TERUMO
INTERVENTIONAL
SYSTEMS

PUSHING BOUNDARIES

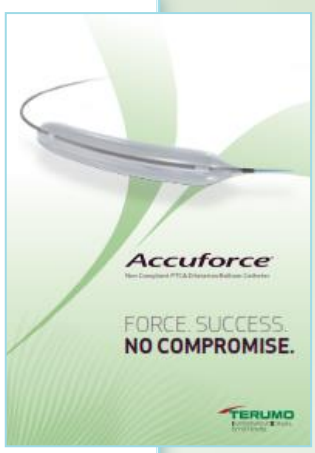
PTCA Balloons NC

Cardio Week II - PCI

- Hiryu
- **Accuforce**

Accuforce Program

- **Introduction**
- Technical Features
- Accessories
- Product Range
- Key Features & Clinical Benefits
- Competition



TERUMO INTERVENTIONAL SYSTEMS

Accuforce
Introduction - Technical

1 Indication

Deliverability (get to the lesion): Combination of …

- **Trackability:** Ability to 'track' over a guidewire and negotiate through curves
  - → Smooth guide wire to tip transition
  - → Shaft transitions & Tip Flexibility/Stiffness
  - → Balloon Material
  - → Coatings -> less interaction is better
- **Pushability:** Ability of the catheter to transmit force from the proximal to the distal end
  - → Shaft Material and Stiffness (transitions): especially in RX catheters
- **Crossability:** Ability to cross the lesion
  - → Tip profile & material
  - → Balloon (primary) profile, material & coatings

- **Recrossability:** Ability to cross the same or another lesion again after deflation
  - → Tip profile & material (durability)
  - → Balloon (secondary) profile, material & coatings

Accuforce
Introduction - Technical

2 Inflation Pressure

NP - Nominal Pressure

- Pressure required for inflation to indicated diameter

RBP - Rated burst pressure

- Rated burst pressure is a conclusion, based on the results of testing: We can say with 95% confidence that 99.9% of the balloons of a population will not burst at or below this pressure

BP - Burst pressure

- Pressure under which one specific balloon gets damaged (burst)

MBP - Mean Burst pressure

- Pressure (rated) under which 50% of the balloons get damaged (burst)

The range between the NP and the RBP is called the working range:

- Ex: For a balloon with NP 12 ATM & RBP 22 ATM
  = Working Range lies between 12 and 22 ATM

Accuforce
Introduction - Technical

3 Balloon Compliance

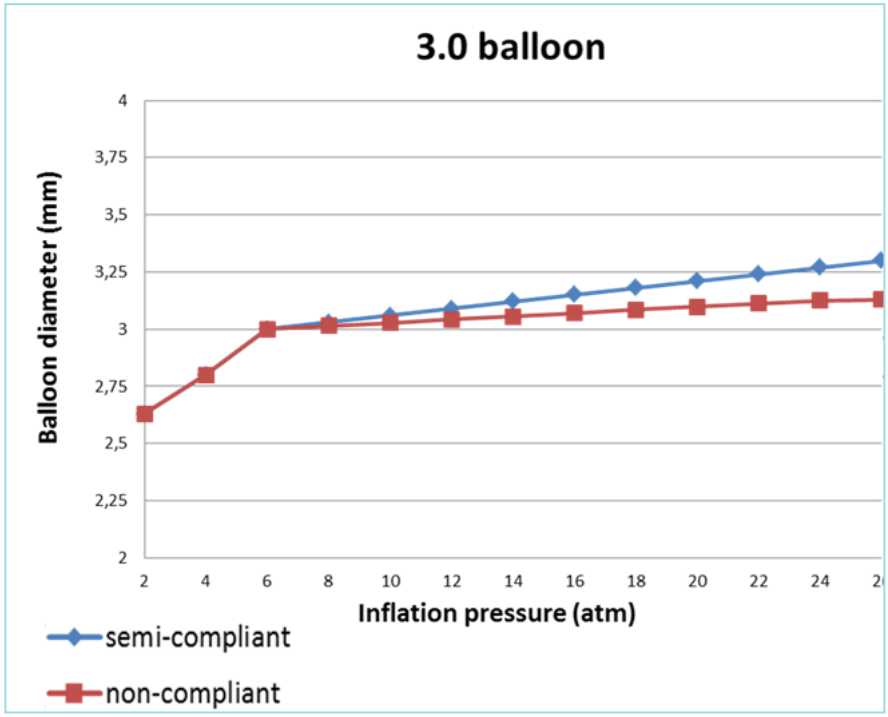
The relation between the pressure (ATM) and balloon growth (in diameter).

Semi- and controlled compliant balloons

- Characteristics between compliant and non-compliant. Growth will be > 5 % between NP (nominal pressure) and RBP (Rated burst pressure).

Non-compliant & low-compliant balloons

- Growth of balloon should be minimal, almost flat. It will stay < 5 % between NP (nominal pressure) and RBP (Rated burst pressure). Instead the balloon will get harder.

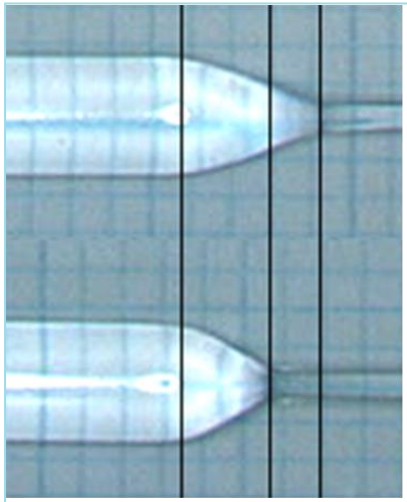


Note: Balloons tend to get more compliant with each inflation/deflation (wear and tare).

Accuforce
Introduction - Technical

4 Precise Dilatation

- **Short shoulders**



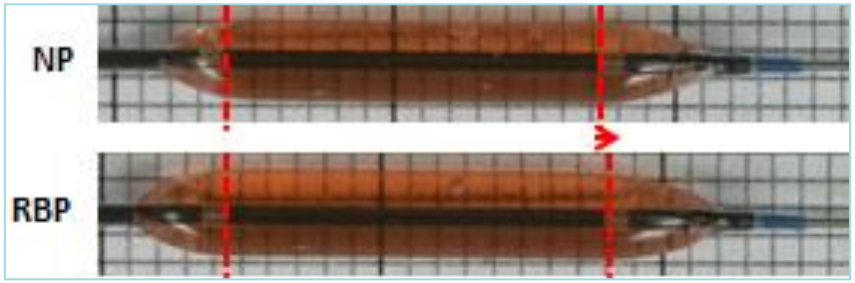
Long vs. Short Tapers

- Long tapers
  →Enhance deliverability
- Short tapers
  → Facilitate precise dilatation

