Interview with Management

Kleiner Device Labs

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On The Call

Jake Hoffberg
Publisher, Equifund

Jordan Gillissie
CEO, Equifund

Michael Hughes
Chief Commercial Officer,
Kleiner Device Labs

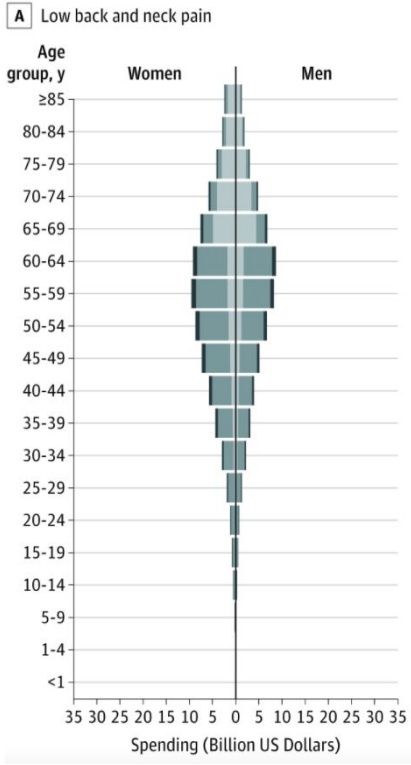
The Big Idea in 147 Words

Every year in America, **~$90 billion** is spent on the diagnosis and management of ***low back pain.***[1] The problem is only **getting worse as people age.**

By 2030, 73 million baby boomers – one in five Americans – will be 65 or older;[2] Studies have found that those over 50 have a 90% chance of some sort of spinal disc degeneration.[3]

While there are non-surgical options that can be used to manage back pain, once a disk has degenerated and become painful or unstable, it cannot be made non-painful without surgical intervention. **That's why it's no surprise to learn that spinal fusion surgery was the fifth most popular surgical procedure for the 65 to 79 age group.**[4]

Today's presentation is about how Kleiner Device Labs is addressing the growing need for the **treatment of low back pain** by **creating innovative medical technology for the $13.85 billion spinal surgery market.**[5]



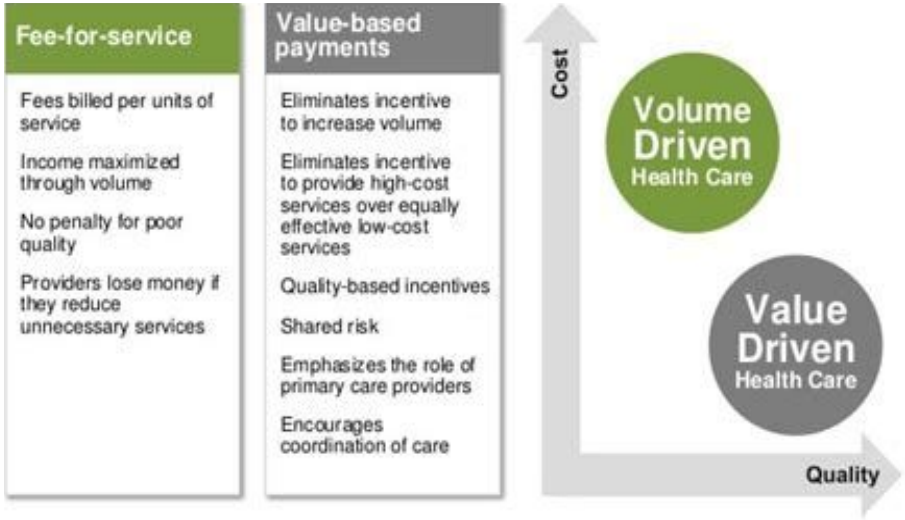
(1) Matthew Davis, Spine, published Sept 1, 2013, Where the United States Spends its Spine Dollars: Expenditures on different ambulatory services for the management of back and neck conditions
(2) United States Census Bureau, published Dec 10. 2019, 2020 Census Will Help Policymakers Prepare for the Incoming Wave of Aging Boomers
(3) Teraguchi, Yoshimura, Hashizume, Muraki, Yamada, Science Direct, publishing Jan 2014, Prevalence and distribution of intervertebral disc degeneration over the entire spine in a population-based cohort: the Wakayama Spine Study
(4) Deiner, Westlake, Dutton, Journal of the American Geriatric Society, May 2014, Patterns of Surgical Care and Complications in the Elderly
(5)Markets and Markets, retrieved Jan 24, 2022, Spinal Implants and Surgery Devices Market worth $13.8 billion by 2025

What's Driving This Change?

