Finetech-Brindley
Sacral Anterior Root Stimulator
(CPC2)

NOTES FOR SURGEONS AND PHYSICIANS

Section 1: BS401 –Notes for Surgeons and Physicians

(Section 2: BS402 – CPC2 Programming Manual)

(Section 3: FTM1055 – Repair Surgery Instructions)

This manual contains the notes from
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This manual MUST be read and understood by all relevant persons prior to using the *Finetech-Brindley SARS* and should be read in conjunction with the other sections.

Section 1: Notes for Surgeons and Physicians

Need help?

If you need advice about any aspect of the *Finetech-Brindley SARS* please:

- email us at info@finetech-medical.co.uk
- contact us or your distributor via our website www.finetech-medical.co.uk
- telephone us on +44 (0)1707 330942

Key to Symbols used in this or others manuals

Contra-indications

These notes describe situations where you should not use the *Finetech-Brindley SARS.*

Warnings and Cautions

Make sure that you understand these notes before using the *Finetech-Brindley SARS.*

Important Note

This symbol appears next to points to remember about the *Finetech-Brindley SARS.*

The *Finetech-Brindley SARS* has been manufactured in the United Kingdom since 1982 by:

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1. DESCRIPTION OF THE CONTROLLER

The Finetech-Brindley Sacral Anterior Root Stimulator (SARS) is an implanted stimulator of sacral anterior roots (usually S2, S3 and S4), which contains no implanted power supply and is driven by electromagnetic induction at the radio frequencies 7 and 9 MHz. Its primary purposes are to improve bladder emptying and thus to eliminate urinary infection, to assist defaecation, and to enable male patients to have sustained full erection when they want it. The operation of implanting it provides the opportunity of deafferenting the bladder by cutting the S2, S3 and S4 posterior roots. Such deafferentation cures reflex incontinence, improves bladder compliance if this was bad, diminishes detrusor sphincter dyssynergia, and ensures that neither use of the implant nor over filling of the bladder will trigger an autonomic dysreflexic attack. Male patients must be warned that it abolishes reflex erection.

Figure 1 shows the whole of a 3 channel implant with intrathecal electrodes. 80% of the implants now in use are of this kind, though about 50% of new implantations are now of 2-channel stimulators, and some centres now prefer extradural electrodes. Below on the right is the block of three passive radio receivers. In the middle are the three cables, ending on the right in sockets for connection to the receivers, and on the left in the two electrode mounts. Above the cables are the sleeve for preventing leakage of cerebrospinal fluid and the three fairings. Figure 2 shows the receiver block in more detail. From each receiver a short piece of cable runs to a plug for connection to one of the three main cables. On the right of the picture are the three jackets that will house the plug and socket joints.

2. IMPLANT CONFIGURATIONS

A 2-channel implant, in which one book is used for S2 and the other for S3 and S4 together, is very advantageous if the spinal canal or the dural theca or both are less roomy than in the average person. Even where space is plentiful, the use of a 2-channel implant simplifies the operation, and probably decreases the risk of damaging the roots. The disadvantages of two as against three independent channels are very slight, since it is hardly ever useful to stimulate S3 and S4 independently of each other. 2-channel implants are now recommended for all patients except those who retain pelvic pain sensitivity.

A 4-channel implant, which has books like those of the 3-channel implant, but four instead of three cables and four instead of three receivers, is appropriate for patients who retain any pelvic pain sensitivity. The receiver blocks of 2-channel, 3-channel and 4-channel implants are illustrated in Figure 5, and their electrode books in Figure 6.

Electrodes for extradural implantation are needed for patients in whom arachnoiditis makes separation of the sacral roots impossible. In some centres (Barcelona; Singapore; Cleveland, Ohio; Turin, Lisbon) extradural electrodes are used for all or nearly all patients. Extradural electrodes are usually used in conjunction with a block of two receivers. Occasionally there is a reason for using a block of three or four receivers.

3. SELECTION OF PATIENTS

3.1 Contraindications

The contraindications for use of the *Finetech-Brindley SARS* are:

- Poor or inadequate bladder reflexes
- Active or recurrent pressure ulcers
- Active sepsis (blood poisoning)
- Implanted cardiac pacemaker

3.2 Complete cord lesions

Almost any patient with a complete non-progressive spinal cord lesion and a reflex bladder can expect benefit from implantation of a *Finetech-Brindley SARS* with a sacral posterior rhizotomy. If the patient at present allows the bladder to empty itself reflexly, the most

conspicuous benefit is continence. If the patient at present suppresses bladder reflex activity with antimuscarinic drugs and practises intermittent self-catheterisation, the obvious benefit is cessation of the need to self-catheterise and the need to take drugs. In either case, illnesses from urinary tract infection almost always become less frequent, and often cease entirely.

It is prudent to wait until three months after a complete cord injury in a woman and nine months in a man before deciding to implant a bladder controller. It is never too late to implant; very successful implantations have been done 25, 28 and 30 years after injury. It is necessary to prove that a sufficient number of intermediate horn cells in the lower sacral segments of the cord survive and that the bladder responds to their activity. Clinical signs that make it likely that an efferent nerve supply to the bladder survives are the four non-vesical sacral-segment reflexes: ankle jerks, bulbocavernosus reflex, anal skin reflex, and reflex erection. If at least three of the four non-vesical sacral-segment reflexes are present and the detrusor pressure (i.e. vesical-rectal pressure difference) shows a systolic increase during cystometry by at least 35 cm H_20 amplitude in a woman or 50 cm H_20 in a man, measured not from zero but from the pressure at which the systolic contraction began, this is sufficient proof. If there are no adequate systolic rises in detrusor pressure during cystometry, or if two or more non-vesical sacral-segment reflexes are absent, the patient is probably unsuitable for a sacral anterior root stimulator. In a few patients, however, stimulation of the sacral segmental nerves through needle electrodes inserted through the sacral foramina will show that bladder responses to direct stimulation of the nerves are good even though reflex responses are lost.

3.3 Incomplete cord lesions

With incomplete cord lesions, three considerations arise that do not apply to complete lesions: uncertainty of prognosis, the wish to preserve sensory function, and the risk that attempts to use the implant may be painful.

It is prudent to wait two years after an incomplete spinal cord injury before deciding to implant a sacral anterior root stimulator, because until then it is uncertain how much recovery will occur.

Patients with good sensory function in the S2 and lower dermatomes are rightly reluctant to lose it; but for some of them the benefit from sacral posterior rhizotomy outweighs the loss. In patients who retain sacral-segment pain sensitivity, the use of a *Finetech-Brindley SARS* usually causes no pain, or only slight and easily tolerated pain, provided that the relevant roots are separated into anterior and posterior components, and only the anterior components trapped. However, six of the 28 such patients treated up to July 1995 find that attempts to use their implants are intolerably painful. A 4-channel implant should be used for patients with pain sensitivity in sacral segments. Five of the six failures due to pain were in patients with 3-channel implants. With a 4-channel implant, the risk of failure in a patient who retains pelvic pain sensitivity is low.

3.4 Multiple Sclerosis

Some patients with multiple sclerosis are suitable, subject to the reservations of the previous section, but only nine such patients are known to have been treated. Four of these have benefited greatly, but five do not use their implants.

3.5 Meningomyelocoele

A minority of adolescent and adult patients with bladder disorders due to meningomyelocoele are theoretically suitable for treatment by sacral posterior rhizotomy and implantation of a sacral anterior root stimulator. At least six such patients have been treated in this way in the years 1991 to 1995.

Sacral anterior root stimulators will probably never be suitable for implantation into young children, because the implant will not grow with the child.

3.6 General considerations

The presence of ureteric reflux is no contra-indication, and may be a strong indication, because the bladder pressure at which implant-driven micturition occurs can be regulated by adjusting the stimulus parameters, and can often be made low enough to prevent the ureteric reflux. Often the changes in the vesico-ureteric valve which allow reflux are a reversible consequence of infection, and elimination of infection with the help of a sacral anterior root stimulator implant leads to lasting cure of the reflux.

Autonomic dysreflexia is also an indication, since it is abolished (at least as triggered from the bladder and rectum) by sacral posterior rhizotomy.

Women have more to gain and less to lose than men. However, tetraplegic women who cannot transfer unaided between chair and toilet seat will not gain in independence by having a sacral anterior root stimulator. Many tetraplegic women choose to have indwelling catheters, despite their disadvantages, because these increase independence.

In patients whose bladder compliance is so poor that the detrusor pressure exceeds 40cm H_20 for a substantial part of each filling phase, it is probable that renal function will deteriorate. The defect of compliance should be remedied without delay. Sphincterotomy and augmentation cystoplasty are two well-known remedies. Sacral posterior rhizotomy and implantation of a sacral anterior root stimulator may be better than either.

Patients with frequent symptomatic urinary infections have more to gain than those without. Patients for whom defaecation takes much time have more to gain than those for whom it is quick. Men with poor or absent reflex erections have more to gain and less to lose than those whose reflex erections already suffice for coitus.

4. PRE-OPERATIVE INVESTIGATIONS

Cystometry is an essential part of the procedure for selecting patients. X-ray screening of the bladder at the same time, though not essential, is desirable.

In patients who have had previous spinal meningitis or subarachnoid haemorrhage, or on whom myelography has been done with an oily contrast medium, separation of the roots will be difficult or impossible because of arachnoiditis. For these patients extradural electrodes must be used, and the posterior rhizotomy may need to be done extradurally by dissection of the ganglia.

Pre-operative magnetic resonance imaging is useful in excluding severe arachnoiditis.

5. WHICH ROOTS TO TRAP

The usual procedure is to trap S2 anterior, S3 anterior, S4 anterior, and S5 without separation into anterior and posterior, all bilaterally. The S5 roots are very small, and sometimes cannot be found.

If a 3-channel implant is used, the S2 and S3 anterior roots are placed in the upper book and the S4 and S5 in the lower. With a 2-channel implant, only the S2 anterior roots are placed in the upper book, and all the rest in the lower.

In a patient with preserved sacral-segment pain sensitivity, the 4-channel implant should be used. This has 1-slot and 3-slot books that resemble those of the ordinary 3-channel implant,

but has four instead of three cables, and four instead of three radio receivers. Only the two pairs of roots that give greatest bladder pressure (usually S3 and S4, but sometimes S2 and S3) should be trapped, and left and right should be trapped separately. Thus after the operation each of the four roots that gave bladder pressure can be stimulated separately, and if stimulation of one or some of them proves to be painful, the painless one(s) can be selected for implant-driven micturition.

6. WHETHER TO CUT POSTERIOR ROOTS

The operation provides the opportunity of cutting posterior roots before placing the anterior roots in the implant slots, and this should be done in the great majority of patients. In S2, S3 and S4, separation of anterior from posterior roots is not difficult unless there is severe fibrosis from previous haemorrhage, meningitis or oily radiographic contrast medium. In S5, which is extremely small, the separation is rarely practicable. It is recommended that S5 be crushed before trapping it. This will interrupt conduction in all its fibres. The motor fibres are likely ultimately to recover their function; the sensory fibres will not.

6.1 Advantages of bilateral posterior rhizotomy of S2 to S4, with crushing of the S5 roots

1. It nearly always causes complete detrusor areflexia, and thus cures reflex incontinence. The areflexia has been observed to last at least 15 years, and will probably prove to be lifelong. In a few patients, such posterior rhizotomy has failed to cause complete detrusor reflexia. In such a case, three possibilities have to be considered: first, that the rhizotomy was incomplete; secondly that in this patient (though, we know, not in most people) afferent fibres that lie in anterior roots, or in posterior roots other than S2-5, can sustain detrusor reflexes; thirdly that the apparently reflex bladder activity is mediated not by the spinal cord but locally by plexuses in the bladder wall or elsewhere in the pelvis. Such pseudo-reflex activity is common during urinary tract infections, but rare in uninfected bladders.
2. It should remove the reflex component of any defect of bladder compliance. In fact the compliance usually becomes completely normal. From this we conclude that mechanical non-compliance from fibrosis is not common in patients with spinal injuries. It does occasionally occur, and can be diagnosed by cystometry under spinal anaesthesia.
3. It greatly diminishes detrusor-sphincter dyssynergia.
4. It abolishes autonomic dysreflexic attacks triggered from the bladder and rectum.

6.2 Disadvantages of posterior rhizotomy

Section of all six of the S2-S4 posterior roots abolishes reflex erection. It also abolishes genital sensation and reflex ejaculation if these were present.

6.3 Recommendations

In all women with complete lesions, the S2, S3 and S4 posterior roots should be cut and the S5 roots crushed, to give the best possible chance of achieving complete freedom from reflex incontinence, and the greatest possible improvement in bladder compliance. Even in those few women in whom the bladder capacity is large and the compliance normal, it is best to cut the posterior roots, since doing so loses nothing, and insures against possible future change in reflex function.

In men with complete lesions the problem is more difficult. If reflex ejaculation is absent and erections are inadequate for coitus, it is certainly best to cut all six posterior roots. If erections are good, or if there is reflex ejaculation, the semen containing motile spermatozoa, the pros and cons of posterior rhizotomy must be discussed with the patient, because men vary in the relative importance for them of erection, fertility and continence. The loss of reflex erection

does not imply that there will be no erection, since excellent erection is achieved by implant in 50% of men, and for patients for whom it is not achieved can use intracavernosal injection of prostaglandin E_1.

In patients with preserved sensory function, the loss of this function to be expected from S2-S5 posterior rhizotomy must be discussed in detail with the patient, who must decide whether it is a fair price to pay for the expected benefit.

7. WHERE TO PLACE THE RECEIVER BLOCK

The commonest site for men is the left lower chest near the anterior axillary line. If this site is chosen, the whole operation can be done with the patient prone. For the other possible sites (anterior thoracic, abdominal or femoral), the patient must be turned during the operation. An anterior thoracic site, roughly in the nipple line, is especially suitable for tetraplegic men with good shoulder movements but no finger movements. Such men can hold a transmitter block (Figure 4) and place it in this very accessible site, but cannot manage the anterolateral thoracic position. Abdominal placement has disadvantages for men, because a belt or tight trouser waistband may compress the skin against the underlying receiver block and cause ischaemic damage, but is good for women. In Germany, the abdominal site is usual for both sexes. Three patients have chosen the anterior surface of the thigh as receiver site, and find it satisfactory. Though the left side (whether of chest or abdomen) is customary and usually preferable, the right side may be preferred by left-handed patients, and by those patients in whom manual evacuation of faeces (which may be greatly assisted by using the implant) is habitually done in the left lateral position.

8. EXTRADURAL IMPLANTATION

Electrodes can be implanted extradurally on the sacral segmental nerves through a laminectomy of the sacrum only, or of the sacrum and L5 vertebra. Electrodes designed for this purpose are illustrated in Figure 7**.** The surgical technique is described in section 17.

Implantation of electrodes should always be done extradurally if the sacral posterior roots have already been cut, since in these circumstances it is easier, quicker and safer than intrathecal implantation.

9. EXTRADURAL DEAFFERENTATION

It is not recommended in the absence of specific indications, because it almost certainly carries a higher risk of anterior root damage and of failure to deafferent completely[14].

10. POSTERIOR RHIZOTOMY AT THE CONUS MEDULLARIS

If for any reason a sacral anterior root stimulator has been implanted without section of all 6 posterior roots, and the patient's subsequent progress shows that section of these roots would be desirable, it can be done through a laminectomy of T12, L1 and L2 close to the conus medullaris. At this site it is easy to distinguish anterior from posterior roots. It is not easy to identify the segmental levels, but accidental section of part or all of the S1 posterior root in addition to S2 to S5 is harmless in a patient with a complete cord lesion. Section of all posterior roots that enter the last 25mm of the spinal cord will ensure that the S2 to S5 roots are cut, and may or may not interrupt the S1 root also.

11. THE BARCELONA PROCEDURE

In Barcelona since January 1990, and now also in Singapore, Cleveland, Oxford, Turin and Lisbon, the standard procedure is to implant the electrodes extradurally and cut the sacral posterior roots at the conus medullaris.

12. CHOICE OF SURGICAL PROCEDURE

The classical operation takes less time than the Barcelona procedure, but not very much less. It requires less total skin incision, and less removal of bone. On the other hand, the Barcelona procedure carries less risk of damaging anterior roots, and almost no risk of failing to cut the posterior roots completely. These are important advantages, and I now think that the Barcelona procedure should be the normal one for surgeons with little experience of implanting sacral anterior root stimulators. But a surgeon who knows the classical operation well and gets good results with it need not change his practice.

The presence of arachnoiditis may influence the choice in either direction. Commonly it affects the lower end of the theca more severely than the region of the conus, and makes the Barcelona procedure preferable. Less often the region of the conus is worst affected, and the classical operation is the better. Occasionally both regions are so severely affected that extradural deafferentation must be done.

13. TECHNICAL MATTERS THAT ARISE BEFORE OPERATION

Silicone rubber adhesive is required for securing the roofs of the electrode books and for filling the sleeve that prevents leakage of CSF and the fairings. (Ref. Appendix 2, A2.8).

14. MONITORING DURING THE OPERATION

It is necessary to check, by observing the effects of stimulation, whether roots or root strands are sensory or motor. The motor responses that must be monitored are those of the bladder, toe flexors, triceps surae, and anal sphincter. The pelvic floor, biceps femoris, gluteus maximus and gluteus medius muscles also respond to stimulation of these roots. The only easily observable effect of stimulation of afferent nerve fibres is rise in blood pressure. This reflex response occurs regularly in patients with lesions above T6. In patients with lower lesions it is small and may be absent. If present, the rise in blood pressure occurs within 3 or 4 heartbeats of the beginning of stimulation, and may be very brief. It is therefore desirable, at least in patients with high lesions, to have continuous intra-arterial recording of blood pressure, displayed on a chart or oscilloscope in such a way that changes lasting only a few seconds can be detected.

The minimal equipment for monitoring the bladder responses is very simple: an indwelling balloon catheter, connected by a 3-way tap to a reservoir of sterile water or saline and to a water manometer. The anal sphincter responses can be palpated, and all other skeletal muscle responses observed by eye. However, most centres choose to record bladder pressure with a transducer and chart recorder, using equipment that allows several pressures to be charted at the same time. The best use for a second channel is to record the pressure in the anal canal. Rectal pressure is less important, but if a third transducer and recording pen are available, they can be used for rectal pressure.

A record of the difference between vesical and rectal pressure is useless, because the bladder and rectum both respond to stimulation of sacral anterior roots.

Whatever technique is used for recording the bladder pressure, there should be provision for draining the bladder and refilling it, because the responses must be recorded from a bladder that is neither very full nor very empty. It should contain between 50 and 100ml.

15. SURGICAL INSTRUMENTS AND STIMULATING EQUIPMENT

The standard instruments for lumbar laminectomy are needed, together with two blunt hooks and a sharp hook for handling and separating nerve roots, microscissors for cutting the arachnoid sheaths of the roots, a tripolar hook electrode for stimulating the roots, and tunnelling instruments for bringing cables under the skin to the receiver site.

The majority of surgeons use the operating microscope for separating the anterior and posterior roots. If an operating microscope is not used, binocular loupes are needed.

A triple hook electrode, with its three electrodes spaced about 2 mm apart, can be bought. The middle electrode is the cathode and the two outers are anodes. This tripolar arrangement minimises the risk of accidental stimulation of other roots by current flowing at a distance from the electrodes. A stimulator suitable for driving the triple hook electrode is also available. This stimulator provides pulses of 350µs duration. There is a capacitor in series with the output to ensure zero net charge transfer. Stimulators that deliver net direct current can damage the roots.

16. SURGICAL TECHNIQUE FOR INTRATHECAL IMPLANTATION

The operation usually takes between 4 and 5 hours.

If the antero-lateral thoracic site is chosen for the receiver, the whole operation can be done with the patient prone. If the abdominal, anterior femoral or anterior thoracic site is chosen, the patient must be turned to supine for implantation of the receiver block.

Premedication with atropine should be avoided, and if the patient has been taking an antimuscarinic drug this should have been stopped at least seven days before the operation. Neuromuscular block, though useful at the beginning of the operation, should be absent at the stage of testing the roots by stimulation.

A laminectomy of the fourth and fifth lumbar vertebrae and the first two pieces of the sacrum is done, yielding 10 to 12 cm of exposed dura. It is sometimes necessary to laminectomize the third lumbar vertebra also. Even if the third lumbar vertebra is not laminectomized, it is usual to remove part of its spinous process. The exposed dura is opened in the midline, and its edge retracted with threads. It is useful to leave 4 to 5 mm of exposed but unopened dura at the cranial end of the laminectomy. The arachnoid is opened, and the roots identified by their size and situation. Size is an excellent criterion: the S1 root is much larger than the S2 and slightly larger than the L5.

17. IDENTIFYING AND SEPARATING THE ANTERIOR AND POSTERIOR ROOTS

It will be seen that each root is bound to the next higher root by a fold of arachnoid. This fold is tough close to the exit of the higher root from the dura, and here it must be cut with microscissors. More cranially, the fold usually tears easily, and needs no cutting. It is best to begin at the S1 exit on one side, cutting the fold that joins the S1 root to the S2 root. The separation is continued until about 3 cm of the S2 root is free from the S1. Then the fold joining the S2 to the S3 root is similarly cut for the first few millimetres and thereafter cut or torn until these two are free from each other as far as the point where the S2 has already been freed from the S1.

The same technique will usually separate the S3 root from the S4, and sometimes the S4 root from the S5. The S5 root may be adherent to the filum terminale. Sometimes no S5 root can be found. Often the arachnoid fold binding the S4 root to the S5 root and/or filum terminale at the S4 exit is very vascular, so that it seems risky to cut it. If so, the separation of S4 can begin at some convenient more cranial point, and need not be continued caudally as far as the S4 exit from the dura.

The whole procedure should then be repeated on the other side, again beginning with the easy separation of the S2 from the S1 root and finishing with the sometimes difficult separation of the S4 from the S5 and filum terminale.

If the identification of the roots is in doubt, it can be confirmed by raising them on to hook electrodes and stimulating them. For somatic motor responses 3 pulses/s should be used. The thresholds are between 0.3 and 1.0V. For examining bladder responses, 30 pulses/s should be used. Thresholds are between 1.5 and 4V. For practical purposes it suffices to use 10V in examining the bladder responses. This will give maximal pressures.

The S4 roots provide motor innervation to the anal sphincter and often the pelvic floor, but to no limb muscle. The S3 roots innervate the pelvic floor and anal sphincter, and usually the toe flexors, but rarely the triceps surae or gluteus maximus and never the biceps femoris or gluteus medius. The S2 roots always innervate the triceps surae, and usually also the glutei, biceps femoris and pelvic floor. Rise in bladder pressure is always obtainable by stimulating S3, usually S4, and often S2.

When the roots have been separated from each other, they should be separated into anterior and posterior components. For the S2 it is usually easy to recognise the boundary between the anterior and posterior roots by inspecting their joint exit from the dura. The anterior root is darker in colour (pinkish grey, contrasting with nearly white posterior root). It lies anteromedial to the posterior root at the exit, and is of about half its cross-sectional area. The posterior root of S2 is made up of two or more distinguishable strands; the anterior nearly always looks single.

It is convenient to begin the separation by lifting up the combined root on a blunt hook, and inserting the point of a sharp hook between the anterior and posterior. When the separation has been begun, it can usually be continued by gently pulling the anterior and posterior apart with two blunt hooks, because the arachnoid sheath that bound them together has already been divided.

When the separation is complete, its correctness is checked by electrical stimulation. In patients with high lesions, stimulation of a posterior root usually causes a rise in blood pressure, and this can be helpful in confirming its identity. It can also provoke troublesome bleeding. When the identity of the posterior root has been confirmed, it should be cut (unless, exceptionally, a decision has been made in advance not to cut it), and a piece roughly 2 cm in length removed.

The S3 root should be treated in the same way as the S2. It is smaller and therefore needs more care, but is otherwise very similar.

The S4 root is still smaller, and often its exit from the dura cannot be seen because of vascular connective tissue. Its separation into anterior and posterior may have to be started several millimetres from the exit. Here the difference in colour between the anterior and posterior can still sometimes be used as a guide to their identity, but the difference of position is unhelpful. Firm identification rests on the results of stimulating.

The S5 root, if present, usually gives little or no bladder pressure on stimulation and is so thin that separating it into anterior and posterior would be difficult. It is reasonable to leave the left and right S5 roots adherent to the filum terminale. This bundle should be stimulated, and if less than 10 cm H_20 bladder pressure is obtained it should be crushed.

Occasionally the posterior and anterior components of the root cannot safely be separated over their whole length because of fibrosis or bridging vessels, but can be separated over the 10 mm or so needed to insert the triple hook electrode for testing. If so, when the time comes for placing the anterior root into its book, the adherent posterior root may have to be placed with it. If this posterior root has been cut more cranially, its presence in the book does no harm at all. If it has been cut more caudally, it does only slight and transient harm (see section 18) If there is not enough splittable root to allow the anterior and posterior

components to be identified by stimulation, it may be necessary to place the unsplit root in the slot without cutting the posterior component. In that case, if the root that cannot be split gives little bladder pressure on stimulation, it may be treated like an S5 root, i.e. crushed before trapping.

The length of an S2 root that needs to be split is about 40 mm. If a 3-channel or 4-channel implant is to be used, an S3 root should be split to the same level, cranially, as an S2 root. Since the point of exit of the S3 roots is usually about 5 mm caudal to that of the S2 roots, this implies that about 45 mm of an S3 root will be split. For a root that is to be placed in the lower book (S4 always and S3 sometimes), it will be sufficient to split 25 mm. If an operating microscope is used for splitting the roots into anterior and posterior components, it should be put aside when the splitting is complete, because for putting the roots into their slots a large field of view is more important than magnification.

17.1 Placing the roots into the implant slots

The implant should first be placed in the spinal canal so that the middle of the lower book is between 3 and 10 mm cranial to the S2 exits from the dura. Placing the roots in the slots with a blunt hook is then easy for a 2-channel implant, and not difficult for a 3- or 4-channel.

In a 2-channel implant, the upper book is used for S2 anterior roots and the lower for the S3 and S4.

In a 3-channel implant, two slots (whichever are most convenient) are used for the left and right S3, and the other two for the left and right S2 or S4, choosing the segment that gives the greater bladder pressures on stimulation.

If (exceptionally) posterior roots are to be spared, it is necessary to place threads round the anterior roots before placing the implant into the spinal canal, and to use these threads for lifting the roots into their slots.

17.2 Fitting the roofs, sleeve and fairings

The roofs should now be fitted to the upper and lower books. Each wall of each book has three square tunnels near its upper margin, in line with the electrodes. Each side of each roof has three projections ("fingers"). The middle finger of one side is longer than the rest. This long finger should be slid into the middle tunnel on the top of one outer wall of the corresponding book, and the other two fingers of this side of the roof into the other two tunnels of the same wall. Then the three equal fingers of the other side of the roof are slipped into the three tunnels of the opposite wall of the book, and the projecting part of the long middle finger of the first side cut off. A small drop of silicone rubber adhesive is applied to each side of the roof to adhesive it to the corresponding wall. Since the adhesive liberates acetic acid while it sets, care must be taken that no adhesive touches any root.

