Applied Medical

A New Generation Medical Device Company

Field Safety Notice

Customer Name

Street Address

Zip Code, City

Country

Product: BARD Latex-free Arterial Embolectomy Catheters & Syntel® Latex-free Arterial Embolectomy Catheters

October XX, 2020

Dear Valued Customer,

This letter is being sent to advise you that Applied Medical has identified a discrepancy in the German translation of the Instructions for Use (IFU) on the BARD & Syntel Latex-free Arterial Embolectomy Catheters. The Embolectomy Catheters are "contraindicated for endarterectomy procedures or for use in the venous system, grafts, shunts, or as a vessel dilator"; however, due to an oversight, the "CONTRAINDICATIONS" section in the German portion of the IFUs was mistranslated to state that Embolectomy Catheters "are contraindicated for endarterectomy procedures for use in venous system, as grafts, shunts, or vessel dilator." Please see below for a table that outlines the model numbers and the error.

Models	Incorrect Instructions	Correct Instructions
A4F00, A4F01, A4F02, A4F03, A4F04, A4F05, A4F06, A4F07, A4F08, A4402, A4403, A4404, A4405, A4406, A4407, A4408	**KOMPLIKATIONEN:** Syntel-Embolektomiekatheter sind kontraindiziert für Endarteriektomieverfahren sowie für den Gebrauch im Venensystem, **als** Prothesen, Shunts oder Gefäßdilatatoren."	**KOMPLIKATIONEN:** Syntel-Embolektomiekatheter sind kontraindiziert für Endarteriektomieverfahren sowie für den Gebrauch im Venensystem, **in** Prothesen, Shunts oder **als** Gefäßdilatator.
CE0260ST, CE0280ST, CE0340, CE0340ST, CE0380, CE0380ST, CE0440, CE0440ST, CE0480, CE0480ST, CE0580, CE0580ST, CE0680, CE0680ST, CE0780, CE0780ST	**KOMPLIKATIONEN:** BARD - Embolektomiekatheter sind kontraindiziert für Endarteriektomieverfahren sowie für den Gebrauch im Venensystem, **als** Prothesen, Shunts oder Gefäßdilatatoren.	**KOMPLIKATIONEN:** BARD - Embolektomiekatheter sind kontraindiziert für Endarteriektomieverfahren sowie für den Gebrauch im Venensystem, **in** Prothesen, Shunts oder **als** Gefäßdilatator.

NOTE: If you are a distributor, please notify any facilities to which you distributed the affected product.

At this time, no further action is needed. Please reach out to your Applied Medical field representative with any questions or concerns.

Applied Medical will ensure that the appropriate Regulatory Agencies have been notified.

Sincerely,

Dolf Bouma
Director Quality & Regulatory Affairs
Applied Medical Europe B.V.

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