



Absorb

Bioresorbable Vascular Scaffold System

Absorb In-Service



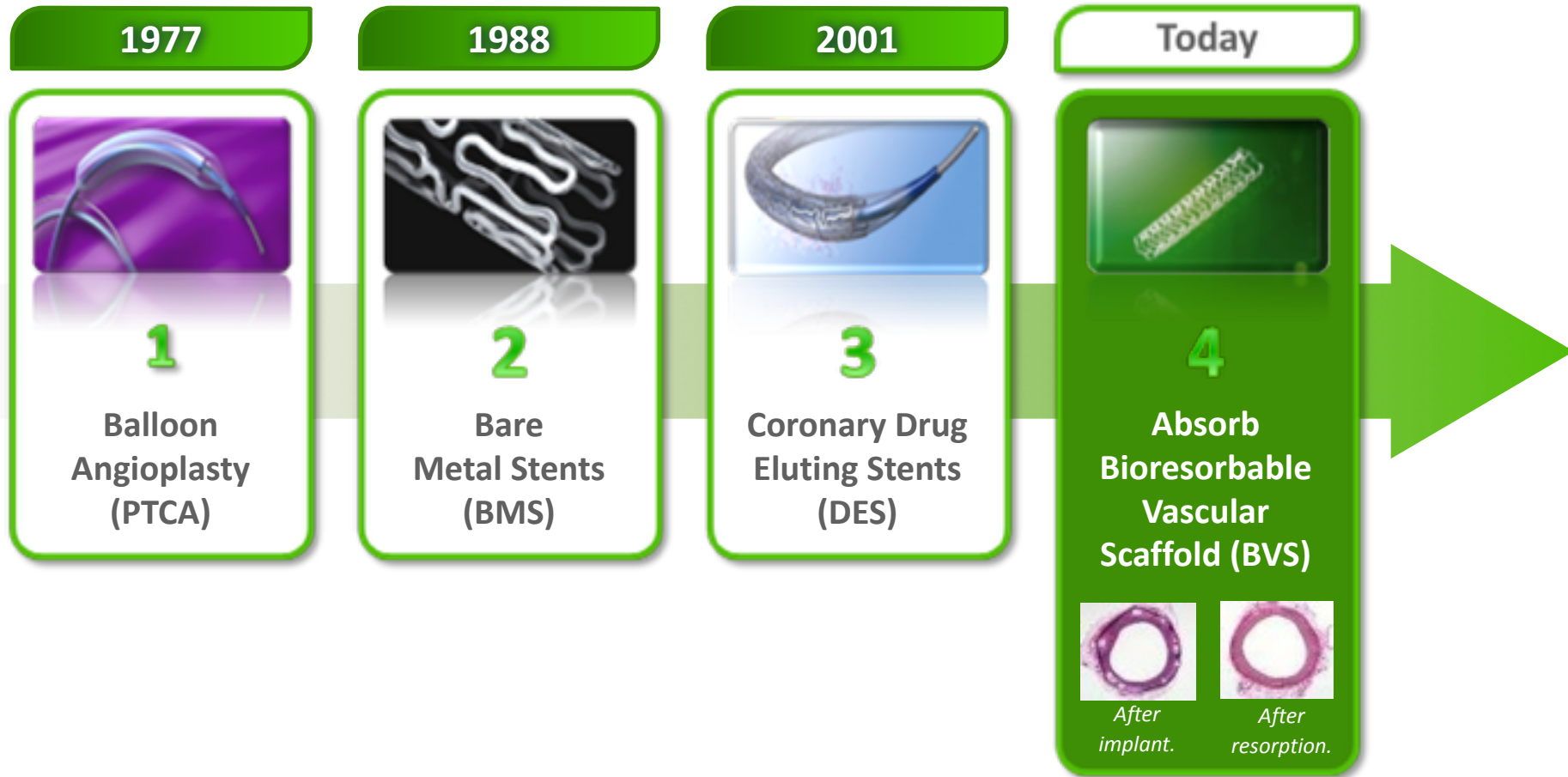
Please check the regulatory status of the device before distribution in areas where CE marking is not the regulation in force.
For presentation outside the U.S. and Japan only.