A sleeve (upper middle in Figure 1, lower in Figure 8) has next to be fitted over the three cables to prevent leakage of CSF along them. The sleeve has a flange which will lie inside the dura mater. The part of the sleeve near this flange is made of fine woven Dacron outside and of silicone rubber inside, but the distal part of the sleeve ("fairing-socket") is of silicone rubber only. The fairing-socket is angled, and the sleeve should be placed so that the cables and their fairings are directed caudally.

The socket of each cable in turn is pushed through one of the three little holes at the flange end of the sleeve after wetting both the cable and the sleeve with saline to lubricate them. The clear cable should first be passed through the middle hole, and then the white and black cables through the outer holes. There must be no crossings or knottings of cables. It is not important whether the black or the white cable lies cranially. The cables are pulled through the sleeve until the flange will lie just within the dura, near the cranial end of the slit in it.

During the pulling, the cables should be twisted by hand as required so that they do not tend to rotate the books. It is probably advantageous also to place two stitches in the intact dura just cranial to the sleeve, with the aim of preventing the dura from tearing in the mid-sagittal line. When the flange lies correctly, the dura is closed tightly round the sleeve with two stitches just caudal to the sleeve.

Next, the fairings (Figure 1 upper left and Figure 8 upper) should be half-filled with silicone rubber adhesive, fitted to the three cables just above the fairing-socket, and then slid down so that about 3 mm of fairing lies within the fairing-socket. Before the fairings are filled, they should be inspected to check that they are of suitable length for the patient. For small patients they often need to have a few millimetres cut off at the wide end.

For half-filling the fairings with silicone rubber adhesive and fitting them to the cables, it is convenient to hold each fairing open with an artery clip as illustrated in Figure 8. When the fairings are in place, silicone rubber adhesive is injected into the fairing-socket with a 2 ml disposable syringe and wide-bore needle or cannula to seal the cables to the silicone rubber lining of the sleeve. The aim is to fill only the fairing-socket and not the cloth-covered part of the sleeve.

The response of the skeletal muscles and bladder to stimulation through each of the three cables should now be tested, and the voltages necessary to obtain them recorded. This information is sometimes useful in setting up voiding programmes. The testing also serves the important function of occupying some time, so that when the surgeon sews the main part of the dural incision, the silicone rubber adhesive in the sleeve and fairings has settled and skinned over, though it will not yet be set in depth.

17.3 Closing the laminectomy wound and making the receiver pouch

When it has been checked that the adhesive is solid on the surface and seals all three fairings to the socket completely, the rest of the dural incision can be closed. The closure should begin at the caudal end, because it is only here that there is a significant risk of gripping a root with forceps or including one in the suture. The risk is minimised if this part of the closure, where special care is needed, is done first. Surgeons who use a continuous suture experience fewer postoperative CSF leaks than those who use interrupted sutures.

The muscle and deep fascia are closed next. Before closing the skin, the cables must be brought through by trocar and cannula to a newly made subcutaneous pouch. If the receiver block is to be abdominal or anterior thoracic, this will be a temporary pouch near the free end of the left eleventh rib. The cables are stored in it while the patient is turned. If the receiver block is to be placed on the anterolateral chest, its permanent pouch is made before completing the closure of the laminectomy wound, and the cables are brought through to it directly, usually in a single pass of the trocar and cannula for each cable. Instead of passing the cables one by one with a trocar and cannula, it is possible to pass all three together with a thoracic drain. The pouch for the receiver block should be between the superficial and deep fascia. In obese patients, the deep part of the fat overlying the receiver block should be removed, sparing the most superficial 10 to 15 mm of fat. The lower border of a thoracic pouch should be at least a centimetre above the costal margin, and no border of an abdominal pouch should come within 5 cm of the costal margin or within 2 cm of the anterior superior iliac spine.

17.4 Connecting and implanting the receiver block

When the pouch is ready, each cable is joined to the similarly coloured cable of the receiver block (clear to clear, white to white and black to black) by making the plug-and-socket connection. Before the plug and socket are joined, a silicone rubber ring must be slipped over the socket and slid about 3 cm along its cable. The corresponding jacket is then opened up and held open with two artery clips. The long pin of the plug is inserted into the

white-marked hole of the socket, and the two short pins of the plug into the two unmarked holes of the socket. This connection is first made loosely; then a drop of silicone rubber adhesive is placed to cover the bases of the pins, and the plug and socket pushed firmly together. The opened jacket is then half-filled with adhesive, the completed joint inserted into it, the jacket allowed to close over the joint, and the rubber ring slipped along to hold the jacket closed. There is a groove on the deep surface of each jacket to indicate where the ring should be. Excess adhesive on the outside of the jacket should be removed.

Next, the receiver block is placed in its pouch so that no cable lies over a receiver, and sewn to the deep fascia at two places. Suitable sites for sewing are marked with crosses in Figure 2**.** Then both incisions are closed.

18. SURGICAL TECHNIQUE FOR EXTRADURAL IMPLANTATION

The first three pieces of sacrum are laminectomized. The spinous process of the L5 vertebra should be removed, because this facilitates the implantation of electrodes on the S2 roots and the safe siting of the cables. It is usually unnecessary to laminectomize the L5 vertebra.

18.1.1 Implantation of electrodes

The tripolar electrode arrays can be supplied with a separate cable for each tripole, but ordinarily two tripoles share a common cable. Thus in the usual 2-channel extradural implant there are 4 tripoles, of which two, sharing a common cable, are used for the left and right S2 roots, and two, also sharing a common cable, are used for the left and right S3 and S4 roots. Attached to each tripolar electrode array close to the cathode is a strip of re-inforced silicone rubber 6mm wide and about 40mm long. One end of this is passed under the appropriate segmental nerve (S2) or nerves (S3 and S4 together). For this purpose it may be necessary to separate an additional length of the S3 or S4 nerve from its anterior attachments. The strip of reinforced silicone rubber should be just loose enough to allow a little sliding. The upper and lower anodes should be laid within a few millimetres of the nerve. It is not important whether they touch it.

When all the electrodes are in place, the cables are tunnelled through to the receiver site and the block of receivers implanted, as in the ordinary intrathecal operation.

18.2 Posterior rhizotomy at the conus medullaris

This is a standard neurological procedure and needs no detailed description here. It is worth mentioning that though the aim is to cut the posterior roots of S2, S3, S4 and S5, it is entirely harmless to cut those of S1 and L5 as well. To know this is useful because it is difficult to identify the segmental nature of a posterior root or rootlet with certainty, though it is easy (except for S4 and S5) to distinguish posterior from anterior roots. The lower end of the line of emerging posterior roots does require special care. There is a small, but not negligible risk of damaging the S4 anterior roots, and a substantial risk (unless great care is taken), of missing the S4 posterior root. For S5 these risks are even greater, but less important. The harm from failing to cut the S5 posterior root, or from accidentally damaging the S5 anterior is probably negligible.

18.3 Extradural deafferentation

This difficult procedure should be attempted only if there is good reason (for example, severe arachnoiditis) for not doing the deafferentation at the conus medullaris, where it is easier and safer. The termination of the theca and the S2 to S5 segmental nerves are exposed, but are not at first separated from their anterior attachments. The ganglia of S2 to S4 are identified on both sides. It is unnecessary to identify the ganglion of S5. The deafferentation is done at the ganglion and immediately cranial to it. It is best to begin with an S2 segmental nerve. A length of the S2 segmental nerve, extending from the lower boundary of the ganglion to about 4 mm above its upper boundary is separated from anterior attachments. A 9 mm longitudinal incision is made in the fibrous sheath of the mobilised segment of nerve. The

margins of the sheath are retracted, and gentle blunt dissection of the contents begun. Endoneurial fibrous tissue, though not absent, is present only as fine strands in this region. The anterior root is typically a discrete white parallel-fibred bundle lying anterior to the yellowish ganglionic tissue. Cranial to the ganglion, the anterior root is one of 3, 4 or 5 white parallel-fibred bundles. It is usually the largest and most anterior bundle. It can be seen to be the only bundle that does not enter the ganglionic tissue. Sometimes inspection leaves no doubt about the identity of the anterior root. If there is doubt, the identity of the anterior root and the bundles into which the posterior root divides must be checked by electrical stimulation. When one bundle has been shown to give appropriate skeletal muscle responses at 1V, 3Hz, and bladder pressure at 10V, 30Hz, and the other bundles have been shown not to give such responses at these voltages, the non-responding (posterior) strands must be cut and the responding strand (anterior) carefully preserved.

The deafferentation is done similarly for all six ganglia. It is more difficult for S3 and still more difficult for S4. The S5 segmental nerves should be crushed to interrupt afferent fibres but allow any efferent fibres to regenerate.

19. THE FIRST TEN DAYS AFTER THE OPERATION

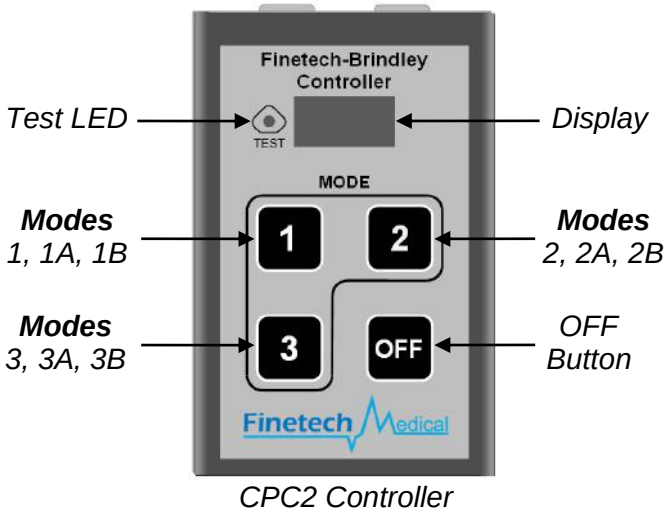
To reduce the risk of leakage of CSF, it is recommended that the patient be not allowed to sit up for the first four days after intrathecal implantation. This precaution is not necessary after extradural implantation.

If CSF does leak after the intrathecal procedure, it usually tracks along the cables and forms a fluctuant swelling around the receiver block. This swelling becomes conspicuous after a few hours of sitting up, and shrinks to nothing after a night of lying flat. Such CSF leaks do not necessarily need surgical repair; the majority of them heal spontaneously if the patient is kept lying down for a few days.

It is generally best to test the implant and bring it into use on the fourth day after the operation. These procedures can be done earlier if the implantation was extradural. To do it earlier may increase the risk of leakage of CSF. To postpone them until the sixth day or later can make the exact diagnosis of anterior root damage difficult. If on the third or fourth day the attempt to bring the implant into use causes autonomic dysreflexia, the attempt should be postponed to the fifth or sixth day, when most of the cut posterior root fibres whose stimulation causes the dysreflexia will have degenerated. Dysreflexia on attempting to use the implant on the 4th day is uncommon except when the central ends of cut posterior roots have been put into the books with the anterior roots.

19.1 The control box

The control box has four push buttons and an Alphanumeric display. The buttons are marked ‘1’, ‘2’, ‘3’ and ‘OFF’. Buttons ‘1’, ‘2’ and ‘3’ are used to select stimulation modes, button ‘OFF’ is used to turn off the controller. There are also sockets for two connectors; one accepts the Transmitter Lead and Battery Charger, the other accepts the SARLINK-2 Interface Lead. (Please refer to User’s Guide and Programmer’s Manual for full instructions). The connectors cannot be plugged into the wrong sockets



CPC2 Controller

and should never be forced in. To unplug a connector, always pull the body of the plug, not the lead.

The control box is also shown in Figure 3.

Normally the stimulation modes are set as follows: -

- Mode 1 for micturition.
- Mode 2 for defaecation.
- Mode 3 for erection.

In all it is possible to set up to nine different modes.

Information
For programming instructions, refer to CPC2 Programming Manual (BS402).

19.2 Examination of skeletal muscle responses

This is covered in detail in 18.3 – 18.7. For the purpose of getting the bladder to work, these tests are unnecessary. However, conducting the tests meticulously for every patient on the 3rd, 4th or 5th day after the operation and then again between the 8th day and 60th day has the great advantage of allowing any operative damage to the anterior roots to be exactly diagnosed. If any roots have been damaged (but not cut through) the damage will not show itself as a loss of skeletal responses until Wallerian degeneration has occurred in the damaged fibres. At the 3rd, 4th, or 5th days, Wallerian degeneration will not have occurred, and the tests show the patient's preoperative physiology, which may be normal or modified by the spinal cord lesion. At 8 or more days, Wallerian degeneration will have occurred. Responses at the 3rd, 4th, or 5th days which are lost at between 8 – 60 days indicate damaged fibres, and should be reported exactly and promptly to the surgeon to help improve the technique.

Fibres that undergo Wallerian degeneration usually regrow and ultimately function normally, but this recovery takes many months.

19.3 Preparing for the tests

The positions of the three implanted receivers are identified. Palpation suffices if the patient is thin. For a patient who is too obese for easy palpation the positions must be found by X-ray screening. The positions are marked on the dressing, or on the skin if the dressing does not extend to the skin under which they lie.

19.4 Preliminary test

Set modes 1, 2 and 3 with the parameters shown in Figures 9.1, 9.2 and 9.3 respectively. Connect the transmitter block to the control box cable. Switch on in mode 3 and bring the transmitter block up to the patient so that primary coil A is close to receiver C. If the operation has been done orthodoxly and everything is working correctly, the patient's feet will plantarflex. After this preliminary check, detailed testing can begin.

19.5 Testing the anal sphincter, puborectalis and toe flexors

The patient should be supine, and preferably should be naked and wholly visible. Movements at the ankles and toe joints should be unobstructed. Stand on the patient's right hand side, insert the gloved index finger of the right hand into the anal canal and with the control box set as for the preliminary check. Bring the transmitter block up to the patient so that each receiver is activated in turn, first A, then B, then C. Primary coil A is used with the program mode 3 to activate receivers A and C (9 MHz), and the B primary coil using program mode 2 to activate receiver B (7 MHz).

