Scaling High-Performance Catheter Production at Speed

Reducing time-to-productivity with innovative manufacturing solutions.

From slower production to increased scrap, scaling catheter production can present challenges for device manufacturers. Innovative manufacturing solutions can overcome these barriers to productivity, helping to simplify manufacturing processes, increase yields, and improve safety when accelerating ramp-up in catheter production.

Market: Medical Device

Sub-Market: Peripheral

Process: Heat Shrink Removal

Challenge: Scaling Production to Meet Market Demand

Category: PTA Balloon Catheters

Zeus Product: FluoroPEELZ™

A Growing Concern – Peripheral Artery Disease

Peripheral artery disease (PAD), caused by atherosclerosis and the subsequent restriction of blood flow in the peripheral arteries, is a growing global health concern affecting more than 236 million people worldwide.[1,2] When looking at trends in the prevalence of PAD, systematic reviews have estimated the number of people living with PAD increased by roughly 45% between 2000 and 2015.[1,2,3] It's clear that despite advancements in medicine around the world, PAD remains a significant issue.

The treatment of PAD largely depends on the severity of the disease. It ranges from simple lifestyle changes to open surgery or, in the most severe cases, amputation of the affected limb. However, advancements in endovascular devices and surgical techniques have resulted in more widespread adoption of minimally invasive surgical interventions to treat this condition.

PTA balloon catheters are among the devices most used in these minimally invasive interventions, especially in treating lower extremity PAD – the most common type.

As the prevalence of PAD has continued to rise, so has demand for PTA catheters capable of delivering new, innovative therapies into the ever-complex anatomies below-the-knee (BTK), with industry reports suggesting the global PTA balloon catheter market is expected to expand at a compound annual growth rate (CAGR) of 9.92% from 2022 to 2030.[4]

With the increasing demand for limb- and life-saving catheter-based PAD interventions, device makers face a critical challenge: scaling catheter production to keep pace.

>230M

people worldwide affected by PAD

Source: https://www.ahajournals.org/doi/10.1161/CIRCRESAHA.121.318535

PTA balloon catheter market expanding at a CAGR of

9.92%

from 2022 to 2030

Source: https://www.grandviewresearch.com/industry-analysis/pta-balloon-catheter-market

Scaling Production to Meet Market Demand

Significantly scaling catheter production, whether at an existing facility or when moving production to a cost-competitive manufacturing environment, typically requires onboarding many new operators. These new operators, often with varying levels of skill, must then be extensively trained in the complex assembly processes of the device.

Assembling advanced catheters, such as PTA balloon catheters, is a time-consuming and tedious process, with the heat shrink fusing sleeve playing an often-overlooked role in manufacturing efficiency.

While FEP heat shrink is a time-tested and popular choice for catheter fusing sleeves, it does have significant drawbacks during the removal phase, as it must be shaved off using a skiving tool and razor blade.

Razor blades on the production floor introduce a hazard not only to the operator, but to the nearly finished device as well. While experienced operators may skillfully and safely remove FEP heat shrink with the skiving tool, they are not immune to the challenges it presents. Traditional skiving tools require frequent blade changes and precise adjustments to remain effective. Improper adjustments or incorrect force applied by the operator can result in the blade cutting too deep or not cutting deep enough – potentially leading to snapping, damage to the device surface, or delamination.

Inexperienced or newly trained operators, on the other hand, face a much steeper learning curve when learning to safely remove the FEP heat shrink from the device, often leading to slower production times and more scrapped parts.

It's clear that manufacturers who are looking to scale production need a better fusing sleeve solution – one that reduces operator training requirements and shortens their time-to-productivity.

Typical Challenges when Scaling Production:

- **Operator Training Requirements**
- **Longer Time-to-Productivity**
- **Operator Safety Challenges**
- **Critical Damage to Devices**

Accelerate Production, Increase Yields, Improve Safety

INTRODUCING FLUOROPEELZ™

A *peelable* heat shrink that removes skiving tools from the production line, *reduces operator training, increases yields,* and *improves safety*.

Unlike traditional FEP heat shrink that must be skived off with razor blades, FluoroPEELZ™ peelable heat shrink allows operators to easily peel, instead of shave, heat shrink away from the catheter after the reflow process.

Simply use the FluoroPEELZ™ slit fixture to slit the end of the heat shrink, peel it back from the catheter surface, and discard. Better yet, FluoroPEELZ™ can be ordered pre-slit for even greater simplicity.

Less Operator Training

Skiving tools take time for new operators to master; even then, they are prone to error. The easy-peel nature of FluoroPEELZ™ dramatically reduces operator training requirements and shortens time-to-productivity.

Higher Yields

Manufacturers scrap fewer catheters and see a significant increase in yield. Using FluoroPEELZ™, customers are anecdotally reporting manufacturing cost savings of 10 - 15%.

Improved Safety

Manufacturers can remove skiving tools and razor blades from the production line, meaning operators work in a safer environment.

"FluoroPEELZ has been a game-changer. By switching from traditional FEP, we're seeing our yields and efficiency numbers improve 10-15%, even approaching 20%."

– Medical Device OEM.

FEATURES

FluoroPEELZ™ Peelable Heat Shrink

Easy-Peel Removal

With a simple linear tear, operators can quickly and easily remove FluoroPEELZ™ after reflow to reveal a smooth surface finish free of imperfections.

High 2:1 Shrink Ratios

High shrink ratios give engineers more flexibility to work and can also eliminate the need for multiple heat shrinks to accommodate catheter transitions. A 2:1 shrink ratio allows the heat shrink to recover successfully over both the larger and smaller sections of the shaft in a tapered catheter. Additionally, higher shrink ratios make loading the heat shrink over small-diameter catheters easier.

