# Core Messaging

**1. VMA provides more reliable data than the standard flexion/extension x-ray test in the assessment of spinal motion to detect instability [1], which allows for more informed surgical decisions.**

CLAIMS:

A. The VMA has been shown to help avoid errors that can occur in up to 1/3rd of standard flexion/extension studies [2].

B. Because the VMA involves device-assisted patient bending, it offers a more controlled, thorough, and repeatable assessment of spinal motion to detect instability.

C. The VMA's advanced image processing software returns measurements that have been proven to be 73% more accurate and 58% more repeatable than today's manual image processing technique [3].

**2. VMA detects spinal motion to detect instability, with greater sensitivity than the standard flexion/ extension x-ray test, allowing surgeons to identify previously unrecognized lumbar radiographic instability.**

CLAIMS:

A. With an increase in the detection of lumbar radiographic instability from a 5% prevalence (for today's standard flexion/extension test) to a 12% prevalence (for VMA), VMA has been proven to be more sensitive [4].

B. However, VMA testing was shown to offer the same 98%+ specificity as today's test in detecting lumbar radiographic instability.

C. This data derives from a Level I evidence study involving over 1,100 subjects and defined lumbar radiographic instability as 5.3 mm or more of dynamic slip [5].

**3. Conversely, when a surgeon uses VMA to rule out lumbar radiographic instability, it can help increase a surgeon's confidence in choosing a more conservative surgical approach.**

CLAIMS:

A. For patients with spondylolisthesis, VMA has been shown to confirm lumbar radiographic stability in more than 80% of evaluated patients, whereas the flex/ex technique has not been shown to be effective in ruling out instability [6].

B. In patients with low grade lumbar spondylolisthesis, ruling out lumbar radiographic instability can provide surgeons with more comfort to select a less aggressive surgical approach (Rampersaud, YR. *J Can Chir Assoc*, 2014) [7].

**4. VMA is clinically tested technology that was validated in the largest Level 1 Evidence study of its kind, unlike the standard flexion/extension x-ray test, which produces highly variable results.**

CLAIMS:

A. VMA's performance was validated in a recently completed, multi-site study of 878 consecutive spine surgery patients and 234 pain free healthy volunteers. This study was the most comprehensive, well-designed study of its kind reported in this category [8].

B. The study most-often cited as they key clinical validation of today's test reported: *"We believe that **no useful information can be derived from [the flexion/extension]** procedure, especially in relation to the need for surgical fusion."* – Dvorak & Panjabi (*Spine*, 1991) [9].

See end of document footnotes and full references. Rev 1050 - 1.0 (07/2015)

# Supporting Messaging

**S1. Radiation Dose to Patient: "Overall, the VMA offers an improved risk-benefit ratio for the patient, because it provides a larger, higher quality set of diagnostic data at a lower radiation exposure risk."**

> CLAIM: VMA diagnostic measurements are more expansive, accurate, and repeatable as compared to the flex/ex. As a fluoroscopy-based test, the VMA presents opportunities to reduce radiation exposure to the patient as compared to plain x-rays, which involve a much higher per-image dose of radiation.

**S2. Workflow/Time for Radiologist: "VMA studies can be read much quicker than standard plain x-ray flexion/extension studies.**

> CLAIM: VMA automates measurements that, for a standard flexion/extension x-ray, have to be done manually by the radiologist. Radiologists have reported that VMA reads can be done in about 2/3rds of the time required to read a standard flexion/extension x-ray study.

**S3. Value to the Radiologist & Surgeon: "With no additional effort, the VMA allows radiologists to provide an unprecedented level of personalization for referring spine surgeons. This enables better coordination between radiologists and surgeons, and ultimately makes radiologist reads more useful to the surgeon."**

> CLAIM: VMA read reports can automatically factor in each surgeon's own definition of instability in terms of when evidence of instability is detected, and the system even lets you use different language describing instability depending on each surgeon's preference.

**S4. Workflow/Time for Radiation Technologist:** "VMA adds no more than 5 minutes to a 15-minute flex/ex while providing a much larger set of images and data to help with patient diagnosis."

**S5. Ease of Integration: "VMA typically requires no new staff or imaging machines and a day or two of training"**

> CLAIM: VMA testing requires a C-arm and radiologic technologist trained in using it. Since most spine clinics and hospitals have both, typically no new staff and imaging is required to begin offering VMA testing. In general, it takes about 12 scans for a rad tech to be trained.

**S6. Connectivity: "VMA can automatically push images and patient reports to any PACS or EMR system, or the hosted online VMA system can be used by clinicians to retrieve report and access images.** (note: no associated claims) Rev 1050 - 1.0 (07/2015)

**Footnotes:** The following footnotes MUST be included when Core Messaging is used.

1. Based on data submitted to FDA demonstrating improved accuracy and repeatability for the VMA relative to the standard flexion/extension x-ray test.

