

Balloon-Forming Innovations Improve Quality and Reduce Cost

David Yanes and Eric Mabry

Catheter balloons are an important device for a variety of cardiovascular treatments. However, their manufacture can be a complicated process that, if completed wrong, can lead to waste and excess costs. This article highlights a number of innovative technologies that are being offered to help balloon manufacturers ensure their products are defect-free the first time.



Medical technology is evolving rapidly—OEMs and end users are demanding smaller, more complex, and more multi-functional products, often made from newer materials with tighter tolerances—with faster turnaround at the lowest possible cost.

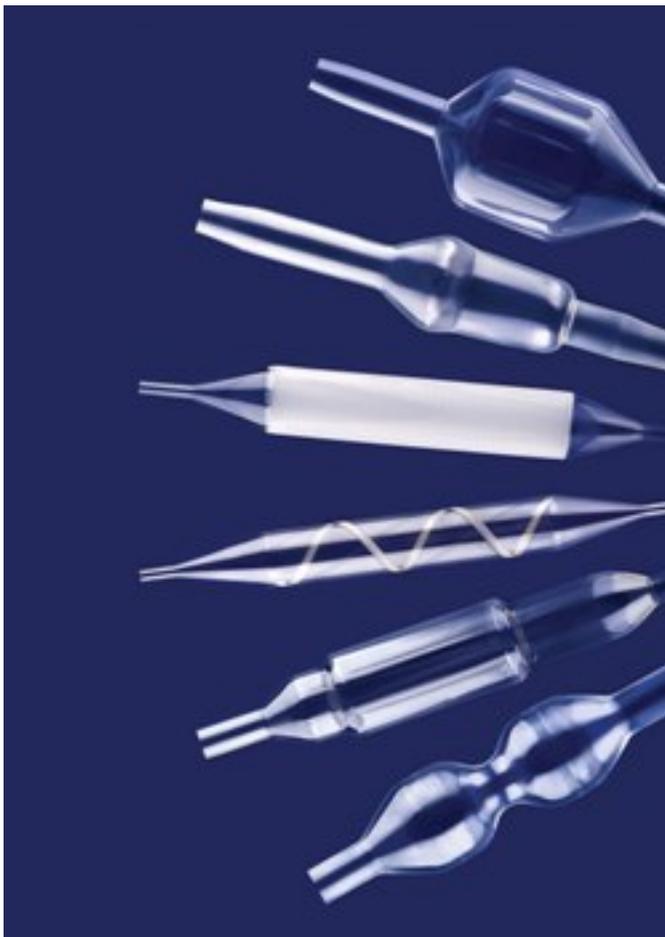
The only way for medical device manufacturers to meet these demands and maintain market share (without sacrificing quality) is by staying on top of new

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technologies, manufacturing processes, advanced materials, quality controls, and best practices to deliver what their customers need. This requires long-term vision and commitment, as well as devoting the time, personnel, and resources to make it happen.

It's not just technology from the manufacturer's realm of operations, either—proactive companies bring together the best technologies and practices from other fields (optics, automation, and computer engineering, for example) to create innovative applications for their own unique set of production needs. If a company can't find exactly what it needs, the next step should be investing in R&D to develop its own proprietary technologies.



Balloon manufacturing is one of the most challenging, high-precision areas among medical device because there are so many critical factors that must be precisely understood, monitored, and controlled at all times to create a safe, high-quality product. Some of these factors include material chemistry and dimension, material preparation, applied force, speed of stretch and forced stretch, rate of inflation, explosive expansion, exponential pressure decay, mold venting, heat flow, chamber pressure, and rate of cooling. Even the slightest variation in any of these parameters during the balloon-forming process can result in low yields, high scrap, product failures, and unhappy customers.

