Platform-Based Development: Faster Paths to Innovation

SITES Medical Commercial Affairs

The Case for Technology Platforms

It's no secret that speed to market for a new product can be critical for an orthopedic company's ability to take market share and grow their business. Most firms will go through a 3-stage, concept-to-launch process which starts with research and development, then manufacturing transfer and finally production manufacturing for product launch.

The time it takes to go from idea to market will depend to some extent on the complexity of the product, the degree to which new technologies or manufacturing processes are being incorporated or the boundaries of known technologies are being pushed, and the use of technologies that are challenging to validate. On this latter point, examples include the application of porous beads which is a manual process and the use of 3D printing which has inherent variability. All these factors may result in more design or manufacturing transfer iteration cycles.

For an experienced team inside the OEM, project duration for relatively simple and straightforward implant systems may take 18 to 24 months while complex implant systems could take 4 or more years.

While the use of the types of technologies mentioned above may allow for consistency across product lines or the use of emerging technologies may enable customization for some perceived benefit, they also introduce:

- Longer project timelines and longer time to revenue due to additional iterations
- Higher risk of technical failure or regulatory failure
- Increased project and product cost

The alternative is the use of platform technologies which offer:

- Pre-validated foundations to reduce technical risk
- Proven materials and designs that perform clinically at required cost
- Reduced regulatory complexity and time to clearance

Technology Platforms Balance Speed and Differentiation

Incorporating platform technologies in development doesn't eliminate innovation, it simply focuses it on areas that matter more to the surgeon or ASC customer.

Advantages include:

1. Reduced Development Time
Build on existing validated components and technologies. Every new material, design feature, and manufacturing method introduces a new potential risk to project duration. Eliminating as many of these risks upfront using proven technologies can reduce the potential for project phase iterations and shorten time-to-market.

2. Lower Risk Profile
Leverage existing data. Proven technology platforms bring with them rich data sets that can significantly reduce risks of poor clinical performance, obtaining regulatory approvals, IP infractions and overall financial performance.

3. Focused Differentiation
Invest in areas that truly impact outcomes, efficiency and cost. There are generally three types of benefit that your medical device customers are seeking: (1) improved outcomes (or user experience); (2) reduced cost; (3) reduced time. A new product development effort must demonstrate at least one significant benefit or the market share gains or savings won't follow. To the extent that the new benefit can be derived without significant risk (e.g. clinical, regulatory, IP, manufacturing) means a successful product gets to market faster.

4. Scalable Innovation
Extend platforms across multiple products and indications. Trust is built over time with surgeons who experience consistent and exemplary product performance. This trust can be leveraged to gain adoption across product types and categories when the key underlying platform technologies are utilized across the portfolio.

In fast-moving markets like ASCs, speed and predictability of new product introductions matter. Platform-based development enables OEMs to innovate faster while managing risk effectively.

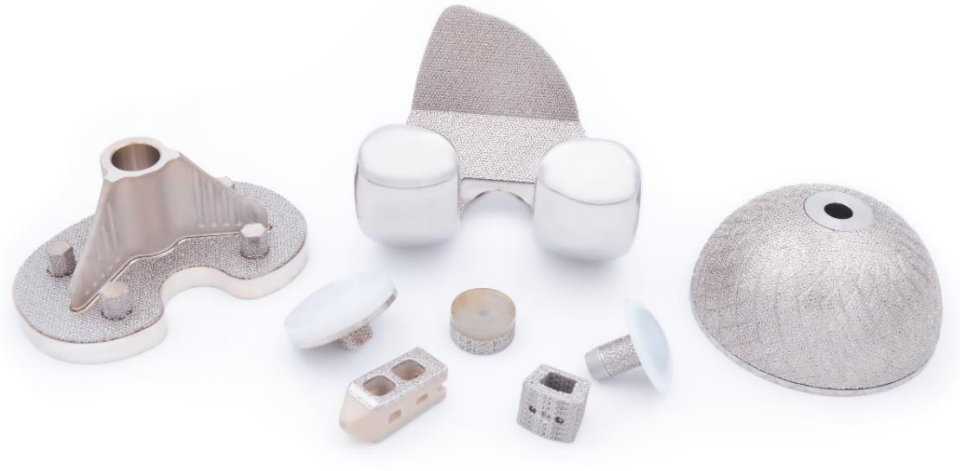
How SITES Medical's Technology Platforms Help Provide a Faster Path to Innovation

There are currently three main technology platforms that enable SITES to deliver products faster and more predictably.

