Medical Device Remanufacturing

Submitted by: GE Healthcare
Medical device remanufacturing is a relevant opportunity for customers and governments

**Recycling Economy**
Chinese Vice Premier Zeng Peiyan pledged that the country will strive to build an environment-friendly society... and strongly promote a recycling economy. “China’s economic and social development is facing increasingly heavy pressure from environment and nature resources, marked by pollution and environmental degradation.”

*Quote from Embassy of the People’s Republic of China web site*
http://www.china-embassy.org/eng/xw/t168563.htm

**Regulation**

**Directive on Waste Electrical and Electronic Equipment (WEEE)**
The Waste Electrical and Electronic Equipment Directive (WEEE Directive) aims to minimize the impact of electrical and electronic goods on the environment. It seeks to achieve this by making producers responsible for financing the collection, treatment, and recovery of waste electrical equipment, and by obliging distributors to allow consumers to return their waste equipment free of charge.
Medical Device Remanufacturing
Good for the environment … Good for people

Enabling:
Re-use of key metals & materials

Increased clinical capability

Lower cost of acquisition

Supercon MR Makeup

Each 1.5T MR magnet contains 15 miles of superconducting wire

<table>
<thead>
<tr>
<th>Magnet Material</th>
<th>lbs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superconducting Wire</td>
<td>1830</td>
</tr>
<tr>
<td>Copper</td>
<td>1600</td>
</tr>
<tr>
<td>Niobium Titanium</td>
<td>230</td>
</tr>
<tr>
<td>Stainless Steel</td>
<td>1490</td>
</tr>
<tr>
<td>Low Carbon Steel</td>
<td>1150</td>
</tr>
<tr>
<td>Aluminum</td>
<td>6600</td>
</tr>
<tr>
<td>Fiberglass Reinforced Epoxy</td>
<td>2100</td>
</tr>
<tr>
<td>Total</td>
<td>13170</td>
</tr>
</tbody>
</table>

MR Electronics

<table>
<thead>
<tr>
<th>Component</th>
<th>Weight (lbs)</th>
</tr>
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<tbody>
<tr>
<td>Opp Console</td>
<td>660</td>
</tr>
<tr>
<td>IPS Cabinet</td>
<td>946</td>
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<tr>
<td>Scan Room Unit</td>
<td>484</td>
</tr>
<tr>
<td>Cables</td>
<td>340</td>
</tr>
</tbody>
</table>
 Permanent MR Magnet & Electronics

Profile magnets are permanent, made up of Iron and Neodymium Iron Boron (NdFeB).

Magnet Weight = 22,000 lbs
• 3,000 lbs NdFeB
• 19,000 Iron

Electronics

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The Eco-Impact of Remanufactured MR is profound. Reusing MR Magnets prevents landfill and recycling expense.

2006 GE magnets saved
• 9 tons of Niobium Titanium (Nb3Ti)
• 61 tons of Copper
• 57 tons of Stainless Steel
• 60 tons of Low Carbon Steel
• 254 tons of Aluminum
• 111 tons of Fiberglass Reinforced Epoxy
• 228 tons of Iron
• 41 tons of Neodymium Iron Boron (NdFeB)

>1.6 Million lbs
Eco-Impact MR - Remanufacturing and Reusing Electronics prevents landfill and recycling burdens

2006 GE MR Electronics saved

- Printed Circuit Boards
  - 412,000 lbs of PCBs and cables
  - 60 lbs of Gold = $628k
  - 200 lbs of Silver = $42k

Medical Device Remanufacturing
Good for the environment … Good for people

Enabling:
- Re-use of key metals & materials
- Increased clinical capability
- Lower cost of acquisition
MR remanufacturing provides clinical gains for healthcare providers

- Increased Pediatric capabilities
- Higher quality brain scans

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Lost Opportunity

Improving global equity in health care access

Healthcare in Developing Regions Today
X-ray Example

- X-Ray Table
- Tube Stand
- Exposed cable
- Film
Underserved Populations

- World population: 6 billion people
- >1.2 billion live on less than $1 a day. Two billion more people are only marginally better off.
- Development and globalization is driving higher expectations for healthcare access and quality

Significant inequity in health care exists

Per Capita Health Care Expenditure, 2006

Source: Espicom
Developing Countries’ Problem

As health care capabilities advance, so do costs of technology.

The equity gap in access often gets wider.

Technology evolution dilemma

Advanced medical devices are designed and built to last 20+ years, with manufacturer support for parts, service, and updates.

But technology evolves much faster … leading-edge users want to upgrade to newer products in 2-3 years.

Solution: Original user trades used system for new technology; manufacturer remanufactures and provides like-new quality at a fraction of the cost.
Expanding Healthcare Affordability
Remanufacturing supports technology upgrade and value needs

- Trade-in Payment Allows Existing Customers to Upgrade
- Returned system remanufactured and re-certified to current new specification
- Backed by full service support and new warranty
- 20-50% Less than new pricing
- Ecologically Friendly ➤ Reduce, Re-Use, Recycle

Original System

Customer upgrades to newer system ... Trade-in used system

Remanufacture & sale to Value Customer

Quality is Key … Safety is #1 priority

- Remanufactured medical devices fall under FDA supervision … as-is used systems do not

- Manufacturers guarantee same quality, warranty, performance as new
Why Remanufacture Medical Devices?

Save Money
→ Advanced technology at reduced cost

Save Resources
→ Reduce energy and natural resource usage
→ Minimize disposal and pollution burden

SAVE LIVES
→ Access to life saving technology
→ “Good-as-new” quality

Need non-discriminatory trade treatment … “same as new”
… with identical quality and safety requirements

Market acceptance and adoption

OEM-remanufactured diagnostic imaging device penetration____

USA >10%
EU 5-8%
Latin America 10-12%
Regulation in major remanufactured medical device markets

**USA:** Devices and remanufacturers must be FDA-registered

**EU:** Devices must be CE-marked and meet same requirements as new devices

Some countries that prohibit remanufactured medical devices

**China:** Imports prohibited from 1998, domestic trade regulation unclear

**Thailand:** Imports prohibited, domestic resales permitted

**Viet Nam:** Imports restricted

**Egypt:** Imports prohibited
Impact of restrictions on access to lower-cost remanufactured devices

Consequences of remanufacturing prohibitions

- Ethical suppliers are blocked
- Non-compliant 3rd parties circumvent rules
- Patients face daunting quality and safety risk
- Access denied to hundreds of millions
Solution

Devices remanufactured by the original manufacturer should be treated “same as new”, with identical requirements, in all trade policy

Save the Environment … Save Lives

THANK YOU