CONtrol of **F**aecal **I**ncontinence using **D**istal **N**euromodula**T**ion (CONFIDeNT)

CRF 1 – Eligibility Criteria

Inclusion Criteria	**Yes**	**No**
Faecal incontinence sufficiently severe enough to warrant intervention		
Failure of appropriate conservative therapies		
Age ≥18		

N.B. Appropriate specialist investigations including structural and functional anorectal assessment would be informative, although not mandatory.

If any of the above criteria are answered NO the participant is not eligible for the study. If the participant is excluded from the study, complete the Screening Log to explain why.

Exclusion Criteria	**Yes**	**No**
Inability to provide informed consent for the research study		
Inability to fill in the detailed bowel diaries required for outcome assessments (this will exclude participants who do not speak / read English)		
Neurological diseases, such as diabetic neuropathy, multiple sclerosis and Parkinson's disease (any participant with painful peripheral neuropathy)		
Anatomical limitations that would prevent successful placement of needle electrode		
Other medical conditions precluding stimulation: e.g. bleeding disorders, certain cardiac pacemakers, peripheral vascular disease or ulcer, lower leg cellulitis		
Congenital anorectal anomalies or absence of native rectum due to surgery		
A cloacal defect		
Present evidence of external full thickness rectal prolapse		
Previous rectal surgery (rectopexy/resection)< 12 months ago (24 months for cancer)		
Stoma *in situ*		
Chronic bowel diseases such as inflammatory bowel disease leading to chronic uncontrolled diarrhoea		
Pregnancy or intention to become pregnant*		
Previous experience of SNS or PTNS		

*If a female participant is of child bearing potential (e.g. pre-menopausal) this includes a discussion regarding appropriate forms of contraception, and the avoidance of becoming pregnant during the trial. If a participant does become pregnant during the trial, they must report this immediately to the research staff.

For females of child bearing potential at screening, please perform urinary pregnancy test.

Result: POSITIVE / NEGATIVE (PLEASE CIRCLE)

If any of the above criteria are answered YES the participant is not eligible for the study. If the participant is excluded from the study, complete the Screening Log to explain why.

DECLARATION: I have reviewed this Case Report Form and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant.

STORE IN PARTICIPANTS CRF FOLDER

CONtrol of **F**aecal **I**ncontinence using **D**istal **N**euromodula**T**ion (CONFIDeNT)

CRF 2: INITIAL ASSESSMENT

CIRCLE YES OR NO AND PROVIDE DETAILS WHERE INDICATED.

DATE OF VISIT 1:	_ _ / _ _ _ / _ _ _ _ (DD/MMM/YYYY)	
DATE OF SCREENING (TODAY):	_ _ / _ _ _ / _ _ _ _ (DD/MMM/YYYY)	
CONSENT TAKEN: (If no, do not continue until obtained)	YES	NO
PARTICIPANT INFORMATION SHEET GIVEN TO PATIENT	YES	NO
SIGNED COPY OF CONSENT FORM GIVEN TO PATIENT	YES	NO

AGE OF PARTICIPANT :	YEARS	
SEX OF PARTICIPANT	MALE	FEMALE

HISTORY OF FAECAL INCONTINENCE - INCLUDING TYPE:

DURATION OF SYMPTOMS: Preceding event or occurrence :

FREQUENCY OF STOOL:	YES	NO	DETAILS:
URGE TO PASS STOOL:	YES	NO	DETAILS:
PASSIVE INCONTINENCE	YES	NO	DETAILS:
URGE INCONTINENCE	YES	NO	DETAILS:
FLATUS INCONTINENCE	YES	NO	DETAILS
EVACUATORY DIFFICULTIES	YES	NO	DETAILS:
STRAINING	YES	NO	DETAILS:
PROLAPSE	YES	NO	DETAILS:
SOILING OF UNDERWEAR	YES	NO	DETAILS:
USE OF PADS	YES	NO	DETAILS:
ABLE TO DEFER DEFECATION	YES	NO	HOW LONG FOR (IN MINUTES): _ _ _ MINUTES
ABLE TO DISTINGUISH FAECES FROM FLATUS	YES	NO	DETAILS:
SENSE OF BLOCK OR BULGE	YES	NO	DETAILS:
DIGITATION REQUIRED	YES	NO	DETAILS:
ANXIETY / PANIC	YES	NO	DETAILS:

URINARY SYMPTOM HISTORY:	YES	NO	
INCREASED FREQUENCY	YES	NO	DETAILS:

URGENCY	YES	NO	DETAILS:
STRESS INCONTINENCE:	YES	NO	DETAILS:
URGE INCONTINENCE:	YES	NO	DETAILS:
OTHER:	YES	NO	DETAILS:

PREVIOUS FAECAL INCONTINENCE TREATMENTS:				YES	NO
CONSERVATIVE MANAGEMENT:	YES	NO	DETAILS:		
BIOFEEDBACK:	YES	NO	DETAILS:		
SPHINCTER REPAIR:	YES	NO	DETAILS:		
OTHER?	YES	NO	DETAILS:		

ALLERGIES:	YES	NO	DETAILS:

MEDICATIONS:

	YES	NO	DETAILS BELOW
MEDICATION	DOSE/FREQUENCY		INDICATION

PAST MEDICAL HISTORY: **[_] NONE**

DATE DIAGNOSIS: (DD/MMM/YYYY)	**CONDITION**	**ONGOING**	
		YES	NO
		YES	NO
		YES	NO
		YES	NO
		YES	NO
		YES	NO
		YES	NO
		YES	NO
		YES	NO
		YES	NO

PAST OBSTETRIC HISTORY:	YES	NO	DETAILS:				
VAGINAL DELIVERIES:	0	1	2	3	4	5	6
EPISIOTOMY/TEARS:	YES	NO	DETAILS:				

ANO-RECTAL PHYSIOLOGY RESULTS (PLEASE ATTACH COPY):		
DIGITAL RECTAL EXAMINATION (IF NO PHYSIOLOGY):		
IF IMPACTED – GIVE DISIMPACTION MEDICATION – GIVEN	YES	NO

FILE THE ORIGINAL, SIGNED AND DATED CONSENT FORM IN THE PARTICIPANTS' 'CONSENT FORM FOLDER' WITH THE CONTACT INFORMATION SHEET.

GIVE ONE COPY OF CONSENT FORM TO THE PARTICIPANT AND FILE ANOTHER COPY IN PATIENT NOTES.

PLEASE ATTACH ANO-RECTAL PHYSIOLOGY RESULTS

STORE IN PARTICIPANTS CRF FOLDER

DECLARATION: I have reviewed this Case Report Form and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant.

Completed by: _ _ _ Verified by: _ _ _

Data entry by: _ _ _

CONtrol of **F**aecal **I**ncontinence using **D**istal **N**euromodula**T**ion (CONFIDeNT)

CRF 3

Please fill in the following document.

It comprises 6 questionnaires which we ask you to fill in before and after treatment, to help to assess how successful your treatment has been.

Many thanks for your co-operation and help in our trial

Unique patient identifier: _ _ _ / _ _ _

Pre-treatment / post treatment (Delete as appropriate)

Date today: _ _ / _ _ _ / _ _ _ _ (dd / mmm / yyyy)

STORE IN PARTICIPANTS CRF FOLDER

Gastrointestinal Quality of Life Index

These questions ask about the effect of bowel symptoms on your quality of life.
Please tick one for each question.

Q1. How often during the past 2 weeks have you had pain in the abdomen?

1) All of the time
2) Most of the time
3) Some of the time
4) A little of the time
5) Never

Q2. How often in the past 2 weeks have you had a feeling of fullness in the upper abdomen?

1) Never
2) A little of the time
3) Some of the time
4) Most of the time
5) All of the time

Q3. How often in the last 2 weeks have you had bloating (sensation of too much gas in the abdomen)?

1) All of the time
2) Most of the time
3) Some of the time
4) A little of the time
5) Never

Q4. How often during the past 2 weeks have you been troubled by excessive passage of gas through the back passage?

1) Never
2) A little of the time
3) Some of the time
4) Most of the time
5) All of the time

Q5. How often during the past 2 weeks have you been troubled by strong burping or belching?

1) All of the time
2) Most of the time
3) Some of the time
4) A little of the time
5) Never

Q6. How often during the past 2 weeks have you been troubled by gurgling noises from the abdomen?

