

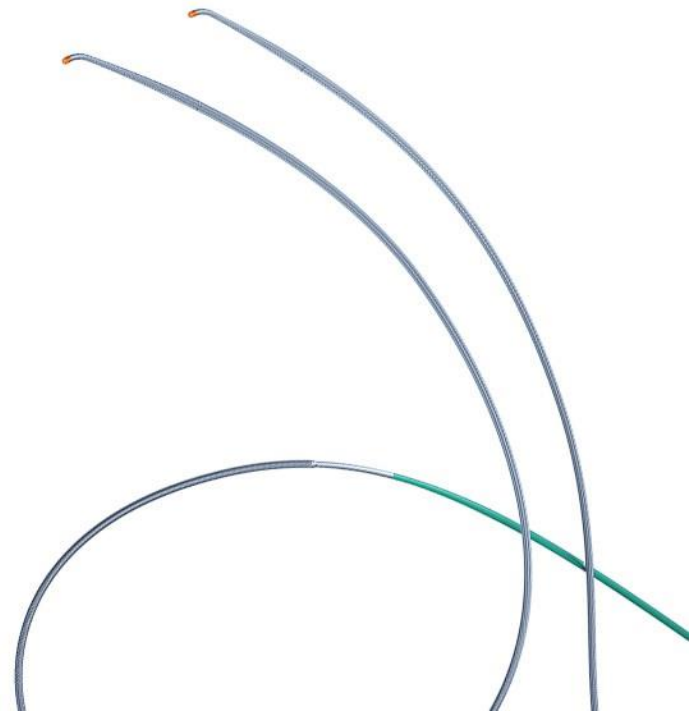


PERIPHERAL

CANADA IN-SERVICE PRESENTATION

Hi-Torque Proceed™ Guide Wire

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Hi-Torque Proceed™ Guide Wire

- ▶ Product Overview
- ▶ Key Messages
- ▶ Design Features
- ▶ Techniques and Escalation Strategies
- ▶ Ordering Information
- ▶ Guide Wire Portfolio
- ▶ Appendix

Hi-Torque Proceed™ Guide Wire

The Unmet Clinical Need

- CLI is a global epidemic, with high clinical, social and economic costs.¹ The number of patients needing lower limb revascularization for severe limb ischemia is expected to increase in the near future.¹
- The increase in endovascular treatment of CLI requires the ability to cross complex lesions. Multi-level lesions and different plaque morphologies present clinicians with new therapy delivery challenges, particularly in navigation and cross.
- In order to improve upon the failure to cross, Abbott developed new and innovative guide wires to meet the clinical challenges of crossing complex lesions² in the lower extremity.

1. Brandao D, Ferreria J, and Masilha A, et al. Below the Knee Techniques: Now and Then. *Angioplasty, Various Techniques and Challenges in Treatment of Congenital and Acquired Vascular Stenoses*. (41-62).

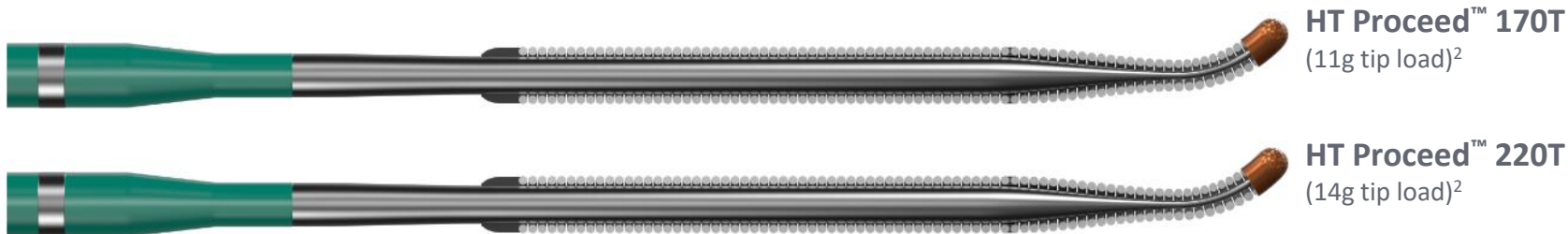
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Hi-Torque Proceed™ Guide Wire

Clinical Value Proposition

The **HT Proceed™ guide wire** provides users with a **tip shape and unique tip design**¹ intended to **improve lesion engagement**² and **navigate into and through complex lesions**.¹

With two wires in the family, HT Proceed™ provides innovative options to access and cross complex lesions¹ that contribute to CLI disease.



Note: Drawing not to scale

1. Data on file at Abbott; 2. Test(s) performed by and data on file at Abbott

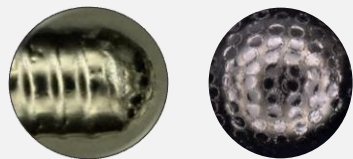
Hi-Torque Proceed™ Guide Wire

Proceed in Engaging² and Navigating through Complex Lesions¹

KEY
MESSAGES

Superb Lesion Engagement

Micro-textured tip¹ improves
lesion engagement²



Precise Control and Navigation

1 mm, 25° angled tip¹ facilitates
navigation through lesion
and optimizes consistency
of wire performance



