Instructions For Use:
NeuroVasx cPAX Aneurysm Treatment System

Neurovascular Embolization Device

US Patent No. 6,312,421; additional patents pending

Caution: Federal Law (USA) restricts this device to use by or on the order of a physician.

Humanitarian Device.
Authorized by Federal Law for use in the adult population (22 years of age and older) for the treatment of wide-necked large and giant sized cerebral aneurysms > 10 mm that require use of adjunctive assist-devices such as stents or balloons.
The effectiveness of this device for this use has not been demonstrated.

Indications for Use:

The cPAX System is intended for use in the adult population (22 years of age and older) for the treatment of wide-necked large and giant sized cerebral aneurysms > 10 mm that require use of adjunctive assist-devices such as stents or balloons.

Contraindications:

Use of cPAX System is contraindicated in:

- Patients with active bacterial infection or
- Patients in whom anticoagulation and antiplatelet therapy is contraindicated.

Warnings:

1. The safety and performance of this system have not been evaluated in patients with ruptured aneurysms.
2. Verify repeatedly that the distal shaft of the Microcatheter is not under stress before detaching the cPAX. Axial compression or tension forces could be stored in the Microcatheter, causing the tip to move during cPAX delivery. Microcatheter tip movement could cause the Aneurysm or Vessel to perforate or rupture.
3. The cPAX, Delivery/Detacher Device (D3), and Jumper Cable (JC) sterile components of the cPAX Aneurysm Treatment System (cPAX System) are intended for single use only. **Do not re-sterilize and/or attempt to clean and reuse the sterile components of the cPAX System.** After use, dispose in accordance with hospital administrative and/or local government policy. Do not use if sterile packaging is breached or damaged.

4. The Power Supply (PS) component of the cPAX System is provided NON-STERILE. The PS is the only component of the cPAX System that is reusable. Do not attempt to sterilize the PS.
5. Do not use any cPAX System sterile components that are outside of their "use by date.".
6. At no time should the tip of the D3 be shaped.
7. Advancement of the D3 outside the distal tip of the cPAX involves risk of aneurysm or vessel rupture.
8. Advancing the D3 proximal end of the marker beyond the proximal marker of microcatheter after detachment without fluoroscopic guidance involves risk of aneurysm or vessel rupture.
9. If at any time during the procedure resistance is encountered, discontinue any further advancement until the cause of the resistance can be determined to minimize risk of aneurysm or vessel rupture.
10. Use caution during adjunctive device usage, as excessive manipulation could cause aneurysm or vessel rupture.
11. At no time should the cPAX and/or D3 be torqued.
12. When using the cPAX System in conjunction with any adjunctive devices, follow all operative and post-operative medication recommendations (e.g. anti-platelet therapy) as stated in the device labeling or as prescribed by the physician.
13. Do not use Power Sources other than the cPAX PS specially built for the cPAX System.
14. Ensure the availability of any necessary equipment needed for concomitant treatment methods.

Precautions:

1. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures at medical facilities with the appropriate fluoroscopic equipment. Physicians should undergo appropriate cPAX System training prior to using it in patients.
2. Exercise care in handling of the cPAX, D3 during the procedure to reduce the possibility of accidental breakage, bending, or kinking.
3. Excessive tightening of the hemostasis valve on the microcatheter to the cPAX may cause the shaft to collapse. This will result in the inability to flush the cPAX or advance or retract the D3. Ensure that only enough tightening torque is used to prevent fluid from leaking between the microcatheter and the cPAX.
4. If resistance is encountered in withdrawing the cPAX which is at an acute angle relative to the microcatheter distal tip, it is possible to avoid cPAX damage by carefully repositioning the distal tip of the microcatheter at the ostium of the aneurysm, or, just slightly inside the parent artery. By doing so the aneurysm and artery act to "funnel" the cPAX back into the microcatheter.
5. Never perform a cPAX detachment outside the tip of the microcatheter.
6. Ensure that the electrical connectors on the D3 and the JC are kept dry.

