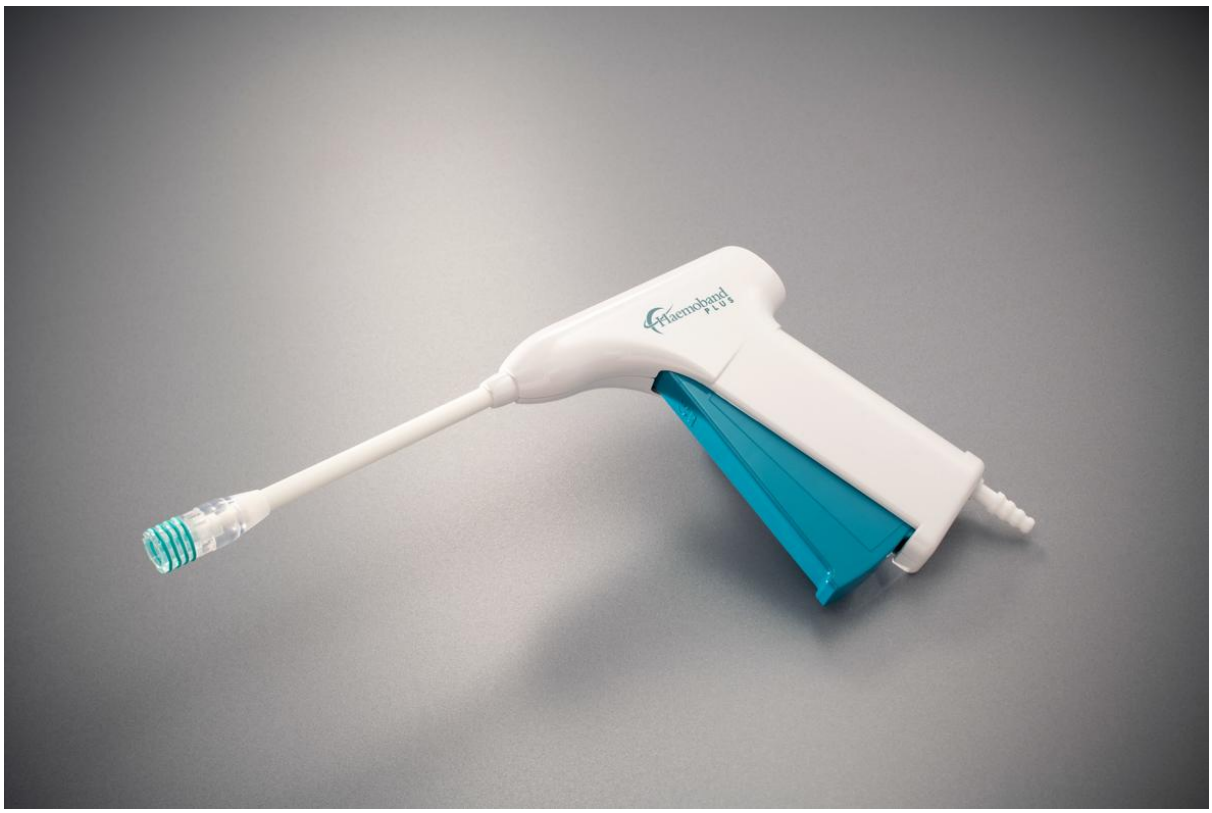
CLINICAL EVIDENCE REPORT

# Haemoband PLUS Multi-Band Ligator



*A comprehensive synthesis of published studies, clinical trials & real-world evidence*

Prepared by Haemoband Surgical March 2026

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# 1. Executive Summary

### The Haemoband-PLUS at a Glance

The Haemoband-PLUS is a multi-action, pre-loaded, single-use suction rubber band ligator designed for the outpatient treatment of Grade I–III internal haemorrhoids. Developed in Belfast, Northern Ireland by Consultant Surgeon Essam Ghareeb, it was the world's first device of its kind when launched in 2005. This report synthesises all published and identifiable clinical data in which the Haemoband or Haemoband-PLUS device was used, and contextualises those findings within the broader evidence base for rubber band ligation (RBL).

