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 OEMs, Hospitals and ASCs

Adoption of single-procedure instruments for orthopaedic and spine 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 implant fixation 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 25 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 and spine 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 sustained benefits include:

- **Ready for surgery procedural kits in pre-sterile tray(s).**
- **Confidence in implant fixation with accurate torque-limiting instruments.**
- **Reduced inventory footprint.**
- **Operating room (OR) efficiency gains and reduced risk of surgical site infection.**
- **Reduction in maintenance and life cycle support costs.**

These value propositions all lead to higher operating theater efficiency and potential increased capacity. Off-the-shelf instrument set access allows the hospital and ASC to capture additional revenues otherwise lost when instruments are not available to meet unscheduled procedures and implant demand.

Torque-Fast® driver instruments with the company’s new 901 kit, shown here, used for spinal fusion procedures, includes high torque-limiting T-Han® shafts and tips. These value propositions all lead to higher operating theater efficiency and potential increased capacity. Off-the-shelf instrument set access allows the hospital and ASC to capture additional revenues otherwise lost when instruments are not available to meet unscheduled procedures and implant demand.

These cost effective, pristine and sterile packed instruments and kits promise to eliminate active and dormant industry concerns expressed by surgeons, OEMs and hospital and ASC 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 and labor cost 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 manufactures 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 object2 such as a bolt or connector. The pushing or pulling a wrench handle, for example, connected to a nut or bolt produces a torque (turning force) that loosens or tightens. Over torque can result in broken connectors or stripped heads and under torque could create risk of implant instability and result in failure.

Single-procedure instruments are factory set with set point accuracy of less than +/- 10% and have a three year post sterilization shelf life. They are designed to be used for one surgical procedure and to withstand scores of actuations in clockwise or counter-clockwise modes and then discarded.

Orthopaedic and Neuro surgeons find these features and benefits important. With patient safety being the primary 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 surgical torque procedures, but at a fraction of the upfront cost, and are used one time and then discarded as part of existing recyle or bioburden programs.

Major Cost Savings and Efficiency Gains

Estimates suggest conversion to disposable torque instruments and kits for orthopaedic procedures could save US hospitals 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 cleaning agents, labor, logistics and administrative charges—all of which the hospital and ultimately the patient, CMS or insurance carrier bears. A typical orthopaedic/spine 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 trauma cases, 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/ASCs 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 controls, 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 is important to attracting leading orthopaedic surgeons, and to creating and sustaining a competitive business model.

ASCs are the primary adopters of disposable instruments and kits given their cost savings and efficiency gains which are critical given ASCs receive lower reimbursement funds than traditional hospitals for identical procedures. Great clinical outcomes at best value are key goals for ASC operators. To meet that goal ASCs want to minimize capital equipment investments, reduce inventory, cut labor costs and improve OR efficiencies, all of which are achieved with single-procedure instrument sets.

Hospitals, 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 an adequate cleaning is to conduct a reprocessing verification test (e.g., microbiologic sampling), but this is not routinely recommended.”6

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 EO re-sterilization 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-infection 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 ensure 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

<table>
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<tr>
<th>Reusable Active &amp; Dormant Concerns with Reusable Instruments</th>
<th>Sustained Value &amp; Benefits to Hospitals/ASCs</th>
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<tr>
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<td>Factory set, 100% accurate. Pristine set of driver tips</td>
<td>Reduces risk of implant failure and enhances patient safety</td>
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<tr>
<td>Upright &amp; Lift Cycle Service/Support Cost. High life cycle costs (hard and soft collars).</td>
<td>Nominal purchase cost, no life cycle cost</td>
<td>Reduced operating and maintenance costs, workforce efficiency gains and improved margin on reimbursement fees</td>
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<td>Lost Revenue From Instrument - Lack of Availability</td>
<td>Ready to use inventory across full range of ortho and spine implants</td>
<td>Provide value and cost savings to customers. Reduce life cycle costs and logistics tail in post-sales service/support centers</td>
</tr>
<tr>
<td>Comprehensive Cleaning / Sterility</td>
<td>Off-the-shelf available. Less inventory and more efficient inventory management.</td>
<td>Embedded single-procedure torque and fixed-driver instruments insure implant models/brand available</td>
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**Reusable Single-Procedure Instrument & Kit Solutions**

- **Active & Dormant Concerns with Reusable Instruments**
  - Calibration accuracy and deformed driver tips
  - Upright & Lift Cycle Service/Support Cost.
  - High life cycle costs (hard and soft collars).
  - Lost Revenue From Instrument - Lack of Availability
  - Comprehensive Cleaning / Sterility

- **Sustained Value & Benefits to Hospitals/ASCs**
  - Factory set, 100% accurate. Pristine set of driver tips
  - Ready to use inventory across full range of ortho and spine implants
  - Off-the-shelf available. Less inventory and more efficient inventory management.

- **Sustained Value & Benefits to Medical Implant OEMs**
  - No cleaning cost or sterilization required.
  - Eliminates SSI and hospital acquired infection (HAI).
  - Helps hospital reduce bioburden and eliminate cleaning, sterilization and other utility costs and labor.

*Note: Factory set and pristine set of driver tips are included with implant or part of comprehensive kit.*
ECA Medical Instruments Pioneering Conversion and Opportunity

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 is 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 88 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 88 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 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. 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.

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