Medtronic News

Medtronic receives FDA approval for InterStim X™ system, the next generation of the most personalized sacral nerve stimulation therapy for bladder and bowel control

- New InterStim X™ system provides 10 to 15 years of battery life without the need to recharge
- Medtronic bladder and bowel control portfolio offers the most personalized options to fit patient lifestyles

DUBLIN, Feb. 22, 2022 /PRNewswire/ -- Medtronic plc (NYSE:MDT), a global leader in healthcare technology, today announced it received approval from the U.S. Food and Drug Administration (FDA) for InterStim X™ — the next generation of the InterStim™ portfolio's recharge-free device – and it is available immediately. InterStim systems are the standard of care in advanced therapy options, and the most personalized system, to deliver sacral neuromodulation (SNM) therapy. Now the only SNM system backed by 90+ clinical studies, 1,000+ clinical articles, 350,000 patients treated and 25 years of experience, also offers patients a decade or more of treatment with either the new recharge-free InterStim X device, or the rechargeable InterStim™ Micro device. Both devices are used in the treatment of overactive bladder (OAB), chronic fecal incontinence (FI), and non-obstructive urinary retention.

"Countless people suffer from symptoms of bladder and bowel control conditions and thanks to significant recent technology advancements, SNM therapy is becoming a more popular option for patients," said Jannah H. Thompson, M.D., FPMRS, president of the Society of Women in Urology, and urologist at Urologic Consultants in Grand Rapids, Michigan. "This is not your grandmother's therapy. It's exciting to tell patients about the personalized, discreet, smart tech-enabled InterStim choices they now have for long-term relief."

The InterStim X device features:

- Proprietary 5th generation battery chemistry that offers more than 10 years of battery life without the need to recharge, providing patients with more freedom and less maintenance. With low energy settings, the device may last up to 15 years.

The InterStim Micro device features:

- Proprietary Overdrive™ battery technology that offers more than 15 years of battery life with regular recharging once a month, and the smallest, most powerful rechargeable SNM device on the market.

Both systems feature:

- The first and only smart programmer - a programming device that looks like a common smartphone so patients may discreetly and independently adjust their choice of 11 therapy settings at home or on-the-go.
- SureScan™ technology that enables full body 1.5T and 3T MRI scans under certain conditions and does not require impedance checks. MRI mode is easy for patients to independently activate or deactivate on the smart programmer.

"We're on a mission to expand access to proven nerve stimulation therapies through technology advancements like InterStim X, InterStim Micro, SureScan MRI technology and the smart programmer, by offering patients personalized therapy options and by reaching them through direct-to-consumer marketing," said Mira Sahney, president of the Pelvic Health business, which is part of the Neuroscience Portfolio at Medtronic. "As we celebrate 25 years of InterStim this year, we're bullish about our next chapter in patient-focused therapy innovation."

More than 37 million adults in the United States — almost one in six — suffer from overactive bladder (OAB),[1,2] and nearly 18 million Americans — about one in 12 — are living with fecal incontinence.[3,4] Many sufferers limit their lives socially, professionally, and personally.[5] However, as many as 45% who suffer from symptoms do not seek treatment and as many as seven in 10 stop using medications within six months due to intolerable side effects or unsatisfying results.[6,7,8]

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered inDublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 90,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

[1] Stewart WF, et al. Prevalence and burden of overactive bladder inthe United States. World J Urol. 2003 May;20(6):327-336.

[2] United Nations, Department of Economic and Social Affairs, Population Division (2011). World Population Prospects: The 2010 Revision, CD-ROM Edition.

[3] Whitehead WE, Borrud L, Goode PS, et al. Pelvic floor disorders network. Fecal incontinence in US adults: epidemiology and risk factors. Gastroenterology. 2009;137: 512-517.

[4] United States Quick Facts. United States Census Bureau Web site. Available at:https://www.census.gov/quickfacts/table/PST045215/00. Accessed July 19, 2016.

[5] Dmochowski RR, Newman DK. Impact of overactive bladder on women inthe United States: results of a national survey. Current Medical Research and Opinion. 2007;23:65-76.

[6] Leede Research, "Views on OAB: A Study for the National Association of Continence."December 16, 2015.

[7] Yu YF, Nichol MB, Yu AP, et al. Persistence and adherence of medications for chronic overactive bladder/urinary incontinence in the California Medicaid Program. Value in Health. 2005;8(4)495-505.

[8] Yeaw J, Benner JS, Walt JG, Sian S, Smith DB, et al. J Manag Care Pharm. 2009;15(9):728-740.

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