

Redsense – helps keep an eye on your venous needles

The Redsense alarm is the first clinically tested monitoring system for venous needle dislodgement during hemodialysis.

Redsense Medical – the Company

- Redsense Medical was started in 2006 after demands made by dialysis professionals for an alarm to more reliably detect venous needle dislodgement during hemodialysis.
- The company has offices in Sweden, the US and Malaysia.
- The Redsense alarm has global patent protection.

Redsense Medical – Background

In dialysis, blood in need of cleaning is drawn from the patient's artery vein and circulated in the dialysis machine. Clean blood is then returned to the body via the venous needle. If the venous needle becomes dislodged, the dialysis machine will continue to draw blood from the patient's artery vein but returns no clean blood to the body. It takes only a few minutes before the dislodgement can have serious, even fatal consequences.

Dialysis equipment must - according to standards - provide a system to protect the patient from extracorporeal blood loss due to dislodgement of the venous needle. Venous pressure monitoring is the acceptable method although it is not an optimal solution. The Redsense alarm is the first clinically tested monitoring system for venous needle dislodgement during hemodialysis.

Redsense is an alarm system for monitoring the venous needle during hemodialysis. The device is an alarm only and does not replace existing safety procedures.

Patients at Risk

Despite the majority of dialysis treatments being conducted under the supervision of medical staff, the venous needle can still become dislodged. In home hemodialysis, a reliable alarm becomes even more valuable¹.

Despite the majority of dialysis treatments being conducted under the supervision of medical staff, the venous needle can still become dislodged. A recent study² estimate 414

¹ In the US, Redsense is approved for use in clinical setting and awaits clearance for use in home hemodialysis. In Europe, it is approved for both clinical setting and home hemodialysis.

episodes of venous needle dislodgement annually in the US dialysis population of 350 000 patients. In this study, the mortality estimate range between 10 and 33% which means that the number of fatal incidents in the US may be between 40 and 136.

Low fistula pressure, which is very common, has been proved to increase the risk³. Traditionally, patients considered as high-risk patients for needle dislodgement have typically been those with a medical condition or behavior which causes restlessness.

Some sources estimate an increased risk during the last two hours of dialysis, when some patients become more restless. No, or poor, visibility of access due to the patient occupying single room or receiving nocturnal dialysis in wards with lights out are other factors that may affect the risk.

Easy to use optical fiber technology

The device has two parts: a sensor patch and an alarm unit. Connected to the alarm unit by a small wire, the single use sensor patch employs fiber optic technology to continuously monitor the venous needle access point. If bleeding begins, the device is designed to sound an alarm.

Market & Sales

- There are 1.7 million dialysis patients worldwide who are given about 200 million hemodialysis treatments every year. The market is increasing due to an ageing population and the rise of diseases such as type II diabetes.
- The Redsense alarm is CE marked and quality approved according to European Standards and has FDA clearance for sales and marketing in the US.
- Production and sales commenced in December, 2007.

Redsense Medical - Contacts

- CEO Patrik Byhmer, Questions on: Company, Investor Relations
Mobile: + 46 703 57 21 64, patrik.byhmer@redsensemical.com
- Sales and Marketing Director Susanne Olason. Questions on markets and sales.
Mobile: + 46 732 30 97 08, susanne.olason@redsensemical.com

² Catastrophic hemorrhage from venous needle dislodgement during hemodialysis: continued risk of avoidable death and progress toward a solution", poster by Stephen Sandroni, MD, Terry Sherockman, RN, MS, and Kathy Hays-Leight RN, Allegheny General Hospital, Pittsburgh. Presented at ASN/Renal Week, Philadelphia, US, November 2008

³ Polaschegg H-D. Venous needle dislodgement: A safety issue. Possible methods for detection and prevention of major blood loss. EDTNA/ERCA Conference, Prague, September 2008.