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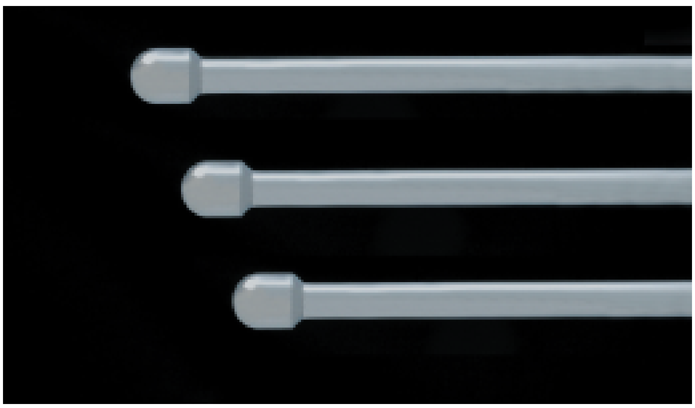
Forging Ball Tipped Guide Wires—Practicality, Performance and Profit

Manufacturing a high quality ball tip guide wire has always been a challenging task. After all, we are talking about creating a cylinder, which may be 170% larger than the diameter of the shaft, on the end of a rod that is frequently upwards of 39” (1,000mm) long and only 1/8” (3.2mm) or smaller in diameter. The result must be a product that performs without failing during surgery and is not cost prohibitive to manufacture. Traditional methods of manufacturing these types of parts have drawbacks, ranging from the high cost of manufacturing to issues with quality, strength and consistency of the final product. Forging addresses the many issues associated with traditional methods of manufacturing ball tips, while providing some distinct advantages to the customer. This is exactly what led Onyx to develop its proprietary forging process for the manufacture of high quality, high strength ball tip guide wires more than seven years ago.



Forged Ball Tipped Guide Wires

Forging is a way to create high strength parts with complex geometries that typically require secondary machining and/or finishing operations to produce the final product. While forging, raw material is compressed through a series of dies under extreme pressure to change the shape of the part. The raw material may be anywhere from room temperature to 1,700 degrees Fahrenheit or more at the beginning of the process. During forging, additional stresses are created in the material, increasing the strength of the final part. The shape of the final part is determined by the shape of the custom tooling used.

Forging sounds like a miracle process until the long lead times and expensive tooling are taken into account. There are a limited number of medical suppliers with forging capabilities, and the tooling is complex, strong, durable and therefore, expensive. Additionally, since forging does not yield finished part geometry, secondary machining and finishing operations can add significantly to the cost of the final part. Hence, in the orthopaedic industry, forgings are traditionally reserved for high dollar value parts like hip stems, where strength requirements and complex geometries justify an investment in tooling and time.

Ball tipped guide wires are not good examples of traditional forgings - their price point simply did not justify the investment in tooling. In the past, other methods of manufacture have been used to produce ball tips including casting, machining from solid bar stock and welding tips onto shafts. Each of these processes has benefits and drawbacks that will be explored in detail below. Casting involves heating metal until it is in a liquid state and can flow into a cavity with the desired shape for the part. Like forging, casting is a process that requires some secondary finishing and an investment in tooling. Specifically, for ball tips, the rod is locally heated at one end until it flows into the cavity of the tool as shown in Figure 1 (see next page). The raw material (blue) is loaded into the casting cavity and heated until it flows (green) and fills the cavity (red). The benefits of casting include relatively simple and moderately priced tooling, flexible geometry of the tip end, moderate production rates and one piece construction of the ball tip.

However, since the material is in a molten state, the part can lose up to 45% or more of its original strength in the heated areas. This is caused by the complete relief of any cold working present in the material during the heating process. Also, because voids can further reduce the strength of the part, care must be taken to

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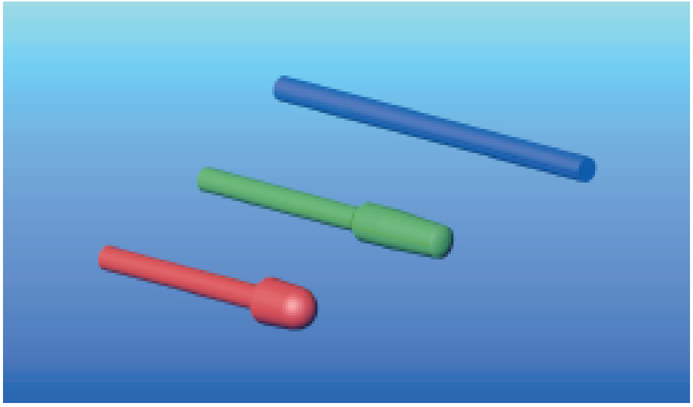

Figure 1

ensure there are no such voids present in the tip or adjacent shaft as a result of the casting process. Many cast parts are 100% eddy current tested to ensure that such voids do not exist in the final product.