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AP2936982-OUS Rev. A

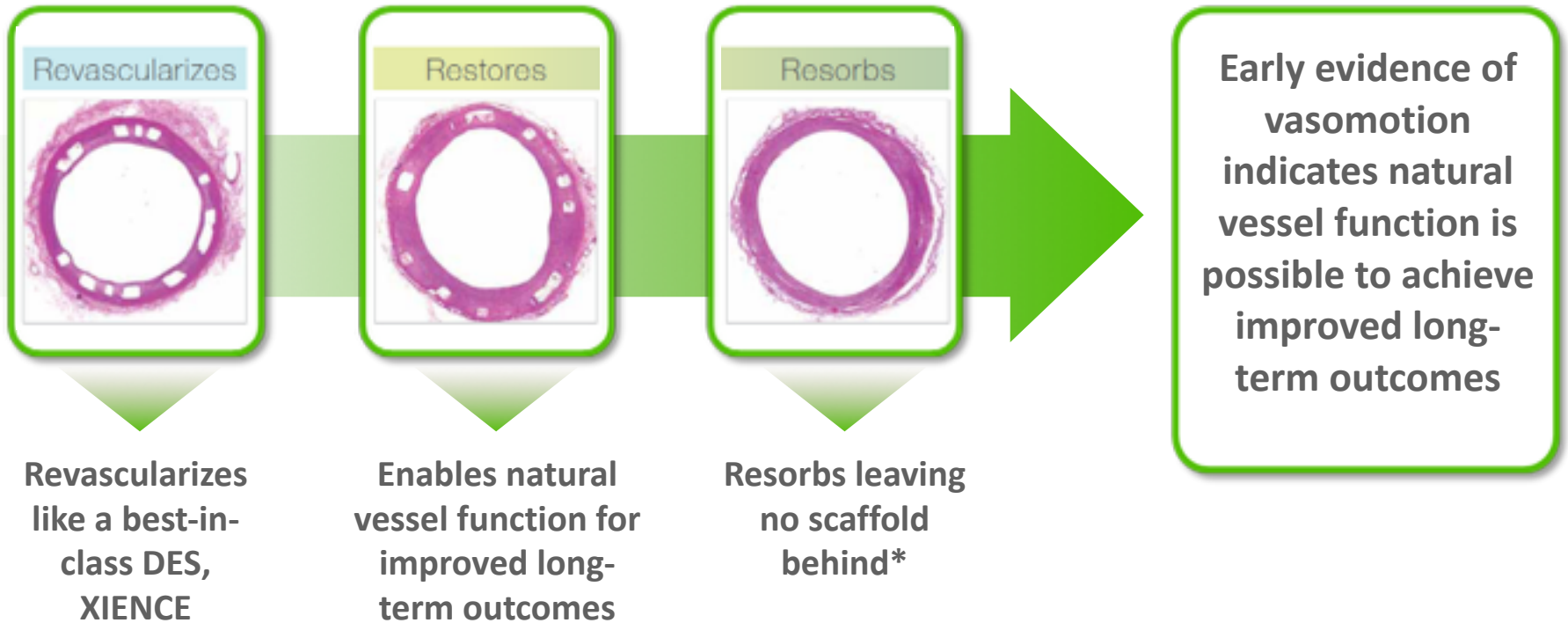


Absorb is the 4th Revolution in PCI therapy



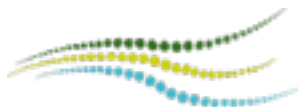
Data and images on file at Abbott Vascular. Histology images are from PORCINE animal models.

Absorb is a Novel Therapeutic Option Designed to Work in Three Phases

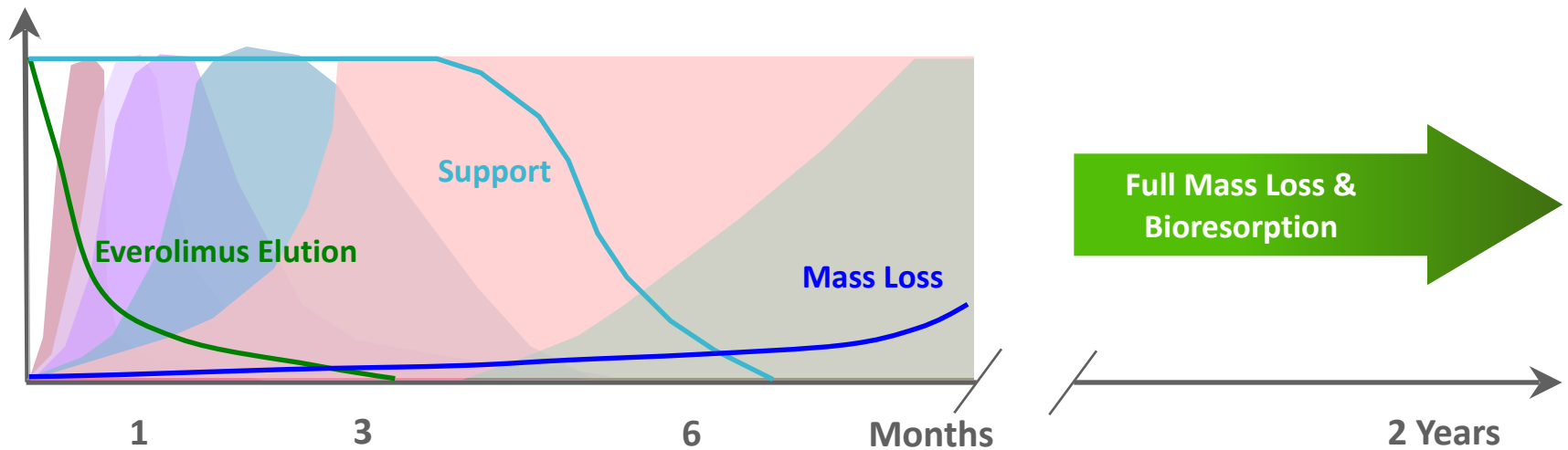


Vascular Reparative Therapy

*Small platinum markers at scaffold edges remain for fluoroscopic landmarking.
Data and images on file at Abbott Vascular. Histology images are from PORCINE animal models.

