

The SITES Medical Make-to-Order Manufacturing Process

SITES Medical Commercial Affairs

The Changing Healthcare Delivery Landscape and Opportunity for Orthopedic OEM's

In the world of orthopedics, it's no secret that more Total Joint Replacement (TJR) procedures are being performed in an outpatient setting today than ever before. This trend is set to continue, as payors and patients appreciate the lower cost, yet high quality care that the healthcare practitioners at these facilities can deliver. While not all patients are candidates for outpatient TJR surgery, one group of researchers estimate that as many as 70 percent of patients could be treated in this setting.¹

These outpatient settings are significantly different from inpatient ones and orthopedic OEM's that desire to compete and win business in these facilities will need to adapt their offerings to meet evolving market demands. One key difference between these settings is the level of reimbursement that each receives from payers, both public and private. Procedure reimbursement is considerably lower in the outpatient setting compared to the inpatient hospital setting, yet procedure profit margins are high. At first glance, this may seem paradoxical. However, the outpatient centers benefit from a generally healthier patient group (they otherwise wouldn't be candidates for procedures in this early-discharge setting), reduced overhead costs from streamlined operations, and a focus on cost and OR efficiency from healthcare provider teams that often have a financial stake in these outpatient facilities. Another key difference between the outpatient and inpatient facilities is that outpatient centers are smaller in size, and physical space for inventory and sterilization equipment is at a premium.

Thus, the new purchase decision drivers amongst outpatient facilities are cost, OR efficiency, space and the potential to avoid sterilization. OEM's should respond to these developing market needs with TJR's at a low cost, that are OR efficient, require negligible inventory space and with fewer instruments to sterilize. Those that do so early, will surely win business in the emerging outpatient market segment.

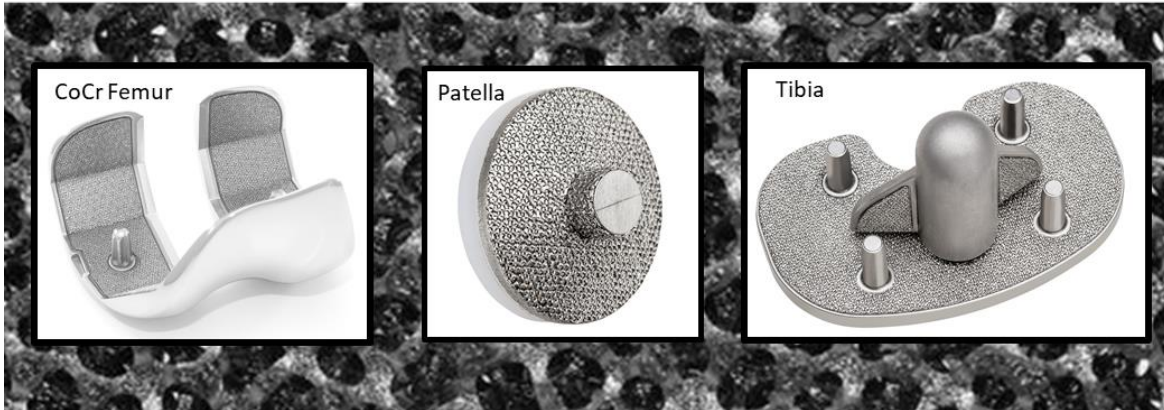
Solution and Historical Impediments

The way to deliver TJR's at a low cost, that are OR efficient, require negligible inventory space and with fewer instruments to sterilize is through low cost cementless implants (avoiding cost of cement and OR time to mix, apply and let cure) that are delivered size specific to the patient within 3 weeks of order (within the surgery scheduling window). This Make-to-Order (MTO) approach requires a low cost, high performance, and robust cementless technology and high levels of process automation.

