STANDARDS FOR FEMALE AND MALE STERILISATION

Division of Research studies & standards
Department of Family Welfare
Ministry of Health and Family Welfare
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**FOREWORD**

**Sterilisation** is the most familiar method of contraception country – wide, and perhaps for this reason alone, will continue to be popular for some time to come, although the national family welfare program has begun to give a higher priority to spacing methods, especially for younger age groups.

This issue of standards is important for program managers and for staff alike. Standards define what is expected of service providers. They enable the health system, at district and sub-district levels, to monitor services and measure results. The large unmet need for reproductive health services identified in the national family survey, 1992-93 as well the current NFHS-2, is cited as evidence that poor quality of health care result in under-utilization of these services. Prescribing standards facilitates the monitoring of inputs and quality of care.

In the field of sterilisation, quality of care is critical. Poor technical inputs can lead to complication and event cost lives which in turn, discredits the entire program. Poor interpersonal communication can raise barriers to utilisation of these services. Negative impressions have an immediate effect on client behaviour, and can prompt a rejection of sterilisation.

The fact is that Sterilisation as a method of contraception is vital to the success of India’s demographic and health goals. The quality of the sterilisation program must continually register improvements which in turn, will lead to wider utilisation of these services.

I thank all the technical expert, in the field of gynaecology, surgery, and anaesthesia as well as the family welfare program managers who have helped update this volume, Dr. S.N. Mukherji (Sr. Consultant), Dr. Lalrintluangi (Dy. Commissioner), Dr. B.K. Kishore (Ass. Commissioner) Dr. R.C.M. Kaza (NCV Project Adv.) Dr. Farah Usmani (UNFPA), and Dr. Jyoti Vajpayee (AVSC) deserve special mention for their valuable contribution.

I compliment the officers and staff of the Research Studies and Standards Division. Department of Family Welfare in the Ministry of Health and Family Welfare for bringing out this edition of the Standards,1999

New Delhi
14 October 1999

[Signature]

Meenakshi Datta Ghosh
Joint Secretary (Policy)
PREFACE

The Ministry of Health and Family Welfare is deeply committed to improving the quality of family welfare services under the national program. Efforts are being made to address quality concerns in different aspect including reducing morbidity and mortality, especially after sterilisation operations. The development and revision of the standards for Male Female Sterilisation is a significant step in this direction. This edition of the standards has been updated taking into account the current understanding, national and international, in the field of surgical contraception.

This revised edition has been brought out by the Department of Family Welfare with contribution from participants at the national three-day workshop organised in April 1999. We are grateful to the eminent participant from all parts of the country for their critical and thorough review and comments. Special thanks also to the technical expert from UNFPA and AVSC for their contribution and help in bringing out this edition.

Dr. Lalrintuarigi
Deputy Commissioner
(RSS)

New Delhi
October 1999.
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INTRODUCTION
The purpose of this document is to appraise doctors, other health personnel and family planning programme managers throughout the country with the expected sterilisation standards with the objective of improving the quality of sterilisation services. This document sets the criteria for eligibility, counseling, informed consent, pre-operative and post-operative procedures, follow up and procedures for management of complication and side-effects. It also highlights the salient steps of the surgical procedure, the recommended practices for infection prevention as well as standards for mobile sterilisation services.

1. ELIGIBILITY /COUNSELLING / INFORMED CONSENT

1.1 Eligibility criteria for sterilisation
1.1.1 The client must have been married.
1.1.2 Male client should preferably be below the age of 60 years.
1.1.3 Female clients should be below the age of 45 years and above 22 year
1.1.4 Although the number of children is not a necessary criterion, the couple should have at least one child whose age is above one year
1.1.5 Clients or their spouses must not have undergone sterilisation in the past (not applicable in cases of failure of previous sterilisation).
1.1.6 Clients must be in a perfectly normal state of mind so as to understand the full implications of sterilisation.
1.1.7 Mentally ill clients must be certified by a psychiatrist and consent, in such cases, should be given by the guardian/spouse.

1.2 Counseling for sterilisation
Counseling is the process of helping clients make informed and voluntary decisions about fertility. The following steps must be taken before the client signs the consent form.
1.2.1 The client must be informed of all the available methods of family planning, including oral pills, IUCD, condoms and sterilisation.
1.2.2 Clients must make an informed decision for sterilisation voluntarily
1.2.3 They must be counseled in the language they understand.
1.2.4 Clients must be made to understand what will happen before, during and after the surgery, as well as be given information on the side-effects and potential complication.
1.2.5 The following features of the sterilisation procedure must be explained to the client.
   a) It is a safe and simple procedure
b) It is a permanent method for preventing future pregnancies.
c) It is a surgical procedure that has a small risk of complications which may require sexual further treatment.
d) It does not effect sexual pleasure, ability or performance.
e) It will not affect the client’s strength or his ability to perform normal day-to-day functions.
f) It has a small chance of failure, even if performed under optimum circumstances.
g) After vasectomy, it is necessary to use a back-up contraceptive method either for 20 ejaculations or of a period of three months.
h) Sterilisation does not provide protection against RTI/STDs or HIV/AIDS.

1.2.6 Clients must be encouraged to ask questions and to clarify doubts, if any.

1.2.7 Clients must be told that they have the option of deciding against the procedure at any time without sacrificing their right to other reproductive health services.

1.2.8 The client must be told that a reversal of this surgery is possible, but the reversal involves a major surgery and its success cannot be guaranteed.

1.3 Informed consent for sterilisation

1.3.1 Consent for sterilisation operation should not be obtained under coercion or when the client under physical or mental stress.

1.3.2 Consent should not be obtained when a woman is sedated or when she experience stress associated with some pregnancy-related events/problems.

1.3.3 Clients must sign a printed application and consent form for sterilisation. (annexure I & IA give the revised formats)

The written consent of spouse is not required for sterilisation operations.

2 STANDARDS FOR FEMALE STERILISATION

Female sterilisation by minilap tubectomy can be performed by a trained MBBS doctor. Whereas laparoscopic sterilisation can only be performed either by a gynaecologist with DGO/MD/MS or a surgeon with a MS degree and trained in laparoscopy. Prior to performing sterilisation operation, a careful clinical assessment...
of the client should be made to ensure their fitness for surgery. There are certain condition that require doctors to be cautious, delay the surgery, refer the client to a specially equipped centre, or counsel the client to opt for alternative contraception. There may be situation when it is better to counsel the female client’s husband to go in for vasectomy.

2.1 Medical contraindications

2.1.1 There are no absolute contraindications to female sterilisation.

2.1.2 The relative contraindications are discussed below. The risk of pregnancy must be weighed against the risk of the sterilisation procedure.

a) Psychiatric disorders
b) Physical illness
   (i) Acute febrile illness
   (ii) Jaundice or other chronic liver disease
   (iii) Anaemia with haemoglobin less than 8gm%
   (iv) Chronic systemic disease, including tuberculosis, bronchial asthma, blood dyscrasias, heart disease, uncontrolled diabetes, hypertension and thyrotoxicosis
   (v) Malignancy
   (vi) Skin conditions, including infection involving operative site
   (vii) Pelvic infection, adhesions or mass.
   (viii) Severe nutritional deficiency, such as generalised oedema, anaemia and vitamin deficiency.
   (ix) Bleeding disorders
   (x) Continuing pregnancy
   (xi) Multiple scars of previous laparotomies

c) Allergy to local anaesthesia (alternative anaesthesia or procedure to be provide in such cases).

d) Gross obesity

e) The following condition apply to post-partum client:
   (i) Puerperal fever
   (ii) Prolonged rupture of membranes (more than 24 hours)
   (iii) Pre-eclampsia or eclampsias
(iv) Ante-partum or post-partum haemorrhage resulting in haemoglobin less than 8gm percent
(v) Trauma to the genital tract
(vi) History of post-partum psychosis.

2.2 Clinical and Technical Procedures

Preparation for surgery includes pre-operative assessment and instructions, a review of the surgical procedure and post operative care. Pre-operative assessment is essential to assess the client’s physical fitness for surgery and also to ensure that the consent for surgery is voluntary and well informed. This assessment can also provide an opportunity for overall health screening and treatment of RTI/STDs, if required.

2.2.1 Clinical assessment and screening of clients

a) Demographic information: Information on age, marital status, occupation, religion education, number of living children and age of the youngest child is required to be elicited.

b) Medical History:

(i) History of illness to screen out the disease mentioned under relative contraindications (2.2.2)
(ii) Immunization status of client for tetanus, and all of the children for tetanus, tuberculosis, diphtheria, pertussis, poliomyelitis and measles.
(iii) Addictions (alchol, smoking and drugs)
(iv) Current medications
(v) Last contraceptive used
(vi) Menstrual History: Date of last menstrual period and current pregnancy status.
(vii) Obstetric history: Number of pregnancies, deliveries (live births and stillborn), abortion (spontaneous and inducted), living children of each sex and age of the youngest child.

c) Physical Examination: This will include recording of the pulse, blood pressure, respiratory rate, temperature, body weight, general condition, and nutritional status, Auscultation of the heart and lungs, examination of abdomen, pelvic examination and other examinations as indicated by the client’s medical history or general physical examination are to be done prior to surgery.
d) **Laboratory Examination**: The essential laboratory investigations include blood test for haemoglobin and urinalysis for sugar and albumin. Other laboratory examination (for example: pregnancy test) can be performed as indicated.

2.2.2 **Final Medical Assessment**

The operating surgeon must verify eligibility, informed consent and confirm the physical fitness of the client including abdominal/ pelvic examination before conducting the surgery.

2.2.3 **Timing of the Surgical Procedure**

a) **Interval sterilisation**: should preferably be performed within seven days after the menstrual period is over (in the follicular phase of the menstrual cycle). However, if the sterilisation is done in pre-menstrual phase, counseling regarding the possibilities of exiting should be ensured.

b) **Post-partum sterilisation** should preferably be done within 48 hours to 7 days of delivery. However, the procedure may be performed at any other time provided there is no infection or contra-indication.

c) **Sterilisation with medical termination of pregnancy (MTP)** can be performed concurrently. However, post MTP tubectomy is not be done in camp condition.

d) **Sterilisation following spontaneous abortion** can be performed with antibiotic coverage and only in the absence of anaemia and infection.

Laparoscopic tubal ligation should not be done concurrently with second trimester abortion and in post-partum period.

