

The crucial trials Medtronic has had to pause



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Covid-19 could mean Medtronic loses out to Abbott, its rival in the mitral valve space.

Geoff Martha has taken over as chief executive of Medtronic in less than ideal circumstances. The world's largest medtech has been hit hard by patients delaying elective surgical procedures so as to stay out of hospital while the Covid-19 pandemic rages on. Last week Medtronic said its weekly US sales for the past few weeks had declined around 60% year over year.

This is bad enough. But the group also said it would pause enrolment into its clinical trials currently recruiting patients, "to allow hospital clinical resources to focus on fighting Covid-19". This could have a longer-term effect, delaying the launch of some of its important new products, most notably Intrepid, its transcatheter mitral valve.

The pivotal US trial of Intrepid is - or was - still in its recruitment phase. [The Apollo study](#) aimed to sign up 1,600 patients with moderate or severe symptomatic mitral regurgitation and compare the minimally invasive valve with surgical valve implantation. Results were expected in the third quarter of 2021.

This is now in doubt, which is a concern since Abbott Laboratories is hot on Medtronic's heels. Abbott's US pivotal of its own mitral valve, Tendyne, is scheduled to conclude in spring 2022, and the group has said nothing about halting recruitment into this or any other study. If Abbott can keep its trial on track, Medtronic's first mover advantage could shrink or disappear entirely.

The mitral race: Medtronic and Abbott's US pivotal studies

Company	Device	Trial name	N	PCD	Trial ID
Abbott Laboratories	Tendyne	Summit	958	Jun 2022	NCT03433274
Medtronic	Intrepid	Apollo	1600	Oct 2021	NCT03242642

PCD = primary completion date. Source: [Clinicaltrials.gov](#) & company communications.

Another transcatheter valve trial will also be affected by the trial halt. [A small study](#) of the Harmony pulmonary valve had been expected to read out in the coming months but according to [clinicaltrials.gov](#) is still recruiting patients. This could slow Medtronic's plans to add a second pulmonary valve to its offering - its Melody device

has been on sale in Europe since 2006 and in the US since 2010.

Lastly, a trial investigating the application of Medtronic's [Visualase laser ablation system to temporal lobe epilepsy](#) could be delayed beyond 2022. The device is used under MRI guidance, and is approved as a surgical device for many different applications; this trial specifically examines its use in patients with drug-resistant epilepsy, a significant unmet need.

Of these trials, Apollo is by far the most important to Medtronic's ambitions. The table below shows *EvaluateMedTech's* consensus sales forecasts for the top five medtechs in 2026, and while Medtronic is still forecast to be at the top Abbott is set to climb the rankings. If Apollo is halted for six months or so and Summit continues as scheduled, the valves could be launched in the US at roughly the same time, giving Abbott a better chance than it might otherwise have had.

Top 5 medtech companies in 2026

	Total medtech sales 2019 (\$bn)	Total medtech sales 2026e (\$bn)	CAGR	Market share 2019	Market share 2026e
Medtronic	30.8	42.4	+5%	6.8%	5.9%
Johnson & Johnson	26.0	33.1	+4%	5.7%	4.6%
Abbott Laboratories	19.9	30.7	+6%	4.4%	4.3%
Stryker	14.9	22.1	+6%	3.3%	3.1%
Siemens Healthineers	16.3	22.1	+4%	3.6%	3.1%

Source: EvaluateMedTech.

Medtronic will report its full-year results for fiscal 2020 next month, and has already cautioned that it expects further pressure from the pandemic, stating that its results will reflect an additional month of impact compared with many other companies that operate on a calendar-based fiscal year.

It also set out where it expects to see the most dramatic effects. The products used in more urgent procedures such as pacemakers and its [Solitaire device](#), used to treat ischaemic stroke, are likely to continue selling; its cryoablation catheters, used in atrial fibrillation, and attempts to move diabetes patients onto its insulin pumps, might be less resilient.

Medtronic's therapies - urgent vs elective

More urgent	Moderately elective	More elective
<i>Cardiac and vascular</i>		
Pacing	Implanted defibrillators	Atrial fibrillation
Aortic	TAVR/structural heart	Endovenous
Coronary	Peripheral	Diagnostics
Cardiac surgery		
<i>Minimally invasive therapies</i>		
Surgery: appendectomy, bowel obstruction, trauma	Surgery: CABG, oncology	Surgery: bariatric, hysterectomy, hernia
Respiratory and patient monitoring		Gastrointestinal
Renal Care		
<i>Restorative therapies</i>		
Spine trauma	Brain modulation	Other spine
Neurovascular: ischaemic stroke	Neurovascular: haemorrhagic stroke	Pain therapies
		Pelvic health
		Ear, nose and throat
<i>Diabetes</i>		
Diabetes supplies		New insulin pump starts
<i>TAVR = transcatheter aortic valve replacement. CABG = coronary artery bypass graft. Source: adapted from Medtronic release.</i>		

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