

18 June 2026

To: Hospitals and Surgeons

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION (REMOVAL)**

Affected Product: A.T.S.® 4000 TS Tourniquet Systems Single and Dual Hose with CPC Connectors, 20-pack

➤ See **Attachment 2 – Affected Product List** for the affected batch numbers.

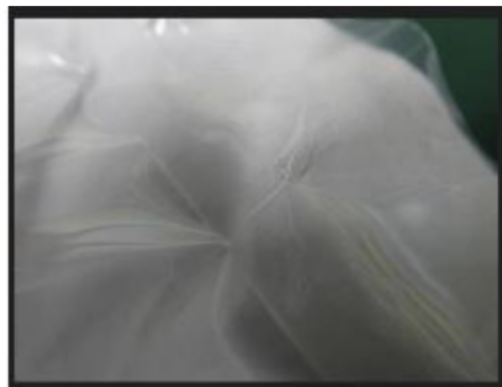


Figure 1: Product packaging sample (left) vs. wrinkles in the sterile pouch seal (right)

Zimmer Surgical, Inc. is conducting a medical device Field Safety Corrective Action for the A.T.S.® 4000 TS Tourniquet Systems Single and Dual Hose with CPC Connectors listed in **Attachment 2 – Affected Product List**. One product complaint was received with no clinical impact reporting that wrinkles were identified in the sealing area of the sterile pouch. Subsequent seal integrity testing conducted internally showed potential sterility breach in 0.92% of inspected products that had visual seal nonconformities.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Clinically insignificant extension of surgery to find another readily available device.	Clinically insignificant extension of surgery to find another readily available device.
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None.	Infection, moderate localized.

Our records indicate that you may have received one or more of the affected products. The affected products were distributed between May 2025 and April 2026. Local deployment may defer. The products are distributed in cases (CS) of 20 pieces. Inside each case there are two boxes (BX) of 10 pieces each.

Hospital Responsibilities

1. Review this Field Safety Notice and ensure that affected personnel are aware of the contents.
2. Immediately locate and quarantine any affected product in your inventory. Your Zimmer Biomet sales representative may assist with removing the affected product(s) from your facility.
3. If any affected product has been further distributed, provide your customer(s) with this Field Safety Notice and ensure documentation.
4. Complete **Attachment 1 – Certificate of Acknowledgement** and send it to **Confidential business information** This form must be returned even if you do not have any affected product available for return.
5. Retain a copy of **Attachment 1 - Certificate of Acknowledgement** with your records in the event of a compliance audit of your facility.
6. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your local Zimmer Biomet representative.

Surgeon Responsibilities

1. Review this Field Safety Notice for awareness of the contents.
2. There are no specific patient monitoring instructions related to this Field Safety Corrective Action that are recommended beyond your existing follow-up schedule.
3. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your local Zimmer Biomet representative.

Other Information

This Field Safety Corrective Action was reported to all relevant Competent Authorities and Notified Bodies as required under the applicable regulations for Medical Devices per Regulation (EU) 2017/745 and guidance MDCG 2023-3. The undersigned confirms that this Field Safety Notice has been delivered to the appropriate Regulatory Agencies. Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing **Confidential business information**

We would like to thank you for your co-operation in advance and regret any inconvenience caused by this Field Safety Corrective Action.

Sincerely,

Personal data

Personal data

ATTACHMENT 1- Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Field Safety Corrective Action Reference: ZFA 2026-00054

Affected Product: A.T.S.® 4000 TS Tourniquet Systems Single and Dual Hose with CPC Connectors, 20-pack

Complete the table below for all affected products returned. If additional space is needed, please provide a spreadsheet and return it with this form. Do not return products with other returns.			
Material Number	Batch Number	Quantity Returned	Piece(s) / Box(es) / Case(s)

Note: Any product not returned is considered disposed under your account and unavailable for use.

