

# NEUMA CATHETER SAFETY DEVICES

Deter and Detect Central Line Tampering



Neuma Innovations LLC

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## OVERVIEW

### INTRODUCTION

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 patients and their associates.

Neuma Innovations has developed a comprehensive suite of catheter safety devices to deter and detect the purposeful abuse and accidental errors that endanger the millions of patients with central lines inserted annually.

#### The Neuma CSL™ (Catheter Safety Lock™)

A single-use clamp that blocks unwanted flow through the line, makes it evident when a central venous catheter has been used for an illicit purpose, and acts as a safeguard against accidental errors.

#### The Neuma CSC™ (Catheter Safety CAP™)

A single-use cap that protects the catheter hub port, prevents the reattachment of the used cap, and shows evidence of tampering.

#### The Neuma CSS™ (Catheter Safety Seal™)

Also a single-use protective cap, the CSS features a perforated self-adhering strip that serves as clear notice the central venous line has been manipulated or abused.

### BACKGROUND

The central venous line (CL) has become a ubiquitous health care device. These catheters are thin, flexible, tubes that extend into the large and deep veins of the body, close to the heart. They provide long-term intravenous access for dialysis and hyperalimentation (intravenous nutrition) as well as for treatment of infections, cancer, and other chronic conditions. Roughly 3 to 4 million central lines are inserted into patients in the United States each year.<sup>(1)</sup>

Growing at a rate of 6% annually, the peripherally inserted central catheter (PICC) accounts for nearly 40% of the CL market with centrally inserted catheters accounting for the remainder.<sup>(1)</sup>



*Arrow® brand double lumen PICC line.*

All PICC lines and most of the balance of centrally inserted catheters have portions of the line that protrude out through the skin for access. This is required to infuse medication or intravenous feeding formulas. Infusion catheters generally attach to the CL through a catheter hub.

While these catheters provide significant advantages over the much shorter peripheral intravenous lines, they also carry significantly greater risks, including infection, thrombosis of the line, and the chance of injecting powerful and dangerous medications too quickly into the deep, central circulation.

In recognition of these risks, many central lines come with a protective sliding clip that pinches the line shut to help prevent unwanted infusions.

The clip can slide open accidentally and be easily manipulated by the patient or others who are not medically qualified to access the lines. When it is surreptitiously opened, it can be closed again without any evidence of tampering. This device therefore lacks security and does not show any tell-tale signs that someone has tampered with it.



*Example of a common sliding plastic catheter clip.*

## COMPLICATIONS OF CENTRAL LINES

The risks for CL complications are significant. The CDC estimated in 2011 that 41,000 bloodstream infections associated with central lines occur each year in the US<sup>(2)</sup>. These infections are life threatening because the lines are pushed deep into the central circulation and infections can spread rapidly throughout the body to virtually any organ, including the brain, heart, lungs, liver and bone marrow.

Furthermore, non-infectious adverse drug events occur in up to 5% of hospitalized patients.<sup>(2)</sup> And a significant number of these events occur through central lines.

The risks for central line complications are especially high in persons who abuse intravenous recreational drugs. These persons are known as intravenous drug users (IVDUs).

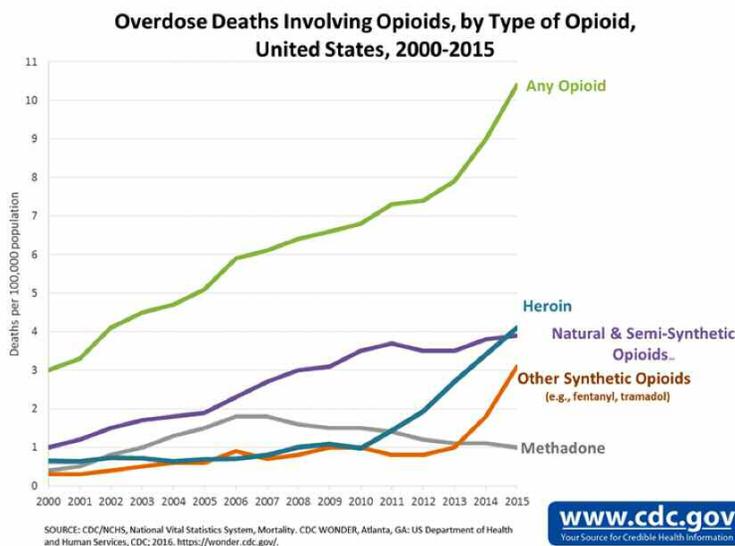
On July 31, 2017, the President's commission on opioid abuse urged President Trump to declare a "national opioid abuse emergency".<sup>(3)</sup> The death rate from opioid overdose has increased well over 300% between 2000 and 2015 with dramatic acceleration in the last few years due to the opioid epidemic.<sup>(4)</sup> Between 2014 and 2015 alone the death rate for young male heroin addicts increased 22%.<sup>(5)</sup> Many hospitals have experienced higher rates of hospitalization of IVDU patients as a result of overdose or infection.

An IVDU who requires a central line for medical therapy will often use the CL to shoot up harmful drugs either while in the hospital or after discharge from the hospital if the central line is left in place for ongoing therapy. This abuse can result in deep infection, reinfection or harmful overdose of a drug delivered directly into the central circulation.

