drea™

A **real** solution for spinal surgery

carevature Technologies

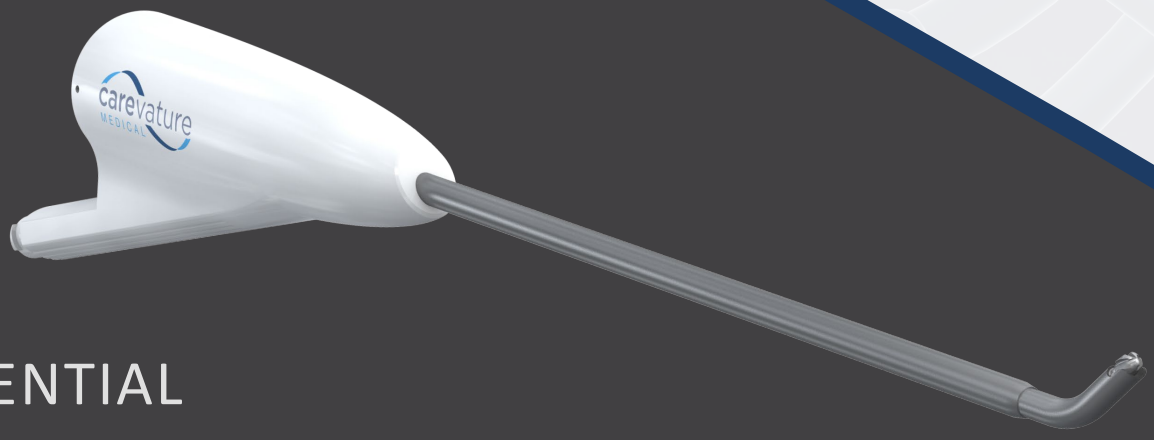
The only
curved, shielded, high-speed bone-removal device
for precise, safe spinal decompression

Surgical precision leads to:

Minimized Complications

Time Savings

Reduced Expenses



POTENTIAL
CLINICAL VALUE

Safety **Access** **Outcomes**

Fundamentally Improves
Spinal Surgery

Decompressing the neural elements is the key to treating spinal **pain**.

Decompression is the first step of most degenerative spine procedures.

View Decompression Video

Decompressing the Spine is:

Critical,
Intricate,
Impactful,
Dangerous,
Time-Consuming,
Under-Resourced,

AND performed with sharp tools that have not changed in decades.

Improved Decompressions » Improved Outcomes

Carevature has fundamentally improved decompression technology that has not advanced in decades by creating **Dreal**, a drill with a curve at the tip that is able to maintain the necessary 40-60K RPMs required to cut bone efficiently.

6 **PATENTS**
Dreal is the **only** curved at the tip, shielded, high-speed bone removal device

- **No capital investment** easy attachment to standard power systems
- **Minimally invasive** compatible with mini-open and tubular approaches
- **Integrated irrigation** temperature control and flush debris
- **Unique options** for cervical, thoracic and lumbar applications
- **Sterile packaged** single-use, safe, sharp and ready for use

FDA CLEARED

12+ **PUBLICATIONS & INDUSTRY PRESENTATIONS**
Peer-reviewed journals & industry conference presentations

2000+ **DOCUMENTED SURGICAL CASES**
1000+ Domestic
1000+International

Procedural Improvement
Opportunities

Decompression technology that preserves healthy, stabilizing bone may reduce the need for fusion.

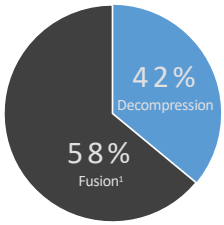
Decompression

is often the first surgical intervention. The procedure relieves pain by removing soft tissue and bone impinging on a nerve root or the spinal cord.

At least 50% of total spinal surgery time is dedicated to decompression.[2,3]

Fusion

often begins with decompression that is followed by the stabilization of two or more vertebrae. Each additional level fused increases surgical time, cost, and the healing process.



63%
Of decompressions are more than 1-level[4]

1.90
Average Levels Fused[5]

Focus on Decompression

- Half of the OR time can be spent in the intricate and dangerous decompression stage of surgery
- Only **7%** of resources allocated to spinal surgery are dedicated to decompression
- **37%** of resources are dedicated to fusion hardware costs[6]

Increase clinical and economic value by focusing on decompression with Dreal

- No capital investment
- Safer surgery with fewer complications[7]
- OR time savings for the most time-consuming stage of surgery[3]
- Improved access to pain generators results in less removal of stabilizing bone[8]
- Improved short-term and potentially long-term patient outcomes[9]

Rethink the emphasis on fusion hardware

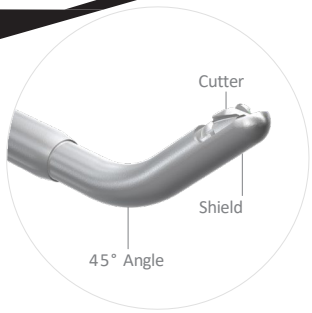
- Fusion devices are expensive and simply stabilize (a good or bad) decompression
- The more aggressive the decompression, the more stabilizing hardware could be necessary
- Reducing fusion hardware equals direct savings to the bottom line

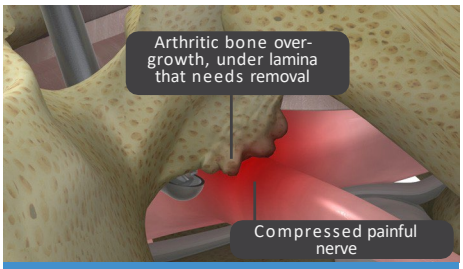
Procedural Efficiency

Key Design Features

Curved at 60,000 RPMs

Dreal's curved tip allows access to pain-causing pathology that is often out of sight.





Lumbar Spine

Pain-causing spine pathology is often around a corner out of sight and proximal to neural anatomy increasing the difficulty & danger of removal.

View curving at high speeds

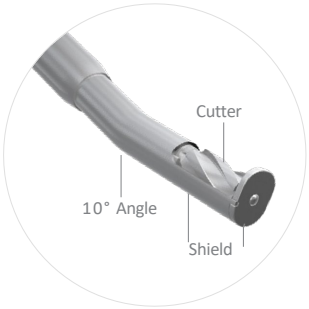
Open Procedures still have hidden pathology particularly in more complicated, multi-level or revision situations.

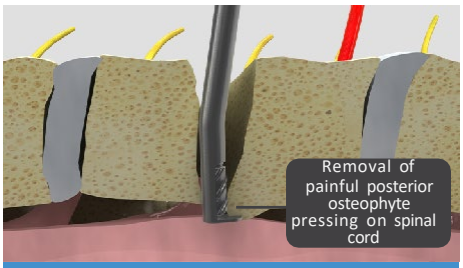
Dreal Technology may enable a shift from open to MIS in select cases.

Minimally Invasive Procedures may have more challenges in reaching pathology with standard, sharp, unshielded instruments.

Shielded

Visualizing the pathology is extremely challenging, often nonexistent, and creates a dangerous environment for sharp tools next to neural elements. Dreal's shielded tip allows precise, efficient removal of pathologic bone.





Anterior Cervical Spine

Protects nearby healthy, stabilizing structural bone

Potentially reduces the need for a more extensive fusion surgery

View 'undercutting' advantage

Shielded vs. Non-shielded Instrumentation

*Refer to **Appendix** for a comparison of Dreal to current instrumentation options

Procedural Effectiveness

Profound Fundamental Improvement

Surgeons are experiencing what CT Scans prove:

It is now possible to improve upon the decompression while saving bony anatomy.

"Studies estimate that 10-15% of uninstrumented decompressions will require a second surgery, either for a revision decompression due to an incomplete decompression the first time, or overzealous, excessive decompression, thereby destabilizing the patient and leading to a revision surgery involving spinal fusion."

