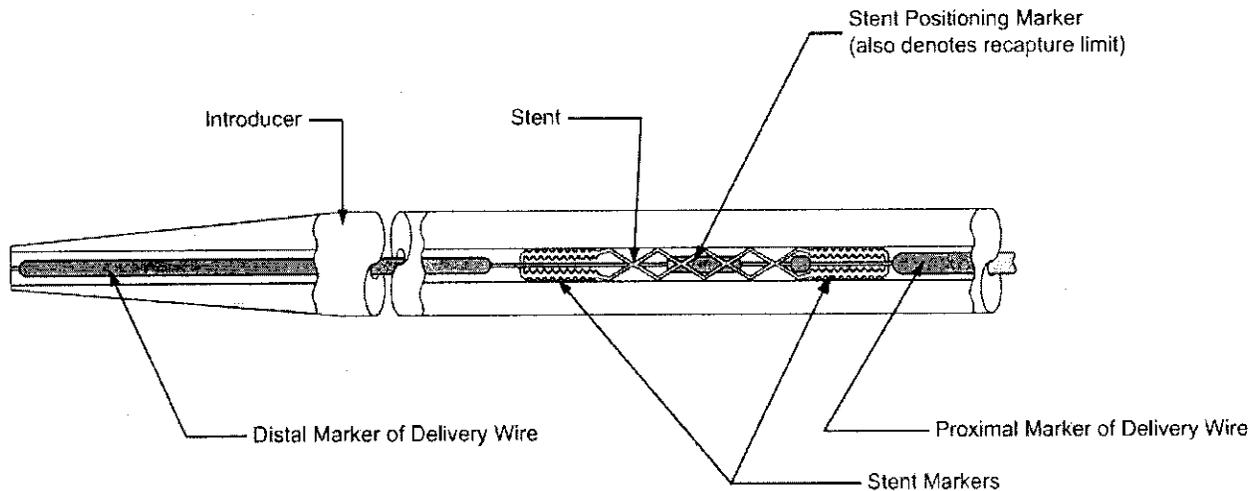




U.S. FOOD AND DRUG ADMINISTRATION

New Humanitarian Device Approval

New Humanitarian Device Approval



CORDIS ENTERPRISE™ Vascular Reconstruction Device and Delivery System - H060001

FDA approved this device under the Humanitarian Device Exemption (HDE) program. See the links below to the Summary of Safety and Probably Benefit (SSPB) and other sites for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: CORDIS ENTERPRISE™ Vascular Reconstruction Device and Delivery System

Manufacturer: Cordis Neurovascular, Inc.

Address: 14000 N.W. 57th Court, Miami Lakes, Florida 33014

Approval Date: May 8, 2007

Approval Letter:

What is it? The CORDIS ENTERPRISE™ Vascular Reconstruction Device and Delivery System is used with embolic coils for the treatment of intracranial aneurysms. It consists of a self-expanding stent and a delivery system. The stent serves as a

scaffold for embolic coils to prevent herniation of the coils into the parent vessel. The stent is a self-expanding, metal (nitinol) mesh in the shape of a tube. The delivery system is composed of an introducer and delivery wire and is used to deliver the stent to the treatment site in the neurovasculature.

How does it work?

- Advance stent system through microcatheter.
- Position the stent by aligning the stent positioning marker of the delivery wire with the target site.
- Unsheath to deploy.
- Carefully retract the microcatheter, while maintaining the position of the delivery wire, to allow the stent to deploy across the neck of the aneurysm.
- The stent will expand as it exits the microcatheter.
- Maintain distal access.
- Exchange microcatheter for coiling procedure.
- Proceed with coiling procedure through stent cells.

When is it used? The CORDIS ENTERPRISE™ Vascular Reconstruction Device and Delivery System is intended for use with embolic coils for the treatment of wide-neck, intracranial, saccular or fusiform aneurysms.

What will it accomplish? The stent serves as a scaffold for embolic coils to prevent herniation of the coils into the parent vessel.

When should it not be used? The CORDIS ENTERPRISE™ Vascular Reconstruction Device and Delivery System should not be used in patients who:

- the aneurysm size and/or parent vessel size does not fall within the indicated range
- cannot take blood-thinning (antiplatelet and/or anticoagulation) drugs to help prevent blood clots
- the angiography demonstrates the anatomy is not appropriate for endovascular treatment

Additional information:

SSPB and Labeling: The SSPB is not yet available and that a link will be established when the SSPB is posted to the web.

Cordis Neurovascular, Inc.

14000 NW 57th Court
Miami Lakes, FL 33014
1-800-327-7714

CORDIS ENTERPRISE™
Vascular Reconstruction Device and Delivery System

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For more patient information, please visit:
www.cordislabeled.com.

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Humanitarian Device (USA ONLY)

The CORDIS ENTERPRISE™ Vascular Reconstruction Device and Delivery System is authorized by Federal Law for use with embolic coils for the treatment of wide-neck, intracranial, saccular or fusiform aneurysms arising from a parent vessel with a diameter of ≥ 3 mm and ≤ 4 mm. Wide-neck is defined as having a neck width ≥ 4 mm or a dome to neck ratio < 2 . The effectiveness of this device for this use has not been demonstrated.

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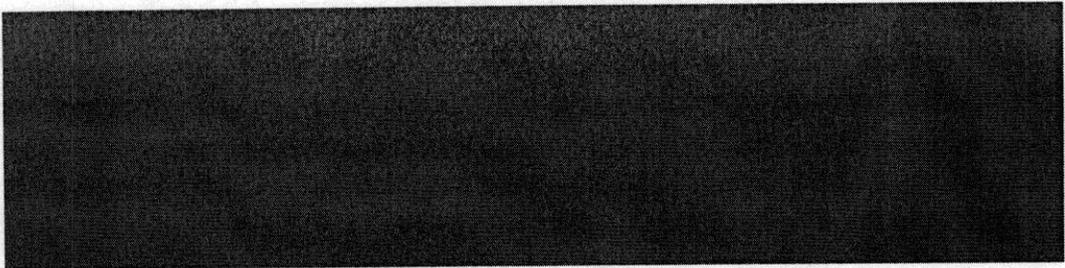
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Introduction

If you or a member of your family has been diagnosed with a cerebral or brain aneurysm, you may have questions about the condition and its treatment, especially if your doctor has recommended a neurovascular intervention using coils or a stent in combination with coils. This booklet will answer some common questions. Please read this booklet and discuss any questions with your physician. Please note that throughout this guide you will see different types of aneurysms located in various places. Treatment techniques may vary depending on your physician.

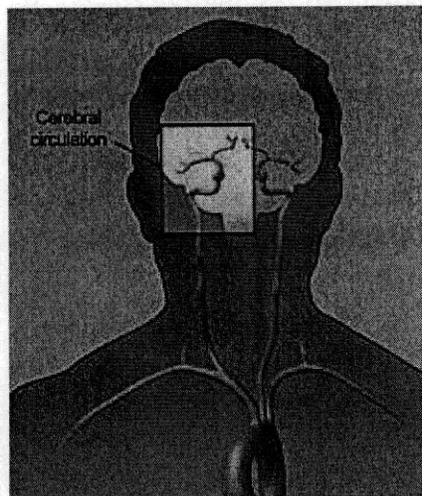


Diagram 1 – Blood vessels of the brain

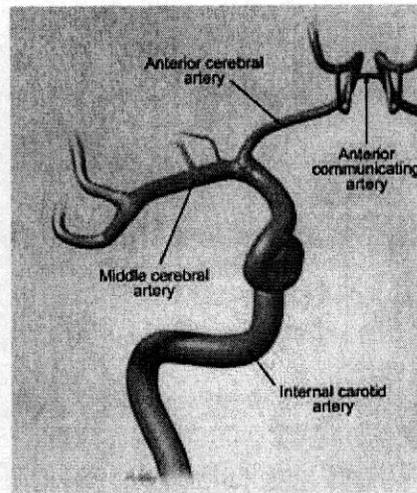


Diagram 2 – Blood vessels of the brain

Coils – An implantable medical device that has long strands of very thin, coiled wire that look like guitar strings but are flexible like telephone cords that facilitate clot formation within an aneurysm.

Neurovascular intervention – A minimally invasive procedure involving the cerebral vascular system where contrast dye is injected into the arteries in the brain via a catheter. Different types of medical devices may be used to treat any abnormalities.

What Is a Cerebral Aneurysm?

An aneurysm is a weak spot in the wall of a blood vessel that stretches or balloons out, forming a thin-walled bubble or sac. Aneurysms can form in blood vessels anywhere in the body. Cerebral aneurysms form in blood vessels of the brain. An aneurysm may become so weak that it ruptures and bleeds, similar to a balloon bursting.

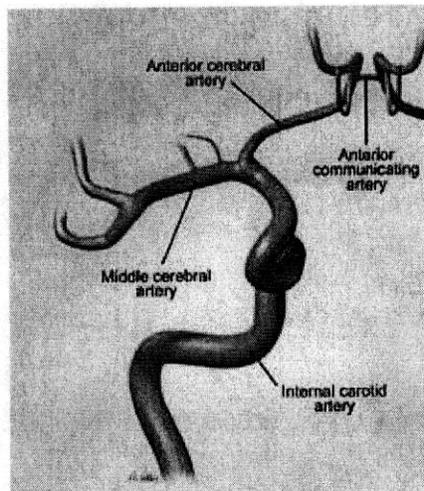


Diagram 3 – Healthy blood vessels

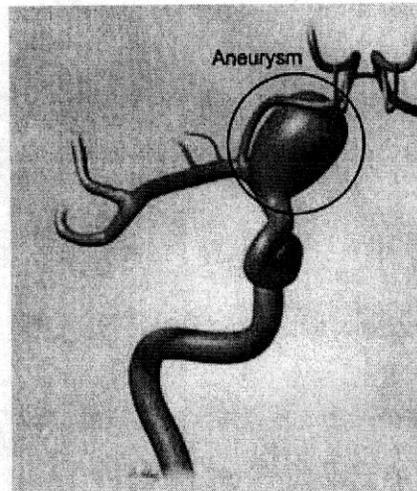


Diagram 4 – Cerebral aneurysm

Aneurysm – A weak spot in the wall of a blood vessel that stretches or balloons out, forming a thin-walled bubble or sac.

Cerebral – Having to do with the brain.

Stent – A specially designed, expandable metal tube that is inserted into a vessel. A stent acts as a scaffold to provide structure for a vessel. In a wide neck aneurysm, a stent is placed across the opening or neck of the aneurysm to secure the placement of coils and to maintain blood flow through the artery in which the stent is placed.

What Are the Risk Factors for an Aneurysm?

Aneurysms most commonly occur in people ages 35 to 60 and are more likely to occur in women. Aneurysms can develop because of infections, use of drugs that damage the blood vessels of the brain (such as amphetamines or cocaine), or an injury to the head. In rare cases, aneurysms are caused by other blood vessel diseases, for example, a disease called fibromuscular dysplasia. Also in some cases, a tendency to form aneurysms runs in families.

