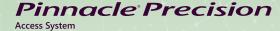
Pinnacle Precision Access System

SMOOTH VASCULAR ACCESS

COMPARATIVE BENCH TOP RESULTS







Pinnacle Precision Access System

THE STANDARD

FOR SMOOTH VASCULAR ACCESS

Bench top testing of PINNACLE PRECISION

Access System Sheath compared to Cook® Medical

Check-Flo® Performer® Introducer Set.

Results show PINNACLE PRECISION Access System Sheath provides superior performance

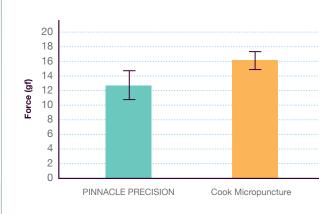
- Needle Penetration Force
- Transition from Guidewire-to-Dilator and Dilator-to-Sheath
- Guidewire Rail Strength
- Sheath Strength Test
- Sheath Penetration Force

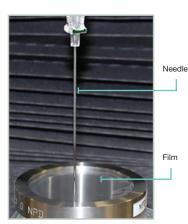
NEEDLE PENETRATION FORCE

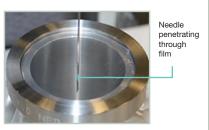
Test Protocol

Needle penetration was measured by the amount of force it took for the needle to penetrate through a 50-micron polyethylene film.

Needle Penetration Force







CONCLUSION

The PINNACLE PRECISION needle technology requires less penetration force compared to the competitive needle.

PINNACLE PRECISION

Cook Micropuncture

Top View



Side View



Bottom View





Construction

The PINNACLE PRECISION needle features:

- Tapered transition from 21G tip to 19G shaft to provide stability upon insertion
- Back bevel cuts on the tip of the needle help facilitate a straighter entry

Clinical Benefit

PINNACLE PRECISION provides access with less force designed to provide a sharper more precise entry through the skin.

Pinnacle Precision

Access System



TRANSITIONS FROM GUIDEWIRE-TO-DILATOR AND DILATOR-TO-SHEATH

Test Protocol

The sheath transition test measured the gap between the distal tip of the sheath and the dilator by bending the sheath at a 45 degree angle with a 7.5mm radius curve.

PINNACLE PRECISION

Guidewire-to-Dilator Transition

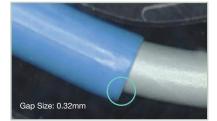


Cook Micropuncture



Dilator-to-Sheath Transition



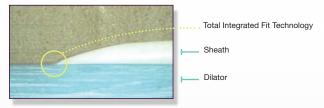


CONCLUSION

PINNACLE PRECISION sheaths have Total Integrated Fit technology which offers a smoother transition between guidewire-to-dilator and dilator-to-sheath providing smaller gaps between transitions.

PINNACLE PRECISION

Cross Sectional Magnified View



Cook Micropuncture

Cross Sectional Magnified View



Construction

PINNACLE PRECISION
Total Integrated Fit tapered sheath technology features a seamless transition between the dilator and sheath.

Clinical Benefit

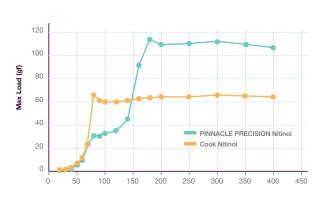
PINNACLE PRECISION smooth transitions help to reduce the risk of gaps and sharp edges catching on tissue and damaging artery walls upon sheath entry, advancement or removal.

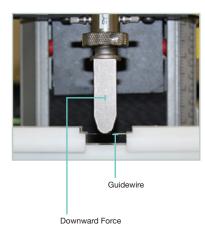
GUIDEWIRE RAIL STRENGTH

Test Protocol

The rail strength of the starter guidewire was measured by testing the stiffness at 18 different points along the guidewire starting at the distal floppy tip down to the back end.

Guidewire Rigidity

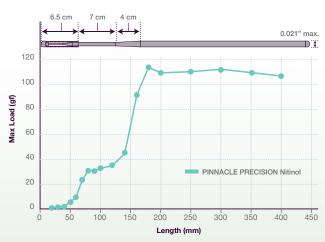




CONCLUSION

PINNACLE PRECISION starter guidewire has a floppy distal tip which progressively gets stronger towards the proximal end resulting in greater rail strength of the guidewire.

