

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 | Sage Vitrification Media kit |
| Device Model | ART-8026 |
| Lot No. | 211112 002333 |
| Manufacturer | CooperSurgicals |
| Country of Origin | US |
| Reference | Link |
| Reason of Recall | NHRA initiates this FSN due to a mislabeled vials labeled as Vitrification Solution (VS) contain Equilibration Solution (ES). This mislabeling can impact the viability of oocytes/embryos when using these kits. |
| Action should be taken | Please stop using the above mentioned medical device and contact the authorized representative Gulf Corporation for Technology at quality@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