REDUCING PARTICULATES FROM METAL PRODUCTS IN MEDICAL DEVICES

Here, Graham Perkins, Medical Sales Manager, Advanex Europe, explains how, for medical device component manufactures, developing new methods to reduce particulates is becoming increasingly important.

Over the years Advanex design and engineering teams have been working in collaboration with some of the world's leading medical device manufacturers to develop techniques for reducing particulates.

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Particulates are minute, separate particles of organic or inorganic matter that contaminate components. Particulates can be generated during the coiling or forming process by friction between the raw material and the tooling, and from foreign bodies such as lubricants that are picked up by contact during manufacturing.

Components can also be contaminated by airborne particulates present in the atmosphere surrounding the process and contact with operators, equipment, packaging materials etc, during manufacturing. Some coiling processes require the raw material to be coated with coiling soap to reduce the effects of friction during the coiling and forming process. Usually these contaminants are removed by secondary processes.

PROCESSES TO REMOVE PARTICULATE

Prevention by Design

In some circumstances particulates can be reduced by prevention. For some applications, bespoke processes have been designed that do not require soap-coated wire and design tooling to reduce frictional effects as far as possible.

Designing and building bespoke manufacturing equipment can provide an advantage for customers as the process can be optimised for the product.

Most spring manufacturers use "bought-off-the shelf" machinery which is very ver-

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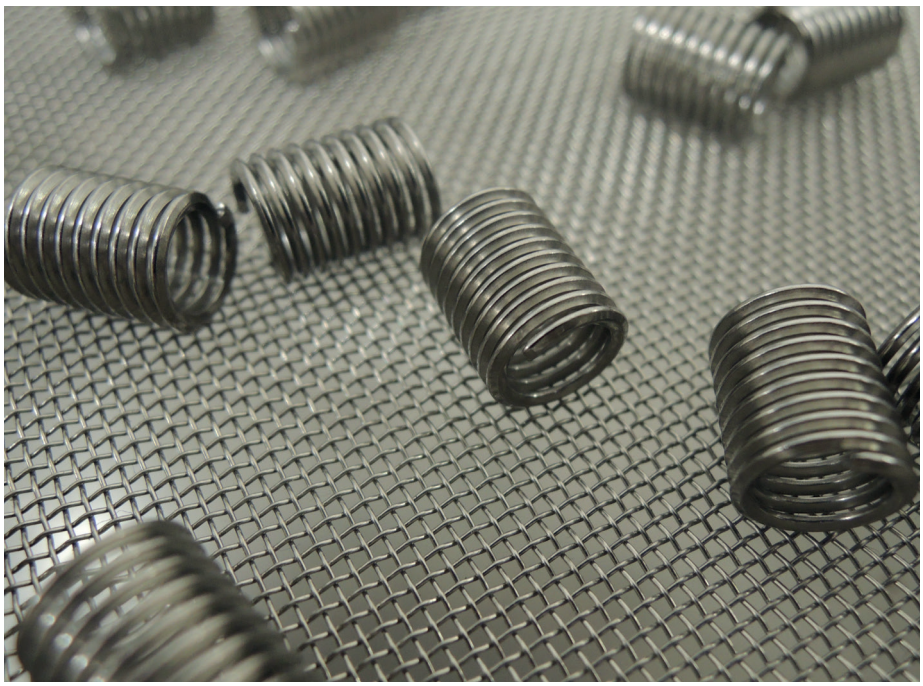

Figure 1: Sieving is a vibratory process that removes particulate by gentle abrasion while supported on a mesh or gauze.

satile and can make a huge variety of products. Traditional spring coilers form springs by continuously pushing wire against an inclined tool which forces the wire to bend and form a coil. This generates high levels of friction, requires lubrication (usually in the form of soap-coated wire) and greatly restricts the rate at which the coil can be formed.

In many cases coil springs are formed by wrapping the wire around a rotating mandrel which generates much lower levels of friction, does not require soap-coated wire and can produce springs at much higher production rates. Mandrel coiling is not as versatile as traditional coiling methods and bespoke sized tooling is required for each product. If the required quantities are high enough, this method can be very economical.

The versatility associated with general purpose spring-coiling equipment for high-volume, mass production requires a relatively large amount of equipment and tooling, some of which is redundant for manufacture of any individual product. All of the machine components provide opportunities for generation of particulates. Bespoke manufacturing equipment is better designed to fit the product so that all components used in the machine construction are critical to the manufacturing process, and there is no redundant equipment.

