CASE SUMMARY

Performance of TJWY Medical Proender® Disposable Embolic Protection Device in Carotid Angioplasty and Stenting

Carotid artery stenosis is a major risk to cerebrovascular health. Clinically, carotid endarterectomy (CEA) and carotid angioplasty and stenting (CAS) are mainly used to treat carotid artery stenosis. According to CREST research results, there was no significant difference between CAS and CEA in 30-day mortality, 4-year homolateral stroke incidence, disabling major strokes incidence, etc. However, CAS has lower incidence rate than CEA on myocardial infarction and cranial nerve palsy. The CAVATAS study suggests that CEA and CAS have similar efficacy and safety, and minor complications can be decreased by endovascular therapy.

CREST Study Results

	CAS	CEA	P
Mortality within 30 days	5.2	4.5	0.38
Disabling major stroke incidence	0.9	0.7	0.52
Homolateral stroke incidence in 4 years after operation	2.0	2.4	0.85
Myocardial infarction	1.1	2.3	0.03
Cranial n. palsy	0.8	4.8	<0.0001

Studies have shown that the overall complication rate of CAS was declining yearly. There are many reasons for this, including the improvement of instruments, such as cerebral protection devices. Therefore, placing the cerebral protection devices has become an essential process in CAS.

Study	No. of cases	Stroke/death rate (%)	
		Without embolic protection	With embolic protection
Henry [21]	315	4.9	2.2
Roubin [23]	1276	6.9	1.8
Wholey (Global Registry) [6]	10653	5.3	2.3
Mathias [20]	405	3.0	1.3
German Registry [14]	1353	2.8	2.0

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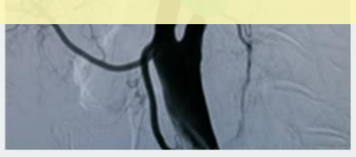
Clinically, when a distal cerebral protection device was selected, in addition to the ability to trap embolus, attention should also be paid to its croassability, retrievability and other performances. Today, we would like to share with you a CAS case using TJWY Medical Proender® Disposable Embolic Protection Device.

Patient information: Male, 65 Y

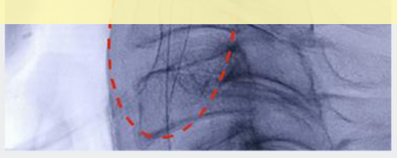
Diagnostic description: Severe stenosis at the proximal segment of the left internal carotid artery



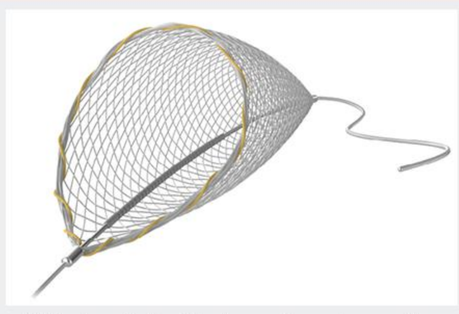
Preoperative DSA shows that stenosis at the proximal segment of the left internal carotid artery is 83%. Balloon dilatation and stenting are planned for the proximal segment of the left internal carotid artery.

The delivery sheath of TJWY Medical Proender® Disposable Embolic Protection Device is removed after it's in place, so that the embolic protection device can be released in situ. The red dotted circle shows that the embolic protection device has been placed at the distal segment of the lesion. The radiopaque ring of the embolic protection device can be seen clearly. The great visibility of Proender® Disposable Embolic Protection Device can help surgeons to clearly know the releasing status of the Embolic Protection Device, therefore to ensure the intraoperative embolus trapping safety. Vasospasm arising from stimulation of intima upon the release of the Embolic Protection Device can be effectively avoided due to flexibility and good biocompatibility of the device.

The proximal and distal markers of the device are shown as in red arrows, and the radiopaque rings of the device is shown in yellow arrows. The Proender® Disposable Embolic Protection Device has good visibility, thereby ensuring that surgeons can accurately know the landing zone of the device and the unfolding status of the device during operation.

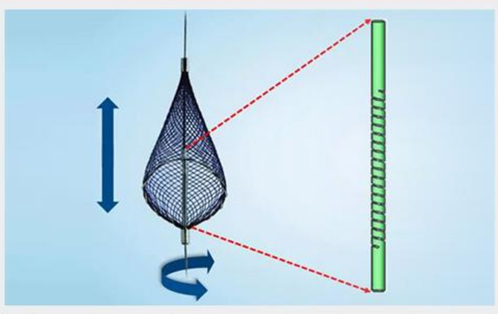


Therefore intimal injury and vasospasm caused by device moving can be avoided.
When the device is retrieved, the retrieval sheath is easy to be pushed. The larger lumen of the retrieval sheath also makes the device easier to be retrieved into the sheath. After the device is fully folded into the retrieval sheath, it can be removed.

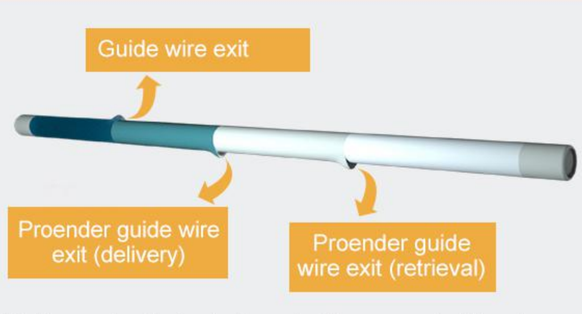


Nitinol soft braided mesh reduces the intravascular pressure, and protect intracranial vessels and tissues.
Radiopaque loop design perfectly fits the vessel and effectively capture embolus,

In addition to the markers at both ends, the design of the radiopaque ring makes it convenient to clearly observe the position and releasing of Proender during the operation.



Independent guide wire design allows Proender to rotate or move axially to a certain extent
Avoid any displacement of the embolic protection device and damage the blood vessel that results in vasospasm.
Laser spiral cutting makes the fixation cannula more flexible and more conducive to pass through the tortuous blood vessels.



Delivery sheath is designed with segmented hardness, softer distal end and excellent anti-kink characteristic.
Retrieval sheath has larger inner diameter and PTFE coating, and its friction is only 50% of that of similar products.
Integrated delivery sheath and retrieval sheath are compatible with 0.014" guide wire, which allows rapid exchange during operation.

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