Pilar CACI 2023

XXXIII CONGRESO NACIONAL

SIPROTEC

SISTEMA INTEGRAL DE PROVISIÓN DE PRÓTESIS

XXIII Congreso Nacional CACI 24 de noviembre 2023.

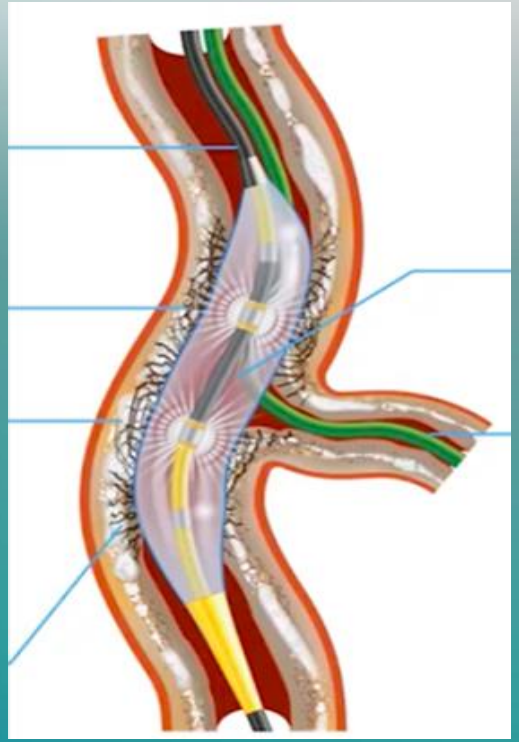
Lic. Palacios Francisco

Compatible con guia 0,014”

Terapia ”selectiva”

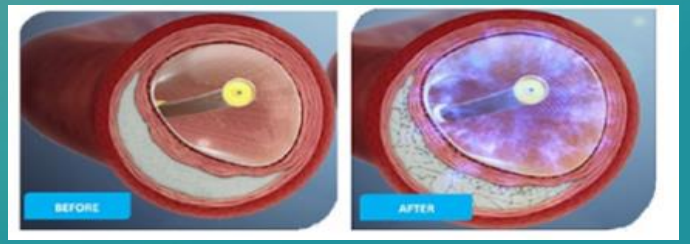
Atraviesa el tejido para llegar al calcio medial

El calcio fracturado permanece dentro de la pared del vaso, lo que disminuye el riesgo de embolización



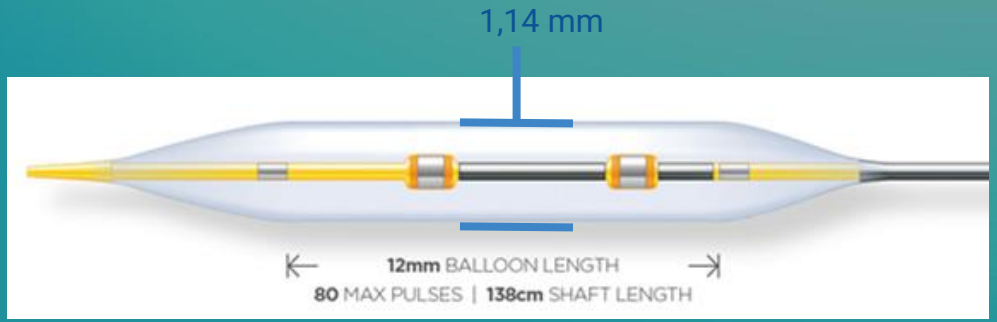
El balón se infla a bajas atm, lo que minimiza el riesgo de daño arterial debido a las altas presiones

Permite colocar un guia de proteccion para el vaso lateral



SHOCKWAVE C²

Diameter (mm)	Length (mm)	Max Pulse Count	Guidewire Compatibility (in)	Guide Catheter Compatibility	Working Length (cm)	Crossing Profile Range* (in)
2.5	12	80	0.014"	6F	138	0.044 +/- 0.002
3.0						
3.5						
4.0						



