

URGENT FIELD SAFETY NOTICE

Yukon® 120mm Straight Rod

**Attn: Attn: Quality or Materials Manager/
Inventory Contacts
Recall Number: RA2022-3015837
June 14, 2022**



Product affected

Catalog number	GTIN	Product description	Lot number(s)	Distribution dates
7601-540120	10888857363804	Yukon Straight Rod 120mm	Starting with PCMW	11/24/2021 to 3/14/2022

Product description

The Yukon Straight Rods are part of the Yukon™ Spinal System, a posterior (cervical/thoracic) spinal fixation system which consists of pedicle screws, rods, hooks, rod connectors and occipital fixation components. The Yukon Straight Rods are made of Titanium Alloy and are offered in 80, 120 and 240 mm lengths and Ø3.5mm and Ø4.0mm diameters.

Product issue

Stryker initiated the removal of a single lot (Lot PCMW) of 120mm Yukon Straight Rods (Cat # 7601-540120) from the market following discovery of discoloration on some of the rods in this lot located in finished goods inventory. Chemical evaluation of the surface of some of these rods indicated the presence of trace amounts of inorganic phosphorous compound.

No adverse events have been reported for this issue.

Potential risks

The trace amount of the phosphorus on the nonconforming rods may produce a mild irritating or inflammatory response. Adverse local tissue reactions (ALTR) may occur related to cytotoxicity with the nonconforming rod and surrounding tissue.

Actions needed

Our records indicate a 120mm Yukon Straight Rod from catalog no. 7601-540120 Lot PCMW was/were previously distributed directly to your facility.

1. **Immediately check your internal inventory and quarantine all subject devices pending return to Stryker.**
 - a. Circulate this Field Safety Notice internally to all interested/affected parties.
2. Inform Stryker if any of the subject devices have been distributed to other organizations.
 - a. Please provide contact details so that Stryker can inform the recipients appropriately.
 - b. If you are a Distributor, note that you are responsible for notifying your affected customers.
3. Please inform Stryker of any adverse events concerning the use of the subject devices.
 - a. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
4. **Complete the attached customer response form.** It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter.
 - a. Therefore, **please complete even if you no longer have any of the subject devices in your physical inventory.**
5. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA

We request your support in finalizing the required steps within 14 calendar days from the date of receipt. Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: _____ **Position:** _____ **email:** _____

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker, we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Sincerely,

XXXXXXXX XXXXXXXX
RAQA Specialist

Business Reply Form

RA2022-3015837- Yukon® 120mm Straight Rod

June 14, 2022

Catalog number*	Product	Lot number	Quantity of lot starting with PCMW identified in each set (If no Lot PCMW rod identified, please enter 0 (zero)).	Quantity of lot starting with PCMW implanted
Cat. no. 7601-540120	Yukon® Straight Rod Ø4.0x120mm	Starting with PCMW		

- If you no longer have affected product on hand, please check here.
- Please state disposition of product no longer on hand: _____

Customer information

Customer name _____

Name of person completing this form _____ Title _____

Direct phone # _____ Email _____

Address _____ City _____ State _____ Postal code _____

Country _____

If you have further distributed any affected product, please indicate to whom:

Product(s) distributed		Quantity distributed	
Facility name		Contact person	
Full address			

Your signature indicates that you have read and acknowledge the purpose of this notification.

Name (print) _____ Signature _____ Date _____

Return completed Business Reply Form to xxxxx@stryker.com.