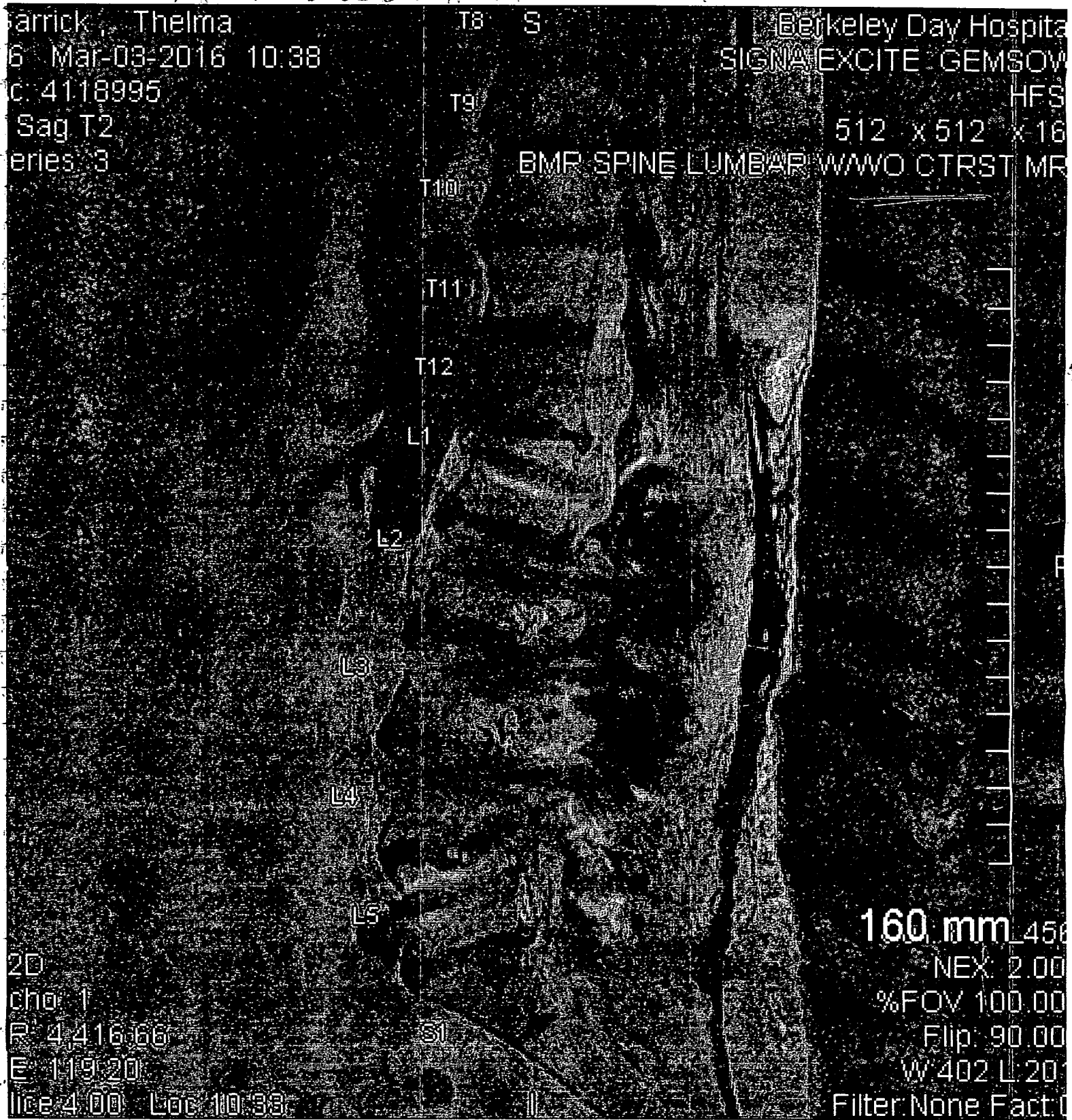


Proof of Surgery
W. J. ...

Sarrick, Thelma
6 Mar-08-2016 10:38
c: 4118995
Sag T2
Series: 3

Berkeley Day Hospital
SIGNA EXCITE GEMSOV
HFS
512 X 512 X 16
BMP SPINE LUMBAR WAVO CTRST MR



~~HEATH~~
Pain distribution post
L1 - L5

18 Mar 08 2016 11:01

4118995

5011ES #

20ES 8

5

Berkeley Day Hospital
SIGNA EXCITE GEMSON

HP3

512 x 512 x 16

EMR SPINE LUMBAR AND CERVICAL




20
 photo 1
 2:41:20
 22:20
 2:40:00 Lot 15 28

coil BC TL45
 d160 images
 NEX: 1.50
 WFOV 100.00
 FID: 90.00
 W: 357 L: 176
 Filter: None Filter

*This is where spine was severed
 infuse inserted and cage
 implanted*

~~Handwritten signature or initials~~

**Informed Consent for Operation/Procedure/
Anesthesia INCLUDING Blood and Blood Products**

Patient Identifier
 MR#: 001646892 DOB: 01/12/37
 GARRICK, THELMA R
 St Francis IPC
 PHYS: KHOURY-MD, GEORGE H

