Health Technology Assessment
Standing, Weight-Bearing, Positional, or Upright Magnetic Resonance Imaging
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Background

Magnetic resonance imaging (MRI) is an accepted method for diagnosis of many conditions. Evidence of benefit of MRI over other forms of imaging or diagnostic testing is demonstrated for a number of conditions including various cancers as well as some musculoskeletal conditions and injuries.

The standard method of MR imaging is performed with a patient in a supine or recumbent position. Traditionally the orientation and design of MR imaging systems requires that patients be horizontal and stationary when scanned.

Somewhat recent developments in imaging technology include systems able to image the body in simulated weight-bearing (axial loading), weight-bearing, positional or kinetic situations. Computed tomography (CT) and MR imaging systems or methods capable of producing images in such conditions are described in peer-reviewed scientific literature, though evidence showing the degree to which such methods are safe, effective, and accurate for use as clinical diagnostic tools is unclear.

Weight-bearing, standing or positional MR Scanners

Innovation in MRI scanner design has led to availability of imaging in weight-bearing positions. Standing or sitting MRIs may be performed with patients in different positions (eg. Extension, flexion, neutral) for comparison of anatomy in various positions. It is theorized that such positional imaging may provide information not available from methods currently used (supine MRI) and that this added information will lead to improved diagnosis, treatment and outcomes. At least one manufacturer offers MR scanners that can be used for weight-bearing imaging (FONAR Indomitable). These open configuration scanners utilize vertical magnet orientation to allow vertical access to the magnetic field and are mid-field strength imagers (0.6 tesla).

Axial-loading, the application of a force on a subject’s body to simulate weight-bearing, has been studied as a means of capturing images in traditional MR or CT scanners (traditional scanners are horizontal in orientation).

Sitting MR scanner technology is also used to study effects of positional imaging for diagnostic use.

Regulatory Information

The US Food and Drug Administration granted 510(k) approval for marketing of the Indomitable Magnetic Resonance Imaging Scanner to the FONAR Corporation in October 2000 (K002490). The scanner is determined to be substantially equivalent to legally marketed predicate devices available prior to May 28, 1976. The Indomitable MRI scanner is currently marketed by the trade names Upright MRI™, Standing Ovation™, Position MRI™, and pMRI™.

Intended Use of the Device

"The intended use of the Indomitable MRI is to acquire and process nuclear magnetic resonance data (NMR) resulting in planar images of the internal structure of the head and body. These images may be diagnostically useful when interpreted by a trained physician. "[1]

Objective of this Review

To determine if there is adequate scientific evidence that demonstrates weight-bearing, standing, positional MRI to be a safe, effective and medically necessary diagnostic test compared to the current standard of care that is supine MRI.

Search Strategy

A Seattle area firm contacted the department to obtain coverage of this technology to treat injured workers in Washington State. The department developed and uses a Medical Technology Screening form (appendix 2) to provide guidance to individuals or companies seeking coverage for new or emerging health technologies including diagnostic tests. This form was sent to the firm and their reply included scientific papers, abstracts from scientific sessions, book chapters and additional references. Seventy-two (72) references were provided.

In addition to requesting and receiving information from this firm, Pubmed and Trip Databases were searched using the terms MRI, FONAR, upright, standing and weight-bearing in various combinations. The bibliographies of relevant papers were also scanned. Limits were used to search for English language publications of human studies. No restriction was placed on publication year or study design. Websites of the FONAR Corporation (www.Fonar.com and www.UprightMRI.com) were reviewed for appropriated research paper references.
A total of 74 papers, abstracts or book chapters were considered for this review.

Studies are included where imaging in vertically open MRI scanners is performed to assess weight-bearing imaging techniques. Not included are abstracts from scientific meetings, review papers and case reports or studies that are not relevant to understanding the diagnostic accuracy, effectiveness, therapeutic decisions or patient outcomes when weight-bearing MRI is used.

Evidence Review

Zamani et al. (1998)[2] enrolled 30 patients in a small feasibility study to compare conventional MR images of the lumbar spine with "functional upright MRI" images. Five asymptomatic volunteers aged 20 to 30 (4 male, 1 female) and 25 consecutive patients aged 22 to 79 were examined. Of the 25 consecutive patients 11 were referred for conventional MRI and then recruited, 14 were referred by their physicians for functional (seated) MRI. No inclusion or exclusion criteria were cited. Two patients were reported to have had prior laminectomies.

