Disposable Processing Bag with Alignment Feature

Cross-Reference Related Applications

This application claims the benefit of U.S. Provisional Patent Application No. 60/927,598, filed on May 4, 2007, the entire contents of which are incorporated by reference herein.

The present invention relates to a bag for use in a holder, such as a vat or carboy, and arranging the bag in a proper alignment within the holder via an alignment feature attached to the bag. More particularly, it relates to a disposable bag for use in a holder, such as a vat or carboy, with the bag having one or ports and an alignment feature attached to the bag adjacent the one or more ports to properly orient the bag in its holder.

Background of the invention

Traditionally, products such as pharmaceuticals, biopharmaceuticals, enzymes, neutraceuticals and the like were processed in stainless steel containers. After use the steel containers had to be cleaned and sterilized. This often required the use of steam and/are caustics to accomplish this task.

Additionally, for regulated products such as pharmaceuticals, the sterilization process had to be validated to show that it could sterilize the device and could so time after time.

Both the cleaning process and the validation are time consuming and expensive and can't be varied without a new validation.

This has led to the use of single use, disposable plastic bags to store and process many of these products. These bags are provided sterile (generally gamma irradiated), do not require cleaning as they are disposed of after use and reduces the validation required by the user and/or shifts the validation to the bag supplier.

These bags contain one or more ports through which liquids, additives, product and the like are added or removed from the bag during processing.

These bags are generally placed into a holder such as steel plastic, fiberglass, graphite or other composite vat, tote or carboy to help hold the weight of the liquid and to protect the bag from rupture due to contact with other items on the manufacturing floor. These holders have an opening in their bottom portion through which the ports extend. As the port arrangements differ by bag type, manufacturer or customer requirement, the bottom of the holders generally have large rectangular

In another embodiment, the plate has two parts, an inner asymmetric portion and symmetric outer portion selectively attachable to the inner asymmetric plate portion and is of a configuration to fit into a standard opening in a holder.

Brief Description of the Drawings

Figure 1 shows a first embodiment of the present invention in cross-sectional view.

Figure 2 shows a second embodiment of the present invention in planar, bottom view.

Figure 3 shows a third embodiment of the present invention in planar view.

Figure 4 shows a fourth embodiment of the present invention in cross-sectional view.

Figures 5 A and B shows fifth embodiment of the present invention in planar view.

Figures 6 A-H show different shapes useful in the embodiments of the present invention in planar view.

Figures 7A and B show another embodiment in planar bottom up view.

Figure 8 shows a further embodiment in planar bottom up view.

Figure 9 shows a knockout plug according to an embodiment of the present invention in cross-sectional view.

Detailed Description of the Invention

In Figure 1 is shown a first embodiment of the present invention in cross-sectional view. A bag 2 is held within a holder 4 such as a carboy or a tote and has one or more ports 6 extending out at least of its lowermost portion 8. An alignment plate 10 is attached to either the bag 2 or its one or more ports 6 as will be discussed below. The plate 10 also provides support for the bottom of the bag while in use in the holder 4 by fitting into and aligning with a hole or opening 12 in the lowermost portion 8 of the holder 4. As can be seen, the port(s) 6 extend through the plate 10 so they may be connected to inlets, outlets, pumps, storage bags, tubing, etc (not shown) as is needed in the process. In this embodiment the plate 10 is attached to the ports 6 of the bag 2 by an attachment device 14 such as a cable tie or a wire wrap or similar device.

To the extent the same elements are used in later Figures, their reference numbers remain the same.

As shown in Figure 2, one surface 16 of the plate 10 may be adhered or welded or molded to the bag 2 during assembly so that its orientation remains the same.

As shown in Figure 3 is an embodiment of the plate containing a graphic design 18 as to the orientation or alignment of the bag 2 when it is inserted into the holder 4 such that the operator will know which way to orient the bag 2 as it is being inserted into the holder 4 and attached to the various other elements such as pumps, filters, inlet hoses, outlet hoses, etc, (not shown). The graphical design 18 may be anything such as an arrow as shown pointing in a given direction to indicate the bag's alignment to the holder 4. It may also include words 19 providing an indication of the direction of the bag or which port is which such as inlet, outlet, etc so an operator may properly align the bag in the holder. Alternatively, the graphic design 18 could be a hash mark, the arrow mentioned above or other symbol that is designed to align with a similar feature on the holder 4 itself (not shown).

As shown in Figure 4 is an embodiment in which the bag 2 has one port 6. In this embodiment the bag 2 also has an alignment device 20 in this case in the form of a nub that extends outwardly from the bag 2 and the alignment plate 10 contains both an opening for the port 6 but also for the alignment device 20 such that the plate 10 is always properly aligned to the bag and not allowed to rotate relative to it. The plate 10 may be attached to the port 6 in this instance by an attachment device 14 again in this instance a ratcheted cable tie. Other alignment devices include but are not limited to twist ties such as plastic coated wire ties, steel or plastic clamps and the like.