Stimulation through receiver A (S4) should cause contraction of the anal sphincter and may activate the puborectalis muscle, causing the anorectal junction to move forwards. It should cause no movement of the lower limbs. If movement of the lower limbs occurs, its most likely cause is accidental activation of receiver B or C. This should be confirmed or disproved by moving the transmitter block. It will probably be found that the presence and strength of lower limb movements depend on the nearness of transmitter A to receiver B or C, not on its nearness to receiver A. Laterality in anal sphincter responses is difficult (perhaps impossible) to diagnose.

Stimulation through receiver B should cause contraction of the anal sphincter and puborectalis muscle. It usually causes flexion of the medial toes or all toes of both feet, but no movement at the ankle joint. If the toe movement is small (as it often is), it can more easily be seen than felt.

Stimulation through receiver C should cause various limb movements whose details will be examined later. It may or may not cause contraction of the anal sphincter and/or puborectalis muscle.

19.6 Testing the pelvic floor muscles

In a man, each ischiocavernosus muscle should be palpated through the perineum and the symmetry or asymmetry of responses to each receiver separately noted. Contraction of this muscle also causes visible retraction of the penis, and it should be noted whether this retraction is symmetrical. In a woman, symmetry or asymmetry should be similarly noted for the pubococcygeus muscle felt vaginally.

19.7 Testing the lower limb muscles other than the toe flexors

For receiver C (but not receivers A and B), movements at the ankle joint and contractions of the biceps femoris, gluteus maximus and gluteus medius should be examined by palpation and/or inspection, and their symmetry or asymmetry assessed. Patients in whom the posterior roots have not all been cut, (and during the first few postoperative days in some patients in whom they have all been cut) reflex as well as direct muscle contractions may occur. The reflex movements can be distinguished from the direct because they nearly always involve muscles not innervated by sacral roots. They usually have higher threshold than direct responses, and are variable on repeated stimulation. If a low frequency of stimulation (i.e. about 8 Hz) is tried, an unfused contraction (tremor) can be seen in a direct response, but not in a reflex response.

19.8 Examining the bladder responses

The indwelling catheter should be connected to a pressure transducer and chart recorder. If two pressure transducers and a recording facility for the difference between two pressures are available, the second transducer can be used for a balloon in the upper vagina or, for a man, in the stomach. The subtraction channel will then have its usual cystometric significance, fluctuations in abdominal pressure being cancelled out. The rectum cannot be used for this purpose, because sacral root stimulation causes contraction of rectal smooth muscle. Usually it is unnecessary to cancel out fluctuations in abdominal pressure, because in most patients, sacral root stimulation will not affect the abdominal pressure. In the few in whom it does, abdominal muscle contractions can usually be distinguished from detrusor contractions by their time-course.

In examining the bladder response it is usually sufficient to test each pair of spinal roots at a single frequency and a single amplitude. The amplitude should be sufficient to stimulate all or nearly all the preganglionic fibres to the bladder and the frequency should be roughly 25 Hz. To achieve this, the main stimulation amplitude should be set to 3. The main stimulation pulse width should be set to about 350µs (for a patient with an average amount of

subcutaneous fat). The main stimulation frequency should be set to about 25Hz. The bladder should now be filled to 100 ml and its responses tested by holding the appropriate transmitter over each receiver in turn and switching on the control box for 15 seconds. The stimulation can be stopped sooner if a very high pressure is attained. As in testing skeletal muscle, transmitter A and program mode 3 are used for receivers A and C. Transmitter B and program mode 2 is used for receiver B.

19.9 Setting a programme for micturition

It is customary to set this on program mode 1.

Information
For programming instructions, please refer to CPC2 Programming Manual (BS402).

If one had to set a micturition programme for a patient with no prior knowledge except a rough assessment of obesity and the knowledge that a *Finetech-Brindley SARS* had been implanted orthodoxly, a sensible choice would be as shown in Figure 9.4.

The main stimulation pulse width of 352µs is for an average patient. This should be adjusted to around 200µs for a thin or 500µs for an obese patient.

All three channels are in use, in bursts, unless the S2 channel (ordinarily C) gives neither bladder pressure nor pelvic floor contraction, in which case it should be out of use.

1. Main stimulation amplitude is set to level 3.
2. Main stimulation frequency is set to 25Hz.
3. Main stimulation on-time is set to about 3 seconds.
4. Main stimulation off-time is set to about 6.4 seconds.
5. Ensure that the prefatigue duration is set to zero
6. Ensure that all interleave numbers are set to zero.

The above programme should now be tested whilst recording the bladder pressure. For this test (in contrast to tests on single channels) the transmitter block must be placed so that transmitters A, B and C lie immediately over receivers A, B and C respectively. A trace roughly resembling Figure 10 should be obtained. There will probably be some leakage of urine round the outside of the catheter, but efficient micturition is not to be expected. Maxima of pressure occur in the gaps between bursts and minima during the bursts. The highest pressure is usually attained during the gap between the third and fourth or between the fourth and fifth bursts. If this highest pressure is below 80 cm H20 in a man or below 60 cm H20 in a woman, the main stimulation on-time should be increased to around 6 seconds and a fresh trial made after waiting 2 minutes. If the highest pressure is above 130 cm H20 in a man or 100 cm H20 in a woman, the main stimulation on-time should be reduced to around 2.4 seconds and a fresh trial made, also after waiting 2 minutes. When the catheter is out and urine free to flow, the pressure reached will be lower. In a man, the first draft micturition programme may cause an inconvenient degree of penile erection. If it does occur, one should try switching off transmitter C.

The next step is to refill the bladder if much urine has been expelled by the preceding test, remove the catheter, try the draft programme, and amend it if it works less well than it should. The information required is the approximate pattern of flow as assessed by eye (a flow meter is less good than a visual assessment), the volume voided, and the residual volume. The residual volume can be estimated by ultrasound or measured by re-catheterization

If the patient has not previously had a sphincterotomy, the micturition will be intermittent, flow occurring during the gaps between the bursts of stimulation, i.e. when the bladder pressure is high and the striated sphincters relaxed. The bursts of stimulation can be recognised by watching the feet, perineum or penis. If when each burst comes the flow from the preceding burst has nearly but not quite ceased, the length of the gap (setting of the space potentiometer) is correct. If flow has quite ceased, the gap is too long. If the closure of the sphincter caused by each burst interrupts a strong stream of urine, the gap is too short.

The stream of urine during each gap should rise smoothly to a maximum and then decrease smoothly, as in Figure 10(i). If it is irregular, as in Figure 10(ii), this indicates detrusor-sphincter dyssynergia, i.e. the striated sphincters contracting irregularly while the bladder pressure is high. Detrusor-sphincter dyssynergia does not occur if the posterior roots from S2 to S4 have all been cut. If it does occur, cystometry and examination of the bulbocavernosus reflex and anal skin reflex will usually provide further evidence of incompleteness of deafferentation. Simple remedies that should be tried include giving (or increasing the dose of) Baclofen and increasing the frequency of pulses within bursts to around 50Hz. If simple remedies fail and the residual volume is unacceptably large, posterior rhizotomy at the conus medullaris may be needed.

19.10 Setting a programme for defaecation

It is customary to set this on program mode 2.

Strong stimulation of S3 or S4 usually, and of S2 sometimes, causes a rise in rectal pressure with latency about 6 seconds and duration about 25 seconds. It will also cause contraction of the anal sphincter. The anal sphincter contraction has a much shorter latency than the rectal contraction, and ceases promptly when stimulation ceases. It is often followed by a fall in anal sphincter pressure to below the resting level. This fall is slow, and it is probably mainly due to inhibition of anal smooth muscle. A programme for bowel emptying should aim to achieve as high as possible a rectal pressure at the time when the anal sphincter is fully relaxed. If all three channels of the implant are used together, at the strength needed for bladder emptying, in bursts of 10 seconds followed by pauses of 20 seconds, this will be roughly achieved.

A more accurate programme can be set up for each patient individually if anal sphincter pressure and rectal pressures are recorded simultaneously. If the duration of bursts and pauses for defaecation is critical, then the patient will have to time them himself, using a watch. The patient starts and stops the bursts by using the relevant program mode (usually mode 2) and the ‘OFF’ button, or by moving the transmitter block alternately into and away from its proper position over the receivers. Often, however, there is a fair range of burst lengths and gap lengths that will suffice. If so, an appropriate combination can usually be achieved by setting as shown in Figure 9.4 (bladder) but increasing the main stimulation on-time to around 8 seconds and the main stimulation off-time to around 17 seconds.

Besides the immediate rise of rectal pressure, stimulation of sacral anterior roots causes an increase in colonic activity. In about 50% of patients, use of the implant as described above expels faeces from the rectum. In the remainder, it fails to do this, but is nevertheless useful because it moves faeces from the pelvic colon into the rectum, and thus makes manual evacuation quicker and more complete.

19.11 Setting a programme for erection

It is customary to set this on program mode 3.

First try a frequency of around 8Hz and an amplitude setting of level 4, continuously. Test S2 alone, then S3 alone. Usually S2 is the main erectile root. If S2 and S3 both give incomplete erection, try them together. Each test should be continued for at least 3 minutes;

implant driven erection can come on very slowly, but when established it stays constant until stimulation ceases. If S2 without S3 gives adequate erection, it is probably the best choice for the practical program even if adding S3 improves the penile rigidity, because leakage of urine is less likely with S2 alone.

8Hz is below tetanic fusion frequency for lower-limb muscles and will make the patient shake. If he finds the shaking too disturbing, the frequency can be increased. At around 12Hz there will be less shaking, and at around 18Hz probably none. If erection is poor with an amplitude setting of level 4 at the pulse duration appropriate for bladder and bowel activation, it may be possible to achieve good erection by setting a greater main stimulation pulse width.

19.12 Setting a programme to treat stress incontinence

Sacral posterior rhizotomy nearly always abolishes reflex incontinence. Disappearance of the reflex incontinence may unmask a significant stress incontinence. There are four options for treating such stress incontinence. In women, operations that raise and support the sphincteric region may be appropriate. In both sexes an artificial sphincter can be considered. But before resorting to operative surgery, it may be good to try two simpler remedies: drugs that stimulate alpha-adrenoceptors (ephedrine, desipramine) and continuous weak stimulation of the sacral anterior roots through the implant. The strength of stimulation must be such that all or most of the somatic motor fibres and none of the parasympathetic fibres are stimulated. Such a strength can always be found, but there may be little margin for error: a small displacement of the transmitter may alter the stimulus from too weak to excite the rhabdo-sphincter fully to strong enough to raise the bladder pressure.

19.13 Testing for damage to anterior roots

Even when the operation seems to have gone well, it is sometimes found afterwards that some anterior roots have been damaged. Such damage does not show itself when the implant is brought into use three or four days after the operation, because the nerve fibres remain capable of function peripheral to the point of damage and enough current spreads from the electrodes along the roots to stimulate the fibres beyond the damaged region. But between the 4th and 7th day the peripheral parts of the fibres undergo Wallerian degeneration and can no longer function. The implant may then work less well, as shown (for example) by an increase in the residual urine volume. Recovery can be expected, and will usually be detectable within 6 months and complete within two years. Not earlier than the 8th day and preferably not later than the 14th day after the operation, a formal test for damage to the anterior roots should be done by re-examining the skeletal muscle responses. If any direct (i.e. non-reflex) responses that were present on the second, third or fourth day are absent on the 8th or a later day, the corresponding anterior root is damaged.

If anterior root damage is so severe that the implant will not give adequate micturition, the bladder must be managed by intermittent self-catheterization or an indwelling catheter until function recovers. Intermittent self-catheterization is usually the better choice. The patient will usually be continent without taking anticholinergic drugs, and therefore is getting some benefit from the operation even while the implant does not work.

Catheterization is also needed if the implant or its external equipment fails. It is therefore recommended that patients for whom a sacral anterior root stimulator implant is planned should if possible learn to do intermittent self-catheterisation.

20. FOLLOW-UP

Between one and three months after the operation if there has been no root damage, or between nine and twelve months after it if there has been root damage, the micturition programme should be revised, and the presence or absence of bladder reflexes examined.

The bladder pressure during micturition should then be measured, and the programme further revised to lower this pressure if it is too high.

The patient should first empty his bladder by implant while sitting on a toilet seat, and the pattern of flow should be examined, and used to amend the length of gap between bursts as in the original setting-up of the micturition programme. A flowmeter allows a permanent record to be obtained if this is wanted, but for clinical purposes inspection of the stream is good enough.

A catheter should then be passed, the residual measured, and cystometry done. The bladder pressure should then be recorded through the small catheter while the patient uses his micturition programme. The urologist should have the control box, with lid removed, in his hand, and a screwdriver ready. If the peak bladder pressure during this micturition at any time exceeds 120 cm H20, or if ureteric reflux occurs when the pressure is high, the mark potentiometer should immediately be adjusted to shorten the bursts of stimulation.

Annual urological check-ups, including examination of the kidneys by ultrasound, are desirable, as with all spinal injury patients. Readjustment of the stimulus parameters in later years is rarely necessary.

21. BENEFITS TO BE EXPECTED

1. Residual urine volumes are diminished, usually to less than 20 ml.
2. Attacks of symptomatic urinary infection cease or become far fewer, and it becomes easier to get the patient's urine sterile.
3. Most patients become fully continent. Bladder capacity, if previously poor, is greatly improved.
4. Bladder compliance, if previously poor, is greatly improved and the risk of damage to the kidneys thereby diminished.
5. The voiding pressure becomes controllable. The practical consequence of this is that ureteric reflux, if it formerly occurred at high but not at low detrusor pressures, will usually cease. Even if it does not cease, the likelihood that re-implantation of the ureters will cure it is greatly improved by bringing the voiding pressure under control.
6. Bowel emptying is assisted by the implant, and may be achievable by implant alone.
7. In about 60% of male patients, sustained full erection sufficient for coitus can be produced by means of the implant.

