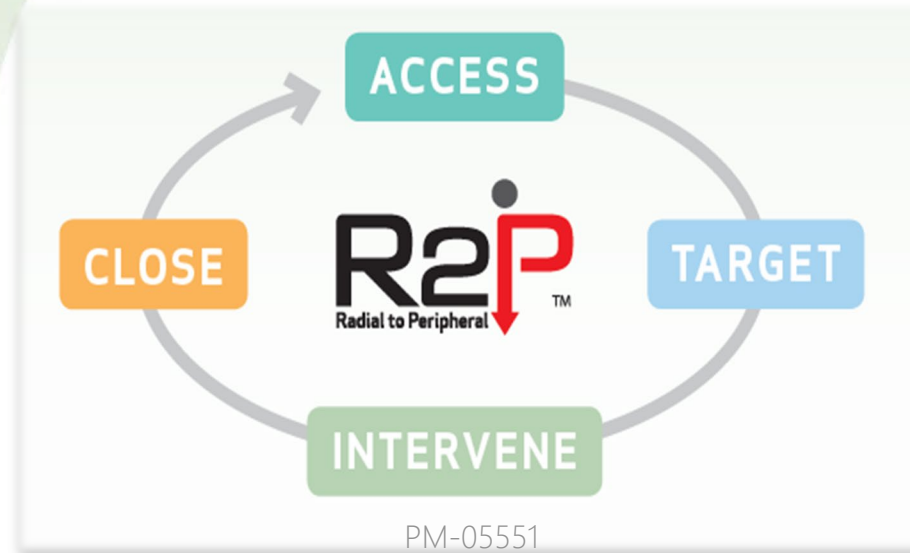


R2P Value Analysis Committee Kit



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

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Procedural and Economic Advantages

What are Femoral Access Challenges?

When Radial Access is Considered

Paradigm Shift in Treatment of Peripheral Arterial Disease

R2P Procedural Advantages

Reimbursement

What are the Femoral Access Challenges?

- ◆ Femoral approach compromised for peripheral procedures
 - ◆ Fem-Fem Bypass
 - ◆ Flush/proximal occlusion
 - ◆ Tortuous/Calcified Iliac
 - ◆ Previously deployed Grafts/Stents

- ◆ How has your physician tackled these patients previously?



Previous femoral-femoral bypass



Totally occluded left iliac,
limited access to right femoral



Significant iliac tortuosity
and calcification



Previous abdominal
aortic (AAA) graft



A **different approach** can support
your **patient challenges**

When Radial Access is Considered

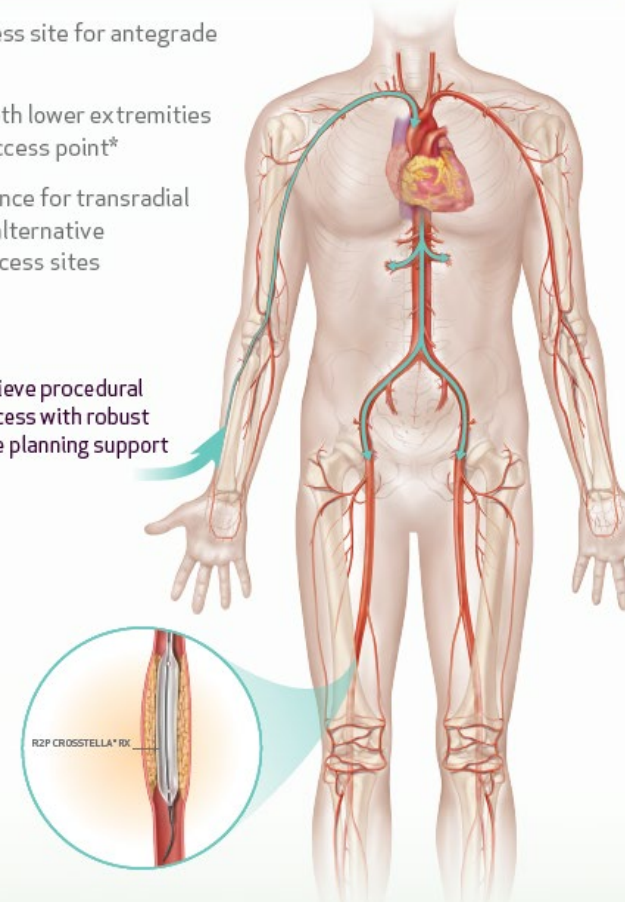
- ◆ To overcome complex or challenging anatomy
- ◆ To mitigate or reduce access site complications
- ◆ To increase procedural and operational efficiencies
- ◆ Robust case planning & appropriate patient selection is essential to increase procedural success