(Goal: Minimal balloon outside treatment area for focal dilatations i.e. less balloon in contact with healthy tissue → benefit: minimizing vessel injury)

- **Minimal elongation (longitudinal growth):**

→ *Especially under high-pressure dilatation, it can induce over-dilation proximal and distal to the lesion and subsequently increase the risk of dissection or restenosis*



Accuforce
Introduction - IFU

5 Indications & contra-indications

INDICATIONS

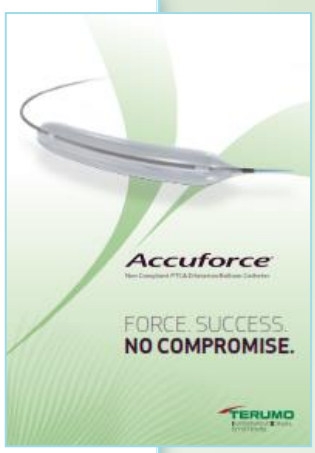
The Accuforce ("dilatation catheter") is intended to be used for percutaneous transluminal coronary angioplasty (PTCA) for the purpose of improving myocardial blood flow in the localized stenotic lesion of the coronary arteries.

CAUTIONS FOR USE

1. **Contraindications (patients/conditions in which PTCA must be avoided)**
   - Lesions in the left main trunk for which no compensation of blood flow by bypass or collateral circulation is available. Failure to observe this warning could result in acute coronary occlusion.
   - Patients who had previous coronary artery spasm due to the possibility of acute coronary occlusion.
   - Pregnancy or suspected pregnancy. X-ray exposure could damage fetus.
2. **Relative contraindications (patients/conditions in which PTCA may carry a higher than usual risk, and should only be attempted if the procedure's benefit outweighs the risk)**
   - Patients in whom coronary bypass surgery is not applicable. Emergency CABG is required for acute-phase ischemic complications.

Accuforce Program

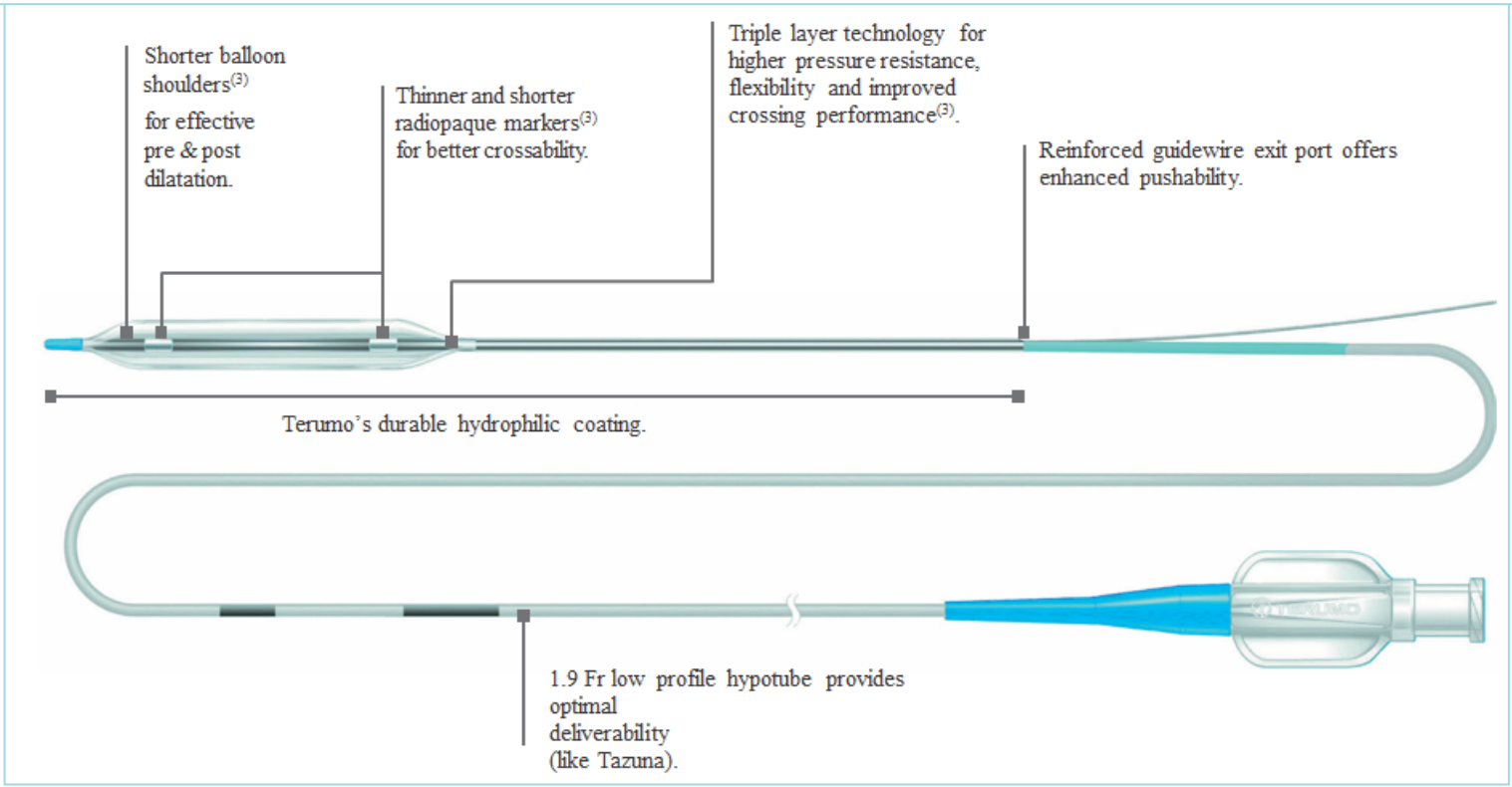
- Introduction
- **Technical Features**
- Accessories
- Product Range
- Key Features & Clinical Benefits
- Competition



Accuforce
Technical Features

1 Product Description

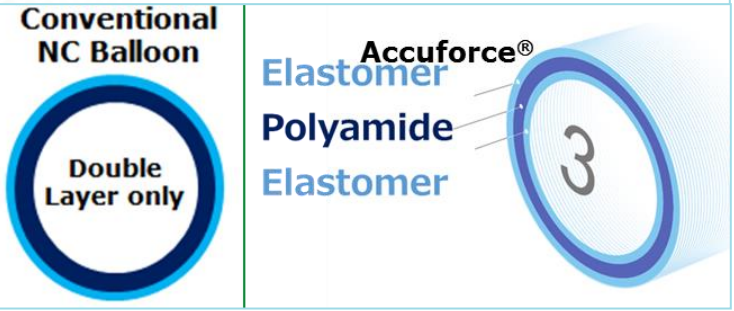
The Accuforce® PTCA dilatation catheter is the last generation of non-compliant balloon catheters.
It will offer improved **dilatation accuracy** under **high pressure** while optimizing the **crossability** vs. Hiryu ®.



Accuforce
Technical Features

2 Impressive Force

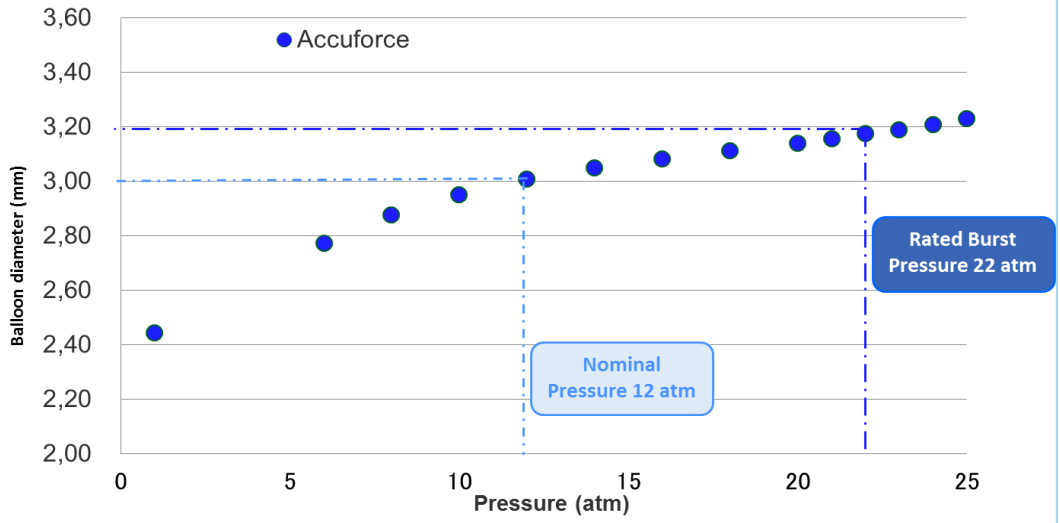
Innovative triple layer balloon structure



Layer	Function
Inner/Outer Elastomer layer	Elastomer = soft material Resistance to high pressure from the inside and against damage to the outside
Middle Polyamide layer (Polyamide = Nylon)	Nylon = Stronger layer To provide additional and safe high pressure resistance

High pressure resistance RBP up to 22 atm!

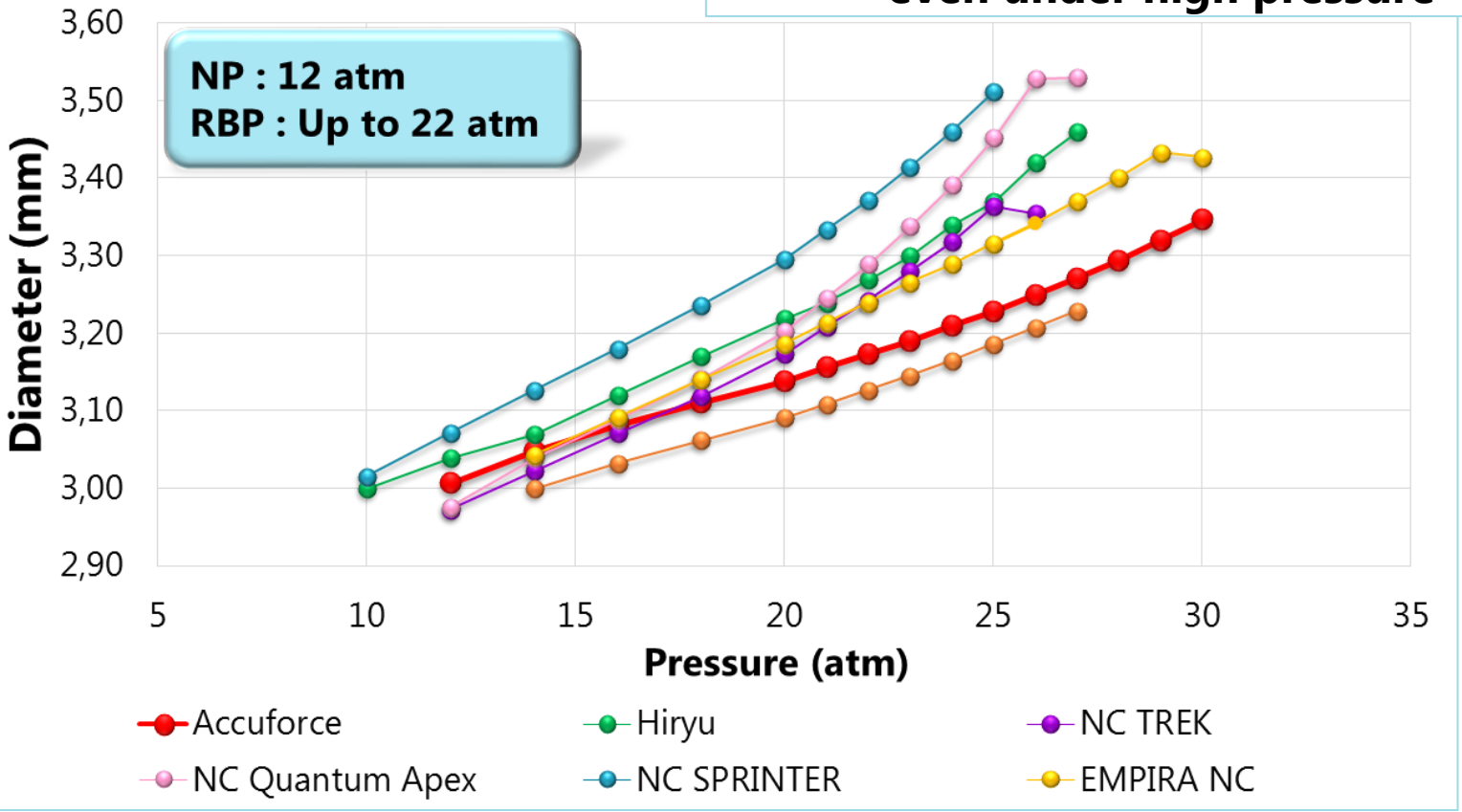
→ Resistance to high pressure is required for severe calcified lesions



Accuforce
Technical Features

2 Impressive Force

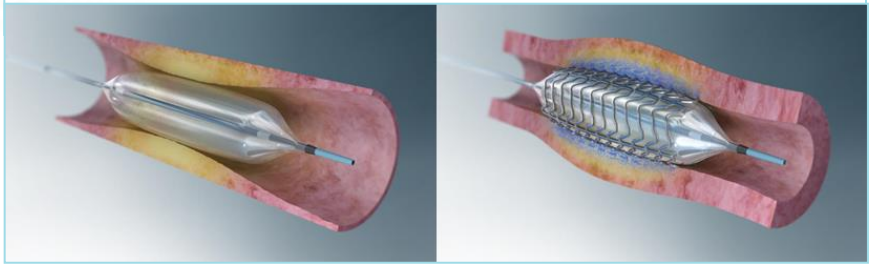
Lower Compliance for safer dilatation, even under high pressure



