



Surety® products to be available in response to NPSA alert - NPSA/2009/PSA004A

InterVene has designed and manufactured a range of non-Luer syringes and accessories for spinal and epidural use in response to NPSA alert NPSA/2009/PSA004A. Having been developed under the project development name of *Spinalok®* (Spinal-OK), this range of syringes and other NPSA-compliant devices for spinal, epidural and regional use has been launched under the brand name *Surety®*, which reflects the safer, non-Luer design of the connector.

The new *Surety®* syringe has been designed to prevent connection with existing IV Luer ports, thereby reducing the chance of fatal misconnection errors occurring in neuraxial procedures. The system has undergone extensive bench testing and was recently submitted for evaluation at the Bath Institute of Medical Engineering where the system was tested for clinical acceptability and user satisfaction. The syringes are CE-marked and are now available via NHS Supply Chain and direct from InterVene.

The company has made available its *Surety®* design to a number of needle manufacturers, who are in the process of modifying their existing spinal and epidural needles to accommodate the *Surety®* syringe. This affords clinicians the opportunity to continue to use a wide range of needles from a variety of needle manufacturers, rather than being forced to use one particular design of needle.

The needle manufacturers, who are listed below, will be introducing needles and spinal / epidural packs during the months leading up to the implementation of the NPSA alert in March 2012.

The *Surety®* system has been designed to retain some of the characteristics of the Luer connector, which has been in use since the 19th century and is universally accepted, indeed the mating surfaces between the needle and syringe are almost the same albeit in reverse orientation. The intention was that a degree of familiarity be retained in order to minimise potential training implications associated with the introduction of a new connector. All *Surety®* products have a distinctive yellow colour and are clearly labelled to indicate "Spinal / Epidural / Regional use only".

In October 2010, the *Surety®* system was presented to the International Standards Committee in Seattle with the intention that a version of the *Surety®* design will be considered for adoption as an ISO standard for neuraxial applications.

InterVene is also working with a number of epidural pump manufacturers with a view to incorporating the *Surety®* connector into administration sets. Although Part A of the alert (NPSA/2009/PSA004A) relates only to bolus injections and lumbar puncture samples, the intention is that kits for epidural procedures with safer *Surety®* connectors (covered by Part B of the Alert) will be available around the same time.

Managing Director of InterVene, Matt Root announced,

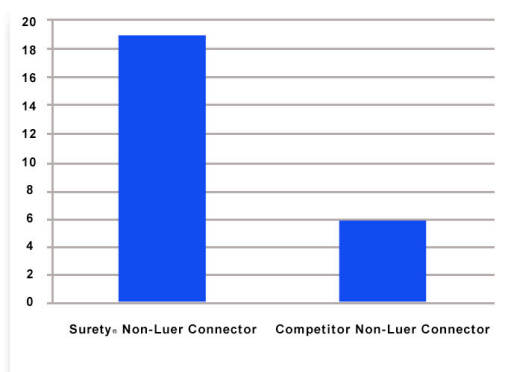
"We are very fortunate in that we have been able to learn a great deal from the NPSA Enteral alert in 2007. We now know how trusts respond to patient safety alerts and I believe that InterVene and our partners are well on track to have things in place to support a smooth and effective transition to safer neuraxial devices by the April deadline. By developing strategic partnerships with established device manufacturers, we have been able to accelerate the

introduction of the *Surety*[®] system and broaden the choice of safer products available in the market.”

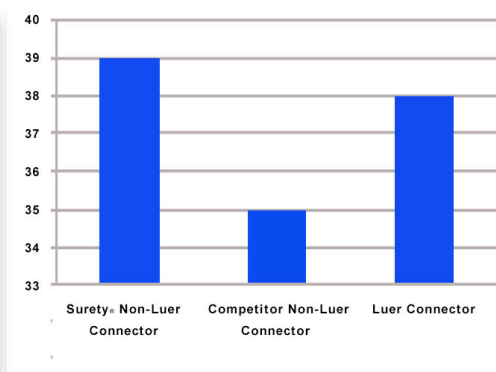
In October 2010 results of a clinical study into the usability of the *Surety*[®] connector (previously branded Spinalok[®]) were published in *Anaesthesia*.¹

Here are some important points from the study:

- 1) There were no reports of leakage, disconnection or displacement during aspiration in any of the test groups for Spinalok[®] (*Surety*[®]).
- 2) In the Spinal tests (n=25) 19 clinicians preferred Spinalok[®] and 6 preferred Neurax[®].
- 3) In the Lumbar puncture tests (n=19), Spinalok[®] (score of 39) performed better than the Neurax[®] system (score of 35) and also better than the currently-used Luer system which was used as the standard (score of 38).



