

U.S. Markets for Vascular Access Devices and Accessories



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iData Research
INTELLIGENCE BEHIND THE DATA

U.S. MARKETS FOR VASCULAR ACCESS DEVICES AND ACCESSORIES

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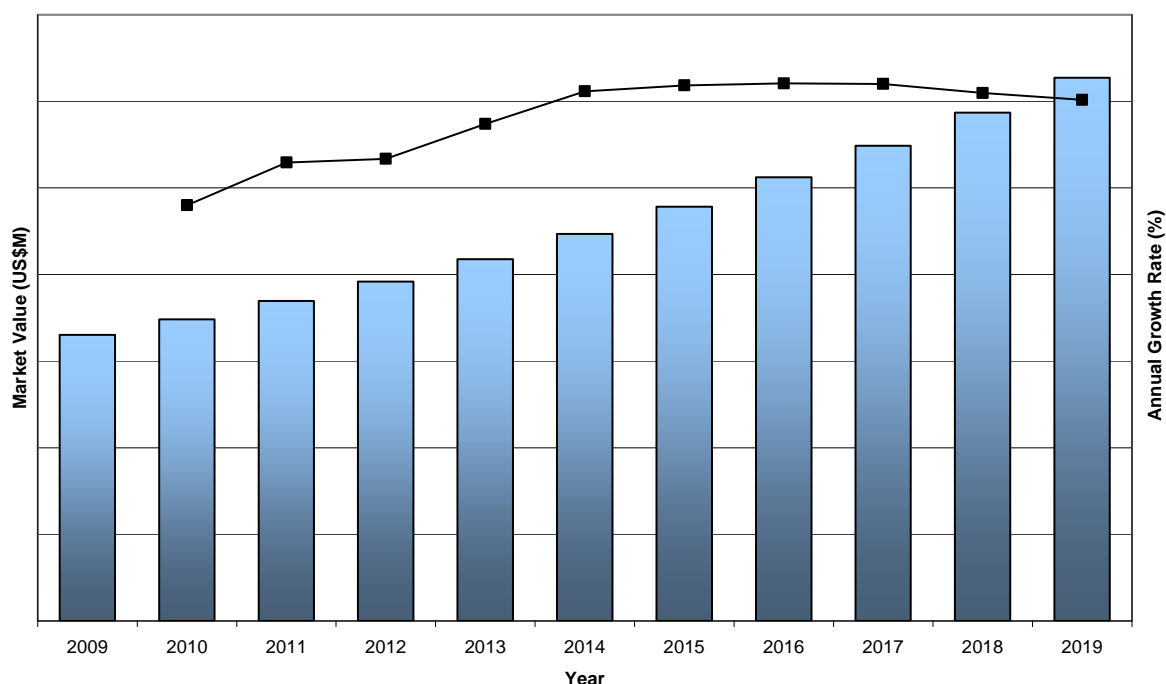
EXECUTIVE SUMMARY

1.1 Total Vascular Access Device Market

In 2012, the U.S. market for vascular access devices and accessories was nearly \$4 billion, a 6.1% increase over the previous year.

The vascular access device market includes implantable ports, port or Huber needles, central venous catheters (CVCs), dialysis catheters, peripherally inserted central catheters (PICCs), midlines and peripheral intravenous catheters (PIVCs). The market also includes hand carried and portable ultrasound systems, ultrasound guidance systems used for vascular access, catheter securement devices and syringes and needles. The overall market for vascular access devices is expected to grow at high single digits over the forecast period, exceeding \$6 billion by 2019.