7. Remove the batteries from the PS when not in use. Insert new AA batteries into the PS at the beginning of each procedure.
8. Read and follow the IFU of all agents or contrast media used with the microcatheter or other accessories.
9. High quality, digital subtraction fluoroscopic road mapping is mandatory to achieve safe catheterization of the aneurysm or vessel and correct placement of the cPAX.
10. Do not sterilize the PS.
11. Angiographic controls should be performed during the implant procedure and prior to detachment to ensure that the cPAX is not protruding into the parent vessel.
12. If at any time during the procedure the "Low Battery" light illuminates on the PS, switch to a back-up PS or install fresh batteries.
13. To maintain stability, the maximum mounting height of the PS should be 6 feet on a standard 27 inch wheel base IV pole.
14. The PS is not suitable for use in the presence of flammable anesthetics.
15. Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC.
16. Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment. This product is intended for use in the electromagnetic environments. The end user of this product should assure it is used in such an environment. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Potential Complications:

Potential complications include, but are not limited to:

- Hematoma at the site of entry
- Vessel perforation, aneurysm rupture
- Parent artery occlusion
- Incomplete aneurysm filling
- Hemorrhage including intracerebral, retroperitoneal or in other locations.
- Embolism of air, blood clots, cholesterol fragments
- Ischemia
- Vasospasm
- Coil migration or misplacement
- Premature or difficult coil detachment
- Clot formation
- Revascularization of the aneurysm
- Neurological deficits including stroke
- Chemical aseptic meningitis
- Hydrocephalus
- Headaches
- Infection

- Cranial neuropathy
- Hair loss
- Reactions due to radiation exposure
- Reactions to anesthesia and related procedures
- Reactions to antiplatelet/anticoagulant agents
- Reactions to contrast agents including allergic reactions and renal failure
- Death.

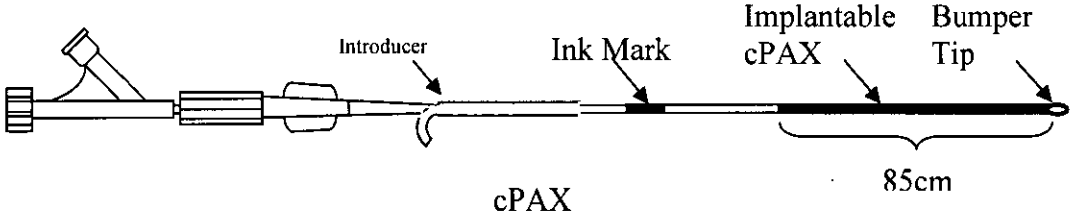
Device Description:
The cPAX System is comprised of a polymeric aneurysm filling material and the means to percutaneously deliver and detach the cPAX into an aneurysm in the neurovasculature. The cPAX System consists of:
1) The cPAX (figure 1) with D3 (figure 2) inside
2) The Jumper Cable (figure 3)
3) The Power Supply (figure 4)

cPAX System Components List

Component Name	Part Number
cPAX – 85cm	90023-001
cPAX Jumper Cable	90024-001
cPAX Power Supply	90015-002

cPAX System Component Description:
The cPAX System consists of 4 components as described below.

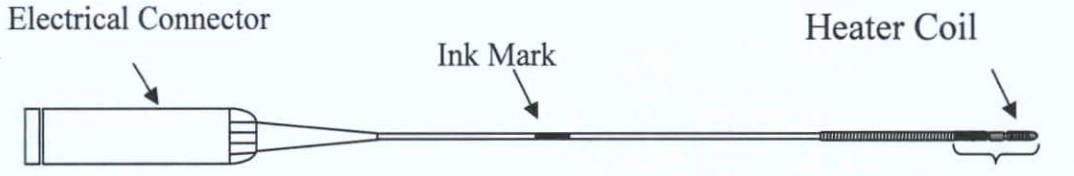
1) The cPAX consists of a proximal shaft and a distal section of detachable polymeric implant material with bumper tip at the distal end. The cPAX has a radiopaque material incorporated within to assist during navigation and placement with fluoroscopy. The cPAX shaft has an ink mark to indicate when fluoroscopic guidance will be required. A manifold with rotating hemostasis valve is attached at the proximal end for flushing the cPAX prior to use. A peel away introducer sheath is used to aid with insertion of the cPAX into the standard microcatheter.



