

# THE NEUMA PICC AND CENTRAL LINE PROTECTION CLAMP

## Introduction and Frequently Asked Questions

### BACKGROUND

The use of central lines for medical treatment is accelerating alongside an epidemic of intravenous drug abuse and opioid overdoses. Medical facilities are experiencing a dramatic need for safe and effective tools that inhibit the abuse of central lines by IVDU patients and their associates.

### PROBLEM

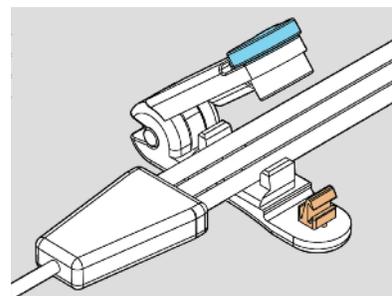
The risks for central line complications are especially high in persons who abuse intravenous recreational drugs. After discharge from the hospital, these patients often use their central line to shoot up harmful drugs. Doctors frequently decide to keep patients with central lines in the hospital when they could otherwise send them home. Providers are unwilling to discharge stable patients because some patients will abuse their line, resulting in a dangerous infection, damage to the central line, or drug overdose and death. The consequences of overdose through an unprotected central line are tragic. Furthermore, the concern about line abuse and the reluctance to discharge patients results in hundreds of millions of dollars in unnecessary medical expenses as a consequence of keeping patients with central lines in hospitals when they could otherwise be receiving their therapy at home or other care facilities.

### SOLUTION

Neuma Innovations has developed a catheter safety device to deter and detect the purposeful abuse and accidental errors that endanger the millions of patients with central lines inserted annually. The Neuma Clamp is a Class 1 510(k) exempt device registered with the FDA, and manufactured using medical grade acetyl plastic.

### FEATURES AND BENEFITS

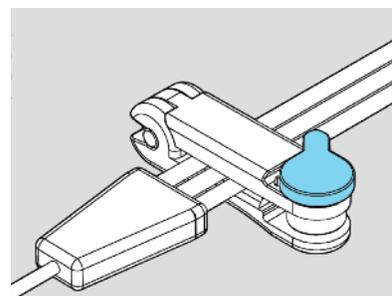
- Deter and Detect Central Line Abuse
- Protect Lines from Contamination
- Improve Patient Safety
- Discharge Patients with More Confidence
- Free up Hospital Beds



#### STEP 1

Place the lines into the walled cradle.

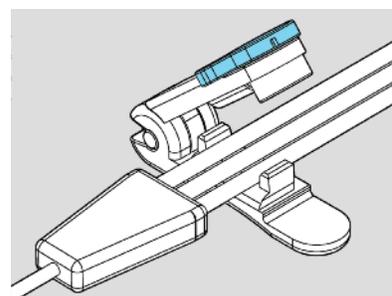
*(Note the orange hook that will hold the clamp closed.)*



#### STEP 2

Pinch the clamp and it will lock shut.

Now the lines are protected.



#### STEP 3

Turn the blue knob to open the clamp. This action breaks off the orange hook and the clamp can't be used again.

# INTRODUCING THE CENTRAL LINE PROTECTION CLAMP

## Introduction and Frequently Asked Questions

### **Why is the Clamp “tamper-evident” and not “tamper-proof”?**

We had 3 primary goals in developing the Clamp: **1)** Protect for the patient **2)** Safeguard the central line or PICC line and **3)** Optimize the use of scarce medical resources. An intravenous drug use (IVDU) patient can always find a way to use drugs, even if the central line is fully protected.

We wanted to help physicians feel more confident that the line would remain clean and useful for treatment. We wanted to minimize danger to patients from line tampering. And we wanted to make it possible to discharge selected patients to appropriate settings so that they would not remain for extra unnecessary weeks in the acute hospital.

Tamper-evident sends an important message to the patient that tampering with the line is dangerous, could lead to death and could jeopardize treatment. The initial placement of the tamper-evident device provides an opportunity for the physician to speak to the patient about the risks and consequences of abusing the line. Tamper-evident also ensures that the care providers know when the patient has put the line at risk. It's then up to the treating team to decide how best to manage the patient.

Making the line tamper-proof would not prevent shooting up in other areas. Tamper-proof would require a much heavier, more expensive and more intrusive device. It would also mean that in the event of an emergency with a line locked off by a tamper-proof device, providers might not have immediate access to the line.

### **Can't the patient just use a needle to shoot directly into the catheter beyond the Clamp?**

The Clamp is applied near the hub leaving little room for a needle. In addition, if the patient does insert the needle directly into the catheter, leaking will be immediately apparent.

### **What size central venous catheters and how many lumens can the Clamp handle?**

The Clamp can accommodate catheters with 1 to 3 lumens and essentially any diameter central or PICC line other than Quinton catheters or similar large bore lines. The Clamp is for shorter, centrally-inserted catheters, PICC lines, mid-line catheters or even peripheral IVs if you intend to leave them in.

