

Becton Dickinson takes a plunge with safer needles

By gearing up to make devices like these,
the company is giving its profits a shot in the arm.

By Philip Siekman

Last November, when President Clinton signed the Needlestick Safety and Prevention Act, health-care workers mentally stood and applauded. But in the Franklin Lakes, N.J., headquarters of Becton Dickinson, top executives collectively exhaled. For medical professionals, the needlestick act could literally mean the difference between life or death. For BD, by far the leading producer of needle devices, it guarantees a huge payoff. With no certainty that a bill would ever get through Congress, the company had gambled half a billion dollars getting ready to provide the very items the new law mandates.

Each year, hundreds of thousands of health-care workers accidentally prick themselves with a needle that could be contaminated with a patient's blood carrying a pathogen as life-threatening as HIV or the often fatal C strain of hepatitis. Over the past decade, BD and other companies have introduced safer designs of so-called sharps, which mainly come in three categories: hypodermic syringes, devices used to take blood samples, and needles used in intravenous systems. But up to now, largely because of the added cost, adoption has been slow. A regular syringe, for example, sells for less than a dime. One of BD's "safety engineered" versions, with a plastic shield that snaps over the needle after use, usually goes for more than a quarter.

Now that a law is on the books requiring the use of safe sharps, the price gap will narrow with higher volume. BD stands to profit handsomely because of its mastery of manufacturing medical devices at extraordinarily high speeds in quantities that would stagger a cookie factory. Says CEO Edward Ludwig, 50: "Making millions if not billions of things with zero defects at a very low cost is really the skill of this company."

With 51 factories around the world, BD dominates the business of making and selling needle-bearing medical devices. It produces some 12 billion of them annually, more than anybody else in each of the three principal categories. Over half of the company's \$2.8 billion in sales for the nine months ended June 30, 2001, and probably a larger portion of its operating income, were generated by products with an attached cannula, the proper name for a hollow-bore needle.

BD managers once thought the company's marketing prowess alone would overcome the cost barrier to safe sharps. But by the late 1990s, after failing for nearly a decade to get much in the way of sales, they were ready to concede they weren't up to the task. By then, however, help was on the way in California. In 1998 a coalition of nurses, health-care workers' unions, and Kaiser Permanente, the state's big HMO, got legislation passed in Sacramento that required the use of safety-engineered sharps. That law became the model for other states and for the federal legislation signed last year by President Clinton.

By the time California passed its law, an internal debate was being waged at BD between some who said the company had to get ready right away for a surge in safe-product demand and those who cautioned that there was no certainty that regulation would become nationwide. The "4G" argument—"gotta gamble on getting going"—prevailed. BD embarked on a massive conversion of its U.S. factories that turn out needle-bearing products. By mid-1999 manufacturing managers were working overtime to design, order, and install high-speed, lower-cost production lines for new, safer devices. BD has now spent about \$300 million on the effort, plus another \$200 million or so on product development.

This is the second time in its history that BD has laid out a lot of money on a major manufacturing change to improve product safety. Starting as partners in 1897 to import fever thermometers from England and hypodermics from France, Maxwell Becton and Fairleigh Dickinson began making both in the U.S. less than a decade later. In the 1960s, when the company was still largely owned and managed by the founders' families, health-care providers began switching from glass syringes and other devices to disposable plastic items to reduce the risk of spreading infection from patient to patient.

To raise capital to finance a changeover to disposables, BD made its first public offering of equity in 1962. In the 1970s it successfully beat back Japanese competition by bringing out better and sharper needles. Since then it has been the industry leader. It has also become what CFO John Considine calls "a very big cash-flow business" with little need to go to the capital markets. BD

earned \$393 million in net profits in its fiscal year ended last Sept. 30, up 43% from the prior year on a minuscule increase in sales, to \$3.6 billion. This year the company should generate as much as \$740 million in cash—profits plus depreciation and other noncash charges. By fiscal 2001, with major projects about finished and the safe sharps market popping, BD ought to be awash in liquidity.

BD can't even guess how many items it ships every year. It still makes fever thermometers, but they're plastic and digital. Other products include clinical laboratory instruments, pharmaceutical research equipment and supplies, and the weekend athlete's friend, ACE bandages. The ACE—the letters stand for “all-cotton elastic”—is a modification of a German product, the kind of thing that happens a lot at BD, since it has never been much of an innovator. BD buys rights or acquires the company that developed a new product, then refines the design with an eye to manufacturing ease as well as user acceptance. Practically every one of the new safer sharps embodies somebody else's invention. Even CEO Ludwig admits, “Most of the things that we've become good at we didn't necessarily invent from scratch. We're great adapters.”

Focused on cutting mills if not pennies from costs, BD and the rest of the health-care business was slow to recognize that product design might be a key to improved medical worker safety. That attitude began to change in the 1980s as doctors and nurses recognized the dangers associated with HIV and more recently hepatitis C, which is up to six times more likely to move from patient to needle-stuck worker.

The earliest efforts to reduce the chances of needlestick focused mostly on safe disposal: putting the sheath back on the needle after use and providing plastic waste containers. But these measures have limitations, including the sad fact that doctors and nurses are as likely to jab themselves trying to put the cover back on a needle as they are when using it. It took an outsider, Janine Jagger, an epidemiologist at the University of Virginia, to propose that safety should be designed into the product.

Jagger was working on reducing injuries in automobile accidents by better design when she started to look at medical devices. Accustomed to tooth-and-nail disputes with car companies, she was surprised by the medical device industry's reaction. At an international AIDS conference, she declared in a presentation, “This is a problem of product design; only industry can change this, and they are not doing enough.” Immediately afterward, she recalls, “this person came up to me from Becton Dickinson and said, ‘We're very interested in what you have to say.’ I was thinking, ‘You mean, we don't have to fight?’”

By 1989, BD had introduced the first in its lineup of safer products. Called the Safety-Lok, it is a syringe with a protective plastic tube. After removing it from a patient, the user can slide the tube forward and lock it in place to cover the needle. Safety-Lok complies with the new federal law but has limitations. Using the mechanism safely requires both hands—at a moment when professionals usually have one hand otherwise engaged. Moreover, hypodermic syringes are a universal tool in hospitals. About seven out of ten are used in labs and other places where there is no chance that health-care workers will be contaminated by patients' blood. If they are not to waste money, clinics and hospitals adopting the Safety-Lok for use on patients need to carry dual inventories.

BD's next effort at syringe safety, called SafetyGlide, can be operated with one hand, thanks to a hinged piece of plastic that can be safely snapped out over the needle by the thumb of the hand holding the syringe. Because it's attached to the needle, not to the

body of the syringe, hospitals can stock standard syringes and equip them as needed with either bare needles or the SafetyGlide.

These innovations do not reduce risk in the worst place to get stuck: around intravenous systems. Needles used to set catheters in veins are much more likely to be filled with a patient's blood than hypodermic needles after intramuscular injections, when any blood is most likely to be on the needle surface. Needles are also used to connect one part of an IV system to another to infuse medication or anesthesia. The patient's blood can flow backward through this setup. In 1992, the federal Occupational Safety and Health Administration (OSHA) issued an alert warning about this danger. That, plus common sense, led most hospitals to replace the needles upstream in IV systems with blunt devices or threaded connections.

The shift to safer IV devices was the first widespread effort to improve health-care workers' safety with new product design—and BD blew it. In 1993 it was forced out of the IV market after rival Johnson & Johnson challenged it successfully for patent infringement. Chastened, BD bought Phase Medical, a small company with its own safe IV system design, polished that up, and got back into the business in 1995.

In 1991, even before it issued the IV system warning, OSHA had published a “blood-borne pathogens standard” that encouraged the use of safety-engineered medical devices but did not require them. Concerned medical workers' unions agitated for regulation that would do so. They were strongly resisted by their employers, who were under intense pressure from HMOs and Medicare to reduce costs. BD's sales force tried in vain to overcome this resistance by pointing out that the higher-priced devices save money: It costs \$600, on average, to test and treat a worker who could have been infected as a result of an accidental needlestick. And that doesn't count the expense of caring for somebody who contracts AIDS or some other serious illness.

After California passed regulations requiring the use of safe sharps, momentum began to build in other states to do something similar despite continued objections from the American Hospital Association. Pressure also began to build at the national level, and in late 1999, OSHA effectively replaced “ought to use” with “must use” in its blood-borne pathogen standard. When some medical administrators said they found the regulations confusing and questioned whether they could be enforced, the rules' proponents, supported by BD and other manufacturers, turned to Congress.

Prospects for a law looked remote at first. House legislation had to originate in a work-force protections subcommittee rife with partisan bickering and chaired by North Carolina's Cass Balinger, a Republican who even his committee staffers concede deserves the prefix “arch” in front of “conservative.” Balinger founded a 260-employee plastic packaging materials company in Hickory, N.C., now run by his son-in-law. First elected to Congress in 1986, he brought along a dour opinion of OSHA or any other government meddling with people trying to earn an honest living by making things. But a good old boy can recognize a good cause. When union representatives recount how Balinger grasped the problem, wrote a sound bill that doesn't inhibit product improvements, and then successfully shepherded it through Congress, you would think they were reporting a conversion as miraculous as Saul's on the road to Damascus.

The federal regulations now going into effect cover all types of medical devices that can cut or puncture the skin, including scalpels. They require health-care employers to have up-to-date plans to reduce worker exposure to needlestick, to keep a log of incidents, to involve frontline nurses and technicians in the se-

lection of safe sharps, and, of course, mandate that they be used. Now comes the job of reducing the expense of building safe devices, of developing additional products, of making them affordable for all health-care facilities, and from the viewpoint of Franklin Lakes, of improving market share and margins for BD.

The manufacturing process starts in BD's needle plant in Columbus, Neb., with coils of thin, 3/4-inch-wide stainless steel, the basic material used in making cannulae. First rolled and

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welded into 1/4-inch-diameter tubing, it is next repeatedly passed through an annealing oven and progressively drawn down through a mandrel and die until it has been reduced to what will be the final wall thickness. The last pass is done cold to harden the steel. After straightening, the thin tubes are cut to length, degreased, and then, in computer-controlled machines, ground at three or more angles to form a point. While the sharper the better from, say, a blood giver's point of view, a needle has to be Goldilocks' "just right"—not too dull and not too sharp. The patient grimaces, but the blood taker relies on a touch of resistance to help keep the needle from going into the vein and out the other side.

Another tough problem is turning out very small or self-hinged bits of plastic. BD's Sumter, S.C., plant, where blood-collection devices are made, has installed a battery of 55 Spanish-made micromolding presses to do some of that work. The small machines look more like a hobbyist's tool than like production equipment. But they work so well making complex shapes no bigger than a spitball that 13 more are coming in from Barcelona.

Reducing product complexity would help lower costs. But the trend is in the opposite direction. The latest generation of BD sharps, either on the market or soon to arrive, employs a tiny spring to pull the needle up into the device after use so that it is

beyond reach of the most careless finger. Retraction occurs when the user presses a button or takes place automatically when the syringe plunger is fully depressed and touches a trigger. The "wow!" factor is undeniable. Zip, and the needle's gone. Not to be overlooked as a stimulant to development: A couple of small competitors have been offering spring-loaded, needle-retracting syringes for some time.

In building a device with a retracting needle, quality matters.

If it's a syringe, it can't activate before all the drug is delivered. Whatever category of device, it can't leak. It has to work every time, if only to keep tort lawyers at bay. And it can't

work too fast. If the needle starts to retract too rapidly, blood on the outside surface could be sprayed into the air, possibly spreading disease. BD's solution is to use conical springs, a high-viscosity gel for dampening the action, and lots of experimentation. With an air that reflects months of frustration, Cal Alexander, vice president of worldwide infusion therapy operations, based in BD's plant in Sandy, Utah, sighs, "We've learned an awful lot about springs over the last few years."

To be sure the springs work right, BD makes its own, forming them one by one and feeding them on the fly to the assembly line. Making it in-house is BD's style. You'd think its production managers had never heard the word "outsourcing." The Sumter plant shut down its glass furnace just a few years ago—and the local managers still seem to regret the loss. But they're more than pleased to show you how they continue to make blood specimen containers from glass tubing, compound their own rubber in a Banbury mill, and stamp out container stoppers in a rainbow of colors.

In late 1998, two years before the federal law that is now creating a huge market, a team led by William Kozy, senior vice president for manufacturing, set out to switch Sandy and Sumter, BD's biggest plants, along with some other U.S. factories, to high-volume production of safe sharps. Even some of the people charged with the task doubted that the conversion could be pulled off as fast as Kozy intended.

Kozy recalls, "There were people on the team who said, 'Look, we can't do this. You're never going to be able to put together the plans to convert all this array of product. You're not going to be able to achieve the speed of production. And you probably won't get the quality or the cost level that you need at startup.' I think most manufacturers would set up a pilot line, do prototype automation, and then go to high-speed automation. We didn't do that."

Since BD had so many plants and so much equipment in place, starting fresh with a new factory was out of the question. And, Kozy points out, people count. "If we were going to go quickly, we had to go where we had know-how." Some small additions have been built to get services like a machine shop out of the middle of a plant. But otherwise the conversion has been done inside existing factory walls while older lines continue to meet demand for conventional products.

It's been a particularly busy time in Utah. In 1999, while waiting for automatic

The Needle Vanishes

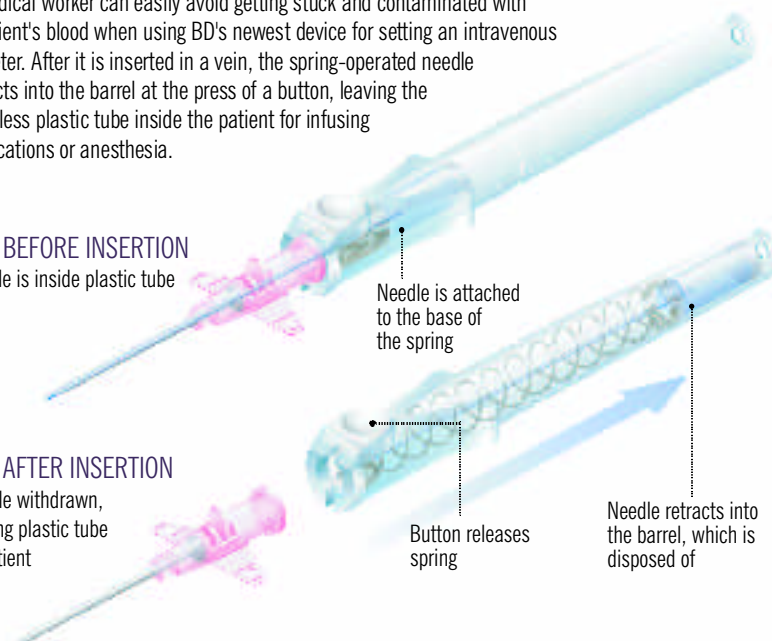
A medical worker can easily avoid getting stuck and contaminated with a patient's blood when using BD's newest device for setting an intravenous catheter. After it is inserted in a vein, the spring-operated needle retracts into the barrel at the press of a button, leaving the harmless plastic tube inside the patient for infusing medications or anesthesia.

1 BEFORE INSERTION

Needle is inside plastic tube

2 AFTER INSERTION

Needle withdrawn, leaving plastic tube in patient



lines, the Sandy plant, pressed to deliver IV product, started semiautomatic production of safety-engineered catheters, hired 175 temporary workers, and then, when the first fully automatic line got running in January 2000, gradually let half of them go.

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To get more room for production, managers converted warehouse space after cutting raw material inventories and moving to just-in-time deliveries. They also pulled out lines for making older types of catheters, shipping them to BD plants in Brazil and Singapore.

Spring-loaded IV catheters produced at BD's Utah plant have 12 parts, increasingly assembled in an automated process with 48 steps carried out at blurring speed. Instead of being a long assembly line in which one production step after another takes place, Sandy's assembly line is a mechanized version of cell production, in which parts are made or subassemblies are produced by teams feeding a central manufacturing line. In this case, the cells are separate machines or automated subassembly stations, more or less perpendicular to the main line, that feed the line through a buffer area that holds a few minutes of production.

One advantage of the system is flexibility. It's relatively easy to modify a product by altering or adding subassembly stations. But planning production this way for relatively short product cycles is something new for BD managers. Except for the shift from glass to plastic, the basic design of the hypodermic needle didn't really change over a century and a half. In the past, says Cal Alexander, “you had these big, very inflexible manufacturing systems cranking out all this stuff at very low cost.”

BD is finishing up conversion and initial installation of its new manufacturing lines—and not a moment too soon for shareholders. Says CFO Considine: “These things have higher absolute gross margins when they get cooking”—meaning, when the production lines are fully automated and running flat out. However, BD has been pricing its new products as though it had already reached this stage in order to hold market share and avoid the need to back down later when there is sure to be increased price competition.

Sales of safe sharps are already starting to cook. Under the new federal law all medical providers, except for relatively few state and

municipal hospitals, were required to convert to safer sharps by April 16. That hasn't happened. Safe versions of some special sharps haven't been developed. But the principal reason is that a conservative medical profession simply hasn't been able to change that quickly. Some hospitals won't fully switch to safe sharps much before 2003. Small medical practices could take a good deal longer. Ask your personal physician what he is doing.

“What law?” is the likely response.

For the nine months ended June 30, BD's sales of safe sharps were the only reason the company has done better this fiscal year than last. While total sales for the period were up a mere \$61 million, or 2%, safe sharps popped 45%—\$288 million, vs. \$198 million. In 2003, when the U.S. medical establishment should be more than 90% converted, BD estimates that sales of these items will be around \$700 million, which is about 170% of what revenues would have been on the same volume of old-style sharps.

Still to come: the rest of the world, where BD generated almost half of last year's total sales. So far, preventing needlestick has been largely a U.S. concern. However, by the time the U.S. market is largely converted, the European and possibly the Japanese market will be coming to a boil. The manufacturing conversion teams will have to do it all over again in BD's foreign factories. Eventually, markets will also open in the developing world.

There's also lots to be done in the U.S. As CEO Ed Ludwig explains, “This is not a ‘nine month and out’ process for us. Even after we convert all the markets, there's going to be the second generation, the third generation, and the fourth generation.” Among the changes foreseen with pleasure by Ludwig, though not necessarily by you, is more medication by syringe. Oral versions of the biopharmaceuticals now being developed tend to break down in the gut before getting absorbed. Your consolation might be that BD's long-term goal is to get rid of needles as we know them.

One product in development uses an array of microneedles to inject medication or vaccine just below the skin, where it's absorbed faster, but above the pain receptors. While waiting for that, you'll just have to wince and bear it. At least the new needles will be safe for the person inflicting the misery as well as yourself. And they'll definitely improve BD's bottom line. **F**

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