cPAX
Figure 1

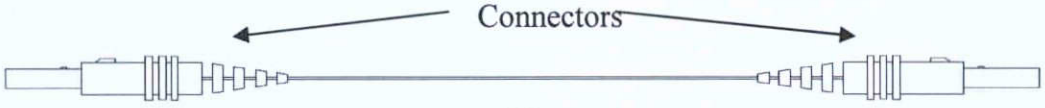
2) The Delivery/Detacher Device is a 0.011" device consisting of a core with an electric lead wire attached to a heater coil at the distal end. It is intended for the delivery of the cPAX into the aneurysm and subsequent

detachment. The distal end of the device is radiopaque to assist in guidance and placement of the device under fluoroscopy, along with a shaft ink mark to indicate when fluoroscopic guidance will be required. The D3 is packaged within the lumen of the cPAX.



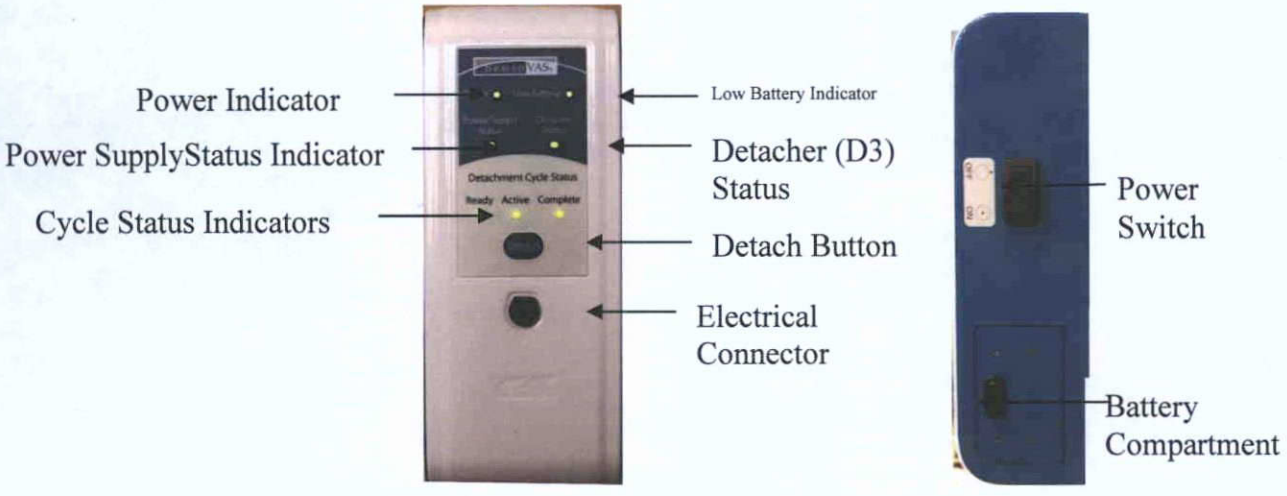
D3
Figure 2

3) The Jumper Cable is a cable that attaches the D3 to the PS. It has a 4-pin male connector on each end. The JC is non-patient contacting.



JC
Figure 3

4) The Power Supply is a reusable, battery operated, pole-mounted device, which provides a fixed direct current output via the JC to the D3 for a fixed cycle time to achieve melt separation of the cPAX. The PS is non-patient contacting.



