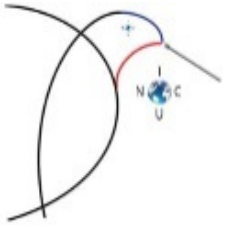
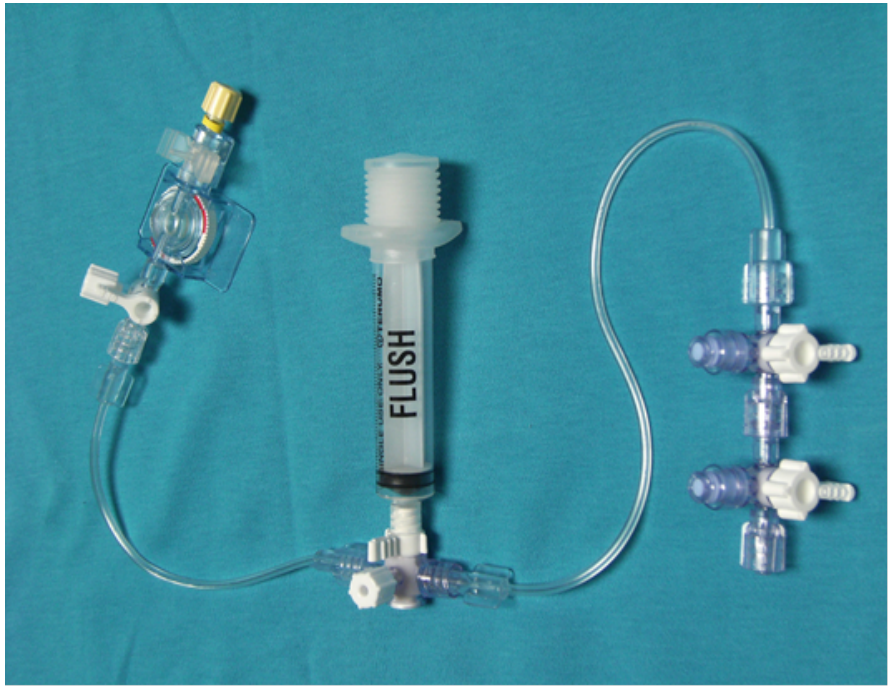
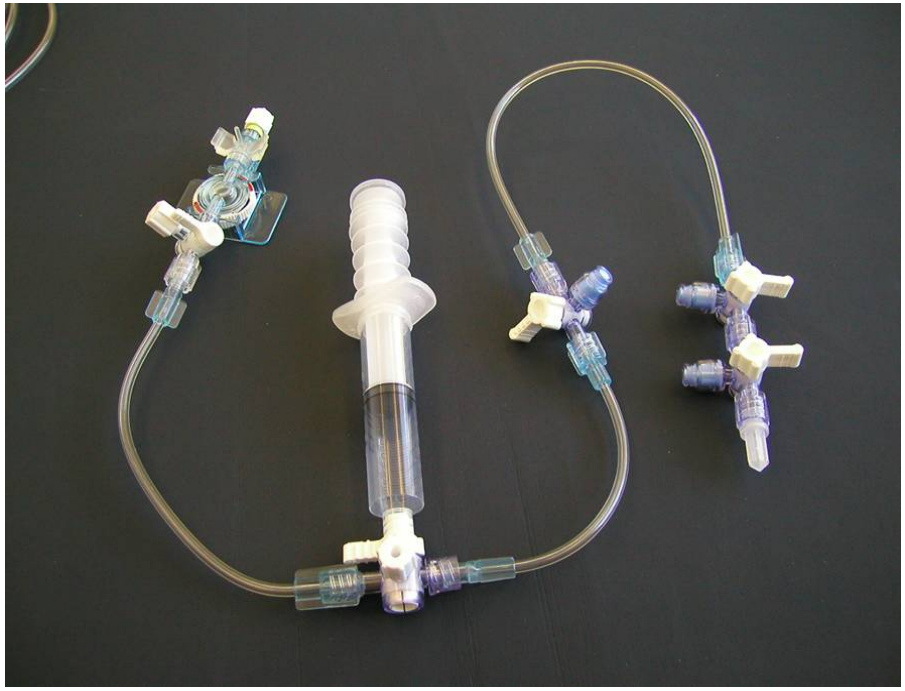