Consider the clinical advantages of choosing **radial to peripheral** intervention¹⁻³

- Lower risk access site for antegrade interventions
- Can address both lower extremities from a single access point*
- Proven preference for transradial access versus alternative non-femoral access sites

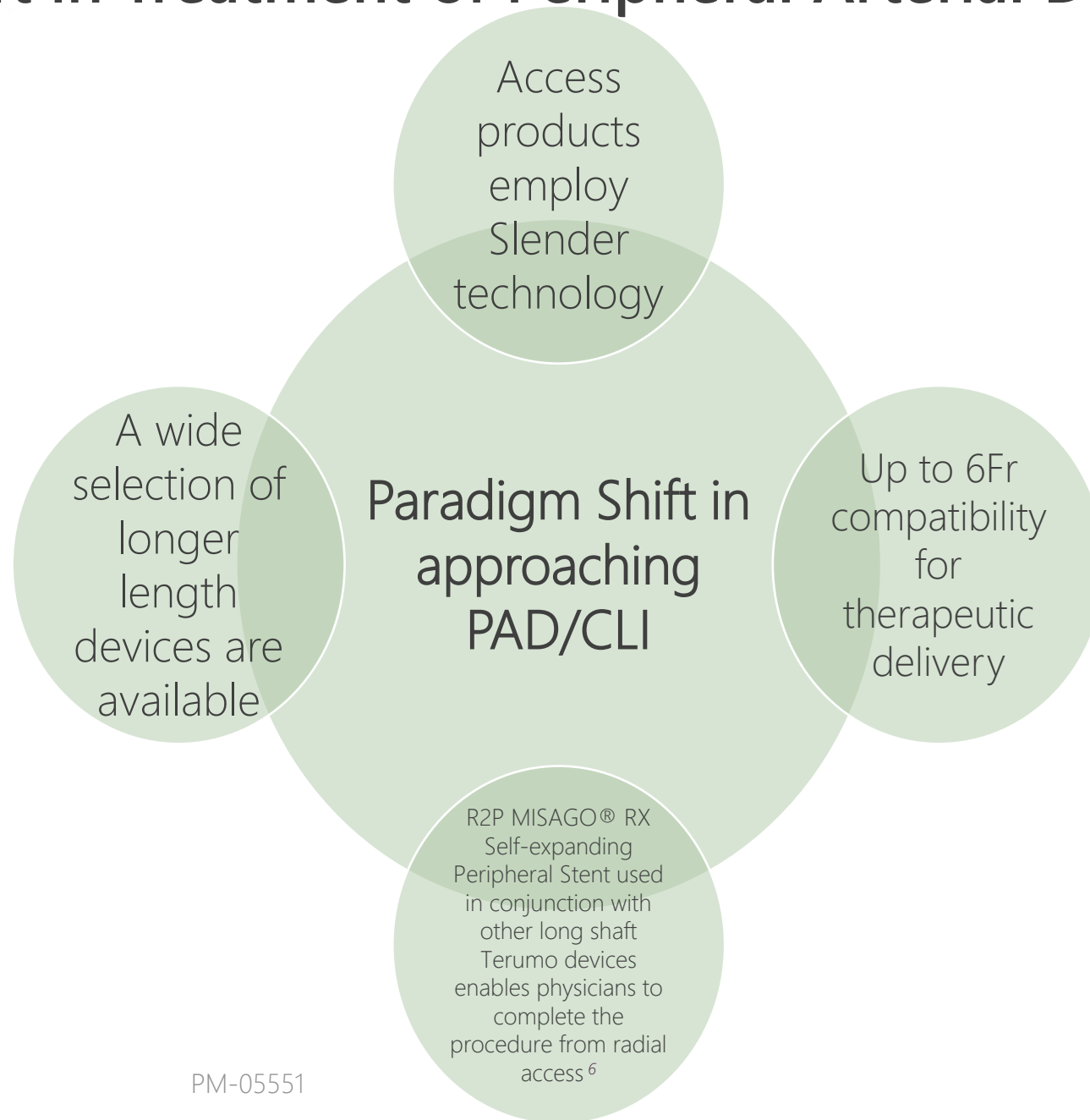
Achieve procedural success with robust case planning support

PTA Balloon across lesion in distal SFA from Radial approach



Radial access can offer an *alternative solution* for treating Peripheral disease

Paradigm Shift in Treatment of Peripheral Arterial Disease



R2P Procedural Advantages

- ◆ Optimize entry site management with Slender Technology
- ◆ Enables the potential for **early ambulation with radial access**, improved patient comfort, and patient satisfaction
- ◆ Early ambulation provides potential cost reduction and **economic benefit** through various avenues.⁷
 - ◆ These avenues include expediting room turnover and increased throughput both through the procedural area and same day recovery unit.⁷



