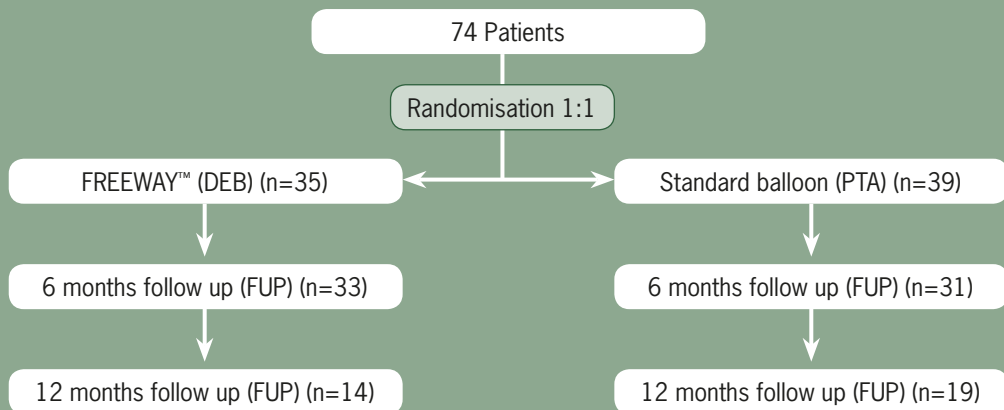


# THE PACUBA TRIAL

FREEWAY™ DRUG-ELUTING BALLOON FOR SFA IN-STENT RESTENOSIS

- Prospective randomized study
- FREEWAY™ drug-eluting balloon PTA versus PTA with standard balloon
- 74 patients with in-stent restenosis in the SFA or PI-segment
- Proven safety & efficacy<sup>1</sup>

# PACUBA Trial<sup>1</sup> – Flow Chart



## Baseline Demographics (n=74)

FREEWAY™ (DEB) vs. Standard balloon (PTA)

	DEB n=35	PTA n=39
Age mean ± SD (years)	68.1 ± 9.2	68.3 ± 0.4
Gender (male) (%)	57	59
Smoker (%)	52	53
Coronary Heart Disease (%)	36	41
Hypertension (%)	79	79
Diabetes (%)	52	38
Hyperlipidemia (%)	55	74
Renal Failure (%)	19	16
Creatinine mean ± SD (mg/dl)	1.03 ± 0.28	0.98 ± 0.25
Obesity (%)	22	21
Family history of PAD (%)	29	28

## Baseline Lesion Characteristics (n=74)

FREEWAY™ (DEB) vs. Standard balloon (PTA)

	DEB n=35	PTA n=39
Length mean ± SD (cm)	17.3 ± 11.3	18.4 ± 8.0
Occlusions (%)	31	28
Reference vessel diameter (mm)	5.7 ± 1.1	5.4 ± 0.9
TASC Classification	TASC A and B (%)	41
	TASC C and D (%)	59

## Principal Investigator

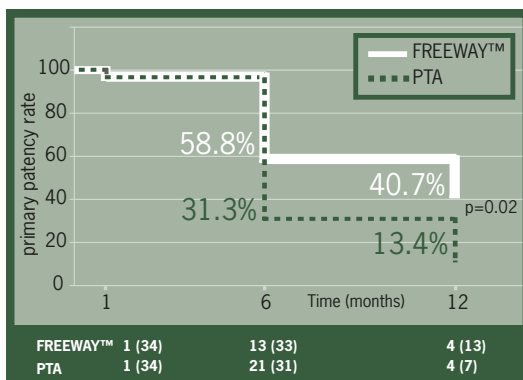
Prof. Dr. Johannes Lammer (Vienna, Austria)

