Overview on balloons and stents

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Overview

- Balloon catheters
  - terminology
  - low-, medium- and high pressure balloons
  - cutting balloon
  - BIB catheter

- stents

Balloon catheters

Use

- Dilation of valvar and vascular stenosis
- Implantation of stents

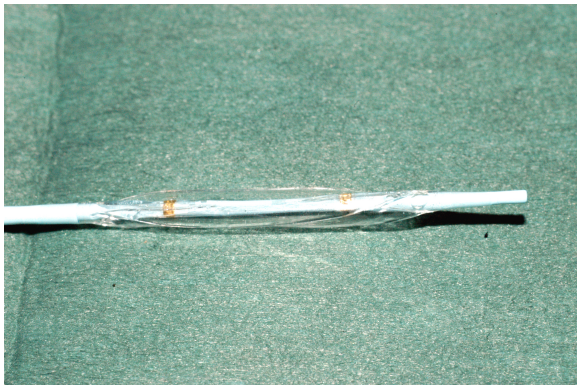
Ideal balloon:

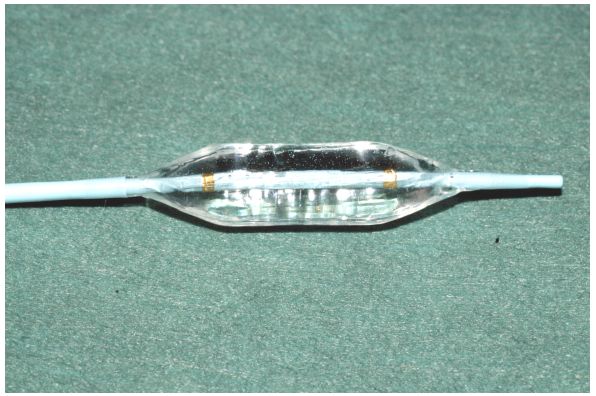
- very low profile, mounted on a catheter with small shaft
- profile remains low after deflation of balloon
- flexible shaft and balloon
- resistant to rupture
- expands to a fixed maximal diameter at maximal inflation pressure

Balloon catheters

Terminology

- Balloon profile = diameter of the deflated balloon → dictates sheath size
- Balloon length = length of the parallel portion of the inflated balloon

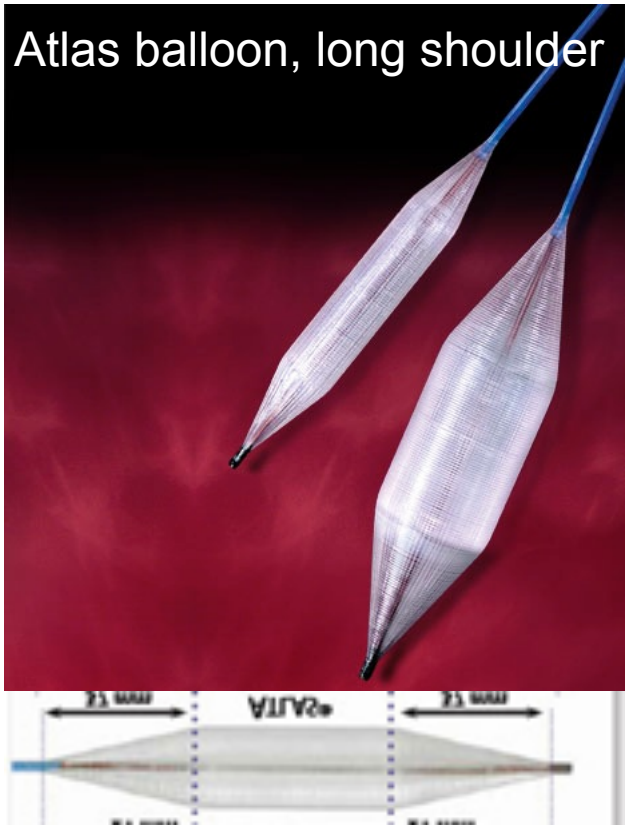




Balloon terminolgy

Shoulders
Short vs. long tapering

Cave:
risk of vascular trauma in curved vessels due to long shoulder

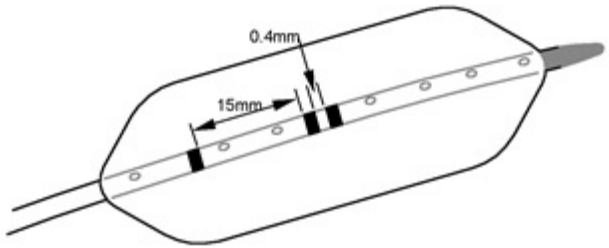


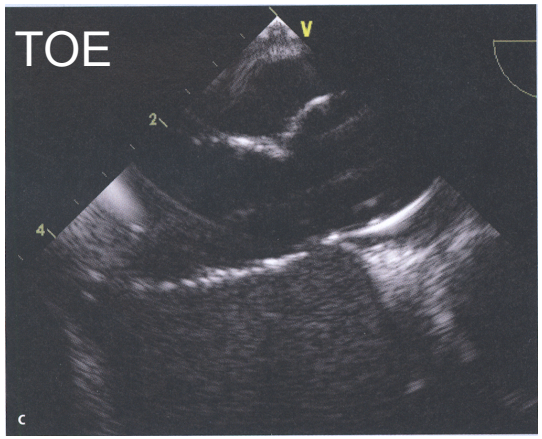
Thyshak balloon, short shoulder

Balloon terminology

Compliance = degree of stretch at low pressure

- Very compliant balloons
  → used for sizing defects e.g. ASDII



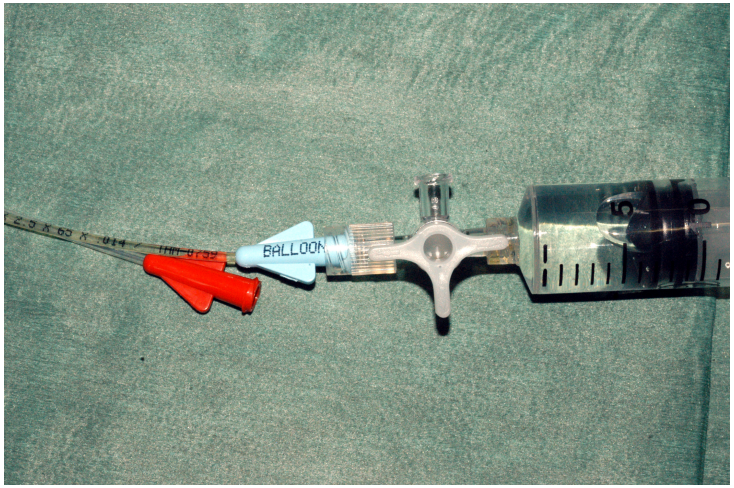


Numed 25 mm diameter,1.5 ATM

- Non compliant balloons
  → used for dilation of stenosis or implantation of stents
  → predictable maximum inflation diameter
  →

