



URGENT: FIELD SAFETY NOTICE
FSCA 3008524126-10/29/2013-002-R

October 31, 2013

Dear Distributor/Hospital,

Orthofix is conducting a **Field Safety Corrective Action** relevant to the following medical device:

Azure Anterior Cervical Plate System
Anterior Cervical Plates
(86-01xx, 86-02xx, 86-03xx, 86-04xx, 86-05xx)

There is a possibility that the locking mechanism of the Azure Anterior Cervical Plate may fracture during or after implantation. This fracture may present a risk to the patient of screw back out and migration with subsequent esophageal injury and/or loss of fixation, instability and non-union.

Our records indicate that you have received affected Azure Anterior Cervical Plates. Please discontinue use of these products immediately.

Immediate Action:

1. Immediately cease any further distribution of the AZURE™ plates.
2. Notify your surgeons and staff customers that Azure™ plates cannot be used and are to be returned to Orthofix Inc. at no cost to you, see Instructions below.
3. Please complete the attached Tracking & Verification form indicating that you have received this letter. It can be returned by email or fax to the contact person on the attached form. This will prevent you from receiving multiple notifications.

Subsequent Distribution: If your firm has provided or sold the affected products identified above to other users, please provide a list of those users to the undersigned and forward this notification to them to assure prompt action.

Credit will be issued upon Orthofix's receipt of the returned product.

Product Return Instructions: To return the Azure plates, please follow these instructions:

1. Check your inventory of Azure Implant Trays 86-0001.
2. Complete the attached form with the quantity you are returning.
3. Contact your local Orthofix representative or Orthofix customer service representative at 214-937-2000 for return instructions and shipment information and replacement with a different Orthofix Anterior Cervical Plate System.

We request your complete cooperation in assisting us with this removal. The actions listed in the enclosed Product Return Instructions are to be taken immediately.

