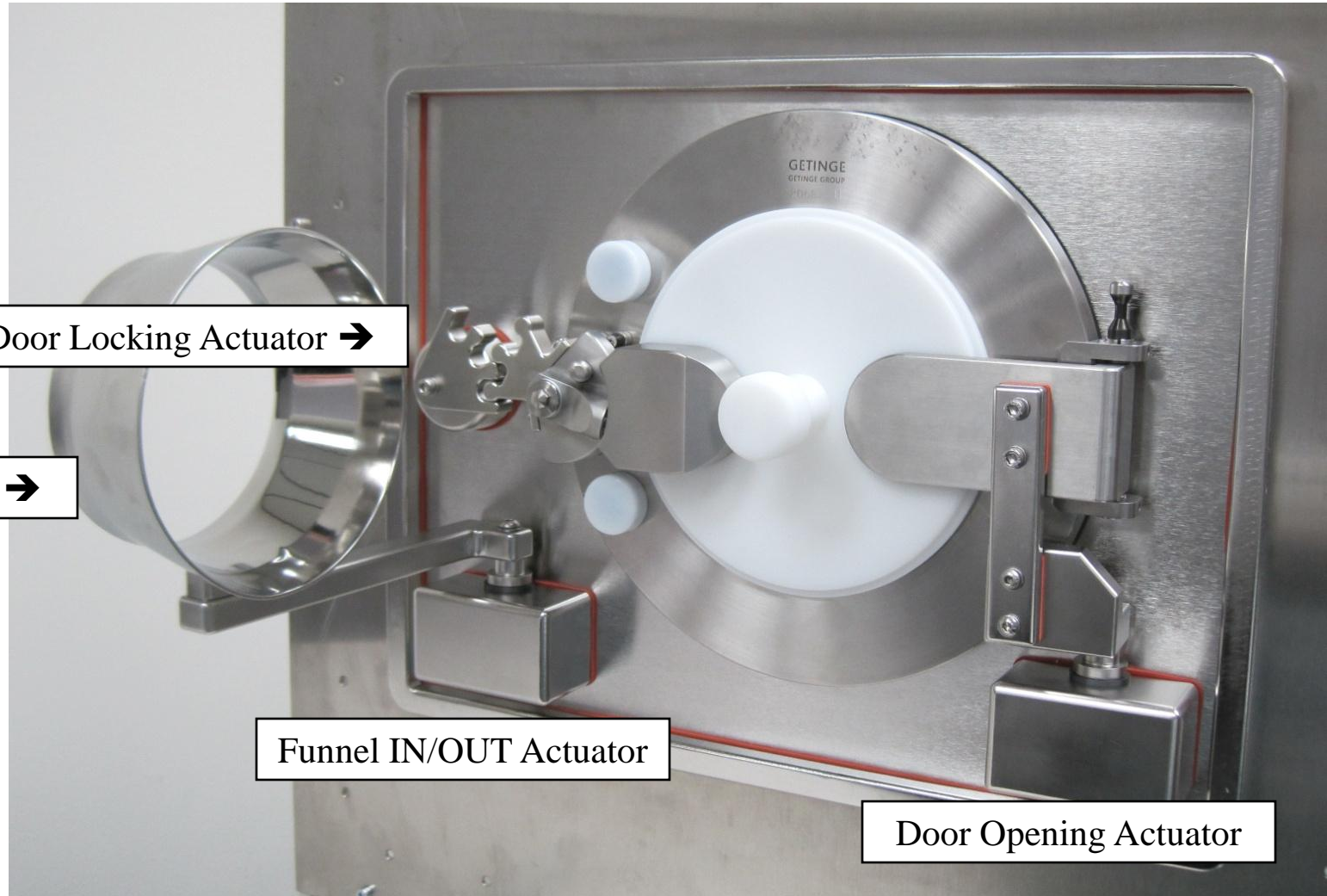


Door Opening Actuator

Door Locking Actuator

Funnel IN/OUT Actuator

190 Alpha XT – Non-Sterile Side



190 Alpha XT – Sterile Side



Actuator details - Alpha XT



Sterile side actuator details - 190 Alpha XT

Alpha XT Features

- Operation solely from the non-sterile (operator) side
- Optional funnel actuator to engage/disengage a funnel into component delivery position
- Built on La Calhene's 190 alpha port but adaptable to any other alpha port manufacturer
- Minor modifications to the alpha port with no impact on the port's door interlock functionality
- Separate actuators for the door locking, door opening and funnel positioning functions
- Positive position lock of the alpha door in the open position
- Positive position lock of the funnel in the engaged and the disengaged positions
- Clean aseptic zone design compatible with wash down operations and VHP decontamination
- Leak tight construction
- Modular design is easily incorporated in new isolator systems or retrofitted into existing installations

