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Medigard 3mL Safety Retractable Syringe - Clinical Trials Results

Further to our announcement of 7 July, 2009, Medigard is delighted to confirm the successful completion of the simulated clinical trial of the Medigard 3mL Safety Retractable Syringe undertaken by the independent organization in the USA. The trials were undertaken by seventeen experienced healthcare workers at four different medical centres on the east coast of America. The trials were performed on a sample block of 500 syringes. Medigard is pleased to announce that the clinical trial resulted in a 100% success rate with its product.

The Report stated that "it is clear that the Medigard Safety Syringe, performed well, was easy to use, had no failure or variations in activation and only minor training was needed to use the device".

The conclusion was

- "The Medigard Safety Syringe was considered by all evaluators to be activated easily and reliably with varying hand sizes,
- The Medigard Safety Syringe did not require more time to use than a non-safety syringe and did not interfere with normal use, and
- The Medigard Safety Syringe retracted and covered the exposed sharp after use."

The report of these trials will form part of Medigard's 510(k) submission to the US Food and Drugs Administration (FDA). Regulatory approval from the FDA will allow the Medigard syringe to be marketed in the USA.

Peter Emery
Chief Executive Officer

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