THE IMPORTANCE OF SPRING AND STAMPING QUALITY IN INHALER SAFETY

An efficacious and safe inhaler is not only dependent on the drug pharmacology, but also on a well-designed and good quality device. It is also desirable that the devices are small and simple to be used by the patient. The majority of inhalation devices contain springs or related stampings and wire forms, which work as the device's energy source and allow the medication to be released. In this article, Frank Reiss, Head of Business Development, and Bergdis Sigurdardottir, Project Manager, both of the medical division of Baumann, explain how medical competence in spring and stamping manufacturing may prove critical for the developers of inhalers.

> "Each type of metal component assembled in an inhaler brings its unique advantages and in many cases functions as its energy source, allowing the medication to be released."

Respiratory diseases have a severe impact on life, health and productive human activity. Chronic respiratory disorders are becoming a more prominent cause of disability and death. According to the Forum of International Respiratory Societies, chronic obstructive pulmonary disease (COPD) affects more than 200 million people and is likely to become the fourth leading cause of death worldwide by 2030. At the same time, asthma affects about 235 million people around the globe.[1] Furthermore, other related diseases such as cystic fibrosis, allergic rhinitis, idiopathic pulmonary fibrosis and lung cancer affect the life of millions of people.

The inhalation route is a fast, effective, and a convenient way to treat pulmonary diseases. Every year more than 900 million dry powder inhalers (DPIs), metered dose inhalers (MDIs) and nebulisers are used throughout the world. The global pulmonary drug delivery system market was estimated to be worth more than US$30 billion in 2015. These figures are expected to increase continually year after year. This trend is caused by:[2]

- Increasing share of older people in the population
- A growing population of smokers and increasing impact from pollution
- Rising number of patients needing combined therapies
- Strengthened R&D activities for asthma and COPD medication
- Innovations in device development.

What many people do not know is that these trends also affect the business of spring and stamping suppliers because the majority of inhalation devices contain their products. Each type of metal component assembled in an inhaler brings its unique advantages and in many cases functions as its energy source, allowing the medication

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Figure 1: Illustrative examples of bespoke springs and stampings.

to be released (Figure 1). That being said, specialised companies and subject matter experts must work hand-in-hand, across the supply chain, to optimise the entirety of an inhaler device. Baumann, as one of the worldwide leading spring and stamping suppliers for medical devices, is the partner of choice for key market players in the industry – be it pharmaceutical companies, contract manufacturers or design offices.

BEING A DEVELOPMENT PARTNER

Based on the chosen technology to administer the drug, it is recommended to involve the supplier early on in the R&D stages of the pulmonary device design. When included in the development phase, the supplier can support the design process by providing their manufacturing experience and engineering competence at the first step to verify the feasibility of the design idea.

A well-developed device is one of the key factors in successful pulmonary drug delivery. When Baumann is approached to support projects by supplying bespoke springs and stampings, they can advise on design specifications and production parameters, ensuring manufacturability in the industrialisation phase. This will assist in defining an effective process from development through assembly into high volume series.

Furthermore, functional samples can be provided to verify the design concept. As soon as the design has been formulated, prototypes can be supplied, which can be used for clinical tests and assembly trials, produced on machines representing the same concept and process as used in serial production. Lastly, upon customer approval, validated parts can be manufactured and serial production can begin.

DESIGN VERIFICATION/ CUSTOMISED SOLUTION

Once a spring has been chosen for the device, the next step is the spring design where the main restrictions are the design space constraints. Baumann offers engineering advice when it comes to designing the spring, where the goal is to maximise the spring function within the available design space based on its specification.

With our experience in spring design and the help of analytical calculation or numerical simulation using a finite element model (FEM), we are able to optimise the spring design together with the device developer (Figure 2). The allowable stress in a spring is calculated based on the predicted relaxation and the mechanical properties of the wire. A great emphasis is placed on the coiling index – the proportion of the wire size to the springs outside diameter – since it helps indicate the ease of manufacturing. In the case of a compression spring, the probability of the buckling can be determined based on the relationship between the unloaded spring length and the outside diameter.

