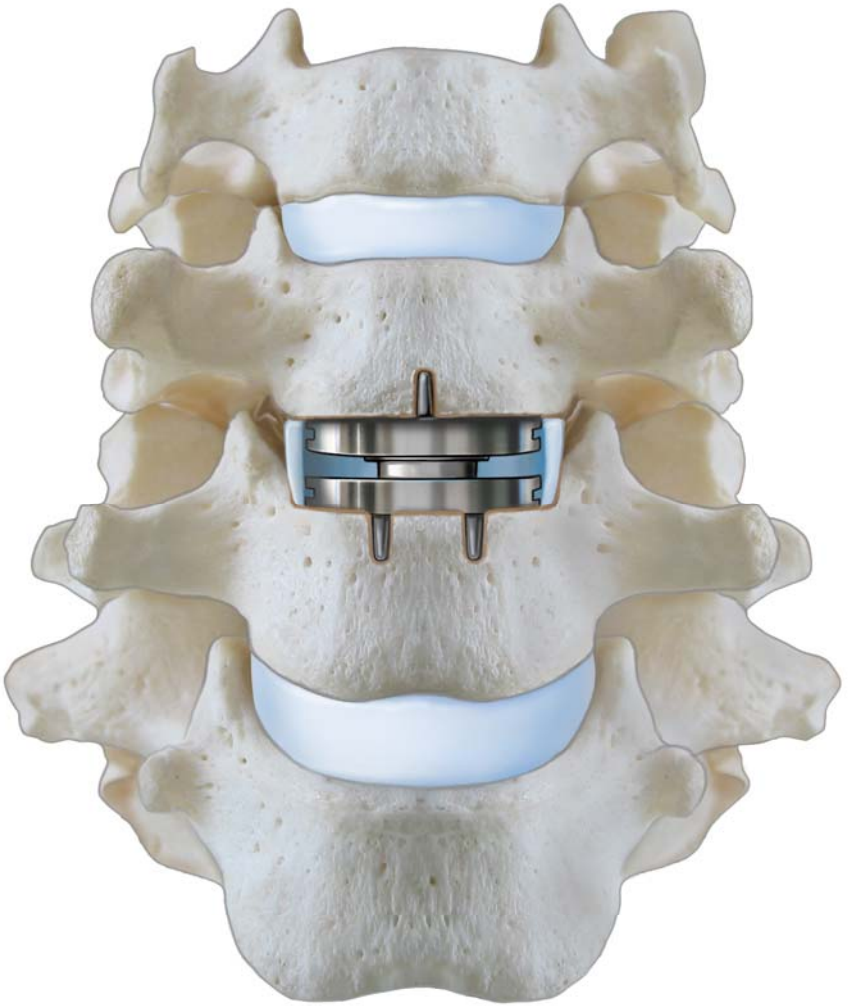
Artificial Disc Replacement
Reimbursement Environment

Charles Gilbride

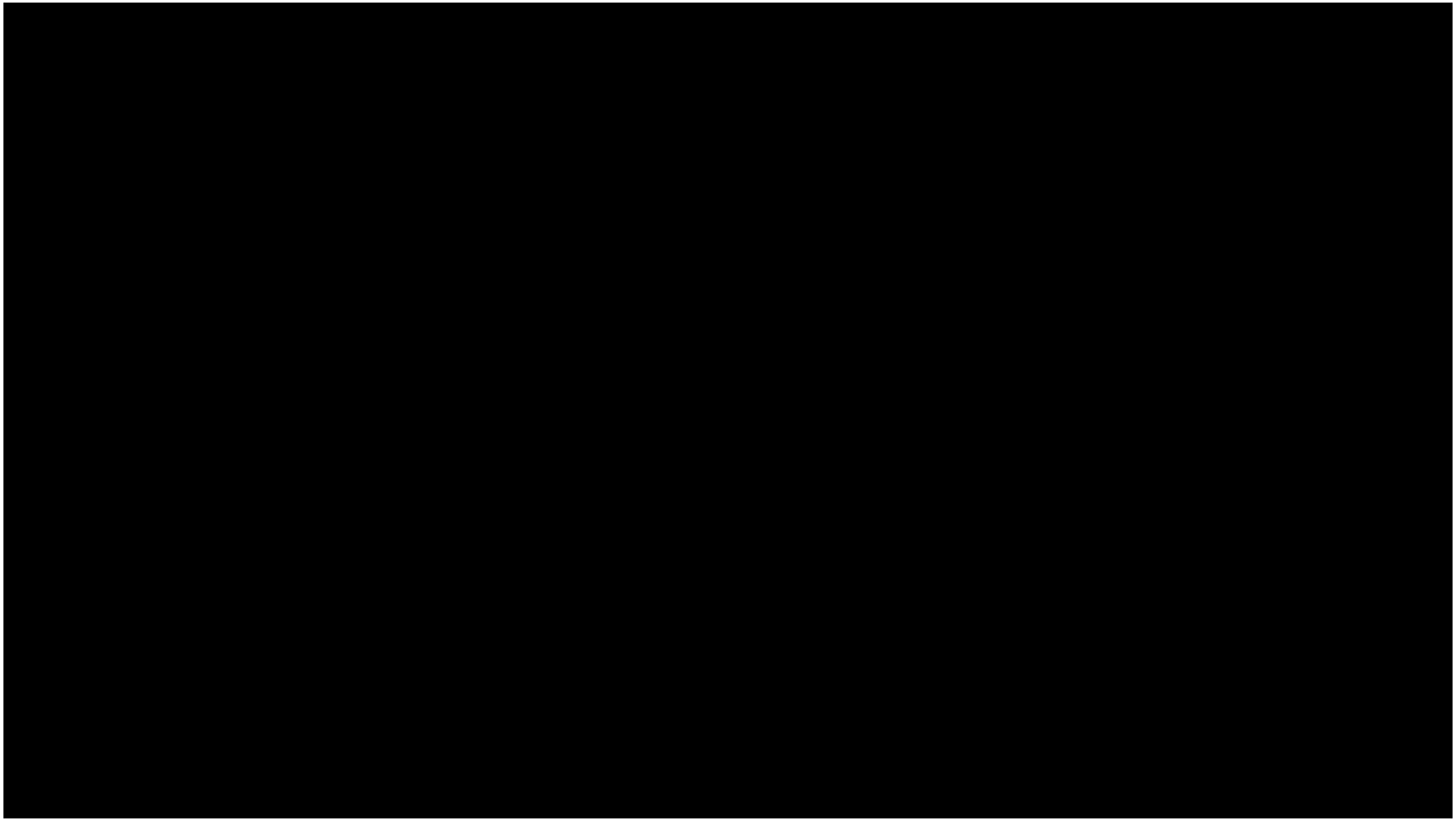
SpinalMotion, Inc.

