DT MedTech Takes on the US Total Ankle Market With Hintermann Series H2®

DT MedTech's H2 total ankle replacement (TAR) system is the newest entrant into the fast growing US TAR Market, which is projected to reach $222MM by 2022 according to SmartTRAK estimates.

By Don Urbanowicz, Urbanowicz Consulting

Don Urbanowicz, Principal of Urbanowicz Consulting LLC, discusses drivers in the fast growing US Total Ankle Replacement (TAR) market and profiles DT MedTech, LLC's Hintermann Series H2® and Hintermann Series H3™ Total Ankle Replacement Systems in an interview with Professor Beat Hintermann, Chairman of the Clinic for Orthopaedics and Traumatology at Kantonsspital Liestal (Switzerland) and Associate Professor at University of Basel, and David Reicher, CEO of DT MedTech.

SmartTRAK's View of the US Total Ankle Replacement Market:

- The US Total Ankle Replacement (TAR) Market, valued at ~ $100 million in 2017, is expanding at an accelerated rate and is expected to reach nearly $222 million by 2022 with a CAGR of 17.5%.
- Newer, next-generation implants – including options for revision total ankle replacement – are driving increased utilization of TAR. Surgeons who were once reluctant to perform ankle replacement surgery are becoming more open to the procedure, given the availability of revision implant options to address failed primary ankles.
- Clinical results, proving survivorship of next-generation implants and revision TAR options, will be key to sustaining growth in this market segment over the next five years. In August of 2017, CMS moved all TARs to DRG 469 and set reimbursement at $19,296 for procedures in 2018 (roughly a $7,000 increase), which is also expected to expand growth in this market.
- Increased surgeon education programs have driven awareness and greater acceptance of ankle replacement as a treatment option among both orthopaedic and podiatric surgeons.
- Patients are becoming more aware of ankle replacement as a treatment option for end-stage ankle arthritis, as physicians and manufacturers engage in patient awareness campaigns.
- The introduction of new implants, including revision ankles, will drive modest ASP increases since newer products will be introduced at higher price points.
- In 2017, Wright (57.7%), Stryker (22.6%) and Integra (16.8%) comprised over 97% of the US TAR Market. DT MedTech is the newest entrant to the US TAR Market with its Hintermann Series H2 ®TAR System.

The Interview: Hintermann's and Reicher's View of the Hintermann Series H3™ and Hintermann Series H2® Systems

Don Urbanowicz: Professor Hintermann and David, thank you for joining me and congratulations on receiving FDA 510(k) clearance on the Hintermann Series H2® two-piece, semi-constrained total ankle replacement system (H2). I'd like to ask a few questions pertaining to both the Hintermann Series H3™ three-piece, mobile-bearing total ankle replacement system (H3) and the H2 system. Beat, allow me to start with you. Please briefly describe the H3 and its design concept.

Beat Hintermann: The H3 is an uncemented, unconstrained, mobile-bearing, three-component system that includes two metallic components and a polyethylene (PE) mobile-bearing insert. With its flat second interface, the mobile bearing provides (in addition to normal flexion-extension mobility) free medio-lateral, antero-posterior, and rotational motion, bounded and stabilized by the malleoli and ligaments. The non-articulating, bone-contacting surfaces have a porous coating of titanium plasma spray and hydroxyapatite.

The design concept is anatomic, including flat resurfacing of the tibia, anatomical resurfacing of the talus, and an insert with minimal thickness. We have found over many years that this combination results in a stable implant and a stable interface.

I would like to add that the polyethylene mobile-bearing inlay, while providing axial rotation, translational movement, physiological flexion, and extension mobility, also intrinsically stabilizes the talus against inversion and eversion. With this, it mimics the ankle joint more closely than any other total ankle available in the marketplace. This prosthesis may, therefore, be used for treatment of major coronal plane deformities and as a salvage of failed ankle replacements where remaining bone stock and ligament support are critical. In contrast to other ankle systems, the H3 does not use intramedullary fixation of its tibial component, but rather presents a flat, anatomically-conforming component that fully supports the resection area. This concept has been proven to provide the most physiological load transfer between the implants and bone, which in turn may result in optimal component stability over the long term.

Finally, it was important to provide a complete system. The H3 is a primary as well as a revision system, providing a range of components for either indication. The H3 has been implanted outside of the US for 15 years, but currently the device is not available for sale or distribution inside the US.

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Don: Tell us about the most recent design evolution of the H3.

Beat: After a pilot study, pegs were added to make the insertion of the talar component more reliable and to provide greater stability. We also added the double-coating of plasma titanium spray and hydroxyapatite. For 15 years, the current H3 has remained unchanged and has yielded a survival rate of ~94% at 10 years.

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Don: What more can you tell us about the H3 clinical results?