Hummi Micro Draw Blood Transfer Device

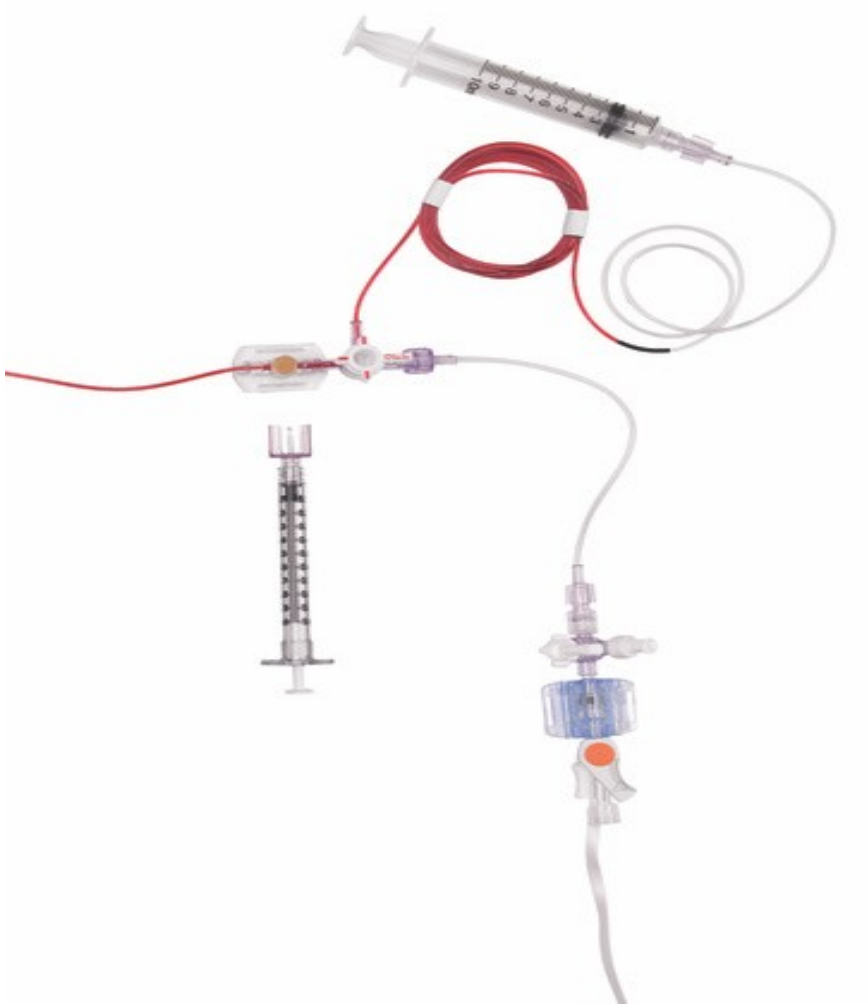
The Next Generation System for Closed Micro Blood Sampling in the Neonate