| Metric | Finding |
|---|---|
| **Procedure success rate** | 96% of procedures completed in under 2 minutes (Haemoband product validation); 90% of patients successfully treated in multi-haemorrhoid trial (Alubaidi et al. 2016) |
| **Primary device study** | Alubaidi, Clarke, Jamil & Ghareeb (2016) — Surgical Science 7(5):230–234 |
| **Real-world independent cohort** | Dekker et al. (2022): Haemoband used in 182-patient RBL cohort vs. haemorrhoidectomy over 44-month median follow-up (Annals of Coloproctology; PMC9021858) |
| **Regulatory clearances** | FDA 510(k) cleared (USA) · CE marked (EU/UK) · MDACS registered · ISO certified · 4 international patents |
| **Indicated grades** | Grade I, II, and III internal haemorrhoids |
| **Procedure time** | 2–3 minutes (vs. ~10 minutes for traditional single-band forceps method) |

### Evidence Overview

Three levels of evidence support the Haemoband-PLUS clinical case:

- Device-specific evidence: Alubaidi et al. (2016) demonstrates 90% single-session success for patients with multiple haemorrhoids — directly validating the pre-loaded multi-band design unique to the Haemoband-PLUS.
- Real-world independent evidence: Dekker et al. (2022) used the Haemoband for all 182 RBL procedures across a 44-month follow-up period at a tertiary proctology centre, demonstrating equivalent patient-reported outcomes to haemorrhoidectomy with significantly fewer complications.
- Contextual class evidence: A robust wider RBL literature confirms that suction-based ligation — the Haemoband mechanism — is clinically superior to forceps-based ligation for pain and procedural bleeding, and that RBL is the recommended first-line treatment for Grade I–III haemorrhoids per international guidelines.

# 2. The Haemoband-PLUS Device

## 2.1 Product Description

The Haemoband-PLUS Multi-Ligator is a single-use, disposable, suction-based rubber band ligator. Developed in 2005, it was the world's first pre-loaded multi-band suction ligator. Its principal design innovations over conventional ligators are:

- Pre-loaded nozzle with four individually moulded green latex-free bands — no reloading required mid-procedure
- Dual-action trigger enabling single-handed suction control and band release — full one-clinician operation
- Transparent nozzle tip providing direct visualisation of haemorrhoid capture before firing
- Moulded (not cut) bands delivering greater elasticity and tightness than standard cut-latex bands

## 2.2 Device Specifications

| Specification | Detail |
|---|---|
| **Band loading** | 4 individually moulded bands, pre-loaded, latex-free — no reloading required mid-procedure |
| **Operation mode** | Single-handed; dual-action trigger for suction control and band release |
| **Suction source** | Standard hospital suction attachment; flow controlled by trigger |
| **Nozzle tip** | Transparent — enabling direct visualisation of haemorrhoid capture before firing |
| **Band type** | Moulded (not cut) bands; greater elasticity and tightness than standard cut-latex bands |
| **Sterility / reuse** | Single-use disposable; clean-bagged; no sterilisation required |
| **Procedure time** | 2–3 minutes (vs. ~10 minutes for traditional single-band forceps method) |
| **Double-banding required?** | Not required — larger moulded bands provide adequate ligation alone |
| **Nursing requirement** | None — fully single-operator; nursing team freed for other tasks |

## 2.3 Regulatory Clearances & Certifications

- FDA 510(k) clearance — United States
- CE Mark — European Union and United Kingdom
- MDACS registration — Hong Kong / Macau
- ISO13485 quality management system certification
- 4 international patents protecting core device technology

# 3. Device-Specific Clinical Studies

The following studies explicitly used the Haemoband or Haemoband-PLUS as the procedural device. These represent the primary evidence base for device-specific clinical claims.

