SPINE SOCIETY OF AUSTRALIA

Judgement in the case of Secretary, Department of Health v Medtronic Australasia Pty Ltd [2024] FCA 1096 was handed down by Justice Needham on the 19th of September 2024.

The Court ordered that Medtronic pay a civil penalty of 22 million dollars in addition to 1 million dollars in costs for supplying therapeutic goods for use in humans that were not entered on the Australian Register of Therapeutic Goods (ARTG).

As most are aware, the case centred on Medtronic supplying Infuse not in accordance with its ARTG listing. Infuse had been approved for use with the LT cage for anterior lumbar interbody fusion at L4/5 and L5/S1.

Two components of the judgement are particularly important for surgeons:

1. Paragraph 36 states that:

"*while the Act prohibited the supply of the Kit without the Cage by Medtronic, whether or not the Kit was supplied with or without the Cage the Act did not prohibit a health practitioner from using the Kit (without the Cage) in surgical procedures. The Secretary does not allege that health practitioners acted unlawfully by using the kit in surgical procedures*", and

2. In paragraph 128, Justice Needham concludes:

"*as to the question of harm arising out of the contraventions, it is clear that the available academic literature refers to a risk of harm, however, there is nothing the evidence before that would indicate any specific harm arose out of any contravention of the Act*".

These two parts of the judgment will reassure the surgeons concerned about potential further consequences arising from the settlement.

The conclusion of the case clears the way for Medtronic to now submit an application with the TGA seeking approval for Infuse.