Directions for Use

Single patient use, do not resterilize. Sterile, non-pyrogenic fluid path in unopened undamaged package.

INDICATIONS FOR USE:
For use with vascular access devices, IV administration and extension sets for the direct injection, continuous or intermittent infusion, aspiration and needlefree delivery of drugs and solutions during IV therapy.

DIRECTIONS:

1. Using aseptic technique, open package and tighten connections where applicable.
2. For standalone Spiros, attach to male luer of administration set or syringe. Twist devices together until a click is heard and the Spiros begins to rotate freely.
3. To prime and use various components, refer to chart below.
4. Once primed, attach to patient’s catheter:
   - rotating luers, ensure the luer is fully engaged prior to locking down the collar;
   - locking blunt cannula connectors, connect to compatible pre-slit/pre-pierced injection port;
   - graduated adapters, push and twist until connector is secure.

NOTES:

- Pressure infusion tubing sets or removable extension sets made with pressure infusion tubing are noted in the name/description of the product. Pressure infusion tubing is rated to 400 psig. Pressure infusion tubing or extension sets should be connected to pressure infusion compatible IV sets only. For sets equipped with Clave/MicroClave Y site: prior to pressurizing, activate the slide clamp and give the pressure infusion through the Clave/MicroClave Y site.
- Disinfect all needlefree ports using an aggressive circular motion for three (3) seconds.
- Do not leave open ports/hubs exposed. Replace sterile end caps as necessary.
- Reduction in bacterial contamination for antimicrobial connectors has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate this have not been performed. Silicone plug contains CAS #7440-22-2 (silver-magnesium-sodium-boron-phosphateglass); polycarbonate cannula contains CAS #265467-11-8 (silver-hydrogen-zirconium-phosphate).
- Reuse negatively impacts performance / sterility potentially resulting in product failure / contamination.
- Slight discoloration of tubing is a normal result of sterilization and does not affect the safety or sterility of the set.
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- This device should be changed in accordance with current, recognized guidelines of IV therapy.
- When using a set with a MicroClave in the middle of the assembly for high pressure procedures assure that the high pressure infusion is conducted through the MicroClave in the middle of the assembly and the upstream clamp is engaged to isolate other upstream components from high pressures.
### COMPONENT: Spinnor Closed Male Luer
- **To Prime**: Attach priming cap to Spinnor and verify flow.
- **To Use**: Spinnor is normally closed until it is fully engaged with a female luer or needlefree connector.
- **To STOP**: Attach to mating device by pushing and twisting until secure.

### CAUTIONS
- Do not use luer style end cap on Spinnor as this will activate the connector and allow flow.

### COMPONENT: Claye MicroClave
- **Prime the connector and set by attaching priming device to connector and inverting to repeat air.
- **Repeat for multiple extensions as necessary.
- **Disrupted connector and allow to dry.
- **For sets/devices containing a rotating collar, ensure the connector is fully engaged prior to tightening the collar.

### Claye MicroClave
- **Flux MicroClave or NanoClave with normal saline or in accordance with facility protocol.
- **Silicone septum may become displaced or damaged if significant backpressures are applied.
- **It is not recommended that connectors be changed after use with blood products.

### COMPONENT: Sirona® Flow Regulator
- **To Infuse**: Attach administration device to sideport and infuse. Sipdrop requires pressure to activate.
- **To Aspirate**: Attach syringe, depress and hold button while drawing back on syringe plunger. When aspiration is complete, release button and valve automatically returns to closed position.
- **Recap port with sterile cap after use.

### CAUTIONS
- Do not leave side ports exposed, replace sterile end caps as necessary.

### COMPONENT: Stoplocks
- **Use directional turn handle to set-up desired action.
- **To Infuse**: Use of a 15 micron filter on administration set is suggested in order to prevent crystals from blocking the Easydrop.
- **To Aspirate**: It is not recommended that connectors be changed after use with blood products.
- **Attach priming cap to Spiros and verify flow.
- **To STOP**: Spinnor is normally closed until it is fully engaged with a female luer or needleless connector.
- **Attach to mating device by pushing and twisting until secure.

### IN-LINE FILTERS
- **Use directional turn handle to set-up desired action.
- **Remove end cap to infuse or aspirate.
- **When complete turn chromatograph OFF and replace end cap.
- **To Infuse**: Use of a 1.2 micron filter. Sets with these filters should be changed at least every 24-hours.
- **To Aspirate**: Use of a 0.22 micron filter. Sets with these filters should be changed at least every 24-hours.
- **Prime filter that clings during infusion should be replaced. Attempting to clear the filter with pressure may lead to breakage.

### EASYDROP® Flow Regulator
- **Flux MicroClave or NanoClave with normal saline or in accordance with facility protocol.
- **Silicone septum may become displaced or damaged if significant backpressures are applied.
- **It is not recommended that connectors be changed after use with blood products.
- **Attach priming cap to Spiros and verify flow.

### COMPONENT: NanoClave Stopcock
- **Use directional turn handle to set-up desired action.
- **Remove end cap to infuse or aspirate.
- **Complete turn chromatograph OFF and replace end cap.
- **Use directional turn handle to set-up desired action.

### CAUTIONS
- Do not use luer style end cap on Spinnor as this will activate the connector and allow flow.
- Do not use needles, blunt cannulas or luer caps on connectors.
- Connectors are compatible with ISO male luer having an internal diameter between 0.062" and 0.110". Connectors straight on (without angled or sliding entry).

### COMPONENT: Easydrop® Flow Regulator
- **To STOP**: Flow rate. High viscosity solutions can cause lower flow rates than indicated on the scale; increase head height to compensate.
- **To change the flow rate adjust the height of the solution container.
- **To stop flow, close clamp and turn Easydrop to OFF position.
- **Attach priming cap to Spiros and verify flow.
- **To STOP**: Use of a 15 micron filter on administration set is suggested in order to prevent crystals from blocking the Easydrop.
- **Adjust Easydrop to the desired rate.
- **To Infuse**: Use of a 0.22 micron filter. Sets with these filters should be changed at least every 24-hours.
- **To Aspirate**: Use of a 0.22 micron filter. Sets with these filters should be changed at least every 24-hours.
- **Prime filter that clings during infusion should be replaced. Attempting to clear the filter with pressure may lead to breakage.

### IN-LINE FILTERS
- **Orient filter such that inlet is vertically above the outlet.
- **Filter will automatically prime in the vertical position.
- **PN solutions (2-in-1) without filters can be administered using a 0.22 micron filter. Sets with these filters should be changed at least every 24-hours.
- **Do not use Easydrop in OPEN position, this will cause an uncontrollable delivery (>1.0 mL/hr).
- **PN solutions (2-in-1) without lipids can be administered using a 0.22 micron filter. Sets with these filters should be changed at least every 24-hours.
- **Prime the connector and set by attaching priming device to connector and inverting to repeat air.

### CAUTIONS
- Do not use luer style end cap on Spinnor as this will activate the connector and allow flow.
- Do not leave side ports exposed, replace sterile end caps as necessary.
- Do not use needles, blunt cannulas or luer caps on connectors.
- Connectors are compatible with ISO male luer having an internal diameter between 0.062" and 0.110". Connectors straight on (without angled or sliding entry).
- MicroClave/NanoClave contains polycarbonate

### COMPONENT: Spinnor Closed Male Luer
- **Attach priming cap to Spinnor and verify flow.
- **Once priming of the set and components is complete, remove cap.
- **Spinnor is normally closed until it is fully engaged with a female luer or needleless connector.
- **Attach to mating device by pushing and twisting until secure.

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