Chart 1-1: Total Vascular Access Device Market, U.S., 2009 – 2019



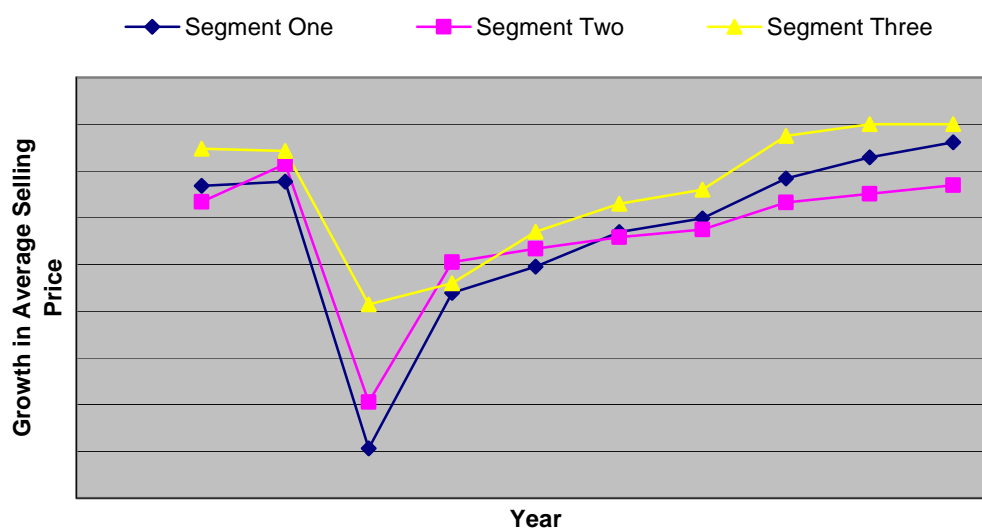
Source: iData Research Inc.

1.2 Implantable Port Market

Power-injectable implantable ports are quickly becoming the standard of care in the United States; especially in hospital settings where patients are more likely to require a computed tomography (CT) scan.

When implantable ports are used in the United States, many physicians are erring on the side of caution and choose to place a power-injectable port. The reasoning for this is that it is more convenient to place a more expensive power-injectable port at the onset in the event that a CT scan is required rather than removing a conventional implantable port and placing a power-injectable port later. Only having to insert one implantable port lessens the chance of a patient developing a bloodstream infection or a needlestick injury occurring, and frees up more nurse and physicians time to complete other tasks. Power-injectable ports have been decreasing in price for the past several years, but recently changes have been even more drastic, with price decreases normally seen in one to two years occurring in three to six months. Prices are decreasing as companies attempt to maintain or expand their market as the market shifts to the use of power-injectable implantable ports almost exclusively. These dramatic decreases in price are causing the market to shift from conventional to power-injectable devices at an even faster rate.

Chart 1-2: Growth Trends in Average Selling Prices by Segment, Implantable Port Market, U.S., 2012



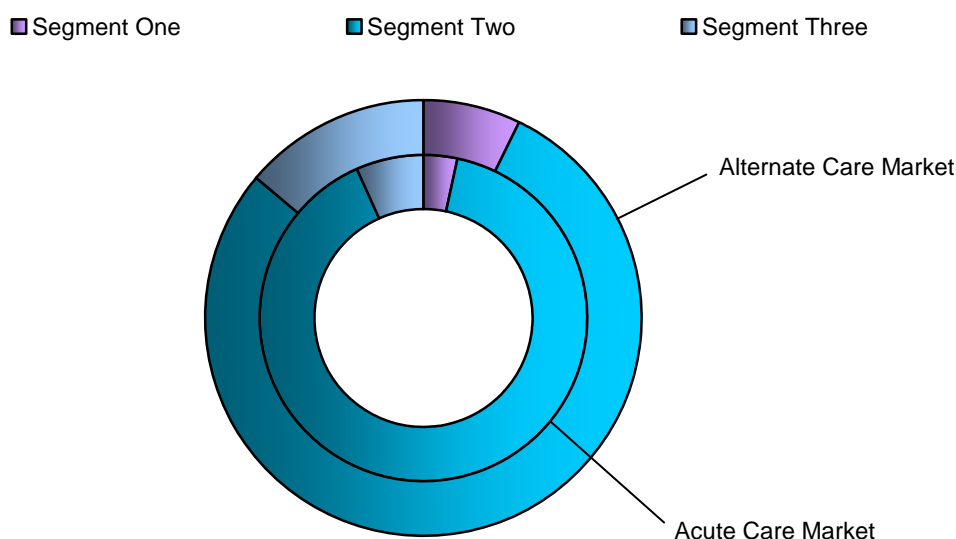
Source: iData Research Inc.