2.2.4 **Pre-operative Instructions**

a) The client must bathe and wear clean and loose clothing to the operation theatre (OT).

b) The client must not ingest anything by mouth 4 to 6 hours prior to surgery.

c) On the morning of surgery, she must empty her bowels, and before entering the OT, empty her bladder.

d) The client must remove nail polish, jewellery or hair pins before entering the OT.

e) She must also remove her glasses, contact lenses and dentures.
f) A responsible adult must be available to accompany the client home after the surgery.

2.2.5 Part Preparation
The operating area should not be shaved. The hair can be trimmed, if necessary. The operating area should be cleaned with soap and water and painted with none-alcoholic antiseptic preparation.

2.2.6 Anaesthesia/Analgesia/Pre-medication

a) Local anaesthesia: This is the preferred choice for tubectomy operation. The following are the requirements for provision of local anaesthesia:

(i) Skin sensitivity to local anaesthetic agent (lignocaine) is not necessary, as it has no established predictive valve for anaphylactic reaction. Most of the reactions of local anaesthesia are due to direct intra-vascular injection.

(ii) 1% lignocaine without adrenaline is the local anaesthetic that is to be infiltrated on the OT table. The maximum doses is 200 mg or 20 cc of 1% lignocaine (10ml of a 2% solution to be diluted with equal amount of distilled water).

(iii) Atropine 0.6 mg (IM) should be given in all cases.

(iv) Pre-operative or intra-operative sedation and analgesia is to be administered, depending on the need. Recommended drugs to be used are given in the following table.

<table>
<thead>
<tr>
<th>Name of drugs</th>
<th>Dose</th>
<th>Route of Administration</th>
<th>Repeat Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Pentazocine + Phenargan</td>
<td>30 mg + 10 mg</td>
<td>IM</td>
<td>15 mg + 5 mg IV</td>
</tr>
<tr>
<td>2. Diazepam</td>
<td>10 mg</td>
<td>IV / IM</td>
<td>5 mg IV</td>
</tr>
<tr>
<td>3. Pentazocine + Diazepam</td>
<td>30 mg + 10 mg</td>
<td>IV + IM</td>
<td>15 mg + 5 mg IV</td>
</tr>
<tr>
<td>4. Pethidine + Phenargan</td>
<td>50 mg + 50 mg</td>
<td>IM</td>
<td>10 mg + 5 mg IV</td>
</tr>
</tbody>
</table>
At least 30 minutes must be allowed for pre-medication to be effective if given intramuscularly.

Client must be monitored after administration of the drugs.

Communication must be maintained with the client throughout the procedure.

**General Anaesthesia:** This is rarely necessary. However, it may be required in the following conditions:

- In case of a non-co-operative patient.
- In case of excess obesity.
- History of allergy to local anaesthetic drugs.
- Any other medical condition.

In the above cases, the provision for general anaesthesia (guideline for personal, facilities, equipment and others) would be as per the requirement of the trained anaesthesiologist.

**Monitoring:** Medical records are to be maintained relating to the vital signs (pulse, respiration and blood pressure), level of consciousness, vomiting and any other relevant information. If any drug is administered, its name, doses, route and time must be recorded. Monitoring is to be done as given below:

- Pre-operatively – Pulse, respiration and blood pressure should be taken prior to pre-medication and thereafter every 15 minutes.
- Intra-operatively – Verbal communication should be maintained with the client and pulse, respiration and blood pressure to be checked every 15 minutes.
- Post-operatively – Pulse, respiration and blood pressure are to be monitored and recorded every 15 minutes for one hour following surgery, or longer if the patient is unstable or not awake.

**Surgical Technique**

**General requirements**

- The client’s bladder must be empty. If there is a doubt, the client must be asked to void urine immediately before the procedure, and catheterised if indicated.
- The operating surgeon should clearly identify each fallopian tube, following it right up to the fimbria. The site of occlusion of the fallopian tube must always be...
within 2-3 cm from the uterine cornu in the isthmal portion (this will improve the possibility of reversal, if required in the future). Care must be taken to avoid damage to the blood vessels, ovaries or surrounding tissues.

(iii) Excision of 1 cm of the tube should be done. Use of cautery and crushing of the tube should be avoided.

(iv) The skin incision is to be closed with absorbable or non-absorbable suture and a small dressing or bandage applied.

b) Minilaparatomy Requirements

(i) An interval many minilaparatomy procedure may benefit from the use of a uterine elevator to bring the fallopian tubes into the operative field.

(ii) The incision for minilaparatomy (interval, post-abortal or post-partum) may be transverse or longitudinal. Its length should not exceed 4 cm.

(iii) Pomeroy procedure should be followed for excision and ligation of tube using a square knot with 1 '0 chromic catgut.

c) Laparoscopy Requirements

(i) To avoid hypoventilation, the patient must not be placed in a Trendelenburg position in excess of 15 degrees.

(ii) A uterine elevator is to be used to visualise the fallopian tube.

(iii) Pneumoperitoneum must not exceed 20 ml of mercury or 1 litre of air or gas (preferably carbon dioxide). Slow insufflation and gradual desufflation should be done.

(iv) The skin incision should not exceed the diameter of the trocar.

(v) The trocar is to be angled towards the hollow of the sacrum. The operator must lift the anterior abdominal wall before introducing the trocar.

(vi) Tubal occlusion must always be done with good quality Falope rings (no cautery is to be used). The following precautions are to be followed in applying in Falope rings:

• Draw the tube slowly and smoothly into the sleeve of the laparoscope after proper identification (include only the
amount of tube necessary to provide adequate occlusion. Refer to para 2.2.7.a(ii) for appropriate site of occlusion).

- To prevent injury to the mesosalpinx/ tube, avoid pulling up or back on the scope or applicator.
- Do not apply the ring in cases of thick, oedematous or fixed tubes. In such cases, tubal occlusion can be done with laparotomy under GA.

(vii) After applying the second ring, the operator should systematically inspect the pelvis to verify that both tubes are occluded, there is no unusual bleeding and that there is no visceral injury.

(viii) The operator expels all the gas from the abdominal cavity slowly before removing the trocar.

2.2.8 Post-operative Care

a) The client is monitored as described in 2.2.6.c (iii)

b) The client may be discharged when the following conditions are met:

(i) After at least 4 hours of the procedure, when the vital signs are stable and the client is fully awake, can walk, drink and talk.

(ii) The client has been seen and evaluated by a doctor, Whenever necessary, the client should be kept overnight.

c) The client must be accompanied by some responsible adult while going home.

d) For clean surgery antibiotics are not necessary. However, analgesics, antibiotics and other medications can be provided/prescribed as required.

e) The client is to be provided with a discharge card, indicating date and type of surgery, method used, name of institution, date and place of follow-up. Both written and verbal post-operative instructions must be provided in the local language.

2.2.9 Post-operative Instruction

The following post-operative advise must be given to the client:

a) Return home and rest for the remainder of the day.

b) Resume only light work after 48 hours and gradually return to full activity by two weeks following surgery.
c) Use medication as instructed.
d) Resume a normal diet as soon as possible.
e) Keep the incision area clean and dry. Do not disturb or open the dressing.
f) Bathe after 24 hours following the surgery. When bathing keep the incision area dry. If the dressing becomes wet, it should be changed.
g) May have intercourse one week after the surgery or whenever she feels comfortable after interval sterilisation. Sterilisation procedures do not interfere with sexual pleasure, ability, or performance.
h) Report to the doctor or clinic if there is excessive pain, fainting, fever, bleeding or pus discharges from the incision.
i) Return to the clinic on the seventh post-operative day for removal of stitches and post-operative check-up.
j) Follow the instruction on where to go for routine and emergency follow-up.
k) Return to the clinic, if there is missed period/suspected pregnancy.
l) If there are any questions, contact the health personnel or doctor at any time.

2.3 Follow-up Procedures

a) All tubectomy clients should be followed-up by the Female Health Worker within 48 hours after surgery at their home.
b) First follow-up: This should be done 7 days after the surgery at the clinic for stitch-removal/ wound examination. Pelvic examination may be done if indicated.
c) Second follow-up: This is recommended after one month or after the client’s first menstrual period, whichever is earlier. If she has missed her period or if experiencing any menstrual abnormality, she must be examined to rule out pregnancy.
d) Emergency follow-up: To be done at any time after surgery.
e) Subsequent follow-up: If the client develops any complications or has queries.

2.4 Complications of Female Sterilisation and Management

2.4.1 Common Intra-operative Complications

a) Vaso-vagal attack - Make the OT table horizontal and administer atropine 0.6 mg IV and oxygen.
b) Respiratory depression or arrest – Keep the air way open; assist
breathing using manual resuscitation equipment with oxygen; assess the circulation by monitoring pulse, blood pressure and respiration; steroid and other supportive therapy to be given as indicated.

c) **Cardiac arrest** – On confirming cardiac arrest, give an immediate chest thump and begin external cardiac massage; assist breathing of the patient as described in (b) above; cannulate a vein and give appropriate resuscitative drugs; apply external counter-shock if an electrical defibrillator is available.

d) **Uterine perforation** – Due to introduction of uterine elevator from below. This needs to be repaired immediately if there is bleeding; otherwise, these patients need to have further hospital observation to ensure they are stable.

e) **Bleeding from the mesosalpinx** – Can be treated through the laparoscope with cautery or ring/clip application. Alternatively, the bleeding should be controlled immediately by laparotomy.

f) **Injury to Urinary Bladder** – Must be closed in two layers and put self-retaining catheter in the bladder for 7 days or as long as necessary.

g) **Injury to Intra-abdominal viscera** (i.e., small or large bowel) and blood vessels - Must be repaired immediately and maintained I-V line. If the operating surgeon is not confident of repairing, he/she must asked for health from a surgical colleague.

h) **Convulsions and toxic reactions to local anaesthesia** – Administer injection of diazepam 5-10 mg IV and oxygen inhalation. Administration of IV fluid is not generally required, but may be given if necessary. Surgery should be stopped immediately to allow the patient to recover. Further surgery should be performed at a centre with full range of services.

### 2.4.2 Immediate Post-Operative Complication

a) **Wound sepsis** - Small stitch abscess is to be treated with drainage and dressings. However, severe needs opening of the incision and drainage of the pus. Further treatment will be with dressing, antibiotics, and analgesics.

b) **Hematoma in the abdominal wall** - A small non-expanding non-infected hematoma will resolve with no therapy, while a large one, particularly if infected, may need drainage and treatment with antibiotics.

c) **Intestinal obstruction, paralytic ileus, and peritonitis** – The
client should be hospitalised if she is not already in hospital, keep the patient on nil orally, put nasogastric suction, IV fluids and give antibiotics and analgesics, as indicated.

d) **Tetanus**- A rare complication. If tetanus is detected, the patient must be transferred to a proper centre for treatment immediately.

### 2.4.3 Delayed Complications

- **Menstrual irregularities** (for example, menorrhagia, scanty period) sometimes occur but these are not complications of sterilisation. Reassurance and treatment according to the cause is required in most cases.

- **Chronic pelvic inflammatory disease**- It usually presents itself as pelvic pain and requires treatment with bed rest, antibiotics and analgesics.

- **Incisional hernia**- A rare complication that needs surgical repair.

- **Psychological problems** (for example, Depression)- Discussion of the problem, clarification of the role of sterilisation and answering questions are important.

- **Failure of the operation, leading to pregnancy**- This may be due to either technical deficiency in the surgical procedure or spontaneous recanalisation. The patient should be offered MTP or be medically supported throughout the pregnancy. She should be offered repeat surgery, as indicated. Ectopic pregnancy must be ruled out as tubectomy predisposes this condition.

All complications, major or minor, arising during surgery or post-surgery must be reported.

### 3 STANDARDS FOR MALE STERILISATION

The male sterilisation procedure, either by conventional or no-scalpel vasectomy, can be performed by a trained MBBS doctor. Prior to performing the sterilisation operation, a careful clinical assessment of the client must be done to ensure their fitness for the surgery. There are certain conditions that require caution, delay or referral to a specially equipped centre. There may be situations when it is better to counsel the client’s wife for tubectomy.

#### 3.1 Medical Contraindications

- **There are no absolute contraindications to male sterilisation**

- **The relative contraindication include the following:**
  - a) Psychological disorders
  - b) Physical illness
(i) Acute febrile illness  
(ii) Jaundice  
(iii) Severe anaemia  
(iv) Chronic systemic disease, bronchial asthma, blood dyscrasias, heart disease, uncontrolled diabetes, hypertension, and thyrotoxicosis.  
(v) Bleeding disorder and other blood dyscrasias  
(vi) Severe nutritional deficiency, (hypoproteinaemia and vitamin deficiency)  
(vii) Skin conditions involving the operative site, such as thickening, infection or oedema, make surgery difficult  
(viii) Local genital conditions, including large varicocele, hydrocoele, inguinal hernia, filariasis (elephantiasis) cryptorchidism, previous scrotal surgery, intra-scrotal.  

c) Allergy to local anaesthesia.  
d) Sexual impairment or sexual problems.  

3.2 Clinical and Technical Procedures  
Preparation for surgery includes per-operative assessment, per-operative instructions, a review of the surgical procedure and post-operative care. This is essential to assess the client’s physical fitness for surgery and also to ensure that the consent for surgery is voluntary and well-informed. Pre-operative assessment can also provide an opportunity for overall health screening and treatment of RTIs/STDs.  

3.2.1 Clinical Assessment and Screening of Clients  
a) Demographic information - The following information is required: age, marital status, occupation, religion, education, number of living children and age of youngest child.  
b) Medical history  
(i) History of illness to screen out disease mentioned under relative contraindications.  
(ii) Immunisation status of men for tetanus and of all children for tetanus, tuberculosis, diphtheria, pertussis, poliomyelitis.  
(iii) Addictions (to alcohol, smoking and drugs)  
(iv) Current medications, if any  
(v) The contraceptive used last by client or his wife.  
c) Physical examination - Pulse and blood pressure, temperature,
general condition and nutritional, as indicated by the client’s medical history.

d) Laboratory examinations- Urinalysis for sugar and any other laboratory examination, as indicate.

3.2.2 Final Medical Assessment
The operating surgeon must verify eligibility, informed consent and the confirm the physical fitness of the client for surgery before conducting the surgery.

3.2.3 Timing of the Surgical Procedure
Can be done at any convenient time on healthy clients with no contraindications.

3.2.4 Pre-operative Instructions
a) Sim’s and/ or Cusco’s speculum
a) The client must trim the public, scrotal and perineal hair.
b) The client must bathe and wear clean and loose clothes to the OT.
c) The client should have a light meal on the morning of the surgery.
d) Before entering the OT, he must empty his bladder.

3.2.5 Part Preparation
It is preferable to trim the hair before operation. The operation area should be cleaned with soap and water and painted with a non-alcoholic antiseptic solution.

3.2.6 Anaesthesia / Analgesia / Pre- medication
a) Pre-medication is optional, and is to be administered only in the case of an anxious client in order to allay anxiety and to relax the scrotum. The drug of choice is tablet Diazepam 5 to 10 mg. Which should be given 30 minutes before the surgery. Adequate time must be allowed for medication to be effective.
b) Local Anaesthesia is recommended for vasectomy procedures. Skin sensitivity to local anaesthesia agent ( lignocaine) is not necessary, as it has no established predictive value for anaphylactic reaction. Most of the reaction of local anesthesia are due to direct intra-vascular injection. The local anaesthetic to be used is 1% lignocaine without adrenaline. The maximum dosage is 200 mg or 20cc of 1% lignocaine or 10cc of 2% lignocaine (10ml solution of 2%, to be diluted with equal amount of distilled water).
c) Monitoring- Vasectomy involves a brief surgery only. Communication must be maintained with the client throughout the operation. Constant communication with the client will alert the
surgeon regarding any, adverse anaesthetic event. However, the staff must be ready to monitor pulse, respiration and blood pressure, and respond to an emergency. A full record of any adverse event must be kept.

### 3.2.7 Surgical Techniques: Conventional Vasectomy

a) **Incision** - The vasectomy operation is to be performed either with two incisions located just below the scrotum on either side, or with one incision on the midline. The length of each incision should not be more than 2cm. Smaller incisions will minimise chances of complication.

b) **Site of vasectomy** - Midscrotal part of vas should be removed. It must not be cut close to the epididymis, over the convoluted part of vas deference.

c) **Excision of vas** - The vas must be separated from tissue and excised in all cases. The portion excised should not be more than 1cm. in length. Removal of excess length of vas may make a recanalisation operation difficult, if it required in future.

d) **Tying of cut ends of vas** - The cut ends of the vas must be tied with non-absorbable suture material (preferably h 2’0’ silk), and the sheath of the vas may be interposed between the two cut ends.

e) **Skin wounds** - The skin wounds should be closed with non-absorbable sutures and covered with a piece of sterile gauze. Use of tincture benzoin causes excoriation of the scrotal skin and should therefore be avoided. Before closing the wound, all bleeding points must be tied so as to ensure complete hemostasis and to prevent bleeding haematoma formation.

f) **Scrotal support** - the patient should wear a suspensory bandage for one week, till stitches are removed.

### 3.2.8 Surgical technique: No scalpel vasectomy (NSV)

The basic difference in NSC procedure over the conventional technique is in the surgical approach to the vas, which through a small puncture in the scrotum rather than by a cut with a scalpel. Thereafter, the surgical procedure of vas ligation is the same as in the conventional method. The long-term clinical reports have shown that NSV is less invasive than the conventional technique, cause fewer complication & takes much less time.

a) **Pre-operative instruction** - Same as given in 3.2.4

b) **Part preparation** - Same as given in 3.2.5
c) **Anaesthesia** – NSV is performed using local anaesthesia. The preferred anaesthesia is 1% lignocaine without adrenaline. The administration of anaesthesia is done strictly perivasally and this responsible for the painlessness of the NSV procedure.

d) **Fixation. Puncture and delivery of vas** - The site of fixation and puncture of the vas will be the junction of the upper and middle third of the scrotum on the midline. The vas is fixed in the midline at the junction of its upper one-third and lower two third by a vas fixation forceps. This is done by the three- finger technique. The skin is then punctured with a vas dissection forceps, the vas is dissected out, the bare vas is delivered out of puncture hole, ligated and excised.

e) **Excision of vas** – About 1cm. length of the bare vas should be ligated and excised. The removal of excessive length of vas may make recanalisation operation difficult, if it is required by the client in future.

f) **Ligature of the vas**- The cut ends of the vas should be tied with non- absorbable suture material (2 ‘0 black silk) and the sheath of the vas should preferably be interposed between the two cut ends.

g) **Delivery of the opposite vas**- The opposite vas should be exactly in the same manner using three- fingers technique at the lower end of the previously made puncture hole. It should be punctured and delivered in the same way through the earlier hole without increasing its size.

h) **Skin wounds**- After excision and ligature of both the vasa, inspect the puncture site for any bleeding. If none, the puncture site is dressed with a small gauze piece. This should be retained for 48 hours, No stitch is applied since the puncture contracts and is nearly invisible after the removal of the instruments.

i) **Scrotal support**- The client should wear normal snugly fitting underwear, or use scrotal support with suspensory bandage.

### 3.2.9. Post-operative care

a) The client should be discharged when the following conditions are met:

(i) Thirty minutes have passed after the surgery.
(ii) The client is alert and ambulatory.
(iii) The client’s vital signs are stable and normal.
(iv) The client has been seen and evaluated by a doctor.
b) Analgesic and other medications if needed must be provided or prescribed prior to sending him home.

c) Following vasectomy, the client should wear tight underpants or a loincloth to keep the scrotum from moving and subsequent possibility of bleeding and haematoma formation.

d) The client is to be provided with a discharge, card, indicating date and type of surgery, name of institution and date and place of follow-up. Both verbal and written post-operative instructions should be given in the local language.

3.2.10. Post-operative instructions

The client should be told to do the following after discharge.

a) Sim’s and/ or Cusco’s speculum
b) Return home and take adequate rest.

c) Resume normal work after 48 hours and return to full activity, including cycling, by one week following the surgery.

d) Take analgesic (pain-killer) and other medicines as advised by the doctor.

e) Resume a normal diet as soon as possible.

f) May bathe after 24 hours with the operated part of the body protected, and in a normal manner 48 hours after the surgery. While bathing, he should keep the operated area dry. If the dressing becomes wet, it should be changed.

g) May have intercourse whenever it is comfortable after the surgery. Vasectomy does not interfere with sexual pleasure, ability, or performance.

h) The client must be told that he does not become sterile immediately after the operation and that he or his wife will have to use another method of contraception for at least 20 ejaculation or of three months (whichever is earlier) following vasectomy. The client must use condom, if his wife is not using contraception

i) The client should report to the doctor or a clinic if there is excessive pain, fainting, fever, bleeding, increase in scrotal size or pus discharge from the operated site.

j) Return to the clinic (in case of conventional vasectomy) for removal of stitches and post-operative check-up in seven days.

k) Report to the clinic for semen analysis after 3 days.
l) If there are any question, contact the health personnel or doctor at any time.

m) The client must be provide with instruction on where to go if complications (such as infections, swelling of the scrotum, fever, increase in pain, bleeding from the wound) arise.

