

URGENT: MEDICAL DEVICE RECALL

AEQUALIS, DARCO, EVOLVE, G-FORCE, HUNTER, ORTHOLOC 3Di, PRO-TOE, SWANSON/HUNTER, TORNIER FLEX

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

Recall Number: RA2024-3843283

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Product affected

Catalog Number	Product description
DWD064	AEQUALIS Resurfacing Head Pin
DWD922	AEQUALIS REVERSED FRACTURE Adaptor
MWD550	AEQUALIS REVERSED II Wrench
58871216	DARCO Headed Screw K-Wire Tissue Protector
4942518CH	EVOLVE EPS Drill Bit
86PS3045	G-FORCE Hex Driver
86PS0410, 86PS0415, 86PS0510, 86PS0515, 86PS0615, 86PS0620, 86PS0725, 86PS0825	G-FORCE Peek Interference Screw
86PS3010	G-FORCE Ratcheting Driver Handle
86PS1005, 86PS1006	G-FORCE Reamer
86PS1000	G-FORCE Suture Loop Guide Rod
TR300000	HUNTER Tendon Rod
58886010	ORTHOLOC 3Di Anterior Tibia Delta Plate
5888701L, 5888701R, 5888702R	ORTHOLOC 3Di Antero Lateral Fibula Tib Plate
58934045, 58934050, 58934055, 58944020, 58944024, 58944026, 58944028, 58944030, 58944035, 58944050, 58944055, 58944060	ORTHOLOC 3Di Cancellous Screw
58913510, 58913518, 58913522, 58913526, 58913528, 58913530, 58913534, 58913538, 58913540, 58913546, 58913550, 58913555	ORTHOLOC 3Di Cortical Screw
58850020	ORTHOLOC 3Di Drill Bit
5888101R, 5888102L, 5888102R	ORTHOLOC 3Di Lateral Fibula Plate
5888802R	ORTHOLOC 3Di Medial Tibia Plate
58885030	ORTHOLOC 3Di Meidal Malleolar Plate
5882000040	ORTHOLOC 3Di Reduction Forceps
58880006, 45712410, 24270004, MWG052	ORTHOLOC 3Di Straight Tubular Plate
45712410	PRO-TOE VO Implant
24270004	SWANSON/HUNTER Flexspan Tendon Spacer
MWG049, MWG052, MWG149	TORNIER FLEX Humeral Head Trial

This is an UPDATE to the voluntary Urgent Field Safety Notice issued in January 2025. This update, including the corresponding Attachment 1, is meant to supplement (and not replace) the notice issued in January 2025.

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 AEQUALIS, DARCO, EVOLVE, G-FORCE, HUNTER, ORTHOLOC 3Di, PRO-TOE, SWANSON/HUNTER, TORNIER FLEX 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.

Actions to be taken

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.
 - a. Sign and return the enclosed Business Reply Form by email to <xxxxxx@stryker.com> to confirm receipt of this notification/documenting product disposition
 - b. **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 communication on this matter. Therefore, please complete even if you no longer have any of the subject devices in your physical inventory.
2. Upon receipt of the complete Business Reply Form, Stryker will contact you to arrange for the return of your product(s).
3. Maintain awareness of this communication internally until all required actions have been completed within your facility.
4. 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.
5. Please inform us of any adverse events and/or report them to the Health/Competent Authorities in accordance with current regulations.

6. Please inform us of any adverse events and/or report them to the Health/Competent Authorities in accordance with current regulations.

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,

Business Reply Form

Account name:
Account Address:

AEQUALIS, DARCO, EVOLVE, G-FORCE, HUNTER, ORTHOLOG 3Di, PRO-TOE, SWANSON/HUNTER, TORNIER FLEX

Recall Number: RA2024-3843283

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Please complete and sign this form. Email the completed form to <XXXXXXXXXX@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

