

Real-World Complications Associated with Diaphragm Pacing Systems: A 10-Year Analysis of the FDA MAUDE Database

BACKGROUND

Diaphragm Pacing Systems (DPS) provide an alternative to mechanical ventilation for patients with high cervical spinal cord injuries (SCI) and central sleep apnea (CSA). Despite their efficacy, long-term reliability and maintenance challenges persist. Characterizing real-world complications associated with these devices are essential for nursing staff managing these high-risk patients.



PURPOSE

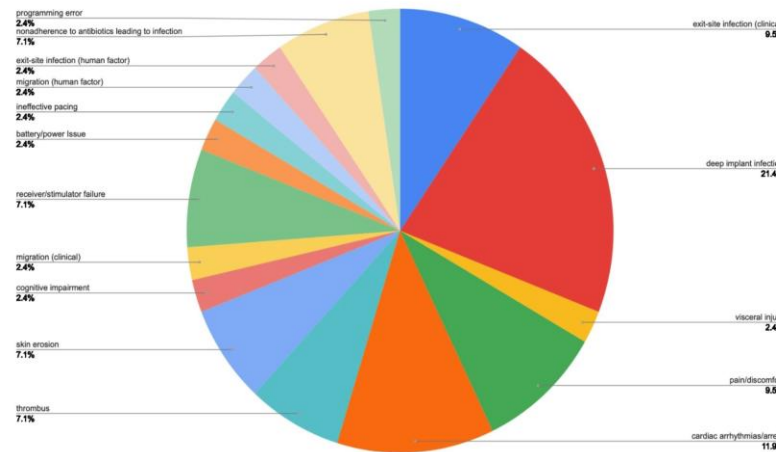
To characterize the frequency and type of adverse events associated with DPS reported to the FDA, focusing on complications relevant to bedside nursing and patient safety.

METHODS

A retrospective review of the FDA Manufacturer and User Facility Device Experience (MAUDE) database was conducted for the period January 2016 to January 2026. Queries included terms such as "NeuRx," "Avery Biomedical," and "Remedē System." Reports were categorized into three domains: (1) Mechanical/Device Failures, (2) Clinical Complications, and (3) Human Factors/Caregiver Issues.



Specific Adverse Events Associated with Diaphragm Pacing Devices



SUGGESTED CLINICAL CONSIDERATIONS

- Aseptic Exit-Site Management
 - Aseptic technique for dressing changes
 - Daily assessment for signs of infection
- Comprehensive Cardiac Surveillance
 - Continuous cardiac telemetry during the initial activation and subsequent titration of the pacing system
- Pharmacological Adherence and Patient Education
 - Emphasis on completion of full antibiotic course
- Emergency Preparedness
 - Back up Ambu bag and mechanical ventilator

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RESULTS

Out of 42 identified adverse events associated with DPS, clinical complications were most prominent. Deep implant infection was the most prevalent individual complication N=9 (21.4%), and infection overall accounted for N=17 (40.5%) of all reports. Mechanical failures were led by receiver/stimulator malfunctions N=3 (7.1%), while the primary human factor issue was patient non-adherence leading to infection N=3 (7.1%). Notably, cardiac arrhythmias or arrest represented the second leading clinical issue N=5 (11.9%).

CONCLUSIONS

While DPS offers significant autonomy, it's associated with distinct physiological and clinical risks. This analysis identifies critical vulnerabilities—specifically device-associated infections and cardiac abnormalities—that necessitate specialized nursing education and rigorous infection control protocols to mitigate risks and ensure the long-term success of the therapy.

REFERENCES

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