What Are the Symptoms of an Aneurysm?

A small, unruptured aneurysm usually does not cause any symptoms. Larger aneurysms may begin to put pressure on nearby structures, resulting in localized pain or headaches. As the aneurysm enlarges, it can begin to put enough pressure on the brain or nearby nerves that the patient experiences vision problems, arm or leg numbness, weakness, memory problems, speech problems, or seizures.

Amphetamines – A central nervous system stimulant that increases energy and decreases appetite; used to treat narcolepsy and some forms of depression.

Cocaine – A substance extracted from the leaves of the cocoa plant that may act as a powerful short-acting stimulant that speeds up the activity of some brain chemicals. Its effects may include euphoria, restlessness, excitement, or a feeling of well-being.

Fibromuscular dysplasia – Fibromuscular dysplasia, commonly called FMD, is a disease that causes one or more arteries in the body to have abnormal cell development in the artery wall. As a result, areas of narrowing, called stenosis, may occur. If enough narrowing causes a decrease in blood flow through the artery, an aneurysm may result.

Are All Aneurysms the Same?

Aneurysms can be different sizes.

- Aneurysms less than 10 mm are considered small.
- Aneurysms 10 mm to 20 mm are large aneurysms.
- Aneurysms larger than 20 mm are called giant aneurysms.

Aneurysms also differ in shape. Some examples are:

- Saccular (like a sack) with a narrow neck (also called berry aneurysms, because they look like a berry growing from the side or branch of a blood vessel; the narrow aneurysm neck looks like the stem of the berry).
- Saccular with a wide neck. In a wide-neck aneurysm, the neck is at least 4 mm wide, or at least half as wide as the distance from the neck opening to the top or dome of the aneurysm.
- Fusiform (spindle-shaped), without a distinct neck.

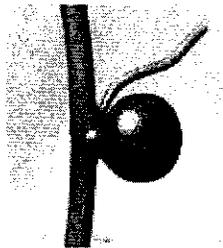


Diagram 5 – Saccular aneurysm

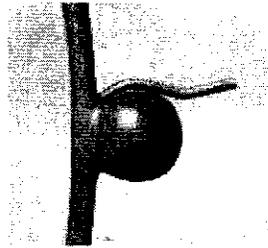


Diagram 6 – Wide-neck saccular aneurysm

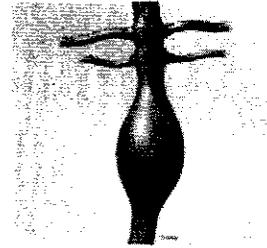


Diagram 7 – Fusiform aneurysm

Finally, aneurysms can be in different locations in the brain. Most develop on the major arteries deep within the center of the brain, either slightly toward the front near the eyes (anterior circulation) or slightly toward the back of the head (posterior circulation). Some people have multiple aneurysms in different places.

Aneurysm size, shape, and location affect how likely it is that the aneurysm will rupture and bleed. Aneurysms are usually less likely to bleed if they are small and uniform in size.

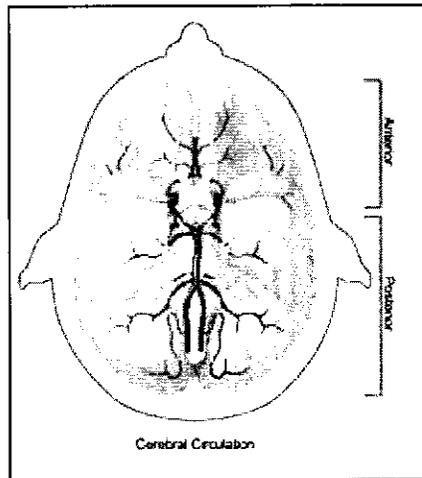


Diagram 8 – Cerebral circulation: Anterior - front view, Posterior - back view

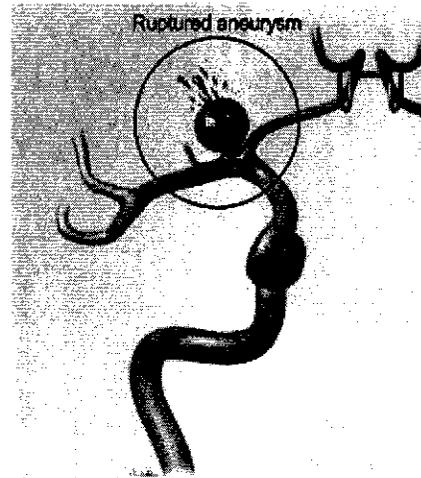


Diagram 9 – A ruptured aneurysm

What Is an Aneurysm Rupture?

You may hear the terms ruptured or unruptured when referring to aneurysms. A rupture happens when the thin wall of an aneurysm tears open, similar to a balloon bursting, which allows blood to spill out into surrounding areas. Bleeding like this is called a hemorrhage.

- When blood from a cerebral aneurysm spills directly into the brain, this is called a hemorrhagic stroke. Symptoms of this serious condition can include arm or leg weakness or paralysis, problems speaking or understanding speech, vision problems, or seizures.
- Following a hemorrhagic stroke, there is a risk of permanent damage to the brain or death, though some people experience only mild effects. If a ruptured aneurysm is not treated, however, there is a substantial risk another bleed may occur.

When an aneurysm bleeds, there is a risk of permanent neurological problems. Some people experience mild effects. If the ruptured aneurysm is not treated, there is a substantial risk that another bleed may occur.

Hemorrhagic stroke – When blood from a cerebral aneurysm spills directly into the brain.

Rupture – Tearing of a tissue.

Some of the risk factors that may cause an aneurysm to rupture are:

- Large Aneurysm
- High Blood Pressure
- Cigarette Smoking
- Heavy Alcohol Consumption
- Family History
- Drug Abuse

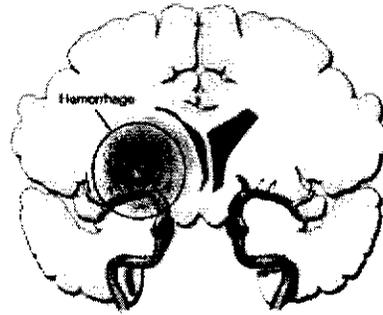


Diagram 10 – Hemorrhagic stroke

What Are the Symptoms of a Cerebral Aneurysm?

A small, unruptured aneurysm (one that has not torn open) usually does not cause any symptoms.

Larger unruptured aneurysms, as they stretch, may begin to put pressure on parts of the brain or nearby nerves. This pressure can cause localized pain or headaches. Also, depending on where the aneurysm is and what parts of the brain it presses on, the person may start to have vision problems, arm or leg numbness, weakness, memory problems, speech problems or seizures.

If an aneurysm ruptures, the person usually experiences a sudden, very severe headache, often described by survivors as “the worst headache of my life!” The headache may be accompanied by nausea, vomiting, stiffness in the neck, blurred or double vision, sensitivity to light, or loss of sensation.

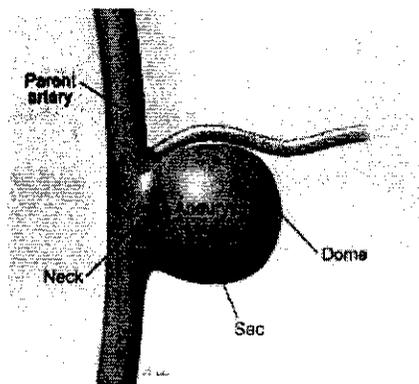


Diagram 11 – In a wide-neck aneurysm, the neck (opening) is at least 4 mm wide, or the neck is at least twice as wide as the dome (top).

What Is a Wide-Neck Aneurysm?

A wide-neck aneurysm is defined as having a neck width (opening at the base of the aneurysm) of at least 4 mm, or a neck at least twice as wide as the height of the aneurysm dome (top of the aneurysm).

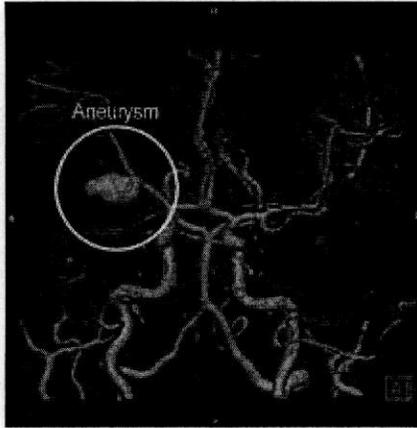


Diagram 12 – CT angiogram showing an aneurysm

How Is an Aneurysm Diagnosed?

An imaging test called CTA (computed tomographic angiography) is used to diagnose a cerebral aneurysm. This test shows the blood vessels in the brain. The patient lies on a table that slides into a CT scanner, shaped like a large ring. A dye is injected to make the blood vessels show up clearly on an x-ray. A series of x-rays are taken to look for abnormalities, such as an aneurysm, in the blood vessels.

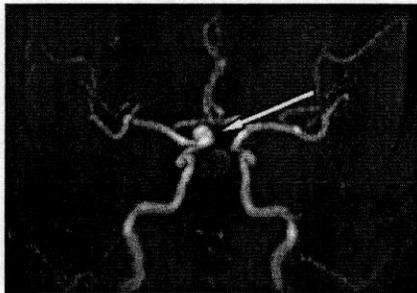


Diagram 13 – Magnetic resonance angiography

In a second test, called MRA (magnetic resonance angiography), patients are placed on a table that slides into a magnetic resonance scanner, and the blood vessels are imaged to detect a cerebral aneurysm. Both of these screening tests are useful to detect most cerebral aneurysms larger than 3-5 mm (about 3/16 inch).

The most reliable test is called a diagnostic cerebral angiogram. This test allows the doctor to look at the blood vessels of the brain and blood flow. In this test, the patient lies on an X-ray table. A small tube (catheter) is inserted through a blood vessel in the leg and guided into each of the blood vessels in the neck that go to the brain. In order for the vessels to show up clearly on the x-ray, contrast dye is injected through the catheter before x-ray pictures are

Computed tomographic angiography – A diagnostic test that uses x-rays taken from many angles to produce cross-sectional images of a part of the body.

Magnetic resonance angiography – A procedure in which radio waves and magnetic fields are used to generate computer images of the body's internal tissues.

taken. Because the dye is injected through a catheter, this test is slightly more invasive and less comfortable. However, it is the most reliable way to detect all types and sizes of cerebral aneurysms. Before any treatment is considered, a diagnostic cerebral angiogram is usually performed in order to fully map a plan for therapy.

If One Aneurysm Forms, Will Others Form?

The presence of one aneurysm is associated with a 15-20 percent chance of having at least one or multiple other aneurysms.

What Are the Symptoms of an Unruptured Aneurysm?