Part #	Description	GTIN	Lot/Serial #	Distr. Dates
86PS0410	PEEK INTERFERENCE SCREWS 4 X 10MM	00840420115379	1706808	
86PS0415	PEEK INTERFERENCE SCREWS 4 X 15MM	00840420115348	1725002	
86PS0510	PEEK INTERFERENCE SCREWS 5 X 10MM	00840420115386	1707704	
86PS0510	PEEK INTERFERENCE SCREWS 5 X 10MM	00840420115386	1707705	
86PS0515	PEEK INTERFERENCE SCREWS 5 X 15MM	00840420115324	1728361	
86PS0515	PEEK INTERFERENCE SCREWS 5 X 15MM	00840420115324	1728364	
86PS0515	PEEK INTERFERENCE SCREWS 5 X 15MM	00840420115324	1754067	
86PS0615	PEEK INTERFERENCE SCREWS 5 X 15MM	00840420115324	1725012	
86PS0620	PEEK INTERFERENCE SCREWS 6 X 20MM	00840420115331	1760088	
86PS0620	PEEK INTERFERENCE SCREWS 6 X 20MM	00840420115331	1760090	
86PS0725	PEEK INTERFERENCE SCREWS 7 X 25MM	00840420115362	1760093	
86PS0825	PEEK INTERFERENCE SCREWS 7 X 25MM	00840420115362	1725234	
86PS1000	SUTURE LOOP GUIDE ROD G-FORCE TENODESIS SYSTEM	00889797058629	3033574	
86PS1005	CANNULATED REAMER 5MM	00889797058643	2582328	
86PS1006	CANNULATED REAMER 6MM	00889797058650	2714990	
86PS3010	RATCHETING DRIVER HANDLE	00889797042345	2567085-2	
86PS3045	DRIVER SHORT HEX 2MM 4 5 G-FORCE TENODESIS SYSTEM	00889797042383	2776353	
24270004	TENDON SPACER SWANSON/HUNTER 24CM X 4MM FLEXSPAN	00840420121868	1787976	
45712410	PRO-TOE VO 2.4 X 16MM 10DG	00840420123053	1744053	
58850020	DRILL BIT 2.0MM X 24MM	00889797063630	2876126	01/Jan/2024
58913522	CORTICAL SCREW FULL 3.5X22MM ORTHOLOC SYSTEM	00840420114204	2596749	-
58913526	CORTICAL SCREW FULL 3.5X26MM ORTHOLOC SYSTEM	00840420114525	2820646	26/May/2024
58913534	CORTICAL SCREW FULL 3.5X34MM ORTHOLOC SYSTEM	00840420114648	2877781	
58913538	CORTICAL SCREW FULL 3.5X38MM ORTHOLOC SYSTEM	00840420114761	2820646	
4942518CH	EVOLVE TRIADCANN SCR 2.5X18MM HEADED FULLY THREADED	00840420116055	2532569	
5882000040	REDUCTION FORCEPS SERRATED	00889797037433	2362234	
58871216	K-WIRE TISSUE PROTECTOR 1.2MM / 1.6MM	00889797020473	2889374	
58880006	STRAIGHT TUBULAR PLATE 6 HOLE ORTHOLOC 3DI PLATING SYSTEM	00840420123510	2926452	
58880007	STRAIGHT TUBULAR PLATE 7 HOLE ORTHOLOC 3DI PLATING SYSTEM	00840420123527	2776850	
58880010	STRAIGHT TUBULAR PLATE 10 HOLE ORTHOLOC 3DI PLATING SYSTEM	00840420123541	2019004681	
58880012	STRAIGHT TUBULAR PLATE 12 HOLE ORTHOLOC 3DI PLATING SYSTEM	00840420123558	2675329	
5888101R	LATERAL FIBULA PLATE RIGHT SM ORTHOLOC 3DI PLATING SYSTEM	00840420126658	2926450	
5888102L	LATERAL FIBULA PLATE LEFT MD ORTHOLOC 3DI PLATING SYSTEM	00840420126665	2777700	
5888102L	LATERAL FIBULA PLATE LEFT MD ORTHOLOC 3DI PLATING SYSTEM	00840420126665	2876144	
5888102R	LATERAL FIBULA PLATE RIGHT MD ORTHOLOC 3DI PLATING SYSTEM	00840420126672	2926448	
58885030	MEDIAL MALLEOLAR PLATE LG ORTHOLOC 3DI PLATING SYSTEM	00840420123633	2735843	
58885030	MEDIAL MALLEOLAR PLATE LG ORTHOLOC 3DI PLATING SYSTEM	00840420123633	2777700	
58886010	ANTERIOR TIBIA DELTA PLATE SM ORTHOLOC 3DI PLATING SYSTEM	00840420123640	2713407	
5888701L	ANTERO LATERAL TIB PLATE LT SM ORTHOLOC 3DI PLATING SYSTEM	00840420126740	2735843	
5888701R	ANTERO LATERAL TIB PLATE RT SM ORTHOLOC 3DI PLATING SYSTEM	00840420126757	2849620	
5888702R	ANTERO LATERAL TIB PLATE RT MD ORTHOLOC 3DI PLATING SYSTEM	00840420126771	3038148	

