

EVIDENCE SUMMARY

Stapled Haemorrhoidopexy - PPH*

NICE recommended surgical option
for prolapsed internal haemorrhoids

* All clinical studies compare conventional haemorrhoidectomy (CH)
with stapled haemorrhoidopexy (PPH-Longo technique).



ETHICON ENDO-SURGERY

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VALUE PROPOSITION

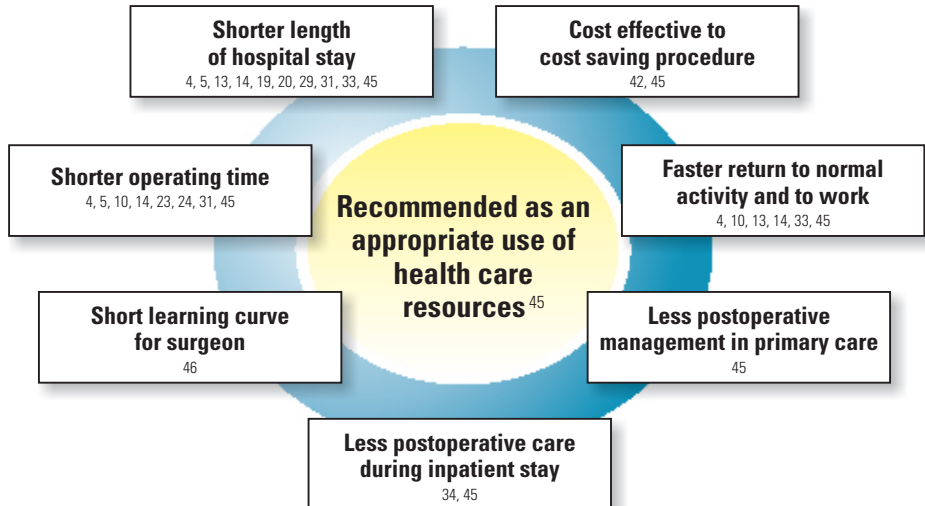
Benefits for the **Physician (Surgeon)**

- **Recommended as a standard surgical treatment option**⁴⁵
- **Comparable complication rate**^{12, 42, 45}
- **Effective long-term symptom resolution offering less postoperative pain**^{12, 37, 45}
- **Shorter operating time**^{4, 5, 10, 14, 23, 24, 31}
(mean -13.71 minutes)⁴⁵
- **Less postoperative care**³⁴
(during inpatient stay and after discharge)
- **Feasible as Day Case procedure**^{7, 17, 32}

Benefits for the **Patient**

- **Less pain**^{1-6, 8-17, 19, 21-37}
(up to 21 days postoperatively)
- **Shorter wound healing time**^{14-16, 29, 32}
- **Shorter time to return to normal bowel function**^{4, 10, 13}
- **Faster return to normal activity**^{4, 10, 13, 14, 33}
(mean -11.02 days)⁴⁵
- **Shorter length of hospital stay**^{4, 5, 13, 14, 19, 20, 29, 31, 33}
(mean -1.23 days)⁴⁵
- **Shorter operating time**^{4, 5, 10, 14, 23, 24, 31}
(mean -13.71 minutes)⁴⁵
- **Enhanced patient satisfaction**^{1, 4, 9, 26, 33, 42}
- **Less postoperative care after discharge**⁴⁵

Benefits for **Provider, Payer and Society**



CONCLUSION

Clinical and Economic Outcomes

- **Proved safety and efficacy** ^{5, 13, 16, 26, 32, 45}
- **Proved effectiveness in real world environment** ⁴³⁻⁴⁶
Conflicting evidence about higher rates of recurrent prolapse ^{11, 12, 38-40, 42, 45}
- **Enhanced patient satisfaction** ^{1, 4, 9, 26, 33, 42}
- **Cost effective to cost saving procedure compared to CH** ^{42, 45}

Patients experience considerably less pain and faster return to normal lifestyle

^{1, 3-5, 7, 9, 10, 13-17, 19, 23, 25, 29, 31, 33, 37, 45}

ENDORSEMENTS

Interventional Procedures Programme (IPP) and Health Technology Assessment (HTA) by different governmental and/or independent scientific institutes ⁴⁰⁻⁴³

- NICE - National Institute for Health and Clinical Excellence (England & Wales) HTA, 2007:
“Stapled haemorrhoidopexy, using a circular stapler specifically developed for haemorrhoidopexy, is recommended as an option for people in whom surgical intervention is considered appropriate for the treatment of prolapsed internal haemorrhoids.”*
- HAS - Haute Autorité de Santé (France), 2005:
„Stapled haemorrhoidopexy is indicated for grade 3 haemorrhoids and, in the short term, it is effective and it is characterized by limited morbidity.”
- NICE - National Institute for Health and Clinical Excellence (UK) IPP, 2003:
“Current evidence on the safety and efficacy of circular stapled haemorrhoidopexy appears adequate to support the use of the procedure.”
- ASERNIP - The Australian Safety and Efficacy Register of New Interventional Procedures (Australia), 2002:
“Stapled haemorrhoidectomy may be a viable addition to the therapy options available for treating haemorrhoids.”

* “The evidence considered refers to the HCS33 circular stapler (models PPH01 and PPH03: Ethicon Endo-Surgery).” ⁴⁵

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Interventional Procedures Programme (IPP) and Health Technology Assessment (HTA)

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|--------------------|---|
| 43. ASERNIP | <i>The Australian Safety and Efficacy Register of New Interventional Procedures (Australia), 2002</i> |
| 44. HAS | <i>Haute Autorité de Santé (France), 2005</i> |
| 45. NICE | <i>National Institute for Health and Clinical Excellence (England & Wales) HTA, 2007 (reference number: TA 128)</i> |
| 46. NICE | <i>National Institute for Health and Clinical Excellence (England & Wales) IPP, 2003</i> |

This summary provides evidence from the published scientific articles reporting about the use of a circular stapling device models PPH01 and/or PPH03 of Ethicon Endo-Surgery in stapled haemorrhoidopexy. It informs about reported clinical and economic outcomes providing an evidence based profile for benefits of stapled haemorrhoidopexy compared to conventional haemorrhoidectomy. Evidence summary is essentially based on RCTs and systematic reviews of current best available scientific evidence, which are mostly part of NICE guidance (HTA) about stapled haemorrhoidopexy published in September 2007 and available on NICE webpage www.nice.org.uk. Readers are encouraged to review the cited studies and articles on their own and form their own conclusions. This summary is offered without warranty of any kind.