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*July 26, 2022*

# Understanding Surgeon Preferences for Spine Hardware & Osteobiologics

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*Senior Director, Medical Device Management*

## | Disclosures

- The presenter has no real or perceived conflicts of interest related to this presentation.

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## Learning Objectives

*At the end of this session, participants should be able to:*

1. Describe the basic components of cervical and thoracolumbar spine fusion procedures
2. Recall the rationale for 2-3 new and premium technologies in spine hardware and osteobiologics
3. Identify potential utilization opportunities and methods to reduce cost per case

# | Agenda

- Industry Overview
- Spine Anatomy
- Spinal Fusion: Basic Hardware Categories
- Common Spinal Fusion Procedures
- Osteobiologics
- Utilization Savings Opportunities

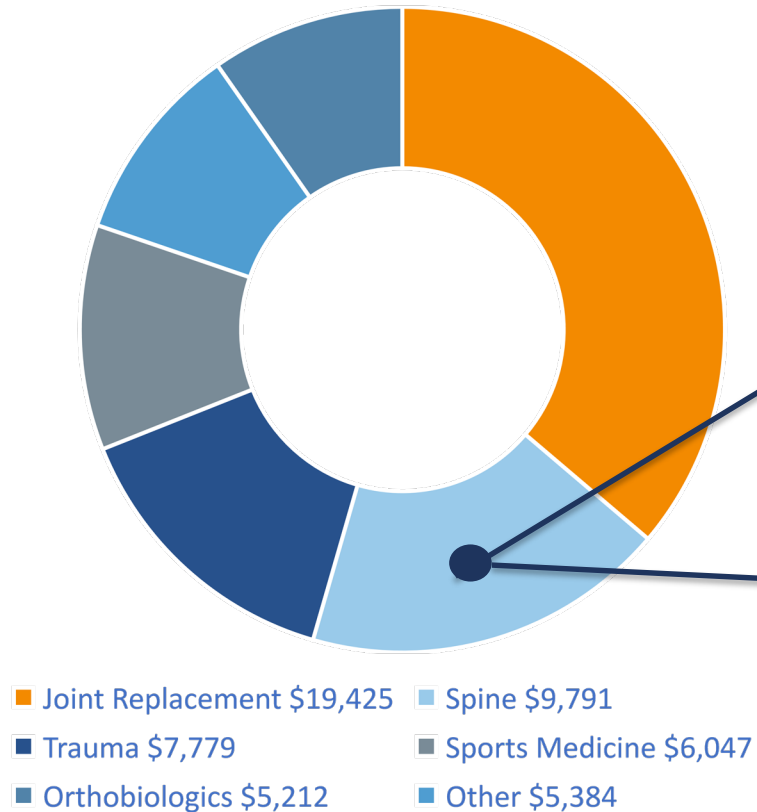


The background of the slide is a blurred photograph of a hospital hallway. In the foreground on the left, an IV drip chamber is visible, hanging from a stand. The hallway in the background shows people walking, but they are out of focus. The overall color scheme is a cool blue.

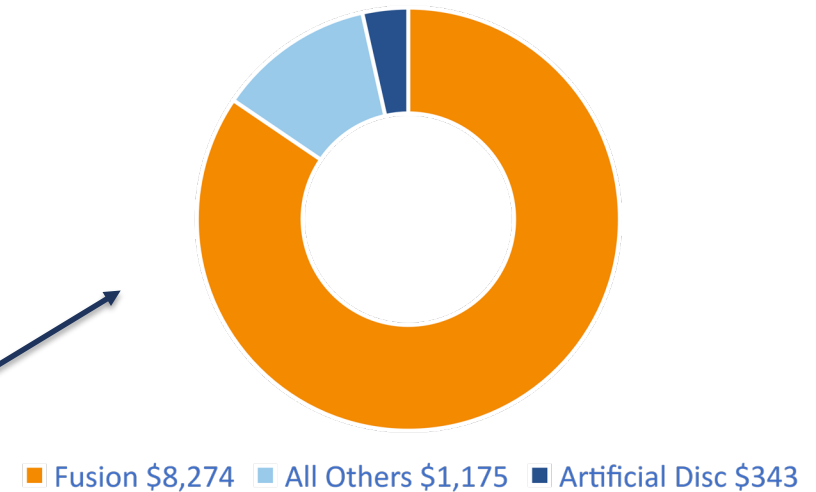
# Industry Overview

## Industry Overview

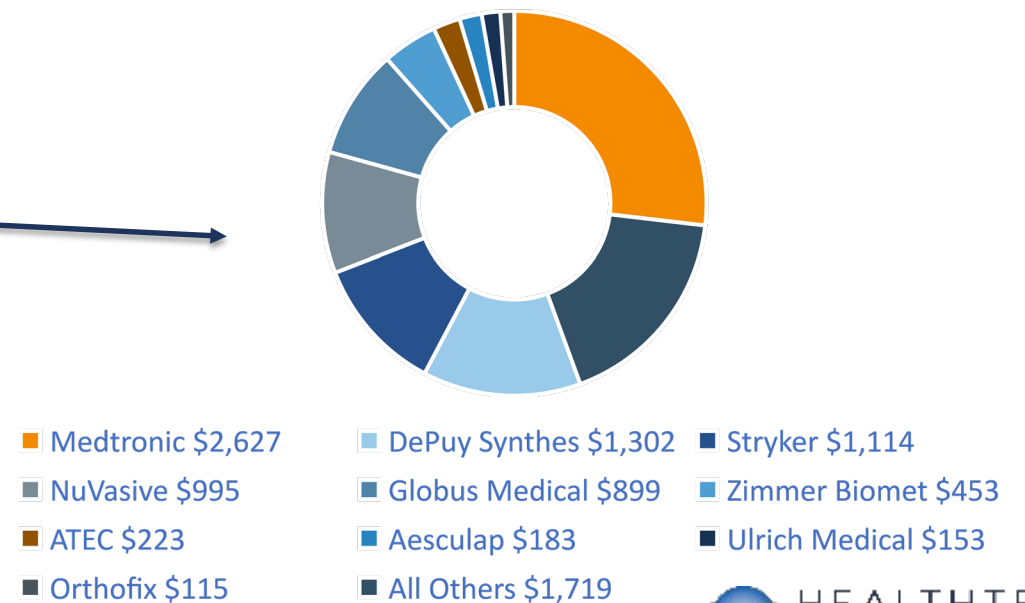
### Orthopedic Product Segments 2021 by Market Share (\$Millions)



### Spine Sales 2021 by Product Type (\$Millions)



### Spine Market Share – Ten Largest Players and All Others (\$Millions)



# Biologics

## Examples:

### Biologics

- Broad term for all biologic products

### Orthobiologic

- Biologics used in spine and orthopedic procedures

### Osteobiologic

- Materials used to promote healing of fractures, fusions and bone voids

Biologic drugs

Hormones

Aesthetic injectables

Vaccines

Surgical biologics

Wound coverings

Tendon grafts

Amniotic tissue

Blood products

Visco-supplementation

Soft tissue grafts

Cartilage grafts

Allograft bone chips

Bone morphogenetic protein (BMP)

Demineralized bone matrix

Cellular Bone Allograft

Synthetic bone graft substitutes

#### Sources:

<https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers>

<https://orthoinfo.aaos.org/en/treatment/helping-fractures-heal-orthobiologics/>

<https://pubmed.ncbi.nlm.nih.gov/15517852/>

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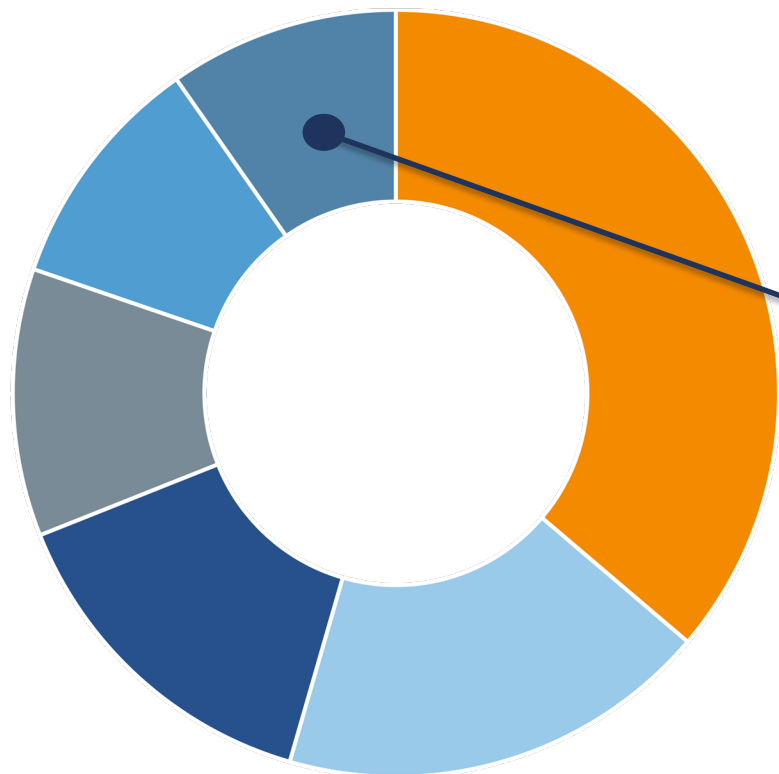
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<https://pubmed.ncbi.nlm.nih.gov/15517852/>



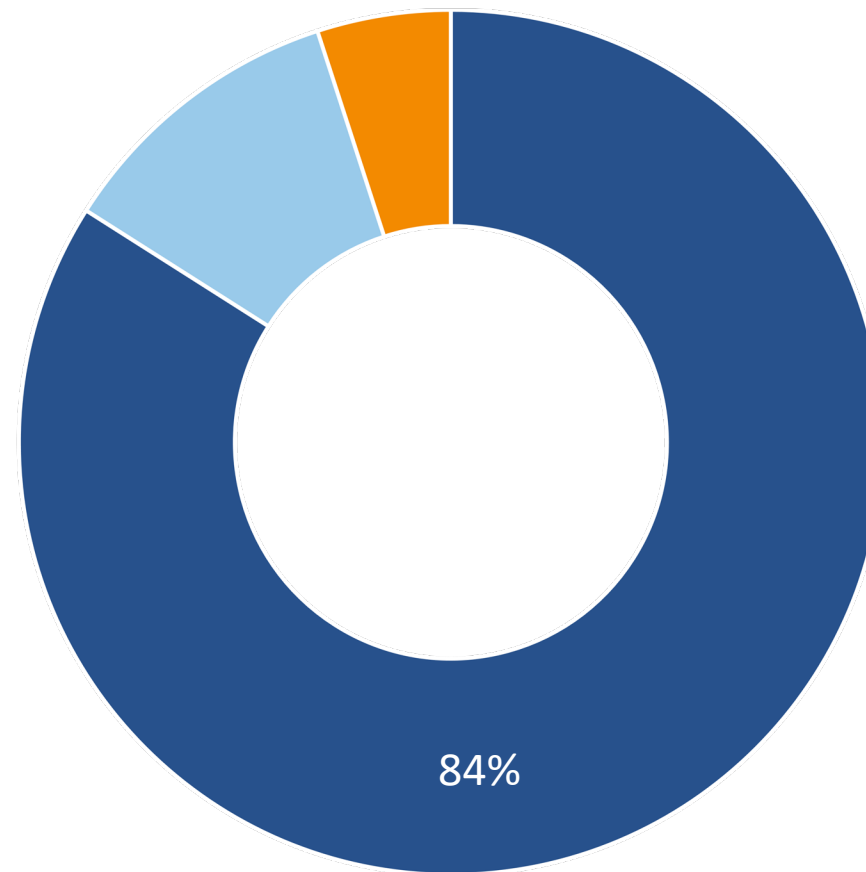
## | Industry Overview – Orthobiologics

Orthopedic Product Segments 2021 by Market Share (\$Millions)<sup>1</sup>



■ Joint Replacement \$19,425 ■ Spine \$9,791  
■ Trauma \$7,779 ■ Sports Medicine \$6,047  
■ Orthobiologics \$5,212 ■ Other \$5,384

Percent of cases with Osteobiologics by procedure type – H1 2021 (%)



■ Recon 5% ■ Trauma 11% ■ Spine 84%

Sources:

*The Orthopedic Industry Annual Report*, June 2022, <http://www.orthoworld.com>

*Orthopedic Network News*, Volume 32, Number 4, October 2021, <http://www.OrthopedicNetworkNews.com>

The background of the slide is a blurred photograph of a hospital hallway. In the foreground on the left, an IV drip chamber is visible, hanging from a stand. The hallway in the background shows people walking, but they are out of focus. The overall color scheme is a cool blue.

# Spine Anatomy

# | What is spinal fusion and why is it performed?

Spinal fusion permanently connects two or more vertebrae in the spine to improve stability, correct a deformity or reduce pain.

Indications treated may include:

- Degenerative disk disease
- Spondylolisthesis
- Spinal stenosis
- Scoliosis
- Fractured vertebra
- Infection
- Herniated disk
- Tumor



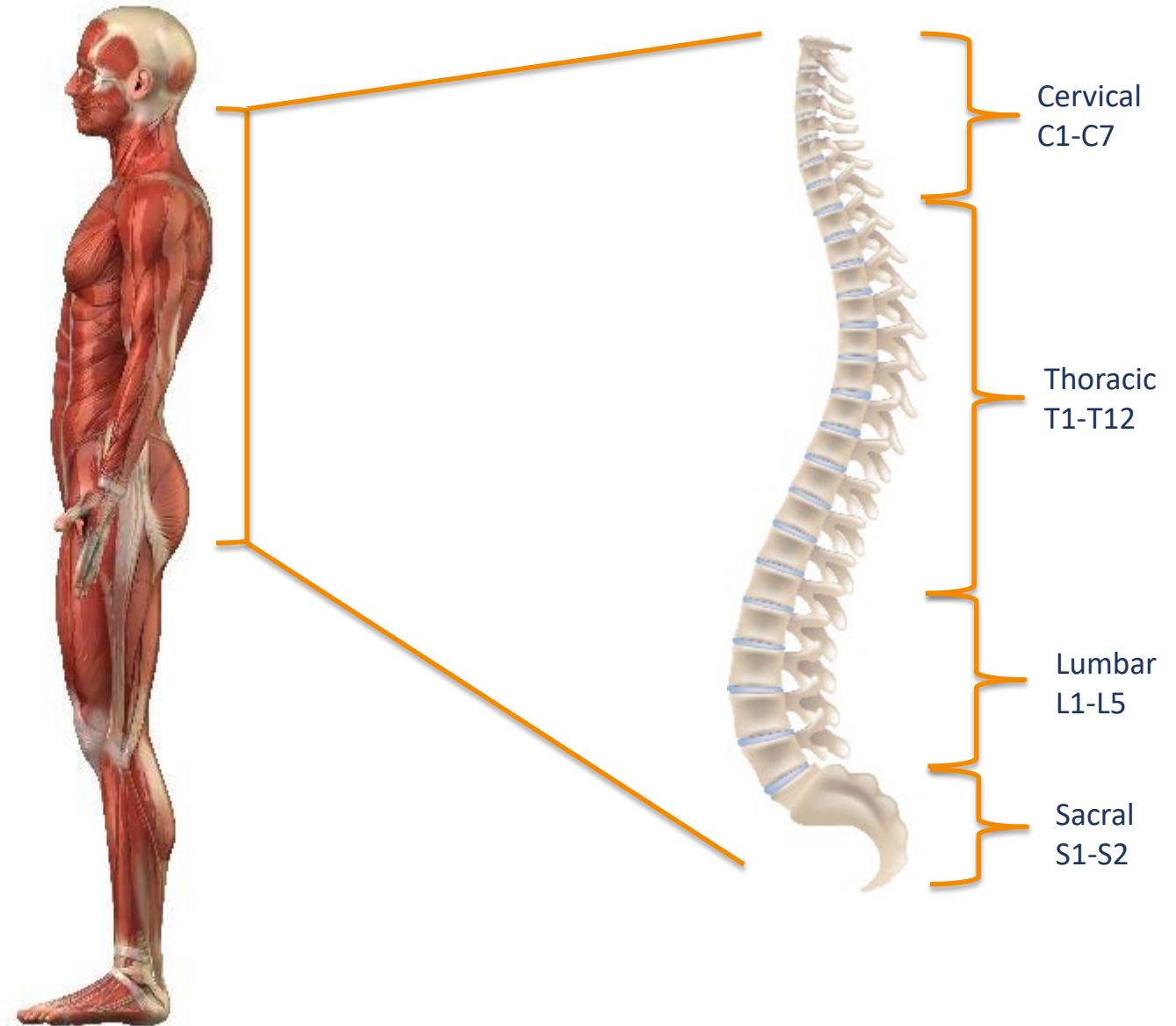
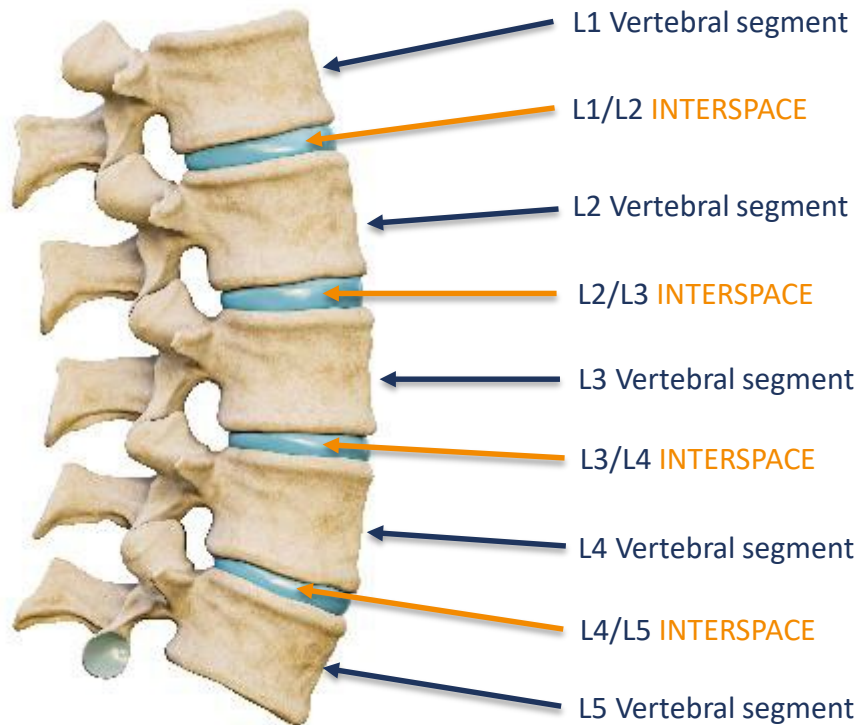
Sources:

Mayo Clinic - <https://mayocl.in/3RMCHbU>

AAOS - <https://bit.ly/3ISxewf>

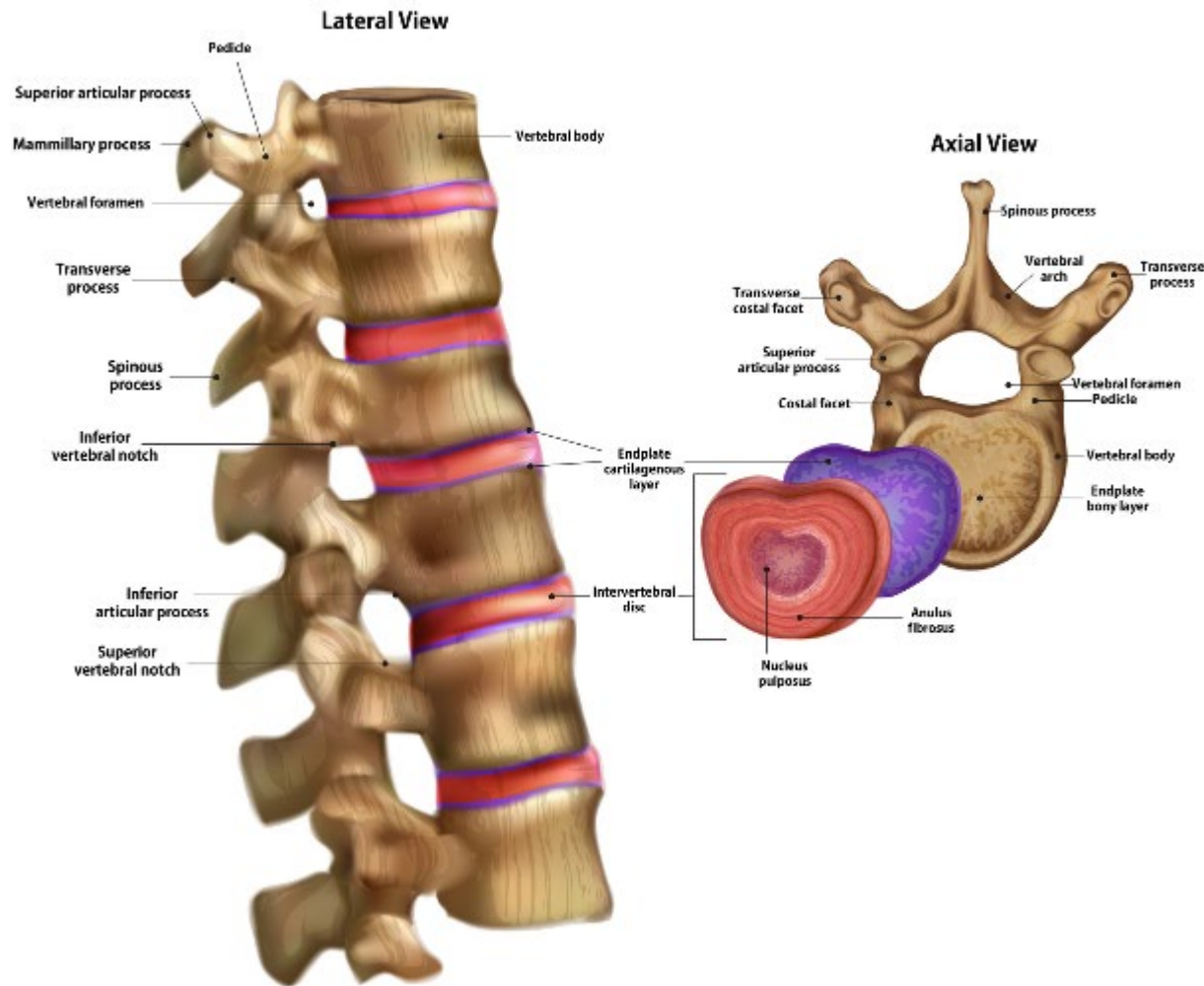
iStockphoto.com

# Spine Anatomy & Terminology



Source: iStockphoto.com

# Spine Anatomy & Terminology



Key structures to know:

- Vertebral body
- Intervertebral disk
- Transverse process
- Spinous process
- Vertebral foramen
- Endplate bony layer



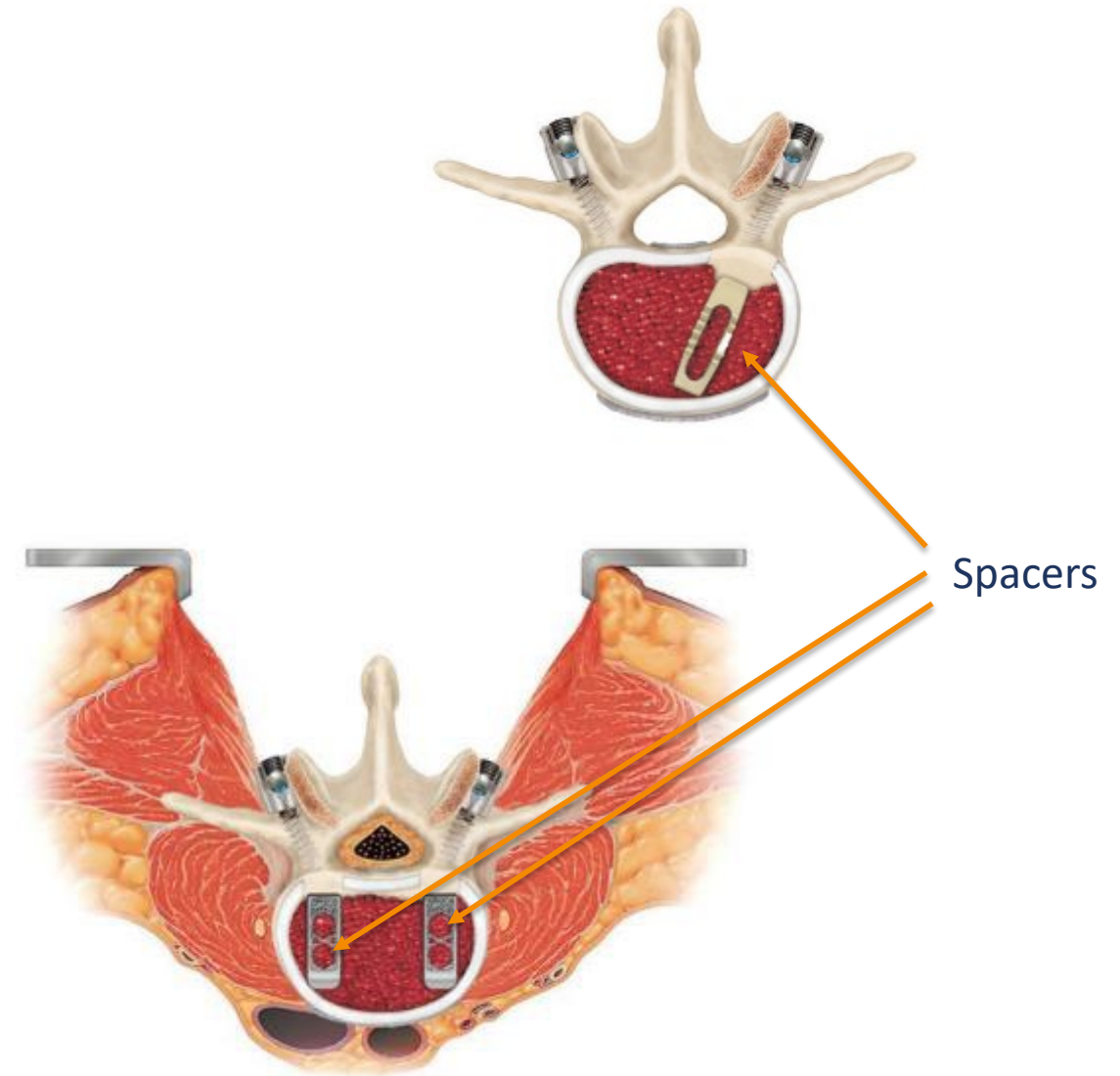
# Spine Fusion: Basic Hardware Categories

## Interbody Spacers

- Implanted in interbody space
- Hollow center for placement of osteobiologic
- Size, shape and quantity per level differs by approach, technique and manufacturer

### Common materials:

- Machined Bone (Allograft)
- Polyether Ether Ketone (PEEK)
- Titanium



### Sources:

Orthop Surg. 2016;8(3):278–284. doi:10.1111/os.12264

The Spine Journal. 2018;18(10):1867-1876. doi:10.1016/j.spinee.2018.03.003

## | Interbody Spacers – ‘Premium’ Technologies

- Expandable cage
  - Less invasive surgery
- 3D Printed titanium
  - Improved osseointegration
- Surface coatings (Titanium or Hydroxyapatite)
  - Improved osseointegration



Sources:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7735473/>

[https://www.thespinejournalonline.com/article/S1529-9430\(21\)01057-3/fulltext](https://www.thespinejournalonline.com/article/S1529-9430(21)01057-3/fulltext)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7661570/>

*Orthopedic Network News*, Volume 32, Number 4, October 2021, <http://www.OrthopedicNetworkNews.com>

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## Plate & Screw Systems

- Add stability to the fusion and prevent loosening of interbody spacer
- Threaded holes for screws that anchor into the vertebral body
- Most frequently used for anterior fusions
- 1 plate may be used for 1 level or for multiple levels



Sources:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3386531/>

*Orthopedic Network News*, Volume 32, Number 4, October 2021, <http://www.OrthopedicNetworkNews.com>

## Stand-alone Interbody (SIB) & Integrated Plates

- Combines interbody spacers with functions of a screw and plate
- May use screws or anchors that attach spacer to vertebrae
- Integrated plates connect plate to interbody spacer to prevent migration and provide stability



SIB with screws



SIB with anchors



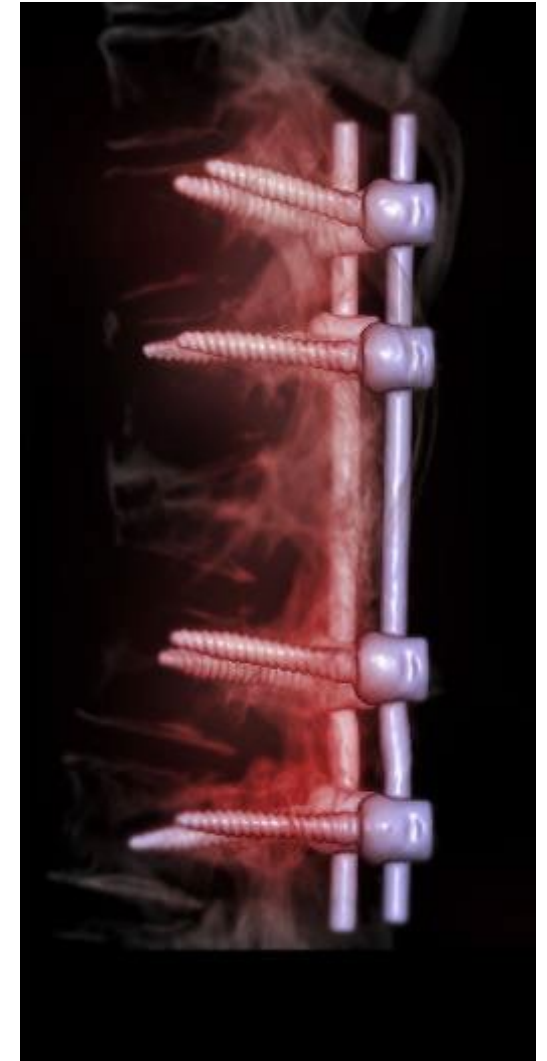
Lateral spacer with integrated plate

Source:

*Orthopedic Network News*, Volume 32, Number 4, October 2021, <http://www.OrthopedicNetworkNews.com>

# Pedicle Screw Systems

- Provide strength and support to fusion while it heals
- Screws are placed above and below interbody space to be fused
- Screw trajectory through the pedicle
- Rods connect to screws
  - Connection in 'Tulip'
  - Set screws
- Minimally invasive systems allow better visibility and use in small incisions
  - Modularity
  - Cannulation



Sources:

iStockphoto

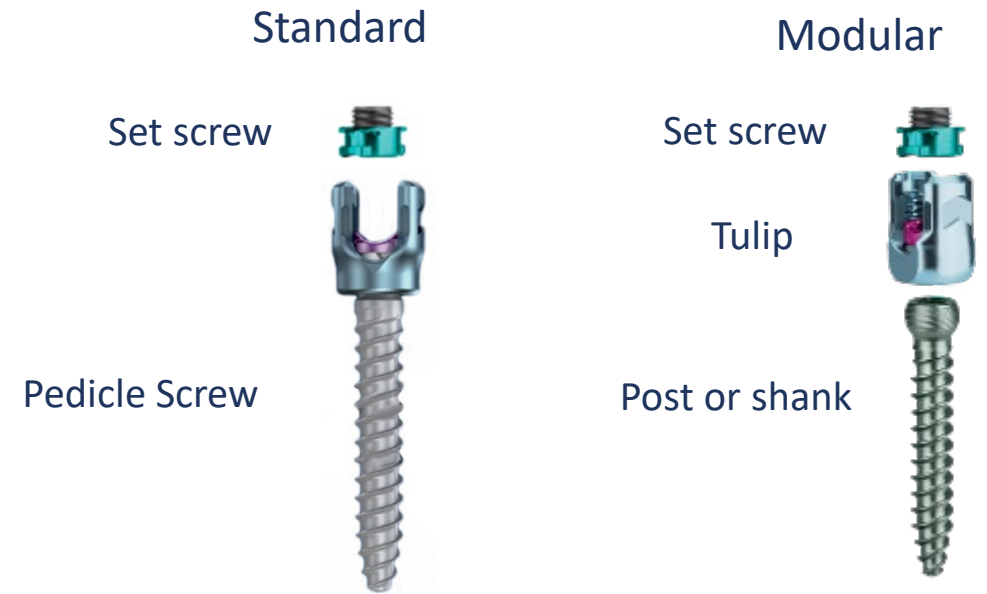
*Orthopedic Network News*, Volume 32, Number 4, October 2021, <http://www.OrthopedicNetworkNews.com>

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## Pedicle Screw – Premium Options

### Modular pedicle screws

- Used in minimally invasive procedures
- Pieces should cost the same together as regular screw



### Cannulated screws

- Wire sets trajectory to place screws under X-ray/navigation



Cannulated Screw

### Fenestrated pedicle screws

- Used with bone cement
- Osteopenic or tumor patients



Fenestrated pedicle screw with cement augmentation

Sources:

*Orthopedic Network News*, Volume 32, Number 4, October 2021, <http://www.OrthopedicNetworkNews.com>

<https://doi.org/10.31616/asj.2018.12.6.1053>

# Common Spinal Fusion Procedures

## | Procedure Names

- Names come from region of the spine, approach (where and how the surgeon reaches the spine) and implant used
- Procedure names are commonly known (sometimes phonetically) by their acronym

Examples:

Anterior Cervical Discectomy and Fusion (ACDF)

Anterior Lumbar Interbody Fusion (ALIF)

Posterior Lumbar Interbody Fusion (PLIF)

Transforaminal Lumbar Interbody Fusion (TLIF)

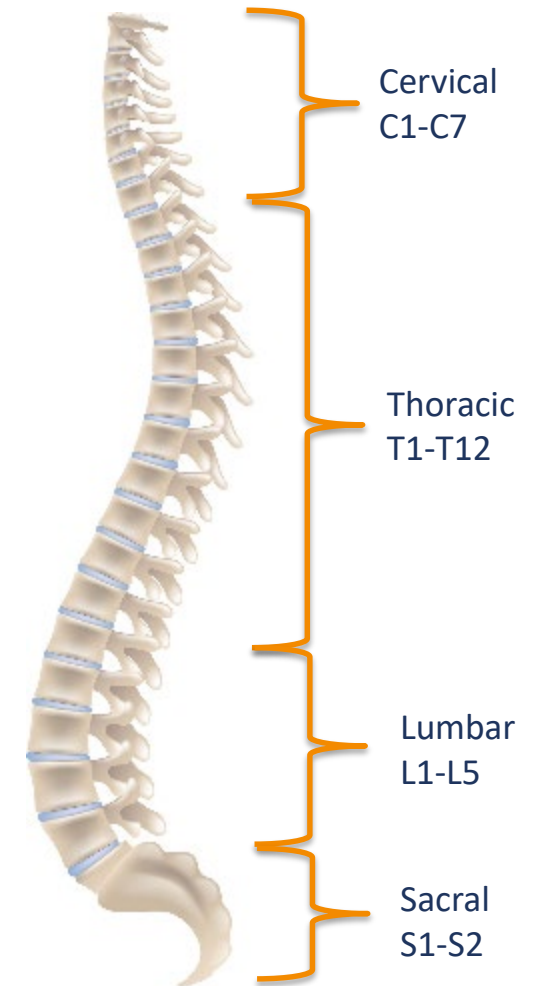
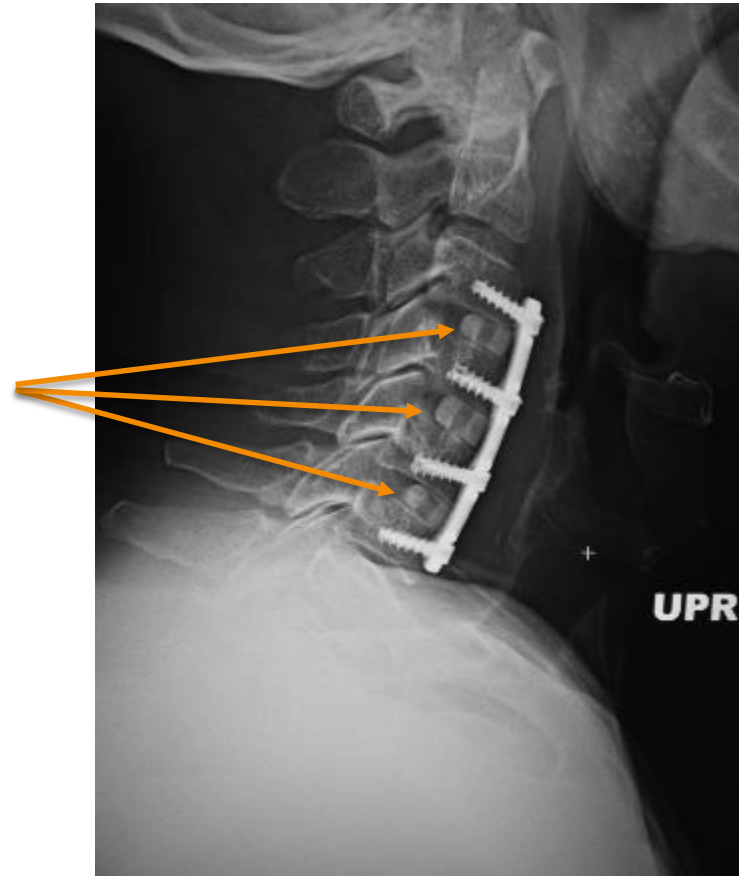
Source: J Spine Surg. 2015 Dec; 1(1): 2–18

# Spine Fusion Levels

Example:

“3 Level ACDF” C3–C6

- Plate spans C3–C6
- Spacer at C3–4, C4–5, C5–6



Source: [https://medapparatus.com/NeckSpine/Images/ACDF\\_lateral.jpg](https://medapparatus.com/NeckSpine/Images/ACDF_lateral.jpg)