2. Data on file with Ortho Kinematics, Inc. A retrospective consecutive case study of 32 cases in which patients received standard flex/ex testing with a radiological read report plus VMA testing detected significant errors, usually omissions, in 14 (or 43%) of cases.

3. Data on file with Ortho Kinematics, Inc. Measurement repeatability (inter-observer disagreement) was measured from an analysis of 62 clinical cases, which found mean absolute disagreement for VMA measurements was 0.3°/0.5 mm verse 3.4°/1.2 mm for ruler and protractor measurements (lumbar) and 1.1°/0.6 mm for VMA measurements verse 4.6°/2.2 mm for ruler and protractor measurements (cervical). The VMA's increase repeatability among these various parameters ranged from 58% to 91%. The average accuracy error (measured via cadaveric studies) of VMA sagittal plane intervertebral rotation measurements was assessed to be 0.6 degrees, while the ruler and protractor method has been reported in the literature (Zhao, 2003) to produce an average accuracy error of 2.2°, which represents a decrease in the average accuracy error of 73%.

4. Davis, RJ, et al. "Measurement Performance of a Computer Assisted Vertebral Motion Analysis System." International Journal of Spine Surgery (2015). Vol. 9. Article 36.

5. Data on file with Ortho Kinematics, Inc. The recently published International Journal of Spine Surgery (see footnote 4) reported the sensitivity and specificity of the VMA in detecting lumbar radiographic instability (defined as dynamic slip of 5.3 mm, or 15% of vertebral body depth) head-to-head vs. standard flex/ex testing based on a dataset of 509 patients and 73 asymptomatic controls. This dataset was expanded to include 878 patients and 234 asymptomatic controls. The analysis of this larger dataset confirmed the same sensitivity and specificity measurements as compared to the measurements reported in the recently published study.

6. Data on file with Ortho Kinematics, Inc. An analysis of 878 patients found that among patients with at least 4.4 mm or more of listhesis (a slip between vertebral bodies visible in a single radiographic view) at a lumbar level, more than 80% of these had dynamic slip (slip between two vertebral bodies as measured between two radiographic views) of less than 4.5 mm. The flex/ex, due to its well-document high measurement variability, has been shown to be unable rule out the possibility of excessive motion (Deitz, 2010).

7. Rampersaud, YR, et al. "Health-related quality of life following decompression compared to decompression and fusion for degenerative lumbar spondylolisthesis." The Journal of the Canadian Chiropractic Association, 57(4), 2014.

8. At 1,100+ total patients, the size of this study exceeds the sizes of other case-control studies of the prevalence of lumbar radiographic instability and had a design consistent with the standards for Level I evidence as it involved consecutive case enrollment and a comparison in each subject of the VMA vs. the current reference standard. The three next largest studies in this category are: n=191 (Wong, 2004), n=168 (Abbott, 2005), and n=142 (Dvorak & Panjabi, 1991).

9. Dvorak, J., Panjabi, M. M., Novotny, J. E., Chang, D. G., & Grob, D. "Clinical validation of functional flexion-extension roentgenograms of the lumbar spine". Spine, 16(8), 943-950, 1991. Rev 1050 - 1.0 (07/2015)

**References:** Full references for studies mentioned in claims


Abbott, J. H., McCane, B., Herbison, P., Moginie, G., Chapple, C., & Hogarty, T. (2005). "Lumbar segmental instability: a criterion-related validity study of manual therapy assessment". *BMC Musculoskeletal Disorders*, 6(1), 56.

Deitz AK, Breen AC, Mellor FE, Teyhen DS, Wong KWN, Panjabi MM. "Kinematics of the aging spine: A Review of Past Knowledge and Survey of Recent Developments, with a Focus on Patient-Management Implications for the Clinical Practitioner", In *the Comprehensive Treatment of the Aging Spine: Minimally Invasive and Advanced Techniques* (eds. by Yue, Guyer, Johnson, Khoo, Hochschuler), Elsevier, 2010.

Dvorak, J., Panjabi, M. M., Novotny, J. E., Chang, D. G., & Grob, D. "Clinical validation of functional flexion-extension roentgenograms of the lumbar spine". *Spine*, 16(8), 943-950, 1991.

Rampersaud, YR, et al. "Health-related quality of life following decompression compared to decompression and fusion for degenerative lumbar spondylolisthesis." The Journal of the Canadian Chiropractic Association, 57(4), 2014.

Wong KWN, Leong KCY, Chan M, Luk KDK, Lu WW. "The flexion-extension profile of lumbar spine in 100 healthy volunteers". *Spine*, Vol 29(15), pp 1636-1641, Aug 2004.

Zhao KD, Yang C, Zhao C, Stans AA, An KN. "Assessment of noninvasive intervertebral motion measurements in the lumbar spine*". J. Biomechanics*, Vol. 190, Rev 2, 1990.