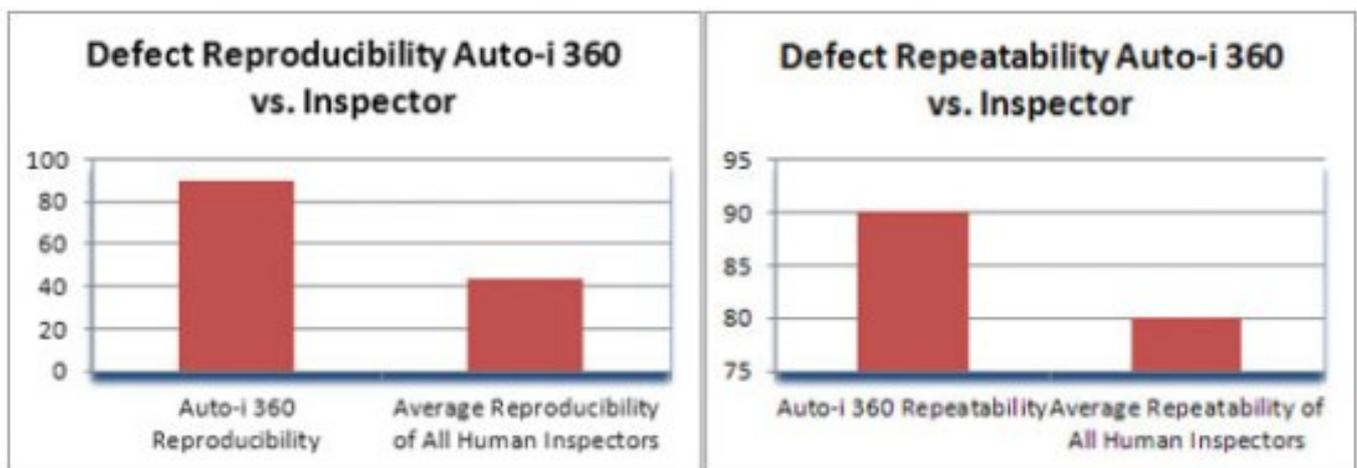
A problem for many balloon manufacturers is the inconsistent behavior of the balloon extrusion from lot to lot—for example, the balloon might not form at a predetermined point or proceed in a predictable direction. These inconsistencies are often the result of lot-to-lot variations in balloon tubing properties. Correcting these

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annoyances requires frequent inspection and adjustments during the extrusion process, which extends balloon development times, reduces production yields, and increases costs.

Other problems can be variations in finished balloon wall thicknesses that can greatly impact burst pressure; this is becoming even more of an issue for some manufacturers as customers push for thinner walls and higher burst strength. There is also the inability to obtain higher neck-down ratios (ratio of balloon diameter to balloon neck diameter); this is a growing challenge as more customers are attaching larger-diameter balloons to smaller diameter shafts. Improper understanding of material behavior, as well as contamination of raw materials, can also lead to structural flaws known as “fish eyes” and “crow’s feet” that can cause balloon failure.



Without the proper investment in material science and technology, balloon manufacturing involves a certain amount of guesswork that can result in low yields and create uncertainty among clients because they never feel totally secure about consistency of product. Balloon manufacturers overcome these challenges by investing in or developing the appropriate technologies and best practices to monitor and control, with high precision, every step of the balloon-forming process. This creates repeatability, which also makes validation easier. This convergence of technologies will:

- Greatly reduce balloon development time and cost
- Reduce delivery times for balloons
- Increase pre- and post-inspection yields
- Improve gross margins
- Improve overall quality and performance of balloons
- Drastically reduce rejection rates of balloon tubing extrusion runs

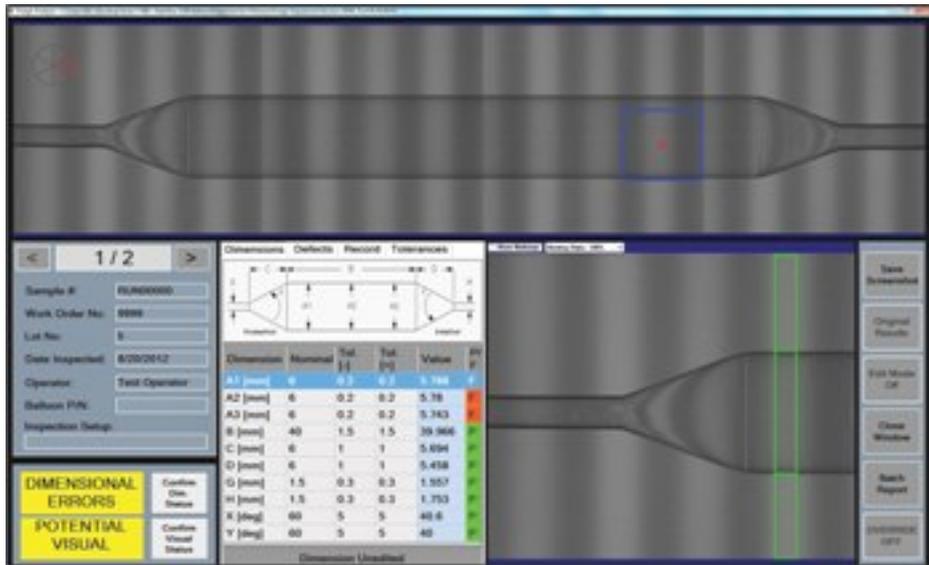
A Parameter Development System Essential for Success

Leading companies have a commitment to truly understand, at a deep level, the complexities and interactions that occur among the technologies, equipment, processes, materials, and manufacturing environments involved in balloon-forming. Both extrusion and balloon forming are very complex processes that involve a multitude of interacting parameters. Consistent, repeatable production of high-

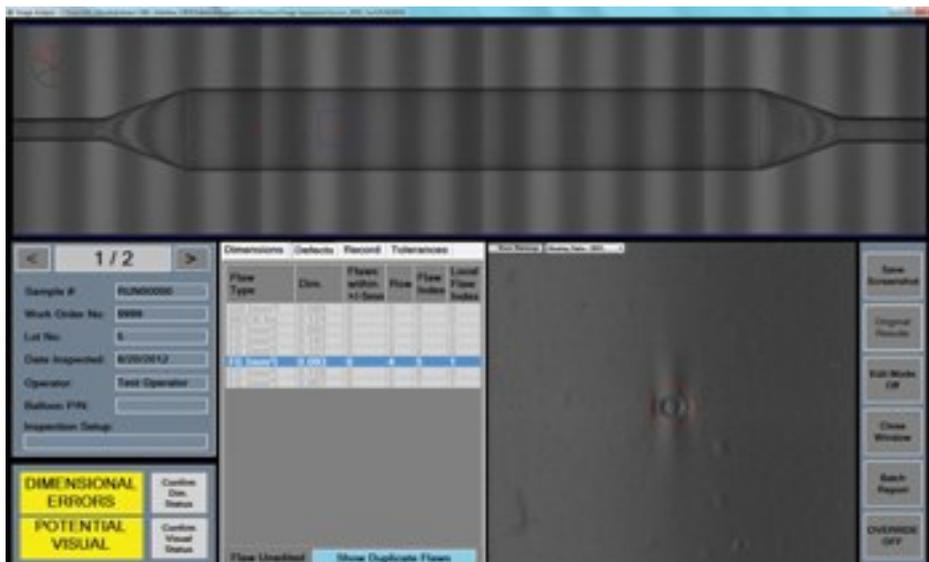
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quality balloons that meet or exceed customer specifications is only possible through precise monitoring and control of all variables, at every stage of the balloon-forming process.



