

Evaluating *Gugguladi Dhoopana Varti* as an Adjunct to *Khanduchakka* Ointment in Postoperative Anorectal Wounds: A Randomised Controlled Trial Research Protocol

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ABSTRACT

Introduction: Postoperative anorectal wounds commonly arise from surgical procedures performed for conditions such as fissure-in-ano, haemorrhoids, perianal abscess, and fistula-in-ano. Due to persistent infection, pain, and delayed wound healing are associated with the complex anatomical site, their management remains challenging. *Khanduchakka* (*Ehretia laevis* Roxb.) is a herbal plant, also known as *Ajan Vruksha*, and is traditionally used for its wound healing and analgesic medicinal properties. *Gugguladi Dhoopana Varti* (fumigation therapy) also has wound-healing, antimicrobial, and anti-inflammatory properties.

Need of the study: *Dhoopana* is described in classical Ayurvedic texts as an important modality for wound management due to its potential antimicrobial and healing properties. However, its application in the management of postoperative wounds has not been adequately evaluated through systematic clinical studies. There is need to evaluate the efficacy and safety of *dhoopana* when applied with *Khanduchakka* ointment in postoperative

wound management, thereby generating clinical evidence to support its incorporation into contemporary practice.

Aim: To evaluate the efficacy of adjunct effect of *Gugguladi Dhoopana Varti* with topical *Khanduchakka* ointment versus topical *Khanduchakka* ointment.

Materials and Methods: A randomised controlled trial will be conducted in Mahatma Gandhi Ayurveda College Hospital and Research Centre (MGACHRC), Salod Hirapur (H), Maharashtra, India, from December 2024 to June 2026, in which 60 patients will be enrolled. In the control group, topical *Khanduchakka* ointment will be applied twice a day for seven days, and in the interventional group, *Gugguladi Dhoopana Varti* with topical *Khanduchakka* ointment will be applied for 10 minutes twice a day for seven days over postoperative anorectal wounds. The parameters like wound bed, *gandha* or smell, discharge, pain, and itching will be evaluated. One-way Analysis of Variance (ANOVA), paired and unpaired t-tests, and the Chi-square (χ^2) test will be applied for statistical analysis. A p-value of <0.05 will be considered statistically significant.

Keywords: Ayurveda, Chemically induced, Drug therapy, Pharmacology, Surgical wound

INTRODUCTION

Delayed wound healing associated with pain is one of the most commonly observed complications after anorectal surgeries [1,2]. This increases patient discomfort postsurgery and significantly affects their quality of life. Postoperative wound management typically incorporates bioactive components such as growth factors, antibacterial agents, and moisturisers. These components aid in wound healing by reducing infection risk and minimising reliance on antiseptic properties [3]. Ayurvedic fumigation, known as *dhoopana Karma*, is recognised as an effective modality for sterilisation and disinfection [4]. Classical Ayurvedic texts describe *dhoopana* as an essential component of *Raksha Karma* (protective practices) [5].

Its therapeutic potential in wound management has also been mentioned under *Vrana Chikitsa* (wound care) [6]. *Gugguladi Dhoopana Varti* [7] and *E. laevis* Roxb. has shown excellent wound-healing, antimicrobial, analgesic, antioxidant, anti-inflammatory, and immunomodulatory properties [8]. These properties are beneficial in reducing postoperative pain, minimising wound exudation, and promoting rapid wound healing [9]. Current research trends, however, have largely focused on costly synthetic dressing materials, limiting exploration of novel herbal fumigation methods. Existing literature supports the use of herbal formulations and *dhoopana* [10] as topical modalities in the management of postoperative anorectal wounds. Combining *dhoopana* therapy

with topical *Khanduchakka* ointment may provide additional benefits through a synergistic effect.

This study uniquely addresses the specialised healing challenges associated with anorectal surgical wounds using fumigation therapy. Therefore, this research aims to evaluate the application of an active wound dressing following anorectal surgery, specifically assessing its impact on postoperative wound healing rate. Considering the complex nature of anorectal wounds, it is essential to explore effective, safe, and promising treatment modalities within alternative medicine to promote early recovery. In the current Indian context, where no comparative studies are available, the present study seeks to evaluate the newer modality, *Gugguladi Dhoopana Varti* with topical *Khanduchakka* ointment versus topical *Khanduchakka* ointment in the management of postoperative anorectal wounds.

