Things You Should Know About Aluminum Extruded Medical Components

Mark Shortt

The TomoTherapy® System uses a specialized system that narrows the radiation beam to target the tumor while minimizing exposure to the surrounding healthy tissue. A coupling component links the actuator to the leaf assembly that opens and closes to deliver the prescribed modulated dosage of radiation. The earlier coupling design—previously machined from steel—was wearing out or breaking prematurely, prompting a system error and sometimes causing the machine to shut down safely.
Image courtesy of Alexandria Industries.

Corrosion and chemical resistance, high strength-to-weight ratio, and the ability to incorporate features—like a snap-fit hinge—that facilitate easier assembly of components are a few of the benefits that medical device manufacturers can achieve with extruded aluminum parts.

Company representatives from Alexandria Industries are quick to point out the advantages that aluminum offers medical device OEMs over other materials that they might be considering for their components. With proper finishing, including anodizing and hardcoating, they say, aluminum products are less porous and cleaner than stainless steel. And the inert chemical compounds in aluminum, combined with proper finishing, are said to help prevent corrosion and chemical absorption—a major key to preventing contamination and easing the cleaning process in medical care applications.

"Aluminum extrusions' high strength-to-weight ratio works well for a range of medical device applications," said Gordon Knott, medical market leader for Alexandria Industries, in an email response. "Aluminum gets stronger as temperatures drop—steel and plastics get brittle and can break—making aluminum an ideal choice for low-temperature applications. Aluminum also is about one-third as heavy as steel, helping minimize overall load weight. Another point to consider is that aluminum rolled shapes, riveted together,

can be replaced by a single aluminum extruded profile, resulting in higher strength while eliminating joining costs."

Alexandria Industries serves as a one-stop component shop—a vertically integrated supplier that offers OEMs a single source to design, produce, assemble, and deliver a range of components. The company, headquartered in Alexandria, Minn., uses high-quality, certified aluminum materials and automated extrusion presses to manufacture a range of precision aluminum extruded components. Alexandria also offers stretch forming and bending after the aluminum has been extruded.

Alexandria's degreed CNC programmers and machinists use 4th and 5th axis precision machining centers with vertical, horizontal, and long-bed capabilities to mill, turn, grind, hone, hob, and broach ferrous and non-ferrous based products. The company's fabrication capabilities include a range of services, from notching and swedging fabrications to complex punching requirements, coupled with TIG and MIG welding expertise.

"We offer metal finishing services, including painting, plating, anodizing, hardcoating, and ExtremEtch™ —a cost-effective aluminum etch process that produces a uniform deep matte finish and effectively hides machine marks and abrasions," said Knott. "For customers who need thermoplastic injection-molded products, engineered-resin prototypes, and polyurethane foam molding abilities, we offer the ability to mold everything from micro-components to picnic tabletops. We also assemble our customers' components to help simplify their downstream final assembly processes or to produce a final, packaged product ready for retail distribution."

On a company-wide basis, Alexandria employs about 580 people, including approximately 18 engineers, at six different facilities. Represented among them are a variety of mechanical, manufacturing, design, applications, and process engineers. That's a good thing, because Knott said that the increasing need for—and cost of—engineering talent is forcing OEMs to rely more on their contract manufacturers and suppliers' engineering services to help design and manufacture their subassembly components. But it's a challenge that Alexandria is prepared to meet. To help solve customers' engineering problems, Alexandria's engineers explain the benefits of getting suppliers involved in the product development processes as early as possible to avoid trouble areas and create better solutions. "This, alone, can help lower their costs and reduce the number of components needed for their medical devices and equipment," said Knott.

Design Tips for Medical Device Manufacturers

There are a number of things that medical device OEMs can do to improve their designs for aluminum extruded medical components, according to Knott. First and foremost, he said, is the need to understand the end use of the product and share that understanding with their supplier.

"When developing new components, medical device designers need to fully understand the end usage and share this information with their aluminum component manufacturer," he said. "The more a manufacturer understands the product end use, the more constructive design guidance they can offer because there are different ways to meet design challenges more effectively, efficiently, and economically, when using aluminum rather than alternative materials. Sharing information with their supplier about the functionality of the part can result in quicker project start-up times and overall product development."

