carevaturerobotics
precision within reach

HARNESSING TECHNOLOGY TO IMPROVE SPINE CARE

Yosi Weitzman, Founder

Aug. 2022

+972 544496620

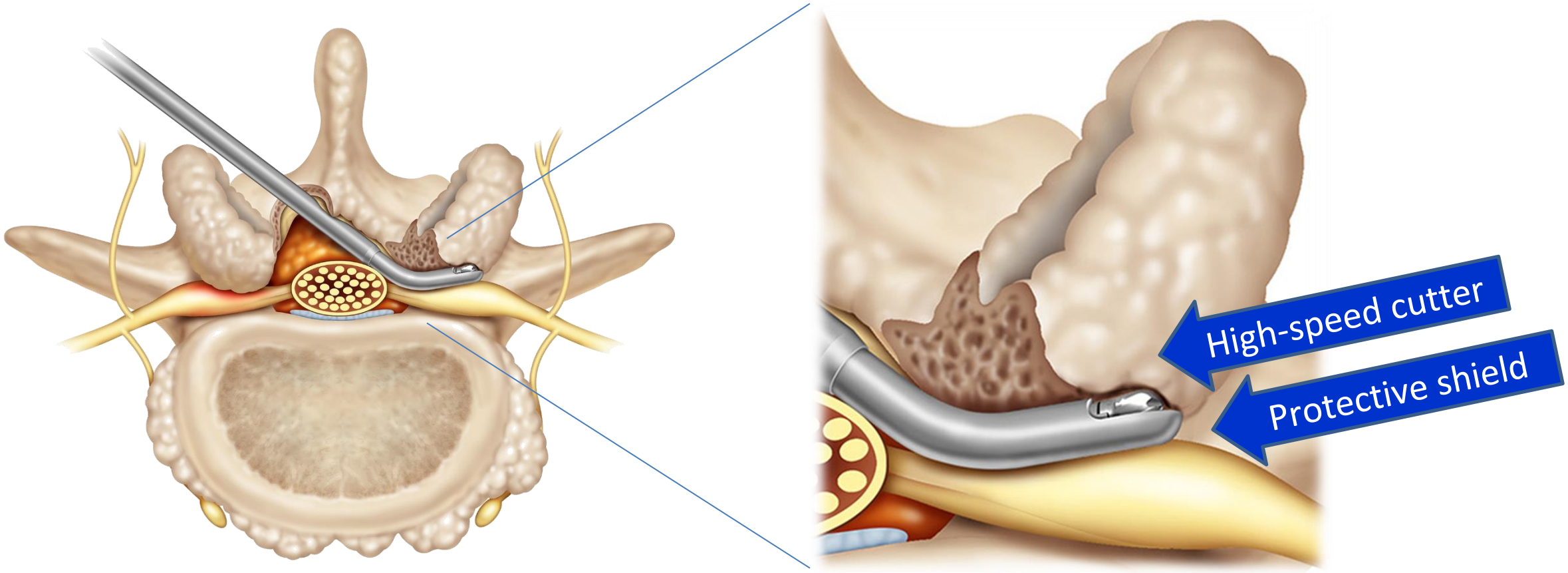
Dreal® Technology Overview

Dreal® Technology: the Power of the Curve

Key Attributes:

- Safe and effective neural decompression “around the corner”
- Healthy tissue preservation
- Cervical-to-sacrum solutions
- Indications for Use: “The Dreal® is intended to cut bone in neurosurgical and spinal applications”

Formative Principle



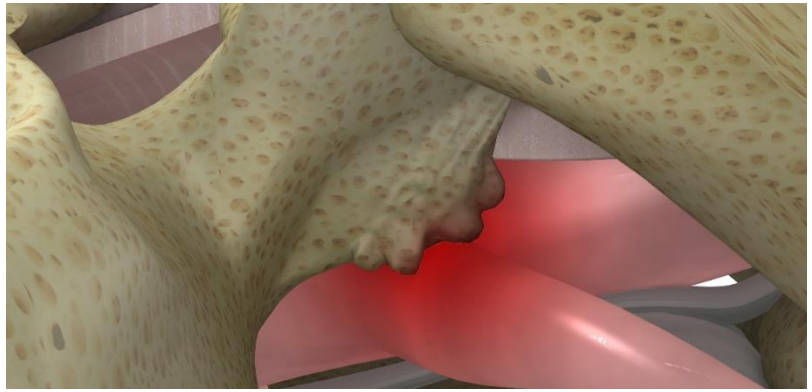
See it live:

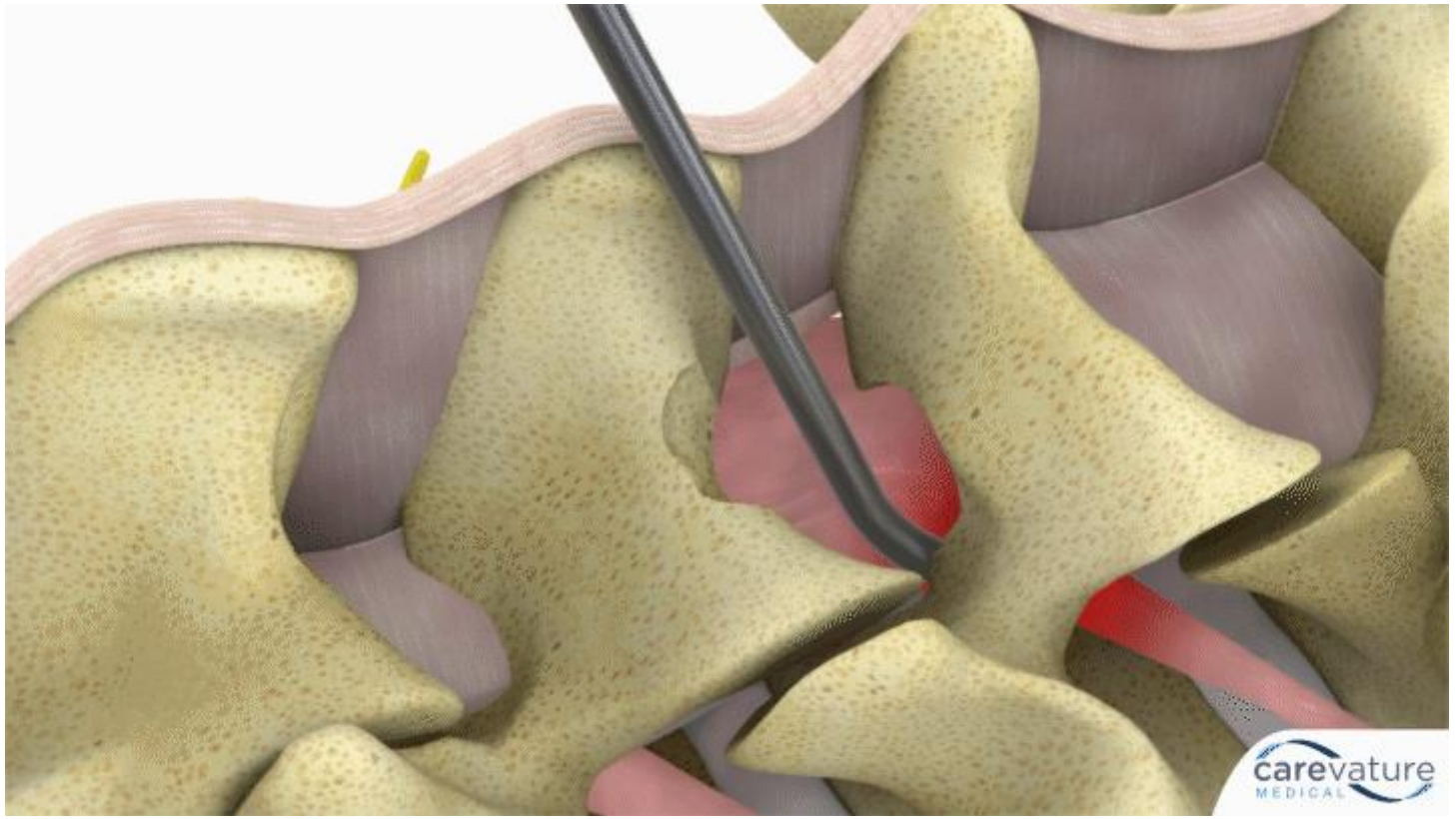
Lumbar MIS Tubular Decompression including contralateral and ipsilateral passes

Dreal® Technology: the Power of the Curve

Clinical importance: "Most lumbar foraminal stenosis existed outside the pedicle's center(1) and was rarely noted in the pars region“ *Murata et.al*

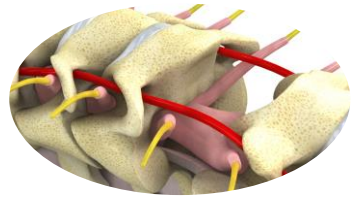
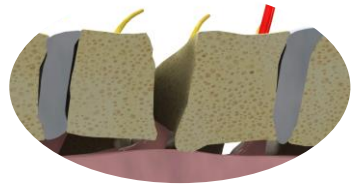
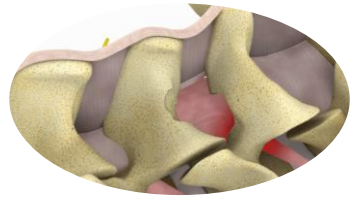
(1) Cannot be reached by standard tools without compromising the facet joint





Watch animation

Dreal®: Clinically and Commercially Validated in > 2,000 cases

Spinal Region	Case Type	US Cases/yr	Device POC?	
Cervical	Anterior Cervical Corpectomy Procedure video	25,400	Yes	 
	Anterior Cervical Discectomy and Fusion Procedure video	280,500	Yes	 
	Posterior Cervical	51,900	Yes	
	Cervical Disc Replacement	31,700	Yes	
Thoracic	Thoracic Decompression and Fusion	51,600	Yes	
Lumbar	Lumbar Disc Replacement	2,190	No	 
	Lumbar Fusion Procedure video	378,600	Yes	
	Lumbar Decompression Procedure video	300,500	Yes	

Peer-Reviewed Post Marketing Publications and Presentations

International Journal of Spine Surgery, Vol. 12, No. 4, 2018, pp. 498–509
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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

ROBERT PFLUGMACHER, MD,[1] ANGELO FRANZINI, MD,[2] SHAKED HOROVITZ,[3] RICHARD GUYER, MD,[4] ELY ASHKENAZI, MD[5]

[1]*Klinik und Poliklinik Für Orthopädie und Unfallchirurgie, Universitätsklinikum Bonn, Bonn, Germany,* [2]*Department of Neurosurgery, Fondazione Istituto Neurologico "Carlo Besta," Milan, Italy,* [3]*Carevature Medical, Ltd, Rehovot, Israel,* [4]*Texas Back Institute, Plano, Texas,* [5]*Israel Spine Center, Assuta Medical Center, Tel Aviv, Israel*

ABSTRACT

Background: Durotomy is a major complication of spinal surgery, potentially leading to additional clinical complications, longer hospitalization, and increased costs. A reference durotomy incidence rate is useful for the evaluation of the safety of different surgical aspects. However, the literature offers a wide range of incidence rates, complicating this comparison. Theoretically, a reference incidence value can be extracted from administrative databases, containing a large number of procedures. However, it is suspected that these databases suffer from underreporting of complications. This study aims to evaluate durotomy incidence using several large-scale databases and to assess the ability to use it as a reference by comparison to durotomy incidences directly associated with 4 bone removal devices, including the commonly used high-speed drill.

Methods: Durotomy overall incidence was estimated from several administrative databases using different methods in order to achieve minimal and maximal estimations. Durotomy incidence rates for 3 bone removal devices were derived using literature meta-analysis, and the incidence for the fourth device was calculated using clinical data.

Results: The incidence range of durotomy according to the databases was 2.0%-7.5%. The calculated incidence of durotomy for the studied devices was 0.4–2.5%. The highest incidence, 2.91%, is associated with the commonly used high-speed drill combined with Kerrison rongeurs and curettes. Since bone-removal devices are just one of the possible causes of dural tears, the general incidence is expected to be higher than the incidence associated with the devices, yet even the maximal estimation, 3.5%, was only slightly higher, suggesting that the speculation of underreporting of dural tears to these databases is probably true, as also supported by the mostly higher incidences reported in the literature.

Conclusions: Hospital administrative databases seem to show a lower-than-reasonable incidence of durotomy, suggesting possible underreporting. Researchers should therefore use this tool with caution. Reduction of the absolute durotomy incidence by approximately 2.5% can be achieved by improving the safety of bone-removal devices.

Complications

Keywords: incidental dural tears, durotomy, tissue-removal devices, high-speed drill

INTRODUCTION

The dura mater encloses the brain, spinal cord, cauda equina, nerve roots, and cerebrospinal fluid (CSF). A durotomy, or dural tear, can occur during spinal surgery, requiring a water-tight dural closure in order to prevent a CSF leak. Without adequate treatment, CSF leak can lead to clinical complications such as pseudomeningocele, meningitis, and re-operation.[1–3] In addition, durotomy often leads to longer hospitalization and increased costs.[4,5]

A reference durotomy incidence rate is useful for evaluating the safety of different surgical aspects, such as surgical devices and alternatives. However, the overall incidence of dural tears varies between different studies, from 0.5 to over 16%,[3,6–10] and in some studies even as high as 40%.[11] This wide variation is a result of many factors, such as the number of cases reviewed, patient age, sex and medical record, the complexity of the procedures performed, surgeon experience, and the number of institutions surveyed.[4,8,10,12,13] Large-scale administrative databases, which include a very large number

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A New High-Speed Shielded Curved Device Allowing Safe Posterior Thoracic Discectomy Through a Modified Transforaminal Thoracic Interbody Fusion Approach: Technique Description and Case Series

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[1]*Israel Spine Center, Assuta Hospital, Tel Aviv, Israel,* [2]*Pennsylvania Spine Institute, Harrisburg, Pennsylvania,* [3]*Texas Back Institute, Plano, Texas*

ABSTRACT

Background: The appropriate approach for surgical removal of thoracic disc herniations is controversial. The posterior approach historically acquired a bad reputation due to high rates of neurologic deterioration subsequent to spinal cord manipulation. The anterior approach has consequently gained popularity but entails a larger magnitude of surgery if open and is technically demanding if approached thoracoscopically. Approaching the thoracic disc posteriorly following unilateral facetectomy and pediculectomy was suggested in 1978. This study presents a technique for posterior unilateral thoracic discectomy through a hemilaminectomy, unilateral facetectomy, and hemipediculectomy, facilitated by a novel curved dorsally shielded high-speed device. Introducing the device ventral to the dural sac allows removal of calcified and soft disc fragments without relying on forceful manual maneuvers and avoiding manipulation of the spinal cord.

Methods: The maximal disc protrusion side is approached through a hemilaminectomy, unilateral facetectomy, and hemipediculectomy removing the superior half of the pedicle and the [illegible] the disc foraminally, allowing its removal using the device. Pedicle fixation and fusion are considered [illegible] (TLIF). Between June 2014 and November 2018, 12 patients (6 men and 6 women) aged 22–74 years underwent posterior thoracic discectomy applying the above approach. The treated levels were D3 to D4 (1), D4 to D5 (1), D5 to D6 (1), D7 to D8 (1), D9 to D10 (1), D10 to D11 (3), D11 to D12 (4), and D12 to L1 (1).

Results: All patients presented with neurologic deterioration and all but 2 with pyramidal signs. All procedures were uneventful, without dural tears. None of the patients deteriorated neurologically. Average back pain visual analog scale scores decreased by 1.2, from 6.6 to 5.4. Average leg pain visual analog scale scores decreased by 2.2, from 6.6 to 4.4. Improvement was noted in Oswestry Disability Index scores and 6 SF-36 metrics.

Conclusions: The new curved device and approach allow for a faster, safer thoracic disc herniation removal.

Clinical Relevance: The proposed technique allows a safer treatment for thoracic disc herniations, reducing complication rates and improving patient outcome.

New Technology

Keywords: discectomy, disc herniation, fusion, high-speed drill, posterior approach, thoracic

INTRODUCTION

Although the incidence of asymptomatic thoracic disc herniation (TDH) may be as high as 37%, as shown in a magnetic resonance imaging (MRI) study on asymptomatic individuals,[1] surgical treatment of TDH comprises between 0.15% and 4% of all disc operations.[2,3] The improvement in diagnostic imaging abilities has led to more frequent and early-stage diagnosis of thoracic disc herniation. Removal of the disc is required when neurologic deterioration occurs secondary to spinal cord compression.

The approach to thoracic disc excision remains controversial. The posterior approach, although familiar to most spine surgeons, lost favor when in a high percentage of surgeries neurologic deterioration occurred.[4] The transpedicular approach and the costotransversectomy approach allow posterolateral access by removing the facet joint and pedicle ipsilateral to the lesion[5,6] or by removing a short segment of rib and the adjacent transverse process,[7] respectively. These approaches provide posterolateral

PharmacoEconomics - Open
https://doi.org/10.1007/s41669-020-00256-1

ORIGINAL RESEARCH ARTICLE

Economic Analysis of Transforaminal Lumbar Interbody Fusion Surgery Utilizing a Curved Bone Removal Device

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Abstract

Background Transforaminal lumbar interbody fusion (TLIF) represents a commonly performed spinal procedure that poses a significant financial burden on patients, hospitals and insurers. Reducing these costs, while maintaining efficacy, may be assisted by a new powered endplate preparation device, designed to shorten procedural time while offering positive impacts on other elements that contribute to the cost of care.

Objective The aim of the study was to assess and compare the individual cost elements of TLIF procedures with and without the use of the device, to determine whether application of this technology translated into any material procedural savings.

Methods The records of 208 single-level TLIF procedures in a single hospital were reviewed. Surgical time, length of hospital stay, blood loss, infection rate, and other parameters were compared for the cases where the device was used (device group; $n = 143$) and cases which used standard tools (control group; $n = 65$). The cost per unit of each element was derived from the literature, online resources, and the hospital's financial department.

Results The analysis revealed a shorter surgery duration in the device group (23 min, after controlling for procedure year and patient characteristics, statistically significant at $p < 0.001$) and lower complication and readmission rates ($p = 0.67$ and $p = 0.21$, respectively) associated with the use of the device, leading to a statistically significant cost reduction of approximately 2060 US dollars (US$) ($p < 0.01$).

Conclusion The study suggests that use of the device may lead to a cost reduction and shorter procedure without deteriorating the clinical outcome.

Key Points for Decision Makers

Spinal procedures are commonly performed, and their rate will continue to rise as the population ages.

Improving procedure outcome and reducing its cost can be beneficial to patients, hospitals and insurers.

Devices aiming to shorten procedure time and reduce complication rates, such as the studied device, may substantially reduce procedure cost.

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1 Introduction

The rate of spinal surgeries in the United States has increased significantly over the past 30 years and continues to grow as new improvements are introduced [1, 2]. The number and proportion of older patients (> 65 years of age), individuals who are more prone to degenerative spinal diseases, is expected to grow further [3], thus increasing the overall expenditure on spinal surgeries. As reimbursement policies shift from fee-for-service to bundled payment models, there is a common incentive for insurers, hospitals, and patients to reduce procedure cost while still maintaining efficacy and safety. Clinical outcome is tightly linked with procedure cost, as complications and readmissions can be costly to all stakeholders and have the potential to reduce or eliminate overall profit to the facility [4].

In this study, we focus upon the key cost drivers of transforaminal lumbar interbody fusion (TLIF), a spinal procedure commonly performed in the USA [5]. Here we report our experience with a new device (Dreal®, Carevature Medical

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Adis

Safety Efficacy Economics

NASS NORTH AMERICAN SPINE SOCIETY

SMISS Society for Minimally Invasive Spine Surgery

INTERNATIONAL JOURNAL of SPINE SURGERY

INTERNATIONAL SOCIETY FOR THE ADVANCEMENT OF SPINE SURGERY ISASS

Safety First!

0.15% of incidental Dural Tears (no neurological injury), compared to 3% (general incidence) - 12% (MIS) with all other manual or powered technologies [Pflugmacher et.al]

Shield Advantage
- Protecting surrounding tissue

Curve Advantage: Significantly reduced no. of device passes
- Reduced operation time
- Reduced nerve irritation
- Reduced infections

Forward-drilling Advantage
- Reduced nerve irritation
- Better handling of dura adherence

Single-Use Advantage
- Reduced infections

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http://ijssurgery.com/content/12/4/498

This information is current as of May 23, 2019.

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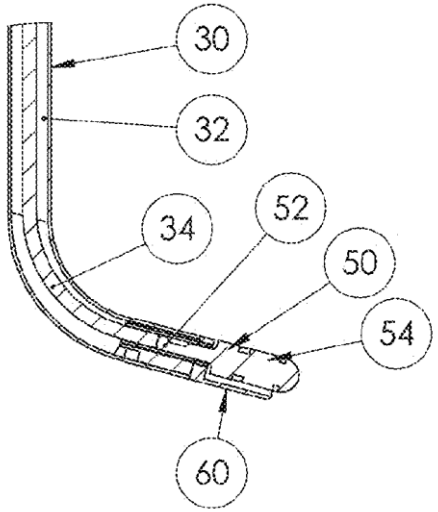
Patented Technology

Total filed applications - 41

Granted/allowed – 21

In preparation – 6



Areas of protection:

- Handheld devices (fixed-angle, flexible, articulating)
- Navigation
- Robotics

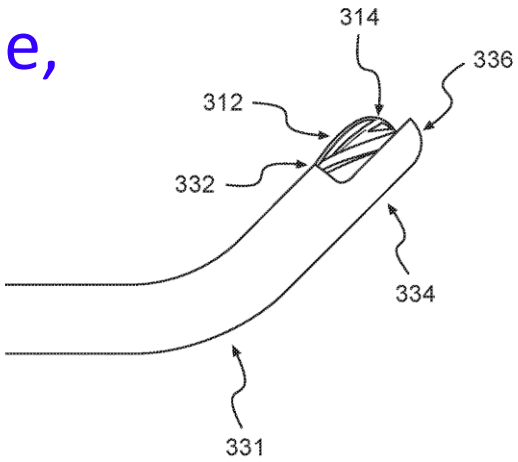
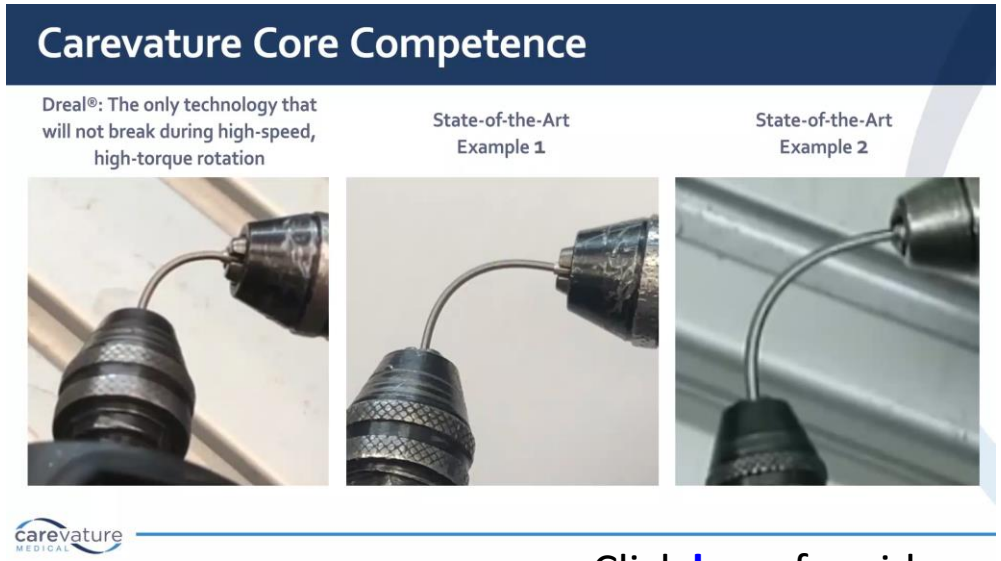
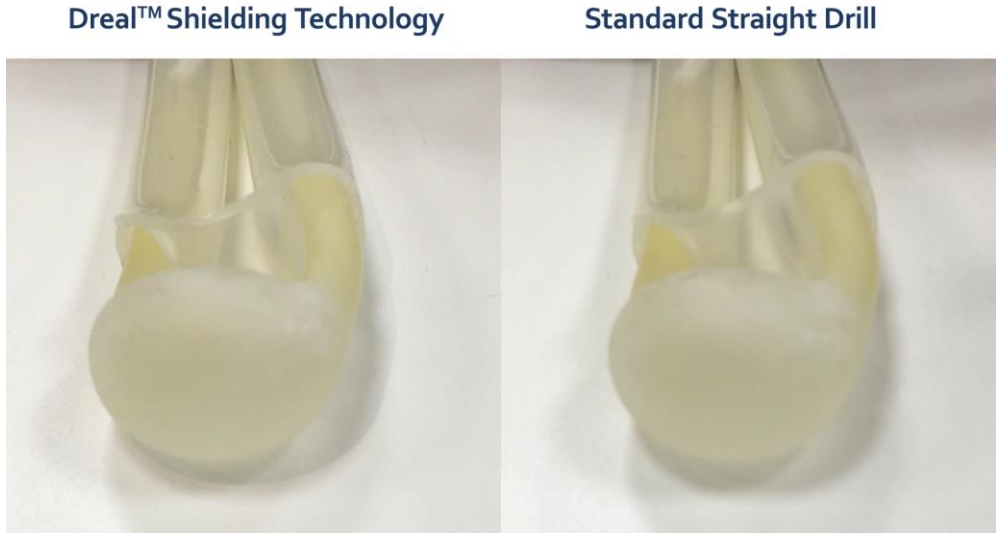


