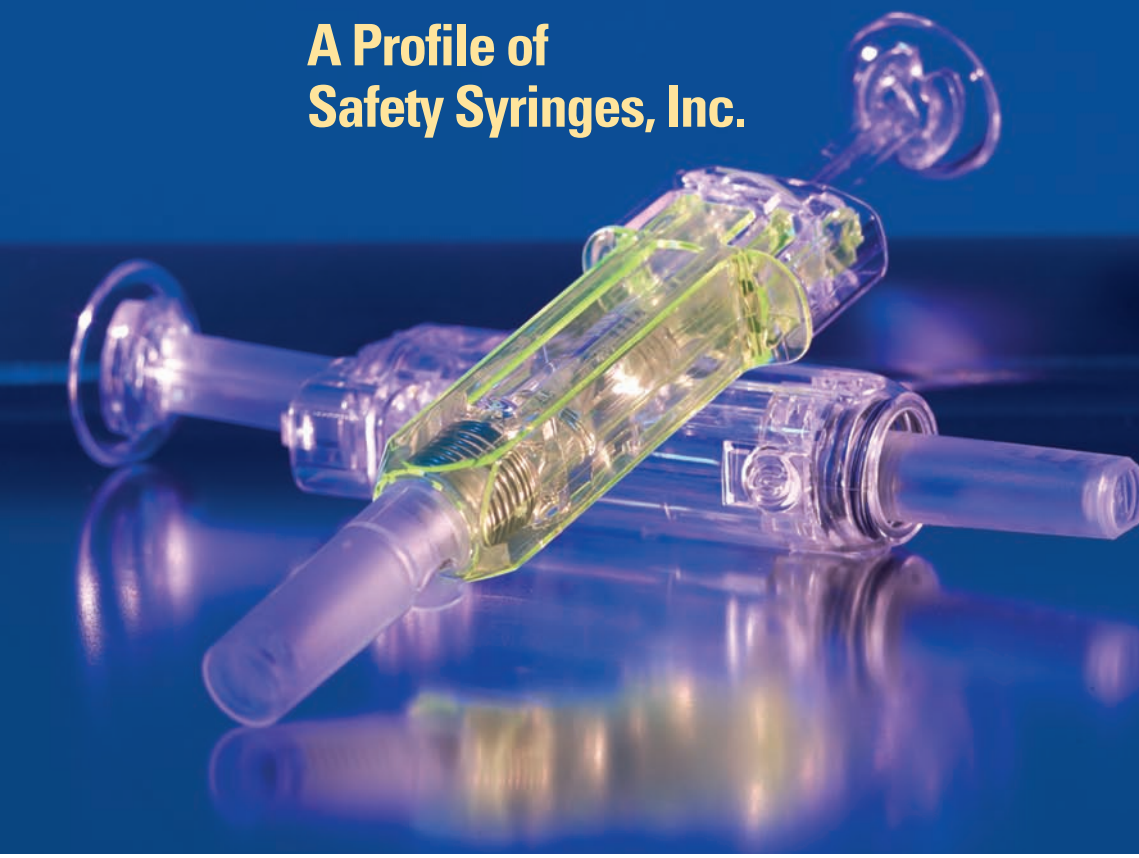
# Living Up to Its Name

## A Profile of Safety Syringes, Inc.



*Accidental needlesticks present healthcare workers and the public at large with the potential dangers of infections, illness, and even death.* ***It's a significant health issue:*** *each year, between 600,000 and 1,000,000 accidental needlesticks are reported in the United States alone, and knowledgeable experts estimate that only one-third of all needlestick incidents are reported.*

As many as 20 blood-borne diseases can be spread through accidental needlesticks, including Hepatitis B, HIV (which can lead to AIDS), diphtheria, gonorrhea, typhus, herpes, malaria, rocky mountain spotted fever, syphilis and tuberculosis. Anyone involved in the delivery of healthcare can be affected, including patients, physicians, nurses and other caregivers, as well as support personnel ranging from housekeeping staff to employees of sanitation and environmental service firms.

The enactment of The Needlestick Safety and Prevention Act in 2000 caused healthcare employers in the U.S. to get serious about protecting workers from the horror of needlesticks. OSHA inspections and citations are now a reality to ensure appropriate protection for healthcare employees. In 2003, European legislation required the replacement of pointed, sharp or fragile work devices with devices or procedures that pose no risk or only very minimal risk of needlestick injury or cuts. Further regulations are in the works for Europe.

## Ahead of the Curve

One company has been ahead of the curve in needlestick injury prevention since before it was required by law. Since 1991, Safety Syringes, Inc., (SSI) of Carlsbad, California has specialized in the development of anti-needlestick devices for the healthcare industry. Today, SSI develops and markets its products to the world's top pharmaceutical companies. SSI doesn't make syringes; SSI makes syringes safer.

Initially, the pharmaceutical industry rejected the idea of promoting needle safety, but federal legislation regulating needlestick protection changed the business landscape. A combination of strategic vision, innovative technologies, and healthcare legislation positioned SSI for success.