Infection of a central line roughly doubles the death rate for any given patient<sup>(6)</sup> and researchers have called for strategies to manage IVDU patients who have multiple infections.<sup>(7)</sup>

Physicians do not have tools to predict which patients might abuse central lines. As Elzey et al reported, "Opioid overdose morbidity and mortality is seen across the entire spectrum of inpatient and outpatient use with significant numbers of adverse events occurring in population segments not identified by high risk indicators... a multi-modal approach could significantly help mitigate the overdose epidemic."<sup>(8)</sup>

*"I have had two patients die of illicit drug overdose using their PICC lines after swearing they were not users. We often keep IVDU patients in the hospital for prolonged periods of time because we fear this complication."*<sup>(3)</sup>



## PRODUCT RATIONALE ONE

Prevention of CL abuse by intravenous drug users IVDUs frequently require long-term antibiotics. Half the cases of heart valve infection in the US occur in IVDUs<sup>(2)</sup>. These infections require from 2 to 6 weeks of intravenous antibiotic therapy through a central line. IVDUs also get infections in the bones, liver, lungs, skin, spleen, and brain – all of which are often treated with long term intravenous therapy through a CL.

Unfortunately, prolonged CL therapy provides persons with drug addiction easy access to the central line, and they use that access to inject illicit drugs. This increases the risk of death from overdose or further infections. No clearly effective strategies currently exist to prevent this line abuse.

While very little data are generally available on the number of drug overdoses or line infections directly attributable to IVDU CL abuse, concerns about those risks often keep patients in the hospital when outpatient therapy would otherwise result in substantial savings. One hospital concluded that between October 2014 and September 2015, half of their blood stream infections were attributable to patient CL manipulation.<sup>(10)</sup> It is experiences like this that lead hospitalists or infectious disease physicians to keep patients in the hospital for prolonged and often unnecessarily long hospital stays.

For instance, the University of Kentucky Medical Center (UK) has estimated that IVDU with central lines spent an extra 2,669 days in their hospital in the 20 months leading up to May 2014. This was 18% of the hospital's extra, unnecessary hospital days and was UK's single leading cause of delayed patient discharge. The financial cost for keeping these patients in hospital is on the order of \$3,000 to \$5,000 per day per patient.

Laura Fanucchi, MD, Assistant Professor of Medicine and at the University of Kentucky Medical Center is working on the problem of delayed discharge. Despite educational efforts, her faculty members have been reluctant to discharge IVDU patients with central lines. After learning about the Neuma CSL, her comment was:

***“This would be extremely helpful. How could anyone say ‘No’ to this product?”***

Dr. Fanucchi recently published data from a survey of hospitalists showing that while 95% of responding hospitalists would consider outpatient intravenous antibiotic therapy for patients without a history of IVDU, only 12% would consider outpatient treatment for patients with a history of IVDU.<sup>(11)</sup>

The University of California, Irvine Medical Center experienced 10,400 extra hospital days beyond predicted in fiscal year 2014. Approximately 20% of these days would have cost the institution nearly \$7 million.

The results of a UCI Medical Center survey confirm the prevalence of physicians' concerns:

- **84%** of physician respondents were “concerned or very concerned” about IVDU patients abusing their central line after being discharged from the hospital.

- **50%** replied they keep patients in the hospital for prolonged periods of treatment due to concerns about CL abuse if the patients are discharged.

- **94%** answered they would choose to send an IVDU patient home with a central line if there were a device that could effectively protect access to the line or warn against CL abuse.

***“We often have issues with patients actively using illicit drugs while still in the hospital, let alone leaving the hospital with PICC lines.”<sup>(9)</sup>***

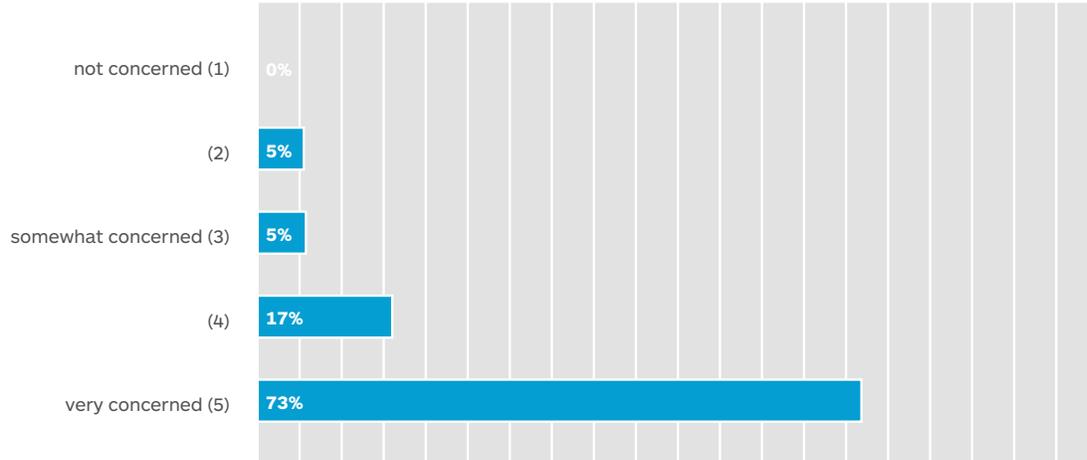
Moreover, physicians who care for IVDU patients acknowledge that many patients inject drugs into their CL even while they are in the hospital.

