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An ACP recognized resource for news and information for and about the phlebology community

INSIDE

Dr. Mackay treats the first patient in Florida using the VenaSeal closure system from Medtronic. (Photos courtesy of Dr. Edward G. Mackay)

Dr. Mackay conducts the first VenaSeal procedure in Florida

By Larry Storer

One of the biggest stories late last year was the introduction in the United States of Medtronic's VenaSeal closure system, the only procedure that uses an advanced medical adhesive to collapse and close diseased veins in patents with symptomatic venous reflux disease.

One physician with detailed knowledge and experience using the VenaSeal closure system is Dr. Edward G. Mackay, MD, FACS, RPVI, RVT, of Florida. Dr. Mackay was the second person to ever treat a patient with VenaSeal during the First in Man trial in the Dominican Republic, and is the first to use this new minimally invasive system in Florida.

One of his medical assistants, June B, had suffered with pain and varicose veins for years. Her left leg had been previously treated with a radiofrequency laser closure system, and on Oct. 25, 2015, her right leg was treated with VenaSeal.

June is just one of more than 30 million Americans who are affected by venous reflux disease. It occurs when valves in the veins of the lower leg no longer function properly, allowing blood to flow backward, or reflux, resulting in enlarged or varicose veins as well as other symptoms.

"Varicose veins may be a sign of a more serious condition known as chronic venous insufficiency, which in severe cases, can result in lifestyle-limiting lower leg pain, swelling, skin damage, and ulcerations," Dr. Mackay explained.

VENASEAL

Medtronic's VenaSeal procedure is the only non-tumescent, non-thermal, non-sclerosant procedure approved for use in the United States that uses a specially formulated medical adhesive to close the diseased vein.

The complete system consists of a dispenser gun, adhesive and associated catheter, guidewire, dispenser tips, and syringes.

VenaSeal demonstrated effective clinical results across three trials, during which

VENASEAL
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Can you handle patients responsible for a third of their bill?

By David Schmiege

Insurance companies and employers purchasing health insurance both accept the premise that higher deductibles and co-pays will lead patients to be more responsible for their health and their healthcare decisions. This change in direction, however, puts more pressure on medical practices to collect patient payments in a timely manner, as these payments represent an ever-increasing part of a practice's overall revenue. Only a diligent effort on the front end will ensure collection percentages remain strong.

As patients assume responsibility for an increasing proportion of their healthcare costs, providers face a potential financial dilemma of having to write off receivables for patients who cannot afford to pay their contractual responsibilities.

Patients are now responsible for an estimated 30 to 35 percent of their healthcare bill.

This article will focus on revenue cycle management processes that can minimize a practice's financial risk.

According to an annual survey conducted by the Kaiser Family Foundation and Health Research & Educational Trust, the percentage of workers enrolled in a health plan with an annual deductible of $1,000 or more has risen dramatically in the past decade, from 10 percent in 2006 to 44 percent in 2015.

The average deductible for single coverage is $1,317, up from $826 in 2009. More people are getting health coverage under the Affordable Care Act (ACA), but 85 percent of individuals who had signed up through exchanges selected Bronze or Silver plans, plans that offer lower coverage with higher deductibles.

With rising patient responsibility, this situation creates a complex set of trends that translates into increased financial risk for practices with poor financial controls.

For most medical practices, passive approaches to collecting patient balances will no longer be acceptable.

BAD DEBT

Sending bad debt to collections is ineffective because the average recovery rate of a collection agency is just 13.8 percent.

COLLECTING PAYMENTS
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SECOND LOOK

6 J&J cuts 3,000 med device jobs

Johnson & Johnson's medical device division has cut 3,000 jobs in an effort to save up to $1 billion in costs by 2018. The cuts comprise about 2.5 percent of the company's global workforce and up to 6 percent of its medical device segment, and will apply to J&J's orthopedics, surgery and cardiovascular businesses.

12 ICD-10 responses favorable

Despite the time and effort – and gnashing of teeth – required to transition to ICD-10, nearly 80 percent of healthcare organizations responding to a survey from KPMG say the switch has been successful.

THE PRACTICE

1 Patient payment strategies

Patients are now responsible for an estimated **30 to 35 percent** of their healthcare bill. This article will focus on revenue cycle management processes that can minimize a practice's financial risk.

SECOND LOOK

1 Historic VenaSeal procedure

Dr. Edward Mackay became the first physician to use Medtronic's new VenaSeal procedure in Florida. VenaSeal is the only non-tumescent, non-thermal, non-sclerosant procedure approved for use in the United States that uses a specially formulated medical adhesive to closes the diseased vein.

20 What's your favorite NOCA?

Over the last few years there have been many new oral anticoagulants that have been approved for the treatment of DVT and PE. This has also corresponded with a shift to treating more patients with DVT and PE as outpatients.

AESTHETICS TODAY

28 CoolSculpting away a double chin

Fat reduction has always been a surgical procedure. But now CoolSculpting, a pain-free, completely non-invasive procedure, is perfect for those who do not want surgery. CoolSculpting kills fat cells by dropping the temperature to just above freezing, causing the fat cells to crystallize and die without damaging the skin.

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THE VTN REPORT

JOHNSON & JOHNSON CUTS 3,000 JOBS IN MEDICAL DEVICE DIVISION

Johnson & Johnson's medical device division has cut 3,000 jobs in an effort to save up to $1 billion in costs by 2018. The cuts comprise about 2.5 percent of the company's global workforce and up to 6 percent of its medical device segment, and will apply to J&J's orthopedics, surgery and cardiovascular businesses. Other medical device units, vision care and diabetes care businesses will not be affected by the move.

If all goes according to the plan, the restructuring will save J&J about $200 million this year, giving the company "added flexibility and resources to fund investment in new growth opportunities and innovative solutions for customers and patients," a J&J spokesman said.

Sales for medical devices dropped 2.9 percent during the first nine months of 2015 and 3.4 percent in the United States.

But J&J is rolling out new offerings to jumpstart its diabetes device businesses and concentrating on recent launches for its spine and trauma businesses. As of July 2015, the company had already submitted more than half of the 30 major device regulatory filings that it promised to accomplish by the end of 2016.

ACP 29th Annual Congress recordings offered

If you missed the 2015 ACP Annual Congress, you can order the entire conference sessions. The ACP is making available the entire recorded library of 2015 Congress sessions, including sessions that will qualify for AMA PRA Category 1 Credit, for the package price of $495 for members and $595 for non-members.

The recorded sessions Include:

- Three and a half days of evidence-based behavioral practice content, relevant to venous education;
- Sessions that will qualify for AMA PRA Category 1 Credit;
- Faculty and speakers include more than 100 U.S. and international venous experts, specializing in the range of phlebology; and
- Presentations. Presentations include: didactic lectures, difficult case presentations, procedural skills, panel discussions, expert and attendee question and answer sessions, and patient demonstrations.

READ MORE: acp.org

AMERICAN VEIN CHANGES EMAIL, WEB ADDRESS; DROP ALL USES OF THE ACRONYM AVVI

American Vein & Vascular Institute's website and email domain has changed from @avviusa.com to @americanvein.com..

The @avviusa.com email and web domain will expire on March 23. This means that as of that date, emails sent to the @avviusa.com domain will stop forwarding to the new @americanvein.com domain.

Also, American Vein & Vascular Institute will be referred in second and subsequent references as American Vein or by its full name, They will no longer be referred to by the acronym AVVI.

CMS ADMINISTRATOR SAVITT INDICATES MEANINGFUL USE IS BEING REPLACED

Meaningful Use Stage 3 is scheduled to start in 2017, but now it looks like it may not happen at all. Acting CMS Administrator Andy Slavitt told a J.P. Morgan audience that CMS would make an announcement March 25 on future health IT incentive programs that would focus on patient outcomes rather than technology usage.

"We have to get the hearts and minds of physicians back. I think we've lost them," Slavitt said, according to *Family Practice News*.

"As any physician will tell you, physician burden and frustration levels are real. Programs that are designed to improve often distract. Done poorly, measures are divorced from how physicians practice and add to the cynicism that the people who build these programs just don't get it," Slavitt continued.

ACP PRO VENOUS REGISTRY CONTAINS 6,000+ PATIENTS, 20,000 PATIENT ENCOUNTERS

The ACP PRO Venous Registry has been growing rapidly since its launch. The database now contains more than 6,000 patients and 20,000 patient encounters from 15 physicians across the U.S.

Vein Clinics of America and Centers for Venous Disease, along with two certified EMR vendors – StreamlineMD and Medstreaming – were recently added to the registry. These additions will make meaningful data available, which can be utilized to improve patient outcomes as well as engage insurers, policymakers and the public.

READ MORE: veinstats.org

ZIP SURGICAL SKIN CLOSURE DEVICE COMPANY RAISES $16.4 MILLION

ZipLine Medical raised $16.4 million in a new round of equity and debt financing, according to an SEC filing posted in mid-January. The company has not stated how it will use the funds raised in the round, but is still seeking another $10.5 million.

Campbell, Calif.-based ZipLine Medical developed and markets its Zip surgical closure device. The Zip is a low-cost, non-invasive skin closure device designed as an alternative to suturing and stapling. The company hopes the non-invasive option will cut down on surgical site-related infections.

The Zip surgical skin closure device is designed to exert uniform closure forces while minimizing scar-promoting tension along the wound and reducing the chance of infection, and has FDA 510(k) clearance.

VIVASURE MEDICAL GETS CE MARK FOR PERCUTANEOUS VASCULAR CLOSURE DEVICE

Vivasure Medical has obtained the CE mark for its percutaneous vascular closure device for large-bore femoral arteriotomies. According to Vivasure, the device is fully bioabsorbable, sutureless and fully synthetic. It includes a delivery system and single-use, patch-like device.

Clinical studies with patients in four EU countries showed a 97 percent device technical success with no major device-related complications. The device is currently not approved in the United States.

CONMED COMPLETES SURGIQUEST ACQUISITION

Conmed has completed its acquisition of minimally invasive surgery technologies provider SurgiQuest. The transaction is valued at $265 million.

SurgiQuest is the manufacturer of the AirSeal system, an access management technology for use in laparoscopic and robotic procedures. AirSeal has been used in more than 250,000 procedures worldwide, and it has been shown to reduce procedure times and post-operative pain.

ABBOTT LAYS OFF 144 IN CLOSING SILICON VALLEY FACILITY

Abbott, which laid off 144 employees from its Redwood City, Calif., manufacturing facility in December, announced in January that it would close the facility during the current quarter to improve the company's competitiveness and "better support its business in an ever-changing environment."

The Redwood City facility makes vascular devices. Abbott is based in Santa Clara, Calif.

MEDTRONIC'S SHARE OF COVIDIEN'S U.S. TAX DISPUTE IS $525 MILLION

Medtronic inherited Covidien's tax-friendly Irish headquarters last year after the companies finalized their $50 billion merger. But the devicemaker also inherited a tax dispute from Covidien's former parent company, and now, Medtronic is paying $525 million to satisfy the U.S. Internal Revenue Service (IRS).

Tyco International, which spun off Covidien in 2007, is settling with the IRS after a years-long battle with the agency. Medtronic will be responsible for paying $525 million or 42 percent of the settlement, and TE Connectivity, a manufacturer of electronic components, will shell out 31 percent, or $475 million. Tyco will pay 27 percent of the settlement, or about $128 million to $142 million, according to a Medtronic regulatory filing.

This started in 2013, when the IRS accused Tyco of trying to get around U.S. income taxes for loans between its foreign-based businesses from 1997 to 2000, to the tune of $2.8 billion. The latest settlement would also apply to similar claims pending from the IRS from 2001 to 2007, Medtronic said in the filing.

