SPRING DEVELOPMENT FOR MEDICAL DEVICES

This article by Neil Fletcher, Technical Sales Manager, Advanex, provides a spring manufacturer's perspective of how springs can be used in medical devices, and how a lengthy and extensive device development process affects normal custom and practice in our industry. The report focuses on spring technology and highlights some of the challenges that spring manufacturers face daily.

Many global organisations will be familiar with our work already but many are not. We believe mechanical springs in drug delivery systems offer the best value for money despite increasing regulatory requirements that are today shared by the entire supply chain. Springs are frequently key to the device function, operation or retraction so it should not come as a surprise to hear that any proposed change in the spring manufacturing process is treated by customers and the regulatory bodies with extreme caution. Lots of extensive device testing and revalidation has to be carried out in response to a relatively small change in how the spring is made.

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As a leading spring manufacturer and component supplier to the medical device market we have witnessed many changes in our business over the years. For instance, traditional spring manufacturing methods would allow different equipment to be used for the same spring dependent on machine availability and workload. Today, only specific validated equipment can be used and in many cases each machine is dedicated to one part only.

Obviously, a carefully controlled and clean working environment approved to ISO 13485 should be maintained, and equivalent processes made available to ensure business continuity and guaranteed supply. Multiple locations, all capable of producing identical components on identical equipment, are also important to minimise strategic or catastrophic risk.

This responsibility should never be underestimated because a patient's life could depend on it! This comment may seem extreme, but if risks can be avoided, they must be avoided. You can see from the photograph that equivalent machines are used and identical process flows are carried out for high-volume production (Figure 1).

Traditional ways of working with spring materials have also evolved into widespread Good Manufacturing Practice (GMP), and accredited practices with extensive controls and de-risking activity. It is comforting to report that extensive testing

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Figure 1: The factory floor at Advanex.

of all products in a medical device is carried out by everyone in the supply chain, and even the spring manufacturing process has to follow a clearly defined validation plan.

It is an added bonus that general purpose spring coiling machines can be used for low-volume developments and, at a later stage in the engineering process when cGMP product is required, more bespoke production equipment can be offered and supplied specifically for higher volume commercialisation.

Dimensional control and extensive quality assurance are the key factors here, but of course the unit cost of each component is crucial when devices are complex and contain lots of features. Spring manufacturers in Europe offer either low volume development capacity or high volume manufacturing capabilities but few offer the complete package. Some companies, such as Advanex, choose to design and develop their own production equipment prior to commercialisation. Our engineering process route is shown in Figure 2.

Confidentiality is key here and supply companies have to sign detailed secrecy and non-disclosure agreements with their clients to protect know-how, intellectual property, and any unique features of the device that create a competitive advantage.

Time-to-market here is constantly being driven downwards as competition in the lucrative drug market increases, and the choice of devices under development continues to grow. Manufacturing and supply contracts are also quite complicated for any spring manufacturing company, and as official documents are compulsory and usually generated by the client, it is worth taking legal advice before signing.

FIT FOR FUNCTION

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Risk analysis is frequently carried out and combined with statistical process controls at the source of manufacture, and consistency of supplied product is maintained and supported by test data with every batch. Full traceability is provided with unique production data and batch samples retained for many years.

Minimising particulate is critical and today we have become just as experienced in cleaning stainless springs as we are with spring manufacturing. Bacterial testing on spring batches can also be provided on request too.

DESIGN FOR MANUFACTURING

Critical features of the component are agreed. Practical working tolerances are specified and the most suitable materials are sourced from the same manufacturer. However, various heat numbers are introduced during validation to monitor this crucial variable.

