Applied Medical

A New Generation Medical Device Company

Advisory Notice

Customer Name
Street Address
City, State, Zip Code

Product: EB030, Voyant® Fine Fusion device

June XX, 2019

Dear Valued Customer,

This letter is being sent to advise you that Applied Medical has identified a discrepancy on the labels of the Voyant Fine Fusion device. The Voyant Fine Fusion device has been CE approved since January 2015; however, due to an oversight, the label on the sterile tray lid of the lots listed in the table below does not contain the required CE mark. Please note that the CE mark is present on both of the outer boxes and in the enclosed Instructions for Use (IFU) and that this oversight on the sterile tray lid has been remedied moving forward.

No further action is needed as the device itself is CE approved and not affected from a functional perspective.

1317342	1323531	1327575	1330210	1332767	1336780	1342645
1317343	1323532	1327576	1330424	1333207	1337001	1342685
1319540	1323533	1327577	1330425	1333208	1337002	1342686
1319541	1323534	1327578	1331003	1333209	1337003	1343563
1320754	1323536	1328339	1331004	1333215	1338100	1343564
1320780	1323537	1328340	1331005	1334901	1338101	1343990
1320781	1324283	1328341	1331006	1334902	1338102	1343991
1321120	1324284	1328945	1331214	1334903	1338103	1343992
1321696	1324285	1328946	1332032	1335643	1339161	1343993
1322850	1324286	1329552	1332033	1335644	1339162	1343998
1322851	1326373	1329607	1332034	1335650	1339163	1347537
1322852	1326374	1329608	1332766	1335651	1341666	1351163
1322853	1326375					

If you have any questions, please contact your local representative.

Sincerely,

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

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