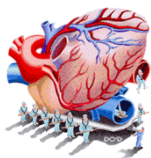


## Dove serve lo stent ?

- 
- ① Infarto miocardico acuto (STEMI)
  - ② Sindrome coronarica acuta
  - ③ Shock
  - ④ Cardiopatia ischemica cronica
    - a. angina stabile
    - b. ischemia silente
    - c. IMA progressivo
    - d. Coronarosclosi
    - e. Angina microvascolare
    - f. Etc etc.



# 2014 ESC guidelines on myocardial revascularization

## Indications for revascularization in patients with stable angina or silent ischaemia

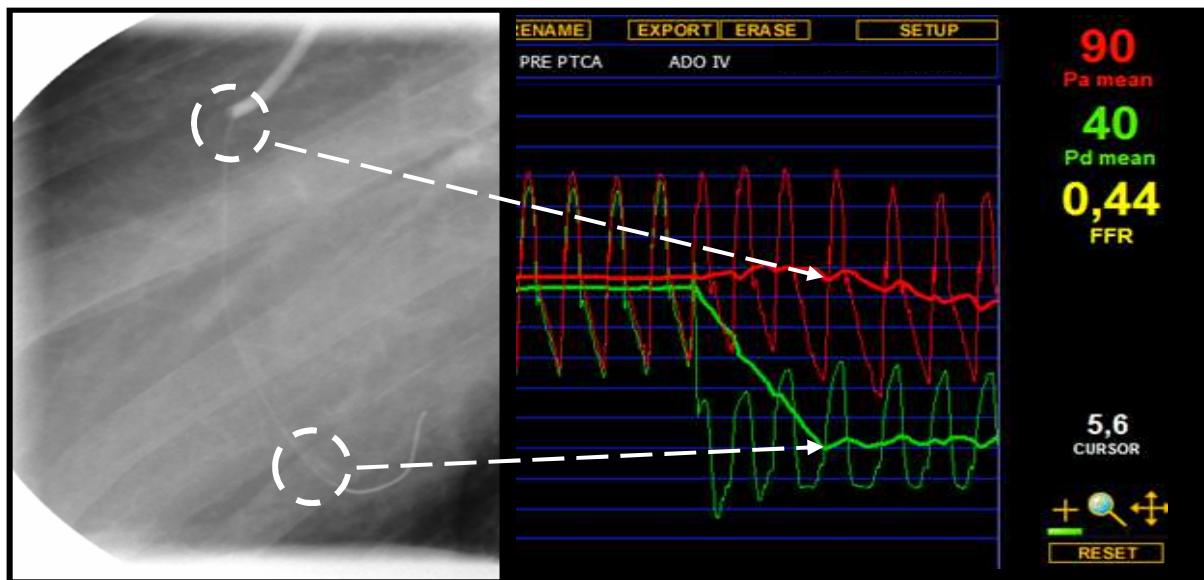
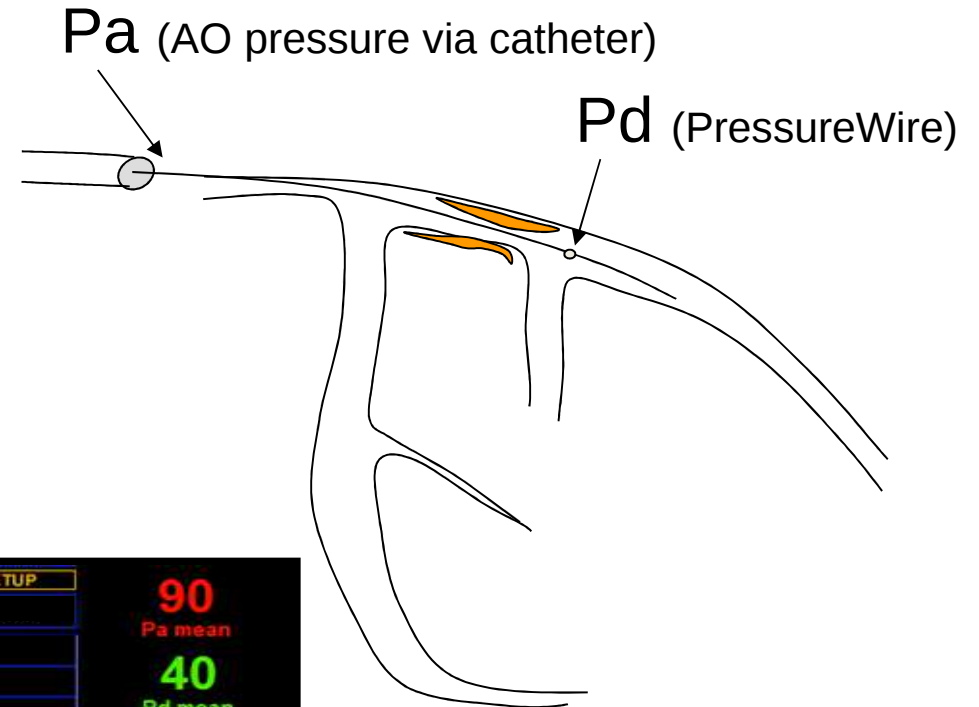
| Extent of CAD (anatomical and/or functional) |                                                                                                                                  | Class <sup>b</sup> | Level <sup>c</sup> | References                    |
|----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|-------------------------------|
| For prognosis                                | Left main disease with stenosis >50% <sup>a</sup>                                                                                | I                  | A                  | 108,134,135                   |
|                                              | Any proximal LAD stenosis >50% <sup>a</sup>                                                                                      | I                  | A                  | 94,108,135,136                |
|                                              | Two-vessel or three-vessel disease with stenosis > 50% <sup>a</sup> with Impaired LV function (LVEF<40%) <sup>a</sup>            | I                  | A                  | 93,94,108,112,121,135,137–142 |
|                                              | Large area of Ischaemia (>10% LV)                                                                                                | I                  | B                  | 54,91,97,99,143,144           |
|                                              | Single remaining patent coronary artery with stenosis >50% <sup>a</sup>                                                          | I                  | C                  |                               |
| For symptoms                                 | Any coronary stenosis >50% <sup>a</sup> in the presence of limiting angina or angina equivalent, unresponsive to medical therapy | I                  | A                  | 54,96,105,108,118–120,145     |