Dublin-based Medtronic is confident that it can put the matter behind it, saying that it "does not expect to recognize any additional charges related to the tentative resolution," the company said in its filing. And Tyco is optimistic about a resolution, saying that it expects to pay its portion of the settlement within the next six months. **VTN**

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Medtronic goes shopping as tax inversion deal stuffs its coffers

Medtronic said in a filing with the U.S. Securities and Exchange Commission that it is paying $500 million in U.S. income taxes on $9.8 billion in cash and investments. The move sets the stage for more merger and acquisition activity.

The move demonstrates the benefits of tax inversion deals like Medtronic's $50 billion purchase of Covidien, under which the combined company renamed itself Medtronic PLC and transferred its corporate headquarters to Ireland.

Half a billion dollars sounds like a big number, but it's only a 5 percent tax rate on the money being brought to the United States, while companies based in the country must pay a 35 percent tax to repatriate overseas earnings. So the company saved $3 billion by conducting the transaction under its new corporate structure.

The transaction completes an internal restructuring of legacy Covidien businesses that reduces the cash and investments held by Medtronic's overseas subsidiaries.

"The Restructuring provides Medtronic with additional financial flexibility and increased confidence in the company's ability to meet its financial commitments, which include continuing to target an 'A' credit profile through a reduction in its debt to EBITDA ratio by the end of fiscal year 2018, returning a minimum of 50 percent of its free cash flow to shareholders through dividends and share repurchases, and pursuing financially disciplined M&A," according to the SEC filing.

Leerink equity analyst Danielle Antalffy said the company now has access to $12.5 billion in cash, with $5.5 billion still overseas. "MDT now has the financial flexibility to more easily deliver on all three financial commitments (described in the SEC filing), which we believe could set the stage for more aggressive M&A going forward," she wrote in a research note.

Potential targets include left ventricular assist device (LVAD) maker HeartWare and percutaneous VAD maker Abiomed, she said. Both companies experienced a spike in their stock price following news of St. Jude Medical's impending $3.4 billion acquisition of LVAD maker Thoratec. HeartWare is Thoratec's only direct competitor, but suitors will likely wait to find out if the FDA approves LVAD's bid for an expanded indication. Thoratec already has the expanded indication that HeartWare seeks.

Antalffy said other arenas of interest to Medtronic include minimally invasive surgical devices and imaging technology. "Regardless, we would expect Medtronic to be more active in M&A over the next 12-18 months now with access to significantly more cash on hand," she stated.

Medtronic has also announced that it will spend $100 million to buy stent retriever cover maker Lazarus Effect. And it will pay up to $458 million for transcatheter mitral valve replacement company Twelve, following the announcement of similar acquisitions by competitors Abbott and Edwards Lifesciences.

In order to complete the $50 billion purchase of Covidien, Medtronic CEO Omar Ishrak had to overcome public anger and new Treasury Department rules designed to make inversion deals less attractive. He said throughout the process that easier (and cheaper) access to cash outside the U.S. was one of the main rationales of the transaction's structure as a tax inversion deal. **VTN**

AngioDynamics sued for patent infringement by Bard Vascular

New York-based AngioDynamics is now facing a patent infringement lawsuit from Bard and Bard Peripheral Vascular because the company's Small Port vascular device and other inplantable power-injectable port products allegedly violate three patents established by Bard.

A judge in Delaware, Sue Robinson, validated the suit this week. AngioDynamics is asking that the case be transferred to where Bard makes it devices in Utah because neither company is based in Delaware.

There was a previous suit filed in 2012 and remains present until the U.S. Patent & Trademark Office board issues a final ruling on the AngioDynamics challenges to the patents.

Judge Robinson declined a request to change venues then as well, citing that traditionally the plaintiff is the one who has more of a say in determining the location of the proceedings. **VTN**

Phlebology Review Course offered

The Phlebology Review Course (PRC), a comprehensive two-day lecture series reviewing the essentials of venous disease and its care, will be March 18-19 at the ACP Training Center in San Leandro, Calif.

The course is provided by experienced phlebologists from several different primary disciplines who are exceptional educators. Topics covered during the course will be emphasized based on the anticipated importance of these topics on the Board Certification Exam to be administered by the American Board of Venous and Lymphatic Disease in the spring of 2016.

The target audience for the PRC includes physicians experienced in caring for patients with venous problems, as well as physicians who are new to the field and want a detailed presentation of the core curriculum of phlebology. In addition to phlebologists, other specialists who treat venous disease will also benefit from the course, including vascular surgeons, general surgeons, family practitioners, interventional radiologists, obstetrician/gynecologists and specialists in internal medicine.

Following the course, attendees should be able to:

- Describe normal venous anatomy and nomenclature.
- Summarize normal and abnormal venous hemodynamics and the derangements associated with chronic venous insufficiency.
- Identify lymphatic anatomy, physiology and pathophysiology.
- Explain the epidemiology, presentation and morbidity of venous disease.
- Assess the performance and interpretation of necessary diagnostic exams including duplex ultrasound.
- Discuss acute venous thrombosis and acute venous thrombosis risk factors.
- Diagnose, treat, or refer superficial thrombophlebitis, deep venous thrombosis and pulmonary embolism.
- Determine the therapy for acute and chronic venous disease including indications, contraindications, risks and benefits. **VTN**

To register, see **netforum.avectra.com/eWeb/DynamicPage.aspx?Site=ACP&WebCode=EventDetail&evt_key=ba43e723-be61-4f66-bb9a-ae2db7c015bb**

Physician burnout is getting worse

Burnout among U.S. doctors is getting worse, according to a study that shows physicians are worse off today than just three years earlier.

Mayo Clinic researchers, working with the American Medical Association, compared data from 2014 to measures they collected in 2011 and found higher measures on the classic signs of professional burnout. More than half of physicians felt emotionally exhausted and ineffective. More than half also said that work was less meaningful.

The data dovetail with a recent JAMA study, which found much greater prevalence of depression among doctors in training than in the general population. Taken together, experts say the problems require solutions that offer a systemic approach. All health care organizations have a shared responsibility to address the situation

"What we found is that more physicians in almost every specialty are feeling this way and that's not good for them, their families, the medical profession or patients," co-author Tait Shanafelt, MD and director of Mayo's Department of Medicine Program on Physician Well-Being, told the *Washington Post*. Going forward, the study states, anti-burnout interventions must go beyond simply training physicians to be more resilient and instead target factors within the practice that contribute to burnout rates.

The research comes in the wake of another recently published study from Mayo that speculates burnout among physicians is largely due to a perception of being part of a "fixing-people production line," and that a shortage of time away from a practice environment contributes to burnout rates.

Researchers at the Center for Excellence in Primary Care at the University of California San Francisco found that practices with high-quality performance typically address these issues, finding ways to lighten physician workloads by assigning tasks that do not require a physician elsewhere within the practice staff. **VTN**

Medtronic adds to Galway unit for manufacturing

Medtronic will build a $14.3 million facility in Galway, Ireland, to manufacture its In.Pact Admiral drug-coated balloon for peripheral artery disease (P.A.D.). It is designed for the interventional treatment of P.A.D. in the upper leg.

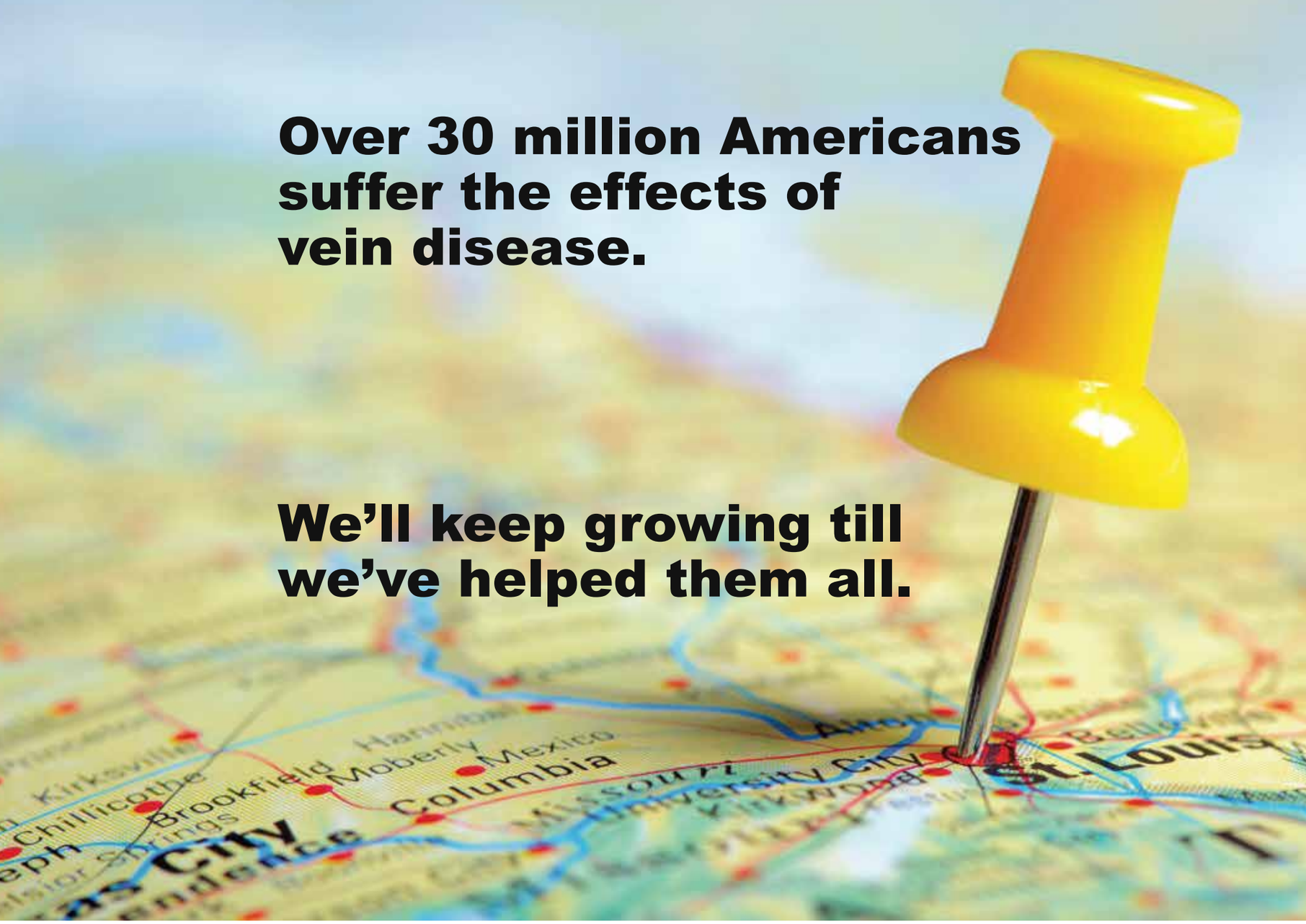
The facility, which will service the U.S. market as well as other countries around the world, will be 20,000 square feet, including 8,000 square feet dedicated to manufacturing.

A company spokeswoman said it will add to Medtronic's presence in the Irish medical technology hub. In addition to Galway, Medtronic sites in Tijuana, Mexico, and Brescia, Italy, also play key roles. **VTN**

Xario 100 targets clinical practices

Toshiba America Medical Systems Inc. has introduced the Xario 100, its newest addition to its ultrasound portfolio. The Xario 100 is a small, versatile and easy-to-use ultrasound system that is ideal for any clinical setting in small clinics, private offices and imaging centers.

