We listened to infusion nurses

Short staffing		reduced set-up time
Shift handoffs		easy labeling system
Reduced complexity		multi-fluid management without electronic devices
Optimizing KVO		AutoStart™ flushes automatically US Pat. 9,352,080
Flow selector Pat. pending		ready flush of syringe/mini IV bag eliminates dead volume loss
Hazardous protection		fully closed system protects you and your patient

SAFER
INFUSION SYSTEMS

Redefining Gravity-Fed IV Infusions

Delivering safety, simplicity, and labor savings
while assuring vein patency

Safer Infusion System's enhanced **AutoStart**™ burette functionality delivering IV infusion excellence for every infusion environment

Our mission: Providing IV infusion systems that optimize caregiver ability to deliver all "10 rights" of medication administration

1) Right Patient
2) Right Medication
3) Right Dose
4) Right Route
5) Right Time & Frequency
6) Right Education
7) Right Reason
8) Right to Refuse
9) Right Response
10) Right Documentation

Initially brought to market as the "AutoStart Burette" in Australia, nursing feedback triggered an extensive redesign receiving additional patent approval delivering enhanced functionality, simplicity, and safety in a low-cost consumable.

Dr. Michael Monsour, who received the Order of Australia medal, is Chairman of Analytica and now Safer Infusion Systems, Inc. In keeping with his exemplary medical services, he was the driving force behind this IV infusion technology solving two problems long associated with traditional burettes.

"First, the drip does not have to be turned off when injecting medicine as with traditional burettes. This eliminates the possibility of the drip not being re-established after the drug dose. Additionally, the caregiver does not need to return to the bedside to determine if all of the medicine has been delivered to re-establish the drip. AutoStart's shuttle valve "restarts" the drip once the medicine has passed through the burette. This saves time for busy caregivers," advises Dr. Monsour.

"Second, the shuttle valve float action prevents air from leaving the burette eliminating any air embolism event. After flushing the medicine dose and exhaustion of a primary IV bag, the float's weight seals the exit nozzle. This tight seal retains a small fluid volume in the burette base."

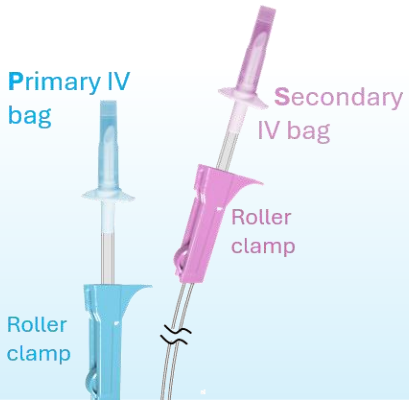
Relying on a gravity feed eliminates complexity, training, capital costs, and maintenance with infusion pumps making the **SIS** ideal for hospitals and infusion centers while paving a smoother, safer, and lower-cost path for hospital-to-home IV infusions. The many capabilities of the single SKU **Safer Infusion System** will shine for tight spaces and mobility demanded for military deployment and emergency transport vehicles.

US 9,352,080 B2

Time savings

Hang one large Primary IV bag (typ. 1,000ml) to prime SIS system + support AutoStart slow and steady catheter flow delivery

