

December 3, 2008

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services,
5630 Fishers Lane, rm. 1061
Rockville, MD 20852.

CITIZEN PETITION

The Prescription Project,¹ a program of Community Catalyst, Inc., a non-profit consumer health care advocacy organization based in Boston, Massachusetts, submits this petition under §4(d) of the Administrative Procedure Act, 5 U.S.C. § 553(e), as well as under 21 C.F.R. §§ 10.25 & 10.30, and 21 U.S.C. § 352, to request the Commissioner of Food and Drugs to take enforcement action regarding online video advertisements posted on www.YouTube.com promoting Medtronic's medical device, the PRESTIGE Cervical Disc, as described below.

ACTION REQUESTED

In order to protect the health and safety of consumers nationwide, the Prescription Project requests that the FDA:

1. Notify medical device manufacturer Medtronic² (NYSE: MDT) that a video³ promoting Medtronic's PRESTIGE Cervical Disk posted on the internet website www.YouTube.com by VNR-1 Communications, a private media company with which Medtronic is connected, is in violation of the broadcast advertising requirements for restricted medical devices under 21 U.S.C. §§ 352(q)(1) and (r)(2), and/or that this video violates other applicable restricted medical device labeling disclosure requirements, as described herein.
2. Require that Medtronic act to remove any noncompliant advertising for the PRESTIGE Cervical Disk from the YouTube.com website, and any other websites under the direction or control of Medtronic, or Medtronic's promotional agents or affiliates.
3. Require that Medtronic post curative ads on YouTube.com, on relevant Medtronic websites, and on any other online outlets in which the original noncompliant videos were posted or promoted. These curative ads should

¹ The Prescription Project is led by Community Catalyst in partnership with the Institute on Medicine as a Profession, and funded by the Pew Charitable Trusts, to advance policies to ensure safe and effective drugs for consumers and reduce the countervailing influence of industry marketing. More information is available at www.prescriptionproject.org.

² Medtronic (NYSE:MDT) is an international corporation whose "World Headquarters" are listed as "710 Medtronic Parkway, Minneapolis, MN 55432-5604. Phone: (763) 514-4000, Fax: (763) 514-4879, Mail Stop: L100" see <http://www.medtronic.com/about-medtronic/locations/index.htm>.

³ The specific video is posted at http://www.youtube.com/watch?v=vde_qcZmiwU; see Exhibit 1, Exhibit 2.

address and correct the erroneous information and impressions fostered by the original ads, and provide consumers with complete device information, including a full statement of device uses, warnings, contraindications, and potential side effects.

STATEMENT OF GROUNDS

I. Increasing market competition fuels DTC advertising of orthopaedic implants, putting consumers at risk.

The advent of new medical technology, coupled with increased direct-to-consumer (DTC) advertising, may create significant risks to consumers. Consumers are put at risk when presented with extremely complex medical information in the limited format of DTC advertising of medical devices. In testimony before the U.S. Senate Special Committee on Aging this past September, Dr. William E. Boden, chief of cardiology at Buffalo General Hospital, emphasized that the decision to use a “specialized medical device ... requires a very sophisticated medical understanding” that few could gain through DTC advertising.⁴

Given this complexity, and the higher stakes associated particularly with medical devices that are implanted through surgery, DTC ads for medical devices such as cervical discs are potentially even more problematic than DTC advertising for prescription drugs.

In addition, many industries employ private public relations firms to create sponsored, prepackaged video segments designed to mimic an independent television news reports, called ‘video news releases’, or VNR’s.⁵ PR firms have shifted from their successful⁶ targeting of TV news broadcasts to a new focus on online sources. As a result, online sources, such as podcasting and newspaper websites, may account for more use than TV broadcasters.⁷ Some feel this shift was caused by PR firms seeking to better target audiences, but avoid government oversight.⁸ Critics have noted that, regardless of the medium, health-related VNR’s are especially problematic, because they make it easier to overstate and misrepresent the benefits of a health product.⁹

⁴ Boden, William E., MD, Testimony before the U.S. Senate Special Committee on Aging, September 17, 2008, page 7, available at <http://aging.senate.gov/events/hr202wb.pdf>, last visited 11-18-2008.

⁵ Peter Phillips et al, Project Censored, Censored 2008: the Top 25 Stories (2007) at 275.

⁶ *Id.* at 278.

⁷ *Id.* at 283.

⁸ *Id.* See also, “Safety Information Sold Separately: Pharmaceutical company dodges federal regulations through fake TV news,” Center for Media & Democracy, <http://www.prwatch.org/fakenews/vnr10>

⁹ *Id.*

II. YouTube video posted by Medtronic's promotional agent VNR-1 is advertising that misbrands the PRESTIGE device.

A. FDA has the authority to regulate advertising of the PRESTIGE disk as a restricted medical device

FDA has the authority to regulate advertising of all 'restricted'¹⁰ medical devices under 21 U.S.C. §§ 352(q) and (r). The PRESTIGE Cervical Disk device is manufactured by Medtronic, Inc, and was approved by FDA for sale as a restricted medical device, and as a prescription device.¹¹ Therefore FDA has the authority to regulate advertising of the PRESTIGE Cervical disk.

B. Medtronic and VNR-1's YouTube video constitutes advertising of the PRESTIGE device.

The kinds of promotional activities that constitute 'advertising' of medical devices is not defined by statute. However, FDA has defined advertising of prescription drugs to "include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems."¹² This list is illustrative and Internet ads are included within its scope. Under traditional canons of statutory construction (including the "plain meaning" of the word "advertising"), this definition is applicable to medical devices as well.

1. The relevant YouTube.com video is posted by VNR-1 Communications, which is acting as a promotional agent of Medtronic

The www.YouTube.com website lists the posting source of this relevant video as being "[f]rom: VNR1Communications." The website <http://www.vnr1.com/about.asp> identifies VNR-1 Communications, Inc, as:

a video production firm...incorporated in October, 1990...[that] is privately owned and is based near the Ballpark in Arlington, Texas, a location that is convenient to national and international client fulfillment. This location, combined with a staff of newsroom-experienced personnel, results in high quality workmanship and modest prices.

Further research strongly suggests that medical device manufacturer Medtronic is a client of VNR-1. For instance, a press release entitled "Balloon Kyphoplasty Provides Relief for Osteoporosis Fractures" published on VNR-1's website indicates that "[t]he content is provided for your free and unrestricted use on behalf of Medtronic." (See Exhibit 3, attached hereto.) Given that VNR-1 is a

¹⁰ A restricted device is a device whose "sale, distribution, or use [requires] the written or oral authorization of a practitioner licensed by law to administer or use such device. . . ." 21 U.S.C. § 360j(e) (2008).

¹¹ FDA approval letter for PRESTIGE Cervical Disk (July 16, 2007) at <http://www.fda.gov/cdrh/pdf7/p070001a.pdf>.

¹² 21 C.F.R. § 202.1(l)(1) (2008).

business producing videos for pharmaceutical, medical device and other health care clients, it is very likely that the YouTube video in question was produced by VNR-1 for, or at the request of, Medtronic.

2. VNR-1's YouTube.com video identifies both the PRESTIGE device, and its manufacturer, Medtronic.

The Medtronic and VNR-1 video, (see electronic reproduction, attached hereto as Exhibit 1; see also transcript, attached hereto as Exhibit 2) depicts a patient recounting her experience suffering from back pain, and her subsequent experience feeling relief after the implantation of the PRESTIGE device. This video identifies the PRESTIGE device in visual text displayed before the audio portion of the presentation begins, three (3) times during the audio portion of the presentation, and again in the visual text at the end of the presentation. This video also clearly identifies device manufacturer "Medtronic" in the graphic text at the beginning of the presentation, and during a graphic in the middle of the video. (See Exhibit 1, Exhibit 2, attached hereto).

3. Medtronic and VNR-1's YouTube.com video makes at least ten (10) product claims about the PRESTIGE device.

The YouTube video makes the following product claims:

(i) that "FDA has given its okay for a new artificial disc that surgeons can use to help patients with chronic neck or arm pain caused by herniated or ruptured spinal disks";

(ii) that "[t]his comes after the U.S. government completed its review of the largest ever clinical trial on neck pain";

(iii) that this new artificial disc "is called the PRESTIGE Cervical Disc, and it is designed to help patients with severe neck problems";

(iv) that to implant a PRESTIGE disc, "[a] surgeon removes the diseased disk from the patient's neck, and inserts the patented ball and trough designed by Prestige Cervical Disc. The surgery takes only a few hours and leaves only a small scar";

(v) that "[p]atients involved in the clinical trial had superior outcomes in neurological and overall success scores";

(vi) that "Prestige [device] patients also returned to work on average 26 percent faster than fusion patients" and that "[t]his meant a renewed life for the active soccer mom";

