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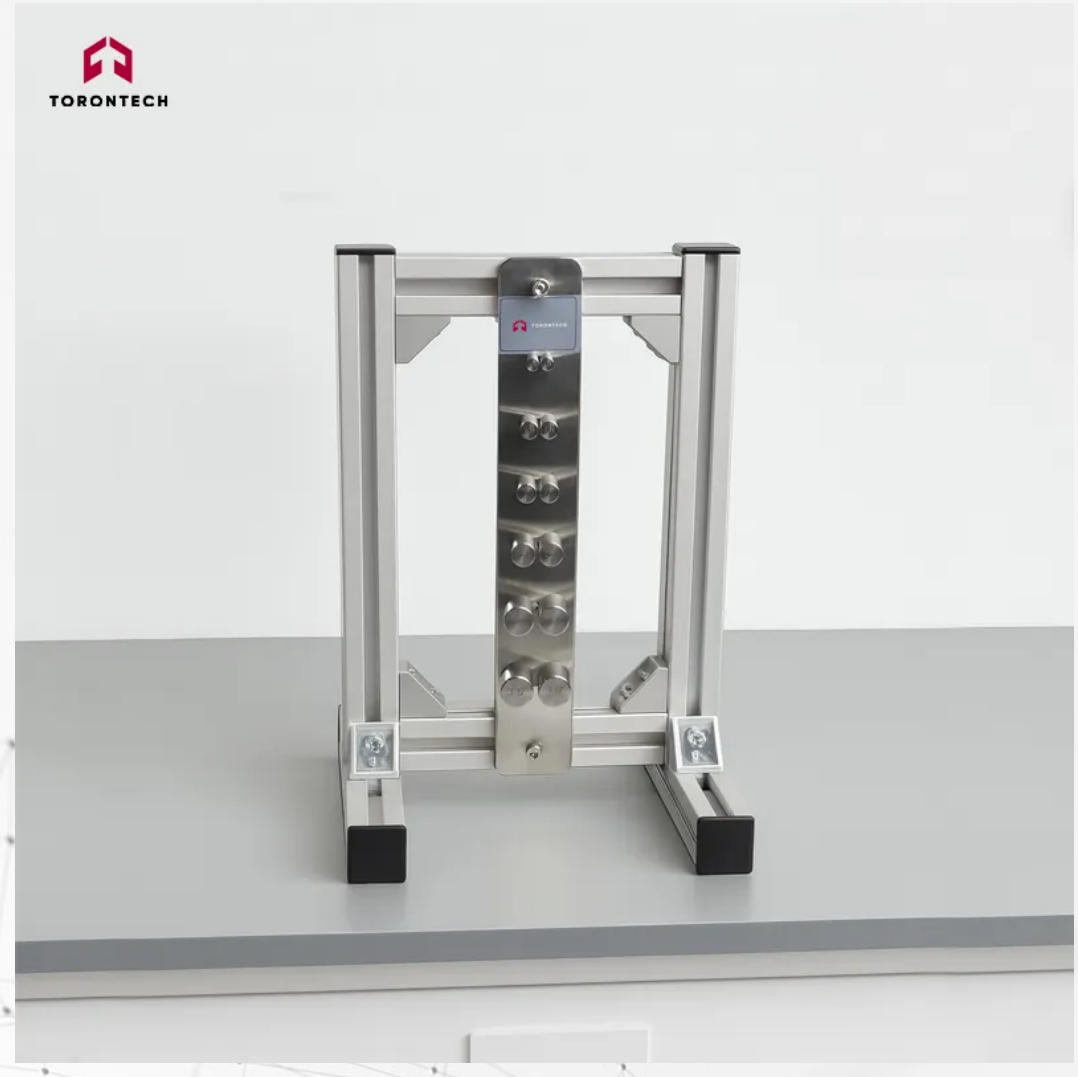


GUIDEWIRE FLEXING TESTER

Manual Tester for Repeated Flexural Fatigue and Coating Integrity Evaluation of Guidewires

