

2023-12-18

URGENT FIELD SAFETY NOTICE

- Manufacturer SRN:** DE-MF-000020091
- FSCA Reference:** 874872 CARDIOHELP Emergency Drive – Removal of the safety washer
- FSCA Type:** New
- Affected Product:** CARDIOHELP Emergency Drive (article number 701048002)
CH Emergency Drive (article number 701076205)
- Affected Serial No.:** Refer to Annex I
- Unique Device Identifier:** 04037691643526
- For Attention of:** Users of the CARDIOHELP Emergency Drive

Dear valued customer,

Maquet Cardiopulmonary GmbH (MCP) would like to inform with this letter about the possible blocking of the CARDIOHELP Emergency Drives.

The CARDIOHELP system is a miniaturized medical perfusion system. Its general function is to drive, to control, to monitor and to protocol the extracorporeal circulation. It acts as a drive unit for a disposable tubing set including at least pump and oxygenator. The CARDIOHELP Emergency Drive (Figure 1) is used in emergencies to manually drive the disposable if the CARDIOHELP-i fails.



Figure 1: CARDIOHELP with Emergency Drive on top

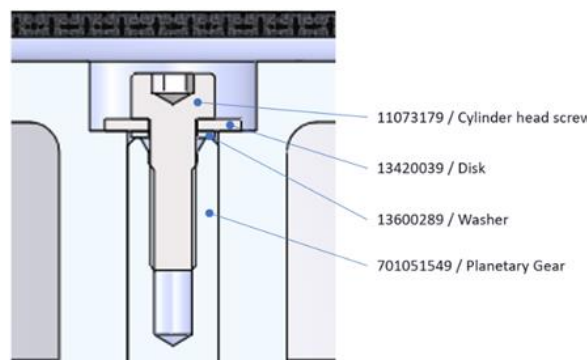


Figure 2: Draft of the position of the safety washer

Problem description

Maquet Cardiopulmonary GmbH became aware of the issue due to a customer complaint. It was reported that the rotation of the CARDIOHELP Emergency Drive hand crank was blocked or impaired. In course of internal investigations, it was found that the safety washer causes this issue. The safety washer was originally

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introduced to the CARDIOHELP Emergency Drive in order to lengthen the shaft of the Emergency Drive by the thickness of the safety washer, thus, reducing the axial pressure on the circlip, safety washer and bearing (Figure 2).

Hazardous situation

Insufficient rotation due to an impaired or blocked CARDIOHELP Emergency Drive can lead to the following hazardous situation:

- The patient is exposed to inappropriate low blood flow.

Potential harms

The potential immediate and/or long-range health consequences associated with an impaired function of the CARDIOHELP Emergency Drive may be any, all, or none of following harms:

- Ischemia
- Hypoxia

Maquet Cardiopulmonary GmbH has identified four complaints due to failure modes described above, however, none reporting patient harm, serious injuries, or deaths.

For CARDIOHELPS with affected Emergency Drives currently not being used in patient treatment:

Affected Emergency Drives are not requested to be returned, however, shall be quarantined and not be used until the removal of the safety washer. A local Getinge representative will contact you to arrange the removal of the safety washer.

For CARDIOHELPS with affected Emergency Drives currently being used in patient treatment:

If an affected Emergency Drive is currently being used for patient treatment, please inform Getinge immediately and the Getinge Service Technician will perform the Field Action as soon as possible.

Please ensure that an alternate means of emergency support is available at all times, which may include a nonaffected Emergency Drive (if available) or a fully charged backup CARDIOHELP console.

Corrective Actions • Removal of the safety washer.

Actions to be taken by the customer: Identify Device Quarantine Device
 Return Device Destroy Device

Details of the further action(s):

• According to our post-market surveillance documentation, you may have products affected by this action in your inventory. Please examine your inventory immediately to determine if you have any affected CARDIOHELP Emergency Drive in your inventory.

• **For CARDIOHELPS with affected Emergency Drives currently not being used in patient treatment:**

Affected Emergency Drives are not requested to be returned, however, shall be quarantined and not be used until the removal of the safety washer. A local Getinge representative will contact you to arrange the removal of the safety washer.

• **For CARDIOHELPS with affected Emergency Drives currently being used in patient treatment:**

If an affected Emergency Drive is currently being used for patient treatment, please inform Getinge immediately and the Getinge Service Technician will perform the Field Action as soon as possible.

Please ensure that an alternate means of emergency support is available at all times, which may include a nonaffected Emergency Drive (if available) or a fully charged backup CARDIOHELP console.

- Please **always** report any adverse events, e.g., ischemia, potentially related to the affected products, to your Getinge representative.
- Duly fill out the enclosed Letter of Acknowledgement and return it to your local Getinge representative by **January 8, 2024**, the latest. Please give **FSCA-874872** as reference in the subject line of your email.

Actions to be taken by the manufacturer Product Removal On-site device modification/ inspection
 Software upgrade IFU or labelling change
 Other None

- Inform all customers possessing the affected products **promptly** about this Field Action by sending the Field Safety Notice for Customers.
- Create an Update Instruction for the removal of the safety washer.
- A local Getinge representative will contact the customer to arrange the removal of the safety washer.

Enclosed documents: • Customer Response Form

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- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please transfer this notice to other organizations on which the action has an impact.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

We apologize for any inconvenience this may cause you and we will do our utmost to carry through this action as swiftly as possible.

As required, we have provided this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local Getinge representative.

Sincerely,

Managing Director

Signature: *Dieter Engel*

*Electronically signed by: Dieter Engel
Reason: I approve this document.
Date: Dec 18, 2023 11:16 GMT+1*

Email: dieter.engel@getinge.com

Person Responsible for Regulatory Compliance (PRRC)

Signature: *Tom Peters*

*Electronically signed by: Tom Peters
Reason: I approve this document.
Date: Dec 18, 2023 11:46 GMT+1*

Email: tom.peters@getinge.com

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GERMANY
Phone: +49 7222 932 - 0
Email: FSCA.cp@getinge.com

CUSTOMER RESPONSE FORM

Subject: 874872 CARDIOHELP Emergency Drive – Removal of the safety washer

Affected Product: CARDIOHELP Emergency Drive (Article number 701048002)
CH Emergency Drive (Article number 701076205)

Affected Serial No.: Refer to Annex I

Please send this form to your local Getinge representative at the latest by **January 8, 2024**.

By completing this document and signing it, I acknowledge that I have read and understand the following associated points:

- I have read and understand this Field Safety Notice for CARDIOHELP Emergency Drives. We will take action as soon as possible according to given instructions.
- I confirm that I have distributed this Field Safety Notice to the affected personal.

- I do not have CARDIOHELP Emergency Drives in my inventory.
- I have the following CARDIOHELP Emergency Drives in my inventory:

Article Number	Product Name	Serial Number	Currently on patient

Your Comments:

Country

Hospital / Clinic (full address)

Date

Name (Function)

Signature

Please return the completed form to your local Getinge representative by email [enter local Getinge mail address](#) or via post [enter local Getinge address](#) or FAX>:

Annex I List of affected serial numbers

This Annex I List of affected serial numbers is considered as a supplementary attachment to the 874872 Field Safety Notice.

Below are listed all serial numbers of products which are affected.

Table 1 general overview

Country	Article	Serial number
Japan	701076205	90425438
USA	701076205	90425443
USA	701076205	90425570
USA	701076205	90425588
USA	701076205	90425716
USA	701048002	90425259
USA	701048002	90425262
Sweden	701048002	90425266
Austria	701048002	90425270
Austria	701048002	90425271
Australia	701048002	90425272
Austria	701048002	90425273
India	701048002	90425274
Austria	701048002	90425275
China	701048002	90425276
China	701048002	90425277
Australia	701048002	90425278
<u>Greece</u>	701048002	90425279
Austria	701048002	90425280
<u>Greece</u>	701048002	90425281
Austria	701048002	90425282
Austria	701048002	90425283
Austria	701048002	90425284
Austria	701048002	90425285
Ireland	701048002	90425286
Thailand	701048002	90425287
Austria	701048002	90425288
Austria	701048002	90425289
<u>Slovenia</u>	701048002	90425290
Austria	701048002	90425291
Austria	701048002	90425293
USA	701048002	90425295
United Kingdom	701048002	90425296
USA	701048002	90425297
Australia	701048002	90425298