REVIEW OF LITERATURE

Anorectal wounds following surgery are typically classified as clean-contaminated or contaminated and are highly prone to infection due to faecal contamination [11]. Traditional medicine has been utilised in the management of wounds, with most therapies being plant-based. Contemporary studies provide evidence suggestive of efficacy for their use in clinical practice and indicate a beneficial effect on wound healing [12]. Standard wound care practices, including appropriate dressing and maintenance of hygiene, remain

the cornerstone in the management of postoperative wounds [13]. Several preclinical studies have demonstrated the wound-healing potential of *E. laevis* Roxb [14]. Moreover, *Dhoopana* is recognised as a unique and effective therapeutic modality for wound fumigation, with accumulating evidence supporting its efficacy [15].

A preclinical study evaluated *E. laevis* Roxb. for its antioxidant and antibacterial analysis. In-vitro assays showed concentration-dependent antioxidant activity (10-100 µg/mL), with the ethyl acetate extract demonstrating better efficacy than the chloroform extract, as indicated by lower half maximal inhibitory concentration values (64.6 µg/mL for 2,2-diphenyl-1-picrylhydrazyl assay and 49.6 µg/mL for superoxide radical scavenging assay). Although both extracts exhibited notable free radical scavenging activity, their effects were lower than standard antioxidants such as quercetin and ascorbic acid. Antibacterial studies revealed broad-spectrum activity against Gram-positive and Gram-negative bacteria, with the ethyl acetate extract showing higher potency, including a maximum zone of inhibition of 24 mm against *Pseudomonas aeruginosa*. The activity is concentration-dependent, with minimum inhibitory concentration values of 12.5-25 µg/mL for the ethyl acetate extract and 25-50 µg/mL for the chloroform extract, indicating superior efficacy of the ethyl acetate fraction [16].

Another experimental study evaluated the wound-healing potential of *E. laevis* Roxb. using histological evidence obtained from time-graded biopsies of wound sites following the application of *E. laevis* Roxb. leaf paste, in comparison with phenytoin paste. The findings indicated that *E. laevis* Roxb. promoted better collagen fibre synthesis and orientation compared to phenytoin. However, a higher quantity of mature collagen was observed on the 15th day in the phenytoin-treated group. No significant differences in scar formation were noted on the 7th day of biopsy. Notably, epithelialisation on the 15th day was greater in the *E. laevis* Roxb. group (98%) compared to the phenytoin group (92%). The presence of collagen on the 15th day was moderate in the *E. laevis* Roxb. treated group, whereas it was comparatively higher in the phenytoin group [17].

Limited clinical evidence is available on *Dhoopana*. The use of *dhoopana* in wound management has been described in classical Ayurvedic literature, particularly in the *Sushruta Samhita* [18]. Recent literature suggests that *dhoopana* is a safe and unique modality in wound healing and may serve as an adjunct in the management of postoperative anorectal wounds.

A case series involving three patients evaluated the efficacy of *Dhoopana Karma* with *Gugguladi Dravya* in postoperative fistulectomy wounds and demonstrated accelerated wound healing characterised by improved wound bed status, reduction in slough, and better wound hygiene. It also showed a marked decrease in pain, discharge, and unpleasant odour, indicating effective control of local infection and inflammation. Additionally, the intervention is found to be safe, well-tolerated, and free from adverse effects, highlighting its potential as a beneficial adjuvant modality in the postoperative management of anorectal wounds [19].

An experimental study was conducted in the Microbiology Unit of the Central Laboratory at the National Institute of Ayurveda, Jaipur, to evaluate the antimicrobial efficacy of *dhoopana* using *Sarshapadi Churna*. The results were found to be satisfactory, as no microbial growth was observed after 10 days of fumigation, indicating a significant antimicrobial effect of the intervention [20].

These findings suggest that both *E. laevis* Roxb. and *dhoopana* may have potential as wound-healing agents, and their synergistic action may complement each other. Further research is required to evaluate their efficacy and safety for clinical applications in postoperative anorectal wounds. Thus, this study aims to evaluate the efficacy of adjunct effect of *Gugguladi Dhoopana Varti* with topical *Khanduchakka* ointment versus topical *Khanduchakka* ointment in the management of postoperative anorectal wounds.

