

THE NEUMA PICC AND CENTRAL LINE PROTECTION CLAMP

Business Case for Procurement and Implementation

EXECUTIVE SUMMARY

Intravenous drug use (IVDU) patients often require central venous catheters (CVCs) for prolonged periods to treat the infections resulting from their drug abuse. During treatment periods, these patients may inject illicit drugs into their CVCs leading to serious complications and death.

Studies have shown that tamper-evident technology can deter line abuse and reliably detect tampering when it does occur. The Neuma Innovations Central Line Protection Clamp (*the Clamp*) successfully deters and detects central line tampering.

The Clamp is a single use device applied to the central, midline or even peripheral line. By *detering* tampering, it decreases the risk of new infection, air embolism, bleeding, and overdose. By *detecting* tampering, it allows the treatment team to take appropriate action to prevent further tampering and complications.

The Clamp protects the patient from significant morbidity and mortality, helps protect the staff and hospital from legal risk, and decreases the cost of hospitalization. In selected patients, the Clamp can dramatically decrease cost per patient through early discharge to skilled nursing facilities or to outpatient treatment. Use of the Clamp may allow us to build partnerships with SNFs and OPATs to facilitate safe, earlier discharge.

PROPOSAL

Patients who abuse intravenous drugs often suffer from severe infections of the heart, bone, lungs, brain and other organs. These infections can require up to 6 weeks of treatment. During these treatment periods, we often insert central venous catheters or midline catheters that remain in place for the entire period of treatment. These catheters are required because IVDU patients generally have very poor veins. It is uncomfortable to be inserting peripheral catheters several times a day, and it is impractical to insert frequent IVs into patients whose drug use has damaged their veins.

The problem we address with this proposal is IVDU patients will often inject illicit drugs into their CVCs. This line tampering is a common occurrence, even in the hospital. Tampering presents a significant risk to the patient, resulting in new infections, air embolism, bleeding and drug overdose.

Tampering also presents a risk to staff members who feel vulnerable to the social and legal risk of caring for these patients. Tampering and line abuse result in dramatically increased costs to the institution due to damaged CVCs, significant life-threatening clinical complications and prolonged hospital stays. IVDU patients with CVCs may spend extra weeks in the hospital because of concerns about discharging them with an unprotected central line. This leads to increased costs, poor resource utilization, and decreased bed availability.

The solution we propose is to adopt the device known as the Neuma Innovations Central Line Protection Clamp. The Clamp is a single-use device that pinches shut the lumens of a central line. It deters line tampering by preventing flow, even when a syringe is applied to the catheter hub. However, when the Clamp is opened its locking mechanism is broken, and the Clamp cannot be locked again, thus detecting CVC tampering when it does occur.

The Clamp is registered with the FDA as a Class 1 510(k) exempt device. One Clamp can hold up to 3 lumens from a central line catheter.

Although not required, Neuma Innovations completed a risk analysis for the FDA. This process included a formal biocompatibility test of the medical grade acetyl plastic used to fabricate the clamp, and a crimp test whereby the lines were pinched by the clamp for a continuous period of 6 months. The lines survived undamaged and no significant risks were identified. Clamps have been opened and shut up to 150 times on a single line, also without damaging the line.

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The impact we hope to achieve is to deter patients from using their lines to inject illicit drugs and to detect tampering when it occurs. This will lead to safer patients, more confident staff, and better resource utilization.

Studies have shown that up to 40% of IVDU patients test positive for illicit drugs while in the hospital. We suspect use in our hospital is similar. Many of these patients could otherwise be discharged early if not for concerns about their tampering with their CVCs.

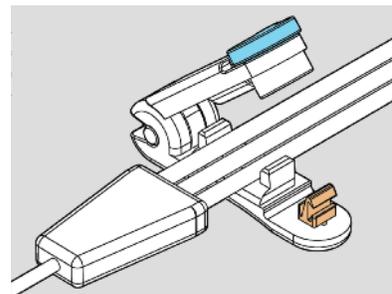
The Clamp costs about \$400 total over a full 6-week course of treatment. This is significantly less than the cost of just one extra hospital day. The return on investment of the Neuma Clamp is truly compelling and justifies adding it to our work flow.

Other institutions use tamper-evident devices like the Clamp to facilitate earlier discharge to more appropriate levels of care. For example, Jennifer Ho successfully treated 29 IVDU patients with PICC lines (*Safe and Successful Treatment of Intravenous Drug Users with a Peripherally Inserted Central Catheter in an Outpatient Parenteral Antibiotic Treatment Service. J Antimicrob Chemother 2010; 65: 2641–2644. doi:10.1093/jac/dkq355. PMID: 20864497*).

Availability of the Clamp will enable us to form valuable partnerships with skilled nursing facilities and Outpatient Antibiotic Treatment Centers (OPATs) to facilitate the early discharge of IVDU patients. This has the potential to dramatically decrease costs for each patient and to open up beds on our inpatient services.

FEATURES AND BENEFITS

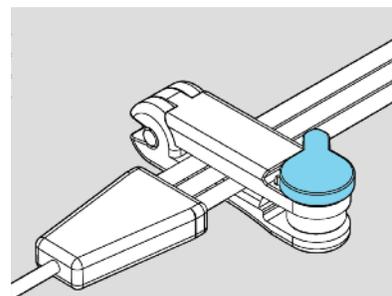
- Deter and Detect Central Line Abuse
- Protect Lines from Contamination
- Improve Patient Safety
- Discharge Patients with More Confidence
- Free up Hospital Beds



STEP 1

Place the lines into the walled cradle.

