How To Select A Pump For Surgical Ablation Applications

Control and high pressures are essential for overall system performance.

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The use of radio frequency (RF) ablation is an important and growing technique at the heart of many new medical treatments. This equipment uses RF energy to ablate or destroy unwanted tissues. When delivered via a catheter, it offers a minimally invasive treatment for a wide variety of conditions, including atrial fibrillation (AF).

These systems typically include a peristaltic pump to provide cooling or temperature control, and this pump must be able to produce and control the high pressures (up to 130 psi) required in this application.

RF Ablation's Medical Applications

Medical devices use RF ablation to treat many medical issues, including heart issues, tumors, and back pain. For example, this technique can be used in treatment systems for AF, a condition that affects 2.7 million people in the United States. The condition is caused by an interruption of the normal, steady heartbeat, which is controlled by electrical signals that travel through the heart's tissues. But, when the heart is in AF, these signals are disrupted, causing the heart to beat irregularly and, often, too fast.

When the heart does not beat in rhythm, it cannot pump blood properly to deliver the energy and oxygen the body needs. This lack of oxygen-rich blood in the body and brain can cause physical and mental fatigue, as well as other AF symptoms. Ablation treatment is effective when the condition is caused by heart wall tissues that no longer conduct these electrical signals properly. The treatment destroys the faulty tissues and provides patients with a permanent cure.

Surgical RF Ablation

A typical ablation system is made up of an RF generator, control and monitoring equipment, the antenna, and a cooling pump. The radio waves are used to create an electrical current that delivers heat to the targeted tissues, which creates a controlled lesion, or burn. That tissue is replaced with healthy tissue through the natural healing process.

The business end of the device is the antenna, which applies energy to the tissue being ablated. The antenna resides at the tip of a catheter or cannula, along with electrical and temperature sensors that are connected to the system controller. The RF generator delivers the energy through the antenna at the specific frequencies and amplitudes prescribed by the treatment. The pump delivers cooling fluid to maintain the correct temperature at the treatment site, and helps to protect the surrounding healthy tissues. Catheters typically use open-loop cooling, which delivers saline directly to the treatment area via small holes. Cannulas typically use a closed loop system, in which saline is recirculated through a double needle.

The pump must provide the prescribed flow rates to provide the correct amount of cooling. To do so, it must overcome the backpressure created by the small inner diameter of the catheter or cannula tubing. These pressures can exceed 100 psi for closed-loop applications. Recently, the market trend among medical device OEMs is to develop smaller diameter catheters for greater precision and reach. These micro catheters require pumps that can overcome the resulting higher back pressures caused by internal diameters as small as 0.014 inches (0.36mm).

Pump Requirements

The pump most often chosen for the job is a peristaltic pump, a type of positive displacement pump. With a peristaltic pump, the fluid is contained within a flexible tube, fitted inside a semi-circular pump casing known as the track. The tube is typically built into a disposable tube set that can be discarded after each procedure, which minimizes cleaning validation.

The tube is pressed against the track by a rotor with two or more rollers attached to its external circumference. As the rotor turns, the part of the tube being compressed is occluded (pinched closed), forcing the fluid being pumped to move through the tube. As the tube re-opens to its natural shape after the roller passes, a vacuum is created, which draws fluid into the pump. The advancing roller then pushes the fluid toward the pump outlet.

A peristaltic pump is designed to give consistent occlusion of the tubing; too much or too little can cause performance issues. Too little occlusion hurts flow and pressure capability, and can cause leaking through the pump. Too much occlusion and the tubing will rapidly wear out, hurting flow performance and causing excessive spallation.

There are two basic types of designs used in peristaltic pumps: *fixed gap* and *spring-loaded*. The "fixed gap" refers to the gap between the rollers and the track where the tube is occluded. This is a simple, yet effective design. However, it is very much dependent on the tube wall thickness to maintain consistent occlusion. Tubing supplied by the pump manufacturer is designed with the correct tolerances to work effectively with a fixed gap pump.

In many medical applications, tubing is not supplied by the pump manufacturer, and is a non-standard size. For a fixed gap design, a custom roller must be specified to adapt to the dimensions and tolerances of the selected tubing.

A spring-loaded peristaltic pump has a spring mounted either on the track or the rollers. The spring provides a positive force pressing on the tube that will compensate for the tube's tolerances. The spring is selected to overcome not only the tubing's compression strength, but also the desired pressure performance of the pumped fluid.

Support Beyond The Product

A purpose-designed off-the-shelf pump is a good start, but not enough to provide an effective solution. The company designing a new medical device must work with a supplier experienced with OEM medical device applications; one that will provide access to its engineering staff, and take the time to understand the unique requirements of the customer's application. The customer/supplier team will work on designing custom configurations, testing them, and agreeing to a written specification. The end result of this process is an optimal pump solution that meets the customer's precise flow and pressure requirements.

It is equally important that the supplier has strong quality systems in place, giving product traceability, and change control. The product must meet the requirements – exactly – with the first order, and with orders placed years into the future.

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