

This form should only be used if the patient has capacity to give consent. If support is required with consent (interpreter, witness, carer, guardian, parent, or any other relevant support) please ensure they are present. If the patient does not legally have capacity, please use an appropriate alternative consent form from your hospital or hub. This form will be the result of a shared decision conversation between a clinician and patient. "You / your / me / my" hereby refers to the patient.

Please note it is common NHS practice for your consent to be taken by a clinician other than the operating or listing surgeon. This clinician will be suitably trained and competent to take consent. They will be referred to as the "responsible healthcare professional" in this form.

You will be provided with additional patient information about your procedure by your hospital or hub site. These will be provided in a language and format that suits you.

You may have questions before starting, during or after your procedure. Contact details are provided for any further queries, concerns or if you would like to discuss your treatment further. The risks quoted in this consent form for surgery assume that you have no additional factors which would increase your risk. The clinician discussing the consent with you will explain if you have health conditions or factors that may increase your risk.

Your details (Print or sticker)

First name:

Last name:

Date of birth:

NHS or Hospital number:

Responsible Health Professional:

My requirements: e.g, transport, interpreter, assistance

Details of Injection of Botox into an anal fissure

Botox injection Procedure:

This procedure involves injecting Botulinum toxin A (Botox) into the internal anal sphincter in order to paralyze the internal anal sphincter, allowing your anal sphincter to relax and the fissure to heal. The amount of Botox used can vary but normally ranges between 50 to 100 IU.

Site and side: (Tick as appropriate)

The procedure is performed in a lithotomy position, meaning lying on your back with your legs flexed 90 degrees at your hips. Your knees will be bent at 70 to 90 degrees, and padded foot rests attached to the table will support your legs. The injection will be administered into the affected area.

Indication for, and purpose of surgery / benefits: (Tick as appropriate)

- Anal fissure still present, pain and/or bleeding after previously trialed medical therapy** (failed medical therapy – normally consists of two attempts of either GTN or diltiazem 2% cream for six weeks).
- Previous intramuscular (internal anal sphincter) botulinum toxin A injection** which has failed to resolve/treat the anal fissure.

Alternatives considered: (Tick as appropriate)

- Conservative management** Conservative management is a term used when a condition is managed without surgery or other invasive procedures or treatments. You may choose not to have surgery and live with these symptoms which may stay the same or get worse. If symptoms worsen you might choose to have surgery later in life if appropriate. Changes such as weight-loss, reducing strenuous activity, physiotherapy, and anti-inflammatory medications may help to reduce symptoms.
- Advancement flap and lateral sphincterotomy** – both these procedures are specialised and should be consented for separately.

Possible early or short-term risks

Expected

Will probably happen



Pain You may not be able to sit comfortably for up to 2 weeks and may require taking time off work. Pain relief options will be discussed with you.

Bleeding A small amount of bleeding from the back passage can be expected and usually settles within a week. If the bleeding is heavy or does not stop within 2 weeks, seek advice from your operating surgeon.

Common

Might happen
(more than 1 in 20)



Failure of treatment This procedure has a success rate of approximately 70%. Anal fissures often fail to heal after Botox treatment and can need further Botox injections or more advanced procedures that are used when Botox fails to work.

Incontinence Patients can experience incontinence to flatus.

Uncommon

Unlikely to happen
(fewer than 1 in 20)



Incontinence Patients can experience incontinence to stools.

Perioperative risks Perioperative complications may increase the length of your hospital stay or require additional treatment including in some cases admission to intensive care.

Significant bleeding Some bleeding is expected during most procedures however significant bleeding may require additional attention. Usually it can be dealt with during the procedure but may lead to a change from the planned procedure or need further emergency treatment.

Possible late or long-term risks

Uncommon

Unlikely to happen
(fewer than 1 in 20)



Further procedures Botox injections can be tried 2 to 3 times to try and repair the anal fissure. Not all anal fissures will heal with Botox. In some cases, perianal surgery may be required to treat the fissure such as an advancement flap or a lateral sphincterotomy.

Patient name:

NHS or Hospital number:

Patient specific risks

Patient
Specific Risks

Patient specific concerns

If you have any **specific concerns or personal risks** to you from your treatment, you can record them here. Please use this space to **record any concerns around allergies / reactions** and also any life saving **procedures that you do not wish to be carried out** without further discussion.

Any extra procedures which may become necessary during the procedure:

Blood transfusion:

Other procedures (please specify): _____

Patient name: _____

NHS or Hospital number: _____

Statement of healthcare professional

(to be filled in by health professional with appropriate knowledge of proposed procedure)

- I am suitably trained and competent and have sufficient knowledge to consent this patient in line with the requirements of my regulatory body.
- I have discussed what the treatment is likely to involve, the benefits and risks of this procedure.
- I have discussed the benefits and risks of any available alternative procedures or treatments including no treatment.
- I have considered any additional patient-specific factors and discussed these with the patient alongside their particular concerns.
- I can confirm that the patient has the capacity to give consent.