Fusion vs. Artificial Disc



*Investigational Device- Not FDA Approved

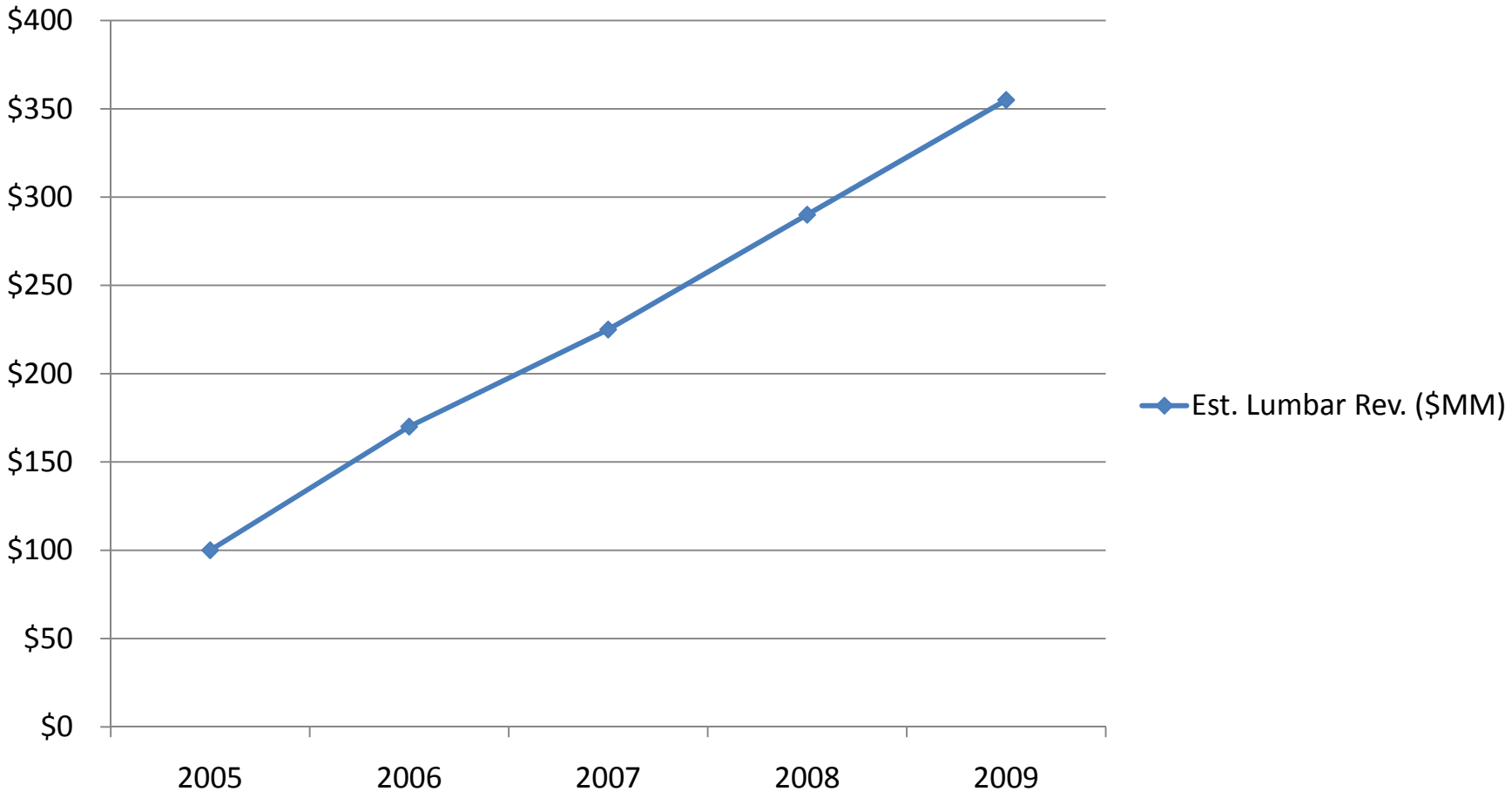
Artificial Disc Technology



*Investigational Device- Not FDA Approved

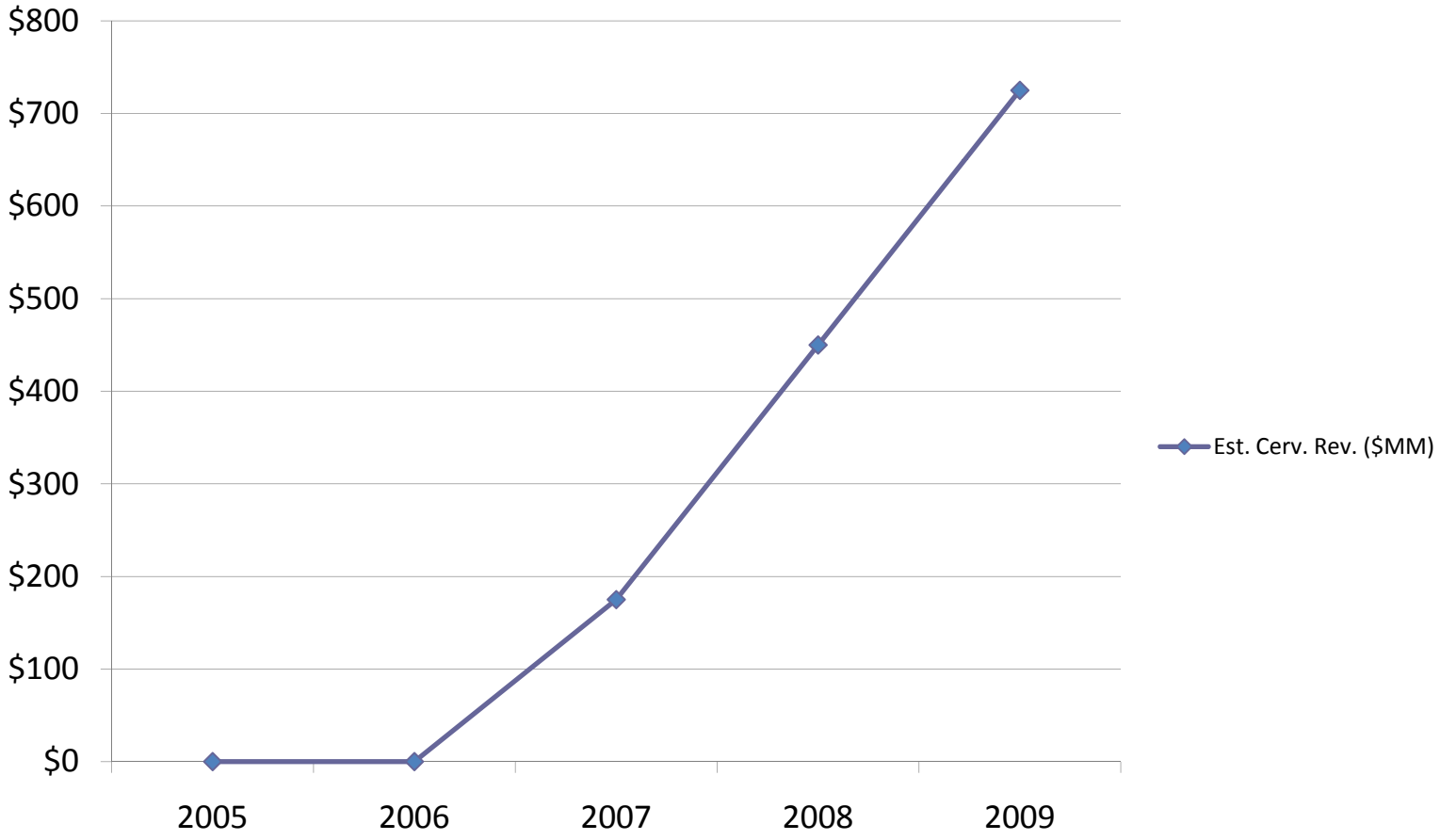
This was then…

Estimated U.S. Lumbar Disc Market (As of 2005)



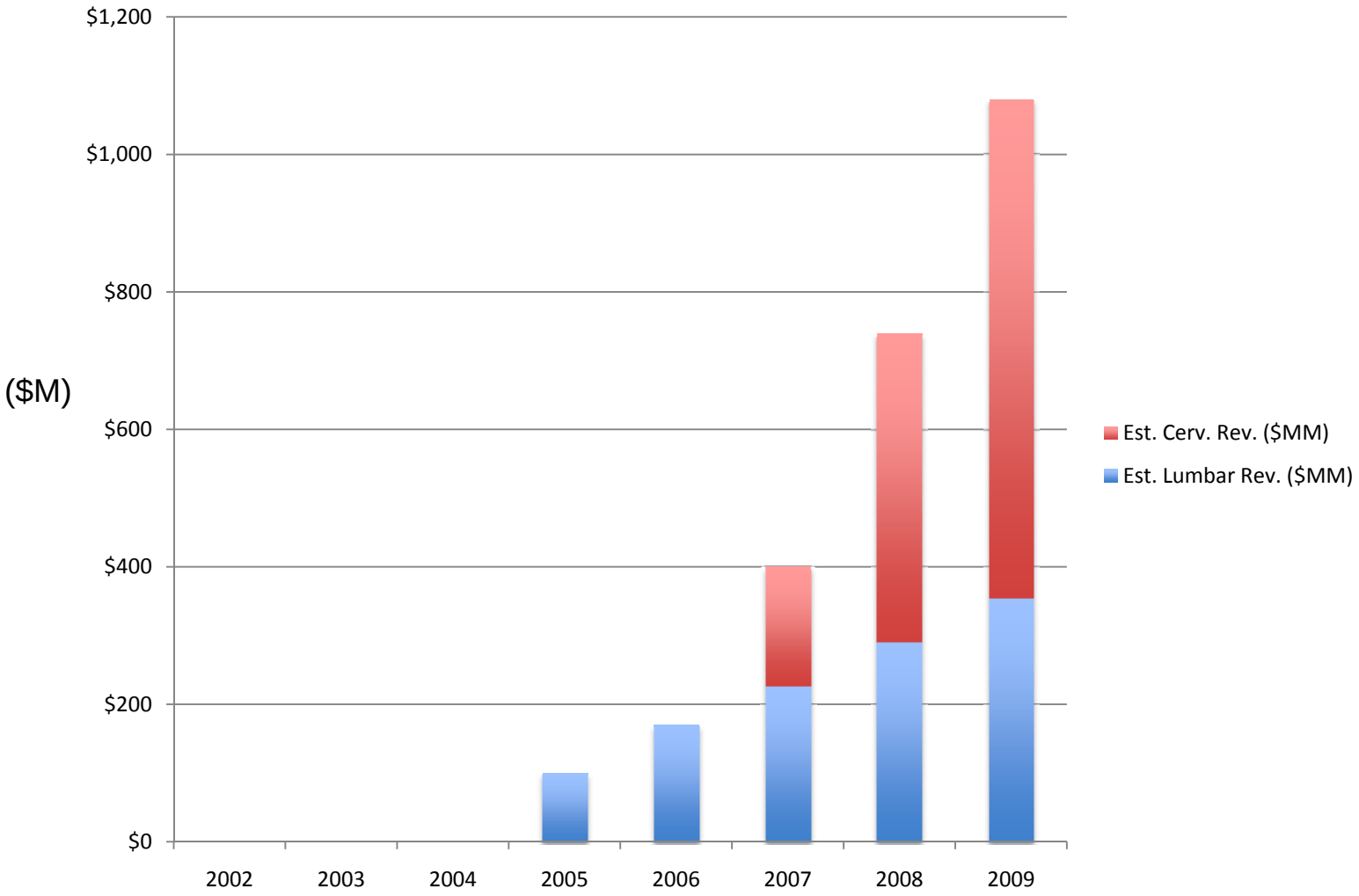
IN VIVO/Windhover Information, Inc. – 2005

U.S. Cervical Disc Market (As of 2005)



IN VIVO/Windhover, Inc. 2005

Estimated Total Disc Market (‘05)



IN VIVO/Windhover Information, Inc. – 2005

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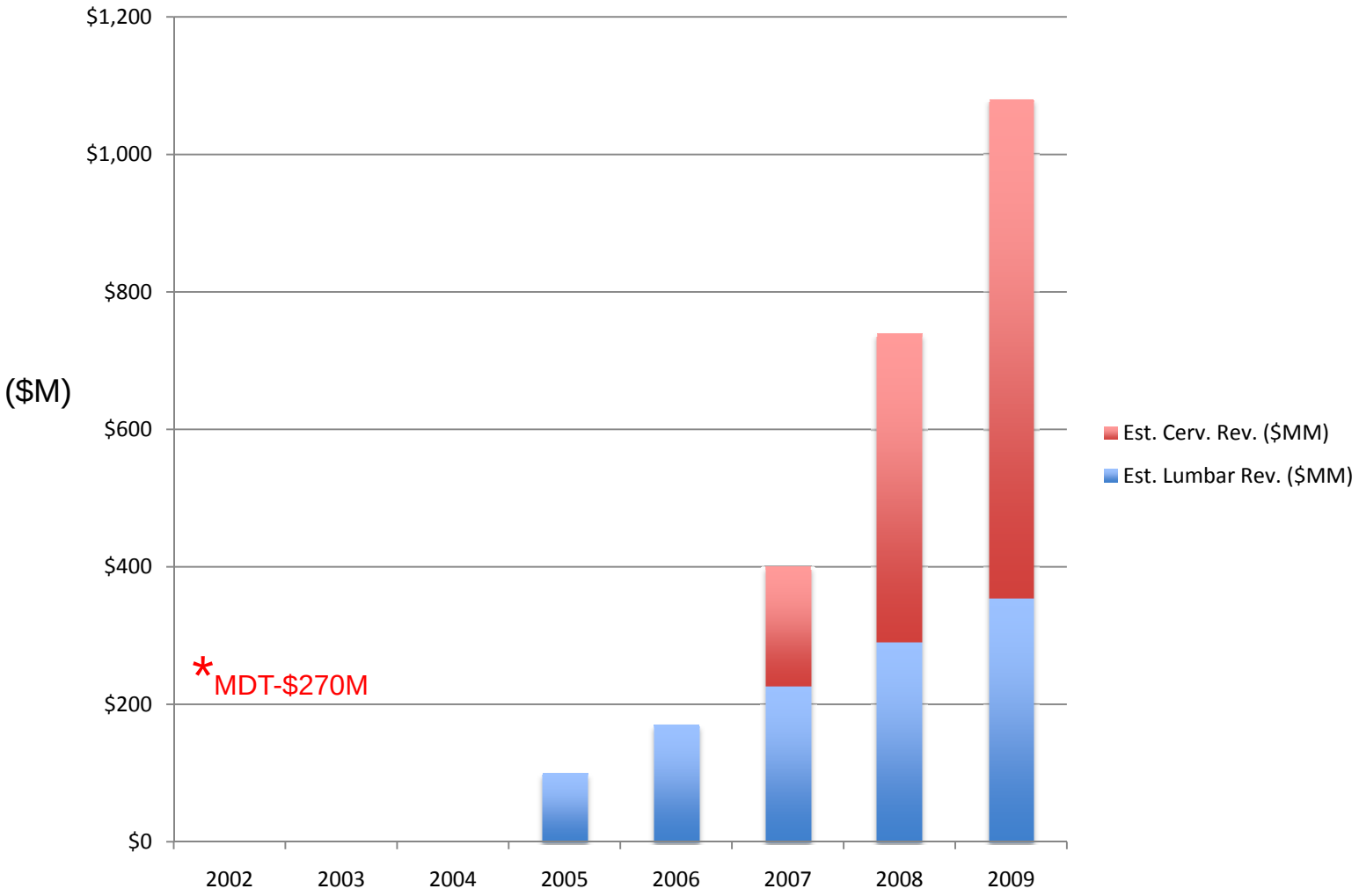

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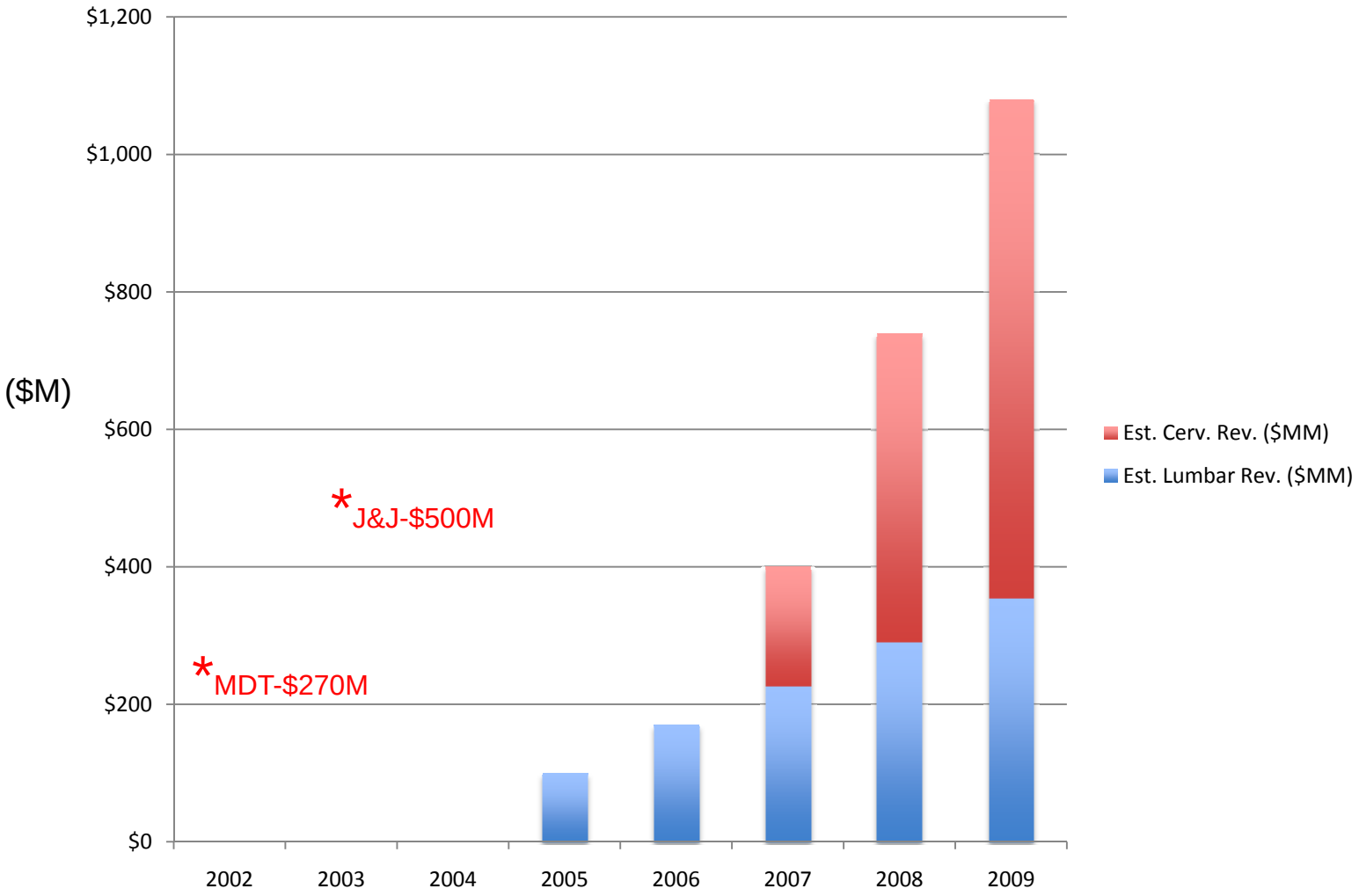