Volume Based vs Value Based: A New Paradigm in Medicine?

Under the current fee-based care system, it can create incentives for pharmaceutical companies and medical devices companies to prioritize profits instead of patients.

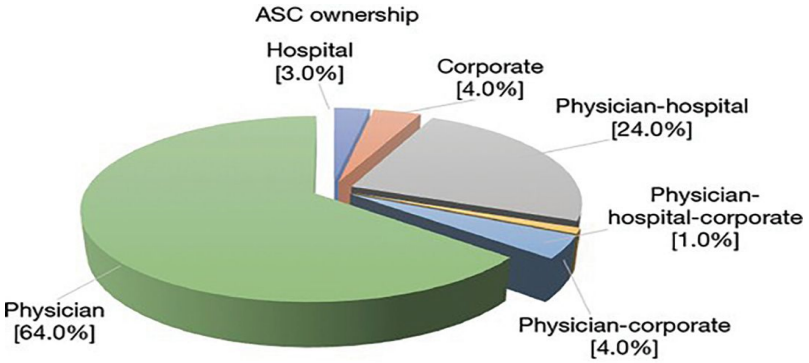
However, this system is not sustainable. That's why there has been growing pressure to change how payors and providers are reimbursed for providing healthcare solutions.



What's Driving This Change?

The Shift to ASC and Outpatient Centers

A paper in the *Journal of Spine Surgery*[1] found that the cost of performing a surgical procedure in an ASC is 45% to 47% lower compared to hospitals. It also estimates that 48% of outpatient procedures are done at ASCs – saving $37.8 billion in healthcare costs for the commercially-insured population. **If all outpatient procedures were done at ASCs, $41 billion more in savings could potentially be realized.**



- ASCs were already estimated to be a $75 billion global market in 2018. By 2026, they are projected to be worth over $120 billion.

- **90% of ASCs in the US have at least some physician ownership, with 65% of them being solely owned by physicians;** The ASC model allows physicians to have more control over the care they deliver to patients.

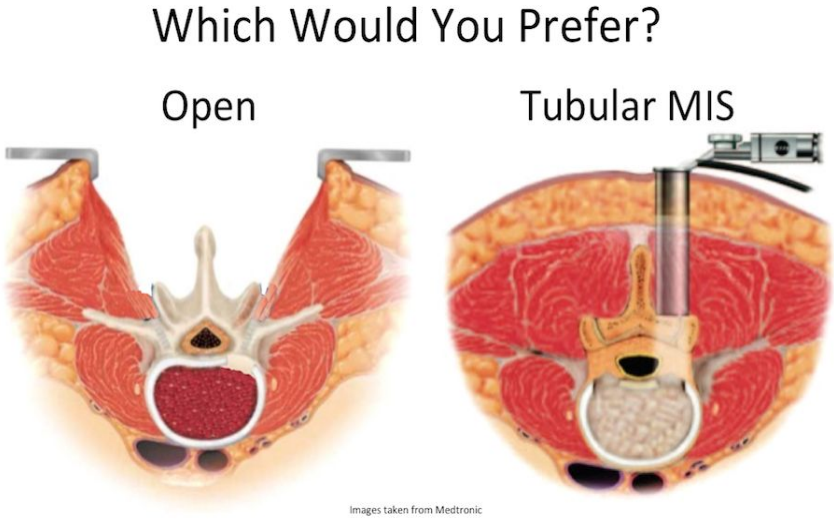
(1) Neil Badlani, Journal of Spine Surgery, published Sept 5 2019, Ambulatory surgery center ownership models
(2) Grandview Research, published May 2019, Ambulatory Surgery Center Market Size, Share & Trends Analysis Report By Application (Orthopedics, Plastic Surgery, Ophthalmology, Gastroenterology, Pain Management), By Region, And Segment Forecasts, 2019 - 2026

What's Driving This Change?

The Rise in Minimally Invasive Surgery (MIS)

In 2020 the global MIS market was ~$39 billion. By 2026, it's projected to increase to $61.2 billion.