Alpha XT Specification

- Nominal port size: 190mm, 270mm, 350mm, 460mm
- Adaptable to La Calhene and CRL alpha ports
- Alpha/Beta door interlock functionality: unaffected
- Alpha door positive lock in the open position
- Alpha door rotation: 90 degrees
- Funnel rotation: 90 degrees maximum (as required by the application)
- Configurable for right hand and left hand operation
- Orientation: Operable from vertical to 45 degree inclination
- Compatible with wash down operations
- Compatible with VHP decontamination
- Leak tight: Ammonia leak test at 250 pascal internal pressure.
- Funnel configuration: As required by the application
- Guide rollers on the beta flange engage guides on the alpha flange during the docking process

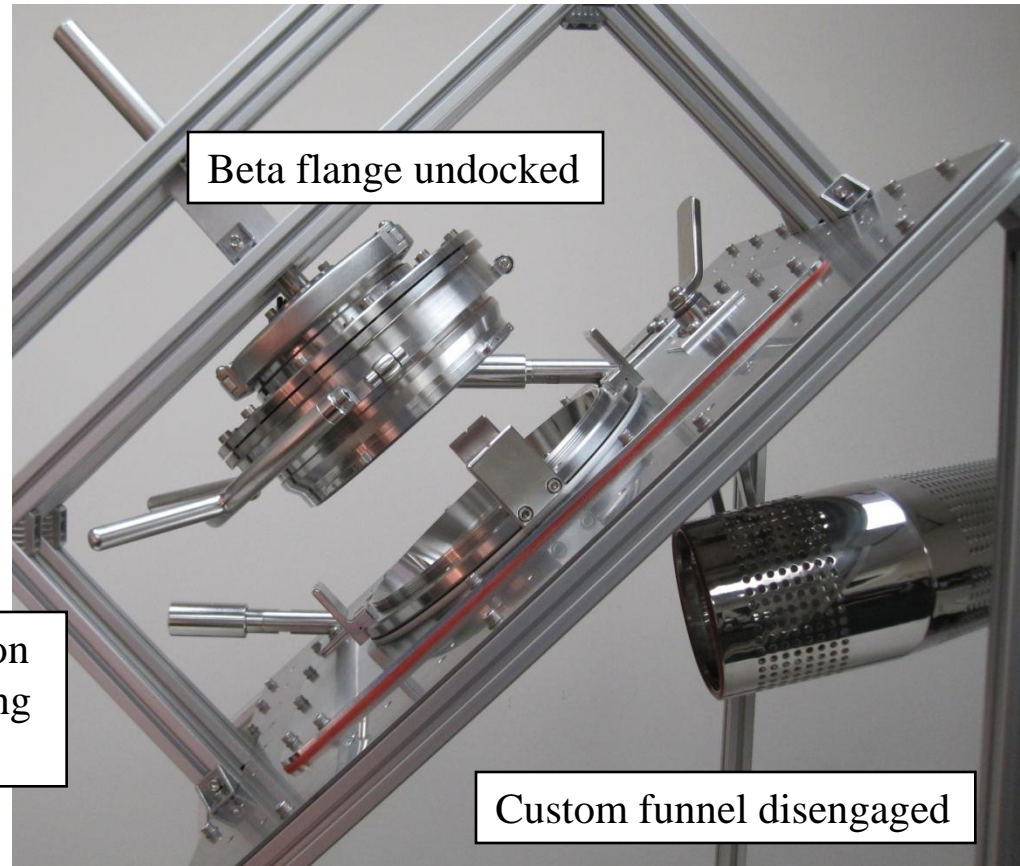
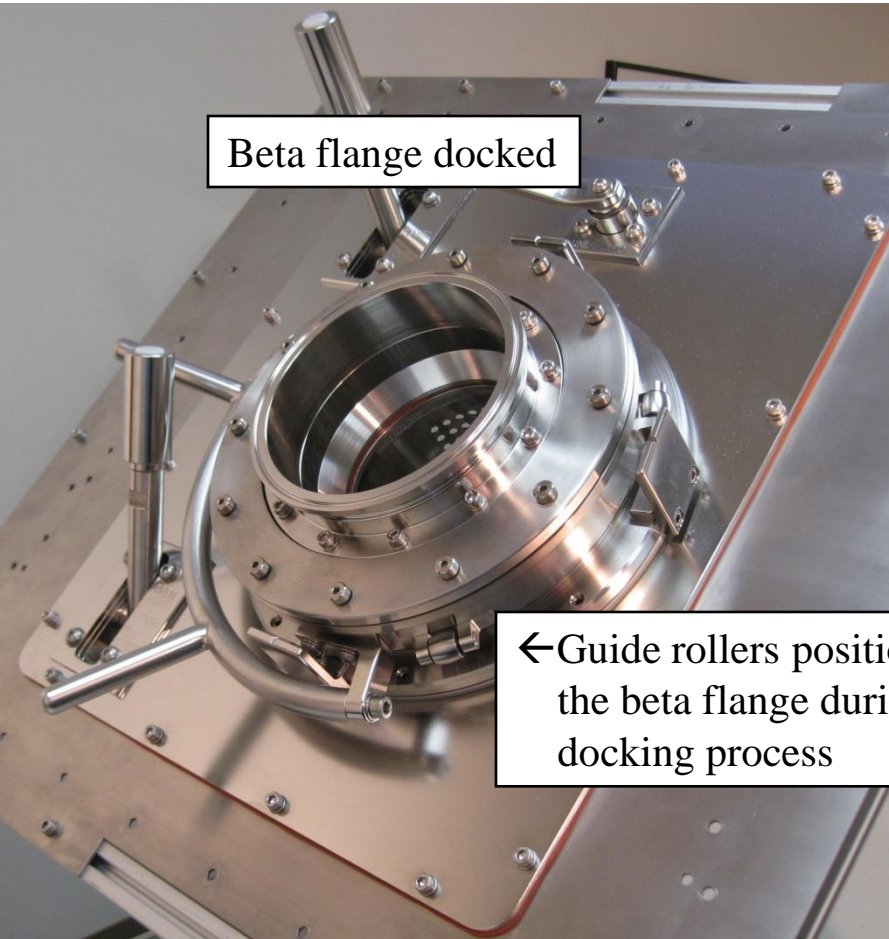
Alpha XT Advantages and Applications

