

O-010

### FIVE-YEAR AUSTRALIAN EXPERIENCE WITH PIPELINE™ FLEX EMBOLIZATION DEVICES WITH SHIELD TECHNOLOGY™: REAL WORLD EVIDENCE (SCOPE-AUS)

<sup>1</sup>H Rice\*, <sup>1</sup>L de Villiers, <sup>2</sup>M Owusu, <sup>3</sup>J Wenderoth, <sup>4</sup>A Chiu, <sup>5</sup>N Manning, <sup>3</sup>A Cheung, <sup>4</sup>T Phillips, <sup>6</sup>C Rapier, <sup>7</sup>S Gatty, <sup>8</sup>L Ninnes, <sup>2</sup>I Hughes, <sup>9</sup>T Green. <sup>1</sup>Department of Interventional Neuroradiology, Gold Coast University Hospital, Southport, Australia; <sup>2</sup>Office for Research Governance and Development, Gold Coast University Hospital, Southport, Australia; <sup>3</sup>Department of Neurointervention, Prince of Wales Hospital, Sydney, Australia; <sup>4</sup>Neurological Intervention and Imaging Service of Western Australia, Sir Charles Gairdner Hospital, Perth, Australia; <sup>5</sup>Department of Interventional Neuroradiology, Liverpool Hospital, Sydney, Australia; <sup>6</sup>IACS Medical Research/Clinical Trials Unit, Gold Coast University Hospital, Southport, Australia; <sup>7</sup>Department of Neurosurgery, Gold Coast University Hospital, Southport, Australia; <sup>8</sup>School of Medicine, Bond University, Robina, Australia; <sup>9</sup>School of Nursing, Queensland University of Technology, Brisbane, Australia

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**Objective** The Pipeline™ Flex Embolization Device with Shield Technology™ has been available in Australia for 4 years to treat intracranial aneurysms of the anterior and posterior circulation in both elective and ruptured presentations. There is the potential for Shield Technology™ device surface modification to reduce platelet adhesion and platelet specific thrombogenicity. The SCOPE-AUS retrospective multicenter observational cohort study will report risk-adjusted safety and effectiveness outcomes in real-world patient populations treated with the Pipeline™ Flex Embolization Device with Shield Technology at four major centers in Australia.

**Methods** Real-world outcome analysis of 500 consecutive cases performed between 01 April 2015 - 30 June 2018 at four major centers in Gold Coast, Sydney and Perth will be presented. Pre-defined data variables are collated in a databank of patient socio-demographics, aneurysm and device characteristics, safety and clinical outcomes. Independent neurointerventionist assessments will determine the effectiveness of intracranial aneurysm treatment using validated grading scales to report complete aneurysm occlusion. Safety endpoints will be adjudicated by an independent neurointerventionalist to classify the aetiology of a neurological adverse event. Data abstraction metrics reporting interrater reliability ( $\kappa$  +0.80) and intrarater reliability (ICC 0.75–0.90) will be presented.

**Results** Comprehensive statistical analysis of the data will report total prevalence, morbidity, mortality and time-to-event analyses at post procedural timepoints (30 days, 6 months and 12 months) using descriptive statistics, Kaplan Meier curves and logistic regression models. Both crude and adjusted estimations of association and risk for confounding or predictive factors in the patient population will be reported. Both relative risk and odds ratios with 95% confidence intervals and p-values will be presented.

**Conclusion** The findings from this study will present real world safety and efficacy outcomes of high volume centers in Australia using the Pipeline™ Flex Embolization Device incorporating surface modification with Shield Technology™ in contemporary practice.

**Human Research Ethics approval number** HREC/17/QGC/331; **clinicaltrial.gov registration** NCT03815149; **Grant funding:** Medtronic External Research Program, Medtronic Australasia Pty Ltd, Australia.

### REFERENCES

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- Guidance for Industry and Food and Drug Administration Staff: Use of Real-World Evidence to Support Regulatory Decision-making for Medical Devices. Document No: 1500012.

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**Disclosures** H. Rice: 1; C; Medtronic External Research Program, ISR-2017-10909. 2; C; Medtronic, Stryker. 5; C; Queensland Health, QScan Radiology Clinics. L. de Villiers: 2; C; Medtronic, Stryker. 5; C; Queensland Health, QScan Radiology Clinics. M. Owusu: None. J. Wenderoth: 2; C; Medtronic. 5; C; NSW Health, Sydney Neurointerventionalist Specialists. A. Chiu: None. N. Manning: None. A. Cheung: None. T. Phillips: None. C. Rapier: None. S. Gatty: None. L. Ninnes: None. I. Hughes: None. T. Green: None.

O-011

### THE SURPASS™ INTRACRANIAL ANEURYSM EMBOLIZATION SYSTEM PIVOTAL TRIAL TO TREAT LARGE OR GIANT WIDE NECK ANEURYSMS – SCENT TRIAL: 3-YEAR OUTCOMES

<sup>1</sup>R Hanel\*, <sup>2</sup>A Coon, <sup>3</sup>P Kan, <sup>4</sup>A Wakhloo, <sup>5</sup>P Meyers. <sup>1</sup>Neurosurgery, Baptist Health System- Jacksonville, Jacksonville, FL; <sup>2</sup>Neurosurgery, Carondelet Neurological Institute, Tucson, AZ; <sup>3</sup>Neurosurgery, Baylor Medical College, Houston, TX; <sup>4</sup>Radiology, Lahey Hospital and Medical Center, Burlington, MA; <sup>5</sup>Radiology, Columbia University, New York, NY

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**Introduction** The Surpass™ Flow Diverter (FD) was developed to treat large or giant wide-neck intracranial (IC) aneurysms not amenable to surgical or current standard endovascular treatment due to location, morphology or known treatment challenges. Compared to commercially available flow diversion technology in the US, the Surpass FD offers additional treatment options that fulfill an unmet clinical need as currently available flow diverter technology is limited to IC aneurysms within the ICA from the petrous to the superior hypophyseal segments. The Surpass FD's Indications for Use allow for placement in the ICA up to the terminus. The Surpass FD is available in diameters from 3 to 5 mm and lengths of 15 to 50 mm, therefore allowing fewer Surpass FD use in the treatment of large and giant aneurysms. The goal of the present study is to present 3-year outcomes of SCENT Trial in special safety and efficacy of this large prospective cohort.

**Methods** The SCENT Trial is an international, multi-center, prospective, single arm trial designed to evaluate the safety and efficacy of the Surpass™ FD in treatment of large or giant wide-neck ( $\geq 4$ mm) IC aneurysms  $\geq 10$ mm in size. We present 36-month outcome data. Secondary effectiveness endpoints measured post-index procedure through 60 months: the percent of aneurysm rupture, Surpass implant stenosis ( $\geq 50\%$  stenosis), Parent artery occlusion at the target aneurysm location, change in mRS compared to baseline, Surpass delivered to cover the aneurysm neck, Raymond Class and complete occlusion at 36 months, Surpass successfully delivered and implanted, Incidence of retreatment at 36 months.