




Parodi Anti-Emboli System™ (PAES™)

U.S. and Foreign Patents Pending

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Directions for Use

STERILE	EO
NONPYROGENIC	
 SINGLE USE	
Rx ONLY	
REF	

Sterile and non-pyrogenic in unopened, undamaged package.

Intended for one time use only. Do not resterilize.

For professional use only.

799-00002



Read instructions prior to use.



Investigational device. Limited by United States law to investigational use only.



Store in a cool, dry place.



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1. SAFETY INSTRUCTIONS

When using the PAES™ (Parodi Anti-Emboli System), please observe these basic precautions to reduce the risk of patient injury or equipment damage.

Before using the PAES:

- The PAES is intended for use by trained physicians experienced in transluminal percutaneous procedures and trained in the use of the PAES.
- Read and understand all instructions pertaining to the PAES before use.
- Follow all warnings and cautions on the product and in these operating instructions.
- Do not use the PAES for anything other than its intended use.

Definition of Terms



WARNING! Hazards or unsafe practices which could result in serious injury or death.



CAUTION! Hazards or unsafe practices which could result in minor injury or product damage.

General Warnings and Cautions

Following are descriptions of general hazards that could result in personal injury to the patient or product damage. Specific warnings and cautions are found in relevant sections of the operating instructions.

WARNINGS



Possible blood vessel damage. Use caution in selecting the sizes of the devices to be used. Never deploy the Parodi Anti-Emboli Catheter or Parodi External carotid Balloon whenever the possibility exists that a device could become trapped in too small a vessel for the device.



Possible blood vessel or catheter damage. Never advance or withdraw an intraluminal device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or wire against resistance may result in damage to the catheter, guidewire or vessel. Pulling back the catheter hub by force may cause catheter separation.



Patient hazard. The PAES will remain sterile and non-pyrogenic as long as the packaging is unopened and undamaged. DO NOT use devices where it is suspected that the integrity of the packaging has been compromised.



Patient hazard. The PAES is intended for one-time use only. DO NOT resterilize.

CAUTIONS



Possible device damage. Store the PAES in a cool, dry place. DO NOT expose the packaged devices to extremes of temperature or humidity.



Possible device damage. The PAES is sterilized with Ethylene Oxide and CANNOT be cleaned or re-sterilized by any means.

2. INTRODUCTION

Intended Use

The Parodi Anti-Emboli System™ (PAES) is intended for use as an adjuvant neuroprotective device during carotid stent supported angioplasty procedures in the internal and common carotid arteries. It operates by preventing emboli, which may be dislodged during carotid artery angioplasty and stent placement, from migrating to the cerebral vasculature.

Device Description

The Parodi Anti-Emboli System (PAES) is a unique device that allows control of blood flow in the internal and common carotid arteries during transcatheter intervention. Either passive or active flow reversal maneuvers may be utilized. The PAES consists of:

- Parodi Anti Emboli Catheter (PAEC)
- Parodi External Carotid Balloon (PEB)
- Accessories (adapter, introducer, and dilator).

The PAEC is a dual lumen, 8 French ID, arterial guiding catheter with a funnel-shaped, cuff balloon. The cuff balloon is inflated through a dedicated, small, parallel lumen for occluding the common carotid. The large, main lumen of the PAEC is used to deploy the PEB and to establish retrograde flow. It is also used to deploy the angioplasty and stenting devices. The 1.3 French PEB is a single lumen, guidewire with a distal occlusion balloon.

The PAEC operates based on the fundamental hemodynamic properties of flow differential. Internal carotid artery flow reversal is achieved by occluding the common carotid artery and then connecting the proximal catheter port to a venous sheath communicating with the main lumen of the guiding catheter and the venous system creating passive retrograde flow. An arterio-venous shunt is used to create this reverse gradient at the level of the common carotid which can be supplemented by aspiration through the guiding catheter, especially when the stent deployment device is introduced. This process prevents dislodged emboli from migrating towards the brain and allows removal of this material safely from the carotid.

Indications for Use

The PAES (PAEC and PEB) is indicated for use in the treatment of symptomatic and asymptomatic patients with lesions in the internal carotid artery or carotid bifurcation region, which are amenable to carotid stent supported angioplasty.

The PAEC device without the PEB is indicated for use in the treatment of symptomatic and asymptomatic patients with lesions in the common carotid or carotid bifurcation region, which are amenable to carotid stent supported angioplasty. The PEB should not be used in those circumstances in which the lesion is in the CCA or at the bifurcation. The lesion should be not crossed with antegrade flow. The PEB is not required when the external carotid artery is substantially or totally occluded.