## Procedure Names – Cervical fusions

### Posterior Approach

PCF

### Posterior Cervical Fusion (PCF)

- Pedicle Screws
- Rods
- Osteobiologics

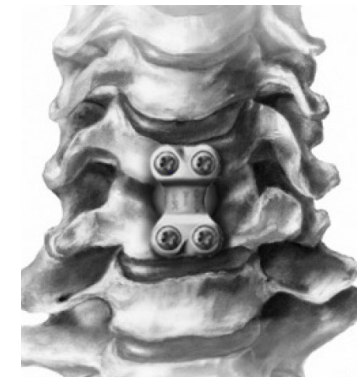


### Anterior Approach

ACDF

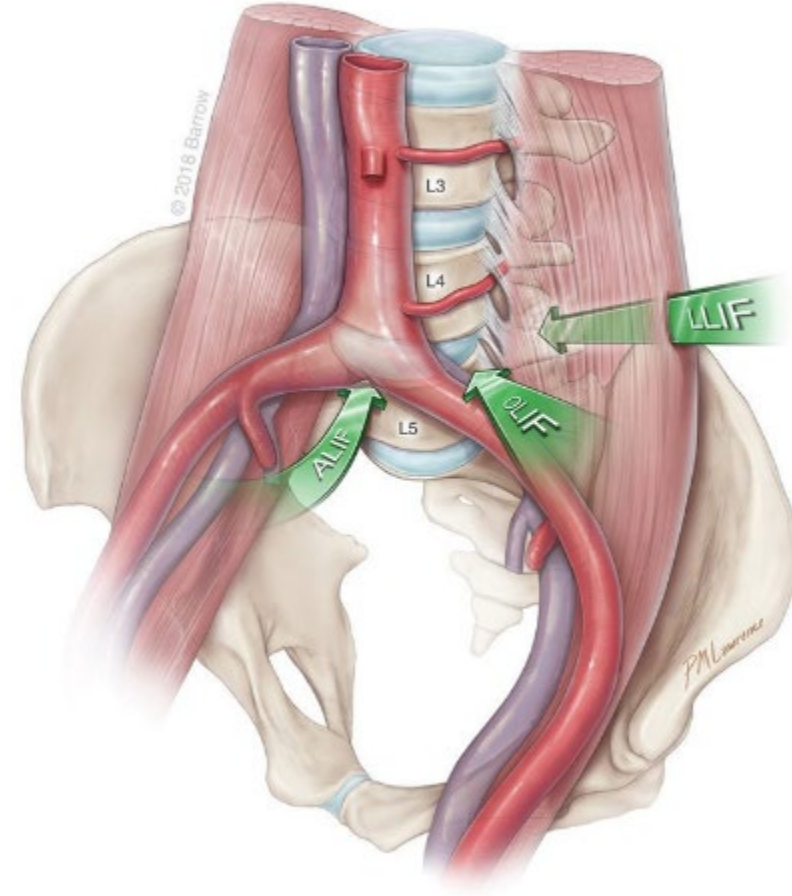
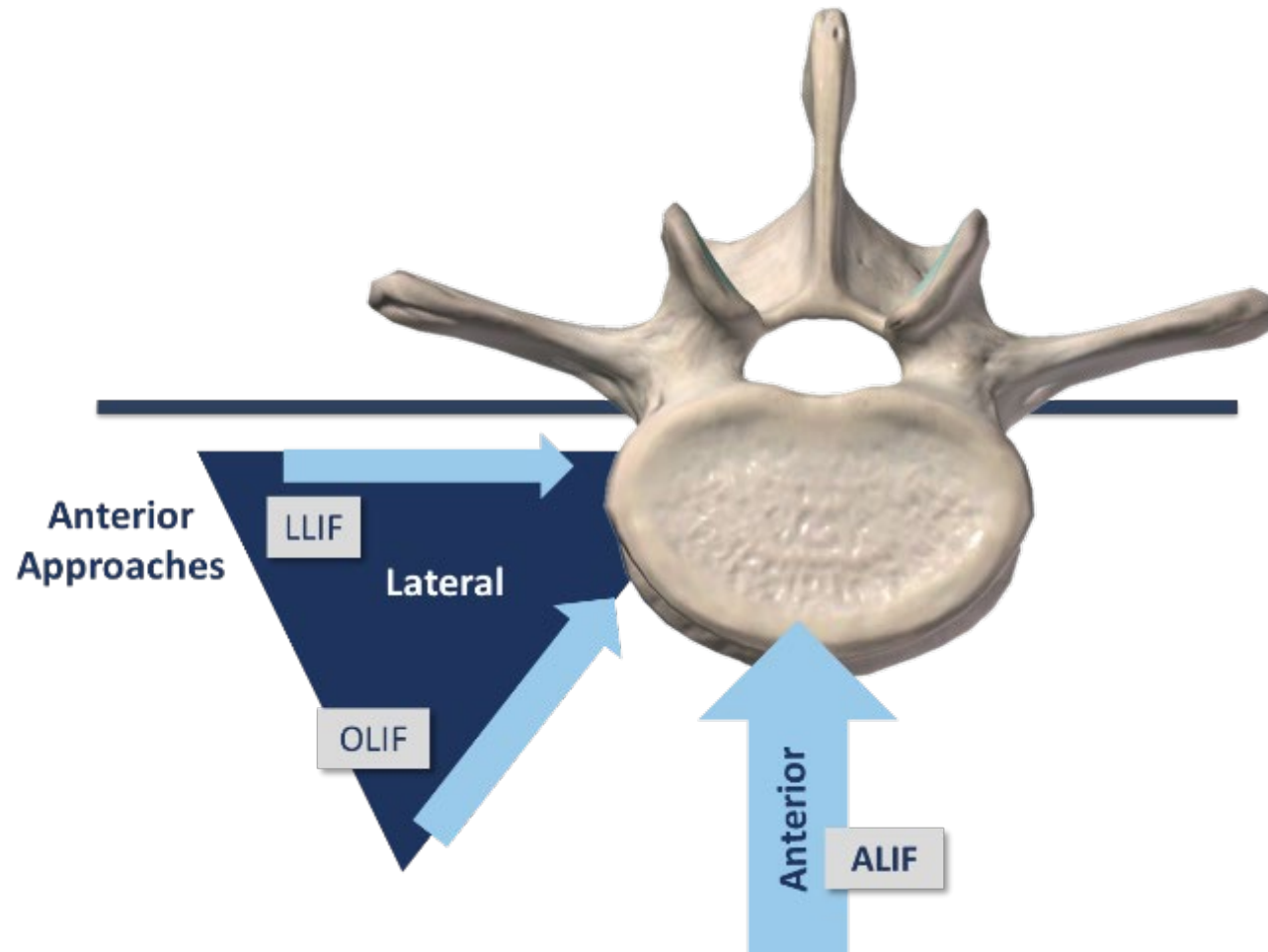
### Anterior Cervical Discectomy and Fusion (ACDF)

- Spacer
  - Plate and screws
  - Osteobiologic
- OR
- SIB-C + screws
  - Osteobiologic





## Anterior Approach Fusions – ALIF, LLIF, OLIF

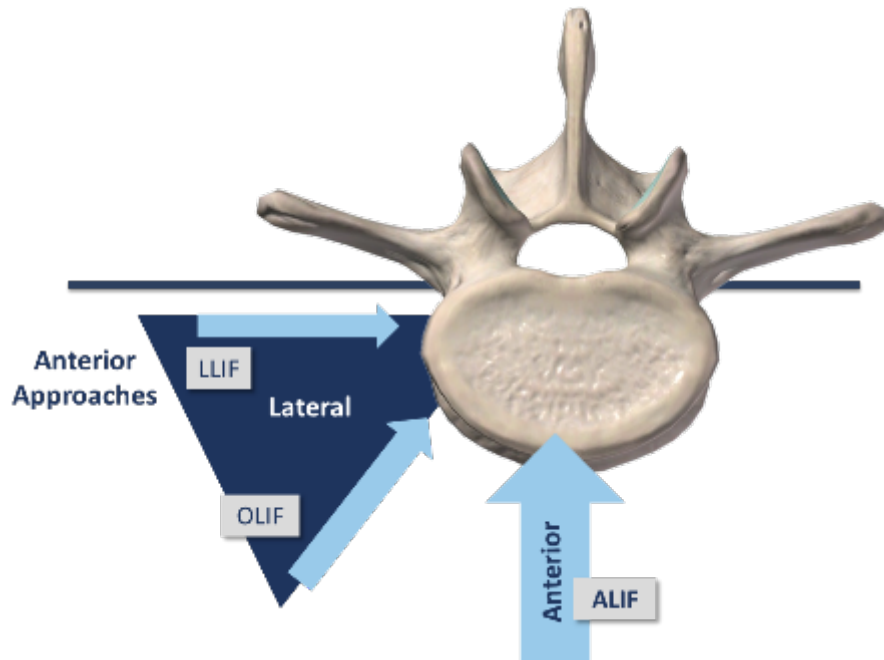


Source:  
DOI:[10.21037/atm.2018.03.24](https://doi.org/10.21037/atm.2018.03.24)

# | Anterior Lumbar Interbody Fusion (ALIF)

Accessed through the abdomen

- Usually requires vascular access surgeon for approach
- Larger size spacer – stability



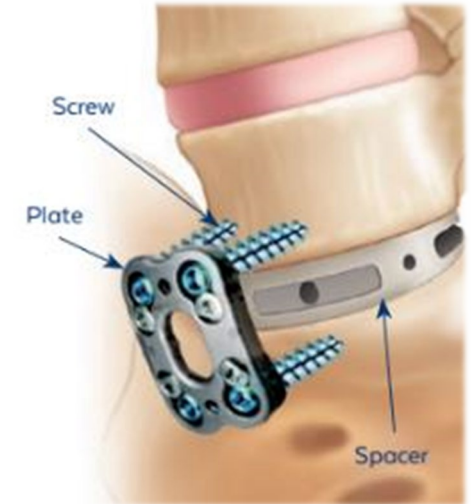
Hardware Components:

- Interbody spacer
- Plate + screws
- Osteobiologic

or

- Standalone interbody spacer
- Screws
- Osteobiologic

Be sure to understand the components used



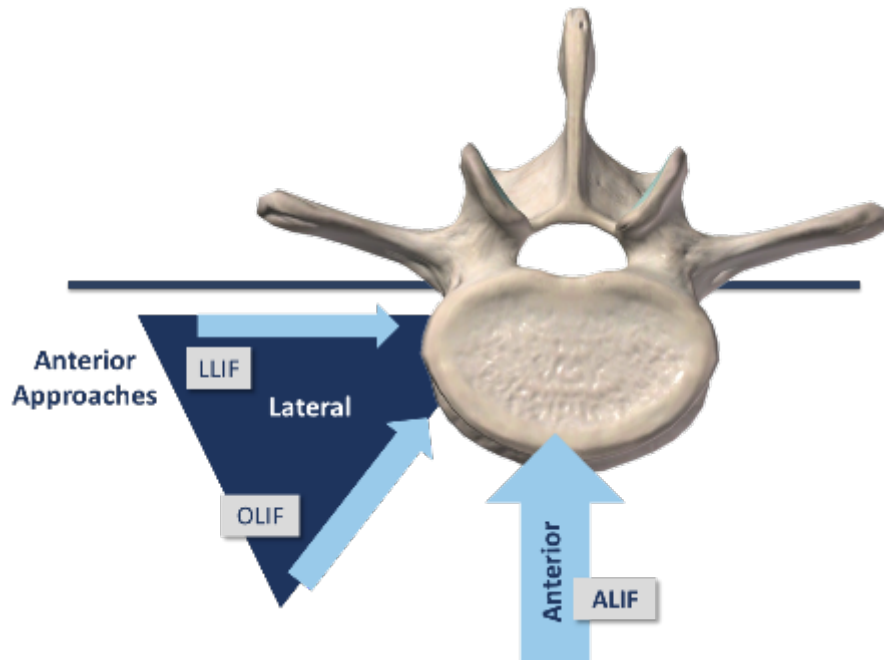
# Lateral Lumbar Interbody Fusion (LLIF)

- Less invasive than ALIF
- Approached from side of the abdomen
  - Other names from vendor specific techniques
    - Direct lateral (DLIF)
    - Extreme lateral (XLIF)
- Oblique Lateral Lumbar Interbody fusion (OLIF) usually uses same implant, different approach

## Hardware components

- Lateral spacer
- Osteobiologic

A plate and screws are sometimes used to prevent migration of the implant



Sources: Operative Techniques in Orthopaedics, 2017-12-01, Volume 27, Issue 4, Pages 223-230  
Orthopedic Network News, Volume 32, Number 4, October 2021, <http://www.OrthopedicNetworkNews.com>

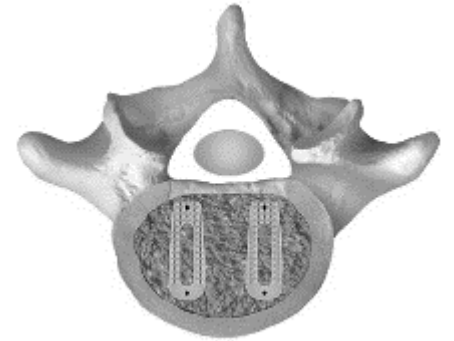
## Posterior Approach – Interbody Fusions\*

- Both procedures have incision in the back
- PLIF usually requires 2 interbody spacers
- TLIF may be curved in shape
- Always understand number of interbodies being used

### Posterior Lumbar Interbody Fusion (PLIF)

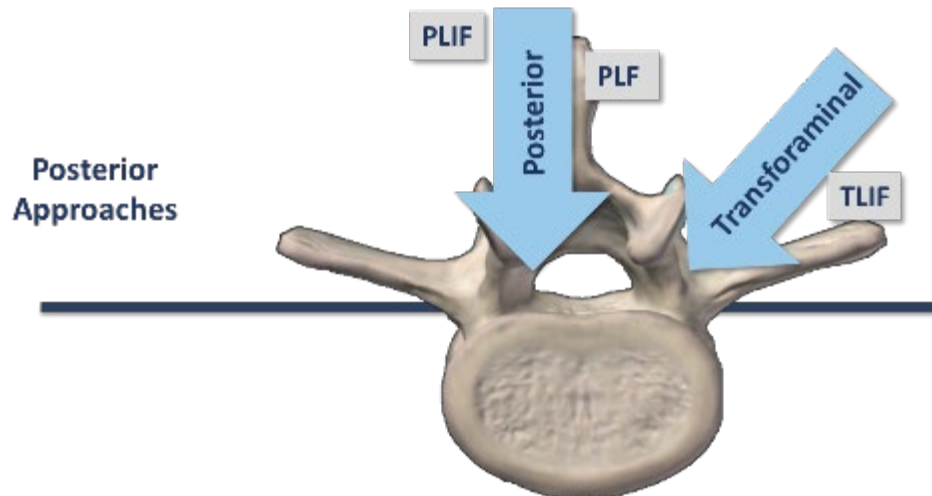
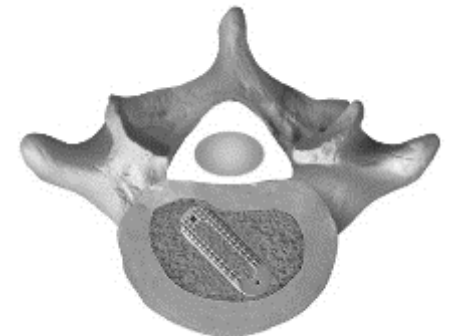
Hardware components

- Spacers – usually x2 per level
- Osteobiologic



### Transforaminal Lumbar Interbody Fusion (TLIF)

- Spacer – usually x1 per level
- Osteobiologic



Source:

*Orthopedic Network News*, Volume 32, Number 4, October 2021, <http://www.OrthopedicNetworkNews.com>

Globus Medical

# Posterior Approach – Non-Interbody Fusion

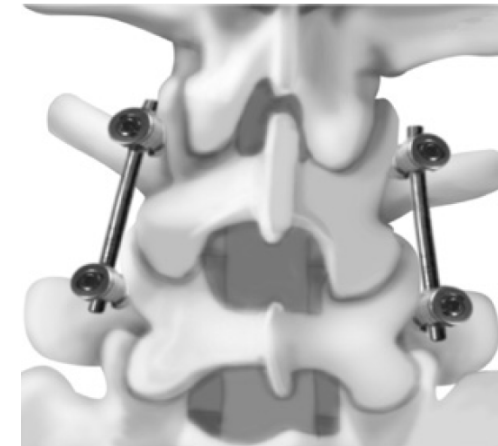
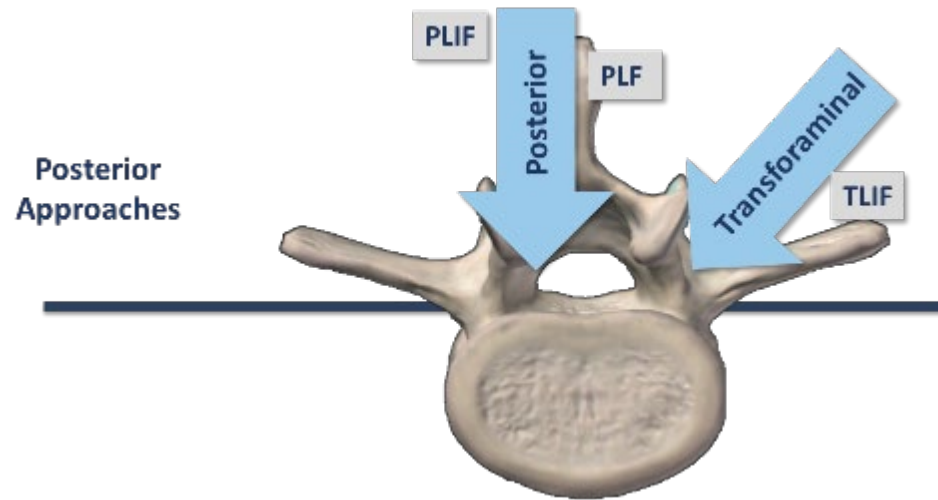
## Posterolateral Lumbar Fusion (PLF)

- Instrumented = using pedicle screws and rods
- Non-instrumented = osteobiologic only

Hardware components: 1 level

- Pedicle screws (4)
  - 2 screws added to each additional level
- Rods
- Set screws (1 for each screw)
- Osteobiologic

Each additional level includes 2 more pedicle screws for bilateral fusions





The background of the slide is a blurred photograph of a hospital hallway. In the foreground on the left, an IV drip chamber and tubing are visible, hanging from a stand. The hallway in the background shows people walking, but they are out of focus. The overall color scheme is a cool blue.

# Osteobiologics

## | Placement of Osteobiologics

Most common locations for placement of bone graft:

- Filling space in interbody spacer
- Backfilling the disk space (PLIF and TLIF most commonly)
- Posterolateral Fusion – posterolateral gutters over transverse processes

# Osteobiologic Graft Types

## Autograft – Graft from same individual as recipient

- Iliac crest bone graft – Gold standard
- Local bone from decompression, decortication for fusion



## Allograft – Bone from the same species (cadaveric donor)

- Structural – bone chips/chunks
- Demineralized bone matrix (DBM)
- Cell based allograft



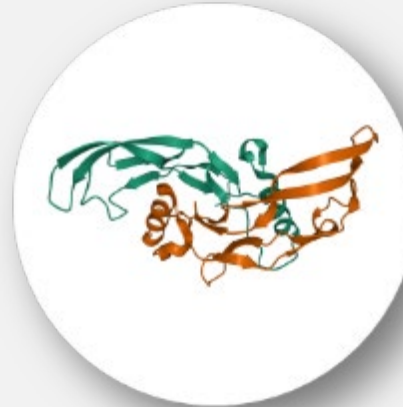
## Synthetic – Graft made from calcium compounds found in mineral phase of bone

- Zero risk of donor disease transmission
- Long shelf life



## Growth factors and peptides – Proteins or protein fragments used to provide an osteoinductive signal to cells

- Highly osteoinductive
- RCT data for FDA approval



Sources:

Operative Neurosurgery: [July 2021 - Volume 21 - Issue Supplement 1 - p S2-S9](#)

Images: iStockphoto; Bioventus



# Osteobiologics: Properties of Action



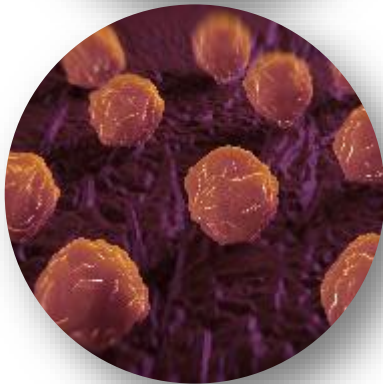
## Osteoconduction

**Scaffold** to support new bone formation  
(bone cannot grow in an empty space)



## Osteoinduction

**Signals** to initiate the bone healing cascade  
(this comes from growth factors - body's chemical messengers)

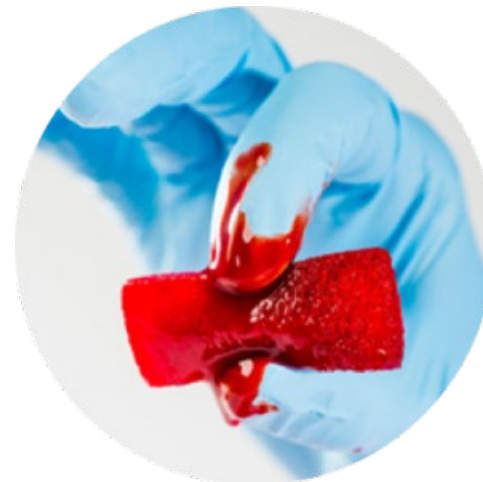


## Osteogenesis

**Cells** for direct bone formation, including  
mesenchymal stem cells and osteoprogenitor cells  
(new bone production)

## Osteobiologic Formats – Handling Characteristics

- Often heard from surgeons: *“I like XYZ biologic because it handles well...”*
- What does this mean? And, why does one osteobiologic work for one surgeon and not another?
- Every format is designed to do a different job. Examples (DBM):
  - Putty – moldable to fit a void
  - Fiber – holds graft together during implantation
  - Cancellous sponge strip – compresses and rebounds
  - Gel – push through small opening from a syringe



## | A Simple Formula for Osteobiologics Preferences\*

Graft type preference  
(Autograft, Allograft, Synthetic, etc.)