Preliminary studies suggest that it is more than hypothetically possible to decrease central line abuse and cost as well as increase patient safety. For instance, a study by the National University Hospital in Singapore found that shifting PICC line antibiotic treatment of IVDU from inpatient to outpatient settings through the use of a dedicated outpatient program resulted in direct medical cost savings up to 44%. However, because the PICC could not be adequately protected, CL complications related to IVDU patients accounted for 28-43% of the financial burden.<sup>(9)</sup> Some institutions are creating unique substance abuse PICC programs to address this concern.<sup>(12)</sup>

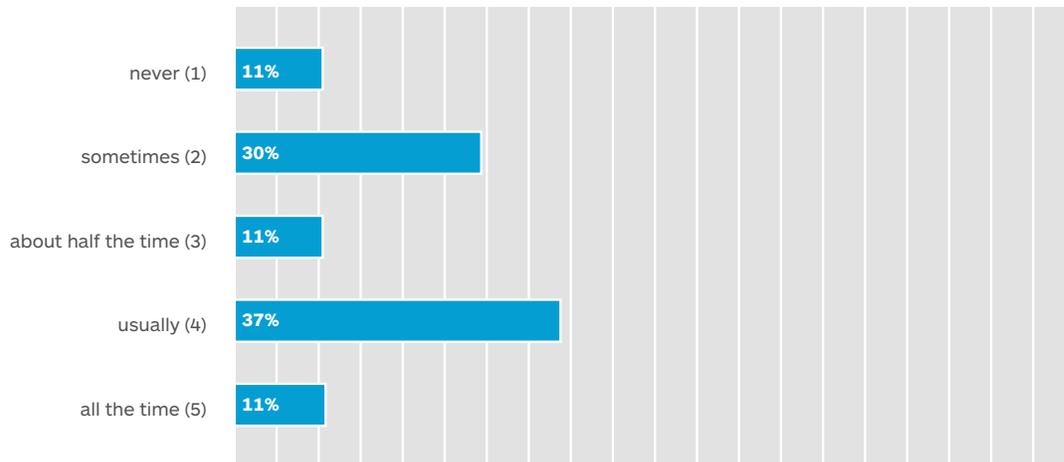
A strategy to prevent CL abuse could dramatically decrease the length of hospital stays for stable IVDU patients, enhance safety, and decrease costs. If this strategy were integrated across the continuum of care, it could possibly decrease CL infections in patients who might otherwise not be suspected of CL abuse or manipulation.<sup>(13)</sup>

**UCI MEDICAL CENTER IVDU SAFE DISCHARGE SURVEY**

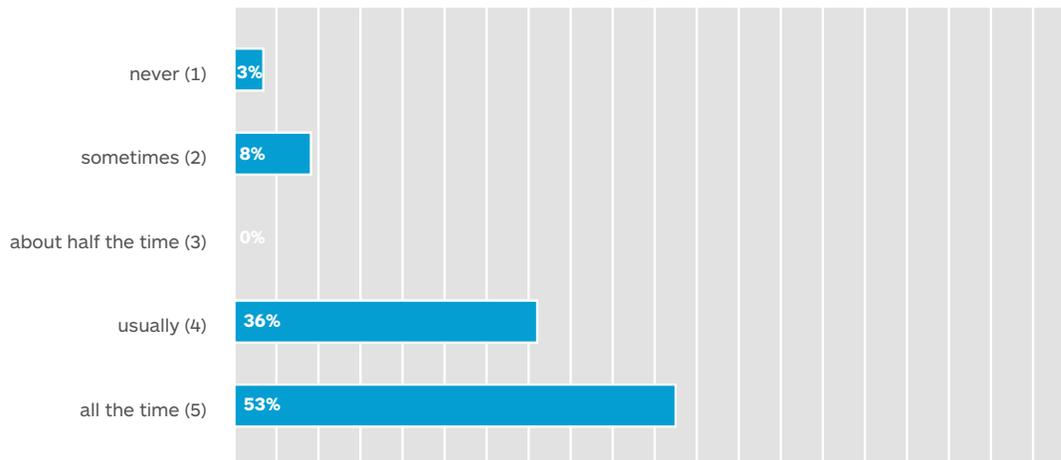
*When you are considering discharging a patient with a central line (PICC or other) who has a significant history of intravenous drug abuse, how concerned are you that the patient will abuse his or her central line?*



*If such an IVDU patient requires a central line (PICC or other) for antibiotics or other needs, how often would you keep the patient in the hospital over concern about abuse of the central line?*



*If you had available a device that would effectively lock the central line and prevent abuse, how often would you send the IVDU patient home with the central line (PICC or other) for prolonged treatment?*



## PRODUCT RATIONALE TWO

### An extra measure of safety for patients with a CL

The Institute of Medicine in its clarion call report “*To Err is Human*” found that 98,000 people die in hospitals each year from preventable medical errors. The greatest of these is medication errors.<sup>(14)</sup>

As noted, central lines are powerful and important tools but carry significant risks. Two of the greatest risks are accidental infusion of the incorrect medication or excessive infusion of fluids or medications through a line that should be turned off. Some CLs have 2 or 3 ports; that is, 2 or 3 lines running through a junction into a single combined catheter that actually enters the body. When the patient has more than one port, each port is often reserved for a specific function. For instance, a cancer patient may have one port for chemotherapy, one port for antibiotics and fluids, and one port for drawing blood for testing. Nurses must keep these ports separate and use them only for their prescribed purposes. Using the Neuma CSL would add a new level of safety.