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Australia	701048002	90425299
Australia	701048002	90425301
Italy	701048002	90425302
USA	701048002	90425303
USA	701048002	90425304
USA	701048002	90425305
China	701048002	90425306
China	701048002	90425307
South Africa	701048002	90425308
USA	701048002	90425310
USA	701048002	90425312
USA	701048002	90425313
Austria	701048002	90425314
Austria	701048002	90425315
Austria	701048002	90425316
Austria	701048002	90425317
China	701048002	90425318
China	701048002	90425321
China	701048002	90425322
Austria	701048002	90425323
China	701048002	90425324
USA	701048002	90425325
Finland	701048002	90425326
Spain	701048002	90425327
Mexico	701048002	90425328
Austria	701048002	90425329
Australia	701048002	90425330
Mexico	701048002	90425331
China	701048002	90425332
China	701048002	90425333
China	701048002	90425334
USA	701048002	90425335
China	701048002	90425336
China	701048002	90425337
China	701048002	90425338
Spain	701048002	90425339
China	701048002	90425340
Germany	701048002	90425341
France	701048002	90425342
France	701048002	90425344
China	701048002	90425346
France	701048002	90425347
France	701048002	90425348

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China	701048002	90425349
China	701048002	90425350
China	701048002	90425353
China	701048002	90425354
China	701048002	90425356
China	701048002	90425358
China	701048002	90425359
France	701048002	90425360
China	701048002	90425362
United Kingdom/MCP	701048002	90425363
Germany	701048002	90425364
Russia	701048002	90425370
Mexico	701048002	90425372
Mexico	701048002	90425373
Russia	701048002	90425374
China	701048002	90425375
Russia	701048002	90425376
China	701048002	90425378
China	701048002	90425379
Mexico	701048002	90425380
China	701048002	90425381
China	701048002	90425382
Mexico	701048002	90425383
China	701048002	90425385
China	701048002	90425386
China	701048002	90425388
Mexico	701048002	90425389
China	701048002	90425390
Mexico	701048002	90425393
China	701048002	90425394
China	701048002	90425396
China	701048002	90425398
China	701048002	90425399
Canada	701048002	90425400
China	701048002	90425401
Russia	701048002	90425404
China	701048002	90425405
China	701048002	90425406
China	701048002	90425408
China	701048002	90425409
China	701048002	90425410
China	701048002	90425411
China	701048002	90425412

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China	701048002	90425413
China	701048002	90425414
China	701048002	90425416
China	701048002	90425417
China	701048002	90425418
China	701048002	90425419
South Korea	701048002	90425420
China	701048002	90425421
China	701048002	90425422
China	701048002	90425423
China	701048002	90425424
China	701048002	90425428
USA	701048002	90425431
USA	701048002	90425434
Spain	701048002	90425435
USA	701048002	90425436
USA	701048002	90425440
USA	701048002	90425442
USA	701048002	90425444
USA	701048002	90425445
USA	701048002	90425446
USA	701048002	90425447
USA	701048002	90425448
USA	701048002	90425449
<u>Hungary</u>	701048002	90425450
USA	701048002	90425451
Canada	701048002	90425452
USA	701048002	90425455
<u>Hungary</u>	701048002	90425456
<u>Hungary</u>	701048002	90425459
USA	701048002	90425461
Canada	701048002	90425462
USA	701048002	90425463
Spain	701048002	90425464
USA	701048002	90425465
Chile	701048002	90425468
USA	701048002	90425470
USA/MCP	701048002	90425472
USA/MCP	701048002	90425473
Spain	701048002	90425478
Spain	701048002	90425481
Spain	701048002	90425482
Canada	701048002	90425483

