PROVEN TO **PERFORM**

Five years of clinical data for the InterStim™ system

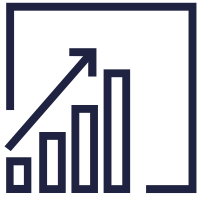
Medtronic

BACKED BY SCIENCE, **DRIVEN TO INNOVATION**

Over twenty years ago, Medtronic introduced Sacral Neuromodulation (SNM) therapy and transformed the treatment options for incontinence. Today, we continue our commitment to Pelvic Health and improving patients lives.

Partnering with Medtronic provides your patients with...

RELIABILITY



250,000 INTERSTIM™ PATIENTS TREATED WORLDWIDE

CONFIDENCE

GLOBAL PRESENCE TO SUPPORT INTERSTIM™ THERAPY

FREEDOM

MORE THAN 80% SATISFIED WITH INTERSTIM™ THERAPY[1,2]

BLADDER CONTROL **PROVEN AT 5 YEARS[3]**

82%

of Overactive Bladder (OAB) patients achieved clinical success* at 5 years.†

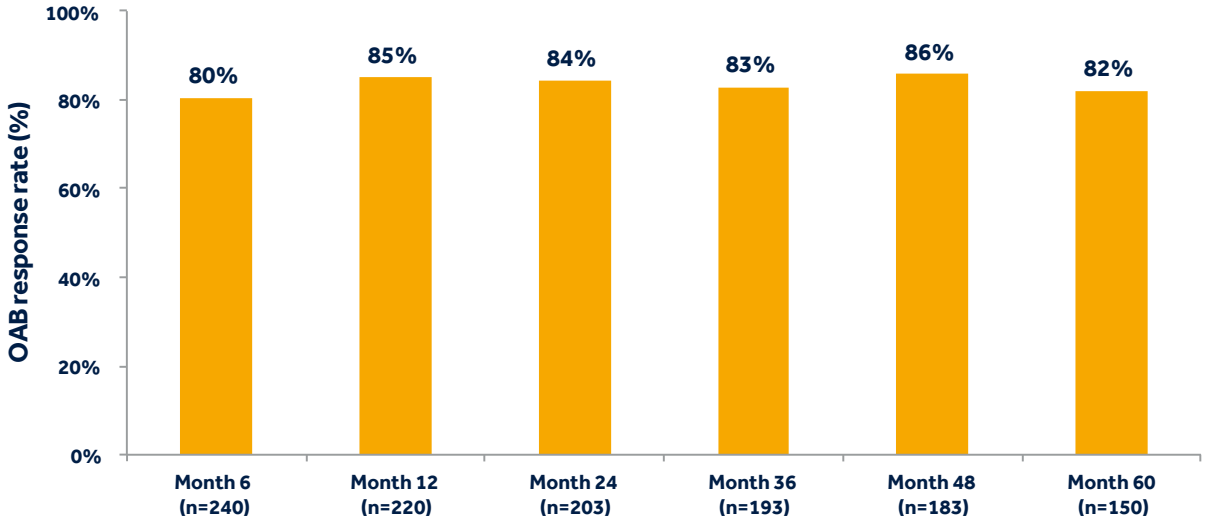
45%

of Urinary Incontinence patients were completely continent at 5 years.†

The most common adverse events were: undesirable change in stimulation, implant site pain, and therapeutic product ineffective.

