

## Medical Devices // Overview of Capabilities

BBK's expertise in supporting medical device studies covers a wide variety of products, including medical imaging and diagnostic devices, surgical adhesive systems, and vascular access ports. Our capabilities in this therapeutic area not only help sponsors gain approval of their medical devices, but have paved the way for successful product launches.



### // Hemodialysis Vascular Access

BBK is adept at creating engaging recruitment materials for medical device studies – in this case a vascular access system – to generate the attention sponsors need to get their product noticed and their global clinical research study enrolled. With regulatory approval in hand, a well-conceived product launch is often the next step.



### // Heart Failure

Recruiting participants for studies of devices that monitor chronic heart failure is a BBK area of expertise. By providing sites with compelling patient materials and then supporting them with outreach and training, BBK is able to help sites maximize enrollment from patient panels and referring physicians in order to achieve recruitment goals.



**A Clinical Research Study**  
evaluating the efficacy and safety of fibrin sealant for dura defect sutures in posterior fossa surgery

### // Surgical Devices

BBK has helped speed to market a wide range of surgical devices, including this surgical adhesion barrier system used in brain surgery. Successful enrollment efforts in this area often hinge on facilitating and maximizing the relationship and communication between the study investigator and the potential study participant.



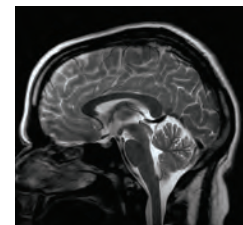
### // Menorrhagia

For certain medical device studies, empathetic messaging is one of the recruitment tactics BBK often employs. For a study of a device to reduce excessive menstrual bleeding, a compelling message empowered women to recognize the study as a viable alternative to hysterectomy. BBK later helped launch the product in the U.S. and the U.K.



### // Vertebral Compression Fracture (VCF)

Discerning the specific motivations for physicians to refer patients and for patients to participate in a particular study is one of the foundations of successful patient recruitment. Oftentimes, BBK is able to boost enrollment of a troubled protocol – such as this approved VCF repair device study – by leveraging these insights to create compelling recruitment programs.



### // Medical Imaging and Diagnostics

BBK has supported recruitment for research studies involving a wide range of medical imaging and diagnostic devices across a number of disparate therapeutic categories, including oncology, cardiology, and surgical intervention. A breakthrough referral-request campaign complemented by effective patient outreach is often the key to on-time enrollment.

## Pivotal Study // Hemodialysis



**Access to Innovation //** The medical community had never seen a device quite like it – an implantable vascular access port to facilitate hemodialysis. BBK created a recruitment campaign that educated physicians and patients about the breakthrough device’s efficacy – and its ability to significantly improve patient quality of life – to support on-time enrollment.

<b>OUR INVOLVEMENT</b>	Before First-Patient-In Date
<b>COUNTRIES</b>	Europe United States
<b>AUDIENCES</b>	Patients Medical Community
<b>KEYS TO ENROLLMENT</b>	Recruitment Toolkit Positioning and Messaging Public Relations

12 Total Sites

Most Critical to Engage

# 20

**Number That Counts //** BBK positioned the device manufacturer as committed to maximizing clinical training – and to building physician knowledge of and confidence in the safety and effectiveness of the new medical device. Result: the medical establishment’s recognition of the product as the first significant advancement in vascular access in 20 years.

**Objectives //** Enroll 200 patients within six months; set the stage for a European product launch

**Challenges //** Medical community’s long-held preference for traditional vascular catheters; unproven breakthrough product from a first-time manufacturer

**Results //** On-time study enrollment; medical community’s acknowledgement of the device’s efficacy; well-conceived product launch led to acquisition of the sponsor company

## Expert Analysis



BBK employed a variety of campaign tactics to overcome this study’s enrollment challenges. Patient recruitment tools were designed to educate physicians and patients alike about the novel product’s efficacy and its breakthrough technology. Public relations raised awareness of the study opportunity in key markets and with referring physicians. Just as important was the clinical training and support that was offered. BBK utilized key opinion leaders in nephrology to “train the trainers” to demonstrate the value of this unique product and the positive impact it would have on patients’ quality of life. Ultimately, BBK’s comprehensive campaign set the stage for a successful product launch, enabling the sponsor company to achieve its ultimate goal – acquisition.