3.3 Follow-up Procedure

a) All client who undergo vasectomy should be visited by a health worker within 48 hours. In NSV cases, the client should also be seen 48 hours after operation.

b) First follow-up: seven days after the surgery, the client should go for removal of stitches (in cases of conventional vasectomy), to have the wound examined and to have his questions answered.

c) Second follow-up: the client should undergo semen analysis after three months.

d) Emergency follow-up: this can be done at any time after the surgery.

e) Subsequent follow-up: Required in cases of any complication or questions.

3.4 Complications of Male Sterilisation and their Management

All complications, major or minor, arising during surgery and/or post-surgery must be reported.

3.4.1 Intra-operative Complications

Although the incidence is rare, the following may be encountered:

a) **Transient drop in blood pressure or dizziness due to vasovagal attack**: In such cases, the procedure should be delayed and the patient be allowed to rest. His face sold be wiped with cold water and his head lowered. An intra-venous injection of atropine(0.6mg0 may be of assistance in this situation.

b) **Convulsions and reaction to local anaesthesia**: In such cases, and injection of diazepam 5-10 mg IV and oxygen inhalation are required. Administration of IV fluids is generally not needed, but may be done depending on the case. In such an event, surgery should be stopped and the patient allowed to recover. Further surgery should be performed only at a centre with a full range of services.

c) **Injury to testicular artery**: this complication is very rare, but if it does occur, first pressure should be used to tamponade both ends of the vessel. Subsequently, both ends of the artery must be ligated.
3.4.2 Immediate Post-operative Complications

a) Swelling of the scrotal tissue, bruising and pain - These short-term minor complication often disappear without treatment within 24 to 48 hours. Ice packs, scrotal support and simple analgesics may provide relief.

b) Hematoma - If small, it can be treated by scrotal support, analgesics, and antibiotics. A large hematoma may, in addition, need evacuation, antibiotics and further treatment. If a hematoma is detected early, it is desirable to cut the stitches, remove the clots and look for the bleeding or oozing points, which should be tied. Referral should be considered.

c) Infection
   (i) Stitch abscess – to be treated with removal of stitch, drainage and dressings.
   (ii) Wound sepsis – In case of severe sepsis, the wound should be opened and pus drained. Further treatment should include application of dressing and administration of antibiotics and analgesics.
   (iii) Orchitis - Cases must be treated with antibiotics, analgesics, scrotal support and bed rest. Severe orchitis may need hospitalisation.
   (iv) Tetanus - A rare complication. If tetanus is detected, the patient must be transferred to a proper centre for treatment immediately.

3.4.3 Delayed Complication.

a) Sperm granuloma – Can occur either at the site of vas occlusion or over the epididymis. The majority of these are symptomless and respond to analgesics and anti-inflammatory drugs. Very occasionally a persistent and painful granuloma may necessitate surgical intervention.

b) Psychological problems – Uncommon, but discussion of the problem, clarification of the role of sterilisation and answering questions are important. Appropriate referral should be given to the patient.

c) Failure of vasectomy – Incidences of failure is quite low, but may occur because of technical deficiencies in the surgical procedure or spontaneous recanalisation. The client wife should be offered
MTP or be medically supported throughout pregnancy. The client should be offered a repeat surgery, as indicated.

There is no association or prostatic or testicular cancer, and cardiovascular disorder with vasectomy.

4 PHYSICAL REQUIREMENTS
This section gives the standards for institution setup required for sterilisation procedures.

4.1 Facilities

4.1.1 The clinic / facility shall be ventilated and fly-proof, with a concrete or tile floor that can be cleaned thoroughly.

4.1.2 Running water must be available in the premises.

4.1.3 Electricity supply with a standby generator and other light source must be available.

4.1.4 Adequate space must be provided for the various programme activities separate areas should be earmarked for the following:

a) Reception area for clients

b) Waiting room for clients and accompanying person.

c) Counseling room offering privacy and facility for uninterrupted discussion.

d) Laboratory with facilities for blood and urine examinations

e) Clinical examination room which assures privacy during medical examination. This room will be used for initial assessment and follow-up

f) Pre-operative preparation room for trimming of hair, washing, changing of clothes and pre-medication.

g) Hand-washing area (an ante-room near the OT for scrubbing) equipped with wash basin having elbow-operated taps.

h) Sterilisation room for autoclaving, washing, and cleaning equipment, and preparation of sterile packs. This should ideally be near the OT.

i) Operation theatre should be isolated and removed from the general thoroughfare of the clinic. Refer section 5.3 for details and maintenance and cleaning of OT.

j) Recovery room or ward must be spacious, well-ventilated
and should be situated adjacent to the OT.

k) **Toilets** - A sufficient number of sanitary-type toilets with running water must be available to client and staff.

l) **Storage area** – There should be a room outside the OT for storage of essential items.

m) **Office room** : It should also be used for keeping client records.

## 4.2 Equipment and Supplies

The section below gives the list of equipment and supplies at the different functional areas essentials for conducting quality sterilisation operation.

a) **Examination room requirements**

(i) Examination table
(ii) Foot stool
(iii) Blood pressure apparatus
(iv) Thermometer
(v) Stethoscope
(vi) Examination Light
(vii) Weighting Scale
(viii) Instrument for pelvic examination

b) **Laboratory**

(i) Hemoglobinometer and accessories
(ii) Microscope
(iii) Red blood cell and white blood cell pipettes
(iv) Neuber counting chamber
(v) Apparatus to estimate albumin and sugar in urine

c) **Sterilisation Room**

(i) Autoclave
(ii) Boiler
(iii) Autoclave drums (bins)

d) **Cleaning room**

(i) Hand brushes
(ii) Heavy- duty gloves
(iii) Basins
(iv) Detergent
(v) Chlorine solution

e) Operating theatre

(i) Operating table capable of Trendelenburg’s position
(ii) Step-up stool
(iii) Spot light in OT
(iv) Instrument trolley
(v) Minilaparatomy kit (see annexure II)
(vi) Laparascopy Kit (see annexure III)
(vii) Conventional vasectomy kit (see annexure IV)
(viii) NO-Scalpel vasectomy kit (see annexure V)
(ix) Blood pressure instrument
(x) Stethoscope
(xi) Extra syringe with needles (22-G, 1 ½ in. long.)
(xii) Emergency equipments and drugs
(xiii) Room heater
(xiv) IV stand
(xv) Waste basket
(xvi) Storage cabinet
(xvii) Buckets, basins for decontamination

f) Recovery room

(i) Patient cot with mattress, pillow, linen and blankets
(ii) B.P. Instrument
(iii) Stethoscope

4.3 Emergency Preparedness

a) Staff Preparation for Emergencies – All staff must be trained to effectively manage emergencies. Staff must be skilled in administration of intravenous fluids and drugs. They must understand which drugs may be used, how to administer them and their expected actions. They must by familiar with the use of all emergency equipment and must check all such equipment before each operating session. The person monitoring the client in the operating room and recovery room must be capable of detecting early signs of complications and be able to take initial emergency action. At least one member of surgical team must know how to administer cardiopulmonary resuscitation. The emergency care
supplies and drugs must be kept in an accessible place known to the staff members.

b) **Emergency equipment** - The equipment listed below must be available for emergency use in the operating room and recovery area. All emergency equipment must be immediately available, ready for use and in good condition. A battery-operated light source should be available for back-up or focused illumination of the operating site.

(i) Stethoscope
(ii) B.P. instrument
(iii) Oral airways (two sizes)
(iv) Nasal airways (two sizes)
(v) Suction machine with tubing and two traps.
(vi) Ambu bag
(vii) Face mask and tubing and oxygen nipple
(viii) Oxygen cylinder with reducing valve and flow meter.
(ix) Blanket
(x) Gauze pieces
(xi) Kidney tray
(xii) Torch (flash light)
(xiii) Syringes and needles, including butterfly sets, IV cannula
(xiv) Intravenous infusion sets and fluids
(xv) Adhesive strapping
(xvi) Sterile laparotomy instruments

c) **Emergency drugs** - The drugs listed below must be available in the operating room and recovery area. The staff should be well informed about the drugs, their use, dose, strength and route of administration, signs of toxicity and treatment of overdose. The following emergency drugs are recommended.

(i) Adrenaline
(ii) Atropine sulphate
(iii) Corticosteroids (Dexamethasone or hydrocortisone)
(iv) Physostigmine
(v) Aminophylline
(vi) Diazepam
(vii) Pentazocine
(viii) Sodium Bicarbonate (7.5%)
(ix) Calcium chloride
(x) Frusemide
(xi) Dopamine
(xii) Dextrose 5% in water
(xiii) Dextrose 5% in normal saline
(xiv) Glucose 25%
(xv) Ringer lactate solution

d) Hospital Back-up - For clinics providing sterilisation operation with limited capability for handling emergencies and other complications, it is important to establish a working relationship with nearby back-up medical facilities in the area. This will help clients receive reliable care. The local back-up facilities must include the supplies, equipment and trained staff required to handle complications.

5 PREVENTION OF INFECTION

5.1 Guiding Principles

It is mandatory to pay meticulous attention to aseptic and antiseptic techniques in all male and female voluntary sterilisation programs. The incidence of incurable blood-borne viruses such as the human immunodeficiency virus (HIV) and hepatitis B virus (HBV) continues to rise. These viruses can spread unknowingly (symptoms may take years to appear), and it may not be possible to distinguish infected individuals from uninfected ones. Therefore, appropriate infection prevention procedures must be practised at all times, with all clients to decrease the risk of transmission. It is important to realise that not only are the clients at the risk of getting infected, but also the staff because of exposure to potentially contaminated blood and other body fluids. The staff includes every one, from the doctor to cleaner. Therefore, proper infection prevention practices, as described below, will decrease the likelihood of infections.

5.2 Hand Washing

Hand washing is vital preventing infections from spreading. Routine hand washing is important before and after examining or having any
direct contact with a client. Hands should also be washed after removing the gloves as the gloves may have holes or may be torn. Plain antiseptic used for routine hand washing and hand should rinsed in a steam of running water, dried with a clean towel and air dried, towels should not be shared, as they get easily contaminated. Micro-organisms can multiply in standing water even when an antiseptic is added. Therefore, practices such as having a common basin where a number of people wash their hand should be avoided.

