

Date: 2022.03.31

Field Safety Notice
SOL-M™ Blunt Fill Needle

For Attention of*: Distributors; Hospitals; Health Care Professionals

Contact details of local representative (name, e-mail, telephone, address etc.)*
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EU Importer:

Sol-Millennium Europe Sp. z o.o.
Twarda 18 St.
00-105 Warsaw
Poland
e-mail: EMEA_QRA@sol-m.com

Field Safety Notice (FSN)
SOL-M™ Blunt Fill Needle

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	SOL-M™ Blunt Fill Needle sterile
1.	2. Commercial name(s)*
	SOL-M™ Blunt Fill Needle
1.	3. Unique Device Identifier(s) (UDI-DI)
	See Appendix A to this FSN.
1.	4. Primary clinical purpose of device(s)*
	The SOL-M™ Blunt Fill Needle is used to pierce the medicine vial septum or ampule and aspirate medication into a syringe. Once the medication is aspirated into a syringe, the contents of the syringe may be injected into an I.V. System or pre-slit septum covering injection sites. The Sol-M Blunt Fill Needle may be removed and replaced with a needle and the contents of the syringe can be injected into individuals. The Sol-M Blunt Fill Needle is not intended for human injections.
1.	5. Device Model/Catalogue/part number(s)*
	See Appendix A to this FSN.
1.	6. Software version
	Not applicable
1.	7. Affected serial or lot number range
	See Appendix A to this FSN.
1.	8. Associated devices
	Not applicable

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Sol-Millennium Medical Inc., with this Field Safety Notice is initiating a voluntary removal for the sterile SOL-M™ Blunt Fill Needles (the list of reference codes and LOT numbers is included in the Appendix A) from the market, effective immediately. Sol-Millennium has determined an increase in coring of the vial rubber stoppers of medication, when reconstituting diluent and accessing vials. Once the medication is reconstituted, visible pieces of rubber were found floating in the medication, in the barrel of the syringe used to aspirate the medication, and in the IV bag used to administer the medication. The affected product was shipped during the time frame of 04/2020 – 01/2022.
2.	2. Hazard giving rise to the FSCA*

	<p>Wherever a blunt fill needle is used to aspirate a medication from a vial with a rubber stopper there is the risk of abrasion, tearing, and cutting of the rubber during the passing of the needle through the rubber stopper. This can result in rubber particles entering the medication vial or being retained in the needle or cannula during events known as fragmentation/coring. During insertion the needle bevel heel can also scoop out large fragments from the stopper. For a rubber particle present in the injection fluid to be injected into the human body, it has to be smaller than the inner diameter of the needle/catheter used for injection</p> <p>The risk is mitigated by the end user during medication preparation procedure. It is an obligatory standard for the end user to check each medication that is withdrawn into the syringe for presence of discoloration or foreign particles, before the medication is administrated into the patient body. In case that the medication contains any visible particles, the vial or the syringe must be discarded and cannot be used for the patient.</p>
2.	<p>3. Probability of problem arising</p> <p>There have been no serious injuries associated with particles caused by the coring that were reported in the accessible literature. There are a handful of reports that cite near-miss situations, without actual injury, and the majority are discussing theoretical adverse events based on common medical knowledge but without real life proof of occurrence. It implies that the probability that a device creates hazardous situation leading to an injury is very low/unlikely.</p>
2.	<p>4. Predicted risk to patient/users</p> <p>Based on the internal and external investigations, the Medical Assessment part of the Health Hazard Evaluation (HHE) where the risk involved is theoretical and given that no identifiable studies relating to coring incidents leading to an adverse event are evident, and the lack any reports to Sol-Millennium of injury related to coring, the situation is one in which use of or exposure to the blunt needle is not likely to cause adverse health consequences. However, Sol-Millennium will remove nonconforming products from the market.</p>
2.	<p>5. Further information to help characterise the problem</p> <p>Coring happens when a needle shears out cores from a rubber closure as it pierces the closure. Several factors can cause coring: the type of stopper, needle, and insertion technique. The variability of the rubber type and the influence of the sterilization can contribute to the coring of the rubber stoppers. Needle gauge, sharpness, and bevel type also contribute to the coring of rubber stopper. Insertion technique can also contribute to the coring of rubber stoppers.</p>
2.	<p>6. Background on Issue</p> <p>Customers reported an increase in coring of the vial rubber stoppers of medication, when reconstituting diluent and accessing vials. Once the medication is reconstituted, visible pieces of rubber were found floating in the medication, in the barrel of the syringe used to aspirate the medication and in the IV bag used to administer the medication. None of the complaints report any patient adverse events.</p>
2.	<p>7. Other information relevant to FSCA</p> <p>Stop any further use of the affected devices.</p>

3. Type of Action to mitigate the risk*

3. 1. Action To Be Taken by the User*

- ☒ Identify Device ☒ Quarantine Device ☐ Return Device ☒ Destroy Device
- ☐ On-site device modification / inspection
- ☒ Follow patient management recommendations
- ☐ Take note of amendment / reinforcement of Instructions For Use (IFU)
- ☐ Other ☐ None

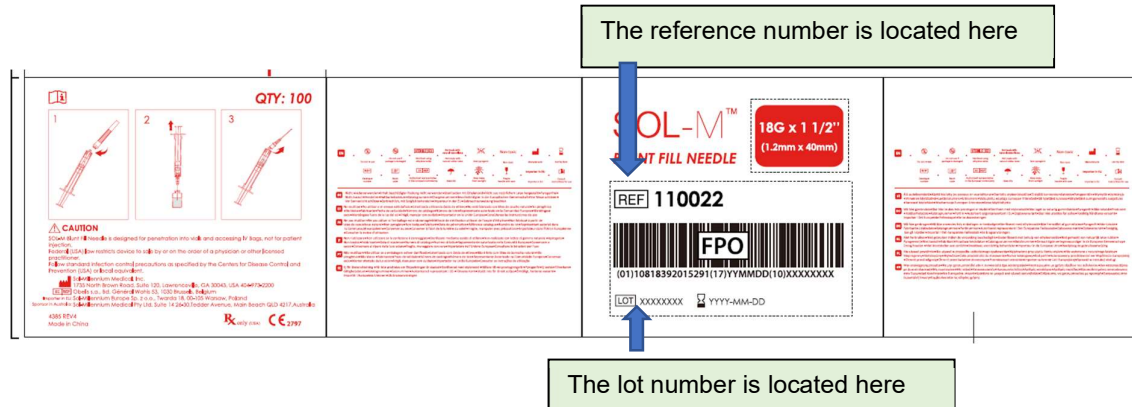
We would appreciate your assistance in the following actions:

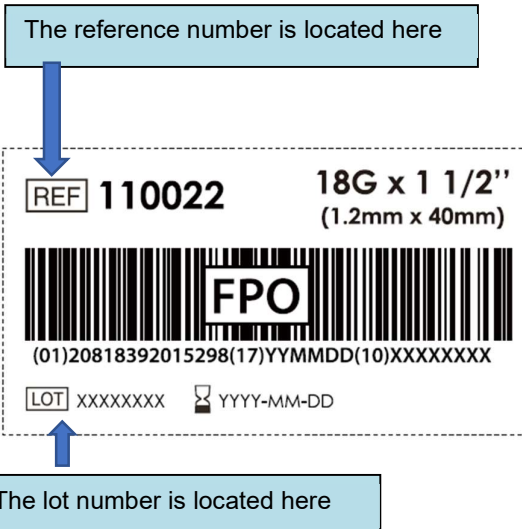
1. **Read** the “2.1. Description of the product problem” section carefully to fully understand the issue involved.
2. Please immediately **examine** your inventory stock to determine if you have any remaining product in your possession.
3. **Stop** any further sale and distribution of product with affected reference and lot numbers.
4. The following illustrations are provided to help you identify the SOL-M™ Blunt Fill Needles. Affected lots are identified by the reference number and lot number on the blister, box and case labels.

Blister Label




Box Label



	<p>Case Label</p> <div data-bbox="592 289 1141 823"> <p>The reference number is located here</p>  <p>The lot number is located here</p> </div>	<ol style="list-style-type: none"> 5. Conduct a physical count and record the data on the Distributor/Importer Reply Form (in case of the distributors/ importers) or Customer Reply Form (in case of the hospitals/ clinics/ etc.) attached to this Notice. 6. Dispose of the affected products through waste system, recycle packaging and document that on the Distributor/Importer Reply Form or Customer Reply Form (as applicable) attached to this Notice. If there is no possibility to dispose of the product in this way, you may return the product to local representative through your normal means. 7. In case of distributors/ importers - return the Distributor/Importer Reply Form via e-mail it to EMEA_QRA@sol-m.com. This is important to complete <u>even, if you have no affected product on hand</u>. Please ensure the form contains a contact name and signature. 8. In case of hospitals/ clinics/ end customers - return the Customer Reply Form via e-mail it to your local distributor or local sales office. This is important to complete <u>even, if you have no affected product on hand</u>. Please ensure the form contains a contact name and signature. 9. Contact your local representative or Sol-Millennium Customer Service on kszewczyk@sol-m.com to understand how to obtain a credit note against affected product. 10. Maintain awareness of this Notice until all affected product has been destroyed/ returned. 11. Share this Notice with anyone who needs to be informed in your facility, or in any facility where potentially affected devices may have been transferred. 12. For any questions about the recall process, please contact Sol-Millennium at EMEA_QRA@sol-m.com or your local sales office.
3.	2. By when should the action be completed?	The action should be completed within 30 days from delivery of this Field Safety Notice.

