

THE HISTORY AND INNOVATION OF VENOUS ACCESS PORTS AND DEVICES

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DISCLOSURES

Elizabeth Wong, CRNA, MSN, is a staff member at
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Elizabeth Wong, CRNA, MSN, is Founder and CEO of DoubleLock Healthcare, Inc, inventor and patent holder of the DoubleLock Sterile Entry Intravenous Port and Syringe System (U.S. Patent #9352141), assignee of the DoubleLock Sterile Entry Intravenous Port and Syringe Interface System (U.S. Patent pending #20240149040). DoubleLock Healthcare, Inc. is a member of the Global Engineered Device Supplier Association and Elizabeth Wong serves on six GEDSA committees that include Neuraxial (NRFit®) Member Committee, Enteral (ENFit®) Member Committee, Neuraxial (NRFit®) Conversion Committee, Enteral (ENFit®) Conversion Committee, Supply Chain and Clinical Advisory Committee, Neuraxial (NRFit®) and Enteral (ENFit®) Joint Member Committee; and DoubleLock Healthcare, Inc. is a member of the Association for the Advancement of Medical Instrumentation (AAMI) which is the U. S. representative to the International Organization for Standardization (ISO) and Elizabeth Wong serves on the Standards Development Committees for Syringes ISO 7886 Series and the Small Bore Connectors ISO 80369 Series.



1995 -STUDENTS OF THE USC PROGRAM OF NURSE ANESTHESIA

AANA CONVENTION IN SAN FRANCISCO



1995 -STUDENTS OF THE USC PROGRAM OF NURSE ANESTHESIA



California Association of Nurse Anesthesiology - 2010

Learning Objectives

1. Discuss the history of medical devices that include needles, syringes, and IV ports
2. Describe why medical device innovation takes place
3. Explain the process and resources for developing a medical device
4. Contrast the difference between a regulatory / enforcement agency, a standard-developing organization, and a trade association

The Beginning of the Journey



Lecture in 2010, AANA Conference -
Anesthesia and Infection Control



Chuck Biddle, PhD, CRNA

Director of Research

Virginia Commonwealth University

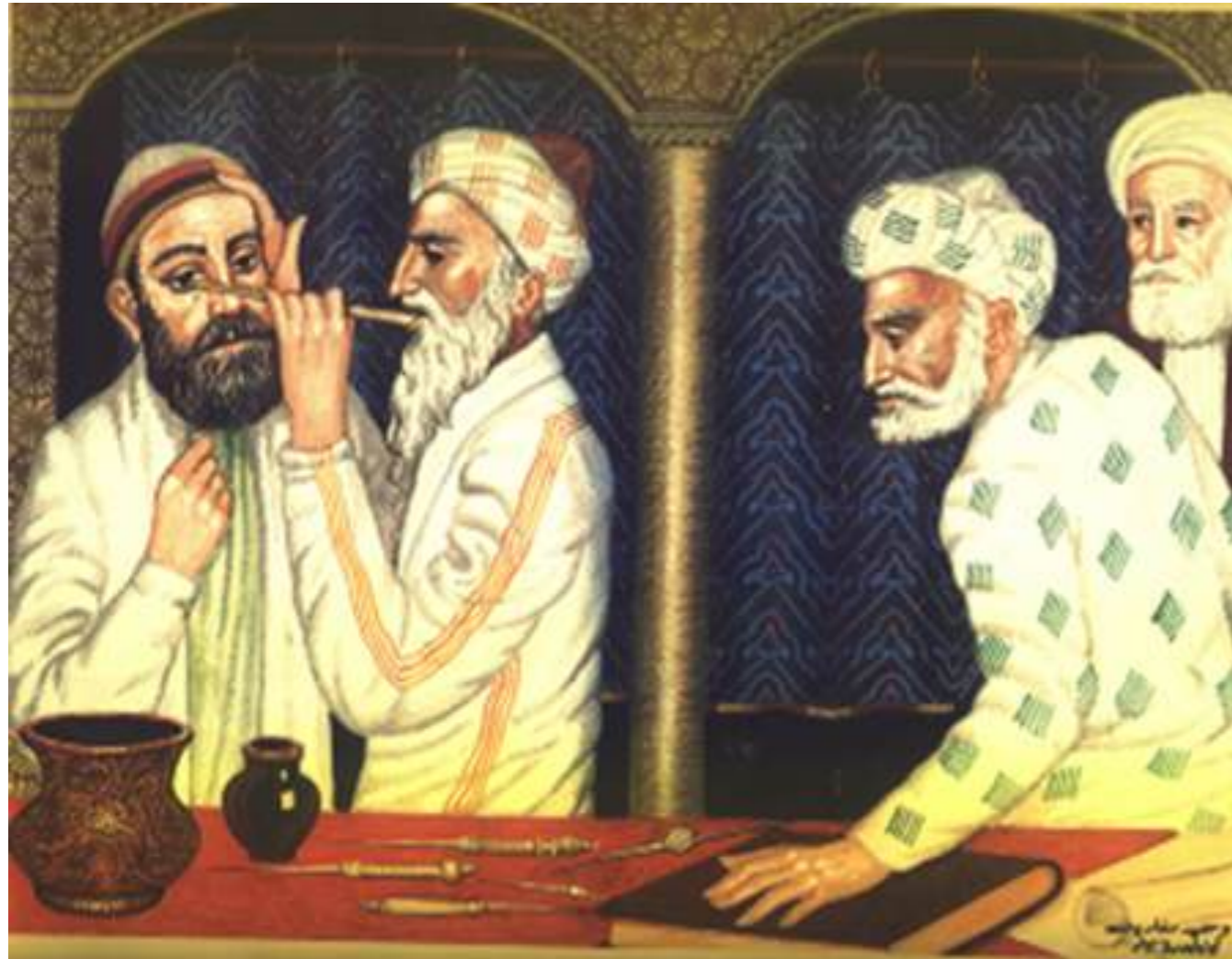
Editor of the AANA Journal (now retired)

History of the Needle



World's oldest needle, at least 50,000 years old, found in the Denisova cave, Siberia, made of bone that “stitches” together human history. *Images from Siberian Times article free to share and use.*

History of the Syringe



The first recorded use of a needle and syringe was in the 9th century, when an Arabian physician named Ammar bin Ali al-Mawsili, used a glass tube needle and syringe to extract a cataract from a patient.

*Image from is 800 years old and no longer copyright protected according to ,
Helena P. Schrader, Historian and Novelist, helenapschrader.com*

IV Therapy - Wine, Ale, Opium

Christopher Wren

(1632-1723) conducted the first successful IV therapy in 1658 by using a **goose quill needle** and **pig's bladder** to infuse a mixture of wine, ale, and opium into a dog's veins. "The dog tolerated it remarkably well."

Image: Courtesy Wikigallery Free to Use and Share



1820s - THE TURNING POINT



Image of Needle Free to Use and Share

**STEEL was
discovered!!**

NEEDLES DISTRICT - ENGLAND:

- **1820 - 5 million needles per week**
- **1850 - 50 million needles per week**

Francis Rynd (1860-1861)
an Irish physician took a
steel sewing needle,
flattened it, formed it into a
tube, and clipped off the
eye. He invented the
hollow needle used for
hypodermic injection in
1844



Image of Francis Rynd Free to Use and Share



DOUBLE LOCK HEALTHCARE, INC.