Color-coded Primary & Secondary IV bag spikes

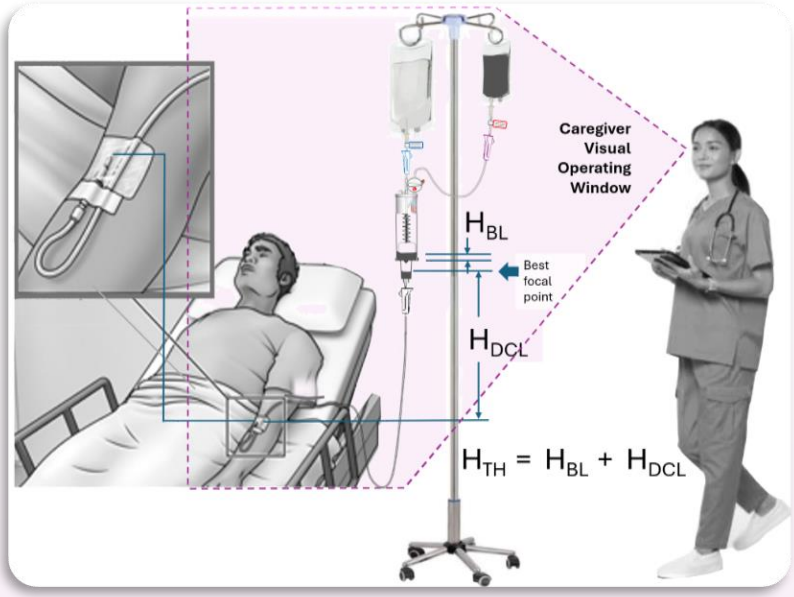


Safety enhancement

Consistency of gravity

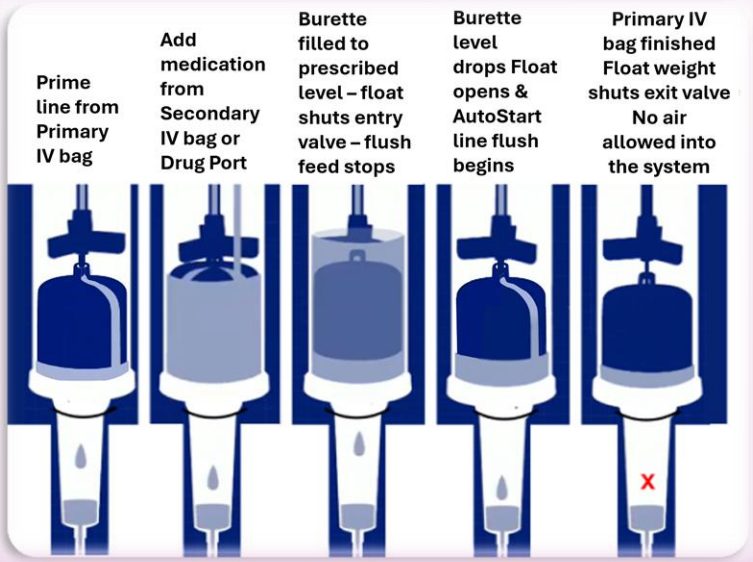
SIS designed for **18" to 24" of static head height** (H_{TH}) above the patient's IV site with a standard IV pole

$$H_{TH} = H_{BL} + H_{DCL}$$



Simpler IV rate control

Focus on drip rate control by roller clamp below the drip chamber - positioned in the middle of the Caregiver Visual Operating Window



AutoStart flows down the central tube in the burette automatically controlled by float shuttle valve

Maintain vein patency with uninterrupted IV flow with minimal caregiver intervention

Protection against CRBSI and occlusion from fibrin build-up

Ready for multiple IV bags

Ready Drug Port syringe flushing

Ready to provide
Micro or
Macro
Drip
protocol

Gentle flow gravity drip best maintains vein patency

No pump-related **micro-pistoning** of catheter in the vein

Primary IV bag

Secondary IV bag

Roller clamp

Roller clamp

Flow Selector Knob

Drug Port

Vent

150 ml Chamber

Primary IV bag label

Secondary IV Bag label

Drug label

AutoStart Float Valve

Push to select Macro Drip Nozzle

Push to select Micro Drip Nozzle

Drip Chamber

Roller clamp

Fill burette from Primary / Pull flush into syringe

Flow Secondary to burette

Push drug or flush up to Secondary

Push drug to burette Push syringe flush to burette

Fill / Flush
SB to Chamber
DP ⟷ SB
DP to Chamber

All functionality in a smaller height format to ensure 18” to 24” of fluid static head above the patient’s IV site

