A review in current technology
David Yanes, Director Advanced Technologies
Andrew Taborda, Technical Engineer
What is the optimal catheter welding platform to attain consistent and high quality welds combined with short cycle times in balloon catheter manufacturing?

Considering advancements in the functionality of balloon catheter production and clean room assembly, process engineers seek value added efficiencies in selecting equipment solutions. Current solutions innovate to reduce incremental time within each step of manufacturing to achieve the most efficient cycle times. State of the art technologies now feature touch screens, high resolution cameras, up to four adjustable cross hairs for quick and precise weld alignment, adding operator visibility and ease of setup in addition to program expandability across a range of catheter materials and sizes. Quick exchange dies and heater tilt plates allow the user to make mechanical changes quickly and easily. High temp dampening heat shields are used to prevent warping of balloon cones or damage to external components by localizing the heat to the welding area.

Tube and Balloon Thermal Fusing Process

The requirement is for quality tube welding with a cost efficient, reproducible process.

The most expensive component in a balloon catheter is often the balloon, and with the recent surge of larger, high pressure and more complicated balloons for new applications around the body, this reality has become more profound.

The balancing act in welding the perfect balloon catheter

When it comes to welding balloons to shaft tubing the first order of business is ‘do no harm.’ One of the top failure modes contributing to low yield production is not adequately protecting balloons from the heat associated with welding and flaring, regardless of the method: hot air, laser, thermal compression. Heat migration can lead to balloon defects that cause low yields from lower burst pressures and other problems.

Additionally, do the two materials homogenously flow together creating a seamless transition between the balloon and the catheter shaft? The quality of this weld transition point is a direct determinant of overall balloon catheter system burst strength, tensile strength and end-user trackability within the human anatomy.

The most costly element behind welding is cycle time. It’s simple math to calculate the difference between 4 minutes and 3 minutes at your labor rate and annual catheter volume. Saving one minute can often save tens of thousands of dollars in a year.

It sounds cliché, however, the prescribed course is to design for manufacture, and weld development has become one of the most critical issues facing catheter manufacturers today.
Methods for Balloon to Shaft Catheter Welding

Current technologies in use for balloon catheter tube welding include thermal compression, hot air systems, and laser bonding. Considerations for selecting a welding system in balloon catheter manufacturing require a thorough examination in the set up and planning for clean room automation. Additionally, forethought of expansion requirements should be considered with the gain of greater manufacturing proficiency.

Thermal Compression

Thermal compression welders provide a homogenous and consistent weld by encapsulating the specified weld area with uniformly heated QX ‘Quick Exchange’ dies that are customized to the diameter of the weld. High temperature heat shields are used to prevent heat from migrating to the balloon and localize the weld to the user specified region. The pneumatically driven and precisely machined dies close around the weld area, isolating it from external environmental changes which lead to high levels of repeatability from weld to weld.

Additionally, this technology allows for quick loading and unloading of the catheter sub-assembly, and a very minimal setup time. Along with interchangeable heads, tilt plates, individual dies (QX dies), set up for various materials and tube sizes are straightforward making this system operator friendly.

Thermal compression welders with temperature control settings accurate to within +/- 2° C initiate welds closest to set point. This paired with thermocouple burnout and wire disconnect detection features work to improve production yields. Furthermore, thermal compression welding prevents movement during the fusing process, unlike the high speed rotary system such as laser welding. With the addition of a touchscreen vision system, operators are able to perform cross hair functions with auto align and capture options making thermal compression machines even more simple to operate with improved accuracy.

The average cycle time with a thermal compression weld system is 5 minutes.

Laser Bonding

Laser welding rotates at high velocity to achieve consistent weld throughout and directs a laser beam to the welding area. The laser beams pass through the polymers and are absorbed, giving off heat to the polymers as it spins. Laser bonding systems tend to be very expensive and are complex machines to operate.

Like thermal compression systems, laser welding features storable specification parameters for maintaining repeatability from lot to lot. However, under rotation of the laser welder, it is often possible to lose position of the weld, especially with longer length balloons due to gap increases between rotary chucks.

Additional time to re-set the equipment results in prolonging overall cycle time. The average cycle time with the laser weld system is 9 minutes.
Hot Air System

Hot air bonding works by directing a stream of hot air to a weld area. This allows the user to use parameters such as flow rate to melt the polymers together. Set up for this platform is easy requiring a minimal training level operator skill set.