+

Biologic “properties of action” needed  
(Osteoconductive, Osteoinductive, Osteogenic)

+

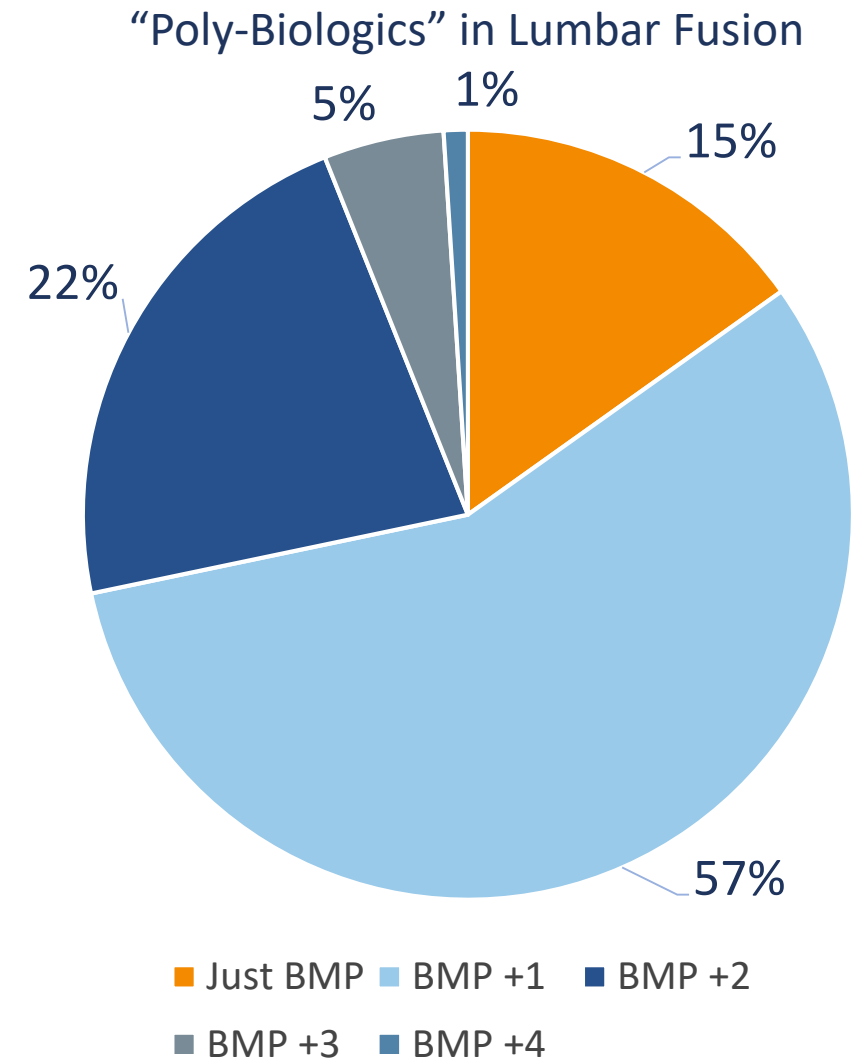
Handling characteristics needed  
(What does the surgeon need the graft to do during the case?)

\*There can be MANY more considerations – these are some of the basics

## Poly-Biologics

Commonly seen – use of multiple biologics

- Surgeon's own “cocktail”
- What's in the mix based on:
  - Desired biologic “properties of action”
  - Handling characteristics



Source:  
Orthopedic Network News, Volume 32, Number 4, October 2021, <http://www.OrthopedicNetworkNews.com>

## Commonly Used Categories of Bone Graft Material With Properties of Action

Product type		Price/cc <sup>1</sup>	Osteoconductive	Osteoinductive	Osteogenic
Bone Chips		\$11	✓		
Demineralized Bone Matrix (DBM)		\$60	✓	✓	
Synthetic Bone Void Fillers		\$94	✓		
Cellular Bone Allograft		\$538	✓	✓	✓
Growth Factors & Peptides		\$887	✓	✓	

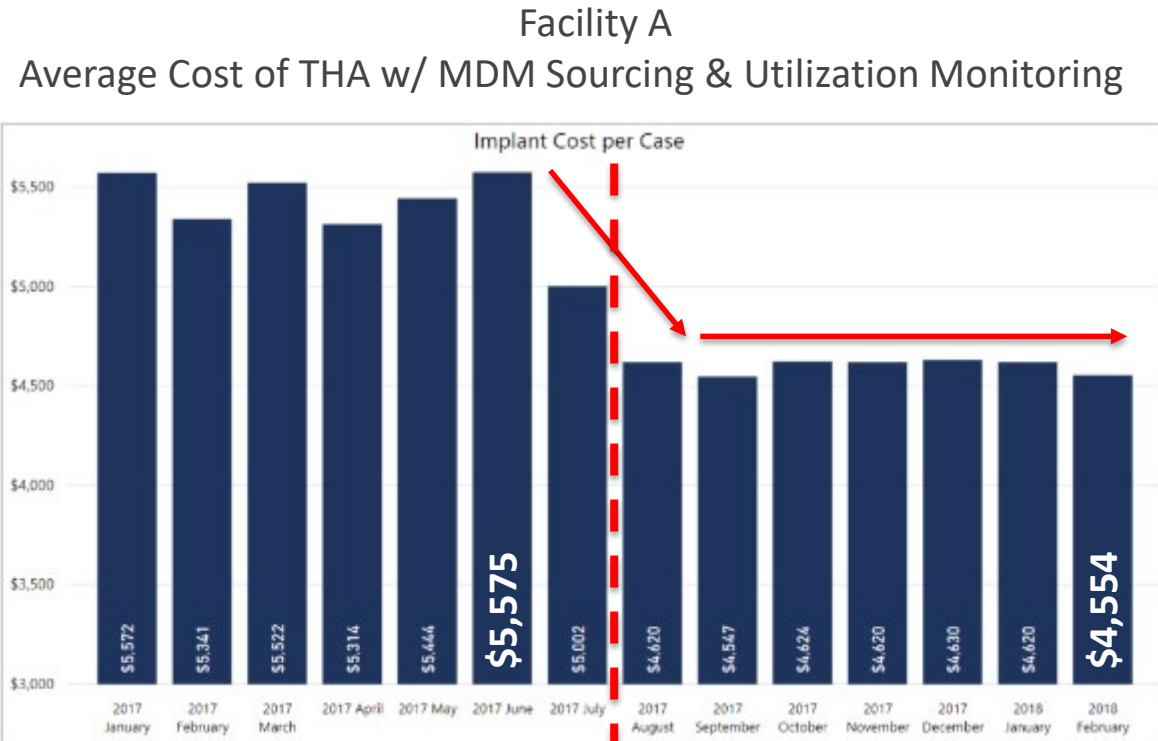
Sources:

Orthopedic Network News, Oct 2021

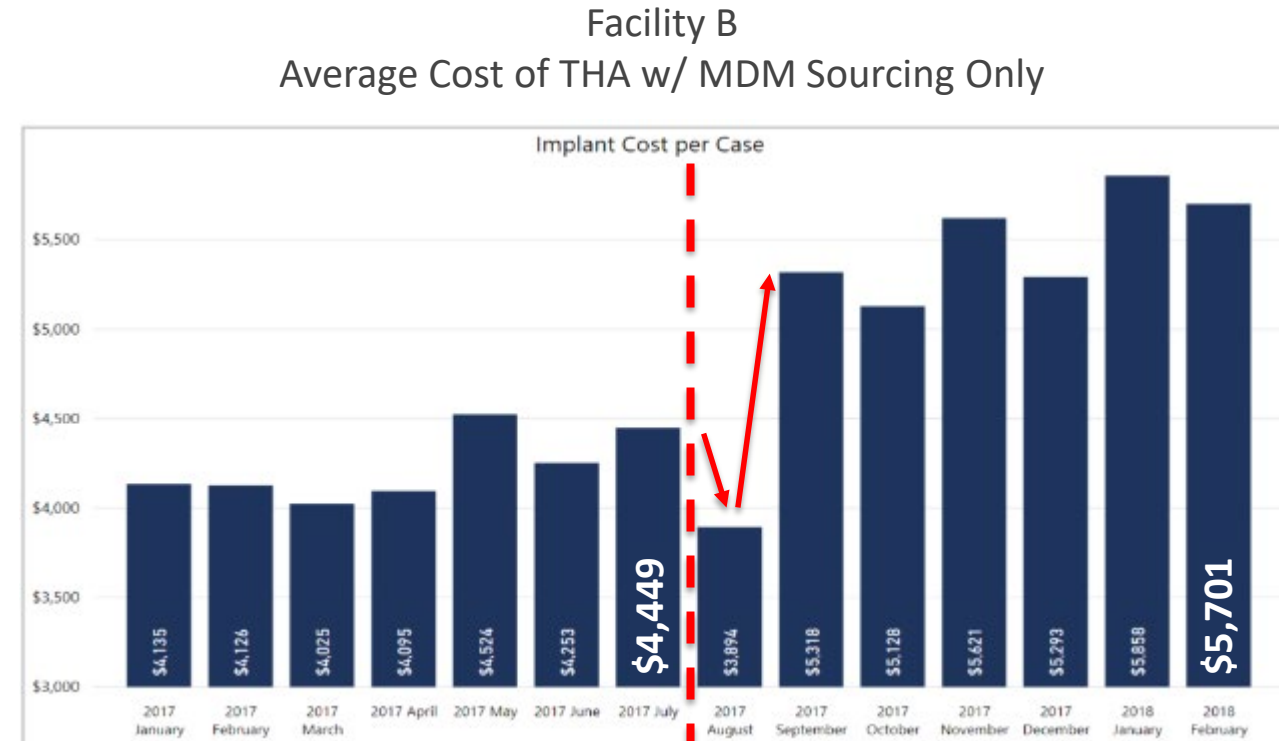
<https://www.mdpi.com/2227-9059/7/4/75/htm>

