Ring Electrode Manufacturing: How Automated Laser Welding Outperforms Conventional Welding Processes

Abstract
3-D electrogram mapping is delivering breakthrough results in the treatment of atrial fibrillation. But its success depends on component and device manufacturing that provides consistent high quality and exceptional precision. While manual resistance welding is still used by many device manufacturers, automated electrode welding processes have the capability to enhance the production of higher electrode density. This paper focuses on how an automated electrode welding process can help companies drive improvement in three significant areas of high-density catheter manufacturing.
Introduction

As the atrial fibrillation (AFib) market grows, demand for improved 3-D electrogram mapping is fueling the innovation of new high-density mapping catheters. Companies that want to maintain their competitive advantage in the electrophysiology (EP) field need to optimize every aspect of catheter development and manufacturing.

While many suppliers focus on the spline and basket assemblies, the electrode and wire sub-assembly is an often overlooked and underappreciated component of the finished device.

Early on, EP systems relied on point-to-point mapping with low resolution that failed to produce a clear picture of the underlying anatomical or mechanical function of the arrhythmia. But over the past few years, advancements in high-density mapping have led to new catheters featuring high electrode counts that provide very detailed high-density electro-maps with as many as 50,000 to 60,000 data collection points.

Automated electrode welding processes have become a more effective way to produce higher electrode density. Compared to manual resistance welding, full welding automation can provide higher quality components, greater precision and manufacturing efficiency, delivering EP catheter performance physicians can rely on.

TABLE OF CONTENTS

Electroanatomic Mapping ........................................ 2
Benefits ..................................................................... 2
Challenges .......................................................... 2

Automated Laser Welding for Ring Electrodes ................. 2
Benefits Overview ................................................ 3
Improving Quality ................................................ 3
Enhancing Precision ............................................. 3
Increasing Production Efficiency .......................... 3
Conclusion and Considerations .................................. 6

Written by Paul McCormick
Paul is a Senior Research and Development Engineer for Integer. He is responsible for product and process design and development for new internal and co-development product opportunities. Paul has over 20 years of experience in computer hard disk drive industries and eight years developing process technologies for medical devices. Paul’s most recent projects have focused on process development for EP catheters.
Electroanatomic Mapping — Benefits and Challenges

Benefits
Nearly 20 years after validating an automated mapping system of microelectrodes on a miniature basket catheter (Rhythmia; Boston Scientific, Natick, MA), multielectrode catheters with high resolution have become the new mainstay for the mapping of complex arrhythmias. By recording and displaying signals with clear, uncompromised clarity, high definition mapping catheters allow physicians to successfully diagnose and treat AFib and other types of arrhythmias with greater confidence.

Challenges
Because accurate mapping requires greater electrode density, precise electrode and wire assemblies have become increasingly critical. Yet many device suppliers currently use manual resistance welding which falls short in several key areas:

- **Multiple testing cycles** – Due to potential variation in electrode assembly performance, product performance is typically more complicated to test, inspect and resolve.
- **Increased cost** – Reliance on a labor-intensive process with higher scrap rates increases the cost of goods sold (COGS) and reduces the device supplier’s ability to competitively price the product.
- **Higher rate of product failures** – During the resistance welding process, there is a higher risk of weld failures (welds popping, wires breaking) which negatively affects electrical performance and could result in lower market adoption and/or product recalls due to product failures.

The Solution: Automated Laser Welding for Ring Electrodes

Integer’s fully automated laser welding process for ring electrode and wire assemblies addresses the need for greater electrode density to achieve desired clinical product performance while significantly improving manufacturing productivity and efficiency. One of the key advantages of Integer’s process is the vertical integration of the welding process that simplifies the supply chain. This automated process yields high production rates, reduces labor-intensive manual processes and minimizes scrap to increase throughput relative to traditional resistance welding.

Seven key steps are built into the process:

1. Laser Cut Wire to Length
2. Laser Ablate & Clean Wire
3. Position Wire
4. Place Ring in Fixture
5. Laser Weld
6. Perform Weld Proof Test
7. Spool Wire & Close Spool
Benefits Overview

This automated process results in three significant areas of improvement:

1. **Quality** – Increased quality and reliability of welded assembly reduces the risk of weld failures, which in turn, decreases costly spline or catheter assembly failures at higher catheter assembly inspection levels.

