Advisory Committee on the Safety of Medical Devices: Meeting 10

Product Details for consideration of Declarations of Interest

Item 3	Safety / Post-market Surveillance Reviews	Intended Purpose / Issues
3.1	**Essure Contraceptive Device** Sponsor: Australasian Medical & Scientific Ltd(*) Manufacturer: Bayer Healthcare LLC(*)	**Intended purpose -** The ESSURE system is indicated for women who desire permanent birth control (female sterilization) by bilaterial occlusion of the fallopian tubes. The Essure system is composed of two devices per kit, one for each fallopian tube. Each kit has three main components: a single-use disposable delivery system, a permanent implantable micro-insert, and a single-use accessory inducer. The Essure Micro-insert is a dynamically expanding Micro-coil that consists of a stainless steel inner coil, a Nickel Titanium (nitinol) expanding, superelastic outer coil, and polyethelene (PET) fibers. The PET fibers are wound in and around the inner coil. **Issues** – 1. Increase in device incidents both in Australia and world-wide across the 2013 to 2014 post-market data. 2. Increased number of Device Incident Reports (DIR) containing unusual adverse events including fatigue, weight gain, headache, nausea and alopecia.

(*) Note 1 – The previous manufacturer of the device is Conceptus Inc. This company was acquired by Bayer Healthcare LLC in June 2013.

Note 2 – At or around this time, there was also a change to the current sponsor from Device Technologies Australia Pty Ltd.

Note 3 - On 12 September 2014, the TGA was advised by Gytech Pty Ltd of the reinstatement of the CE Mark.