



ALL LOCATIONS TOLL FREE 1-800-243-1912

## Stent Safety

Minimally invasive treatments for heart disease have advanced enormously since the advent of stents, benefiting millions of patients around the world.

While stents have proven to be a safe and effective treatment, their use may, on rare occasions, result in the incidence of what is known as stent thrombosis or the formation of a blood clot within the stent.

The following **Frequently Asked Questions** guide will help you understand the topic. Please speak with your cardiologist about the benefits and risks associated with all treatment options for coronary artery disease.

### **What are stents?**

Stents are small metal mesh tubes used to prop open clogged blood vessels in the heart after an angioplasty procedure is completed. Using a stent will lower the risk of restenosis, or re-blockage, of the artery more than balloon angioplasty alone. However, even with a stent in place restenosis may still occur in a substantial proportion of people.

### **What is the difference between bare-metal and drug-eluting stents?**

Bare-metal stents do not have any drug released from the stent itself.

The newest stents, called drug-eluting stents, release an anti-inflammatory drug which significantly reduces the risk of restenosis in the treated artery, a common occurrence with bare-metal stents.

### **What are the approved and off-label uses for drug-eluting stents?**

*Approved uses* for drug-eluting stents include: treatment of discrete, previously untreated lesions in native coronary vessels, newly diagnosed coronary lesions, < 25-33 mm long, and in clinically stable patients without serious medical conditions.

*Off-label uses* for drug-eluting stents include: complex conditions (multivessel disease or acute myocardial infarction) or complex lesions (saphenous-vein bypass grafts, bifurcating lesions, lesions requiring overlapping stents, or lesions from an acute myocardial infarction).

### **What is stent thrombosis?**

Stent thrombosis is the formation of a blood clot that can occur within the stent, following the implantation of a stent. While a rare event, a stent thrombosis can close off the artery, blocking the flow of blood to the heart and can potentially lead to a heart attack.

### **What is the difference between in-stent restenosis and stent thrombosis?**

In-stent *restenosis* is the re-blockage of an artery previously treated during an angioplasty procedure. In-stent restenosis is caused by increased tissue growth within the stent and can lead to chest pain and, in some cases, a heart attack. Restenosis occurs more frequently with bare-metal stents. *Stent thrombosis* is a blood clot that forms and may close off an artery, blocking the flow of blood to the heart. While a rare event, stent thrombosis commonly leads to a heart attack.

### **Is stent thrombosis dangerous?**

Yes. While a rare event, stent thrombosis can lead to a heart attack, which can be fatal.

### **When can a stent thrombosis occur?**

While rare, stent thrombosis events have occurred at a variety of times after implantation. As a result, they are classified as “early” when they occur within the first 30 days after the procedure, “late” when they occur between 30 days and 1 year after implantation and “very late” when they occur more than a year after the implant.

### **What are the risk factors for stent thrombosis?**

The risk factors for stent thrombosis include:

1. Having a complex lesion (bifurcation, lesions from a heart attack, lesions requiring overlapping stents, small stent diameter (2.5 mm or less), residual dissection)
2. Having coexisting medical conditions such as kidney disease, acute coronary syndrome or myocardial infarction, low ejection fraction, or diabetes.
3. Having delayed arterial healing.
4. Stopping antiplatelet (anticoagulating) treatment too early.
5. Off-label use of drug-eluting stents may increase the risk of both early and late stent thrombosis.

### **What are the warning signals for a stent thrombosis?**

The warning signs include chest discomfort, discomfort in other areas of the upper body, shortness of breath, cold sweat, nausea, lightheadedness or fainting (collapse). If you experience one or more of these signs, don't wait longer than 5 minutes before calling for help. Call 911. Get to the hospital right away.

### **Is there something I can do to prevent a stent thrombosis from occurring?**

The most important thing you can do is to take your anticoagulating medication, also known as dual anti-platelet therapy, **for the full duration it is prescribed.**

This therapy, which is typically made up of aspirin and clopidogrel (sold in the United States under the brand name Plavix®) is given to you specifically to avoid the risk of a blood clot.

### **How long do I need to take the anticoagulating medication?**

The two medications used to prevent clotting are usually taken for at least 12 months **after** drug-eluting stent implantation in people who are not at high risk for bleeding.

Patients at a higher risk for stent thrombosis may be asked to take the anticoagulating medications for longer than 12 months. Your cardiologist will discuss the duration of anticoagulating treatment with you.

### **I am scheduled for another surgical procedure. Is it safe for me to stop my anticoagulating medication?**

It is *very important* that you tell your cardiologist about any upcoming surgeries or dental procedures **before you have your stent placed.** This information may change the cardiologist's decision on the type of stent to use.

If you already have a stent and are taking anti-clotting medications, you should talk to your cardiologist *prior* to making any changes to your prescribed anti-clotting therapy.

**Do NOT stop** your anti-clotting treatment without speaking to your cardiologist.

### **Are these reports of blood clots unique to drug-eluting stents?**

Stent thrombosis is an adverse event that has been observed with both bare-metal and drug-eluting stents. Scientists are currently investigating whether there is an increased risk of late or very late stent thromboses with drug-eluting stents.

### **If I am scheduled for an angioplasty procedure, should I request a bare-metal stent instead of a drug-eluting stent?**

As per a U. S. Food and Drug Administration statement issued on September 14, 2006

(<http://www.fda.gov/cdrh/news/091406.html>), drug-eluting stents remain safe and effective when used according to the FDA-approved indications. For a personalized assessment of the benefits and risks associated with the use of bare-metal or drug-eluting stent in your individual case, please consult with your interventional cardiologist, who is in the best position to evaluate which stent is right for you.

### **I have already received a drug-eluting stent. Am I at risk?**

While there is always a risk for a blood clot with any stent, the risk is low, particularly if you are taking your prescribed anti-platelet therapy as directed by your physicians. We strongly recommend that you also speak with your cardiologist to receive a detailed assessment of the risks and benefits associated with the use of stents in your individual case.

### **Is the risk of thrombosis the same for all drug-eluting stents?**

The risk of thrombosis with any stent remains low. Although the FDA-approved drug-eluting stents use different drugs and different polymers, there is insufficient data at this moment to determine with certainty whether there are different stent thrombosis rates between the two products.