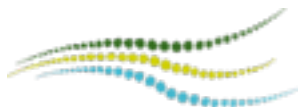


Absorb is a Novel Therapeutic Option Designed to Work in Three Phases



- Platelet Deposition
- Matrix Deposition
- Leukocyte Recruitment
- Re-endothelialization
- SMC Proliferation and Migration
- Vascular Function

Forrester JS, et al., J. Am. Coll. Cardiol. 1991; 17: 758. / Oberhauser JP, et al., EuroIntervention Suppl. 2009; 5: F15-F22.



Absorb Bioresorbable Vascular Scaffold System

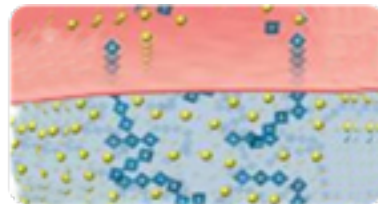
Bioresorbable Scaffold

- Poly (L-lactide) (PLLA)
- Based on proven MULTI-LINK pattern
- Naturally resorbed, fully metabolized*



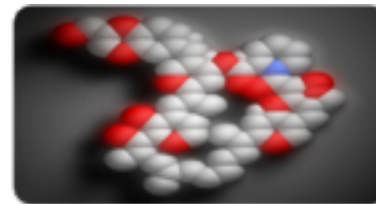
Bioresorbable Coating

- Poly (D,L-lactide) (PDLLA)
- Naturally resorbed, fully metabolized



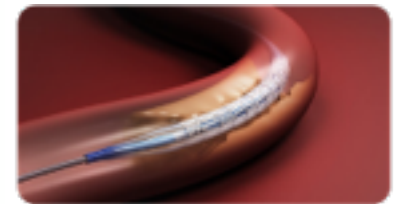
Everolimus

- Similar dose density and release rate to XIENCE V



XIENCE V Delivery System

- World-class deliverability



All illustrations are artists' renditions

*Except for platinum markers

The Clinical Need for a Bioresorbable Vascular Scaffold

Rationale

Vessel scaffolding is only needed transiently*

Vision

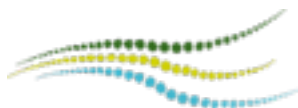
**Improve Long Term Outcomes for Patients
by Leaving No Scaffold Behind¹**

Potential Benefits

- **Restore the vessel to a more natural state, capable of natural vascular function**
- **Eliminate chronic sources of vessel irritation and inflammation**
- **Vessels remain free for future treatment options**
- **Reduce the need for prolonged DAPT²**
- **Allows for use of non-invasive imaging techniques (CCTA)**
- **Improve patient quality of life**

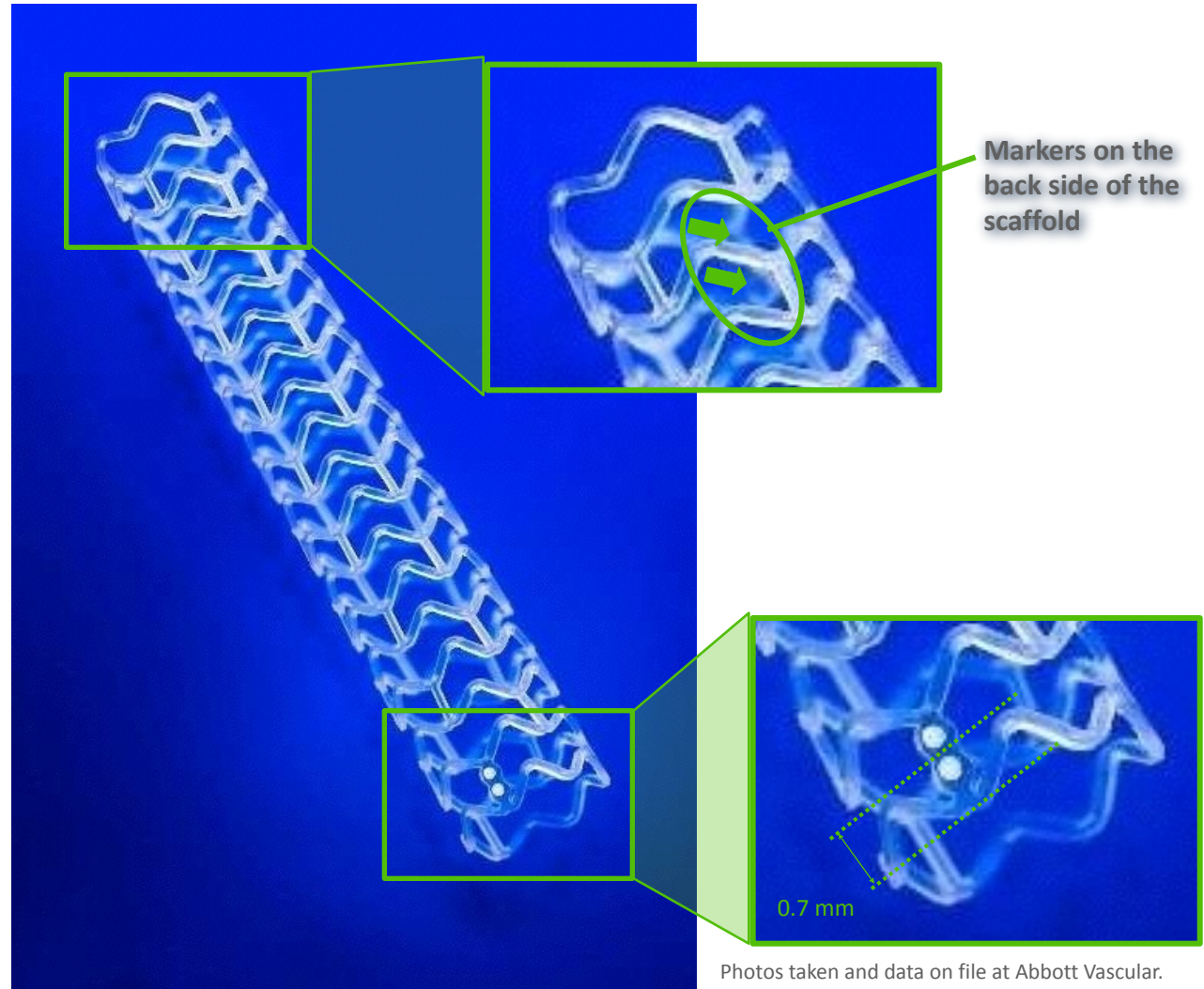
*Serruys PW, et al., Circulation 1988; 77: 361. Serial study suggesting vessels stabilize 3-4 months following PTCA.

1 – Small platinum markers at scaffold edges remain for fluoroscopic landmarking. 2. The Absorb IFU indicates DAPT for a minimum of 6 months.

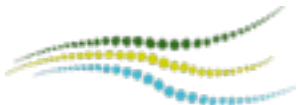


Scaffold Marker Beads

- There are two pairs of platinum marker beads – one pair at each end of the scaffold
- The markers on the scaffold are aligned with markers on the delivery catheter



NOTE: the struts are not visible under fluoroscopy



Guiding Catheter Compatibility

- **Guiding catheter compatibility:**

- **6F / 0.070"** / 1.8 mm minimum inner diameter (i.e., inner diameter must be ≥ 0.070 " / 1.8 mm)

NOTE: do not insert a 5-in-6, or a 6-in-7 GuideLiner into a 6F or 7F guiding catheter, as doing so will result in an inner diameter that is too small for use with the Absorb BVS:

- The 5-in-6 GuideLiner has an inner diameter of only 0.056"
- The 6-in-7 GuideLiner has an inner diameter of only 0.062"

NOTE: only the 7-in-8 GuideLiner provides an adequate inner diameter (0.071" ID), however, this device requires an 8F guiding catheter

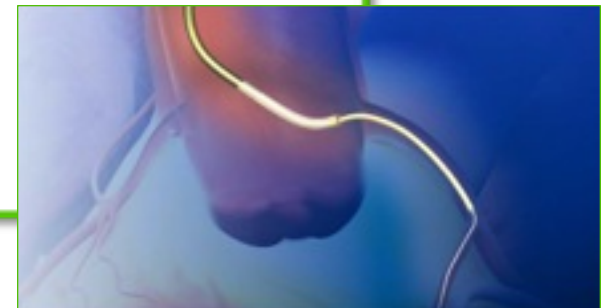
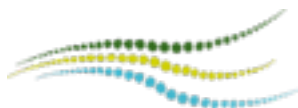


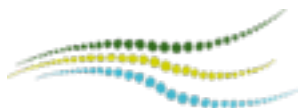
Image from Vascular Solutions website

For specific details refer to the Absorb IFU, Sections 10.4 and 10.5



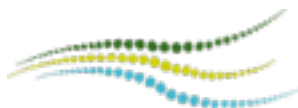
3 Ps for Optimal Implantation of Absorb

1. Proper Vessel Sizing
2. Preparation of the Lesion
3. Pay attention to Expansion Limits



#1 Proper Vessel Sizing

- Quantitative imaging is recommended for the assessment of target vessel diameter at baseline for appropriate Absorb BVS size selection.
- One of the following tools may be used:
 - QCA – utilizing the D_{\max} technique
 - IVUS
 - OCT
- It is recommended to administer a standard dose of intracoronary nitroglycerin prior to finalizing the reference vessel sizing within the treatment zone



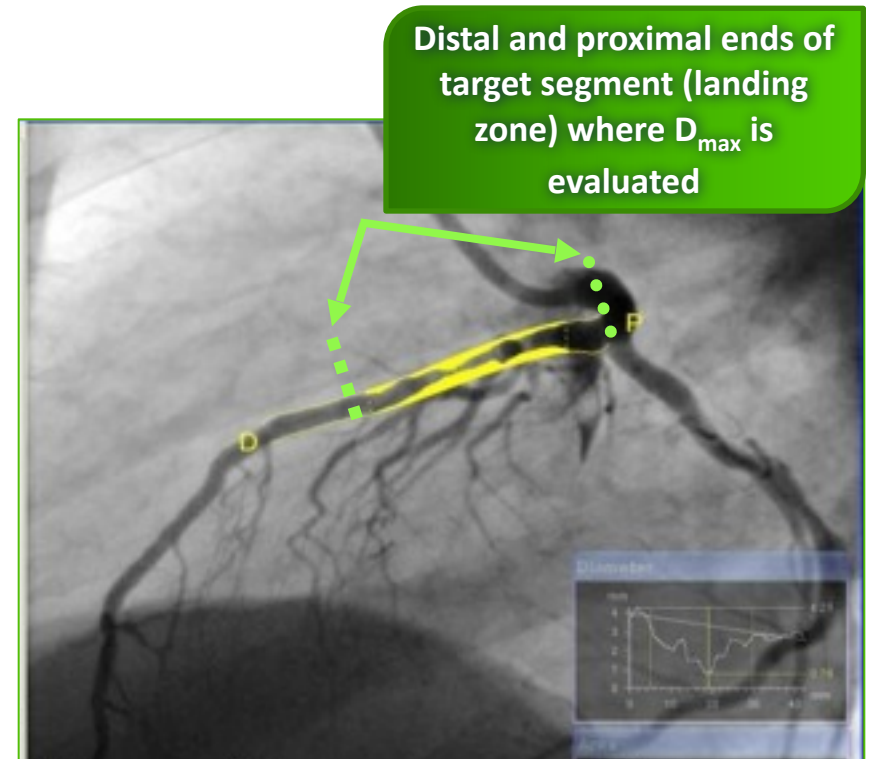
#1 Proper Vessel Sizing

Vessel Sizing Using On-line QCA (D_{max})

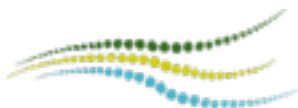
- Measure the vessel diameter using the on-line QCA parameters distal D_{max} and proximal D_{max} :
 - The maximum lumen diameter evaluated at the distal and proximal ends of the target segment to be scaffolded, respectively.

Target Vessel Diameter	Absorb BVS Size to be Used
≥ 2.0 mm and ≤ 3.0 mm	2.5 mm
≥ 2.5 mm and $\leq 3.3^*$ mm	3.0 mm
≥ 3.0 mm and $\leq 3.8^*$ mm	3.5 mm

[Watch Video \(click here\)](#)



*Allows for 1.1:1 scaffold:artery sizing without exceeding expansion limit



#1 Proper Vessel Sizing

Vessel Sizing Using IVUS

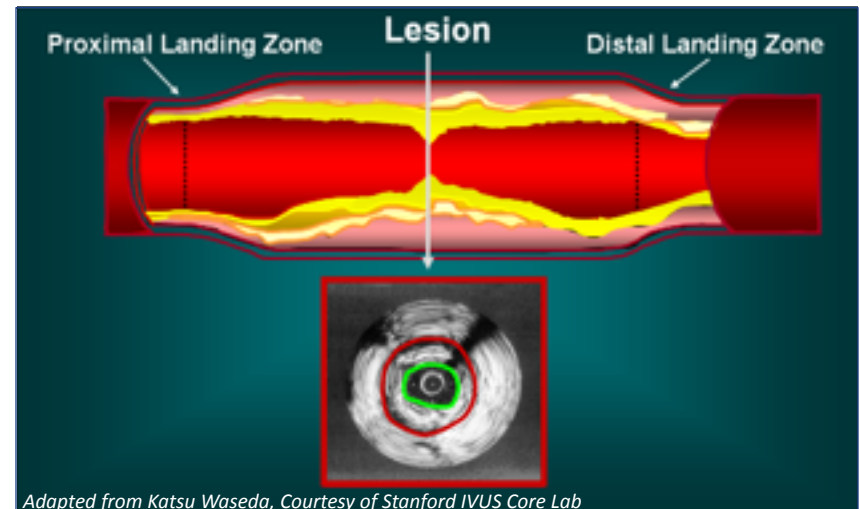
- Lumen diameter should be measured within the proximal and distal landing zone for the scaffold
 - Max-LD_{prox} AND Max-LD_{dist} must be within the upper and lower limits specified for the scaffold size

Target Vessel Diameter

Absorb BVS Size to be Used

≥ 2.0 mm and ≤ 3.0 mm	2.5 mm
≥ 2.5 mm and ≤ 3.3* mm	3.0 mm
≥ 3.0 mm and ≤ 3.8* mm	3.5 mm

Watch Video (click here)

