FDA Approves Biodegradable Sealant Patch

BY ALICIA AULT

The Food and Drug Administration has approved a biodegradable sealant patch, TachoSil, for cardiovascular surgery.

The sealant, a dry collagen sponge coated with fibrinogen and thrombin, is manufactured by Nycomed Austria GmbH of Linz, Austria, and is already available in 30 countries.

When placed in a wound, the fibrinogen and thrombin become activated and convert into fibrin. That allows a clot to form, preventing bleeding and sealing the tissue. According to the FDA, the sponge breaks down within the body in 4-6 months.

"This approval provides an additional tool for surgeons to help control mild and moderate bleeding from blood vessels during cardiovascular surgery when standard surgical techniques are ineffective or impractical," Dr. Karen Midthun, acting director of the FDA's Center for Biologics Evaluation and Research, said in a statement.

According to data submitted to the agency by Nycomed, TachoSil stopped bleeding within 3 minutes in 75% of 119 cardiovascular surgery patients given the sponge, vs. 33% in the control group.

The FDA said that the sponge can cause allergic reactions, but that such reactions were not statistically higher for TachoSil study patients.

In data submitted to support European approval, the most common side effect was fever. The European Medicines Agency cautioned that thromboembolic complications were possible if TachoSil was unintentionally placed within a blood vessel. The FDA warned that TachoSil is not intended for such use. ■