

**Case 21 Leipzig 9:
female, 74 years**

Chronic total occlusion left SFA

Operator: A. Schmidt, S. Düsing

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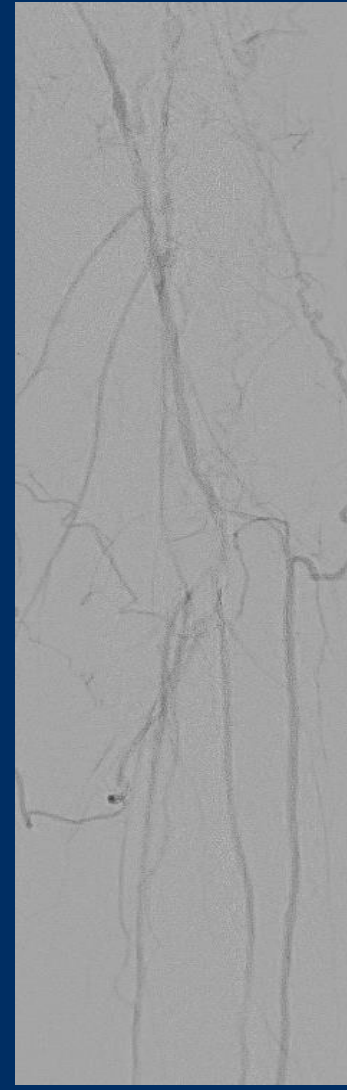
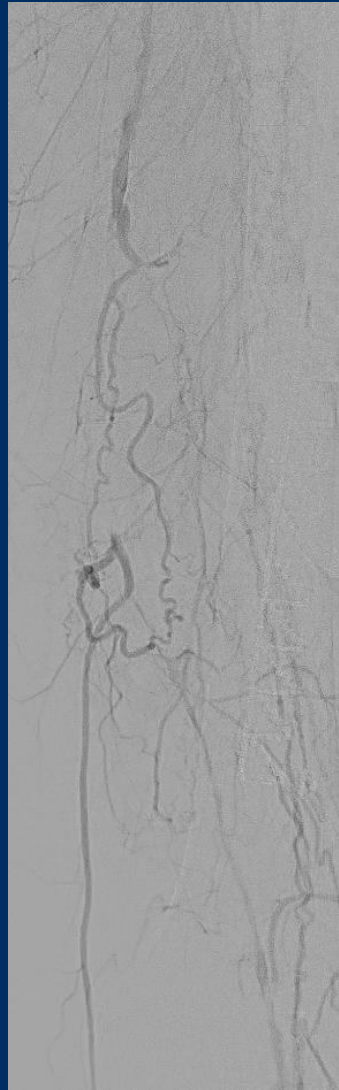
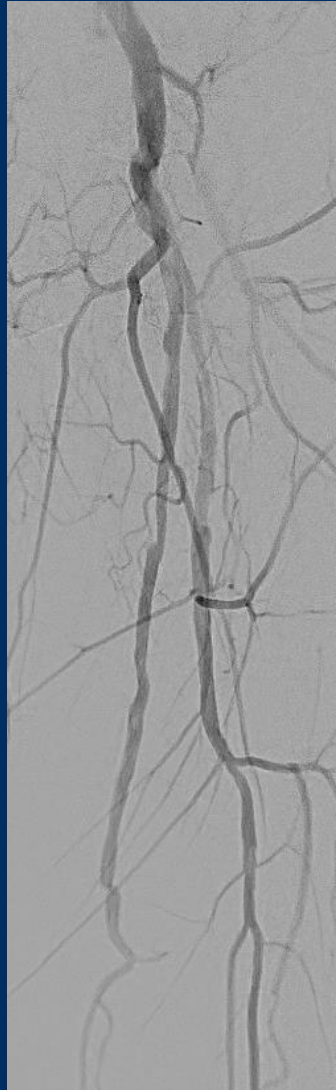
- **Clinical data:**

- Severe claudication left, ABI left 0.44
- Walking capacity 50 meters
- CAD, PTCA 2010
- Failed recanalization-attempt 12/2020m (also reentry-device failed)

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- **Risk factors:**
 - Hypertension
 - Former smoker (50PY)
 - HLP

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- **Procedural Steps:**
 - Right femoral access and cross-over approach
 - Additional retrograde approach via proximal ATA - with 2.9 French pedal sheath
 - PTA, scoring-/cutting-balloon Enforcer
 - Stenting with DES Zilver-PTX

Zilver[®] PTX[®] Freedom From TLR Prediction Model

Objective and background

- **A prediction model to determine the impact of patient and lesion factors on freedom from TLR through 5 years for patients who are candidates for Zilver PTX treatment for femoropopliteal lesions**
- **Patient and lesion factors from 5 global clinical studies used to develop a prediction model for freedom from TLR**
- **Data from over 2200 patients used to create the model**

Factors Included in Prediction Model

Patient Demographics	Lesion Characteristics
Sex	Lesion length
Age	RVD
Diabetes	Popliteal involvement
Hypertension	Total occlusion
Hypercholesterolemia	Calcification
Renal disease	Prior interventions
Smoking status	Number of patent runoff vessels
Rutherford classification	

Zilver® PTX® Freedom From TLR Prediction Model

Visit the interactive web-based prediction tool to see how Zilver® PTX® might help your patients:

<https://cooksfa.z13.web.core.windows.net>

COOK MEDICAL

Zilver® PTX® Predictability Model

Disclaimer

The Dataset includes data collected from Cook-sponsored studies, including pre-market data, post-approval data, and real-world data collected as a requirement of approval. The model generates predictions for freedom from target lesion revascularization based on the Dataset. The model outcomes resulting from the Dataset are provided for transparency and as part of ongoing scientific exchange regarding clinical evidence associated with the Zilver® PTX® stent.

Terms and Conditions

The following Terms and Conditions apply for use of the Zilver® PTX® Predictability Model. Using the model indicates your acceptance of the following Terms and Conditions so long as you retain any of the Dataset, regardless of format or storage method.

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- The Dataset will only be used for non-commercial research purposes and will not be used for any illegal purpose.
- No Print out or electronic version of the Dataset or its contents may be used by you in any litigation or arbitration matter whatsoever under any circumstances.
- Cook Medical is not responsible for any data from the Dataset that has been modified, altered, or manipulated by any party.
- Allowing public access to the Dataset does not confer any proprietary rights to the data contained therein to third parties.

Patient Demographics

Sex Male Female

Age (yrs) <65 65-74 75-84 85+

Diabetes No Yes

Hypertension No Yes

Hypercholesterolemia No Yes

Renal Insufficiency No Yes

Smoking Never Current Past

Limb Status Claudicant CLI

Lesion Characteristics

Lesion Length (mm) <50 50-99 100-149 150-199 200-249 250-299 300+

Reference Vessel Diameter (mm) <5 >=5

Popliteal Involvement No Yes

Chronic Total Occlusion No Yes

Lesion Calcification None Mild/Mod Severe

Prior Intervention No Yes

Tibial Runoff Vessels 2+ 0/1

Results

	12 Months	24 Months	36 Months	48 Months	60 Months
Freedom from TLR	94.7%	90.2%	87.8%	87.1%	85.4%
Standard Error	1.4%	2.5%	3.1%	3.3%	3.7%
Lower 95% CI	91.9%	85.4%	81.8%	80.9%	78.4%
Upper 95% CI	97.5%	95.3%	94.1%	93.8%	93.0%

Predicted Freedom From TLR @ 1 year

Patient Demographics

- Sex Male Female
- Age (yrs) <65 65-74 75-84 85+
- Diabetes No Yes
- Hypertension No Yes
- Hypercholesterolemia No Yes
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- Smoking Never Current Past
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Lesion Characteristics

- Lesion Length (mm) <50 50-99 100-149 150-199 200-249 250-299 300+
- Reference Vessel Diameter (mm) <5 >=5
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- Chronic Total Occlusion No Yes
- Lesion Calcification None Mild/Mod Severe
- Prior Intervention No Yes
- Tibial Runoff Vessels 2+ 0/1

Results

	12 Months
Freedom from TLR	71.0%
Standard Error	7.7%
Lower 95% CI	57.3%
Upper 95% CI	87.9%