Advancing Options for Crossing Complex Lesions

Next-generation
014 specialty wire

**2 levels of penetration power
and tip loads²** provides options
for various lesion types



1. Data on file at Abbott; 2. Test(s) performed by and data on file at Abbott

Hi-Torque Proceed™ Guide Wire

Superb Lesion Engagement

Micro-textured tip¹ is designed to:

- **Improve lesion engagement²**
- **Reduce tip deflection off lesion²**

Uncoated tip¹ provides improved tactile feedback for tip positioning and navigation

Tapered tip¹ for lesion penetration



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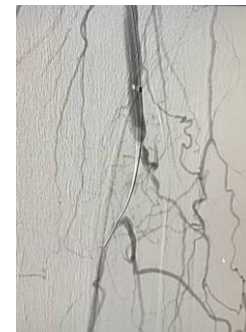
Hi-Torque Proceed™ Guide Wire

Precise Control and Navigation

- 1 mm, 25° angled tip¹ **facilitates navigation** through lesion and optimizes performance of the wire
- **Pre-shaped tip¹** reduces shaping variability for predictable performance and ease of use
- **Tip maintains shape** even when crossing complex lesions¹
 - When compared to other wires used in complex cases, tip shape retention is rated comparable or better¹
- Bare coil¹ wire design also improves tactile feedback for navigation and maneuverability
- Hydrophilic coating¹ designed for lesion crossability



Drilling and tapping techniques were used with HT Proceed™ 170T Guide Wire to penetrate into the PT (true lumen) and cross



Hi-Torque Proceed™ 170T Guide Wire

Images courtesy of Dr. Sedillo, Cardiovascular Solutions Institute

1. Data on file at Abbott

Hi-Torque Proceed™ Guide Wire

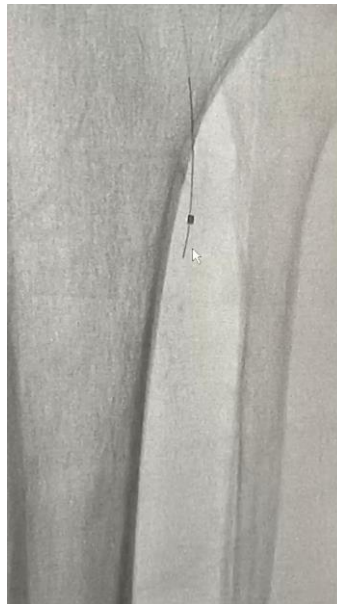
Precise Control and Navigation

Hi-Torque HT Proceed™ 170T Guide Wire

Content courtesy of Dr. Gino Sedillo, Cardiovascular Solutions Institute, Bradenton, FL

Case Synopsis: Contralateral BTK procedure for CLI patient; 40 mm TASC D lesion in left TPT and PT

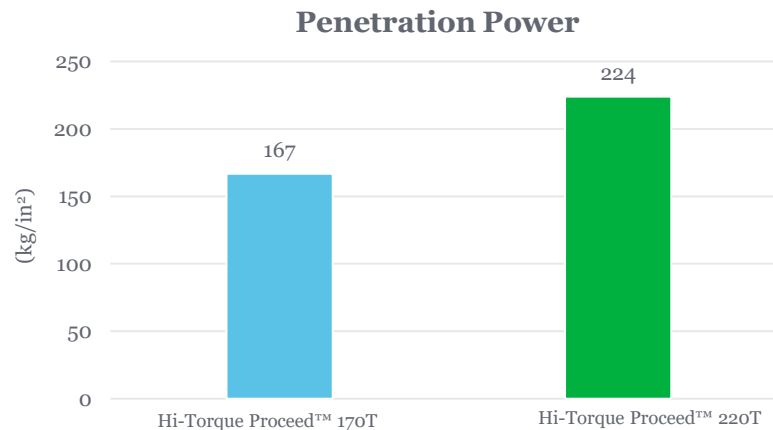
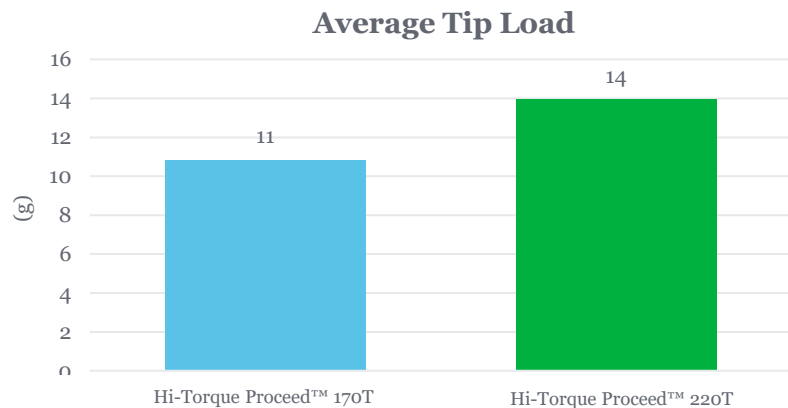
- .035" TrailBlazer[‡] and .035" Glidewire[‡] used for initial (unsuccessful) attempt to cross
- HT Proceed™ 170T Guide Wire and TrailBlazer[‡] then selected with initial success crossing the diseased segment
- Eventually switched to lower profile .018 Sterling[‡] balloon to be used with HT Proceed™ 170T Guide Wire to complete crossing
- Drilling and tapping techniques were used with HT Proceed™ 170T Guide Wire to penetrate into the PT (true lumen) and cross
- Final result was a patent TPT (coronary stent BTK) and PT



