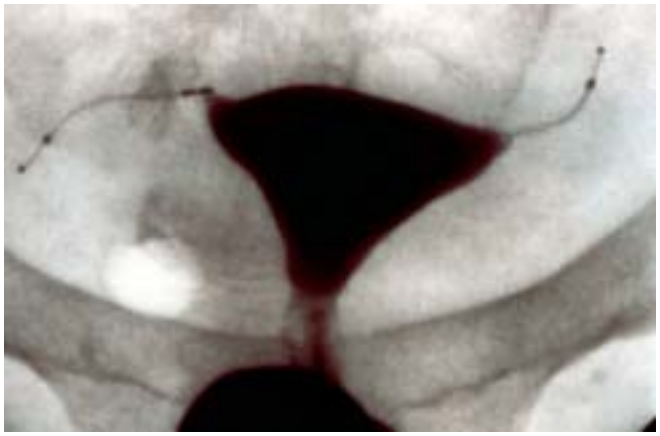
essure®

The alternative to incision

HSG Protocol



Performing and Evaluating Hysterosalpingograms Three Months Post-Micro-insert Placement

Three months following the Essure micro-insert placement procedure, the patient should be scheduled for an HSG. The HSG is performed to evaluate: 1) micro-insert location; and 2) fallopian tube occlusion. Only if micro-insert location is satisfactory and, there is evidence of bilateral occlusion of the fallopian tubes, may the physician instruct the patient to discontinue use of alternative contraception and rely on the Essure micro-inserts for pregnancy prevention.

The following steps should be followed for performing and evaluating the HSG.

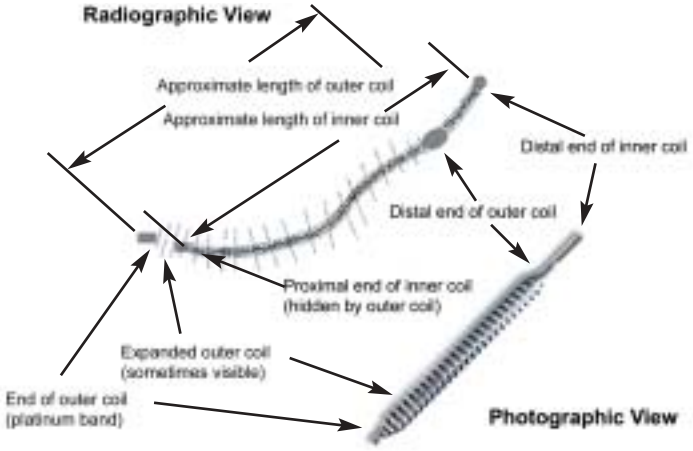
Performing the HSG

One objective of the HSG is to evaluate the relationship of the proximal end of the inner coil of the micro-insert to the uterine cornua, thus verifying that the micro-insert spans the UTJ. In order to achieve this, the following guidelines should be adhered to:

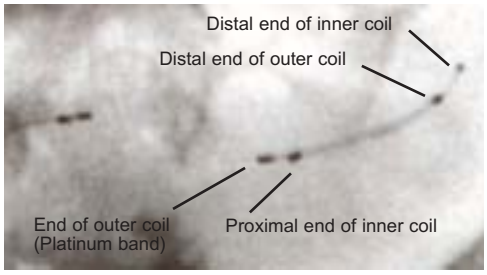
1. The uterine cavity silhouette must be clearly seen with good cornual filling.
2. The fluoroscopy beam with respect to the uterus should be as close to A/P projection as possible.
3. A good cervical seal should be maintained throughout the procedure to ensure good uterine distension, so do not dilate unless necessary.
4. Downward traction on the cervical tenaculum may be required in patients having a midpositional uterus, to allow for ideal images of the uterine cavity. The speculum should be removed prior to fluoroscopy in order to assure the best possible visualization of uterine anatomy.
5. A minimum of six still radiographs should be taken to assess micro-insert location and tubal occlusion. A description of each radiograph is provided below with associated pictures.

NOTE: Assessment of the location of the micro-inserts on HSG is not the same as noted on hysteroscopy. Therefore, a correctly placed micro-insert may appear to be more distal on HSG than noted at the time of hysteroscopy.

Radiographic Markers



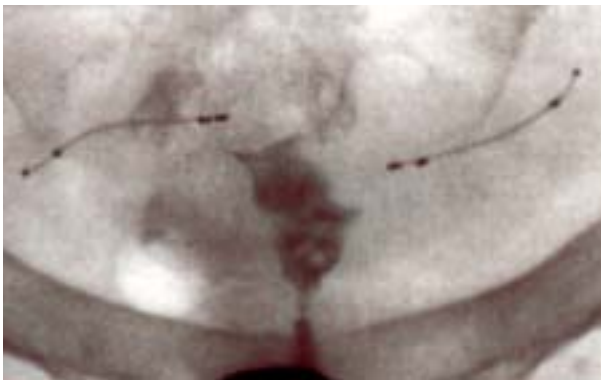
Radiograph 1 – "Scout Film"



Micro-insert markers on patient left corresponds to radiographic view illustration

