Material Advancements Could Spark Growth in the Interbody Device Market

By Adam Suhy, PhD

In the long history of spine fusion surgery, only a few materials have gained popularity. The PEEK and solid titanium cages introduced in the early 1990s have not changed significantly in the last 30 years. However, new materials and manufacturing processes promise to improve fusion rates and outcomes for patients.

New Materials

Spine implants made of novel materials are still fairly niche; a small number of companies manufacture interbody devices made of carbon-fiber-reinforced polymer, polyether ketone ketone (PEKK), silicon nitride (PEEK), and silicon nitride (Si3N4). However, new materials and manufacturing processes promise to improve fusion rates and outcomes for patients.

Active Implants’ NUsurface Offers Novel Meniscus Treatment Alternative

By Mary Haller and David Harmon

Active Implants’ NUsurface meniscus implant offers a novel treatment for patients who have torn or otherwise damaged their meniscus and are not yet candidates for joint replacement.

Surgeons Report 4.2 Percent Growth in Arthroplasty Procedures in Q4-2019

By David Harmon

US orthopedic surgeons responding to Market Scope’s Q4-2019 knee, hip, and shoulder surveys said arthroplasty procedures increased 4.2 percent in Q4-2019 compared with the same quarter last year. Our analysis includes 79 surveys representing 112 surgeons.

Change From Q4-2018

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knee</td>
<td>+3.5%</td>
</tr>
<tr>
<td>Hip</td>
<td>+5.0%</td>
</tr>
<tr>
<td>Shoulder</td>
<td>+5.8%</td>
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</tbody>
</table>

Extrapolating from survey data, Market Scope estimates that almost 393 thousand procedures were performed during the quarter. Growth was distributed across all subspecialties, ranging from 3.5 percent growth for knee arthroplasty to 5.8 percent growth for shoulder arthroplasty. Total procedures increased 8.1 percent when compared with a seasonally weaker Q3-2019.

Knee Arthroplasty

Survey respondents reported that knee surgery procedures increased 3.5 percent in Q4-2019 when compared with Q4-2018. Procedures were up 7.9 percent when compared with a seasonally weaker Q3-2019. Market Scope estimates that US knee arthroplasty procedures grew by 2.6 percent for the full year 2019 to 915 thousand.

Change at the practice level varied broadly, with 56.6 percent of surgeons reporting that volumes were unchanged compared with the same quarter last year. Almost 36 percent reported

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Material Advancements

(continued from p. 1)
ceramics, or other PEEK composites.

Ico-tec and Carbofix, makers of carbon fiber implants, for example, offer devices coated with titanium to improve integration. The companies claim that these implants provide clear imaging and are ideal for tumor patients because the implants will not interfere with tumor identification or complicate radiotherapy planning.

Oxford Performance Materials uses PEKK to create a product called OsteoFAB. It is produced through a laser sintering process using the company’s proprietary OXPEKK material. The company claims that the implants combine many of the positive attributes of PEEK and titanium, such as bone-like elasticity, radiolucency, and surface texture that promotes bone growth. 3D printing allows for personalized implant design and decreased cost.

CTL Amedica is a primary producer of interbody devices made with silicon nitride ceramics. The company claims that ceramic interbody devices encourage greater bone formation than PEEK or titanium, improved protein absorption, and increased osseointegration. Additionally, CTL claims that the risk of biofilm formation is reduced due to natural bacteriostatic properties of silicon nitride. Finally, the material is semi-radiolucent, which allows easy visualization without the need for radiomarkers.

Modifications to Existing Materials

PEEK implants tend to have poor bone integration and high rates of pseudoarthrosis, while titanium implants experience subsidence and imaging issues. Despite these well-known issues, these materials are still widely used. Some manufacturers are modifying these materials or inventing new manufacturing techniques to improve results.

Bombarding PEEK implants with accelerated neutral atom beam technology (ANAB) produces nano-texturing that increases cell attachment. This process was developed by Exogenesis. Vallum Corporation has commercialized a 510(k)-cleared implant called PEEKplus that is modified by ANAB through an agreement with Exogenesis.

In addition to treating the surface of PEEK implants, manufacturers have changed the polymer mix to promote bone growth. PEEK is currently available with integrated hydroxyapatite (HA). HA is the same mineral that makes up most of bone. Studies in sheep have shown increased bone ongrowth compared to PEEK alone.

The most recent PEEK composite to reach the market is Zfuse from DiFusion Technologies. The Xiphos interbody device was cleared for use in the US in November 2019. The material is made of PEEK and zeolite, an aluminosilicate mineral that is negatively charged and hydrophilic. Initial research shows greater ongrowth and ingrowth of bone. Research presented at the 2019 NASS annual meeting suggests that the material discourages the fibrous encapsulation typical of standard PEEK and encourages a favorable shift in the phenotype of macrophages to an anti-inflammatory state.

In our Q4-2019 survey, 89 percent of surgeons responded that
material and surface texture were of high importance when selecting an interbody device. Porosity was highly important to just over 75 percent of respondents.

History of Interbody Device Materials

The implants we have today are much more advanced than those used by Berthold Hadra, a surgeon in Austin, Texas, who took the first step into instrumented spinal fusion in 1891. He used silver wire to fixate the interspinous processes of a patient with a dislocated cervical spine fracture. The patient improved slightly, and the process was repeated for patients with tuberculosis-related fractures in the spine, known as Pott’s disease. Further attempts to fixate using steel rods and autograft were conducted in the early 20th century.

The metals—typically steel—used in the 1920s to fixate the spine suffered from corrosion issues. The first step in advancing material science’s role in spine surgery came with the adoption of vitallium, an alloy used in dentistry for its corrosion resistance.

Early documentation of interbody fusion includes a 1944 study by Henry Briggs and Paul Milligan. The authors describe a posterior lumbar interbody fusion (PLIF) technique used in 70 patients. The procedure included locally harvested autograft and partial removal of lamina and facets to access the disc space. Discectomy was performed, and a bone peg was inserted in the intervertebral space. Iliac autograft was also used when needed.

One of the first interbody cages not made of allograft was the Bagby Bone Basket, a fenestrated stainless-steel cylinder. It was first used to treat wobbler syndrome in horses by fusing the cervical spine with an anterior procedure.

George Bagby presented his work at the 1984 NASS annual meeting. A modified version of Bagby’s device was made of titanium before it was used in humans in 1992. However, titanium and stainless steel showed incompatibility with MRI and CT imaging; artifacts from the metal made visualization of soft tissues very difficult. Additionally, subsidence has been an issue with inflexible materials like titanium, which leads to failure.

The shortcomings of titanium and stainless steel gave way to the use of polyether ether ketone (PEEK) for spinal fusion in the 1990s. Its biocompatibility, elasticity, and radiolucency made it an attractive alternative to metal implants.

Since the adoption of PEEK as a material for interbody devices, only 3D-printed titanium has made a notable impact on the market. Most of the largest manufacturers now offer devices made of 3D-printed titanium.

While many new materials will not gain market traction, a few may generate sufficient evidence to encourage evaluation of current paradigms. The manufacturer of the next adopted material stands to gain substantially; even a small share of the $4.7 billion interbody device market is significant.

Study Suggests Biofilms Corrode Titanium Spine Implants

A study by Ayers, PhD, et al. in the journal Orthopedics examined 60 explanted titanium spine implants for evidence of corrosion associated with biofilms. Areas of the implants with biofilm had significantly more corrosion pits, while areas with mechanical wear but no biofilm had few or no pits. The authors concluded that further analysis of the microbiomes is necessary, but that local microbiome films should be considered as a potential cause of implant corrosion.

Preservation of Posterior Tibial Slope Leads to Better Clinical Outcomes in Study

A study published in January in the journal Orthopedics demonstrated that maintaining a patient’s natural posterior tibial slope improves TKA outcomes. Howard et al. examined radiographic and clinical outcomes of 215 consecutive TKAs using the same implant.

One group of patients received an arbitrary posterior slope (3–5 degrees), while the other group had their slopes measured with lateral radiographs and mimicked during implant placement. Patients with a prosthetic slope within 3 degrees of their natural slope had better range of motion and functional outcome scores (WOMAC, SF-12).
Active Implants

(continued from p. 1)

Active Implants, about the company’s current and future plans.

Surgeons who adopt NUface are trained in the procedure. Klyce said the biggest difference for surgeons is removing nearly all of the menisci; typically, they either take as little as possible or remove the entire anatomy for a TKA. It is crucial that surgeons leave the horns and the rim to accommodate space for the implant.

In the hands of an experienced surgeon an initial NUface placement surgery usually takes about one hour and requires a two- to three-inch arthrotomy incision to accommodate the implant. The patient’s natural meniscus is removed almost completely, except for the rim and anterior and posterior “horns,” which keep the implant in place. The manipulation required to place the implant sprains the joint, which is healed through physical therapy postoperatively. Patients are ambulatory right after surgery and can return to normal activities in six weeks.

If a patient needs a replacement for his or her NUface, the exchange procedure is easier than the initial placement. Klyce said the procedure takes only about 30 minutes, and the patient is able to return to normal activities in about two weeks. The difference is that the patient’s knee ligaments adjusted to the height of the implant when it was initially replaced, so the sprain is less severe the second time. The implant can be replaced as many times as it needs to be to prolong or prevent knee replacement surgery.

