FDA approves device for diabetic foot ulcers

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(HealthDay)—The Integra Omnigraft Dermal Regeneration Matrix has been approved by the U.S. Food and Drug Administration to treat diabetic foot ulcers.

The device—made of silicone, cow collagen, and shark cartilage—is placed over the sore and provides an environment that favors development of new skin and tissue, the agency said in a news release. The Omnigraft device was first approved in 1996 to treat life-threatening burns when a skin graft isn't possible. The device is now approved for diabetic foot ulcers lasting longer than six weeks that don't involve any exposed bones, joints, or tendons.

In clinical studies, the device was used in combination with standard foot ulcer care, which involved cleaning the wound, covering it with a surgical bandage, and keeping weight off the affected foot. Some 51 percent of Omnigraft users had healed ulcers after 16 weeks, compared to 32 percent of participants treated with standard ulcer care alone, the FDA said.

Adverse reactions to the device included infection, increased pain, swelling, nausea, and new or worsening ulcers. The device shouldn't be used by people allergic to any of its components or who have an infected wound, the agency said.

Omnigraft is produced by Integra Lifesciences, based in Plainsboro, N.J.

More information: More Information