

Indications for Use

510(k) Number (if known)
K220677

Device Name
Kurin Blood Culture Collection Set with Kurin Lock Technology

Indications for Use (Describe)

The Kurin Blood Culture Collection Set is intended to obtain blood samples through the patient's vasculature via venipuncture or Peripheral IV (PIV) access. As it enters the Kurin Lock, blood initially fills a side channel then flows into the sample collection device (syringe or bottle) via an adjoining sampling channel to reduce blood culture contamination rates*.

When supplied with a pressure-rated extension set, the pressure-rated extension set is intended to be utilized separately with infusions systems to administer IV fluids, medications, blood and blood products into the patient's vascular system and may be safely used with power injectors at pressures up to 325 psi.

*The Kurin Blood Collection System is for use as a blood collection system and its Kurin Lock allows the specimen of blood from the patient to be sidelined prior to the collection of the test sample to reduce the frequency of blood culture contamination when contaminants are present in the initial blood sample compared to blood cultures drawn using standard practice without the Kurin Lock.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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