

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,<sup>1</sup> 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](http://www.YouTube.com)<sup>2</sup> promoting Stryker's medical device, the Cormet Hip Resurfacing System, as described herein.

### **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 Corin Group PLC (NYSE: CRG) and device distributor Stryker<sup>3</sup> (NYSE: SYK) that a video<sup>4</sup> promoting the Cormet Hip Resurfacing System posted on the popular internet website [www.YouTube.com](http://www.YouTube.com) by MediaLink (a private media company with which Stryker has business connections) 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 Stryker act to remove any noncompliant advertising for the Cormet Hip Resurfacing System from the YouTube.com website, and any other websites<sup>5</sup> under the direction or control of Corin Group, Stryker, or their agents, promoters, or distributors.

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<sup>1</sup> 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](http://www.prescriptionproject.org).

<sup>2</sup> See <http://www.youtube.com/watch?v=Q4tZVHxZArI>, last visited Dec. 2, 2008; an electronic reproduction is attached as Exhibit 1, transcript attached as Exhibit 2.

<sup>3</sup> Stryker (NYSE:SYK) is a medical device company, with corporate offices in Kalamazoo, MI. Its website (<http://www.stryker.com/en-us/corporate/AboutUs/CorporateCompliance/index.htm>) states that Stryker is recognized "as one of the Top 10 medical device companies."

<sup>4</sup> See note 2, supra.

<sup>5</sup> See, e.g., Exhibit 3.

3. Require that Stryker post curative ads on YouTube.com, on relevant Stryker websites, and on any other online outlets in which the original noncompliant videos were posted or promoted. These curative ads should 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 the Cormet device's 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.<sup>6</sup>

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

In addition, the pharmaceutical and medical device industries, like others, are increasingly employing public relations (PR) firms to create sponsored, prepackaged video segments designed to mimic an independent television news reports. These are called 'video news releases' or VNRs.<sup>7</sup> PR firms have shifted from their successful targeting of TV news broadcasts to a new focus on online sources<sup>8</sup>. As a result, online sources, such as blogs, podcasts, video posting websites and newspaper websites, may account for more VNR use than TV broadcasters.<sup>9</sup> Some warn that this shift allows PR firms to more closely target their audiences, but avoid government oversight.<sup>10</sup> Critics have noted that, regardless of the medium, health-related VNRs are especially problematic, because they make it easier to overstate and misrepresent the benefits of a health product.<sup>11</sup>

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<sup>6</sup> 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.

<sup>7</sup> Peter Phillips et al, Project Censored, *Censored 2008: the Top 25 Stories* (2007) at 275.

<sup>8</sup> *Id.* at 278.

<sup>9</sup> *Id.* at 283.

<sup>10</sup> *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>

<sup>11</sup> *Id.*

## II. Promotional YouTube videos misbrand the Cormet device through omission of all warnings, side-effects, or intended use disclosures.

### A. FDA has the authority to regulate advertising of the Cormet Hip Resurfacing System, a restricted medical device

FDA's has the authority to regulate advertising of all 'restricted'<sup>12</sup> medical devices under 21 U.S.C. §§ 352(q) and (r). The Cormet Hip Resurfacing System ("Cormet device" hereinafter) has been approved<sup>13</sup> by FDA since July 3, 2007 as a restricted medical device, and as a prescription device.<sup>14</sup> The Cormet device is distributed in the US by Stryker. Therefore FDA has the authority to regulate advertising of the Cormet device.

### B. MediaLink's YouTube video constitutes advertising of the Cormet device.

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."<sup>15</sup> 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 MediaLink, Inc., which is a promoter or advertising agent of Stryker.

The www.YouTube.com website lists the posting source of this video as being "From: MediaLink" and further identifies<sup>16</sup> the source as "MediaLink, Inc" with the website <http://www.medialink.com/>. This listed website, in turn, identifies MediaLink as:

[producers of] award-winning video and audio content  
that is promoted and distributed ...on behalf of our  
750 clients, which include Fortune 100 corporations,

<sup>12</sup> A restricted device is one whose "sale, distribution, or use [requires ] the written or oral authorization of a practitioner licensed by law to administer or use such device ... if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness." 21 U.S.C. §360j(e)(2008).