The Xario 100 features a 19-inch LCD monitor with advanced imaging technologies that come from Toshiba's high-end ultrasound units, including Advanced Dynamic Flow and Differential Tissue Harmonics. **VTN**



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Despite continued growth, Drs. Labropoulos and Gasparis stay focused on maintaining interactivity as the root of the symposium. If you haven't experienced VS, join the growing number of physicians that consider it their go-to resource for venous education this April 14-16, 2016.

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Registration opens for 2016 West Coast Vein Forum

Registration is now open for the 2016 West Coast Vein Forum, Sept. 8-10 at the Monterey Plaza Hotel in Monterey, Calif. This forum is primarily for practitioners from diverse disciplines who include treatment of venous disease in their practice.

Daniel L. Monahan, MD, is the course director for the 2016 forum. He opened Monahan Vein Clinic in 2001, and is the only physician in the Sacramento region to focus his entire practice on the treatment of vein disease. Board-certified in surgery and a Fellow of the American College of Surgeons, Dr. Monahan has the greatest experience with radiofrequency ablation in the Sacramento area, and routinely uses advanced endovenous techniques.

Faculty includes John Blebea, MD, MBA; Joe Caprini, MD; Bo Eklof, MD, PhD; Steven Elias, MD; Kathleen Gibson, MD; Robert Kistner, MD; Fedor Lurie, MD, PhD; William Marston, MD; Mark Meissner, MD; Mel Rosenblatt, MD; and Julianne Stoughton, MD.

The West Coast Vein Forum was created as a unique educational opportunity in the western states for those with experience in treating venous disease. Rather than a comprehensive overview, the curriculum will focus on a variety of topics involving challenges and controversies that face the practicing vein specialist.

Each session will include experts providing brief lectures on topics in venous treatment followed by extended time of panel discussion and audience participation. In succeeding years other topics will be introduced, thus making this an annual educational opportunity for western states' practitioners to stay abreast of current issues and state of the art practice in venous disease. **VTN**

TO REGISTER: avf.execinc.com/edibo/WCVF16

2016 ACP events

The ACP has listed the following items for your 2016 calendar:

- **Phlebology Review Course**
  March 18 - 19, 2016
  ACP Training Center
  San Leandro, Calif.
- **Ultrasound Course**
  April 9, 2016
  San Leandro, Calif.
- **Physician Schlerotherapy Course**
  May 14, 2016
  ACP Training Center
  San Leandro, Calif.
- **The 2016 ACP Annual Congress**
  November 3 - 6, 2016
  Anaheim Marriott
  Anaheim, Calif.

ICD-10 transition reaction positive

Despite the time and effort required to transition to ICD-10, nearly 80 percent of healthcare organizations responding to a survey from KPMG say the switch has been successful.

ICD-10 has been called "absolutely essential" for moving healthcare forward for its ability to track quality and efficiency of care, as well as to potentially better track public health threats such as Ebola.

However, it posed the potential to disrupt payments to providers until their billing departments could get it right.

In the survey of 298 attendees to a KPMG webcast, 28 percent said the transition has been smooth and another 51 percent described it as "a few technical issues, but overall successful." About 11 percent described the transition as a "failure to operate in an ICD-10 environment."

Their biggest issues, respondents said, were rejected medical claims, clinical documentation and physician education, reduced revenue from coding delays and information technology fixes.

Even with the implementation in place, 46 percent of respondents said they were thinking of pursuing initiatives in clinical documentation improvement, revenue cycle optimization, and electronic health record and IT system optimization. At the same time, 25 percent said they had no plans to do so.

Initial reports from payers and hospitals about the transition found them calling it relatively successful.

Physicians are upbeat about their potential profits for 2016, according to the third annual Practice Profitability Index, though they list the transition to ICD-10 as one of the biggest threats to profitability. **VTN**

Patient sues Bard over injury from a faulty IVC filter

A patient from Buffalo, N.Y., has filed a personal injury product liability lawsuit against C.R. Bard and Bard Peripheral Vascular Inc. for injuries she allegedly sustained as a result of surgical implantation of the Bard G2 IVC Filter.

Gary Leigh Piazza said she believed she was wronged by the manufacturer. "I was in great pain for months. I was on pins and needles, thinking, 'is this thing going to kill me tonight?' Now I have a humongous scar on my belly that wraps around my waist. It's a constant reminder. This reminder – this big scar on my belly forever – I feel maimed. And I'm still swollen across my abdomen, even today."

In January of 2010, Piazza had a Bard G2 IVC Filter implanted into the vessel leading to her heart in order to filter out any dangerous blood clots. In May 2015, she started to feel an extremely powerful stabbing and burning pain in her abdomen and lower back. The lawsuit was filed Dec. 14, 2015, in United States District Court in the Western District of New York. Piazza is a resident of Buffalo, New York.

Wendy R. Fleishman of the national plaintiffs' law firm Lieff Cabraser Heimann & Bernstein, LLP, said Piazza's doctors learned that the IVC filter had moved out of place and broken. Little pieces of the filter were floating in her blood vessels toward her heart, lungs and brain. The IVC filter had actually cut into her aorta and possibly other organs as well. Her doctors performed a "massive" surgical removal operation.

"As a medical device manufacturer, Bard has an obligation to develop, test and validate the safety of its products prior to selling them," Fleishman stated. "Had Bard done this rather than sell a defective and unreasonably dangerous device, Gary Leigh Piazza would not have been severely injured as described in the complaint. We want other patients to know about the risks and potential danger the IVC filter may cause so they continue to have their doctors monitor the placement of the filters."

The lawyers are seeking additional clients.

FDA WARNING LETTER

Fleishman said that on July 13, 2015, the FDA issued a Warning Letter to Bard notifying that its IVC filters were adulterated and misbranded under federal law because the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation were not in conformity with the current good manufacturing practice requirements of the Quality System Regulations.

She also said the FDA also notified Bard that it had failed to comply with adverse patient event reporting requirements, including a consistent pattern of Bard underreporting the severity of injuries caused by device failures and failing to report device malfunctions all together. The FDA cited numerous examples of Bard reporting G2 and other IVC filter failures resulting in deaths and other serious injuries as if there was no patient injury involved. **VTN**

Medical device tax delayed as a part of $1.8B budget bill

The medical device tax has been suspended for two years. Industry, which has been waiting years to read those words since the 2.3 percent excise tax was enacted as part of the Affordable Care Act, reacted with jubilation.

The suspension, set to last two years, occurred at the end of last year when President Barack Obama signed a $1.8 billion taxation and spending bill that contained a variety of holiday goodies for various industries in the form of extended tax credits, as well as spending on the pet issues of both political parties. It also ended the threat of a looming government shutdown.

The temporary freeze follows a relentless battle by AdvaMed and med-tech lobbying groups to repeal the tax. The efforts finally paid off, albeit only for two years, though the industry is betting that a temporary suspension will turn into a permanent repeal (or perhaps endless extensions of the suspension, as is often done on Capitol Hill).

Opponents of the Affordable Care Act funding mechanism argued that because it was a tax on sales, it hit small (often unprofitable) companies, such as Warsaw, Ind.'s 80-person OrthoPediatrics, the hardest.

"Luckily now we'll be able to go back and review that and remove the expense and cash that we had put in to the budget for the medical device tax and instead replace that with incremental programs developing new projects," OrthoPediatrics' CFO Fred Hite said.

Whether the suspension becomes permanent depends in large part on who becomes the next president.

Republicans have generally supported killing the excise tax. During a 2014 speech at the annual AdvaMed convention, Democratic presidential candidate Hillary Clinton hedged on the issue of repeal, saying "I think it [a decision] has to be made within the context of a larger set of issues that have been raised by the ongoing implementation of the Affordable Care Act," and "We have to look and see what are the pluses and minuses." **VTN**

Groups oppose 30-hour-shifts in some programs

Two advocacy groups have called for a halt to new programs experimenting with the return of the 30-plus hour work shifts for novice doctors.

Young doctors may be better rested with work-hour restrictions, but patients don't seem to benefit at all. Some residents say that the shorter shifts hurt continuity of care because they must go home when their time is up and hand off patient care to another clinician.

The restrictions are most problematic for surgeons, according to a recent article published by *Slate,* because they must hand off patients in the middle of an operation or other urgent situations.

"The surgical community in particular is concerned about this and feels duty hour

restrictions have impaired continuity of care," Karl Bilimoria, MD, a professor at Northwestern University's Feinberg School of Medicine, told the publication

The consumer advocacy group Public Citizen and the American Medical Students Association (AMSA) have asked the federal government to intervene and put a stop to the 30-plus hour work shifts practice, *The Washington Post* reported. They claim the long shifts pose serious health risks to student doctors as well as patients. **VTN**

CALL FOR ABSTRACTS

American Venous Forum

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TAKE THE LEAD.

Internet Marketing Strategies for Success

MAKING THE MOST OF SOCIAL MEDIA PRESENCE

By Alyssa K. Schmiege

Alyssa K. Schmiege

For the most part, social media is a fairly simple way to grow and keep an audience and patients. Done right, regular posts to Facebook, Twitter, Google+, and other platforms can have a huge reach with relatively little effort on your end. But to really make social media work for you, it's not quite as hands-off as you might think.

Effective social media requires attention to detail. To make your posts go the distance and grow your audience, you need to stay involved after you hit "post." Focused engagement on your part can go a long way to keeping patients aware of, interested in, and loyal to your vein practice.

TIPS TO SUCCEED

Be a presence. You don't just want to be present on social media, you want to be a *presence.* This means making sure you're active enough to stay in the game. You don't need to bombard your followers with posts, but make sure you're pushing enough out there to stay part of the conversation. An ideal frequency is two or three posts a week.

Acknowledge receipt. Reply "likes" with "likes" and "follows" with "follows." This is social media, after all, so keep it social. Just as you return a wave or hello on the street, return any social media engagement. It's part of being part of the game and building your network.

What are people talking about? Keep social media a two-way conversation. Don't simply push out links and statements about your services and qualifications — pay attention to other conversations relevant to your practice and join these discussions.

Find your voice and keep it focused. Part of building your social media presence and growing your vein practice is establishing yourself or your practice as an expert in vein disease. To do so, keep your activity mostly focused on how you want to be recognized.

As a phlebologist, for example, who wants to build your reputation as a vascular specialist? Try to keep much of your activity focused on vein disease and treatment options. You can add in other appropriate topics and fun engagement, such as community or charity events, here and there, but make sure anyone who visits your profile will come away with a clear understanding of who you are.

SEO ESSENTIALS FOR PRACTICES

Search Engine Optimization or SEO is the process of optimizing your website and is key to expanding your existing patient base. In the medical field. SEO can play a big part in making a patient choose your website over your competitors. It is important to have an SEO strategy so that you can get past your competitors.

Listed below are a few essentials you need to consider when optimizing your website. Rules to follow include:

Choose the right keywords. Keywords drive SEO so it is important to choose the right ones. Make a list of all the vein disease and treatment option keywords that your practice could be associated with and find out which ones are searched for the most by using tools like Google Keyword Planner.

Content is king. Most people who use search engines are looking for answers. If you can create top-quality, original content then you can show them that you are experienced and know what you're talking about.

Instead of writing repetitive material every day, write two or three short posts each week that are interesting and to the point. Decide topics by thinking of frequent questions that your patients ask you.

Title tags and meta description. Title tags and meta descriptions are the way your website shows up in a Google search. This directly affects the views that you get, so make sure that you get to the point and be creative. If your patients are intrigued by your title tag and description, they're more likely to pick to your site even if a competitors site ranks higher.

