

# A Look at the Reuse of Insulin Needles



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## The Early Days of Needle Reuse

In the early days of insulin administration, patients injected insulin using glass syringes with detachable needles. The users had to boil the needles between uses and soak them in alcohol to sterilize the needles as best they could. To make the pain of injections more bearable, users spent hours sharpening their needles on a stone between uses to try to reverse the comfort deterioration from repeated use.

Over the years, manufacturers have made dramatic improvements in the comfort and convenience of insulin injections. With the introduction of disposable, single-use insulin syringes with attached needles, users were freed from the arduous tasks of boiling, soaking and sharpening. With the disposable syringes came thinner needles, improvements in the needle point geometry and a freshly lubricated needle for every injection. Therefore, comfort of injections improved and the tissue trauma associated with injections declined.

## Reuse and Disposable Syringes

When disposable syringes were first introduced, most users fully embraced the concept of single-use disposable syringes and used them once as intended. Others used the disposable syringes, but did not use them only once. "It is wasteful to throw away a perfectly good syringe after one use" they may have reasoned. These patients used their disposable syringes multiple times, and may have made up their own regimen to care for the syringes between uses; some continuing to soak them in alcohol between uses or wiping them with alcohol and others storing them in the refrigerator.

Consequently, there was and still is awareness by professionals that some patients reuse disposable syringes. Despite syringe labels that advise single-use only, this perception appears to have resulted in health care professionals developing occasional "unofficial" guidelines ranging from "use each syringe for no more than one or two days" to "use a syringe until it is no longer comfortable." Other cautions may have included directions not to soak the needles in alcohol or wipe them with alcohol between uses (to avoid making the needles less comfortable by removing the lubricant).

Although one might imagine that patients who reused syringes would get infections at the

injection site from using non-sterile needles, in fact infections were reported infrequently. There were studies documenting that pain increases with needle reuse, but acceptable pain level was viewed as a personal matter for the patient to decide, and not a medical matter as long as the increased pain didn't negatively impact compliance with the prescribed injection regimen. As a result, some patients may have been advised that as long as only one person used the needles, bathed regularly and took all of the required injections, they could reuse the syringes.

Today, it is recognized that reuse of insulin needles is not uncommon, even among younger patients who did not have the personal history of having once used glass syringes with detachable needles. The most common reason for reuse of insulin needles is not cost. Instead, convenience and a reluctance to throw away something that is not yet "worn out" or "finished being used," are the most prevalent reasons for reuse. Over 70% of patients who inject insulin have insurance that covers their needles, and yet many still prefer to reuse insulin needles.

## Needles Became Even Thinner

Since the introduction of disposable insulin syringes, manufacturers have continued to innovate and offer thinner, even more comfortable needles. When the outer diameters of the needles became thinner, the inner diameters (inner lumen, that the insulin passes through) were not reduced in size proportionately. One reason for this was that if the inner lumen were too narrow, it would take an unacceptably long time to fill a syringe. Another was a concern that the force on the plunger, required to push the insulin through a very narrow passageway, would be too great. As shown on the chart below, when the outer diameters of the needles dropped significantly, so did the wall thickness of the needles. The 0.063mm wall thickness of today's 31G needle is the thickness of 4 white blood cells. (Wintrobe, 1993).

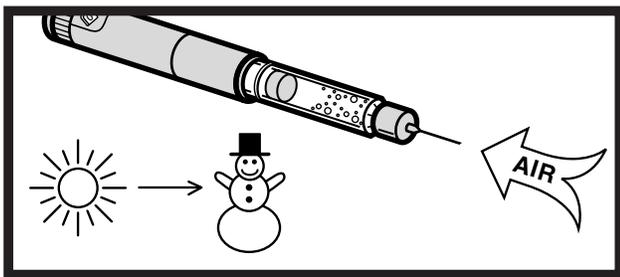
<b>Needle Dimensions (mm)</b>		
<u>Gauge</u>	<u>Outer Diameter</u>	<u>Wall Thickness</u>
24	.559	.133
25	.508	.133
30	.305	.076
31	.254	.063

As needles and their wall thickness become smaller, reuse becomes more of a problem, because of the potential of needle tips to bend into the form of a hook and break with repeated use. The needles are so fine that the tip damage cannot be seen with the naked eye. It can only be seen with high-resolution electron microscopes.

