

OPEN PAYMENTS: Are You Ready?

Daniel J. Carlat, MD, Director,
Prescription Project, The Pew Charitable Trusts

Tara R. Shewchuk, Vice President,
Ethics and Compliance, Medtronic Spinal

John T. Randolph, Vice President and Chief Compliance
Officer, UMass Memorial Health Care



Disclosure

- Daniel J. Carlat is the founding editor of The Carlat Psychiatry Report and owner of Carlat Publishing, LLC (no business involvement or income while employed by Pew) as well as an associate clinical professor of psychiatry at Tufts University School of Medicine
- Tara R. Shewchuk, as an employee of Medtronic, is compensated by and holds stock in the company.



©.Original Artist
Reproduction rights obtainable from
www.CartoonStock.com



"Under disclosure rules, I'm required to tell you I own stock in the company whose drug I'm prescribing."




  **More Stuff
More Secure**
Our updated line of security solutions [Learn More](#)


Top Psychiatrist Didn't Report Drug Makers' Pay

By GARDINER HARRIS
Published: October 3, 2008

One of the nation's most influential [psychiatrists](#) earned more than \$2.8 million in consulting arrangements with drug makers from 2000 to 2007, failed to report at least \$1.2 million of that income to his university and violated federal research rules, according to documents provided to Congressional investigators.

 TWITTER

 LINKEDIN

 SIGN IN TO E-MAIL OR SAVE THIS

 PRINT

 REPRINTS



Well

Tara Parker-Pope
on Health

Take Blood Pressure in Both Arms

March 3, 2014, 11:31 AM

Birth by C-Section May Raise Obesity Risk

March 3, 2014, 10:45 AM

The Perils of Toughing It Out

March 3, 2014, 12:01 AM

The Pasta Is Gluten-Free

February 28, 2014

Ask Well: Medicines for Motion Sickness

February 27, 2014



Dollars for Docs: The Top Earners

by [Hanna Trudo](#) and [Theodoric Meyer](#)
ProPublica, March 12, 2013, 11 a.m.

 21 Comments |  Republish |  Email |  Print

March 13: This post has been [corrected](#).

When [Dollars for Docs](#) first launched in 2010, ProPublica spoke with several of the [dozens of doctors](#) who had earned more than \$200,000 from their speaking and consulting work for drug companies. Now, with records from more companies and more years of data, [we've identified 22 doctors](#) who've earned at least \$500,000 since 2009 — including one, Jon Draud, who was paid more than \$1 million.

Most of these in-demand speakers hail from a just handful of states: four each from New York and Texas, and two each from California, Massachusetts, Pennsylvania and Tennessee. Half are psychiatrists, including three of the top four earners. The most

Connect with Facebook to share articles you read on ProPublica. [Learn more »](#)

 **Enable Social Reading**

251

 Tweet

8

 Share

8

 +1

 231

 Like



[News](#) ▾ [Sports](#) ▾ [Business](#) ▾ [Entertainment](#) ▾ [Lifestyles](#) ▾ [Opinion](#) ▾ [Politics](#) ▾ [YourHub](#) ▾

HOT TOPICS: [Daily Digest](#) [I-25 Pileup](#) [Denver Weather](#) [DIA Maintenance](#) [Ukraine](#) [Peyton Manning](#) (

[Home](#) [Story](#)

 [Print](#)  [Email](#)

DENVER AND THE WEST

Hospitals to put doctors' relationships with pharmaceutical companies under the microscope

By [Michael Booth](#)

The Denver Post

POSTED: 01/17/2011 01:00:00 AM MST | UPDATED: 3 YEARS AGO

44 COMMENTS



Physician Payments Sunshine Act

1. Companies (not doctors) must report payments to Health and Human Services (HHS)
2. HHS must post the payments on a website that is user-friendly, searchable, aggregatable, and downloadable



Who is subject to reporting?

- All teaching hospitals
- All physicians with a medical license, whether practicing or not
- Includes dentists, optometrists, podiatrists, chiropractors
- Does *not* include:
 - Nurse practitioners
 - Physician assistants
 - Residents and medical students
 - Employees of drug companies



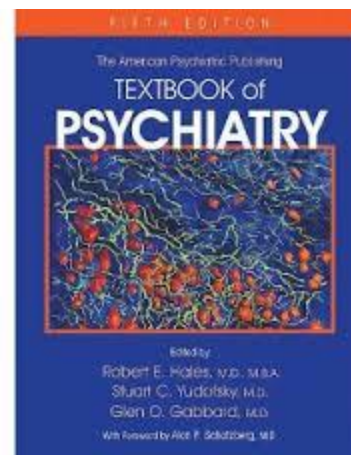
What will be reported?