Use social media. Social media marketing is a must for the medical field. It is the most effective way to reach your patient audience and promote your clinical expertise. Sign up for Facebook and Twitter and use these mediums wisely. Interacting with current and prospective patients makes you more approachable.

HOW STRONG IS YOUR REPUTATION?

It is vital for a medical practice to have a good reputation. Patients seek treatment with a doctor/medical practice that has a positive reputation in the community.

However, today, your clinical reputation is almost synonymous with your online reputation. Nowadays, when a patient requires medical care, they may start their search for treatment options online, and after conducting multiple searches, select a doctor or practice.

What influences their decision? Both search rankings and reviews. In other words, it relies on online reputation. Clearly, it is not something to be neglected as it affects every business, especially medical practices.

You can Manage Your Rep:

List your practice on appropriate sites. There are a number of sites available where you can list your practice. You should, first, obtain a Google+ page. Then, list your practice in sites catering to your geographical area and your particular niche. Also, list your practice on general review sites like Yelp, as well as social media sites like Facebook and Twitter.

Obtain reviews. Ask your patients to leave reviews for your practice if you feel they are please with the care provided. You should inform them of their various choices. You can make it easier by putting up links to various review sites on your website. You can also direct patients to your Facebook page.

Reply to reviews. It is not enough to get reviews, you should also reply to them. Just a thank you reply for good reviews will suffice. For negative ones, you have to do more. You should try to get the reviewer to convert his/her review to a positive one. Contact them and find out how you can repair the relationship and turn them into a happy patient.

Implement SEO practices. Search rankings play as important a role as reviews when it comes to your practice's reputation. They are, in fact, interconnected. It is not good to neglect either of them. Implementing good SEO techniques will help your site, and your practice in turn by making it more visible online. It will allow you to draw in more patients and get more reviews that can improve your reputation.

TURNING VISITORS INTO PATIENTS

Sometimes medical practices don't understand why they can see a reported increase in traffic to their website without an increase in their patient-base. There are many reasons why individuals visiting medical practice websites leave the page and move on to something else, but sometimes it's as simple as poor design.

The face of the Internet is always transforming; think of how many times Facebook has changed its layout in the past few years. It's important to redesign your web page(s) to keep your site cutting edge for representing your medical practice.

Possible reasons why visitors to your site may not be turning into patients:

Your website is dated. Aesthetic design is essential to website traffic. If your website isn't visually stimulating, well-designed and professional looking, visitors are likely to move on to something else.

Websites must have attention-grabbing images, interactive drop-down menus, and working links. It's also important that doctors view their website as a representation of their practice. Often your website is the first impression your clinical qualifications will be making on potential patients — so it should be a positive, lasting one!

Clutter. If potential patients can't find the information that they are looking for, they are likely to leave your website. It's important that the navigation bar or center of your webpage is clear and appropriately organized. Also, your homepage should be full of the most important information such as your clinical experience, treatment options and contact information!

Your website blends in. Make sure that visitors to your page will have seen or experienced something different than what

many other medical webpages provide. Make sure your page is personalized! A great way to personalize your practice website is to include video physician introductions, video patient testimonials, photos of staff members and office photos

You don't have a clear and concise call to action. A "call to action," is a button on a website that tells a visitor what to do. For example, add a button to your website that says, ***"Schedule a Complimentary Vein Screening today!"*** or ***"Request an appointment today!"***. Include what you want them to do and make sure you're conveying a sense of urgency.

Your website won't load on a mobile device. More and more people are using their smart phones and tablets to surf the web or look up information.

If your site isn't mobile-compatible or reactionary, then individuals won't be able to access your page and are less likely to access from a PC or laptop at a later time.

ADD VIDEO TO WEB

Video optimization is becoming more important as a mainstream aspect of search engine optimization. It can be a great way for you to expose your practice and clinical qualifications to potential patients that otherwise would not have been familiar with your practice. Adding videos to your website can help you stand out amongst the competition and open up new avenues of exposure on the Internet.

What are the benefits in terms of traffic, visibility, etc.?

Enhanced listing in search results. Not only can videos show up as text links alongside other web results, they can also be embedded into the search results. This means there is an opportunity to have the actual video presented to the user as a result of their normal Google search.

Multiple listings for a given search. Having your site and multiple videos show up for the same search can allow you to potentially dominate the search results.

Additional sources of traffic & exposure. Submitting videos to portals like YouTube allow you additional exposure that you wouldn't receive otherwise by not only allowing their visitors to view your video and see your message, but additionally linking to your practice's site to receive further information.

OTHER BENEFITS OF VIDEO?

Dynamic presentation. They provide an unbeatable introduction to who you are and what you do. Add life to your website by inserting video amongst the static text!

Establish a "comfort level" with a prospective patient. When a potential patient views a video on your website, it helps them establish a personal connection with you and your practice.

Enhances user experience. Videos are proven to dramatically increase the average time a user spends on a given website. The longer you have a captive audience, the better chance you have of them becoming a patient. **VTN**

Alyssa Schmiege *is the director of client social media strategy for Vein Specialists of America. She can be reached at Alyssa@veinbusiness.com or 630-992-0060.*

Can you handle patients responsible for a third of their bill?

By David P. Schmiege

David Schmiege

COLLECTING PAYMENTS
continued from page 1

ASSESS CURRENT PROCESSES

Because healthcare reform has brought higher patient copays and deductibles, patient payments continue to grow, becoming a larger percentage of your total monthly revenues. Effective patient collections are more critical to the financial health of your practice with every passing day.

Begin by meeting with your staff to discuss the importance of:

- instilling a culture of responsibility among all employees;
- improving patient engagement;
- satisfaction through a better understanding of your practice's financial policies; and
- supporting your practice's financial viability through collaborative efforts to collect patient copays and past due balances.

Encourage input and discussion among staff responsible for registration, appointment scheduling, insurance verification and pre-certs. Your staff should provide valuable insights into their departmental processes and serve as champions for implementing improved processes.

The goal of staff discussions is to develop and implement protocols that will foster patient compliance by improving the patient experience. Ensure that all patients receive clear, consistent and timely communication that would enable them to make fully informed decisions about their financial obligations to the practice;

Other goals are to:

- Deliver financial assistance to proactively and consistently offer payment plans to those who cannot pay their balance in full;
- Achieve financial stability. Establish appropriate patient payment processes to achieve stability in financial risk.

PATIENT REVENUE GROWING

The percentage of revenue attributable to patients is steadily increasing. How long before it reaches 50 percent?

Let's examine areas of increased attention.

Co-pay collections

- Your goal should be to collect *100 percent of co-pays and past-due patient balances every day.* Measure your staff effectiveness by daily tracking scheduled collections vs. actual collections. Ask each staffer who collects copays/deductibles to complete an "If Not, Why Not?" report each day for the monies they do not collect.
- Communicate with your patients using your website, EMR patient portal, appointment reminder calls, etc., that the patient responsibility for promptly paying co-pays and past due balances before additional services are rendered.
- Improve the "Ask." You will find that some employees are instinctively better at collecting patient payments. Have other employees observe their techniques. If you have a small staff, consider having your front-office personnel take a field trip to another office to learn.

Identify patient responsibility before the patient's visit

- Check insurance eligibility on every patient prior to every visit to identify what co-pay and/or deductible are due; and ensure the patient's insurance is active.
- Let your patients know what payment you will expect at the time of their visit. Eliminate potential patient excuses, such as, "I didn't know the cost of today's appointment would apply to my deductible."
- Numerous online insurance eligibility programs permit you to do real-time eligibility/benefit status verification at the time of service.

Payment options.

- Patients are creatures of their own habits. Make sure you have payment options that make it *easy* for them to pay you.
- Accept cash, checks, debit cards, and credit cards. More payment options mean more time-of-service collections.
- Accept check and credit card payments through your website.

Payment plans

- Set up payment plans for those patients who don't have the money and indicate that they are willing to pay their bill in installments.
- A payment plan should be documented in writing and signed by the patient. The payment plan should spell out what will happen if the patient misses a payment.
- Payment plans should not extend beyond six months, with tiered thresholds based on the amount due.
- Explore a **"credit card on file"** (CCOF) program. Many dermatology and aesthetic practices require a patient to keep encrypted credit-card information on file.

Once an insurance claim is processed and contractual adjustments are made, the remaining balance due from the patient is charged to the credit card and the patient is sent a final statement summarizing the transaction. This process keeps your accounts receivable due from patient to a low, manageable level. A CCOF program will be more readily accepted by patients once primary care practices implement these financial controls.

Although it is a terrific business tool, patient resistance is high when you are the first medical practice in your community with this financial requirement. It is a financial control that is long overdue.

The concept of CCOF is similar to that of a hotel's payment policy. When a patient checks in at the reception desk, they are asked to leave a credit card on file. The credit card information is entered into your EMR payment system and securely stored. After the visit, submit the insurance claim as usual. Once the claim is adjudicated and the EOB posted, recall the credit card information and process the payment. Send a zero balance statement to the patient.

Similar to a hotel, the medical practice is protected from non-paying patients

A CCOF program can also be used to set-up payment plans with patients, regardless of whether they have insurance or not. A CCOF program collects scheduled payments in a non-aggressive, efficient way.

Are your patient collections strategies going to succeed in 2016?

The challenges of collecting from patients are rising. It may be time for your practice to make a change in how you collect patient's payments.

Benchmark your patient collection strategies to see if you're set up to increase profits or increase patient receivables in 2016. Below are a few questions related to your revenue cycle processes to guide your discussion with your staff.

1. **Have your patient receivables grown in the past 12 months?**
   Yes No Not sure
2. **Do patient receivables make up more than 20% of total revenue?**
   Yes No
3. **Are patient receivables more than 60 days past due?**
   Yes No
4. **On average, do you send more than 1 statement per patient?**
   Yes No
5. **Do you make collection calls to more than 5% of your patients?**
   Yes No
6. **Are less than 50% of patients paying their bills online?**
   Yes No
7. **Does it take more resources (time and collection cost) to collect from patients who have not met their deductible?**
   Yes No
8. **Do you have conversations with patients about their financial responsibilities BEFORE their visit?**
   Yes No

9. **Do you use online patient eligibility verification tools?**
   Yes No
10. **Do you bill more than 20% of patients AFTER adjudication?**
    Yes No

If you answered mostly "yes", it may be time to consider a change in how you communicate your practice's financial policy and collect from patients. **VTN**

David Schmiege *is the president and CEO of Vein Specialists of America. Have an idea for a future article? David can be reached at 630-638-0060 or David.Schmiege@VeinBusiness.com.*

OCR launches online platform to help health IT developers

The Department of Health and Human Services' Office for Civil Rights (OCR) has launched an online platform that enables health technology developers to ask questions and express concerns about HIPAA privacy protection.

The platform, according to OCR, will help the agency to better understand where to focus guidance efforts geared toward developers, particularly those in the mobile health space.

In its announcement, OCR said the nation is experiencing an explosion of technology using data about the health of individuals in innovative ways to improve health outcomes.

"Building privacy and security protections into technology products enhances their value by providing some assurance to users that the information is safe and secure and will be used and disclosed only as approved or expected. Such protections are sometimes required by federal and state laws, including the HIPAA Privacy, Security and Breach Notification Rules. Yet many Health developers are not familiar with the HIPAA Rules and how the rules would apply to their products."

ACT | The App Association called the platform "a step in the right direction" for OCR, but added that there is much work still to be done to clarify HIPAA to mobile health technology developers. Executive Director Morgan Reed said connectivity is poised to revolutionize healthcare by giving individuals greater access to their own health information and improving outcomes. **VTN**

NOACs
My favorite novel oral anticoagulants for DVT, PE

By T.C. Wright, MD, FACP

Over the last few years there have been many new oral anticoagulants that have been approved for the treatment of DVT and PE. This has also corresponded with a shift to treating more patients with DVT and PE as outpatients.