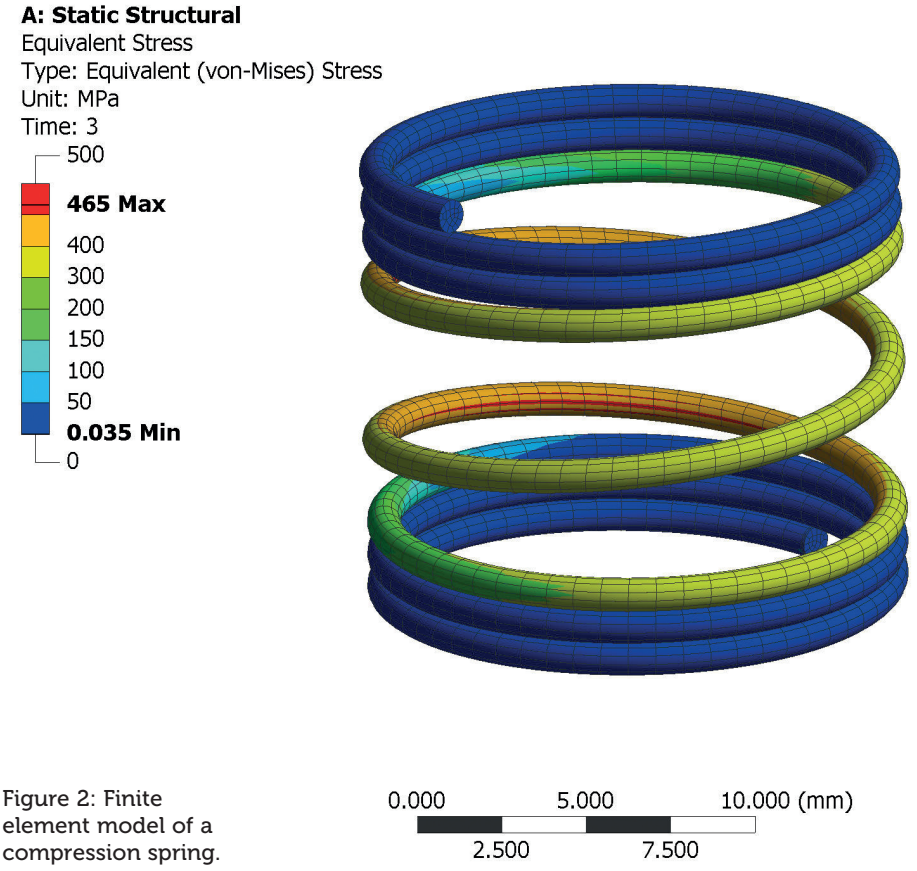

Figure 2: Finite element model of a compression spring.

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However, the spring function is only one part of what needs to be considered. Another reason to involve spring manufacturers early in the device design phase is that they also share similar interests in developing a clear and robust design specification in order to avoid undesired complications in future stages of development and production. This includes factors like optimising the spring design to avoid problems in the device's assembly line and making sure it fits the requested process.

To illustrate this, let's consider wire material.[3] The wire supplier needs to be capable of delivering the capacity of the required specification and make sure there is traceability in the supply chain of raw material. This is important because, as a medical production, being able to trace every produced spring batch is critical.

Another important point to consider is the tangling of the spring. The risk of tangling may often be minimised by considering certain features in the design. If that is not feasible, it allows for an early start to find a suitable packaging concept.

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REALISING THE SOLUTION

After deriving comfort with the spring calculation, prototypes of the springs are created to confirm the design and to evaluate the wire processibility. A particularly important feature is that all prototypes are produced on machine concepts mimicking the one that will be used in future serial production.

It serves the purpose of the product feasibility check and helps identify improvement possibilities at an early stage in the project as well as to evaluate the manufacturability of the chosen concept at a high scale. In addition it ensures stable and robust production processes in later serial production.

The work in the prototyping phase will be performed in close collaboration with the customer. Important aspects will be considered such as whether the technical performances can be met, if the wire material is suitable and the risk of spring tangling. Only then will a clear picture of whether the spring is up to its task be possible.