Balloon terminology

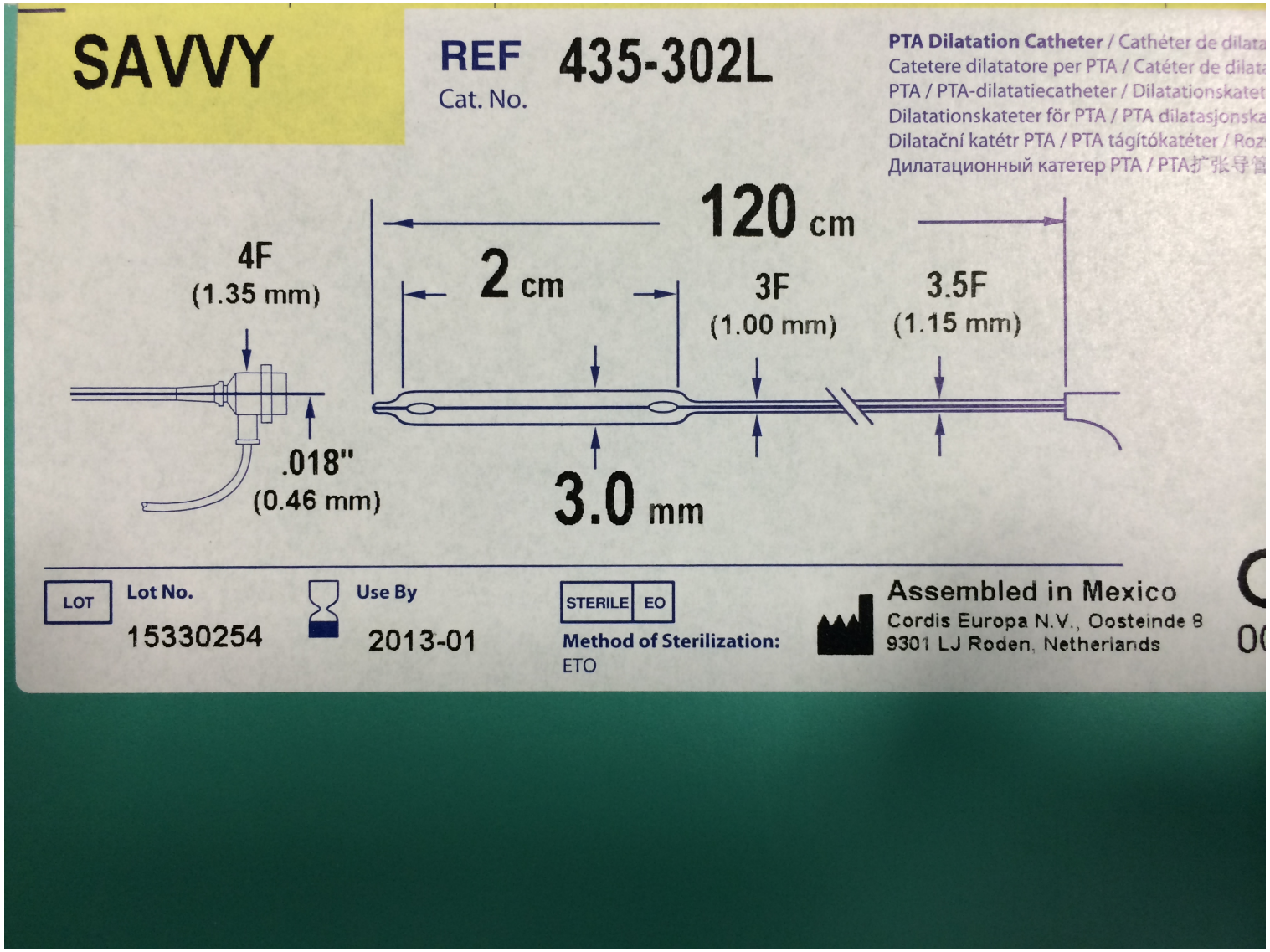
Inflation/deflation time depends on:
- Properties of the balloon
- Ratio of contrast to saline
  visibility vs. in/deflation time



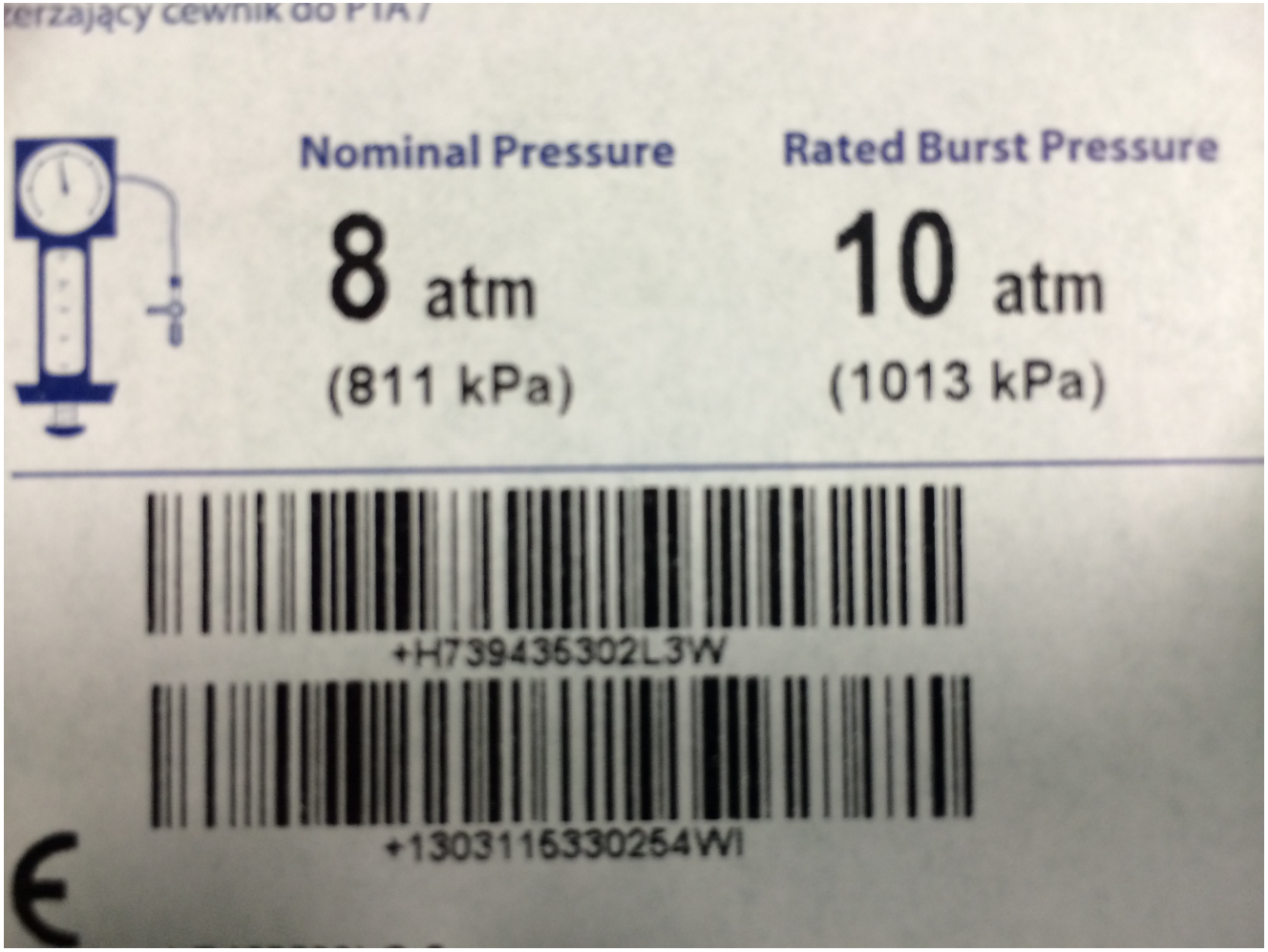
Hint:
- the balloon lumen always comes off
  the shaft at an angle
- avoid inadvertent inflation
  of the balloon

Low vs. high pressure balloons
- Low: up to 5 bar (e.g. Numed Tyshak Mini)
- Medium-high pressure: 5 - 15 bar (Cordis Opta)
- Ultra high pressure: 15 - 30 bar (Bard Atlas)

Balloon catheters



Balloon catheters



Low-pressure balloon (< 5 ATM): Tyshak II

Properties
- Small profile
- Low pressure
- Flexible shaft/balloon
- Fast in-/deflation
- Little tapering
- Low burst pressure

Tyshak II® Specifications

Balloon Diameter (MM)	Balloon Length (CM)	Introducer Size (FR)	Shaft Size (FR)	Usable Length (CM)	Guide Wire (Inches)	Rated Burst (ATM)	*Nominal Pressure (ATM)	Catalog No.
4.0	2.0	4	4	70	0.021	6	4.5	PDC500
4.0	2.0	4	4	100	0.021	6	4.5	SN003
4.0	10.0	4	4	70	0.021	6	4.5	PDC551
5.0	2.0	4	4	70	0.021	6	4.5	PDC501
5.0	2.0	4	4	100	0.021	6	4.5	SN004
5.0	3.0	4	4	70	0.021	6	4.5	SO020
6.0	2.0	4	4	70	0.021	4	3.5	PDC502
6.0	2.0	4	4	100	0.021	4	3.5	SN005
6.0	3.0	4	4	70	0.021	4	3.5	SO021
7.0	2.0	4	4	70	0.021	4	3.5	PDC503
11.0	3.0	5	5	90	0.025	3.5	3	SO017
11.0	4.0	5	5	90	0.025	3.5	3	SO002
12.0	2.0	5	5	90	0.025	3.5	3	SO008
12.0	2.0	6	6	90	0.035	3.5	3	SO014
12.0	3.0	5	5	90	0.025	3.5	3	PDC507
12.0	4.0	6	6	90	0.035	3.5	3	PDC508

Use
- Valvuloplasty PS and AoS
- Dilation of compliant vessel stenosis
- Pre- stent delineation of stenosis
- **Not for stent implantation!**

Balloon valvuloplasty for PS

Low-pressure balloon (< 5 ATM) Mini-Tyshak

Product specifications

Balloon Diameter (MM)	Balloon Length (CM)	Introducer Size (FR)	Shaft Size (FR)	Usable Length (CM)	Guide Wire (Inches)	Rated Burst (ATM)	*Nominal Pressure (ATM)	Catalog No.
4.0	2.0	3	2.5	65	0.014	6	4.5	PDC400
5.0	2.0	3	2.5	65	0.014	6	4.5	PDC401
6.0	2.0	3	2.5	65	0.014	4	3.5	PDC402
7.0	1.0	3	2.5	65	0.014	4	3.5	SO101
7.0	2.0	3	2.5	65	0.014	4	3.5	PDC403
8.0	1.0	3	2.5	65	0.014	4	3.5	SO102
8.0	2.0	3	2.5	65	0.014	4	3.5	PDC404
9.0	1.0	4	3.5	65	0.014	3.5	3	SO103
9.0	2.0	4	3.5	65	0.014	3.5	3	PDC405
9.0	4.0	4	3.5	65	0.014	3.5	3	PDC407
10.0	1.0	4	3.5	65	0.014	3.5	3	SO104
10.0	2.0	4	3.5	65	0.014	3.5	3	PDC406
10.0	4.0	4	3.5	65	0.014	3.5	3	PDC408

Use

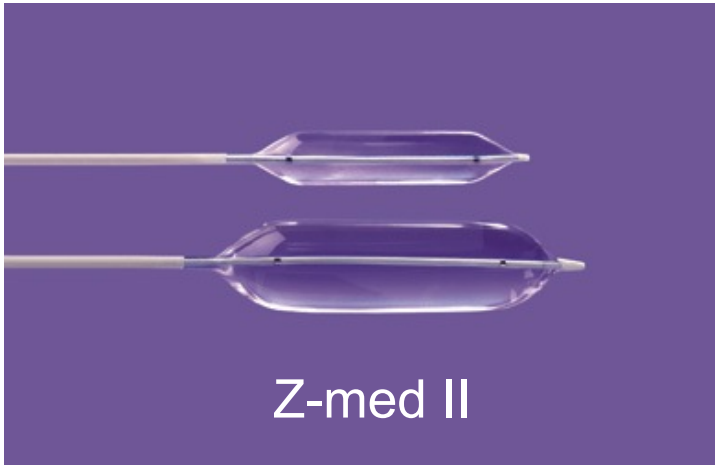
- in small neonates and infants (3 and 4 F sheath)

Medium pressure balloons (up to 15 ATM)

Small diameters (≤ 12 mm)
- OPTA® (Cordis)
- ULTRA-THIN® (Meditech, BS)

Large diameters (→30 mm)
- Z-med II® (Numed)
- CRISTAL BALLOON® (Balt)

Use
- Valve dilation beyond infancy
- Dilation of conduit and stents
- Implantation of stents


Z-med II

High-pressure balloons (up to 20 ATM)

Smaller diameters
- POWERFLEX® (Cordis)
- BLUE MAX® (Meditech)

Larger diameters (-> 25 mm)
- MULLINS-X® (Numed)

Properties
- Larger profiles
- Less flexible
- Inflate and deflate slower

Use
- Stent placement and dilation
- Conduit stenosis

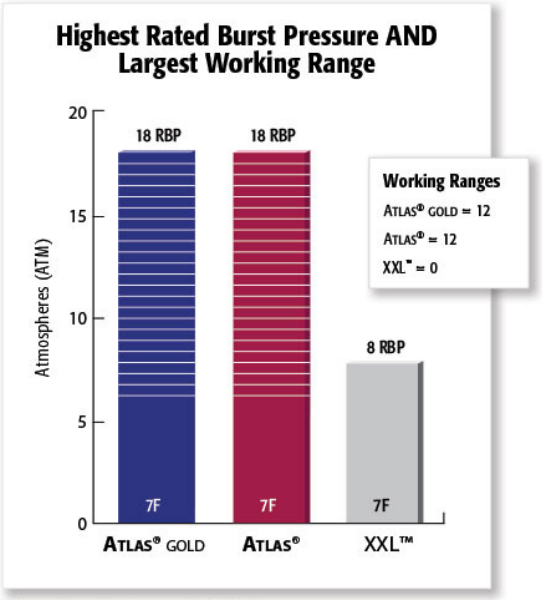
Very high burst resisting balloon

CONQUEST®, ATLAS® (Bard)

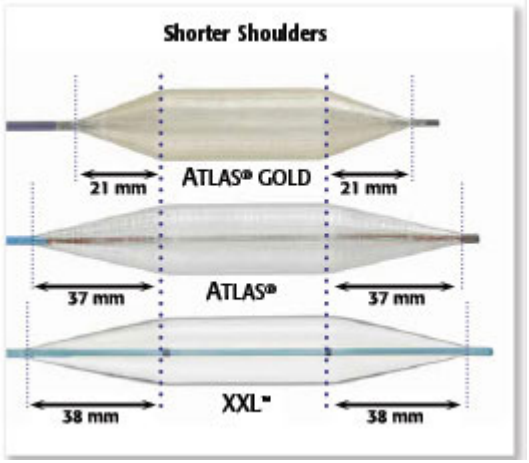
- Fixed diameter at very high pressure (12-26 mm)
- (Large) shoulders (Atlas vs. Atlas Gold)

Use:

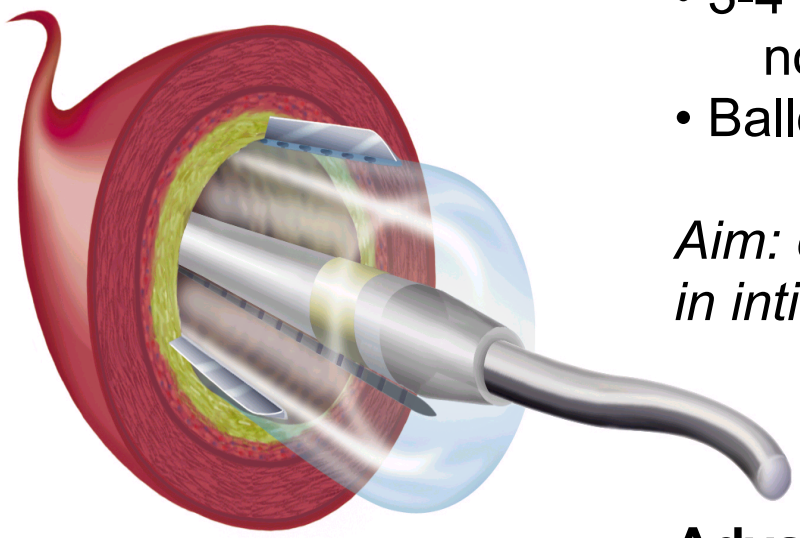
- Dilation of resistant stenosis,
  e.g. conduits before PPVI



Information taken from product labeling.
14 mm x 4 cm balloons.