1.3 Port Needle Market

Port needles are undergoing a conversion to safety devices. In 2012, over 77% of all port needles sold in the U.S. were safety port needles.

Due to regulations from the Occupational Safety and Health Administration (OSHA), the market has been transitioning to the use of more safety port needles in an attempt to lessen the number of needlestick injuries across the United States. This transition to safety devices has been occurring more quickly in the acute care market setting because OSHA regulations are not as strictly enforced in alternate care sites. As a result, the decreases in the use of conventional port needles will not be as rapid in the alternate care segment. While complementary devices such as implantable ports are transitioning to a market where power-injectable devices are becoming the standard of care, this is not occurring in the port needle market. Because power-injectable port needles sell for a higher price than traditional port needles, it does not make sense economically to use a power-injectable port needle for the infusion of chemotherapy and other drugs or for simple blood draws. As the incidence of cancer increases, it is expected that the number of contrast medium injections will increase overall in the market but the market will not become a purely power-injectable port needle market.

Chart 1-3: Total Port Needle Market Value by Needle Type and Treatment Setting, U.S., 2012



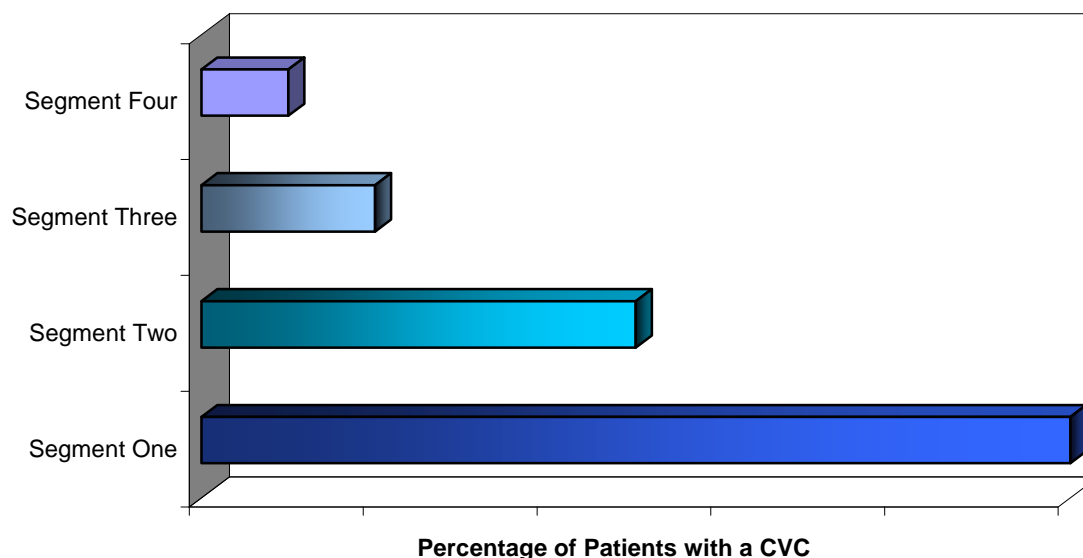
Source: iData Research Inc.

1.4 Central Venous Catheter Market

Antimicrobial central venous catheters (CVCs) are quickly becoming the standard device used in the United States because of concerns over catheter-related bloodstream infections. In 2012, almost 75% of the CVCs sold in the U.S. were either impregnated or antiseptic CVCs.

The use of central venous catheters (CVCs) in the U.S. varies greatly from setting to setting. In the neonatal intensive care unit (NICU), if you include arterial and venous umbilical catheters, 100% of the patients will have a CVC placed at some point during their stay. In intensive care units (ICUs) or critical care units (CCUs) approximately 50% of the patients there will use a central venous catheter. In emergency rooms (ER), around 10% to 20% of the patients will have a CVC placed. In high trauma ERs, they are more likely to place more CVCs and the average would be closer to 20%. In low trauma ERs that act as triage centers for bigger hospitals, the average is closer to 10%. Even though CVCs are being out competed in some instances by other devices such as peripherally inserted central catheters (PICCs), the advent of antimicrobial and antiseptic CVCs has the potential to increase their use of CVCs in all treatment settings.

