HIL\&Knowlton

MEMO

To: Holly Glass, Chris Ganser, Janet Hudnall, Donna Passero and Brian Berry

From: Lee Lynch and Kimberly Ocampo

Date: May 10, 2004

Subject: Recovery Filter Crisis Communications Plan

This document provides a step-by-step guide for implementing an immediate communications strategy to ensure C.R. Bard is prepared for any news coverage that may result from pending investigations surrounding the Recovery Vena Cava Filter.

The information presented in this plan is privileged and confidential and is for internal use only.
RECOVERY® FILTER CRISIS COMMUNICATIONS PLAN

OVERVIEW

As with previous crisis plans Hill & Knowlton has prepared for C. R. Bard, this guide will help Bard’s Corporate Communications Team prepare for and properly manage controversial or negative stories surrounding the Recovery® Vena Cava Filter.

The proliferation of unfavorable press in top-tier media outlets can cause an onslaught of negative activity: a company’s employee morale may suffer, stock prices may plummet, analysts may downgrade the affected company’s rating, and longstanding reputations may be ruined temporarily or even permanently. Extensive preparation is critical to help prevent the spread of damaging coverage.

Currently, Bard is investigating the reported migration of the Recovery Vena Cava Filter in two separate incidences.

The first reported incident under investigation took place at Baptist Hospital of Miami, FL, following bariatric surgery. The coroner’s report states that filter migration is the cause of death. Bard is conducting its own investigations to research the validity of this claim and hired Dr. Luke Brennecke of Pathology Associates in Frederick, MD to conduct a subsequent pathological evaluation of the thrombus surrounding the vena cava filter removed during the autopsy.

The summary provided in the GMP12968 PATH Report signed by Dr. Brennecke follows:

The clot formation was an antemortem event; it had most likely been deposited around the device over a period of a couple of days. The location of the device during clot deposition could not be determined. The bacterial colonizing the clot most likely represents post mortem growth of normal saprophytic bacteria. Because extensive (destructive) sampling of the clot was prohibited (telephonic instructions), no tissue was sampled from around the hooks that were still embedded within the clot. Should they be sampled, it is possible that segments of the mural architecture (IVC or elsewhere) might be present.

It is important to note that, according to hospital records, the patient was a morbidly obese male, weighing between 450 - 500 lbs. The filter was placed in a normal sized vena cava and there were no immediate complications. According to a Pathology Associates report, the filter was found to be intact, and the large thrombus surrounding the filter was approximately 10 cm long x 3 cm in diameter. To date, no formal lawsuit from the family of the deceased has been filed.
The second incident took place in Grand Rapids, MI. From the information available to date, we know that the Recovery Filter was placed in a female patient for deep vein thrombosis. The filter had been placed approximately 13 days prior to death, March 31, 2004. The patient was then released from the hospital on April 6, 2004 and expired on April 13, 2004. The medical examiner's report states that the cause of death is cardiac rupture as a result of a puncture to the right ventricle by an inferior vena cava filter.

The size of the clot at the time of the autopsy was approximately 3 cm in diameter by 50 cm in length. There were no design or manufacturing defects found to be associated with the filter. The BPV Product Assessment Team has concluded that the Recovery Filter captured a large embolic load with resulting increase in venous pressure that lead to inferior vena cava dilation greater than 26 mm resulting in migration. Final autopsy report will be available during the week of May 4.

The attached pages provide recommendations and critical information relating to the following components of your crisis communications program:

- I. Re-distributing Bard's Communications Policy
- II. Media Monitoring
- III. Message Approval
- IV. Establishing A Core Response Team
- V. Audience Outreach Team
- VI. Top Media Interview Dos and Don'ts
- VII. External Allies/Experts
- VIII. Key Studies
- IX. News Breakdown
- X. Newsmaker's Bill of Rights
- XI. Proactive Media Outreach
- XII. Step-by-Step Management of Most Likely Scenarios:
- XIII. H&K Team Contact Information
- Addendum:
  - A. Key Messages - Recovery Vena Cava Filter: General Messages
  - B. Key Messages for Specific Incidents:
    * Specific to Miami Incident
    * Specific to Grand Rapids, MI Incident
    * Specific to Both Incidents
  - C. Draft General Letter-To-The-Editor
  - D. Draft Miami Letter-To-The-Editor
  - E. Draft Miami Letter-To-The-Editor
  - F. Media Lists
  - G. Recent Sample Article: Bariatric Surgery in General
1. Redistributing Bard's Communications Policy

To prevent any Bard employee from speaking with members of the media, it would be wise to redistribute Bard's communications policy company-wide twice each year beginning with 2Q 2004. If Bard is notified that a lawsuit has been filed, dissemination of the communications policy again specifically to the Bard Peripheral Vascular Division as well as C.R. Bard Corporate employees, should be considered.

Anyone who may be most likely to receive phone calls from members of the media (e.g., administrative staff for corporate executives and field sales representatives who sell vena cava filters) must have copies of the communications policy and should be required to sign a confirmation form that they have read and understand these guidelines.

All Bard employees must know to direct any media inquiries directly to Holly Glass. With the communications guidelines redistributed several times each year, employees will have this information top-of-mind.
II. Media Monitoring

H&K has begun monitoring regularly for any print, broadcast and online news coverage related to the company or the Recovery Vena Cava Filter. To do this effectively, H&K is using the Factiva database, Google News and Video Monitoring Services (VMS). Particular emphasis is placed on news generated from the following markets: greater New York City (Bard Corporate HQ); Tempe, Arizona (Bard Peripheral Vascular HQ); Miami, Florida (location of case under investigation) and Grand Rapids, Michigan (location of case under investigation).

We are searching for the following terms:

- C.R. Bard
- Bard Peripheral Vascular
- Recovery Vena Cava Filter
- Vena cava filter
- Pulmonary embolism
- Baptist Hospital (Miami, FL)

- Miami Cardiac & Vascular Institute (MCVI)
- [NAME OF LAW FIRM FILING SUIT IF SUIT IS FILED]
- Any filter mentions in Grand Rapids, MI

III. Message Approval

Key messages (see appendix, still to be reviewed and finalized) serve as the foundation for responding during any media interviews that may arise as a result of the pending investigations. It is critical that this messaging be updated as new details arise.

The approved messaging will be incorporated into external materials that will be distributed to Bard's sales force, customers, physicians, employees, suppliers and others, as needed. Bard is then prepared to handle any media inquiries. Furthermore, H&K's on-camera Q&A Training will help prepare spokespeople for any local or trade press inquiries that are posed; additional "on-the-spot" training and messaging discussions should be considered prior to responding to national top-tier press inquiries.
VI. Top Media Interview Dos and Don'ts

Following is a list of general dos and don'ts for interviews with major top media outlets.

Dos

- Offer a physician spokesperson for comment.
- Offer a researcher, patient or corporate executive for further insight.
- Offer medical studies validating Recovery Vena Cava Filters or retrievable vena cava filters in general.
- Ask for a list of questions, parameters of the story and permission to record your own video of the interview or any interviews with Bard employees, patients or physicians.
- Offer video of Bard's headquarters, if you already have a tape available.
- Manage the story. Draw the line at non-company spokespersons, "trial witnesses", salespersons, product designers, etc.
- Stay focused on the success rate and clinical effectiveness of the product, rather than the claims. Stick to your key messages.
- Include day-before and day-of key audience notification in your communications strategy. Assume key audiences such as employees, physicians, shareholders, customers and field sales reps will see the story. Be prepared to notify them about when the segment will air or has just aired, and provide a clear, convincing cover letter with your key messages, as well as a breakdown of comments made in the story matched with corresponding facts.

Don'ts

- Play favorites with the members of the media.
- Answer a question with "No Comment."
- Don't try to minimize the problem.
- Don't release sensitive or proprietary information.
VII. External Allies/Experts

Physician Spokespeople
If a reporter calls for comment, Bard should have reputable physicians confirmed to participate in interviews to attest to the product's success rate and the value it provides to patients.

