

The Rafaelo Procedure for the treatment of haemorrhoids

Information for patients

What are haemorrhoids?

Haemorrhoids (also known as 'piles') are swollen vascular cushions (blood vessels) around or just inside the anal canal (back passage). There are two kinds of haemorrhoid: *internal* and *external*. Internal haemorrhoids are covered by the mucosal lining of the rectum, and often remain on the inside (Grade 1). Although usually not painful, internal haemorrhoids may descend and prolapse out of the anus, usually during defecation (passage of stool). Internal haemorrhoids that prolapse and reduce back inside by themselves are classified as Grade 2, while those that only reduce with gentle pushing are Grade 3. External haemorrhoids (Grade 4) are permanently on the outside of the anus, and are covered by skin. If a blood clot forms within a haemorrhoid, this is very painful, and is called a 'thrombosed pile'.

What causes haemorrhoids?

The haemorrhoidal cushions are normal anatomical structures, but obesity, pregnancy and childbirth, constipation and straining or heavy lifting can all contribute to the enlargement of these cushions and the development of symptoms, such as bleeding, itching and soreness, discomfort, mucous discharge and prolapse.

What treatments are available?

Dietary changes, to increase oral fluid and fibre intake thereby softening the stool may reduce the time spent sitting on the toilet and the need for straining during defecation. Other lifestyle improvements, avoiding straining when lifting may also prove beneficial. There are a variety of treatments for haemorrhoids, depending on the grade. Smaller internal haemorrhoids may be treated successfully by rubber band ligation (banding) or injection. These and other non-excisional surgical treatments such as haemorrhoidal artery ligation have the advantage of avoiding the considerable pain associated with a

formal surgical haemorrhoidectomy. For large Grade 4 haemorrhoids, such treatments are less likely to prove successful and a surgical haemorrhoidectomy is usually required.

The **Rafaello Procedure** is a novel treatment that utilises safe and reliable radio frequency technology to reduce, and in most cases, eliminate, the common symptoms of internal (Grade 1-3) haemorrhoids. Similar technology has been used successfully for many years to treat varicose veins in the legs, and this has now been adapted and modified for the treatment of haemorrhoids by the insertion of a special needle probe into the haemorrhoidal cushion, through which radio frequency energy is applied which aims to shrink the haemorrhoids by heating the tissue.

What are the benefits of The Rafaello Procedure?

The Rafaello Procedure is a minimally-invasive, day case procedure, which typically takes no longer than 15-20 minutes to perform. It can be carried out using only local anaesthetic (although some patients may choose to have a mild sedative, or even a general anaesthetic). Most patients report very little pain or discomfort, and as a result the post-operative recovery time is very short.

What are the risks of The Rafaello Procedure?

All treatments and procedures have risks. The most common risks post-procedure and during the following 2 weeks include discomfort, mild bleeding or spotting or anal discharge. Other rarer post-procedure complications might include recurrence of symptoms, infection, ulceration, fissure, or significant bleeding/haemorrhage.

Your consultant will discuss the benefits and risks of The Rafaello Procedure during your initial consultation.

Is The Rafaello Procedure safe and effective?

The Rafaello Procedure is a novel treatment, which means that there is not yet much good evidence about how well it works, it's long-term effects, or how safe it is for treating haemorrhoids. The National Institute for Health and Care Excellence (NICE) has approved the procedure when it is carried out with special arrangements for clinical governance, consent and audit or research (NICE Interventional procedures guidance IPG589).

What should I expect after The Rafaelo Procedure?

After the procedure you will be given some painkillers to take home with you. The recovery time from the procedure is normally between one and seven days, depending on the severity of the haemorrhoids. You may be able to return to work immediately or within a couple of days after the procedure. You will be seen again in clinic typically between 6 and 8 weeks after the procedure.

It is important to avoid becoming constipated after the procedure as straining may cause unnecessary bleeding and discomfort. A healthy diet that includes plenty of fibre, fruit and leafy vegetables together with a good oral fluid intake will all help to avoid constipation.

When and where should I seek help?

If you experience significant bleeding or pain, you go to your nearest A&E Department.

You should also seek help if you develop a high temperature above 38.5C (101 F) with fever or chills, vomiting or nausea, any difficulty passing urine or constipation for more than 3 days despite using laxatives.