ClearView
Overview 2009

BREAKTHROUGH ADVANCE IN BLOOD DRAWING WITH VEIN ENTRY INDICATION™

ClearView Patient Safety Technologies' patented Flash Passive Safety™ technology reveals visible blood flow at the instant of vein penetration without activation or additional instruction. Its technology offers a universal solution that is simple and achieves reliable passive, optical venipuncture control.

Accidental needle stick injuries are a quiet crisis in healthcare systems around the globe, and the U.S. insurance industry spends over $1 billion annually stemming from inadequate and unsafe needle technologies. Safer blood drawing devices are needed that mitigate the dangerous and costly aspects of needlestick injuries during routine blood draws. The Center for Disease Control and other agencies that track needle sticks report over one million incidents annually in the U.S. Most agree needle stick accidents and injuries are vastly under reported, and that the number of sticks is far higher.

The U.S. Congress passed the Needle Stick Safety & Prevention Act (2000) giving OSHA wide authority to implement procedures designed to insure industry innovation of safety components, and insure provider adaptation of safety features towards mitigating the prevention of inadvertent needlesticks. Since the law's enactment, safety components have been developed and are available throughout the U.S. Most of these are aimed at protecting health care workers from inadvertent sticks due to exposed needles *after* blood is drawn--by capping, blunting, sheathing, or retracting the needle tip out of harm's way, and disposed in safety-engineered containers now mandatory.

The next major technology advance in patient and health care worker safety lies in providing ability to detect with certainty that a needle's tip is inside the vein properly *before* the introduction of evacuated sample vial to the procedure. Vein entry indication (VEI™) provides a critical capability to lesson accidental needle sticks, injuries to veins, compromised blood samples, and the associated huge economic costs to society, as insurance companies pay in the U.S. alone over $400 million annually *solely* from claims resulting from *testing* for HIV and hepatitis infection to a million-plus health care workers stuck while performing their jobs — and, usually hurt-- not because of procedure, but because of unsafe technology.

INDICATORS ADVANCE STANDARD VACUTAINER TECHNOLOGY

The standard technology for a multiple tube blood collection procedure is the vacutainer-type needle device. The heart of this technology is a small plastic component (a.k.a. blood stopper, or multiple sample sleeve) that rests on the non-patient end of the needle cannula, and acts to holds back blood flow at the moment of vein entry so that blood does not spill out. The rubber stopper is the heart of all vacutainer devices regardless of manufacturer. The stopper was invented by Terumo Japan's largest needle company, and first distributed in the U.S. in the early 1970's by Becton Dickinson (BD), the foremost manufacturer of blood drawing devices worldwide. Terumo's technology married to BD's vacuum sample tube quickly became the ubiquitous worldwide standard allowing collecting multiple samples swiftly… and without blood flowing on the patient, floor, or phlebotomist .

The new system greatly advanced the speed and cost of blood drawing, but the world's people have received a trade-off, because, while the Terumo patented invention prevents blood from flowing, by definition it also stops "flash" or "flashback", the telltale sign of proper venipuncture that has been a safety feature common in syringe and hypodermic needle devices relied upon for a hundred-plus years.

The collection vial's negative pressure keeps its inside sterile, and the vacuum creates the draw' as in 'blood draw.' However, if the needle's tip is not inside the vein when the collection tube is applied, the procedure becomes unsafe--beginning with the health care worker attempting to locate the vein by prodding or poking. Retracting the needle for a second entry creates more tension, and sudden movements by patients on the second attempt to find a vein are well known issues for all those who draw blood professionally. With vein entry indication technology, the procedure from beginning to end gives reason for a calmer environment for both patient and phlebotomist, because the certainty of successful collection is built into the technology.

