OSCOR COMPANY OVERVIEW

Legacy, Products, Services & Capabilities
OUR LEGACY

Oscor Inc. was founded by Dr. Ing. Peter Osypka to introduce his implantable German Lead Technology to the USA Market in 1982.

Dr. Osypka has over 50 years pioneering in the field of implantable medical technology and electrophysiology.

Among his most renowned patents you will find:

- Retractable pacing lead mechanism
- First Quadrifilar Coil
- Coated Conductor Wire

Dr. Osypka was the first to introduce temperature controlled high frequency cardiac ablation to the industry.

Dr. Osypka’s technology are today’s standard in the cardiac pacing & ablation technology.
COMPANY TIMELINE

- **Founded**
- **1982**
- **Worlds first retractable Screw-in Pacing Lead**
- **1984**
- **Oscor sold to Sulzer Medica**
- **1986**
- **Engineering, Tool and Mold**
- **1988**
- **Oscor repurchased**
- **1996**
- **Technology and Innovation Center**
- **1998**
- **Oscor Caribe**
- **2000**
- **Adelante Peel Away Introducer**
- **2002**
- **Destino Steerable Sheath**
- **2004**
- **Oscor Europe GmbH**
- **2006**
- **EO Sterilization Expansion 4 Pallets Added to OC**
- **2008**
- **US - Warehouse and Logistic facility Expansion**
- **2010**
- **Oscor divests Lead Business**
- **2012**
- **Magnum Introducer**
- **2014**
- **EO Sterilization Expansion Phase I 2X4 pallets added at OC**
- **2016**
- **Final Packaging & Global Distribution From Dominican Republic**
- **2018**
- **Breezeway II / Destino XL**
- **2020**
- **EO Exterilization Expansion From Dominican Republic**
- **2021**
- **2022**
- **Final Packaging & Global Distribution From Dominican Republic**
COMPANY FACTS

FOUNDED
1982

HEADQUARTERS
Palm Harbor, FL - USA

FACILITIES
2 - USA
2 - Dominican Republic
1- Germany

EMPLOYEES
900+

GLOBAL REACH
• Products sold in over 100+ countries
• Global distribution under OEM basis

CORE AREAS OF BUSINESS
• Cardiac Rhythm Management
• Structural Heart
• Cardiovascular
• Interventional Radiology
• Interventional Cardiology
• Neuromodulation
THE ADVANTAGE

- Celebrating 39+ Years in the Medical Device Industry!
- Highest Global Industry Quality System Certifications for Medical Device Manufacturing
- Products with RA approvals including FDA, CE, Canada, Australia, Japan, China and over 100+ countries
- Manufacturing dedicated to Medical devices 100%
- Cleanroom ISO Class 7 (10K) & 8 (100K)
- Structured for Medical OEM
- Complete Vertical Integration
- Offshore Manufacturing Capability
- In-house Sterilization
- Notable 510K & PMA under CM Agreements

- Significant IP Portfolio
- Brand Recognition
- Proud Supplier to Key Industry Players
- CEO Commitment
- Privately Owned
- Financial Autonomy
- IP Trustworthy
QUALITY POLICY

APPROACHING QUALITY ENTIRELY

Oscor strives to offer products of the highest standards in quality, reliability, service and support. In everything we do we will try to be the most innovative, and the most customer and patient-oriented supplier.

CONTINUOUSLY IMPROVEMENT

Oscor is committed to continuous quality improvement and will invest in its employees, systems, and technology to provide physicians with the tools necessary to improve patient’s safety, while reducing recovery times and treatment costs.

PREVENT & DETECT ISSUES EARLY

Oscor is committed to Employee Empowerment. Management will provide the training, tools and resources necessary to empower employees to make quality decisions. It is the responsibility of each employee to detect and prevent quality issues as well as participate in continuous quality improvement to help meet and exceed customer expectations.

SUSTAINABILITY

Oscor strives to be an environmentally conscious manufacturer. Our manufacturing focuses on the most efficient and productive use of raw materials and natural resources to minimize any adverse impact on workers and the natural environment.