Chart 1-4: Percentage of Patients with a CVC by Hospital Setting, Vascular Access Device Market, U.S., 2012



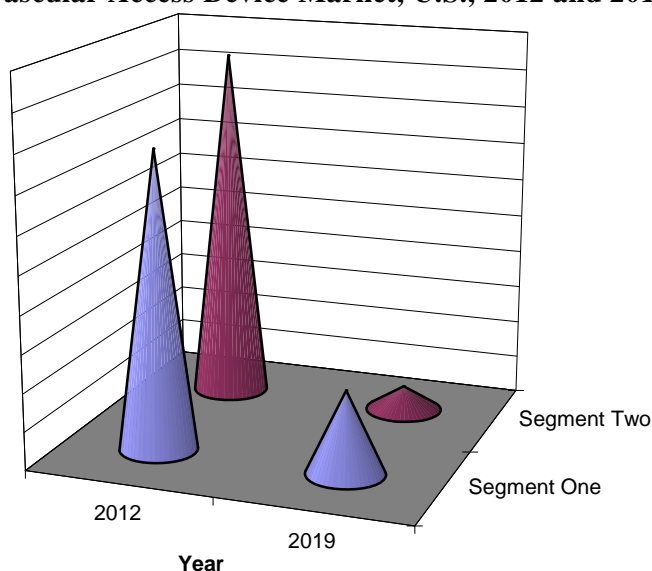
Source: iData Research Inc.

1.5 Peripherally Inserted Central Catheter and Midline Market

The U.S. PICC market is continuing its shift toward power-injectable devices exclusively. The rapid decrease in the price of these devices due to competitive and economic pressures is causing most of the growth in the market, as well as an increase in the overall patient population.

The market for power-injectable PICCs has grown rapidly over the last few years, and this trend is expected to continue. Historically, power-injectable PICCs were used with patients who had a high probability of receiving a CT scan. However, clinicians are now utilizing power-injectable PICCs for patients who could possibly require imaging in the future, and power-injectable PICCs are rapidly becoming the standard of care for patients in the United States. Manufacturers have lowered the ASP of power-injectable PICCs to drive the adoption rates and prices are approaching those of conventional PICCs. In addition, growth in the market for power-injectable PICCs has simultaneously increased the market for polyurethane PICCs, as power-injectable PICCs are predominantly constructed from polyurethane. However, silicone PICCs are still frequently used in pediatrics due to the material's softness and inertness. Midline or midterm catheters were previously less favorable in the U.S, but the advent of new device features and catheters that do not require the use of the modified Seldinger technique when being placed have helped the devices regain popularity. Midline catheters have a potential market of over 15 million placements just in the hospital segment alone and are expected to grow several magnitudes faster than the PICCs.

Chart 1-5: Power-Injectable and Conventional PICCs as a Percentage of Total Unit Sales, Vascular Access Device Market, U.S., 2012 and 2019



