# Cerebral Protection Devices in Transcatheter Procedures

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Intraprocedural stroke is a well-documented and feared potential risk of cardiovascular transcatheter procedures (TPs). Moreover, subclinical neurological events or covert central nervous system infarctions are concerns related to the development of dementia, future stroke, cognitive decline, and increased risk of mortality. Cerebral protection devices (CPDs) were developed to mitigate the risk of cardioembolic embolism during TPs. They are mechanical barriers designed to cover the ostium of the supra-aortic branches in the aortic arch, but newer devices are able to protect the descending aorta. CPDs have been mainly designed and tested to provide cerebral protection during transcatheter aortic valve replacement (TAVR), but their use in both Catheterization and Electrophysiology laboratories is rapidly increasing.

stroke transcatheter procedures cerebral protection devices filter deflector supra-aortic

## 1. Introduction

The advent of cardiac transcatheter procedures (TPs) paved the way for minimally invasive approaches performed without the need for thoracotomy. Given the lower intraprocedural risk compared to cardiac surgery, these approaches allowed us to treat a lot of patients previously judged ineligible. To date, TPs have revolutionized the treatment of the most common heart diseases, such as ischemic heart diseases, valvopathies, heart failure (HF), and arrhythmias, leading to improved life expectancy, QoL, and functional status [1][2][3][4]. A number of transcatheter interventions are performed in both Catheterization labs (Cath labs) and Electrophysiology labs (EP labs) today. Percutaneous coronary interventions (PCI), transcatheter aortic valve replacement (TAVR), left atrial appendage closure (LAAC), atrial fibrillation (AF), and other arrhythmia ablations are among the most common TPs, covering approximately 90% of all interventional cardiology procedures. However, these approaches, in particular those by intracardiac or arterial route, are not free from the risk of severe complications. Among all, stroke is a well-documented and feared potential risk of TPs [5][6][7][8], posing a tremendous strain on patients, their families, and the healthcare system [9]. Subclinical neurological events or covert central nervous system infarctions are also a significant risk and are related to the development of dementia, future stroke, cognitive decline, and increased risk of mortality [10][11][12]. Procedure-related stroke or new ischemic cerebral infarctions may result from a variety of patient- and disease-related causes, such as the severity of atherosclerosis, age, gender, dyslipidemia,

history of AF, HF and/or technical aspects of the procedure itself, including mechanical manipulation of instruments or interventional devices. Because of their thrombogenic nature, acute thrombus may originate at any part of endovascular catheters. Thrombus formation on transseptal sheaths despite adequate anticoagulation was reported in 9% of cases [13], as well as the thrombogenicity of guidewires [14][15]. Therefore, the thrombogenicity of endovascular catheters cannot be avoided completely in every left-sided procedure despite an ACT level > 300 s, and the risk increases in long-lasting procedures, such as ventricular (VT) tachycardia ablation. Arterial wall tissue was frequently found in the filters, accompanied by smaller amounts of calcified and necrotic core tissue. The origin of this type of debris might be the manipulation of the ablation catheter within the aortic root, ascending aorta, and aortic arch. Debris may also originate from myocardial and valve tissue by advancing and manipulating the catheters into the left ventricle via the mitral valve [16]. Apart from biological tissue, foreign material was found in the filters of patients undergoing different TPs, probably arising from hydrophilic polymer coatings used on guidewires, catheters, previously implanted ICD leads, and transseptal sheaths, which have been shown to produce clinically relevant particles [14][17][18]. New medical devices are being developed to help mitigate this risk of cardioembolic embolism during TPs. Cerebral protection devices (CPDs) are mechanical barriers designed to cover the ostium of the supra-aortic branches in the aortic arch. They are characterized by a low-profile allowing the implantation by the radial or femoral artery, filter capabilities, and stability during the procedure. Their implantation is temporary and covers the duration of the procedure, after which, they are removed. CPDs have been designed and tested in particular to reduce the cardioembolic risk during TAVR, but their use in Cath labs and EP labs is rapidly increasing. According to recent studies and meta-analyses, CPD use is safe in terms of bleeding and vascular complications, but its real effectiveness in decreasing stroke rate and other major cardiovascular embolic events is still a matter of debate [19][20][21]. Significant reduction in MACE and mortality was sometimes reported, without differences in acute kidney injury. On the contrary, significantly lower subclinical brain lesions have been detected by diffusion-weighted magnetic resonance imaging (DW-MRI) in all studies [22][23]. Data on their use in clinical practice beyond TAVR is still limited. However, there is growing evidence of CPD safety in LAAC and VT ablation with concomitant left atrial appendage (LAA) or left ventricular thrombosis [18][24].

