A PENTON PUBLICATION

NOVEMBER 2012

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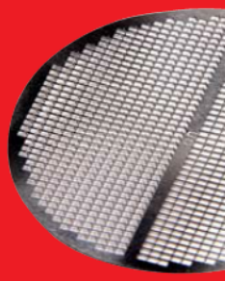

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The handle design introduces a quick attach-and-release mechanism that saves time in fixture assembly and minimizes the number of instruments required.

TPE/PP OVERMOLDED HANDLES: SOLID FEEL, SOFT TOUCH

FROM BUSINESS, DESIGN, AND END-USER PERSPECTIVES, TPE/PP OVERMOLDING IS AN EXCELLENT CHOICE FOR SURGICAL INSTRUMENTATION HANDLES.

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ARTICLE FOCUS:

- Material benefits
- Branding considerations
- Cost and timing issues

Although surgical instrumentation handles are commonly overmolded using silicone, a thermoplastic elastomer (TPE)/polypropylene (PP) overmold can offer amazing benefits, including cost, quality, and all-important branding opportunities. This article explores the many attributes associated with the TPE/PP handle solution versus that of liquid silicone injection molding (LIM).

From a material processing standpoint, silicone is infamous for becoming airborne, migrating into unlikely places, and causing electrical board failures and paint adhesion issues on unrelated products across the manufacturing floor. Because of this, MackMedical decided to take a different approach to manufacturing surgical instrumentation handles. We wanted to create an ergonomic handle with a very solid feel that also had great grip and branding capabilities. The solution? A handle with a PP substrate and a TPE overmold. These handles—although embraced by some OEMs and loved by surgeons—are still new to the industry.

Material benefits

The benefits of using a TPE/PP overmold rather than silicone are multifaceted. From a business perspective, TPE/PP can provide a higher quality product than silicone and is less abrasive on tooling (which protects capital investment). From a design standpoint,

The redesigned instruments feature a basic handle style with ergonomic soft-grip handles that are insert molded with a double overmold. The first material is a high heat polypropylene, and the second is a custom blended, thermoplastic elastomer (TPE).

Stryker's orthopedic products—whether knee, hip, or spine—reflect the same branding initiative so that they're immediately recognizable by OR staff.

the use of a TPE/PP overmold allows for a branding opportunity with several colors. The image is sharper and there are no voids, because TPE is able to fill areas of the mold that silicone is not. For the end-user, the TPE/PP combo provides a very solid feel, while still absorbing tool vibrations during surgery. TPE is easily cleaned, is nonhygroscopic, and does not shrink as much as silicone. So in some cases, there would be less opportunity for voids in the instrument that can trap bodily tissue during surgical use.

Processing ease. TPE/PP overmolded parts are consistently high in quality with minimal flash. Neither resin is abrasive, so tool wear is minimal and dimensions are extremely stable.

Silicone, on the other hand, has a low viscosity, which leads the material to flash very easily. Silicone is also extremely abrasive, resulting in premature tool wear and migrating finished part dimensions, especially in the gates and shut-off areas (creating increasing amounts of flash). Even after the tool has been tightened up to minimize flash, the normal production of parts will erode the tool, causing part dimensions to change and flash to continually increase.

Silica, the main component in silicone, is the culprit behind this phenomenon. Found in nature as sand and quartz, silica is a highly abrasive compound that will slowly erode even the most abrasion-resistant metals. The quick fix for undesirable part flash is manual flash removal or cryogenic deflashing. Both options not only introduce additional cost and cycle time, but may also trigger extra cleaning to counteract any chemical or human contact.

Part design. Material selection is critical to proper part design. Designing a surgical handle with a TPE/PP overmold will open up a world of opportunity for the designer. Some of the key design benefits are as follows:

- Because of the flash issue described above, higher tolerances for flash may need to be set when working with silicone, but not for the TPE/PP combination.
- Since TPE is not abrasive, the TPE part will hold its dimensions and tolerances over the life of the program, whereas silicone dimensions will migrate. The print tolerances may need to be more generous with silicone to account for this shift.
- TPE will fill shapes and sharp edges, giving a true geometry with completely filled part corners. Silicone cannot make a perfect shape if sharp corners are desired. A radius will always form in corners with silicone, and there will not be a sharp finish with lettering or part edges. Unless secondary operations are performed, designers will need to compromise when working with silicone, incorporating curves instead of edges.
- The shrink rate of TPE is 0.9–2.6%, whereas silicone's shrink rate is 2.5–4.2%, including postcuring. TPE will have a much tighter fit to adjacent metal edges on a handle, which will create much less space to potentially trap bodily tissue and other contaminants during surgery.
- The PP substrate shrinks rigidly around the metal shaft of the instrument and the TPE bonds to the PP. Neither the PP nor the TPE can be peeled away from the metal like silicone can. It is critical to note once again that TPE/PP in this application

minimizes the number of places where bioburdens can hide on the instrument.

