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-B. 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.

Surety® 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 fully independent mechanical and microbiological testing and Surety® needles have now been used in well over 250 hospitals with an estimated 10,000+ needles having been used on patients. Surety® products are available via NHS Supply Chain and direct from manufacturers.

InterVene 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. At the time of writing there are 97 Surety® products available via NHS Supply Chain, including 15 different 22G Surety® spinal needles, with more to be added in the near future.

Surety® partners, who have not already launched Surety® products will be doing so during the forthcoming weeks.

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 administration bag and epidural pump manufacturers with a view to incorporating the Surety® connector into administration systems. Although Part A of the alert (NPSA/2009/PSA004A) relates only to bolus injections and lumbar puncture samples, kits for epidural procedures with safer Surety® connectors (covered by Part B of the Alert) are already available.

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 positioned to respond to the inevitable clamour for non-Luer products when the deadline arrives. 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. Uptake of Surety® in hospitals has
been impressive. The NPSA alert is yet to kick in and already over 30 hospitals have already converted from Luer to Surety®.”

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).

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, evidenced by two 10ml LOR syringes and a specifically designed, non-Luer catheter feeder.

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.”
New products being developed for the Surety® range include the following:

1. **Surety® Syringe to Syringe Adapter**
   Pharmacy departments have highlighted a need to mix syringe contents therefore a Surety® syringe-to-syringe adapter has been designed to satisfy this need.
   - **Manufacturing Code (MPC):** SSAD100
   - **NHS Supply Chain Code (NPC):** FWF012
   - **Pre-VAT Price:** £ 17.36 (Box of 100)
   - **Estimated Launch:** March 2012

2. **Surety® Blunt Drawing-up Needle (non-filter)**
   Another request from pharmacy; certain drugs that are suspended in solution are filtered out by our 5 micron particulate filters (SNBF1838 and SNBF1850).
   - **Manufacturing Code (MPC):** SNB1838
   - **NHS Supply Chain Code (NPC):** TBA
   - **Pre-VAT Price:** £ 18.07 (Box of 100)
   - **Estimated Launch:** March 2012

3. **Surety® 0.2 micron bacterial filter drawing up needle**
   Another pharmacy request is the provision of a Surety® 0.2 micron filter needle to complement our range of drawing up needles and filter straws. A standalone filter is also in development.
   - **Manufacturing Code (MPC):** SNBF1838T
   - **NHS Supply Chain Code (NPC):** FTR1085
   - **Pre-VAT Price:** £ 40.46 (Box of 100)
   - **Estimated Launch:** March 2012

4. **Surety® Blood Patch Kit**
   The contents of the kit are:
   - 1 x 21G butterfly needle with one way valve and Surety® needle hub
   - 1 x Tourniquet Single Use
   - 1 x 10ml Surety® lock syringe
   - 1 x 20ml Surety® lock syringe
   - 2 x Surety® syringe caps
   - **Manufacturing Code (MPC):** SBP0020
   - **NHS Supply Chain Code (NPC):** FWC261
   - **Pre-VAT Price:** £ 33.28 (Pack of 5)
   - **Estimated Launch:** March 2012

5. **Surety® Ommaya Reservoir Kit**
   The contents of the kit are:
   - 1 x 25G 5/8” Butterfly needle with Surety® needle hub adapter and pinch clamp
   - 1 x 27G 5/8” Butterfly needle with Surety® needle hub adapter and pinch clamp
   - 2 x 10ml Surety® lock syringes (both with syringe label)
   - 2 x syringe caps
   - 2 x labels for recording CSF collection:
     - **Manufacturing Code (MPC):** SOR2110
     - **NHS Supply Chain Code (NPC):** FWC262
     - **Pre-VAT Price:** £ 48.55 (Pack of 5)
     - **Estimated Launch:** March 2012

If you have any other specific product demands please email us on info@suretydevices.com.
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

