Best Practice

Customized Cleaning Lines: One Giant Step for Superior Cleaning

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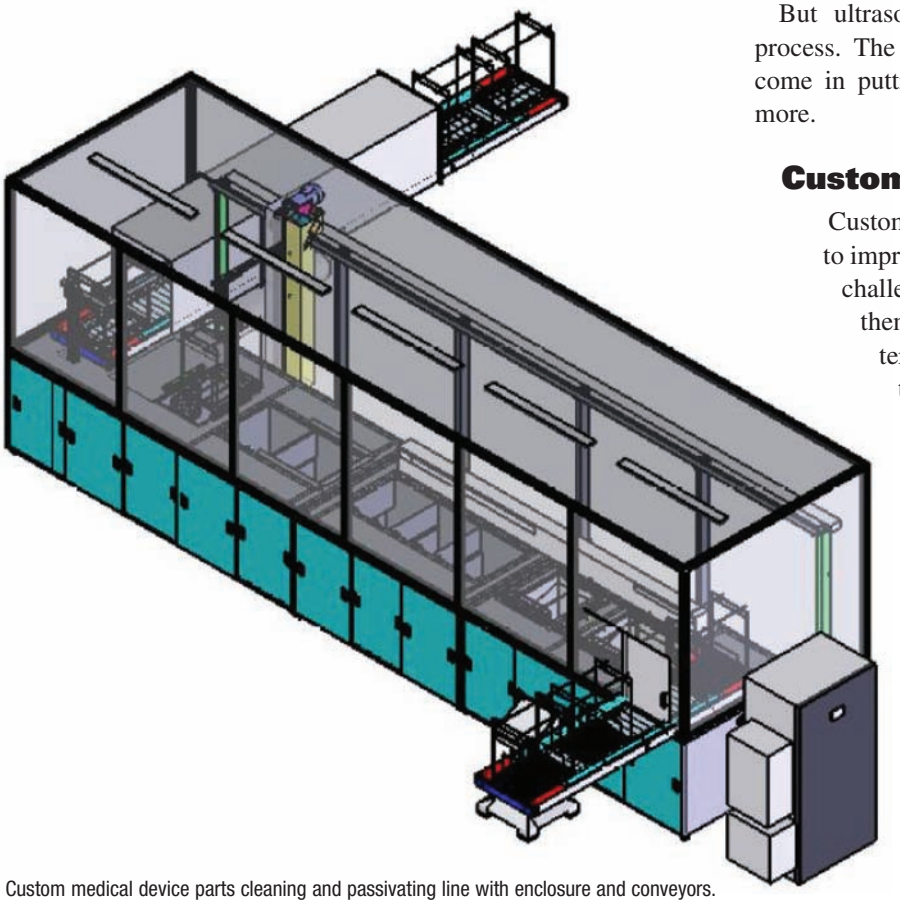
A well designed cleaning line customized to the user's requirements can function successfully for years to come and may even evolve with the business model.

In the world of medical device manufacturing, getting on top and staying there means paying considerable attention to advertised features like innovative part design, durable substrates and biocompatible coatings. But in the medical world—as in other critical fields like aerospace and high purity—cleanliness is also crucial, and one less than clean part can spell disaster. Partnering for thorough, reliable, repeatable, document-able cleaning is rapidly becoming indispensable to success and non-negotiable with increasing scrutiny by agencies like the FDA. Customized cleaning equipment is a big part of the solution and the stay-ahead initiative.



Custom medical device parts cleaning and passivating line with enclosure and conveyors.

Images courtesy of Miraclean Ultrasonics.