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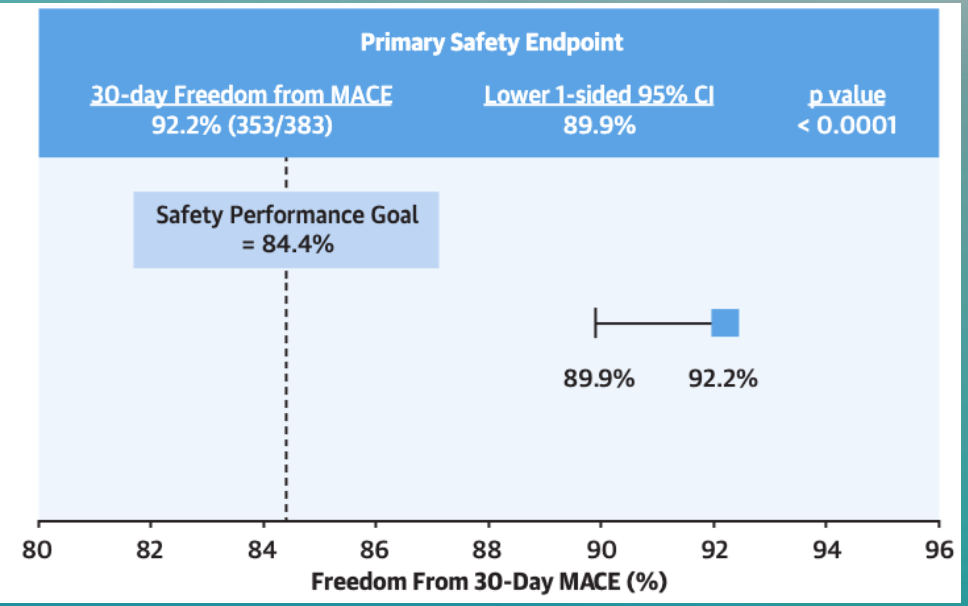
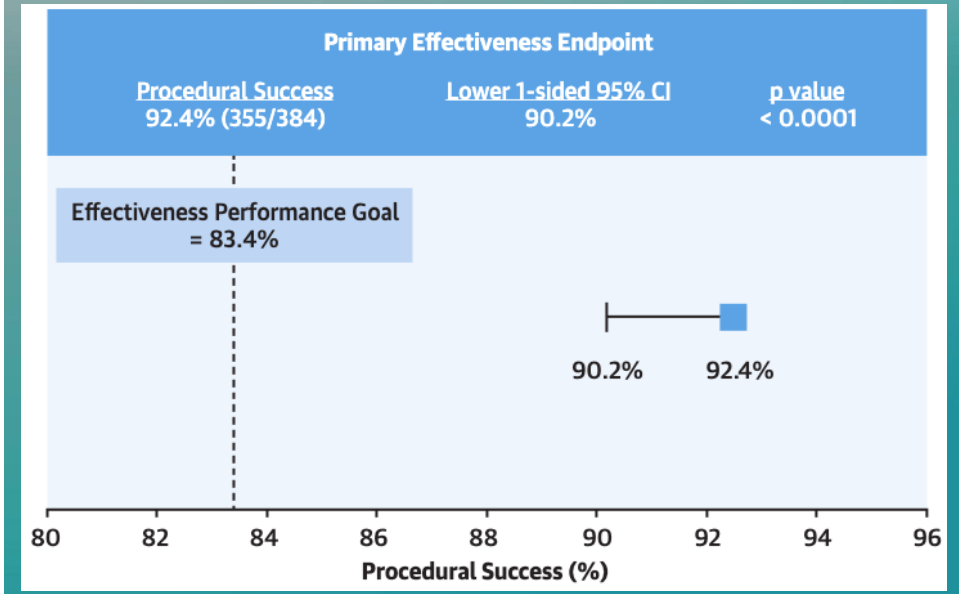
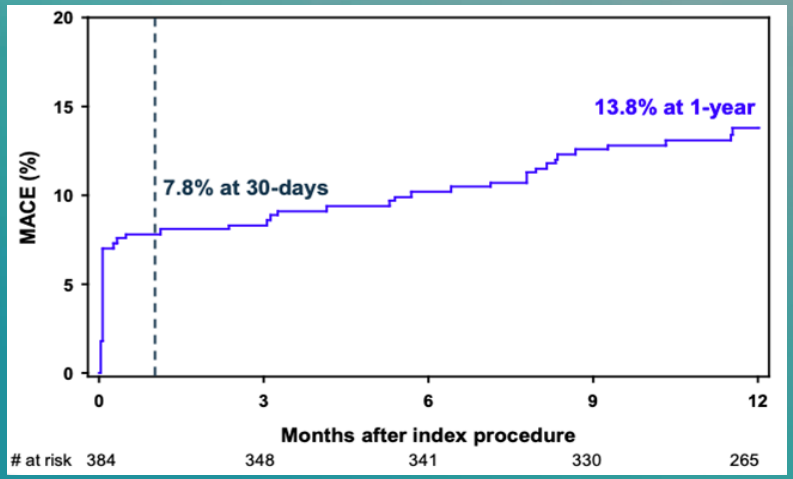
CAD III…. Resultados

