

## KEEPING URINARY CATHETERS FROM BLOCKING

*One of the nation's top urologists, Dr. Todd A. Linsenmeyer, is participating in clinical trials of a NovaBay product that kills bacteria causing a serious medical problem—the encrustation and blockage of urinary catheters. In this interview, Dr. Linsenmeyer describes the importance of solving the problem.*

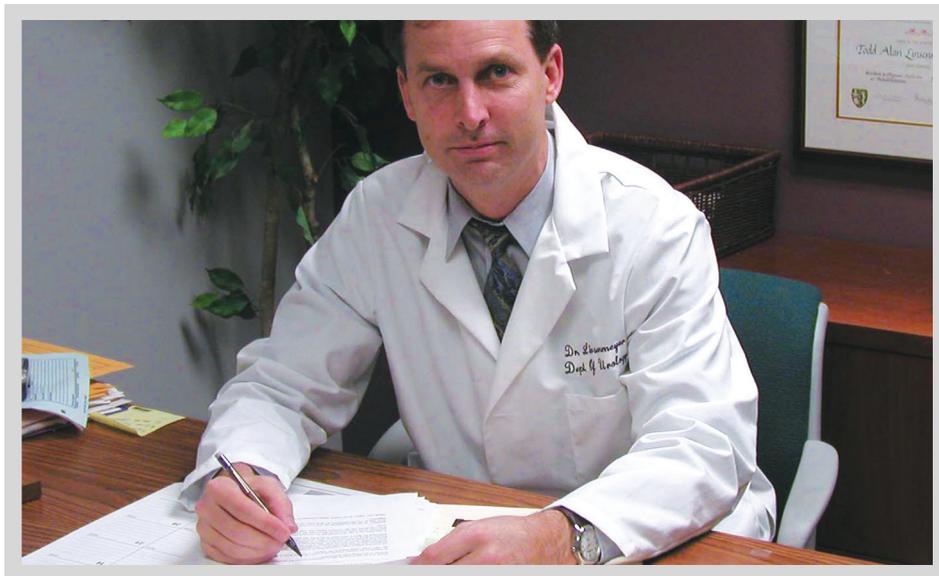
### Introduction:

Because of spinal cord injuries, multiple sclerosis, strokes, or other neurogenic bladder conditions, an estimated 74,000 patients in the U.S. that rely on indwelling catheters routinely suffer from blockage and encrustation. These catheters typically become coated with bacteria and bacterial biofilm, but in some individuals, the bacteria produce localized crystal deposits that build up and block the catheter. This blockage can cause everything from bladder stones and urinary tract infections to a potentially life-threatening condition called autonomic dysreflexia. “Urinary catheter blockage and encrustation have severe consequences that are often unappreciated,” explains Dr. Todd A. Linsenmeyer, director of urology at the Kessler Institute for Rehabilitation in New Jersey.

NovaBay Pharmaceuticals, Inc. (NYSE MKT: NBY) a biopharmaceutical company based in Emeryville, California, is tackling these problems. The company's key innovation was creating a stable version of potent natural antimicrobial substances that white blood cells produce when they detect invaders. NovaBay scientists created a formulation of the product, called auriclosene (NVC-422), that can be irrigated through catheters, killing the bacteria that cause the blockages.

The product has been tested by Dr. Linsenmeyer and other physicians in Phase 2 clinical trials, with encouraging results. In this Q&A, Dr. Linsenmeyer discusses the problems of catheter blockage—and the benefits of solving those problems.

Dr. Linsenmeyer has repeatedly been named one of the nation's leading urologists in medical guides and US News and World Report rankings, and has also won numerous awards.



A graduate of Stanford University and the University of Hawaii School of Medicine, Dr. Linsenmeyer served as an Army urologist and completed an additional residency in physical medicine and rehabilitation at Stanford before becoming director of urology at the Kessler Institute in 1989.