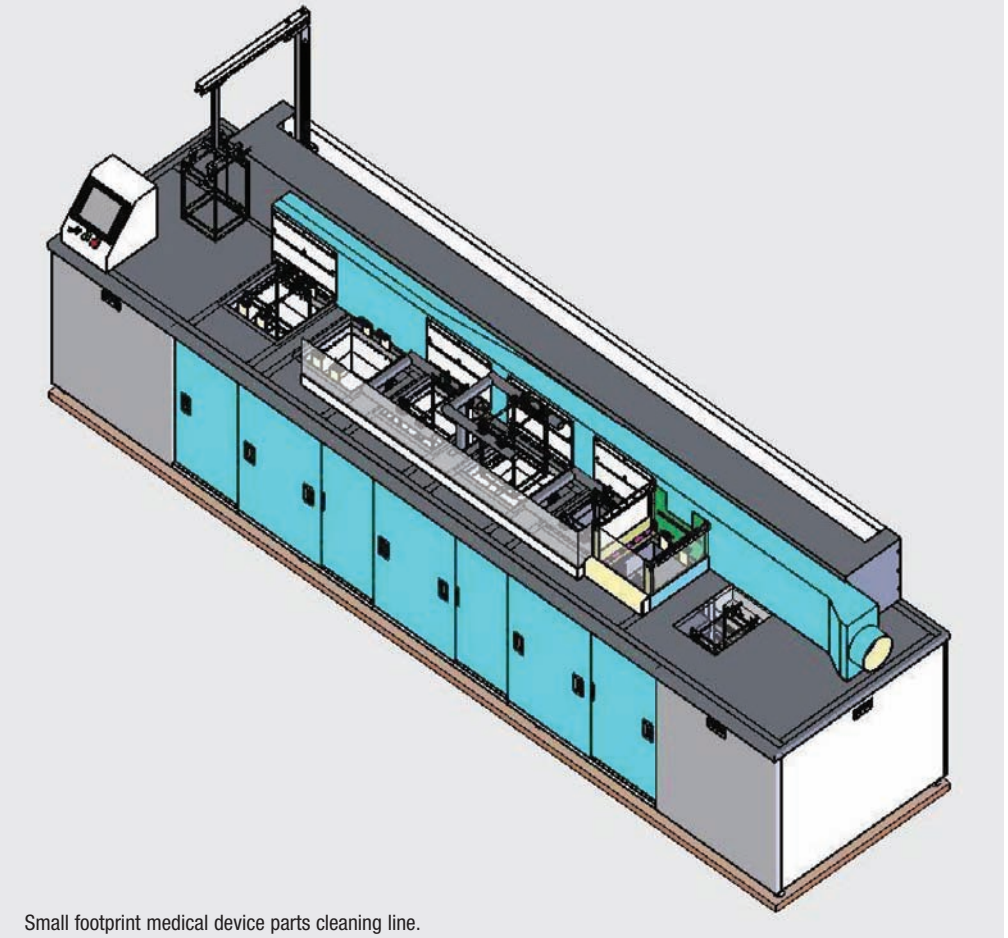
At the same time, water-based ultrasonic cleaning has come a long way in the last 10 to 15 years. Some of the improvements have been in ultrasonic technology itself. These include the introduction of power control to dial up or down the ultrasonic intensity to permit the cleaning of diverse substrates and soils. Higher ultrasonic frequencies have been perfected which create smaller cavitation bubbles that access tinier geometries. Multiple frequency generators have been introduced to vary the cavitation and improve performance through multiple levels of impingement.

But ultrasonics are only one dimension of the cleaning process. The real breakthroughs in production cleaning have come in putting a custom package together that looks at far more.

Customizing a Cleaning Process

Customizing a new cleaning process is a real opportunity to improve what you have. That means analyzing what the challenges and determining factors are and addressing them.[1] The challenges and determining factors in terms of defining any parts cleaning process include the following: part substrate, size and geometry; soil(s), process specifications (clean only, clean and passivate, stage clean, final clean, etc.), lot size (volume and weight) and lot integrity, throughput requirements (production goals) and cleanliness measurement (visual, particle count, bio-burden, etc.).