Since BD introduced its BD Vacutainer™ System over forty years ago, over thirty patents have been issued to major needle device manufacturers to correct the lack of flashback caused by the vacutainer blood stopper component. Most of these ideas are not practical or not reliable, but the few that are practical have been recently productized. These safety needles represent a new level of safety aimed to mitigate the high cost to society of lesser technologies. Introduced by BD, Terumo, and the European conglomerate Greiner, the new safety needles verify that the needle's tip is properly positioned inside the vein at the beginning of the procedure; i.e. *prior to the introduction of the evacuated blood collection vial under negative pressure.*

VEI™ BENEFITS PATIENTS AND HEALTHCARE WORKERS

With VEI, the health care worker can collect blood with absolute confidence, because confirmation of correct needle placement at the beginning of the procedure is critical to a truly safe needle system. As to patient safety, if the sample collection vial is applied when the needle is not properly inside the vein, its vacuum sucking can collapse a weak vein, produce hematomas, cause internal bleeding, inflict pain, and compromise the integrity of the blood specimen by the aspiration of tissue fluids and cells. Reliably confirming flashback ensures that a wasteful, potentially harmful collection of tissue-contaminated blood need not be submitted for testing when results may be compromised. Safety from the start of the procedure minimizes probing, prodding, and resulting patient discomfort and injury from which sudden and unexpected movements that often lead to needle stick accidents to health care workers. With VEI, persons with difficult to find or "rolling" veins – and, healthcare workers themselves – are assured that blood draws won't cause avoidable injury and suffering.

COST SAVINGS

Manufacturers, insurance companies, health care workers, and patients -- which *we all are* at some time or another -- benefit from passive safety needles that provide reliable VEI.

TECHNOLOGY LANDSCAPE

Luminetx (U.S.) has developed a $20,000 vein viewing machine. Vascular Technologies (Israel) is working on an expensive component that produces an audible sound at the point of venipuncture. As for needles, Greiner Bio-One International's (Germany) Vacuette Visio Plus™ flashback system promises "greater safety and confidence." Terumo (Japan) has recently introduced its Venoject II Flashback Needle™, and BD – responsible for developing

the current standard, has patents to over 20 needle inventions to solve the problem created by the vacutainer system. Recently, the needle giant introduced its BD Vacutainer Flashback System™. BD's product advertisements state the new flashback solution promotes "greater confidence," adds "greater comfort," and helps to avoid "needle probing." And, BD's new flash passive safety™ device helps with phlebotomy education by providing "easy training".

ClearView Patient Safety Technologies, an invention development company, has received patents for its flash safety™ solution that provides optically verifiable venipuncture control. ClearView's passively activated technology is an improvement to the ubiquitous blood stopper, and actually turns this universal plastic component itself into the flash indicator- -one that can be applied to any brand, straight or butterfly devices, without high cost or major mold changes.

Like the Terumo and Greiner solutions, the ClearView system reliably allows the collection vial to be inserted in the procedure without risk of compromising the integrity of the specimen, or creating an unsafe patient situation should the needle's tip not be inside the vein. Health care workers require no additional instruction or effort to see the immediate flash of blood. These factors and others are used by insurance and medical technology suppliers in evaluating the relative safety of needle features.

BD, Terumo, and Greiner's VEI solutions are integrally designed needle devices that have plastic housing that is complex to manufacture with a void inside the hubs, and structures to support the void that must be sterile. Conversely, ClearView's solution is a universal component that can be retrofitted on the more than 3 billion vacutainer devices used worldwide annually.

Technology mentioned:

Fortune Magazine, March 2005, "Innovation, Stick It To 'Em", by Patricia B. Gray
Becton Dickinson Brochure: "Venous Blood Collection With Greater Confidence"
Greiner (Germany) www.gbo.com/en/index_2076.php
Terumo (Japan) www.terumo.co.jp/medipro/MD/index.html
ClearView (USA) www.flashsafety.com
Luminetx (USA) www.luminetx.com
Vascular Technologies (Israel) www.vascular.co.il/index1.html

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