

ATTENTION: MEDICAL DEVICE VOLUNTARY RECALL

CERTAIN LOTS of TRUEplus® and Store Brand 0.3cc Insulin Syringes

August 31, 2018

Dear Valued Customer:

The purpose of this letter is to inform you that the manufacturer of our TRUEplus® and Store Brand Insulin Syringes has announced a voluntary product recall of a limited number of 0.3cc Insulin Syringe lots distributed in the United States.

Though we have determined that product supplied to you is **NOT** part of this voluntary recall, we want to make you aware and provide you with the following information for your records if needed. If you do find affected product in your inventory, please notify us immediately and follow the directions provided below.

The manufacturer initiating this voluntary recall has determined that certain lots of TRUEplus and Store Brand 0.3cc Insulin Syringes manufactured during a specific timeframe contain a defect in which a small crack in the top end of the barrel near the needle creates the inability to aspirate insulin into the syringe barrel from the insulin vial. Inability to draw insulin into the syringe deems the syringe unusable.

There are 26 affected lots that were manufactured for Trividia Health from April 30, 2018 thru August 21, 2018, of which 3 lots were distributed by Trividia Health for sale in the United States. The other 23 affected lots have been contained and not released in the market. Trividia Health has not received any reports of patient injuries related to this voluntary recall.

This voluntary recall is being conducted by the manufacturer with the knowledge of the Food and Drug Administration. If you have any questions, please call Trividia Health Customer Service Department toll-free at **1-800-588-1685** Monday-Friday 8AM-5PM EST (excluding holidays) or e-mail trividia0818CS@trividiahealth.com.

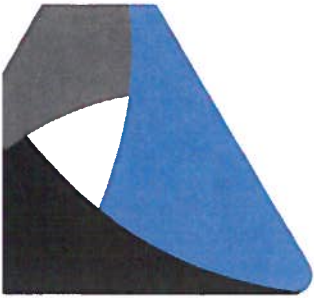
Patient safety is a top priority at Trividia Health and we apologize for any inconvenience this voluntary recall may cause you.

Sincerely,

Trividia Health

If you find you have affected syringes in your facility or within your pharmacies, please follow these instructions below and information requested in Appendix A.

- **Distributors:** Determine whether you have any affected 0.3cc Insulin Syringes in inventory by examining the syringe lot number printed on the syringe outer case/shipper label, on the side of the syringe box or on the syringe 10ct bag. The affected lot numbers are provided in attached Appendix A. If you have any Insulin Syringes with these lot numbers, return the product per your normal return procedures. In addition, please notify your customers of this voluntary product recall. Request that they return Insulin Syringes only with lot numbers identified in this voluntary recall, and then use your normal return procedures including the form in Appendix A. Once you have received all affected product to be returned, please call Trividia Health Customer Service at **1-800-588-1685** Monday-Friday 8AM-5PM EST (excluding holidays) or e-mail trividia0818CS@trividiahealth.com to obtain prepaid return labels and return instructions.
- **Pharmacists/DME Providers:** Determine whether you have any affected 0.3cc Insulin Syringes in inventory by examining the syringe lot number printed on the syringe outer case/shipper label, on the side of the syringe box or on the syringe 10ct bag. The affected lot numbers are provided in attached Appendix A. If you have any product with these lot numbers in inventory or receive any product with these lot numbers from patients, please process the affected Insulin Syringes per your normal return procedures (including the form in Appendix A) or call our Trividia Health Customer Service Department toll-free at **1-800-588-1685** Monday-Friday 8AM-5PM EST (excluding holidays) or e-mail trividia0818CS@trividiahealth.com. Please advise any patients with affected Insulin Syringes to return product directly to your pharmacy, and then follow your normal return procedures. Note that patients may continue to use syringes under these brands for lots not included in this voluntary recall.
- **Health Care Professionals:** Determine whether you or your patients have any affected 0.3cc Insulin Syringes by obtaining the syringe lot number printed on the side of the syringe box or on the syringe 10ct bag. Then call Trividia Health Customer Care Department toll-free at **1-800-588-1685** Monday-Friday 8AM-8PM EST (excluding holidays) or e-mail trividia0818CC@trividiahealth.com to determine if you or your patients have affected product. If you or your facility has affected product, please process the affected Insulin Syringes per your normal return procedures through your distributor (including the form in Appendix A). Please advise any patients with recalled product to contact Trividia Health Customer Care Department toll-free at **1-800-588-1685** Monday-Friday 8AM-8PM EST (excluding holidays) or e-mail trividia0818CC@trividiahealth.com If your patients have any affected syringes, the Trividia Health Customer Care Department will help with return and replacement information. Patients are asked to return the affected syringes directly to their pharmacy or place of purchase for replacement product. Note that patients may continue to use syringes under these brands for lots not included in this voluntary recall.
- **People with Diabetes:** Determine whether you have any affected 0.3cc Insulin Syringes by obtaining the syringe lot number printed on the side of the syringe box or on the syringe 10ct bag. Then call Trividia Health Customer Care Department toll-free at **1-800-588-1685** Monday -Friday 8AM-8PM EST (excluding holidays) or e-mail trividia0818CC@trividiahealth.com to determine if you have affected product. If you have any affected syringes, the Trividia Health Customer Care Department will help with return and replacement information. Return the affected syringes directly to your pharmacy or place of purchase for replacement product. If you do NOT have any affected syringes, you may continue to use syringes under these brands for lots not included in this voluntary recall.



