

Revolutionary Designs

New passive, self-sheathing safety syringe

by Ron Stoker

I started my career in medical device development back in 1981. Things were quite different back then. As I compare today's technology to those of that era—there is simply no comparison.

For example:

- ▶ 1980—hepatitis-B vaccine invented;
- ▶ 1981—first space shuttle, Columbia, was launched on April 12, 1981. The journey lasted only 54 hours and 21 minutes;
- ▶ 1981—MS-DOS was invented, later that year the first IBM-PC;
- ▶ 1984—CD-ROM was invented as well as the Apple Macintosh.

When I tell my kids that we didn't have any of the devices that they use today, they roll their eyes in their heads and tell me they think I was born in 1881!

However, when compared to the safety technologies of today, the medical equipment of yesterday also seems pretty

archaic. I believe 20 years from now some of the medical devices we are using today will be extinct, replaced with much safer products for both patients and healthcare workers.

When I began my career in medical device development it was years before needleless systems would replace the ubiquitous needle.

I received my first needlestick in the mid-1980s while developing a catheter valve system. Although I never received any treatment for the needlestick injury, my wife and I were both concerned about the possibility of getting HIV and hepatitis. Fortunately for us, the worst part of the experience was the horrendous wait to find out if I had acquired a bloodborne pathogen disease.

In September 1998, California became the first state in the country to enact a law aimed at protecting healthcare workers from exposure to bloodborne diseases such as hepatitis and HIV/AIDS. The bill was introduced after a series of articles appeared in the *San Francisco Chronicle* asserting that 1 million healthcare workers are injured in the United States each

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year as a result of needlesticks. Since that time many additional states have passed Needlestick Safety Legislation. In addition, a number of other states have introduced needlestick safety bills.

During that time, I was the senior product manager for a large medical device company. When the California law was passed, 25 percent of my market share potentially disappeared with it because we did not have a single safety product included in the kits for which I was responsible. I started learning everything I could about sharps safety products.

In November 2000, President Clinton signed into law the Needlestick Safety and Prevention Act (HR 5178.) The law required OSHA to amend the Bloodborne Pathogens Standard by expanding the definition of “Engineering Controls” to include safer medical devices, such as sharps with engineered sharps-injury protection and needless systems. It also required employers to seek input from “non-managerial employees” to evaluate the “engineered sharps-injury protection devices.”

On January 18, 2001, the revised Bloodborne Pathogens Standard, which accommodates changes required by the Needlestick Safety and Prevention Act, was published in the Federal Register. This revised standard went into effect on April 18, 2001. OSHA provided a 90-day education period to help educate employers. This “reach-out” period ended on July 17, 2001. The enforcement of the new requirements in the revised standard began on July 17, 2001.

Facilities started to be fined for noncompliance. New requirements included the use of needleless systems, products with engineering controls (sharps disposal containers, self-sheathing needles, safer medical devices such as sharps with engineered sharps-injury protections) that isolate or remove the bloodborne pathogen hazard from the workplace.

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Perception that Sharps Injuries Do Not Occur

However, some problems still remain. There are pockets in the hospital that still share a perception that it is incredibly wrong. That perception is that sharps injuries do not occur very often, and when they do they are unavoidable. This group of individuals simply accepts needlestick and other sharps injuries as part of the job.

Now, after a decade of focusing on sharps injury prevention, it is clear to me sharps injuries are altogether too common. They should be unacceptable to all of us. I believe they are within our power to prevent.

Is there still a need to prevent needlestick injuries? I think so. Again, sharps injuries are altogether too common. Needlestick injuries continue to frequently occur, and also frequently transfer serious or fatal infections of HIV, hepatitis B, and hepatitis C. The World Health Organization (WHO) reports that each year an estimated 8 billion to 12 billion injections are given with more than 50 percent being unsafe. As a result of needlestick injury, more than 8 million new Hepatitis B, more than 2 million new Hepatitis C, and 100,000-plus new HIV infections are transmitted each year. These numbers may actually be much higher, as many needlestick injuries go unreported.

Using safety products can help reduce or even eliminate many of these injuries. I have frequently mentioned my concept of a “pyramid of safety” to prevent needlestick and other sharps injuries. The concept is basically this: picture a pyramid with a broad base. The higher you go up the pyramid, the more danger you have of a sharps injury occurring.

Level 1: Sharp-free Products

The broad bottom base consists of products where the sharp has been eliminated completely. In other words: no needle, no risk. Examples of products in this category would include needleless IV connectors, needleless jet injectors for medication delivery and so on.