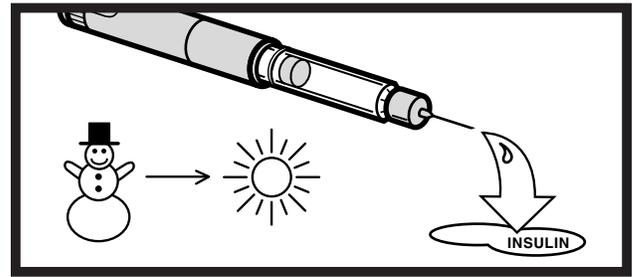
### Special Considerations for Pen Needles

There are additional concerns when it comes to reuse of insulin pen needles. Reuse of insulin pen needles is almost always accompanied by carrying the pen with the needle attached. For greater convenience, some patients report using only one pen needle for each disposable pen or insulin cartridge, carrying the device with the needle attached, between uses. Therefore, pen users who carry their pens with the needle attached, risk micro-tissue damage. The same is true of syringe users who reuse. A pen needle is a two-ended needle, with one end that punctures the insulin cartridge and the other end that penetrates the skin. By leaving a needle attached to a pen, even if the needle is covered, patients are leaving an open-passageway into the insulin cartridge. A study entitled *The Kinetics of Insulin Administration by Insulin Pens* (Ginsberg, Parkes, and Sparacino 1994) demonstrated that air enters insulin cartridges when the pen needle is left on the pen and the pen is exposed to alterations in temperature.

When patients carry the pen from warm places to cool places (such as when they go outdoors in winter, or into an air-conditioned building in summer) the insulin in the pen contracts, drawing air into the cartridge through the attached needle. When there is added air in an insulin cartridge, the dose delivered is very inaccurate and up to 2/3 of the dose may not be delivered.



Conversely, when patients carry the pen from cool places to warm places (such as when they go outdoors in summer, or into a heated building in winter), the fluid in the cartridge expands and leaks out through the attached needle. If the cartridge contains NPH either alone, or as part of a premix, and the patient has not just re-suspended the insulin chances are that the crystals will be settled on the bottom of the cartridge and what will leak out will be fluid without crystals. This will change the concentration of the insulin that remains in the cartridge, altering the effectiveness of future doses from that cartridge or pre-filled pen.



The study concluded that “patients should be instructed to remove the insulin pen needle immediately after each injection and only replace it with a fresh needle just before the next injection....If patients follow this simple procedure and remove their needle after each injection, the insulin pen is a safe, accurate device.”

There are some patients who do not carry their pens with the needle attached, but who do reuse the needles. For these patients there is an additional issue with how they keep the back end of the needle clean between injections. New pen needles come with a paper seal over the end of the needle that penetrates the insulin cartridge. Once this seal is removed to attach the needle to the pen, there is not a good way to keep the needle clean between uses.

When syringes are reused the needle is placed into the bacteriocidal insulin solution between uses. This may be why there are fewer infections than expected. This is not true of pen needles in which bacteria are free to grow on the needles.

### Microscopy Findings

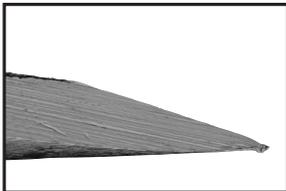
In three studies on reuse conducted at the Klinik Hellbachtal in Germany in 1997 patients were asked to save their pen needles and lancets after use, and label them with the number of times they had been used. Electron micrographs were taken at the University of Grenoble, France, during 1997 by Dr. Jacques Garden of pen needles and lancets that had been used by patients, according to their own normal reuse patterns in the treatment of their diabetes. The needles were then photographed under microscopic powers ranging from 370x to 5000x. The observers noted the following (Look, Strauss 1998):

- Significant tip damage can occur after only one injection and was seen with all manufacturers studied.
- The majority of needles and lancets showed tip damage when reused, despite the fact that pen needles only penetrate human skin with each use, not a vial stopper.
- Some needles were actually missing their tips — raising the question of whether the tips might be imbedded in the patient’s skin.
- Tip damage did not always increase proportionately with the number of times the needle was used. There were patients whose

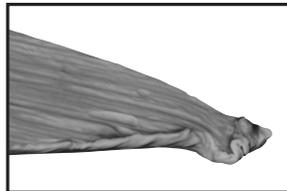
needles remained in good condition with repeated use. Therefore, skin type and injection technique may play roles in the degree of needle tip damage after use. In actual practice though, all reuse must be discouraged, as the damage occurs to such a small area of the needle tip that it cannot be detected without a high powered electron microscope — even where the needle tip has broken off.

While reused syringes were not included in this particular study, it is reasonable to assume that the damage to reused syringe needles is even greater than the damage to reused pen needles and lancets, as syringe needles must go through the rubber stopper of syringe vials before each skin penetration.

Photographs showing the type of damage that can occur with needle reuse.\*



Used needle  
magnified 370 times



Same used needle  
magnified 2000 times

\* Photographs from Dieter Look and Kenneth Strauss study:  
"Nadeln mehrfach verwenden?" Diabetes Journal 1998, 10: S. 31-34.