1) Never
2) A little of the time

3) Some of the time
4) Most of the time
5) All of the time

Q7. How often during the past 2 weeks have you been troubled by frequent bowel movements?

1) All of the time
2) Most of the time
3) Some of the time
4) A little of the time
5) Never

Q8. How often during the past 2 weeks have you found eating to be a pleasure?

1) Never
2) A little of the time
3) Some of the time
4) Most of the time
5) All of the time

Q9. Because of your disorder, to what extent have you restricted the kinds of foods that you eat?

1) Not at all
2) A little
3) Somewhat
4) Much
5) Very much

Q10. During the past 2 weeks, how well have you been able to cope with everyday stresses?

1) Extremely poorly
2) Poorly
3) Moderately well
4) Well
5) Extremely well

Q11. How often during the past 2 weeks have you been sad about being ill?

1) Never
2) A little of the time
3) Some of the time
4) Most of the time
5) All of the time

Q12. How often during the past 2 weeks have you been nervous or anxious about your disorder?

1) All of the time
2) Most of the time
3) Some of the time
4) A little of the time

5) Never

Q13. How often during the past 2 weeks have you been happy with life in general?

1) All of the time
2) Most of the time
3) Some of the time
4) A little of the time
5) Never

Q14. How often during the past 2 weeks have you been frustrated about your disorder?

1) Never
2) A little of the time
3) Some of the time
4) Most of the time
5) All of the time

Q15. How often during the past 2 weeks have you been tired or fatigued?

1) All of the time
2) Most of the time
3) Some of the time
4) A little of the time
5) Never

Q16. How often during the past 2 weeks have you felt unwell?

1) Never
2) A little of the time
3) Some of the time
4) Most of the time
5) All of the time

Q17. Over the past week, have you woken up in the night?

1) Every night
2) 5-6 nights
3) 3-4 nights
4) 1-2 nights
5) Never

Q18. Since your disorder started, have you been troubled by changes in your appearance?

1) Not at all
2) A little bit
3) Somewhat
4) A moderate amount
5) A great deal

Q19. Because of your disorder, how much physical strength have you lost?

1) A great deal
2) A moderate amount
3) Somewhat
4) A little bit
5) Not at all

Q20. Because of your disorder, to what extend have you lost your endurance?

1) Not at all
2) A little bit
3) Somewhat
4) A moderate amount
5) A great deal

Q21. Because of your disorder, to what extent do you feel unfit?

1) Extremely unfit
2) Moderately unfit
3) Somewhat unfit
4) A little unfit
5) Fit

Q22. During the past 2 weeks how often have you been able to complete your normal daily activities? (school, work, household)

1) All of the time
2) Most of the time
3) Some of the time
4) A little of the time
5) Never

Q23. During the past 2 weeks how often have you been able to take part in your usual patterns of leisure or recreational activities?

1) Never
2) A little of the time
3) Some of the time
4) Most of the time
5) All of the time

Q24. During the past 2 weeks, how much have you been troubled by the treatment for your disorder?

1) Not at all
2) A little
3) Somewhat
4) Much
5) Very much

Q25. To what extend have your personal relations with people close to you (family or friends) worsened because of your disorder?

1) Very much
2) Much
3) Somewhat
4) A little
5) Not at all

Q26. To what extent has your sex life been impaired (harmed) because of your disorder?

1) Not at all
2) A little
3) Somewhat
4) Much
5) Very much

Q27. How often during the past 2 weeks have you been troubled by fluid or food coming up into your mouth (regurgitation)?

1) All of the time
2) Most of the time
3) Some of the time
4) A little of the time
5) Never

Q28. How often during the past 2 weeks have you felt uncomfortable because of your slow speed of eating?

1) Never
2) A little of the time
3) Some of the time
4) Most of the time
5) All of the time

Q29. How often during the past 2 weeks have you had trouble swallowing your food?

1) All of the time
2) Most of the time
3) Some of the time
4) A little of the time
5) Never

Q30. How often during the past 2 weeks have you been troubled by urgent bowel movements?

1) Never
2) A little of the time
3) Some of the time
4) Most of the time
5) All of the time

Q31. How often during the past 2 weeks have you been troubled by diarrhoea?

