Personal Protective Equipment and Closed System Transfer Devices

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Disclosure

- Seth Eisenberg has consulting agreements with:
  - BD
  - ICU Medical
  - Medtronic
  - B Braun

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Personal Protective Equipment

- Must be worn during:
  - Receipt and storage
  - Transport
  - Compounding (sterile and nonsterile)
  - Administration
  - Deactivation/decontamination, cleaning, and disinfecting
  - Spills
  - Waste disposal
  - Handling excreta
- Must be disposed of in designated HD waste container

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Personal Protective Equipment

- Different PPE is required for different activities
- **Compounding**
  - Gowns
  - Head covers
  - Hair covers
  - Shoe covers
  - Two pairs of chemotherapy gloves

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Personal Protective Equipment

- Different PPE is required for different activities
- **Administration**
  - Gowns
  - Two pairs of chemotherapy gloves
  - Facial protection for high risk of splashing
    - Examples: surgery, working above eye level

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Personal Protective Equipment

- Different PPE is required for different activities
- **Spills**
  - Gowns
  - Two pairs of chemotherapy gloves
  - Facial protection
  - Respiratory protection for drugs that vaporize

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Personal Protective Equipment

- Different PPE is required for different activities
- **Excreta**
  - Gowns
  - Two pairs of chemotherapy gloves
  - Facial protection if risk of splashing

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Gloves

- Two pairs of ASTM D6978 tested gloves
- Do not use the older ASTM F739 standard

- Cuffs must be long enough to allow the inner glove remain under the cuff of the gown and the outer glove to sufficiently cover the gown

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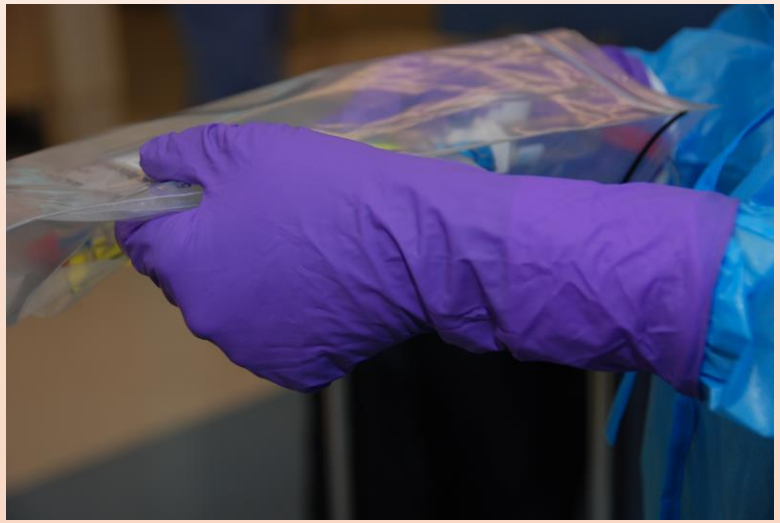
Photo courtesy of S. Eisenberg

Gloves

- Do not need to be the same brand or thickness
- Consider trying several brands over/under to determine which combination works best



Photos courtesy of S. Eisenberg

Gloves

- Worn for **all** HDs (antineoplastic, non-antineoplastic, and reproductive risk HDs)
- Powder free
- Gloves used for compounding must be sterile
- Maximum wear time of 30 minutes
  - Note that not all gloves resist all HDs for the same length of time

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Breakthrough Time Example

Drug	Minimum breakthrough time (minutes)	
	Cardinal Cool Blue	Cardinal Esteem
Carmustine (BCNU)	7.28	17.14
Cisplatin	>240	>240
Cyclophosphamide	>240	>240
Doxorubicin	>240	>240
Etoposide	>240	>240
5FU	>240	>240
Methotrexate	>24	Not Tested
Paclitaxel	>40	>240
Thiotepa	2.67	1.16

https://www.accessdata.fda.gov/cdrh_docs/pdf12/K122696.pdf;

- Be sure to know your product!

Warning: Do not use with Carmustine (BCNU) (3.3 mg/ml) and Thiotepa (10 mg/ml).

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USP <800> vs NIOSH

Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering control
All types of hazardous drugs	Receiving, unpacking, and placing in storage	no (single glove can be used, unless spills occur)	yes, when spills and leaks occur	no	yes, when spills and leaks occur	no
Intact tablet or capsule	Administration from unit-dose package	no (single glove can be used)	no	no	no	N/A
Tablets or capsules	Cutting, crushing, or manipulating tablets or cap-sules; handling uncoated tablets	yes	yes	no	yes, if not done in a control device	yes†
	Administration	no (single glove can be used)	no	yes, if vomit or potential to spit up‡	no	N/A

NIOSH 2016 Table 5. p32.

Gowns

- Disposable, single-use
- Cannot be worn outside of HD handling area
- Shown to resist HD
  - Ask manufacturer to provide documentation
  - ASTM is currently working on a gown standard
- Must close in the back
- No seams or openings in front
- Long sleeves with elastic or knit cuffs

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Respiratory Protection

- Required for spills of drugs that vaporize at room temperature

- Carmustine
- Etoposide
- Cyclophosphamide
- Thiotepa
- Nitrogen Mustard
- 5-FU
- Cisplatin
- Ifosfamide

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Connor, Shults & Fraser, Mutation research. 2000;470(1):85-92.; Kiffmeyer et al, The Pharmaceutical Journal. 2002;268(March):7

60 second chemistry review

Vapors and Aerosols

- **Vapors**: small particles (e.g. perfume)
- **Aerosols**: larger particles (e.g., Windex™)
- N95 or N100 are for aerosols and particulates
- **Vapors** require a canister respirator or PAPR (Powered Air Purifying Respirator) with organic vapor cartridge

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DHHS (NIOSH) Publication No. 2009–106; USP<800> 2016

Vapor Protection

Full Face Respirator with OV canister

PAPR (Powered Air Purifying Respirator) with OV cartridge

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Photos courtesy of Seth Eisenberg

Closed System Transfer Devices

- A Closed System Transfer Device (CSTD) will be **required** for administration of antineoplastic HDs
- Designed to "restrict hazardous drug liquid or vapor from escaping into the environment."
- CSTDs are **recommended** for compounding

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Closed System Transfer Devices

There are 2 components to CSTDs:

1. A vial adaptor designed to prevent the escape of aerosols, vapors and droplets

2. A connector used to transfer drug into IV bags and on IV tubing and syringes to prevent droplets

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Photo Credit: S. Eisenberg

Closed System Transfer Devices

- Although not "required" for compounding, facilities without a CSTD will likely adopt one for both departments
  - Requires collaboration between departments
- The CSTD that works best in pharmacy may not work best for nursing
  - Not all CSTDs are compatible with needless caps/tubing
- Hybrid systems, or 2 different brands have been successfully used in facilities

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7 CSTD Systems Available

- Phaseal (BD)
- Chemo Safety System [Texium] (CareFusion/BD)
- OnGuard (B Braun)
- Halo (Corvida)
- Equashield (Equashield Medical)
- ChemoClave (ICU Medical)
- ChemoLock (ICU Medical)

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CSTDs For Administration

- Should be used wherever connection or disconnection occurs on secondary and primary tubing

Eisenberg, S. PPPmag, 2014, February

Photo Credit: S. Eisenberg

Drips Happen!

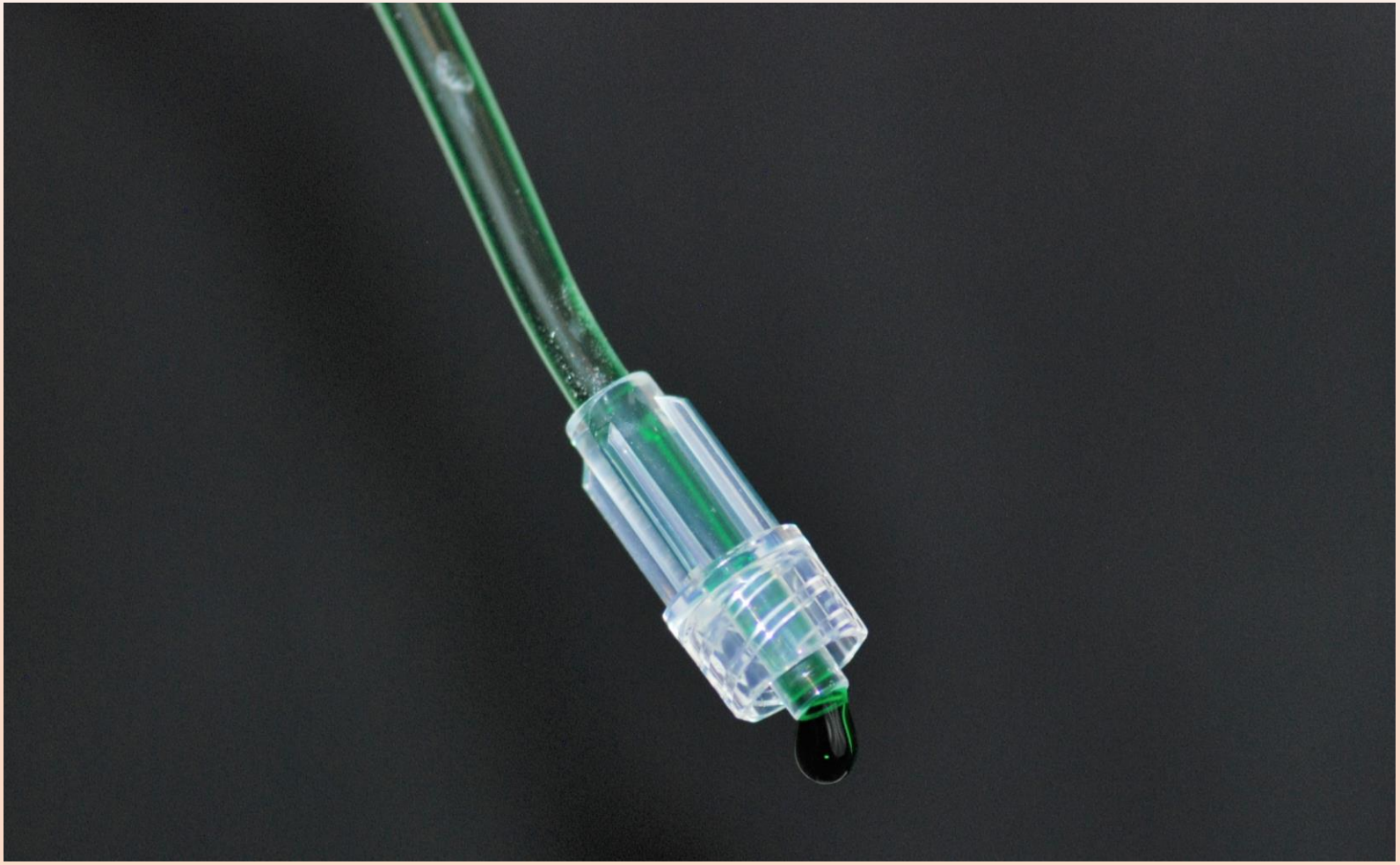

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Photo Credit: S. Eisenberg

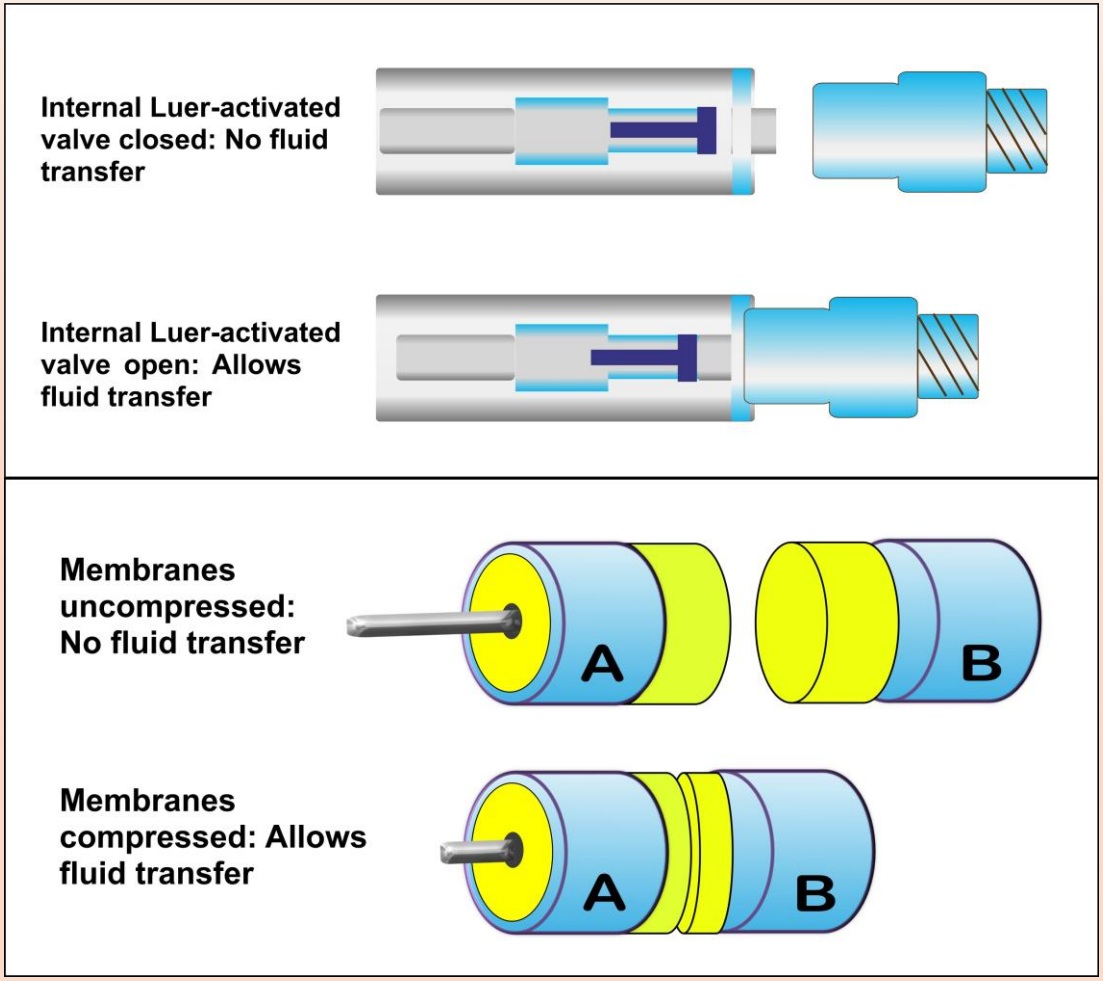
CSTDs

- For administering drugs in a syringe

- On chemotherapy bags if attaching at bedside or disconnecting bag from tubing

Photo Credit: S. Eisenberg

CSTD Designs



- ICU Spiros
- CareFusion Texium

- B Braun On Guard
- BD Phaseal
- Corvida Halo
- Equashield
- ICU ChemoLock (needless)

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CSTD Comparison

Manufacturer	Device	Luer / Membrane	Notes
BD	Phaseal	Membrane	First to market (1999)
BD	ChemoSafety [Texium]	Luer	Designed to work with CareFusion Smartsite™ valve
B Braun	OnGuard	Membrane	Dual layer microfilters on vial adapter
Corvida	Halo	Membrane	New; limited availability
Equashield	Equashield II	Membrane	Dual-chamber syringes
ICU Medical	ChemoClave	Luer	Universal luer compatibility
ICU Medical	ChemoLock	Membrane	Needless