3.	3. Particular considerations for: Not applicable Is follow-up of patients or review of patients' previous results recommended? Not applicable	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes The Distributor/Importer Reply Form or Customer Reply Form should be completed and returned within 30 days from delivery of this Field Safety Notice.
3.	5. Action Being Taken by the Manufacturer* <div style="display: flex; justify-content: space-between;"> <div> <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> Software upgrade <input type="checkbox"/> Other </div> <div> <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> None </div> </div> <p>Sol-Millennium has performed a root cause investigation and taken immediate corrective action. There are no other lots involved in that. Other lots were already inspected for the condition after manufacture. Sol-Millennium is voluntary taking this action.</p>	
3.	6. By when should the action be completed?	The action should be completed within 30 days from delivery of this Notice.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3.	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Not applicable	

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Not applicable
4.	3. For Updated FSN, key new information as follows:	
	Not applicable	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Not applicable	
4.	6. Anticipated timescale for follow-up FSN	Not applicable
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Sol-Millennium Medical Inc.
	b. Address	1735 North Brown Rd, Suite 120; Lawrenceville, Georgia 30043; USA
	c. Website address	www.sol-m.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
	YES	
4.	9. List of attachments/appendices:	1. Appendix A – list of product references, batches and UDI codes 2. Distributor/Importer Reply Form 3. Customer Reply Form
4.	10. Name/Signature	Manu Kalia Director, Quality Assurance signature  31-Mar-2022

Transmission of this Field Safety Notice	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer (EMEA_QRA@sol-m.com), distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*</p>

Appendix A – list of product references, batches and UDI codes

Reference number	LOT number	Product's name	UDI-DI code
110021	05007020	SOL-M Blunt Fill Needle 18G*1"	81839201390
110021	08106082	SOL-M Blunt Fill Needle 18G*1"	81839201390
110021	08106082	SOL-M Blunt Fill Needle 18G*1"	81839201390
110022	05003027	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05006007	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05006034	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05009065	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05011033	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05012033	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05012034	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05012041	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05012043	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05012045	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05012046	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05012056	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05012057	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05103013	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05105009	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05105009	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05108026	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05108027	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05108029	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05108030	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05108031	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05108032	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05108034	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05109097	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05110031	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	08106075	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	08106076	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
110022	05109040	SOL-M Blunt Fill Needle 18G*1 1/2"	81839201529
BN1815	00201225	Blunt Fill Needle 18G*1 1/2"	35168807575
BN1815	00210305	Blunt Fill Needle 18G*1 1/2"	35168807575
BN1815	00210308	Blunt Fill Needle 18G*1 1/2"	35168807575
BN1815	00210310	Blunt Fill Needle 18G*1 1/2"	35168807575
BN1815	00210312	Blunt Fill Needle 18G*1 1/2"	35168807575

FSN Ref: 3014312726-2/16/15-001-R

FSCA Ref: 3014312726-2/16/15-001-R

Field Safety Notice SOL-M™ Blunt Fill Needle

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	3014312726-2/16/15-001-R
FSN Date*	17.03.2022
Product/ Device name*	SOL-M™ Blunt Fill Needle
Product Code(s)	See Appendix 1 to this Form
Batch/Serial Number (s)	See Appendix 1 to this Form

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
<input type="checkbox"/>	*I confirm receipt of the Field Safety Notice and that I read and understood its content.	<i>Customer to complete or enter N/A</i>
<input type="checkbox"/>	*I performed all actions requested by the FSN.	<i>Customer to complete or enter N/A</i>
<input type="checkbox"/>	*The information and required actions have been brought to the attention of all relevant users and executed.	<i>Customer to complete or enter N/A</i>
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	<i>Add quantity, Lot/Serial Number/Date Returned in Appendix 1 to this Form</i>
<input type="checkbox"/>	*I have destroyed affected devices – enter number destroyed and date complete.	<i>Add quantity, Lot/Serial Number/Date of destruction in Appendix 1 to this Form</i>

