

We,

Christoph Miethke GmbH & Co. KG
Ulanenweg 2
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Want to inform about a recall of potential affected products with possible problems occurring if the deflector wants to be moved on the ventricular catheter. In this case it cannot be avoided consequently that by trying to move the deflector a defect can occur at the catheter that might remain unnoticed. Potentially effected is a very low amount of the potentially possible products (s. list of LOTS). Because the ventricular/deflector combination is a component of the entire shunt system some different article numbers are affected. In case that the surgeon is not sure that due to the try of moving the deflector he defected one of the article/LOT combinations an investigation is recommended with the patient.

Affected Aesculap LOTS:

81748983, 4505103855, 4505103867, 4505106655, 4505113521, 4505122266, 4505125545, 4505129128, 4505134629, 4505134634, 4505134635, 4505134636, 4505137364, 4505137388, 4505150340, 4505150364, 4505150371, 4505150384, 4505150394, 4505150452, 4505156633, 4505156634, 4505156642, 4505164365, 4505164381, 4505168804, 4505171900, 4505174213, 4505184498, 4505184506, 4505187582, 4505187583, 4505187584, 4505191505, 4505193511, 4505193544, 4505199667, 4505209344, 4505209350, 4505209356, 4505212089, 4505215183, 4505224378, 4505231303, 4505236602, 4505246780, 4505246785, 4505246796, 4505246798, 4505249722, 4505249729, 4505252662, 4505268863, 4505278460, 4505278461, 4505283379, 4505286302, 4505286307, 4505293272, 4505293273, 4505298769, 4505298773, 4505307922, 4505313584, 4505313599, 4505313601, 4505313602, 4505323698, 4505366616, 4505394315, 4505442915

Affected products are wearing the Article Number:

FV078P, FV322T, FV323T, FV324T, FV340T, FV341T, FV342T, FV343T, FV431T, FV432T, FV433T, FV434T, FV435T, FV436T, FV459T, FV460T, FV462T, FV463T, FV489T, FV494T, FV495T, FV676T, FV770T.

Please send concerned products wearing one of these Aesculap LOTS in conjunction with one of the mentioned Article Numbers back to:

Aesculap AG,
Department QMV,
Am Aesculap Platz
78532 Tuttlingen
GERMANY

Potsdam, 2014-04-15

Christoph Miethke GmbH & Co. KG
Regulatory Affairs



Dipl.-Ing. Jörg Knebel (Vice President Quality
Management)