(vii) that patient "Stacey Brixon, who had "excruciating neck pain that eventually left her unable to do simple things like look over her shoulder" or "pick [her] head up from the pillow [without using] two-hand[s]...and...had difficulties just walking down the hall for the first few steps, 'cause my spinal cord was so compressed...";

(viii) that "[a]fter trying months of non-operative treatments, such as cold compresses and painkillers, [patient] Stacey [Brixton] sought the help of orthopaedic surgeon Dr. Thomas Zabelick [spelling uncertain], [and then she] enroll[ed] in a clinical trial for the new PRESTIGE Cervical Disc" and

(ix) that patient "Stacey first came to see me [the doctor speaking] because of really debilitating pain. She was a high level athlete, really busy in her life, both her educational life, at school, at work, and she was a high-level tri-athlete as well, and had developed a disc herniation in her neck";

(x) that patient Stacey Brixton, after participating in the PRESTIGE clinical trial "would say [she is] a hundred percent" and that she is "doing great."

C. The PRESTIGE video does not meet either the statutory disclosure requirements for advertising of medical devices, or any possibly applicable standard for broadcast advertising under the FDA's 2004 draft Guidance.

A restricted medical device is deemed to be misbranded if its advertising does not contain the "requisite accompanying statements" including "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications...."¹³

1. The FDA approved labeling for the PRESTIGE device includes serious warnings, precautions, and risks.

The FDA approved labeling¹⁴ for the PRESTIGE Cervical Disc device includes warnings that "[d]ue to the proximity of vascular and neurological structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage with the use of this device."¹⁵ Significant risks are associated with the use of this device, or with any spinal surgery. Some of the many risks associated with the use of the device include "deficit or damage to the spinal chord, nerve roots, or nerves possibly resulting in paralysis ... loss of neurological function ... [i]nability to resume activities of normal daily living; [and] [d]eath."¹⁶

2. The PRESTIGE ad does not include "a brief statement of the intended uses... and relevant warnings, precautions, side effects, and contraindications."

Medtronic and VNR-1's YouTube video provides no statements regarding these or any other warnings, precautions, side effects, or contraindications. In addition, the video's promotional description of the PRESTIGE device's use probably would not satisfy the required statement of intended uses. Either or both of these shortcomings mean that this video misbrands the PRESTIGE device.

¹³ 21 U.S.C. §352(r) (2008).

¹⁴ FDA approved labeling for the PRESTIGE® Cervical Disc System - P060018 (July 16, 2007); see <http://www.fda.gov/cdrh/pdf7/p070001c.pdf>.

¹⁵ *Id.* at 4.

¹⁶ *Id.* at 8, 9.

3. The PRESTIGE video, lacking fair balance, is misleading, and thus misbrands the device under §352(q).

Additionally, under 21 U.S.C. § 352(q), a device ad may be misbranded if it is “false or misleading in any particular.” A failure to provide a balanced presentation between intended uses and associated risks is misleading. As described above, the Medtronic and VNR-1 YouTube.com video takes no steps to apprise consumers of any of the risks, warnings, precautions, or side effects associated with the use of the PRESTIGE device. Lacking such statements, the video cannot achieve fair balance, and is misleading. Therefore this video misbrands the PRESTIGE device.

4. Even under the less rigorous disclosure requirements for ‘broadcast advertising’ the PRESTIGE video misbrands the device.

Statutory sections 21 U.S.C. §§ 352(q) and (r) constitute the totality of current legal requirements for consumer-directed broadcast advertisements of restricted devices, since the FDA has not promulgated any regulation clarifying those sections, nor finalized any guidance on them. The FDA’s Feb. 2004 draft Guidance for Industry and FDA on Consumer-Directed Broadcast Advertising of Restricted Devices¹⁷ remains a draft.

However, some may argue that the 2004 draft Guidance, even in its unfinalized draft form, should be considered the FDA’s current thinking and interpretation of those sections of 21 U.S.C. § 352, and would therefore provide a “safe harbor” for device manufacturers complying with the Guidance. Even assuming this lower standard were applicable (which we do not believe to be the case), Medtronic and VNR-1’s YouTube.com video would fail to meet this lower standard of required disclosures.

a) The video does not satisfy the prerequisites for broadcast ads under the 2004 draft Guidance.

