***SACRAL NEUROMODULATION: STANDARDISED ELECTRODE PLACEMENT TECHNIQUE***

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**ABSTRACT**

**Introduction**

Sacral neuromodulation (SNM) (sacral nerve stimulation SNS) has become an established therapy for functional disorders of the pelvic organs. Despite its overall success, the therapy fails in a proportion of patients. This may be partially due to inadequate electrode placement with suboptimal coupling of the electrode and nerve. Based on these assumptions the technique of sacral spinal neuromodulation has been redefined. All descriptions relate to the only currently available system licensed for all pelvic indications (Medtronic Interstim®).

**Method**

An international multidisciplinary working party of 10 individuals highly experienced in performing SNM convened two meetings (including live operating) to standardize the implant procedure. This report addresses the main steps to optimal electrode lead placement in temporal sequence.

**Results**

Key elements of the electrode placement are radiological marking, the use of a curved stylet, the entry of the electrode into the sacral foramen and its progression through the foramen, its placement guided by a combination of a typical appearance in fluoroscopy and achieving specific motor/sensory responses with stimulation. The report describes quadripolar electrode placement and then either insertion of a connecting percutaneous extension lead or permanent implantation of the programmable device.

**Conclusion**

Standardisation of electrode placement may ensure close electrode proximity to the target nerve providing a higher likelihood for optimal effect with less energy consumption (better battery longevity), more programming options with more electrode contacts close to the nerve and reduced likelihood of side effects. The potentially better clinical outcome needs to be demonstrated.

**Introduction**

Sacral spinal neuromodulation (sacral neuromodulation, SNM) has become an established therapy for functional disorders of the pelvic organs, including both urinary and anorectal indications. Despite its overall success, the therapy fails in a proportion of patients [1-3]. This may be partially due to suboptimal electrode placement.

Neuromodulation is based on the fundamental concept of delivering electrical charges to the nervous system by placing some form of stimulating electrode adjacent to the target neural tissue. SNM is a form of peripheral nerve stimulation that applies low-intensity chronic stimulation to a sacral spinal nerve (usually S3). Available systems for SNM incorporate a basic final assembly of an electrode lead connected to an implanted pulse generator (IPG). The current commercially-available electrode lead incorporates 4 equally-spaced electrode contact points on a flexible lead that is inserted percutaneously under image guidance and anchored in place by several tines (barbs) that contact with soft tissue and bone in the corresponding sacral foramen (Figure 1). The four electrodes can be employed singly or in combination to produce a voltage-driven electrical field that interacts with the target nerve to achieve pulsed depolarisation of axons. Since current draw is dependent on impedance of intervening tissue, and the decay of the electronic field (equated to the exponent of the distance from the cathode) close electrode proximity to the target nerve provides a higher likelihood for optimal effect [4] with less energy consumption (better battery longevity), more programming options if more electrode contacts are close to the nerve, reduced likelihood of side effect and potentially better clinical outcome. Based on these assumptions the technique of sacral spinal neuromodulation has been redefined.

**METHODS**

An international multidisciplinary working party of 10 individuals highly experienced in performing SNM convened in November 2015 and June 2016 for live operating sessions with concomitant discussion to standardize implant procedure for the treatment of pelvic organ dysfunction. The discussion included recently published modifications of the technique [4,5]. This report addresses the main steps to optimal electrode lead placement in temporal sequence. Key elements of the electrode placement are radiological marking, the use of a curved stylet, the entry of the electrode into the sacral foramen and progression through the foramen, its placement guided by a combination of typical appearance on fluoroscopy and achieving specific motor/sensory responses with stimulation. All descriptions necessarily relate to the only currently available system licensed for all pelvic indications (Medtronic Interstim). The report describes quadripolar electrode placement (sections A-F) and then either connecting percutaneous extension lead insertion (for advanced testing) (section G1) or permanent implantation of the programmable device (impulse generator) (section G2). Note is made that the guidance does not cover mode of anaesthesia. There is little consensus on this subject and it is beyond the scope of this manuscript.