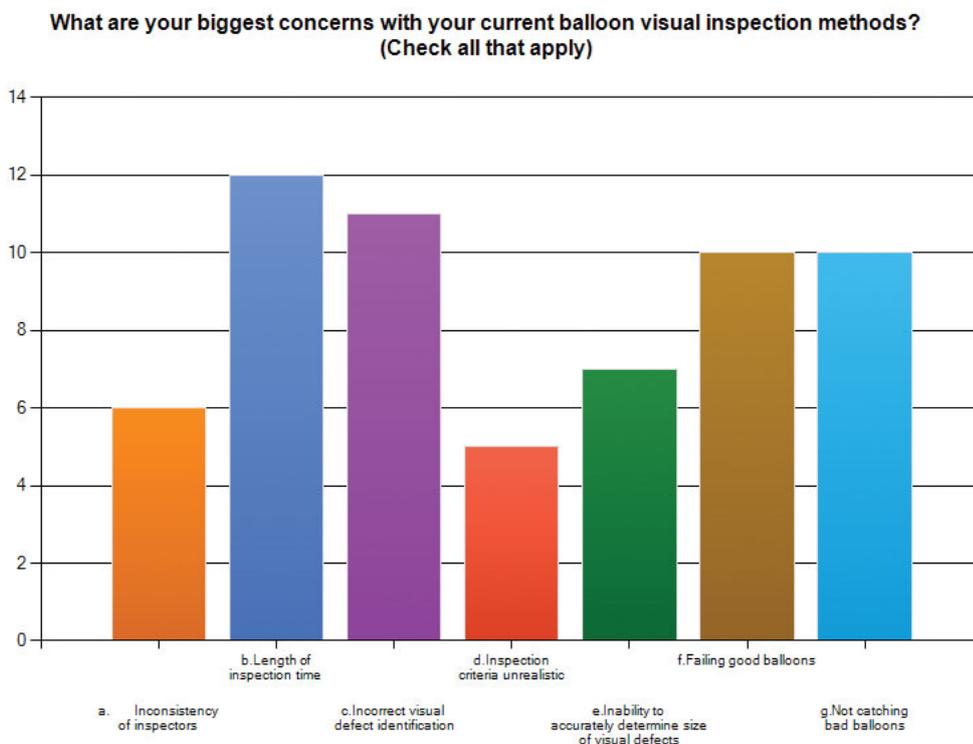
To achieve this, [Interface Catheter Solutions](#) [1] created a proprietary parameter development system (PDS) that enables the step-by-step scientific assessment of each individual parameter. This computerized, testing device allows engineers to quickly assess the individual properties of tubing as they relate to the balloon-forming process, as well as determine optimum balloon-forming parameters. These include temperature, inflation pressure and flow, and radial expansion and axial stretch—both in terms of rate of change, uniformity, and absolute accuracy. The system can also identify small variations in mechanical properties between individual extrusion lots that may lead to flaws in the balloon wall.



Tubing characteristics can be established on a lot-to-lot basis so balloon-forming parameters can be quickly adjusted in production. Tubing lot rejections and subsequent re-runs for unsubstantiated reasons can also be eliminated. Other advantages of the PDS are improved yields, reduced scrap, shorter machine set-up times, and faster production.

Optimized Parison Forming

Engineers can rely on the parameter development system to accurately configure the parison, which is essential for a successful balloon-forming operation. The parison defines the cone angles and the body of the balloon. The left and right sections of the tubing are necked down to make them harder than the non-necked section of tubing. The non-necked tubing is considered the parison; its length depends on the material type, desired wall thickness, and dimensional requirements, including body length, cone, and neck. The hardened sections on either side of the parison allows for stretch and blow control during the primary and secondary stretch operations. If these sections are not drawn down correctly, the force and distance required to displace the material during balloon blowing will be unpredictable and inconsistent.



[2]To optimize parison forming, Interface Catheter Solutions developed a computerized parison stretcher that provides accurate, repeatable results for neck-down tubing in preparation for balloon forming. This equipment can stretch up to three parisons with the same parameters and precisely control stretch speed, temperature, distance, and timing for consistent results and optimal production yields. The stretcher is PLC-controlled and easy to program with a touch screen. Custom jaws can handle a wide range of sizes and balloon tubing materials, including nylon, polyethylene, polyurethane, and polyethylene terephthalate (PET), making it easy to load the tubing and clamp into place. The jaws extend during the tube-heating process and retract when not in use. The parisons are gripped by air-powered soft clamps located on each side of the heater jaws, which provide a secure grip during the heating and stretch cycle to obtain a well-defined transition on the parison.

