Procedure for Prolapse & Hemorrhoids

An alternative approach to the surgical treatment of hemorrhoids
More than 50 percent of the U.S. population will develop symptomatic hemorrhoids in their lifetime. Many patients may not be aware of a surgical option that comfortably treats their condition and allows them to return to normal activity with a faster recovery and less pain than conventional hemorrhoidectomy.

Procedure for Prolapse and Hemorrhoids (PPH) is a fast, less painful surgical option for patients with advanced cases of hemorrhoids. PPH is not a hemorrhoidectomy in principle; it is a hemorrhoidopexy.

The procedure is indicated for:

- Patients with second- and third-degree hemorrhoids after failure of other therapies
- Patients with fourth-degree hemorrhoids (except those with large external components)
- Patients with rectal mucosal prolapse

* Compared to conventional hemorrhoidectomy
How PPH Works

Procedure for Prolapse and Hemorrhoids restores hemorrhoidal tissue to its original, normal anatomical position.

Using a specifically designed circular stapler from Ethicon, Inc., the prolapse of hemorrhoidal tissue is reduced by excising a band of the prolapsed anal mucosa membrane. This is accomplished by pulling prolapsed tissue into the circular stapler, removing excess tissue while stapling the remaining hemorrhoidal tissue. As a result, hemorrhoidal tissue is restored to its original anatomical position.

Treating hemorrhoids by surgically reducing the anal mucosal prolapse using a circular stapler is an original technique, as conceived in 1994 by Dr. Antonio Longo. Since then, thousands of surgeons have applied this technique.

PROXIMATE® PPH Hemorrhoidal Circular Stapler Set

The PROXIMATE® PPH Hemorrhoidal Circular Stapler Set is a trusted alternative to conventional hemorrhoid procedures, shown to provide superior patient outcomes.*

- **Faster Recovery** — Patients experience a quicker return to normal activities compared to those treated with standard treatments.²,³

- **Less Pain** — PPH is performed above the dentate line inside the anal cavity, affecting fewer nerve endings than traditional procedures.²,³

To help promote a successful surgical experience, Ethicon provides professional education, training and support for the PPH™ Set — and all of our high-quality devices.

For more information, contact your Ethicon Sales Professional or visit us at [www.ethicon.com/pphstapler](http://www.ethicon.com/pphstapler).

*Superior is defined as faster recovery time and less pain for stapled hemorrhoidopexy versus conventional hemorrhoidectomy.²,³
Clinical Results

The first prospective randomized multicenter trial completed in the U.S. compared PPH to Ferguson Hemorrhoidectomy.\(^2\)

Study conclusions:

• PPH offers the benefit of less postoperative pain, fewer requirements for analgesics and less pain at the first bowel movement.
• PPH provides similar control of hemorrhoid symptoms compared to Ferguson Hemorrhoidectomy.
• The need for an additional hemorrhoid treatment at one-year follow-up from surgery was similar between the PPH and Ferguson patient groups.
• During the one-year follow-up period, significantly fewer patients having the PPH procedure required additional anorectal procedures.

Patient Selection Considerations

Keep in mind the following considerations when identifying appropriate patients:

• Consider patient anatomy
  - Avoid males with long, tight anal canals
  - Manage/avoid patients with major external components
• Avoid patients suffering from IBS/bowel disorders
• Avoid patients with rectal pain prior to the procedure

It is important to manage patient expectations prior to the PPH procedure by explaining what PPH can and cannot do for the patient.

Patient Education

To review treatment options with patients, Ethicon has prepared a brochure and website (pphinfo.com) that define hemorrhoids and treatment options using clear, direct language. Use these materials when consulting with patients to help manage their expectations.