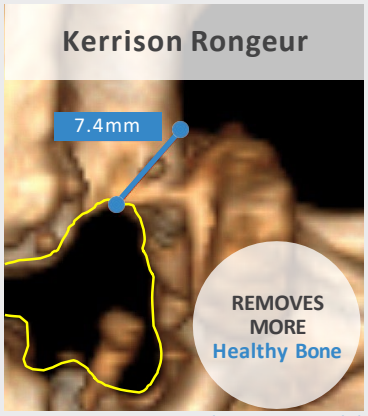
Larry Khoo, MD
Neurosurgeon, Spine Clinic of Los Angeles

Dreal decompresses BOTH sides of the spinal canal through a small, one-sided approach. The curved tip allows safe access to pain-causing pathology while reducing the removal of structural bone.

Lumbar Spine with Osteophytes pressing upon exiting nerve roots

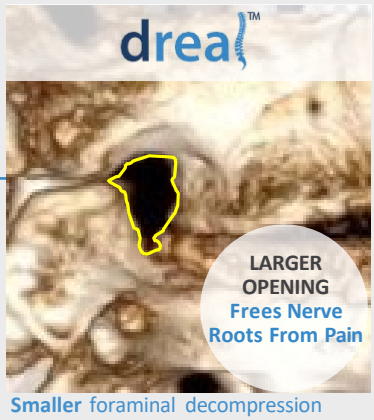
Dreal reduced removal of bone width **23.5%**

Spares Anatomy, increasing stability

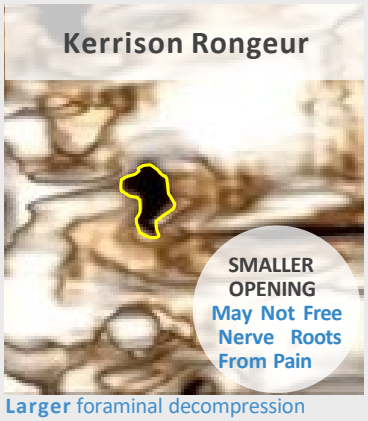


Removes Anatomy, decreasing stability

Dreal increased foraminal volume **163%**



Smaller foraminal decompression



Larger foraminal decompression

Decompression outcomes with the Dreal drill were compared to traditional methods using CT scans, before and after the procedures; 15 levels (3 cadavers, 5 levels each) were operated on by 3 skilled surgeons.[8]

Consider Dreal to Potentially:

- **Improve decompression outcomes**
- **Prevent or delay decompressions from becoming fusions**
- **Improve fusion outcomes by improving the decompression**
- **Reduce the number of fusion levels in a multi-level case**
- **Improve the outcome of an interlaminar or interspinous procedure**

Clinical Value

Reduces Risk of Common Procedural Complications

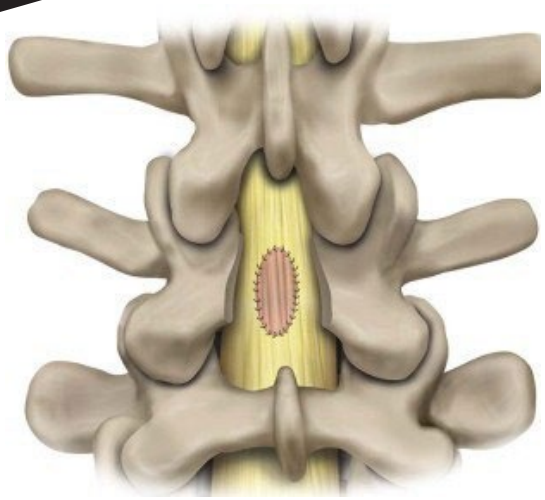
Incidental Dural Tears Lead to:

40% Longer Hospital Stay

4.97 with durotomy vs. 3.56 days without[10]
(increase of greater than one day on average)

57% Increased Risk of Neurological Complications

4.94% with durotomy vs. 3.16% without[10]



