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CLINICAL SUMMARY

Medtronic InterStim® Therapy

Medtronic-sponsored research

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Additional information available for the InterStim Therapy system

Documents packaged with this product:

- For general system information, including contraindications, warnings, precautions, resterilization, component disposal, adverse events, patient counseling, and electromagnetic interference information, refer to the *Information for Prescribers (IFP) Manual*.
- For therapy-specific information, refer to the *Indications Insert*.
- For information regarding device compatibility, refer to the *System Overview and Compatibility Insert*.
- For warranty information, refer to the *Limited Warranty and Special Notice Insert*.

Documents packaged with the clinician programmer software application card:

- For neurostimulator selection, battery longevity calculations, and specific neurostimulator specifications refer to the *System Eligibility, Battery Longevity, Specifications Reference Manual*.

Introduction

The safety and efficacy of Medtronic InterStim Therapy has been investigated by four Medtronic-sponsored studies — one prospective clinical trial, two retrospective studies, and one post-approval study:

- Single Stage Implant, Clinical Study
- Staged Implant, Retrospective Study
- Buttock Neurostimulator Placement, Retrospective Study
- InterStim System, Post-Approval study

The configuration of the neurostimulation systems used in the studies included an Itrel II or Model 3023 neurostimulator¹, a non-tined lead (Model 3886 or 3080), and a lead extension.

The summaries below present results from the individual studies, as well as information about the study designs and methods.

Single Stage Implant, Clinical Trial

The Medtronic InterStim System using the Single Stage Implant Technique was evaluated in a multicenter trial at study centers in the United States, Canada, and Europe for the indications of urge incontinence, urgency-frequency, and retention.

Patients Studied

Urge Incontinence Study² – One hundred eighty-four urge-incontinent patients were enrolled in the study (36 males). The mean age was 47 years (range 20 to 79 years). These 184 patients underwent at least one, and in some cases up to six test stimulation procedures. Of these 184 screened patients, 112 had a successful test stimulation result (experienced at least a 50% improvement in leaking variables). Of these 112 patients who were eligible for implantation, 100 (9 males) were implanted with the InterStim System. Fifty-eight patients (6 males) have data at six months follow-up and 38 patients (4 males) have data at twelve months follow-up.

Urgency-Frequency Study – Two-hundred twenty urgency-frequency patients were enrolled into the study (44 males). The mean age was 41 years (range 17 to 78 years). These 220 patients underwent one, and in some cases, up to six test stimulation procedures. Of the 220 screened patients, 80 had a successful test stimulation result (experienced at least a 50% reduction in urgency-frequency parameters). Of the 80 patients who were eligible for implantation, 64 (6 males) were implanted with the InterStim System. Forty-six patients (5 males) have data at six months follow-up and 33 patients (5 males) have data at twelve months follow-up.

¹ The Model 3023 Neurostimulator used in the study is functionally equivalent to the Itrel II neurostimulator.

² The six and twelve-month efficacy data for the urge-incontinent patient group is from the original study and has not been updated. However the safety data for all three patient groups was updated.

Retention Study – One hundred seventy-seven retention patients were enrolled into the study (46 males). The mean age was 43 years (range 17 to 81 years). These 177 patients underwent one, and in some cases, up to five test stimulation procedures. Of the 177 screened patients, 68 had a successful test stimulation result (experienced at least a 50% reduction in residual volume). Of the 68 patients who were eligible for implantation, 55 (7 males) were implanted with the InterStim System. Forty-seven patients (4 males) have data at six months follow-up and 38 patients (3 males) have data at twelve months follow-up.

Study Design and Methods

Design – The clinical study was a multicenter prospective randomized trial. All of the enrolled patients completed a test stimulation procedure of the sacral nerves. The test stimulation results were used to determine patient eligibility for randomization.