- Direct payments
- Indirect/Third party payments
- Ownership and investment in companies, but not in publically traded companies



Most Commonly Reported



The following will not be reported

- Samples
- Industry-supported CME lectures
- Food and small gifts at large conferences
- Anything under \$10 in value (unless cumulatively over \$100)
- Stocks



Dates to Know

August 1, 2013

September 30, 2014



Sunshine Act Pop Quiz



What must drug and device companies report under the Act?

- A. All payments to doctors for promotional talks
- B. All payments of \$10 or more to doctors or teaching hospitals for marketing or research
- C. All payments of \$10 or more to doctors, nurses, and other HCPs for marketing or research
- D. All payments of \$500 or more to doctors or teaching hospitals for marketing or research



Who Will See the Payments?

- A. They will be available only to those who file a Freedom of Information Act petition
- B. They will be available only to the FDA, NIH, and other government entities
- C. They will be reported to physicians and teaching hospitals only
- D. They will be posted on a public website with no access limitations



What are Hospitals' Responsibilities under the Sunshine Act?

- A. You must keep records of all payments you've received and report them to CMS
- B. You must audit all payments received by physicians you employ
- C. You are not required to do anything at all
- D. You may no longer accept payments from industry



Conflict of Interest Policies

- Create a COI Committee
- Consider the following three types of policies



Painless Policies

- Disclose financial interests
- No ghostwriting
- No industry travel and lodging funds



Flu Shot Policies (only hurt for a second)

- No industry funded meals or gifts
- No promotional speaking



Real Headache Policies (the pain will go away...eventually)

- No industry funding for CME courses
- Restrict sales representative presence
- Extend COI policies to off-site courtesy staff



Learn the Best Practices for Academic Medical Centers

- Pew Task Force
JAMA article:
<http://jama.jamanetwork.com/article.aspx?articleid=1788465>
- Pew report:
Pewhealth.org/COIBestPractices



Industry Perspectives on Provider Collaboration

Tara R. Shewchuk
Vice President, Ethics and Compliance
Medtronic Spinal



Fulfilling an Unmet Medical Need





WORKING TOGETHER TO ADVANCE INNOVATION

Collaborating with physicians is vital to innovation and advancing patient care. Physicians provide unique clinical insights and a deep understanding of physiology that's important to product development. They also have the first-hand expertise to help educate and train other healthcare providers on the appropriate use of medical devices. To preserve these valuable partnerships and demonstrate that they're conducted appropriately, Medtronic has been leading an industry-wide transparency effort.

THE PARTNERSHIP THAT BUILT A COMPANY



EARL BAKKEN,
Medtronic Co-Founder

DR. C. WALTON LILLEHEI,
Heart Surgeon

Our first revolutionary product — a wearable, battery-powered heart pacemaker developed in the 1950s — was the result of a close collaboration. Pioneering heart surgeon Dr. C. Walton Lillehei of the University of Minnesota Medical School was looking for a more practical pacemaker that didn't rely on AC — wall outlet — power. So Dr. Lillehei collaborated with Medtronic co-founder Earl Bakken and together they developed a revolutionary new way to treat abnormal heart rhythms.

Collaboration Often at Heart of Therapy Options to Treat Many Conditions



Diabetes



Coronary



Endovascular Therapies



Surgical Technologies



Neuromodulation



Spine



CRDM



Structural Heart



Collaboration with Providers

- Identify unmet patient needs
- Develop *innovative* solutions and *methods* for solutions, quickly
- Test solutions, ensuring rigorous requirements of regulatory agencies are met
- Train and educate on when to use product or therapy, and how to do so safely and effectively
- Inform providers and patients about our products
- Provide technical support



The New Environment: Snapshot of Research Funding

- From 1940 to 1965, NIH and other federal agencies contributed the majority of biomedical research funding
- During the 1970s, commercial funding grew as a result of constraints on the federal budget and other factors
 - By 2001, industry support reached 55-60% of the total R&D spending
 - Continued collaboration with industry is critical to continued life sciences innovation



