



SCIENT'X

DYNAMIC SOLUTIONS FOR THE SPINE

10000 Boulevard de la Vallée
Bellefleur, Québec
G3H 5K7
Canada
Téléphone : (418) 833-1111
Fax : (418) 833-1112
E-mail : info@scientx.com

[REDACTED]

July 7, 2009.

Object: Isobar TTL - Module In polyaxial screws recall notification

References: 12VTLPXX-XX -inner nut polyaxial screws

Letter Ref.: **Recall_12VTLP_062009**

Dear Mr. [REDACTED]

Scient'x, a Manufacturer of medical devices for spinal surgery, has voluntary initiated recall of certain lots of **Isobar TTL - Module In polyaxial screws** (references 12VTLP_) due to potential risk of TTL In pedicle screw disassembly intraoperatively. This voluntary recall is performed with notification and approval of country National Competent authorities AFSSAPS.

This potential risk **does not concern** inner nut monoaxial screws of Isobar TTL - Module In family (references 12VTLM_).

You will find enclosed the list of references, lots numbers and quantities concerned by this recall procedure Ref. **Recall_12VTLP_Listing**. **This document indicates the precise list of devices shipped (sales and/or consignment) to your company.**

Scient'x has received several complaints where a TTL IN pedicle screw disassembled intraoperatively. The TTL IN pedicle screw ref. 12VTLPXX-XX is composed of three parts:

- The bone screw,
- The screw head,
- The washer.

It was determined that the screw head can potentially be disassembled when pressure is applied to the head when the screwdriver is not properly engaged with the head of the screw during repositioning or replacement of the incorrectly positioned screw.

It is not possible to inadvertently disassemble the TTL IN polyaxial pedicle screw if the insertion screwdriver is properly secured to the device.

To date no reports of clinical complication have been reported to Scient'x.

The potential disassembly of the polyaxial screw does not affect the safety of devices implanted once the polyaxial mechanism locked.



SCIENT'X

DYNAMIC SOLUTIONS FOR THE SPINE

Our records show that some parts concerned by this voluntary recall procedure have been shipped to your company. In accordance with National Competence authorities, we ask you to:

- Identify and recall the parts on consignment on your market,
- Identify and segregate all concerned parts of your inventory,
- Inform concerned hospitals of this procedure,
- Complete the enclosed information document ref. "Recall_12VTLP_062009" and send it by fax as soon as possible to [REDACTED] (fax# +33 130 43 82 77)

Once this document is received, we will contact you to arrange the return of the devices concerned.

We apologize for the inconvenience caused by this product recall, and thank you for your attention to this request.

Scient'x is dedicated to continuously providing spinal products that exhibit the highest standards of Quality and Safety for patients and users.

Very Best Regards,

[REDACTED]
Quality & Regulatory Affairs Manager

Enclosed:
Recall_12VTLP_062009
Rappel_12VTLP_Listing

To the attention of Charles Alban Grandière - SCIENT'X

Customer	████████████████████
----------	----------------------

Part Number	Lot Number	Sold Quantities	Consigned Quantities	Returned Quantities
12VTLP62-50	934R	4		

Date:	Name : Titlle: Signature:	Stamp of the company:

Isobar™ TTL – Module In

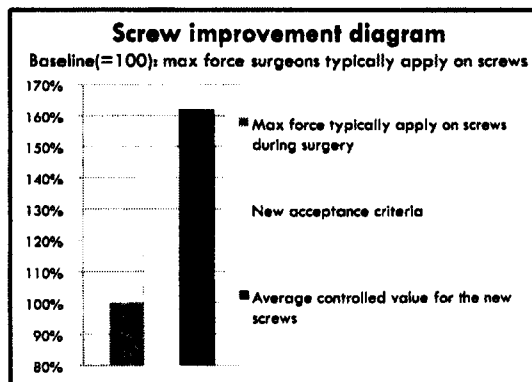
INFORMATION ABOUT THE PRODUCT RECALL

Six complaint reports have been reported to Scient'x concerning the intra-operative disassembly of the poly axial screw (12VTLPx-xx uniquely). None of these situations resulted in any clinical consequences for the operated patients. However, the company elected to notify Afssaps, and chose then to go forward with a recall of some lot numbers. The recall actions will follow a regulatory process: information will be sent to your centers and partners. Additionally, Afssaps will post it on their website.

Why the company choose to recall this product

The poly axial screw is composed of 3 parts: the tulip head, the bone screw and the washer that locks the head mobility once the construct has been tightened by the set screw. In order to maintain this washer in place, a **caulking process** has been designed. The only function of the caulking is to maintain the washer in the tulip head before and during the surgery (prior to inserting the rod). After the surgery, the position of the washer is maintained by the rod and the set screw. The status of the caulking has no effect postoperatively on the mechanical integrity of the pedicle screw and durability of the construct.

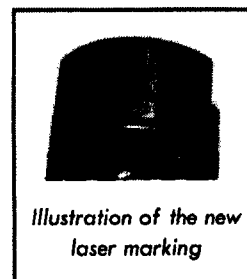
In all cases, **inappropriate use** of the screwdriver (22TRV31) was the root-cause of the disassembly. Scient'x has validated a **significantly improved manufacturing process** that produces a caulking the strength of which **exceeds by far** the maximum force surgeons typically apply to the screw head during surgery. Nevertheless, under no circumstances should the insertion screwdriver (22TRV31) be utilized for removing or repositioning a poly axial screw (as stated in the Product Bulletin #001 and the new surgical technique).



Field actions

The manufacturing of screws produced by the new caulking process has been accelerated in order to support the expedient replenishment of screws in the field. A regulatory communication along with a **sales circular note** have been forwarded to our distributors and hospitals explaining the exchange policy.

As stated in the regulatory communication, a list of screw lot numbers should be sent back to Scient'x. In order to easily identify the new screws that will be shipped to the field, an additional laser marked character has been placed on the tulip head. Specifically, we have added a dark dot to the right of the "X" logo. Additionally, all new screws will have new lot numbers.



Important: a new Surgical Technique (Version 2.0 June 09) has been validated. All previous versions (whether printed or electronic) must be withdrawn from the field and replaced by this one. The new version is enclosed with this communication and hard copies can be requested from the Marketing Department.

Contact Information:

SCIENT'X S.A.
Bâtiment Calypso – Parc Ariane 3
5, rue Alfred Kastler
78280 Guyancourt France
TL +33 (0)1 39 30 69 30
FX +33 (0)1 30 43 82 77
www.scientx.com – info@scientx.com