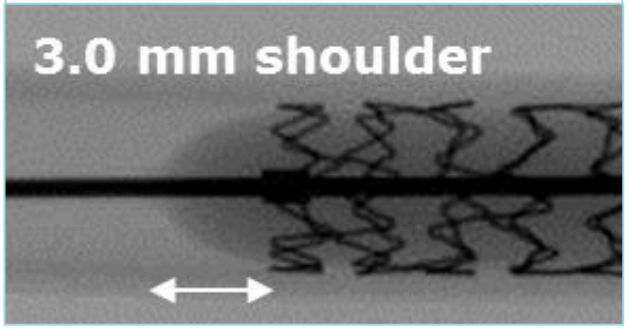
Accuforce
Technical Features

3 Accurate

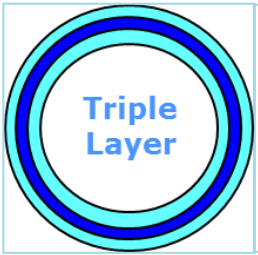
Effective and focused dilatation
→ Precise dilatation of the lesion
→ Precise post-dilatation of the stent



Short rounded balloon shoulders



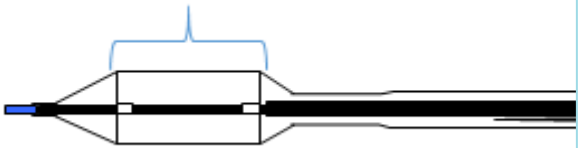
Low compliance
→ No risk of over-dilatation of the balloon



Triple layer balloon structure

Better grip without slipping effect
→ More dilatation accuracy in short lesions

No coating on short balloons (6 & 8mm)

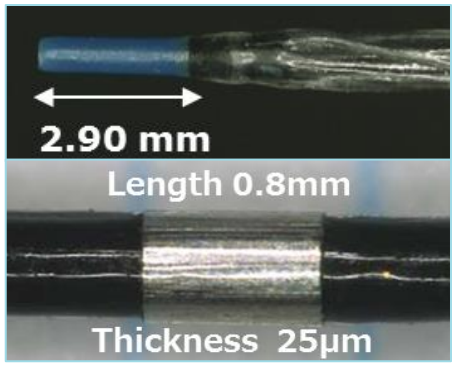


Accuforce
Technical Features

4 Deliverable

Improved crossability & re-crossability

→ Short distal tip
→ Shorter & thinner radiopaque markers
→ Softer balloon part thanks to Elastomer rate increase



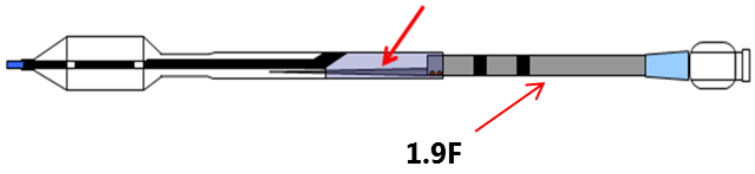
Advanced pushability & kink resistance

(for severe calcified lesion treatment)

Short stainless steel stylet in the mid shaft

→ To reinforce guide wire exit port and prevent kinking
→ To increase proximal to distal push transmission

Short stainless steel stylet in the inner shaft

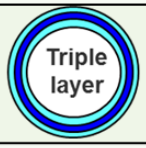
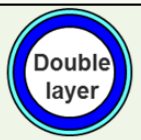
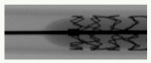
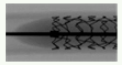
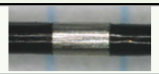
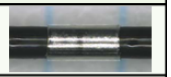


Similar to Tazuna

Improved deliverability

→ Particular complex procedures possible, especially KBT (Kissing Balloon Technique)

Accuforce
Technical Features vs Hiryu

	Accuforce	Hiryu
NP / RBP	12 atm / up to 22 atm	10 atm / 20 atm
Tip	35% Shorter (2.90 mm)	4.5mm
Tip entry profile	0.43 mm	
Crossing profile	0.036"	0.034"
Balloon Structure		
Balloon Shoulders	Shorter tapers 3.0mm 	Longer distal taper 5.0mm 
Balloon coating	6-8mm short balloons: No coating Others: Full hydrophilic coating	6-10mm short balloons: Hybrid coating Others: Full hydrophilic coating
Radiopaque markers	Thinner /shorter 	
Mid Shaft	2.5 F + Reinforcer 	2.6 F + Spiral cut pattern 
Proximal Shaft	1.9 F (like Tazuna)	2.0 F
Distal Shaft(F)	2.6 F	2.5~2.6 F
Prox. shaft Coating	No	Yes (PTFE)
Available sizes	Ø2.0 mm and more lengths	No Ø2.0 mm, L<20MM
Catheter length	145 cm	

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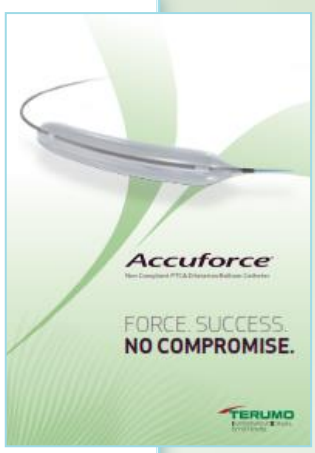


TERUMO INTERVENTIONAL SYSTEMS

Accuforce
Accessories

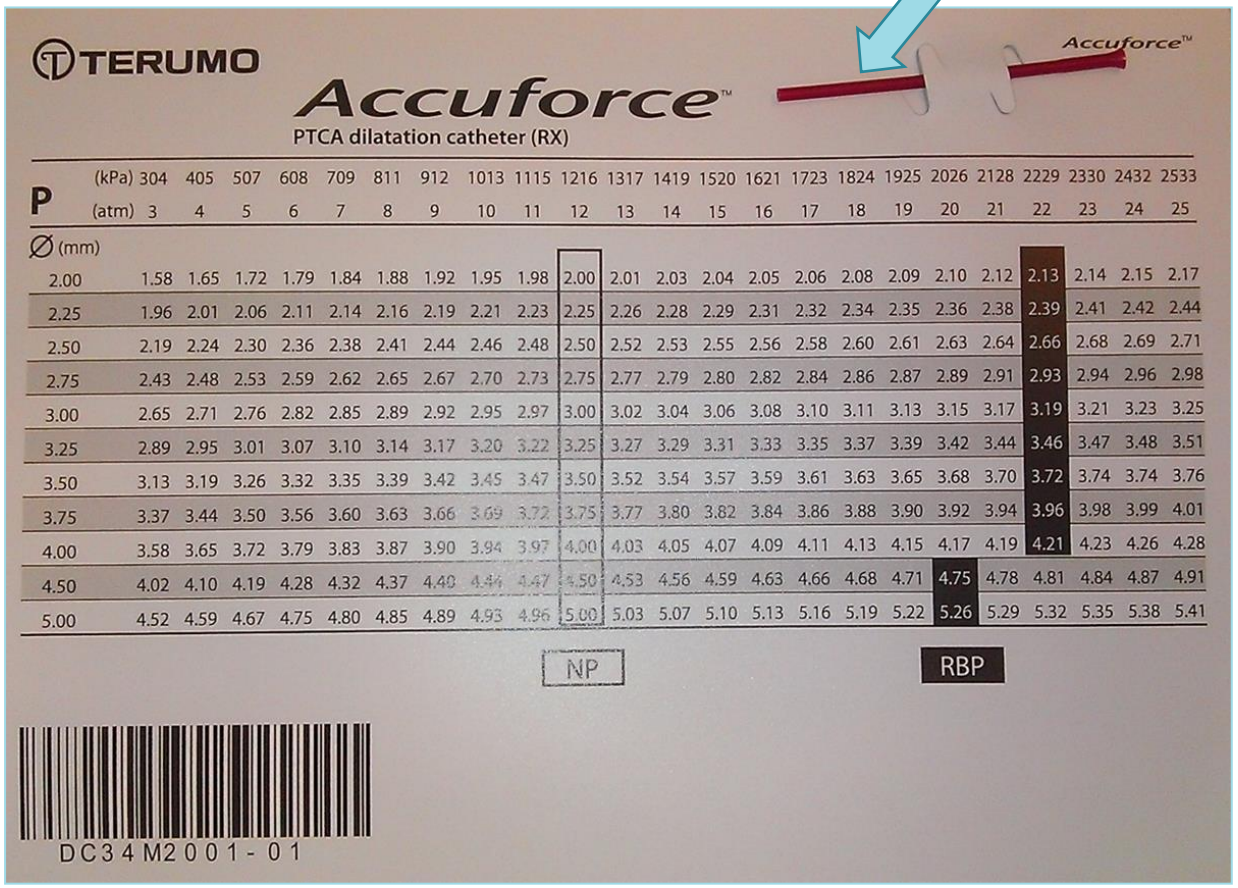
1 Catheter Clip

Included in package of Accuforce

Accuforce
Accessories

2 Balloon Protection Sheath

Better to call it re-wrapping tool



P (kPa)	304	405	507	608	709	811	912	1013	1115	1216	1317	1419	1520	1621	1723	1824	1925	2026	2128	2229	2330	2432	2533
(atm)	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Ø (mm)																							
2.00	1.58	1.65	1.72	1.79	1.84	1.88	1.92	1.95	1.98	2.00	2.01	2.03	2.04	2.05	2.06	2.08	2.09	2.10	2.12	2.13	2.14	2.15	2.17
2.25	1.96	2.01	2.06	2.11	2.14	2.16	2.19	2.21	2.23	2.25	2.26	2.28	2.29	2.31	2.32	2.34	2.35	2.36	2.38	2.39	2.41	2.42	2.44
2.50	2.19	2.24	2.30	2.36	2.38	2.41	2.44	2.46	2.48	2.50	2.52	2.53	2.55	2.56	2.58	2.60	2.61	2.63	2.64	2.66	2.68	2.69	2.71
2.75	2.43	2.48	2.53	2.59	2.62	2.65	2.67	2.70	2.73	2.75	2.77	2.79	2.80	2.82	2.84	2.86	2.87	2.89	2.91	2.93	2.94	2.96	2.98
3.00	2.65	2.71	2.76	2.82	2.85	2.89	2.92	2.95	2.97	3.00	3.02	3.04	3.06	3.08	3.10	3.11	3.13	3.15	3.17	3.19	3.21	3.23	3.25
3.25	2.89	2.95	3.01	3.07	3.10	3.14	3.17	3.20	3.22	3.25	3.27	3.29	3.31	3.33	3.35	3.37	3.39	3.42	3.44	3.46	3.47	3.48	3.51
3.50	3.13	3.19	3.26	3.32	3.35	3.39	3.42	3.45	3.47	3.50	3.52	3.54	3.57	3.59	3.61	3.63	3.65	3.68	3.70	3.72	3.74	3.74	3.76
3.75	3.37	3.44	3.50	3.56	3.60	3.63	3.66	3.69	3.72	3.75	3.77	3.80	3.82	3.84	3.86	3.88	3.90	3.92	3.94	3.96	3.98	3.99	4.01
4.00	3.58	3.65	3.72	3.79	3.83	3.87	3.90	3.94	3.97	4.00	4.03	4.05	4.07	4.09	4.11	4.13	4.15	4.17	4.19	4.21	4.23	4.26	4.28
4.50	4.02	4.10	4.19	4.28	4.32	4.37	4.40	4.44	4.47	4.50	4.53	4.56	4.59	4.63	4.66	4.68	4.71	4.75	4.78	4.81	4.84	4.87	4.91
5.00	4.52	4.59	4.67	4.75	4.80	4.85	4.89	4.93	4.96	5.00	5.03	5.07	5.10	5.13	5.16	5.19	5.22	5.26	5.29	5.32	5.35	5.38	5.41