5.3 Facilities (Operation Theatre and Post-operative ward)

5.3.1 Location and Structure

a) OT should be isolated from the part of clinic that is open to public.

b) It should be enclosed, free of dust and fly-proof.

c) The inside of OT should have tiled walls or concrete floor that can be easily and thoroughly cleaned.

d) It should have adequate lighting.

e) The windows in the OT should be 1.8 m. (6 ft.) above the floor or high enough to prevent cross-ventilation in the operative field.

f) The OT should preferably be air-conditioned. When air-conditioning is not possible, pedestal fans may be used.

g) The recovery room and post-operative ward should be located adjacent to the OT. The area should be spacious and well ventilated. The number of beds will depend on the available space inside.

5.3.2 Maintenance

a) The OT should be locked when not in use, and it should not be used for any other purpose, especially storage of articles.

b) The OT should be thoroughly scrubbed and disinfected at least once a week on non-working day.

c) Ideally, operations on infected cases should not be performed in the same OT where sterilisation operation is performed, as the latter are classified as a “clean” surgical procedure. If the same OT has to be used, it should be thoroughly cleaned and disinfected preferably after the surgery.

5.3.3 Movement in and around OT

a) The entry of people and their movement inside the OT should be minimised, as the number of micro-organisms are directly related
to the number of people and their movement.

b) During surgery, keep the door of the OT closed.

c) Only the personnel performing / assisting should enter the OT.

d) The OT should never be used as a trough – fare.

e) The arrangement within the OT should permit smooth movement of the staff.

5.3.4 Cleaning of the OT

a) Before surgery

(i) Clean the floor with a mop soaked in 0.5% chlorine solution.

(ii) Clean the table / counter top with a cloth soaked in 0.5% chlorine solution.

b) After surgery

(i) Remove the used drape from the operating table and decontaminate it by soaking for 10 minutes in 0.5% chlorine solution.

(ii) Decontaminate all operating room surfaces that come into contact with the patient (such as the table) between procedures by wiping them with 0.5% chlorine solution followed by rinsing with water.

(iii) The operating table, counter / table tops, light handles should be wiped with a detergent and 0.5% chlorine solution.

d) Weekly cleaning - Scrub the room with a recommended disinfection. Washing should be performed from top to bottom.

5.4 Processing of equipment, instrument and reusable items

Decontamination and cleaning of equipment, instrument and other items, followed by sterilisation or high-level disinfection can minimise the risk of transmitting infection to both the client of the health service providers. Since disinfection does not reliably destroy all bacterial endospores, instrument and other items used during surgery should be sterilised. When that is not possible, high level disinfection is the only acceptable alternative for processing instruments and other items for use.

5.4.1 Decontamination

Surgical instrument, reusable, gloves and decontaminated prior to cleaning. Immediately after use, these items should be placed in a plastic bucket containing a solution of 0.5% chlorine for 10 minutes. Chlorine rapidly inactivates both HIV and HBV, making the instruments safer for use.
staff to handle during cleaning. After 10 minutes, the items should be removed from the chlorine solution and rinsed with water or cleaned immediately. Soaking instruments for excessive period of time in chlorine solution may damage them. It is strongly advice that utility gloves are worn during this and subsequent steps. A new chlorine solution should be prepared at the beginning of each day. The advantage of chlorine is that is inexpensive, is very effective as it quickly inactivates HIV and HBV, and is also very useful for decontamination of large surface areas (takes as little as 6 seconds).

**Preparation of 0.5 percent Chlorine solution**

Mix 15 gram of commercially available bleaching powder (about one tablespoon full / three teaspoon full) in one litre of tap water.

### 5.4.2 Cleaning

- Cleaning is crucial step in instrument processing and it greatly reduces the number of micro-organism and endospores on instruments and equipment. Before the equipment is disinfected or sterilised, a thorough mechanical cleaning is necessary to remove blood and organic materials.
- After decontamination, the instruments and other items should be scrubbed vigorously with a brush in lukewarm water with detergent to remove all blood, tissue and other residue. Detergent should be used as water alone will not remove proteins or oils.
- Hot water should not be used because it can coagulate protein such as blood, making is hard to remove.
- Soap is not recommended as it can leave a residue.
- The items should then be rinsed thoroughly with water and allowed to air-dry. Items to be high-level disinfected by boiling can be directly placed in a pot of water after cleaning.

### 5.4.3 High level disinfection (HLD)

High–level disinfection is effective in eliminating all micro-organisms (viruses, bacteria, protozoas and fungi) except some bacterial endospores. It is most appropriate for instruments that come in contact with unbroken skin or mucous membranes such as uterine elevators, specula and gloves for pelvic examination. In addition, HLD is the only acceptable alternative for processing instruments and other items for reuse if sterilisation is not possible. HLD can be achieved either by boiling or by soaking in a chemical depending on the heat- resistant properties of the object that are to be disinfected.
5.4.4 Sterilisations

Sterilisation eliminates all micro-organisms (bacteria, viruses, fungi and parasites) including bacterial endospores from instruments and other items. Sterilisation is recommended for items that come in contact with the blood stream or tissues beneath the skin. Some of these are reusable needles, syringes and surgical instruments. To be effective, sterilisation must be preceded by decontamination, careful cleaning and thorough rinsing. Sterilisation can be done by using steam (autoclave) or soaking in a chemical solution.

a) **Steam sterilisation (autoclave)**

- Always consult specific operating instruction supplied by the manufactured.
- Decontaminate, clean and dry all instruments that are to be autoclaved.
- Wrap cleaned instruments in cloth or newspaper or place unwrapped instruments in a metal container.
- Arrange wrapped packs in the chamber or drum to allow free circulation of heat or steam to all surface.
- Items such as scissors and forceps should be sterilised in

b) **HLD by boiling**

- Instruments for HLD must be decontaminated, cleaned with detergent and water prior to boiling.
- Once the water starts boiling, boil for 20 minutes in a pot with a lid.
- Articles must be completely immersed in water.
- Do not add anything to the pot after boiling begins.
- After boiling remove objects with sterile or previously disinfected forceps.
- Use object immediately or store them in a covered, dry disinfected container for up to 7 days.

b) **HLD by chemical Method**

- after decontaminating cleaning and drying used objects, soak for 20 minutes in a solution containing 2% glutaraldehyde (for example, cidex).
- Thoroughly rinse the object with boiled water before use
- Use objects immediately or place them in a covered, dry, disinfected container.

Items should never be kept soaking in water or solution such as Savlon, Spirit, Carbolic acid, Cidex etc. Always store HLD items dry.
Standards for Female and Male Sterilisation, February 2003

• Sterilise instruments for the recommended time as shown in box below:

Steam sterilisation standards

<table>
<thead>
<tr>
<th>Time</th>
<th>20 minutes for unwrapped and 30 minutes if wrapped instruments and lines and 10 minutes for gloves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>121* c</td>
</tr>
<tr>
<td>Pressure</td>
<td>15 lb /sq inch</td>
</tr>
</tbody>
</table>

b) Sterilisation by chemical method

• Decontaminated, cleaned and dried items are put in 2% glutaraldehyde solution (Cidex) for at least 8 to 10 hours.
• Item such as scissors and forceps should be put into the solution in an open position.
• Do not add or remove any items once timing starts.
• Items should be rinsed well with sterile water (not boiled water), air dried and stored in a covered sterile container for up to seven days.
• This method is most suitable for endoscopes and plastic cannulas.

Sterilised packs are good for one week if kept dry and intact.

5.4.5. Processing Laparoscopes

Surgical laparoscopes are delicate instruments and must be handled with great care. Laparoscopes and accessories should be sterilised or high-level disinfected using the chemical method by soaking in 2% Glutaraldehyde solution as it does not damage rubber, plastics or lens cements. However, all the steps of decontamination and cleaning must be followed before putting the laparoscopes in chemical solution.

a) Decontamination: Immediately after use, gently wipe the laparoscope, fibreoptic light source and cable plastic tubing using a cloth soaked in 60-90% ethyl or isopropyl alcohol to remove all blood and organic material. As alcohol rapidly kills HBV and HIV, this step protect handlers against possible hepatitis B and AIDS infections.

b) Cleaning: Place the dissembled parts of laparoscope in a basin of clean water. Wash all outer surfaces using a soft cotton cloth. Clean inner channels with a clean brush supplied with laparoscopic kit.
c) **High-level disinfection** - Put a clean and dried, dissembled equipment in a basin of 2% glutaraldehyde (e.g Cidex) for 20 minutes. The disinfectant must touch all the surface of the laparoscope to be effective. Rinse twice with HLD water (water boiled for 20 minutes and cooled) to remove all traces of the disinfectant.

d) **Sterilisation** - To sterilise, soak the clean and dried, dissembled laparoscope in 2% glutaraldehyde for 8-10 hours. Rinse twice with sterile water to completely remove all traces of the disinfectant and store in a sterile, covered container.

<table>
<thead>
<tr>
<th>Summary of materials</th>
<th>Methods of sterilisation and high-level disinfection</th>
<th>Duration of Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linens (drapes, sponges, scrub suits, operating packs, etc)</td>
<td>Autoclave</td>
<td>121°C at 15 lbs/sq. inch pressure for 30 minutes. Should be used within one week.</td>
</tr>
<tr>
<td>Rubber goods (gloves, Catheters, and rubber Tubing)</td>
<td>Autoclave</td>
<td>121°C at 15 lbs/sq. inch pressure for 10 to 15 minutes.</td>
</tr>
<tr>
<td></td>
<td>HLD Boiling</td>
<td>20 minutes</td>
</tr>
<tr>
<td></td>
<td>Immersing in chemical Solution: Sporicidin** Cidex</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sterilisation Time</td>
<td>6 ¾ Hours 10 Hours</td>
</tr>
<tr>
<td>Surgical Instruments*</td>
<td>Dilution Disinfection (HLD) – Time Dilution</td>
<td>1 in 5 None 10 minutes 20 minutes 1 in 16 None</td>
</tr>
<tr>
<td></td>
<td>Autoclave</td>
<td>121°C at 15 lbs. Inch pressure for 30 mts. For wrapped &amp; 20 mts. For unwrapped items.</td>
</tr>
<tr>
<td></td>
<td>HLD Boiling</td>
<td>20 minutes</td>
</tr>
<tr>
<td></td>
<td>Immersing in chemical Solution: Sporicidin** Cidex</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sterilisation Time</td>
<td>6 ¾ Hours 10 Hours</td>
</tr>
<tr>
<td></td>
<td>Dilution Disinfection (HLD)-Time Dilution</td>
<td>1 in 5 None 10 minutes 20 minutes 1 in 6 None</td>
</tr>
</tbody>
</table>
• Unwrapped surgical instruments are for immediate use. If wrapped instruments can be used for up to one week.
• If cidex is not available, Sporicidin can be used.

5.5 Procedures for pre-operative preparation of clients

Proper pre-operative preparation of the client is extremely important in sterilisation operations as it helps prevent infection. The following are the procedure that should be followed.

a) The client should bathe before surgery, preferably before coming to the clinic or in the clinic. In all the cases, the site of operation should be carefully and thoroughly cleaned with soap and water.

b) The client’s history of cuts and wounds for the month preceding surgery should be evaluated and he/she should be examined for any infected foci.

c) If the client has a local infection, the operation should be postponed and temporary contraception provided.

d) Shaving of hair at the operative site should not be done before surgery as bacteria may enter through cuts and nicks, leading to increased potential for post-operative infection. However, if the hair obstruct the operating area, it should be trimmed with scissors just before surgery.

e) The client should preferably change from their street clothes into theatre clothes before entering the OT. If not feasible, they should at least wear clean clothes.

5.6 Procedure of administering proper injection

Proper administration of parenteral injections to the clients can prevent many cases of injection abscess and transmission of infections such as HIV and HBV. The following guiding principle should be followed:

a) Skin area over the injection site should be cleaned and disinfected with povidine (Betadine), savlon, spirit etc.

b) Aspirate before injection and ensure that the needle is not touched with spirit cotton, swab or any other material.

c) After use immediately decontaminate reusable syringe and needles by flushing with 0.5% chlorine solution three times or throw away disposable needles as described in Section 5.12.2.

d) Use of multi dose vials of injection:
   (i) A needle must never be used to draw up a solution from the multi dose vial, once it has been used for a client’s injection.
(ii) After a syringe is used for an injection. It must not be used again to withdraw more solution from the vial, even if the needle is changed.

(iii) Never leave the needle in the vial between uses, as it may lead to contamination of the contents in the vial.

(iv) Use a fresh, clean, autoclaved or boiled needle and syringe for withdraw the content from the vial every time.

5.7 Surgical personnel

5.7.1 Guiding Principles

a) All the personnel working in the OT must change their shoes before entering.

b) For female sterilisations. The personnel must change into theatre clothes (i.e. gowns, caps masks). For vasectomy procedures medical personnel must at least wear caps, masks and surgical gloves.

c) Personnel who have any infection should not enter the OT at all.

d) The surgical mask should cover the bridge of the nose at all times.

e) Movement of the personnel into and out of the OT should be as minimal as possible.

f) Personnel in the OT should wear short-sleeved shirt, have short and clean fingernails and remove all jewellery.

5.7.2 Surgical Scrub

a) The surgeon and his/her assistant must scrub both their hands and forearms up to above the elbow thoroughly with soap and water or antiseptic agents (as listed in Annexure VI).

b) To scrub, the hands should be held above the level of elbows, thoroughly washed up to the elbows with water and antiseptic solution. Clean under fingernails with a small stick or brush. Then beginning at the finger tips and using a circular motion, the hand and then arm up to the elbow should be vigorously washed. The procedure should be repeated for the other hand. While holding the hands above the elbows, the hands and fore arms should be rinsed, finger strips first. The entire procedure should be repeated several times so that the scrub lasts for 3 to 5 minutes. The hands and forearms should be dried with a sterile towel.

c) When plain soap is used, it is best to rinse hands with alcohol or rub 3 to 5 ml, of an alcohol glycerin mixture (2 ml. Glycerin in 100 ml alcohol) on the hands until dry. A small stick or a brush
should be used for cleaning fingernails and soft brush or cloth used on all surfaces of the hands and forearms.

d) Ideally, the surgeon and his/her assistant should scrub thoroughly between each procedure. In high volume settings, this may not be feasible because the skin cannot tolerate the irritation caused by frequent scrubbing. In such setting, the surgical staff should do a three-minute scrub or alcoholic glycerin rub (as in 5.7.2.C) every hour or after every five cases (whichever comes first) to prevent recolonisation of the skin by micro-organisms.

e) Gloves must be changed in between every case. In case these are torn, a surgical scrub should be done.

f) In case the staff leave the OT for any other reason, they should scrub before putting on gloves.

5.8 Skin preparation and surgical draping

a) The operative site should be prepared immediately pre-operatively with an antiseptic solution, such as an iodophor (Betadine), 60 to 70% solution of ethyl alcohol or chlorhexidine gluconate (Savlon).

b) Alcohol preparation should not be applied to the sensitive genitalia. Iodophor and chlorhexidine are safe for use on mucous membranes and can be used to clean the vagina and cervix.

c) Iodophors require 1 to 2 minutes to work because there must be time for the release of free iodine which inactivates the micro-organisms.

d) Antiseptic solutions should be liberally applied at least two times on and around the operative site, which should be thoroughly cleaned by gentle scrubbing.

e) The antiseptic solution should be applied in a circular motion, beginning at the site of incision and working out for several inches.

f) The excess antiseptic solution should not be permitted to drip and gather beneath the client’s body as this may cause irritation.

g) After preparing the operative site, the area should be covered with a sterile drape.

5.9 Surgical technique

Good surgical technique that minimises tissues trauma and ensure adequate haemostasis will reduce the occurrence of infection. In vasectomy haemostasis is critical to help prevent development of scrotal haematomas and the accompanying risk of infection.
5.10 Post-operative care

a) After the operative procedure, an ordinary sterile should be applied on the surgical wound.

b) The operated site should be kept clean and dry.

c) Routine use of prophylactic antibiotics is not necessary.

d) The client can take bath usually 24 hours after the surgery, keeping the operation site dry.

e) Every client should receive clear, simple instructions for post-operative care, written as well as oral, and in their own language. All clients undergoing vasectomy or tubectomy should be instructed on how to take care of their wound and dressing, what side-effects to expect. When to resume normal activities and what to do and where to go in case of complication.

5.11 Self-protection of health care providers

Health care providers and other and clinical staff (cleaners, laundry & waste disposal staff) run the risk of getting infected with HIV, HBV or other infections, while performing various procedures such as surgical operation, injection, wound dressing, deliveries etc. or coming in contact with contaminated materials during cleaning or waste disposal. HIV and HBV viruses are contained in the biological fluids coming into contact with broken skin or mucous membrane of a healthy person. All clients should be seen as potential sources of infections. Since often it is not possible to tell who is infected. Therefore, precaution should be applied to all in the following manners.

a) Health care providers should protect themselves by using fluid-resistant gowns and gloves during all procedure involving contact with biological fluids. Protective glasses should be worn in situations where there is a possibility of conjunctival contact.

b) Frequent hand-washing with soap after examination of each client or after touching instruments and other materials is a very important precaution. It should be followed by all clinical staff at all time.

c) All used instruments and other objects (e.g. needle, syringe, gloves etc.) should be decontaminated immediately after use by immersing them for 10 minutes in 0.5% chlorine solution before further handling.

d) All reusable instruments and materials should be adequately cleaned and properly sterilized or subjected to high-level disinfection.

e) Contaminated surfaces like examination couches, operating tables, walls, floors etc. should be wiped with 0.5% chlorine solution after every procedure.
Cleaners and other staff working in laundries should wear protective heavy-duty gloves and gum boots while cleaning and handling soiled materials and linens.

5.12 Disposal of wastes, needles and other materials

5.12.1 Waste disposal: Contaminated wastes are a potential source of infection for staff as well as the local community. Therefore, the wastes should be disposed of properly.

a) The staff should wear utility gloves when handling and transporting wastes and wash the gloves as well as their hands when finished.

b) Wastes should be preferably be burnt. Burning kills microorganisms and hence the waste method for disposal contaminated wastes. The burning should preferably be done in an incinerator or a steel drum as opposed to open burning.

c) If burning is not possible, wastes should be put in a pit and buried, but never be thrown outside or left in open pits.

d) Wastes to be picked up by the municipality should be contained in closed dumpsters prior to removal.

e) Solid wastes, including dressing and other items contaminated with blood and organic materials, should be disposed of in leak-proof, washable containers conveniently located in the O.T. / procedure rooms.

f) Wastes Liquid should be poured down in a utility drain into a toilet or latrine with a flush, otherwise buried. Avoid splashing when disposing of liquid wastes.

5.12.2 Disposal of sharp: Accidental needle stick injuries are mostly self-inflicted and occur either during removal of the needle from the syringe or during cap replacement.

a) For disposable syringes, used needles should not be bent, broken, recapped or removed from the syringe before disposal.

b) Immediately after use, the sharp objects (hypodermic needles, scalpel blades, suture needles) should be disposed of in a puncture-resistant container with a lid made of either metal or heavy, rigid, plastic or cardboard.

c) The container with sharp object or needles should be tightly capped,
plugged or taped-closed when it is three-quarters full.

d) The containers with needles and sharp object should be disposed of by burning/burying on site.

**Summary of waste Disposal and Decontamination**

**Step I**
While still wearing gloves dispose of contaminated waste items (gauzge, cotton etc.) by placing these I a leak-proof container (e.g. plastic bag). Put sharp object into one plastic bucket containing 0.5% chlorine solution and other metal instruments into a second plastic bucket.

**Step II**
Make sure all object are completely immersed. Soak for 10 minutes in plastic bucket containing 0.5% chlorine solution.

**Step III**
Remove the used sheet from the operating table and decontaminate if by soaking for 10 minutes in 0.5% chlorine solution.

**Step IV**
Decontaminate all operating room surface that come into contact with the patient (such as the table) between procedures by wiping them with 0.5% chlorine solution followed by rinsing with water.

**Step V**
Before removing gloves, immerse hands completely in a bucket containing 0.5% chlorine solution to clean bloodstain. Remove gloves carefully by turning them inside-out and discard disposable gloves in a waste container, or place reusable gloves in 0.5% chlorine solution and soak for 10 minutes.

6. **STANDARDS FOR MOBILE SERVICES**

This section gives the standards for mobile sterilisation services. Every attempt should be made to ensure that mobile services are par with those available at the static centres. The following are the important areas where standards should be maintained in the mobile sterilisation services.

6.1 **Facility requirements**

6.1.1 Mobile sterilisation services should be offered in an institution (PHC or CHC) where either an OT facility or a clean, separate room is available for conducting operating work. Under no circumstance should mobile sterilisation
services be conducted in a school building or panchayat bhavan or any other such building.