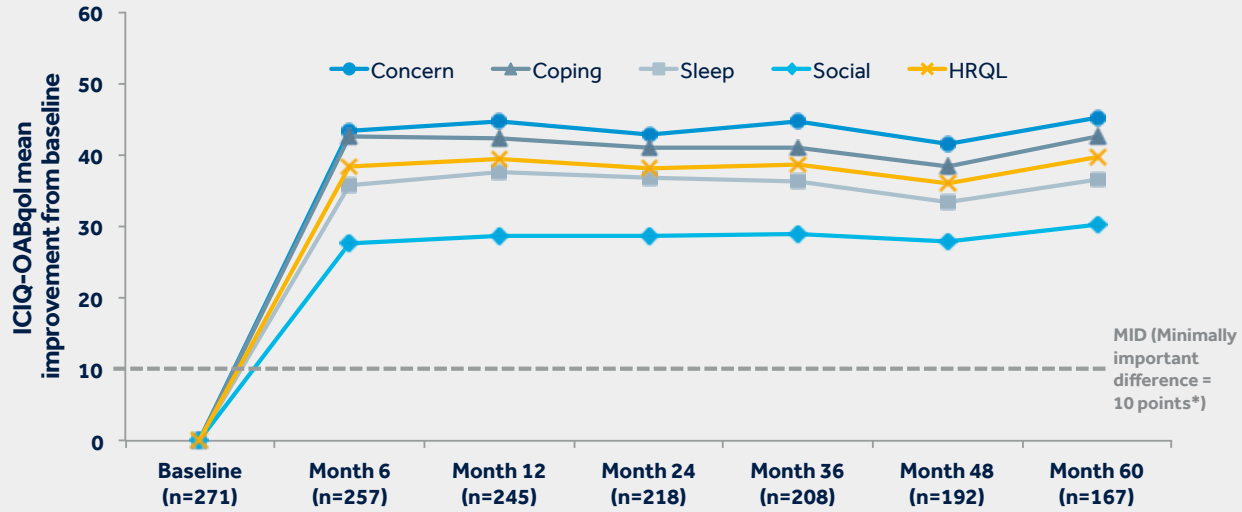
* Clinical success was defined as ≥ 50% improvement in average leaks or voids/day or a return to normal voiding (<8 voids/day).
† Completers analysis

INTERSTIM™ DEMONSTRATED SUSTAINED LONG-TERM EFFICACY†[3]



† Numbers reflect completers analysis, which includes all implanted subjects with diary data at baseline and at each follow-up. Clinical success was 83% at 12 months, 76% at 36 months and 67% at 5 years using