Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2014-RN-01174-1
Product Name/Description[iii]	Endo Wrist One Vessel Sealer (INS-410322) for the da Vinci Si (IS3000) Surgical System (Single use active endotherapy device used in endoscopic procedures for cutting and or coagulating tissue) Model Number: 410322 ARTG Number 132453
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Action Commencement Date[vi]	4/11/2014
Responsible Entity[vii]	Device Technologies Australia Pty Ltd
Reason / Issue[viii]	- During a surgical procedure, if the blade does not return to its original position within a specified timeframe, the system determines the instrument has an "exposed blade". The da Vinci Si System is designed to display a recoverable fault when an "exposed blade" error occurs. A recoverable fault means that you may continue using the system after addressing the error. Activating and firing the knife blade while the jaws are more than 4 mm open increases the likelihood of an exposed blade error. Currently, the Vessel Sealer applies bipolar energy between the electrode surfaces on the interior surface of the instrument jaws in order to coagulate vessels up to 7 mm in size. Users are then instructed to keep the Master Grips fully closed during the sealing cycle. Opening the grip on the masters reduces the pressure applied to the vessel during sealing, which may result in insufficient sealing performance.
Recall Action[ix]	Recall for Product Correction
Recall Action Instructions[x]	Device Technologies Australia is informing their customers of the changes to the user manual to reduce the potential for exposed blade errors and providing a software upgrade to reduce the potential for insufficient sealing. Device Technologies Australia is informing the customers to continue using the Endo Wrist One Vessel Sealer. A Device Technologies Australia product specialist / technician will contact the customer and provide the updated User Manual and schedule the software upgrade which will be available in December 2014.
Contact Information[xi]	1300 338 423 - Device Technologies

Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological