

THE STATE OF SOUTH CAROLINA  
In the Supreme Court

APPEAL FROM CHARLESTON COUNTY  
Diane Shaffer Goodstein, Circuit Court Judge

Appellant Case No. 2018-001842

Thelma R. Garrick..... Appellant

v

Dr. George H. Khoury and Bon Secours Roper St. Francis..... Respondents  
West Ashley

SUPPLEMENT TO RECORD ON APPEAL

Thelma R. Garrick, Pro Se  
195 Crescent Oaks Court  
Orangeburg, South Carolina 29115  
(803) 534-9912

Attorneys for Respondents:  
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(843) 577-4000

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Charleston, South Carolina 29401

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Charleston, South Carolina 29401

Mr. Stephen Lynwood Brown, Esquire  
25 Calhoun St., Suite 400  
Charleston, South Carolina 29401

**RECEIVED**

SEP 10 2019

SC Court of Appeals

Appellant Case No. 2018-001842

September 13, 2019

TO: THE HONORABLE JUDGES OF THE SOUTH CAROLINA COURT OF APPEALS

RE: Supplement to the Record on Appeal

Enclosed you will find information that needs to be added to the Record on Appeal. This information/evidence is nothing new or added but Appellant realizes that it is a very important part of the case and should be added at this time (see Designation of Matter, in the Table of Contents). Appellant apologizes for the inconvenience to the Court.

Respectfully,



Thelma R. Garrick  
195 Crescent Oaks Court  
Orangeburg, South Carolina 29115  
Attorney Pro Se  
(803) 534-9912

/tg

Enclosures

Copies have been forwarded this 13<sup>th</sup> day of September, 2019 separately to the Attorneys of the Respondents:

Mr. Joseph John Tierney, Jr., Esquire,  
Mr. Stephen Lynwood Brown, Esquire and  
Mr. Russell Grainger Hines, Esquire by U.S. mail  
to: P. O. Box 993  
Charleston, South Carolina 29402-0993  
(843-577-4000)

THE STATE OF SOUTH CAROLINA  
IN THE COURT OF APPEALS  
(In the Supreme Court)

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Appellant Case No. 2018-001842

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Appeal From Charleston County  
Court of Common Pleas  
Diane Schafer Goodstein, Circuit Court Judge  
Circuit Court Case No. 2018-CP-10-01163

---

Thelma R. Garrick

Appellant

v.

Dr. George H. Khoury and Bon  
Secours St. Francis West Ashley

---

SUPPLEMENT TO THE RECORD ON APPEAL

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Thelma R. Garrick  
195 Crescent Oaks Court  
Orangeburg, S. C. 291151  
(803-534-9912  
Attorney Pro Se

Dated: September 13, 2019

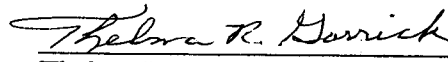
SUPPLEMENT TO RECORD ON APPEAL

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Appellant certifies that the Records on Appeal herein contains all material proposed to be included by any of the parties and only material pertaining to those matters discussed.

August 26, 2019/tg

 , Appellant  
Thelma R. Garrick, Pro Se

September 13, 2019

TO: THE HONORABLE JUDGES OF THE SOUTH CAROLINA COURT OF APPEALS

RE: Supplement to the Record on Appeal

The Appellant would like for the additional evidence/information be added as a Supplement to the Record on Appeal. All information is found on the Designation of Matter in the Initial Brief and the Record on Appeal. Thank you.

ADDITION TO RECORD ON APPEAL

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(Designation of Matter from Initial Brief - item #2, page 2 of 3) Record on Appeal, Civil Action Summons and Complaint, Item II	28-34
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e.) Infuse bone graft lawsuit results	34 (1e) 1 of 4
f.) Payments, royalties paid by Medtronic	34 (1f) 1 of 9
g.) Photos depicting nature of surgery and bone mines covering spine (The abnormal bone growth is further proved by wrist photos and an abnormal hand at present. (covered by Item 15, Designation of Matter with Initial Brief)	34 (1g) 1 of 14
Mediation – Item VI, pages 51-60 of Record on Appeal, paragraph 1, Page 58-60	
a.) Medicare documentation proving implants were not mentioned in billing to them	60 (a) 1 of 14

Appellant Case No. 2018-00001842

Transcript and Court Order VIII:  
(Proof of follow up on the Order to Dismiss)

Pages 66:

- |     |   |              |
|-----|---|--------------|
| a.) | Letter to Judge Goodstein               | 66(a) 1 of 3 |
| b.) | Letter from Judge Goodstein             | 66(b) 1 of 1 |
| c.) | Letter to Ms. Armstrong, Clerk of Court | 66(c) 1 of 1 |

Expert Witness, Record on Appeal, Item IX, page 70-83 83 (a) 1 of \_\_

Appellant is waiting for appointment for an Independent Medical examination but as time is short she is asking the Court's indulgence to delay this information at this time. (Appellant will bring this record and the Tape Recorder with Dr. Khoury's message to the Court. She has found that the White Coat Brotherhood is a very tight knit group.)

Respectfully yours,



Thelma R Garrick  
195 Crescent Oaks Court  
Orangeburg, South Carolina 29115  
(803) 534-9912


Attorney Pro Se

Copies of these records have been forwarded this day to  
Attorneys for the Respondents, separately by U.S,  
Postal service this day to:  
Mr. Joseph J. Tierney, Jr., Esquire  
Mr. Russell Grainger Hines, Esquire  
Mr. Stephen Lynwood Brown, Esquire  
P. O. Box 993  
Charleston, South Carolina 29402-0993  
(843) 577-4000.

/tg

Enclosures: Final Brief and Supplement to the Record on Appeal

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

MR#: 001846892 DOB: 01/12/37  
 GARRICK, THELMA R  
 St Francis IPC  
 PHYS: KHOURY-MD, GEORGE H  
  
 ACCT#: 15232-00085 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 @ L4/5  
 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. Not
- (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 Donald (McDonald)

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 9:05

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



Bo Secours St. Francis Hospital  
Operative Report  
08/20/2015

Designation of Matter

GARRICK, THELMA R  
1523200065  
George H Khoury MD  
Page 1

Page 1 of 2

Patient DOB: 01/12/1937

No implants Listed

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: George Khoury, MD.

ASSISTANT: Summer Landers, PA-C. Summer Landers 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 label that made me extremely ill

False

over

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 shared) 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, NC

Patient DOB: 01/12/1937

No Implants Listed

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 - I would never agree to this!*

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. No* After informed consent was obtained, the *one* patient was brought to the operating room and underwent general anesthesia. *said* The patient underwent somatosensory evoked potentials, EMGs at all times during the *an* case, and no abnormalities were seen. The patient was rolled in the prone *thin* position on chest rolls, with all pressure points padded. The lower back was *to me* routinely prepped and draped in a sterile fashion. The patient was given *see* preoperative antibiotics. *initially*

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. ?

*I worked full time for a law firm and part time thereafter until surgery.*  
*Still no specific names of implants.*  
*Implants not listed operative report, billing, to Medicare, anywhere until last medical records received (Final record I received only gave screw numbers. Almost a total cover-up!*

Bon Secours St. Francis Hospital  
Operative Report  
08/20/2015

GARRICK, THELMA R  
1523200065  
George H Khoury MD  
Page 3

Patient DOB: 01/12/1937

George H Khoury, MD  
TR: In DD: 08/20/2015 11:50 TD: 08/20/2015 13:44 Job#: 445690  
DOC#: 554216

Authenticated by GEORGE H KHOURY MD On 08/21/2015 04:32:04 PM

346 Page 3 of 5

PRINTED BY: gillpa

DATE

12/28/2016

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

GARRICK, THELMA  
1646892

George H Khoury MD  
Page 1

Patient Date of Birth: 01/12/1937



ACCT#: 15232-00065 08/20/15

No Implants Listed

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.

only 1 shot  
These symptoms were after surgery! Only pain before was in left sciatic nerve. He did a spinal stenosis operation in 2011? Only 1 steroid injection, no rehab.

Dr. Khoury took one off of gabapentin before the surgery of 8-20-15 and I will allow it!

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. He opened the door for his first two surgeries only!

SOCIAL HISTORY: She does not smoke or drink.

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

And 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: \_\_\_\_\_


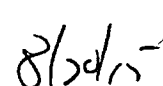
George H Khoury, MD

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:  

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

*gao*

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.

Lioresal® is a registered trademark of Medtronic, Inc.

USA Rx Only

Rev 0815



**SYNCHROMED EL** Distribution Port in Lumbar

**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. Khoury said my  
body was rejecting  
what he had put in me  
the Pain Distribution  
Port.

Tested device while  
in hospital in 'in him  
pain! butal nerves  
refused to let me  
go to surgery to proceed  
when I told her I was  
in too much pain

34c) Pages 1 of 3

technical errors or improper use of implanted infusion pumps and result in additional surgical procedures, a return of underlying symptoms, or a clinically significant or fatal drug under- or overdose. Refer to the appropriate drug labeling for specific under- or overdose symptoms and methods of management. Avoid using short wave (RF) diathermy within 30 cm of the pump or catheter. Diathermy may produce significant temperature rises in the area of the pump and continue to heat the tissue in a localized area. If overheated, the pump may over infuse the drug, potentially causing a drug overdose. Effects of other types of diathermy (microwave, ultrasonic, etc.) on the pump are unknown. An inflammatory mass that can result in serious neurological impairment, including paralysis, may occur at the tip of the implanted catheter. Clinicians should monitor patients on intraspinal therapy carefully for any new neurological signs or symptoms. For intraspinal therapy, use only preservative-free sterile solution indicated for intraspinal use. Use only Medtronic components indicated for use with this system. Failure to firmly secure connections can allow drug or cerebrospinal fluid (CSF) leakage into tissue and result in tissue damage or inadequate therapy. A postoperative priming bolus should not be programmed if the pump is a replacement and the catheter has not been aspirated.

Refer to appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration information, and screening procedures. Physicians must be familiar with the drug stability information in the technical manual and must understand the dose relationship to drug concentration and pump flow rate before prescribing pump infusion. Implantation and ongoing system management must be performed by individuals trained in the operation and handling of the infusion system.

Inform patients of the signs and symptoms of drug under- or overdose, appropriate drug warnings and precautions regarding drug interactions, potential side effects, and signs and symptoms that require medical attention. Instruct patients to notify their clinician of travel plans, to return for refills at prescribed times, avoid activities such as strenuous exercise or contact sports that jar, impact, twist, or stretch the body, to always carry their Medtronic device identification card, to avoid manipulating the pump through the skin, and to notify healthcare professionals of the implanted pump before medical tests/procedures. Patients must consult their physician before engaging in activities involving pressure or temperature changes (e.g., scuba diving, saunas, hot tubs, hyperbaric chambers, flights, skydiving, etc.).

#### PRECAUTIONS:

The pump is ethylene oxide sterilized. Do not use if the product or package is damaged, the sterile seal is broken, or the "Use By" date has expired. Do not reuse or resterilize the pump; it is intended for "single use only." Do not expose the pump to temperatures above 43°C or below 5°C. Consider use of peri- and post-operative antibiotics for pump implantation, for any subsequent surgical procedure, or if infection is present. For patients prone to CSF leaks, clinicians should consider special procedures, such as a blood patch. Follow instructions for emptying and filling the pump during a replacement or revisions that require removal of the pump from the pocket. Explant the pump postmortem if incineration is planned (to avoid explosion), or if local environmental regulations mandate removal. Return explanted devices to Medtronic for analysis and safe disposal. Do not implant a pump dropped onto a hard surface or showing signs of damage. Implant the pump less than 2.5 cm from the surface of the skin. Ensure pump ports will be easy to access after implant, that the catheter is not kinked and secured well away from pump ports before suturing. Keep the implant site clean, dry, and protected from pressure or irritation. If therapy is discontinued for an extended period of time, fill the reservoir with preservative-free saline in intraspinal applications or appropriate heparinized solution (if not contraindicated) in vascular applications.

The magnetic field or telemetry signals produced by the programmer may cause sensing problems and inappropriate device responses with an implantable pacemaker and/or defibrillator. Electromagnetic interference (EMI) is an energy field generated by equipment found in the home, work, medical, or public environments. Most EMI normally encountered will not affect the operation of the pump. Exceptions include: injury resulting from heating of the pump which can damage surrounding tissue (diathermy, MRI), system damage which can require surgical replacement or result in loss/change in symptom control (defibrillation, electrocautery, high-output ultrasonics, radiation therapy), and operational changes to the pump causing the motor to stop, loss of therapy, return of underlying symptoms, and require confirmation of pump function (diathermy, high magnetic field devices, hyperbaric/hypobaric conditions, magnetic resonance imaging (MRI)). MRI will temporarily stop the pump motor's rotor due to the magnetic field of the MRI scanner and suspend drug infusion during MRI exposure. The pump should resume normal operation upon termination of MRI exposure. Prior to MRI, the physician should determine if the patient can safely be deprived of drug delivery. If

34(c) 2 of 3

not, alternative delivery methods for the drug can be utilized during the MRI scan. Prior to scheduling an MRI scan and upon its completion, pump status should be confirmed.

**ADVERSE EVENTS:**

Include, but are not limited to, cessation of therapy due to end of device service life or component failure, change in flow performance due to component failure, inability to program the device due to programmer failure, CAP component failure; inaccessible refill port due to inverted pump, pocket seroma, hematoma, erosion, infection, post-lumbar puncture (spinal headache), CSF leak, radiculitis, arachnoiditis, bleeding, spinal cord damage, meningitis (intrathecal applications), anesthesia complications, damage to the pump, catheter and catheter access system due to improper handling and filling before, during, or after implantation; change in catheter performance due to catheter kinking, disconnection, leakage, breakage, occlusion, dislodgement, migration, or catheter fibrosis; body rejection phenomena, surgical replacement of pump or catheter due to complications; local and systemic drug toxicity and related side effects, complications due to use of unapproved drugs and/or not using drugs in accordance with drug labeling, or inflammatory mass at the tip of the catheter.

Lioresal® is a registered trademark of Medtronic, Inc.

USA Rx only

Rev 0911

**ISOMED**

**ISOMED CONSTANT FLOW INFUSION SYSTEM**

Product technical manuals and the appropriate drug labeling must be reviewed prior to use for detailed disclosure.

**INDICATIONS**

US: Chronic intrathecal infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain and chronic intravascular infusion of floxuridine (FUDR) for the treatment of primary or metastatic cancer. Outside of US: Chronic infusion of drugs or fluids tested as compatible and listed in the product labeling.

**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. Do not use the Personal Therapy Manager accessory to administer oploid to oploid-naïve patients or to administer ziconotide. Blood sampling through the catheter access port is contraindicated.

**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 technical errors or improper use of implanted infusion pumps and result in additional surgical procedures, a return of underlying symptoms, or a clinically significant or fatal drug underdose or overdose. Refer to the appropriate drug labeling for specific underdose or overdose symptoms and methods of management. Avoid using short wave (RF) diathermy within 30 cm of the pump or catheter. Diathermy may produce significant temperature rises in the area of the pump and continue to heat the tissue in a localized area. If overheated, the pump may over infuse the drug, potentially causing a drug overdose. Effects of other types of diathermy (microwave, ultrasonic, etc.) on the pump are unknown. An inflammatory mass that can result in serious neurological impairment, including paralysis, may occur at the tip of the implanted catheter. Clinicians should monitor patients on intraspinal therapy carefully for any new neurological signs or symptoms. For intraspinal therapy, use only preservative-free sterile solution indicated for intraspinal use. Use only Medtronic components indicated for use with this system. Failure to firmly secure connections can allow drug or cerebrospinal fluid (CSF) leakage into tissue and result in tissue damage or inadequate therapy. A postoperative priming bolus should not be programmed if the pump is a replacement and the catheter has not been aspirated. Refer to appropriate drug

*Dr. Khoury told me my body was rejecting (what he put in me) the implant*

*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.**

*yes, per  
Medtronic  
Employee*

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.**

*yes*

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."

