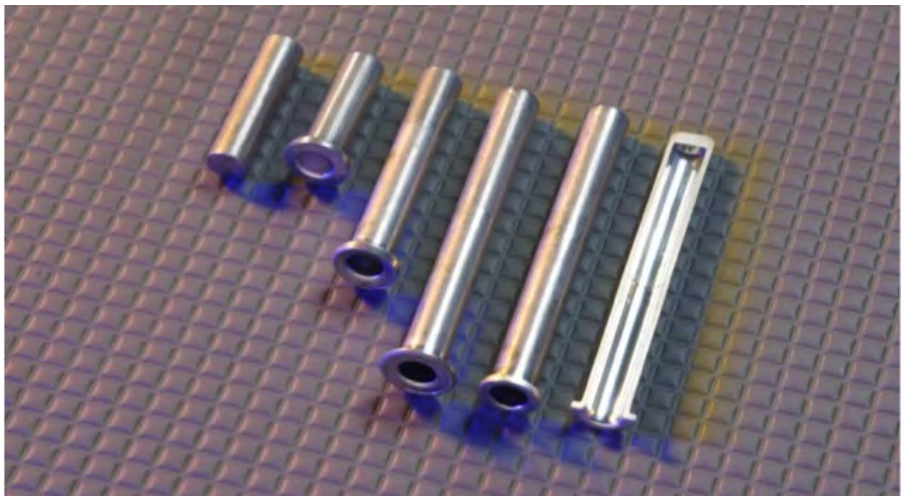
The medical device pioneers

Technical article

Innovation in the manufacture of medical devices has generated some of the most exciting inventions of the past century. That pioneering spirit lives on and benefits from the increasing pace of change within modern technologies. This has resulted in some fascinating new developments, such as needle-free drug delivery systems.



Medical devices have changed rapidly in the last century or so. The X-ray allowed us to see deep inside the body without the need for intrusive and often risky surgical procedures. In the last 50 years, we have begun to see the impact that computers have had on healthcare, capable of monitoring patients 24/7 and producing drugs on a mass-scale and making effective pain relief available and affordable to everybody in society.

One of the latest innovations is the development of innovative drug delivery systems, involving the design and production of specialised component parts by companies such as Italy Precision who have applied the precision engineering expertise gained in heavier industries to great effect in areas such as medical device technology.

Many people still have this image of engineering as being oily, harsh and dirty, and completely divorced from the clean sterile world of medicine and pharmaceuticals. In reality, of course, this could not be further from the truth as almost all medical equipment and devices consist of engineered parts. Indeed, even plastic parts have to be engineered, some using injection molding, pressure or vacuum forming, but many being formed using traditional engineering techniques, such as milling and turning. Everything from syringes and surgical instruments to parts that are even inside the body, like vascular stents, undergo some sort of engineering process in their manufacture.

In particular, Italy Precision is pioneering the use of cold forming to produce high precision, bespoke components for the pharmaceutical sector. By comparison with conventional component manufacturing methods, precision cold forming can be used to produce extremely high quality components, which have superior mechanical characteristics and a better surface finish, with considerably less scrap; in many instances, component costs can be reduced by up to 70%, while lead times can be cut by a similar amount.

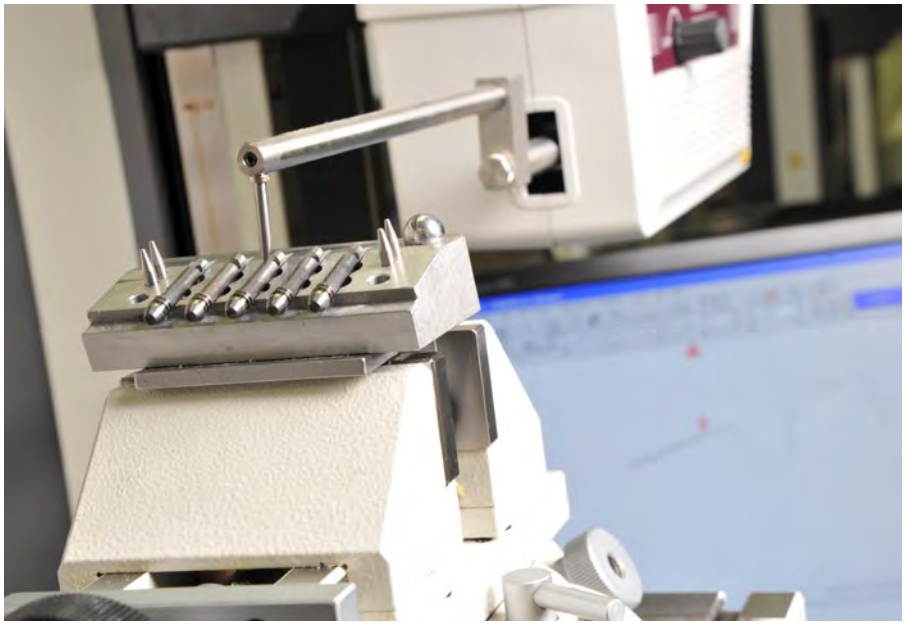
Essentially, cold forming is the process of producing components at low, usually ambient temperatures without removing any material, where billets of advanced engineering metals, such as copper, brass, aluminum or steel alloys, are extruded under pressure in a specially designed die set. A simple blank, which has been sawn or cropped from a round bar or wire, or a cold headed pre-form, is placed within a die and a punch is applied to the blank. As a result of the force, typically anything up to 2,000 tons, the blank then takes on the form of the punch and the die.

