

**KECK MEDICAL CENTER OF USC OFFERS
NEW TREATMENT FOR CHRONIC REFLUX DISEASE**

LOS ANGELES — Clinical trial results published in the *New England Journal of Medicine* in February offer additional evidence that a new device may help relieve chronic heartburn symptoms that standard treatment cannot. The Keck Medical Center of USC was one of 14 U.S. and European medical centers to test the device prior to its March 2012 approval by the U.S. Food and Drug Administration.

John Lipham, M.D., associate professor of surgery at the Keck School of Medicine of USC, led clinical investigation of the device at USC as part of his ongoing work to find alternative ways to treat gastroesophageal reflux disease (GERD), or chronic heartburn.

“These results show that there is another option for the millions of people suffering from chronic reflux,” Lipham said. “Currently, the Keck Medical Center of USC is one of only 30 sites in the country certified to implant the device.”

The LINX Reflux Management System, manufactured by Minnesota-based Torax Medical, Inc., is like a bracelet made up of magnetic, titanium beads implanted around the end of the esophagus, where the lower esophageal sphincter is located. The lower esophageal sphincter is the valve that prevents reflux, and GERD develops when this valve is weakened.

Implantation of the device is potentially an outpatient procedure that can be completed in 15 to 20 minutes, Lipham said.

Lipham and his colleagues assessed 100 patients with GERD before and after surgery, finding that acid reflux decreased, reflux symptoms improved and the use of medication to manage those symptoms decreased for most patients. Severe regurgitation was eliminated in all patients. More than 9 in 10 patients reported satisfaction with their overall condition after having the procedure, compared to 13 percent before treatment while taking medication.

Follow-up studies are still required to assess long-term safety.

Lipham says the LINX device is best for patients with mild to moderate reflux that cannot be adequately controlled by medication or for patients who do not want to take medication to manage the disease. More than 60 million Americans experience heartburn at least once a month and some studies have suggested that more than 15 million experience heartburn symptoms every day, according to the American College of Gastroenterology.

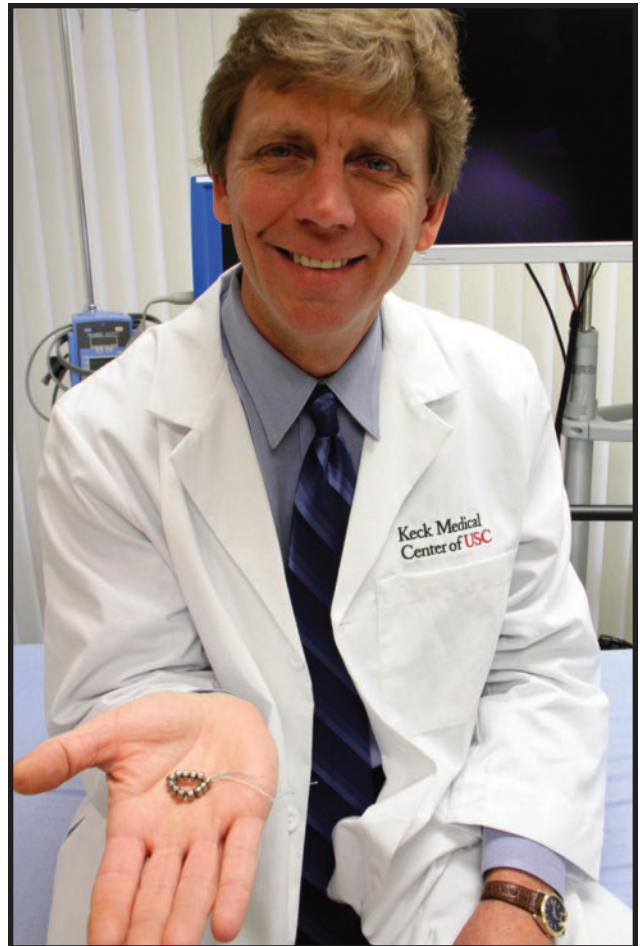


Photo courtesy of University of Southern California

Surgical treatment of reflux disease had been limited to a procedure called a Nissen fundoplication, which involves recreating the esophageal sphincter. While fundoplication is recommended for those with severe reflux, it is a complicated procedure that prevents the ability to belch or vomit and often leads to bloating or gas problems.

The most common adverse events experienced with the LINX included difficulty swallowing, pain when swallowing food, chest pain, vomiting, and nausea. It is important to note that patients with LINX will no longer be able to undergo magnetic resonance imaging (MRI) procedures. The magnetic beads interfere with the machine and can cause the device to be damaged and the patient to be injured.

