ZIPLINE® MEDICAL RECEIVES INDIA REGULATORY APPROVAL FOR NON-INVASIVE ZIP® SKIN CLOSURE SYSTEM

New Zip® Clinical Study Demonstrates Significantly Higher Tissue Perfusion Compared to Staples in Total Ankle Replacement Surgery

CAMPBELL, Calif. – May 9, 2017 – ZipLine® Medical, Inc., an innovator in skin closure, today announced Central Drugs Standard Control Organization (CDSCO) approval of its Zip® Surgical Skin Closure device in India. This clearance will give the company access to the $3.5 billion medical device market in India, including growing specialties where the Zip has shown significant clinical and economic benefits, such as total joint replacement in orthopedics, and Cesarean-section and hysterectomy in obstetrics and gynecology.

The Zip is a non-invasive and easy to use skin closure device that replaces sutures, staples and glue for surgical incisions and lacerations. Clinical studies have demonstrated significant time savings and less procedure variability that can decrease hospital costs and improve efficiencies. Studies have also demonstrated fewer wound complications, and the comfortable and simple removal can reduce post-discharge home health and clinic visits that affect overall healthcare cost in a bundled care environment.

A patented force distribution design results in secure wound closure, excellent scar quality and high patient satisfaction. The Zip’s micro-adjustability and reversibility provide surgeons with precise control during closure, and care teams with security that they can adjust closure post-surgery, if needed. Unlike staples or sutures, there are no skin punctures with the Zip that can create pathways for bacteria. The Zip’s benefits have been demonstrated in clinical studies in orthopedic total-joint arthroplasty, foot and ankle surgery, pediatric cardiothoracic surgery, electrophysiology and dermatology.

In addition, clinical study results from the University of Florida demonstrated an 18 percentage point higher tissue perfusion rate versus baseline with the Zip compared to staples (p<0.001) after closure for total ankle replacement procedures. The results were presented in a poster at the American College of Foot and Ankle Surgeons (ACFAS) conference in Las Vegas in March.

Jason Piraino, DPM, MS, FACFAS, who presented the results, commented, “Maintaining adequate perfusion is one of the most important factors in ensuring wound healing. High perfusion correlates to fewer complications, such as dehiscence and infection. The Zip demonstrated a significant perfusion advantage over staples in our study.”

ABOUT ZIPLINE MEDICAL
ZipLine Medical is an innovator in cost-effective, non-invasive surgical skin closure devices that deliver high patient satisfaction and surgeon efficiency. Zip Surgical Skin Closure devices have been used in more than 100,000 cases, and in over 30 countries. worldwide. ZipLine Medical was founded by Amir Belson, M.D. and is headquartered in Campbell, CA. For more information, visit www.ziplinemedical.com.

Zip® Surgical Skin Closure devices are classified by the U.S. FDA as ‘Class I, 510(k) Exempt’ and have received the CE Mark and CFDA approval.

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