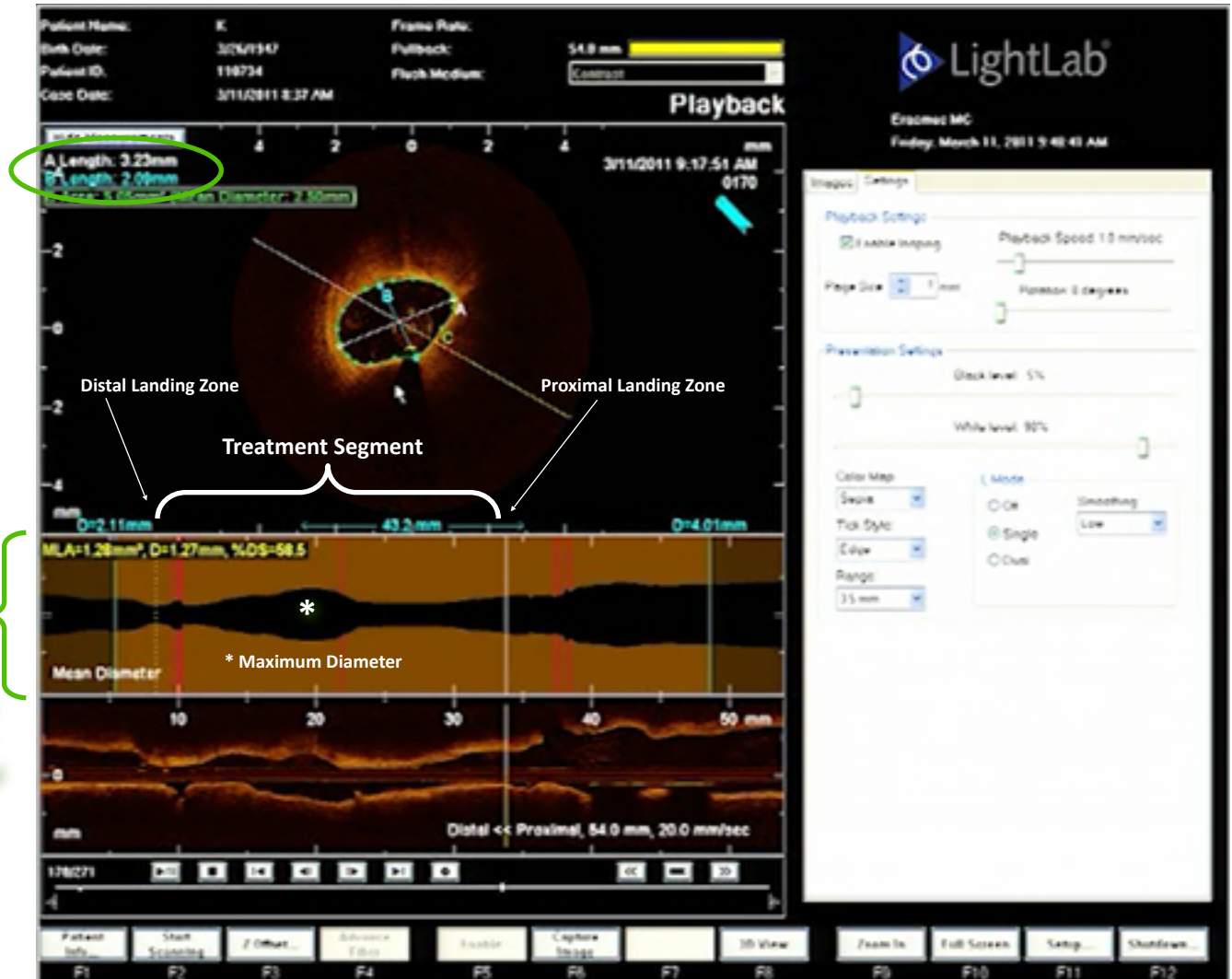


*Allows for 1.1:1 scaffold:artery sizing without exceeding expansion limit

#1 Proper Vessel Sizing

Vessel Sizing Using OCT

Lumen diameter measurements
(in this case at the Proximal Landing Zone)

