

May 2018

URGENT Field Safety Notice: #1739180

FSCA identification: Product recall PFA#1739180

Action type: Field Safety Corrective Action: Recall

Legal Manufacturer: Stryker Leibinger GmbH & Co. KG, Boetzingenstrasse 41,
79111 Freiburg, Germany

Description: QuikFlap Neuro Implants: potential for compromised sterile barrier

Catalogue Numbers: see attached list

Lot Number: see attached list

Dear Customer:

Stryker Leibinger GmbH & Co KG, Division Craniomaxillofacial, has initiated a Product Field Action for the devices identified above. The purpose of this letter is to list the hazards potentially associated with the Product Field Action.

Issue

During laboratory testing, Stryker became aware that for products of more than 3 years of shelf life there is a potential for the peel pouch (sterile barrier) to become compromised due to transportation forces. A compromised sterile barrier could result in the surgeon selecting a back-up device or, if not recognized, an unintended implantation of a potentially non-sterile device.

Potential Hazards

A compromised sterile barrier could potentially cause:

- Additional time under anesthesia due to prolongation of surgery
- Implantation of potentially non-sterile device

Mitigating Factors

- The initial sterilization remains effective
- Per the IFU, 'Sterile products are sterile only if the package is not damaged or opened.'
Compromised packaging results in the loss of vacuum inside the peel pouch.
- A breach of the outer peel pouch has been only seen on packages at shelf life end after 5 years and after an excessive transportation testing.
- Packaging evaluations reveal that a contamination due to the described issue is considered unlikely. Any contaminate to remain viable and cause infection would require several unfavorable circumstances to occur.

Type of Action

Recall of subject devices

Immediate Action

Our records indicate that you may have received one or more of the subject devices. It is Stryker's responsibility 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. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker.
2. Circulate this Field Safety Notice internally to all interested/affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Inform Stryker if any of the subject devices have been distributed to other organisations.
 - 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.
5. Please inform Stryker of any adverse events concerning the use of the subject devices.
6. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
7. 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. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.
8. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA
 - a) On receipt of the form, a Stryker Representative will contact you to organise any applicable ongoing actions.

We request that you respond to this notice within 07 calendar days from the date of receipt. The target date for completion of this action is 29 June 2018 and your timely response will enable us to ensure that we meet this target.

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: Nina Goddard
Position: RAQA Specialist
Telephone: 01635 262 476
E-mail: nina.goddard@stryker.com



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.

Yours faithfully,

A handwritten signature in blue ink, appearing to read "ngoddard".

Nina Goddard
Regulatory Affairs and Quality Assurance

PFA #1739180: Affected products

Product code	Product description	Affected lot numbers
12-01520S	QUIKFLAP, 3 X 2-HOLE DOG BONE PLATES WITH 1.5X4MM SELF DRILLING SCREWS	1000085083, 1000089303, 1000089990, 1000095193, 1000100539, 1000104523, 1000107792, 1000110518, 1000116215, 1000124115, 1000129492, 1000134144, 1000139985, 1000146194, 1000151496, 1000156358, 1000164801, 1000167015, 1000170704, 1000174837, 1000178195, 1000181123, 1000183608, 1000188543, 1000192851, 1000197301, 1000209029, 1000219395, 1000221066, 1000237512, 1000239649, 1000240995, 1000251376, 1000259411, 1000275865, 1000286361, 1000290245,
12-01521S	QUIKFLAP, 3 X 2-HOLE DOG BONE PLATES WITH 1.5X4MM SELF TAPPING SCREWS	1000193584
12-01522S	QUIKFLAP, 3 X 2-HOLE PLATES WITH TAB, 1.5X4mm SELF DRILLING SCREWS	1000096159, 1000096935, 1000096936, 1000097334, 1000097915, 1000101820, 1000109424, 1000115216, 1000119029, 1000125079, 1000125080, 1000130030, 1000136426, 1000141584, 1000147073, 1000151497, 1000156030, 1000157137, 1000162227, 1000163908, 1000167016, 1000169751, 1000176390, 1000178196, 1000181747, 1000184371, 1000186595, 1000187362, 1000191062, 1000193585, 1000194476, 1000199414, 1000205660, 1000210937, 1000211803, 1000212626, 1000214335, 1000222495, 1000233193, 1000239650, 1000247182, 1000256556, 1000266164, 1000270836, 1000277104, 1000283590, 1000287393, 1000294080, 1000086193, 1000298088
12-01524S	QUIKFLAP, 1X14MM BURR HOLE COVER, 2 X 2-HOLE PLATES, 1.5X4mm SELF DRILLING SCREWS	1000225769, 1000239651, 1000254801
12-01526S	QUIKFLAP, 1X20MM BURR HOLE COVER, 2 X 2-HOLE PLATES, 1.5X4mm SELF DRILLING SCREWS	1000213465, 1000239652, 1000245174, 1000255707,
12-01528S	QUIKFLAP, 1X14MM BURR HOLE COVER, 1.5X4mm SELF DRILLING SCREWS	1000221067, 1000239653, 1000245175, 1000261686
12-01530S	QUIKFLAP, 3 X 2-HOLE DOG BONE PLATES WITH 1.5X4MM SELF DRILLING SCREWS	1000107793, 1000107794, 1000107795, 1000111407, 1000113293, 1000119681, 1000119682, 1000124116, 1000130031, 1000134145, 1000139203, 1000141585, 1000148808, 1000150571, 1000156031, 1000159892, 1000166365, 1000168534, 1000169198, 1000170705, 1000171359, 1000174838, 1000176391, 1000183609, 1000188544, 1000189237, 1000191063, 1000193586, 1000195789, 1000202429, 1000215159, 1000217674, 1000220165, 1000224225, 1000231906,