PS
Figure 4

Specifications for Power Supply

1. Store PS in a cool, dry place. Environmental conditions for storage and transport:
    a. Temperature: -40°C to +70°C.

b. Relative humidity: 10% to 100%.
c. Atmospheric pressure: 500 to 1060 hPa.

2. PS is internally powered equipment, Rated IPX1.
3. Clean PS by wiping with disinfectant after use. Take care when cleaning in the vicinity of the Electrical Connector.

MR Compatibility

The cPAX embolization material is nonmetallic, non-conducting, and nonmagnetic. The cPAX embolization material was determined to be MR-safe according to the terminology specified in the American Society for Testing and Materials (ASTM) International Designation F2503-08, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. MRI testing demonstrated that the cPAX embolization material is MR safe and shows no apparent movement, temperature rise, or artifacts when exposed to 3-Tesla MRI conditions.

Required Additional Items for the Aneurysm Treatment Procedure:

- A second PS
- New AA batteries
- A non-tapered guiding catheter to facilitate a 2 Marker Infusion Microcatheter access to the vessel
- 2 Marker Infusion Microcatheter - The cPAX is compatible with the Prowler Plus Microcatheter with an inner diameter of 0.021" and a nominal length of 150cm
- Continuous flush setup with two rotating hemostasis valves (RHV's), two bags of appropriate flush solution (saline), and two 3-way stopcocks
- 0.010", 0.014", or 0.016" steerable guidewire (for placement of the microcatheter)
- Syringes; 1cc or 3cc, 20cc

Optional Items for the Aneurysm Treatment Procedure:

- A framing coil, finishing coil, balloon, or stent may be needed to achieve the desired occlusion of the aneurysm.

<u>Instructions for the cPAX System Use</u>

To prepare the cPAX System for use, all system components, including the PS, must be prepped prior to initiating the implant procedure according to the following instructions.

1.0 cPAX Preparation for Use

1.1 cPAX Preparation

1.1.1 Remove cPAX protective hoop assembly from the pouch. Attach a 20cc or larger syringe filled with saline to the side arm adapter of

the hoop and empty the syringe contents until saline exits the opposite end of the hoop.

1.1.2 Remove the cPAX from its hoop by grasping the cPAX and the tab of the introducer together. Attach a 1cc or 3cc syringe filled with saline to the flush port of the cPAX. Inject the saline until it exits the RHV on the cPAX. Tighten the RHV so no further saline can exit during injection. Continue the injection until a steady drip of saline is seen exiting the tip of the cPAX. Ensure that the distal tip of the D3 is at the tip of the cPAX.

1.1.3 During flushing the cPAX, if no saline is seen at the distal tip after 30 seconds:

1.1.3.1 Check the D3 movement and resume flushing the cPAX for an additional 30 seconds.

1.1.3.2 If no flush is achieved after 60 seconds, remove all, or a portion of the D3 and flush the cPAX. Re-insert the D3 after flush is achieved.

1.1.4 Keep the cPAX hydrated by placing it in a bowl or tray filled with saline. Keep the introducer positioned at the proximal end of the cPAX as shown in Figure 1. **Do not allow the D3 connector to contact any liquids or be submerged in the bowl of saline.**

1.1.5 If difficulty or damage is encountered during the preparation of the cPAX, discard and select a new cPAX.

1.2 PS Preparation (Figure 4)

1.2.1 Remove the PS from its shipping box and mount it to an IV pole.

1.2.2 Insert new batteries into the removable battery pack. Observe polarities as marked in the battery pack.

1.2.3 Turn the PS "on". The PS performs a system check for its electrical integrity. If the PS indicates "low battery", replace batteries. If the PS continues to indicate a failure, replace PS.

1.3 JC Preparation

1.3.1 Remove the JC from pouch and lay it in the sterile field.

1.3.2 Connect one end to the PS. This end of the JC is no longer sterile. DO NOT return this end to the sterile field.

1.4 D3 Preparation

1.4.1 Attach the sterile male connector on the JC securely to the female connector on the D3. The PS will automatically check the electrical integrity of the D3. If the PS indicates a D3 failure replace the D3.

