

FOR IMMEDIATE RELEASE

New Kleiner Spine Graft Delivery Tool Improves Outcomes for Patients, Surgeons, Hospitals and Payers

Denver, January 10, 2018 – Kleiner Device Labs today announced full commercial availability of a new spinal bone graft delivery tool, the $\underline{\text{KG}^{\circ}}$ 1, featuring a patented design that facilitates less-invasive procedures and has been proven in clinical testing to reduce spinal fusion failure rates by $68\%^{1}$.

"In my own surgical practice, I was frustrated by unacceptable failure rates in spinal fusions and bad outcomes for my patients that were driven by existing graft delivery tools that jam, don't distribute graft material to the right locations or quantity, or required excessive manipulation that creates soft tissue inflammation or damage. The round, end dispensing tools left me frustrated and with 'am I done yet?' questions," said Jeff Kleiner, M.D., founder and CEO of Kleiner Device Labs.

"In testing, we found that the KG 1's design solves all these problems, and use of the new tool, alone, improved my spinal arthrodesis rate from 75% to 92%¹," added Kleiner.

The benefits for patients include higher success rates and far fewer remedial second surgeries, less post-operative pain and infection risk, and less use of bone morphogenetic protein (BMP).

For surgeons, the KG 1 facilitates less-invasive procedures, faster surgeries, and reduces frustrations and guesswork in the OR.

Michael J. Rauzzino, M.D., of <u>Front Range Spine and Neurosurgery in Denver</u>, added, "I have found that I have been able to get a great deal more graft material into the disc space in a much more quantifiable and rapid fashion. The delivery device has been very simple and easy to use and I have used it for both minimally invasive as well as in open applications. It has been particularly helpful for me in the minimally invasive fusions we do, greatly increasing the amount of bone graft material that I have been able to get into the interspace. I have also found it extremely helpful for our minimally invasive lateral approaches to the spine where due to the depth of the wound and the anatomy, it was difficult to get a good deal of bone graft into the interspace."

Srdjan Mirkovic, M.D. of NorthShore Orthopaedic Institute in Chicago added, "Over the last five months in my T-lif and L-Lif operations, I have been able to expedite bone graft insertion for these procedures and avoid the problems that I encountered with round, end-dispensing bone funnels including cannula tip visualization, jamming, injury to the bony end plates of the disk space and failure to distribute bone graft in the disk space. I found that I was able to introduce more scaffold and cells and still have room for my fusion cage. It has decreased my operating time, eliminated the frustration and challenge of interbody grafting and improved my early

fusion results without using BMP. It has worked well with all of the flowable graft extender and ground autograft that I have used."

For hospitals and payers, facilitating surgeons' use of the KG 1 can reduce the costs of spinal fusion surgery through reducing the number of remedial procedures, higher OR throughput and reduced use of BMP.

The patented KG 1 graft delivery tool includes a cannula, plunger and detachable funnel, which facilitates easier loading of graft material. The KG 1's unique shape allows easier entry into the disk interspace, minimizing soft tissue damage or irritation. The bi-portal design ejects graft material to fill both sides of the disk space while leaving a central void for insertion of a fusion cage. The KG 1 is disposable, guaranteeing sterility of the instrument and eliminating the system costs of cleaning and restocking. Made of Lexan®, the KG 1 has been strength tested and proven beyond normal surgical applications.

The KG 1 is available commercially from the company and through authorized distributors, as well as to Veterans Administration and military healthcare facilities on the GSA schedule through Government Marketing & Procurement.

For KG 1 technical specifications, instructions for use, or clinical efficacy information, please go to the company's web site.

Images of the KG 1 are available on Flikr, here.

About Kleiner Device Labs

Kleiner Device Labs is creating new tools and devices to advance minimally invasive spine surgery and improve outcomes and costs for patients, surgeons, hospitals and payers. Kleiner Device Labs is headquartered in Incline Village, California. More information is available on the company's web site at http://www.kleinerlabs.com/.

Lexan is a registered trademark of Sabic Global Technologies B.V. KG is a registered trademark of Kleiner Device Labs/Spinal Surgical Strategies

¹Kleiner, et. al., Med Devices and Tech, 2016

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