IN VIVO/Windhover Information, Inc. – 2005

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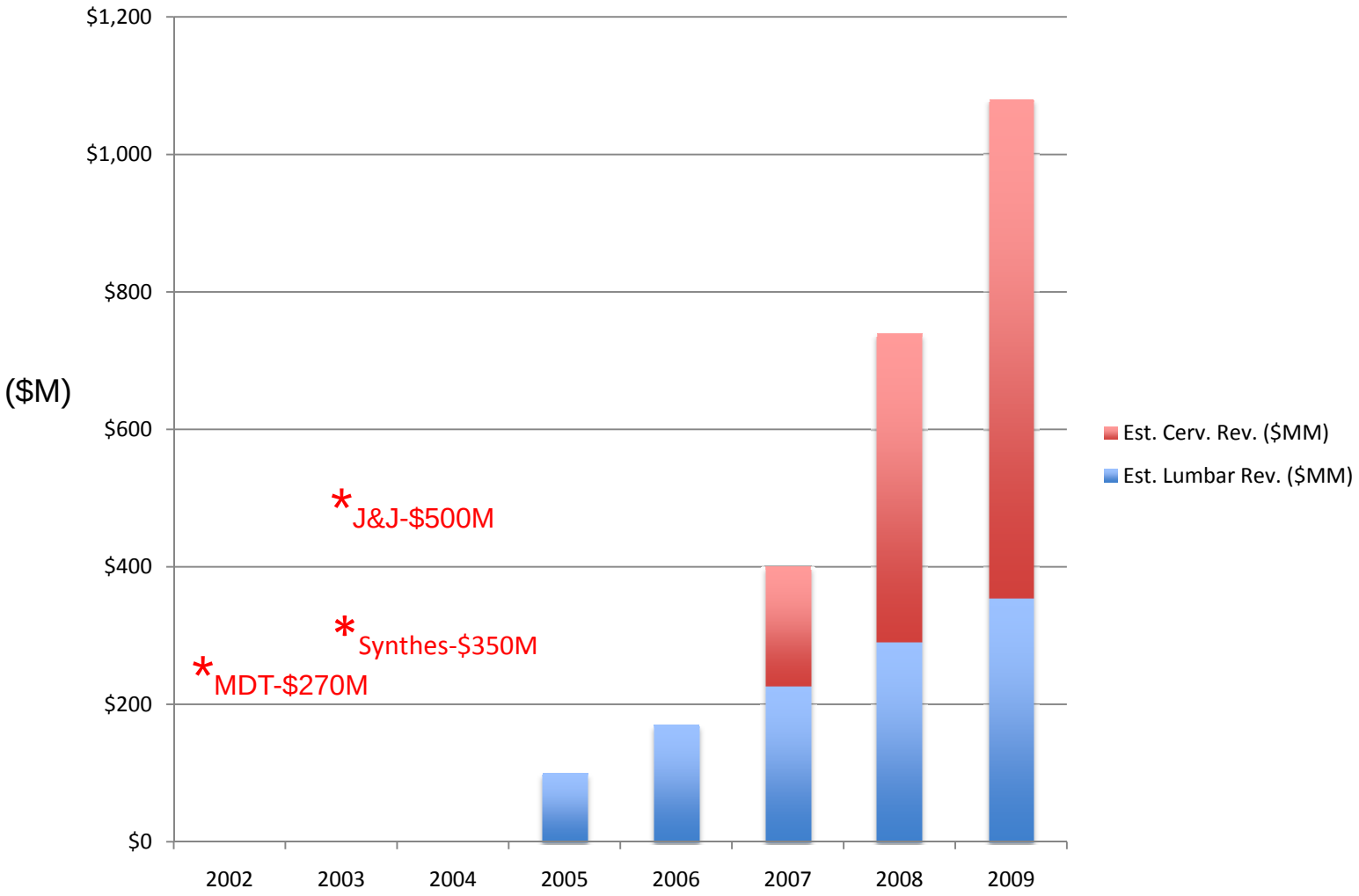

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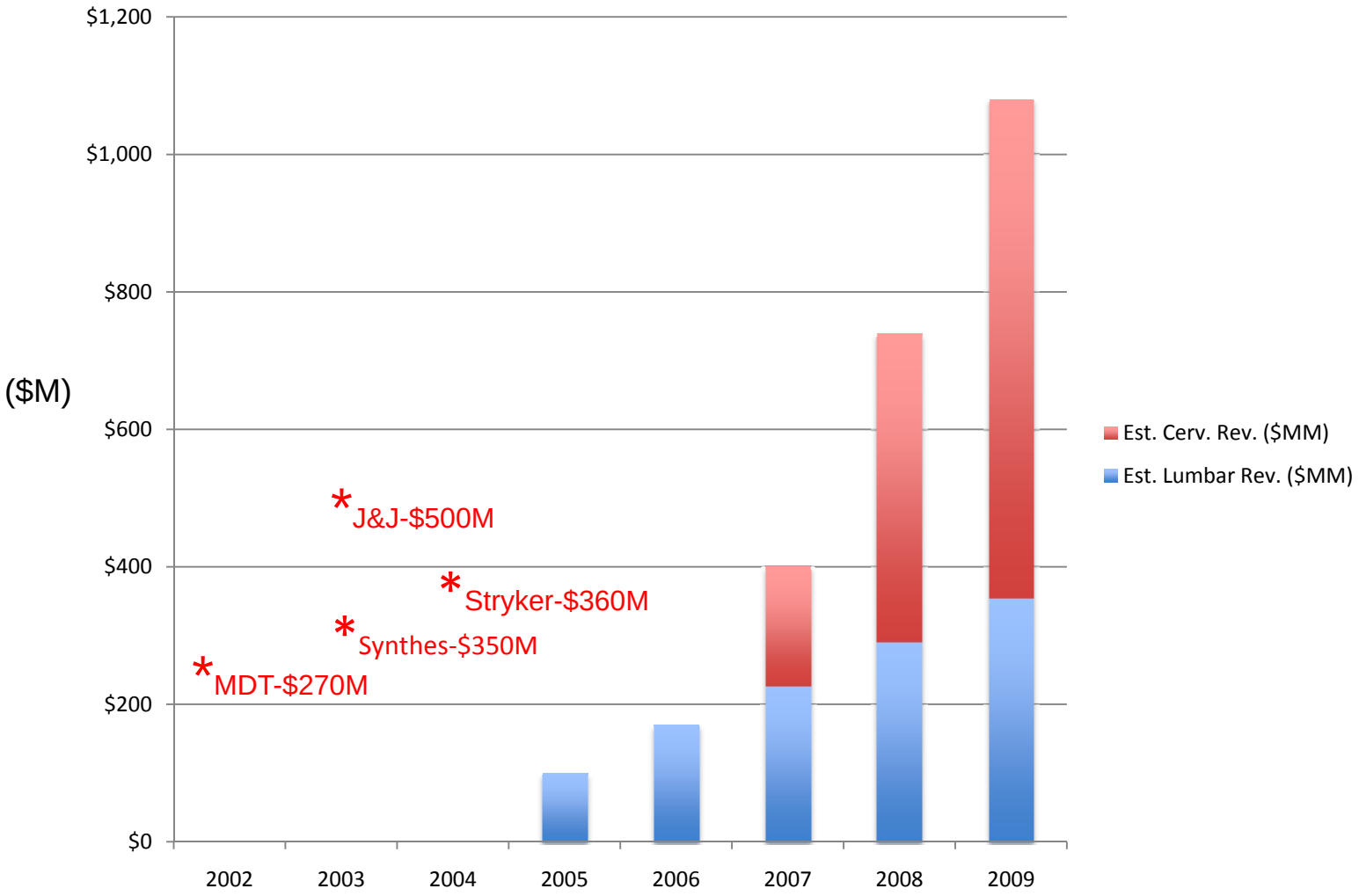


IN VIVO/Windhover Information, Inc. – 2005

24 Cervical Discs - 2008

Cervical Artificial Discs - 2008	
Aesculap	Active-C
Amedica	Valeo TDR-C
Biomet	Rescue
Cervitech	PCM
DePuy Spine	DISCOVER
Eden	Welldisc-C
Globus Medical	Secure-C
LDR	Mobi-C
Medtronic	Bryan
	Prestige ST & LP
Nexgen Spine	Physio-C
NuVasive	CerPass
Orthofix	Advent
Pioneer	NuNec
Pisharodi Surgicals	Pisharodi Cervical TDR
Ranier Technology	CAdisc C
Scient-x	DiscoCerv
SeaSpine	Catalina Cervical Disc
Spinal Kinetics	M6-C
SpinalMotion	Kineflex|C
Stryker	CerviCore
Synthes	Prodisc-C
Vertebron	V Motion C
X-Spine	Cervical TDR

