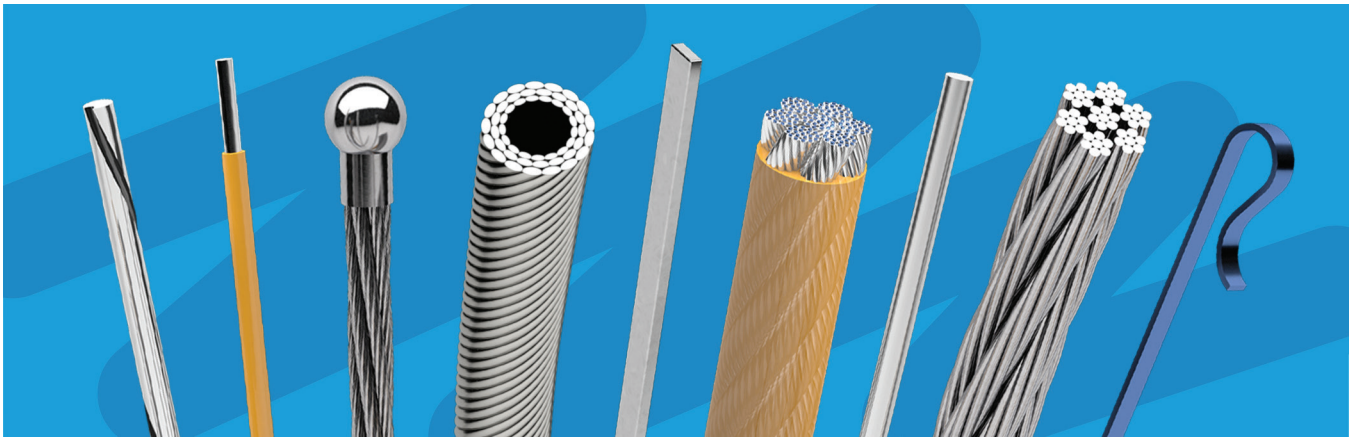


Advancing Nitinol from Melt to Medical Device

How new production methods are expanding what Nitinol can do for implantable devices.

The medical device industry runs on Nitinol. Stents, heart valve frames, guidewires, orthopaedic implants, and dozens of other devices depend on this nickel-titanium alloy for its superelastic and shape memory properties. Yet for years, the supply chain behind it has been narrow. The majority of Nitinol ingot has come from a small handful of melt sources, and Fort Wayne Metals has invested heavily to reduce manufacturers' exposure to capacity constraints, long lead times, and single-point-of-failure risk.

That picture is changing. Advances in melting technology, specifically the addition of plasma arc melting (PAM) alongside established vacuum arc remelting (VAR), have produced a new generation of Nitinol with tighter microstructural control. And a first-of-its-kind collaborative validation effort, the PRIME project, has tested this material through every step of the supply chain, from ingot to finished device, across multiple independent manufacturers.

For design engineers, this is good news. The material options available today are cleaner, better characterized, and backed by more data than at any point in Nitinol's history.

Inclusions matter — but it's not the full story

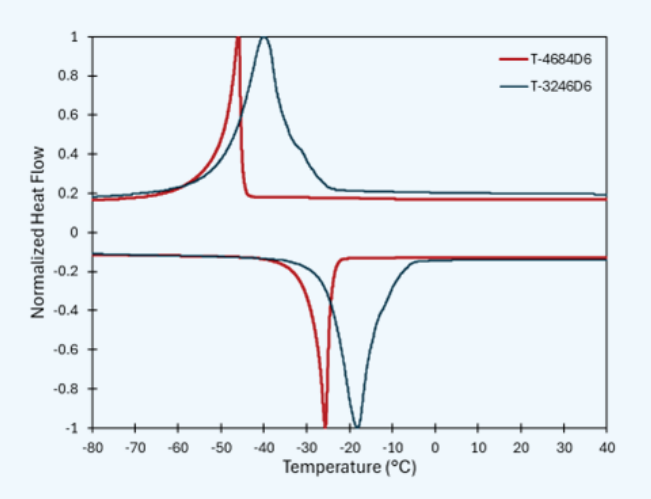
Nitinol's fatigue life has been shown to be governed by crack growth, which can often initiate from internal defects. Non-metallic inclusions, primarily titanium carbide and titanium rich oxide particles near the surface, commonly act as those crack initiation sites under cyclic loading. Early load cycle fatigue fractures then result, impacting the material's fatigue performance. Improving the internal cleanliness of wrought Nitinol has been shown to lead to longer fatigue life.