Smaller aneurysms usually have no symptoms. As an aneurysm enlarges, however, it can produce headaches or localized pain. If an aneurysm gets very large, it may produce pressure on the normal brain tissue or adjacent nerves. This pressure can cause difficulty with vision, numbness or weakness of an arm or leg, difficulty with memory or speech, or seizures.

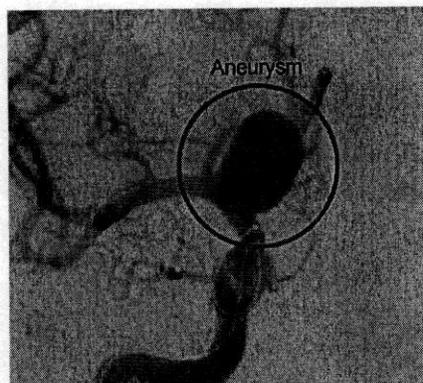


Diagram 14 – An angiogram showing an aneurysm

What Treatments Are Available?

Currently, there are three main treatment options for cerebral aneurysms: medication, neurosurgery, or neurovascular intervention. The treatment recommended for each patient depends on many factors, such as the aneurysm's size, shape and location, whether it has ruptured or not, and the patient's individual situation.

Contrast dye (x-ray dye) – A substance that is opaque to x-rays, used to permit visualization of internal body structures.

Diagnostic cerebral angiogram – A test used to diagnose abnormalities with the blood vessels of the brain. It is also used to determine if an aneurysm is present. This test involves guiding a small tube (catheter) from the leg blood vessels into the blood vessels of the neck and injecting contrast (dye) to see the blood flow.

Medical Therapy

Not all aneurysms require invasive treatment. If an aneurysm is small, unruptured, and not causing symptoms, the doctor may instead prescribe medications to control risk factors such as high blood pressure. Regular checkups are necessary to monitor blood pressure and other medical conditions. Regular imaging tests will show if the aneurysm begins to grow or change.

Neurosurgery

Neurosurgery to repair an aneurysm involves making an opening in the skull, gently spreading the brain tissue apart to expose the aneurysm, and placing a small metal clip on the neck of the aneurysm. The clip pinches the neck of the aneurysm closed to disconnect blood flow to the aneurysm.

During the surgery, the patient is given general anesthesia. If there are no complications during or after the surgery, most patients stay in the hospital four to six days and recover fully after several weeks or months.

Neurovascular Intervention

Neurovascular intervention involves approaching the aneurysm from inside the blood vessels and filling it with material that acts as a barrier to prevent blood from flowing into it, thus sealing off blood flow to the aneurysm.

During a neurovascular intervention procedure, the patient lies on an x-ray table, and images are taken throughout the procedure using a machine called a fluoroscope. A special dye is injected through a microcatheter within the blood vessels so that the physician can see the aneurysm inside the brain and guide medical devices to it without opening the skull.

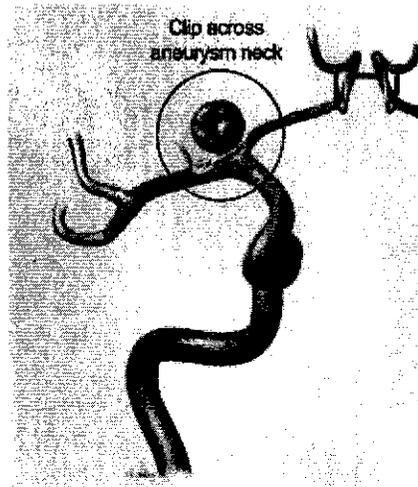


Diagram 15 – A surgically clipped aneurysm

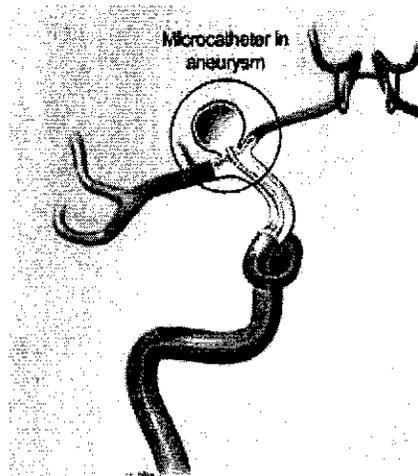


Diagram 16 – Microcatheter is positioned in the opening of the aneurysm

If there are no side effects or complications during or after the procedure, most patients stay in the hospital one or two days and recover fully after about a week.

Coil Embolization Procedure

This is a type of neurovascular intervention procedure. There are a few different types of material used to fill an aneurysm. The most common are coils – long strands of very thin, coiled wire that look like guitar strings but are flexible like telephone cords.

In a coil embolization procedure, the physician packs several of these coils into the aneurysm one by one until it is full. The coils will remain inside the aneurysm, and a clot or embolus will form around them, making it difficult for any more blood to enter the aneurysm. Because the body's natural response to the coils creates an embolus, the procedure is called coil embolization.

In this procedure, the physician first makes a small incision or puncture in the patient's inner thigh and inserts a tube into a large blood vessel in the leg. This tube is a catheter sheath introducer. Then, a thin guidewire is inserted through the catheter sheath introducer. Because the guidewire is metal, the physician can see it on the x-ray screen (fluoroscopy) to guide it through the blood vessels up to the brain and to the aneurysm itself.

Catheter sheath introducer – A hollow tube placed in a blood vessel and used to aid in the insertion of additional catheters or devices.

Embolization – Blocking a blood vessel or aneurysm so that blood can no longer flow into it.

Embolus – A clot or other plug that may obstruct circulation.

Fluoroscopy – An x-ray procedure in which x-rays are transmitted through the body onto a fluorescent screen; beneficial in observing the movement of joints or organ systems (e.g., the movement of material through the arterial system).

Guidewire – A flexible wire over which other devices, such as catheters, are guided to their target site.

Microcatheter – Small, thin, flexible tubes threaded into vessels to allow injection of contrast into specific areas or for the insertion of medical devices. Micro – a small catheter.

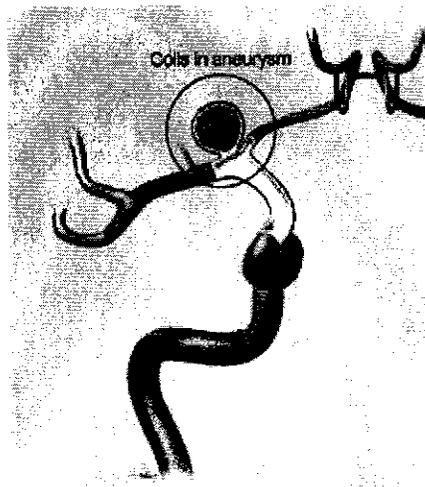


Diagram 17 – An aneurysm packed with coils

Over this guidewire, the physician threads a couple of long, thin tubes called catheters. A guiding catheter is threaded up to the base of the skull, and a smaller microcatheter runs from there through the blood vessels inside the brain to the aneurysm itself.

Then, the guidewire is removed. The physician threads the coils into the microcatheter one at a time and pushes them all the way up into the aneurysm. More coils are packed in until the aneurysm is completely full.

Coil Embolization Using an Intracranial Stent

Some types of aneurysms are difficult to treat with coils alone. For example, a wide-neck aneurysm may have such a large opening that the coils might not stay inside; they could fall back into the blood vessel and block or partly block the blood flow.

In these cases, the physician may first insert a stent inside the blood vessel where the aneurysm is located. A stent is a small, wire mesh tube that looks like a tiny roll of chain-link fence. In a coil embolization procedure for a wide-neck aneurysm, the stent is placed across the aneurysm neck and extends past the opening on both sides. This will help support the blood vessel.

The physician then inserts the coils as described above, threading them between the wires of the stent and into the aneurysm.

The stent acts as a small scaffold to hold the coils inside the aneurysm so they will not fall back into the vessel.

Guiding catheter – A catheter positioned in a blood vessel to allow for the passage of other devices through the catheter to a target site.

What Is the CORDIS ENTERPRISE™ Vascular Reconstruction Device?

The CORDIS ENTERPRISE™ Vascular Reconstruction Device is a type of intracranial stent. It is made of a flexible metal material called nitinol and is self-expanding.

When used in a procedure, the stent is squeezed into a very narrow tube that is part of its "delivery system" so that it will fit through the catheters.

When it is positioned precisely at the target site, the physician gently pushes the stent out of the tube, and it expands to its original shape, pressing firmly against the inner wall of the artery.

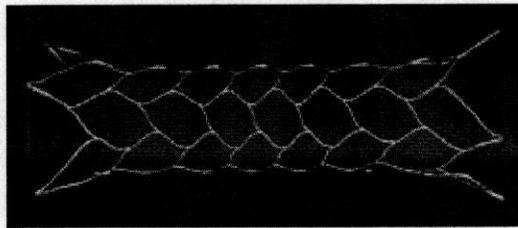


Diagram 18 – An expanded CORDIS ENTERPRISE™ VRD/stent

What Are the Potential Risks and Benefits of the Intracranial Stenting Procedure?

Some of the potential adverse events or complications that may be associated with intracranial stenting include:

- Rupture and bleeding of the aneurysm or blood vessel
- Aneurysm recanalization
- Death
- Allergic reactions or drug reactions
- Irregular heart rhythm
- Emergency neurosurgery

The effectiveness of the CORDIS ENTERPRISE™ Stent for use in treating wide-neck cerebral aneurysms has not been demonstrated.

Aneurysm recanalization – A previously treated aneurysm that refills with some blood and may require re-treatment.

Nitinol – A type of metal that "remembers" its shape and will return to that shape after being deformed.

In-Stent Restenosis and Other Potential Complications

Stenosis refers to narrowing or blockage in a blood vessel. When a stent is implanted in a blood vessel, the lining of the vessel is injured. The body initiates a natural healing response to repair this injury. Although the healing response is important, in some cases, it is exaggerated. This exaggerated response can lead to the accumulation of scar tissue within the stent, narrowing or blocking the blood vessel. This is called in-stent restenosis. In-stent restenosis can lead to a lack of blood flow and may result in damage to the brain.

A similar potential problem is stent thrombosis, or formation of a blood clot (thrombus) within the stent. Stent thrombosis can occur soon after stent implantation (acute stent thrombosis) or after some time (delayed stent thrombosis). Stent thrombosis can block blood flow through the vessel, potentially leading to ischemic stroke.

Stent migration (movement of the stent from its original precise position) also may occur. Other potential complications are re-opening of the aneurysm, puncture-site related complications, or blockage of side vessels by the stent.

Potential long-term complications of intracranial stents are unknown.

Ischemic stroke – Lack of blood flow in the brain, blood vessels, or major arteries leading to the brain may result in loss of consciousness, paralysis, or other symptoms depending on the extent of brain damage.

In-stent restenosis – A re-narrowing or blockage of an artery within a stent.

Stenosis – Narrowing of a blood vessel.

Thrombosis – Formation, development or presence of a thrombus.

Thrombus – An aggregation of blood frequently causing obstruction.