The rising popularity of minimally invasive surgeries goes hand in hand with ASCs. Because minimally invasive surgeries are often safer, faster, and cheaper than traditional open theatre surgical procedures… many would opt for this option if given a choice.



Not all surgeries can be done in a minimally invasive manner. But as technology continues to improve, this will only increase.

(1)Expert Market Research, retrieved Jan 21, 2019, Global Minimally Invasive Surgery Market: By Product Type: Surgical Devices, Laparoscopy Devices, Monitoring and Visualisation Devices; By Application; By End Use; Regional Analysis; Historical Market and Forecast (2017-2027); Market Dynamics; Value Chain Analysis; Competitive Landscape; Industry Events and Developments

Introducing: Mike Hughes

37 Years of Results

- Accomplished med-device sales executive.
- Track record of sales results, specific to the spine industry.
- Tenure with large companies like J&J and Zimmer Biomet, and smaller companies during high growth like Lanx, Interpore Cross, and Vertiflex
- Joined Kleiner Device Labs full time as CCO, May 2021, to launch the KG2

The Problems Today That Must Be Solved…

Cost Pressures on ASC Model

However, healthcare is an expensive business.

Between reimbursement rates, liability insurance, administration, and medical infrastructure – and the pressures of COVID-19 – ASCs need a large amount of capital to stay in business (much less turn a profit).

Even for identical procedures, reimbursement rates are lower for ASCs compared to hospital outpatient departments.

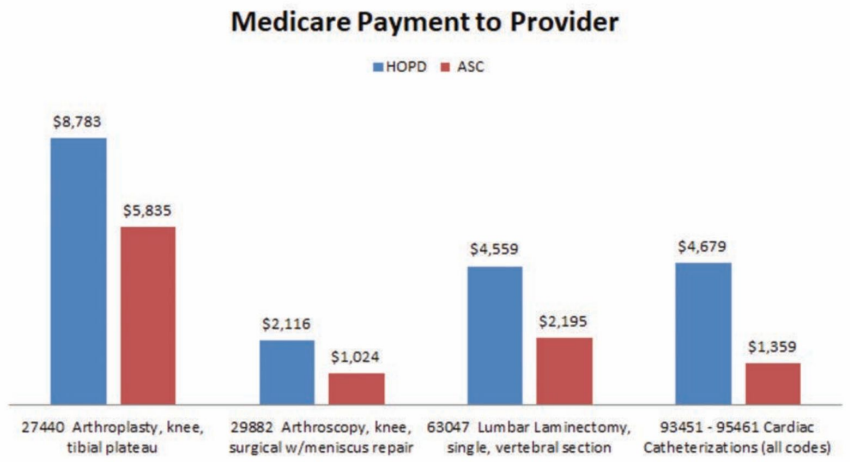


Figure 1. Medicare payment to provider by procedure. Calculated at https://www.medicare.gov/procedure-price-lookup/. Accessed January 20, 2020. *HOPD=hospital outpatient department; ASC= ambulatory surgery center.*

The Problems Today That Must Be Solved...

Staffing Shortages

According to Merritt Hawkins, there will be about 24,350 orthopedic surgeons in the U.S by 2025, but a projected demand for 29,400 — representing a deficit of 5,050.[1]

This impending physician shortage, paired with increasing industry consolidation, has some ASC leaders worried the physician-owned business model of ASCs will be jeopardized.

This is exacerbated as more physicians are being employed by hospitals. By the end of 2020, nearly 70 percent of physicians reported being employed by hospitals, with a steady acceleration in the latter half of the year.[2]

BECKER'S SPINE REVIEW

"As the generation of independent surgeons that founded many ASCs 20 to 25 years ago approach retirement, there may be fewer surgeon investors available to replace them,"[3]

-Scott Thellman, MD, surgeon at Lawrence (Kan.) Plastic Surgery

(1) Merritt Hawkins, published July 21, 2021, 2021 Review of Physician and Advanced Practitioner Recruiting Incentives
(2) Laura Dydra, Becker's ASC Review, published July 1, 2021, 70% of physicians are now employed by hospitals or corporations
(3) Patsy Newitt, Becker's ASC review, published Sept 29 2021, Will physician shortages threaten independent ASC ownership?

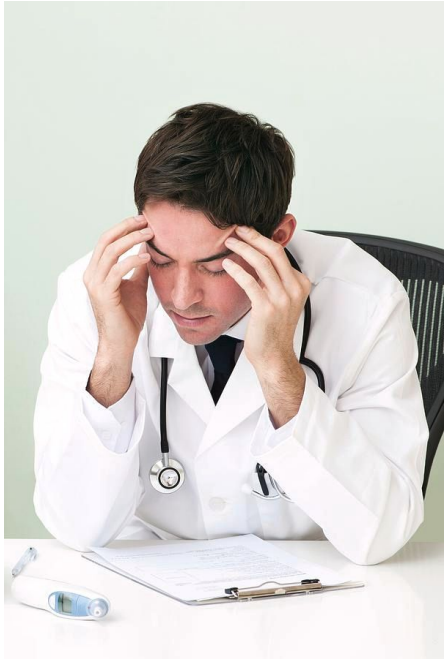
The Problems Today That Must Be Solved...

Steep Learning Curve for MIS

Minimally invasive spinal surgeries are *delicate*, *highly complex* procedures. One small slip during one of the many steps and you might risk damaging surrounding tissues or a vital structure.

At the same time, surgeons cannot afford to be left behind as minimally invasive surgeries continue to grow in popularity – especially if they want to enjoy the financial rewards of being an ASC owner.

This barrier could be lowered if minimally invasive surgeries were less complicated.



The *REAL* Problem That Must be Solved?

Specialized Products Designed Specifically for the Needs of ASCs

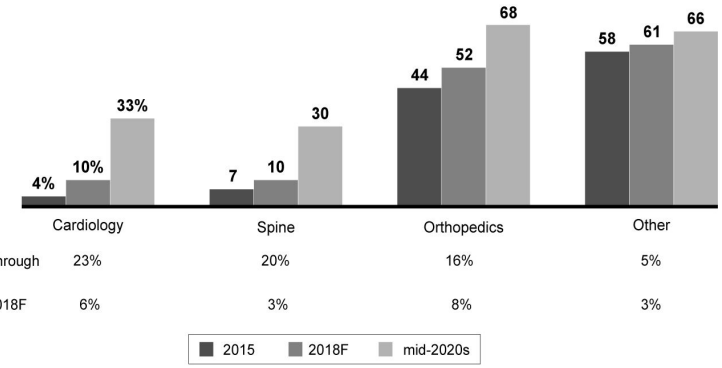
Spine procedures often represent 20% to 25% of orthopedic procedures but contribute more than 50% to the profit.[1]

The tradeoff is that their failure rates can scare away both potential customers and the surgeons needed to operate the ASCs.

Add on cost pressures and the steep learning curve it takes for surgeons to learn the skills necessary to perform minimally invasive spinal surgeries at ASCs, we saw a clear opportunity.

We need to create new products specifically designed to for the growing demands for MIS in the ASC setting.

Percentage of procedures performed in ambulatory surgery centers



Notes: Other includes ophthalmology, gastroenterology, pain management, dermatology, urology, podiatry, ENT (respiratory), OB/GYN, neurology, general surgery, plastic surgery, oral surgery; pain management reflects nonspinal pain management procedures only
Sources: VMG; Definitive Healthcare; Ambulatory Surgery Center Association; MedPac; Bain & Company Medtech Physician Survey, 2019 (n=360)

"Our analysis shows single-specialty centers focused on orthopedics, cardiology and spinal surgery will see the fastest growth in volume of procedures through the mid-2020s." [2] – Bain & Company

(1)Kurd MF, Schroeder GD, Vaccaro AR. Spine Surgery in an Ambulatory Setting: What Can Be Done Safely? JBJS Rev 2015. [Crossref] [PubMed]
(2) Tim van Biesen and Todd Johnson, Bain & Company, published Sept 23 2019, Ambulatory Surgery Center Growth Accelerates: Is Medtech Ready?