Patients were randomized into either an immediate implantation of the InterStim System (treatment arm) or six-month delay from implant (control arm). After completing the six-month delay arm, control group patients could elect to cross over to the treatment arm of the study. All implanted patients were followed at six-month intervals until completion of the study.

Methods – The effect of InterStim Therapy on dysfunctional voiding behavior was evaluated using a voiding diary as the primary outcome measure.

During the test stimulation period, voiding diary results completed at baseline and during the test stimulation were compared. If the results showed a minimum of 50% improvement in dysfunctional urinary symptoms, the patient was eligible for randomization.

Voiding diaries were completed at baseline and at six months for control group patients and at baseline, one, three, six, and twelve months post implant (and at six-month intervals thereafter) for the treatment group patients. Concomitant medical treatment, such as medications, was allowed in both the control and treatment arms of the study.

Study Results

The Medtronic InterStim System was implanted in 219 patients in the clinical study. These 219 patients were followed for 0 to 47 months with a mean follow-up time of 17.6 months.

Adverse Events

Approximately 52% of patients experienced 201 adverse events related to InterStim Therapy. Of the 201 adverse events, 8% required no intervention, 38% required non-surgical intervention, and 54% required hospitalization or surgical intervention. None of these events resulted in permanent injury, however 9% were not resolved at the time of database closure.

The following therapy-related events were observed in the clinical trial (with the probability of adverse events in the first 12 months indicated in parentheses):

- Pain at neurostimulator site (15.3%)
- New pain (9.0%)
- Suspected lead migration (8.4%)
- Infection (6.1%)
- Transient electric shock (5.5%)
- Pain at lead site (5.4%)
- Adverse change in bowel function (3.0%)
- Technical problem (1.7%)
- Suspected device problem (1.6%)
- Change in menstrual cycle (1.0%)
- Adverse change in voiding function (0.6%)
- Persistent skin irritation (0.5%)
- Suspected nerve injury (0.5%)
- Device rejection (0.5%)
- Other¹ (9.5%)

Surgical Revision – Thirty-three percent of implanted patients required surgical intervention to resolve an adverse event. The leading events requiring revision surgery were pain at the neurostimulator site (13.7% of implanted patients) and suspected lead migration (7.8% of implanted patients).

The probability of 1 adverse event requiring revision surgery was 29% at 12 months and 41% at 24 months. The probability of a second surgical intervention was 9.4% at 12 months and 14.3% at 24 months.

Seven implanted InterStim System patients had their systems explanted. Three were explanted due to pain at the neurostimulator implant site, one due to new pain, one due to adverse change in bowel function, and two due to infection.

¹ Other adverse events included the following: change in sensation of stimulation (9), grand mal seizure when stimulation inactivated (1), hematoma or seroma (1), urinary hesitancy (1), neurostimulator turns on and off (2), lack of orgasm (1), lack of efficacy (2), numbness and tingling (3), foot/leg movement (6), strong anal sensation (1), unable to perceive stimulation (2), stress urinary incontinence (1), swollen feeling in abdomen (1), vaginal cramps (1), superficial connection (1), and possible skin perforation at neurostimulator (1).

Efficacy

Voiding diary results showed statistically significant reductions in dysfunctional voiding symptoms in patients implanted with the InterStim System as compared to baseline.

Table 1 through **Table 3** show the percentage of patients who experienced a successful result ($\geq 50\%$ improvement in baseline symptoms) as recorded in voiding diaries at six and twelve months follow-up post implant. These results were obtained in patients refractory to conservative treatments.

Urge Incontinence Efficacy Results

As **Table 1** indicates, 47% of implanted patients were dry at six months and an additional 28% reduced the frequency of leaking episodes by $\geq 50\%$ for a total clinical success rate of 75% of implanted patients.¹

Table 1. Six and Twelve Month Post Implant Results for Urge Incontinence (% of Patients with Successful Result).

