

Medtronic seeks guidelines change with Tyrx data



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A positive readout for Medtronic's Tyrx envelope could mean an extra \$1,000 per cardiac implant in the company's pocket.

Medtronic is going to have to hope that the pivotal trial of its Tyrx absorbable antibacterial envelope turns out positive: the data are being presented at two major cardiology conferences on opposite sides of the Atlantic on consecutive days in mid-March.

The device, already widely approved, is a bioresorbable polymer mesh pouch impregnated with the antibiotics minocycline and rifampin. The idea is that a surgeon places a pacemaker or other cardiac device into the envelope before it is implanted, whereupon it works to prevent infections ([Medtronic pushes the envelope with Tyrx buy, January 7, 2014](#)).

Medtronic believes that a hit in [the Wrap-It trial](#) could lead to a change in guidelines that would boost uptake of the device.

The study has enrolled more than 7,000 patients who are having their first cardiac resynchronisation therapy defibrillator implanted or are undergoing replacement or revision of any sort of cardiac implantable electronic device.

Half of the patients will be randomised to receive their new implant placed inside the Tyrx envelope; the other half will receive it bare. The trial is necessarily single-blinded.

Its endpoint is the first occurrence of device infection resulting in the device being removed; an invasive procedure without system removal, such as the implant site being opened; treatment with antibiotics if the subject is not a candidate for system removal, and infection recurrence after the course of antibiotics is finished or evidence of deep infection; or death.

Persuasion

If the Tyrx product is shown to guard against these severe and hugely expensive events – without, of course, causing any of its own – it does seem likely that cardiology societies will recommend that their members use it.

It will also provide Medtronic with a cost-effectiveness case that will have hospitals falling over themselves to get hold of the envelope. In the US, if a patient is readmitted to hospital for treatment of a cardiac device infection the hospital is not paid by the Centers for Medicare and Medicaid Services for the subsequent treatment.

So keen are hospitals to avoid this scenario that Medtronic says around a third of its cardiac devices are implanted in a Tyrx envelope already. If Wrap-It hits and guidelines change this figure will rise sharply.

The envelope is not restricted to Medtronic's own implants; the company sells it for use with any manufacturer's cardiac device, and charges around \$1,000. More than 100,000 implantable cardioverter defibrillators and 300,000 pacemakers are implanted in the US every year, so the device's annual sales could number hundreds of millions of dollars.

If all this plays out as Medtronic hopes, it will represent a huge return on investment for the world's biggest medtech. Medtronic acquired the device's originator in 2014 for just \$160m.