RAIN Sheath®

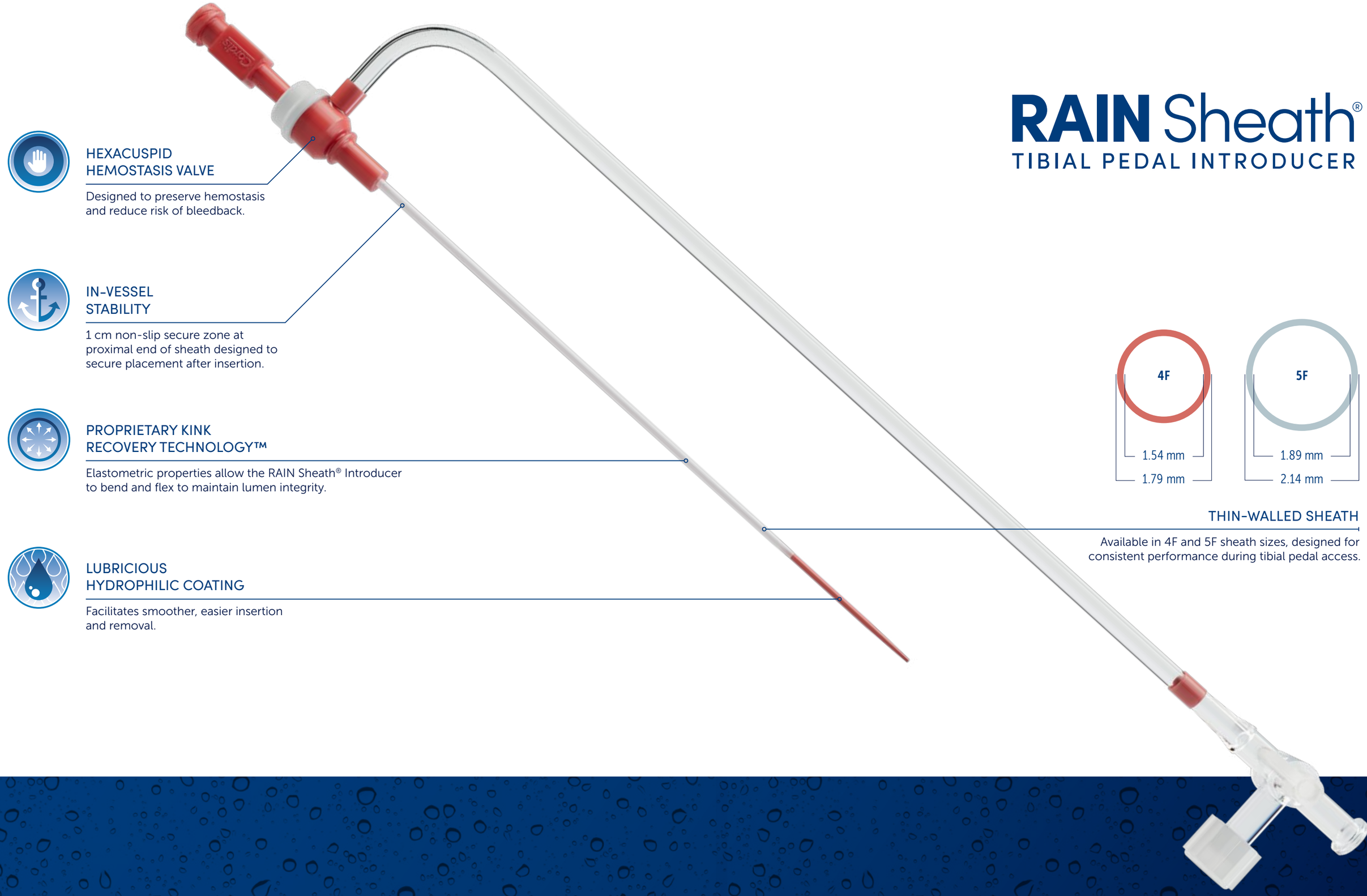
TIBIAL PEDAL INTRODUCER

Expanded Indications.
Expanded Access Options.

Cordis®

RAIN Sheath®

TIBIAL PEDAL INTRODUCER



HEXACUSPID HEMOSTASIS VALVE

Designed to preserve hemostasis and reduce risk of bleedback.

IN-VESSEL STABILITY

1 cm non-slip secure zone at proximal end of sheath designed to secure placement after insertion.

PROPRIETARY KINK RECOVERY TECHNOLOGY™

Elastometric properties allow the RAIN Sheath® Introducer to bend and flex to maintain lumen integrity.

LUBRICIOUS HYDROPHILIC COATING

Facilitates smoother, easier insertion and removal.

THIN-WALLED SHEATH

Available in 4F and 5F sheath sizes, designed for consistent performance during tibial pedal access.

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RAIN Sheath® Introducer for Tibial Pedal Procedures

SHEATH SIZE	CANNULA LENGTH	MINI-WIRE	MINI-WIRE COMPATABILITY	NEEDLE	PRODUCT CODE
4F	10 cm	Bare Stainless Steel	0.021˝ x 45 cm	21G Bare Needle	TP506410S
		Bare Nitinol	0.021˝ x 43 cm	21G Bare Needle	TP506410N
5F	10 cm	Bare Stainless Steel	0.021˝ x 45 cm	21G Bare Needle	TP506510S
		Bare Nitinol	0.021˝ x 43 cm	21G Bare Needle	TP506510N

Contraindications and Warnings for the RAIN Sheath® Tibial Pedal Introducer

INDICATIONS FOR USE

- The RAIN Sheath® Tibial Pedal Introducer is indicated to facilitate placing a catheter through the skin into the lower extremity peripheral vasculature below the knee.

CONTRAINDICATIONS

- None Known.

WARNINGS

- Use of alcohol, antiseptic solutions, or other solvents should be avoided, as they may adversely affect the device.
- Do not leave the CSI in place for extended periods of time without a catheter in place.
- Do not use a hydrophilic or polymer wire, with the bare needle, as this may damage the integrity of the wire coating or jacket.
- Manipulate the mini-guidewire slowly and carefully to avoid damage to the vessel wall, while monitoring the tip position and movement using standard catheterization technique.
- Once the vessel dilator is removed, manipulate the sheath introducer slowly and carefully to minimize the chances of kinking.
- Persons with allergic reactions to nickel may suffer an allergic response to components of this device.
- During the procedure, provide a proper anticoagulant or antiplatelet therapy to the patient.
- Do not use power injector for contrast media injection from the side port.
- Do not manually re-shape the tip of the mini-guidewire by applying external force intended to bend or affect the shape of mini-guidewire.
- This product is designed and intended for single use. It is not designed to undergo reprocessing and resterilization after initial use. Reuse of this product, including after reprocessing and/or resterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused.
- This device contains the following substance defined as CMR 1 A and/or CMR 1 Band/or endocrine disrupting substances in a concentration above 0.1 % weight by weight: Cobalt; CAS No. 7440-48-4; EC No. 231-158-0.
- Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

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