stryker

URGENT:
MEDICAL DEVICE RECALL

AEQUALIS, CHARLOTTE, DART-FIRE, ORTHOLOC, ORTHOLOC 3Di, PRO-TOE, SWANSON/HUNTER

Attn: Health Care Professionals, Operators of Medical Devices, Distributors

Recall Number: RA2024-3843283

Product affected

Catalog number	Product description
DWD922	AEQUALIS REVERSED FRACTURE Adaptor
43110009, 43S10001	CHARLOTTE Compression Staple
45112000	CHARLOTTE Screwdriver
45S10001, 45S10002, 45S10003	CHARLOTTE Snap-Off Screw
5881003540	DART-FIRE Washer
58934040	ORTHOLOC 3DI Cancellous Screw
58913512, 58913514, 58913516, 58913518, 58913520, 58913522, 58913526, 58913538, 58913542, 58913544, 58913555	ORTHOLOC 3DI Cortical Screw
58190018	ORTHOLOC 3Di Cutting Guide
58190016	ORTHOLOC 3Di Displacement Inserter
588S50025, 588S80020	ORTHOLOC 3DI Drill Bit
58820024, 588S20024	ORTHOLOC 3DI Temp Fixation Pin
5201000204	ORTHOLOC Less Met T Plate
45712410	PRO-TOE VO Implant
24270003, 24270004, 24270005, 24270006	SWANSON/HUNTER Flexspan Tendon Spacer

The purpose of this notification is to advise you that Wright Medical Technology, Inc. and Tornier SAS (wholly owned subsidiaries of Stryker) are conducting a field action on specific lots of Swanson/Hunter, Charlotte, Pro Toe, Ortholoc, Ortholoc 3DI, Dart Fire, and Aequalis implants and/or instruments. Please refer to Attachment 1 for the full listing of catalog and lot numbers within the scope of this field action that were identified as disseminated to distributors and end users.

Product description

This Product Field Action includes implants and instruments from the T&E Upper Extremities and Lower Extremities portfolios. The items in scope are utilized in foot, and, shoulder, and small bones surgeries.

Product issue

Stryker has determined that the devices listed in Attachment 1 were shipped to countries within the EU and the UK after the CE certification for these devices expired.

Potential risks There are no patient/user health hazards. The lack of current regulatory approval for these devices does not impact device function. All devices were manufactured to specification.

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 to locate the product(s) listed on the attached Business Reply Form, remove them from their point of use, and isolate/quarantine the unit(s) to prevent accidental use.
2. Sign and return the enclosed Business Reply Form by email to <XXXXX@stryker.com> to confirm receipt of this notification/documenting product segregation.
    a. **Response is required, even if you may not have any physical inventory on site anymore.** 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 eliminate the need for us to send further unnecessary communications on this matter. Therefore, please complete even if you no longer have any of the subject devices in your physical inventory.
3. Upon receipt of the completed Business Reply Form, Stryker will contact you to arrange for the return of your product(s).
4. Maintain awareness of this communication internally until all required actions have been completed within your facility.
5. If you have further distributed the affected product, please notify the applicable parties at once about this recall. You may copy and distribute this notification letter.
    a. If possible, inform us if any of the subject devices have been distributed to other organizations, including contact details.
    b. If you are a distributor, note that you are responsible for notifying your affected customers.
6. Please inform us of any adverse events and/or report them to the Health/Competent Authorities in accordance with current regulations
7. 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:

In line with the recommendations of the Medical Device Coordination Group Guidance document Ref MDCG 2023-3 and EU MDR 2017/745, 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 and regret any inconvenience caused. We would like to reassure you that Stryker is 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 name:
Account Address:

AEQUALIS, CHARLOTTE, DART-FIRE, ORTHOLOC, ORTHOLOC 3Di, PRO-TOE, SWANSON/HUNTER

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Please complete and sign this form. Email the completed form to <XXXX@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#	Product Description	Lot#	Quantity on hand*

*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 to whom:

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

Attachment 1 – impacted catalog numbers and lots

Catalog#	Desciption	GTIN	Lot#	Distribution Dates
24270003	TENDON SPACER SWANSON/HUNTER 24CM X 3MM FLEXSPAN	00840420121851	1789022	28/May/2024 - 14/Nov/2024
24270003	TENDON SPACER SWANSON/HUNTER 24CM X 3MM FLEXSPAN	00840420121851	1787972	
24270003	TENDON SPACER SWANSON/HUNTER 24CM X 3MM FLEXSPAN	00840420121851	1788542	
24270003	TENDON SPACER SWANSON/HUNTER 24CM X 3MM FLEXSPAN	00840420121851	1787971	
24270003	TENDON SPACER SWANSON/HUNTER 24CM X 3MM FLEXSPAN	00840420121851	1789646	
24270003	TENDON SPACER SWANSON/HUNTER 24CM X 3MM FLEXSPAN	00840420121851	1674976	
24270004	TENDON SPACER SWANSON/HUNTER 24CM X 4MM FLEXSPAN	00840420121868	1788543	
24270004	TENDON SPACER SWANSON/HUNTER 24CM X 4MM FLEXSPAN	00840420121868	1789647	
24270004	TENDON SPACER SWANSON/HUNTER 24CM X 4MM FLEXSPAN	00840420121868	1787973	
24270004	TENDON SPACER SWANSON/HUNTER 24CM X 4MM FLEXSPAN	00840420121868	1789650	
24270005	TENDON SPACER SWANSON/HUNTER 24CM X 5MM FLEXSPAN	00840420121875	1787978	
24270005	TENDON SPACER SWANSON/HUNTER 24CM X 5MM FLEXSPAN	00840420121875	1788557	
24270005	TENDON SPACER SWANSON/HUNTER 24CM X 5MM FLEXSPAN	00840420121875	1780338	
24270006	TENDON SPACER SWANSON/HUNTER 24CM X 6MM FLEXSPAN	00840420121882	1787979	
43110009	COMPRESSION STAPLE 25I-20L CHARLOTTE F AND A SYSTEM	00840420108593	3159397	
45112000	SNAP OFF SCREWDRIVER CHARLOTTE F AND A SYSTEM	00840420190642	3070153	
45712410	PRO-TOE VO 2.4 X 16MM 10DG	00840420123053	1787043	
58190016	SHIFT FIX DISPLACEMENT INSERTR ORTHOLOC 3DI PLATING SYSTEM	00889797019460	2660193	
58190018	SHIFT FIX CUTTING GUIDE ORTHOLOC 3DI PLATING SYSTEM	00889797019484	2841401	
58820024	TEMP FIXATION PIN 1.4MM LG	00889797063623	3137717	
58913512	CORTICAL SCREW FULL 3.5X12MM ORTHOLOC SYSTEM	00840420114112	2877779	
58913514	CORTICAL SCREW FULL 3.5X12MM ORTHOLOC SYSTEM	00840420114112	2877781	
58913516	CORTICAL SCREW FULL 3.5X16MM ORTHOLOC SYSTEM	00840420114082	2877757	
58913518	CORTICAL SCREW FULL 3.5X18MM ORTHOLOC SYSTEM	00840420114129	2877729	
58913518	CORTICAL SCREW FULL 3.5X18MM ORTHOLOC SYSTEM	00840420114129	2877779	
58913518	CORTICAL SCREW FULL 3.5X18MM ORTHOLOC SYSTEM	00840420114129	2877757	
58913526	CORTICAL SCREW FULL 3.5X26MM ORTHOLOC SYSTEM	00840420114525	2820630	
58913538	CORTICAL SCREW FULL 3.5X38MM ORTHOLOC SYSTEM	00840420114761	2877733	
58913542	CORTICAL SCREW FULL 3.5X42MM ORTHOLOC SYSTEM	00840420114884	2820646	
58913542	CORTICAL SCREW FULL 3.5X42MM ORTHOLOC SYSTEM	00840420114884	2596749	
58913555	CORTICAL SCREW FULL 3.5X55MM ORTHOLOC SYSTEM	00840420114655	12060661660077	
58934040	CANCELLOUS SCREW FULL 4.0X40MMORTHOLOC SYSTEM	00840420114693	2877757	
5201000204	LESS MET T PLATE 7 HOLE ORTHOLOC PLATING SYSTEM	00840420124388	2019002280	
5881003540	WASHER 3.5 / 4.0MM SCREW	00889797998161	2023005747	
5881003540	WASHER 3.5 / 4.0MM SCREW	00889797998161	2024002208	

Catalog#	Desciption	GTIN	Lot#	Distribution Dates
43S10001	COMP STAPLE 13I-11L STERILE CHARLOTTE F AND A SYSTEM	00840420129734	1756810	28/May/2024 - 14/Nov/2024
45S10001	SNAP OFF 2.0 X 11MM STERILE CHARLOTTE F AND A SYSTEM	00840420130242	1757131	
45S10002	SNAP OFF 2.0 X 12MM STERILE CHARLOTTE F AND A SYSTEM	00840420130259	1733907	
45S10003	SNAP OFF 2.0 X 14MM STERILE CHARLOTTE F AND A SYSTEM	00840420130266	1744353	
58820024	TEMP FIXATION PIN 1.4MM LG	00889797063623	3139688	
588S20024	STERILE TEMP FIX PIN 1.4MM LG ORTHOLOC 3DI PLATING SYSTEM	00889797055178	1759591	
588S50025	STERILE DRILL BIT 2.5X60MM ORTHOLOC 3DI PLATING SYSTEM	00889797055208	1744035	
588S80020	STERILE DRILL BIT 2.0X30MM ORTHOLOC 3DI PLATING SYSTEM	00889797055260	1745297	
58913516	CORTICAL SCREW FULL 3.5X16MM ORTHOLOC SYSTEM	00840420114082	2877775	
58913520	CORTICAL SCREW FULL 3.5X20MM ORTHOLOC SYSTEM	00840420114228	3140797	
58913522	CORTICAL SCREW FULL 3.5X22MM ORTHOLOC SYSTEM	00840420114204	2926477	
58913544	CORTICAL SCREW FULL 3.5X44MM ORTHOLOC SYSTEM	00840420114792	2926474	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA001	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA002	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA003	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA004	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA005	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA006	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA007	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA008	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA009	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA010	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA011	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA012	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA013	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA014	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA015	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA016	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA017	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA018	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7795BA019	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7889BA001	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7889BA002	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7889BA003	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7889BA004	

Catalog#	Desciption	GTIN	Lot#	Distribution Dates
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7889BA005	28/May/2024 - 14/Nov/2024
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8439BA001	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8439BA002	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8439BA004	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8439BA005	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8439BA007	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8439BA008	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8439BA009	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8439BA010	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8439BA011	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8439BA012	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8439BA013	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8439BA014	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8439BA015	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8439BA016	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8439BA017	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8439BA018	