

APRIL/2-4/2009  
SÃO PAULO, S.P., BRAZIL



## DYNAMIC LUMBAR PEDICLE SCREW/ROD- BASED STABILIZATION DEVICES

### EVIDENCE - BASED MEDICINE

JEFFERSON WALTER DANIEL

DISCIPLINA DE NEUROCIRURGIA DA FACULDADE DE CIÊNCIAS  
MÉDICAS DA SANTA CASA DE SÃO PAULO

## DYNAMIC PEDICLE STABILIZATION DEVICE HISTORY

- **1992: GRAF LIGAMENT SYSTEM**

GRAF H: Lumbar instability:  
surgical treatment without fusion.  
**Rachis 412: 123-37, 1992.**



## DYNAMIC PEDICLE STABILIZATION

### BIOMECHANICAL CONSIDERATIONS

- PROTECTION AND RESTORATION OF FACETS AND DISCS;
- COMBINATION WITH DISC ARTHROPLASTY;
- REDUCTION OF CONSTRUCT FAILURE IN THE AGING SPINE;
- PREVENTION OF FUSION RELATED SEQUELAE (ADJACENT-LEVEL DISEASE, PSEUDOARTHROSIS, FLAT BACK);
- INCREASED ANTERIOR LOAD SHARING TO AUGMENT INTERBODY FUSION;
- CONTROLLED MOTION AFTER LAMINECTOMY.  
KHOUEIR P et al.: Classification of posterior dynamic stabilization devices.  
**NEUROSURG FOCUS 22(1): 1-8, 2007.**



## DYNAMIC PEDICLE STABILIZATION

### CLASSIFICATION FOR POSTERIOR DYNAMIC STABILIZATION DEVICES

CLASSIFICATION	INDICATION	DEVICE
INTERSPINOUS SPACER DEVICES	NEUROGENIC CLAUDICATION	WALLIS, X STOP, DIAM, OTHERS
PEDICLE SCREW/ROD-BASED DEVICES	UNLOAD DISCS & FACETS, FUSION, PREVENT ADJACENT SEGMENT DISEASE, CONTROL MOTION	GRAF LIGAMENT, <b>DYNESYS, COSMICS, ALADYN</b>
TOTAL FACET REPLACEMENT SYSTEMS	FACET DISEASE, PREVENT ADJACENT SEGMENT DISEASE, CONTROL MOTION	TFAS, TOPS, STABILMAX NZ

KHOUEIR P et al.: Classification of posterior dynamic stabilization devices.  
**NEUROSURG FOCUS** 22(1): 1-8, 2007.

# DYNAMIC PEDICLE STABILIZATION

## EVIDENCE - BASED MEDICINE

### QUESTION STRUCTURE

- P PATIENT (ALL DEGENERATIVE SPINAL DISEASES);
- I INTERVENTION (DYNAMIC STABILIZATION);
- C COMPARISON OR CONTROL;
- O OUTCOME.

### REASON OF CONTROVERSY

- ABSENCE OF COMPARISON.

# DYNAMIC PEDICLE STABILIZATION

## EVIDENCE - BASED MEDICINE

### LITERATURE ANALYSIS (MARCH/07/2009)

- METHOD

  - PubMed

- MeSH

  - LUMBAR VERTEBRAE and SURGERY:

  - ITEMS: 4557

- LIMITS

  - ENGLISH, HUMAN, CORE CLINICAL JOURNAL:

  - ITEMS: 448

# DYNAMIC PEDICLE STABILIZATION

## EVIDENCE - BASED MEDICINE

### LITERATURE ANALYSIS (MARCH/07/2009)

- SEARCH
  - LUMBAR VERTEBRAE and SURGERY and DYNESYS (LINKS):
  - ITEMS: 151 RELATED ARTICLES



# DYNAMIC PEDICLE STABILIZATION

## EVIDENCE - BASED MEDICINE

### LITERATURE ANALYSES (MARCH/07/2009)

- CLINICAL STUDY CATEGORY
  - RANDOMIZED CONTROLLED TRIAL:
    - ITEMS:302
    - ITEMS FOR POSTERIOR DYNAMIC STABILIZATION
- SYSTEMATIC REVIEWS
  - SYSTEMATIC SURVEY:
    - ITEMS:121
    - ITEMS FOR POSTERIOR DYNAMIC STABILIZATION



# DYNAMIC PEDICLE STABILIZATION

EVIDENCE - BASED MEDICINE

## LITERATURE ANALYSIS

- CLASSIFICATION OF EVIDENCE ON THERAPEUTIC EFFECTIVENESS
  - CLASS III
- RECOMMENDATION
  - OPTION
- INDICATION OF USE
  - UNCLEAR CLINICAL CERTAINTY

# DYNAMIC PEDICLE STABILIZATION

## FEDERAL FOOD AND DRUG ADMINISTRATION

[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [A-Z Index](#)

### **Guidance for Industry and/or FDA Reviewers/Staff**

Guidance Document for the Preparation of IDEs for Spinal Systems

Document issued on: January 13, 2000

This document supersedes document the preliminary background document for the future development of a spinal IDE guidance dated 8/26/98.

