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**June 17-18
Chicago**

**The 11th Annual Orthopaedic
Manufacturing & Technology Exposition and Conference**

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Dr. Tools[®] Signature Series Instrumentation

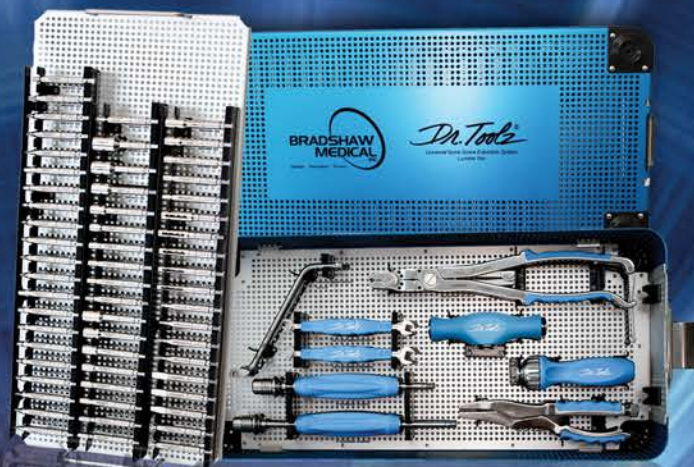
Our Dr. Tools[®] Universal Spine Screw Extraction Systems will provide you with all of the instrumentation you will need for your next product launch, including:

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In addition, all sets have passed sterilization and cleaning validation testing.