Hi-Torque Proceed™ Guide Wire

Advancing Options for Crossing Complex Lesions¹

- Next generation .014 specialty wire
- **Two levels of penetration power and tip loads** provide options for various lesion types²

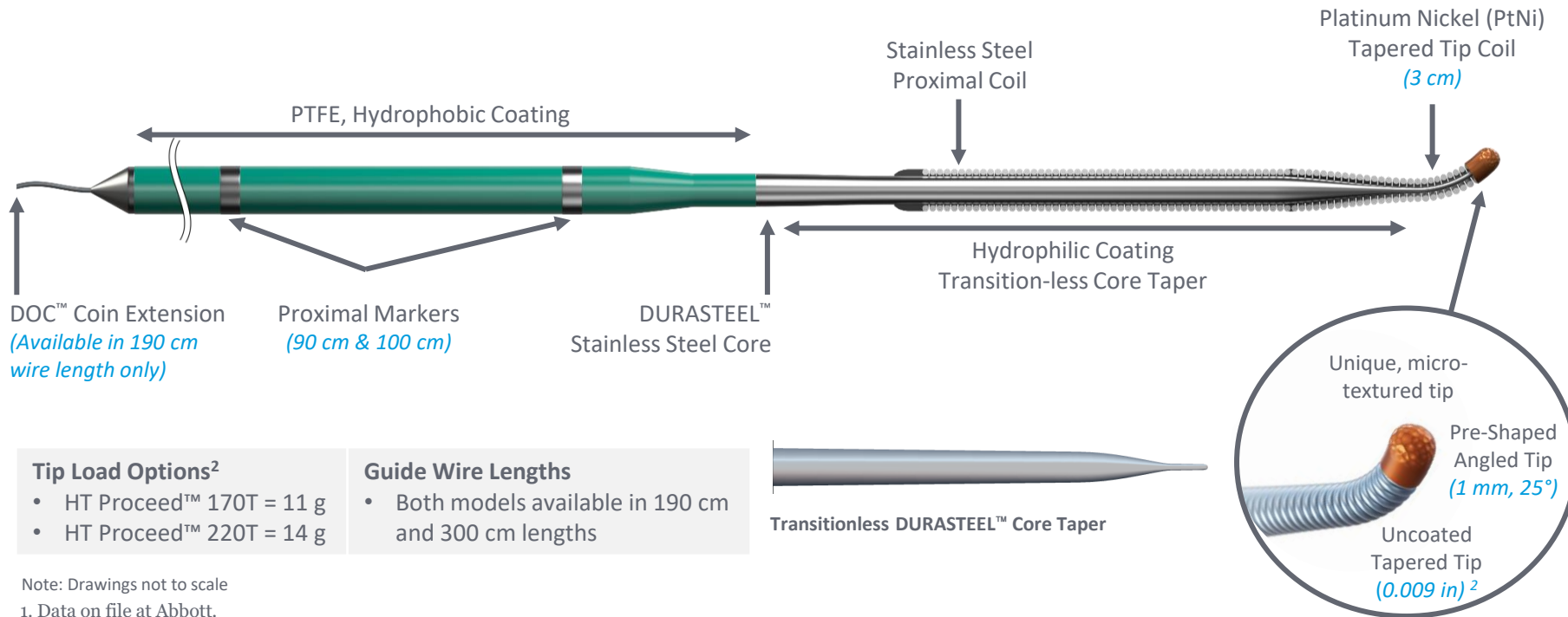


1. Data on file at Abbott; 2. Test(s) performed by and data on file at Abbott

Hi-Torque Proceed™ Guide Wire

Product Design Overview¹

DESIGN
FEATURES



Tip Load Options²

- HT Proceed™ 170T = 11 g
- HT Proceed™ 220T = 14 g

Guide Wire Lengths

- Both models available in 190 cm and 300 cm lengths

Note: Drawings not to scale

1. Data on file at Abbott.

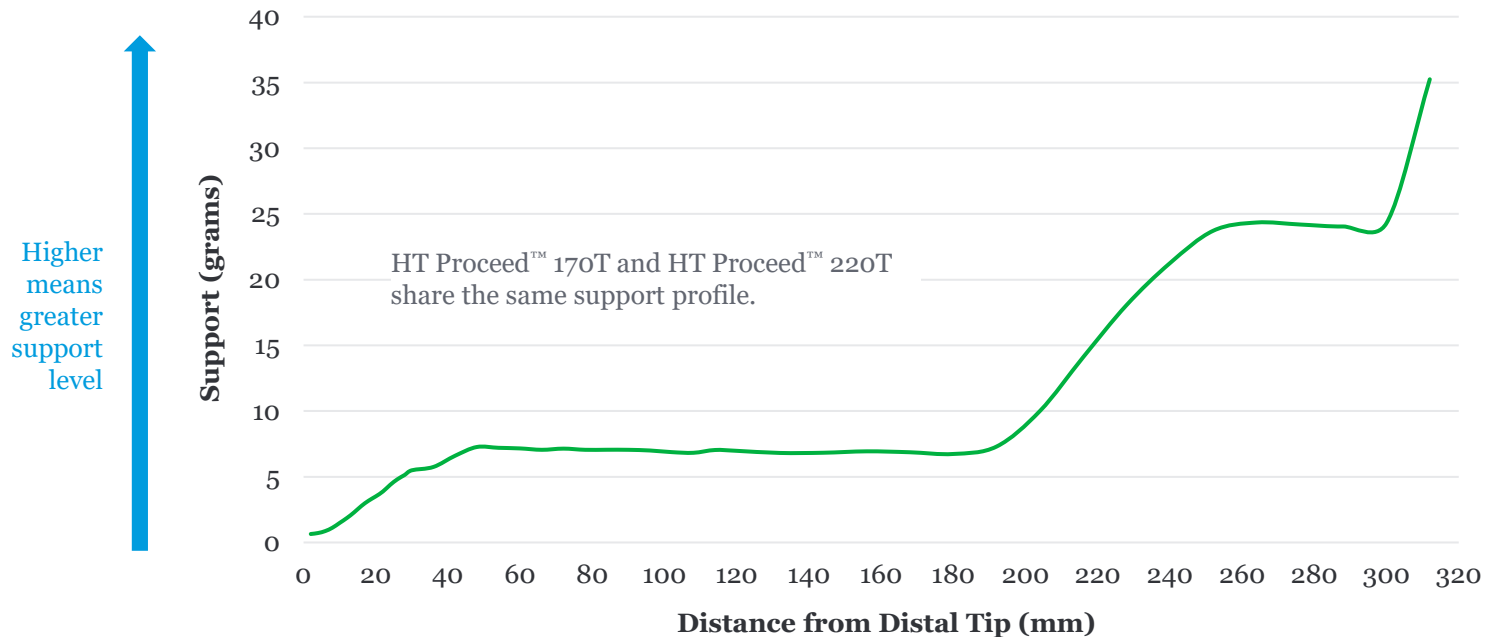
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Abbott Specialty Guide Wires

Hi-Torque Proceed™ Guide Wire



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Hi-Torque Proceed™ Guide Wire Penetration Power¹

PENETRATION POWER is a Function of Tip Load and Area at the Tip

- Tip load (traditionally provided in grams, and converted to kilograms for calculation)
- Area is calculated using tip diameter, in inches

Guide Wire Tip



$$\text{Area} = (\pi d^2)/4$$

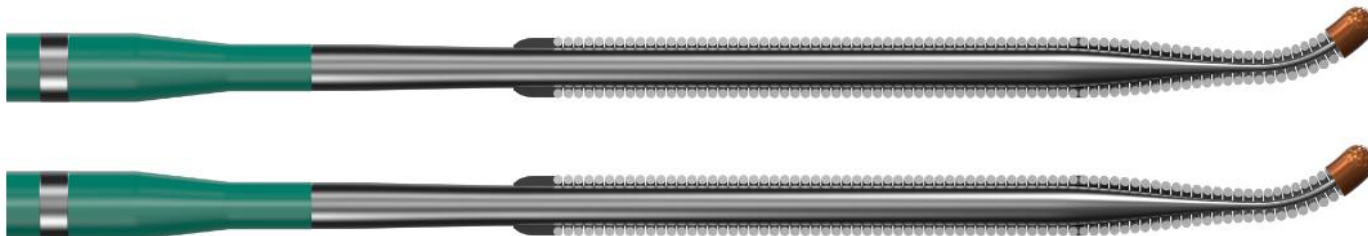
Example Calculation

- Tip load = 12 g (.012kg)
- Tip diameter = .014 in

Penetration Power is:

$$= .012 / ((\pi * .014^2) / 4) \\ = 78 \text{ kg/in}^2 \text{ Penetration Power}$$

- For two wires with the same tip diameter, the Penetration Power will be greater for the wire with the higher tip load
- For two wires with same tip load, the Penetration Power will be greater for the smaller tip diameter wire
- Increase in Penetration Power improves ability of the wire to cross lesions



HT Proceed™ 170T

Penetration Power = 167 kg/in²

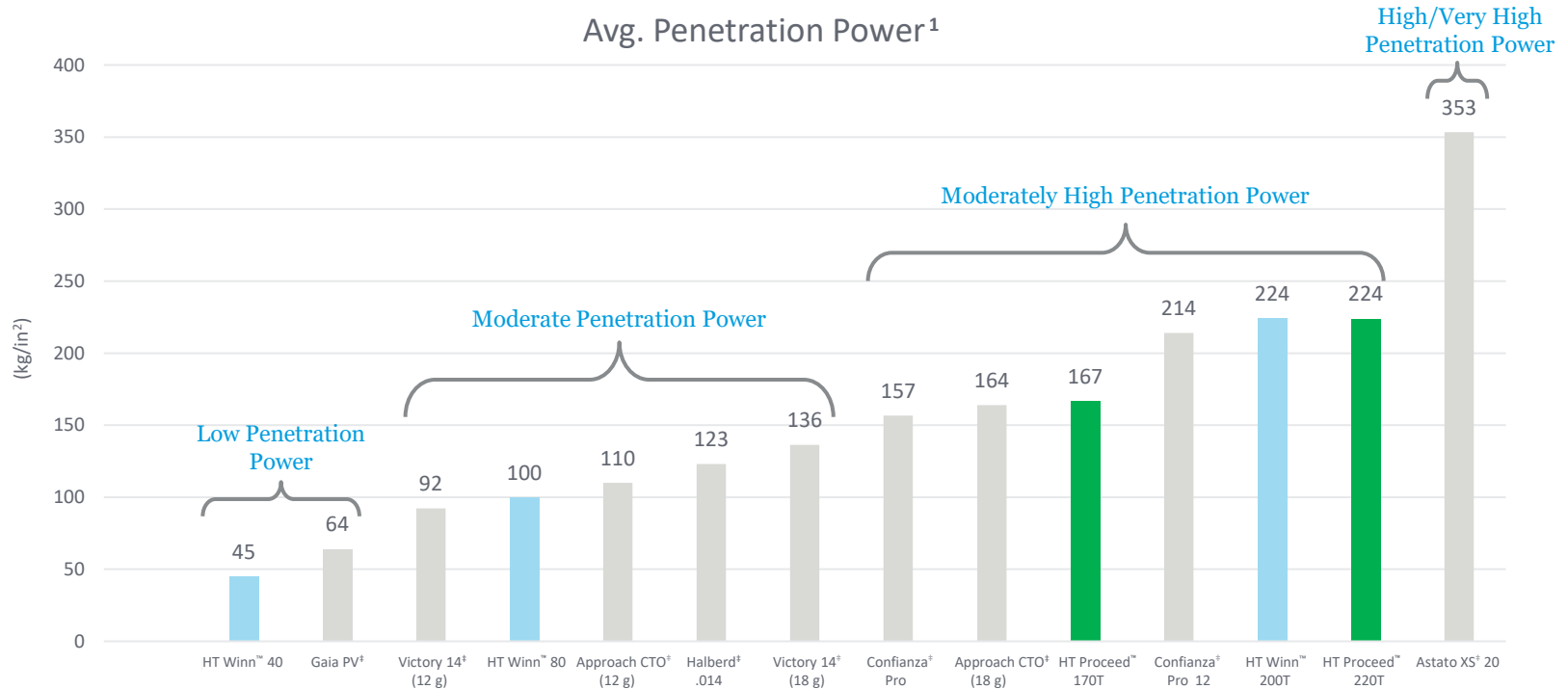
HT Proceed™ 220T

Penetration Power = 224 kg/in²

Note: Drawing not to scale

1. Test(s) performed by and data on file at Abbott.

Wide Range of Options in Specialty Wires Based on Penetration Power

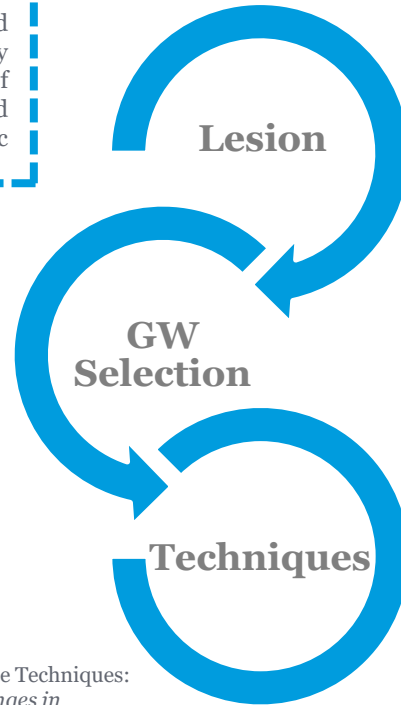


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A combination of guide wire escalation strategies and techniques are often used for effectively crossing complex lesions

The **LESION** being treated defines crossing and treatment options. Classification is influenced by factors such as: location, lesion morphology, level of calcification, lesion length, quality of inflow and outflow vessels, etc

GUIDE WIRE SELECTION is influenced by performance characteristics needed, such as steerability, trackability, pushability, crossability, visibility, durability, tip load, penetration power, and tactile feedback



TECHNIQUES¹





In crossing stenosed lesions, strategy is to avoid dissections. Navigation workhorse wires are commonly used to cross stenosed lesions

In crossing occluded lesions, strategies include:

- Cross through true lumen using different wires and techniques:
 - **Specialty wires** for **drilling and sliding** techniques
 - **Penetration wires** for **penetration and tapping** techniques
- Cross subintimally
 - **Workhorse** wires that prolapse

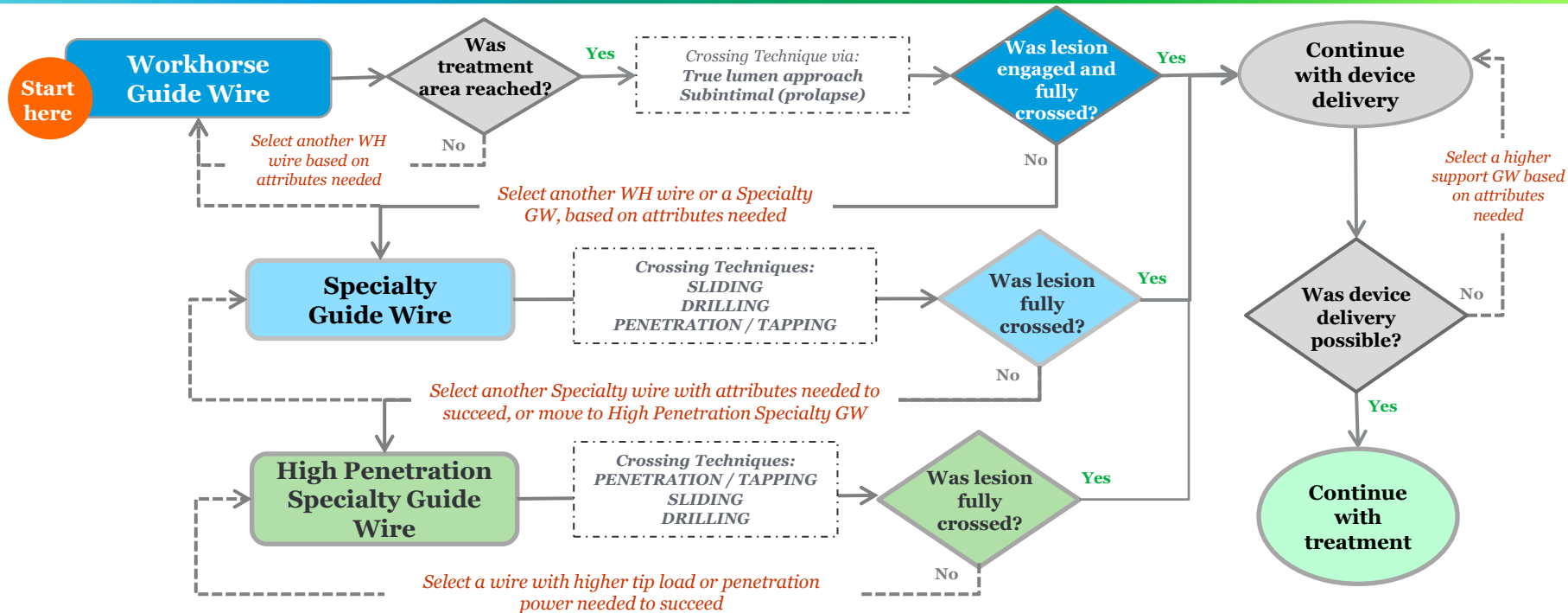
1. Brandao D, Ferreria J, and Masnilha A, et al. Below the Knee Techniques: Now and Then. *Angioplasty, Various Techniques and Challenges in Treatment of Congenital and Acquired Vascular Stenoses*. (41-62)

Guide Wire Techniques and Selection for Crossing Complex Lesions

				
Technique	Drilling (True Lumen)	Sliding (True Lumen)	Penetration / Tapping (True Lumen)	Subintimal Dissection (Subintimal)
Definition	Short oscillating rotations while modestly pushing against lesion to cross	Slide through microchannels to cross lesion	Direct forward probing and tapping to cross lesion	Prolapse guidewire into tight loop and cross through subintimal plane
Goal	Directional control	Slide through	Spear through	Alternate path
Wire Type	Specialty, Workhorse	Specialty, Workhorse	Penetration	Workhorse
Desirable GW characteristics	<p>Small tip bend for tip control and navigation</p> <p>Ability to engage lesion</p> <p>Bare coils for good tactile feedback</p> <p>Tip stability, tip durability, tip does not easily loop</p> <p>High tip load compared to workhorse wires</p>	<p>Hydrophilic polymer jacket for lubricity</p> <p>Straight or shapeable tip (long tip bend)</p> <p>Steerable</p>	<p>Straight, tapered tip</p> <p>Higher tip loads</p> <p>High penetration power</p> <p>High body support for pushability</p>	<p>Ability to prolapse into tight loop for controlled dissection</p> <p>Able to recover from tight loop during prolapse</p> <p>Shapeable and durable tip</p> <p>Hydrophilic guidewire for lubricity</p> <p>Intermediate or stiff body for support and pushability</p>

Source: Brandao D, Ferreria J, and Masnilha A, et al. Below the Knee Techniques: Now and Then. *Angioplasty, Various Techniques and Challenges in Treatment of Congenital and Acquired Vascular Stenoses*. (41-62)