Reimbursement Codes (HCPCS Codes)

- ◆ GLIDESHEATH SLENDER
 - ◆ C1887: Guiding Catheter
- ◆ R2P DESTINATION SLENDER
 - ◆ C1887: Guiding Catheter
- ◆ R2P SLENGUIDE
 - ◆ C1887: Guiding Catheter
- ◆ R2P GLIDEWIRE
 - ◆ C1769: Guidewire
- ◆ NAVICROSS
 - ◆ C1887: Guiding Catheter
- ◆ GLIDECATH
 - ◆ C1887: Guiding Catheter
- ◆ R2P METACROSS RX
 - ◆ C1725: Catheter, Transluminal Angioplasty, Non-Laser
- ◆ R2P CROSSTELLA RX
 - ◆ C1725: Catheter, Transluminal Angioplasty, Non-Laser
- ◆ R2P MISAGO
 - ◆ C1876: Stent, Non-coated/Non-covered with Delivery System
- ◆ TR BAND
 - ◆ None; Does not fall into the “Pass Through” Categories of Devices

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Product Overview

Product Description
Features and Benefits

Product Description:

Glidesheath Slender[®]

Hydrophilic Coated Introducer Sheath



Indication: GLIDESHEATH SLENDER is indicated to facilitate placing a catheter through the skin into the radial artery.

- 7/6 Fr size
- 10 cm and 16 cm length
- Proprietary thin-wall technology and hydrophilic coating facilitate ease of insertion and removal during peripheral procedures

Features and Benefits:

- 1 *Terumo Glide Technology hydrophilic coating enables easy insertion and removal*
- 2 *Perform diagnostic and interventional procedures without the need to switch to a larger sheath*
- 3 *Ultra thin-wall technology*
- 4 *Low profile sheath to reduce arteriotomy size¹*

Product Description:

R2P *Destination Slender*[™]
Guiding Sheath



Indication: R2P DESTINATION Slender is intended to be used for the introduction of interventional and diagnostic devices in the lower extremities of the peripheral vasculature through an access site, including but not limited to the radial artery.

- 6 Fr size
- 119 cm and 149 cm length
- Full hydrophilic coating allows for smooth transition within the radial artery and Slender Technology provides optimal performance during peripheral procedures

Features and Benefits:

- 1 *Unique thin wall design*
- 2 *Provides a conduit for lower extremity interventions from a radial approach*
- 3 *Enables smaller arterial access while maintaining 6Fr compatibility*
- 4 *Designed to reduce potential for arterial spasm during introduction and removal¹*

Product Description:

R2P SlenGuide™
Guiding Catheter



Indication: The R2P (radial to peripheral) SlenGuide is designed for the introduction of interventional and diagnostic devices into the peripheral vasculature of the lower extremities.

- 7 Fr size
- 120 cm and 150 cm lengths
- Guiding catheter with distal hydrophilic coating and Slender Technology for optimal performance during peripheral procedures

Features and Benefits:

- 1 *Unique thin wall design*
- 2 *Enables smaller arterial access while maintaining 6Fr compatibility*
- 3 *Provides a conduit for lower extremity interventions from a radial approach*
- 4 *Designed to reduce potential for arterial spasm during introduction and removal¹*

Product Description:

Glidewire[®]

Hydrophilic Coated Guidewire



Indication: GLIDEWIRE Hydrophilic Coated Guidewires are designed to direct a catheter to the designed anatomical location during diagnostic or interventional procedures

- Straight, Angled, 1.5 mm and 3 mm JTip
- 350 cm, 400 cm and 450 cm lengths
- Includes multiple procedural options in shaft stiffness, tip shapes and wire configurations for easier vessel navigation

Features and Benefits:

- 1 *Terumo Glide Technology hydrophilic coating*
- 2 *Excellent crossability and trackability for challenging lesions as well as enhanced trackability through tortuous anatomy.*
- 3 *High durability with kink resistance and shape preservation as well as flexibility for easy artery navigation.*
- 4 *Excellent pushability for lesion access and notable torquability for procedure control.*

Product Description:

Glidecath[®]

Hydrophilic Coated Catheter



Indication: GLIDECATH is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the vascular system. It is also used to lead a guide wire or a catheter into the target site.

- 4 Fr size
- 150 cm length
- Offers excellent pushability and torque control with multiple tip shapes for selectivity and access to the peripheral vasculature

Features and Benefits:

- 1 *Provides excellent trackability and torque control⁸*
- 2 *Designed for optimal vessel selectivity and access to peripheral vasculature*
- 3 *Multiple tip shapes offered; Straight, Angle, PV Multicurve, Pigtail, Cobra 2, JR 4.0 & IMA*
- 4 *Double braided stainless steel for increased pushability*

Product Description:

Navicross[®]

Support Catheters



Indication: NAVICROSS is intended to guide and support a guide wire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline or diagnostic contrast agents.