Resignation of Walter pp 2 of 3  
letter 8, pp 81

8-20-15  
Infuse - bone graft  
device - a definite  
from Medtronic personnel  
per Garner 1-4-18

BUSINESS

# Medtronic says it's close to resolving Infuse lawsuits

Medtronic did not release figures for the confidential settlements. The company reported that it set aside \$300 million for all of its legal settlements in the fiscal year that ended in April, according to the Securities and Exchange Commission filing.

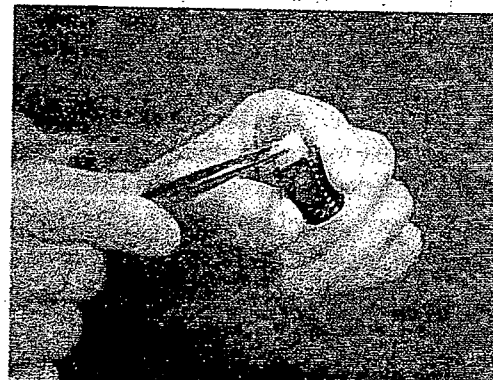
By Joe Carlson (<http://www.startribune.com/joe-carlson/271816721/>) and Jim Spencer (<http://www.startribune.com/jim-spencer/81726751/>) Star Tribune staff writers

JUNE 28, 2017 - 9:07PM

Medical device giant Medtronic PLC has told investors that the company is ready to close the book on one of its biggest and longest-running legal headaches, involving the controversial back-surgery product Infuse.

Infuse includes a genetically engineered protein that causes bones to fuse rapidly after lower back pain surgery. Thousands of patients claim the chemical was used inappropriately, causing permanent, debilitating injuries. In a securities filing Tuesday, Minnesota-run Medtronic revealed that it has reached agreements to settle "substantially all" of the 6,000 actual and threatened Infuse lawsuits.

Ads by ZIFC



(<http://stmedia.startribune.com/images/Infuse1.JPG>)  
MIKE NELSON, HANDOUT

Medtronic Inc.'s "Infuse" device

?

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The company said it is cooperating with attorneys general in five states that have sent subpoenas and document requests for information on how Medtronic studied, marketed and sold Infuse. Late last year Medtronic set aside an undisclosed amount of money "in connection with" the inquiries from attorneys general in California, Illinois, Massachusetts, Oregon and Washington, the Tuesday SEC filing said.

"We continue to cooperate in the State AG inquiries and are hopeful an acceptable resolution can be reached," Medtronic spokesman Eric Epperson said via e-mail Wednesday. Spokespeople with each of the state offices declined to comment.

Medtronic had previously disclosed reaching settlements in more than 4,000 Infuse patient lawsuits. In December, a judge in St. Louis cleared the way for the first jury trial involving personal injuries allegedly caused by Infuse. Such a trial could have revealed

Did Dr. Khoury  
implant this when  
spine was cut  
into and grafted  
back together?  
help conversation  
yes, per Vicki Barnett  
Medtronic 3-4-18

34(d) Page 2 of 17

thousands of pages of sealed internal documents that other plaintiffs could have used in their cases.

Medtronic has always denied the allegations in lawsuits from patients, investors and employees-turned-whistleblowers who claimed over the years that Medtronic promoted sales of Infuse for surgeries that were never proven to be safe and effective uses of the chemical. The company says it strictly follows the law on promotion of medical devices, and it cannot control when doctors use it in unapproved ways, like in pediatric surgery.

The so-called "off-label" use of medical devices is legal because the U.S. Food and Drug Administration regulates only products, not the practice of medicine. Many of the injured patients allege in their lawsuits that they found out about the use of Infuse only after their surgery ended with complications. Some say Medtronic sales reps were present in the operating rooms during their surgeries.

Infuse was approved in 2002 by the FDA for use in adults getting a relatively uncommon type of back surgery. Almost immediately after approval, doctors began widely using the product in ways that the FDA never evaluated for safety, according to statistics published in peer-reviewed journals.

In 2007, Medtronic compiled a database of more than 3,600 Infuse surgeries, the vast majority of which were off-label. The Star Tribune reported last year that more than 1,000 of the surgeries resulted in adverse events, which Medtronic did not report to the FDA for more than five years. The data included a pattern of injuries from a particularly risky off-label use of Infuse in neck surgery — a surgery that later prompted an FDA public warning.

Medtronic paid a \$40 million settlement to the Justice Department in 2006 to resolve whistleblower allegations that it paid "kickbacks" to induce doctors to use its spine products. The company paid at least \$85 million in a settlement to shareholders in 2012 to resolve allegations that it failed to reveal that most sales of Infuse were for off-label surgeries. In 2014, Medtronic said it paid \$22 million to 950 injured Infuse patients. The company denied wrongdoing in each settlement.

The SEC filing on Tuesday did not reveal the exact amount of money Medtronic has agreed to pay for its remaining 6,000 Infuse patient cases. The filing says the company wrote off \$300 million for "certain litigation charges" including the Infuse settlements in the fiscal year ended in April. That was up from \$26 million in litigation charges booked in 2016.


Earlier Infuse settlements broke awards into tiers depending on the severity of the injury, with those who were most badly hurt collecting the largest amounts. The individual amounts received in personal injury cases are reduced by attorneys' contingencies that often range from 33 to 40 percent of the award, as well as insurance company "clawbacks" of money paid to cover surgeries.

Pat Beaudry of Apple Valley was left with chronic pain on his left side after getting Infuse during back surgery. Today he uses a cane and often cannot move his left leg. He says his left hand is numb. He still takes opioids daily. He will never be able to work again.

"My settlement was based on \$27,000," Beaudry said Wednesday by phone. "By the time it was done, I got \$2,200. ... I am so disappointed in the medical system, but also in the legal system."

*SC legislature set a ceiling for medical malpractice at 300,000*

*Extreme pain left side  
Inability to return to recreational, job, personal sexual activities noted  
See Operative Report*

 *Result of Experimental Surgeries!*

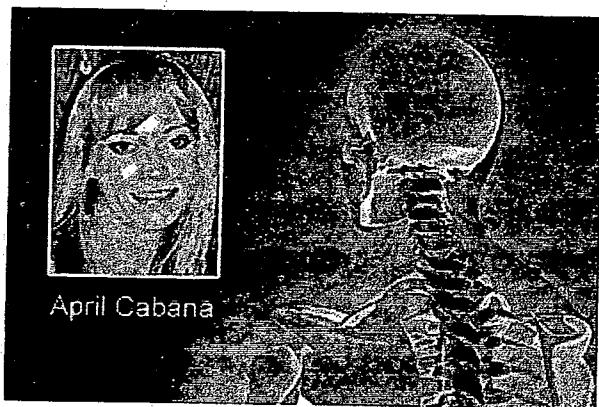
MEDTRONIC DEVICE LAWSUIT: 1-800-827-0087

<https://www.baumhedlundlaw.com/defective-medical-device-injuries/medtronic-infuse-bone-graft-device-lawsuit/>

A California state court judge ruled in favor of a California resident represented by Baum, Hedlund, Aristei & Goldman, allowing her lawsuit against Medtronic to move forward. This is good news for patients across the country who received the Medtronic INFUSE® Bone Graft medical device procedure in an off-label manner, not approved by the FDA.

### **Lawyers Investigate Hospitals Where Spine Surgeries Caused Patients Severe Pain, Excessive Bone Growth and Other Complications**

Baum Hedlund's first Infuse case involves back surgery patient, April Cabana, who originally sued Medtronic, in addition to Stryker Biotech, her doctor, and Pomona Valley Hospital Medical Center, on July 13, 2011 after two different medical devices implanted during two different back surgeries resulted in debilitating and permanent injuries to her spine.



Baum Hedlund has Defeated Preemption

In Ms. Cabana's Case Three Times

1. August 20, 2012 re Medtronic Infuse
2. September 9, 2013 re Medtronic Infuse
3. September 9, 2013 re Stryker OP-1 Putty

Were you injured by a defective medical device? Do you have a medical device that was implanted in an unapproved, off-label manner? If so, Contact Baum Hedlund today for a free consultation

For Your Free Case Evaluation Please Contact Us

If you have experienced excessive bone growth after back or neck surgery involving Medtronic INFUSE®, please contact our law firm at 800-827-0087 or provide information below:

What is Medtronic INFUSE Bone Graft?

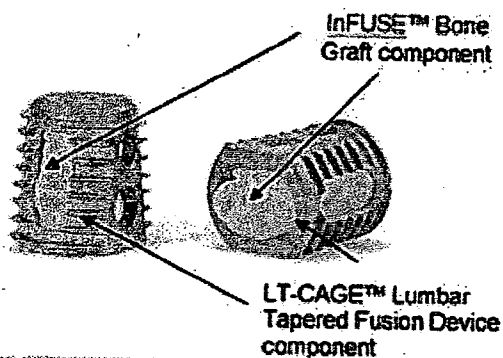


Photo showing the 3 parts of InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device - P000058

The FDA approved InFuse Bone Graft Device in 2002 for a limited type of spinal fusion surgery to alleviate severe back pain. InFuse Bone Graft Device is a liquid substance produced by a genetically engineered Chinese hamster ovary cell line. It is a recombinant bone morphogenetic protein ("BMP") that is supposed to stimulate controlled bone growth and fuse the vertebrae.

October 31, 2012

The U.S. Senate Finance Committee issued a lengthy report showing that medical device maker Medtronic, Inc. paid doctors hundreds of millions of dollars to manipulate studies and write favorable articles on the company's popular bone graft product, InFUSE. **Read More**

Trouble for Medtronic INFUSE

Medtronic has been under scrutiny for years now concerning allegations of illegal off-label promotion and use of InFuse Bone Graft Device, financial conflicts of interest by researchers, under-reporting of complications and overblown reports of

superior clinical results. About 85% of Infuse use is off-label according to MedPage Today.

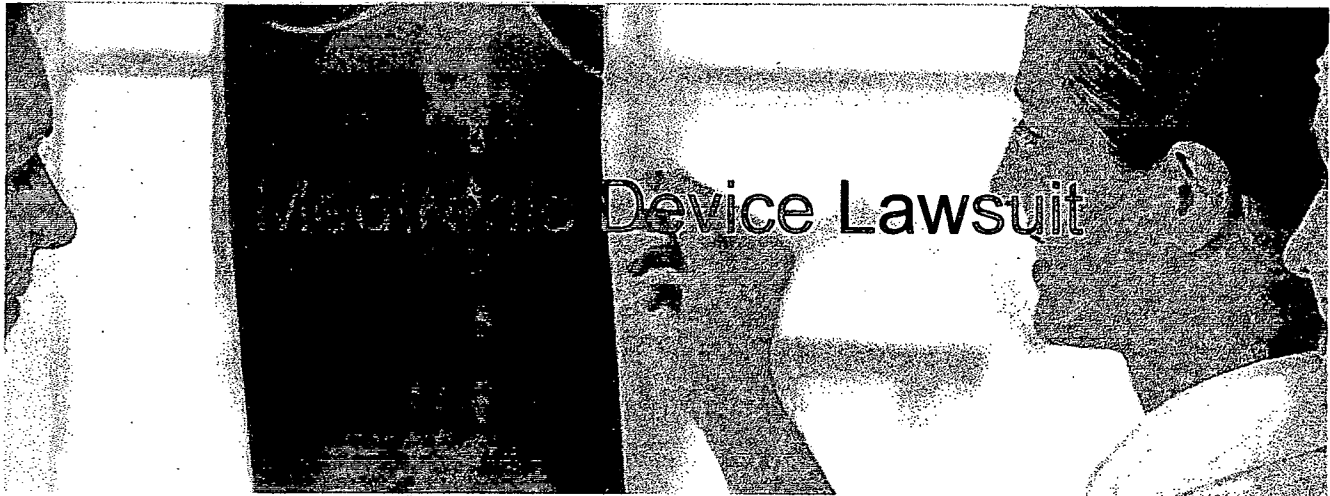
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- Medtronic paid \$85 million in March of 2012 to settle a shareholder lawsuit accusing it of making misleading statements concerning Infuse Bone Graft Device. According to a Reuters report, the settlement resolves claims that Medtronic failed to reveal that as much as 85.2 percent of Infuse sales depended on so-called "off-label" uses, where doctors sometimes paid by Medtronic would prescribe the product for applications not approved by the FDA.
- Although the U.S. Department of Justice closed its investigation into Medtronic's marketing and alleged off-label use of Infuse Bone Graft in May of 2012, Senators Charles Grassley (R-Iowa) and Max Baucus (D-Mont.) have investigations pending looking into allegations that Medtronic failed to report Infuse Bone Graft side effects and that the company may have had financial ties to clinical investigators. *was paid \$40,000,000*
- Last summer Medtronic commissioned researchers at Yale University with a \$2.5M grant to conduct an independent review of the safety and effectiveness of Infuse Bone Graft, including all patient data generated during the Infuse clinical trials. Although Yale stated it would make the results of its review public by summer of 2012, it has yet to do so.

**Medtronic Paid Millions to Manipulate InFUSE Studies, Senate Finance Committee Investigation Finds**

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## Medtronic Infuse Bone Graft Device Lawsuit

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Interested in exploring your legal rights? Tell us about your case. Contact us or call 800-827-0087 for a free, no-obligation consultation.

*\*Designates a required field*

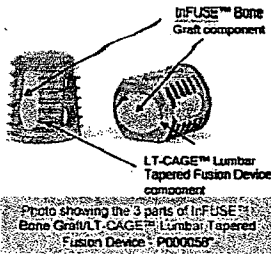
Subject \*

WERE YOU INJURED BY A DEFECTIVE MEDICAL DEVICE? DO YOU HAVE A MEDICAL DEVICE THAT WAS IMPLANTED IN AN UNAPPROVED, OFF-LABEL MANNER? IF SO, CONTACT BAUM HEDLUND TODAY FOR A FREE CONSULTATION

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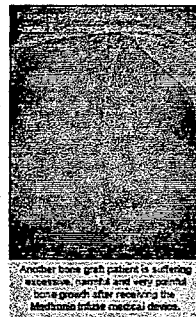
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Medtronic Paid Millions to Manipulate InFUSE Studies, Senate Finance Committee Investigation Finds



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Cases as a Result of  
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Item 15

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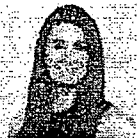
Written by [Terry Turner](#) Writer

- [Email](#)

Terry Turner is an Emmy-winning journalist with more than 25 years of experience in radio, television, print and digital media. He joined Drugwatch in April 2017. His work at Drugwatch has been cited in prominent publications including [The New York Times](#) and the [Washington Examiner](#). Some of his qualifications include:

- Centers for Disease Control and Prevention certificates in Health Literacy
- American Bar Association associate membership in Health Law Section
- About 12 years' experience working for the U.S. Department of Defense

### [More About Terry Turner](#)



Edited By [Emily Miller](#) Editor

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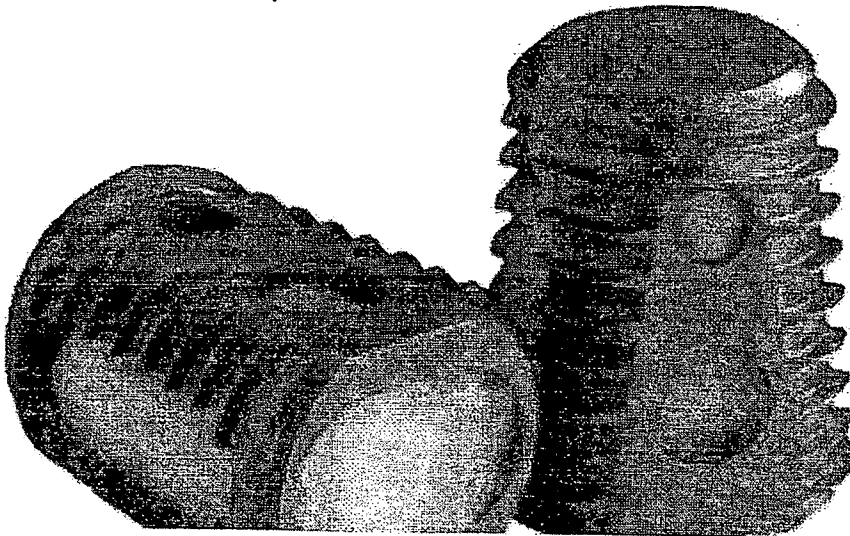
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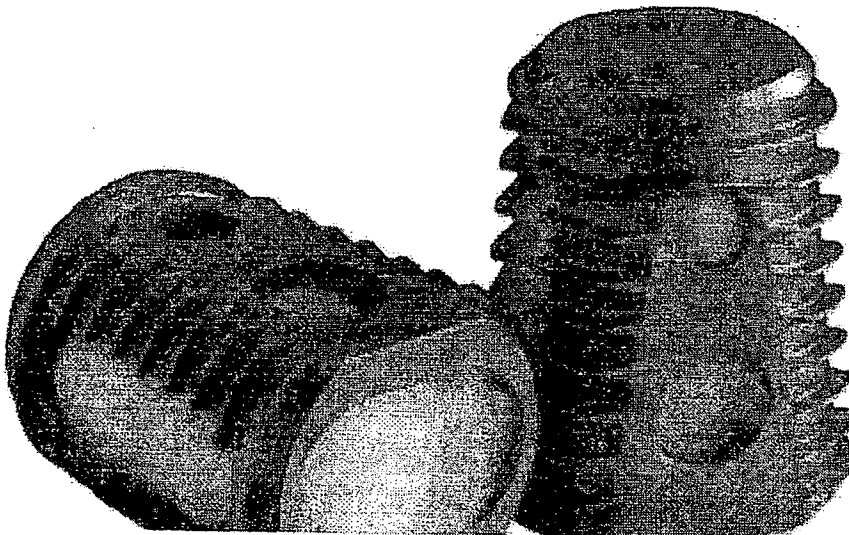
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## Medtronic Settles 950 INFUSE Bone Graft Lawsuits for \$22M

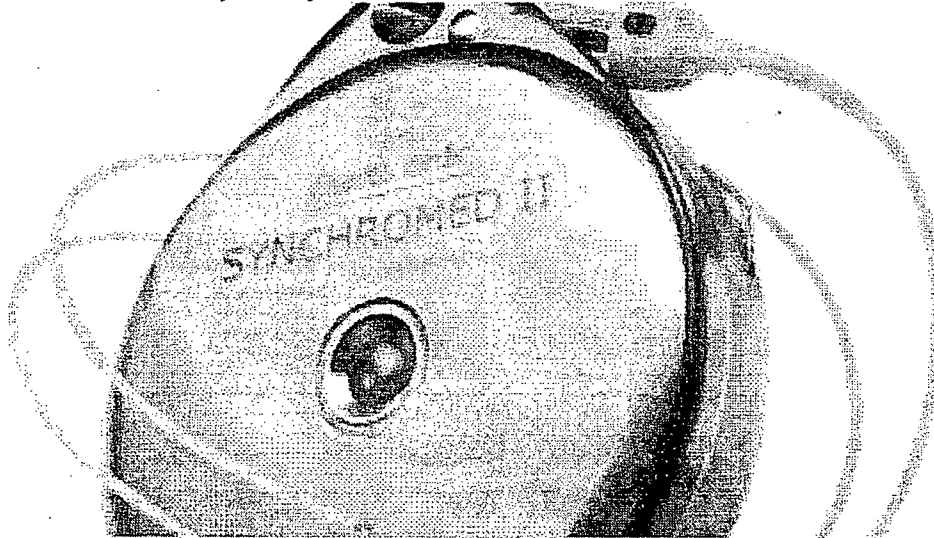
Staff Writer May 6, 2014



## Q&A with INFUSE Bone Graft Lawyer Laura Yaeger



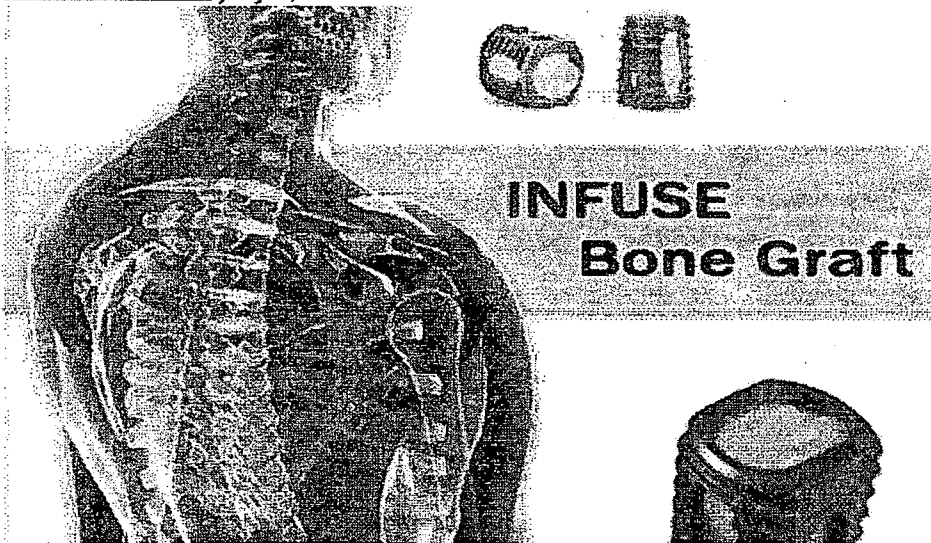
Michelle Llamas January 7, 2014



## Amid INFUSE Bone Graft Controversy, Medtronic's Pain Pump Blamed for Patient Deaths



Michelle Llamas July 5, 2013



## Yale Study: INFUSE Bone Graft Offers Little Benefit, Can Cause Complications



Michelle Llamas June 20, 2013

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Two patients who received Infuse bone grafts at the University of California Los Angeles (UCLA) later sued the teaching hospital, surgeon Jeffrey Wang and Medtronic for alleged injuries resulting from the off-label use of the product.

The plaintiffs, Ralph Weiss and Jerome Lew, alleged that in both surgeries Medtronic's Infuse product was used in ways not approved by the FDA.

#### **Settlement Fact**

UCLA settled with Weiss and Lew for a combined \$8.45 million.

The patients further alleged that Wang failed to inform them of a financial relationship between the surgeon and the product manufacturer. The lawsuits claimed that Wang received hundreds of thousands of dollars in grants and royalties from Medtronic.

UCLA settled with Weiss and Lew for a combined \$8.45 million, with Weiss receiving a little more than \$4.25 million. Medtronic also settled with Lew for an undisclosed amount.

UCLA said it only settled so the school and its medical program could "move forward," but it did not respond to any of the allegations made by the plaintiffs.

### **Medtronic Pays \$40M Settlement to U.S. DOJ**

Medtronic paid \$40 million to the U.S. Department of Justice to settle charges that it had violated the Anti-Kickback Statute.

The statute is a part of the federal False Claims Act and was designed to ensure a physician's independent medical judgment in making decisions affecting a patient's health, free from enticement by companies such as Medtronic.

The government alleged that between 1998 and 2003 Medtronic paid kickbacks to physicians in various forms, including sham consulting agreements, royalties and lavish trips.

### **Medtronic pays Shareholders \$85M Settlement in Infuse Lawsuit**

Medtronic's shareholders brought their own lawsuit against the company, alleging it made misleading statements regarding Infuse. Although the manufacturer denied any wrongdoing, it agreed to settle for \$85 million in 2012.

The settlement resolves, among other claims, Medtronic's failure to disclose how much of its success of Infuse was dependent upon it being used in off-label manners. Shareholders further alleged that Medtronic's Infuse sales, as well as its shares, fell after the company's disclosure of the Justice Department investigation.

In December 2016, the Eighth U.S. Circuit of Appeals revived a second shareholder lawsuit following a lower court's ruling that the plaintiff shareholders filed their suit too late.

The appeals court's decision said that shareholders would not have been aware of potential problems concerning Medtronic's Infuse studies until the 2011 publication of an article in The Spine Journal that called Medtronic's alleged fraudulent actions into question.

Plaintiffs included West Virginia Pipe Trades Health and Welfare Fund, the Employees' Retirement System of the State of Hawaii and Germany's Union Asset Management Holding AG.

Please seek the advice of a medical professional before making health care decisions.

Attorneys also pointed out that one of the components had never gained FDA approval. The Infuse device used in Keim's surgery also didn't include all of its intended parts.

Product liability expert David Prince of Mitchell Hamline School of Law said in a news report that the ruling was "a very big deal" for the thousands of plaintiffs who had been waiting on the sidelines.

In ruling that the pre-exemption doctrine did not apply in Keim's case, the court opened the floodgates for thousands of other Infuse lawsuits to move forward.

## **Medtronic Paid \$22 Million in Earlier Infuse Settlements**

Earlier, in 2014, Medtronic paid a total of \$22 million to settle about 950 claims from plaintiffs allegedly injured after Infuse was used in their spinal surgeries. The settled lawsuits accused the company of manipulating studies and engaging in misleading marketing tactics.

The company said the settlement was rendered to "disputed claims" and confirmed that the compromise was in no way an admission of liability. Medtronic said it stood by its product, which has been used in more than 1 million patients since FDA approval in 2002.

The company projected spending \$120 million to \$140 million on settlements — including the \$22 million one — in the fourth quarter that year.

## **Medtronic, 5 States Reach \$12M Settlement**

In December 2017, Medtronic agreed to pay five states \$12 million to resolve a deceptive advertising lawsuit claiming the company misled doctors and the public about its Infuse bone grafts.

State attorneys general had argued Medtronic worked in secret to manipulate research articles on Infuse. They claimed the company then used those articles appearing in medical journals to market the device and increase sales.

"By using these misleading claims, the company created a higher demand for Infuse," Oregon Attorney General Ellen Rosenblum said in a statement. "It is unacceptable for a company to use company-sponsored literature with misleading data to try to show that its product is more effective than other therapies."

In 2012, the U.S. Senate Finance Committee found Medtronic had been "heavily involved" in research and writing behind published studies of Infuse. The committee also determined the company had paid the doctors who authored the studies \$210 million.

The lawsuit had claimed Medtronic

- misrepresented which Infuse uses were FDA approved
- marketed the device as safer than it actually was
- played down the risks the device posed to patients.

In agreeing to the settlement, Medtronic denied any wrongdoing. But the company will have to follow new requirements on how it uses information from research in promotional and marketing efforts.

The state governments of California, Illinois, Massachusetts, Oregon and Washington state each shared in the settlement.

## **UCLA Hospital Pays \$8.45M Settlement with Infuse Patients**

Off-label/improper use of Infuse Bone Graft in cervical spine surgery; undisclosed financial relationship between the doctor performing his surgery and Medtronic; not receiving consent to operate in an off-label manner

### **Lori Byrnes**

**Allegations:**

Off-label/improper use of Infuse Bone Graft in spinal fusion surgery; negligence; fraud; loss of consortium (refers to the loss of benefits of a familial relationship)

**Injuries:**

Severe, continuous pain; bony overgrowth; economic losses

### **Ralph Weiss**

**Allegations:**

**Allegations:**

Off-label/improper use of Infuse Bone Graft in cervical spine surgery; undisclosed financial relationship between the doctor performing his surgery and Medtronic

**Injuries:**

Infection

### **Patricia Caplinger**

**Allegations:**

Promoting Infuse for non FDA-approved uses; Medtronic sales representative recommended off-label use to surgeon

**Injuries:**

Spine injuries requiring additional surgeries; drop foot condition in right leg that led to torn ligament in right knee; bone overgrowth

### **Ralph Royer**

**Allegations:**

Off-label/improper use of Infuse Bone Graft in cervical spine surgery

**Injuries:**

Bony overgrowth; additional surgeries; pain and suffering

## **Court Date Forces \$300M Infuse Settlement**

In December 2016, a Missouri court set a trial date for an Infuse lawsuit filed by Trisha Keim, effectively backing Medtronic into a corner. Within seven months, the company reported it had set aside \$300 million to settle "substantially all" of the 6,000 lawsuits it still faced. Keim's case never went to trial.

Until the court set a case for trial, Medtronic had been able to have the courts keep thousands of pages of internal company documents sealed. A jury trial would have made the documents public and available for thousands of other plaintiffs to use in their lawsuits against Medtronic.

Medtronic had previously argued that the "preemption doctrine" shielded Infuse from lawsuits. The argument was that FDA approval meant the device was protected for all lawsuits, including those over off-label uses.

But Keim's lawyers argued that the Infuse device used in her surgery "departed from its intended design, including that the parts were sold separately rather than together."

Medtronic has settled 4,000 of the lawsuits and reportedly planned to settle almost all of the pending 6,000 lawsuits.

The latest settlement was expected to put an end to all remaining and future Infuse bone graft lawsuits against Medtronic.

Infuse bone graft settlements were projected to total more than \$460 million.

## Status of Infuse Bone Graft Lawsuits

Financial documents filed with the federal government in June 2017 reported Medtronic planned to settle "substantially all" of the remaining 6,000 or so lawsuits over its Infuse device.

The company told the Securities and Exchange Commission it had put aside \$300 million to cover "certain litigation charges."

The settlement was likely to resolve pending Infuse lawsuits against Medtronic as well as end plans for any future widespread Infuse litigation over the same allegations.

Medtronic had resolved more than 4,000 other Infuse lawsuits through earlier settlements. These included a \$22 million settlement with 950 Infuse patients in 2014. Medtronic settled others for undisclosed amounts.

In addition, the company paid \$85 million to settle a shareholders lawsuit in 2012 for failing to reveal most Infuse sales were for off-label uses.

In December 2017, Medtronic paid \$12.5 million to settle a lawsuit filed by five states' attorneys general claiming the company had deceptively or fraudulently marketed Infuse.

The U.S. Department of Justice also investigated Medtronic. The investigation ended in a \$40 million payout to settle allegations of illegal kickbacks to doctors as incentive to use Medtronic's Infuse product.

### Fact

Medtronic has paid more than \$460 million to settle lawsuits over its Infuse Bone Graft.

## Why People Sued Over Infuse Bone Grafts

A 2008 lawsuit filed in California claimed that the off-label use of Infuse for a neck surgery is what killed a 74-year-old woman.

Other patients have filed thousands more lawsuits claiming the device has caused complications ranging from unwanted bone growth to cancer.

People filing lawsuits blamed off-label use for their injuries in 85 percent of the cases.

Lawsuits named Medtronic, the hospitals where their spinal surgeries were performed and/or the surgeons who performed their procedures.

*Appellant's X-ray shows abnormal bone growth. Also a broken wrist not properly treated shows abnormal bone growth where wrist cannot be repaired!*

### Jerome Lew

#### Allegations:

Off-label/improper use of Infuse Bone Graft in cervical spine surgery; undisclosed financial relationship between the doctor performing his surgery and Medtronic; not receiving consent to operate in an off-label manner

#### Injuries:

## *Court Orders Search Results*

**Number of Matched Records:** 1

**Court Order - 2014-04-15-02**

**Summary:** The Supreme Court of South Carolina Re: Revised Order Concerning Personal Identifying Information and Other Sensitive Information in Appellate Court Filings Appellate Case No. 2013-002681 ORDER On August 13, 2007, this Court issued an interim O  
[/courtOrders/displayOrder.cfm?orderNo=2014-04-15-02](#)

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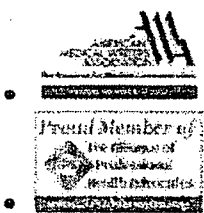
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## Infuse Bone Graft Lawsuits

Since 2008, more than 10,000 people have sued Medtronic over serious complications they claim resulted from the company's Infuse bone graft. The company spent most of a decade settling 4,000 of the lawsuits, often in individual and confidential agreements. In June 2017, the company reported it had set aside \$300 million to resolve virtually all pending and planned Infuse lawsuits against Medtronic, which could mean an end to lawsuits injured patients could file.