2. **Precision** – Enhanced precision in wire positioning and weld diameter size supports electrode miniaturization needed for high electrode density catheters.

3. **Efficiency** – Fast and repeatable processes increase production rates to meet high-volume demand.

Benefits of Integer’s Automated Laser Welding for Ring Electrodes

| QUALITY of welded assembly reduces the risk of failures due to problems such as welds popping and wires breaking. In addition, the high quality weld decreases the costly risk of spline assembly or catheter assembly failures during later inspections. | • Mechanical strength of weld connection is 100% automatically tested
• Laser welding provides a flatter weld spot, creating additional space for multiple wires within an electrode spline assembly |
| --- | --- |
| PRECISION of welded assembly provides the ability to weld smaller electrodes and smaller diameter wires for higher electrode density catheters. | • Laser welding produces a smaller weld spot than typical resistance welding (.003” vs .007” for typical resistance weld) which can reduce the risk of leaks
• Wire can be positioned more precisely inside electrode ring (especially challenging for smaller rings) which reduces risk of fluid leaks
• Precise automated laser stripping of wire coating reduces risk of unnecessary exposed wire and potential for an electrical short |
| EFFICIENCY through greater speed and repeatable processes drive increased production rates to meet high volume demand. | • Vertical integration of welding process reduces the need for coordination with outside vendors
  – Integer draws the wire, coats the wire, strips the wire and welds the wire to the electrode ring
• High production rate (100-200 welded assemblies per hour)
• Fewer manual processes than resistance welding
• Less scrap/higher throughput of welded assemblies due to the automated laser process
• 100% automated testing lessens risk of costly spline assembly or catheter failures during later assembly testing |
Imprecise Weld Placement Creates Leak Paths That Require Secondary Processing to Prevent Fluid Ingress

Imprecise weld placement and larger weld size associated with traditional resistance welding can create leak paths caused by:

1. Decreasing the distance from the hole in the catheter wall to the left ring edge or,
2. The signal wire extending beyond the weld towards the right ring edge and deflecting the catheter tube away from the ring ID

Automated laser welding enhances both the product development and launch process. In development, it strengthens reliability by minimizing the number of variables to investigate, evaluate and troubleshoot during the design process. Automated quality control also minimizes the potential for waste and product failures downstream in the supply chain — in the testing of spline assemblies or finished EP mapping catheters — where the cost of repairing poor quality is greater.
Smaller Weld Spot

Integer Electrode Ring with Wire

Competitor Electrode Ring with Wire

Integer’s automated laser welding process

- Produces smaller weld spots than resistance welding (0.003” vs 0.007” typical for resistance welding)
- Provides a flatter weld spot that provides additional space for multiple wires within an electrode spline assembly

Precise Wire Stripping

Integer Electrode Ring with Wire

Competitor Electrode Ring with Wire

Precise automated laser stripping of wire coating reduces unnecessary exposed wire and potential for an electrical short
Conclusion and Considerations —

Making the move to Integer’s automated laser welding for ring electrodes can result in significantly improved high-density catheter manufacturing. Automation increases efficiency, while also providing the consistent high quality and exceptional precision needed to meet the demands of 3-D electrogram mapping.

However, there are a number of key considerations to achieve maximal effectiveness of your final EP diagnostic catheter design:

- Consider market trends and end-user requirements driving the need for greater electrode density to cover the entire surface of the left atrium of the heart for the purpose of capturing all arrhythmia signals
- Determine catheter size and how that impacts design of the product’s component parts
- Consider the mechanical design outputs and electrical outputs required to optimize distal electrical spline assembly performance requirements and specifications
- Assess your current ring-on-wire manufacturing and assembly processes and their ability to deliver on sizing, quality and COGS requirements
- Evaluate the vendor’s automated laser welding capability, along with their ability to provide vertically integrated sub-assembly solutions that support product miniaturization, meet quality/performance requirements and optimize cost

Outsourcing complex EP electrode assemblies allows device manufacturers to maintain their focus on high value initiatives while leveraging core manufacturing capabilities from an outsourcing partner. Integer’s major investment and expertise enables them to provide the right solution at the right time, whether it’s electrophysiology components or finished devices.

Contact Integer at CV-Solutions@integer.net to discuss your EP catheter needs.

References