The Neuma devices could be incorporated into a “time out” procedure, a step back from an infusion or blood draw to ensure that the therapy was being administered correctly. This process would provide a valuable extra step for patient safety.

### THE IMPORTANCE OF PRESERVING WORKFLOW

Any devices designed to address the concern of CL abuse must fit easily into the current care workflow and must also preserve the functionality and accessibility of the CL. The devices in the Neuma Suite™ meet both of these requirements.

Neuma devices are *tamper evident*, not *tamper proof*. Tamper proof or locking devices could make the CL unavailable in the event of an emergency or might even damage the CL. The Neuma products are single-use devices and cannot be replaced onto the CL once removed, clearly highlighting the manipulation of the CL. In addition, the Neuma CSC prevents staff from intentionally or unintentionally reattaching a used cap, thereby preserving sterility.

The devices preserve workflow. The CSC and the CSS both replace the current caps placed on most central and peripheral ports. Both of these devices are used in the same manner and with the same intent as current conventional caps. The CSL is applied separately but with similar convenience as the current clamp attached to most central lines, the use of which is recommended by the manufacturer “for patient safety”.<sup>(15)</sup> None of the Neuma devices require tools for application or removal.

As noted, physicians cannot predict which patients might manipulate their CL. Therefore, an enhancement to a device currently in use helps protect against abuse or manipulation by patients or their associates not suspected of IVDU. Under these circumstances it is particularly important that the devices seamlessly fit into the usual workflow.

## PRODUCT DESIGN MILESTONES

### A NEED WAS DISCOVERED

The problem of line abuse by IVDU patients was identified. Further Research and empirical evidence confirmed the negative impact on health care and financial costs were commonplace.

### FOCUS GROUPS AND EVALUATIONS

Focus groups and surveys were conducted with infusion therapy professionals, doctors and hospital administrators. The information was aggregated and incorporated into the final product designs.

### PROTOTYPES AND PRODUCTION UNITS

Proof of principle prototypes were fabricated and evaluated. Final injection molded parts of the CSC were produced and tested in the field.

### FDA

The Neuma Safety Clamp was registered with the FDA as a 510(k) device.

### IP PROTECTION

Patents were filed for all three devices in the Neuma Central Line Protection Suite.

## THE NEUMA CENTRAL LINE PROTECTION SUITE: THREE INNOVATIVE DEVICES

### THE NEUMA CATHETER SAFETY LOCK



#### DETER AND DETECT TAMPERING

The Neuma Catheter Safety Lock is a single-use small plastic clamp that snaps onto a central line in such a way that greatly deters abuse of the line while it is in place and renders it obvious when someone has tampered with the line.

#### AN ADDED LEVEL OF SAFETY

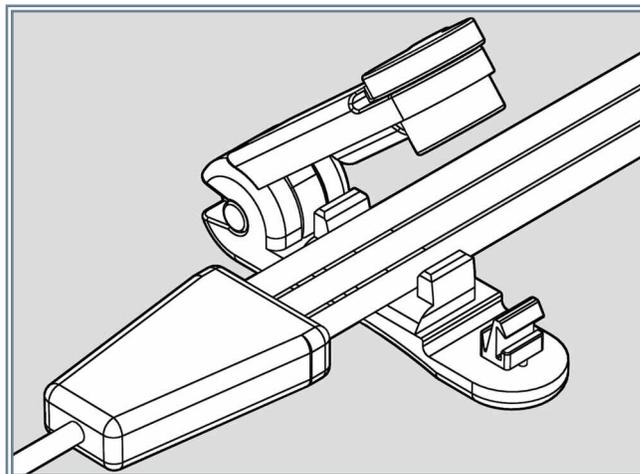
As part of an institutionalized “time out” procedure, The Neuma Catheter Safety Lock adds a new measure of protection by requiring the practitioner to remove and replace the CSL each time the lines are used.

Furthermore, it is recommended that a standardized patient education document be used to certify that patients have been informed of the consequences of abusing protective devices.

