Enhancing Impact Resistance and Toughness in Molded Medical Parts

Impact resistance and toughness are obvious requirements for applications such as sports equipment, protective eyewear and portable electronics such as cell phones and game controllers. Increasing numbers of medical devices require similar performance. Miniaturization efforts have lead to portable versions of many desktop devices. Any portable device can certainly be dropped or otherwise subjected to impact loads or physical abuse.

For many medical devices, the need for impact resistance and toughness can be less obvious. Typically, surgical devices such as filters, oxygenators, or collection containers would not see impact loads during normal use. But because the consequences of an impact failure are so dire, even a slim chance of an accidental impact failure must be seen as a serious risk. We also need to consider more than just the in-use mechanical loads. Molded parts often see their harshest mechanical loads during manufacturing and shipping.

Factors such as medical device portability and the high risks associated with part failure compel medical device manufacturers to optimize part toughness. This article addresses ways to maximize the impact resistance and toughness of molded medical products.

Material Selection

Medical grade polymers differ greatly in their basic impact and toughness performance, so choosing the right material is crucial. Izod impact test measurements provide a good comparative measure of a material's impact performance. In the Izod impact test, a pendulum swings through and breaks a standard test bar mounted in a cantilever fashion at the bottom of the pendulum arc. The difference in the starting and ending heights of the pendulum swing determines the impact strength of the test specimen.

A standardized notch is usually added to the impacted edge of the test specimen to represent features such as inside corners that are common in most designs. Results for notched samples are listed as notched Izod impact values and should not be compared to unnotched values. Fig. 1 shows notched Izod impact strength values (converted to SI units from ASTM testing) for a variety of medical plastics. Makrolon® polycarbonate grades deliver some of the highest impact values of any rigid, medical thermoplastic.

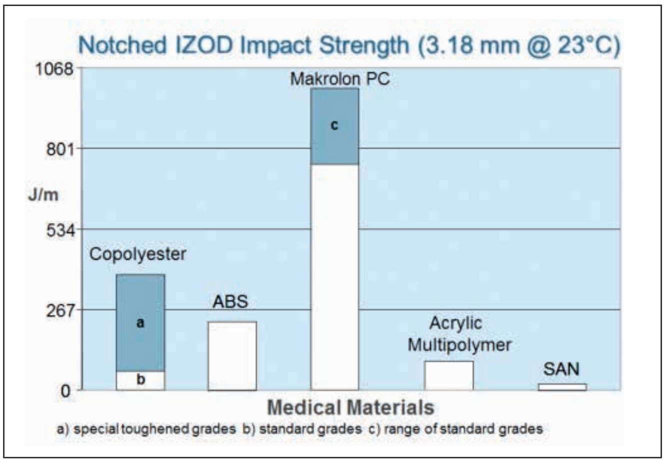
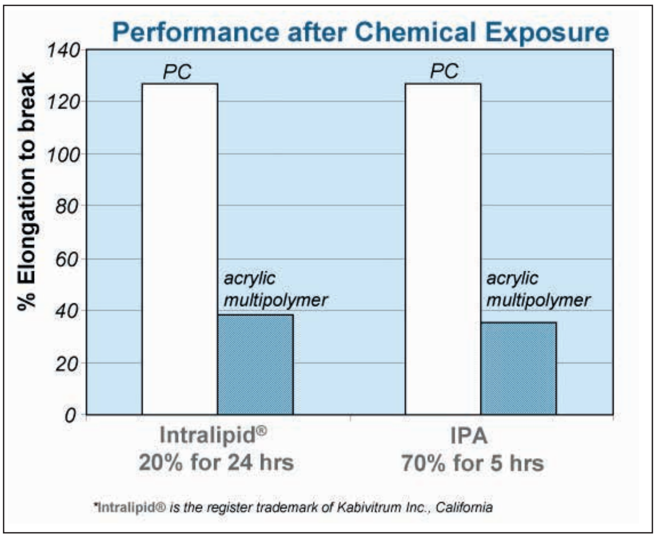


Fig. 1

Covestro also offers medical grades of Bayblend® PC/ABS and Makroblend® PC/PET with notched Izod impact values of about 750 J/m, exceptionally high values which nearly match those for regular polycarbonate.

The tensile-elongation-at-break test is another measure of material toughness. This test measures the strain at fracture, as a percentage of elongation, for a tensile bar elongated at a steady rate in a tensile tester. Materials with higher tensile-elongation-at-break tend to be tougher and more resistant to crack failure.

Chemical agents can reduce elongation-at-break performance, so it is important to consider the chemical environment anticipated for the device. Fig.2 shows how Makrolon® PC retains very high elongation values when subjected to a common lipid solution and to isopropyl alcohol.



*Intralipid® is the register trademark of Kabivitrum Inc., California

Fig. 2

Plastics have a tendency toward brittle behavior at low temperatures and ductile behavior at elevated temperatures. Impact resistance and toughness are therefore more of a concern at low temperatures. Most devices used in hospitals would only see low temperatures during shipping or storage. Proper packaging is therefore important if the material exhibits brittleness at the lowest shipping and storage temperatures.

Portable devices, AEDs and oxygen concentrators for example, could also experience low temperatures while in use. Materials with good low temperature toughness should be specified for such applications. Many Makrolon® PC, Bayblend® PC/ABS and Makroblend® PC/PET grades exhibit excellent impact strength and toughness at –30 °C and colder.

Stress Concentrators

A standard goal in proper design, avoiding stress concentrators, becomes particularly important in impact applications. Impacts create high energy waves that pass through the part and interact with the part geometry. Design features such as sharp corners, notches, holes and steps in thickness can focus the impact energy and initiate fracture.