**RESULTS**

***A. Patient position and preparation***

Equipment

* Standard operating-room table
* Multiple (usually minimum 4) pillow/rolls for extra support of chest and pelvis and to compensate for lumbar lordosis
* Ground Pad, (Medtronic 041826)
* External Test Stimulator (ENS, Verify)

Procedure

The patient should be positioned in the prone position with the head, thorax and hips well supported. Feet and toes should be lifted off the table (usually with a pillow under the shins) to ensure verification of toe and foot response upon stimulation. The main purpose of correct positioning is to be able to achieve the correct angle from which to enter the foramen. Therefore, lumbar lordosis should be reduced as much as possible (Figure 2). For X-ray, the aim is for a straight line between the spinal process of the sacrum and lumbar spine in the lateral plane. In obese patients surface anatomy may blur the position of the bones.

The patient’s buttocks can be taped apart so that the cheeks are open for observation of the anus during electrostimulation. Although this can be uncomfortable and even embarrassing for the patient (if the procedure is performed under local anaesthesia) it can be helpful in cases of unclear response.

The hand-held screener needs to be operated by an un-scrubbed assistant. A grounding pad to the patient is fixed where it can be easily checked (e.g., the patient’s heel) and connect the patient’s screener to it and the screener cable (Figure 3).

An antiseptic solution is used to sterilize the skin of the sacral region and the immediately surrounding area (including the posterior superior iliac crests, between the lateral edges of the greater sciatic notches, and above the crease between the buttocks and upper thighs). Sterile drapes are placed to delimit a rectangle enclosing the surgical site and anus. A transparent adhesive sterile drape can be used; this will allow direct observation of the anal response without any contamination of the operating field. Sterility is of utmost importance because the procedure involves implantation of foreign material, and infection will necessitate removal. The draping should allow the surgeon to observe the anal bellows response and the feet to control for stimulation-induced movement and to monitor the potential of sacral nerve stimulation.

*Trouble-shooting*

1. *The patient is positioned with lordosis: This may prevent optimal electrode placement because the sacrum is not positioned horizontally.*

***B. Use of X-ray and marking***

**Equipment**

* C-arm
* Antero-posterior and lateral imaging of the sacrum with continuous fluoroscopy

Procedure

Originally, lead placement was an open surgical procedure through a midline incision; the electrode was placed inside the third sacral foramen under direct visualization of the dorsal foraminal opening. With the introduction of percutaneous lead placement, the procedure became more “blinded” and required the use of reliable landmarks. These are numerous and include the superior iliac spine, the L5-S1 transition, the tip of the coccyx or tip of the sacrum, the sciatic notch, and the midline. Based upon these landmarks, the presumed bony location of S3 foramen can be drawn on the skin, marking the needle entry point. The best responses are found when the lead is placed as close to the nerve as possible, its emergence into the pelvis being at the medial and superiorlevel of the foramen [7].

Although these bony landmarks can usually be identified easily, the operator’s experience is essential for correct positioning, as the orientation of the sacral bone and the amount of subcutaneous fatty tissue varies among individuals. Indeed, cadaver studies have shown large variability in size and distance of bony sacral landmarks: e.g., the distance from the upper part of the S3 foramen to the tip of the coccyx has a mean of 9.26 cm, but in only 18 cadavers the range was 3.4 cm [8,9]. If one relies on bony landmarks alone, lead placement could easily be at S2 or S4 in some of these patients. Similar observations have been made in relation to the distance from the midline to the foraminal edge [8]. This individual variability illustrates the disadvantages of using "thumb rules" and highlights the need for proper measurement in each individual, which can only be done with X-ray.

The procedure starts with an A-P view of the sacrum (Figure 4), provided the patient is ideally positioned (no lordosis) on an X-ray table (Figure 2).

X-ray landmarks are the medial edges of the foramina. The medial edges are marked with a vertical line on each side (This line is marked on the skin and usually runs almost parallel to the midline although not always and may vary side to side if there is some degree of scoliosis) and a line connecting the lower edges of the sacroiliac joint. All are marked on the skin producing an ‘H’ figure. The intersecting points of this ‘H” represent the upper medial part of the third sacral foramen, the ideal site for lead entry (Figures 5a,b). The final appearance on the skin is shown in figure 6 noting that the H may not be symmetric with the natal cleft.

After marking with an AP view, the C-arm is rotated lateral for imaging of the entire sacrum for the electrode insertion (Figures 7, 8).

*Trouble-shooting*

1. *Patient is not positioned perpendicularly for the lateral fluoroscopy image: This may result in difficulty identifying the relevant sacral reference structures. Reposition the patient or readjust the operating table.*
2. *Overlying bowel gas makes identification of AP anatomy difficult. This is a common problem that is reduced if a simple enema is given before surgery.*
3. *Surface markings appear greatly asymmetrical either in relation to midline or vertical axis. This is not unusual and relates to degrees of scoliosis that persists despite an external appearance of the patient being straight on the table. This highlights the critical need for X-ray guidance.*
4. *Imaging of the sacrum identifies a sacral malformation. Ideally this should have been determined before listing the patient for intervention. If a malformation is discovered for the first time intra-operatively and the 3rd sacral foramen is absent then the procedure will have to be abandoned. The technique may work in partial bony agenesis/ malformation of the S3 level [10]*

***C. Foramen needle placement***

Equipment

* Two standard-length ‘Foramen’ needles [Length 9cm, 20 Gauge]. Further 12.5 cm 20 Gauge foramen needles are available for obese patients. [Medtronic 041828: [Medtronic 041829]
* Introducer kit: Lead introducer, a directional guide and a dilator. [Medtronic 042294]
* External Test Stimulator (ENS / Verify).

Procedure

The operator stands on the patient’s side (usually the right side if the surgeon is right handed) and tests the right or left side. No data exist indicating which side is the more relevant for sacral nerve stimulation and there is individual variance.

Using the ‘H’ guide already done (Figures 5 & 6) the point of initial entry for foramen needle placement is determined using lateral imaging and a suitable radio-opaque marker like a surgical clamp or forceps. A point someway cephalad to the surface marking of S3 can be estimated on lateral radiograph by extending an imaginary line from the upper border of the S3 hillock in the angle of the inter-vertebral fusion plane of S2-3. Once this point has been determined (and local infiltrated if local anesthetic is used), the needle should ideally be inserted at the angle of the fusion plane (Figure 8a) or very close to this angle (figure 8b) [note that equally good responses can be obtained with either] and strictly in the vertical line of the central body axis (the upright of the “H”) (Figure 9). As this is only an estimate, it is recommended that the needle be inserted only a short distance. Further lateral radiographs of the sacrum should then be taken to make minor adjustments to the entry site and angle before reaching (and in the case of local anesthesia, infiltrating) the deeper tissues adjacent to the periosteum. Once a perfect approach has been determined by adjustment, the needle can be advanced. When using local anesthesia, the syringe attachment (after removal of the stylet) can be used for deeper infiltration. Care should be taken not to infiltrate within the sacral foramen, as this risks abolishing the response to stimulation testing.

With minor adjustments in angle, but avoiding significant deviation from the central axis it should be possible to advance the needle into the upper and most medial section of the sacral foramen. Once it is entered, fluoroscopy can be used to advance the needle to the inner table of the sacrum. Usually the entry into the foramen is felt as a penetrating movement through a ligamentous structure as opposed to hitting the bone. Once at this indicative level, testing stimulation can be performed with the external pulse generator (ENS) (Figure 10). The aim is to achieve an anal motor (if performed under general anesthesia) response (bellows) +/- toe/forefoot response at a low current, i.e. < 2mA. It is then common practice to reduce the stimulation amplitude to a lower level (e.g. 1mA) and make small adjustments to the depth of the needle to maximize the motor response.

At this stage, the needle stylet can be removed and the directional guide inserted. It is critical not to advance the guidewire beyond the depth of the needle (by using the markings provided on the wire or X-ray control). This is emphazised because it is very easy inadvertently to push the needle in with the guidewire such that both advance considerably beyond the inner table of the sacrum and thus penetrate the fascia. (N.B.: This is an even greater risk when the introducer is inserted: see below). Once the guidewire is placed, the skin at the point of introduction is incised for 0.5cm in order to comfortably permit the introducer to be inserted. The needle is then removed, leaving the guidewire in situ.