Current Methods for Umbilical Blood Sampling

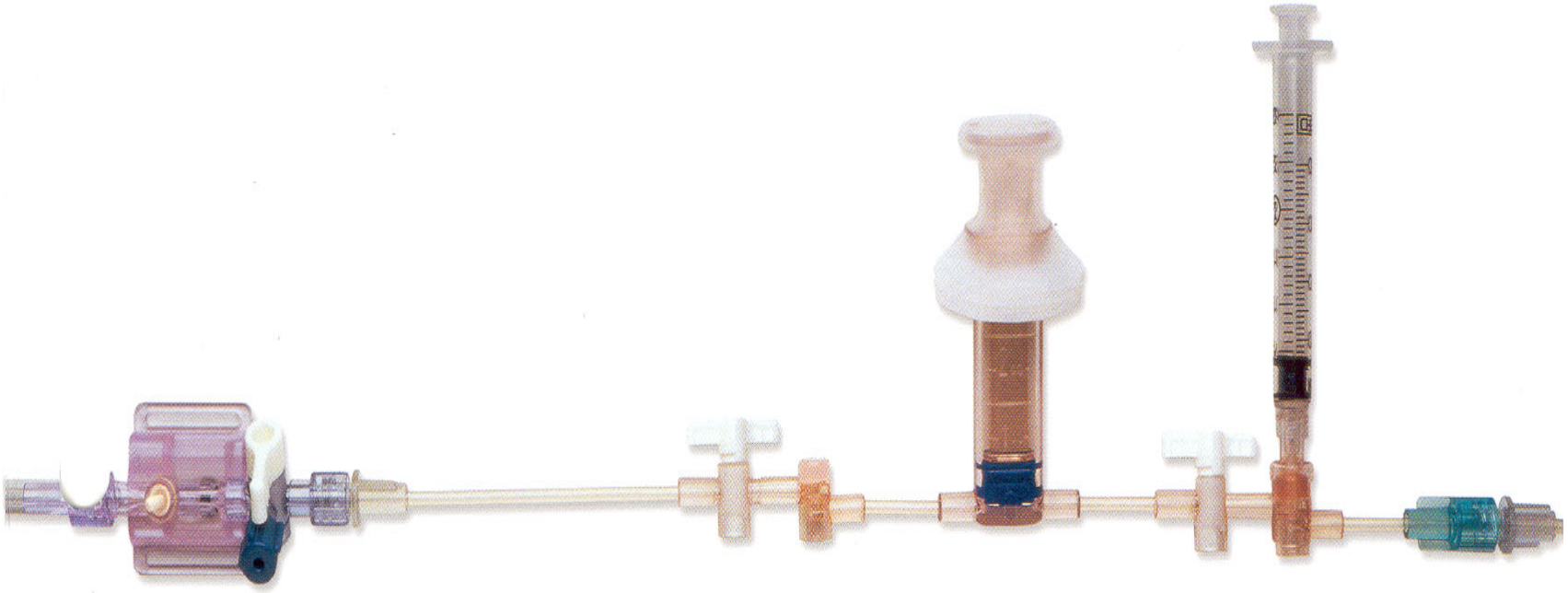




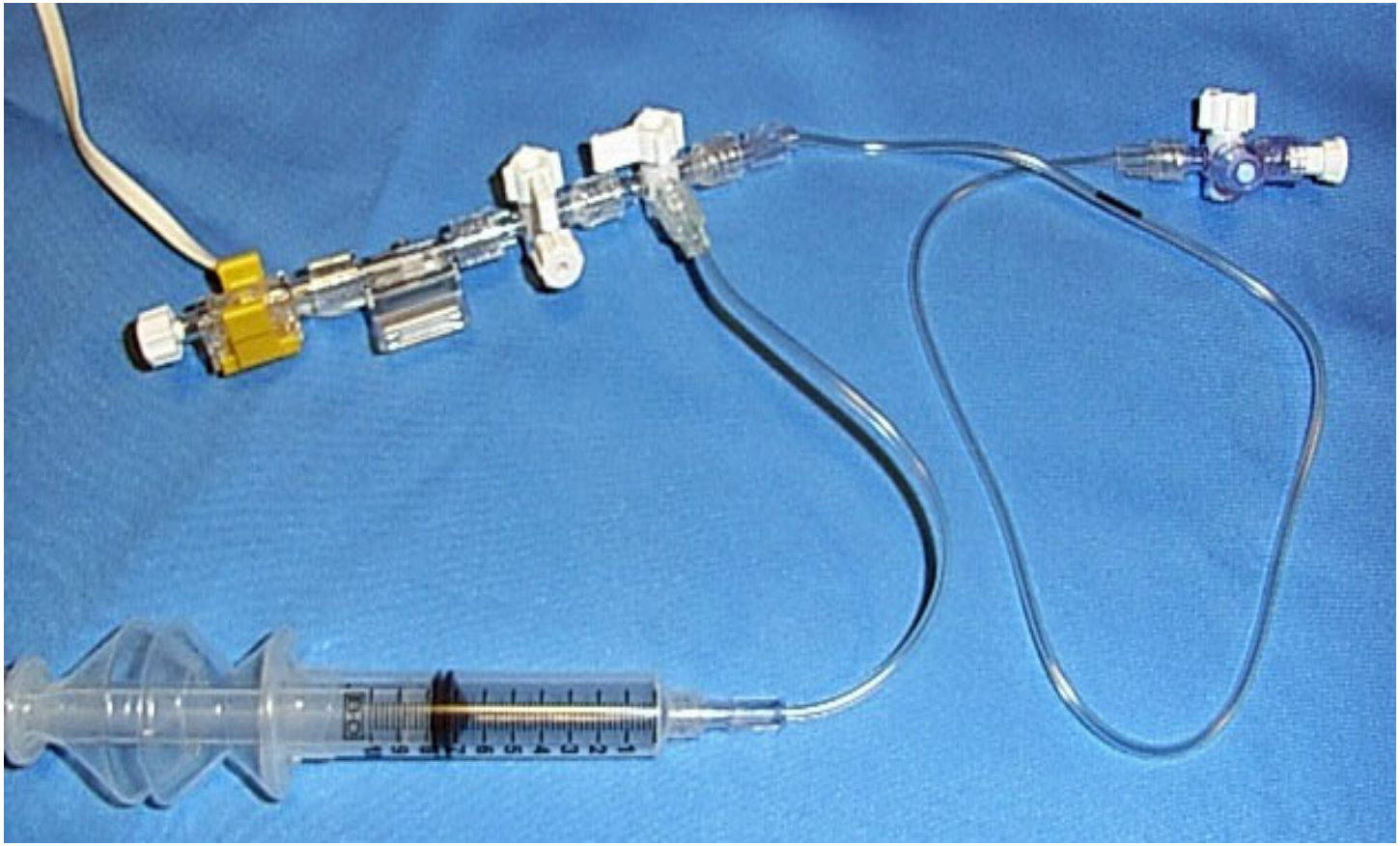
Current Methods for Umbilical Blood Sampling



Current Methods for Umbilical Blood Sampling



Current Methods for UAC Blood Sampling



Open Stopcock Method for Blood Draw

Advantage: None - Easy to Do …. Always done this way.

Weakness: Many

- Very high infection risk for patient
- Requires up to 4 separate line accesses per draw
- No standardized blood waste volume or flush volume
- Blood exposure risk for caregiver
- Stopcocks in line become reservoirs for bacterial growth
- Difficult to clear stopcock after draw (too much flush)

Issues with Current UAC Blood Draw Methods/Kits

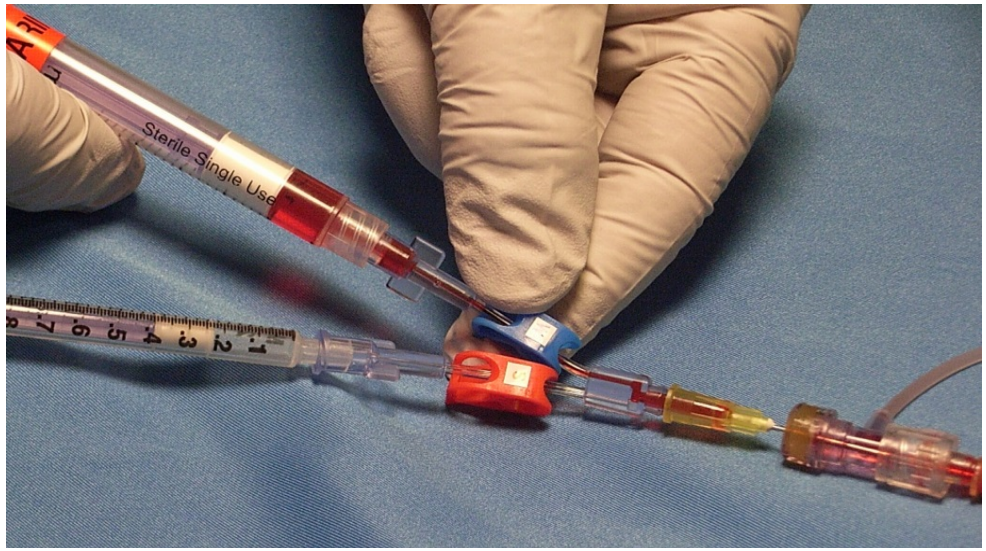
- Complexity of setup, maintenance and troubleshooting
- Damping of waveform from inline components and air entrapment. Higher air embolism risk
- Requires blood be drawn into arterial line for sampling.
- Blood/Tubing contact issues – fibrin sheath – infection risk from residual blood in line and stopcocks
- Blood/fluid volume movement excessive for neonatal hemodynamic stability. High clearance and flush volumes.
- All current methods require 3 to 6mL total fluid movement
- Presents high risk for development of IVH with total volume movement of 3 – 6mL during blood draw
- Some require external flush and added blunt cannula for every draw
- Not compatible with PAL blood draw method
- Some inline kits closed only for draw and not flush
- Methods for use not standardized

