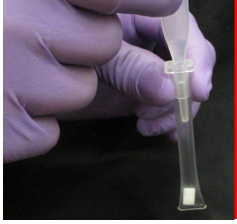

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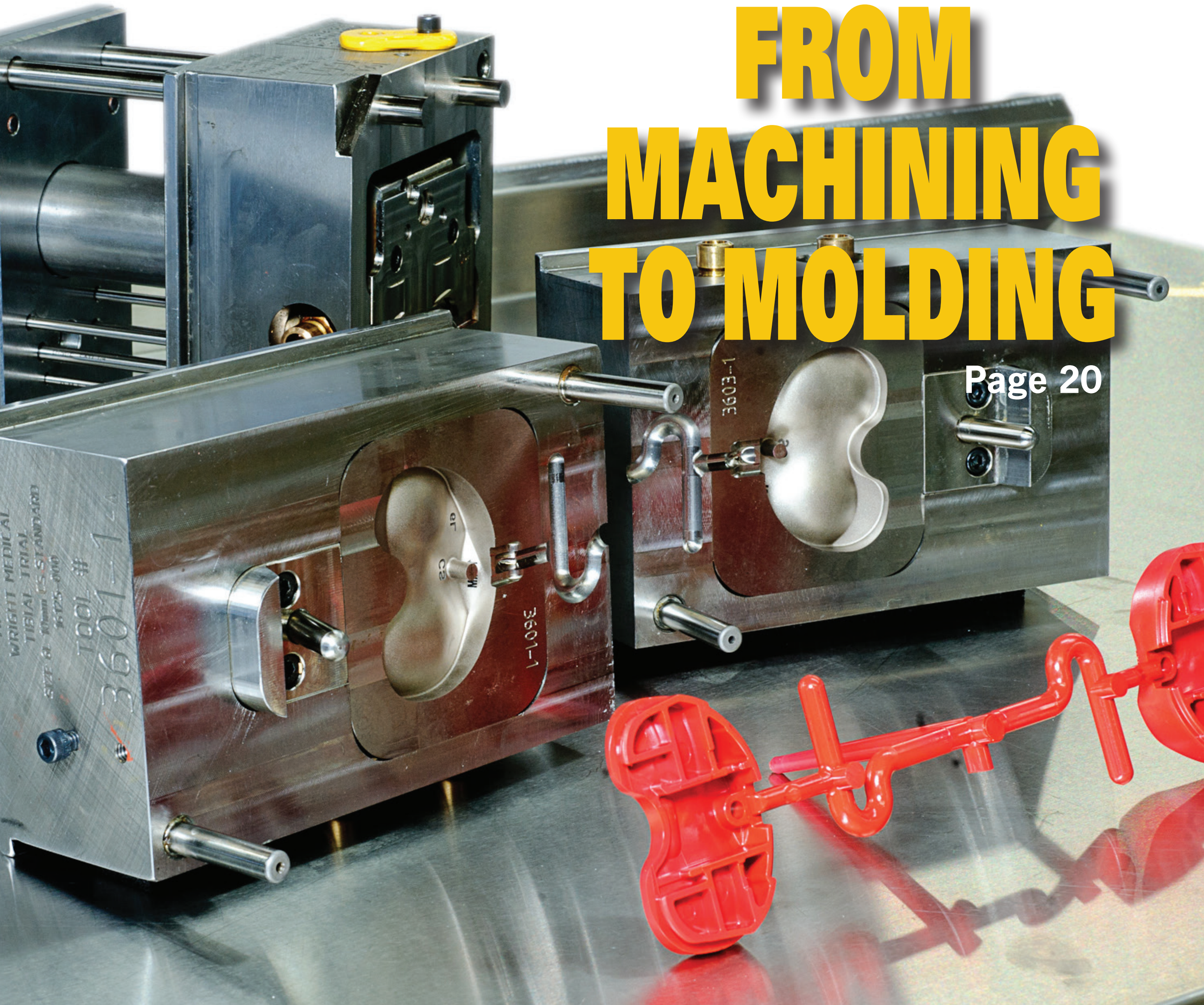