Partnering with Providers to Enhance Solutions & Quality

Product Research & Development

Training & Education

Advisory Services

Royalties



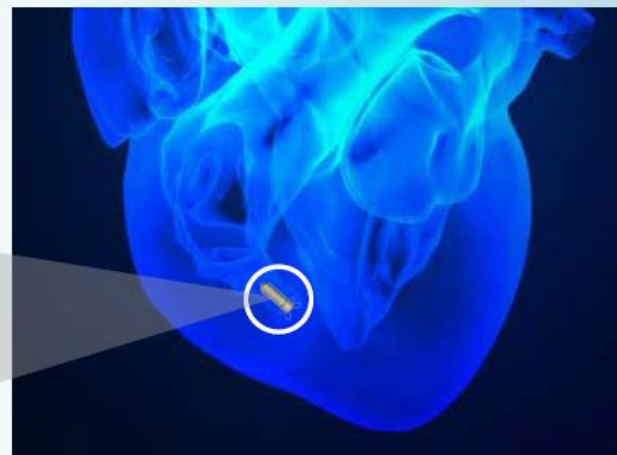


A BIG LEAP IN MINIATURIZATION

When it comes to putting medical devices in the human body, smaller is usually better. Besides being less noticeable to patients, smaller devices also require less disruption to the body during implantation. Over the years, we've continually made many of our products smaller. But now we're taking miniaturization to a revolutionary new level.

The pacemaker we're currently developing is being designed to be the size of a vitamin capsule.

Because of its small size, this pacemaker could someday be delivered in a whole new way: By a catheter inserted into the leg and threaded up to the heart.*



ECONOMIC VALUE

By reducing procedure time we may help improve hospital efficiencies.



CLINICAL OUTCOMES

Reducing the size of implantable devices to this level could someday make delivery less invasive, with the goal of reducing procedure time, speeding recovery, and lowering the risk of infection.



SOCIETAL IMPACT

New implant procedures, with the goal of making them more accessible to more doctors, can be important in underserved markets with large numbers of patients.

*This concept is in very early development; its success and risk have not been evaluated.

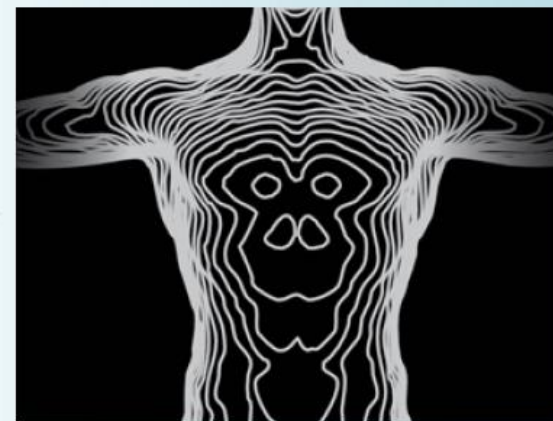
For complete safety information on the products mentioned in this story, please see or print the corresponding slides at the end of this document.

To learn more, visit medtronic.com.



MAKING OUR THERAPIES EASIER ON THE HUMAN BODY

We've become the industry leader in minimally invasive techniques, which are procedures that are easier for doctors to perform and less disruptive on the human body. Depending on the procedure, the benefits may include shorter procedure time, less blood loss, or faster recovery than with traditional procedures.



ECONOMIC VALUE

Reducing procedure times can make hospitals more efficient.



CLINICAL OUTCOMES

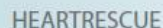
Patients who undergo minimally invasive CABG with Medtronic products have shorter hospital stays and return faster to daily living. Studies suggest patients who undergo minimally invasive spinal surgery experience less blood loss, have shorter hospital stays, and are walking earlier than patients who undergo traditional procedures.



SOCIETAL IMPACT

By making surgeries less invasive, we can help patients get back to being productive members of society, faster.

To learn more, visit medtronic.com.

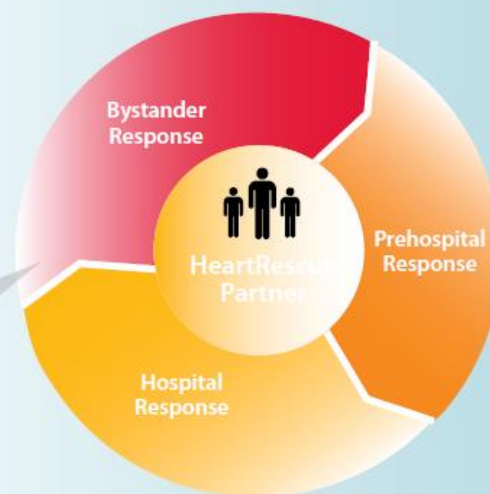


Innovating for life >



Each year 295,000 Americans are struck by sudden cardiac arrest. Only 8% survive nationally – a statistic that hasn't changed in 30 years.¹ The Medtronic Foundation is leading an unprecedented collaborative effort to improve the odds for SCA victims.