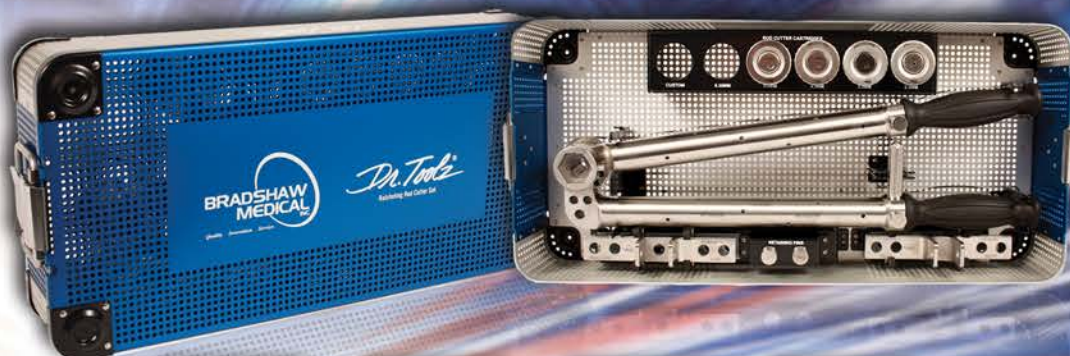
Lumbar Screw Extraction System



Cervical Screw Extraction System



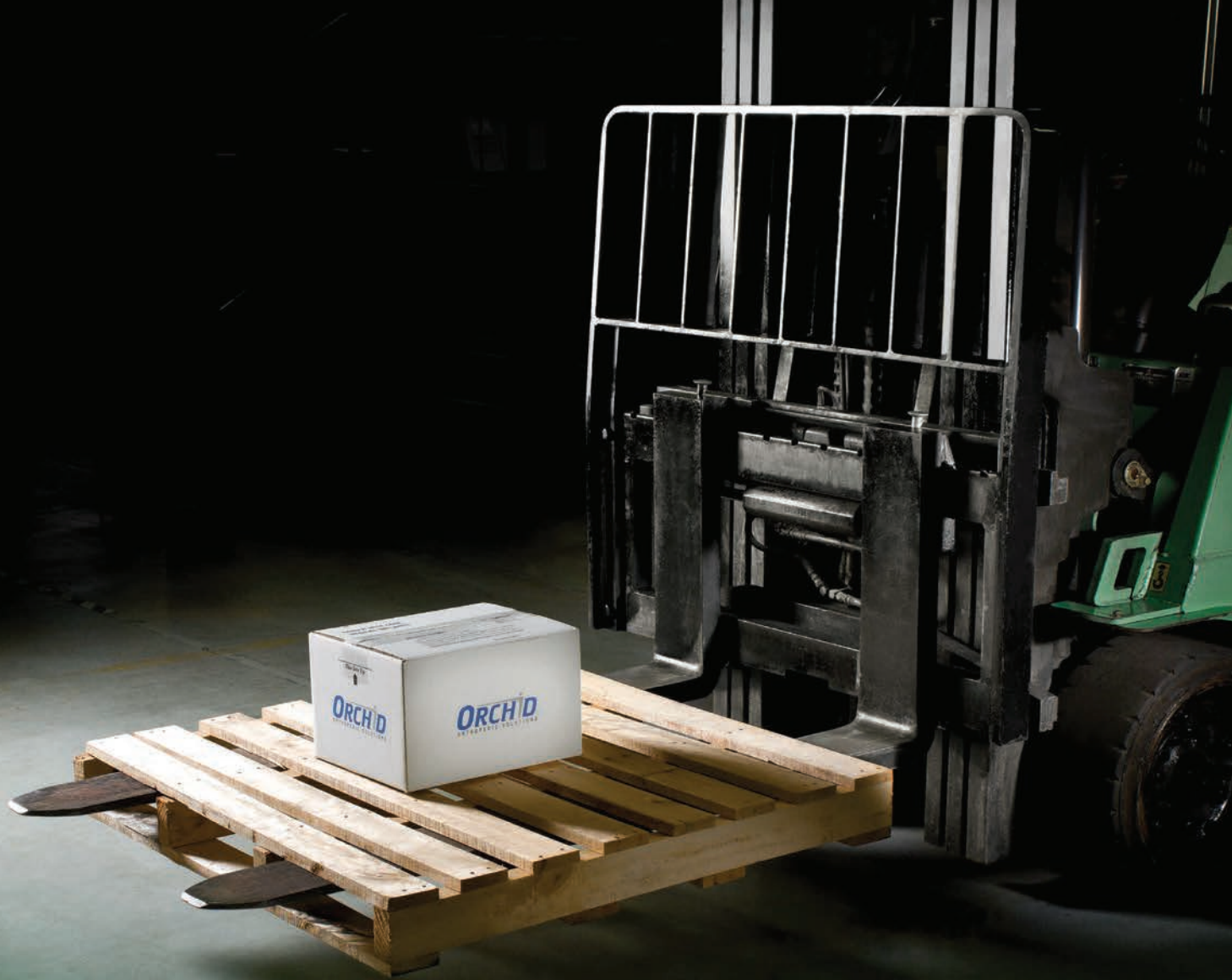
Ratcheting Rod Cutter System with Interchangeable Cartridges



Patent US 8,109,181 B2, US 7,740,249 B1, US D581,763 S, US D562,665 S. Additional Patents Pending

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“OMTEC is a great resource for discovering potential suppliers, meeting with existing suppliers and keeping up with technology advancements.”

—Mark Hall, Global Commodity Leader—Implants | Operations, Smith & Nephew

OMTEC is the only conference dedicated to empowering the people involved in the orthopaedic manufacturing process – design engineers, procurement, supply chain management, materials, quality, regulatory/clinical affairs, product development and even executives.

Education is the backbone of OMTEC, and subject matter is prioritized by device company leadership to ensure that attendees gain practical advice to put to immediate use, while nurturing longer-term directives.

OMTEC's 130+ exhibitors complete the attendee experience by providing the people-power and expertise required to get the right things done, swiftly.

Please confirm your attendance to what is sure to be the best OMTEC yet! We look forward to serving you!

www.OMTECexpo.com

Carolyn LaWell, Content Manager
and Advisory Panel Liaison
carolyn@orthoworld.com

Francine Bursic, Director of Customer Care
fran@orthoworld.com



SCHEDULE AT A GLANCE

Tuesday, June 16

All invited!

Welcome/Customer Appreciation Reception

6:00 p.m. – 7:30 p.m.