*Trouble-shooting*

1. *No response to electrical stimulation with foramen needle: If no response is detected at all (even at high amplitude), re-check the equipment. A tip here is that increasing the stimulation above about 3mA invariably causes distortion of the ECG trace on anesthesia monitoring, thus confirming that the external pulse generator is operational.*
2. *A poor response to needle electrical stimulation (i.e. anal motor +/- toe response only at high amplitude): Assuming that the radiological position is satisfactory (after trying to optimize the position by minimal changes of the angulation without exiting the skin), repeat needle insertion on the contralateral side at S3. If this is not successful, repeat the maneuver targeting S4.*
3. *An abnormal motor response (e.g. ipsilateral buttock contraction or foot rotation): Re-perform needle insertion and check radiological landmarks again: the needle is not in the foramen or not at the correct level (usually S2 if foot rotation).*

***D. Introducer placement***

Equipment:

* Introducer kit (Medtronic 042294): Lead Introducer (introducer sheath, directional guide, dilator).

Procedure

The guidewire in place has two marks at each end corresponding to the 9 and 12 cm foramen needle. These markers correspond to the different lengths of the needle electrodes (9 or 12.5 cm) and the length of the introducer. It helps to identify the depth of insertion. The incision for the introducer can be extended in cranial direction, because it will allow at a later stage to bury the inserted electrode underneath the skin.

When the dilator is inserted, it is crucial to avoid inadvertent deep placement of the introducer that may create a false path for the tined lead electrode. It is also very easy to push the guidewire further into the pelvis while pushing the introducer. Thus, continuous or intermittent fluoroscopy is advised to control advancement of the dilator (Figure 11). The radiopaque marker on the sheath of the introducer at the border of the plastic part should no longer be used as a reference for the depth of the introducer placement. Rather, the reference point for depth of introduction is now the tip of the introducer (distance between the radiopaque marker of the introducer sheath and the plastic tip of introducer sheath is around 4 mm). The risk of creating a false tract for electrode placement must be avoided.

The operator should heed the following steps:

1. To leave the metallic directional guide free to avoid forcing the tract during dilator positioning.

2. To push the dilator carefully with both hands, handling the top part of it.

3. To use continuous (or at least intermittent) fluoroscopy to ensure that the tip of the dilator is located in the deep limit of the sacral foramina and not ventral to the ventral opening of the foramen.

4. To monitor the potential migration of the directional guide during insertion of the dilator. If two hands are used during the insertion (see Step 2, above) and the direction of the metallic guide is respected, usually the dilator runs down through the guide. However it is best to get an assistant to firmly hold the guidewire while you advance the introducer. In case of guide migration, it should be retracted.

*Trouble-shooting*

1. *The directional guide slips through the foramen into the pelvis: It must be withdrawn under fluoroscopy.*
2. *Insertion of the introducer at skin level requires pressure: The skin incision needs to be enlarged.*

*3. The introducer is positioned too far in, exiting the foramen ventrally: It must be withdrawn under fluoroscopic guidance.*

***E. Tined lead electrode placement***

Equipment

* Tined lead electrode 28 cm (also available in 33cm and 41cm for obese patients) (tined lead, stiff stylet, curved stylet, percutaneous extension, tunneling tool, boot, torque wrench) (Medtronic 3889-28, -33, -41).

The tined lead electrode carries 4 electrode contacts measuring 3 mm each with spacing of 3 mm (Figure 1). The distance between the most proximal electrode and the most distal set of tines is 10 mm. At the top of the tined lead electrode 4 contacts, each 2.2 mm correspond to the 4 contacts on the electrode tip. Electrode contacts are termed “0” (most distal), “1”,”2”,”3” (most proximal).

Procedure

Once the introducer is in place, with the radiopaque marker inside the sacral foramen, (Figure 11), introduction of the electrode follows.

The electrode comes pre-packaged with a stiff, straight stylet. With the modified technique described here, this is exchanged for a softer stylet with a flexible and curved tip (Figure 1). The insertion of the electrode into the introducer should orient the curved tip in the direction of the natural path of the target nerve: into a caudo-lateral direction.

The aim of electrode placement is to position the four contacts in close proximity to the target sacral spinal nerve. This is achieved if low-intensity stimulation results in an adequate motor/sensory response (depending on whether the procedure is performed under general or local anesthesia). An optimally placed electrode has specific appearance on A-P and lateral fluoroscopic views (Figure 12). This can best be achieved if the foramen is entered at its medial and upper edge (hence optimized needle placement above) and by avoidance of a false track (see section D). The electrode will subsequently follow the natural course of the foraminal lumen. In general intermittent stimulation and fluoroscopic control are advised throughout the procedure at any step that can result in a change of the electrode position.

