

Seals Designed to Improve Medical Device Performance

Insulin pumps, oxygen compressors, and surgical drills are included among hundreds of life-supporting machines manufactured by the medical device market. Each device is composed of highly-engineered seals and sealing components that are critical to its ability to perform as intended. In an oxygen compressor, for example, low-friction reciprocating motion piston seals support the machine's continuous operation. Unreliable sealing components in an oxygen flow device can compromise its performance and be life-threatening to the end-user. Consequently, seal design and materials are an important part of the design process.

As we consult with medical device manufacturers about sourcing seals for their unique applications, three common challenges surface. First, FDA-compliant materials are required. This ensures that seals and sealing materials in medical devices are of the highest quality and suitable for their planned use, which often could involve contact with the human body. It also enables full traceability of materials and manufacturing processes for operator and patient safety.

Second, medical devices require seals designed for the extreme heat demands of autoclaving. In an autoclave steam sterilization environment, every part and component within a piece of equipment is subjected to temperatures ranging from 250 to 375 °F. This may occur for an extended period over the life of the device based on the time required to clean it properly. For reliable device performance, a careful informed approach to selecting seals designed to durably withstand the rigors of autoclaving is recommended.

The third and possibly one of the most complex challenges medical device manufacturers face is the market's limited pool of seal suppliers with the technical knowledge and expertise to develop FDA-compliant solutions to meet existing and emerging equipment trends. Devices are becoming more advanced, must operate for longer cycles than ever before and process various fluids including cleansing agents at high speeds, temperatures, and pressures. In addition, many devices are portable,

requiring expertise in designing seals that enhance the longevity and reliability of battery-powered equipment.

Looking beyond the seal

High-speed medical devices, such as surgical drills and cutting instruments function in a rotary motion that requires dynamic sealing solutions. This operating environment is also characterized by high temperatures. PTFE-based materials are typically used in a dynamic sealing environment while ethylene propylene diene monomer (EPDM) may be used on the static side of the seal. EPDM can be acquired as FDA-compliant and is high-temperature tolerant which is suitable for autoclaving.

The mating components of a high-speed device also play an important role in sealability. By working with a seal supplier that can provide full applications engineering support, manufacturers benefit from the development of equipment designed with the best operating conditions for the seal. For example, in manufacturing a shaft for a rotary component, the process can be greatly enhanced when the engineering envelope expands beyond seal design. If the interaction of the seal with all relative equipment and components are properly evaluated, solutions to make the entire device work better become much clearer.

This was the case for a manufacturer of skin grafting and wound debridement devices that are being used in surgery across the U.S.

Redefining excision science

Surgical procedures involving skin grafting and wound debridement for a burn patient can be very complex and lengthy. By designing more advanced surgical devices, it can affect and help improve the outcome and recovery of a burn patient. Improving patient lives and outcomes by advancing innovation, product development, and the marketing of medical devices for healthcare professionals in the surgical market are primary objectives for [Exsurco Medical, Inc.](#) when the company began to design an air-powered medical device that allows precision skin grafts and excision for surgical patients.

During the device development process, the manufacturer encountered a sealing challenge. A solution was needed to handle extremely high temperatures generated from continuous rotary speeds at 10,000+ rpm. This affects the interface between the seal and its dynamic surface. A low-wear solution with the ability to dissipate localized heat where the seal contacted the shaft was the focus. The composition of a seal's surface contact design is important to manage how it handles heat derived from speed and friction.

The solution also had to be designed to eliminate trapping contaminants under the seal, in the motor, or any of the device's electronics for complete autoclaving. This called for a seal without spring energizers because of the risks associated with contaminants getting caught between the spring and the seal.

Exsurco partnered with Polymer Concepts Technologies, Inc. to conduct a thorough assessment of the sealing needs for the skin grafting device and how the seals interact with mating components. This resulted in the design and development of a PTFE lip seal that features a proprietary processing method for enhanced performance as temperatures rise. Success was achieved through an in-depth understanding of the application, full collaboration between the two parties, and appropriate selection of design and materials.