Male Cap

Female cap

F-F Adapter

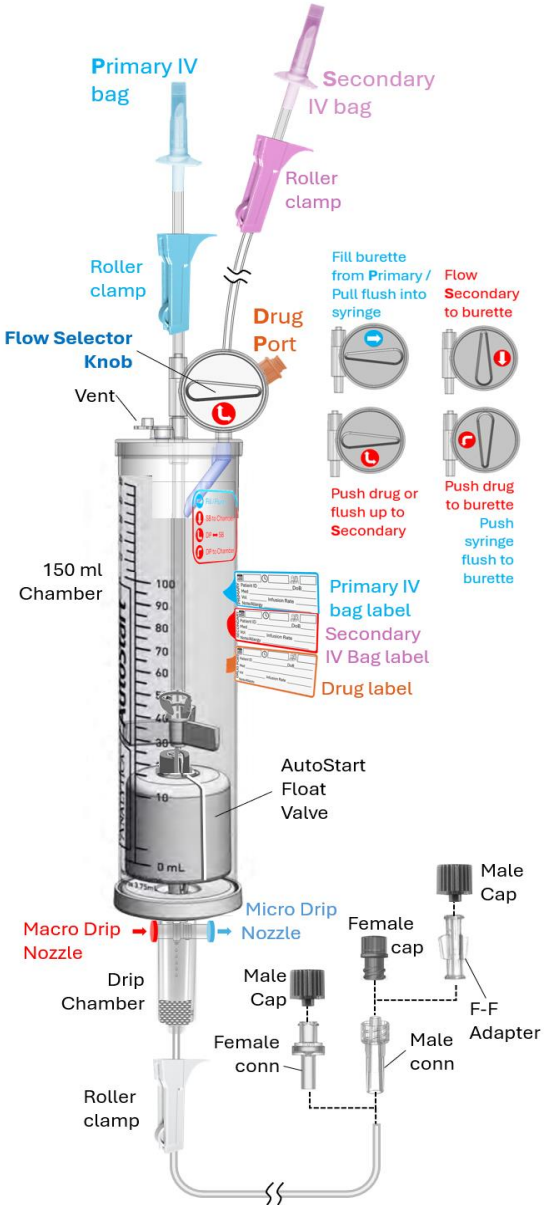
Male Cap

Female conn

Male conn

Included sterile labels

and indelible pen



Set Up of Primary IV Bag

Connect an IV Bag. Fluid will flow into and fill the chamber and stop at approximately 10 milliliters

The White Roller Clamp / Valve below the drip chamber controls the drip rate for infusion flow to the patient's catheter

Medication Delivery

Secondary IV Bag – Dosing of Undosed Bag

Turn Flow Selection Knob to the North

Open Pink Roller Clamp – to prime fluid down to the Chamber & turn Flow Selector Knob to the East

Attach injector for medicinal load to Needleless Drug Port Connector & push full dose up to **Secondary IV Bag - Closed system safely handles hazardous fluids**.

Turn Flow Selection Knob to the West and & pull full flush into the injector syringe

Turn Flow Selection Knob to the East & push flush up to **Secondary IV Bag** & **close Pink Roller Clamp**

Turn Flow Selection Knob to the North & open Pink Roller Clamp allowing IV Bag flush to drain into the chamber. Note: By controlling this flow rate, there can be a minimal wetting of the burette Chamber

Upon exhaustion of **Secondary IV Bag** fluid in the chamber, **AutoStart** mode commences to flush the line supporting vein patency

Secondary IV Bag - Dosed

Turn Flow Selection Knob to the North

Open Pink Roller Clamp – Dispense contents of dosed **Secondary IV Bag** into Chamber

Medication flow rate is managed by the White Roller Clamp establish-ing the prescribed drip rate in the **Drip Chamber**

Upon exhaustion of the **Secondary IV Bag** fluid in the chamber, **AutoStart** mode commences to steadily flush the IV line supporting vein patency at the catheter site

Drug Port Dose to Filled Chamber

Turn Flow Selector Knob to the South & add medication via injection through Needless Drug Port Connector

