

MANUFACTURER OF PHARMACEUTICAL EQUIPMENT OF THE FUTURE

THE IMPRO ASPU SYSTEM: General Description

The Autoclavable Stopper Placement Unit from IMPRO is designed to assemble HYPAK® SCF® syringe barrels and stoppers after the syringes have been processed through an independent filling machine operation.

This unit is intended to provide an efficient means of stoppering filled syringes in a pharmaceutical sterile cleanroom. the Autoclavable Stopper Placement Unit, or "ASPU", consists of **two interconnected units --the main vacuum chamber and the Control Box**. The chamber is usually placed on a sterile laminar flow bench next to a filling machine. The Control Box which is intended for wall-mounting inside the clean area, is connected to the main chamber by means of a connector hose, which supplies the air, nitrogen and vacuum necessary for the operation of the chamber unit.





Utilities needed for the operation of this unit are:



▶ Compressed Air

80-120 PSI (metric: 5-8 bars) 5 CFM minimum (metric: 8m3/h)

Nitrogen

60-120 PSI (metric: 4-8 bars) 5 CFM minimum (metric: 8m3/h)

▶ Vacuum

17.0 CFM recommended (metric:28.8m3/h) 6.25 CFM Minimum (metric 10.6m3/h)

The ASPU will evacuate a portion of the air in the syringes and replace that air with nitrogen, thereby reducing the percentage of oxygen in the stoppered syringe.

The Control Box supplied with this unit also has an optional control to perform the nitrogen "back flush" operation once or twice depending on the oxygen sensitivity of the drug being filled. With this feature, the oxygen content can be reduced.

After performing the nitrogen flush operation(s), the unit will automatically draw "final" vacuum to any desired level. This vacuum will determine the size of the "bubble" left between the drug and the stopper, after insertion of the stopper.

When the "final" vacuum reaches it set point, the stoppers are automatically inserted in the syringe barrels. The chamber is then vented with filtered air to bring the pressure level inside the chamber back to atmospheric level and allow the stoppered syringes to be removed.



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IMIPIRO ASIPUI SYSTEMI



Nested Syringe Vacuum Stoppering machine



This system can stopper the following amount of syringes based on the amount of ml used:

0.5 ml => 100 syringes 1.0 ml => 100 syringes 2.0 ml => 100 syringes 3.0 ml => 100 syringes

5.0 ml => 64 syringes 10 ml => 42 syringes 20 ml=> 30 syringes We also offer a 1.0 ml syringe for 160 syringes, which is known as 10x16. The 10x16 system requires a special stoppering nest designed by Impro Systems. Call us at 954-782-3829 for more info.

The air and nitrogen enter the chamber through a 0.2 micron sterilizing filter, located on top of the chamber unit, eliminating the need for using sterile compressed air and nitrogen. (For recommended sanitation of the vacuum chamber procedures, see Maintenance Section of the manual.)

The unit is completely air-operated through the use of state of the art pneumatics, including an "integrated air circuit" (IAC) for years of trouble-free service. The controls have been designed to minimize the number of line connections inside the Control Box and virtually eliminate any maintenance.

Each ASPU is equipped with a set of plunger pins and plates matching the size of the syringes being processed, as ordered by the customer. Additional sets of pins and plates for other size syringes may be ordered.