The melting method, atmosphere control, raw material purity, and remelting steps all determine the size, distribution, and volume fraction of inclusions in the final ingot. For engineers designing fatigue-critical implants, the question of how the starting material was melted is a design input rather than an upstream abstraction. As a result, the quality of the melting process is a foundational element that can impact the material performance down the road in an application.

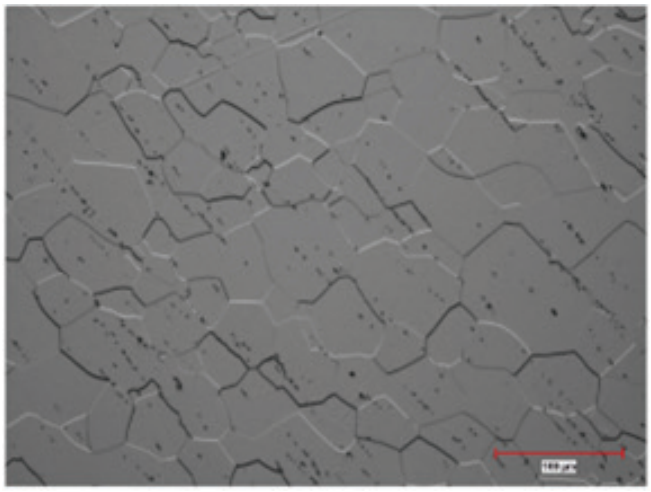
Two generations of material variants dominate the current market:

Gen I finishes with the VAR process, meeting the specification requirements used for medical devices established by ASTM F2063. This standard permits maximum inclusion sizes of 39 micrometers and area fractions up to 2.8%.

Gen II is produced by premium melting processes like PAM, which uses a plasma torch in a pressurized inert atmosphere. This approach prevents carbon contamination and better controls the ingot structure, yielding ingots with maximum inclusion sizes of 20 micrometers or less, and inclusion area fractions held to 1.5 wt% or below. Fort Wayne Metals' Gen II material, Altus™ Nitinol, tightens the area fraction limit further to 1.2 wt%.



Differential scanning calorimetry of the supplied bars from FW Metals showing the fully annealed transformation temperatures.



Representative micrograph of the supplied bar (T-4684D6) from FW Metals showing the grain size met the requirements of ASTM F2063.

Gen I is typically used in standard stents, while Gen II, characterized by smaller, fewer inclusions, supports more demanding neurovascular applications. Generation selection depends on the device's performance requirements.

What the PRIME data says

The PRIME (PRoficient Ingot Material Evaluation) project was designed to answer the question that matters to anyone selecting Nitinol: Does this material work in real manufacturing, tested by real companies using their standard processes?

Five organizations participated, spanning the full process chain: Fort Wayne Metals as the melt and wrought bar supplier, tube manufacturers Euroflex and Vascotube, and medical device contract manufacturers Admedes and MeKo. Each partner used its own equipment, protocols and acceptance criteria, and no one adjusted their process to accommodate the new material.

Gen I (VAR): Peripheral stent validation

VAR heat met all ASTM F2063 requirements for chemistry, mechanical properties, microcleanliness, transformation temperature, and grain size. Nickel content measured 56.0 and 56.1%, and grain size numbers of 6 exceeded the specification's requirement of 4 or finer. Oxygen was 210 ppm, nitrogen was 40 ppm, hydrogen was less than 10 ppm, and carbon was 30 ppm.

The tube manufacturers drew 2.00 x 0.22-mm tubing [0.07874 x 0.00866 in]. Maximum inclusion sizes in the finished tubes ranged from 4 to 10 micrometers, with area fractions between 0.20 and 0.64%. Tube drawing itself reduced inclusions substantially from wrought condition measurements, showing that cold working provides an additional margin of micro-cleanliness beyond what the wrought material provides.

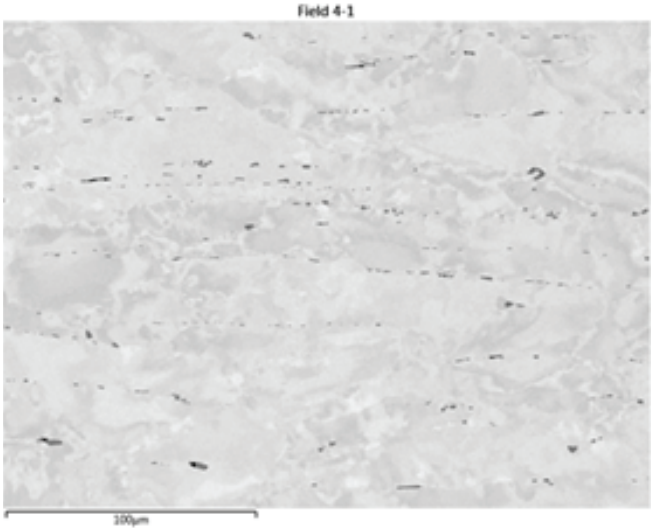
From that tubing, Admedes and MeKo produced 87 peripheral stents. No complications arose during laser cutting, heat treatment, or electropolishing. The qualification results:

- **Tensile strength (ASTM F2516)**: 1,155 to 1,227 MPa [167.51859 to 177.9613 ksi] ultimate tensile strength, and elongation at fracture 17.5 to 27.5%.
- **Surface quality**: No material-related defects under light microscopy or SEM.
- **Corrosion (ASTM F2129)**: Breakdown potentials above 900 mV or no breakdown, confirming corrosion resistance.
- **Radial force and DSC**: Results consistent with anticipated outcomes based on Af temperature and strut geometry.

The material dropped into established workflows and met every standard acceptance criterion.

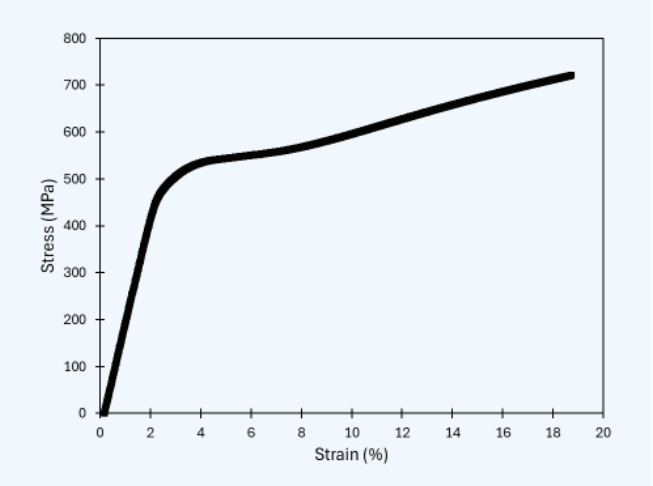
Gen II (PAM): Heart valve frame validation

Two PAM heats met ASTM F2063 chemistry, mechanical properties and microstructure requirements with grain size numbers of 6.5 and 5.0. This material on average exhibited 200 ppm oxygen, 25 ppm nitrogen, less than 10 ppm hydrogen, and 35 ppm carbon. At the mill product stage, maximum inclusion sizes measured 16.6 and 19.9 micrometers, with area fractions of 1.0 and 1.4%. The current product meets 1.2% area fraction.



Inclusion analysis of FW Metals mill product (T-4684D6) using 500x magnification

The partners manufactured a larger tube for this evaluation: 7.00 mm [0.27559 in] outer diameter and 0.50 mm [0.019685 in] wall thickness, which is the kind of tube used in structural heart applications. Inclusion analysis on the finished tubes showed a reduction from the starting bar. Maximum inclusion sizes dropped to 4 and 7 micrometers, with area fractions between 0.20 and 1.0%.



Representative tensile test of the supplied bar from FW Metals showing that the fully annealed tensile strength and elongation met the requirements of ASTM F2063.

Using this tubing, Admedes and MeKo produced heart valve frames, which have a more demanding geometry than peripheral stents. MeKo manufactured 25 frames per material lot, and Admedes produced 15 to 22. Again, no complications during any manufacturing step.

- **Transformation temperature**: Target Af of 20°C [68°F] plus or minus 5 degrees achieved after heat treatment.
- **Radial force**: Consistent crimp behavior from 36 mm [1.41732 in] outer diameter down to 7 mm [0.27559 in].
- **Corrosion**: High breakdown potentials or no breakdown across all samples.
- **Surface quality**: No material defects detected by SEM or light microscopy.

Both studies reached the same conclusion. The material processed without accommodation and met all quality criteria that device manufacturers apply to incoming material from established sources.

Fort Wayne Metals and the path to vertical integration

Fort Wayne Metals traces its origins to 1946, when founder Ardelle Glaze started a wire shop in Fort Wayne, Indiana. The company entered the medical market in 1970 and began drawing Nitinol wire in the early 1990s.

Over the following decades, its product portfolio expanded to include DFT® wire, strands and cables, strip, bar, shape-set assemblies, and actuator wire. Fort Wayne Metals delivered more than 20,000 pounds of Nitinol strands and cable assemblies in 2024 alone.