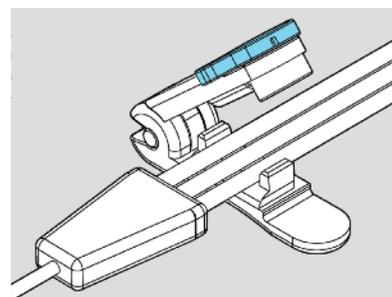
(Note the orange hook that will hold the clamp closed.)



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.

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BUDGET

The cost for implementation is the purchase price of the device plus the time for training. Inservice training is available online at the Neuma Innovations website: www.neumainnovations.com. The training can be completed in approximately 10 minutes, including the written post-test for certification.

Each Clamp is individually packaged and comes in a box of 100 count Clamps.

Shipping can be through our local arrangement covered by our direct account in which case Neuma Innovations does not charge for shipping.

Neuma Innovations is both the manufacturer and distributor, and the Clamp is purchased directly from them. Neuma allows direct purchase with a credit card at <https://www.neumainnovations.com>

Neuma Innovations also supports invoicing with terms of 30 days net. Accounts for purchase orders can be established and Neuma Innovations is enthusiastic to join purchasing cooperatives to facilitate purchases.

NEUMA ACCOUNT INFORMATION

Product number: *CLAMP-2018-1*
Customer support: *support@neumainnovations.com*
Clinical support: *lrucker@neumainnovations.com*
Payment terms: *net 30 days (1%)*
Shipping: *USPS Priority Shipping*
Mail Address: *Neuma Innovations LLC*
751 Endfield Way
Hillsborough, CA 94010

NOTES

Enter your notes here:

Estimated number of patients needing treatment:

Estimated cost of training, procurement and storage:

Estimated number of boxes stored in the event of an urgent admission:

We recommend the purchase of this many total boxes of clamps:

Proposed Budget:

(1 box of 100 clamps cost \$395. Neuma offers quantity discounts.)

Request for Taxpayer Identification Number and Certification

**Give Form to the
requester. Do not
send to the IRS.**

▶ Go to www.irs.gov/FormW9 for instructions and the latest information.

Print or type. See Specific Instructions on page 3.	<p>1 Name (as shown on your income tax return). Name is required on this line; do not leave this line blank. Hal Rucker</p> <p>2 Business name/disregarded entity name, if different from above Neuma Innovations LLC</p> <p>3 Check appropriate box for federal tax classification of the person whose name is entered on line 1. Check only one of the following seven boxes.</p> <p><input checked="" type="checkbox"/> Individual/sole proprietor or single-member LLC <input type="checkbox"/> C Corporation <input type="checkbox"/> S Corporation <input type="checkbox"/> Partnership <input type="checkbox"/> Trust/estate</p> <p><input type="checkbox"/> Limited liability company. Enter the tax classification (C=C corporation, S=S corporation, P=Partnership) ▶ _____</p> <p>Note: Check the appropriate box in the line above for the tax classification of the single-member owner. Do not check LLC if the LLC is classified as a single-member LLC that is disregarded from the owner unless the owner of the LLC is another LLC that is not disregarded from the owner for U.S. federal tax purposes. Otherwise, a single-member LLC that is disregarded from the owner should check the appropriate box for the tax classification of its owner.</p> <p><input type="checkbox"/> Other (see instructions) ▶ _____</p>	<p>4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):</p> <p>Exempt payee code (if any) _____</p> <p>Exemption from FATCA reporting code (if any) _____</p> <p><small>(Applies to accounts maintained outside the U.S.)</small></p>
	<p>5 Address (number, street, and apt. or suite no.) See instructions. 751 Endfield Way</p> <p>6 City, state, and ZIP code Hillsborough, California 94010</p>	<p>Requester's name and address (optional)</p>
	<p>7 List account number(s) here (optional)</p>	

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. Also see *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number											
or											
Employer identification number	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">8</td> <td style="width: 10%;">3</td> <td style="width: 10%;">-</td> <td style="width: 10%;">1</td> <td style="width: 10%;">6</td> <td style="width: 10%;">2</td> <td style="width: 10%;">5</td> <td style="width: 10%;">6</td> <td style="width: 10%;">8</td> <td style="width: 10%;">8</td> </tr> </table>	8	3	-	1	6	2	5	6	8	8
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Part II Certification

Under penalties of perjury, I certify that:

- The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
- I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
- I am a U.S. citizen or other U.S. person (defined below); and
- The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here	Signature of U.S. person ▶	Date ▶ <u>August 15, 2018</u>
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General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to www.irs.gov/FormW9.

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS must obtain your correct taxpayer identification number (TIN) which may be your social security number (SSN), individual taxpayer identification number (ITIN), adoption taxpayer identification number (ATIN), or employer identification number (EIN), to report on an information return the amount paid to you, or other amount reportable on an information return. Examples of information returns include, but are not limited to, the following.

- Form 1099-INT (interest earned or paid)
- Form 1099-DIV (dividends, including those from stocks or mutual funds)
- Form 1099-MISC (various types of income, prizes, awards, or gross proceeds)
- Form 1099-B (stock or mutual fund sales and certain other transactions by brokers)
- Form 1099-S (proceeds from real estate transactions)
- Form 1099-K (merchant card and third party network transactions)
- Form 1098 (home mortgage interest), 1098-E (student loan interest), 1098-T (tuition)
- Form 1099-C (canceled debt)
- Form 1099-A (acquisition or abandonment of secured property)

Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN.

If you do not return Form W-9 to the requester with a TIN, you might be subject to backup withholding. See What is backup withholding, later.