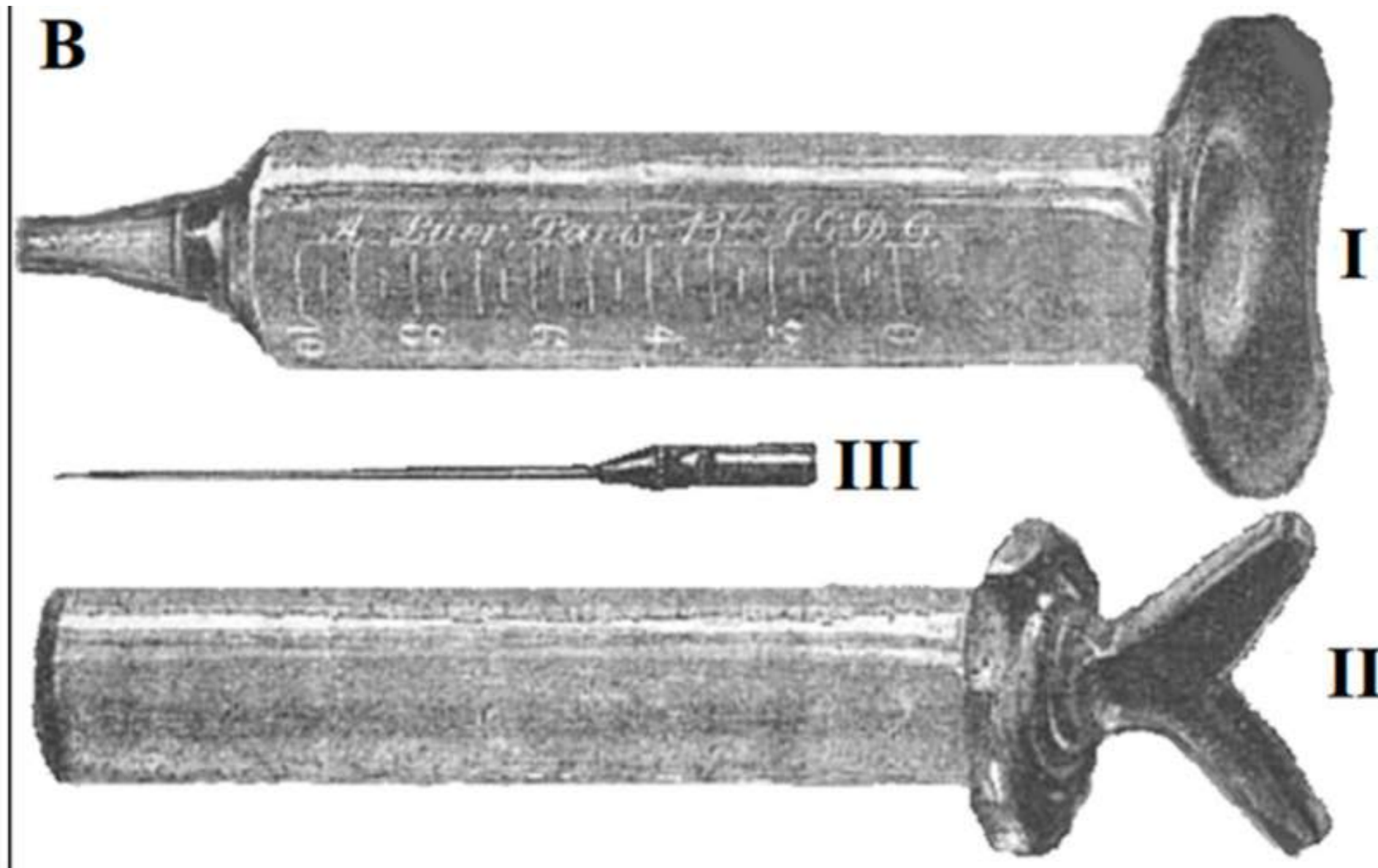


Charles Gabriel Pravaz (1791-1853) Glass Syringe, Silver Hypodermic Needle, Cage and Screw Plunger created in 1853.



Image of Charles Gabriel Pravaz and Syringe Free to Use and Share

Fig. 4. — A Pravez-type syringe, made of glass and silver



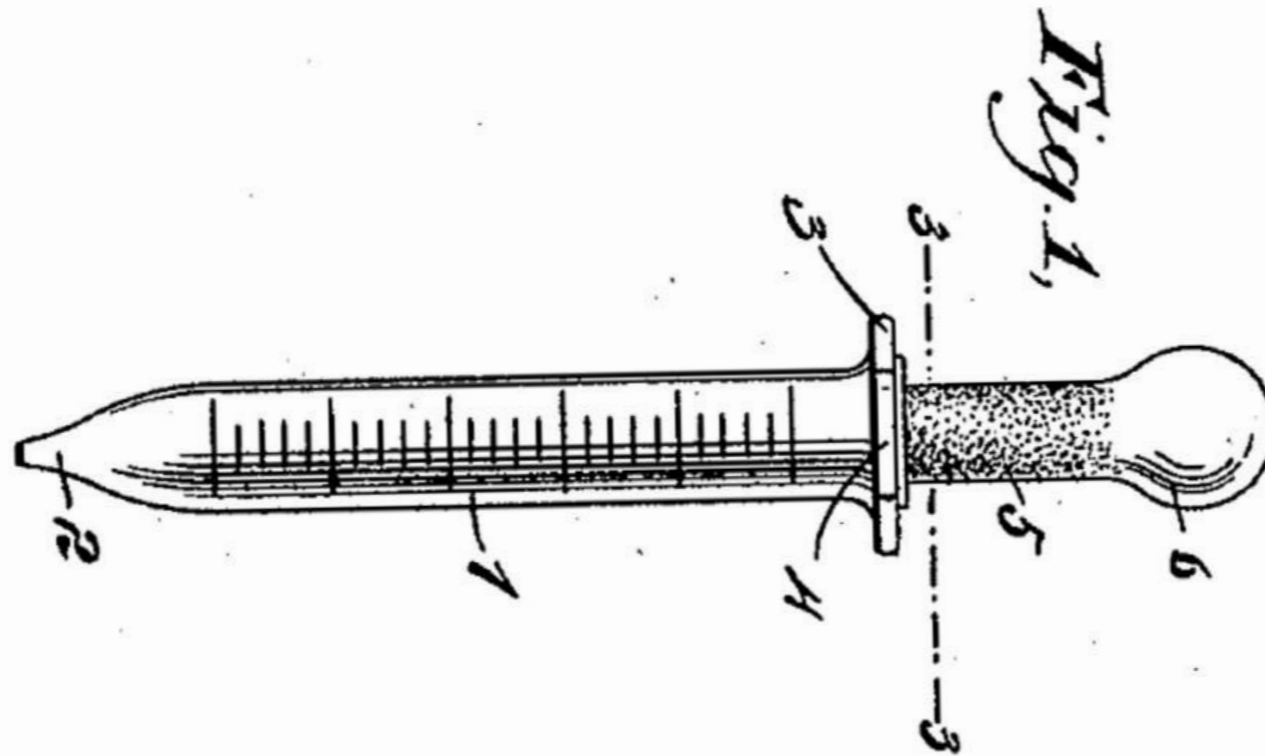
Georges Guillaume Amatus Luer (1802–1883)

All glass syringe, detachable needle, sliding plunger created in 1860

Image of Luer Syringe Free to Use and Share



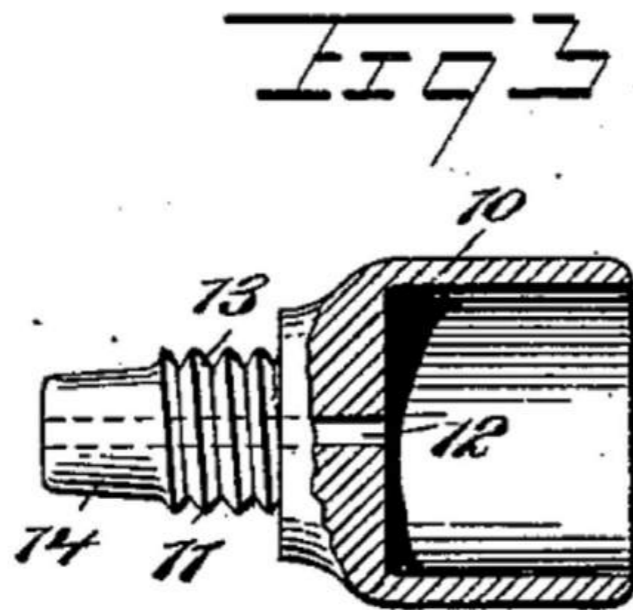
DOUBLE LOCK HEALTHCARE, INC.



Hermann Wulfing-Lüer (business manager and son-in-law).
Syringe. U. S. Patent 583,382. Application filed December, 11,
1896. Image courtesy of the United States Patent and Trademark Office.