IN VIVO, June 2008

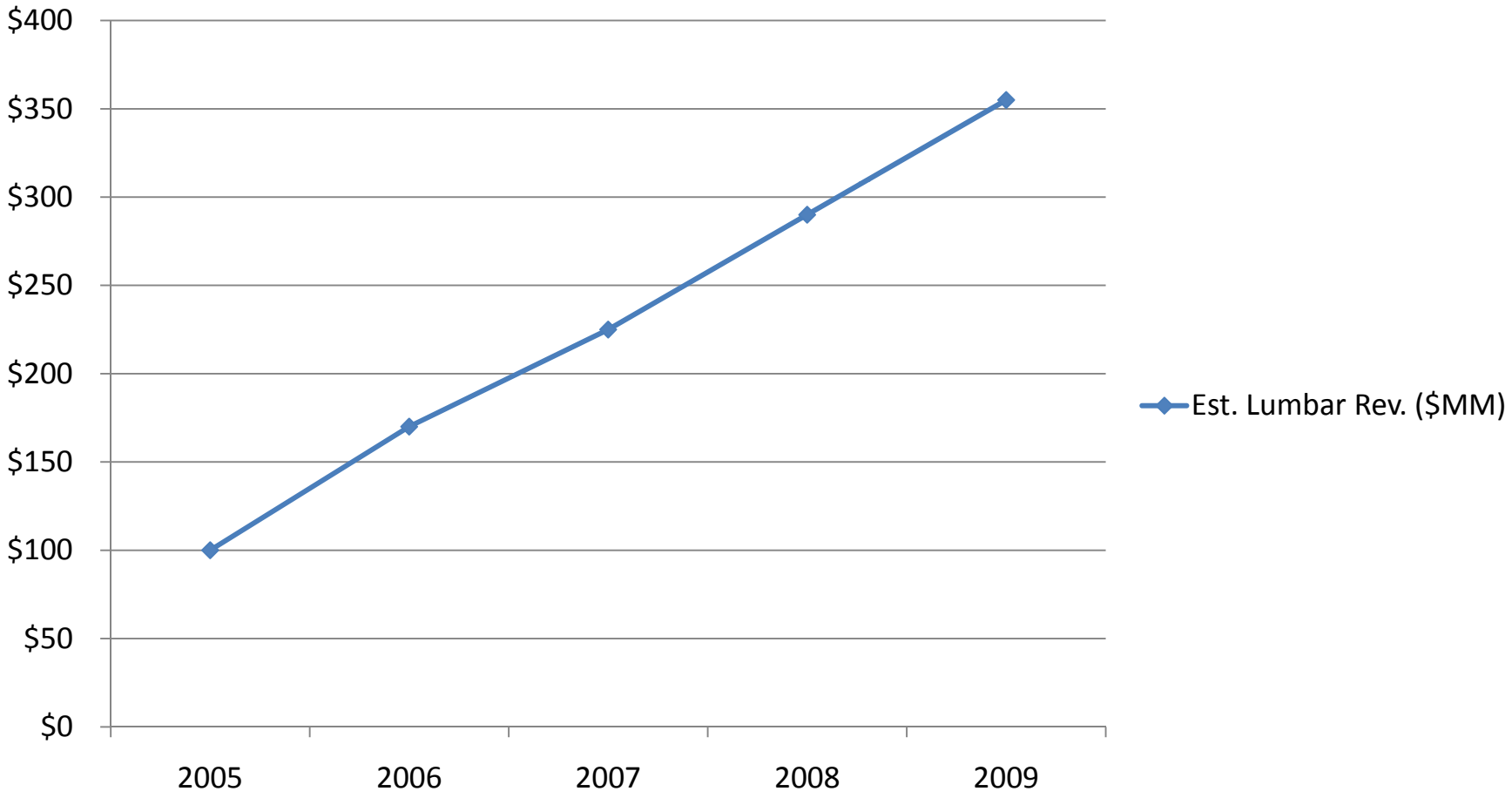
28 Lumbar Discs - 2008

Lumbar Artificial Discs - 2008	
Aesculap	Active-L
Axiomed	Freedom
Biomet	Min-T
DMT	TrueDisc PL
DePuy Spine	Charite
Eden	Welldisc-L
Globus Medical	TRIUMPH
LDR	Mobidisc
Medtronic	Maverick
Nexgen Spine	Physio-L
NuVasive	Elastomeric Lateral TDR
	XL-TDR
Pisharodi Surgicals	Pisharodi Lumbar TDR
Ranier Technology	CAdisc L
SeaSpine	La Jolla Lumbar Disc
Spinal Kinetics	M6-L
SpinalMotion	Kineflex Lumbar
	Kineflex Lateral
SpineMedica	SaluDisc
Stryker	FlexiCore
Synthes	Prodisc
Takiron	Anterior FABRICUBE
	Posterior FABRICUBE
Theken Disc	eDisc
Trans1	PDR
US Spine	Spartacus
Vertebron	LMP Device
Zimmer	Dynardi

IN VIVO, June 2008

This is now…

Estimated U.S. Lumbar Disc Market (As of 2005)



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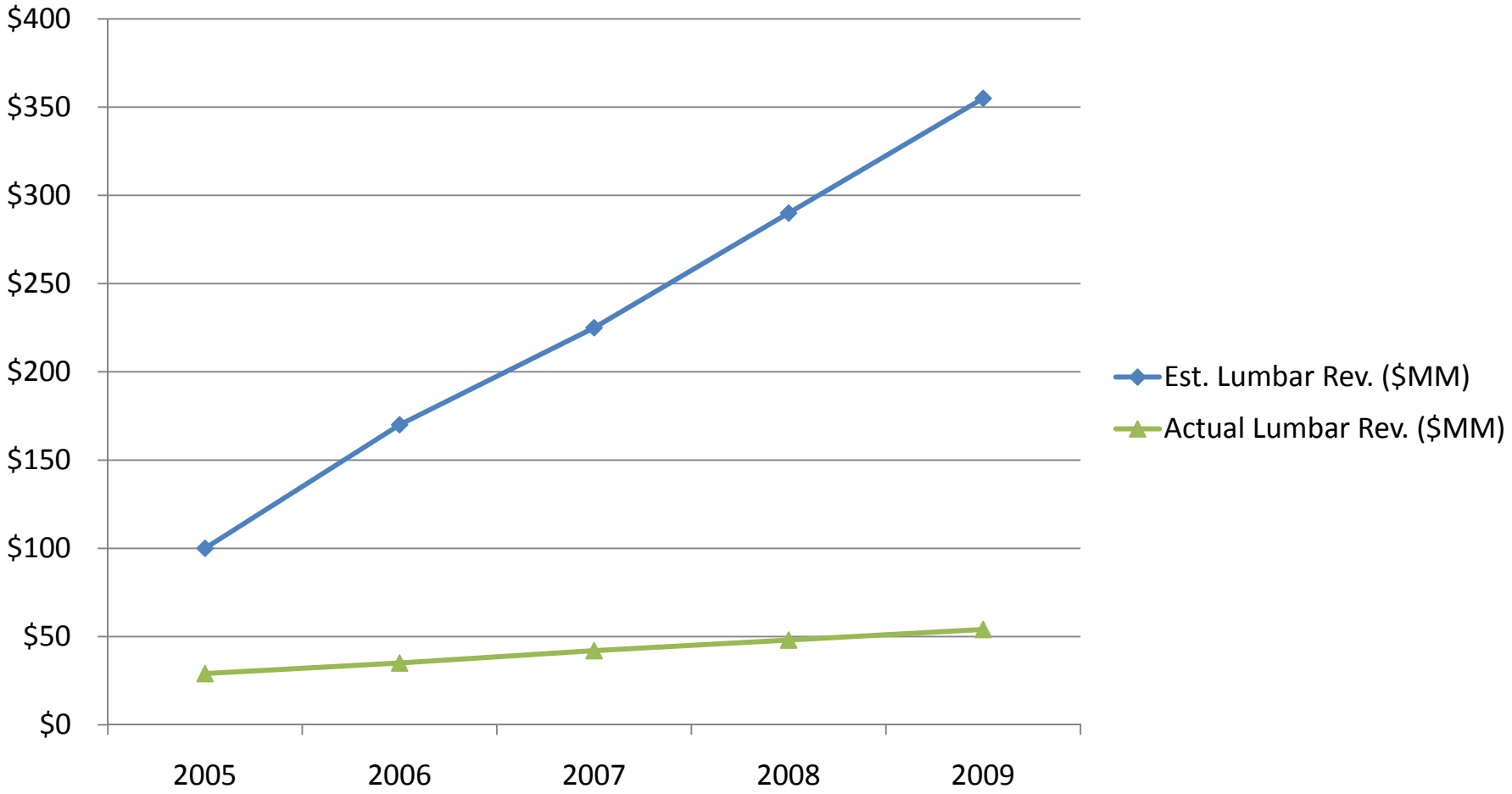
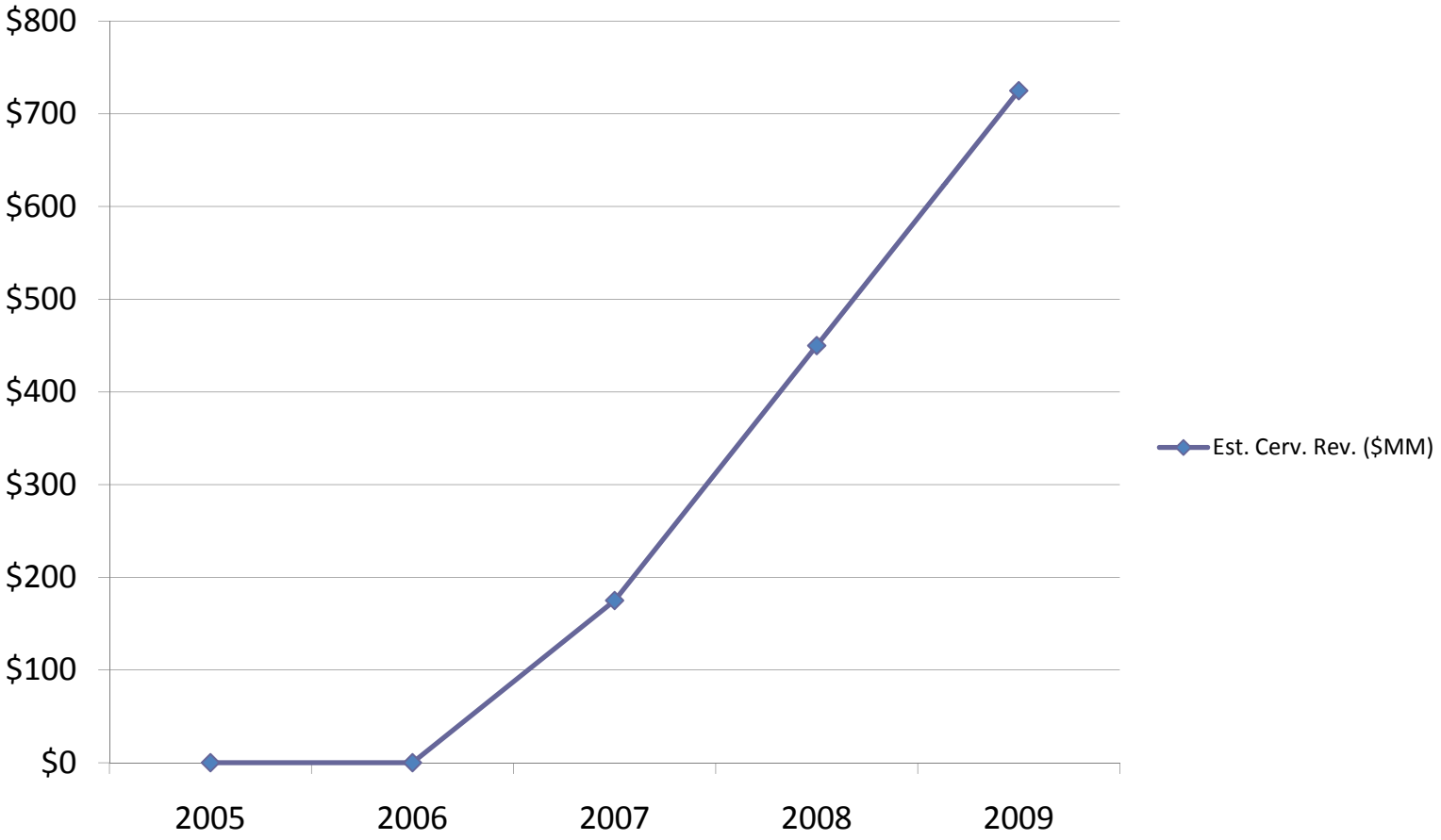
U.S. Lumbar Disc Market