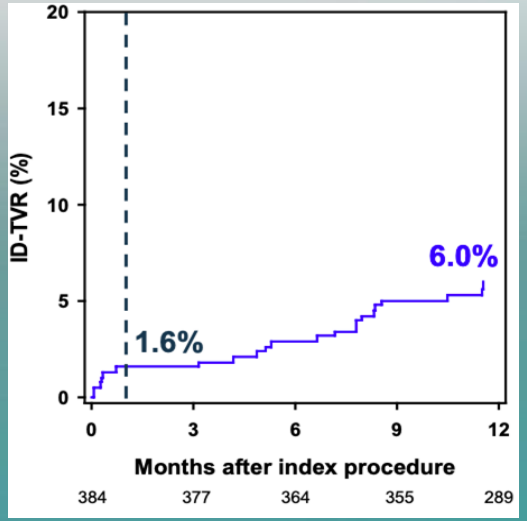
30 días

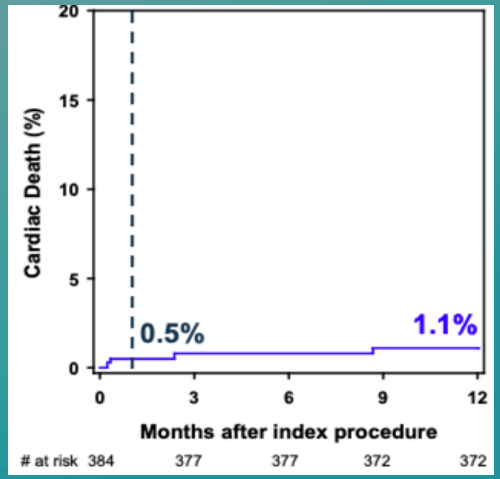




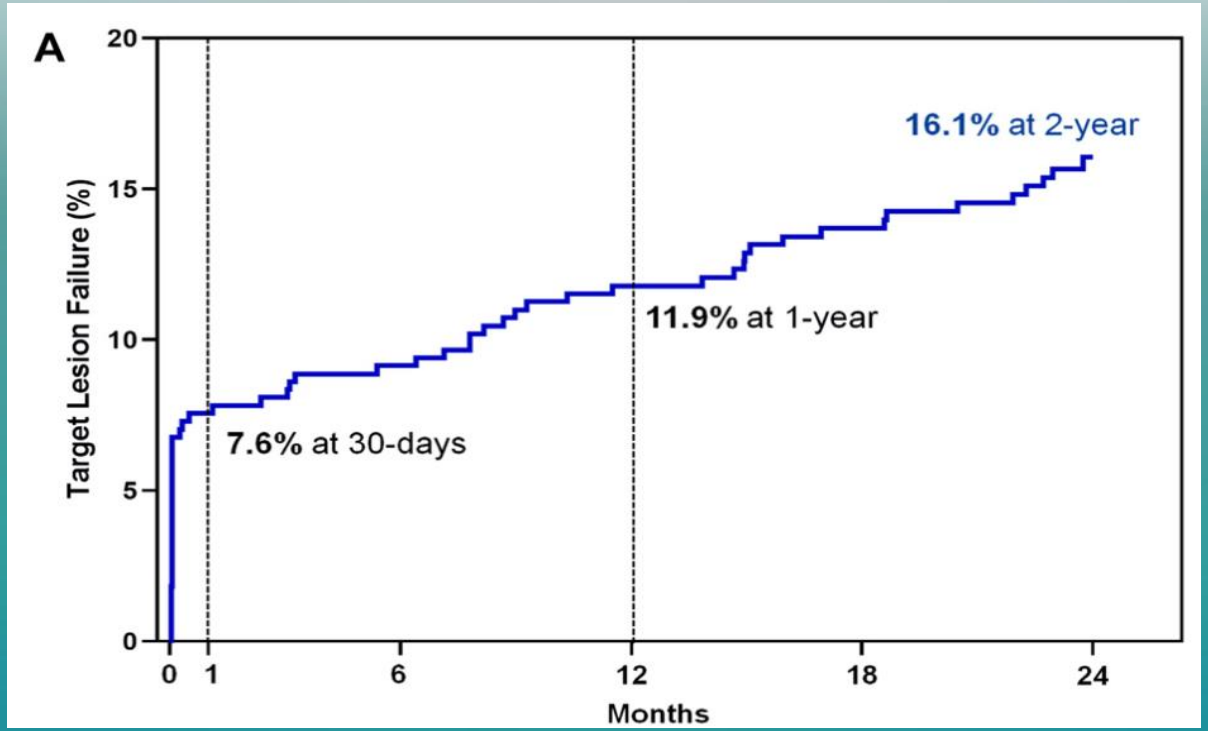
1 año

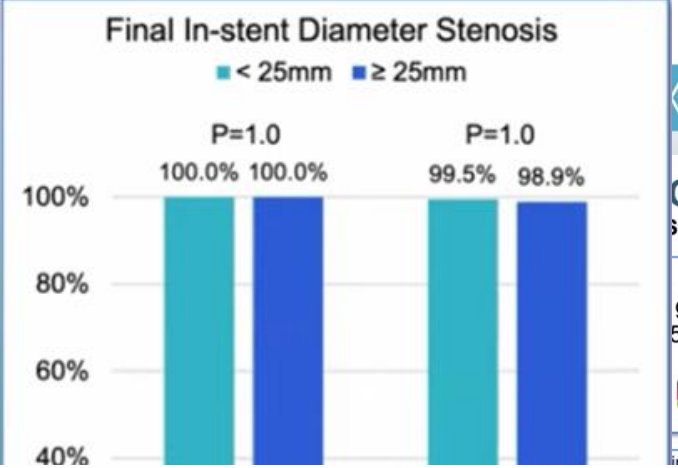

MACE (%)
20
15
10
5
0
7.8% at 30-days
13.8% at 1-year
0
3
6
9
12
Months after index procedure
at risk 384 348 341 330 265

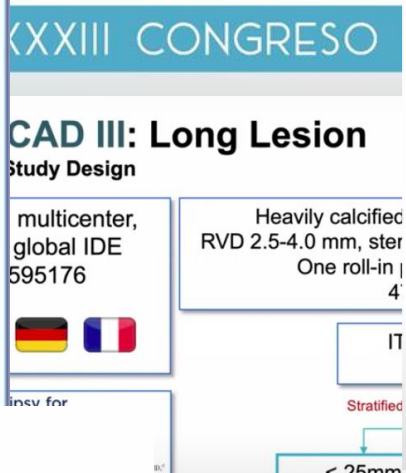

ID-TVR (%)
20
15
10
5
0
1.6%
6.0%
0
3
6
9
12
Months after index procedure
384 377 364 355 289

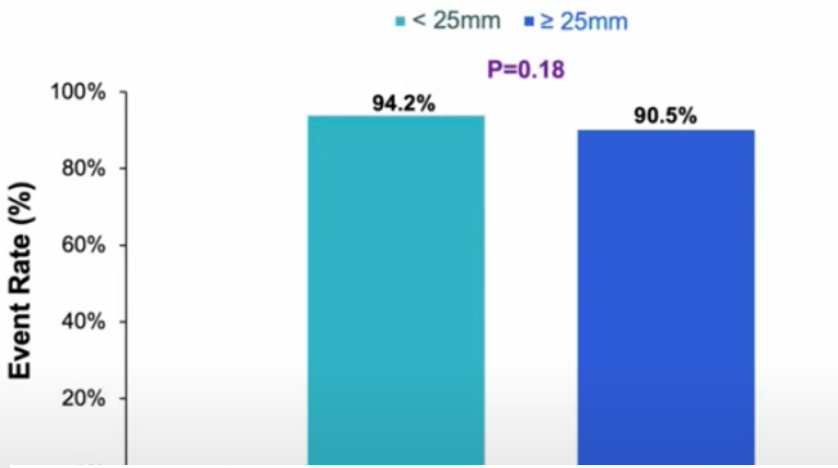

Cardiac Death (%)
20
15
10
5
0
0.5%
1.1%
0
3
6
9
12
Months after index procedure
at risk 384 377 377 372 372