1) All of the time
2) Most of the time
3) Some of the time
4) A little of the time
5) Never

Q32. How often during the past 2 weeks have you been troubled by constipation?

1) Never
2) A little of the time
3) Some of the time
4) Most of the time
5) All of the time

Q33. How often during the past 2 weeks have you been troubled by nausea?

1) All of the time
2) Most of the time
3) Some of the time
4) A little of the time
5) Never

Q34. How often during the past 2 weeks have you been troubled by blood in the stools?

1) Never
2) A little of the time
3) Some of the time
4) Most of the time
5) All of the time

Q35. How often during the past 2 weeks have you been troubled by heartburn?

1) All of the time
2) Most of the time
3) Some of the time
4) A little of the time
5) Never

Q36. How often during the past 2 weeks have you been troubled by uncontrolled stools?

1) Never
2) A little of the time
3) Some of the time
4) Most of the time
5) All of the time

Patient Centered Outcomes Form

Recent studies show that patients with bowel incontinence think the following issues are the most important.
For each, please indicate *how* important *you* think they are for you **TODAY** using a scale from zero to ten with:

1 Not important at all ..... 10 being vitally important

Q1. Unpredictability of when bowel accidents may happen:

1 2 3 4 5 6 7 8 9 10

Q2. Always needing to know toilet locations:

1 2 3 4 5 6 7 8 9 10

Q3. Hygiene and odors:

1 2 3 4 5 6 7 8 9 10

Q4. Effect on social life:

1 2 3 4 5 6 7 8 9 10

Q5. Effect on employment:

1 2 3 4 5 6 7 8 9 10

Q6. Strategies to help you cope with symptoms:

1 2 3 4 5 6 7 8 9 10

Q7. Embarrassment:

1 2 3 4 5 6 7 8 9 10

Q8. Fear of bowel accidents:

1 2 3 4 5 6 7 8 9 10

SF-36 Health Survey

INSTRUCTIONS: This survey asks your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Please answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

Q1 In general, would you say your health is:

1)	Excellent	1
2)	Very good	2
3)	Good	3
4)	Fair	4
5)	Poor	5

Q2 Compared to one year ago, how would you rate your health in general now?

1)	Much better now than one year ago	1
2)	Somewhat better than one year ago	2
3)	About the same as one year ago	3
4)	Somewhat worse than one year ago	4
5)	Much worse now than one year ago	5

Q3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Activities	**Yes, limited a lot**	**Yes, limited a little**	**No, not Limited at all**
Vigorous activities such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playir golf.	1	2	3
Lifting or carrying groceries.	1	2	3
Climbing several flights of stairs.	1	2	3
Climbing one flight of stairs.	1	2	3
Bending, kneeling or stooping.	1	2	3
Walking more than a mile.	1	2	3
Walking half a mile.	1	2	3
Walking one hundred yards.	1	2	3
Bathing or dressing yourself.	1	2	3

Q4 During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Were limited in the kind of work or other activities	1	2
Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

Q5 During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
Cut down on the amount of time you spent on work or other activities	1	2
Accomplish less than you would like	1	2
Didn't do work or other activities as carefully as usual	1	2

Q6 During the past 4 weeks, to what extend has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors or groups?

1) Not at all 1
2) Slightly 2
3) Moderately 3
4) Quite a bit 4
5) Extremely 5

Q7 How much bodily pain have you had during the past 4 weeks?

1) None 1
2) Very mild 2
3) Mild 3
4) Moderate 4
5) Severe 5
6) Very severe 6

Q8 During the past 4 weeks how much did pain interfere with your normal work (including both work outside the home and housework)?

1) Not at all 1
2) A little bit 2
3) Moderately 3
4) Quite a bit 4
5) Extremely 5

Q9 These questions are about how you feel and how things have been with you during the past 4 weeks. For each question please give the one answer that comes closest to the way you have been feeling.
How much of the time during the past 4 weeks ….

