

## URGENT FIELD SAFETY NOTICE

### Teosyal® Ultimate and Teosyal® PureSense Ultimate AST-1601

Dear Customer,

This communication provides you with some information regarding a voluntary Field Safety Corrective Action that TEOXANE is conducting on a limited number of Teosyal® Ultimate and Teosyal® PureSense Ultimate products.

#### Which situation was reported?

An internal audit has shown that we have released three batches of Teosyal® Ultimate and Teosyal® PureSense Ultimate products with needles expiring three to seven months before the expiry date indicated on the product packaging.

We have conducted a risk analysis of the situation, and we do not anticipate any safety concerns with those products. However, because we cannot guarantee the continued sterility of the needles beyond their expiry date as marked by the needles' manufacturer, we made the decision to conduct this Field Safety Corrective Action.

#### Which batch numbers are concerned?

The following three product batches are concerned by this Field Safety Corrective Action:

Batch #	Serial #	Product	Expiry Dates	
			Syringe	Needles
TST-142103	All	Teosyal® Ultimate	2016-05-31	2016-02-29
TSTL-143902	All	Teosyal® PureSense Ultimate	2016-09-30	2016-02-29
TSTL-154704	TSTL-1547045xxx TSTL-1547046xxx TSTL-1547047xxx	Teosyal® PureSense Ultimate	2017-11-30	2017-06-30

#### Am I affected by this issue?

You are receiving this Field Safety Corrective Action because our records show that you purchased products from the above-mentioned batches.

#### What should I do?

If the products that you received have already been used, then there is nothing more to do from your side. As indicated above, we do not anticipate any safety concerns resulting from using the needles provided with the products.

If you still have the products, please contact TEOXANE's Authorized Distributor for information about returning the products for replacement.

We would like you to confirm to your Authorized Distributor the quantity purchased and whether the products have already been used.

**Transmission of this Field Safety Notice:**

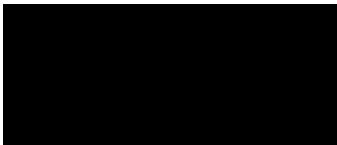
This notice needs to be forwarded to all those who need to be aware within your organisation or to any organisation where the devices have been delivered.

If you have any questions regarding this notification, please contact PARVUS at 00603.7665.3382.

The undersigned confirms that the appropriate Regulatory Agencies have been notified.

Sincerely,

TEOXANE S.A.



Olivier Anki  
Director, Quality & Regulatory Affairs