1. *Validated Porous Technology*

   SITES Medical's OsteoSync® Ti is a high performance, lower cost porous technology that has been well characterized for bone ingrowth via animal studies and for mechanical performance through a battery of tests. It has a high coefficient of friction and tighter than traditional tolerances for enhanced initial implant stability and a combination of macro, micro, and nano-scale features that foster best-in-class bone ingrowth. Over 350,000 OsteoSync devices representing a broad range of applications have been implanted since 2014, indicating low product performance risk across the field of orthopedics.

   OsteoSync's method of manufacture as well as its attachment to a variety of orthopedic materials, including titanium, cobalt chrome, UHMWPE, PEEK and PCU, is also well understood so minimal, if any additional work is required to prove this out, reducing time to market and technical risk. An FDA Masterfile has been established which streamlines the regulatory approval process, resulting in 510k clearances averaging under 90 days.



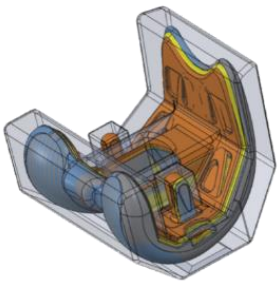
OsteoSync Ti Application Breadth

2. *High Velocity Materials*

SITES Medical has developed a set of off-the-shelf, oversized castings and forgings ("High Velocity Materials") that accommodate a wide variety of implant designs and sizes. This avoids the need to develop custom casting and forging tools with associated design cycles of up to 12-months and allows for design iterations without having to redesign tools.

Once the design is locked, a Quadruple Option Casting or Forging can be developed which is OEM and size specific to lower costs. It's called Quadruple Option as it can be used for left and right components, narrow and wide components, plus cementless and cemented designs and implant trials. A singular set of castings or forgings reduces time to market and development cost.

Another category of High Velocity Materials is machinable blanks and related generic materials. These also accommodate multiple sizes and geometries and enable shorter development time, lower cost and leaner inventory. They can also be used across product classes. Examples of these High Velocity Materials include overmolded UHMWPE porous patellas, reverse shoulder glenoid bonded blanks and OsteoSync plates.



Oversized Casting/Forging

Overmolded Porous Patella Blank

Reverse Shoulder Glenoid Blank

3. *Zero Setup Time*

A Zero Setup Time manufacturing platform is an ideal manufacturing state where a production line can switch from one production part number to another with no measurable downtime, no manual adjustments and no loss in quality or productivity. The benefits of such an approach are significant and include:

a. Produce smaller batch sizes economically, matching end-user demand and reducing finished goods inventory and WIP
b. Reduce time to market by decreasing lead time
c. Increase machine utilization and decrease manufacturing costs

SITES Medical has developed several technologies that enable near-zero setup time manufacturing including Dimensional Stabilization, Standard Fixturing, Automated Production, and Automated Inspections.

Dimensional Stabilization Process
This proprietary SITES Medical process reduces dimensional movement that can occur during stress inducing (or relieving) manufacturing operations, such as porous-material bonding, machining, and polishing. Femoral knee components are especially susceptible to this movement. The Dimensional Stabilization process involves a vacuum furnace thermal cycle and attention to pre and post cycle processing step details to minimize reintroduction of stress into the components. This stabilizes the parts, minimizing manual rework, supporting uninterrupted process flow, and enabling automation. As a result, parts move through manufacturing faster and more predictably.

Standard Fixturing
Standard fixtures are work holding devices that are designed to accommodate many different parts or product families with little or no modification. SITES Medical has developed a set of standard fixtures for different part families which reduce setup time, improve repeatability, and increase manufacturing flexibility. These standard fixtures are one of the foundations of efficient, high-mix, low-volume manufacturing that is required for the orthopedic industry.

Automated Production
SITES Medical employs automated handling and inspection for select products. The systems can currently run unattended for up to 36 hours, ensuring fast and predictable output at lower cost.

Automated Handling for 5-Axis Mill and CMM

Automated Handling for Wire EDM

Conclusion

The need to accelerate new product developments and introductions is only becoming more important as OEMs search for ways to maintain a competitive edge, especially in the rapidly evolving market shift to the ASC, where surgeons often have a financial interest therefore efficiency, cost effectiveness, and clinical performance are primary implant selection criteria.

It is a structural transformation that OEMs must recognize. Companies that employ platform technologies can deliver implants with proven clinical feature sets, innovate where it matters most, reduce concept to launch duration and manufacture more economically and reliably.