Hummi Micro Draw & Micro T Connector

For Infection Control and IVH Risk Reduction

The Next Generation System for Closed Micro Blood Sampling for the Neonate

Also Providing an Important Addition to Your IVH Bundle



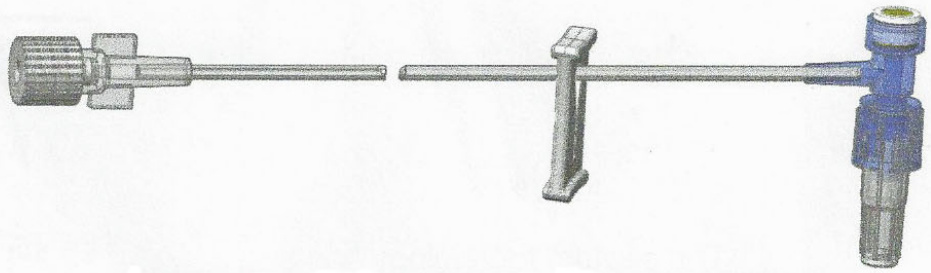
- **Provides microbial barrier protection with closed port access directly to the catheter hub for blood sampling. Only 1 access per blood draw.**
- **No blood is drawn into the arterial line for sampling, allowing for 70% lower clearance volume and 80% lower flush volume vs. current UAC sampling methods.**
- **Minimizes the risk for alteration in cerebral blood flow by reducing overall blood and fluid movement during sampling to 1.3mL.**
- **Standardizes the UAC draw procedure, reduces pressures and air embolism risk with the use of self venting syringes.**

Split Septum Micro T-Connector

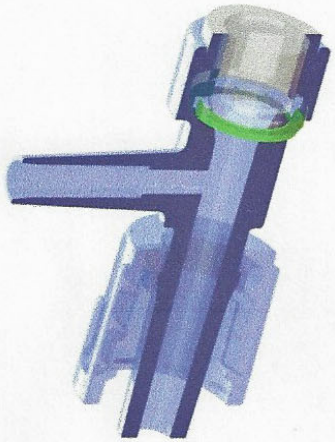
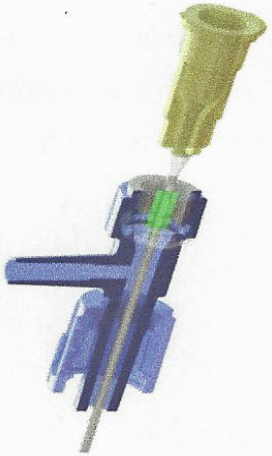
with Unique Split Septum Design providing 3-Levels of *Microbial Barrier Protection*