FIG. 3a



Click **here** for video



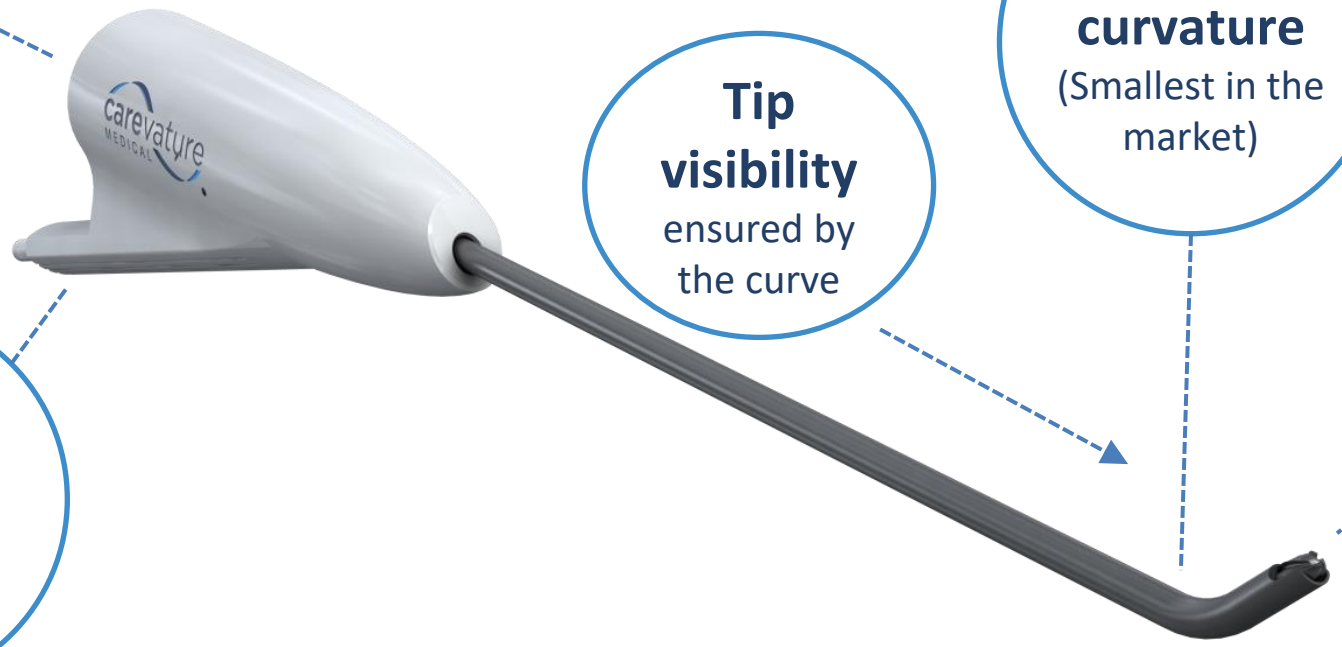
Click **here** for video

‘Handheld’ Product Line

Dreal® : Powerful. Versatile. Efficient.

60,000 rpm
Only curved system strong enough for bone cutting

Integrated irrigation



Tip visibility
ensured by the curve

9mm radius curvature
(Smallest in the market)

2-3mm tip diameter
(Smallest in the market)

Unique forward drilling feature

Sterile-packed, Disposable, Shielded, Curved at the tip, High Speed technology for safe, targeted & efficient bone removal in the cervical, thoracic & lumbar spine

Dreal® : Full Portfolio

Standard-shaft Line

C3S45FUS
C3S45FU
C3S45FI
C3L10DS (cervical)
2L75FU (cervical)

Bayoneted-shaft Line

B3S45FUS
B3S45FU
B3S45FIS
B3S45FI

B3S45FUS

B3S45FU

B3S45FIS

B3S45FI

C3L10DS

2L75FU

ART- Dreal® (next Generation, R&D Stage): An Articulated tip with Integrated Real-Time Visualization

Main characteristics:

- 3mm tip diameter
- Bone removal at 60,000RPM
- Tip bending range 0-90°
- Solid holding of tip-angle at any position
- Can remove bone while bending