 ACCT#: 15232-00065 08/20/15

1. I give my permission to Dr. (include any assistants) Khoury
 to perform the following procedure(s) Lumbar laminectomy / Removal of hardware + fusion @ L4/L5
 on Thelma Garrick (patient's name)
2. I understand that during the procedure(s) new findings or conditions may appear and require an additional procedure(s) for proper care.
3. My doctor has discussed with me the items listed below:
 - (a) the nature of my condition;
 - (b) the nature and purpose of the procedure(s) that I am now authorizing;
 - (c) the possible complications and side effects that may result, problems which may be experienced during recuperation, and the likelihood of success;
 - (d) the benefits to be reasonably expected from the procedure(s);
 - (e) the likely result of no treatment; and
 - (f) the available alternatives, including the risks and benefits.
 - (g) My physician has also explained that, in addition to the specific risks involved in the procedure(s), there are other possible risks that accompany any surgical and diagnostic procedure. I acknowledge that neither my physician nor anyone else involved in my care has made any guarantees or assurances to me as to the result of the procedure(s) that I am now authorizing.
- (for physician use to add any specific risks he/she deems necessary)
- (h) I know that other clinical staff may help my doctor during the procedure(s) and have been told of any surgical assistants that will assist my doctor.
4. I understand that the procedure(s) may require that I undergo some form of anesthesia, which may have its own risks. My doctor or a representative from the department of anesthesiology, has informed me of the course of anesthesia that is recommended (if any) along with its possible risks and alternatives.
5. Any tissue or specimens taken from my body as a result of the procedure(s) may be examined and disposed of, retained, preserved, or used for medical, scientific, or teaching purposes by the hospital.
6. I understand that my procedure(s) may be photographed or videotaped and that observers may be present in the room for the purpose of advancing medical care and education.
7. I understand that, during or after the procedure(s) my doctor may feel it necessary to give me a transfusion of blood or blood products. My doctor has discussed with me the alternatives to, and possible risks of transfusion.
8. I understand what my doctor has explained to me and have had all my questions fully answered.
9. Additional comments: _____

Having talked with my doctor and having the opportunity to read this form, my signature below acknowledges my consent to the performance of the procedure(s) described above.

Signature of Patient or Legal Representative Thelma R Garrick Date 8-20-15 Time 9:05

If Legal Representative, Relationship to Patient _____

Witness [Signature] [Signature]

Verbal or Telephone Consent
 Name of Legal Representative _____ Relationship to Patient _____ Date _____ Time _____

Witness _____ Witness _____

1. I have explained the risk, benefits, potential complications, and alternatives of the treatment to the patient and have answered all questions to the patient's satisfaction, and he/she has granted consent to proceed.

Physician or Authorized PA/APRN Signature [Signature] Date 8/20/15 Time [Signature]

Rev 11/08; 1/09; 2/10; 8/14



1-16-2012

Personal Notes after

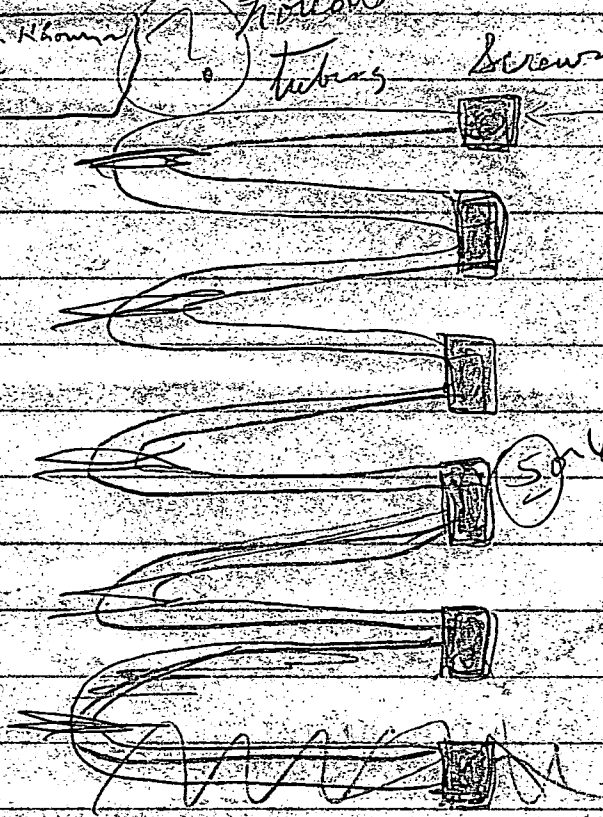
2-25 Pain down back to take shots on 1st March, T Appointment
3-06 Leg pain 2 weeks later? severe side effect. He informed me I was
not reporting what he put in me
June 22.15 Discussed the operation and 6-22
Agreed on junior relieve nurse

Dec 20, 2015

Notes
3-1-16

D. K. Khoury explained in detail about operation.
Operation performed with a test apparatus
being implanted in back! Unbearable pain!
body rejecting at that time?
2) Follow up visits, back getting worse
(10-24 Jan + 1 Mar 3 m.c.d / over. not told my body rejecting!
England I will have to be removed but need to take
shots first? Very sick on 7th when in office from
12 days of steroids. Had to stop on way back to
start throwing up - dehydrated, steroids from system.

Found out on 3-17-16 with D. Khoury
miss the use of Mettronic
Distributer port



Wants me to take paper
steroid shot? next part
held on...
Needles inserted
in screws (top) with mass
steroid shot, then
it is engaged
to filter down
over time.

However, I was
not working
because nurse
said they would
put steroid shot
in the screws
(shows very much)

4-18-16 D. Khoury

Said I had it turned on wrong side.
Asked how he could do this without my knowledge
or permission? He did not even lift shoulder.
Questions (I did not get to ask)

April 18th - need to know!