A Guide Wire Escalation Strategy for Crossing Complex Lesions

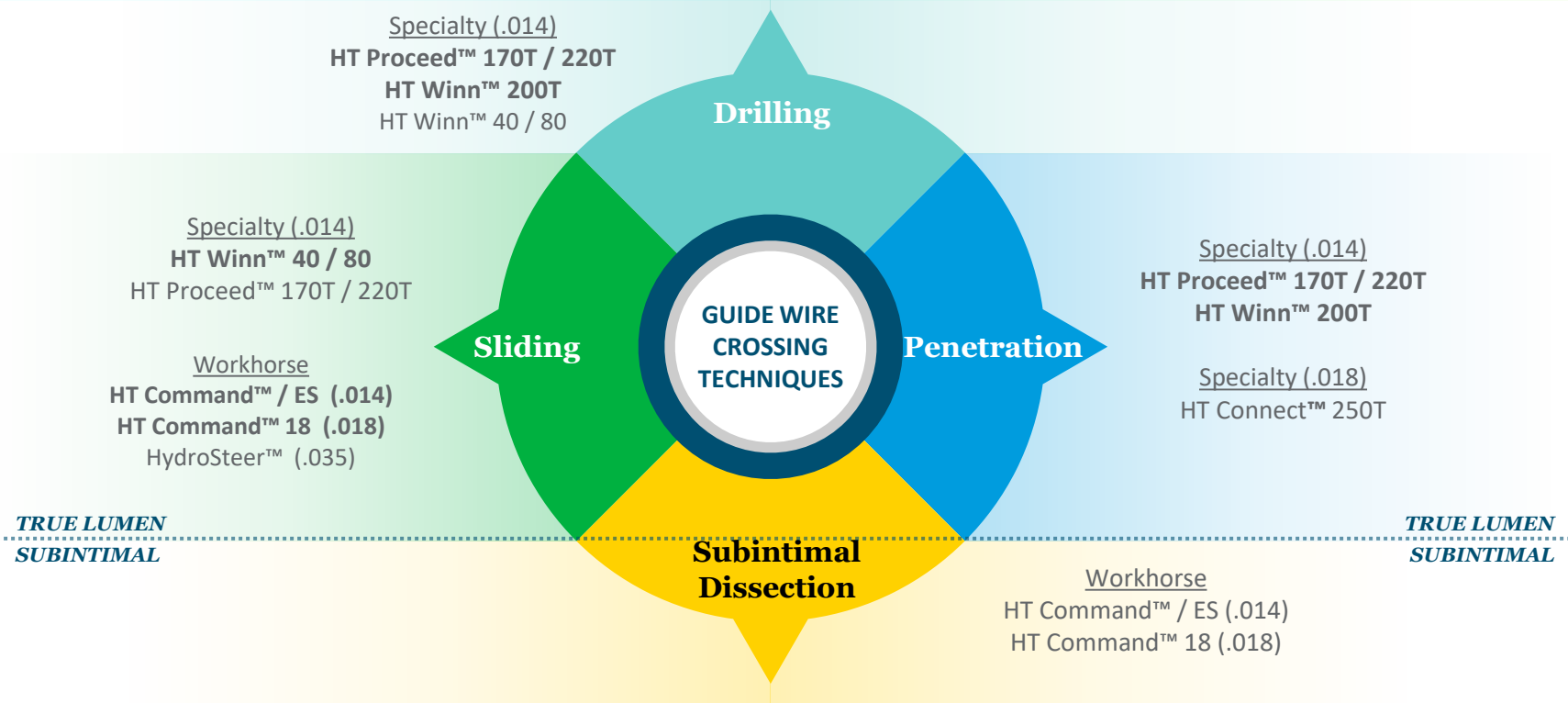


Note: GW Escalation Strategy based on guide wire design and crossing techniques used during lower limb interventions. Support devices may be used to facilitate crossing techniques. Assume crossing lesion in proximal to distal approach.

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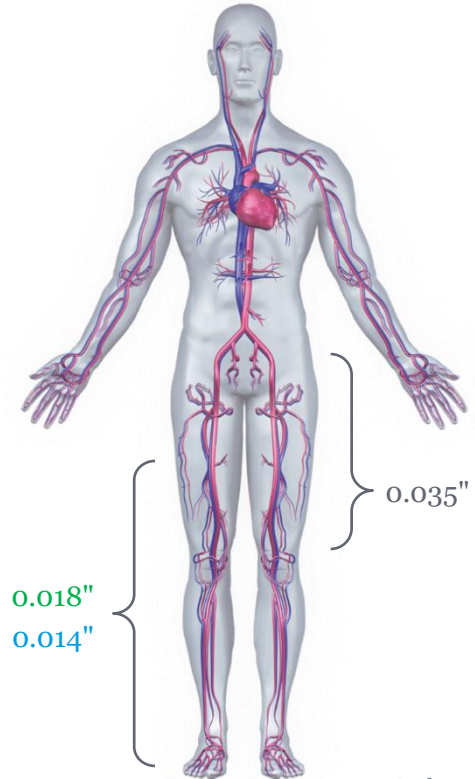
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Crossing Techniques and Abbott Workhorse and Specialty Wires Commonly Used



Abbott Provides Complete Toolbox of Guide Wires for Above/Below Knee Endovascular Interventions

Platform	Category	Brand
0.035"	Access	GuideRight™
	Navigation Workhorse	HydroSteer™
	Supportive Delivery	Hi-Torque Supra Core™
0.018"	Navigation Workhorse	Hi-Torque Command™ 18 LT Hi-Torque Connect™ Flex
	Supportive Workhorse	Hi-Torque Command™ 18 ST Hi-Torque Connect™
	Supportive Delivery	Hi-Torque Steelcore™ Hi-Torque Steelcore™ LT
	Specialty	Hi-Torque Connect 250T™
	Navigation Workhorse	Hi-Torque Command™
	Supportive Workhorse	Hi-Torque Command™ ES
0.014"	Supportive Delivery	Hi-Torque Spartacore™
	Specialty	Hi-Torque Proceed™ 170T Hi-Torque Proceed™ 200T Hi-Torque Winn™ 40 Hi-Torque Winn™ 80 Hi-Torque Winn™ 200T



Hi-Torque Proceed™ Guide Wire Product Matrix

ORDERING
INFORMATION

Product	CE Part Number	Length	Tip Load ¹
Hi-Torque Proceed™ 170T, Angled	1030901	190 cm	11 g
Hi-Torque Proceed™ 170T, Angled	1030902	300 cm	11 g
Hi-Torque Proceed™ 220T, Angled	1030903	190 cm	14 g
Hi-Torque Proceed™ 220T, Angled	1030904	300 cm	14 g

Quantity: Sold in boxes of 5 each

Shelf life: 24 months

Data on file at Abbott.