For its placement the electrode is pushed through the introducer until the first white marker reaches the introducer’s upper edge. This indicates that the entire electrode is still covered by the introducer. If the electrode is pushed in further gently and without force, up to the second marker, the 4 contacts exit off the introducer, the tines still being inside the introducer and not deployed. The electrode follows the path of least resistance, usually the course of the target nerve. Pushing of the electrode is done under fluoroscopy to ensure adequate entry direction and movement into the pelvis. Once the electrode is positioned, test stimulation is applied to each of the four contacts at the external top of the electrode, which correspond to the contacts at the tip of the electrode. Ideal placement is achieved when an adequate stimulation response is evoked with ≤ 2 mA at each contact. This may require revision/optimization of the initial placement: the position can be altered by rotating the bent electrode or by gentle withdrawal or pushing in (or a combination of these movements), all preferably done with intermittent low-intensity stimulation and imaging. During movements, it is important to hold the introducer sheath and lead together when adjusting lead position. Obtaining a correct position is imperative because withdrawing the introducer sheath will deploy the tines and anchor the lead.

The highest likelihood to be close to the nerve is at its exit at the ventral opening of the foramen because distal to that level the path of the nerve may vary [12]. If the most distal electrode contact “0” gives a good response to stimulation throughout electrode positioning it is indicative that the electrode lead follows the path of the nerve.

*Trouble shooting*

1. *Only one or two contacts of the electrodes are in proximity to the target nerve resulting in adequate motor/sensory response: Rotating of the electrode, reinsertion into the introducer with the curved tip pointing in a different direction is advised. As a second step removal and reinsertion and repositioning of the needle electrode with subsequent reinsertion of the introducer may become necessary.*
2. *Concomitant motor response of the forefoot/toe occurs prior to the pelvic floor response. Repositioning of the electrode is advised. See 1.*
3. *Despite measures in (1), few contacts continue to provide low amplitude stimulation. Accepting less than four contacts close to the nerve is a compromise, which for practical reasons may be accepted. This must remain at the discretion of the surgeon.*

***F. Removal of the introducer***

Equipment: none

Procedure

While holding the lead in place, the operator can now retract the introducer sheath. This must be done gently as this outward pulling may result in a dislodgement of the electrode either dorsally or ventrally. As with electrode placement, this step should be performed under fluoroscopy that adjustments can be made to prevent movement. To accomplish this it may be useful to exert a turning or wobbling movement on the sheath without compressing it, as some resistance may be present that can pull on the lead.

After and during the removal of the introducer sheath, the position of the lead can be tested by stimulating the 4 electrode contacts (0, 1, 2, 3). If the evoked responses are the same as previously, the introducer lead stylet can be removed, again keeping the lead itself fixed. Intermittent fluoroscopy helps to confirm the stable position of the electrode.

Once the introducer is removed the electrode position is confirmed by fluoroscopy and stimulation, again at each single electrode contact. The introducer can only be fully removed if the electrode stylet is removed, which results in an even more flexible electrode. Documentation of the final electrode position with fluoroscopy is advised. Ideally in a lateral view the distances between the more distal electrode contacts appear to be less then between the more ventral ones based on the fact of a lateral deviation of the electrode from the midline, which can be confirmed by an AP view. (Figure 12, 13).

*Trouble shooting*

1. *No response to electrode placement: As noted in C. (above), increasing stimulation over about 3mA invariably will cause distortion of the ECG trace on anesthesia monitoring, thus confirming that the external pulse generator is operational. If that is not sufficient, reinsertion of needle and introducer is needed.*
2. *The electrode bends in the wrong direction once it exits the foramen ventrally. This may owe to incorrect positioning or increased tissue resistance (e.g. after surgery in the pelvis). Repositioning of the electrode is advised. With increased tissue resistance, replacing the softer electrode stylet with the stiffer one may aid reinsertion of the electrode.*
3. *Not all four electrode contacts result in an optimal response (as described above). The more contacts that can be used as active electrodes, the more options are available for programming. Clinical outcome can be sufficient with only one good contact, but then stimulation settings will be limited and only unipolar stimulation will be possible. In practical terms, with at least two good contacts either bi- or unipolar stimulation can be selected.*
4. *The lead must be retracted after the tines have deployed: The lead should be removed with gentle traction and can eventually be placed again after the introducer has been replaced.*

***G1. Tunneling, IPG pocket and percutaneous extension lead***

Equipment:

* Connecting extension
* Tunneling device

Procedure

Once the tined lead is positioned the next step is to tunnel the electrode to a pocket in the buttock and then to tunnel the percutaneous extension that will be used for the external stimulation during the test-period.