Specifically, the device is indicated for use with the following patients:

- Symptomatic patients with > 70% stenosis in the corresponding internal carotid artery, common carotid artery, or carotid bifurcation region documented through angiography and/or echo Doppler ultrasound within the past 30 days.
- Asymptomatic patients with > 80% stenosis in the internal carotid artery, common carotid artery, or carotid bifurcation region documented through angiography and/or echo Doppler ultrasound within the past 30 days.

Contraindications

The PAES and/or the PAEC alone are contraindicated for use on patients exhibiting the following conditions:

- Inability to accept a temporary pacing electrode.
- Recent acute neurological events, including TIA's, or minor or major strokes within 5 days prior to the procedure as diagnosed by neurological exam, head CT Scan or MRI, and Trans-Cranial Doppler.
- A state of dementia.
- Presence of any myocardial infarction within 14 days and who are hemodynamically unstable.
- Coumadin treatment that has not been stopped within 72 hours before treatment.
- Severe chronic renal insufficiency (plasma/serum creatinine > 2.5 mg/dl). An alternative in these cases is to use gadolinium as contrast media not exceeding 90 ml of the solution.
- More than two (2) stenoses in the internal carotid artery or total occlusion of the target vessel.
- Severely calcified lesions where balloon pre-dilatation will not achieve adequate luminal diameter to allow successful stent delivery and deployment.
- Ostial common carotid artery disease.
- Intracranial tumors, arterial vascular malformations, aneurysms, or severe intracranial stenosis distal of the target lesion.
- Arterial anatomy, severe vessel tortuosity, or structure of the lesion, not allowing correct positioning of the PAES.
- Severe peripheral vascular disease preventing femoral access or existing hemorrhagic disease or coagulation problems and/or inability to obtain hemostasis at the femoral puncture site.
- Inability to respond to commands required to determine intra-procedure level of consciousness (i.e., unable hear the commands and physically unable to squeeze with the hand contralateral to the target lesion).

If transcranial Doppler ultrasound is used to monitor cerebral perfusion in conjunction with the PAES, it is contraindicated for use on patients exhibiting an inadequate temporal window for imaging blood flow in the middle cerebral artery via transcranial Doppler ultrasonography.

3. INTERVENTION PROCEDURE

Access Femoral Artery

1. Under local anesthesia using a modified Seldinger technique, introduce a 5 or 6 French sheath into the mid common femoral artery.
2. Under fluoroscopy, advance a soft-tipped, steerable guidewire to be used for sheath introduction.
3. Following sheath placement, administer 5000 U of Sodium Heparin.

Image the Carotid Arteries with Arteriography

1. Under fluoroscopy guidance, advance a guidewire as far as the aortic arch.
2. Introduce a 5 to 6 French pigtail catheter over the wire and positioned it in the ascending aorta.
3. Remove the guidewire.
4. Obtain a road-mapping image in the left oblique position using a pump injection of 40 ml of iodinated contrast media.
5. Once the anatomy of the arch is defined, advance the guidewire and remove the pigtail. Access the right or left carotid artery using an appropriately curved diagnostic catheter.

Note: Passive curve catheters (i.e., Headhunter (H1), Vitek, Weinberg, etc.) are recommended with attempts at avoiding Simmons Sidewinder® or more active curve catheters if possible.

Note: Occasionally, in very tortuous vessels, passive curve catheters will be necessary. All the catheters for both carotid arteries should be 100 or 125 cm in length.

6. Once the artery is cannulated, carry out an arteriogram using road mapping. Obtain appropriate oblique images to define the carotid bifurcation. The angiographic field should include the tip of the catheter and the carotid bifurcation.
7. Inject a second dose of 5,000U of Heparin through the introducer. Maintain the activated coagulation time (ACT) between 200 and 250 seconds with additional Heparin doses if needed.

Access the External Carotid Artery

1. Under road mapping, position the soft tip guidewire in the external carotid artery (ECA).
2. Route a soft-tipped, malleable, diagnostic catheter over this wire and then anchor it into the distal external carotid artery.
3. Using meticulous fluoroscopic guidance, exchange the soft tip guidewire for a long TAD® (Mallinckrodt) or Super Stiff Amplatz® (Boston Scientific Corporation) guidewire.

Position the PAEC

1. Replace the 5 or 6 French introducer with a 10, 11, or 12 French sheath.
2. Advance the 80 cm long Parodi Anti-Emboli Catheter (PAEC) with the Parodi Anti-Emboli Dilator in place over the wire through the introducer. Position the PAEC in the common carotid artery (CCA) about 4 to 5 cm below the carotid artery bifurcation.

Note: In very tortuous anatomy, instead of using the dilator a 100 or 110 cm, 5 or 6 French multipurpose catheter can be placed into the CCA; then, the PAEC is advanced over the catheter into the appropriate position in the CCA.

 Position the PEB

1. A 6 French peel-away guiding catheter is then placed in the ECA using the guidewire that is inside the ECA.

Note: If a 6 French peel-away guiding catheter is not available:

- Remove the guidewire from the ECA.
 - Advance the Parodi External Balloon (PEB) under fluoroscopic guidance into the ECA.
 - Proceed to the next step (**Access the Femoral Vein**) to access the femoral vein.
2. Remove the guidewire. In very tortuous anatomy, the guidewire may be left inside the PAEC to prevent kinking.
 3. Place the Parodi External Balloon (PEB) in the ECA through the 6 Fr PAEC guiding catheter.
The PEB may be inserted without use of a guiding catheter. However, take care to prevent kinking the wire while the PEB is being introduced into the PAEC. A 6 Fr introducer may be used to cross the valves. The PEB can then be placed inside the PAEC via the 6 Fr introducer.

**WARNING!**

Patient hazard. Care must be taken to ensure that the PEB is fully inserted into the ECA to permit clear passage of the therapeutic or diagnostic device into the ICA.

4. Remove the 6 French guiding catheter.

 Access the Femoral Vein

Insert a 10 French introducer sheath percutaneously in the common femoral vein.

 Image the Carotid Artery Before Occlusion

An arteriogram of the carotid artery is performed injecting 5 ml of contrast media. Perform this injection with the head of the patient in the lateral projection or in the projection in which the carotid bifurcation is clearly defined.

Note: Before injecting any contrast media, suction should be applied with a 10 ml syringe to ensure cleanliness of the central lumen of the PAEC device.

Occlude the Common Carotid

Using less than 1 ml of a diluted (25% contrast, 75% saline) contrast media, first de-aerate the balloon of the PAEC by drawing back on the syringe to apply suction, then inflate the balloon with the contrast media until complete occlusion of the artery is achieved.



CAUTION!

Possible device damage. The balloon of the PAEC is small and can very easily be over-inflated. Infuse no more contrast media than is necessary to achieve occlusion as observed fluoroscopically.

Image the Carotid Artery After Occlusion

Perform a second arteriogram to define the flow pattern at the bifurcation after the CCA occlusion and confirm the complete occlusion of the CCA. The flow pattern after occluding the CCA shows that flow from the ECA usually fills the ICA and travels towards the brain.

Occlude the External Carotid

Using less than 0.5 ml of a diluted (25% contrast, 75% saline) contrast media first de-aerate the balloon of the PEB by drawing back on the syringe to apply suction, then inflate the balloon with the contrast media until complete occlusion of the external carotid artery is achieved.



CAUTION!

Possible device damage. The balloon of the PEB is small and can very easily be over-inflated. Infuse no more contrast media than is necessary to achieve occlusion as observed fluoroscopically.

Retrograde Flow

Cerebral protection is completed by connecting the side port of the PAEC to the venous introducer using a short connector with a blood filter interposed.

Monitor Patient Response to Occlusion

1. With both balloons inflated, observe the tolerance of the patient to occlusion. (See below Note Regarding Occlusion.) EEG and Transcranial Doppler monitoring may provide additional information about patient tolerance to carotid occlusion.

Notes:

- Flow velocity in the TCD usually drops and in few seconds starts to rise. If after a period of stabilization the velocity of the middle cerebral artery remains less than 50% of the initial value under the same mean arterial pressure, it means that the patient most

probably will need a different approach. Persistent drop of the flow velocity to half of the initial value often indicates cerebral ischemia.

- If a Transcranial Doppler (TCD) Monitor is used, at the moment the external artero-venous connection is created, the TCD could show inversion of the flow towards the PAEC and away from the brain. In some cases, the TCD does not show flow reversal in the Middle Cerebral artery. In these cases, an external transducer of a color Duplex System applied on the neck should show reversion of flow of the ICA. The system is now ready for cerebral protection.
 - A small amount of contrast media can be injected into the CCA directly or through a 5 Fr diagnostic catheter placed beyond the tip of the PAEC to insure the presence of flow reversal.
2. Check mental and motor status.
 3. Three or four minutes after occlusion occurs, decide if the procedure should be continued.

**WARNING!**

Patient hazard. Mean blood pressure should be maintained at a level of 90 ± 10 mm of mercury. Meticulous control of blood pressure also should include attempts at avoiding hypertension, since that may increase the risk of cerebral bleeding.

**CAUTION!**

Possible device damage. The balloon of the PAEC is small and can very easily be over-inflated. Infuse no more contrast media than is necessary to achieve occlusion as observed fluoroscopically.

Augmented Flow Reversal During Lesion Crossing and Angioplasty

1. When the lesion is crossed or the balloon is deflated, use a 20 ml syringe to increase blood flow by aspiration.
2. After suctioning, redirect the blood from the syringe into the femoral vein through the filter using a three-way stopcock.