Another option for producing ball tips is machining them from solid bar stock. Machining from bar stock produces very strong parts, provides excellent geometry capabilities and requires minimum investment is specific custom tooling. However, like casting, it does have several drawbacks. First, the equipment that is used is typically a Swiss-style CNC lathe that may range in price from $150,000 to in excess of $300,000, a hefty investment. Assuming a basic feed rate of 0.0025 in/rev and 3,500 rpm spindle speed (these are good parameters for a moderate surface finish and moderate to good chip control), the cycle time for a 40” ball tip would be around 5 minutes. Even running 24 hours a day, at 85% efficiency, the production rate would only be 245 pieces per day. This can tie up a very expensive and capable piece of equipment for a low price point part. The surface finish of the completed part will be rougher than that of ground bar stock and may include imperfections due to chip wrap and the re-grips needed to make such a long part. Because of the amount of diameter removed from the shaft, the bar stock will lose some of the stresses that hold it straight. This means that the shaft of the completed part will have some sort of corkscrewing to it instead of remaining as straight as the raw bar stock. Finally, a lot of expensive medical grade raw material ends up as waste in the bottom of the machine.

Another traditional ball tip production method is welding. A small part the shape of the tip is machined from bar stock and welded to a rod that is the diameter of the shaft. This has several benefits. First, the cycle time to machine the tip can be 35 seconds or less. Second, significantly less raw material scrap is produced vs. machining. Also, welding allows for a tip diameter to be much larger than the shaft diameter, as they are made from two different pieces of metal. But welding has its own particular set of issues. Since the ball tip is an assembly of two pieces, there is the possibility of separation during surgery. Welding locally anneals the raw materials being joined, reducing the strength of the part by up to 45% or more from its cold worked state. The possibility of weld porosity also exists and must be checked, since it would reduce the strength of the weld. Finally, depending on geometry and surface finish requirements, the welded tip can require secondary finishing or machining.

When Onyx first started manufacturing ball tips more than seven years ago, we used a welding process as required by our customers' specifications. Onyx had reservations with welding because of concerns about the quality and consistency of this process and ultimately, over finished part strength. During discussions with our customers, we discovered that they too had reservations about the strength of welded ball tip guide wires due to previous field failures during surgeries. We began an investigation into the use of custom inspection equipment to test every weld for porosity and strength, but had misgivings about the additional cost in equipment and time. Furthermore, this did not address the root cause of the problem: inconsistencies in the welding process. Laser welding was considered for its enhanced process control, but still did not address the strength issue. Ultimately, the most intriguing idea was forging the tip with one piece of material, and the benefits of using only one piece to manufacture a ball tip justified further investigation. Subsequent prototyping and testing proved the merit of this idea and led us to develop a custom forging machine, tooling and process that enables the use of one set of tooling to produce a wide variety of ball tip geometries. Extensive process controls were developed and validated to ensure a consistent high strength result. In our validation tests, the forged parts were on average 70% stronger than the welded parts.

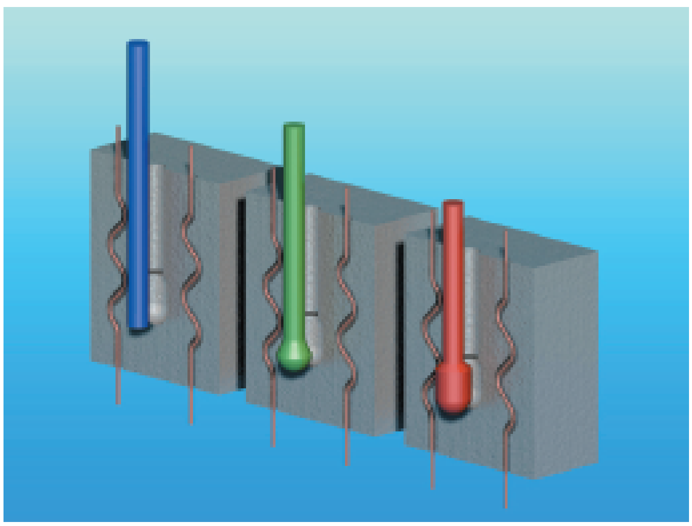

Figure 2

The forging process for ball tips begins with a long rod of raw material, typically 316L stainless steel, with a diameter equal to the shaft diameter of the final part. The material is heated to a forging temperature and placed into the forging machine. Figure 2 shows the progression of the part through the various stages of the forge tooling. The blue part represents the un-forged raw material; green represents the intermediate stages the part passes through on its way to the final pass, represented in red. Finally, the rough blank is taken to a turning center for a 45 second finish turning operation. With one set of tooling, enough material is displaced to allow for a variety of tip geometries after the finish machining step. Using the forging process described above, Onyx can produce over 750 high quality ball tips per day.

Ball tipped guide wires look deceptively simple but are complex parts to manufacture. Casting, welding, machining and forging are all viable options for producing these parts, each with its own benefits and drawbacks. Onyx chose to develop a forging process that we believe combines the properties of high strength, flexible final part geometry, low cost tooling, high production volumes and a cost effective finished product. We have found that this unique combination of benefits fulfills the needs and exceeds the expectations of our customers.

As the Vice President of Manufacturing at Onyx Medical Corporation, Patrick is responsible for manufacturing technology, development and manufacturing operations. Patrick has 15 years of engineering and design experience and holds numerous patents. Prior to joining Onyx, Patrick worked as a project manager and lead design engineer at IDEO Product Development and Summagraphics Corporation. Patrick holds a Bachelors degree in Mechanical Engineering from the University of Texas at Austin.

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