ENGINEERING STROKE SOLUTIONS

Acandis GmbH. Theodor-Fahrner-Straße 6. D-75177 Pforzheim

Acandis GmbH
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E-Mail: info@acandis.com
Internet: www.acandis.com

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 x20 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 x20 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 x40 mm
01-107043	DERIVO®2 Embolisation Device	4.5 mm x40 mm
01-107047	DERIVO®2 Embolisation Device	5.0 mm x40 mm
01-107048	DERIVO®2 Embolisation Device	5.0 mm x 50 mm
01-107052	DERIVO®2 Embolisation Device	5.5 mm x40 mm
01-107053	DERIVO®2 Embolisation Device	5.5 mm x 50 mm
01-107057	DERIVO® 2 Embolisation Device	6.0 mm x40 mm
01-107058	DERIVO® 2 Embolisation Device	6.0 mm x 50 mm

Acandis GmbH
Theodor-Fahrner-StraRe 6
D 7S177 Pforzheim
HRB 727935, Amtsgericht Mannheim
USt-IdNr.: DE312308370

Geschäftsführer:
Dr. Andreas Schüssler
Kirsi Schüssler

Steuernummer: 41404/30111

Bankverbindungen:
Sparkasse Plorzheim Calw (BLZ 666 500 85) Kto.-Nr. 7 466 382
IBAN: DE8166650085 0007 4663 82 BIC: PZHSDE66XXX
Baden-Württembergische Bank (BLZ600 501 01) Kto.-Nr. 2 027 524
IBAN: DE236D05 01010002 0275 24 BIC: SOLADEST

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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 toa 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
xxx

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D 75177 Pforzheim

Geschäftsführer:
Dr. Andreas Schüssler
Kirsi Schüssler

Bankverbindungen:
Sparkasse Pforzheim Calw (BLZ 666 500 85) Kto.-Nr. 7 466 382
IBAN: DE81 6665 0085 0007 4663 82 BIC: PZH5DE66XXX

HRB 727935, Amtsgericht Mannheim
USt-IdNr.: DE312308370

Steuernummer: 41404/30111

Baden-Württembergische Bank (BLZ 600 50101) Kto.-Nr. 2 027 524
IBAN: DE23 6005 0101 0002 0275 24 BIC: SOIADEST

ENGINEERING STROKE SOLUTIONS

Recall of medical device:

DERIVO® 2 Embolisation Device

Article number	Name	Size	Numberof pieces in storage	Numberof 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 x20 mm		
01-107004	DERIVO® 2 Embolisation Device	2.5 mm x25 mm		
01-107005	DERIVO® 2 Embolisation Device	3.0mmx10mm		
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 x25 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		
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01-107048	DERIVO®2 Embolisation Device	5.0 mm x 50 mm		
01-107052	DERIVO®2 Embolisation Device	5.5 mm x40 mm		
01-107053	DERIVO®2 Embolisation Device	5.5 mm x 50 mm		
01-107057	DERIVO® 2 Embolisation Device	6.0 mm x40 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.

Acandis GmbH
Theodor-Fahrner-5tralle 6
O75177 Pforzheim
HRB 727935, Amtsgericht Mannheim
U5t-IdNr.: DE312308370

Geschäftsführer:
Dr. Andreas 5chüssler
Kirsi 5chüssler

5teuernummer: 41404/30111

Bankverbindungen:
5parkasse Pforzheim Calw (BLZ 666 500 85) Kto.-Nr. 7 466 382
IBAN: DE81 6665 0085 0007 4663 82 BIC: PZH5DE66XXX
Baden-Württembergische Bank (BLZ 600 501 01) Kto.-Nr. 2 027 524
IBAN: DE23 6005 0101 0002 0275 24 BIC: 50LADE5T

ENGINEERING STROKE SOLUTIONS

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-Straβe 6
75177 Pforzheim
Germany

Acandis GmbH
Theodor-Fahrner-Stralle 6
D 75177 Pforzheim
HRB 727935, Amtsgericht Mannheim
USt-IdNr.: DE 312308370

Geschäftsführer:
Dr. Andreas Schüssler
Kirsi Schüssler

Steuernummer: 41404/30111

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IBAN: DE23 6005 01010002 0275 24 BIC: SOLADEST