To this end, Knott said, Alexandria always asks its customer for "a lot of information" when the company receives a component print. "We ask 'Do you have a prototype? Do you have assembly prints? What does this go into? Do you have any mock-ups of the assembly?' That's because we really want to see how the part functions. Is it just structural, or is it a dynamic moving part in an assembly? We analyze the tolerancing of the mating parts to make sure that there's a fit, and that the tolerance is correct for what's required for the part's function," he explained.

"Once we get assembly prints, we try to get into a design for manufacturing discussion, and it's good to do that at the customer's plant," Knott continued. "With today's technology, you can do webinars, but it always seems to be so much more beneficial to be face-to-face. If there's a mock-up, we can go out to their lab and look at what they're doing, or what they're trying to do, and then, understanding that, we can start offering the best possible solution."

It's also essential to recognize the areas of the part that are critical to its function, he said. In order to maximize the benefits of aluminum, designers who are looking to achieve

benefits like increased strength, lighter weight, or ease of assembly with mating components should think through the crucial dimensions and features of their component. Aluminum extrusions, he noted, offer optimum strength-to-weight ratio in cases where wall thickness or profile adjustments can be made to lower the component's weight while ensuring its overall strength.

Designers also stand to benefit if they understand mating components, specifically with regard to part features and final assembly. Due to its versatility, Knott said, the aluminum extrusion process is well-suited for incorporating features that make it easier to assemble components with their mating pairs. A snap-fit hinge, for example, facilitates easy assembly without the use of special tools (see case history below, "An Ounce of Extrusion, A Pound of Cure"). And features like dovetail slots, screw bosses, and internal screw chases can significantly reduce assembly time with mating components, saving money and freeing workers to perform other value-add work, he added.

Another key is to select the best aluminum alloy for the manufacturing process and product usage. It's important for design engineers to understand their component's critical design absolutes, functional needs, estimated annual usage, and product manufacturing processes when choosing their preferred aluminum alloy, Knott said. "Different alloys offer different properties, and some are better for certain processes than others. Some alloys extrude at a faster rate, some are easier to bend, and some accommodate machining processes better than others." The choice of alloy can also have a significant effect on surface finish, he added.

The following case history was contributed by Alexandria Industries.

An Ounce of Extrusion, a Pound of Cure

One of the leading radiation oncology companies that is helping patients live longer, better lives is Sunnyvale, Calif.-based Accuray. Like many medical equipment manufacturers, Accuray relies on tightly orchestrated relationships with its component suppliers to help design, develop, and integrate components to bring to market leading equipment, such as its TomoTherapy® System, which is manufactured at its Madison, Wis., facility.

The TomoTherapy System involves complex computing and hundreds of mechanical parts. It is the only radiation system specifically designed for integrated, 3D image-guided, intensity modulated radiation therapy (IMRT) and 3D conformal radiation therapy. Based on a computed tomography (CT) scanner platform, the TomoTherapy System enables helical dose delivery through continuous 360-degree gantry rotations for specified beam angles. These unique features, combined with daily 3D image guidance, allow oncologists to precisely apply an individualized dose to any target volume, during each treatment fraction.

Challenge

Each component contributes to overall equipment accuracy and uptime performance. The TomoTherapy System boasts one of the most reliable uptime rates in the industry at approximately 99 percent, but when shortcomings with a supplier's couplings for the system's electro/pneumatic/mechanical assembly threatened its accuracy and uptime, Accuray sought an immediate solution.

**The Accuray coupling measures about an inch long.
Photo courtesy of Alexandria Industries.**

Coupled to a pneumatic actuator, the system's 64 mechanical leaves shutter open and close to deliver the prescribed modulated dosage of radiation to the diseased cells. Instances of the couplings used to connect the leaves with the actuator breaking would prompt a system error, causing the machine to safely shut down.

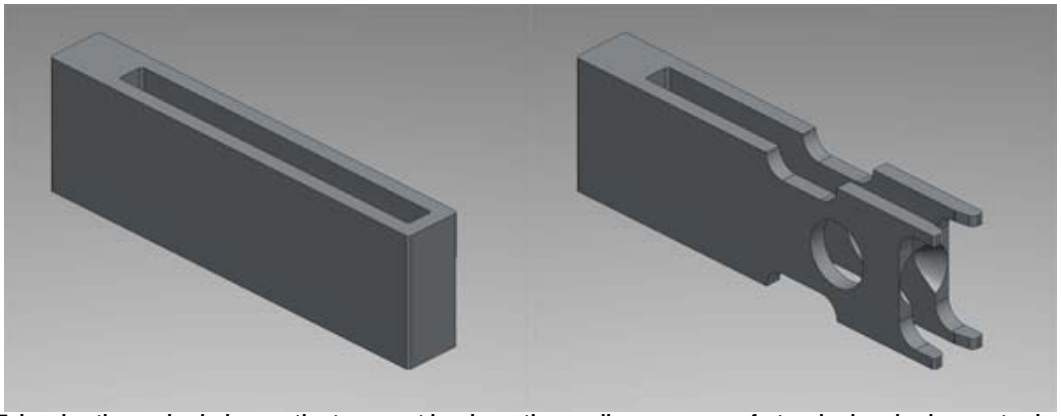
The couplings were machined from stock steel using electrical discharge machining (EDM)—a complicated machining process that requires several manufacturing steps—and come with a relatively high part price when included with other processes for this part.