Hofbräuhaus Chicago

Wednesday, June 17

Keynotes, panels, education sessions:

7:30 a.m. – 4:00 p.m.

Exhibit Hall Open: 9:00 a.m. to 5:30 p.m.

Networking Reception

(on the exhibit floor):

4:00 p.m. – 5:30 p.m.

Thursday, June 18

Keynotes, panels, education sessions:

7:30 a.m. – 4:00 p.m.

Exhibit Hall Open: 8:00 a.m. – 2:00 p.m.

Conference adjourns: 4:00 p.m.



**“OMTEC improves each year.
All of the pertinent subjects
are covered well...”**

*—Larry Rains, Procurement Specialist II,
MicroPort Orthopedics*

ATTENDANCE AND REGISTRATION

Registration includes:

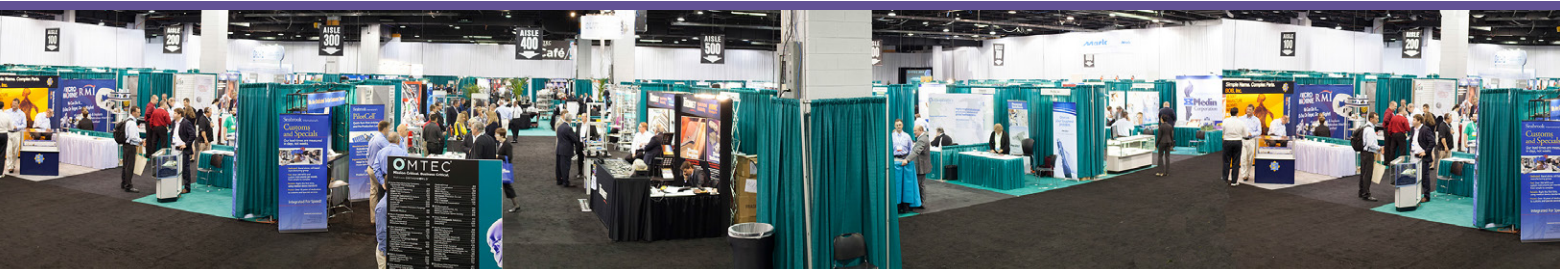
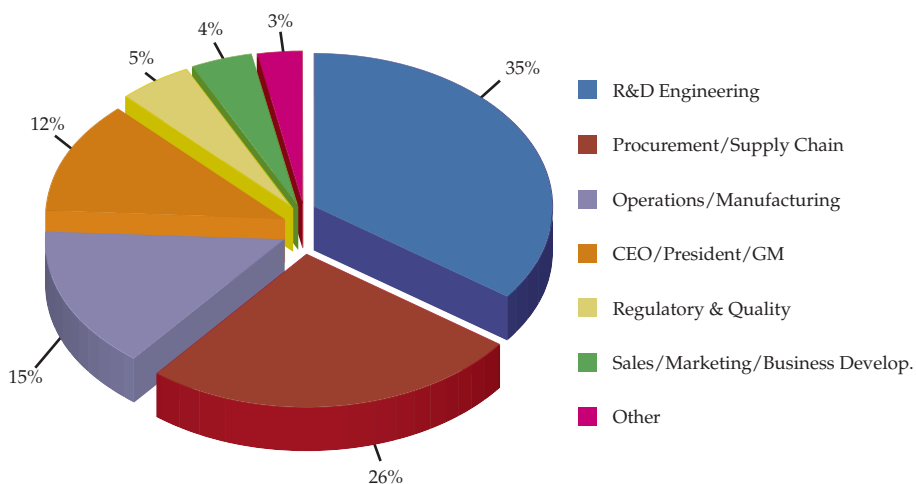
- All education sessions, keynotes and panel discussions*
- All meals and refreshment breaks
- Access to the exhibit floor
- Networking reception Wednesday afternoon in the Exhibit Hall cafe
- Welcome reception Tuesday evening at Hofbräuhaus Chicago
- Special rates on *BONEZONE*® subscriptions

