

«Hospital_Name»

«Users_Name»

«Department»

«Customer_Address»

«Zip_Code» «City»

«Country_name»

<Reference: 92803235-FA>

XX December 2021

Urgent Field Safety Notice - Urgent Medical Device Recall Jagtome™ RX, Hydratome™ RX, Dreamtome™ RX, Cannulating Sphincterotomes, and Jagtome™ Revolution RX

Dear «Users_Name»,

Boston Scientific Corporation is conducting a removal of specific lots of Sphincterotomes as detailed in Attachment 1. Through internal investigation, Boston Scientific has determined that the inner pouch for the specified lots of devices impacted by this removal may be damaged which may compromise the sterile barrier.

Use of a Sphincterotome from a package with a sterile barrier breach as in the current issue presents a risk of infection. The most serious health risk that could occur from use of a non-sterile Sphincterotome is a post-procedure bile duct infection that could be managed with medical evaluation and treatment with oral or intravenous antibiotics. Boston Scientific is not aware of any patient consequences resulting from this issue.

Our records indicate that your facility received some of the concerned product. **The Attachment 1 below provides a complete list of all affected products**, including Product Description, Material Number (UPN), GTIN and Lot/Batch numbers and expiry date. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice.**

Further distribution or use of any remaining product affected by this action should cease immediately.

INSTRUCTIONS:

1- Please immediately discontinue use of the Boston Scientific product reported in the list and remove all of the affected units from your inventory, regardless of where these units are stored in your facility. Segregate the units in a secure place, pending return to Boston Scientific.

2- Please complete the attached Verification Form even if you do not have any product to return.

3- When completed, please return the Verification Form to your local Boston Scientific office for the attention of «Customer_Service_Fax_Number» on or before **xx January 2022**.

4- If you have products to return, please package them in an appropriate shipping box and **contact «Customer_Service_Tel» of your local Boston Scientific office**, to arrange return.

5- Please pass this notice to any healthcare professional from your organization that needs to be aware and to any organization where the potentially affected devices have been transferred (if appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Your Competent Authority is being notified of this Field Safety Notice.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction. We are committed to continuing to offer products that meet the highest quality standards that you expect from Boston Scientific.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,



Marie Pierre Barlanga
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form

Attachment 1 : Affected Product Listing

Product Description	Material Number	GTIN	Batch Number	Expiration Date Range
Dreamtome™ RX Cannulating Sphincterotome	M00584040	08714729778264	27446479	June 6, 2024 - October 13, 2024
			27448337	
			27470857	
			27473288	
			27479007	
			27488955	
			27519099	
			27583248	
			27584920	
			27609359	
			27610230	
			27616517	
			27674795	
			27679150	
			27681372	
			27682823	
			27710650	
			27715915	
			27740170	
			27742966	
			27746783	
			27747640	
			27770749	
			27779090	
			27781488	
			27784284	
			27806906	
			27808089	
			27813903	
			27818805	
			27869283	
			27872956	
			27955178	
			27958586	
			27965294	
			28021413	
			28054973	
			28118052	

Product Description	Material Number	GTIN	Batch Number	Expiration Date Range
Dreamtome™ RX Cannulating Sphincterotome	M00584040	08714729778264	28296777	June 6, 2024 - October 13, 2024
			28296779	
	M00584060	08714729778288	27463326	
			27468730	
			27553568	
			27590928	
			27629941	
			27684747	
			27764231	
			27794744	
			27837500	
			27931763	
			27986550	
			28058938	
	M00584050	08714729778271	27453804	
			27457431	
			27549729	
			27556712	
			27575367	
			27579180	
			27605386	
			27605881	
			27660096	
			27667092	
			27672343	
			27708191	
			27709633	
			27787771	
			27789167	
			27899695	
			27924755	
			27971482	
			27976277	
			27979230	
			28047306	
			28054381	
	M00584070	08714729778295	27625066	
			27805561	

Product Description	Material Number	GTIN	Batch Number	Expiration Date Range
Dreamtome™ RX Cannulating Sphincterotome	M00584000	08714729778226	27566791	June 6, 2024 - October 13, 2024
			27604633	
			27690970	
			27802364	
			27951185	
			28028721	
	M00584020	08714729778240	27802363	
	M00584010	08714729778233	27566790	
			27641143	
			27852432	
	M00584030	08714729778257	27692922	
Hydratome™ RX Cannulating Sphincterotome	M00583040	08714729755197	27439836	June 3, 2024 - September 17, 2024
			27440919	
			27493069	
			27496980	
			27499896	
			27750785	
			27753215	
			27825981	
			27879216	
			27880741	
			27931764	
			27934862	
			28032489	
			28043447	
	M00583060	08714729755210	27442309	
			28020415	
	M00583050	08714729755203	27503545	
			27539248	
			27622371	
			27830206	
			27836999	
			27892995	
			27940790	
	M00583070	08714729755227	27556713	
			27684748	
			27949033	
	M00583000	08714729755159	27852433	

