www.fda.gov/consumer/updates/tlss051407.html

Rapid Response Helps Save Limbs

Scientists and medical experts at the Food and Drug Administration responded quickly when they were alerted to a critical need for a medical device that can help save the arms and legs of soldiers injured in combat and other trauma victims.

In less than a week, FDA reviewed the Temporary Limb Salvage Shunt (TLSS) and cleared the device for marketing in the United States on Feb. 9, 2007. Such reviews typically require 60 to 90 days.

"The scientific review was completed rapidly, but not recklessly," says FDA Commissioner Andrew C. von Eschenbach, M.D. "FDA staff literally put the vascular shunt … into the battlefield when they helped accelerate its approval."

Essentially a hollow tube, the shunt works by connecting the ends of a severed blood vessel together to restore blood flow to an injured limb until a permanent repair can be made.

"This device offers surgeons a new tool to potentially avoid the need for limb amputation following traumatic injury," says Daniel Schultz, M.D., Director of FDA's Center for Devices and Radiological Health (CDRH). "This device has been used successfully by other countries, and is particularly important to serve our men and women in the Armed Forces who are seriously injured in combat."

FDA approval of the device, made by Vascutek Ltd. of Renfrew, Scotland, is not limited to military use. The TLSS can be used as a temporary bypass shunt in any limb-threatening trauma cases in which there has been damage to a major blood vessel.

A Call for Help

The shunt approval started with a telephone call from Lt. Col. Todd Rasmussen, M.D., a vascular surgeon in the U.S. Air Force. Rasmussen called A. Doyle Gantt, Jr., an FDA biomedical engineer within CDRH, to alert FDA to the need for the shunt in the battlefield.

"As soon as we got the call, we thought, 'this is an opportunity to make a real difference,'" says Gantt, who then alerted his manager, David Buckles, Ph.D., Chief of FDA's Peripheral Vascular Devices Branch. Responding to the high-priority need, Buckles and Gantt immediately took action.

"We discussed how to proceed and what regulatory mechanism we were going to use to get the military access to this device," says Gantt. Under federal law, there are several different ways a medical device sponsor can get its product approved. Internal FDA discussions and a series of conference calls with Rasmussen and Vascutek helped determine the appropriate regulatory mechanism and steps to take to speed the review process.

Vascutek worked closely with FDA's Division of Cardiovascular Devices to prepare the information required by the agency to conduct a scientific and regulatory review. "FDA is always willing to assist manufacturers to help them comply with FDA requirements for medical devices," says Buckles.

"The manufacturer had a lot of information already about the product," says Gantt. "It had been used by the British army about 10 years ago, and the manufacturer had information about the safety and success of the device from that experience along with information collected more recently."

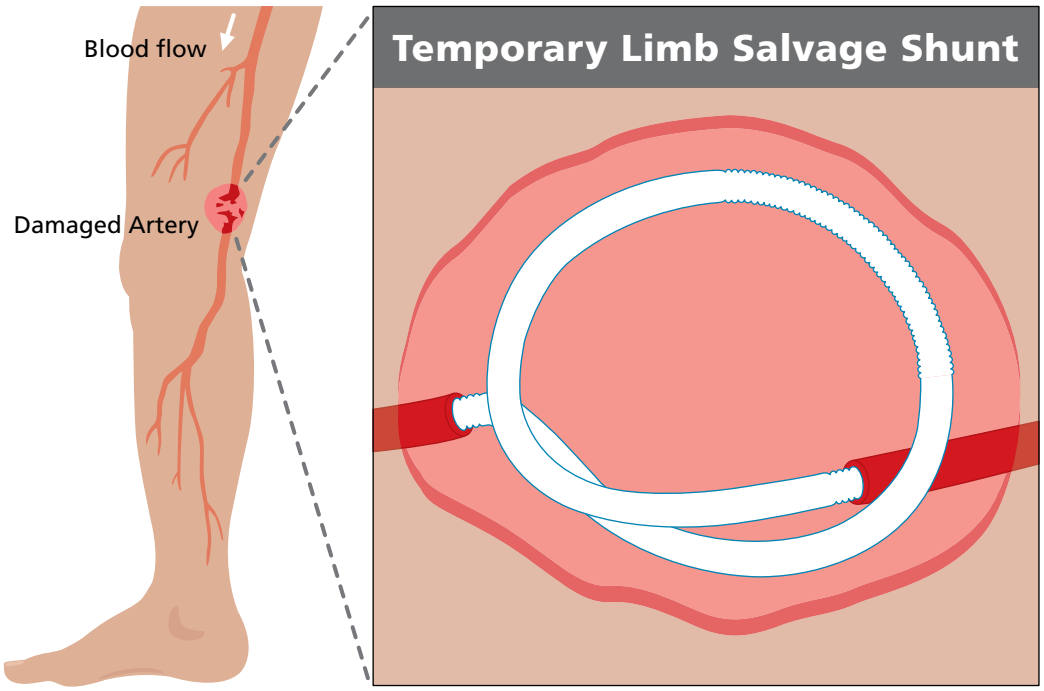
FDA received Vascutek's application for marketing the device on Feb. 2, 2007. The agency completed its review five days later.