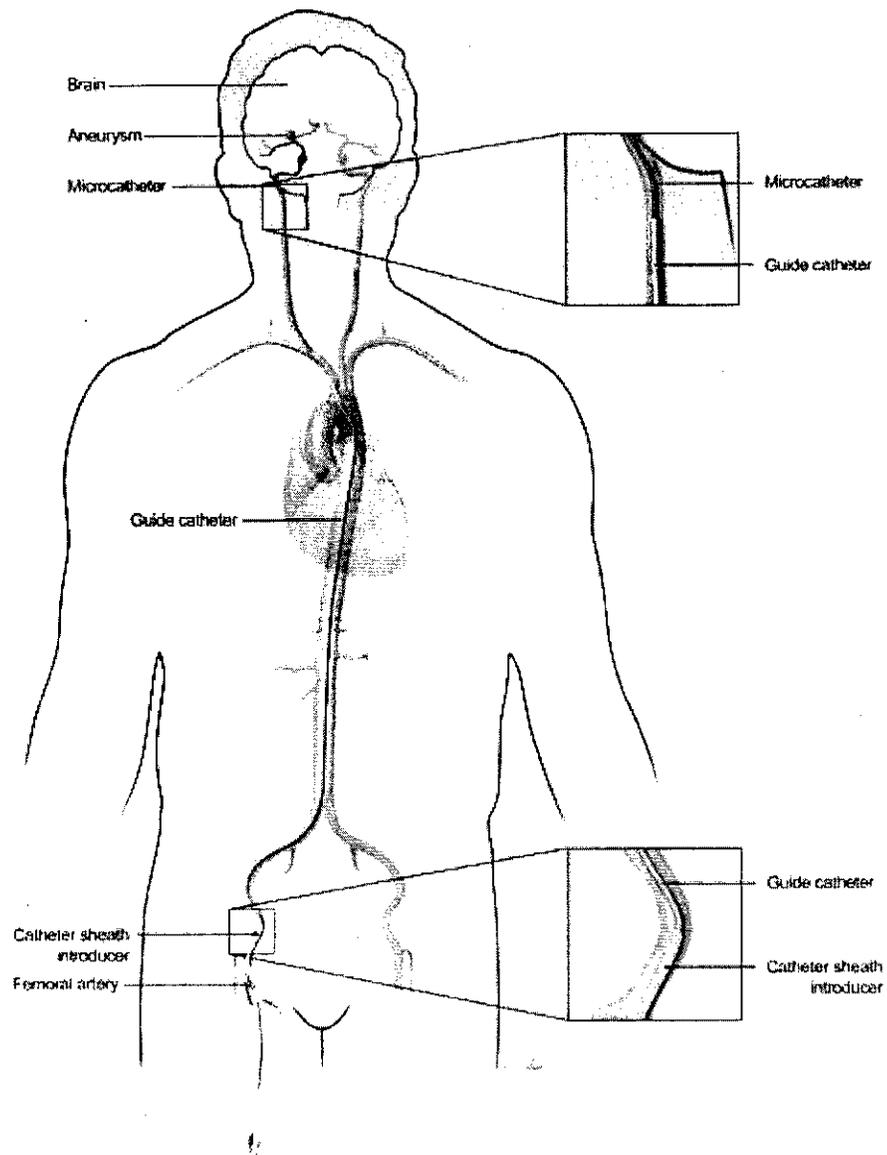


Diagram 19 – During a neuroradiologic procedure, a catheter is placed into an artery and then guided up into your brain.

How Is the Intracranial Stenting Procedure with the CORDIS ENTERPRISE™ Stent Performed?

Step-by-Step Procedure:

- A small opening is made in the inner thigh area. A short, narrow tube, called a catheter sheath introducer, is inserted into the artery of the leg through the small puncture site. A guidewire is placed through a longer, narrower tube, called a guiding catheter. The guiding catheter is passed through the catheter sheath introducer through the leg, neck, and into the brain and is placed at the base of the skull. Then a microcatheter is placed through the guiding catheter to the brain.
- X-ray dye is injected through the microcatheter to allow the doctor to see the blood vessels of the brain on an x-ray machine called a fluoroscope.
- With x-ray guidance, the doctor navigates the microcatheter into the blood vessel that contains the aneurysm.
- The stent, mounted on a delivery wire, is introduced into the microcatheter. The stent is pushed through the microcatheter into the aneurysm site. The stent is positioned precisely across the neck of the aneurysm. The microcatheter is then pulled back gently, while pressure is applied to the stent to keep it in place. The stent expands open against the vessel walls.

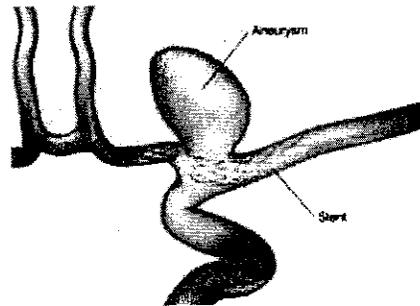


Diagram 20 – First the stent is placed across the neck of the aneurysm.

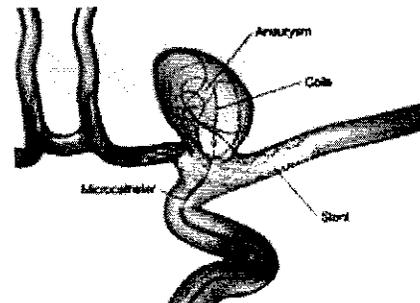


Diagram 21 – Then the coils are placed through the microcatheter which is placed through the stent cells (open areas) into the aneurysm. Physicians may use different techniques to place catheters inside the brain to access the aneurysm. In diagram 20, the microcatheter is placed through the middle cerebral artery. In diagram 21, the microcatheter is placed from a different vessel, the internal carotid artery.

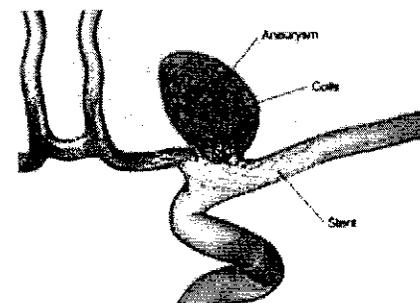


Diagram 22 – The stent remains implanted across the neck of the aneurysm and the coils remain inside the aneurysm.

- The stent delivery system is removed. A guidewire and microcatheter are then introduced through the guiding catheter and navigated through the open areas within the stent into the aneurysm, to facilitate the placement of coils.
- After the procedure is complete, the stent and the coils will remain implanted inside the patient and typically most other products will be removed. The patient will then follow physicians orders after the procedure.

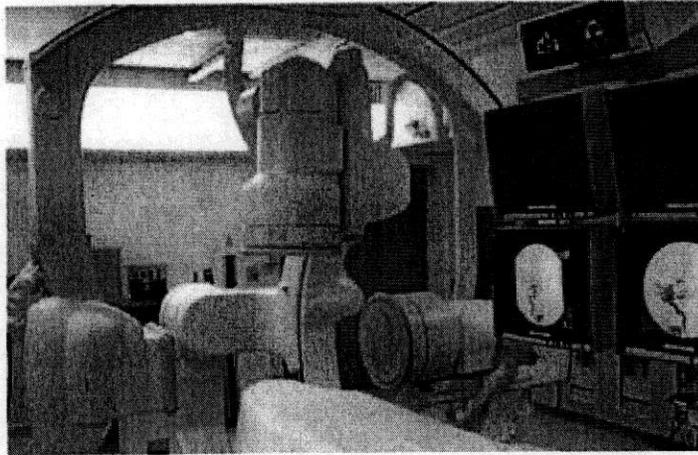


Diagram 23 – Photo of a typical angiographic suite where diagnostic and interventional neurovascular procedures are performed.

What Happens after the Procedure?

After the procedure, you may be moved to a special care unit where nurses will be able to monitor your heart rhythm and blood pressure very closely. The catheter sheath introducer may be removed at this time, and pressure will be applied to the puncture site until bleeding stops. If the catheters were inserted through your leg, you may be instructed to lie flat and not bend your leg for several hours. The nurses will monitor your incision for changes to ensure it is healing properly. **WARNING:** If you see any blood or feel warmth at the puncture site, tell your nurse immediately.

Once you return to your room, you may be able to eat and drink and your family may visit, depending on your doctor's orders. Eat foods that are light until you are able to sit upright. Drink all of the fluids offered to you, because they will help to flush the x-ray dye through your kidneys and out of your body. Your doctor will advise you when you can get out of bed and walk.

Many people go home the day after the procedure. The amount of time that you stay in the hospital depends on your doctor's discharge orders. These orders will be based on several factors, including any difficulties you may have experienced during the procedure and how well the puncture site is healing.

Taking Your Medications

- After you leave the hospital, you may be instructed to take blood thinning medications (also called anti-platelet or anti-coagulant medications). Depending on what medications your doctor prescribes, you may need to have follow-up blood tests to monitor the effects of the medication on your blood. These can be done at your local hospital laboratory or primary care doctor's office, and you may have breakfast before having the blood taken.
- **CAUTION:** It is very important that you take your medications exactly as prescribed, because they are intended to prevent the potential complications described earlier. Be sure not to miss any doses.
- **WARNING:** Call your doctor if you feel that you cannot tolerate your medications; if you develop any side effects such as bleeding, upset stomach, or rash; or if you have any questions.

What Follow-up Is Required after Treating Your Aneurysm?

After your aneurysm is treated, you will need to visit your doctor as recommended. Your physician may ask you to return to the hospital or clinic to have a CT scan, MRA, or diagnostic cerebral angiogram to see how your aneurysm is responding to treatment.

MRI Testing – WARNING

Before you have an MRI scan, or for questions about the coils or stent, you can provide the information below for details specific to each product. Additionally, questions can be directed to Cordis Neurovascular, Inc. at 1-800-327-7714. Choose Product Complaints option.

TRUFILL DCS ORBIT™ COIL

Through non-clinical testing, the TRUFILL DCS ORBIT™ and TRUFILL® DCS Detachable Coils have been shown to be MRI Conditional at field strengths of 3-Tesla or less, SAR of 2.0 W/kg for 20 minutes of MRI.

CORDIS ENTERPRISE™ Vascular Reconstruction Device

The CORDIS ENTERPRISE™ Vascular Reconstruction Device (VRD) has been shown to be MRI Conditional in MRI systems operating under the following conditions: static magnetic field of 3-Tesla or less, spatial gradient field of 720-Gauss/cm or less, and a maximum MRI system reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning.

Tesla – A unit measure of magnetic strength.

Summary

You have an important role to play to ensure that your procedure will be successful. Review this booklet, cooperate with your physician, and follow through with your responsibilities as part of the patient / medical team. If you have any questions or concerns, please contact your physician to discuss them.

For more information or to access the CORDIS ENTERPRISE™ Stent Implant Card and/or Patient Education Guide, please visit www.cordislabeling.com.

Glossary of Terms

Amphetamines – A central nervous system stimulant that increases energy and decreases appetite; used to treat narcolepsy and some forms of depression.

Aneurysm – A weak spot in the wall of a blood vessel that stretches or balloons out, forming a thin-walled bubble or sac.

Aneurysm recanalization – A previously treated aneurysm that refills with some blood and may require re-treatment.

Angiogram – A test used to visualize vessel abnormalities by injecting a special (contrast) dye into the vessels via a catheter. This allows the doctor to see on x-ray where the vessel abnormality is located.

Catheter sheath introducer – A hollow tube placed in a blood vessel and used to aid in the insertion of additional catheters or devices.

Cerebral – Having to do with the brain.

Cocaine – A substance extracted from the leaves of the cocoa plant that may act as a powerful short-acting stimulant that speeds up the activity of some brain chemicals. Its effects may include euphoria, restlessness, excitement, or a feeling of well-being.

Coils – An implantable medical device that has long strands of very thin, coiled wire that look like guitar strings but are flexible like telephone cords and facilitate clot formation within an aneurysm.

Computed tomographic angiography – A diagnostic test that uses x-rays taken from many angles to produce cross-sectional images of a part of the body.

Contrast dye (x-ray dye) – A substance that is opaque to x-rays, used to permit visualization of internal body structures.

Diagnostic cerebral angiogram – A test used to diagnose abnormalities with the blood vessels of the brain. It is also used to determine if an aneurysm is present. This test involves guiding a small tube (catheter) from the leg blood vessels into the blood vessels of the neck and injecting contrast (dye) to see the blood flow.

Embolic – Having to do with an embolus, which is a blood clot or other foreign material that causes blockage in a vessel.

Embolization – Blocking a blood vessel or aneurysm so that blood can no longer flow into it.

Embolus – A clot or other plug that may obstruct circulation.

Fibromuscular dysplasia – Fibromuscular dysplasia, commonly called FMD, is a disease that causes one or more arteries in the body to have abnormal cell development in the artery wall. As a result, areas of narrowing, called stenosis, may occur. If enough narrowing causes a decrease in blood flow through the artery, an aneurysm may result.

Fluoroscopy – An x-ray procedure in which x-rays are transmitted through the body onto a fluorescent screen; beneficial in observing the movement of joints or organ systems (e.g., the movement of material through the arterial system).

Guidewire – A flexible wire over which other devices, such as catheters, are guided to their target site.

Guiding catheter – A catheter positioned in a blood vessel to allow for the passage of other devices through the catheter to a target site.

Hemorrhage – Loss of blood from damaged blood vessels.

Hemorrhagic stroke – When blood from a cerebral aneurysm spills directly into the brain.

In-stent restenosis – A re-narrowing or blockage of an artery within a stent.

Interventional neuroradiology / INR also known as endovascular surgery – A medical specialty that addresses problems of the cerebral vascular system using minimally invasive or endovascular techniques. This usually includes vascular procedures that are intracranial (within the skull) and extracranial (outside the skull, but above the heart).

Ischemic stroke – Lack of blood flow in the brain, blood vessels, or major arteries leading to the brain may result in loss of consciousness, paralysis, or other symptoms depending on the extent of brain damage.

Magnetic resonance angiography – A procedure in which radio waves and magnetic fields are used to generate computer images of the body's internal tissues.

Microcatheter – Small, thin, flexible tubes threaded into vessels to allow injection of contrast into specific areas or for the insertion of medical devices.

Micro – a small catheter.

Narcolepsy – A sleep disorder consisting of recurring episodes of sleep during the day and often disrupted sleep at night.

Neurology – The medical science that deals with the nervous system and disorders affecting it.

Neurovascular intervention – A minimally invasive procedure involving the cerebral vascular system where contrast dye is injected into the arteries in the brain via a catheter. Different types of medical devices may be used to treat any abnormalities.

Nitinol – A type of metal that “remembers” its shape and will return to that shape after being deformed.

Parent artery – The artery from which a given artery (the branch) originates.

Radiopaque – An object that blocks x-rays so that it creates an outline of the structure being looked at on x-ray film.

Rupture – Tearing of a tissue.

Stenosis – Narrowing of a blood vessel.

Stent – A specially designed, expandable metal tube that is inserted into a vessel. A stent acts as a scaffold to provide structure for a vessel. In a wide neck aneurysm, a stent is placed across the opening or neck of the aneurysm to secure the placement of coils and to maintain blood flow through the artery in which the stent is placed.

Tesla – A unit measure of magnetic strength.

Thrombosis – Formation, development or presence of a thrombus.

Thrombus – An aggregation of blood frequently causing obstruction.

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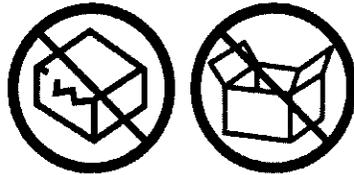
Instructions For Use

CORDIS ENTERPRISE™ Vascular Reconstruction Device and Delivery System

Explanation of symbols on labels and packaging:

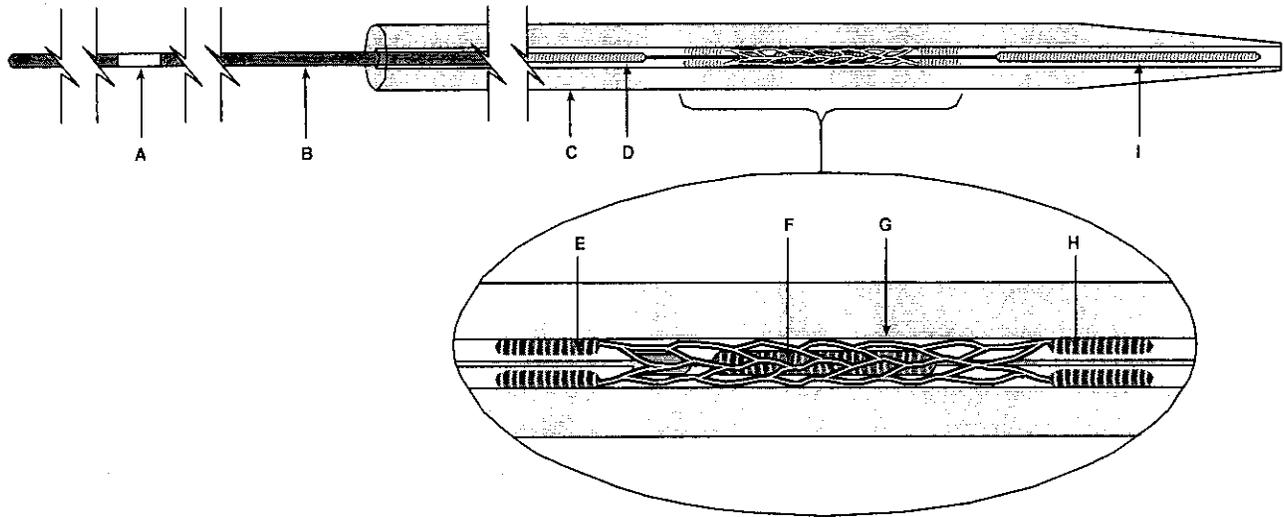


Store in a cool, dark, dry place.



Do not use if package is open or damaged.

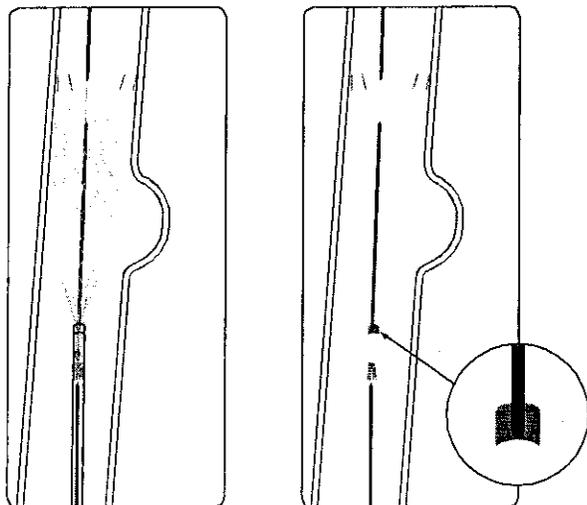
Figure 1: CORDIS ENTERPRISE™ Vascular Reconstruction Device and Delivery System



Note: Items are not drawn to scale

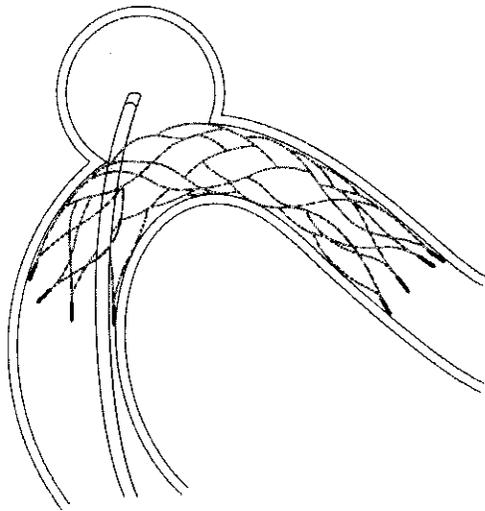
- A: Reference marker (150 cm from delivery wire tip)
- B: Proximal delivery wire
- C: Introducer
- D: Proximal marker of delivery wire
- E: Proximal stent markers
- F: Stent positioning marker of delivery wire
- G: Stent body
- H: Distal stent markers
- I: Distal marker of delivery wire

Figure 2: Vascular Reconstruction Device deployed to recapturability limit (Proximal end of the stent positioning marker is even with the distal infusion catheter markerband). LEFT: vessel and infusion catheter shown as transparent to indicate Vascular Reconstruction Device and Delivery Wire landmarks. RIGHT: schematic of fluoroscopic view.



Note: Items are not drawn to scale

Figure 3: Infusion catheter positioned in aneurysm through Vascular Reconstruction Device cells.



Note: Items are not drawn to scale

English

Humanitarian Device (USA ONLY): Authorized by Federal Law for use with embolic coils for the treatment of wide-neck, intracranial, saccular or fusiform aneurysms arising from a parent vessel with a diameter of ≥ 3 mm and ≤ 4 mm. Wide-neck is defined as having a neck width ≥ 4 mm or a dome-to-neck ratio < 2 . The effectiveness of this device for this use has not been demonstrated.

STERILE. Sterilized with ethylene oxide gas. Nonpyrogenic. For one use only. Do not resterilize.

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

I. Device Description

The **CORDIS ENTERPRISE™ Vascular Reconstruction Device (VRD) and Delivery System** is comprised of a self-expanding stent (VRD) and a delivery system (Figure 1). The delivery system is comprised of a delivery wire and an introducer. The stent is pre-loaded on the delivery wire inside the introducer.

The implantable stent is made of Nitinol and has a closed cell design. The stent has four markers on each end, and is coated with a polymer.

