

Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	Embozene
Manufacturer	Boston Scientific
Country of Origin	Ireland
Lot No.	27832148-26441995-27980743-28587818-28587819-27233780-27271480-27831725-27825091-27712271-27711874-28371623-28393059-27408073-27170407-28022237-28606829-27271480-27718599
Reference	NHRA
Reason of Recall	NHRA initiates this FSN to recall the medical device (Embozene) from Bahrain market, this device is used for Arteriovenous malformations and it is subjected to a recall because it is <u>not approved by NHRA</u> due to lack of the quality documents that ensure safety and quality of the medical device and as a result may put patient health at risk.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative Sky Dot at nael@skydott.com / marwa.m@skydott.com to take the necessary action for recall.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.