9% Of cases result in Dural Tears[4]

$735 Average Per Case Direct Cost of Dural Sealant[5]

Durotomy: The Financial Impact

- **Durotomies are a common complication of spinal surgery, and a factor in some malpractice cases**
- **Fear of durotomy often hinders thorough decompression, which could lead to additional surgery**
- **Post-surgical patient immobilization following durotomy is significantly increased**

$2.8M
average amount of payment for malpractice cases settled or decided for incidental durotomy[11]

8x
longer immobilization: Durotomy patients are kept in bed for 24 hours, vs. 3-4 hours with no durotomy[12]

Use of Dreal significantly reduced incidence of dural tears[7,17] compared to standard instruments

Dreal Reduces Dural Tear Rate by 20x*

Compared to Conventional Burrs and Kerrisons

(*) 3 incidental dural tears with no neurological injury using Dreal vs. 3% using Kerrison Rongeurs and high-speed drills[7, 17]

Clinical Value

A breakthrough that could reduce hardware expansion into adjacent levels

Preservation of structural bone **can reduce the number of spinal levels requiring a fusion** which results in lower blood loss. Patients that underwent a two-level decompression and a one-level fusion had a **significantly shorter operative time** and **significantly less blood loss** than patients that underwent a two-level decompression with a two-level fusion.[3]

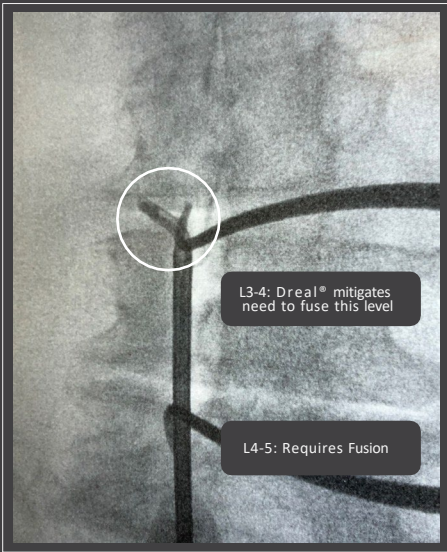
Blood Loss 161mL

OR Time $2,359[13]
63 mins @ $37.45/min

Dreal directly addresses the source of the clinical complaint through minimally invasive, precise, safe, and efficient neural decompression. This allows targeting of specific bony pathology while protecting the adjacent nerves and preserving nearby healthy bone critical to spinal function and stability.

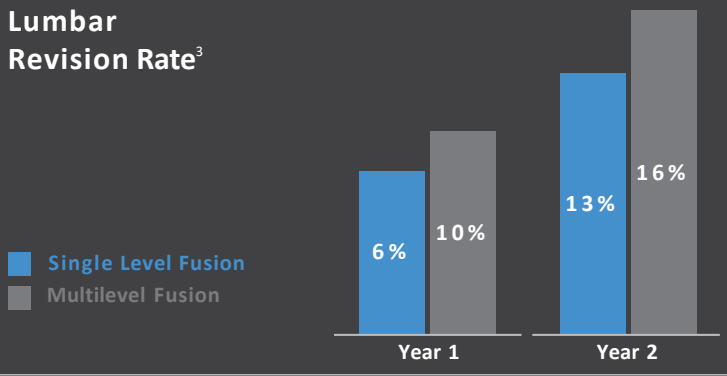
Revision Rate

 # Levels Fused



- 1.90 average number of levels fused
- A single level fusion often has one or more adjacent levels with pathology
- Dreal addresses a common cause of failed spinal surgery: failure to fully decompress the nerve

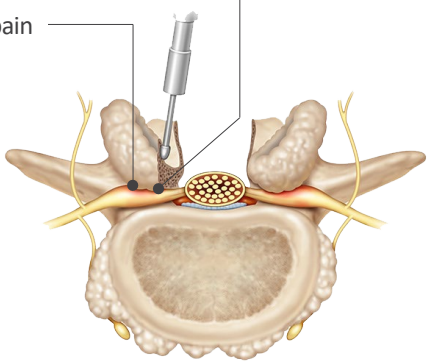
Lumbar Revision Rate[3]