The pocket in the buttock

A felt tip marker marks the final placement of the IPG in the buttock, preferably on the side of the tined lead. The final placement should allow the patient to sit, lie flat on the back and lie on that side without discomfort. Also the IPG must be accessible for the patient to activate/de-activate with the patient’s programmer (Medtronic Patient Programmer 3037 Icon). Depending on patient’s stature positioning of the pocket 3-4 cm lateral to the sacral bone, 4-6 cm inferior iliac crest avoids contact with bony structures (Figure 13). This is especially important in thin patients. Preoperative marking of the IPG position is advisable.

Local anesthetic with norepinephrine is injected along the designed tracts if under local anesthesia. The incision should be long enough to ensure safe dissection to the subcutaneous fascia (Scarpa´s fascia). A small pocket is prepared under Scarpa´s fascia, large enough to contain the connector of percutaneous extension but superficial to the epimysium of the gluteal muscles.

Tunneling of percutaneous extension

From the newly created pocket, the percutaneous extension is tunneled subcutaneously across the midline to the opposite side. This allows to minimize the risk of infection during the test period. The route is marked with a felt tip and local anesthetic with norepinephrine (if the procedure is done under local anesthesia) is injected. A small stab wound is made and the tunneling tool with tube is inserted and care is taken to secure the tip enters the pocket in buttock. The tunneling tool is removed leaving the tube in place. The percutaneous extension lead is then inserted through the tube from the pocket side.

Tunneling of tined lead to the pocket

The tunneling tool is bent to allow a curved route from the sacral bone to the buttock. The route is marked with a felt tip and local anesthetic with norepinephrine is injected if under local anesthesia. The tunneling tool with tube is inserted at the incision over the sacral bone where the lead protrudes through the skin and targeted to the pocket in buttock. The tunneling tool is removed leaving the tube in place and the lead is passed through the tube. The electrode is placed in the set screw connector so far that the blue tip of the electrode end is visible. The 4 screws are tightened with a torque wrench and the silicone boot - which was placed before the connection - is pulled over the connector and secured with a non-absorbable suture at each end of the connection. The pocket and stab wounds are closed.

***G2: Implantable programmable device insertion***

Equipment

* Impulse generator (IPG) (Medtronic Interstim 3058)

Procedure

When a chronic SNM is decided following a positive test-period, a subcutaneous pocket is created as described above, large enough to hold the IPG tight. The electrode is then connected to a Medtronic 3058 IPG: The electrode is connected (in case of a two staged procedure after disconnection of the extension lead) by insertion into the IPG until the blue tip of the electrode is visible in the transparent connection head of the IPG and fixed by closing the screw.

***H. Antibiotic prophylaxis***

These recommendations are based on expert opinion and not evidence based. [13,14]. Antibiotic prophylaxis in SNM comes with standard measures of prevention of the infectious risk that include detection of infectious risk factors (skin disease for instance), careful preoperative skin preparation and operative setting of high standard regarding aseptic conditions of the procedure. Careful intraoperative skin prep (iodine solutions or similar) and sterile draping are mandatory. The entire procedure either for implantation of the tined-test lead or implantable pulse generator (IPG) is conducted in strictly sterile conditions. During the test-phase whatever its duration instructions have to be given to the patient to keep clean and well covered the exit point of the lead extension. The other wounds are treated as usual.

**Prophylactic antibiotics during implantation**

Protocol may vary with regard to infectious risk in patient’s special conditions (diabetic or immuno-compromised) or due to environmental bacterial pressure and/or general recommendations in institutions or countries.

It is recommended to give one dose of intravenous prophylactic antibiotics before the implantation of a tined lead as well as an IPG implantation. Recommended drugs such cover cutaneous and enteric flora; commonly used are: Augmentin 625 mg iv, Cephazolin 2g slow IV, in case of allergy: Vancomycin 15 mg/kg/60 min or Clindamycin 600 mg slow IV. This has to be done approximatively 30 minutes before a procedure done under local anaesthesia and at induction in case of general anaesthesia.

