

# The ULTRASCORE™ Scoring Balloon

Designed for controlled plaque modification

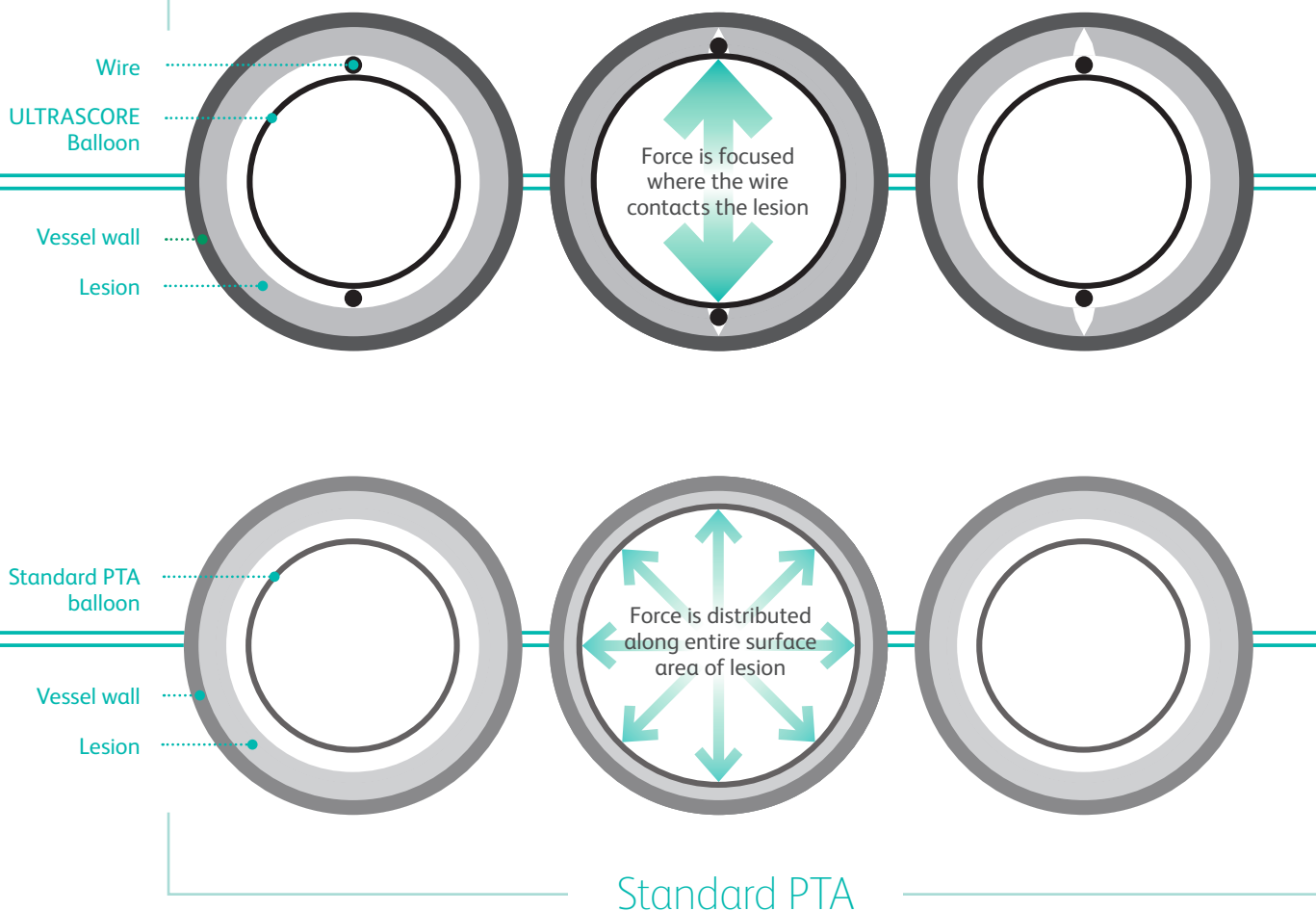


# Controlled plaque modification

Compared to a standard PTA balloon of the same size, the ULTRASCORE focused force PTA balloon:

- Is designed to **longitudinally fracture plaque** at **lower inflation pressures**
- May allow for a more **controlled plaque fracture** and **less vessel recoil**, even in calcified lesions

## How ULTRASCORE focused force PTA balloon works



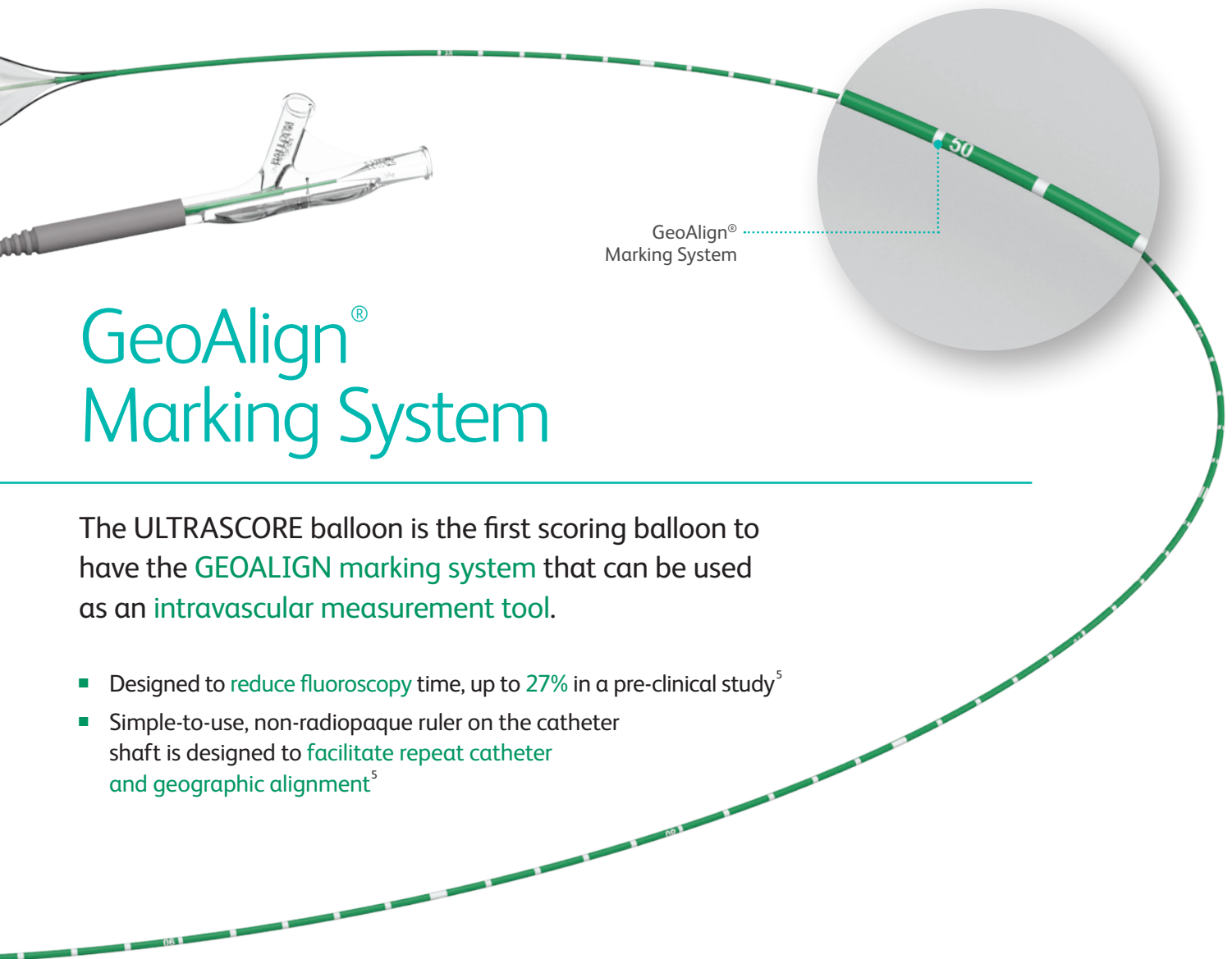
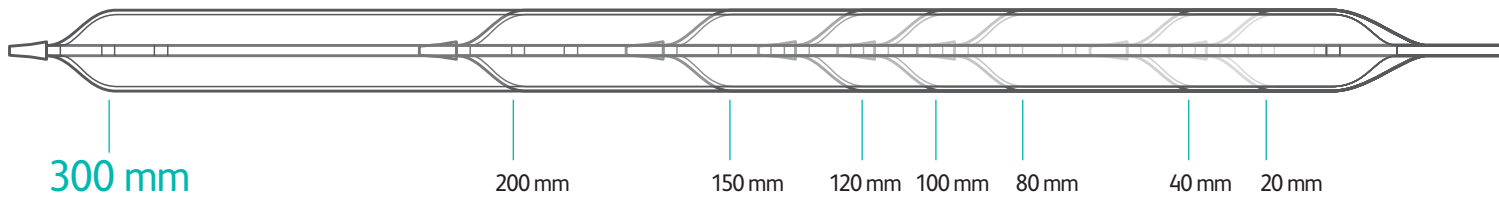
4 As of March 2018.

