stryker

URGENT:
FIELD SAFETY NOTICE

CLAW™ II 4 Hole Plate / DARCO® Locking Screw

Attn: Risk Management, Distributors

Recall Number: PFA 2856919

<Month DD, YYYY/ DD Month YYYY>

Product affected

Catalog number	GTIN	Product description	Lot number(s)	Distribution Dates
40240430	00840420110725	CLAW™ II ORTHOLOC™ 3DSi 4 Hole Plate	1642103	Dec 2018 – Jan 2020
DC2825016	00840420101525	DARCO® Locking Screw OD: 2.7mm L: 16mm	1643355	Jan 2019 – Jul 2021

Dear Customer,

The purpose of this notification is to advise you that Stryker (Trauma & Extremities/ Wright Medical Division) is conducting a voluntary recall regarding specific lots for CLAW™ II 4 Hole Plates and DARCO® Locking Screws. Please refer to the table above for catalogue and lot numbers that were identified as shipped to distributors and end users.

Product description

-The CLAW™ II Polyaxial Compression Plating System consists of plates and screws of various anatomic configurations and lengths. All plates and screws are manufactured from implant grade stainless steel. The plates accept 2.7mm and 3.5mm ORTHOLOC™ 3DSi locking screws.
-The DARCO® Locking Bone Plate System is designed with rhombus (parallelogram) plates of biocompatible titanium. The plates use either 2.7mm or 3.5mm screws which intersect each other in pairs.

Product issue

This letter is to inform you of a medical device recall regarding two specific lots for the CLAW™ II 4 Hole Plates and DARCO® Locking Screws. Subsequent to receiving a non-conforming event report, an internal investigation was conducted and confirmed that two specific lots of CLAW™ II 4 Hole Plates and DARCO® Locking Screws contain the incorrect product in the package. The CLAW™ II 4 Hole Plates contain DARCO® Locking Screws and vice versa. Therefore, Wright Medical, the manufacturer of the CLAW™ II 4 Hole Plates and DARCO® Locking Screws, initiated this voluntary recall (Wright Medical is a wholly owned subsidiary of Stryker).

Potential risks

The incorrect plates and screws found within the packaging of products emanating from these two lots is highly detectable. If during the surgery the mix-up is noticed, the potential harm is prolongation of surgery. However, in the unlikely event that the mix-up is not noticed potential harm could lead to a change of surgical method.

Actions to be taken by the Customer/User:

Our records indicate that you may have received one or more of the subject devices. It is Stryker's responsibility, and Wright Medical, as the manufacturer to ensure that customers who may have received these affected products also receive this important communication. We therefore request that you read this notice carefully and complete the following actions.

1. Inform individuals within your organization who need to be aware of this device recall.
2. Immediately check your internal inventory to locate **the packaged** product listed on the attached business reply form and remove them from their point of use.
3. Immediately check all stock areas and/or operating room storage to determine if any devices from the affected product list are at your facility. Response is required, even you may not have any physical inventory on site anymore.
4. Quarantine and discontinue use of the recalled devices.
5. Upon receipt of the completed business reply form, Stryker Representative will contact you to arrange for the return and replacement of your product(s).
6. Maintain awareness of this notice internally until all required actions have been completed within your facility.
7. 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.
8. 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.
9. Complete the attached customer response form (acknowledgement 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. Therefore, please complete even if you no longer have any of the subject devices in your physical inventory.
10. Return the completed form to your nominated Stryker Representative (indicated below) for this Action.

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.

We request that you **respond to this notice within 7 calendar days** from the date of receipt.
We appreciate your cooperation, and we recognize the inconvenience this may cause your facility.

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
Telephone
Fax

We would like to reassure you that Wright Medical and Stryker are committed to ensuring that only conforming devices, meeting our high internal quality standards and your expectations, remain on the market.

Sincerely,

stryker

Business Reply Form

Account number:
Account name:
Account Address:

CLAW™ II 4 Hole Plate / DARCO® Locking Screw

Recall Number: PFA 2856919

<Month DD, YYYY/ DD Month YYYY>

Please complete and sign this form. Email the completed form XXX@stryker.com by **<MMM DD YYYY>**.

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

Catalog number	Product	Serial/Lot number(s)	Quantity on hand*	Quantity confirmed implanted
40240430	CLAW™ II ORTHOLOC™ 3DSi 4 Hole Plate	1642103		
DC2825016	DARCO® Locking Screw OD: 2.7mm L: 16mm	1643355		

*If all devices have been used and no affected devices are available for return, please enter 0 (zero).

Form completed by:

Printed Name		**Title**	
Signature		**Phone**	
Date		**Email**	

If you have further distributed any affected product, please indicate the quantities below:

Product(s) Distributed		**Quantity** Distributed	
Facility Name		**Contact Person**	
Full Address			

Attachment 1: Example Labels of Affected Products