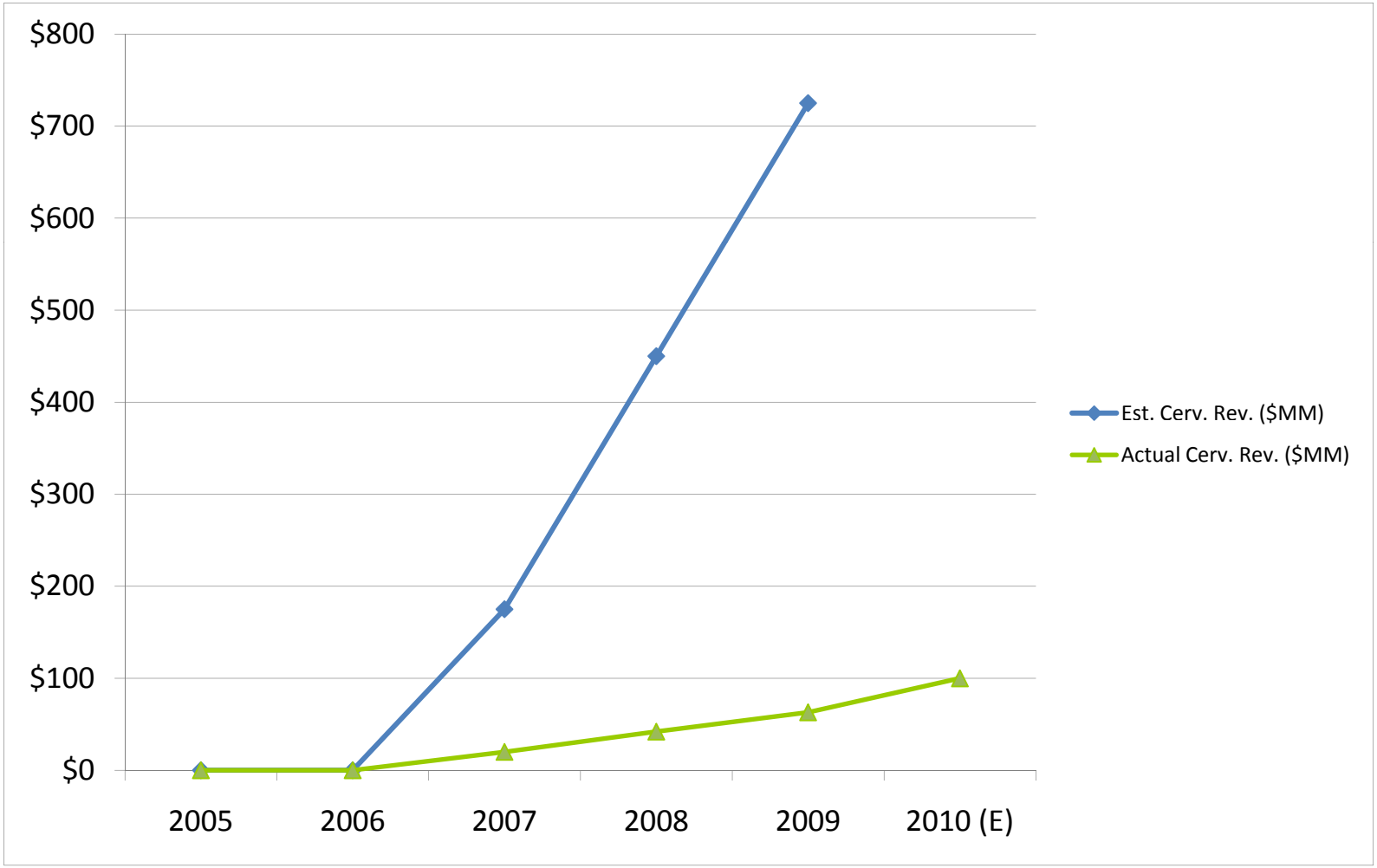
IN VIVO/Windhover Information, Inc. – 2005, LSI Intelligence, iData Research

U.S. Cervical Disc Market (As of 2005)



IN VIVO/Windhover, Inc. 2005

U.S. Cervical Disc Market



IN VIVO/Windhover Information, Inc. – 2005, LSI Intelligence, iData Research

What Happened?

- Lumbar Issues
  - CMS issued Negative NCD February 2006
    - Q's over adverse events, long term outcomes and poor revision strategy.
    - Insufficient evidence for "net health benefit"
  - Revised in May 2006 as Negative NCD for ≥ 60 yrs old
  - Set negative tone for private payors to follow
  - **Percentage lumbar fusions applicable to TDR- lower than originally expected**
  - Bad PR- class action lawsuit against J&J

What Happened?

- Cervical
  - CMS decision has never been issued
  - Over 110M commercial lives are covered
  - **Percentage of cervical fusion applicable to TDR is very high**
  - IDE studies showing superiority to fusion
  - New Cat I CPT code (22856) effective 1/1/2009

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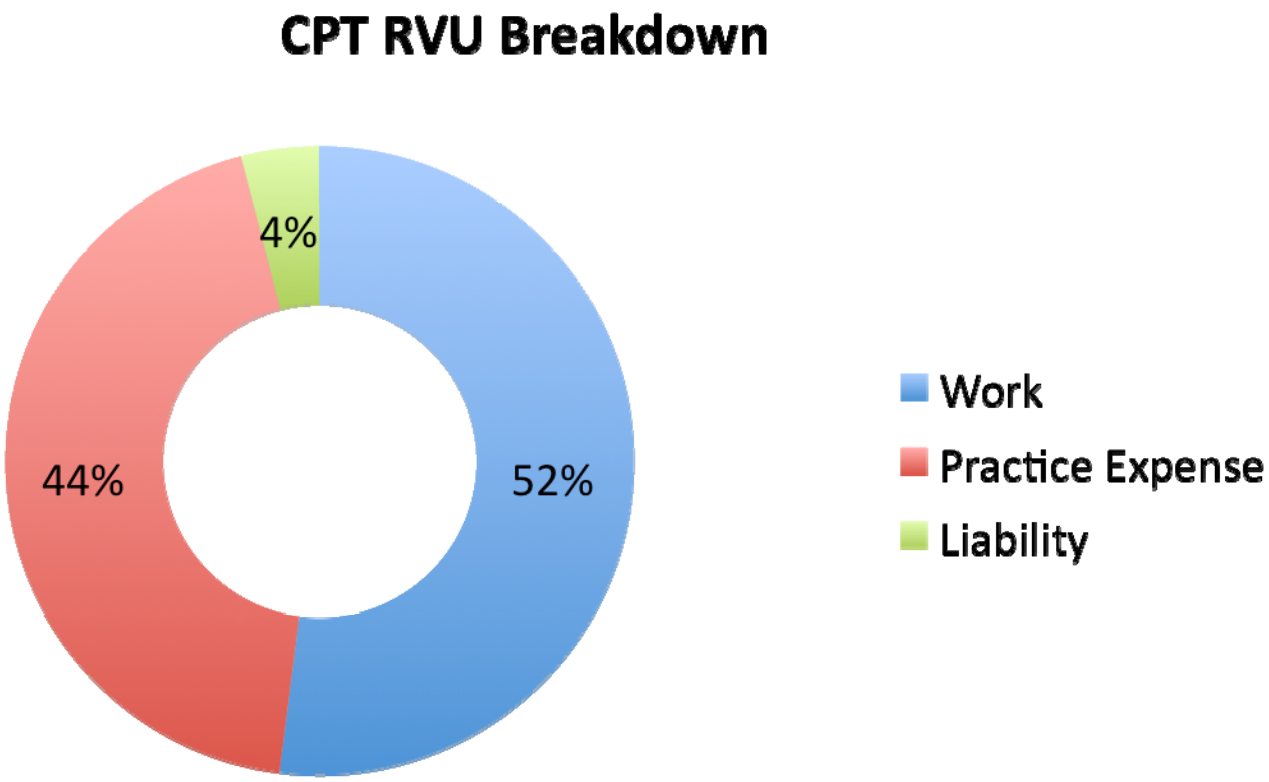
  - So what gives???....
  - Surgeon incentive to fuse

Break Down the Code…

CPT Basics



Procedure Comparison

Cervical Fusion Surgery

- Approximately 75 min long
- Hospital stay 1 overnight
- 90+% success rate
- Similar recovery observed

Cervical Arthroplasty Surgery

- Approximately 75 min long
- Hospital stay 1 overnight
- 90+% success rate
- Similar recovery observed

…so similar surgeon reimbursement rates???

Fusion Code Stack Up…

Cervical Fusion-Multiple codes

- Discectomy (33.06 RVU's)
- Anterior Plate
- Anterior Fusion
- Interbody Fusion
- Other misc
- Total…..77.22 RVU's

…major RVU Discrepancy

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Cervical Disc- 1 bundled code

- Disc Arthroplasty, Cervical
  - *Including discectomy!!!*
- Total……40.07 RVU's

"Total disc arthroplasty (artificial disc), anterior approach***, including discectomy*** with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical"

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Net RVU's: 44 vs. 7

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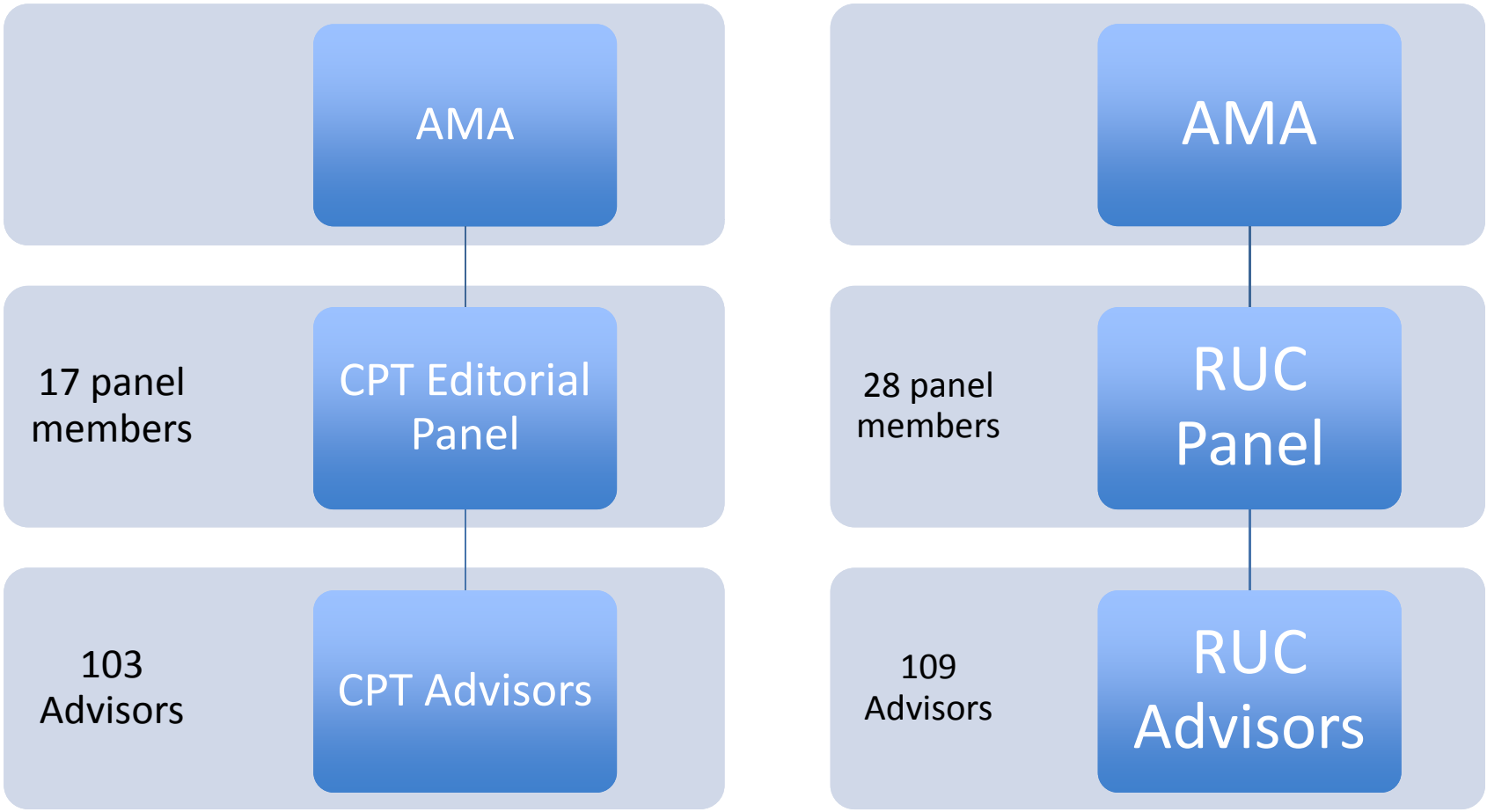
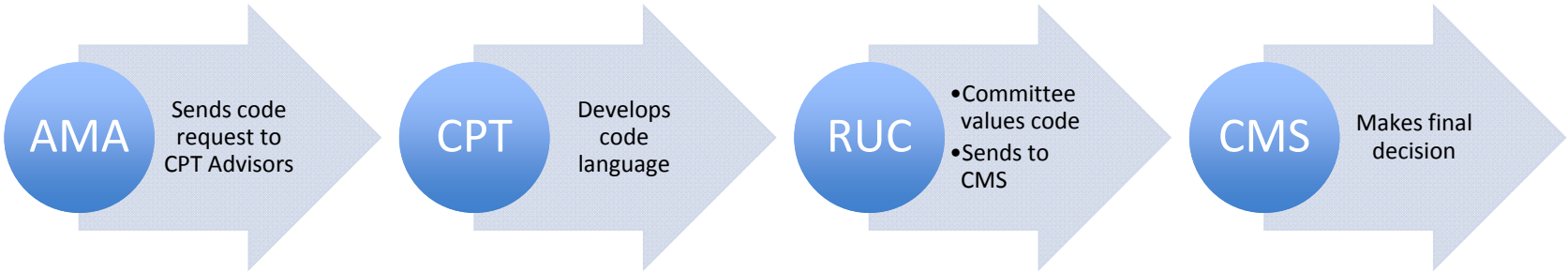
AMA CPT & RUC Structure



New CPT Code Process



THE SPINE COUNCIL

SUMMER, 2010 VOL #01 ISSUE #01

The Bundling of Anterior Cervical Discectomy and Fusion: Is this the beginning of the end?

By Gordon Donald, MD, Managing Partner, NJ Spine Group, LLC
Member, Board of Directors, The Spine Council

As practicing spine surgeons, we perform anterior cervical surgery on patients for different pathologies. Everyone would recognize that performing an anterior cervical fusion on a patient with simple one level discogenic disease is significantly different than one level anterior fusion with decompression of the spinal cord for spondylotic myelopathy. Appropriately, we code for our procedures with an anterior fusion code (22554 for 1 level anterior cervical arthrodesis) and an anterior cervical discectomy and decompression code (63075 for one level anterior neural decompression). Beginning in 2011, this coding paradigm has changed to bundle these two codes into one. This is clearly another large step in categorizing specialized spinal surgery as routine and "all the same".

Supporters of this concept would argue that anterior cervical arthrodesis is seldom reported without anterior cervical discectomy or decompression of neural structures. Their solution is simply to make one code. Though arthrodesis and decompression may commonly be done together, this coding solution negates the ability to accurately represent the surgery performed. After all, CPT coding was developed to provide a clear representation of a surgical procedure performed, not only for billing purposes, but also for research and to advance clinical science. It is incomprehensible, in this world of computerized data collection and analysis, that having one code is simply easier to manage than two. If the perceived problem is that one code is perhaps overused, the solution should be managing this by proper indications and documentation. Perhaps the underlying rationale for this change was simply to pay for one code and one procedure instead of two.

The reality is that not all anterior arthrodeses require direct neural decompression, though most do. If direct neural decompression is not recognized as a distinct procedure and compensated as such it will be less commonly performed, resulting in decreased quality of care to our patients. The stark reality is that if people are not recognized for and compensated for the specifics of what they do, the quality with which things are done will decrease to the least common denominator. By nature, people will do a lesser job, as is the case when there is no recognition or compensation otherwise provided. By not recognizing discectomy and decompression of neural structures as a specific procedure, this procedure will likely diminish in frequency and quality. This will only result in secondary decompression procedures that will ultimately increase the cost of care.

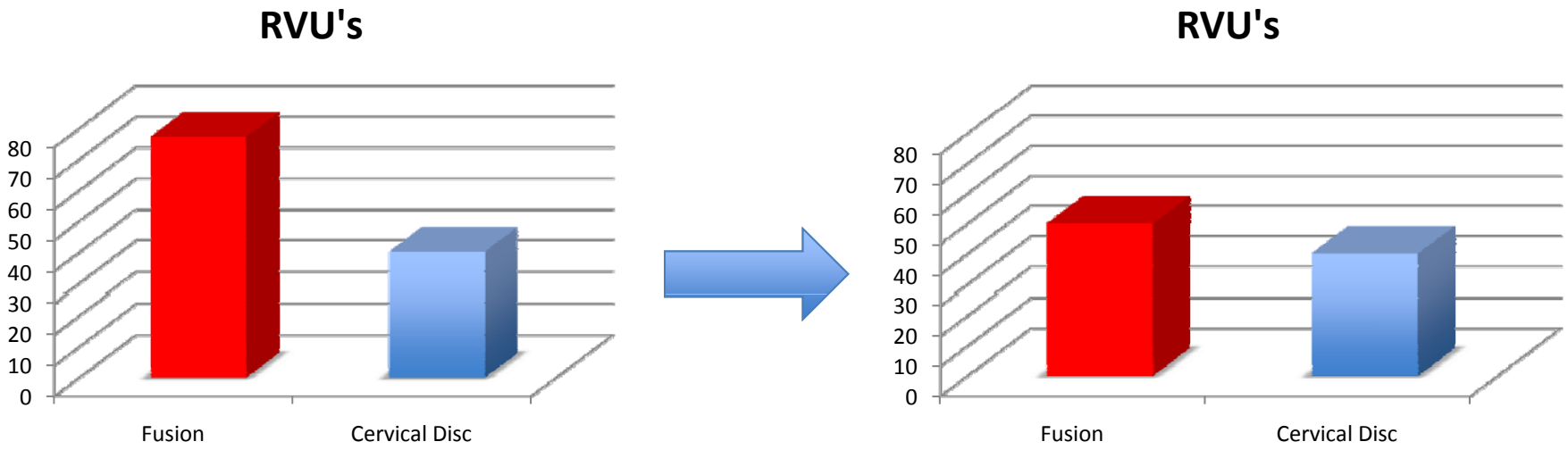
It is interesting to contemplate how such a thoughtless decision could be made in the first place or how such inane arguments could be put forth to simply support a cost-cutting change. This decision is ultimately made by AMA/RUC, who is charged with managing CPT coding, owned by the AMA. However, as spine surgeons, we have representatives from NASS, AANS, and CNS that hold advisory positions to AMA/RUC. Where were their voices in supporting their member surgeons and opposing these changes? Do our spine societies simply acquiesce to the whims of AMA? Do they really represent our best interests as surgeons?

I would suggest that this is just the bellwether of things to come. The winds are shifting and the momentum is turning to lessen recognition for the procedures that we perform as spinal surgeons. Bundling of one service into another will continue and it will continue to lessen the perceived value of what we do. This will be devastating to our profession and to the quality of service to our patients. It would seem apparent that we can no longer rely on our spinal societies to protect our best interests or the best interests of our patients. We need to project a collective voice in opposition to this practice.

Gordon Donald, MD, Managing Partner for NJ Spine Group, LLC, is also a member of the Board of Directors for THE SPINE COUNCIL. Dr. Donald is involved is spinal surgical research and the development of new instruments, devices and techniques to advance the field of spinal surgery.

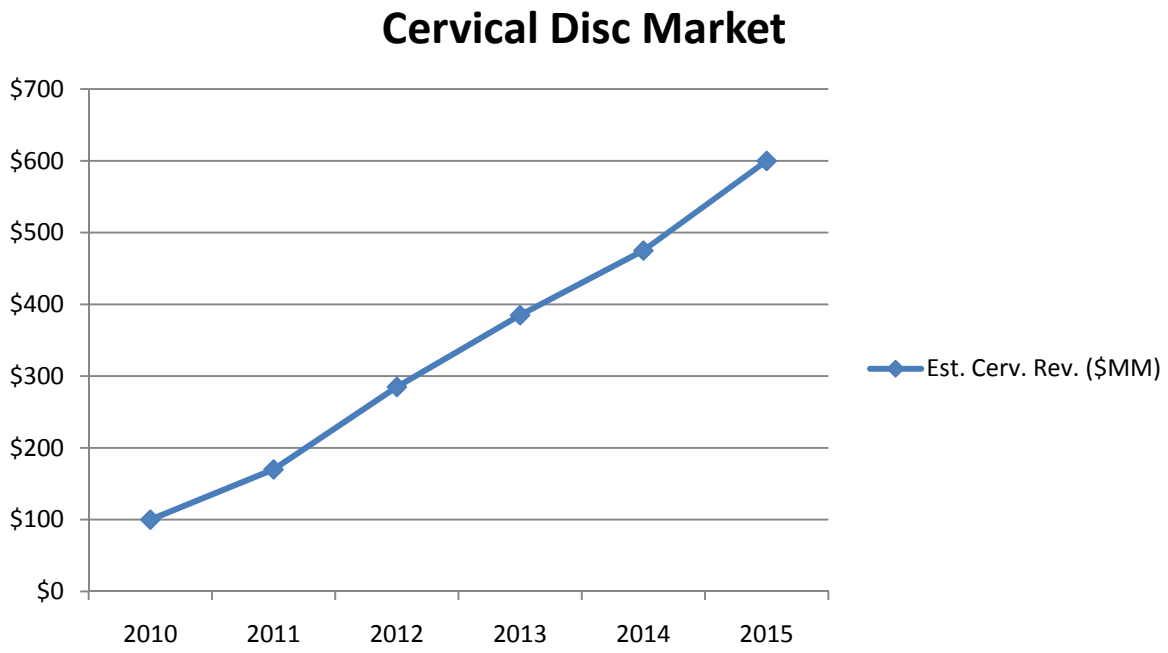
- Beginning 2011, anterior cervical fusion code 22554 and anterior cervical discectomy 63075 will be bundled, as determined by AMA's RUC committee in charge of CPT coding

Leveling of RVU’s



Cervical Market on the Rise

- Elimination of incentive to fuse over implanting a disc
- Three or more new discs expected on market in 2011
- New long term data (5 yr.) showing superiority over fusion
  - Data which the private insurers have been asking for



iData Research 2010

Thank you!

cgilbride@spinalmotion.com