The 2004 draft Guidance “describe[s] an approach that FDA believes can fulfill the brief statement [requirement for] consumer-directed broadcast advertisements for restricted devices.”¹⁸ But the 2004 draft Guidance’s “approach presumes that such advertisements” do all of the following:

- Communicate that the device is restricted to sale, distribution, or use only upon authorization of a licensed practitioner.
- Present information about its effectiveness and information about risk in a balanced manner.
- Include a thorough major statement conveying all of the device’s most important warnings, precautions, side effects, and contraindications in consumer-friendly language.

¹⁷ FDA, Draft Guidance for Industry and FDA. Consumer-Directed Broadcast Advertising of Restricted Devices, Feb. 10, 2004, at <http://www.fda.gov/cdrh/comp/guidance/1513.html>.

¹⁸ Id. at 2.

- Communicate all information relevant to the PRESTIGE device's indication (including a brief statement of the intended use(s) of the device and any limitations to use) in consumer-friendly language.

Here, VNR-1 and Medtronic met none of these prerequisites. The PRESTIGE video presents no information on the product's intended uses, restrictions on its sale, or on its warnings, precautions, or side effects. Thus, even if the standards of the draft Guidance were held to apply, the device is misbranded.

- b) The video provides no *major statement and adequate provision* as required of broadcast ads.

Assuming that compliance with the Draft Guidance would satisfy the requirements of 21 U.S.C. § 352, Medtronic and VNR-1 could have satisfied the "brief statement" requirement of § 352(r)(2) by both (i) making a *major statement* disclosing "the most serious and the most common risks associated with the [PRESTIGE] device in either the audio or audio and visual parts of the presentation, and " (ii) by making "*adequate provision* for dissemination of the approved or permitted package labeling in connection with the broadcast presentation."¹⁹ Such *adequate provision* may be accomplished by providing a toll-free number, a reference to publications containing additional product information, an Internet web page address or a clear communication that consumers should consult their health care providers for additional information

Medtronic and VNR-1 met neither the major statement nor adequate provision requirements. Therefore the video misbrands the PRESTIGE device.

III. Medtronic and VNR-1's YouTube video does not fall under any exception or exclusion for medical devices.

A. The YouTube video is advertising, not 'labeling' of a medical device.

An exemption from the advertising disclosure requirements for restricted medical devices is allowed for promotional "printed matter... the Secretary determines to be labeling...."²⁰

Labeling is defined as "[b]rochures, booklets, mailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips,...sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and...for use by medical practitioners ...and which are disseminated by or on behalf of its manufacturer, packer, or distributor."²¹

¹⁹ *Id.* at 3,4.(emphasis added).

²⁰ Under 21 U.S.C. §352(r) (2008).

²¹ 21 C.F.R. §202.1(l)(2) (2008).

The YouTube video does not fall within this exception under 21 U.S.C. § 352(r) because by its plain language, the exception applies only to “printed matter.”

In addition, the YouTube video is logically best characterized as advertising, not labeling. The regulation defining prescription drug labeling (21 C.F.R. § 202.1(l)(2) references such materials as are “for use by medical practitioners.” In contrast, statute 21 U.S.C. § 352(n) states that advertising presented “directly to consumers in television or radio format” shall make the required disclosures clearly and conspicuously.

Given that YouTube.com is a medium designed and intended for easy use by the general public (as opposed to, say, a website clearly intended for use by medical professionals and described as such), VNR-1's posting the video in this location directly targets the public, making it advertising presented “directly to consumers.” FDA has previously cited prescription drug videos on YouTube as advertising that misbranded the drugs in question.²²

B. Alternatively, the YouTube videos, even construed as ‘labeling’ are deficient of disclosure requirements for devices under 21 U.S.C. §352(f).

In light of the broad definition of the term ‘labeling’ to include materials distributed separately from the drug or device²³ an argument might be made that the videos qualify as labeling. Statute 21 U.S.C. § 352(f) specifies that a device is misbranded unless its labeling contains “(1) adequate directions for use and (2) such adequate warnings” with respect methods, dosage, use in children, or pathological conditions, etc “as are necessary for the protection of the user....”

The PRESTIGE video does not contain any such adequate directions for use or such adequate warnings. The failure to include these required disclosures violates 21 U.S.C. § 352(f), thus rendering the device misbranded.

In addition, even if construed as ‘labeling,’ this video would violate 21 U.S.C. § 352(a), which deems a “device ... to be misbranded...[i]f its labeling is false or misleading in any particular.” The absence of information concerning contraindications, warnings, and the like for the PRESTIGE device makes this video false and misleading, misbranding the PRESTIGE device.