The below physician has been identified to serve as a spokesperson who can speak to the value of the filter.

Gary S. Cohen, MD
Chief, Interventional Radiology
Temple University Medical Center
3401 N. Broad St.
Philadelphia, PA 19140

Third Party Industry Organizations and Potential Allies
Board members and other prominent leaders from ally organizations may be able to lend their credibility to Bard by providing ally spokespersons who can speak to the value of the retrievable Recovery Vena Cava Filter products (or retrievable vena cava filters in general) and Bard's position as a leader both in terms of innovation and customer care/safety. Allies may include representatives from the following organizations:

- Society of Interventional Radiology
- Association for the Advancement of Medical Instrumentation
- Medical Device Manufacturers Association
- Society for Vascular Surgeons

We currently are researching whether these organizations would be willing to speak to the media if an inquiry arises. For regional or local media outlets, it may be necessary to provide local sources. As the scenario develops, we may work with other third-party associations to determine local spokespersons.

In addition, Bard may want to consider either securing the partnership of a general medical device or consumer organization that can speak broadly about the value of Bard's products for consumers, such as:

- The Medical Device Manufacturers Association
- Center for Consumer Affairs or
- American Council on Consumer Interests (ACCI)
Finally, another consideration is for Bard to create a third-party organization that focuses on the enormous benefit of medical progress for consumers to override the negative perceptions created through a few (often frivolous) lawsuits.
VIII. Key Studies

Two studies are available specific to the Recovery Filter.

The Recovery Filter has been used in Canada by a single investigator and two colleagues at six Toronto area hospitals in 58 subjects, under the Special Access regulations. Although essentially only one physician used the device, removal was performed by three physicians with different support staff and imaging equipment.

Of the 58 filters implanted, a total of 48 have been retrieved, 8 remain in place, and 4 patients have died with filters in place of causes unrelated to filter placement or retrieval (leukemia, cancer, polyarteritis and pulmonary aspergillosis, and hemorrhagic stroke). Time to removal ranged from 1 to 161 days, average 60 days.

In addition, the Recovery Filter underwent testing (bench top or animal studies or a combination of both) according to FDA guidelines to obtain FDA concurrence.

[NEED ABSTRACTS FOR THE ABOVE AND ADDITIONAL HUMAN STUDIES]

Summaries of key medical studies highlighting the success rate of Bard's Recovery Vena Cava Filter products and other vena cava filters can be found in the appendix. We have produced three separate sections of summarized studies: one focuses on the success of (permanent) vena cava filters in general; the second focuses on retrievable vena cava filters as a whole; and the third details studies on Bard's Recovery Vena Cava Filter specifically. These summaries will serve as handouts and references for the media.

IX. News Breakdown

There are many various forms a news story can take and often one precedes another. To understand how news stories are originally generated and often end up featured on weekly news magazine shows, an explanation of how the media generally works is provided below. Please note there are always exceptions to the standards.

Wires — Associated Press, Bloomberg, Dow Jones, Reuters
Trades — The Gray Sheet, MDDI, Medical Device Litigation Reporter
News Magazine — U.S. News & World Report, Time, Newsweek
Daily News Program — Dateline, World News Tonight
Weekly News Program — 60 Minutes, 60 Minutes II, 48 Hours Investigates, 20/20
Wires
Electronic wire services are the most immediate sources for breaking news. Wire stories have the most power in terms of garnering national attention and generating widespread coverage because they are “picked up” by all media outlets. Since these stories are published in real time, they are often very short and have limited third-party sources. Many times, these stories are updated continuously as the story develops throughout the day or week.

National and Top Market Dailies
Most newspapers subscribe to wire services and look to the wires to determine news assignments. While many leading papers run complete wire stories, often editors use a wire story as a starting point to develop the story with local tie-ins, such as the story’s impact on the community or using local experts for attributions. As a side note, nearly all newspapers will immediately post full wire stories on their Web sites.

Trade Publications
The trade journals are very influential in the medical device industry and will certainly be read by Bard’s competitors. They will cover the issue in-depth and may discuss its impact on the entire industry. Trade coverage may also lead to more general coverage.

News Magazines
News magazines will typically develop a story based on an initial wire story, and/or news item in a top daily or trade publication. However, these publications will provide a much more in-depth analysis of the issue. They will conduct extensive research on the companies involved and the sources being used in the story. They dig deep and uncover information that is often under the radar. These stories can take weeks to develop.

Broadcast
As a general rule, broadcast follows print. Once the print story hits, broadcast interest in the story will likely escalate.

For daily broadcast segments, producers will either request an interview with a Bard spokesperson to take place at the local affiliate station or arrange for a video crew to come to Bard’s headquarters. Broadcast segments on nightly news programs can take several days to develop.

Weekly programs like “60 Minutes” or “48 Hours” can take several weeks or even months to develop. Producers also will send a crew to the corporate headquarters to film the facility and interviews. They will likely make numerous trips to Bard’s headquarters. They will conduct extensive interviews and ask pointed questions.
X. Newsmaker's Bill of Rights

As we respond to media inquiries and arrange interviews, remember that Bard has certain rights as newsmaker and reporters have their expectations.

1. The right to know the interview topic(s) in advance.
2. The right to know the identity and affiliation of the reporter.
3. The right to state your key points and, if appropriate, restate them.
4. The right to have some control over the interview environment.
5. The right to bring up relevant topics and points not specifically asked during questioning.
6. The right to know how the interview material is being used and whether others are being interviewed for the story.
7. The right to respond to accusations.
8. The right to correct misstatements and misinformation during an interview.
9. The right to restate obscure or lengthy questions.
10. The right to finish responses without interruption as long as your answer is concise and relevant.

Reporter's Expectations

1. Reasonable access to legitimate news sources.
2. Consideration of the reporter's deadline and logistical needs.
3. A timely response to an inquiry.
4. A concise and direct answer to a relevant question.
5. If available, printed or pictorial material to flesh out the interview information.
6. The availability of corporate spokespersons for follow-up inquiries, when necessary, for clarification.
7. Corrected information, if incorrect information is inadvertently given.
8. Proactive follow-up by newsmaker with new information or corrected information.
9. An opportunity to build an ongoing relationship.
10. The same kind of courtesy and respect that the newsmaker desires.

XI. Proactive Media Outreach

We do not recommend proactive outreach to media at this time. We believe that taking a low-key approach, in an effort to avoid drawing attention to the issue, is the most appropriate strategy.
XII. Step-by-Step Management of Most Likely Scenarios

**Note: If any of these scenarios occurs, H&K will immediately implement the Bard News Bureau, through which H&K's Bard Team members (Frank Mankiewicz, Lee Lynch, Kimberly Ocampo and Melissa Busse) will work with other members of H&K's Media/Crisis/Litigation team and CR Bard Vena Cava Core Team members to determine and implement strategy and media outreach.**

1. **Scenario #1: Family of the deceased files a suit seeking damages from C. R. Bard. [LAW FIRM] issues a press release.**
   1. H&K will monitor any press announcements made by the plaintiff's law firm, as once a press release is issued, it may generate news coverage.
   2. If a press release runs on the wire, H&K will send an email to the Core Response Team. The email will include the press release and any other relevant information. H&K will also call Holly Glass, Janet Hudnall and Donna Passero with this information.
   3. H&K will immediately begin to monitor for any resulting press coverage.
   4. As soon as press coverage begins to appear, we will activate the CRT:
      a. H&K will send e-mails to the CRT, including press coverage to date if available and a scheduled conference call time.
      b. H&K will follow up with phone calls to all CRT members, informing each member of the upcoming conference call,
      c. During the call, CRT members will agree on media strategy and responses. Strategy may include contacting reporters responsible for coverage and providing them with summarized studies and a statement based on approved key messages from the company.
      d. As determined, CRT members may be responsible for informing Audience Outreach Team members.
   5. H&K will continue to monitor for additional coverage.
Scenario #2: A reporter calls Bard for comment.
1. The media inquiry comes in to Holly Glass.
2. Holly will notify Lee Lynch at H&K.
3. Depending upon the size and reach of the news outlet, either H&K or Holly Glass will call the reporter to find more information about the type of questions he or she may ask.
4. H&K will provide, through e-mail to the CRT, the list of anticipated questions and a time for a strategy conference. H&K also will gather and distribute to the team as much information as possible about the reporter.
5. H&K will follow up with phone calls to all CRT members, informing each member of the conference call.
6. During the call, the CRT members will agree on media responses.
7. As determined, CRT members may be responsible for contacting Audience Outreach Team members to inform them of the interview and pending coverage.
8. Holly Glass will conduct the media interview with H&K facilitating as appropriate. Summarized studies will be provided to the reporter.
9. H&K will follow up with the reporter as necessary.
10. H&K will put together a document detailing potential impact of the pending article (e.g., tone of interview, reach of wire service if interview was conducted by wire reporter, etc.) and recommended next steps.
11. H&K will monitor for resulting and additional coverage.
Scenario #3: Filter migration or bariatric surgery (see example of recent negative story in appendix), in general, gets negative media coverage without singling out Bard or the Recovery Filter.

1. H&K will research the background of the reporters writing the negative stories and will forward this information, along with copies of the articles, to Holly Glass.

2. Holly Glass and H&K will determine the appropriate response (if any) on a case-by-case basis. Response may include the development of a letter-to-the-editor, pitching a "reactive" or follow-up interview to reporters in an effort to preempt any negative stories being written about Bard and its filter product and/or to help position Bard as a leader in this category.

3. If the scenario requires the development of a letter-to-the-editor, H&K will tailor the attached template, as required, and will forward the draft to all CRT members for review and approval.
   a. H&K will contact all CRT members to set up a time for a conference call.
   b. During the conference call, the CRT will review, edit and approve the letter.
   c. If the letter will be signed by a physician, H&K and Holly Glass will work to secure the physician spokesperson's approval and forward an edited version to the CRT for final review.
   d. H&K will forward the letter to the appropriate editorial contacts and monitor for coverage.

4. If the scenario requires an interview, H&K will provide Holly Glass with quick "refresher" course on media coaching tips and techniques.
   a. Holly Glass, H&K and the Audience Outreach Team will determine the appropriate messages and communications vehicle to inform Bard's key constituents prior to the airing of the program.
   b. Holly Glass will conduct the media interview with H&K facilitating as appropriate. Summarized studies will be provided to the reporter.
   c. H&K will follow up with the reporter as necessary. H&K may arrange a follow-up interview with the physician spokesperson and/or a patient, as determined if necessary.
   d. H&K will put together a document detailing potential impact of the pending article (e.g., tone of interview, reach of wire service if interview was conducted by wire reporter, etc.) and recommended next steps.
   e. H&K will monitor for resulting and additional coverage.
Scenario #4 – News Bureau - A major news story breaks about the lawsuit and the “snow ball” effect kicks in, generating much negative media coverage on Bard and the Recovery Vena Cava Filter.

If this scenario occurs, H&K will immediately implement its Bard News Bureau to respond to all incoming media inquiries efficiently and effectively.

Media Contact Lists
H&K has identified the most likely reporters to write stories on lawsuits, based on past research for the mesh hernia repair product crisis plan. We have also identified the following:
- Legal and healthcare beat reporters at the wire services, top 25 daily newspapers and top financial news outlets
- Editors at health and medical device trade publications
- Editorial board contacts at the top 25 dailies, should Bard want to proactively secure background meetings with these influential reporters
- News directors at the major networks broadcast affiliates (NBC, ABC, CBS, and Fox) in Bard’s key markets relating to the investigation (presently, Miami, FL and Grand Rapids, MI)

Following this document are the identified media outlets.

Toll-Free Line for Reporters
When and if necessary, Bard may consider activating a toll-free number, manned by appointed, trained persons to take messages of all incoming media inquiries. H&K can implement this phone line within hours.

Call Reports
As media inquiries come in, H&K will format all information regarding incoming media calls into call reports and submit these reports to Holly Glass. These reports will include the date and time of the initial inquiry, the name of the reporter, his/her publication, beat, purpose of call, questions he/she may have and dates and times of interview request. H&K will also gather as much information about each reporter as is available.

Prepared Statements
Depending on the amount of media inquiries and the rate at which they come in, it may be necessary to distribute a previously prepared statement. A sample statement has been created and approved by legal counsel. This statement reflects Bard’s inability to comment on pending litigation and reinforces the need for approved key messages. It can be easily modified to address specific inquiries from media or new developments in pending cases.

HILL & KNOWLTON 600 New Hampshire Avenue, NW Suite 601 Washington, DC 20037
T 202 333-7400 F 202 333-1828
If it is necessary, Bard may issue the prepared statement on PR Newswire. H&K has an existing account with PR Newswire already established.

The statement may be updated as Bard develops its position or as new information is gathered and actions are taken.

**News Monitoring**
H&K will continue to conduct daily monitoring for any stories related to litigation. For wire and print stories, H&K uses the Factiva Database, for online stories, H&K searches Google and Google News, and for broadcast stories, H&K works with VMS. VMS is monitoring nationally, but placing extra emphasis on markets where incidents are under investigation. H&K will prepare a report assessing the news coverage on a daily basis during the crisis situation, or as necessary.

**News Evaluation**
After the media coverage is generated and interest has dwindled, H&K will critique the coverage and provide an overall analysis of the scenario and make specific recommendations.

**News Conference**
In most situations, news conferences are neither necessary nor desirable. However, Bard should be prepared to move forward quickly with a news conference if deemed necessary. Holding a news conference should be considered when:

- Written or electronic dissemination of a statement will not satisfy the media covering the situation.
- The situation is extremely serious and media requests have reached a level or volume when they no longer can be handled through individual telephone calls.
- Company actions can be best explained through a news conference that reaches all media at the same time with information, personal statements and visual documentation.

The major disadvantage to holding a news conference is that the forum allows for rigorous and potentially damaging questioning. News conferences can require intense preparation for the spokesperson and the CRT, including further message development, question anticipation and spokesperson training.
H&K will coordinate all logistics, including announcement, location, time, audio/visual equipment.

1. **Announcement:** H&K will draft the news conference announcement and distribute it across PR Newswire. The announcement will mention the issue, and list the spokesperson, time, location, and contact for further information. Pending on the scope of the situation, this information may also be posted on Bard’s Web site. Following the distribution of the announcement, H&K will follow up with telephone calls to obtain a preliminary headcount and identify key reporters.

2. **Location:** The location will be convenient for reporters and Bard executives. There will be a separate entrance and exit for the spokesperson, so he/she is not forced to wind through rows of reporters to get to the podium or to exit the facility.

3. **Audio Visual Equipment:** H&K will coordinate the rental or usage of all a/v equipment, including a podium, microphones, video camera, etc. Bard should tape the conference for its own records.

4. **Materials:** Bard press kits will be made available to all attendees, containing all collateral materials including fact sheets, recent press releases and executive biographies.

5. **Agenda:** H&K will develop a specific agenda for the news conference. The spokesperson will note the agenda and the specified timeline of the event.

6. **Outside speakers:** As the situation is evaluated, H&K may advise having a physician or third-party organization (industry) spokesperson available to answer specific medical-related questions.
Scenario #5 – News Bureau – Another negative migration case causes Bard to remove the Recovery Filter from the market.

1. Janet Hudnall contacts Holly Glass, who notifies H&K.
2. H&K immediately begins to monitor for news, coordinate a CRT conference call and prepare for roll out of News Bureau activities.
3. During the call, Donna Passero talks the CRT through the product recall process. The CRT determines the appropriate strategy, messaging and next steps.
4. Following the call, H&K provides the action items resulting from the call and an outline of CRT members' roles and responsibilities.
5. In conjunction with Holly Glass, H&K will draft all tactical plans and response materials, including initial statement customized according to audience (e.g., media, Wall Street, Bard employees, sales force, customers and physicians).
6. H&K coordinates follow-up call with both CRT and Audience Outreach Team to review materials and secure approval.
7. Audience Outreach Team notifies its appropriate target audiences.
8. H&K and Holly Glass activate the News Bureau, as outlined above in Scenario #3.

