



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.

If you have any questions regarding the removal and return of this product to Orthofix, please contact Orthofix Customer Service by telephone at 214-937-2000.

Should you have any other questions or concerns, please contact [REDACTED] Vice President of Quality and Regulatory Affairs, by telephone at [REDACTED] or by e-mail at [REDACTED]@Orthofix.com or [REDACTED] Sr. Regulatory Affairs Specialist by telephone at [REDACTED] or by e-mail at [REDACTED]@orthofix.com. Thank you for your assistance with this matter.

This Field Safety Notice has been provided to the appropriate competent authorities.

[REDACTED]
Group Product Manager, Cervical
Cell Phone: [REDACTED]
Office Line: [REDACTED]
Email: [REDACTED]@orthofix.com
Customer Service: 888-298-5700

List of Affected AZURE ACP Plates: Part & Lot Numbers

Part No.	Lot(s)	Part Description
86-0118	All lots	1 Level Plate 18mm
86-0119	All lots	1 Level Plate 19mm
86-0120	All lots	1 Level Plate 20mm
86-0122	All lots	1 Level Plate 22mm
86-0124	All lots	1 Level Plate 24mm
86-0126	All lots	1 Level Plate 26mm
86-0128	All lots	1 Level Plate 28mm
86-0130	All lots	1 Level Plate 30mm
86-0132	All lots	1 Level Plate 32mm
86-0134	All lots	1 Level Plate 34mm
86-0136	All lots	1 Level Plate 36mm
86-0230	All lots	2 Level Plate 30mm
86-0232	All lots	2 Level Plate 32mm
86-0236	All lots	2 Level Plate 36mm
86-0238	All lots	2 Level Plate 38mm
86-0240	All lots	2 Level Plate 40mm
86-0242	All lots	2 Level Plate 42mm
86-0244	All lots	2 Level Plate 44mm
86-0246	All lots	2 Level Plate 46mm
86-0448	All lots	2 Level Plate 48mm
86-0250	All lots	2 Level Plate 50mm
86-0252	All lots	2 Level Plate 52mm
86-0254	All lots	2 Level Plate 54mm
86-0350	All lots	3 Level Plate 50mm
86-0352	All lots	3 Level Plate 52mm
86-0354	All lots	3 Level Plate 54mm
86-0356	All lots	3 Level Plate 56mm
86-0358	All lots	3 Level Plate 58mm
86-0360	All lots	3 Level Plate 60mm
86-0362	All lots	3 Level Plate 62mm
86-0364	All lots	3 Level Plate 64mm
86-0366	All lots	3 Level Plate 66mm
86-0368	All lots	3 Level Plate 68mm
86-0370	All lots	3 Level Plate 70mm
86-0372	All lots	3 Level Plate 72mm
86-0374	All lots	3 Level Plate 74mm
86-0376	All lots	3 Level Plate 76mm
86-0378	All lots	3 Level Plate 78mm
86-0380	All lots	3 Level Plate 80mm
86-0382	All lots	3 Level Plate 82mm
86-0384	All lots	3 Level Plate 84mm
86-0386	All lots	3 Level Plate 86mm
86-0388	All lots	3 Level Plate 88mm
86-0464	All lots	4 Level Plate 64mm

Part No.	Lot(s)	Part Description
86-0466	All lots	4 Level Plate 66mm
86-0468	All lots	4 Level Plate 68mm
86-0470	All lots	4 Level Plate 70mm
86-0472	All lots	4 Level Plate 72mm
86-0474	All lots	4 Level Plate 74mm
86-0476	All lots	4 Level Plate 76mm
86-0478	All lots	4 Level Plate 78mm
86-0480	All lots	4 Level Plate 80mm
86-0484	All lots	4 Level Plate 84mm
86-0488	All lots	4 Level Plate 88mm
86-0492	All lots	4 Level Plate 92mm
86-0496	All lots	4 Level Plate 96mm
86-0400	All lots	4 Level Plate 100mm
86-0404	All lots	4 Level Plate 104mm
86-0408	All lots	4 Level Plate 108mm
86-0412	All lots	4 Level Plate 112mm
86-0416	All lots	4 Level Plate 116mm
86-0420	All lots	4 Level Plate 120mm
86-0580	All lots	5 Level Plate 80mm
86-0585	All lots	5 Level Plate 85 mm
86-0590	All lots	5 Level Plate 90 mm
86-0595	All lots	5 Level Plate 95 mm
86-0500	All lots	5 Level Plate 100 mm
86-0505	All lots	5 Level Plate 105 mm
86-0510	All lots	5 Level Plate 110 mm
86-0515	All lots	5 Level Plate 115 mm
86-0520	All lots	5 Level Plate 120 mm
86-0525	All lots	5 Level Plate 125 mm