Bags 2 containing two or more ports 6 that extend through the plate 10 do not necessarily need a separate alignment device 20 but may have one if desired.

While the plate 10 in the above embodiments is shown as being a rectangle, the shape of the plate 10 and its corresponding hole 12 is not limited to such. It may be any symmetric or asymmetric shape or design that is desired, such as any polygon including but not limited to triangles, squares, pentagons, hexagons, heptagons, octagons and the like. They may also be circular or oval. They may also be combinations of the different shapes such as two circles of different sizes or two polygons of different sizes or different shapes.

Multiple plates 10 may also be used, with each one associated either with at least one port 6 or an alignment device 20.

Any of the embodiments discussed above may if desired contain the graphical design 18 discussed above.

The coated layers may provide additional cleanliness to the plate or act as a bonding layer between the plate and the bag to which it is attached if such bonding is desired. It also reduces the potential for flash or rough surfaces on the plate to pierce the adjacent bag.

The plate may in the case of plastics, composites and metals either formed from a blank sheet of material or molded as the finished plate. Wood can be formed from a blank and shaped into the desired configuration and port arrangement.

Additionally, wireless tracking devices such as RFID chips, Zigbee® or Bluetooth® devices may also be included on the plate to provide manufacturing data about the plate, the bag to which it is attached and with devices having read/write capabilities to track the use of the bag at the user's facility. There information relating to a trackable event such as entry into inventory, use, the material made or stored in the bag, etc can added by the user to the tag. Such a tag 100 is shown in Figure 5A.

What is Claimed

1. A system comprising a holder having an opening in its lowermost portion, the opening having an outer edge that is asymmetrical shaped and a disposable processing bag formed of one or more pieces of plastic sealed to form a closed container, one or more ports formed in the bag to provide access to an interior of the bag for the introduction and/or removal of materials to the bag and an alignment plate attached to the bag adjacent the one or more ports and wherein the plate has one or more openings aligned to match the one or more ports of the bag, the plate has an outer edge that is asymmetrical shaped and corresponding to that of the opening of the holder, wherein the opening and the plate are both in the shape of a four-sided polygon having opposite first and second sides parallel to each other and a third and fourth sides converging relative to each other and intersecting the first and second sides at an angle of greater than 0 degree and less than 180 degree and the plate fits into and aligns with the opening in the holder in only one orientation for proper alignment of the bag within the holder.

2. The system of claim 1 wherein the plate is attached to the one or more ports by one or more cable ties.

3. The system of claim 1 wherein the plate is welded to surface of the bag adjacent the one or more ports.

4. The system of claim 1 wherein the plate is molded to an adjacent surface of the bag.

5. The bag of claim 1 wherein the plate has one or more openings aligned to match the one or more ports of the bag and the plate is overmolded to an adjacent surface of the bag.

6. A system comprising a holder having an opening in its lowermost portion with an outer edge that is an unique shape and a disposable processing bag formed of one or more pieces of plastic sealed to form a closed container, one or more ports formed in a bottom of the bag to provide access to an interior of the bag for the introduction and/or removal of materials to the bag and an alignment plate attached to a device selected from the group consisting of the

bag and the one or more ports of the bag and wherein the plate has one or more openings aligned to match the one or more ports of the bottom of the bag, the plate has a uniquely shaped outer edge corresponding to that of the opening of the holder such that the plate fits into and aligns with the opening in the holder in only one orientation for proper alignment of the bag within the holder.

7. The system of claim 6 wherein the plate is in the form selected from the group consisting of uneven polygons, partial polygon/partial circular designs and two or more rectangular or circular designs of different sizes.

8. The system of claim 6, wherein the plate is attached to the one or more ports by one or more cable ties.

9. The system of claim 6, wherein the plate is welded to surface of the bag adjacent the one or more ports.

10. The system of claim 6, wherein the plate is molded to an adjacent surface of the bag.

11. The bag of claim 6, wherein the plate has one or more openings aligned to match the one or more ports of the bag and the plate is overmolded to an adjacent surface of the bag.

12. A system comprising:

a holder;

a disposable processing bag containing one or more ports, the bag formed of one or more pieces of plastic sealed to form a closed container; and

an alignment plate with one or more holes that align with one or more ports,

wherein the plate is affixed to the bag or one or more ports such that the plate cannot be realigned or moved out of register, the holder comprising an opening in its lowermost portion, the opening having an outer edge shape that corresponds to an outer edge shape of the plate such that the bag with the affixed plate will fit into the opening in a single orientation.

13. The system of claim 12, wherein the plate is in the form selected from the group

consisting of uneven polygons, partial polygon/partial circular designs and two or more rectangular or circular designs of different sizes.

14. The system of claim 12, wherein the plate is attached to the one or more ports by one or more cable ties.

15. The system of claim 12, wherein the plate is welded to surface of the bag adjacent the one or more ports.

16. The system of claim 12, wherein the plate is molded to an adjacent surface of the bag.

17. The bag of claim 12, wherein the plate has one or more openings aligned to match the one or more ports of the bag and the plate is overmolded to an adjacent surface of the bag.