Scenario #6 – A competitor tips off media.
Any of the above scenarios may play out.
Appendix

A. Key Messages – Recovery Vena Cava Filter: General Messages

1. The Recovery Vena Cava Filter, a Bard Peripheral Vascular product, is a well-designed and tested inferior vena cava (IVC) filter that, when properly placed and intact, helps to reduce or prevent the risk of blood clots traveling to the lungs or heart.
   - The Recovery Vena Cava Filter is indicated for use as both a permanent and retrievable device to reduce and prevent any blood clots from the legs that may break off and travel, or “migrate”, through the bloodstream to the lungs or heart.

2. The Recovery Vena Cava Filter is proven in its safety and efficacy.
   - A properly placed filter can resist the force of a fair amount of blood clot; however, large clots and the forces of exertions, such as bowel movements, can overwhelm any filter’s retentive capability, resulting in possible migration. This is true for all IVC filters.
   - Estimates based on available data suggest that these types of events are not occurring with excess frequency when compared with other vena cava filters.

3. The retrievability of the device is valuable and appealing from a clinical perspective to medical professionals and patients.
   - retrievable filters are designed to be removed once the risk of pulmonary embolism has subsided.
   - The actual filter mechanism works exactly the same in retrievable and non-retrievable filters. Non-retrievable filters cannot be easily removed without injury to the patient.
4. At Bard, our number one priority is our commitment to our patients.
   - With any report of an adverse event, we take an immediate, systematic approach and form a multi-disciplinary team to thoroughly investigate the incident.
   - Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take our responsibility to patients very seriously.
   - Bard has been in business for nearly a century, and we are known for our commitment to providing innovative, life-enhancing medical technologies.
B. Key Messages:

Specific to Miami Incident:

1. We have been notified of the death of a patient whose medical treatment in Miami included the insertion of Bard's Recovery Vena Cava Filter. First and foremost, we extend our deepest sympathies to the patient's family. At Bard, our number one priority is our commitment to our patients.
   - Bard has been in business for nearly a century, and we are known for our commitment to providing innovative, life-enhancing medical technologies.

2. With any report of an adverse event, we take an immediate, systematic approach and thoroughly investigate the incident.
   - Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility to patients.

3. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event. We do know that:
   - The filter was placed in a normal sized vena cava and there were no immediate complications following surgery.
   - The filter was found to be intact, deposited in the patient's right atrium post-mortem, and a large blood clot surrounding the filter was approximately 30 cm long x 3 cm in diameter.
   - If asked about the relative health of the patient, please respond, "The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can be the cause of blood clots."

If asked about the Grand Rapids, MI incident in the course of these messages, use the following statement: We have been notified of an incident that recently occurred in Grand Rapids, MI, involving the death of a patient whose medical treatment included the insertion of Bard's Recovery Vena Cava Filter. We have very few details that can be discussed at this point. We placed the Recovery filter on sales hold while conducting initial evaluations of the circumstances surrounding the incident. The product has since been released from hold.
Specific to the Grand Rapids, MI Incident:

1. We have been notified of the death of a patient whose medical treatment in Grand Rapids, MI included the insertion of Bard’s Recovery Vena Cava Filter. First and foremost, we extend our deepest sympathies to the patient’s family. At Bard, our number one priority is our commitment to our patients.
   o Bard has been in business for nearly a century, and we are known for our commitment to provide innovative, life-enhancing medical technologies.

2. With any report of an adverse event, we take an immediate, systematic approach and thoroughly investigate the incident.
   o Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility to patients.

3. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event. We do know that:
   o The filter was placed in a normal sized vena cava and there were no immediate complications following surgery.
   o The Recovery filter was on sales hold while we conducted initial evaluations of the circumstances surrounding this incident. The product has since been released from hold.

If asked about the Miami incident in the course of these messages, use the following statement: We have been notified of the death of a patient whose medical treatment in Miami included the insertion of Bard’s Recovery Vena Cava Filter. A multi-disciplinary team is thoroughly investigating the incident. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event. We do know that:
   o The filter was placed in a normal sized vena cava and there were no immediate complications following surgery.
   o The filter was found to be intact, deposited in the patient’s right atrium post-mortem, and a large blood clot surrounding the filter was approximately 10 cm long X 3 cm in diameter.
   o [If asked about the relative health of the patient, please respond, “The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can be the cause of blood clots.”]
If Asked About Both Incidents:

1. We have been notified of two recent, unrelated incidences. One occurred in Miami, the other in Grand Rapids, MI. We have very few details that can be discussed at this point about the Grand Rapids incident. The Miami incident involved the death of a patient whose medical treatment included the insertion of Bard’s Recovery Vena Cava Filter. First and foremost, we extend our deepest sympathies to the patient’s family. At Bard, our number one priority is our commitment to patients.
   - Bard has been in business for nearly a century, and we are known for our commitment to providing innovative, life-enhancing medical technologies.

2. With any report of an adverse event, we take an immediate, systematic approach and thoroughly investigate the incident.
   - Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility to patients.

3. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event. We do know that:
   - The filter was placed in a normal-sized vena cava and there were no immediate complications following surgery.
   - The filter was found to be intact, deposited in the patient’s right atrium post-mortem, and a large blood clot surrounding the filter was approximately 10 cm long X 3 cm in diameter.
   - [If asked about the relative health of the patient, please respond, “The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can be the cause of blood clots.”]

If asked specifically for more information about the Grand Rapids, MI incident, use the following statement: We have been notified of an incident that recently occurred in Grand Rapids, MI, involving the death of a patient whose medical treatment included the insertion of Bard’s Recovery Vena Cava Filter. We have very few details that can be discussed at this point. We placed the product on hold while we conducted initial evaluations of the circumstances surrounding this incident. The product has since been released from hold.
C. Draft General Letter-To-The-Editor

MONTH XX, 2004

Dear Editor,

As a physician who has implanted more than [NUMBER] Recovery Filters, I can certainly attest to the quality of Bard Peripheral Vascular's vena cava filter product. In actual practice and in reported studies, this life-saving clot-trapping device has been proven to be safe and effective when a patient's condition indicates a vena caval filter: thrombo-embolic disease (TED) with contraindication for anticoagulation, failure of anticoagulation, massive pulmonary embolism, or chronic, recurrent pulmonary embolism.

The Recovery Vena Cava Filter plays an important role in helping to reduce or prevent blood clots from traveling to the lungs or heart. These blood clots, unimpeded, can cause pulmonary embolism that can sometimes be fatal.

As a physician and a trainer of other physicians who implant and retrieve Recovery Filters, I come in contact with many patients and physicians who have experienced the life-protecting benefits of Bard's vena cava filter product. I can only speak for myself when I say that the retrievable nature of the Recovery Filter is valuable and an added benefit. In my experience, I have been able to safely remove the device once the risk of pulmonary embolism has been reduced.

Sincerely,

Physician's Name
Medical Facility
City
D. Draft Miami Letter-To-The-Editor

MONTH XX, 2004

Dear Editor,

(Insert name)'s article, "Insert Title" did not shed light on the proven safety and efficacy of the Recovery Vena Cava Filter. As a physician who implants more than [NUMBER] Recovery Filters a week, I can certainly attest to the quality of Bard Peripheral Vascular's vena cava filter product.

The Recovery Vena Cava Filter plays an important role in helping to reduce or prevent blood clots from traveling to the lungs or heart. These blood clots, unimpeded, can cause pulmonary embolism that can sometimes be fatal.

I can only speak for myself when I say that the retrievable nature of the Recovery Filter is valuable and an added benefit. It allows the physician to safely remove the device once the risk of pulmonary embolism has been reduced.

As a physician, and a trainer of other physicians who implant and retrieve Recovery Filters, I come in contact with many patients and physicians who have experienced the life-protecting benefits of Bard's vena cava filter product. Based on an understanding of all details surrounding the incident reported in the aforementioned article, I have to question the validity of the claims mentioned in this newspaper. These claims fly in the face of published and practice evidence supporting the safety and efficacy of Bard's innovative and effective vena cava filter product.

Sincerely,

Physician's Name
Medical Facility
City
**E. Draft Grand Rapids Letter-To-The-Editor**

MONTH XX, 2004

Dear Editor,

(Insert name)'s article, "Insert Title" did not shed light on the proven safety and efficacy of the Recovery Vena Cava Filter. As a physician who implants more than [NUMBER] Recovery Filters a week, I can certainly attest to the quality of Bard Peripheral Vascular's vena cava filter product.

The Recovery Vena Cava Filter plays an important role in helping to reduce or prevent blood clots from traveling to the lungs or heart. These blood clots, unimpeded, can cause pulmonary embolism that can sometimes be fatal.

I can only speak for myself when I say that the retrievable nature of the Recovery Filter is valuable and an added benefit. It allows the physician to safely remove the device once the risk of embolism has been reduced.

As a physician, and a trainer of other physicians who implant and retrieve Recovery Filters, I come in contact with many patients and physicians who have experienced the life-protecting benefits of Bard's vena cava filter product. Based on an understanding of all details surrounding the incident reported in the aforementioned article, I have to question the validity of the claims mentioned in this newspaper. These claims fly in the face of published and practice evidence supporting the safety and efficacy of Bard's innovative and effective vena cava filter product.

Sincerely,

Physician's Name
Medical Facility
City
F. Media Lists
H&K has identified medical/health and legal/litigation reporters and editorial board contacts at the following outlets:

Wires
- Associated Press
- Bloomberg
- Copley
- Cox
- Dow Jones
- Gannett
- Knight Ridder
- McClatchy
- Newhouse
- Reuters
- Scripps Howard
- Times
- Tribune
- UPI
- Universal Press Syndicate

Top Dailies
- The Wall Street Journal
- USA Today
- The New York Times
- Los Angeles Times
- The Washington Post
- Daily News (New York)
- Chicago Tribune
- Newsday
- New York Post
- Houston Chronicle
- Chicago Sun-Times
- Chicago Tribune
- San Francisco Chronicle
- The Boston Globe
- The Boston Herald
- The Dallas Morning News
- Miami Herald
- The Arizona Republic
- The Atlanta Constitution
- The Philadelphia Inquirer
- The Star-Ledger (Newark)
- Star-Tribune (Minneapolis)
- Detroit Free Press
- The Plain Dealer
- Rocky Mountain News
- Denver Post
- Austin Statesman
- Austin Business Journal
  [PLACEHOLDER FOR MAJOR PRINT OUTLETS IN AND NEAR GRAND RAPIDS, MI]

Medical/Health and Legal/Litigation Reporters at Top Financial Outlets
- Bloomberg (print and broadcast)
- BusinessWeek and Businessweek.com
- CNBC
- CNNfn
- Dow Jones
- Financial Times
- Forbes
- Fortune
- Investor's Business Daily
- SmartMoney
- The Street.Com

Editors at Relevant Medical, Health and Medical Device Publications
- The BBI Newsletter
- Biomedical Instrumentation & Technology
- Biomedical Safety & Standards
- BNA's Health Law Reporter
- Clinica World Device and Diagnostic News
- Diagnostic Insight
- The Gray Sheet
- Health News Daily
- In Vivo
- The Healthcare News
- Medical Device and Diagnostics Industry
- Medical Device Daily
- Medical Devices and Surgical Technology Week
- Medical Product Manufacturing News
- Medical Device Litigation Reporter
News directors at the major networks broadcast affiliates in Bard’s key markets

**New York/New Jersey**
- WABC-TV (ABC)
- WCBS-TV (CBS)
- WNBC-TV (NBC)
- WNYW-TV (FOX)

**Miami**
- WPLG-TV (ABC)
- WFOR-TV (CBS)
- WTVJ-TV (NBC)
- WSVN-TV (FOX)

**Phoenix/Tempe**
- KNXV-TV (ABC)
- KFOX-TV (CBS)
- KPNX-TV (NBC)
- KSAZ-TV (FOX)

[PLACEHOLDER FOR MAJOR BROADCAST OUTLETS IN AND NEAR GRAND RAPIDS, MI]
G. Recent Sample Article: Bariatric Surgery in General

04/11/2004 04:19:17
As Obesity Surgeries Soar, So Do Safety, Cost Concerns
Rob Stein, Washington Post Staff Writer

Source: The Washington Post
Date: April 11, 2004
Section: A Section
Page: A01

The number of overweight Americans resorting to stomach-shrinking surgery is rising so rapidly that health experts and insurance companies are increasingly becoming alarmed about the safety, effectiveness and mounting costs of the operations.

While the operations can produce dramatic benefits for very obese people, some hospitals and surgeons may be rushing too quickly to satisfy the surging demand, offering the lucrative procedures without adequate training, experience and support, experts say.

At the same time, the operations, which force people to eat less by reducing the size of their stomachs, are being performed too commonly on people who might be able to lose weight through diet and exercise, particularly younger adults and teenagers, they say.

Alarm has intensified because of scattered reports of severe complications and deaths around the country. In Massachusetts, for example, a special panel has begun assessing the procedure for state health authorities after several patients died following surgeries.

Citing uncertainty about the safety of the procedures and lingering questions about their long-term effectiveness, a growing number of insurance companies have begun balking at paying for the operations, which cost the nation close to $3 billion a year.

To try to resolve some of these issues, the National Institutes of Health has launched a five-year, $15 million research project to gather data about the operations, identify patients most likely to benefit and learn more about how they work.

In the meantime, the American Society for Bariatric Surgery, which represents surgeons who perform the procedures, has established an independent nonprofit corporation that in June will begin identifying "centers of excellence" deemed most qualified to do the complicated operations. The group is also gathering scientists at Georgetown University next month in the hopes of reaching a consensus on the risks and benefits of the treatment.
The rising concerns about stomach surgery illustrate the uncertainties that can occur with the emergence and proliferation of new surgical procedures, which often do not undergo the same level of testing, scrutiny and government oversight as new drugs or medical devices.

In addition, the debate over whether insurers should pay for the surgery illustrates the tension that is mounting as the obesity epidemic adds billions of dollars to the nation’s medical bill. Millions of Americans already meet the criteria for the operation, which costs about $25,000, and millions more are expected to join those ranks as obesity rates soar.

"Insurance companies are feeling the first pressure of the increasing costs of the rising obesity epidemic from this procedure," said Roland Sturm, who studies the economic impact of obesity for the Rand Corp., a private research organization. "If we look into the future, the rising obesity epidemic will continue to have tremendous effects on health care costs. It's an astonishingly big factor. And it's only going to get bigger."

As the number of obese Americans has soared and new, less invasive laparoscopic versions of stomach surgery have been introduced, the number of people undergoing the operations has skyrocketed, spurred by the lack of effective alternatives and by celebrity patients such as NBC's "Today" show weatherman Al Roker. The number of surgeries shot up from about 16,000 a year in the early 1990s to an estimated 103,000 in 2003 — and is expected to approach 150,000 this year, making it one of the fastest-growing procedures. Many centers report long waiting lists.

Surgeons perform several variations, but all involve sharply restricting the size of the stomach, either by stapling most of it closed or sealing it off with elastic bands and bypassing portions of the digestive system to reduce the number of calories that can be absorbed. The procedures can enable severely obese people to lose hundreds of pounds, alleviating disabilities and preventing, even sometimes reversing, serious health problems, most notably diabetes and high blood pressure.

But the operations are complicated, and patients are prone to life-threatening complications, including bleeding, blood clots, leakages and infections. Even if they have no serious complications, patients often experience unpleasant side effects, including a phenomenon known as "dumping" — nausea, vomiting and diarrhea — when they overeat. As a result, patients have to undergo intensive counseling and monitoring to make sure they eat appropriately and do not suffer nutritional deficiencies.