The delivery wire is composed of a Nitinol corewire with radiopaque markers.

The introducer consists of a polymer tube with a tapered distal end. It is designed to protect the stent from damage and creates an uninterrupted passage for the stent to be transferred from the introducer into the infusion catheter.

The **CORDIS ENTERPRISE Vascular Reconstruction Device and Delivery System** is designed for use under fluoroscopy with the **PROWLER®SELECT™ Plus** Infusion Catheter, (a 0.021" inner diameter, 5 cm distal length infusion catheter manufactured by Cordis Neurovascular, Inc.).

Caution: Compatibility with other infusion catheters has not been established.

The **CORDIS ENTERPRISE Vascular Reconstruction Device** is available with the following stent sizes:

Unconstrained Stent Diameter (mm)	Unconstrained Stent Length (mm)	Recommended Parent Vessel Diameter (mm)	Length Foreshortening		% Open Area	
			%	mm	4 mm	3 mm
4.5	14	3 – 4	6.7	1.1	96.8	95.9
4.5	22	3 – 4	7.7	1.9	94.1	92.6
4.5	28	3 – 4	9.8	3.2	92.3	90.1
4.5	37	3 – 4	10.9	4.7	89.8	86.8

II. Intended Use

The **CORDIS ENTERPRISE Vascular Reconstruction Device and Delivery System** is intended for use with embolic coils for the treatment of wide-neck, intracranial, saccular or fusiform aneurysms arising from a parent vessel with a diameter of ≥ 3 mm and ≤ 4 mm. Wide-neck is defined as having a neck width ≥ 4 mm or a dome-to-neck ratio < 2 .

III. Contraindications

Intracranial artery stenting is generally contraindicated in the following patient types:

- Patients in whom the aneurysm size and/or parent vessel size does not fall within the indicated range.
- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
- Patients in whom the angiography demonstrates the anatomy is not appropriate for endovascular treatment, due to conditions such as:
 - o Severe intracranial vessel tortuosity or stenoses
 - o Intracranial vasospasm not responsive to medical therapy

IV. Warnings

- The stenting procedure should be carried out under the direction of personnel with the requisite interventional training, especially intracranial stent procedures. Appropriate facilities should be available for managing the potential complications of the procedure.
- The device is designed to be manipulated while under high-quality fluoroscopic observation. If resistance is met during manipulation, determine the cause of resistance before proceeding.
- The appearance of the temperature exposure indicator label, found on the inner pouch, must be lighter than the surrounding gray color box. The acceptance criterion of the label is delineated by the graphic with the green check mark. Do not use if the temperature exposure indicator label is as dark or darker than the surrounding gray color box because the unconstrained stent diameter may have been compromised by exposure to high temperature. The reject criterion for the label is delineated by the graphics marked with a red "X".
- Do not use if the inner package is opened or damaged.
- Persons with allergic reactions to nickel titanium (Nitinol) may suffer an allergic response to this implant.
- Adverse events may occur without warning. At all times a fully equipped emergency cart and resuscitation equipment should be readily available, and personnel competent in recognizing and treating adverse events of any severity should be on hand.

V. Precautions

- Experience with stent implants indicates that there is a risk of stenosis. Stenosis may require dilatation of the vessel segment containing the stent. The risks and long-term outcome following dilatation of endothelialized stents is unknown at present.
- The **CORDIS ENTERPRISE Vascular Reconstruction Device and Delivery System** is not intended for use as a stand-alone device, i.e. without subsequent coil embolization of the aneurysm.
- Do not use the **CORDIS ENTERPRISE Vascular Reconstruction Device and Delivery System** if any component appears damaged or missing.
- Confirm that the device labeling clearly indicates the size of the stent to be used.
- Do not expose the system to organic solvents (e.g., alcohol).
- For single use only. Do not resterilize or reuse.
- Use product prior to the "Use By" date.
- Store system in a cool, dark, dry place.
- Dispose of all used devices in accordance with hospital policy for biohazardous materials.

- Coil protrusion during embolization may not be visualized fluoroscopically because of the superimposition of the stent and coil mass. Intermittent angiograms in multiple views may be necessary to ensure there are no coil loops protruding into the parent artery.
- Do not recapture the stent more than once.
- During deployment, the stent will foreshorten. Refer to the “Device Description” section to examine foreshortening values for each of the stent sizes.
- The performance and safety of two or more overlapped stents has not been established. The ability of the stent to withstand post balloon dilatation has not been established.
- Select a stent length that is at least 10 mm longer than the aneurysm neck to maintain a minimum of 5 mm on either side of aneurysm neck.
- Use caution when crossing the deployed stent with guidewires or accessory devices.

VI. Observed and Potential Adverse Events

Observed Adverse Events from Clinical Study

Twenty-eight subjects were entered into the clinical study and treated with a **CORDIS ENTERPRISE Vascular Reconstruction Device**. A Clinical Events Committee reviewed all adverse event listings and adjudicated all reported serious adverse event summaries during the course of the study. An adverse event was defined as any untoward medical occurrence in a subject compared to pre-existing conditions that occurred during the clinical investigation.

Fifty-seven adverse events that were considered to be at least possibly procedure or device related occurred in 20 subjects. The majority (68.4%) of these events occurred by 30 days. Table 1 summarizes all device or procedure related adverse events, including Serious Adverse Events.

Table 1: Adverse Events¹

Device or Procedure Related Adverse Events	Number of Occurrences	Number of Subjects (%) N = 28	Time of Occurrence		
			Procedure	1 - 30 days	31 days - 6 months
Headache	8	5 (17.9%)	1	2	5
Insertion site hematoma/bleeding	5	5 (17.9%)	5	0	0
Laboratory abnormality	5	4 (14.3%)	0	1	4
TIA	3	3 (10.7%)	1	2	0
Mid, Low back pain	3	3 (10.7%)	2	1	0
Floaters, blurry vision	3	2 (7.1%)	0	2	1
Left, Right-sided weakness	2	2 (7.1%)	0	1	1
Intracerebral hemorrhage ²	2	2 (7.1%)	0	2	0
Aneurysm recanalization	2	2 (7.1%)	0	0	2
Not feeling right	2	1 (3.6%)	0	2	0
Nausea	2	2 (7.1%)	1	1	0
Fever	2	2 (7.1%)	1	1	0
Edema	2	2 (7.1%)	1	1	0
Cerebral infarct	1	1 (3.6%)	0	1	0
Cranial nerve II deficit	1	1 (3.6%)	0	1	0
Stenosis of stented segment	1	1 (3.6%)	0	0	1
Cranial nerve palsy	1	1 (3.6%)	0	1	0
Failure deliver stent	1	1 (3.6%)	1	0	0
Panic attack	1	1 (3.6%)	0	0	1
Confusion	1	1 (3.6%)	0	1	0
Neck pain	1	1 (3.6%)	1	0	0
Arm cramps	1	1 (3.6%)	1	0	0
Upset stomach	1	1 (3.6%)	1	0	0
Pain at insertion site	1	1 (3.6%)	1	0	0
Hip pain	1	1 (3.6%)	1	0	0
Cold hands and feet	1	1 (3.6%)	1	0	0
Eyes fixed unable to focus	1	1 (3.6%)	0	0	1
Visual field decrease	1	1 (3.6%)	0	0	1
Facial numbness	1	1 (3.6%)	0	1	0

Database closure 07/13/2005

¹ Includes both non-serious adverse events and CEC adjudicated serious adverse events

² One subject died post-operatively, resulting in a death rate of 3.6% (1/28)

Based on the Clinical Events Committee adjudication, seven patients experienced one or more serious adverse events for an estimated rate of 25.0% (Table 2).

Table 2: Adjudicated Serious Adverse Events Related to Procedure or Device

Device or Procedure Related	All Subjects (N = 28)	95% Confidence Interval
Any Procedure or Device Related	25.0% (7/28)	[10.7%, 44.9%]
Intracerebral Hemorrhage ¹	7.1% (2/28)	[0.9%, 23.5%]
Aneurysm Recanalization	7.1% (2/28)	[0.9%, 23.5%]
TIA (Transient Ischemic Attack)	7.1% (2/28)	[0.9%, 23.5%]
Cerebral Infarct	3.6% (1/28)	[0.1%, 18.3%]
Cranial Nerve II Deficit	3.6% (1/28)	[0.1%, 18.3%]
Cranial nerve palsy	3.6% (1/28)	[0.1%, 18.3%]
Groin Hemorrhage	3.6% (1/28)	[0.1%, 18.3%]

¹ One of these subjects died post-operatively, resulting in a death rate of 3.6% (1/28) with a 95% confidence interval of [0.1%, 18.3%]. A **CORDIS ENTERPRISE Vascular Reconstruction Device** and coils were successfully deployed to treat the aneurysm without any reported technical complications. The death was classified as secondary to the subject's presenting intracerebral hemorrhage.

Potential Adverse Events

Potential adverse events that were not observed in the clinical study but that may be associated with the use of the CORDIS ENTERPRISE™ Vascular Reconstruction Device and Delivery System or with the procedure include:

- | | |
|---|------------------------------------|
| Allergic reaction including, but not limited to contrast, Nitinol metal and medications | Myocardia infarction |
| Arrhythmia | Neurological deficit |
| Arteriovenous fistula | Infection at insertion site |
| Coil migration/prolapse into normal vessels adjacent to the aneurysm | Perforation |
| Dissection | Pseudoaneurysm |
| Emboli (air, tissue or thrombotic) | Renal failure |
| Emergent neurosurgery | Rupture, vessel or aneurysm |
| Incomplete aneurysm occlusion | Seizures |
| Infection | Stent migration/embolization |
| Injury to normal vessels or tissue | Stent thrombosis/occlusion |
| Ischemia | Stroke |
| Occlusion of side branch | Total occlusion of treated segment |
| | Vasospasm |
| | Vessel thrombosis |

VII. Clinical Study

This was a prospective, non-randomized feasibility study conducted at five institutions in the United States. The goal of the study was to demonstrate the safety and feasibility of the **CORDIS ENTERPRISE™ Vascular Reconstruction Device and Delivery System**. Subjects were eligible if they presented with a ruptured (Hunt and Hess Grade I – III) or non-ruptured intracranial wide neck saccular aneurysm that was deemed by the attending interventional neuroradiologist to be an acceptable candidate for endovascular coil embolization. Wide neck was defined as having a neck width ≥ 4 mm or a dome-to-neck ratio < 2.

The study included four periods: screening period, treatment period, thirty-day follow-up and six-month follow-up. Subjects were evaluated with an independent neurological assessment and cerebral angiography preoperatively, with a cerebral angiography immediately postoperatively, with a neurological examination prior to hospital discharge and at 30 days follow-up, and with a neurological examination and cerebral angiography at 6 months.