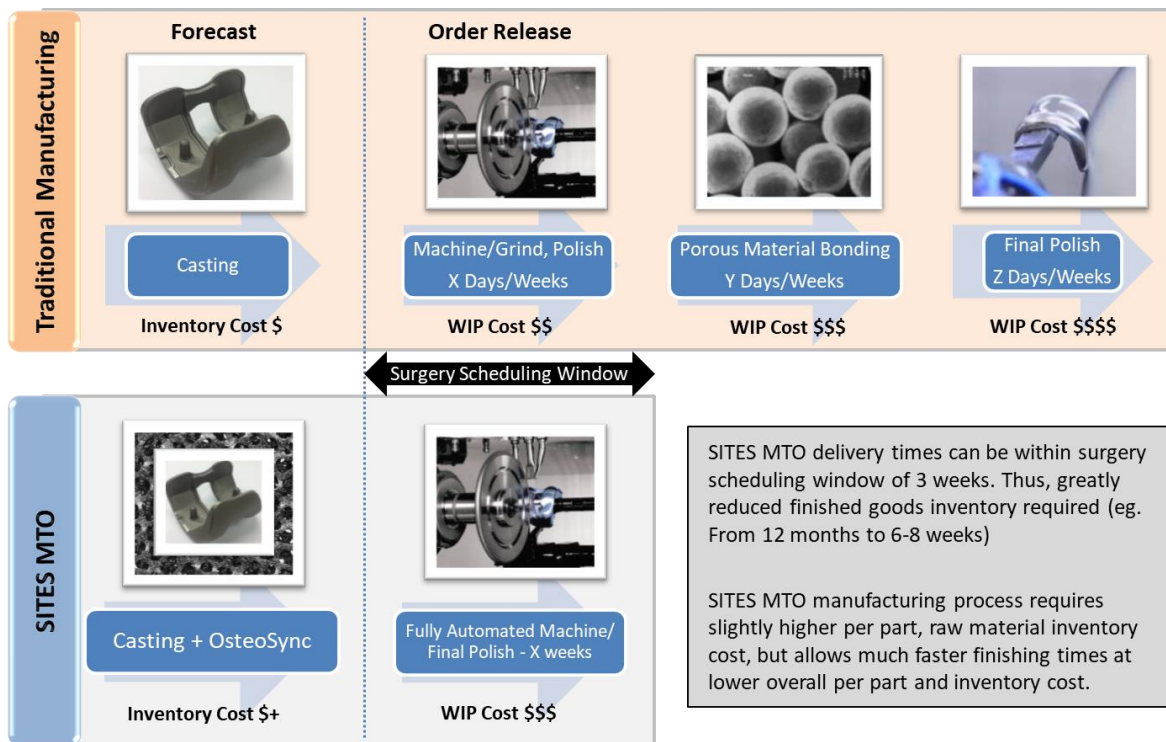
Why hasn't anyone done this yet? To begin with, many of the contemporary porous ingrowth technologies are expensive to manufacture. Older, cheaper variants lack the ingrowth performance required for the younger, more active patients that will be treated at the outpatient facilities. In addition, today's TJR manufacturing methods (eg. casting, 3D printing, grinding, porous material bonding, polishing) create stresses in the part that can lead to dimensional movements during successive operations and out-of-spec parts, which means that manual intervention is required to bring them back into spec at each step of manufacturing (or scrapping of the implant) which increases COGS. This impedes process automation. The other impediment to an MTO process is that traditional implant manufacturing processes and technologies require long lead times due to material transfer, queue time, labor intensity and additional manufacturing steps.

Solution Realized: SITES Make-to-Order TJR

SITES Medical has developed two critical technologies that overcome the historical impediments to an automated and validated Make-to-Order process. The first is a component stabilization process which greatly reduces dimensional movement seen in traditional manufacturing methods. The second is a porous ingrowth technology (shown below in a magnified view along with TKR components incorporating the material) that features best-in-class ingrowth (2 times the implant-to-bone shear strength of titanium plasma spray in head to head testing², and 3 to 5 times the bone volume ingrowth of 3D printed materials^{3,4,5}) but at a low cost.



The technology, called *OsteoSync Ti*TM, is also robust and easy to clean which facilitates automated manufacturing. *OsteoSync Ti* can be applied early in the manufacturing process and then a completely automated manufacturing process can be used to finish out the part as shown in the schematic below.



The SITES Medical CoCr Stabilization and *OsteoSync Ti* technologies are already in commercial use. The MTO process requires size inputs which are readily obtainable from systems that many OEM's already use such as patient specific instruments or robotic platforms – each of these takes in calibrated images (radiograph, CT, MRI) that can be used for implant size determination and they facilitate implant placement with a minimum of instrumentation and often in single-use, disposable form.

Impact on OEM's

A Make-to-Order approach with high-performance, low cost cementless implants presents an incredible opportunity for an OEM to address the unique needs of the growing outpatient TJR market segment and gain share or better maintain margins in a falling price environment. MTO also offers the OEM an opportunity to eliminate many months-worth of inventory that is traditionally kept on-hand to ensure high service levels for customers. OEM's typically hold 12 months of inventory and this can be reduced to approximately 2 months. This represents a massive savings on inventory holding cost, including excess and obsolete inventory charges on the P&L. Furthermore, it offers reduced development-to-launch cycle time as there is no need to build an inventory to support a launch.

Undoubtedly, this trend towards outpatient TJR surgery is one of the most significant market shifts in decades and a Make-to-Order manufacturing approach with high-performance, low cost cementless implants positions forward-thinking OEM's with unprecedented opportunities for top and bottom line improvements.

More information can be obtained by contacting SITES Medical, or by visiting www.sitesmedical.com.

References:

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