Turn Flow Selector Knob to the West and pull flush into injector syringe

Push syringe flush into the chamber. Check valve prevents flow into the Primary line. In the West position, Primary fluid may be allowed to fill the chamber to a prescribed level for dilution of the injected medication, or the Flow Selector Knob can be turned back to the South. **Note: The syringe may remain attached if hazardous material is in use for no exposure.**

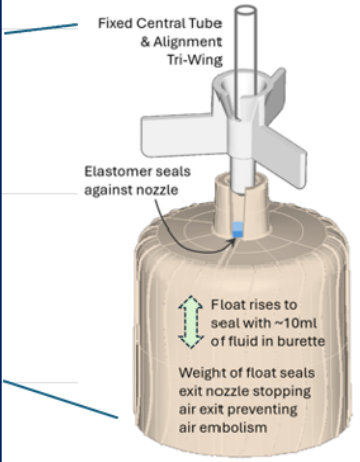
Medication flow rate to the patient is managed by the White Roller Clamp establishing the prescribed drip rate in the Drip Chamber.

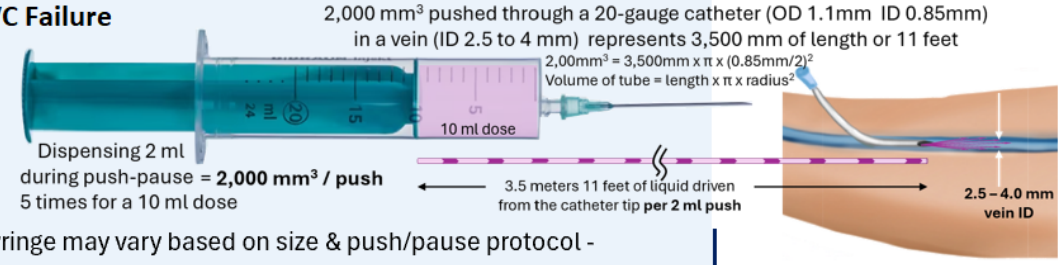
Flush of Dosed Secondary IV Bag

An injector syringe may be attached to the Needless Drug Port Connector. Turn the Flow Control Knob to the West and pull a flush into the injector

Turn Flow Control Knob to the East & push flush up to the **Secondary IV Bag,** then turn Knob to the North sending **Secondary IV Bag** flush to the chamber

Safety Concern	Risk	Design Feature
Air Embolism	**Increased mortality**	Weight of float shuttle valve ensures complete sealing of liquid to prevent air passage - operating to an extreme angle of 60° suitable for use in transport vehicles
Closed System	**Infection / Contamination**	Ready spike connections for Primary IV bag (typically 1,000 ml), Secondary IV bag, & a Drug Port for delivery of meds to the burette or to dose/flush the Secondary IV bag
Syringe Flush	**Cross Contamination**	Eliminates any need for a separate flushing syringe. Always ready flush pull from the AutoStart feed line
Secondary IV Bag Flush	**Full Dose Delivery**	A 50 ml Seondary Bag infusion may retain 7 ml of drug volume or 14% loss of the prescribed dose without adequate flush - SIS supports flushing Secondary IV bag
Catheter Flush	**PIVC Failure**	SIS AutoStart function automatically restarts IV flow after medication optimizing continuous flow conditions at the catheter preventing internal luminal occlusion
Medication Dilution	**Interrupted Therapy**	Burette filled to dilution specification from Primary IV bag, followed by precision dose at Drug Port or from a Secondary IV bag . After full dose delivery to burette, AutoStart initiates to accomplish full flush.
Protocol Adherence	**Infection / Drug priority**	Observational studies demonstrate a high incidence of non-conformance: 1) closed system to counter lack of hand washing 2) AutoStart ensures flushing protocol 3) **Incorrect positioning of Secondary IV bag eliminated**
Flushing Pressure Best to flush through the burette for a steady drip rate	**PIVC Failure**	2,000 mm^3 pushed through a 20-gauge catheter (OD 1.1mm ID 0.85mm) in a vein (ID 2.5 to 4 mm) represents 3,500 mm of length or 11 feet Dispensing 2 ml during push-pause = **2,000 mm^3 / push** 5 times for a 10 ml dose 10 ml dose 2,00mm^3 = 3,500mm x π x (0.85mm/2)^2 Volume of tube = length x π x radius^2 3.5 meters 11 feet of liquid driven from the catheter tip **per 2 ml push** 2.5 – 4.0 mm vein ID Bolus flush to catheter by syringe may vary based on size & push/pause protocol - AutoStart and gravity feed ensure low and constant flushing pressure
Cybersecurity	**Any electronic device**	Relying on gravity-feed only, **SIS eliminates all concerns and costs associated with electronic pumps**
Documentation	**Shift Change Handoff**	Included sterile labels and marker ensure timely medication documentation; Establishes process ownership