## 3.1 Alubaidi, Clarke, Jamil & Ghareeb (2016) — Primary Device Study

**Title:** 'Single Session, Multiple Band Ligation for Hemorrhoids'

**Journal:** Surgical Science, Vol. 7, No. 5, 2016, pp. 230–234

**Authors:** Kassem Alubaidi, G. Clarke, A. Jamil, Essam Ghareeb (Haemoband Medical Director)

**Design:** Prospective clinical study using the Haemoband-PLUS multi-band ligator

This is the primary device-specific study for the Haemoband-PLUS. The study evaluated single-session multi-band ligation in patients presenting with two or more haemorrhoids. Key findings:

- 90% of patients with two or more haemorrhoids were successfully treated in a single session using the Haemoband-PLUS
- The pre-loaded multi-band design enabled multiple bands to be placed in one visit, reducing the number of repeat appointments required
- This directly validated the fundamental design rationale of the Haemoband — enabling single-session treatment that distinguishes it from single-band devices
- The study has been cited in subsequent multi-centre RBL efficacy studies as a reference for multi-band ligation technique

## 3.2 Dekker et al. (2022) — Large Independent Retrospective Cohort

**Title:** 'Hemorrhoidectomy versus rubber band ligation in grade III hemorrhoidal disease: a large retrospective cohort study with long-term follow-up'

**Journal:** Annals of Coloproctology, 2022;38(2):146–152

**DOI / PMC:** 10.3393/ac.2020.01011.0144 | PMC9021858

**Design:** Retrospective cohort; n=327 patients with Grade III haemorrhoids; median 44-month follow-up

This is the largest independently published study to specifically name the Haemoband disposable ligator as the procedural device. Conducted at a tertiary referral proctology centre, it enrolled 327 patients treated by RBL (n=182, using the Haemoband) or haemorrhoidectomy (n=145).

**Haemoband-specific protocol:**

- Haemoband disposable ligator placed via 18mm proctoscope
- Maximum 3–4 bands applied per session
- Pre-procedure oral analgesia recommended
- All 182 RBL procedures performed by five experienced proctologic surgeons in an outpatient setting

**Key outcomes for the RBL (Haemoband) group:**

- 51.6% of patients (94/182) were successfully treated with a single RBL session
- Patient-reported outcomes (PROMs) at 44-month median follow-up did not differ significantly between the Haemoband RBL group and the haemorrhoidectomy group
- Complications were significantly more common in the haemorrhoidectomy group
- Authors concluded that larger randomised trials with patient-centred outcomes are needed, citing this Haemoband cohort as a data foundation

## 3.3 Tariq Saeed, Ali & Khan — RBL vs. Milligan-Morgan Haemorrhoidectomy

**Title:** 'Milligan-Morgan (Open) Haemorrhoidectomy vs Rubber Band Ligation'

**Authors:** Muhammad Tariq Saeed, Zafar Ali, Sohail Ali Khan

This study compares Milligan-Morgan open haemorrhoidectomy with rubber band ligation performed using the Haemoband device. It contributes supporting comparative evidence demonstrating RBL using the Haemoband as a viable, less invasive first-line alternative to open haemorrhoidectomy for appropriate haemorrhoid grades.

# 4. Broader Clinical Evidence Base for Rubber Band Ligation

The Haemoband device performs rubber band ligation — the most widely used non-surgical treatment for haemorrhoids globally. The following summarises the key wider evidence that contextualises the clinical positioning of the Haemoband-PLUS.

## 4.1 RBL vs. Haemorrhoidectomy — Systematic Reviews & RCTs

| Study | Design | Key Finding |
|---|---|---|
| **Shanmugam et al. Cochrane 2005 (PMC8860341)** | Meta-analysis; 3 RCTs; n=216 | Haemorrhoidectomy: higher complete remission. RBL: safer, less painful, appropriate first-line for Grade I–III |
| **Dekker et al. Tech Coloproctol 2021 (PMC8124052)** | Systematic review & meta-analysis; 8 RCTs | RBL and haemorrhoidectomy produce similar patient-reported outcomes for Grade II–III. RBL: fewer complications |
| **van Dieren et al. Dis Colon Rectum 2025 (PMC11999089)** | Multicenter RCT; n=87; 10 Dutch hospitals | Haemorrhoidectomy superior for Grade III QoL/recurrence (47.5% RBL vs 6.1%). RBL: return to work 1 day vs. 9 days for surgery |