Primary objectives:

- To study the efficacy of healing effect of *Gugguladi Dhoopana Varti* with topical *Khanduchakka* ointment in the management of postoperative anorectal wounds.
- To study the efficacy of healing effect of *Khanduchakka* ointment in the management of postoperative anorectal wounds.

Secondary objectives: To compare the efficacy of the healing effect of *Gugguladi Dhoopana Varti* with topical *Khanduchakka* ointment and *Khanduchakka* ointment in the management of postoperative anorectal wounds.

Null hypothesis: *Gugguladi Dhoopana Varti* with topical *Khanduchakka* ointment is not more efficacious than *Khanduchakka* ointment in the management of postoperative anorectal wounds.

Alternate hypothesis: *Gugguladi Dhoopana Varti* with topical *Khanduchakka* ointment is more efficacious than *Khanduchakka* ointment in the management of postoperative anorectal wounds.

MATERIALS AND METHODS

A single-blinded, double-arm randomised controlled trial will be conducted at Mahatma Gandhi Ayurveda Hospital, Wardha, from December 2024 to June 2026. Participants willing to enroll in the study will be considered upon providing informed written consent. The proposed study has clearance under IEC number MGACHRC/IEC/June-2024/819. Registration for the trial is recorded under CTRI/2025/03/081856, dated 06.03.2025.

Inclusion criteria:

- Patients presenting with postoperative anorectal wounds including fissure-in-ano, haemorrhoids, perianal abscess, and fistula-in-ano;
- Age between 18 and 60 years, regardless of gender, occupation, and socio-economic status;
- Individuals ready to provide informed consent and prepared to adhere to clear directions.

Exclusion criteria:

- Individuals below 18 years or above 60 years of age will be excluded from the study;
- Patients diagnosed with asthma or diabetes mellitus will also be excluded;
- Additionally, known cases of immunocompromised conditions such as tuberculosis, Human Immunodeficiency Virus (HIV) infection, hepatitis B, and sexually transmitted diseases will not be included;
- Participants with a known history of malignancy will likewise be excluded from the study.

Sample size calculation:

$$n = \frac{2(Z_{\alpha/2} + Z_{\beta})^2 \sigma_p^2}{\delta^2}$$

In the absence of prior randomised controlled trials evaluating *Gugguladi Dhoopana Varti* and *Khanduchakka* ointment in postoperative anorectal wound management, estimates were derived from the most comparable published study assessing topical intervention for postoperative anorectal pain. The study reported a mean VAS score of 2.96 ± 0.98 in the control group and 1.92 ± 0.88 in the intervention group [21].

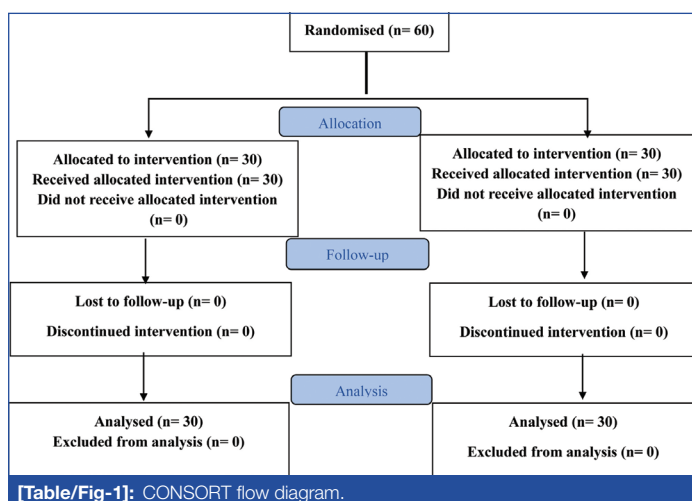
The following assumptions were used:

- Level of significance (α) = 0.05 (two-tailed)
- Power ($1-\beta$) = 80%
- $Z_{\alpha/2} = 1.96$
- $Z_{\beta} = 0.842$
- Expected mean difference (δ) = 1.04
- Pooled standard deviation (σ_p) = 0.931

Based on these parameters, the minimum required sample size is calculated to be 13 participants per group. To compensate for a possible 7% dropout rate, the adjusted sample size is:

$$n = \frac{13}{1 - 0.07} = 13.9 \approx 14 \text{ participants per group}$$

However, considering the exploratory nature of the study, lack of direct prior evidence for the studied Ayurvedic interventions, and to enhance statistical robustness which will ensure adequate power for secondary outcome measures (such as wound healing, oedema, and discharge), the final sample size is increased to 30 participants per group. Thus, the total sample size for the study is 60 participants, with 30 participants allocated to each group with allocation ratio 1:1 [Table/Fig-1].