	Six Months Post Implant (n = 58 patients)	Twelve Months Post Implant (n = 38 patients)
Any Leaking Episode		
Dry	47%	45%
$\geq 50\%$ Reduction	28%	34%
Total Clinical Success	75%	79%
Heavy Leaking Episodes		
Eliminated	77%	70%
$\geq 50\%$ Reduction	13%	10%
Total Clinical Success	90%	80%

Of patients who experienced heavy leaking episodes at baseline (soaked pad or clothing), 77% of patients eliminated heavy leaking episodes completely at six months and an additional 13% reduced the average severity of leaking (to less than two tablespoons) by $\geq 50\%$ for a total clinical success rate of 90% of implanted patients. These results were sustained at twelve months.

¹ The six and twelve-month efficacy data for the urge-incontinent patient group is from the original study and has not been updated. However the safety data for all three patient groups was updated.

As compared to control patients who did not receive an implant, the group of implanted patients demonstrated significantly improved quality of life (SF-36 Health Survey) at six months with respect to:

- Physical functioning ($p = 0.001$)
- General health ($p < 0.0001$)
- Vitality ($p = 0.018$)

Urgency-Frequency Efficacy Results

As **Table 2** indicates, 34% of implanted patients had $\geq 50\%$ reduction in the number of voiding episodes/day and another 14% decreased into the normal range (4 to 7 voids/day)¹, 54% of implanted patients had $\geq 50\%$ increase in the volume voided per void, and 83% of implanted patients demonstrated an improvement in the degree of urgency prior to void. These results were sustained at twelve months.

Table 2. Six and Twelve Month Post Implant Results for Urgency-frequency (% of Patients with Successful Result).

	Six Months Post Implant (n = 46 patients)	Twelve Months Post Implant (n = 33 patients)
$\geq 50\%$ Reduction in Voids/Day	34%	33%
Normal Number of Voids (4-7) in Voids/Day ^a	14%	31%
$\geq 50\%$ Increase in Volume Voided/Void	54%	61%
Improved Degree of Urgency Prior to Void ^b	83%	82%

^a In patients with a baseline frequency of >7 voids per day.

^b Success is defined as increased voided volumes with the same or reduced degree of urgency.

¹ In patients with a baseline frequency of >7 voids per day.

As compared to control patients who did not receive an implant, the group of implanted patients demonstrated significantly improved quality of life (SF-36 Health Survey) at six months with respect to:

- Physical functioning ($p < 0.0001$)
- Role physical ($p = 0.01$)
- Bodily pain ($p = 0.01$)
- General health ($p = 0.003$)
- Vitality ($p = 0.01$)
- Social functioning ($p = 0.002$)
- Mental health ($p = 0.01$)

With respect to the three patient groups, urodynamic test results indicated that the InterStim Therapy does not adversely affect a patient's ability to void.

Additionally, patients implanted with the InterStim System perceived a significantly greater degree of improvement in General Health Status (SF-36 Health Survey) at six months as compared to control patients who did not receive the implant ($p < 0.0001$).

Retention Efficacy Results

As **Table 3** indicates, 53% of the patients eliminated catheterization use completely at six months and an additional 19% reduced residual catheter volume by $\geq 50\%$ for a total clinical success of 72% of implanted patients. These results were sustained at twelve months.

**Table 3. Six and Twelve Month Post Implant Results for Retention
(% of Patients with Successful Result).**

	Six Months Post Implant (n = 47 patients)	Twelve Months Post Implant (n = 38 patients)
Residual Catheter Volume		
Eliminated Catheterization	53%	61%
$\geq 50\%$ Reduction	19%	16%
Total Clinical Success	72%	77%

As compared to control patients who did not receive an implant, the group of implanted patients demonstrated significantly improved quality of life (SF-36 Health Survey) at six months with respect to bodily pain ($p = 0.03$).