Level 2: Passive Products

The next level up consists of passive safety products. No active participation by the clinician is required to activate the safety mechanism. Clinicians use the device as they normally would and the safety mechanism is automatically activated. There are no buttons to push or levers to activate, for example auto-retractable syringes. Although the product safety activation is done without active participation by the clinician, *there still needs to be both audible and visual feedback that the safety mechanism has been activated.*

Level 3: Active Safety Products

The third level consists of safety products that require activation of the safety feature by the clinician. An example of an active safety product would be a needle that requires the user to manually push a button, push a lever, adjust a shield or twist the barrel in order to activate the safety feature. The active safety product, as with the passive safety product, needs to have both audible and visual feedback that the safety mechanism has been activated.

Level 4: No Safety Product

The final tier of the pyramid is occupied by standard scalpels/syringes, etc. with no safety features. They should not be used if there is an acceptable alternative.



Global Revolution in Needle Design

Seventeen years ago, during an international conference, Janine Jagger, a recognized needlestick safety expert, called upon syringe makers to develop syringes with safety features that would protect not only U.S. healthcare workers, but all foreign medical workers. She said, “Worldwide demand for needle technology must not be viewed merely as a business opportunity. It is a necessity that can be met with nothing less than a global revolution in needle design.” I

think Dr. Jagger has this exactly right. It has required a revolution in medical device design to get where we are today. I also believe we have more innovative designs to come. This revolution should continue and provide us with new designs that can better protect healthcare workers and patients alike. It has been fun for me to watch as medical device manufacturers come up with new and innovative designs that could help to virtually eliminate needlestick injuries.

Worldwide, there are approximately 35 billion syringes used each year. It has been estimated that today’s syringe market is about \$5.6 billion annually. The estimated market for safety syringes is growing about 8 percent each year. The safety syringe market is currently estimated at approximately \$1.69 billion.¹

Several manufacturers have come forward in recent months with unique safety syringes that have had a revolutionary design. I recently became aware of a new safety product that fits in the category of passive products. It is called the Turtle Safety Syringe and is manufactured by Medical Safety Technologies Inc., a designer and supplier of medical devices.

The Turtle Safety Syringe is a passive, self-sheathing safety syringe, which never exposes the needle to the healthcare professional during the entire injection process. This offers the clinician protection from deadly needlestick injuries and accidents during every aspect of use. The syringe cannot be reused or re-sterilized. See Figure 1.

Basically, the safety system consists of a safety protective housing which encloses a syringe and needle. The housing automatically covers the hypodermic needle until an injection is made or fluid is withdrawn from a vial. By holding the index finger and thumb on two safety locking tabs and applying downward pressure to the nose of the syringe, the needle exits a protective sheath and punctures the surface being injected. See Figure 2.

Figure 1. Turtle™ Safety Syringe

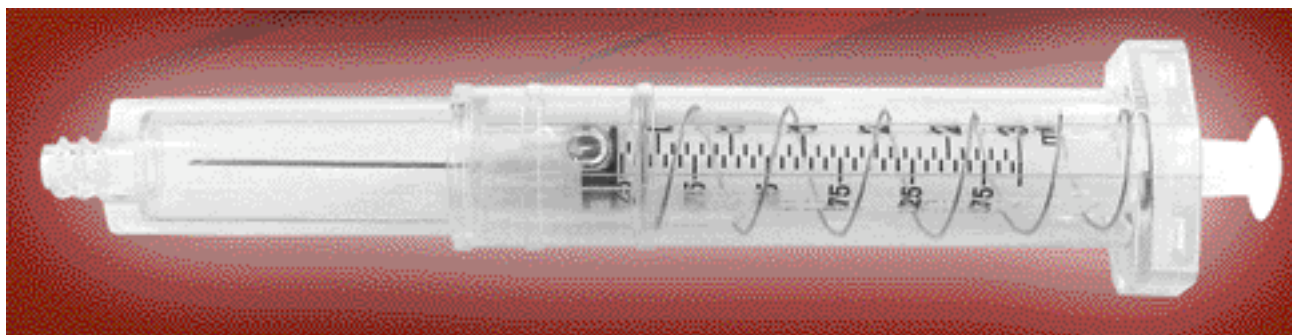



Figure 2.



Figure 3.



