Welding

Critical manufacturing processes for the Medical Device Industry
Gabe Kustra

- Performance Review Institute (PRI), Staff Engineer
- 10 years of experience in the Medical Device Industry
- Career specialty in laser and resistance welding
- Worked in active implantables, orthopedics, sterile disposables, and diagnostic imaging
- Held positions in product development, manufacturing, and supplier quality
- Experience as a manual welder and machinist
Ra’shaaun Lane, DePuy

- DePuy Synthes Joint Reconstruction, Senior Supplier Quality Engineer
- 6+ years of experience in the Medical Device industry
- Worked in clinical diagnostics, endoscopy/urology, patient temperature management, and orthopedics
- Held positions in product development, production and quality
Brent Esch, GE Healthcare

GE Healthcare, Supplier Quality Lead Engineer

- 10 years of welding experience in Mining and Medical Device industries
- Current member of the MedAccred welding subcommittee
- Work with developing suppliers for welding & inspection activities
- Experience working in welding NPI’s, manufacturing engineering, and supplier quality
Agenda

- Critical Welding Processes
- Risk Assessment of Welded Parts
- Examples of Product Failure
- Welding Process Compliance
- Product Failure Scenarios
- Top Non-conformances in Process Audits
- Root Cause Analysis
- Corrective Actions
Critical Welding Processes

- Medical Device Welding Processes
  - Laser
  - Resistance
  - Electron Beam
  - GTAW

Welding Processes can be much different from each other in terms of how energy is used to create a weld and the process variables which need to be controlled to produce consistent results.

The Medical Device industry includes such a wide range of products, that the applications for welds serve many purposes. Welded assemblies come in all sizes.
Critical Welding Processes

- Materials include:
  - Common metals and alloys: Steels, Stainless Steels, Aluminum, Titanium
  - Precious metals: Gold, Platinum and Palladium alloys
  - Exotic metals: Tantalum, Niobium, and Molybdenum
  - Special alloys: Cobalt-chrome, Nitinol, MP35N
- Welds are used for more than just structural applications. They are also used for hermetic seals, and electrical connections.
- The size applications range from tiny implantable devices up to large room-size diagnostic machines.
- Some welded components are critical for patient safety while others are not.
Risk Assessment for Welded Parts

Determining which parts are most critical can be done by establishing the level of risk to the patient’s safety if that part were to fail. If the part utilizes a welding process in order to manufacture it, the components, materials and manufacturing processes should be controlled when making the high risk part. The OEM will decide which level of risk is associated with each part.

Some parts don’t pose a risk to patient safety at all if they fail. In this case a lower level of process control may be acceptable.
### Examples of FDA Product Recalls - Welding

<table>
<thead>
<tr>
<th>Product</th>
<th>Recall Class</th>
<th>Reason</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear Accelerator</td>
<td>II</td>
<td>Defective weld. Due to this defect it is possible for the weld seam to break and to cause the overhead suspension to fall down. This can lead to a severe injury to a patient or any other person.</td>
<td>35 units</td>
</tr>
<tr>
<td>Endoscopic Shaver Blade</td>
<td>II</td>
<td>Insufficient weld between the shaft tube and tip, could result in the tip separating from the shaft tube during use.</td>
<td>744 units</td>
</tr>
</tbody>
</table>
Compliance to the process is critical

- Receiving
  - Welding consumables must meet specifications
  - Materials can be identified upon receiving and are controlled
- Preparation
  - Cleanliness of parts prior to welding
  - Part handling and storage
- Process
  - Control of welding fixtures
  - Use of work instructions
  - Approved welding parameters
- Inspection
  - In-process testing conducted in accordance with requirements
  - Test data availability
  - Maintaining traceability
Welding process compliance ensures:

- **Product Quality**
  - Poor quality welds are not always obvious
  - Energy used to create welds can damage adjacent components

- **Solutions**
  - Repeatable machine setups
  - Compliance to established settings
  - In-process testing
  - Preventive Maintenance
Product Failure example:

The manufacturing of active implantable devices such as pacemakers, ICDs, and neurostimulators is highly dependent on welding processes. A small circuit board, battery, and other electronic components are sealed inside of a titanium enclosure which gets laser welded shut.

An ideal weld schedule is established through a series of experiments that ensures the desired weld properties will be met and also the sensitive electronics inside are not adversely affected.

Deviation from the welding parameters could increase the heat input during welding and damage or compromise internal components and connections.

Patient safety is at risk when heat sensitive parts are compromised due to a welding process that is not adequately controlled.
Product Failure example:

- Surgical instruments are frequently manufactured as welded assemblies. They can be held to high dimensional tolerances when completed.
- Welding processes must be developed to produce welds that meet the strength requirements, finish requirements, and retain dimensional requirements.
- If there is any variation in the welding process or setup, the weld can be insufficient, and the only way to detect it is through testing which may or may not be feasible for production.
- Tools with insufficient welds can make it to the field and fail in service which is a risk to patient safety. Controls must be in place to ensure all requirements are met.
Top Non-conformances in process audits

- Compliance to weld schedule
- Failure to follow procedure
- Tools and fixtures not identified in work instructions
- Equipment and instruments not calibrated in the range of use
- Undocumented steps
- Inadequate/absence of procedures
Root Cause Analysis

A root cause should not identify employees or training as the culprit. It should identify the flaw within the company’s quality system!

- Human errors can occur regardless of experience.
- Employees can be better trained, but training is only a temporary solution.

The best root cause tells us why the company’s quality system or operating procedures allowed the mistake to happen.

The company is held responsible for product escapes regardless of the actions of employees. When a root cause investigation exposes the flaw in the company’s quality system, a permanent corrective action must be implemented in order to ensure that the solution stays with the company.
Corrective Action

Corrective actions must be systematic changes within the company’s quality system or procedures. They must ensure, whatever went wrong cannot go wrong again.

Strong corrective actions include:
- Error proof tooling
- Locked weld settings (when possible)
- Shop routers that require documented confirmation
- Documented preventive maintenance schedules
- Proceduralized internal audits/walkthroughs
- Improved change control process
What is the Medical Device industry doing to improve the quality of welded products and Supply Chain Oversight?

- Welding Task Group
  - Stryker, DePuy (J&J), GE Healthcare,
  - Open to subject matter experts from OEMs, CMs and Suppliers
  - Develop Audit Criteria
  - Approve SME auditors
  - Grant Supplier accreditations

- MedAccred Accreditation is used by OEMs/CMs as a criteria to award new business and oversee their critical process supply chain quality.

- Suppliers use MedAccred Accreditation to ensure final product quality and improved manufacturing operations.
Questions?

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