MONITORING PERFORMANCE OF SACRAL NEUROMODULATION SYSTEMS IN A REAL-WORLD POPULATION: THE PRODUCT SURVEILLANCE REGISTRY

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Objective

The Product Performance Registry serves as an ongoing source of acute and chronic product performance, patient safety and clinical outcomes associated with the use of market-released products.

Background

Sacral neuromodulation (SNM) through InterStim® therapy has been shown to be a safe and effective treatment for urgency urinary incontinence, urinary urgency-frequency, non-obstructive urinary retention, and chronic fecal incontinence.

To continually monitor safety and performance of this therapy, a registry was developed to prospectively track performance and outcomes data in real-world sacral neuromodulation patients. This registry creates a standardized, uniform way to follow a large cohort of patients over time for variables of interest.

Study Design and Methods

The Product Surveillance Registry (PSR) is a prospective, long-term, multi-center global registry originated for SNM in 2010.

The PSR enrolls both newly-implanted patients and patients receiving a replacement neurostimulator device, and each group is followed prospectively for events related to device, procedure or therapy. In 2013, the PSR was expanded to include the collection of patient reported outcome measures (e.g. PGI-I) and more detailed procedure information.

To meet the objective on providing ongoing patient safety information, adverse and device events are classified as a product performance related (PPR) or non-product performance related event.

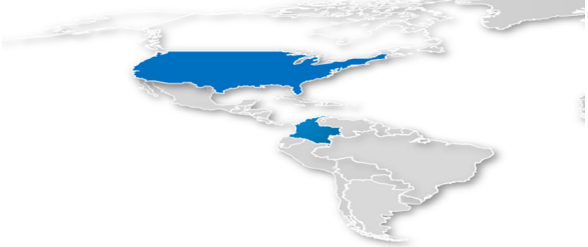
A PPR event is defined as possibly due to a device-related issue, and non-PPR events are undesirable experiences occurring to the patient, that possibly resulted from or was related to the implant procedure, therapy, or delivery of therapy, and cannot be classified as a product performance related event.

Results

As of October 31, 2017, 20 centers in North and South America have enrolled 969 sacral neuromodulation patients in the PSR (Figure 1).

Figure 1: Geographic Contribution to PSR-SNM Registry

969	553	20	3,100+
Patients enrolled in the registry	Patients active in the registry	Sites contributing to the registry	Years of device experience in the registry



- As shown in Table 1, 83.2% of patients were receiving their first implant and 83.3% were female.
- The most common treatment indications were urgency urinary incontinence (41.5%) and urinary urge-frequency (31.8%) (Table 2).
- As an ongoing registry, not all patients may have demographic information included in the database at the time of the data cut-off or data were not collected for that variable in earlier versions of the protocol.

Table 1: Patient Demographics

Patient Characteristics	Total Enrolled Patients Mean ± SD (N) Median [Min, Max] or % (n/N)
Age	60.4 ± 16.0 (967)
BMI	31.2 ± 8.7 (805)
Sex	
Male	16.7% (159/953)
Female	83.3% (794/953)
Device Status	
Initial device	83.2% (778/935)
Replacement device	16.8% (157/935)
Diabetes	26.5% (185/697)

Table 2: Primary Treatment Indication

Primary Treatment Indication [a]	Total Enrolled Patients (Percent)
Urgency Urinary Incontinence	402 (41.5%)
Urgency-Frequency	308 (31.8%)
Urinary Retention	117 (12.1%)
Fecal Incontinence	46 (4.7%)
Interstitial Cystitis	19 (2.0%)
Other	77 (7.9%)
Total Patients	969

[a] Refer to product labeling for approved indications in your geography

InterStim device survival* (freedom from a product performance event) is 98.9% at two-years for the InterStim device and 98.5% at two years for the InterStim II device.

Lead survival during the same time period is 90.4% for model 3889 and 94.0% for model 3093.

Cumulatively, the PPR event rate is 6.1 events/100 patient years of follow-up. Of the non-product performance events, common categories were therapeutic non-responders (15.5% of reported events), medical device site pain or discomfort (10.0%), with the majority being urinary tract infections (UTI) (45.7%) unrelated to device or therapy.

Data from the PSR is included in a product performance report which is updated annually.

Conclusion

The PSR prospectively captures valuable real-world information from a heterogenous group of centers.

This information is used to guide future product development efforts aimed at improving product reliability and quality. In addition, data from the registry provide information about the treatment practices of physicians using these therapies.

With higher demands for post-market surveillance from multiple stakeholders, this registry can serve those evolving needs as well as inform clinicians and patients on safety and effectiveness of this important therapy.

This registry is sponsored by Medtronic

If the device's event/censoring date was the same as the patient's consent date, it was not included in the analysis.