Many components of the system design are defined by an analysis of these factors. These include the size of the tank work areas (and therefore the heat and ultrasonic power required), the number of process steps (including the number of clean, rinse and dry stations required to meet cleanliness standards and production goals), the weight capacity of the hoist



Small footprint medical device parts cleaning line.

(and therefore the design), the chemistry that is most appropriate for effective soil removal on the substrates being cleaned and the fixturing of the parts to optimize cleaning time and performance.

Optimizing a Medical Device Cleaning Operation

Medical device cleaning has been an important area of customized cleaning line development over the past 10 years. Intermediate stage cleaning in implant manufacturing is one example of significant improvement, as was the case for one major manufacturer.

The challenge in this stage of this manufacturing process is the removal of buffing compound or rouge from stainless steel. Exacerbating the problem is that buffing compound hardens when it dries, so if cleaning is not immediate, it becomes even more challenging. Part cleanliness criteria may be no visible soil under magnification, particle count or the successful application of biocompatible coating.

The existing cleaning equipment in this case consisted of an ultrasonic cleaning tank powered with 40 kHz ultrasonics (the universal frequency) and heat. This was followed by two independent static rinses. The problem has been that the parts still require time-consuming hand-cleaning after they come out of the second rinse. There are traces of buffing compound and some white spotting. This is marginally acceptable when throughput is low and the cleaning that is happening is still better (quicker, less labor intensive) than trying to do the whole job by hand.

Even with the existing equipment, this process could be improved. The chemistry can be changed to one that is better designed to remove buffing compound. The cleaning tank can be filtered and sparged (surface skimmed) so that you're not pulling out clean parts through floating soils. The rinse water can be flowed. Since the parts won't corrode, the rinse water feed can be DI or purified water instead of city water to minimize or eliminate spotting. All of these are early steps in customization.

Taking the Next Step

However, demand is growing and production escalating. Skilled personnel and labor dollars are required to produce the parts, not clean them. At the same time, cleaning has become an important process that needs to be performed correctly the first time and monitored because the customer wants documentation. Tweaking this three-station starting point into a reliable and successful automated cleaning line requires process analysis, testing, development and implementation.

In this case, testing and experience has demonstrated that attaining the required level of cleanliness for this type of soil removal on a production scale requires two cleaning tanks. The first removes the gross soil and the second provides a more precision removal of the remaining contaminant. This is customization step one.

Tanks are sized to accommodate the largest required load based on lot integrity and throughput goals. More than one lot or order of parts can be processed in a load by using subdivided baskets or racks with multiple sides. Customized fixturing is a key to prevent masking or nesting of parts which will compromise cleaning, and also to minimize possible part damage during processing. When the parts geometry might trap significant solution, this might even include a rotating superstructure which integrates with the system automation and provides indexed rotation of fixtured parts in each process tank.

The customized, automated process is controlled by a PLC with a touch-screen operator interface. Process steps and times are programmed in and multiple programs are available. Process settings can be changed onsite via password protected screens. Programs can be selected via the touch-screen, or initiated with a bar code scan if the system is so-equipped. Out of specification performance can be alarmed and/or may halt process, depending on customers' requirements. In many cases, this level of process control honors the requirement for having a process specification in place and verifying the implementation of it. Where additional proof of monitoring is required, data can also be logged and stored in systems equipped with a PC and statistical process control.

The cleaning tanks are equipped with heat, filtration and sparging (surface skimming). For process control, in this case, the appropriate chemistry can be automatically monitored via conductivity and fed by an integrated pump system.

Custom medical cleaning line with ventilated enclosure.

Ultrasonics are matched in frequency and watt density to the part substrate and soil. Adding agitation has further improved results. In practice this combination of mechanical actions has cut cleaning time in half while also eliminating manual re-cleaning.