<sup>13</sup> FDA approval letter for FDA Approval Letter for the Cormet Hip Resurfacing System, dated July 3, 2007, available at <http://www.fda.gov/cdrh/pdf5/p050016a.pdf>.

<sup>14</sup> *Id.* at 2 ("The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 . . . . FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.")

<sup>15</sup> 21 C.F.R. 202.1(l)(1)(2008).

<sup>16</sup> See <http://www.youtube.com/user/Medialink>.

business-to-business firms, associations, and not-for-profit organizations....we strive to continually deliver business innovation to help our clients achieve their goals.

The MediaLink website <http://www.medialink.com/> further describes the MediaLink's unique narrative marketing strategy for "telling, not selling" products to consumers.<sup>17</sup> Further research documents that MediaLink produced this video for Stryker, posted it on other websites<sup>18</sup> (See Exhibit 3) and helped distribute it jointly with Stryker.<sup>19</sup> (See Exhibit 4).

2. The Cormet YouTube.com video makes specific product claims about the device.

The MediaLink YouTube video (see electronic reproduction, attached hereto as Exhibit 1; see also transcript, attached hereto as Exhibit 2) depicts a patient recounting his experience suffering from pain and mobility loss, and his subsequent choice to have hip replacement surgery using the Cormet device. This video identifies the Cormet device in the textual graphics and audio portions of the presentation.

This YouTube video makes the following product claims:

- (i) that "Russell Ely ...an active 49-year-old ...[and] avid athlete [who] was forced to put his passion for sport and exercise on hold" was able to get "back to my active lifestyle and the things that I love to do" after using the Cormet device;
- (ii) that "[i]nterest in hip resurfacing procedures is on the rise globally due to the bone-conserving nature of the procedures, and anticipated potential benefits related to post-operative activities and range of motion";
- (iii) that "Cormet hip-resurfacing technology offers patients two potential benefits. First, it's bone-conserving";

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<sup>17</sup> The MediaLink website further describes the company as follows: "From webisodes and search engine marketing campaigns to corporate and sales video presentations, Medialink produces and distributes award-winning, high-impact brand messages, sophisticated corporate image pieces and other compelling public-facing content. Narrative Marketing™ is Medialink's unique storytelling approach that commands attention and motivates audience response via the Web, TV and radio. Our clients range from Fortune 50 global companies to niche marketers who embrace narrative marketing as the ideal vehicle for "telling, not selling" audiences the benefits of their products and services. Marketers also turn to Medialink for production expertise on longer-form video with higher production values that elegantly weave together appropriate acting talent, music and special effects. These more complex presentations can help to communicate the excitement of a product launch at a retail venue, illustrate the usefulness of a new technical feature from an original equipment manufacturer, or explain the nuances of a business program roll-out." See <http://www.medialink.com/marketers/default.aspx>.

<sup>18</sup> See <http://www.mefedia.com/entry/new-alternative-to-hip-replacement-surgery/5863935/> (website presents a 1:43 min video entitled "New Alternative To Hip Replacement Surgery" which seems to be identical to the YouTube video, and identifies this video as "Produced for Stryker..... Submitted By: Medialink" ); see also paper reproduction attached hereto as Exhibit 3.

<sup>19</sup> See <http://www.bio-medicine.org/medicine-news-1/VIDEO-from-Medialink-and-Stryker-3A-New-Alternative-to-Hip-Replacement-Surgery-9277-1/> ; see also paper reproduction attached hereto as Exhibit 4.