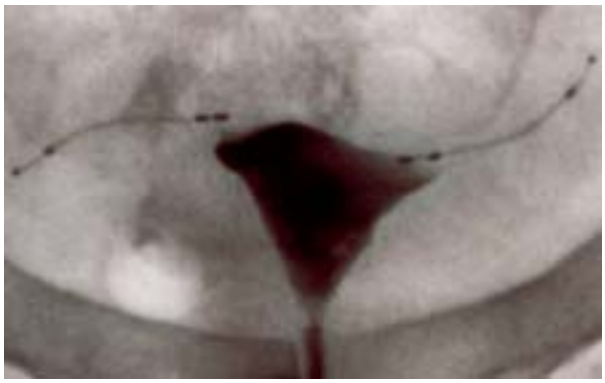
Capture an image of the uterus immediately prior to infusion of contrast into the uterine cavity. The Essure micro-inserts should be clearly seen. The lie and curvature of the micro-inserts should be noted.

Radiograph 2 – Minimal Fill of the Cavity



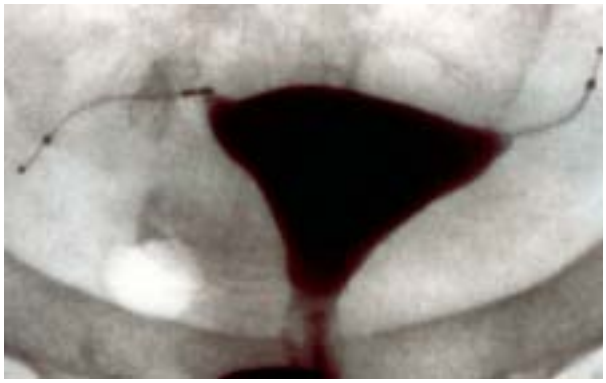
Capture an image of the uterus after a small amount of radio opaque contrast is instilled into the uterine cavity. This image should demonstrate evidence of an adequate seal of the uterine cervix and the beginning of opacification of the uterine cavity. In this radiograph, contrast material is likely not to have reached the uterine cornua. If the uterine cavity silhouette is not seen in a nearly A/P projection, the fluoroscopy beam and/or the patient need to be adjusted.

Radiograph 3 – Partial Fill of the Cavity



Capture an image of the uterus when it is nearly full of contrast or opacified. The cornua may not yet have been adequately distended. Proximal (uterine) portions of the Essure micro-insert may not yet be obscured by the advancing contrast.

Radiograph 4 – Total Fill of Cavity



Capture an image of the uterus when the uterine cavity is completely filled to patient tolerance or maximal distension of the cornua has been achieved, whichever comes first. In this image, the advance of contrast (i.e., opacification) is likely to meet or obscure the proximal (uterine) portions of the Essure micro-inserts.

NOTE: An increase in volume of the intracavitary contrast, with resultant increase in intrauterine pressure is often needed to allow for a satisfactory image.

CAUTION: An increase in intrauterine pressure beyond that needed to produce image #4 serves no purpose and should be avoided, so as to avoid undue patient discomfort and the possibility of resultant vasovagal reaction such as profound bradycardia, lightheadedness, sweating and fainting.
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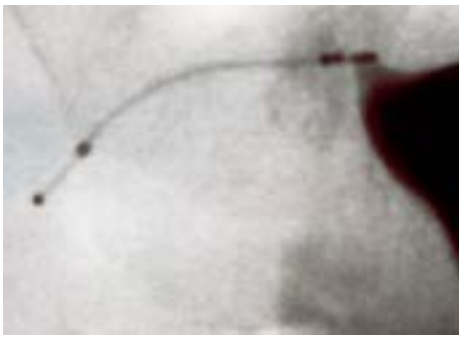
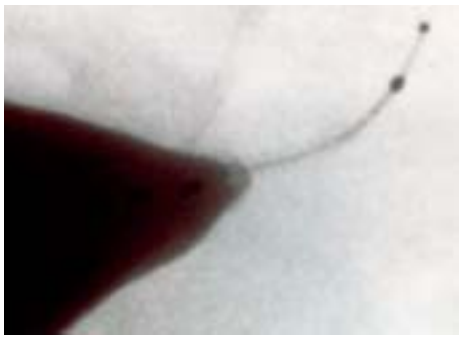
Radiograph 5 & 6 – Magnifications of Uterine Cornua



Magnification of right cornua



Magnification of left cornua

Once the uterine cornua are filled to maximum distension, magnified views of both right and left cornua should be obtained, highlighting the position of the micro-insert in reference to the uterine cornua.

Evaluating HSGs

When evaluating the HSG, it is important to first confirm that the appropriate radiographs described above are provided, a good A/P image of the uterine silhouette is obtained, and the uterus is maximally distended in at least one view. The HSG will need to be immediately repeated if:

1. The appropriate sequence of radiographs has been captured but one or both uterine cornua are not maximally distended;
2. The projection of the silhouette is fundal rather than A/P;
3. The appropriate sequence of radiographs was not taken, and/or the uterine cornua are not distended or are otherwise obscured making evaluation of micro-insert position impossible or equivocal.

