Where Component Design Functionality And Cost Reduction Converge: Cold Formed Medical Devices Vs. Traditional Manufacturing Techniques

Author: Tim Kardish, President/CEO
tkardish@sussexwire.com

Date: May 7, 2014

The need to control and reduce costs by manufacturers of surgical instruments, medical devices and healthcare consumable goods has been accelerated by a variety of current persistent trends. These include changes in reimbursement practices, an increasing population of Medicare patients, and tax implications associated with the Affordable Care Act.

These dynamics are causing surgical instrument and medical device manufacturers to search for design, modeling and manufacturing technologies that improve NPD (new product development) efficacy and time to market while reducing manufacturing and assembly costs.

A large percentage of surgical instruments and medical devices contain precision engineered miniature and micro metal components produced from a wide variety of expensive -- and often precious -- raw materials. Manufacturers are focused on reducing these raw material costs, and, at the same time, looking for ways to save labor intensive assembly costs while improving yield and component reliability.

First, it's important to identify and understand the strengths and weaknesses of the several techniques available for manufacturing micro miniature components. Each of the following practices can be a good solution for a specific range of applications, but with each comes a variety of considerations, such as tooling cost, lead time, strength, part configuration and cost of ownership that must be evaluated to determine the best manufacturing method to apply to a specific part.

This brief will compare the pros and cons of screw machining (or Swiss machining), stamping, metal injection molding, and cold forming (or cold forging), and provide examples of how cold forming can improve production efficiency, quality and cost of ownership in medical device manufacturing.

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TRADITIONAL MANUFACTURING PROCESSES

Screw Machining / Swiss Machining

Advantages

- **Tooling:** Relatively low cost for short run projects compared with stamping, MIM, or cold forming.
- **Shape:** Can handle several variations among major and minor ODs around the length of the part.
- **Lead Time:** Tooling time from print to first article can be shorter (via CNC) than stamping, MIM, or cold forming.

Disadvantages

- **Scrap:** Cutting away material is integral to the process, and removal of material causes scrap. Even if the scrap is recovered, it requires an additional step and added process cost.
- **Production rates:** Screw machining can produce 12-15 parts/minute, depending on the size and geometry of the part. Stamping and cold forging can produce up to 90 to 300 parts/min.
- **Strength:** Machining destroys the grain structure of the metal, versus simply modifying the grain structure as in stamping, MIM or cold forming, all of which – to a greater or lesser degree - preserve the native structural properties of the material.
- **Secondary operations:** Machining often requires deburring, polishing, and finishing.
- **Part cost:** Parts which take longer to produce have a higher contribution of fixed direct and indirect overhead costs.

Stamping

Advantages

- **Shape:** Stamping is a good, economical solution for long-run 2-dimensional configurations.
- **Strength:** Stamping retains original material strength in the center of the shape because it is being reshaped rather than cut.
- **Production velocity:** Much faster than machining, about equal to cold forming.

Disadvantages

- **Scrap:** Stamping removes material from sheet goods, similar to screw machining.
- **Tooling:** Can be cost prohibitive versus machining, particularly for short runs; about the same or a little less than cold forming.
- **Lead time:** Tooling time from print to first article can be quite long, comparable to cold forming.

Stamping (continued)

Disadvantages

- **Strength:** On deep draw operations (which deliver a more 3-dimensional shape), stamping can produce only a single wall thickness which could compromise its structure depending on the application. At the part's boundaries, there can also be some weakness.
- **Secondary operations:** Often requires deburring, polishing, and finishing. Near-finished parts often need other processes to produce features such as knurled rings, external ribs, or extensively milled morphologies, which are not necessary with cold forming.
- **Part cost:** With tooling capital amortized over long runs, stamping alone can be performed relatively economically; however, accounting for scrap plus the addition of any required secondary operations, costs can exceed those of cold forming.