Dabigatran (Pradaxa) was the first approved by the FDA in 2010, and it works by inhibiting thrombin. It was followed quickly by Rivaroxaban (Xarelto), Apixaban (Eliquis), and Edoxaban (Savaysa), which all work inhibiting factor Xa. They were initially approved for atrial fibrillation but have rapidly added other indications such as DVT and PE treatment and prophylaxis.

These newer agents are much more convenient than vitamin K antagonist, warfarin, to administer because they can be given in fixed doses without routine coagulation blood monitoring. Patient acceptance and adherence is much greater NOAC than with Warfarin.

S.Y. Chen, MD, PhD, found one year compliance with warfarin prescriptions for VTE to be only 23 percent.[2] Initially all of the NOAC were touted to have lower rates of bleeding compared to Warfarin.

They all appear to be associated with less intracranial bleeding; however, the rare intracranial bleed that does occur may be even more serious. At first they all appeared to have less GI bleeding after further experience and analysis of GI Bleeding, Dabigatran and Rivaroxaban appear to have similar rates of GI bleeding and vitamin K antagonist. All the NOACs, except Apixaban, should be adjusted and used with caution in patients with significant renal insufficiency.

The biggest knock on the NOACs has been the lack of specific reversal agent. Although this has recently changed with the FDA approval of Idarucizumab (Praxbind) for reversal of the anticoagulant effects of Dabigatran. Idarucizumab is a humanized monoclonal antibody that neutralizes the anticoagulation activity of dabigatran.

For the other agents, if there is a life threatening bleed, Prothrombin Complex Concentrate (PCC) administration is recommended. Edoxaban also was associated with lower overall mortality in patients treated for atrial fibrillation.[1] Edoxaban also is a single once daily dose of 60mg, but it requires co-administration with a Heparin for the first five to 10 days.

CONCLUSION

Putting all that together, after nearly five years of experience, my two favorite NOACs are Apixaban and Edoxaban. Whether I use one or the other depends on two factors: Overall convenience vs safety.

The safest one appears to be Edoxaban, but it requires the use a low molecular weight Heparin or IV Heparin for the first five days, which makes it slightly less convenient.

Apixaban is also much safer than Warfarin and safer than Rivaroxaban and Dabigatran. Apixaban is more convenient to start and Apixaban is also my choice if they have renal impairment because of its hepatic clearance. To me the most convenient is Apixaban. The final decision to me depends on the patient factors such as overall bleeding risks and or their tolerance to slightly more complicated starting regimens. **VTN**

***Thomas Wright MD, FACP**, is the medical director of the Laser Vein Center in St Louis, Mo. He is a diplomate of ABVLM and his research interests include endovenous ablations, tumescent anesthesia and lipedema.*

RESOURCES

[1]Edoxaban versus Warfarin in Patients with Atrial Fibrillation. Robert P. Giugliano, MD, Christian T. Ruff, MD, MPH, Eugene Braunwald, MD,. for the ENGAGE AF-TIMI 48 Investigators. N Engl J Med 2013; 369:2093-2104, Nov. 28, 2013. DOI: 10.1056/NEJMoa1310907

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2016
PwC sees a year of change in healthcare

In 2016, millions or American consumers will have their first video consults; be prescribed their first health apps and use their smartphones as diagnostic tools for the first time. 2016 also will be the year that many Americans, faced with higher deductibles, manage medical expenses with new tools and services rolled out by their insurance companies, healthcare providers, banks and other new entrants.

This will be the year that, shift by shift, visit by visit, nurses doctors and other clinicians learn to work in new ways, incorporation insights gleaned from data analysis into their treatment plan.

PwC's Health Research Institute's annual Top health industry issues report highlights the forces that are expected to have the most impact on the industry in the coming year, with a glance back at key trends from the past decade.

Bedless hospitals. Mega hospital and insurer mergers. A growing consumer appetite for virtual health interactions. Those are among PwC's predictions for top healthcare industry trends for the new year in a new year report.

"2016 will be a year of firsts for players within healthcare as the industry adapts to the main forces driving the new health economy: The rise of consumerism, the focus on value, downward pressure on costs, technological innovation and the impact of new entrants," PwC stated in a press release..

The upcoming year will also be marked by how well the healthcare industry handles greater demand with rising costs and trends like industry consolidation, according to Kelly Barnes, PwC's US health industries leader. "It will be businesses that prioritize addressing consumer needs and increasing value that should succeed," Barnes said.

The report identifies the following 10 forces that will have the most impact in 2016:

Merger mania: PwC said the industry will see more high-profile mergers and acquisitions in 2016 as regulators debate how consolidation impacts consumers. Consolidation creates larger health systems and insurers, so branding is critical. The report notes that well-known healthcare systems may have a market advantage; Americans are willing to drive further for care from a well-known system. However, consumers are not willing to pay more for care from top-ranked hospitals.

Escalating drug prices: The industry will search for a fair drug pricing formula in the upcoming year, according to the report. Prices have reached a "boiling point," and the way to reach some sort of agreement will require collaboration among insurers, patients and new value-assessment groups.

Biosimilar drugs: One way to combat skyrocketing prices will be biosimilar drugs, according to the report. These drugs are near substitutes for original brand drugs and could bring significant price discounts.

Cybersecurity concerns: Even "best in field" hospitals will struggle to attract patients if they are hacked, the PwC report stated citing research from its Health Research Institute's 2015 consumer survey. Consumers are especially concerned about the vulnerability of connected medical devices to security breaches and cyberattacks. And recent hacks of organizations, including insurance companies like Anthem, show that organizations that are unprepared to deal with breaches can face lawsuits, lost revenue and harm to their reputations, the report states.

Technology gives more power to consumers: Adoption of health-related smartphone apps has doubled in the last two years, from 16 percent of consumers in 2013 to 32 percent this year, according to the report. Both technology and shifts in financial incentives mean "care will begin to move into the palms of consumers' hands," the PwC report stated.

Behavioral healthcare moves to the forefront: After years of being on the backburner, the industry will start to recognize that mental health is important to the well-being of employees and consumers, according to the report. Indeed, PwC notes that one out of five American adults experiences a mental illness every year. These conditions cost businesses more than $440 billion each year. Healthcare organizations and employers will look at behavioral care as "key to keeping costs down, productivity up and consumers healthy," the report stated.

Care moves to community settings: Value-based payment models will prompt healthcare systems to "pursue lower-cost settings more aggressively than before while

employing creative approaches to distributing care." This may mean eliminating inpatient care and creating more bedless hospitals and virtual care centers where clinicians oversee patients from a variety of locations. Such changes in care delivery will be "fueled by alternative payment models, technological advances and powerful new database tools," according to the report.

Consumers become "money managers." Higher deductibles and co-insurance mean consumers will need help managing health spending. And this will require the industry to create new tools and services, such as payment plans and pricing information, to help consumers pay for services.

High-tech databases: New database tools and the resulting deep data analysis of information on health consumers will provide valuable insights necessary to improve patient care and consumer health, according to the report.

Cost of care: Healthcare systems seeking value-based care will "dig in to calculate the true cost of services," in the process finding ways to improve efficiency as well as care. **VTN**

READ MORE: pwc.com/us/en/health-industries/top-health-industry-issues.html

Medical devices security tested

Security researchers accuse the U.S. Food and Drug Administration of being "a toothless dragon" in dealing with medical device vulnerabilities, according to recent report

In the report, hacker Billy Rios recounts how the Mayo Clinic, in 2013, engaged him and other "white hat" hackers and set them off in teams in an effort to exploit about 40 different medical devices.

"Every day, it was like every device on the menu got crushed," Rios said. "It was all bad. Really, really bad."

Mayo later began exercising what security expert Kevin Fu calls "the power of the purse" – requiring vendors to meet strict security testing standards. Fu predicts we will see more warnings from the FDA, similar to those it issued in July over Hospira infusion pumps. The agency said the pumps "could allow an unauthorized user to control the device and change the dosage the pump delivers."

Rios detailed vulnerabilities in the Hospira Symbiq line of pumps and reported that information to the FDA. It took more than a year for the agency to take action, according to Bloomberg.

"We have to create videos and write real exploit code that could really kill somebody in order for anything to be taken seriously," he said. "It's not the right way." **VTN**

VENASEAL
continued from page 1

patients quickly returned to normal activities with minimal or no bruising.

Patients who have an aversion to needles are very happy with VenaSeal. Unlike heat-based treatments, the VenaSeal closure system does not require multiple tumescent anesthesia injections of a dilute local anesthetic, and it eliminates the risk of burning or nerve injury associated with thermal-based procedures. Patients also did not need to use compression stockings post-procedure.

THE PROCEDURE

Dr. Mackay said the actual procedure takes less than half-an hour, and an ultrasound is used to guide and position the catheter.

"I numb the location where I will access the vein with a minor needle stick. Once the area is numb, I insert the catheter in specific areas along the diseased vein, and deliver small amounts of the medical adhesive. After treatment, the catheter is removed and a bandage placed over the puncture site.

"Some patients are apprehensive about the VenaSeal closure system procedure adhesive that is left in the body following the procedure," Dr. Mackay said. "But only a very small amount of adhesive is used to close the vein, and Medtronic says the body will naturally absorb the adhesive over time."

FLORIDA'S FIRST VENASEAL PATIENT

Dr. Mackay said that June presented with a pretty straightforward saphenous insufficiency, complaining of pain in her legs and unsightly varicose veins.

He said that she went right back to work after both the RF procedure and the VenaSeal procedure.

"She tolerated both of them very well, but she did feel that without the local and everything else in the RF procedure, her leg felt just like a normal leg right off the bat with VenaSeal.

"The symptoms she was having from the veins was immediately gone. She worked a full day after the VenaSeal procedure; with the RF on the other leg, she had worked only a couple of hours before the day was over.

"The results with both procedures was very good, but she said there was a pretty dramatic difference in feeling immediately with VenaSeal. She said this feels incredible.

"June said the comfort level was better with VenaSeal because she didn't have to wear compression stockings, she didn't get the needle sticks, and she felt fine when it was over. With the RF, she had a numb feeling, had to wear the stockings and had a heavy feeling from all that tumescence."

She was obviously very happy with the VenaSeal closure system.

Edward G. Mackay, *MD, FACS, RPVI, RVT, is a double board-certified general and vascular surgeon in the Tampa Bay area focused solely on treating venous disease. Dr. Mackay earned his Medical Degree from the University of Florida Medical School in 1986. After a five-year General Surgery residency, Dr. Mackay completed a Vascular Surgery fellowship with the University of Tennessee Medical Center. He trains physicians from all over the world in the techniques of leading-edge endovenous procedures. He is co-director of the International Vein Congress (IVC) in Miami, which attracts hundreds of physicians from around the world to its annual meeting. Dr. Mackay is also an author and co-author for several published articles focusing on vein therapies, including contributing a chapter for Dr. Jose Almeida's book, Atlas of Endovascular Venous Surgery. Dr. Mackay has three IAC-accredited clinics in Florida: St. Petersburg, Largo and Palm Harbor. He may be contacted at 800-527-VEIN.*

"After my VenaSeal procedure with Dr. Mackay, I felt instant relief from the pain and there was no heaviness in my legs. It was like the problem was fixed right away and my legs were thanking me! I didn't have any downtime from my job and I didn't have to wear compression stockings afterwards in this Florida heat! Even weeks later, I have no issues!"