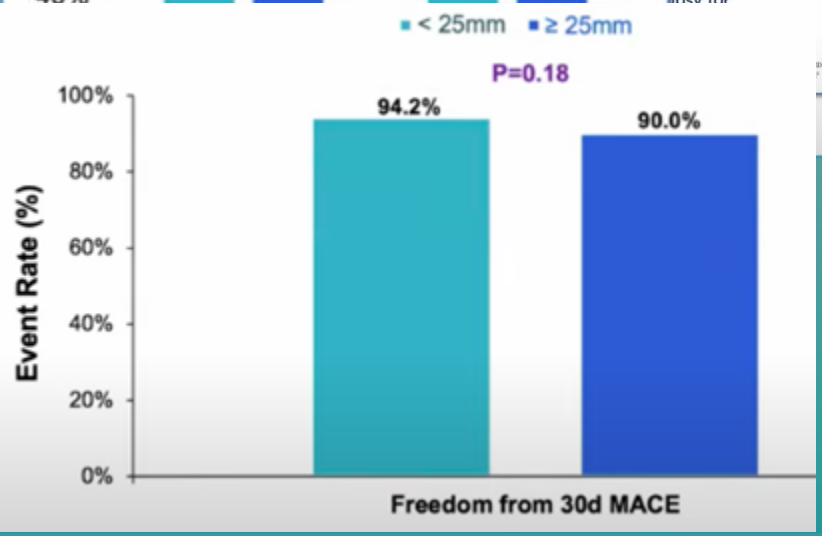
2 años

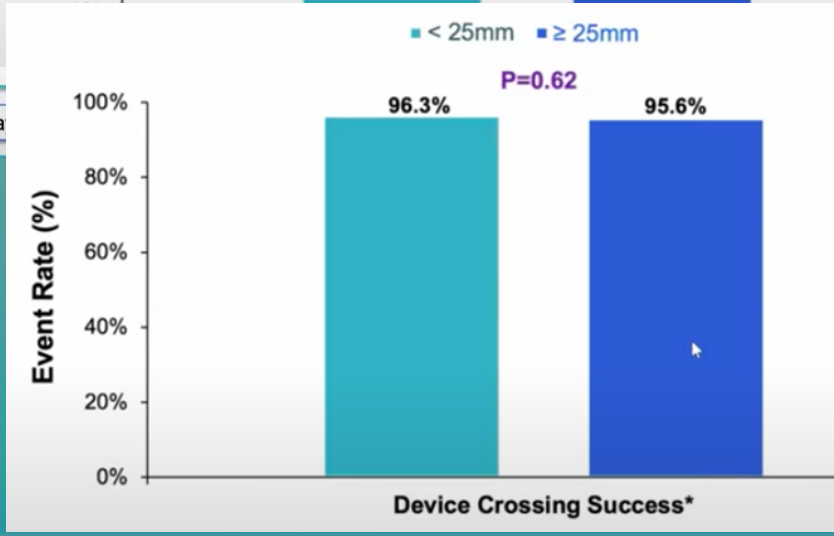

A
Target Lesion Failure (%)
20
15
10
5
0
16.1% at 2-year
11.9% at 1-year
7.6% at 30-days
0
1
6
12
18
24
Months


Final In-stent Diameter Stenosis
< 25mm
≥ 25mm
P=1.0
P=1.0
100.0%
100.0%
99.5%
98.9%
100%
80%
60%
40%


XXIII CONGRESO
CAD III: Long Lesion
Study Design
multicenter,
global IDE
595176
Heavily calcified
RVD 2.5-4.0 mm, ster
One roll-in
Stratified
< 25mm
30-da


< 25mm
≥ 25mm
P=0.18
94.2%
90.5%
Event Rate (%)
100%
80%
60%
40%
20%


< 25mm
≥ 25mm
P=0.18
94.2%
90.0%
Event Rate (%)
100%
80%
60%
40%
20%
0%
Freedom from 30d MACE


< 25mm
≥ 25mm
P=0.62
96.3%
95.6%
Event Rate (%)
100%
80%
60%
40%
20%
0%
Device Crossing Success*

	C2	C2+
Longitud	12 mm	12 mm
Pulsos	80	120
Ciclos	8	12
Longitud de tratamiento	42 mm	62 mm
Cateter Guia Compatible	6 Fr	5 Fr
Funda Esteril	No	Si

SHOCKWAVE M5+

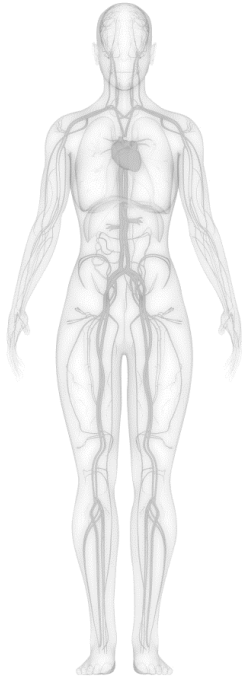
+ FASTER
Increase procedural efficiency with 50% quicker cycle time