Registration Category	Early	Regular	Onsite
Device Company Exhibit Floor	\$89.00	\$189.00	\$279.00
Device Company Full Conference	\$289.00	\$389.00	\$479.00
Supplier/Consultant/Other Full Conference	\$775.00	\$875.00	\$965.00
Student/Surgeon/Academia	\$49.00	\$49.00	\$49.00

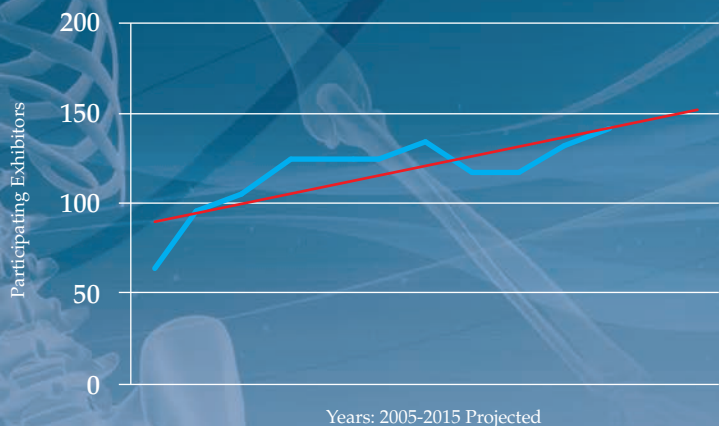
*Exhibit floor registration excludes education

OMTEC attracts a diverse contingent of OEM decision makers. In 2014, attendees represented 69 companies... from Zimmer, Stryker, DePuy/Synthes and Biomet to Acumed, Globus, K2M, Tornier and Wright Medical.

OMTEC 2014
Device Company/OEM Attendees by Professional Focus



OMTEC Exhibitors: 2005-2015 Projected



Contract manufacturers are at the core of OMTEC's exhibitor base, numbering well over 100 since 2007. Today, attendees can expect to see testing labs, materials providers, packaging and sterilization experts and more. The following pages showcase the 93 companies that have confirmed thus far!

OMTEC 2015 KEYNOTES

What's Ahead for the Orthopaedic Industry?

OMTEC's CEO panel discussion and surgeon perspective highlight the critical regulatory and economic dynamics shaping the orthopaedic industry.

The State and Future of the Orthopaedic Industry—CEO Interview



What does the future hold for the orthopaedic industry? The CEO panel discussion returns to offer insights and solutions on ways that OEMs are adapting to complex regulatory and economic changes. The morning keynote opens OMTEC, providing a high-level overview of topics discussed in further depth over the next two days: U.S. and international regulatory changes, emerging technologies and solidifying supplier relationships.

Moderator:

Doug Kohrs, Past President and CEO, Tornier N.V.



Mr. Kohrs has more than 30 years of experience in the medical device industry, primarily as a founder or executive of innovative companies. He served as the Chief Executive Officer and President of Tornier from 2006 to 2012, and Chief Executive Officer and President of American Medical Systems Holdings from 1999 to 2005. He currently serves as President of the Foundation for Essential Needs and on boards at Proto Labs, Inova Spine, Boi2 Technologies, OmniGuide and Tenex Health.

Panelists:

B. Sonny Bal, M.D., J.D., Chairman of the Board, President and CEO, Amedica Corporation



Dr. Bal has served on Amedica's Board of Directors since February 2012, as Chairman of the board since August 2014 and as President and Chief Executive Officer since October 2014. He is Professor and Chief of Adult Reconstruction at the University of Missouri - Columbia and Adjunct Professor of Material Sciences at the University of Missouri at Rolla. Dr. Bal is a member of the American Academy of Orthopaedic Surgeons, the American Association of Hip and Knee Surgeons and the International Society of Technology in Arthroplasty.

Rod K. Mayer, President and CEO, Nextremity Solutions, Inc.



Mr. Mayer has served in the orthopaedic industry since 1977, most recently as President and Chief Executive Officer of Nextremity Solutions. Mr. Mayer started his orthopaedic career with DePuy, spending 18 years in various roles. His overall history in the industry includes sales, distribution and business development. In 2002, Mr. Mayer founded DVO Extremity Solutions LLC. Mr. Mayer co-led the development, growth and eventual sale of DVO to Tornier in March 2007. He then served as Vice President of Sales Execution and was a member of Tornier's executive management team. Mayer co-founded Del Palma Orthopedics and currently serves as a Director. Mr. Mayer also serves on the Boards of Conventus Orthopedics and SDG Holdings.

Medical Advancements: Balancing Cost and Outcomes



In an era of declining reimbursement, how can manufacturers successfully develop and sell new products? Should manufacturers strive for transformational or incremental improvements to devices? The surgeon keynote, an inventor himself, outlines the decision-making approach he takes when adopting new technologies and offers industry examples of what it takes to build recognized and accepted devices today.



Wael K. Barsoum, M.D.

**President, Cleveland Clinic Florida
Chairman of Surgical Operations and Vice
Chairman of the Department of Orthopaedic
Surgery, Cleveland Clinic**

In addition to his leadership positions at the Cleveland Clinic, Dr. Barsoum holds a joint appointment in the Department of Biomedical Engineering, and is involved in the training of future physicians as the Director of Research and Education for the Orthopaedic Adult Reconstructive Surgery Section and Association Professor of Surgery at the Cleveland Clinic Lerner College of Medicine at Case Western Reserve.

Dr. Barsoum has a full clinical practice as a staff orthopaedic surgeon. He specializes in adult hip and knee reconstructive surgery.

Dr. Barsoum is an avid researcher and innovator. He is the principal investigator for a variety of clinical basic science and translational studies, and has 45 patents applied for or granted. Dr. Barsoum has received the Cleveland Clinic Foundation Innovations Award nine times, and also received the prestigious Cleveland Clinic Sones Award for Innovation.



Dirk Kuyper of IlluminOss Medical and Michael Butler of Life Spine provided the CEO perspective during the OMTEC 2014 Keynote.

World-renowned speakers and experts will convene to provide three days of lectures, technical presentations and interactive discussions. Whether your background is R&D, Purchasing, Supply Chain, Regulatory or Business Development, you'll gain tactics to:

- **Comply efficiently and effectively with regulatory changes**
- **Identify strategic partners**
- **Promote internal cost- and time-savings methods**

While education is classified under the broad categories of Research & Development, Supply Chain Management, Legal, Clinical & Regulatory and Business Critical, many of the sessions pertain to multiple professional titles, due to the increasing need to collaborate across departments.

RESEARCH & DEVELOPMENT

■ Applying Human Factors and Usability Engineering to Optimize Device Design

FDA has shown a greater concern for human factors in device development. This session provides an overview of FDA requirements and best practices for engineers.

Speaker: Rob Ngungu, RAC, Director, Regulatory Affairs & Product Development Strategy, Austen BioInnovation Institute

■ Design Verification: What to Do When a Testing Standard Doesn't Exist

Manufacturers must verify that a device properly reflects the requirements specified. These best practices should be followed when a standard verification test doesn't exist.

■ Lessons from FDA Recalls: Design and Develop the Best Package for Your Device

This presentation will address current challenges of the environment in which medical device packaging is used. It will explore critical elements of designing the best package for your device, including considerations of materials and barrier properties, sterilization compatibility, environmental challenges and regulatory compliance.

Speaker: Alison Tyler, Technical Director, Beacon Converters

■ Drive Built-in-Quality into Your Manufacturing Process

A key component of Lean Manufacturing focuses on improving quality with the stated objective of: "Do not Accept/Build/Ship a Defect." True gains in quality are ultimately achieved when an organization embraces and works toward a Built-in-Quality culture. This talk will explain the concept of BIQ and what is needed to achieve it in any organization.

Speaker: Joe Mazzeo, Owner, Integrated Lean and Quality Solutions, LLC

CAPA: Why is My Process Not Working?

Tuesday Workshop —New in 2015!

Having a strong Corrective and Preventive Action Process (CAPA) in place is crucial for orthopaedic device manufacturers in a time of frequent recalls, increased warning letters for repeat offenders and burdensome medical device reporting requirements.

A process to identify and eliminate non-conformances and potential non-conformances allows companies to realize cost-savings in the short-term, and could redefine a company culture focused on far-term accomplishments.

There are multiple reasons why your CAPA process may be failing. The two root causes of failure are:

- Lack of management commitment to dedicate the time and resources to administering this process of corrective and preventive actions.
- Most companies issue too many CAPAs that are low risk, and most are likely deserving of a simple correction to fix the issue.

Not all situations require that preventive actions be taken, and there are times when companies want to independently take preventive action to solve a potential problem before it occurs.

Taking corrective action should be evaluated with several factors in mind. The most common involve using trends and risk management tools. How often does it happen? How important or critical is the issue? How are customers impacted? The answers will determine whether a corrective action is needed or just a correction.

Further, the degree of CAPA taken to eliminate or minimize existing or potential nonconformities should be appropriate to the scale of the problem and proportionate to the risks encountered.

Establishing a viable risk management process is critical to determine why your CAPA process may be failing.

John Gagliardi, President, MidWest Process Innovation, will lead the CAPA workshop. This article was adapted from his December 2014 BONEZONE® article of the same name.

SUPPLY CHAIN MANAGEMENT

■ **Strategies to Overcome Supply Chain Pain Points**

Orthopaedic manufacturers face numerous headwinds with reform driving the need for new efficiencies, as well as transformational shifts in the supply chain. The top strategies for addressing regulatory compliance, cost and product protection as well as future supply chain investment trends will be revealed.

Speaker: Robin M. Hooker, Director of Healthcare Marketing, UPS

■ **Master Strategic Sourcing Execution**

An optimized purchasing department decreases costs and improves bottom lines. Learn how strategic sourcing basics, such as spend management, commodity management/segmentation, the sourcing process and key challenges in execution, unite to create a successful strategy.

Speaker: Jeff Burris, Principal, Advanced Purchasing Dynamics

■ **OEMs Weigh In on Supply Chain Quality Issues**

Quality requirements driven by regulatory bodies and industry are requiring more rigorous infrastructure and capabilities throughout the supply chain. Representatives from larger OEMs will discuss trends and solutions for working with suppliers to maintain quality.

■ **Europe: Regulatory Review and Supplier Panel on Market Trends and Solutions**

Asia: Regulatory Review and Supplier Panel on Market Trends and Solutions

These separate presentations will bring attendees up to speed on the changing regulatory landscapes in Europe and Asia. Then, we'll facilitate panel discussions with exhibitors from each continent to speak about market trends, the advantages they bring to the table and suggestions for OEMs on ways to better partner with international companies.



OMTEC attendees have rated speakers an average of 1.5, excellent to good, for the last two years. An attendee favorite, John Gagliardi of MidWest Process Innovation, will present a Tuesday workshop on CAPA and moderate a Q&A with FDA directors.

Strategies to Overcome Supply Chain Pain Points

Orthopaedic device manufacturers face obstacles in their supply chains as a result of numerous headwinds, such as increased regulations, product protection challenges, cost management, contingency planning and access to global markets.

This is demonstrated by results from UPS' Seventh Annual *Pain in the Supply Chain* survey, which asked 530 supply chain and logistics executives how they're reacting to the rapidly-changing healthcare environment. The survey focused on the pharmaceutical, biotech and medical device industries in the U.S., Canada, Western Europe, Asia and Latin America.

According to the survey, the top trends impacting the orthopaedic device supply chain are changing or increasing regulatory requirements, followed by cost management and product security.

How can orthopaedic device manufacturers address these critical pain points and strengthen supply chains? They must:

- Meet regulatory requirements
- Overcome protection challenges
- Manage costs
- Mitigate risks
- Enter new markets

Effective strategies to take on these challenges include:

- **Identify areas for investments.** Investments in new technology top this list and are specific to order management, online ordering systems and product protection technologies.
- **Develop lean inventory models and trunk stock reduction.** Optimize your inventory and run leaner, tighter inventory models in the field.
- **Develop strategic partnerships at home and abroad.** Build infrastructure overseas and leverage logistics and distribution partnerships.
- **Prepare for preventative actions.** Develop a plan for handling potentially disruptive events.