**LARGE AREA OF ISCHEMIA (>10% LV)**

# FRACTIONAL FLOW RESERVE

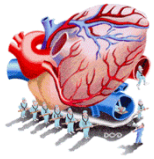
gold standard of ischemia assessment in cath lab

$$FFR = \frac{Pd}{Pa}$$



$FFR_{myo} = \frac{Pd}{Pa}$   
at hyperemia

$$FFR_{myo} = \frac{40}{90} = 0.44$$



# Intervention or not ?

**FFR on all angiographic stenosis > 50%**

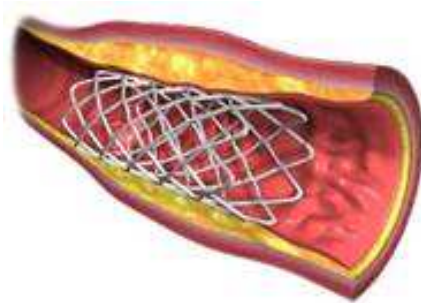
**PCI / revascularization**

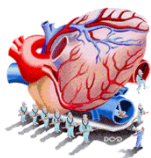
**Optimal medical therapy**

**0**

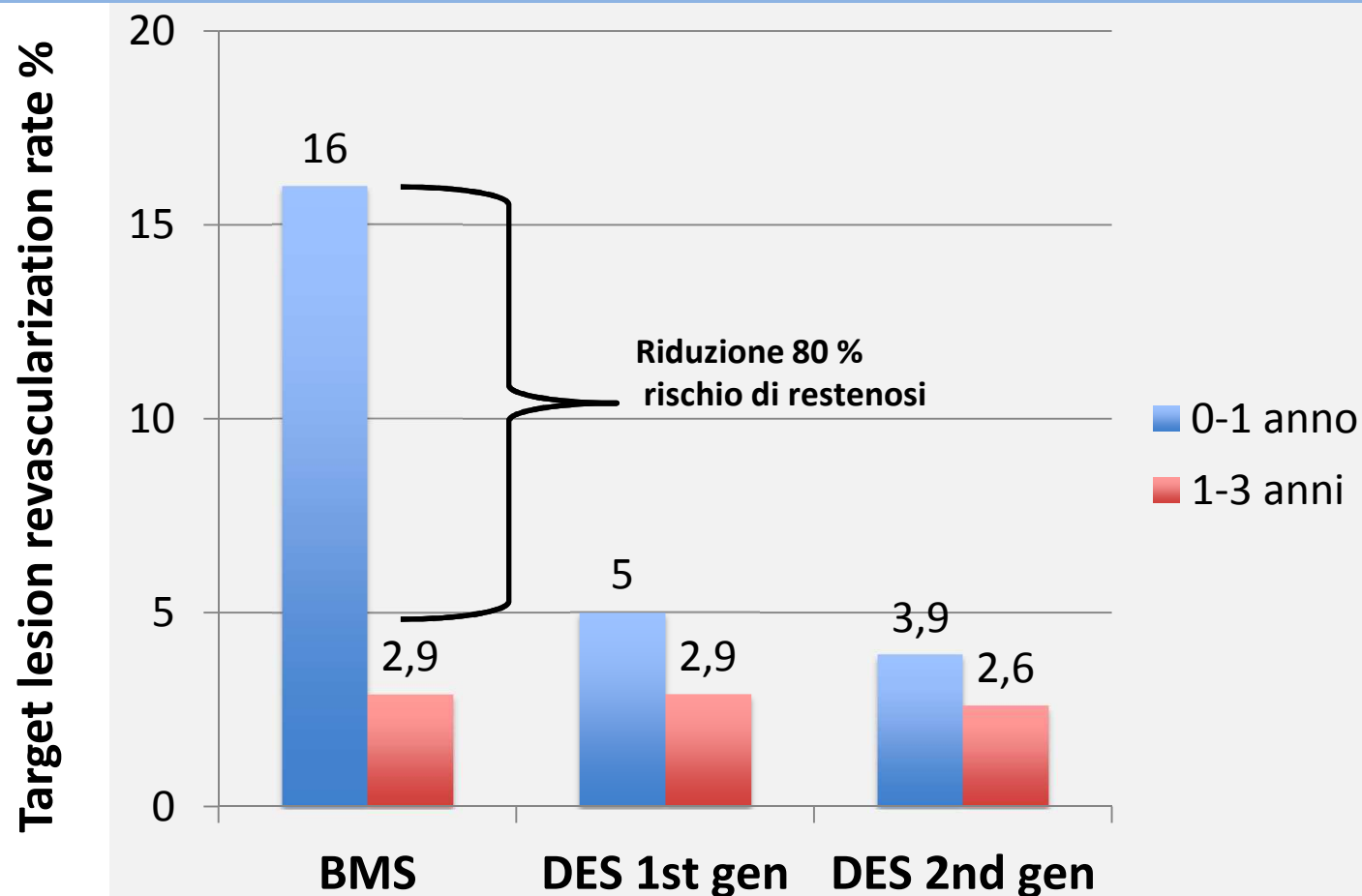
**0.75 0.80**

**1.0**

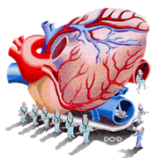




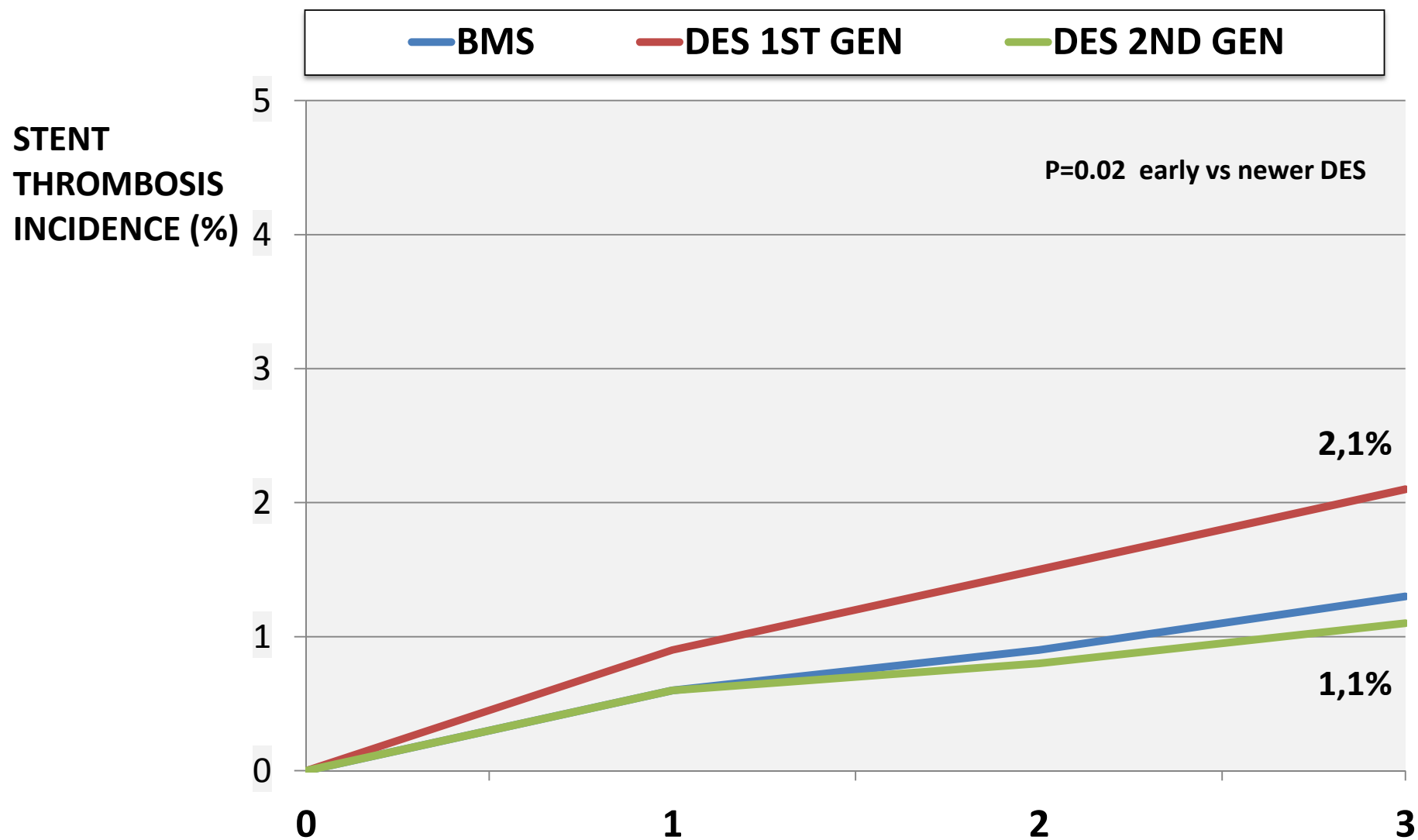
# EFFICACIA CLINICA

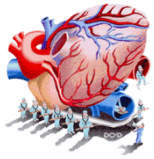