		1000233773, 1000236827, 1000239654, 1000245176, 1000251377, 1000254803, 1000262514
12-01531S	QUIKFLAP, 3 X 2-HOLE DOG BONE PLATES WITH 1.5X4MM SELF TAPPING SCREWS	1000181748, 1000295062
12-01532S	QUIKFLAP, 3 X 2-HOLE PLATES WITH TAB, 1.5X4mm SELF DRILLING SCREWS	1000100540, 1000100541, 1000101992, 1000101994, 1000103661, 1000110486, 1000113766, 1000115217, 1000115218, 1000131912, 1000147952, 1000157990, 1000159893, 1000164241, 1000165529, 1000170706, 1000173343, 1000175688, 1000179042, 1000179720, 1000187363, 1000191064, 1000193587, 1000200400, 1000202174, 1000202430, 1000204636, 1000209030, 1000211804, 1000215160, 1000225770, 1000230169, 1000232401, 1000235430, 1000238413, 1000245177, 1000247183, 1000255708
12-01534S	QUIKFLAP, 1X14MM BURR HOLE COVER, 2 X 2-HOLE PLATES, 1.5X4mm SELF DRILLING SCREWS	1000230170, 1000235431, 1000265421
12-01536S	QUIKFLAP, 1X20MM BURR HOLE COVER, 2 X 2-HOLE PLATES, 1.5X4mm SELF DRILLING SCREWS	1000232402, 1000237513
12-01538S	QUIKFLAP, 1X14MM BURR HOLE COVER, 1.5X4mm SELF DRILLING SCREWS	1000167017, 1000167829, 1000171360, 1000172321, 1000173866, 1000175689, 1000178993, 1000187364, 1000198471, 1000198472, 1000202431, 1000205662, 1000215879, 1000217675, 1000226524, 1000233194, 1000238414, 1000259405
12-01540S	AXS PP, 3 X 2-HOLE DOG BONE PLATES WITH 1.5X4MM SELF DRILLING SCREWS	1000201514, 1000203740, 1000216825, 1000220166, 1000233195, 1000237514, 1000238415, 1000245178, 1000252563, 1000254189, 1000254403, 1000255709, 1000256557, 1000257448, 1000258647, 1000258648, 1000258649, 1000259406, 1000259407, 1000260281, 1000260282, 1000261023, 1000261024, 1000261687, 1000261688, 1000262515, 1000262516, 1000262517, 1000263497, 1000264403, 1000264404, 1000264405, 1000265422, 1000268571, 1000268572, 1000201514, 1000287394, 1000292115, 1000293285,
12-01541S	AXS PP, 3 X 2-HOLE DOG BONE PLATES WITH 1.5X4MM SELF TAPPING SCREWS	582, 1000254804, 1000258650, 1000259408, 1000261022, 1000262518, 1000262519
12-01542S	AXS PP, 3 X 2-HOLE PLATES WITH TAB, 1.5X4mm SELF DRILLING SCREWS	1000201620, 1000203741, 1000215161, 1000221838, 1000224226, 1000230171, 1000232403, 1000233774, 1000235432, 1000236133, 1000238416, 1000245179, 1000251379, 1000254404, 1000255711, 1000257449, 1000258651, 1000258652, 1000259409, 1000260283, 1000260284, 1000260285, 1000261025, 1000261026, 1000261689, 1000261690, 1000261691, 1000263498, 1000263499, 1000263500, 1000263501, 1000263502, 1000264407, 1000264408, 1000265423, 1000265424, 1000266165, 1000266166, 1000266167, 1000267009, 1000267010, 1000267748,

		1000267749, 1000267750, 1000268573, 1000268574, 1000269518, 1000269519, 1000270162, 1000270163, 1000270837, 1000270838, 1000285715, 1000287395, 1000289257, 1000201620, 1000288210, 1000290246, 1000291275, 1000292116, 1000294081
12-01544S	AXS PP, 1X14MM BURR HOLE COVER, 2 X 2-HOLE PLATES, 1.5X4mm SELF DRILLING SCREWS	1000201635, 1000215162, 1000230807, 1000236134, 1000253512, 1000256558, 1000258653, 1000260286, 1000263503, 1000261692, 1000265425, 1000265426
12-01546S	AXS PP, 1X20MM BURR HOLE COVER, 2 X 2-HOLE PLATES, 1.5X4mm SELF DRILLING SCREWS	1000201581, 1000215163, 1000230808, 1000252564, 1000256560, 1000259410, 1000260287, 1000263504, 1000211563, 1000267011, 1000267751
12-01548S	AXS PP, 1X14MM BURR HOLE COVER, 1.5X4mm SELF DRILLING SCREWS	1000201577, 1000215164, 1000218602, 1000248070, 1000254405, 1000261028, 1000262520, 1000264409, 1000266168, 1000288211, 1000289258, 1000292117

PFA #1739180: Acknowledgement Form

FSCA identification: Product recall PFA#1739180

Action type: Field Safety Corrective Action: Recall

Legal Manufacturer: Stryker Leibinger GmbH & Co. KG, Boetzingenstrasse 41,
79111 Freiburg, Germany

Description: QuikFlap Neuro Implants: potential for compromised sterile barrier

Catalogue Numbers: see attached list

Lot Number: see attached list

I acknowledge receipt of the Field Safety Notice for RA2018-1739180 and can confirm that:

We have not located any of these devices in our inventory: <i>(please delete if not applicable)</i>				
We have located the following devices:				
Product Description	Product Reference	Lot Number	Qty implanted	Qty to return
We have further distributed subject devices to the following organisations:				
Facility Name				
Facility Address				

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO 01635 580300
OR EMAIL TO nina.goddard@stryker.com