

















Automation Is Key to Medical Device Assembly

One hardly needs sophisticated market research to conclude that the global market for medical devices will continue to rise for the foreseeable future. One need only open a newspaper to read the latest data on the COVID-19 pandemic.

But, if you want to put a number on it... According to market research firm The Business Research Co., global sales of diagnostic products, dental equipment, ophthalmic devices, imaging equipment, cardiovascular devices, surgical equipment, orthopedic devices, patient monitoring devices, diabetes care devices, respiratory devices and other products totaled nearly \$456.9 billion in 2019, having increased at a compound annual growth rate (CAGR) of 4.4 percent since 2015. Thanks to COVID-19 and other factors, sales are expected to grow at a CAGR of 6.1 percent in subsequent years, topping \$603.5 billion in 2023.

As ever, North America remains the single largest market for medical devices, accounting for some 39 percent of global sales.

That rosy forecast is reflected in the data from ASSEMBLY's 25th annual Capital Equipment Spending Survey. Some 44 percent of medical device manufacturers will spend more on assembly technology this year than they did in 2020, while only 22 percent will spend less. In comparison, just 32 percent of all U.S. assembly plants will spend more in 2021, while 24 percent will spend less. Medical device manufacturers will spend, on average, \$637,857 on assembly technology this year, a substantial increase from the 2020 average of \$397,562.

It's a good bet that the lion's share of that money will be spent on automation. In this exclusive ebook from ASSEMBLY, you'll see how a variety of medical device assemblers have set about automating their assembly lines. Projects run the gamut from a manually fed, five-station robotic system for assembling sheaths for endoscopes, to a near lights-out system in which products go from raw resin to finished, sterile packages with almost no labor involved.

We hope the reports in this eBook provide inspiration for your own automation projects, and we urge you to challenge our sponsors to meet your automation needs.

John Sprovieri, chief editor, ASSEMBLY



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Automated Assembly of Medical Devices

Surgical instruments, airflow sensors and endoscopic sheaths are among the many medical devices produced on automated assembly systems.

John Sprovieri - Chief Editor

Disposable devices are essential components of every medical, dental and veterinary practice. Using disposables lowers costs, increases efficiency, and reduces the spread of infection.

According to market research firm Grand View Research, worldwide sales of disposable medical devices reached nearly \$248 billion in 2019. What's more, sales are expected to grow at a compound annual rate of 16.7 percent from 2020 to 2027.

Grand View attributes that growth to the increasing number of surgical procedures, the rising incidence of hospital-acquired infections, and, of course, the COVID-19 pandemic. A growing prevalence of chronic diseases, such as diabetes and



A pair of rotary indexing dials are used to assemble an actuation device for a surgical instrument. Photo courtesy Demco Automation.

cardiovascular diseases, is also expected to boost sales of disposables. For instance, according to the International Diabetes Federation, the number of people with diabetes is expected to increase from 366 million worldwide in 2011 to 552 million by 2030.

Catheters, syringes, inhalers, testing supplies and other disposables must be produced by the millions annually. Meeting that kind volume can only be accomplished with automation. As the examples below illustrate, systems integrators have designed and built some innovative machines for medical device assembly.

Surgical Device Produced on Rotary Indexers

Rotary indexing dials have been a mainstay of automation systems for decades. They are simple, inexpensive, fast, precise and reliable. What's more, they can assemble a lot of product in a relatively small footprint and with a minimal number of fixtures.

So, when a medical device company needed to assemble an actuation device for a surgical instrument, a pair of rotary indexing dials were just what

the doctor ordered.

The system was designed and built by **Demco Automation** of Quakertown,
PA. The project began with the Wedge, the company's standardized assembly platform.
The modular platform is available in one- and two-indexer versions. For the actuation de-

When a medical device company needed to assemble a part for a surgical instrument, two rotary indexers were just what the doctor ordered.

vice, the two-indexer machine was used.

"Two rotary indexing dials in one base machine enable processing in different nests and provide additional access for setup and maintenance," says Stephen Maund, Demco's president and CEO. "All the processes fit comfortably in a compact footprint."

For added flexibility and multitasking, the system is equipped with multiple SCARA robots and programmable pickand-place mechanisms.

The actuation device is approximately 0.5 inch in diameter

and 0.8 inch long. It consists of seven components, including injection-molded polycarbonate parts, synthetic rubber O-rings and a stainless steel cannula. A UV-cure adhesive and a silicone lubricant are also needed for the assembly.

The parts are supplied by standard vibratory bowl feeders, miniature step feeders and miniature vibratory bowl feeders. The latter are just 3 inches in diameter and were tooled by Demco.

Fiber-optic through-beam sensors and laser displacement sensors are used throughout the system to verify the size and presence of parts. Due to the small size of the assembly, a precision, dual-channel leak tester checks the integrity of the seals.

The system can assemble some 208 actuation devices per hour.
"The overall production rate is

actually much slower than other systems we have built, due to the extra time needed for curing the adhesive and leak testing the finished assemblies," Maund points out.

The actuation device has two variants. To accommodate each variant, one process station includes a SCARA robot fed by two bowl feeders, which are activated according to the product recipe. A vision system verifies that the right component is exiting the bowl in the right orientation. "The user enters work orders by scanning a bar code, and the system does the rest," says Maund.

One of the most challenging aspects of designing and building the assembly system had nothing to do with technology—it was a matter of space. "One challenge was the need to fit a system that has 24 stations through a set of standard double doors," Maund recalls. "Since our assembly platforms are very modular, we were able to configure the assembly process to fit within three sections: dial 1, hand-off and dial 2. By designing the machine framing to easily separate and reconnect accurately, the sections were disconnected, rolled into the clean room entrance, and reconnected."

A team effort, both internally and externally, was critical to the project's success. "Our technical team met with the customer on numerous occasions to discuss how best to design certain components with the primary goal to reduce risk and maximize success of the assembly process while maintaining product performance," says Maund. "For this application, there were features within an injection-molded component that were designed to improve automated feeding, orienting and gripping. We worked together with the customer's manufacturing engineers and product engineers in various locations across the U.S."

For more information, call Demco Automation at 888-419-3343 or visit <u>www.demcoautomation.com</u>.

Linear Indexers Assemble Test Cartridges

Diagnostic testing has changed radically in the past 20 years. At one time, physicians would have to send every specimen to a laboratory and wait hours or days to get test results. Now, in

many cases, they can simply place a few drops of blood, urine or other fluid into a disposable cartridge, insert it into a desktop analyzer, and get the results in minutes.

Rapid diagnostic tests are now available for blood glucose, blood gas and electrolytes, blood coagulation, cardiac markers, hemoglobin, cholesterol, drug screening, pregnancy testing, fecal occult blood analysis, food pathogens, and even infectious diseases, such as COVID-19 and HIV.

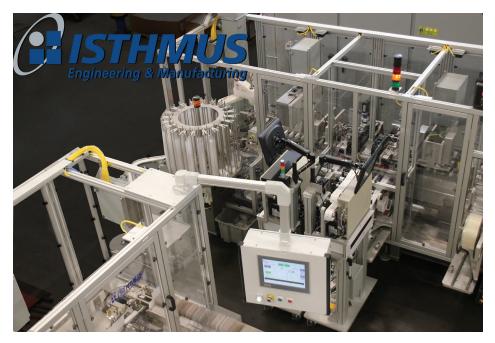
The system can assemble multiple SKUs with varying part geometry.

Systems integrator **Isthmus Engineering & Manufacturing** of Madison, WI, was recently asked to design and build an automated system to assemble disposable diagnostic test cartridges at a rate of 60 parts per minute. Each cartridge is approximately 1 inch wide, 4 inches long and 2 inches tall. The assembly consists of a cartridge body, liquid reagents, an elastomer seal, an ink-jet printed label, a product tray and a shipping case. The body, tray and case are made of injection-molded and extruded plastic.

Isthmus designed a system consisting of two precision link indexers with active tooling. To prevent contamination of the test materials, the system was designed to operate in a clean

room. Pharmaceutical-grade materials and components were necessary, and the system includes a restricted access barrier system with HEPA filtration.

Parts are supplied with vibratory bowls, staging carousels and flex feeders with vision-guided robots. The latter are used for some parts to minimize particulate generation in the clean room. The reagents are dispensed using precision peristaltic pumps. The system also includes equipment for ultrasonic welding, laser trimming and ink-jet printing. Inspection technologies include a vision system for optical character verification, precision balancers for weight verification, and ultrasonic fill-level sensors.



This system assembles 60 diagnostic test cartridges every minute. *Photo courtesy Isthmus Engineering & Manufacturing.*

The system can assemble multiple SKUs with varying part geometry, tray differences and liquid media. "Automatic changeover was incorporated for most variants," says Jake Birrenkott, an applications engineer at Isthmus. "This was accomplished using flexible motion control and universal fixtures and tooling."

The system presented some challenges, Birrenkott recalls. The reagents were not easy to dispense, and engineers needed to cope with some part-to-part variability. The machine had to meet strict targets for accuracy, throughput and overall equipment efficiency. It also needed to interface with the customer's MES software. Isthmus engineers also worked with the customer to develop a foil-sealing process for the assembly, optimizing key process parameters, such as sealing time and holding force.

For more information, call Isthmus Engineering at 608-512-1146 or visit <u>www.isthmuseng.com</u>.

System Assembles Airflow Sensors

Microbridge mass airflow sensors are used to measure the flow of air or gas in various medical and industrial applications.

The sensor operates on the theory of heat transfer. Gas is directed across the surface of the sensing element. Output voltage varies in proportion to the mass of air or other gas flowing through the inlet and outlet ports of the sensor's housing, which is designed to precisely control the flow of gas across the sensing element. The sensor is designed so that it can be easily mounted to a printed circuit board.

In medical devices, the sensors are used in continuous positive airway pressure equipment, sleep apnea monitors, nebulizers, spirometers, and oxygen conservers and concentrators. In industrial applications, they are used for variable air volume damper control, fuel-to-air ratio sensing, leak detection, and clogged filter detection.

Systems integrator **Genesis Automation Inc.** of St. Charles, IL, was recently contracted to design and build an automated system to assemble and test these sensors at a rate of 500 parts per hour. The Genesis team designed a modular, conveyor-based system with multiple secondary part-handling systems, including a custom-built epoxy curing oven and a multistation rotary indexing dial.

The sensor measures 0.5 inch tall, 1 inch wide and 1.25 inches long. It consists of five parts: a plastic body, an epoxy adhesive, a thick-film ceramic substrate, a metal lead-frame strip, and a plastic dust cap. An extruded plastic shipping tube, in three variations, also had to be handled.

The system is designed to run several variants of the sensor. "Recipes selected on the HMI automatically set the system for the intended part," explains Adam Gustafson, applications engineer at Genesis. "There are three distinct product housings with different mounting and geometric features. All part nests and

A vision-guided robot picks and places parts.

tooling were designed to be compatible with the different part designs, which avoids the need for changing out the tooling when switching from one design to another. We also designed the system to accommodate future part variations in the series."

Vibratory bowl and inline feeders are used to feed the body and dust cap. A magazine unloader feeds a matrix of ceramic substrates into machine. An edge-belt conveyor receives the substrates and introduces them to a station where they are cut into individual pieces. The metal leads are supplied on a reel, and the shipping tubes are fed with a custom-made vertical magazine.

A servo-controlled Cartesian robot equipped with a positive-displacement valve dispenses the epoxy, which bonds the ceramic substrate to the plastic body. A vision-guided Cartesian robot picks and places ceramic substrates onto one of three different tube bodies. The leads are press-fit, then soldered onto the ceramic substrate using a micro-flame. The dust caps are press-fit onto the sensor body. At the end of the line, completed sensor assemblies are loaded into the shipping tubes.

The system includes a variety of test and inspection technologies. For example, an electrical test verifies the functionality of the ceramic substrate prior to assembly. Leak and flow tests are performed on each finished assembly. And, machine vision is used:

- to inspect the width, position and continuity of the bead of epoxy.
- to inspect singulated ceramic substrates to ensure they are the correct shape and free from cracks, chips and burrs.

ASSEMBLY AUTOMATED ASSEMBLY OF MEDICAL DEVICES



This modular system assembles airflow sensors at a rate of 500 parts per hour. Photo courtesy Genesis Automation.

- to inspect the leads for presence, position and profile after completion of the pressing, soldering and singulation operations.
- to inspect the solder joints.
- to verify that the dust caps have been properly installed.

All final assemblies that pass inspection and test criteria are laser-marked for tracking and quality control purposes.

The most challenging aspect of designing and building the system was developing the process for soldering the leads to the

ceramic substrate. "This required considerable process development time to optimize the chemistry and temperature for a good solder joint," says Gustafson. "We also provided input regarding the content and type of solder flux to use on leads."

Another challenge was how to control the ceramic dust and debris generated when the ceramic matrix was cut into individual substrates. "We solved that problem by designing a down-draft exhaust system to contain the dust," says Gustafson. "We also gave input regarding the geometry of the

ASSEMBLY AUTOMATED ASSEMBLY OF MEDICAL DEVICES

perforations to use on the matrix of thin-film ceramic substrates to provide clean edges during singulation."

The system meets FDA requirements for CFR21 Part 11 and Current Good Manufacturing Practices. The system's control software also includes Pareto analysis to support the customer's Industry 4.0 initiatives.

For more information, call Genesis Automation at 630-587-0444 or visit <u>www.genesisautomation.com</u>.

System Assembles Sheaths for Endoscopes

The endoscope has revolutionized the diagnosis and treatment of cancer, ulcers, knee injuries and other medical problems.

During endoscopic surgery the surgeon inserts a thin, flexible tube with a video camera through a small incision or a natural orifice, like the mouth or nostrils. The tube has a channel for tiny surgical instruments, which the surgeon uses while viewing the organs on a computer monitor. This technique allows the surgeon to see inside the patient's body and operate through a much smaller incision than would otherwise be required with traditional open surgery.

The benefits of endoscopic surgical procedures include:

- Small incisions, few incisions, or no incision.
- Less pain.
- · Low risk of infection.
- Short hospital stay.
- Quick recovery time.
- Less scarring.
- Reduced blood loss.



RND Automation designed and built this rotary indexing machine to assemble covers for endoscopic cameras. It assembles approximately four covers per minute. *Photo courtesy RND Automation.*

Given the benefits, it's no surprise that more than 75 million endoscopies are performed each year in the United States. Endoscopic instruments are typically cleaned and sterilized for reuse, so the "business end" is covered by a flexible, disposable cover. Millions of these covers must be produced annually. The only way to meet that kind of demand is through automation.

Recently, **RND Automation**, a systems integrator in Lakewood Ranch, FL, was commissioned to design and build a machine to assemble covers for endoscopic cameras. The cover

The sheaths are fed manually, but robots handle everything else.

consists of three parts: a plastic connector, a flexible Mylar sheath, and a crystal lens. Each cover is 4 millimeters in diameter and ranges from 300 to 400 millimeters long.

RND engineers designed a rotary dial indexing system that glues, cures, inspects, leak tests, and packages the covers. The machine assembles approximately four covers per minute.

Due to the flexible nature of the product, the parts are loaded manually onto a mandrel. At the next station, dispensing valves with needle tips apply a bead of medical-grade UV-cure adhesive around the base of the connector and the tip of the sheath. The valves are mounted to linear actuators that extend and retract. The mandrel rotates as adhesive is applied.

"The challenge on this system was consistent and correct placement of the adhesive," says Sean Dotson, president and CEO of RND Automation, a certified integrator for FANUC, Epson and Universal Robots. "By using a wicking tip, we were able to get the correct amount of adhesive on the part."

At the next station, a UV lamp cures the adhesive. Again, the mandrel rotates to ensure the adhesive is cured evenly. At the fourth station, a machine vision system mounted on a linear slide inspects the bonded joints at each end. LEDs

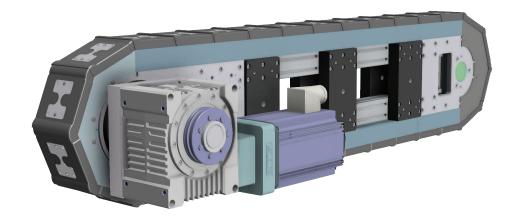
provide backlighting to highlight potential defects. Here, too, the mandrel rotates so the vision system can inspect the entire joint line.

At the last station, a FANUC LR Mate six-axis robot unloads the finished covers, inserts them into a leak test instrument. Good assemblies are loaded into thermoformed trays. Faulty assemblies are placed in a bin. Full trays are conveyed out of the system.

The system can produce 10 different SKUs. By changing out the tooling mandrel, multiple cover sizes can be run. The recipe is changed on the HMI, and the rest of the machine adjusts automatically.

To see a video of the system in action, click <u>www.youtube.</u> com/watch?v=2zTPueNHztM.

For more information, call RND Automation at 941-870-5400 or visit <u>www.rndautomation.com</u>.



Motion Index Drives provides practical experience to design and build high speed automated systems specifically for the medical equipment manufacturing sector. Motion Index Drives line of precision link conveyors are built to be the heart of a linear manufacturing machine requiring high accuracy, speed, and quality. The precision link conveyor is designed to have an automation process done on it from start to finish. The conveyor indexes a precise stroke (from a few millimeters to a meter). After the indexing is done, equipment mounted around the conveyor performs a function to a product not just at one location, but at multiple locations along the entire length of the conveyor. This requires high accuracy, which is a very important aspect of medical manufacturing. Motion Index Drives conveyors deliver very high accuracies of +/-0.06mm (+/-0.002") at each and every link position.

Every link is checked for accuracy by testing each LFA and LFAS model <u>precision link indexing conveyor</u> that is shipped. Our <u>custom engineered measurement</u> system developed



MOTION INDEX DRIVES

specifically for our precision link indexing conveyor takes measurements for an entire 24 hour period and automatically documents this into an electronic Excel report. By numbering each link, we can easily pinpoint any accuracies that fall out of the guaranteed measurement range. When this occurs, we can simply remove the link that has accuracy problems and re-test with a new link to validate its accuracy.

The MID precision link conveyor is manufactured with an inner structure manufactured from aluminum extrusion. The aluminum extrusions allows for extremely long lengths that are straight and rigid while also being extremely friendly to mount accessories and customized options. Mounted to the central framework is the link track. The conveyor makes the track out of steel, where it is machined, hardened, and ground. The links in the conveyor are made of a very high grade aluminum. Aluminum links have many benefits including having a third the mass of steel, thus a third the internal inertia of steel links. This allows for very high speed of indexing and for the drive unit to be smaller and/or allows the customers tooling to be heavier without having to oversize the drive unit or jeopardize index time. Each link contains 4 sealed cam followers that are lubed

for life. These are pressed into needle bearings at the joints of the links so there is no wear or moving parts contacting the aluminum links themselves.

How important is it to commission programmable units correctly?

There are many ways to get to a specific indexing time when controlling a servo motor or AC motor with encoder. The most common mistake and the costliest is failing to adhere to manufacturers' recommended movement profile. Over 95% of failures are due to extremely aggressive accelerations and/or decelerations programmed into drives when trying to get to a desired process time. Yes, this is industrial equipment; however, servo motors have a tremendous amount of startup torque and sometimes very strong mechanical brakes. The amount of force on the mechanical components increases exponentially if done incorrectly. If you program a servo motor and drive too aggressively and put 5 times or more force than the system was sized for, there will be a premature failure.

Options

The fixed mechanical option would utilize a rotary cam indexer or a parallel cam indexer to achieve a predetermined linear stroke. The cam profile used in either type of indexer will provide a smooth acceleration and deceleration as well as a mechanical locking dwell at the end of the stroke. This option will allow you to operate the indexing conveyor with a simple VFD or contactors to control the motor. The VFD would

be held at a constant Hz and be treated like a contactor. Commissioning time when using the fixed indexer for your operation will be the quickest and most cost-effective option. The limitation is that the system has a predetermined stroke that cannot be changed as it is controlled by the "Fixed" indexer unless you change to a more flexible option. If a change is required to go to a more flexible solution the entire chassis can be repurposed and a programmable transmission device can be installed in its place with a few minor changes to adapt the new programmable mechanism.

Servo Indexer

The similarity to the fixed indexer is that they both use "Zero Backlash" cam technology. The difference is the servo indexer uses a constant lead cam, absent of any modified sine profile that you will have in the fixed cam indexer. The benefit to this system is its flexibility to change the stroke length by changing the VFD program that is controlling the motor. With the cam system operating under pre-load conditions (cam and cam followers), the RT programmable series can achieve single digit arc seconds of accuracy. The RT series can be adapted to accept almost any type of servo motor brand or AC motor equipped with an absolute encoder. All the positioning with the programmable RT indexer is based on encoder counts, which relies on higher end drives to control the movement. Commissioning time and cost is based on how experienced the controls engineer is that will be performing this task.

Low Backlash Gear Reducer

The similarity between the servo indexer option and the low backlash gear reducer is that both need a servo motor or AC motor with brake to control the movement profile to achieve the necessary stroke between each process. Both can be adapted to accept most servo and AC motor brands. With bypassing the RT series servo indexer, you will be compromising some accuracy overall. Typically, the low backlash gear reducers used on these linear indexing systems have less than 1 arc minute of backlash and still maintain a very high accuracy. These low backlash gear reducers are used quite often on LFA linear precision conveyors that require flexibility. One major advantage over the RT servo cam indexer option is that higher indexing speeds can be achieved, because you do not have to go through a second reduction of the cam/cam follower mechanism. The RT series servo system can get much higher accuracy, but is limited on the RPM that the internal barrel cam can turn. Commissioning time is the same as what is experienced with the servo indexer option.



