

### Ultrasonic Testing of Medical Grade Bar Products

#### **What is Ultrasonic Testing?**

Ultrasonic testing (UT) is a form of non-destructive testing (NDT) that is commonly used to detect flaws (inclusions) that may exist in material which are not visible to the naked eye. UT testing is accomplished through the use of systems that generate high frequency sound waves (between .5 – 15Mhz), and incorporate a pulser/receiver, a series of transducers, and a display device. The pulser/receiver provides high frequency energy to the transducer (s). In turn, the transducer generates high frequency/ultrasonic energy in the form of sound waves. The sound waves propagate through the material, and are reflected back to the transducer. As these sound waves propagate through a given material under evaluation, the time in which the reflected sound wave comes back to the transducer is monitored by the receiver and compared to a standard. In the event there is a discontinuity in the wave path (caused by a crack) part of the sound wave will be reflected back from the inclusion surface faster than the reflection from the back surface of the material. The transducer will then generate an electrical signal that can be displayed for evaluation, and can be compared to the standard to determine if the flaw is in excess of acceptable limits. *Figure 1* provides a simplistic overview of the process.

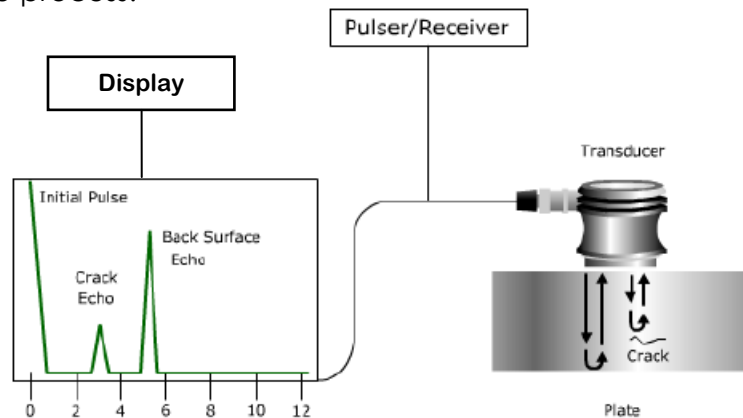


Figure #1: Simplistic Overview of UT Evaluation Process

The primary advantage associated with ultrasonic testing is the accuracy and speed in which a given material can be evaluated. Even the smallest indicator can quickly and easily be interpreted to determine if a potential flaw exists. Many medical implant products and instruments created from stainless steel, titanium, or cobalt chrome require UT evaluation to assure the component is free from defects before use.

Banner Medical has installed and commissioned a state of the art Ultrasonic Testing unit in our Carol Stream, IL facility. We elected to acquire this highly sophisticated piece of equipment for two reasons: 1) to provide our customers the ability to cost effectively and readily comply with industry wide and customer specific requirements, and 2) to give customers the ability to design a process which mitigates risk in their operations. *Figure 2* depicts our UT equipment installed and commissioned:



*Figure # 2: Immersion Ultrasonic Test Unit, Banner Medical Carol Stream, IL*

Recent revisions to ASTM F136 and ASTM F138 require manufacturers of stainless and titanium implants to assure that bar products used in their process (.375" diameter and greater) were UT tested at FINAL diameter. Essentially, this means that if a bar was UT tested and subsequently ground to a different diameter, it must be UT tested again in order to conform to the current revisions of both Standards.

The pertinent excerpts from the specifications follow:

ASTM F136-13 (latest revision) Titanium Alloy for Surgical Implant Applications

"10.1 All centerless ground or peeled and polished round bar  $\geq 0.375$  in. (9.5 mm) in nominal diameter shall be ultrasonically inspected at final diameter according to AMS 2631, Class A1. Equivalent test methods may be substituted when agreed upon by purchaser and supplier." <sup>2</sup>

ASTM F138-13 (latest revision) Implantable Stainless Steel Bar and Wire

"11.3 All centerless ground or peeled and polished round bar  $\geq 0.375$  in. [9.5 mm] in nominal diameter shall be ultrasonically inspected at final diameter according to AMS 2630, Class A1. Equivalent test methods may be substituted when agreed upon by the purchaser and supplier." <sup>1</sup>



In addition to the specifications listed above, the current version of ASTM F67 (Grade 1, 2, 3, and 4 of commercially pure titanium), and ASTM F562 (MP35N) are now calling for ultrasonic inspection of peeled, ground, and polished bar  $\geq .375$ " O.D. per AMS 2630. As ASTM specifications associated with medical grade material continue to be revised, the frequency in which ultrasonic testing becomes a requirement will increase. It is essential for implant manufacturers to understand these specification revisions and how they apply to their business.

Moreover, it is important that industry participants understand that Banner Medical is able to offer a "single source" solution relative to this issue. More specifically, Banner Medical can provide material that has been UT tested which conforms to both ASTM specifications. We are not just offering a testing solution; we are offer a material/testing solution, i.e. a complete solution.

#### ***Optimized Supply Chain Management***

Manufacturers no longer have to purchase material from Vendor X and then send the material to Vendor Y to have it UT tested - Hoping that material doesn't fail the test. This supply chain takes an inordinate amount of time, creates extra work for the manufacturer, and increases shipping costs. **Purchasing UT tested material directly from Banner Medical eliminates all these forms of waste.**

In addition to the UT requirements of ASTM F136 and ASTM F138, we are also able to help OEMs and their sub-contractors conform to customer specific requirements. Some OEMs, for example, require UT testing on stainless grades which are outside the scope of F136 and F138. Since we stock a wide variety of stainless grades and sizes, we can most often provide a customer exactly the material they needed tested to the UT specification of the OEM with which they are working. **Again, providing this option to a manufacturer allows them to reduce costs, save time, and they don't have to worry about what to do with the material that did not pass UT inspection.**

#### ***Risk Mitigation***

Our desire to give customers the best option to mitigate risk is the second reason identified that drove the investment and commissioning of our UT equipment.

In many cases, manufacturers need material integrity assurances which reach beyond established standards. For instance, many high volume instrument programs are not covered by ASTM F138 or ASTM 136, nor are they covered by OEM specific UT requirements. However, a fracture during production or in the field would be devastating. In many of these cases, customers can mitigate risk by specifying UT testing. This has been proven to be an excellent strategy in many cases.

Furthermore, OEM's and Contract Manufacturers realize risk mitigation benefits and improved supply chain efficiency by ultrasonic testing material before the machining process. With proven and validated machining processes in place, many may be able to eliminate the need for downstream non-destructive testing. Post machining dye penetrant, magnetic particle, or UT evaluation of finished components can be removed from the process. Supply chain complexity, cost, and delivery time to the market are reduced. In addition, machining cost of processing defective material, freight to and from a testing house, and sorting and disposition of faulty product is eliminated.

Even the most meticulous melting and rolling practices cannot ensure 100% defect free product. By specifying UT inspection as final process step, manufacturers are able to cost effectively mitigate risk and prevent defective material from reaching their floor or even the operating room.

This practice is even more cost effective when Banner Medical performs the UT inspection because we are able to ship 100% UT tested material, relieving the manufacturer of the cost and burden of scraping defective material which they may have sent to an outside processor.

In summary, OEMs and their sub-contractors may require UT inspection of medical grade bar products for any number of reasons. There are a number of options available to them. Banner Medical provides medical implant and instrument manufacturers with the most cost effective UT testing option available in the market.

***Executive Summary of Banner Medical's UT Inspection Capability***

<b>Minimum Round Bar Diameter</b>	<b>.125"</b>
<b>Maximum Round Bar Diameter</b>	<b>4.00"</b>
<b>Minimum Flat Bar Width</b>	<b>.500"</b>
<b>Maximum Flat Bar Width</b>	<b>4.125"</b>
<b>Grades Tested</b>	<b>TI 6AL-4V ELI, 316LVM, 17-4, 440A, 440C, 455, 465, 420, 303, 304, 13-8, Nitronic, CoCr, many others</b>
<b>Typical Lead Time</b>	<b>7-10 days</b>
<b>Standards Tested</b>	<b>Virtually any industry wide or customer specific standard</b>

Sources:

1. ASTM F138-13
2. ASTM F136-13
3. ASTM F562-13
4. ASTM F67-13