

Sterile Disposable Products Manufacturer and Outsourcing Partner Offering Custom Solutions for OEM Medical Device and Diagnostic Companies



Jeff Barrett
President and CEO
J-Pac Medical

CEOCFO: *Mr. Barrett, what is the focus at J-Pac Medical?*

Mr. Barrett: We are a manufacturing outsourcing partner for OEM medical device companies. We have different segments of the business, all centering around the single-use sterile device market.

CEOCFO: *What are some of the challenges in the market and in creating a product that is high quality?*

Mr. Barrett: There are two major challenges. First, there is a tremendous push to outsource manufacturing because these large OEM medical device companies are under significant pressure to have more innovation and customer focus at a lower cost. Thus, they are quickly realizing that manufacturing is best left to others while they focus on product development and sales.

Second, successful medical device companies need to be a lot more flexible than they have in the past. This includes making product changes or being flexible with delivery. They need to achieve this while minimizing internal infrastructure requirements that can be very costly and can become outdated as products change. That is where companies like us come in because we enable them to focus on customers while we focus on manufacturing.

There is significant pressure to reduce costs across the whole supply chain. The regulatory complexity continues to grow so medical device OEMs are looking to companies like J-Pac to focus on quality and cost. Similarly, manufacturing outsourcing partners have to bear more risk in today's regulatory environment. One example of this is that J-Pac is one of only a handful of companies with expertise in implantable textiles. These biomaterials are implanted into tissue as a permanent repair system for the body or can be bioabsorbable, where they are actually absorbed by the body over time. A common application of this is hernia repair. These products are particularly challenging because of the regulatory risk if something goes wrong. We are extremely confident in our ability to manufacture these devices and have a flawless history of doing so.

CEOCFO: *If you have maintained all of the proper standards, are you still subject to the lawsuits?*

Mr. Barrett: We do what we can to minimize our risk but in the end, in our country, whoever touches the product in the entire supply chain is at risk of getting involved in litigation if something goes wrong. Fortunately, J-Pac has a long history of producing perfect quality in this market. We are careful to select customers that have a proven market presence while being somewhat cautious of startups in this market. We do work with startups but we have to be very careful in the implantable device market because of the risk involved. We tend to work with startups in some other segments of our business but for implantable devices, we tend to work mainly with blue-chip device companies.

CEOCFO: *What might you do surrounding quality that perhaps other companies in your industry do not?*

Mr. Barrett: Three things set us apart from other outsourcing companies. First, we have an incredible amount of experience – over 35 years. We have an incredibly well-trained and committed workforce. Second, we have a tremendous amount of technical expertise in the markets we serve and use that expertise to offer customers creative and cost-effective improvements to their products. The third piece is that we take great pride in our ability to execute. To execute on quality, we are compliant with the ISO and FDA regulations. We also are registered to handle drugs that are used with medical devices. This requires significant controls.

I think what also makes us different is we are incredibly transparent to our customers. With some customers we have weekly or monthly business reviews. They know exactly what is going on with the manufacture of their products as if it

was their own manufacturing operation. We are not afraid to discuss challenges we face. We feel our customers respect that. We are transparent with our customers so that they understand that we are working together with them to resolve issues in order to move forward. Other companies tend to put more of a barrier between them and their customers; our model is different.

CEO CFO: *What goes in to customizing a solution?*

Mr. Barrett: At J-Pac we try to make the product better and more manufacturable while reducing cost and improving quality. For example, for one of our implantable textile customers we improved their product by offering unique manufacturing technology that the designer of the product was not aware of. In this case we were able to form the textile into an anatomically correct shape without the need for expensive sewing techniques. That is a perfect example of where we customize a solution for the customer so it's a win for both of us.

CEO CFO: *Do your clients outsource all the production of a particular item?*

Mr. Barrett: The majority of the time, we would be a final integrator. This is when we would do the final manufacturing, most of the assembly, the packaging and sterilization. We would manage the supply chain for the customer. If the medical device that is shipping to the customer has fifty components in it, we might manufacture some of the key components and manage the supply chain of the others to provide a turnkey solution to the customer. More and more medical device OEMs need to be working with companies who have the supply chain capabilities as well as manufacturing.

“When outsourcing manufacturing you need a partner that you can trust. You need to be able to sleep at night and know that you are going to get the highest quality product on time. That is why people come to J-Pac - because they trust us. We have the experience and expertise to do it right. We have the operations capabilities to execute and do it perfectly. Those three things together are why our customers should come to us. Perfect quality, complex devices, delivered on time and in partnership.” - Jeff Barrett

CEO CFO: *Are there a lot of parts to a given device?*

Mr. Barrett: It depends on the device. Some of the devices we do are complicated. We make sterile thermoplastic devices that are used to sustain patients with advanced heart disease. In other cases, the product involves integrating many components into a custom designed thermoformed package so that it is convenient for the surgical team. We are seeing medical device companies more focused on having us integrate, package and sterilize the complete product so it can go directly to the customer. This can include both the main medical device as well as accessory products used in the procedure.

