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July 26th, 2024

URGENT Field Safety Notice
FA-24-004
Immediate Attention Required

Dear Valued Customer,

Beaver-Visitec International, Inc. (BVI) has been made aware of a voluntary recall of low dead space syringes, and luer slip tip syringes manufactured by Sol-Millennium Medical (Sol-M), Inc. As syringes manufactured by Sol-M are present in some of our BVI CustomEyes Procedure Packs, we are voluntarily initiating a recall of these products. Please note that this action is specific to the Sol-M manufactured syringes contained in BVI CustomEyes Procedure Packs - the remaining components of BVI CustomEyes Procedure Packs are unaffected and suitable for use once you have completed the activities described in this letter.

Background

The U.S. Food and Drug Administration (FDA) has issued an updated Field Safety Communication¹ for syringes manufactured in China. Citing concerns of quality and safety, FDA recommends that healthcare providers transition away from using plastic syringes manufactured by China-based manufacturers, unless use of these syringes is absolutely necessary until they can complete the transition to syringes that are not manufactured in China. If these syringes continue to be used, users should closely monitor for leaks, breakage, and other problems. Adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Further, as BVI has been made aware of a voluntary recall of low dead space syringes, and luer slip tip syringes manufactured by Sol-Millennium Medical (Sol-M), Inc., and as these syringes are present in some BVI CustomEyes Procedure Packs, we are voluntarily initiating a recall of these products.

The affected Sol-M syringes are listed below:

BVI Part#	Description	Sol-M Part#
60300579	Syringe Luer Lock (1ml)	P180001PBSP
60300580	Syringe Luer Slip (1ml)	P180011LDSBS
60300582	Syringe Luer Lock (1 ml)	P180001PP

¹ <https://www.fda.gov/medical-devices/safety-communications/update-evaluating-plastic-syringes-made-china-potential-device-failures-fda-safety-communication>



Actions required of you

1. Please immediately determine if any of the affected CustomEyes Procedure Packs are within your facility. In such case, quarantine them, and discontinue use until correct recall labels are applied. Please refer to Appendix 1 – CustomEyes Procedure Packs List.
2. If you have further distributed this product, please notify your customers by initiating a sub-recall. Consider all potential users of this product in your user supply chain. You are encouraged to use a copy of this recall notification letter when contacting your customers.
3. Please follow the attached instructions for placing the recall labels on the products containing Sol-M syringes, which inform the users to not use the affected syringes. If additional recall labels are needed, contact bvi2958@sedgwick.com. Product may be returned to inventory once properly over-labeled. Refer to Appendix 2 – Over labeling Instructions.
4. At the point of clinical use, the Sol-M syringes are to be discarded. Photographs of Sol-M syringes are enclosed to assist in identification. Appendix 3 – Images.
5. Ensure that appropriate personnel within your organization are made aware of this field action.
6. To maintain awareness, we suggest to post this “URGENT MEDICAL DEVICE RECALL NOTICE” and Sol-M syringe photographs on or near the affected products in your inventory location.
7. Please fill out, scan and email the completed Business Response Form to BVI Sedgwick at bvi2958@sedgwick.com within seven (7) days.

BVI is committed to providing high quality products to you and apologizes for any inconvenience this field action may cause. If you have any questions, please reach out to your Sales Representative.

Sincerely,

A handwritten signature in black ink, appearing to read "Agnieszka Drzewiecka".

Agnieszka Drzewiecka
Global Customer Complaints, Vigilance and Post-Market Manager
BVI Medical



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**Please complete and return this Business Response Form
within seven (7) days from the issuance date.**

Please check the appropriate response(s)

STEP 1

I have read the information related to this matter and I have **none** of the affected product on hand at present. I confirm that I have posted this notice in a visible location once future supplies are in our inventory.
[please proceed to Step 2]

or

I have read the information related to this matter and I confirm that I over labelled affect CustomEyes Procedure Packs with the provided label, returned them into inventory and posted the notice near the affected products.

STEP 2

Your company name: _____

Address: _____

BVI Customer Account # (if known) _____

If purchased through a distributor, please let us know the following information

Distributor Name: _____

Telephone: _____

Contact name: _____

Title: _____ Email: _____

Please enter the date you completed this form: ___/___/_____

STEP 3

Please email this completed Response Form to bvi2958@sedgwick.com

****Thank you for your assistance in this matter****



Appendix 1 - Affected CustomEyes Procedure Packs

Part No	Lot/Batch No	UDI	Part No	Lot/Batch No	UDI
584003	6063717	30886158141496	58001315	6071469	30886158023389
584404	6071194	30886158141151	58001331	6069181	30886158023532
584545	6074344	30886158140710	58001338	6074329	30886158023785
584550	6048601	30886158140758	58001373	6058442	30886158024386
584587	6071014	30886158141083	58001373	6064858	30886158024386
584625	6074323	30886158141502	58001374	6062022	30886158031926
584630	6067412	30886158141557	58001375	6058779	30886158024379
584643	6068270	30886158141717	58001376	6062023	30886158031919
584712	6070547	30886158142455	58001376	6064080	30886158031919
584727	6055965	30886158008096	58001380	6071744	30886158023846
584742	6072504	30886158008188	58001382	6068015	30886158024300
584770	6067190	30886158008973	58001382	6071277	30886158024300
584785	6075214	30886158009000	58001382	6073797	30886158024300
58000023	6073123	30886158009253	58001394	6071306	30886158024041
58000056	6065306	30886158008980	58001395	6070544	30886158023815
58000056	6069372	30886158008980	58001411	6064644	30886158023914
58000120	6071452	30886158009512	58001417	6071011	30886158024645
58000126	6061650	30886158009307	58001417	6072526	30886158024645
58000126	6072066	30886158009307	58001423	6062969	30886158024027
58000162	6065820	30886158018675	58001467	6071209	30886158024409
58000162	6071739	30886158018675	58001478	6069663	30886158024317
58000168	6072077	30886158009574	58001484	6061631	30886158024133
58000192	6071161	30886158009963	58001484	6062125	30886158024133
58000195	6071454	30886158009765	58001486	6071440	30886158033746
58000195	6072091	30886158009765	58001486	6074586	30886158033746
58000195	6073548	30886158009765	58001501	6059497	30886158024171
58000266	6073117	30886158009901	58001501	6059849	30886158024171
58000287	6073793	30886158013182	58001503	6069199	30886158024348
58000288	6069388	30886158013496	58001511	6060235	30886158024232
58000305	6060099	30886158013632	58001521	6071460	30886158024690
58000305	6069182	30886158013632	58001526	6070130	30886158031476
58000305	6070757	30886158013632	58001527	6071514	30886158031483
58000404	6073569	30886158018385	58001545	6062861	30886158031995
58000426	6069170	30886158019894	58001545	6064638	30886158031995
58000455	6062130	30886158018644	58001548	6069646	30886158031703
58000477	6072535	30886158019115	58001554	6071824	30886158024553
58000479	6071531	30886158019108	58001568	6059666	30886158024683