<u>Hospital acknowledgement</u>				
By signing below, I acknowledge that I have received, read, and understand the contents of this Field Safety Notice. All required activities are complete or are being completed.				
Facility Name				
Facility Address				
Post Code		City		Country
Printed Name				
Title				
Date		Signature		

ATTACHMENT 2 - Affected Product List

Material Number	60-1812-101-00	Material Description	A.T.S.® 4000 TS Tourniquet Systems Dual Hose with CPC Connectors
Batch Number		UDI Numbers	
78938271		Individual (piece): (01)00889024367173(17)271125(10)78938271 Box (10-pack): (01)00889024378469(17)271125(10)78938271 Case (20-pack): (01)00889024381162(17)271125(10)78938271	
78938272		Individual (piece): (01)00889024367173(17)271126(10)78938272 Box (10-pack): (01)00889024378469(17)271126(10)78938272 Case (20-pack): (01)00889024381162(17)271126(10)78938272	
78938273		Individual (piece): (01)00889024367173(17)271127(10)78938273 Box (10-pack): (01)00889024378469(17)271127(10)78938273 Case (20-pack): (01)00889024381162(17)271127(10)78938273	
80555986		Individual (piece): (01)00889024367173(17)280206(10)80555986 Box (10-pack): (01)00889024378469(17)280206(10)80555986 Case (20-pack): (01)00889024381162(17)280206(10)80555986	
80555987		Individual (piece): (01)00889024367173(17)280102(10)80555987 Box (10-pack): (01)00889024378469(17)280102(10)80555987 Case (20-pack): (01)00889024381162(17)280102(10)80555987	
80555988		Individual (piece): (01)00889024367173(17)280210(10)80555988 Box (10-pack): (01)00889024378469(17)280210(10)80555988 Case (20-pack): (01)00889024381162(17)280210(10)80555988	
80555989		Individual (piece): (01)00889024367173(17)280214(10)80555989 Box (10-pack): (01)00889024378469(17)280214(10)80555989 Case (20-pack): (01)00889024381162(17)280214(10)80555989	
80555990		Individual (piece): (01)00889024367173(17)280217(10)80555990 Box (10-pack): (01)00889024378469(17)280217(10)80555990 Case (20-pack): (01)00889024381162(17)280217(10)80555990	
80568849		Individual (piece): (01)00889024367173(17)280225(10)80568849 Box (10-pack): (01)00889024378469(17)280225(10)80568849 Case (20-pack): (01)00889024381162(17)280225(10)80568849	
82010858		Individual (piece): (01)00889024367173(17)280409(10)82010858 Box (10-pack): (01)00889024378469(17)280409(10)82010858 Case (20-pack): (01)00889024381162(17)280409(10)82010858	
82010859		Individual (piece): (01)00889024367173(17)280403(10)82010859 Box (10-pack): (01)00889024378469(17)280403(10)82010859 Case (20-pack): (01)00889024381162(17)280403(10)82010859	
82196691		Individual (piece): (01)00889024367173(17)280415(10)82196691 Box (10-pack): (01)00889024378469(17)280415(10)82196691 Case (20-pack): (01)00889024381162(17)280415(10)82196691	