Dreal technology offers a solution to address decompression risks during spinal surgery:

Too Conservative possibilities: (not removing enough bone)

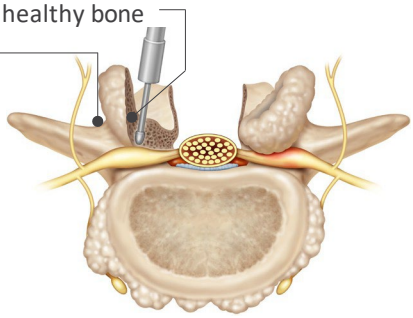
- Painful pathology is not fully removed
- Patient remains in pain



Need for another surgery

Too Aggressive possibilities: (removing too much bone)

- Nerve damage from sharp tools
- Dural tears
- Unnecessary removal of healthy bone
- Instability



Need to fuse this level

Economic Value

By efficiently and effectively addressing risk and uncertainty

dreal™ **Can potentially provide:**

Short-Term Savings

Through interoperative safety, specifically the reduction in incidental durotomies.

Long-Term Savings

Through a more thorough decompression, reducing pain and the need for further surgical intervention. This, coupled with the anatomy-sparing features of the Dreal, could reduce future destabilization issues.

Dreal can positively impact even the most challenging cases including select, targeted indications.

Dreal is for bone removal only and is not indicated for all decompressions, such as soft tissue removal in discectomies.

Coding and Reimbursement

$22K-$100K+[14]

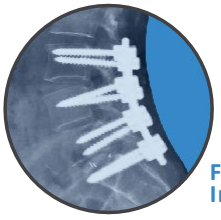
Facility Reimbursement Range associated with most common DRGs associated with **Dreal** (453 – 460)+

Dreal represents only a fraction of this reimbursement, positively impacting the bottom line:

1.9% **of Private Pay Reimbursement**

+The 2020 national average payment rates are offered for educational and strategic planning purposes only. Actual facility reimbursement depends upon payer mix and specific contract terms.

Direct costs and other variables that can be reduced through the use of Dreal technology:



Fusion Implants

Biologics and Sealants

Specialty Disposables

Operative Time

Length of Hospital Stay

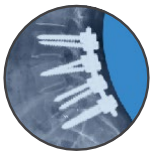
Costs Associated w/ Complications

Other Possible Complications

Economic Value

Impacting the Bottom Line

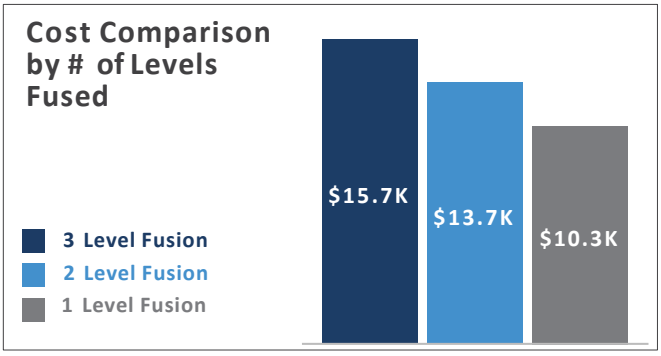
Dreal technology provides the opportunity to downgrade a multi-level fusion, significantly impacting the bottom line. Here's how.