When Bradley Brunker, a senior sustaining engineer from Accuray's Madison campus, examined solutions for the failing couplings, his criteria were both technical and economical. Industry-leading performance was mandatory, and he also wanted to be able to reduce the full assembly part count, part cost, and, ultimately, the labor cost to assemble it. And he needed to do it fast.

Solution

When thinking about how he should change the coupling to enhance its mechanical properties, Brunker determined that the component should be extruded from aluminum instead of machined from steel. His previous experience with extruded aluminum products proved to him that the metal alloy's properties, combined with hard-coat anodizing, would give him the reliability he needed in addition to the lower cost per part he was seeking.

Brunker turned to Minnesota-headquartered Alexandria Industries to help design, engineer, and manufacture a component that all treatment facility sites—and their patients—could rely on.



**Enhancing the mechanical properties to prevent breakage, the couplings were manufactured using aluminum extrusion (6063 T6 aluminum), machining (CNC robotic milling), and Type III hard-coat anodizing, increasing wear resistance and simplifying mating assembly for an intended snap-fit design.
Images courtesy of Alexandria Industries.**

Design engineers with medical market expertise from Alexandria Industries worked closely with Brunker to create the part's die and ensure the extruded pieces were made to exact specifications using Finite Element Analysis (FEA) studies to prove part measurement.

They identified slight design variations from the original design that would improve the part's overall strength and durability, and assure repeatability from the tooling.

According to Rob Zahn, vice president of manufacturing at Accuray, "The Alexandria Industries engineering team assigned to Bradley's project worked closely with him to tweak the design. Their experience, industry knowledge on finishing techniques, and ability to communicate clearly and efficiently saved a significant amount of design time."

After extruding the components, Alexandria Industries technicians machined and anodized the surfaces to the exact specified hard-coat thickness tolerance to increase wear resistance and simplify mating assembly for its intended snap-fit design.

As a final manufacturing step, an identification tag was laser etched on each component. This tag is recorded so Accuray and Alexandria Industries can track and monitor each component for quality assurance purposes.

A camber clamp assembly, manufactured by Alexandria Industries for use on a wheelchair. The assembly illustrates the versatility of aluminum extrusion combined with hardcoat anodizing, a combination that helps prevent corrosion and chemical absorption and eases the cleaning process in medical care applications.
Photo courtesy of Alexandria Industries.

Results

There were some premature wear issues with the previously EDM-produced couplings—Accuray wanted to extend the life of the couplings to at least 10 years. Accuray performed four months of mechanical testing on multiple prototype assemblies, running numerous sets of the coupling components from Alexandria Industries through 10 million cycles. The result: zero failures.

Another goal for this project was to lower the total part count and assembly labor cost. Because the coupling was extruded, the design could be shaped in such a way that it could snap-fit to its mating components. The leaf, coupling, and another redesigned component easily snapped together and cut the assembly labor by 30 to 60 minutes for each completed assembly.

Using an aluminum-extruded part also cut component manufacturing costs by nearly 90 percent and took only a quarter of the time to produce. And because of the couplings' snap-fit geometry, Accuray also was able to eliminate a tool previously used for assembly.

Accuray began putting the updated sub-assemblies in field in mid-2012 and has installed approximately 10,000 new coupling components to date.

“Part of the high cost to develop new medical device products can be attributed to outsourcing component manufacturing from various suppliers,” Zahn said. “Managing these relationships takes a heavy financial and logistical toll, slowing the time to market and driving up the cost. By working with Alexandria Industries, we were able to streamline the process, which saved the company something much more important than money. It saved us time and helped ensure our TomoTherapy equipment stays up and running for the people who need it most—those with cancer.”

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