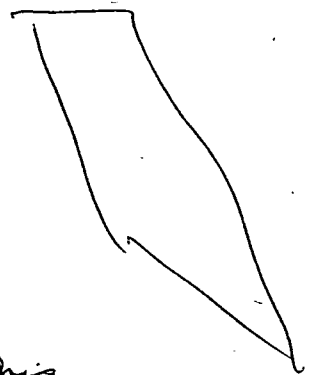
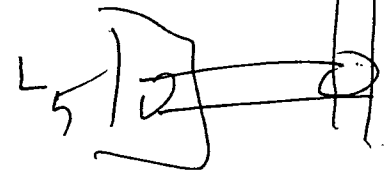
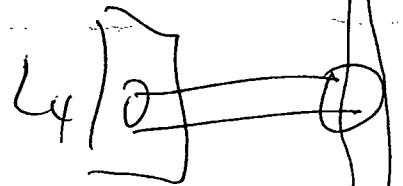
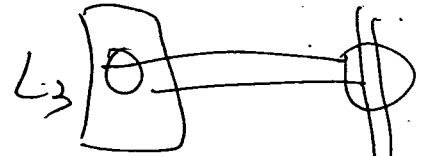
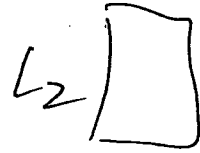
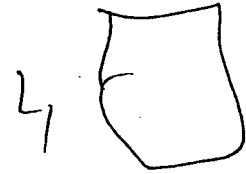
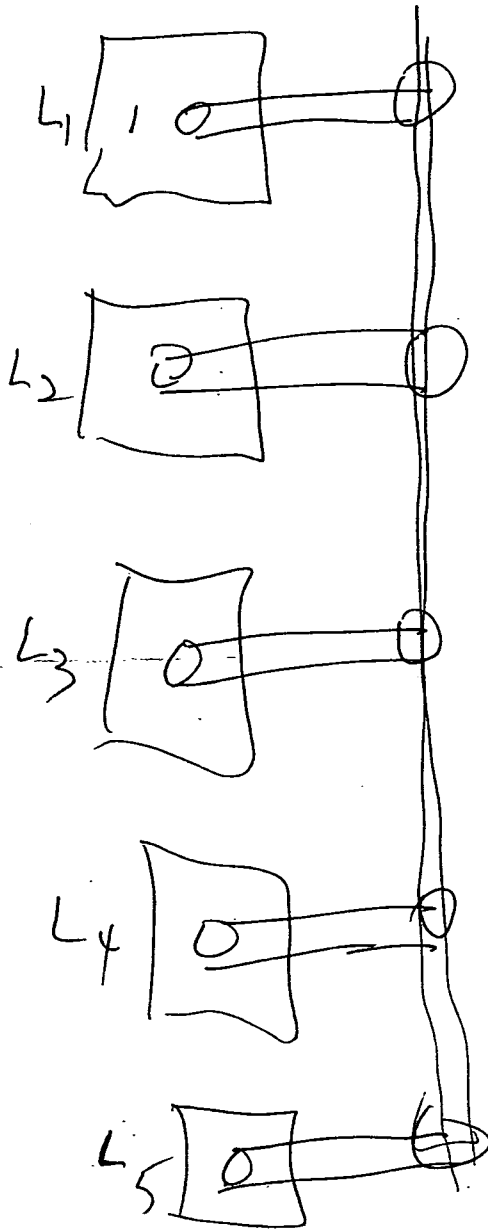
1. Removal - Risked?
2. Back pain - opens side bone
sun over bed, ~~to~~ lumber
make box on one side + crutch, soul
3. Left sciatic pain - did not relieve
pressure
4. Spasm between shoulder blades, above waist
with twinge, movement like swerve, "turning
motion"?

Agnew, Dr. at
MUSC, said I would
be sick a long time,
it would be a disaster,
I could not advise
method to think
concepts of I can
always to just
a small dose
of steroids!
I will be in
with steroid
was out of
my system
How was I
chosen on a
subject

(Metronomic Distribution Post)
per Sherry ~~_____~~ ~~_____~~ ~~_____~~
in a telephone conversation on
March 1, 2017 (SB)

Left

Right



Dr. Krowy drew this
when I showed him my drawing,
from what he showed me on 3-7-16,
said I had it on the wrong side.

Drawn by ~~_____~~ (on 3-7)

Bon Secours St. Francis Hospital
History and Physical

08/20/2015

MR#: 001646892 DOB: 01/12/37
GARRICK, THELMA R
St Francis IPC
PHYS: KHOURY-MD, GEORGE H



ACCT#: 15232-00065 08/20/15

GARRICK, THELMA
1646892

George H Khoury MD
Page 1

Patient Date of Birth: 01/12/1937

REASON FOR ADMISSION: She is admitted for lumbar stenosis and instability admitted for two-level laminectomy and fusion with pedicle fixation.

? Was supposed to be a fusion to relieve pressure on sciatic nerve only.

HISTORY OF PRESENT ILLNESS: A 78-year-old female who has had previous lumbar surgery and has had a fusion L3-4, 4-5 with pedicle fixation bilaterally. The patient has had long-term conservative treatment for continued pain. A number of epidural steroid injections this year since January and pain medication, although sometimes she takes a muscle relaxer. She has had trouble with some activities of daily living when she stands too long and when she gets out of bed lying down for it, she has some pain. She has been reduced to sometimes using a walker and a cane to get around. Review of her MRI showed junctional stenosis at the 1-2, 2-3 level next to the fusion at 3, 4 and 5. She is admitted now for two-level decompression and fusion with pedicle fixation.

Spinal synovium was after surgery! Only pain before was in left sciatic nerve! He did a special stenosis operation in 2011? Only 1 steroid injection, no rehab.

The patient has been on medications including Travatan, Advil, lisinopril, aspirin, Lisinopril, Lopressor, isosorbide dinitrate, Lasix, Ambien, gabapentin and Flexeril. She had history of hypertension, osteoporosis, reflux, mitral valve prolapse. She has had left shoulder surgery, right shoulder surgery, two-level fusion, two-level ACDF, operation on her thumb, breast tumors removed, breast reduction, gallbladder disease, right hand tendon repair, renal artery stents and cataract surgery.

SOCIAL HISTORY: She does not smoke or drink.