1. Test(s) performed by and data on file at Abbott.

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Appendix: Hi-Torque Proceed™ Guide Wire vs. Other .014 Specialty Wires

Company	Abbott		Asahi				BSX	Cook
Product	HT Proceed™ 170T, HT Proceed™ 220T ^{1,2}	HT Winn™ 40, HT Winn™ 80, HT Winn™ 200T ^{1,2}	Halberd ^{2, 3,4}	Astato [†] XS 20 / XS 40 ^{† 2,3,4}	Confianza Pro [†] / Pro 12 ^{† 2,5}	Gaia PV [‡] (0.18" wire) ^{2,3,4}	Victory 14 [‡] (12g, 18g) ^{2,6}	Approach CTO [‡] (12g, 18g) ^{2, 7, 8}
Positioning	Complex lesion w calcification	Complex lesion*	Complex lesion	Highly calcified	Complex lesion w calcification	Complex lesion	Calcified lesions	unknown
Tip Shape	Angled, 1mm at 25°	Straight	Straight, mini-preshape	Straight	Straight	Straight, mini-preshape	Straight	Straight
Tip Diameter (in)	0.009	0.012, 0.012, 0.009	0.013	0.010, 0.009	0.009	0.014	0.013	0.013
Tip Design	Tapered, Micro-textured Tip	Tapered	Micro-cone	Tapered	Tapered	Micro-cone, Tapered	Straight	Straight
Tip Coating	Uncoated tip	Uncoated tip	Uncoated ball tip	Uncoated ball tip	Hydrophobic	Uncoated ball tip	Hydrophilic	unknown
Tip Load (g)	11, 14	5, 11, 14	17	26, 40	10, 14	10	13, 19	15, 22
Penetration Power (kg/in ²)	167, 224	45, 100, 224	123	353, unknown	157, 214	64	92, 136	110, 164
Cover/Coils	Bare coils	5 mm exposed tip; distal polymer	Bare coils	Bare coils	Bare coils	Bare coils	Polymer sleeve	unknown
Core Design	Transitionless core grind	Transitionless core grind	Composite Core	Conventional Core	Conventional Core	Composite Core	Conventional Core	unknown
Coating Type	Hydrophilic	Hydrophilic	Hydrophilic	Hydrophilic	Hydrophilic	Hydrophilic	Hydrophilic	PTFE
Material	DURASTEEL Stainless Steel	DURASTEEL Stainless Steel	Stainless Steel	Stainless Steel	unknown	Stainless Steel	Stainless Steel	Stainless Steel
Radiopaque Coil Length (cm)	3 cm	3 cm	5 cm	17 cm	20 cm	15 cm	unknown	unknown
Wire Lengths (cm)	190, 300	190, 300	200, 235, 300	180, 300 / 200, 300	180, 300	200, 235, 300	190, 300	135, 190, 300

*HT Winn™ 40, HT Winn™ 80, and HT Winn™ 200T are used as part of guide wire escalation strategies. 1,3,4,5,6,7,8 Data on file at Abbott; 2. Test(s) performed by and data on file at Abbott. See slide 22 for References.

Guide Wire Competitive Comparisons

Tip Load & Penetration Power^{1,2}

Guide Wire	Company	Avg. Tip Load (g)	Avg. Tip Diameter (inch)	Avg. Penetration Power (kg/in ²)*
Astato XS [‡] 20	Asahi	26	0.010	353
Hi-Torque Proceed™ 220T	Abbott	14	0.009	224
Hi-Torque Winn™ 200T	Abbott	14	0.009	224
Confianza [‡] Pro 12	Asahi	14	0.009	214
Hi-Torque Proceed™ 170T	Abbott	11	0.009	167
Approach CTO [‡] (Tip Load 18 g)	COOK Medical	22	0.013	164
Confianza [‡] Pro	Asahi	10	0.009	157
Victory 14 [‡] (Tip Load 18 g)	Boston Scientific	19	0.013	136
Halberd [‡]	Asahi	17	0.013	123
Approach CTO [‡] (Tip Load 12 g)	COOK Medical	15	0.013	110
Hi-Torque Winn™ 80	Abbott	11	0.012	100
Victory 14 [‡] (Tip Load 12 g)	Boston Scientific	13	0.013	92
Gaia PV [‡]	Asahi	10	0.014	64
Hi Torque Winn™ 40	Abbott	5	0.012	45

* Table ranked by highest penetration power.

1. Test(s) performed by and data on file at Abbott; 2. Data on file at Abbott

Slide 20

1. Data on file at Abbott.
2. Test(s) performed by and data on file at Abbott.
3. Endovascular Today U.S. Product Guide <https://evtoday.com/device-guide/us/hydrophilic-guidewires>, Accessed January 30, 2021
4. Asahi Peripheral Guide Wire brochure
5. Asahi product website <http://www.asahi-intecc.co.jp/en/medical/pci/others.html>, accessed November 25, 2020
6. Boston Scientific website <https://www.bostonscientific.com/en-US/products/guidewires/victory-guidewire.html>, accessed November 25, 2020
7. Cook Medical website https://www.cookmedical.com/products/di_cmwcto_webds/, accessed November 25, 2020.
8. Endovascular Today Product Guide – Mandril Specialty Guide Wires, <https://evtoday.com/device-guide/us/mandrilspecialty-guidewires>, Accessed January 29, 2021

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