We're Not the Only Ones Trying to Solve this Problem

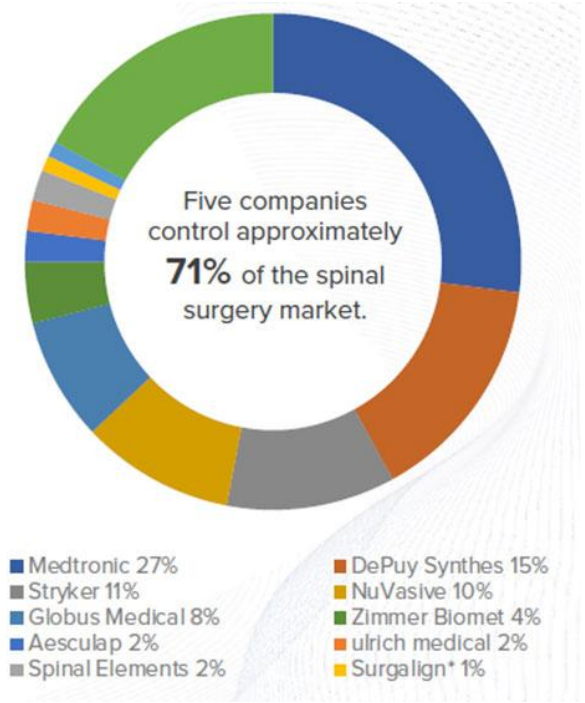
"Big Spine" Sees the ASC Opportunity…

Medtronic, Stryker, DePuy (a division of Johnson & Johnson), Zimmer Biomet,

However, "Big Spine" has a bias towards "innovation through acquisition" vs internal research and development!

As these large players battle for growth, this could represent an excellent opportunity for a strategic investment in a startup MedTech company who can help them stay competitive.

- ***In the past few years, we've seen acquisitions ranging from almost $500 million to over $1.5 billion in this space.***



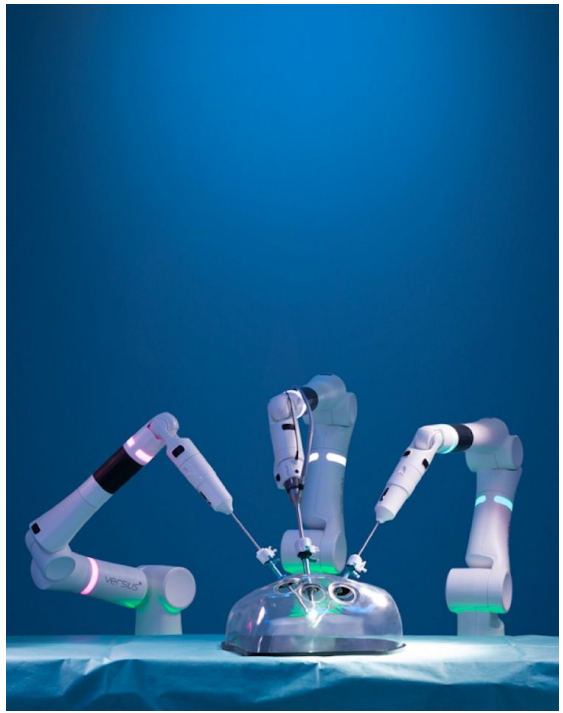
We're Not the Only Ones Trying to Solve this Problem

…But is Trending Towards Expensive Surgical Robots and Automation.

Artificial intelligence, machine learning, robotics and 3D-printing technologies have become the latest buzzword in MedTech.

However, simply automating existing processes alone isn't enough. In some cases, these new technologies add additional costs – and training burdens – that have the potential to increase patient risk.

And for ASCs, the up front investment – often in the millions of dollars – to purchase a robot that is highly specialized in nature is prohibitive to adoption.



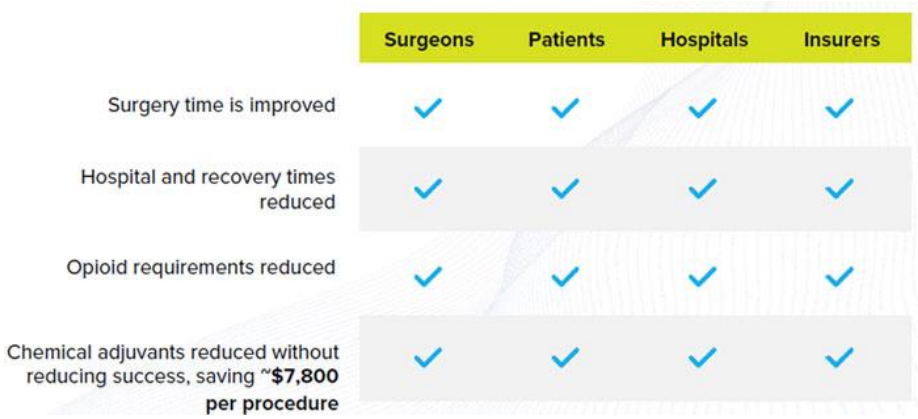
Why We're Different

Designed With All Stakeholders in Mind…

Dr. Kleiner has performed more than 6,000 spinal surgeries in his private practice. One of his biggest motivations for creating new spinal surgical devices was to reduce the post-operative pain his patients felt.