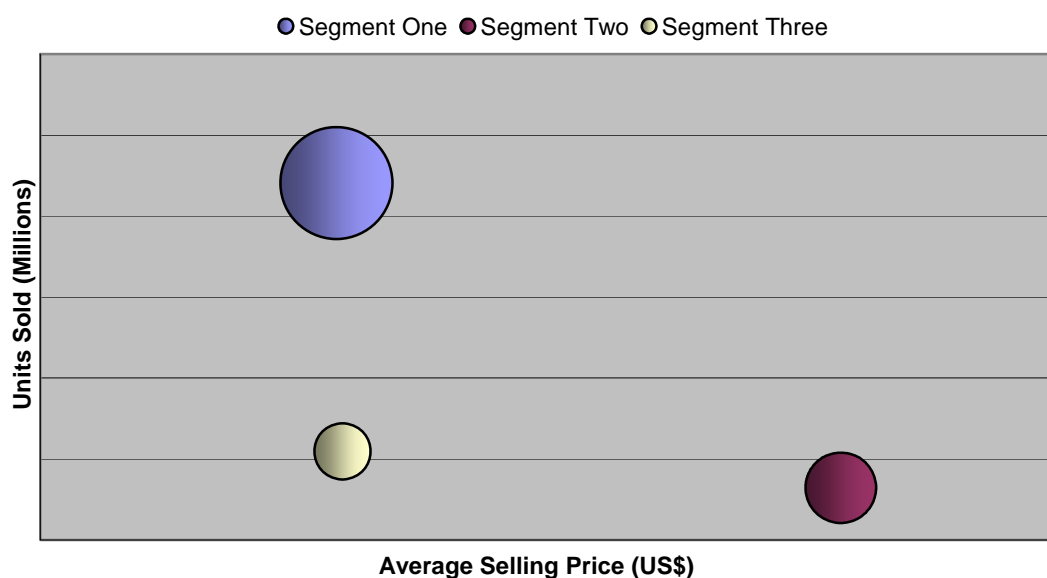
Source: iData Research Inc.

1.6 Peripheral Intravenous Catheter Market

In 2012, the closed system PIVC market accounted for over 10% of the total PIVC unit sales but because of their high prices compared to other safety PIVCs, they accounted for just under 24% of the total market value that year.

The closed system PIVC market is the most rapidly growing individual segment in the total U.S. PIVC market. This market is dominated by Becton Dickinson who has been the only company with a closed system safety PIVC for many years. This has allowed Becton Dickinson to keep prices high for closed system PIVCs due to lack of competitive pricing pressures and in 2011 a closed system PIVC sold for over twice the price of other types of safety PIVCs. However, companies such as Tangent Medical have recently received approval from the Food and Drug Administration (FDA) for their own closed system and their entry into the market has the potential to cause prices to start to decrease.

Chart 1-6: Total Safety PIVC Market by Segment, U.S., 2012



Note: The size of the bubble represents the market size.

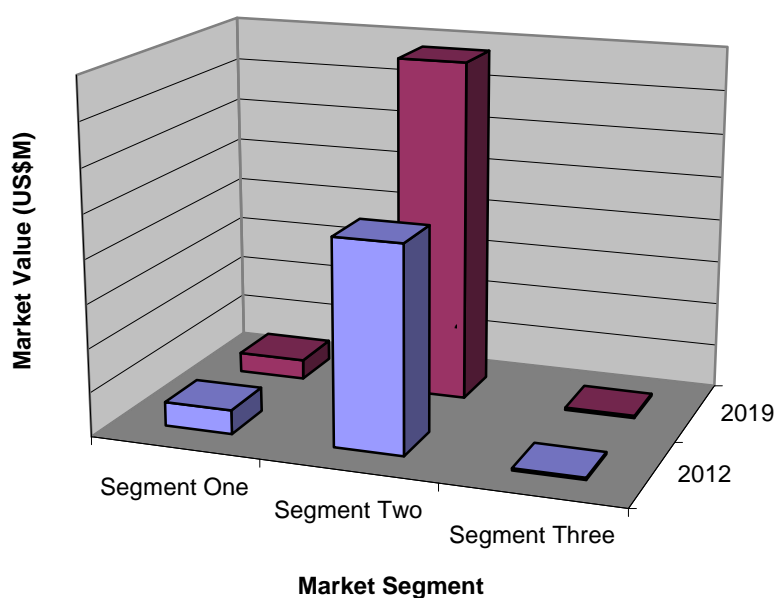
Source: iData Research Inc.

1.7 Dialysis Catheter Market

In 2012, 8.6% of all chronic dialysis catheters placed were antimicrobial chronic dialysis catheters and 6% of all dialysis catheters placed were antimicrobial. Since the introduction of antimicrobial dialysis catheters in 2007, the market has consistently grown at double-digit rates.