# Utilization Savings Opportunities

# Utilization Monitoring to Prevent Savings Erosion Post-Contract Launch



- Continuous monitoring allows facilities to maintain case cost reductions achieved in sourcing
- Vendor knowledge of monitoring pre-empts abuse of on-contract premium products






- Without utilization monitoring, vendors can quickly erase cost savings by using on-contract premium products

New Contracts Effective Date – Aug 2017





## Construct Variation in Similar Cases – 1 Level ACDF Example\*

### Example 1

	PEEK Spacer	\$1,021
	Cervical Plate + 4 screws	\$1,525
	1cc DBM	\$160
<b>Total</b>		<b>\$2,706</b>

### Example 2




	Ti Stand alone interbody + 2 screws	\$4,285
	1.2cc Cell-Based Allograft	\$549
<b>Total</b>		<b>\$4,834</b>

\* Potential examples from *Orthopedic Network News*, Volume 32, Number 4, October 2021, <http://www.OrthopedicNetworkNews.com>






## Right Sizing Osteobiologics - 1 Level ACDF Example

### Example 1

	PEEK Spacer	\$1,021
	Cervical Plate + 4 screws	\$1,525
	1cc Cell-Based Allograft	\$349
<b>Total</b>		<b>\$2,895</b>

### Example 2

	PEEK Spacer	\$1,021
	Cervical Plate + 4 screws	\$1,525
	5cc Cell-Based Allograft	\$1,801
<b>Total</b>		<b>\$4,347</b>

# | Challenges: Managing Spine & Osteobiologics Utilization

## Challenges

## Strategies

Multiple spine fusion procedures



Focus on the most common procedures first

You can have excellent contract pricing but high average case costs



Understand the options being used at your facility. Look for outliers in usage by facility and physician

Many biologics vendors and options



Work with physicians to understand their preferences for key procedures. Be sure to communicate costs where appropriate

Procedures can be 1 level to many levels



Be sure you are comparing like procedures. Coding only designates 1 level or multiple levels

# Example dashboard

Physicians  
**11**

Vendors  
**30**

Procedures  
**841**

Total Spend  
**\$8.4M**

Date of Surgery

7/1/2017 6/30/2018

Division

All

Market Name

All

Facility Name

Facility S

Physician Last Name

All

Clinical Procedure

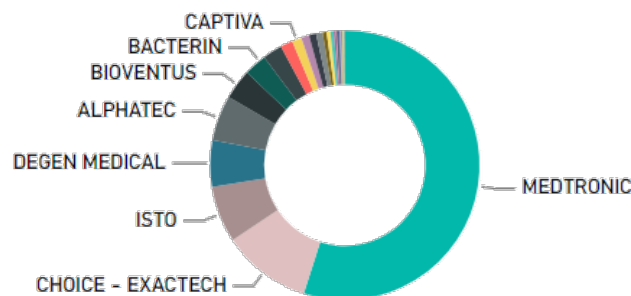
All

## Spine and Osteobiologic Spend

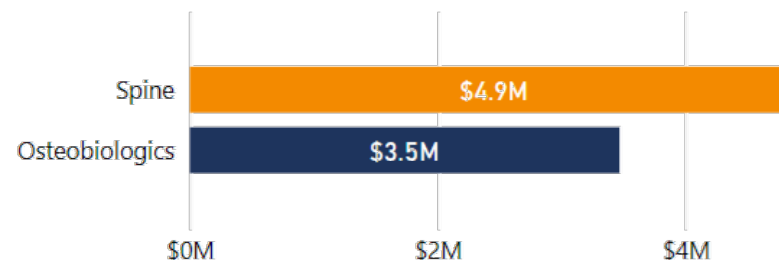
October 2016 - June 2018

Year	Quarter	Procedures
2017	Qtr 3	185
	Qtr 4	240
2018	Qtr 1	208
	Qtr 2	208

Total Spend by Vendor



Total Spend by Spine/Osteo



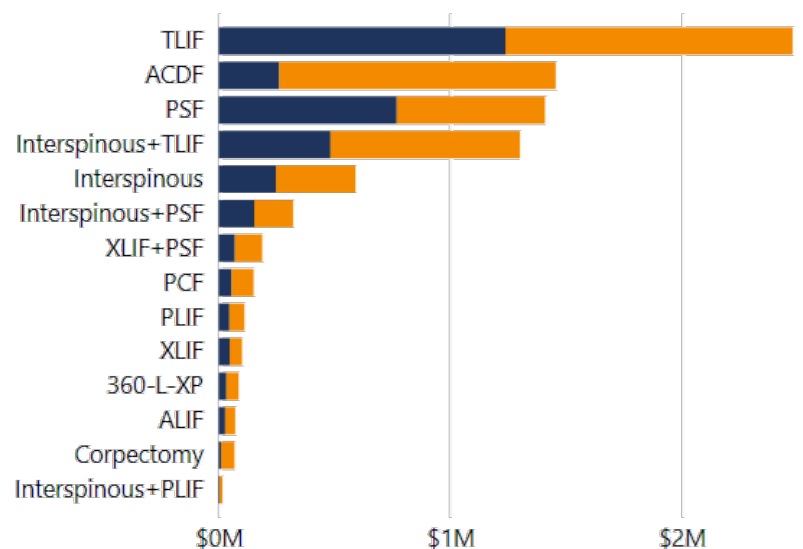
Total Spend by Facility Name

● Osteobiologics ● Spine



Total Spend by Clinical Procedure and Spine/Osteo

● Osteobiologics ● Spine



Clinical Procedure	Procedures
ACDF	362
TLIF	159
PSF	126
Interspinous+TLIF	70
Interspinous	37
Interspinous+PSF	21
PCF	15
XLIF+PSF	14
XLIF	11
Corpectomy	10
PLIF	6
ALIF	4
360-L-XP	3
360-L-AP	1
Interspinous+PLIF	1
TDR-C	1
<b>Total</b>	<b>841</b>

## Example

### ACDF – 1 level

- Most cervical spacers use 1.0cc to 1.5cc of bone graft
- Cases below show 13cc and 11cc
- Worth investigating further

Date of Surgery

7/1/2017 6/30/2018

Procedures

17

Implant Cost Per Case

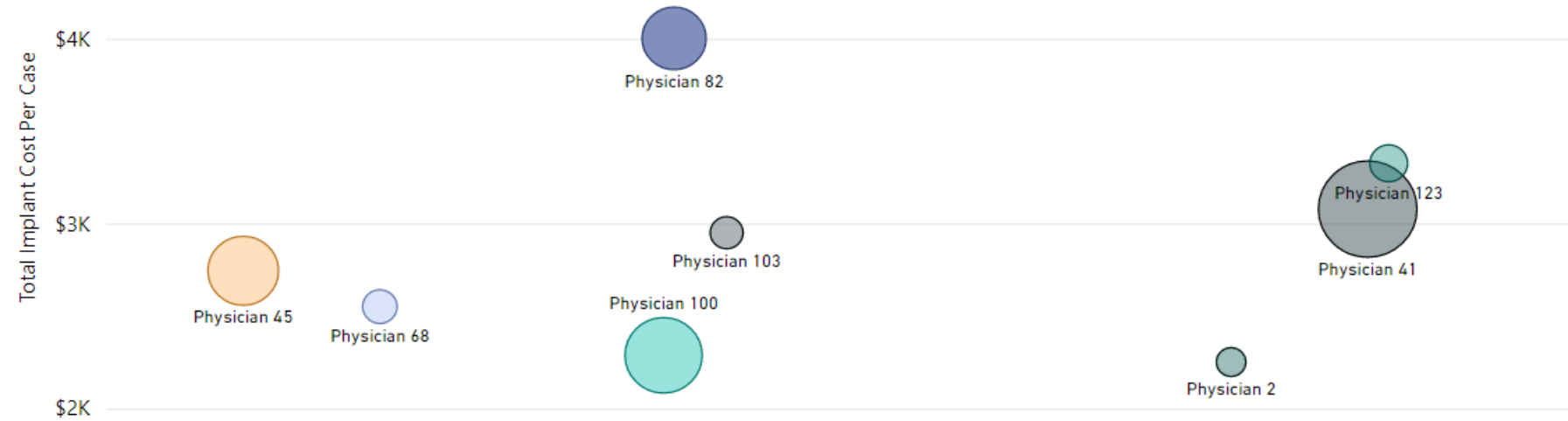
\$4,002

Div. Implant Cost Per Case (all date range)

\$2,655

Year	Quarter	Procedures
2017	Qtr 3	3
	Qtr 4	6
2018	Qtr 1	4
	Qtr 2	4

Average Implant Cost per Case by Physician



Proxy Pt Num	Physician Last Name	Proc - Levels	Spine/Osteo	Clinical Platform	Vendor	Product Name	cc/ml	Wasted Qty	Used Qty	Unit Cost	Total Spend
6720	Physician 82	ACDF-1	Osteobiol...	Allograft - Specialized			2.7	0	3		
				Synthetic - Bioactive			5.0	0	1		
			Spine	Cervical Plate - 1 Level				0	1		
				Cervical Spacer				0	1		
				Cervical Plate Screw				0	4		
				Total							
	6913	Physician 82	ACDF-1	Spine	Cervical Plate - 1 Level				0	1	
Cervical Spacer								0	1		
Cervical Plate Screw								1	4		
Osteobiol...				Allograft - Specialized			2.7	0	2		
				Synthetic - Bioactive			5.0	0	1		
				Total						1	

# | Summary

## Pulling It All Together

- Focus on the most common procedures. Spine cases can be complicated and done many different ways
- Compare like cases when considering spine costs
  - Compare same procedure types (e.g. ACDF vs ACDF)
  - Compare same number of levels
- Look to osteobiologics first for potential waste
- Surgeons are the most valuable ally for utilization savings
  - Be sure they understand the true cost differences between products
- **Tools like dashboards from Medical Device Management (MDM) can greatly reduce the work involved**

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# Thank you...

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