

# 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 many Total Joint Replacement (TJR) procedures are being performed in an outpatient setting today, than ever before. This trend is set to continue, as payers 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 75 percent of patients could be treated in this setting.<sup>1</sup>

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. Inpatient 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 the early diagnosis setting), reduced overhead costs from streamlined operations, and a focus on cost and OR efficiency from healthcare providers teams that otherwise influential stakeholders in these inpatient facilities. Another key difference between the inpatient and outpatient facilities is that outpatient centers are smaller in size, and physical space for inventory and medication equipment is at a premium.

Thus, as care providers decision drivers amongst outpatient facilities are cost, OR efficiency, space and the potential to avoid overutilization, 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 conventional implants (avoiding cost of cement and OR time to drill, apply and fit cases) that are delivered size specific to the patient within 1 week of order (within the surgery scheduling window). This Make-to-Order (MTO) approach requires a low cost, high performance, and robust conventional technology and high levels of process automation.

Why hasn't anyone done this yet? To begin with, many of the contemporary process ingenuity technologies are expensive to manufacture. Older, cheaper variants lack the ingenuity 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 inaccuracies during successive operations and sub-optimal parts, which means that manual intervention is required to bring them back into spec at each step of manufacturing (or scrapping 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 times, labor intensity and additional manufacturing steps.