35% to 50% of PIVCs fail, according to 2021 *Infusion Therapy Standards of Practice,* before their intended use is complete due to complications like phlebitis, infiltration, occlusion, or infection. Comparing infusion nurse-inserted catheters to generalist nurse insertions found lower rates of leakage, phlebitis, and infiltration (statistically significant), but still noted complications in 20-30% of cases even with skilled hands, (A 2005 study in the Journal of Infusion Nursing (Palefski & Stoddard))

How we are helping to improve outcomes :

Simplify IV fluid setups with a single, universal system that

1) Facilitates the correct static head for optimum gravity feed

2) Eliminates the potential for air embolism in the IV line

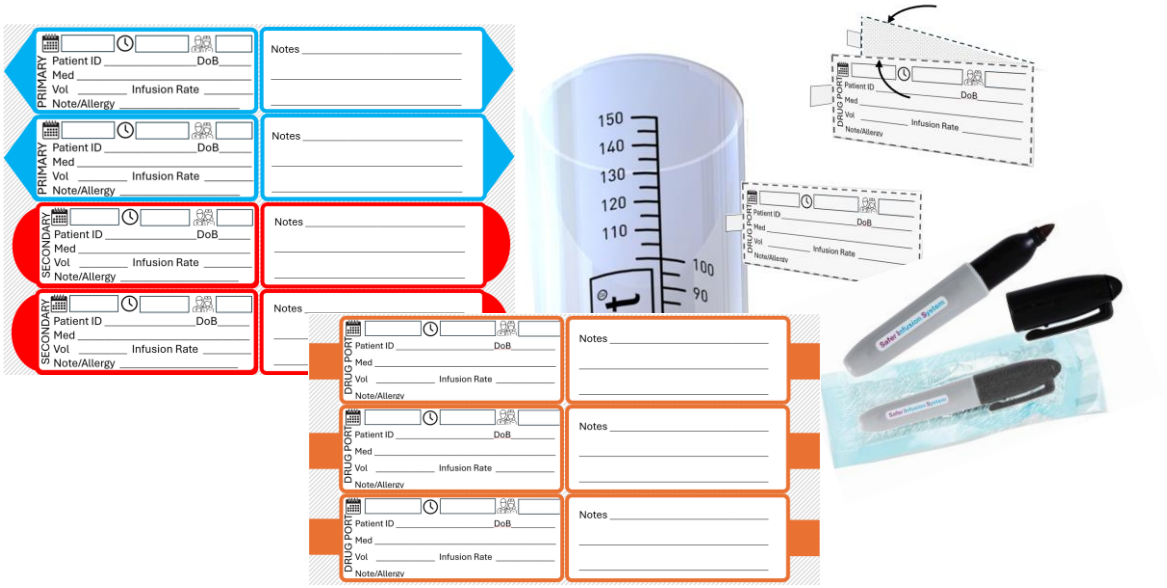
3) Adapted for multiple inputs all delivered with gentle drip flow

4) Positions the drip chamber at eye level for caregiver awareness

5) Re-establishes saline flow after any medicinal input without caregiver intervention for steady catheter flow to optimize vein patency

