Manufacturing Medical Devices for Radiology

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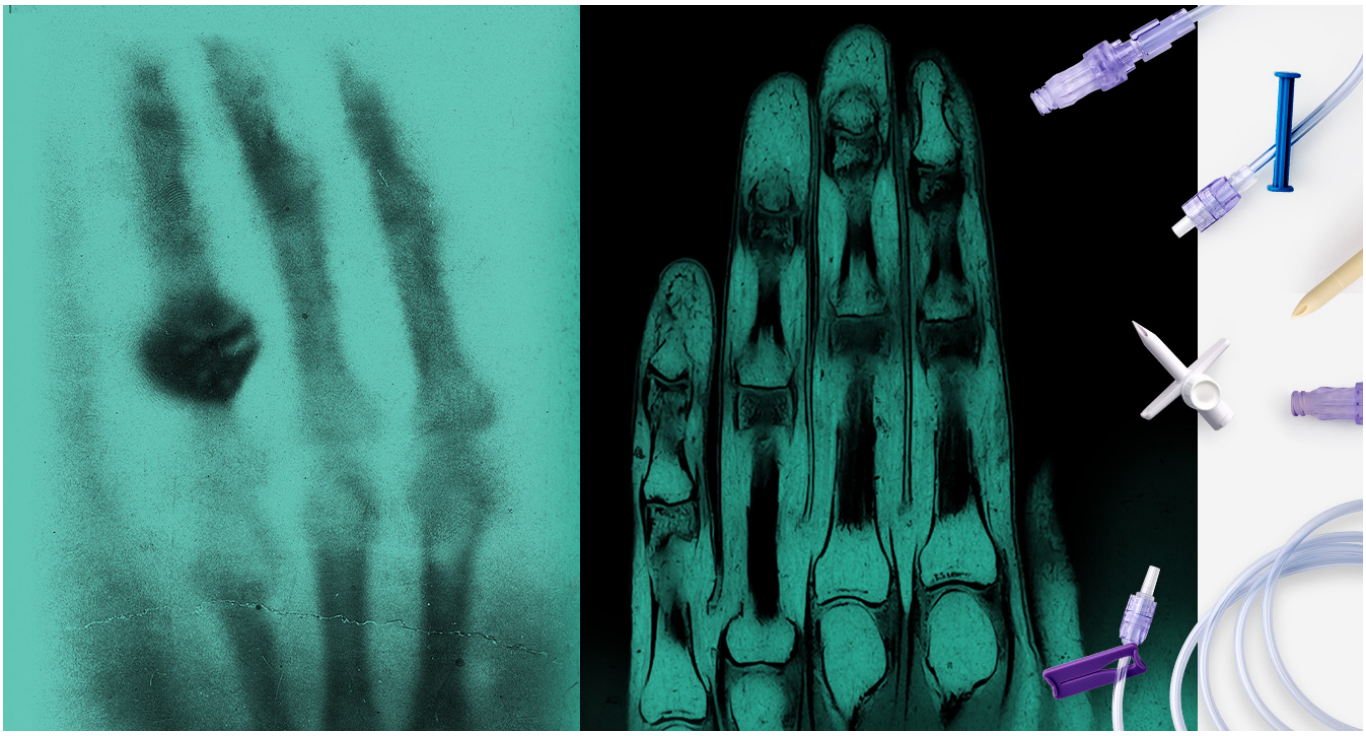

In general, the more specialized a field of medicine is, the more specialized their medical devices. Procedures become more intricate. Tolerances need to be tighter. User requirements are more demanding.

The tenet is true with disposable medical devices that deliver contrast media intravenously for radiological procedures. Fundamentally, the devices move fluid from one place to another, the same core function as a simple IV set. But the demands of modern imaging procedures require device engineers to accommodate a number of additional specifications.

Contrast media devices can incorporate power injectors that use increasingly high dynamic pressure to get the mixture of contrast media and saline into the body as quickly as possible to make the timing of contrast media delivery more precise, concentrate the media in the desired area for optimal visualization, and speed procedures for time and cost savings. The high pressure requires a number of design upgrades to ensure reliable device function.

Components and Tubing

Everyday medical devices that convey fluids will normally experience pressures below 30 PSI. The higher pressures in contrast media applications require all components and tubing to be pressure rated. For example, conventional normally closed check valves that allow for intermittent injection of fluids while preventing backflow are typically rated for only 45 PSI.[1] Some manufacturers offer a high-pressure option that will handle 400 PSI for specific applications.[1]

Similarly, any tubing for the device needs to accommodate the higher pressure without the possibility of bursting or deformation. That usually means stepping up to stiffer tubing to offer a good balance of hardness and flexibility.

