



ECA MEDICAL INSTRUMENTS.
Trusted Surgical Solutions

Orthopaedic Implant OEMs,
Hospitals and ASCs Gain Sustained
Benefits With Introduction of
**Single-Procedure Torque-Limiting
Instruments and Kits**

Single-Procedure Torque-Limiting Instruments and Surgical Kits Provide Calibration Accuracy and Operational Gains for Both OEM and Hospital



Figure 1. New single-procedure surgical instrument kits are designed for all orthopaedic procedures. The ECA Model 901 kit, shown here, used for spinal fusion procedures, includes high torque-limiting T-Handle, mid-torque palm handle and two fixed-driver instruments with the company's new WickAway® technology.



Figure 2. ECA has designed and produced over 20 million surgical instruments resulting in over 500 million error free actuations for cardiac, neuromodulation, cardiovascular and orthopaedic procedures including general reconstruction, spinal fusion, small bone and trauma and CMF. Family of products include torque instruments from 1 lb./in to 90 lb./in with both uni and bi-directional torque.

Adoption of single-procedure instruments for orthopaedic implants and procedures is taking hold across the industry as new products and complete surgical procedure kits enter the market. Pent up demand for single-procedure instruments is on the rise as both medical device makers and surgeons now have a viable alternative to traditional reusable torque wrenches which are expensive to purchase, maintain, and service. Of greatest impact with orthopaedic instruments is the concern for companies to provide accurate torque calibration guarantees for each new implant procedure.

ECA Medical Instruments® is leading the conversion to disposable torque instruments and kits by providing medical device and implant original equipment manufacturers (OEMs) with a wide range of standard and custom solutions. ECA is the world leader in designing and manufacturing disposable torque-limiting instruments and kits in the Cardiac Rhythm Management, Cardiovascular, Neuromodulation, Orthopaedic, Spine, Cranio-Maxillofacial and Trauma markets. Since 1979, the company has designed and delivered nearly 20 million single-use instruments to OEM and private label customers resulting in over 500 million precise and flawless surgical actuations.

Implant OEMs are kitting disposable instruments and complete procedural kits with their orthopaedic devices allowing surgeons to use them as substitutes, alternatives, or drop-in replacements to traditional surgical tools.

Hospital and ambulatory surgery center (ASC) managers and OEMs alike see the immediate cost and convenience benefits of having disposable surgical torque kits on hand. These benefits include:

- Presentation in a ready-to-use pre-sterile tray(s).
- Confidence in actuation accuracy.
- Minimal Inventory footprint.
- Operating room (OR) operations are reduced by the ability to avoid sterile processing departments with disposable instrumentation.
- Reduction in maintenance costs.

These value propositions all lead to higher operating theater efficiency and potential increased capacity. Available tooling access allows the

hospital to capture additional revenues when instruments are not available to meet unscheduled procedures and implant demand.

These cost responsible™ and sterile packed instruments and kits promise to eliminate active and dormant industry concerns expressed by surgeons, OEMs and hospital leaders that are commonly tied to use of reusable torque instruments in orthopaedic procedures. Some may pose patient safety risks while others create recurring operations and maintenance costs leading to operating room inefficiencies. They are:

- Lack of guaranteed torque accuracy. Instruments may fall out of calibration during normal wear and tear, cleaning or dropping, or other undetected damage to the tool.¹
- Cleaning cost and sterility. The Sterile Processing Department (SPD) must clean and sterilize every unit after surgery. Utility, cleaning agents, medical waste costs, and management required.
- Life cycle costs. Semi-annual or more frequent return trips to the OEM for inspection, testing and recalibration add logistics tail and carbon footprint as well as instrument tracking challenges.
- Lost revenue for OEMs when instruments are not available for unscheduled or trauma procedures. This can lead to the potential for competitive implant manufacturers to step in and fill the void.
- Increased inventory management, supply chain processing, and workload for operating room nurse charged with OR clean room inventory and surgical instrument preparation and kitting.

Guaranteed Torque Accuracy

Both the OEM implant providers and surgeons should expect a 100% confidence level that the torque instrument is in exact calibration. Exact torque is critical when tightening fasteners, anchors, screws and connectors used to secure all orthopaedic implants. Torque is a measure of the turning force on an object such as a bolt or connector. The pushing or pulling the handle of a wrench, for example, connected to a nut or bolt produces a torque (turning force) that loosens or tightens.² Over torque can result in broken connectors or stripped heads and under torque could create risk in implant instability and result in failure.

