

Urgent!
Field Safety Notice (FSN)
-Annex II-
List of affected products



This Annex II is considered as a supplementary attachment to the Field Safety Notice of FSCA-2018-03-27

FSCA Number: 2018-03-27

FSCA Title: Arterial Cannula – broken vent plug

Affected Product: Products including 3/8” vent plug (70000.8256)
(see list below)

Affected Timeframe: Non-coated: March 2015 up to now
Coated: March 2016 up to now

| List of affected non-coated products | |
|--------------------------------------|-----------------------------|
| Material No. | Material Text |
| 70100.2206 | A20-0101#Arterielle Kanüle |
| 70100.2207 | A20-0105#Arterielle Kanüle |
| 70100.2208 | A20-0106#Arterielle Kanüle |
| 70100.2209 | A20-0107#Arterielle Kanüle |
| 70100.2211 | A20-2101 #Arterielle Kanüle |
| 70100.2213 | A20-2105#Arterielle Kanüle |
| 70100.2214 | A20-2106#Arterielle Kanüle |
| 70100.2215 | A20-2107#Arterielle Kanüle |
| 70100.2218 | A20-5105#Arterielle Kanüle |
| 70100.2219 | A20-5106#Arterielle Kanüle |
| 70100.2220 | A20-5107#Arterielle Kanüle |

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| Material No. | Material Text |
| 70100.2222 | A20-7101#Arterielle Kanüle |
| 70100.2224 | A20-7105 #Arterielle Kanüle |
| 70100.2225 | A20-7106#Arterielle Kanüle |
| 70100.2226 | A20-7107#Arterielle Kanüle |
| 70100.2227 | A22-0101#Arterielle Kanüle |
| 70100.2228 | A22-0105#Arterielle Kanüle |
| 70100.2229 | A22-0106#Arterielle Kanüle |
| 70100.2230 | A22-0107#Arterielle Kanüle |
| 70100.2233 | A22-2101 #Arterielle Kanüle |
| 70100.2234 | A22-2105#Arterielle Kanüle |
| 70100.2236 | A22-2107#Arterielle Kanüle |
| 70100.2239 | A22-5105#Arterielle Kanüle |
| 70100.2240 | A22-5106 #Arterielle Kanüle |
| 70100.2241 | A22-5107#Arterielle Kanüle |
| 70100.2243 | A22-7101#Arterielle Kanüle |
| 70100.2244 | A22-7105#Arterielle Kanüle |
| 70100.2245 | A22-7106#Arterielle Kanüle |
| 70100.2246 | A22-7107#Arterielle Kanüle |
| 70100.2247 | A24-0101#Arterielle Kanüle |
| 70100.2248 | A24-0105#Arterielle Kanüle |

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| Material No. | Material Text |
| 70100.2249 | A24-0106#Arterielle Kanüle |
| 70100.2250 | A24-0107#Arterielle Kanüle |
| 70100.2253 | A24-2101 #Arterielle Kanüle |
| 70100.2254 | A24-2105#Arterielle Kanüle |
| 70100.2256 | A24-2107#Arterielle Kanüle |
| 70100.2260 | A24-5105#Arterielle Kanüle |
| 70100.2261 | A24-5106#Arterielle Kanüle |
| 70100.2262 | A24-5107#Arterielle Kanüle |
| 70100.2263 | A24-7101#Arterielle Kanüle |
| 70100.2265 | A24-7105#Arterielle Kanüle |
| 70100.2266 | A24-7106#Arterielle Kanüle |
| 70100.2267 | A24-7107#Arterielle Kanüle |
| 70100.2270 | INACTIVE ACF 1890 V#Arterial Cannula |
| 70100.2318 | ACR 1890 V#Arterielle Kanüle |
| 70100.2327 | INACTIVE ACR 2190 V#Arterial Cannula |
| 70100.2388 | AS 18 V#Arterielle Kanüle |
| 70100.2391 | INACTIVE AS 18 V -85 B#Arterial Cannula |
| 70100.2397 | INACTIVE AS 21 V#Arterial Cannula |
| 70100.2400 | INACTIVE AS 21 V -85 B#Arterial Cannula |
| 70100.2405 | INACTIVE AS 24 V#Arterial Cannula |