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Orthopedic Devices Branch  
Division of General and Restorative Devices  
Office of Device Evaluation

## DYNAMIC PEDICLE STABILIZATION

### FEDERAL FOOD AND DRUG ADMINISTRATION

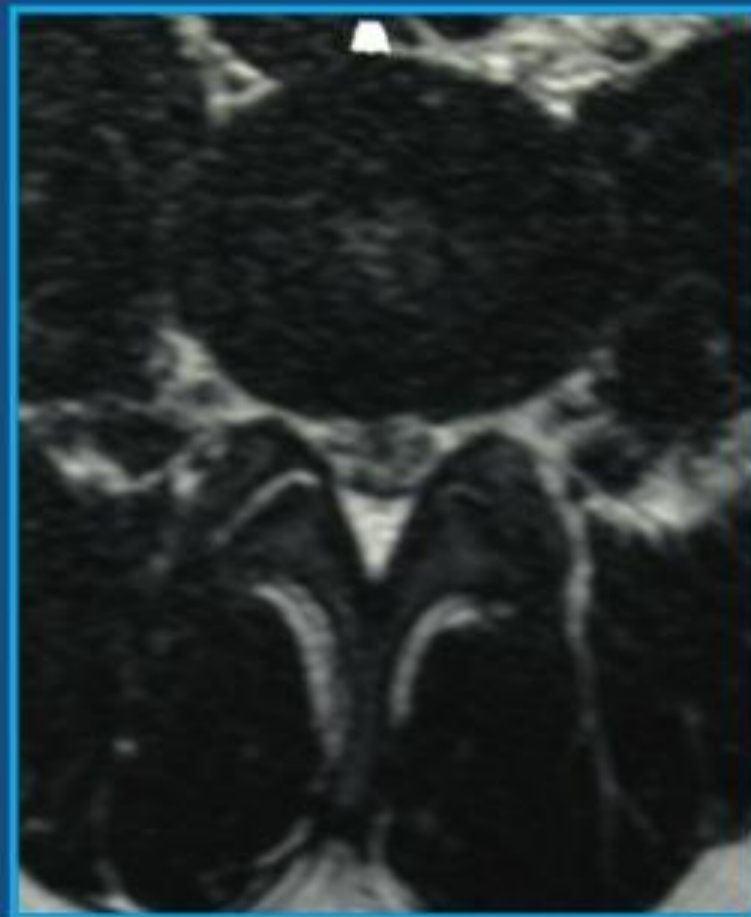
- 4.1 Lumbar Degenerative Disc Disease (DDD)
  - **instability** as defined by 3mm translation or 5° angulation;
  - **osteophyte** formation of facet joints or vertebral endplates;
  - decreased **disc height**, on average by >2mm, but dependent upon the spinal level;
  - **scarring/thickening** of ligamentum flavum, annulus fibrosis, or facet joint capsule;
  - **herniated** nucleus pulposus;
  - **facet joint** degeneration/changes; and/or vacuum phenomenon.



## DYNAMIC PEDICLE STABILIZATION

### PATHOGENESIS: PHASE 1 - DYSFUNCTION

KIRKALDY-WILLIS et al.: ...pathogenesis of lumbar spondylosis... **SPINE** 3: 319-28, 1978.



## DYNAMIC PEDICLE STABILIZATION

### INDICATIONS OF USE

#### INCLUSION CRITERION

- SKELETALLY MATURE;
- SEGMENT INSTABILITY INFERIOR TO 3 mm;
- ABSENCE OF OSTEOPHYTES ON FACET JOINTS;
- PRESERVED DISC HEIGHT;
- DISC SPARING;
- PREVENTION OF ADJACENT-LEVEL DEGENERATION.

#### EXCLUSION CRITERION

- SCOLIOSIS;
- SPONDYLOLISTHESIS/  
SPONDYLOLSIS;
- VERTEBRAE  
METASTASES;
- TRAUMA;
- PSEUDOARTHROSIS;
- SECOND SURGERY;
- SPINAL SEGMENT FUSION.

## DYNAMIC PEDICLE STABILIZATION CONCLUSIONS

- INSUFFICIENT EVIDENCE TO RECOMEND A TREATMENT STANDARD OR GUIDELINE;
- OPTIONAL SURGICAL METHOD;
- INDICATED IN THE DEGENERATIVE DYSFUNCTIONAL DISC AND FACET PHASE.