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Did you feel full of life?	1	2	3	4	5	6
Have you been a very nervous person?	1	2	3	4	5	6
Have you felt so down in the dump that nothing could cheer you up?	1	2	3	4	5	6
Have you felt calm and peaceful?	1	2	3	4	5	6
Did you have a lot of energy?	1	2	3	4	5	6
Have you felt downhearted and low	1	2	3	4	5	6
Did you feel worn out?	1	2	3	4	5	6
Have you been a happy person?	1	2	3	4	5	6
Did you feel tired?	1	2	3	4	5	6

Q10 During the past 4 weeks, how much time has your physical health of emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

1) All of the time 1
2) Most of the time 2
3) Some of the time 3
4) A little of the time 4
5) None of the time 5

Q11 How TRUE or FALSE is each of the following statements to you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
I seem to get ill more easily than other people					
I am as healthy as anybody I know					
I expect my health to get worse					
My health is excellent					

Quality of Life Scale for Faecal Incontinence

Q1. In general, would you say your health is:

1) Excellent
2) Very good
3) Good
4) Fair
5) Poor

Q2. For each of the items, please indicate how much of the time the issue is a concern for you due to accidental bowel leakage. (If it is a concern for you for reasons other than accidental bowel leakage then tick the box under Not Applicable (N/A).

Due to accidental bowel leakage:

	Most of The time	Some of the time	A little of the time	None of the time	
a) I am afraid to go out	1	2	3	4	N/A
b) I avoid visiting friends	1	2	3	4	N/A
c) I avoid staying the night away from home	1	2	3	4	N/A
d) It is difficult for me to get out and do social things	1	2	3	4	N/A
e) I cut down on how much I eat before I go out	1	2	3	4	N/A
f) Whenever I am away from home I try to stay near a toilet as much as possible	1	2	3	4	N/A
g) It is important to plan my schedule (daily activities) around my bowel pattern	1	2	3	4	N/A
h) I avoid traveling	1	2	3	4	N/A
i) I worry about not being able to get to the toilet in time	1	2	3	4	N/A
j) I feel I have no control over my bowels	1	2	3	4	N/A
k) I cant hold my bowel movement long enough to get to the bathroom	1	2	3	4	N/A
l) I leak stool without even knowing it	1	2	3	4	N/A
m) I try to prevent accidents by staying near a bathroom	1	2	3	4	N/A

Q3. Due to accidental bowel leakage, indicate the extent to which you AGREE or DISAGREE with each of the following items. (If it is a concern for you for reasons other than accidental bowel leakage then check the box under Not applicable N/A)

Due to accidental bowel leakage:

	Most of The time	Some of the time	A little of the time	None of the time	
a) I feel ashamed	1	2	3	4	N/A
b) I do not do any of the things I want to do	1	2	3	4	N/A
c) I worry about bowel accidents	1	2	3	4	N/A
d) I feel depressed	1	2	3	4	N/A
e) I worry about others smelling stool on me	1	2	3	4	N/A
f) I feel like I am not a healthy person	1	2	3	4	N/A
g) I enjoy life less	1	2	3	4	N/A
h) I have sex less often than I would like to	1	2	3	4	N/A
i) I feel different from other people	1	2	3	4	N/A
j) The possibility of bowel accidents is always on my mind	1	2	3	4	N/A
k) I am afraid to have sex	1	2	3	4	N/A
l) I avoid traveling by plane or train	1	2	3	4	N/A
m) I avoid going out to eat	1	2	3	4	N/A
n) Whenever I go to a new place, I specifically seek out the bathrooms	1	2	3	4	N/A

Q4. During the past month, have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile?

1) Extremely so – to the point that I have just about given up
2) Very much so
3) Quite a bit
4) Some - enough to bother me
5) A little bit
6) Not at all

Cleveland Clinic Faecal Incontinence Score

Please tick the ONE statement that you think most closely apply to you in each section:

Q1. How often did you loose control of solid bowel motions?

1) Never
2) Rarely (less than once a month)
3) Sometimes (once a month or more)
4) Weekly
5) Daily

Q2. How often did you loose control of liquid bowel motions?

1) Never
2) Rarely (less than once a month)
3) Sometimes (once a month or more)
4) Weekly
5) Daily

Q3. How often did you loose control of wind?

1) Never
2) Rarely (less than once a month)
3) Sometimes (once a month or more)
4) Weekly
5) Daily

Q4. How often did leakage of bowel motion or wind cause you to alter your lifestyle or avoid your usual activities?

