



PICC GUARD

PICC Guard – FDA 510(k) Cleared– K191195

A patented device that provides tamper-evidence and tamper-resistance to PICC lines and other central line catheters.



OVERVIEW

Problem

A peripherally inserted central catheter (PICC) line is a device placed for long-term intravenous access. High-risk patients with a history of intravenous drug use (IVDU) commonly have infections that require PICC lines for long-term antibiotic therapy. The most common problem arises when the patient has the opportunity to self-administer illicit drugs or other substances either at home or in the hospital. The PICC Guard provides tamper-evidence and tamper-resistance to address this problem. See home page of PICCGuard.com for additional populations that may benefit.

Intravenous drug users have high rates of difficult to treat infections and have increased needs for central line catheters and intravenous antibiotics.

High-risk intravenous drug users often require longer inpatient treatment in part due to the risk of line abuse causing further complications.

The PICC Guard adds a layer of tamper-evidence and tamper-resistance both in the inpatient and outpatient setting.

Solution

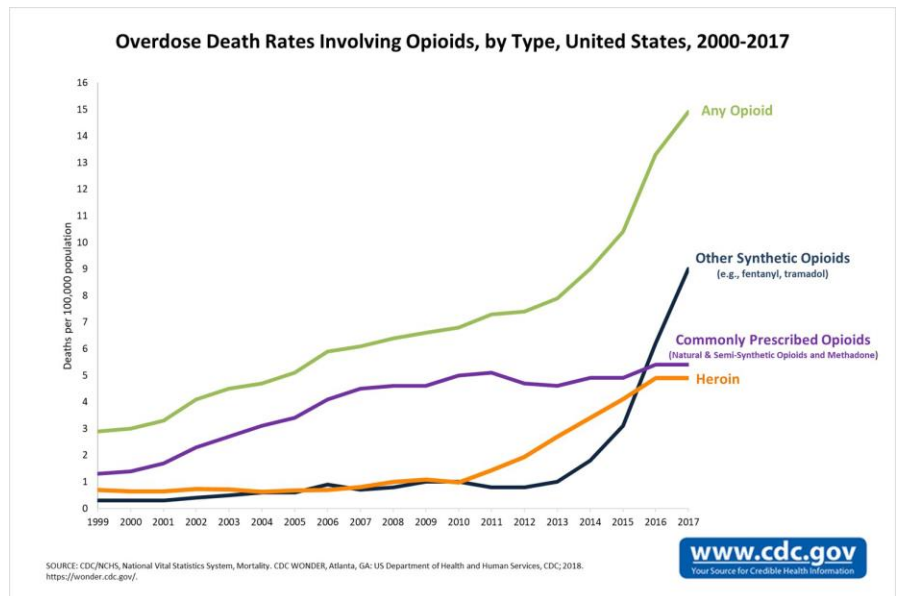
By placing a PICC Guard over the end of a central line, a health care provider can monitor and detect whether or not a patient has tampered with his/her central line. With its one-way tamper-evident locking mechanism, this robust device cannot be removed without being destroyed. Please refer to the following link for an inservice video with detailed instructions on how to apply and remove the PICC Guard:

www.piccguard.com/in-service.

