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WHITE PAPER

DELIVERING HIGH QUALITY SURGICAL TREATMENT TO MORE PATIENTS THROUGH COST-OPTIMIZED STERILIZABLE MOTORS

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Surgeons worldwide prefer surgical hand tools that utilize the most advanced technology to deliver the highest performance and improve patient outcomes. To keep the cost of procedures down, the most sophisticated tools must be used in high volume which requires steam sterilization (autoclaving) between patients. High volume surgery centers (often referred to as Tier-I) can both afford the upfront cost of these premium tools and perform enough surgeries to bring the cost per patient to an affordable level. However, this expense model may not be ideal for smaller scale operations (Tier-II and Tier-III), so they seek surgical tools with a lower purchase price. This is a challenge because many lower priced tools sacrifice performance, are less durable and therefore may not survive enough surgeries and sterilizations.

This paper describes how the right motor can maximize hand tool performance and durability, while keeping the tool affordable for cost sensitive surgical centers. This saves and improves lives by creating access to top of the line surgical care to more patients.

COST SENSITIVE MARKETS FOR SURGICAL HAND TOOLS

Asia is the primary market for cost-effective surgical tools. The number of surgeries performed in this region is rapidly increasing due to medical tourism, socio-economic growth and better awareness of surgical options. Furthermore, the aging Asian population are experiencing higher rates of arthritis and other age-related conditions that often require surgical intervention. Even younger populations are seeking surgical care more often as their lifestyles become more active with travel and sports.

Globally, rural areas are another source of demand for lower priced tools as their hospitals may not have the patient throughput of large urban centers to amortize premium tool costs. Table 1 summarizes the requirements of these hospital systems.

HOSPITAL TYPE	TIER-I	TIER-II	TIER-III
Location	Large Metro Areas	Mid-sized Cities	Small Cities & Rural Areas
Approx Surgeries per Week	10+	3 to 10	< 1
Approx Surgeries over Tool Life	~1000	~500	~200
Target Motor Price	$250+	$200-$250	$150-$200

Table 1. Typical Surgical Tool Requirements by Hospital Type

SURGICAL HAND TOOL DESIGN

A transition is underway to move away from conventional corded and pneumatic hand tools using AC motors to using battery powered tools with lightweight brushed DC or brushless DC (BLDC) motors. However, the available low cost brushed DC and BLDC motor options are plagued with issues like inferior performance and shortened durability due to steam sterilization. They also lead to poor tool ergonomics due to larger size and higher weight required to meet the minimum speed and torque. Their poor efficiency also requires large and heavy batteries and dissipates more heat into the surgeon's hand.

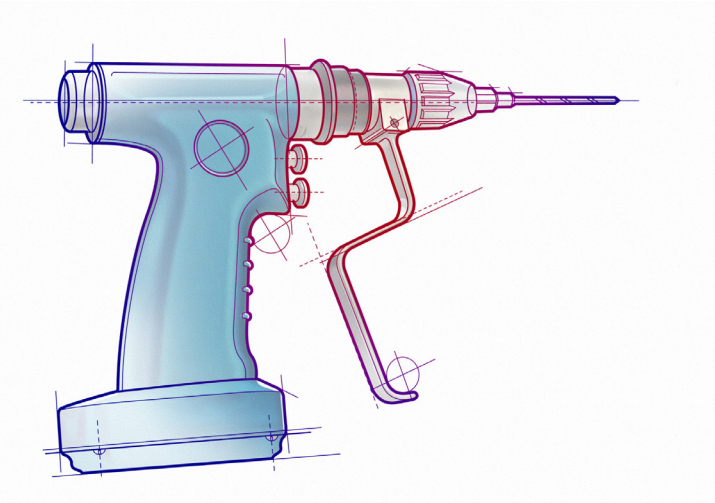

Figure 1. Example of a Powered Surgical Hand Tool

HOW STEAM STERILIZATION WORKS

The most common sterilization method used in hospitals is steam sterilization, also called autoclaving. During autoclaving, surgical hand tools are exposed to 100% humidity,135°C and pressure variations up to 30 minutes. Most autoclaves also have additional vacuum cycles to facilitate steam penetration and kill bacteria, viruses, fungi and spores that can hide inside microscope cavities in the device. Repeated exposure to this environment is what typically causes significant electrical and corrosion problem for motors and devices that have not been sufficiently well-designed to withstand these conditions.

Figure 2. How Steam Sterilization Works

- **Temperature: 121-135°C (Superheated Steam)**
- **Pressure: 2-3 bar**
- **Duration: 6-30 Mins.**

Without a cost-effective, high-performance motor option available, some surgical hand tool designers resort to selecting a motor not suited to survive sterilization and add protective sealing in the hand tool casing. This leads to bulkier tool designs that often do not survive well in autoclave. Unlike other electrical components that the tool designer might be familiar with protecting, a motor has a shaft passing through it that provides a direct path for moisture. It is especially difficult to prevent pressurized steam from entering this pathway. An autoclavable motor supplier with experience in the surgical hand tool industry knows how to seal the electronic portion of the motor from the rotating shaft, a feat that cannot be accomplished at the tool level. As a result, the cost savings of using a non-autoclavable motor are usually offset by increased costs elsewhere in the tool and higher development costs due to lack of experience. Inferior durability through autoclaving also results in higher total cost of ownership for the customer because they must either risk cancelling surgeries while a failed tool is replaced or purchase extra tools as back-ups.

Another alternative explored by some companies is to avoid sterilizing the motor by placing it in a part of the tool that is protected from contamination during surgery and then removing it prior to sterilizing the hand-tool. But this is generally considered a less safe approach because contamination can still reach the motor via the coupling to the drill or saw bit. In order to match the safety standards of Tier-I products, Tier-II and Tier-III hospitals must upgrade to fully sterilizable hand-tools using fully sterilizable motors.

