

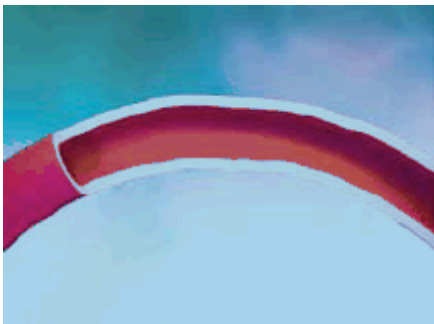
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## New FDA Approved Drug-Eluting Stent

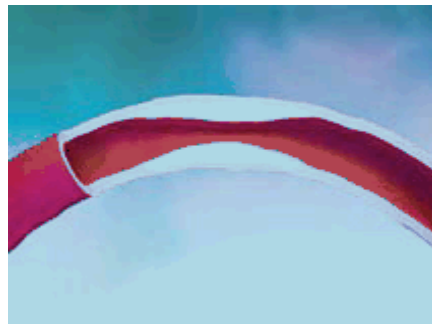
*Austin, TX, Feb 08.* A major milestone recently occurred when the FDA approved the Endeavor<sup>®</sup> drug-eluting stent for Americans with coronary artery disease. The Endeavor<sup>®</sup> stent is the first new drug-eluting stent to be approved by the FDA in more than three years, an endorsement of the safety advantages it delivers for heart disease patients in the United States. As the first in a new generation of drug-eluting stents, the Endeavor<sup>®</sup> stent could again enable millions of patients to benefit from a minimally invasive alternative to bypass surgery.

Extensive clinical data shows the new Endeavor<sup>®</sup> stent to be effective at reducing restenosis (the re-narrowing of treated arteries) by more than 50% with excellent long-term safety results. The Endeavor<sup>®</sup> drug-eluting stent was built for safety, effectiveness, and deliverability; the three most important criteria for evaluating these devices. It does so with a safety profile more commonly associated with bare-metal stents which are considered the benchmark for stent safety. In extensive clinical trials, this device has shown to be associated with exceptionally low rates of blood clots and heart attacks, unlike the first generation of drug-eluting stents.

*How it works:* The Endeavor<sup>®</sup> stent combines a drug that prevents cell proliferation and a biocompatible polymer that enables rapid and complete elution of the drug into the surrounding tissue. The polymer mimics the surface of a red blood cell and coats a unique modular stent engineered from a strong, yet flexible, cobalt alloy which allows the struts of the stent to be extremely smooth and thin. Together these components allow comprehensive healing to take place, enveloping the stent safely in the artery wall away from the bloodstream.



**1 (a).** *Healthy coronary artery.* A healthy coronary artery allows oxygenated blood to flow freely to the heart muscle.



**1 (b).** *Unhealthy coronary artery.* In coronary artery disease, fatty deposits accumulate on the artery wall, restricting the flow of oxygenated blood to the heart. This can cause chest pain (angina) or heart attack (myocardial infarction).

To learn more about the Endeavor<sup>®</sup> drug-eluting stent and cardiovascular disease, please visit our website at [www.capitalcardio.com](http://www.capitalcardio.com). To schedule an appointment to discuss your cardiovascular health with one of our board certified cardiologists, please call 512-445-5998.

## Coronary Artery Disease

Coronary artery disease (CAD) is the narrowing and hardening of the small coronary arteries that supply blood to the heart muscle. It is the most common type of heart disease—about 13 million Americans have CAD. It is the leading cause of death in the US in both men and women, killing more than half a million Americans each year.



CAD occurs when the coronary arteries become clogged due to the buildup of fatty deposits, called plaque, on the inner walls. More precisely, this plaque is called atherosclerotic plaque, which literally means growths with a porridge-like consistency. This process of plaque development is referred to as atherosclerosis.

As the blood supply is restricted, so is the supply of oxygen to the heart. This leads to angina and heart attacks. Angina is the severe and sharp chest pain people feel as parts of the heart muscle are starved of vital oxygen.

A heart attack results from a blockage in a coronary artery, preventing oxygen from reaching a section of the heart muscle and resulting in the death of heart tissue.

### LONG TERM DAMAGE

The damage accumulates over time, weakening the heart muscle and making it more vulnerable. The damage also contributes to heart failure, where the heart becomes too weak to pump sufficient blood to the rest of the body. The gradual build-up of damage also increases the likelihood of heart rhythm disturbances, or arrhythmias, as the electrical conduction pathways in the heart become disrupted.

### RISK FACTORS

Everyone can reduce the risk of CAD by exercising more, staying slim, eating healthily and not smoking. Other risk factors that can be controlled include high blood cholesterol, high blood pressure and diabetes. Getting old and having a family history of heart disease cannot be controlled, making it all the more important to avoid the other risk factors because the more risk factors you have, the greater your chance of developing CAD.

### SIGNS AND SYMPTOMS

The most common symptoms of CAD are chest pain or discomfort (angina), pain in one or both arms or the left shoulder, and shortness of breath. The severity of symptoms varies widely. You should not delay a doctor visit just because the chest discomfort is not severe. In some people, the first sign of CAD is a heart attack.