Single-procedure instruments are factory set with set point accuracy of less than +/- 5% and have a four year post sterilization shelf life. They are designed to be used for one procedure and to withstand scores of actuations

in clockwise or counter-clockwise modes and then discarded.

Orthopaedic surgeons find these features and benefits important. With patient safety being of significant priority, a surgeon's confidence and comfort level is increased knowing a precision torque instrument has been provided that exclusively guarantees accurate and sterile torque performance. No longer do they have to guess if their torque instruments are calibrated or available, much less...clean!

While torque accuracy is top priority to patient safety and implant success, life cycle cost reduction is also important. Single-procedure kits and instruments eliminate the rising costs associated with post procedure cleaning, handling, re-stocking, re-sterilization work, documentation and logistics fees. Disposable instruments and kits, in contrast, offer all the features and robustness needed in critical implant procedures, but at a fraction of the upfront cost, and are used one time and then discarded as part of existing recycle or bioburden programs.

Major Cost Savings and Efficiency Gains

Estimates suggest conversion to disposable torque instruments and kits for orthopaedic procedures could save US hospital and ASCs hundreds of dollars per procedure or over \$1 billion annually. That includes the reduction in hard and soft dollar costs to purchase the instruments, store in OR inventory, sterilize and kit, cost of utilities and



Figure 3. ECA makes both standard and custom single-procedure instruments and kits to meet OEM customer needs. ECA's rapid prototyping to production process allows medical device OEMs to create custom instrument sets for a wide range of implants including minimally invasive clavicle repair and AC joint repair like this custom T-handle configuration for Suspension™ Orthopaedic Solutions.



Figure 4. Single-procedure torque-limiting instruments and kits are bundled with the orthopaedic implant or packaged as an accessory kit sometimes with implant plates, screws and fasteners. In either case they arrive fully gamma irradiated or Ethylene Oxide (EtO) sterilized, eliminating the need for costly and labor intensive hospital/ASC sterilization, instrument sorting, cleaning and re-sterilization.



Figure 6. Surgeons require exacting torque when securing orthopaedic implants. Single-procedure torque-limiting instruments provide 100% guarantee of factory set torque for every procedure and every patient.

cleaning agents, labor, logistics and administrative charges—all of which the hospital and ultimately the patient, CMS or insurance carrier bears. A typical orthopaedic implant and reconstructive surgery hospital/ASC in the US could save over \$1 million per year in operating and maintenance costs alone.

Conversely, disposable instrument kits promote higher OR uptime and implant device usage. Estimates suggest, for example, a 10% increase in operational readiness to support unscheduled procedures and traumas offering significant upside revenue potential and operational efficiencies. For a high patient load hospital or ASC that could mean another 50 to 100 procedures per year or over \$2.5 million in additional revenue.

Leading OEMs and hospitals are working to roll back costs and streamline operations in every department of the hospital. Huge cost savings are being achieved through tighter management of the supply chain and inventory control, strategically using fewer vendors, and a priority focus on higher return on investment for every Operating Room specifically those in the orthopaedic arena. A recent survey of ASCs indicates adoption of new and innovative tools and instruments are important to attracting leading orthopaedic surgeons, and to creating and sustaining a competitive business model.

Hospital, ASC and OEM Value

Hospitals and ASCs are seeking to add value with application of technology and process improvements across the enterprise. This is achieved by improving areas such as the OR clean room, and controlling inventory management. By reducing sterile processing department (SPD) labor, eliminating the instrument logistics tail and reducing risk of hospital infection can reduce unnecessary expenditures and loss of revenue.

Conversion to disposable torque and related surgical instruments and kits can reduce the workload of the hospital and ASC sterile processing departments (SPDs) and reduce the risk of surgical site infection (SSI) and hospital acquired infection (HAI). Risk Management Departments in multiple clinical settings have become focused on topics of heightened concern and have created significant containment, training and eradication costs in recent years to reduce the impact of legal challenges within their organization.^{3,4,5}

According to the Centers for Disease Control “although the effectiveness of high-level disinfection and sterilization mandates effective cleaning, no “real-time” tests exist that can be employed in a clinical setting to verify cleaning. If such tests were commercially available they could be used to ensure an adequate level of cleaning. The only way to ensure adequate cleaning is to conduct a reprocessing verification test (e.g., microbiologic sampling), but this is not routinely recommended.”

Single-procedure instruments and kits eliminate the sterilization steps, risk and cost. All the units come as accessory kits with each implant and are sterilized by the OEM implant manufacturer arriving at the hospital, or ASC sterilized and ready for the orthopaedic procedure. Once used, the disposable units are discarded for handling using the hospital’s green initiative and bioburden programs for reducing landfill materials.

Stainless steel materials may be recycled and plastic handles, trays and Tyvek covers either cleaned and recycled or disposed of as medical waste. Various disposal options can be utilized including: landfill untreated, landfill treated; grind, autoclave, and landfill; recycle; incinerate; incineration with generation of steam or electricity and Pyrolysis.

Regardless of what approaches are taken, the disposable instrument and kits produce a far smaller carbon footprint than reusable devices given the extensive cleaning materials/agents, utility use (water, electricity), gamma or EtO reesterilization and the freight, gasoline cost and related transportation steps needed for semi-annual or greater recalibration and test.

Disposable products and instruments for medical applications and biopharma are also supported by the regulatory agencies. One single-use champion is the U.S. Food & Drug Administration (FDA). David Doleski, acting branch chief, New Drug Manufacturing Assessment Branch Office, part of the FDA's Office of Compliance, indicated that although his agency would not be providing formal guidance on single-use, he underscored the value gained through mitigation of cross-contamination and industry cost savings. He cited advantages as:⁶

- Reduced need for cleaning and sterilization systems and validation.

- Reduced risk of cross-contamination.
- Improved containment.
- Greater control over aseptic operations.

Doleski urged industry suppliers to thoroughly test their systems to insure high quality and predictable performance. He also said it was the supply chain's challenge to educate the user community on single-use quality metrics and processes to forge industry/vendor partnerships. These include vendor/material qualification considerations, manufacturing agreements, vendor audits, notification of product changes, and certificates of analysis for endotoxin, particulates and bioburden.

The availability and rapid adoption of disposable torque-limiting instruments and kits is a significant step toward achieving OEM, hospital and ASC patient safety, implant success, business and operational goals. They offer exact torque accuracy for every procedure, promote improved patient safety and care and greater operational efficiencies. They help innovative orthopaedic implant makers gain broader adoption of their unique brands or generic devices across the market.⁷

Some of the sustained benefits and value single-procedure torque instruments and kits offer to both OEM and Hospital/ASC are:

Problematic Reusable vs. Single-Procedure Instruments

Reusable	Single-Procedure		
Active & Dormant Concerns with Reusable Instruments	Single-Procedure Instrument & Kit Solutions	Sustained Value & Benefits to Hospitals/ASCs	Sustained Value & Benefits to Medical Implant OEMs
Calibration accuracy	Factory set, 100% accurate.	Reduces risk of implant failure and enhances patient safety.	Sterile factory calibrated instrument included with implant or part of comprehensive kit.
Upfront & Life Cycle Service/Support Cost. High life cycle costs (hard and soft dollars).	Nominal purchase cost, no life cycle cost.	Reduced operating and maintenance costs, workforce efficiency gains and improved margin on reimbursement fees.	Provide value and cost savings to customers. Reduce life cycle costs and logistics tail in post-sales service/support centers.
Lost Revenue From Instrument - Lack of Availability	Ready to use inventory across full range of implants.	Off the shelf available. Less inventory and more efficient inventory management.	Embedded single-procedure torque and fixed-driver instruments insure implant models/brand available.
Comprehensive Cleaning / Sterility	Packaged as sterile off the shelf accessory pack or complete surgical procedure kit.	No cleaning cost or sterilization required. Eliminates SSI and hospital acquired infection (HAI). Allows Sterile Processing Department (SPD) efficiency and productivity gains.	Helps hospital reduce bioburden and eliminate cleaning, sterilization and other utility costs and labor. Reduces burden on logistics cost centers.

ECA Medical Instruments Pioneering Conversion and Opportunity



Figure 7. Medical grade stainless steel shafts and tips make single-procedure torque instruments robust, creating exacting torque and surgeon confidence throughout the implant procedure.