We are working with partners across the country to improve response systems by coordinating training and best practices among the 3 critical stages of response.



CLINICAL OUTCOMES

If successful, The HeartRescue Project will demonstrate significantly improved out-of-hospital SCA survival rates within 5 years in the geographies it funds.



SOCIETAL IMPACT

The program is strengthening systems of care and increasing community awareness about a major healthcare issue.

1. *Circulation*, 2010; 121:e46 (survival rate based on all cases of EMS-treated out-of-hospital cardiac arrest)

To learn more, visit medtronic.com.



EASIER MANAGEMENT OF CHRONIC DISEASES

For people with chronic diseases like diabetes and heart conditions, managing their condition is a lifelong collaboration with healthcare teams. We've made the process easier with our CareLink systems, which allow patients with certain insulin pumps and heart devices to download information captured by their device and transfer that data via a secure server to the CareLink website. This creates a seamless link so everyone has the information needed to make smart, timely healthcare decisions.



ECONOMIC VALUE

Greater efficiency of care,
with fewer office visits for
patient and physician alike.



CLINICAL OUTCOMES

In one study, CareLink systems use among patients with diabetes led to significant blood glucose (A1C) reductions. In one study for heart device patients who used the CareLink Network, the time from a clinically actionable event to when they were treated was 17.4 days less than heart device patients who didn't use remote monitoring, via the CareLink Network with automatic CareAlert® Notifications.



**SOCIETAL
IMPACT**

With chronic disease rates on the rise, CareLink systems give patients more ownership over managing their conditions to help relieve the burden on healthcare systems.

To learn more, visit medtronic.com.

The New Environment

The New York Times

Group Urges Ban on
Medical Giveaways



As Full Disclosure Nears, Doctors'
Pay for Drug Talks Plummets

THE WALL STREET JOURNAL

Orthopedists Fail
to Disclose Payments

BusinessWeek

Teaching Doctors –
or Selling to Them?

- With the potential for conflicts of interest, public and governmental scrutiny of physician collaboration has increased
- Industry continues to evaluate current collaboration practices, identify best practices across the industry, and ensure that policies, procedures and related processes protect patient interests



Protecting Patients' Interests

Collaboration between providers and industry must be carefully managed, as it presents the potential for competing interests, both real and perceived

Goal is to minimize this potential for conflict so that ...

- Patients can ***trust*** that treatment decisions are motivated by what is best for their health
- We can sustain and enhance medical innovation through ***principled collaboration***



The Medtronic Approach

As the industry's leader, Medtronic is committed to core principles aimed at preserving the best of collaboration for the benefit of patients, while minimizing the possibility of actual or perceived conflicts of interest in the delivery of healthcare

Principles

- Preserve integrity of the doctor-patient relationship
- Remain transparent about payments and policies

Key Approaches

- Needs-Based Collaboration
- Fair Compensation
- Timely & Transparent Disclosure
- Conflict of Interest Mitigation
- Continuous Improvement
- Industry Norms



Example: Needs Assessment Process

The Needs Assessment process examines key aspects of each HCP/HCO relationship, including:

What?

- Defines *in advance* **what services** we need to hire from HCPs/HCOs and why they can't be performed in-house

Why?

- Requires project owner to **demonstrate *bona fide* need** for consulting services *in advance*

Who?

- Defines the **overall need for external HCP/HCO support up-front** in a manner consistent with strategic plan

How much?

- Explains necessary HCP/HCO **qualifications** and ensures only those who match the qualifications are selected

But also...

