Designing Battery Packs for Surgical Power Tools that Withstand Autoclaving Sterilization

(Credit: ahnsungdai/iStock)

Executive Summary

There is a growing trend towards battery-powered surgical tools to support various orthopedic procedures involving bone cutting, tissue coagulation, and microscopic surgery.

The "musts" associated with surgical tools used in operating rooms pose challenges for surgical device OEMs and their suppliers. For starters, tools must be sterile and therefore designed to withstand repeat exposure to sterilization processes. The tools must also be ergonomically designed for mobility and universal use by male or female surgeons. Their power sources must be high performing and reliable. And they must meet the complex regulatory standards required for FDA Class II medical devices.

Battery-powered surgical instruments offer several benefits over corded tools, such as increased portability and efficiency. Modern surgical tools that are equipped with long-lasting Lithium Ferro (Iron) Phosphate (LFP) battery technology provide several advantages over legacy technologies, including high-energy density, longer use, and faster recharge times. However, the battery packs must be designed to withstand a device-sterilization process used in operating rooms (ORs) known as autoclaving. This involves subjecting the battery pack to high heat, steam, and pressure.

One company driving advancements in lithium battery technology and battery pack design for surgical tools is Inventus Power. As a leader in the design and manufacturing of highly engineered battery and power solutions with more than 60 years of experience in supporting medical device OEMs, Inventus Power utilized its expertise and expanded its capabilities to custom design, develop, and validate autoclavable battery packs that meet all ergonomic and performance requirements for its OEM customers' battery-powered surgical devices.

Introduction

The development of powered surgical tools began in the 1890s when motorized systems for bone surgery were first introduced.[1] It wasn't long before modern surgical saws with electric motors became the norm along with electrosurgical knives for tissue cutting.[2] Today, the global surgical power tools market is forecasted to grow at a compound annual growth rate of 6.07% from 2025 to 2034, jumping from $365.05 million for 2025 to $620.2 million in 2034.[3]

Perhaps the most significant market for powered surgical tools is orthopedic procedures. Driven by an increasingly active population (just check out the tennis/pickleball courts in your area), a growing geriatric population, and advancements in surgical techniques, orthopedic procedures over the next five years are projected to grow rapidly[4]— elective hip and knee replacements by almost 30% and shoulder replacements by more than 50%. These trends point to great opportunities for medical device makers able to provide hospitals and surgical care centers with the mobile, flexible, and ergonomically superior surgical power tools they require.

Advancements in Battery Technology

The advantages of battery-powered surgical tools are significant and are becoming the norm in modern operating rooms. Advancements in battery technology over the years have resulted in the development of smaller, more powerful ergonomic tools with longer lifespans and faster charging capabilities.

The evolution of battery chemistry in surgical tools over the past few decades reflects broader advancements in energy storage, medical device miniaturization, and the push for more efficient operating rooms. Early rechargeable tools used Nickel-Cadmium (Ni-Cd) and later transitioned to Nickel-Metal Hydride (NiMH) for better energy density. In the early 2000's, many

The most significant market for powered surgical tools is orthopedic procedures. (Credit: Portra/iStock)

devices started transitioning to Lithium-ion (Li-ion) for even higher energy density and fast charging capabilities.

While Li-ion remains the most dominant chemistry used today for modern surgical hand tools, advancements in lithium-ion battery technology have further propelled innovation in surgical tool design. Integration with smart battery management systems (BMS) enable connection between the battery packs and the host system to monitor, communicate, and diagnose performance information. With real time feedback on the state of charge and battery health, the risk of sudden failure during procedures is preventable.

Other advancements in Li-ion battery technology have enhanced surgical tool development. Today, the most prevalent variant of lithium-ion battery chemistry used for the cells in battery packs found in surgical devices is Lithium Ferro (Iron) Phosphate (LFP). Because LFP has a greater margin for robustness and performance benefits, the surgical medical-device industry has largely shifted to LFP technology.