By preserving key components of the patient’s anatomy, the NUface implant is held in place without sutures. According to Klyce, the implant was sutured in early-stage ovine models, but the outcomes were not as favorable as the free-standing implants.

Currently, the NUface is only made for medial meniscus replacement. Forces placed on the lateral meniscus are more complex than those placed upon the medial; Klyce compared it to the amount of motion in the cervical spine versus the lumbar. Active Implants does plan to have a lateral meniscus implant in the future, but the current push is to get the medial implant on the global market. According to Klyce, nearly seven out of 10 meniscus procedures are performed on the medial aspect.

Thus far, NUface has been used in two clinical trials: VENUS and SUN. Results from these two studies are being pooled for analysis. There are three NUface patients for every control patient in the pool. Those in the control group received injections until 18 months into the 24-month study. An analysis of 100 patients was presented by Wayne Gersoff, MD, at the Deutscher Kongress für Orthopädie und Unfallchirurgie in Oct. 2019. At the six- and 12-month assessment, patients with the NUface implant had statistically significant improvement in KOOS pain scores compared with the control group. Klyce said the FDA pays closest attention to Knee Injury and Osteoarthritis Outcome Scores (KOOSs) for pain and overall improvement. Active Implants has set 20 points of improvement over baseline as its measure of clinical success for the NUface therapy.

For now, NUface trial patients must have prior meniscus surgery to qualify for the study. The company hopes that NUface will eventually become a first-line treatment for meniscus pain and tears, but it seeks to gain approval as a revision treatment for now. Klyce mentioned that approximately 1 million patients receive a meniscectomy every year and 150 thousand annually progress to become NUface candidates.

Active Implants is hoping to submit its FDA de novo application in mid-2020 after the last SUN trial patients have their two-year follow-up exams. Klyce mentioned that the implant’s breakthrough status has meant many meetings with the FDA over the past years; he is hopeful that the de novo will be approved quickly because many details of the implant have already been discussed.

Active Implants received CE marking for NUface in 2008, and the device was approved in Israel in 2011. Since then, the company has been seeking approvals and reimbursement in many other countries. Surgeons in Germany and the Lombardy province of Italy adopted the
Royal Biologics announced Jan. 9 that it has launched Magnus, a spine-derived cellular bone allograft, that is preserved in DMSO-free cryoprotectant. Results from a recent study showed 96 percent fusion among 75 patients who received Magnus during transforaminal lumbar interbody fusion surgery. Scendia Biologics also sells a DMSO-free allograft, which was covered in the December 2019 issue of this publication.

Coronavirus Likely to Have Short-Term Impact on Market

By Mary Haller and Dave Harmon

As of Feb. 12, there were over 45 thousand confirmed cases of the 2019 Novel Coronavirus (2019-nCoV) around the world. The WHO declared a Public Health Emergency of International Concern on Jan. 30.

Regulatory attempts to quarantine exposed travelers have increased, as have attempts to halt travel to affected areas. While the immediate health concerns posed by the coronavirus may impact medical markets such as orthopedics, these effects will likely dissipate once the outbreak is controlled.

2019-nCoV has been identified as a betacoronavirus, the same type of virus as MERS and SARS. It likely emerged from an animal population, but it is now being spread between humans.

Scientists are scrambling to develop antiviral treatments for 2019-nCoV, but drug development, trial, and approval is a slow process. In the meantime, doctors are using treatments for other viruses such as HIV and providing palliative care for the symptoms of the virus.

Market Scope estimates that China accounts for roughly 6 percent of orthopedic industry revenues. Wuhan and the surrounding area are small portions of the total Chinese market; although local market disruption may be significant, the impact on the global orthopedic industry is insignificant for now.

So far, there is little mention of the virus in quarterly earnings calls, but the story is rapidly unfolding. The biggest concern for the medical device industry is the diversion of resources from elective surgery to screening and care of coronavirus sufferers.

Wells Fargo published a summary of its Feb. 3 consultant call about the virus’ impact on medical device, life science tools, and diagnostic industries. Analysts expect that non-urgent and elective medical procedures will be postponed until the outbreak is under control; however, a catch-up period is likely to happen later in the year. Wells Fargo’s consultant said travel bans and other mandates may cause a potential shortage in medical devices, as well.

The 17th Hong Kong International Orthopaedic Forum and other conferences are being postponed until the outbreak is controlled. Market Scope views the Chinese market as resource constrained without the ability to catch up in the near term. Postponed elective surgeries will likely become missed opportunities. Nonetheless, the Chinese market is a small portion of the overall orthopedic market. While the virus will have short-term impacts on orthopedic business, the outbreak will likely be controlled before long-term implications form.

 Orthopedic Market Perspectives

Orthopedic News

As of Feb. 12, there were over 45 thousand confirmed cases of the 2019 Novel Coronavirus (2019-nCoV) around the world. The WHO declared a Public Health Emergency of International Concern on Jan. 30. Regulatory attempts to quarantine exposed travelers have increased, as have attempts to halt travel to affected areas. While the immediate health concerns posed by the coronavirus may impact medical markets such as orthopedics, these effects will likely dissipate once the outbreak is controlled. 2019-nCoV has been identified as a betacoronavirus, the same type of virus as MERS and SARS. It likely emerged from an animal population, but it is now being spread between humans. Scientists are scrambling to develop antiviral treatments for 2019-nCoV, but drug development, trial, and approval is a slow process. In the meantime, doctors are using treatments for other viruses such as HIV and providing palliative care for the symptoms of the virus. Market Scope estimates that China accounts for roughly 6 percent of orthopedic industry revenues. Wuhan and the surrounding area are small portions of the total Chinese market; although local market disruption may be significant, the impact on the global orthopedic industry is insignificant for now.

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$695 Million in Disclosed Deals Announced Since Mid-December

By Mary Haller

Twelve noteworthy deals were announced between mid-December 2019 and mid-January 2020. Six of these did not disclose amounts. The largest disclosed amount by far was RTI’s sale of its OEM business to a private equity firm for $490 million. In addition, there were seven other acquisitions, two rounds of private funding, one minority investment, and one grant from the Defense Advanced Research Projects Agency (DARPA).

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<thead>
<tr>
<th>Date</th>
<th>Company</th>
<th>Amount</th>
<th>About</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/17</td>
<td>Parvizi Surgical Innovation</td>
<td>Not disclosed</td>
<td>Philadelphia-based Parvizi Surgical Innovation announced a minority investment in Navbit Holdings, an orthopedic device company that is developing a disposable navigation system for acetabular cup placement during THA. The device is called the Navbit Sprint, and it is designed to lower post-op dislocation rates. The amount of the investment was not shared.</td>
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<tr>
<td>12/18</td>
<td>BioPoly</td>
<td>$2.9M</td>
<td>BioPoly, a manufacturer of cartilage replacement material for joint resurfacing, received $2.89 million in an oversubscribed round of private equity funding. The initial offering was for $2 million. Funds will be used to bring the product to the US market and launch an expanded line in Europe.</td>
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<tr>
<td>12/18</td>
<td>Conventus Orthopaedics, IntraFuse</td>
<td>Not disclosed</td>
<td>Conventus Orthopaedics acquired IntraFuse for an undisclosed amount. IntraFuse’s FlexThread intramedullary implants are used for minimally invasive fracture repairs. This gives Conventus its first lower extremity products.</td>
</tr>
<tr>
<td>12/20</td>
<td>Naviswiss</td>
<td>$5M</td>
<td>Naviswiss, a provider of miniature surgical navigation for joint replacement, closed a $5 million round of private equity funding. The funds will be used for product development and market-entrance costs in the US and Japan.</td>
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<tr>
<td>12/20</td>
<td>Stryker, ZipLine Medical</td>
<td>Not disclosed</td>
<td>Stryker acquired ZipLine Medical in late December for an undisclosed amount. ZipLine Medical created the Zip surgical skin closure system, which was outlined in the June 2019 issue of this publication. This deal was not publicized, but the ZipLine website now states that the company is part of Stryker.</td>
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<td>1/6</td>
<td>OrthoPediatrics, Vilex</td>
<td>Not disclosed</td>
<td>OrthoPediatrics sold the assets of the adult orthopedic products of Vilex in Tennessee to Vilex, LLC, for an undisclosed amount. Vilex was also granted license to manufacture and sell products with external fixation technology developed by Orthex (OrthoPediatrics affiliate). OrthoPediatrics acquired Vilex in Tennessee and Orthex in June 2019 with plans to divest the adult business. OrthoPediatrics focuses solely on pediatric applications.</td>
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<tr>
<td>Date</td>
<td>Company</td>
<td>Amount</td>
<td>About</td>
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<tr>
<td>1/6</td>
<td>Anika Therapeutics, Parcus Medical, Arthrosurface</td>
<td>Up to $195M</td>
<td>Anika Therapeutics announced two acquisitions: Parcus Medical for $35 million up front with up to $60 million in contingent payments and Arthrosurface for $60 million with $40 million in contingent payments. Collectively, the two companies were expected to generate roughly $41 million in revenue for the full year of 2019. In addition to its existing joint preservation and regenerative therapies, Anika will now offer shoulder, knee, hip, and distal extremity products for outpatient surgery and surface implants for knee, shoulder, hip, and extremities. The executive teams of both companies will join Anika and continue to lead their respective businesses. Anika will also gain approximately 40 direct sales representatives, 150 US distributors, and 70 international distributors.</td>
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<tr>
<td>1/7</td>
<td>Johnson &amp; Johnson, Verb Surgical</td>
<td>Not disclosed</td>
<td>Johnson &amp; Johnson entered an agreement to acquire the remaining ownership stake of Verb Surgical, a technology company developing an end-to-end platform for surgery. The platform will include robotics, instrumentation, navigation, and data analytics. The financial details of the transaction were not disclosed.</td>
</tr>
<tr>
<td>1/9</td>
<td>Medtronic, Stimgenics</td>
<td>Not disclosed</td>
<td>Medtronic acquired Stimgenics, developers of a novel spinal cord stimulation (SCS) platform, for an undisclosed amount. Stimgenic’s SCS waveform is called differential target multiplex (DTM); it is designed for patients with chronic pain. A recent study of this technology can be found on p. 11.</td>
</tr>
<tr>
<td>1/13</td>
<td>RTI Surgical</td>
<td>$490M</td>
<td>RTI Surgical is selling its OEM business to Montagu, a European private equity firm, for $480 million in cash and $10 million in additional considerations. This sale will make RTI a pure player in the spine business. After closing, the OEM business will contractually develop and manufacture certain products for RTI.</td>
</tr>
<tr>
<td>1/16</td>
<td>Embody</td>
<td>$2.5M</td>
<td>Embody, a soft-tissue repair company, received a $2.5 million grant from the Defense Advanced Research Projects Agency (DARPA). The firm will use the money to develop its Microbrace ACL technology. Microbrace uses collagen microfiber technology to repair the ACL and provide a 3D structure for regrowth. Once the Microbrace is commercialized, the company will apply the collagen technology to other soft tissue applications.</td>
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that procedures grew during the quarter compared with Q4-2018, and the remaining 7.5 percent reported a decline in volume. On average, those reporting increases in volume said that procedures were up 6.6 percent, while those reporting declines said procedures were down an average of 0.7 percent.