Alpha XT Advantages

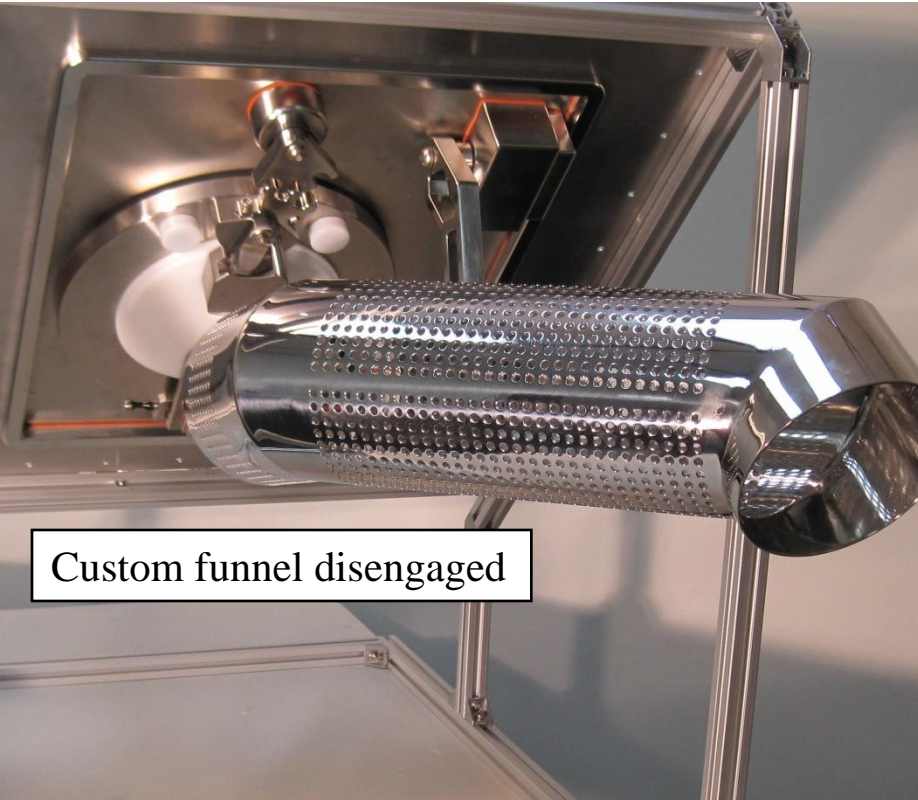
- All docking operation are conducted from the operator side of the isolator
- Manipulation of the delivery funnel is conducted from the operator side of the isolator
- Funnel is precisely positioned concentric to the alpha port inside diameter