He also has received three spinal surgeries himself. The end result? An inventor – and businessman – who is willing to put the needs of the patient first.

To do this, it means starting with the most important part of the whole procedure: ***getting enough bone graft in the right place and making the procedure easier for the surgeon to perform.***



	Surgeons	Patients	Hospitals	Insurers
Surgery time is improved	✓	✓	✓	✓
Hospital and recovery times reduced	✓	✓	✓	✓
Opioid requirements reduced	✓	✓	✓	✓
Chemical adjuvants reduced without reducing success, saving ~**$7,800 per procedure**	✓	✓	✓	✓

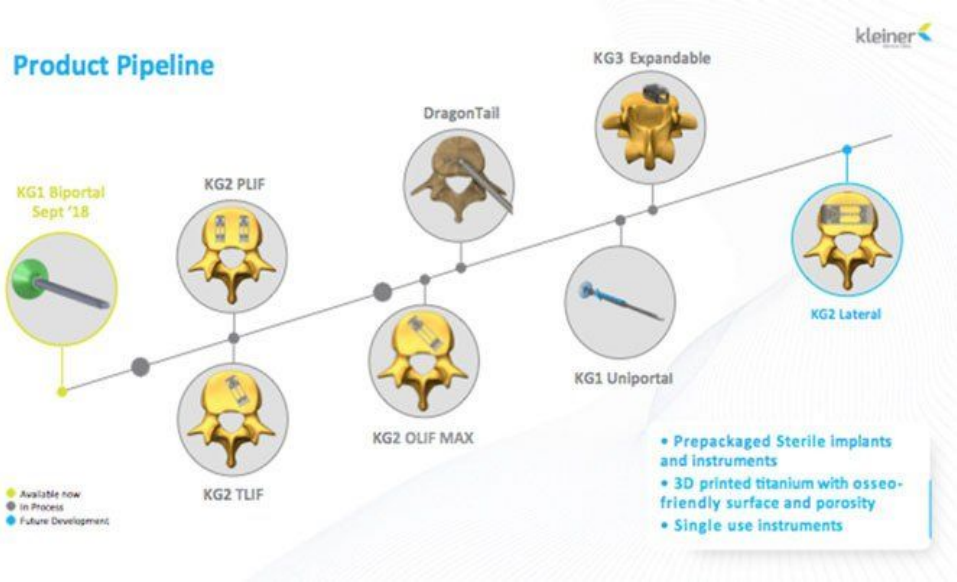
The healthcare industry must figure out ways to reduce costs without sacrificing quality of care. Kleiner Device Labs' technology has ***the potential to improve patient outcomes, lowers costs, and make surgeons' lives easier.***

Our Investment Thesis

A Portfolio of MIS Spinal Surgical Tools

The Kleiner Devices Labs team is in position to supply this growing market – which demands safety, improved outcomes and quicker return to function at a lower price – with exactly what it needs…

An elegant suite of products that have the potential to lower costs, increase profit margins, reduce risk, require less training, and create better results for patients!



Why This Problem Is Hard To Solve

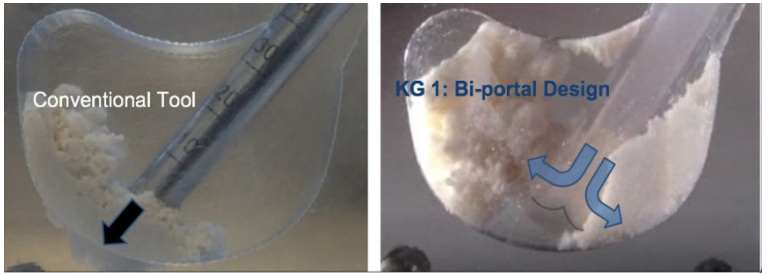
The Bone Graft Solution

As a surgeon, Dr. Kleiner saw first-hand how difficult it was to get the right amount of bone graft into the disc space – not to mention having it fill the entire cavity properly.