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- [First Jury Trial](#)
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- [State Settlements](#)
- [Infuse Patients, UCLA Settle](#)
- [Medtronic Settles DOJ Case](#)
- [Shareholders Sue](#)

### Infuse Bone Graft Lawsuit Facts

1. **Number of Lawsuits** Approximately 10,000 (almost all settled)
  2. **Plaintiff Injuries** Increased pain, weakness, spinal injuries and additional surgeries
  3. **Defendants** Medtronic; certain hospitals and physicians/surgeons
  4. **Plaintiff Locations** Oklahoma, California, Florida, Kentucky and Missouri
  5. **Litigation Status** "Substantially all" of roughly 10,000 lawsuits have been settled
  6. **MDL Location** None
  7. **Settlements** More than \$460 million total: \$22 million to settle about 950 claims; \$300 million to settle roughly 6,000 claims; more than 3,000 claims settled for undisclosed amounts; \$40 million to the DOJ; \$85 million to settle a shareholder lawsuit; \$12 million to settle deceptive marketing lawsuit filed by five states
- By [Terry Turner](#)
  - Edited By [Emily Miller](#)
  - This page features [29 Cited Research Articles](#)

Last modified: May 15, 2018

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### Related Pages

- [INFUSE Bone Graft Overview](#)
  - [Lawsuits](#)

People who sued Medtronic claimed the company pushed doctors to use its [Infuse Bone Graft](#) for treatments for which it had not been approved, known as "off-label" use.

About 10,000 patient lawsuits claimed Medtronic marketed Infuse for off-label uses that contributed to patient injuries, and in some cases, death.

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

139254

Joe Carlson  
Star Tribune  
612-673-4779

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

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

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# GEORGE H KHOURY

Allopathic & Osteopathic Physicians|Neurological  
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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  
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Year: 2015



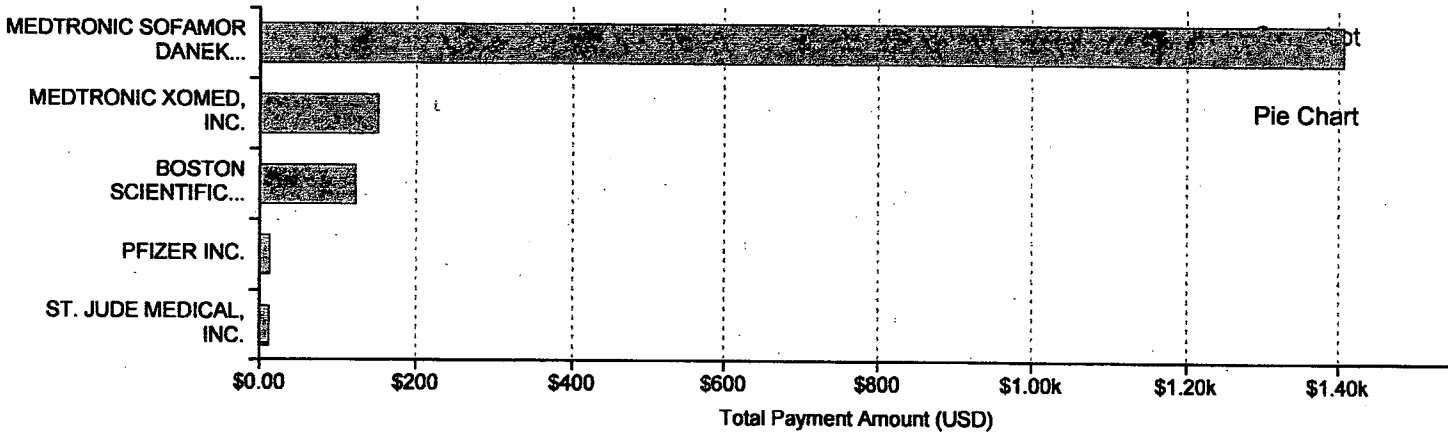
Payment Type: General



What are the different payment types?

## Top Companies Making General Payments

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[Pie Chart](#)

## 5 Companies Making General Payments

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Company Making Payments	Total Payments	Total Amount	Total Amount (%)
<a href="#">MEDTRONIC SOFAMOR DANEK USA, INC.</a>	12	\$1,408.26	82.3%
<a href="#">MEDTRONIC XOMED, INC.</a>	1	\$152.96	8.9%
<a href="#">BOSTON SCIENTIFIC CORPORATION</a>	1	\$124.30	7.3%

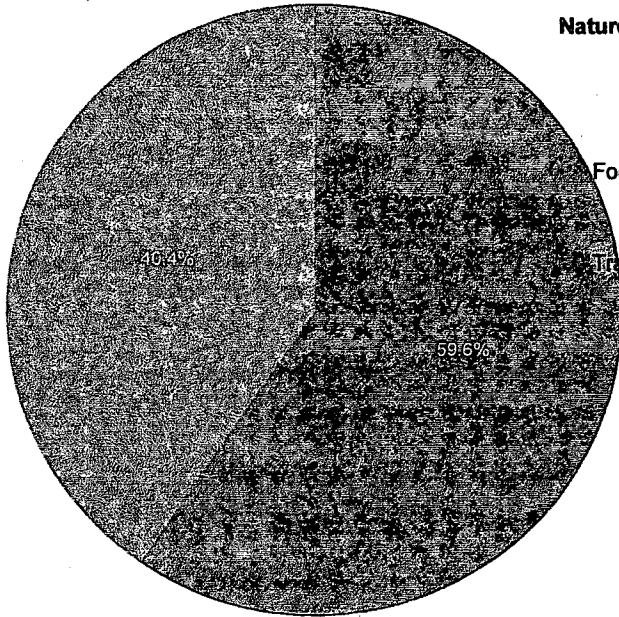
<u>PFIZER INC.</u>	1	\$13.70	0.8%
<u>ST. JUDE MEDICAL, INC.</u>	1	\$12.55	0.7%

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

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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	

Company Making Payment	Nature of Payment	Date	Amount	Third Party Payment	Disputed?
<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

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<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

in medicine. Altogether, Medtronic paid \$90 million in royalties in 2014, more than any other device company in the country.

"The goal of these kinds of fees is to influence prescribing behavior," said Dr. Michael Carome, health research director at the consumer advocacy group Public Citizen. The payments are "in the financial interests of the company and the physicians," he added, "not in the best interest of the patients."

Medtronic disagrees. Company officials argue that payments to physicians propel innovations that relieve pain and promote healing. "When a new technology is used to improve care and outcomes for a large number of patients, it makes sense for a physician to benefit from their inventive contributions," Medtronic spokeswoman Cindy Resman said in an e-mail.

Royalties paid for patented and licensed innovations comprise the largest slice of payments to doctors, \$800 million last year, according to data released last month under the federal Open Payments program. Seven of the top 10 companies or divisions paying royalties last year sell medical devices for skeletal problems.

One of the most controversial medical products on the market, Medtronic's bone-growth system Infuse includes a synthetic human protein that has helped tens of thousands of patients overcome serious back pain but left thousands of others claiming they were injured. Medtronic acknowledges risks like unexpected bone growth and sexual dysfunction in men.

Many questions about Infuse center on the credibility of early research, because at least 11 studies that omitted key safety data were written by doctors who were paid millions in royalties from Medtronic.

South Dakota neurosurgeon Dr. Larry Teuber is skeptical that all industry royalties are truly for product development, given the large profits to be made by devicemakers and hospitals on orthopedic surgeries like spinal fusions.

“Remember, the markup on these devices is huge,” said Teuber, who used to run a surgery center in Rapid City. “The reason they pay money is to get these guys to use their implants. Royalties are just another twist in the story.”

Critics ranging from Teuber to the national health insurer Humana say that royalty arrangements can be structured in the orthopedics business to reward doctors for promoting a device or drug, rather than for inventions that substantively improve a product.

In an ongoing federal lawsuit against Medtronic, Humana accuses the company of paying “disguised royalties” to study authors who wrote peer-reviewed journal articles about uses of Infuse not approved by the Food and Drug Administration. Medtronic vociferously denies Humana’s allegations.

Many of the authors named in the 2014 Humana suit were first identified in a 2012 Senate Finance Committee report that criticized what it called biased Infuse research. Those doctors collected more than \$11 million in royalties from Medtronic last year.

Resman said royalties are common in the orthopedics world because doctors bring special insight into the sensitive anatomy of the spine.

“These products are often advanced by the physicians who understand the anatomy, approaches, and placement of these technologies,” Resman wrote to the Star Tribune. “These inventive contributions are really part of [research and development] activity that is more unique to spine and orthopedics.”

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.

Because of its high cost, Infuse is meticulously monitored by insurers like Humana.

A 2011 study in the journal *Surgical Neurology International* said hospitals typically pay \$5,000 to \$6,000 for a large package of BMP. Teuber said hospitals frequently bill insurers for double or triple what they paid for medical devices.

Humana charges that Medtronic "expanded BMP sales by paying large amounts of money to 'Key Opinion Leader' (KOL) spine surgeons around the country, many of whom then published articles, or appeared at special 'dinners' or continuing education seminars advocating BMP use," in ways that were not approved by regulators.

The company has long denied such allegations. Resman noted that payments to physicians are based on a small percentage of sales, and that the amounts are closely monitored. "We have a lot of oversight in our process to ensure our process of determining royalties is appropriate and based on fair market value," she wrote.

California spine surgeon Dr. Charles D. Rosen, co-founder of the Association for Medical Ethics, said the public debate over such payments is important, and federal payment disclosures like those last month act as a fail-safe in making the right decisions for patients. "When you read a paper by a bunch of doctors and it says, 'This device is good,' then you might start to use it if you know the research is independent," Rosen said. "If you find out that all the doctors have royalties and million-dollar consultancies, it doesn't mean you're going to rule out the device. But you will think twice about it because it may be a biased review."

Case No. 2018-001842

Thelma R. Garrick

v.

Dr. George H. Khoury and Bon Secours Roper St. Frances

TO: The Honorable Judges of the South Carolina Court of Appeals

RE: Results from the operation of 8-20-15 by the Respondents. Again, without Appellant's knowledge or permission.

Appellant has included copies of her wrist to show you the progression of the abnormal bone growth caused by the Infuse Bone Device the Respondents implanted in her spine. This will happen to any future bones that may be broken or fractured.

As you can see from the other photos of the MRIs or Xrays this abnormal bone (has also been referred to as artifacts and bone mine) growth is throughout the Appellant's spine hindering any readings of things that happen to her spine. Without saying, this does not bode well with the Appellant's future.

Dr. Khoury or a layperson, anyone, studying these photos cannot say Appellant is not in pain.