CEO CFO: *Do you maintain inventory?*

Mr. Barrett: Yes, we do. VMI, which stands for Vendor Managed Inventory, is popular with our customers. They will give us a forecast of long-term demands with firm releases off that forecast to be shipped with short cycle time. This means we have to maintain some levels of inventory for our customers as well as provide extremely quick manufacturing time. Many of our higher volume customers want to know that there is inventory on-hand and we include that in our service.

CEO CFO: *How do you keep up with new ideas and regulations?*

Mr. Barrett: We have to stay abreast of not only the manufacturing quality regulations but also the latest manufacturing technology. The regulations we follow are constantly changing, which is another reason OEMs seek outsourcing so that they do not have to have the overhead required to manage it.

For example, there was just a change through a regulation that we need to follow and we have to have all the procedures in place by this coming October, so that adds a level of expense. We have dedicated people whose job it is to see what is going on with regulations. We subscribe to certain databases and we know what changes are coming with regulations. We actually have to stay up with our customers' technologies as well so that we understand the product's use and can add more value to our customers by suggesting improvements. For example, with a cardiac device, we are not the experts in the cardiac procedure but we need to be up-to-date on it to understand what our customers are trying to achieve. We need to be cognizant of changes and trends in the marketplace so that we can add more value to the customer. More and more, your contract manufacturers are becoming partners with these device companies, not just somebody who puts things together.

CEO CFO: *Is it easy to find personnel that understand the importance of high standards?*

Mr. Barrett: We have pressure from our customers to provide these products in a cost-effective manner. That means you need to be in a low-cost area to make them. At the same time, you have to follow incredibly rigorous regulatory and

engineering requirements and that means you need skilled, educated people as well. Having both talent and a low cost of manufacture can be very challenging. We are lucky that we are in New Hampshire, which is a very pro-business state and has a highly educated workforce, but also has a lower cost base than other geographies. We have the best of both worlds by having incredible technical talent and a reasonably low cost of manufacture. Luckily, we are within an hour of the Boston area so we can attract a lot of the engineering talent and expertise that we need. We are in a good position to add a lot of value to our customers for a reasonable cost.

CEOCFO: *How is business currently?*

Mr. Barrett: Business is good. We are growing rapidly. We are seeing a lot of our customers making acquisitions of smaller companies and they are looking to solidify their supply chain for these new products. We are meeting with a lot of our customers about new companies or technologies that they just purchased. That is how a lot of medical device companies today are getting new products. There is less and less internal development and more and more acquisition. In my career I have been on that side of the business for many years so I understand what our customers need.

CEOCFO: *How do you reach out to potential customers?*

Mr. Barrett: We are a high-touch company. We like to form a personal relationship with our customers so we do a lot of in-person visits and frequent phone and email communication. We get many referrals from happy customers. In parallel with that, we try to go to the major shows to display our capabilities. We attend shows that our customers exhibit at so that we can better understand how our customers sell their products and have the opportunity to speak to the end customer.

CEOCFO: *What is the competitive landscape?*

Mr. Barrett: It is a very competitive market. You are seeing consolidation at the high-volume end of the medical device manufacturing outsourcing market. This is typically single-use medical devices that are made in the millions of units and thus are cost-sensitive and require manufacturers with a low-cost international profile. We specialize in the mid-volume to low-volume market that requires specialization as well as flexible manufacturing capabilities. We have to be careful about the products and projects that we undertake. You can get excited about a product but in the end, you have to step back and say, "Hey, this might not be a great fit for us long-term because this is a product where there will be pressure to move it off-shore." We try to stay away from those.

CEOCFO: *What has changed in your approach over time?*

Mr. Barrett: We are changing how we are interacting with our customers and how we are speaking with our customers. It is a cultural change. I was on the other side so I understand what our customers value and it is much more than being a contract manufacturer. I have worked at the OEM medical device companies, so I understand what it's like to be in their shoes. I think that is a major cultural shift that I am bringing to the company. I am focused on making sure that we are listening. If you listen to your customers hard enough, they will tell you how to sell them. It is not so much about what you can do; it is about what they need.

CEOCFO: *Why choose J-Pac Medical?*

Mr. Barrett: When outsourcing manufacturing you need a partner that you can trust. You need to be able to sleep at night and know that you are going to get the highest quality product on time. That is why people come to J-Pac - because they trust us. We have the experience and expertise to do it right. We have the operations capabilities to execute and do it perfectly. Those three things together are why our customers should come to us. Perfect quality, complex devices, delivered on time and in partnership.

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