To reduce the risk of stroke, CPDs have been developed to prevent debris and clots from embolizing the brain [25]. Clots can already be present at the time of the procedure or can develop during it. CPDs are usually inserted throw a radial or femoral artery access. The positioning of the device can be challenging, particularly if atherosclerotic plaques are located in the vicinity of the ostium of supra-aortic vessels or aortic arch, hampering the implantation and positioning of the device which may even promote plaque disruption and, consequently, cerebral embolization. Therefore, in patients with several risk factors for atherosclerosis, such as smoking, diabetes, obesity, and kidney disease, a preprocedural chest computed tomography angiography (CTA) may be indicated [26]. CTA can also reveal some arteriopathies, such as vascular tortuosity or aneurysms, which can preclude the use of the device or its corrected deployment. The actual efficacy of the CPDs depends on the capacity to protect the three main branches of the aortic arch and the ability of the specialists to deploy it without disrupting aortic arch plaque. They can be classified as filters or deflectors: filter devices can retain embolic material, while deflector devices reject the debris towards the descending aorta [27]. Despite deflector systems not being capable of entraping embolic material but only diverting it towards the descending aorta, no cases of embolism in inferior districts have been

reported so far. There are eight types of CPDs [28]. In general, all devices are constituted by various shapes of heparin-coated polyurethane membranes of around 100 µm size pores.

# 2. Deflector Systems

– Embrella (Edwards Lifesciences, Irvine, CA, USA) received a European CE mark approval in 2010. It was developed to deflect embolic material during TAVR [29]. This device is inserted by right radial or brachial approach with a 6 Fr sheath. The distal end is an umbrella-like device with two heparin-coated polyurethane membranes (pore size: 100 µm). The CPD is placed through the greater curvature of the aorta, safeguarding the brachiocephalic and left common carotid artery. Since the left subclavian artery is not covered by the device, Embrella provides only partial protection to supra-aortic vessels. According to the pilot study PROTAVI-C, the device was successfully positioned in 100% of the TAVR procedures (N = 41) [30]. Although its use was associated with a reduction in lesion volume evaluated by DW-MRI, it did not prevent the occurrence of new cerebral microemboli.

– TriGuard (Keystone Heart, Caesarea, Israel) received a European CE mark in 2014 [31]. It is advanced through a 9 Fr arterial sheath placed into the left femoral artery and deployed to cover the ostia of the three supra-aortic trunks. Its new generation, the TriGuard 3, incorporates a self-expanding deflection filter composed of a structural radiopaque nitinol frame and an ultra-thin polymer mesh (nominal pore size 115 × 145 µm). The device is heparin-coated to reduce thrombogenicity and increase lubricity. The full system includes a delivery subsystem for crimping and loading the device into an 8F sheath [32]. The device was primarily developed to provide cerebral protection during TAVR [33][34]. In recent years, its use in LAAC and VT ablation procedures has rapidly increased and provided encouraging results that could pave the way for new employment in electrophysiological procedures [35][36].

– ProtEmbo CPS (Protembis, Aachen, Germany, EU) received a European CE mark in 2014. This device covers all three supra-aortic vessels, and its low-profile design provides delivery by left radial access. The heparin-coated mesh has the smallest pore size (60 µm) among all available CPDs. For this reason, it might even safeguard the cerebrum from smaller-sized debris [32][37]. The PROTEMBO C trial evaluated the safety and performance of the ProtEmbo CPS in TAVR patients [38]. The CPD met the primary safety and performance endpoints compared to prespecified historical performance goals. Enrolled patients had smaller brain lesion volumes on DW-MRI compared to prior series and no large single lesions (>150 $mm^3$). The ongoing PROTEMBO SF (ClinicalTrials.gov Identifier: NCT03325283) is a prospective, observational, multicenter, intention-to-treat study of the safety and feasibility of the ProtEmbo CPS in subjects with severe symptomatic native aortic valve stenosis indicated for TAVR.

