

Dear Madam/Sir,

With the following listed cannulas, provided by free life medical,

- Revas® Dual Lumen cannula, all sizes, sterile
- REVAS® Venous Femoral cannula, all sizes, sterile
- REVAS® Universal ECLS cannula V/A, all sizes, sterile
- REVAS® Venous Femoral cannula pre-bent tip, all sizes, sterile

A possible damage to the connectors in form of tension cracks might occur.

Due to this reason all lots/batches of the here listed cannulas are blocked with immediate effect. We therefor request you not to use any of the listed cannulas. We will exchange the affected cannulas as soon as possible

Blocked products:

Code	Product description	LOT
FLK VV19 FLK VV23 FLK VV27 FLK VV31	REVAS® Veno-venous Dual Lumen cannula, application up to 30 days sterile	all
FLK VV19R FLK VV23R FLK VV27R FLK VV31R	REVAS® Veno-venous Dual Lumen cannula, application up to 30 days Rheopax coated, sterile	all
FLK V10 B22 FLK V10B24 FLK V10B26	REVAS® Venous Femoral cannula, ECMO/ECLS, application up to 30 days, sterile	all
FLK V10 B22R FLK V10B24R FLK V10B26R	REVAS® Venous Femoral cannula, ECMO/ECLS, application up to 30 days, Rheopax coated, sterile	all
FLK V20B18 FLK V20B20 FLK V20B22	REVAS® Universal ECLS cannula V/A, 3/8" connector, sterile	all
FLK V20B18R FLK V20B20R FLK V20B22R	REVAS® Universal ECLS cannula V/A, 3/8" connector, Rheopax coated, sterile	all
FLK V19 B18 FLK V19 B20 FLK V19B22	REVAS® Venous Femoral cannula with pre-bent tip, sterile	all

FLK V19 B18 R FLK V19 B20R FLK V19B22R	REVAS® Venous Femoral Cannula with pre-bent tip, Rheopax® coated, application up to 30 days, sterile	all
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This safety indication does not affect cannulas that were supplied after March 12th March, 2019 and does also **not** affect the Revas **arterial** femoral cannulas.

We sincerely regret and apologize this incident and rely on your cooperation and understanding.

Tanja Biel

The logo for free life medical GmbH features a stylized heart icon to the left of the text "free life" in a large, bold, black, lowercase, sans-serif font. Below "free life" is the text "medical GmbH" in a smaller, black, lowercase, sans-serif font.

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Tanja Biel 12.03.18

Quality Management/QMR/QMA