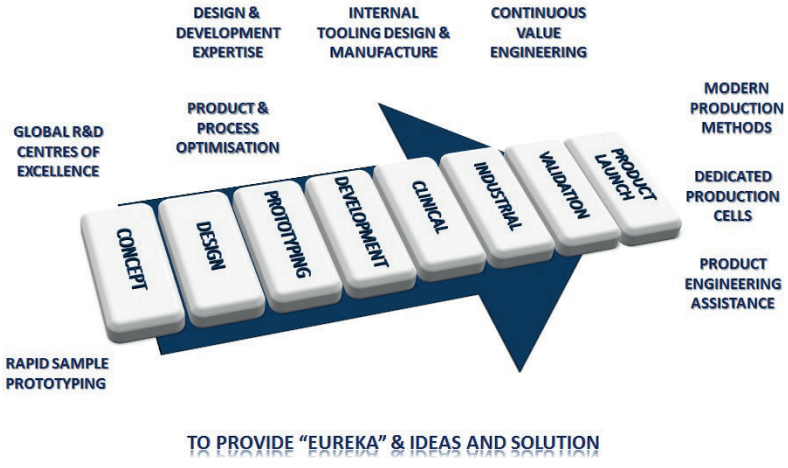

Figure 2: The engineering process route.

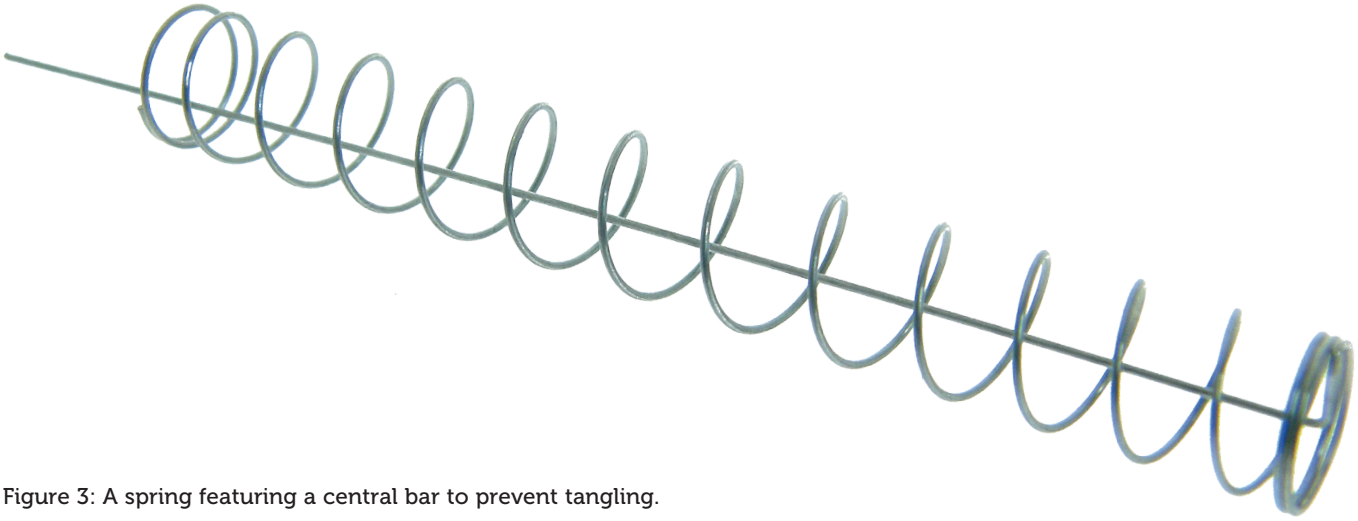

Figure 3: A spring featuring a central bar to prevent tangling.

DESIGN FOR PERFORMANCE

Springs are normally heat stabilised immediately after forming. The loading requirements at selected positions will determine what spring shape is required but once selected the shape can be specified as part of the dimensional control and features.

Heat treatment on stainless steel springs is necessary to relieve the stresses induced in the wire drawing and spring coiling processes, to stabilise the spring dimensions, and to raise the elastic limit. This process is usually carried out by means of an in-line oven. The heat treatment temperature requires careful consideration since, ideally, the spring will benefit functionally, from temperatures of 400-450°C, although temperatures this high can result in discolouration of the wire, which most design authorities do not like. The heat treatment temperature selected therefore represents a compromise between optimum performance and acceptable surface colour.