### **We're not going to pull the line or stop treatment even if the patient tampers with it. Why would we want to know if the patient is tampering with the line?**

In many cases, abusing the line is more dangerous than changing treatment or even ending treatment. Not knowing that the patient is tampering with the line is dangerous for the patient and for your hospital. The Clamp will alert you to tampering. An open Clamp is a better alert than a second infection, an air embolism or a deadly overdose.

The treatment contract template we recommend spells out what will happen if the patient is discovered to have tampered with the line. The patient and the treatment team should have a documented conversation about the rules of treatment and the consequences for breaking those rules.

### **Will use of the Clamp really lead to early and appropriate discharge from the acute hospital?**

A survey of 64 hospitals in the UK, Singapore, New Zealand and Australia showed that about 50% of those surveyed send IVDU patients to nursing homes with PICC lines and believe that practice is safe and effective. Others never do, but there is no evidence that sending patients to nursing facilities is more dangerous than keeping them in the hospital with central lines. The decision depends on your patients, your

# THE NEUMA PICC AND CENTRAL LINE PROTECTION CLAMP

## Introduction and Frequently Asked Questions

hospital and your doctors. However, many institutions do send patients to skilled facilities.

Surveys of internal medicine hospitalists in California and Kentucky have been conducted. Without the Clamp, only about 20% of hospitalists would even consider discharging an IVDU patient with a central line or PICC line. With a device like the Clamp in place on the line, about 75% of a group of hospitalists said they would be willing to send patients who are stable to a more appropriate level of care.

Outpatient Antibiotic Treatment Centers (OPATs) are a cost-effective site to discharge patients to complete antibiotic therapy. They live at home but come back as outpatients for antibiotics on a daily or even twice daily basis. The Clamp makes tampering evident in OPAT patients. Jennifer Ho\* successfully treated a group of 29 IVDU patients with central lines protected by tamper-evident technology in her OPAT without any excess complications.

### What can we do if the patient is found to be tampering with the central line?

Here are some recommendations. You and your staff may have additional approaches:

- Re-educate the patient about the dangers of tampering with the central line.
- Alert the nursing staff to watch for suspicious behavior or to pay special attention to the patient, perhaps with more frequent checks.
- Search the room for illicit drugs.
- Engage the patient in a discussion about why he or she tampered with the line and about his or her goals for treatment.
- Restate the guidelines and document your conversation with the patient.
- Implement random drug testing.

- Limit or eliminate visitors.
- Switch to oral or IM antibiotics for the final weeks of treatment.
- Decrease the treatment duration.
- Switch to a less frequent IV regimen and use a peripheral line once a day.
- Require the patient to start medical addiction treatment with buprenorphine, methadone or even naltrexone.
- Insist on a behavioral health consult.
- Don't allow the patient to leave the floor.
- Install a sitter or a camera.
- Contact your infectious disease consultants for ideas about treatment options.
- Remove the line or let the patient know that the next time he tampers with the line, you will remove it.
- Engage a responsible family member or reliable friend to be with the patient.
- Beef up your documentation of warnings to the patient to protect yourself in the event that something bad happens.

### How can the Clamp be useful when the patient is sent home, especially if nurses do not come to the home for every infusion?

Obviously, there's no point to having the patient apply and remove his own Clamp. It's important to have the patient in a supervised environment when the antibiotics are administered and the Clamp is changed under observation. However, some insurance companies and Medicare supplemental plans will send nurses for every infusion, especially if you can devise a once-daily regimen. Some hospitals may want to create integrated programs that view the expense of nurse visits as a fair trade-off for discharging the patient to a

## THE NEUMA PICC AND CENTRAL LINE PROTECTION CLAMP

### Introduction and Frequently Asked Questions

more cost-effective environment. Family members or trusted friends are often recruited to give the antibiotics. These same folks could be in charge of monitoring and applying the Clamp. If family members can handle the infusions, they can also successfully include the Clamp as part of the treatment.

#### **Should the Clamp be applied for patients still in the hospital?**

Yes. Patients with a history of IVDU often inject while in the hospital. Whenever you suspect or know of IV drug abuse, you should use the Clamp.

#### **What are the legal implications of using the Clamp?**

You should always consult your own legal counsel. However, the risky activity is the insertion of the central line or PICC line, not the application of the Clamp to that line. Using the Clamp is a way to protect the patient from his addiction. The treatment contract and documentation of discussions with the patient about the dangers of abusing the line are an excellent defense against legal actions if you make the decision to insert a line in any IVDU patient. We also strongly recommend using a treatment contract.

#### **Is the Clamp FDA approved?**

The FDA recognizes several different levels for medical devices. "Class 1 Exempt" applies to devices that are very similar to already existing devices and are of little or no risk. The Clamp is FDA Class 1 Exempt. However, we took the extra step of completing an FDA risk analysis of the Clamp, and we registered the device with the FDA.

#### **Is the Clamp sterile?**

No. The Clamp is manufactured in a clean room and packaged in a clean environment. Each Clamp is packaged individually, and all lots have unique identification. Since the Clamp is applied to a non-sterile external line and is in touch with the skin, sterility is unnecessary and could not be maintained.

In addition, the Clamp is made of a medical grade plastic that has been tested for biocompatibility with direct skin contact.

#### **Will the Clamp damage the central line?**

No. During testing, we kept Clamps on lines continuously for up to 6 months without any damage to the lines. We have also opened and locked up to 150 fresh Clamps on the same line without damage to that line.

#### **Our institution has an informal policy that we never discharge IVDU patients with PICC lines. Is it safe to do so?**

Many institutions have a never-discharge formal or informal policy. And there is certainly a rational case to be made for that policy. However, the policy is not uniform, and the science, while certainly not comprehensive or absolutely conclusive, actually may lean a bit toward discharging patients under the right circumstances.

Laura Fanucchi et al at the University of Kentucky showed that nearly 40% of all IVDU patients with PICC lines tested positive IN THE HOSPITAL for illicit drugs (PMID 300332946). So, even hospitalized IVDU patients with PICCs should have a Clamp to deter and alert to abuse of the line.

Camsari & Libertain showed that given certain criteria, one can predict which patients will do well when discharged with OPAT follow-up. (PMID 29057191). And Ho successfully treated 29 IVDU outpatients with PICC lines in an OPAT by using a tamper-evident approach (PMID 29864497). In another study, patients discharged to an outpatient OPAT were just as likely to successfully complete treatment as were those discharged to a SNF (PMID 29766017). The bottom line is that no site, not even the inpatient service, is immune to line tampering, and, under the right circumstances, many patients can be treated successfully as outpatients. As with all patients, one very rational policy is to individualize treatment to best suit the patient and to always

# THE NEUMA PICC AND CENTRAL LINE PROTECTION CLAMP

## Introduction and Frequently Asked Questions

do what it takes to protect the patient and the line, no matter the venue.

### **What is a treatment contract?**

A “treatment contract” or “treatment agreement” is a document that sets out the rules for treatment and the relationship between the patient and the treating team. It also spells out the consequences of tampering with the central line. The contract is a very useful tool to help educate your patient about the risks and consequences of tampering with the central line.

The document also protects you and your institution. The Clamp does not require informed consent since it is not a procedure and is a routine recommended by the manufacturers of central lines. The central line insertion requires informed consent, but that consent does not require mentioning the consequences of tampering with the line. The treatment contract does set those out in detail and documents that you have spoken with your patient about them. You do not have to use a treatment contract with a patient, but we strongly recommend its use.

You can find a sample treatment contract template in the “Downloads” section of the Neuma Innovations website:  
[www.neumainnovations.com/neuma\\_downloads](http://www.neumainnovations.com/neuma_downloads)

### **What is Medical Addiction Treatment?**

“Medical Addiction Treatment” is the use of medications to control addiction in opioid use disorder patients. Drugs such as methadone, buprenorphine and naltrexone attach to the opioid brain receptors in various ways. They decrease craving and control the behaviors of addiction. Clinicians skilled and certified in their use administer them, but the training does not need to be extensive. For instance, a licensed physician can be certified to use buprenorphine through an 8-hour course that is often offered online and without charge. You can't

require patients to take these medications. However, if they do so, studies have shown they are several times more likely to remain abstinent than with behavioral therapy alone.

### **How can I purchase the Clamp?**

The device comes in boxes with 100 individually wrapped Clamps. Prices and terms are available on the Neuma Innovations website:  
[www.neumainnovations.com/shop\\_now.html](http://www.neumainnovations.com/shop_now.html) .

You can also purchase via an invoice or arrange an account to submit a purchase order. Contact us directly via [sales@neumainnovations.com](mailto:sales@neumainnovations.com) or by the contact phone number on the website.

### **How do I learn to use the Clamp?**

The Clamp is very simple to use, and we have a comprehensive inservice video on our website. Anyone on your staff can view the video on their own time, and new staff can be directed to the site for training. We also have a post-test document on our website under the Downloads tab that can be used to certify staff.

### **How much does it cost to add the Clamp to our treatment work flow?**

You can find a price list on our website under the “Shop Now” tab. We provide volume discounts. The added cost for the treatment of a patient varies depending upon the number of times per day that you give an infusion. The Clamp is a single use device that must be changed with each new infusion or flush. Multiply the number of daily changes by the length of anticipated treatment. The average total fee to include the Clamp is between \$300 and \$400 for a 6-week treatment, a small addition compared to the expense of a sitter for 6 weeks or the treatment of an infection or overdose. The entire cost for the Clamp for 6 weeks of treatment is about 1/10 what it costs to keep a patient in the hospital for just one day.