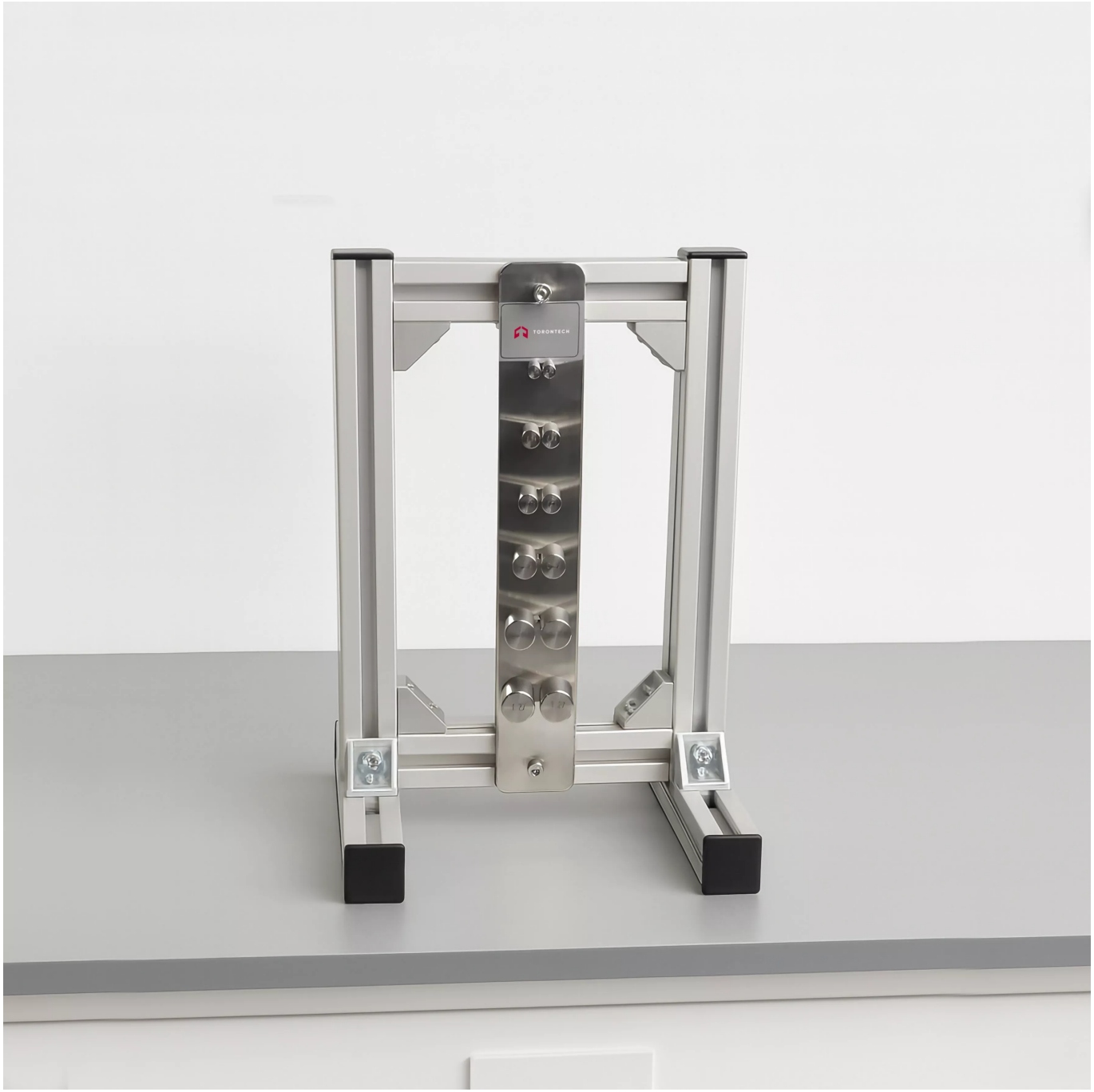
ToronMed™ GFT01 Guidewire Flexing Tester is designed to evaluate the flexural durability and surface integrity of intravascular guidewires under repeated reverse bending. The guidewire is subjected to repeated flexing between two rigid cylinders to simulate the mechanical fatigue that occurs during clinical navigation. After testing, the guidewire is inspected for coating flaking, surface damage, and potential fracture points.

This bench-top fixture is ideal for R&D validation, quality assurance, and regulatory testing of guidewires in accordance with ISO 11070 requirements.

APPLICATIONS

Applications

Application Area	Testing Objective
Intravascular Guidewires	Reverse bending fatigue resistance
Coated Guidewires	Coating adhesion and flaking integrity testing
QA and Batch Testing	Mechanical durability and surface finish review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Standards Compliance

The ToronMed™ GFT01 is designed in accordance with:

- ISO 11070 – Sterile, single-use intravascular catheter introducers, dilators, and guidewires – Mechanical performance test methods
- Designed to reflect additional regional procedures, including YY0450.1-2020 (not cited unless jurisdictionally required)

Materials & Build

- Rigid frame constructed from high-grade aluminum alloy
- Contact and wear surfaces made from 304 stainless steel for extended durability
- Compact benchtop design for lab and production environments

FEATURES

- Complies with ISO 11070 for testing sterile, single-use guidewires
- Test assembly includes two fixed rigid cylinders, each with a diameter 20× the guidewire’s maximum outer diameter
- Adjustable gap between the cylinders: 1–3× the outer diameter of the guidewire to simulate realistic deflection ranges
- Supports a full range of common guidewire sizes: 0.30 mm, 0.35 mm, 0.46 mm, 0.53 mm, 0.64 mm, 0.69 mm, 0.71 mm, 0.81 mm, 0.89 mm, 0.97 mm, 1.14 mm, 1.19 mm, 1.27 mm
- Constructed from high-strength aluminum and corrosion-resistant stainless steel
- Simple, robust manual design for repeatable and cost-effective flexural testing

Test Method

The test procedure simulates repeated bending of the guidewire around two cylinders. The guidewire is manually flexed back and forth, mimicking insertion, withdrawal, and navigation inside blood vessels. After a prescribed number of cycles, the sample is visually examined for damage, coating delamination, or material failure.

The guidewire is manually wound around a cylindrical former with a diameter defined by ISO 11070 (10× the wire’s outer diameter). After winding, the guidewire is carefully unwound and examined visually or under magnification to assess fracture points or material fatigue. This method ensures compliance with guidewire integrity requirements for safe clinical use.

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