Cutting balloon



Properties

- 3-4 atherotomes mounted on non-compliant high pressure balloon
- Balloon diameter 2 – 8 mm

Aim: creating cuts for controlled tears in intima and media

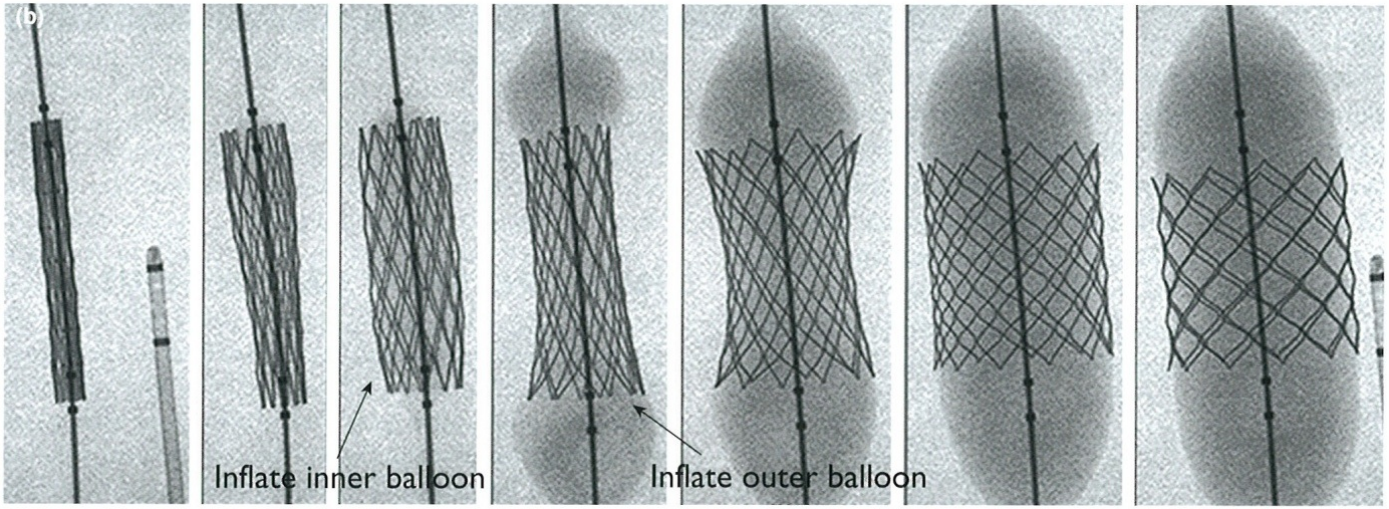
Advantages of cutting vs conventional balloon dilation

- Less barotrauma
- Less elastic recoil
- Less wall reaction

BIB catheter

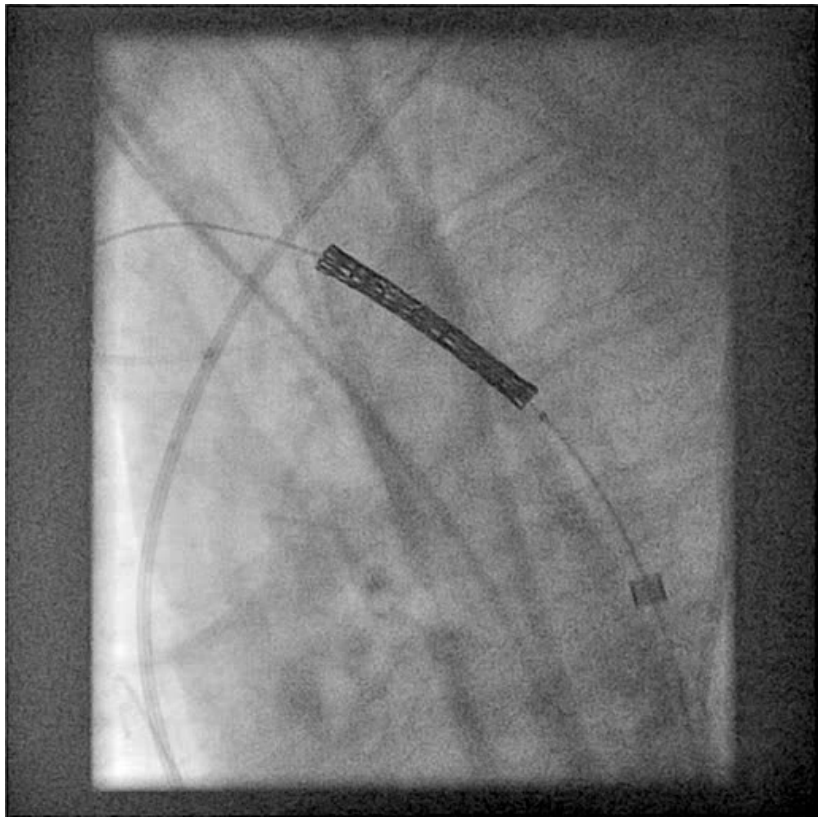
„Balloon in balloon (BIB)“ catheter

- For stepwise controlled expansion and positioning of stent
- Diameter 8 – 24 mm
- Length 25 – 55 mm
- 0.035” guidewire

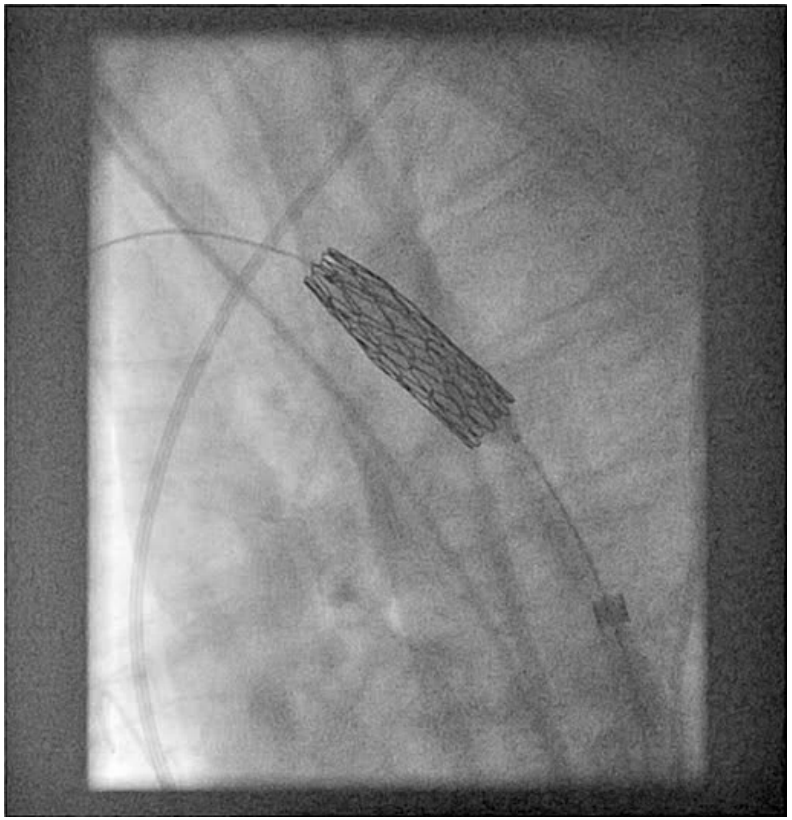


Stenting of native CoA in a 63-year-old patient

Positioning of a covered CP stent on BIB catheter



Inflation of inner balloon



Inflation of outer balloon

Overview

- Balloon catheters

- Stents
  - design
  - self expandable vs. Balloon expandable
  - uncovered vs. covered