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Spain	701048002	90425484
Canada	701048002	90425485
Canada	701048002	90425486
USA	701048002	90425488
Canada	701048002	90425489
Canada	701048002	90425490
Spain	701048002	90425492
USA	701048002	90425494
USA	701048002	90425495
USA	701048002	90425496
USA	701048002	90425498
USA	701048002	90425500
USA	701048002	90425501
USA	701048002	90425502
USA	701048002	90425508
USA/MCP	701048002	90425511
HongKong	701048002	90425512
New Zealand	701048002	90425514
India	701048002	90425518
Mexico	701048002	90425519
USA	701048002	90425520
USA	701048002	90425522
USA	701048002	90425523
USA	701048002	90425524
USA	701048002	90425525
Mexico	701048002	90425526
USA/MCP	701048002	90425534
Pakistan	701048002	90425535
France	701048002	90425536
Spain	701048002	90425537
USA	701048002	90425539
USA	701048002	90425542
Spain	701048002	90425543
Spain	701048002	90425544
Spain	701048002	90425546
HongKong	701048002	90425554
Jordan	701048002	90425556
HongKong/MCP	701048002	90425562
HongKong	701048002	90425567
China	701048002	90425572
China	701048002	90425573
China	701048002	90425575
China	701048002	90425576

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China	701048002	90425577
China	701048002	90425578
China	701048002	90425579
China	701048002	90425580
Switzerland	701048002	90425587
China	701048002	90425596
China	701048002	90425597
China	701048002	90425598
China	701048002	90425600
China	701048002	90425602
Japan	701048002	90425603
Japan/MCP	701048002	90425606
Japan/MCP	701048002	90425607
China	701048002	90425608
China	701048002	90425609
China	701048002	90425610
China	701048002	90425611
China	701048002	90425612
China	701048002	90425613
China	701048002	90425614
China	701048002	90425615
China	701048002	90425617
China	701048002	90425618
China	701048002	90425619
China	701048002	90425620
China	701048002	90425621
China	701048002	90425622
China	701048002	90425623
Taiwan/ China	701048002	90425624
China	701048002	90425625
China	701048002	90425626
China	701048002	90425627
China	701048002	90425628
China	701048002	90425630
China	701048002	90425632
China	701048002	90425633
China	701048002	90425635
United Kingdom	701048002	90425637
Canada	701048002	90425638
United Kingdom	701048002	90425639
China	701048002	90425640
China	701048002	90425641
China	701048002	90425642

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China	701048002	90425643
China	701048002	90425645
China	701048002	90425646
Spain	701048002	90425652
China	701048002	90425658
Spain	701048002	90425659
China	701048002	90425660
China	701048002	90425661
China	701048002	90425663
Spain	701048002	90425664
China	701048002	90425665
Spain	701048002	90425666
Canada	701048002	90425667
Spain	701048002	90425668
China	701048002	90425669
Spain	701048002	90425670
Spain	701048002	90425671
Spain	701048002	90425672
China	701048002	90425673
China	701048002	90425674
China	701048002	90425676
<u>Canada</u>	<u>701048002</u>	<u>90423588</u>
<u>Canada</u>	<u>701048002</u>	<u>90423743</u>
<u>Canada</u>	<u>701048002</u>	<u>90423669</u>
<u>Canada</u>	<u>701048002</u>	<u>90424373</u>
<u>Canada</u>	<u>701048002</u>	<u>90424368</u>
<u>Canada</u>	<u>701048002</u>	<u>90422581</u>
<u>Canada</u>	<u>701048002</u>	<u>90422569</u>
<u>Canada</u>	<u>701048002</u>	<u>90425631</u>
<u>Canada</u>	<u>701048002</u>	<u>90425636</u>
<u>France</u>	<u>701048002</u>	<u>90420317</u>
<u>France</u>	<u>701048002</u>	<u>90420458</u>
<u>France</u>	<u>701048002</u>	<u>90424244</u>
<u>France</u>	<u>701048002</u>	<u>90420851</u>
<u>France</u>	<u>701048002</u>	<u>90420367</u>
<u>Slovenia</u>	<u>701048002</u>	<u>90422041</u>
<u>USA</u>	<u>701048002</u>	<u>90421980</u>
<u>USA</u>	<u>701048002</u>	<u>90421507</u>
<u>USA</u>	<u>701048002</u>	<u>90424277</u>
<u>Hong Kong</u>	<u>701048002</u>	<u>90425549</u>
<u>USA</u>	<u>701048002</u>	<u>90425366</u>
<u>USA</u>	<u>701048002</u>	<u>90422817</u>

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