Participants will be enlisted from the *Shalyatantra* outpatient department, Wardha. Randomisation will be performed using a computer-generated randomisation table, which ensured an unbiased allocation of participants into two groups. The allocation sequence will be concealed in Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE). The recruitment of patients will be conducted sequentially, adding one participant at a time until the predetermined target sample size is achieved.

Participants expressing a desire to discontinue during the trial will be allowed to withdraw and will be replaced accordingly. Additionally, if a patient develops an acute illness not related to the intervention during the trial that could impact the study, the affected participant will be withdrawn and replaced.

The *dhoopana* procedure will be performed using a prepared *varti* under controlled conditions, and appropriate precautions will be taken to minimise exposure to excessive smoke. The size of the *varti* will be adjusted according to the wound requirement to avoid excessive smoke generation. Patients will be carefully monitored for any adverse events such as smoke intolerance, allergic reactions, respiratory discomfort, or local irritation at the wound site. In case any such reaction occurs, the procedure will be immediately discontinued, and appropriate medical management will be provided. All adverse events, if any, will be properly documented and managed accordingly.

All patients will undergo standardised procedures, including lateral internal sphincterotomy, excision of the sentinel tag for fissure-in-ano, Milligan-Morgan haemorrhoidectomy, incision, and drainage for perianal abscess, and fistulotomy or fistulectomy with seton or *ksharasutra* (Ayurvedic seton) for fistula-in-ano. All operations will be performed under spinal anaesthesia.

For the control treatment, Group A, which includes the topical application of *Khanduchakka* ointment twice a day for seven days, will be administered along with intravenous antibiotics for three days postsurgery. Oral antibiotics, analgesics, and laxatives will be started

on postoperative day 4. For the interventional treatment, Group B, which includes the topical application of *Khanduchakka* ointment with *Gugguladi Dhoopana Varti* for 10 minutes twice a day for seven days, will be administered along with intravenous antibiotics for three days postsurgery. Oral antibiotics, analgesics, and laxatives will be started on postoperative day 4.

Follow-up will be done on the 15th and 30th day for both groups.

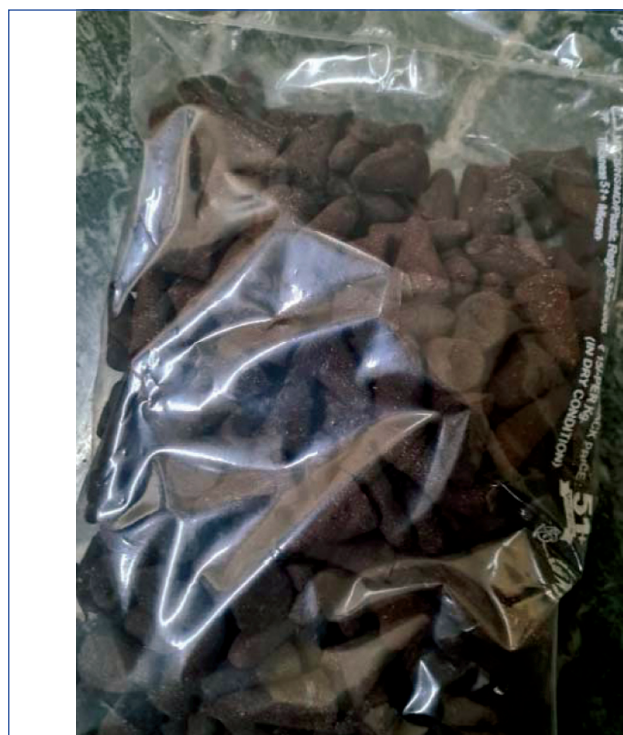
The medication will be formulated at Dattatray Ayurveda Rasashala within the Mahatma Gandhi Ayurvedic College Hospital and Research Centre in Wardha, which holds a GMP certificate and operates as an Ayurvedic pharmacy.

Collection and procurement of the drugs: The raw materials required for the preparation of *Gugguladi Dhoopana Varti* and *Khanduchakka* ointment will be procured from the local market, and their authentication will be carried out by the Department of Dravyaguna, Wardha.

Preparation of *Gugguladi Dhoopana Varti*: The obtained raw materials [Table/Fig-2] will be shade-dried and ground into fine powder separately using a mechanical grinder, then sieved through a mesh and stored in airtight containers. The fine powders of all the ingredients will be mixed to obtain a homogeneous mixture. This mixture will be dissolved in a sufficient quantity of distilled water, and *varti* (sticks) of uniform size and thickness will be prepared as per the principles of *Varti Kalpana*. The prepared *varti* will be designated as *Gugguladi Dhoopana Varti* and will be stored appropriately [Table/Fig-3].

Sr. No.	Composition	Quantity
1	<i>Guggul (Commiphora wightii)</i>	14.28%
2	<i>Agaru (Aquilaria agallocha)</i>	14.28%
3	<i>Sarjarasa (Vateria indica)</i>	14.28%
4	<i>Vacha (Acorus calamus)</i>	14.28%
5	<i>Sarshap (Brassica campestris)</i>	14.28%
6	<i>Nimba (Azadirachta indica)</i>	14.28%
7	<i>Saindhava Lavan (Rock salt)</i>	14.28%
8	Distilled water	Q.S.

[Table/Fig-2]: Composition of *Gugguladi Dhoopana Varti*.



[Table/Fig-3]: Formulation of *Gugguladi Dhoopana Varti*.

Analytical study of Gugguladi Dhoopana Varti: Evaluation of organoleptic parameters such as colour, odour, and consistency will be carried out through visual observation. Evaluation of physicochemical parameters such as loss on drying, pH, water-soluble extract, and methanol-soluble extract will also be performed.

Preparation of Khanduchakka ointment

Fresh plants of *E. laevis* Roxb. will be collected from the campus of the study Institute and will be authenticated by the Department of Dravyaguna (Pharmacology and Materia Medica - Herbal).

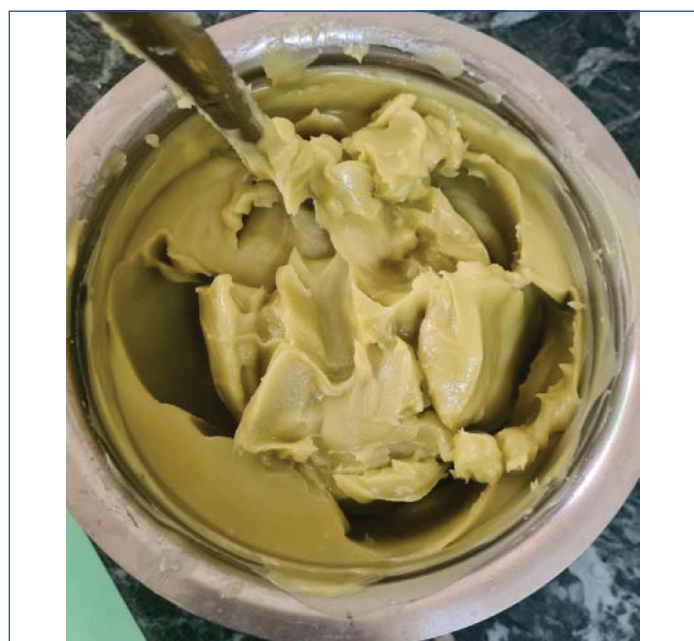
Preparation of *E. laevis* Roxb. decoction extract (Kwatha): The *E. laevis* Roxb. decoction extract is prepared by combining one part of fresh *E. laevis* Roxb. plants with 16 parts of water, resulting in a proportion of 1/8th part for the final product through heat. This corresponds to using one kg of *E. laevis* Roxb. and 16 litres of water, yielding a total quantity of two litres for the *E. laevis* Roxb. decoction extract [22].

Preparation of *E. laevis* Roxb. paste (Kalka): A paste of fresh *E. laevis* Roxb. plants with a little water are created using a mortar and pestle, resulting in the formation of a paste. A paste weighing 125 gm will be prepared [23].

