

Procedure Tray • H/S Catheter Set with Integrated Stylet for Hysterosonography and Hysterosalpingography 61-3205 (5F) • 61-3207 (7F) Instructions for Use

Device Description:

The H/S Procedure Tray contains components routinely used for conducting Hysterosonography or Hysterosalpingography procedures. The tray contains a 5F or 7F H/S Catheter Set with Integrated Stylet. The H/S Catheter Set with Integrated Stylet provided in the tray is not compatible with oil-based contrast media. All components are latex free.

The H/S Procedure Tray contains (1) H/S catheter Set with Integrated Stylet, (1) sanitary napkin, (1) packet povidone-iodine solution, (1) packet lubricating jelly, (1) fenestrated drape, (1) 36" x 36" drape, (1) over-wrap 30" x 30", (1) 18 gauge needle, (3) 8" swabs, (1) 20 cc syringe, (1) 36" extension tube set, (1) disposable vaginal speculum, (1) cervical dilator. All tray components are sterile and for single use only.

Intended Use/Indications:

The 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.

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 1.5 cc for the 5F catheter or 3 cc for the 7F catheter or the balloon may burst.


Adverse Events:

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 included with the H/S Catheter with Integrated Stylet 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 catheter may be shaped/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 20 cc syringe.
7. The 36" extension tube set can be connected to the blue hub of the H/S Catheter with Integrated Stylet and allows injection of contrast media from outside the x-ray field during Hysterosalpingography procedures.

EXPLANATION OF SYMBOLS


 Reorder Number


 Batch Code

 Use By

Rx Only U.S. Federal law restricts this device to sale by or on the order of a physician.


 Sterilized Using Ethylene Oxide


 Do not re-use


 Do not re-sterilize

 Caution

 Consult instructions for use

 Do not use if package is damaged

 Not made with natural rubber latex

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