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

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.

What is Claimed:

1. 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, the plate has an outer edge that is asymmetrical shaped and corresponding to that of the opening of a corresponding 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 bag of claim 1, wherein the plate is attached to the one or more ports by one or more cable ties.

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

4. The bag 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. The bag of claim 1 further comprising a wireless device attached to the plate.

7. The bag of claim 1 further comprising a wireless device attached to the plate, wherein the wireless device is an RFID chip.

8. 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 the bag or to one or more ports of the bag, wherein the plate