Preparation of *E. laevis* Roxb. Oil (Tail): The *E. laevis* Roxb. oil will be formulated by combining one part paste, four parts *Sesamum indicum* oil (*Til tail*) and 16 parts decoction extract, resulting in a proportion of 1/4th part for the final product through heat. This corresponds to using 125 gm of paste, 500 gm of *S. indicum* oil and two litres of decoction extract, yielding a total quantity of 490 gm for the *E. laevis* Roxb. oil [24]. The ointment base will be prepared by blending the following ingredients: 66.7% *E. laevis* Roxb. oil, 23.3% white beeswax, 5% stearic acid, and 5% cetostearyl alcohol, as shown in [Table/Fig-4]. The mixture will be subjected to continuous heating and trituration until a uniform consistency is achieved, as shown in [Table/Fig-5]. The formulated ointment will be stored and will be used for the trial.

S. No.	Composition	Quantity
1	<i>E. laevis</i> Roxb. oil	66.7%
2	White beeswax	23.3%
3	Stearic acid	5%
4	Cetostearyl alcohol	5%

[Table/Fig-4]: Composition of Khanduchakka ointment.



[Table/Fig-5]: Formulation of Khanduchakka ointment.

Analytical study of Khanduchakka ointment: Evaluation of organoleptic parameters such as colour, odour, and texture will be carried out through visual observation. Evaluation of physicochemical parameters such as determination of loss on drying at 105°C, determination of pH value, spreadability test, rancidity test, determination of iodine value and peroxide value, evaluation of microbiological contamination (growth), and long-term stability, will be performed.

OUTCOMES

Primary outcome: Assessment of the wound bed or *Vranatala* will be performed using a structured grading tool based on the TIME Principle/framework (T- Tissue, I- Infection, M- Moisture, E- Edge). In this tool, T (Tissue) is assessed by the presence and quality of granulation tissue, I (Infection) by the presence of slough, M (Moisture) by the amount of wound discharge (slight, more, or profuse), and E (Edge) by the nature of wound margins (smooth or irregular). The grading criteria are as follows: 0 - smooth, irregular and with healthy granulation tissue; 1 - smooth, irregular, slight discharge and less granulation tissue; 2 - rough, regular wet with more discharge and having slough; 3 - rough, irregular with profuse discharge and much slough [25].

Secondary outcome: Gandha (Smell) will be evaluated using a grading assessment tool [Table/Fig-6] [26].

S. No.	Criteria	Score
1.	No smell	0
2.	Minimum bad smell	1
3.	Moderate bad smell	2
4.	Unpleasant	3
5.	Foul smell	4

[Table/Fig-6]: Assessment tool for Gandha (Smell) [26].

Discharge or exudate type will be assessed as follows: 0 - none; 1 - bloody; 2 - serosanguineous, thin, watery, pale, red/pink; 3 - serous, thin, watery, clear; 4 - purulent, thin or thick, opaque, tan/yellow, with or without odour [27].

Pain will be assessed using the Visual Analogue Scale (VAS) [28].

Itching will be assessed using the Peak Pruritus Numerical Rating Scale: 0 - no itch or disturbance; 10 - worst imaginable itch or disturbance [29]. The peak pruritus Numeric Rating Scale (NRS) is a single-item scale used to assess the severity of itching. It evaluates the "worst" itch experienced by the patient over the previous 24 hours.

Improvements in the outcomes, including wound bed, granulation tissue, smell, discharge, formation, pain and itching, are anticipated as enhancements in the wound healing. Evaluation of primary outcome parameters like wound bed, and secondary outcome parameters like smell, discharge, pain, and itching assessment will be conducted on days 1, 3, 5, and the 7th day. Follow-up assessments are scheduled for the 15th and 30th day.

STATISTICAL ANALYSIS

Statistical analysis will be conducted using Statistical Package for the Social Sciences (SPSS) statistical software version 29.0. ANOVA test will be applied within the groups for the gradations of each variable. The pairwise comparison will be carried out using the t-test, assessing changes in wound bed, smell, discharge, pain, and itching over time. The count data will be reported as a percentage, and the comparison will be carried out using the Chi-square (χ^2) test. A p-value of <0.05 will be considered statistically significant.

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