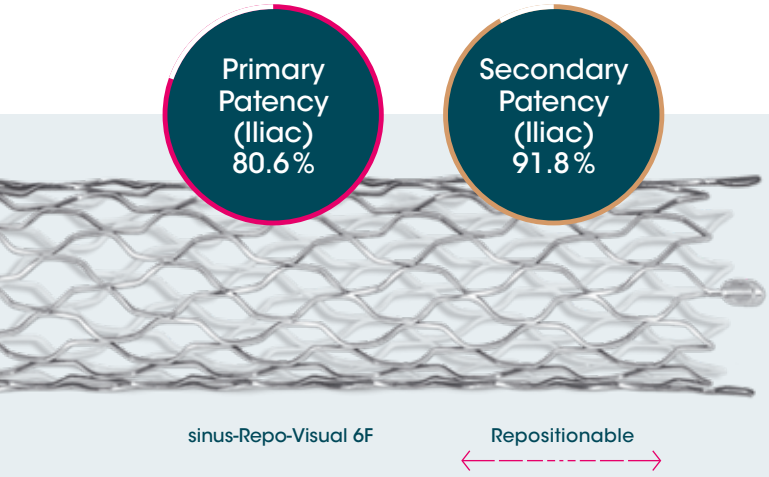
PMCF

ENDOVASCULAR TREATMENT OF LOWER EXTREMITY ATHEROSCLEROSIS WITH **sinus-Repo-Visual 6F**



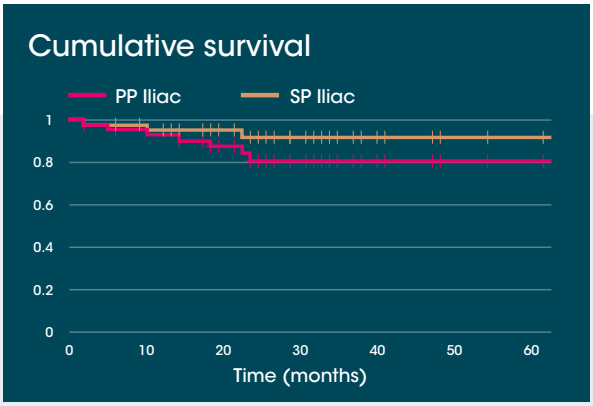


Figure 1: Kaplan Meier survival analysis of freedom of loss of primary (cumulative survival) on subgroup iliac and secondary patency on subgroup iliac for subjects followed-up (time in months) after treatment with sinus-Repo-Visual 6F

PERFORMANCE AND SAFETY OUTCOMES FOR ILIAC SUBGROUP FOR SUBJECTS TREATED WITH **sinus-Repo-Visual 6F**

Study name	PMCF 12 months	PMCF 24 months	PMCF 36 months
Study design	Retroperspective observation		
Stent	sinus-Repo-Visual 6F		
Primary patency all patients	92.9%	80.6%	80.6%
Secondary patency	92.9%	91.8%	91.8%
Freedom from TLR in % [95% CI]	97.8%	91.7%	91.7%
Freedom from MAE in % [95% CI]	95.6%	89.4%	83.5%
Freedom from death in % [95% CI]	100%	92.1%	89.0%

Primary patency rate (through different times)**:** Proportion of patients with primary treatment success AND with freedom of the following events:
a) in-stent thrombosis,
b) in-stent re-stenosis > 50% of the stent diameter, AND
c) re-intervention to maintain patency of the treated segment.
Secondary patency: Proportion of patients with initial treatment success AND without the occurrence of permanent loss of flow in the treated segment, irrespective of any interval therapies.

Freedom of Target Lesion Revascularization (TLR): Proportion of patients with freedom of any re-intervention on the target vessel to restore or maintain flow within the treated segment.
Clinical success: Proportion of patients with improvement of ≥1 Rutherford category

Data has been provided by
optimed Medizinische Instrumte GmbH

Proven safety and effectiveness in pelvic artery treatment, focusing on common and external iliac arteries

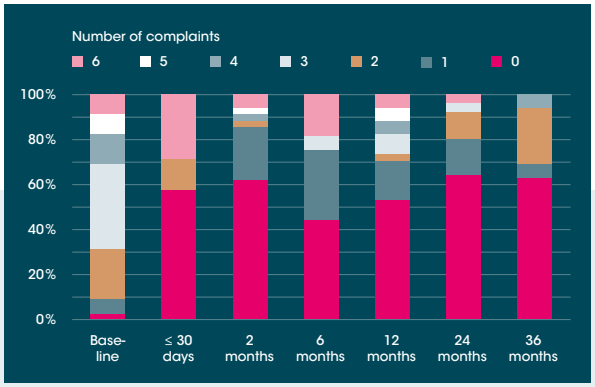


Figure 2: Rutherford Class of Study Population (iliac) over time
The number of complaints has decreased drastically

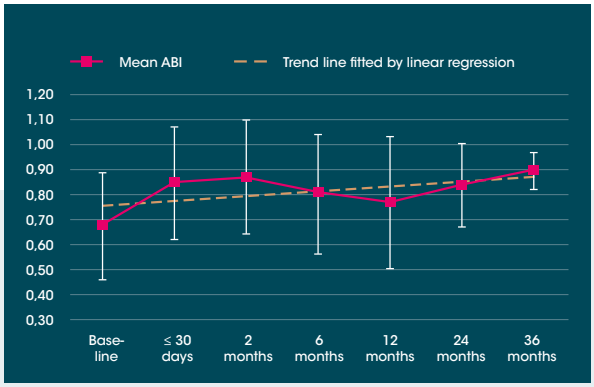


Figure 3: Mean ABI with standard deviation for the subgroup of iliac patients treated with sinus-Repo-Visual 6F

ADVERSE EVENT SUMMARY

Preferred term MedDRA (location, if applicable)	**Number and rate of subjects (N=60) with event in %**			
	≤30 days	≤12 months	≤24 months	Through follow-up
Adverse device effects (n, %)				
Peripheral artery dissection (target lesion)	2 (3,3%)			
Vascular stent stenosis (target lesion)	0 (0,0%)	1 (1,7%)	5 (8,3%)	6 (10,0%)
Vascular stent thrombosis (target lesion)	0 (0,0%)	5 (8,3%)	12 (20,0%)	15 (25,0%)
Major adverse events (n, %)				
Death (within 30 days)	0 (0,0%)			
Limb amputation major (index limb)	0 (0,0%)	0 (0,0%)	0 (0,0%)	2 (3,3%)
Target lesion revascularization (TLR)	0 (0,0%)	3 (5,0%)	5 (8,3%)	7 (11,7%)

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Also discover the **TOPOS study**

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CE 0124
Order Code 9997-0026EN
Rev (08/2024) | ©optimed