FROM MACHINING TO MOLDING

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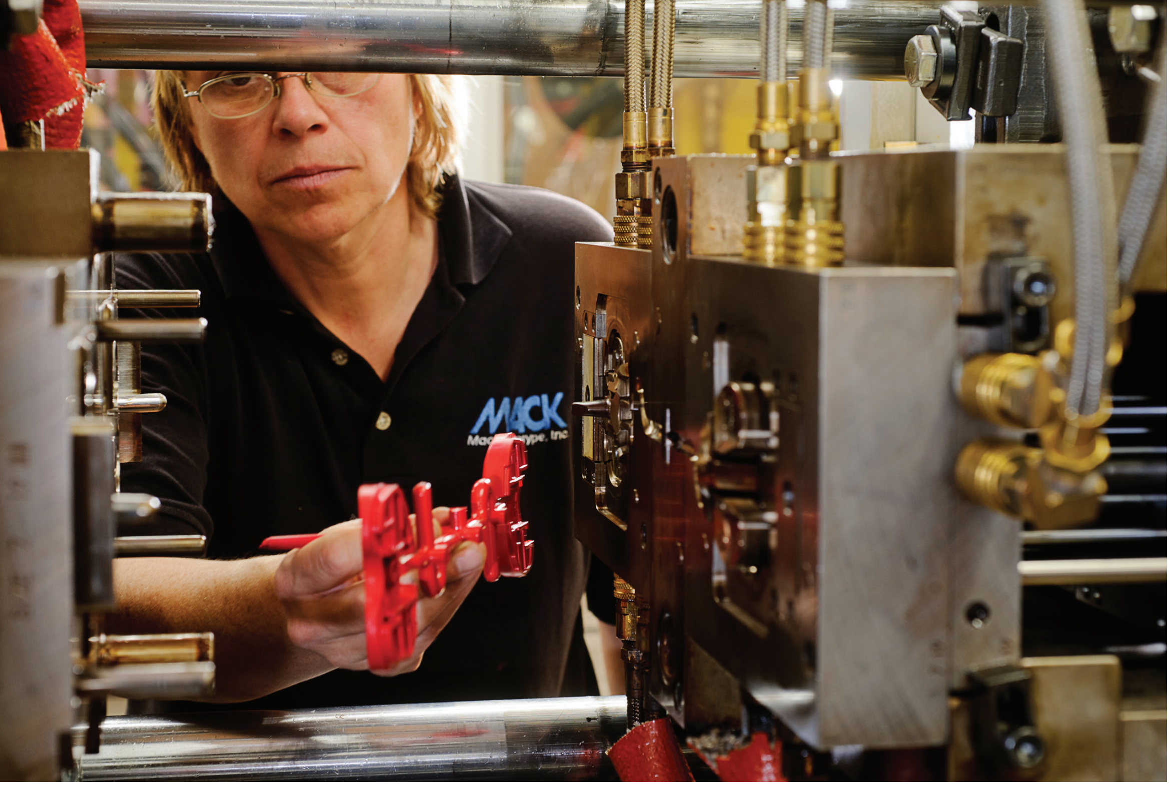

Beth Hunt, molding supervisor, Mack Prototype, Inc, removes molded tibial trials from the press.

CREATIVE DESIGN CUTS COST OUT OF HIGH-MIX, LOW-VOLUME MANUFACTURING

HOW ONE COMPANY SAVED $2.5 MILLION IN TOOLING AND REDUCED INDIVIDUAL PART COST BY NEARLY 74%.

In the orthopedic world, tibial trials refer to the plastic instruments used during knee replacement surgery that mimic the final implant and help surgeons determine the proper size and thickness needed for a correct fit. The size varies, of course, from patient to patient, even knee to knee.

Wright Medical Technology, Inc, had traditionally CNC-machined these instruments from extruded stock made of costly engineering polymers, which are available in very limited grades, colors, and shapes. But with eight basic diameters in both right- and left-knee configurations, and up to six or more different surface geometries for various reconstruction requirements, the inventory needed to fully supply the tibial trial product line is immense, not to mention expensive to produce.

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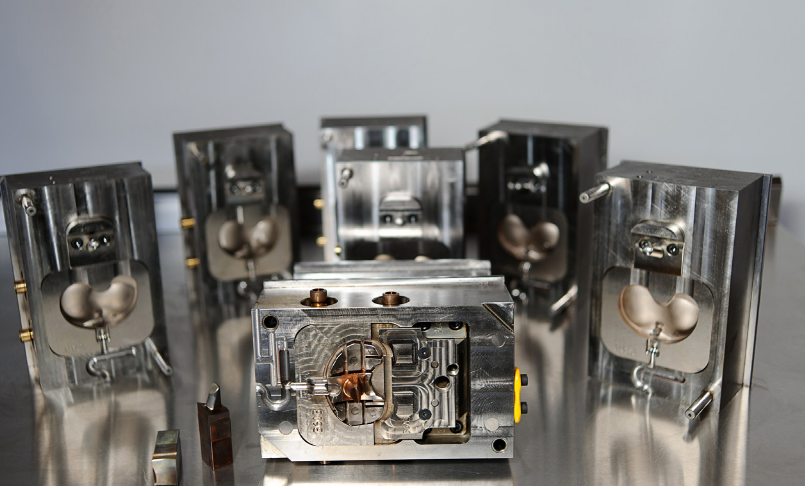
ARTICLE FOCUS:
- Shifting from machining to molding
- Addressing high-mix, low-volume challenges
- Creating a master unit die to reduce part count

