

# Manufacturing and Assembling the Prefilled ApiJect Injector\*

## Blow-Fill-Seal 12 Steps



1

**Resin Storage Silo**  
Pharmaceutical-grade plastic resin pellets are stored in large quantities and fed into the BFS machine.



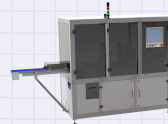
2

**Product Delivery Tanks**  
A batch of the formulated drug product is stored in these tanks and fed into the BFS machine.



3

**Rotary BFS Machine**  
In a continuous 3-second process, the Blow-Fill-Seal (BFS) machine forms plastic containers from molten resin, aseptically fills each with sterile liquid, and seals them.



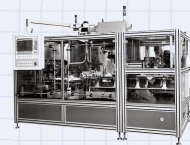
4

**Punch and Laser Machine**  
The excess plastic around the strip is "punched" away. Then a laser etches the lot number and expiration date on each BFS container.



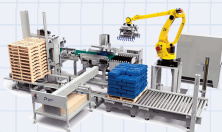
5

**Separator**  
The strip of 25 BFS containers is broken up into "cards" of 5 BFS containers each.



6

**Leak Detector**  
Each card is inspected for tiny leaks using a vacuum decay process. Any BFS card found with a leak is discarded.



12

**Palletizer**  
Boxes loaded with cartons are placed onto pallets and ready to be transported to their final destination.



11

**Aggregator & Shipper**  
After the cartons are filled, serialized, and sealed, they are placed in shipping boxes.



10

**Cartoner**  
Erects the cartons and then fills them with the wrapped units. Paper inserts may be added as well to provide instructions or other critical information.



9

**Flow Wrapper**  
All of the cards are placed in a foil pouch to create an impenetrable barrier.



8

**BFS Container Labeler**  
A self-adhesive label is placed on each BFS container. If requested, the label can have an NFC tag embedded in it with a unique serial number.



7

**Multi-Aspect Inspection Machine**  
The cards are inspected at numerous angles for damage and large particulates in the BFS containers. Any rejected cards are discarded.

**2-Facility Supply Chain**

U.S. and South Korea

Can be done all in U.S. in the future

## Needle Hub 12 Steps



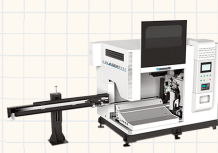
1

**Needle Manufacturing Machine 1**  
Rolling/heating machine unspools a stainless-steel ribbon, curls this metal "tape" into a tube shape, then welds tube shut along seam.



2

**Needle Manufacturing Machine 2**  
Stretching machine heats the stainless-steel tubes, then stretches them into long, thin configuration, reducing tube diameter to needle dimensions.



3

**Needle Manufacturing Machine 3**  
An initial cutting machine slices the stretched-out, stainless-steel tube into rod lengths for easier handling.



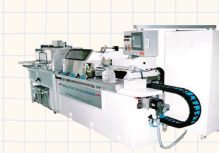
4

**Needle Manufacturing Machine 4**  
Groups of stainless-steel rods are bundled together and temporarily packaged with shrink-wrap for convenient machine handling.



5

**Needle Manufacturing Machine 5**  
A second cutting machine slices each bundle of stainless-steel rods into needle length.



6

**Needle Manufacturing Machine 6**  
Grinding machine bevels the ends of the needle-length rods to sharp points, often giving the points 3-5 converging faces.



12

**Needle Hub Assembly Molding Machine**  
A needle is glued into the Hub base, then set to dry for 10 minutes. Needle Cap is attached.



11

**Needle Cap Injection Molding Machine**  
Molten plastic injected into the precision-shaped cavity of a metal mold, casting the plastic as a Needle Cap.



10

**Needle Hub Connector Injection Molding Machine**  
Molten plastic is injected into the precision-shaped cavity of a metal mold, casting the plastic as a solid Needle Hub Connector.



9

**Needle Hub Base Injection Molding Machine**  
Molten plastic is injected into the precision-shaped cavity of a metal mold, casting the plastic as a solid Needle Hub base.



8

**Needle Manufacturing Machine 8**  
Needles are stacked and boxed in primary packaging, then packaged in cartons for shipment.



7

**Needle Manufacturing Machine 7**  
Stainless-steel needles are automatically sterilized (washed, dried, etc.) and polished in an aseptic environment.

All information is illustrative. Actual machines and processes may vary. Prefilled injector shown is a prototype and not cleared by regulators. ©2023 ApiJect Systems, Corp. All rights reserved.