Prospective, Multi-Center Study of Flow Diversion for Small and Medium-Sized Aneurysms: Results of the Premier Trial

Purpose: To evaluate the effectiveness and safety of using the Pipeline Embolization Device (PED) device to treat unruptured, small/medium, wide-neck intracranial aneurysms in the internal carotid or vertebral artery distribution selected for this study.

Trial Design: prospective, interventional, single-arm, multi-center; N=141; 22 centers.

| Primary Endpoint at 1 year: Efficacy: complete occlusion of the aneurysm with no significant |
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| artery stenosis. Safety: major stroke in the artery's territory or neurological death. |

30 days

30 days - 1 year

| Major Stroke or neurological death - safety | 1.4% | 0.7% | 2.1% | |
|---|------|------|------|--|
| Conclusions : the primary safety and efficacy endpoints were met at 1 year using this device for unruptured, wide-neck, small and medium-sized aneurysms in the internal carotid or vertebral artery distribution selected for this study. | | | | |



1 Year

83.5%

Trial Results

Complete occlusion - efficacy