

February 14, 2019

Urgent: Terumo Medical Corporation/Terumo Medical Canada Inc. Issues Voluntary Recall of Select List of Hypodermic Needles

Dear ASD Healthcare Customer:

Terumo Medical Corporation/Terumo Medical Canada Inc. is initiating a voluntary recall of a select list of hypodermic needles. The affected lot information is listed below.

Terumo initiated this withdrawal as a precautionary measure due to a limited number of complaints related to loss of package integrity that may comprise the sterility of the product.

Terumo provided the following affected lot information:

| Product Description | Lot Number |
|--|------------|
| Terumo Needle · Aiguille 18G x 1" T.W. | 180714C |
| Terumo Needle · Aiguille 18G x 1" T.W. | 180723C |
| Terumo Needle · Aiguille 18G x 1" T.W. | 181011C |
| Terumo Needle · Aiguille 21G x 1" T.W. | 180712C |
| Terumo Neolus Needle 22G x 1 | 181022C |
| Terumo Needle · Aiguille 23G x 1" T.W. | 180811C |
| Terumo Needle · Aiguille 23G x 1" T.W. | 180929C |
| Terumo Needle · Aiguille 23G x 1" T.W. | 181013C |
| Terumo Needle · Aiguille 23G x 1" T.W. | 181115C |
| Terumo Needle · Aiguille 30G x 1/2" R.W. | 181005C |
| Terumo Needle · Aiguille 30G x 1/2" R.W. | 181113C |

There have been no reports of serious injury or infection to date. **To reduce any risk, we ask for your cooperation in taking the following action:**

- **Review your Terumo Hypodermic Needle inventory** immediately to identify and isolate affected inventory in order to prevent future use.
- **Complete the Recall Acknowledgement Form (see the full recall notice on the following pages)** and provide a copy with your returned product.
- **Use ASD Healthcare's online [Request a Return](#) tool to begin the return process.** A return label and further return directions will then be provided.
- Arrange for product to be returned to ASD Healthcare.

For the full recall notice and acknowledgement form, please view the attached documents in the following pages.

If you have any questions or concerns, please contact ASD Healthcare's customer service at **800.746.6273**.

Urgent Voluntary Medical Device Recall

Terumo® Hypodermic Needles

February 14, 2019

Dear ASD Healthcare Customer:

This letter is to notify you of Terumo Medical Corporation/Terumo Medical Canada Inc.'s voluntary recall of a select list of hypodermic needles due to a limited number of complaints related to loss of package integrity that may compromise the sterility of the product. Terumo is committed to ensuring that all our products meet the highest standards of quality and take matters such as this very seriously.

PRODUCT DETAILS

Lot Numbers: Refer to Table 1

No other Hypodermic Needles are affected by this action. Please ensure only affected product is returned.

Our records indicate that you may have received some of the affected lots of product through distributor ASD Healthcare. There have been no reports of serious injury or infection to date. To reduce any risk, we ask that you immediately discontinue use of the affected lots.

- 1. Review your Terumo Hypodermic Needle inventory immediately to identify and isolate affected inventory in order to prevent future use.**
- 2. Complete the enclosed Recall Acknowledgement Form and provide a copy with your returned product.**
- 3. Use ASD Healthcare's Request a Return tool to begin the return process. A return label and further return directions will then be provided.**
- 4. Arrange for product to be returned to ASD Healthcare.**

Our customers are our top priority and we want to ensure they have a high-quality product which meets their daily needs. We greatly appreciate your understanding and prompt assistance and apologize for any inconvenience this may have caused.

Please contact ASD Healthcare's customer service with any questions or concerns regarding this process: **800.746.6273**.

Sincerely,

Terumo Medical Corporation

Table 1: Affected Lot

| Item Code | Lot No. | Description |
|-----------|---------|---|
| NN1825R | 180714C | Terumo Needle· Aiguille 18G x 1" T.W. |
| NN1825R | 180723C | Terumo Needle · Aiguille 18G x 1" T.W. |
| NN1825R | 181011C | Terumo Needle· Aiguille 18G x 1" T.W. |
| NN2125R | 180712C | Terumo Needle · Aiguille 21G x 1 " T.W. |
| NN2225R | 181022C | Terumo Neolus Needle 22G x 1 " |
| NN2325R | 180811C | Terumo Needle· Aiguille 23G x 1" T.W. |
| NN2325R | 180929C | Terumo Needle· Aiguille 23G x 1" T.W. |
| NN2325R | 181013C | Terumo Needle· Aiguille 23G x 1" T.W. |
| NN2325R | 181115C | Terumo Needle· Aiguille 23G x 1" T.W. |
| NN3013R | 181005C | Terumo Needle· Aiguille 30G x 1/2" R.W. |
| NN3013R | 181113C | Terumo Needle· Aiguille 30G x 1/2" R.W. |



Recall #: 4998

Recall Acknowledgement Form
Terumo® Hypodermic Needles

«Customer Name»
«Account#»

This is to acknowledge receipt of the above referenced recall notification dated 2.14.19.
We received the following lots affected by the recall:

| Item Code | Lot No. | Description | Quantity to be Returned (eaches) |
|-----------|---------|-------------|----------------------------------|
| | | | |

I hereby certify that I have reviewed the table of affected product and confirm we have quarantined the annotated product lots and quantities. I have contacted ASD Healthcare to arrange for the product return.

Date

Name (Print)

Account Number

Signature

Facility Name

Telephone Number

Please place a copy of this completed form in any return product shipment to ASD Healthcare.