Winning TKR Business in the Out-patient Setting

SITES Medical Commercial Affairs

With the increasing shift of TKR procedures to the out-patient setting, demands on implant manufacturers are increasingly moving towards the need to deliver value (ie. health outcomes/dollar spent). In this whitepaper, we examine the magnitude and drivers of the shift in procedures, the economics of cemented vs cementless TKR in the ASC, and two enabling technologies to allow additional value delivery in this increasingly important care delivery market segment.

Increasing Shift of TKR Procedures to the Out-patient Setting

According to analysts at Sg2, 52% of TKR procedures will be performed in an outpatient setting by 2026.¹ A lower cost of care for payers and increased profit for providers are the driving forces behind this movement to outpatient TKR. Out-patient hospitals and independent Ambulatory Surgical Centers (both will be referred to as ASC's in this whitepaper) have found ways of increasing their profits from these procedures despite reduced reimbursement relative to in-patient hospital levels.

To be successful, these ASC's have focused on driving out cost. They have some natural advantages in that they screen for younger and healthier patients who can be discharged within 23 hours, resulting in reduced costs from the shorter length of stay and fewer complications with this healthier cohort. However, ASC's are also highly cost-conscious due to their lower reimbursement. They scrutinize every element of procedure cost and source of inefficiency to find savings and often have the support of the surgeon from surgeon ownership (or profit-sharing) which ensures they have a financial stake in procedure economics. In addition, ASC's also enjoy lower overhead costs from simplified operations.² Clearly, much has been accomplished by these entities.

Cemented TKR Concerns

Yet most TKR procedures performed are cemented which adds time and cost to the procedure and can affect outcomes. Sharkey et al found that the most common reason for TKR revision was component aseptic loosening, at 40% of all failures.³ Tibial debonding appears to be a key reason for failure as cement holds up well in compression, but not in tension, and these and other forces (eg. shear) are at play in knee kinematics. One study by Arsay et al showed survivorship of only 97.8% at 5 years with tibial debonding as the endpoint.⁴ Furthermore, a study by Chow et al found that cementing contributes to knee malalignment as 44% of knees in their study showed ligament imbalance after cementation. Prior to cementation, all knees were determined to be balanced with the use of OrthoSensor technology.



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The Case for Cementless TKR Components

Why not employ fully cementless TKR (femur, tibia, patella) instead of cemented TKR? Despite the concerns regarding cemented TKR mentioned above, some remain worried that cementless implants don't perform as well clinically, but several randomized controlled studies show that this is not the case.^{6,7} Cementless TKR is perceived as more expensive by the care providers and indeed, these components have traditionally cost more to produce. However, there are savings from cementless TKR that may level the field. Cement and mixing accessories can cost between \$100 and \$300 per case.⁸ Add to that the overhead cost of the OR team as they wait for the cement to cure, which has been estimated to be \$62/ minute (range \$22 to \$133/min) for approximately 10 minutes (conservatively) or \$620 per procedure.⁹ Summing these up puts the cost of cement at \$720 to \$920. There is also the opportunity cost to the hospital and surgeon. If a care provider does 5 cemented TKR's on a given day, they could save 5 X 10 minutes per case, or 50 minutes total by switching to cementless TKR's. For many institutions, that is enough time to add another case to the schedule, bringing in \$1000's in additional contribution margin for the hospital and additional revenue for the surgeon.

Here is the Win-Win for OEMs and Care Providers

It stands to reason that if an orthopedic OEM can provide a cementless implant system for all ASC facilities at a price that is cost-neutral (ie. no more than the direct and indirect costs of cement as noted above), then the care provider benefits from reduced OR time, an opportunity to schedule more cases/earn additional revenue, and reduced storage space (assuming they stock both cemented and cementless implants along with bone cement today). The OEM benefits from reduced inventory requirements and, if their cementless implant system is cost-effective, healthy margins and share gains.

SITES Medical Enabling Technologies

SITES Medical, an organization entirely focused on Value-Driven Innovation in orthopedics, has developed two proprietary and critical enabling technologies to facilitate an OEM's profitable penetration into this growing market segment. One is a highly porous titanium ingrowth material, called *OsteoSync Ti*, with proven ingrowth capabilities and at a lower cost than other highly porous materials. Unlike other materials, it can be reliably attached to CoCr substrates such as knee femoral components. It can also be attached to titanium substrates and polyethylene can be direct compression molded into it, providing a complete cementless knee solution that can be cemented based on patient needs or surgeon preference.



The second enabling technology is a CoCr stabilization process that reduces the dimensional movement associated with today's manufacturing methods, which in turn reduces manual re-work and inspection steps, scrap rate and lead time. Additional cost advantages have been noted by manufacturers using this process. Combined, these technologies allow delivery of a high-performance cementless knee system at a price that ASC's will appreciate.

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These technologies are available to OEM's today. More information can be obtained by contacting SITES Medical, or by visiting <u>www.sitesmedical.com</u>.

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