- Justifies **number** of services and HCPs/HCOs required to meet the need and compensation amounts

- Contains significant detail to allow for thorough vetting by relevant functional groups (e.g., compliance, executive leadership)
- Stands alone as a record of justification



Needs Assessment Process Steps

1

Planning

Identify need for external service provider

Create needs assessment document (Project Brief)

Submit Project Brief for Committee review and approval or rejection

2

Engagement

Identify and nominate HCPs/HCOs meeting selection criteria

Ensure internal Royalty and Clinical consulting rules are followed

Review and approve or reject nominated HCPs/HCOs

3

Monitoring

Determine FMV rate using FMV calculator

Execute agreement with approved HCPs/HCOs

Track and monitor holistic HCP/HCO service provider engagement
Manage consultant to Compensation Cap



Other Conflict of Interest Safeguards

- Agreements require certain transparency disclosures by collaborators, including to their institutions and even to their patients
- Restrict participation of royalty earners in clinical studies
- Exclude royalty payments for devices implanted within the hospitals where the royalty-earning surgeon practices
- Ensure collaborator agreements set forth rigorous and objective standards for defining and measuring valuable contributions the collaborator must meet in order to receive a royalty payment



Open Payments: It Will Not Be Perfect



OOPS! MEDICAL DEVICE COMPANY IDENTIFIES WRONG PHYSICIAN

POSTED ON NOVEMBER 8, 2007 BY TODD RODRIGUEZ

Earlier this week, a number of major orthopedic medical device companies, as part of an anti-kickback settlement agreement, began posting on their websites the names of physicians to whom the companies have paid consulting fees. Now, as a perfect example of why this "transparency" is a danger to all physicians, a Michigan newspaper is reporting that one of the companies, Smith and Nephew, incorrectly identified a physician on its website. Apparently the physician in question does not and never had a consulting relationship with the company. A spokesman for Smith & Nephew blamed the mix up on some kind of sorting error.


-  [Print](#)
-  [Comments](#)
-  [Trackbacks](#)
-  [Share Link](#)



Expect Discrepancies: Recent Example

- Buerba, Fu and Grauer analyzed device company voluntary transparency data and compared it to physician self-disclosed data at 2011 NASS Annual Meeting
- Disclosure rules varied between two data sources
- Authors concluded that discrepancies between company postings and physician self-disclosures ranged anywhere between 30% and 52%

Rafael Buerba, Michael Fu, Jonathan Grauer, *Discrepancies in spine surgeon conflict of interest disclosures between a national meeting and physician payment listings on device manufacturer websites*, The Spine Journal, 13 (2013) 1780-1788



Even with Open Payments, expect continued discrepancies given varied interpretation by manufacturers of regulations

Helpful “To Dos” for Providers

- Review Open Payments data (or your own databases) for your Top 20 collaborators
- Formulate a standardized “dispute resolution” process
- Stay abreast of CMS positions on “indirect” transfers of value (e.g., Fellowship grants, Scholarship support, and Research)
- Understand Open Payments transparency of physician investment / ownership interests in manufacturers / GPOs



Key Take Aways

- Collaboration between industry and providers is integral for innovation and, most importantly, good for patients
- Appropriate collaboration requires guardrails to protect against actual or perceived conflicts of interest
- Transparency is one important safeguard, but has limitations and will not be perfect





IMPORTANT SAFETY INFORMATION

An implantable pacemaker system relieves symptoms of heart rhythm disturbances. They do this by restoring normal heart rates. A normal heart rate provides your body with the proper amount of blood circulation. The pacemaker system is intended for patients who need rate-adaptive pacing or chronic pacing or for patients who may benefit from synchronizing the pumping of the heart chambers.

Risks associated with pacemaker system implant include, but are not limited to, infection at the surgical site and/or sensitivity to the device material, failure to deliver therapy when it is needed, or receiving extra therapy when it is not needed. After receiving an implantable pacemaker system, you will have limitations with magnetic and electromagnetic radiation, electric or gas powered appliances, and tools with which you are allowed to be in contact.

This treatment is prescribed by your physician. This treatment is not for everyone. Please talk to your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this treatment, results may vary.

Last updated: 27 Jun 2011

*This concept is in very early development; its success and risk have not been evaluated.



INDICATIONS, SAFETY, AND WARNINGS

MEDTRONIC ATTAIN ABILITY MODEL 4196, ABILITY PLUS MODEL 4296, AND ABILITY STRAIGHT 4396 LEADS

Steroid eluting, dual electrode, transvenous, over the wire, cardiac vein pacing leads. The Model 4396 lead has tined fixation.

Indications

The Attain Ability Models 4196, 4296, and 4396 steroid eluting, dual electrode, IS-1, transvenous leads are indicated for chronic pacing and sensing in the left ventricle via the cardiac vein, when used in conjunction with a compatible Medtronic Cardiac Resynchronization Therapy (CRT) system. Extended bipolar pacing is available using these leads in combination with a compatible CRT-D system and RV defibrillation lead or with a compatible CRT-P system and RV pacing lead.

Additionally, unipolar pacing is available using the leads in combination with a compatible CRT-P system.

