



## E.T.O STERILIZATION OF PREPARED STANDARD KSHARSUTRA AND MOCHRAS COATED KSHARSUTRA

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### ABSTRACT

Ksharasutra is para-surgical procedure effectively used in the management of Ano rectal diseases. In this research study snuhi letax was replaced by Mochras resin, thus new Mochras coated ksharsutra was made to easily available in market. **Aim:** 1.To promote healing process and prevent recurrence of disease.2.To make economical, easily available and ETO sterile ksharsutra. **Material & Method:** Standard Kshar Sutra (Snuhi Apamarga Ksharsutra) made of Barbour's linen thread No.20, Snuhi Ksheer, Apamarga Kshar,Haridra Powder. Mochras coated Kshar Sutra (Mochras Apamarga ksharsutra) made of Barbour's linen thread No.20, Mochras Resin, Distil water, Apamarga Kshar, Haridra Powder. **Result & Conclusion:** Mochras i.e gum resin of salmalia Malabarica is easily available drug, can keep for longer period ,very safe to use. Mochras which is astringent<sup>1</sup> in nature checks abnormal secretions, discharge, microbial growth<sup>2</sup>, bleeding and pain<sup>3</sup>. It pacifies kapha, pitta & Rakta, relieves bleeding disorder and burning sensation<sup>4</sup>.It promote wound healing<sup>5</sup>, good for binding purpose

**KEYWORDS :** Ksharsutra, Mochras resin, Mochras coated Ksharasutra. ETO Sterilization

### INTRODUCTION

Ksharasutra is para-surgical procedure which is found more effective in the management of fistula-in-ano.Ksharsutra is basically a medicated thread having the coating of alkali material called Kshara. Kshara is prepared by using the ash of plant. Ksharasutra is routinely prepared with Snuhi Ksheera (latex), Apamarga Kshara and Haridra powder. In conventional method collection of Snuhi latex is time consuming and laborious. Thus I make up my mind to work on preparation of new, advanced, remodeled and unused ksharsutra i.e Mochras coated ksharsutra for ligation. Here snuhi ksheer was replaced by Mochras resin. Mochras i.e gum resin of salmalia Malabarica is easily available drug, can keep for longer period ,very safe to use. Mochras which is astringent<sup>1</sup> in nature checks abnormal secretions, discharge, microbial growth<sup>2</sup>, bleeding and pain<sup>3</sup>. It pacifies kapha, pitta & Rakta, relieves bleeding disorder and burning sensation<sup>4</sup>.It promote wound healing<sup>5</sup>, good for binding purpose and used to reduces the symptoms & side effect of kshar karm i.e pain, itching, burning sensation, tenderness, discharge ect. while snuhi sheer is difficult to available, can't keep for longer period, dried fast, unsafe and many side effects

Material required for Ksharsutra preparation –

#### 1. Standard Kshar Sutra (Snuhi Apamarga Ksharsutra)

1. Barbour's linen thread No.20
2. Snuhi Ksheer
3. Apamarga Kshar
4. Haridra Powder

#### 2. Mochras coated Kshar Sutra (Mochras Apamarga ksharsutra)

1. Barbour's linen thread No.20.
  2. Mochras Resin
  3. Distil water
  4. Apamarga Kshar
  5. Haridra Powder
- Ksharsutra cabinet.
  - Ksharsutra hangers.
  - Sterilized poly bags.
  - Sterile Gauze piece.
  - Sterile Gloves.
  - Sterile Mask and Cap.
  - Sterile syringe.
  - Sterile plastic utensile and spoon.

#### 1. Standard Kshar Sutra (Snuhi Apamarga Ksharsutra)

- Method of Preparation:
  - Firstly surgical Barbour's linen thread No.20 was spread throughout the length of Ksharsutra hangers.
  - Each thread on the hanger was then smeared with freshly collected snuhi ksheera with the help of sterile gauze piece after wearing sterilized gloves in both hands.
  - Thread was sterile by Dhupana dravya and dried under fan in Ksharsutra manufacturing room.
  - The process is repeated for 11 days. On 12<sup>th</sup> day , after smearing of snuhi ksheera, the thread was coated with Apamarga kshar(collected from market).
  - The same procedure was repeated for 7 days. On 19<sup>th</sup> day , after smearing snuhi ksheera over the thread ,fine powder of Haridra churna(by grinding dried rhizome)coated over it.
  - The final three coating is done by the same procedure. Every efforts is made to maintain the hygienicity in the whole procedure.