In 2013, the company opened its Advanced Materials Development (AMD) facility in Columbia City, Indiana, with a VAR furnace for melting Nitinol used in a variety of medical devices. A second VAR furnace and a PAM furnace followed. Today, the AMD facility supports more than 75% of the company's Nitinol sales to the medical industry. Annual melting capacity is projected to exceed 800,000 pounds by the end of 2026, with projects underway targeting more than one million pounds.

Fort Wayne Metals also operates dedicated R&D furnaces that can produce custom ingots and deliver wire-form samples in weeks rather than months. Compositions that prove out in the lab can be scaled to production on the AMD facility's larger furnaces.

What the data means for device design

The PRIME results have several practical implications for engineers working with Nitinol.

Tighter inclusion control at the tube level. Gen II tubing showed maximum inclusions of 4 to 7 micrometers after tube drawing, compared to 4 to 10 micrometers for Gen I. Both are well below the ASTM F2063 limit of 39 micrometers, but the Gen II numbers put the material in a regime where inclusions are less likely to act as critical crack initiators under physiological loading.

Processability without special handling. Four independent manufacturers processed both Gen I and Gen II material using their existing, validated workflows. No parameter adjustments were needed for laser cutting, heat treatment, expansion, or electropolishing. Engineers specifying this material should not need to revalidate their manufacturing processes.

Consistent mechanical behavior across suppliers. Tensile properties, transformation temperatures, radial force, and corrosion resistance were consistent across tube batches and device manufacturers. Variations are attributable to differences in test methods, sample geometries, and heat treatment parameters, not the material itself.

A second qualified ingot source. Supply chain concentration has been a persistent concern in the Nitinol market. Having both VAR- and PAM-melted material validated through independent multi-company testing gives engineers and procurement teams a viable option for dual-sourcing without compromising material quality.

New alloy and form options enabled by melt control

When a supplier controls the melt process, it can iterate on alloy composition and processing far faster than when it depends on outside ingot sources. That, coupled with more than three decades of processing experience, enables us to optimize the overall characteristics and performance of the Nitinol we deliver. Several specialized Nitinol variants are now available that address specific design challenges:

Linear Elastic Nitinol exhibits a near-linear stress-strain response with increased strength while maintaining superelastic recovery. For guidewires and devices where higher pushability or column stiffness matter, it provides a mechanical profile that standard superelastic Nitinol does not offer. Linear Elastic Nitinol is available in diameters from 0.0762 to 0.635 mm [0.003 to 0.025 in].

NiTiNbY, or NiTi #7, is a quaternary alloy with 50 to 100% higher plateau strength than standard binary Nitinol. The niobium and yttrium additions reduce temperature sensitivity, preserving superelastic behavior even at cryogenic temperatures. Engineers can use it to downsize devices while maintaining radial strength, or to design for thermal environments where standard Nitinol's performance would degrade.

DPS® wire provides elevated plateau stress for applications needing increased stiffness in the superelastic region, strains of 1.5 to 6%, along with resistance to further bending after an initial deflection.

USN® wire targets the elastic region below 1.5% strain, offering high modulus for low-strain applications where column stiffness is the priority.

Silk® Nitinol delivers an oxide-free surface that reduces snagging during braiding, a practical benefit for anyone manufacturing braided stents or other woven constructions.

Helical Turkshead Nitinol wire features a square twisted cross-section that reduces surface contact area by roughly 60% compared to round wire of equivalent diameter, lowering friction and improving 1:1 torque transmission for vascular navigation.

Nitinol Flat DFT® Wire creates a wider radiopaque platinum surface for improved fluoroscopic visibility compared to a round DFT® wire of equivalent diameter.

What comes next

The PRIME collaboration plans to extend its tube investigations to fatigue testing, putting Gen II material's tighter inclusion control to a quantitative test under cyclic loading conditions that simulate long-term implant service. Other tube sizes processed into neurovascular stents and peripheral stents from Gen II material have already shown positive outcomes.

Benchtop rotating beam fatigue testing of Altus™ Nitinol wire has shown equal or better results compared to other Gen II offerings. The upcoming PRIME fatigue data on tubing and finished devices will bridge the gap between wire-level characterization and the device geometries engineers may consider for design.

If you're selecting Nitinol today, the picture is much better than it was five years ago:

- Gen II material offers measurably smaller inclusions at the tube level, with multi-company validation data available and transparent.
- The supply base has also expanded with both VAR and PAM capacity.
- The range of alloy compositions and product forms has widened to address design problems that standard binary superelastic Nitinol cannot solve on its own.

Taken together, these advances in cleanliness, supply, and variety mean more room to push device performance.

To learn more, visit fwmetals.com