Problem worth solving

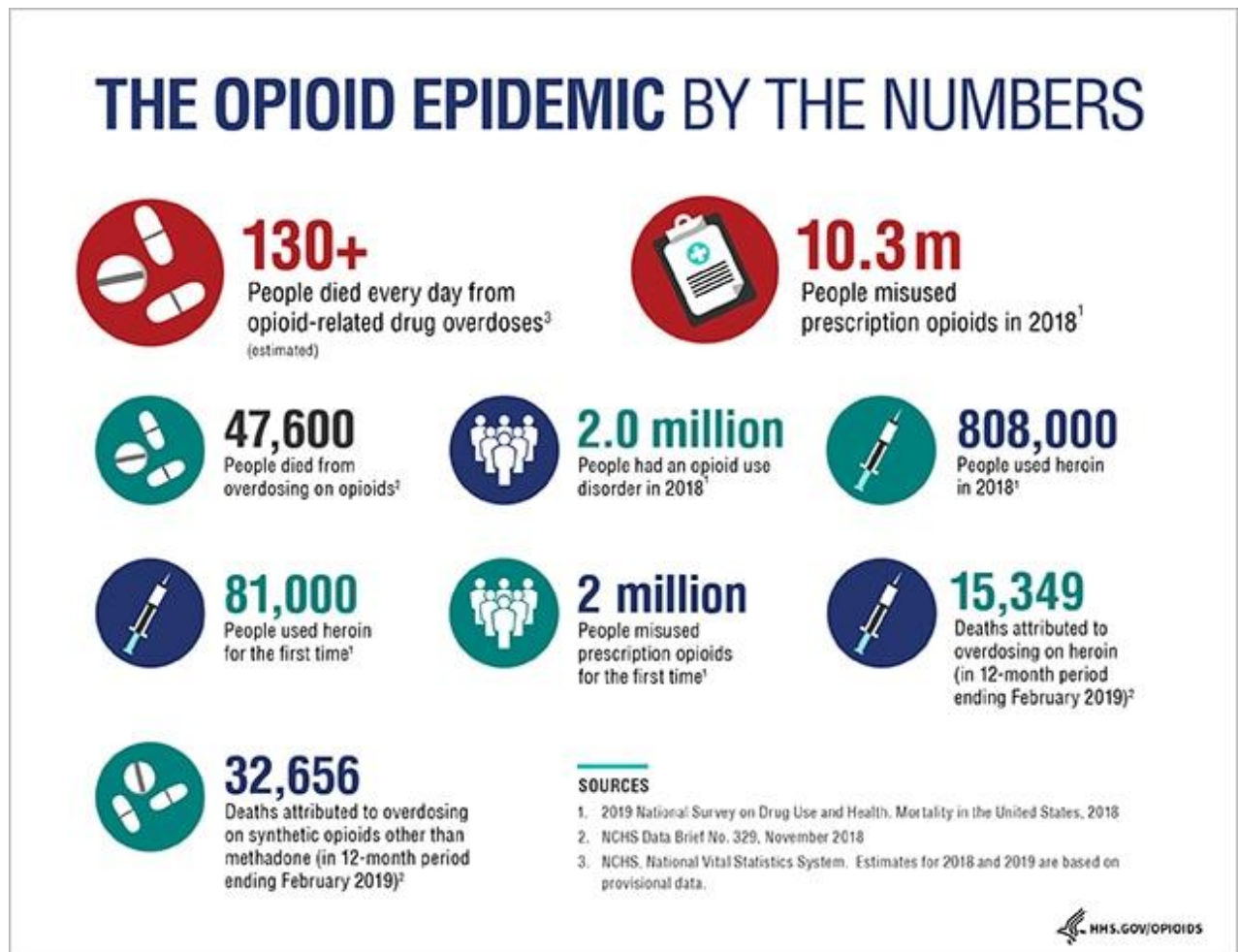
The latest numbers from the Center for Disease Control and Prevention show that 64,700 people died from drug overdoses in 2016¹. That is a 21 percent increase over the year before¹. According to the report, more Americans died from drug overdoses in 2016 than the number of American deaths in the entirety of the Vietnam War, totaling 58,200.

In addition to drug overdose, among intravenous drug users there is an increase in blood infections and sepsis requiring long-term intravenous antibiotic therapy where central line administration is indicated².



OVERVIEW (Continued)

IVDUs are commonly screened out for outpatient antibiotic therapy (OPAT) and PICC lines due to the perceived likeliness that they will abuse the line to inject illicit drugs^{3,4}. IVDUs tend to have about twice as many PICC line complications compared to non-IVDUs^{5,6}.



“Our biggest problems are usually the patient’s poor living conditions, drug abuse, (and) lack of compliance.” - Comments from a 2013 Infectious Disease Society of America meeting highlight the need for a mechanism to prevent patients from abusing PICC lines.