Most surgeons and medtech companies ignored fixing the grafting problem simply because it was hard to do.

The Kleiner Device Labs KG™ System improves and streamlines the entire process by allowing more bone graft material to be delivered – and for both the graft delivery and cage implantation to be done – in a single continuous step.

Because no matter how well-built the interbody cage is, it will fail without the graft material



Round cannulas have limited ability to disperse grafting material (left) and the potential for clogging or jamming. The KG system (right) allows bi-portal extrusion of graft and maximizes volume and distribution.

How Our Technology Works

A Square Peg in a Square Hole

If you've ever heard the expression a "square peg in a round hole," the most popular spinal fusion techniques literally attempt to fit a round peg into a square hole; the funnel for delivering the bone graft had a round opening – even though the opening for receiving the bone graft was rectangular.

Dr. Kleiner's innovation was to re-engineer the insertion system to match its shape to the opening in the spine; literally creating a square peg to fit a square hole.

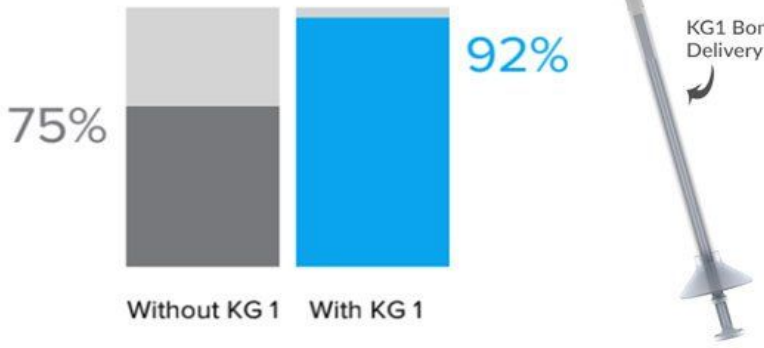
[Click here for a demonstration]

Kleiner Device Labs' first invention – *the KG1* – has already seen spinal fusion success rates increase from 75% to 92%. The KG1 has achieved FDA 510(k) Clearance and is commercially available and sold in the US and OUS.

Their newest product – *the KG2* – has also received FDA 510(k) Clearance. The product is set to undergo Alpha Trials in 2022-Q1 in order to generate clinical data required for marketing claims

Value Proposition (Why Surgeons Buy)

Fusion success rate dramatically increases with KG 1



Sources: Kleiner et al, Med Devices and Tech, 2016 (pre-launch, clinical investigatory information)

"Very simple and easy to use"

Michael Rauzzino MD, FACS
Front Range Spine and Neurosurgery

"Eliminated the frustration and challenge of interbody grafting"

Srdjan Mirkovic MD
Northshore Orthopedic Institute

"Greatly improves optimal bone graft delivery"

Stephen Pehler
Colorado Orthopedic Consultants

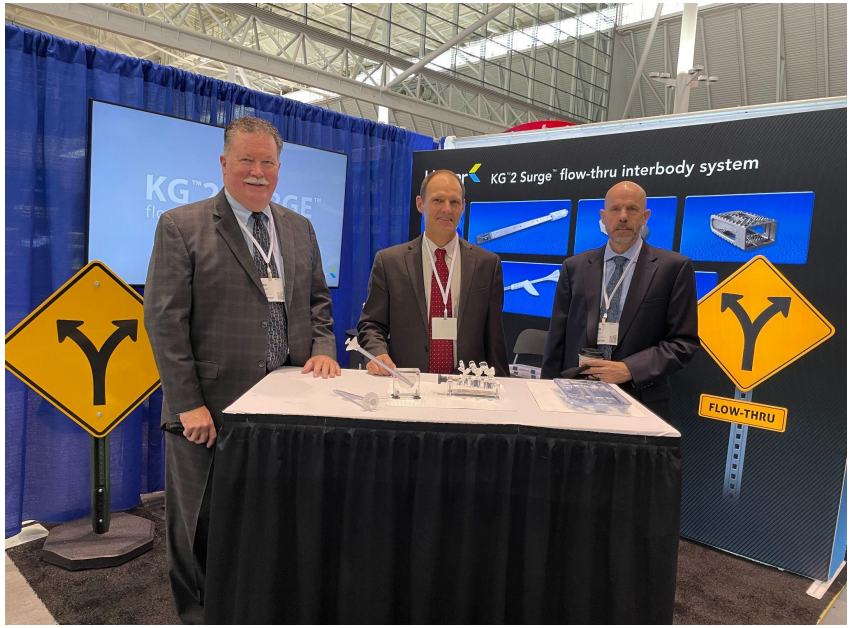
The Kleiner Spinal Surgical System transforms a complex, multi-step process into a simple, single-step procedure – and by extension reduces surgical risk, surgeon fatigue, and operating time.

