19612 • GyneCath™ H/S Procedure Tray • Size 5F
for Hysterosonography and Hysterosalpingography

DEVICE DESCRIPTION

The GyneCath™ H/S Procedure Tray contains components routinely used for conducting Hysterosonography or Hysterosalpingography procedures. The 5F GyneCath Catheter provided in the tray is not compatible with oil-based contrast media. All components are not made with natural rubber latex.

Tray contents: one GyneCath Catheter (5F), one 1.5cc syringe, one disposable vaginal speculum, one 20cc syringe, one 18 gauge needle, one 36” extension tube set, one cervical dilator, one pack povidone-iodine solution, one pack lubricating jelly, three 8” swabs, one sanitary napkin, one over-wrap 30” x 30”, one fenestrated drape and one 36” x 24” drape. All tray components are sterile for single use only.

WARNINGS

- Contents supplied sterile. Do not use if sterile barrier is damaged.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Dispose of in accordance with all applicable Federal, State and local Medical/Hazardous waste practices.

INDICATIONS FOR USE

The GyneCath H/S Procedure Tray components are used to administer contrast media during Hysterosonography or Hysterosalpingography procedures.

CONTRAINDICATIONS

Hysterosonography or Hysterosalpingography should not be performed under the following conditions: known or suspected pregnancy, suspected infection or sexually transmitted disease, profuse bleeding.

PRECAUTIONS

The use of oil-based contrast media such as ethyl esters may interact with the balloon of the catheter, causing possible balloon rupture. The use of oil-based contrast media is not recommended.

Do not exceed the recommended balloon inflation volume of 1.5cc for the 5F catheter, or the balloon may burst.

ADVERSE REACTIONS

Some patients may have a hypersensitivity to contrast media.

INSTRUCTIONS FOR USE

1. Open the over-wrap drape to form a 30” x 30” sterile field.
2. Position the patient to allow pelvic access and prepare the vaginal area with the povidone-iodine and swabs provided.
3. Follow the instructions on the pouch of the GyneCath Catheter provided in the tray to complete either the Hysterosonography or Hysterosalpingography procedure.
4. Lubricating jelly is provided to be used to facilitate cervical dilator or catheter insertion.
5. The cervical dilator is used to find the external os by pushing the narrow end gently against the cervix until it enters the cervical canal. The shape retaining tip may be curved as necessary to facilitate insertion. Further insertion of the flexible tip will follow the natural path of the canal until it reaches and goes through the internal os.
6. The 18 gauge needle is provided to withdraw contrast media from its container using the 20cc syringe.
7. The 36” extension tube set can be connected to the blue hub of the GyneCath Catheter and allows injection of contrast media from outside the x-ray field during Hysterosalpingography procedures.

EXPLANATION OF SYMBOLS



Reorder Number



Batch Code


Use By


Caution


Do not use if package is damaged or opened.


Consult instructions for use


Do not re-use



Do not resterilize

R_xOnly **CAUTION:** U.S. Federal law restricts this device to sale by or on the order of a physician.



Not made with natural rubber latex



Sterilized Using Ethylene Oxide


Manufacturer


Cooper Surgical, Inc.
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Made in the USA

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