

White paper

Metal bellows push performance boundaries for medical devices



In recent years, medical device companies have been innovating at a rapid pace to keep up with demands for improvements in procedures and patient care. Miniaturized, implantable, portable and connected devices are just some of the types making inroads.

Another significant factor is the need to commercialize products in compressed timelines to achieve a competitive advantage. In this flurry of activity, sometimes alternative routes for components are not pursued due to time or cost issues. As creatures of habit, we have a tendency to gravitate toward the known vs. the unknown. The same can be said for selecting components for medical devices. It can be challenging to think outside the box, or even explore options that might ultimately result in breakthrough applications.

To illustrate the point, let's look at bellows used in medical devices. Medical device product engineers most likely have more experience with plastic or rubber bellows, thus they are likely to specify these when designing a product, completely overlooking metal bellows.

However, with increased innovation which is placing more demands on components—such as those requiring materials that will not degrade inside the body—now is an ideal time to consider how metal bellows can help improve your medical device. This paper will review four options for using metal bellows: flexible joints, portable infusion pumps, an XYZ-axis manipulator and a double-bellows pump.

Superior attributes of edge-welded metal bellows compared to rubber, plastic

Metal bellows are flexible, hermetically sealed, spring-like components that react to environmental conditions such as temperature or pressure to deliver precise mechanical motion. Bellows can generate pressure to pump fluid through the body. They can be designed to not require power or electricity. They also can be used for compression, extension, actuation, volume compensation and more. Here are some comparisons to rubber and plastic (epoxies, fiberglass, etc.) bellows:

- Rubber needs to be three to four times thicker than metal to achieve the same strength
- Metal bellows weigh less than rubber
- Rubber bellows require more space than metal bellows
- Metal handles pressure better than rubber and plastic
- Metal has better UV and chemical resistance than plastic and rubber
- Metal is reliable, clean, serviceable and reusable
- Metal bellows do not degrade causing device failure or contamination
- Edge-welded metal bellows are lead and copper-free
- Leak tight to ultra-high vacuum standards are achievable with edge-welded bellows

Flexible joint: Fluid-filled 4-core flexible assembly

This design is a quadruple bellows core assembly filled with fluid (saline or sterile solution). The joint is capable of offsetting laterally, bending at the middle for angular movement and extending. Being fluid-filled enables support in a vertical position without hindering angular or lateral movement. However, the fluid-filled interior does limit compression of the assembly. Potential applications include:

- Joint replacement
- Spinal disc replacement
- Flexible joint in a robot or exoskeleton
- Flexible joint in a leg or arm prosthetic



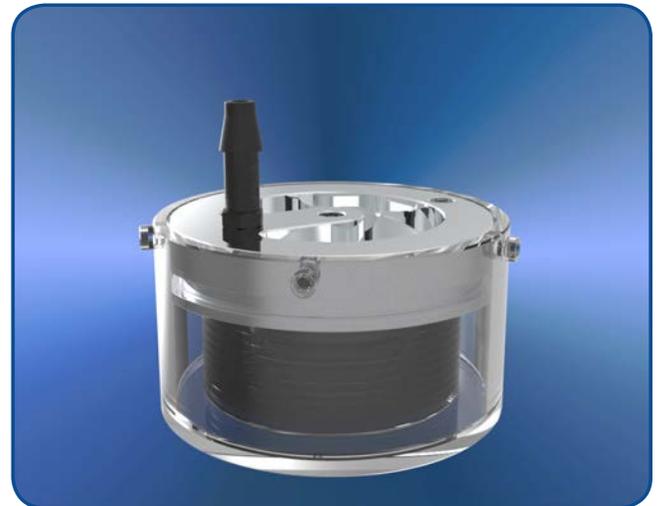
Application example: Metal bellows used as medical positioning equipment

A metal bellows enabled a medical professional to maintain a precise position while performing a procedure on a joint. This resulted in an improved outcome for the patient. The size of the metal bellows tool allowed for more visibility and room to perform the procedure quicker and safer. Also, the smaller size meant that it weighed less and was easier to handle than alternative positioning equipment.

Portable infusion pumps: 2-chamber bellows for applications that do not require electricity

One chamber is pre-charged with a gas and the other chamber can be filled with a gas or a liquid. In some cases the second chamber can have a dry powder chemical. The charged gas acts as a mechanical force that pushes out the contents of the second chamber once a side port is opened. This action occurs by compressing the bellows. Potential applications include:

- External IV drug delivery pump
- Internal drug infusion pump
- Charged propellant delivery system
- Military (drug delivery IV packs for field combat situations)