- Straight, Angled
- 135cm and 150cm lengths
- Double tapered tip provides the smallest crossing profile, giving a near seamless catheter-to-guidewire transition to aid in crossing simple or complex lesions in the peripheral vasculature

Features and Benefits:

- 1 *Best-in-class pushability*⁷
- 2 *Double tapered tip provides the smallest crossing profile*

- 3 *Double- braided stainless steel and three uniquely spaced radiopaque markers*
- 4 *Excellent wire-to-catheter transition enhancing crossing profile*

Product Description:

R2P™ *Metacross*® RX PTA Balloon Dilatation Catheter



Indication: The R2P METACROSS RX PTA balloon dilatation catheter is intended to dilate stenosis in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

- 3-8 mm diameter x 20-200 mm length
- 200 cm shaft length
- The longest radial to peripheral capability and Rapid Exchange (RX) technology are designed to mitigate excessive device management and use of contrast media during a peripheral procedure

Features and Benefits:

- 1 *Tapered core wire from distal tube tip to proximal end of catheter*
- 2 *Unique technology stands apart from competition with the longest radial access to peripheral capability.²*
- 3 *Designed to mitigate excessive device management during procedures.²*
- 4 *Designed to mitigate amount of contrast media that may be used during the procedure.²*

Product Description:

R2P™ Crosstella® RX



Indication: The R2P CROSSTELLA RX PTA balloon dilatation catheter is intended to dilate stenosis in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

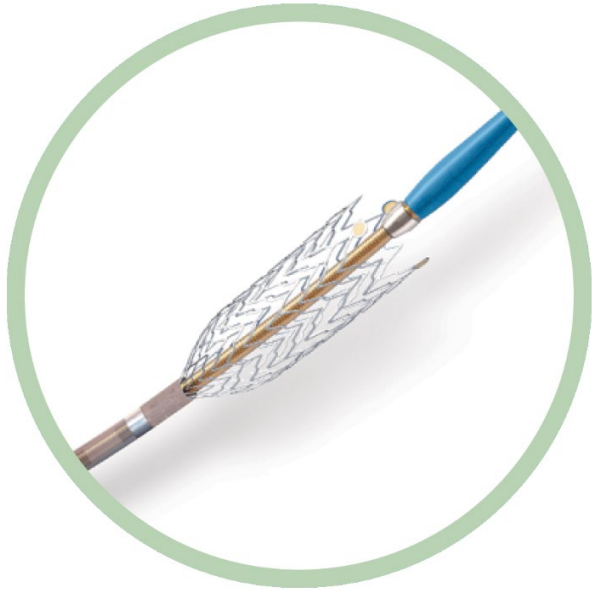
- 2-6 mm diameter x 40-200 mm length
- 200 cm shaft length
- The longest 0.018" Rapid Exchange (RX) PTA Balloon designed for use in radial to peripheral procedures

Features and Benefits:

- 1 *RX system is designed for ease of use by increasing procedural efficiency and reducing fluoroscopy time.²*
- 2 *CROSSTELLA RX PTA Balloon Dilatation Catheter provides the lowest deflation time results when tested against a competitor.²*
- 3 *Engineered to provide best-in-class pushability to help in crossing the lesion.²*
- 4 *CROSSTELLA RX PTA Balloon Dilatation Catheter provides excellent crossability when tested against competitor.²*

Product Description:

R2P™ Misago®
RX Self-expanding Peripheral Stent



Indication: The 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 and/or proximal popliteal artery with reference vessel diameters ranging from 4mm to 7mm and lesion length up to 150mm

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

- 6Fr sheath compatibility, 6-8 mm diameter x 40-150 mm length
- 200 cm shaft length with 6 gold reference markers
- Rapid Exchange design offers you optimized control and handling.

Features and Benefits:

- 1 Nitinol construction with a direct link design.
- 2 Rapid Exchange (RX) or "monorail" delivery system is designed for ease of use by increasing procedural efficiency and reducing fluoroscopy time.⁶
- 3 Minimizes jumping, recoil or foreshortening with a simplified thumbwheel system that allows for single operator deployment.⁶
- 4 The continuous spine-free stent is designed to promote optimal blood flow and eliminate high-strain stress zones that can lead to fracture.⁶

Product Description:

TR Band Radial Compression Device



Indication: TR Band is a compression device to assist hemostasis of the radial artery after a transradial procedure.