Direct Drive

A major advantage to using the direct drive option is the ability to achieve both really high accuracy and fast indexing speeds. The LFA precision conveyor systems can be equipped with dual direct drive motors to optimize the performance, mostly to achieve higher speeds. This option of direct drive system is the most expensive option of the four and most time consuming and difficulty to integrate. The direct drive system takes a very experienced controls engineer to implement and make sure it is operating correctly to not cause mechanical failures of the linear indexing system.

Motion Index Drives precision link conveyors are no maintenance and all mechanical components in oil are sealed as a standard. We can customize our products to comply with Clean Room specifications whether it be steel plating, special coatings, or having your unit completely sealed to eliminate intrusions.

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PRECISION LINK CONVEYORS and MEDICAL MANUFACTURING





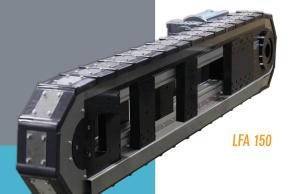


Motion Index Drives precision link indexing conveyors are manufactured with high grade aluminum links to accomplish high accuracy and precise solutions. MID conveyors have half of the internal inertia of our competitors, allowing for faster index times. All of our conveyors are custom made to your application.

- Positional Accuracy of +/-0.07mm (+/-0.003")
- Repeatability of +/-0.04mm (+/-0.0015")
- Fast Index Times
- High Grade Aluminum
- Maintenance Free
- Clean Room Ready



LFA 100





Merit includes manufacturing engineers on product development teams. "[They] provide valuable insight into design for manufacturability," says Peterson. Photo courtesy Merit Medical Systems.

Automation Helps Medical Device Maker Compete

John Sprovieri - Chief Editor

ASSEMBLY AUTOMATION HELPS MEDICAL DEVICE MAKER COMPETE

Merit Medical Systems Inc. is a leading manufacturer of disposable medical devices used in interventional, diagnostic and therapeutic procedures, particularly in cardiology, radiology, oncology, critical care and endoscopy.

Founded in 1987, Merit initially focused on injection- and insertmolding of plastics and electronic and sensor-based technologies. The company's first product was a specialized control syringe for injecting contrast solution into a patient's arteries for a diagnostic cardiac procedure called an angiogram.

Today, Merit offers more than 20,000 products in 120 families. Headquartered in South Jordan, UT, the company employs more than 5,700 people worldwide and operates packaging and manufacturing facilities in West Jordan, UT; Chester, VA; Malvern, PA; Pearland, TX; Galway, Ireland; Joinville, Brazil; Melbourne, Australia; Paris, France; Singapore; Tijuana, Mexico; and Venlo, The Netherlands.

Neil Peterson, Merit's vice president of operations, has had a front-row seat for much of the company's explosive growth. When he joined Merit as a manufacturing engineer in 1994, the company tallied \$30 million in sales. The company rang up nearly \$995 million in sales in 2019, and it could be a billion-dollar company in 2020.

In November 2019, Merit Medical earned a Manufacturer of the Year Award from the Utah Manufacturers Association. The award recognizes manufacturers that demonstrate expertise and outstanding business practices as well as contribute to the communities where they do business.

We sat down with Peterson to talk about medical device manufacturing, automation and century-long business plans.





ASSEMBLY: In a recent interview, Merit's CEO, Fred Lampropoulos, said the company has a 100-year business plan. Does that influence how you invest in manufacturing technology?

Peterson: Fred is a very forward-looking leader, which has served us well. This year, we're on pace for 24 percent growth on our top line. Last year, it was 20 percent. At those growth rates, it's good to have somebody leading the ship who is looking that far ahead, because things can get out of hand quickly if you don't.

We've always been good about investing profits back into the company, whether it's acquiring new buildings, automation or other companies. Fred encourages us to look at new technologies and to invest in automation—especially here in South Jordan. Automation has allowed us to be more efficient and cost-effective in every aspect of the business, from processing raw materials through to assembly, packaging and shipping.

We have a highly automated system for shipping finished goods. The system cost more than \$6 million, and it allows us to automatically pick products from our warehouse, as opposed to operators going out and getting the products.

We've also automated raw material handling. For example, we have 61 injection molding machines here that run 24/7 in clean rooms. When a batch of parts is finished and accepted, those totes—and there could be 10 or 20—get placed on a conveyor, which automatically transfers them to a warehouse 500 yards away. The system reads a bar code on the totes—recording the part number, lot number and quantity—and stores them automatically. I don't need to have anyone touch them.

There are 22,000 tote locations in our raw material parts inventory. When we get an order for finished assemblies, we scan a bar code on the bill of materials, and the system automatically retrieves what's needed, taking the oldest lots first. An operator consolidates the parts into a large bin and delivers all the parts to the assembly line.

We have products that go from resin to finished, sterile packages with almost no labor involved. If we are going to compete on quality and price, we need automation.

ASSEMBLY: You produce a variety of products each day. How does that affect how your assembly systems are designed?

Peterson: We're always adding new products to our

portfolio. When we introduce a product, the sales volume is typically low, so we usually start with a manual assembly process. As volume increases, we'll do a return-on-investment analysis. We're spending this much on labor. We can spend this much on automation. If the return on investment is good enough, we'll automate. Many of our assembly lines evolve from manual, to semiautomatic, to fully automatic processes over time. By the time a line becomes a fully automatic process, the equipment is very specific to that product. It's not equipment that will run whatever you want.

ASSEMBLY: When you need automation, do you use a systems integrator or do you build it in-house?

Peterson: We have a team of automation engineers here who are very good at designing and building automation. Our projects range from a \$1,000 desktop fixture to a small, \$200,000 assembly machine. That's our wheelhouse.

When you start getting into \$2 million automated lines, we don't have enough people to design and build such systems in a reasonable amount of time. At that point, we'll hire an integrator. But, we work very closely with the integrator on specifications, design reviews and acceptance testing.

ASSEMBLY: According to your annual report, when Merit likes an idea for a new product, it assembles a project team comprised of individuals from sales, marketing, engineering, manufacturing, legal and quality assurance. Why is it important for manufacturing to be at the table?



Many of Merit's assembly lines evolve from manual, to semiautomatic, to fully automatic processes over time. Photo courtesy Merit Medical Systems.

Peterson: It's critical for manufacturing to be involved.

When we have an idea for a new product, the team asks several questions. Does it serve a medical need? Is it a business that Merit wants to be in? Can we manufacture it at a low-enough cost that we can sell it for a profit? That last question is a very big hurdle to get over. You can have an idea for a great new product, but if it costs \$1,000 to make, and the market is only willing to pay \$100 for it, then it's a nonstarter.

Our manufacturing engineers can provide valuable insight into design for manufacturability. Often, the people who design a new product don't understand automation. For example, they may not know how to feed and orient parts reliably for

automation. But, as a product moves from manual to automated assembly, you don't want to have to redesign all the parts from scratch. One mold can cost \$300,000, so you don't want to spend that more than once.

ASSEMBLY: What's the most challenging aspect of making a catheter?

Peterson: Catheters are tricky and difficult to automate. You've got a slender tube that might be 4 feet long, and it's hard to handle. The coating and finishing processes are automated, but there's a lot of manual assembly: loading and unloading fixtures; bonding hubs; and shaping the tips.

In this case, the goal is to design the process to be as repeatable and efficient as possible. Lines are laid out for singlepiece flow, and each process step has been optimized.

ASSEMBLY: What assembly technologies have made a big impact on your operations?

Peterson: Lasers have come a long way. We're now using lasers to mark parts instead of pad printing. Working with ink is slow, and changeovers take a long time. Lasers are very quick. There's no changeover time, cleanup or fumes. We're also using lasers to drill holes in catheters.

Vision systems have also come a long way. For example, we use vision to inspect every needle we make—and we make approximately 8 million needles a year! If that needle tip is not perfectly sharp, the vision system will identify it and reject it. Ten years ago, when we were inspecting needles manually, we

used to get 30 complaints per month for damaged needle tips. Now, we might get one a year.

ASSEMBLY: What manufacturing challenges do you expect in the future?

Peterson: Our biggest challenge today is a shortage of labor. We've had to move some manufacturing to Tijuana out of necessity. These are products that involve a lot of manual labor and are difficult to automate.

Another challenge we've experienced in the past five to 10 years has been obsolescence of raw materials. Most of our products are made from molded or extruded plastic, such as polycarbonate, ABS or nylon. It can take 14 months to two years to validate a new material for a medical device. That includes process validation, design validation, biocompatibility testing and approval by regulatory agencies. That's not just the FDA, but anywhere we want to sell our product—Europe, Japan, China or Korea.

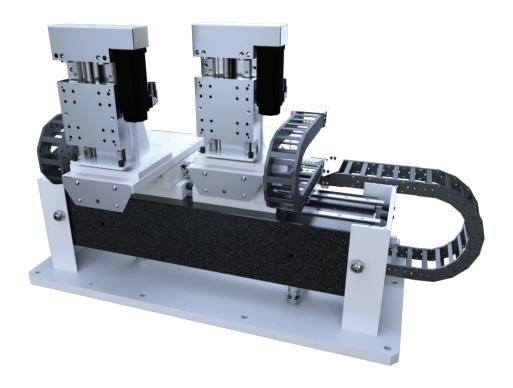
In the past few years, we've been getting more and more notifications that a material we've been using is no longer available or has been changed. That has placed a large strain on my engineering resources to identify and validate replacement materials. Compatibility testing alone can cost \$100,000.

As a result, we've learned to be very careful about which suppliers we work with and what resins we use.

"We have products that go from resin to a finished package with almost no labor involved."—Neil Peterson, Merit Medical Systems

WEISS Delivers Value & Efficiency to Medical & Life Sciences





At <u>WEISS North America</u>, our solutions satisfy the needs of many different industries. When it comes to the Medical and Life Sciences industries, WEISS manufactures high-performance motion control solutions using our standard product offering and our team of automation professionals works closely with our customers to produce a solution that satisfies the demands of their particular application.

In medical design and life science manufacturing there are many unforeseen factors that can impact the day to day activities or overall decision-making process. We are all living through this right now with the global impact of the Covid-19 virus – making it more and more difficult for all of us to meet the market demand and supply an accurate forecast. The demand for solutions to be delivered with an expedited timeline is one of these factors.

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WEISS North America has always taken pride in the quality of our product and customer service. We know that response time is critical in order to meet the demand of the market and the demand of our customers. With this in mind, we work diligently with our customers to produce a fully tested and validated system that will minimize their risk and lower their overall cost of integration. By WEISS inheriting some of the risk, it allows our customers to put more focus where it is needed, thereby completing the project more efficiently and quickly satisfying the market's critical demand.

Syringe production, laboratory automation, microscopy, highly-accurate dispensing applications used in conjunction with a vision system, medical consumables such as mask production, and various systems configured for diagnostic testing are all examples of applications where WEISS has been successful in providing a comprehensive subsystem that integrates perfectly with the customer's assembly or manufacturing machine.

In one such example, one of our customers contacted us to provide immediate support in the development of an assembly system used in the manufacture of SARS-CoV-2 virus testing kits. Due to the outbreak of COVID-19, our customer was required to design and build the system within eight weeks. "When the request came in for the machine to be ready in eight weeks, I immediately thought this is crazy," remarked one of our customer's project leads. "We can't build a machine in eight weeks. But then my next thought was... there has to be a way to do it." That is when they turned to WEISS North America.



ASSEMBLY WEISS

"At WEISS, when a customer expresses a need for quick turnaround, no matter the situation, we want to meet the requirement," said Josh Treter, WEISS North America's General Manager. "In this case, it was that much more rewarding to know that assisting at an expedited pace would, in the end, provide information to many people to help alleviate the problems caused by the pandemic." It took WEISS just sixteen days to understand the specific requirements of the application, specify the components, develop the control packages and ship the order to the customer, who integrated the WEISS components into their assembly system.

Each system utilizes six high-speed and highly accurate WEISS HP140 pick and place units with varying horizontal and vertical stroke, as well as process-specific control packages. Each HP140 unit and control package performs a unique function within the assembly system throughout the production process, such as precisely picking and placing the various plastic wafers, fiber membranes, vials and other components that make up the test kits. "Paired with our automatic lubrication

When a customer expresses a need for quick turnaround, no matter the situation, we want to meet the requirement.

— Josh Treter, General Manager, WEISS North America



units, these maintenance free handling systems are capable of the low duty cycle/high throughput requirement that is needed to produce millions of test kits per month.", says Treter.

The typical timeframe for building and delivering a 60-foot machine that is capable of producing 6,000 units per hour is 35 weeks. With the help of WEISS North America, our customer was able to compress that into an 8-week timeframe. Being able to meet the high demand of this project and its unimaginable lead-time requirements would have been impossible without tremendous effort and cooperation between everyone involved. "Our business model was strong prior to the pandemic, but I think there are always efficiencies to improve upon," says Treter. "Taking the time to step back and operate differently out of necessity has opened our eyes to different ways of thinking that, in normal times, we wouldn't have

experienced. Because of this, our model going forward can only become stronger."

Another recent example of our work within the Medical and Life Science industries is in the area of blood sensors. A WEISS precision linear system with a granite substructure was developed and integrated into a larger system. This system is used during the dispensing process in the production of blood sensors. Using the stable granite substructure enables the system to achieve optimal rigidity across multiple axes and ultimately achieve position steps of 1 µm. Standard linear axes are combined with one another for the assembly and alignment system and supplemented with a rotary unit for rotary alignment. Communication between the higher-level PLC and axis systems takes place via a WEISS control package with its own software and a



specially adapted protocol. The combination of high-precision axis systems on the granite substructure achieves optimal rigidity in order to carry out the required small increments for the camera-controlled positioning.

WEISS can customize systems to meet virtually every need or we can use our standard platforms, including linear motors, torque motors, highly-accurate and robust delta robots, MK cross tables, our linear transfer system and, of course, our high-quality index tables. Using our standard, proven solutions limits your risk and decreases your overall cost of integration while providing you with ease of use and programmability when used with our WEISS Application Software (W.A.S. 2).

An integral part of the Weiss global network and leaders in rotary and linear motion automation solutions, WEISS North America, Inc. (ISO-9001 Certified) manufacturers high-quality cam-, servo-, and linear motor-driven automation components and solutions. WEISS supplies rotary index tables, palletized conveyors, linear motor-driven pick-and-place units, cam- and servo-driven assembly chassis, ring index tables, machine bases and tool plates. WEISS leverages over 50 years of reliable global expertise to comprise an integrative, customer-specific approach to deliver innovative solutions that enable our customers to be more efficient, effective, and competitive.

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This feeding system delivers a small tungsten shaft for a tool to assemble pacemakers. Photo courtesy West Coast Vibratory Feeders.

Feeders for Medical Device Assembly

Medical device manufacturers have many options for feeding parts in automated assembly systems.

John Sprovieri - Chief Editor

Medical devices pose a special challenge to designers of parts feeding equipment. Parts for such devices can be tiny, sharp, clingy, floppy, tangly—or some combination of those properties. To make matters worse, feeding systems must be easily cleanable, compatible with clean rooms, and relatively quiet. Piece of cake, right?

In fact, as the examples below illustrate, suppliers of parts feeding equipment have developed some ingenious ways to solve such challenges.

Bowls Feed Vials for Fluid Samples

Due to the COVID-19 pandemic, a manufacturer of diagnostic testing supplies needed to dramatically increase production of fluid collection vials. So, the OEM called the integrator that designed and built its vial assembly and packaging line. Could eight new parts feeding systems be added to the line? Of course, said the integrator.

Although the feeders would have to be rushed into production, the integrator could not afford any problems with feed rates, misoriented parts or sanitation. Human hands could not touch the vials throughout the entire feeding and packaging process. The integrator called **Fortville Feeders Inc.** in Fortville, IN, for help.

Fortville designed eight feeding systems that are completely contained within a medical-grade stainless steel enclosure. The feeders are built from 316 stainless steel, instead of the more common 304 stainless steel. Fortville uses 316 stainless steel for all of its medical-grade feeders, because that alloy contains molybdenum for extra corrosion resistance against the chlorides used to clean and disinfect production equipment for medical devices. Since Fortville stocks the higher grade of stainless steel, the lead time for manufacturing the feeders was significantly shorter. Fortville also has the testing capabilities that many medical device manufacturers require to prove conformity to the 316 standard.

Lexan doors and windows in the top of each unit allow operators to monitor the progress of the parts without contaminating the sterilized area. These doors are framed in an extruded aluminum casing that is equipped with a plastic seal

to keep airborne contaminants from settling in the grooves of the frame. When the bowls are empty or the feeders must be sterilized, the doors can be lifted for quick access to the bowls and tracks.

Each system accurately moves a variety of vials at a high rate of speed. Fortville's engineers had to consider the various products that needed to be fed and design the bowls for maximum flexibility. For instance, one feeder system handles six different vials, all with slightly different geometry. All the vials are fed with caps intact. Some caps are cylindrical; some are designed with flat gripper sides. The bodies of the vials also differ in size and shape.

The OEM was able to integrate the feeders into its assembly automation and put the eight lines into service without any problems. All specifications were met, and each feeder works cohesively with the existing automation.

For more information, call Fortville at 317-485-5195 or visit <u>www.fortvillefeeders.com</u>.

Feeder Helps Device Maker Keep Pace

A pacemaker is an implantable medical device that uses electrical pulses to regulate the heart. They are life-saving devices for people with certain cardiac conditions, such as arrhythmia, congenital heart disease and deterioration of the heart muscle from age.

More than 1.25 million pacemakers were implanted worldwide in 2019, and that number is expected to increase to 1.43 million by 2023.



These enclosed feeders supply fluid-collection vials to an automated packaging system. Photo courtesy Fortville Feeders Inc.

West Coast Vibratory Feeders of Corona, CA, was recently asked to design and build a vibratory bowl to feed a small metal shaft for a tool used to assemble pacemakers. Made from tungsten, the shaft is just 0.8 inch long and 0.05 inch in diameter, with a 0.065-inch diameter head. In the assembly system, a gripper would pick up the shaft and move it to another position where it would be press-fit into a plastic head.

The shaft had to be presented in the hanging position, in single file, at a rate of 80 parts per minute.

"Designing a bowl to feed this part was relatively simple, but building it to medical grade standards was difficult," says Sean Wilcox, president of West Coast Vibratory Feeders. The bowl is constructed from 316 stainless steel. All joints are TIG welded top and bottom, and all the weld seems are polished. Stainless steel hardware is used throughout the bowl.

All steel components on the drive unit are powder coated. "Some shops simply use spray paint, which can easily scratch and cause rust to be present in a clean room environment," says Wilcox.

"What really sets us apart is that we polish our bowls to a mirror finish," he continues. "This removes any scratches that can accumulate bacteria. Once the build is completed, we send the bowl to get passivated and electropolished to further remove any impurities that may exist in the stainless steel. The use of sanding tools and polishers can impregnate the stainless with contaminants, and electropolishing gives the bowl a final clean surface."

For more information, call West Coast Vibratory Feeders at 951-582-9386 or visit <u>www.westcoastvibratoryfeeders.com</u>.

Centrifugal System Feeds Parts at High Speed

Vibratory bowl feeders are not the only way to feed parts. One alternative is the centrifugal feeder. This type of feeder is comprised of a rotating center disc mounted on an angle and a horizontally mounted rotating bowl. The disc and the bowl rotate independently of each other at variable speeds. At its highest point, the edge of the disc is slightly higher than the running surface of the bowl, which enables the parts to load.

These feeders do not use vibration to singulate and orient parts. Instead, they rely on centrifugal force. Parts drop onto

the rotating disc, and centrifugal force whisks them to the periphery of the circle, where they encounter mechanical and pneumatic tooling designed to capture parts that are correctly oriented and reject parts that are not.

Centrifugal feeders are fast. Depending on the part, feed rates of more than 800 parts per minute are possible. Compared with vibratory bowl feeders, centrifugal feeders are quieter and gentler on parts, since there is less part circulation. The less that parts circulate, the fewer scuffs or surface imperfections that result from part-to-part contact.

Centrifugal feeders work best with flat round parts, such as bottle caps and bearing rings, and cylindrical parts, such as rollers.

Performance Feeders Inc. of Oldsmar, FL, recently designed and built a centrifugal system to feed a cylindrical part for a medical device at rate of more than 800 parts per minute. Featuring a vertical elevating prefeeder and high-speed gravity roller tracks, the system was developed to run 24/7 in a continuous production environment, while fitting in the smallest footprint possible and preserving the integrity of the parts being fed.

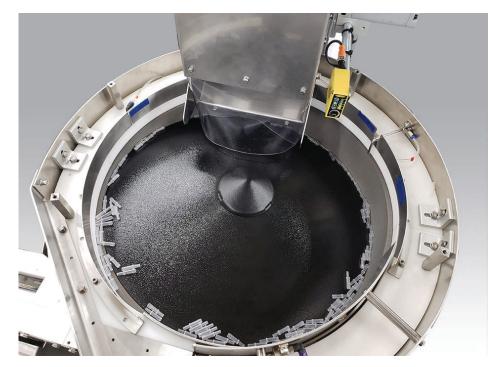
The prefeeder meters the parts into the centrifugal feeder. A level sensor signals the prefeeder to turn off when the bowl is full. The prefeeder's hopper enables an operator to load parts at an ergonomic height.