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<input type="checkbox"/>	*No affected devices are available for return/ destruction	Customer to complete or enter N/A
<input type="checkbox"/>	Other Action (Define):	
<input type="checkbox"/>	*I do not have any affected devices.	Customer to complete or enter N/A
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	Pre-filled by sender/requester
Customer Helpline	Pre-filled by sender/requester
Postal Address	Pre-filled by sender/requester
Web Portal	Pre-filled by sender/requester
Fax	Pre-filled by sender/requester
Deadline for returning the customer reply form*	Pre-filled by sender/requester

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

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FSCA Ref: 3014312726-2/16/15-001-R

Appendix 1 – list of product references, batches ~~and UDI codes~~

Reference number	LOT number	Product's name	Product disposal: D-destruction R-return NA – not applicable	Date of product disposal (date of destruction/ or date of return)	Number of units destroyed/ returned	Comments
110021	05007020	SOL-M Blunt Fill Needle 18G*1"				
110021	08106082	SOL-M Blunt Fill Needle 18G*1"				
110021	08106082	SOL-M Blunt Fill Needle 18G*1"				
110022	05003027	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05006007	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05006034	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05009065	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05011033	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05012033	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05012034	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05012041	SOL-M Blunt Fill Needle 18G*1 1/2"				

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Reference number	LOT number	Product's name	Product disposal: D-destruction R-return NA – not applicable	Date of product disposal (date of destruction/ or date of return)	Number of units destroyed/ returned	Comments
110022	05012043	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05012045	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05012046	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05012056	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05012057	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05103013	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05105009	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05105009	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05108026	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05108027	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05108029	SOL-M Blunt Fill Needle 18G*1				

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Reference number	LOT number	Product's name	Product disposal: D-destruction R-return NA – not applicable	Date of product disposal (date of destruction/ or date of return)	Number of units destroyed/ returned	Comments
		1/2"				
110022	05108030	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05108031	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05108032	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05108034	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05109097	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05110031	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	08106075	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	08106076	SOL-M Blunt Fill Needle 18G*1 1/2"				
110022	05109040	SOL-M Blunt Fill Needle 18G*1 1/2"				
BN1815	00201225	Blunt Fill Needle 18G*1 1/2"				

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Reference number	LOT number	Product's name	Product disposal: D-destruction R-return NA – not applicable	Date of product disposal (date of destruction/ or date of return)	Number of units destroyed/ returned	Comments
BN1815	00210305	Blunt Fill Needle 18G*1 1/2"				
BN1815	00210308	Blunt Fill Needle 18G*1 1/2"				
BN1815	00210310	Blunt Fill Needle 18G*1 1/2"				
BN1815	00210312	Blunt Fill Needle 18G*1 1/2"				

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Field Safety Notice
SOL-M™ Blunt Fill Needle
Distributor/ Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	3014312726-2/16/15-001-R
FSN Date*	17.03.2022
Product/ Device name*	SOL-M™ Blunt Fill Needle
Product Code(s)	See Appendix 1 to this Form
Batch/Serial Number (s)	See Appendix 1 to this Form

2. Distributor/ Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	EMEA_QRA@sol-m.com
Distributor/Importer Helpline	kszewczyk@sol-m.com
Postal Address	Sol-Millennium Europe Sp. z o.o. Twarda 18 St. 00-105 Warsaw Poland
Web Portal	N/A
Deadline for returning the Distributor/Importer reply form*	30 April 2022

4. Distributors/Importers (Tick all that apply)		
<input type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	<i>Distributor/Importer to complete or enter N/A</i>
<input type="checkbox"/>	*I have checked my stock and quarantined inventory	<i>Distributor/Importer to enter quantity and date</i>
<input type="checkbox"/>	*I have identified customers that received or may have received this device	
<input type="checkbox"/>	*I have informed the identified customers of this FSN	<i>Date of communication:</i>
<input type="checkbox"/>	*I have received confirmation of reply from all identified customers	
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned	<i>Add quantity, Lot/Serial Number/Date Returned in Appendix 1 to this Form</i>

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4. Distributors/Importers (Tick all that apply)		
	and date complete.	
<input type="checkbox"/>	*I have destroyed affected devices – enter number destroyed and date complete.	<i>Add quantity, Lot/Serial Number/Date of destruction in Appendix 1 to this Form</i>
<input type="checkbox"/>	*Neither I nor any of my customers has any affected devices in inventory	<i>Distributor/Importer to complete or enter N/A</i>
Print Name*		<i>Distributor/Importer print name here</i>
Signature*		<i>Distributor/Importer sign Here</i>
Date *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

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FSCA Ref: 3014312726-2/16/15-001-R