Contraindications

Coronary vasculature – The leads are contraindicated for patients with coronary venous vasculature that is inadequate for lead placement, as indicated by venogram.

Steroid use – Do not use in patients for whom a single dose of 232 µg of dexamethasone acetate cannot be tolerated.

Warnings and Precautions

The Model 4196, 4296, and 4396 leads were designed for optimal pacing when used in a unipolar or extended bipolar configuration. The standard bipolar configuration may result in markedly elevated pacing thresholds or produce anodal stimulation.

Chronic repositioning or removal of leads may be difficult because of fibrotic tissue development. The clinical studies for these leads were not designed to evaluate the removal of left ventricular leads from the coronary venous vasculature.

Output pulses, especially from unipolar devices, may adversely affect device sensing capabilities. If a patient requires a separate stimulation device, either permanent or temporary, allow enough space between the leads of the separate systems to avoid interference in the sensing capabilities of the devices. Previously implanted pulse generators and implantable cardioverter defibrillators (ICDs) should generally be explanted.

People with metal implants such as pacemakers, ICDs, and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, and/or the need to reprogram or replace the device.

Leads should be handled with great care at all times. Use an anchoring sleeve with all leads. Ensure the anchoring sleeve is positioned close to the lead connector pin, to prevent inadvertent passage of the sleeve into the vein. Use care when handling stylets. Any severe bending, kinking, stretching, handling with surgical instruments, or excessive force when inserting a stylet may cause permanent damage to the lead. When using Model 4196, 4296, or 4396 leads, only use compatible stylets (stylets with downsized knobs and are 3 cm shorter than the lead length). Other stylets may extend beyond the lead tip, causing lead tip seal damage or injury or perforation of the cardiac vein or heart. Rust stylets are not recommended with this lead due to the risk of conductor coil or insulation perforation.

Use care when handling guide wires. Damage to the guide wire may prevent the guide wire from performing accurate torque response control and may cause vessel damage. Do not use excessive force to retract the guide wire from the lead. Refer to the literature packaged with the guide wire for additional information on guide wires.

Do not use magnetic resonance imaging (MRI) on patients who have this device implanted. MRI can induce currents on implanted leads, potentially causing tissue damage and the induction of tachyarrhythmias.

For the Model 4196, 4296, or 4396 leads, total patient exposure to dexamethasone acetate should be considered. Drug interactions of dexamethasone acetate with this lead have not been studied. It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of this highly localized, controlled-release lead. For a list of potential adverse effects, refer to the Physician's Desk Reference.

Do not force the guide catheter or leads if significant resistance is encountered. Use of guide catheters and/or leads may cause trauma to the heart.

Keep external defibrillation equipment nearby for immediate use during acute lead system testing, the implant procedure, or whenever arrhythmias are possible or intentionally induced during the post-implant testing. Backup pacing should be readily available during implant. Use of the delivery system or leads may cause heart block.

To minimize the likelihood of trauma to the vein and to maintain lead flexibility while advancing the lead through the vein, keep the stylet withdrawn 1 to 2 cm or select a more flexible stylet.

Do not insert the proximal end of the guide wire through the lead tip seal without using the guide wire insertion tool. Inserting the guide wire without the guide wire insertion tool could cause damage to the lead tip seal or to the conductor core or insulation.

During lead implant and testing, use only battery-powered equipment or line-powered equipment specifically designed for this purpose to protect against fibrillation that may be caused by alternating currents.

Potential Complications

Potential complications related to the use of transvenous leads include, but are not limited to the following patient-related conditions: cardiac dissection, cardiac perforation, cardiac tamponade, coronary sinus dissection, death, endocarditis, erosion through the skin, extracardiac muscle or nerve stimulation, fibrillation or other arrhythmias, heart block, heart wall or vein wall rupture, hematoma/seroma, infection, myocardial irritability, myopotential sensing, pericardial effusion, pericardial rub, pneumothorax, rejection phenomena, threshold elevation, thrombosis, thrombotic or air embolism, and valve damage.

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult Medtronic's website at www.medtronic.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

MEDTRONIC ATTAIN 4194 LEAD

Indications

The Attain 4194 steroid eluting, IS-1 transvenous lead is indicated for chronic pacing and sensing in the left ventricle via the cardiac vein, when used in conjunction with a compatible Medtronic Cardiac Resynchronization Therapy (CRT) system. Extended bipolar pacing is available using this lead in combination with a compatible CRT-D system and RV defibrillation lead or with a compatible CRT-P system and RV pacing lead.