the modified completers analysis (subjects who either had baseline and follow-up evaluation or withdrew early due to device-related reasons and are considered failures).

INTERSTIM™ DEMONSTRATED SUSTAINED QUALITY OF LIFE (QOL) IMPROVEMENTS AT 5 YEARS[3]



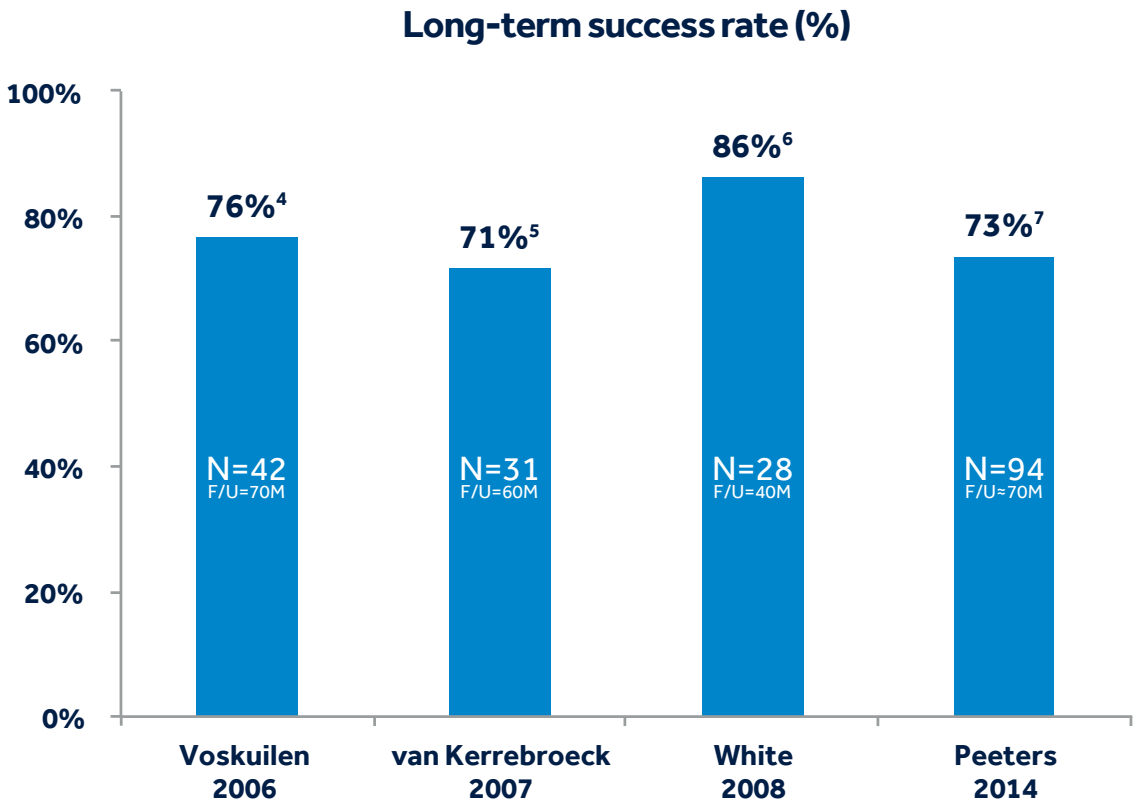
*Coyne KS, et al. 2006. Determining the importance of change in the OAB-q. J Urol 176:627-32.
All paired tests comparing follow-up to baseline had a p-value <0.0001.