Validated for use with the Hummi Micro Draw Blood Transfer Device

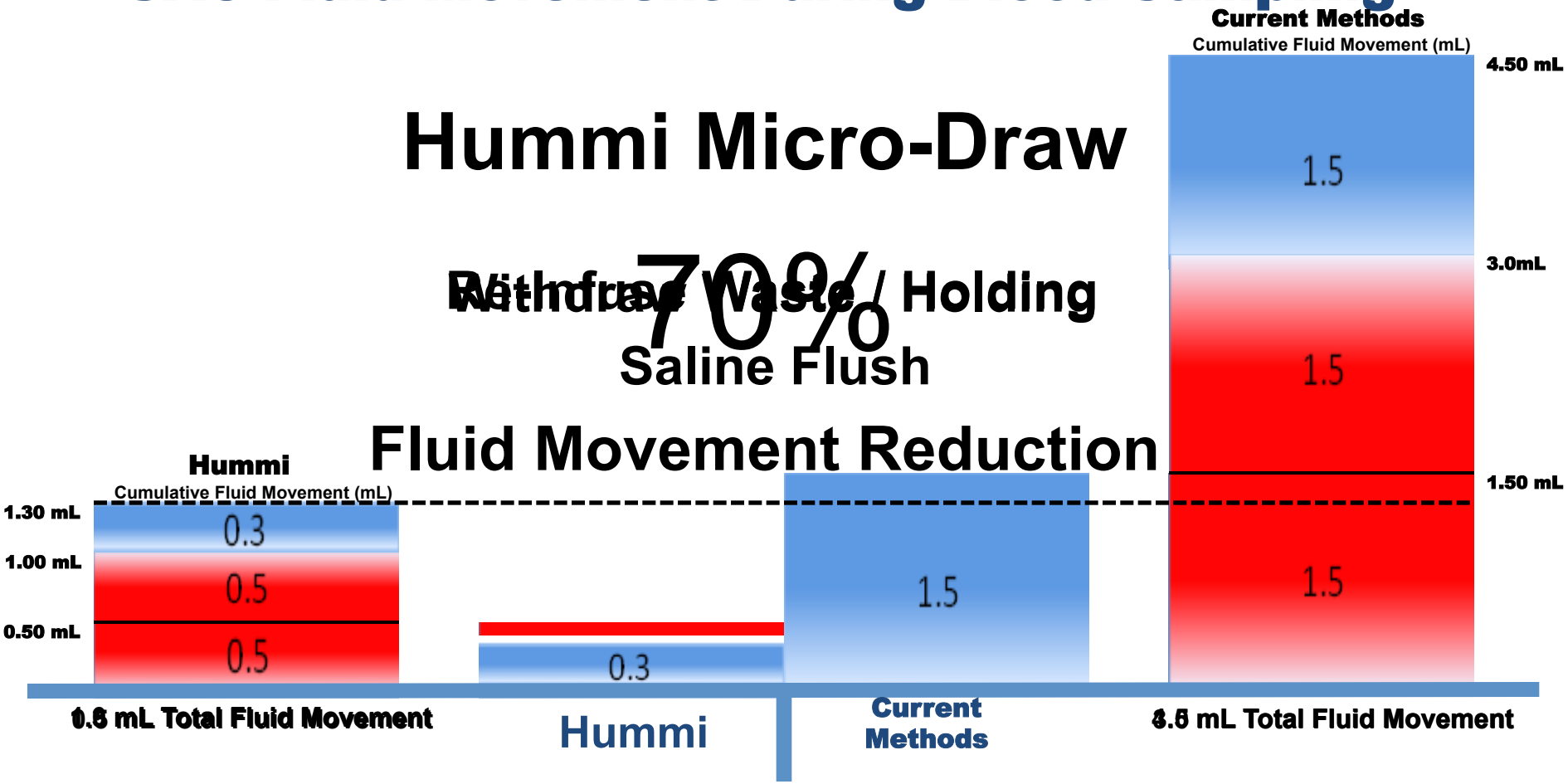
- A smooth, easy to disinfect septum promotes a safe and effective microbial barrier
- Split Septum design provides *Microbial Barrier Protection at all times*
- Designed for easy insertion with the Hummi (<1 foot pound insertion force)[1]
- Tested to 150 septum insertions with the Hummi Micro Draw Device[1]
- Pressure Tested to 20 psi/1hr without leak[1]
- Tested to -10 psi vacuum with Hummi Micro Draw in place[1]
- Microbore tubing with secure luer locking collar
- Materials are DEHP and Latex Free[1]
- Low internal volume 0.25mL (+/- .01)[1]
- Holds Hummi Micro Draw device securely in place during sampling



The unique split septum design technology has been validated with 3-separate bacteria (S. aureus, S. epidermis and E. coli) by an outside GLP laboratory using a 96-activation protocol with non-locking cannula

First Level of Protection:	**Second Level of Protection:**	**Third Level of Protection:**
A 360° compressed seal proven to provide a safe and effective microbial barrier protection between the septum and the needle-free connector housing.	A smooth, easy to disinfect septum surface, promotes a safe and effective microbial barrier.	The *split septum* design protects the internal fluid path
 When not accessed, the unique septum design forms a safe and effective microbial barrier.	 The septum technology has a rigid band to form a compression seal providing Microbial Barrier Protection at all times.	 The split septum remains sealed until the Hummi Blunt Cannula is inserted into the fluid path.

UAC Fluid Movement During Blood Sampling



Volume of Fluid Movement as a Percentage of Total Blood Volume
during Umbilical Catheter Blood Sampling