Contraindications

• **Coronary vasculature** – This lead is contraindicated for patients with coronary venous vasculature that is inadequate for lead placement, as indicated by venogram.

• **Steroid use** – Do not use in patients for whom a single dose of 1.0 mg dexamethasone sodium phosphate cannot be tolerated.

Warnings and Precautions

The Model 4194 was designed for optimal pacing when used in a bipolar configuration. The standard bipolar configuration may result in markedly elevated pacing thresholds or produce anodal stimulation.

• Chronic repositioning or removal of leads may be difficult because of fibrotic tissue development. The clinical study was not designed to evaluate the removal of left ventricular leads from the coronary venous vasculature.

• Output pulses, especially from unipolar devices, may adversely affect device sensing capabilities. If a patient requires a separate stimulation device, either permanent or temporary, allow enough space between the leads of

the separate systems to avoid interference in the sensing capabilities of the devices. Previously implanted pulse generators and implantable cardioverter defibrillators should generally be explanted.

• People with metal implants such as pacemakers, implantable Cardioverter Defibrillators (ICDs), and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, and/or the need to reprogram or replace the device.

• Leads should be handled with great care at all times. Use an anchoring sleeve with all leads. Ensure the anchoring sleeve is positioned close to the lead connector pin, to prevent inadvertent passage of the sleeve into the vein. Use care when handling stylets. Any severe bending, kinking, stretching, handling with surgical instruments, or excessive force when inserting a stylet may cause permanent damage to the lead. When using the Model 4194, only use compatible stylets (stylets with downsized knobs and are 3 cm shorter than the lead length). Other stylets may extend beyond the lead tip causing lead tip seal damage or injury, or perforation of the cardiac vein or heart. Rust stylets are not recommended with this lead due to the risk of conductor coil or insulation perforation.

• Use care when handling guide wires. Damage to the guide wire may prevent the guide wire from performing accurate torque response control and may cause vessel damage. Do not use excessive force to retract the guide wire from the lead. Refer to the literature packaged with the guide wire for additional information on guide wires.

• Do not use Magnetic Resonance Imaging (MRI) on patients who have this device implanted. MRI can induce currents on implanted leads, potentially causing tissue damage and the induction of tachyarrhythmias.

• For the Model 4194 lead, total patient exposure to dexamethasone sodium phosphate should be considered. Drug interactions of dexamethasone sodium phosphate with this lead have not been studied. It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone sodium phosphate apply to the use of this highly localized, controlled-release lead. For a list of potential adverse effects, refer to the Physicians' Desk Reference.

• Do not force the guide catheter or leads if significant resistance is encountered. Use of guide catheters and/or leads may cause trauma to the heart.

• Keep external defibrillation equipment nearby for immediate use during acute lead system testing, the implant procedure, or whenever arrhythmias are possible or intentionally induced during the post-implant testing.

• Backup pacing should be readily available during implant. Use of the delivery system or leads may cause heart block.

Continued on next page



- To minimize the likelihood of trauma to the vein and to maintain lead flexibility while advancing the lead through the vein, keep the stylet withdrawn 1 to 2 cm or select a more flexible stylet.
- Do not insert the proximal end of the guide wire through the lead tip seal without using the guide wire insertion tool. Inserting the guide wire without the guide wire insertion tool could cause damage to the lead tip seal or to the conductor core or insulation.
- During lead implant and testing, use only battery-powered equipment or line-powered equipment specifically designed for this purpose to protect against fibrillation that may be caused by alternating currents.

Potential Complications

Potential complications related to the use of transvenous leads include, but are not limited to the following patient-related conditions: cardiac dissection, cardiac perforation, cardiac tamponade, coronary sinus dissection, death, endocarditis, erosion through the skin, extracardiac muscle or nerve stimulation, fibrillation or other arrhythmias, heart block, heart wall or vein wall rupture, hematoma/seroma, infection, myocardial irritability, myopotential sensing, pericardial effusion, pericardial rub, pneumothorax, rejection phenomena, threshold elevation, thrombosis, thrombotic or air embolism, and valve damage.

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

MEDTRONIC ATTAIN STARFIX 4195 LEAD

Indications

The Attain StarFix Model 4195 steroid-eluting, transvenous lead with deployable lobes is intended for chronic pacing and sensing of the left ventricle via a cardiac vein, when used in conjunction with a compatible implantable pulse generator or implantable cardiac defibrillator.