Methods

All patients were imaged using a 0.5 Tesla open configuration GE MRI scanner (GE Medical Systems, Milwaukee, WI). Four volunteers and 11 recruited subjects underwent conventional MRI in the traditional, supine position. The remaining subjects did not undergo imaging in the conventional manner.

All subjects had lumbar spine scans with a 0.5 Tesla open-configuration GE Signa SP scanner in the upright configuration. Patients were scanned in a sitting position. For patients who had both types of scans, the studies were done within 2 consecutive days.

Results
Summary of results showed no appreciable change from supine to sitting position in posterior disk bulge or foraminal size for the 15 subjects scanned by both methods. In extension, an increase in posterior disk bulge was observed in 27% of subjects, apparently compared to the neutral position (not supine).

The authors report that no attempt was made to correlate symptoms with MR findings. The functional MRI axial images were of poor quality possibly due to the design of the surface coils, and sagittal images only were acquired in the upright configuration. Sagittal and axial images were acquired in the conventional scans.

Authors' Conclusions
The authors conclude that functional (sitting, standing) MRI may, in the future, be helpful to the occasional patient with disk protrusion/herniation or foraminal stenosis and equivocal conventional MR studies.

Wildermuth et al (1998)[3] compared quantitative measurements of the sagittal diameter of the lumbar dural sac obtained from positional MR imaging with those from functional myelography and assessed the influence of various positions on the dural sac and intervertebral foramina.

Subjects were a consecutive series of patients referred for lumbar myelopgraphy and were recruited for positional MR studies following completion of myelography.

Exclusion criteria:
a) MR imager not available within 1 week of myelography,
b) Patient refusal to participate,
c) Patient underwent surgery immediately,
d) Patient not mobile enough to travel on own to institution with open MR scanner.

Lumbar myelography was performed on outpatient basis in standard fashion with contrast injected at L2-3 or L3-4 unless previous findings indicated severe abnormalities at these levels.

MR Imaging was performed with a vertically open 0.5 Tesla GE system. Imaging performed with a flexible transmit-receive wraparound surface coil. Sagittal T2-weighted fast spin-echo MR imaging was chosen for this investigation. This sequence was performed with the patient in the supine position and then seated during flexion and extension.

Quantitative assessment of the diameter of the dural sac at each level in the lumbar intervetebral discs were made and compared between myelography and MRI, and between positions of MR images.

Qualitative assessment of forminal size was performed. The initial study plan was for quantitative assessment, but this was not possible due to scoliosis, motion artifacts in patients with severe pain and visible differences due to positioning between sequences. The qualitative scores were 1- normal segment, 2- slight foraminal stenosis and deformity of epidural fat, 3- marked foraminal stenosis with fat only partially surrounding exiting nerve root, 4- advanced stenosis.

Results
Forty patients were referred for lumbar myelography. Ten patients were excluded on the basis of exclusion criteria.

Indications for myelography referral were: preoperative planning (n=19) for spondylolysis with spondylolisthesis (n=5), instability (n=3), and segmental stenosis (n=11), persistent symptoms without diagnosis in four patients and difficult postoperative situations in seven patients including persistent symptoms without diagnosis (n=4), and recurrent symptoms of segmental stenosis (n=3).

Table 1: Mean sagittal diameters of the dural sac on myelograms and MR images in relation to body position.

	Supine Neutral			Upright Flexion			Upright Extension		
Intervertebral Space	Myelography	MR Imaging	R Value	Myelography	MR Imaging	R Value	Myelography	MR Imaging	R Value
L1-L2	14.0	14.3	0.97	14.9	14.3	0.91	14.5	14.0	0.96
L2-L3	13.0	12.7	0.97	13.5	13.2	0.86	13.3	12.8	0.90
L3-L4	11.5	11.4	0.96	12.8	12.5	0.91	11.6	11.5	0.92
L4-L5	12.0	11.2	0.93	12.9	12.5	0.94	11.9	11.6	0.96
L5-S1	12.1	11.6	0.90	12.5	12.6	0.94	12.3	12.1	0.81

Table 2: Positional MR imaging- Position dependence of sagittal diameter of the dural sac.

		P value	
Intervertebral Space	Supine versus flexion	Supine versus extension	Flexion versus extension
L1-L2	0.470	0.29	0.300
L2-L3	0.240	0.44	0.240
L3-L4	0.012	0.42	0.035
L4-L5	0.005	0.24	0.039
L5-S1	0.042	0.11	0.13

Table 3: Qualitative assessment of foraminal scores in various positions.