### TREATMENTS

Common treatments for CAD include angioplasty, coronary artery bypass graft surgery (CABG) and medical (drug) therapy. Angioplasty is a procedure used to open blocked or narrowed coronary arteries with a balloon that is threaded into the blocked artery along a catheter. Usually, during angioplasty a stent is placed in the artery to keep it propped open after the procedure. CABG surgery uses arteries or veins from other areas in your body to bypass your diseased coronary arteries.

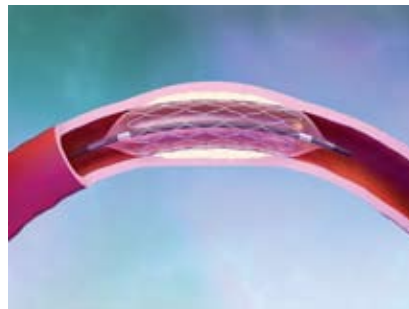
## Illustrations



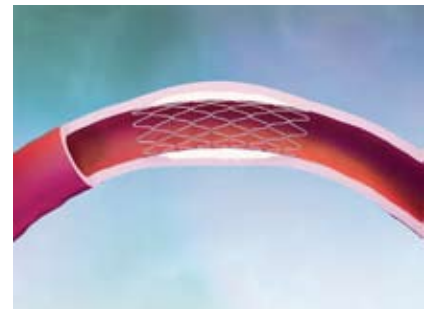
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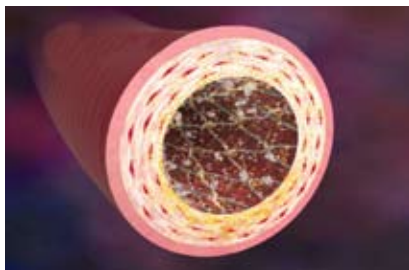
**1 (b).** *Unhealthy coronary artery.* In coronary artery disease, fatty deposits accumulate on the artery wall, restricting the flow of oxygenated blood to the heart. This can cause chest pain (angina) or heart attack (myocardial infarction).



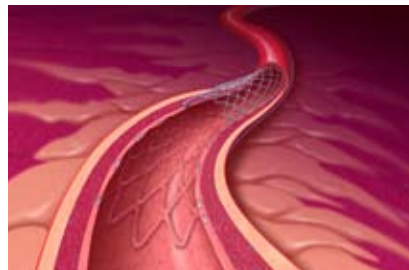
**2 (a).** *Stent placement.* A stent is a tiny wire mesh tube used to prop open a coronary artery after it has been cleared of a blockage in a minimally invasive procedure called balloon angioplasty. The balloon is inflated to compress the plaque against the wall of the artery and to expand the stent.



**2 (b).** *Stented artery.* After the balloon is deflated and removed, the stent remains in place to keep the artery open.

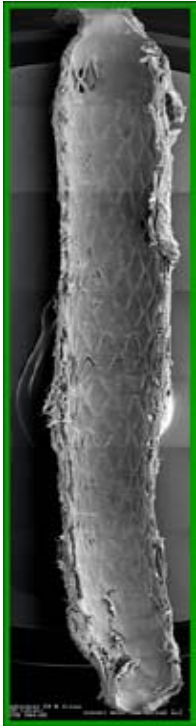


**3.** *Drug elution.* Drug-eluting stents are coated with medication (indicated with yellow dots) to reduce the chance of an artery becoming clogged again by slowing the growth of excessive tissue as the artery walls heal following angioplasty. The medication is released, or eluted, into the arterial wall over a period of a few weeks.



**4.** *Healthy healing.* Over time, new tissue forms over the stent in a process called endothelialization. This forms a biological shield between the stent and the bloodstream, helping reduce the chance of potentially dangerous blood clots forming around the stent.

## Electron microscopy images



5 (a) Endeavor Stent



5 (b) Taxus Stent



5 (c) Cypher Stent

5 (a,b,c). *Healing response differences.* These three electron microscopy images of stented arteries show a difference in healing response between the three drug-eluting stents available in the United States. Twenty-one days after stent implantation, 75% of the (a) Endeavor stent struts are covered with new tissue, compared with approximately 50% for the (b) Taxus stent from Boston Scientific and 30% for the (c) Cypher stent from Johnson & Johnson. Foreign bodies exposed to the bloodstream increase the likelihood of the formation of dangerous blood clots.

## Photographs



**6. Crimped on delivery system.** The Endeavor drug-eluting stent is crimped tightly around a wrapped balloon using a combination of heat and pressure. This tight wrap yields a low profile, improving deliverability of the stent through the artery.



**7. Expanded on balloon.** The Endeavor drug-eluting stent uses a proprietary manufacturing technique that provides for precise alignment of the stent on the balloon, thereby minimizing the balloon overhang extending beyond the ends of the stent and protecting healthy tissue during stent deployment.



**8. Curved.** The Endeavor stent is made from an advanced cobalt alloy, which results in thin struts for exceptional deliverability and unmatched flexibility. In addition, its unique modular design and custom laser fusion patterns allow greater conformability to the curvature of the vessel and less focal stress to the arterial wall.