Material Number	60-1812-101-00	Material Description	A.T.S.® 4000 TS Tourniquet Systems Dual Hose with CPC Connectors
Batch Number	UDI Numbers		
82196692	Individual (piece): (01)00889024367173(17)280419(10)82196692 Box (10-pack): (01)00889024378469(17)280419(10)82196692 Case (20-pack): (01)00889024381162(17)280419(10)82196692		
82331021	Individual (piece): (01)00889024367173(17)280423(10)82331021 Box (10-pack): (01)00889024378469(17)280423(10)82331021 Case (20-pack): (01)00889024381162(17)280423(10)82331021		
82331022	Individual (piece): (01)00889024367173(17)280427(10)82331022 Box (10-pack): (01)00889024378469(17)280427(10)82331022 Case (20-pack): (01)00889024381162(17)280427(10)82331022		
82418900	Individual (piece): (01)00889024367173(17)280501(10)82418900 Box (10-pack): (01)00889024378469(17)280501(10)82418900 Case (20-pack): (01)00889024381162(17)280501(10)82418900		
82418901	Individual (piece): (01)00889024367173(17)280507(10)82418901 Box (10-pack): (01)00889024378469(17)280507(10)82418901 Case (20-pack): (01)00889024381162(17)280507(10)82418901		
82639501	Individual (piece): (01)00889024367173(17)280513(10)82639501 Box (10-pack): (01)00889024378469(17)280513(10)82639501 Case (20-pack): (01)00889024381162(17)280513(10)82639501		
82761025	Individual (piece): (01)00889024367173(17)280516(10)82761025 Box (10-pack): (01)00889024378469(17)280516(10)82761025 Case (20-pack): (01)00889024381162(17)280516(10)82761025		
83343102	Individual (piece): (01)00889024367173(17)280529(10)83343102 Box (10-pack): (01)00889024378469(17)280529(10)83343102 Case (20-pack): (01)00889024381162(17)280529(10)83343102		
84859541	Individual (piece): (01)00889024367173(17)280820(10)84859541 Box (10-pack): (01)00889024378469(17)280820(10)84859541 Case (20-pack): (01)00889024381162(17)280820(10)84859541		
84859542	Individual (piece): (01)00889024367173(17)280902(10)84859542 Box (10-pack): (01)00889024378469(17)280902(10)84859542 Case (20-pack): (01)00889024381162(17)280902(10)84859542		
86156905	Individual (piece): (01)00889024367173(17)281112(10)86156905 Box (10-pack): (01)00889024378469(17)281112(10)86156905 Case (20-pack): (01)00889024381162(17)281112(10)86156905		

Material Number	60-4009-101-00	Material Description	A.T.S.® 4000 TS Tourniquet Systems Single Hose with CPC Connectors
Batch Number	UDI Numbers		
79701946	Individual (piece): (01)00889024376786(17)271022(10)79701946 Box (10-pack): (01)00889024380455(17)271022(10)79701946 Case (20-pack): (01)00889024382336(17)271022(10)79701946		
79701947	Individual (piece): (01)00889024376786(17)271028(10)79701947 Box (10-pack): (01)00889024380455(17)271028(10)79701947 Case (20-pack): (01)00889024382336(17)271028(10)79701947		
79701948	Individual (piece): (01)00889024376786(17)271030(10)79701948 Box (10-pack): (01)00889024380455(17)271030(10)79701948 Case (20-pack): (01)00889024382336(17)271030(10)79701948		
80555938	Individual (piece): (01)00889024376786(17)280325(10)80555938 Box (10-pack): (01)00889024380455(17)280325(10)80555938 Case (20-pack): (01)00889024382336(17)280325(10)80555938		
80555939	Individual (piece): (01)00889024376786(17)280402(10)80555939 Box (10-pack): (01)00889024380455(17)280402(10)80555939 Case (20-pack): (01)00889024382336(17)280402(10)80555939		
80555940	Individual (piece): (01)00889024376786(17)280326(10)80555940 Box (10-pack): (01)00889024380455(17)280326(10)80555940 Case (20-pack): (01)00889024382336(17)280326(10)80555940		
80581869	Individual (piece): (01)00889024376786(17)280911(10)80581869 Box (10-pack): (01)00889024380455(17)280911(10)80581869 Case (20-pack): (01)00889024382336(17)280911(10)80581869		
80581870	Individual (piece): (01)00889024376786(17)280331(10)80581870 Box (10-pack): (01)00889024380455(17)280331(10)80581870 Case (20-pack): (01)00889024382336(17)280331(10)80581870		
80765021	Individual (piece): (01)00889024376786(17)280402(10)80765021 Box (10-pack): (01)00889024380455(17)280402(10)80765021 Case (20-pack): (01)00889024382336(17)280402(10)80765021		