THE PROBLEM

Needles are not secure
and pop off when a drug
is forcefully injected

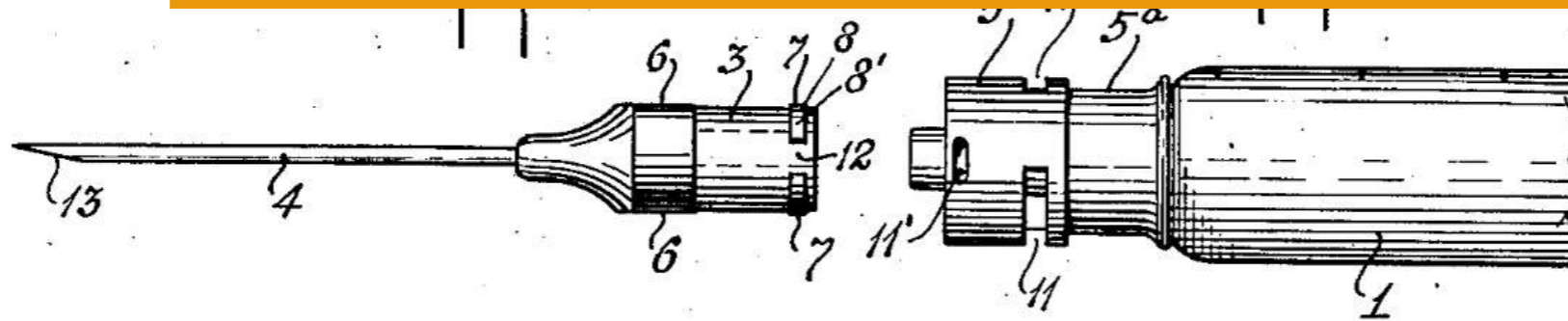


Fairleigh S. Dickinson.
Hypodermic Syringe.
U. S. Patent 723,588.
Application filed
January 15, 1901. Image
courtesy of the United States
Patent and Trademark Office.

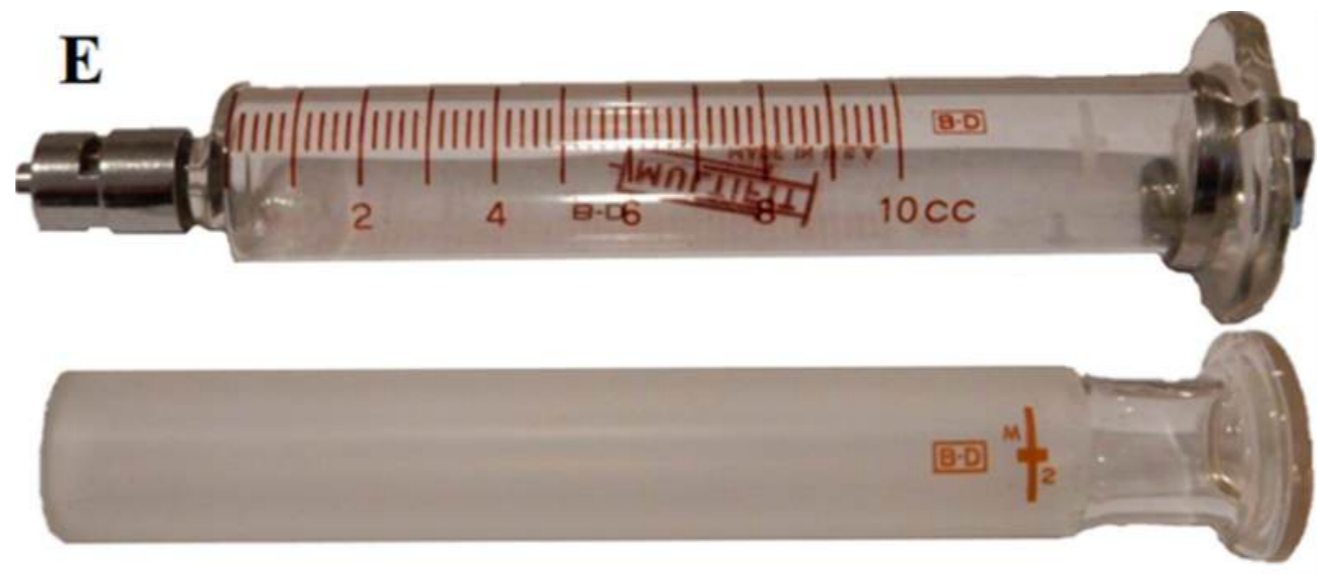
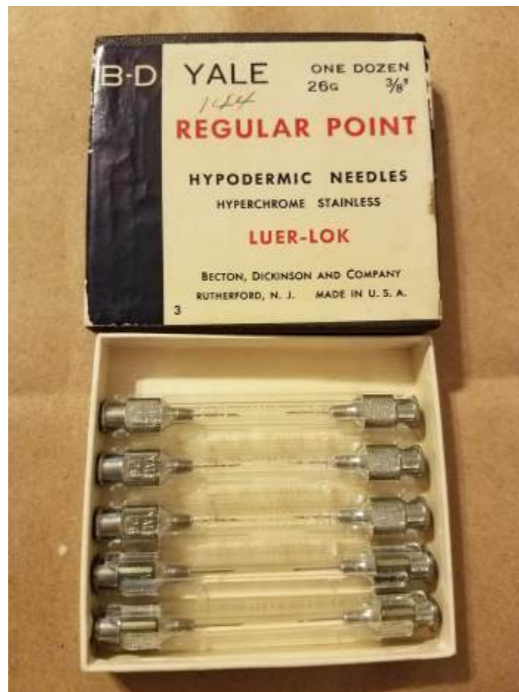
THE PROBLEM

Threads are too fine.
Needles are not secure
and pop off when a drug
is forcefully injected

THE LÜER-LOK



Fairleigh S. Dickinson. Syringe. U. S. Patent 1,793,068. Application filed January 6, 1930. Image courtesy of the United States Patent and Trademark Office.



Only change since 1930 is material used; disposable glass in 1940 and disposable plastic in 1960. Luer-Lock connectors are used in 6 physiological systems: respiratory gas, enteral, neuraxial, urinary, limb cuff, and intravascular.

The Problem: Syringe Tip Contamination

Microbial contamination of syringes during preparation: The direct influence of environmental cleanliness and risk manipulations on end-product quality



Microbial contamination of anesthetic syringes in relation to different handling habits

June 26, 1928.

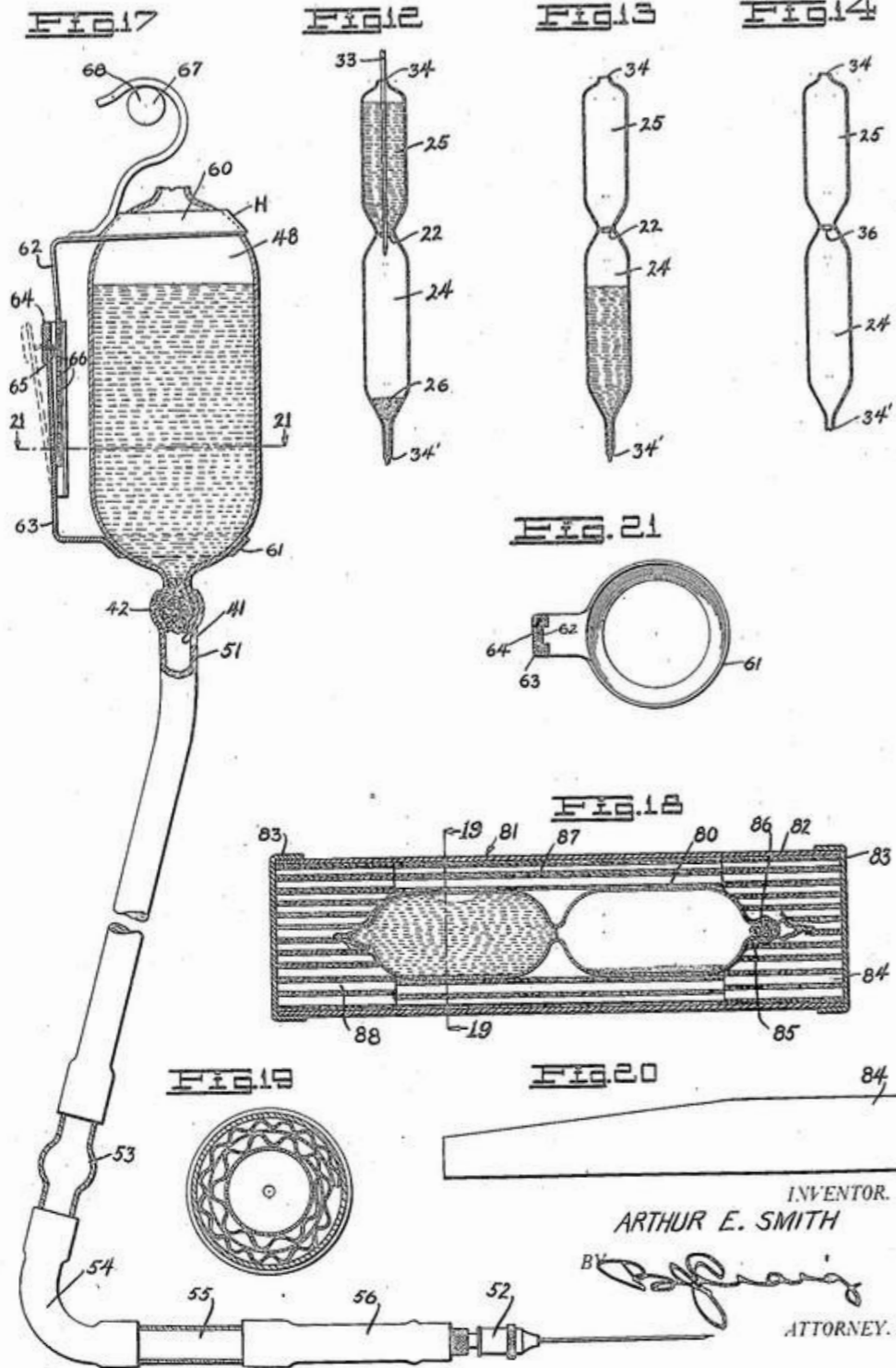
1,674,927

A. E. SMITH

AMPUL

Filed Jan. 5, 1926

2 Sheets-Sheet 2



Arthur E. Smith. Ampul Patent 1,674,927

filed January 25, 1926. Image

courtesy United States Patent and
Trademark Office.

Drug in clear area.
 Solution in hashed area.
 Needle enters from above and
 pierces the thin membrane.
 The drug and solution mixes.
 The tubing is made of rubber or
 plastic permitting the fluid to flow
 through the hypodermic needle
 into the vein.

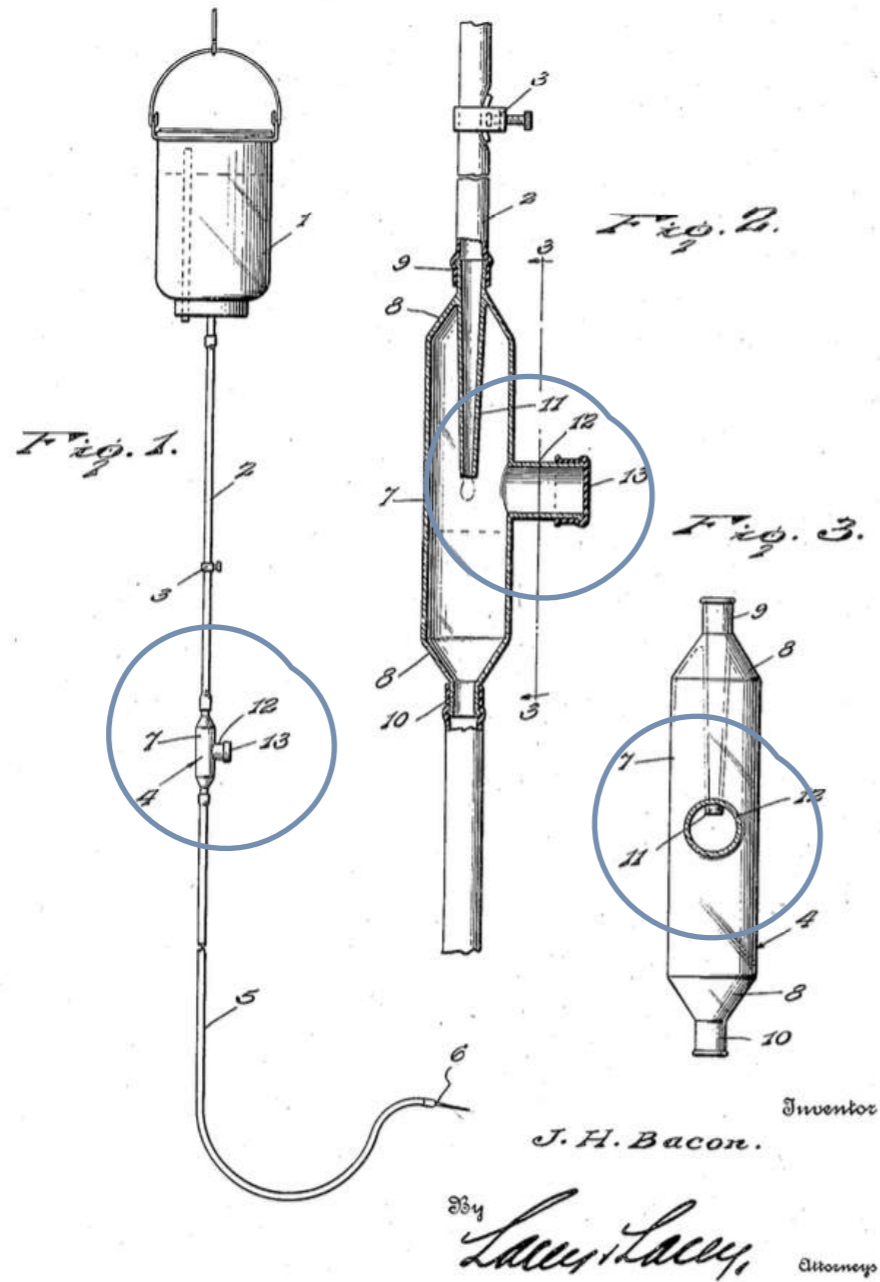
THE PROBLEM

No IV Ports

Sept. 13, 1938.

J. H. BACON
SURGICAL APPLIANCE
Filed April 6, 1936

2,129,983



Jay Harvey Bacon. Surgical Appliance. Patent 2,129.983. Filed April 6, 1936.

Image Courtesy of the United States Patent and Trademark Office.

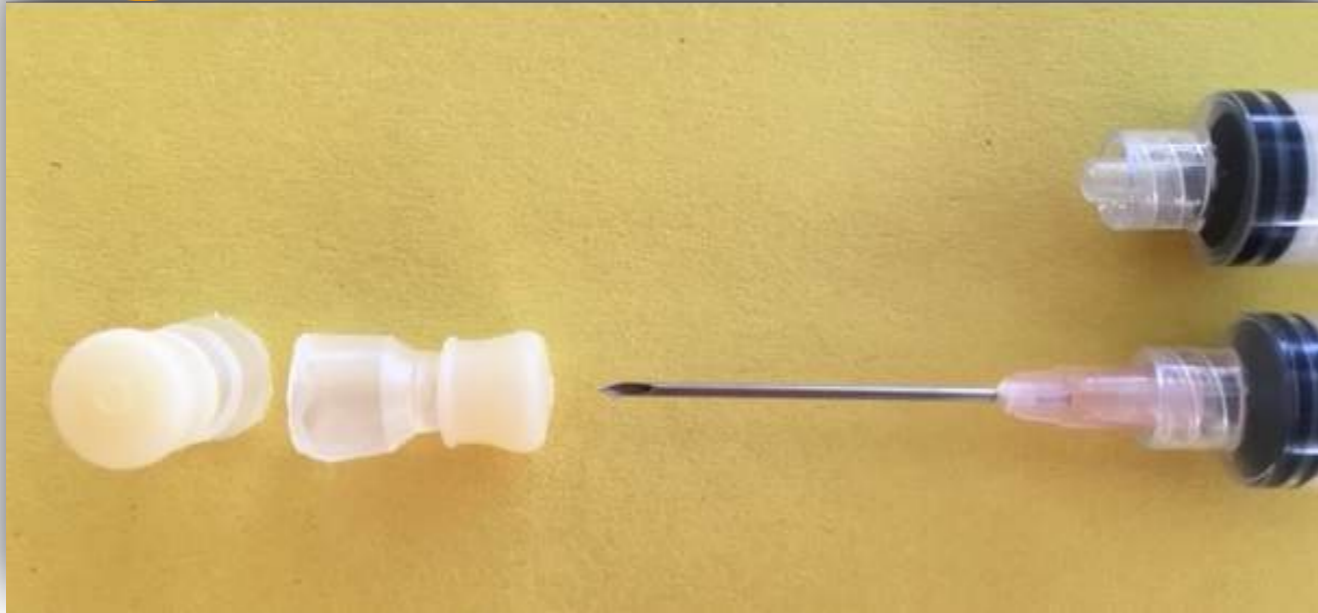
RUBBER STOPPER IV PORTS

1st
Generation

Rubber Stopper IV Port

1st

Generation



(1991)

FDA Issues Safety Alert for Hypodermic Needles on Secondary IV Administration Sets

(1992)

Chlarello L. Testimony on needlestick prevention technology. Presented before US Congress Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Energy. Washington, DC; February 7, 1992.