1.4.2 If a new D3 is required during treatment, prepare an individually packaged D3.

1.4.2.1 Attach a 20cc or larger syringe filled with saline to the side arm adapter of the hoop and empty the syringe contents until

saline exits the opposite end of the hoop. **Do not allow the D3 connector to contact any liquids**

1.4.2.2 Remove D3 from hoop, insert into the cPAX and repeat step 1.4.1.

2.0 Aneurysm Treatment Procedure

2.1 It is recommended that the cPAX be used with a Prowler Plus Microcatheter with an internal diameter of 0.021" I.D. (.5mm) or greater, 150 cm in length with an attached RHV. The valve will ensure a fluid-tight seal around the cPAX. Maintain a continuous saline flush through the microcatheter throughout the procedure.

2.2 Place the tip of the microcatheter into the neck of the aneurysm using standard technique.

2.3 Advance the introducer distally on the cPAX until the introducer covers the bumper tip.

2.4 Open the RHV on the microcatheter and carefully insert the introducer and cPAX into the valve. Tighten the valve seal around the introducer to prevent movement of the introducer, but not so tightly as to inhibit cPAX or D3 movement.

2.5 Advance the cPAX through the introducer into the Microcatheter. The introducer may be moved proximally on the cPAX once the bumper tip and flexible portion of the D3 has been introduced into the Microcatheter.

2.6 If at any time during the procedure resistance is encountered, discontinue any further advancement or retraction until the cause of the resistance can be determined.

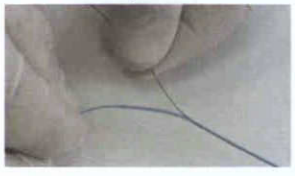


Figure 5

2.7 Continue to advance the cPAX through the Microcatheter until the cPAX Ink mark is reached. The introducer may be removed at this point or at any time beyond this point as desired by grasping the tab of the introducer and the cPAX just proximally and pulling the introducer away from the cPAX as shown in Figure 5.

2.8 Under fluoroscopic observation continue to advance the cPAX into the lumen of the Microcatheter. The proximal end of the radiopaque marker of the D3 should not extend more than 2-3mm distal of the microcatheter proximal markerband during advancement of the cPAX. (Figure 7)

2.8.1 While advancing the cPAX through the microcatheter and vascular tortuosity, confirm D3 movement within the cPAX.

2.8.2 If resistance in D3 movement is encountered, determine at what point within the vasculature the resistance is encountered.

2.8.3 At the point of resistance, retract the cPAX until the D3 movement is free. Note this location.

2.9 Hold the D3 steady at the noted location, then advance the cPAX over the D3 and fill the aneurysm.

2.10 Continue deploying the cPAX into the aneurysm until the desired occlusion of the aneurysm is confirmed with contrast enhanced fluoroscopic imaging or entire cPAX has been deployed.

3.0 cPAX Detachment

3.1 Advance the D3 within the cPAX until the D3 Ink mark reaches the microcatheter RHV.

3.2 Continue to advance the D3 under fluoroscopic guidance until the radiopaque marker aligns with the proximal marker of the microcatheter as shown in Figure 6.