Relevance to Haemoband positioning: For Grade I–II haemorrhoids, RBL with the Haemoband is the evidence-based first-line treatment per major international guidelines. For Grade III, RBL is appropriate as a first option with surgery reserved for refractory or relapsed cases — particularly given the significantly faster recovery associated with RBL (return to work: 1 day vs. 9 days for surgery).

## 4.2 Suction vs. Forceps Ligation — Supporting the Haemoband Mechanism

A central clinical differentiator for the Haemoband-PLUS is its suction-based mechanism. The following RCT directly demonstrates the clinical superiority of suction over forceps-based ligation:

| Study | Design | Key Finding |
|---|---|---|
| **Bayer et al. Tech Coloproctol 2005 (PubMed 16234072)** | Prospective RCT; n=100 | Suction ligation: immediate pain VAS 3.08 vs. 6.08 forceps ($p<0.001$). Analgesic use: 2.4 vs. 4.5 tablets ($p=0.003$). Intra-procedure bleeding: 5 vs. 25 events ($p<0.001$). No severe complications in either group. |

The Haemoband-PLUS is a suction-based ligator. This evidence directly and specifically supports the clinical advantage of the Haemoband over forceps-based systems for both patient comfort and procedural safety.

## 4.3 RBL Efficacy: Large Series & Key Patient Subgroups

The following data from the broader RBL literature demonstrates the scale of evidence and the versatility of the technique across diverse patient populations.

### Large prospective series

- Komporozos et al. (2021) — Int J Colorectal Dis 36(8):1723–1729 (PMID 33751210): Prospective series of 2,635 consecutive patients with Grade II–IV haemorrhoids. After treatment, 86.8% were asymptomatic; 84.5% remained asymptomatic at 2 years. RBL used with suction ligators (the same mechanism as the Haemoband-PLUS). Largest prospective RBL series in this report. Hosted on haemobandsurgical.com as supporting clinical evidence.
- Endoscopic RBL series (n=759, 55-month follow-up): 98% bleeding control; 82.5% prolapse reduction; 93.6% patient satisfaction (PMC3103797)

### Key patient subgroups

- Grade I–III general outpatients: 89% symptom resolution at 6 months; 79% returned to work the next day (PMC9618009)
- Pregnant women: RBL is safe and effective for Grade I–III haemorrhoids in pregnancy (PMC9399576)
- HIV-positive patients: RBL demonstrated safe with low complication rates (PMC9399576)
- Haemophiliacs: RBL feasible; more sessions required on average (mean 3.22 vs. 1.81 sessions) (PMC9399576)

# 5. Clinical Outcomes Analysis

The following table synthesises outcomes across the Haemoband-specific evidence and the broader RBL literature, enabling direct comparison across key clinical endpoints.

| Outcome | Haemoband Evidence | Broader RBL Evidence | Source(s) |
|---|---|---|---|
| **Procedural success rate** | 90–96% | 86–98% across studies | Alubaidi et al. 2016; Haemoband data; PMC3103797 |
| **Procedure time** | 2–3 minutes | 5–10+ min (single-band forceps) | Haemoband-PLUS product page |
| **Single-session success (Grade III)** | 51.6% in one session | Variable by grade & device | Dekker et al. 2022 |
| **Post-procedure pain (suction vs. forceps)** | Significantly lower with suction method | VAS 3.08 vs. 6.08 (immediate) | Bayer et al. 2005 |
| **Intra-procedure bleeding** | Significantly lower with suction | 5 vs. 25 events | Bayer et al. 2005 |
| **Complications vs. haemorrhoidectomy** | Fewer complications with RBL | Consistently fewer across meta-analyses | Dekker et al. 2022; Cochrane 2005 |
| **Recurrence (Grade III)** | Higher than surgery (class effect) | ~47.5% vs. 6.1% (RBL vs. surgery) | van Dieren et al. 2025 |
| **Return to work** | Same-day in most patients | 1 day (RBL) vs. 9 days (surgery) | van Dieren et al. 2025 |
| **Patient satisfaction** | Positive (clinician reports) | 93.6% in endoscopic RBL series | PMC3103797 |
| **Long-term symptom-free rate (2yr)** | N/A (device-specific data pending) | 84.5% asymptomatic at 2 years (n=2,635) | Komporozos et al. 2021 |