1) Never
2) Rarely (less than once a month)
3) Sometimes (once a month or more)
4) Weekly
5) Daily

Q5. Do you wear a pad or plug because of leakage of bowel motion?

1) Yes
2) No

Q6. Do you use any medicines to help slow the bowel down (e.g. immodium or codeine)?

1) Yes
2) No

Q7. If there was no toilet nearby, could you delay a bowel motion for 15 minutes?

1) Yes
2) No

EQ-5D Health Questionnaire (EuroQoL Group 1990)

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Q1. **Mobility**

- ☐ I have no problems in walking about
- ☐ I have some problems in walking about
- ☐ I am confined to bed

Q2. **Self-Care**

- ☐ I have no problems with self-care
- ☐ I have some problems washing or dressing myself
- ☐ I am unable to wash or dress myself

Q3. **Usual activities** (e.g. work, study, housework, family or leisure activities)

- ☐ I have no problems with performing my usual activities
- ☐ I have some problems with performing my usual activities
- ☐ I am unable to perform my usual activities

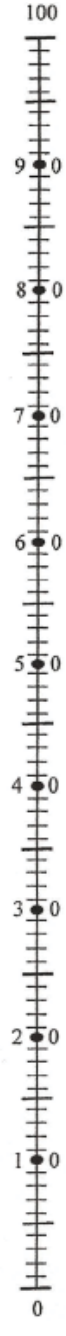
Q4. **Pain/Discomfort**

- ☐ I have no pain or discomfort
- ☐ I have moderate pain or discomfort
- ☐ I have extreme pain or discomfort

Q5. **Anxiety/Depression**

- ☐ I am not anxious or depressed
- ☐ I am moderately anxious or depressed
- ☐ I am extremely anxious or depressed

Q6. To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.
We would like you to indicate on this scale how good or bad your own health is today, in your opinion.
Please do this by drawing a line on the scale that indicates how good or bad your health state is today.



Many thanks for completing this questionnaire.

DECLARATION: I have reviewed this Case Report Form and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant.

Completed by: Participant / Interviewer	Verified by: _ _ _	Data Entry by:
_ _ _		
Date: _ _ / _ _ _ / _ _ _ _	Date: _ _ / _ _ _ / _ _ _ _	Date: _ _ / _ _
_ / _ _ _ _		

CONtrol of **F**aecal **I**ncontinence using **D**istal **N**euromodula**T**ion (CONFIDeNT)

RANDOMISATION INFORMATION - CRF 4

UNIQUE PARTICIPANT IDENTIFIER: _ _ _ / _ _ _

DATE OF RANDOMISATION (TODAY): _ _ / _ _ _ / _ _ _ _ (dd / mmm / yyyy)

ALLOCATION AT RANDOMISATION: PTNS / SHAM (DELETE AS APPROPRIATE)

FILE IN THE RANDOMISATION FILE

IN A SECURE AND LOCKED CABINET SEPARATE TO ALL OTHER PARTICIPANT INFORMATION AND CRF'S TO BE ACCESSABLE ONLY TO UNBLINDED RESEARCH STAFF.

DECLARATION: I have reviewed this Case Report Form and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant.

CONtrol of **F**aecal **I**ncontinence using **D**istal **N**euromodula**T**ion (CONFIDeNT)

DOCUMENTATION FOR VISITS 2-13 (CRF 5)

No	Date	PTNS: Setting and response (S = sensory; m = motor)	Adverse events (If yes fill in AE log)	Pad usage (Any change? Y/N)	Medication use - Any change? (If yes fill in con meds log)	Recorded By* (signature)	Verified By (initials)
1	_ _ / _ _ _/ _ _ _ _	mA: _ _ Response: S / M Location: Side: L / R	YES / NO	YES / NO Details:	YES / NO	_ _ _	_ _ _
2	_ _ / _ _ _/ _ _ _ _	mA: _ _ Response: S / M Location: Side: L / R	YES / NO	YES / NO Details:	YES / NO	_ _ _	_ _ _
3	_ _ / _ _ _/ _ _ _ _	mA: _ _ Response: S / M Location: Side: L / R	YES / NO	YES / NO Details:	YES / NO	_ _ _	_ _ _
4	_ _ / _ _ _/ _ _ _ _	mA: _ _ Response: S / M Location: Side: L / R	YES / NO	YES / NO Details:	YES / NO	_ _ _	_ _ _
5	_ _ / _ _ _/ _ _ _ _	mA: _ _ Response: S / M Location: Side: L / R	YES / NO	YES / NO Details:	YES / NO	_ _ _	_ _ _
6	_ _ / _ _ _/ _ _ _ _	mA: _ _ Response: S / M Location: Side: L / R	YES / NO	YES / NO Details:	YES / NO	_ _ _	_ _ _