Product Description	Material Number	GTIN	Batch Number	Expiration Date Range
Hydratome™ RX Cannulating Sphincterotome	M00583000	08714729755159	28028722	June 3, 2024 - September 17, 2024
	M00583010	08714729755166	27641142	
			28045346	
Jagtome™ Revolution RX	M00584240	08714729953234	27481920	June 11, 2024 - September 21, 2024
			27524107	
			27525279	
			27530542	
			27574053	
			27598798	
			27652479	
			27722062	
			27722511	
			27742261	
			27758891	
			27795634	
			27846706	
			27897451	
			27969768	
			28027118	
			28070708	
	M00584250	08714729953241	27482864	
	M00584260	08714729953258	27482863	
			27532553	
			27602969	
			27652583	
			27723139	
			27758892	
			27796835	
			27846707	
			27899139	
			27966498	
			28021411	
Jagtome™ RX Cannulating Sphincterotome	M00573000	08714729776710	27690967	June 7, 2024 - October 15, 2024
			27949032	
	M00573020	08714729776734	27571949	
	M00573030	08714729776741	27951184	
	M00573040	08714729776659	27465198	
			27515974	

Product Description	Material Number	GTIN	Batch Number	Expiration Date Range
Jagtome™ RX Cannulating Sphincterotome	M00573040	08714729776659	27595732	June 7, 2024 - October 15, 2024
			27625064	
			27720618	
			27737252	
			27765472	
			27833280	
			27883444	
			28002224	
			28296772	
	M00573050	08714729776666	27535120	
			27643043	
			27730949	
			27836207	
	M00573060	08714729776673	27522394	
			27566792	
			27589267	
			27618168	
			27726335	
			27758466	
			27795807	
	M00573070	08714729776543	27822419	
			27737251	
			27970819	
	M00573080	08714729776642	28289451	
			27505913	
			27563424	
			27629942	
			27731957	
			27755861	
			27839657	
			27846391	
			27986551	
			27991931	
			28036372	
	M00573090	08714729776550	27632862	
			27855805	
	M00573100	08714729776536	27465196	
			27566099	

Product Description	Material Number	GTIN	Batch Number	Expiration Date Range
Jagtome™ RX Cannulating Sphincterotome	M00573100	08714729776536	27603464	June 7, 2024 - October 15, 2024
			27641141	
			27731956	
			27855806	
			27998506	
			28297081	
	M00573110	08714729776529	27857328	
	M00573500	08714729121169	27604634	
			27692921	
	M00573540	08714729121251	27491776	
			27595731	
			27618170	
			27718421	
			27758432	
			27764571	
			27830207	
			27858381	
			28002225	
			28289452	
	M00573550	08714729121268	27571950	
			27591704	
			27625065	
			27773387	
	M00573560	08714729719533	27458135	
			27472063	
			27553565	
			27649356	
			27706277	
			27758465	
			27773622	
			27821544	
			27865086	
			27986549	
			28017367	
			28289453	
	M00573570	08714729121275	27821545	
			28019275	

Please Complete the form even if you do not have any affected product & send it to your Local Office:
«Customer_Service_Fax_Number»

Verification Form – Urgent Medical Device Recall
Jagtome™ RX, Hydratome™ RX, Dreamtome™ RX, Cannulating Sphincterotomes, and
Jagtome™ Revolution RX
92803235-FA

1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated xx December 2021.
2. **Boston Scientific records indicate you have received the following affected product** (*additionally please check inventory against complete list of affected product provided*)

Material N° (UPN)	Lot / Batch N°	Customer PO	Qty Sent	Qty to return

3. We confirm that all areas where affected product could be located have been checked.
4. **TICK ONE OF THESE STATEMENTS*, SIGN THIS FORM** and send it to «Customer_Service_Fax_Number»
 - ☐ We do not have any affected product.
 - ☐ We have found affected product(s): Please confirm the quantity to return above. *If you are returning product not listed above, please **add the UPN, Lot/Batch/Serial number and the quantity to return**.*

TO RETURN PRODUCTS:

1. Contact «Customer_Service_Tel» of your Local Office to arrange return of any affected product
2. Prepare the package
3. Follow the instructions given by your Local Office about collection of the package

NAME* _____ **Title** _____

Telephone _____ **Email** _____

Customer' SIGNATURE* _____ **DATE*** _____
* Required field dd/mm/yyyy