Angioplasty and Stenting

1. Advance a 0.018" extra-support guidewire across the lesion into the Internal Carotid Artery (ICA).
2. Predilate the lesion with a 3.5 or 4 mm diameter balloon.
3. Deflate and remove the balloon.
4. Advance the stent delivery system over the wire.

**WARNING!**

Patient hazard. If there is any possibility that the stent will extend into the carotid bifurcation, care should be used in selecting and placing the stent considering the possibility of trapping the PEB in the ECA. A self-expanding stent, such as a Wall-Stent®, is recommended.

5. Once the stent is in the appropriate position, it is deployed and dilated, usually with a 5 mm diameter and 2 cm length balloon.

Monitor Patient Response to Arterial Dilatation

Hypotension, bradycardia, and even cardiac arrest can occur when the artery is dilated due to stimulation of baroreceptors. Inject atropine (0.5 mg) before dilatation and have metaraminol (Aramine) ready for use in case extreme hypotension develops. Venous access allows rapid insertion of a temporary pacemaker if needed.

Remove the PEB

1. Remove the PEB.

During deflation of the PEB, a strong negative pressure is applied by the syringe to aspirate potential particles attached to the balloon.

2. Leave the ICA guidewire inside the stent in case further instrumentation is needed.



WARNING!

Patient hazard. In the unlikely event that the PEB becomes ensnared on the tail of a stent extending into the carotid bifurcation, DO NOT EXERT UNDUE PRESSURE TO REMOVE IT. Remove the ICA guidewire. Cut the hub off the proximal end of the PEB. Thread a 6 French guiding catheter over the PEB and up to the point that it covers the balloon. Then both the PEB and the sheathing catheter can be removed. Attention should be paid to the length of the PEB in comparison to the length of the guiding catheter. If the length of the PEB outside the sheath is too short, a snare can be used to fix the end and advance the guiding catheter over the shaft of the snare and the PEB.

Image Arteries Post-Procedure

Perform a completion arteriogram, including intra-cranial views.

Remove Guidewire

Remove the ICA guidewire.

Remove PAEC

Deflate the PAEC balloon. During deflation, a strong negative pressure is applied by the syringe to aspirate potential particles attached to the balloon.

Remove Remaining Guide Wires and Catheters

1. Remove all remaining systems, leaving the 10 Fr introducer in the CFA, which is removed when the ACT is normalized.
2. Filters should be sent to the Pathology department to be examined and particles retrieved analyzed.

Note Regarding Occlusion

In case the patient does not tolerate occlusion, a decision must be made to abort the procedure, employ an alternative cerebral protection system (e.g., a distal carotid filter), or proceed without protection. In addition, general anesthesia should be immediately available. Once intolerance of the patient to balloon inflation is seen, balloons should be immediately deflated. At the same time, strong aspiration of the PAEC is applied in order to remove particles that could be trapped by the balloons. If the decision is made to continue the procedure, general anesthesia may be applied and the ancillary system may be used.

If intolerance to temporary carotid occlusion occurs in the middle of the procedure, mean arterial pressure should be raised immediately if needed, and pentothal anesthesia initiated if the patient develops seizures. The procedure should be rapidly terminated or at least the stage of the procedure completed. In any event, before deflating the balloons negative pressure is applied to remove any particles trapped by them.

If the operator learns that the patient is not going to tolerate carotid occlusion, he or she can decide to use it under general anesthesia using pentothal to decrease the cerebral demand of oxygen. The procedure when carefully planned can be performed in 5 to 7 minutes without using a distal carotid protection filter.

It is advisable, however, not to subject the patient to cerebral ischemia regardless of the duration of the procedure. In this case, with the patient under general anesthesia, the operator proceeds in the following manner: the PAES and PEB are positioned and inflated; a filter is advanced through the lesion under protection and opened beyond the stenosis, then the balloons are deflated. Protection is established with the filter and balloon dilatation and stenting accomplished as described before.

4. ACCESSORIES

In addition to the materials and equipment normally used in the conduct of transluminal percutaneous interventional angioplasty and stenting procedures, it is recommended that the following devices be available:

Guidewire	Wooley 0.35x260 (Mallinckrodt)
Guidewire	TAD II Wooley 0.18 x 0.35 x 260 (Mallinckrodt)
V-18 control wire	Hydrophilic Coating 0.18 x 300 cm (Boston Scientific)

BALLOON DILATATION CATHETERS (Boston Scientific)

Symmetry or Talon 2.5 x 2 / 4T / 135 cm

Symmetry or Talon 3.0 x 2 / 4T / 135 cm

Symmetry or Talon 4.0 x 2 / 4T / 135 cm

Symmetry or Talon 5.0 x 2 / 4T / 135 cm

Symmetry or Talon 6.0 x 2 / 4T / 135 cm

ARTERIO-VEINOUS SHUNT Consisting of 180-micron pore, blood transfusion filter, four-way stopcock, and appropriate tubing

Venous introducer



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