SOME OF OSCOR’S ACCOMPLISHMENTS:

- First implantable active fixation cardiac pacing lead in the US
- First coated wire technology used in implantable stimulation leads
- Leader in implantable lead adaptors and lead extensions
- Legal manufacturer and contract manufacturing of Class II and III devices
- Complete vertical design and manufacturing capabilities, including sterilization
- Supplier of implantable devices to leading medical device companies
- Deep knowledge and experience in development and contract manufacturing of implantable neuro-stimulation devices and leads, including but not limited to:
  - Percutaneous Leads
  - Subcutaneous Leads
  - Paddle Leads and Cuff Leads
  - Implantable Stimulation Systems (RF)
  - Lead Extensions
  - Tunneling Tools and Delivery Systems

Notable Portfolio of Implantable Device Experience

With over 35 years, Oscor is a leading manufacturer of Class III implantable devices according to US FDA and ISO 13485 requirements.
Oscor’s team has effectively supported industry-leading medical device companies with the commercialization of implantable devices such as:

- Cardiac pacing and defibrillation leads
- Pain management device lead and lead extension systems
- Vagal nerve stimulation leads
- Custom cuff stimulation leads
- Incontinence stimulation system
- Deep brain stimulation leads
- Implantable urology leads
- Implantable lead extensions and adaptors
- Various introducer and tunneling tools and kits
- Other Class III implantable systems and pumps

Oscor provides comprehensive product development, regulatory support and commercialization services adhering to FDA & ISO 13485 requirements. Offering a wide area of already validated components and processes, Oscor offers turnkey solutions for cost and time sensitive projects by leveraging existing validated technology including:

- Lead body configurations (Silicone, Polyurethane, Tecothane)
- Lead conductor configurations (stranded wire, coils, coated wire)
- Lead connectors (IS1, DF1, DF4, IS4, 2/4/8 polar inline, bifurcations)
- Fixation anchors, tines and screws
- Other lead components and accessories such as lead and connector bifurcations, tines, anchors, suture sleeves, O-rings, stylets, stylet grips, tunneling tools, introducers, dilators, set screws, set screw blocks, torque wrench)
Oscor has extensive knowledge and expertise in long term implantable device development, test and validation applicable to Class II and III devices. Oscor offers significant IP portfolio, stringently controlled system combined with scalable manufacturing capabilities to satisfy national to global regulatory and distribution requirements.

We provide our customers with facilities in the US and Germany dedicated to product development, prototyping and engineering, and low cost manufacturing and sterilization facilities in the US and Dominican Republic.

Our manufacturing facilities are equipped with first class equipment and dedicated clean rooms that operate according to Oscor’s quality system and incorporates customer specific guidelines.

GLOBAL DISTRIBUTION FACILITIES:

USA, FLORIDA
4 facilities with over 100,000 sq ft engineering and cleanroom manufacturing space

DOMINICAN REPUBLIC
2 facilities with over 120,000 cleanroom manufacturing space

GERMANY
Engineering, Sales and Warehouse facilities – EU Representative

GLOBAL
Global distribution partners in over 70 countries!
Oscor is completely vertically integrated, offering the following processes optimized for the in-house manufacturing of implantable devices:

- Mold and tool design and manufacturing
- Injection molding (Silicone / LIM, PEEK and Thermoplastic)
- CNC/Swiss/EDM machining, laser welding, cutting, ablating
- Extrusion
- Coil winding, braiding
- Soldering
- Curing / Coating
- Swaging
- Reflow
- Testing
- Packaging
- Sterilization

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<th>STANDARD</th>
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<td>Active implantable medical devices - Four-pole connector system for implantable cardiac rhythm management devices - Dimensional and test requirements</td>
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<td>EN 45502-2-1</td>
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<td>ST0011</td>
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Offering comprehensive support and regulatory services to bring your product to global market approval:

- US and EU Representative
- FDA Registered
- 510(k) and PMA device experience
- ISO 13485:2013 certified
- CMDCAS (Canada) certified
- JAPAN Accreditation
- Australia Accreditation
- ISO 13485:9001 certified offshore facilities with identical equipment
- Manufactured according to directive 93/42/EEC and 90/385/EEC
- Post Market Surveillance Services
- Oscor Quality System is approved by the best industry leading medical device companies

All Oscor facilities are registered and certified to the highest industry standards, including:

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<th>FDA</th>
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