Medtronic's Infuse Product And Sterility: Questions Remain

After being on the market for more than decade, doctors still can't say with any certainty whether Medtronic's spine surgery product known as Infuse increases the risk of a complication that causes sterility in men.

But two independent reviews of the safety and effectiveness of the product published today heighten concerns about the complication and raise questions about why warnings weren't sounded years earlier.

The complication -- retrograde ejaculation [1] -- occurs when semen and sperm enter the bladder instead of the urethra.

It is believed that Infuse, a potent biological agent that stimulates bone growth, may inflame nerves and tissue surrounding the spine, including nerves that control whether semen enters the bladder or the urethra.

On Monday, two groups of independent researchers reported that Infuse offered little benefit over conventional spinal fusion, which requires harvesting a small amount of the patient's own hip bone, and that it may be linked to serious harms, including retrograde ejaculation.

Researchers with Oregon Health & Science University analyzed clinical trial data from Medtronic involving 146 men who underwent spinal fusion surgery. Less than 2 years after surgery, 6% of those who got BMP-2 developed the complication, compared with 1% who underwent traditional spinal fusion surgery.

That translates into a risk that was 4.3 times greater, but because there were not enough patients in the sample, the increased rate was not considered to be statistically significant.

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