SAFETY FEATURE EVALUATION FORM
SAFETY SYRINGES



Date: _____ Department: _____ Occupation: _____
 Product: _____ Number of times used: _____

Please circle the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

During Use: agree _____ disagree

1. The safety feature can be activated using a one-handed technique..... 1 2 3 4 5 N/A
2. The safety feature **does not** obstruct vision of the tip of the sharp..... 1 2 3 4 5 N/A
3. Use of this product requires you to use the safety feature..... 1 2 3 4 5 N/A
4. This product does not require more time to use than a non-safety device..... 1 2 3 4 5 N/A
5. The safety feature works well with a wide variety of hand sizes..... 1 2 3 4 5 N/A
6. The device is easy to handle while wearing gloves..... 1 2 3 4 5 N/A
7. This device **does not** interfere with uses that do not require a needle..... 1 2 3 4 5 N/A
8. This device offers a good view of any aspirated fluid..... 1 2 3 4 5 N/A
9. This device will work with all required syringe and needle sizes..... 1 2 3 4 5 N/A
10. This device provides a better alternative to traditional recapping..... 1 2 3 4 5 N/A

AFTER USE:

11. There is a clear and unmistakable change (audible or visible) that occurs when the safety feature is activated..... 1 2 3 4 5 N/A
12. The safety feature operates reliably..... 1 2 3 4 5 N/A
13. The exposed sharp is permanently blunted or covered after use and prior to disposal..... 1 2 3 4 5 N/A
14. This device is no more difficult to process after use than non-safety devices..... 1 2 3 4 5 N/A

TRAINING:

15. The user **does not** need extensive training for correct operation..... 1 2 3 4 5 N/A
16. The design of the device suggests proper use..... 1 2 3 4 5 N/A
17. It is **not** easy to skip a crucial step in proper use of the device..... 1 2 3 4 5 N/A

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions which you feel should be asked regarding the safety/ utility of this product?

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It utilizes a proprietary design to ensure that the needle is never exposed from the moment the syringe is taken from its original packaging, through the injection process, and finally to sanitary disposal. The device remains in locked position with needle covered by the protective sheath. This protects anyone coming into contact with the syringe. The stainless steel spring keeps the protective sheath over the needle at all times, before, during and after use.

While holding locking tabs under thumb and index fingers, exert forward pressure to inject needle into patient, or to draw up medication. See figure 3 on page 20.

I have a pillow sitting by my computer. I have played with this syringe for several weeks now, constantly holding the locking tabs and injecting my pillow and releasing the tabs and watching the needle always being covered. I simulated aspirating medication into the syringe, injecting into a patient, and disposal. This product provides:

- ▶ Automated protection before use;
- ▶ Automated protection during use;
- ▶ Automated protection after use;

- ▶ Automated protection during disposal;
- ▶ Automatic protection if dropped, bumped, pushed or pulled.

And because the Turtle syringe provides protection automatically and passively, the user does not have to do anything for the safety feature to engage. Its safety features cannot be bypassed. Because the Turtle is completely passive, medical care professionals don't have to do anything different; they can maintain their own technique.

The product has been received well by clinicians. Rosie Rentera, RN, in McAllen, Texas said: "We have been using the Turtle Safety Syringe for about six weeks now and have witnessed firsthand that this new technology works. The needle is truly never exposed, which is something our nursing staff can appreciate."

I would recommend that clinicians look at this product and evaluate it for use in their clinics. As always document your evaluations and make sure that they are placed in your Exposure Control Plan. A Safety Syringe Evaluation Form is included for your evaluation (page 22). The Evaluation form is copyrighted Dr. June Fisher and TDICT and is used by permission.

For more information, call 866.403.6784, visit www.medicalsafetytechnologies.com or send an e-mail to info@medicalsafetytechnologies.com.

Reference

1. [Medicalsafetytechnologies.com](http://www.Medicalsafetytechnologies.com)

Ron Stoker is the founder and executive director of ISIPS, the International Sharps Injury Prevention Society, and is a frequent contributor to Managing Infection Control magazine. He speaks frequently at national and international meetings on sharps safety, hand hygiene and infection control issues. He is coauthor of the "Compendium of Infection Control Technologies." For more information on the Compendium, go to www.medicalsafetybook.com. Mr. Stoker is providing a number of webinars focusing on a variety of sharps injury prevention safety products. He is currently adding to his list of safety products shown at <http://isips.org/safetyproductlist.php>. Are you aware of a safety product that reduces sharps injuries or bloodborne pathogen exposure that should be added to the list? Please send an e-mail to info@ISIPS.org.