### Medical Consequences of Needle Reuse

“Reuse of Sharps in Diabetic Patients: Is It Completely Safe?” (Look, Strauss 1998) analyzed the three studies conducted by D. Look at the Klinik Hellbachtal in Molln, Germany in 1997 and drew the following conclusions based on the evidence demonstrated in the studies.

1. Tissue microtrauma: When a deformed needle is used, it lacerates tissue, causing microtrauma. This can result in locally significant bruising and bleeding. Volunteers in the German studies who reused lancets were found to have more residual bleeding in sites where a more heavily reused lancet was employed for the blood letting.
2. Embedded needle tips: The studies showed that excessive reuse (>7 times/needle) was often associated with a breaking off of the microscopic end of the needle tip. The medical consequence of embedded metal tips is unknown at this time.
3. Correlation with greater incidence of lipodystrophy: According to the analysis of the German studies cited above, local growth factors may be released and join with insulin to form lumpy nodules called “lipodystrophy.” Although at this time there is not proof that reuse leads to lipodystrophy (“lipos”), there is

a correlation between reuse and lipodystrophy. While “lipos” are not frequently reported, it is estimated that 20-45% of injecting patients with Type 1 diabetes mellitus and 3.6% with Type 2 diabetes mellitus will have “lipos” (Saez-de Ibarra, Gallego 1998) once a search is conducted. These are often easier to feel than to see and can be disfiguring. People often prefer to inject into them because it is less painful.

### Lipodystrophy and Control

A study published at the 1997 International Diabetes Federation (IDF) conference, Helsinki, Finland (Franzen, Ludvigsson, 1997) found that in the study group, versus control, HbA1C decreased with “lipo” decrease. The average decrease was between 7.0 and 7.9% in the experimental group, versus no change in the control group. In the experimental group, the improvement in lipohypertrophy and HbA1C came about after intensified instruction regarding injection technique (site rotation) and clean needle use while the control group received traditional instruction in injection technique.

### FDA Guidelines

Recently there has been a great deal of media coverage about the practice of institutions reusing medical devices that are labeled as being for single use. The FDA Compliance Policy Guidelines Sec. 300.500 (1987) states: “Since disposable devices are not intended by the manufacturer or distributor for reuse, any institution or practitioner who re-sterilizes and/or reuses a disposable medical device must bear full responsibility for its safety and effectiveness.

### Insurance Concerns

When patients who have been reusing syringes stop reusing, there are bound to be concerns about whether their insurance will cover the increased number of syringes that are required. For example, if a patient takes three injections per day, and in the past has been using each syringe three times, his or her mail order plan may have been sending one box of 100 syringes every three months. In this case, the plan may be dispensing one syringe per day, not because they expect their members to reuse, but because they were never advised that the patient was taking three injections per day. If a plan does cover syringes, however, it should cover the proper number that will allow the patient to use them according to the directions. Therefore, if patients are not being given enough syringes to use one syringe per injection, they should advise their pharmacist or plan of the number of needles they need per day. To help avoid these problems, prescribers should make it a practice to indicate the number of needles needed per day on the prescription.

## Moving Forward

BD, the leading manufacturer of insulin needles, is making a commitment to begin educating patients about the risks associated with reuse of insulin needles by doing the following:

1. A statement advising against reuse will be added more prominently to syringe, pen needle and lancet boxes and syringe 10-pack bags.
2. Patient literature including photos from the microscopy study will be included in syringe box inserts, patient mailings and in literature available to health care professionals for distribution to patients.
3. Slides of the enlarged reused needles will be available for use at patient training classes, upon request.
4. For pen users, BD will make available a small pouch on a key-chain that can be used to make it more convenient to carry needles when they are away from home.

It is recommended that those training patients to inject insulin do the following:

1. Include a discussion on the risks of needle reuse in their patient training sessions.
  - Patients should be taught to understand that when they dispose of a syringe, pen needle or lancet after one use, they are not being wasteful, but rather, they are helping reduce their risk of tissue damage and of having needle tips embedded in their skin.
  - Since as a practical matter, patients will not be able to examine their reused needles under a high-powered electron microscope, all patients should be advised to assume that they are among the vast majority of patients in whom the needle tips become hooked or broken off with repeated use.
2. Include the number of needles or lancets needed per day on all prescriptions for syringes, pen needles and lancets and advise patients not to accept fewer needles or lancets than they need, from their plan.

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*Call BD Health Care Professional Services at 1-888-367-9539 (Monday-Friday, 9 a.m. to 5 p.m., Eastern Time) if BD may be of service in helping you to help your diabetes patients.*



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