COMPLIANCE

Oscor is committed to comply with Quality System Requirements and to maintain the effectiveness of the QMS required by ISO 13485 § 5.3, 21 CFR 820 and other applicable regulatory agencies.
COMPANY ENTITIES

OSCOR INC.
S-Corporation
US (FL)

卖 / 买卖组件和组装件 (intercompany)

OSCOR CARIBE LLC*
Dominican Republic
*合格在多米尼加共和国自由贸易区

Sell Finished Devices
Oscor Branded

OSCOR EUROPE GmbH
Germany

Sell Finished Devices, OEM Branded Product and Contract Manufacturing Services

OSCOR INC.
USA & Globally
FACILITIES

Oscor Inc – World Headquarters
Palm Harbor, FL

Oscor Inc – Technology & Innovation Center
Palm Harbor, FL

Oscor Europe – Sales & Distribution Center
Düsseldorf, Germany

Oscor Caribe – Manufacturing Center of Excellence
Santo Domingo, DR

Oscor Caribe – Manufacturing Center of Excellence
Santo Domingo, DR
# FACILITY & CAPACITY OVERVIEW

<table>
<thead>
<tr>
<th>FACILITIES</th>
<th>LOCATION</th>
<th>SIZE</th>
<th>CLEAN ROOM SIZE</th>
<th>CLEAN ROOM UTILIZATION</th>
<th>EMPLOYEES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oscor Inc.</td>
<td>World Headquarters</td>
<td>Palm Harbor, FL</td>
<td>135,000 sq ft</td>
<td>40,000 sq ft</td>
<td>295+</td>
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<tr>
<td>Technology &amp; Innovation Center</td>
<td></td>
<td></td>
<td>(2 facilities)</td>
<td>70%</td>
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<tr>
<td>Logistic and Distribution</td>
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<tr>
<td>Oscor Caribe</td>
<td>Manufacturing Center of Excellence - Building #1</td>
<td>Santo Domingo, DR</td>
<td>50,000 sq ft</td>
<td>30,000 sq ft</td>
<td>30%</td>
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<td></td>
<td>Manufacturing Center of Excellence - Building #2</td>
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<td>90,000 sq ft</td>
<td>70,000 sq ft</td>
<td>80%</td>
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<tr>
<td>Oscor Europe</td>
<td>Sales &amp; Distribution Center for Germany &amp; EU</td>
<td>Düsseldorf, Germany</td>
<td>5,000 sq ft</td>
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## FACILITY REGISTRATION OVERVIEW

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<th>FACILITIES</th>
<th>LOCATION</th>
<th>FDA REGISTRATION #</th>
<th>LAST FDA VISIT</th>
<th>ISO CERTIFICATES</th>
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<td>Oscor Inc.</td>
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<tr>
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<td>Palm Harbor, FL USA</td>
<td>1035166</td>
<td>March 2017</td>
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<td>Global Distribution &amp; Logistics Center</td>
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<td>Oscor Caribe LLC</td>
<td>Manufacturing Center of Excellence</td>
<td>Santo Domingo, DR</td>
<td>3004785273</td>
<td>April 2016</td>
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<td>Oscor Europe GmbH</td>
<td>Sales &amp; Distribution Center</td>
<td>Düsseldorf, Germany</td>
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# CAPABILITIES BY LOCATION

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<tr>
<th>CAPABILITIES</th>
<th>OSCOR USA</th>
<th>OSCOR CARIBE</th>
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<tbody>
<tr>
<td>Product Design</td>
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<tr>
<td>Design Consulting</td>
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<tr>
<td>Rapid Prototype</td>
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<tr>
<td>3D Printing</td>
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<tr>
<td>Design Feasibility</td>
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<tr>
<td>Design Verification Testing</td>
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<tr>
<td>Mold Design &amp; Flow Analyses</td>
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<td>Mold Making &amp; Validation</td>
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<td>Injection Molding Thermoplastic</td>
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<td>Injection Molding LIM (Silicone)</td>
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<td>PEEK Molding</td>
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<td>Insert Molding</td>
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<td>Micromolding (&lt;0.001g)</td>
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<td>CNC / Swiss Machining</td>
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<td>Centerless Grinding</td>
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<td>Component Detailing</td>
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<td>Component Qualification</td>
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<td>Laser Welding</td>
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<tr>
<td>Laser Marking/Engraving</td>
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<tr>
<td>Laser Cutting</td>
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<td>Ultrasonic Welding</td>
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<td>Nitinol Processing &amp; Forming</td>
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<td>Extrusions</td>
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<td>Braiding</td>
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<td>Catheter Multi Layer Reflowing</td>
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<td>Coating - Hydrophilic</td>
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<td>Coating - Hydrophobic</td>
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<td>X Ray Testing</td>
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<td>Kit Assembly</td>
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<td>Turnkey Packaging</td>
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<td>Labeling &amp; UDI</td>
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<td>EO Sterilization</td>
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<tr>
<th>CAPABILITIES</th>
<th>OSCOR USA</th>
<th>OSCOR CARIBE</th>
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<tr>
<td>Global Regulatory Consulting</td>
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<td>Device Registration</td>
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<td>OEM Branding of Finished Devices</td>
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<td>Post Market Surveillance</td>
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<td>After Hour Technical Support</td>
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<td>Global Distribution Network</td>
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<th>CAPABILITIES</th>
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<td>European Representative</td>
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<td>Customer Service &amp; Support</td>
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<tr>
<td>Sales &amp; Distribution</td>
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</tbody>
</table>
OSCOR GLOBAL PRESENCE