Click here for video of Articulating Tip and Real-Time- Visualization

Robotic Decompression

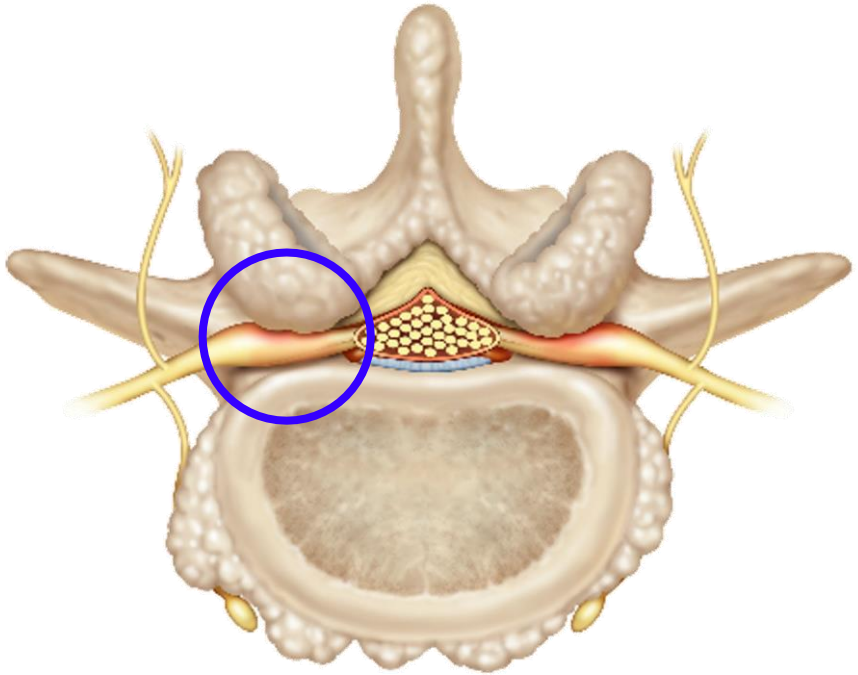
UNMET Need: Nerve-Bone Interface

Current and future robots for BONE

Pedicle Screw Placement

Knee-Joint Preparation

?



Current and future robots for SOFT TISSUE

General Surgery Gynecology

Cardiology Urology

Today's Spinal Robots

MEDTRONIC

Delivery of Pedicle Screws (Lumbar Fusion)

ZIMMER BIOMET

Delivery of Pedicle Screws (Lumbar Fusion)

GLOBUS

Delivery of Pedicle Screws (Lumbar Fusion)

NUVASIVE

Delivery of Pedicle Screws, Rod Bending (Lumbar Fusion)

ACCELUS

Delivery of Pedicle Screws (Lumbar Fusion)

- Do not participate in treatment of the underlying pathology (impinged nerve)
- Designed for tools and implants **to avoid contact** with neural tissue
- Offer **accuracy of 1-2mm at best** (rely on fluoroscopy-based imaging)
- **Not suitable** for neural decompression

Developing Robotic Decompression: Rationale

Marketing considerations

- Cost-compatible with hospital, outpatient and ASC settings
- Participation in 100% of surgical procedure
- Smooth transition from robotic to manual and back
- Small footprint, easy setup, intuitive to use

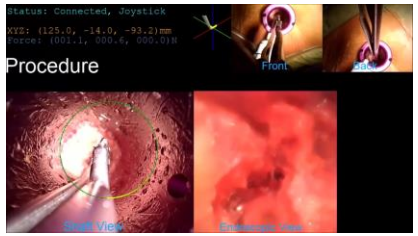
Technical and regulatory considerations

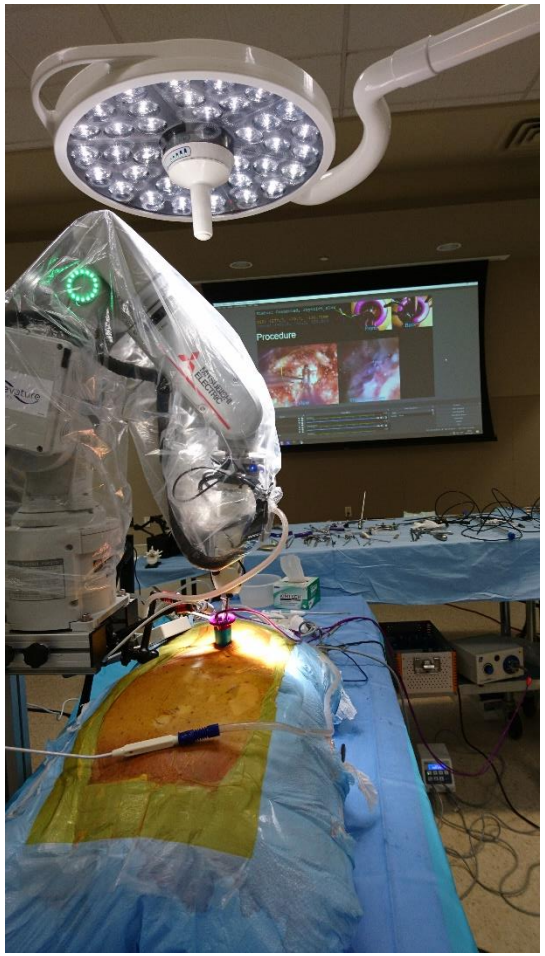
- Surgeon control
- Vision guidance
- Force sensing
- Pre-planning and navigation as surrogate

Proof of Concept

10 separate Animal and Cadaver Labs completed with 10 (4 IL, 6 US) individual Surgeons

Click here to watch video





Proof of Concept Results

- “This could revolutionize spine surgery”
- ”Well beyond my expectations”
- “Could use it tomorrow”

Question [1=poor, 5=best]	Avg	STD
Please assess the **viability of “vision-guided teleoperation”** approach as a potential solution for Robotic Decompression	**4.7**	0.5
Please assess the **overall surgical outcomes**	4.3	0.6
Did the **neural structures remain intact**?	Yes	
Was **adequate decompression** achieved?	3.9	0.7
Overall satisfaction with the procedure	4.4	0.7

Product Timeline

Single-arm Platform

FIM:
3Q ahead

510(k) submission:
6Q ahead

Multiple-arms Platform

510(k) submission: 9Q ahead

Click here to watch video

Comparable Exits

Company	Sector	TAM	Deal Size	Acquired By
Carevature	Spine	1,000,000		
Mazor	Spine	400,000	$1,700M	Medtronic
Mako	Reconstructive Orthopaedics	1,500,000	$1,650M	Stryker
Mobius-Cardan*	Spine	400,000	$500M	Stryker
Blue belt Technologies*	Knee Arthroplasty	900,000	$275M	Smith and Nephew
Corindus	Angioplasty	900,000	$1,100M	Siemens

* Companies with no revenues prior to acquisition

Current Status

Company Status as of Mid. September 2022

- The company ceased its operation
- Employees were released
- Essential activities (e.g. meeting IP deadlines) are maintained
- The company is submitting a liquidation motion to Israeli court
- Financial brief:
  - Outstanding liabilities ~$400K
  - Cash ~$120K
  - Inventory ~$100K

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Restart Mechanism

- The court will appoint a trustee to liquidate the company's assets and serve all liabilities
- A proposal submitted to the court, which will cover the outstanding liabilities, is likely to be accepted
- All assets, physical and intellectual, of the company remains under its possession
- The timeframe for proposing, with minimal risk that the trustee will seek multiple competing buyers, is estimated by ~2 weeks

Restart Alternatives: Overview

- Each alternative stands for itself, and is somewhat overlapping with the other alternatives (e.g. management, IP, G&A)
- A combined program should not be represented by adding numbers of each separate alternative
- With the ‘Legacy’ alternative, sales can be maintained to an estimated level of ~$300K next year, without rebuilding infrastructure

Alternative 1: Legacy Product Line

- Allows revenue generating based on existing customers of ~$300K next year, with potential of expansion
- Maintains the regulatory approvals (FDA, CE)
- Maintains IP

Legacy Line Program	Q4-2022	Q1-2023	Q2-2023	Q3-2023	Q4-2023	Sub-total
Challenges/milestones:	CE MDD, ISO audits			CE MDR audit		
Headcount	$92,954	$92,954	$92,954	$92,954	$92,954	$464,770
Consulting	$43,335	$20,340	$20,340	$20,340	$10,906	$115,259
Regulation	$11,000	$0	$0	$0	$11,000	$22,000
IP	$15,000	$15,000	$15,000	$15,000	$15,000	$75,000
Manufacturing aids	$3,000	$3,000	$3,000	$3,000	$3,000	$15,000
US Operation	$24,000	$24,000	$24,000	$24,000	$24,000	$120,000
G&A	$30,947	$30,947	$39,947	$30,947	$30,947	$163,733
Total	$220,236	$186,240	$195,240	$186,240	$187,806	**$975,762**

Alternative 2: Robotics - First in Man Trials

- Will be the first platform to perform Robotic Decompression on humans
- Maintains current IP and develop new, relevant, IP

	Calendar Q1	Calendar Q2	Calendar Q3	Calendar Q4	
Robotics Program	R&D		V&V	FIM	Sub-total
Challenges/milestones:				FIM trials	
R&D	$337,343	$365,506	$409,308	$411,558	$1,523,715
Headcount	$176,887	$176,887	$195,283	$195,283	$744,340
Consultants	$40,871	$40,371	$41,871	$43,371	$166,484
Equipment	$3,000	$3,000	$3,000	$3,000	$12,000
Materials	$12,600	$3,000	$3,000	$3,000	$21,600
Labs	$0	$30,875	$46,313	$46,313	$123,500
IP	$24,000	$24,000	$24,000	$24,000	$96,000
SAB	$7,500	$7,500	$7,500	$7,500	$30,000
Clinical	$0	$0	$0	$0	$0
Travel and entertainment	$19,000	$17,000	$17,000	$17,000	$70,000
Other	$53,485	$62,873	$71,342	$72,092	$259,792
G&A	$33,844	$33,844	$42,844	$33,844	$144,375
Total	$371,187	$399,349	$452,152	$445,402	**$1,668,090**

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