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Membrane Devices & Adapters

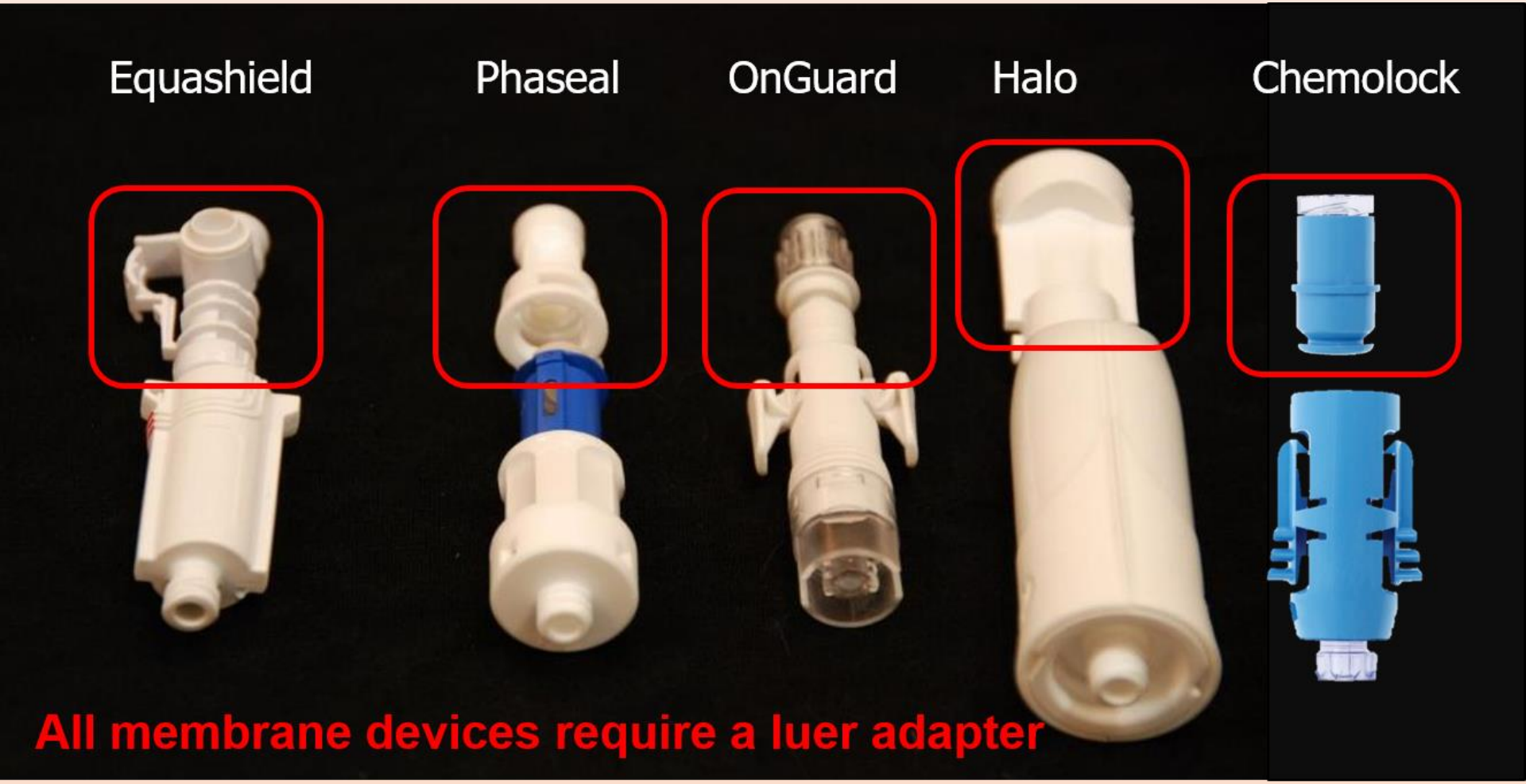
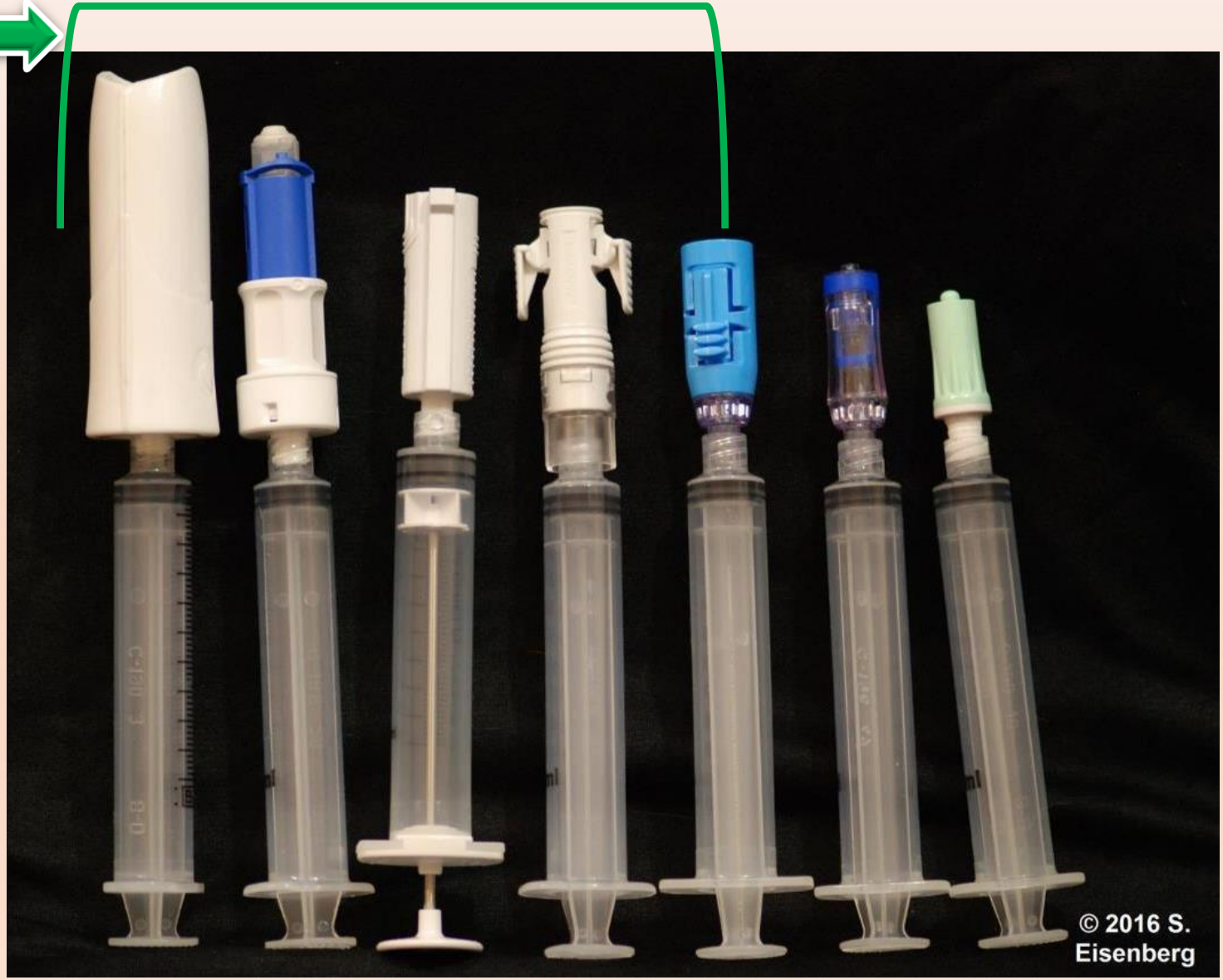