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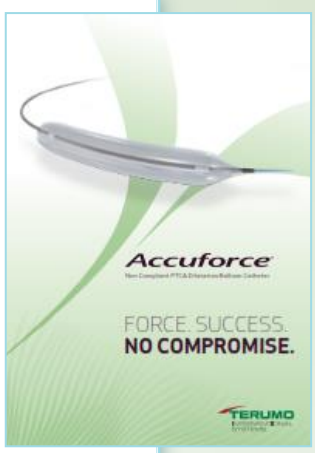
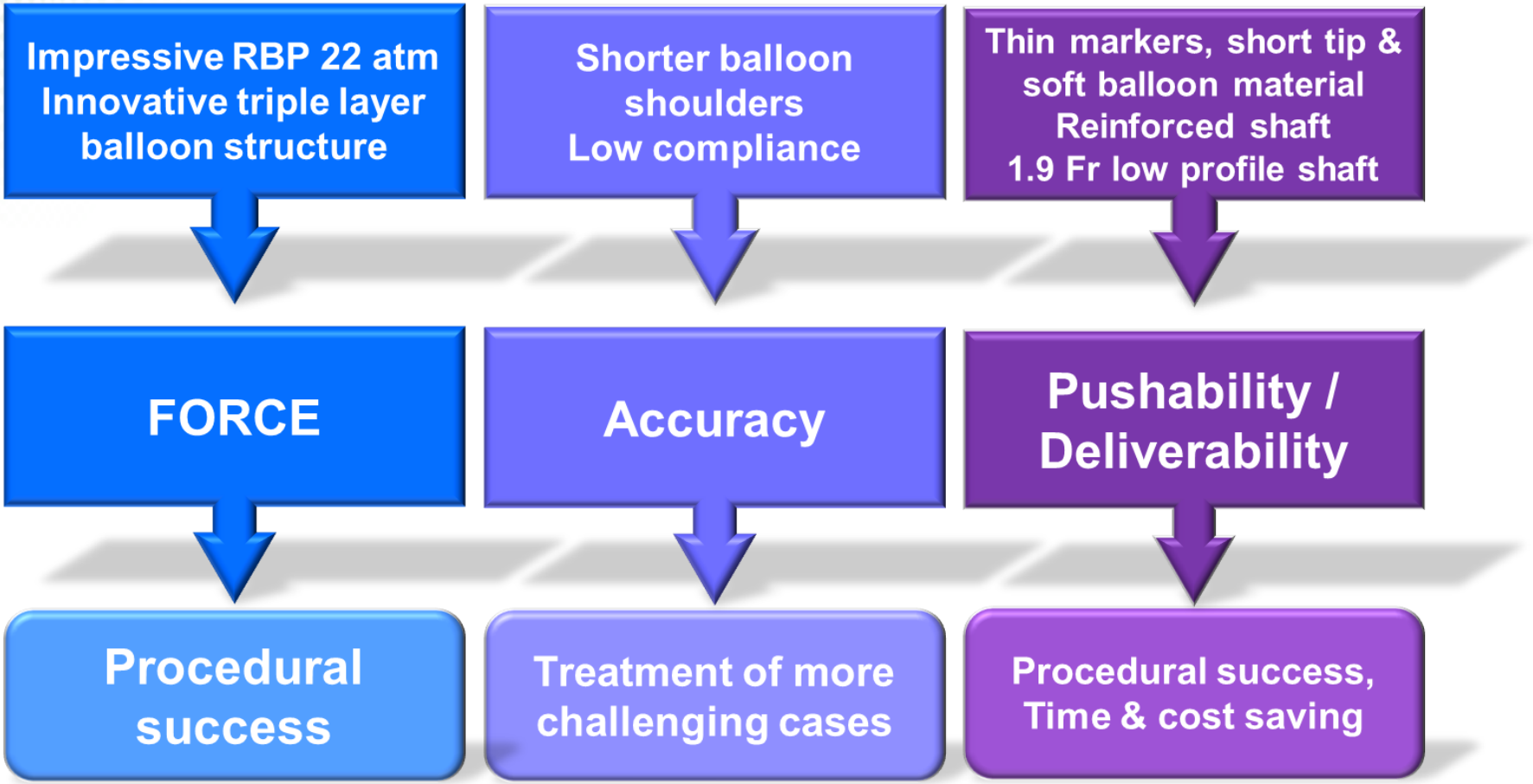


TERUMO INTERVENTIONAL SYSTEMS

Accuforce
Key Features & Clinical Benefits



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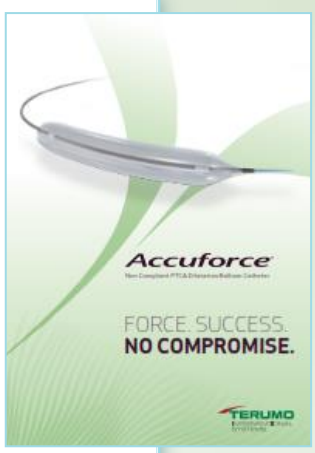

TERUMO INTERVENTIONAL SYSTEMS

Accuforce
Product Range

1 Ordering Information

Stent length / Product code							
Balloon diameter	6	8	12	15	20	25	30
2.00	DC-RM2006HSW	DC-RM2008HSW	DC-RM2012HHW	DC-RM2015HHW	DC-RM2020HHW		
2.25	DC-RM2206HSW	DC-RM2208HSW	DC-RM2212HHW	DC-RM2215HHW	DC-RM2220HHW		
2.50	DC-RM2506HSW	DC-RM2508HSW	DC-RM2512HHW	DC-RM2515HHW	DC-RM2520HHW	DC-RM2525HHW	DC-RM2530HHW
2.75	DC-RM2706HSW	DC-RM2708HSW	DC-RM2712HHW	DC-RM2715HHW	DC-RM2720HHW		
3.00	DC-RM3006HSW	DC-RM3008HSW	DC-RM3012HHW	DC-RM3015HHW	DC-RM3020HHW	DC-RM3025HHW	DC-RM3030HHW
3.25	DC-RM3206HSW	DC-RM3208HSW	DC-RM3212HHW	DC-RM3215HHW	DC-RM3220HHW		
3.50	DC-RM3506HSW	DC-RM3508HSW	DC-RM3512HHW	DC-RM3515HHW	DC-RM3520HHW	DC-RM3525HHW	DC-RM3530HHW
3.75	DC-RM3706HSW	DC-RM3708HSW	DC-RM3712HHW	DC-RM3715HHW	DC-RM3720HHW		
4.00	DC-RM4006HSW	DC-RM4008HSW	DC-RM4012HHW	DC-RM4015HHW	DC-RM4020HHW		
4.50	DC-RM4506HSW	DC-RM4508HSW	DC-RM4512HSW	DC-RM4515HSW			
5.00	DC-RM5006HSW	DC-RM5008HSW	DC-RM5012HSW	DC-RM5015HSW			

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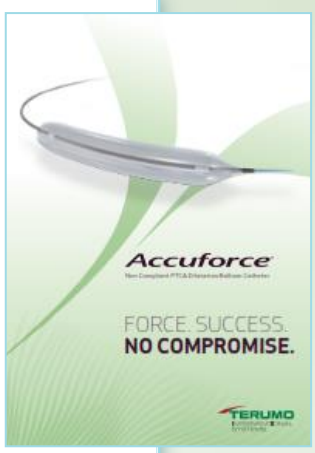
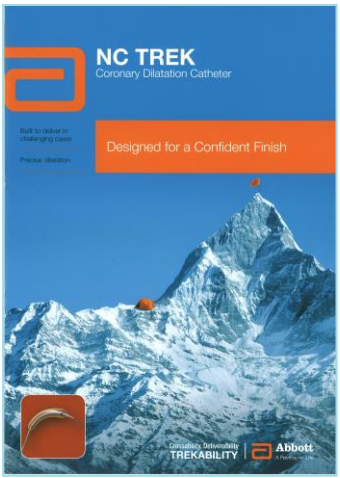