(iv) and that “the anatomic nature of this device offers certain younger, more active patients with the personalized solution to get back to those activities important to them”;

(v) that “[i]n this innovative process, the end of the thigh bone, or femur, is capped with a metal covering, made of strong cobalt chromium metal much like the capping of a tooth. This fits neatly into a metal cup that sits in the hip socket”;

(vi) that “[s]hould the device need replacing sometime in the future, a conventional total hip replacement can typically be used, making it an attractive option for younger and more active osteoarthritis patients”;

(vii) that “[h]ip resurfacing can offer the right patient a more bone-conserving procedure than traditional hip replacement”;

(viii) that hip resurfacing “helps that patient get back to their normal lifestyle” and

(ix) that “this advanced resurfacing technology [is] helping hip-pain sufferers like Russell get back in the game.”

C. The Cormet 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 is false or misleading in any particular”<sup>20</sup> or if it does not contain the “requisite accompanying statements in advertisements.”<sup>21</sup>

1. The Cormet YouTube video does not include “a brief statement of the intended uses ... and relevant warnings, precautions, side effects, and contraindications.”

Under 21 U.S.C. § 352(r), device ads are misbranded unless they carry certain “requisite statements in advertisements” including “a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications....”

MediaLink’s YouTube video provides no statements regarding warnings, precautions, side effects, or contraindications. In addition, the video’s promotional description of the Cormet 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 Cormet device.

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

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,

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<sup>20</sup> 21 U.S.C. §352(q)(1)(2008).

<sup>21</sup> 21 U.S.C. §352(r) (2008).

the MediaLink 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 Cormet device. Lacking such statements, the video cannot achieve fair balance, and is misleading. Therefore, this video misbrands the Cormet device.

3. Even under the less rigorous disclosure requirements for 'broadcast advertising' the Cormet 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 Devices remains a draft.<sup>22</sup>

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), MediaLink'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."<sup>23</sup> 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.
- Communicate all information relevant to the 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, MediaLink did not meet any of these prerequisites. The Cormet video presents no information on the product's intended uses, restrictions on its

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<sup>22</sup> 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>.

<sup>23</sup> Id. at 2.

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 Cormet YouTube 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 USC §352, Medialink and Stryker 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 [Cormet ] 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.”<sup>24</sup> 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

MediaLink and Stryker met neither the major statement nor adequate provision requirements. Therefore, the device is misbranded.

### **III. MediaLink’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 material which constitutes “printed matter ... the Secretary determines to be labeling ....”<sup>25</sup>

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.”<sup>26</sup>

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

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<sup>24</sup> *Id.* at 3,4.(emphasis added).

<sup>25</sup> Under 21 U.S.C. §352(r) (2008).

<sup>26</sup> 21 C.F.R. §202.1(l)(2) (2008).

practitioners.” In contrast, statute §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 is an online 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), MediaLink’s posting of the video on the YouTube site 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.<sup>27</sup>

B. Alternatively, the YouTube videos, even construed as ‘labeling’ remain 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 device<sup>28</sup> 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 Cormet 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 ... misbranded ...[i]f its labeling is false or misleading in any particular.” The absence of information concerning contraindications, warnings, and the like for the Cormet device makes this video false and misleading, and thus misbrands the Cormet device.

1. The Cormet video doesn’t meet the prerequisites for exempt prescription device labeling.

A significant exception to some of the device labeling requirements exists for “prescription devices,” i.e. devices whose “use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device....”<sup>29</sup> In such a case, “‘adequate directions for use’ cannot be prepared” so the device is exempt from the *adequate directions for use* requirement under 21 U.S.C. § 352(f)(1).

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<sup>27</sup> 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](http://www.fda.gov/foi/warning_letters/s6936c.htm);

<sup>28</sup> *Kordel v. United States*, 335 U.S. 345, 350 (1948).

<sup>29</sup> 21 C.F.R. §801.109 (2008)

While the Cormet device appears to fall within this exception's definition,<sup>30</sup> it is not applicable for two reasons. First, this exception requires that certain criteria must be met. This includes 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, this prescription device exemption applies only to adequate directions for use under § 352(f)(1). It does not extinguish the manufacturer's duty under § 352(f)(2) to ensure that a devices' labeling provides "such ...**adequate warnings** against use ...as are necessary for the protection of users ...."<sup>31</sup> (emphasis added).

Here, the Cormet YouTube 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 C.F.R. § 801.109.

#### C. No other exceptions apply to the Cormet device

The misbranding prohibitions under 21 U.S.C. § 352 generally, including the advertising provisions under § 352(r), may be superceded by any applicable requirements under statutory sections 360d, 360e, or 360j(g)<sup>32</sup>. However, none of these exceptions (for investigational devices under § 360j, or for special labeling as a performance control for Class II devices under § 360d and § 360e) apply to the Cormet device.<sup>33</sup>

### **IV. Conclusion**

We urge the FDA to promptly take the enforcement actions against MediaLink and Stryker'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.

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<sup>30</sup> Supra, note 14, the Cormet device has been approved as a 'prescription device' under 21 C.F.R. 801.109

<sup>31</sup> See 21 U.S.C. § 352(f)(2) (2008).

<sup>32</sup> See 21 U.S.C. § 360(j) (2008).

<sup>33</sup> While the Cormet device may have been a device for investigational use at an earlier time, this exclusion would not apply to the YouTube videos, which are publicly available, and not discretely targeted to applicable practitioners. Therefore, the exemption for devices for investigational use under 360j(g) does not apply. Similarly, the Cormet device has not been reclassified as a Class II device under §360e, for the purpose of including the videos as special labeling imposed as special control requirements under §360d.

**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.

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

**LIST OF ATTACHMENTS**

- Exhibit 1 Electronic media copy of video entitled “New Alternative to Hip Replacement Surgery” listed as from “MediaLink” posted at <http://www.youtube.com/watch?v=Q4tZVHxZArI> with a length of 1:43 min.
- Exhibit 2 Transcript of video entitled “New Alternative to Hip Replacement Surgery” listed as from “MediaLink” posted at <http://www.youtube.com/watch?v=Q4tZVHxZArI> with a length of 1:43 min
- Exhibit 3 Printout of website documenting MediaLink’s relationship to Stryker, available at <http://www.mefedia.com/entry/new-alternative-to-hip-replacement-surgery/5863935/>
- Exhibit 4 Printout of website showing connection between Stryker and MediaLink, available at <http://www.bio-medicine.org/medicine-news-1/VIDEO-from-Medialink-and-Stryker-3A-New-Alternative-to-Hip-Replacement-Surgery-9277-1/>

## **Exhibit 1**

**Electronic media copy of video entitled “New Alternative to Hip Replacement Surgery” listed as from “MediaLink” posted at <http://www.youtube.com/watch?v=Q4tZVHxZArI> with a length of 1:43 min.**

## **Exhibit 2**

**Transcript of video entitled “New Alternative to Hip Replacement Surgery” listed as from “MediaLink” posted at <http://www.youtube.com/watch?v=Q4tZVHxZARl> with a length of 1:43 min**

[Announcer]

Russell Ely is an active 49-year-old man. Russ is a salesman from Toledo Ohio and an avid athlete who was forced to put his passion for sport and exercise on hold.

[Russell]

Well, I made the decision to focus on the mechanics of the problem, rather than mask it with painkillers. My doctor suggested resurfacing. Now, I've gotten back to my active lifestyle and the things that I love to do.

[Announcer:]

Interest in hip resurfacing procedures is on the rise globally due to the bone-conserving nature of the procedures. And anticipated potential benefits related to post-operative activities and range of motion.

[cut to Dr. Bernard Stulberg, screen text:]

Dr. Bernard Stulberg, Cleveland Center for Joint Reconstruction

[Dr. Stulberg:]

Cormet hip-resurfacing technology offers patients two potential benefits. First, it's bone-conserving. Second, the anatomic nature of this device offers certain younger, more active patients with the personalized solution to get back to those activities important to them.