Respectfully,

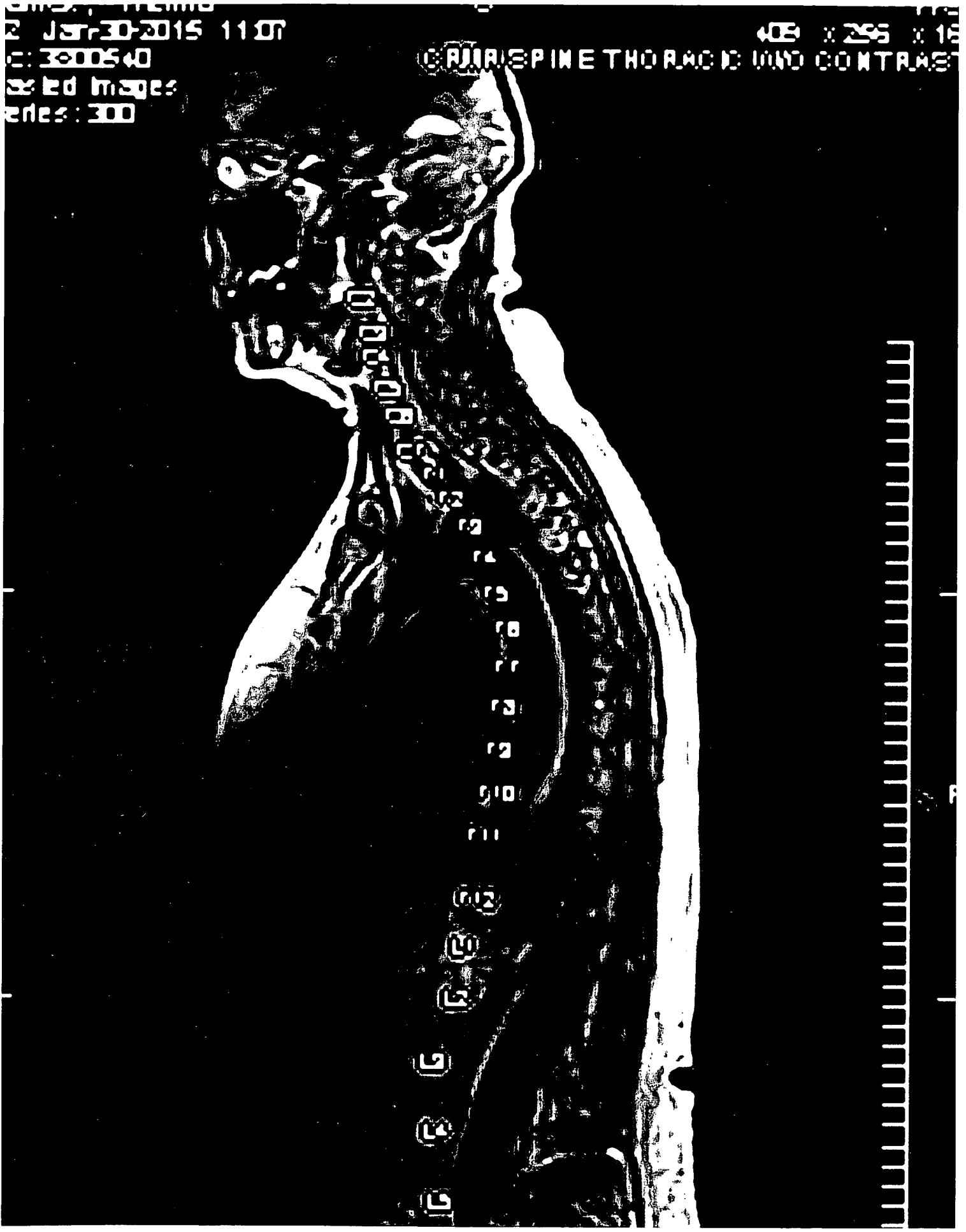


Thelma R. Garrick, Pro Se

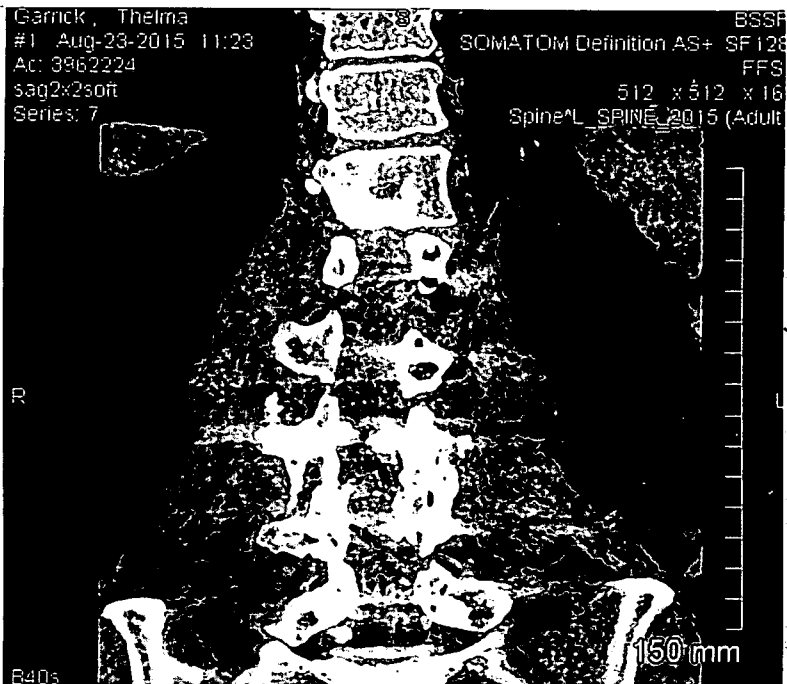
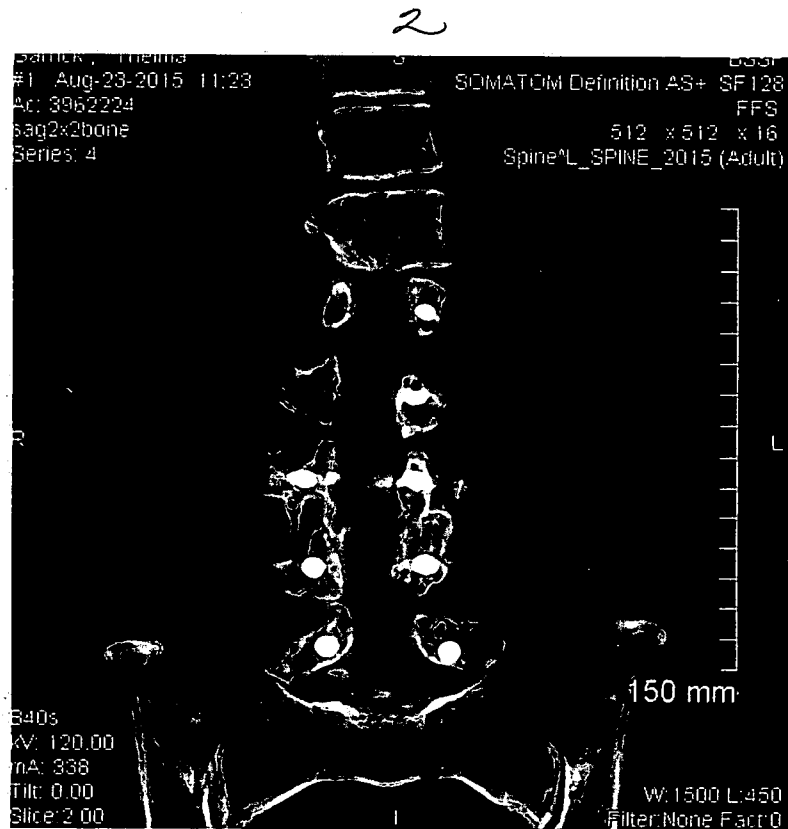
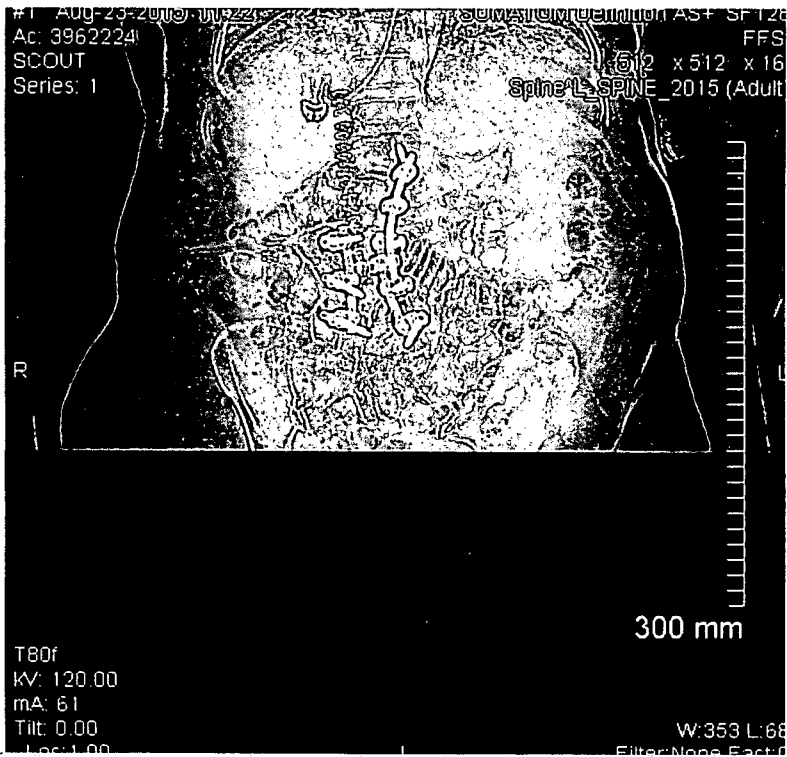
/tg

2 Jan 30 2015 11:07  
3900540  
Selected Images  
Series: 300

405 : 295 : 18  
GADOLINETHORACIC AND CONTRAST



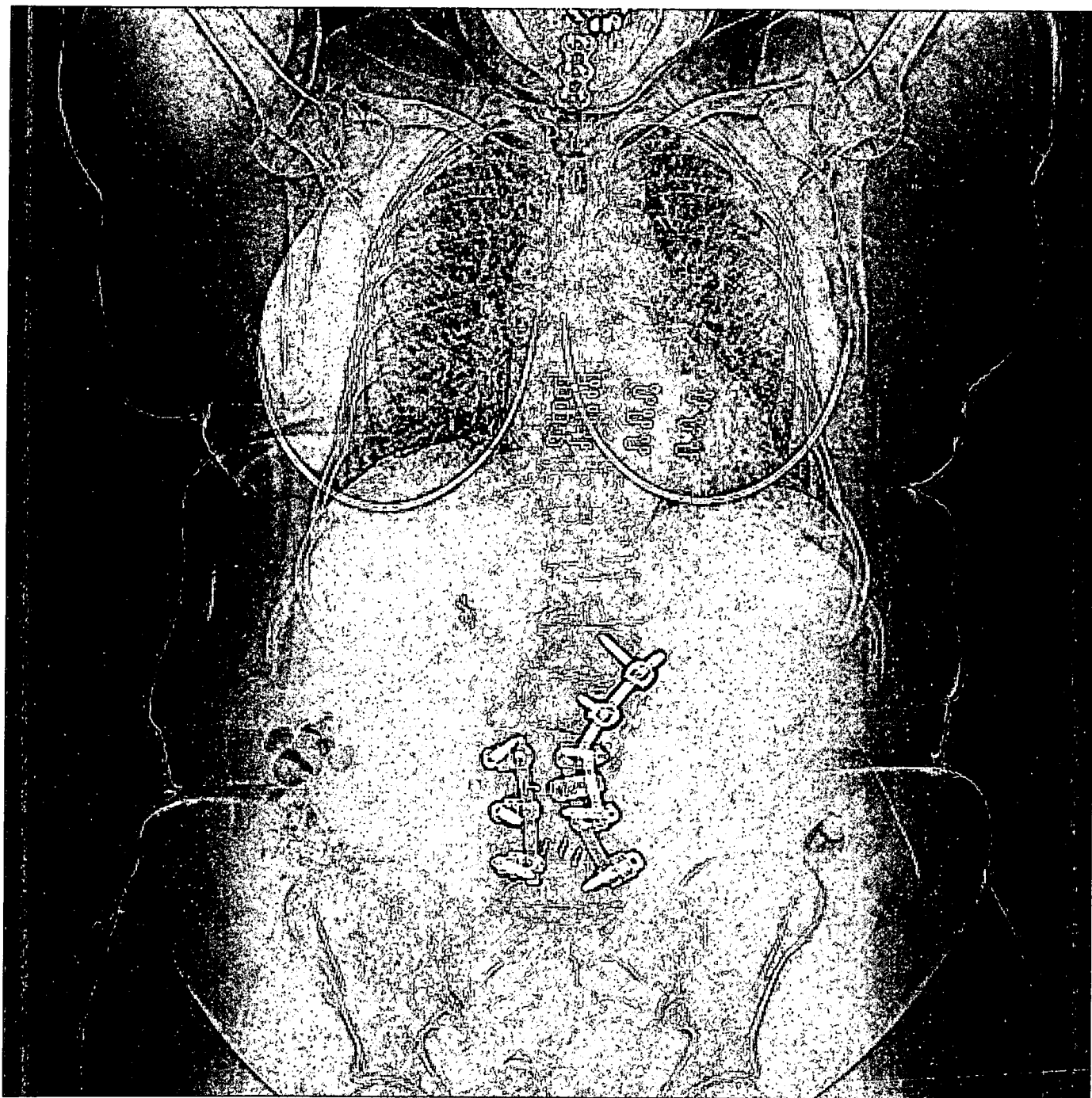
Before surgery  
34(G) 29/14



34 (16) 39 14

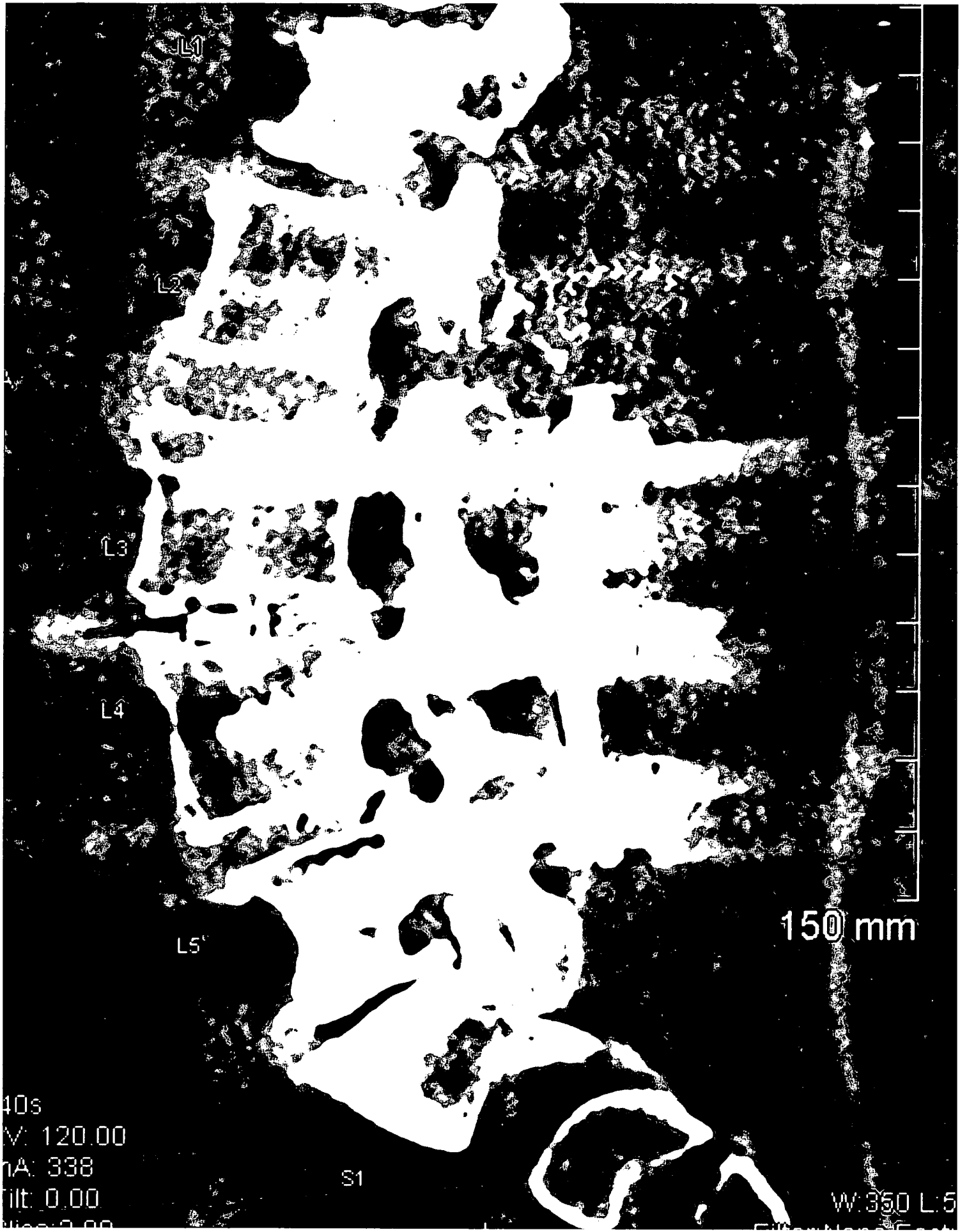
Distribution Pain Port - 3 views  
 (Synchronised FL Drug Infusion system)

View 3 gives abnormal bone growth!



34(10) 4 of 14

34 (IG) 5 of 14



L1

L2

L3

L4

L5

150 mm

40s  
V: 120.00  
nA: 338  
tilt: 0.00  
size: 9.00

S1

W: 350 L: 5

Garrick, Thelma  
#1 Aug-23-2015 11:23  
Ac: 3962224  
cor2x2bone  
Series: 5

S  
SOMATOM Definition AS+ SF1  
FF  
512 x 512 x 1  
Spine^L\_SPINE\_2015 (Adu

34 (6) 6914

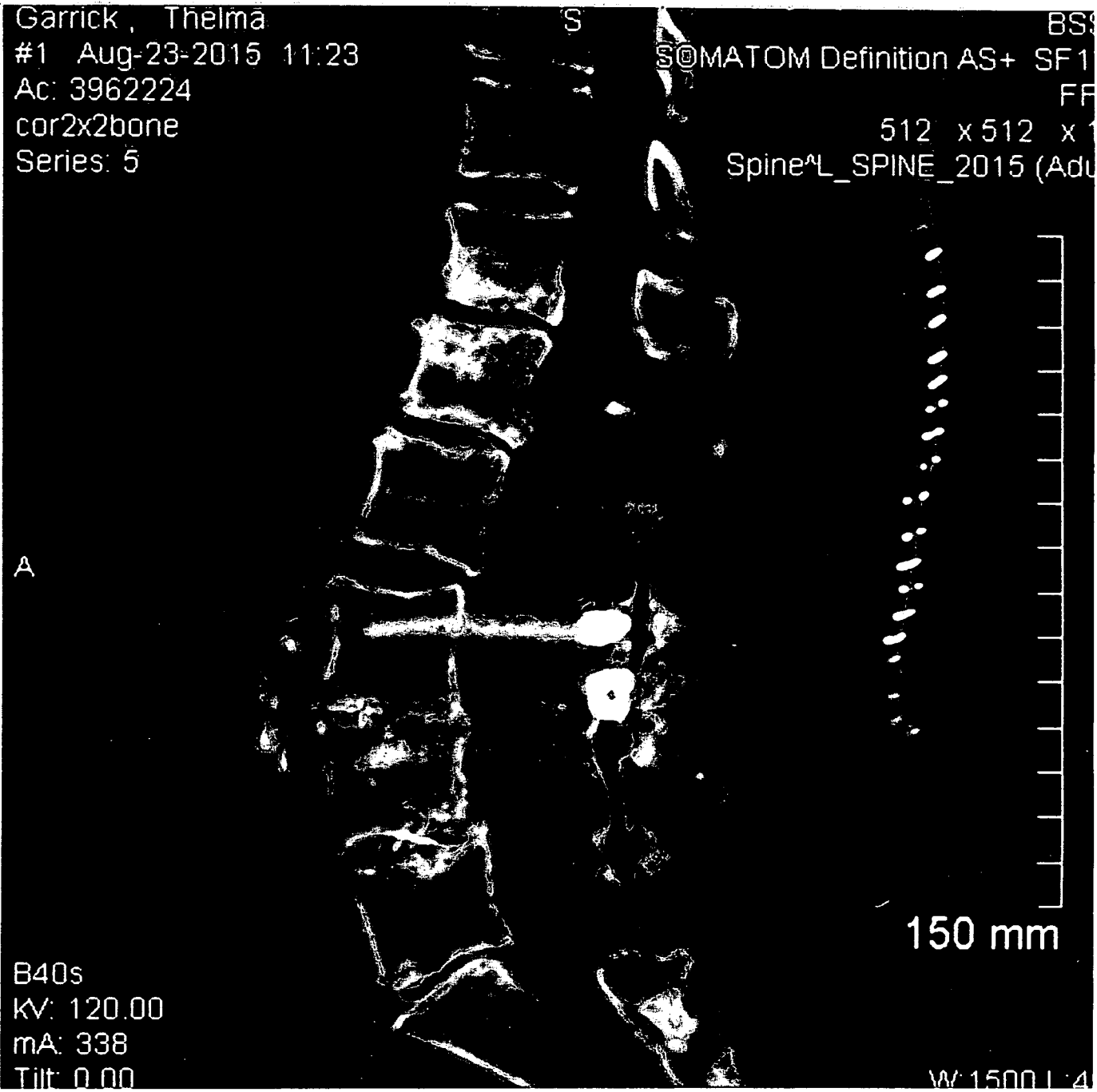
Weight pulling spine  
out of alignment

A

B40s  
KV: 120.00  
mA: 338  
Tilt: 0.00

150 mm

W: 1500 L: 4



#5 Jan-30-2015 11:41  
Ac: 3800542  
L Sag T1 FS +C  
Series: 17

Optima MR450w JICMRI  
FFS

612 x 512 x 16  
CRMP SPINE THORACIC W/O CONTRAST

A

P



34(16)7414

2D  
Echo: 1  
TR: 2,449.29  
TE: 20.80

Coil: TL Spine 36 6  
160 mm  
NEX: 1.00  
%FOV 100.00  
Flip: 160.00  
W: 2589 L: 1294