- Direct Sales Affiliates
- Upcoming Regions
- Oscor Inc. Facilities
- Emerging Markets Upcoming Manufacturing & Distribution Centers 2021-22
STRATEGICALLY LOCATED

Palm Harbor, FL

Miami, FL

1hr and 45min

Santo Domingo, Dominican Republic
OSCOR CARIBE – OFF SHORE MANUFACTURING

Medical Device Manufacturing Dominican Republic - Quick Facts

- 44 hour work week
- All machinery, equipment and raw material used in production enter Duty Free to into Oscor Production Facilities
- All Medical Device Products enter the USA Duty Free under the DR-CAFTA, Free Trade Agreement
SUPPLY CHAIN – OI & OC

CUSTOMERS

TAX FREE ZONE

GLOBAL HOSPITALS

GLOBAL DISTRIBUTORS
OEM & CM

GLOBAL WAREHOUSE
LOCATIONS

Managed By OI
OSCOR FINISHED DEVICES IN DISTRIBUTION
MEDICAL DEVICE PORTFOLIO

INTRODUCER SYSTEMS

GUIDING SHEATHS

IMPLANTABLE DEVICES
DESTINO STEERABLE SHEATH PORTFOLIO FDA, CE, CANADA & JAPAN CLEARED

Destino™
Bi-Directional Steerable Guiding Sheath

- Sheath ID: 8.5F, 10F, 12F
- Sheath Lengths: 61, 67 or 71 cm
- Curve Size: 17, 22 or 50 mm

Specifications vary per model.

Destino™ Reach
Bi-Directional Steerable Guiding Sheath

- Sheath ID: 8.5F, 10F, 12F
- Sheath Lengths: 67, 71, 73, 75, 77 cm
- Curve Size: 17, 22 or 50 mm

Specifications vary per model.

Destino™ Twist (Interventional & EP)
Deflectable Steerable Guiding Sheath

- Sheath ID: 6.5F, 7F, 8.5F, 12F, 13.5F
- Sheath Lengths: 45, 55, 65, 67, 71, 73, 75 or 90 cm
- Curve Size: 9, 17, 22, 30, 35, 39 or 50 mm

Specifications vary per model.
DESTINO PORTFOLIO THE MOST COMPREHENSIVE IN THE INDUSTRY:

3F  4F  5F  6.5F  7F  8.5F  10F  12F  13.5F  14F  15F  16F  17F
OSCOR EP CATHETERS OPTIONS

D-RODEO Mini

D-RODEO Ultra

D-RODEO HD

MINI LOOP
ULTRA & HD LOOP
BASKET

*NOT ALL DEVICES ARE APPROVED
OSCOR INTRODUCER SYSTEMS

PEEL AWAY

NON-PEEL AWAY
OSCOR ADAPTORS & PORT PLUGS

ADAPTORS

VV Plug

LV Plug

IS4-DF4 Plug
CONTRACT PRODUCT DEVELOPMENT & MANUFACTURING
CUSTOM ACCESS INTRODUCER

- Introducers for vascular access
- Multi-lumen and multi-layer shafts
- Hydrophilic and hydrophobic coatings
- Soft, atraumatic tips
- Hemostatic valve system
- Luer connectors and ports
CUSTOM CATHETER DEVELOPMENT

- Transseptal Access
- Deflectable guiding sheaths
- EP diagnostic
- Ablation catheters
IMPLANTABLE DEVICE DEVELOPMENT

- Percutaneous Leads
- Subcutaneous Leads
- Paddle leads and Cuff Leads
- Implantable stimulation systems (RF)
- Implantable ICD and Pacing Leads
- Neurostimulation leads
- Implantable Adaptors
- Implantable Connectors
- Custom implantable products
DESIGN & DEVELOPMENT

- Product Design
- Design Consulting
- Design Feasibility Assessment
- Control Pilot Line Limited Clinical Builds
- Design Verification & Validation Testing
RAPID PROTOTYPING