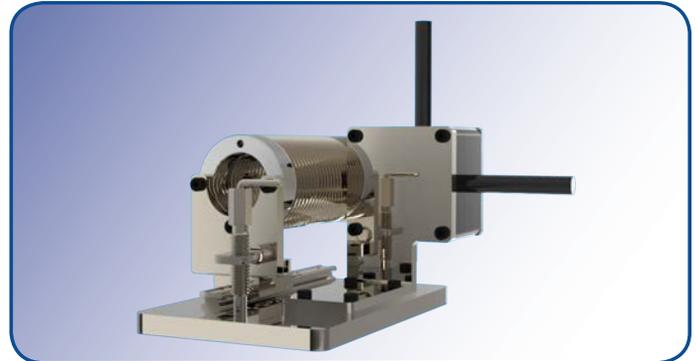
Application example: Metal bellows used in an infusion pump

Titanium or stainless steel bellows can be used with infusion pumps which deliver pain management medication. For example, if the patient has been in a serious accident and is experiencing a great deal of pain, the physician may recommend an implantable infusion pump. A catheter is connected to the spine and the device is set to meter a specific amount of medication. A metal bellows that has been charged with gas can be used to open the device's valve which enables the drug to be delivered. (This is ideal for portability and/or for areas that do not have electricity.) The patient can then visit the physician periodically to refill the device with medication via an external port.

XYZ-axis bellows manipulator: Using a bellows core to pinpoint treatment and/or reduce unnecessary exposure

XYZ-axis manipulator with a bellows used as a cover or container for laser and/or proton therapy. Precision manipulation can be achieved while under vacuum. Ideal for pinpoint accuracy procedures such as spot laser treatment for certain cancers. Potential applications include:

- Precision laser surgery
- Optics alignment
- Wafer alignment and manipulation
- Proton therapy



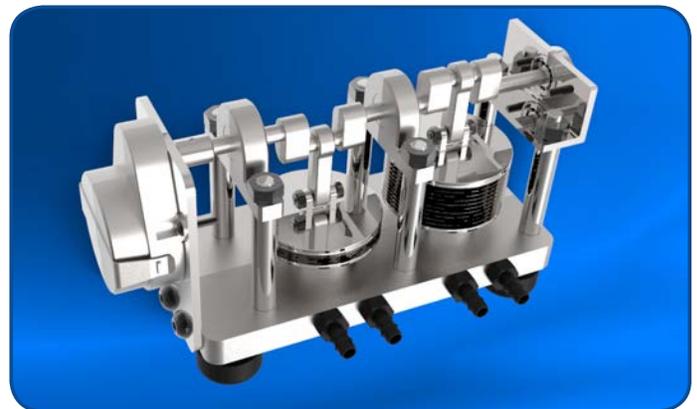
Application example: XYZ-axis bellows manipulator for proton and/or laser procedures

Edge-welded metal bellows are ideal for targeted treatment areas that require precise XYZ-axis manipulation and positioning. A manufacturer of a therapy device needed a bellows that could be manipulated on all three axes so that treatment could be provided with pinpoint accuracy while under vacuum. Metal is the ideal material for this bellows type to hold the seal, prevent leaking and allow the position manipulation necessary for treatment.

Double bellows pump: Fluid pump using two bellows cores and an electric motor

This assembly is a mechanical fluid pump featuring a double bellows pumping unit for fluid or gas. This concept is not limited to medical or aerospace applications. Potential applications include:

- Medical fluid pumps
- Medical gas pumps
- Hydraulic fluid pumping
- Engine oil priming units
- Freon pumping unit
- Extraction pumps
- Fuel transfer pumps
- Life support circulation pump



Application example: Double metal bellows pump used for medical fluid flow

A double metal bellows pump is ideal to pump or draw fluid or compress gas. In this application, a company was looking to improve the function of its portable fluid filtration unit. A bellows assembly was already being used as a pulse dampener too create a smooth laminar fluid flow. In these types of applications high pulses can rupture a vein or artery, so smooth fluid flow is imperative. An alternate solution would be to incorporate a double bellows pump to insure proper performance and smooth fluid flow. This equipment can be designed small enough to fit into luggage for traveling and to enable medical care on the go.

Not all metal bellows are equal

BellowsTech, LLC, an MW Industries company, is a premier manufacturer of high quality, dependable edge-welded bellows and assemblies. Engineers in a broad spectrum of industries rely on BellowsTech products for the highest cycle life, responsive design, wide material selection, and leak-tight performance.

Our expert engineers partner with you to produce truly optimized designs and fast prototypes, as well as full production runs. They can manufacture in all sizes and material combinations to fit your unique applications.

With proprietary welding technology, in-house tooling and machining, and custom solutions, BellowsTech can supply a completed assembly with the best price-to-performance ratio in the industry. The company excels at new designs with custom capabilities and also offers repair and replacement services.

BellowsTech is ISO 9001:2008 certified, AS9100C compliant and dedicated to your overall satisfaction.

For additional information on finding the best solution for your medical device, please contact us at:

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