


## 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	StageOne™ and StageOne™ Select Bone Cement Spacer Molds
Lot No.	432165 , 557880
Manufacturer	Zimmer Biomet
Country of Origin	USA
Reference	<a href="https://www.hpra.ie/docs/default-source/field-safety-notices/march-2020/v43199_fsn.pdf?sfvrsn=2">https://www.hpra.ie/docs/default-source/field-safety-notices/march-2020/v43199_fsn.pdf?sfvrsn=2</a>
Device picture	
Reason of Recall	NHRA initiates this FSN due to a potentially insufficient cleaning process or to potentially inadequate process monitoring for cleaning parameters.
Action should be taken	Please stop using the above defected medical device and contact the authorized representative YMH at <a href="mailto:me.regulatory@ymh.com.bh">me.regulatory@ymh.com.bh</a> 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](mailto:Medical_Devices@nhra.bh)