

BONEZONE

COMMERCIALIZATION SOLUTIONS FOR THE ORTHOPAEDIC INDUSTRY



Innovation in Spine: Suppliers and Service Providers Weigh In

Posted in Voice of Industry | September 20, 2017 | Comments (0)

Tags: spine, NASS

By: BONEZONE

Moving a product from idea to market calls on the expertise of many players. In preparation for attending the NASS Annual Meeting in October, we took time to speak to supplier and service provider companies to get a read on current trends and future advancements in spine.

The leaders we spoke with mentioned 3D printing, biologics, coatings, single-use instruments and exerting their expertise to help customers speed time to market, navigate regulatory obstacles and provide additional value that can be passed on to the surgeons and patients. While their answers were diverse, two distinct themes emerged: new technology and improved patient outcomes. Of course, these themes go hand in hand and are, in part, what makes the spine market exciting. Here we share these leaders' answers, in their own words.



Lee Crowe
Tegra Medical



Gautam Gupta, Ph.D.
3D Systems



Lane Hale
ECA Medical Instruments



Dawn Lissy
Empirical



Kelly Lucenti
Millstone Medical



Steve Maguire
Orchid Design



David Yonce
DSM Biomedical

Today's Trends

BONEZONE: What excites you about the spine market right now?

Lee Crowe, Vice President, Sales and Marketing, Tegra Medical: The spine market is seeing some great advancements that are helping patients lead more normal lives. We're excited to observe this growth and the related advancements in new technologies.

Gautam Gupta, Ph.D., Vice President, Business Development & Global Sales, Healthcare, 3D Systems: Solutions for the spine have been quick to evolve, with a great deal of innovation in recent years. It is exciting and humbling to witness a revolution lighting up the spinal solutions market right now, with almost the entire industry rapidly adopting 3D printing to bring amazing new capabilities to the design and manufacturing of interbody fusion devices. The technology has empowered smaller companies and start-ups to introduce new innovative designs and compete on equal footing with larger players, and that type of disruption is fascinating to watch and be a part of.

Lane Hale, President & CEO, ECA Medical Instruments: The growth of the spine market continues to be robust. With the aging population, there will continue to be growth and opportunities to innovate in order to find better solutions for treatment. Also, the continued additions of procedures being approved for reimbursement in outpatient centers will boost the market by providing cost savings.

Dawn Lissy, Founder & President, Empirical: In the past 12 to 18 months, Empirical has worked with several groups that have new and outside-the-box technologies to address existing patient pain issues. These are all devices that would require a Class III regulatory path, which the spine industry really hasn't seen since entry of the artificial disc. It feels like the beginning stages of the next chapter in new technologies for the spine market. For devices that fall into the 510(k) regulatory path, new manufacturing processes for existing devices (such as additive manufacturing) is the current exciting angle to improve solutions in the spine market.

Kelly Lucenti, President, Millstone Medical: Two things: the movement towards sterile packaging (from non-sterile) for spine products to mitigate patient risk and promote decreased infection rates at hospitals; and universal packaging solutions that cut down OEM validation costs, time to market and offer designs that fit a vast number of implants into a fairly small footprint.

Steve Maguire, General Manager, Orchid Design: I believe that spine has been and continues to be a market that provides the most opportunity for improved patient outcomes and care. The total cost of our healthcare system can be significantly impacted by better surgical and nonsurgical approaches to back pain and disability. Based on this, there continues to be significant research and investment in new and improved technologies to diagnose and treat this complex problem. For those who have experienced back pain, it is obvious that we need to do better!

David Yonce, Vice President, Innovation and R&D, DSM Biomedical: Traditionally, titanium, stainless steel and PEEK have been successful materials but historically have known limitations, evidenced by the recent trend to coat PEEK with less hydrophobic options. With continuous advancement in material sciences, we expect more effective materials to become

the norm. Advancements in biomaterials can be seen beyond the traditional academic settings, as small and large companies look to commercialize advanced biomaterials for orthopaedic applications. We anticipate that many of these biomaterials will displace or augment the current, more permanent and less biologically-friendly solutions.

Tomorrow's Advancements

BONEZONE: What do you see as the greatest innovations impacting spine in the coming years?

Lee Crowe, Vice President, Sales and Marketing, Tegra Medical: Traditional spinal surgery (such as anterior cervical discectomy and fusion) relieves pain, but can leave patients with a limited range of motion. Some important innovations include procedures such as cervical disc arthroplasty, which uses implants that provide correct motion for the spine instead of fusion. We're also closely watching new advancements in biological solutions.

Gautam Gupta, Ph.D., Vice President, Business Development & Global Sales, Healthcare, 3D Systems: I am witnessing an unprecedented effort in the industry to adopt 3D printing to come up with innovative designs for interbody fusion devices. Some companies have taken the lead and are blazing the trail, while others are quickly catching up with powerful new offerings that combine aspects of 3D printing software and hardware. It will be very interesting to see how these offerings compete in the marketplace in coming years, and how they allow these companies to differentiate themselves from their competitors.

Lane Hale, President & CEO, ECA Medical Instruments: There is continued need to find ways to streamline and reduce overall system costs while improving patient safety. The movement to single use, surgery ready, sterile instrument kits is addressing these areas, especially for ASCs. By using single use, sterile instrument kits, other medical device sectors and other segments in orthopaedics are realizing improvement in OR efficiency, reduction in costs of managing and reprocessing reusable instruments, as well as reducing the risk of infection in patients. This is especially needed as more procedures are done in ASCs, where there are fewer resources to sufficiently manage the cleaning and sterilization of reusable instruments.

Dawn Lissy, Founder & President, Empirical: The greatest innovations impacting the spine market in the coming years are additive manufacturing, combination devices, and the new technologies that are currently in development to have completely new approaches and outside-the-box thinking to solve spine pain for patients (as discussed in question 1).

Kelly Lucenti, President, Millstone Medical: We expect to see continued technological advancements in robot assisted, minimally invasive surgical techniques as well as biologics emerging in the market.

Steve Maguire, General Manager, Orchid Design: There are four key areas that I see advancing the surgical side of spine:

- Implant coatings and surface treatments are advancing to enhance the bone/implant interface as well as encourage bony fusion. Technologies such as titanium coating on PEEK, integration of trabecular structures into implants with 3D printing and nano technologies are all driving to enhance fusion.
- Image guided/navigation technologies continue to improve and allow for more precise and less invasive surgical techniques. Additionally, endoscopic techniques are being adopted, allowing for direct visualization, access and repair.
- Motion Preservation in the spine (disc replacement) has been evolving for over 30 years and has now become more mainstream in treatment continuums. As longer term data becomes available, I believe that it will continue to justify the value of the approach for longer term patient benefit.
- Biologic disc repair and regeneration will continue to be a "holy grail" in spine. Many years of nucleus replacement technologies have not resulted in effective, proven solutions. However, the world of genetically engineered cells is rapidly advancing and provides hope for nucleus regeneration in the future.

David Yonce, Vice President, Innovation and R&D, DSM Biomedical: Interbody spacers have been the focus of increased functionality over the past few years, from coatings to expandable designs. It's likely that we will continue to see material advancements in this space. It's also likely that we will begin to see more development around other hardware to augment their biologic and biomechanical properties. Globally, we've seen advanced polymers continue to play a heavy role in motion preservation and dynamic stabilization, which is beginning to affect the traditional pedicle screw-based fusion market. Following cues from the interbody spacer market, we may see functional coatings applied to some of these devices as well, whether they be anti-microbial, anti-adhesion or something more interesting.

We expect that these trends and advancements will be well represented in conversations and new product launches at NASS.

The companies interviewed [will be exhibiting](#) at NASS, and so will we. We look forward to further discussions in Orlando. Until then, [email us your thoughts](#) on the spine market.

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