TERUMO INTERVENTIONAL SYSTEMS

Accuforce Competition

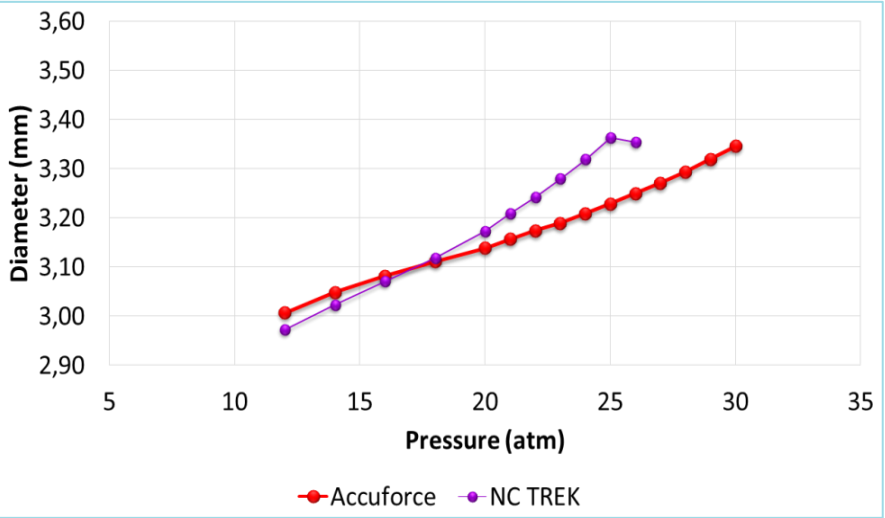
1 Abbott Vascular – NC Trek

	Accuforce	NC Trek
Balloon Size Diameters	2.0-5.0	1.5-5.0
Balloon Size Lenght	6/8/12/15/20/25/30	6/8/12/15/20/25
NP	12	12
RBP	22	18
Entry Profile	0.43mm	0.52 mm in house
Distal/Mid Shaft	2.6/2.5F	2.7/2.5F
Prox shaft	1.9F	2.3F
Balloon Material	Nylon/ elastomer	Pebax/Crossflex
Coating	Hydrophilic M coat	Hydrophilic



Accuforce Positioning

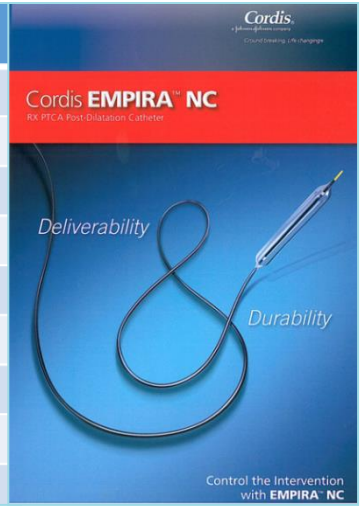
+ Accuforce has a better tip entry profile
  → *0.43mm vs 0.52mm for NC Trek*
+ Accuforce has thinner markers with better visibility
  → *20µm for Accuforce vs 70µm for NC Trek*
+ Accuforce has a higher RBP
  → *RBP 22 for Accuforce vs 18 for NC Trek*
+ NC Trek is more compliant



Accuforce Competition

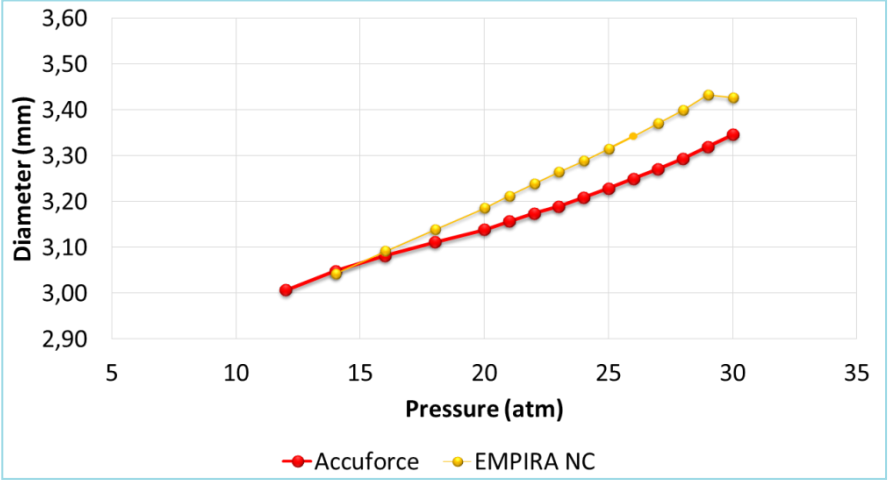
2 Cordis – Empira NC

	Accuforce	NC Empira
Balloon Size Diameters	2.0-5.0	2.0 – 4.0 mm
Balloon Size Lenght	6,8,12,15,20,25,30	6,8,12,15,20,25,30
NP	12	14
RBP	22	20
Entry Profile	0.43mm	
Distal/Mid Shaft	2.6/2.5 F	2.7/2.6
Prox shaft	1.9 F	1.9F
Balloon Material	Nylon/ Elastomer	Duralyn
Coating	Hydrophilic M coat	Hydrophilic



Accuforce Positioning

+ Accuforce has a better balloon flexibility combined with a lower compliance
+ Accuforce has a higher RBP
  → *RBP 22 for Accuforce vs 20 for Empira NC*
+ Empira NC is less durable (feedback from the field)



Accuforce Competition

3 Medtronic – NC Euphora

	Accuforce	NC Euphora
Balloon Size Diameters	2.0-5.0	2.0 – 5.0 mm
Balloon Size Lenght	6,8,12,15,20,25,30	6,8,12,15,20,27
NP	12	12
RBP	22	20
Entry Profile	0.43mm	0.41mm
Distal/Mid Shaft	2.6/2.5 F	2.5F
Prox shaft	1.9 F	
Balloon Material	Nylon/ Elastomer	LightI
Coating	Hydrophilic M coat	Duratrac

