

Nocturnal Dialysis - FDA clears the Redsense Safety Device for 8 hours

The Redsense safety device is the only device cleared by FDA to monitor patients for potential blood loss from the hemodialysis needle puncture site. With an 8 hour FDA clinical clearance, Redsense is available to help protect patients undergoing treatment in clinics for longer than 5 hours - such as Nocturnal Dialysis.

Dialysis equipment today is required to have a system that protects patients from blood loss in the event of venous needle dislodgement. The commonly accepted solution is to monitor by the venous pressure alarm, but a better solution has long been required. Even with the routine supervision of medical staff, the venous needle can still become dislodged. When this happens, the dialysis machine will continue to draw blood from the patient's artery, but without returning blood in the loop circuit, meaning the patient's blood ends up elsewhere. If undetected, this blood loss can have serious consequences in only a few minutes. During Nocturnal treatments, the patient's attentiveness can alter, which may increase the risk of venous needle dislodgement as a result. The Redsense safety device provides a solution to this problem and helps detect venous needle dislodgement instantaneously; it only takes a few milliliters of blood on the fiber optic sensor to sound the alarm.

Redsense Medical CEO Patrik Byhmer comments: *"This is where Redsense really can make a difference. It's very satisfying being able to increase the level of safety for patients undergoing nocturnal hemodialysis, while reducing the potential risk exposure to the clinics. This FDA clearance is a huge step in the right direction for Redsense to become the recognized standard of care in VND patient safety, in line with existing regulations".*

More information:

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The product:

The Redsense device is intended to monitor for potential blood loss from the hemodialysis access site for patients undergoing hemodialysis treatment at home or in the clinical setting. The device includes a blood sensor incorporated into an adhesive dressing. The sensor monitors potential blood leakage from the needle puncture site via an infrared light and will alarm if needle dislodgement or blood leakage is detected.

The company:

Redsense Medical and the Redsense safety device are the results of close co-operation between medical staff and engineers. The company has offices in Sweden and in the U.S.