As it is performed at ambient temperatures, cold forming is a far quicker process than more conventional options, allowing manufacturers to achieve much shorter production processes. This in turn means that components can be made to order extremely quickly, cutting lead times and the need to store high volumes of spare parts onsite. Production cycle times can be cut still further on multi-station machinery, which can be particularly useful in large production runs.

The medical device pioneers

Technical article

Italy Precision CNC Machining Inc.



Aside from tangible cost savings, cold forming makes for superior quality products by plasticising metals along their grain boundaries, rather than cutting across, thus producing parts with extremely low levels of stress deformation and high levels of mechanical integrity, resulting in far greater performance and reliability. Furthermore, cold forming offers outstanding levels of definition, even on parts with complex contours. Typically, dimensional tolerances can be to within plus or minus two microns, with the added benefit of extremely fine surface finishes, which in many cases, require no further machining or polishing.

Additionally, parts undergo work hardening during the cold forming process, improving their machinability and durability still further. Work hardening dislocates the structure of the metal in a way that prevents further dislocations, resulting in a stronger component. As this increase in strength is comparable to that of heat treating, it can be more cost effective to cold work a less costly and weaker metal than to hot work a more expensive metal, particularly where a precision finish is required.

The cold forming process also makes it possible to produce component parts with a superior finish, both internally and on the surface. Accurate internal profiles and complex external profiles are possible, enabling precision parts to be manufactured that can have a significant impact on the performance of the equipment in which they are used.

Furthermore, there is almost no limit to the shape, size or complexity of the metal components that can be produced using cold forming.

Simple cold headed parts or highly complex cold formed and finished machined components can be produced for a diverse range of applications.

In recent years, the accelerating pace of medical equipment development has wrought dramatic improvements in areas such as body scanning and drug delivery. Just last year, we supplied key components for an innovative, needle-free drug delivery system introduced by our US partner Zogenix. By utiliing precision cold forming and engineering techniques we were able to produce a highly efficient system that helps reduce patient stress. This case study illustrates that when the know-how of an expert precision engineering firm and a collaborative partner come together the results can be innovative and truly ground-breaking.

Zogenix was founded with the goal of enhancing and differentiating medicines using new technologies to relieve the suffering of people with CNS and pain disorders. The company's leading product, SUMAVEL DosePro (sumatriptan injection) system, is a drug-device combination that enables needle-free delivery of subcutaneous sumatriptan for the acute treatment of migraines and cluster headaches.

The medical device pioneers

Technical article

The company has been working with Italy Precision on the development of this unique product since its inception. Zogenix had heard of the benefits of cold forming in terms of both quality and manufacturing cost savings and approached Italy Precision to produce one component of the DosePro device by cold forming. They were so impressed with the innovative solution that they then asked us to make a second component, again to demanding tolerances.

Using our intricate cold forming processes we were able to achieve a specially engineered part with a highly accurate pressure and finish that would enable the drug to be shot into the system without the need for a needle. A mirror surface on the inside of the piston and the angles in the design also played a crucial role in ensuring that the trigger mechanism works effectively.

We began to work closely with Zogenix to enhance the design of the DosePro system and suggested that we could manufacture a number of integral elements of the system in-house and within their budget. With assistance from Simon West at E-Tech, we set to work creating the bespoke machining

and tooling needed to manufacture one of the components and together developed and tested the parts until an optimum solution was found.

The precision-made components produced by Italy Precision, including an aluminium chamber and steel ram, have been specially engineered to administer the drug into the user's body without the need for a needle. As a result, medication can be administered quickly, simply and without anxiety. The success of the design is partly due to the high quality finish and intricate production of the cold formed parts, which make it possible for the administration mechanism to work.

Bill Feinstein, Director, Operations Planning and Procurement at Zogenix, believes that the partnership between the two companies has been key to the successful development of DosePro, stating,

"Throughout the manufacture process, Italy Precision have been extremely collaborative, throwing the necessary resources at challenges to help us find the best solutions. DosePro is a product based on physics and comprises many parts that all have to work exactly the way they are intended and in harmony together. Italy Precision has played a vital role in making this possible. We're extremely excited about launching this truly revolutionary system, and look forward to continuing to work with Italy Precision in the future".

With solutions such as this already enhancing the manufacture of medical devices, it's perhaps surprising that cold forming is not more widely adopted in this and other industries.

Italy Precision CNC Machining Inc.
Branch Address: Via Busto Fagnano, 40, 21057 Olgiate Olona VA, Italia.
Headquarters Address: Building 4, Dazhonggang Industrial Zone, Shajing Street, Baoan, Shenzhen, China. 518125
Phone: +86-755-27299111
Fax: +86-755-27294782
Email: inquiry.it@made-parts.com