(1993)

The use of needles in the practice of anesthesiology and the effect of a needle-less intravenous administration system. Berry AJ. *Anesth Analg.* 1993. PMID: 8484516

THE PROBLEM

NEEDLE-STICK INJURY

Y-TYPE OPEN LUMEN LUER-LOCK IV PORT CONNECTOR - 1951

2nd
Generation

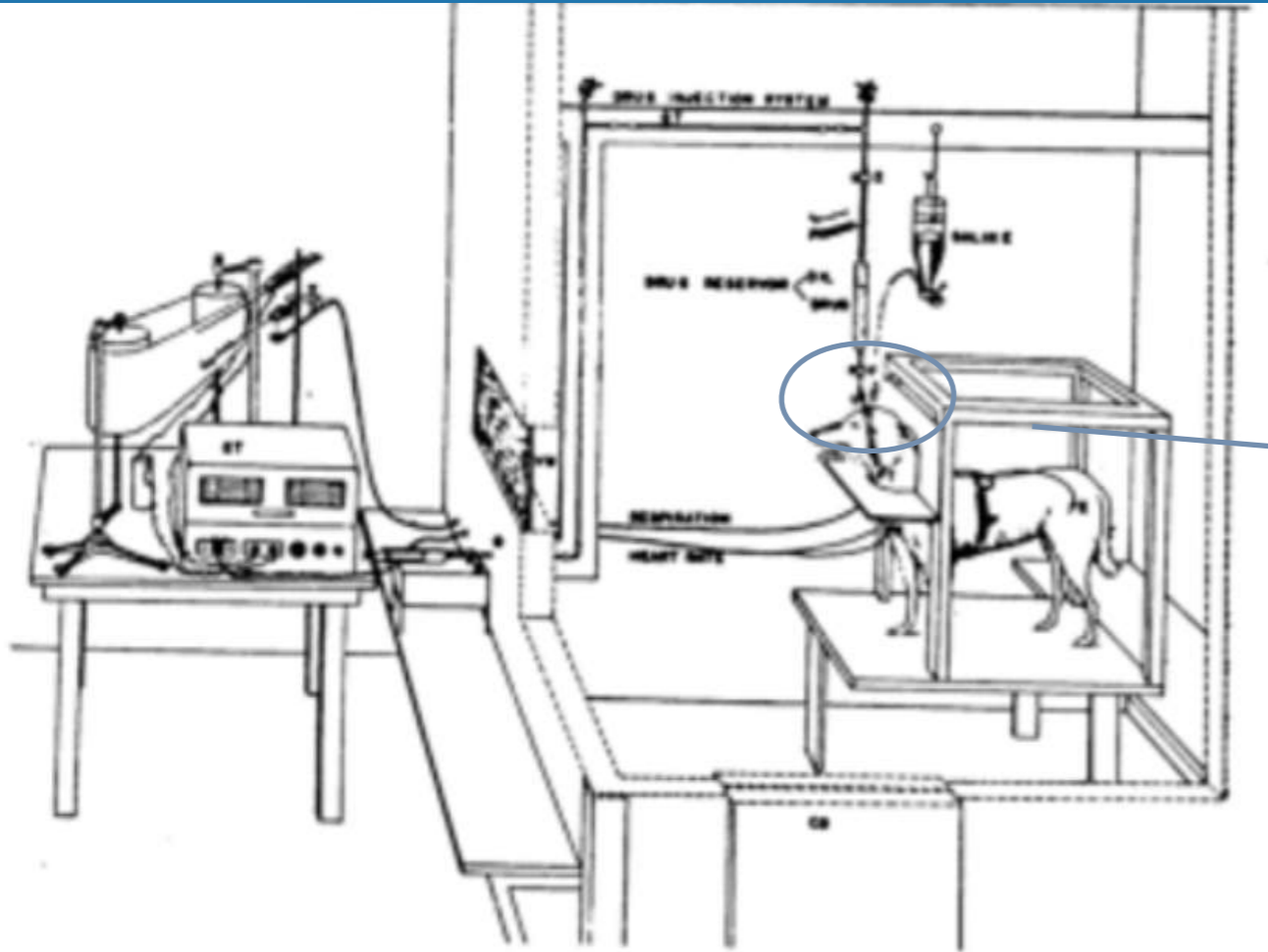


FIG. 1. Arrangement of injection apparatus and dog during experiment: *E*, electrodes for heart rate; *P*, pneumograph; *PT*, plastic (polyethylene) tubing; *T*, Y-tube; *GT*, oil-filled glass tubing; *CT*, cardiometer; *CD*, camera door; *O*, outlet for oil-filled tubing; *VW*, viewing window—one-way vision from outside camera; 1, 2, and 3, stopcocks.

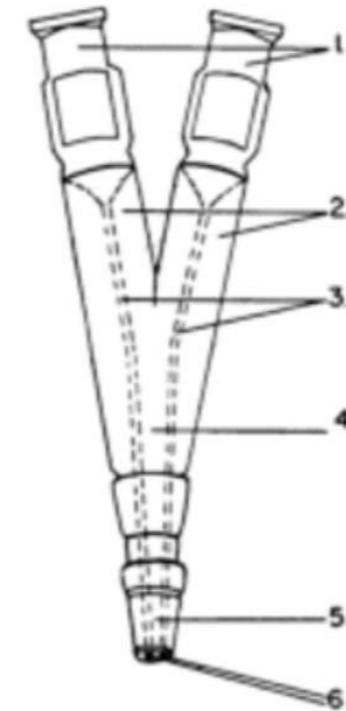


FIG. 2. Y-tube showing details of construction: 1, adapters of arms; 2, arms of Y-tube; 3, inner tubes; 4, stem of Y-tube; 5, adapter; and 6, open ends of inner tubes.

Image Courtesy of the
American
Association for the
Advancement of Science

THE PROBLEM

Bacteria Transmission

Open-Lumen Luer-Lock IV Port

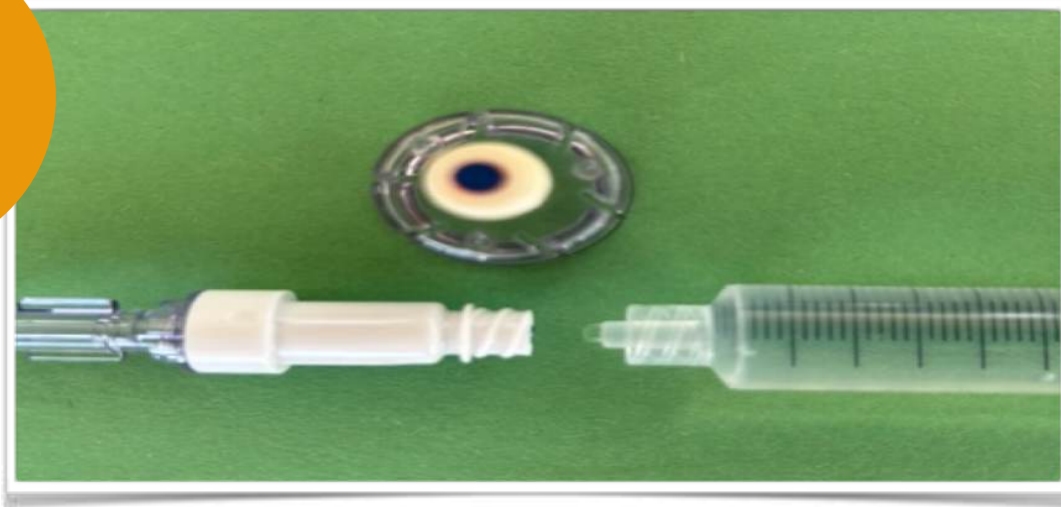


Muffly et al.

