

How to Properly Open RTU Vial/ Bottle Trays:

1. Inspect the package.

Remove the package from the box and inspect the package for defects. Ideally, the package of vials or bottles should still be under vacuum. This can be easily observed by noting if the packaging material tightly conforms to the contours of the vials or bottles.

Note that the loss of vacuum during transportation does not mean the product has been contaminated. The purpose of the vacuum is to immobilize the vials or bottles during transit to reduce the likelihood of breakage.

If the vacuum of the outer plastic package is lost, but the inner plastic package is still under vacuum, the bottles are still immobilized, and no further action is required.

If the vacuum of the inner and outer package has been lost, inspect the package to ensure that the vials or bottles have not been damaged during transit. Also, carefully inspect the package to ensure that it has not been cut or punctured so that the integrity of the autoclave bags has been compromised. The package should not be used if the autoclave bags have been cut or punctured.

2. Wipe the outside of the outer plastic bag to remove gross debris.

Once the package has been inspected and released for production use, wipe the exterior of the outer plastic bag to remove gross debris. This can be done with a dry cleanroom wiper or slightly damp with clean water or IPA. This step aims to limit the gross debris that can be brought into the cleanroom and limit the transfer contamination from the outer plastic bag to the inner plastic bag when the outer plastic bag is removed.

The protocols for removing the outer plastic bag will vary based on your facility, equipment, and process design. In some cases, the outer plastic bag will be removed outside the cleanroom, while in other cases, the outer plastic bag will be removed within the cleanroom. In either case, wiping the package's exterior is a good practice to remove gross debris.

3. Remove the outer plastic bag.

Remove the outer plastic bag by cutting open the end of the bag with sharp scissors. For this operation, the tray of vials or bottles should be placed on a clean solid surface: preferably stainless steel or Formica. The end of the bag should be cut, and the tray of vials or bottles removed from the bag using a gentle sliding motion.

This operation can be performed outside the cleanroom, but preferably inside the cleanroom or an airlock. If the process is performed outside of the cleanroom; the tray of vials or bottles should be immediately transferred into the cleanroom to limit exposure to an uncontrolled environment. This will limit the potential for transfer contamination as the inner bags are sequentially opened.

Do not attempt to remove both the inner and outer plastic bags simultaneously!

4. Move the package of bottles into the cleanroom.

If the tray of vials or bottles has not been moved inside the cleanroom, it should be moved into the cleanroom before the inner plastic packaging layer is removed.

5. Remove the inner plastic bag.

Remove the inner plastic bag by cutting the end of the bag with sharp scissors. For this operation, the tray of vials or bottles should be placed on a clean solid surface; preferably stainless steel or Formica. The end of the bag should be cut, and the tray of vials or bottles removed from the bag using a gentle sliding motion.

This operation should be performed inside the cleanroom or an airlock. Note that the inner plastic bag is not a sterile surface; therefore, handling protocols should account for this when deciding where this operation should occur.

6. Sanitize the outer autoclave bag.

The location for this operation depends entirely on the design of the facilities and equipment of the customer. Note that the outside of the outer autoclave bag is not a sterile surface. While the autoclave bag has been steam sterilized, subsequent handling operations and contact with the non-sterile inner plastic bag can compromise the sterility of the outer surface of the outer autoclave bag. The autoclave bag's outer surface should be considered low bioburden and not sterile.

If the package is to be moved to a sterile location, it should be sanitized before placing it in the sterile area. Even if the package is not moved to a sterile area, it should, at a minimum moved to an area that is controlled to have a low bioburden.

The purpose of the sanitization process is not only to prevent contamination of the sterile/low-bioburden area but also to limit transfer contamination from the outer autoclave bag to the inner bag when the outer bag is removed.

Different sanitization methods are available, and we do not recommend any specific method other than wiping the bag surface with a compatible sanitization chemical. It is the customer's responsibility to select the proper chemicals to be used for this process so that they are compatible with the materials of the autoclave bag as well as the equipment and facilities of the customer.

