Accu-Tube

METAL TUBING SPECS:

3 TIPS FOR A SMOOTH HANDOFF

By Glen Brach, PE
Vice President, Engineering

Introduction

If medical device designers are like the first leg of a relay race, precision stainless steel tubing manufacturers are the second leg. Precision stainless steel tubing is the foundation of most medical devices. With a smooth handoff, tubing suppliers can efficiently provide tubing that meets the designer's needs for the next leg. But the handoff is critical. If the designer's specifications (specs) are incomplete or unclear, they'll lose valuable time in the race to the finish line.

Why are specifications so important? Obviously, detailed specs help ensure that customers get the tubing that meets their requirements. But specs can also be a significant cost driver. Consider what happens when specs are incomplete. The tubing supplier has to go back and ask for the missing information, which could cause delays. Or, the tubing supplier might make assumptions that could result in a higher quote.

We understand that designers and contract manufacturing organizations often "inherit" product designs that are years or even decades old. This means it's usually not an option to clarify what the original design engineer had in mind. In these cases, it's worth the time to do your due diligence and perform the tests and analyses needed to fill in missing specs or clarify imprecise specs.

This white paper will share three tips for a clean handoff, or tips to make your specs more robust so that your project moves smoothly on to the next leg and maintains its momentum toward the finish line.

3 TIPS FOR A SMOOTH HANDOFF

#1 Consider a Range of Materials

Most medical device tubing is made from common stainless steel alloys including 304 and 316. 17-7 is emerging as a replacement for 300-series alloys when you need higher performance. Standard material specification sheets identify the pros and cons of each material. A strong tubing supplier has the expertise to suggest a material that could better meet your needs or save time or cost.

EXAMPLE:

A customer came to us looking for help designing a next-generation orthopedic driver. Early testing of the device using 304 tubing resulted in mechanical failure with a fixed ID and OD due to the interaction of the tube with the balance of the device. The customer needed a stronger tube, and 304 or 316 alloys would not meet that goal. We suggested exploring 17-7 as an alternative. With a higher tensile strength than 304 and the ability to heat treat to further increase its strength, 17-7 looked very attractive on paper.

The Accu-Tube team worked for 3 months to develop the entire manufacturing process, and the result was a tube that exceeded the performance requirements of the design.

#2 Know Your Dimensional Tolerances

Figure 1: Centerless grinding enables OD tolerances as tight as +/- .00025"

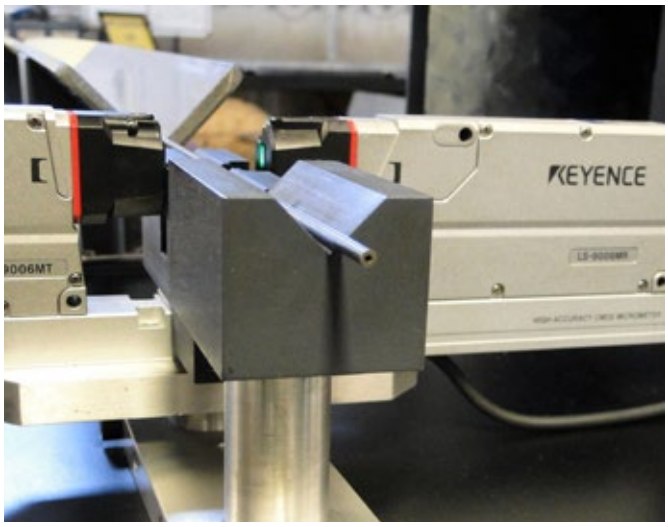

Figure 2: A optical micrometer can measure OD tolerance as low as ± .00002"

The tolerances you specify for inner diameter (ID) and outer diameter (OD) play a major role in the cost of precision stainless steel tubing. As a rule of thumb, specify tolerances only as tight as functionally necessary. The tighter the spec, the more specialized processes are required, which can add cost.

Another rule of thumb is to apply the tightest tolerance to the OD of the tube rather than the ID. Why?