COMPRESSION STOCKINGS

Dr. Mackay said that Medtronic's protocols do not require wearing compression stockings, but he thinks the jury may still be out on that issue.

"I'm not 100 percent convinced that compression is not going to be required of anybody, he said. "I don't know if the data is that strong because they [stockings] are required with RF. That's been argued in a lot of meetings, and I don't know if we have an answer to it yet.

"I think some people with varicose veins might get phlebitis after treatment, so they're probably better off with stockings. But June did fine without the stockings, and didn't have any problems."

June B, Dr. Mackay's medical assistant, became the first patient in Florida to have this next-generation procedure to close varicose veins in her leg.

POST-OP INSTRUCTIONS

Dr. Mackay said he has been sticking with the same post-op protocol as he does for RF. "For the time being I'm still doing about a week post-op ultrasound. But it will remain to be determined as time goes by if I'm going to continue to require that."

But his primary instruction is to keep moving – walk, walk, walk – and resume their normal activities. He tells patients to stay away from heavy lifting and excessive exercise for 48 hours, but walking is definitely required.

"There hasn't been a report with DVT with this procedure yet, so I'm not sure if it's just a matter of time or if maybe there's just something about this that makes it less likely to get a thrombosis."

DR. OZ PATIENT

Valerie Cardone had the same procedure on national television as part of "The Dr. Oz Show." Vascular surgeon Dr. Charles Dietzek used VenaSeal to correct varicose veins in her right leg in a 30-minute televised procedure.

"I felt a minor prick where he numbed my leg and then only some slight pressure during the actual procedure," she said. "I was easily able to talk with Dr. Oz and had no problem answering his questions while Dr. Dietzek was still working on me.

I experienced a small amount of pain as he finished up, but otherwise it was an easy and quick procedure. When I got home after the long ride from New York City, I made sure I spent about 20 minutes on the treadmill walking, just as Dr. Dietzek advised."

She said that each day after the procedure, she spent about 40 minutes walking on the treadmill. "This was more than the recommended 15 to 20 minutes per day for four days a week, but I felt great so I did a little extra. The only day I had any discomfort was the day after the procedure. I felt a little achy and used the recommended pain reliever. After that I had no pain.

"I am thrilled with the recovery for this! I was able to go back to work the next day, I am able to do daily exercise, and I don't have to wear compression stockings. Because it's been less than a week, since the procedure I have only seen a slight difference in the appearance of my varicose veins, but I understand it will take about a full week to see the results."

ADVERSE EFFECTS

Dr. Mackay has had only one complaint about the procedure.

"I've had one patient who had some discomfort. She had zero pain in the first two days post-op, but on the third day she had some pain around the knee. When I discussed it with some of the VenaSeal people, they said they saw a few cases of this and they are attributing it to phlebitis.

"The pain passed quickly. We had her take anti-inflammatories. That's why I wonder if compression stockings wouldn't help people like that. If she had worn stockings, she might never have had the discomfort.

"It would be a preventative thing. I'll make that decision over time if I see it more often. Then I will consider asking them to wear the stockings, at least for a few days initially.

"One of the more recent ones we did on the post-op scan showed some abnormality at the junction, but it was just glue and not really a thrombosis. You can tell by looking at a thrombosis because it is very echolucent. This was more echogenic.

Another concern might be about an allergenic reaction, but he said he has never seen one. "If a patient has ever had a reaction to the acrylic they use in nail polish, that might be a reason to avoid this procedure."

CONCLUSION

This next-generation VenaSeal closure system is just the newest way of closing veins, but it has virtually no pain, bruising or the danger of nerve damage associated with it, and most people may not need to wear compression stockings.

Today's thermal energy procedures use heat to close the vein, and the intense heat requires a larger volume of numbing medication, which is delivered through numerous needle sticks. These injections may cause pain and bruising after the procedure.

He said the procedure appeals to patients who are needle phobic, and the numbing needle sticks involved with thermal procedures create very high anxiety. So the idea of one or two needle sticks to numb the area is appealing.

"Of course, right now without insurance reimbursement, patients are going to have to be willing to pay for the VenaSeal option," Dr. Mackay said. "Someday, if we get reimbursed on par with RF, laser and the other options, its acceptance will just depend on how we present it to our patients." **VTN**

ACP continues to advance venous education at 29th Annual Congress

By Michael Armitage

The ACP remains at the forefront of venous related education with the recently held 29th Annual Congress, Nov.12-15, 2015, at the Hilton Bonnet Creek in Orlando, Fla.

This past November, the American College of Phlebology (ACP) hosted what has become the largest and most comprehensive meeting dedicated to venous and lymphatic disorders in the United States. Under the direction of Program Co-Chairs Lisa Amatangelo, MD, RVT, FACPh, and Melvin Rosenblatt, MD, FACPh, the scientific program set the standard with innovative and engaging content, respected faculty from around the world and opportunities for all levels of skill and knowledge.

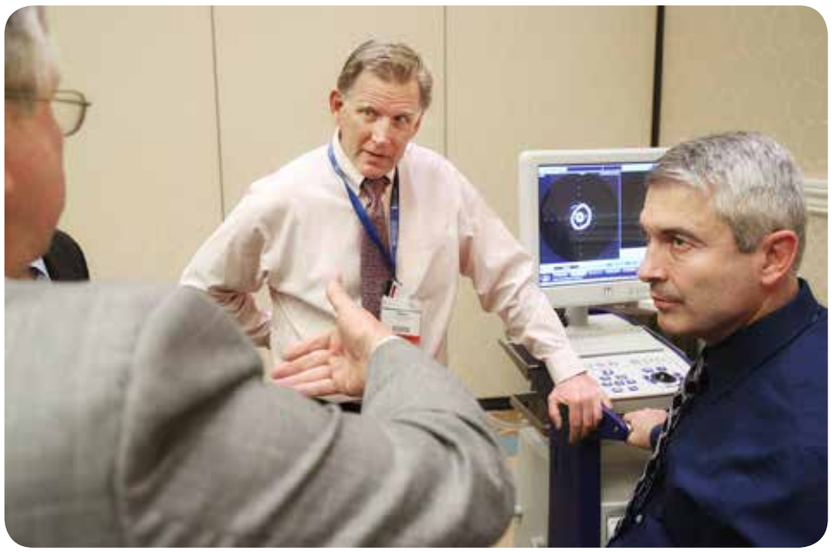
In addition to cutting-edge content, the meeting remains the largest of its kind in the United States, drawing 1,367 total attendees, which includes 998 registrants, more than 100 faculty and 78 exhibiting companies and organizations.

"The 2015 Annual Congress was a tremendous success by any standard," ACP President Mark Forrestal, MD, FACPh, said. "I have been coming to the ACP Congress for a long time now and this year was the best yet. The Program Committee, volunteers and staff made this the premier meeting in vein care."

Program highlights focused on interactivity with hands-on workshops in sclerotherapy, compression, non-thermal saphenous vein treatments and superficial venous imaging. Additional special interest sessions and pre-Congress tracks allowed attendees to target their personal education goals with topics covering basic phlebology, ultrasound, practice management, aesthetics and advanced phlebology & deep veins.

Dr. Amatangelo said the Program Committee developed a program that built on last year's successful approach: allow for as much interaction with faculty as possible. "Our aim has always been to provide attendees with the tools that they need to improve the standard of care in their practices."

Along with the scientific sessions, the Annual Congress also presented sessions to help providers manage insurance challenges, understand the literature in venous disease, deal with ethical challenges and learn about credentialing and accreditation.



SPECIAL EVENTS

The Annual Congress curriculum was challenging, but the sunny atmosphere of Orlando provided a relaxed backdrop for networking and engaging with colleagues.

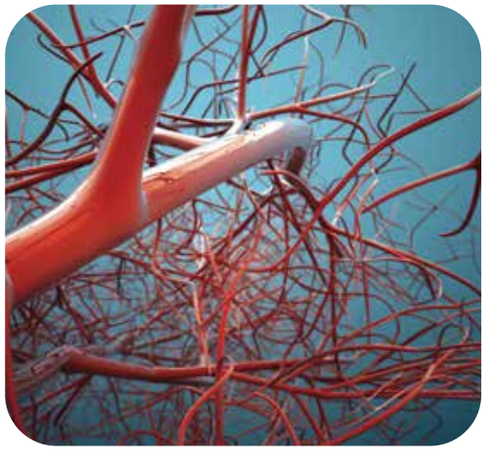
The 9th Annual ACP Foundation (ACPF) Golf Outing kicked off the event on Wednesday with 65 players, representing vein care and industry, all with the goal of raising money for the ACP Foundation. One of the most successful events for the Foundation, the Golf Outing raised more than $50,000 for venous related research and education.

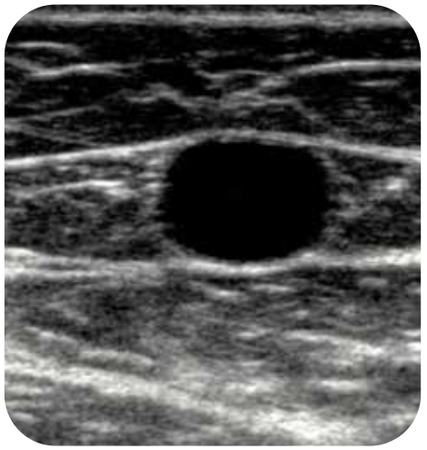
On Thursday, the inaugural ACPF Fun Run & Walk saw 95 runners participate in a friendly 5k dash around the beautifully manicured grounds at the Hilton Bonnet Creek.

In addition to camaraderie and exercise, the event raised more than $20,000.

The Foundation also raised another $50,000 through the Silent Auction, which was held onsite all three days of the conference. Attendees could bid on more than 100 items, ranging from medical devices and services to vacations to sports memorabilia.

For those not at this historic meeting, the recorded content from all three and a half days is available on the ACP's Online Education Center at **education.phlebology.org**. And, be sure to mark your calendars for the 30th Annual Congress – Nov. 3-6 at the Anaheim Marriott in Anaheim, Calif. **VTN**





the premier association for vein care professionals.

The American College of Phlebology (ACP) is comprised of more than 2,000 physicians and allied health care professionals, who are setting the pace and direction for growth in the field of vein care. The ACP offers members advocacy, continuing education and training in the latest procedures with the goal of improving standards and the quality of patient care.

If you treat or have an interest in venous and lymphatic disease, the ACP is an unequivocal resource for your practice.

together we thrive

- continuing education
- latest news & information
- clinical guidelines
- practice management resources
- improved patient outcomes
- member advocacy

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Get more information on how to join by visiting www.phlebology.org or by calling 510.346.6800

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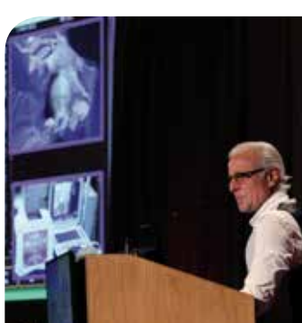

The 14th annual International Vein Congress delivers exciting, cutting edge venous education to vascular surgeons, interventional radiologists, and cardiologists. Live procedures, case studies, and the interactive V2 Symposium are just a few of the reasons that venous specialists attend IVC annually.

Learn from renowned faculty, including Dr. Seshadi Raju, one of the original pioneers in venous stenting.

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FUJIFILM's new VisualSonics offers UHF US system for clinic settings

FUJIFILM VisualSonics, part of FUJIFILM SonoSite, won the CE Mark and is launching the Vevo MD, what the company calls "the world's first ultra-high frequency (UHF) clinical ultrasound system."

