Laser applications

In the Medical Device Industry

Speaker:
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President
HDE Technologies, Inc.
Presentation outline

- Laser applications - examples
- Market information
- Lasers and skill set requirements
- Laser and laser processing standards
- Laser weld education – the future of laser welding technology
Laser welding application

Automotive:

- Tailor Blank Welding
- Different gage materials
- Different alloys of metals

Toyota

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Laser welding application

Personal hygiene products
Laser welding application

Blood circulating pump

Implantable – heat sensitive components inside

Titanium – 0.005” to 0.010” walls
Laser welding application

Pacemaker

Implantable – heat sensitive components inside.

Titanium – 0.010”
Laser welding application

EnRhythm Pacemaker

Pacemaker.

Implantable – heat sensitive components inside. Final closure weld.

Titanium – 0.010”
Laser welding application

Batteries and other sealed devices, similar to this electronic relay.

Hermetically sealed.

Leach
Laser welding application

- Medical tubing (hypodermic needles)
- Consumer products
- Oil pipe lines
Laser welding application

Surgical devices and instruments
Laser drilling application

Pharmaceutical (time release) devices.

Controlled diameter and depth of holes.

Very high volume.

Alza
Laser drilling application

Suture components.
The ‘blind’ needle.
Diameter = 0.003” and larger.
Diameter of hole = 0.001” wall!!
Laser cutting application

Implantable metal stents.

OD = 0.020” and larger tubing.

Wall thickness = 0.001” and larger.

Width of cut = 20 um (0.000 8”)

Medtronic/Covidien
Market information

- Lasers: $2.3B
- Laser systems: $8.2B
- Laser engraving: ..................17%
- Metal working (cut-drill-weld): .....70%
- Micro-processing (small comp.): .. 7%

Comparisons:
- Caterpillar Tractor sales $55B/yr
- Medical Device Industry $380B/yr (= $30B/mo)
## Market Information

### Medical Device Industry – 2014

Top 25 companies – most of them use lasers!

<table>
<thead>
<tr>
<th>Company</th>
<th>2013 revenue</th>
<th>2014 revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Abbott Laboratories</td>
<td>21,848</td>
<td>20,247</td>
</tr>
<tr>
<td>2. Medtronic plc</td>
<td>16,743</td>
<td>17,255</td>
</tr>
<tr>
<td>3. Baxter International Inc.</td>
<td>15,259</td>
<td>16,761</td>
</tr>
<tr>
<td>4. Stryker Corp.</td>
<td>9,021</td>
<td>9,675</td>
</tr>
<tr>
<td>5. Becton, Dickinson &amp; Co.</td>
<td>8,169</td>
<td>8,468</td>
</tr>
<tr>
<td>6. Boston Scientific Corp.</td>
<td>7,143</td>
<td>7,380</td>
</tr>
<tr>
<td>7. St Jude Medical Inc.</td>
<td>5,501</td>
<td>5,605</td>
</tr>
<tr>
<td>8. Zimmer Holdings, Inc.</td>
<td>4,623</td>
<td>4,573</td>
</tr>
<tr>
<td>9. Smith &amp; Nephew plc</td>
<td>4,351</td>
<td>4,617</td>
</tr>
<tr>
<td>10. CareFusion Corp.</td>
<td>3,556</td>
<td>4,081</td>
</tr>
<tr>
<td>11. Terumo Corp.</td>
<td>4,297</td>
<td>4,051</td>
</tr>
<tr>
<td>12. Getinge AB</td>
<td>3,933</td>
<td>3,408</td>
</tr>
<tr>
<td>13. CR Bard Inc.</td>
<td>3,020</td>
<td>3,324</td>
</tr>
<tr>
<td>14. Varian Medical Systems, Inc.</td>
<td>2,976</td>
<td>3,050</td>
</tr>
<tr>
<td>15. Dentsply Int'l Inc.</td>
<td>2,951</td>
<td>2,952</td>
</tr>
<tr>
<td>16. Nipro Corporation</td>
<td>2,687</td>
<td>2,843</td>
</tr>
<tr>
<td>17. Alere Inc.</td>
<td>3,029</td>
<td>2,537</td>
</tr>
<tr>
<td>18. Hologic Inc.</td>
<td>2,458</td>
<td>2,549</td>
</tr>
<tr>
<td>19. Edwards Life Sciences Corp.</td>
<td>2,046</td>
<td>2,323</td>
</tr>
<tr>
<td>20. bioMerieux SA</td>
<td>2,187</td>
<td>2,210</td>
</tr>
<tr>
<td>21. Intuitive Surgical, Inc.</td>
<td>2,244</td>
<td>2,116</td>
</tr>
<tr>
<td>22. Sonova Holding AG</td>
<td>2,146</td>
<td>2,085</td>
</tr>
<tr>
<td>23. Coloplast A/S</td>
<td>2,184</td>
<td>2,059</td>
</tr>
<tr>
<td>24. Teleflex Inc.</td>
<td>1,685</td>
<td>1,802</td>
</tr>
<tr>
<td>25. Sysmex Corp</td>
<td>1,655</td>
<td>1,757</td>
</tr>
</tbody>
</table>
Market information
Laser Industry – number of lasers/personnel

- Lasers in industry in the USA: (est) 10,000
- Lasers in med device mfg co’s: (est) 6,000

*In the medical device mg companies:*

- Personnel (3 persons/laser): (est) 18,000
  1. Laser ‘operators’: (est) 12,000
  2. Laser ‘service/repair’: (est) 2,000
  3. Engineering ‘staff’ : (est) 4,000
Number of persons with formal certifications in lasers or laser processing:

*In the non-medical device mfg companies:*
(automotive, aerospace, defense, general metal fabrication, etc.)