**Pajunk UK Limited**  
Swan Building  
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

**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

**Vygon (UK) Limited**  
The Pierre Simonet Building  
V Park, Gateway North  
Latham Road  
Swindon  
Wiltshire SN25 4DL  
Telephone: +44 (0) 1285 657051  
Contact: Graham Milward – graham.milward@vygon.co.uk  
Website: www.vygon.com

**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

**B. Braun Medical Ltd**  
Thorncliffe Park. Sheffield. S35 2PW  
Contact: Greame Cameron - graeme.cameron@bbraun.com  
Telephone: +44 (0) 114 2259000  
Website: www.bbraun.co.uk

**CME Medical UK Limited**  
Kincraig Business Park  
Kincraig Road  
Blackpool, FY2 0PJ  
Email: Quentin Bellingham – qbellingham@cmemedical.co.uk  
Telephone: 01253 894646  
Web: www.cmemedical.co.uk

**Hospira (UK) Limited**  
Queensway  
Royal Leamington Spa  
Warwickshire CV31 3RW  
Telephone: +44 (0)1926 835434  
Contact: Neil Ross  
Neil.Ross@hospira.com  
Website: www.hospira.co.uk

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.
Surety® products now available are as follows:

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<th>Product</th>
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<th>Box Size</th>
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25g x 90mm Quincke needle with Surety® safety connector
25g x 90mm pencil point with introducer Surety® connector REGANESTH
25g x 90mm Quincke + introducer with Surety® connector
25g x 90mm + 30mm introducer spinal needle pencil point with Surety® safety connector
26g x 90mm spinal needle pencil point with Surety® safety connector
26g x 90mm + 30mm introducer spinal needle pencil point with Surety® safety connector
27g x 90mm spinal needle pencil point with Surety® safety connector
27g x 90mm Quincke + introducer with Surety® connector
27g x 90mm with introducer Sprotte Set and Surety® Safety connector
27g x 90mm with introducer Sprotte Needle with Surety® Safety connector
27g x 90mm + 30mm introducer spinal needle pencil point with Surety® safety connector

Long Spinal Needles
16g x 250mm Non Luer needle (Intrathecal) Quincke Surety Needle
16g x 250mm Non Luer needle (Intrathecal) Quincke Surety Needle
22g x 103mm + 38mm introducer spinal needle pencil point with Surety® safety connector
22g x 120mm pencil point with Surety® connector REGANESTH
22g x 120mm Quincke needle with Surety® safety connector
22g x 120mm Sprotte needle with introducer - with Surety® Safety connector
22g x 150mm + 42mm introducer spinal needle pencil point with Surety® safety connector
22g x 150mm Quincke needle with Surety® safety connector
22g x 180mm Quincke needle with Surety® safety connector
24g x 103mm + 38mm introducer spinal needle pencil point with Surety® safety connector
24g x 103mm Sprotte needle with introducer - with Surety® safety connector
24g x 120mm pencil point + introducer with Surety® connector REGANESTH
24g x 120mm Sprotte needle with introducer - with Surety® safety connector
24g x 120mm with introducer Sprotte Set and Surety® Safety connector
24g x 123mm + 42mm introducer spinal needle pencil point with Surety® safety connector
24g x 150mm Sprotte needle with introducer - with Surety® safety connector
24g x 150mm Non Luer needle (Intrathecal) pencil point with surety connector
25g x 103mm Sprotte needle with introducer - with Surety® safety connector

25g x 90mm Quincke needle with Surety® safety connector
25g x 90mm pencil point with introducer Surety® connector REGANESTH
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27g x 90mm + 30mm introducer spinal needle pencil point with Surety® safety connector