Alpha XT Applications

- Transfer of sterile components from a BetaBag directly into the vibratory bowl of the filling line without the operator entering the isolator chamber.
- Transfer of sterile components from a tank directly into the vibratory bowl of the filling line without the operator entering the isolator chamber. See Beta NR-HP system for details.
- Transfer of sterile components through the bulkhead of a class 100 suite.

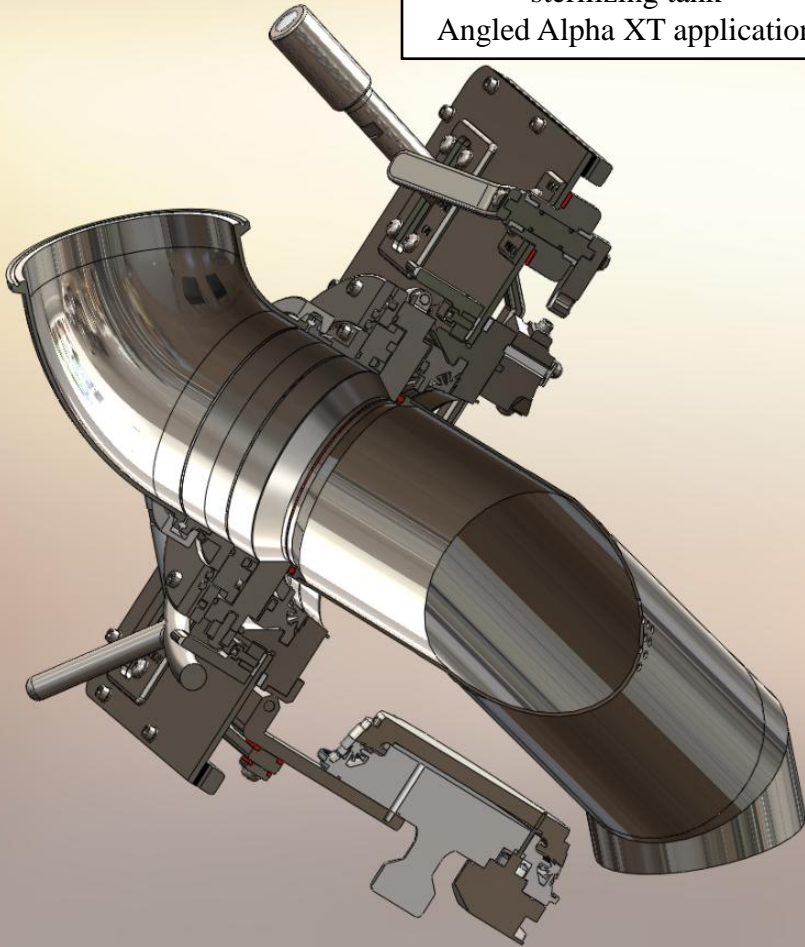


Alpha XT can be mounted up to 45degrees and any orientation