SSI was first to introduce a product line addressing needle safety for the pre-filled syringe market, initially with manually activated UltraSafe® needle guards. By 2001, pharmaceutical companies began to attach SSI's needle safety devices to syringes pre-filled with injectable drugs. The product's ease of use helped to gain user acceptance and fueled the development of the UltraSafe Passive® drug delivery system. The launch of UltraSafe Passive® in 2002 with one of the world's elite pharmaceutical companies helped to solidify SSI as the market leader.

## How It Works

UltraSafe Passive® is elegant both for its simplicity of concept and precision of execution. (Twenty-three issued U.S. and international patents and several more patents pending protect all of the company's products.)

The device includes a plastic body designed to hold a pre-filled glass syringe fitted with a capped hypodermic needle. When a healthcare provider prepares to give a patient an injection, the cap is removed to expose the needle. After the injection is administered, the needle automatically retracts into the protective plastic body.

The automatic needle retraction, powered by a spring inside the plastic body, is “passive” because it requires no activation on the part of the healthcare provider. No special training is needed, only one hand is required, and the protective barrier remains in effect during disposal.

## Security Built In

To ensure that the contents of a pre-filled syringe remain genuine and unadulterated to the point of use, UltraSafe Passive® delivery systems are available with tamper-evident security features. Front-end security includes a tear-away needle cap that cannot be replaced intact. Back-end security includes a specially engineered back plate to ensure the plunger remains in the syringe.

Combined, these front-end and back-end security features provide the highest level of security available in an injectable drug delivery system. Importantly, the tamper evident protection stays with the medication from the point where the syringe is filled to the point where the injection is administered.

## Countering Counterfeiters

The counterfeiting of brand name products is a global problem, and imitation drugs have gained the attention of organized crime. The number of investigations by the U.S. Food and Drug Administration into counterfeit drugs has tripled in the past few years.

SSI is offering innovative products to help reduce the threat of drug counterfeiting.

SSI is the first and only provider of an overt deterrent system, which helps prevent or make evident attempts to adulterate or counterfeit unit-dose, pre-filled pharmaceutical presentations. The tamper-evident version of UltraSafe Passive® provides another layer of protection at the unit-of-use level, which is what the FDA recommends for the counterfeiting solution.

## Manufacturing Partnerships

SSI conducts product development and automated component assembly operations at its facility in Carlsbad. Partnering relationships with companies that specialize in automation, secondary packaging and labeling enable SSI to continue to focus its internal efforts on product development.

"We work with major global pharmaceutical companies, and what we do goes far beyond just selling them a product," says Mark Hassett, Vice President Marketing - Business Development with Safety Syringes, Inc.

"Companies that are making a million syringes at a time are highly automated. By partnering with the leading equipment manufacturers for automation, we can offer our customers drug delivery devices as well as a relationship with an automation provider that understands our products. We have done the same thing with drug packaging and label specialists. SSI provides an integrated solution."

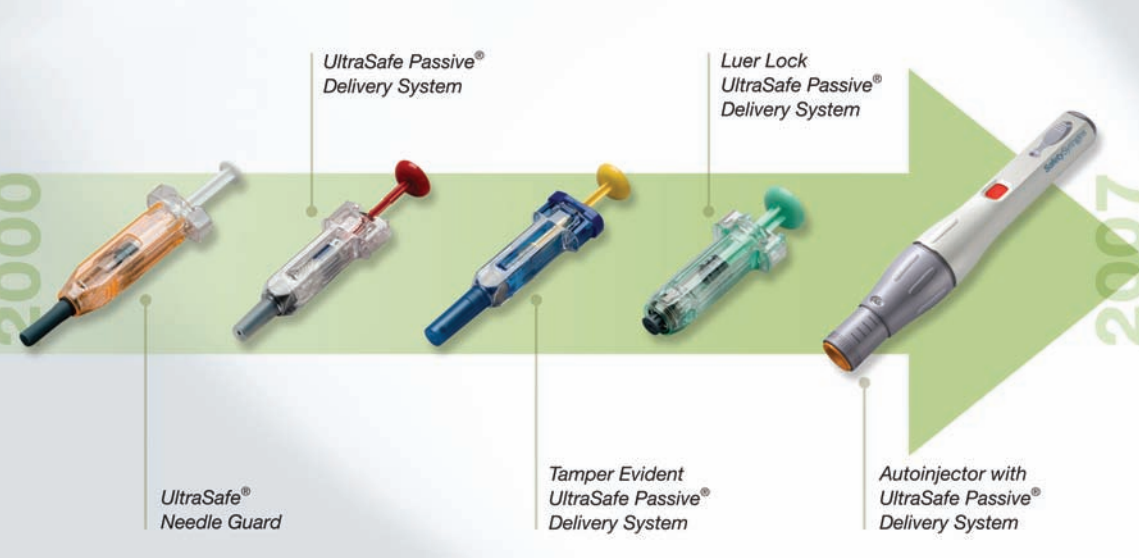
One benefit of such partnerships is a shortened time to market, as each partner in the relationship focuses on its specific area of expertise.

