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## **Material from pig intestine is remedy for deep sores, incontinence**

WEST LAFAYETTE, Ind. – A material derived from an unlikely source – the small intestine of a pig – is revolutionizing many medical procedures.

It is being used to cure chronic sores, treat incontinence in women and repair internal organs and hernias. The federal Food and Drug Administration has cleared five applications of its use so far, the most recent coming this month for "full thickness" wounds so severe that they sometimes result in amputation.



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**Photo caption below**

**[Link to Quicktime Movie of tissue repair](#)**

The material prompts the human body to replace damaged tissues with little or no scarring, recreating the healing efficiency of young children. Purdue University scientists isolated it from layers of tissue called small-intestine submucosa, or SIS, after they discovered more than a decade ago that the small intestine possessed unusual healing properties.

"This is not just something that looks promising; this is now proven to work," says Stephen F. Badylak, a senior research scientist at Purdue's Department of Biomedical Engineering, where scientists in the 1980s discovered SIS's healing qualities unexpectedly while looking for ways to make substitute blood vessels.

The material has since been developed for patient care by start-up company [Cook Biotech Inc.](#), located at the Purdue Research Park in West Lafayette. SIS has been used so far to cure skin wounds and chronic sores,

treat urinary incontinence in women, repair internal organs, and save the limbs of people suffering from deep wounds that were previously not treatable.

Veterinarians also are using it for numerous types of surgeries, including those that have prevented amputations and healed eye injuries that otherwise would have resulted in blindness.

Researchers do not yet know exactly how SIS works, but they do know that it essentially functions as a natural framework for repairing and growing tissue and that it contains numerous proteins and "growth factors" that signal the healing process.

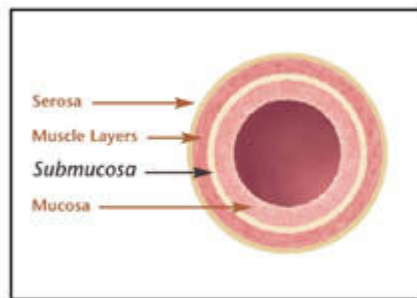
"It is basically Mother Nature's scaffold for wound healing," says Badylak, who discovered its unusual characteristics while working with Leslie Geddes, Purdue's Showalter Distinguished Professor Emeritus of Biomedical Engineering. "SIS causes the body to heal more like an infant or a young child would heal, as opposed to an adult."

Such healing efficiency nearly eliminates the formation of post-surgical scars, which deform and interfere with the healthy functioning of tissues.

"Scars are the bane of all surgeons," he says.

Once applied to skin wounds or sutured internally, the material prompts the body to build new tissue, inexplicably replacing the intestine-derived material with new human or animal tissue. Moreover, the replacement tissue matches the tissue that existed originally in that part of the body.

"The body sees the implanted material and says, 'That needs to be repaired,' so it dismantles the material as it grows new cells of its own type," says Neal Fearnot, president of Cook Biotech and a



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Purdue adjunct professor of biomedical engineering. "We know of no cases of rejection in either humans or

animals."

Once SIS is placed within a body, it aids in the proliferation of new blood vessels, which is important for the wound-healing process. The blood vessels nourish the graft and supply vital molecules that the body needs to rebuild the damaged tissue. The material also strengthens in response to stress, much like natural tissue.

Surgeons have recently begun using SIS for a new human application, hernia repair.

"It's going to be a very good thing for mankind," says Matthew Parmenter, a Bloomington, Ind., physician who was one of the first doctors to use SIS for wounds and open sores and who now has treated about 150 patients successfully.

Among the results reported so far:

- Persistent, open sores that simply would not go away even after years of treatment healed in a matter of weeks. Such skin ulcers are caused by poor circulation, diabetes, injury or constant pressure in patients who must remain in bed or in a wheelchair for extended periods. Some of the wounds were so severe that they might have otherwise resulted in amputations.
- Veterinarians as well have been surprised to see that dogs recovered from usually devastating injuries in which the skin on their legs was torn off in accidents, a phenomenon known as "degloving," which previously would have resulted in amputation. Not only did all of the skin grow back, which is unusual in itself, but the hair grew back as well. Horses and other animals suffering from eye injuries severe enough to have caused blindness healed when SIS was placed over the injury.
- Of 18 women treated for urinary incontinence, all regained urinary control within a week of surgery. SIS also has been used to make effective repairs to internal organs, such as the urinary bladder or kidneys, that would have otherwise been impossible.

Alvin Rutner, a Stanford University urologist, has been using SIS to treat women with urinary incontinence since January 1999. Incontinence

develops as the bladder sags, usually as a result of multiple childbirths, because ligaments holding the bladder have weakened or failed. In its sagging position, stress is exerted on the urethral muscle so that it cannot close properly, causing incontinence. Simply coughing or laughing can cause the uncontrolled release of urine. Doctors use SIS to fashion a sling with which to pull the bladder back up to a more normal position. The body replaces the SIS over time with its own tissue, leaving a natural suspension.

Although this procedure has been well known for years, doctors have never had a truly suitable material. They have used various synthetic materials, which erode over time and are prone to infection. Surgeons also have used material from cadavers to fashion the sling, but it is often difficult to obtain this material on short notice and in the right sizes. Cadaverous tissues also raise concerns about disease and viruses and must be screened carefully before using.

SIS comes from the middle layers of the pig's small intestine. It is a complex matrix of collagens, other proteins and growth factors, a combination that somehow tells the body how to rebuild tissue.

Pig tissues have had a long history of medical use in humans.

"There are many anatomical similarities between pigs and humans, especially in the cardiovascular system," says Cook Biotech vice president Mark Bleyer.

However, scientists do not yet know exactly which of SIS's numerous components are essential for it to function, a subject for future research.

"Wound healing is a terrifically complicated process," Badylak says. "There is a lot that is not understood."

If researchers knew more about SIS, they might be able to further tailor the material for specific organs and for certain uses for which there are presently no effective treatments. Fearnot, whose company is now developing the material for several uses, is studying about 80 potential future applications.

"We are just on the tip of the iceberg," he says.

Cook Group Inc. companies of Bloomington, Ind., have been licensed to market all SIS applications except for orthopedic uses, which have been licensed to DePuy Orthopaedics Inc. of Warsaw, Ind.

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**NOTE TO JOURNALISTS:** B-roll, audio tapes, and before-and-after photos of wounds that were healed with SIS are available from Jessica Webb, Purdue News Service, (765) 494-2079, [jwebb@uns.purdue.edu](mailto:jwebb@uns.purdue.edu).

#### **PHOTO CAPTION NO. 1:**

Doctors are using this material, made from pigs' intestines, to heal sores and wounds in humans, to repair hernias, and to treat urinary incontinence in women. When moistened, the material, called SIS for small-intestine submucosa, is flexible and easy to handle. (Photo by Cook Biotech Inc.) *A publication-quality photo is available at the [News Service Web site](#) and at the [ftp site](#). Photo ID: Badylak.SIS.flex*

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#### **PHOTO CAPTION NO. 2:**

This cross section diagram of the small intestine

shows the location of the submucosa. (Graphic by Cook Biotech Inc.) *A publication-quality photograph is available at the [News Service Web site](#) and at the [ftp site](#). Photo ID: Badylak.SIS.gram*