Funding for the clinical trial came from Torax Medical, ClinicalTrials.gov No. NCT00776997.

Article cited: Ganz, R.A., Peters, J.H., Horgan, S., Bemelman, W.A., Dunst, C.M., Edmundowicz, S.A., Lipham, J.C., Luketich, J.D., Melvin, W.S., Oelschlager,

B.K., Schlack-Haerer, S.C., Smith, C.D., Smith C.C., Dunn, D., & Taiganides, P.A. (2013). Esophageal sphincter device for gastroesophageal reflux disease. *New England Journal of Medicine*, 368(8), 719-727. Published Feb. 21, 2013; doi:10.1056/NEJMoa1205544

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SWALLOW SOLUTIONS LAUNCHES THERAPEUTIC DEVICES TO IMPROVE DYSPHAGIA

Brent Benson to Head New Sales & Marketing Effort

Swallow Solutions LLC, a company dedicated to improving the health and quality of life of individuals suffering with swallowing disorders -- known as dysphagia -- has launched a therapeutic device specifically designed to treat this disorder.

Swallow Solutions LLC is registered and the MOST® (Madison Oral Strengthening Therapeutic) device is listed with the FDA. The MOST device is allowed for sale a Class 1 device in the United States. Multisite clinical trials are underway to provide the data necessary to garner Medicare and private health care reimbursement.

To head up the product launch and outreach efforts, the Madison, WI-based company has hired Brent Benson, a 13-year veteran of medical device and pharmaceutical sales to the health care sector, to the newly-created position of Director of Sales and Marketing.

Already, the first generation MOST device, introduced in August, is being shipped to hospitals, extended care facilities and speech pathologists around the country; the next generation MOST 2.0 will be launched in the coming year.

Benson points out that swallowing disorders

negatively impact the health and quality of life of a sizeable portion of the US population. Affecting more than 15 million adults and many millions of infants and children, dysphagia becomes increasingly common as the population ages. As we get older, our muscles weaken – including the muscles of the head and neck. Aspiration of foods “down the wrong pipe” leading to pneumonia, malnutrition, and dehydration, which are just a few of the swallowing-related complications older people can face.

“The products offered by Swallow Solutions have been developed to address these swallowing problems in patients of all ages and medical conditions,” Benson explains. By strengthening head and neck muscles integral to swallowing, the device has been shown to improve dysphagia after an eight-week regimen.

The possibility of providing an alternative to tube feeding and the complications that may result from that method of nutritional intake, as well as the positive impact improved swallowing can have on a person’s quality of life and overall health, were important motivators in the founding of Swallow Solutions.

Benson enthuses, “A lot of these patients who are dysphagic and can’t swallow can go back to normal lives and eat regular food after just the initial eight-week study, removing any connection to a feeding tube for sustenance. It can be truly life changing.”

The MOST device consists of a relatively high tech instrument that works with a laptop. It has a customized, adjustable mouthpiece that provides pressure readings from embedded sensors that indicate performance levels and calculate therapeutic strengthening targets. Dysphagic stroke patients who completed an eight-week regimen using target values for strengthening goals in a federally funded study improved swallowing function; as well, healthy older adults demonstrated “younger” swallow pressures after performing the same protocol.

Swallow Solutions CEO Dr. Robert Carlson, MD is delighted with the enthusiasm that has greeted the MOST device to date. He is convinced that Benson’s appointment as Director of Sales and Marketing will position the company to build the sales infrastructure, customer service and support that will help put the devices in the hands of those who can benefit from them. “We are very fortunate to have someone of Brent’s caliber and experience join us,” he says. “With Brent, we are confident our product reach will expand

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as the company grows.”

“It’s a steep learning curve,” says Benson, “but there are exciting challenges ahead to look forward to.”

To place an order for the most device, please call **608-238-6678 (most)** or email

brentbenson@swallowsolutions.com

The MOST device is manufactured in Madison WI, and is based on pioneering research at the University of Wisconsin School of Medicine and the Madison VA Hospital by a team of leading clinicians and researchers in the field of swallowing and dysphasia, headed by Dr. JoAnne Robbins, PhD, CCC-SLP, BRS-S, Professor at the University of Wisconsin School of Medicine and Public Health and Associate Director of the Geriatric Research Education and Clinical Center (GRECC) of the Veterans Hospital in Madison. The research is protected by patents owned by the Wisconsin Alumni Research Foundation (WARF), which are licensed to Swallow Solutions.