### Interview:

**Q:** Do many people use indwelling catheters?

**Linsenmeyer:** Indwelling catheters are the most common type of bladder management in women five years after a spinal cord injury, and the second type of bladder management in men five years after such an injury. In addition, many patients without spinal cord injury also use indwelling catheters.

**Q:** What are the advantages of using indwelling catheters vs. just inserting one when a patient needs to urinate?

**Linsenmeyer:** Indwelling catheters can allow a person a lot of independence, particularly if they do not have enough hand function to undress and catheterize themselves, or if they do not have a caregiver who can assist them with this. In general we would rather not put the burden on family members or “significant others”, from having to perform intermittent catheterization every 4-6 hours of their partner. Indwelling catheters are also very helpful when a person is travelling or at work or out for the evening. In those cases undressing and trying to perform intermittent catheterization may not be practical or convenient.

**Q:** So what are the problems that indwelling catheters cause?

**Linsenmeyer:** One of the major problems with an indwelling catheter is the risk of getting catheter encrustation. That could cause catheter blockage or the formation of bladder stones, which can then themselves block catheters.

**Q:** Why is this an issue?

**Linsenmeyer:** If a catheter blocks, the bladder becomes over distended. This can cause small tears in the bladder wall and a decrease in blood flow at the surface of the bladder, which then can allow the normal colonized bacteria to start a true bladder infection. The stretching can also cause blood in the urine or leaking around the catheter. And in some spinal cord patients (those with injuries above T6—the 6th thoracic vertebra who have lost function below the waist), blockage can cause a condition called autonomic dysreflexia. Autonomic dysreflexia is a sudden severe elevation in the person's blood pressure that does not resolve until the bladder is emptied. In addition to causing a terrible pounding headache, autonomic dysreflexia has the potential to cause more serious problems such as a stroke if not taken care of immediately.

**Q:** How often do these problems occur?

**Linsenmeyer:** Catheter encrustation occurs in up to 30 percent of those with indwelling catheters.

**Q:** So what can be done about it?

**Linsenmeyer:** We don't have any "sure fire" treatments for the prevention of future encrustation and stones. Some people try to irrigate their catheters with saline or drink a lot of water, but this has not been found to be effective.

One of the most effective things we do is to have the person perform frequent (every one to two weeks) catheter changes in an attempt to limit encrustation. But encrustation can still occur even with this.

**Q:** You have been testing NovaBay's auriclosene anti-microbial product, which is designed to be infused into catheters to kill bacteria and reduce the blockage problem, in a randomized double-blind clinical trial. How did you get involved in the trial?

**Linsenmeyer:** I received a phone call from NovaBay CEO Dr. Najafi, who had found some of my articles discussing bladder stones. He explained his study was investigating an irrigant to try to prevent bladder stones. Since bladder stones and encrustation is such a big problem, after reviewing the protocol I agreed to be one of the investigators.

**Q:** What have you learned from the trial?

**Linsenmeyer:** I and the staff and the patients were all "blinded," so no one knew what the person was having irrigated into their catheter and whether they were getting the NovaBay product or a saline solution. However everyone had the "true" NovaBay irrigation solution at some point during the course of the trial. Several of my patients had catheters that remained patent for the duration of the treatment arm 26 days.

**Q:** So do you think NovaBay's product can improve the quality of patients' lives and reduce healthcare costs?

**Linsenmeyer:** As previously mentioned, I work for Kessler Institute, a division of Select Medical, and our policy does not allow for the endorsement of any particular products. But I will say that I am very encouraged that NovaBay is investigating ways to prevent catheter encrustation since this a significant problem. A truly effective reliable irrigation solution would not only help reduce potential risks of catheter blockage, it would also reduce health care costs associated with frequent catheter changes, frequent cystoscopies (using a tiny camera inserted through the urethra to look for bladder stones), removal of bladder stones, and trips to doctors and the emergency room for problems such as urinary tract infections.

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