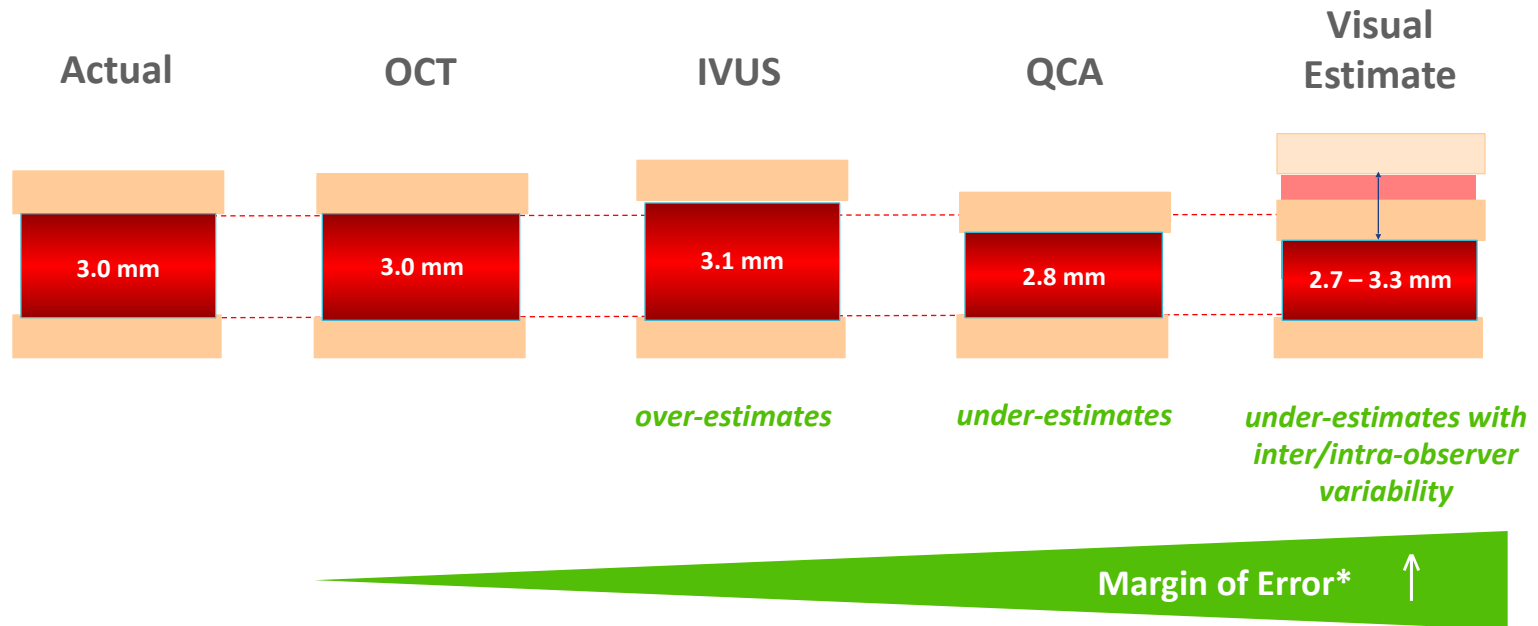


Graphical contour map
of the vessel lumen

(maximum lumen diameter should be measured within the treatment segment, including the proximal and distal landing zones)

#1 Proper Vessel Sizing

Limitations of Various Vessel Sizing Techniques



Recognize the risk of under-estimating vessel size by visual estimation

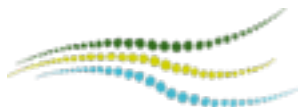
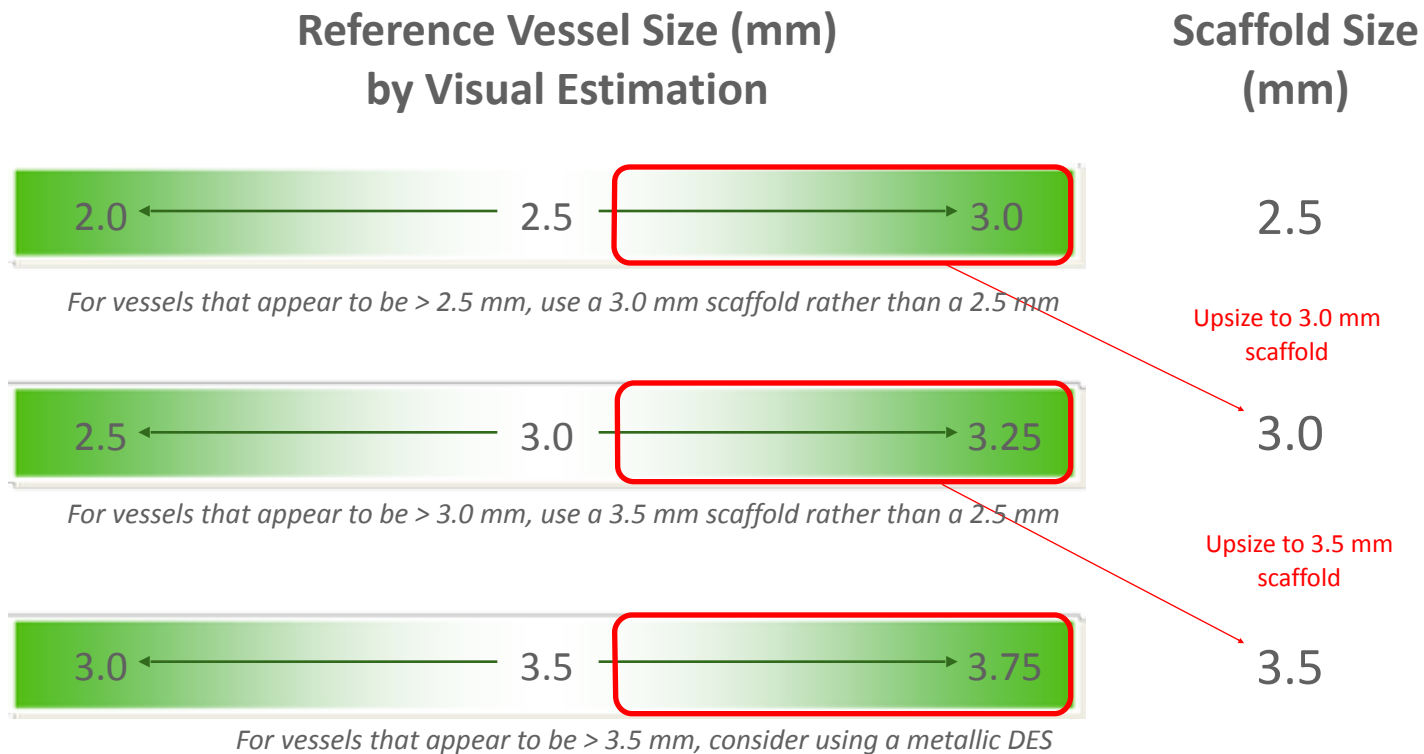
Use pre-dilatation to help guide and confirm vessel size

*Margin of error estimates based on resolution for each imaging modality:
Resolution of OCT and IVUS: Bezerra, H.G., J Am Coll Cardiol.: Cardiovasc Interv. 2009; 2: 1035.
Resolution of QCA: Dahm, J. and van Buuren, F. Int J Vasc Med. 2012.
Offset and variability of visual estimate: data on file at Abbott Vascular.

Vessel Sizing Alternative

When Visual Estimation of Vessel Size is Necessary

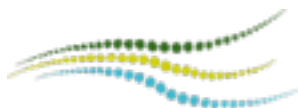
- Recognize the risk of under-estimating vessel size by visual estimation



#2 Preparation of the Lesion

- **Assess the vessel proximal to the target lesion to ensure smooth delivery to the lesion.**
 - It is not recommended to treat patients having excessive tortuosity proximal to or within the lesion.
- **Predilatation is strongly recommended.**
 - Choose a predilatation balloon that is shorter than the scaffold length.
 - Choose a balloon diameter that matches the RVD.
 - Predilatation may be useful to help determine vessel size.
- **Confirm full expansion of the predilatation balloon – do not treat patients with a greater than 40% residual stenosis after predilatation (i.e., heavily calcified lesions)**
 - More extensive lesion preparation may be required to modify resistant plaque.
- **An unexpanded scaffold should not be reintroduced into the artery once it has been pulled back into the guiding catheter or removed from the body.**

This is consistent with the Absorb IFU, Section 6.2 and 10.6



#3 Pay Attention to Expansion Limits

- When expanding the scaffold, be sure to stay within the expansion limits of the device:

Nominal Scaffold Diameter	Maximum Dilatation Limit
2.5 mm	3.00 mm
3.0 mm	3.50 mm
3.5 mm	4.00 mm

CAUTION: Do not dilate the scaffold beyond the maximum dilatation limit. Expansion beyond the dilatation limits listed above, may result in scaffold damage.

This is consistent with the Absorb IFU, Section 10.7

#3 Pay Attention to Expansion Limits: Bifurcation Lesions

- Avoid scaffolding across any side branch ≥ 2.0 mm
- Side branches should only be dilated when clinically indicated
 - Infarction (e.g. ECG Abnormalities)
 - Arrhythmias
 - Chest Pain
 - $\geq 70\%$ diameter stenosis in the ostium of the side branch
 - **Physicians may opt to utilize the sequential side branch access technique¹** for unanticipated side branch closure, **ONLY** if flow **MUST** be restored to the side branch, as follows:
 - First, dilate the side branch **ONLY**, using the smallest balloon possible to re-establish flow
 - Second, dilate the main branch **ONLY**, with the delivery catheter, or appropriately sized post-dilatation balloon
- **Do not use post-dilatation kissing balloon technique***

*Kissing balloon technique is considered off-label and techniques referenced must be indicated by physician only.

¹Foin, N., et al. J Am Coll Cardiol Intv. 2012; 5: 47-56.

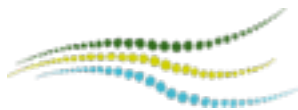
Expansion Patience While Inflating

- Deploy the scaffold slowly by pressurizing the delivery system in 2 atm increments every 5 seconds, until the scaffold is completely expanded.
- Maintain pressure for 30 seconds.
 - If necessary, the delivery system can be deflated and re-pressurized or further pressurized to ensure complete apposition of the scaffold to the artery wall.

Do not exceed RBP of the balloon or maximum deployment diameter of the scaffold.



This is consistent with the Absorb IFU, Section 10.7



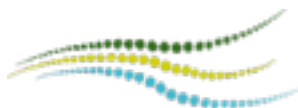
#3 Pay Attention to Expansion Limits: Post-dilatation Guidelines

- Under-deployment of the device may result in malapposition
- If the initial angiographic appearance is suboptimal, the scaffold may be further expanded using a low profile, high-pressure, noncompliant balloon dilatation catheter.
- Use the following guidance for the maximum diameter of the noncompliant post-dilatation balloon:

Scaffold Size	Maximum Noncompliant Balloon Diameter	Post-Dilatation Limit
2.5 mm	2.75 mm	3.0 mm
3.0 mm	3.25 mm	3.5 mm
3.5 mm	3.75 mm	4.0 mm

- With proper lesion preparation and vessel sizing, post-dilatation may not be required; avoid unnecessary post-dilatation

This is consistent with the Absorb IFU, Section 10.7



Re-crossing a Deployed Scaffold

- **If difficulty is encountered when re-crossing a deployed Absorb scaffold, consider the following:**
 - Minimize guidewire bias; gentle backward force on the guidewire as devices are being advanced will center the wire and minimize wire bias
 - If resistance is encountered due to catching on struts, avoid forceful pushing, instead try one of the following:
 - Winging the balloon (inflate/deflate) may help centralize the balloon tip
 - Change the angle of introduction by manipulating the guide catheter
 - Use a buddy wire or wiggle wire

Derived from Whitbourn, R., ABSORB EXTEND Investigator Meeting

Summary – the Do's and Don'ts

- **Do:**

- Properly and carefully size the vessel
- Prep the lesion thoroughly
- Pay attention to expansion limits

- **Don't:**

- Treat bifurcations with side branches ≥ 2.0 mm...and never use the kissing balloon technique*
- Post-dilate unnecessarily...and never beyond the expansion limits
- Re-insert the device after it has been removed from the body
- Push against resistance during delivery, or when passing other catheters through a deployed scaffold

*Kissing balloon technique is considered off-label and techniques referenced must be indicated by physician only.