Contraindications

This lead is contraindicated for patients with coronary venous vasculature that is inadequate for lead placement, as indicated by venogram. Do not use in patients for whom a single dose of 30 µg (micrograms) of beclomethasone dipropionate (BDP) cannot be tolerated.

Warnings and Precautions

- Leads, stylets, and guide wires should be handled with great care at all times. When using the Model 4195 lead, only use compatible stylets (stylets with downsized knobs and are 3 cm shorter than the lead length). Verify that the stylet does not extend beyond the lead tip prior to inserting the lead in the delivery system. Implanting the lead with the stylet extending beyond the lead tip could cause injury or perforation of the cardiac vein or heart.
- Output pulses, especially from unipolar leads, may adversely affect device sensing capabilities.
- Back-up pacing should be readily available during implant. Use of leads may cause heart block.
- For the Attain StarFix Model 4195 lead, total patient exposure to beclomethasone 17,21-dipropionate should be considered when implanting multiple leads.

No drug interactions with inhaled beclomethasone 17,21-dipropionate have been described. Drug interactions of beclomethasone 17,21-dipropionate with the Model 4195 lead have not been studied.

- People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, or the need to reprogram or replace the device.
- Do not use magnetic resonance imaging (MRI) on patients who have this device. MRI can induce currents on implanted leads, potentially causing tissue damage and the induction of tachyarrhythmias.
- Always use an acute retention clip to reposition or remove the lead. Always attempt to undeploy the lobes before repositioning or removing the lead. If a lead must be removed or repositioned, consider referring the case to an experienced extraction center. Do not implant the acute retention clip.
- Previously implanted pulse generators, implantable cardioverter defibrillators, and leads should generally be explanted.

Extraction Warning

The risk and difficulty of removing the Medtronic Attain StarFix Model 4195 lead after a long implant time has not been studied. In light of the novel fixation mechanism of the Model 4195 lead, there may be unique risk and difficulty associated with chronic removal. If a lead must be removed or repositioned, consider referring the case to an experienced extraction center. Do not implant the acute retention clip.

Potential Complications

Potential clinical complications resulting from the use of transvenous leads include, but are not limited to, the following: air embolism, avulsion of the endocardium, valve, or vein, cardiac dissection, cardiac perforation, cardiac tamponade, coronary sinus dissection, death, endocarditis and pericarditis, erosion through the skin, extracardiac muscle or nerve stimulation, fibrillation or other arrhythmias, heart block, heart wall or vein wall rupture, hematoma/seroma, infection, myocardial irritability, myopotential sensing, pericardial effusion, pericardial rub, pneumothorax, rejection phenomena, threshold elevation, thrombosis, thrombotic embolism, and valve damage.

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Last updated: 22 Sep 2010

Teaching Hospital Perspectives

John T. Randolph

Vice President and Chief Compliance Officer
UMass Memorial Health Care



Implications of the Sunshine Act

- Hospitals
- Physicians
- Patients
- Media



Faculty Conflict of Interest Disclosure

- Imperative:
 - Full disclosure
 - Timely
 - Updating the disclosure
 - Proactive discussion of relationships



Faculty Conflict of Interest Disclosure

- Proactive Management of Relationships
 - Minimize surprises with media
 - Compliance with Institutional Policies
- Ensure Integrity of Decisions and Appearance
 - Patient care
 - Clinical research
 - Business decisions



Compliance with Institutional Policies

- Clarity/comprehensiveness of policies
- Communication to faculty
 - All?
 - Employed only?
- Applicable to Hospital?
- Educate faculty re: External Reporting
 - Sunshine Laws
 - State reporting



Sunshine (“Open Payments”) Reporting

- September 2014 (possibly later)
- Reconciliation approaches
 - Centralized
 - Incorporate in COI
- The media (and possibly patients)



Take Aways

- Policies

- Do you have policies addressing:
 - Relationships with Industry?
 - Disclosure requirements?
- Are they clearly communicated to faculty?

- Education

- Have your faculty been educated regarding:
 - Relationships with Industry?
 - Sunshine and other (ie: State) public databases?

- Reconciliation process

- Is responsibility for overseeing Sunshine reporting assigned?
- Is responsibility for responding to media inquiries assigned?



Thank you



Daniel J. Carlat
dcarlat@pewtrusts.org



John T. Randolph
john.randolph@umassmemorial.org



Tara R. Shewchuk
tara.r.shewchuk@medtronic.com