The endpoints of the study were 1) an adverse event assessment post-procedure, at discharge, at thirty days and six months after treatment, 2) neurological status assessed by an independent neurologist at discharge, at thirty days and six months after treatment compared to the baseline evaluation and 3) technical feasibility for all subjects with a deployed stent to evaluate the percent aneurysm occlusion immediately post-procedure and at six months after treatment, to evaluate for successful stent placement with satisfactory coil mass position post-procedure, and to assess for coil mass position at six months after treatment.

Patient Data

Thirty subjects were enrolled into the study. The average age of the 30 subjects enrolled in this study was 57.8 years and a majority of the subjects were female (76.7%). A medical history of hypertension was reported in 66.7% of the subjects enrolled and 40.0% had cardiovascular disease. The most commonly reported neurological event was pounding/pulsatile headache (43.3%) and 26.7 % had a history of Altered Mental Status. At baseline, 23.3% of the subjects had undergone an intracranial embolization procedure. Baseline data for these patients are presented in Table 3: Patient Demographic, Table 4: Medical History, Table 5: Neurological History and Table 6: Previous Neurological Surgical Procedures.

Table 3: Patient Demographics

Subject Characteristics	Total (N=30)
Gender	
Male	7 (23.3%)
Female	23 (76.7%)
Age (years)	
Mean	57.8
Range (min, max)	22.0 – 77.0
Standard deviation	13.9
Age Group (years)	
≤ 39	2 (6.7%)
40-49	6 (20.0%)
50-59	8 (26.7%)
60-69	6 (20.0%)
≥ 70	8 (26.7%)

Table 4: Medical History

Subject Characteristics	Total (N=30)
Medical History	
(non-exclusive, N, % or mean ± SD)	
Hypertension	20 (66.7%)
Cardiovascular Disease	12 (40.0%)
Musculoskeletal Disease	8 (26.7%)
Psychological	8 (26.7%)
Chronic Pulmonary Disease	7 (23.3%)
Gastrointestinal Disease	7 (23.3%)
Immunologic	6 (20.0%)
Endocrine / Metabolic Disease	5 (16.7%)
Diabetes	3 (10.0%)
Renal Disease	3 (10.0%)
Hepatic / Pancreatic Disease	2 (6.7%)
Lymphatic	2 (6.7%)
Connective Tissue Disorder	1 (3.3%)
Hypersensitivity or Contrast Material	1 (3.3%)
Peripheral Vascular Disease	1 (3.3%)
Other	20/29 (69%)

Table 5: Neurological History

Subject Characteristics	Total (N=30)
Neurological History (non-exclusive, N, % or mean ± SD)	
Pounding/Pulsatile Headaches	13 (43.3%)
Altered Mental Status	8 (26.7%)
Cranial Nerve Palsy	5 (16.7%)
Seizures	5 (16.7%)
Subarachnoid Hemorrhage	5 (16.7%)
CVA (stroke)	4 (13.3%)
Deterioration	3 (10.0%)
TIA	2 (6.7%)
Other	7 (23.3%)

Table 6: Previous Neurological Surgical Procedures

Subject Characteristics	Total (N=30)
Previous Neurological Surgical Procedures	
Intracranial Embolization	7 (23.3%)
Intracranial Radiosurgery	1 (3.3%)
Intracranial Clipping	1 (3.3%)

Two of the 30 subjects met angiographic exclusion criteria during the pre-procedure angiography and were not treated with a **CORDIS ENTERPRISE Vascular Reconstruction Device**. Of the 28 subjects who were entered into the clinical study and treated with a **CORDIS ENTERPRISE Vascular Reconstruction Device**, the aneurysms were most commonly located in the internal carotid/ophthalmic location (57.1 %). Five aneurysms (17.9%) were located in the vertebrobasilar system. Table 7 summarizes the locations of the treated aneurysms.

Table 7: Aneurysm Location

Aneurysm Location	Total	
	N	%
Carotid/Ophthalmic	16	57.1
Distal 1/3 Basilar (including apex)	4	14.3
Posterior Communicating	3	10.7
Cavernous Carotid	1	3.6
Carotid Bifurcation	1	3.6
Middle Cerebral	1	3.6
Posterior Cerebral	1	3.6
Vertebral	1	3.6

Aneurysm and Parent Artery Dimensions

An independent angiographic core laboratory was used to assess the aneurysm and parent artery dimensions. Table 8 contains the pre-procedure, post-procedure, and six month aneurysm dimensions. Table 9 contains the parent artery dimensions. At pre-procedure, the mean aneurysm dome height and width were 8.2 mm and 8.6 mm, respectively. The mean neck width was 5.3 mm, and mean dome width-to-neck ratio was 1.43. The mean proximal/distal diameter of the parent vessel pre-procedure was 3.4/3.0, and 3.3/2.9 at six months.

Unaccounted for data include N/A (not available) or N/D (not determinable) assessments. N/A was assigned by the core laboratory if the measure was not appropriate, such as in the case of measuring neck width for a fusiform aneurysm. N/D was assigned when the core laboratory was unable to perform the measurement due to poor image quality or complex aneurysm shape resulting in visual overlap with the parent artery, or if the measurement could not be determined due to the presence of coils from a previous embolization procedure.

Table 8: Aneurysm Dimensions

Parameters Measured	Pre-Procedure (N = 28) 1, 2	95% Confidence Interval	Post-Procedure (N = 28) 1, 2	95% Confidence Interval	Six Months (N = 28) 1, 3	95% Confidence Interval
Dimensions of Aneurysm						
Neck Width (mm)						
Mean ± SD (n)	5.3 ± 1.6 (23)	[4.6, 6.0]	5.5 ± 1.7 (18)	[4.6, 6.3]	5.2 ± 1.8 (21)	[4.4, 6.0]
Range (min., med., max.)	(2.9, 5.0, 8.7)		(2.8, 5.1, 9.1)		(2.0, 5.1, 8.3)	
Maximum Dome Height (mm)						
Mean ± SD (n)	8.2 ± 4.9 (28)	[6.3, 10.1]	9.0 ± 5.0 (23)	[6.7, 9.9]	8.4 ± 4.1 (22)	[6.6, 10.3]
Range (min., med., max.)	(2.6, 6.5, 25.0)		(2.7, 8.0, 24.8)		(2.6, 8.3, 17.9)	
Maximum Dome Width (mm)						
Mean ± SD (n)	8.6 ± 4.0 (27)	[7.0, 10.2]	8.9 ± 4.8 (27)	[6.8, 9.8]	8.5 ± 3.9 (25)	[6.9, 10.1]
Range (min., med., max.)	(3.2, 7.0, 18.0)		(3.1, 7.2, 24.1)		(2.6, 7.8, 17.5)	
Dome Width: Neck Width Ratio						
Mean ± SD (n)	1.43 ± 0.40 (23)	[1.26, 1.61]	1.37 ± 0.34 (18)	[1.20, 1.54]	1.50 ± 0.41 (20)	[1.31, 1.69]
Range (min., med., max.)	(1.0, 1.3, 2.8)		(1.01, 1.28, 2.37)		(1.0, 1.4, 2.4)	

Numbers are % (numerator/denominator) or mean ± 1 SD.

¹ Unaccounted for data include observations classified as N/A = Not Available or N/D = Not Determinable.

² Twenty-eight subjects were available for post-procedure measures. Two of the 30 enrolled subjects were not entered into the study due to a pre-procedure angiographic exclusion criteria and therefore are not included in the post-procedure measurements.

³ Twenty-seven subjects were available in follow-up. Two of the 30 enrolled subjects were not entered into the study due to a pre-procedure angiographic exclusion criterion and one subject died after the procedure.

Table 9: Parent Artery Dimensions

Parameters Measured	Pre-Procedure (N = 28) 1, 2	95% Confidence Interval	Post-Procedure (N = 28) 1, 2	95% Confidence Interval	Six Months (N = 28) 1, 3	95% Confidence Interval
Dimensions of Parent Artery						
Proximal Diameter (mm)						
Mean±SD (n)	3.4 ±0.7 (28)	[3.1, 3.6]	3.4 ± 0.7 (28)	[3.1, 3.6]	3.3 ± 0.8 (27)	[3.0, 3.6]
Range (min., med., max.)	(1.7, 3.3, 4.7)		(1.8, 3.3, 4.9)		(1.9, 3.3, 4.9)	
Distal Diameter (mm)						
Mean±SD (n)	3.0 ± 0.8 (28)	[2.7, 3.3]	3.0 ± 0.8 (28)	[2.7, 3.2]	2.9 ± 0.7 (27)	[2.6, 3.1]
Range (min., med., max.)	(1.9, 2.9, 4.8)		(1.9, 2.9, 4.8)		(1.7, 2.8, 4.1)	

Numbers are % (numerator/denominator) or mean ± 1 SD.

¹Unaccounted for data include observations classified as N/A = Not Available or N/D = Not Determinable.

²Twenty-eight subjects were available for post-procedure measures. Two of the 30 enrolled subjects were not entered into the study due to a pre-procedure angiographic exclusion criteria and therefore are not included in the post-procedure measurements.

³Twenty-seven subjects were available in follow-up. Two of the 30 enrolled subjects were not entered into the study due to a pre-procedure angiographic exclusion criterion, and one subject died after the procedure.

Procedure Success Measures (Technical Feasibility Endpoints)

Twenty-seven of 28 subjects entered into the study received the **CORDIS ENTERPRISE Vascular Reconstruction Device** and were followed for six months. One subject died post-operatively. Two subjects received two stents.

Technical success was judged based on angiographic core lab assessment. Successful stent placement with satisfactory coil mass position immediately post-procedure was 100%. Successful stent placement was defined as stable stent placement with complete coverage across the aneurysm neck and parent artery patency, while satisfactory coil mass position was defined as the stent maintaining coil position within the sac with parent artery patency. Maintenance of coil mass position was 95.8% at six months. The protocol-defined procedural success measures are provided in Table 10.

Table 10: Procedure Success Measures

Parameters Measured	Post-Procedure (N = 28) ^{1, 2}	95% Confidence Interval	Six Months (N = 28) ^{1, 3}	95% Confidence Interval
Procedure Success Measures				
Proximal Parent Artery Coverage (mm)				
Mean±SD (n)	10.0 ± 3.5 (26)	[8.6, 11.4]	- ± - (0)	[-, -]
Range (min., med., max.)	(3.6, 9.9, 20.3)		(-, -, -)	
Distal Parent Artery Coverage (mm)				
Mean±SD (n)	7.5 ± 2.8 (26)	[6.4, 8.7]	- ± - (0)	[-, -]
Range (min., med., max.)	(1.3, 7.0, 13.6)		(-, -, -)	
Stable stent Placement with Complete Neck Coverage	100.0% (26/26)	[86.8%, .%]	- (- / -)	[-, -]
Maintenance of Coil Mass Position	100.0% (23/23)	[85.2%, .%]	95.8% (23/24)	[78.9%, 99.9%]
Procedure Success ⁴	95.5% (21/22)	[77.2%, 99.9%]	- (- / -)	[-, -]

Numbers are % (numerator/denominator) or mean ± 1 SD.