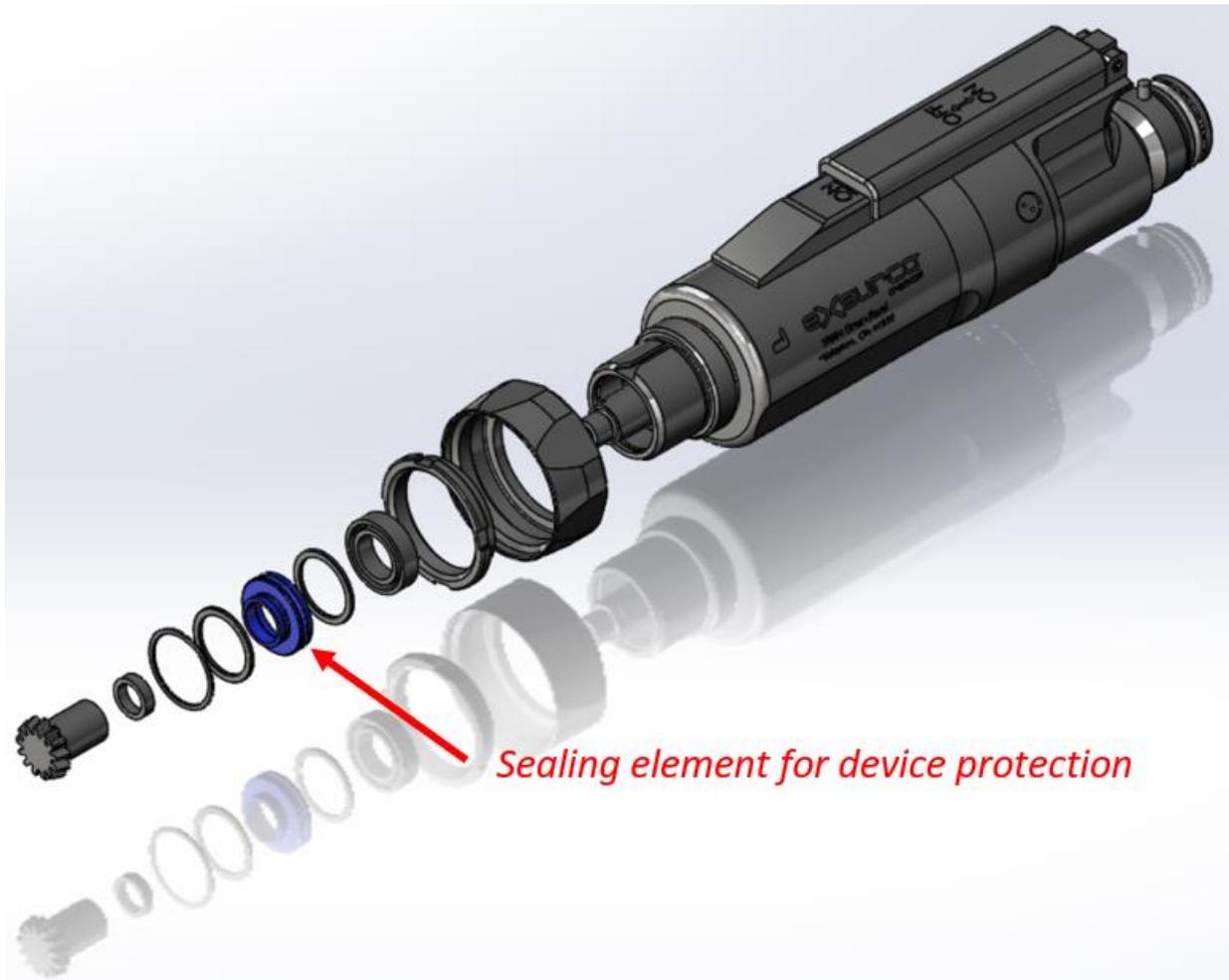
Conclusion

In conclusion, seals can truly provide peak performance to a life-saving device. The applications engineering experience is critical in proper design, development and manufacture of precise devices to create, not only a manufacturable item, but one that is sustainable. "Thinking outside the box" is important in any design and development situation, and teaming up with a supplier to find the answers "inside the box" can make all the difference in the world.

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GRAPHICS ATTACHED:

(1)



Innovative, advanced products help medical professionals perform complex procedures that improve patient lives

(2)



PCTI designed a polymer seal to meet the skin grafting and wound debridement device's extremely high rotary speeds of 10,000+ rpm

PHOTO RESOURCE:

See Photos|Videos|Resources on Exsurco's website:

<https://www.exsurco.com/product/amalgatome-md-x100556-split-thickness-recovery-device/>