Stent implantation

Indication

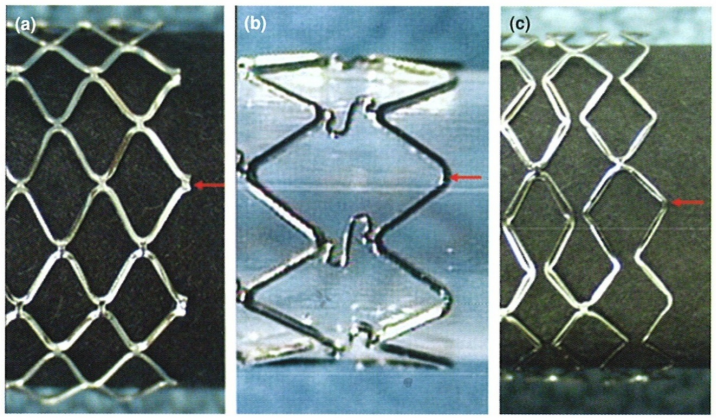
- Recoil after balloon dilation
- External compression
- Stretching
- Early post-op stenosis

Be aware of

- Iatrogenic stenosis due to final small stent diameter
- Occlusion of side branch vessel

The ideal stent

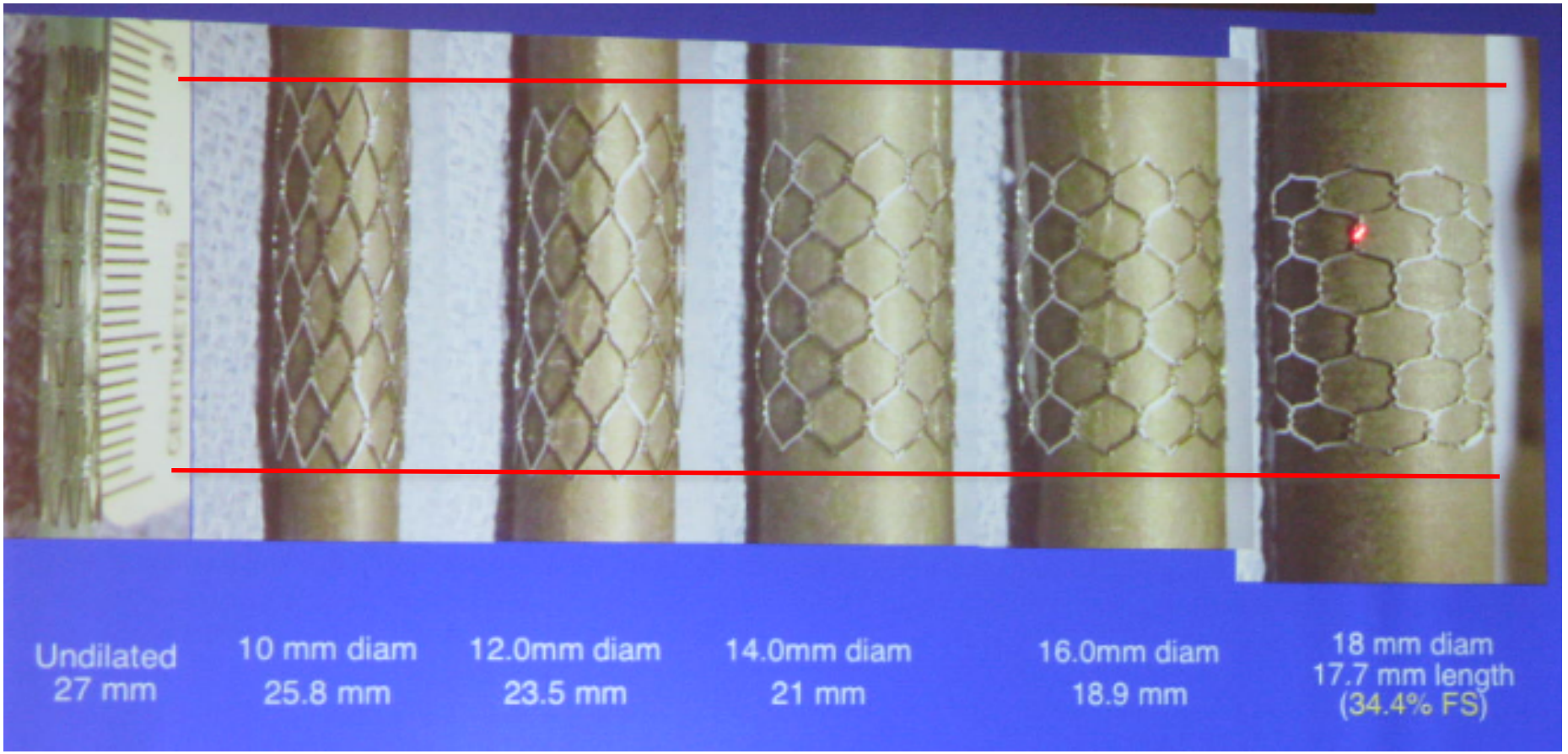
- Low profile
- Flexible
- High radial strength
- Good visibility
- Minimal foreshortening
- Ability to redilate to adult size diameter
- Allow access to side branches
- atraumatic due to rounded edges



