



***ViaSpan Solution (Swissmedic authorisation number: 57'387)***  
***Potential for Product Contamination***

## **BATCH RECALL**

Dear Healthcare Professional,

Bristol-Myers Squibb SA (BMS) and Swissmedic would like to inform you of **a batch recall** regarding ViaSpan solution indicated for the preservation of isolated liver, kidney, or pancreas prior to implantation in a recipient.

### **Summary**

- A potential for ViaSpan contamination by *Bacillus cereus* during the manufacturing process was discovered following routine testing procedures and investigations by the production site.
- At the present time, there is no evidence of contamination in the ViaSpan that has been released to the marketplace.
- Bristol-Myers Squibb has decided, as a precautionary measure to:
  - recall all batches/lots of potentially affected ViaSpan in those countries where alternatives to ViaSpan exist.
- Please see below for affected batches/lots:

<b>Material</b>	<b>Material Description</b>	<b>Batch</b>	<b>Expiry (MM/DD/YY)</b>
1285636	VIASPAN SOL 50G/L (6BAGX1000ML) CH	16E10223	09/30/2012
1285636	VIASPAN SOL 50G/L (6BAGX1000ML) CH	16EG0074	07/31/2012

- If you have any affected batches/lots, please follow the instructions below:
  - Block immediately all remaining product of Viaspan
  - Send the complete stock to  
Alloga AG  
Retouren  
Buchmattstrasse 10  
3400 Burgdorf

**Based on this information, for those patients where an organ transplant has taken place, the following guidance is provided to healthcare professionals**

- As a precautionary measure, close medical monitoring is recommended for any patients who recently underwent an organ transplantation in which ViaSpan had been used or will be used as an organ preservation solution.
- Health care personnel working in transplant units should be alert and vigilant to detect any signs and symptoms of systemic as well as local infections (central nervous system, heart, respiratory or cutaneous) occurring in those post-transplant patients.
- All necessary usual medical measures to characterize and treat infections as well as to preserve newly transplanted organs should be undertaken in conformity with the standard of care in place in any given institution (transplant center, hospital).

**Further information on recommendations to healthcare professionals**

- *Bacillus cereus* is a Gram-positive aerobic or facultatively anaerobic, motile, spore-forming, rod-shaped bacterium that is widely distributed environmentally. *Bacillus cereus* is associated mainly with food poisoning. In addition to food poisoning, it causes a number of systemic and local, non-gastrointestinal-tract infections in susceptible patients, such as individuals who are immunologically compromised transplant recipient that may lead to organ rejection and/or other severe medical conditions.
- Antimicrobials noted to be effective in the empirical management of a *Bacillus cereus* infection while awaiting antimicrobial susceptibility results for the isolate include ciprofloxacin and vancomycin. Antimicrobial treatment of *Bacillus cereus* infections should take into account local infectious disease knowledge and practices.

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**Bristol-Myers Squibb**

### **Adverse reaction reporting**

Suspected adverse reactions should be reported to the Swissmedic.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Any suspected adverse reactions for ViaSpan may also be reported to Bristol-Myers Squibb via telephone 041 767 7200 or via email at [daniel.frey@bms.com](mailto:daniel.frey@bms.com).

### **For further information**

Should you have any questions regarding the use of ViaSpan, please contact Bristol-Myers Squibb Medical Information 041 767 7200 or via email at [luciana.beggiora@bms.com](mailto:luciana.beggiora@bms.com).

Yours sincerely,

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Dr. med Katrin Moser-Schirr  
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Bristol-Myers Squibb SA

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Dr. Manfred Schroeder  
Director Regulatory Science / fvP  
Bristol-Myers Squibb SA