- Open Lumen - open portal for bacteria
- No surface area to disinfect
- Greater incidence of drug staying in the dead-space of the ports
- Increased incidence of microbial growth in dead-space
- Associated with increase in morbidity and mortality

CLOSED-LUMEN LUER-LOCK IV PORTS

3rd
Generation



needle-less IV port & syringe
= **exposed, large surface area, easily contaminated with bacteria.**

(1990-1993)

POSTOPERATIVE INFECTIONS TRACED TO CONTAMINATION OF AN INTRAVENOUS ANESTHETIC, PROPOFOL

(1993)

Use of Disinfectants To Reduce Microbial Contamination of Hubs of Vascular Catheters

(1995)

THE PROBLEM #1

Bacteria Transmission

Relevance of the Catheter Hub as a Portal for Microorganisms Causing Catheter-Related Bloodstream Infections

PROTECT THE IV PORT! (After Market Treatments)

Wipe IV Port with an alcohol swab and wait 30 seconds for the IV Port to dry prior to every access



**Manufacturer's Recommended IV Port Treatment
= Hospital Policy**

IV Port Asepsis Compliance

Infection prevention in the operating room anesthesia work area

Munoz et al.

- “<<20% of providers comply with IV port asepsis”

Review Article

**Disinfection of Needleless Connector Hubs: Clinical Evidence
Systematic Review**

Moureau and Flynn

- “Compliance with IV port asepsis is 10%”

THE PROBLEM #1

Low compliance

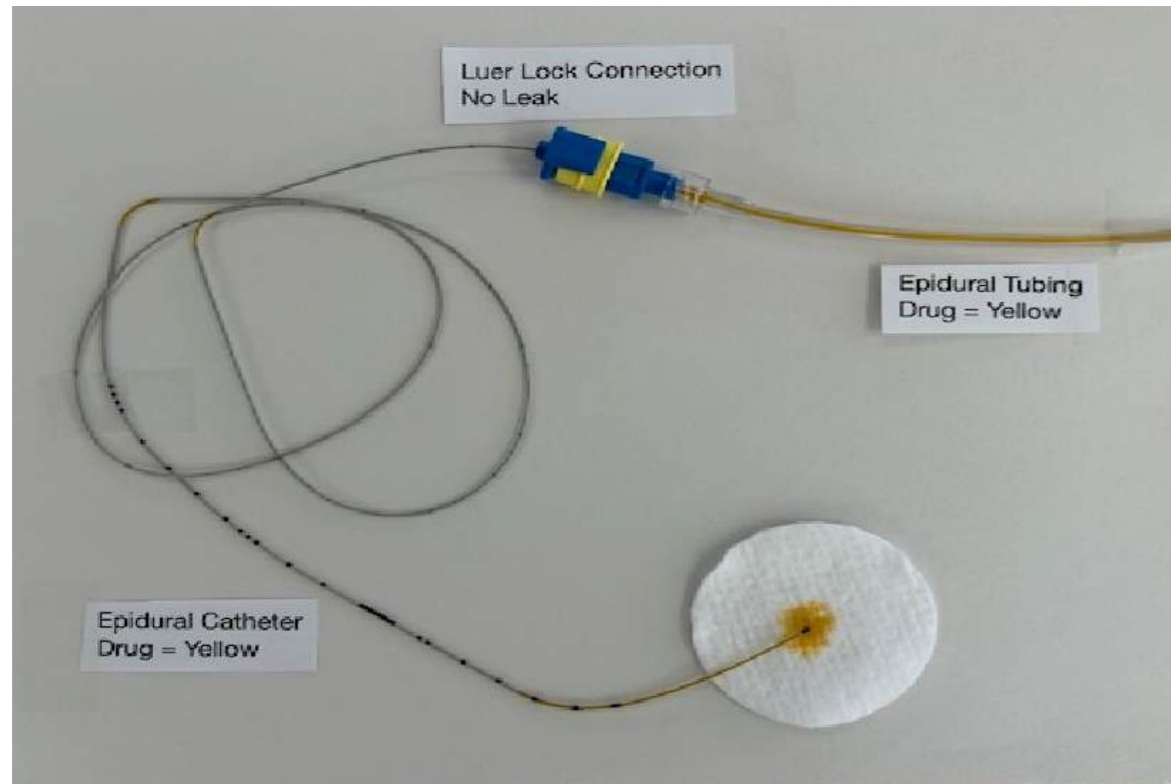
PROTECT THE IV PORT! (After-Market Protection and Treatments)



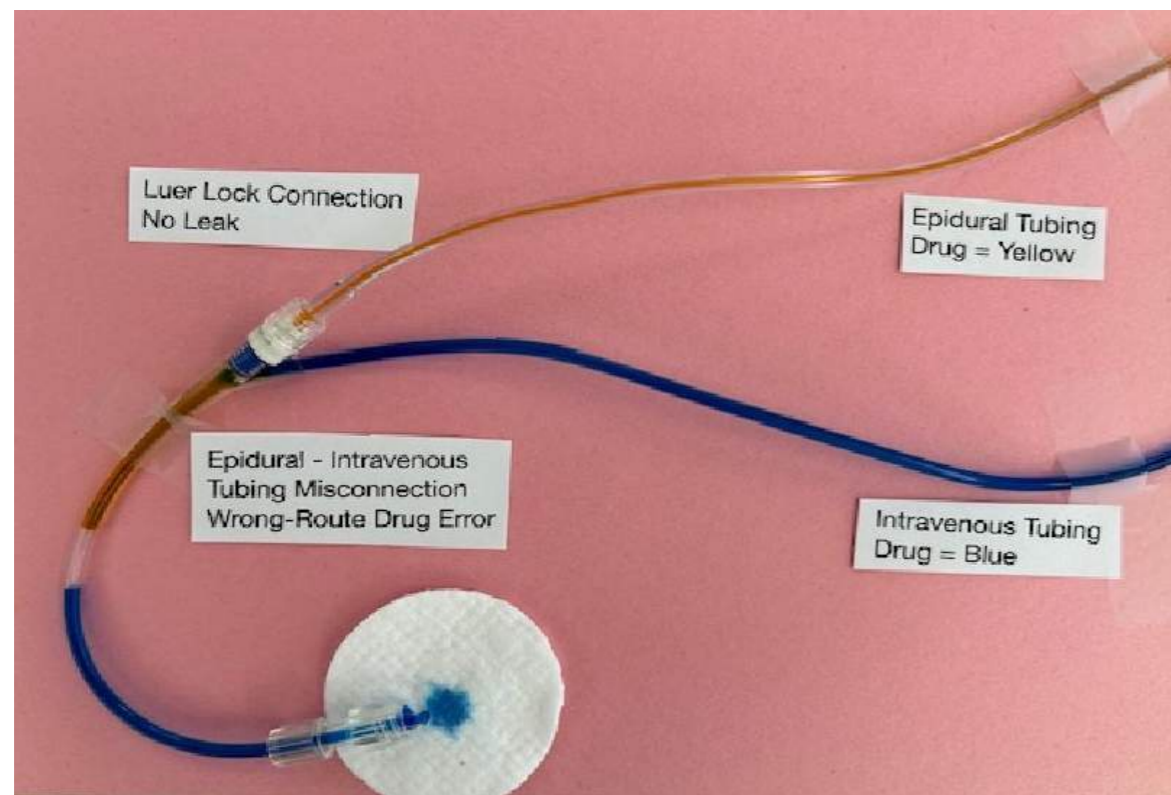
THE PROBLEM

#2

TUBING MISCONNECTIONS AND WRONG-ROUTE INFUSION DRUG ERRORS



Epidural tubing connected to an epidural catheter. (Epidural drug is dyed yellow for easier visualization).

