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IV Extension Sets
Clave®/MicroClave®/NanoClave® Connectors
Antimicrobial Clave®/MicroClave® Connectors
Spiros® Closed Male Luer

DF-5001 Rev 18 (06/17)

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. Spiros is now permanently attached to luer.
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-sodium-hydrogen-zirconlum-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.

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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;
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- 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	TO PRIME	TO USE	CAUTIONS
Spiros Closed Male Luer	• Attach priming cap to Spiros and verify flow. • Once priming of the set and components is complete, remove cap.	• Spiros is normally closed until it is fully engaged with a female luer or needlefree connector. • Attach to mating device by pushing and twisting until secure.	• Do not use luer style end cap on Spiros as this will activate the connector and allow flow.
Clave MicroClave NanoClave Antimicrobial Clave Antimicrobial MicroClave	• Prime the connector and set by attaching priming device to connector and inverting to expel air. • Repeat for multiple extensions as necessary.	• Disinfect connector and allow to dry. • Attach syringe or infusion set by pushing straight into the connector and twisting until a friction fit is achieved. Do not overtighten as this could damage the silicone.. • For sets/devices containing a rotating collar, ensure the luer connector is fully engaged prior to tightening the collar. • Flush Clave in accordance with facility protocol. • Flush MicroClave/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; devices should be flushed after use with blood in accordance with facility protocol.	• Do not use needles, blunt cannulas or luer caps on connectors. • Connectors are compatible with ISO male luers having an internal diameter between 0.062” and 0.110”. Access connectors straight on. (without angled or sliding entry). • MicroClave/NanoClave contains polycarbonate
1o2® Valves	• Loosen cap on side port, depress button briefly and observe flow out of port. • Tighten side cap, or remove and attach primed administration device.	• **To Infuse**: Attach administration device to side port and infuse. Sideport 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.	• Do not leave side ports exposed, replace sterile end caps as necessary.
Stopcocks Clave Stopcock NanoClave Stopcock	• Use directional turn handle to set-up desired action. • Loosen cap to allow flow. • For stopcocks w/ valves or needlefree connectors on sideports, infuse to prime.	• Use directional turn handle to set-up desired action. • Remove end cap to infuse or aspirate. • When complete turn handle OFF to sideport and replace end cap.	• Do not leave side ports exposed, replace sterile end cap as necessary.
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 lipids can be administered using a 0.22 micron filter. Sets with these filters should be changed at least every 72-hours. • IVFE or TNA (3-in-1) solutions containing lipids must be administered using a 1.2 micron filter. Sets with these filters should be changed at least every 24-hours. • Performance may be impacted by, use of alcohol; nature of fluid used, concentration and duration of use.	• A filter that clogs during infusion should be replaced. Attempting to clear the filter with pressure may lead to breakage.
Easydrop® Flow Regulator Easydrop double scale flow regulator has one scale for liquids having density lower than 10% (light solutions) and a second scale for liquids having higher density (40% scale).	• Easydrop is provided in the **OPEN** position, verify fluid is passing through. • Turn Easydrop to **OFF** position and verify fluid has stopped. • If fluid is dripping when in **OFF** position, replace unit.	• 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. • Dial numbers are approximate. Drop counting is necessary to confirm proper 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 height of the solution container. Raise the container to increase flow rate, lower the container to decrease flow rate. • To stop flow, close clamp and turn Easydrop to **OFF** position.	• Do not use Easydrop in **OPEN** position, this will cause an uncontrolled delivery (≈3 liters/hr). • Blood, emulsions, or medications not totally soluble in the carrier solution can not be administered through the Easydrop regulator. • Drop counting is necessary to confirm flow rate. If necessary, adjust the height of the IV solution container to increase or decrease flow rate. • To assure **OFF**, turn Easydrop to **OFF** position and close clamp. • Administer bolus injection below controller only.

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