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| Material No. | Material Text |
| 70100.2408 | INACTIVE AS 24 V -85 B#Arterial Cannula |
| 70100.2466 | ASR 18 V#Arterielle Kanüle |
| 70100.2467 | INACTIVE ASR 18 V -84#Arterial Cannula |
| 70100.2468 | INACTIVE ASR 18 V -85 A#Arterial Cannula |
| 70100.2469 | INACTIVE ASR 18 V -85 B#Arterial Cannula |
| 70100.2477 | INACTIVE ASR 21 V#Arterial Cannula |
| 70100.2478 | INACTIVE ASR 21 V -84#Arterial Cannula |
| 70100.2479 | INACTIVE ASR 21 V -85 A#Arterial Cannula |
| 70100.2489 | INACTIVE ASR 24 V#Arterial Cannula |
| 70100.2490 | INACTIVE ASR 24 V -84#Arterial Cannula |
| 70100.4375 | HK 36 PB -91 V#Arterielle Kanüle |
| 70100.4379 | HK 36 SF -91 V#Arterielle Kanüle |
| 70100.4391 | INACTIVE HK 36 SS -90 V#Arterial Cannula |
| 70100.4413 | INACTIVE HK 45 SE -91 V#Arterial Cannula |
| 70100.4414 | HK 45 SH -91 V#Arterielle Kanüle |
| 70100.4422 | INACTIVE HK 46 SE -91 V#Arterial Cannula |
| 70100.4425 | HK 46 SH -91 V#Arterielle Kanüle |
| 70100.4426 | HK 46 SH -91 V UB100#Arterielle Kanüle |
| 70100.4427 | HK 46 SM -91 V#Arterielle Kanüle |
| 70100.4436 | INACTIVE HK 47 SE -84 V#Arterial Cannula |

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| Material No. | Material Text |
| 70100.4997 | JVP 38#Entlüftungsstopfen 3/8 |
| 70101.3132 | A20-2107 UB 20#Arterielle Kanüle |
| 70101.3135 | A22-2107 UB 20#Arterielle Kanüle |
| 70101.3136 | A24-2107 UB 20#Arterielle Kanüle |
| 70101.3176 | AS 18 V UB 20#Arterielle Kanüle |
| 70101.3185 | INACTIVE AS 24 V UB 20#Arterial Cannula |
| 70101.3186 | ACR 1890 V UB 20#Arterielle Kanüle |
| 70101.3197 | INACTIVE ACR 2490 V UB 20#Arterial Cann |
| 70101.9285 | HK 46 SM -91 V U#Arterielle Kanüle |
| 70102.0645 | INACTIVE HK 36 SN -91 V#Arterial Cannula |
| 70102.0646 | INACTIVE HK 37 SN -91 V#Arterial Cannula |
| 70102.2489 | INACTIVE AC 2190 V#Arterial Cannula |
| 70102.5959 | INACTIVE ASR 21 V -85 C#Arterial Cannula |
| 70102.8271 | HD 0201#OP Zusatzset Variante A |
| 70103.1627 | AS 21 V-J#Arterielle Kanüle |
| 70103.1911 | ASR 21 V-J#Arterielle Kanüle |
| 70103.2183 | AS 18 V-J#Arterielle Kanüle |
| 70103.2328 | HK 46 SH -91 V-J#Arterielle Kanüle |
| 70103.2596 | INACTIVE ASF 21 V-J#Arterial Cannula |
| 70103.3712 | ACR 1890 V-J#Arterielle Kanüle |

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| Material No. | Material Text |
| 70103.3714 | ASR 18 V-J#Arterielle Kanüle |
| 70103.3958 | INACTIVE 462424V UB 50#PERFUSION CANN |
| 70103.5764 | ACR 2190 V-J#Arterielle Kanüle |
| 70105.6148 | H 94500#Cabaret de pompe Chicoutimi |
| 70106.5669 | INACTIVE AS 18 V -85 B UB 20#Art Cann |
| 70107.0178 | H 111400#OP Zusatzset Variante A |
| 70107.1693 | HQV 117700#CliCo HLM-Set |

| List of affected coated products | |
|---|--|
| Material No. | Material Text |
| 701002554 | INACTIVE BE-AS 21 V#Arterial Cannula |
| 701002563 | INACTIVE BE-ASR 21 V#Arterial Cannula |
| 701002686 | INACTIVE BE-HK 46 SE -91 V#Art Cann |
| 701002687 | INACTIVE BE-HK 46 SH -91 V#Art Cann |
| 701013066 | INACTIVE BE-A20-0105#Arterial Cannula |
| 701017339 | INACTIVE BE-A22-0105#Arterial Cannula |
| 701028636 | BE-A24-0105#Arterielle Kanüle |
| 701028952 | BE-A20-5106#Arterielle Kanüle |
| 701033438 | INACTIVE BE-HK 45 SH -91 V#Art Cann |
| 701062633 | BE-HQV 94002#MECC System with Quadrox iR |

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Please note: SSUs are called to actively find out whether the listed devices have been forwarded or sold into any other country. That country where the unit is currently located is also an affected country. Please send any information about forwarding and selling to other countries to:
FSCA-2018-03-27.cp@getinge.com

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

For follow up actions, please contact us on FSCA-2018-03-27.cp@getinge.com

Sincerely,

Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY