

# Nile<sup>®</sup> polymer-free bifurcation DES BIPAX clinical study final report 60 months follow-up

Follow-up results of the BIPAX clinical trial involving the NILE Pax bifurcation DES have been reported by the Cardiovascular Research Center, the trial Core Laboratory

The following data describes the cumulative MACE rates obtained in patients following entry criteria for the different timelines set in the BIPAX study protocol MIN0803 up to 60 months

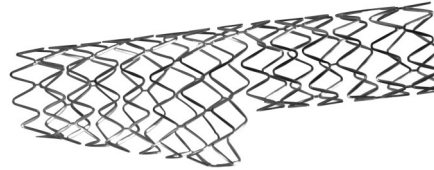


Table: Cumulative MACE in patients following entry criteria, N=95 (Per Protocol Population, PPP)\*

n=95	In-hospital	30 days	6 months	9 months	12 months	24 months	36, 48, 60 months
Any death	1% (1)**	1% (1)**	1% (1)**	2% (2)**	2% (2)**	2% (2)**	4.2% (4)***
MI	0% (0)	0% (0)	1% (1)	1% (1)	1% (1)	1% (1)	1.1% (1)
TLR (any)	0% (0)	0% (0)	4.2% (4)	12.6% (12)	13.6% (13)	14.7% (14)	14.7% (14)
Clinically-driven	0% (0)	0% (0)	4.2% (4)	8.4% (8)	9.5% (9)	10.5% (10)	10.5% (10)
TVR (any)	0% (0)	0% (0)	4.2% (4)	12.6% (12)	13.6% (13)	14.7% (14)	14.7% (14)
ST	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)

\*6 patients excluded not following study criteria: 2 patients with lesion length in the PV >25mm at baseline; 1 patient with lesion length in the SB >10 at baseline; 1 patient with bifurcation lesion type 1 Medina 0,0,1; 1 patient treated with bare metal stent in the SB during index procedure; and 1 patient with an ongoing acute MI at index procedure.

\*\* Patients with non-cardiovascular death. \*\*\* Includes three patients with non-cardiovascular death.

# Nile<sup>®</sup> polymer-free bifurcation DES

apr<sup>+</sup>medtech

## Product features

Single stent strategy with continuous side-branch access

Polymer-free abluminal paclitaxel layer (5µm) with semicrystalline coating ensures 98% of the drug delivered to the lesion

Complete reversion to regular chromium cobalt stent at 45 days

Modular stent design provides homogenous coverage at the carina without cell overstretch

Unique design means no angulation restrictions

Metal:Artery ratio of 10% - 15%

Two independent Rx PTCA with peel away to facilitate device loading

Tapered side-branch balloon to preserve carina and minimise cell overstretch when kissing

Compatible with 6F guide catheter

## Ordering information

For additional information, or to order this product, please call our Customer Support Team on **01844 340 620** or email [info@aprmedtech.com](mailto:info@aprmedtech.com).

Diameter (mm)		Length (mm)
Main branch balloon	Side branch balloon	18mm
2.5	2.0	NIPAX001
3.0	2.0	NIPAX002
3.0	2.5	NIPAX003
3.5	2.5	NIPAX004
3.5	3.0	NIPAX005



Manufactured by:

minVASYS

Additional product information is available at:

[aprmedtech.com](http://aprmedtech.com)

[aprmedtech.com](http://aprmedtech.com)

APR Medtech Ltd

The Sanderum Centre, 30a Upper High Street, Thame, Oxfordshire, OX9 3EX

t. +44 (0)1844 340 620

f. +44 (0)1844 340 621

e. [info@aprmedtech.com](mailto:info@aprmedtech.com)