1. The PRESTIGE video doesn't meet the prerequisites for exempt prescription device labeling.

A significant exception to the device labeling requirements exists for “prescription devices,” i.e. devices whose “use is not safe except under the

²² See, e.g., FDA Warning Letter, re NDA # 21-303, Adderall XR® Capsules (Sept. 25, 2008) available at http://www.fda.gov/foi/warning_letters/s6936c.htm;

²³ Kordel v. United States, 335 U.S. 345, 350 (1948).

supervision of a practitioner licensed by law to direct the use of such device...."²⁴
In such a case, " 'adequate directions for use' cannot be prepared" so the device
is exempt from the *adequate directions for use* requirement under § 352(f)(1).

As previously stated, the PRESTIGE device is approved by FDA as such
a 'prescription device' under 21 C.F.R. § 801.109.²⁵ But this exemption is not
applicable to the YouTube video for two reasons. First, this exception applies
only if certain criteria are met, including that, under 21 C.F.R. § 801.109(d), "the
labeling,...whether or not it is on or within a package...distributed by or on behalf
of the manufacturer... furnishes or purports to furnish information for the use of
the device, including **indications**, effects, routes, methods, and frequency and
duration of administration **and any relevant hazards, contraindications, side
effects, and precautions....**" (emphasis added.)

In addition, the exemption applies only to a manufacturer's duty to provide
'adequate directions for use' under § 352(f)(1). The exception does not
extinguish the manufacturer's duty to ensure that a drug or devices' labeling
provides "such...adequate warnings against use...as are necessary for the
protection of users . . ." under § 352(f)(2).²⁶

Here, the PRESTIGE video does not furnish, or attempt to furnish, any
information on any hazards, contraindications, side effects or precautions, all of
which are necessary for the protection of device users. Therefore, this video
cannot qualify for an exception under 21 CFR § 801.109.

C. No other exceptions apply to the PRESTIGE Cervical Disk

The misbranding prohibition under 21 U.S.C. § 352, including the
advertising provisions under § 352(r), may be superceded by any applicable
requirements under §§ 360d, 360e, or 360j(g).²⁷ However, none of these
exceptions (for investigational devices under § 360j, or for Class II devices under
§ 360d and § 360e) apply to the PRESTIGE device.

IV. Conclusion

We urge the FDA to promptly take the enforcement actions against
Medtronic and VNR-1's noncompliant advertisements as described in the "Action
Requested" section herein, and help send a strong message to all device and
drug manufacturers that such violations will not go unnoticed or unenforced.

²⁴ 21 C.F.R. §801.109 (2008)

²⁵ Supra note 12.

²⁶ See 21 U.S.C. §352(f)(2) (2008).

²⁷ See 21 USC § 360(j) (2008)

ENVIRONMENTAL IMPACT STATEMENT

We believe that the action requested herein is exempted from the requirement of an environmental impact statement pursuant to 21 C.F.R § 25.30(a).

ECONOMIC IMPACT STATEMENT

(Not required upon initial submission.)

CERTIFICATION

The undersigned certifies on this Third day of December, 2008, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

(Signature)

Allan Coukell, Director of Policy
The Prescription Project of Community Catalyst
30 Winter Street, 10th Floor
Boston, MA 02108 §§
(617) 338-6035

LIST OF ATTACHMENTS

- Exhibit 1 Electronic media copy of video posted at http://www.youtube.com/watch?v=vde_gcZmiwU entitled "Neck Pain?" listed as being "[f]rom: VNR1Communications" and added "August 22, 2007" with a length of 2:09 min.
- Exhibit 2 Transcript of video posted at http://www.youtube.com/watch?v=vde_gcZmiwU entitled "Neck Pain?" listed as being "[f]rom: VNR1Communications" and added "August 22, 2007" with a length of 2:09 min.
- Exhibit 3 VNR-1 Press release establishing a promotional collaboration between Medtronic and VNR-1, available online at http://www.vnr1.tv/display_video.asp?id=385

Exhibit 1

**Electronic media copy of video posted at
http://www.youtube.com/watch?v=vde_qcZmiwU entitled "Neck Pain?"
listed as being "[f]rom: VNR1Communications" and added "August 22,
2007" with a length of 2:09 min.**

Exhibit 2

**Transcript of video posted at
http://www.youtube.com/watch?v=vde_qcZmiwU entitled "Neck Pain?"
listed as being "[f]rom: VNR1Communications" and added "August 22,
2007" with a length of 2:09 min.**

[Text displayed over Medtronic logo]

Anchor Intro

The U.S FDA has given its okay for a new artificial disc that surgeons can use to help patients with chronic neck or arm pain caused by herniated or ruptured spinal disks.