+ FURTHER
Broaden access options with an increased catheter working length of 135cm

+ LARGER
Optimally treat larger diameter vessels with new 8.0mm size

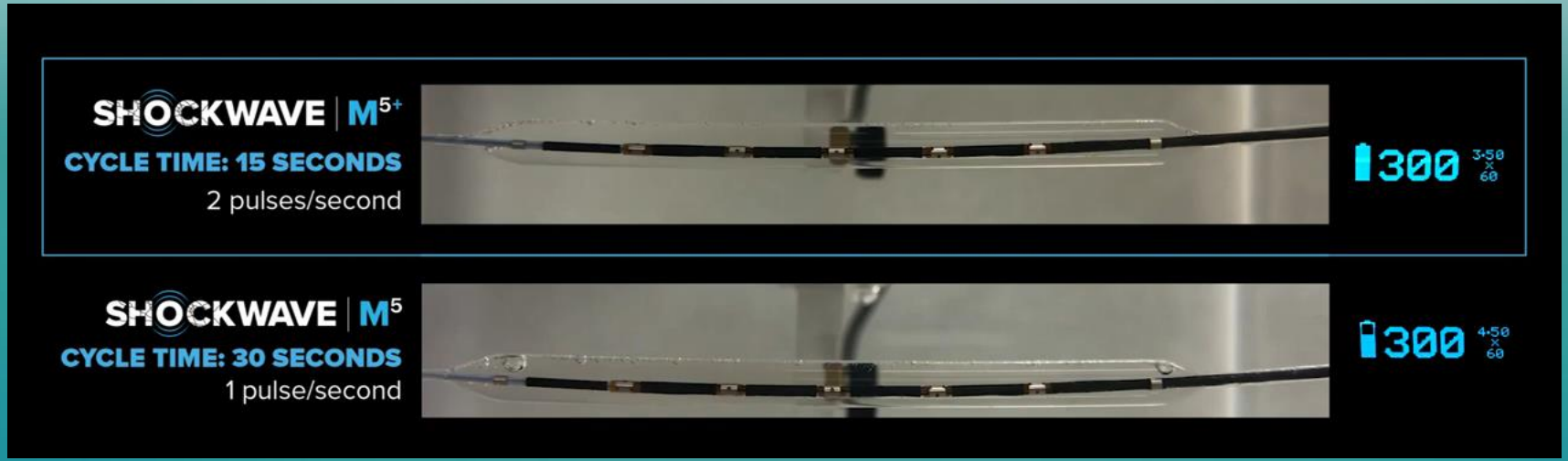
LONGITUD

Shaft de trabajo 135 cm



VELOCIDAD

2 pulsos/segundo



TAMAÑO

Nuevo tamaño de 8 mm de diámetro

Balloon Diameter (mm)	Balloon Length (mm)	Sheath Compatibility	Catheter Working Length	Pulses/ Cycle	Cycles	Pulses (Max)	Balloon Crossing Profile (in)
3.5	60	6F	135	30	10	300	.054
4.0	60	6F	135	30	10	300	.054
4.5	60	6F	135	30	10	300	.057
5.0	60	6F	135	30	10	300	.061
5.5	60	6F	135	30	10	300	.062
6.0	60	6F	135	30	10	300	.065
6.5	60	6F*	135	30	10	300	.066
7.0	60	6F*	135	30	10	300	.068
8.0	60	7F	135	30	10	300	.074

SHOCKWAVE | M5+

Característica	M5	M5+
Longitud	110 cm	135 cm
Pulsos	300	300
Velocidad	1 pulso/seg	2 pulsos/seg
Tamaños	3.5-7 mm	3.5-8 mm

Siprotec Technical Center

SIPROTEC

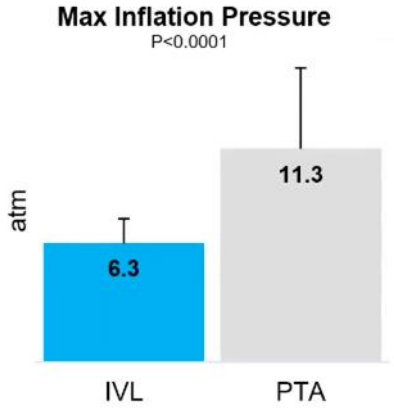
PAD III

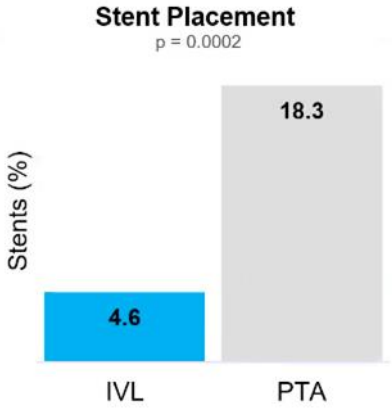
⬇ 40%
Lower pressure to achieve better results with IVL

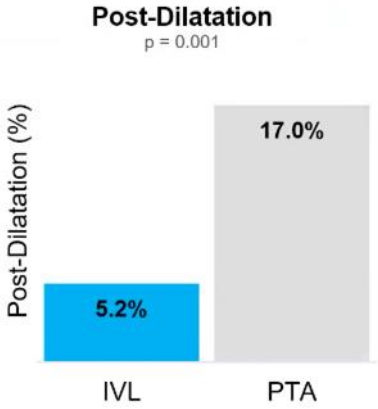
⬇ 75%
Reduction in provisional stent placement risk with IVL