High-Efficiency Water Jackets

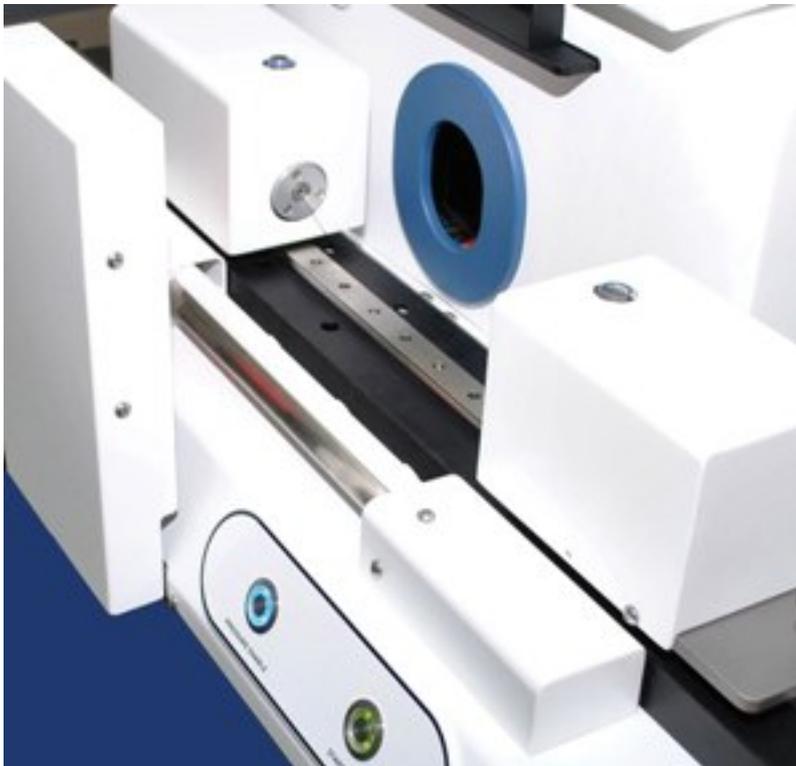
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Controlled heating is a critical phase of balloon forming. High-efficiency water jackets provide a more uniform heating and cooling environment for balloons during the balloon-forming process. They can accommodate a large range of balloon sizes and lengths. The latest models have been improved to create a more uniform thermal profile, shorter process times, and repeatable ramping capabilities. The uniform thermal profiling enhancements result in balloons that are much more consistent in wall thickness that result in higher burst pressures. The high-efficiency water jacket improvements also provide better control and cycle times, which improve balloon cost. Other advantages include quick installation and set-up, smooth thermal ramping, stable plateau, faster thermal stability, and uniform heating of circumference and length of molds. When water jackets are combined with upgraded balloon-forming equipment that provides better directional flow for water cooling and air purge control, the result is very consistent and repeatable balloon production.

Automated Visual Inspection System

Significant balloon defects can be difficult to find, categorize, and measure, especially using the manual contact measurement and inspection tools that are still considered the standard today. These tools are also inferior for determining precise critical dimensions such as interior diameter, wall thickness, and concentricity. This leads to missed gels and fisheyes and often generates inspector disagreements on defect type, which lead to high scrap, low yields, lack of control, and lack of improvement.



To address these problems, Interface Catheter Solutions has developed an automated balloon inspection system that provides both visual inspection and dimensional measurement of medical balloons in a single operation, thereby increasing and improving both throughput and accuracy. Cycle time is about 30-60 seconds, depending on the size of the balloon. Using a high-speed, five-megapixel camera and telecentric measuring lens to provide high-resolution images (seven micrometers for small balloons at 40x and

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28 micrometers for large balloons at 10x), this technology enables quick identification and classification of visual defects such as gel spots, fish eyes, crow's feet/strain lines, zipper lines, and embedded foreign particulates, as well as provides highly precise, repeatable dimensional measurements, using non-contact, high-resolution camera technology. It is also equipped with filtering options for non-translucent or matt- and textured-finish balloons that improve the ability to identify defects within these finishes—another challenge for inspectors.

Conclusion

Balloon tubing must meet critical production standards to achieve important performance characteristics such as minimal wall thickness and improved burst pressures. These parameters must be within prescribed limits and must be consistently reproduced in all subsequent production runs.

Using a scientific approach to develop a balloon optimization system allows balloon catheter manufacturers to speed up cycle times, improve burst pressures, maximize quality, increase yields, limit scrap, reduce costs, improve customer satisfaction, and gain market share.

To accomplish this, balloon manufacturers must incorporate a number of advanced technologies and systems to precisely control the many variables that can impact balloon production. In fact, by providing innovative technological capabilities and options that weren't available a few years ago, these manufacturers enable balloon engineers to expand their design capability and create new products to address unmet market needs.

David Yanes is the director of equipment technology at Interface Catheter Solutions. Eric Mabry is the VP of equipment engineering with the company. Interface Catheter Solutions is the only vertically integrated provider of outsourced solutions for balloon and catheter manufacturing. The company has been solely focused on the balloon catheter market since 1995 and continually sets industry standards through process improvements and equipment advancements in balloon catheter manufacturing.

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Links:

[1] <http://www.interfaceusa.com/>

[2] <http://www.mdtmag.com/sites/mdtmag.com/files/legacyimages/visual-inspection-survey-ch.jpg>