	Supine Neutral		Upright Flexion		Upright Extension	
Score	**Observer 1**	**Observer 2**	**Observer 1**	**Observer 2**	**Observer 1**	**Observer 2**
1	10	8	14	17	3	6
2	242	249	235	236	242	245
3	4	4	2	3	6	5
4	256	261	251	256	251	256

Table 4: Qualitative assessment of foraminal scores between various positions.

	Neutral versus flexion		Neutral versus extension		Flexion versus extension	
Change in Score	Observer 1	Observer 2	Observer 1	Observer 2	Observer 1	Observer 2
Higher	10	8	14	17	3	6
Same	242	249	235	236	242	245
Lower	4	4	2	3	6	5
Total	256	261	251	256	251	256

Authors' Conclusions

Lumbar myelography and positional MR imaging are comparable for quantitative assessment of sagittal dural sac diameters. In a selected patient population:

- Only small changes in sagittal diameter of the dural sac and foraminal size can be expected between various body positions,
- The information gained in addition to that from standard (supine) MR imaging is limited.

Schmid et al (1999)[4] evaluated physiologic changes in the cross sectional area of the spinal canal and neural foramina in 12 young asysmptomatic volunteers. Subjects were imaged in a 0.5 tesla open configuration MRI scanner (Signa Advanced SP GE) in neutral, upright flexed, upright extended and supine extended positions. The cross sectional area of the spinal canal and the thickness of the ligamentum flavum were measured at the L4-L5 level on axial images. The anteroposterior diameter of the spinal canal and cross-sectional areas of the neural foramina were measured on sagittal images from L1 to S1.

Results

Cross-sectional area of the spinal canal varied significantly between body positions (see table).

Mean Cross-sectional area of the spinal canal										
Paramete r	Mean Measure				Mean difference					
	Up Neutral	Up Flex	Up Ext	Sup Ext	Up Neu vs Up Flex	Up Neu vs Up Ext	Up Neu vs Sup Ext	Up Flex vs Up Ext	Up Flex vs Sup Ext	Up Ext vs Sup Ext
Lig. Flavum thickness (mm)	2.3	1.8	4.3	3.3	-0.5	2.0	1.0	2.5	1.5	1.0
p					NS	<0.0001	<0.0001	<0.0001	<0.0001	<0.0004
Spinal canal area at disc (mm^2)	240.7	268.0	224.1	235.8	11.3%	-6.9%	-2.0%	-16.4%	-12.0%	5.2%
p					<0.002	<0.03	NS	<0.0001	<0.0001	NS
Spinal canal area at pedicle (mm^2)	275.5	273.8	268.9	278.4	-0.6%	-2.4%	1.1%	-1.8%	1.7%	3.5%
p					NS	NS	NS	NS	NS	NS

Authors' Conclusions

In asymptomatic volunteers MR imaging shows position dependent changes in the spine. Extended positions best revealed important findings.

The clinical usefulness of this technique needs to be proven. Compared with asymptomatic volunteers motion artifacts will be a problem in patients with severe pain or in elderly patients.

Further studies are needed to investigate the value of positional MR imaging in patients with disc abnormalities of questionable clinical significance as commonly found with standard MRI.

Weishaupt et al. (2000)[5] identified and enrolled 36 patients after MR imaging of the lumbar spine (supine). Inclusion criteria were low back or leg pain for more than 6 weeks, unresponsive to non-surgical treatment and surgery not indicated or not urgent based on clinical findings. Patient age was between 20 and 50 years. Disk protrusion or extrusion without compression of neural structures was also required at one or more levels.

Conventional MR imaging was done with a 1.0 Tesla Siemens scanner. Positional MR imaging was performed with a 0.5 Tesla GE scanner in a seated position. Quantitative assessment of the cross-sectional area of the dural sac was performed by one author. Qualitative assessment by 2 radiologists included analysis of disk abnormalities, degree of nerve root compromise and foraminal size. If agreement was not reached a 3rd radiologist decided which diagnosis would be used. Pain was assessed with a visual analog scale following the positional MRI. Patients were asked to rate the pain experienced in flexion and in extension. The difference in flexion-extension pain scores was compared with morphologic differences.

Comparison of findings on conventional imaging to positional imaging was performed to evaluate whether positional imaging can show nerve root compromise not seen with conventional techniques. Blinding of results from conventional findings is not noted.

Results

Thirty patients were scanned in the positional manner. Six could not be scanned due to excessive pain. Changes in the cross-sectional area of the dural sac were found between the supine and seated positions. Patient characteristics are not reported in detail.

Seventy-six (76) intervertebral spaces at L2-3 through L5-S1 were analyzed. Quantitative differences in dural sac area were statistically significant between the supine neutral and seated extension positions (9.6%, $p<0.001$) as well between seated flexion and extension positions (9.4%, $p<0.001$). No difference was seen between supine neutral and seated flexion ($p=0.82$).

Qualitative results for disk form, relationship to nerve root and foraminal stenosis are shown in table 1. These results show that changes in grading of nerve root compromise and foraminal stenosis between supine imaging and upright flexion or extension imaging did not consistently lead to higher or lower grades and did not reach statistical significance at the level at $p=0.05$.

Table 1: Changes in disk form, nerve root compromise and foraminal stenosis among positional MR images.

	Supine neutral to seated flexion	Supine neutral to seated extension	Seated flexion to seated extension
Disk form			
P value	0.97	1.00	0.97
# disks higher grade	0	6	4
# disks same grade	72	69	72
# disks lower grade	4	1	0
Nerve root compromise			
P value	0.06	0.06	0.20
# disks higher grade	32	26	27
# disks same grade	112	118	109
# disks lower grade	8	8	16
Foraminal stenosis			
P value	0.46	0.48	0.08
# disks higher grade	6	16	24
# disks same grade	128	130	112
# disks lower grade	18	6	16

Authors' Conclusions

The authors conclude that positional MRI more frequently shows minor forms of neural compromise than conventional MRI and that positional pain differences are related to position-dependent foraminal size. They also conclude that position dependent foraminal stenosis may be valid and positional MRI may add value when this is suspected.

Weishaupt et al. (2003)[6] assessed the effect of prone (plantar flexion), supine (dorsiflexion), and upright weight-bearing body positions on visibility, position, shape and size of Morton Neuroma during MRI. Forty-one patients with suspected Morton's neuroma underwent MR imaging of the symptomatic foot in a 1.0 tesla Seimens Expert scanner. Following standard imaging patients were asked to undergo imaging in an open configuration system in the supine and weight-bearing positions if they met inclusion criteria (presence of at least 1 Morton neuroma of 5mm or larger). MR images were reviewed by 1 of 2 radiologists prior to inclusion in the study.

Prone imaging was performed in the 1.0 tesla scanner. Supine and weight-bearing images were performed in a 0.5 tesla Signa SP (GE) scanner. Images were evaluated by 2 radiologists blinded to patient information. Visibility of Morton's neuroma in different body positions were rated from 3 to 0 (4 point scale, 3= good, 0= neuroma not visible) for qualitative assessment. Quantitative assessment of the size of the neuroma was also performed by one radiologist with electronic calipers.

Results

A total of 18 patients with Morton neuromas (20 neuromas) were enrolled. No additional neuromas were found in MR images. Mean visibility scores were lower for patients in either supine or weight-bearing positions.

Visibility of Morton Neuroma on MR Images Obtained at different Body Positions			
Visibility Score	Prone* Number (%)	Supine Number (%)	Weight-bearing Number (%)
0 –not visible	0(0)	0(0)	0(0)
1-poor	0(0)	0(0)	2(10)
2-moderate	0(0)	8(40)	8(40)
3-good	20(100)	12(60)	10(50)
Prone vs. weight-bearing p=0.002, supine vs. weight-bearing p=0.005, prove vs. supine p=NS.			

Quantitative evaluation showed significant differences in size (tranverse diameter) between prone vs. supine, and prone vs. upright positions. Supine vs. upright positions were not significantly different.

Authors' Conclusions

The authors conclude that 1) Morton neuroma appears significantly different in different body positions on MR imaging, 2) visibility of Morton neuroma is best on MR images in the prone position, and 3) patients having suspected Morton neuroma should be imaged in the prone, rather than the supine position.

Vitaz et al. (2004)[7] completed a prospective review of 20 patients imaged in an open configuration MRI unit (0.5 tesla Signa SP GE). Weight-bearing cervical images were performed with patients in flexed, neutral and extended positions. Patients were referred to one center by their neurosurgeon or orthopedic spine surgeon and all had neck pain consistent with radiculopathy or myelopathy. The primary goal of this study was to determine the feasibility and reproducibility of performing upright-seated images in 3 positions.

One investigator reviewed all images and patients were divided into 3 group: 1) one or two level herniated disc or cervical spndylosis, 2) multilevel herniated disc/spondylotic disease or 3) craniocervical junction abnormalities. Images were evaluated for qualitative changes between the 3 imaging positions which were rated mild, moderate or severe.

Results

Twenty patients were imaged in upright, weight-bearing positions. Nine male and 11 female patients, average age 53, were included.

Qualitative review showed no change between image positions in 2 patients (10%). Two patients exhibited isolated increases in anterior compression (10%). Five patients had changes in posterior structures (25%). Eleven patients had both anterior and posterior changes (55%). Changes were judged mild in 4 (20%), moderate in 7 (35%) and severe in 7 (35%).

Authors' Conclusions

The authors conclude that upright, dynamic, weight-bearing cervical MRI offers a noninvasive option for the imaging of complex disorders of the cervical spine. Further studies are needed to correlate clinical symptoms with the imaging results as well as direct comparison of supine and upright imaging.

The authors "do not suggest that this technique should be used to replace conventional supine MRI, but it may prove useful as an adjunctive study for complex spinal disorders."

Payment Issues

MR Billing Codes for Weight-bearing, Positional Imaging

There are not specific CPT® codes for weight-bearing MRI procedures, however, in the AMA CPT Assistant published in November 2005, Volume 15, Issue 11, the following comment is published in reply to a question about appropriate coding of lumbar spine imaging in a weight-bearing position:
"The existing CPT codes for MRI are silent with regard to patient positioning. Accordingly, this should be coded as 72148…"

Alternatively, weight-bearing MRIs have been billed using miscellaneous radiology codes.

MR Scanner Costs

According to Upright™ MRI of Seattle in an 'Explanation of Services' document, "the purchase price for this unique equipment [Fonar Stand-up ™ MRI] in not comparable to lower cost devices that cannot provide the positional MRI applications. At $1.8 million dollars, the purchase price is twice that of conventional scanners."

The Department's Experience

Between September 2005 and April 2006 the department received imaging bills for upright MR on approximately one hundred eleven (111) injured workers. Based on billing data, the average number of positional scans performed per patient was approximately 2.5.

Other Insurers

Aetna's Clinical Policy Bulletin 0093[8], Open Air, Low Field Strength, and Standing MRI Units, revised May 5, 2006. This Aetna policy states:

> "Magnetic resonance imaging (MRI) is considered medically necessary for appropriate indications without regard to the field strength or configuration of the MRI unit. Aetna considers intermediate and low field strength MRI units to be an acceptable alternative to standard full strength MRI units.
>
> Aetna considers "open" MRI units of any configuration, including MRI units that allow imaging when standing (Stand-Up MRI) or when sitting, to be an acceptable alternative to standard "closed" MRI units.
>
> Aetna considers repeat MRI scans in different positions (such as flexion, extension, rotation and lateral bending) to be experimental and investigational."

The background section of this policy bulletin includes the following excerpt:

> "The clinical value of standing MRI or postion MRI imaging in various positions (e.g., flexion, extension, rotation and lateral bending) has not been systematically evaluated in clinical studies. It has not been demonstrated in published prospective clinical studies that performing MRIs in these various positions can consistently detect problems that cannot be detected with a standard MRI."

Cigna Health Care Coverage Position number 0170[9], updated 9/15/2005, determines standing MRI to be experimental, investigational or unproven as there is a lack of published evidence, including clinical trials. Cigna Healthcare does not cover standing, vertical, upright, positional or dynamic MRI. It is considered experimental, investigational or unproven.

Premera Blue Cross Corporate Medical Policy: Standing MRI[10]. Effective February 14, 2006

> "The data that is available on the diagnostic efficacy of standing magnetic resonance imaging (MRI) compared to conventional MRI is very limited. These small studies indicate potential future clinical applications for specific populations, but large,

> randomized, controlled trials are needed to show sufficient evidence of diagnostic efficacy as compared to conventional MRI as well as other imaging modalities. Therefore, standing MRI is considered investigational because of lack of evidence in published, peer-reviewed clinical trials."

Regence Blue Cross Blue Shield, Idaho, Oregon, Washington, Utah. Policy # 49[11]. Upright Magnetic Resonance Imaging. Effective February 7, 2006.
Upright MRI for the diagnosis and management of any condition, including, but not limited to cervical, thoracic or lumbosacral back pain, is considered investigational.

Uniform Medical Plan, Washington State Health Care Authority. Effective date January 31, 2006. The UMP policy conclusion is positional MRI including standing, sitting and vertical is experimental and investigational as there is no evidence of additional benefit over standard MRI.