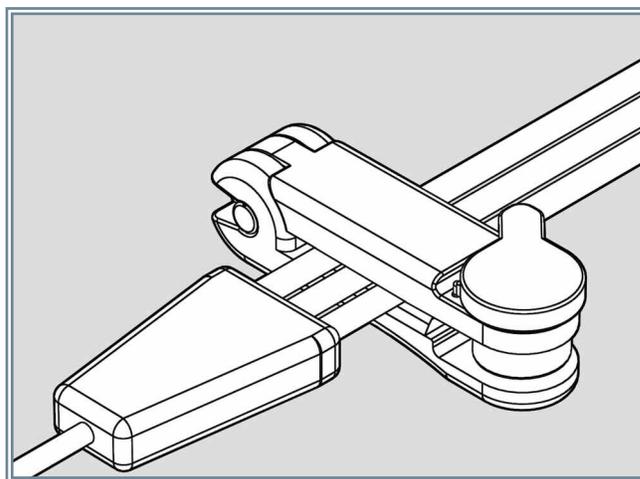
#### HOW TO USE THE NEUMA CSL

The three photos to the right illustrate how easy it is to use the device. In the closed state, the lines are pinched shut and cannot be accessed without destroying the clamp. When the device is opened, the hook that locks the clamp is snapped off.

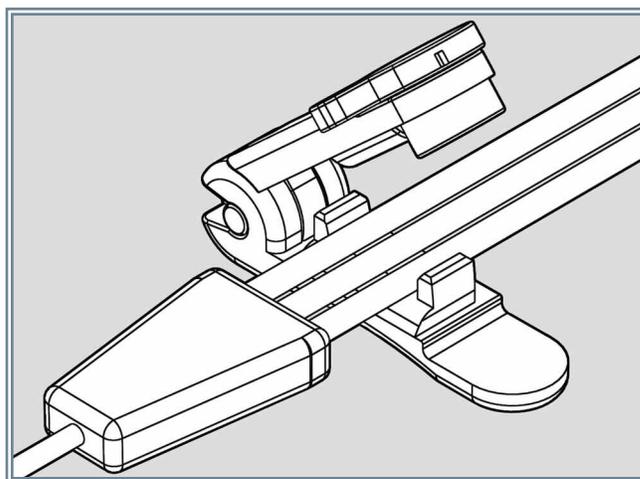
After the hook is broken, the device cannot be used again, and it is visibly evident to the practitioner if the device has been tampered with by the patient.



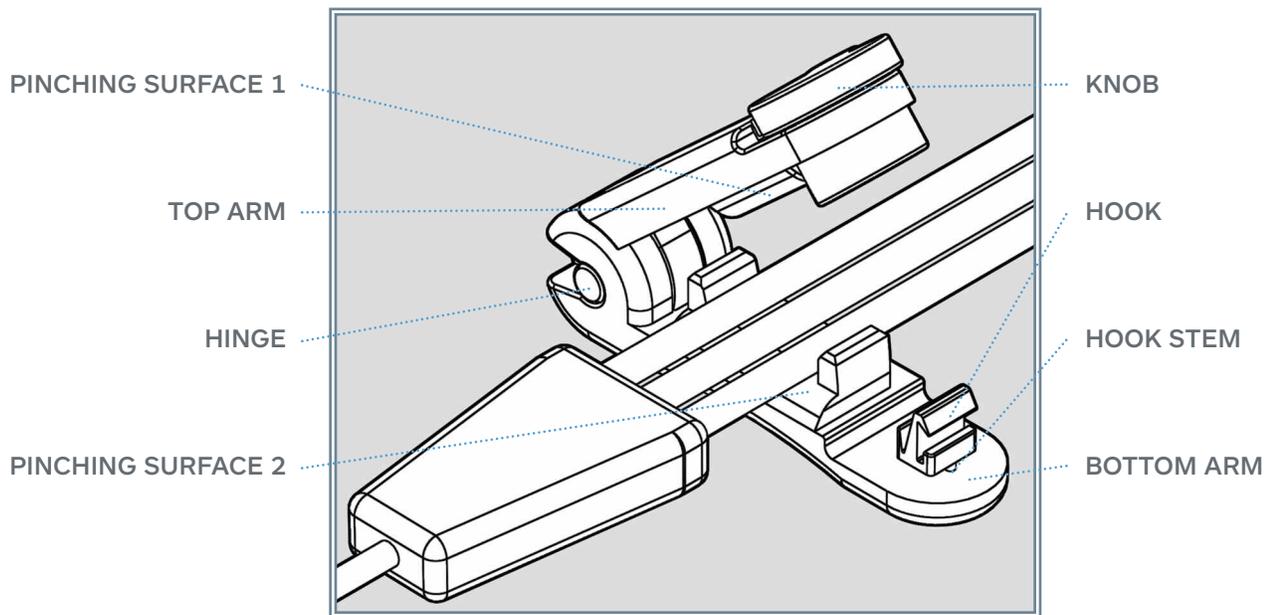
**STEP ONE**  
*Place the lines into the walled cradle.*



**STEP TWO**  
*Close the CSL and it will automatically lock shut. The catheter lines cannot be accessed until the clamp is opened.*



**STEP THREE**  
*Twist the knob to open the CSL. This action breaks the hook off the bottom arm and captures it in the top cylinder for easy disposal. The clamp cannot be locked on the line again.*



## FEATURES AND BENEFITS

**FEATURE:** There are two pinching surfaces.  
**BENEFIT:** Flow through the line is securely closed.

**FEATURE:** The pinching surfaces have large radii.  
**BENEFIT:** The line is not damaged when pinched.

**FEATURE:** Turning the paddle breaks the pin that connects the hook to the arm.  
**BENEFIT:** It is visibly obvious when the device has been opened or tampered with, and the device cannot be used more than once.