ALLERGIES: ADHESIVE BANDAGES, SULFA, DEMEROL, TYLENOL, VALIUM, STATINS, NEURONTIN, METFORMIN, INVOKANA. Steroids, gabapentin, Ayrax, Ambien

PHYSICAL EXAMINATION: She is alert and oriented in no acute distress. Cranial nerves are intact. Pupils equal, round, reactive to light and accommodation. Fundi are negative. TMs are normal. Chest is clear. Heart: Normal S1, S2, without gallops or murmur. Abdomen is benign. The patient has well-healed neck and low back incisions. She has marked decreased range of motion in her back. She walks with a shuffling gait and sometimes uses a cane and walker with the gait and there is no focal neurological findings.

In severe pain when sent by ambulance to Nursing Home. Took a week before pain went to a level of what I call operation pain.

ASSESSMENT: The patient with lumbar stenosis, moderate intractable pain, activities of daily living have been shown to be decreasing and treatment including recent epidural steroid injections and medications and physical


Did he not do the spinal stenosis surgery when he ruptured a disc and I had to have another surgery?

therapy have not worked. The patient is admitted for two-level laminectomy and fusion. Hopefully we can connect that with the previous hardware and not have

No he did not explain surgery.

Bon Secours St. Francis Hospital
History and Physical
08/20/2015

MR#: 001646892 DOB: 01/12/37
 GARRICK, THELMA R
 St Francis IPC
 PHYS: KHOURY-MD, GEORGE H



ACCT#: 15232-00065 08/20/15

GARRICK, THELMA
1646892
George H Khoury MD
Page 2

Patient Date of Birth: 01/12/1937

to remove the screws. The risks, benefits, complications and alternatives were outlined, the patient understood and was agreeable. *Not so!*

Update to the History and Physical if appropriate

- I have reviewed the H/T/P and re-examined the patient and there are no changes to the physical examination and/or history of present illness.
- I have reviewed the H/T/P and re-examined the patient and the following changes have occurred to the physical examination and /or history of present illness:

[x] Refer to the Admission Home Medication Orders (inpatient) or Outpatient/OBSERVATION medication list (outpatient) for current medications.
 Physician Signature: _____ Date: _____ Time: _____

George H Khoury, MD
 TR: *n DD: 08/17/2015 08:54 TD: 08/17/2015 09:24 Job#: 444209
 \X09090909090909090909\DOC#: 552375

Authenticated by GEORGE H KHOURY MD On 08/18/2015 08:10:37 AM

George H Khoury MD

cc: *[Signature]* *[Signature]* *[Signature]* TR: *n DD: 08/17/2015 08:54:32 TD: 08/17/2015 09:24:06 JOB#: 444209 DOC#: 552375

~~Dr. Khoury's name~~
~~6/1/15/13~~

~~_____~~
~~_____~~

Patient DOB: 01/12/1937

Blanks due to inaudible dictation.

PREOPERATIVE DIAGNOSIS: Lumbar stenosis with lumbar instability, L1-2, L2-3.

POSTOPERATIVE DIAGNOSIS: Lumbar stenosis with lumbar instability, L1-2, L2-3.

NAME OF PROCEDURE: L1-2, L2-3 laminectomy, and then a lateral fusion from L1 to L3, and then segmental fixation from L1 to L3 with pedicle fixation, use of the operating microscope, lateral C-arm fluoro, morselized bone graft for the lateral fusion from L1 to L3 with BMP.

SURGEON: _____

ASSISTANT: _____, PA-C. _____ assisted in all phases of the case, including the 2-level laminectomy, the 2-level lateral fusion, morselized bone graft and BMP, the use of the operating microscope, the segmental fixation with the use of stereotactic navigation and O-arm operating microscope.

ESTIMATED BLOOD LOSS: 500 mL.

OPERATIVE SPECIMEN: None.

INDICATIONS FOR PROCEDURE: A 78-year-old female with symptoms compatible with back and leg pain, with worsening neurological symptoms and reduced level of activity, and problems with activities of daily living over the last number of months. The patient has had in the last 6 months a number of epidural steroid injections and physical therapy, both at home and at the therapy place, a number of injections during this period of time, and none of those have afforded her any relief, and she has gradually been curtailing her activities because of pain and disability. _____ medicines has not helped at all. Her x-rays had shown progression of lumbar stenosis from T12 to L2, and it is felt the patient would benefit from a decompression and fusion to help her with her pain, her level of disability, and increase her daily activities. Risks, benefits, complications and alternatives were outlined. The risks of general anesthesia, bleeding, infection, risk of nerve root injury, spinal cord injury, paralysis, loss of bowel, bladder and sexual function were explained. The possibility of reoperation, intraspinal or intraabdominal hemorrhage, lumbar instability, recurrent disk rupture was noted. Long-term complications

False
not made
me
strongly
rel

False

None of this was explained to me!
Under no circumstance would I have agreed! I only had a pinched left sciatic nerve pain.

Learned on 3-1-17 (Dr. Khoury's nurse Dawn) (TK)

The testing device is a Medtronic distribution part. (This company has multiple law suits against them.)

In this telephone conversation I was still not informed of the Medtronic cage. This only came out without explanation at Duke's Health, Durham

Patient DOB: 01/12/1937

including chronic pain and disability, inability to return to recreational, job, personal, sexual activities were noted. All of these risks were outlined. The patient understood and was agreeable. *false*

FINDINGS AT SURGERY: The patient had stenosis and instability both at L1, L2-3 level. A good decompression and fusion was done.

DESCRIPTION OF OPERATIVE PROCEDURE: *It was under heavy sedation.* After informed consent was obtained, the patient was brought to the operating room and underwent general anesthesia. The patient underwent somatosensory evoked potentials, EMGs at all times during the case, and no abnormalities were seen. The patient was rolled in the prone position on chest rolls, with all pressure points padded. The lower back was routinely prepped and draped in a sterile fashion. The patient was given preoperative antibiotics. *See initial file*

We marked out the incision using x-ray as a guide, infiltrating the area with 1% lidocaine with epinephrine. Using a 10-blade scalpel, we incised the skin and subcutaneous tissue, coagulating with Bovie, and this got us down to the lumbosacral fascia. We divided the muscles subperiosteally to expose the spine from L1 to L3. X-ray confirmed the proper levels.