Photo Credit: S. Eisenberg

CSTD Size Comparison

Does not include luer adapters



CSTD Direct Spikes

- Allows for **connecting** tubing at the bedside
- Eliminates the need to prime tubing in pharmacy
  - Reduces opportunity for tubing contamination in the BSC
  - Saves pharmacy time and space
- Available from all CSTD manufacturers

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CSTD Direct Spike Examples

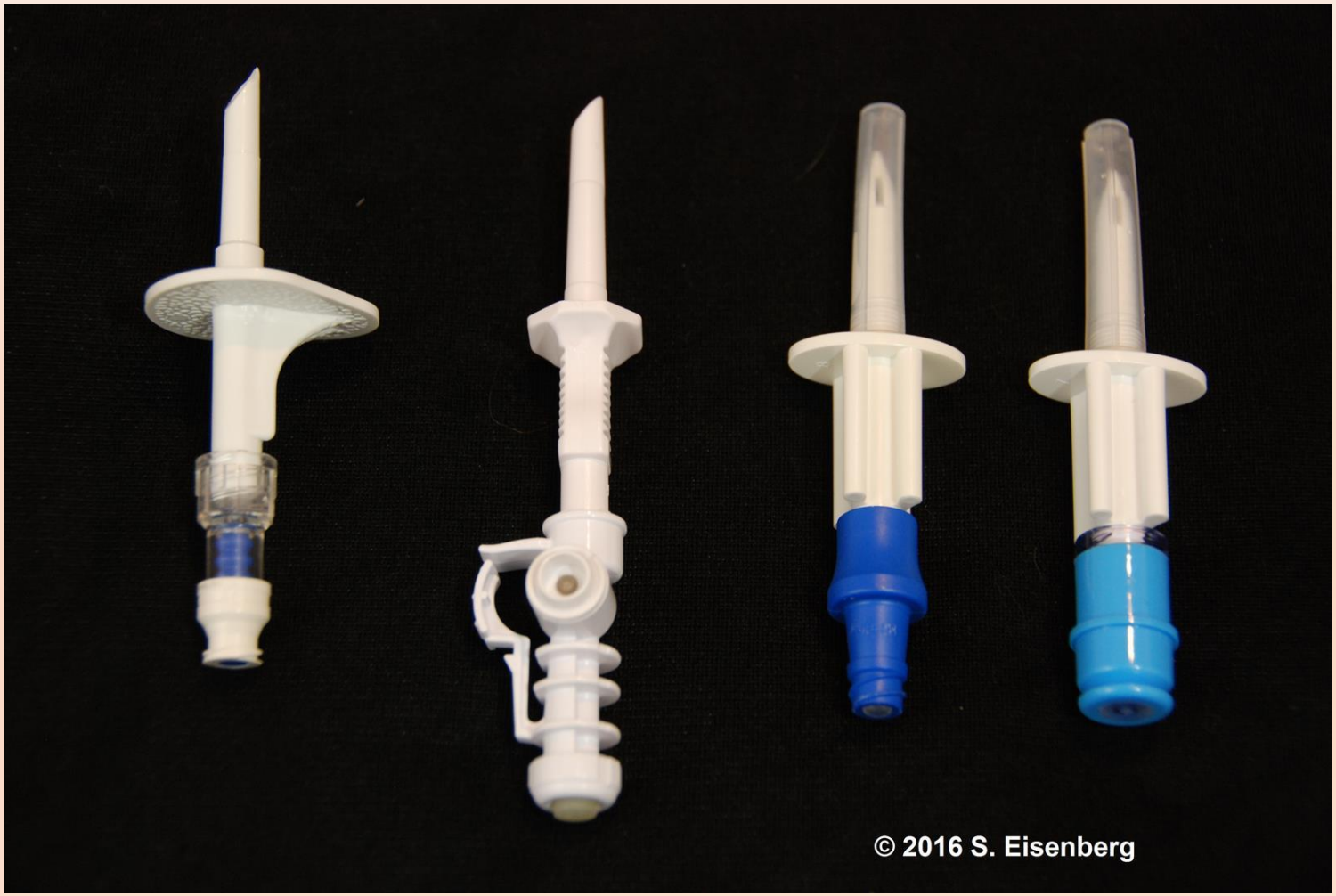

Photo Credit: S. Eisenberg

Direct Spike Example

Bag arrives with CSTD Direct Spike

Photo Credit: S. Eisenberg

CSTD Dry Spike

- Similar to Direct Spike, but designed to use **existing** primary tubing.
- Allows for spiking of tubing at the bedside without risk of puncturing the IV bag
- Eliminates the need to prime tubing in pharmacy, and reduces opportunity for tubing contamination in the BSC
- Available from all CSTD manufacturers

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CSTD Dry Spike Examples

ICU ChemoLock

BD Phaseal

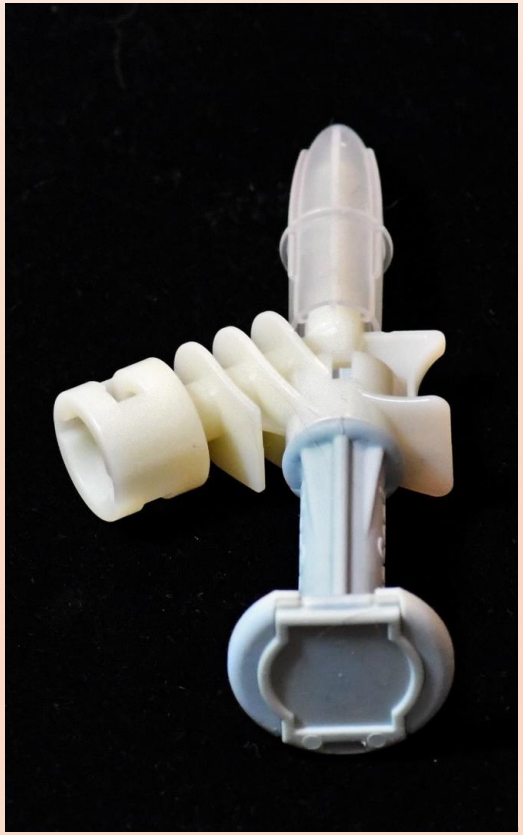

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Photo Credit: S. Eisenberg

CSTD Circle Priming

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Photo Credit: S. Eisenberg

CSTD Effectiveness

- No standardized test for effectiveness
- NIOSH developed a test protocol in 2016, although a number of issues were identified by manufacturers
- Products that passed:
  - Phaseal
  - OnGuard
  - Equashield
  - ChemoLock

CSTD Effectiveness

- NIOSH is currently working with manufacturers on a second testing protocol
- NIOSH will not be performing independent tests
- Manufacturers will use test to measure effectiveness
- Regardless of results, ANY CSTD is better than NO CSTD

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Summary

- Proper PPE will be required for the administration of HDs
  - Double ASTM 6978 gloves
  - Chemotherapy tested gown
- CSTDs will be required for the administration of antineoplastic HDs
  - 7 brands available
  - Each device has its strengths and weaknesses

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