COMPETITION COMPARISON

EVERY YEAR

1 million healthcare workers in the U.S. are stuck with hypodermic needles that may be infected with Hepatitis B, Hepatitis C or HIV.
Over 1000 of them contract serious infections.
Over 80% of these injuries could be prevented.

In some countries as many as 90% of the injections given are unsafe.
24 million people in developing countries around the world are infected yearly.
More than 580 million people in the world are chronic carriers of these diseases.
An estimated 1.3 to 1.6 million die.
Countless others in the private sector including housekeepers, janitors, and trash handlers are not even counted in these statistics.
The medical community was aware of this problem for years.

SO WHY WASN'T A SOLUTION PUT INTO PLACE ASAP?

Purchasing decisions were made primarily on cost.
Purchasing contracts set up with major group purchasing organizations (GPOs) limited the choices.
Existing syringe manufacturers were reluctant to invest in new designs.
And, why change? They already controlled the industry.

SOMETHING NEEDED TO BE DONE

Frontline medical professionals were the first to demand safer syringes.
In April of 1998 the San Francisco Chronicle printed the “Deadly Needle Series”, putting California legislators on notice.
In September, 1998 Cal/OSHA passed the first legislation mandating the use of safety needle products in California.
In November of 2000 President Clinton signed the Federal Needlestick Safety and Prevention Act requiring the use of safety devices.
Purchasing decisions in hospitals are no longer based solely on cost.
Purchasing agents are now required to listen to needle stick committees comprised of medical professionals; and they want something effective.
23 states have passed additional needlestick legislation and 17 states currently have legislation pending.
Group purchasing organizations have been brought before the US senate for their monopolistic
practices. Retractable Technologies filed and prevailed in an antitrust suit against Premier, Novation, and Kendall Healthcare. The case with the fourth defendant, BD, was settled out of court for $100 million. These events are causing the major syringe manufacturers to lose their grip on market domination. The stage is set for smaller manufacturers to enter the market. Outside the United States markets are beginning their own transition to safety-engineered devices.

THE COST OF CHANGE

The cost of needlestick injury follow-up in the U.S. per incident is around $3,000. Accident follow ups cost the US medical industry $1.2 billion annually. Annual treatment for contracted diseases in the US is $1.8 billion. A total of $3 billion is spent annually in the US on needlestick injuries. This is three times the amount spent on conventional syringes. And almost 3 times the cost of converting to safety syringes.

The balance of power is in transition, and the stage is set for the right product to gain more market share than has been achievable in recent history.

THERE ARE CURRENTLY FOUR GENERAL TYPES OF SAFETY SYRINGES.

- Sheathing tube syringes
- Sliding needle covers
- Hinged needle Covers; and
- Spring retractable syringes

SHEATHING TUBE SYRINGES

BD Safety-Lok
Kendall Monoject
Require two hands to operate.
Require a second hand moving closer to the needle to activate them.
Harder to read the scales because of the sheath.
Many reported problems of being able to reliably engage the safety mechanisms.
Must retract from the injection site, exposing the needle before actuation.
Take up more room in expensive sharps containers.
Use of the BD Safety-lok syringe increased needle sticks at Kaiser Permanente. The Kendall syringe requires a second operation in order to lock it in place. The same old problem with a new twist.

**SLIDING NEEDLE COVERS**

BD Safety Glide  
Kendall Magellan (needle only)  
Require a grip change.  
Safety feature actuation requires a thumb or finger in closer proximity to the needle.  
Must retract from the injection site, exposing the needle before actuation.  
Kaiser’s use of the BD Safety Glide failed to reduce needle sticks during one year of widespread use.

**HINGED NEEDLE COVERS**

BD Eclipse  
Terumo Surguard  
Necessitate reaching next to the needle to move the cover out of the way in order to give an injection.  
Require a grip change to operate a safety feature.  
Puts at least one finger in close proximity to the needle after the injection.  
Must retract from the injection site, exposing the needle before actuation.  
Cumbersome to use.  
Flipping motion as the needle snaps into the cover can cause blood splatter.

**SPRING RETRACTABLE SYRINGES**

NMT  
Vanishing Point  
BD Integra  
Splatter on activation.  
Aerosol residual contents, potentially spreading contagious viruses.  
Difficult to actuate, requiring over 9 lbs of push.  
Actuation can cause movement of the needle resulting in tissue trauma.  
Weak springs don’t always pull the needle out of the patient.  
The needle hanging up in the muscle and skin flips back, splattering the needle’s contents on the operator.  
Viruses can be picked up through contact with the eye, nose, mouth, or skin.
OTHER DISADVANTAGES OF THE COMPETITORS' SAFETY SYRINGES

Difficult to learn to use.
Require extensive training.
Lack of instructions on the device pouches.
Lack of confirmation that the safety mechanism is locked.
Many safety syringes are currently discarded in sharps containers without actuation because they are difficult or cumbersome to activate.
As a group they give healthcare workers a false sense of security.
Calling them Safety Syringes is a major misnomer.

OUR BIO-SAFTY NEEDLE DESIGN U.S. PATENT # 7,465,294
IS OFFERING THE FOLLOWING ADVANTAGES

Eliminates accidental needle-stick injuries through its blunt-point cannula design;
Facilitates exquisitely simple safe disposal (no recapping required);
Provides user-friendly implementation (one-hand activation) with no separate movement required to deploy the needle tip;
Provides for zero wasted space (no residual volume), yielding sizable savings in the efficiency of medication delivery;
Furnishes improved child and adult patient safety through elimination of choking risk by excluding the need for a separate straight dental needle cap;
Significantly reduces packaging costs through elimination of the requirement for a solid needle cap;
Will be used with standard syringes, IV catheters and phlebotomy collection devices, and Offers a profoundly cost-effective design, being composed of four inexpensive parts, offering health care providers worldwide new cost-reduction opportunities.
The hermetic connection between the needle and syringe will provide for zero air bubble, thus significantly saving medication.