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COLLABORATION TO INNOVATION

A new way to manufacture thick-wall stainless steel tubing that's cheaper, faster, and more reliable

> By Kevin McGrath Chief Executive Officer



Introduction

"There *must* be a better way." A few years ago, I worked for an orthopedic instrument manufacturer that routinely purchased thick-wall, gun-drilled/seamless stainless steel tubing for devices like drills and reamers. Gun drilling is a slow, costly process with constrained capacity, and it's notorious for missing delivery dates. That got me thinking about alternatives.

Fast forward to 2020. As CEO of Accu-Tube, I saw an opportunity in the acquisition of Mercury Tube, which manufactures larger-diameter stainless steel tubing than traditional medical device tubing fabricators. Engineering teams from both sites collaborated to develop a new innovation: thick-wall tubing that is welded and drawn rather than gun drilled. This new tubing can replace gun-drilled/seamless stock for some applications.

The advantages?

- Lower cost: 30%-50% lower
- Faster delivery: 50% faster
- Reliable supply: Predictable production process

This white paper will explain why we developed this innovation and the benefits it brings to the medical device industry.

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Limitations in thick-wall tubing manufacturing

Tube manufacturers face several limitations in fabricating thick-wall tubing. Medical device tubing manufacturers have optimized production of tubing with wall thicknesses from .005 inch up to .035 inch. To make this thick-wall tubing, we start with a large-diameter tube and draw it down many times. This requires larger equipment than what is traditionally used to manufacture medical tubing.

Common alloys used in thick-wall tubing applications also have limitations. For example, inexpensive materials such as 304 stainless steel cannot be heat treated and lack the strength needed for many orthopedic instrument applications. These factors have forced tubing manufacturers to rely on gun-drilled/seamless bar stock (440, 455, and 17-4) to fabricate drivers, reamers, and drills used for many orthopedic procedures. These alloys can be heat treated to achieve higher strength, but they're costly.

Collaboration to innovation

The engineering teams at both Accu-Tube sites collaborated to overcome these limitations, each bringing strengths and capabilities to the table. The former Mercury Tube site had the larger equipment needed to manufacture thick-wall tubing.

Accu-Tube brought 30 years of experience manufacturing 17-7 stainless steel tubing. Why 17-7? Initially, we manufactured 17-7 to replace 304 stainless steel in popular laparoscopic applications. For this thick-wall tubing, 17-7 provides the strength of current alloys with a much lower fabrication cost.



Collaboration to innovation (continued)

Used in medical device applications for more than 20 years, 17-7 is very similar to the popular 17-4 stainless steel, with the addition of aluminum and a slightly higher nickel content. (See Table 1, Chemical Comparison of 17-4 and 17-7 Stainless Steel.)

These changes allow the material to become **formable**. The formability of 17-7 makes it possible to manufacture welded-and-drawn tubing. The ability to heat treat it like 17-4 makes it attractive for demanding orthopedic applications. Figure 1 compares ultimate tensile strength of 17-7 with other popular alloys including 304, 17-4, and 400 series.

Key points:

- In its cold-worked condition, 17-7 is stronger than 304
- When heat treated, 17-7 is stronger than 17-4

	STAINLESS STEEL TYPE	
Chemical Analysis (%)	17-4 PH CONDITION H 900	17-7 PH CONDITION CH 900
Carbon (C)	.07 max	.09 max
Manganese (Mn)	1 max	1 max
Silicon (Si)	1 max	1 max
Chromium (Cr)	17	17
Nickel (Ni)	4	7
Other	4.00 Cu	.75/1.50 Al
Typical Hardness (RC)	43	46
Corrosion Resistance	Excellent	Excellent

Table 1: Chemical Comparison of 17-4 and 17-7 Stainless Steel

300 254 Ultimate Tensile Strength (ksi) 250 245 200 200 190 160 150 150 140 145 100 100 50 0 Full Hard Cold Heat Annealed H900 Annealed H900 Annealed Heat Worked Treated Treated (CH900 process) 304 Accu-Tube Accu-Tube 17-4 17-4 455 455 440A 440 17-7 17-7 **Common Alloys**

Figure 1: Comparison of Ultimate Tensile Strength for Common Stainless Steel Alloys

Customer benefits

This collaboration allowed us to address a market need for a lower-cost solution that is scalable and capable of providing cannulated stock for a portion of our applications that is currently gun drilled. By converting to welded-and-drawn tubing, our customers will see:

• Lower cost While gun-drilled/ seamless stock can cost \$15–\$25 per foot, our thick-wall tubing ranges from \$8–\$12 per foot

- Shorter lead times Our lead time is 4–6 weeks, about half the time for gun drilling (for 1,000–10,000 feet)
- More reliable supply We can produce 1,000–10,000 feet with predictable yields and manufacturing cycle times
- Swiss-style-machine ready

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- Centerless ground outside diameters
- Square-cut ends





How is welded-and-drawn tubing made?

Let's take a moment to discuss the process of fabricating welded-and-drawn tubing. (See Figure 2.) We start with a metal strip to produce "as-weld" tubing. This is done in a mill that forms the strip into a circle and welds the seam.

The tubing then goes through draw cycles to reach final specifications like inside diameter (ID) and outside diameter (OD). Specs also include the degree of hardness of the tubing. Our thick-wall tubing can go through 7 to 9 draw cycles.