The big deal is that the Vevo MD comes with transducers that run at frequencies up to 70 MHz. Typically, clinical ultrasound gets up to about 15 MHz.

With the higher frequencies comes a higher spatial resolution, but a substantial decrease in the penetration depth. This should allow for spotting and visualizing small objects within the body such as nerves, vasculature just below the skin, the skin itself, and perhaps intraoperatively to help avoid damaging fragile tissues.

The UHF ultrasound produces images at up to 30 micrometer resolution, which may open up a whole new set of things for docs to look at that were previously ignored due to a lack of appropriate imaging.

READ MORE: http://www.medgadget.com/2016/01/vevo-md-first-ultra-high-frequency-clinical-ultrasound-from-fujifilm-sonosite.html?trendmd-shared=0

Acelity acquires Snap system

Acelity, looking to accelerate its plans for a disposable negative-pressure wound therapy, has acquired the Snap portable NPWT device from Spiracur for an undisclosed amount.

San Antonio, Texas-based Acelity, which is preparing for an initial public offering that could bring up to $1 billion, said the Snap system is designed to treat hard-to-heal wounds with a portable, unpowered device.

"The addition of the Snap system complements our existing suite of clinically-proven products that speed healing and reduce costs to health systems around the world," President and CEO Joe Woody said. "We will continue to develop and enhance our offerings through innovation and acquisitions to remain at the forefront of healing solutions. VTN

READ MORE: acelity.com

For additional Product News, see Page 31

CoolSculpting is a pain-free way to get rid of double chin

By Melanie Petro, MD

Fat reduction has always been a surgical procedure. There are many reasons that surgery is just not an option for some people. CoolSculpting, a pain-free, completely non-invasive procedure is perfect for those who do not want to use their vacation days for recovery time. A patient can sit for a couple hours and have their fat frozen then return home or to work and their family, friends and coworkers will never know.

CoolSculpting kills fat cells by dropping the temperature to just above freezing causing the fat cells to crystallize and die. This does not cause any damage to the skin.

The story of how CoolSculpting was developed is almost as interesting as the results of the treatment itself.

The idea behind CoolSculpting was the brainchild of two doctors, Dr. Rox Anderson and Dr. Dieter Manstein, affiliated with Harvard Medical School and Massachusetts General Hospital. The two doctors were both familiar with a strange phenomenon known as "popsicle panniculitis," which has to do with the loss of cheek fat that occurs while sucking on a frozen popsicle.

With trial and error, Drs. Anderson and Manstein discovered that fat is much more sensitive to cold than nerves, skin, muscle and other body tissue. The doctors were able to pinpoint a precise temperature that served to maximize the destruction of fat, while leaving all of the other structures unharmed, and thus the concept of cryoliposis was created.

When fat cells are exposed to extreme cold, they become terminally injured and gradually die. There is absolutely no increase in either cholesterol levels or lipid levels in the blood as a result.

It is important to consider who the ideal patient is for this treatment. It is perfectly suited for someone with an area that is just too difficult to change despite diet and exercise.

The size of the area that can be treated is determined by the size of the handpiece, and the most recent development is the "CoolMini," which was developed to treat the "double chin," an area, everyone with one is concerned about.

A "double chin" makes thin people look fat, young people look old and is certainly not "selfie" friendly. In an age where pictures are more prolific than ever, people are seeing themselves more than most of us have ever wanted to. We cannot escape our flaws – especially facial flaws as people tend to snap pictures and tag us on a whim.

A "double chin" patient is very aware of their appearance from virtually every angle. They look "up and over," and do all they can not to see the excess fatty tissue or the shadow it creates in a picture.

CoolMini is the perfect technology at the perfect time. We are finding new uses for the smaller applicator every day, and now have two machines. I am always happy to give options to patients who otherwise may not be able to change the things that bother them the very most. Liposuction of the neck, and certainly body, requires a skin turgor that many patients just do not have.

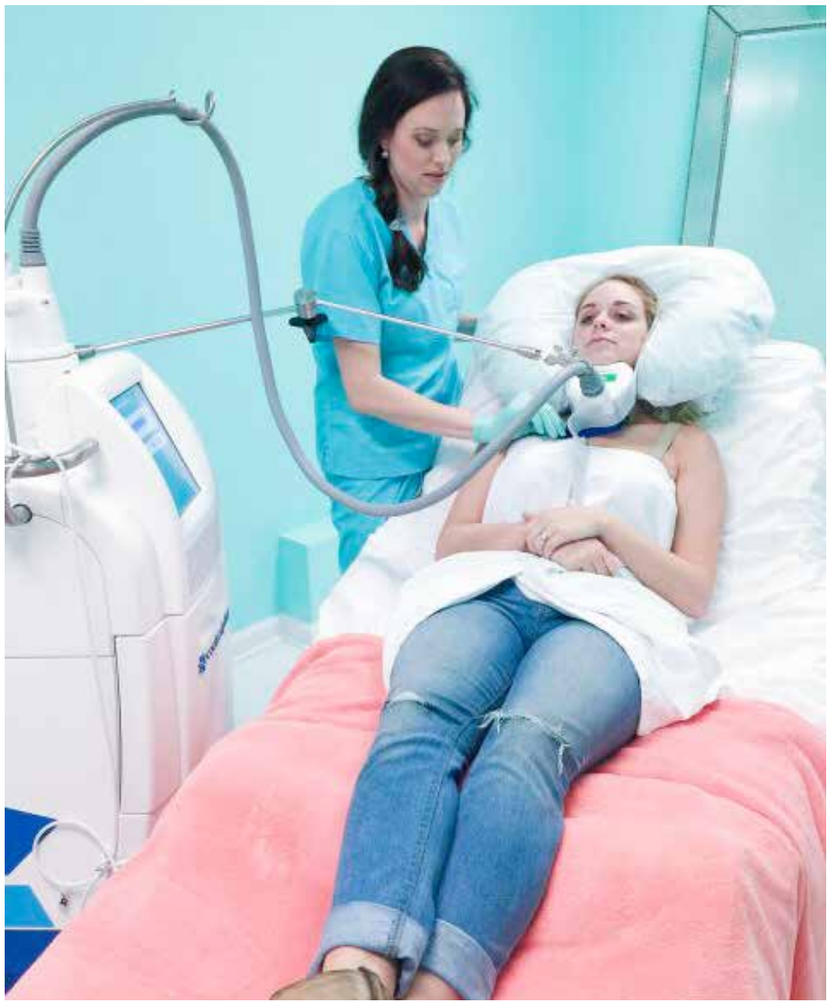
There is no greater joy than helping you feel the best you can about how you look, as it certainly translates into how you feel about everything. Boosting self-confidence for anyone in anyway is more powerful than absolutely anything.

VEAZEY REINDL

"I have always been self-conscious about my double chin," Veazey Reindl said. "Even on my wedding day when I was at my thinnest, I worried during my entire photo shoot that I was posing at an angle where my double chin would be visible. When the photographer would suggest I look down in photos, I would refuse. In my case, this area is genetic – no matter how much I exercised or dieted, I always had the same little fat pocket right under my chin. I honestly thought learning to pose where my double chin was not captured in photographs was my only solution.

"When Dr. Petro suggested I try CoolSculpting for this area, I was hesitant, but because she explained there would be no downtime and no pain I decided to give it a try.

"Now that it has been two months since the procedure, and I can see the results, I



Dr. Petro performs the CoolSculpting procedure on Veazey Reindl.

KATIE PILKERTON (above) before and after CoolSculpting

VEAZEY REINDL (right) before and after CoolSculpting

Photos courtesy of Petro Cosmetic Surgery

would suggest this to everyone who worries about this area. My husband even noticed! Now I don't have to make sure my face is tilted upwards in pictures, and I feel so much more confident about my overall appearance.

KATIE PILKERTON

For as long as she could remember, Katie Pilkerton said her biggest insecurity has always been her double chin.

"My friends always laugh when we take photos and I immediately pose to my "good angle. I have trained myself to only take photos a certain way because of my profile. I have a pocket of fat directly under my chin which kept me from seeing my jawline. I used to think I needed a chin implant – something to make my chin and neck not look like one!

"When Dr. Petro suggested CoolSculpting, I was very excited about the results I was going to get after hearing about the procedure and viewing photos."

Pinkerton said that the treatment was not uncomfortable at all. "There is a minimal pull at the area, but that feeling fades after five minutes. You sit with the applicator on for 1 hour and then you are done. I was able to watch a short Netflix movie while having it done. I was completely relaxed and comfortable the whole time. I love the fact that there was no downtime! I did not bruise and I had extremely minimal swelling.

"Every day I saw a noticeable difference. Now I can snap a photo at any angle! People are asking, 'Have you lost weight? You look great.' I take photos and see myself in the mirror and now I have a jawline. I am much more comfortable with the shape of my face as a whole. I would definitely refer this procedure to any one who is uncomfortable with the "double chin." **VTN**

***Melanie L. Petro, MD**, is board certified in facial plastic and reconstructive surgery, otolaryngology, cosmetic surgery, and certified by the American Board of Venous and Lymphatic Medicine. She practices aesthetics and phlebology at Petro Cosmetic Surgery and Alabama Vascular and Vein Center and they share AAAHC accredited surgical center. She may be contacted through petromd.com.*

FDA OKs Merz hand dermal filler

The U.S. Food and Drug Administration (FDA) has approved Merz North America's injectable dermal filler Radiesse for hand augmentation to correct volume loss in the dorsum of the hands. Radiesse is an opaque dermal filler composed of synthetic calcium hydroxylapatite microspheres suspended in a water-based gel carrier.

"Radiesse provides an immediate volumizing effect and can help to reduce the prominence of tendons and veins in the hands, delivering smooth, natural-looking results that can last up to 1 year," a company spokesman said.

It was first approved in the United States in 2001, and has since had subsequent approvals, including for correction of nasolabial folds in 2006. It has been approved in 52 countries for off-label hand augmentation. **VTN**

Treatment options for acne and acne scars

By Eric S. Schweiger, MD

More than 50 million people have acne in the United States, yet it is still one of the only skin issues that the majority of the population tries to tackle alone. Many acne sufferers will either pick at their skin or self-treat it with products they find in drugstores, online or through an infomercial, and the results can be sub-optimal.

My job as a dermatologist is to not only help my patients achieve clear skin as quickly as possible, but to also make sure their skin remains clear in the future. The best acne treatments include a combination of therapies and is certainly not a one-size fits all approach. Treating acne has become a true combination of art and science. At Schweiger Dermatology Group, we take a multi-pronged approach and make sure to treat the patient, not just the pimple.

COMBINATION MEDICAL THERAPY

First line treatments for our acne patients is always medical therapy, and usually a combination of several different prescription medications. We typically use a product containing benzoyl peroxide and clindamycin in the morning. To minimize bacterial resistance, we only use clindamycin in combination with benzoyl peroxide whenever possible. This product is often combined with a retinoid in the evening. To minimize irritation we will usually limit retinoid use to three times per week. For those who can tolerate it, I like to alternate the retinoid with an OTC salicylic-glycolic acid pad in the evening.

For moderate acne we will add an oral medication on their first visit. I do not believe a patient must fail topical treatments to start oral therapy. In addition, I believe that isotretinoin is not used as much as it needs to be, and for severe acne patients with any evidence of scarring this will always be discussed and considered early on in treatment. Finally, we encourage our patients to come in for intralesional cortisone injections whenever flaring.

IN-OFFICE TREATMENT

Many of our patients will also do in-office treatments to maximize results and achieve clearance faster. We have had impressive results with Photodynamic Therapy, or PDT, for the treatment of acne.