Benefits 6 and 7 are independent of posterior rhizotomy. Benefits 1 to 5 can only be expected in full measure if all six posterior roots are cut, but some change in the right direction follows section of only some of the roots, and has been seen even where no posterior root was cut (but perhaps some were accidentally damaged).

22. HARMFUL EFFECTS THAT MAY BE SEEN

Damage to one or more of the roots during the operation is common in the intrathecal procedure, but much less common in the extradural. Usually only one root is affected. It is important that the surgeon should be told when he has damaged an anterior root, so that he can improve his technique. Occasionally several roots are damaged. The implant may then be unusable from about the 6th day after the operation until the damaged efferent fibres have recovered. They may recover as early as 8 weeks, but more often take from 4 to 6 months for the bladder and pelvic floor and 8 months for the glutei. Fibres to the triceps surae and toe muscles take longer to regenerate, and may never do so. Damage to posterior roots, whether intentional (rhizotomy) or accidental, has in no case been followed by any functional recovery.

Sacral posterior rhizotomy usually decreases colonic and rectal motor activity; sacral anterior root stimulation always increases it. Thus if an implant is not used, the patient is likely to be more constipated after the operation; if it is used, even if only for micturition, he is likely to be less constipated.

Reflex erection is always lost if the usual practice of cutting all six posterior roots is followed. The patient must be warned of this early in the pre-operative discussions. Erection may be impaired (from accidental root damage) even if no posterior roots are cut.

Many patients have noticed an increase in sweating over the lower part of the body and/or changes (mostly considered to be for the worse) in the pattern of their lower-limb reflexes. These changes have never been permanent. The old pattern usually returns within 3 months, and always within a year.

In three patients a lumbar scoliosis present before the operation has increased during the 11 years (one case) or 5 years (both the others) since the operation. One of these patients has needed surgical stabilisation.

23. WHAT TO DO WHEN A STIMULATOR FAILS

When there is any doubt about the functioning of an implant, the first step is to verify that the external equipment is delivering appropriate trains of pulses. A test area is provided on the front of the control box. With the control box operating and transmitter block connected, hold the transmitter block over the test area with each coil (channel) in turn and the green test LED will emit light when this transmitter is functioning.

The three channels of the implant are independent of each other, and it is unlikely that all could fail at the same time. Complete failure of a sacral anterior root stimulator that formerly worked well is almost sure to be due to failure of the external equipment.

23.1 External equipment failures

The commonest external equipment failures are battery faults and fractures of wires in the cable that joins the control box to the transmitter block.

To test the batteries press and hold button ‘1’ for about 3 seconds. The LED display will show the remaining battery capacity to the nearest 10 percent; the firmware version will be shown if the button is held down for more than 7 seconds.

The cable that joins the control box to the transmitter block is not as durable as the rest of the system and retraction of the insulation or fracture of the fairing of the plug at either end is not a rare event. When the insulation is retracted or a fairing fractures, the spare cable should be used and a new cable should be obtained, because the risk of a wire failure is then increased, though it may not happen for years. It is very unusual for a wire to fail in a cable that looks externally in good condition.

Several patients have dropped control boxes in to the WC bowl. This does no harm provided that the control box is removed from the water, wiped over with a damp cloth and mild disinfectant and dried.

For failure of the external equipment other than the above, consult Finetech Medical Ltd.

24. IMPLANT FAILURES[11]

Ninety-eight implant failures occurred up to August 1994 in the 500 sacral anterior root stimulators implanted between April 1978 and February 1992. Thirty-six were failures of single receivers in the receiver block or their plug-and-socket connectors. Forty-five were

cable failures, and for seventeen it is not known whether receivers or cables have failed. The over-all failure rate is 98 failures in 1922 implant-years, i.e. one failure per 19.6 implant-years. It is lower for recent than for old implants, because of technical improvements. Most of the failures were repairable and have been repaired. In the nine patients with unrepairable failures, new stimulators were implanted extradurally. Of the 6 stimulators implanted in 1978 and 1979, two are still in use in 2002.

24.1 Establishing that an implant failure exists

The characteristic sign is a sudden change, noticed by the patient, in what the implant does. Usually this is the loss of something that formerly happened. Occasionally it is the sudden appearance of a new motor response to use of the implant. The latter can occur if one anodal wire breaks; then the tripolar electrode system, which ordinarily stimulates only nerve fibres that run through the book, becomes a dipole and also stimulates other nerve fibres at a distance.

If good notes have been kept, the physician will easily be able to confirm that a response that was formerly present has been lost, or (less often) that a new response has appeared. He then only needs to verify that the transmitters are working, and this establishes that the failure is in the implant, except for the two special situations described in the next section.

Rapid changes in the somatic or autonomic responses to an electrically intact implant are of two kinds, one fairly common and the other uncommon.

1. The common kind results from damage to anterior roots at operation. When this occurs, the damaged roots generally give good responses to electrical stimulation through the implant during the first 5 days after the operation, but on the 6th, 7th or 8th day they cease to respond. Almost certainly the good responses during the first 5 days depend on spread of current to a part of the root distal to the point of damage, and the disappearance of the responses on the 6th, 7th or 8th day is due to Wallerian degeneration.

2. A few patients have allowed their bladders to become very over-filled. When the distension was relieved, the bladders were found to respond poorly or not at all to sacral root stimulation, though the skeletal muscle responses remained normal. These overstretched bladders recovered after a few weeks of proper bladder drainage.

Slow changes in responses are unlikely to be confused with implant failures. They are of four kinds:

1. Thresholds rise during the first year after implantation because of the growth of fibrous tissue around the nerve roots. The rise is not great, and has never been found to be of practical importance for the bladder or rectum. However, a few patients who need strong stimulation to obtain penile erection in the early months after implantation find that after a year or two they can no longer get adequate erection at all.

2. If anterior root fibres have been damaged during the implantation, they recover, by regrowth from above, during the first year after the operation, causing steady improvement in the performance of the implant.

3. In patients who are incompletely deafferented, use of the implant may cause reflex contractions of trunk and limb muscles or sweating or flushing, either during or immediately after stimulation. These reflex effects often change with time, either slowly over many months or more quickly in connection with episodes of urinary infection, injuries to the lower limbs or intake of antispasmodic drugs.

4. In 8 of the first 500 patients, the stimulator worked well for some months or years and then its performance deteriorated, though it remained electrically intact. Many fibres of the trapped roots had evidently ceased to function.

24.2 Diagnosing the site of a failure

Sometimes a failure is intermittent, and the implant can be altered from functioning to non-functioning or from non-functioning to functioning by pressing through the skin on a specific part of it. This gives an excellent indication of the site of failure.

X-ray pictures showing the whole implant should be taken. Occasionally they will show a beak in a cable, but the majority of cable failures, and nearly all connector and receiver failures, are undetectable even in excellent X-ray pictures.

24.3 Equipment for repairing implant failures

Spare cables, special repair receiver blocks, and connector blocks for repairing cables are available.

The patient should have an indwelling catheter connected either to a pressure transducer or a water manometer.

Besides the standard instruments for minor surgery, it is very useful to have jeweller's forceps for handling the thin platinum-iridium wires and a Macdonald's dissector for spreading the silicone rubber adhesive.

It will be necessary to burn the cut ends of cables during the operation.

Silicone rubber adhesive is needed. For repairs (in contrast to primary operations) a stiff adhesive is better than a liquid one.

25. PROCEDURES FOR REPAIRING IMPLANT FAILURES

25.1 Known site in a cable, not near either end

Make a 10 cm incision over the site of the failure, roughly parallel to the direction of the cables. Exposure of the cables and untangling of any coils of cable can be done either with cutting diathermy or with a knife. It is important to make the correct choice between the two techniques. If a knife is used, accidental damage to a cable can occur very easily. Cutting diathermy, on the other hand, will not damage the cables even if used directly in contact with them. It carries no risk of thermal damage to the trapped spinal roots provided that the diathermy electrode does not directly touch a wire of the cable. Such direct contact at the site of the cable may occur if all three wires and the insulation are broken right through, or if any of the wires were so bent at the point of failure that it protruded through the insulation. These are uncommon kinds of failure, and show very clearly in X-ray pictures. In the commoner kind of failure where one or more of the three wires is fatigue-fractured without substantial distortion, so that the fault is invisible or inconspicuous in the X-ray pictures, the broken wires do not protrude through the insulation. Usually the insulation is intact, and even if it is torn, the slit in it will not pass enough diathermy current to endanger the trapped root, because the resistance of the fibrous tissue, blood or tissue fluid in the slit is very high.

For the above reasons, if no break in the cable is visible in X-ray pictures, all exposure of cables should be done by cutting diathermy. If a break is visible, the broken region should be exposed by knife. As soon as it has been found, the further dissection of cables that will be needed should be done with cutting diathermy.

When the faulty region and at least 6 cm of cable on each side of it has been exposed, the faulty region should be cut across unless the fault was already a complete break. The wires of both stumps should then be exposed by burning. These wires are of 95% platinum, 5% iridium. Each is coated with polyamide insulating varnish. They are embedded in silicone rubber. Hold the cut end of each cable gently in a large artery clip about 12 mm from the extreme end, and burn the last 12 mm. The flame of a match or cigarette lighter is suitable for igniting the silicone rubber insulation. This burns with an easily visible flame and leaves an ash of silica and carbon which coheres if not touched, but crumbles easily into a grey powder. While the cable is burning it should be held pointing upward from the artery clip. Burning will continue downward until the burning region is within about a millimetre of the jaws of the clip, and then cease, because the jaws conduct away enough heat to extinguish it.

When burning has ceased, remove the ash with a wet swab and untwist the helices of the three wires. Their distal parts will be bright platinum-iridium, free from polyamide varnish. Within 2-3 mm of the unburnt silicone rubber they will be yellowish-brown, the colour of the insulating varnish. A short intermediate segment will be covered with heat-damaged varnish, which is black, adheres poorly and may break loose. Stimulate though each wire of the lower cable stump in turn, using 2V 3Hz to elicit the appropriate skeletal muscle responses and 10V 30Hz to elicit bladder responses. If responses are obtained, check that they have roughly the same threshold (within a factor of 2) for each wire. If so, there is no fault below the one that was identified pre-operatively, and the break can be mended with a cable-connecting block. Two cable-connecting blocks should be ready when a repair of a single cable break is being done, because it is easy to make a mistake in the first attempt at re-connection, and such a mistake can be rectified at once if a spare block is available. The task is to connect each wire of the upper stump of the broken cable to a wire of the lower stump by pulling them into opposite ends of a common tunnel. It is desirable that the middle (cathodal) wires of the upper and lower stumps be connected to each other.

If the middle wires are correctly connected, it is of no importance whether the upper and lower wires of one stump are connected to the corresponding or non-corresponding ones of the other stump. But if the middle wire of one stump is connected to the upper or lower wire of the other, the electrodes will constitute a dipole instead of a symmetrical tripole. The functional result is likely to be slightly less good.

Identify the middle wires of the two stumps, and thread each through one of the two pull-through loops of the middle tunnel of the cable-connecting block (Figure 11). Pull the two twisted pull-through wires of this middle tunnel until the bright well-burnt parts of the middle wires of the two cables are well inside the tunnel. Then do the same threading and pulling procedure in each of the side tunnels of the connecting block. Each tunnel receives an anodal wire from the lower stump at one end and an anodal wire from the upper stump at the other.

Next, the six twisted pull-through wires must be pulled further, until 3-4 mm of each wire runs nearly straight from cable to tunnel, and no wire runs so close to another as to be in danger of touching it. If they do accidentally touch, a short-circuit will not necessarily occur, because these parts of the wires probably retain their polyamide varnish; but it would be unsafe to rely on this. When the wires from cables to tunnels have been neatly laid out, the twisted pull-through wires should be cut off. Then the cables are slipped into the longitudinally split fairing-tubes, and silicone rubber adhesive is injected into the fairing-tubes around the cables, around the wires where they run from cables to tunnels and then liberally over the whole upper surface of the tunnel block, bare-wire regions and the adjacent 3-4 millimetres of the fairing tubes, and also the outer surfaces of the alumina walls. The aim is that when the reinforced silicone rubber sheet is wrapped round, it encloses no voids that can fill with

blood or tissue fluid. This aim does not have to be achieved perfectly, but it is important that no space that might fill with blood bridges the gap between any two conductors.

Wrap the silicone rubber sheet round, adding more adhesive if necessary so that it sticks everywhere, and tie a ligature round the middle to hold it in place until the adhesive is set. Then check again for voids, inject adhesive if necessary to fill them, and tie a ligature round each fairing-tube.

It is not necessary or reasonable to wait for setting, as it will take an hour or more before this is complete. All that remains is to make the pouch in which the new junction will lie, place the new junction in it, and close the wound. For the first hour after injecting the adhesive, care is needed to do nothing that would cause a direct pull on either of the two joined cables. After an hour, the repair is very strong.

25.2 Failure in or near the receiver block

Make an incision over the receiver block and deliver it from its pouch. Cut through all three cables close to the connector-jackets, burn their ends and test by stimulation through each of the 9 wires to prove that there is not a second fault further down. All three cables must be connected to a repair receiver block. The procedure for doing this is similar to that used for cable repairs, but slightly easier, because the wires have to be pulled only in one direction through tunnels, not simultaneously in opposite directions.

For the nine wires of the three cables the repair receiver block has only six tunnels, each with a single pull-through wire and loop. The two anodal wires of each cable share a common tunnel. The order of tunnels, from left to right when looking at the repair block with the receivers uppermost, is black anodal, black cathodal, white anodal, white cathodal, clear anodal, clear cathodal. Plus and minus signs are marked on the block as reminders that the anodal of each pair of tunnels is on the left.