Survey respondents said primary total knee arthroplasty accounted for 78.4 percent of all procedures in Q4-2019, which is down slightly from 78.9 percent in Q4-2018. Primary unicompartmental knee arthroplasty accounted for 8.4 percent of procedures, which is up from both Q4-2018 (8 percent of procedures) and Q4-2017 (7.7 percent of procedures).

Respondents said revisions totaled 10.2 percent of procedures, and patellofemoral joint resurfacing procedures accounted for 3 percent.
Hip Arthroplasty

US hip surgeons reported a 5 percent growth in hip arthroplasty during Q4-2019 compared with Q4-2018 and a 7.9 percent increase compared with a seasonally weaker Q3-2019. We estimate that US hip procedures grew 4 percent for the full year 2019 and that nearly 448 thousand hip arthroplasties were performed in 2019.

Respondents reported an average of 70.1 procedures during Q4-2019. Almost 53 percent of surgeons reported less than 50 hip arthroplasties during the quarter. Roughly 38 percent performed more than 50 and less than 200, and 8.8 percent said they performed more than 200. Many hip surgeons also offer knee arthroplasty or other orthopedic surgery.

Survey respondents said primary total hip arthroplasty accounted for 80.6 percent of all hip procedures in Q4-2019, which is down slightly from 80.7 percent in Q4-2018. Hemiarthroplasty accounted for 8.3 percent of procedures; this is roughly the same as last year.

Shoulder Arthroplasty

Shoulder arthroplasty is the fastest-growing orthopedic procedure category in the US. Surgeons reported 5.8 percent growth in Q4-2019 when compared with Q4-2018 and 9.9 percent growth compared with a seasonally weaker Q3-2019. Market Scope estimates that almost 132 thousand shoulder arthroplasty procedures were performed in 2019, which represents 5 percent growth from 2018.

More than 60 percent of shoulder surgeons reported that their Q4-2019 procedure volumes were higher than last year, and the remaining 40 percent reported that procedure volumes were the same. No respondents reported a decline in procedures.

Respondents said revision procedures accounted for 9.9 percent of all procedures. Hip resurfacing accounted for just over 1 percent of procedures.