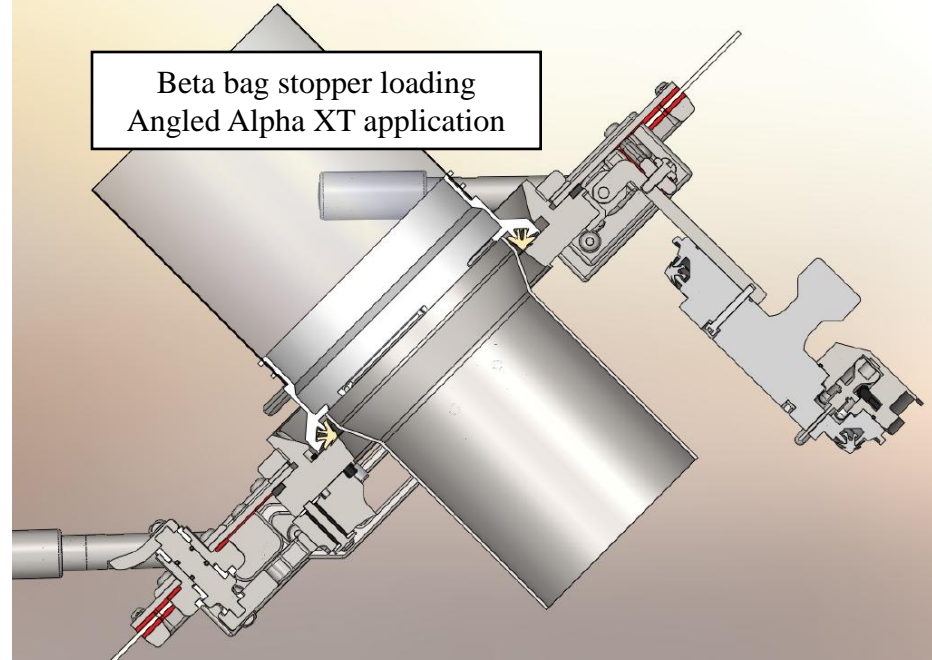


Funnel customized to the application

Stopper loading from
sterilizing tank
Angled Alpha XT application

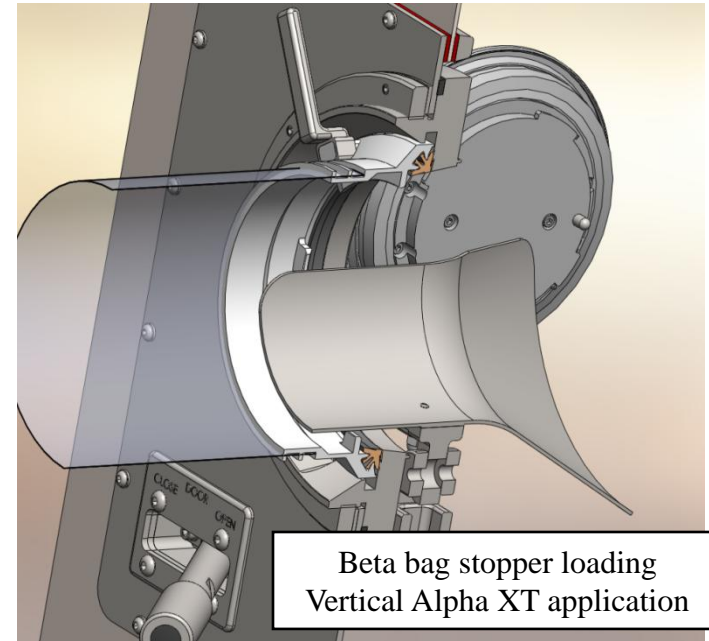


Beta bag stopper loading
Angled Alpha XT application



Stopper Flow into Isolator

Beta bag stopper loading
Vertical Alpha XT application



Summary – XT System

1. Description
2. Alpha XT
3. Beta NR-HP Flange

190 NR-HP Beta Flange Description

The 190 NR-HP beta flange is 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 with custom turning handle and guide rollers