Measuring 20 inches in diameter, the centrifugal feeder rotates clockwise and pre-orients the parts end to end, in random fashion, using mechanical sweeps and air jets. The parts are then discharged from the feeder to high-speed gravity roller tracks,

which perform the final orientation of the parts. The exterior of the system is constructed from stainless steel. The bowl itself is made from anodized aluminum with a Teflon hard-coat.

Various sensors control the speed of the system, allowing the feeder to speed up or slow down based on the amount of parts in the processing queue. A glass fiber sensor array monitors the amount of parts in the roller track to prevent them from backing up into the bowl.

For more information, call Performance Feeders at 813-855-2685 or visit <u>www.performancefeeders.com</u>.



This centrifugal feeder supplies a cylindrical part for a medical device at rate of more than 800 parts per minute. *Photo courtesy Performance Feeders Inc.*

Strategic Technology Innovations for Improved Manufacturing Productivity

More advanced technology equals higher workforce productivity—this is the simple equation that drives enterprise strategy for many manufacturing leaders. But technology and productivity do not always increase in direct correlation with one another. Instead, it is only by strategically investing in the right technology solutions that manufacturers can ensure effective productivity gains for their workforce.

With technology refresh cycles renewing rapidly at a pace of only 4 to 5 years, manufacturers need to understand how best to keep pace with the adoption of strategic solutions that will result in long-term, factory-wide productivity benefits. **Let's discover how.**



Staying on Top of Manufacturing Technology Trends

Evaluating top industry trends gives manufacturers a glimpse into the future of industrial technology and which solutions are necessary to unleash long-term productivity benefits. Today, overarching manufacturing technology trends include:

- Embedded intelligence and intelligence at the edge.

 By moving data processing and analytics to where manufacturing is actually taking place, factories can ensure better connectivity and a better flow of actionable data. Today, 75% of the data generated within the manufacturing industry is generated at the edge.
- Tools for error cognition. Of the data generated at the edge, only 6% is actioned. That's because humans simply don't have the manpower to accurately review the abundance of edge data and recognize potential patterns or problems.
- New, user-oriented business models. Finally, manufacturers are realizing that the future is not solely about the product being utilized—it's about how a product

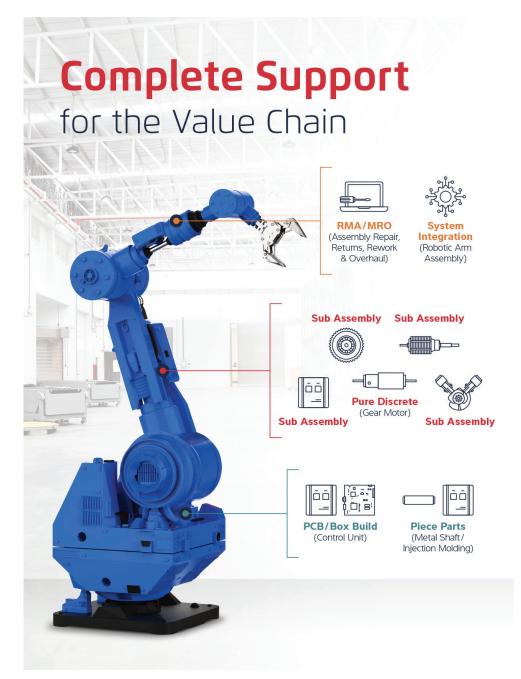
is being used and how it ties to business outcomes such as improving productivity while reducing the cost of quality. Instead of buying a system or a machine, people would subscribe to the machine and buy the machine as a service, where the capital cost of the machine is not on the balance sheet. Instead, they would pay an operational cost, on a monthly/quarterly/yearly/annual basis.

In addition to trending technology insights, 'technology enablers' are another key factor to consider in the technology adoption process. Today, these enablers include ubiquitous sensing, cloud computing, digital twins, predictive analytics, and more—each of which will influence the creation, adoption, and convergence of key manufacturing technologies and the landscape of workforce productivity. Ultimately, these enabling concepts and trends will converge with AI models for deep learning to drive new opportunities for manufacturing productivity, like more connected field service, smarter edge applications, Al-based cybersecurity, and more.

Understanding Digital's Impact on Modern Manufacturing Productivity

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While these trends and enablers are crucial points of consideration for tech adoption and subsequent productivity gains, manufacturers should also look to their most prevalent productivity pain points when considering where to begin with productivity improvements.



For example, manufacturers face many information challenges ranging from the collection of data, to optimizing its application, to ensuring its quality. They are also bogged down by equipment maintenance that must be completed to prevent unplanned downtime. Another pressing challenge is the shortage of skilled workforce. In fact, Frost & Sullivan estimates that 25% of the industrial engineering workforce is 55 years or older. On top of the workforce shortage, it is also noted that the niche skills necessary to perform particular jobs will become outdated in just a few years. Safety and cross-factory communication also top the lists when manufacturers discuss their most pressing challenges.

The most universal obstacle to productivity, however, is the convergence of these smaller challenges. It is the fracturing of the manufacturing value chain, which takes place as factories attempt to keep costs low, innovation high, and consumer checkpoints frequent.

Luckily, digital innovations are helping manufacturers unify the segments of their value chain once more. For example, by developing a strong foundation of Industrial IoT (IIoT) capabilities, factories can increase necessary visibility and traceability within the manufacturing product flow. Additionally, by shifting toward digitalization in a factory, manufacturers can empower operators with interactive, visual work instructions to optimize production flow—which has been proven to improve workforce productivity by 10 to 12%. Finally, by instituting connected manufacturing intelligence and the use of analytics to drive alerts, manufacturers can keep data flowing between factory sites, and between factories and consumers.

Rely on Strategic MES Solutions to Drive Factory-Wide Productivity

Clearly, strategic technology adoption can empower the workforce to drive tangible benefits to manufacturing enterprises—all while promoting areas that elevate job satisfaction. There is one technology, however, that stands out among the rest as a key piece of the productivity puzzle: Manufacturing Execution Systems (MES). With an MES, intelligence can be gathered horizontally and vertically from machines, devices, systems, and people. The most advanced MES will facilitate transactions, processes, and logistics seamlessly, thereby collecting and analyzing data that can be leveraged by the entire enterprise, always keeping insights in context for maximum utility.

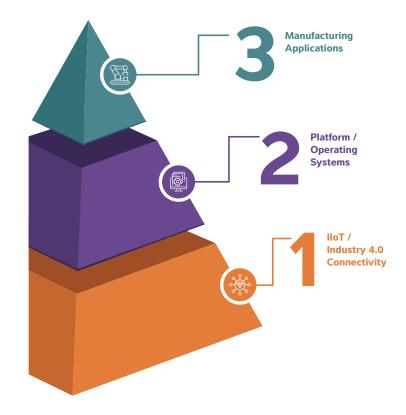
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ASSEMBLY AEGIS

- RMA/MRO: Control of field repair activities via an MES route and process control system, as well as MRO teardown and rebuild to new configuration.
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- Manufacturing Intelligence
- Active Rules Engine
- Connectivity (IIoT Edge & Business Systems)



Ramping Up For COVID

Medical device makers dramatically increase production to tackle pandemic.

John Sprovieri - Chief Editor

Through Jan. 3, 2021, the COVID-19 pandemic had claimed more than 1.8 million lives globally, including 360,246 Americans. While most of us can only despair at those numbers, medical device manufacturers around the world are ramping up assembly lines to fight the disease.

The needs are immense. Consider the task of vaccinating the population. The U.S. has worked to rush availability of coronavirus vaccine through a multibillion-dollar federal program called Operation Warp Speed, which is aimed at fast-tracking the development, testing, regulatory approval and distribution of COVID-19 vaccines. The first, the Pfizer-BioNTech coronavirus vaccine, was granted emergency-use authorization by the FDA on Dec. 11, 2020. The second, the Moderna vaccine, was authorized seven days later.



This robotic assembly system can produce 18 syringes per hour. *Photo courtesy Farason Corp.*

The U.S. has prepurchased hundreds of millions of doses of the vaccines, and the Trump administration vowed that at least the initial round of vaccinations would be available to all Americans free of charge. Initially, the administration hoped to vaccinate some 20 million people by the end of December, and then an additional 20 million to 25 million people in January.

Since both vaccines require patients to receive two doses spaced weeks apart, healthcare workers will need a lot of syringes—hundreds of millions of them. Fortunately, medical device manufacturers and automation suppliers are answering the call.



In just four months, Philips was able to quadruple ventilator production in the U.S. *Photo courtesy Royal Philips.*

In December 2020, **Becton, Dickinson and Co.** announced plans to invest approximately \$1.2 billion over a four-year period to expand and upgrade manufacturing capacity and technology for pre-fillable syringes and advanced drug delivery systems across its six global manufacturing locations and add a new manufacturing facility in Europe.

The new manufacturing facility in Europe is expected to be operational by the end of 2023. The investment will also fund capacity expansion, new product innovations, manufacturing technology enhancements and business continuity improvements across its existing network, all designed to

maximize supply and reduce risks for pharmaceutical companies that rely on ready-to-fill syringes for their injectable drugs.

"Since 2018, BD has added 350 million units of manufacturing capacity for glass barrel pre-fillable syringes, and this new commitment will invest in additional upgrades at all of our Pharmaceutical Systems manufacturing facilities and across multiple product categories," says Eric Borin, worldwide president of BD Pharmaceutical Systems. "In addition, this investment positions BD to have the needed surge capacity for increased pre-fillable syringe demand during times of pandemic response or periods of significant growth of new injectable drugs and vaccines."

BD will distribute the investment assembly plants in Columbus, Nebraska; Cuautitlán, Mexico; Fukushima, Japan; Le Pont-de-Claix, France; Swindon, United Kingdom; and Tatabánya, Hungary.

In July 2020, **Smiths Medical** announced that it had received an order for 78.6 million syringes from the federal Biomedical Advanced Research and Development Authority (BARDA) as part of Operation Warp Speed. In addition, BARDA awarded \$20 million to Smiths Medical as part of a \$38 million capital project to boost production capacity at the company's syringe factory in Keene, NH.

"Smiths Medical has risen to the challenge of COVID-19 patient care and now delivery of a future COVID-19 vaccination," says JehanZeb Noor, CEO of Smiths Medical. "[We have also] increased production of ventilators, infusion pumps, extended dwell catheters and other respiratory products necessary for

ASSEMBLY RAMPING UP FOR COVID

treating COVID-19 patients. The current global crisis has galvanized our culture to serve patients and transform the healthcare industry."

Automating Assembly

Assembling tens of millions of syringes in a short period of time can only be done with automation, and systems integrators have long been up to the challenge.

For example, **Farason Corp.** of Coatesville, PA, recently designed and built a highly efficient robotic system to assemble syringes at a rate of 18 parts per minute. Assuming the system runs 24/7, it can assemble more than 9.4 million syringes per year.

Six compact LR Mate six-axis robots from **FANUC America Corp.** handle a variety of parts and assemble them into syringes. All the robots are equipped with custom end-of-armtools, and multiple vision inspections are performed throughout the process to ensure quality.