The design of each machine component and its potential for generating particulate matter is carefully considered. Sharp edges and situations where high levels of friction can occur are generally avoided. Using materials which reduce friction and have high wear resistance such as carbide, polished stainless steel, hard eloxated/hard anodised aluminium and other US FDA approved materials, can be employed. Opportunities for particulate to collect such as blind holes and internal corners are avoided wherever possible.

Vibratory Deburring

This is the process of removing burrs from components in order to smooth surfaces and edges. During the manufacturing process, operations such as cutting can leave raised edges or small pieces of material known as burrs that can become detached from the parent component. These can be removed by deburring using centrifugal, vibratory bowls and high density ceramic or synthetic media.

Laser Deburring

Cutting round section wire can often leave burrs where the wire has been cut. For some components, Advanex has offered laser deburring which provides a "dome" shaped end to the wire by firing a high powered laser beam directly onto the end of the wire.

Sieving

Advanex Europe can also offer in-line and off-line sieving. Sieving is a vibratory process that removes particulate by gentle abrasion while supported on a mesh or gauze. The particulate is separated from the components by dropping through the mesh. The size of the mesh is critical to the success of the sieving operation (Figure 1).

Solvent and Aqueous Cleaning

Solvent and aqueous cleaning are dedicated washing processes and are suitable for most metallic materials. These both require the component to be immersed in a heated liquid media, either solvent or water based, for a specific period. The components are usually tumbled within the media or the media agitated during the process. Particulate is washed from the components and removed by filtration of the media. Aqueous cleaning is generally more environmentally friendly than solvent-based cleaning processes.

Ultrasonic Cleaning

Ultrasonic cleaning is carried out in conjunction with either solvent or aqueous based cleaning processes. This involves using an ultrasound generating transducer immersed within the media that creates bubbles using high frequency (20-400 kHz) sound waves to agitate the media. This "cavitation" process removes contaminants that are adhered to, or embedded into the surfaces of materials such as metals, plastics and ceramics etc.

Acid Cleaning ("Pickling")

Acid cleaning, or "pickling", is usually performed in citric or hydrochloric acid solution, and removes a thin, surface layer of the material taking the embedded particulate and other contaminants with it. It is often performed as a pre-treatment prior to passivation of stainless steels.

Clean Manufacturing Areas

Some spring making processes such as traditional coiling methods that require soap-coated wire, generate large amounts of particulate. Other methods such as mandrel coiling with bright wire are inherently cleaner, but still generate particulates to a lesser degree.

The amount of residual particulate that is acceptable to the customer will largely depend upon the application of the product. Manufacturing areas that are clean and dedicated to the customer's product and isolated from other processes need to be designed to match the process and the product specification, with the aim of reducing foreign matter introduced by operators and the surrounding environment contaminating the product (Figure 2).

Depending on the process and customer requirements, some clean areas will only

require the operators to wear protective clothing, others have interlocking doors and maintain a positive air pressure etc. Manufacturing within these areas can maintain particulate to levels where the cleaning burden on the component can be dramatically reduced without the high costs and limitations imposed by clean-room manufacture.

Clean Rooms

Clean rooms are graded by the number of allowed particles per unit of volume. A Class 100,000 cleanroom, for example, can have up to 100,000 per cubic foot of air.

Where springs are ultimately to be assembled into devices within cleanrooms, customers will need the component parts to be free from biological contamination, as well as particulate matter. Class 10,000 (ISO 7) cleanrooms can be installed so that parts can be cleaned in-house. This allows the product to be passed into the cleanroom via an airlock 'pass-through', directly from the clean manufacturing area. Once inside the cleanroom, the parts are ultrasonically cleaned to remove any contamination, double-bagged within the cleanroom, and passed out through a further airlock to await despatch. The parts can then go into the customer's cleanroom, with the outer bag removed, so that no contamination is taken in via the outer packaging.

Figure 2: View of an Advanex clean manufacturing facility. Advanex Europe is approved to ISO13485.

Control of the efficacy of the cleanroom can be achieved by performing regular bioburden tests on cleaned parts. This will give assurance that the parts meet the prescribed microbial limit for the number of bacteria present.

CONCLUSION

As the medical device market evolves to become ever more sophisticated, metal part manufacturers face constant pressures in being able to reduce particulate in the production and assembly of components.

Advanex Europe is approved to ISO13485.