Likewise, low temperature heat treatment is recommended for carbon spring steels. For these materials, the temperature is normally in the range 200-375°C.

Critical features of the design as described in the URS are monitored during production and data collected at an agreed frequency. The specified components have to withstand ageing and extreme environmental testing, and must not prevent the device from working, sometimes years into the future. Usually, device testing of this nature provides the most relevant data but selected component testing may also support this activity.

DESIGN FOR ASSEMBLY

Several highly experienced suppliers of automatic assembly equipment provide practical solutions to improve handling and feeding of components during assembly. However, the spring supplier can also advise on how their components can be supplied and protected during transit by relatively low-cost improvements. The most common practice of using re-useable tray packing in rigid containers is favoured due to the small footprint required for a tray handling system.

One novel design concept for high index compression springs includes a central bar which prevents tangling. The bar has to be removed during final assembly but then this delicate spring (Figure 3) can be bowl fed into the perfect position for loading in to the device.

Springs in medical devices often have large indices. The index of a spring is calculated by dividing the mean diameter by the wire diameter, and the result is used by springmakers as a measure of coilability. The normal spring index range is considered to be 5 to 13, but the higher limit is frequently exceeded in device applications. Values of over 20 are common, and figures over 30 are certainly not unknown.

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The spring pitch is also an important feature. The pitch is the distance between the centre of the wire on any coil to the centre of the wire on the adjacent coil. If the pitch is around two wire diameters in size, the springs may tangle badly when parallel to each other in processing or storage. Larger pitches may allow 'cross tangling' to occur. Frequently, the spring may be designed with closed-coil sections, at each end, and/or in the centre, with the intention of reducing or eliminating the likelihood of tangling. The designs of medical device springs though, often mean that a degree of tangling is inevitable, so the device assembler must decide if this difficulty is acceptable, or

Figure 4: An ISO Class Clean Room at Advanex.

whether bespoke packaging is needed to avoid the issue fully. If this is necessary, the cost of the springs will be increased by the need for manual packing, or for automated packing if the required volumes are large enough to justify the investment in robotic equipment.

Also of importance in spring geometry is the slenderness ratio. This is calculated by dividing free length of the spring by its mean diameter, and is a measure of stability. If the relative deflection of the spring exceeds a calculated critical value, the spring will buckle, meaning that it will require support if this is to be avoided. A spring which needs support will be less predictable in terms of the forces it will deliver. This is because there will be a degree of friction between the inner or outer diameter of the working coils of the spring, and its mating components. This friction may interfere with the calculated force at any given position.

APPLICATIONS

Safety syringes have a safety mechanism built into the syringe. One very successful patented design uses a mechanical spring to retract the hypodermic needle back into the syringe body after only one use. The spring is held under load for a considerable time until it is activated. Therefore relaxation and ageing tests are extensively carried out under extreme conditions.

For many years now, safety syringes have been available as the preferred alternative to the conventional syringe that is still extensively used by doctors and hospitals around the world. Originally designed to prevent needlestick injury to both health professionals and patients, the single-use safety syringe has, without doubt, saved millions of lives over the years. Using a more expensive safety syringe has its own commercial challenges of course but as the number of units increase the unit cost will fall and the cost differential to conventional syringes will reduce.

As you might expect the required level of cleanliness of the spring component here matches, and in some cases exceeds, that of inhalers, and extensive testing and regulatory approvals have to be gained and maintained.

SUMMARY

This article is not a detailed scientific report and is based on the personal experience of the author and our industry knowledge only. The intention here is to share our experiences with a wider audience and does not intend to favour any one manufacturer of devices. We regularly see many innovative and creative ideas during our development work but these are always supported by full confidentiality agreements. Therefore we are not allowed to share details of any such device and have deliberately limited direct references to devices that have been in the public domain for over five years, and our know-how on design and manufacturing of springs for medical devices.

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THE AUTHOR

Neil Fletcher, Technical Manager, has worked for Advanex for over 39 years in a variety of technical roles. Neils' role as Technical Manager involves offering support and advice to customers regarding their spring requirements.