Staged Implant, Retrospective Study

The Staged Implant is intended for patients who have an inconclusive test stimulation with the currently marketed Medtronic Model 3057 Test Stimulation Lead. For those patients, the staged approach may aid in determining the therapeutic benefit of SNS. Test stimulation typically lasts 3-5 days but should not exceed seven (7) days to minimize the risk of infection.

Study Results

In this study, retrospective clinical data was collected for 80 patients in Europe and the US who received a Staged Implant.

Adverse Events

Approximately 51% of patients experienced 75 adverse events. Nine events occurred during the screening phase of the Staged Implant. One event occurred during the neurostimulator implant and 65 events occurred after the neurostimulator implant. Of the 75 adverse events, 20.0% required no medical intervention, 42.7% required non-surgical intervention, and 33.3% required hospitalization or surgical intervention. Three events had not been treated at the time of database closure.

The following adverse events occurred during screening with the chronic lead for a Staged Implant: pain (2.5% of screened patients) and technical device problems (8.8% of screened patients).

Seventy-three of the 80 patients who were screened went on to an implant of the neurostimulator. During or after the chronic neurostimulator implant, the following categories of adverse events were recorded (with the 12-month probabilities of occurrence in parentheses): pain, including pain at the neurostimulator site, pain at the lead site, or new pain (20.6%); infection (6.3%); technical/device problems including suspected lead migration, suspected device problems, and any change in neurostimulation pattern (20.1%); elimination problems including any reported change in bowel or voiding behavior that was not reported at baseline (5.5%); and other (12.0%).¹

Potential adverse events that may occur, but were not reported in the clinical study, include permanent undesirable sensations.

¹ Other adverse events included the following: draining at midline incision (2), wound dehiscence (1), problems with handheld programmer (2), neurostimulator positioned too high in abdomen (1), urinary incontinence during intercourse (1), erectile dysfunction (1), neurostimulator turning OFF and ON due to magnetic fields (1), cramps in back/leg/toe with psychological problems (1), intolerance (allergy) to neurostimulator (1), neurostimulator migration (1).

Efficacy

Participating physicians reported that 76 of the 80 patients (95%) had a successful screening period with the Staged Implant. Of the 73 patients who went on to implantation of the neurostimulator, 60 patients (82.2%) were assessed to have a successful outcome during an average follow-up of 1.6 years (range 0.02-8.5 years). Forty-seven of the 80 patients who were screened with a chronic lead for a Staged Implant had also been screened with a temporary Model 3057 Test Stimulation Lead. Twenty-four of the 47 patients (51%) reported never having a successful test stimulation using the Model 3057 Lead prior to receiving a Staged Implant. Twenty-one of these patients had a successful screening with the chronic lead. Use of the chronic lead for screening as part of a Staged Implant may allow patients with inconclusive results from screening with the Model 3057 Lead to benefit from InterStim Therapy.

Buttock Neurostimulator Placement, Retrospective Study

Data was collected on 31 patients implanted with buttock placement of the neurostimulator as part of a Medtronic Post-Approval Study.

Adverse Events

The following adverse events were reported (with the 12-month probability of occurrence indicated in parentheses): pain at neurostimulator site (3.4%), new pain (33.6%), suspected lead migration (3.8%), infection (10.3%), pain at lead site (7.2%), sensation of electric shock (3.4%), suspected device problem (7.8%), other (20.7%).¹

Surgical Revision – The 12-month probability that buttock placement patients required neurostimulator revision surgery to treat an adverse event was 7.9%. The 12-month probability of buttock placement patients having an adverse event requiring any kind of surgical revision was 15%.

¹ Other adverse events included the following: persistent skin irritation (1), technical problems during test stimulation or implant (2), hematoma at lead (1), hematoma at neurostimulator (2), movement of neurostimulator (1), neurostimulator turning OFF and ON due to magnetic fields (1), wound seroma (1), fever (1).

InterStim System, Post-Approval Study

The Medtronic InterStim System was evaluated in this post-approval study to assess the long-term effects of sacral nerve stimulation for the indications of urge incontinence, urgency-frequency, and retention at centers in the United States, Canada, and Europe.

Note: The minimally invasive InterStim tined lead (Models 3889 and 3093) became commercially available after patients were enrolled in this study and therefore was not used in this study. The implantable devices used in this post-approval study consisted of the InterStim neurostimulator (Model 3023), Itrel II neurostimulator (Model 7424), InterStim non-tined lead (Models 3080 and 3886), and accessories.

Patients Studied

One hundred fifty-two patients were implanted with the InterStim System that was used in this post-approval study. Of these 152 patients, 96 patients had a primary diagnosis of urinary urge incontinence, 25 patients had a primary diagnosis of urinary urgency-frequency, and 31 patients had a primary diagnosis of urinary retention.

Study Design and Methods

Design – This study was a multicenter, non-randomized post-approval study. Of the 152 patients that participated in this post-approval study, 129 patients crossed over from Medtronic’s Single Stage Implant Clinical Trial. In total, sixty-month post implant follow-up data assessing the long-term effects of sacral nerve stimulation was collected for 152 patients.

Methods – Patients were to complete annual visits through sixty months follow-up post implant, inclusive of any follow-up that occurred in Medtronic’s Single Stage Implant Clinical Trial for those patients that participated in that study. Investigators recorded the incidence of therapy-related adverse events over the course of the study. The long-term effects of sacral nerve stimulation were assessed using a voiding diary as the primary outcome measure. Clinical success was defined as a $\geq 50\%$ improvement in those voiding diary parameters. A sensitivity analysis was conducted on the efficacy data to account for patients missing follow-up visits, or otherwise failing to provide a voiding diary during a follow-up visit (i.e. lost to follow up rate). In this analysis, clinical success rates were first calculated for the “evaluable” patient population, which is the population of patients that were not lost to follow-up. Another analysis was conducted in which patients that were lost to follow-up had their baseline values (pre-InterStim Therapy voiding diary values) imputed for any missing data when calculating clinical success rates at each follow up period.

Study Results

One hundred fifty-two patients were implanted with the InterStim System that was used in this post-approval study. These 152 patients were followed through sixty months post implant. Eleven patients withdrew from this study prior to implant.

Adverse Events

Approximately 69% of patients experienced 271 adverse events through sixty months follow-up post implant. The following device- or therapy-related adverse events were observed in this post-approval study (with the percentage of patients indicated in parentheses).

- New pain/undesirable change in stimulation (29%)
- Pain at PNE or implant site (21%)
- Suspected device problem (10%)
- Suspected lead migration (9%)
- Infection – PNE or implant site (9%)
- Sensation of electrical shock (8%)
- Pain at PNE or implant site – Lead (9%)
- Undesirable change in voiding function (7%)
- Technical problems during PNE/implant (5%)
- Other¹ (35%)

Surgical Revision – Forty-two percent of implanted patients required surgical intervention to resolve an adverse event through sixty months post implant. The leading events requiring revision surgery were pain at neurostimulator site (11.8% of implanted patients), and suspected lead migration (7.9% of implanted patients).

Thirty-two out of 152 implanted patients (21%) had 1 adverse event requiring revision surgery at sixty months follow-up. Seventeen out of 152 implanted patients (11%) had 2 adverse events requiring revision surgery at sixty months follow-up.

