BRAY GROUP LTD

Portia by Bray

Vaginal Ring Pessaries

Women's Health

Pessaries Overview & Clinical Review by Bray Group Ltd

CE-Marked Device | **Class IIb** | **NICE NG123** | **Made in Britain**

CE-Marked · UKCA Aligned · Latex-Free · Manufactured in Britain

Contents

What is Pelvic Organ Prolapse (POP)?

CONDITION OVERVIEW

Pelvic organ prolapse (POP) is the descent of one or more pelvic organs — bladder, uterus, vaginal vault, small bowel, or rectum — into or beyond the vaginal canal, due to weakness or disruption of pelvic floor support structures. POP affects up to 50% of parous women and can cause significant pain, discomfort, and functional impairment.

What Causes POP?

- Pregnancy, labour & vaginal childbirth — most common
- Obesity
- Chronic cough (respiratory disease)
- Constipation
- Pelvic organ cancers
- Hysterectomy
- Genetics — connective tissue weakness

What Are the Symptoms?

- Pressure or fullness in the pelvic area
- Low backache
- Painful intercourse
- Feeling that something is falling out
- Urinary leaking or urgency
- Constipation or loss of bowel control
- Spotting or vaginal bleeding

How Is POP Diagnosed?

- Medical history and pelvic examination
- May be found during routine cervical smear
- Additional tests to assess organ involvement
- POP-Q staging (standardised measurement)
- Compartment assessment (11a, 11b, 11c)
- Imaging if required
- MDT assessment in complex cases

Vaginal pessaries are a long-established and proven solution for POP. A healthcare professional will assess the correct size following medical examination. Successful patient fitting rates are high.

Clinical Classification of Pelvic Organ Prolapse

CLASSIFICATION

POP-Q Classification System

The Pelvic Organ Prolapse Qualification (POP-Q) is internationally recognized and standardised method for describing the staging pelvic organ prolapse - endorsed by IUGA and AUS. Measurements in cm relative to the hymen.

Stage 0	No prolapse
Stage I	Leading edge >1 cm above hymen
Stage II	Leading edge within ±1 cm of hymen
Stage III	>1 cm below hymen, not complete eversion
Stage IV	Complete vaginal eversion

Ring pessary for Stage I–II · Space-occupying pessaries for Stage III–IV

Compartment Classification (11a / 11b / 11c)

IIa

Anterior Compartment

- Involves the bladder and anterior vaginal wall
- Commonly referred to as cystocele, support pessary
- May cause urinary symptoms (SUI, voiding dysfunction)
- Continuous use less than and up to 30 days (short term use)

IIb

Posterior Compartment

- Involves the rectum and posterior vaginal wall
- Includes rectocele and sometimes enterocele
- Associated with defecatory dysfunction
- Continuous use for up to 6 months (long term use)

IIc

Apical Compartment

- Involves uterus, cervix, or vaginal vault
- Often contributes significantly to severity
- May coexist with anterior and/or posterior defects

Clinical Indications & Guideline Recommendations

INDICATIONS

Pessary Use is Indicated For:

- Symptomatic POP (all stages, depending on device type and fit)
- Patients wishing to avoid, defer, or unfit for surgery
- Women in preoperative period or awaiting surgical intervention
- Postpartum or future pregnancy considerations
- Coexisting stress urinary incontinence (selected pessary types)

Key Principles Across Guidelines

- Individualised fitting by appropriately trained clinicians (HCP)
- Clear patient education including self-management where appropriate
- Regular follow-ups to assess fit, symptom relief, and complications
- Shared decision-making considering patient preference and severity

International Guideline Support

NICE NG123 2019	Urinary incontinence and pelvic organ prolapse in women. Recommends vaginal pessaries as a non-surgical option with appropriate counselling, fitting, and regular follow-ups.
RCOG & BSUG UK	Support pessary use as part of conservative management, emphasising individualised assessment, correct fitting, and structured ongoing review.
IUGA & AUS Intl.	Highlights vaginal pessaries as a safe and effective option for long-term use, particularly for women wishing to avoid surgery or with significant comorbidities.