Guidewire Rigidity



6.5 cm - Floppy Palladium Coil with Tapered Nitinol Core

7.0 cm - Uniform Nitinol Core

4.0 cm - Tapered Nitinol Core

Construction

The PINNACLE PRECISION 0.021" guidewire features:

- Floppy 6.5cm taper on the distal tip which is designed to enhance trackability and visibility
- Solid Nitinol back end to provide a strong rail for the sheath to track over

Clinical Benefit

PINNACLE PRECISION has the only 0.021" wire on market which provides greater rail strength to help reduce the risk of buckling through scarred or calcified arteries.

Pinnacle Precision

SHEATH STRENGTH TEST

Test Protocol

The sheath strength test measured the flexural strength of the introducer sheath tube construction without the dilator by recording the amount of force required to bend the sheath in a three point bending test set-up.

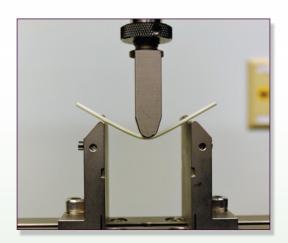
Sheath Strength Test





CONCLUSION

PINNACLE PRECISION has a higher sheath tube bending strength than the competitive sheaths.



Construction

PINNACLE PRECISION kink resistant material and design helps to maintain lumen patency throughout the procedure.

Clinical Benefit

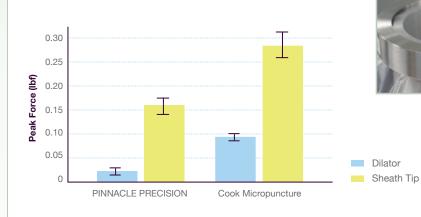
PINNACLE PRECISION Sheaths are designed for difficult insertion through calcified or scarred arteries to provide smooth and reliable vascular access.

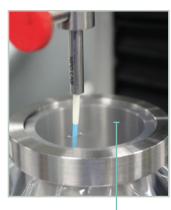
SHEATH PENETRATION FORCE

Test Protocol

The sheath penetration test measured the amount of force needed for the dilator and sheath to penetrate a 50-micron polyethylene film. The sheaths were tracking over the starter guidewire that are provided in the respective kits.

Penetration Force





Polyethylene film

CONCLUSION

Competitive sheath requires 77% higher insertion force to penetrate through the polyethylene film than PINNACLE PRECISION.



Construction

PINNACLE PRECISION has a combination of features which enable smooth and reliable vascular access that include:

- Greater rail strength with 0.021" starter guidewire
- Total Integrated Fit tapered sheath technology which is designed to provide smooth transitions from guidewire-to-dilator and dilator-to-sheath

Clinical Benefit

PINNACLE PRECISION provides access with less force retaining a smooth dilator-to-sheath transition with less risk of damage to the sheath upon penetration.

PUSHING BOUNDARIES

Terumo Interventional Systems is committed to your success with innovative procedural solutions and ongoing support for your most challenging cases.

We are relentlessly seeking new ways to help you apply effective solutions and achieve better outcomes for more patients.



PINNACLE PRECISION Access System includes:

Sheath length, 10cm | Wire length, 43cm (Nitinol), 45cm (Stainless Steel) | Tapered needle gauge, 21G/19G | 10 per shelf box

CODE	SHEATH SIZE (Fr)		NEEDLE
70-4160	4	Nitinol	Echogenic
70-4130	4	Stainless Steel	Echogenic
70-5160	5	Nitinol	Echogenic
70-5130	5	Stainless Steel	Echogenic
70-6160	6	Nitinol	Echogenic
70-6130	6	Stainless Steel	Echogenic
70-7160	7	Nitinol	Echogenic
70-7130	7	Stainless Steel	Echogenic
70-8160	8	Nitinol	Echogenic
70-8130	8	Stainless Steel	Echogenic
70-4165	4 Stiff*	Nitinol	Echogenic
70-4135	4 Stiff*	Stainless Steel	Echogenic
70-5165	5 Stiff*	Nitinol	Echogenic
70-5135	5 Stiff*	Stainless Steel	Echogenic

*Includes a stiff dilator for greater pushability.

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

References:

Data on file at Terumo: 20170018

Note: Bench testing results may not be indicative of clinical performance.