Positioning

+ Accuforce has a higher RBP
  → *RBP 22 for Accuforce vs 20 for NC Euphora*

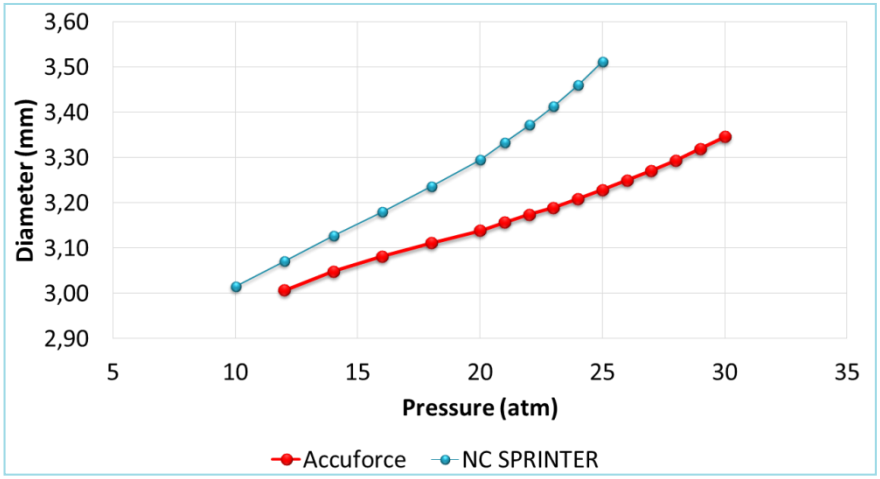
Accuforce
Competition

3 Medtronic – NC Sprinter

	Accuforce	NC Sprinter
Balloon Size Diameters	2.0-5.0	2.0 – 5.0 mm
Balloon Size Lenght	6,8,12,15,20,25,30	6,9,12,15,21,27
NP	12	12
RBP	22	18
Entry Profile	0.43mm	0.41mm
Distal/Mid Shaft	2.6/2.5 F	2.6/2.4F
Prox shaft	1.9 F	1.9F
Balloon Material	Nylon/ Elastomer	Soft Fulcrum plus
Coating	Hydrophilic M coat	Duratrac

Positioning against NC Sprinter

+ NC Sprinter has a very steep compliance compared to Accuforce (see chart)
+ Accuforce has a higher RBP
  → *RBP 22 for Accuforce vs 18 for NC Sprinter*



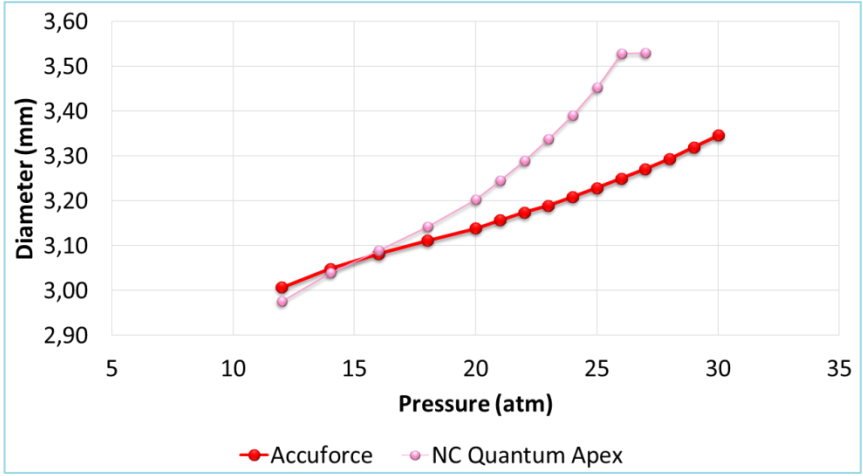
Accuforce Competition

4 BSC – Quantum Apex

	Accuforce	NC Quantum Apex
Balloon Size Diameters	2.0-5.0	2.0 – 4.0 mm
Balloon Size Lenght	6,8,12,15,20,25,30	6,8,12,15,20,30
NP	12	12
RBP	22	20
Entry Profile	0.43mm	0.432mm
Distal/Mid Shaft	2.6/2.5 F	2.7/2.4F
Prox shaft	1.9 F	1.8F
Balloon Material	Nylon/ Elastomer	Optiq
Coating	Hydrophilic M coat	Hydrophilic/phobic

Accuforce positioning

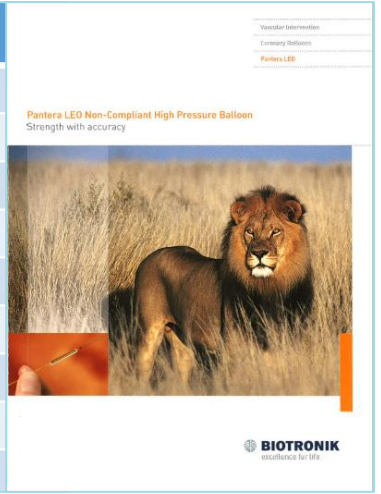
+ Accuforce has a bigger size range
+ Accuforce has a higher RBP
  → *RBP 22 for Accuforce vs 20 for Quantum Apex*
+ Quantum Apex has a very steep compliance compared to Accuforce (see chart)



Accuforce
Competition

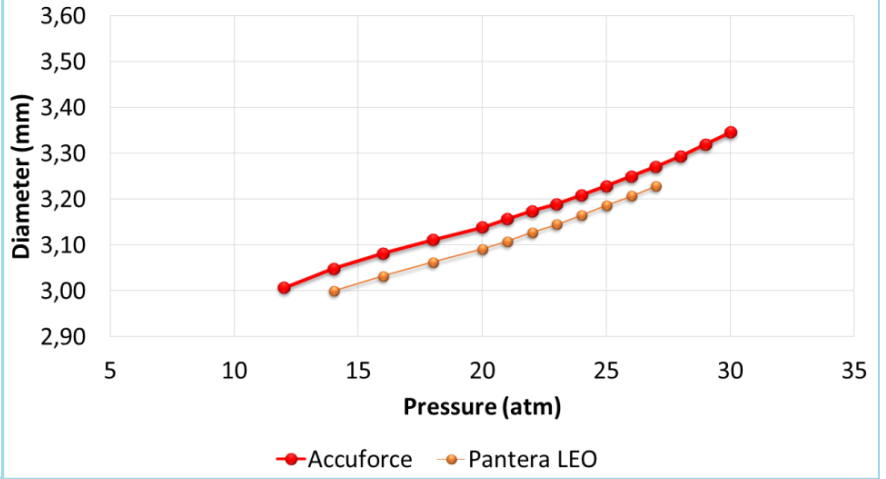
5 Biotronik – Pantera LEO

	Accuforce	Pantera Leo
Balloon Size Diameters	2.0-5.0	2.0 – 5.0 mm
Balloon Size Lenght	6,8,12,15,20,25,30	8-30mm
NP	12	14
RBP	22	20
Entry Profile	0.43mm	
Distal/Mid Shaft	2.6/2.5 F	2.6
Prox shaft	1.9 F	2.0
Balloon Material	Nylon/ Elastomer	
Coating	Hydrophilic M coat	



Accuforce positioning

+ Accuforce has a higher RBP
  → *RBP 22 for Accuforce vs 20 for Pantera Leo*
+ Accuforce has a clearly better deliverability than Pantera Leo, both pushability and flexibility are much better



Thank You

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SYSTEMS

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