# There is no consensus regarding the benefit of antibiotic impregnated sheet use, wound irrigation with antibiotic solution or local gentamicin-collagen sponge implantation. In general no routine antibiotics are needed post-operatively. Some experts recommended broad spectrum oral antibiotics for a period of 5-7 days.

**References**

1. Noblett K. Neuromodulation and female pelvic disorders. Curr Opin Urol 2016; 26:321-7.

2. Siegel S, Noblett K, Mangel J, Griebling TL, Sutherland SE, Bird ET et al. Three-year follow-up results of a prospective, Multicenter study in overactive bladder subjects treated with sacral neuromodulation. Urology 2016; 94: 57-63.

3. [Altomare DF](https://www.ncbi.nlm.nih.gov/pubmed/?term=Altomare%20DF%5BAuthor%5D&cauthor=true&cauthor_uid=25644687), [Giuratrabocchetta S](https://www.ncbi.nlm.nih.gov/pubmed/?term=Giuratrabocchetta%20S%5BAuthor%5D&cauthor=true&cauthor_uid=25644687), [Knowles CH](https://www.ncbi.nlm.nih.gov/pubmed/?term=Knowles%20CH%5BAuthor%5D&cauthor=true&cauthor_uid=25644687), Muñoz Duyos A, Robert-Yap J, Matzel KE et al. Long-term outcomes of sacral nerve stimulation for faecal incontinence.Br J Surg 2015; 102: 407-15.

4.Gleason: Electrophysiological fundamentals of neurostimulation. World J Urol 1991; 9: 110-113.

5. Williams ER, Siegel SW Procedural techniques in sacral nerve modulation Int Urogynecol J 2010; 21 (Suppl 2): S453–S460.

6. Jacobs SA, Lane FL, Osann KE, Noblett KL. [Randomized prospective crossover study of interstim lead wire placement with curved versus straight stylet.](https://www.ncbi.nlm.nih.gov/pubmed/23737158) Neurourol Urodyn. 2014;33:488-92.

7. Schmidt RA, Senn E, Tanagho EA. Functional evaluation of sacral nerve root integrity. Report of a technique. Urology 1990; 35: 388-92.

8. Deveneau NE, Greenstein M, Mahalingashetty A, Herring NR, Lipetskaia L, Azadi A. et al. Surface and boney landmarks for sacral neuromodulation: a cadaveric study. International urogynecology journal 2015; 26: 263-8.

9. Povo A, Arantes M, Matzel KE, Barbosa J, Ferreira MA, Pais D et al. A Surface anatomical landmarks for the location of posterior sacral foramina – implications in the technique of sacral nerve stimulation. Techniques in Coloproctology 2016; 20: 859-864.

10. Brunner M, C. Zui, Matzel KE. Sacral nerve stimulation for faecal incontinence in patients with sacral malformation. Int J Colorectal Dis. 2016 Dec 30. doi: 10.1007/s00384-016-2748-6. [Epub ahead of print].

11. Lagares-Tena L, Corbella-Sala C, Navarro-Luna A, Muñoz-Duyos A. Sacral

neuromodulation in a faecal incontinence patient with unknown sacral partial

agenesis. Colorectal Dis. 2017 Mar 20. doi: 10.1111/codi.13661. [Epub ahead of print])

12. Zirpel L, Su X, Wotton J, Reinking N, Steiner A, Nelson D, et al. Correlation of sacral nerve lead targeting and urological efficacy: motor mapping, electrode position, and stimulation amplitude <https://www.ics.org/2016/slot/15453>.

13. Maeda Y, O'Connell R, Lehur PA, Matzel KE, Laurberg S, European SNS Bowel Study Group. [Sacral nerve stimulation for faecal incontinence and constipation: a European consensus statement](http://onlinelibrary.wiley.com/doi/10.1111/codi.12905/abstract?campaign=wolacceptedarticle). Colorectal Dis 2015; 17: O74-87.

14. Leroi AM, Damon H, Faucheron JL, Lehur PA, Siproudhis L, Slim K, et al. Sacral nerve stimulation in faecal incontinence: position statement based on a collective experience. Colorectal Dis 2009: 11; 572–583.