PROVEN SAFE IN A WIDE RANGE OF PATIENTS[4,5]

- SNM using the InterStim™ system is a safe and effective treatment for patients with OAB and non-obstructive urinary retention who have failed or are not candidates for more conservative treatments.
- InterStim™ demonstrated sustained and significant improvements in quality of life for patients with OAB and non-obstructive urinary retention at 5 years.

The most common adverse events experienced during clinical studies included pain at implant sites, new pain, lead migration, infection, technical or device problems, adverse change in bowel or voiding function, and undesirable stimulation or sensations. Any of these may require additional surgery or cause return of symptoms.

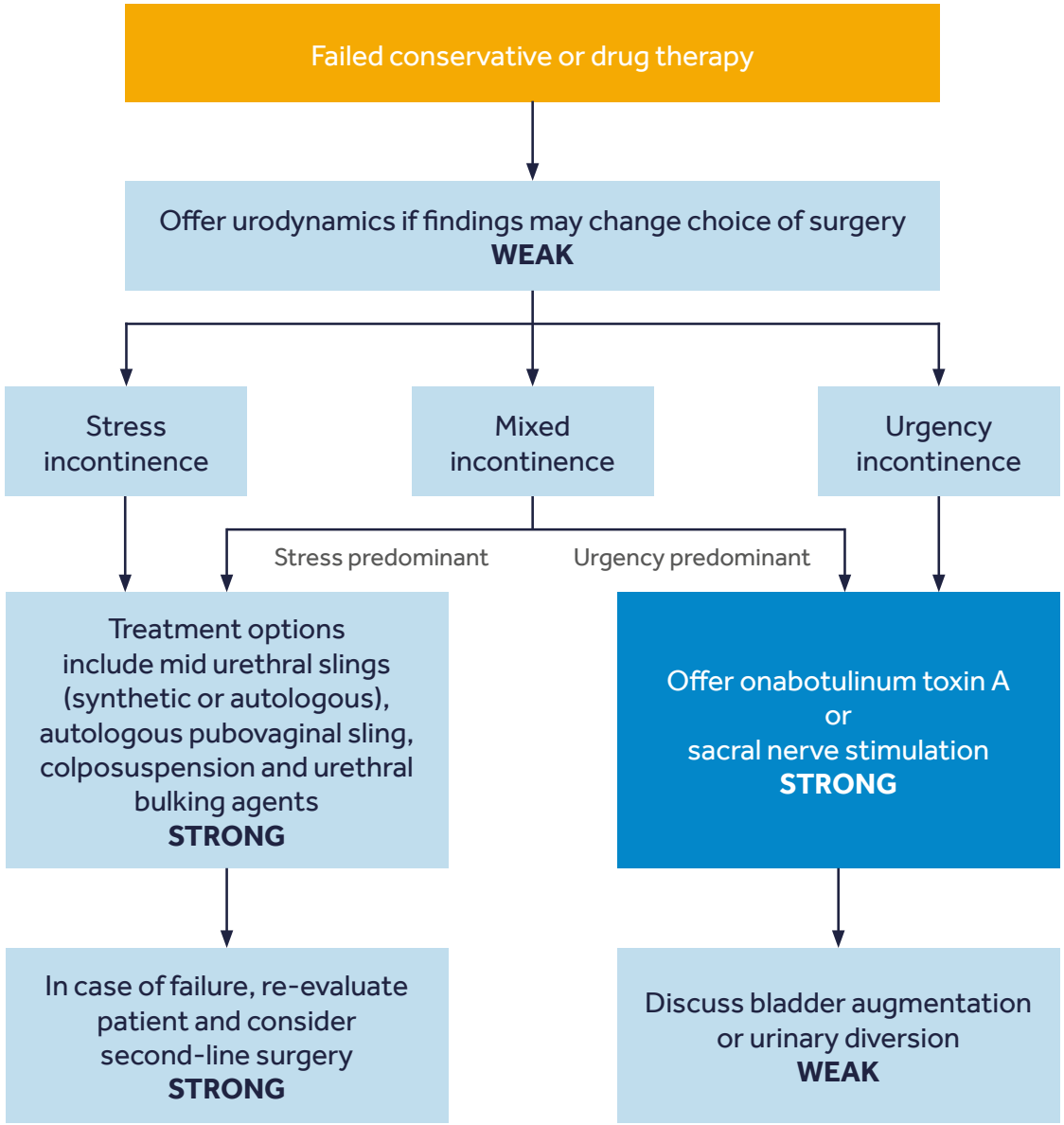
Non-obstructive Urinary Retention



Clinical success was defined as 50% or greater improvement from baseline in primary voiding diary variable(s) or subjective patient satisfaction.

