VELETRI® (epoprostenol)
Discontinuation of CADD-Legacy Pumps and Issues Notice for CADD Infusion System Infusion Sets

SUMMARY

DISCONTINUATION OF CADD-LEGACY PUMPS

- ICU Medical is discontinuing the sale of CADD™-Legacy PCA (model 6300), CADD™-Legacy 1 (model 6400), and CADD™-Legacy Plus (model 6500) ambulatory infusion pumps and CADD Sentry Medication Delivery Manager Software effective December 31, 2022.[1]
    - Service and repair for these products will be available through December 31, 2027 depending on component availability.

CADD-SOLIS VIP PUMPS

- ICU Medical has developed the CADD®-Solis VIP pumps to meet the needs of customers and the healthcare industry. Patients have transitioned from the CADD™-Legacy to the CADD®-Solis pumps for more than ten years.[1]
    - The CADD-Legacy pump could achieve rates up to 125 mL/hr. The CADD-Solis VIP pump can achieve rates up to 250 mL/hr with standard flow sets and rates up to 500 mL/hr with high flow sets. The rates also depend upon the therapy mode set on the VIP.[2]
    - The CADD-Legacy pump was programmed in mL/24 hr and the CADD-Solis VIP pump rate is programmed in mL/h.[2]
    - The CADD-Solis platform includes additional options including protocol libraries, wireless connectivity, and five delivery modes. Further information is available on the ICU Medical website.[1]
- Questions regarding the CADD®-Solis VIP pump, including requests for device training, should be emailed to ClinicalTeam.HomeInfusion@icumed.com.[2]
    - Inquiries and requests sent to this inbox will be addressed within 24 hours. If a brochure or instruction can address the question, it will be provided.
    - If additional information is needed, Smiths Medical will contact the healthcare provider to address questions with one of their live support staff.

VELETRI INFUSION PUMP

- The ambulatory infusion pump used to administer VELETRI should: 1) be small and lightweight, 2) be able to adjust infusion rates in 2-ng/kg/min increments, 3) have occlusion, end-of-infusion, and low-batter alarms, 4) be accurate to ±6% of the programmed rate, and 5) be positive pressure-driven (continuous or pulsatile) with intervals between pulses not exceeding 3 minutes at infusion rates used to deliver VELETRI. The reservoir should be made of polyvinyl chloride, polypropylene, or glass.[3]

ISSUES NOTICE FOR CADD INFUSION SYSTEM INFUSION SETS

- In December 2022, Smiths Medical issued a letter notifying of two potential issues with CADD™ Infusion System Infusion Sets. Then, on February 2, 2023, the FDA identified this as a Class I recall; the recall communication is available on the FDA website.[4] In June 2023, Smiths Medical issued an updated notice to the December 2022 letter, stating that additional lots may potentially be impacted by the 2 issues described below.[5]
    - Issue 1: Lack of delivery or underdelivery related to tubing occlusion, despite the pump displaying that the infusion is running properly.
    - Issue 2: False "No Disposable Attached (NDA)" alarms.

- For certain patient situations, use of alternative CADD infusion sets may be recommended. Customers may also contact Smiths Medical customer service (1-800-258-5361).

REFERENCES

1. ICU Medical. Discontinuation notice for CADD-Legacy PCA, CADD-Legacy 1 and CADD-Legacy Plus models. June 1, 2022.

2. Data on File. CADD-Solis VIP Pump Inquiries. US-SRSM-4558; 2023.

3. Data on File. Veletri. CCDS. Janssen Research & Development, LLC. EDMS-ERI-205912254; 2022.

4. Smiths Medical. Medical Device Correction for CADD Infusion System Infusion Sets for use with CADD Pumps. December 9, 2022.

5. Smiths Medical. Updated Urgent Medical Device Correction for CADD Infusion System Infusion Sets for use with CADD Pumps. June 13, 2023.