- TPE is nonhygroscopic and won't absorb water during repeated autoclave procedures, whereas silicone is hygroscopic and the material will swell during autoclave. This will need to be factored in when designing cases and trays.
- TPE and PP are both thermoplastics, which can be recycled (reground and reprocessed). LIM silicone is a two-part thermoset that, once vulcanized, cannot be recycled. This is becoming an important design consideration, as hospitals are becoming increasingly concerned with their environmental footprint.

Branding. The surgical handle is a perfect vehicle for advertising the name of a company or platform. It serves as an extension of the OEM's commitment to creating world-class instruments and can create a lasting first impression, if done well. The look, feel, and performance of the handle are key to its success.

The TPE/PP combination creates an opportunity to tout a company's logo in a contrasting color. TPE and PP complement each other well in that they bond chemically, creating a virtually seamless interface between the two materials. Silicone, by nature, does not bond with other materials. Although it is possible to overmold silicone with other materials, it generally does not produce a strong bond. And any bond that does materialize can exhibit frictional failures with normal surgical use. In order to adhere silicone to other resins, it is customary to pretreat it with a chemical primer, adhesive, or plasma etch, which adds both cost and complexity to a project. It is also possible to insert-mold another resin into silicone; however, with silicone's tendency to flash and its inherent adhesion issues, the probability of success is limited and the cost would be high. With TPE overmolding, good adhesion with crisp letters and no gaps is the final result.

Voice of the customer. The first thing surgeons notice when grabbing a handle is the feel of the material. They want a firm grip that conveys quality. They want to feel connected to the instrument on the end of the handle. And they want a soft-touch material that absorbs the vibration that naturally occurs during use.

With a TPE/PP overmold, surgeons benefit from the stability of the rigid PP combined with the soft touch of the TPE, resulting in a solid touch with a soft feel and vibration absorption. While silicone handles are soft enough to absorb vibration, some of the feeling of connectedness is sacrificed, especially when torque is applied.

In an interview with John Grecco, senior designer, knee engineering, Stryker Orthopaedics, he stated that Stryker had tried to develop both TPE and silicone, but found the TPE to be the least expensive and fastest to market, while also providing good ergonomics and appearance. By contrast, he said the silicone was very difficult to process. "We weren't able to fill the part geometry all the way. It looked like a blob on a stick," he said.

When molding the two-part silicone, resin is delivered cold to the tool cavity, where it is heated and the silicone vulcanizes. Stryker was unable to sufficiently heat the cavity so that the silicone would react with the metal instrument shaft in the tool. The company also tried an all-TPE handle, but it was too soft. The OEM liked the "firmness of the PP substrate and tactile feel of the TPE overmold. The TPE overmold provided the desired shock absorption." The silicone handle was said to have a "greasy feel" without a firm grip. The silicone was "too soft of an elastomer and didn't have enough firmness, whereas ours is rigid for ergonomics, but also absorbs vibration."

"When you pick up a handle, you want it to feel like it belongs in your hand," added Grecco. "When in use, the surgeon wants to feel a direct connection from the handle to the surgical site."

Cost and timing

Beyond the superior look and feel of a TPE/PP overmolded handle, both the tooling and resulting part are less expensive to manufacture than that of its silicone counterpart, potentially cutting time-to-market by as much as half.

Silicone tooling is more complex for two reasons. First, if a cold-runner system is chosen to deliver the silicone to the mold, common among low-viscosity LSR materials, it is more complicated than a hot-runner system, so naturally adds cost and lead-time. Secondly, silicone is notorious for flash, as previously mentioned. The high-precision tooling and gating required to control the silicone shut-off areas usually call for extensive design and machining time, which translates into a considerable capital investment and extended delivery dates. It can take up to twice as long to build a LIM silicone tool versus an injection mold for TPE/PP. Due to its complexity, especially related to shut-offs, the silicone tooling process is often iterative as the bugs are worked out of parting-lines, resulting in missed launch dates.

The TPE/PP overmolded part offers a perfect combination of attributes that leads to a lower cost part. Both TPE and PP have faster cycle times and are less expensive resins than silicone. Due to the lower specific gravities of TPE and PP, less resin is used, resulting in lower part weight. Higher yields can also be expected. All told, the TPE/PP combination produces a significantly less-expensive part. Silicone's complex tooling and processing can also translate into longer development time, which increases time-to-market.

Conclusion

When designing an orthopedic instrumentation handle, it is worthwhile to consider a TPE/PP overmold. The combination of materials with the injection molding process can provide a higher quality product than silicone. It is less abrasive on tooling, protecting your capital investment. It allows a branding opportunity with sharp, crisp images and several colors. And it provides a solid feel with a soft touch at lower cost and less time-to-market—a winning combination.