- Retrograde ejaculation (RE) is caused by damage to the nerves which control ejaculation. Those nerves lay over the disc space, which may be damaged during an anterior surgical approach. Rates vary, L5-S1 higher than L3-L4 for example, but combined, literature usually quotes the rate of RE as taking place in less than 1% of cases.
- With an issue like RE, in which there is literature showing it to be a procedural adverse event, it is important to look at data from randomized, FDA-regulated trials in which there are multiple surgeons participating, instead of looking at data from a non-randomized data set, such as a single surgeon's own patients, as was the case at the Stanford study.
- In the original randomized clinical trial that was used for supporting FDA approval of INFUSE, the number of men who experienced RE was not enough to statistically link the problem to the product. Medtronic disclosed these RE rates by study arm in its PMA submission and also included the information in its labeling.
- Medtronic takes patient safety very seriously and further evaluated the RE issue following the product's approval. There was another large randomized clinical trial where INFUSE (177 patients) was used as a control comparison to a lumbar disc (405 patients) with a similar open anterior surgical approach. In that study, the rates of RE were nearly identical to those who received Infuse and those who did not.
- During the clinical trials and when Medtronic submitted the PMAs, we disclosed each surgeon's financial interests based on FDA regulations. Our primary endpoint data were also summarized and compared between the surgeons who had financial interests and those who did not in the PMAs submitted to FDA.