


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 | A Li-Gator Single Use Laparoscopic Clip Applier |
| Model No. | 360-010-001 |
| Codes | 8250 I8251 I8252 I8820 I8821 I8822 I8823 I8824 I8825 I9571-A I9572-A I9573-A I9716-A I9717-A I9718-A I9719-A J0113-A J0114-A J0115-A J0225-A J0227-A J0228-A J0229-A J0230-A J0231-A J0240-A J0243-A J0287-A |
| Manufacturer | Genicon, Inc |
| Reference | https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=183658 |
| Device picture |  |
| Reason of Recall | NHRA initiates this FSN due to Device malfunction causing the applier to jam, and clip loading failures. |
| Action should be taken | Please stop using the above mentioned medical device and contact the authorized representative 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