#12 Jan-30-2015 11:41  
Ac: 3800542  
L Sag T1 FS +C  
Series: 17

Optima MR450w JICMRI  
FFS

512 x 512 x 16

CRMR SPINE THORACIC W/O CONTRAST

A

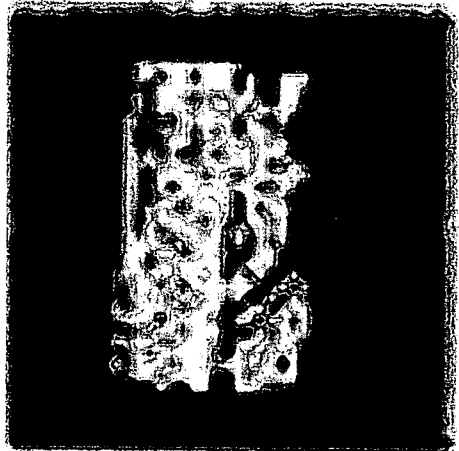
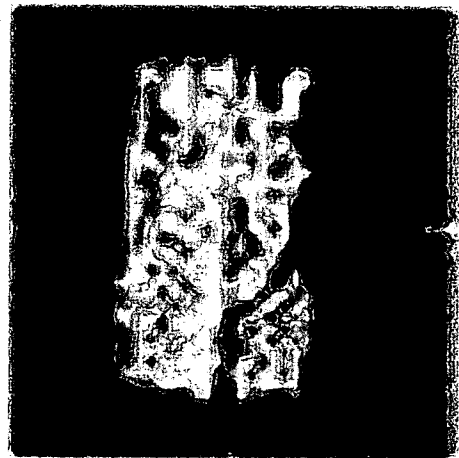
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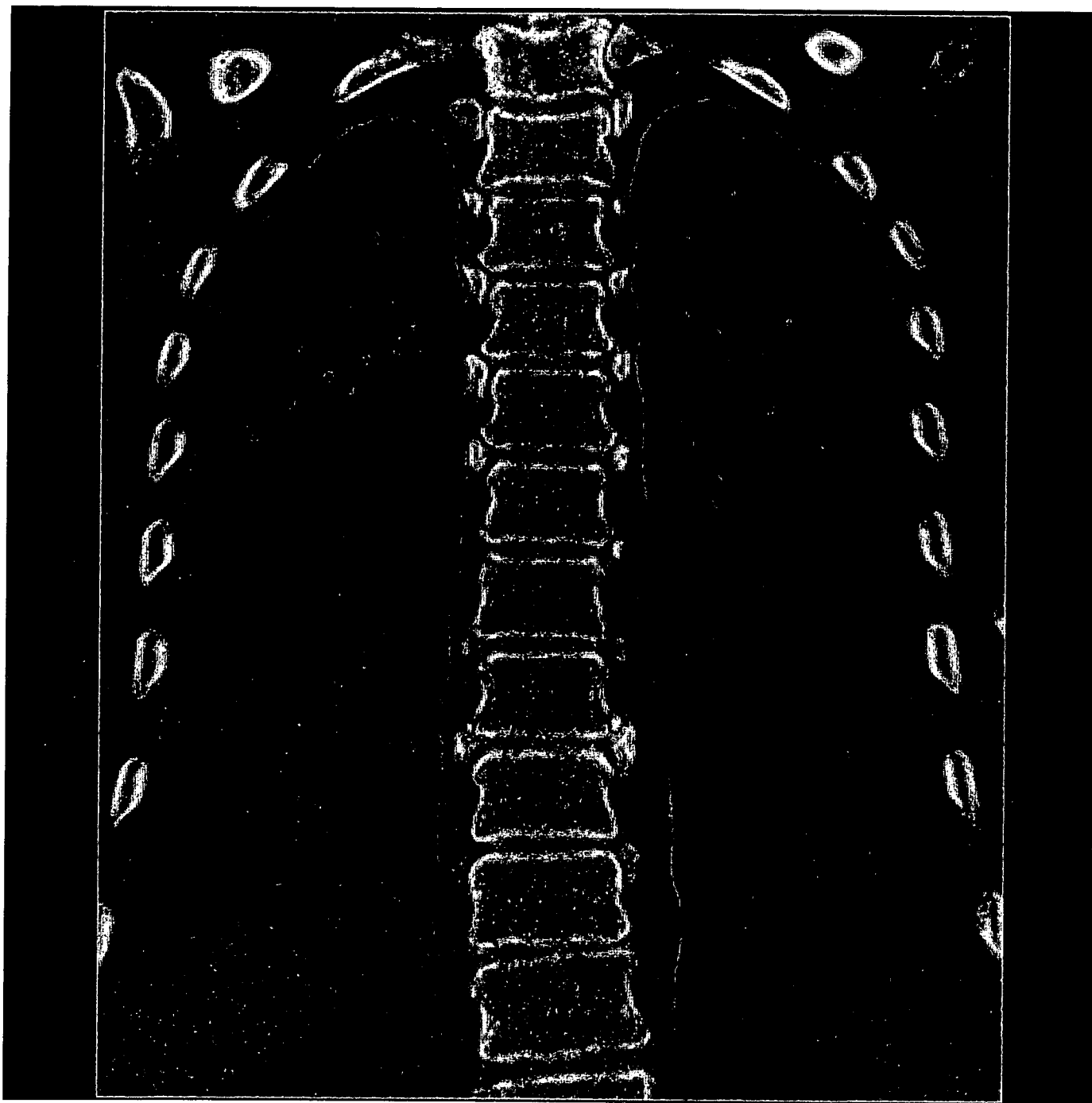
4168 0973

20  
Echo: 1  
TR: 2,449.29  
TE: 20.80

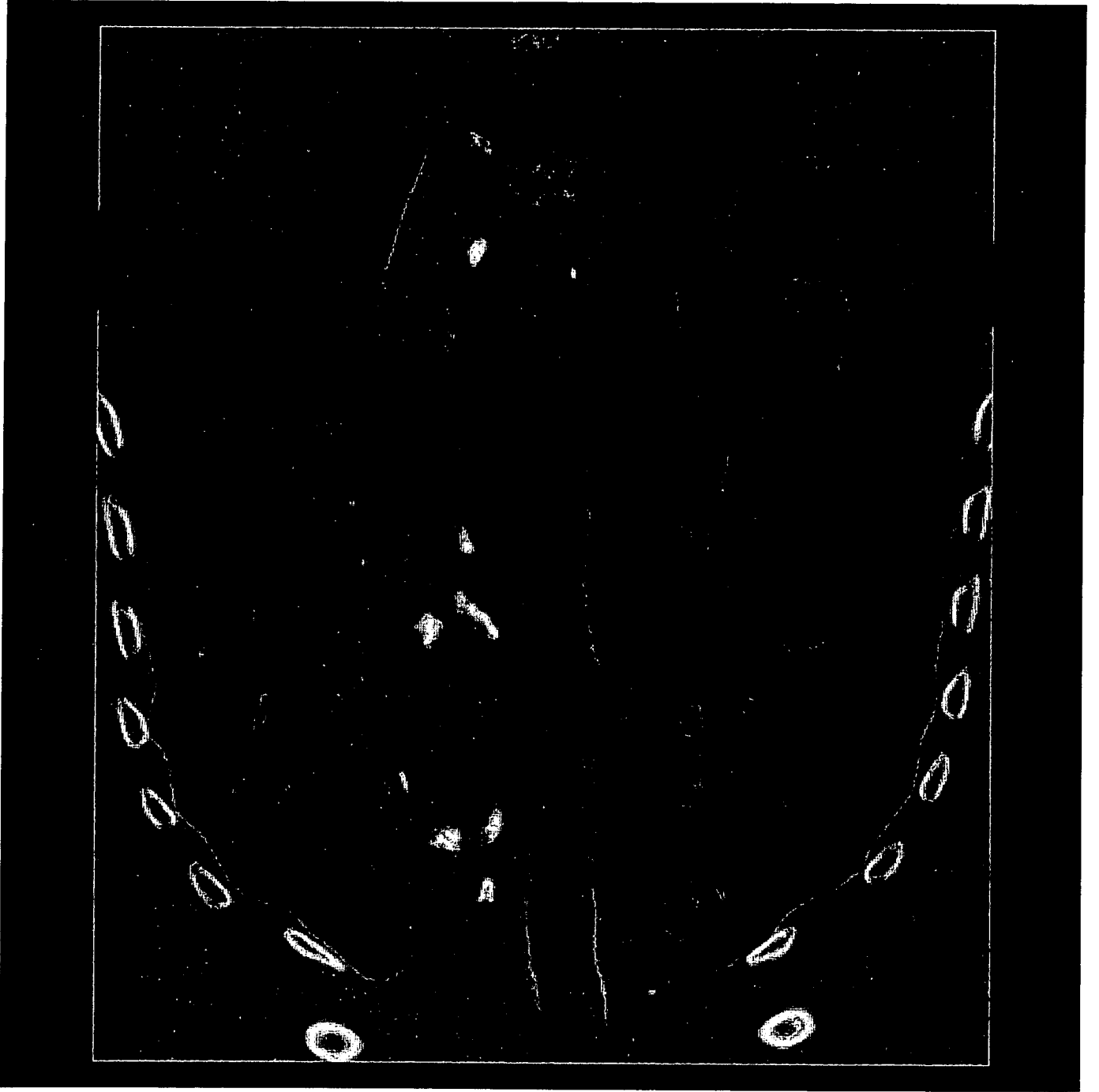
Coil: TL Spine 36 6  
160 mm  
NEX: 1.00  
%FOV 100.00  
Flip: 160.00  
W: 2589 L: 1294