- Regular 24 cm and Long 29 cm
- The #1 preferred radial hemostasis device⁵ on the market provides a more precise way of applying pressure to the radial artery

Features and Benefits:

- 1 *Precise compression to achieve radial hemostasis*
- 2 *Air titration provides a more precise way of applying pressure to the radial artery⁴*
- 3 *Dual balloon technology provides precise compression of the radial artery without compromising local nerve structure³*
- 4 *Hemostasis achieved at low pressures, minimizing the chances of applying occlusive force*

[BACK](#)

3.) Ono K. Experience of the TR BAND for the Diagnostic Catheter Procedure. Yuri Union General Hospital in Akita Pref., September 2004

4.) Pancholy S. Impact of Two Different Hemostatic Devices on Radial Artery Outcomes after Transradial Catheterization Journal of Invasive Cardiology, Vol 21, No. 3, March 2009

5.) Data on file.

Materials Management

Ordering Information and Brochure

510(k) Clearance Letter and PMA Approval Letter

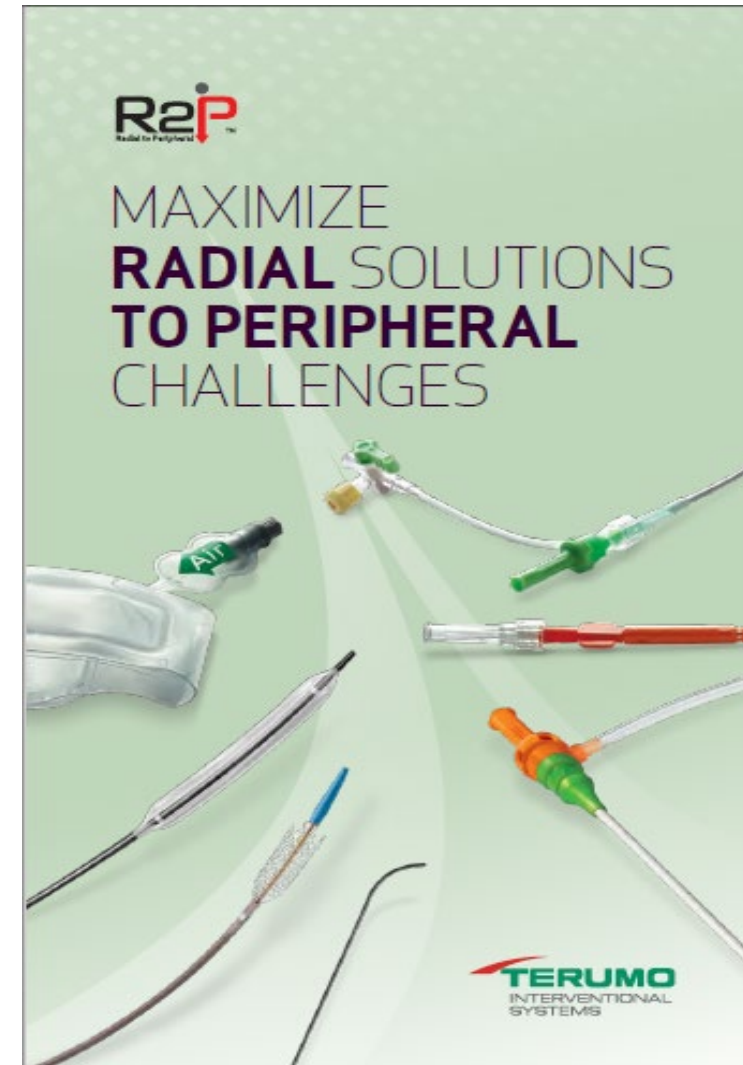
Instructions for Use

Service and Support

Ordering Information Form and Brochure

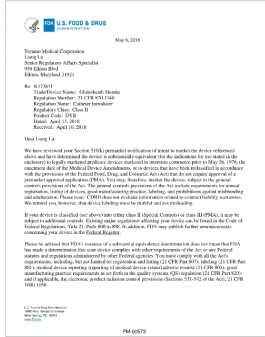
Radial to Peripheral ORDERING FORM

AMT	PRODUCT CODE	DESCRIPTION	AMT	PRODUCT CODE	DESCRIPTION
SHEATHS					
GLIDESHEATH SLENDER® Hydrophilic Coated Introducer Sheath Nitinol Kit (5 per box)					
	50-1060	6 Fr, 10 cm, 0.021" GW		GR3534	Standard, 0.035", 350 cm, 3 mm J Tip
	50-1070	7 Fr, 10 cm, 0.021" GW		GR3538	Standard, 0.035", 400 cm, 3 mm J Tip
GLIDESHEATH SLENDER® Hydrophilic Coated Introducer Sheath Access Kit (5 per box)					
	60-1060	6 Fr, 10 cm, 0.021" GW		GR3545	Standard, 0.035", 450 cm, 3 mm J Tip
	60-1660	6 Fr, 16 cm, 0.021" GW		GS3536	Stiff, 0.035", 350 cm, Straight
	60-1070	7 Fr, 10 cm, 0.021" GW		GS3541	Stiff, 0.035", 400 cm, Straight
	60-1670	7 Fr, 16 cm, 0.021" GW		GS3546	Stiff, 0.035", 450 cm, Straight
	60-1065	6 Fr, 10 cm, 0.025" GW		GS3535	Stiff, 0.035", 350 cm, 45° Angle
	60-1075	7 Fr, 10 cm, 0.025" GW		GS3540	Stiff, 0.035", 400 cm, 45° Angle
GLIDESHEATH SLENDER® Hydrophilic Coated Introducer Sheath Stainless Steel Kit (5 per box)					
	80-1060	6 Fr, 10 cm, 0.021" GW		GS3543	Stiff, 0.035", 450 cm, 45° Angle
	80-1660	6 Fr, 16 cm, 0.021" GW		GS3533	Stiff, 0.035", 350 cm, 1.5 mm J Tip
	80-1070	7 Fr, 10 cm, 0.021" GW		GS3539	Stiff, 0.035", 400 cm, 1.5 mm J Tip
	80-1670	7 Fr, 16 cm, 0.021" GW		GS3544	Stiff, 0.035", 450 cm, 1.5 mm J Tip
	80-1065	6 Fr, 10 cm, 0.025" GW		CATHETERS	
	80-1075	7 Fr, 10 cm, 0.025" GW		GLIDECATH® Hydrophilic Coated Catheter (5 per box)	
R2P™ DESTINATION SLENDER™ Guiding Sheath (1 per box)					
	GS-R65T1C12W	119 cm, 6 Fr, Straight		CG430	150 cm, 4 Fr, PV Multicurve
	GS-R65T1C15W	149 cm, 6 Fr, Straight		CG431	150 cm, 4 Fr, Straight
R2P™ SLENGUIDE™ Guiding Catheter (1 per box)					
	WG-575T1L23A	120 cm, 7 Fr, Straight		CG432	150 cm, 4 Fr, Angle
	WG-575T1L53A	150 cm, 7 Fr, Straight		CG433	150 cm, 4 Fr, Pigtail
GUIDEWIRES					
GLIDEWIRE® Hydrophilic Coated Guidewire (5 per box)					
	GR3536	Standard, 0.035", 350 cm, Straight		CG434	150 cm, 4 Fr, Cobra 2
	GR3541	Standard, 0.035", 400 cm, Straight		CG435	150 cm, 4 Fr, JR 4.0
	GR3546	Standard, 0.035", 450 cm, Straight		CG436	150 cm, 4 Fr, IMA
	GR3535	Standard, 0.035", 350 cm, 45° Angle		NAVICROSS® Support Catheter (1 per box)	
	GR3540	Standard, 0.035", 400 cm, 45° Angle		NC35130	Straight Tip, 0.035" x 135 cm
	GR3543	Standard, 0.035", 450 cm, 45° Angle		NC35131	Angle Tip, 0.035" x 135 cm
	GR3533	Standard, 0.035", 350 cm, 1.5 mm J Tip		NC35150	Straight Tip, 0.035" x 150 cm
	GR3539	Standard, 0.035", 400 cm, 1.5 mm J Tip		NC35151	Angle Tip, 0.035" x 150 cm
	GR3544	Standard, 0.035", 450 cm, 1.5 mm J Tip		PTA BALLOON	
R2P™ METACROSS® RX PTA Balloon Dilatation Catheter (1 per box)					
	BD-P30020ER	200 cm, 6 Fr, 3 mm x 20 mm		BD-P30040ER	200 cm, 6 Fr, 3 mm x 40 mm
	BD-P30060ER	200 cm, 6 Fr, 3 mm x 60 mm		BD-P30080ER	200 cm, 6 Fr, 3 mm x 80 mm
	BD-P30100ER	200 cm, 6 Fr, 3 mm x 100 mm		BD-P30120ER	200 cm, 6 Fr, 3 mm x 120 mm
	BD-P30150ER	200 cm, 6 Fr, 3 mm x 150 mm		BD-P30200ER	200 cm, 6 Fr, 3 mm x 200 mm



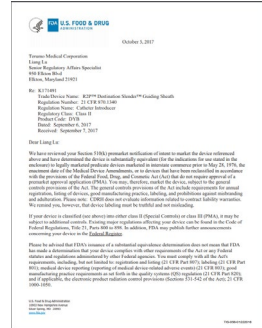
510(k) Clearance Letters & R2P MISAGO PMA Letter

Glidesheath Slender®
Hydrophilic Coated Introducer Sheath



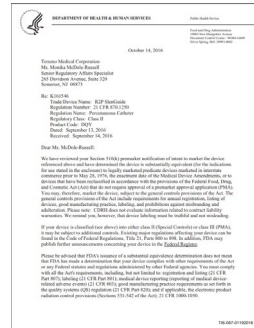
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R2P Destination Slender®
Guiding Sheath



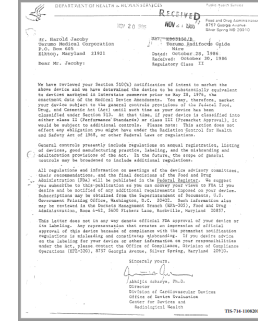
K193125

R2P SlenGuide®
Guiding Catheter



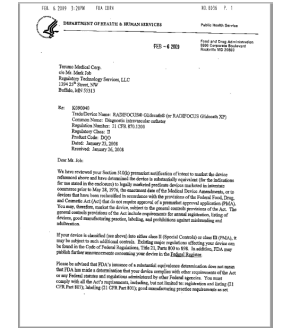
K161546

Glidewire®
Hydrophilic Coated Guidewire



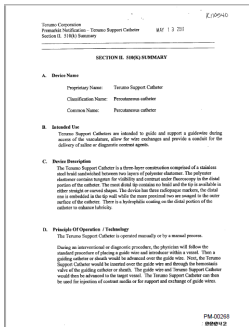
K152740

Glidecath®
Hydrophilic Coated Catheter



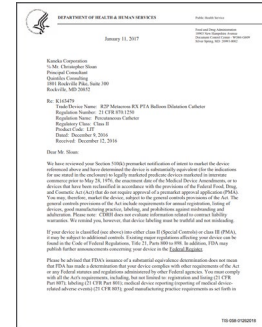
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Navicross®
Support Catheters



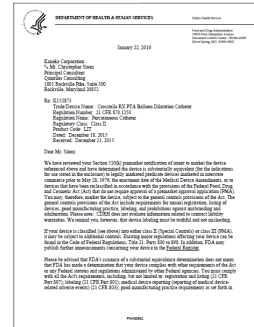
K110540

R2P Metacross® RX
PTA Balloon Dilatation Catheter



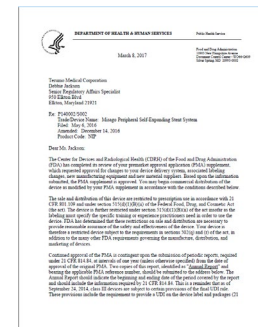
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R2P Crosstella® RX
PTA Balloon Dilatation Catheter



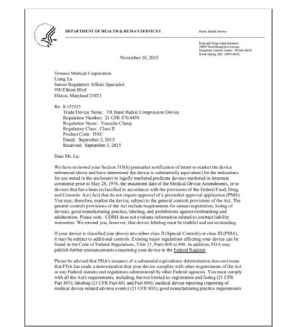
K152873

R2P Misago®
RX Self-expanding Peripheral Stent



P140002/S002

TR Band®
Radial Compression Device



K152525

Instructions for use

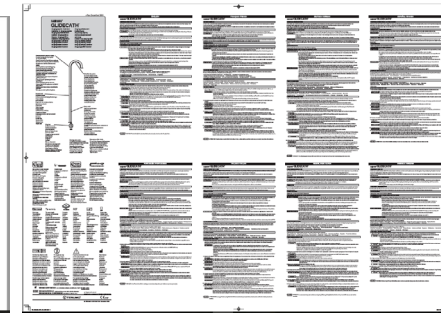
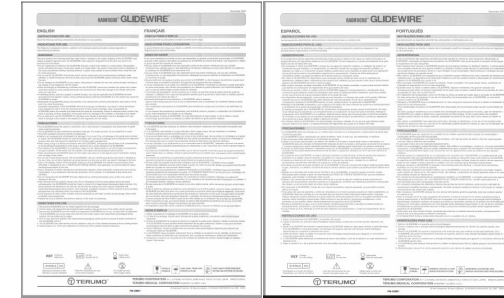
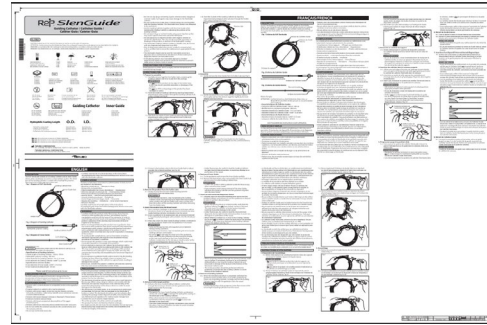
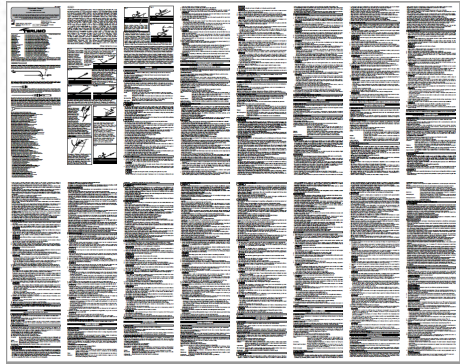
Glidesheath Slender[®]
Hydrophilic Coated Introducer Sheath