Types of Pessaries — Selection Guide

PESSARY TYPES

Support Pessaries

FIRST LINE — **Ring Pessary (± Support)**

- First-line device in most cases
- Suitable for Stage I–II prolapse
- Ring with support for additional apical support
- Favoured for ease of insertion and self-management

MODERATE — **Shaatz Pessary**

- Dish-shaped with central support
- Used when ring pessary is insufficient
- Offers greater structural support

SELECTED — **Hodge Pessary**

- Now less commonly utilised
- May be considered in selected cases (e.g., uterine retroversion)

Types of Pessaries — Selection Guide

PESSARY TYPES

Space-Occupying Pessaries

ADVANCED — **Gellhorn Pessary**

- Indicated for Stage III–IV prolapse
- Provides strong apical support via suction
- Typically requires clinician-led management

MULTI-COMPARTMENT — **Cube Pessary**

- Uses suction to maintain position
- Effective in advanced or multi-compartment prolapse
- Requires daily removal to minimise mucosal damage

SEVERE — **Donut Pessary**

- Suitable for severe prolapse
- Less commonly used due to insertion/removal challenges

SPECIALIST — **Gehrung Pessary**

- Adjustable, U-shaped device
- For complex or compartment-specific prolapse
- Requires specialist expertise for fitting

No single 'best' pessary is supported by strong evidence. Ring pessaries are typically first-line; other types introduced as clinically needed based on individual fit and patient tolerance.

Portia by Bray — Product Overview

PORTIA PRODUCT

Product Specifications

Device Description	White, smooth, torus-shaped intravaginal ring pessary
Indication	Conservative management of POP — POP-Q Stage I–II
Materials	Flexible PVC (12.5 mm wall) and Rigid Polythene LDPE (7.5 mm wall)
PVC Sizes	16 sizes — 50 mm to 110 mm diameter
Polythene Sizes	15 sizes — 50 mm to 100 mm diameter
Regulatory Status	CE-marked · Directive 93/42/EEC
Classification	Class IIb medical device
Latex Status	Latex-free
Supply	Non-sterile, individually packaged, single-patient, single use
Manufacturing	Designed and manufactured in the United Kingdom
Prescription	Prescribed by HCP following clinical assessment
Replacement	Recommended maximum in situ period: 6 months

Key Clinical Benefits

16+	6 mth	2 types	CE IIb
Sizes in PVC Right fit for every patient	Max in situ per MHRA guidance	PVC & Polythene Matched to clinical need	MHRA framework UKCA aligned

⚠ *Caution: vaginal discomfort or poor fit · vaginal bleeding/ulceration · active infection · pelvic inflammation · inability to comply with follow-up*

Regulatory Classification & Follow-Up

REGULATORY

Medical Device Classification

Class IIa	Medium risk. Short- to medium-term use in body orifice. Invasive but no interaction with vital organs in high-risk manner.
Class IIb (Portia)	Higher medium risk. Long-term use >30 days. Removed, cleaned, and replaced at regular intervals — classified IIb under MHRA framework.

Replacement Guidance — Management Intervals

Self-managing	Only through HCP-led programmes for selected patients
Clinician-managed	Review, removal, and replacement typically every 3–6 months
Device replacement	Portia by Bray: maximum 6 months. Earlier if wear, symptoms, or clinical findings indicate. Single use

Follow-Up — Complications & Management

Complication	Description	Management
Vaginal discharge	Most reported side effect	Infection review; topical oestrogen
Vaginal ulceration	Pressure damage	Remove; allow healing; reassess fit
Infection	Bacterial vaginosis	Treat infection; review; alternative device
Bleeding	Mucosal damage	Urgent assessment; remove; investigate
Expulsion	Pessary falls out	Reassess sizing; different device type
Urinary symptoms	Voiding difficulty	Reassess fit and position; specialist referral

Topical oestrogen is often recommended in postmenopausal women to maintain vaginal mucosal integrity and reduce complication rates.