## Study Center

Allgemeines Krankenhaus Wien

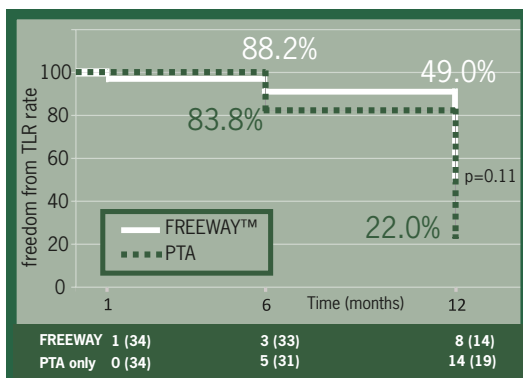
## 6 and 12 months FUP – Primary Patency rate

Kaplan-Meier estimation of the primary patency rate of patients treated with paclitaxel eluting balloon angioplasty (DEB FREEWAY™) versus standard balloon angioplasty (PTA).



## 6 and 12 months FUP – Freedom from clinically driven TLR

Kaplan-Meier estimation of the freedom from clinically driven target lesion revascularization (TLR) rate of patients treated with paclitaxel eluting balloon angioplasty (DEB FREEWAY™) versus standard balloon angioplasty (PTA).



## Conclusion

In in-stent restenosis lesions of femoropopliteal arteries

- Safety & efficacy is proven.
- DEBs achieve a significantly higher 1-year primary patency rate.
- Treatment with PTA only is not a recommendable therapy.

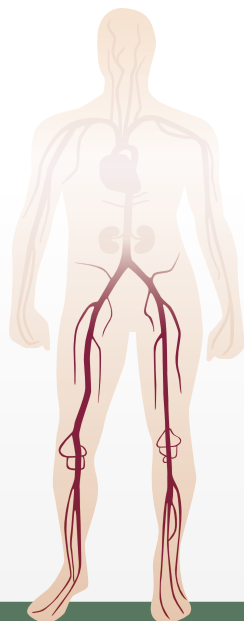
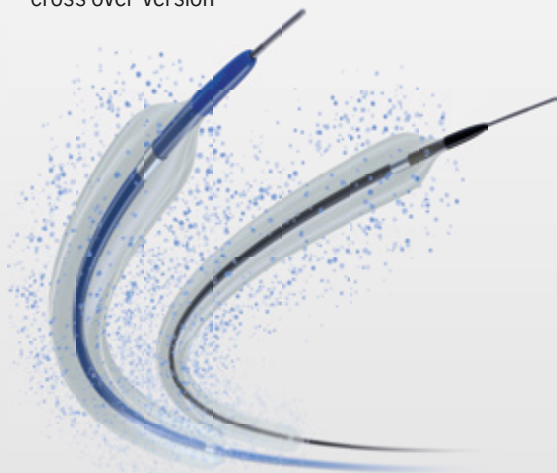
<sup>1</sup> Kinstner et al. "Paclitaxel-eluting balloon versus standard balloon angioplasty in in-stent restenosis of the superficial femoral and proximal popliteal artery." JACC 2016 9(13): 1386-1392

# FREEWAY™

DEB – DRUG ELUTING BALLOON FOR  
PERIPHERAL SOLUTIONS – ONE STEP AHEAD

**Wide available DEB OTW product portfolio for de-novo, restenotic and AV-fistula lesions:**

- **FREEWAY™ 014** – Specifically designed for the treatment of infragenual interventions below the knee  
0.014" OTW – Excellent balloon and crossing profile, smooth tip, very fast deflation time
- **FREEWAY™ 035** – Specifically designed for the treatment of femoropopliteal arteries  
0.035" OTW – Excellent balloon with good pushability and secondary profile
- Amorphous, non-crystalline bioshell coating
- 2–8 mm balloons
- 20–230 mm balloon lengths in antegrade and cross-over version



## FREEWAY™ 014

DRUG-ELUTING PTA BALLOON  
TECHNOLOGY

Specifically designed for infrapopliteal  
interventions

40–150 mm balloon lengths

## FREEWAY™ 035

DRUG-ELUTING PTA BALLOON  
TECHNOLOGY

Specifically designed for peripheral  
interventions

20–230 mm balloon lengths

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