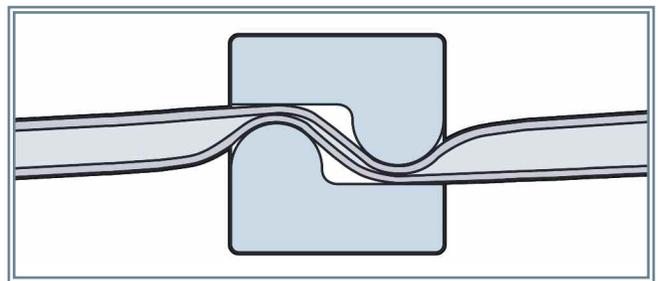
**FEATURE:** The pinching surfaces are nested.  
**BENEFIT:** Needle access is physically blocked.

**FEATURE:** Turning the paddle opens the CSL.  
**BENEFIT:** The rotary motion doesn't require a lot of force and minimizes the risk of accidentally tugging on the line when opening the device.

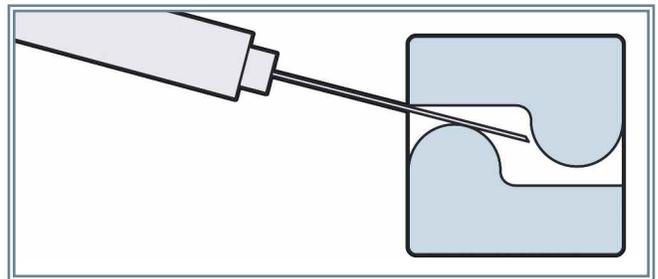
**FEATURE:** The broken hook gets captured in the top arm.  
**BENEFIT:** There are no extra pieces to dispose of.

**FEATURE:** The hinge is press-fit into a blind hole.  
**BENEFIT:** The device cannot be disassembled without destroying it.

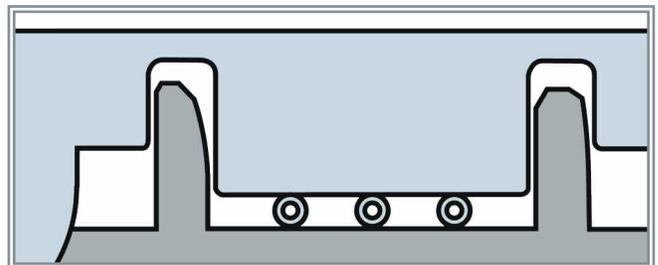
**FEATURE:** The cradle walls mate into the top arm.  
**BENEFIT:** The catheter lines cannot be removed.



*Cross section showing the two pinching surfaces closing off flow in the catheter line.*



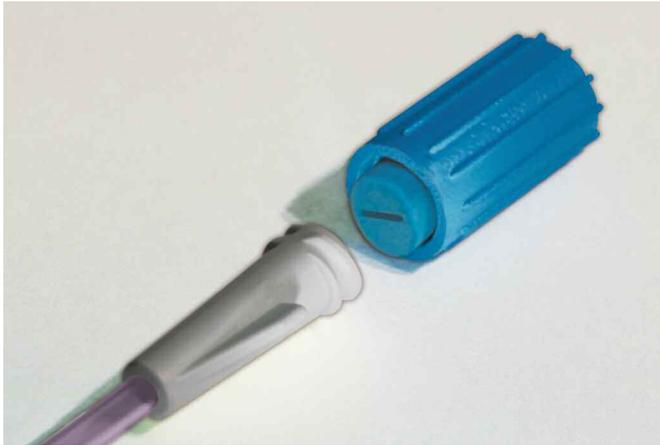
*The pinching surfaces also block straight needle access.*



*Section view shows how the catheter lines are trapped between the cradle walls when the device is closed.*

**THE NEUMA CENTRAL LINE PROTECTION SUITE:  
THREE INNOVATIVE DEVICES**

**THE NEUMA CATHETER SAFETY CAP**



**THE SAME INFUSION WORKFLOW**

The Neuma Catheter Safety Cap is a single-use screw-on port cap. Infusion therapists use the Neuma cap in the same way they use other screw-on protective caps, but when the Neuma cap is removed, an integrated internal piston pops out and locks into place so the cap cannot be used a second time.

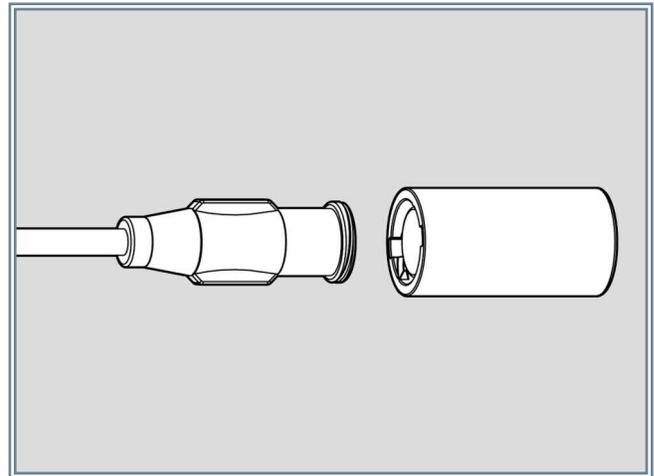
**TAMPER EVIDENT**

Unlike other common port caps, the Neuma CSC features an internal piston that slides out and locks in place to render the cap unusable. If patients remove the cap to abuse the line, they will not be able to put the cap back on the port; the infusion therapist will know the line is at risk.