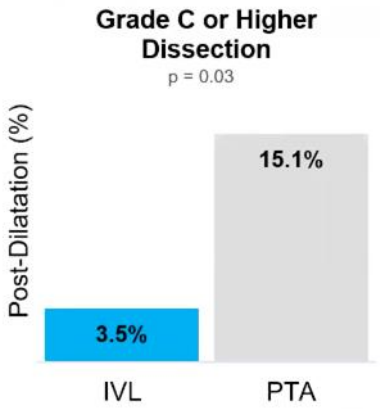
⬇ 69%
Reduction in need for post-dilatation with IVL

⬇ 77%
Reduction in Type ≥C Dissection with IVL

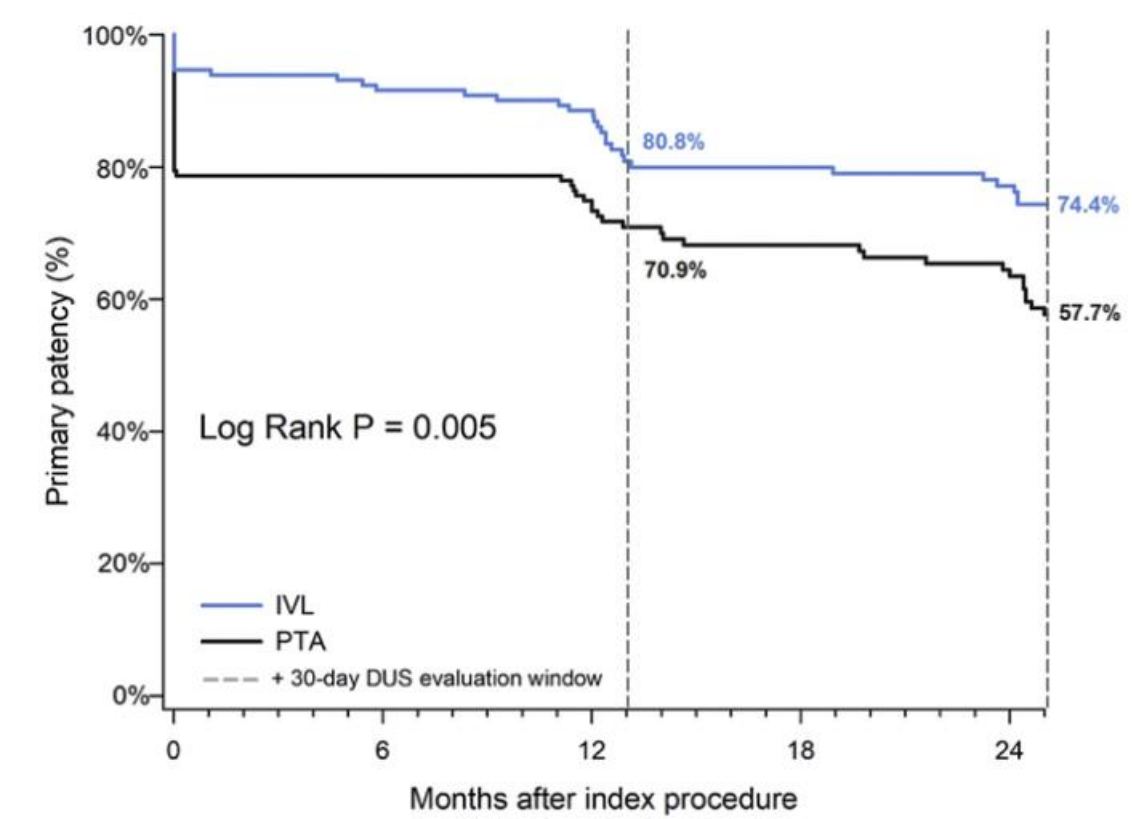






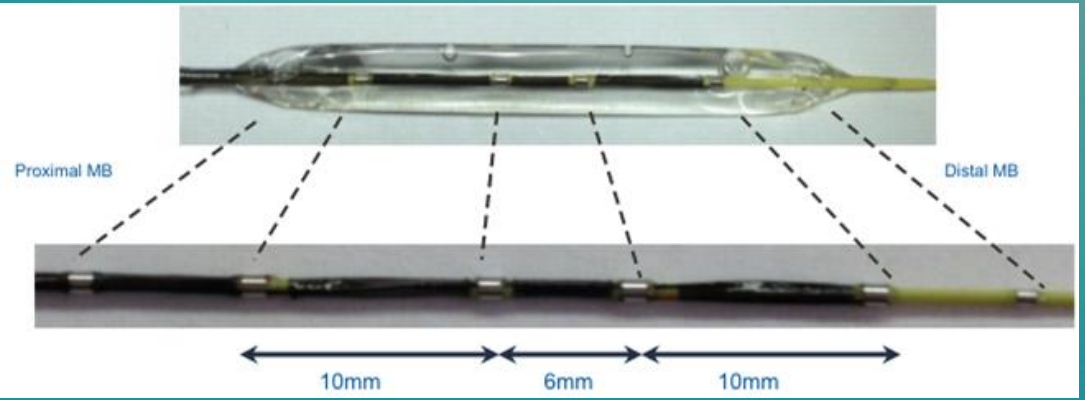


1 y 2 años


100%
80%
60%
40%
20%
0%
Primary patency (%)
80.8%
74.4%
70.9%
57.7%
Log Rank P = 0.005
IVL
PTA
+ 30-day DUS evaluation window
0
6
12
18
24
Months after index procedure