Beat: After 15 years, the patient results with the H3 are very encouraging and support the safety and efficacy of the product. It's important to understand that the results reported by non-conceptor studies are similar to those of conceptor studies, indicating that the H3 ankle is a reliable solution for successful replacement of the osteoarthritic ankle. In particular, the H3 ankle has been shown to enable a surgeon to successfully replace the malaligned ankle, which allows for an extension of indications. The unique design also enables the surgeon to successfully revise a failed total ankle replacement and to revise a failed or painful ankle arthrodesis to a functional total ankle replacement.

David Reicher: Don, let me add something, since I think Beat has understated the excellent long-term clinical results with the H3. The proof of a successful implant is the survival rates, which in essence correlate to patient outcomes. All physicians desire and expect the best outcomes for their patients, and the H3 has delivered on that expectation. But, another important aspect of the design is that there is very little stress shielding. This has been verified by histological evaluation of implants which have been explanted from

patients due to amputation–not failures or death. The H3 also allows for earlier ambulation and weight-bearing due to bone-implant contact surfaces being parallel. Earlier ambulation and weight-bearing advantages include less atrophy of the muscles, better vascular flow, and loaded apposition of the bone-implant interface.

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Don: Thank you, David. Beat, what specifically are the indications for the H3?

Beat: The indications are broad. Aside from the standard primary osteoarthritis (OA) indication, the H3 has been successfully used outside of the US in patients to treat post-traumatic OA, systemic OA, secondary OA due to limited (< 2/3) avascular necrosis, as a salvage for failed ankles and painful fusions, and to manage instability and malalignment of < 40 degrees of varus and < 20 degrees of valgus.

Don: David, when did you first meet Professor Hintermann and what were your initial impressions?

David: It was at the 2011 AAOS Annual Meeting, and I was asked to assist Beat with a business matter. As you are aware, Beat is a prolific writer, and I had read many of his previously-published articles to prepare for the meeting. He impressed me with his passion for improving patient quality and outcomes. I also discovered that Beat has developed an incredible clinical database while documenting every total ankle he has ever performed. And, setting this clinical and technical passion aside, Beat is authentic to his core and soft-spoken – a true gentleman, a true physician, a true scientist, and an inspired inventor.

Don: David, when did DT MedTech acquire the Hintermann portfolio of lower extremity foot and ankle products, and how is DT MedTech funded?

David: DT MedTech acquired the Hintermann portfolio in May of 2015, and it is virtually self-funded. We currently have a great team of employees from our Data Trace Companies, complemented by fully dedicated independent experts.

Don: David, please tell us about the commercial success of H3 and which countries have the strongest H3 presence.

David: We calculate that over 25,000 Hintermann Series H3™ three-piece total ankles have been implanted in markets outside the US since its introduction 15 years ago. The H3 is either the #1 or #2 total ankle prosthesis in the markets in which it is sold outside of the United States...As such, resultant sales are strong – the first quarter of 2018 saw a revenue increase of over 60% compared to the same period in 2017.

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Don: What is the US regulatory status of the H3?

David: Don, I'll answer this way– our objective is to commercialize the H2 and the H3 in as many countries as is economically feasible, and that will eventually include the US. But, the H3 has not yet been approved by the FDA for sale, use or distribution in the United States.

Don: Beat, given the success of the H3, why did you and DT MedTech decide to develop the H2?

Beat: Well, we were motivated to develop an ankle which provides intrinsic stability based upon what we have learned from a decade and a half of the H3 clinical experience. We observed that, with the H3, the position

(A/P and internal/external rotation) of the PE component does not change with flexion and also does not change over time.

Utilizing this observation as a driving hypothesis, we developed a semi-constrained solution that is implanted in the same exact manner as the proven H3, but can be free to locate its optimal anatomic configuration intra-operatively and then be locked in place to provide stability against translational and rotational forces within the replaced ankle, thus protecting the ligaments from potential overloading. The end result was that we have effectively combined the advantages of the proven H3 mobile-bearing system into the semi-constrained H2 system.

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Don: What are the advantages for the surgeon when using the H2?

Beat: There are several advantages. First, we use the same instruments for the H3 primary and revision system that we do for the H2 primary and revision system (except for a screwdriver and tool to measure the relative A/P position of the tibial axis relative to the talar implant dome). This allows the surgeon intra-operative flexibility, in places where both products are legally marketed, to select either the H2 or H3 implant – whichever best suits the patient. Second, the H2 and H3 talar components are identical – only the tibial component and PE insert have changed for the H2. Third, in revision surgery, the PE insert can be replaced without disrupting the tibial or talar components. Finally, the surgeon can decide during surgery the amount of intrinsic stability the patient requires.

To me, it is the first customized ankle prosthesis on the market. Since most OA ankles don't have a normal anatomy, the H2 will allow the surgeon to focus on ideal positioning of the tibial and talar implants followed by the intra-operative adaptation of the PE insert to that optimal anatomic position.