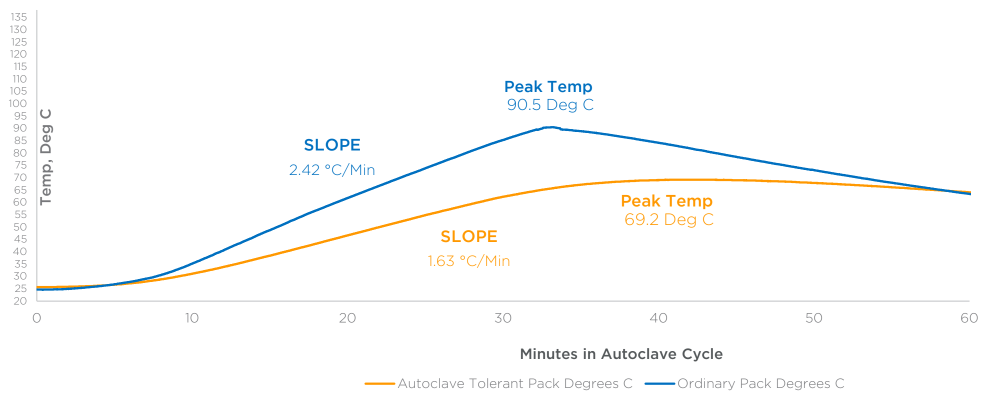
Battery Design Challenges and Autoclaving Considerations

When designing battery packs for any application, it's important to understand the entire ecosystem of the end device to ensure the battery pack is designed for its intended use and to withstand misuse. Designing battery packs for medical devices can be more complex than other applications. In the case of battery-powered surgical tools, a battery pack designer & manufacturer, such as Inventus Power, must have an intimate knowledge of the surgical tool's features and performance expectations so that the battery pack can be customized and designed specifically for each tool. Additionally, when a medical device OEM seeks FDA approval, the battery pack must also adhere to all FDA regulations. Proper documentation and component traceability are essential and the battery pack supplier's experience with the FDA process provides medical device manufacturers with confidence in knowing that the battery component won't fail them during the approval process and that they won't have to go back and reiterate to gain FDA approval.

Other design challenges have to do with the product's life expectancy and ergonomic factors. Whereas battery-powered personal devices, such as smart phones and tablets have average lifespans of 2 to 5 years, medical devices tend to have a much higher life expectancy – at least 7 to 10 years. That higher expectation requires much better performance of the battery packs to survive sterilization processes and minimize wear and tear on the battery packs. Proper sourcing of components – cells, transistors, internal circuits, etc. – that

Autoclave Temperature Test
Lithium Iron Phosphate (LFP) Battery Pack

Ordinary LFP Battery Pack vs. Autoclave-Tolerant LFP Battery Pack



Battery Pack	Peak (Deg C)
Ordinary	90.5
Autoclave Tolerant	69.2

Fig. 1 – Autoclave temperature test.

comprise the battery packs can significantly improve reliability and longevity of the battery pack.

As for the sterilization process known as autoclaving, this is a critical design consideration. Simply put, autoclaving is a sterilization process that uses a pressure cooker-like device to create high-pressure, heat-saturated steam to high temperatures (typically 121 °C or 134 °C) to kill bacteria, viruses, and fungi. In most ORs, the battery pack goes directly into autoclave, requiring enclosures made of a high-temperature thermoplastic material which reflects heat while providing a seal that withstands the high-pressure steam. Typically, a battery pack is expected to survive a minimum of 100 use cycles before it is replaced. Subjecting a lithium-ion battery pack to this environment can significantly impact performance. Fortunately, there are ways to design a Li-ion battery pack to survive high heat sterilization cycles, though it takes an experienced battery manufacturer to achieve (see Figure 1).

There's also an alternative method calling for aseptic packs from which the batteries are removed before sterilization. With such packs, only the outer casing, made of high-temperature thermoplastic material, is autoclaved. Meanwhile, the inner battery pack can be made using regular "normal" plastic housing material, such as polycarbonate or acrylonitrile butadiene styrene (ABS). Because the battery itself is not subjected to the high heat of the autoclave, the life of the battery can be extended to as many as 300 to 400 cycles. The downside: it changes the surgical team's workflow as surgeons and nurses must be able to insert the non-sterile batteries inside the sterile packs.