KEY PROPOSED BENEFITS

DISCHARGE

INFECTION
CONTROL

TAMPER
-EVIDENT
-RESISTANT

Increase Discharge Rates

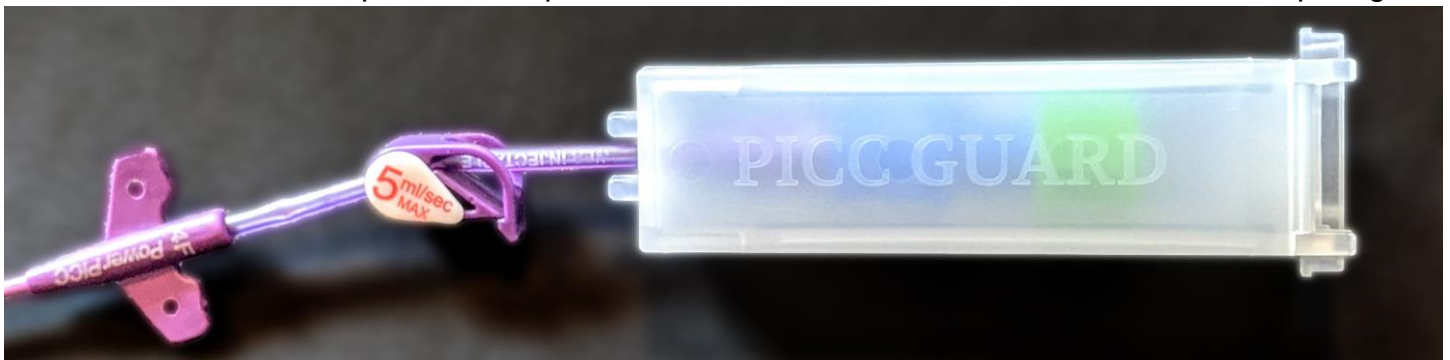
The PICC Guard will allow for a trial of outpatient therapy in select high-risk patients. The potential benefit of outpatient therapy is well-established including:

- Improved morbidity and mortality rates
- Earlier enrollment and involvement in rehabilitation services (inpatient or outpatient facilities, 12-step programs, support groups)
- Increased patient satisfaction
- Tremendous cost savings – the cost of a hospital day is effectively replaced by the cost of PICC Guard(s).

“I am currently in the hospital with a PICC line and they are planning to keep me here six weeks because of past IV drug use. I will miss this semester of school if I stay this long...”
“...What has to be done to get this product?” – Unsolicited e-mail message.

Tamper-evident and Tamper-resistant

Fear of patients using their PICC line to inject drugs is a commonly cited barrier to offering OPAT to IVDUs. The PICC Guard provides tamper-resistance and allows the HCP to monitor for tampering.



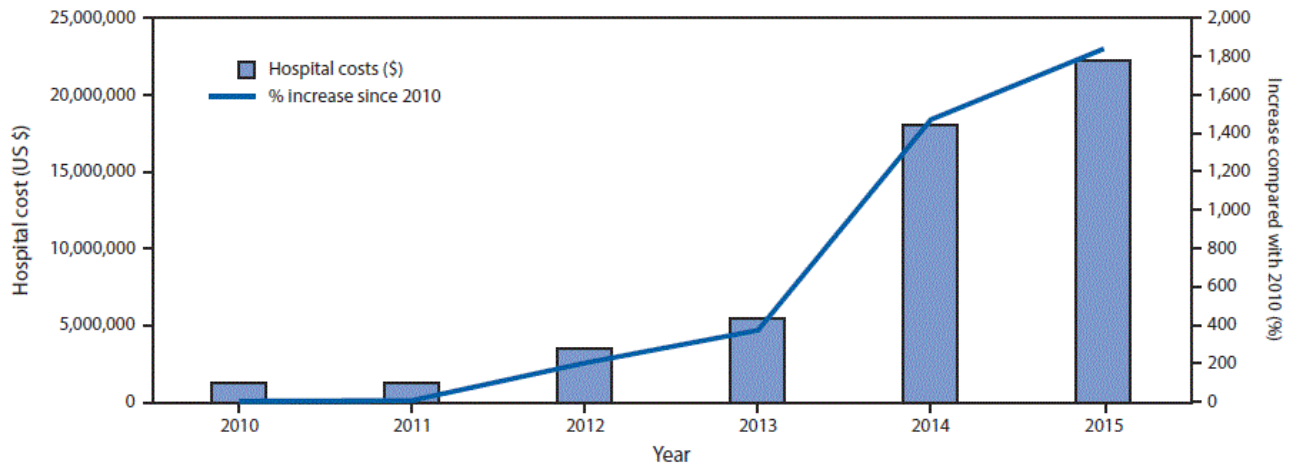
The PICC Guard is a robust hard-plastic device that cannot be removed from the Luer hub without being destroyed.

