Orthopaedic Instrumentation: **Traditional-to-Disposable Conversion**

Before converting orthopaedic instruments into disposables, there are critical steps that must be taken for a successful launch.

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Today, many orthopaedic OEMs are investigating the development of disposable instrumentation to replace traditional orthopaedic instruments. Disposables provide many benefits not only for the OEM, but also for the hospital and patient. Patients benefit from a lower risk of infection. Hospitals avoid the time and cost burdens of cleaning and resterilization. Disposables enable OEMs to reduce the amount of capital equipment they must own. Making the shift to disposables requires many steps, and shortcuts along this road are perilous. They generally lead only to longer time to market.

Getting Started

Based simply on strength requirements, some applications are more logical to convert than others. It is essential to first evaluate how much strength is needed in a single-use application. Although there are some tough engineered plastics available today, metal generally has more impact strength than plastic. As such, parts that lend themselves well to an injection-molded disposable application do not require the strength or ductility of metal. For instance, cutting guides, implant trials, and spacer blocks may be optimal for conversion, but a part that will be directly impacted or pried with significant force may not (see "Partnering with a Contract Manufacturer").

Product Design and Development

Resin selection should occur early in the product development phase. Material choices for disposables are less restrictive and less expensive than the autoclavable materials commonly used for reusable instruments and handles. Still, they must be strong and impact resistant, as disposables are usually ultrasonically cleaned, blister packed, and gamma irradiated after molding. Materials commonly used include acrylonitrile butadiene styrene (ABS), acrylic, nylon, polycarbonate (PC), and polypropylene (PP). One advantage of some of these resins is that they can be molded in their transparent form, allowing surgeons to see through the instruments during a procedure. Gamma sterilization can cause color shift in some transparent or translucent resins, however, so it's important to work closely with the material provider, which can offer guidance in this area. Another advantage of certain resins is that they can be color coded, which allows operating room personnel to identify the correct instrument at a glance.

Establishing a complete list of requirements (design inputs) for the product early on is critical to the material selection process. Once an OEM and its supplier identify the best resin family based on the required performance properties, the next step is to select a first choice and a backup for later co-specification.

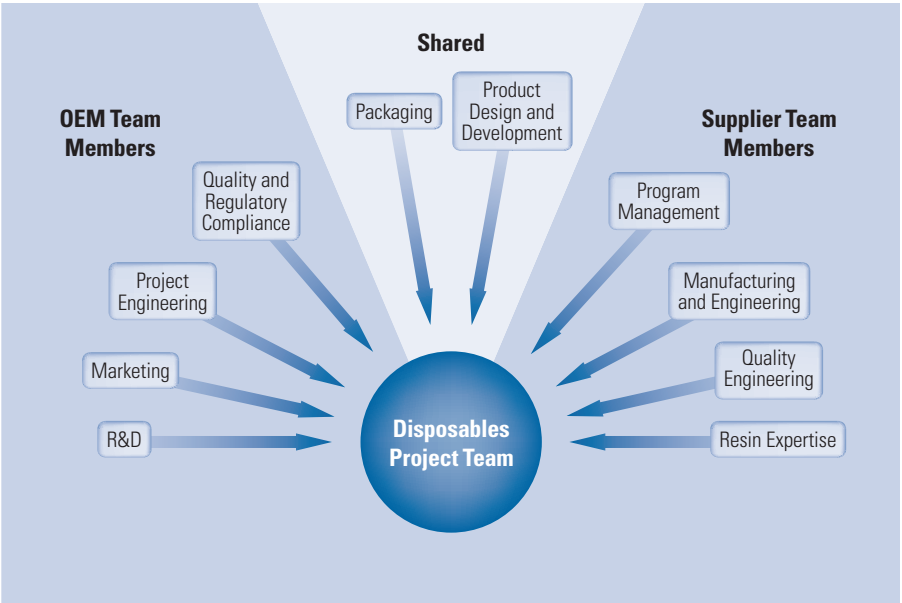

Figure 1. Both the OEM and the supplier bring unique areas of expertise to the project team.

After the preliminary design, resin selection, and design for manufacture are completed, prototyping can begin. Prototyping allows the OEM to gather feedback from its customers. New technologies, like fused deposition modeling, have made the prototyping process quick and inexpensive. Depending on the complexity of the part and the tightness of the final tolerances, a prototype tool may be the next step in ensuring a seamless product launch.

A prototype tool is beneficial for both the OEM and the supplier-manufacturer. From an OEM's perspective, injection-molded prototype parts can provide invaluable insight into potential design issues that were not anticipated during the product design phase. From a contract manufacturer's perspective, the prototype tool illustrates exactly how the part will behave in manufacturing and helps verify assumptions made during tool design. If a new technology, process, or tool design is being entertained, a prototype tool can also verify the best approach to take for production.

With a prototype tool, the OEM and supplier can make data-driven decisions prior to designing production tools. For example, some instrument trials have complex shapes that may shrink and warp in unexpected ways. An experienced plastics design team, with the help of computer-aided engineering, can simulate warpage. If this simulation is followed by prototyping to verify both shrink and warp assumptions, the team can be confident that the tool design and assumptions are valid prior to a capital tooling investment.

Performing full process development on a prototype tool can save, in the long run, several times the amount of time and money invested in the tool itself. As part of process development, the typical elements that help the molder get a feel for the tool are in-mold rheology, short shot study, gate seal study, stability run, and pack pressure study. A design of experiment (DOE) can also be performed, if necessary. Full process development and DOEs help the molder determine the process boundaries of a stable process.