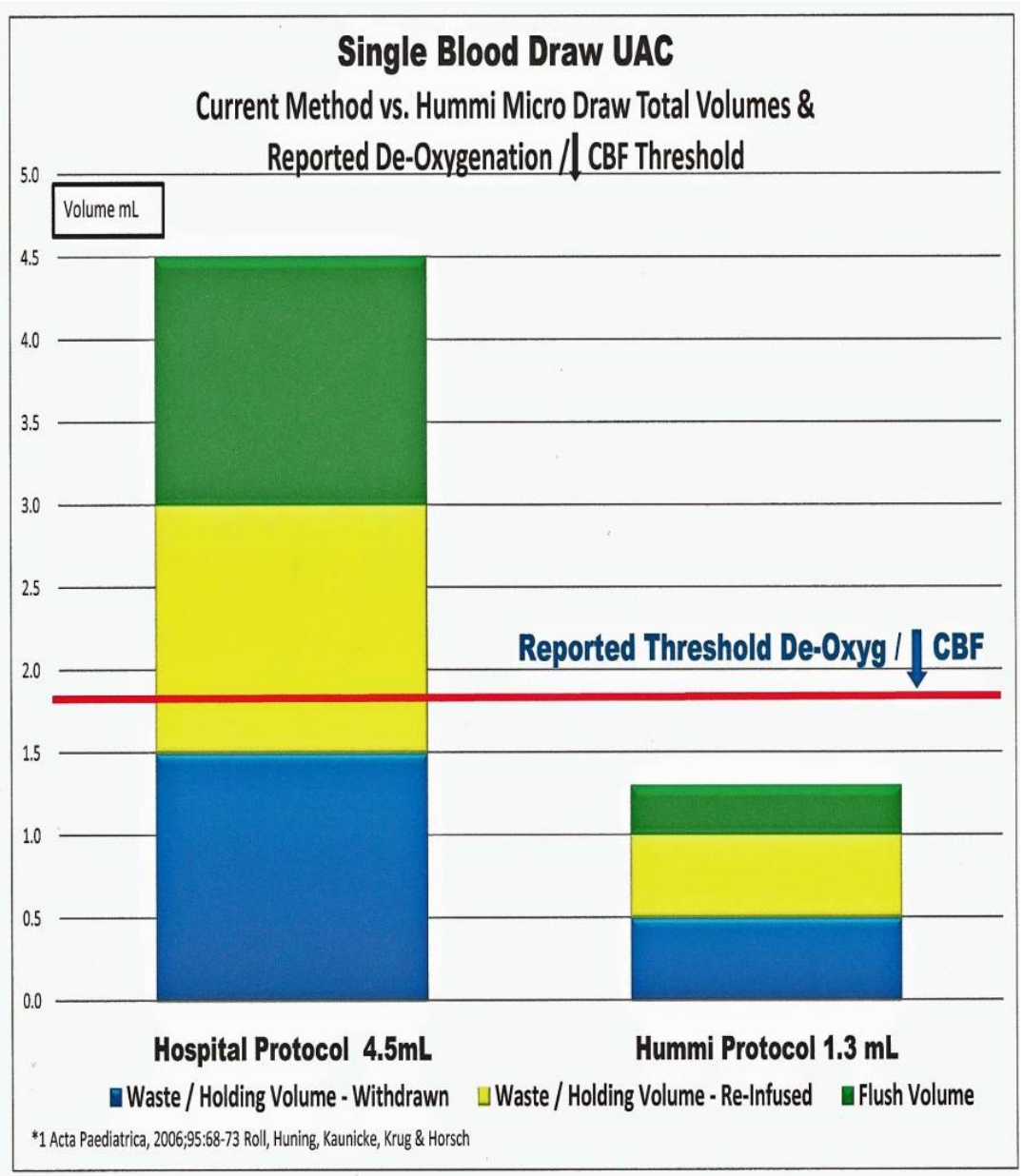
UAC Catheter - Approximate mL fluid fill volumes : 2.5 Fr. = 0.10mL 3.5 Fr. = 0.16mL 5.0 Fr. = 0.22mL

UAC Catheter - HUMMI approx. mL withholding volume : 2.5 Fr. = 0.30mL 3.5 Fr. = 0.40mL 5.0 Fr. = 0.50mL

Neonate's Weight Grams / Ounces and Approximate Total Blood Volume	CURRENT NICU PRACTICE Approximate Fluid Volume (mL) Movement Per Blood Draw		HUMMI mL Fluid Volume Movement Per Blood Draw	Clinical Improvement HUMMI Micro-Draw Blood Transfer Device
	1.50	mL Blood Holding Withdrawn	0.50	
	1.50	mL Blood Holding Returned	0.50	
	1.50	mL Line Flush Volume	0.30	
	4.50	Total ML Fluid Volume Movement	1.30	HUMMI vs. CURRENT NICU PRACTICE 71.1% *Overall Fluid Volume Movement Reduction*

Grams	Pounds / Ounces (1GM - 0.036 oz)	Approx. mL Total Blood Volume	CURRENT NICU Total Fluid mL Volume Movement	CURRENT NICU Percent of Neonate's Total Blood Volume	HUMMI Total Fluid mL Volume Movement	HUMMI Percent Neonate's Total Blood Volume	HUMMI Neonate's Total Body Fluid mL Volume Movement Reduction	HUMMI Fluid mL Volume Movement Reduction
1,000	2.25 lb = 36 oz	75.0	4.50	6.0%	1.30	1.7%	4.3%	3.20
950	2.14 lb = 34.2 oz	71.3	4.50	6.3%	1.30	1.8%	4.5%	3.20
900	2.03 lb = 32.4 oz	67.5	4.50	6.7%	1.30	1.9%	4.7%	3.20
850	1.91 lb = 30.6 oz	63.8	4.50	7.1%	1.30	2.0%	5.0%	3.20
800	1.80 lb = 28.8 oz	60.0	4.50	7.5%	1.30	2.2%	5.3%	3.20
750	1.69 lb = 27.0 oz	56.3	4.50	8.0%	1.30	2.3%	5.7%	3.20
700	1.58 lb = 25.2 oz	52.5	4.50	8.6%	1.30	2.5%	6.1%	3.20
650	1.46 lb = 23.4 oz	48.8	4.50	9.2%	1.30	2.7%	6.6%	3.20
600	1.35 lb = 21.6 oz	45.0	4.50	10.0%	1.30	2.9%	7.1%	3.20
550	1.24 lb = 19.8 oz	41.3	4.50	10.9%	1.30	3.2%	7.8%	3.20
500	1.13 lb = 18.0 oz	37.5	4.50	12.0%	1.30	3.5%	8.5%	3.20
450	1.13 lb = 18.0 oz	33.8	4.50	13.3%	1.30	3.9%	9.5%	3.20
400	0.90 lb = 14.4 oz	30.0	4.50	15.0%	1.30	4.3%	10.7%	3.20
375	0.84 lb = 13.5 oz	28.1	4.50	16.0%	1.30	4.6%	11.4%	3.20
350	0.79 lb = 12.6 oz	26.3	4.50	17.1%	1.30	5.0%	12.2%	3.20

UAC Single Blood Sampling using Hummi Micro-Draw



Complications of Prematurity

Four major complications of prematurity contribute to 90% of all the costs related to the treatment of the premature infant.