58000479	6073788	30886158019108		58001568	6073550	30886158024683
58000501	6073086	30886158019085		58001579	6074019	30886158031575
58000508	6070809	30886158018552		58001602	6064637	30886158032060
58000567	6064890	30886158019306		58001605	6062364	30886158031520
58000568	6069614	30886158020432		58001608	6067129	30886158031537
58000594	6073112	30886158019948		58001609	6064451	30886158031544
58000603	6069800	30886158019436		58001622	6062867	30886158031728
58000628	6069204	30886158019627		58001622	6072189	30886158031728
58000628	6074036	30886158019627		58001624	6064651	30886158031865
58000709	6069363	30886158019955		58001629	6061298	30886158031773
58000711	6073236	30886158020357		58001631	6061721	30886158031780
58000749	6071465	30886158020258		58001634	6073601	30886158031698
58000757	6069002	30886158020265		58001635	6063185	30886158031681
58000757	6071184	30886158020265		58001635	6067384	30886158031681
58000759	6050813	30886158020302		58001637	6064640	30886158031858
58000775	6070132	30886158020319		58001649	6073574	30886158032053
58000781	6056022	30886158020333		58001658	6063718	30886158032091
58000781	6067191	30886158020333		58001658	6065086	30886158032091
58000789	6048500	30886158020395		58001658	6067685	30886158032091
58000789	6049553	30886158020395		58001658	6073791	30886158032091
58000803	6069183	30886158020517		58001691	6063240	30886158032107
58000813	6068010	30886158020524		58001693	6062795	30886158031971
58000813	6075202	30886158020524		58001695	6062796	30886158031957
58000828	6071164	30886158020746		58001699	6071000	30886158031964
58000866	6074581	30886158021132		58001706	6074000	30886158032473
58000867	6054595	30886158020753		58001711	6070885	30886158032442
58000867	6064075	30886158020753		58001711	6074819	30886158032442
58000867	6071826	30886158020753		58001712	6074820	30886158032428
58000867	6075095	30886158020753		58001713	6074823	30886158032428
58000873	6062129	30886158020807		58001721	6063578	30886158032121
58000873	6074045	30886158020807		58001737	6064860	30886158032480
58000910	6062356	30886158021545		58001737	6069172	30886158032480
58000921	6073120	30886158021309		58001753	6074601	30886158032497
58000960	6060636	30886158022122		58001764	6072080	30886158032435
58000985	6072192	30886158021460		58001774	6066202	30886158032886
58001014	6071020	30886158021729		58001775	6067403	30886158032800
58001014	6075094	30886158021729		58001775	6070758	30886158032800
58001019	6069184	30886158022566		58001795	6074613	30886158033340
58001019	6069624	30886158022566		58001809	6071159	30886158032787
58001019	6075235	30886158022566		58001818	6075189	30886158033180

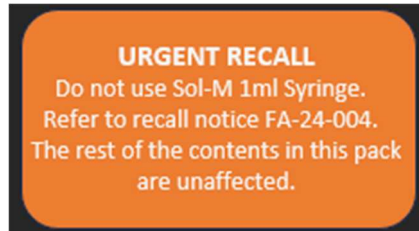


58001020	6068035	30886158022573		58001825	6074001	30886158032893
58001025	6064450	30886158021637		58001836	6066752	30886158032985
58001048	6069190	30886158022344		58001838	6069366	30886158033203
58001054	6071307	30886158022078		58001845	6069639	30886158033210
58001073	6070760	30886158021934		58001865	6069158	30886158033166
58001110	6073585	30886158022177		58001876	6069398	30886158033234
58001113	6069376	30886158023839		58001878	6074027	30886158033678
58001113	6070126	30886158023839		58001928	6074346	30886158033777
58001113	6073273	30886158023839		58001933	6073549	30886158033555
58001118	6070127	30886158022238		58001934	6070801	30886158033562
58001123	6047610	30886158022467		58001943	6071510	30886158033623
58001123	6049448	30886158022467		58001944	6070908	30886158033630
58001123	6050478	30886158022467		58001967	6074600	30886158033715
58001138	6064069	30886158022320		58001970	6074016	30886158033760
58001157	6065072	30886158022931		58001973	6071751	30886158034002
58001174	6068288	30886158022474		58001973	6072074	30886158034002
58001176	6069393	30886158022443		58001999	6072061	30886158034019
58001177	6074599	30886158023822		58002000	6071764	30886158034026
58001200	6068518	30886158022757		58002042	6073501	30886158034309
58001212	6072094	30886158022818		58002063	6074347	30886158034453
58001304	6069386	30886158023778		58002074	6074312	30886158034484
58001305	6070642	30886158023761		58002075	6074313	30886158034460
58001306	6072093	30886158023754		58002078	6074316	30886158034521
58001314	6049642	30886158023440		58002080	6074317	30886158034514



Appendix 2 – Over labeling Instructions

1. Visually verify the recall label is in the following format, containing all details as presented below.



2. If you require additional number of labels, please email: bvi2958@sedgwick.com specifying the required number and providing full postal address.
3. Apply the above label to the top part of each pack. Ensure that one recall label is applied per one procedure pack. Affixed recall label must not cover any labels/information present in a pack.



4. Procedure Packs may be returned to inventory once over labelling has been completed.



Appendix 3 – Photo Examples of Sol-M Syringes