"It's extremely difficult surgery," said Paul Emsberger, an associate professor of nutrition at Case Western Reserve University. "Even when it's done perfectly, there can be a lot of problems."
According to federal guidelines issued in 1991, the procedure is supposed to be performed only on people who are at least 100 pounds overweight — and primarily on those who are also suffering severe health problems because of their weight. While most people getting the procedure probably meet those criteria, there is concern that increasing numbers of people who weigh less are also undergoing the procedure.

"Many people who are not morbidly obese are trying to get this procedure. It's rapidly viewed as the answer to obesity, and more and more say, 'I can get surgery done as an answer to my problem,'" said Barry Schwartz of Blue Cross and Blue Shield of Florida. "We've actually seen a couple of patients who decided with their doctor that they would eat more so they could qualify. It's perverse."

Schwartz and other critics say the surge in popularity is enticing some hospitals and surgeons to try to capitalize on the interest.

"Many hospitals and physicians see this as a cash cow," Schwartz said. "We've seen surgeons who did a weekend course and then started doing this high-risk surgery. Make no mistake about this: This is high-risk surgery. The quality of service is going down, and the risk to patients is going up."

Some researchers also question the reliability of the data on the safety and effectiveness of the procedures.

"We don't have quality longer-term studies that give us good data on long-term safety and effectiveness," said Frank Lefevre, an associate professor of medicine at Northwestern University who evaluated the procedures for the Blue Cross and Blue Shield Association.

Already alarmed by skyrocketing health costs overall, a number of insurers, including Blue Cross and Blue Shield of Florida and Nebraska and Humana Inc., are discontinuing coverage for the operations.

"We've had an explosion in obesity and an explosion in the demand for quick fixes, if you will, to the problem of obesity," said Helen Darling, president of the National Business Group of Health, which represents major corporations on health issues. "It's beginning to dawn on insurance companies and employers that even after the surgery, there are a lot of big expenses and a lifetime of care. Many employers and insurance companies feel this is just not affordable today."

Some experts liken the situation to what happened with bone marrow transplants for breast cancer in the 1990s, when terminally ill breast cancer patients clamored for the procedure until carefully designed studies finally showed it did not save lives.
"Whenever a new technique seems to be providing benefit, it tends to proliferate," said Jonathan Moreno, a University of Virginia bioethicist who studies surgical procedures. "Oftentimes, these things gradually become the standard of care without going through any studies."

Proponents of the surgery say the procedures have undergone extensive study and have been clearly shown to help patients, enabling many to shed one-third to one-half of their excess body weight or more and keep it off for many years.

"I think these insurance companies may be using this as an excuse to avoid their responsibility. They think they can get away with this because of the prejudice that's out there for people who are obese," said Harvey Sugerman, president of the American Society for Bariatric Surgery. "I think it's a travesty."

For patients who have been suffering for years and been unable to lose weight despite repeated diets and exercise regimens, the operations are life-altering, he said. "It's an amazing operation. It's hard to describe how helpful it is to these patients. You have a patient who comes in who can hardly breathe, their legs are all swollen up, they have diabetes and high blood pressure, and they come back to you in three months, and they're all gone. They feel wonderful."

While the procedures can be dangerous, Sugerman and others said that for appropriate patients, the benefits clearly offset the risks, which are on a par with the dangers of operations for other life-threatening conditions involving seriously ill patients.

"It's actually surprising how good the results are," said David R. Flum, a University of Washington surgeon. "If you look at all the options available for the treatment of obesity, we know one thing for sure: Nonsurgical approaches, even the most radical approaches, even the most aggressive nonsurgical approaches, are horribly ineffective."

But Flum and some other experts acknowledge the complication rates are unclear. Most published studies have involved highly experienced surgeons operating on ideal candidates. Some research indicates the complication and mortality risks may be much higher than reported, especially as less experienced surgeons begin performing the procedures on a wider spectrum of patients.

"We really don't know what's happening in the real world, and there's a lot of reason to be really worried about that," said Flum, who is helping evaluate the procedures for the NIH consortium. "In the real world, surgeons may do many fewer patients per year. They are learning the procedure. Or picking patients who may not do as well. A lot of things have got us worried."

http://www.washingtonpost.com
"MCVI" is the more commonly known name for the group of physicians in Miami of which Dr. Powell, the filter implanting physician, is a part.

No. The number is not 6 now. This is the data that is in the product's package insert (IFU). These facts still hold for the Canadian cohort.

I'm not sure which papers are being referenced here (the first and second papers, specifically). I think this entire 1st sub-bullet is problematic. We don't know how many filters have been implanted; we only know how many we've sold. Also, "success" really depends on how you look at it. Does lack of complaints equal success?

An IVC filter does not prevent blood clots; it just keeps it from traveling to the lungs.

Do we want to add that this was at post-mortem?

Probably need to add additional comments about the initial conclusions of this incident.

Include that this was at post-mortem?

Include that this was at post-mortem?

Probably need to add additional comments about the initial conclusions of this incident.

Although blood clots can originate in the arms, Recovery is not indicated for SVC use, therefore it does nothing to prevent PE from upper-extremity DVT (when used as labeled)

Must stay away from calling all physicians "surgeons". The specialty with the largest proportion of IVC filter use is Interventional Radiologists. Filters are also used by cardiologists.

Although blood clots can originate in the arms, Recovery is not indicated for SVC use, therefore it does nothing to prevent PE from upper-extremity DVT (when used as labeled)

Must stay away from calling all physicians "surgeons". The specialty with the largest proportion of IVC filter use is Interventional Radiologists. Filters are also used by cardiologists.

Although blood clots can originate in the arms, Recovery is not indicated for SVC use, therefore it does nothing to prevent PE from upper-extremity DVT (when used as labeled)
Internal Q&A: CR Bard Recovery Vena Cava Filter  
Version May 10, 2004

Note: Internal Q&A to be used by approved Corporate spokespeople to respond consistently to inquiries from media. Not to be handed out externally to any audiences.

1. What is the Recovery Vena Cava Filter and how does it work?

Introduced in April 2003, the Recovery® Nitinol Vena Cava Filter is a blood clot trapping device designed to prevent pulmonary embolism by mechanical filtration. The filter is implanted percutaneously in the Inferior vena cava (IVC). The Recovery Filter has the additional feature of being able to be percutaneously removed after implantation. The Recovery Filter may be used as a permanent or temporary device.

The Recovery Filter System consists of the Filter and Delivery System. The Filter consists of twelve nitinol wires emanating from a central sleeve. These twelve wires form two levels of filtration. The device is intended to be used in vena cava with diameters of up to 28 mm and is currently available for femoral vein approach only.

2. What is the difference between a retrievable vena cava filter and a non-retrievable vena cava filter?

A non-retrievable vena cava filter is indicated for permanent use; once inserted into the vena cava, the device is left in place. On the other hand, after implantation, a retrievable vena cava filter may be removed at the physician’s discretion, usually once the risk of a venous thromboembolism or pulmonary embolism is reduced.

The Recovery Filter is designed to act as a permanent filter. When clinically indicated, the Recovery Filter may be percutaneously removed. The Recovery Filter’s hooks allow the filter to remain rigid and provide anchoring, but deform when the filter apex is engaged with the specially designed removal device (Recovery Cone® Removal System) and pulled upward.
3. What is the market share of the Recovery Filter for the overall vena cava filter market?

6% (in units).

4. What is the market share of the Recovery Filter for the retrievable vena cava filter market?

We have sold over 8,500 units of the Recovery Filter to date. We understand that the overall total market for all retrievable and non-retrievable vena cava filters is approximately 130,000 units.

While the retrievable segment of the vena cava filter market is rapidly growing, for the past 12-month period, the market is estimated to have been approximately 30,000 units. Of that, Recovery had a 25% share.

5. How many Recovery Vena Cava Filters have been inserted in the US and, separately, around the world?

[NA] We have sold over 8,500 units of the Recovery Filter to date.