For additional information on Swallow Solutions LLC or the MOST device, visit their website at **www.swallowsolutions.com** To schedule an interview with a representative of Swallow Solutions, kindly contact Falk Associates at 773.883.2580.

REIMBURSEMENT ANNOUNCEMENT FOR CELLVIZIO OPTICAL BIOPSIES

Mauna Kea Technologies, leader in the optical biopsy market and developer of Cellvizio®, the fastest way to see cancer, announced recently that Cellvizio procedures in the upper GI tract have been added to the Ambulatory Surgical Center (ASC) approved procedure list.

Ambulatory Surgical Centers are health care facilities focused on providing same-day surgical care, including diagnostic and preventative services, often times found to be more convenient than hospital-based outpatient procedures. The U.S. Centers for Medicare and Medicaid Services (CMS) has approved the payment rate of \$520 per previously-awarded Category 1 Current Procedural Terminology (CPT®) codes for the use of Cellvizio® during endoscopy procedures in the upper gastrointestinal tract.

GI related procedures make up 24% of all specialties served at ambulatory surgical centers. There are approximately 5,000 ambulatory surgical centers across the United States, each one performing more than 3,700 GI endoscopy procedures each year, representing

a total of about 18 million GI procedures.

Cellvizio is used at hospitals throughout the United States and the rest of the world to provide physicians live-cellular level views of the GI tract to help identify and rule out cancer and guide treatment decisions in real-time.

“We’re pleased with the addition of Cellvizio optical biopsies to the list of approved procedures performed in ambulatory surgical centers across the country and believe this opens a much larger market segment for Cellvizio in the United States, our largest clinical market,” said Sacha Loiseau, PhD, Founder and CEO of Mauna Kea Technologies. “This is a major milestone in our efforts to make optical biopsies available to a majority of patients with suspected GI diseases, in order to grant them access to a streamlined diagnostic work-up and to a faster treatment decision.”

The Category I CPT codes issued by the American Medical Association (AMA) include 43206 for the Cellvizio esophageal optical endomicroscopy and 43252 for esogastroduodenoscopy with optical endomicroscopy. The CPT codes went into effect on January 1, 2013.



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MEETINGS CALENDAR

April 19, 2013 Maryland Viral Hepatitis Summit

Four Points by Sheraton BWI, Baltimore, MD – This event is a “must attend” for anyone and everyone working with those who are infected with or affected by viral hepatitis. 5.5 Continuing education credits for physician assistants, nurses, certified public health and addiction professionals. Register by April 12, 2013 for only \$75! Attendees may register online at: <http://www.hepatitisfoundation.org/NEWS/Summits.html>

May 17–22, 2013 SGNA 40th Annual Course

Austin, TX – Celebrating 40 years of Annual Course education, The Society of Gastroenterology Nurses and Associates brings together the best and brightest GI/endoscopy professionals to drive the future of our field. For more information visit: www.sgna.org

May 18–21, 2013 Digestive Disease Week

Orange County Convention Center, Orlando, FL – Digestive Disease Week® (DDW) is the largest and most prestigious meeting in the world for the GI professional. Every year DDW attracts approximately 15,000 physicians, researchers and academics from around the world. Choose from over 400 sessions, including clinical and research symposia, state-of-the-art lectures and research and topic fora, covering a wide array of topics and presented by a world-renowned faculty unsurpassed in their field. For more information visit: www.ddw.org

September 21-24 2013 GASTRO 2013 APDW/WCOG SHANGHAI, Asian Pacific Digestive Week 2013, World Congress of Gastroenterology

Shanghai Expo Center, Shanghai, China – A World Congress in Asia! Submit your abstract and register today and take advantage of Early Bird Registration fees. The Early Bird Registration deadline is April 15, 2013. The Regular Registration deadline is August 15, 2013. For further information regarding the upcoming Congress, visit the Gastro 2013 APDW/WCOG Shanghai website at: www.gastro2013.org

October 24–26, 2013 Annual Probiotic Symposium *Probiotics: Current Perspectives and Controversies*

San Antonio, TX – Attend the 7th Annual Probiotic Symposium for a unique opportunity to learn about the current perspectives and controversies in probiotics research and use in clinical practice. CME Credit for Physicians and other Healthcare Professionals will be available. Save \$100 – Register before October 6, 2013. For more information visit: www.ProbioticSymposium.com