Patient information leaflet provided: Yes / No – Details: _____

Copy of consent form accepted by patient: Yes / No

Name: _____

Job title: _____

Date: _____

Signature: _____

Statement of patient

Please read this form carefully. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

You must consent to the following section to proceed with your surgery:

- I confirm that I have read and understood pages 1 to 5 of the consent form.
- I understand the diagnosis and agree with the course of treatment described on this form.
- I have had the opportunity to discuss treatment alternatives, including no treatment.
- I have had the purpose, aims and possible risks of treatment explained to me.
- I understand that the operating person, who will have appropriate expertise to carry out the procedure, may not have been involved in my pre-operative assessment or care to date.
- I understand my anaesthetic options will be or have been discussed with an

anaesthetist where we will jointly decide which option is best for me. I understand that the type of anaesthesia may need to be altered if there are any complications during the procedure.

- I have been told about additional procedures which are necessary prior to treatment or may become necessary during my treatment. This may include permanent skin marks, photographs, and / or tissue samples to help with treatment planning and identification.
- I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health. I have spoken to my health care professional about any lifesaving procedures I do not wish to happen.
- I understand that relevant and appropriate patient specific data for this procedure will be collected and may be used in the context of providing clinical care, and/or audit purposes in compliance with Data Protection Act (2018).

Additional Consent: This section will not stop you from receiving surgery but will help with future learning and training. Please tick if you consent:

- I understand that there may be health care professionals that are training during my procedures such as medical students, and trainee nurses. I consent that they may participate in examinations relevant to my procedure, supervised by a fully qualified professional.

- I understand that information collected during my procedure including images, may be used for education and research (which may be published in medical journals). All information will be anonymised and used in a way that I cannot be identified.
- I agree that my health records may be used by authorised members of staff, who are not directly involved in my clinical care, for research approved by a research ethics committee and in compliance with the Data Protection Act (2018).

Tick if relevant: I confirm that there is no risk that I could be pregnant.

Name: _____

Date: _____

Signature: _____

Statement of interpreter witness

(where appropriate)

- I have interpreted the information contained in this form to the best of my ability and in a way in which I believe they can understand.
- or
- I confirm that the patient is unable to sign but has indicated their consent.

Name: _____

Signature: _____

Patient name:

NHS or Hospital number:

Anaesthesia

Anaesthetic is used to allow surgery to take place painlessly. It may include medicines which put you to sleep or those which only numb the area you are having operated on while you remain awake. This can be done in a variety of ways and your anaesthetist will advise you on your options and talk to you about the risks, complications, and benefits of types of anaesthetic. If there are particular anaesthetic risks/concerns for any particular patient these should be separately documented in the patient's records.

Anaesthetic options and risks will be discussed with you on the day of surgery with an anaesthetist. This is a shared decision-making process, and you will jointly decide and agree which anaesthetic option is best for you. Please remember that if there are any complications during surgery, your anaesthetist may need to alter the type of anaesthesia and will explain this to you before the procedure.

For further information about the types of anaesthetic you may receive, and potential risks please see information below.

Types

Risks



<https://www.rcoa.ac.uk/documents/anaesthesia-explained/types-anaesthesia>

<https://www.rcoa.ac.uk/patient-information/patient-information-resources>

If you do not wish to access the additional patient information via link or QR code, please speak to your clinician and they will provide you with a hard copy. These will be provided in a language and format that suits you.

To be filled out by Anaesthetist (On day of surgery)

Name of Anaesthetists on the day:

Date:

I confirm I have discussed the different anaesthetic options with the patient, including risks and benefits and we have jointly decided what the preferred anaesthetic is.

Please note the preferred method of Anaesthesia as discussed between the patient and anaesthetist below:

Signature:

To be filled out by your responsible healthcare professional (On day of surgery)

Reconfirmation of consent / Withdrawal of consent (where appropriate)

Reconfirmation of consent:

Withdrawal of consent:

See advance decision to refuse treatment:

Name:

Date:

Signature:

The responsibility for informed consent is between the patient and the consenting clinician and the NHS trust. NHS England, Getting It Right First Time (GIRFT) and associated organisations are supplying this resource which should be used/amended by the clinician as they see fit according to their clinical judgement. NHS England, GIRFT and associated organisations do not accept any liability for the consent collected using this resource or the subsequent treatment including surgical and additional procedures.