At the first station, a robot picks parts from two vibratory inline tracks and places them on top of handles. Then, a second robot picks and transfers the parts to a fixture for the next series of assembly steps.

A third robot picks plungers from a discharge conveyor and inserts them into seals that are fed from a vibratory inline track. The robot then places the plunger subassemblies into the handles and both pieces are fused together.

A fourth robot transfers the fused assemblies into a downstream fixture. At the next station, the fifth robot, equipped with a dual-purpose end of arm tool, picks parts from



Ventec, a startup medical device manufacturer, was operating at full capacity in March 2020, producing a few hundred ventilators per month. In April, GM offered to help Ventec assemble the devices at its parts plant in Kokomo, IN. Within a month, the first ventilators jointly produced by GM and Ventec were delivered to hospitals in the Chicago area. *Photo courtesy General Motors Co.*

a vibratory inline track and a star-wheel and places them into separate fixtures.

Finally, the sixth robot, equipped with a five-up end-of-armtool, mimics a walking-beam mechanism. Five grippers move

ASSEMBLY RAMPING UP FOR COVID

back and forth from station to station, continually picking and placing syringes, while pneumatic slides perform the last assembly steps.

Syringes that pass inspection are placed into a collection bin. If the system must be reset, the robots clear the fixtures of parts, depositing them into reset bins. This eliminates the need for



In July 2020, Smiths Medical announced that it had received an order for 78.6 million syringes as part of Operation Warp Speed.

Photo courtesy Smiths Medical.

an operator to manually perform this task.

To see the assembly system in action, click here: https://bit.ly/2XiZi4V.

Ventilator Production

Roughly 20 percent of symptomatic COVID-19 patients require hospitalization and about 5 percent end up in the intensive care unit. Most of those in intensive care require ventilators. The devices essentially breathe for the patient, who is sedated with a long plastic tube placed down the throat and into the windpipe.

That has created a surge in demand for ventilators. Tens of thousands of the devices would be needed just meet COVID-related demand in the U.S. in 2020.

In April 2020, the federal government invoked the Defense Production Act to ramp up domestic production of ventilators, personal protective equipment, and other supplies to combat the pandemic. The U.S. Department of Health and Human Services (HSS) awarded contracts for ventilator production to several manufacturers: **General Electric Co., General Motors Co., Hamilton Medical Inc., Hillrom, Medtronic, Royal Philips, ResMed Inc., Vyaire Medical Inc.** and **ZOLL Medical Corp.** All totaled, the contracts called for the production of more than 41,000 ventilators by the end of May and more than 187,000 ventilators by the end of 2020.

The contract with Philips, for example, called for the company to assemble 43,000 ventilators by December 2020. To meet that goal, the company poured millions of dollars into its factories in California and Pennsylvania and hired hundreds of additional workers. By July, the company was producing 4,000 ventilators per week, representing a fourfold increase from the company's production in March and an eightfold increase from its output before the pandemic, according to Steve Klink, who leads the company's press office. Ordinarily, that kind of production rampup would have taken one to two years.

That kind of ramp-up is even more noteworthy considering that a Philips ventilator contains more than 650 complex, high-reliability components, such as sensors and blowers, and more than 1 million lines of computer code.

By August 2020, Philips had delivered 12,300 ventilators to HHS. (HHS would later cancel the order for the remaining 30,700 units, as COVID treatments evolved and the devices became less necessary to keep patients alive.)

ASSEMBLY RAMPING UP FOR COVID

Other medical device manufacturers also quickly increased production. For example, between January and July 2020, ResMed assembled more than 150,000 ventilators and continuous positive airway pressure devices—more than 3.5 times its output over the same period last year, according to Jayme Rubenstein, ResMed's public relations director. ResMed also scaled up ventilator mask production more than tenfold.

"The main challenge we had to solve to increase production concerned securing enough components during a time of decreased supply," says Rubenstein. "There was higher demand for these supplies from all ventilator manufacturers—both leaders in the field and nontraditional makers. There were also higher costs associated with components and shipping parts and finished goods.

"We also quickly established safety procedures for our essential workers, who were building and distributing our devices, to ensure their well-being."

If ramping up production took a monumental effort, ResMed doesn't expect to return to "normal" production. "ResMed doesn't intend to 'scale down' after the pandemic ends," adds Rubenstein. "We will pivot back toward producing a more normal balance of sleep and respiratory care devices per customers' demand. But, our digital health solution development will continue to ramp up. COVID-19 has accelerated demand and adoption of remote monitoring, remote therapy setup tools, patient engagement apps, and other digital products. As more clinicians and patients understand the value of these products, demand for them will only increase as time goes on—long after this health emergency is behind us."

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In April 2020, HHS awarded Hamilton Medical a contract to assemble 25,574 ventilators by July 3. Photo courtesy Hamilton Medical Inc.



With multiple companies looking to boost production of ventilators in 2020, parts shortages became a major stumbling block. Photo courtesy ZOLL Medical Corp.

Zimmer Group - Application examples of handling solutions in the medical & pharmaceutical industry

The Zimmer Group is one of the world's leading manufacturers of automation, machine and furniture damping components as well as process technology. In addition, we are also an important partner of numerous well-known companies in the medical and pharmaceutical sectors, among others.

In the following, we will discuss some current application examples in these industries. For example, a Swiss pharmaceutical company uses grippers of the Zimmer Group's electric grippers series. These support the analysis of coronavirus samples in a fully automated system for laboratory diagnostics. Grippers of the same type are currently used in



coronavirus test centers in China. The electrically driven grippers for small parts, which are very easy to control, are responsible for sample handling, e.g. reliable transport and safe opening of the lids of highly infectious sample tubes. For these special tasks, the grippers offer adjustable gripping forces via IO-Link between 40 N and 500 N and jaw strokes between six and sixteen millimeters. In addition, the electrical grippers are equipped with a mechanical self-locking mechanism that prevents the highly infectious sample tubes from being lost or dropped, for example in the event of a power failure. In this way, the grippers hold the sample firmly - even without power supply. Another reason that convinced the customer was their maximum robustness and reliability. The housing of the electric grippers are made of hard-anodized aluminum, and the Zimmer Group's developers used a flat guide system that has been tried and tested for decades. This allows 10 million cycles to be handled without maintenance.

For a German medical technology manufacturer, our handling solutions are used in systems for filling sterile solutions (dialysis, bag filling with sugar solution).

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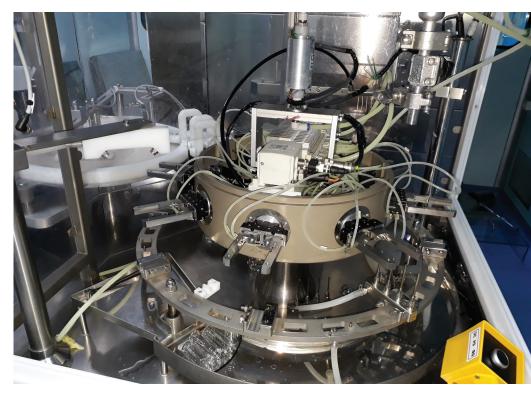
Another customer example is that of a global healthcare company. Here, our radial grippers are used for the loading and handling of so-called EasyBags - liquid food for ventilated corona patients, among others.

Compact electric gripper series

In addition to liquid food, monitoring systems for corona patients are also essential for survival, but who is supposed to operate these devices in pandemic times, when it is particularly important to keep a distance between patients? The company Cobot Team from Portland, Oregon, has come up with the right ideas. The result is a collaborative robot (Cobot) with a special HRC (human-robot-collaboration) gripper from Zimmer Group. It now supports the hospital staff, among other things, in adjusting the amount of oxygen for a COVID-19 patient.

Press release "a cobot gripper in the fight against corona"

Another application example - this time without corona cover - comes from Tunisia. Here, grippers and swivel units of the Zimmer Group automate a cleaning machine for sterile glass vials for the company SEA electronics. They used grippers of the GPP5000 series with their robust, hard-coated steel-in-steel linear guide designed for real universal use. Depending on the variant, they have a number of features (speed, high gripping forces, long gripper jaw lengths) and thus offer the right solution for every application. When used



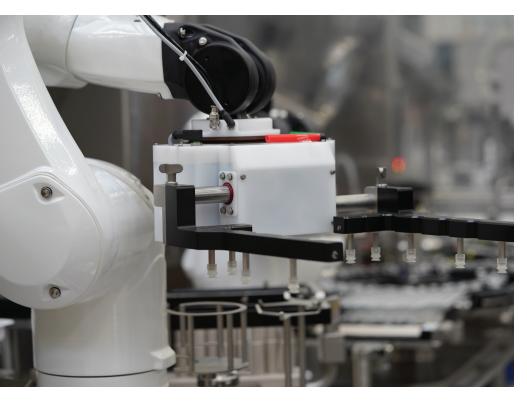
The grippers and swivel units of the Zimmer Group installed in the cleaning machine for vials. Photo courtesy of Zimmer Group.

with a protector, the grippers have a sealing class of IP67 - ideal for use in clean rooms or in the damp environment of the cleaning machine.

Universal and robust gripper series GPP5000

Gripper solution for handling in the aseptic filling process of pharmaceutical products

Bausch+Ströbel Maschinenfabrik Ilshofen (B+S) filling and packaging systems are used worldwide to process high-quality



GEH6000IL gripper from Zimmer Group in use at Bausch+Ströbel clean room application

liquid and powdered drugs, syringes, vials, cartridges or ampoules - from object cleaning and sterilization to labeling or syringe assembly. The VarioSys system from B+S is a flexible production system for biotechnological products and pharmaceuticals. It allows fully automatic opening of tubes and enables RTU-("Ready to use") vials in nests (packaging units) to be opened, denested, filled and stored fully automatically. The cover foil of the tubes is released by a thermal process. For this

purpose, the tubes are transported into the appropriate positions by a clean room robot or gripper. After opening, a second gripper removes the RTU vials from the nest and transfers them to the next module for further bulk processing.

One big challenge for the Zimmer Group, in addition to perfect interaction with the robot, concerned the use of these grippers in a cleanroom system. Right from the outset this excluded the use of pneumatic grippers—for reasons of space alone, due to the cables and exhaust air. It was decided relatively quickly, therefore, to use a purely mechatronic gripper solution.

On account of the aforementioned challenge posed by the cleanroom, the grippers had to be designed with special consideration for the specifications of technical cleanliness, because they can come into direct contact with syringes and vials and/or with the nest. Commercially available grippers are not immune to particle transfer and unwelcome spreading of particles. Abrasion debris from the gripper itself can produce unwanted foreign objects. This means they present a particular challenge to designers of cleanliness-sensitive systems. As one of the first design measures, therefore, B+S chose easily removable and sealed enclosures or sheathings with a closed surface for the grippers to prevent particles from intruding into the process.