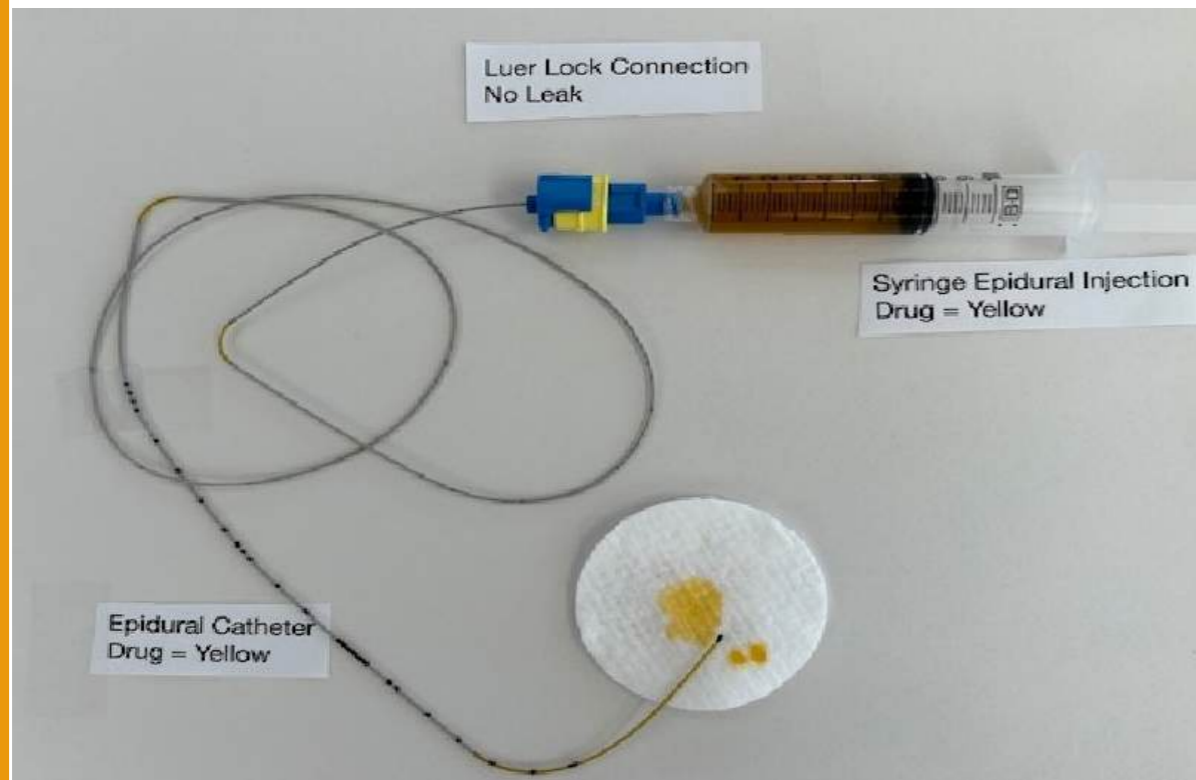


The epidural tubing (epidural drug dyed yellow for easier visualization) is connected to an IV port embedded in IV tubing (IV drug dyed blue for easier visualization).

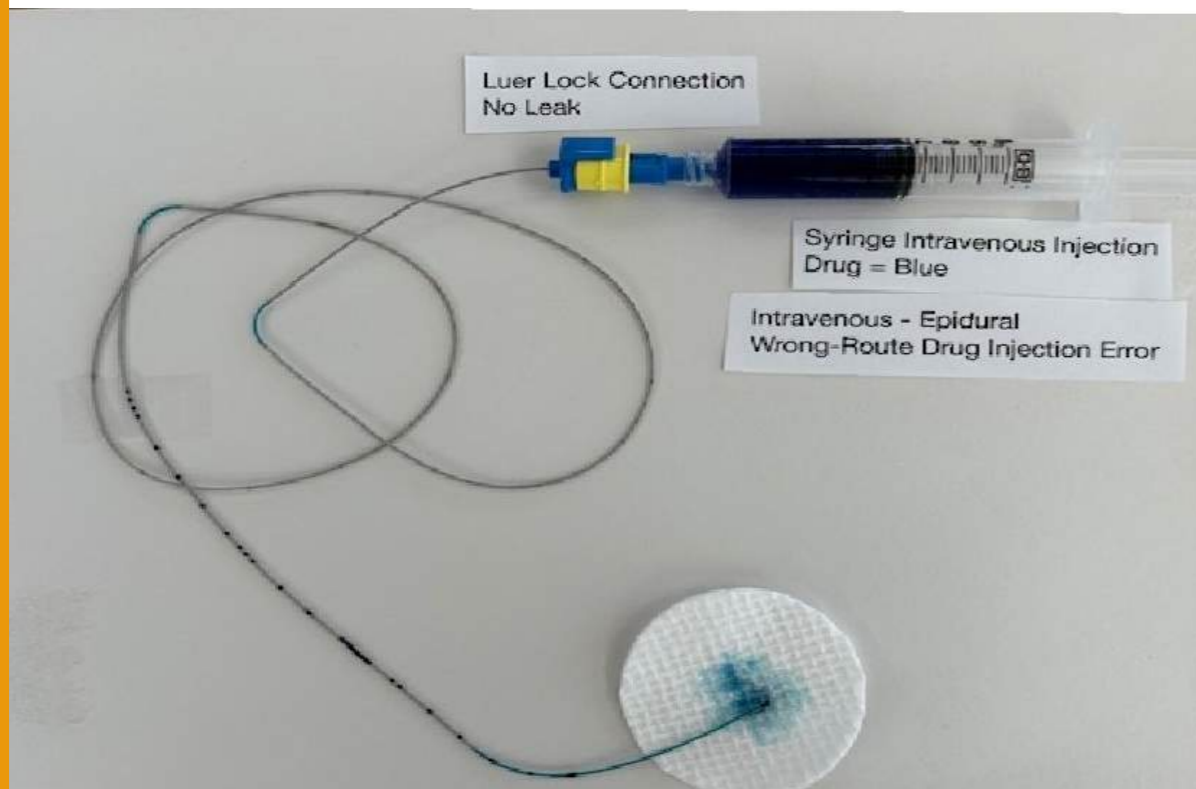
THE PROBLEM

#2

TUBING MISCONNECTIONS AND WRONG-ROUTE INJECTION DRUG ERRORS



An epidural bolus injection of drug (yellow dye) into the open-lumen luer-lock connector in an epidural catheter.



An intravenous bolus injection of drug (blue dye) into the open-lumen luer-lock connector in an epidural catheter.

The FRONTLINE CLINICAL PROVIDER'S LAMENT



Why doesn't "someone" just create a cleaner, faster, safer IV port and syringe that aims to prevent a source of healthcare-associated infections, tubing misconnections, and wrong-route infusion or injection drug errors?



Coachella Valley Economic Partnership Start-Up Incubator Program

CVEP's CEO Named
One of the Top 50
Economic Developers
in North America



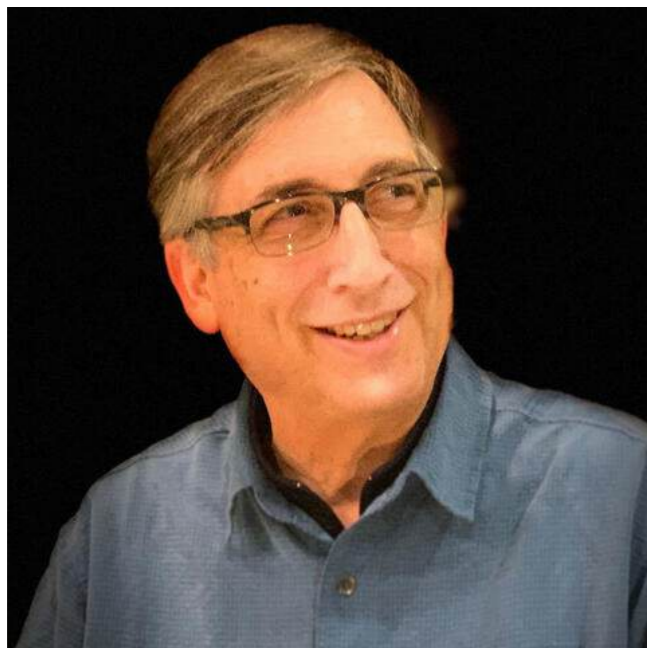
[LEARN MORE](#)

Joe Wallace, CEO

- 1. Goal is to incite vision-driven transformation**
- 2. Guidance**
- 3. Counseling**
- 4. Resources**
- 5. Networking**

DoubleLock Healthcare, Inc. is a member of CVEP since 2018.

