


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 | |
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| Device Name | USS II Polyaxial 3D Heads |
| Manufacturer | Synthes GmbH |
| Country of Origin | USA |
| Reference | https://www.bfarm.de/SharedDocs/Kundeninfos/EN/11/2019/15446-19_kundeninfo_en.pdf?__blob=publicationFile&v=1 |
| Device picture |  |
| Reason of Recall | NHRA initiates this FSN due to unusual intra-operative sounds associated with use of the above-mentioned medical device and cracking of the USS II Polyaxial 3D Head ring. patients who received the affected implants may suffer from poor spinal mechanics, non-union or malunion, pain, dislocation, and/or loosening. |
| Action should be taken | In case of having the above defected medical device, please stop using it and contact you Authorized Representative to take the necessary action for withdrawal. |

For more information please contact Medical_Devices@nhra.bh

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| | For patients who already using the affected implants, manufacturer recommend that the surgeons perform routine clinical follow-up and discuss potential clinical implications and risks, and in case of any adverse event, please contact NHRA to take the necessary action. |
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Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh