Springing to Life

One of the oldest forms of energy storage, spring development continues to advance today in the fields of pens and auto-injectors. What is the role of a spring in the medical device world, and what development challenges need to be overcome?

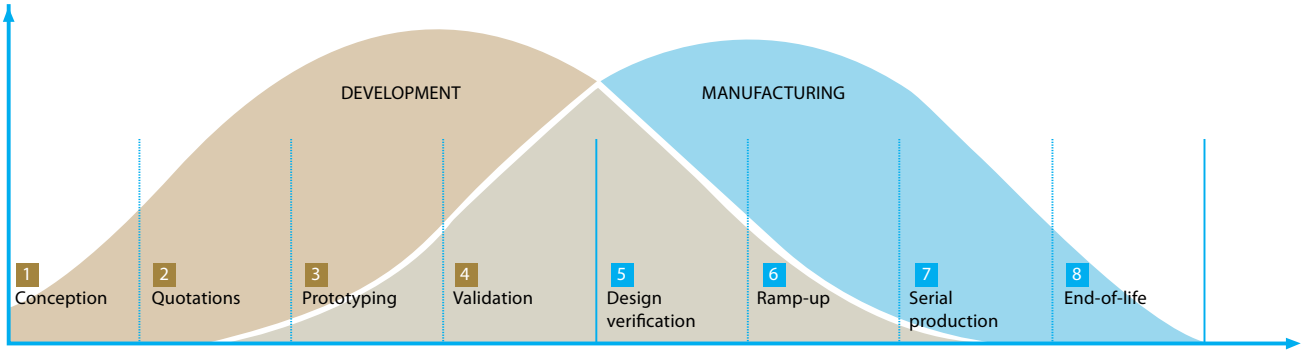
Dr Tolga Goren at BAUMANN Springs

The basic spring equation was first published by Robert Hooke in 1660 – a full 27 years before Newton's laws of motion – yet the design and production of springs continues to be a challenging process as the demand for greater comfort and safety of drug delivery devices increases. This holds true for even the most unassuming compression spring, which must fulfil a variety of requirements. These could range from meeting demanding geometry constraints to manufacturability with a given process capability, ease of assembly into the device, stability in operation against buckling, corrosion resistance, and shelf life before the onset of material creep.

Furthermore, the range of spring designs used in pens and auto-injectors has expanded in recent years to include torsion springs, extension springs, wave springs and constant force springs, as well as related metal components like stamped parts. Each type brings unique advantages, but also challenges, to the device design space. As the springs in a pen or auto-injector represent a significant fraction of the part price, and also play a critical role in the assembly process, it is vital to make informed decisions in spring design. This article considers the most common spring-related hurdles encountered by medical device design offices, original equipment manufacturers and contract manufacturers throughout the product lifecycle (see Figure 1).

Cost Structure

The first spring question encountered by device design teams is typically whether a custom-designed spring should be developed and prototyped, or whether choosing pre-designed springs from a manufacturer's catalogue is feasible. Quickly getting a prototype in hand can be very attractive, but will the decisions made with a fast prototype, a different material or new production process still be relevant for a global product launch? This can be a difficult decision to make without an understanding of the spring production process; however, involving a spring manufacturing partner with profound knowledge of medical requirements early on can bring their experience to bear on the project parameters that impact the development, such as wire supplies, manufacturability, ramp-up and global expansion of production, total cost of ownership and more. Figure 2 (page 40) shows a typical simulation of spring stress that can be used in the early design stages.



1 Initial conception and early design work
2 Request for volume quotations
3 Prototyping and pre-design verification
4 Nomination and validation preparation; qualification of equipment, tooling and measurement methods
5 Process validation and design verification
6 Serial ramp-up
7 Serial production: process optimisation, addition of production lines or suppliers
8 End-of-life management

Figure 1: Illustrative lifecycle of a spring project in drug delivery devices

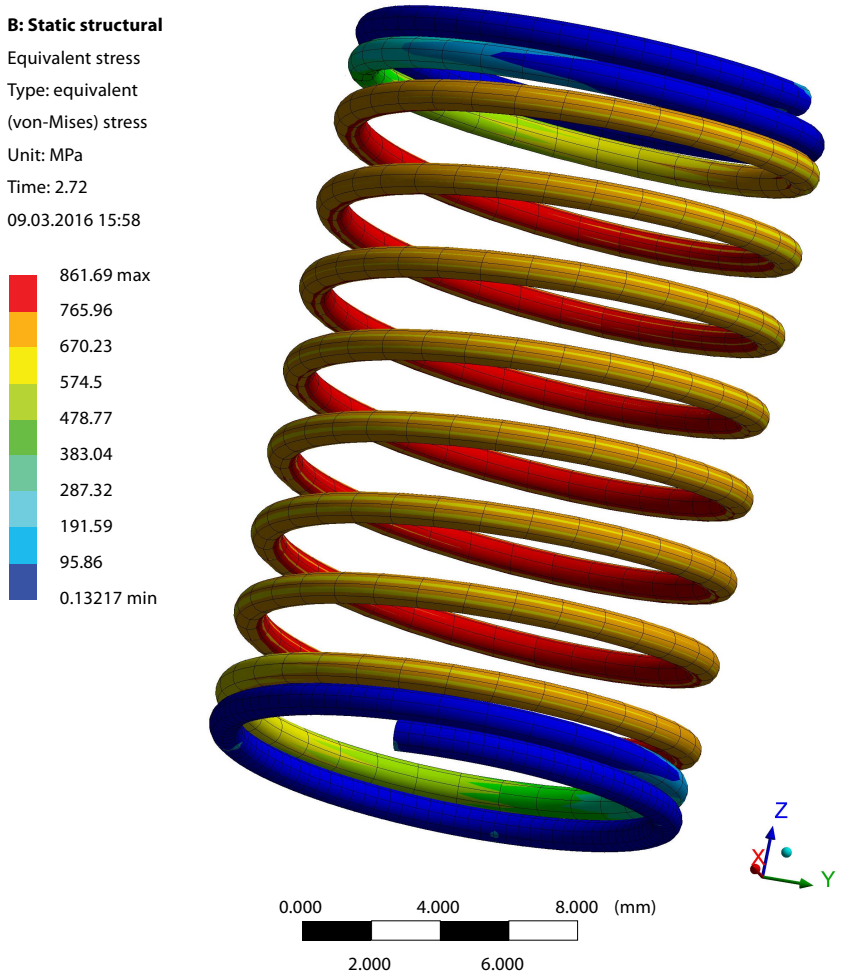


Figure 2: Finite element method simulation of a compression spring used in initial conception and early design work

Unlike injection molding, the tools necessary for spring production usually represent only a small part of the overall cost and time budget for standard spring types. However, the raw material can add a significant initial lead time and cost for prototypes, as large-scale wire manufacturers typically do not offer a minimum order quantity below some hundreds of kilos, with lead times of up to three months. It is often tempting to simply use a different, more readily available wire source for initial samples, as this can save significant cost and time. Such samples, however, cannot be used to validate the output of spring simulations in terms of material stiffness, coiling performance or spring ageing, which can vary considerably by wire manufacturer and type.

The machine setting process depicts a relatively fixed time cost, occupying a trained machine setter and the machine for the duration of the process – typically about one day for most common compression and torsion springs. For small prototype runs, this step represents a significant fraction of the total cost, while for large series runs it diminishes compared to factors such as machine run speed, packing speed and raw material costs. It is during the setting process that the first spring samples are produced and checked against the drawing specifications. Once the machine is correctly set, the parts can be produced, with typical coiling rates on the order of thousands of parts per hour.

Catalogue versus Bespoke

The important questions to consider concerning catalogue versus bespoke springs can be summarised as follows:

- Can a large batch size or high annual volumes of springs be forecast? The relative part price for small batch sizes is driven up by the fixed cost of machine setting; however, for larger-scale series production, the cost impact will diminish compared to

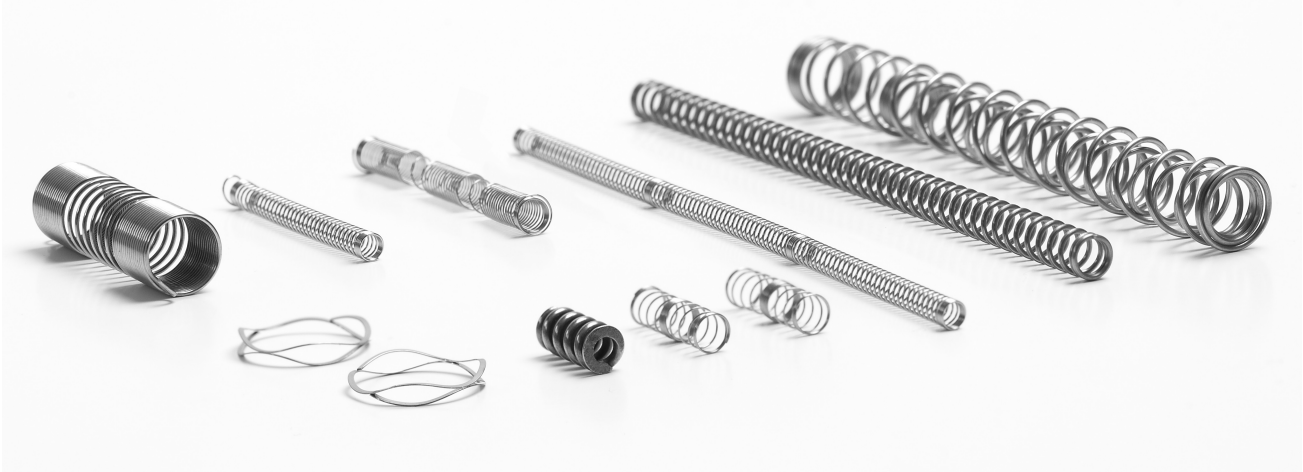


Figure 3: Illustrative examples of bespoke springs

the capacity and efficiency of the customised production process

- Are the spring design requirements/ tolerances ambitious, or the materials unusual? A catalogue spring will likely not take the full advantage of space constraints, meet a high-process capability requirement of a given feature, or be available with a specific coating or packaging
- Are there any non-standard requirements imposed on the spring due to the assembly process? Common design decisions to reduce assembly problems, such as tangling, may include a progressive coil pitch or a differently-sized end coil relative to the body
- Will the production capability need to be adaptable to design changes, or are there any additional service requirements, such as dual-sourcing raw materials?
- Do the test methods, quality control, production facilities and validation capabilities have to meet specific expectations or standards beyond the relevant norms, for example ISO 13485? A bespoke spring implies a bespoke process, which may imply better customer support from the spring manufacturer
- Does the project timeline allow for the implementation and testing of a customised spring design? While catalogue springs are often quickly acquired, the abovementioned design, process or cost compromises involved in using them may impact the project negatively later on

It is clear that some applications are well served by catalogue springs; nevertheless, if the answer to any of these questions is yes, a bespoke spring is probably required, and in general bespoke springs hold a clear majority in the pen and auto-injector space (see Figure 3). As in other industries, the trend towards individualisation and tailor-made solutions is also evident in the spring and stamping industry, and in the sector of drug delivery devices.

Spring Design

There are many sizes of wire available for spring design. The ISO norm EN 10270 describes the wire grades, sizes, tensile properties and other parameters. Departing from EN norms can significantly increase the raw material cost and reduce availability. High-carbon steel wire, also known as music wire or piano wire, offers good mechanical properties at an attractive cost, but generally does not provide sufficient corrosion protection without a coating. Stainless steel wire offers intrinsic corrosion protection, but carries an associated cost. The EN norm specifies wire to 0.01mm precision increments; the availability and relative cost of different wire sizes varies widely across manufacturers, as it depends on what sizes other customers are ordering from a given supplier.

Steel wire can also be purchased pre-coated for increased corrosion protection or reduced friction, which can improve coiling performance and also facilitate bowl feeding. Zinc-aluminum and nickel coatings are common choices for spring wire due to their good coilability – in contrast, for example, to pure zinc coatings, which can flake off during the coiling process. Springs may also be coated post-coiling; however, this should be avoided for most pen and auto-injector spring designs, as the presence of dead coils or other hard-to-reach spots can compromise the corrosion resistance of the spring.

The value add from the spring manufacturer typically also includes treatments subsequent to coiling, such as heat treatment, cleaning, inspection and packaging. Much of the know-how and expertise that can make a competitive difference has to do with processes; particularly in cases where tailor-made machines, tools and processes are the preferred or required choice for the design solution, these process steps must be aligned, as the spring must be in specifications after these steps – not before. In such cases, close collaboration between the customer, spring manufacturer and the technology partner of the production process is key. A surprisingly common decision early in the design stage is the addition of features that add significant complexity and cost to the spring production, such as grinding or speciality packaging, without due consideration (see case study).

Ideally, key functions like machine and equipment building – but also technology and process development – should be fully

Ground Springs in Pens and Auto-Injectors: A Case Study

The most common example of extra complexity in springs for medical devices is grinding of the spring ends, which produces a flat end coil for the spring to stand straight. Ground ends may be easier to assemble in some cases, and distribute the transmitted force evenly on the surface. However, grinding requires significantly narrower production tolerances on the spring geometry. The grinding step itself requires a separate machine, which runs either in-line – thereby limiting the overall run rate – or else is fed off-line, requiring intermediate storage and bowl feeding, and increasing the scrap rate due to tangling.

Grinding is a dirty process which produces metal particles and removes any wire coatings. Therefore, extra cleaning and passivation steps are typically required. The inspection of ground springs must include checking for toe-in of end coils, parallelity of the ends, burring, cleanliness before coating/ passivation, and coating quality or corrosion resistance afterwards. Naturally, each of these steps must be validated to medical standards. While ground ends may save on total cost in some cases, they should not be added to a design without significant consideration.

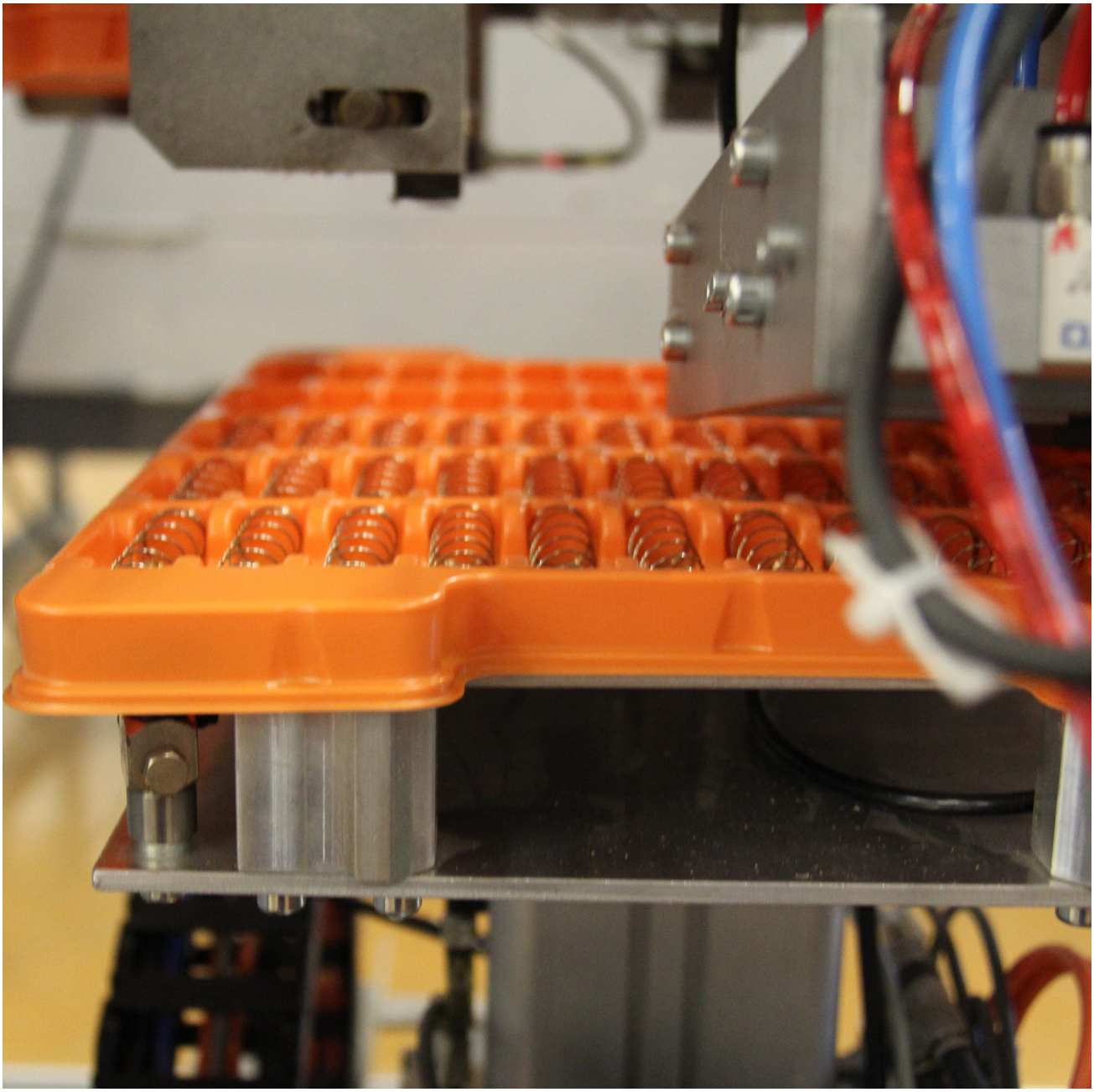


Figure 4: Tray packaging as an example of a customised service

integrated functions to ease cooperation, as well as implement specific customer demands and standards. While it is certainly true that some device designs may require such expensive process steps to save on total cost, the decision to include these kinds of features should not be taken without an understanding of the impact on yield and part price.

Tangling and Ageing

Spring tangling – a critical consideration for the assembly process – will depend on the spring geometry as well as the wire coating. Some springs do not readily tangle; some springs tangle readily, but are easily separated by bowl feeding; and the worst springs tangle irreversibly. Tray packaging can be an attractive, though more expensive, option (see Figure 4); aligned packaging to prevent crossing or end-to-end tangling may be a simpler and more cost-effective solution.

One fact of life that every spring designer must face is spring ageing. Springs slowly relax when stored in a compressed state, so their force at a given length will decline over time – typically a sharp drop that slowly flattens out. This load loss, if not accounted for by the designer, can lead to unreliable function of the device, causing stress or even danger to the patient. Both the wire material choice and the stress on the designed spring over the working distance influence the setting loss of the compressed spring. Setting the spring (actuating it once across its working distance) prior to or during assembly can reduce the subsequent ageing loss – effectively, this is designed to partially pre-age the spring.

Next Steps

Avoiding the involvement of a spring manufacturer until the design has reached a mature state (design freeze) is, unfortunately, all too common. Much like seeking timely legal counsel, feedback from a development/engineering partner is more valuable early on, as problems of working geometry, assembly process and manufacturability can often be nipped in the bud if taken as design feedback, minimising the risk of delays or problems in device production at a later stage. The cost of involving a spring producer at an early stage is typically low; in the business of medical spring production, spring manufacturers share the interest of the device designer in developing a clear and robust design specification.

In a pen or auto-injector, which can consist of dozens of individual plastic components, the importance of a handful of springs can be easy to overlook. But as drug delivery devices evolve towards increasingly ambitious designs, delivering medicines of higher viscosities with controlled forces while saving on space and weight, the limits of spring design are constantly being explored. Centuries of spring-making experience now work together with modern simulation tools and medical production standards (see Figure 5) to redefine the limits of spring production and to power a new range of pens and auto-injectors that can be designed with the patient – not the device – first.

About the author

Dr Tolga Goren studied Materials Science at the ETH Zurich, Switzerland, and is Project Manager in Division Medical of BAUMANN Springs, a leading manufacturer of springs and stamped components with locations in 11 countries around the world. The family-owned group was established in 1886 and employs more than 1,500 people. The company's dedicated, ISO 13485-certified global medical division offers expert knowledge in the medical and pharmaceutical industries in the segments of drug delivery devices, blood collection, syringes, diagnostics and airway products, and addresses the unique needs of its global customers with a medical mindset.

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Figure 5: Dedicated, ISO 13485-certified medical production area