After 21 days and exposure to Dhupana dravya, each thread from the hangers is cut out with a range of 1c.m.and sealed it in sterilized air tight poly bags.

#### 2. Mochras Coated Kshar Sutra (Mochras Apamarga Ksharsutra)

- Method of Preparation:
  - The method is same as preparation of Snuhi Apamarga Ksharsutra, except instead of Snuhi ksheera, Mochras solution was used.
  - To get semi liquid form of Mochras gum resin(collected from market), 1 part of mochras powder(5gm)was added in 2 part of distill water(10ml) & stir well so that it becomes pure & of desired consistancy.
  - Surgical Barbour's thread No.20 was tied though length on hanger.
  - The Mochras solution was smeared on thread and hanger was dried under fan.
  - The process repeated for 11 days, on 12<sup>th</sup> day again, the thread was smeared with Mochras solution & then coated with fine powder Apamarga kshar and then dried.
  - The same procedure was repeated 7 days. On 19<sup>th</sup> day the thread was smeared with Mochras solution and fine

powder of Haridra churna coated over it and dried.

- The procedure was repeated for 3 days and dried.
- Prepared both Ksharsutra were kept in Ksharsutra cabinet for 12 hr. for 2 days under U.V. light radiation for sterilization.
- Then Ksharsutra was kept in air tight poly bags under proper hygiene using fumigate room,sterile gloves, mask and cap.

**Drug Review Method Of Preparation Of Mochras Ksharasutra**

Ingredients of Mochras ksharsutra	Sr. No.	Mochras Ksharasutra	No. of Coatings
Barber's Surgical thread linen no.20	1	Mochras	11
Mochras resin (Gum of Salmalia Malabarica)	2	Mochras + Apamarga Kshar	7
Apamarga kshar (Achyranthus Aspera)	3	Mochras + Haridra Churna	3
Haldi powder (Curcuma Longa)	4	Total	21

**Material Required For Ksharsutra Preparation:**



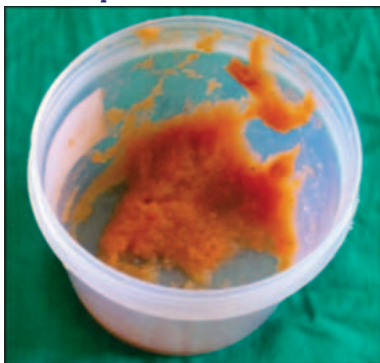
1. Barbour's Thread 2. Snuhi Ksheer 3. Apamarga Kshar 4. Haridra Powder



1. Barbour's Thread 2. Mochras Powder 3. Apamarga Kshar 4. Haridra Powder



**Instrument/tools Required**



**Semi Liquid Form Of Mochras Resin**

**Preparation of Ksharsutra**



**Coating The Thread With Snuhi Ksheer/mochras, Apamarga Kshar & Haridra**

**Prepared Ksharsutra:**



**Standard Ksharsutra**

**Mochras Ksharsutra**

**❖ Sterilization**

Sterilization is a process by which freeing an article, a surface or a medium of all microorganism both in vegetative and in spores state by removing or killing them, while disinfection does not acts on spore states of organisms<sup>1</sup>.

In modern era sterilization procedure is done by heat, chemicals or radiation. The sterilization is done to sterilize Suturing material, instruments, operation theaters, patients ward, ICUs, the substance like catheters, tubes, drains, syringes, needles, pads, bandages, cotton etc.

**• Various Methods Are Used For Sterilization Like:-**

➤ **Heat:**

**Dry-**

- 1) Hot air oven – in this procedure longer exposed to dry heat about 160– 190° C for 6– 12 min
- 2) Flaming – by Bunsen Burner or Alcohol lamp until it glows red.
- 3) Incineration – combustion of organic substance contained in waste material.

**Moist-**

- 1) Autoclave – 120° C at 20 psi for 60 min or 134° C for 18 min.
- 2) Tyndallization – simple boiling water method for 20 min.

➤ **Chemical:**

In case of heat sensitive substance like fiber optics, electronic, plastic ect. are sterilized by Ethylene oxide, nitrogendioxide, ozone, glutaraldehyde, formaldehyde, H<sub>2</sub>O<sub>2</sub>, per acetic acid (0.2%)

➤ **Radiation :**

**Non Ionizing** – UV light for plastic substance.

**Ionizing** – Gamma radiation by radio isotopes(cobalt-60, caesium-137), x-rays electron beam.

**❖ Raksha karma (Sterilization in Ayurveda):**

Acharya Sushruta includes Raksha karma in the heading of shasti upakramas to protect Atura from 'nishachara'(invisible

creatures). (Su.Chi.1/32)

➤ **Dhoopana:**

Ayurveda recommends fumigation ( Dhoopana ) as a method of sterilization (Rakshoghana vidhi) in OT rooms and various chambers ( such as Kumaragar, Sutikagar, vranitagara etc.) and for instruments (Yantra- Shastra), wound (Vrana) etc. methods like Kashaya , Dhupana , Parishekah ,Agnitapan,sunlight etc are used.