Gain the knowledge you need to discover opportunities for supply chain optimization.

Robin M. Hooker, Director of Healthcare Marketing, UPS, will lead a solution-oriented session on this topic at OMTEC.

This article was adapted from an article by Hannah Corcoran of ORTHOWORLD that appeared on BONEZONEpub.com.

LEGAL, CLINICAL & REGULATORY

■ UDI: Lessons in Implementation

What do you need to know about UDI today? This session will provide attendees with an overview of approaching U.S. deadlines, handling situations yet to be defined by FDA and forthcoming regulations in Europe.

Speaker: Karen Conway, Executive Director for Industry Relations, GHX

■ UDI: How Do I Make This Data Work for Me?

Compliance with UDI initiatives involves a multi-department effort. Once data has been collected and entered into the Global Unique Device Identification Database, how can manufacturers use that data to improve internally? UDI experts from medical device manufacturers will share their own experiences.

Speaker: Karen Conway, Executive Director for Industry Relations, GHX

■ Materials: A Regulatory Update

Raw material scrutiny has increased globally in recent years. This session offers ways to develop successful strategies in the U.S., Europe and emerging markets.

■ FDA Update: What's New in Orthopaedic Devices?

FDA presents its current priorities, and what they mean specifically for the orthopaedic industry. A generous amount of time will be left for Q&A.

Speakers: Mark Melkerson, Director, Division of Orthopedic Devices, Office of Device Evaluation, CDRH and William MacFarland, Director, Division of Manufacturing and Quality, Office of Compliance, CDRH

■ Improve Your Device Submission Process

This session details best practices for approaching a 510(k) submission and FDA changes to the process moving forward.

Speaker: Mark Melkerson, Director, Division of Orthopedic Devices, Office of Device Evaluation, CDRH

BUSINESS CRITICAL

■ Consolidation: What's it All About?

This panel brings together OEMs and Suppliers that recently went through M&A activity to discuss the benefits, trends and what the increased activity means for the entire supply chain.

Moderator: Don Urbanowicz, Principal, Urbanowicz Consulting

■ Leadership: How to Successfully Hone Your Skills

No matter if you lead or work at a small company or a large, global enterprise, the need for effective leadership is key to your organization's success. This talk discusses how any company, of any size, and its leaders can and will benefit from focusing on ways to improve leadership performance.

Speaker: Joe Mazzeo, Founder, Integrated Lean and Quality Solutions

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■ Standing Out in the Changing Job Market

This session will provide insight into ways to position your strengths and how to identify new opportunities inside and outside of the orthopaedic industry.

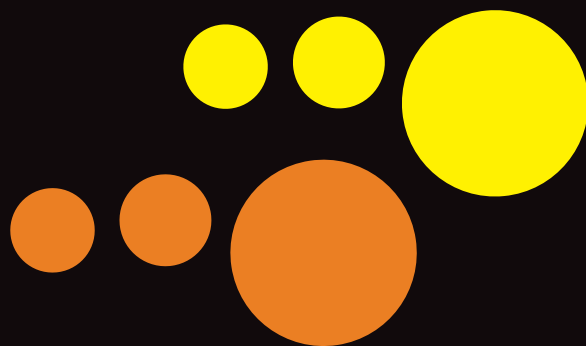
■ The Risk of Doing Business: Current Enforcement Focus and Strategies for Ensuring Compliant Product Promotion in the U.S.

This presentation will discuss legal and regulatory risk, as well as key mitigation strategies, in connection with promoting medical devices in the U.S. Topics will address new or evolving regulatory expectations impacting commercial operations, including recent updates to Open Payments disclosure obligations.

Speaker: Vahan Minassian, Manager, Compliance & Ethics at Compliance Implementation Services (CIS)

KNOWLEDGE CENTER and TECHNICAL SEMINAR AREA

The Knowledge Center and Technical Seminar Area provide high-demand education for OEMs and suppliers. Located on the Exhibit Hall floor (just follow the yellow and orange circles), these education sessions place attendees at small, round tables and are meant to provide greater conversation and collaboration.