**Progressione dell'efficacia clinica con innovazione degli stent nel tempo: rivascularizzazione ripetuta.**



# Innovazione tecnologica IMPATTO SU SICUREZZA CLINICA





# SCAFFOLD BIORASSORBIBILI (BVS)

*Absorb Represents the 4th Revolution in PCI*

1977

Andreas Gruentzig performs the first PTCA in Zurich, Switzerland



Balloon  
Angioplasty  
(PTCA)

1988

Julio Palmaz and Richard Schatz develop a stainless steel stent for coronary applications



Bare  
Metal Stents  
(BMS)

2001 - 2003

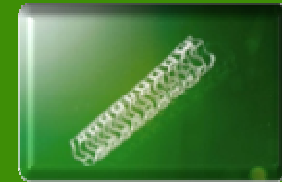
Drug-eluting stents are introduced to the European and U.S. markets



Coronary Drug  
Eluting Stents  
(DES)

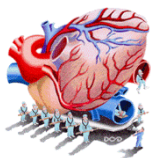
2006

First in man BVS implantation



Absorb  
Fully  
Bioresorbable  
Vascular  
Scaffold (BVS)

Advancements in PCI

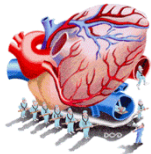


# Qual'è il senso originale della parola SCAFFOLD?

Esecuzione per impiccagione?

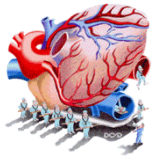
Impalcatura temporanea che può essere rimossa dopo aver riparato la casa?





# BVS under investigation

|             |                                                                                      |                         |                                                                                       |
|-------------|--------------------------------------------------------------------------------------|-------------------------|---------------------------------------------------------------------------------------|
| AMS 1       |    | DESolve                 |    |
| DREAMS 1    |    | AMARANTH                |    |
| DREAMS 2    |    | ART18Z<br>(ART 2nd Gen) |    |
| IGAKI-TAMAI |    | MIRAGE                  |    |
| BVS 1.0     |   | FANTOM                  |   |
| BVS 1.1     |  | QUALIMED                |  |
| ReZolve     |  | XINSORB                 |  |



# Absorb BVS: Design Components

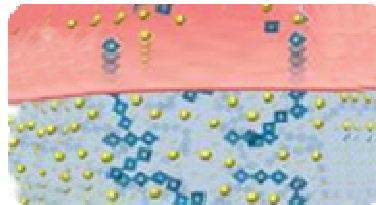
## Bioresorbable Scaffold

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



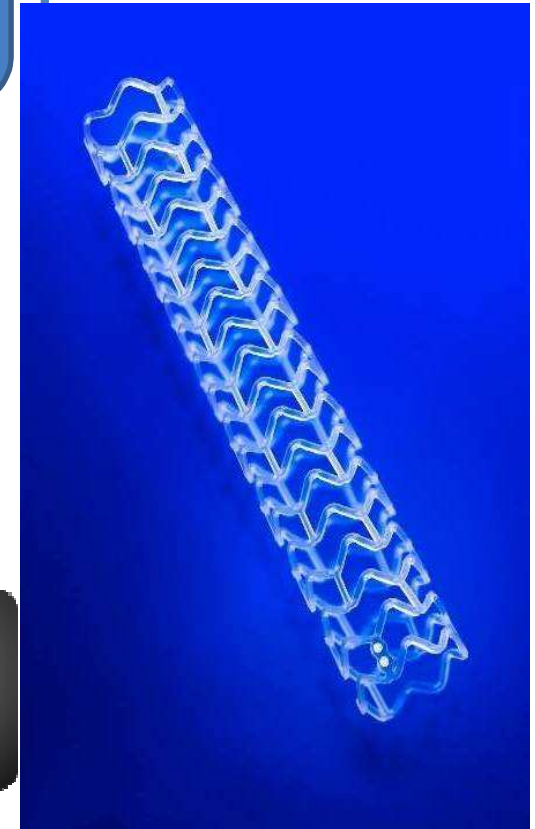
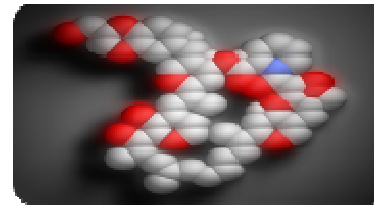
## Bioresorbable Coating