¹Unaccounted for data include observations classified as N/A = Not Available or N/D = Not Determinable.

²Twenty-eight subjects were available for post-procedure measures. Two of the 30 enrolled subjects were not entered into the study due to a pre-procedure angiographic exclusion criteria and therefore are not included in the post-procedure measurements.

³Twenty-seven subjects were available in follow-up. Two of the 30 enrolled subjects were not entered into the study due to a pre-procedure angiographic exclusion criterion and one subject died after the procedure.

⁴Successful stent placement with satisfactory coil mass position angiographically assessed immediately post procedure without the occurrence of procedural serious adverse events. The duration of the procedure was defined as the time the stent delivery system was introduced into the infusion catheter until the time the guiding catheter was removed from the subject.

02

The independent core lab assessment of mean percent aneurysm occlusion for the different follow-up time points in the study is presented in Table 11. The mean post-procedure percent aneurysm occlusion was 87.9%, becoming 92.0% at six months. The mean values were further categorized by percent occlusion.

Table 11: Percent Aneurysm Occlusion – Independent Core Laboratory

Parameters Measured	Post-Procedure (N = 28) ¹	95% Confidence Interval	Six Months (N = 28) ³	95% Confidence Interval
Occlusion of Aneurysm				
Mean±SD (n)	87.9% ± 14.4 (24 ²)	[81.8%, 94%]	92.0% ± 13.9 (25 ⁴)	[86.2%, 97.7%]
Range (min., med., max.)	(30.0%, 95.0%, 95.0%)		(33.0%, 95.0%, 100.0%)	
Percent Occlusion				
100%	0.0% (0/24)	[-, 14.2%]	36.0% (9/25)	[18.0%, 57.5%]
95% - 99%	58.3% (14/24)	[36.6%, 77.9%]	28.0% (7/25)	[12.1%, 49.4%]
< 95%	41.7% (10/24)	[22.1%, 63.4%]	36.0% (9/25)	[18.0%, 57.5%]

¹ Twenty-eight subjects were available for post-procedure measures. Two of the 30 enrolled subjects were not entered into the study due to a pre-procedure angiographic exclusion criteria and therefore are not included in the post-procedure measurements.

² Four subjects did not have a percent aneurysm occlusion measurement due to N/A = Not Available or N/D = Not Determinable.

³ Twenty-seven subjects were available in follow-up. Two of the 30 enrolled subjects were not entered into the study due to a pre-procedure angiographic exclusion criterion and one subject died after the procedure.

⁴ Three subjects did not have a percent aneurysm occlusion measurement due to N/A = Not Available or N/D = Not Determinable.

Neurological Assessments (Neurological Status Endpoint)

Neurological Assessments were performed pre-procedure, at discharge, 30 days, and six months post procedure. The mean NIH Stroke score was 1.4 pre-procedure and 0.3 at six months. The majority of subjects (75.9%) were rated Grade 0 or Grade 1 on the modified Rankin scale pre-procedure, and 80.7% of subjects were Grade 0 or Grade 1 at six months. One subject was enrolled with acute subarachnoid hemorrhage. The Hunt & Hess score for this subject had degraded from a Grade III to Grade IV just prior to the procedure. The subject expired after the procedure as a result of intracerebral hemorrhage. For the clinical neurological examinations which included vision, motor, sensory, speech, mutation, and cranial nerve deficit, most subjects experienced either no change or improved status from pre-procedure assessment to six months.

VIII. Magnetic Resonance Imaging (MRI)

Non-clinical testing demonstrated that the **CORDIS ENTERPRISE Vascular Reconstruction Device** is MR Conditional based on ASTM F 2503-05. A patient with the **CORDIS ENTERPRISE Vascular Reconstruction Device** can be scanned, immediately after placement of this implant, under the following conditions:

-Static magnetic field of 3-Tesla or less

-Spatial gradient field of 720-Gauss/cm or less

-Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning.

In non-clinical testing, the **CORDIS ENTERPRISE Vascular Reconstruction Device** produced a temperature rise of less than or equal to 0.5°C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3-W/kg for 15-minutes of MR scanning in a 3-Tesla MR system.

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the **CORDIS ENTERPRISE Vascular Reconstruction Device**. Optimization of MR imaging parameters is recommended.

IX. Preparations for Use

In addition to the **CORDIS ENTERPRISE Vascular Reconstruction Device and Delivery System**, the following items are recommended:

- Appropriately sized Cordis Sheath Introducer
- A **PROWLER SELECT Plus** Infusion Catheter (0.021" inner diameter, 5 cm distal length infusion catheter manufactured by Cordis Neurovascular, Inc.)
- **TRUFILL®** family of Detachable Coils and **TRUFILL® DCS Syringe**
- Appropriately sized exchange length guidewire for the selected infusion catheter
- **ENVOY®** Guiding Catheter for the selected infusion catheter
- Two or more Y connector/Rotating Hemostasis Valves (RHV) with ≥ 0.076 " lumen diameter
- Sterile heparinized saline solution

Vascular Reconstruction Device and Delivery System Selection

Appropriate selection of the **CORDIS ENTERPRISE Vascular Reconstruction Device and Delivery System** is important for patient safety. In order to choose the optimal **CORDIS ENTERPRISE Vascular Reconstruction Device and Delivery System** for any given lesion, examine pre-stent procedure angiograms.

X. Directions for Use

1. Gain vascular access according to standard practice.
2. Navigate the infusion catheter (.021" **PROWLER SELECT Plus** Infusion Catheter, 5 cm distal length) over a guidewire at least 1.2 cm distal to the aneurysm neck.
3. Remove the guidewire.
4. Maintain flush through the infusion catheter per standard endovascular practice.
5. Select an appropriate **CORDIS ENTERPRISE Vascular Reconstruction Device and Delivery System**.
6. Carefully inspect the Vascular Reconstruction Device and Delivery System package for damage to the sterile barrier.
7. Peel open the pouch using aseptic technique.
8. Carefully place the dispenser hoop into the sterile field.
9. Remove the delivery wire from the clip on the dispenser hoop. Grasp the proximal end of the introducer and the delivery wire at the point where it exits the introducer. Hold the delivery wire and introducer together to prevent stent movement. Remove the **CORDIS ENTERPRISE Vascular Reconstruction Device and Delivery System** from the dispenser hoop.
 - Do not partially deploy the stent from the introducer.
 - Confirm that the delivery wire does not move relative to the introducer during removal of the **CORDIS ENTERPRISE Vascular Reconstruction Device and Delivery System** from the dispenser hoop.
 - Confirm that the tip of the delivery wire is entirely within the introducer.
 - Confirm that the delivery wire is not kinked and that the introducer tip is not damaged. **DO NOT CONTINUE** if either defect is observed; return the unit to Cordis Neurovascular, Inc.
 - **Warning:** Do not shape the tip of the delivery wire.
10. Partially insert the distal end of the introducer into the RHV connected to the infusion catheter. Tighten the RHV locking ring. Flush the y-connector of the RHV with sterile saline and verify that fluid exits the proximal end of the introducer.

Warning: Purge the device carefully to avoid the accidental introduction of air into the system.
11. Advance the introducer until it is fully engaged with the infusion catheter hub (.021" **PROWLER SELECT Plus** Infusion Catheter), then tighten the RHV locking ring.

Warning: Confirm that there are no air bubbles trapped anywhere in the system.

Caution: The introducer must be properly engaged with the infusion catheter hub to enable stent introduction into the infusion catheter.
12. Advance the delivery wire to transfer the stent from the introducer into the infusion catheter.

Warning: Delivery wire should not be torqued to gain access into the aneurysm.
13. Continue advancing the delivery wire into the infusion catheter until the distal edge of the delivery wire reference marker (150 cm from the delivery wire distal tip) enters the introducer. Loosen the RHV locking ring, remove the introducer, and set it aside.

Note: Fluoroscopy may be used up to this point at the physician's discretion.

Warning: Do not apply undue force if resistance is encountered at any point during stent manipulation. Withdraw the unit and advance a new one.
14. Track the stent through the infusion catheter to the tip.
15. Position the stent for deployment by aligning the stent positioning marker of the delivery wire with the target site (Figure 2).
16. If stent positioning is satisfactory, carefully retract the infusion catheter, while maintaining the position of the delivery wire, to allow the stent to deploy across the neck of the aneurysm. The stent will expand as it exits the infusion catheter.

Warning: Do not detach the stent if it is not properly positioned in the vessel.

17. If stent positioning is not satisfactory, the stent may be recaptured and repositioned. The stent may be recaptured until the point where the proximal end of the stent positioning marker is aligned with the infusion catheter distal markerband (recapturability limit) (Figure 2). If stent repositioning is required, gently advance the infusion catheter over the deployed stent (do not pull the stent back into the infusion catheter), reposition the system, and re-deploy the stent in the new location.

Note: When advancing the infusion catheter over the stent during recapture, it may be necessary to keep the stent stable with tension on the delivery wire.

Caution: If resistance is felt while recapturing the stent, do not continue to recapture the device. Withdraw the infusion catheter slightly to un-sheath the stent (without exceeding the recapture limit), and then attempt to recapture the stent again.

Caution: The stent may be fully recaptured once.

Note: Be careful to maintain delivery wire access through the detached stent to facilitate access distal to the deployed stent, if necessary.

Note: Maintain adequate stent length (approximately 5 mm) on each side of the aneurysm neck to ensure appropriate neck coverage.

18. Prior to removing the delivery wire, position the microcatheter distal to the stent to maintain access through the stent. Remove and discard the **CORDIS ENTERPRISE Delivery System**.

19. Advance an exchange-length guidewire through the .021" **PROWLER SELECT Plus** Infusion Catheter.

20. Remove the .021" **PROWLER SELECT Plus** Infusion Catheter and advance a .014" (according to the **TRUFILL** family of Detachable Coils Instructions for Use) inner diameter infusion catheter.

21. Use the guidewire and infusion catheter to access the aneurysm through the stent cells (Figure 3).

Note: Access to the aneurysm may be facilitated by the use of an infusion catheter that has been shaped.

22. After the infusion catheter is positioned within the aneurysm, detachable coils may be delivered into the aneurysm according to conventional methods.

Caution: Compatibility of the **CORDIS ENTERPRISE Vascular Reconstruction Device and Delivery System** has only been established with the **TRUFILL** family of Detachable Coils.

Warning: Observe stent marker position during the coiling procedure to ensure that the stent does not migrate from its deployed position.

23. After placing the last coil, verify that the stent has remained patent and properly positioned. Carefully remove the microcatheter through the stent cells.

24. After completing the procedure, withdraw and discard all applicable accessory devices.

Protected under one or more of the following U.S. Patents:

6,612,012; 6,673,106; 6,818,013; 6,833,003; 6,955,685; 6,960,227; 6,960,228; 7,001,422; 7,037,331 and other U.S. patents pending.

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