METHOD	ADVANTAGES	DISADVANTAGES
Disposable Tool	**No autoclaving required** **Lowest risk of infection**	**Higher cost per surgery** **Higher level of medical waste**
Sealed Tool	**Motor semi-protected from autoclave**	**More complex tool design** **Shorter tool life**
Removable Motor	**Motor not autoclaved** **Longer life**	**Complex sterilization process** **Higher risk of infection**
Autoclavable Motor	**Simple tool design** **Longer life** **Low risk of infection**	**Motor must survive autoclave**

Table 2. Comparison of Sterilization Management Options

AUTOCLAVABLE MOTION SOLUTION OPTIONS

Regardless of the number of cycles the tool is designed to last, the best way to achieve high safety and reliability for the life of the tool is to use a motor that incorporates autoclave resistance features. For tools designed for Tier-I markets, high-end motor options will incorporate all the necessary material choices and sealing required to maximize the life of the tool through repeated autoclave sterilization. The additional surgeries performed per tool will more than pay for the additional purchase price. But for tools targeting Tier-II and Tier-III markets, the useful life of the tool may be limited for other reasons and high-end motor features will not return value. In this case a motor utilizing a selective combination of autoclave resistance features will deliver the best outcomes and lowest cost per surgery.

While this paper has focused on the motor, gearing and controls are also degraded by autoclave and must be part of life target and sterilization protection considerations as well. A full motion solution partner with experience in the surgical hand tool market will have options for motors, gearhead and controllers covering various life targets and cost limits. To take advantage of such a partner's full breadth of products, customization capabilities and design consultation expertise, it is critical to collaborate with them at the concept or even ideation stage of device development. **P**

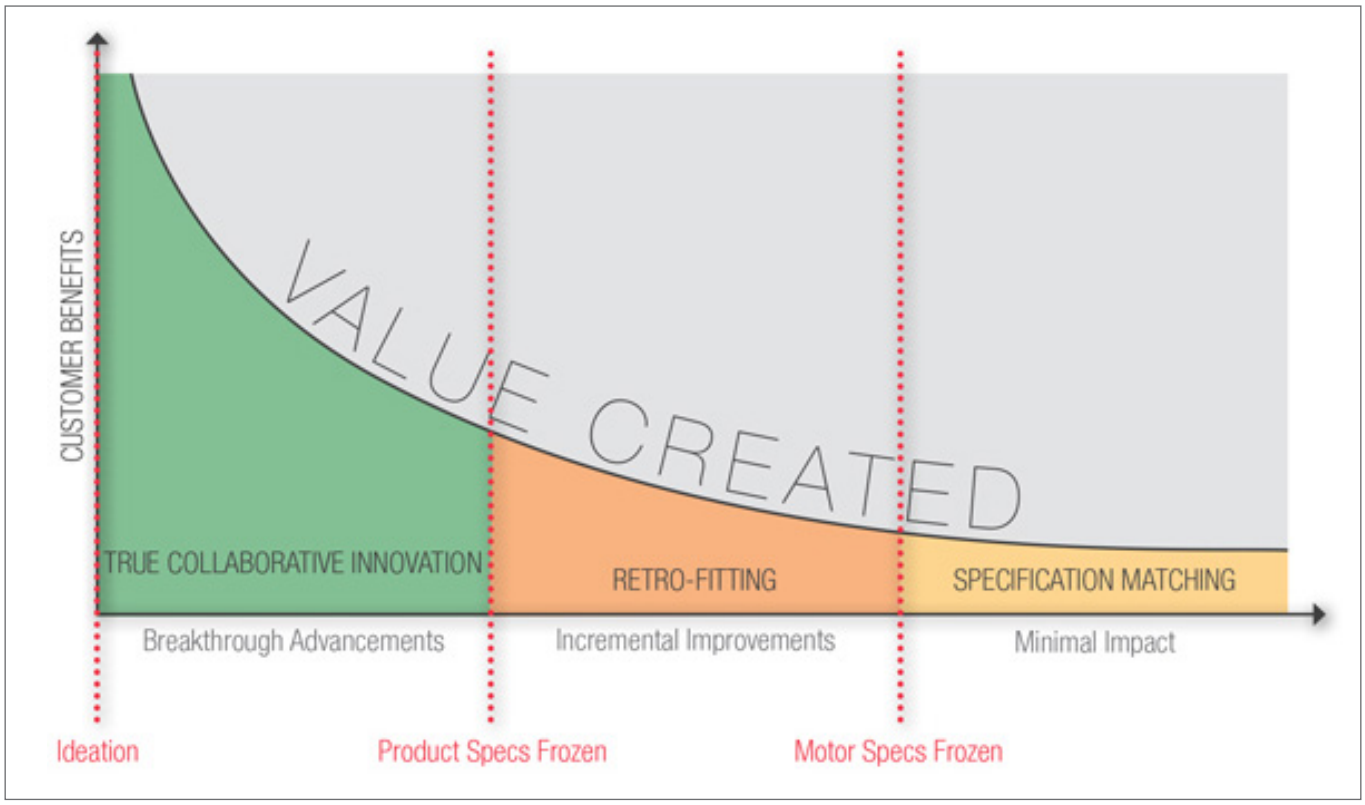

Table 3. Benefits of Early Engagement with Motor Supplier

FOR MORE INFORMATION:

110 Westtown Road
West Chester, PA 19382
T: +1 610 235 5499
F: +1 610 696 4598
sales.america@portescap.com
www.portescap.com

CONTACT AN ENGINEER:
www.portescap.com/en/contact-portescap

Anand Hasurkar
Manager - Product Engineer
Anand.Hasurkar@portescap.com

Portescap