- 3D Modeling & Printing
- CAD Design
- CNC Machining
- Injection Molding
- Existing Validated Components
- Matured Processes
- Material Traceability
- Fully Functional Samples
- Made to Impress Samples
CNC MACHINING

• Quick Prototyping
• Multi-axis CNC Swiss Turning
• High Speed Multi-Axis Machining
• CNC EDM Sinker and EDM Wire
• Laser Welding, Marking, Cutting, Ablating
• Centerless Grinding
• CAD/CAM Simulation
• Automation
• Inline Inspections / SPC Controls
INJECTION MOLDING

- Cleanroom Injection Molding (*Thermoplastic, PEEK, LIM*)
- Insert Molding
- Component Qualification
- Mold Validation
MOLD MAKING

• Mold Design and Development
• Material Selection and Compounding Solutions
• Mold Flow Analyses
• Fully Automated Mold Making
• Component Qualification
EXTRUSION

- Multi-lumen experience including
  - Polyimide
  - Polyurethane
  - Pebax
  - Nylon
• Braided and coiled shafts
• Full range of braid material, sizes and shapes
SURFACE TREATMENTS

- Reflow processing
- Coating
- Surface Treatment
- Tipping
- Nitinol forming and processing
- Bonding
- Pad Printing
- Laser Marking
DEVICE TESTING

- Mechanical
- Electrical
- Design Verification Testing
- Analysis
CLEANROOM MANUFACTURING

- Over 150,000 sq ft of ISO 14644-1 Class 7 and 8 certified cleanroom environment
- Manufacturing of minimal invasive and long term implantable devices
CLEANROOM PACKAGING

- Kit Assembly
- Pouch Sealing
- Tray sealing
FINAL PACKAGING

- EU and USA UDI Labeling
- Final packaging into product box/labeling
- OEM Label Branding
STERILIZATION

• Over 15 Years experience
• Validated Complex implantable and disposable devices & packaging configurations
• Various Cycles Available 8% EO to 100% EO
• Turnaround time as short as 12h
• Dedicated sterilization and microbiology team on staff
• US and Dominican Republic facilities
• FDA registered, ISO 13485 and ISO 11135 certified
• Capacity available!
STERILIZATION LOCATIONS

INHOUSE:
1 x 500 Liter - 8% EtO

CONTRACT EO SUPPLIER:
ISL - 5 Pallets & 10 Pallets Chamber

INHOUSE:
1 x 500 Liter, 8% EtO
1 x 6000 Liter (2 Pallets), 8% EtO
1 x 12000 Liter (4 Pallets), 8% EtO – Construction
1 x 12000 Liter (4 Pallets), 8% EtO – On Order
## CURRENT STERILIZATION CAPACITY

<table>
<thead>
<tr>
<th>IN-HOUSE CAPABILITIES</th>
<th>UM</th>
<th>OSCOR INC - (8% EtO) Available Sterilization Capacity (Introducers / Month)</th>
<th>OSCOR CARIBE - (8% EtO) Available Sterilization Capacity*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization (EO) – 500 L Chamber</td>
<td>EA</td>
<td>8,000</td>
<td>8,000</td>
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<tr>
<td>Sterilization (EO) – 6,000 L Chamber</td>
<td>EA</td>
<td>N/A</td>
<td>80,000</td>
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<tr>
<td>Sterilization (EO) – 12,000 L Chamber</td>
<td>EA</td>
<td>N/A</td>
<td>150,000</td>
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</tbody>
</table>

OSCOR YEARLY CAPACITY UTILIZATION % / AVAILABILITY – BASED ON OSCOR EXISTING PRODUCT PACKAGING CONFIGURATION.
GLOBAL REGULATORY SERVICES

- Global Regulatory Consulting
- Device Registration
- Post Market Surveillance
- Global Medical Device Reporting
- Post Market Surveillance Support
GLOBAL DISTRIBUTION

- Global Supply Chain Management
- Warehousing
- Customer Support Management
- After Hour Technical Support
- Global Distribution Network
CERTIFICATIONS IN USA & DOMINICAN REPUBLIC FACILITIES:

- FDA Registered
- ISO 13485:2016
- MDSAP CERTIFIED
- FDA & ISO 13485 certified offshore facilities with identical equipment as USA.
- Manufacturing devices according to directive 93/42/EEC and 90/385/EEC Soon EU-MDR
- Approved & proud supplier to most leading medical device companies!
THANK YOU

727.937.2511 | sales@oscor.com | www.oscor.com