After burning each cable and testing it by stimulation, its middle wire is identified and pulled into the appropriate cathodal tunnel and its two anodal wires together pulled into the appropriate anodal tunnel. The rest of the procedure is analogous to that of repairing a cable, except that instead of fairing-tubes to hold the emerging cables in place, the repair receiver block has a flap of thick reinforced silicone rubber sheet. Each cable should be sewn to this sheet as soon as its three wires have been pulled to the right distance into their two tunnels and laid out so that they are in no danger of touching. The sewing prevents harm if a cable is accidentally pulled on, and also prevents it from rotating. When all three cables are connected and sewn down, cut off the pull-through wires. The looped ends of the cable wires will probably not have been pulled so far as to emerge at the receiver ends of the tunnels, but if they have, then cut off these loops also. At the other ends of the tunnels, cut off the free ends of the cable wires, or, if they are less than 2 mm in length, merely bend them so that there is no risk of a short-circuit. Again check that none of the wires running from burnt cables to tunnels touch, and then insulate and seal the structure by applying stiff silicone rubber adhesive. It should be squeezed from the tube directly on to the wires running from cables to tunnels, and then pushed down with a Macdonald's dissector so that all wires are embedded in it. When this has been done, the flap of thin silicone rubber sheet should be wrapped round the tunnel block connector, and two ligatures tied round it.

Remove unnecessary surplus adhesive with the dissector. A little adhesive extending along the free beginning of each cable is advantageous, especially if the adhesive is tapered so that it is thick where the cable leaves the reinforced silicone rubber sheet and thins progressively, ceasing about 8-10 mm away.

The pouch that contained the original receiver block will need slight enlargement.

The repair block can then be placed in it, and the wound can be closed. It is not necessary to wait for the adhesive to set.

25.3 Failure near the subarachnoid space

Such failures cannot be mended with reasonable assurance that the mend will be durable. Extradural electrodes should be implanted, and connected to a new receiver block.

25.4 Failure at an unknown site

There are two options. The choice between them may in the future depend on the statistics of failures; at present it is very arbitrary.

First option: (assumption that the fault is near the receiver block). Begin as if there were a known failure in the receiver block. If, on testing the cut and burnt cable of the faulty channel, normal responses are found, fitting a repair receiver block will cure the fault. If there are no responses from at least one of the wires, cut as much more from the cable as will just allow it to be connected to a repair receiver block to be placed in the original pouch. If on burning and testing, normal responses are found, fit a repair receiver block. If the responses are still defective, make a temporary closure of the wound, and turn the patient to supine. Proceed as in the second option.

Second option: (assumption that the fault is not near the receiver block). Make a 6 cm skin incision beginning at the midline scar of the laminectomy incision at the point where the cables leave the laminectomy wound. The incision must run in the direction of the cables. Ideally it should lie exactly over the cable of the faulty channel. By dissection with cutting diathermy (guided by palpation and if necessary by X-ray examination) find and expose the cable of the faulty channel. Cut it through at a place estimated to be between 8 and 12 cm from its exit from the dura, burn its lower stump, and test each of the three wires by electrical stimulation. If at least one of the wires gives no responses, there is a fault below the place where you have cut the cable. Such faults can be repaired provided that the fault is not within 5 cm of the dura. If repair is judged to be too difficult, new electrodes should be implanted extradurally, following the procedure of p 18. If all the wires give appropriate responses, the fault (whose existence you should have confirmed just before beginning the operation) must be above the place where you cut the cable, and it is therefore repairable. To the lower stump of cable connect a 50 cm length of new cable, following the procedure of pp 31-32. Before placing the new cable-joining block in its pouch, pass the new cable into the receiver pouch if this is accessible with the patient prone, or into a temporary pouch in the flank if the receiver block is too anteriorly placed to be reached. Close the wound in which the re-connection has just been done, turn the patient so that the receiver pouch can be opened if this has not been possible in the prone position, remove the old receiver block and replace it by a new repair receiver block as described on p. 33. Examination of the specimen will subsequently show what the fault was. In any case it has been mended.

If two channels are faulty and the site of failure is unknown, but is proved by the above procedure to be high enough to be repairable, it is best to replace all three cables, not only those of the two faulty channels. Faults are uncommon, so two faults in the same patient are likely to have a common cause, which may have begun to damage the third cable but not yet have interrupted conduction in it.

If the guess involved in either of these options proves wrong, unnecessary surgery has been done. On present knowledge, it seems that the second option should be preferred.

If it has been decided that a fault is unrepairable and that extradural electrodes should be used, these should be implanted on all the S2-S4 roots, not only on those for which the old implant has failed. This is because the circumstances that have caused an unrepairable fault

in one cable of an implant are likely, a few years later, to cause faults at corresponding places on the other cables.

26. ELECTROMAGNETIC COMPATIBILITY (EMC)

Medical electrical equipment requires special precautions regarding EMC. The *Finetech-Brindley SARS* needs to be put into service in accordance with the EMC information provided below. Portable and mobile radiofrequency (RF) communications equipment can affect medical electrical equipment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The *Finetech-Brindley SARS* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Finetech-Brindley SARS* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 2	The *Finetech-Brindley SARS* must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The *Finetech-Brindley SARS* is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The *Finetech-Brindley SARS* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Finetech-Brindley SARS* should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/ output lines	2kV lines 1kV lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV differential mode	1kV L-L	Mains power quality should be that of a typical commercial or

	±2 kV common mode	2kV L-E	hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (>95 % dip in U_T) for 5 cycles 70 % U_T (>95 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Not applicable	*Finetech-Brindley SARS* is designed not to operate while connecting to the mains.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable. No magnetically sensitive devices

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The *Finetech-Brindley SARS* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Finetech-Brindley SARS* should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RFIEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the *Finetech-Brindley SARS*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1,2\sqrt{P}$
Radiated RFIEC 61000-4-3	3 V/m 80MHz to 2,5 GHz	3 V/m	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment

			marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *Finetech-Brindley SARS* is used exceeds the applicable RF compliance level above, the *Finetech-Brindley SARS* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *Finetech-Brindley SARS.*

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

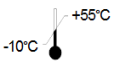
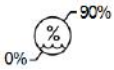
Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the *Finetech-Brindley SARS*.

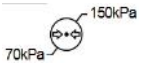
The *Finetech-Brindley SARS* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *Finetech-Brindley SARS* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Finetech-Brindley SARS* as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	**Separation Distance According to Frequency of Transmitter *m***		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (*m*) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, objects and people.

27. GRAPHICAL SYMBOLS

Symbol	*Description*
	Read instructions before use.
	Caution: Consult accompanying documents.
	Contra-indications.
	Important note.
	CE Mark and registration number of the Notified Body for Finetech Medical Ltd.
	Type BF Electrically Isolated (Floating) Applied Part. Providing a high degree of protection against electric shock.
	Class II equipment.
IP22	Degree of protection against solids (touch by fingers ≥12.5mm) and ingress of water (dripping < 15 degrees from vertical).
	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations.
	The catalogue number of the unit.
	Serial number of the unit.
	Manufacturing batch code of the assembly.
	Manufactured by Finetech Medical Ltd.
	Date of manufacture; year and month. YYYY-MM
	Date of sterility expiry; year and month. The use by date; 2 years duration is standard. YYYY-MM
	Sterile by steam or dry heat.
	Do not use if package damaged.
	Do not reuse.
	Protect from heat.
	Protect from moisture.
	Transport and Storage conditions- temperature.
	Transport and Storage conditions- humidity.

	Transport and Storage conditions- pressure.
	MR Conditional

28. DECLARATION OF CONFORMITY

Finetech Medical declares that this product is in conformity with the essential requirements of Active Implantable Medical Devices Directive 90/385/EEC, as amended by 2007/47/EC.

For additional information, contact Finetech Medical.

29. REFERENCES

1. Brindley G S, Polkey C E & Rushton D N (1982) Sacral anterior root stimulator for bladder control in paraplegia. Paraplegia, 20, 365-381.

2. Brindley G S, Polkey C E, Rushton D N & Cardozo L (1986) Sacral anterior root stimulators for bladder control in paraplegia: the first 50 cases. J Neurol Neurosurg Psychiatr, 49, 1104-1114.

3. Egon G, Colombel P, des Roseaux F, Philippi R & Herland, M. (1989) Electrostimulation des racines sacrées antérieures chez le paraplégique. A propos de 13 observations. Annales de Réadaptation et de Médecine physique, 32, 47-57.

4. Brindley G S & Rushton D N (1990) Long-term follow-up of patients with sacral anterior root stimulator implants. Paraplegia, 28, 469-475.

5. MacDonagh R P, Sun W M, Smallwood R, Forster D M C & Read N W (1990) Control of defaecation in patients with spinal injuries by stimulation of sacral anterior nerve roots. Brit Med J, 300, 1494-1497.

6. Sauerwein D (1990) Die operative Behandlung der spastischen Blasenlähmung bei Querschnittlähmung. Urologe (A), 29, 196-203.

7. van Kerrebroek, P E V, Koldewijn E, Wijkstra H & Debruyne F M J (1991) Intradural sacral rhizotomies and implantation of an anterior sacral root stimulator in the treatment of neurogenic bladder dysfunction after spinal cord injury. World Journal of Urology, 9, 126-132

8. Sarrias, M, Sarrias, F & Borau, A (1993) The "Barcelona" technique. Neurourology & Urodynamics 12, 509-512

9. Koldewijn, E L , van Kerrebroek, P E V, Rosier, P, Wijkstra, H & Debruyne, F M J (1994) Bladder compliance after posterior rhizotomies and anterior sacral root stimulation. Journal of Urology, 151, 955-960

10. Brindley G S (1994a) Electrical stimulation in vesicourethral dysfunction. Urodynamics, 2nd edn, ed. A.Mundy, T.Stephenson, A.Wein, publ. Churchill Livingstone, pp 481-494

11. Brindley G S (1995a) The first 500 patients with sacral anterior root stimulators: implant failures and their repair. Paraplegia, 33, 5-9

12. Brindley G S (1995b) The sacral anterior root stimulator as a means of managing the bladder in patients with spinal cord lesions. Neuroprostheses, ed. G.Brindley & D.Rushton, publ Bailliere Tindall

13. van Kerrebroek, P E V, van der Aa, H E , Bosch, J L & Koldewijn, E L (1997) Sacral rhizotomies and electrical bladder stimulation in spinal cord injury Eur Urol., 31, 263-271

14. Sauerwein D, Ingunza W, Fischer J, Madersbacher H, Polkey C E, Brindley G S, Colombel P & Teddy P J (1990) Extradural implantation of sacral anterior root stimulators. J Neurol Neurosurg Psychiatr, 50, 681-684.

15. Egon G, Barat M, Colombel P, Visentin C, Isambert JL, Guerin J (1998) Implantation of anterior root stimulators combined with posterior sacral rhizotomy in spinal injury patients. World Journal of Urology, 16, 342-9.

APPENDIX 1: VOLTAGES, CURRENTS AND CURRENT DENSITIES

As an approximate guide, in a patient with an average amount of subcutaneous fat, the voltage between anodes and cathode is likely to be roughly 15V. After full growth of fibrous tissue, the corresponding current will be roughly 40 mA, the current densities roughly 700 mA/cm2 at the cathode and 300 mA/cm2 at each anode, and the charge densities roughly 150 µC/cm2 per pulse at the cathode and 75 µC/cm2 per pulse at the anode, for 250 µs pulses. These densities relate to macroscopically measured electrode areas. Because of micro-roughness, the current densities and charge densities at the platinum-electrolyte interface will be between 1.5 and 10 times lower.

Exact measurement of voltages, currents, or current densities in the patient is impossible except during surgical exposure. The best that can be done otherwise to satisfy one's curiosity (I have never met a situation where the knowledge was of any clinical importance) is to connect a receiver to a dummy load, and place it at a distance from the transmitter equal to the estimated distance between the patient's implanted receiver and the surface of his skin. A realistic dummy load will be roughly 400 ohms, corresponding to 80 ohms for the platinum-iridium helical cable and 300-350 ohms for the access resistance of the tissues when fibrous reaction to the implant is complete, i.e. at least 3 months after implantation. In the early weeks after implantation, the access resistance is lower. The metal-electrolyte junction adds a negligibly small series reactance if one is considering only pulses of less than 200ms duration.

APPENDIX 2: ADDITIONAL INFORMATION

A2.1 Year of authorisation to affix ‘CE’ mark.

Authorisation to affix the CE mark to the *Finetech-Brindley SARS* was granted originally in 1996.

A2.2 Sterility

The implant is dispatched sterile in double pouches.

A2.3 Method of sterilisation

The packaged product is sterilised by high pressure steam in a steam steriliser for wrapped goods and porous loads, conforming to BS3970 part 3, and operated in accordance with Health Service Technical Memorandum No. 10. The sterilisation cycle has been validated by both thermometric and biological indicator determinations. The operating cycle includes a pulsed air-removal stage before the sterilisation hold period. The sterilisation is carried out at 134°C, (+3°C, -0°C), with a maximum allowable overshoot of 5°C. The hold time is not less than 3 minutes and not more than 4 minutes.

A2.4 Damage to sterile packages

If, on unpacking the equipment, it appears that the sterile package has suffered any damage, the package and its contents should be returned to the supplier immediately.

A2.5 Life of the implant

The life of an implant, not subject to mechanical damage or component failure, is believed to be set by degradation of the silicone rubber. It is expected to happen (though it has not yet been observed) after 20-25 years. The integrity of the implant in degraded silicone rubber cannot be guaranteed; removal or replacement of the implant should therefore be considered after 20 years.

A2.6 Battery life

The battery pack within the control box should give several years use; the lifetime actually obtained will depend on the exact charging and discharging routines. The approaching end of battery life is signalled by the need to charge more frequently than previously. When this happens, the control box should be returned to the supplier for new battery to be fitted.