This comes after the U.S. government completed its review of the largest ever clinical trial on neck pain.

It is called the PRESTIGE Cervical Disc, and it is designed to help patients with severe neck problems.

[Medtronic logo] Medtronic

[0:11, Audio starts, announcer:]

Stacey Brixon likes to compete. As an amateur tri-athlete, she has traveled from Switzerland to Hawaii, running, swimming, and biking. But this physical therapist with a PhD and the married mother of two hit a big road bump after 2002. After two minor auto accidents, Stacey started to have excruciating neck pain that eventually left her unable to do simple things like look over her shoulder.

[Stacey:]

In the mornings, I was unable to pick my head up from the pillow, you know, it was a two-handed maneuver, and I had difficulties just walking down the hall for the first few steps, 'cause my spinal cord was so compressed, and I was so tired of being miserable.

[Announcer]

After trying months of non-operative treatments, such as cold compresses and painkillers, Stacey sought the help of orthopaedic surgeon Dr. Thomas Zideblick. He recommended she enroll in a clinical trial for the new PRESTIGE Cervical Disc.

[Dr. Zideblick]

Stacey first came to see me because of really debilitating pain. She was a high level athlete, really busy in her life, both her educational life, at school, at work, and she was a high-level tri-athlete as well, and had developed a disc herniation in her neck.

[cut to animation text, bottom of screen:]

Animation footage furnished by Medtronic Sofamor Danek USA Inc.

[Announcer:]

A surgeon removes the diseased disk from the patient's neck, and inserts the patented ball and trough designed by Prestige Cervical Disc. The surgery takes only a few hours and leaves only a small scar. Patients involved in the clinical trial had superior outcomes in neurological and overall success scores. Prestige patients also returned to work on average 26 percent faster than fusion patients. This meant a renewed life for the active soccer mom.

[Stacey:]

I would say I'm a hundred percent, and I don't know how you can be a hundred percent when you have an artificial something, anywhere, but I think that I am, so, it's, I'm doing great.

[text displayed after audio ends:]

For more on Prestige Disc, click onto our website at [www.\(insert station web site here\).com](http://www.(insert station web site here).com), or visit www.Necksurgery.com

Exhibit 3

**(VNR-1 Press release establishing a promotional collaboration between
Medtronic and VNR-1, available online at
http://www.vnr1.tv/display_video.asp?id=385)**

ATTENTION: Assignments Desk & Medical Reporters
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Balloon Kyphoplasty Provides Relief for Osteoporosis Fractures

****Great Mother's Day Story to Tie Into the Holiday****

Osteoporosis causes an estimated two million fractures in the elderly each year in the United States, according to the National Osteoporosis Foundation. May has been designated National Osteoporosis Awareness and Prevention Month in hopes of helping people prevent the debilitating fractures that come with this disease.

People with a family history of osteoporosis are most at risk, but with early detection, much discomfort can be avoided. Many people who have suffered spinal fractures from osteoporosis can now repair the fracture and get relief from pain with a procedure called Balloon Kyphoplasty. The procedure can help patients get back to a life with mobility.

KYPHON® Balloon Kyphoplasty incorporates technology developed by Gary K. Michelson, M.D.

For more about osteoporosis or how Balloon Kyphoplasty helps osteoporosis patients, visit www.nof.org or www.spinalfracture.com

This video feed features tracked and untracked packages detailing Balloon Kyphoplasty. Patients and a doctor are featured in the feed with a full range of office and activity shots. Sounds bites are from patients and doctors. This feed also features animation demonstrating the Balloon Kyphoplasty procedure.

For Questions or Technical Assistance, Please Call the Sat Station @ 972-293-3500 or Rob @ 817-794-0555

- **The content is provided for your free and unrestricted use on behalf of Medtronic.**
- **For information about the story, contact Denise Franklin at (408) 548-5394, cell (831)-915-8994.**
- **It is requested that the source of this video content be identified during broadcast.**
- **Questions concerning the source of this content should be directed to VNR-1 Communications, Inc., 817-794-0555.**