¹ Adverse events classified as “other” by the investigator include the following (number of patients reporting): lack/loss of efficacy/stimulation benefit (10), pain (7 total: 2 back pain, 1 buttock lumbar, 1 left flank when bending, 1 vaginal pain with heavy lifting, 1 left leg, 1 around anus), device turning on and off (6), hematoma or seroma (5), battery depletion (4), persistent skin irritation (3), stimulation of foot/toe (3), cramping (2 total: 1 left foot, 1 vaginal and left buttock), decreased sense of stimulation (2), security turning stimulators on/off (2), too much effect around anus (2), two urinary tract infections (1), and 1 each of the following: black stool, bladder unstable, bowel perforation or peritonitis, change in CT results, device explant and replacement (reason not stated), device in magnet mode, resulting in no stimulation and requiring patient self-catheterization, extension connector implanted too deep, requiring corrective surgery, inability to turn device on, fever of unknown origin, interference with EKG, intermittent/incomplete retention, irritation on defecation, lack of efficacy due to lead migration, lack of orgasm, lead break, leg jerking while asleep, parasthesia right leg, persistent fever, pulse generator migration, pulse generator migration with bending, stimulation increased with flying, stimulation of leg resulting in pain, stimulation resulting in chest pain and irritation, stimulation felt at different spots, stimulation at pulse generator site, stimulator turned off by sewing machine, stress incontinence, suspected nerve injury, tightness at rectum, and wound incisional drainage.

Efficacy – Voiding diary results showed statistically significant reductions in dysfunctional voiding symptoms in patients implanted with the InterStim System used in this post-approval study as compared to baseline. **Table 4** through **Table 9** show the percentage of patients who experienced a successful result ($\geq 50\%$ improvement in baseline symptoms) as recorded in voiding diaries at twelve and sixty months follow-up post implant. These results were obtained in patients refractory to conservative treatments.

Urge Incontinence Efficacy Results – Ninety-six urge incontinent patients were enrolled into the study. **Table 4** shows the results for all 96 urge incontinence patients enrolled in the study, with conservative assumptions (no change from baseline) for patients lost to follow-up or with missing diary data at twelve and sixty months post implant (Intent to Treat Patient Population). At twelve months post implant, 51% of patients had $\geq 50\%$ reduction in leaks per day, and 50% of patients had $\geq 50\%$ reduction in heavy leaks per day. At sixty months post implant, 37% of patients had $\geq 50\%$ reduction in leaks per day, and 42% of patients had $\geq 50\%$ reduction in heavy leaks per day.

Table 4. Twelve and Sixty Months Post Implant Results for Urge Incontinence (Intent to Treat Patient Population)

	Twelve Months Post Implant	Sixty Months Post Implant
	% (n)	% (n)
$\geq 50\%$ Reduction in Leaks/Day	51% (49/96)	37% (36/96)
$\geq 50\%$ Reduction in Heavy Leaks/Day ^a	50% (40/80)	42% (35/84)

^a Excludes patients who reported no heavy leaks at baseline, twelve and sixty months post implant.

Table 5 shows the results for the urge incontinence patients who remained in the study and reported diary data at twelve and sixty months post implant (Evaluable Patient Population). At twelve months post implant, 68% of patients had $\geq 50\%$ reduction in leaks per day, and 71% of patients had $\geq 50\%$ reduction in heavy leaks per day. At sixty months post implant, 59% of patients had $\geq 50\%$ reduction in leaks per day, and 71% of patients had $\geq 50\%$ reduction in heavy leaks per day.

Table 5. Twelve and Sixty Months Post Implant Results for Urge Incontinence (Evaluable Patient Population)

	Twelve Months Post Implant	Sixty Months Post Implant
	% (n)	% (n)
$\geq 50\%$ Reduction in Leaks /Day	68% (49/72)	59% (36/61)
$\geq 50\%$ Reduction in Heavy Leaks /Day ^a	71% (40/56)	71% (35/49)

^a Excludes patients who reported no heavy leaks at baseline, twelve and sixty months post implant.

Urgency-Frequency Efficacy Results – Twenty-five urgency-frequency patients were enrolled into the study. **Table 6** shows the results for all 25 urgency-frequency patients enrolled in the study, with conservative assumptions (no change from baseline) for patients lost to follow-up or with missing diary data at twelve and sixty months post implant (Intent to Treat Patient Population). At twelve months post implant, 40% of patients had $\geq 50\%$ reduction in voids per day, 60% of patients had $\geq 50\%$ increase in volume voided per void, and 68% of patients reported an increase in voided volume with the same or reduced degree of urgency. At sixty months post implant, 28% of patients had $\geq 50\%$ reduction in voids per day, 40% of patients had $\geq 50\%$ increase in volume voided per void, and 40% of patients reported an increase in voided volume with the same or reduced degree of urgency.

