

To affected distributors / clinical centers

January 20th, 2022**Recall of medical device:**
DERIVO® 2 Embolisation Device

Article number	Name	Size
01-107001	DERIVO® 2 Embolisation Device	2.5 mm x 10 mm
01-107002	DERIVO® 2 Embolisation Device	2.5 mm x 15 mm
01-107003	DERIVO® 2 Embolisation Device	2.5 mm x 20 mm
01-107004	DERIVO® 2 Embolisation Device	2.5 mm x 25 mm
01-107005	DERIVO® 2 Embolisation Device	3.0 mm x 10 mm
01-107006	DERIVO® 2 Embolisation Device	3.0 mm x 15 mm
01-107007	DERIVO® 2 Embolisation Device	3.0 mm x 20 mm
01-107008	DERIVO® 2 Embolisation Device	3.0 mm x 25 mm
01-107009	DERIVO® 2 Embolisation Device	3.5 mm x 10 mm
01-107010	DERIVO® 2 Embolisation Device	3.5 mm x 15 mm
01-107011	DERIVO® 2 Embolisation Device	3.5 mm x 20 mm
01-107012	DERIVO® 2 Embolisation Device	3.5 mm x 25 mm
01-107039	DERIVO® 2 Embolisation Device	4.0 mm x 40 mm
01-107043	DERIVO® 2 Embolisation Device	4.5 mm x 40 mm
01-107047	DERIVO® 2 Embolisation Device	5.0 mm x 40 mm
01-107048	DERIVO® 2 Embolisation Device	5.0 mm x 50 mm
01-107052	DERIVO® 2 Embolisation Device	5.5 mm x 40 mm
01-107053	DERIVO® 2 Embolisation Device	5.5 mm x 50 mm
01-107057	DERIVO® 2 Embolisation Device	6.0 mm x 40 mm
01-107058	DERIVO® 2 Embolisation Device	6.0 mm x 50 mm

Dear Sir/Madam,

Acandis GmbH is initiating a voluntary medical device recall of the aforementioned articles of the product DERIVO® 2 Embolisation Device. Product sizes whose article numbers are not listed here are not affected by the corrective action and can continue to be used without restriction.

Cause for recall:

We have received an increasing number of complaints from customers who have reported difficulty in delivery of devices through the catheter in certain sizes.

Potential hazard:

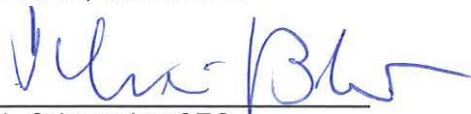
Under certain circumstances, this described problem leads to a potentially dangerous situation for the patients. However, in addition to a significant prolongation of the procedure and thus also a prolongation of the duration of anesthesia and fluoroscopy, there are also possible damages resulting from this situation. For patients who have already been implanted with a DERIVO® 2 Embolisation Device, there is no increased risk, as the described problem is limited to the delivery (i.e. before implantation).

Immediate actions:

1. Please return the aforementioned article numbers immediately, no later than 31.01.2022.
2. Confirm via the attached form that you have received this letter. Please return this filled and signed form via fax or email to the Acandis GmbH.

We sincerely apologize for any inconvenience this recall may cause for you and greatly appreciate your support. Should you have any additional questions, please do not hesitate to contact your contact partner within our organization.

Pforzheim, 20.01.2022


Dr. A. Schuessler; CEO


S. Höfele; Director RA & PRRC

Recall of medical device:
DERIVO® 2 Embolisation Device

Article number	Name	Size	Number of pieces in storage	Number of pieces used
01-107001	DERIVO® 2 Embolisation Device	2.5 mm x 10 mm		
01-107002	DERIVO® 2 Embolisation Device	2.5 mm x 15 mm		
01-107003	DERIVO® 2 Embolisation Device	2.5 mm x 20 mm		
01-107004	DERIVO® 2 Embolisation Device	2.5 mm x 25 mm		
01-107005	DERIVO® 2 Embolisation Device	3.0 mm x 10 mm		
01-107006	DERIVO® 2 Embolisation Device	3.0 mm x 15 mm		
01-107007	DERIVO® 2 Embolisation Device	3.0 mm x 20 mm		
01-107008	DERIVO® 2 Embolisation Device	3.0 mm x 25 mm		
01-107009	DERIVO® 2 Embolisation Device	3.5 mm x 10 mm		
01-107010	DERIVO® 2 Embolisation Device	3.5 mm x 15 mm		
01-107011	DERIVO® 2 Embolisation Device	3.5 mm x 20 mm		
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01-107039	DERIVO® 2 Embolisation Device	4.0 mm x 40 mm		
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01-107047	DERIVO® 2 Embolisation Device	5.0 mm x 40 mm		
01-107048	DERIVO® 2 Embolisation Device	5.0 mm x 50 mm		
01-107052	DERIVO® 2 Embolisation Device	5.5 mm x 40 mm		
01-107053	DERIVO® 2 Embolisation Device	5.5 mm x 50 mm		
01-107057	DERIVO® 2 Embolisation Device	6.0 mm x 40 mm		
01-107058	DERIVO® 2 Embolisation Device	6.0 mm x 50 mm		

Please fill in columns and tick as appropriate:

- ☐ We have located the above mentioned number of affected pieces in our storage; they have been returned. We kept a copy of this letter for our documentation.
- ☐ The above mentioned number of affected pieces have already been used. We have used the affected item. We kept a copy of this letter for our documentation.

Comments:

Clinical center / Distrubutor: _____

Name / Title: _____

Phone number: _____

Date and Signature: _____

Please return this form to the following address:

By e-mail: Regulatory@acandis.com

or

By post: Acandis GmbH
Department Regulatory Affairs
Theodor-Fahrner-Straße 6
75177 Pforzheim
Germany