



Precision metal components

improve connected medical device performance

By David Philbrick,
Business Development Manager,
Paragon Medical

Extensive technological inroads in drug delivery devices and surgical platforms are enabling significant improvement in the quality of patient care. Many of these fall under the “connected device” category, which means they communicate to healthcare providers via a network such as WIFI, Bluetooth or other protocols.

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 result in a more compact size.

In the early days of these devices, a spring was used to perform a mechanical function, such as a release of energy. Today’s Bluetooth enabled devices require much more sophisticated components such as battery or timing contacts that assist in triggering device circuitry. These components enhance the capability of the device which allows data collection to occur autonomously.

The pathway to connectivity

Many next generation pharmaceutical and surgical devices will share one thing—the ability to gather and disseminate data that will improve patient care. The utilization of the right type of battery or circuit timing contacts, circuit routing, component coatings and non-magnetic metal alloy integration are just a few of the component characteristics that 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 are some examples of battery and device timing contacts:

Gold-plated bellows. Microscopic bellows components can be designed for use in creating electrical circuit contacts in wearable devices, auto injectors and inhalers. They are ideal for “noisy” electrical environments where the traditional “pogo” style pins are too rigid in the circuit design 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 the vibration that enables reliable continuity of the circuit.



Connected devices

Connected devices feed information back to physicians and help ensure proper utilization by the patient. As a result, it is increasingly critical to make sure component design will support desired functionality in electrical-based systems.

In addition to drug delivery products, specific areas where this technology is making inroads are inhaler products used for respiratory therapy, hand-held laparoscopic/endoscopic devices and powered electrosurgical/robotic surgical platforms.

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/volume, as well as device 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. Further, the integration of Bluetooth and near field communications (NFC) enable 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 utilization. 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.

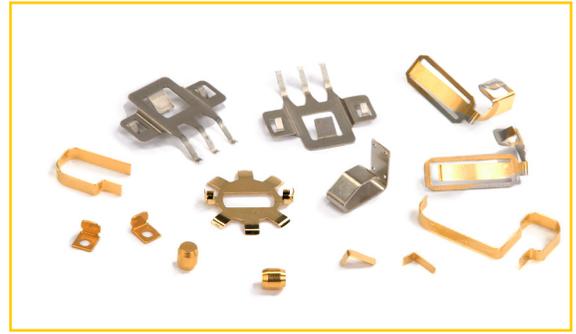


Coiled wire-forms and springs

These components 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 molded 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 for improved connectivity.

Leaf springs or stampings

The spring characteristics of these components 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 molded device housings. These components also can be designed to utilize 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 trigger the circuit connection. In this instance, a non-magnetic metal alloy integration may be required to minimize any undue magnetic signature that would influence the circuit timing by energizing the leaf spring that would influence the circuit timing.



The importance of working with suppliers who can troubleshoot and provide solutions

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 commercialization 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 commercialization success. Product failure is not an option—particularly for a product that creates improved patient therapies and developing smart device platforms.

The supplier's ISO 9001 and ISO 13485 certifications should be evident. Plus, a supplier who can demonstrate FDA Medical Device Establishment Registration and Device Listing capabilities as well as Good Manufacturing Practices 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, your supplier will have state-of-the-art, in-house metrology capability. 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 OEM build the bridge needed to support the FDA submission on the device or project. The supplier's ability to provide supporting measurements helps meet OEM statistical protocols and verify quality expectations.

Conclusion

In addition to the attributes listed above, it's important for your supplier to have a competent level of experience working with design of electrical contacts and circuit connectivity for emerging smart medical devices. It is also desirable for your 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 Paragon Medical

We act as a **close partner throughout development** to optimize product designs with collaborative solutions that help you deliver the best patient care at the highest total value.

We have the **advanced manufacturing capabilities** needed for medical device component and product manufacturing. We have the ability to engineer and manufacture metal components and assemblies such as springs, stampings, ultra-high precision machined parts, bellows and laser technologies.

We deliver a level of innovation that reduces partner-customer risk and supplier-managed quality that **simplifies your supply chain**, allowing you to bring your products to market faster.

Finally, because we have over 100 years of experience as well as a **commitment to quality** and to **developing long-term partnerships** with our customers, you can be confident in Paragon Medical as your manufacturing partner.



Paragon Medical

To learn more visit [ParagonMedical.com](https://www.paragonmedical.com) or contact us at 704.280.8875 | sales@paragonmedical.com

Copyright Paragon Medical