The dialysis catheter market is segmented into acute, chronic, antimicrobial and peritoneal dialysis catheters. The market for antimicrobial dialysis catheters is still relatively small in comparison to the equivalent market for CVCs; however, the antimicrobial dialysis catheter market is expected to surpass the latter by 2017. Two factors limiting market growth are the struggles facing manufacturers in making long-dwelling dialysis catheters with lasting antimicrobial effects, and the lack of long-term data on the efficacy of antimicrobial coatings on dialysis catheters. The use of peritoneal dialysis was going out of favor in the U.S. in previous years. However, because of the rise in home care treatments in the United States, peritoneal dialysis is expected to start to make somewhat of a resurgence by 2017. Peritoneal dialysis is easy and inexpensive to perform compared to hemodialysis, and has the added convenience of being able to performed overnight and at home, freeing up hospitals beds more quickly. Hemodialysis is a huge part of Medicare and Medicaid and the U.S. government is always looking for alternative treatments that lower costs so it is expected that peritoneal dialysis will eventually begin to be used more in hospitals as well.

Chart 1-7: Market Value by Segment, Dialysis Catheter Market, U.S., 2012 and 2019



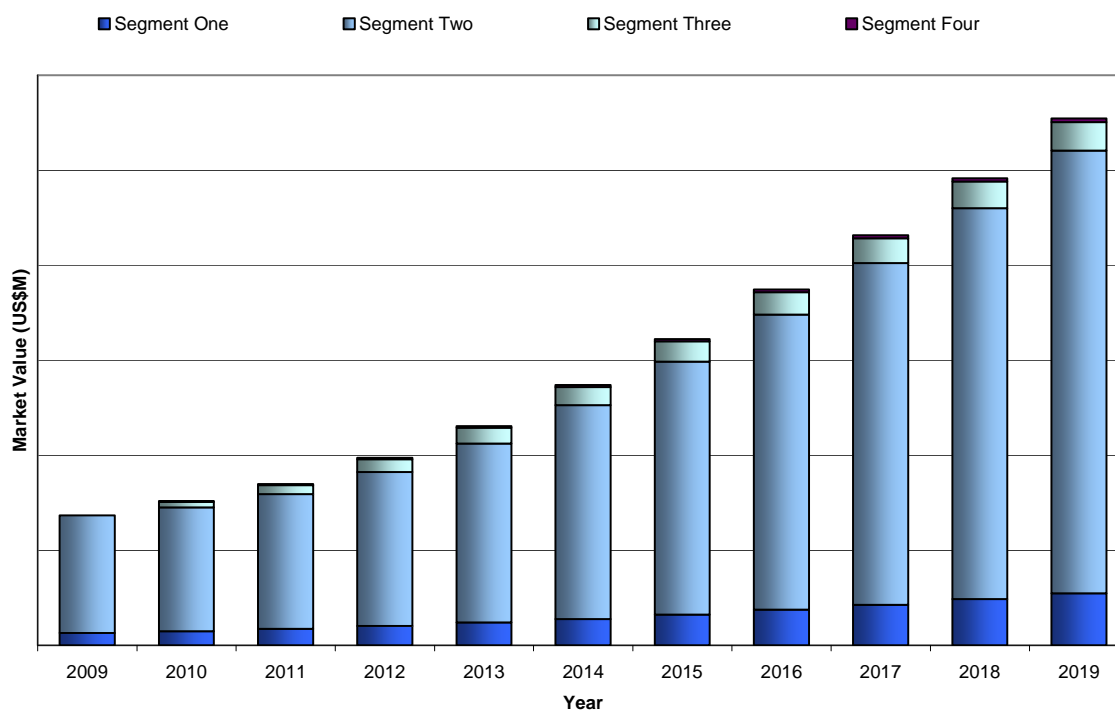
Source: iData Research Inc.

1.8 Ultrasound Vascular Access Devices and Accessories Market

In 2012, the market for ultrasound devices used in vascular access guidance continued to show strong growth, especially the hand held and portable ultrasound segment. These products incorporate electrocardiogram and infrared-based technologies in order to guide vascular access devices, such as PICCs and CVCs.

Ultrasound guidance for catheter placement procedures has been clinically proven to improve placement success rates and reduce catheter placement complications. Electrocardiogram-based (ECG) guidance for positioning catheter tips was a popular tool first in Europe, but was virtually non-existent in the United States until 2010. Teleflex Medical and C. R. Bard have products available that incorporate ultrasound with ECG allowing clinicians to position the catheter tip correctly in the superior vena cava. The market value, ASP and units sold of this potential tip location market are analyzed in this report within the context of the ultrasound vascular access equipment and accessories market.

Chart 1-8: Ultrasound for Vascular Access and Tip Location Market by Segment, U.S., 2007 – 2017



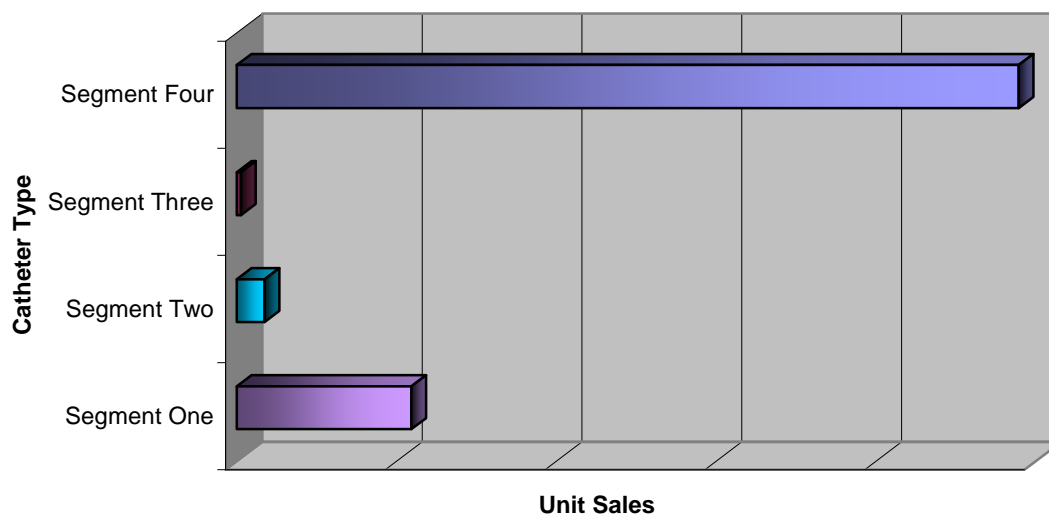
Source: iData Research Inc.

1.9 Catheter Securement Device Market

In 2012, manufactured catheter securement devices were used for securing 3.8% of all vascular access catheters.

There were over 330 million vascular access catheters sold in the United States in 2012 and each required a stabilization device to prevent catheter movement. These were primarily secured with tape and dressings, while CVCs and dialysis catheters were mainly secured with sutures. Manufactured catheter securement devices (MCSDs) provide alternatives to these methods. These devices have been proven to reduce catheter migration, pistoning and unscheduled restarts. While MCSDs are used for securing the majority of PICCs, their use with other vascular access catheters has been limited, but it is expected to grow in the future. There were over 315 million PIVCs sold in the U.S. in 2012 and these devices had no MCSD devices specifically made for their securement. However, if a company can develop a device for use with PIVCs that is also cost effective, the catheter securement device market will increase substantially in the future.

Chart 1-9: Total Catheter Securement Device Unit Sales by Segment, Vascular Access Device Market, U.S., 2012



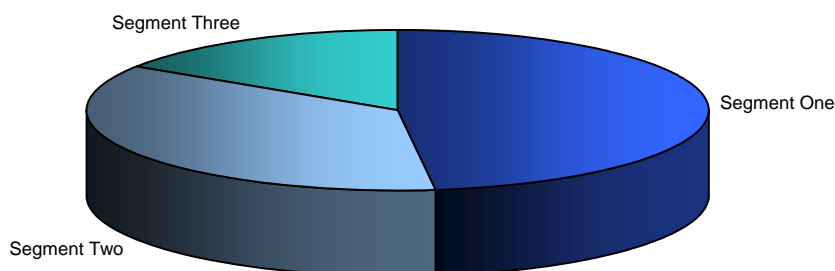
Source: iData Research Inc.