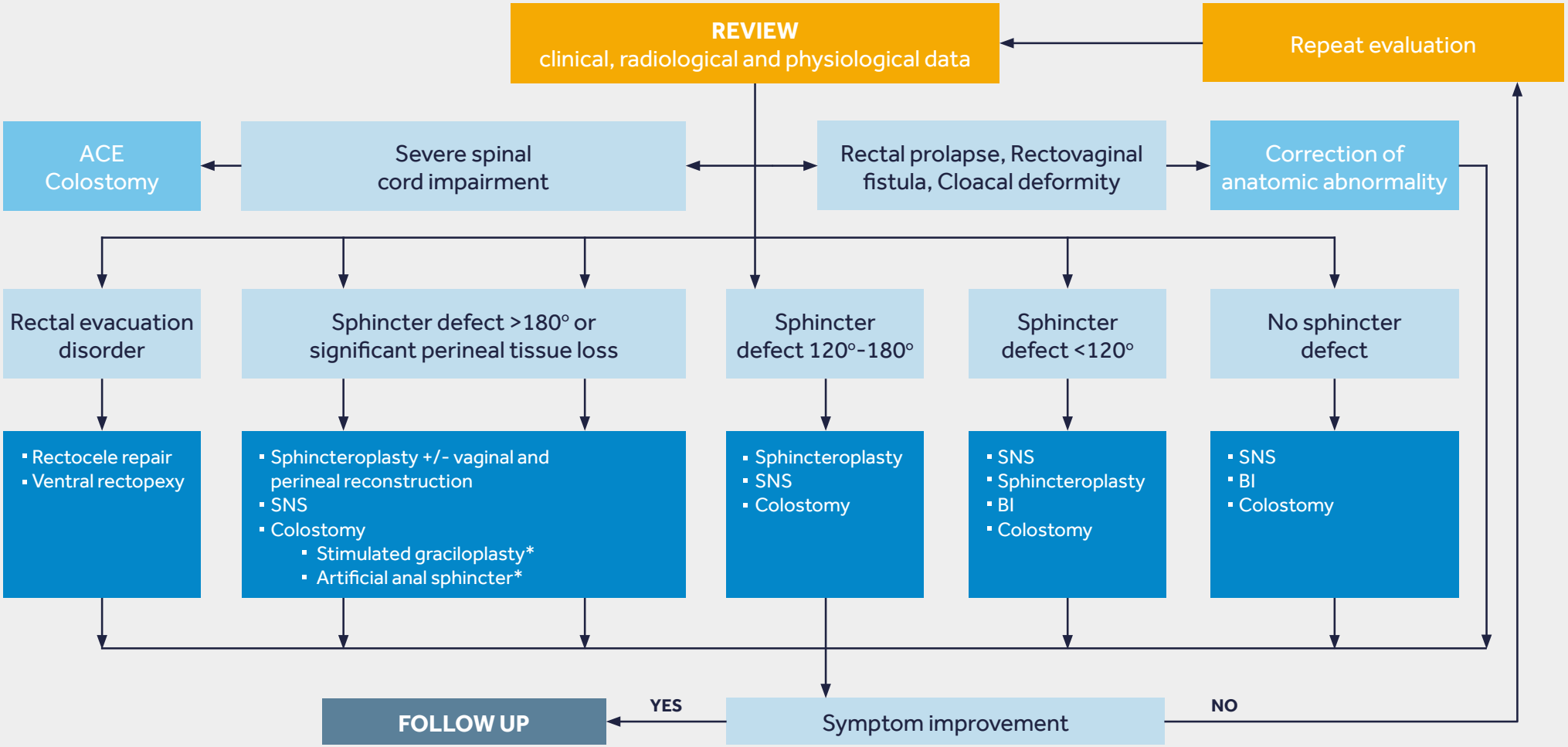
SIGNIFICANT SYMPTOM IMPROVEMENT DEMONSTRATED AT 5 YEARS

SNM with InterStim™ therapy[8]: established by international guidelines



SPECIALIZED MANAGEMENT OF URINARY INCONTINENCE IN WOMEN: SURGICAL TREATMENT

ICI* 2017: Surgical management of fecal incontinence[9]



ACE: Antegrade Continence Enema, **BI:** Biomaterial injection
SNS: Sacral Nerve Stimulation, *Not widely available.

Novel therapies
- Magnetic anal sphincter
- Radiofrequency energy treatment
- Puborectal sling
- Stem cell therapy
- Vaginal pessary - Eclipse™

*International Consultation on Incontinence)

BOWEL CONTROL **PROVEN AT 5 YEARS**[10]

The most common adverse events through 5 years (≥5% of patients, n=120) are implant site pain, parasthesia, change in sensation of stimulation, implant site infection, urinary incontinence, neurostimulator battery depletion, diarrhea, pain in extremity, undesirable change in stimulation, and buttock pain.

89%

of bowel patients achieved clinical success* at 5 years.[10†]

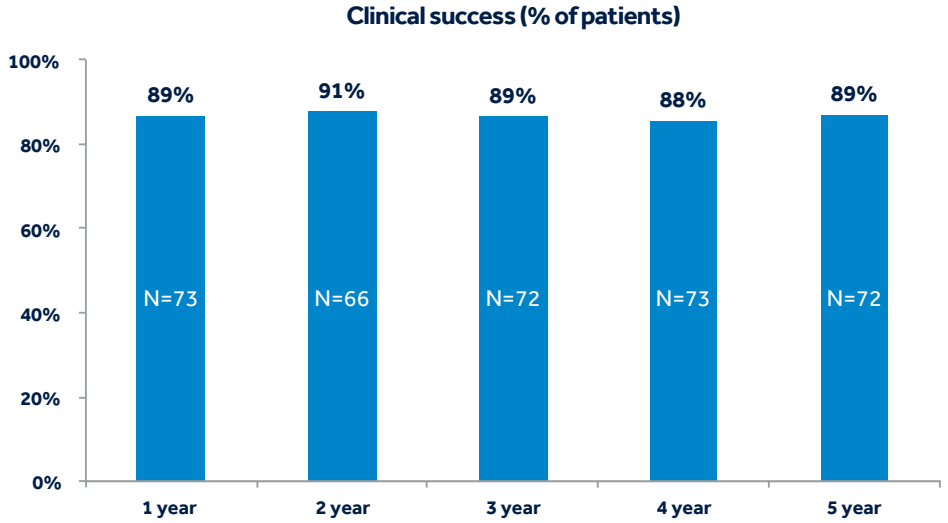
36%

of bowel patients achieved complete continence.[10†]

* Clinical success was defined as ≥ 50% reduction of FI episodes/week.

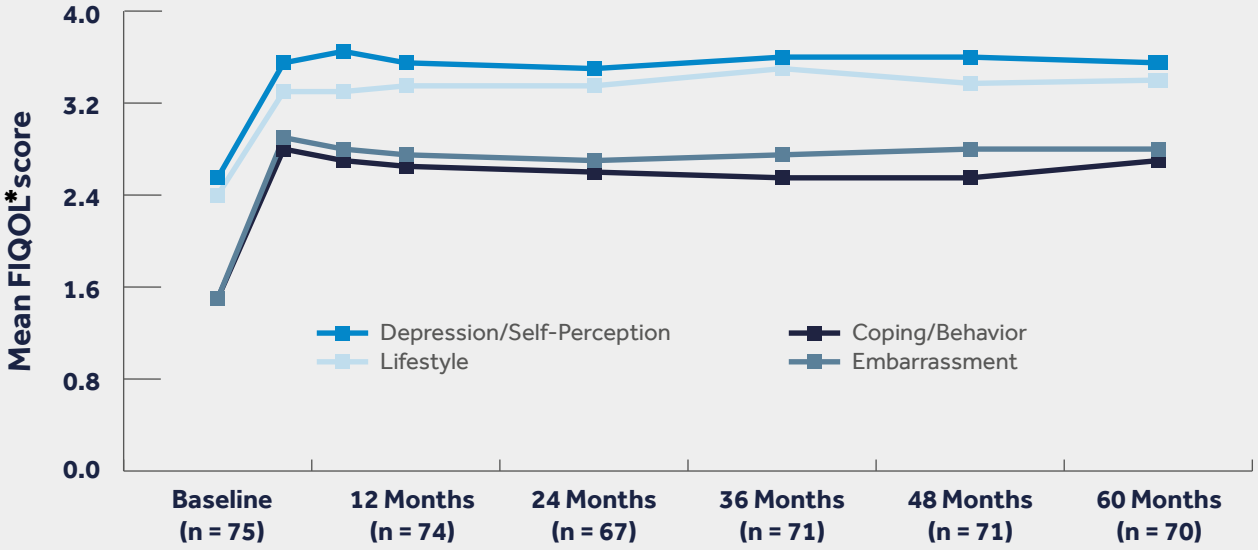
† Completers analysis

INTERSTIM™ DEMONSTRATED SUSTAINED LONG-TERM EFFICACY FOR FECAL INCONTINENCE[10]



Completers analysis with the proportion of patients with therapeutic success (≥50% improvement)

INTERSTIM™ DEMONSTRATED SUSTAINED QOL IMPROVEMENTS AT 5 YEARS[10]



Study data demonstrate significant improvement in patient quality of life for patients with chronic FI, including physical and psychological well-being, as determined by a variety of accepted measures.[3] Mean FIQOL component scales at each visit for patients with at least 5 years of follow-up (higher score indicates better quality of life).

* Fecal Incontinence Quality of Life (FIQOL)

More than **250,000** patients treated globally.

See the device manual for detailed information regarding the instructions for use, implant procedure, indications, contraindications, warnings, precautions, and potential adverse events.
For further information, contact your local Medtronic representative or consult the Medtronic website at www.medtronic.ca

References

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