Metal Injection Molding (MIM)

Advantages

- **Scrap:** None, very similar to cold forming. The process involves filling a mold with a powdered metal composite, so there is no waste to speak of.
- **Shape:** Excellent process for highly complex asymmetric shapes, rather than purely axial symmetric shapes, as with cold forming.
- **Strength:** Very good, but not as strong as in cold forming. MIM may exhibit issues with lateral fatigue potential depending on directionality of the stresses on the part. MIM often has issues with achieving "density" on par with cold forming.
- **Production velocity:** Quite good but not as fast as stamping or cold forming.

Disadvantages

- **Lead time:** Tooling can be more time consuming than that of cold forging. Multiple process steps often require several castings which can take additional tune-up time. One of the issues is material shrinkage of 25-30%, which makes it nearly impossible to manufacture predictable parts with variations in wall thickness without extensive trials.
- **Secondary operations:** MIM parts must be batch processed in a vacuum heat treating furnace to evacuate the supporting matrix from the finished part. Operation and maintenance costs relative to the vacuum sintering process contribute significant over head, increasing total cost of part ownership.
- **Part cost:** Because of multiple steps, the process costs more than machining, stamping or cold forming.

Cold Forming: A Better Alternative?

Not as well known in micro-miniature component manufacturing, cold forming, or cold forging, is the application of force to the end of a precise metal cut-off blank contained within a die. The force exceeds the material's elastic limit or yield strength causing plastic flow. Cold forming retains the material's structural properties rather than compromising it as machining processes do. Cold forming is used for component heading, upsetting, extruding, sizing, piercing, trimming, threadrolling, blank rolling and pointing operations.

Cold Forming (continued)

Advantages

- **Scrap:** Very little to no material is sacrificed in part manufacture, except in trimming, which may account for less than 2% of the part mass. Cold forming produces a "near net shape" (and frequently a complete net shape) part.
- **Shape:** Cold heading can be engineered to achieve virtually any variation of wall thickness, i.e., many different wall thicknesses in the same part.
- **Strength:** Cold forging retains the native material structural integrity, or original grain structure, of the material because it has not destroyed or removed any part of the material; i.e., final part formation process eliminates destruction of grain. Rather, it reforms it into a final part. So cold forming leverages its final form from the native mechanical nature of the part, including tensile strength, ductility and hardness.
- **Production velocity:** Cold forming has a throughput volume of part production ranging from 90-300 parts/minute, so it absorbs overhead over a greater production of parts.
- **Simplified Final Device Assembly:** Cold forming can eliminate assembly by reducing the number and type of components and consolidating multiple parts into a single cold formed product. It reduces additional assembly operations by virtue of delivering a more complete part than would be possible using discrete operations.
- **Elimination of Secondary Operations:** There is no need for finishing to debur and/or tumble parts to remove rough edges. Cold forging leaves clean, rolled edges versus screw machine or stamped parts which frequently require deburring. Also, cold forming eliminates the need to connect two parts together by brazing, which is at once a time-consuming process and also produces an assembly with a potential weak point versus a cold formed part (eg: headed pin with lead and heat sink).
- **Part Cost:** Because of its near net shape process and elimination of scrap, higher production velocity, and the ability to amortize tooling cost over long runs of parts, cold forming yields a lower part cost versus other manufacturing technologies. With cold forming, material cost saving in certain medical device applications is directly proportional to the cost of the raw material, for instance, where platinum, palladium, niobium, or platinum/iridium are commonly used in components found in electro-regulating implantable devices and diagnostic/monitoring devices.

Disadvantages

- **Lead time:** Longer than screw machining from design to first part, but about the same or shorter than stamping and MIM.

Examples of Cold Formed Components in Medical Devices

Surgical Endoscopy Forceps

In this device, a single high tensile stainless steel (piano-type) drive wire is used rather than the more common braided wire (rope). The jaw fastens to the end of the drive wire using a specially cold-formed loop in a single piece. The “distal tip” is cold formed rather than machined, giving it tremendous strength but retaining a tiny morphology. Benefits include:

Surgical Endoscopy Forceps (continued)

Disposable endoscopy forceps stainless steel drive wire cam actuator

- **Control:** Single piano wire (fine gauge stainless steel) material provides enhanced tactile response and a much improved surgical experience for the doctor versus braided wire.
- **Confidence:** Surgeons can feel better about the outcome of the procedure, with less risk of a failed or improper procedure.
- **Size:** Single-drive wire device is half as large as that made with a braided wire version.

