CASE STUDY

Scaling a Specialty Catheter for a Global Medtech Leader

Solving a nitinol-to-balloon assembly challenge by working closely with the developer, then growing into a finished-device supplier as the product was acquired and scaled worldwide.

The Project

A venture-backed startup developed an innovative peripheral PTA balloon catheter featuring a shape-set nitinol structure mounted directly on the balloon. The developer engaged Forj Medical to supply portions of the device, and after Forj helped improve the challenging manufacturing processes, they moved the entire product to Forj. When a top 30 global medical device company acquired the product, Forj evolved from component supplier to finished-device manufacturer, shipping packaged, rebranded product straight to sterilization and on to the OEM's distribution center.



The Challenge

- **Mounting a shape-set nitinol structure** onto the balloon
- **Packaging & sterilization** had to fit the OEM's newly validated sterile cycle
- **Cost pressure** as every component was purchased from outside vendors
- **Post-acquisition transfer** from component supply to finished device without burdening the OEM's quality system
- **Rapid volume growth** as the OEM expanded beyond the U.S. and Europe

The Solution

- **Proprietary mounting process** developed by engineers who saw the failures firsthand
- **In-house nitinol shape setting,** forming, balloon bonding & catheter testing
- **Fast-turn qualification** into the OEM's validated sterile cycle
- **Second sourced & qualified** outer shaft, inner member & hub in parallel with sterile validation
- **Mature, high-yield offshore production** in Singapore under a QMS built for multinational OEMs; Forj manages all suppliers

The Result

from component to finished, sterile-ready device

- **+50%** monthly volume in 12 months
- **5 yrs** pricing-stability runway from component cost savings
- **0** OEM touches, direct to sterilizer & distribution
- **✓** enabled expansion into new global markets

Catheter manufacturing capabilities

from component to finished, sterile-ready device

- Balloon Bonding & Assembly
- Nitinol Shape Setting & Cage Forming
- Device-to-Balloon Mounting
- Balloon Catheter Testing
- Packaging & Sterilization Management
- Supply Chain Management

COMPONENT SUPPLY ▸ FINISHED DEVICE ▸ DIRECT-TO-DISTRIBUTION

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