

FSN Ref.: RAN 21022

Date: 29.03.2021

Urgent Field Safety Notice

Safe Cut, Bone Marrow, Marrow Cut, MR Safe Cut

For Attention of: User and distributors

Contact details (name, e-mail, telephone, address etc.)
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Customer Contact: Kerstin Lindstedt
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Telephone: +49(0)30 3198225-34

Telefax: +49(0)30 3198225-99

E-Mail: k.lindstedt@somatex.com
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SOMATEX Medical Technologies GmbH

Hohenzollerndamm 150/151

14199 Berlin

Germany

Urgent Field Safety Notice

Safe Cut, Bone Marrow, Marrow Cut, MR Safe Cut

Risk of unsterility

1. Information on Affected Devices			
1. Device Type	Biopsy needles		
2. Commercial name(s)	Safe Cut, Bone Marrow, Marrow Cut, MR Safe Cut		
3. Primary clinical purpose of device(s)	The products are used for the puncture and histological extraction of tissue from the bone marrow in the area of pelvic bone.		
4. Device Model/Catalogue/ part number(s) and LOT Numbers	<u>Safe Cut:</u>		<u>MR Safe Cut:</u>
	REF 181130	REF 181140	REF 181145
	LOT 86738	LOT 86741	LOT 86755
	LOT 86742	LOT 86744	LOT 86764
	LOT 86747	LOT 86746	LOT 86777
	LOT 86749	LOT 86750	LOT 86779
	LOT 86763	LOT 86771	LOT 86786
	LOT 86770	LOT 86774	LOT 86825
	LOT 86778	LOT 86787	LOT 86834
	LOT 86780	LOT 86797	LOT 86836
	LOT 86781	LOT 86803	LOT 86837
	LOT 86793	LOT 86818	LOT 86910
	LOT 86801	LOT 86824	LOT 86923
	LOT 86804	LOT 86830	
	LOT 86819	LOT 86835	
	LOT 86821	LOT 86838	
	LOT 86826	LOT 86842	
	LOT 86839	LOT 86844	
	LOT 86848	LOT 86854	
	LOT 86849	LOT 86856	
	LOT 86855	LOT 86860	
	LOT 86857	LOT 86862	
	LOT 86863	LOT 86873	
			REF 601210
			LOT 86756

LOT 86872	LOT 86878	
LOT 86877	LOT 86880	
LOT 86879	LOT 86886	
LOT 86882	LOT 86888	
LOT 86885	LOT 86897	
LOT 86887	LOT 86909	
LOT 86899	LOT 86913	
LOT 86902	LOT 86918	
LOT 86907	LOT 86920	
LOT 86914		

Bone Marrow:

REF 180910	REF 180935	REF 180960	REF 180965
LOT 86748	LOT 86739	LOT 86752	LOT 86743
LOT 86762	LOT 86740	LOT 86765	LOT 86745
LOT 86768	LOT 86751	LOT 86773	LOT 86753
LOT 86784	LOT 86766	LOT 86791	LOT 86761
LOT 86792	LOT 86794	LOT 86798	LOT 86795
LOT 86799	LOT 86827	LOT 86800	LOT 86823
LOT 86805	LOT 86833	LOT 86822	LOT 86829
LOT 86820	LOT 86847	LOT 86840	LOT 86832
LOT 86841	LOT 86859	LOT 86852	LOT 86858
LOT 86843	LOT 86889	LOT 86853	LOT 86870
LOT 86845	LOT 86892	LOT 86867	LOT 86876
LOT 86864	LOT 86893	LOT 86875	LOT 86884
LOT 86881	LOT 86894	LOT 86883	
LOT 86891	LOT 86903		
LOT 86898	LOT 86904		
LOT 86901	LOT 86911		
LOT 86905	LOT 86912		
LOT 86908			

<u>Marrow Cut:</u>		
REF 180980	REF 180990	REF 180995
LOT 86790	LOT 86754	LOT 86788
LOT 86850	LOT 86772	LOT 86789
LOT 86866	LOT 86785	LOT 86831
LOT 86868	LOT 86796	LOT 86890
LOT 86869	LOT 86802	
	LOT 86828	
	LOT 86846	
	LOT 86871	
	LOT 86874	
	LOT 86895	
	LOT 86896	
	LOT 86900	
	LOT 86906	

2. Reason for Field Safety Notice (FSN)	
1. Description of the product problem	There is a potential risk that the sterilization process was not successful and the products are therefore potentially unsterile.
2. Hazard giving rise to the FSCA (Field Safety Corrective Action)	Using a non-sterile product poses a risk of infection for the patient.

3. Type of Action to mitigate the risk	
1. Action To Be Taken by the User and Distributors	<input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Cease use <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> for distributors: complete the distributor reply form (page 6 to 9) of this documents and submit it to SOMATEX – contact information see page 1 <input checked="" type="checkbox"/> for user: complete the user reply form (page 10 to 13) of this documents and submit it to your distributor – contact information see page 13 <input checked="" type="checkbox"/> Return Device
2. By when should the action be completed?	As soon as possible
3. Is User and Distributor Reply Required?	Yes. Information shall be sent to SOMATEX (for distributors) or to the distributor (for user), if affected products are used or still on stock. After SOMATEX received this information, SOMATEX will contact the distributor to organize the return of the affected products.

4. General Information	
1. FSN Type	New
2. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
Name / Signature	 <hr style="width: 200px; margin: 0 auto;"/> Jörg Heise Managing Director

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. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</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, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback</p>

Field Safety Notice Distributor Reply Form

1. Field Safety Notice (FSN) information			
FSN Reference number	RAN 21022		
FSN Date	29.03.2021		
Product/ Device name	Safe Cut, Bone Marrow, Marrow Cut, MR Safe Cut		
Product Code(s) and Batch/LOT Number (s)	<u>Safe Cut:</u>		<u>MR Safe Cut:</u>
	REF 181130	REF 181140	REF 181145
	LOT 86738	LOT 86741	LOT 86755
	LOT 86742	LOT 86744	LOT 86764
	LOT 86747	LOT 86746	LOT 86777
	LOT 86749	LOT 86750	LOT 86779
	LOT 86763	LOT 86771	LOT 86786
	LOT 86770	LOT 86774	LOT 86825
	LOT 86778	LOT 86787	LOT 86834
	LOT 86780	LOT 86797	LOT 86836
	LOT 86781	LOT 86803	LOT 86837
	LOT 86793	LOT 86818	LOT 86910
	LOT 86801	LOT 86824	LOT 86923
	LOT 86804	LOT 86830	
	LOT 86819	LOT 86835	
	LOT 86821	LOT 86838	
	LOT 86826	LOT 86842	
	LOT 86839	LOT 86844	
	LOT 86848	LOT 86854	
	LOT 86849	LOT 86856	
	LOT 86855	LOT 86860	
	LOT 86857	LOT 86862	
	LOT 86863	LOT 86873	
	LOT 86872	LOT 86878	
	LOT 86877	LOT 86880	
	LOT 86879	LOT 86886	
	LOT 86882	LOT 86888	
	LOT 86885	LOT 86897	
LOT 86887	LOT 86909		
LOT 86899	LOT 86913		
LOT 86902	LOT 86918		
		REF 601210	
		LOT 86756	

LOT 86907	LOT 86920	
LOT 86914		

Bone Marrow:

REF 180910	REF 180935	REF 180960	REF 180965
LOT 86748	LOT 86739	LOT 86752	LOT 86743
LOT 86762	LOT 86740	LOT 86765	LOT 86745
LOT 86768	LOT 86751	LOT 86773	LOT 86753
LOT 86784	LOT 86766	LOT 86791	LOT 86761
LOT 86792	LOT 86794	LOT 86798	LOT 86795
LOT 86799	LOT 86827	LOT 86800	LOT 86823
LOT 86805	LOT 86833	LOT 86822	LOT 86829
LOT 86820	LOT 86847	LOT 86840	LOT 86832
LOT 86841	LOT 86859	LOT 86852	LOT 86858
LOT 86843	LOT 86889	LOT 86853	LOT 86870
LOT 86845	LOT 86892	LOT 86867	LOT 86876
LOT 86864	LOT 86893	LOT 86875	LOT 86884
LOT 86881	LOT 86894	LOT 86883	
LOT 86891	LOT 86903		
LOT 86898	LOT 86904		
LOT 86901	LOT 86911		
LOT 86905	LOT 86912		
LOT 86908			

Marrow Cut:

REF 180980	REF 180990	REF 180995
LOT 86790	LOT 86754	LOT 86788
LOT 86850	LOT 86772	LOT 86789
LOT 86866	LOT 86785	LOT 86831
LOT 86868	LOT 86796	LOT 86890
LOT 86869	LOT 86802	
	LOT 86828	
	LOT 86846	
	LOT 86871	
	LOT 86874	

FSN Ref.: RAN 21022

		LOT 86895	
		LOT 86896	
		LOT 86900	
		LOT 86906	

2. Distributor Details	
Company Name	
Address	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Return acknowledgement to Sender	
Email	k.lindstedt@somatex.com
Distributor Helpline	+49(0)30 3198225-34
Postal Address	SOMATEX Medical Technologies GmbH Hohenzollerndamm 150/151 14199 Berlin Germany
Web Portal	www.somatex.com
Deadline for returning the Distributor reply form	As soon as possible

4. Distributors (to be completed by the Distributor - Tick all that apply)		
<input type="checkbox"/>	I confirm the receipt, the reading and understanding of the Field Safety Notice.	
<input type="checkbox"/>	I have checked my stock and quarantined inventory	Distributor to enter quantity and date
<input type="checkbox"/>	I have identified customers that received or may have received this device	
<input type="checkbox"/>	I have attached customer list	
<input type="checkbox"/>	I have informed the identified customers of this FSN with page 1-5 and page 10-13	Date of communication:
<input type="checkbox"/>	I have received confirmation of reply from all identified customers	
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory	
	Print Name	
	Signature	
	Date	

After submitting this information to SOMATEX, SOMATEX will contact you to organize the return of the affected products.

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.

Field Safety Notice User Reply Form

1. Field Safety Notice (FSN) information			
FSN Reference number	RAN 21022		
FSN Date	29.03.2021		
Product/ Device name	Safe Cut, Bone Marrow, Marrow Cut, MR Safe Cut		
Product Code(s) and Batch/LOT Number (s)	<u>Safe Cut:</u>		<u>MR Safe Cut:</u>
	REF 181130	REF 181140	REF 181145
	LOT 86738	LOT 86741	LOT 86755
	LOT 86742	LOT 86744	LOT 86764
	LOT 86747	LOT 86746	LOT 86777
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	LOT 86819	LOT 86835	
	LOT 86821	LOT 86838	
	LOT 86826	LOT 86842	
	LOT 86839	LOT 86844	
	LOT 86848	LOT 86854	
	LOT 86849	LOT 86856	
	LOT 86855	LOT 86860	
	LOT 86857	LOT 86862	
	LOT 86863	LOT 86873	
	LOT 86872	LOT 86878	
	LOT 86877	LOT 86880	
	LOT 86879	LOT 86886	
	LOT 86882	LOT 86888	
	LOT 86885	LOT 86897	
	LOT 86887	LOT 86909	
	LOT 86899	LOT 86913	
	LOT 86902	LOT 86918	
			REF 601210
			LOT 86756

LOT 86907	LOT 86920	
LOT 86914		

Bone Marrow:

REF 180910	REF 180935	REF 180960	REF 180965
LOT 86748	LOT 86739	LOT 86752	LOT 86743
LOT 86762	LOT 86740	LOT 86765	LOT 86745
LOT 86768	LOT 86751	LOT 86773	LOT 86753
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LOT 86792	LOT 86794	LOT 86798	LOT 86795
LOT 86799	LOT 86827	LOT 86800	LOT 86823
LOT 86805	LOT 86833	LOT 86822	LOT 86829
LOT 86820	LOT 86847	LOT 86840	LOT 86832
LOT 86841	LOT 86859	LOT 86852	LOT 86858
LOT 86843	LOT 86889	LOT 86853	LOT 86870
LOT 86845	LOT 86892	LOT 86867	LOT 86876
LOT 86864	LOT 86893	LOT 86875	LOT 86884
LOT 86881	LOT 86894	LOT 86883	
LOT 86891	LOT 86903		
LOT 86898	LOT 86904		
LOT 86901	LOT 86911		
LOT 86905	LOT 86912		
LOT 86908			

Marrow Cut:

REF 180980	REF 180990	REF 180995
LOT 86790	LOT 86754	LOT 86788
LOT 86850	LOT 86772	LOT 86789
LOT 86866	LOT 86785	LOT 86831
LOT 86868	LOT 86796	LOT 86890
LOT 86869	LOT 86802	
	LOT 86828	
	LOT 86846	
	LOT 86871	
	LOT 86874	

FSN Ref.: RAN 21022

		LOT 86895		
		LOT 86896		
		LOT 86900		
		LOT 86906		

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.	Customer to complete or enter N/A		
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot Number:	Date Returned(DD/MM/YY):
		Qty:	Lot Number:	Date Returned(DD/MM/YY):
		Qty:	Lot Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
<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			
	Signature			
	Date			

4. Return acknowledgement to sender	
Email	
Customer Helpline	
Postal Address	
Web Portal	
Fax	
Deadline for returning the customer reply form	

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.