# 3. Filter Systems

## 3.1. Supra-Aortic Filters

– Sentinel (Boston Scientific, Marlborough, MA, USA) received a European CE mark in 2014 and is the most widely used CPD so far. It is formed by a dual system filter basket containing two polyurethane mesh filters with 140 µm pores. It is advanced through a 6 Fr delivery catheter from the right radial over a 0.014 inch guidewire. It consists of a proximal filter (diameter of 9–15 mm) delivered in the brachiocephalic artery and a distal filter (diameter of 6.5–10 mm) delivered in the left common carotid artery. Through an articulating sheath, the device can be sealed into the aortic arch according to its anatomy [27]. Since the Sentinel device is deployed into supra-aortic vessels, the diameter of the supra-aortic vessels must be previously measured by CTA, because proximal and distal filters are developed to be accommodated within a brachiocephalic artery of 9 to 15 mm, and a common carotid of more than 3 mm [39]. The left vertebral artery remains unprotected. Sentinel devices have only one available size, so complete sealing might not be obtained in all aortic anatomies. Several uses of this device for LAAC and VT ablation have been reported [18][36].

– The Wirion (Abbott, Chicago, IL, USA) is a single filter usually employed for carotid stenting and lower extremity endovascular interventions [40]. It consists of a distal filter (filter basket and locking mechanism) and a rapid exchange delivery catheter. The exchange catheter has a 1.1 mm crossing profile and can be mounted on any 0.014 inch guidewire and via 6F or greater guiding catheters. The filter basket is made of a self-expanding nitinol scaffold and a nylon filter membrane with 100 µm pores. The filter can efficiently be deployed in vessels with a diameter ranging from 3.5 to 6.0 mm and at any location along the guidewire, using a proprietary remote locking system (handle at the proximal end of the delivery catheter). Since this device protects only one vessel at a time, it cannot be used alone for TPs at high risk of cardioembolism. A study reported the utility of Wirion in combination with Sentinel to complete the protection of the left vertebral artery in patients undergoing TAVR [31].

– Emblok Embolic Protection System (EPS, Innovative Cardiovascular Solutions, Grand Rapids, MI, USA) is currently only for investigational use. It is formed by an 11 F sheath device containing a 4 Fr pigtail catheter advanced through femoral access. The filter system is a 125 µm pore-size nitinol that allows the embolic filter and a radiopaque pigtail catheter to be advanced simultaneously through femoral access. It fits in various anatomies of the aorta with a diameter of up to 35 mm. The prospective, nonrandomized, multicenter, first-in-man pilot study was designed to evaluate the efficacy and safety of cerebral embolic protection utilizing the EPS-enrolled 20 patients undergoing TAVR [41]. The device was successfully placed and retrieved in all cases, and no neurological events were observed. Cerebral total new lesion volume was similar to other trials on cerebral protection during TAVR. An ongoing prospective, multicenter, single-blind, randomized controlled trial enrolling >500 patients aims to evaluate the safety, effectiveness, and performance of the EMBLOK EPS during TAVR by randomized comparison with a commercially available embolic protection device (ClinicalTrials.gov Identifier: NCT05295628).

## 3.2. Full Body Filters

– Emboliner (Emboline, Santa Cruz, CA, USA) device system is currently only for investigational use. It is advanced from a 9 Fr transfemoral sheath used for the 6 Fr pigtail catheter for TAVR. It is engineered to protect all three cerebral vessels and the whole body. Early results from the SafePass 2 trial were presented in

Transcatheter Cardiovascular Therapeutics 2019, reflecting no adverse events at 30 days with 100% procedural success.

– Captis (Filterlex Medical, Caesarea, Israel) is currently under development and carries a deflector mechanism with ipsilateral transfemoral access. Positioned in the aortic arch and descending aorta, it promises to provide full cerebral and body protection. The results of the prospective, single-arm, first-in-human study presented at EuroPCR 2022 involving 20 patients who underwent TAVR showed 100% technical device performance success, including deploy and retrieve and any interferences with the TAVR procedure. There were neither device-related complications nor cerebrovascular events (ClinicalTrials.gov Identifier: NCT04659538).

**Figure 1** shows current CPDs used in cardiovascular TPs, while **Table 1** summarizes the pros and cons of each device.