Major Complications of Prematurity

1. **RDS** - Respiratory Distress Syndrome
2. **BPD** - Broncho Pulmonary Dysplasia
3. **NEC** - Necrotizing Enterocolitis
4. **IVH / PVL** – Intraventricular Hemorrhage and Periventricular Leukomalacia

What is IVH & PVL?

Intraventricualr Hemorrhage (IVH) of the newborn is bleeding into the fluid filled areas (ventricles) inside the brain. The condition occurs most often in babies that are born prematurely.

Periventricular Leukomalacia (PVL) is a type of brain injury. PVL actually represent small "holes" in the brain due to the death of small areas of brain tissue around the normal fluid filled cavities (ventricles) of the brain.

Often these 2 conditions are referred to as PVH/IVH, or PV/IVH as they are often present together, and have prematurity as a key factor for development.

IVH – Why?

- Primarily attributed to:
- Increased Vascular Fragility
- Disturbances to Cerebral Blood Flow (CBF)
- Possibly, but Not Often Disorder of Platelet Count, Coagulation

Dr. John Golden, D.O. Neonatologist, Pediatrix Medical Group of WA, Tacoma General Hospital, Sept. 2014

As Part of an IVH Bundle the Hummi Micro Draw has Unique Clinical Implications for Reducing Risk Factors for IVH / PVL

Hummi Micro-Draw Blood Transfer Device has clinical implications for reducing the known risk factors for IVH / PVL development from the use of:

1. Umbilical Arterial Catheters (UAC)

and …

2. Umbilical Venous Catheters (UVC)

What is a Bundle?

- "A bundle is a selected set of interventions or
- processes of care distilled from evidence-
- based practice guidelines that when implemented
- as a group provide a more robust picture of the
- quality of care provided."

- The implementation of the bundle is aimed at
- tracking change in practice and reporting how often
- these evidence-based interventions are used.
-

Levy et al Critical Care Med 2004

Key Neonatal Risk Factors and Clinical Characteristics for Development of IVH / PVL

1. Prematurity
2. Low Gestational Age
3. Low Birth Weight
4. **Use of Umbilical Artery Catheter (UAC) or Umbilical Venous Catheter (UVC)**

Other Risk Factors

5. Use of Inotropic Agents for hypotension

6. Metabolic Acidosis

7. Development of RDS – Respiratory Distress Syndrome

8. Mechanical Ventilation

9. Development of Sepsis

10. Surgical Procedure

11. Transfusion of Red Blood Cells

Incidence of IVH / PVL in Premature Infants with Umbilical Catheter Use

Lee et.al 2010:

	Case Group IVH / PVL	Control Group IVH / PVL
Umbilical Arterial Catheter (UAC)	**23.7%**	**7.6%**
Umbilical Venous Catheter (UVC)	**27.9%**	**5.1%**

Literature Review

1988 - 2010

The Risk for IVH Development

Reduction in intra-ventricular hemorrhage by elimination of fluctuating cerebral blood flow velocity in preterm infants …

Perlman, et.al Have demonstrated that the alteration from auto-regulation to a pressure passive circulatory pattern appears to be an important step in the development of PV / IVH.

New England Journal of Medicine
1988; 309 – 204 - 9

Blood Withdrawal and Infusion via Umbilical Catheters

The withdrawal and infusion of blood via the umbilical catheter can cause a significant rapid change of cerebral blood flow of preterm infants.

Bray, et.al
Biol. Neonate 2003; 84: 187 - 193

The Risk for IVH Development

Umbilical Artery Catheter Blood Sampling Volume and Velocity: Impact on Cerebral Blood Volume and Oxygenation in Very Low Birth Weight Infants Roll et al.

"Changes in cerebral hemodynamics and Oxygenation are thought to be major causes of Intracranial Hemorrhage and Periventricular Leukomalacia in premature infants."

Roll, et.al
Acta Paediatrical 2006; 95: 68 - 73

The Risk for IVH Development

Umbilical Artery Catheter Blood Sampling Volume and Velocity: Impact on Cerebral Blood Volume and Oxygenation in Very Low Birth Weight Infants Roll et al.

This study demonstrates that blood sampling from an Umbilical Arterial Catheter (UAC) induces an inevitable decrease in Cerebral Blood Volume and Cerebral Oxygenation in preterm infants.

In contrast to our expectations, <u>reducing sampling velocity failed to prevent the reduction of oxygen supply to the preterm infant's brain associated with the blood withdrawal from a UAC.</u>

Sampling volume appears to be central in determining the magnitude of this decrease.

Roll, et.al
Acta Paediatrica, 2006; 95: 68 - 73

The Risk for IVH Development

Risk Factors for Periventricular – Intraventricular Hemorrhage in Premature Infants

Use of umbilical catheters and infusion and transfusion of blood products are all related to circulatory volume changes directly.

"These findings suggest that hemodynamic changes of systemic and cerebral circulation are important for the development of PV – IVH in preterm newborns."