## Pivotal Study // Menorrhagia



**Unexpected Solutions** // BBK's empathetic campaign empowered patients to recognize the device's use of heated saline as not only an alternative, but a desirable treatment option. This approach also helped the sponsor develop good relationships with physicians, and laid the groundwork for developing the product's brand.

<b>OUR INVOLVEMENT</b>	Before First-Patient-In Date
<b>COUNTRY</b>	United States } 21 Total Sites
<b>AUDIENCES</b>	Patients } Most Difficult to Engage
	Physicians
	Site Staff
	Referring Physicians
<b>KEY TO ENROLLMENT</b>	Patient Messaging

# 9

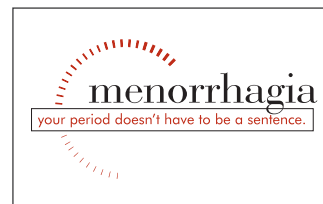
**Number That Counts** // Within nine short months, BBK was able to develop, receive approval from local IRBs, and implement a patient recruitment campaign composed of a site tool kit and TV advertising, reinforced by print and radio. This nine-month period also helped the sponsor establish relationships with investigators and their physician colleagues via enthusiastic word of mouth.

**Objective** // Enroll 248 patients with menorrhagia in nine months

**Challenges** // Reach and motivate patients who were unaware they had a medical condition, had given up on treatment, or had misperceptions of the available treatments

**Results** // Study enrolled on time; BBK launched product in both the US and the UK; successful launch enabled sponsor company to achieve its ultimate goal – acquisition

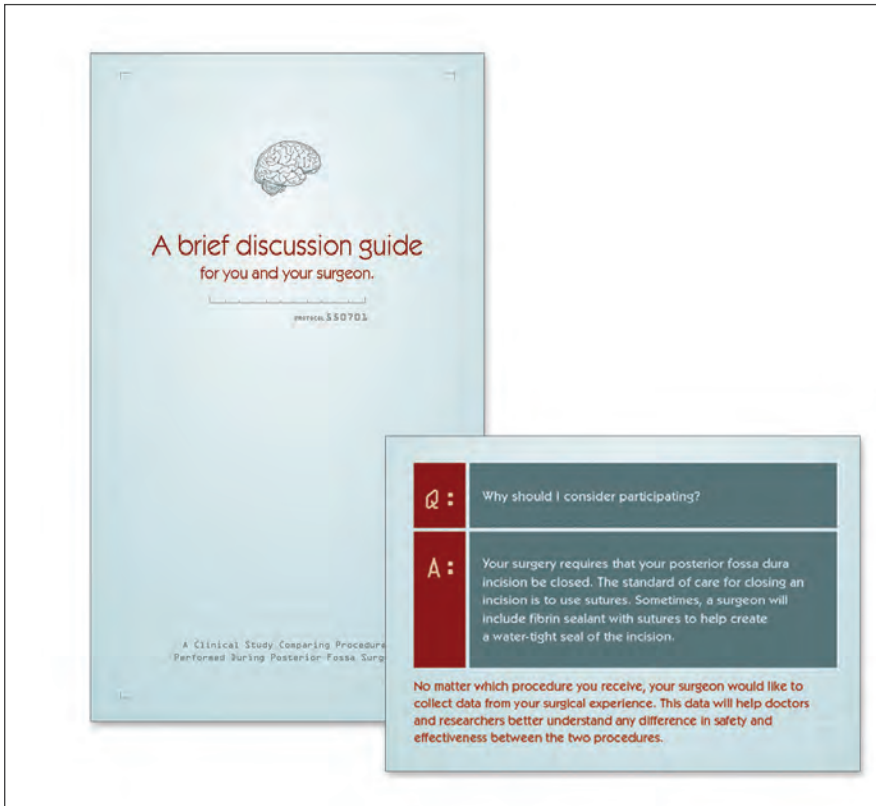
## Expert Analysis



This study was evaluating a medical device for reducing excessive menstrual bleeding. At the time, it was common for women with this condition to be told by their OB/GYN that the only available treatment was a hysterectomy. As a result, many chose

to suffer in silence, often remaining house-bound during their periods. BBK's tactful but no-nonsense campaign empowered patients to recognize the study as a viable alternative to hysterectomy. In addition to enrolling the study, the outreach campaign optimized awareness of both the condition and its treatment, and helped the sponsor build relationships with physicians. BBK later helped launch the product in the United States and the United Kingdom.

## Exploratory Phase II Study // Posterior Fossa Surgery



**Identifying and Motivating Investigators //** Facing major delays in site initiation, this study sought 15 new sites to increase enrollment rates. BBK's site selection provided 40 highly qualified sites and our creative campaign helped investigators overcome the challenge of explaining a complex randomization process. BBK significantly increased the enrollment rate.

<b>OUR INVOLVEMENT</b>	After First-Patient-In Date
<b>COUNTRY</b>	United States
<b>AUDIENCES</b>	Patients
	Investigators
<b>KEY TO ENROLLMENT</b>	Understanding Motivations

19 Sites, Seeking 15 More

Most Difficult to Motivate

# 2

**Number That Counts //** BBK brought to bear the two-fold solution of 1) site selection to boost site initiation rates; and 2) creative materials to facilitate informed consent rates. Helping patients know their options, and inspiring physicians to approach and consent more study candidates led to success. A thorough knowledge of the audiences and how to motivate them made the difference.

**Objectives //** Increase enrollment rates; identify 15 new sites.

**Challenges //** Fewer than half of all sites were activated; explaining study randomization kept surgeons from introducing the study to and discussing it with eligible patients.

**Results //** BBK provided 40 top-ranked sites, tools to support investigator approach and consent rates, and ultimately increased enrollment rates.

## Expert Analysis



Physicians hesitated to bring up study participation due to a concern that patients would doubt their technical abilities when they explained the randomization design – to either wound sealant or surgical technique. BBK's solution was to provide investigators with a more accurate positioning – that

they would make the best decision for patient care at the moment of surgery, even if it meant removing patients from the study. This messaging was embedded in the materials, making it easy for both patients and investigators to communicate. To further inspire surgeons, BBK produced a newsletter that ranked investigators by enrollment numbers, thus subtly appealing to their competitive natures. Enrollment rates increased significantly.

## Prospective Studies // Vertebral Compression Fracture (VCF) Repair



**Concentrating on Motivations** // BBK increased the enrollment of three studies of an approved VCF repair device by discerning the specific motivations for physicians to refer patients to, and for patients to participate in, each of the studies; implementing compelling programs and materials leveraged these insights.

OUR INVOLVEMENT	
After First-Patient-In Date	
COUNTRY	
United States	Three Studies
AUDIENCES	
Patients	Most Important to Motivate
Referring Physicians	
Investigators	
Site Staff	
KEYS TO ENROLLMENT	
Study Positioning	
Study Messaging	

# 3

**Number That Counts** // The campaigns for these three studies each followed a basic, three-step process to achieve rapid results. First, identify the barriers to enrollment. Second, determine the positioning and messaging to overcome the given barrier. Third, develop programs and materials that quickly and insightfully present the messages that will garner both attention and response.

**Objectives** // Develop recruitment programs and materials for three clinical studies of an approved VCF repair device

**Challenges** // Studies were behind in enrollment; study treatment already approved and readily performed

**Results** // BBK quickly identified the motivations to refer/participate for each of the three studies, and developed study-specific materials that helped get enrollment back on track

## Expert Analysis



For varying reasons, three separate studies of an approved VCF repair device were experiencing enrollment rates far lower than anticipated. To help increase the numbers of eligible patients seen by each site, BBK quickly determined the enrollment barriers that faced each of the studies and then

crafted the means to overcome these obstacles. For example, for the study examining the medical device for the repair of VCFs associated with cancer treatment, potential referring oncologists typically were unaware that the intensity of the pain experienced by patients often left them bedridden. By positioning study participation as a means of helping to ensure patients could attend their chemotherapy sessions, BBK generated an influx of referrals.