Spinal Evaluation



Lumbar Puncture Evaluation

- 4) In the Epidural tests, Spinalok[®] performed less well, but the reasons for this were largely to do with the composition of the epidural pack that was used. Also, no catheter feeder was provided and the Spinalok[®] LOR syringe was not available for some of the trial. Epidural kit is not covered by part A of the NPSA alert but is covered by part B, which comes into force in April 2013. The company has learned from the feedback in the epidural tests and made appropriate adjustments to pack components.
- 5) During the trial, a connection to a particularly wide-bore, Luer, three-way tap was made, giving rise to a slight design modification. It should be noted that here is no international standard for the internal diameter of a male Luer connector such as the one found on this three-way tap, which means that male Luer connectors may be manufactured to a range of different sizes. This is one of the reasons that the NPSA Patient Safety Alert (NPSA/2009/PSA004A) - *Safer spinal (intrathecal), epidural and regional devices – Part A* states that healthcare establishments should, “Eliminate the use of three-way taps and adaptors with Luer connectors, which enable connection of specified devices to intravenous devices.”
- 6) “The process of independent evaluation, feedback and revision of devices makes the two manufacturers’ products unique amongst currently available equipment.”

InterVene is proud to announce that the following companies are manufacturing NPSA-compliant spinal / epidural needles, procedure packs or epidural pump sets with *Surety*[®] connectors:

Sarstedt Limited

68 Boston Road
Leicester LE4 1AW
Telephone: +44 (0) 116 235 9023
Contact: Ron Dunderdale - healthcare@sarstedt.co.uk
Website: www.sarstedt.com

Blue Box Medical Limited

Unit 29
New Forest Enterprise Centre
Chapel Lane
Totton
Southampton
Hants SO40 9LA
Telephone: +44 (0)23 8066 9000
Contact: Marc Buckingham - marc@blueboxmedical.co.uk
Web Site: www.blueboxmedical.co.uk

Rocket Medical plc

Research & Development
Sedling Road, Washington
Tyne & Wear NE38 9BZ
Email: Nick Tyrell - nick@rocketmedical.com
Telephone: 01923 651432
Web: www.rocketmedical.com

CME McKinley UK Limited

Kincraig Business Park
Kincraig Road
Blackpool, FY2 0PJ
Email: Carole McLaughlin –
cmclaughlin@cme-mckinley.co.uk
Telephone: 01253 894646
Web: www.cme-mckinley.co.uk

Pajunk UK Limited

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Prestwick Park
Prestwick
Northumberland NE20 9SJ
Telephone: +44 (0) 1661 871 203
Contact: Stephen Brown -
stephen.brown@pajunk.co.uk
Website: www.pajunk.co.uk

Vygon (UK) Limited

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Latham Road
Swindon
Wiltshire SN25 4DL
Telephone: +44 (0) 1285 657051
Contact: James Leek - james.leek@vygon.co.uk
Website: www.vygon.com

B. Braun Medical Ltd

Thorncliffe Park. Sheffield. S35 2PW
Contact: Marco Lorenz –
marco.lorenz@bbraun.com
Telephone: +44 (0) 114 2259000
Website: www.bbraun.co.uk

Aspen Medical Europe Limited

Thornhill Road
Worcestershire
B98 9NL
Telephone: +44 (0)1527 587709
Contact: Tom Moss –
tom.moss@aspenmedicaleurope.com
Website: www.aspenmedicaleurope.com

For more information on the range of *Surety*[®] products being manufactured and the availability of products for clinical evaluations please make contact with the above companies direct.

For more information, please visit the InterVene website www.ivltd.co.uk, email surety@ivltd.co.uk or call InterVene on +44 (0) 1246 828088.

ⁱ Cook et al (2010) – *Anaesthesia* - Journal of the Association of Anaesthetists of Great Britain and Ireland
A simulation-based evaluation of two proposed alternatives to Luer devices for use in neuraxial anaesthesia pp 1069 -1079.