In addition to the higher pressure, the relatively dense contrast solutions need to be removed from the container to the injector itself. Most contrast solutions are commercially available in vials. This may require a correctly sized vented spike to access the vial and tubing large enough to allow a consistent flow to the injector container.

Joints and Heat Treating

Bonded joints are a natural source of weakness in any design. They must withstand the same pressures as the components. One way of accomplishing this is by using stronger solvents. Where a low-pressure medical device might use one particular blend of solvents, a high-pressure application might look to a different ratio or use a different blend of solvents to yield a stronger bond. Whatever solvent ratio is used, it is critical to make sure the solvent is compatible with the materials in the tubing and components to lessen the chance of cracks or leaks.[2]

Also, some manufacturers opt to anneal their products to prevent cracking or dimensional change, which could have a negative impact on commonly used polycarbonate resin in valves.[6] Full transparency about how components will be processed is essential.

Additional Considerations

Some kits may opt to include a peripheral IV catheter. Given that a peripheral IV line in the antecubital or forearm area is preferred for most power injections, the proper gauge (usually 20-gauge) is ideal for flow rates of 3 mL/sec or higher.[7] The gauge also needs to be appropriate for the viscosity of the contrast media solution and needs to be rated for the specific power injection pressure. For the safety of clinicians and patients, a peripheral IV catheter with passive needlestick protection is recommended. Likewise, for patient and clinician safety, strongly consider including swabbable needleless connectors for situations where a peripheral IV is already established.

Scientific evidence continues to grow regarding the potential negative health effects of patient exposure to DEHP.[8,9,10] The American Medical Association, among other professional organizations, has approved policies encouraging hospitals and physicians to reduce and phase out the use of products containing DEHP.[11]

Outside of product specifications, function and composition, supply chain integrity is another factor to weigh when selecting components or a device from a contract manufacturer. Supply shortages experienced during the pandemic prevented some devices from being produced because of missing components, sometimes as small as a check valve. Supply chain integrity is critical, as is having a secondary validated supplier at the ready.

Overall, devices for the injection of contrast media for radiology procedures have several unique requirements that are critical to incorporate into the design in addition to expected attributes of safety, ease of use and accuracy. Working with an established contract manufacturer can bring extensive expertise to the challenge of engineering devices that are reliable, cost-effective and resistant to supply chain disruptions.

Materials matter. Over the past 20+ years, many government agencies and healthcare organizations have grown increasingly concerned about the risks posed by toxic chemicals including Di(2-ethylhexyl) phthalate (DEHP).

From Concept to Manufacturing and Assembly

Medical devices are designed to meet the performance specifications laid out by product managers. Contract manufacturing partners will also look at them through a manufacturing lens based on experience, available equipment and regulatory knowledge. The perspective can result in design and engineering changes intended to enhance the quality, lower the long-term cost, simplify the manufacturing or assembly process, or improve documentation — all while ensuring the original specifications are maintained.

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Here are some specific ways that design and engineering expertise from a contract manufacturer may influence final design.

Design for Manufacturing

Creating a part in a CAD system is one thing. Having it successfully emerge from an injection molding machine or assembly line is another. Our extensive experience allows us to help customers maintain the integrity of the design while adding moldability and assembly attributions that reflect how the machine will bring each part to life.

Design for Scalability

Many medical devices begin their lifecycle below the high-volume threshold, sometimes with manual procedures. Successful scaling to high-volume manufacturing requires foresight and planning to streamline the production process early in the lifecycle. Our engineers might take a five-year view on a project and suggest changes that will make scaling less cumbersome and less expensive.

Design for Safety, Ease-of-Use and Accuracy

Whether finding ways to prevent needlesticks among medical professionals or incorporating materials that are compatible with the liquids that a device holds or conveys, our engineers can apply their expertise into contract manufactured products. Safety is ultimately in everyone's best interest. The same holds true for ease-of-use and accuracy. Designing and selecting components that help reduce the risk of medical error, simplify clinician procedures and enhance the accuracy with which those procedures are performed is paramount to improved patient outcomes.

Product Documentation

Documentation is becoming a bigger and bigger part of contract manufacturing projects. And we can only expect the front-end documentation requirements to become stricter. B. Braun has well-established monitoring tools and testing processes to show we are meeting regulatory requirements before devices are submitted for approval. We may suggest changes to design or production to ensure the proper data can be obtained.

In the end, we believe a collaborative effort between our customers' engineers and the B. Braun team will yield a device that performs as designed and can be manufactured efficiently now and into the future.

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