KEY PROPOSED BENEFITS (Continued)

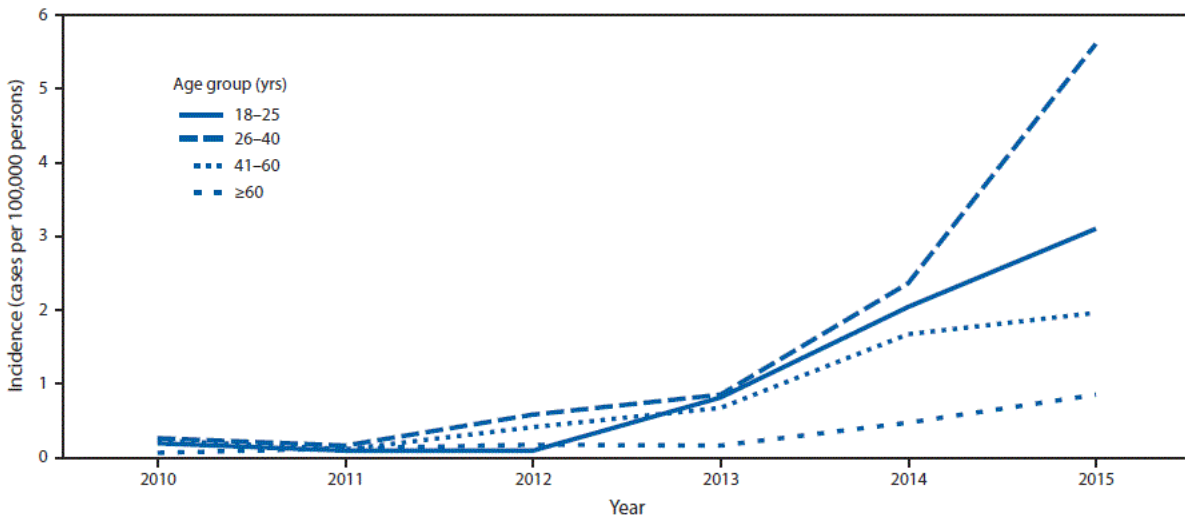
Infection Control

Unwarranted access to Luer hubs on central lines with dirty syringes introduces bacteria, which can lead to sepsis or endocarditis. Endocarditis rates have been increasing in the IVDU population in recent years⁷. Placing a PICC Guard over the end of a central line provides a barrier of access by syringe to the Luer hub.

IVDU-Associated Endocarditis Cost⁷



IVDU-Associated Endocarditis Incidence⁷



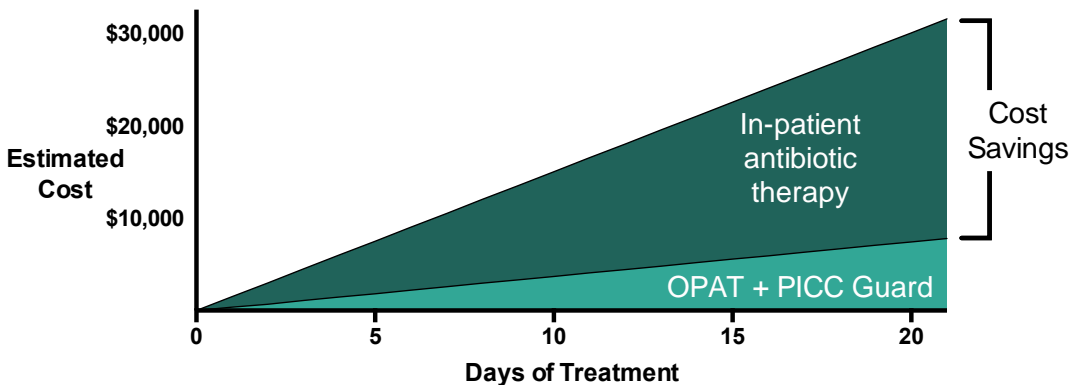
Source:

Hospitalizations for Endocarditis and Associated Health Care Costs Among Persons with Diagnosed Drug Dependence - North Carolina, 2010-2015. MMWR Morb.Mortal.Wkly.Rep., 2017, 66, 22, 569-573, United States

COST ANALYSIS

We suggest 3 primary areas where the PICC Guard has substantial cost benefit:

Cost Benefit of PICC Guard in OPAT



“Taken as a group, the 21 high-risk patients who needed IV antibiotics spent 571 days at home rather than in a hospital or rehab facility — saving as much as \$865,000 (based on estimates of \$1,500 per hospital day). That doesn't include the cost of home care visits by a nurse.” — The Case for Sending Drug Users Home From the Hospital With Open IV Lines,

Decreasing Patient Days in Hospital

If placement of a PICC Guard results in earlier discharge to outpatient antibiotic therapy, decreased inpatient days could be attributed to the PICC Guard. At one institution the average cost of a hospital day for the administration of intravenous antibiotics is \$1500, while the average cost for medical respite was \$350 per day⁸. Though costs vary widely regionally and between hospital systems, with the cost of the PICC Guard at \$12.64 per device, the savings per episode of OPAT would be at minimum in the tens of thousands.

Decreasing Central Line Associated Bloodstream Infections (CLABSI)

Illicit drug injection is a risk factor for central line-associated bloodstream infections (CLABSI). Providing tamper-resistance and tamper-evidence, the PICC Guard has potential to decrease CLABSI rate⁹. The average cost for a single CLABSI is \$45,000¹⁰. For every prevented CLABSI, the cost of the PICC Guard would replace the cost of the CLABSI.

Decreasing Overdose (Inpatient and Outpatient)

The average cost to treat overdose patients admitted to hospital intensive care units is approaching \$100,000 (\$92,408 in 2015) per event¹¹. The PICC Guard has potential to decrease the incidence of overdose both in the hospital and outpatient setting. Additionally, the PICC Guard could allow for a trial of outpatient addiction rehabilitation while receiving intravenous antibiotic therapy.

“I am aware of more than one case in which a patient did this [injected their IV line] and overdosed and died while in a hospital or other healthcare facility.” — Kimberly new, RN, JD – Knoxville, TN¹²



TESTED AND APPROVED

Compliant with FDA and CFR 820 Code

PICC Guard is the first and only FDA 510(k) cleared tamper-resistant catheter access cover intended to control unauthorized access to a central venous catheter (product code PZW – only device in this category).

Tested and Optimized

PICC Guard has been through extensive biocompatibility and performance testing for use in a clinical setting. Several prototypes of PICC Guard have resulted in the culmination of a robust and reliable device.

Made in America at the Highest Standards

The PICC Guard is made in America and manufactured in an ISO 13485 facility.



SUMMARY

The PICC Guard is an FDA 510(k) Cleared Class II medical device. As a tamper-resistant and tamper-evident catheter access cover, it is intended to control unauthorized access to a central venous catheter when covering the shaft and Luer hub of central line catheters. It is designed to be robust and is American made in an ISO 13485 facility. It's use varies widely and has potential benefit in many situations where tamper-evidence and tamper-resistance can improve care by decreasing hospital days, decreasing central line associated bacterial infections and decreasing opioid overdoses in select patient populations. The PICC Guard benefits can have a significant impact both in patient outcomes and satisfaction as well as hospital costs.

REFERENCES

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