

## **New anchoring device for navigate device to difficult access target**

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### **Purpose:**

To present results of first-in-man (FIM) trial and approving trial of our new developed device to safely deliver large-bore or stiff device to intracranial target lesion instead of long wire exchange method.

### **Methods:**

Our new device (SD-01) is a 320 cm long exchange wire with a retrievable stent, 2 or 3mm diameter and 10 or 15mm length, designed to assist with exchange maneuvers and device delivery. We conducted 5 cases of FIM trial and 31 cases of approving trial to show safety and efficacy of SD-01 for device delivery avoid long wire exchange method. Primary endpoint is successful device delivery without serious adverse event (SAE) related to SD-01.

### **Results:**

Target diseases are 29 cerebral aneurysms and 7 cerebral artery stenosis in total. SD-01 can navigate to target lesion, ICA in 2 cases, M2/3 in 30 cases, A1 in 1 case and P2/3 in 3 cases, by 0.0165-0.017 microcatheter in 34 cases and 0.027 in 2 cases. Anchoring procedure by SD-01 and device delivery was successful in all cases. No serious adverse event (SAE) occurred in FIM trial and 3 procedure related SAE occurred but only 1 possible device related SAE in approving trial.

### **Conclusions:**

SD-01 is a useful device for safe device delivery in cases requiring long wire exchange method.