Hintermann Series H2®
Total Ankle Replacement System

Source: DT MedTech, LLC

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Don: Will the H2 indications be different from the H3?

Beat: The H2 is cleared in the US for use with cement. Other than that, the indications are basically the same. But, I do believe that we can use the H2 to successfully address more deformed and unstable ankles than we were previously able to address with the H3. Additionally, since the H2 is cleared for revision ankle arthroplasty, it also allows for another alternative in the revision segment.

Don: We discussed the advantages for the surgeon. How about for the patient?

Beat: Good question. I believe the intrinsic stability of the ankle provided by the H2 will protect ligaments and tendons from potential overload, reduce pain originating from the overload of soft tissues, and provide more stability against translational forces that are prevalent in everyday situations, such as when a patient walks

down stairs or on uneven ground. I'm also hopeful that there will be fewer complications from overloaded periarticular structures and a very low incidence of revision.

Don: David, what is the regulatory and commercialization status of the H2?

David: The Hintermann Series H2® semi-constrained total ankle replacement system was cleared by the FDA 510(k) process in November of 2017 for cemented primary and revision total ankle arthroplasty. We expect to perform our initial procedures in the US in May of 2018.The global launch of the H2 is scheduled for September of 2018.

Of course, the device has already been successfully implanted in over 30 patients outside of the United States since its release in February. In fact, our initial three cases were concluded on February 6th – two were primary procedures and the other a (dis)arthrodesis (sometimes referred to as a take-down of an arthrodesis). All of these H2 implantations are functioning well, two months post-operatively.

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Don: What about ASP – how are you pricing the H2, and how will it compare to the H3?

David: The H2 will be priced competitively, both within and outside the United States. Prices outside the US vary by country, and the H2 will be priced similarly to the H3.

Don: Tell us about your training program.

David: We feel that we're very good at training on total ankle arthroplasty. Over a two-year period several years back, DT MedSurg, LLC (a Data Trace Company) trained over 500 orthopaedic surgeons and 150 podiatrists on a competitive total ankle. To prepare for the Hintermann H2 limited launch, we've already conducted three major cadaveric training programs, which included surgeons based in the US, Switzerland, Germany, Denmark, Italy, Canada, and South America. More training programs are planned throughout 2018.

Don: How will you position the H2 and H3 with surgeons and hospitals at OUS sites?

David: One main attraction outside of the US that helps us greatly with our strategy for the H3 and H2 systems is that they both utilize the same instrument set and surgical technique. This allows surgeons to maximize intra-operative flexibility of implant choice based on patient requirements. No other total ankle system in the world can make that claim. Due to the existing mature use and experience with the H3, the H2 system can be deployed simply as a product line extension which utilizes the prior experience and investment our customers already have with our H3 system. In new markets, the H2 allows DT MedTech to penetrate those markets which show, for whatever reason, prevalent use of a two-piece competitive design over the mobile-bearing H3.

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Don: SmartTRAK data confirms that there are 12 competitors in the global market with total ankles. The H3 has been met with success in OUS markets. What will make the H2 successful?

David: The H3 has 15 years of published, validated clinical results in its current generation. The design of the H2 has taken the best features of the H3 and incorporated them into the H2. The talar component, which is the same for the H3 and H2, remains the key to the success of both systems. The H2 will continue to provide stability, anatomical conformity, and the range of motion required for a successful total ankle replacement. So, patient outcomes for the H2 are expected to be similar or better than the H3.

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Don: David, one final question. You have CEO experience, but not with a medical device company. What have you learned over the past two-plus years?

David: Everything starts with a great team of dedicated people – and that includes Professor Hintermann – along with great products incorporating a disruptive technology, like the H3 and H2 systems. You need to develop, hire, or outsource the expertise that you don't have – and we've been fortunate on the design, manufacturing, and regulatory/clinical sides in working with some of the best companies, surgeons and non-surgical experts in the world. And, investing to ensure that your quality systems and manufacturing processes are measured and held at the highest standard – that's money well-spent. Finally, all companies need to be well-capitalized, and we have been fortunate to have the capital to ensure future success.

In the end, the patient outcomes and safety are most important. By focusing on these key areas, DT MedTech will secure a significant market share in one of the fastest growth areas in orthopaedics– total ankle replacement.

Don: Professor Hintermann and David, thank you again, and best wishes for continued success.

Don Urbanowicz is Principal of Urbanowicz Consulting, an advisory firm with a musculoskeletal focus seeking to enable clients to achieve strategic and transaction-related goals by capitalizing on market opportunities. UC offers a unique perspective on how large global companies approach strategy, valuation, negotiations, due diligence and integration, and a thorough understanding of achieving success throughout all phases of the transaction process.

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