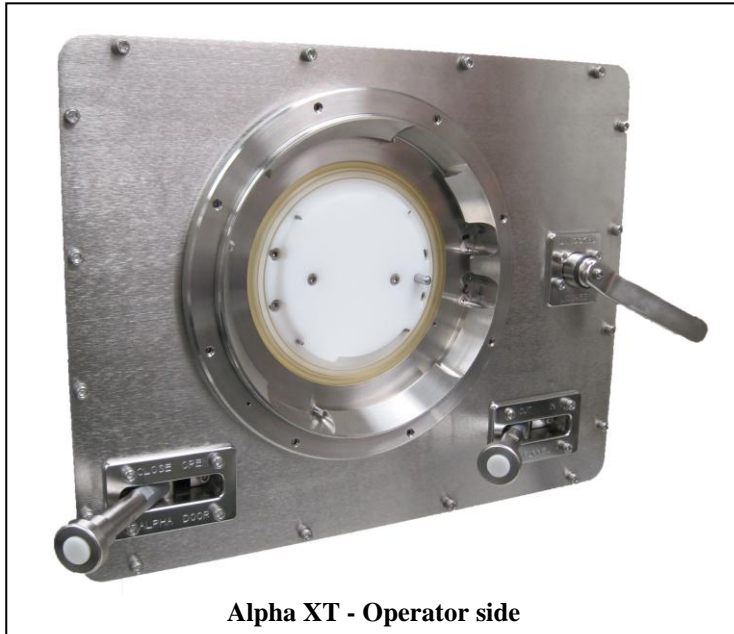


Press Release – Alpha XT System Development

Dynamic Design Pharma (DDP) is pleased to announce the development of a proprietary Alpha port that allows docking the beta flange and opening the alpha door without requiring the gloved entry by the operator into the isolator chamber. Built on La Calhene's DPTE platform, the Alpha XT's functionality can be adapted to any alpha port available on the market including for example CRL's products.



Alpha XT - Operator side



Alpha XT - Sterile side

System Description

The Alpha XT system is an alpha port that is operated solely from the non-sterile, operator side. Such operations include docking of a canister, a beta bag or tank, locking/unlocking of the alpha door, opening/closing of the alpha door and, for those applications requiring it, swinging a funnel into and out of position.

The door and funnel lever system, besides maintaining a leak tight penetration through the bulkhead, also includes positive locking features at the two ends of the positioning stroke.

The modifications to the alpha flange are minimal and are conducted on areas of the hardware that do not affect the port's docking functionality or the integrity of the aseptic transfer.

System application

The most typical application of the Alpha XT is the transfer of small components, such as stoppers, caps, etc. into a filling line. The applications though are unlimited. One example of another application for the system might be the transfer of sterile components through the bulkhead of a Class 100 filling suite. The funnel that is shown in the

enclosed images can be configured to take any shape that meets the requirements of the application. The system can be installed at any desired angle up to 45 degrees from vertical and it can be configured for left hand or right hand operation.

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Alpha XT - Door Open/Close Lever detail



Alpha XT - Door Lock Drive detail

Retrofit to existing systems

The Alpha XT system is ideal for implementation onto isolator systems undergoing development. It is also conducive to the retrofit of component transfer systems of existing filling lines to achieve the elimination of operator entry into the isolator chamber during transfer operations.

Beta NR-HP Flange

The Beta NR-HP is a standard La Calhene beta flange incorporating Dynamic Design Pharma's NR Flange that, by means of a proprietary dynamic seal and bearing system, permits the rotation of the beta flange relative to the triclamp adapter, while maintaining the required leak-tight seal.



Beta NR-HP - Tank Connection side



Beta NR-HP - Beta door side

Typically the Beta NR-HP flange is attached to the end of a tank or transfer system and is steam sterilized prior to component introduction and transfer. To allow for this sterilization method, the Beta NR-HP flange includes features that permit steam sterilization of the system, including the dynamic seal, by the simple installation of an external clamp. A similar flange, the Beta NR, can be used to perform aseptic transfers whenever steam sterilization is not the method used to obtain asepsis.

Conclusion

The Alpha XT allows the operator to operate the RTP port without entering the isolator chamber. Whether used in conjunction with the Beta NR-HP flange or a standalone alpha port system, it is the ideal transfer system from an operational improvement and risk minimization standpoint.

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