



NICOS GROUP Inc.

80 Oak street, Norwood NJ 07648

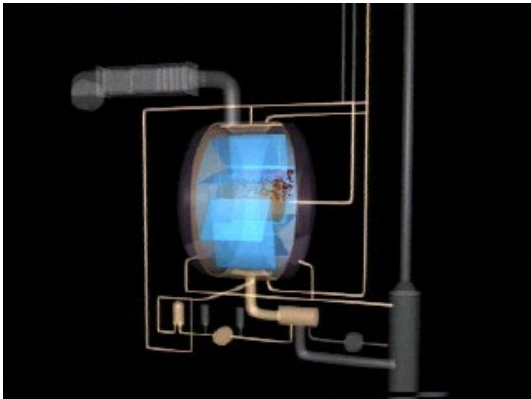
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Stopper Processors

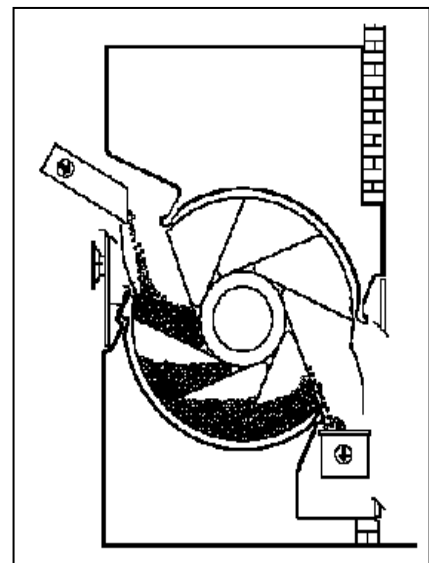
Washing, rinsing, siliconizing, sterilizing, drying, cooling

All machines are fully automated machines, available in six sizes designed to meet the latest cGMP Standards. The smallest unit can process 6,000 x 20 mm. standard stoppers; and the largest unit, roughly 96,000 x 20 mm. standard stoppers. The complete cycle time for Model LST, which includes sterilization, is approximately 3.5 hours offering guaranteed residual moisture content up to 0.01%. The duration of the complete cycle without sterilization is approximately 2-2.5 hours.



Flexibility An outstanding feature of this machine is that it can be used for rubber stoppers, aluminum line-seals (combi-caps), syringe plungers, and screw caps for vials with the same proven results. The highly efficient built in CIP-SIP system allowed several FDA certified pharmaceutical companies to process both rubber and aluminum components in the same machine.

Individual basket concept. Individual baskets aid in better physical separation of the stoppers. To load all the stoppers into one main chamber encourages clumping and interlocking which diminishes surface exposure. **By separating the stoppers, there is little or no mass weight to cause interlocking, offering a maximum surface exposure during each phase of an entire cycle.**





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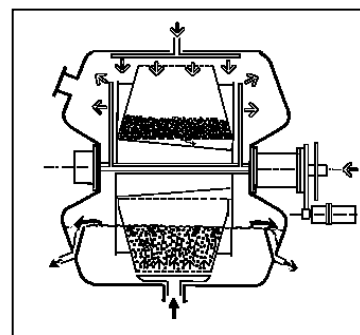


A complete cycle includes:

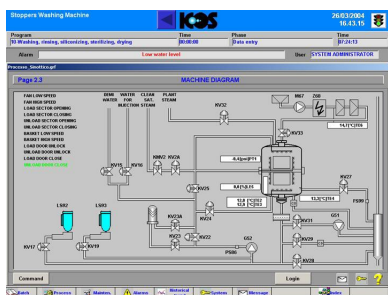
- washing (with or without detergent)
- rinsing
- siliconizing (with silicone oil or emulsion)
- sterilization at 121°
- hot air drying
- cooling

A critical factor in uniformity and effectiveness of the stopper processing is the capability of increasing surface exposure during the cycle. By separating the stoppers we increase the surface exposure to process fluids:

- Enhancing particle elimination and reducing particle generation due to friction
- Reducing the amount of silicone to be used during the siliconizing phase (making easier the CIP cycle!)
- More efficient drying phase



Other reasons for the worldwide success of our machine:



- Slow rotation is used during the process. This helps to eliminate stress cracking, particle generation, twinning and clumping.
- Excellent steam distribution. All of our customers have achieved temperature deviation not exceeding $\pm 0.1^{\circ}\text{C}$, during validation.
- The units are customized for the worldwide marketplace by using readily available components and preferred components with a worldwide network of distributors.

All of the stopper processor models can easily interface with isolators proposed and supplied by any of the world's current manufacturers, in which ICOS has extensive experience.

All standard ICOS equipment is furnished with CFR21 part 11 compliant control systems. Ifix platform is available as well as Siemens or Allen Bradley PLC.

Why use the stopper washing-sterilizing unit?

The use of only one piece of equipment reduces material handling significantly. It is easier to validate, occupies less floor space, requires less maintenance, and at the same time improves the quality of your product(s).