PDT uses blue light along with a light-sensitizing medication, called aminolevulinic acid, to target acne. After the medication is applied to the skin and allowed to absorb, the blue LED light is then used to activate the medication.

This process not only kills the acne-causing bacteria, but it decreases excess sebum production on the skin. PDT is one of the few acne treatments that can actually decrease the activity of the sebaceous glands and lead to semi-permanent results. There is minimal downtime with PDT, and most patients will do two to three treatments.

EATING RIGHT FOR CLEAR SKIN

Many patients nowadays want to know what else they can do at home to help combat acne.

A favorite topic that frequently comes up is diet. While changing a patient's diet alone may not result in clear skin, it can be a part of the acne-fighting puzzle. It also can make acne patients feel empowered, so I included an entire chapter in my book "100 Acne Tips & Solutions" devoted to the new findings on diet and acne. In a study in "The Archives of Dermatology"[1] researchers looked at 3,600 adolescents and found that the overweight or obese teens had more potential to develop acne than the teens of normal weight. This was especially true for the young women.

Researchers think androgens might be to blame for the link between being overweight and acne, as androgen production is brought on by obesity. More evidence that diet may play into acne management is a report from the American Academy of Dermatology[2] that found a low-carbohydrate, low-glycemic diet, like the South Beach Diet, may in fact help reduce acne. In the study, 80 percent of South Beach Diet followers noticed a marked improvement in their skin within three months of beginning the diet, while 91 percent of them said they decreased the acne medication they were taking after starting the diet. During in-office consultations, our providers are encouraged to discuss how to make healthy food choices with their acne patients.

TREATING ACNE SCARS F.A.S.T.

At Schweiger Dermatology Group, we utilize a treatment I developed called F.A.S.T. — Focal Acne Scar Treatment — for treating pitted acne scars. F.A.S.T. utilizes the same fractional CO_2 laser as other acne scar removal procedures, but it focuses on just the scars, leaving normal skin nearby untreated. This results in high efficacy with faster healing.

All of our F.A.S.T. patients receive an aggressive erbium fractionated laser treatment 4-6 weeks post fractional CO2 treatment. This second treatment enhances the results and reduces any residual dyspigmentation from the ablative treatment. Results vary, but typically patients see 30 percent to 70 percent improvement after their one F.A.S.T. treatment cycle. Full findings from F.A.S.T. were published in the *Journal of Drugs in Dermatology*[3]. VTN

Eric Schweiger, MD, FAAD, *is the founder and C.E.O. of Schweiger Dermatology Group (SDG), a cosmetic and medical dermatology practice in the New York metro area. The mission of Schweiger Dermatology Group is to make high-quality dermatology services easily accessible to people around the greater New York City area. Today, SDG provides dermatology care to more than 150,000 patients annually.*

SOURCES

[1]A Population-Based Study of Acne and Body Mass Index in Adolescents

Halvorsen et al. Arch Dermatol.2012; 148: 131-132.

[2]American Academy of Dermatology

Source reference: Rouhani P, et al "Acne improves with a popular, low glycemic diet from South Beach" J Am Acad Dermatol 2009; 60(suppl): Abstract P706.

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Focal Acne Scar Treatment (FAST), a new approach to atrophic acne scars: a case series.

Schweiger ES, Sundick L.

Healthcare growth jumps 5.5% in 2014

Healthcare spending grew at a rate of 5.5 percent in 2014, reaching $3 trillion or at an equivalent of $9,523 per person.

The study was conducted by the Office of the Actuary at the Centers for Medicare & Medicaid Services (CMS) and published in *Health Affairs.*

In 2013, by contrast, healthcare spending grew at a much lower pace, 2.9 percent. The report agrees with recent warnings from the federal government that spending rates would rebound in the coming years from historical lows.

Overall healthcare spending as a portion of the U.S. gross domestic product increased from 17.3 percent to 17.5 percent.

Faster growth was attributed to coverage expansion associated with the Affordable Care Act and faster growth in prescription drug spending. VTN

ArtVenture Medical testing new version of EOS Gen II

ArtVentive Medical Group Inc. has conducted its first animal study of its next generation of the ArtVentive Endoluminal Occlusion System (EOS Gen II). The EOS is designed for use in the peripheral vasculature and offers immediate and permanent vessel occlusion in arterial and venous settings.

The ArtVentive EOS is a catheter-based, self-expandable device, which facilitates permanent and immediate occlusion of peripheral vessels. The ArtVentive EOS is designed to serve as a safe and reliable alternative to major surgery in certain cases.

"This new generation of the ArtVentive EOS peripheral device represents a significant step forward in the EOS technology and design, offering profile reductions, reversibility, enhanced control over deployment and the opportunity to advance into new indications. These advancements allow for the development of devices of varying diameters – with the ability to treat smaller and larger vessel sizes – necessary to meet growing market demands," President and CTO Leon Rudakov, PhD, said. "The first EOS Gen II animal study produced excellent clinical results, demonstrating the safety and effectiveness of this advanced embolization therapy."

ArtVentive Medical Group Inc., with corporate headquarters in Carlsbad, Calif., is a, multi-faceted medical device company focused on developing, manufacturing and marketing globally a family of devices featuring the ArtVentive EOS. VTN

READ MORE:
artventivemedical.com

Argon Medical buys 3 vascular products from Rex

Argon Medical Devices Inc. has completed the acquisition of three vascular products from Rex Medical LLC., including: the OptionELITE Retrievable Vena Cava Filter, CLEANER Rotational Thrombectomy System, and UltraStream Chronic Hemodialysis Catheter.

All three product families have displayed significant growth under Argon's leadership. The addition of these safe and proven technologies to Argon Medical's portfolio firmly establishes the company's position in the treatment of venous disease.

The acquisition includes all associated intellectual property related to these products, adding to a strong existing interventional portfolio which will enable Argon to further access existing markets in addition to penetrating new segments.

"Acquiring these differentiated technologies uniquely positions Argon Medical Devices as a market leader in the minimally invasive vascular therapy category," said George A. Leondis, president of Argon Medical Devices. "Building on the momentum already established as a licensee of these products, we are further focusing our efforts on the venous disease space, providing safe and effective tools for venous therapy, and strengthening our growth in strategic global markets."

According to the U.S. Surgeon General, between 350,000 and 600,000 people each year in the United States are affected by blood clots and between 100,000 and 180,000 people die of pulmonary embolism each year.

The acquisition further enables Argon Medical Devices to offer customers comprehensive procedure-based solutions. The OptionELITE is the only IVC filter with FDA clearance for delivery via the popliteal vein, the same access site through which DVT treatment in the legs is commonly initiated.

CLEANER is the only wall-contacting rotational thrombectomy system with FDA clearance for use in the peripheral vasculature, and also may be delivered via the popliteal vein to enable filter placement and DVT treatment through a single access site. This technique eliminates significant procedural time compared to other techniques and reduces patient trauma

Argon manufactures medical products and devices for interventional radiology, vascular surgery, interventional cardiology, critical care and oncology procedures worldwide. VTN

READ MORE: argonmedical.com

FDA OKs Finacea (azelaic acid) for rosacea treatment

The U.S. Food and Drug Administration (FDA) has approved topical azelaic acid 15 percent foam (Finacea, Bayer Healthcare) for treatment of the inflammatory papules and pustules of mild to moderate rosacea..

The approval is based on results from two pivotal vehicle-controlled 12-week clinical trials examining the efficacy and safety of twice-daily application of azelaic acid in more than 1,300 individuals 19 to 92 years old with papulopustular rosacea.

In both trials, active treatment with azelaic acid foam led to a higher Investigator's Global Assessment success rate compared with vehicle control (32.1 percent vs 23.4 percent in trial 1 and 43.4 percent vs 32.5 percent in trial 2).

Both trials also demonstrated a greater reduction in the mean nominal change of inflammatory lesion count from baseline to end of treatment at week 12 with active treatment (–13.2 vs –10.3 in trial 1 and –13.3 vs –9.5 in trial 2).

The most common adverse reactions with azelaic acid (≥0.5 percent) are local application site pain (6.2 percent), pruritus (2.5 percent), dryness (0.7 percent), and erythema (0.7 percent), the company stated.

A Bayer Healthcare spokesman said there have been isolated reports of hypopigmentation after use of azelaic acid. Because azelaic acid has not been well studied in patients with dark complexion, they advise that clinicians monitor these patients for early signs of hypopigmentation.

Azelaic acid may cause irritation of the eyes, and contact with the eyes, mouth or other mucous membranes should be avoided.

The propellant in Finacea foam is flammable, and patients should be instructed to avoid fire, flame and smoking during and immediately after application. The package should not be punctured or incinerated or exposed to heat.

Finacea will be available by prescription beginning in September. VTN

Report analyzes new P.A.D./PVD pipeline insights

Research and Markets has added the report "Peripheral Arterial Disease (P.A.D.)/ Pulmonary Vascular Disease (PVD)-Pipeline Insights" to its offering.

The report provides in-depth analysis of the pipeline assets across the P.A.D./PVD marketplace. The main objective of this report to track competitor pipeline molecules, related research activities, technology, collaborations, in-licensing and out-licensing deals. It helps to identify emerging players with potentially strong product information and create effective counter-strategies to gain competitive advantage.

It covers pipeline molecules at various stages of development such as pre-registration phase, clinical phases (Phase III, Phase II and Phase I), pre-clinical and discovery phases. The report also provides P.A.D./PVD related therapeutic assessments by molecule type, route of administration, monotherapy and combination products. The report also highlights the discontinued and inactive projects in pipeline for Peripheral Arterial Disease (PAD)/ Pulmonary Vascular Disease (PVD).

The scope of the report:

- The report provides a P.A.D./PVD landscape across the globe.
- The report provides drug profiles which includes product description, MOA, licensors and collaborators, technology, development partner and chemical information.
- Coverage of the P.A.D./PVD pipeline on the basis of target, MOA, route of administration, technology involved and molecule type.
- The report reviews key players involved in the therapeutics development for P.A.D./PVD and also provide company profiling.
- Pipeline products coverage based on various stages of development from NDA filings to discovery.
- Provides pipeline assessment by monotherapy and combination therapy products, stage of development and molecule type. VTN

READ MORE:
researchandmarkets.com/research/gf4vg3/peripheral

2016 venous thromboembolism report offered

A new report provides information on the therapeutic development for venous thromboembolism, complete with comparative analysis at various stages, therapeutics assessment by drug target, mechanism of action (MoA), route of administration (RoA) and molecule type, along with latest updates, and featured news and press releases.

The Research and Markets report, "Venous Thromboembolism - Pipeline Review, H2 2015" also reviews key players involved in the therapeutic development for Venous Thromboembolism and special features on late-stage and discontinued projects.

The report enhances decision making capabilities and help to create effective counter strategies to gain competitive advantage. It strengthens R&D pipelines by identifying new targets and MOAs to produce first-in-class and best-in-class products. VTN

READ MORE:
researchandmarkets.com/research/6hcpkv/venous

Prior authorization freely automated in CoverMyMeds

Prior authorization (PA) season is underway.

That means new health plans, medication formulary changes and prescription renewals for patients. With providers and their staff already spending 20 hours per week on prior authorizations, you can expect a significant increase in administrative waste.

CoverMyMeds can alleviate this requirement. More than 400,000 providers already use CoverMyMeds to save up to 15 minutes per PA request, at no cost. Now is the time to implement electronic prior authorization (ePA) within your health system.

CoverMyMeds seamlessly integrates with EHR systems to provide hospitals and prescribers with ePA functionality at the point of prescribing. VTN

READ MORE:
covermymeds.com/main/

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