5 When the catheter is exposed to the vascular system, the location of the balloon should be confirmed while under high quality fluoroscopic observation. GEOALIGN® Markers are not a replacement for fluoroscopy. Animal study (repeat PTA in swine artery) was performed by 3 physicians who tested the LUTONIX® 035 DCB (no drug) and the ULTRAVERSE® 035 PTA Catheter, both with GEOALIGN® Markers, to POBA with no GEOALIGN® Markers [n=112, test n = 96 (with and average placement time of 66 seconds), control n = 16 (with an average placement of 90 seconds)]. Animal data on file, Bard Peripheral Vascular, Inc., Tempe, AZ. Animal test results may not be indicative of clinical performance. Different test methods may yield different results.

# Broadest scoring balloon portfolio<sup>4</sup>

on the U.S. market

## LONGEST SCORING BALLOON LENGTHS ON THE U.S. MARKET<sup>4</sup>



## GeoAlign<sup>®</sup> Marking System

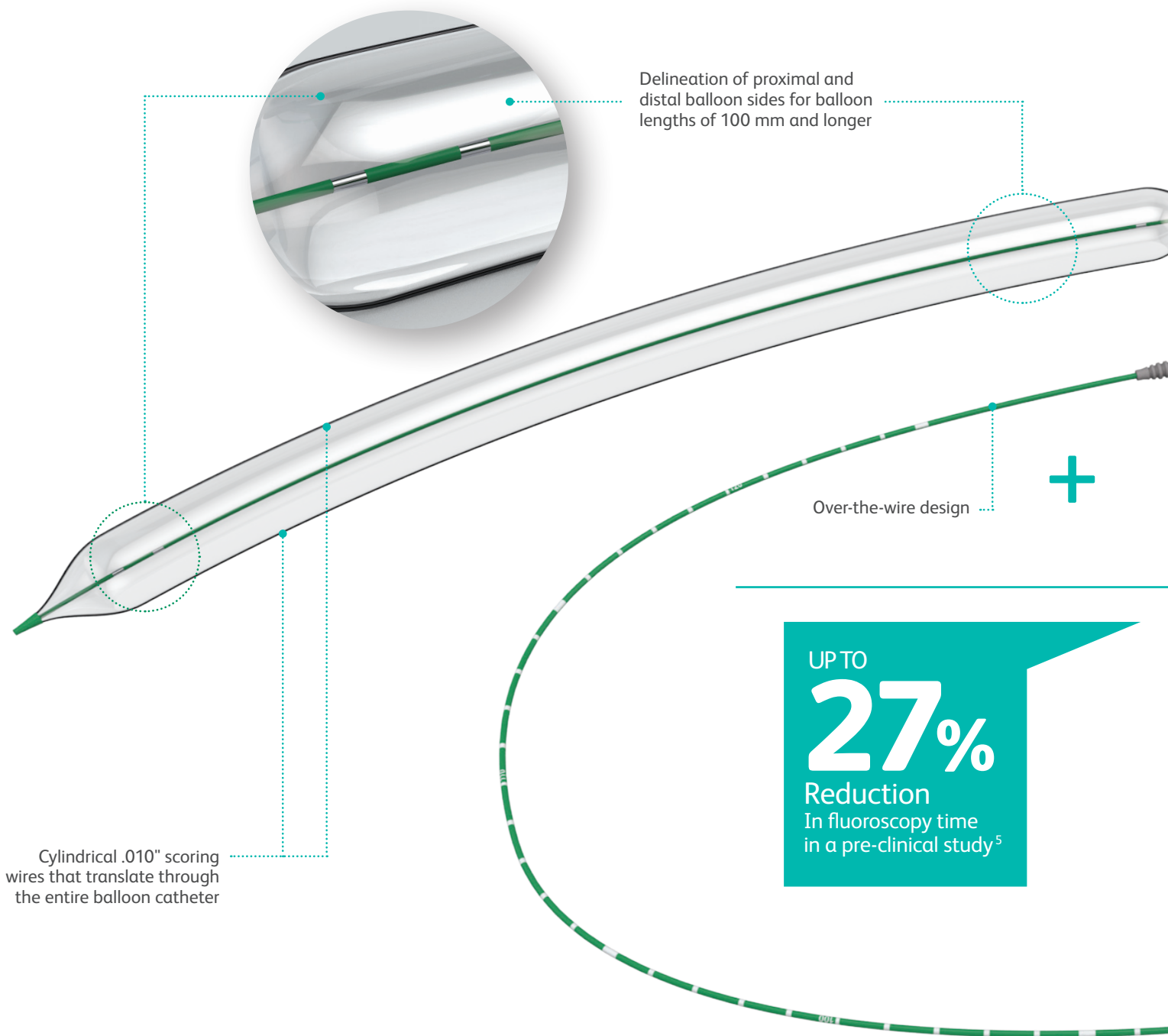
The ULTRASCORE balloon is the first scoring balloon to have the **GEOALIGN** marking system that can be used as an **intravascular measurement tool**.

- Designed to **reduce fluoroscopy** time, up to **27%** in a pre-clinical study<sup>5</sup>
- Simple-to-use, non-radiopaque ruler on the catheter shaft is designed to **facilitate repeat catheter and geographic alignment**<sup>5</sup>

# Low profile, over-the-wire design +

ULTRASCORE focused force PTA balloon is available on a .035" and .014" platform, and is the lowest profile scoring balloon on the U.S. market.<sup>4</sup>

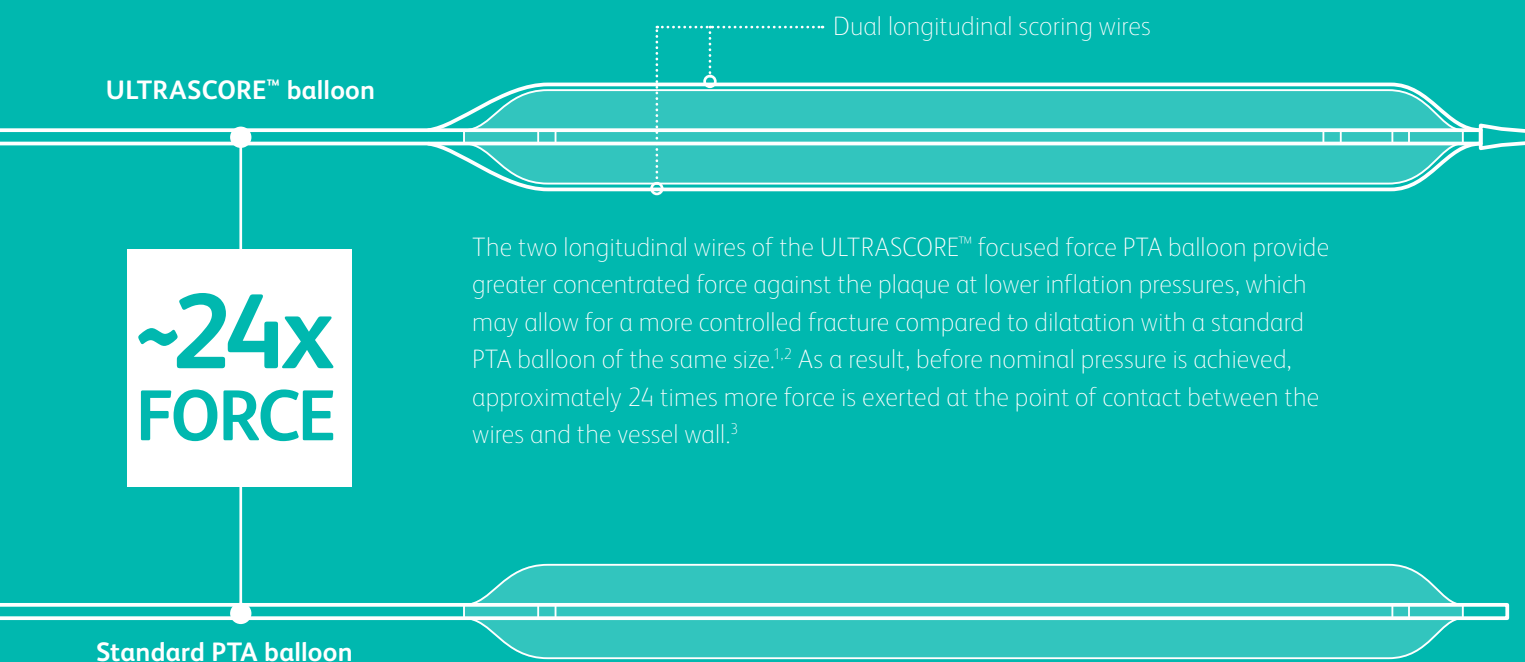
- Only 4F scoring balloon on the U.S. market<sup>4</sup>
- First .035" scoring balloon commercially available on the U.S. market<sup>4</sup>
- Hydrophilic coating for optimized deliverability on .014" platform<sup>4</sup>