Clinical Evidence — Key Results at a Glance

Peer-reviewed studies supporting Portia by Bray vaginal pessaries

82.8%

Successful fitting
Stage IV POP patients
(Zhou et al., 2024, n=157)

>90%

Patient satisfaction
Following successful fitting
(Zhou et al., 2024)

76%

Achieved continence
Pessary use for SUI
(Klein et al., 2022, n=376)

60%

Continuation rate
at 12 months for POP
(Ontario HTA, 2021)

Study Index

HTA · 15 studies	Ontario Health 2021	60% continuation at 12 months. Pessaries likely cost-effective for POP & SUI. High patient satisfaction.
Prospective · n=157	Zhou et al. 2024	82.8% successful fitting in Stage IV POP. >90% satisfaction. 90% prolapse symptom improvement.
Systematic Review · n=376	Klein et al. 2022	76% achieved continence for SUI. UDI scores -46.7%. IIQ scores -67.8% (p<0.0001).
Lit. Review · 192 studies	Al-Shaikh et al. 2018	High satisfaction for SUI. Minor complications. Pessaries recommended as first-line conservative option.
Narrative Review · 313	Rantell et al. 2025	Fitting success 41–97%. >90% resolution of bulge/pressure. Structured follow-up is critical.
RCT · n=276	Cheung et al. 2016	Pessary + PFMT: PFDI -29.7 vs -4.7 control (p<0.01). Greater QoL improvement with pessary.
Crossover RCT · n=134	Cundiff et al. 2007	Ring and Gellhorn equally effective. No significant difference in symptoms or quality of life.
Retrospective · 8 years	Yang et al. 2018	Ring = first-line, easiest self-management. Gellhorn = second-line for advanced prolapse.

Clinical Studies — HTA & Stage IV POP

Peer-reviewed evidence supporting vaginal pessaries

Study 8.1: Ontario Health 2021 — Health Technology Assessment

Ontario Health Technology Assessment Series 2021;21(3):1–155 | PMID: 34055111

Design:

Systematic review of 15 studies evaluating effectiveness, safety, cost-effectiveness, and patient preferences for vaginal pessaries for POP and SUI.

60%	Cost-eff.	Positive
Continuation rate at 12 months	Likely cost-effective for POP & SUI	Patient satisfaction & symptom relief

Conclusion:

Pessaries likely cost-effective for POP & SUI. Positive patient experiences with symptom relief and improved daily functioning. Barriers include wait times and out-of-pocket costs.

Relevance: Confirms pessaries as a cost-effective non-surgical option with high patient satisfaction when access barriers are addressed.

Study 8.2: Zhou et al. 2024 — Prospective Study, Stage IV POP, n=157

International Urogynaecology Journal 2024;35(1):59–67 | PMID: 37542565 | DOI: 10.1007/s00192-023-05594-2

Design:

157 patients with symptomatic Stage IV POP underwent pessary fitting. Outcomes included fitting success rates, patient satisfaction, and prolapse and urinary symptom improvement.

82.8%	>90%	90%
Successful fitting all patients	Patient satisfaction both types	Prolapse symptom improvement

Conclusion:

High success in Stage IV POP. Ring pessaries: 44.6% fitting success; 84.3% achieved independent self-management. Prolapse and urinary symptoms improved significantly.

Relevance: Over 80% success in most advanced prolapse directly supports ring pessaries as viable first-line option, with excellent self-management rates.

Clinical Studies — Stress Urinary Incontinence Evidence

Peer-reviewed evidence supporting pessaries for SUI

Study 8.3: Klein et al. 2022 — Systematic Review & Meta-Analysis, n=376

Female Pelvic Medicine & Reconstructive Surgery 2022;28(6):e171–e178 | DOI: 10.1097/SPV.0000000000001180

Design:

Systematic literature search identifying 10 studies involving 376 patients. Two independent reviewers assessed SUI outcomes for vaginal pessaries per PRISMA guidelines.

76%	46.7%	67.8%
Achieved continence vs 0% pre-treatment	UDI score reduction p<0.0001	IIQ score reduction p<0.0001

Conclusion:

Pessaries are effective for SUI with improvements in subjective symptoms and objective measures. Adverse events decreased with longer-term use (>6 months).