[Animation of hip]

[Text on animation screen:]

Healthy femoral head, Cormet Head resurfaced,  
Cormet Cup, Pelvis, Femur

[Announcer]

In this innovative process, the end of the thigh bone, or femur, is capped with a metal covering, made of strong cobalt chromium metal much like the capping of a tooth. This fits neatly into a metal cup that sits in the hip socket. Should the device need replacing sometime in the future, a conventional total hip replacement can typically be used, making it an attractive option for younger and more active osteoarthritis patients.

[Dr. Stulberg]

Hip resurfacing can offer the right patient a more bone-conserving procedure than traditional hip replacement, and helps that patient get back to their normal lifestyle.

[Announcer]

Cormet hip resurfacing was introduced internationally in 1997 by Corinth, who pioneered the modern development of this technology. Recently approved and released by the FDA, Stryker is now bringing this advanced resurfacing technology to the United States, helping hip-pain sufferers like Russell get back in the game. I'm Emily Wright.

## **Exhibit 3**

**(Printout of website documenting MediaLink's relationship to Stryker,  
available at <http://www.mefedia.com/entry/new-alternative-to-hip-replacement-surgery/5863935/>)**



Videos

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Description:

With over 43 million Americans suffering from arthritis, hip replacement is becoming a common procedure. But a new alternative to traditional hip replacement, called hip resurfacing, is on the rise due to the bone conserving nature of the procedure, minimized risk of dislocation and potential benefits related to post-operative activities and increased range of motion. Introduced internationally in 1997, Cormet Hip Resurfacing technology has recently been approved and released by the FDA for use in the United States. In this innovative process, the end of the thigh bone, or femur, is capped with a metal covering, much like the capping of a tooth and fits neatly into a metal cup that sits in the hip socket. Should the device need replacing at some time in the future, a conventional total hip replacement can typically be used, making it an attractive option for younger and more active osteoarthritis patients. Produced for Stryker Ranked 2.90 / 5 | 1,048 views | No comments Click here to watch the video Submitted By: Medialink Tags: health medical hip replacement resurfacing surgery stryker cormet

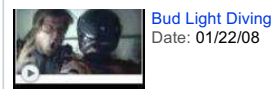
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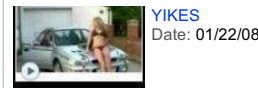
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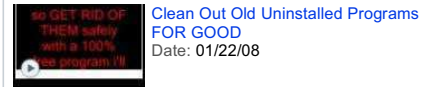
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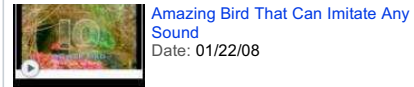
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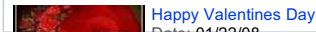
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## **Exhibit 4**

**(Printout of website showing connection between Stryker and MediaLink, available at <http://www.bio-medicine.org/medicine-news-1/VIDEO-from-Medialink-and-Stryker-3A-New-Alternative-to-Hip-Replacement-Surgery-9277-1/> )**

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NEW YORK, Jan. 8 /PRNewswire/ -- With over 43 million Americans suffering from arthritis, hip replacement is becoming a common procedure. But a new alternative to traditional hip replacement, called hip resurfacing, is on the rise due to the bone-conserving nature of the procedure, minimized risk of dislocation and potential benefits related to post-operative activities and increased range of motion.

(See video from [stryker](#) at: <http://media.medialink.com/WebNR.aspx?story=34296>)

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Introduced internationally in 1997, Cormet Hip Resurfacing technology has recently been approved and released by the FDA for use in the United States. In this innovative process, the end of the thigh bone, or femur, is capped with a metal covering, much like the capping of a tooth and fits neatly into a metal cup that sits in the hip socket. Should the device need replacing at some time in the future, a conventional total hip replacement can typically be used, making it an attractive option for younger and more active osteoarthritis patients.

Registered journalists can access video, audio, text, graphics and photos for free and unrestricted use at <http://www.mediaseed.tv>.

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