Ask your Ethicon Sales Professional, or visit www.ethicon.com/pphstapler to download a copy of the patient brochure from the PPH Circular Stapler product page. Patients should be directed to pphinfo.com for educational information.
The PROXIMATE® PPH Hemorrhoidal Stapler (PPH03) includes:

• 33mm Hemorrhoidal Circular Stapler
• ST100 Suture Threader
  - Hook tip catches suture ends while 100mm threader passes through casing ports
• CAD 33 Circular Anal Dilator
  - Clear obturator provides smooth insertion and view of the dentate line
• PSA33 Purse-String Suture Anoscope
  - 90° top window for visibility while creating purse string
  - Clear plastic to improve visibility for surgeons

Key Features and Benefits

• Two staggered rows of titanium staples in 33mm diameter size
• Application in the anal canal for transection and resection of internal tissue
• Increased staple line compression on tissue and key blood vessels (compared to PPH01)
• Quick-close knob for rapid instrument open and close while maintaining controlled tissue compression
• Suture threader ports for easy retrieval of suture through instrument housing
• Housing markings indicate proper depth of insertion
• Fixed anvil eliminates accidental detachment
**Procedural Considerations**

**PROXIMATE® PPH Hemorrhoidal Stapler: Indications**

The PROXIMATE® PPH Hemorrhoidal Stapler (PPH03) has application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.

**PPH Procedural Contraindications**

Do not use PROXIMATE® PPH Hemorrhoidal Stapler (PPH03) for:

- Stapled Transanal Rectal Resection (STARR) procedure
- Combined tissue thickness greater than 1.5mm
- Internal diameter of rectum that does not accommodate instrument/accessories
- Ischemic or necrotic tissue

PPH03 is contraindicated for the Stapled Transanal Rectal Resection (STARR) procedure. If used on tissue less than 1.0mm in thickness (or greater than 1.5mm), an inadequate mucosal repair and inadequate hemostasis could result.

Carefully consider use of PROXIMATE® PPH Hemorrhoidal Stapler (PPH03) in terms of:

- Abscess or full rectal wall thickness resection
- Nonreducible prolapsed hemorrhoids on the perianal skin
- Fissures
- Previous prostate radiation
- A cute thrombosed internal hemorrhoids
- Previous rectal surgery (scarring may cause difficulties in various stages)
The typical morphological situation of the hemorrhoidal and mucosal prolapse is caused by weakening and breakage of the supporting muscular and connective fibers. Prolapse implies the distal dislocation of the internal hemorrhoidal cushions that push the external hemorrhoidal sacs in an outward and lateral direction, thus causing the sacs to protrude. The upper hemorrhoidal vessels extend, while the middle and lower hemorrhoidal vessels are subject to the formation of “kinks.”

The hemorrhoidal volume may remain normal or may swell due to the phlebostasis. It also may regress toward atrophy. In fourthdegree prolapse, the dentate line is positioned almost outside the anal canal, and the rectal mucous membrane permanently occupies the muscular anal canal.
**Description of the Technique**

**Step 1: Reduce Prolapse, Introduce Instrument**

PPH can be performed under local, regional or general anesthesia. The patient is positioned in the prone jackknife, lithotomy or left lateral position. The anal verge is gently massaged and dilated before inserting the dilator. It is recommended that the obturator be inserted alone as part of the dilation process. This will help prevent damage to the internal sphincter.

The obturator then is removed and the circular anal dilator, with the obturator in place, is inserted. This pushes the mucosal prolapse back into the anal canal. It is important that the tubing aspect of the dilator, which is 3cm in length, overlies the dentate line. This will help prevent damage to the dentate line and the internal sphincter. The skin is milked out to flatten the tissue. This will help ensure that the dilator has been inserted far enough to protect the dentate line.

The flange of the circular anal dilator is provided with four slots in order to secure it to the perianal skin holding it firmly in place. The circular anal dilator is fully inserted and affixed to the perineum with three to four sutures.

The transparent circular anal dilator allows easy introduction of the instrumentation, view of the dentate line and protection of the internal sphincter and the dentate line.
Step 2: Purse-String Suture

The clear purse-string suture anoscope is inserted through the circular anal dilator, placing the circumferential purse string at the correct height (2cm to 3cm above the apex of the hemorrhoids at the tip of the anoscope) and depth (only mucosa and submucosa). The new, clear purse-string suture anoscope assists in the measurement of the distance between the purse string and the dentate line, while simplifying its placement. Use of 2-0 Prolene® SH or Monocryl® on a UR-6 needle is recommended for the purse string. The purse-string sutures are placed close together (six to 12 small bites) to allow better traction of the mucosal prolapse. Each insertion of the needle is near the exit point of the last insertion. The purse string should be at the same level circumferentially.

At each stitch, the clear purse-string suture anoscope is extracted, then rotated and inserted again. Rotating the new, clear pursestring suture anoscope while it is fully inserted in the circular anal dilator can twist the mucosa and cause an improper asymmetric purse-string suture. A finger is placed in the anus and the purse string is tightened to check that there is uniform circumferential closure and no skips or gaps. The location of the purse-string suture ultimately must result in a staple line that resides at least 2cm above the dentate line. The circular anal dilator preserves the unstriated sphincter and permits the atraumatic placement of a purse-string suture.
Step 3: Circular Stapler and Suture Threader

Once the purse-string suture has been completed, the hemorrhoidal circular stapler is fully opened and inserted with the anvil placed beyond the purse-string suture. It must be confirmed that the anvil is positioned beyond the purse string. A careful examination is conducted to confirm that the entire circumference of the mucosa is up against the center of the rod. A surgical knot is made to secure the tissue onto the anvil shaft, and, with the help of the suture threader, the ends of the threads are pulled through the lateral channels of the stapler.
Step 3: Circular Stapler and Suture Threader (continued)

The ends of the suture are knotted externally or fixed using a clamp. The entire casing of the stapler is introduced into the anal canal. During the introduction, it is advisable to partially tighten the stapler.

As the stapler is tightened, it is gently pushed into the anal canal, while moderate traction is maintained on the purse string so that the prolapsed mucosa begins to be drawn into the stapler casing. The stapler is examined to ensure that it is aligned along the axis of the anal canal.
Step 4: Closing and Firing

Prior to firing, the 4cm mark on the stapler casing is positioned at the level of the anal verge, placing the staple line at the proper height. If the patient is female, check the posterior vaginal wall to be certain that it has not been incorporated in the staple line.

As the stapler is closed completely, the orange indicator will advance to the low end of the green gap setting scale, toward the smaller “B” (shape of the shortest closed staple height). Tighter staple compression may reduce the risk of bleeding from the staple line. Be certain not to touch the safety until the device is ready to fire. Release the safety, and fire in one fluid motion.

Keeping the stapler fully closed for approximately 30 seconds before firing and approximately 20 seconds after firing acts as a tamponade, which may help promote hemostasis. A one-half to three-quarters turn of the adjusting knob of the stapler facilitates its extraction.

Additional turns can cause interposition of mucosa between the anvil head and the upper edge of the circular anal dilator.
Step 5: Post-Firing

Open the circular stapler one-half to three-quarters of a turn for easy extraction. Additional turns could cause interposition of mucosa between the anvil head and the upper edge of the circular anal dilator.

The purse-string suture anoscope may be reinserted for careful inspection of the staple line to make sure it is completely intact and to apply stitches for any bleeding (2.0 Vicryl® recommended).

Packing the anal canal is not recommended, as this may cause pain. Some surgeons use a foam-like product to improve hemostasis or a catheter to detect late bleeding.

Checking the doughnut is recommended. It should contain a 3cm-wide strip of rectal mucosa and possibly hemorrhoid tissue, with no or minimal muscle.

Correct placement of the muco-mucous suture over the anorectal ring is at least 2cm to 4cm from the dentate line.
Potential Complications

Risks and Complications

As with any surgical procedure, there are risks that accompany PPH:

1. If too much muscle tissue is drawn into the device, it can result in damage to the rectal wall, resulting in inflammation or infection.
2. The internal muscle of the sphincter may be damaged, resulting in short-term or long-term dysfunction, such as severe pain or incontinence.