Recent Highlights

North American Spine Society (NASS) Annual Meeting

On September 22nd, 2021, Kleiner Device Labs announced they'd officially received FDA market clearance for their KG™2 Surge™ ("KG2") flow-thru interbody system.

This came just in time to debut their breakthrough spinal surgical device at the North American Spine Society (NASS) annual meeting (which happened from Sept 29th - Oct 02, 2021).



The Path Forward

Alpha Launch Candidates

"Alpha Surgeons" represent an initial group who will be the first to use a new device in live patient procedures.

KDL has hand-picked a small team of orthopedic spine & neuro-surgeons who represent a cross section of surgical theaters, from hospitals to surgery centers.

Several of these surgeons participated in a cadaver testing laboratory exercise last April. This means they already have some familiarity with the device.

The first surgeries done by this group will document procedure processes and results, which will be presented to surgeons more broadly in the U.S.

This will provide important proof points for the healthcare systems – and the insurers who predominantly pay for the spinal fusion procedures – ***to assess the efficacy of our products (and provide required clinical data for any marketing claims needed to promote our products).***

Our Track Record So Far

Milestone	Date
Validation Cadaver Lab	Apr ‘21
FDA 510(k) Clearance	Sep ‘21
Initial “Alpha” Launch	Q1-Q2 ‘22

Our Team

Jeff Kleiner
CEO

During 25 years as a spinal surgeon Dr. Kleiner became progressively more focused on decreasing the amount of pain that his surgical patients experienced. The minimally invasive techniques that surgeons wanted to perform were hampered by instruments that created longer procedures and compromised the outcome.

He, In collaboration with experienced spinal medical device engineers from Zimmer Biomet, developed a suite of tools designed to make it easier to perform less painful, minimally invasive spine surgery. Those tools produced better patient outcomes, reduced operating time, and lowered costs for all stakeholders.

Alan Burkholder
CTO

Alan graduated from Case Western Reserve University with an MS and BS in Mechanical engineering and from Goshen College with a BA in Physics. He started his engineering career over 20 years ago at Energizer Battery Company working on high speed production equipment design and has been working in spine product development for the last 13 years, during which time he served as Director of new product development for Zimmer Biomet Spine.

Alan ramped up to full-time in August of 2019 and will accelerate our upcoming products. He has been working with Dr. Kleiner and Dr. Causey over the past year on the fusion cage design prototype and its prospective July 2020 alpha launch.

Our Team

Konstantin Caploon
Chief Legal Officer

Konny is a seasoned and business-oriented attorney with executive management experience. Corporate experience as head of IP, and as general counsel. Significant work with business strategy, innovation, risk management, budgeting, IP portfolio management, litigation, L&A, transactional matters, negotiation, dispute resolution, healthcare compliance, client communication and counseling.

Konny has nearly 20 years of experience as an attorney and served as general counsel for the Biomet Bone Healing business.

Greg Causey
VP Engineering

Greg has worked in the spine industry for nearly 20 years. Over that time he has held engineering management positions in a number of spinal companies including: Interbody Group, Theken Spine; VP Engineering, Lanx; VP R&D, Biomet Spine; VP Engineering X-Spine/Xtant.

Since 2016 he has worked as an independent consultant to the spine/orthopedic industry specializing is new product development, osseointegrative research, and quality/regulatory. Dr. Causey received his PhD in mechanical engineering from Case Western Reserve University. He has presented at US and International conferences on osseointegrative research and holds a number of patents related to spinal implant systems and technology.

Q&A

What questions do you have?

Considering an Investment?

Please visit their offering page for more information

https://equifund.com/kleiner/