Lee, et.al
Journal Korean Medical Science
2010; 25: 418 - 424

More Delicate Hemodynamic Balancing Has Come To Be More Essential …

"As the survival rate of extremely preterm infants has remarkably increased recently, " more delicate hemodynamic balancing has come to be more essential than any other perinatal factors that have been proposed in previous studies for the prevention of PV-IVH".

Lee et. al 2010, The Korean Academy of Medical Science

"The goal of maintaining hemodynamic balance in the neonate is paramount in reducing the risks for the development of IVH (Intraventricular Hemorrhage) and PVL (Periventricular Leukomalacia), which are the primary causative factors in the development of Mental Retardation and Cerebral Palsy in the premature infant."

Lee et. al 2010, The Korean Academy of Medical Science

Benefit For the IVH Bundle Hummi Micro Draw

- **Maintaining stable cerebral blood flow is paramount to avoiding damage to premature brain cells due to excessive volumes and pressures created during a blood sampling procedure with umbilical catheters**

- **The Hummi reduces blood and fluid volume movement by 70% during blood sampling from umbilical catheters and eliminates negative pressures during blood collection, thus reducing the risk of altering cerebral blood flow.**

The Hummi moves only 1.3mL in total fluid when doing a blood draw vs. 4-6mL with current methods.

Known de-oxygenation has been reported at 1.8mL of total fluid movement during a blood draw.

Benefit for IVH Bundle Hummi Micro Draw

- Lee summarizes by stating that **upsetting the delicate balance of the blood flow to the premature infants brain is a major factor in the development of IVH / PVL.**

- **Keeping this balance of blood flow, pressure changes and oxygen imbalance during blood sampling procedures is one of the most important perinatal factors for the prevention of IVH/PVL in premature infants.**

- **the Hummi provides the opportunity to reduce these risk factors as demonstrated by Roll, Perlman, Bray & Lee**

Hummi Closed Needleless Micro-Draw Blood Transfer Device and Micro T System

The Hummi Micro-Draw and Micro T T-Connector System

A simple, closed, yet effective solution to reducing the risk factors for the development of IVH / PVL and Infection in the premature infant when using umbilical catheters.

Why not use the product (for your IVH bundle) that provides for reduced infection risk and the lowest possible blood / fluid movement in and out of the low birth weight baby, when it has been demonstrated that current methods definitely pose a higher risk in use for UAC blood sampling?

Hummi Needleless Micro-Draw Blood Transfer Device

Hummi Micro-Draw Blood Transfer Device

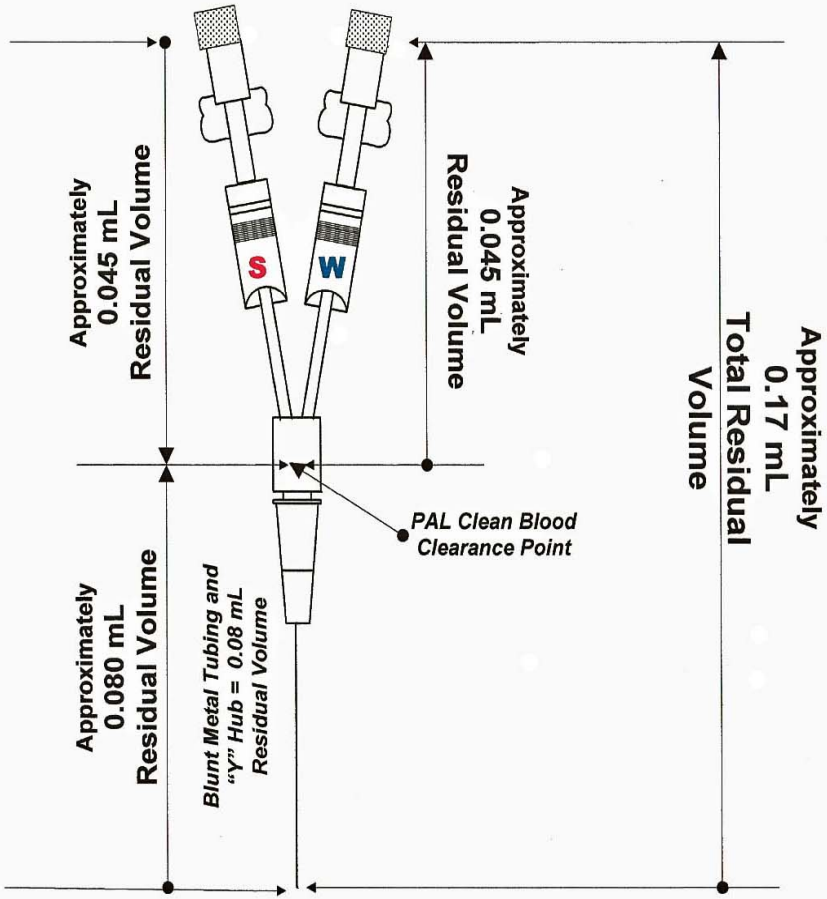
S Sample Microbore Tubing Volume – 0.045 mL

W Waste Microbore Tubing Volume – 0.045 mL

Blunt Tubing & "Y" Hub Volume – 0.080 mL

Approximately
0.17 mL
Total Residual
Volume

Approximate Residual Fluid Volumes



Hummi Needleless Micro-Draw Blood Transfer Device

Questions ?