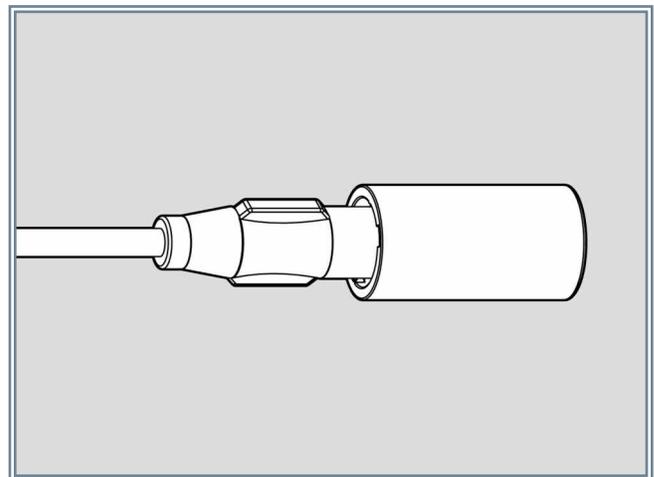
**HOW TO USE THE NEUMA CSC**

Using the Neuma CSC is no different than using a common catheter port protective cap. When the cap is removed, however, the internal piston automatically ejects the piston and locks it in place as shown. The infusion therapist does not need to perform any additional steps.

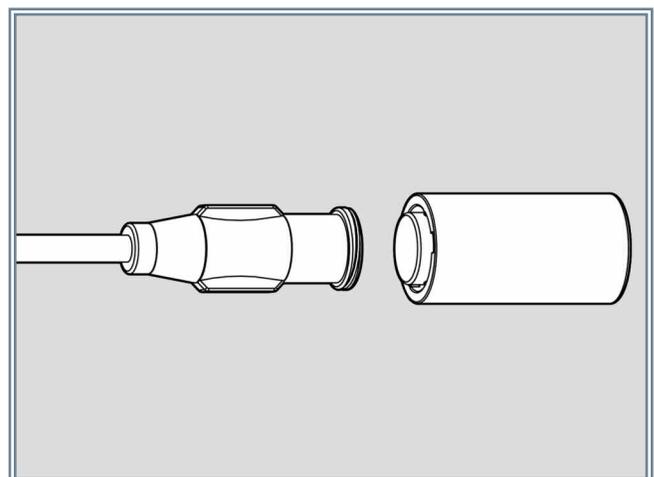
Note that the Neuma Cap can be used in tandem with the Neuma Clamp.



**STEP ONE**  
*Screw the new cap on to the threaded catheter port.*



**STEP TWO**  
*The cap now protects the line and the spring-loaded piston hidden inside the cap has rotated to a new position to be released when the cap is removed.*



**STEP THREE**  
*Unscrew the cap. The piston automatically pops out and locks in place. The cap cannot be used again.*

**THE NEUMA CENTRAL LINE PROTECTION SUITE:  
THREE INNOVATIVE DEVICES**

**THE NEUMA CATHETER SAFETY SEAL**



**“DO NOT BREAK THIS SEAL”**

The Neuma Catheter Safety seal is a single-use screw-on port cap that includes an adhesive tape that must be torn off to remove the cap. The Neuma CSS is a conspicuous visual message not to tamper with the line.

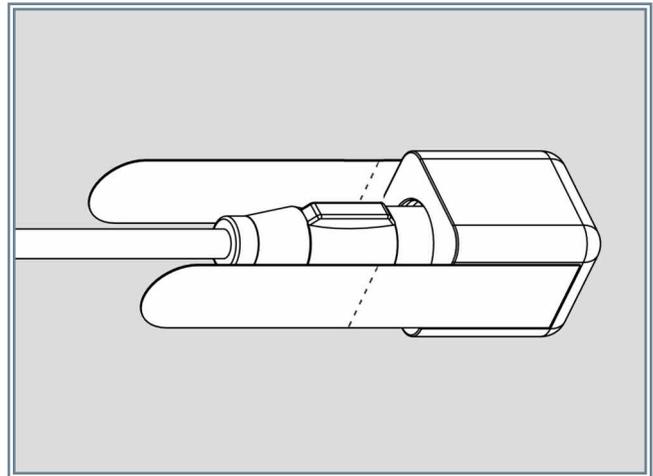
**TAMPER EVIDENT**

Similar to the other Neuma devices, if patients break the tape and remove the cap to abuse the line, the infusion therapist will know the line is at risk because the patient cannot put the cap back on the line.

