
Urgent Field Safety Notice

MEDICAL DEVICE RECALL

8mm Vector TAS Screws Recall Due to Manufacturing Error

1 August 2013

Dear Valued Customer:

Ormco BV Europe is voluntarily recalling one (1) lot of **8 MM Vector TAS Screws** which may have been shipped to your office between December 2011 and July 2013.

The following table lists the lot number included in the scope of this notification.

Product	Part Number	Lot Numbers
8 MM Vector TAS Screw	601-0021	112911
Vector TAS Starter Kit (10 Patient)	601-0010	112911 (8 MM Screws from within the kit)

Description of the problem:

We are requesting return of the product because we have found that some screws in this lot were machined undersized at the top of the threads may potentially cause a weakening of the screw. Use of the undersized product may result in breakage of the screw during insertion or removal when torqued, possibly requiring surgical removal of any remaining pieces.

Doctors should note the following statement:

Authorized Ormco Distributors, please inform your end-users of the following statement:

If the affected 8 MM screw is believed to already be placed or in treatment, proceed with the treatment. When ready for removal, take special care removing the screw and do not over-torque it upon removal.

Advise on action to be taken by the user:

Please review the table above to determine if you have any of the affected product in your inventory. If you have any of the affected product listed above, **please contact Ormco BV Europe Customer Care at +31-33- 4536161 to make arrangements for return and replacement.**

ORMCO BV EUROPE KINDLY REQUESTS YOUR COOPERATION IN COMPLETING AND FAXING BACK THE ENCLOSED REPLY FORM IN ORDER TO CONFIRM YOUR RECEIPT OF THIS RECALL NOTIFICATION, REGARDLESS OF WHETHER YOU HAVE ANY PRODUCT IN YOUR INVENTORY.

ORG1306



If you are an authorized Ormco international distributor, we request that you identify those customers that may have been shipped the affected product and contact these customers within forty-eight (48) hours of receipt of this notification in order to inform them of this issue, retrieve their affected product and ***relay the special instructions regarding placement and/or removal of the affected screw.***

This recall is being conducted in cooperation with EU competent authorities for Ormco's authorized representative and in the countries where this FSCA is has been reported.

Ormco BV Europe sincerely apologizes for the inconvenience this situation causes you and your customers.

Thank you for your patience and support.

Sincerely Yours,



Wendy Garman
Director, Regulatory Affairs



RECALL ACKNOWLEDGEMENT FORM

Product Description

8mm Vector TAS Screw

Product	Part Number	Lot Numbers
8 MM Vector TAS Screw	601-0021	112911
Vector TAS Starter Kit (10 Patient)	601-0010	112911 (8 MM Screws from within the kit)

We acknowledge receipt of the 8 MM Vector TAS Screw Recall Notification. We have checked our inventory and were able to locate one or more of the above-mentioned product. We will be returning the product to Ormco Corporation.

Authorized Ormco Dealers: Additionally, we acknowledge that we will identify those customers that may have been shipped the affected product lot and contact these customers within forty-eight (48) hours of receipt of this notification in order to inform them of this issue, recover their affected product and **relay the special instructions regarding placement and/or removal of the affected screw.**

Part Number	Lot Number	Quantity being returned

We acknowledge receipt of the 8 MM Vector TAS Screw Recall Notification. We have checked our inventory and were unable to locate any of the above-mentioned product.

Authorized Ormco Dealers: Additionally, we acknowledge that we will identify those customers that may have been shipped the affected product lot and contact these customers within forty-eight (48) hours of receipt of this notification in order to inform them of this issue, recover their affected product and **relay the special instructions regarding placement and/or removal of the affected screw.**

Contact Person (Please Print)

Facility

Signature

Date

Please fax this form to the following number:
+31-33-4559457