The complication rates of PPH are comparable to those of conventional hemorrhoidectomy.

Post Operative Complications

Improper use of PPH can lead to complications, which include bleeding, urinary retention, stenosis or thrombosis. An article compared results from several studies, as listed in the following chart.4

<table>
<thead>
<tr>
<th></th>
<th>Ho</th>
<th>Boccasanta</th>
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<td>Mean follow-up (months)</td>
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<td>Mean hospital stay (days)</td>
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<td>Bleeding (%)</td>
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<td>Urinary Retention (%)</td>
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<td>Stenosis (%)</td>
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<td>Thrombosis (%)</td>
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Complications from Other Treatment Options

Each hemorrhoid treatment option presents the potential for complications.

<table>
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<tr>
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<th>Early</th>
<th>Late</th>
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<tbody>
<tr>
<td>Sclerotherapy</td>
<td>- Recurrence</td>
<td>- N/A</td>
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<tr>
<td>Infrared coagulation</td>
<td>- Recurrence</td>
<td>- N/A</td>
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<tr>
<td>Rubber band ligation</td>
<td>- Bleeding&lt;br&gt;- Pelvic sepsis</td>
<td>- Death (rare)</td>
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<td>Hemorrhoidectomy</td>
<td>- Severe post-op pain for 2 to 3 weeks&lt;br&gt;- Wound infection&lt;br&gt;- Post-op bleeding&lt;br&gt;- Swelling of skin bridges&lt;br&gt;- Incontinence&lt;br&gt;- Urinary retention</td>
<td>- Anal stenosis&lt;br&gt;- Formation of skin tags&lt;br&gt;- Recurrence&lt;br&gt;- Anal fissure&lt;br&gt;- Incontinence</td>
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<tr>
<td>PPH</td>
<td>- Bleeding&lt;br&gt;- Incontinence&lt;br&gt;- Urinary retention</td>
<td>- Bleeding&lt;br&gt;- Thrombosis&lt;br&gt;- Anal stenosis</td>
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Talk to your patients with advanced hemorrhoids about PPH

This alternative approach to the surgical treatment of hemorrhoids provides superior patient outcomes.*

Less Pain

• PPH is performed above the dentate line inside the anal canal, affecting fewer nerve endings than traditional procedures.

Fast Recovery

• Patients experience a quicker return to normal activities compared to those treated with conventional techniques.²

Short Procedure

• PPH usually is performed in 25 to 30 minutes under local, regional or general anesthesia.²

*Superior is defined as faster recovery time and less pain for stapled hemorrhoidopexy versus conventional hemorrhoidectomy.²³
Ordering Information

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Electronic Ordering Options

All purchase orders are made to Johnson & Johnson Health Care Systems, Inc. (JJHCS). The following electronic order placement methods are preferred:

**Johnson & Johnson Gateway:**
www.jnjgateway.com/commerce
(For questions about your order, visit the website or call 1-866-JNJ-GATE.)

**Global Healthcare Exchange (GHX):**
www.ghx.com
(For questions about your order, visit the website or call 1-800-YOUR-GHX.)

**Electronic Data Interchange (EDI):**
JJHCS EDI Help Line: 1-800-262-2888

Nonelectronic/Manual Ordering Options

Call JJHCS at 1-800-255-2500 between 8:30 a.m. and 9:00 p.m. eastern time or fax your order to 1-732-562-2212 or 1-800-997-1122.

Customer Support

For product use assistance, clinical guidelines, service and repair, emergency assistance, copy of a 510(k) clearance letter, or complaints, please contact our Customer Support Center by calling 877-ETHICON (384-4266). Our support center is staffed 24 hours a day, 7 days a week by qualified nurses to answer your product-related questions. Visit www.ethicon.com/pphstapler for more information. For complete product details, see the Instructions for Use.
References