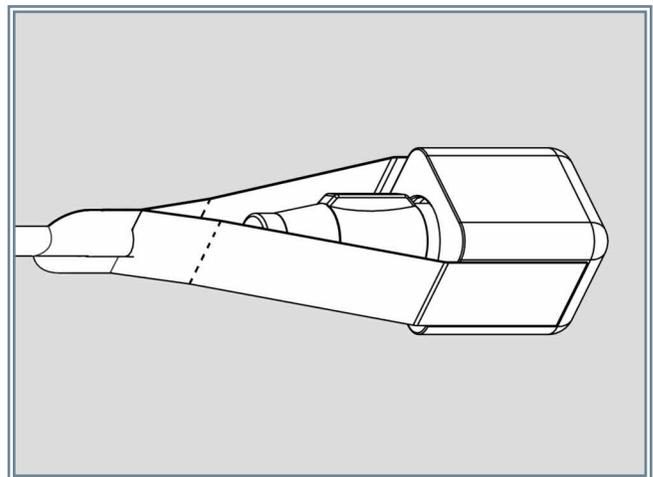
**HOW TO USE THE NEUMA CSS**

Using the Neuma CSS is similar to using a common catheter port protective cap. Unscrewing the cap tears the adhesive strip which is easily removed because the strips use a self-adhering silicone tape that does not stick to the catheter line.

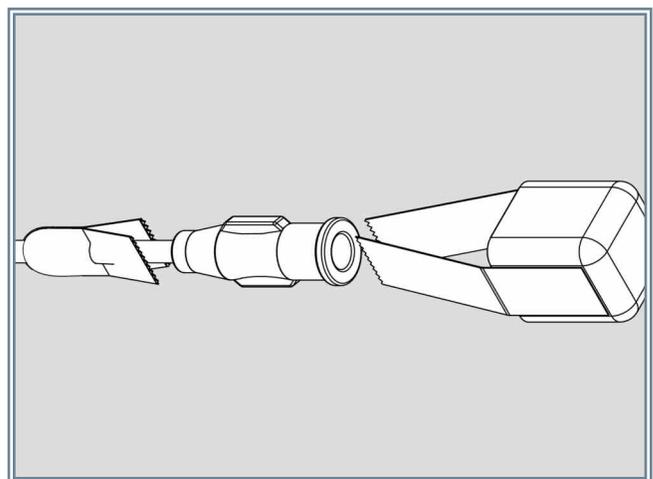
Note that the Neuma CSS can also be used in tandem with the Neuma Clamp.



**STEP ONE**  
*Screw the new cap on the threaded catheter port.*



**STEP TWO**  
*Pinch the adhesive strips together.  
(The self-adhering tape will not stick to the catheter line.)*



**STEP THREE**  
*Unscrew the cap and the adhesive strips will tear along the perforations. Dispose of the cap and the strips.*

## IT'S DIFFICULT TO MAKE SOMETHING SIMPLE

Three years of R&D. Hundreds of prototypes. Extensive lab and field testing. Neuma's user-centric design process has produced a cost-effective suite of products that are easy to use, fit into the existing work flow and require no tools.

## A UNIQUE BUSINESS OPPORTUNITY

A marketplace seeking out a product before the product has been launched is a uniquely exciting business opportunity. Neuma has received many requests for information about our devices, demonstrating impressive demand from target customers.

### >> UNSOLICITED INQUIRIES:

*"Our PICC team is looking for a device to prevent drug addicts from injecting into their PICC line. Would it be possible to get a few samples of this device?"*

~ Lead Purchasing Agent, Exeter Hospital

*"I work on a vascular access team that is also responsible for maintaining CVCs. We have a fairly high drug abuse population and have pondered a solution to them accessing the line."*

~ RN, CCRN, VAST

*"We have a large IV drug problem in our area... We would definitely be interested in... the product."*

~ Director, Infection Control & Patient Safety, Einstein Medical Center

*"Our institution has a fair amount of IV substance abusers, and we usually are locked into putting in short term Vascular Access devices and keeping the patient here in our facility for the duration of their term of antibiotic therapy, because these patients cannot be trusted with CV access. I am very interested in your product."*

~ Vascular Access Specialist,  
Broward Health North

*"We are looking into a catheter injection port lock for our PICC lines and came across your product."*

~ Contract Coordinator, Halifax Health

## A COMPELLING RETURN ON INVESTMENT

It's not often that a new product costing less than \$20 can save a hospital \$4,000 per day.

Pictured below is an Arrow® PICC ErgoPack™ System. In addition to the central line, this package includes many accessories such as injection needles, hand gel, a sharps disposal cup, clamps, a scalpel and a surgical gown.



For very little additional cost, Neuma catheter safety devices could be added to a CL package like the one pictured.

From the perspective of the medical device vendor, the ROI on this small additional cost would be:

- (1) an excellent CL product feature differentiation;
- (2) a significant new revenue stream from future sales of the disposables .

And, as noted previously, there is the potential for hospitals and other medical service providers to save hundreds of millions of dollars annually by using Neuma devices.

The vendor, the hospital, the insurance provider and the patient all benefit from the adoption of Neuma devices into the CL product line.

## INTELLECTUAL PROPERTY

### PATENT PROTECTED

The Neuma Catheter Safety Lock™ is patent protected. The Neuma Catheter Safety Cap™ and Neuma Catheter Safety Tape™ are patent pending.

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\* An "opportunity day" is a day over the usual expected duration of a hospital stay based on Medicare data.

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