DIAMETER (mm)	LENGTH (mm)	GUIDEWIRE COMPAT. (in)	SHEATH COMPATIBILITY (in)	WORKING LENGTH (cm)	CROSSING PROFILE RANGE (in)	PULSES/CYCLE	PULSES (max)
2.5	40	0.014	5Fr	135	.048	20	160
3.0	40	0.014	5Fr	135	.048	20	160
3.5	40	0.014	5Fr	135	.048	20	160
4.0	40	0.014	5Fr	135	.050	20	160

S4



DISRUPT BTK

By The Numbers

20

Patients from 3 sites

100%

Moderately/severely calcified lesions

75%

Rutherford Category V

Compelling Safety & Performance

in Severely Calcified Lesions*

95%

Procedural Success

0%

Perforations, Embolization, Slow/No Reflow, Abrupt Closure

26%

Final residual Stenosis with an acute gain of 1.5mm

0%

Major adverse event at 30 days

100%

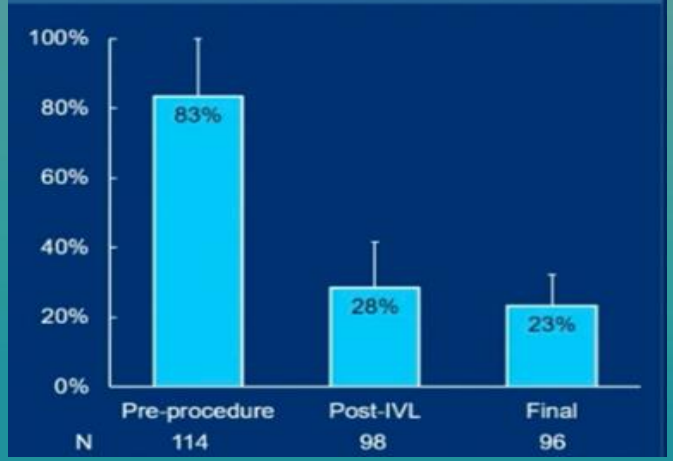
Freedom From CD TLR at 30 days

PAD III OS Sub-study:
IVL treatment of calcified infrapopliteal arteries

Heavily calcified *de novo* infrapopliteal lesions
IVL +/- adjunctive therapy*
July 2018 – Aug 2020
N = 101 patients; 114 BTK lesions; 15 global sites

Sub-study objective: Assess 'real world' peri-procedural outcomes of S[4] IVL treatment of calcified BTK lesions†

Diameter Stenosis*



Complications	Post-IVL N=98	Final N=96
Dissections D-F	3.1%†	0%
Perforation	0%	0%
Distal Emboli	1.0%	0%
Slow Flow/ No Reflow	0%	0%
Abrupt Closure	0%	0%

Ongoing….