Implantables: Cost Savings[5]

Reducing a 2 Level Construct to a 1 Level = **$3,389 Savings**

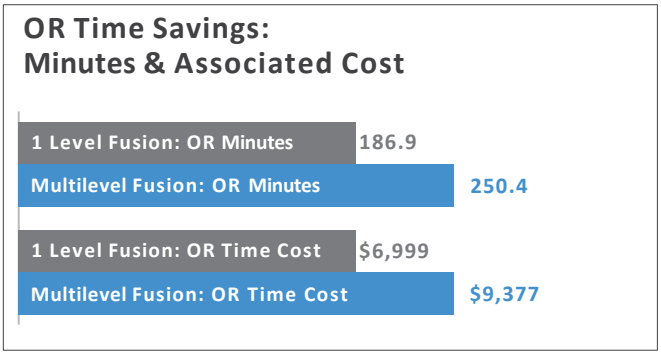
Reducing a 3 Level Construct to a 1 Level = **$5,312 Savings**



OR Time Savings

Reducing a Multilevel Construct to a 1 Level = **63.5 Minutes Saved**[3]

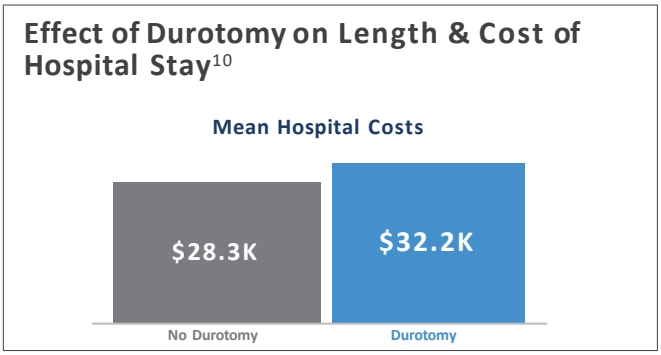
Reducing a Multilevel Construct to a 1 Level = **$2,378 Reduced OR Time Expense**[15]



Minimized Complications and Associated Costs

Dreal's dural tear rate is **20x** lower than standard high-speed burrs[7,17]

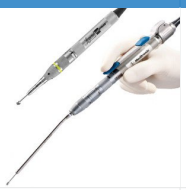
Incidental durotomy leads to direct cost increase of **$3,873**[10]



Use of Dreal led to an estimated savings of $2,060 per case[16]

A recent peer-reviewed published article **validated the economic value outlined above**

Appendix: Commonly Used Tools in Spinal Decompression Surgery

	Dreal® Technology	Standard Kerrison Rongeur	Standard High-Speed Drill	Pneumatic Kerrison	Ultrasonic	I/O Flex
						
Tip Detail						
Year Introduced	2017	1908	1992	2005	1995	2009
Brands	Carevature	Multiple	Medtronic, Stryker, Anspach	Aesculap	Misonix, Stryker	Spinal Elements
Average Cost	<$500	~$650-$2,950	$120 - $300	~$100	$400 - $700	$2,500 - $3,500
Capital Expense Required?	No	No	Yes, $30,000 - $50,000	Yes, ~$25,000		
Shielded to Protect Nerves?	Yes	No	No	No	No	No
Curved Near the Tip?	Yes	No	No, some models are slightly angulated or "bowed" near the grip but no acute curve near the tip.	No	No	Yes
Access "around the corner" to remove bony pathology?	Yes	No	No	No	No	Yes
Safety Profile (dural tear rate) [7,17]	0.15%	2.91%	2.91%	2.91%	1.95%	Unreported
Ability to "undercut" and precisely remove pathology while preserving healthy, structural bone?	Yes	No	No	No	No	Yes
Ability to perform thorough, precise, efficient, and safe foraminal decompression?	Yes	No	No	No	No	Yes
Potential to reduce number of spinal levels to be fused, and to reduce hardware spend?	Yes	No	No	No	No	Yes
Can be used through a tube for microscopic, MIS decompression?	Yes	Yes	Yes	No	No	No
Single Use, Sterile-Packed	Yes	No	Yes	No	Yes	Yes
Requires reprocessing/sterilization?	No	Yes	No	Yes	No	No
Requires Neuromonitoring?	No	No	No	No	No	Yes
Integrated Irrigation	Yes	No	Sometimes	No	No	No
Maintenance required?	No	Yes	No	Yes	Yes	No
Significant Number of Device Passes Required?	No	Yes	No	Yes	No	No
Number of devices needed for the decompression	1	2 to 4	1	2 to 4	1	5