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

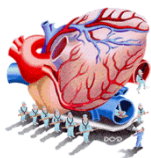


## Everolimus

- Similar dose density and release rate to XIENCE V



\*Except for platinum markers



# Resorption: Vascular Response in a Porcine Model

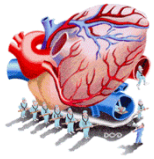
**Absorb BVS**

**Resorption Site**

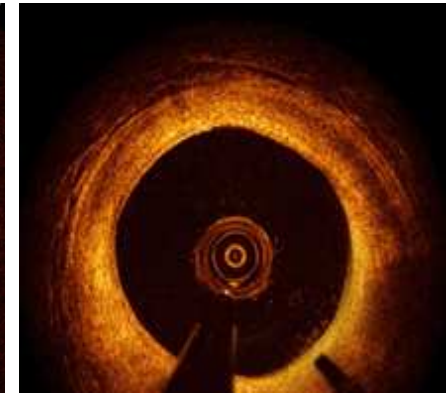
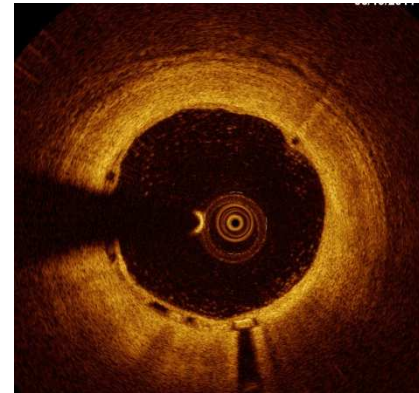
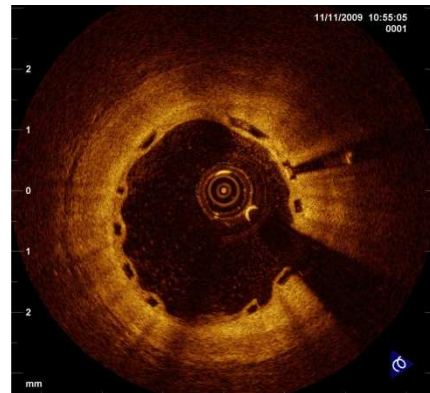
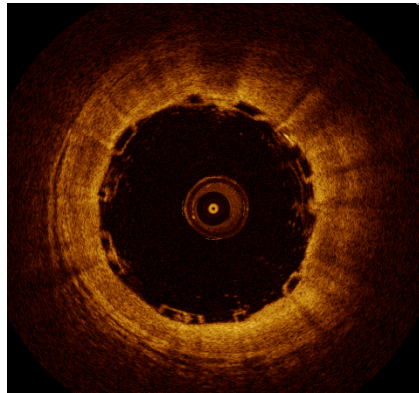
Polymer is replaced by an increasingly cellular provisional matrix



**XIENCE V**



# The Bioresorbable Scaffold is a Template for Vessel Healing



**Baseline**



**6 months**



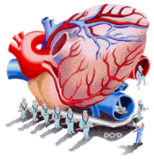
**2 Years**



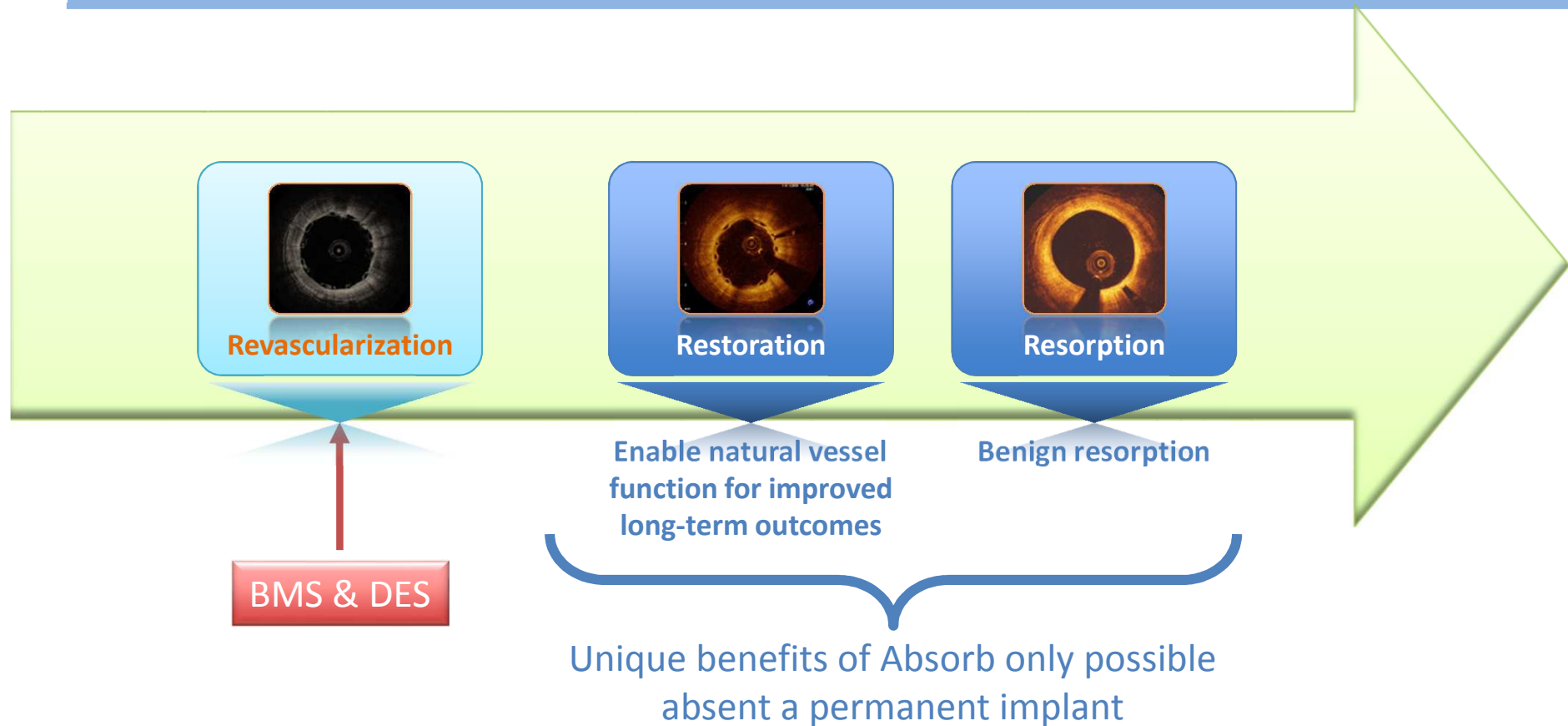