High Optical Clarity

Because FluoroPEELZ™ is clear, spotting defects in the catheter during production is much easier. Operators can visually inspect the products and see beneath the heat shrink—no more guesswork.

Suitable for Long Catheters

PTA balloon catheters can be quite long. The longer the catheter, the greater the risk that damage will occur. FluoroPEELZ™ allows for long, continuous lengths of the heat shrink and an easier subsequent removal after the reflow is complete. A single operator can easily peel FluoroPEELZ™ away from the catheter without the need for additional help.

> "Transferring processes to operators is fast and effective. Training operators to learn the nuances of FEP removal is time consuming. Using FluoroPEELZ allows our employees to work confidently and efficiently."
>
> – Medical Device OEM.

AVAILABLE SIZES

FluoroPEELZ™ Peelable Heat Shrink

FluoroPEELZ™ is available in various sizes, depending on the application. Typical FluoroPEELZ™ size ranges are listed below.

FLUOROPEELZ™ TYPICAL SIZE RANGES				
SHRINK RATIO	EXPANDED ID	RECOVERED ID	WALL THICKNESS	WALL THICKNESS TOLERANCE
1.3:1	0.015″ – 0.500″ (0.381 mm – 12.7 mm)	0.012″ – 0.385″ (0.305 mm – 9.779 mm)	0.008″ – 0.013″ (0.203 mm – 0.330 mm)	± 0.002″ (± 0.051 mm)
1.4:1	0.015″ – 0.500″ (0.381 mm – 12.7 mm)	0.011″ – 0.358″ (0.279 mm – 9.093 mm)	0.009″ – 0.013″ (0.229 mm – 0.330 mm)	± 0.002″ (± 0.051 mm)
1.5:1	0.015″ – 0.500″ (0.381 mm – 12.7 mm)	0.010″ – 0.334″ (0.254 mm – 8.484 mm)	0.010″ – 0.014″ (0.254 mm – 0.356 mm)	± 0.002″ (± 0.051 mm)
1.6:1	0.016″ – 0.500″ (0.406 mm – 12.7 mm)	0.010″ – 0.313″ (0.254 mm – 7.950 mm)	0.010″ – 0.018″ (0.254 mm – 0.457 mm)	± 0.002″ (± 0.051 mm)
1.7:1	0.017″ – 0.500″ (0.432 mm – 12.7 mm)	0.010″ – 0.295″ (0.254 mm – 7.493 mm)	0.010″ – 0.018″ (0.254 mm – 0.457 mm)	± 0.002″ (± 0.051 mm)
1.8:1	0.030″ – 0.500″ (0.762 mm – 12.7 mm)	0.017″ – 0.278″ (0.432 mm – 7.061 mm)	0.013″ – 0.018″ (0.254 mm – 0.457 mm)	± 0.002″ (± 0.051 mm)
1.9:1	0.032″ – 0.500″ (0.813 mm – 12.7 mm)	0.017″ – 0.264″ (0.432 mm – 6.706 mm)	0.013″ – 0.018″ (0.330 mm – 0.457 mm)	± 0.002″ (± 0.051 mm)
2.0:1	0.034″ – 0.500″ (0.864 mm – 12.7 mm)	0.017″ – 0.250″ (0.432 mm – 6.35 mm)	0.013″ – 0.018″ (0.330 mm – 0.457 mm)	± 0.002″ (± 0.051 mm)

HEAT SHRINK PROPERTIES				
WORKING TEMP.	SHRINK RATIOS	RECOVERY TEMP.*	SPECIAL FEATURES	APPLICATIONS
200 °C / 392 °F	Up to 2:1	215 °C / 420 °F ± 10 C° / 18 F°	• Peelable • Clear • Class VI approved resins available	• Catheter manufacturing • Packaging • Manufacturing aids

**We recommend beginning the recovery process at 215 °C (420 °F). Anticipate adjusting this temperature in 10 C° (18 F°) increments, upward or downward, until desired recovery characteristics are achieved.*

A Critical Development for Catheter Manufacturing

Endovascular intervention is incredibly important for the treatment of peripheral artery disease (PAD), dramatically reducing open surgery rates and accelerating patient recovery time.

Given the global rise of this debilitating condition, PTA balloon catheters have an increasingly critical role to play as the future of medicine unfolds.

Catheter production methods must keep pace with innovation in endovascular techniques. No part of the production process should hinder productivity or yield. Yet the removal of heat shrink, a critical step in production, often gets overlooked and can lead to damaged devices and high scrap levels.

FluoroPEELZ™ peelable heat shrink eliminates this costly production challenge for medical device OEMs.

By embracing FluoroPEELZ™, OEMs can significantly improve their production processes and their ability to support the demand for the widening use of catheters when treating peripheral artery disease.

References

[1] Aday AW, Matsushita K. Epidemiology of Peripheral Artery Disease and Polyvascular Disease. Circulation Research. 2021;128(12):1818-1832. doi: https://doi.org/10.1161/circresaha.121.318535

[2] Song P, Rudan D, Zhu Y, et al. Global, regional, and national prevalence and risk factors for peripheral artery disease in 2015: an updated systematic review and analysis. The Lancet Global Health. 2019;7(8):e1020-e1030. doi: https://doi.org/10.1016/s2214-109x(19)30255-4

[3] Fowkes FGR, Rudan D, Rudan I, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. The Lancet. 2013;382(9901):1329-1340. doi: https://doi.org/10.1016/s0140-6736(13)61249-0

[4] PTA Balloon Catheter Market Size & Share Report, 2022-2030. www.grandviewresearch.com. https://www.grandviewresearch.com/industry-analysis/pta-balloon-catheter-market

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