APPENDIX A
MEDICAL DEVICE VOLUNTARY RECALL RETURN RESPONSE
Acknowledgement and Receipt Form – Response Required
CERTAIN LOTS of TRUEplus® and Store Brand 0.3cc Insulin Syringes

I have read and understand the recall instructions provided in the August 31, 2018 letter.
 Yes ___ No ___

Any adverse events associated with recalled product? Yes ___ No ___

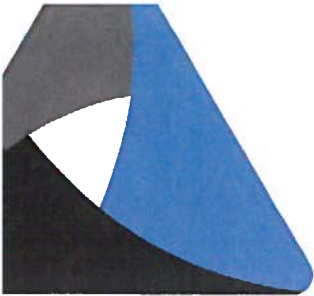
If yes, please explain and provide details to the Trividia Health Customer Care Department via e-mail: trividia0818CC@trividiahealth.com

0.3cc Insulin Syringe Lots: In the chart below please fill in the appropriate quantities next to the corresponding Lot # you have of affected inventory.

Product/ Brand Names	Manufacturer's Product /Catalog Number	Lot Number shipped to Customer	UDI Number	Quantity in inventory	Quantity returned by patients	Quantity being returned to Trividia Health
TRUEplus 0.3cc 29G	S4H01A29-100	NP18196	Bag - (01)00021292005801(17)210722(10)NP18196			
			Box - (01)00021292004972(17)210722(10)NP18196			
			Case - (01)10021292004979(17)210722(10)NP18196			
Leader 0.3cc 31G	S4002A31-100	NP18123	Bag - (01)00021292005863(17)210603(10)NP18123			
			Box - (01)00096295125405(17)210603(10)NP18123			
			Case - (01)50096295125400(17)210603(10)NP18123			
Leader 0.3cc 31G	S4002A31-100	NP18130	Bag - (01)00021292005863(17)210625(10)NP18130			
			Box - (01)00096295125405(17)210625(10)NP18130			
			Case - (01)50096295125400(17)210625(10)NP18130			

Return Response Box:

Please provide any additional information, if applicable.



Distributors:

Please acknowledge the following:

I have checked my stock and have quarantined inventory consisting of _____ (please list the type of Insulin Syringes in quarantine: ie. individual insulin syringes, bags, boxes, or cases)

I have identified and notified all of my customers who were shipped or may have been shipped this product by (specify date _____ and method of notification _____);

Questions: (when applicable)

Please have Customer Service contact me.

Signature of Receipt _____

Name/Title	
Company Name	
Telephone	
Email address	

PLEASE SEND THE COMPLETED RESPONSE FORM TO TRIVIDIA HEALTH CUSTOMER SERVICE DEPARTMENT VIA E-MAIL TO:

trividia0818CS@trividiahealth.com