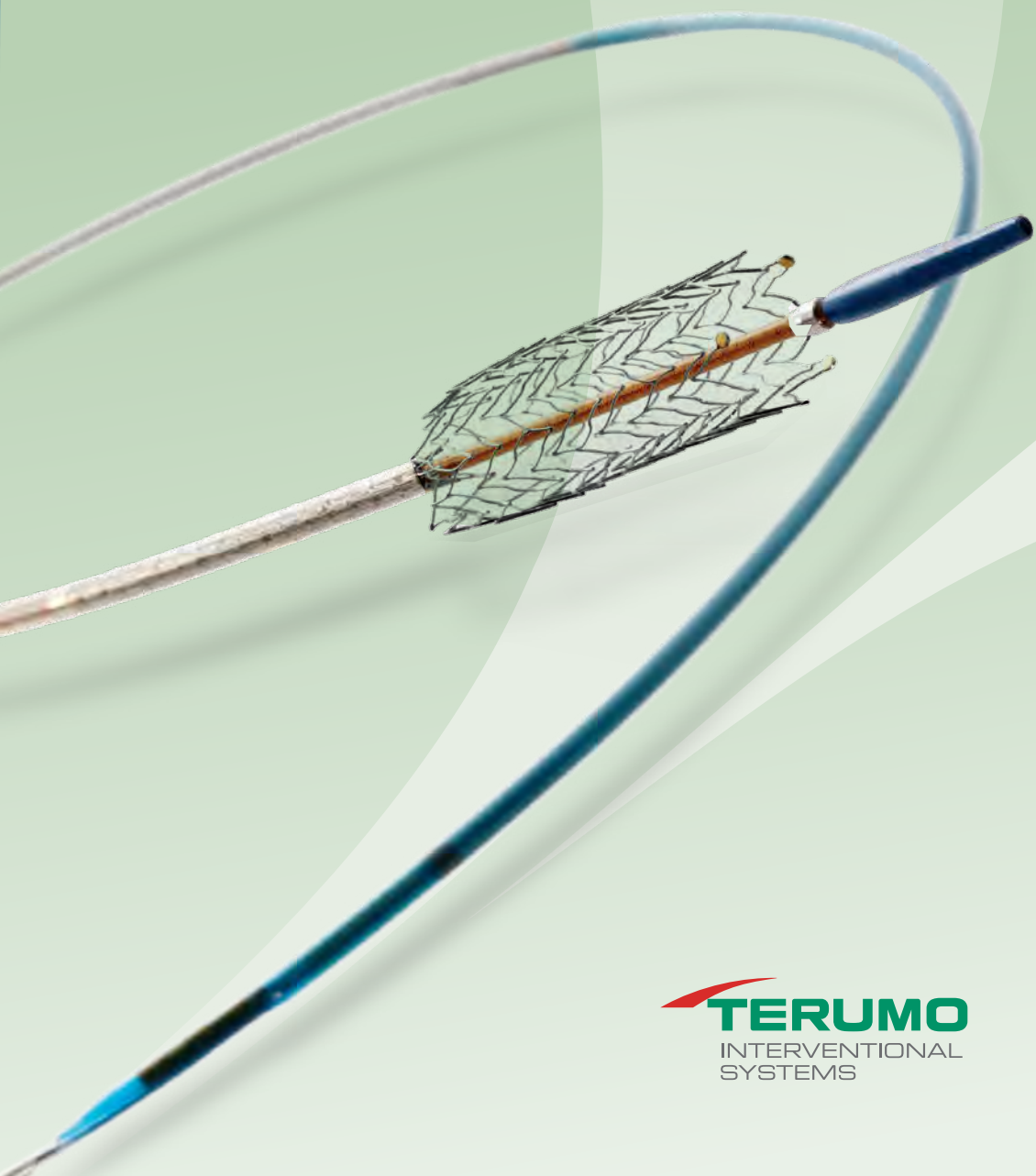
R2P® Misago®

RX Self-expanding Peripheral Stent

BUILT TO BEND
TESTED TO LAST



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R2P® Misago®

RX Self-expanding Peripheral Stent

BUILT TO BEND TESTED TO LAST

Independent bench study comparing 7 leading femoropopliteal stents demonstrated MISAGO® had the **lowest stent abrasiveness, no fractures, and no wall penetration** under severe simulated limb flexion conditions.[1]

About the Study

A Method of Assessing Peripheral Stent Abrasiveness Under Cyclic Deformations Experienced During Limb Movement.
Keiser et al., Acta Biomaterialia, (Impact Factor: 10.6), 2022.