Long Spinal Needles
16g x 250mm Non Luer needle (Intrathecal) Quincke Surety Needle
16g x 250mm Non Luer needle (Intrathecal) Quincke Surety Needle
22g x 103mm + 38mm introducer spinal needle pencil point with Surety® safety connector
22g x 120mm pencil point with Surety® connector REGANESTH
22g x 120mm Quincke needle with Surety® safety connector
22g x 120mm Sprotte needle with introducer - with Surety® Safety connector
22g x 150mm + 42mm introducer spinal needle pencil point with Surety® safety connector
22g x 150mm Quincke needle with Surety® safety connector
22g x 180mm Quincke needle with Surety® safety connector
24g x 103mm + 38mm introducer spinal needle pencil point with Surety® safety connector
24g x 103mm Sprotte needle with introducer - with Surety® safety connector
24g x 120mm pencil point + introducer with Surety® connector REGANESTH
24g x 120mm Sprotte needle with introducer - with Surety® safety connector
24g x 120mm with introducer Sprotte Set and Surety® Safety connector
24g x 123mm + 42mm introducer spinal needle pencil point with Surety® safety connector
24g x 150mm Sprotte needle with introducer - with Surety® safety connector
24g x 150mm Non Luer needle (Intrathecal) pencil point with surety connector
25g x 103mm Sprotte needle with introducer - with Surety® safety connector

25g x 90mm Quincke needle with Surety® safety connector
25g x 90mm pencil point with introducer Surety® connector REGANESTH
25g x 90mm Quincke + introducer with Surety® connector
25g x 90mm + 30mm introducer spinal needle pencil point with Surety® safety connector
26g x 90mm spinal needle pencil point with Surety® safety connector
26g x 90mm + 30mm introducer spinal needle pencil point with Surety® safety connector
27g x 90mm spinal needle pencil point with Surety® safety connector
27g x 90mm Quincke + introducer with Surety® connector
27g x 90mm with introducer Sprotte Set and Surety® Safety connector
27g x 90mm with introducer Sprotte Needle with Surety® Safety connector
27g x 90mm + 30mm introducer spinal needle pencil point with Surety® safety connector

Long Spinal Needles
16g x 250mm Non Luer needle (Intrathecal) Quincke Surety Needle
16g x 250mm Non Luer needle (Intrathecal) Quincke Surety Needle
22g x 103mm + 38mm introducer spinal needle pencil point with Surety® safety connector
22g x 120mm pencil point with Surety® connector REGANESTH
22g x 120mm Quincke needle with Surety® safety connector
22g x 120mm Sprotte needle with introducer - with Surety® Safety connector
22g x 150mm + 42mm introducer spinal needle pencil point with Surety® safety connector
22g x 150mm Quincke needle with Surety® safety connector
connector
25g x 103mm + 38mm introducer spinal needle pencil point with Surety® safety connector
25g x 120mm pencil point + introducer with Surety® connector REGANESTH
25g x 120mm Sprotte needle with introducer - with Surety® Safety connector
25g x 123mm spinal needle pencil point with Surety® safety connector
25g x 123mm + 42mm introducer spinal needle pencil point with Surety® safety connector
26g x 103mm + 38mm introducer spinal needle pencil point with Surety® safety connector
26g x 103mm + 38mm introducer spinal needle pencil point with Surety® safety connector
27g x 103mm + 38mm introducer spinal needle pencil point with Surety® safety connector
27g x 103mm with introducer Sprotte Needle with Surety® Safety connector
27g x 120mm Non Luer needle pencil point + introducer with Surety connector REGANESTH
27g x 123mm spinal needle pencil point with Surety® safety connector

Introducer Needles
20g x 30mm introducer for 24/25g spinal needles with Surety® safety connector
20g x 38mm Surety® Non-Luer Introducer Needle
20g x 38mm introducer for 24/25g spinal needles with Surety® safety connector

Epidural Packs
Needle Epidural Catheter Epidural kit
16 gauge x 80mm Tuohy 21g catheter with Surety connector Lock
Needle Epidural Catheter Epidural kit
16 gauge x 80mm Tuohy 21g catheter with Surety connector Slip