As inside corners or notches become sharper, the part's impact performance will diminish. Fig. 3 shows the effect of notch radius on the Izod (ASTM) impact performance of unfilled polycarbonate. Decreasing the notch radius from 0.25 to 0.13 mm sharpens the notch and reduces Izod impact strength by about 75 %. This highlights the importance of maintaining a reasonable radius at inside corners such as those formed where tubing ports or support posts joint the main body of the part.

A proper inside-corner radius also improves fatigue resistance, and has been found to be critical in mechanically loaded features which are subjected to vibration during shipping. We typically recommend a minimum radius of 0.25 to 0.38 mm for inside corners subjected to impact or fatigue loads. For features under particularly high mechanical loads, it is often wise to select the largest fillet radius the design can tolerate without creating excessive sink and packing problems.

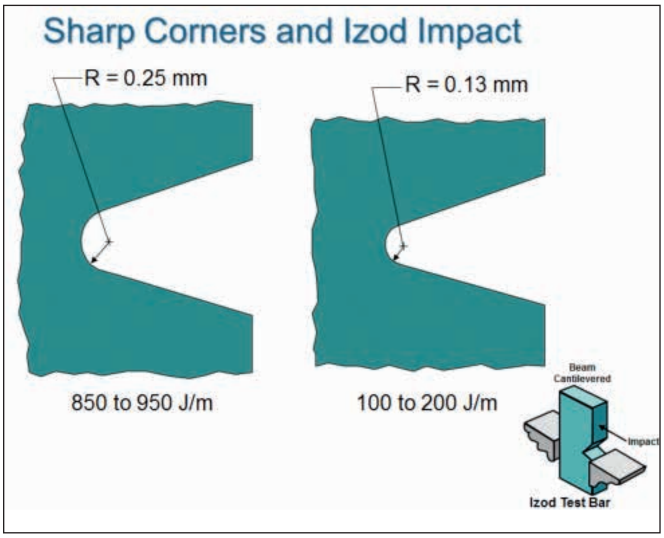


Fig. 3

Typically fillet radii of 0.40 to 0.75 mm provide a good compromise between mechanical performance and part moldability. The inside corner or notch radius needs to be specified as a range that includes a minimum allowable radius rather than by a call out such as "0.13 mm radius permitted" which allows no radius.

Molding and Finishing

Position gates and knit lines away from areas subjected to impact loads. The areas around gates tend to have elevated levels of molded-in stress and diminished impact performance. In addition, improper gate removal can leave rough edges and scratches which can act as stress concentrators. Knit lines typically exhibit lower strength than neighboring areas and can concentrate stresses along the fine V-notch that forms the visible knit lines. Knit lines in unfilled Makrolon® PC grades typically exhibit at least 90 % of the ultimate material strength at weld lines, much higher than for most materials. Unfilled Bayblend® PC/ABS and Makroblend® PC/PET grades tend to exhibit about 80 % of ultimate strength at knit lines.

Part Geometry

Designers often attempt to enhance impact performance by adding ribs or by increasing wall thickness. While this sometimes works, stiffening the part in this way can also have the opposite effect, since adding ribs can introduce stress concentration points that initiate cracks and part failure (see previous section).

Often a better strategy is to design the part to flex, so it can absorb and distribute the impact energy. This can involve reducing thickness or redistributing ribs to accommodate controlled flexure. Avoid boxy shapes with rigid edges and corners in favor of rounded shapes that spread impact forces over a broader area.

Medical parts often have delicate protrusions such as small ports or sensor connections which can be particularly susceptible to damage from accidental impact or mishandling. When possible, locate these features in areas where they would be shielded by other features of the part design or assembly. If necessary, add protective ribs or contour the part shape to provide protection for these fragile features.

Portable medical devices can benefit from the same sort of elastomeric overmolding as is common in devices such as portable test meters, bar code scanners, and personal electronics. The elastomeric overmoldings can provide impact and scratch protection as well as additional styling options. Typically the lower-melt temperature elastomer is molded over a rigid molded substrate. Features can be molded into the parts to mechanically interlock the elastomer to the substrate, but for best performance, an elastomer/substrate combination should be chosen that provides good adhesion between the shared surfaces. Covestro grades of Texin® and Desmopan® TPU elastomers provide excellent adhesion to most Makrolon® PC and Bayblend® PC/ABS grades. Table 1 ranks the adhesive strength of TPU to a variety of plastic substrates. The 2-shot molding process, in which the elastomer is molded over the substrate within seconds after the substrate mold opens, provides the best adhesion.

Table 1 – Adhesion Strength of Overmolded TPU to Various Substrates

Substrate	Adhesion Results
ABS	Excellent
PC	Excellent
PC/ABS	Excellent
Rigid TPU	Excellent
Rigid PVC	Good
Copolyester	Good
Acrylic	Good
ASA	Good
SAN	Good
PET	Good
PBT	Fair
PA	Fair
PE	Poor
PP	Poor

Summary

Miniaturization has led to increasing numbers of portable medical devices requiring impact resistance and toughness. Even devices designed for controlled hospital environments can be exposed to abusive mechanical loads during manufacturing and shipping, or during accidental impact. For these applications, consider the following rules of thumb to improve product performance:

- select a material with good impact performance throughout the part's working-temperature range;
- consider impact loads and temperature exposure during manufacturing, and shipping;
- avoid stress concentrators and sharp inside corners and notches;
- favor rounded product shapes that spread impact energy over broader areas;
- design protection for delicate product features;
- avoid boxy shapes and overly rigid designs;
- consider overmolded TPU to add durability and toughness to portable devices.

The right combination of material and design can result in enhanced product durability, safety, and reliability.

For more information on Covestro products in medical applications, please request from your sales support contact our Guidance document: Guidance on Use of Covestro Products in a Medical Application.

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