

## **ECA Medical Instruments Receives CE Mark for Surgical Instruments and Kits**

The Associated Press

NEWBURY PARK, Calif.--(BUSINESS WIRE)--Mar 19, 2013--ECA Medical Instruments, the leading designer and manufacturer of single-procedure torque-limiting and fixed-driver surgical instruments and procedural kits for the medical industry and surgeons worldwide, announced today the company has received the prestigious CE Mark designation. Earning the CE Mark allows the company's single-procedure precision surgical instruments and kits to be more easily adopted for use by customers across the EU medical device market.

CE Mark or Conformité Européenne marking certificate was earned by ECA following comprehensive audit of the company's quality management systems, processes and validations by auditor and registrar G-Med North America a division of LNE/G-Med in France. Earning the CE Mark follows ECA's January 2013 registration with the U.S. FDA as a Class 1 medical device company.

The CE designation underscores ECA's commitment to meeting requirements of its EU based medical implant device customers. ECA makes single-procedure instruments and kits for the cardiac rhythm management (CRM), cardiovascular, neuromodulation and orthopaedic implant markets.

"Achieving the CE Mark will accelerate adoption of our single-procedure instruments and procedural kits across the EU medical implant community," said John Nino, ECA's President and Chief Executive Officer. "Our EU based CRM and Neuro customers have added assurance we meet EU wide directives while our existing and new orthopaedic implant customers will gain access to new ECA instruments and kits tailored for their medical devices and surgical procedures," he said.

ECA's products are in high demand as device makers, hospitals and surgeons work to solve current safety and financial challenges posed by using reusable instrument sets, which have expensive purchase price and have high life cycle costs including heavy use of chemicals and utilities for cleaning and large carbon footprints for logistics.

Surgeons and hospitals in the EU now have a viable and cost effective alternative to existing instruments which may not be in proper torque calibration, sterility is not always assured and the life cycle cost to support and inventory these tools is spiraling placing increased surgical risk and financial burden on both national and EU wide healthcare system. Conversely ECA's torque instruments are 100% calibrated, are delivered sterile ready or sterile packed and the single-use designation eliminates any chance of contracting surgical site infections.

ECA makes a complete portfolio of disposable torque-limiting and fixed-driver

surgical instruments and multi-instrument surgical kits used to secure screws, fasteners and connectors used for CRM, neuromodulation, cardiovascular and orthopaedic implants. The company is a principal supplier to major medical implant manufacturers worldwide including developers of pacemakers, defibrillators, ventricle assist devices and essentially every type of orthopaedic implant including spine, small bone, extremities, trauma, cranial-maxillofacial, knee, hip, shoulder and general reconstruction products.

ECA Medical Instruments provides off-the-shelf as well as modified standard and full custom instruments and surgical kits. The firm's Rapid Instrument Customization (RIC) program allows OEM implant makers to work in full collaboration with ECA's design and new product introduction team to quickly create unique instruments and also convert existing reusable instruments and designs to contemporary and cost effective disposable products. Major surgical instrument product lines are: Precision torque-limiting instruments from 2 oz./in. to 10 Nm (90 lb./in.) Fixed-Driver instruments including new Wick Away® technology products Surgical procedure kits for orthopaedic implants Sterile-ready and sterile-pack solutions Specialty products including inserters, cannulas, Kerrisons and cavity carvers and more ECA surgical instruments and kits may be purchased off-the-shelf for private label or OEMs may work with the ECA design team to collaborate on custom designs and configurations. ECA products are sold direct to OEMs and also via Greatbatch Medical, a global partner.

ECA Medical Instruments, an American Capital company, was founded in 1979 and located in southern California. ECA is the industry leader in single-procedure torque-limiting instruments and kits. The company has manufactured and delivered over 20 million precision torque instruments to the world's leading producers of CRM, neuromodulation, cardiovascular and orthopaedic implants resulting in over 500 million precision surgical actuations. Every 22 seconds of everyday an ECA torque instrument is used to secure a medical implant—one patient at a time. ECA is an ISO 13485 and FDA registered company and was named Business of the Year 2012 by the Pacific Coast Business Times. Find out more at our web site at [www.ecamedical.com](http://www.ecamedical.com).

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