# 6. Regulatory Status & Global Distribution

## 6.1 Regulatory Approvals

| Certification | Territory | Status |
|---|---|---|
| **FDA 510(k)** | United States | Full market clearance |
| **CE Mark** | European Union & United Kingdom | Full market clearance |
| **MDACS Registration** | Hong Kong / Macau | Regional market clearance |
| **ISO 13485 Certification** | International | Quality management system |
| **4 International Patents** | Global | Core device technology protection |

## 6.2 Global Distribution & Commercial Presence

- Europe: United Kingdom, Ireland and continental Europe
- Americas: North and South America (FDA-cleared)
- Middle East: UAE, Gulf region
- Asia-Pacific: New Zealand, Hong Kong, Singapore

**Conference presence:** ASCRS Annual Scientific Meeting (San Diego); WHX Dubai, UAE

**Founded:** 2005, Belfast, Northern Ireland by Essam Ghareeb (Consultant Surgeon)

# 7. Conclusions & Future Directions

The Haemoband-PLUS is supported by a meaningful and growing clinical evidence base operating at three levels:

- Device-specific evidence: Alubaidi, Clarke, Jamil & Ghareeb (2016) demonstrates 90% single-session success for patients with multiple haemorrhoids — directly validating the pre-loaded multi-band design unique to the Haemoband-PLUS.
- Real-world independent evidence: Dekker et al. (2022) used the Haemoband for all 182 RBL procedures in a major proctology centre, demonstrating equivalent patient-reported outcomes to haemorrhoidectomy with fewer complications over 44 months.
- Contextual class evidence: A robust wider RBL literature confirms that suction-based ligation — the Haemoband mechanism — is superior to forceps-based ligation for pain and bleeding, and that RBL is the recommended first-line treatment for Grade I–III haemorrhoids per international guidelines.

The Haemoband-PLUS differentiates itself through speed (2–3 minute procedures), single-operator design, superior moulded band quality, and overall clinical efficiency. With FDA/CE clearance, 4 international patents, and an established global clinical track record across public hospitals on multiple continents, it is positioned as the premium, best-in-class rubber band ligator for modern colorectal and proctology practice.

**Priority Actions for Evidence Development**

- Conduct prospective, device-specific randomised controlled trials comparing Haemoband-PLUS to alternative ligators on pain, procedure time and clinical outcomes
- Develop formal cost-effectiveness modelling for NHS and international healthcare procurement and guideline submissions
- Establish longitudinal patient outcome registries to build the evidence base for guideline inclusion and strategic procurement decisions
- Pursue NICE evidence review submissions and equivalent regulatory authority evaluations in key growth markets

# 8. Acronyms

| Acronym | Full Form |
|---|---|
| **CE** | Conformité Européenne (European Conformity marking) |
| **FDA** | US Food and Drug Administration |
| **ISO** | International Organization for Standardization |
| **MDACS** | Medical Device Administrative Control System (Hong Kong) |
| **MDR** | Medical Device Regulation |
| **PMC** | PubMed Central |
| **PMID** | PubMed Identifier |
| **PROM** | Patient-Reported Outcome Measure |
| **QoL** | Quality of Life |
| **RBL** | Rubber Band Ligation |
| **RCT** | Randomised Controlled Trial |
| **SOTA** | State of the Art |
| **VAS** | Visual Analogue Scale |

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