1.10 Syringe and Needle Market

Safety devices are segmented into syringe-based and needle-based technologies, with shielding needle-based devices accounting for over 15% of all the needle products sold in the United States in 2012. The fastest growing needle segment will be the insulin pen needle market due to changes to reimbursement that does not include the cover of the devices.

Syringes and needles are the most basic form of vascular access devices and are used extensively for injections, blood draws and infusion through vascular access catheters. Initiatives to reduce needlestick injuries have led to the use of needleless devices, safety syringes and safety needles. Safety syringes include retractable and sliding sleeve safety syringes, while safety needles include pivoting and shielding needle technology. Price, device features and technological limitations are all taken into account when facilities make their purchasing decisions. A moderate ASP, the ability to perform various tasks, and the relatively low force needed to activate the safety mechanism have all contributed to the preference for shielding needle-based safety devices. A significant portion of the market will never convert to safety devices because some applications pose a minimal risk. However, the use of safety syringes and needles is much more widespread in hospitals than in alternate care site facilities, such as doctors' offices, due to the strict enforcement of Occupational Safety and Health Administration (OSHA) regulations.

Chart 1-10: Total Safety Syringe Market by Safety Mechanism, Vascular Access Device Market, U.S., 2012



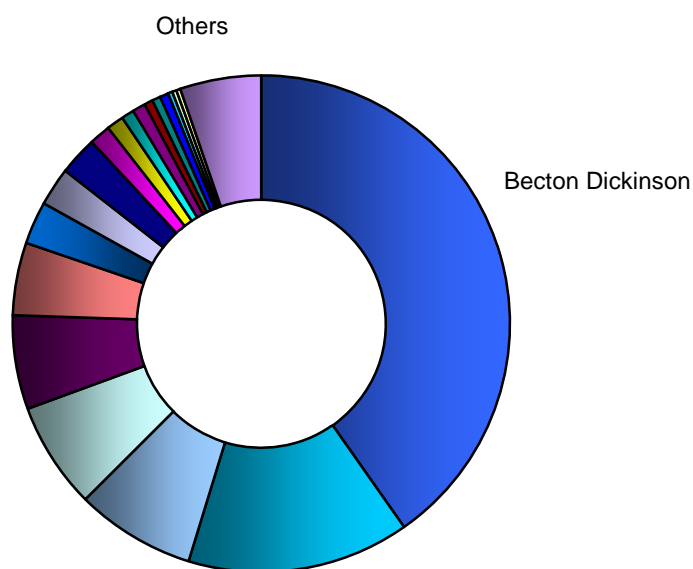
Source: iData Research Inc.

1.11 Competitive Analysis

In 2012, the market leader of the nearly \$4 billion vascular access market in the U.S. was Becton Dickinson.

Becton Dickinson (BD) led the total market for vascular access devices by dominating large segments, such as peripheral intravenous catheters (PIVCs) and syringes and needles. Other major competitors in the U.S. market included C. R. Bard, Covidien, Teleflex Medical, Smiths Medical and SonoSite. C. R. Bard, in particular, led more market segments than any other company in the total market. Together with SonoSite, C. R. Bard competed within the growing vascular access-specific ultrasound segment, which is positioned to represent an increasing proportion of the vascular access market over the forecast period. Other competitors in the vascular access market included AngioDynamics/Navilyst Medical, Medcomp, GE Healthcare, B. Braun, and Terumo Medical. Some companies such as Medcomp commanded significant market share in one segment for which a high proportion of revenue was realized, while other companies, such as AngioDynamics/Navilyst Medical were involved in several segments but held only moderate to minimal market share.

Chart 1-11: Leading Competitors, Vascular Access Device Market, U.S., 2012



Source: iData Research Inc.