6) Enables a ready minibag or syringe flush for complete drug delivery

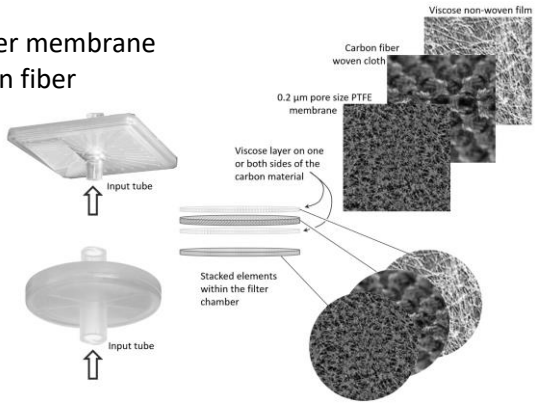
7) Emphasis on sterile labeling of each fluid event for quality of care



Safer Infusion Systems solves your toughest infusion challenges – handling hazardous antineoplastic compounds. **SIS Oncology™'s** comprehensive materials approach takes caustic and light-sensitive fluids in stride, protecting the caregiver and patient while optimizing infusion success through gentle, gravity fluid delivery replacing electronic pumping to enhance vein patency. Note: When extreme precision is necessary, the SIS is entirely compatible with electronic pump devices.

Pigmentation of molded & extruded materials blocks UV & visible light

0.2-micron PTFE filter membrane stacked with carbon fiber membrane for vapor management



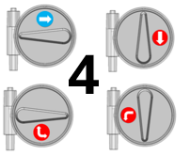
The Gravity Grand Slam

1 Hang single closed system SIS burette

Large saline feed **+** **2** AutoStart steady flush

3 Sterile input options

Flow Control Options **4**



for IV infusion success:

Infection prevention

Promotion of vein preservation

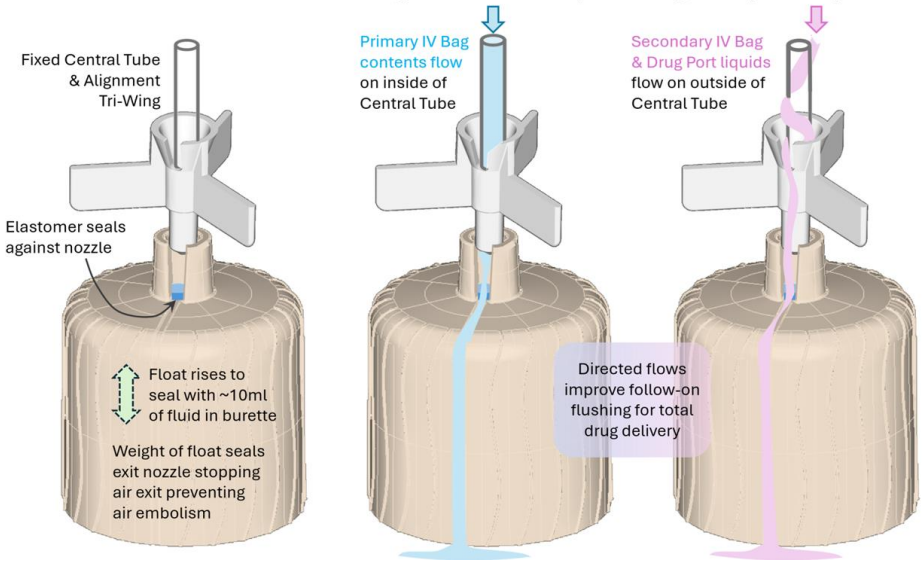
Guarantee of proper static head gravity feed

Air embolism prevention with float valve

Ask for our white paper: *"Revitalizing Gravity-Fed IVs to Improve Vein Patency and Eliminate Caregiver Errors Through Standardization"*

Contact for distribution / licensing
(805) 377-1690
tcampbell@saferinfusion.com

Heart of AutoStart : Buoyant volume & float weight activate this shuttle valve for automatic gentle IV flow optimizing vein patency



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