Table 6. Twelve and Sixty Months Post Implant Results for Urgency-Frequency (Intent to Treat Patient Population)

	Twelve Months Post Implant	Sixty Months Post Implant
	% (n)	% (n)
$\geq 50\%$ Reduction in Voids/Day	40% (10/25)	28% (7/25)
$\geq 50\%$ Increase in Volume Voided/Void	60% (15/25)	40% (10/25)
Improved Degree of Urgency Prior to Void	68% (17/25)	40% (10/25)

Table 7 shows the results for the urgency-frequency patients who remained in the study and reported diary data at twelve and sixty months post implant (Evaluable Patient Population). At twelve months post implant, 43% of patients had a $\geq 50\%$ reduction in voids per day, 65% of patients had $\geq 50\%$ increase in volume voided per void, and 74% of patients reported an increase in voided volume with the same or reduced degree of urgency. At sixty months post implant, 39% of patients had $\geq 50\%$ reduction in voids per day, 56% of patients had $\geq 50\%$ reduction in volume voided per void, and 56% of patients reported an increase in voided volume with the same or reduced degree of urgency.

Table 7. Twelve and Sixty Months Post Implant Results for Urgency-Frequency (Evaluable Patient Population)

	Twelve Months Post Implant	Sixty Months Post Implant
	% (n)	% (n)
$\geq 50\%$ Reduction in Voids/Day	43% (10/23)	39% (7/18)
$\geq 50\%$ Increase in Volume Voided/Void	65% (15/23)	56% (10/18)
Improved Degree of Urgency Prior to Void	74% (17/23)	56% (10/18)

Retention Efficacy Results – Thirty-one retention patients were enrolled into the study. **Table 8** shows the results for all 31 retention patients enrolled in the study, with conservative assumptions (no change from baseline) for patients lost to follow-up or with missing diary data at twelve and sixty months post implant (Intent to Treat Patient Population). At twelve months post implant, 68% of patients had $\geq 50\%$ reduction in catheterizations per day, and 68% of patients had $\geq 50\%$ reduction in the volume per catheterizations. At sixty months post implant, 48% of patients had $\geq 50\%$ reduction in catheterizations per day, and 58% of patients had $\geq 50\%$ reduction in the volume per catheterizations.

Table 8. Twelve and Sixty Months Post Implant Results for Retention (Intent to Treat Patient Population)

	Twelve Months Post Implant	Sixty Months Post Implant
	% (n)	% (n)
$\geq 50\%$ Reduction in Catheterizations/Day	68% (21/31)	48% (15/31)
$\geq 50\%$ Reduction in the Volume/Catheterizations	68% (21/31)	58% (18/31)

Table 9 shows the results for the retention patients who remained in the study and reported diary data at twelve and sixty months post implant (Evaluable Patient Population). At 12 months post implant, 78% of patients had $\geq 50\%$ reduction in catheterizations per day, and 78% patients had $\geq 50\%$ reduction in the volume per catheterizations. At sixty months post implant, 65% of patients had $\geq 50\%$ reduction in catheterizations per day, and 78% of patients had $\geq 50\%$ reduction in the volume per catheterizations.

Table 9. Twelve and Sixty Months Post Implant Results for Retention (Evaluable Patient Population)

	Twelve Months Post Implant	Sixty Months Post Implant
	% (n)	% (n)
$\geq 50\%$ Reduction in Catheterizations/Day	78% (21/27)	65% (15/23)
$\geq 50\%$ Reduction in the Volume/Catheterizations	78% (21/27)	78% (18/23)



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