**Various Types Of Dhupana Yogas Are Used To Purify The Room**

- Sarshap, nimba, ghrita, lavana are used to fumigate the room twice daily for 10 days.(Su.Su.19/28)
- Hingu, nimba, guggula, akshata(oryza sativa)
- Honey, body hair of goat, horn of sheep.

These Dhupana yogas are also used for vrana dhupana, fumigation of clothes, room, vrana bandhan dravyas etc to purify vrana from visha(harmful substance). wound purification is done by Dhupana dravya like guggulu, aguru,sarjras,vchha,swet sarsap powder, lavan,nimb patra mixed with ghee.(Su.Su.5/18) while air by laksha, haridra, ativisha, haritaki, kustha, valaka , ela, mustak , priyangu. guggula. Somraji, agaru, nimba etc.

❖ **Sterilization Of Ksharsutra**

Prepared Standard and Mochras ksharsutra should be sterilized before use. Prepared Ksharsutra were kept in Ksharsutra cabinet for 12 hr. for 2 days under U.V. light radiation for sterilization.Then Ksharsutra was kept in air tight poly bags under proper hygiene using fumigate room,sterile gloves, mask and cap.

**Sterility Test**

Ksharsutra were given for sterility test to Department of Microbiology, Dr. S.N. Medical college , Jodhpur. Sterility test was failed.

**Result: Aerobic Non-pathogenic Organism Grown On Culture.**

Lack of sterilization leads to complication like infection and delayed wound healing of fistulous track.

- Then Ksharsutra was Ethylene oxide (ETO) Sterilized and sterilization lots were tested as per I.P. and sterility assurance. Packed and sealed as Suturing material.
- Ksharsutra were ETO Sterilized at ISCON SURGICALS LTD. at Heavy industrial area,Jodhpur.(An ISO 9001:2008 & ISO 13485 Certified Company)  
Website:www.pricon.co.in, E.mail: info@pricon.co.in

❖ **ETO Sterilization of Ksharsutra:**

Fumigants play an important role in health. They contribute to the conservation and durability of a multitude of raw materials and manufactured products during production, storage and final use.

Ethylene oxide gas sterilization (Fumigation) is employed in a chamber in which temperature can be controlled & exposure period of 3 to 6 hours is needed.It is use to fumigate O.T, wards, organ machine,instruments,blankets, pillows, suturing material ect.

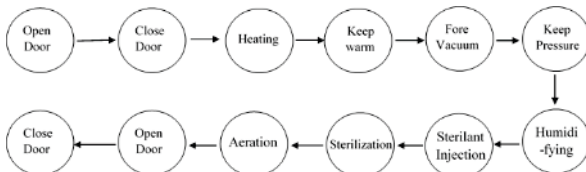
**ETO Sterilizer operation process**

➤ **Sterilization Parameters:**

Sterilization Temperature Set Point	50 °C (Summers) & 55°C (Winters)
Temperature Range	55 ±5°C (Summers)
	60 ±5°C (Winters)
Expose Time	480 minutes

Pre Conditioning Time	60 minutes (Warm 30 min. + Vacuum 30 min.)
Pre Vacuum Pressure	-50 kPa
Pressure Holding Time	5 minutes
Humidity Range	30 %RH – 80% RH
Aeration Vacuum Pressure	-25 to -30 kPa
Aeration Cycles	3 times
Flushing Duration	30 minutes
ETO Weight	4.5 kg

➤ **Sterilization Process Flow :**



**Packing:**

Ksharsutra was packed in Medical grade pouches each having length 30 ± 1cm under proper hygiene using fumigate room,sterile gloves, mask and cap and then kept in ETO Sterilization operation process. This packing shows :

- Content sterile if the package is intact.
- One time use only.
- Content remain ETO sterile for 3 years.

Thus ksharsutras were sterilized by above parameters and process flow.

**Precautions**

- Ensure that the instrument is clean and free from dust.
- The level in water tank for being normal.
- All the switches in the electric panel for being set in zero(non-working) position.
- The vacuum, venting valve and Eto gas feed valve for being at closed-state.
- The door seals for being intact and well oiled.