ECA Medical Instruments is the pioneer and industry leader in designing and manufacturing precision single-procedure torque-limiting instruments and surgical kits for orthopaedics. The rapid adoption of disposable instruments and kits by OEMs, orthopaedic surgeons, ambulatory surgery centers (ASCs) and hospitals are providing credible and safe options to conventional reusable instruments and products. It's also helping accelerate mandated cost saving programs combined with efficiency and productivity gains in healthcare delivery. Whether adopted as complimentary, substitute or drop-in replacements disposable torque-limiting products are becoming clear favorites for securing medical implants and application in all orthopaedic procedures. They are driving down per unit and life cycle costs, eliminating recalibration and re-sterilization, reducing the risk of infection and providing mandated sustainability gains across the enterprise.

ECA stands at the forefront of innovative single-procedure torque-limiting instrument and specialized kit solutions for accurately securing fasteners and connectors for a wide range of orthopaedic implants, CMF, spine, reconstructive surgery and small bone and trauma procedures. Our customers are leading orthopaedic OEMs and healthcare product suppliers worldwide.

Patented and ergonomic single-use torque instruments for orthopaedic procedures range from 1 lb. /in. (0.112 Nm) to 90 lb. /in. (10 Nm) and crafted from surgical stainless steel and engineered resins. The ECA engineering and product development team can expertly modify standard instruments or unique customer designs – including reusable instrument conversion to single-use instruments – and quickly transform them from concepts to prototype to production.

Advances in engineered polymers permit design and production of high quality and robust products using various handle styles (Axial, Palm and T-Handles) to 90 lb./in (10 Nm) or higher and for hundreds of precision actuations in the most demanding implant and reconstructive procedures. Disposable instruments use medical grade, surgical stainless steel shafts and tips and are assembled in Class 7 clean rooms.

ECA single-procedure instruments are available in a variety of styles, configurations and torque ranges. Our standard product procedural set allows our customers to quickly tailor or private label an instrument design to their application or to serve as a guide for a modified standard or full custom solution. They may be over-molded, color coded, modified in both features and ergonomics, including grip types and geometry to fit customer requirements.



Figure 8. A wide range of torque, instrument styles, grips and configurations are available for medical implant OEM customization.

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References:

1. Interview with Mr. Rob Collins, CEO, Suspension Orthopaedic Solutions, Arnold Maryland, October 2012.
2. *Merriam-Webster Dictionary*, 2012, <http://www.merriam-webster.com/dictionary/torque>.
3. Dirty surgical tools put patients at risk, *NBC Nightly News*, February 24, 2012
<http://video.msnbc.msn.com/nightly-news/46505476#46505476>.
4. Guideline for Disinfection and Sterilization in Healthcare Facilities (2008), *Centers for Disease Control and Prevention* http://www.cdc.gov/hicpac/Disinfection_Sterilization/5_0cleaning.html.
 - a. Alfa MJ, DeGagne P, Olson N, Puchalski T. Comparison of ion plasma, vaporized hydrogen peroxide and 100% ethylene oxide sterilizers to the 12/88 ethylene oxide gas sterilizer. *Infect. Control Hosp. Epidemiol.* 1996;17:92-100.
 - b. Alfa MJ. Flexible endoscope reprocessing. *Infect. Control Steril. Technol.* 1997;3:26-36.
 - c. Alfa MJ, Degagne P, Olson N. Worst-case soiling levels for patient-used flexible endoscopes before and after cleaning. *Am. J. Infect. Control* 1999;27:392-401.
 - d. Rutala WA, Weber DJ. *Low-temperature sterilization technology: Do we need to redefine sterilization?* *Infect. Control Hosp. Epidemiol.* 1996;17:89-91.
5. Karen Cheung-Larivee, *Fierce Healthcare*, Feb 23, 2012, Dirty surgical tools a dangerous, growing problem.
6. David Doleski, Acting Branch Chief, New Drug Manufacturing Assessment Branch Office of Compliance, CDER, FDA, *BPSA International Single-Use Summit Regulatory Perspective on the Adoption of Single-Use Technologies* July 28, 2011 Washington, DC.
7. Maggie F. Shuler, MD, PhD • Alan Franklin, MD, PhD • John Myers, MD • Sunil Gupta, MD. Disposable vs Reusable Surgical Instruments: How to Decide? Which instruments should you choose based on cost and procedure? *Retinal Physician*, 1 September 2010.



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ECA Medical Instruments is fully committed to the impact disposable medical devices have on landfills. ECA supports eco-friendly programs that aggressively pursue environmentally sustainable manufacturing practices and supports all hospital Green Initiatives. ECA Medical Instruments fully supports the Reduce, Repurpose, Recycle initiatives in the medical device industry.



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