References

1. NIS 2016 Database (assuming 1.8% CAGR)
2. Försth P, Ólafsson G, Carlsson T, et al. A Randomized, Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis. N Engl J Med. 2016
3. Smorgick Y, Park DK, Baker KC, et al. Single- versus multilevel fusion for single-level degenerative spondylolisthesis and multilevel lumbar stenosis: four-year results of the spine patient outcomes research trial. Spine
4. Lurie JD, Tosteson TD, Tosteson A, et al. Long-term outcomes of lumbar spinal stenosis: eight-year results of the Spine Patient Outcomes Research Trial (SPORT). Spine (Phila Pa 1976). 2015;40(2)
5. Orthopedic Network News, 2019 Spinal Surgery Update, Volume 30, Number 4, Oct. 2019
6. Beckerman D, Esparza M, Lee SI, et al. Cost Analysis of Single-Level Lumbar Fusions. Global Spine J. 2020;10(1)
7. Pflugmacher R, Franzini A, Horovitz S, Guyer R, Ashkenazi E. Suitability of Administrative Databases for Durotomy Incidence Assessment: Comparison to the Incidence Associated With Bone-Removal Devices, Calculated Using a Systemic Literature Review and Clinical Data. Int J Spine Surg. 2018;12(4)
8. Ashkenazi E, Peloza J, Khoo L, Millgram M, Guyer R: "Improved Bone-removal Using a New Device in Open and Minimal Invasive Approaches: Cadaver Study and a 2-center Experience with 143 Patients" Presented at International Society of Advanced Spine Surgery meeting, February, 2020
9. Peloza J, Millgram M, Jacobian E, Kolsky D, Guyer R, Le Huec JC, Ashkenazi E:"Improved Efficacy of TLIF Procedures Due to a New Device: Preliminary Cadaver Study and a 209-Patient Retrospective Study in a Single Center", presented at Lumbar Spine Research Society, Nov 12, 2020
10. Buck JS, Yoon ST. The Incidence of Durotomy and its Clinical and Economic Impact in Primary, Short-segment Lumbar Fusion: An Analysis of 17,232 Cases. Spine (Phila Pa 1976). 2015;40(18)
11. Wesley M. Durand, Adam E. M. Eltorai, Govind Shantharam, J. Mason DePasse, Eren O. Kuris, Alicia E. Hersey, Mark A. Palumbo, Alan H. Daniels. Medical Malpractice Claims Following Incidental Durotomy Due to Spinal Surgery. SPINE, 2017; 1
12. AO Spine Education: Step-by-Step Guide: Minimally invasive tubular approaches to lumbar spine decompression and dural repair—surgical techniques Education Prepared by: Dr Avelino Parajon MD, Chief of Section of Neurosurgery, Hospital Universitario Ramón y Cajal Dr Roger Härtl, Weill Cornell Medical College, Professor of Neurological Surgery, Director of Spinal Surgery
13. Childers CP, Maggard-Gibbons M. Understanding Costs of Care in the Operating Room. JAMA Surg. 2018;153(4)
14. CMS INPATIENT PROSPECTIVE PAYMENT SYSTEM (IPPS). Range includes variable Medicare payments based upon DRG, with an average increase of 1.5-2x estimated for private payers
15. Understanding Costs of Care in the Operating Room. JAMA SURGERY, 153(4):e176233, February 2018
16. Peloza J, Millgram M, Jacobian E, Kolsky D, Guyer R, LeHuec JC, Ashkenazi E: "Economic Analysis of Transforaminal Lumbar Interbody Fusion Surgery Utilizing a Curved Bone Removal Device" PharmacoEconomics Dec 31, 2020
17. Ruvinsky, I: "CLINICAL EVALUATION REPORT – DREAL" Carevature CE submission