We proceeded to do a laminectomy at L1 to L3 with the use of the Leksell rongeur, Kerrison punch and a high-speed air drill, decompressing the canal from L1 to L3, the stenosis due to thickened ligaments and overhanging facets. In the process of the decompression, due to scar tissue, a small hole was made in the dura. This was sutured primarily, and a watertight suture was made, and then this was covered later with _____. Once the decompression was finished, we went far lateral to expose the lateral facet and the transverse process area, decorticating these areas for the lateral fusion. We laid morselized bone graft along with BMP bilaterally for the lateral fusion. An alligator clamp was then placed on the T12 spinous process. A preimplantation O-arm spin was used. Using this information, we put in 5.5 x 50 and 55 mm pedicle screws at L1 and L2. We used the domino connector, and connected it to the previous fusion rods from L3 to L5. Everything was tightened down securely, and final x-rays were satisfactory. Hemostasis was achieved. The wound was closed in layers with 0 Vicryl in an interrupted fashion and staples. A sterile dressing was applied.

The patient was flipped back in the supine position, extubated and awakened from anesthesia, and taken to the recovery room in stable condition. ?

21 7 31

From: **Carlson, Joe** Joe.Carlson@startribune.com
Subject: **RE: Medtronic devise**
Date: **Nov 16, 2017, 10:23:58 AM**
To: **Jessica Moore** juaprmom@windstream.net

Hello Jessica. I'm sorry to hear about your Aunt Thelma's situation. I'd be interested in learning more if you'd ever want to talk by phone. My direct line here in the office is 612-673-4779.

Regarding your question -- The public portal for anyone to find payments from manufacturers to doctors is here: <https://openpaymentsdata.cms.gov/>

I took the liberty of searching for the doctor's name you provided, and yes, Dr. Khoury received payments from Medtronic in each of the four years available for searching. Here's the 2016 data:
<https://openpaymentsdata.cms.gov/physician/8356/payment-information> (Note that you can only see one year of data at a time. Since there are four years of data available currently, you have to make sure to click on 2016, 2015, 2014, and 2013 to see all the payments.)

Hope this helps,

-Joe

Joe Carlson
Star Tribune
612-673-4779

-----Original Message-----

From: **Jessica Moore** [mailto:juaprmom@windstream.net]
Sent: **Wednesday, November 15, 2017 7:12 PM**
To: **Carlson, Joe** <Joe.Carlson@startribune.com>
Subject: **Medtronic devise**

GEORGE H KHOURY

Allopathic & Osteopathic Physicians|Neurological Surgery

2145 HENRY TECKLENBURG DR
 SUITE 220
 CHARLESTON, SC 29414-5893

Address shown may reflect one of the following: practice location, hospital affiliation, or third party billing assignment. Additional addresses may be found in the [NPI Registry](#).

Summary Payment Information

[Review or dispute your reported data](#)

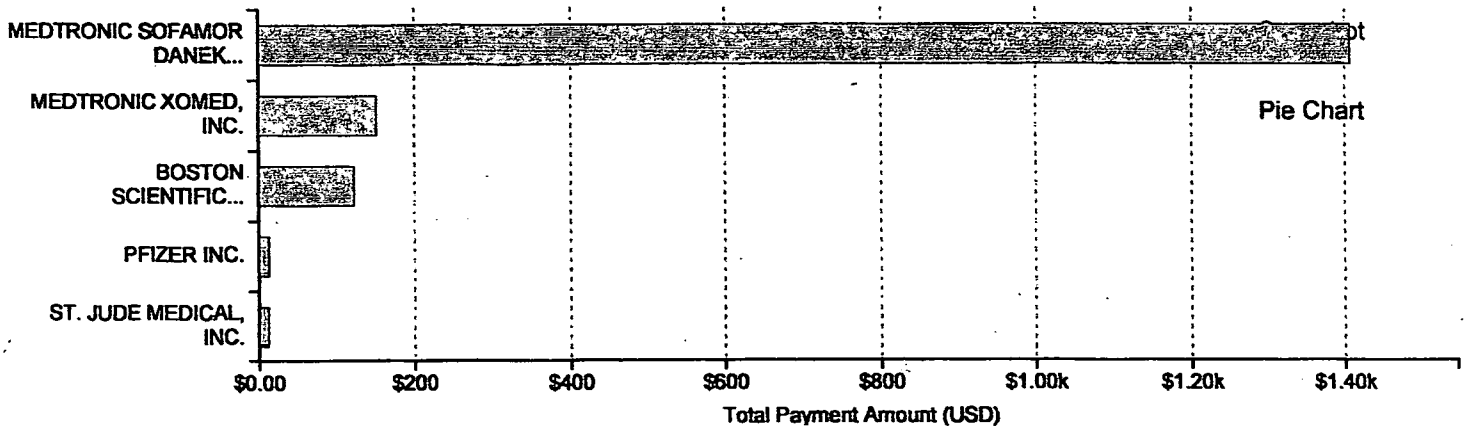
Year: 2015

Payment Type: General

What are the different payment types?

Top Companies Making General Payments

[Collapse this section](#)



[Pie Chart](#)

5 Companies Making General Payments

[Collapse this section](#)

Filter Records

[Open Filters](#)

Company Making Payments	Total Payments	Total Amount	Total Amount (%)
MEDTRONIC SOFAMOR DANEK USA, INC.	12	\$1,408.26	82.3%
MEDTRONIC XOMED, INC.	1	\$152.96	8.9%
BOSTON SCIENTIFIC CORPORATION	1	\$124.30	7.3%

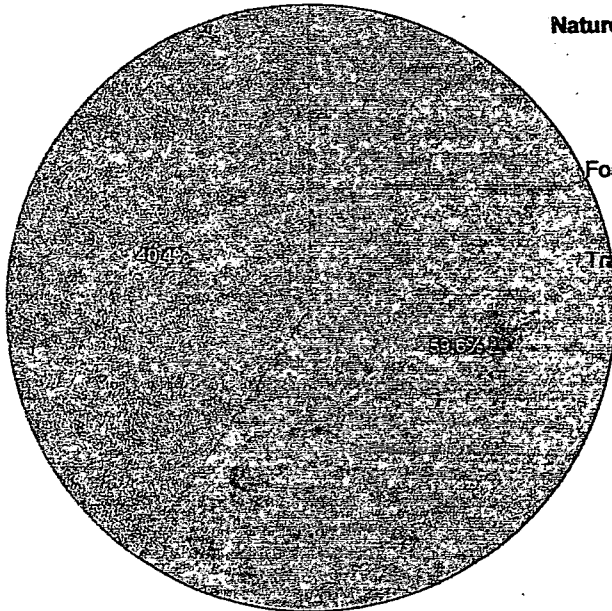
<u>PFIZER INC.</u>	1	\$13.70	0.8%
<u>ST. JUDE MEDICAL INC.</u>	1	\$12.55	0.7%

Displaying records 1-5 of 5.

Records per page: 5

Summary by Nature of Payment

[Collapse this section](#)



Nature of Payment	Total Payments	Total Amount	Total Amount (%)
Food and Beverage	13	\$1,020.04	59.6%
Travel and Lodging	3	\$691.73	40.4%

What are the different natures of payment?

General Payments Received

[Collapse this section](#)

Filter Records

[Open Filters](#)

[Download Data](#)

Company Making Payment	Nature of Payment	Date	Amount	Third Party Payment	Disputed?	Comment
<u>BOSTON SCIENTIFIC CORPORATION</u>	Food and Beverage	09/08/2015	\$124.30	No Third Party Payment	No	
<u>MEDTRONIC SOFAMOR DANEK USA, INC.</u>	Travel and Lodging	01/24/2015	\$51.85	No Third Party Payment	No	

Physician Profile for **GEORGE H KHOURY** - Open Payments Data - CMS

Company Making Payment	Nature of Payment	Date	Amount	Third Party Payment	Disputed?	Comment
<u>MEDTRONIC</u> <u>SOFAMOR DANEK</u> <u>USA, INC.</u>	Food and Beverage	01/23/2015	\$11.93	No Third Party Payment	No	
<u>MEDTRONIC</u> <u>SOFAMOR DANEK</u> <u>USA, INC.</u>	Travel and Lodging	01/22/2015	\$211.68	No Third Party Payment	No	
<u>MEDTRONIC</u> <u>SOFAMOR DANEK</u> <u>USA, INC.</u>	Food and Beverage	01/22/2015	\$114.04	No Third Party Payment	No	
<u>MEDTRONIC</u> <u>SOFAMOR DANEK</u> <u>USA, INC.</u>	Food and Beverage	01/06/2015	\$19.48	No Third Party Payment	No	
<u>MEDTRONIC</u> <u>SOFAMOR DANEK</u> <u>USA, INC.</u>	Travel and Lodging	01/22/2015	\$428.20	No Third Party Payment	No	
<u>MEDTRONIC</u> <u>SOFAMOR DANEK</u> <u>USA, INC.</u>	Food and Beverage	01/23/2015	\$42.99	No Third Party Payment	No	
<u>MEDTRONIC</u> <u>SOFAMOR DANEK</u> <u>USA, INC.</u>	Food and Beverage	05/04/2015	\$55.00	No Third Party Payment	No	
<u>MEDTRONIC</u> <u>SOFAMOR DANEK</u> <u>USA, INC.</u>	Food and Beverage	09/29/2015	\$145.53	No Third Party Payment	No	

Displaying records 1-10 of 16.

1 2

Records per page: 10

OpenPaymentsData.CMS.gov A federal government website managed by the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

- [SIGN UP FOR EMAIL UPDATES](#)
- [Data.CMS.gov](#)
- [OpenPaymentsData.CMS.gov](#)
- [Data.Medicare.gov](#)
- [Data.Medicaid.gov](#)
- [Data.HealthCare.gov](#)
- [FOIA](#)
- [No Fear Act](#)
- [Privacy Policy](#)
- [FAQ's](#)
- [CMS contact info](#)
- [Help with file formats & plug-ins](#)

ARTICLE:

<http://www.startribune.com/new-federal-data-shine-a-light-on-medtronic-payments-to-doctors/313962621/>

New federal data shine a light on Medtronic payments to doctors

Minnesota device maker has become a flash point in a national debate about the role of money in medicine.

By Joe Carlson and Jim Spencer Star Tribune staff writers

JULY 11, 2015 — 11:22PM

new federal data show that Medtronic continues to pay millions of dollars to doctors whose research on a controversial spinal product has come into question.

The Minnesota-run company's spine division, Medtronic Sofamor Danek, paid \$60.7 million in royalties to 79 doctors and their affiliates in 2014, according to the data. That includes money that went to the authors of disputed studies of the back pain treatment Infuse, a product that has sparked hundreds of patient injury lawsuits.

Dr. Ken Burkus, a Georgia surgeon and lead author on six studies that omitted adverse events related to Infuse, got \$374,000 in royalties last year. Dr. Regis Haid, an Atlanta neurosurgeon who led one of the studies, got \$2.3 million. Payments for both were sent to third-party companies; neither returned calls for comment.

Although Medtronic's propensity for paying royalties is not unique, the Minnesota device maker has become a flash point in a national debate about the role of money

The scrutiny of Infuse has focused on how Medtronic paid authors and then, according to e-mails released by the Senate Finance Committee in 2012, edited their journal articles to make Infuse seem safer and less painful than other techniques to fuse vertebrae through spine surgery.

More recent studies have turned up risks and adverse events that weren't reported in those early studies, even as the spinal-surgery community rapidly adopted Infuse.

More than 6,000 patient-injury claims have been filed in court or are awaiting filing, securities filings say. Medtronic has paid an average \$23,000 per case to settle 950 cases, and set aside another \$140 million for future legal costs. According to patients' lawsuits, sales of Infuse exceeded \$4 billion from 2002 to 2011.

The FDA approved a narrow use for Infuse in 2002, but journal articles have since attempted to show the benefits and risks of using it in non-FDA-approved ways to expand its market share. Humana's lawsuit lists the oft-repeated estimate that at least 85 percent of the use of the key Infuse component, a bone-growth protein called BMP, is outside of what the FDA approved.

Examining the data

The proliferation of studies touting these off-label uses, and the tide of studies showing higher injury rates than first reported, prompted the North American Spine Society to publish an unusual retrospective of the data last December.

The resulting 33-page policy document says many patients getting a spinal-fusion procedure don't need BMP. Patients who don't need it include healthy people who are only getting two lower vertebrae fused, most pediatric patients, and patients getting routine fusions of neck bones.

additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug underdose or overdose. Avoid using shortwave (RF) diathermy within 30 cm of the pump or catheter. Effects of other types of diathermy (microwave, ultrasonic, etc.) on the pump are unknown. Drug infusion is suspended during MRI; for patients who can not safely tolerate suspension, use alternative drug delivery method during MRI. Patients receiving intrathecal baclofen therapy are at higher risk for adverse events, as baclofen withdrawal can lead to a life threatening condition if not treated promptly and effectively. Confirm pump status before and after MRI. Reference product labeling for information on sources of EMI, effects on patient and system, and steps to reduce risks from EMI.

PRECAUTIONS:

Monitor patients after device or catheter replacement for signs of underdose/overdose. Infuse preservative-free (intraspinal) saline or, for vascular applications, infuse heparinized solutions therapy at minimum flow rate if therapy is discontinued for an extended period of time to avoid system damage. EMI may interfere with programmer telemetry during pump programming sessions. EMI from the SynchroMed programmer may interfere with other active implanted devices (e.g., pacemaker, defibrillator, neurostimulator).

ADVERSE EVENTS:

Include, but are not limited to, spinal/vascular procedure risks; infection; bleeding; tissue damage, damage to the system or loss of, or change in, therapy that may result in additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug underdose or overdose, due to end of device service life, failure of the catheter, pump or other system component, pump inversion, technical/programming errors, injection into the pocket or subcutaneous tissue, or improper use, including use of non-indicated formulations and/or not using drugs or system in accordance with labeling; pocket seroma, hematoma, erosion, infection; post-lumbar puncture (spinal headache); CSF leak and rare central nervous system pressure-related problems; hygroma; radiculitis; arachnoiditis; spinal cord bleeding/damage; meningitis; neurological impairment (including paralysis) due to inflammatory mass; potential serious adverse effects from catheter fragments in intrathecal space, including potential to compromise antibiotic effectiveness for CSF infection; anesthesia complications; body rejection phenomena; local and systemic drug toxicity and related side effects; potential serious adverse effects from catheter placement in intravascular applications.

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USA Rx Only

Rev 0815

SYNCHROMED EL

SYNCHROMED EL DRUG INFUSION SYSTEM BRIEF SUMMARY:

Product technical manual must be reviewed prior to use for full disclosure.

INDICATIONS:

US: Chronic intraspinal (epidural and intrathecal) infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain, chronic intrathecal infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain, and chronic intrathecal infusion of Lioresal® intrathecal (baclofen injection) for the management of severe spasticity, chronic intravascular infusion of floxuridine (FUDR) or methotrexate for the treatment of primary or metastatic cancer.

CONTRAINDICATIONS:

When infection is present; when the pump cannot be implanted 2.5 cm or less from the surface of the skin; when body size is not sufficient to accept pump bulk and weight; when contraindications exist relating to the drug; drugs with preservatives.

WARNINGS:

Comply with all product instructions for initial preparation and filling, implantation, programming, refilling, and injecting into the catheter access port (CAP) of the pump. Failure to comply with all instructions can lead to

*on 3-7-16
Dr. K said my
body was rejecting
the pain distributor
part. (And part
to large for
the size of my
lumbar.)*

*Advice from
Lawyer in California*

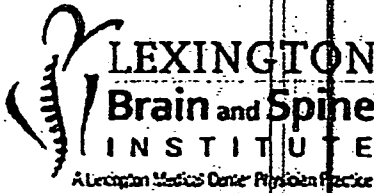
***** Go DIRECTLY TO THE HOSPITAL IN-PERSON TO GET THESE REPORTS – THEY WILL GIVE THEM TO YOU RIGHT THERE ON THE SPOT. IF YOU REQUEST THE INFORMATION THROUGH THE DOCTOR OR THROUGH THE HOSPITAL BY WRITTEN OR TELEPHONE REQUEST IT CAN TAKE AS MUCH AS 3-MONTHS TO GET THEM BACK.**

IF the device(s) used were / are an Infuse Bone Graph Device, specifically a Bone Morphogenetic Protein ('BMP') device the law firm wants you to call back and you could potentially be part of their on-going law suit. I do not think this is the device that was implanted in your back, though.

Once we get the specifics on the device implanted in you we can research it more. It all starts with identifying the device, which requires you getting those records!

I expressed my concern over why – with your record of allergies to medications – you would be a candidate for this device designed supposedly to distribute medication along the spine to the screw AND asked if Medtronic ever paid doctors to use / implant devices.