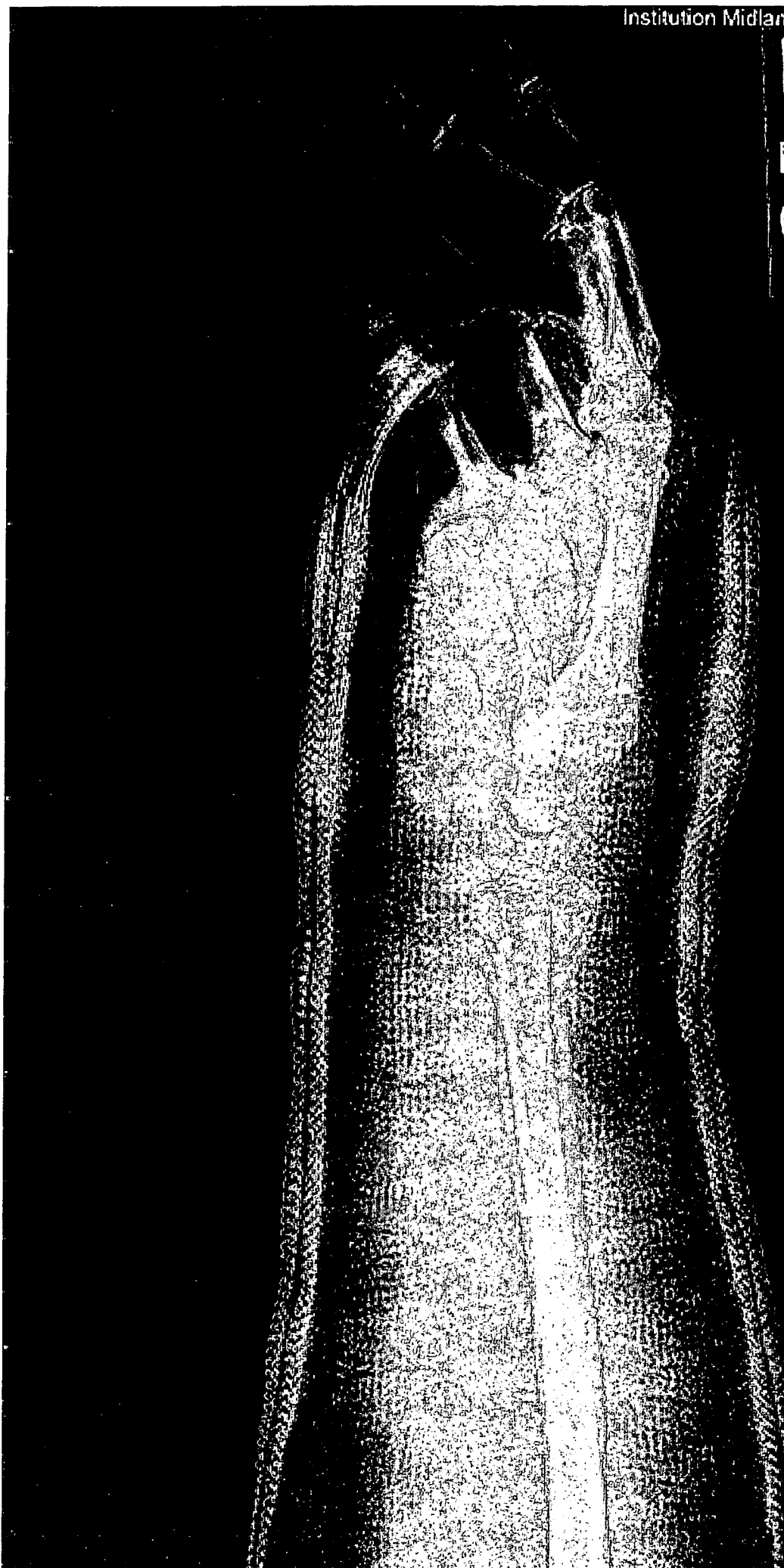
Bone maia  
34(G) 9 of 14



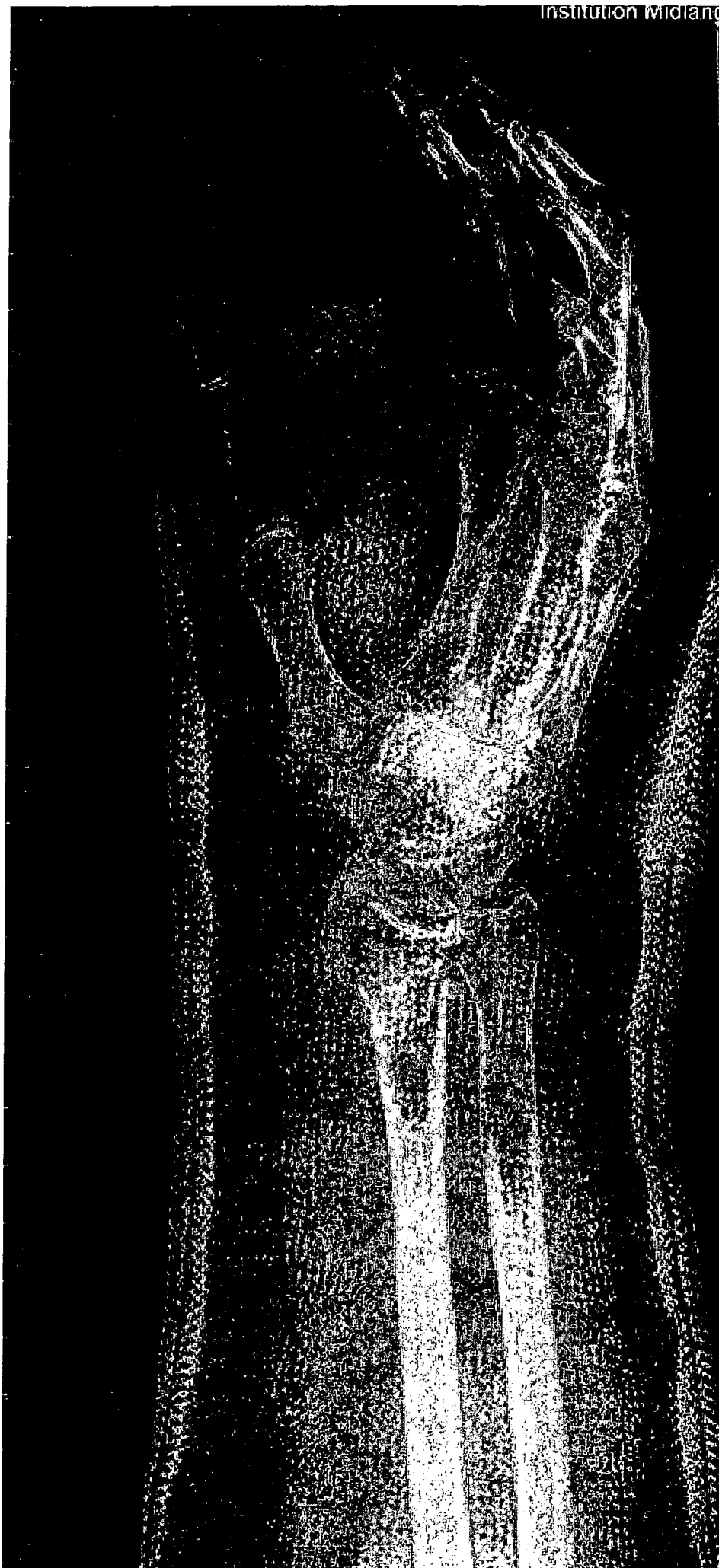
34(16)10 07 14



34(16) 11 of 14



*Broken  
wrist  
  
(About  
injury  
Device)*



*It would not pin bone together!  
See abnormal bone growth encasement.*



*Reveret of the diffuse device implanted in spine.  
(Now abnormal hand with disability.)*



# Medicare Summary Notice for Part B (Medical Insurance)

The Official Summary of Your Medicare Claims from the Centers for Medicare & Medicaid Services

THELMA R GARRICK  
195 CRESCENT OAKS CT  
ORANGEBURG SC 29115-3397

JRB

**THIS IS NOT A BILL**



397792 109167

<b>Notice for Thelma R Garrick</b>	
Medicare Number	WXX-XX-9400A
Date of This Notice	November 6, 2015
Claims Processed Between	August 7 - November 6, 2015

## Your Claims & Costs This Period

Did Medicare Approve All Services?	NO
Number of Services Medicare Denied	7
See claims starting on page 3. Look for NO in the "Service Approved?" column. See the last page for how to handle a denied claim.	
Total You May Be Billed	\$1,124.22

## Your Deductible Status

Your deductible is what you must pay for most health services before Medicare begins to pay.

**Part B Deductible:** You have now met your \$147.00 deductible for 2015.

## Be Informed!

Get your Medicare Summary Notices (MSNs) in a new and exciting way - electronic delivery! Access your electronic MSNs (eMSNs) monthly at MyMedicare.gov. Go paperless and help Medicare save money! Login to MyMedicare.gov to sign up. Need help? Call 1-800-MEDICARE (1-800-633-4227) TTY 1-877-486-2048.

## Providers with Claims This Period

- July 30, 2015  
Edisto Regional Health Servi
- August 7, 2015  
Advanced Diagnostic Imaging
- August 20, 2015  
Charleston Anesthesia Group
- August 20, 2015  
Nurse Anesthesia Of SC
- August 20 - August 25, 2015  
Roper Radiologists PA
- August 20 - August 26, 2015  
Roper St Francis Phy Netw

You saw more providers this period. Go to your complete list of claims, starting on page 3.

*No mention of Actual Operation Listing implants!*

*Appellant learned of severed spine. (Requested information to find out why another surgeon said "they cut you in half and altered your entire spine.")*

¿Sabía que puede recibir este aviso y otro tipo de ayuda de Medicare en español? Llame y hable con un agente en español. 如果需要国语帮助, 请致电联邦医疗保险, 请先说“agent”, 然后说“Mandarin”.

1-800-MEDICARE (1-800-633-4227)

# Your Claims for Part B (Medical Insurance)

Part B Medical Insurance helps pay for doctors' services, diagnostic tests, ambulance services, and other health care services.

Your provider has agreed to accept this amount as full payment for covered services. Medicare usually pays 80% of the Medicare-approved amount.

## Definitions of Columns

**Service Approved?:** This column tells you if Medicare covered the service.

**Amount Medicare Paid:** This is the amount Medicare paid your provider. This is usually 80% of the Medicare-approved amount.

**Amount Provider Charged:** This is your provider's fee for this service.

**Maximum You May Be Billed:** This is the total amount the provider is allowed to bill you and can include a deductible, coinsurance, and other charges not covered. If you have Medicare Supplement Insurance (Medigap policy) or other insurance, it may pay all or part of this amount.

**Medicare-Approved Amount:** This is the amount a provider can be paid for a Medicare service. It may be less than the actual amount the provider charged.

397792 199167  
0002 OF 0007

**July 30, 2015**  
 Edisto Regional Health Serv, (803)247-2428  
 P.O. Box 1245, Orangeburg, SC 29116-1245

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
Dr. Chan, Kam						
Established patient office or other outpatient, visit typically 25 minutes (99214)	Yes	\$141.00	\$101.78	\$79.79	\$20.36	A,B,C
Hemoglobin A1C level (83036-QW)	Yes	42.00	13.21	12.95	0.00	A,C,D

(continued)

### Notes for Claims Above

Continued →

- A** The approved amount is based on a special payment method.
- B** This claim shows a quality reporting program adjustment.
- C** After your deductible and coinsurance were applied, the amount Medicare paid was reduced due to Federal, State and local rules.
- D** This service is paid at 100% of the Medicare approved amount.

Page 60(a) Pages 2 of 14

**July 30, 2015/Edisto Regional Health Servi continued...**

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
Blood glucose (sugar) level (82947-QW)	Yes	16.00	2.18	2.14	0.00	E,F,G H
<b>Total for Claim #02-15215-494-250</b>		<b>\$199.00</b>	<b>\$117.17</b>	<b>\$94.88</b>	<b>\$20.36</b>	<b>I</b>

**August 07, 2015**

Advanced Diagnostic Imaging, (803)536-1106  
 4777 US Highway 259, Longview, TX 75605-7668  
 Referred by Chan, Kam

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
Dr. Patterson, Steven G., M.D.						
Ultrasound behind abdominal cavity (76770)	Yes	\$246.00	\$105.00	\$82.32	\$21.00	E,F,J
<b>Total for Claim #02-15222-135-710</b>		<b>\$246.00</b>	<b>\$105.00</b>	<b>\$82.32</b>	<b>\$21.00</b>	<b>I</b>

**Notes for Claims Above**

Continued →

- E** The approved amount is based on a special payment method.
- F** After your deductible and coinsurance were applied, the amount Medicare paid was reduced due to Federal, State and local rules.
- G** A change in payment methods has resulted in a reduced or zero payment for this procedure.
- H** This service is paid at 100% of the Medicare approved amount.
- I** We have sent your claim to your Medigap insurer. Send any questions regarding your benefits to them. Your Medigap insurer is BCBS OF SOUTH CAROLINA.
- J** This claim shows a quality reporting program adjustment.

**August 20, 2015**  
**Charleston Anesthesia Group, (843)402-1000**  
 PO Box 5708, High Point, NC 27262-5708  
 Referred by Khoury, George H

397792 199167  
 0000 00 00000

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
<b>Dr. Gerding, Rex W., M.D.</b>						
Anesthesia for procedure on spine and spinal cord (00670-QK)	Yes	\$2,128.00	\$284.10	\$222.73	\$56.82	K,L
Active warming used intraoperatively for the purpose of maintaining normothermia, or at least 1 body (4250F)	NO	0.01	0.00	0.00	0.00	M
Duration of general or neuraxial anesthesia 60 minutes or longer, as documented in the anesthesia re (4255F)	NO	0.01	0.00	0.00	0.00	M
<b>Total for Claim #02-15245-356-980</b>		<b>\$2,128.02</b>	<b>\$284.10</b>	<b>\$222.73</b>	<b>\$56.82</b>	<b>N</b>

**Notes for Claims Above**

**Continued →**

- K** After your deductible and coinsurance were applied, the amount Medicare paid was reduced due to Federal, State and local rules.
- L** The approved amount is based on a special payment method.
- M** This code is for informational/reporting purposes only. You should not be charged for this code. If there is a charge, you do not have to pay the amount.
- N** We have sent your claim to your Medigap insurer. Send any questions regarding your benefits to them. Your Medigap insurer is BCBS OF SOUTH CAROLINA.

*Page 60 (a) Page 4 of 14*

August 20, 2015

Nurse Anesthesia Of SC, (843)402-1436

P.O. Box 5309, High Point, NC 27262-5309

Referred by Khoury, George H

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
Hensley, C. A.						
Anesthesia for procedure on spine and spinal cord (00670-QX)	Yes	\$2,072.00	\$284.10	\$222.73	\$56.82	O,P
Active warming used intraoperatively for the purpose of maintaining normothermia, or at least 1 body (4250F)	NO	0.01	0.00	0.00	0.00	Q
Duration of general or neuraxial anesthesia 60 minutes or longer, as documented in the anesthesia re (4255F)	NO	0.01	0.00	0.00	0.00	Q
<b>Total for Claim #02-15245-357-010</b>		<b>\$2,072.02</b>	<b>\$284.10</b>	<b>\$222.73</b>	<b>\$56.82</b>	<b>R</b>

**Notes for Claims Above**

Continued →

- O After your deductible and coinsurance were applied, the amount Medicare paid was reduced due to Federal, State and local rules.
- P The approved amount is based on a special payment method.
- Q This code is for informational/reporting purposes only. You should not be charged for this code. If there is a charge, you do not have to pay the amount.
- R We have sent your claim to your Medigap insurer. Send any questions regarding your benefits to them. Your Medigap insurer is BCBS OF SOUTH CAROLINA.

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**August 20, 2015**

**Roper Radiologists PA, (843)720-4738**  
 PO Box 2363, Indianapolis, IN 46206-2363  
 Referred by Khoury, George H



39792 199167  
0004 OF 0007

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
<b>Dr. Anderson, Andrew K.</b>						
X-ray of spine, 1 view (72020-26) professional charge	Yes	\$75.00	\$7.61	\$5.97	\$1.52	S,T
<b>Total for Claim #02-15238-026-400</b>		\$75.00	\$7.61	\$5.97	\$1.52	U

**August 20, 2015**

**Roper St Francis Phy Netw, (843)958-8877**  
 PO Box 751649, Charlotte, NC 28275-1649

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
<b>Landers, Summer</b>						
Fusion of lower spine bones, posterior or posterolateral approach (22612-AS)	Yes	\$2,619.60	\$210.14	\$164.75	\$42.03	S,T
Partial removal of middle spine bone with release of spinal cord and/or nerves (63047-AS51)	Yes	1,812.60	72.83	57.09	14.57	S,T,V
<b>Claim #02-15237-461-040</b>						

(continued)

**Continued →**

**Notes for Claims Above**

- S** The approved amount is based on a special payment method.
- T** After your deductible and coinsurance were applied, the amount Medicare paid was reduced due to Federal, State and local rules.
- U** We have sent your claim to your Medigap insurer. Send any questions regarding your benefits to them. Your Medigap insurer is BCBS OF SOUTH CAROLINA.
- V** This surgery was reduced because it was performed with another surgery on the same day.

*Page 60(a) 6 of 14*

**August 20, 2015/Roper St Francis Phy Netwk continued...**

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
Insertion of posterior spinal instrumentation for spinal stabilization, 3 to 6 vertebral segments (22842-AS)	Yes	1,242.60	101.72	79.75	20.34	W,X
Fusion of spine bones, posterior or posterolateral approach (22614-AS)	Yes	636.60	52.28	40.98	10.46	W,X
Computer-assisted spinal procedure (61783-ASXU)	<b>NO</b>	487.20	0.00	0.00	0.00	Y
Partial removal of spine bone with release of spinal cord and/or nerves (63048-AS)	Yes	345.00	28.25	22.15	5.65	W,X
<b>Total for Claim #02-15237-461-040</b>		<b>\$7,143.60</b>	<b>\$465.22</b>	<b>\$364.72</b>	<b>\$93.05</b>	<b>Z</b>

**August 20, 2015**  
**Roper St Francis Phy Netwk, (843)958-8877**  
 PO Box 751649, Charlotte, NC 28275-1649

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
Dr. Khoury, George H., M.D.						
Fusion of lower spine bones, posterior or posterolateral approach (22612)	Yes	\$4,366.00	\$1,545.14	\$1,211.39	\$309.03	W,X

**Claim #02-15237-461-050**

(continued)

**Notes for Claims Above**

Continued →

- W The approved amount is based on a special payment method.
- X After your deductible and coinsurance were applied, the amount Medicare paid was reduced due to Federal, State and local rules.
- Y Medicare does not pay for an assistant surgeon for this procedure/surgery.
- Z We have sent your claim to your Medigap insurer. Send any questions regarding your benefits to them. Your Medigap insurer is BCBS OF SOUTH CAROLINA.

August 20, 2015/Roper St Francis Phy Netwk continued...

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
Partial removal of middle spine bone with release of spinal cord and/or nerves (63047-51)	Yes	3,021.00	535.50	419.83	107.10	a,b,c
Insertion of posterior spinal instrumentation for spinal stabilization, 3 to 6 vertebral segments (22842)	Yes	2,071.00	747.95	586.39	149.59	a,b
Fusion of spine bones, posterior or posterolateral approach (22614)	Yes	1,061.00	384.43	301.39	76.89	a,b
Harvest of bone from same spine incision for graft (20936)	NO	910.00	0.00	0.00	0.00	d,e
Computer-assisted spinal procedure (61783-59)	Yes	812.00	228.54	179.17	45.71	a,b
Donor bone graft for spine surgery (20930)	NO	722.00	0.00	0.00	0.00	d,e
Partial removal of spine bone with release of spinal cord and/or nerves (63048)	Yes	575.00	207.75	162.88	41.55	a,b
<b>Total for Claim #02-15237-461-050</b>		<b>\$13,538.00</b>	<b>\$3,649.31</b>	<b>\$2,861.05</b>	<b>\$729.87</b>	<b>f</b>

*Did not mention implant -*

Continued →

Notes for Claims Above

- a The approved amount is based on a special payment method.
- b After your deductible and coinsurance were applied, the amount Medicare paid was reduced due to Federal, State and local rules.
- c This surgery was reduced because it was performed with another surgery on the same day.
- d Payment is included in another service received on the same day.
- e You cannot be billed separately for this item or service. You do not have to pay this amount.
- f We have sent your claim to your Medigap insurer. Send any questions regarding your benefits to them. Your Medigap insurer is BCBS OF SOUTH CAROLINA.