Workers' Compensation Insurers

Idaho State Fund provides coverage for Upright™ MRI services. Criteria for use are unwritten and not available. Payment is per the Idaho State Fund fee schedule at 100% of initial scans and 50% of fee schedule for each additional scan (personal communication).

Professional Organizations

No professional societies appear to have published positions, technology assessments or guidelines for appropriate use of standing, weight-bearing, positional magnetic resonance imaging.

Conclusions

There is limited scientific data available on the accuracy and diagnostic utility of standing, upright, weight-bearing or positional MRI. Well-designed clinical trials are necessary to effectively determine the potential benefits and value of this diagnostic imaging method.

This conclusion is supported by a review published by Weishaupt and Boxheimer of weight-bearing imaging (including axial loading methods) of the spine with MRI in 2003[12]. They concluded that conventional imaging of the lumbar remains the appropriate choice for assessment of degenerative disc disease. In a subsequent publication by Vitaz in 2004 the authors concluded similarly that weight-bearing MRI should not replace supine imaging, though it may be useful as an adjunct to traditional imaging[7].

Multiple authors of the research contributing to the understanding of weight-bearing or simulated weight-bearing imaging conclude that more research demonstrating clinical effectiveness is required[4, 7, 12-14].

There is not evidence from well-designed clinical trials demonstrating the accuracy or effectiveness of weight-bearing MRI for specific conditions or patient populations. Though positional, weight-bearing MRI is cited as allowing for improvement in sensitivity and specificity[15], no studies appear to have addressed the diagnostic accuracy compared to conventional MRI or other diagnostic tests. There is not published and peer-reviewed scientific evidence from studies designed to minimize potential biases showing how weight-bearing MRI contributes to the planning and delivery of therapy (therapeutic impact) or to improved health outcomes (impact on health) among patients generally or among injured workers.

Due to the lack of evidence addressing diagnostic accuracy or diagnostic utility, standing, weight-bearing, positional magnetic resonance imaging is considered investigational and experimental.

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Department of Labor and Industries
Office of the Medical Director
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PO Box 44321
Olympia WA 98504-4321

MEDICAL DEVICE COVERAGE REQUEST

Information provided will be used by the Office of the Medical Director in evaluating the medical device.

Your Name:	Company Name:
Mailing Address:	Date
City State ZIP + 4	FAX Number: ( )
Telephone Number: ( )	E-Mail Address:
Name of Device:	Manufacturer of Device:

Please provide answers on a separate sheet. Number answers to correspond to numbered questions.

1 a. Why do you believe this device merits consideration and review by the Office of the Medical Director?
b. What is the device intended to do?

2 a. What published, peer-reviewed literature documents the efficacy of this device or the science that underlies it?
Please enclose articles or a bibliography
b. Specify which, if any, of the enclosed articles look at the clinical effectiveness of the device and its impact on return to work of injured workers.
c. Are there any other sources that would provide useful information?
Please enclose or provide bibliography

3. FDA approval:
a. Does the device have FDA approval?
b. When was the device approved?
c. For what indications is the device approved for by the FDA?
d. What approval process was employed (e.g., 510(k), PMA, IDE)?
If approved under the 510(k) process, what device is it substantially equivalent to?
Please include approval letter and other relevant supporting documents to or from the FDA.

4. How is this device (1) different from and (2) more efficacious than <u>devices</u> that currently address the medical conditions for which this device has been approved?

5. How is this device (1) different from and (2) more efficacious than current <u>medical treatment procedures</u> or <u>diagnostic alternatives</u> for this type of injury?

6. Total cost for the device:
a. What is the total cost for the device for which the Department of Labor and Industries will be charged?
b. What are the on-going costs associated with the device during the patient's use?
c. How does this cost compare with other medical treatment procedures or diagnostic alternatives for this type of injury?

7. How would this device increase the quality of care the Washington State workers would receive?

8. How would this device return Washington State workers to work more quickly than existing devices and medical treatment procedures currently do?

9. Which State Workers' compensation programs reimburse for use of this device?
Please provide contact names and phone numbers

10. Which private insurers reimburse for use of this device?
Please provide contact names and phone numbers

11. Have any relevant medical organizations (e.g., AMA) expressed an opinion on this device?
If so, please provide verification documents and contact names and numbers if possible.

12. What safety and efficacy issues does use of this device raise?

For OMD Use	Date Received:	OMD Personnel
Action:		Submitter Advised/Date:
Comments:		