BIORESORBABLE SCAFFOLDS (BRS): THE 2026 RESURRECTION AND CURRENT STATUS

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I THE RATIONALE: "LEAVE NOTHING BEHIND"

- **The Core Concept:** A **Bioresorbable Scaffold (BRS)** provides transient mechanical radial support and antiproliferative drug elution for **3 to 12 months** during the acute phase of vessel recoil and neointimal healing, and then completely resorbs—leaving the native coronary artery uncaged.
- **Theoretical Long-Term Benefits:**
  - **Restoration of Physiological Vasomotion:** Uncages the vessel to restore cyclic pulsatility, adaptive shear-stress remodeling, and endothelial vasomotion.
  - **Preservation of Future Revascularization Options:** Avoids a permanent "full metal jacket," preserving distal anastomotic targets for future **CABG** and eliminating permanent side-branch jailing.
  - **Non-Invasive Imaging Compatibility:** Eliminates metallic blooming artifacts on follow-up **Coronary CT Angiography (CCTA)**.

II FIRST-GENERATION FAILURE: LESSONS FROM ABSORB BVS

- **Clinical Failure (ABSORB II, III, and AIDA Trials):** The first-generation **Absorb Bioresorbable Vascular Scaffold**—constructed from **poly-L-lactic acid (PLLA)** eluting everolimus—was withdrawn globally in 2017 after randomized trials and meta-analyses demonstrated **higher Target Lesion Failure (TLF)** and a **2- to 3-fold higher rate of definite/probable Device Thrombosis** (both early and very late, between 1 and 3 years) compared with thin-strut metallic **everolimus-eluting stents (Xience)**.
- **Three Root Causes of First-Generation Failure:**
  - **Thick, Wide Struts (157 micrometers):** Nearly double the thickness of contemporary metallic DES (60 to 80 micrometers), causing endothelial shear-stress disturbance, platelet activation, delayed endothelialization, and severe lumen loss when implanted in small vessels (reference diameter less than 2.25 to 2.50 mm).
  - **Suboptimal Implantation Technique:** Early trials implanted scaffolds without routine 1:1 pre-dilation, intravascular imaging sizing, or high-pressure post-dilation.
  - **Intraluminal Scaffold Dismantling:** During slow hydrolytic degradation of PLLA (taking 36 to 42 months), loss of structural integrity caused malapposed or discontinuous polymer struts to prolapse into the vessel lumen, triggering **very late scaffold thrombosis**.

III SECOND- AND THIRD-GENERATION ADVANCES

- **Thin-Strut Polymeric Scaffolds (Sub-100 Micrometers):** Second-generation PLLA scaffolds—such as the Indian-engineered **MeRes100** (sirolimus-eluting PLLA scaffold with **100-micrometer** strut thickness and hybrid closed/open cells, resorbing in 24 to 36 months) and **Fantom** (desaminotyrosine polycarbonate, 125 micrometers)—markedly reduce flow separation and thrombogenicity.
- **Resorbable Magnesium Scaffolds (Magmaris to Freesolve [DREAMS 3G]):**
  - **Magmaris (DREAMS 2G):** First-generation sirolimus-eluting magnesium scaffold (150-micrometer struts; 95 percent resorbed into amorphous calcium phosphate within 12 months).
  - **Freesolve (DREAMS 3G — BIOMAG-I Trial):** Next-generation sirolimus-eluting **BIOMAG magnesium alloy** scaffold featuring **thinner struts (99 to 147 micrometers)**, higher radial strength (minimizing late recoil), and **complete 99.6 percent resorption at 12 months**.
  - **Iron-Based Scaffolds:** Ultrathin nitrided-iron bioresorbable scaffolds (**IBS**, 53-micrometer struts) provide metallic DES-like radial strength and trackability.

Scaffold Generation & Name	Backbone Material	Strut Thickness	Complete Resorption Time	Key Clinical Trial / Registry Evidence
Absorb BVS (1st Gen — Withdrawn)	Poly-L-lactic acid (PLLA)	**157 um**	36–42 months	**ABSORB III & AIDA:** 2–3x higher scaffold thrombosis vs. Xience (**ESC Class III**)
MeRes100 (2nd Gen Polymer)	Sirolimus-eluting PLLA	**100 um**	24–36 months	**MeRes-1 & MeRes-1 Extend:** 0% scaffold thrombosis and 1.87% MACE at 3 years
Magmaris / DREAMS 2G (Metal)	Sirolimus-eluting Magnesium	**150 um**	~12 months (95%)	**BIOSOLVE-IV Registry:** Low scaffold thrombosis (0.5–0.7%) in simple lesions
Freesolve / DREAMS 3G (3rd Gen Metal)	Sirolimus-eluting **BIOMAG Magnesium**	**99–147 um**	**12 months (99.6%)**	**BIOMAG-I Trial (2023/2024):** Low late lumen loss and no scaffold thrombosis at 12 months

IV THE MANDATORY "PSP" IMPLANTATION PROTOCOL

- **Why PSP is Essential (ABSORB IV & Pooled PSP Analyses):** Post-hoc analyses and the **ABSORB IV Trial** demonstrated that strict adherence to the **PSP (Prepare, Size, Post-dilate) Protocol** plus excluding small vessels (<2.25–2.50 mm) reduces scaffold thrombosis by **up to 70 percent**:
- **P — Prepare the Lesion (Pre-Dilation):** Aggressive predilation using a **1:1 vessel-sized non-compliant balloon** (or scoring/cutting balloon); the scaffold must not be implanted unless full balloon expansion with less than 30 percent residual stenosis is achieved.
- **S — Size Appropriately (Mandatory Intravascular Imaging):** Reference vessel diameter must be measured between **2.50 mm and 3.75 mm** (strictly avoiding vessels smaller than 2.50 mm), guided by **OCT or IVUS** rather than visual estimation.
- **P — Post-Dilate at High Pressure:** Mandatory post-dilation using a **Non-Compliant (NC) balloon at 16 to 20+ atm** sized up to **0.25 to 0.50 mm larger** than the nominal scaffold diameter (never exceeding the maximum expansion limit of a polymeric scaffold to avoid strut fracture).

V CLINICAL EVIDENCE AND CURRENT GUIDELINE STATUS

- **Current Guideline Stance (ESC Revascularization Guidelines):** Following the failure of first-generation Absorb BVS, the ESC Guidelines assigned a **Class III (Level C) recommendation against the routine clinical use of first-generation bioresorbable scaffolds outside of clinical studies**.
- **Contemporary Niche Indications (Investigational / Selected Use of Newer-Generation BRS):**
  - **Lesion Profile:** Discrete, *de novo*, non-ostial, non-calcified or mildly calcified lesions in **vessels 2.50 to 3.75 mm in diameter** (excluding left main, true bifurcations requiring two stents, chronic total occlusions, and saphenous vein grafts).
  - **Patient Profile:** Selected **young patients** with single-vessel or long LAD disease (including "hybrid" PCI combining a proximal metallic DES with a mid/distal BRS or Drug-Coated Balloon to preserve the mid-LAD for future LIMA grafting), always performed under **OCT or IVUS guidance** and followed by **at least 12 months of Dual Antiplatelet Therapy (DAPT)**.

KEY REFERENCES

- **Ali ZA, Gao R, Kimura T, et al.:** Three-Year Outcomes With the Absorb Bioresorbable Scaffold: Individual-Patient-Data Meta-Analysis From the ABSORB Randomized Trials, *Circulation*, 2018.
- **Seth A, Onuma Y, Costa R, et al.:** Three-year clinical and two-year multimodality imaging outcomes of a thin-strut sirolimus-eluting bioresorbable vascular scaffold: MeRes-1 extend study, *EuroIntervention*, 2019.
- **Haude M, Wlodarczak A, van der Schaaf RJ, et al. (BIOMAG-I Investigators):** Safety and performance of the third-generation drug-eluting resorbable coronary magnesium scaffold system in the treatment of subjects with de novo coronary artery lesions: 6-month results of the prospective, multicentre BIOMAG-I first-in-human study, *eClinicalMedicine*, 2023.
- **Verheye S, Wlodarczak A, Montorsi P, et al. (BIOSOLVE-IV Investigators):** Twelve-month outcomes of 400 patients treated with a resorbable metal scaffold: insights from the BIOSOLVE-IV registry, *EuroIntervention*, 2020.