For B+S the flexibility of the grippers was also of critical importance, because the system itself has a very adaptive or modular design and the packaging sizes can change at any time. As a result, the two grippers best suited to the respective task, GEH6180IL and GEH6040IL were selected from the extensive

Zimmer Group portfolio. Both electric grippers have a large stroke and a servo drive with an integrated controller. The brushless drive technology guarantees not only individual force adjustment, but also control of position and speed. The safety of the system is also an aspect that cannot be neglected, because fragile glass and plastic are handled most. Accordingly, the grippers also have a mechanical self-locking mechanism, which prevents a vial from falling in the event of a power failure.

Electrical long stroke gripper series GEH60001L

The fact that Zimmer Group was also able to respond very quickly to necessary modifications was particularly appreciated by B+S. They also appreciated the fact that the grippers have only a single cable outlet—that represented a very big advantage for the strictly tight space conditions in the clean-room. Furthermore, equipping the system with IO-Link made it easy to read out specific data, such as the temperature measurement, position and number of cycles.

The ease of configuring parameters and the many additional features of the GEH grippers were very appealing B+S, as well as the active and open communication with the Zimmer Group experts.

<u>Press release "Zimmer Group provides a sure hold in</u> cleanrooms"

Application examples from other technology areas of the Zimmer Group

In addition to fitting patients with prostheses using our damping technology components (PowerStop dampers for the med-tech company Ottobock), it is also worth mentioning that we also manufacture our own products, which minimize the risk of corona infection.

Damping technology in prostheses at Otto Bock

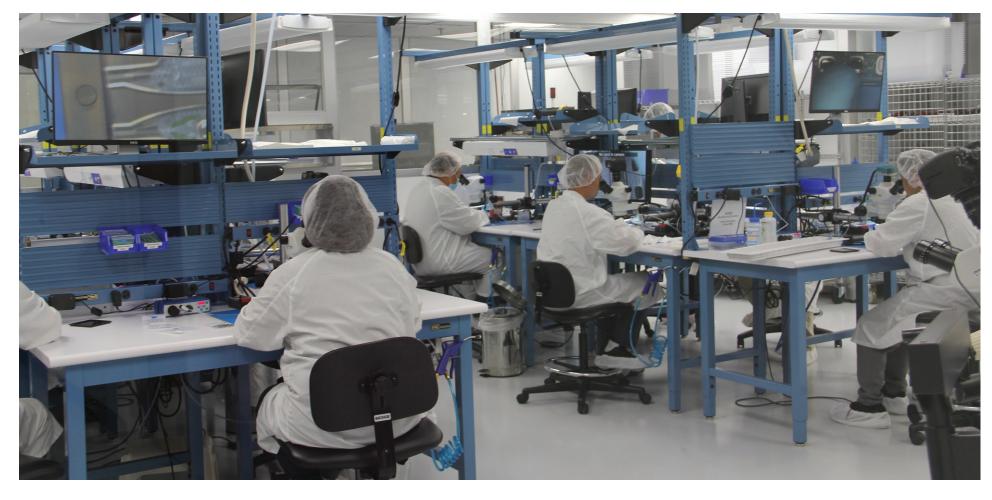
Zimmer Kunststofftechnik GmbH - a subsidiary of the Zimmer Group - recently introduced a hygienic and antibacterial attachment for door openers. The hygienic door opener Hand-Held allows doors to be opened and closed with the elbow or forearm. This reduces the spread of microorganisms and minimizes the risk of infection. The Hand-Held is compatible with most door handles, easy to install, quick to clean and is suitable for use in companies, authorities, public buildings, clinics or in private environments.

Hand-Held hygienic door opener

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Cirtec's headquarters in Brooklyn Park includes two Class 10,000 clean rooms. Photo courtesy Cirtec Medical Corp.

Contract Manufacturer Keeps Pace

Cirtec Medical masters the process of assembling implantable medical devices.

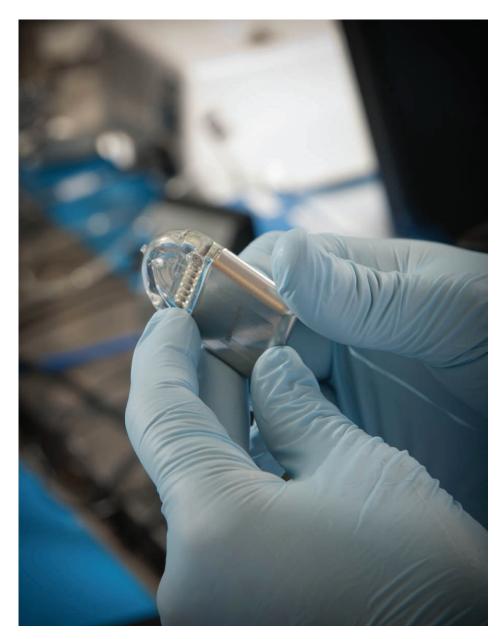
John Sprovieri - Chief Editor

Based in Brooklyn Park, MN, Cirtec Medical Corp. provides end-to-end design and manufacturing services for Class II and III medical devices. The company specializes in devices for neuromodulation, implantable drug delivery, cardiac rhythm management, structural heart support, ventricular assistance and minimally invasive surgery.

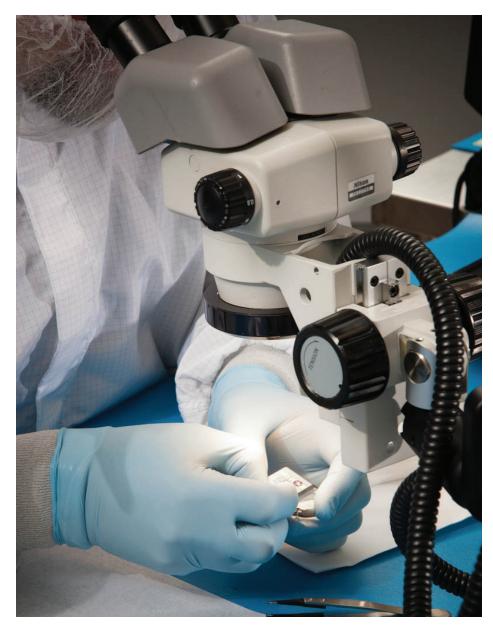
Cirtec's customers range from small start-ups to some of the largest medical device OEMs in the world. The company's services range from design, development and prototyping to clinical builds, small batch-builds and large-volume commercial manufacturing.

In November 2020, Cirtec announced that it was leasing an additional 85,000-square-foot building in Brooklyn Park. The expansion is expected to create 200 jobs, while retaining 350 existing employees in Minnesota. The new, state-of-the-art facility will become the company's Neuromodulation Center of Excellence and focus on manufacturing active implantable devices and clean room assembly of neuromodulation leads, implantable pulse generators and accessories. In addition, it will allow for expanded engineering competencies in mechanical, process, quality, electrical engineering, software, firmware and testing. Other capabilities will include silicone injection molding, plastic injection molding, final packaging and ethylene oxide sterilization.

It's the second major expansion of the company's Minnesota operations in three years. Cirtec also has operations in Chandler, AZ; Enfield, CT; Los Gatos, CA; Lowell, MA; Birkenfeld, Germany; and Alajuela, Costa Rica.



Cirtec focuses on assembling electromechanical devices and small implantable devices, such neurostimulators and pacemakers. *Photo courtesy Cirtec Medical Corp.*



Cirtec focuses on assembling electromechanical devices and small implantable devices, such neurostimulators and pacemakers. *Photo courtesy Cirtec Medical Corp.*

Recently, we sat down with Cirtec's CEO, Brian Highley, to talk about the business of contract manufacturing of medical devices. A 27-year veteran of the medical device industry, Highley joined CIRTEC in 2014 from Nypro, where he served as vice president and general manager of the company's medical device and consumer health segment. He has also held engineering and management roles at FlexMedical, Avail, Baxter, Medtronic, Smith & Nephew and Philips Medical.

ASSEMBLY: Tell me about the process of working with a contract manufacturer like Cirtec. What does Cirtec do to ensure everything goes smoothly?

Highley: The process varies. We are a contract design and manufacturing company, so our customers will engage us at a couple of points. Some customers ask us to handle the entire process, from design through manufacturing. Others are simply transferring the manufacturing of a product to us, either from another contract manufacturer or from their facility to ours.

Either way, planning and communication are the keys to a smooth process.

ASSEMBLY: What can your customers do to ensure a successful outcome?

Highley: That's often the challenge. Ideally, the customer has a well-defined specification for what they want. However, that's often hard to do, because in some cases, they don't have a design ready to go. They don't have a specification, and they're creating one along the way. Some customers have us define

their specifications and collaboratively develop the product, but that's rare. Generally, our customers know what they want, but they just don't have clearly defined specifications.

Problems arise when customers haven't done their homework. They haven't clearly defined what they want in terms of the design, the manufacturing process, the testing process and even commercialization. We can put together a scope of work document, but it will only be as accurate as the loosely defined specification.

ASSEMBLY: As a contract manufacturer, Cirtec produces a variety of products. How does your company handle highmix production?

Highley: We try to keep the work within our core capabilities. We focus on producing electromechanical devices and small implantable devices, such neurostimulators and pacemakers. We won't bid on things like disposable devices. The last thing we want to do is take on assembly or manufacturing processes that are misaligned with our internal capabilities. We focus on what we're good at.

Contract manufacturers get into trouble when they try to take on everything for everybody.

ASSEMBLY: Cirtec just announced that it will be expanding its operations in Brooklyn Park. What are your plans for the new facility?

Highley: We are adding a new facility. Our current facility is called BP One. The new facility will be called BP Two. Right now,



Planning, communication and clear specifications are the keys to a smooth process when working with a contract manufacturer. Photo courtesy Cirtec Medical Corp.

all of our machining and assembly processes are located in BP One. Our goal is to set up all of our assembly operations in BP Two and have all of our machining operations in BP One. We're also shifting our engineering offices to BP Two. This will enable us to focus the right people on the right businesses.

ASSEMBLY: You've been CEO for more than six years now. How have Cirtec's manufacturing operations changed in that time?

Highley: When I first arrived, the business was primarily an engineering firm with some "job shop" capabilities. We didn't have a lot of assembly business. Over the years, we've become much more of an assembly business. We have also emphasized our design services, but with a focus on the product rather than the process. We've grown into a full-service manufacturing operation for medical devices, providing end-to-end services, including sterilization and packaging. It's been a huge shift, but we've been successful.

ASSEMBLY: What assembly or manufacturing technologies have made a big impact on your operations?

Highley: We have invested in more technology and better technology over the years. We've always been known for laser welding and hermetic sealing of small medical devices, but we're better at it now than ever before. We have also added new capabilities, such as extruding and injection molding.

ASSEMBLY: What can non-medical manufacturers learn from how Cirtec runs its manufacturing operations?