National Science Foundation Innovation Corp Program at U. C. Riverside



- 1. Business Plan**
- 2. Market Research Plan**
- 3. Customer / Problem Discovery Interviews**
- 4. Commercialization Plan**
- 5. Laboratory space**
- 6. Lectures**
- 7. Grant writing support**

UC Riverside
NSF I-Corps Program
Liaison: Jay Gilberg

DoubleLock Healthcare, Inc. participated in the iCorp Program in 2022.

**THE
SOLUTION**

DOUBLELOCK Sterile Entry IV Port and Syringe System

Redefining IV Drug Delivery Proof-of-Concept Prototype

Not FDA Cleared or Approved yet

Value Proposition

- No aftermarket treatment needed
- Eliminates needle-stick injuries
- Unique Connector (ISO 80369) to prevent tubing misconnections
- Prevents bacteria transmission via IV ports
- Prohibits drug leakage
- Provides 100% compliance with IV port & syringe tip asepsis



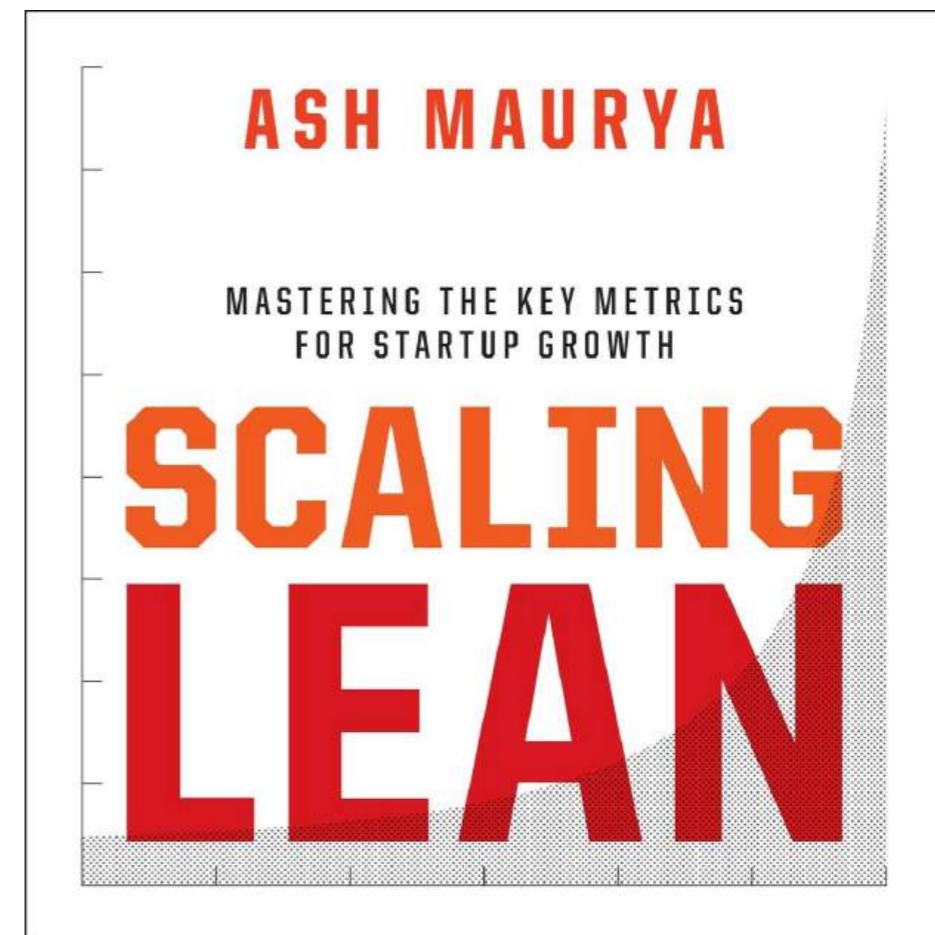
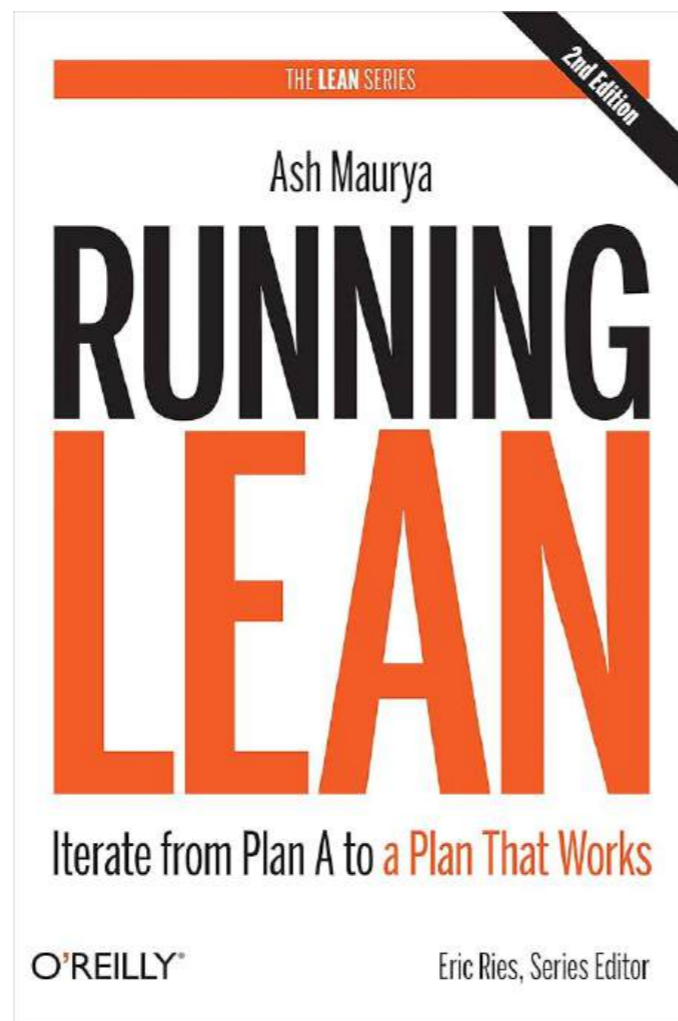
4th
Generation



The **DoubleLock** Sterile Entry IV Port and Syringe System + **DoubleLock** Healthcare Family of Products

== AIMS TO BE THE NEW STANDARD-OF-CARE IN IV DRUG DELIVERY

MassChallenge is the global network for innovators working to solve massive challenges.



Our mission is to equip bold entrepreneurs to disrupt the status quo and to create meaningful change.

DoubleLock Healthcare, Inc. participated in MassChallenge in 2023.

STANDARD DEVELOPING ORGANIZATIONS

Association for the
Advancement of
Medical Instrumentation
(AAMI) -
U. S. National



International
Organization for
Standardization
(ISO)
International organization
comprised of
171 National Organizations



Global Engineered Device Supplier Association

serves as the bridge between standard-developing organizations, manufacturers, distributors, suppliers, professional organizations, and healthcare facilities to implement ISO 80369 standards.



AANA Convention
San Diego, 2024
(L-R)
Elizabeth Wong, CRNA
Madison Webb, Exec. Asst
Ben Davis, ED & CEO

REVIEW

1. Discussed the history of medical devices that include needles, syringes, and IV ports
2. Described why medical device innovation takes place (based on need, and verbal or research based-feedback)
3. Explained the process of developing a medical device; recognition of a problem, idea generation, research, start-up incubators, accelerators, networking, acquiring resources, joining relevant organizations (AAMI, ISO, GEDSA), prototyping, and testing
4. Contrasted the difference between a regulatory / enforcement agency (U.S. - FDA), a standard-developing organization (U. S.- AAMI and international ISO), and a trade association (GEDSA)

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Francis Rynd

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Georges Guillaume Amatus Luer (1802–1883)

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Y-Type OpenLumen IV Port

A method of intravenous injection of drugs from a distance in conditional reflex studies. TEITELBAUM HA, GANTT WH. *Science*. 1951 May 25;113(2943):603-5. PMID: 14845680

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