UP TO  
**27%**  
Reduction  
In fluoroscopy time  
in a pre-clinical study<sup>5</sup>

# Designed to fracture plaque longitudinally at lower inflation pressures compared to standard PTA

## ULTRASCOPE focused force PTA balloon design



The two longitudinal wires of the ULTRASCOPE™ focused force PTA balloon provide greater concentrated force against the plaque at lower inflation pressures, which may allow for a more controlled fracture compared to dilatation with a standard PTA balloon of the same size.<sup>1,2</sup> As a result, before nominal pressure is achieved, approximately 24 times more force is exerted at the point of contact between the wires and the vessel wall.<sup>3</sup>

A standard PTA balloon distributes force to the entire surface area of the vessel wall. At the same nominal inflation pressure as the ULTRASCOPE focused force PTA balloon, a standard PTA balloon generates less force against the lesion.<sup>1,3</sup>

## Standard PTA

1 Based on a simulated finite element analysis. Data on File, Bard Peripheral Vascular, Inc., Tempe, AZ. May not be predictive of clinical performance. Different test methods may yield different results.

2 For purposes of this analysis, initiation of plaque failure was deemed to occur when the strain exceeds 18%. UltraScore focused force PTA balloon was predicted to initiate failure at .32 ATM, while a standard semi-compliant PTA balloon was predicted to initiate failure at 10.3 ATM. Data on file, Bard Peripheral Vascular, Inc., Tempe, AZ. Simulated analyses may not be predictive of actual clinical performance. Different test methods may yield different results.

3 Based on theoretical calculation using equation  $P=F/A$ . Data on File, Bard Peripheral Vascular, Inc., Tempe, AZ. May not be predictive of clinical performance. Different test methods may yield different results.