6. Do you have any studies that prove the safety and efficacy of the Recovery Vena Cava Filter?

Yes. We have studies that prove the safety and efficacy of the Recovery Vena Cava Filter. For example, the Recovery Filter was safely and effectively used by an investigator and two colleagues at six Toronto area hospitals. In this Toronto study, of the 58 filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 patients have died with filters in place of causes unrelated to filter placement or retrieval.

In addition, the Recovery Filter underwent testing (bench top or animal studies or a combination of both) according to FDA guidelines to obtain FDA concurrence.

We are happy to provide a full listing of study summaries to you.
7. What are pulmonary emboli and what are the risks associated with them?

Pulmonary emboli are blood clots that form in large veins, such as those in the thigh, and then travel to the lungs. In the lungs, they block blood flow, which can cause shortness of breath, chest pain, faintness, low blood pressure, lung damage, and in severe cases, sudden death. Such clots are particularly likely to form in a variety of unusual circumstances, including prolonged immobility, after hip surgery, after major traumatic surgery and in obese individuals after weight reduction ("bariatric") surgery.

8. Under what circumstances would the Recovery Vena Cava Filter be used?

The Recovery Filter is indicated for use in the prevention of recurrent pulmonary embolism through permanent or temporary placement in the vena cava in the following situations:

a. Pulmonary thromboembolism when anticoagulants are contraindicated.

b. Failure of anticoagulant therapy for thromboembolic disease.

c. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.

d. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The device is intended to be used in vena cava with diameters of up to 28 mm, and when clinically indicated, the Recovery Filter may be percutaneously removed at the physician’s discretion.

9. How is the Recovery Vena Cava Filter inserted?

The Recovery Vena Cava Filter is inserted into a femoral venous access route during a procedure performed by a medical professional. The "Instructions for Use" provide more information about the insertion and removal procedures.

10. Who designed the Recovery Filter?

Bard purchased the product design and manufacturing from a valued partner. Bard has thoroughly assessed and tested the product and stands behind its design in every way.
11. What is the name of the company that designed the Recovery Filter?

That information can be found in public records.

12. Have there been any design changes in the Recover Filter over the years?

There have been changes in the delivery system but not the filter itself.

13. What level of expertise is required to properly insert the Recovery Vena Cava Filter?

Physicians who have undergone training for minimally invasive, endovascular procedures can place the Recovery Vena Cava Filter. These physician specialties include, but are not limited to, interventional radiologists, vascular surgeons, trauma surgeons, cardiology, and general surgeons as well as residents and fellows of those disciplines.

Placement of the Recovery Filter, in general, is quick (10 minutes) if there is easy access to the femoral vein. The procedure has been described by physicians as easy to perform.

14. How are doctors trained on the proper use of the Recovery Vena Cava filter? How extensive is this training?

There is currently no formal training requirement imposed on users by Bard for filter insertion.

Filter retrieval is under a limited market release process which requires the user to either 1) attend a one-day hands-on workshop or 2) have a qualified sales representative present for the initial three (3) cases.

15. What are the potential complications associated with the Recovery Vena Cava filter?

Potential complications observed for all types of inferior vena cava filters including the Recovery Filter include filter migration, perforation of the vena cava wall by filter legs, and vena caval occlusion or obstruction.
16. How often does the Recovery Filter actually migrate?

As of the end of April 2004, out of 8,500 devices sold in the U.S., there have been six reported cases of migration.

There is risk of migration with any vena cava filter. There is no single definitive cause of filter migration. The buildup of a large clot or series of clots, the movement of the walls of the vena cava due to respiration and improper filter placement can cause migration. There are also other factors that could potentially cause a filter to migrate, and many questions still remain as to exactly why filters migrate. In addition, filters may appear to have migrated due to x-ray equipment variation, patient position, measurement error, and respiration.

17. How does your rate of migration for the Recovery Filter compare to that of your retrievable and nontretrievable device competitors?

Estimates based on available data suggest that these types of events are not occurring with excess frequency when compared with other vena cava filters.

18. Are retrievable filters more susceptible to migration than non-retrievable filters?

Estimates based on available data suggest that these types of events are not occurring with excess frequency when compared with other vena cava filters.

19. What causes filter migration?

Filter migration occurs whenever the force trying to move the filter exceeds the holding power of its fixation arms. A properly placed vena cava filter can constrain a significant amount of blood clot, but large blood clots can overwhelm the filter's retentive capabilities. Other recognized causes of filter migration include improper implantation technique, unusual patient exertion (such as straining at bowel movements) and fracture or failure of the filter wires. All marketed filters in the US have reported instances of filter migration. [NAA3]

It also is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.
20. What is the "acceptable" rate of migration for vena cava filters?

Realistically, migrations do occur. All marketed filters in the US have reported instances of filter migration. Experts continue to debate what constitutes an acceptable rate of migration, relative to the risk of not using the filter.

21. What are the dangers associated with filter migration?

Most filter migrations are harmless to the patient and include filter movement of a few centimeters. In unusual cases, a filter containing a large amount of clot may migrate through the bloodstream to the lungs or heart. These complications can require surgical removal of the filter and clot, and rarely cause death. Without the filter, this amount of clot would generally have passed directly to the lungs or heart, causing substantial harm on its own.

22. If a retrievable filter provides the added benefit of retrievability and creates no greater risk of migration or other complications, why would any physician choose to use a non-retrievable filter?

I cannot speak on behalf of physicians but understand that non-retrievable filters can be less expensive than retrievable filters. Presumably, if a physician believes there will be no reason to remove the filter, it might make sense to choose the less expensive non-retrievable option. However, there is no way to predict with 100% accuracy whether or not a patient is going to require the filter for the rest of his/her life. I understand though, that an increasing number of physicians choose retrievable over non-retrievable vena cava devices after gaining greater understanding of the safety, efficacy and added benefits of retrievable filters.

23. Migration of a Recovery Filter was recently listed as the cause of death for a patient in Miami. Can you tell us why this specific filter migrated?

As with any report of an adverse event, we took an immediate, systematic approach to determine the cause and events. With this particular event, we formed a multi-disciplinary team to thoroughly investigate the incident. From the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event.

We do know that there was a very large blood clot or an accumulation of blood clots, measuring 10 cm in length and 3 cm in diameter, which deposited around the filter over a period of several days. The large blood...
clot or accumulated clots may have enveloped the filter and traveled through the bloodstream to the patient's heart, causing sudden death. The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can be the cause of blood clots.

24. If filter migration was not the cause of death, why was it listed as the cause of death on the coroner's report?

I cannot speak for the coroner. What I can tell you at this point, however, is that from the information available to date, no conclusions can yet be drawn regarding the role of the Recovery filter in this event.

We do know that there was a very large blood clot or an accumulation of blood clots, measuring 10 cm in length and 3 cm in diameter, which deposited around the filter over a period of several days. The large blood clot or accumulated clots may have enveloped the filter and traveled through the bloodstream to the patient's heart, causing sudden death. The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can be the cause of blood clots.

25. Is it possible that the filter was not inserted properly?

I do not want to speculate on the role of filter placement in this incident. What I can say is that, while improper filter insertion or placement can cause migration, we believe a blood clot as large as the one that enveloped the filter in this incident can very likely cause death.

26. Is there any reason to believe that the Recovery Filter is to blame for this patient's death?

I do not want to speculate on the role of the Recovery Filter in this incident. What I can say is that we believe a blood clot as large as the one that enveloped the filter in this incident can very likely cause death.

27. Has Bard been sued by the family of the deceased?

Not to my knowledge.
28. Has the Recovery Filter been associated with other deaths in the past?

Yes. A patient in Lacrosse, Wisconsin died with a Recovery Filter in place. The cause of death cited was pulmonary embolism.

29. Has Bard been sued because of death or damage caused by migration in the past?

Not to my knowledge.

30. In the late 80's, weren't Bard's balloon angioplasty medical devices permanently pulled from the market because of safety issues?