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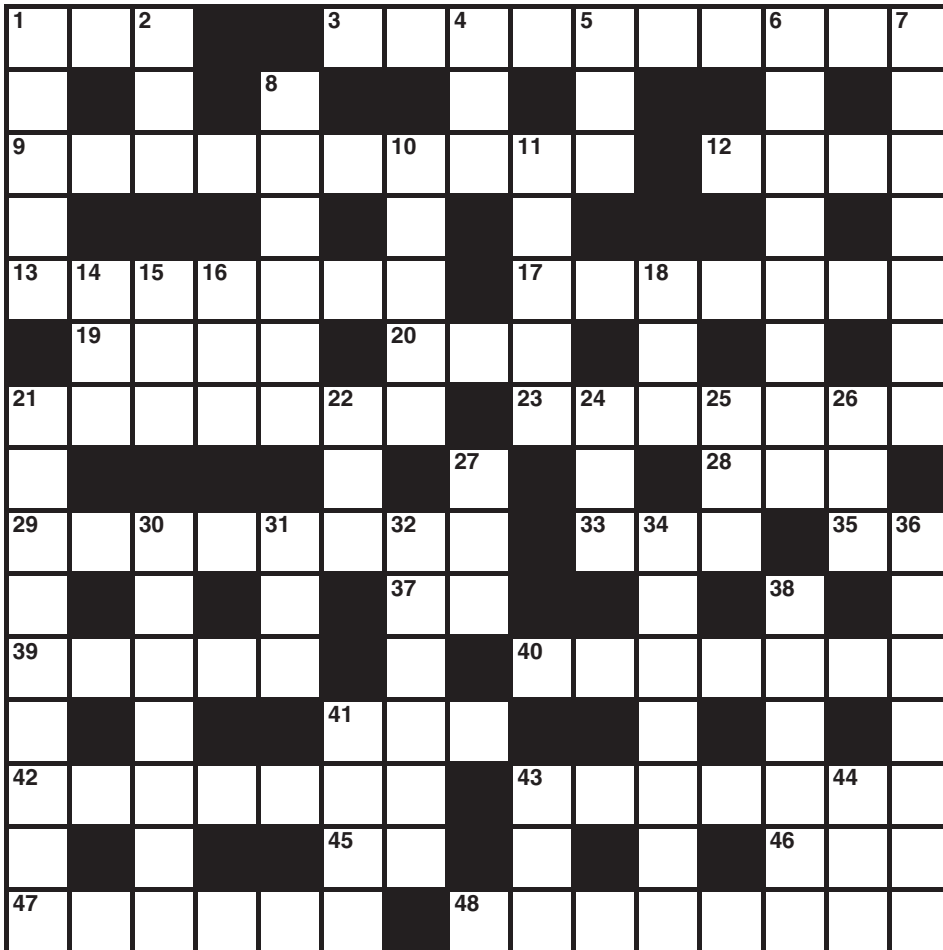
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by Myles Mellor

DOWN

1. Huh7- ____ cells
2. Antigen-presenting cell, for short
4. Third of a family
5. Senesce
6. Benign polyps of the bowel
7. Dilation of a hollow organ
8. Recovered
10. Spasm
11. Concave shapes
14. Practice
15. Bile acids, for short
16. Single, prefix
18. Type of intestinal blockage, for short
21. Nucleic acid molecules that copy themselves
22. Website symbol
24. Draw liquid
25. Plot
26. Chi preceeder
27. Eroded, with into
30. Tumor-like mass caused by granulomatous reaction in the intestine
31. Estimated blood loss, for short
32. Larger quantity than needed
34. Junction between two neurons
36. Abnormally enlarged or twisted blood vessels
38. Vein that carries blood into the liver
41. Layman term for intestines
43. "Good" cholesterol
44. Post-E.R. area

ACROSS

- | | |
|--|---|
| <ol style="list-style-type: none"> 1. Lithocholic acid, for short 3. Having only one random variable 9. Base 12. Overcome 13. Category of adenoma of the colon 17. ____ trichromic 19. Logical 20. Unique 21. Matter remaining 23. Surgical openings 28. ____ rule 29. Thrombocyte | <ol style="list-style-type: none"> 33. Phenylsulphtalein, for short 35. Drip 37. Symbol for xenon 39. Relating to an intestinal area 40. Shape 41. Make sense 42. Bad smelling 43. Liver related 45. Cross the ____ 46. Type of bandage 47. Stoppage of a body fluid flow 48. Tiny sac in the lungs |
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(Answers on page 58)