The Knowledge Center is host to interactive roundtables on market segment trends, covering R&D and manufacturing updates on hip, knee, spine and extremities.

The Technical Seminar Area is dedicated to solutions that save time and money. This year's 30-minute demonstrations will show how to put the following processes to good use:

Additive Manufacturing
Design for Manufacturability
Device Cleaning
Device Inspection
Device Sterilization

“Educational sessions were very helpful for UDI. The opportunity to build strong relationships... is priceless.”

—Rachelle Yusufbekov, Associate Quality Engineer,
Captiva Spine

“The hall layout was great and I had plenty of time to accomplish all of my objectives. The educational sessions were all A+.”

David Finch, Senior Director Procurement & Planning,
MicroPort Orthopedics

UDI: Lessons in Implementation

More than one year has passed since FDA issued its final rule requiring device manufacturers to assign and label their products with unique device identifiers (UDIs) and provide additional data about those products to the Global UDI Database (GUDID), yet questions remain for orthopaedic device manufacturers.

September 24, 2014 was the deadline for all Class III devices sold in the U.S. to be in compliance with the rule. There are reportedly records on more than 30,000 class III devices in the GUDID. Many more devices still need to come into compliance, as Class III devices represent only about 10 percent of available products. Most available products are Class II (around 43 percent), which must comply by September 2016.

All implantable devices, regardless of class, have to comply by September 24, 2015. Compliance for implantable devices presents distinct challenges and raises several questions. FDA is working with industry to solve challenges presented by procedural trays and other processes related to implantable devices.

Questions include:

- How are UDIs applied to products that often end up out of their packaging and in procedure trays before they are used in surgeries?
- How do hospitals and surgery centers capture that data on products if the UDI is no longer physically associated with the product?

UDI is an industry-wide initiative, and some of these more complex questions can only be addressed through industry-wide collaboration.

Karen Conway, Executive Director for Industry Relations, GHX, will lead the OMTEC sessions on UDI. This article was adapted from her December 2014 BONEZONE® article, “UDI: Many Questions Remain.”

EXHIBITOR LISTINGS

On behalf of the industry at large, we extend a special thank you to the following exhibitors for sponsoring critical content and networking opportunities for OMTEC 2015.



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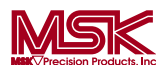
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NETWORKING ACTIVITIES



Customer Appreciation/Welcome Reception Tuesday, June 16, 6:00 p.m. – 7:30 p.m. Hofbräuhaus Chicago

Sponsored by ORTHOWORLD
(The drinks are on Paragon Medical!)

Join your peers, partners and friends for light fare and drinks at this always-fun-and-productive kick-off celebration.

Keynotes

Attendees and exhibitors alike are invited to Wednesday morning and Thursday afternoon keynote addresses, where powerful insights are delivered over breakfast and lunch. Banquet style seating facilitates opportunities to meet new partners or customers! Keynote addresses continue to be a highlight of the OMTEC experience.



Knowledge Center and Technical Seminar Area

Introduced in 2014, these two energy hubs on opposite ends of the exhibit floor facilitate interaction between the knowledge seeker and the expert.

Breakfast with the Experts

Thursday morning, a select group of presenters will host "topic tables" to engage you in specific, direct dialogue. Past topics have included Unique Device Identification (UDI), Packaging and Design Controls. Seating is limited to eight to ten guests per table to guarantee meaningful conversation.



Networking Reception Wednesday, June 17, 4:00 p.m. – 5:30 p.m. Exhibit Hall Café

Everyone is invited to celebrate the end of day one by mingling over light fare and drinks in the Exhibit Hall Café. Giveaways and raffles add a fun way for exhibitors to meet new customers and for attendees to discover new partners.

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A special thank you to the panel for helping us offer content that is pertinent and powerful.

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by critiquing the execution of the entire exhibitor experience:
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