


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 | Imager II Angiographic Catheters - 5F curved tip shapes |
| Device Model | M001314661/M001314101/M001314261/M001315151/M001314251/M001314081/ M001314071/M001314091/M001314341/M001314111/M001314151/M001314211/M001314 221/M001314581/M001314781 |
| Manufacturer | BOSTON SCIENTIFIC |
| Reference | https://www.hpra.ie/docs/default-source/field-safety-notices/august-2020/v44430_fsn.pdf?sfvrsn=2 |
| Device picture |  |
| Reason of Recall | NHRA initiates this FSN due to potential for the catheter tip to become detached during a procedure or during procedure preparation. The most common injury related to the tip detaching inside the patient would be the need for intervention to retrieve the fragment or the fragment remaining in the patient's vessel, potentially requiring additional intervention and/or prolonged hospitalization. There is a possibility that a potentially life-threatening embolism of the device fragment could result. |
| Action should be taken | Please stop using the affected medical device and contact the Authorized Representative Gulf Pharmacy at regulatory@gctbahrain.com to take the necessary action for recall. |

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

For more information please contact Medical_Devices@nhra.bh