(continued on next page)
OrthoSensor specializes in sensor-assisted technology, and McLaren Applied is known for electronic systems and machine learning. These two companies announced Jan. 10 that they are creating a joint venture called EnMovi Ltd. EnMovi will focus on products combining wearable patient technology, such as MotionSense, and cloud-based data analytics, such as OrthoLogIQ, to provide better care for surgical orthopedic patients.

**Economic Trade Agreement Between US and China Includes Biologics**

The US and China entered a new trade agreement on Jan. 15 that is designed to protect intellectual property rights. Counterfeit pharmaceuticals were included in the agreement: “The parties shall take effective and expeditious enforcement action against counterfeit pharmaceutical and related products containing active pharmaceutical ingredients, bulk chemicals, or biological substances.”

**Medtronic Issues Field Safety Notice for Mazor X Positioner**

Medtronic issued a field safety notice Jan. 7 for its Mazor X surgical system with Positioner Type II latching device. The positioner, which locks onto the OR table through a pneumatic system, may loosen over time and detach from the table due to a slight air leak. The company has received seven complaints of unexpected release as of November 2019.

**Q4-2019 Arthroplasty Surgical Location**

- **Inpatient Hospital**: 78.4%
- **Outpatient Hospital**: 12.5%
- **Independent ASC**: 9.1%

**Q4-2019 Change in Shoulder Procedures by Doctor**

- **Increased 60%**
- **Same as Last Year 40%**
Brexit: Jan. 31, 2020

The United Kingdom (UK) will be leaving the European Union (EU) on Jan. 31; it joined in 1973. However, the two groups have until Dec. 31, 2020, to hammer out the details of their new relationship. Trade agreements, law enforcement, utilities, and more will need to be settled. If the UK and EU cannot decide upon a free trade agreement during the transition period, the UK’s goods may be subject to tariffs.

According to the withdrawal agreement, the UK will be free to negotiate its own trade deals with other countries, and the UK will pay roughly £30 billion to the EU. During the transition period, the UK will follow EU rules.

DTM Stimulation Provides Superior Relief in Medtronic Study

Medtronic announced Jan. 21 that results of a randomized controlled trial were published, comparing conventional spinal cord stimulation (SCS) with Differential Targeted Multiplexed (DTM) SCS. Patients in both arms of the study received stimulation with Medtronic’s Intellis platform; 94 patients were included in the results.

After three months, 80 percent of patients receiving DTM stimulation reported a greater than or equal to 50 percent reduction in their pain as measured by VAS. Comparatively, only 51 percent of patients receiving conventional stimulation achieved this result.

Oscocimab May Provide Another Treatment Option for Thromboprophylaxis

Most patients undergoing joint replacement are given anticoagulants to prevent blood clot formation after surgery (thromboprophylaxis). A recent study, published in JAMA on Jan. 14, compared osocimab with commonly used anti-clotting drugs enoxaparin (Lovenox) and apixaban (Eliquis). Oscocimab is a human monoclonal antibody that inhibits factor XIa in the coagulation cascade; it is being developed by Bayer.

The study included 600 patients who underwent knee replacement and received osocimab, enoxaparin, or apixaban to prevent clotting. The primary outcome was venous thromboembolism incidence from 10 to 13 days after surgery. Three of the postoperative doses of osocimab (0.6, 1.2, and 1.8 mg/kg) met the noninferiority criterion (5 percent margin) compared with enoxaparin. Jeffrey Weitz, MD, et al. concluded that further study is needed to establish the safety and efficacy of osocimab compared to traditional treatments.

KiOmed Pharma’s OA Injectable Receives CE Mark, Company Signs Distribution Agreement

KiOmed Pharma, a provider of animal-free therapeutic solutions for patients with high-impact pathologies, announced Jan. 23 that its single-injection implant for knee OA pain received CE marking. The injectable implant is designed to lubricate damaged cartilage and preserve remaining synovial fluid by combatting free radicals. The product is based on KiOmedicine, an animal-free, bioresorbable polymer.

The company also said it signed a collaboration agreement with TRB Chemedica for exclusive marketing and distribution rights to the product in select markets.
Orthopedic US FDA 510(k) Clearances

By Adam Suhy, PhD

During the past month, the FDA cleared 44 orthopedic medical devices through the 510(K) pathway. One-third (15) of the devices are for spine, another nine are indicated for extremity fixation, and seven are for soft tissue repair.

Cutting Edge Spine received clearance for a lateral interbody device to complement its portfolio of HA-enhanced PEEK interbody devices. Additionally, Nexxt Spine received clearance for one of its Nexxt Matrixx interbody devices as well as the TrellOss-L MPF. The TrellOss line has been marketed by Zimmer Biomet, but this marks the first clearance for the line of interbody devices in the US.

Five of the approved spine implants are rod and screw systems. The remaining 10 spine implants are interbody devices. Navigated instruments for Osseus Fusion Systems’ Black Diamond pedicle screw system were cleared, as well.

An additional 27 orthopedic devices were cleared in the last month. These include six hip devices, two shoulders, one knee, one elbow, and one bone wedge for foot, ankle, or tibial use.

The Avenger radial head system from In2Bones marks the company’s first clearance of an elbow replacement device. Another update to the Persona Personalized knee system from Zimmer Biomet gained clearance. Both shoulder implants are manufactured by Arthrex.

As of Jan. 26, the FDA has cleared 29 devices in 2020. This is significantly less than the 47 devices that received clearance during the same period last year.

Review of 2019

Despite the government shutdown that started in late 2018 and lasted for five weeks, the number of orthopedic clearances in 2019 outpaced those in 2018. The final count of the orthopedic devices that we track was 575 in 2019.

It is possible that the threat of the government shutdown encouraged earlier submissions and resulted in increased clearances early in the year.

### Year-Over-Year Comparison

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<td>0</td>
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<td>3</td>
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<td>Biologics</td>
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<td>Soft tissue</td>
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<td>0</td>
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<td><strong>Total</strong></td>
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- **Spine, 15**
- **Biologics, 1**
- **Imaging/Nav., 1**
- **Other, 27**
- **Fixation, 9**
- **Soft tissue, 7**
- **Hip, 6**
- **Shoulder, 2**
- **Knee, 1**
- **Other Ortho, 1**
- **Elbow, 1**
Orthopedic Market Perspectives

**FTC Takes a Closer Look at Proposed Stryker, Wright Merger**

The US Federal Trade Commission (FTC) is taking a closer look at the proposed merger between Stryker and Wright Medical; the commission’s concerns were outlined in a Jan. 2 SEC filing.

Stryker announced Nov. 4 plans to acquire Wright Medical for $4.7 billion cash. Both Stryker and Wright received second requests from the FTC; these procedures are used to further investigate mergers that may have anti-competitive implications. With this delay, the companies expect the deal to close in the second half of 2020.

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**Exactech Names Johnson New CEO**

Exactech, a Florida-based orthopedic implant company with solutions for extremities, knees, and hips, announced Jan. 7 that Darin Johnson will be taking David Petty’s place as president and CEO. Petty was the first official employee of the company, and he has served as CEO since 2014. After the transition, he will become vice chairman of the board.

Johnson has been part of the company since 2002 and was most recently the senior vice president of extremities.

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**ContraFect’s Exebacase May Eradicate Persistent Prosthetic Joint Infections**

ContraFect Corporation announced Jan. 13 that it received Temporary Authorizations for Use (ATUs) from the French National Agency for Medicines and Health Products Safety to administer exebacase to four patients with chronic post-op prosthetic joint infections. Exebacase is a clinical-stage, lysin-based direct lytic agent that is designed to treat persistent joint infections.

Exebacase has already completed a Phase II clinical trial for *Staph aureus* bacteremia in the US; it is the first lysin to undergo clinical testing in the US. ContraFect is currently planning a Phase III trial to support an FDA Biologics License Application (BLA).

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**geko Device Is Designed to Reduce Post-Surgical Edema**

Sky Medical Technology, based in England, has FDA approval for its geko device.

The device is designed to prevent lower limb edema after joint replacement surgery by stimulating the common peroneal nerve. This triggers blood flow in the calf and foot, preventing fluid buildup and venous thromboembolism (VTE).

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**Bone Biologics’ rhNELL-1 Promotes Bone Formation in Preclinical Study**

rhNELL-1, a recombinant human protein growth factor, effectively promoted bone formation in a pre-clinical ovine study, Bone Biologics announced Jan. 7. The treatment was well-tolerated by the subjects, and there were no findings of inflammation.

Bone Biologics will be conducting a human trial of 30 patients in Australia to evaluate the safety and efficacy of rhNELL-1. Selected patients undergoing TLIF surgery must have degenerative disc disease in one level between vertebrae L2-S1, and they may also have Grade I spondylolisthesis or retrolisthesis.

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**FDA Warns Conformis Over Sterility**

The FDA released a warning letter that it sent to Conformis on Dec. 10. The agency said Conformis failed to maintain good manufacturing practices and sufficiently fix sterilization issues regarding its knee implants.

Conformis insisted in its Dec. 17 SEC filing that cycle failures of its Vaporized Hydrogen Peroxide (VHP) sterilizers do not compromise the sterility of its final products. The company announced plans to decommission all of its VHP sterilizers and said it requested FDA approval to use a new sterilization unit.
**Orthopedic Market Perspectives**

**RTI’s Tetrafuse PEKK Achieves Positive Preclinical Results**

Preclinical results for RTI Surgical’s Tetrafuse PEKK (polyetherketoneketone) material in an ovine model were announced Dec. 17. PEKK implants were found to have significantly greater bony apposition and pushout strength after fusion compared with PEEK.

The material was also compared with titanium-coated PEEK and found to have significantly greater implant integrity and radiographic properties. The company has sold over 5 thousand implants made with Tetrafuse in the US as of June 2019.

**InfuTronix Pump Controls Post-Op Pain After Extremity Surgery**

Patients who underwent upper or lower extremity surgery and who were given a Nimbus II PainPro infusion pump from InfuTronix Solutions achieved positive results, confirmed a study Dec. 19. The Nimbus II PainPro is an infusion pump that administers a non-narcotic local anesthetic through a peripheral nerve catheter. The pumps provided patients with intermittent drug boluses and offered additional boluses as needed.

The study, conducted at the University of Pittsburgh Medical Center, found that patients given the pump for three days post-op felt that their pain was controlled; satisfaction ratings averaged 9.4 out of 10. After the pump was removed, however, pain and opioid use increased, suggesting that longer treatment with the pump is warranted.

**FDA Announces New Commissioner**

Stephen Hahn, MD, was sworn in as the 24th commissioner of the FDA on Dec. 17. Hahn replaces Scott Gottlieb, MD, who resigned in April 2019.

Hahn is an oncologist; he completed a residency and a fellowship in medical oncology at the National Institute of Health’s National Cancer Institute and earned the rank of commander in the US Public Health Service Commissioned Corps. Most recently, he served as the chief medical executive at The University of Texas MD Anderson Cancer Center.

**RTI Surgical’s Symmetry System Gains Cigna Coverage**

RTI Surgical announced Dec. 16 that Cigna has issued a positive coverage policy for sacroiliac joint fusion using all FDA-cleared devices, including RTI’s Symmetry system. RTI obtained Symmetry through its acquisition of Zyga Technology in early 2018.

Other SI fusion devices cleared for use in the US include Orthofix’s Sambascrew, SI-Bone’s Ifuse, Globus Medical’s Si-Lok, and Rialto from Medtronic. Over a dozen SI joint fusion devices have been cleared.

**Zebra Medical Vision Signs Co-Development and Commercialization Agreement With DePuy**

Israel-based Zebra Medical Vision announced Dec. 19 that it has entered an agreement with DePuy Synthes to integrate its artificial intelligence with orthopedic imaging. Zebra’s deep-learning technology creates 3D models from X-ray images. This would lower the cost of pre-surgical planning, which traditionally involves CTs or MRIs.

DePuy plans to introduce Zebra’s system as part of the VELYS Digital Surgery platform, which provides patient solutions and optimization, surgical planning, surgical implementation, and post-op monitoring.

**RSIP Vision Releases AI-Based Shoulder Replacement Planning Solution**

RSIP Vision announced Jan. 28 that its new shoulder replacement solution will integrate with existing planning programs and provide surgeons with a 3D anatomical joint model. The company claims that the program will dramatically improve surgical planning capabilities and decrease the risk of complications by allowing surgeons to have a more accurate idea of how the patient’s shoulder will respond during surgery.
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Underlying Market Scope’s estimates and forecasts is a detailed analytical model that includes doctor surveys and other primary market research data, disease models, insurance and public health system data, proprietary Market Scope databases of doctors and surgery centers, and manufacturers’ financial reports. Each data set provides part of the story; data synthesis and triangulation provide a complete view of the market.

Available Reports

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- Hip Arthroplasty Market
- Interbody Device Market
- Knee Arthroplasty Market
- Spine Biologics Market
- Spine Neuromodulation Market
- Spine Surgery Market

Upcoming Reports

- Spine Fixation Market
- Shoulder Arthroplasty Market


Hip arthroplasty—including primary THA, revision THA, and hemiarthroplasty—is a major revenue component of the orthopedic market. Global demand for these procedures is rising alongside expanding elderly population segments and increased access to care in historically underserved countries. New technology and innovative implant designs promise to shift the cost-benefit ratio of the procedures, which coincides with pressure from global health care system to decrease costs.

This report provides an in-depth analysis of the global hip arthroplasty market with forecasts through 2024. It is designed for manufacturers, providers, market analysts, and investors who are interested in the hip arthroplasty market and related products.

Key topics include:

- Hip pain and surgical trends
- Surgeons by region
- Facilities providing hip arthroplasty
- Economics of hip surgery
- Leading implant designs and pipeline products
- Profiles of top manufacturers

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