Highley: Medical device manufacturing is a highly regulated industry, so you really need to have smart and sound engineering in place. We do a lot of design validation work, and we have to create strong design history files. You also have to develop a strong supply chain. All of that adds to your product development time, but it significantly reduces the risk of a bad product launch.

Now, if you're making televisions, maybe it's not worth going through all that extra effort. But, if you're in the automotive or aerospace industry, the processes we've put in place are well worth doing. It's just smart business.

ASSEMBLY: What manufacturing challenges do you expect in the future?

Highley: We just acquired a new company, NovelCath, a vertically integrated manufacturer of highly engineered catheter delivery systems. In the future, we will continue to expand our capabilities to support our customers. We will also continue to invest in our engineering organization so we can help our customers design, develop and launch new products. We're also looking to expand in Europe.



Festo is more than a global manufacturer of <u>process control</u> and <u>factory automation</u> solutions. We are a trusted partner, helping our customers build better products, streamline production, and cut costs through innovation.

Today's technological revolution is powered by engineering breakthroughs and transformative innovation, but it is defined by something far simpler...to make life easier. At Festo, our mission is to make the world a more convenient, comfortable and efficient place, and not simply for consumers. We are committed to the manufacturers who build the products, the men and women who need time-saving **engineering tools** and energy efficient components in order to succeed.

For over 40 years in the U.S. (and 80 years globally), Festo has been fueled by the desire to help "build a better machine," through a combination of innovative products, expert advice

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and differentiated customer support. We are driven by a desire to serve and an obligation to observe. To analyze. To inspire. To engineer with an intense focus on every last detail. To transform the way people work—and the way companies compete.

Everything we do at Festo is guided by five values: not business values, but fundamental principles that guide our actions and the way we work as a company and with our customers:

- **We are ambitious**, shaping our destiny by relentlessly pursuing success.
- **We are determined**, meeting challenges through courage, hard work, agility, and the drive to win.
- **We are visionary**, having the foresight to look beyond the horizon, seeing "what's next," and having the road map to get there.
- We are respectful, understanding the value of others, embracing collaboration, and learning from each other's perspectives.
- We are dependable, making our word our bond, and nurturing relationship built on trust and reliability.

Our values, along with these key differentiators, help us turn the power of intelligent automation into a catalyst for customer transformation:

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Quality is one of the supporting pillars of Festo, and has been since our independent, privately owned company began in 1925. It's not just evident in the components and solutions we build, but in our daily operations...how we work together...how we manage...how we serve our customers.

At Festo, quality is not just an attribute but a holistic approach, practiced internally and externally, throughout production, training, services and logistics processes, delivered consistently and at the highest level, from our products to our people.

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With over 250 branch offices in 176 countries and national companies in 61 countries, you can rest assured that our products and services are in close proximity and available to you.

Here in the U.S., we have invested in a new, state-of-the-art Regional Service Center in Mason, Ohio. Covering over 200,000 square feet, this centrally located plant is an efficient product supply organization comprised of logistics, production, purchasing and engineering, with guaranteed short delivery times and excellent delivery reliability.

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Cost-effective products with quality you can depend on

At Festo, we are also committed to keeping things simple and cost-effective. Order anything from our core product range as indicated by a star, and you will get Festo quality at an attractive price...and in short time. These industrial automation components are ready for immediate delivery.

Our core product range is easy to order with just a few clicks. Price, availability and order tracking—everything is completely transparent!

From inspiration to innovative automation solutions

As innovators, we often find inspiration in unusual places. Nature, for example, is bringing us into new realms for tomorrow's automation technologies today. While some people just see an elephant swinging its trunk or a manta ray swimming, we see a new way to transform manufacturing and give our customers an edge.

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The Life Science industry draws on a wide range of technologies, services and products. While the objectives within each sector may differ, the need for innovation and rapid development is critical for companies industry-wide. Festo delivers on both fronts. With our team of highly specialized engineers and a vast array of customers resources, we produce tested and proven product solutions that help you meet your performance objectives while optimizing time-to-market.

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Key Care-Abouts for Assembly in the Medical Device Industry

As the medical industry in general continues to expand its presence and importance in society, those companies which cater to medical device assembly have likewise grown in size and number. Due to the specific requirements of their industry, there are a whole host of key care-abouts which have to be addressed when delivering equipment and services to these assembly companies, including quality assurance, technical cleanliness, and efficiency. Let's take a look at these areas one at a time and learn how they can be tackled with modern fastening and feeding technology.

Quality Assurance

 Traceability – One of the key aspects of any quality program is traceability. In particular, in today's manufacturing environment it is often no longer enough for a screw joint to simply be torque-controlled. Instead, there can be a need to both measure and record the





DEPRAG COCKPIT

torque value of every critical joint. DEPRAG's MINIMAT-EC and EC-Servo driver technologies offer such capability. In the case of the MINIMAT-EC, motor current is used to monitor and control torque which makes possible a torque accuracy of < 2% standard deviation. The EC-Servo line takes a different approach and instead measures torque directly with a transducer, thus allowing even greater torque accuracy. Each driver's

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- sequence controller is capable of storing and transferring this data to factory automation software for further analysis, as necessary.
- Data Analysis & Process Control Storing the torque data from an assembly process is only part of the battle and does limited good unless this data can be summarized in a format which makes *analysis* possible.
 DEPRAG's Cockpit software solution allows torque data from potentially hundreds of drivers across an entire factory to be summarized and displayed graphically, including in a control chart format, thus allowing process characterization. Moreover, DEPRAG Cockpit can interface and deliver information to factory automation software, thus enabling true Industry 4.0 compatibility.
- Operator Guidance Another important means of enhancing quality and minimizing human error in a manual assembly process is the implementation of operator guidance. This can include poke yoke features both in the design of the part (so that parts can only be assembled one way) as well as the workstation itself (so that a part can only be loaded in a single, correct orientation). In addition, through a careful combination of hardware and software it is also possible to guide the operator smoothly through the correct assembly sequence. DEPRAG provides just such a solution in the Position Control Stand (PKS), which not only ensures all fasteners are tightened to the preset torque, it also makes sure the correct tightening sequence is followed as well.

Technical Cleanliness

Whether a manual or automated screwdriving application, choosing the right equipment in an assembly station is critical in the fight against *particulate contamination*. Given this, let's examine a number of methods and components which are at our disposal:

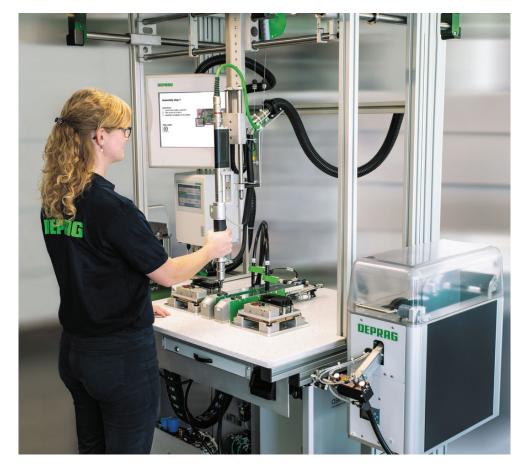
- Quality Fasteners This is certainly one area were the adage holds true, "You get what you pay for." One of the key requirements in reducing particulate contamination in any fastening joint is the use of high-quality fasteners. Not only does this increase the likelihood that the screw or other threaded part will adhere to the specified dimensions and tolerances, it also typically increases the overall cleanliness of the fastener. Moreover, some fastener makers offer product lines with a special focus on cleanliness. It pays to take a critical look at your fastener supply chain and inquire about the available options.
- Choice of Feeder There are a number of different screw feeder types in use, and all have certain advantages. However, one type which is particularly well suited for use in clean environments is DEPRAG's sword feeder. With screws scooped up from the reservoir with only a gentle up-and-down motion of the sword or segment, this feeder type inherently generates fewer particles than conventional vibratory feeders. Another feeder configuration which is also low-abrasion in nature is the step feeder. Especially suited to longer screws, in

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- this case linear feed rails serve as a "step" to capture fasteners and smoothly convey them out of the reservoir.
- Vacuum Suction Regardless of the feeder type used, the blast air necessary to convey a screw down the feed hose can itself force particles toward the assembly and the fastener joint. Since this is undesirable, one means of addressing this is to first briefly capture the screw exiting the feeder in a separate holding device, DEPRAG's Particle Killer, so that vacuum can be applied. This suction allows contaminants to be extracted, at which point the screw can then be further conveyed toward the assembly.
- Underfloor Screwdriving For automated applications
 where approaching the part vertically from beneath is
 possible, an underfloor or inverted screwdriving spindle
 installation should be considered. By driving the fastener
 from beneath, any particles generated as a result of bit fastener interaction will fall away from the assembly, not
 onto it, allowing gravity to work to your advantage.

Efficiency

Every industry strives for increasingly higher levels of efficiency in an effort to improve the bottom line, and the medical device industry is certainly no exception. One of the key ways of accomplishing this is, of course, to employ various degrees of automation in the assembly process. DEPRAG offers two fundamental approaches in this regard, the intelligent workstation and full turnkey automation, both of which we'll explore now.



INTELLIGENT MANUAL WORKSTATION

Intelligent Workstation – An intelligent manual workstation still maintains an operator as an integral part of the fastening process. However, as the name implies, this ergonomic workbench incorporates a number of features in an effort to improve the overall assembly process. These could include many of the items already mentioned above, including a part fixture with integrated

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- sensors to supervise correct part loading (poke yoke), a PKS to assure the correct fastening sequence is followed, fastener feeding to improve efficiency, and DEPRAG Cockpit to ensure traceability and process data capture.
- Full Automation If there is a desire to remove an operator from the fastening process altogether, for instance in an effort to shorten cycle time, full automation in the form of a DCAM (DEPRAG Compact Assembly Module) can be employed. This standard footprint assembly cell with a two- or even three-axis robot can be customized as necessary to meet the customer's needs. Such customization can include single or multi-spindle setups, as well as a variety of operator interface arrangements such as slide tables, rotary indexing tables, and manual part placement with a safety light curtain. Spindles can be mounted on DEPRAG's well-proven Screwdriving Function Module (SFM) to provide z-axis motion.

In summary, there are indeed a number of important careabouts which must be addressed when delivering equipment to companies focused on medical device assembly. These include quality assurance, technical cleanliness, and efficiency. DEPRAG offers flexible solutions to meet the needs in all of these areas, and our qualified product specialists are ready to assist you with your specific application. Please visit us at www.depragusa.com or send your inquiries to info@depragusa.com.





Prevent Particle Contamination with DEPRAG.

When the cleanliness of a production line plays a key role in product quality, an assembly partner should be chosen who can deliver ALL important aspects of a screwdriving system. It is the best way of ensuring that each component and each process, such as feeding, positioning, and screwdriving, works together in harmony. The entire system can then be examined, evaluated, and enhanced with technical cleanliness in mind, from DEPRAG.

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