6.1.2 The facility should be well-ventilated and clean.

6.1.3 Running water must be available.

6.1.4 Electricity supply with a stand by generator and light source must be available.

6.1.5 Adequate space must be provided for
   a) Reception and registration
   b) Waiting area for persons accompanying the clients.
   c) Counseling room
   d) Pre-operative room, to be used for part preparation, changing of client’s street cloths into clean OT clothes, conducting minor laboratory tests (Hb percent and urine examination)
   e) Pre-operative waiting area for clients
   f) Ante-room to OT, that should be used for hand-washing, scrubbing, instrument-washing and processing (HLD/sterilisation).
   g) Operation theater – This should be isolated and fitted with fly-proof netting. The OT should be large enough to allow the operating staff to move freely, and to accommodate all the necessary equipment. Lighting should be adequate and the room should be easy to enter and leave in case of an emergency. The room should be cleaned and washed thoroughly a day before sterilisation operation takes place and kept locked when not in use.
   h) Post-operative recovery room - It must be spacious and well-ventilated. The number of beds will be determined by the available space. The room should be clean, and be situated adjacent to/near the OT.

6.2 Staffing and responsibilities

6.2.1 The mobile team should have- surgeon (1), OT nurse (1), OT assistant (1). The local service site should provide- medical officer (1), nurse /ANM (1), OT attendant (1), staff for registration of clients (1) and staff maintaining proper client record (1).

6.2.2 Co-ordination with and utilisation of staff the area is desirable for appropriate IEC activities, monitoring and smooth running of the mobile services.

6.2.3 Primary responsibility for organising mobile sterilisation services will be with the staff of the block PHC/CHC.
6.2.4 Surgery will be done by the operating team coming from static sterilisation centre either from the district or the state. The surgical team must be experienced, well-trained in the procedure and fully equipped with staff and required material.

6.2.5 The mobile operating team will have the responsibility for final selection of appropriate client, including speculum and vaginal examination (in case of female sterilisation), verification of informed consent, assurance of quality of care, including cleanliness and infection prevention, surgery and post-operative recovery.

6.2.6 No clinical training shall be conducted in mobile sterilisation programme. In exceptional situations, training can be permitted in mobile services, for example, when a new technique needs to be introduced, (such as NSV). In this situation, the complete responsibility would lie with the clinical trainer.

6.3 Timing and number of cases

6.3.1 Mobile sterilisation services should preferably be conducted between 11 a.m. and 3 p.m. so that the team can have at least three to four hours of operating time. This will also ensure sufficient time for post-operative observation as well as allow the team and clients to reach their destination by the end of the day.

6.3.2 During mobile sterilisation services, the optimum number of cases to be operated per day by one mobile surgical team is twenty.

6.4 Instruments/equipment

For vasectomy and NSV, five sets of instruments, and for minilaparotomy and laparoscopic operations, at least two sets of instruments/equipment should be carried by the mobile team. Annexures II-IV give the list of equipment in each set.

6.5 Emergency preparedness

6.5.1 Staff preparation

All staff of the mobile team and operating centre must be skilled in administration of intravenous fluids and drugs, external cardiac massage and other resuscitative measures. They must be familiar with the use of ambu bag. They must know which drugs are to be used, how to administer them and their expected action.

6.5.2 Emergency Equipment and supplies

The equipment listed below must be available for emergency use in the operating room and recovery area. All emergency equipment must be immediately available and in good functioning condition.
(i) Stethoscope
(ii) B.P. instruments
(iii) Oral airways (two sizes)
(iv) Nasal airways (two sizes)
(v) Suction machine with tubing and two traps
(vi) Ambu bag
(vii) Face mask and tubing and oxygen nipple
(viii) Oxygen cylinder with reducing valve and flow meter
(ix) Blanket
(x) Gauze pieces
(xi) Kidney tray
(xii) Torch (flash light)
(xiii) Syringe and needles, I.V cannula including butterfly sets
(xiv) Intra venous infusion sets and fluids
(xv) Adhasive strapping
(xvi) Sterile laparotomy instruments

6.5.3 Emergency Drugs

The drugs listed below must be available in the operating room and recovery area. The staff need to be well-informed about their availability, use, does, strength and route of administration as well as signs of toxicity and treatment for overdose. The following injectable preparations of the emergency drugs should be available.

(i) Adrenaline
(ii) Atropine Sulphate
(iii) Corticosteroids (Dexamethasone or Hydrocortisone)
(iv) Physostigmine
(v) Aminophylline
(vi) Antihistamine (phenargan, Avil)
(vii) Diazepam
(viii) Pentazocine
(ix) Sodium Bicarbonate(7.5%)
(x) Calcium Gluconate (10%)
(xi) Frusemide
(xii) Dopamine
(xiii) Dextrose 5% in water
(xiv) Dextrose 5% in normal saline
(xv) Glucose 25%
(xvi) Ringer lactate solution

6.5.4 Back-up Referral Facility
A higher centre/district hospital facility must be identified and transport available transfer clients to the referral centres in case of any complications which can not be managed during mobile sterilisation service.

6.6 Counseling/ Informed Consent/ Eligibility Criteria
The standards for counseling established in Section I must be adhered to for mobile services also. Counseling is the responsibility of the ANM/ nurse/ doctor of the centre organising the service. This can be done prior to or during the day of the sterilisation procedure. The final assessment of the clients in terms of their eligibility and regarding an informed choice and decision for sterilisation is the responsibility of the operating team staff.

6.7 Clinical Assessment
Pre-operative assessment of the patient’s medical status is extremely important to ensure that high-risk clients are not operated on in mobile/ camp settings. Preliminary assessment and selection of client will be responsibility of the medical officer of the centre where services are being offered. Final selection of client including vaginal examination (in case of female sterilisation) will be done by the operating doctor of the mobile team.

6.8 Asepsis standards in mobile sterilisation services
All steps of infection preparation, as mention in an earlier chapter (Chapter 5) should be observed. Salient features are given below:
6.8.1 The client must change into clean clothing prior to surgery.
6.8.2 The OT staff and the operating team must change into clean OT attire.
6.8.3 standard OT gowns, masks, caps, and gloves must be used. A different set of gloves should be used for each case.
6.8.4 All OT staff must wash their hands before and after the procedure and after handling instruments/equipment.
6.8.5 The operating doctor and assistant must go in for proper surgical
scrubbing before the procedure, and after 5 cases or one hour, whichever is earlier, provided they do not touch anything in between the cases.

6.8.6 Sterilised or HLD equipment / instruments / Lines must be used for each client during the sterilisation

6.8.7 All used instruments and gloves must be decontaminated in 0.5% chlorine solution (freshly prepared with water and bleaching powder before starting the sterilisation procedure)

6.8.8 All instruments/ equipment must be cleaned, followed by HLD/ sterilisation, prior to reuse in another client.

6.8.9 Skin preparation and surgical draping.
   a) The operative site should be prepared immediately pre-operatively with an antiseptic solution. The preferred one is povidone iodine (betadine) if it is not available, chlorhexidine gluconate (Savlon) and 60 to 70% solution of ethyl alcohol can be used.
   b) Antiseptic solution should be liberally applied at least two times on and around the operative site, which should be thoroughly cleaned by gentle scrubbing.
   c) The antiseptic solution should be applied in a circular motion, beginning at the site of incision, and several inches around it. This inhibits immediate recontamination of the site with local skin bacteria.
   d) After preparing the operative site, the area should be covered with a sterile drape.

6.9 Anaesthesia

6.9.1 Only local anaesthesia will be offered in mobile setting.

6.9.2 An anaesthesia should preferably accompany the mobile team, especially for tubectomy performed in mobile setting.

6.10 Surgical Technique

6.10.1 Good surgical technique that minimises tissue trauma and ensures adequate haemostasis will reduce the occurrence of infection. In vasectomy, haemostasis is critical in preventing the development of scrotal haematomas and the accompanying risk of infection. During post-partum tubectomy, care should be taken to prevent injury to blood vessels and to prevent haematoma and subsequent risk of infection.

6.10.2 Medical termination of pregnancy (MR/MTP) should not be performed with tubectomy during mobile sterilisation services.
6.10.3 No post-partum tubal ligation is to be done on a mobile sterilisation service on a client who delivered at home and whose tetanus toxoid immunisation status is not known.

6.11 Client Discharge after Mobile Services

6.11.1 The surgeon or member of the surgical team must see all operated clients at least once during the post-operative period before he/she leaves the centre.

6.11.2 All operated clients must be examined before discharge by the medical officer of the centre where mobile sterilisation services have been organised.

6.11.3 Both verbal and written post-operative instruction and follow-up schedule
must be provided to the client before discharge. These should be in the client’s local language.

6.12 Follow up
Follow up services will be provided by the health worker of the respective area and medical officer of the nearest PHC/CHC as per schedule of sterilisation services.

7. REFERENCES


ANNEXURE-1

APPLICATION AND INFORMED CONSENT FOR STERILISATION OPERATION

Name of Client  Shri/Smt ______________________________________________________
Address of Client _____________________________________________________________
Spouse’s name  Shri/Smt _______________________________________________________
Father’s name   Shri __________________________________________________________
Operating Centre _________________________________________________________________

Dear doctor

Please arrange to have me sterilised. My age is _____________________ and my spouse’s age
is_________________. I am/was married. I/ We have ____________________ male and
________________________________ female living children. The age of the youngest child is
_____________________ years.

  • The decision to undergo the sterilisation operation has been taken independently by
    me without any outside pressure, inducement, or force.
  • I am aware that other method of contraception are available to me which have been
    properly explained
  • The eligibility criteria for the operation have been explained to me, and I affirm that
    I am eligible to undergo the operation according to the criteria
  • I know that for all practical purpose this operation is permanent and that, after the
    operation I will unable to have any more children.
  • I also know that there are still some chances of failure of the operation, for which the
    hospital/ institution and operating doctor will not be held responsible by me or my
    relatives or any other person whomsoever. I will report to the centre/doctor if there is
    any missed menstrual cycle of mine/my spouse within two weeks.
  • My spouse has not been sterilised previously.
  • I am aware that I have the option to decide against the sterilisation procedure at any
    time without sacrificing my rights to other reproductive health services.
  • I am aware that I am undergoing on operation which carries an element of risk.
• I agree to come for follow-up to the centre/doctor as instructed. Failing which I shall be responsible for consequence, if any.

• I am aware that I agree to undergo the operation under any type of anaesthesia which the doctors think suitable for me and to be given other medicines as considered appropriate by the doctors concerned.

The above information has been read/read out and explained to me, in my own language.

Signature, Name & Address of Witness*   Signature of Acceptor/Client

* Witness can be any person not associated with the service centre.

Applicable to the cases where the client cannot read and the above information is read out.

1. The client has been fully counseled about various available methods of contraception and the above method.

   ______________________________
   Signature of Counsellor**
   Name and Full Address

2. I certify I have satisfied myself that Shri/Smt______________________________ is within the eligible age-group and is mentally and medically fit for a sterilisation operation. There is no evidence that he/she has undergone a sterilisation operation previously). I have explained to the client that this form has the authority of a legal document.