The Recovery Vena Cava Filter products we are discussing today are considered safe and effective by the medical community and had nothing to do with the situation you mentioned. In the late 1980s, a C.R. Bard subsidiary named USCI manufactured balloon angioplasty catheters, which were taken off the market. The details of criminal and civil lawsuits associated with these catheters are well documented. USCI was sold and no individual involved in those incidents is currently with the company. Since then, the entire executive management team has been changed. Today, Bard maintains an excellent working relationship with the FDA.

31. What other Bard products have been pulled from the market and for what reasons?

Bard has been in business for nearly a century, and we are known for our commitment to provide innovative, life-enhancing medical technologies to our patients. Hold can occur for a variety of safety and non-safety related reasons. In cases in which safety was a concern, products were placed back on the market after further testing. The Recovery Vena Cava Filter products we are discussing today are considered extremely safe and effective by the medical community.

32. What Bard products have been put on hold in the past two years?

As a course of company policy, we do not discuss previous product recalls. When such a recall occurs, we quickly and proactively provide necessary information to impacted customers, physicians and patients. The Recovery Vena Cava Filter products we are discussing today are considered safe and effective by the medical community.
33. Have you pulled any products over the past five years that have not been put back on the market? If yes, why were they pulled?

As a course of company policy, we do not discuss previous product recalls. When such a recall occurs, we quickly and proactively provide necessary information to impacted customers, physicians and patients. The Recovery Vena Cava Filter products we are discussing today are considered safe and effective by the medical community.

34. How does Bard receive and respond to reports of adverse events associated with its Recovery vena cava filter?

With any report of an adverse event, we take an immediate, systematic approach to thoroughly investigate the incident. Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility of developing and delivering safe medical devices.

35. Are there any physicians I can talk with about the safety and efficacy of the Recovery Vena Cava Filter?

John A. Kieselman, MD
Anthony O. Verbiux, MD,
Gary S. Cohen, MD
Thomas B. Kinney, MD
Christoph A. Binkert, MD
William S. Filling, MD

36. Appropriate question must be developed and addressed regarding MAUDE database. Space holder question: Can you explain the data in the FDA's MAUDE database for the Recovery Filter as compared to other vena cava filters?
It is impossible to determine the number of filters that have actually been placed. The only data point that we can provide is the number that have been sold.

Again, this is difficult to determine. All we know is how many have been sold. Also, does lack of complaints mean that it was safely used?

It is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.

This is not necessarily true.
External Q&A: CR Bard Recovery Vena Cava Filter
Version May 10, 2004

[Note: External Q&A are intended to be used by Bard Core and Audience Response Team members to consistently respond to questions from external audiences, and can be handed out to media, customers, physicians, suppliers, investors and other Bard audiences.]

1. What is the Recovery Vena Cava Filter and how does it work?

Introduced in April 2003, the Recovery® Nitinol Vena Cava Filter is a blood clot trapping device designed to prevent pulmonary embolism by mechanical filtration. The filter is implanted percutaneously in the inferior vena cava (IVC). The Recovery Filter has the additional feature of being able to be percutaneously removed after implantation. The Recovery Filter may be used as a permanent or temporary device.

The Recovery Filter System consists of the Filter and Delivery System. The Filter consists of twelve nitinol wires emanating from a central sleeve. These twelve wires form two levels of filtration. The device is intended to be used in vena cavae with diameters of up to 28 mm and is currently available for femoral vein approach only.

2. What is the difference between a retrievable vena cava filter and a non-retrievable vena cava filter?

A non-retrievable vena cava filter is indicated for permanent use; once inserted into the vena cava, the device is left in place. On the other hand, after implantation, a retrievable vena cava filter may be removed at the physician's discretion, usually once the risk of a venous thromboembolism or pulmonary embolism is reduced.

The Recovery Filter is designed to act as a permanent filter. When clinically indicated, the Recovery Filter may be percutaneously removed. The Recovery Filter's hooks allow the filter to remain rigid and provide anchoring, but deform when the filter apex is engaged with the specially designed removal device (Recovery Cone® Removal System) and pulled upward.
3. How many Recovery Vena Cava Filters have been inserted in the US and, separately, around the world?

We have sold over 8,500 units of the Recovery Filter to date.

4. Under what circumstances would the Recovery Vena Cava Filter be used?

The Recovery Filter is indicated for use in the prevention of recurrent pulmonary embolism through permanent or temporary placement in the vena cava in the following situations:
   a. Pulmonary thromboembolism when anticoagulants are contraindicated.
   b. Failure of anticoagulant therapy for thromboembolic disease.
   c. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
   d. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The device is intended to be used in vena cava with diameters of up to 28 mm, and when clinically indicated, the Recovery Filter may be percutaneously removed at the physician's discretion.

5. Do you have any studies that prove the safety and efficacy of the Recovery Vena Cava Filter?

Yes. We have studies that prove the safety and efficacy of the Recovery Vena Cava Filter. For example, the Recovery Filter was safely and effectively used by an investigator and two colleagues at six Toronto area hospitals. In this Toronto study, of the 56 filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 patients have died with filters in place of causes unrelated to filter placement or retrieval.

In addition, the Recovery Filter underwent testing (bench top or animal studies or a combination of both) according to FDA guidelines to obtain FDA concurrence.

We are happy to provide a full listing of study summaries to you.
6. **What are pulmonary emboli?**

Pulmonary emboli are blood clots that form in large veins, such as those in the thigh, and then travel to the lungs. In the lungs, they block blood flow, which can cause shortness of breath, chest pain, faintness, low blood pressure, lung damage, and in severe cases, sudden death. Such clots are particularly likely to form in a variety of unusual circumstances, including prolonged immobility, after hip surgery, after major traumatic surgery and in obese individuals after weight reduction ("bariatric") surgery.

7. **How is the Recovery Vena Cava Filter inserted?**

The Recovery Vena Cava Filter is inserted into a femoral venous access route during a procedure performed by a medical professional. The “Instructions for Use” provide more information about the insertion and removal procedures.

8. **Have there been any design changes in the Recover Filter over the years?**

There have been changes in the delivery system but not the filter itself.

9. **How are medical professionals trained on the proper use of the Recovery Vena Cava filter?**

There is currently no formal training requirement imposed on users by Bard for filter insertion.

Filter retrieval is under a limited market release process which requires the user to either 1) attend a one-day hands-on workshop or 2) have a qualified sales representative present for the initial three (3) cases.

10. **Are there potential complications associated with vena cava filters?**

Potential complications observed for all types of inferior vena cava filters including the Recovery Filter include filter migration, perforation of the vena cava wall by filter legs, and vena caval occlusion or obstruction.
11. What is the “acceptable” rate of migration for vena cava filters?

Realistically, migrations do occur. All marketed filters in the US have reported instances of filter migration. Experts continue to debate what constitutes an acceptable rate of migration, relative to the risk of not using the filter.

12. What causes filter migration?

Filter migration occurs whenever the force trying to move the filter exceeds the holding power of its fixation arms. A properly placed vena cava filter can constrain a significant amount of blood clot, but large blood clots can overwhelm the filter's retentive capabilities. Other recognized causes of filter migration include improper implantation technique, unusual patient exertion (such as straining at bowel movements) and fracture or failure of the filter wires. All marketed filters in the US have reported instances of filter migration. [NA2]

Also is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.

How does your rate of migration for the Recovery Filter compare to that of our retrievable and nonretrievable device competitors?

Estimates based on available data suggest that these types of events are occurring with excess frequency when compared with other vena cava filters.


No

15. Has Bard been sued because of death or damage caused by migration of a Recovery Vena Cava Filter in the past?

No
16. How does Bard receive and respond to reports of adverse events associated with its Recovery vena cava filter?

With any report of an adverse event, we take an immediate, systematic approach to thoroughly investigate the incident. Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility of developing and delivering safe medical devices.

17. Are there any physicians I can talk with about the safety and efficacy of the Recovery Vena Cava Filter?

John A. Kaufman, MD
Anthony C. Vennix, MD
Gary S. Cohen, MD
Thomas B. Kinney, MD
Christoph A. Binkert, MD
William S. Rilling, MD
Impossible to know how many have been placed. We have sold over 8500 as of the end of April.

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