

HSG/SIS PROCEDURE TRAY

PROCEDURE TRAY FOR HYSTEROSONOGRAPHY AND HYSTEROSALPINGOGRAPHY

LOT xxxxxTx

RxONLY

STERILE EO

EXP: 20xx-xx-xx

DEVICE DESCRIPTION

The HSG/SIS Procedure Tray contains components routinely used for conducting Hysterosonography or Hysterosalpingography procedures. The tray contains either a 5F or 7F HSG/SIS Catheter Set. The HSG/SIS Catheter Set provided in the tray is not compatible with oil-based contrast media. This product is not made with natural rubber latex.

The HSG/SIS Procedure Tray contains one HSG/SIS Catheter Set, one sanitary napkin, , two packets povidone-iodine solutions, two 6" sponge swabs, one packet Povidone-Iodine Ointment, one packet lubricating jelly, one fenestrated drape, five gauze pads 3" x 3", 2 eaches sterile gauze 3"x3" 12ply, one over-wrap 30" x 30", one 18 gauge safety needle, three 8" swabs, one 20cc syringe, one 36" extension tube set, one disposable vaginal speculum, one cervical dilator. All tray components are sterile for single use only.

INTENDED USE/ INDICATIONS

The HSG/SIS Procedure Tray components are used to administer contrast media during Hysterosonography or Hysterosalpingography procedures.

CONTRAINDICATION

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

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 HSG/SIS Catheter or 3.0cc for the 7F HSG/SIS Catheter or the balloon may burst.

ADVERSE EVENTS

Some patients may have a hypersensitivity to contrast media.

DIRECTIONS 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 included with the HSG/SIS 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 safety 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 HSG/SIS Catheter and allows injection of the contrast media from outside the x-ray field during Hysterosalpingography procedures.