Once the process parameters are determined, the OEM and supplier must agree on the critical dimensions and the measurement method. Dimensions and methods can be determined using gauge repeatability and reproducibility studies and through a collaborative agreement between engineering and metrology regarding the best measurement technique and geometric dimensioning and tolerancing (GD&T) interpretations. When the supplier and OEM correlate measurement methods at an early stage, it ensures that both will interpret the print and measure the part in the same way.

ADVANCED PRODUCT QUALITY PLAN	METROLOGY ACTIVITIES
Print review	Gauge R&R
Process flow	First-article inspection (FAI)
pFMEA	Capability study
Control plan	—
Part quality requirements	**VALIDATION & QUALIFICATION ACTIVITIES**
Work instructions	Installation qualification (IQ)
Part traveler	Operational qualification (OQ)
List of consumables	Process qualification (PQ)
Source inspection documentation	—

Table I. A solid quality plan should include the processes and procedures outlined above. It should be initiated early in the product design and development phase.

Full Product Manufacturing

Prototyping is complete, the results have been analyzed, and the production tool has been placed with a reputable toolmaker. Now is a good time to finalize both the quality plan (sometimes referred to as an advanced product quality plan or APQP) and manufacturing qualification/validation plan, which should have been initiated during early product design and development discussions (see Table I). The quality plan ensures that every aspect is completed once the tool arrives.

Labeling and Packaging. Labeling and packaging design can also be completed during this period using the prototype parts. The tool build creates some downtime. Using this period to address labeling and packaging can shorten the schedule. It can also position the team for successful and structured validation and part qualification. Packaging validation activities, sterility testing, and shelf-life testing should be conducted concurrently with the manufacturing validation and the tool qualification process.

Protocols. When the tool arrives, it is time for the supplier-manufacturer to execute to the protocols and plans previously established and agreed upon. Tools must be checked for functionality, and then the formal process development work can begin, employing many of the same mechanisms used earlier when performing process development on the prototype tool. Once this is finished, all validation activities should now be completed per the agreed-upon protocol and signed off by both the supplier and the OEM.

The last step, of course, is to turn on the presses. But this part is simple if no shortcuts were taken during the following product development process:

- Develop a cross-functional team.
- Identify suitable instruments to convert to disposables.
- Choose the best resin.
- Thoroughly develop the product design, using prototyping to verify and finalize the design.
- Implement full process development using the prototype tools.
- Develop quality and validation plans, followed by validation activities on both the disposable instrument and the packaging.

All of these major steps, and the minor ones in between, are critical to a successful new product launch. Bypassing any of them typically lengthens time to market. So when considering traditional-to-disposable conversions, follow this blueprint to reduce capital equipment investments and bring about improved health and financial benefits to hospitals, physicians, and ultimately, to the patients they serve.

References

1. GHTF/SG3/N17R9:2008, "Guidance on the Control of Products and Services Obtained from Suppliers." (Brussels: Global Harmonization Task Force, 2008).

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Partnering with a Contract Manufacturer

Early supplier involvement can greatly improve the chances of a successful launch. Experts in the manufacturing of disposables can offer critical suggestions regarding the design and manufacturing of such instrumentation. The supplier should have related orthopaedic design for manufacturability (DFM) experience to avoid common pitfalls when it comes to actually manufacturing the parts in a production setting.

Additionally, the supplier should have a solid design team with experience in converting similar instrumentation. A disposables manufacturer should also have resin expertise complemented by material databases, finite element analysis, and filling simulation software. It should have prototyping capabilities that allow both the OEM and supplier to perfect the design and process prior to production. Its quality systems should support the rigor of medical manufacturing and complement the OEM's procedures and expectations. These expectations vary from one OEM to another, but almost always include certification to ISO 13485 and validation competencies.

A regulatory compliance group should be in place to ensure conformity to the FDA's current good manufacturing practices. It is also essential that a supplier implement purchasing controls to manage supply-base risk. A report released from the Global Harmonization Task Force Study Group Three, "Guidance on the Control of Products and Services Obtained from Suppliers," states

> manufacturers are required to define and document the type and extent of controls applied to suppliers and to maintain objective evidence that products and services meet predefined specifications. . . . Failure to. . . have objective evidence of the controls associated with supplier activities could result in a major noncompliance."[1]

The supplier should have a solid team of personnel with the appropriate skill sets related specifically to the manufacture of disposables. These capabilities should be beyond full contract manufacturing competencies that support lot ID marking, part labeling, and any other secondary operations that are required for the specific application. Systems for postproduction risk assessment and corrective and preventive action should also be in place.

A robust document control system with a formal change control process is also integral to a successful product launch. For disposables manufacturing, the OEM and supplier must clearly define the document transfer process up front so that one party does not make changes without the other's input and approval. This applies across the spectrum, including part design, tooling, and manufacturing.

Finally, and perhaps most importantly, the supplier must have the financial wherewithal to support an engineering-rich and quality-oriented approach necessary for a successful medical program launch, as well as the lengthy product development and regulatory approval cycle that typically accompanies it. Modern, well-maintained equipment and facilities are also important, and are often a reflection of a company's financial strength.

One Team. Once the supplier is chosen and the project team is developed, it is important to think of both the OEM and supplier as a unified team (see Figure 1). Both parties bring unique areas of expertise that are critical to the ultimate success of the product conversion.

Typically, the OEM has expertise with product R&D and marketing, project engineering, and quality and regulatory compliance requirements. The supplier should be able to bring product design and development, resin expertise, program management, manufacturing engineering, and quality engineering to the team. Packaging, particularly for disposables, is also a key part of the project team and should be assessed at the infancy of the project.

The OEM and supplier should work together to design and develop a disposable part that meets the end-user's needs and is manufacturable. With early collaboration, the OEM can contribute valuable design inputs, and the supplier can offer guidance toward a robust part design based on process knowledge, past successes, and previous lessons learned.