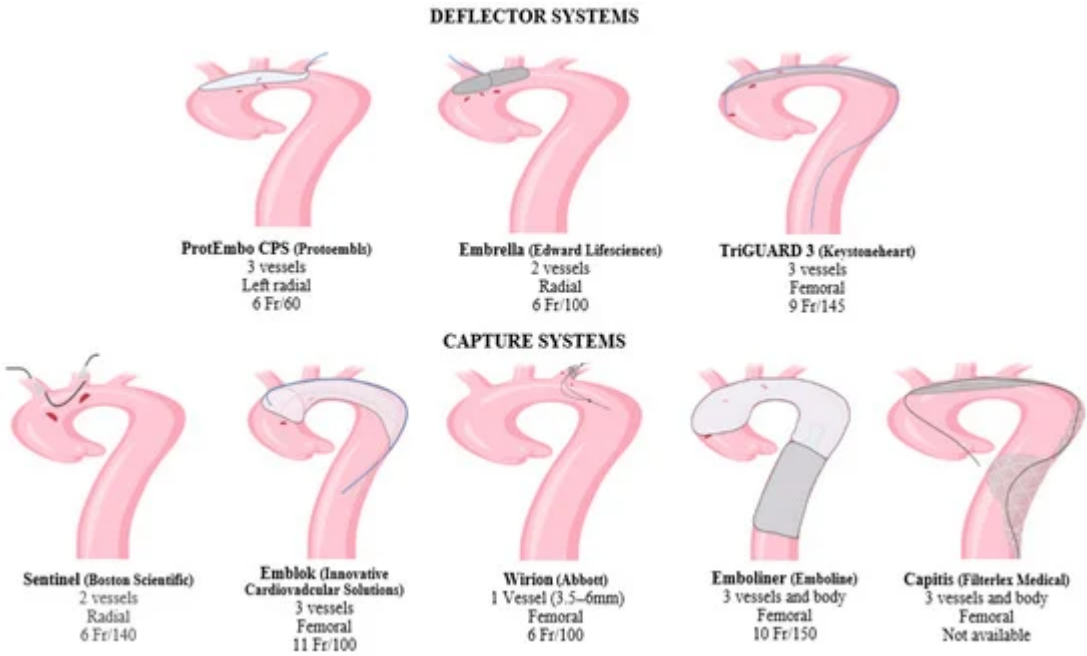


**Figure 1.** Current cerebral protection devices used in cardiovascular transcatheter procedures and main technical features (name, coverage, access site, sheath/pore size [mm]).

**Table 1.** Pros and cons of current cerebral protection devices.

| Device | Pros | Cons |
|---|---|---|
| ProtEmbo CPS [38] | Small size sheath (6 Fr);<br>Left radial/brachial access;<br>Mesh with the smallest pore size available;<br>100% successful device positioning. | Partial coverage of the supra-aortic trunk;<br>New cerebral lesions were detected, but smaller;<br>Available evidence only for TAVR. |
| Embrella [30] | Small size sheath (6 Fr);<br>Right radial/brachial access;<br>100% successful device positioning. | Partial coverage of the supra-aortic trunk;<br>New cerebral lesions were detected, but smaller;<br>Available evidence only for TAVR. |

| Device | Pros | Cons |
|---|---|---|
| TriGuard 3 [36][42] | Intermedium size sheath (9 Fr);<br>Implantable through both the left and right femoral arteries;<br>Full coverage of the supra-aortic trunk;<br>Can be left in the aortic arch for days;<br>100% successful device positioning;<br>Large amount of evidence;<br>Available evidence for TAVR, LAAC, and VT ablation. | Femoral access;<br>Procedural concerns if transcatheter procedure performed through the retro-aortic path;<br>New cerebral lesions were detected, but smaller. |
| Sentinel [36][43] | Small size sheath (6 Fr);<br>Right radial/brachial access;<br>94.4% successful device positioning;<br>Largest amount of evidence;<br>Available evidence for TAVR, LAAC, and VT ablation. | Partial coverage of the supra-aortic trunk;<br>New cerebral lesions were detected but smaller. |
| Emblok [41] | Implantable through both the left and right femoral arteries;<br>100% successful device positioning. | Intermedium size sheath (11 Fr);<br>Femoral access;<br>Procedural concerns if transcatheter procedure performed through the retro-aortic path;<br>New cerebral lesions were detected, but smaller;<br>Available evidence only for TAVR. |
| Wirion [31] | Small size sheath (6 Fr);<br>Right radial/brachial access;<br>Very low amount of evidence. | Nonsufficient coverage of the supra-aortic trunk;<br>Available evidence only for TAVR; |
| Emboliner | Coverage of the supra-aortic trunk and descending aorta;<br>Implantable through both the left and right femoral arteries. | Data on the first-in-man study is not yet available. |
| Capitis | Coverage of the supra-aortic trunk and descending aorta;<br>Implantable through both the left and right femoral arteries. | Data on the first-in-man study is not yet available. |


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