From machining to molding

Faced with the challenge of cost-effectively manufacturing a high part number mix at low volumes, Wright engineers began developing injection-molded versions of the instruments. First, they reduced the number of instruments needed to cover the wide spectrum of knee sizes by developing a series of spacer parts to use with a thinner tibial trial. These spacers, developed in three thicknesses, can be used with any of the multiple tibial implant part geometries (six, in the case of this program) that are available to meet specific patient requirements. So instead of manufacturing all of the required 420 tibial trial configurations, the spacer unit design dramatically reduced the part number count to 258.

The concept of "stacking" parts to create multiple thicknesses is intuitive, but the interface between the parts that form the assembly was a critical design element. The connection had to be user-friendly in an operating room environment,



A master unit die (MUD) concept was developed that could produce 24 different part numbers using only four complete modular dies, five additional cavities, and two core subinserts.

allowing the stacked assembly to function as a single piece. The attachment had to be secure for handling during use but easy to separate for adjustment and substitution in a surgical environment. Separation ease was also important for postsurgical cleaning and sterilization. A positive snap fit could have proven difficult to assemble and disassemble and may have reduced part longevity due to wear and mechanical fatigue. Ultimately, **Wright Medical** settled on a friction-fit concept, using multiple broad planes as mating surfaces to create an interference fit.

Production challenges

With the critical design parameters defined, Wright Medical still faced a number of production challenges given the high-mix, low-volume nature of the program, including:

- Proving out the new design concepts.
- Cost-effective tool development for a daunting number of parts.
- Mold change times for low-volume production of many part numbers.
- Tool handling for multiple changeovers during a single production shift.

To fully develop the model and refine the feel of friction-fit between the spacers and tibial trials, Wright partnered with Mack Prototype, Inc, to develop single "proof of concept" tools for one tibial trial and one spacer. With these two tools, engineers could accurately calculate shrinkage in the specific part configurations and conclusively evaluate part fit. It was critical to determine the optimal interference needed between parts to create the desired feel and function requirements of the customer. Sample parts also allowed for engineering and marketing evaluation of part markings, surface finishes, and final configurations of the products.

From a tooling perspective, the two companies used the initial tools to develop an efficient strategy for producing the many similar molds that would be needed to build out the program. The project scope called for 420 different part combinations to cover all of the most commonly used implant configurations. Rarely used outliers were omitted—the traditional CNC-machined trials would remain cost-effective for these seldom used applications.

The tools would be running polyphenylsulfone (PPSU) resin, which was chosen for its ability to withstand chemical, thermal, and radiation exposure, as well as its ability to withstand the repeated cleaning and sterilization cycles required of multiple-use surgical instruments. PPSU is also readily colorable and meets FDA requirements for surgical instruments of this nature.

Creative tooling

Because the top surface of the part, which is the functional interface with the mating femoral implant, has various articulating surface conditions, individual dies were required for each part. The bottom surface, however, is virtually identical for all parts of a particular size group. So to reduce the overall part count, the companies took advantage of this commonality by using the master unit die (MUD) tool concept, where standard prefabricated bases are inserted with custom core/cavity units.

Taking advantage of all possible redundancies within a product grouping, a MUD concept was developed that could produce 24 different part numbers using only four complete modular dies, five additional cavities, and two core sub-inserts. This greatly decreased the number of molds required for the entire launch, resulting in substantial savings in both cost and lead time.

It also allowed for quick-change tooling, which is critical for molding complete part families in relatively low quantities. The smaller mold size is easy to handle without mechanical assistance, and quick to reconfigure, allowing for multiple changeovers during a single production shift. Additionally, the molds heat up and cool down quickly, easily accommodating steel temperatures in excess of the 300°F required to properly process PPSU resin.

Conclusion

Creatively using combinations of trials and spacers, the entire breadth of the program (420 tibial trial configurations) was covered by 258 unique molded part numbers, including 48 spacer molds (three thicknesses each of eight sizes in both right- and left-knee configurations), 48 complete tibial trial molds, and an additional 162 cavities. This approach reduced the total number of complete modular inserts by 210, cutting the tooling cost nearly in half. And the conversion from conventional CNC-machined trials to the injection-mold replacements resulted in a realized part cost reduction of nearly 75%. Tooling payback is reasonably expected within the first year of production.

The bottom line for both OEMs and contract manufacturers today is cost reduction. While slashing profit margins is one way to achieve cost-competitiveness, it is by no means the only alternative. In this instance, innovative part design and creative tooling proved to be the winning combination.