No	Date	PTNS: Setting and response (S = sensory; m = motor)	Adverse events (If yes fill in AE log)	Pad usage (Any change? Y/N)	Medication use - Any change? (If yes fill in con meds log)	Recorded By (initials)	Verified By (initials)
7	_ _ / _ _ _/ _ _ _ _	mA: _ _ Response: S / M Location: Side: L / R	YES / NO	YES / NO Details:	YES / NO	_ _ _	_ _ _
8	_ _ / _ _ _/ _ _ _ _	mA: _ _ Response: S / M Location: Side: L / R	YES / NO	YES / NO Details:	YES / NO	_ _ _	_ _ _
9	_ _ / _ _ _/ _ _ _ _	mA: _ _ Response: S / M Location: Side: L / R	YES / NO	YES / NO Details:	YES / NO	_ _ _	_ _ _
10	_ _ / _ _ _/ _ _ _ _	mA: _ _ Response: S / M Location: Side: L / R	YES / NO	YES / NO Details:	YES / NO	_ _ _	_ _ _
11	_ _ / _ _ _/ _ _ _ _	mA: _ _ Response: S / M Location: Side: L / R	YES / NO	YES / NO Details:	YES / NO	_ _ _	_ _ _
12	_ _ / _ _ _/ _ _ _ _	mA: _ _ Response: S / M Location: Side: L / R	YES / NO	YES / NO Details:	YES / NO	_ _ _	_ _ _

*DECLARATION: I have reviewed this Case Report Form and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant.

CONtrol of **F**aecal **I**ncontinence using **D**istal **N**euromodula**T**ion (CONFIDeNT)

POST TREATMENT INFORMATION - CRF 6

VISIT 14: DATE TODAY: _ _ / _ _ _ / _ _ _ _ (dd / mmm / yyyy)

1. DO YOU THINK YOU RECEIVED 'REAL' PTNS STIMULATION OR THE 'SHAM' STIMULATION?

   REAL PTNS **SHAM STIMULATION** (Please circle)

2. DID YOU SUFFER ANY SIDE EFFECTS OR ADVERSE EVENTS FROM THE TREATMENT?

   YES **NO** (Please circle)

   If yes, please give details:

3. DID THE TREATMENT HAVE ANY EFFECT ON YOUR URINARY SYMPTOMS?

   I DID NOT HAVE ANY URINARY SYMPTOMS (Please circle)

   MADE SYMPTOMS WORSE

   NO EFFECT

   MILD IMPROVEMENT

   SIGNIFICANT IMPROVEMENT

   SYMPTOMS CURED

   Additional Comments regarding urinary symptoms please:

4. DID THE TREATMENT HAVE ANY EFFECT ON THE AMOUNT OF LOPERAMIDE (IMMODIUM) OR CODEINE YOU USE?

   USE HAS INCREASED

   USE HAS REMAINED THE SAME

   USE HAS DECREASED

   Not applicable - I DID NOT USE THESE MEDICATIONS THROUGHOUT THE STUDY

5. DID THE TREATMENT HAVE ANY EFFECT ON YOUR USE OF INCONTINENCE PADS?

   USE HAS INCREASED

   USE HAS REMAINED THE SAME

   USE HAS DECREASED

   Not applicable - I DID NOT USE INCONTINENCE PADS THROUGOUT THE STUDY

6. ARE THERE ANY OTHER COMMENTS YOU WOULD LIKE TO MAKE ABOUT THE TREATMENT OR THIS TRIAL?

7. CAN YOU DESCRIBE HOW YOU FELT PRIOR TO YOUR TREATMENT?

8. CAN YOU DESCRIBE HOW YOU FELT DURING YOUR TREATMENT?

9. CAN YOU DESCRIBE HOW YOU FEEL NOW, FOLLOWING YOUR TREATMENT?

CONtrol of **F**aecal **I**ncontinence using **D**istal **N**euromodula**T**ion (CONFIDeNT)