Relevance: Significant objective and subjective improvements confirm pessaries as an effective non-surgical SUI option with a safety profile that improves over time.

Study 8.4: Al-Shaikh et al. 2018 — Literature Review, 192 Studies

International Journal of Women's Health 2018;10:195–201 | DOI: 10.2147/IJWH.S152616

Design:

Review of 192 original research articles, clinical trials, and reviews (2000–2016). Also reviewed guidelines from AUA, CUA, AUS, NIH, and NICE. Focus on SUI with vaginal pessaries.

High	Minor	First-line
Patient satisfaction across all literature	Complications—discharge most common	Recommended for SUI management

Conclusion:

Vaginal pessaries are an effective, well-tolerated conservative treatment for SUI. Good symptom control when appropriately fitted and maintained through regular follow-up.

Relevance: High satisfaction and minor complication profile across a large evidence base reinforce pessaries as a recommended first-line conservative option for SUI.

Clinical Studies — International Review & RCT Evidence

Peer-reviewed, PubMed-indexed research directly validating pessary use

Study 8.5: Rantell et al. 2025 — International Narrative Review, 313 Studies

International Urogynaecology Journal 2025;36:533–550 | Published 28 January 2025

Design:

Narrative review by international multidisciplinary group. 540 articles screened; 313 included. Covered fitting success, continuation, outcomes, complications, and evidence gaps.

41–97%	>90%	21–97.7%
Fitting success range across studies	Resolution of vaginal bulge/pressure	Continuation rate range reported

Conclusion:

Pessary use effective across a wide range of patients. Over 90% symptom resolution following successful fitting. Evidence gaps remain in device selection guidance.

Relevance: Largest and most recent international review confirms pessary effectiveness. Emphasises structured follow-up and patient education as critical to successful outcomes.

Study 8.6: Cheung et al. 2016 — Single-Blind RCT, n=276

Obstetrics & Gynaecology 2016;128(1):73–80 | DOI: 10.1097/AOG.0000000000001489

Design:

Women with Stage I–III POP randomised to PFMT alone (n=137) vs PFMT + vaginal pessary (n=139). 12-month follow-up using PFDI & PFIQ questionnaire scores.

PFDI Score (POP domain)	PFIQ Score (POP impact)
Pessary: −29.7	Pessary: −29.0
Control: −4.7	Control: +3.5

p<0.01 for both outcomes | Completion: 95.0% vs 93.4%

Conclusion:

Adding a vaginal pessary to pelvic floor exercises produced significantly greater improvement in prolapse symptoms and quality of life, with similarly low complication rates.

Relevance: This RCT directly validates that vaginal pessary use produces significantly greater POP symptom improvement and quality of life benefit than pelvic floor training alone.

Clinical Studies — Ring vs Gellhorn Pessary Comparison

Direct comparative evidence informing pessary selection

Stidy 8.7: Cundiff et al. 2007 — Randomised Crossover Trial, n=134

American Journal of Obstetrics & Gynaecology 2007;196(4):405.e1–405.e8 | DOI: 10.1016/j.ajog.2007.02.018

Design:

134 women randomised to use ring with support and Gellhorn pessaries for 3 months each. Predominantly postmenopausal with mean age 61, median POP-Q Stage III.

Both	Similar	Choice
Equally effective No significant difference	PFDI & PFIQ improvement both	Based on fit & patient preference

Conclusion:

Both ring with support and Gellhorn pessaries were equally effective in improving prolapse symptoms and quality of life. Choice should be based on fit, anatomy, and comfort.

Relevance: The strongest comparative RCT confirms ring and Gellhorn are equally effective — device selection should be patient-centred rather than based on claimed superiority.

Study 8.8: Yang et al. 2018 — Retrospective Observational Study, 8 Years

PMCID: PMC6096563 | PMID: 29978415 | 8-year clinical dataset

Design:

Retrospective observational study of 8 years of clinical data comparing ring and Gellhorn pessary use in routine practice — fitting success, continuation, and outcomes.