Medical Staples

These seemingly common and fairly simple staples used in joining tissues are actually manufactured to very tight tolerances. They are perfectly suited to the cold forming process because it is the optimal method to achieve the unique morphology of the shape and tolerances that the part demands. Benefits include:

Titanium bone staple

- **Tolerances:** Cold forming applies a combination of manufacturing operations to cut, form 40 degree points on the ends (+15 degrees/- 5 degrees), and form the wire into a final U-shape to dimensional control standards of (min +/- 0.002").
- **Reduced cost:** All these operations are done in a single pass eliminating all secondary operations with the exception of passivation to prevent corrosion.

Hypodermic Needle Hubs

This part is the mechanical interface between the cannula and the syringe. The hub provides a mechanical bond to ensure that the cannula and syringe don't break where media is tough, as in the case of dental and veterinary medicine when encountering hard or resistant matrix such as gums, hide, etc. Benefits of the cold headed part include:

Hypodermic needle aluminum hubs and inserts

- **Strength:** Enhanced mechanical integrity of aluminum, which is a light, non-corrosive material with excellent mechanical properties. Cold forming produces better mechanical strength versus machining.
- **Finish:** Cold heading and the associated finishing operations in this application produce a smoother, burr-free product.
- **Cost:** Cold formed aluminum provides attractive strength (and can be much more easily shaped) at a much lower material cost than stainless steel. Throughput can be in excess of 165 parts/minute by cold forming, with no scrap, reducing the cost of the part. The ribs on the OD of the part are formed in a die, a much cheaper/faster/more dimensionally consistent process than milling by machining or screw machining.

Educating The NPD Team

With so many extraordinary advantages of cold forming, why do NPD professionals depend on traditional metal component manufacturing technologies? Cold forming is a proven technology in use since the mid 20th century, but it is not widely known or appreciated in the general product design community.

Design for machining is a required undergraduate academic course in Mechanical Design and Manufacturing Engineering degree programs. In contrast, very little course work is devoted to cold forging, so it has become an unfamiliar practice. In fact, there are only a handful of universities world-wide that offer extensive course work in cold forming technology. Aalto University in Finland is one of them. Since product design/development staffs have little academic or institutional education on the benefits of cold forming, they design using techniques they are familiar with, such as screw machining, stamping, MIM, etc.

In the commercial world, there is likewise limited access to training on cold forming / forging design and manufacturing techniques. Since there are few companies performing cold forging, most of the commercial training is offered by the machine manufacturers themselves. National Machinery is one of the suppliers of cold heading equipment for large parts. Micro-scale parts are commonly made on equipment from Nakashimada (Japan), which is one of the only companies in the world making cold forming equipment for long life cycle, small size precision parts. National Machinery offers courses in cold forging, and may be one of the only commercial resources doing so in the US. But while the principles of large scale cold forming are the same for micro size parts, the scale and precision are dramatically different.

Because of the lack of educational and commercial training resources, new product design staff are reliant on partnering with vertically integrated cold forming / forging engineering and manufacturing firms to help them achieve their goals. These firms provide collaborative development and prototyping within the construct of non-recurring engineering (NRE) agreements. The fruits of these agreements often manifest in supplier contracts for cold formed parts, but not always. Materials companies such as Carpenter Technologies can provide some knowledge, but mostly with cold forging companies themselves, not their customers. Only in conjunction with a cold forging company such as Sussex Wire, Inc. located in Easton, PA can a potential part customer achieve a genuine proof of concept.

Conclusion

Surgical instrument and medical device manufacturers can benefit from a broader perspective encompassing cold forming / forging design and manufacturing to reduce cost and increase time-to-market and NPD efficacy.

SussexWire incorporated

www.sussexwire.com

4 Danforth Drive
Easton, PA 18045 USA

Tel: 610-250-7750 Fax: 610-250-8875

Email: info@sussexwire.com