Rinsing is also critical and has been customized and optimized in a number of ways. Multiple rinses are recommended and at least three are preferred if the budget and space permit. Counterflowing or cascading some or all of the rinses reduces water consumption. Ultrasonics in one or more rinses can drive rinse water into complex part geometries, improving the opportunity for successful rinsing. The final rinse is typically heated to elevate part temperature to expedite subsequent drying, but the prior rinses may be ambient if the specification permits, which also reduces operating costs. Monitoring the final rinse with conductivity or resistivity can minimize water consumption and provide a process control to help measure and ensure rinsing efficiency and cleaning success.

Spray-off on the final rinse is sometimes indicated and is included on this line to assure that the last water that the parts encounter is the purest. Air blow off (with filtered air if required) expedites subsequent drying. In some larger work area applications, an oscillating air knife enhances blow off.

The dryer on this medical device cleaning line is a re-circulating hot air dryer which is equipped with an optional HEPA filter to meet particle count requirements. More than one dryer station may be indicated in higher throughput scenarios where drying time may become a bottleneck. Tunnel dryers can also be an alternative where space allows and might be an additional bonus in situations where moving the loads from point A to point B in the work cell is an advantage to the next step in the process.

Even on a line such as this that is equipped with a single re-circulating hot air dryer, a staged unload conveyor has proved to provide significant advantages. The parts retain heat coming out of the dryer and are too hot to handle for at least several minutes. The powered take away conveyor stages several loads in an ambient cool off zone. On similar lines in a final clean environment, the unload conveyor may be tunneled and equipped with HEPA filtration.

Adding Passivation and Other Processes

Multiple station cleaning lines can be customized to include nitric or citric passivation with the addition of two or more tanks. These would be the acid tank and at least one dragout rinse. ASTM A967 also suggests the option of a neutralization tank, which would then be followed ideally by another rinse. The chemistries can be automatically monitored and fed to minimize operator contact. Process steps and times are controlled and implemented by the system automation. Out of process conditions can again be programmed to alarm out or shut down the process, which is further assurance that parts have been handled according to the required specification.

Other processes such as copper sulfate, pickling, HF etch, etc.,

Customized implant stage cleaning line.

that might be required to meet customer specifications can also be accomplished, again with the addition of more tanks constructed to be compatible with the chemistry. Work with an experienced supplier when specifying equipment to handle hazardous chemicals. Not only the tank interiors but also the associated plumbing must be considered. One aerospace manufacturer recently shared a story of a multiple station cleaning, passivating and pickling line that had to be completely re-plumbed on the floor a couple of months after delivery when the plumbing, which was incompatible with the process chemistries, began to disintegrate on site.

Again, with these processes additional rinses, constructed of chemistry-appropriate materials, become part of the picture. Properly designed and sized exhaust systems are also an important component. Powered covers on tanks or system enclosures that are compatible with the particular chemistry can also be used to contain, minimize and manage vapors as well as humidity on customized lines.

Where There's a Will There's (Frequently) a Way

Principles of productivity and performance mean that a custom line can even be successfully designed for an outsource/job shop which doesn't know for sure what parts it will be processing next. New racks or baskets can be designed as new types of parts come along. Process times and programs can be altered. Chemistries can be changed. Tank liners can be added. Additional tanks can be powered with ultrasonics, or different frequencies can be implemented to achieve a different purpose. Agitation, spray, turbulation, rotation, blow off and other features can be incorporated.

A well designed cleaning line customized to the user's requirements can function successfully for years to come and may even evolve with the business model. An early automated medical device cleaning line still functions today, almost 24/7, more than 10 years later. Its second generation counterpart is a further customized line featuring more and different ultrasonics and sanitary plumbing. This second generation line is now cleaning new parts that were not even a gleam in an engineer's eye when the line was delivered a few years ago. This new cleaning application has been accomplished with new customized fixturing—everything else on the line is as specified when delivered. **pcm**

Notes

1. Brian Sutton, technical director of Miraclean® Ultrasonics, which partners with a number of industries to optimize and customize cleaning processes.