Ring	Gellhorn	Both
First-line choice Easiest self-management	Second-line Advanced prolapse	Effective long-term use

Conclusion:

Ring pessaries used most frequently and best suited to self-management. Gellhorn is the natural second-line choice for more advanced prolapse or after ring failure.

Relevance: 8-year real-world data validates the ring-first clinical pathway — ring pessaries are the practical default choice with Gellhorn as the effective escalation option.

References & Clinical Resources

Clinical Studies Referenced

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7. Cundiff GW, et al. Symptom relief outcomes of a randomized crossover trial of the ring and Gellhorn pessaries. Am J Obstet Gynaecol. 2007;196(4):405.e1–405.e8.

8. Yang JF, et al. Ring and Gellhorn pessaries used in patients with pelvic organ prolapse: a retrospective study of 8 years. PMCID: PMC6096563.

Disclaimer: This document is intended for healthcare professional use only. It does not constitute medical advice. Clinical decisions should be made in accordance with local guidelines and individual patient circumstances.

Portia by Bray — Sizing, Materials & Clinical Guidance

Sizing Guide

Flexible PVC

- 16 sizes available
- 12.5 mm wall thickness
- 50 mm to 110 mm diameter
- Softer construction — preferred for patient comfort and self-management

Rigid Polythene

- 15 sizes available
- 7.5 mm wall thickness
- 50 mm to 100 mm diameter
- More rigid — may provide more secure positioning in some patients

Fitting & Clinical Guidance

Fitting procedure	A simple, non-surgical procedure performed by an HCP following clinical assessment and a painless internal examination
Self-management	In appropriate cases, patients may be supported to self-manage removal and reinsertion under an HCP-led programme
Follow-up	Regular review (every 3–6 months) to assess fit, symptom relief, tissue integrity, and patient satisfaction
Replacement	Maximum 6 months in situ — or earlier if wear, symptoms, or clinical findings indicate the need
Topical oestrogen	Often recommended in postmenopausal women to maintain vaginal mucosal integrity and reduce complication rates

Key Evidence Summary — Why Pessaries Work

All 8 studies confirm safety, efficacy and patient satisfaction

82.8%

Successful fitting
Stage IV POP (Zhou 2024)

>90%

Patient satisfaction
Post fitting (Zhou 2024)

76%

Continence achieved
SUI (Klein 2022)

60%

12-month continuation
POP (Ontario 2021)

Key Clinical Messages

NICE NG123 aligned	Vaginal pessaries recommended as first-line non-surgical option for symptomatic POP
RCT validated	Pessary + PFMT produces significantly greater POP symptom improvement than PFMT alone (Cheung 2016, $p<0.01$)
Ring = first-line	Ring and Gellhorn equally effective (Cundiff 2007 RCT) — ring preferred for ease of self-management (Yang 2018)
Safe long-term	Adverse events decrease with longer-term use; complications manageable with structured follow-up and monitoring
Cost-effective	Health Technology Assessment (Ontario 2021) confirms pessaries are likely cost-effective for both POP and SUI

BRAY GROUP LTD

Portia by Bray

Why Choose Portia by Bray?

Uncomplicated Healthcare

Clinically Validated

8 peer-reviewed studies including RCTs, systematic reviews and a 2025 international consensus review — all confirming pessary effectiveness and safety.

Guideline-Supported

Aligned with NICE NG123, RCOG, BSUG, IUGA, and AUS. First-line conservative recommendation for symptomatic POP.

CE-Marked & MHRA Compliant

Class IIb medical device. CE-marked under Directive 93/42/EEC. UKCA aligned. Manufactured in Britain.

Right Fit for Every Patient

16 PVC sizes · 15 Polythene sizes · Flexible PVC and Rigid Polythene options matched to patient need.

Proven Patient Outcomes

>90% symptom resolution following successful fitting. 82.8% success in Stage IV POP. High patient satisfaction across all studies.


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Bray Group Ltd,
1-5 Regal Way, Faringdon, Oxfordshire SN7 7BX UK
t +44 (0) 1367 240736
e info@bray-healthcare.com
www.bray-healthcare.com

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