A2.7 Warming of the transmitter block

When the oscillators in the transmitter block are fed with pulses which are simultaneously large, long and frequent, it is possible for the block to become warm and uncomfortable for the patient to use. Although this situation is unlikely to occur with practical stimulus parameters, the remote possibility of it happening should be borne in mind.

A2.8 Silicone adhesive for use during surgery

The recommended material is sterile Med-A silicone adhesive.

A2.9 MRI scanning

MR Conditional

Risk Assessment: *Experience shows that MRI scanning of patients with Finetech-Brindley (Vocare) sacral anterior root bladder stimulator implants is harmless if a 1.0 or 1.5 Tesla scanner is used. A 0.5 Tesla scanner is very probably harmless. Scanners of 0.2 Tesla are known by experience to be slightly unsafe. Several Stoke Mandeville (UK) spinal centre patients have been scanned in such a scanner, and toe movements and mild autonomic dysreflexia were reported. This was not surprising, as the radio frequency of a 0.2 Tesla scanner is 8.4MHz, very close to the frequency to which the Finetech-Brindley receivers are most sensitive. The frequency of the pulsed radio field in a MRI scanner in MHz is 42 times the magnetic field in Tesla. The greater action of low-magnetic field scanners than high-magnetic field ones is to be expected from theory.*
In addition to the information given above, FDA approval has been granted to allow MRI scanning of Finetech-Brindley Bladder Stimulator System recipients in the USA. The testing has shown that, within indicated limits of scanning hardware and exposure, patients and implanted hardware can be safely scanned using MRI. The following summarises the key points of the MRI precautionary technical information associated with approval in the USA and should be considered sensible guidelines in all cases.

Preparation for Scanning:

- The function of each electrode should be tested prior to MRI scanning. Imaging a patient with a broken implanted lead may result in excessive heating around the break in the lead. This potential risk of scanning a patient with a broken implanted lead would have to be considered on a case-by-case basis against the benefits of scanning.
- Patients should be advised to empty their bladders prior to MRI scanning by testing the stimulated response of each channel.
- The patient's external equipment must not enter a room where an MRI scanner is located. The implant only operates when coupled with the external equipment.

MRI Scanning Conditions – MRI scanning can be performed on individuals implanted with the Finetech-Brindley SARS <u>only</u> under the following conditions:

- A 1.5T (Tesla) scanner with a spatial gradient of 450 gauss/cm or less can be used (this covers the majority of MRI scanners used today).
- Scanners between 1.0T and 1.5T (Tesla) level can be used.
- The imaging mode used must not load the patient with an average Specific Absorption Rate (SAR) of more than 1.1 W/kg for a scan of 30 minutes duration.
- Unconventional or non-standard MRI modes must not be used.
- The use of Transmit Coils other than the scanner's Body Coil or a Head Coil is prohibited.

During Scanning:

- Patients must be closely monitored during scanning and asked to report any unusual sensations or muscle activity.

Image Quality:

- If the location to be scanned is in the same area or relatively close to the position of the implanted receiver, artefacts may compromise the quality of the image.
- In non-clinical testing, the worst case image artefact caused by the device extends approximately 124mm^2 from the implantable receiver when managed with a gradient echo pulse sequence and a 1.5T MRI system.
- In non-clinical testing, the worst case image artefact caused by the device extends approximately 255mm^2 from the implantable receiver when managed with a spin echo pulse sequence and a 1.5T MRI system.

After Scanning:

- The implant should be checked for correct function with the external equipment, outside of the scanning area.

A2.10 Cutting diathermy

Cutting Diathermy is harmless to the patient and to the implant. It is in fact recommended for repair procedures as less likely to cause damage to the implant than use of a knife.

A2.11 X-ray procedures

X-ray procedures do not affect the implant.

A2.12 ECG Tracings

Perturbation of ECG Tracings is to be expected if the bladder controller external equipment is switched on in the neighbourhood of a patient with ECG electrodes in place. The ECG will return to normal soon after the external equipment is switched off.

A2.13 Transport and Storage

The equipment should be transported and stored within the following limits of environmental temperature, humidity and atmospheric pressure.

Temperature:	-10°C to + 55°C
Humidity:	0 to 90%
Pressure:	70kPa to 150KPa

A2.14 Re-use

Implantable components should not be re-used. The external equipment may be used by another patient after appropriate adjustment to the control box.

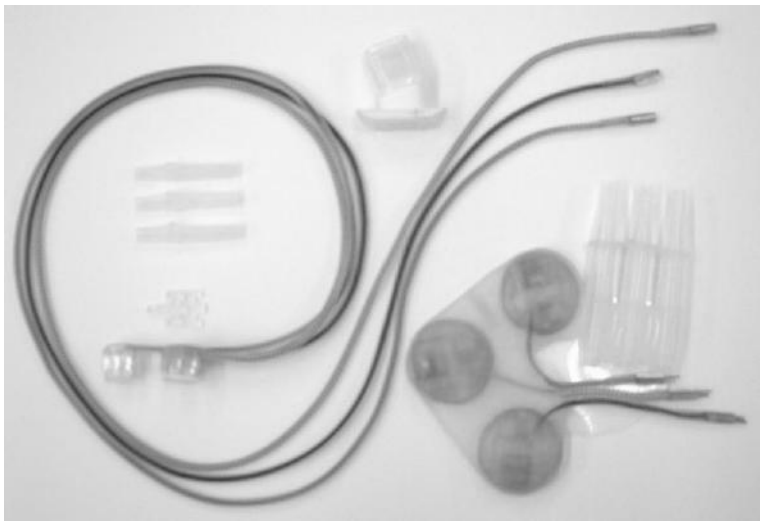


Figure 1: Complete 3 Channel Implant

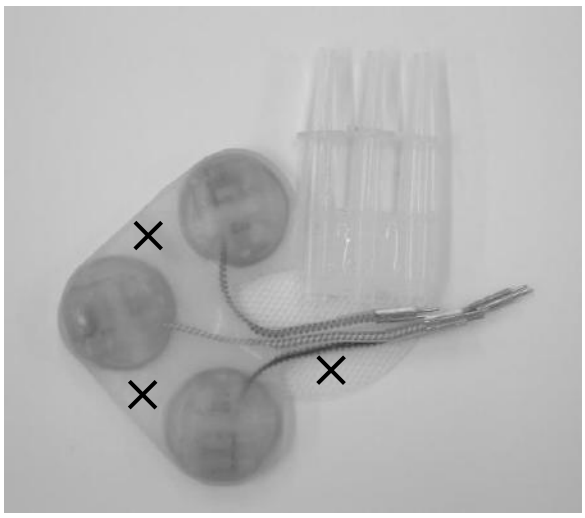


Figure 2: 3 Channel Receiver Block

Figure 3: CPC2 Control Box

Figure 4: Transmitter Block and Lead

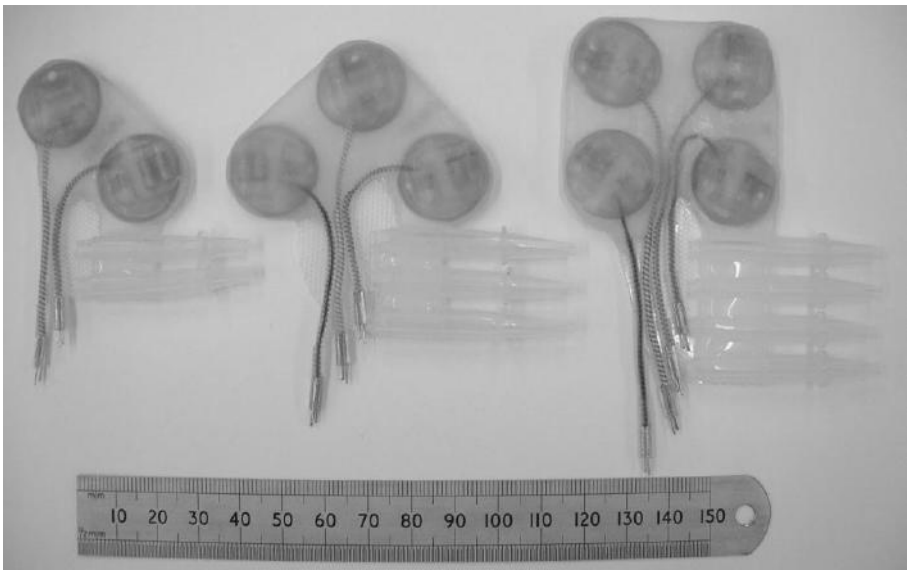


Figure 5: 2, 3 and 4 Channel Receiver Blocks

Figure 6: 2 and 3 Channel Intrathecal Electrodes

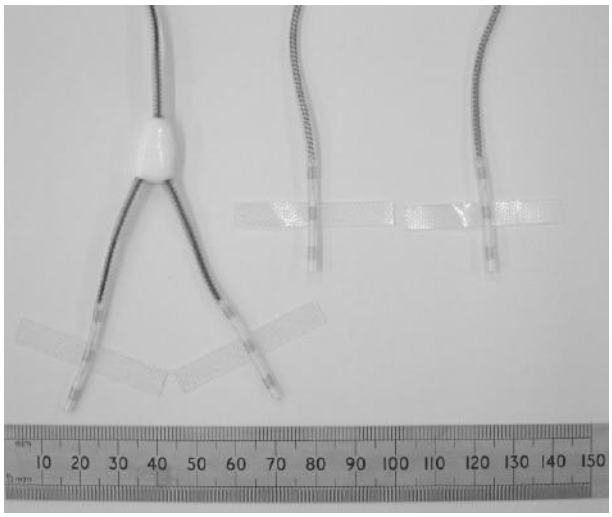


Figure 7: Extradural Electrodes

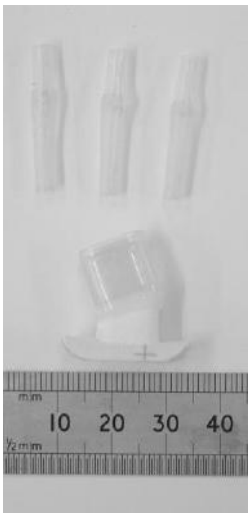


Figure 8: Sleeve and Fairings

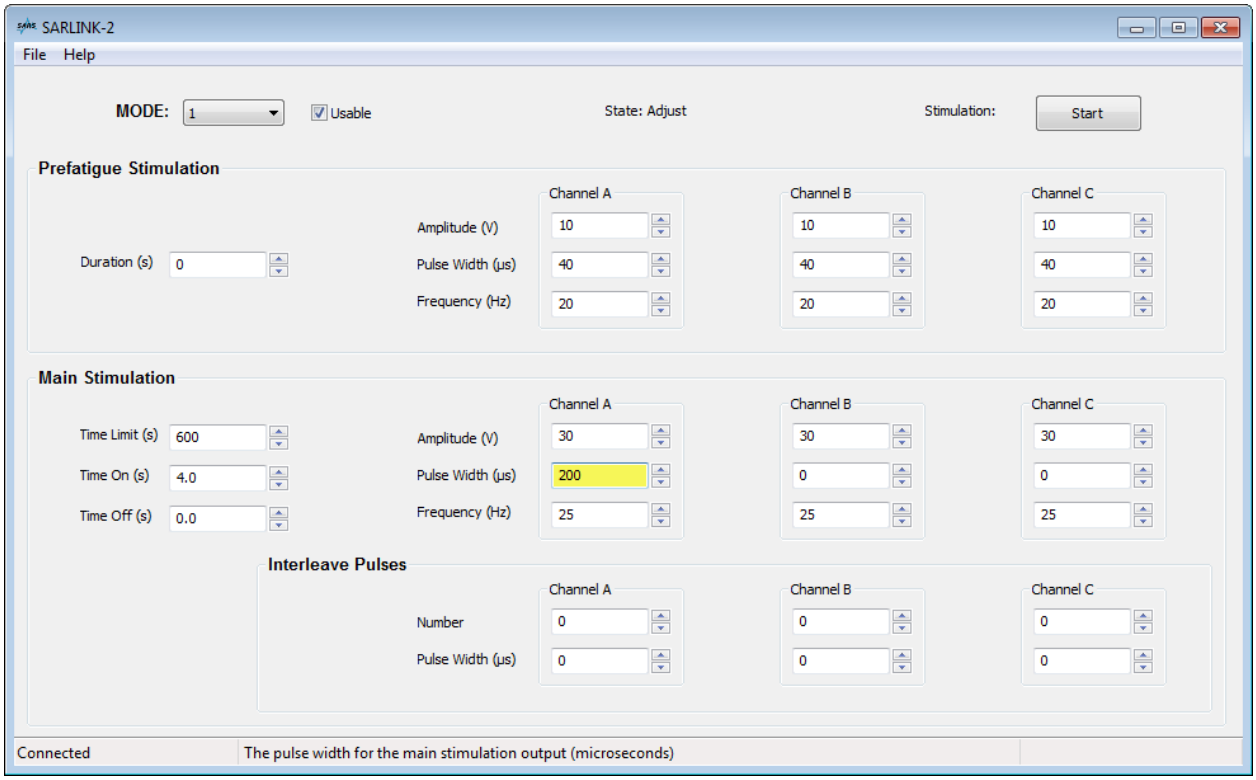


Figure 9.1: Mode 1 (Test parameters)

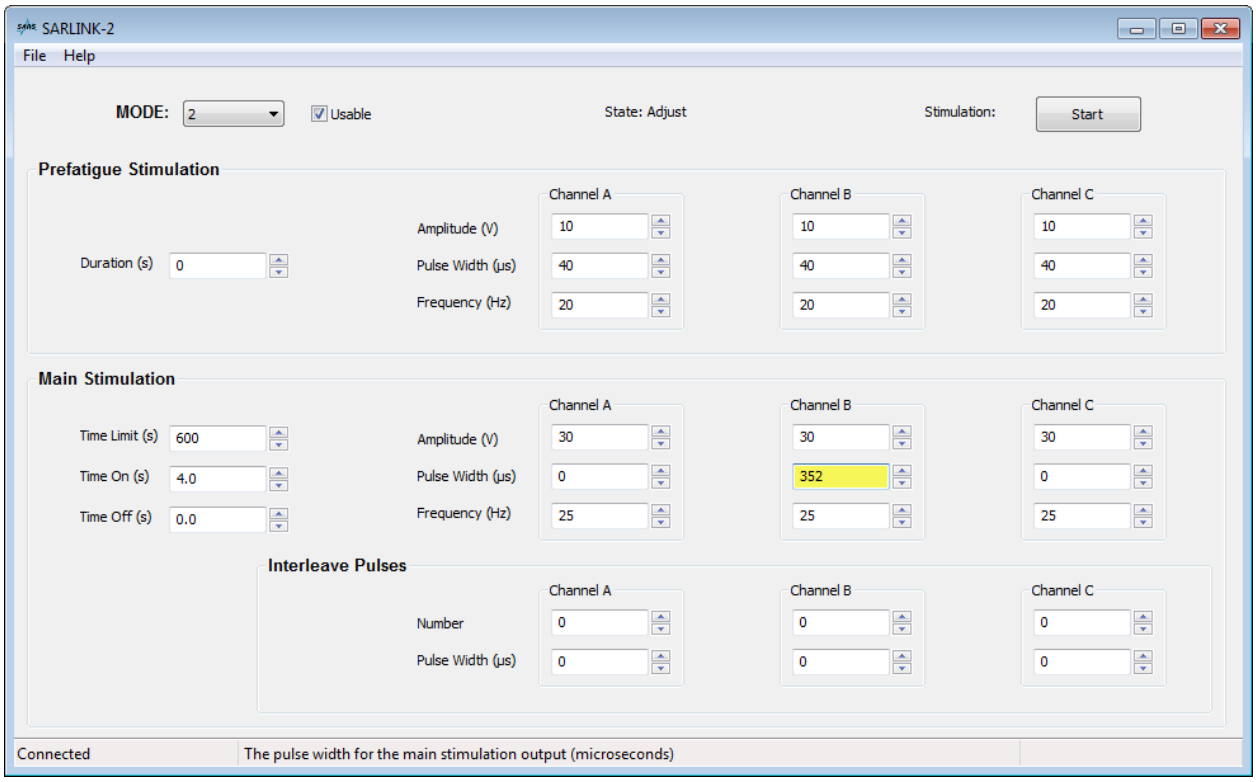


Figure 9.2: Mode 2 (Test parameters)

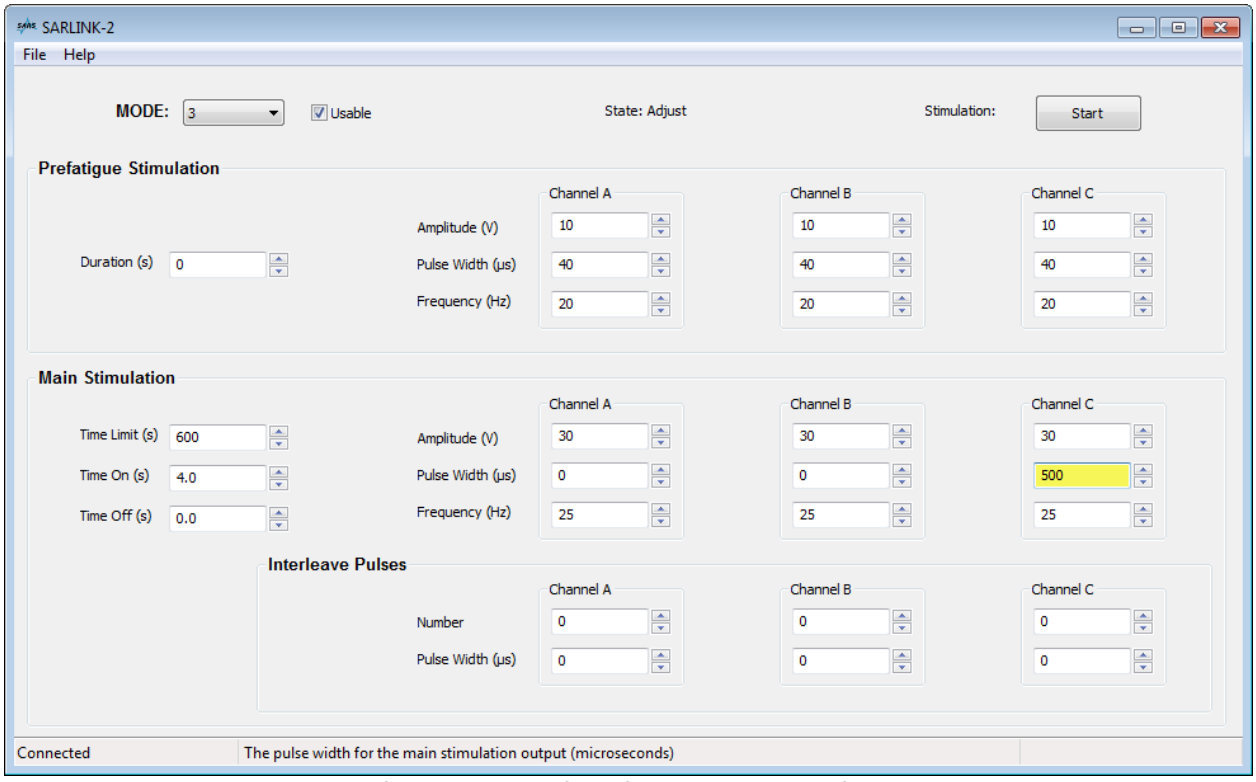


Figure 9.3: Mode 3 (Test parameters)

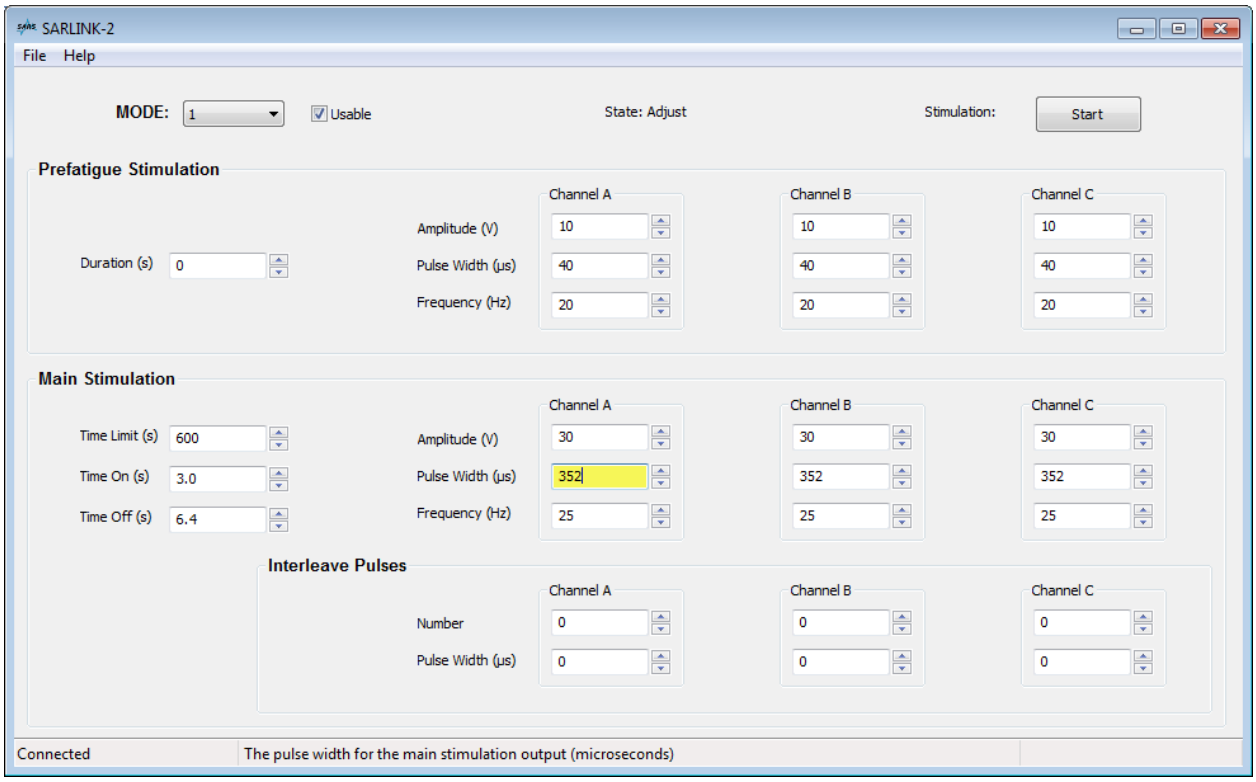


Figure 9.4: Mode 1 (Example program for micturition)

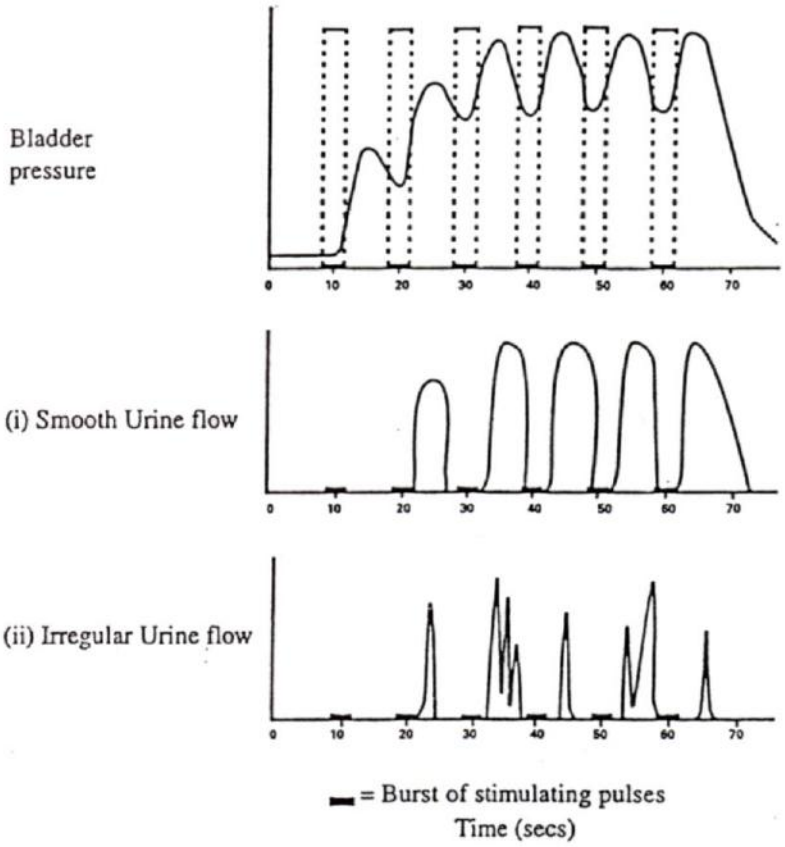


Figure 10: Urine Flow Patterns

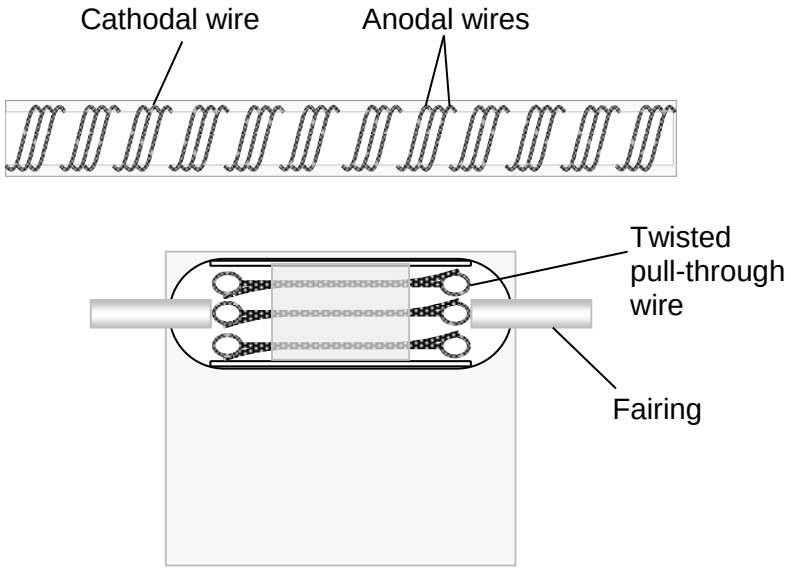


Figure 11: Cooper Cable and Repair Tunnel Block

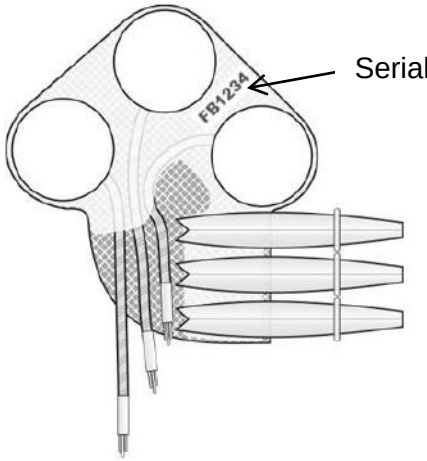
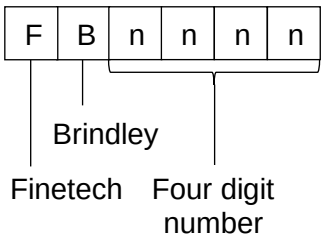
Part Reference	***Description***
3-channel Receiver (example)  	Implant is serialised using radio opaque characters in the format FBnnnn. These can be viewed by taking an X-ray of the implant site. 

Figure 12: Implant Identification

NOTES

