

Rev 2: February 2020
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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*

	<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

The reference number is located here

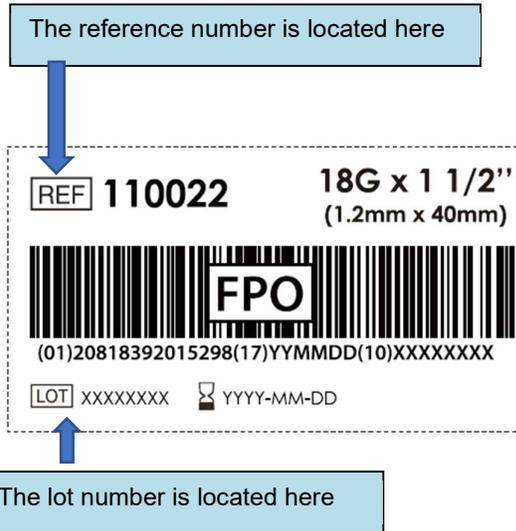
The lot number is located here

Box Label

The reference number is located here

The lot number is located here

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.
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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