FINAL STUDY VISIT - CRF 7

DATE TODAY: _ _ / _ _ _ / _ _ _ _ (dd / mmm / yyyy)

PLEASE INDICATE WHICH APPLIES TO PATIENT DURING THEIR LAST STUDY VISIT:

☐ PATIENT WITHDREW EARLY FROM STUDY (ENSURE 'EARLY WITHDRAWAL FROM STUDY' CRF IS COMPLETED)

☐ PATIENT COMPLETED STUDY AND ALL THE FOLLOWING DOCUMENTATION IS COMPLETE:

- ☐ CRF 1
- ☐ CRF 2
- ☐ CRF 3– PRE-TREATMENT
- ☐ CRF 3– POST-TREATMENT
- ☐ CRF 4
- ☐ CRF 5
- ☐ CRF 6
- ☐ BOWEL DIARY – PRE-TREATMENT
- ☐ BOWEL DIARY – POST-TREATMENT
- ☐ ADDITIONAL CRFS AS NECESSARY

I CONFIRM THAT THIS PARTICIPANT HAS COMPLETED THE TRIAL IN ACCORDANCE WITH THE APPROVED PROTOCOL, REC CONDITIONS OF APPROVAL AND IN LINE WITH GOOD CLINICAL PRACTICE GUIDELINES.

Principal Investigator Signature: _____

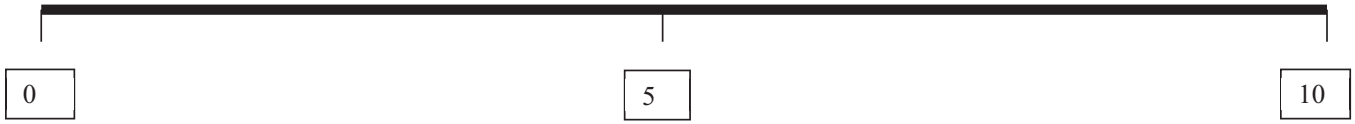
Name: _____ Date: _ _ / _ _ _ / _ _ _ _

STORE IN PARTICIPANTS CRF FOLDER

LIKERT SCALE OF SUCCESS

PLEASE INDICATE ON THE SCALE BELOW HOW SUCCESSFUL YOU FEEL YOUR FAECAL INCONTINENCE TREATMENT IN THIS TRIAL HAS BEEN.

0=COMPLETELY UNSUCCESSFUL TO 10 = COMPLETELY SUCCESSFUL



DECLARATION: I have reviewed this Case Report Form and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant.

Completed by: Participant/Interviewer
Date: _ _/_ _ _/_ _ _ _

Verified by: _ _ _
Date: _ _/_ _ _/_ _ _ _

Data Entry by: _ _ _
Date: _ _/_ _ _/_ _ _ _

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Controlled bowel movements (no incontinence: underwear, pads or pants remained clean)														
How many times did you go to the toilet (controlled)?														
Uncontrolled bowel movements (incontinence: underwear, pads or pants got dirty)														
How many times did you NOT make it in time to toilet (rush)?														
How many times did you not feel the bowel movement but only afterwards (passive leakage)?														
Staining/ minor soiling of underwear														
Did you stain/soil your underwear, pants or pad(s) today?	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no
Pad usage/Enema/ Suppository														
Pad(s) used for	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no

incontinence?														
Enema Suppository administrated?	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no
Social functioning														
Did your (faecal) incontinence limit you in your daily activities (e.g. leaving the house, shopping etc)?	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no	Yes /no
Stool consistency														
What was your stool consistency today? (Circle one)	Solid/ mushy / liquid	Solid/ mushy / liquid	Solid/ mushy / liquid	Solid/ mushy / liquid	Solid/ mushy / liquid	Solid/ mushy / liquid	Solid/ mushy / liquid	Solid/ mushy / liquid	Solid/ mushy / liquid	Solid/ mushy / liquid	Solid/ mushy / liquid	Solid/ mushy / liquid	Solid/ mushy / liquid	Solid/ mushy / liquid