

# WEBINAR BRIEF:

## Beyond the Balloon — What's Next in Balloon Catheter Technology

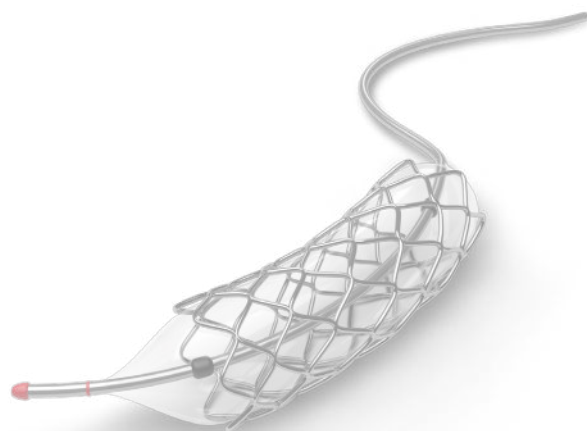


### Presenter:



### Ryan Phife

*Manager of Prototyping and  
Technical Services*  
Confluent Medical Technologies



### OVERVIEW

In the DeviceTalks Tuesday session titled “Beyond the Balloon: What’s Next in Balloon Catheter Technology,” Ryan Phife, a senior engineer at Confluent Medical Technologies, showcased how the company’s material science expertise and vertically integrated manufacturing capabilities continue to shape the next generation of minimally invasive devices.

Providing an in-depth overview of balloon catheter technology, including design considerations, manufacturing processes, material selection and emerging trends in the field. Phife shared insights from decades of experience developing, transferring, and manufacturing minimally invasive medical devices, emphasizing Confluent’s vertically integrated approach and its value to both large OEMs and startups.

### KEY TAKEAWAYS



**Innovation is constant.** Balloons continue to evolve through new materials, coatings, and applications.



**FDA clarity on PFAS** gives manufacturers more confidence while still encouraging alternative material exploration.



**Partnership matters.** A manufacturing partner with regulatory knowledge and vertical integration accelerates success.



**Emerging technologies** — from PFA to drug-eluting and laser-modified balloons — are expanding therapeutic possibilities.



**Material choice is critical.** The right material depends on compliance, application, and manufacturability balance.

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## A CAREER BUILT ON BALLOONS

Phife began his early days in the industry — a career that began hands-on in balloon development. After earning his biomedical engineering degree from Cal Poly San Luis Obispo, he joined Interface Catheter Solutions, where he helped design and produce catheter components.

“My very first job was balloon development,” he recalled. “I was on the floor every day, setting up and breaking down machines, developing processes, and building balloons,” says Phife.

That experience helped him understand the complexity behind manufacturing precision.

“It gave me a strong understanding of the expertise needed to set up a machine, what goes into it, and the challenges of getting on spec,” says Phife.

Interface later merged with Nitinol Devices & Components, forming Confluent Medical Technologies, where Phife has remained for more than a decade.

## FROM THE FIRST CATHETER TO TODAY’S ADVANCED DEVICES

The history of balloon catheter innovation traces its roots back to 1929 when Dr. Werner Forssmann performed the first cardiac catheterization—on himself.

“He tricked a nurse into helping him place a catheter in his artery and then walked down to the X-ray department to prove it was safe,” says Phife.

By the 1970s, balloon catheters were widely adopted, laying the groundwork for innovations such as drug-eluting stents, radial access devices, and specialized coatings.

“This technology isn’t new, but it’s always evolving,” says Phife. “Cardiovascular disease continues to rise, and balloons remain a reliable, minimally invasive treatment.”



## EXPANDING APPLICATIONS BEYOND THE VASCULAR

While vascular intervention remains central, balloon technology has expanded across multiple specialties — from GI and ENT to orthopedic and neurovascular applications.

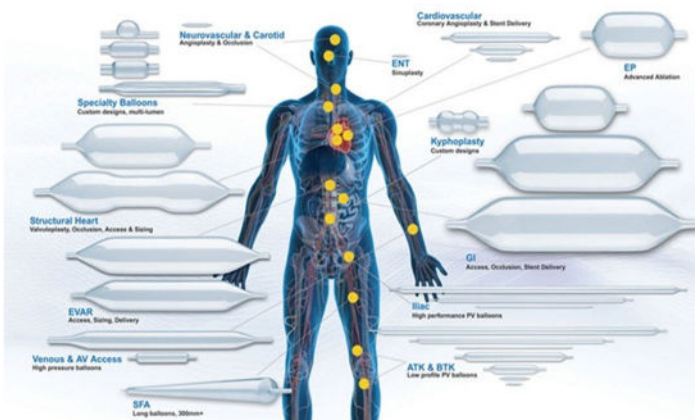
“Anywhere in the body where there’s a restriction and you need to open something up — there’s potential for a balloon,” says Phife.

This adaptability, he noted, is driving continued investment in material science and device customization.

## WHY MINIMALLY INVASIVE STILL WINS

Balloon catheters align perfectly with the broader shift toward minimally invasive treatment.

“It reduces what you have to put the patient through, it’s not a long OR time — just a small incision for access,” says Phife.



## PARTNERSHIP AND PROCESS EXPERTISE

The value of working with a manufacturer that understands the entire product lifecycle — from concept to compliance is ideal.

“We know what tests are going to be required,” says Phife. “Even though we’re not doing the submission for you, we know what the FDA will ask for, what worst-case scenarios look like, and how to spec your design accordingly.”