- There's more flexibility in the tube manufacturing process for achieving tighter OD tolerances than ID tolerances
- ODs are also easier to measure

Let's look at each of these factors for both OD and ID:

OD

When manufacturing precision stainless steel tubing, we can maintain moderate tolerances at a low cost through standard drawing and straightening processes. But when we need to achieve even tighter tolerances, we can use centerless grinding for most tubing.

Accu-Tube is one of only a handful of tubing suppliers that does centerless grinding in-house. This capability allows us to maintain a tolerance of ± .001" or even ± .0005" on most diameters, and in many cases we can achieve ODs as tight as ± .00025" using precision grinding passes. These tight tolerances are necessary for preparing tubes for Swiss machining. In fact, we produce more than 3 million feet of SWISS-READY tubing annually.

ODs are typically measured using a micrometer, which generally provides an accurate and non-subjective reading. At the tightest OD tolerances (< ± .0005"), cost can increase because you now need additional operations such as optical micrometer measurement, ring gaging, or 100% inspection.

ID

As with OD sizing, we can achieve moderate ID tolerances from the draw and straightening processes at a low cost (± .002"). Unlike the OD, there are no economical solutions to refine the finished size of the ID after these processes are completed. When you need a tight ID tolerance (< ± .002"), custom tooling and additional process controls may be necessary, which can significantly increase cost.

Quality inspectors typically measure the ID using pin gauges. In this case, measurement resolution is limited by the pin sizes available, typically in .0005" increments.

#3 Quantify Your Tensile Strength

A. Stainless Steel Types 304, 304L, 316, 316L, 321

Temper	Tensile Strength (ksi = 1000 psi)
Annealed	110 ksi MAX
½ Hard	120–150 ksi
Full Hard	140 ksi MIN

B. Stainless Steel Type 17-7

Temper	Tensile Strength (ksi = 1000 psi)
Annealed	145 ksi MAX
Cold Worked	160 ksi MIN
Heat Treated	200 ksi MIN

Figure 3: Typical Tubing Tensile Strength

We frequently see tensile strength specs like “1/2 hard” or “full hard.” These terms originated from wire specifications and are no longer part of tubing standards. To avoid this subjectivity, we recommend that your drawing include a numerical tensile strength specification. (See Figure 3.)

Specifying hardness (“Rockwell C 36,” for example) is also a challenge. Depending on the application, a tube may need to be very “soft” (annealed) or very “hard” (cold-worked). Getting an accurate measurement of a tube’s hardness can be difficult, due to the size of the wall and the tube’s small diameter.

For soft (annealed) tubes, we recommend specifying a MAXIMUM (MAX) tensile strength. For a “hard” or “high-strength” tube (cold-worked), specify a MINIMUM (MIN) tensile strength. You can specify a numerical tensile range, but the tightness of the range can be a cost driver due to potential variation in the chemistry between heat lots of strip material used to manufacture the tubing.

Conclusion

With an understanding of how specifications impact cost, you can create specifications that meet all your functional needs while providing the most economical manufacturing solution.

As you work on finalizing your design specifications, feel free to give us a call. Our engineering team has decades of experience helping customers design tubes for a wide variety of applications, and we've seen a lot! Before the design verification build, we can help you design a tube that meets your performance requirements, is repeatable, and can be consistently delivered. If you need prototypes to help set your specifications, you can find a selection of our stainless steel tubing on chamfr.com, in stock and ready to ship.

A relay team is a great metaphor for the process of developing a medical device. In both cases, each team member must get their timing and performance just right to ensure a smooth handoff. Precise execution requires teamwork, communication, and cooperation. Each team member—whether they're running the first or the last leg—must understand and commit to their role in ensuring their team crosses the finish line first.

About Glen Brach

Glen has been with Accu-Tube for more than 25 years. He has a comprehensive understanding of manufacturing precision stainless steel tubing and developed the current processes to accurately and consistently produce tubing in 17-7 PH and 300-series alloys. He has a bachelor's degree in Mechanical Engineering from Iowa State University.

About Accu-Tube

Accu-Tube is a market leader in manufacturing welded-and-drawn precision stainless steel tubing to 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. A selection of our stainless steel tubing is available for your prototyping needs on chamfr.com. For more information, visit www.accutube.com.