



FDA Approval and US Launch of the Resolute Integrity Drug-Eluting Stent

WCG and Medtronic, Jan 1, 2013

Summary: 2013 Silver Anvil Award of Excellence Winner — Marketing Consumer Products — Health Care

In February 2012, the Resolute Integrity drug-eluting stent (DES) from Medtronic was FDA-approved as the first and only device-of-its-kind to treat the CAD of patients with diabetes. It represented a major medical breakthrough for both the cardiology and diabetes communities.

However, the Resolute Integrity DES was the last of three drug-eluting stents approved by the FDA within a three-month period. Due to a highly competitive marketplace, Medtronic needed to differentiate the stent in a way that would resonate with their various target audiences. To accomplish this, Medtronic partnered with WCG to develop an integrated communications plan that would drive adoption of the Resolute Integrity DES by hospitals and physicians after U.S. approval.

Marketing consumer products includes programs designed to introduce new products or promote existing products to a consumer audience.

Full Text: SITUATION ANALYSIS

The leading cause of death in the United States, coronary artery disease (CAD) is also the cause of death in more than half of the country's diabetes population. Historically it's been difficult to treat CAD patients with diabetes due to their smaller arteries, longer lesions and persistently elevated blood-sugar levels, which all increase the rate of negative clinical outcomes and long-term safety risks.

Drug-eluting stents are implantable medical devices used worldwide for the treatment of CAD. Once a stent is implanted in the narrowed segment of a coronary artery, it provides a scaffold to keep the artery open and restore normal blood flow to the heart. Stenting procedures are a less invasive treatment option compared to open heart surgery, which requires longer hospital stays and recovery time.

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RESEARCH

WCG utilized its proprietary analytics offering to conduct an in-depth offline and online audit to

identify key influencers in the heart disease and diabetes communities. The influencers were then ranked by who drives the most quality conversations to target throughout the campaign in order to extend the reach of our key messages to the greatest extent possible. Medtronic and WCG also undertook the following primary and secondary research:

Primary:

- Met with physicians to review clinical data from the global RESOLUTE Clinical Program, showing that the Resolute Integrity stent performed particularly well in diabetes patients. Combined with the fact that more than 30 percent of U.S. patients who receive a stent have diabetes, we ultimately decided to focus heavily on this promoting this distinguishing feature.

Secondary:

- Scrutinized industry reports and internal Medtronic market analyses to obtain a deep understanding of how other drug-eluting stents performed in diabetes patients so we could position the Resolute Integrity stent effectively and solidify the strategic direction of our campaign.
- Compiled compelling U.S. statistics from online database sources to support the correlation between heart disease and diabetes in order to draw attention to the severity of these conditions and the unmet clinical need for this patient population.

PLANNING

Based on the breadth and depth of the research, an 18-month integrated communications plan was developed. The plan included: message/brand development, marketing collateral, advocacy relations, clinical and consumer media outreach, influencer engagement (both physician and patient), clinical data promotion and social media activities.

Launch Objectives:

- Prepare the U.S. market for immediate adoption of the Resolute Integrity stent among new and existing physician customers.
- Establish the correlation between heart disease and diabetes, and the Resolute Integrity stent's first-of-its-kind diabetes indication.
- Showcase the Resolute Integrity stent's clinical performance in complex patients, including those with diabetes.

Communications Strategies:

- Identify key heart disease and diabetes influencers to extend reach of messages as far as possible.
- Develop audience-specific messaging to market the device to the individual needs of our key consumers.
- Leverage all key milestones via news and social media channels to maximize message delivery.
- Enlist internal spokespeople and external physicians to deliver our messaging.

Target Audiences: Interventional cardiologists, referring physicians, hospital administrators, heart disease patients with diabetes and endocrinologists/diabetes educators.

- Due to the wide variety audiences and their individual needs, WCG prioritized them by identifying the Resolute Integrity stent's unique value proposition for each audience, what action we wanted them to take from our messaging, and the potential impact each audience could make on the stent's usage .

EXECUTION

Due to the integrated nature of the campaign, our communications plan was executed via the following tactics:

Pre-approval:

- **Compiled a robust media list** of the key influencers and other contacts who routinely wrote about heart disease and diabetes advancements to pitch with audience-specific messages upon approval.
- **Identified and media trained diabetes patients, as well as physicians** who participated in the RESOLUTE US clinical trial – data from which led to the FDA approval of Resolute Integrity – to act as external spokespeople.
- **Designed an educational heart disease and diabetes infographic** for consumer, media and hospital use to further bring the story to life in a visual manner and increase the visibility of diabetes and CAD.
- **Produced heart disease and diabetes b-roll/animation package** with experienced physician champion
- **Created a comprehensive hospital marketing and PR toolkit** to offer to all Medtronic customers in the U.S. who adopted the device so that they could promote it in their local market.
- The following **customizable template toolkit materials** were available to download via a password-protected website:
 - hospital newsletter,
 - hospital website copy,
 - media pitch,
 - press release,
 - product animation and b-roll,
 - product images with captions,
 - heart disease and diabetes backgrounder, and
 - product fact sheet.

Time of Approval:

- **Distributed multimedia press release** across U.S. news channels that was accompanied by the product fact sheet, disease backgrounder, b-roll, animation and product images.
- **Conducted national media outreach** upon approval to national consumer outlets, clinical cardiology and device trade media, diabetes-focused media outlets and hospital administration magazines.
- **Worked closely with local PR departments from 33 target-market hospitals** to leverage physician spokespeople and obtain local market media coverage.
- **Developed Medtronic's first social media plan for an FDA approval** by creating new branded channels (i.e. Twitter, YouTube, SlideShare and Flickr) to disseminate educational content.
- **Orchestrated national satellite media tour** with credible physician spokesperson to educate consumers about the connection between heart disease and diabetes via television and radio segments.
- **Built awareness at major national cardiology medical meetings** via a surround-sound PR approach to secure high-quality media articles around compelling data presentations and own the share-of-voice in the coronary stent space.

Post-Approval:

- **Featured Resolute Integrity in top-tier cardiology/professional media outlets** via diabetes-focused patient case studies that showed the use of the Resolute Integrity stent outside of the U.S. clinical trial.
- **Partnered with the International Diabetes Foundation during Diabetes Awareness Month** to extend campaign messages; now exploring additional partnerships with

U.S.-based diabetes advocacy groups.

- **Continued campaign momentum at 6 medical meetings** (e.g. ACC, AACE, ADA, TCT) to maximize message receptivity among our target audiences.

EVALUATION

The successful campaign achieved the following results:

- **Generated more than 250 positive media articles** throughout the span of the communications plan as the Resolute Integrity stent was being brought to market.
- **Secured over 40 in-depth cardiology and diabetes trade stories** resulting from support at national cardiology medical meetings; consistently achieved more stent-focused media coverage compared to competitors.
- **Engaged with 16 of the top heart disease and diabetes influencers.**
- **Generated original multiple local news stories in 18 of our target 33 markets;** also secured coverage in 10 markets outside of our initial targets.
- **Contributed to increasing Medtronic's DES share in a highly competitive market** from
 - 10% to
 - 30% in the first few quarters following launch.
- **Helped garner the launch team Medtronic's highest honor – the *Star of Excellence* award.**

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