190 NR-HP Beta Flange Features

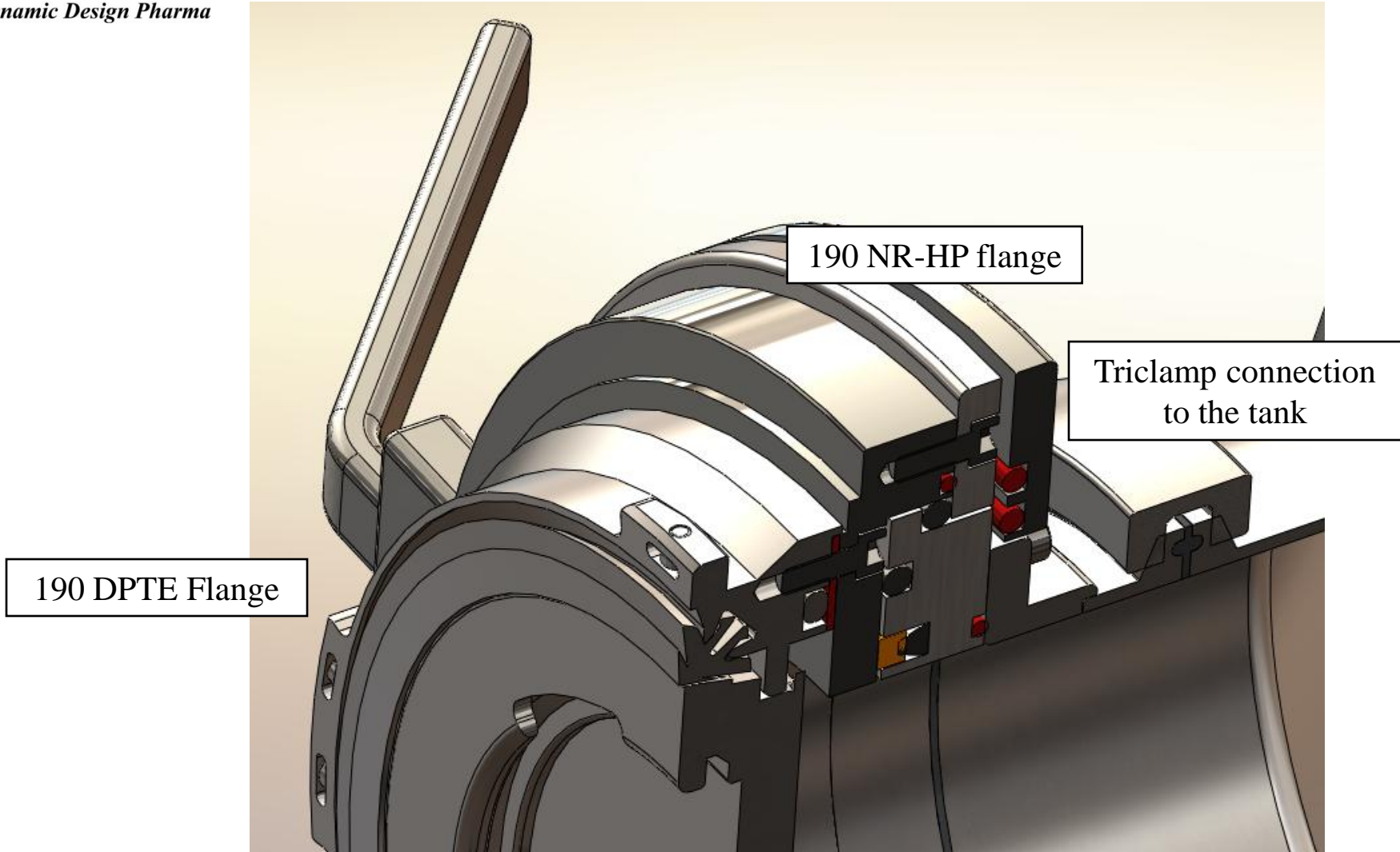
- Bearing and dynamic seal system that permit rotation of beta flange in relation to the canister/tank body
- Custom turning handles with low turning force
- Sealing interface to La Calhene's standard beta flange
- 6 inch triclamp interface to the system to be docked
- High pressure sealing system for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

Summary – XT System

1. Improves the aseptic and operational conditions of small components introduction into the filling line
2. The Beta NR-HP flange permits docking of bulky components, such as a tank, without rotation

Thank You