R2P Destination Slender[®]
Guiding Sheath

R2P SlenGuide[®]
Guiding Catheter

Glidewire[®]
Hydrophilic Coated Guidewire

Glidecath[®]
Hydrophilic Coated Catheter



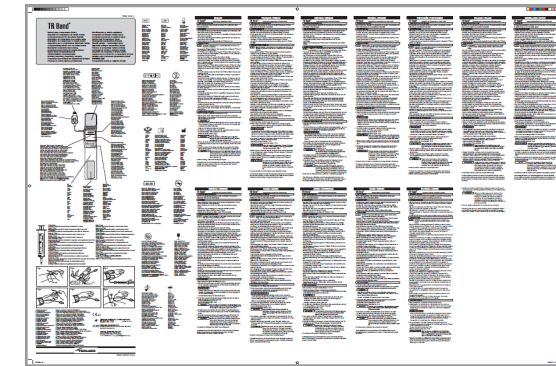
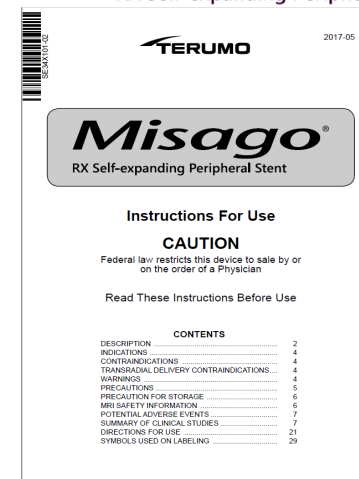
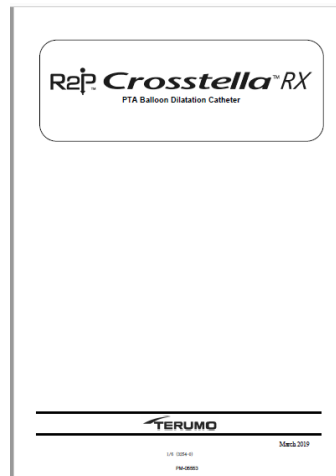
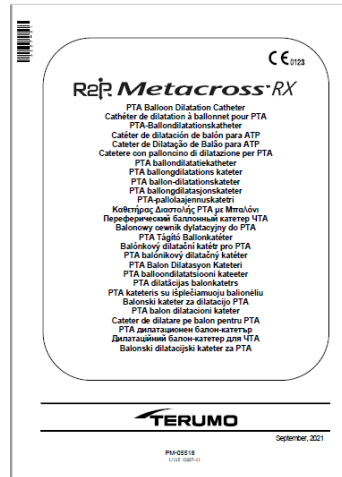
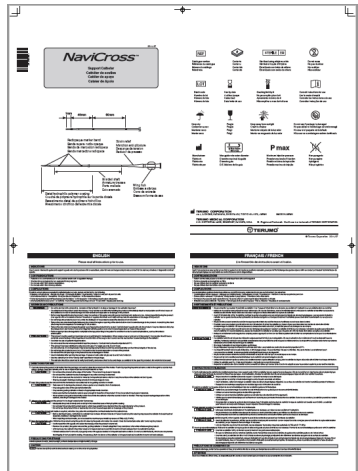
Navicross[®]
Support Catheters

R2P Metacross[®] RX
PTA Balloon Dilatation Catheter

R2P Crosstella[®] RX
PTA Balloon Dilatation Catheter

R2P Misago[®]
RX Self-expanding Peripheral Stent

TR Band[®]
Radial Compression Device



Service and Support

- ◆ Terumo Medical Corporation- Corporate Headquarters
265 Davidson Ave
Suite 320
Somerset, NJ 08773
- ◆ United States Customer Care
Phone:800-888-3786
- ◆ Inside Sales
Phone:800-862-4143
- ◆ Accounts Receivable
Phone:800-283-7866