NONE

*In the medical device mfg companies:*
NONE

**Conclusion: there is a NEED!**

In traditional welding, AWS issues approx. 1,000 re-certifications and 500 new certifications per MONTH!
Market information
Addressing the ‘NEED’

1. Identify the details of the ‘need’
   Analyze the skill sets for the various job functions
2. Identify the schools with mfg programs and welding facilities
3. Plan to upgrade the current 120 AWS ATF-s (or develop new ATF-s)
4. Train the instructors
5. Identify the facilities requirements & find funding
6. Determine/develop instructional materials (incl. published Standards)
7. Develop the curriculum
Lasers for industrial welding

Typical laser welding system used by med device mfg companies

Weld station

Control panel

Power supply & computer
Lasers for industrial welding

Control panel – typical

1. CCTV display – seam tracking
2. Program entry
3. Post processor info entry
4. Special commands, etc.
Lasers for industrial welding

Laser welding systems at the College of the Canyons

Small footprint

Great variety of laser settings

Programmable motion system
Measuring the quality of laser beams

As required for calibration and EQ and PQ

1. Pulse shape – temporal profile
2. Spatial profile (distribution of the laser power across the laser beam)
3. Laser power (energy)
Measuring the quality of laser beams

As required for calibration and EQ and PQ

1. Temporal profile (pulse shape)
2. Spatial profile
3. Laser power (energy)
Measuring the quality of laser beams

As required for calibration and EQ and PQ

1. Temporal profile (pulse shape)
2. Spatial profile (determines the diameter of the focused laser beam)
3. Laser power (energy)

Gentec EO

100 mm dia
up to 12,000 w
Inspection of laser welds

As required for PQ

Visual appearance of the weld
Measure dimensions

Cross section
Measure dimensions
Inspection of laser welds

As required for PQ

Metallography

Cut and polish weld samples

 Measure the hardness of the welds

EWI

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Inspection of laser welds

As required for PQ

Peel test – tensile test

Confidential
Inspection of laser welds

Real time weld monitoring CW

As required for PQ
New AWS C7.4 requirement

Non-destructive method
Confirms the quality of the weld in real time
Printed record for each weld

Prometec
Inspection of laser welds

Real time weld monitoring Pulsed

As required for PQ
New AWS C7.4 requirement

HDE

Monitors the following parameters
For EACH PULSE:

1. Focus
2. Penetration
3. Weld Fit up
4. Misalignment
5. Porosity

Can be calibrated off line!
Inspection of laser welds

Real time weld monitoring Pulsed

Images of all welds saved

Full statistical reports

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Inspection of laser welds

Real time weld monitoring Pulsed

Pulsed laser weld monitor as installed at College of the Canyons
Curriculum development

Sources of information and training

1. Published Standards
2. Published articles and ‘recommended practices’
3. Engineering programs (BA)
4. Equipment suppliers
5. End users
6. Private professional development (e.g. HDE)
7. People with some years of hands on experience
Curriculum development

Published Standards

- AWS – American Welding Society
- EN – European Standards (Norms)
- ISO – International Organization for Standardization
- Lloyd’s Register – Guidelines for CO2 laser welding
- Customer Specifications
Curriculum development

Main subjects covered in published Standards

1. Optics - testing
2. Laser equipment – EQ
3. Procedure qualification – PQ
4. Operator qualifications (e.g. revised AWS C7.4)
Main subjects covered in AWS C7.4/C7.4M:201x

Process Specifications for Laser Beam Welding

1. Provides standards for Equipment Qualification (EQ)

2. Provides standards for Process Qualification (PQ)

3. Provides standards and guidelines for Operator Qualification (OQ)

4. Gives the schools and the ATF facilities the ability to:
   4.1 **Short term:** Test, qualify and certify the currently employed
   4.2 **Long term:** Educate and test qualified laser welders (AA and BA)
Curriculum development

Suggested plan

Split the material in to 3 levels of learning

At all levels the main topics will remain the same, but the coverage in each level will be more complete

(proportion of classroom to hands-on shop instruction will change)

At the completion of the curriculum the candidate may take another test to get the AWS Laser Welder Certification
Curriculum development

Suggested plan

Main topics for each level of learning

1. Basic concepts – lasers, optics, etc.
2. Measuring the quality of laser beams (EQ)
3. Cutting and drilling – metallurgy, testing, etc.
4. Welding – metallurgy, testing, compute parameters, etc.
5. Setting up jobs on the laser equipment
6. Inspection methods (PQ)
7. Documentation control
Curriculum development

Suggested plan

Equipment requirement

Level 1: Access to laser equipment for demos only

Level 2: Need laser equipment installed and running

Each laser system can accommodate up to 6 persons

Level 3: Need laser AND testing equipment installed
Laser applications

In the Medical Device Industry

End of presentation

Thank you
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