Appendix 1 – list of product references, batches ~~and UDI codes~~

Reference number	LOT number	Product's name	Total number of units purchased	(A) Number of units to be recalled (from customers/hospitals etc.)	(B) Product still in your inventory stock	Product disposal: D-destruction R-return NA – not applicable	Date of product disposal (date of destruction/ or date of return)	(A+B) Number of units of destroyed/ returned	Comments
110021	050070 20	SOL-M Blunt Fill Needle 18G*1"							
110021	081060 82	SOL-M Blunt Fill Needle 18G*1"							
110021	081060 82	SOL-M Blunt Fill Needle 18G*1"							
110022	050030 27	SOL-M Blunt Fill Needle 18G*1 1/2"							
110022	050060 07	SOL-M Blunt Fill Needle 18G*1 1/2"							
110022	050060 34	SOL-M Blunt Fill Needle 18G*1 1/2"							
110022	050090 65	SOL-M Blunt Fill Needle 18G*1 1/2"							
110022	050110 33	SOL-M Blunt Fill Needle 18G*1 1/2"							
110022	050120 33	SOL-M Blunt Fill Needle 18G*1 1/2"							
110022	050120	SOL-M Blunt Fill							

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Reference number	LOT number	Product's name	Total number of units purchased	(A) Number of units to be recalled (from customers/hospitals etc.)	(B) Product still in your inventory stock	Product disposal: D-destruction R-return NA – not applicable	Date of product disposal (date of destruction/ or date of return)	(A+B) Number of units of destroyed/ returned	Comments
	34	Needle 18G*1 1/2"							
110022	050120	SOL-M Blunt Fill							
	41	Needle 18G*1 1/2"							
110022	050120	SOL-M Blunt Fill							
	43	Needle 18G*1 1/2"							
110022	050120	SOL-M Blunt Fill							
	45	Needle 18G*1 1/2"							
110022	050120	SOL-M Blunt Fill							
	46	Needle 18G*1 1/2"							
110022	050120	SOL-M Blunt Fill							
	56	Needle 18G*1 1/2"							
110022	050120	SOL-M Blunt Fill							
	57	Needle 18G*1 1/2"							
110022	051030	SOL-M Blunt Fill							
	13	Needle 18G*1 1/2"							
110022	051050	SOL-M Blunt Fill							
	09	Needle 18G*1 1/2"							
110022	051050	SOL-M Blunt Fill							
	09	Needle 18G*1 1/2"							
110022	051080	SOL-M Blunt Fill							

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Reference number	LOT number	Product's name	Total number of units purchased	(A) Number of units to be recalled (from customers/hospitals etc.)	(B) Product still in your inventory stock	Product disposal: D-destruction R-return NA – not applicable	Date of product disposal (date of destruction/ or date of return)	(A+B) Number of units of destroyed/ returned	Comments
	26	Needle 18G*1 1/2"							
110022	051080	SOL-M Blunt Fill							
	27	Needle 18G*1 1/2"							
110022	051080	SOL-M Blunt Fill							
	29	Needle 18G*1 1/2"							
110022	051080	SOL-M Blunt Fill							
	30	Needle 18G*1 1/2"							
110022	051080	SOL-M Blunt Fill							
	31	Needle 18G*1 1/2"							
110022	051080	SOL-M Blunt Fill							
	32	Needle 18G*1 1/2"							
110022	051080	SOL-M Blunt Fill							
	34	Needle 18G*1 1/2"							
110022	051090	SOL-M Blunt Fill							
	97	Needle 18G*1 1/2"							
110022	051100	SOL-M Blunt Fill							
	31	Needle 18G*1 1/2"							
110022	081060	SOL-M Blunt Fill							
	75	Needle 18G*1 1/2"							
110022	081060	SOL-M Blunt Fill							

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Reference number	LOT number	Product's name	Total number of units purchased	(A) Number of units to be recalled (from customers/hospitals etc.)	(B) Product still in your inventory stock	Product disposal: D-destruction R-return NA – not applicable	Date of product disposal (date of destruction/ or date of return)	(A+B) Number of units of destroyed/ returned	Comments
	76	Needle 18G*1 1/2"							
110022	051090	SOL-M Blunt Fill							
	40	Needle 18G*1 1/2"							
BN1815	002012	Blunt Fill Needle 18G*1							
	25	1/2"							
BN1815	002103	Blunt Fill Needle 18G*1							
	05	1/2"							
BN1815	002103	Blunt Fill Needle 18G*1							
	08	1/2"							
BN1815	002103	Blunt Fill Needle 18G*1							
	10	1/2"							
BN1815	002103	Blunt Fill Needle 18G*1							
	12	1/2"							