Another valuable capability is to perform lifecycle tests (for example, relaxation and ageing test) on the springs to verify the features used in the spring calculation. This needs to be confirmed by the device manufacturer with full diagnostic device testing.

In the case of more complex springs or specific requirements from the customers, for example automatic packaging in trays or setting the spring to its compressed length before delivery, Baumann's in-house machine manufacturer can develop customised equipment or tailor-made machine concepts suitable for each project.

GLOBAL MEDICAL PRODUCTION

Baumann has a global medical division (ISO13485 certified), with the mission of providing the same quality in products, service and processes to customers worldwide (Figures 3 and 4). Therefore, the medical division has developed its own validation procedure complying with high medical industry standards.

The validation procedure comfortably accommodates customer requirements. Having these documents readily available

Figure 3: Baumann's global footprint.

Figure 4: Dedicated, ISO 13485-certified medical production area.

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Figure 5: Illustration of inhaler device.

accelerates the validation process and reduces the amount of time required from entering the prototyping stage till starting serial production. This validation process is performed for every component manufactured in serial production. It is used to verify that the manufacturing facility and processes for the produced article are capable of generating reliable results which envelop the defined requirements. This includes the component's risk evaluation[4] and all equipment qualifications. The validation report collates the outcome and findings produced in the validation run.

Another important aspect to be applied in all production sites around the globe is complying with Good Documentation Practice (GDP).

RELIABLE BUSINESS PARTNERSHIP

Throughout the clinical trials and approval process of the drug and its device, collaboration should carry on. Hence, the production ramp-up and market introduction of the new product can jointly be prepared. In order to mitigate supply chain risks and avoid a delay in market introduction, it is imperative that commercial terms and conditions are defined, and long-term strategic elements are set in place. This includes capacity commitments, handling of volume fluctuation as well as safety stock build-up, aligned decisions for investments and milestones for global expansion of production.

Baumann has experienced that effective communication, by openly and pro-actively approaching these matters and seeking for timely feedback from involved stakeholders, is highly valued by their business partners. Such a basis of trust is the foundation for a successful, long-term business relation and continuous improvement measures during serial production. It is also the groundwork of supply chain security and optimises the total cost of ownership in the overall project during commercialisation of the product (Figure 5).

CONCLUSION

We want to let device developers become aware of the importance of a close and open collaboration, to prevent problems occurring with supplying of springs and stamping as well as in the assembly of the device. An early involvement of suppliers in the medical device development process is recommended to prevent problems that might occur later on – especially if a customised solution is demanded. It is essential that medical component suppliers understand customer needs and meet medical requirements. At the same time robust and scalable processes must be in place for serial production and to ensure supply chain security.

REFERENCES

1. *Forum of International Respiratory Societies (FIRS), "Respiratory diseases in the world: Realities of Today – Opportunities of Tomorrow". Annual Report 2013*
2. *Transparency Market Research, "Global Pulmonary drug Delivery Device Market". Report, 2017.*
3. *Wright RN, "Wire Technology – Process Engineering and Metallurgy". Elsevier, 2011.*
4. *General Motors Corp, "Potential Failure Mode and Effects Analysis". FMEA 4th Edition, 2008.*

ABOUT BAUMANN

For more than 125 years, Baumann Group has been a symbol of Swiss precision and quality. The Baumann Group is known worldwide as a leading company in spring and stamping manufacturing. The family-owned group, now in its fifth generation, has eleven production sites around the globe, where more than 1,500 people design and produce technically sophisticated products for targeted industries, including the automotive, electrical engineering and medical technology sectors.

In the dedicated, ISO13485-certified medical division Baumann addresses the unique needs of customers in the medical and pharmaceutical industry. Baumann has the know-how to tackle the specific challenges, extraordinary standards, and strict requirements of the industry, and stand as recognized expert and supplier. A specialised team with local professionals in the US, Europe, and Asia will work closely with customer teams, not only to develop the best component for a device, but also to provide a tailor-made solution for a specific customer project. Thus Baumann's partner benefit from this expertise as a long-standing world leader in springs and stampings.

ABOUT THE AUTHORS

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SPRINGS AND STAMPINGS FOR MEDICAL DEVICES

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