**5 Years**

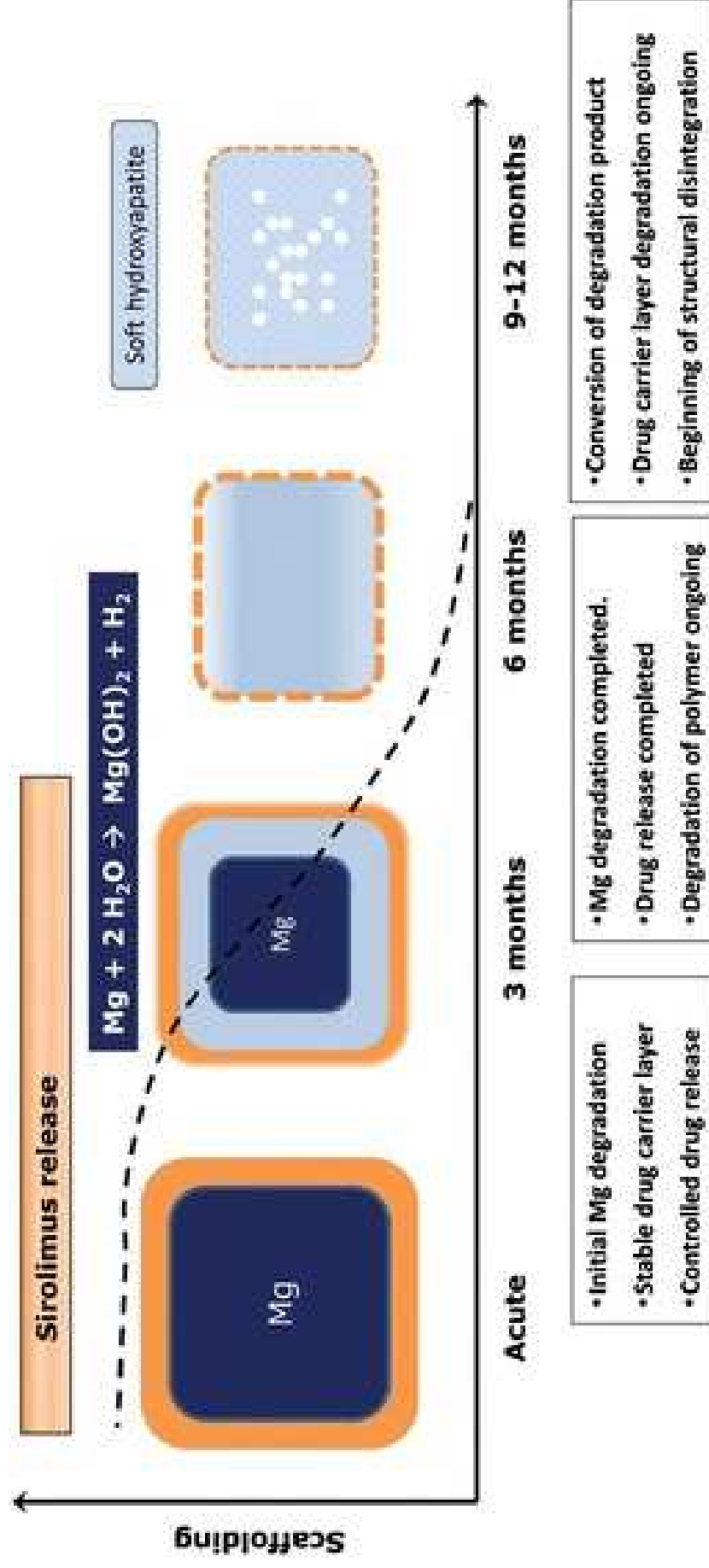
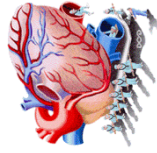
Smooth muscle cells fill the spaces between the framework of the scaffold's template