That knowledge helps customers streamline their development path and avoid delays. Many balloon devices, he added, qualify for 510(k) submissions, which speeds time to market.

## MATERIALS, DESIGN, AND TRADE-OFFS

There is an ongoing challenge of balancing profile size, flexibility, and burst strength.

“Balloon design is all about trade-offs,” says Phife. “You want lower French sizes but high burst pressures. Don’t make it too thick, but don’t make it too thin that you risk fatigue failure.”

Common materials include nylon 12 (Grilamid L25), Pebax, and urethane-based compounds. Each offers unique performance characteristics depending on compliance needs and application.

## PFAS AND MATERIAL INNOVATION

The FDA recently stated it is not taking steps to restrict PFAS (per- and polyfluoroalkyl substances), long used in medical device manufacturing for their lubricity and chemical resistance in devices, though many manufacturers are still exploring alternatives.

“I’ve seen people go to HDPE as an alternative,” says Phife. “It’s not quite as good, but it can go through a similar sterilization process and provide low friction at a lower cost.”

Other innovations include lubricious coatings for catheter liners. “That’s pretty novel,” says Phife. “The FDA has strict requirements for coatings, but it’s another interesting design path.”

## CONFLUENT’S VERTICALLY INTEGRATED ADVANTAGE

Phife provided a detailed look at Confluent’s global Centers of Excellence, which support the entire continuum from development through high-volume production:



**Fremont, CA:** Nitinol materials and components



**Orange County, CA:** Balloon catheter and extrusion development



**Austin, TX:** Advanced catheters and R&D (coiling, braiding, overmolding)



**Chattanooga, TN:** High-precision polymer tubing and thin-film PTFE liners



**Warwick, RI:** Textile technologies



**Costa Rica:** High-volume, end-to-end manufacturing

“We can build your extrusion components, attach and assemble, package, label, and palletize for sterilization. It’s true end-to-end manufacturing.”

**Ryan Phife**

*Manager of Prototyping and Technical Services,*

Confluent Medical

Confluent’s Costa Rica facility, located in the Coyoil Free Trade Zone, handles large-scale production, coating, packaging, lasering, and sterilization in partnership with STERIS.

“We can build your extrusion components, attach and assemble, package, label, and palletize for sterilization,” says Phife. “It’s true end-to-end manufacturing.”

## PARTNERING FROM STARTUP TO SCALE

Confluent works with both large OEMs and early-stage startups.

“We have customers like Johnson & Johnson, Edwards, and Cordis — but also a startup with four people where we’re helping develop and test their first submission,” says Phife.

That flexibility allows Confluent to support clients at any stage of development — from defining material requirements to executing custom tests for novel designs.

“We’re not just a machine shop,” he explained. “We’re here to help you get where your device needs to go.”

## EMERGING TRENDS AND NEXT-GEN BALLOONS

Several new frontiers in balloon technology:



**Pulse Field Ablation (PFA):** “It’s making major waves,” says Phife. “Balloons can help deploy electrodes that ablate cardiac tissue, then collapse again — an elegant way to ensure consistent contact.”



**Laser Modification:** Using laser drilling to create micro-perforations allows drug elution directly through the balloon wall — a design that “lets the drug weep out for direct contact with the vessel.”



**Filter Applications:** Altering balloon geometry and collapse dynamics can enable new embolic filters or protection devices.

Drug-eluting technologies remain a major focus.

“It’s a simple idea that provides long-term relief,” says Phife, referencing a urethral stricture project where localized drug delivery prevented restenosis.

There is also a rise of hyper-compliant balloons made from urethanes.

“When I started, everyone wanted the highest burst pressure possible,” says Phife. “Now I see more creative uses of compliant materials. They’re challenging to work with, but really rewarding.”

## THE VALUE OF VERTICAL INTEGRATION

Confluent’s vertically integrated supply chain as a key differentiator.

“When your customer and your supplier are internal, it makes everything easier,” says Phife. “I can run a balloon, walk it over to the engineer, and get feedback in minutes. It’s a faster, more collaborative process.”

This structure simplifies logistics, shortens lead times, and allows for real-time problem-solving — particularly when developing and transferring new products to scale.

“Having a partner that understands the history, the testing, and the manufacturing process — from development through scale — really sets you up for success,” says Phife.

## CONCLUSION

Confluent Medical Technologies’ comprehensive expertise in balloon catheter development, emphasizing both technological innovation and practical manufacturing strategies from material selection and laser-enabled modifications to drug delivery and hyper-compliant designs, shows how vertical integration, deep technical knowledge, and collaborative partnerships enable faster, more efficient, and high-quality device development.



**Ryan Phife**

*Manager of Prototyping and  
Technical Services*  
Confluent Medical Technologies

Ryan graduated from California Polytechnic State University with a degree in Biomedical Engineering and started as a balloon development engineer at Interface Catheter Solutions in 2013. When ICS was purchased by NDC in 2015 (now Confluent Medical Technologies), Ryan transitioned into catheter development and transferred the first catheter project (Kyphoplasty) to the new Costa Rica facility. In 2024, Ryan became the Prototyping Manager for Confluent’s Balloon Catheter Division and assists customers with early concepts and design iterations. Ryan is a proud father of an 18 month old daughter and spends his free time enjoying concerts and playing golf.

Confluent specializes in expert design and development of large-scale manufacturing specializing in interventional catheter-based devices and implants.

To learn more, visit: [confluentmedical.com/](https://confluentmedical.com/).

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