# ULTRASCORE™ ordering codes

150 cm shaft | .014" guidewire compatible

Diam. (mm)	RBP (ATM)	Balloon length								Sheath compatibility
		20 mm	40 mm	80 mm	100 mm	120 mm	150 mm	200 mm	300 mm	
2	14	<input type="checkbox"/> US1415022	<input type="checkbox"/> US1415024	<input type="checkbox"/> US1415028	<input type="checkbox"/> US14150210	<input type="checkbox"/> US14150212	<input type="checkbox"/> US14150215	<input type="checkbox"/> US14150220	<input type="checkbox"/> US14150230	4F
2.5	14	<input type="checkbox"/> US141502H2	<input type="checkbox"/> US141502H4	<input type="checkbox"/> US141502H8	<input type="checkbox"/> US141502H10	<input type="checkbox"/> US141502H12	<input type="checkbox"/> US141502H15	<input type="checkbox"/> US141502H20	<input type="checkbox"/> US141502H30	
3	14	<input type="checkbox"/> US1415032	<input type="checkbox"/> US1415034	<input type="checkbox"/> US1415038	<input type="checkbox"/> US14150310	<input type="checkbox"/> US14150312	<input type="checkbox"/> US14150315	<input type="checkbox"/> US14150320	<input type="checkbox"/> US14150330	
3.5	14	<input type="checkbox"/> US141503H2	<input type="checkbox"/> US141503H4	<input type="checkbox"/> US141503H8	<input type="checkbox"/> US141503H10	<input type="checkbox"/> US141503H12	<input type="checkbox"/> US141503H15	<input type="checkbox"/> US141503H20	<input type="checkbox"/> US141503H30	
4	14	<input type="checkbox"/> US1415042	<input type="checkbox"/> US1415044	<input type="checkbox"/> US1415048	<input type="checkbox"/> US14150410	<input type="checkbox"/> US14150412	<input type="checkbox"/> US14150415	<input type="checkbox"/> US14150420	<input type="checkbox"/> US14150430	5F
5	12	<input type="checkbox"/> US1415052	<input type="checkbox"/> US1415054	<input type="checkbox"/> US1415058	<input type="checkbox"/> US14150510	<input type="checkbox"/> US14150512	<input type="checkbox"/> US14150515	<input type="checkbox"/> US14150520	<input type="checkbox"/> US14150530	
6	12	<input type="checkbox"/> US1415062	<input type="checkbox"/> US1415064	<input type="checkbox"/> US1415068	<input type="checkbox"/> US14150610	<input type="checkbox"/> US14150612	<input type="checkbox"/> US14150615	<input type="checkbox"/> US14150620	<input type="checkbox"/> US14150630	
7	10	<input type="checkbox"/> US1415072	<input type="checkbox"/> US1415074	<input type="checkbox"/> US1415078	<input type="checkbox"/> US14150710	<input type="checkbox"/> US14150712	<input type="checkbox"/> US14150715	<input type="checkbox"/> US14150720	<input type="checkbox"/> US14150730	

130 cm shaft | .035" guidewire compatible

Diam. (mm)	RBP (ATM)	Balloon length								Sheath compatibility
		20 mm	40 mm	80 mm	100 mm	120 mm	150 mm	200 mm	300 mm	
4	14	<input type="checkbox"/> US3513042	<input type="checkbox"/> US3513044	<input type="checkbox"/> US3513048	<input type="checkbox"/> US35130410	<input type="checkbox"/> US35130412	<input type="checkbox"/> US35130415	<input type="checkbox"/> US35130420	<input type="checkbox"/> US35130430	5F
5	14	<input type="checkbox"/> US3513052	<input type="checkbox"/> US3513054	<input type="checkbox"/> US3513058	<input type="checkbox"/> US35130510	<input type="checkbox"/> US35130512	<input type="checkbox"/> US35130515	<input type="checkbox"/> US35130520	<input type="checkbox"/> US35130530	6F
6	14	<input type="checkbox"/> US3513062	<input type="checkbox"/> US3513064	<input type="checkbox"/> US3513068	<input type="checkbox"/> US35130610	<input type="checkbox"/> US35130612	<input type="checkbox"/> US35130615	<input type="checkbox"/> US35130620	<input type="checkbox"/> US35130630	
7	10	<input type="checkbox"/> US3513072	<input type="checkbox"/> US3513074	<input type="checkbox"/> US3513078	<input type="checkbox"/> US35130710	<input type="checkbox"/> US35130712	<input type="checkbox"/> US35130715	<input type="checkbox"/> US35130720	<input type="checkbox"/> US35130730	
8	10	<input type="checkbox"/> US3513082	<input type="checkbox"/> US3513084	<input type="checkbox"/> US3513088	<input type="checkbox"/> US35130810	<input type="checkbox"/> US35130812	<input type="checkbox"/> US35130815	<input type="checkbox"/> US35130820	-	

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