***"Albert Einstein observed, 'The significant problems we face cannot be solved at the same level of thinking we were at when we created them.' We totally agree. And since 1999, SSI has specialized in the development of anti-needlestick devices for the healthcare industry that have led the way."***

*Christer O. Andreasson*
*Chairman and CEO*
*Safety Syringes, Inc.*

**On August 1, 2007, a new needle safety mandate—TRBA 250—took effect in Germany. TRBA 250 regulates protection from needlestick injuries and is significantly more stringent than its previous version. One of the key components of this new mandate is that it is a "must" regulation and among other things it stipulates the use of "one-handed needle safety solutions."**

**In order to meet increased demand, SSI continues to expand its product platform and manufacturing capacity and to maintain and even improve its on-time delivery record. These are a few reasons why the pharmaceutical industry has helped SSI become the worldwide leader in safety systems for prefilled syringe presentations, such as the UltraSafe Passive® Drug Delivery System.**




## Automation With Compressed Air

SSI's manufacturing operation is highly automated with many processes relying on compressed air. "A substantial portion of the technologies we use in automated assembly are pneumatic," says Dustin Hahn, Director of Engineering for SSI. "When parts are moving from one place to another or down the assembly line, the movement is powered by compressed air."

One example is the UltraSafe Passive® needle retractor springs, which are wound in SSI's plant. Compressed air pushes the finished springs through a pressure tube to the location where they are fed into the needle guard body during assembly.

When he was designing SSI's newest automated manufacturing operation (installed in fall 2006), Hahn specified oil-free air compressor systems from Atlas Copco. "As a medical products manufacturer, we need a reliable source of clean, dry air that's oil-free. You can't have any residual oil on a part that you're delivering to a medical company, so it's good to just eliminate oil from the equation altogether." For SSI's new operation, Hahn specified two completely redundant Atlas Copco ZT90VSD-FF oil-free systems with inline IMD adsorption dryers. The compressors are set up in a lead/lag arrangement, with the lead compressor switching every month to balance out wear and maintenance.

"Atlas Copco has developed new technologies for zero loss drying and storing of compressed air," says Hahn. "The inline IMD dryers we purchased will produce dry air with zero loss. The initial cost is more, but the savings from the lack of lost air makes the IMD dryers a good investment. Energy savings will result in payback within a year."

The ZT90VSD-FF also features Atlas Copco's Variable Speed Drive (VSD) technology, which precisely matches the production of compressed air to the demand. "We chose Variable Speed Drive systems for the operating cost savings," Hahn explains. "Our demand for air fluctuates continuously, so it's more advantageous to run compressors that only produce the air you actually need. The system generates from 125 to 526 CFM automatically as needed. It's more expensive to purchase a Variable Speed compressor, but after about eight months the additional investment will be recovered through lower operating costs." Beyond the payback point, the Atlas Copco's VSD system provides continuous dividends through greater operating efficiency.

Above all, Hahn says his experience with compressed air has reinforced his focus on the bottom-line value of operating efficiency. "Compressed air is your most expensive utility and you pay for all the air you compress," he says. "Anything you do to improve efficiency and prevent waste saves you money. It's best to evaluate a purchase based on your total cost, long-term. Over the long haul you can save a lot more money by going with Atlas Copco. You get what you pay for."

**Did You Know?**

Atlas Copco reaches more than 160 markets around the globe.

## Auto-Injection

SSI's UltraSafe Passive® delivery system is now available for self-injecting patients. Owen Mumford, a leading manufacturer of self-injection devices, developed an auto-injector that is compatible with the UltraSafe Passive® device, adding a level of safety by limiting sharps exposure to people and pets in households with self-injecting patients.

**The self-injection market is growing on several fronts:**

- Erythropoetin (EPO) drugs, which stimulate the production of red blood cells (commonly prescribed to cancer patients)
- Heparins (anti-coagulants to treat deep vein thrombosis)
- Drugs that stimulate the production of white blood cells (prescribed for patients with infectious diseases)
- Drugs that treat autoimmune diseases (multiple sclerosis, rheumatoid arthritis, psoriasis, allergies, irritable bowel disease, cancer, and AIDS)
- Promising new treatments for Parkinson's disease and migraine


## An Ounce of Prevention

According to the American Hospital Association, the direct costs for medical evaluation and follow-up treatment for a single needlestick injury range from $200 to $1,200. Costs involved in treating an HIV-infected healthcare worker total more than $500,000. Additional costs can take the form of loss of life, loss of income, civil suit awards, litigation expenses and higher insurance premiums.

The pharmaceutical industry has become very proactive in moving forward with safety measures before regulations require it. Quite simply, it costs a lot less to add in a safety feature than it costs to settle a class action lawsuit. By significantly lowering the risk of accidental needlesticks, SSI products ultimately reduce healthcare costs.

***www.safetysyringes.com***