Rev 2: February 2020
FSN Ref: 3014312726-2/16/15-001-R

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

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.)*
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*

	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 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.
2.	3. Probability of problem arising
	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.
2.	4. Predicted risk to patient/users
	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.
2.	5. Further information to help characterise the problem
	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.
2.	6. Background on Issue
	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.
2.	7. Other information relevant to FSCA
	Stop any further use of the affected devices.

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

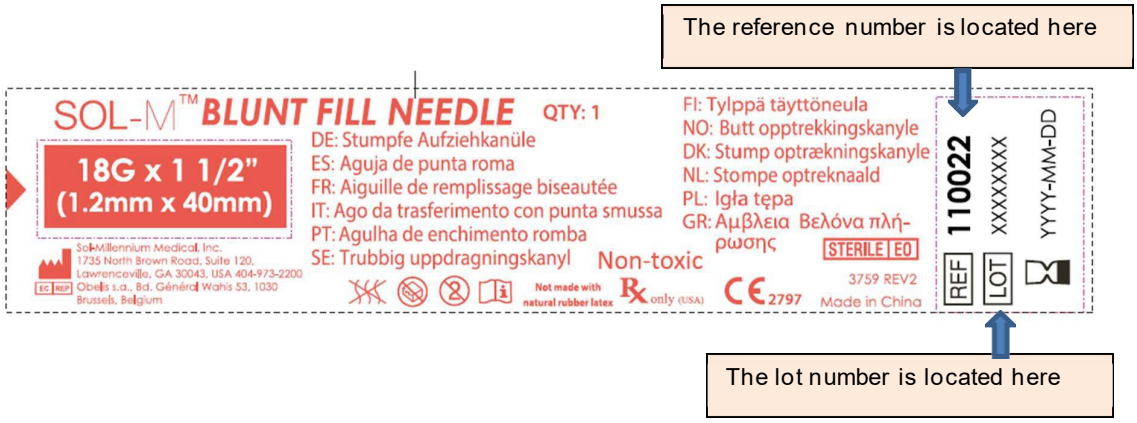
☐ Take note of amendment / reinforcement of Instructions For Use (IFU)

☐ Other ☐ None

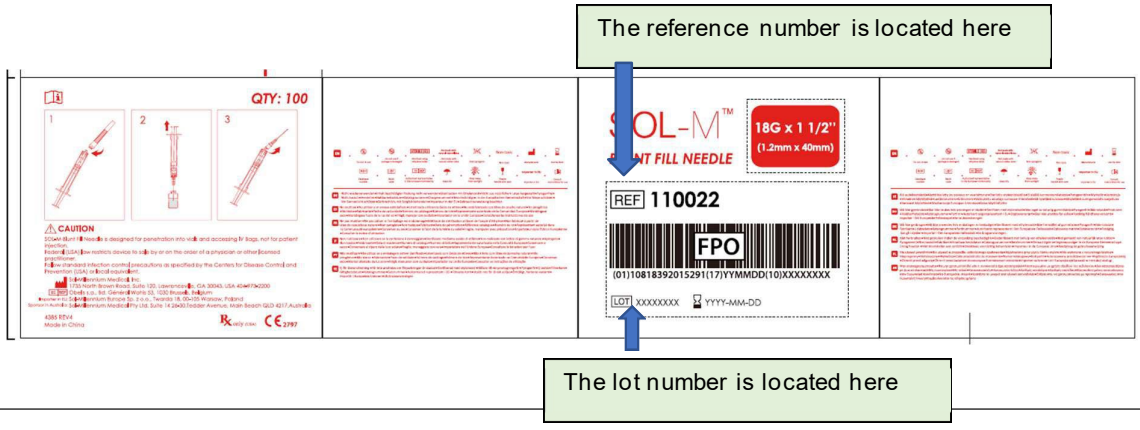
We would appreciate your assistance in the following actions:

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.

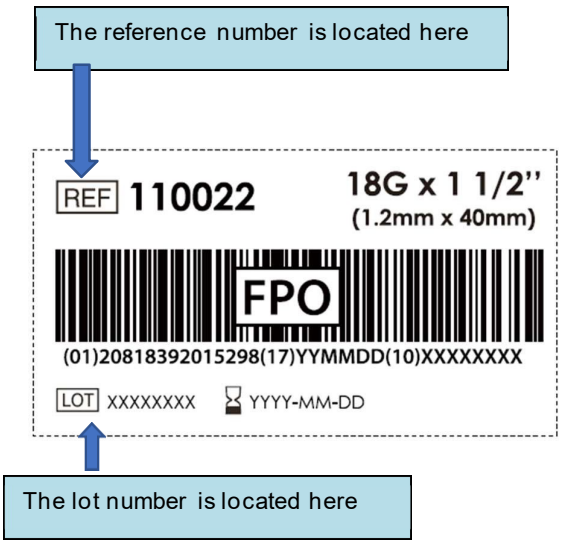
Blister Label



Box Label



Case Label



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 even, if you have no affected product on hand. 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 even, if you have no affected product on hand. 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*** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None 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.	
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	… …

	Transmission of this Field Safety Notice
	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. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. 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.*

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