MW® INDUSTRIES inc.

Economy Spring

PRECISION METAL COMPONENTS IMPROVE CONNECTED MEDICAL DEVICE PERFORMANCE

In this article, David Philbrick, Business Development Manager, Economy Spring (MW Industries), discusses the critical role a variety of metal springs and components play in a connected drug delivery device and presents an example of how failure to consider them properly can send a successful commercialisation sideways.

This article is based on an MW Industries white paper: "Precision Metal Components Improve Connected Medical Device Performance".

Extensive technological inroads in drug delivery devices and surgical platforms are enabling significant improvement in the quality of patient care. One of the major ways in which this is happening is through the incorporation of connectivity. While a significant amount of technology goes into the development of connected devices, sometimes the smallest components, such as springs, wire-forms, stampings and bellows, can enhance the performance of the electrical circuitry in the device and reduce its size.

Take autoinjectors as an example. In the early days of these devices, a spring was used to perform a mechanical function, by way of storing and releasing energy. Today's electronic, connectivity enabled devices require much more sophisticated components such as battery or timing contacts that assist in triggering device circuitry. These components are crucial parts of the internal circuitry that facilitates the advanced features of an electronically upgraded device and, whilst they are seemingly simple, it requires expertise to get the most out of them.

"Today's electronic, connectivity enabled devices require much more sophisticated components such as battery or timing contacts that assist in triggering device circuitry."

"The battery, circuit timing contacts, circuit routing, component coatings and non-magnetic metal alloy integration are just a few of the components whose characteristics need to be carefully designed to ensure that the device will work properly."

David Philbrick
Business Development Manager
T: +1 860 621 7358 Ext 3370
F: +1 860 621 7882
E: dphilbrick@mw-ind.com

Economy Spring
29 DePaolo Drive
Southington
CT 06489
United States

www.mw-ind.com/brands/economy-spring

BOX 1: CONNECTED DEVICES

Connected devices feed information back to physicians and help ensure that they are being properly utilised by the patient. As a result, it is increasingly critical to make sure component design will support this desired functionality in electronic systems.

In the field of drug delivery, the specific areas where this technology is making significant progress are inhalers and autoinjectors. However, in the broader context of the healthcare world, connectivity is making its way into hand-held laparoscopic/endoscopic devices and powered electrosurgical/robotic surgical platforms as well.

With pharmaceutical applications, patients are now able to administer their own drug treatments in a more controlled manner. Improvements in device functionality have resulted in automatic dose tracking, as well as tracking the timing and frequency of therapy. Physicians can effectively monitor patient care automatically through data analysis, which will tell them if the device is being used properly. Pharma companies can also harvest data on device usage to develop more effective devices and therapies in the future. Further, the integration of Bluetooth and near field communications (NFC) enables self-administered drug devices to communicate via the internet and mobile apps.

Surgical devices also are taking advantage of the latest in connected technology. Examples include monitoring the physician's use of the device during procedures and determining effectiveness of device utilisation. Additional capabilities include automatic activation of device safety features, as well as autonomous data output to a clinical repository or patient files. This data harvesting can be used to enhance surgical procedures, create next generation devices and improve patient care.

> "If the gold coating technique, spring characteristic and proper metal alloy have not been designed effectively in a connected device product, the chances that the device will not function properly are exponentially higher."

THE PATHWAY TO CONNECTIVITY

Many next generation pharmaceutical and surgical devices will share one thing – the ability to gather and disseminate data (see Box 1). The battery, circuit timing contacts, circuit routing, component coatings and non-magnetic metal alloy integration are just a few of the components whose characteristics need to be carefully designed to ensure that the device will work properly. Part of that decision-making process requires that you are working with a supplier who has the knowledge, capability and reputation of delivering high quality, precision components.

Here follow some examples of battery and device timing contacts that may be utilised in a connected device.

Figure 1: Gold-plated bellows.

Gold-Plated Bellows

Microscopic bellows components (Figure 1) can be designed for use in creating electrical circuit contacts in wearable devices, autoinjectors and inhalers. They are ideal for "noisy" electrical environments where the traditional "pogo" style pins are too rigid in the circuit design, or where there is excessive motion or vibration that results in damaged pins or connections. The bellows are designed to absorb shock and able to withstand sudden jarring motions at a circuit connection (similar to a spring) and dampen vibrations, enabling reliable continuity of the circuit.

Coiled Wire-Forms and Springs

These components (Figure 2) come in a variety of sizes and shapes and are ideal for battery contacts where the spring force creates positive pressure to the power source. They can also facilitate complex routing in a moulded housing or a circuit path through a device. Wire-forms can also be gold plated for improved electrical and corrosion resistance resulting in reduced metal oxidation.

Figure 2: An example coiled wire-form.

Leaf Springs or Stampings

The spring characteristics of these components (Figure 3) can assist with battery and circuit board design while generating positive spring pressure to maintain connectivity. The leaf springs can also be designed as finger contacts for various timing events in the device motion, deflection or actuation of the device. The result is enhanced device functionality based on contact motion and spring recovery within the moulded device housings. These components also can be designed to utilise selective gold-plated or banded strip material to reduce the gold coverage on the entire component. This technique results in significantly reduced part costs with gold placed at the exact contact points.

In addition to battery and timing contacts, there are also metal components that can be used in an electrical circuit function where magnetism helps to trigger the circuit connection. In this instance, a non-magnetic metal alloy integration may be required to minimise any undue

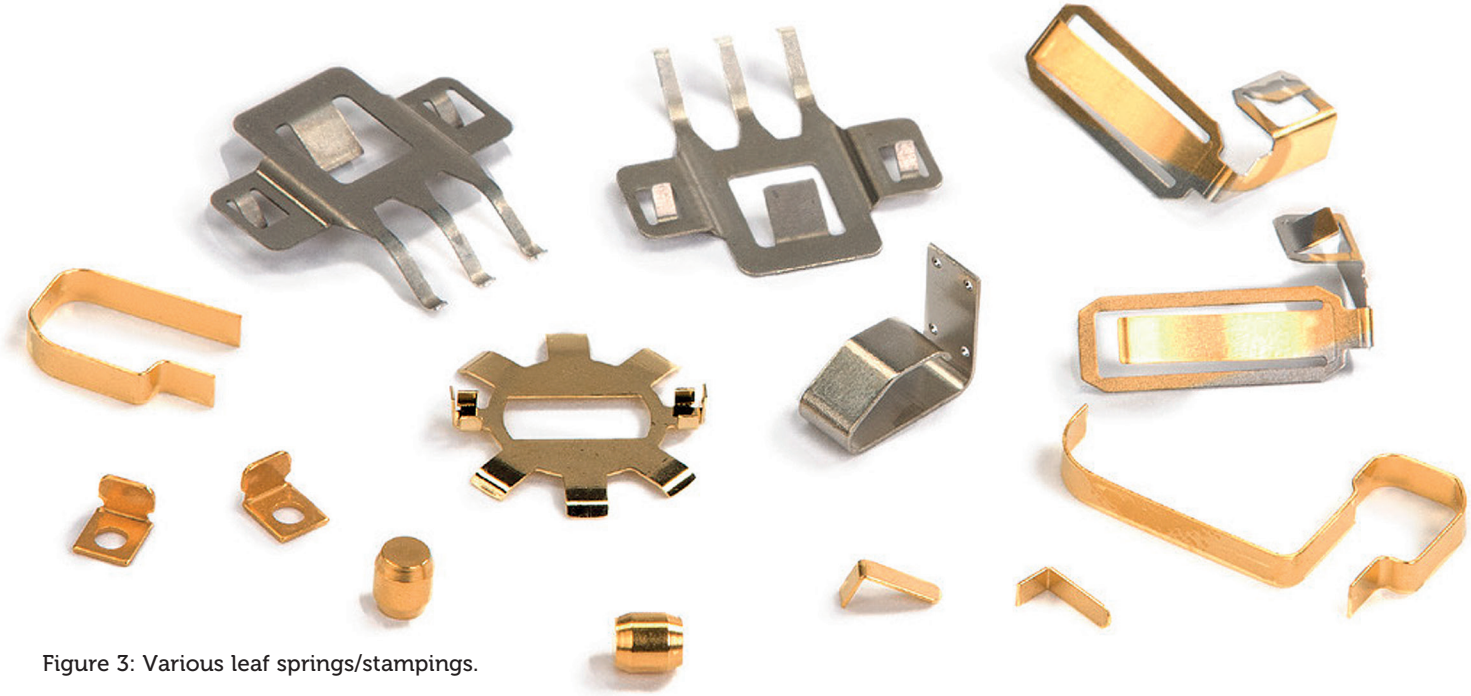


Figure 3: Various leaf springs/stampings.

"The resulting actions eliminated the voltage/current variation experienced in the finished product, which led to consistent circuit functions and timing in the device."

magnetic signature that would influence the circuit timing by energising the leaf spring and thus inappropriately influencing the circuit timing.

THE IMPACT OF FAILURE

If the gold coating technique, spring characteristic and proper metal alloy have not been designed effectively in a connected device product, the chances that the device will not function properly are exponentially higher. In practice, this could mean that the device does not administer the medication dose correctly, thus negatively impacting patient care, or corrupts the data collection process, supplying incorrect data to the end-user (e.g. healthcare professional, data analyst). At the very least, such outcomes are undesirable and will have a serious negative impact on perceptions of the device's quality and reliability. In a worst-case scenario, there is a significant adverse effect on patient health, due to device malfunction or a physician unwittingly prescribing a flawed treatment due to inaccurate data. As a real-world example, below is a scenario of how an incorrectly defined coil spring drawing was adversely affecting a connected device.

Situation

A large contract manufacturing organisation (CMO) was having problems with maintaining consistent voltage/current levels on a circuit in a connected drug delivery device it manufactures. The resistance level of the coil spring was becoming an issue as commercialisation activity ramped up. Spurred by experiencing higher instances of electrical performance variability, upon investigation they discovered that their spring supplier could not hold the required tolerance of the spring's free length defined on the part drawing. During incoming inspection, the existing spring design experienced a very high rejection frequency. The fallout due to the free length was, on average, 40%.

Problem

At the time, it was unknown to the CMO that the variation in free length was the primary contributor to vast differences in the spring's resistance level. The spring was very long, coupled with a large coil count (70 inactive coils) and a poorly-dimensioned free length tolerance defined by the part drawing. Initially, the free length tolerance was designed to help control the amount of wire in the spring. As a result, it would control the resistance level needed to trigger the circuit in the finished product.

Unfortunately, the part drawing focused on the free length rather than establishing a measurement for the resistance level of the spring itself. To make matters worse, the spring supplier was also rejecting a very high volume of springs on the manufacturing line resulting in high internal scrap. Since they could not meet 100% of the free length tolerance as noted on the part drawing, the supplier was forced to ship a small percentage of "long springs" to keep up with the increase in demand. These conditions led to the variation of the voltage/current levels in the device.

Solution

Upon a thorough investigation by the Economy Spring team, it was discovered that the resistance measurement was required on the part drawing and in-process resistance checks were needed to control the amount of material in the finished spring. By incorporating this measurement technique, a new spring was designed to minimise the voltage/current variation, resulting in an increased free length tolerance.

The recommendation of these print changes reduced internal scrap at the spring supplier, increased throughput on the CMO manufacturing line and reduced fallout at incoming inspection. The resulting actions eliminated the voltage/current variation experienced in the finished product, which led to consistent circuit functions and timing in the device.

CHOOSING YOUR SUPPLIER

It's important to do your homework so that the suppliers you select to be part of your journey can help you race to the finish line, instead of creating problems and obstacles along the way. Choosing the right supplier will have a positive impact on the all-important speed-to-market timeline. A wrong supplier will not only prevent you from reaching your commercialisation goals

quickly, but it could also negatively impact the functionality of your device.

Robust Quality Control System

Having a robust quality system is critical to ensure the life of the project and its commercialisation success. Product failure is not an option – particularly for a product that should create improved patient therapies and be the centre of a developing smart device platform.

The supplier's ISO 9001 and ISO 13485 certifications should be evident. Plus, a supplier who can demonstrate US FDA Medical Device Establishment Registration and Device Listing capabilities as well as GMP illustrates their commitment to consumer safety and product reliability.

You want to make sure that your component supplier is more than capable of providing the appropriate quality planning. Control plans, process flow diagrams and Process Failure Mode and Effects Analysis (PFMEA) need to be in place so that a change is not made after validation approvals. Emphasis on the PFMEA design in your supplier's environment will help understand the weakest part of their process and make sure adequate controls are in place to address ongoing issues.

Metrology Capability

Ideally, a supplier will have state-of-the-art, in-house metrology capabilities. Components need to be accurately measured and data needs to be supplied to meet statistical requirements. Automated measurement systems and the ability to collect data without human interpretation has become more prevalent. This level of activity helps the original equipment manufacturer (OEM) build the bridge needed to support the FDA submission on the device or project. The supplier's ability to provide supporting measurements helps the OEM to meet statistical protocols and verify quality expectations.

CONCLUSION

In addition to the attributes listed above, it's important for a supplier to have a competent level of experience working with design of electrical contacts and circuit connectivity required of emerging smart medical devices. It is also desirable for a supplier to have a broad geographic footprint so that solutions are located in close proximity to your manufacturing location. Lastly, but equally as important, look for a supplier with a strong engineering staff that can address all of the twists and turns that are likely to take place through the product development lifecycle.

When these attributes are in place, drug and surgical device OEMs stand a greater chance of launching commercially-successful products, which provide both the patient and physician with smart device experiences that can deliver powerful results.

ABOUT THE COMPANY

Economy Spring, a division of MW Industries, is a manufacturer of advanced medical device components, including highly-engineered, precision metal components and assemblies such as springs, surgical sharps, needles, laser machined tubing, staples, titanium clips and complex assemblies. The company deploys its end-to-end product lifecycle know-how and design expertise to shorten product development time and lower costs. Economy Spring's >40-year track record helps deliver product reliability and performance in demanding surgical and drug delivery applications. The company is registered with the US FDA and has ISO9001 certified and ISO13485 compliant quality processes.

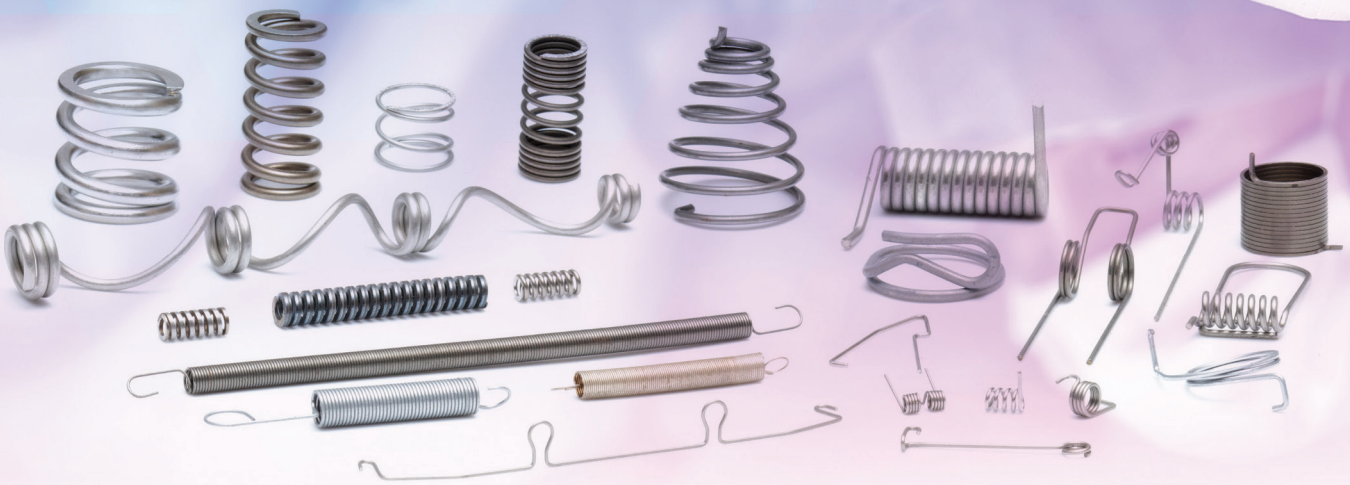
ABOUT THE AUTHOR

Dave Philbrick is Business Development Manager & Lead Product Engineer for Economy Spring, an MW Industries Company. For more than 38 years he has been involved in supporting new product development for medical instrumentation & drug delivery systems for Medical / Pharma OEM's. He is a specialist in metal component development, design and integration.

MW® INDUSTRIES inc.
Medical Solutions

METAL COMPONENTS FOR MEDICAL DEVICES

END-TO-END METAL COMPONENT SUPPLIERS TO THE MEDICAL INDUSTRY



MW Medical Solutions is focused on designing and manufacturing highly engineered precision metal components and assemblies for medical OEM

Fluid Delivery | Dispensing | Drug Delivery

Surgical | Diagnostic | Implantable Products

MW® INDUSTRIES inc.
Economy Spring

BellowsTech
MW Industries, Inc.

Servometer®
MW Industries, Inc.

HELICAL PRODUCTS COMPANY
MW Industries, Inc.

www.mwmedicalsolutions.com