



## New Invention

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### ADR KSHARSUTRA KIT: A BREAKTHROUGH IN THE STANDARDIZATION OF KSHARSUTRA

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#### ABSTRACT

'Ksharsutra' can be defined as an Ayurvedic medicated thread coated with herbal alkaline drugs. 'Ksharsutra therapy' has been described as a treatment of choice for the treatment of fistula-in-ano due to low recurrence rate. However, Ksharsutra procedure is not yet globally accepted basically due to lack of standardization and poor acceptability by modern surgeons due to lack of training and fear of complications. Standardization of 'Ksharsutra' requires standardization in preparation process and quality standards including its packaging, storage, labeling and developing scientific parameters for maintaining its uniform coating, pH, microbial check etc. To overcome all these limitations, 'ADR- Ksharsutra Kit' which is a disposable, non traumatic 'Ksharsutra Carrier cum Application device' made up of High Density Poly Ethelene was invented by me. The Ksharsutra prepared as per ICMR guidelines after UV treatment, is embedded in the instrument and is kept in airtight silver foil sachet and sealed. The method of 'ADR-Ksharsutra' application is simple and time conserving. The tip of the 'ADR-Ksharsutra Carrier cum Application device' is introduced in the external opening and allowed to follow the track up to the internal opening situated in the anal canal. Once the tip comes out through the internal opening, cap is removed and the Ksharsutra is held and then instrument is withdrawn from outside opening. By doing this, the embedded Ksharsutra is automatically placed in the fistula track whose two ends are tied together. 'ADR-Ksharsutra' has truly made the entire procedure very smooth. No probe is required in the procedure and Ksharsutra kept in the instrument remains sterile as well. Hence, this 'Ksharsutra carrier cum application device' will be helpful in Globalization of Ksharsutra technique for fistula ablation.

**Keywords:** Ksharsutra, Fistula in ano, Sushrut samhita, Bhagandar, Nadvirana chikitsa

#### INTRODUCTION

'Ksharsutra' is a medicated device or an Ayurvedic cutting set on or coated thread prepared by repeated smearing of alkali of *Achyranthes aspera* plant, latex of *Euphorbia nerifolia* and turmeric powder on a 20 zero Barber's surgical linen thread. The material, possess proteolysis, caustic and anti-septic properties and promotes simultaneous cutting and healing.

'Ksharsutra' is para surgical procedure mainly employed in Fistula-in-ano or Bhagandar. Though several operative procedures have also been described for the treatment of fistula-in-ano but 'Ksharsutra' has been advocated as a treatment of choice by ancient Ayurvedic scholars.

The Ksharsutra is inserted into the fistulous tract under suitable anesthesia with the help of a specially designed probe and is replaced with a newer Ksharsutra on every 7<sup>th</sup> day by Ride and Rail method till the fistula is completely healed up.

Validation was done by ICMR through randomized, double blind, multi-centric clinical trials which revealed that the recurrence rate in patients of fistula-in-ano treated with Ksharsutra therapy was just 4 percent while about 11 percent in patients treated with surgery.

This unique 'Ksharsutra procedure' is yet not globally accepted basically due to lack of standardization in the Ksharsutra preparation process and poor acceptability by modern surgeons due to lack of training and fear of complications.

Basically, standardization of 'Ksharsutra' requires standardization in preparation process and quality standards including packaging, storage, labeling and developing scientific parameters for maintaining its

uniform coating, pH, microbial check etc. Some of these standards are incorporated in Ayurvedic Pharmacopoeia of India (API).

However, I believe that there is still lot of scope for standardization of 'Ksharsutra' especially to make it more user friendly and acceptable even by Modern surgeons. Keeping this in mind I have invented 'ADR Ksharsutra Kit' which is an unique disposable, non traumatic 'Ksharsutra Carrier cum Application device' having 'Sterilized embedded Ksharsutra'.

#### MATERIALS AND METHODS

##### Method of preparation of Ksharsutra

The surgical linen thread of size 20 is spread throughout the length and breadth of the hanger of the specially designed cabinet known as Ksharsutra Cabinet. The thread is smeared with latex, uniformly and carefully, all around the thread, with the help of clean gauze piece soaked in the Snuhi Kshira. After smearing all the threads on the hanger, the hanger is placed in the Ksharsutra cabinet for drying.

After eleven such coatings with Snuhi Kshira, 12<sup>th</sup> coating of Snuhi Kshira is done and wet thread is then passed through a heap of finely powdered Apamarga Kshara immediately. After smearing all the threads with Kshar, the hanger is shaken gently allowing the excess particles of Kshar to fall down. This process is repeated till seven coatings of Snuhi Kshira and Apamarga Kshara is achieved, thus completing 18 coatings on the thread. The remaining 3 coatings are performed with Snuhi Kshira and fine powder of Haridra as per the above said procedure making a total 21 coatings on the thread.

Finally, the ultraviolet lamp of the Ksharsutra cabinet is put on daily for 20-30 minutes to maintain sterile atmosphere right from the 1<sup>st</sup> day of coating. The threads of a uniform length i.e. 30-32 cm are cut for packing. Further, the sealed Glass Tubes/ air tight container are kept in a cabinet and exposed to ultraviolet radiation.

### Physico-chemical characters of standardized Ksharsutra

Length of thread: 29 to 31 cm and Weight: 0.9 to 1 g  
 Diameter/Thickness: 1.75 to 2.0 mm  
 Tensile Strength: Breaking load not less than 5 kg,  
 Loss on drying at 105<sup>o</sup>C: Not more than 5 per cent  
 Water-soluble extractive: Not less than 85 per cent  
 Hexane-soluble extractive: Not less than 6 per cent  
 Sulphated ash: 80 to 82 per cent  
 pH (1% aqueous solution): 9.3 to 10.5  
 Total alkalies (calculated as carbonates): Not less than 20% w/w

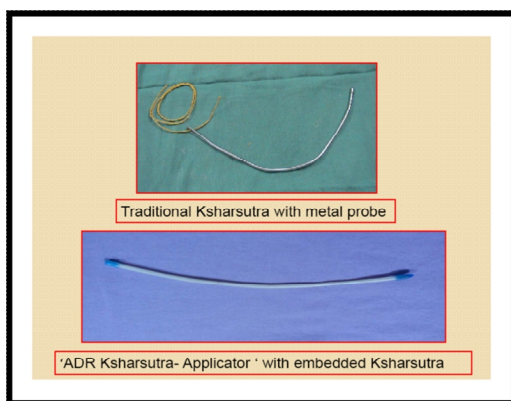


Figure 1: Traditional Ksharsutra (with metal probe) and 'Ksharsutra Carrier cum Application device'



Figure 2: ADR Ksharsutra-Kit

### Advantages of Ksharsutra

- Ksharsutra is a chemical fistulectomy rather than surgical fistulectomy.
- It's a simple, safe and sure minimum invasive para surgical treatment for fistula in ano with lower recurrence ranging between 3 to 5% only as it destroys residual anal glands.
- Fully Ayurvedic, cost effective management, can be performed in minor O.T. condition.

- No damage to anal sphincter due to simultaneous cutting and healing hence, no chance of incontinence.
- It's an ambulatory procedure hence, no hospitalization required.
- Minimum scar formation at the site of wound.

### Ksharsutra Carrier cum Application device

The 'Ksharsutra Carrier cum Application device' is malleable tube made up of HDPE (High Density Poly Ethylene material approved by FDA) having inner diameter of 1.8 mm and outer diameter of 3 mm. It has front and rear caps. The tip of front cap is somewhat conical shape whereas, rear cap is flat. The Ksharsutra prepared by Standard method having diameter/thickness around 1.75mm is placed in the sterile 'Ksharsutra Applicator' (disposable malleable tube) and then front and rear caps are fixed. The Ksharsutra after UV treatment is embedded in the instrument is kept in airtight silver foil sachet and sealed. Two more sterile Ksharsutras (kept in polythene packets) are also separately provided with the same kit. The physico-chemical Characters of Ksharsutra, its indication, manufacturing details along with its expiry date etc. are labeled properly.

### RESULT AND DISCUSSION

Ksharsutra Technique is radically practiced in India and with some modification this technique exists even in Sri Lanka, Nepal, Japan and China. ICMR and CCIM are taking lot of efforts to propagate this Ksharsutra procedure but main hurdles in its global acceptability are:

- Ksharsutra practices are limited mainly to the Ayurved teaching Institutes.
  - There is always fear of complication due to doubtful sterilization of available Ksharsutra.
  - No uniformity and standardization in Probe design.
  - The present metal probe though malleable is quite hard and not user friendly. So, there remains possibility of iatrogenic trauma, injury to inner structures, false track formation and possibility of slippage and contamination of Ksharsutra during the procedure.
  - No assurance regarding following ICMR guidelines during preparation of available Ksharsutra .
  - Packaging quality is of available Ksharsutra is poor. The physico-chemical characters of Ksharsutra, its indication, manufacturing details along with its expiry date, retail prize etc. are not labeled properly on the packet.
  - No company or pharmacy is manufacturing or distributing standardized Ksharsutra. Hence Ksharsutra is not readily available at medical shops.
- To overcome all above limitations of present Ksharsutra I have invented 'ADR Ksharsutra -Kit' which is unique disposable, non traumatic 'Ksharsutra Carrier cum Application device' . We have used this 'ADR Ksharsutra -Kit' in established fistulas and found it very easy to deliver Ksharsutra in fistula track. The procedure is truly time conserving, thus will be useful in Globalization of Ksharsutra procedure for the ablation of fistula in ano.

### **Method of Application**

'Ksharsutra Carrier cum Application device' has truly made the entire procedure very smooth. After, giving the patient suitable anesthesia and position firstly, fistula track is identified. After that, anal canal is visualized with the help of Sim's speculum and then, tip of the 'Ksharsutra Carrier cum Application device' is introduced in the external opening and allowed to follow the track up to the internal opening situated in the anal canal. Once the tip comes out through the internal opening, cap is removed and the Ksharsutra is firmly held with the mosquito artery forceps. After this 'ADR-Ksharsutra applicator' is withdrawn (taken back) from outside opening. By doing this, the embedded Ksharsutra is automatically placed in the fistula track whose two ends are tied together.

### **CONCLUSION**

'ADR-Ksharsutra Kit' is a sterile disposable, non traumatic 'Ksharsutra Carrier cum Application device' which is user friendly device and application procedure is time conserving. No instrument (Probe) is required. Minimum tissue handling makes it an ambulatory procedure in true sense. 'Ksharsutra' used in 'ADR-Ksharsutra Kit' is prepared as per ICMR guidelines. The physico- chemical characters of Ksharsutra, its indication, manufacturing details along with its expiry date, Maximum Retail Price (MRP) etc. are labeled properly in attractive airtight sachet. 'ADR Ksharsutra-Kit' will be helpful in standardization and globalization of Ksharsutra technique for Fistula Ablation and acceptable even to modern surgeons.

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