INTRODUCTION

Medical-grade textiles have been proven to deliver the high degree of versatility and performance that OEMs need to create implantable devices that best meet the needs of today’s surgeons – and patients. As a result, the market for medical textiles is rapidly growing.

Although textile structures have been utilized in certain surgical procedures for decades, recent technology innovations are allowing textile devices to serve greater purposes and be a successful option for a broader range of medical applications.

Understanding the most important factors that go into textile implant manufacturing can help OEMs ensure that the best final product is designed to meet the needs of their end-user. Selecting a single source partner such as J-Pac Medical to oversee devices from inception to manufacturing, through packaging and sterilization, reduces the complexity and likelihood of human error from having multiple partners involved in development and across the supply chain.
Surgical implant optimization is being pushed out of the operating room and into the device manufacturing process, with heavy reliance now being placed on the device manufacturer to provide a product that is ready to implant with little or no revision needed by the surgeon.

Medical textiles are emerging as an ideal option for creating more "active" device forms like resorbable or drug/device combination products. Resorbable textiles will break down naturally in the body post-implantation, which supports improved clinical outcomes by eliminating foreign material in the body and any need for additional implant removal procedures. These implants can be customized into unique anatomical shapes and incorporate various chemistries that can help direct the healing process and reduce potential complications, such as infection. Additionally, resorbable textile implants don't interfere with imaging and radiotherapy like other permanent implants may.

Resorbable textile implants have already gained a foothold in the orthopedics market as an ideal option to aid in tissue regeneration and strength building at the surgical site. Textiles are also frequently used in sports medicine, trauma, wound management, tissue replacement, plastic surgery, women's health, and neural and endoscopy applications.

CRITICAL MEDICAL TEXTILE IMPLANT CONSIDERATIONS

Taking a raw textile material and transforming it into an optimal medical implant is a complex process. There are many important considerations that must go in to medical textile implant manufacturing in order to ultimately create devices that are effective and fit for purpose. Choosing a qualified partner like J-Pac Medical early in the development process that understands and brings expertise in critical areas such as manufacturing, packaging and sterilization for textile-based implants ultimately saves OEMs time and money by reducing unexpected issues later on.

Correctness of the Shape

Resorbable and non-resorbable polymers can be used to create implantable textile devices that are custom-shaped to meet specific anatomical and biological requirements, as well as facilitate shape transformation in situ. Customization of an implant's shape by the manufacturer can also reduce surgical procedure time by minimizing or eliminating currently needed intraoperative adjustments, and can also provide surgical repairs with reductions in tension inherent with non-customized implants. The value of a pre-shaped textile implant has been most notably demonstrated in the area of hernia repair, but potential applications exist across general, cardiovascular and orthopedic surgical applications.

J-Pac Medical can develop textiles in two-dimensional and three-dimensional implantable forms in any number
of configurations. The company further understands the unique needs of different surgical applications and can offer strategic counsel in the product development phase – coupled with the necessary process capabilities including precision cutting, shaping, forming and assembly capabilities during manufacturing which can optimize implant performance for purpose.

Specialized textile engineering techniques enable J-Pac Medical to capitalize on the unique properties of different materials. Braiding, weaving, knitting and non-woven textile manufacturing processes help to significantly enhance strength, texture, flexibility, and other performance characteristics for customized device requirements. For engineers, the possibilities for improved mechanical performance and anatomical accuracy are limitless, which will ultimately benefit the patient.

Interface to instrumentation to support minimally invasive methodologies

A textile-based implant is only completed when it is coupled with a methodology to place the device properly in-situ in the most minimally invasive manner possible. In meeting this objective, it is sometimes necessary to add attachments to what will be the final implant that will interface effectively with needed instrumentation. These attachments to the implant are removed post-implantation, but nonetheless are critical to an optimized implantation procedure.

The same cutting, shaping and forming capabilities that drive the manufacture of an anatomically correct textile implant can also support this critical instrument integration and needed deployment features that can minimize the invasiveness of any given implantation method.

Integration of different materials

One of the greatest benefits of implantable textile devices is that they can be patient-specific and developed for specialized end-user needs. Devices can be made entirely of absorbable components or of a combination of resorbable and non-resorbable parts. They can even be used for controlled delivery of drug or biological agents directly at the site of implantation.

It is important to choose the right textile materials and manufacturing partner to optimize the performance of the finished device for its intended purpose. J-Pac Medical’s team has the expertise to work with different types of materials – even hard to handle materials – and incorporate multiple materials into a device when beneficial for more optimized implants. Using thermal processing capabilities as a founda-
tion for material manipulation, supported by a blend of tooling, materials, automation, and process expertise will result in more innovative solutions to complex customer challenges.

In instances where resorbable and/or lyophilized materials are included in the implant, the manufacturer should utilize low humidity clean room manufacturing environments (dry rooms) to extend the WIP Time (Open Exposure Time) for materials and components that are moisture sensitive, and also to drive product consistency that can be impacted by uncontrolled humidity. J-Pac has production controls in place to negate any product impact that can be brought on by overexposure to humidity.

**Customized Edge Treatments**

Most textiles are produced in a bulk form as rolls, sheets, or reels of all sorts of multi-filament woven, knitted or braided textiles. Traditional cutting processes are capable of providing a unit/part with the proper length or outline but in a manner that allows the ends of textiles to fray, making the edges of the implant rough, and potentially generating particulate or degrading the textile's structural integrity.

J-Pac Medical has cutting methods that will create semi-sealed edges on cut parts that drastically reduce the amount of particulate, and greatly enhance the “surgical hand” of the implant by creating smoother, more flexible, cleaner and more structurally stable implants with improved tissue passage characteristics that significantly benefit both the patient and the surgical team.

Optimized edge treatment processes during manufacturing can offer broader benefits that may include:

- Enhanced edge quality of implantable medical textiles, which may minimizes tissue inflammation and scar tissue formation
- Reinforced edge feature that can enhance stability and suture pull-out
- Integrated deployment feature that can enable device delivery through cannula
- Smoother edge to enhance tissue passage
- Advance manufacturability of the finished device, which reduces component preparation time within the overall device assembly process.

**Packaging and Sterilization**

For implants that incorporate resorbable materials, the packaging must provide the necessary barrier to ensure efficacy over the claimed shelf life. These barrier put-ups may also incorporate modified atmosphere (gas-flushed) packaging in order to extend shelf life, and/or can include desiccants and scavengers to gain the same outcome.

For implants that incorporate a three-dimensional shape, the package must protect and maintain the desired anatomical shape. The package not only must protect the implant through
distribution and while on the shelf, but also must provide an intuitive and convenient platform to support sterile delivery technique in surgery.

If the implant is provided with instruments to be used during implantation, the packaging also needs to support the intended use of these instruments and aid the nursing staff and surgical team to gain easy access in the order the items are needed.

Regarding sterilization, in instances where actives (drug/device combinations) and/or a combination of resorbable and non-resorbable polymers are in use in a single device, a package format and flow may need to be developed to accommodate multiple sterilization flows such that each polymer chemistry present is sterilized in a manner not detrimental to its ultimate performance. In some cases, it may be necessary to perform separate sterilization flows for various components of the implant that are mated downstream in the supply chain to assemble the final kit. While these instances are not common, they will become more relevant as actives are incorporated into that textile implants.

J-Pac Medical's sterilization services are conducted and validated in close collaboration with our trusted strategic partners to deliver market-ready products to customers. Sterilization methods include Eto, Gamma, VHP, and autoclave and among others.

J-PAC MEDICAL: THE RIGHT MEDICAL TEXTILE MANUFACTURING PARTNER FOR OEMS

There are a broad set of requirements to be considered in the effort to develop and implement an optimized textile implant. As OEMs consider a manufacturer for medical textile implants, all the aspects that have been presented here must be considered. With the large number of integrated potential issues, partnering with a supplier like J-Pac Medical that has experience with all aspects of medical textile device manufacturing, including packaging and sterilization, can pay dividends through the entire product lifecycle.

With more than a decade of expertise in the manipulation of rolls and sheets of medical grade polymers and a reputation for excellence in manufacturing with difficult to handle materials, J-Pac Medical is able to produce the highest quality two-dimensional or three-dimensional implantable textile devices custom-shaped to meet specific anatomical and biological requirements.

J-Pac Medical provides forming, cutting and assembly capabilities for biomedical textiles and films backed by the extensive expertise needed to create two- or three-dimensional shapes with woven, knitted, braided or non-woven textiles, films, and more.

With efficient processing capabilities for delicate, brittle films and materials that meet industry standards, J-Pac Medical is able to achieve material utilization of 85% or better, which
increases the efficiency of production, reduces waste, and decreases cost to the customer.

The benefits of partnering with J-Pac Medical to manufacture implantable textile devices include:

- Reducing overhead for legacy products
- Freeing-up internal capacity
- Working with a single point of contact from start to finish, allowing potential obstacles to be identified and over come before delivery schedules are delayed
- Ability to form complex two-dimensional and three-dimensional shapes
- Cutting overall costs
- Proven Class II/III compliance and adherence to stringent quality and validation standards at every step of the supply chain.

J-Pac Medical has experience including, but not limited to, developing:

- Hernia repair products
- Nerve conduits
- Cardiovascular plugs
- Heart valve sewing cuffs
- Collapsible orthopedic anchors
- Diabetic wound care tissue scaffolds
- Osteoconductive bone grafts
- Scoliosis correction devices
- Suture loops
- Sternal closure devices
- Partially to fully resorbable soft tissue repair products
- Drug and device combination products

By working with J-Pac Medical from start to finish, consistent quality management, validation, tracking and reporting processes can be applied at every stage from development to manufacturing. The packaging of implantable textiles devices will also provide assurance of a high quality end product fit for the stringent demands of the medical market.
ABOUT J-PAC MEDICAL

J-Pac Medical is a trusted manufacturing and packaging outsourcing partner to medical device and diagnostic companies seeking to deliver superior quality, improve time-to-market and simplify the supply chain for single-use medical devices. With more than 30 years of experience in complex thermoplastic devices and packaging, J-Pac Medical has the unique technology that allows it to manufacture anatomically correct, class III implantable textile assemblies, lab-on-chip reagent blisters, and complex thermoformed packaging. Additionally, the company offers full-service supply chain management, packaging and sterilization.

The largest medical device companies in the world rely on J-Pac Medical to help meet the most difficult development, manufacturing, and logistics and supply chain challenges. For more information, visit www.j-pacmedical.com.

J-Pac Medical is FDA Registered (#1221051) as a Medical Device Manufacturer and a Device Labeller/Relabeller; and Certified to ISO 13485 standards through BSI.