**Sterility Test:**

ETO Sterilized Standard ksharutra & Mochras Ksharsutra were again given for sterility test to Department of Microbiology, Dr. S.N. Medical college , Jodhpur.

**Process:** Sample were inoculate into peptone water over night at 37°C and next day sub cultured on Blood agar, Mac Conkeys agar &Nutrient agar. After 48 hours of incubation no growth was seen over culcture plates.

**Result: No Aerobic Pyogenic Organism Grown On Culture.**



**U.V. Ksharasutra Cabinet**



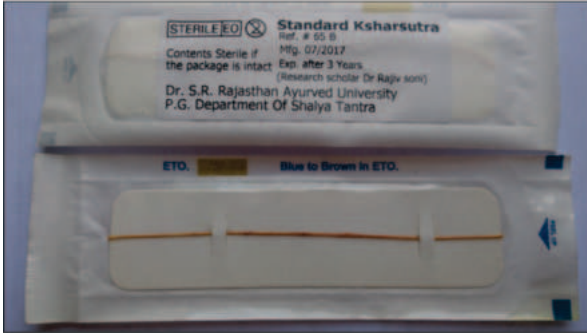
**Sterility Test: 1) Standard Ksharsutra 2) Mochras Ksharsutra 3) Control Test Tube**



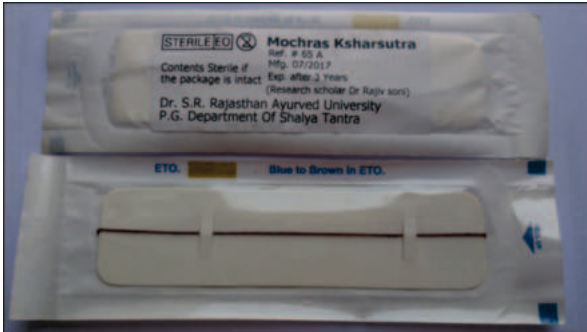
- (2) Charaksamhita sutra sthan 4/31, PP.90
- (3) Charaksamhita sutra sthan 4/46-47, PP.95-96
- (4) ShriBhram Shankar Mishra, Bhavprakash, Purvardha, Chukhamba Publication Edition Reprint 2015 BhavprakashNighantu, Vatadivarg 29/56-57, PP.538
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**ETO Sterilization Of Ksharsutra**

**ETO Sterile Ksharsutra Packed In Medical Grade Pouches**



**Standard Ksharsutra**



**Mochras Ksharsutra**

ISCON 1023 CE Marked ISCON SURGICALS LTD. (An ISO 9001:2008 & ISO 13485 Certified Company) 22/4 Heavy Industrial Area, Jodhpur - 342 005 (Raj.) INDIA Tel: 0291-2749550 Fax: 0291-2749550 Email: info@iscon.co.in Website: www.iscon1023.com S.L. No. R-4/17649/2018M-28

June 25, 2018.

**CERTIFICATE OF STERILITY**

This is to certify that the following product are ETO Sterile and the sterilization lots were tested as per I.P. and sterility assurance.

S. No.	Ref.	Item Name	Mfg. Dt.	Exp. Dt.
1	65A	Mochras Ksharsutra	07/2017	After 3 Years
2	65B	Standard Ksharsutra	07/2017	After 3 Years

ISCON SURGICALS LTD.  
 Analytical Chemist

**DEPARTMENT OF MICROBIOLOGY (Dr. S.N. MEDICAL COLLEGE, JODHPUR)**

Name:- Dr. Rajiv Soni  
 M.S. Scholar  
 Ayush Medical Officer  
 Department of Shalya Tantra  
 Dr. S.R. Rajasthan Ayurved University, Jodhpur  
 Culture Report:-

Sample:- 1. Mochras kshar sutra (Mochras Apamarga kshar sutra)  
 2. Standard kshar sutra (Sushbi Apamarga kshar sutra)

Sample Received:- 10/10/2017

Sample were inoculate into peptone water over night at 37<sup>o</sup> C and next day sub cultured on Blood agar, Mac Conkeys agar & Nutrient agar. After 48 hours of incubation no growth was seen over culture plates.

**Result:-** No aerobic pyogenic organism grown on culture.

Achana Bora  
 Assistant Professor  
 Department of Microbiology  
 Dr. S.N. Medical College,  
 Jodhpur

DR. P. ...  
 Professor & Head  
 Department of Microbiology  
 Dr. S.N. Medical College,  
 Jodhpur

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