DISRUPT BTK II

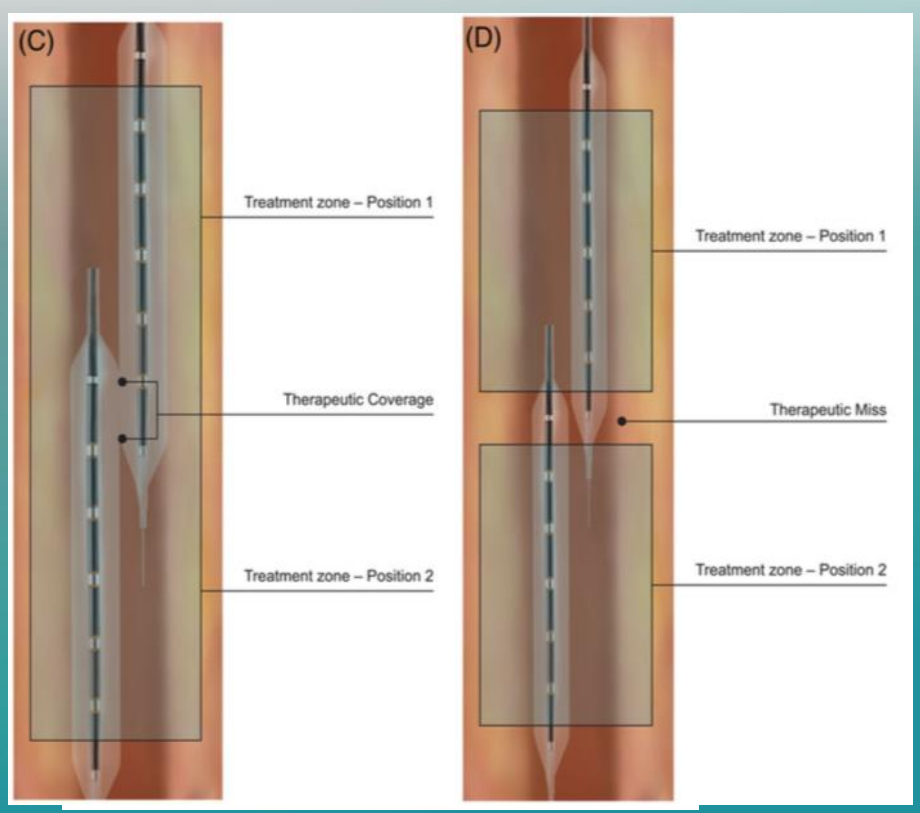
250 Patients

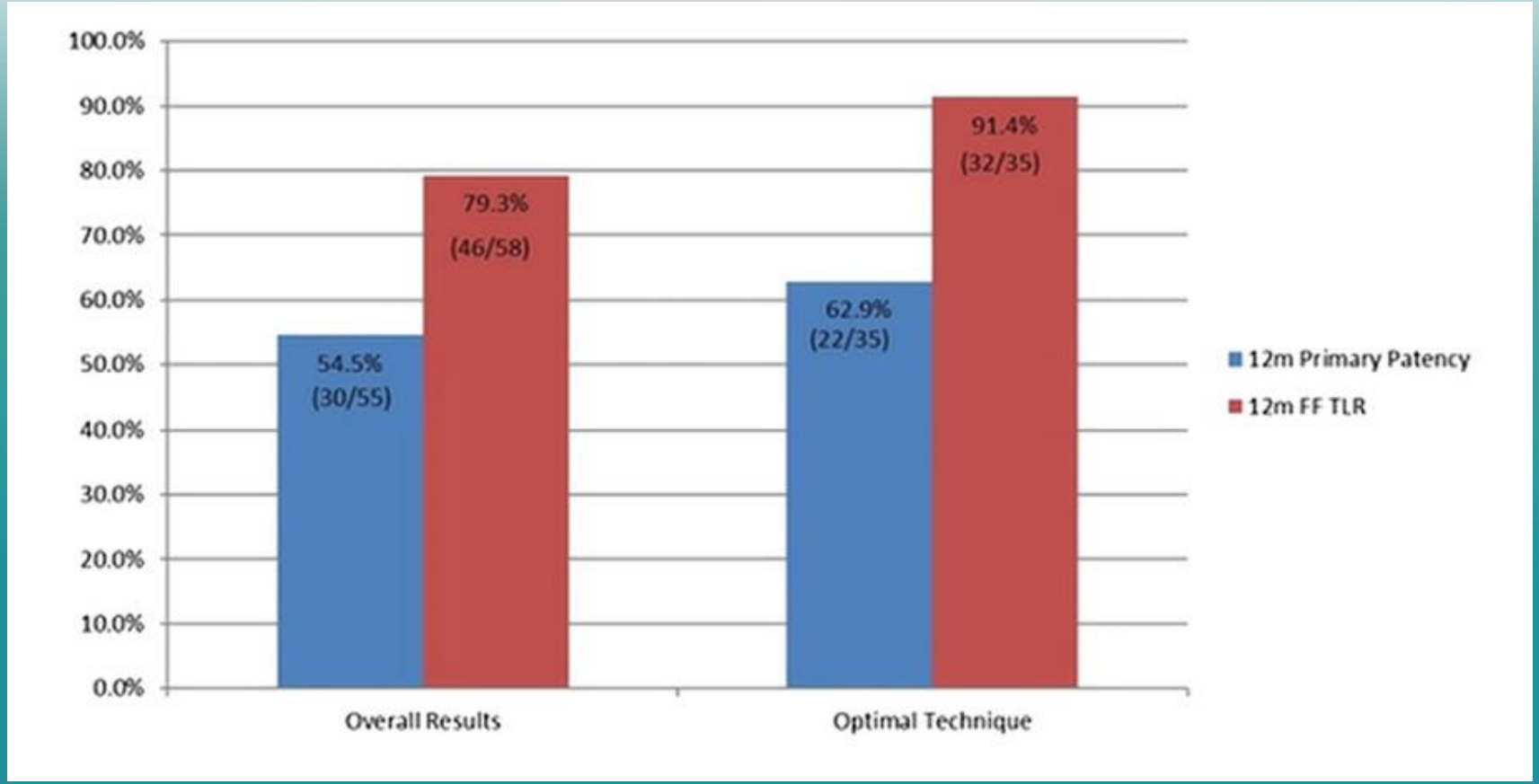
40 Global sites

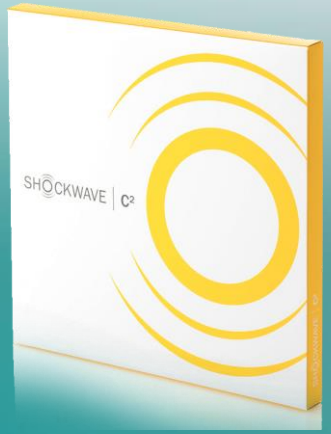
Lesion lengths up to **200mm**

Outcomes out to **2 Years**

TÉCNICA ÓPTIMA




100.0%
90.0%
80.0%
70.0%
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
54.5%
(30/55)
79.3%
(46/58)
62.9%
(22/35)
91.4%
(32/35)
Overall Results
Optimal Technique
12m Primary Patency
12m FF TLR



C2+
Coronario
120 pulsos
5 Fr
Rapid Exchange

M5+
Periférico Suprapatelar
300 pulsos
6 Fr/ 7 Fr
Over The Wire

S4
Periférico Infrapatelar
160 pulsos
5 Fr
Over The Wire

Take home message

- Shockwave es eficaz, seguro un tiene una curva de aprendizaje corta.
- Modifica el calcio profundo, reduciendo las probabilidades de recoil elástico temprano.
- Debido a su mecanismo de acción disminuye las probabilidades de no-reflow.
- IVL fue superior a la PTA en el éxito del procedimiento agudo y demostró un tratamiento atraumático:
  - Reducción en % de la estenosis del diámetro antes de la colocación del soporte de DCB
  - Baja presión máxima de inflado
  - Reducción de la frecuencia y gravedad de las disecciones
  - Tasa de dilatación e implantación de stent inferior
  - El FUP a 1 y 2 años mostraron superioridad en la permeabilidad de los vasos tratados.

¡MUCHAS GRACIAS!

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