Inventus Power has proven successful designing and manufacturing autoclavable battery packs for several surgical tool OEMs. By incorporating phase-change materials along with some innovative design techniques for the housing, the company was able to significantly increase use cycles of an autoclavable battery pack.

During development, Inventus Power tested different variations of battery packs – those with phase-change materials and those without – and ran them through an autoclave to ensure the device's ability to withstand that environment. By understanding the OEM customer's testing requirements and working with them to balance size and weight with performance, durability, and cost, Inventus Power was able to deliver a reliable and high performing autoclavable battery pack that is capable of 150+ use cycles.

Supplier Selection Criteria

Choosing a battery supplier for a complex medical device application, like one that requires autoclavable design, can be tricky; there are many battery manufacturers with varying levels of experience and expertise in the areas most critical for medical-device OEMs. The supplier you select should meet the following criteria:

- **Engineering and manufacturing experience using lithium battery technology.** This experience must also include designing for long life (seven to ten years) of medical devices; knowledge of FDA requirements; and familiarity with autoclave sterilization.
- **Experience in qualifying and testing medical (specifically surgical) equipment.** Considered FDA Class II devices, these tools adhere to specific manufacturing and quality-control standards, and in most cases require a 510(k) to demonstrate equivalence to a predicate device; that is, they must have the same intended use and technological characteristics.

Inventus Power has proven successful designing and manufacturing autoclavable battery packs. (Credit: romaset/iStock)

- **Established tracing process.** In the event of an issue with the device while in use, the supplier must be able to provide the device manufacturer with complete traceability, as FDA will expect this of the OEM. In other words, the supplier must be ready to answer the same type of questions as the OEM.
- **Ongoing knowledge of battery industry, medical device standards and sourcing trends.** The global economy is ever-changing, due to trade policies such as tariffs, geopolitical tensions, and regional technological advancements. Suppliers must be ready, at any time, to source components from multiple countries of origin while tracking prices to provide a constant, cost-effective supply of product.

Onward and Upward

With there being a readily available global supply of iron and phosphate and the effectiveness of LFP battery technology maintaining a high rating in many applications, today's market for LFP battery packs in powered surgical tools remains strong. Another plus: Once LFP batteries reach the end of their operational life, recycling initiatives may allow for the reuse of the iron phosphate materials.5

Looking ahead, with more of us living longer and active lives, and the number of elective surgeries requiring battery-operated surgical tools and, in many cases, battery-equipped surgical robotics, on the rise, battery chemistry and technology will likely continue to advance beyond LFP chemistry.

By testing and staying current on battery-material innovations, pricing trends, and worldwide regulations, battery manufacturer Inventus Power continuously evaluates technology to ensure that the optimal solution is recommended for an OEM's medical device application.

"At Inventus Power, we are relentless in our pursuit of the safest power solutions as we closely track developments in the battery market," says Bob Zielke, Senior Director of Business Development at Inventus Power "We have a group of experts here that do nothing but follow developments in leading-edge battery technologies that are coming down the road. As soon as they become viable and ready, we want to be the first to use, deploy, and offer them to our customers. The money and resources we spend on research and development are part of our value proposition."

So, whether you represent a medical-device OEM in the surgical-tool segment or are looking for a reputable battery supplier to help design and manufacture your medical device innovation, consider this your invitation to discover more about Inventus Power's advanced battery systems and its manufacturing and engineering capabilities. Visit www.inventuspower.com.

Footnotes

1. Do you think the first saw was designed to be a surgical saw or tool for cutting trees? https://acf.com.tr/articles
2. William T. Bovie and electrosurgery, https://pubmed.ncbi.nlm.nih.gov/864002
3. Surgical Power Tools Market Size, https://www.precedenceresearch.com/surgical-power-tools-market
4. Seven factors affecting orthopedic procedures in nonacute settings, https://www.vizientinc.com/what-we-do/supply-chain/vizient-viewpoints/factors-affecting-orthopedic-procedures
5. Recycling of Lithium Iron Phosphate Cathode Materials from Spent Lithium-Ion Batteries, https://pubs.acs.org/doi/10.1021/acs.iecr.3c01208

For more information, visit www.inventuspower.com