

Aseptic Transfer Techniques

Paragon 28[®], Inc. offers various sterile packaged configurations that provide a barrier to maintain sterility until the device is ready for use. Aseptic transfer techniques for these sterile packages are described below.

All individuals shall be trained in accordance with hospital protocols and shall follow hospital procedures in respect of hygiene control. Transferring the contents of a sterile package to the sterile field typically requires two individuals and clear communication between them. The non-sterile member of the operating team is the individual handling the outer packaging and presenting the sterile packaged device to the sterile field. The sterile member of the operating team is the individual receiving the sterile packaged device.

Individuals involved in the aseptic transfer should focus on three primary goals throughout this technique:

- Preventing the sterile package from touching the outside of the sterile barrier.
- Preventing the sterile devices or sterile package from falling or contacting any surfaces other than the sterile field.
- Preventing the sterile team member from touching the outside of the sterile barrier at any point during the transfer.

To begin the aseptic transfer technique, the non-sterile team member confirms the integrity of the sterile barrier system by checking for seal damage, tears or punctures. If the sterile barrier or device has been compromised, do not use the product and report the device in accordance with the device-specific instructions for use document (<u>www.paragon28.com/ifus</u>).

The aseptic transfer techniques provided below pertain to Paragon 28®, Inc. sterile packaged devices contained in pouch packaging.

A. Package contains a device only.

Orient the package to enable presentation to the sterile field. Starting at the chevron end of the pouch, the non-sterile team member peels open the pouch to reveal the device. The transfer can be made one of two ways below:

- The non-sterile team member then deposits the device carefully into the hands of the sterile team member or into a container on the sterile field.
- The sterile team member can retrieve the device while the non-sterile team member holds the packaging open.
- B. Package contains a device that is contained within a secondary unsealed package. The secondary unsealed package must be transferred to the sterile field.

Orient the package to enable presentation to the sterile field. Starting at the chevron end of the pouch, the non-sterile team member peels open the pouch to reveal the contents. The transfer can be made one of two ways below:

- The non-sterile team member then deposits the contents carefully into the hands of the sterile team member or into a container on the sterile field.
- The sterile team member can retrieve the secondary unsealed package which contains the device.

The sterile team member may dispose of the secondary unsealed packaging and the device shall remain within the sterile field.

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