Once we've achieved our specs, the tubing is straightened and centerless ground to final size.



Figure 2: Process for Fabricating Welded-and-Drawn Tubing



Tubing performance

At this point, engineers might be wondering, "How do I know it's not going to blow out at the seam?" Good question!

First, we take the tubing through **multiple draw cycles**. Each progressive drawing operation "irons out" or homogenizes the weld zone, allowing the tubing to perform more like seamless tubing. By **drawing the tubing over a mandrel**, we smooth the weld zone into the ID.

Figure 3 is a cross section of an "as-weld" tube. You can see how the weld bead drops into the ID. Figure 4 shows a cross-section after drawing the tube over a mandrel. In addition to rounding out the ID, we've improved the geometry and homogenized the weld zone into the adjacent material, providing further strength.

Concentricity and true position are critical attributes for many orthopedic instruments. Because we start with a strip, welded-and-drawn tubing is superior to gun-drilled/seamless stock. The strip is of uniform thickness, whereas gun-drilled stock relies on the drill walking perfectly down the axis of the rod that it's drilling.

With **near net shape tubing**, you're not restricted to fractional ODs like you are with gun drilling. We can adjust our draw schedules to achieve a custom configuration for your application. By optimizing the OD, you can reduce subsequent machining operations, which saves additional cost. For example, if your finished part OD is .150 inch, we can make tubing that exact size rather than the next larger fractional size of .1875 inch.

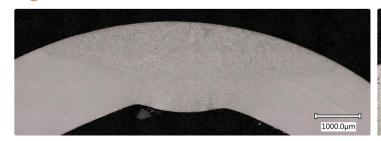


Figure 3: Cross Section of "As-Weld" Tube

Figure 4: Cross Section After Drawing Tube Over a Mandrel







Tubing specifications

Our thick-wall tubing will be available in summer 2021 with IDs starting at .049 inch and ODs ranging from .15 inch to .75 inch. With in-house centerless grinding capability, we can grind these heavy tubes to +/- .0005 inch. Our wall thickness limit is around .100 inch. (See Figure 5, Thick-Wall Tubing Capability Summary.)

The relationship between the OD and wall thickness is critical to our process. I like to think of our OD-to-wall ratio in 3 zones, like a traffic light:

- > 3 = green light
- ~ 3 = yellow light
- < 2.5 = red light

The lower the OD-to-wall ratio, the more unpredictable the material becomes as we draw it.

Our initial focus was on common K-wire sizes and 17-7 stainless steel. As we continue to refine our process, we can fabricate tubing with an ID as small as .049 inch with an OD of .191 inch. Applications with larger IDs or thinner walls will be less challenging, with the potential to create a wall thickness of .100 inch. Prototype quantities will be available in summer 2021 on <u>Chamfr.com</u> or by <u>contacting us.</u>

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Conclusion

This product is a departure from the current approaches to manufacturing thick-wall tubing. We look forward to working with innovative companies that are considering alternatives to gun-drilled/seamless stock and are open to new ideas. With a cost of just \$8–\$12 per foot, our thick-wall tubing could provide a cost-effective and reliable alternative.

The medical device industry is always looking to reduce costs. By offering a lower material cost, our end customers (medical device OEMs) may also be able to convert some reusable products to single-use products.

What's next for thick-wall tubing? We're currently working to tighten our ID tolerance capability, to increase centerless grinding capacity, and to explore additional alloys for thick-wall tubing. Engineering teams at both Accu-Tube facilities are excited to continue collaborating on creative new products and manufacturing methods that will help our customers reduce cost, save time, and boost reliability.

Figure 5: Thick-Wall Tubing Capability Summary

Thick-Wall Tubing Capability Summary

Stainless steel alloys

- 17-7
- 304/304L
- 316/316L

Size ranges

- OD: .150" to .750"
- ID: .049" and up
- OD ground to +/- .0005"
- Largest wall thickness: .100"
- ID tolerance: +/-0.003"
- OD tolerance: +/- 0.0005"

OD-to-wall ratio

- > 3 = green light
- ~ 3 = yellow light
- < 2.5 = red light
- Stock tubing sizes*

Chamfr.com

- .1875" x .049"
- .1875" x .055"
- .1875" x .0625"
- .250" x .062"
- .250" x .134"

Applications

- Orthopedic instruments: drills, reamers, and cutting tools
- Minimally invasive surgical instruments
- Reduced-cost instruments for conversion to single use

* Available summer 2021

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About Kevin McGrath

Kevin brings more than 25 years of medical device industry experience in profit & loss management, manufacturing operations, sales, business development, and mergers & acquisitions. He has a bachelor's degree in marketing from the Metropolitan State University of Denver and has completed the High-Performance Leadership Program at the University of Denver.

About Accu-Tube

Accu-Tube is a market leader in manufacturing welded-and-drawn precision stainless steel tubing for medical device OEMs and CMOs. We specialize in processing a select group of high-quality stainless steel alloys such as 17-7, 304, 304L, 316L, and 321 that meet the rigorous standards of the medical device industry. With nearly 50 years of experience, we combine deep materials expertise with a keen understanding of the medical device market to help you choose the right materials, finishes, and processes for your clinical application. Find a selection of our stainless steel tubing for your prototyping needs on <u>Chamfr.com</u>. For more information, visit <u>accutube.com</u>.