   ______________________________
   Signature of Operating doctor
   (Name and address)

   Signature of medical officer
   (Name and address)

   ** Counsellor can be any health personnel including doctor.

   ** Counsellor can be any health personnel including doctor.

   Annexure- 1A
APPLICATION AND INFORMED CONSENT RE-STERILISATION OPERATION

Name of Client  Shri/Smt ____________________________
Address of Client ______________________________________
Spouse’s name  Shri/Smt ____________________________
Father’s name  Shri __________________________________
Operating Centre ________________________________________

Dear doctor

Please arrange to have me re-sterilised/sterilised as my/my spouse’s previous operation has field. My age is ________________________ and my spouse’s age is ________________________. I am/was married and my spouse is alive. I/ We have __________________ male and __________________ female living children. The age of the youngest child is ___________________ years.

• The decision to undergo the sterilisation operation has been taken independently by me without any outside pressure, inducement, or force.
• I am aware that other method of contraception are available to me which have been properly explained
• The eligibility criteria for the operation have been explained to me, and I affirm that I am eligible to undergo the operation according to the criteria
• I know that for all practical purpose this operation is permanent and that, after the operation I will unable to have any more children.
• I also know that there are still some chances of failure of the operation, for which the hospital/ institution and operating doctor will not be held responsible by me or my relatives or any other person whomsoever. I will report to the centre/doctor if there is any missed menstrual cycle of mine/my spouse within two weeks.
• My spouse has not been sterilised previously.
• I am aware that I have the option to decide against the sterilisation procedure at any time without sacrificing my rights to other reproductive health services.
• I am aware that I am undergoing on operation which carries an element of risk.
• I agree to come for follow –up to the centre/doctor as instructed. Failing which I shall be responsible for consequence, if any.
• I am aware that I agree to undergo the operation under any type of anaesthesia which the doctors think suitable for me and to be given other medicines as considered appropriate by the doctors concerned.

The above information has been read/read out and explained to me, in my own
Standards for Female and Male Sterilisation, February 2003

language.

Signature, Name & Address of Witness*  
• Witness can be any person not associated with the service centre.
Applicable to the cases where the client can not read and the above information is read out.

1. The client has been fully counseled about various available methods of contraception and the above method.

Signature of Counsellor**
Name and Full Address

2. I certify I have satisfied myself that Shri/Smt ____________________________ is within the eligible age-group and is mentally and medically fit for a sterilisation operation. There is no evidence that he/she has undergone a sterilisation operation previously. I have explained to the client that this form has the authority of a legal document.

Signature of Operating doctor
(Name and address)
Signature of medical officer
(Name and address)

DENIAL OF RE-STERILISATION/STERILISATION

I certify that Shri/Smt ____________________________ is not a suitable client for Sterilisation/sterilisation for the following reasons:

1.
2.

He/She has been provided the following alternative method of contraception.

Signature of counsellor ** or Doctor making decision
(Name and address)

** Counsellor can be any health personnel including doctor.

ANNEXURE- II

MINILAPARTOMY KIT

ITEM  QUANTITY

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<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>Sponge-holding forceps</td>
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</tr>
<tr>
<td>Surgical drape (towel with central hole)</td>
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</tr>
<tr>
<td>Syringe, 10cc</td>
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</tr>
<tr>
<td>Needle, 22-G. 1 ½”</td>
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</tr>
<tr>
<td>Scalpel</td>
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</tr>
<tr>
<td>Scalpel blade, size 15</td>
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</tr>
<tr>
<td>Allis forceps</td>
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</tr>
<tr>
<td>Small artery forceps</td>
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<tr>
<td>Needle holder</td>
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<tr>
<td>Straight scissors</td>
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<tr>
<td>Curved scissors</td>
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<tr>
<td>Babcock clamp, medium size</td>
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<tr>
<td>Small Langenbeck (right-angle abdominal)</td>
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<tr>
<td>Retractor</td>
<td>2</td>
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<tr>
<td>Dissecting forceps, toothed</td>
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</tr>
<tr>
<td>Dissecting forceps non-toothed</td>
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<tr>
<td>Uterine elevator (for interval procedure)</td>
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<td>Speculum, Vaginal, Sim’s medium</td>
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<td>Small stainless steel bowl</td>
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<td>Volsellum</td>
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<td>Tubal hook, Ramathibodi</td>
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</tr>
<tr>
<td>‘O’ chromic catgut</td>
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<tr>
<td>Small round-bodied, curved needle</td>
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<tr>
<td>Small cutting needle</td>
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<td>Non-absorbable suture material</td>
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<td>Bandage</td>
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<tr>
<td>SS kidney tray</td>
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## ANNEXURE-III

### LAPAROSCOPY

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<tbody>
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<tr>
<td>Light source for laparoscope with spare bulb</td>
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<tr>
<td>Emergency light source</td>
<td>1</td>
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<tr>
<td>Fiber-optic cable</td>
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<tr>
<td>Trocar with cannula</td>
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<tr>
<td>Operating laparoscope or Laprocator</td>
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<td>Carbon dioxide gas cylinders</td>
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<tr>
<td>Pneumoperitoneum insufflation apparatus</td>
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<tr>
<td>Falope ring loader</td>
<td>2 Pairs</td>
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<tr>
<td>Approved Falope-ring</td>
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<tr>
<td>Dissecting forceps, toothed</td>
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<tr>
<td>Scalpel with # 11 blade</td>
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<tr>
<td>Sims vaginal speculum</td>
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<td>Uterine sound</td>
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<tr>
<td>Volsellum</td>
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<td>Straight scissors</td>
<td>1</td>
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<td>Needle holder</td>
<td>1</td>
</tr>
<tr>
<td>Sponge Holding Forceps</td>
<td>2</td>
</tr>
</tbody>
</table>
Catgut suture, 0 or 00 .......................... 1
Small curved cutting needle .................. 1
Leukoplast/ Band aid ........................... 1
Iodophor solution ............................. 1QS
Syringe 10 cc ................................... 1
Needle, 22-G, 1 ½ ............................... 1
Gauze ........................................... 4
Cidex container (plastic with cover) ........ 1
SS tray (to rinse the Laparoscope) .......... 2
SS small bowls ................................ 2
SS kidney tray ................................ 1

**ANNEXURE-IV**

**VASECTOMY**

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<tbody>
<tr>
<td>Guaze pieces ....................................</td>
<td>8</td>
</tr>
<tr>
<td>Towel with central hole ..........................</td>
<td>1</td>
</tr>
<tr>
<td>Mosquito artery forceps, curved ..................</td>
<td>2</td>
</tr>
<tr>
<td>Mosquito artery forceps, straight ...............</td>
<td>2</td>
</tr>
<tr>
<td>Allis forceps ...................................</td>
<td>2</td>
</tr>
<tr>
<td>Needle holder ....................................</td>
<td>1</td>
</tr>
<tr>
<td>Thumb forceps, toothed ...........................</td>
<td>1</td>
</tr>
<tr>
<td>Mayo scissors ....................................</td>
<td>1</td>
</tr>
<tr>
<td>Scalpel handle ...................................</td>
<td>1</td>
</tr>
<tr>
<td>Scalpel blade, size 15 ...........................</td>
<td>2</td>
</tr>
<tr>
<td>Stainless steel bowl, small .....................</td>
<td>1</td>
</tr>
<tr>
<td>Sponge holder ....................................</td>
<td>1</td>
</tr>
<tr>
<td>Surgical tray with cover ........................</td>
<td>1</td>
</tr>
<tr>
<td>Gloves, sizes 6 ½, 7 ½ ..........................</td>
<td>2pairs each</td>
</tr>
<tr>
<td>Silk suture, 2-0/ Nonabsorbable suture ........</td>
<td>1</td>
</tr>
<tr>
<td>Small round- boiled, curved cutting needle ......</td>
<td>1</td>
</tr>
<tr>
<td>Syringe, 5cc ....................................</td>
<td>2</td>
</tr>
<tr>
<td>Needle, 22-G, 24G ................................</td>
<td>1</td>
</tr>
<tr>
<td>Suspensory bandage ................................</td>
<td>1</td>
</tr>
<tr>
<td>Iodophor solution ................................</td>
<td>1QS</td>
</tr>
</tbody>
</table>
### Antiseptic Solutions Useful for Sterilisation Procedures

<table>
<thead>
<tr>
<th>Potential Uses</th>
<th>Gram Positive</th>
<th>Most Gram Negative</th>
<th>TB</th>
<th>Viruses</th>
<th>Fungi</th>
<th>Endospores</th>
<th>Relative speed of action</th>
<th>Affected by Organic matter</th>
<th>Surgical Scrub</th>
<th>Skin Preparation</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohols (60%-90% ethyl or isopropyl)</td>
<td>Very Good</td>
<td>Very Good</td>
<td>Good</td>
<td>Good</td>
<td>Good</td>
<td>None</td>
<td>Fast</td>
<td>Data vary</td>
<td>Yes</td>
<td>Yes</td>
<td>Not for use on mucous membranes</td>
</tr>
<tr>
<td>Chlorhexidine (4%) Hibitane.. (Hibiscrub)</td>
<td>Very Good</td>
<td>Good</td>
<td>Poor</td>
<td>Fair</td>
<td>Fair</td>
<td>None</td>
<td>Slow</td>
<td>Slight</td>
<td>Yes</td>
<td>Yes</td>
<td>Has good persistent effect</td>
</tr>
<tr>
<td>Hexachlorophene (3%) (pHisoHex)</td>
<td>Good</td>
<td>Poor</td>
<td>None</td>
<td>Fair</td>
<td>Poor</td>
<td>None</td>
<td>Slow</td>
<td>Slight</td>
<td>Yes</td>
<td>No</td>
<td>Not for use on mucous membranes</td>
</tr>
<tr>
<td>Aqueous iodine preparations (3%) or iodine and alcohol (tincture of iodine)</td>
<td>Very good</td>
<td>Very good</td>
<td>Good</td>
<td>Good</td>
<td>Poor</td>
<td>Intermediate</td>
<td>Slight</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Not for use on mucous membranes</td>
</tr>
<tr>
<td>Iodophore (1:2.500) (Betadine)</td>
<td>Very good</td>
<td>Good</td>
<td>Good</td>
<td>Good</td>
<td>Good</td>
<td>None</td>
<td>Slow</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Can be used on mucous membranes</td>
</tr>
</tbody>
</table>