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® 2heal® Embolisation Device

Article number	Name	Size
01-104001	DERIVO® 2heal® Embolisation Device	2.5 mm x 10 mm
01-104002	DERIVO® 2heal® Embolisation Device	2.5 mm x 15 mm
01-104003	DERIVO® 2heal® Embolisation Device	2.5 mm x 20 mm
01-104004	DERIVO® 2heal® Embolisation Device	2.5 mm x 25 mm
01-104005	DERIVO® 2heal® Embolisation Device	3.0 mm x 10 mm
01-104006	DERIVO® 2heal® Embolisation Device	3.0 mm x 15 mm
01-104007	DERIVO® 2heal® Embolisation Device	3.0 mm x 20 mm
01-104008	DERIVO® 2heal® Embolisation Device	3.0 mm x 25 mm
01-104009	DERIVO® 2heal® Embolisation Device	3.5 mm x 10 mm
01-104010	DERIVO® 2heal® Embolisation Device	3.5 mm x 15 mm
01-104011	DERIVO® 2heal® Embolisation Device	3.5 mm x 20 mm
01-104012	DERIVO® 2heal® Embolisation Device	3.5 mm x 25 mm
01-104039	DERIVO® 2heal® Embolisation Device	4.0 mm x 40 mm
01-104043	DERIVO® 2heal® Embolisation Device	4.5 mm x 40 mm
01-104047	DERIVO® 2heal® Embolisation Device	5.0 mm x 40 mm
01-104048	DERIVO® 2heal® Embolisation Device	5.0 mm x 50 mm
01-104052	DERIVO® 2heal® Embolisation Device	5.5 mm x 40 mm
01-104053	DERIVO® 2heal® Embolisation Device	5.5 mm x 50 mm
01-104057	DERIVO® 2heal® Embolisation Device	6.0 mm x 40 mm
01-104058	DERIVO® 2heal® Embolisation Device	6.0 mm x 50 mm

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Dear Sir/Madam,

Acandis GmbH is initiating a voluntary medical device recall of the aforementioned articles of the product DERIVO® 2heal® 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® 2heal® 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.

[redacted]

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

Geschäftsführer:
Dr. Andreas Schüssler
Kirsi Schüssler

Steuernummer: 41404/30111

Bankverbindungen:
Sparkasse Pforzheim Calw (BLZ 666 500 85) Kto.-Nr. 7 466 382
IBAN: DE81 6665 0085 0007 4663 82 BIC: PZHSDE66XXX
Baden-Württembergische Bank (BLZ 600 501 01) Kto.-Nr. 2 027 524
IBAN: DE23 6005 0101 0002 0275 24 BIC: SOLADEST

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Recall of medical device:

DERIVO® 2heal® Embolisation Device

Article number	Name	Size	Number of pieces in storage	Number of pieces used
01-104001	DERIVO® 2heal® Embolisation Device	2.5 mm x 10 mm		
01-104002	DERIVO® 2heal® Embolisation Device	2.5 mm x 15 mm		
01-104003	DERIVO® 2heal® Embolisation Device	2.5 mm x 20 mm		
01-104004	DERIVO® 2heal® Embolisation Device	2.5 mm x 25 mm		
01-104005	DERIVO® 2heal® Embolisation Device	3.0 mm x 10 mm		
01-104006	DERIVO® 2heal® Embolisation Device	3.0 mm x 15 mm		
01-104007	DERIVO® 2heal® Embolisation Device	3.0 mm x 20 mm		
01-104008	DERIVO® 2heal® Embolisation Device	3.0 mm x 25 mm		
01-104009	DERIVO® 2heal® Embolisation Device	3.5 mm x 10 mm		
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01-104057	DERIVO® 2heal® Embolisation Device	6.0 mm x 40 mm		
01-104058	DERIVO® 2heal® 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.

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IBAN: DE23 6005 0101 0002 0275 24 BIC: SOLADEST

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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

Acandis GmbH
Theodor-Fahrner-Straße 6
D 75177 Pforzheim
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