Tess explained that this is ILLEGAL, HOWEVER, Medtronic has been caught paying doctors in the past. Medtronic has even had Representatives INSIDE the surgery room with doctors while the surgery is performed. She said, "Hopefully this was not the case, that Medtronic did not pay the doctor for this device to be used."



Lexington Brain and Spine Institute
155 N. Hospital Dr,
Ste 200
West Columbia SC
29169-4800
Outpatient

Garrick, Thelma R
MRN: M000460300, DOB: 1/12/1937,
Sex: F
Encounter date: 6/27/2018

Garrick, Thelma R

MRN: M000460300
Description: 81 year old female

Office Visit 6/27/2018
Lexington Brain and Spine Institute

Provider: Gunter, Brett C, MD (Neurosurgery)
Primary diagnosis: Stenosis of lateral recess of lumbar spine
Reason for Visit: Follow-up

Progress Notes

Gunter, Brett C, MD (Physician) - Neurosurgery

LEXINGTON BRAIN AND SPINE INSTITUTE FOLLOW UP VISIT

DATE OF SURGERY/PROCEDURE:
Lumbar Laminectomy 2015
Lumbar Fusion 8/2015 Dr. Khoury Charleston

Chief Complaint
Patient presents with:
• Follow-up
MRI and CT review

SUBJECTIVE:
Thelma R Garrick is a 81 y.o. female seen today in follow up for evaluation of back and leg pain.

Low back: 60%. The patient describes diffuse axial back pain throughout her lower lumbar spine. Her symptoms generally present in worsening fashion with prolonged standing and walking. Mechanical activities such as bending, twisting, lifting, and basic housework also worsen her syndrome. She describes intermittent spasm of her back particularly with leaning forward. She is able to find some relief with sitting, although it takes a while for her pain ease off.

Bilateral legs: 40%. The patient describes LEFT greater than RIGHT pain and spasm. She describes about 90% of the pain in the LEFT, 10% on the RIGHT. She has a sensation of dysesthesias into her RIGHT thigh, however this is relatively manageable. She describes very reproducible radiating pain into her LEFT buttock into the LEFT lateral thigh to the anterior thigh to about the knee. Her symptoms are present primarily with standing and walking as well as mechanical type activities.

HPI
Review of Systems

OBJECTIVE:

Vitals:

06/27/18 1050

BP: 153/82
Pulse: 62

PHYSICAL EXAM:**Vitals:**

06/27/18 1050

BP: 153/82
Pulse: 62

GAIT: Ambulates without external stabilization
GENERAL: appropriate for age
HEAD: normocephalic
EYES: pupils equal and reactive, extraocular movements intact
EARS: external anatomy unremarkable
THROAT: oropharynx clear to visual inspection
LUNGS: clear to auscultation bilaterally
HEART: regular rate and rhythm
ABDOMEN: soft non-distended, nontender
EXTREMITIES: warm, moist, pulses present
BACK: unable to flex or extend

NEUROLOGICAL EXAM:

MENTAL STATUS: awake alert and oriented to person, place and time
SPEECH: fluent and conversant

POWER EXAM:

LOWER EXTREMITIES:
HIP FLEXORS: power 5/5 bilaterally
QUADRICEPS: power 5/5 bilaterally
HAMSTRINGS: power 5/5 bilaterally
ANTERIOR TIBIALIS: power 5/5 bilaterally
EXTENSOR HALLICUS LONGUS: power 5/5 bilaterally
GASTROSOLEUS: power 5/5 bilaterally
SENSORY EXAM:
LOWER EXTREMITIES: sensation intact to light touch
REFLEXES: lower extremity reflexes symmetric and intact

IMAGING:

CT scan of the lumbar spine demonstrates what appears to be fractured instrumentation at L2-3 where there is some sort of the construct connection. There is a presumed nonunion at L1-2 and L2-3. There is an apparent solid bony union at L2-3 and L3-4.
MRI of the lumbar spine demonstrates lateral recess stenosis at L2-3 and degenerative changes consistent with nonunion at this level. There are advanced degenerative changes at L5-S1.

ASSESSMENT:

Complex patient with advanced degenerative changes and instrumentation failure with a pseudoarthrosis.

Not! I have reviewed in detail the risks, benefits, and alternatives. I have informed the patient and family of the fact that not all medical procedures and techniques have been studied for FDA "approval", and by necessity some procedures and devices may be used in a manner that has

not been studied (considered "off label"). I have specifically discussed with the patient and family the risks of worsening neurologic function, even death, infection, significant bleeding including injury to surrounding structures. These injuries may lead to the need for additional surgery or treatment. I have informed them that artificial devices or products from animal, human, or inanimate origin may be used. I have instructed them that the devices that may be used are subject to mechanical failure and may need to be replaced or revised. I have fully described the expected procedure and some possible deviations that may occur by necessity. After this discussion they have instructed me to proceed. I have given them opportunity to ask questions. They have voiced an understanding of the risks, benefits, and alternatives.


PLAN:

Revision thoracolumbar fusion with removal of previous instrumentation, LEFT sided transforaminal lumbar interbody fusion L2-3 possible L1-2 thoracolumbar fusion T11-S1 right-sided transforaminal lumbar interbody fusion L5-S1 specifically with the use of infuse bone morphogenic protein and other levels and procedures as indicated

Gunter, Brett C

This note was created with voice recognition software. Typographical and grammatical errors, as well as errors of content are related to the software capture, and every attempt is made to correct these prior to note submission.

Instructions

 Return if symptoms worsen or fail to improve.

After Visit Summary (Automatic SnapShot taken 6/27/2018)

Additional Documentation

Vitals: BP 153/82 Pulse 62

Flowsheets: Custom Formula Data

Encounter Info: Billing Info, History, Allergies, Detailed Report, Reviewed This Encounter, Patient Report

Orders Placed

None

Medication Changes

As of 6/27/2018 11:56 AM

None

Visit Diagnoses

Stenosis of lateral recess of lumbar spine M48.061