Part #	Description	GTIN	Lot/Serial #	Distr. Dates
5888802R	MEDIAL TIBIA PLATE RIGHT MD ORTHOLOC 3DI PLATING SYSTEM	00840420126832	2019004660	
58913510	CORTICAL SCREW FULL 3.5X10MM ORTHOLOC SYSTEM	00840420114532	2877745	
58913518	CORTICAL SCREW FULL 3.5X18MM ORTHOLOC SYSTEM	00840420114129	2021000337	
58913518	CORTICAL SCREW FULL 3.5X18MM ORTHOLOC SYSTEM	00840420114129	2019002737	
58913528	CORTICAL SCREW FULL 3.5X28MM ORTHOLOC SYSTEM	00840420114594	2610548	
58913530	CORTICAL SCREW FULL 3.5X30MM ORTHOLOC SYSTEM	00840420114631	2877736	
58913540	CORTICAL SCREW FULL 3.5X40MM ORTHOLOC SYSTEM	00840420114846	2820638	
58913546	CORTICAL SCREW FULL 3.5X46MM ORTHOLOC SYSTEM	00840420114723	2021000355	
58913550	CORTICAL SCREW FULL 3.5X50MM ORTHOLOC SYSTEM	00840420114549	2849599	
58913555	CORTICAL SCREW FULL 3.5X55MM ORTHOLOC SYSTEM	00840420114655	12651341660078	
58934045	CANCELLOUS SCREW FULL 4.0X45MM ORTHOLOC SYSTEM	00840420114730	2820638	
58934050	CANCELLOUS SCREW FULL 4.0X50MM ORTHOLOC SYSTEM	00840420114716	2877759	
58934055	CANCELLOUS SCREW FULL 4.0X55MM ORTHOLOC SYSTEM	00840420114747	2023009588	
58944020	CANCELLOUS SCREW PART 4.0X20MM ORTHOLOC SYSTEM	00840420114952	2820638	
58944024	CANCELLOUS SCREW PART 4.0X24MM ORTHOLOC SYSTEM	00840420115157	2021003648	
58944026	CANCELLOUS SCREW PART 4.0X26MM ORTHOLOC SYSTEM	00840420115102	2019003846	
58944028	CANCELLOUS SCREW PART 4.0X28MM ORTHOLOC SYSTEM	00840420115096	2582206	
58944030	CANCELLOUS SCREW PART 4.0X30MM ORTHOLOC SYSTEM	00840420115065	2820646	
58944035	CANCELLOUS SCREW PART 4.0X35MM ORTHOLOC SYSTEM	00840420114785	2582206	
58944050	CANCELLOUS SCREW PART 4.0X50MM ORTHOLOC SYSTEM	00840420114679	2021003658	
58944055	CANCELLOUS SCREW PART 4.0X55MM ORTHOLOC SYSTEM	00840420114976	2820638	
58944060	CANCELLOUS SCREW PART 4.0X60MM ORTHOLOC SYSTEM	00840420115072	2582206	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0026BB008	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0026BB009	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0026BB010	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0026BB015	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0026BB017	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0026BB022	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0026BB030	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0026BB031	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0026BB035	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0026BB036	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0026BB040	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0026BB041	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0026BB046	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0026BB049	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	9907BA001	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	9907BA002	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	9907BA005	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	9907BA010	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	9907BA014	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	9907BA021	

Part #	Description	GTIN	Lot/Serial #	Distr. Dates
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0027BB035	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0027BB036	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0027BB037	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0027BB038	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0027BB039	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0027BB040	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0027BB041	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0027BB042	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0027BB043	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0027BB044	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0027BB045	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0027BB046	
DWD064	AEQ RESURFACING HEAD PIN DO NO IMPLANT DIA 25MM LENGTH 150MM	03700386931802	0027BB047	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	7940BA002	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8440BA004	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8440BA011	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8440BA018	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8637BA003	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8637BA005	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8637BA012	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8637BA013	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8638BA001	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8638BA002	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8638BA006	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8638BA014	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8441BA002	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8441BA010	
DWD922	AEQUALIS REVERSED FRACTURE HEMI PROSTHESIS ADAPTOR 36MM	03700386931901	8441BA014	
MWD550	AEQ FX2 HUMERAL TRAY OPEN END WRENCH DIA 4MM	03700386958700	24A830	
MWG049	FLEX SHOULDER SYSTEM STB HUM HEAD TRIAL DIA.48 H.18 ECC.1,5	03700386977909	24A310	
MWG052	FLEX SHOULDER SYSTEM STB HUM HEAD TRIAL DIA.51 H.20 ECC.1,5	03700386977930	24A327	
MWG149	FLEX SHOULDER SYSTEM STB HUM HEAD TRIAL DIA.48 H.18 ECC.4	03700386978074	24A294	
TR300000	HUNTER TENDON ROD 3MM X 24.5CM	00840420128942	1787456	