Hot air systems, dependent upon temperature controlled rooms, offer less precision with difficulty to any degree of accuracy. In addition, with the hot air system, gauging placement of the thermocouple is not only less accurate, but also requires more time in set up designating a lesser confidence interval. These inconsistencies and inaccuracies lead to uneven welds and will lower production yields. Undesirable movement during the hot air fusing process can cause harmful migration of heat to the balloon, further reducing production yields.

Additional inconsistencies exist with the uncontrolled environment inherent to the hot air platform. Environmental changes and movement surroundings throughout the work day contribute to these inconsistencies with air flow disruption and thermal pockets relative to thermodynamic entropy.

Hot air systems gained popularity because of the low acquisition cost for R&D labs, although most hot air systems do not offer program storage and may potentially lead to welding irregularities and variations. In a “design for manufacture” environment, multiple variables like manufacturing transferability need to be considered jointly with acquisition cost and cycle times.

The average cycle time with the hot air system is 8 minutes.

Annual Cost Analysis of Balloon Catheter Weld Technologies

<table>
<thead>
<tr>
<th>Welding Method</th>
<th>Avg Estimated Acquisition</th>
<th>Amortized Cost/Year</th>
<th>Avg Cycle Time (min)</th>
<th>Labor Rate/min</th>
<th>Annual Units</th>
<th>Annual Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thermal Compression</td>
<td>$45,000</td>
<td>$4,500</td>
<td>5</td>
<td>$0.83</td>
<td>20,000</td>
<td>$87,500</td>
</tr>
<tr>
<td>Laser</td>
<td>$80,000</td>
<td>$8,000</td>
<td>9</td>
<td>$0.83</td>
<td>20,000</td>
<td>$157,400</td>
</tr>
<tr>
<td>Hot Air</td>
<td>$10,000</td>
<td>$1,000</td>
<td>8</td>
<td>$0.83</td>
<td>20,000</td>
<td>$133,800</td>
</tr>
</tbody>
</table>

Clean Room Production Line Footprint

<table>
<thead>
<tr>
<th>Welder Footprint</th>
<th>Square Feet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thermal Compression</td>
<td>4</td>
</tr>
<tr>
<td>Laser</td>
<td>15</td>
</tr>
<tr>
<td>Hot Air</td>
<td>2</td>
</tr>
</tbody>
</table>

In clean room equipment planning for bench top systems, manufacturing space is at a premium as catheter volumes increase.
**Balloon Catheter Fusing that is Cost Effective**

**Process engineered accuracy leads to high yields and cost efficiency**

With the demand for increased functionality, improved safety, and new clinical applications for balloon catheters there is increased pressure on engineers to jointly consider balloon maximum burst pressure, shaft compatibility and diameter, and weld strength. A 30ATM balloon specification is not uncommon in new product development this decade. Balloon blowing, as well as balloon folding & wrapping technology has improved to a point where this is possible, but it has put enormous pressure on shaft tubing design as it relates to the “weakest length in the chain.” Will the weld withstand 30ATM and if so, how about the shaft?

Managing operator insight, with ease, the desired result is a quality weld bond with exact replication paired with consistency reaching for 100% yield on the production floor. Considerations of most importance rank in cycle time, the quality of the weld, and overall production line efficiency. In addition, the ability to expand the use of the equipment across a variety of materials and a bench top footprint lend to a leaner manufacturing process.

Once the weld program is developed, the transfer to manufacturing needs to be a turnkey operation to ensure success. Variables include operator training, weld setup for lines that make multiple products, weld cycle time, and visual inspection. The ideal system would include high magnification and resolution, ergonomic screen with cross-hairs for lining up the catheter properly and inspecting the weld in-line, foot pedal capability, and highly visible process parameters for quick checks and problem diagnosis.

Partnering with a manufacturing based knowledge center for balloons, extrusion, welders, and weld development will lead to cost effective solutions in choosing the best equipment platform for any phase of balloon catheter development and manufacturing.
About Interface Catheter Solutions

Interface Catheter Solutions provides balloon catheter development and production solutions for catheter manufacturers worldwide from finished device manufacturers to component device companies.

Headquartered in Southern California and solely focused in the balloon catheter market since 1995, Interface presents a vertically integrated approach to maintain repeatable and consistent production processes for high quality, high yield balloon catheters. Interface Catheter Solutions has refined the art of process engineering with material science in the development of 2,300+ balloon designs. Interface is ISO 13485:2003 certified operating multiple cleanrooms.

27721 La Paz Road
Laguna Niguel, CA 92677
949-448-7056
www.interfaceusa.com