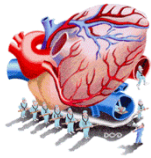
Restored physiologic environment drives structural and functional changes toward a stable neomedia



# Absorb is Different than DES







# Scaffold bioriassorbibili

un nuovo target nella terapia della malattia coronarica

## POTENZIALI VANTAGGI del riassorbimento:

- ① Ripristino della fisiologica funzione del vaso: vasomotricità, rimodellamento di accomodamento....
- ② Abolizione di uno stimolo pro-infiammatorio cronico indotto dal metallo o dal polimero.
- ③ Liberazione della coronaria dal metallo per un futuro gesto chirurgico di bypass.
- ④ Liberazione di una biforcazione (o un ostio) con accesso fisiologico al collaterale
- ⑤ Ricanalizzazione del vaso quando serve e poi scomparsa quando non più utile (es. dissezioni coronariche).

# Documento di consenso su utilizzo dei BVS all'interno del Laboratorio di Emodinamica dell'Ospedale di Parma – Aprile 2015 – versione finale

Stante il ridotto numero di BVS stanziati dalla regione per la nostra AO (n=25, fino a Febbraio 2016) appare opportuno definire un consenso condiviso riguardante le indicazioni di utilizzo degli stessi (che siano allineate ovviamente alle vigenti direttive regionali), in modo da garantire *trasparenza* all'accesso al nuovo dispositivo da parte dell'utenza e *appropriatezza* all'utilizzo del medesimo.

Le **indicazioni cliniche** sono le seguenti:

1. UA/NSTEMI
2. cardiopatia ischemia stabile

**Indicazioni angiografiche:**

- stenosi, non severamente calcifica, della Discendente Anteriore al tratto medio-distale (diametro di riferimento 2.5-3.8 mm) in paziente sotto 70 anni, se possibile candidato futuro ad intervento di CABG.
- rivascolarizzazione completa in paziente < 45 anni.
- dissezione coronarica spontanea.

Stenosi calcifiche, CTO e biforcazioni, pur rappresentando un possibile campo di interesse futuro, sono da considerarsi come *non ideali*.

**Controindicazioni assolute:**

- Paziente non candidato all'utilizzo di un DES
- Vaso con diametro di riferimento <2,5 o >4.0 mm