

Shorten Time-To-Market By Thinking About Protective Parts Early

It can take years to design and develop a high-tech medical device and get it through regulatory approvals. With all the thought and energy that goes into the design of the device itself, it's easy to forget about caps and plugs needed to protect the device during shipping or sterilization. Although the average cost of these closures is less than 1 percent of the value of the device they protect, they ensure the device gets to the end user in perfect operating condition. Partnering with a company that has years of experience in high-volume production of protective parts can save money, ensure your product is ready to ship on time, and protect your device from damage.

A simple part with an important job

Once a device leaves the manufacturing plant, it becomes vulnerable to damage. Although a variety of packaging protection options such as protective wrap or plastic trays are often used, these do not provide customized, sure-fit protection. Caps and plugs designed to protect your device cushion delicate fittings and precision edges and secure open ports better than generic, one-size fits all packaging solutions.

Although protective parts may seem simple, it's important to think about them early in the design process. Waiting until the device is finished to decide what protection is needed can cause significant delays in getting the product to market, especially if protective parts need to be designed and manufactured. Even worse, not considering protection until customers complain about damage can hurt your relationships and overall trust in the brand.

Early consideration of protective parts can also allow off-the-shelf parts to be incorporated into the design. For example, if the exact size of a port isn't key to the function of the device, it may be possible to use a standard hole or tube size that would allow an off-the-shelf plug to be used for protection. This not only saves money but also time, since many catalog parts can be shipped the same day.

Whether your device needs a custom or off-the-shelf protective closure, there are many considerations in choosing the right part. How the protective part will be used is one of the first factors to think about. If the part will be removed by your customer after shipping, use a part with easy-grip features to ensure removal is quick, easy, and ergonomic. If a nurse wearing gloves must quickly remove a protective part in the emergency room, a part with a wide flange might be recommended to ease that process. A device with multiple ports can be protected by caps that are color-coded to convey important assembly instructions to the end user. For example, colored parts can show where oxygen lines should be connected or distinguish input and output ports.

If the protective part stays on the device during use, it may need to be more durable or provide a certain type of cushioning or grip. Additional functionality can also be

incorporated into protective parts. For example, caps that are reused can be designed with a tether to keep them with the device and ensure they are not lost.

Material is another important factor for protective parts. For example, some devices require medical-grade materials with a chain of custody, or pedigree, that meet FDA standards. A molder experienced in working with medical parts will help facilitate communication with the resin supplier and ensure the supplier has all necessary information about the part. If the part must be sterilized, the material must be able to withstand sterilization temperature. Also, if ETO sterilization will be used, the cap must have tracks that allow the part to vent, ensuring it doesn't "blow off" during the process.

How and where the protective part will be placed onto the device or instrument also influences its design. Parts that will be assembled by hand may need different ergonomic features than those that will be assembled using a robot. Protective parts that will be assembled in a cleanroom should be polybagged to keep them clean. Even the box that will house the device and the shipping method are important to consider when choosing a protective closure that is the right size and provides the correct amount of cushioning against impact.

Custom doesn't mean expensive

Although there is a perception that custom parts are expensive and require months to produce, companies that provide custom protective solutions on a regular basis can offer streamlined processes. For injection-molded parts, building the mold base is the most time-consuming and expensive part of the process. Partnering with a company that offers mold bases that accept interchangeable inserts can cut the time and costs by up to half compared to the more traditional method of creating a mold base for each new injection-molded part. If a standard mold base can be used, the molder only builds the cores and cavities unique to the part or may even be able to use a tool supplied by the customer.

Whether or not interchangeable inserts can be used, look for a molder that has a set process for custom parts. This process should include concept and design services, prototyping, tool fabrication, scalable production, a first-article approval process, packaging options, and inventory management programs. A molder with an in-house engineering team can provide valuable insight early in the design process regarding the manufacturability of the overall design, how protective parts can be incorporated into the design, and which materials would perform best in the application environment. Working with a company that has in-house rapid prototyping and in-house tool fabrication can save time by shortening time to production and by handling any tool problems or design changes that arise during production without having to send tools out for changes.

A molder that offers multiple molding processes, such as injection, extrusion, compression, or vinyl dip molding, can offer you options and help you choose the best process to produce a custom part. A vendor with multiple processes makes a stronger

long-term partner as they are a viable option for future projects. This can save time and money by allowing multiple parts for a variety of different projects to be produced at the same pre-approved, audited facility.

When picking a partner to make protective closures for a medical device, it is also important to understand the process they use for product approval. Ask your supplier if they have an internal quality management system with full transparency and redundancy programs. Strong part design and molding capabilities will not save a project if the part quality and consistency can't be trusted.

Outsourcing brings savings

Some medical device manufacturers have the capability to make their own protective parts. Although this may be feasible in some cases, it can take focus away from the molding of more critical components and sometimes result in higher costs than outsourcing these parts to a company that has optimized the process of making caps, plugs, and other components. Even though caps and plugs may be viewed as simplistic, not giving them the proper attention during the design and production stages can lead to incorrectly molded parts or parts that aren't ready in time. These problems can cause significant delays in shipping the final product.

Outsourcing caps and plugs comes with several advantages. It can free up employees to focus on product design or other projects and also means these products don't take up valuable machine time or have to be scheduled in between other projects. Companies that deal heavily in protective products can pass on their resin purchasing power in the form of lower costs. Outsourcing also provides set pricing for these parts. It can be difficult to calculate the internal costs for making protective parts, especially if they have to be inventoried or their production must be matched to that of the device.

For all of these reasons, it can be more efficient to outsource these products to a company used to making many orders, shipping many products holding inventory, and using advanced shipping notifications.

In summary, partnering with a trusted supplier of protective plugs and caps can ensure these parts receive the full attention needed to keep your device protected and shipping on time.

About Caplugs

Caplugs is a leader in plastic molding of product protection and components that has been serving the medical industry for 65 years. We can provide same-day shipping for our catalog product line that includes thousands of precision-molded caps, plugs, tubing, connectors, and other parts to protect your medical equipment and devices during sterilization and shipping. For custom parts, Caplugs can save you time and money by using mold bases that accept interchangeable inserts. Our dedicated team of in-house design engineers will collaborate with you every step of the way to develop custom parts that fit your exact requirements. We offer comprehensive manufacturing

capabilities, rigorous process controls, and a wide range of materials to serve the medical market. With more than 1,300 medical customers, a series of ISO certifications, a Class 8-certified cleanroom, and a stringent quality management process, Caplugs understands the unique challenges and needs of the medical field.