7. Remove the outer autoclave bag.

Again, the location for this operation is completely dependent on the design of the facilities and equipment of the customer; however, the operation should be performed on a sanitized or sterile surface.

Aseptic protocols should be used when handling the autoclave bag once it has been sanitized. This will ensure that the inside of the outer autoclave bag and its contents remain sterile.

Cut open the end of the outer autoclave bag using sharp, sterile scissors or a sharp, sterile cutting knife. The end that is opposite the printed flap of the bag is the side that should be cut open. The cut should be inside the seals on the end of the bag.

Cut through both layers of material (white Tyvek and clear polyethylene) using the scissor-cutting motion. We do not recommend dragging the scissors through the material to cut it. Using a sterile cutting knife, it is preferable to only cut through the clear polyethylene material rather than the clear polyethylene and Tyvek layers together.

Do not attempt to cut or remove both autoclave bags simultaneously!

Once you have cut open the end of the bag, cut down each side of the bag just inside the factory seal. Whether using scissors or a knife, it is preferable only to cut the clear polyethylene side of the bag. Cut the material down the length of each side of the bag. Be careful not to cut the inner autoclave bag when cutting the bag.

At this point, the bag should be cut on three sides. Take the cut end of the bag and fold it back to reveal the tray of bottles sealed in the inner autoclave bag.

Gently remove the autoclave bag from underneath the tray of vials or bottles by lifting a corner of the tray, grasping the folded flap and end of the bag, and sliding the bag out. Alternatively, the tray of bottles may be lifted off the bag and moved to another sterile surface.

8. Move the tray of bottles to the sterile filling area.

If the tray is not already in the sterile filling area, it should be moved to the sterile area. The inner autoclave bag and its contents are sterile, and they must be handled aseptically to ensure that the sterility of the bottles is not compromised. The tray should be placed on a hard, clean, sterile surface. Note that it is crucial that the working surfaces must be not only biologically clean but also free from visible particles.

9. Remove the inner autoclave bag.

The technique for removing the inner autoclave bag is the same as the outer one. Aseptic protocols must be used when handling the autoclave bag and its contents.

Cut open the end of the inner autoclave bag using sharp, sterile scissors or a sharp, sterile cutting knife. The end that is opposite the printed flap of the bag is the side that should be cut open. The cut should be inside the seals on the end of the bag.

Note that if you use the same pair of scissors or cutting tool to remove the outer autoclave bag, the scissors or cutting tool should be resterilized before using them to cut the inner autoclave bag. This precautionary measure ensures that no transfer of biological contamination occurs via the cutting tools.

If using scissors, cut through both layers of material using the scissor-cutting motion. We do not recommend dragging the scissors through the material to cut it. Using a sterile cutting knife, it is preferable to only cut through the clear polyethylene material rather than the clear polyethylene and Tyvek layers together.

Once you have cut open the end of the bag, cut down each side of the bag just inside the factory seal. Whether using scissors or a knife, it is preferable only to cut the clear polyethylene side of the bag. Cut the material down the length of each side of the bag. Be careful not to cut the plastic tray with scissors or a knife, as this will generate plastic particles.

At this point, the bag should be cut on three sides. Take the end of the bag and carefully fold it back to reveal the tray of vials or bottles. Before exposing the tray of vials or bottles, orient the tray to make use of first air principles when exposing the tray of vials or bottles. For example, if the tray is situated on a table between the technician and the HEPA filters, the tray should be oriented such that the cut flap of the bag is folded back from right to left or left to right.

When folding the bag's cut flap back, ensure that the Tyvek bag is not stuck to the bottles. This happens rarely, but if it happens, it can cause Tyvek fibers to contaminate the bottles. If the Tyvek bag is sticking to the bottles, this may indicate that Tyvek fibers will be present on the openings of the bottles.

Gently remove the autoclave bag from underneath the tray of vials or bottles by lifting a corner of the tray, grasping the folded flap and end of the bag, and sliding the bag out. Alternatively, the tray of bottles may be lifted off the bag and moved to another sterile surface. When working with the exposed bottles, the technician's movements must be carefully controlled to prevent both biological and particulate contamination of the bottles.