- **Research Type:** Independent, university-led bench study
- **Funding:** No financial support from Terumo
- **Authors:** Keiser et al., University of Nebraska

Key Findings

- Lowest cumulative Abrasion Damage Score (ADS)
- No stent fractures
- No wall penetration
- Lowest cumulative vessel trauma observed

Study Design

University-led study assessed the mechanical abrasiveness of 7 femoropopliteal stents **utilizing a synthetic FPA abrasion** model under the following deformations:

- Axial Compression (25%)
- Bending (90°)
- Torsion (±26°/cm)

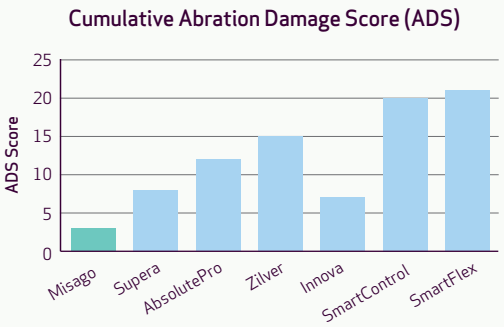
These conditions simulate **5 years of daily limb movement.**
The Abrasion Damage Score (ADS) measured:

- Degree of vessel wall abrasion
- Strut fracture occurrence
- Wall penetration through synthetic arterial tissue

Results

Cumulative ADS Comparison

Lowest score for MISAGO (3) vs competitors (7–21).



DESIGNED FOR **DURABILITY**

The R2P® MISAGO® RX Self-expanding Peripheral Stent demonstrated a high degree of flexibility and durability among competitors tested during mechanical fatigue-tests.[1]

- Lower ADS Correlated with higher clinical 12-month primary patency[1]
- The Misago flexible architecture minimizes vessel trauma[1]
- No stent fractures observed for Misago under simulated daily motion[1]

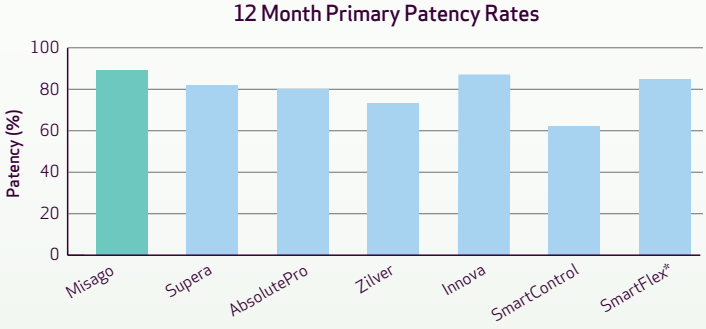
Fractures & Wall Penetration Matrix[1]

FRACTURES & WALL PENETRATION MATRIX			
STENT	**AXIAL**	**BENDING**	**TORSION**
MISAGO™	None	None	None
Supera	None	None	Fracture / Penetration
AbsolutePro	None	Fracture / Penetration	None
Zilver	Fracture / Penetration	Fracture / Penetration	Fracture
Innova	None	Fracture / Penetration	None
SmartControl	Fracture / Penetration	Fracture / Penetration	Fracture / Penetration
SmartFlex	Fracture / Penetration	Fracture / Penetration	Fracture / Penetration

MISAGO = None across all modes.
Supera, AbsolutePro, Zilver, Innova, SmartControl, SmartFlex show higher fracture/penetration rates. [1]

12-month Patency Outcomes[1]

MISAGO = 88% patency (highest among comparators). Competitors: 62–86%.



Access the full article: https://doi.org/10.1016/j.actbio.2022.09.044

Primary patency rates shown are sourced from published clinical studies on each comparator device. These values were not derived from the benchtop abrasion study described in this brochure.

* SmartFlex value reflects primary assisted patency; unassisted primary patency not reported.

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Important Disclaimers

- Bench testing may not be indicative of clinical performance in all patients.
- The Abrasion Damage Score (ADS) is an investigational, non-validated metric created by study authors.
  - Score range (per mode): 1–2 = minimal abrasion, 3–5 = moderate abrasion or isolated fracture/penetration, 6–7= severe abrasion with multiple fractures/penetration.
  - Cumulative ADS reflects results across axial compression (25%), bending (90°), and torsion (±26°/cm).
- Clinical decisions should always consider patient-specific anatomy and risk factors.

References:

1. Keiser et al., A method of assessing peripheral stent abrasiveness under cyclic deformations experienced during limb movement. *Acta Biomaterialia, 2022.*

Indications:

The RP2® MISAGO® RX Self-expanding Peripheral Stent is indicated to improve luminal diameter in symptomatic patients with de novo or restenotic native lesions or occlusions of the Superficial Femoral Artery (SFA) and/or proximal popliteal artery with reference vessel diameters ranging from 4 mm to 7 mm and lesion length up to 150 mm.

Important Safety Information:

Do not use this device in patients who exhibit angiographic evidence of severe thrombus in the target vessel or lesion site before/after undergoing Percutaneous Transluminal Angioplasty (PTA) procedure, patients with contraindication to antiplatelet and/or anticoagulation therapy, patients who are judged to have a lesion that prevents proper placement or deployment of the stent, a lesion that is within an aneurysm or an aneurysm with a proximal or distal segment to the lesion, or a lesion through which a guidewire cannot pass. This device should only be used by a physician who is familiar with, and well trained in, Percutaneous Transluminal Angioplasty (PTA) techniques, stent implantations, and transradial access.

RX ONLY. Refer to the product labels and package insert for complete warnings, precautions, potential complications, and instructions for use.

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