Vascutek Ltd.

Temporary Limb Salvage Shunt (TLSS)

'FDA staff literally put the vascular shunt … into the battlefield when they helped accelerate its approval.'

'The hope is that in 30 to 60 minutes, a surgeon can insert the shunt to maintain blood flow in the limb until it can be repaired.'



FDA/Michael Ermarth

The Temporary Limb Salvage Shunt (TLSS) restores blood flow to an injured limb by connecting the severed ends of a blood vessel until a permanent repair can be made.

A Ticking Clock

"If a blood vessel in an extremity is injured, it starts the clock ticking," says Rasmussen, adding that there's only so much time—about four hours—to save a limb. "If a limb doesn't get enough blood, the muscles and nerves won't work and, essentially, the limb will die."

Because of where many of these blood vessel injuries occur—in the battlefield—they're not amenable to repair, says Rasmussen. Medical facilities in combat areas aren't equipped for limb repair, and surgeons must treat life-threatening injuries before limb-threatening ones.

"The hope is that in 30 to 60 minutes, a surgeon can insert the shunt to maintain blood flow in the limb until it can be repaired," Rasmussen says. Then the soldier can be evacuated to a medical facility with the surgical expertise and equipment to make the repair.

A Unique Device

There are many different shunts on the market, but no other shunts have been cleared for temporary use specifically in trauma settings. The TLSS has several features that make it optimal for this use.

The device has beveled ends that help the surgeon quickly and effectively place it within the severed blood vessel. It also has graduated markings so that the surgeon knows where to cut the tubing for proper placement of the device. Extra reinforcement in the center of the device allows it to be cut to a shorter length if needed, retaining the strength of the tubing so that it doesn't collapse.

The device is formed from two layers of plastic, the outer layer being a membrane with elastic properties. "The membrane has a self-sealing capability," says Gantt, "so if they need to administer drugs through the shunt, such as blood thinners, they could stick a needle—a hypodermic syringe—into the outer membrane. When they withdraw the needle, the membrane will seal and blood won't be lost through the shunt."

Other types of drugs, besides blood thinners, that may be given through the shunt have not been determined yet, says Rasmussen. "Another reason why we're excited about this shunt's approval and its physical characteristics is that it will stimulate research," he says. "We can find out what kind of medicine may be beneficial and help with the quality of the save. Instead of a limb just being a statistics save, we want a quality save—one that works well too."

Rasmussen calls the shunt a "useful adjunct" for vascular surgeons. "During the Second World War, if a blood vessel was severed in an extremity, the risk of losing a limb was 50 percent," he says. "Now, it's less than 10 percent, based on our experience in management of vascular injuries. It's not just because of the shunt, but the shunt is one piece of the puzzle." FDA