Palmaz Genesis-XD Mega – LD eV3

Foreshortening of stent

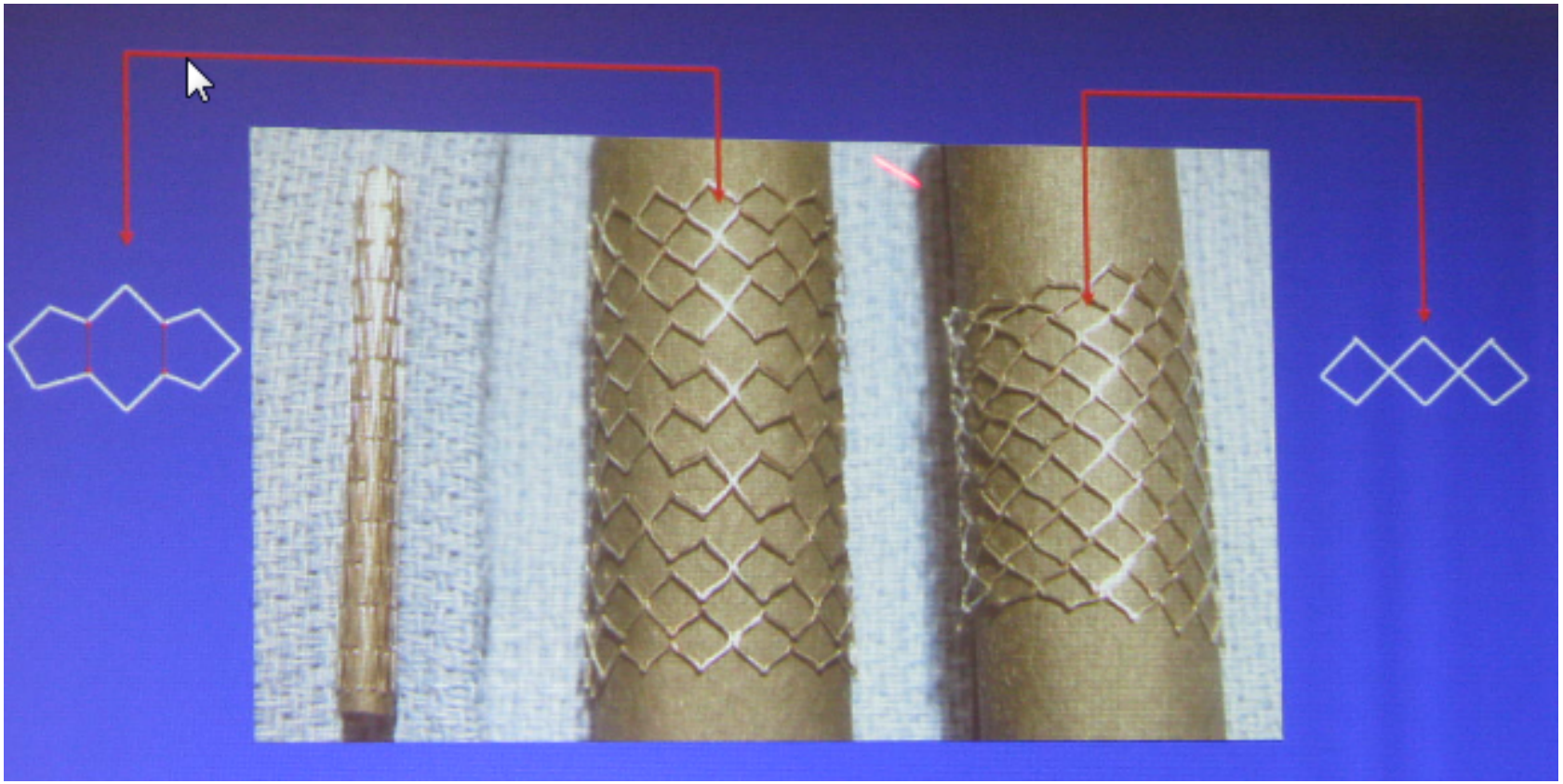
Serial dilation



F. Ing

Foreshortening of stent

Open vs closed cell design (18 mm balloon)



F. Ing

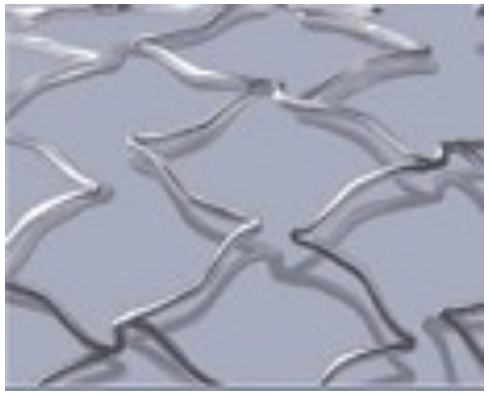
Stent characteristics: open vs. closed cell design

Open cell

- Flexible
- Little foreshortening
- Access to side branches

but

- More tissue prolapse
- Less radial strength
- Recoil



Open cell stent

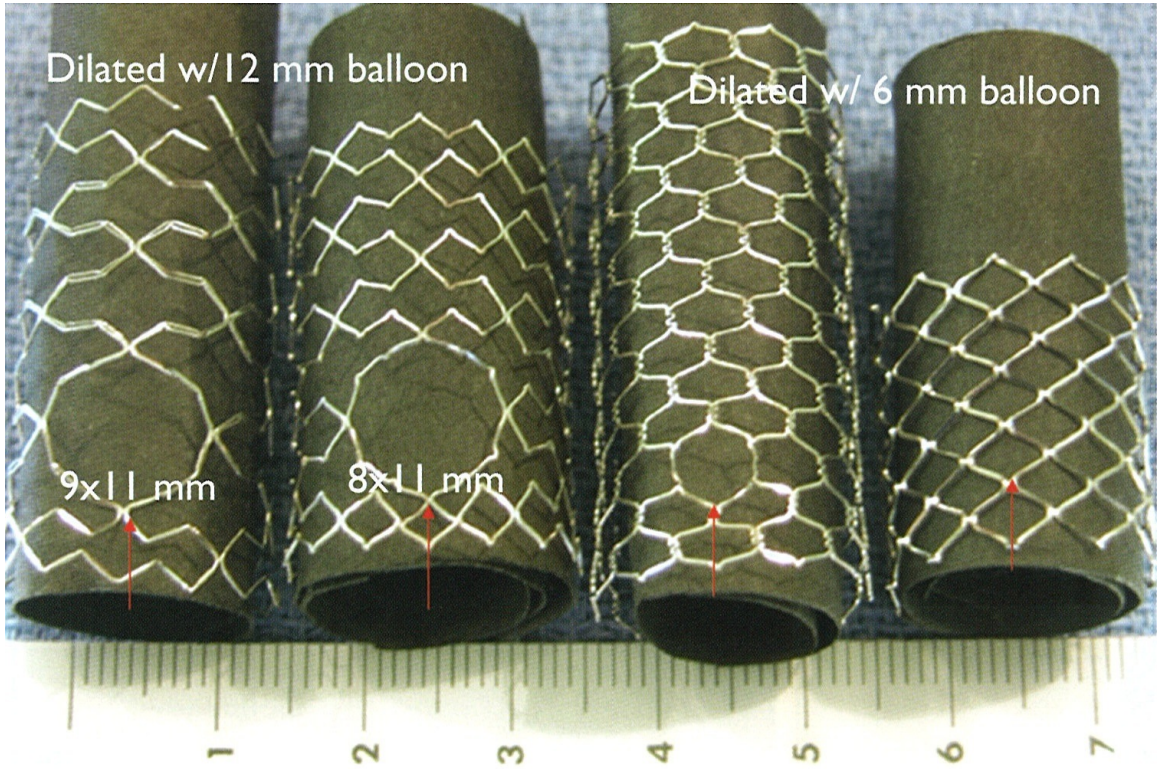
Closed cell stent

Closed cell

Stent characteristics: open vs. closed cell design

Dilation of cells

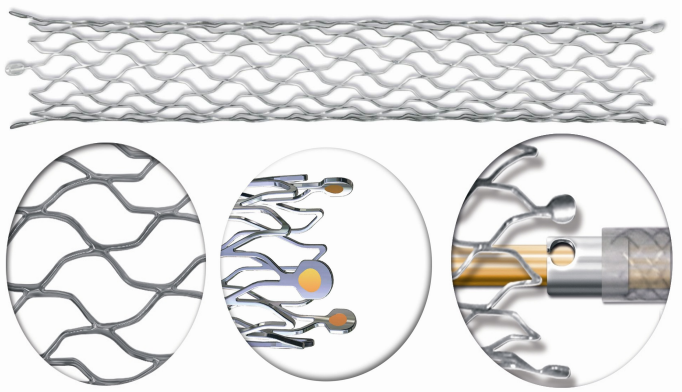
open cell closed cell



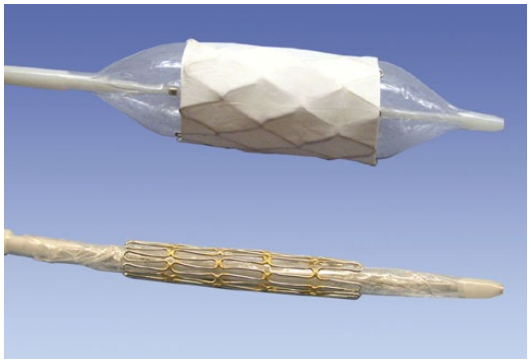
Doublestrut Mega-LD Genesis Palmaz

Stent characteristics
self- vs. balloon expandable stents

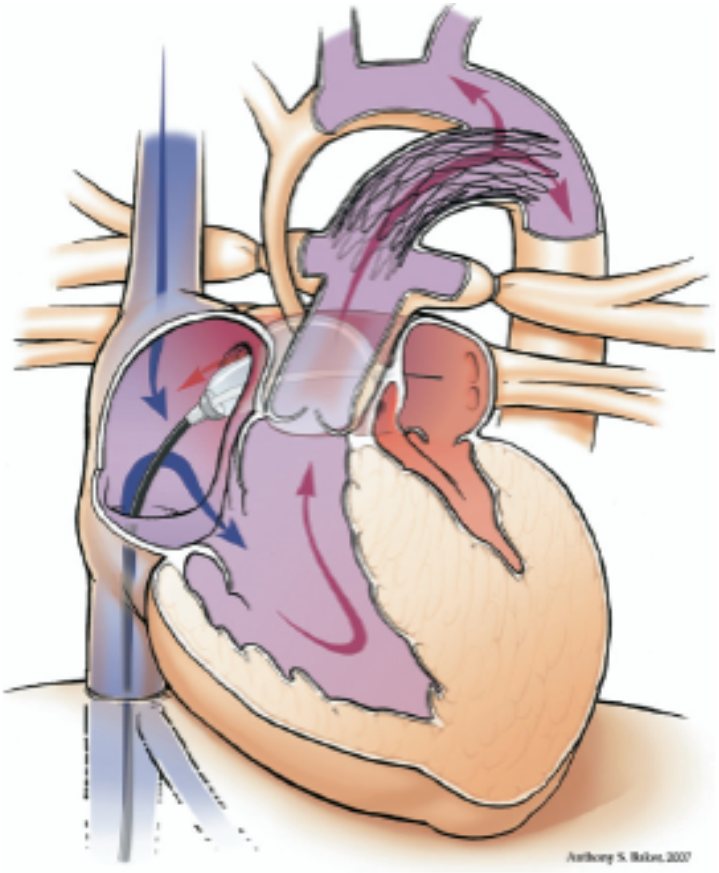
Self expandable
- Flexible, low profile,
- Good adherence to vessel wall
- Reduced radial strength

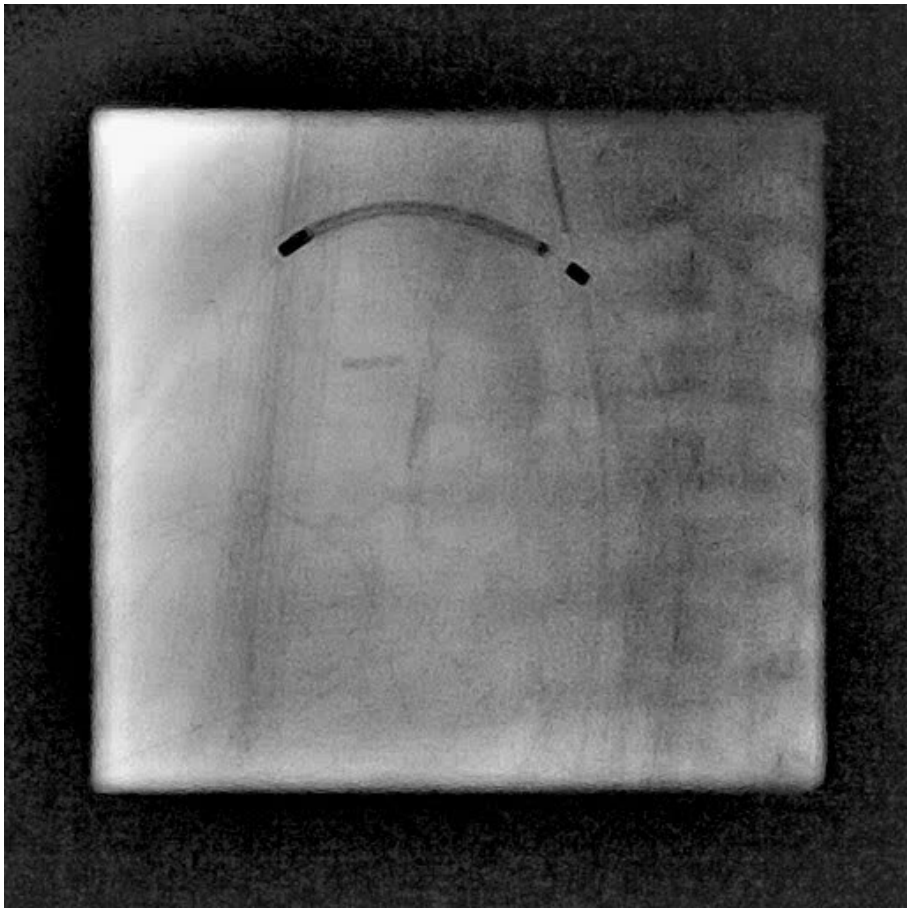


Balloon expandable
- Precise positioning
- High radial strength
- Hand-crimped vs. premounted



Hybrid approach for HLHS: Stenting PDA (Sinus-Superflex, OptiMed)





Self-expanding stents for HLHS (OptiMed)

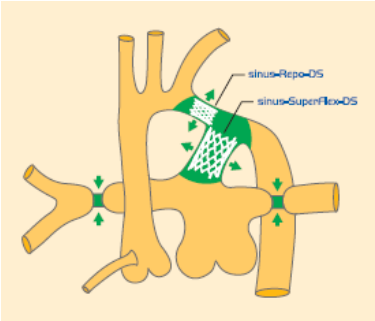
Sinus-Superflex-DS (for PDA)

- Open cell design

Stent Ø	Stent Length	Application System	Order-Nr.
mm	mm	F / cm	
7	15	4	8807-2015
7	18	4	8807-2018
8	12	4	8808-2012
8	15	4	8808-2015
8	18	4	8808-2018
8	20	4	8808-2020
9	20	4	8809-2020

Sinus-Repo-DS (for pre-ductal CoA)

- Closed cell design
- Repositionable (up to 80% of stent length)



Stent Ø	Stent Length	Application System	Order-Nr.
mm	mm	F / cm	
5	9	4	8905-2009
6	9	4	8906-2009

Balloon expandable stents

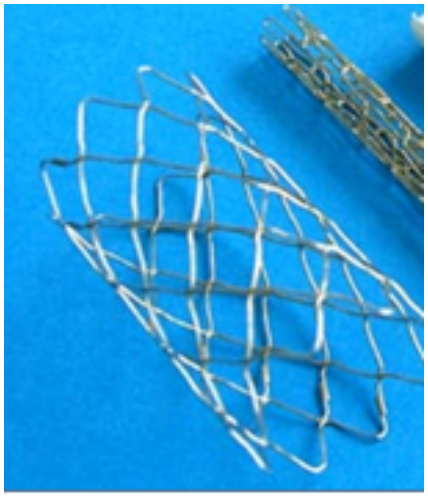
Properties

- Uncovered vs. covered
  e.g. large stents
- (Drug eluting)
- (Resorbable)

Extra-large stents: dilatable up to 25 mm (cortesy to C.Ovaert)

Palmaz XL 4014, 5015	Intrastents LD Max (16,26,36 mm)	CP 8 zigs (16,22,28,34,39,45 mm)	Andrastent XL & XXL (13 to 57 mm)
Unmounted	Unmounted	Unmounted or premounted	Unmounted
Stainless steel	Stainless steel	Platinum/iridum	Cobalt chromium
14 to 25	9 to 25	8 to 24	15-25 mm 20-32 mm
Closed cells	Open cells	Closed cells	Hybrid cell design
Rigid	Flexible	Robust, flexible, rounded edge	flexible
FS: 25% at 25 mm	FS: < 20% when serial	FS: 35% at 24 mm, 14% at 18 mm	FS XL: 35% at 25 mm, < 10% at 18 mm

Numed-CP stents, uncovered



- Length 16 - 45 mm
- Dilatable up to 24 (and more) mm
- Use for stenting:
  CoA, pulmonary arteries, IVC/SVC

INFLATED BALLOON DIAMETER	CP8Z16 (LENGTH AFTER EXPANSION) (% SHORTENING)	CP8Z22 (LENGTH AFTER EXPANSION) (% SHORTENING)	CP8Z28 (LENGTH AFTER EXPANSION) (% SHORTENING)	CP8Z34 (LENGTH AFTER EXPANSION) (% SHORTENING)	CP8Z39 (LENGTH AFTER EXPANSION) (% SHORTENING)	CP8Z45 (LENGTH AFTER EXPANSION) (% SHORTENING)
12mm	1.61cm (2.8%)	2.18cm (0.8%)	2.62cm (4.4%)	3.23cm (3.1%)	3.72cm (1.9%)	4.17cm (3.8%)
14mm	1.54cm (6.5%)	2.08cm (5.4%)	2.56cm (6.8%)	3.15cm (5.4%)	3.66cm (3.6%)	3.97cm (8.4%)
15mm	1.51cm (8.5%)	2.02cm (7.9%)	2.51cm (8.6%)	3.10cm (7.0%)	3.54cm (6.6%)	3.94cm (9.2%)
16mm	1.48cm (10.6%)	1.98cm (10.1%)	2.45cm (10.7%)	3.00cm (9.8%)	3.48cm (8.2%)	3.84cm (11.4%)
18mm	1.43cm (13.7%)	1.89cm (14.0%)	2.38cm (13.3%)	2.88cm (13.5%)	3.20cm (15.6%)	3.71cm (14.5%)
20mm	1.32cm (20.0%)	1.80cm (17.9%)	2.30cm (16.3%)	2.63cm (20.9%)	2.96cm (21.9%)	3.27cm (24.7%)
22mm	1.23cm (25.4%)	1.67cm (23.9%)	2.09cm (24.0%)	2.46cm (26.0%)	2.85cm (25.0%)	3.15cm (27.3%)
24mm	1.05cm (36.4%)	1.46cm (33.8%)	1.91cm (30.3%)	2.07cm (37.9%)	2.27cm (40.1%)	2.83cm (34.9%)

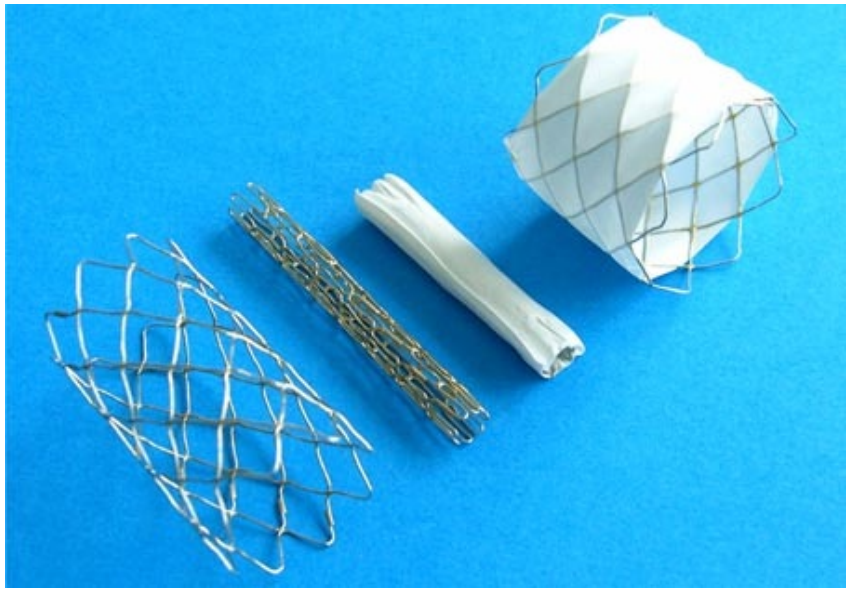
Covered stents

Use

- CoA
- Prevention and closure of vascular leaks
- Closure of TCPC fenestration

Numed CP-stent

- Un- and premounted
- 16 – 45 mm length
- Dilatable up to 24 mm



Covered stents

Premounted

Covered Stents, Advanta V12

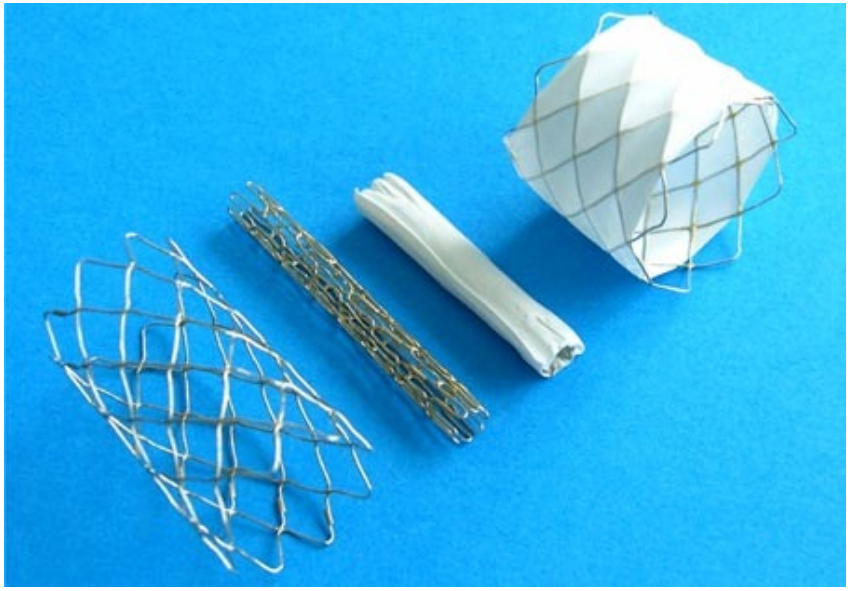
- Large Diameters 12,14 & 16 mm
- Lengths 29, 41 & 61 mm
- Low Profile
- 0,035” guidewire compatible
- Ability to post dilate to **22 mm**

- Diameter 5-7 mm,
- Lengths 16, 21, & 24 mm
- Ultra Low Profile
- 0.014” guidewire compatible
- Ability to post dilate to **8 mm**
- Superior deliverability in small vessels
- And tortuous anatomy

- Diameters 5-10mm
- Lengths 16, 22, 38 & 59 mm
- Low Profile
- 0.035” guidewire compatible
- Ability to post dilate to **12 mm**

Take Home Message

Covered stents



Use
- CoA
- Prevention and closure of vascular leaks
- Closure of TCPC fenestration

Numed CP-stent
- un- and premounted
- 16 – 45 mm length
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- premounted