397792 199167

**August 21, 2015**  
**Roper Radiologists PA, (843)720-4738**  
 PO Box 2363, Indianapolis, IN 46206-2363  
 Referred by Khoury, George H

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
Dr. Northam, Meredith C, M.D.						
X-ray of chest, 1 view, front (71010-26) professional charge	Yes	\$75.00	\$9.02	\$7.08	\$1.80	g,h
<b>Total for Claim #02-15236-082-490</b>		\$75.00	\$9.02	\$7.08	\$1.80	i

**August 21, 2015**  
**Roper Radiologists PA, (843)720-4738**  
 PO Box 2363, Indianapolis, IN 46206-2363  
 Referred by Khoury, George H

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
Dr. Northam, Meredith C, M.D.						
Imaging of abdomen (74020-26) professional charge	Yes	\$75.00	\$13.24	\$10.38	\$2.65	g,h
<b>Total for Claim #02-15238-028-930</b>		\$75.00	\$13.24	\$10.38	\$2.65	i

**Continued →**

**Notes for Claims Above**

- g** The approved amount is based on a special payment method.
- h** After your deductible and coinsurance were applied, the amount Medicare paid was reduced due to Federal, State and local rules.
- i** We have sent your claim to your Medigap insurer. Send any questions regarding your benefits to them. Your Medigap insurer is BCBS OF SOUTH CAROLINA.

**August 21 - August 22, 2015**

Roper St Francis Phy Netwk (843)958-8877  
 PO Box 751649 Charlotte, NC 28275-1649  
 Referred by Khoury, George H



397792 199167  
 0006 of 0007

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
<b>August 21, 2015/Dr. Schneider, Juli L.</b>						
Initial hospital inpatient care, typically 50 minutes per day (99222)	Yes	\$405.00	\$133.59	\$104.73	\$26.72	j,k
<b>August 22, 2015/Dr. Schneider, Juli L.</b>						
Subsequent hospital inpatient care, typically 35 minutes per day (99233)	Yes	309.00	101.68	79.71	20.34	j,k
<b>Total for Claim #02-15240-538-670</b>		<b>\$714.00</b>	<b>\$235.27</b>	<b>\$184.44</b>	<b>\$47.06</b>	<b>l</b>

**August 23, 2015**

Roper Radiologists PA, (843)720-4738  
 PO Box 2363, Indianapolis, IN 46206-2363  
 Referred by Steichen, John D

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
<b>Dr. Rand, John</b>						
CT scan of lower spine (72131-26) professional charge	Yes	\$289.00	\$49.34	\$38.68	\$9.87	j,k
<b>Total for Claim #02-15238-030-310</b>		<b>\$289.00</b>	<b>\$49.34</b>	<b>\$38.68</b>	<b>\$9.87</b>	<b>l</b>

Continued →

**Notes for Claims Above**

- j** The approved amount is based on a special payment method.
- k** After your deductible and coinsurance were applied, the amount Medicare paid was reduced due to Federal, State and local rules.
- l** We have sent your claim to your Medigap insurer. Send any questions regarding your benefits to them. Your Medigap insurer is BCBS OF SOUTH CAROLINA.

Page 60 (a) 10 of 14

**August 23 - August 24, 2015**

Roper St Francis Phy Netwk, (843)958-8877

PO Box 751649, Charlotte, NC 28275-1649

Referred by Khoury, George H

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
<b>August 23, 2015/Dr. Schneider, Juli L.</b>						
Subsequent hospital inpatient care, typically 25 minutes per day (99232)	Yes	\$216.00	\$70.61	\$55.36	\$14.12	m,n
<b>August 24, 2015/Dr. Schneider, Juli L.</b>						
Subsequent hospital inpatient care, typically 25 minutes per day (99232)	Yes	216.00	70.61	55.36	14.12	m,n
<b>Total for Claim #02-15240-538-600</b>		<b>\$432.00</b>	<b>\$141.22</b>	<b>\$110.72</b>	<b>\$28.24</b>	<b>o</b>

**August 25, 2015**

Roper Radiologists PA, (843)720-4738

PO Box 2363, Indianapolis, IN 46206-2363

Referred by Graves, Sherry M

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
<b>Dr. Robards, Jay</b>						
X-ray of chest, 2 views, front and side (71020-26) professional charge	Yes	\$75.00	\$10.78	\$8.45	\$2.16	m,n
<b>Total for Claim #02-15240-044-540</b>		<b>\$75.00</b>	<b>\$10.78</b>	<b>\$8.45</b>	<b>\$2.16</b>	<b>o</b>

Continued →

**Notes for Claims Above**

- m The approved amount is based on a special payment method.
- n After your deductible and coinsurance were applied, the amount Medicare paid was reduced due to Federal, State and local rules.
- o We have sent your claim to your Medigap insurer. Send any questions regarding your benefits to them. Your Medigap insurer is BCBS OF SOUTH CAROLINA.

**August 25 - August 26, 2015**

Roper St Francis Phy Netwk, (843)958-8877  
 PO Box 751649, Charlotte, NC 28275-1649  
 Referred by Khoury, George H

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
<b>August 25, 2015/Dr. Turner, Kyle A., DO</b>						
Subsequent hospital inpatient care, typically 25 minutes per day (99232)	Yes	\$216.00	\$70.61	\$55.36	\$14.12	p,q
<b>August 26, 2015/Dr. Turner, Kyle A., DO</b>						
Subsequent hospital inpatient care, typically 25 minutes per day (99232)	Yes	216.00	70.61	55.36	14.12	p,q
<b>Total for Claim #02-15251-419-870</b>		<b>\$432.00</b>	<b>\$141.22</b>	<b>\$110.72</b>	<b>\$28.24</b>	<b>r</b>

397792 199167

**September 03, 2015**

Orangeburg Family Phys, (803)531-3911  
 1205 Hutto St, Orangeburg, SC 29118-1454

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
<i>Jolly Avera - approx 2 wks</i>						
<b>Dr. Shuler, Vann Beth M.</b>						
Initial nursing facility visit, typically 35 minutes per day (99305)	Yes	\$125.00	\$123.81	\$97.07	\$24.76	p,q,s
<b>Total for Claim #02-15247-421-790</b>		<b>\$125.00</b>	<b>\$123.81</b>	<b>\$97.07</b>	<b>\$24.76</b>	<b>r</b>

**Notes for Claims Above**

- p** The approved amount is based on a special payment method.
- q** After your deductible and coinsurance were applied, the amount Medicare paid was reduced due to Federal, State and local rules.
- r** We have sent your claim to your Medigap insurer. Send any questions regarding your benefits to them. Your Medigap insurer is BCBS OF SOUTH CAROLINA.
- s** This claim shows a quality reporting program adjustment.

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# Your Claims for Part B (Medical Insurance)

Part B Medical Insurance helps pay for doctors' services, diagnostic tests, ambulance services, and other health care services.

Your provider has agreed to accept this amount as full payment for covered services. Medicare usually pays 80% of the Medicare-approved amount.

## Definitions of Columns

**Service Approved?:** This column tells you if Medicare covered the service.

**Amount Medicare Paid:** This is the amount Medicare paid your provider. This is usually 80% of the Medicare-approved amount.

**Amount Provider Charged:** This is your provider's fee for this service.

**Maximum You May Be Billed:** This is the total amount the provider is allowed to bill you and can include a deductible, coinsurance, and other charges not covered. If you have Medicare Supplement Insurance (Medigap policy) or other insurance, it may pay all or part of this amount.

**Medicare-Approved Amount:** This is the amount a provider can be paid for a Medicare service. It may be less than the actual amount the provider charged.

**August 20, 2015**

Rtna, PC, (615)346-8182

PO Box 116327 Atlanta, GA 30368-6327

Referred by Khoury, George H

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
Dr. Cruz, Marcos J., M.D. Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nea (G0453)	Yes	\$250.00	\$31.22	\$24.48	\$6.24	A,B,C

(continued)

**Claim #09-15348-071-560**

**Continued →**

### Notes for Claims Above

- A** The approved amount is based on a special payment method.
- B** This claim shows a quality reporting program adjustment.
- C** After your deductible and coinsurance were applied, the amount Medicare paid was reduced due to Federal, State and local rules.

*Page 60(a) 13 of 14*

August 20, 2015/Rtna, PC continued...

Service Provided & Billing Code	Service Approved?	Amount Provider Charged	Medicare-Approved Amount	Amount Medicare Paid	Maximum You May Be Billed	See Notes Below
<i>D. Cruz</i> Insertion of needles and skin electrodes for measurement and recording of stimulated sites in the ar (95938-26) professional charge	Yes	1,100.00	43.93	34.44	8.79	D,E,F
Needle measurement and recording of electrical activity of muscles of arms or legs (95861-26) professional charge	Yes	900.00	79.09	62.00	15.82	D,E,F
<b>Total for Claim #09-15348-071-560</b>		<b>\$2,250.00</b>	<b>\$154.24</b>	<b>\$120.92</b>	<b>\$30.85</b>	<b>G</b>

**Notes for Claims Above**

- D** The approved amount is based on a special payment method.
- E** This claim shows a quality reporting program adjustment.
- F** After your deductible and coinsurance were applied, the amount Medicare paid was reduced due to Federal, State and local rules.
- G** We have sent your claim to your Medigap insurer. Send any questions regarding your benefits to them. Your Medigap insurer is BCBS OF SOUTH CAROLINA.

July 17, 2018

*After letter received  
from attorney for  
Respondents a*

Honorable Judge Goodstein  
c/o Court of Common Pleas  
Charleston County Judicial Center  
100 Broad Street, Suite 106  
Charleston, South Carolina 29401-9401

Reference: Notice of Motion Scheduling, Motion Roster 285  
Case No.: 2018-CP-10-1163

Your Honor:

This Notice of Motion Scheduling was typed on June 13, 2018 and I received it on June 18<sup>th</sup> and tried to contact Ms. Caroline Leonard immediately. I tried at least four times and left messages on several occasions into July but she never returned my calls. I realize that she is very busy in court and only had my telephone number to contact me.

The Notice's deadline to ask for a continuance request was July 3<sup>rd</sup> at 5PM. I did meet the deadline with a certified letter that was delivered to the Clerk of Court on July 2<sup>nd</sup> at 8:31 AM: with a copy to their attorneys arriving at 8:16 AM. Plenty of time to let Plaintiff know if the continuance had been accepted prior to July 12<sup>th</sup>. I awaited an answer that should have been forthcoming from the court. I realize that this was an easy out for the court. I do not know what transpired because I am told that you and the Defendants attorney met on the 12<sup>th</sup>. I requested information on July 16<sup>th</sup> from Ms. Leonard and she said she would get back to me but has not to this date. I did what the Notice of Motion Scheduling stipulated but the court did not get back to me. If you penalize me instead of the court following through, I will appeal. I have two very good reasons to appeal.

However, originally I had every intention to meet the court date of July 12<sup>th</sup> until I went to another (4<sup>th</sup> consult trying to get help) neurosurgeon at the Brain and Spine Clinic at Lexington Hospital. The news was even more devastating than before because of the damage to the spine when they put in the Pain Distribution Port and the MRI also showed that the port has broken into at the spine causing movement and knife sharp pain, it is defective.

This doctor wants to perform the following experimental surgery. (He did not realize that I would get a copy of his report.) I have briefly given you the facts of the surgery necessary. Like Dr. Khoury, he did not discuss this with me.

"I have reviewed in detail the risks, benefits, and alternatives. I informed the patient and family of the fact that not all medical procedures and techniques have been studied or 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 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. (NOT)

"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."

After reading this word for word would you let this doctor operate on you? Well, if I had known the risks Dr. Khoury says he informed me, I would not have let him operate on me either with only a pinched left sciatic nerve. I realize now there is no help for me because of the surgery performed by Dr. Khoury.

With this evidence the court can see what Dr. Khoury, the hospital and his team did to me; again I reiterate – WITHOUT MY KNOWLEDGE OR PERMISSION. There was no neglect with the operation it had to have been well planned to have all this already set up in the operating room on August 20, 2015. And instead of him doing the surgery allowed two men, representatives from Medtronic, did most of the operation with a Robotic arm (Medtronic Stealth Navigation System). This comes under Medical Battery.

Yet the Court Justice System condones this action by showing me that since I am not an attorney they wish to dismiss my case saying I have no evidence. I have a taped telephone message and a telephone conversation at my home where he said "I think about you every night". Well God is better to him than I am because I prayed he would think about me every morning, every night and every time he went into the operating room.

When I filed this case having no funds to secure an attorney and eliminating every source for one, I asked to go before an Honest Judge because I did not have the expertise to have a jury trial but I am having second thoughts. I have a message and that message is to let everyone one know what is being done to the elderly people. But first I have to have closure on the destruction done to my life.

Judge Goodstein, you know me and know that I do not give up when an injustice has been done. Please do not let a Court's mistake dismiss this case. Thank you.

Yours truly,

  
Thelma R. Garrick, Plaintiff

cc: **Honorable Julie J. Armstrong**  
**The Court of Common Pleas**  
**Charleston County Judicial Center**  
**100 Broad Street – Suite 106**  
**Charleston, South Carolina 29401-9401**

cc: **Mr. Joseph J. Tierney, Jr., Esquire**  
**Young Clement Rivers LLC**  
**P. O. Box 993**  
**Charleston, South Carolina 29403**



State of South Carolina  
The Circuit Court of the First Judicial Circuit

DIANE SCHAFFER GOODSTEIN  
JUDGE

POST OFFICE BOX 234  
ST. GEORGE, SOUTH CAROLINA 29477

August 7, 2018

Ms. Thelma Garrick  
195 Crescent Oaks Court  
Orangeburg, SC 29115

Ms. Garrick:

I am in receipt of your letter dated on July 17, 2018. Please be advised that this is considered ex parte communication. Judicial ethics do not allow a judge to have any form of communication with a party in an action outside of the proper setting (which in in the courtroom with all the necessary parties present).

Sincerely,

A handwritten signature in cursive script that reads "Diane S. Goodstein".

Diane S. Goodstein, Judge  
First Judicial Circuit

Did not send her correspondence  
until after July 12th. Case dismissed 7-25-18.

G. Garrick

August 9, 2018

Honorable Julie J. Armstrong  
Court of Common Pleas  
Charleston County Judicial Center  
100 Broad Street, Suite 106  
Charleston, S. C. 20401-940

Reference: Case #2018-CP-10-1163  
Notice of Motion Scheduling, Motion Roster 285

Honorable Julie J. Armstrong:

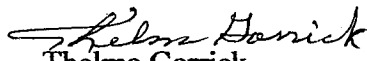
I am unable to pursue the illegal court hearing and illegal dismissal of my case by Judge Diane Goodstein at the moment, because of a broken right arm from a fall caused from the defective Medtronic Pain Port experimental device *implanted in my lumbar spine*.

I will also be pursuing attorneys through the Internet, talk shows, and newspapers, whatever it takes to see Justice is done; not only for my case but others that have not come to light here in the South. (The use of the abnormal bone growth by the Medtronic "Infuse" I believe is wide spread. Yes, I have proof not only verbally but also on an MRI and recent CAT scans of what it can do.) I did not need an expert witness because I have the evidence of what has been done through medical technology.

Also, Judge Goodstein should have recused herself because of an old case where she and I butted heads. Why did I not say something? I continue to be naive! A judge is supposed to be impartial to both parties and make discerning decisions according to the evidence presented, not just on an expert witness who gets big dollars to appear in court. (I would not trust such a witness.)

I am deeply disappointed in our legal system and will go to every agency to try to have laws changed not to harm people. Our laws are like unto the laws added to Moses' laws from God. They help those in power rather than the victims.

Yours,

  
Thelma Garrick  
195 Crescent Oaks Ct.  
29115

cc: Dr. George H. Khoury  
Bon Secours St. Francis, W. Ashley  
Young Clement Rivers LLC

66 (c)

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