3.2.1 If resistance due to tortuosity is encountered, retract the cPAX and D3 simultaneously approximately 3cm.

3.2.2 Advance the D3 within the cPAX approximately 3cm.

3.2.3 Simultaneously advance the cPAX and D3 approximately 3cm.

3.2.4 Repeat steps 3.2.1 through 3.2.3 to achieve marker alignment as shown in Figure 6.

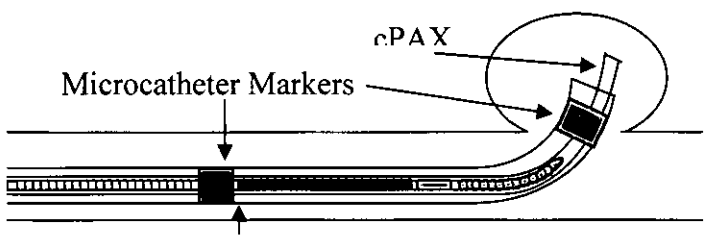


Figure 6 – D3 / Microcatheter Marker Alignment

3.3 Confirm that the Detacher Status and Ready lights are green on the PS.

3.4 Simultaneously pull back on the cPAX and D3 approximately 1cm to relieve any stored energy from the system.

3.5 Press the "Detach" button on the PS. The PS will automatically energize the D3 as indicated by a series of long beeps and an illuminated "Active" light.

3.6 When the PS tone changes from long to rapid beeps simultaneously pull back the cPAX and D3 approximately 2cm to separate the cPAX. The PS "Complete" light will illuminate when the active cycle is complete.

3.7 Disconnect the D3 from the JC.

3.8 Under fluoroscopy slowly pull the cPAX and D3 simultaneously approximately 3cm to confirm cPAX separation and that the implanted cPAX within the aneurysm is stable.

3.8.1 If the cPAX within the aneurysm is being retracted during the confirmation check, simultaneously push the cPAX and D3 back to the original position prior to retracting and perform another detachment cycle.

3.8.2 When an additional detachment procedure is required, securely reconnect the JC to the D3 and repeat steps 3.4 – 3.9. Note: D3

must be disconnected and reconnected to the JC to perform another detachment cycle.

3.8.3 If more than two attempts are required or a D3 fault is indicated by the PS:

3.8.3.1 Remove and replace the D3 with a new D3 and repeat detachment, or,

3.8.3.2 Simultaneously remove the cPAX and D3 and repeat treatment with a new cPAX and D3.

3.9 If additional filling is required to angiographically occlude the aneurysm, select another cPAX and repeat this procedure until the desired level of angiographic occlusion is achieved.

3.10 After detachment is confirmed an end of the implanted cPAX will be inside the microcatheter. Simultaneously advance the non-implanted cPAX and D3 until the proximal end of the marker on the D3 is situated approximately 2 mm distal of the proximal marker on the microcatheter. This will push the end of the implanted cPAX material into the aneurysm. (Figure 7)

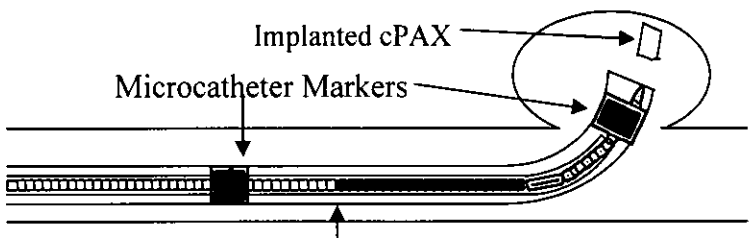


Figure 7 - D3 / Microcatheter Marker Alignment

3.11 Simultaneously retract microcatheter, cPAX and D3 and discard.

Storage Information: Store in a cool, dry place. Keep away from heat.

Symbol Glossary

Lot Number

Catalogue Number

European Representative

Do Not Reuse

Use Before Date

Sterile, Radiation

Manufactured By

Attention, See Instructions for Use

Serial Number

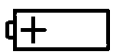
BF Applied

Direct current only

Class II device

Off

On



Observe Polarities

Keep away from heat.

Store in a cool dry place.

Medical Equipment
With Respect to Electric Shock, Fire, and Mechanical Hazards Only, In Accordance with UL 60601-1, CAN/CSA C22.2 No. 601.1, and IEC 60601-1

Manufactured By:

7351 Kirkwood Lane No. Suite 112, Maple Grove, MN 55369, USA
Telephone: 1-800-479-0256 Fax : 763-315-0966
www.neurovasx.com

60050-001

60050-001