Micro-insert Location

In evaluating micro-insert position it is important to note the “markers” for the proximal end of the micro-insert (the end of the inner coil and the platinum band of the outer coil). Micro-insert position is then evaluated according to its relationship to the distended uterine cornua. Measurements of these relative distances can be taken with a caliper. Ideal micro-insert location is when the inner coil of the micro-insert crosses the utero-tubal junction. The inner coil is the critical component for evaluation because the PET fibers, that cause fibrosis and occlusion, are located on the inner coil of the micro-insert.

NOTE: Assessment of the location of the micro-inserts on HSG is not the same as noted at hysteroscopy. Therefore, a correctly placed micro-insert may appear to be more distal on HSG than noted at the time of hysteroscopy.

The following scale should be used to categorize assessment of micro-insert location:

Expulsion or Proximal Placement (micro-insert not placed far enough into tube)

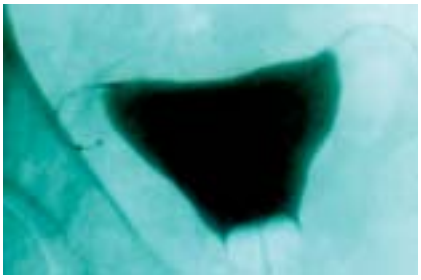
1. The micro-insert is not present (expulsion) OR more than 50% of the length of the inner coil of the micro-insert is trailing into the uterine cavity (too proximal placement).

Complete expulsion of left micro-insert

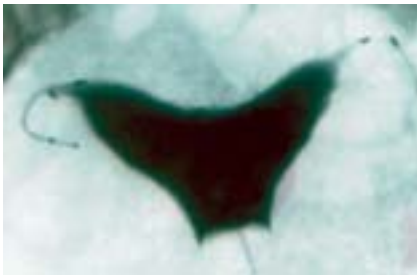
Expulsion of left micro-insert into uterus

Satisfactory Placement

2. Distal end of the inner coil is within the tube with less than 50% of the length of the inner coil trailing into the uterine cavity, OR the proximal end of the inner coil appears to be up to 30 mm into the tube from where contrast fills the uterine cornua.



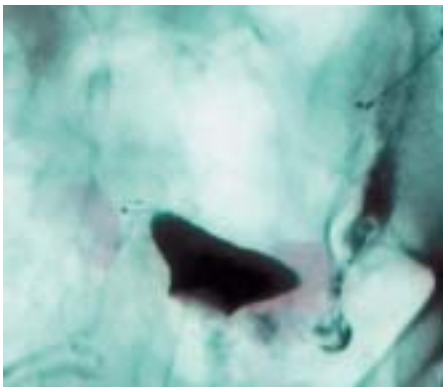
Satisfactory location



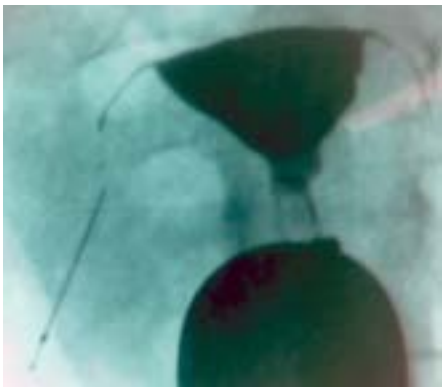
On patient left side, proximal end of inner coil is <30 mm from contrast at cornua

Distal Placement (micro-insert placed too far in tube) or Peritoneal Location

3. Micro-insert is in the tube but proximal end of the inner coil appears to be more than 30 mm distal into the tube from the contrast filling the uterine cornua, OR the micro-insert is within the peritoneal cavity.



Micro-insert in peritoneal cavity



Distal placement of micro-insert

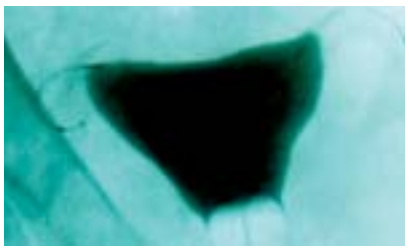
A patient with micro-insert location that is rated to be in categories 1 or 3 <u>should not rely</u> on the Essure micro-inserts for contraception.

Occlusion

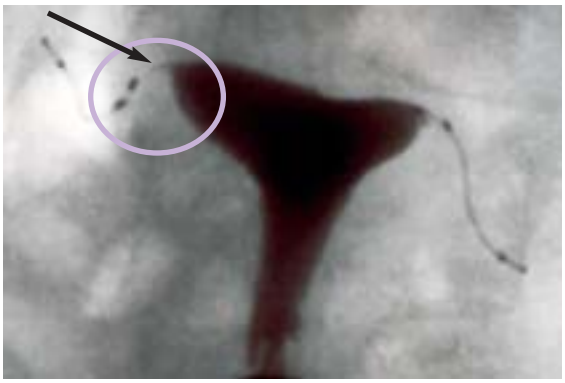
The most critical aspect of evaluating tubal occlusion is determining whether the contrast is visible in the tube beyond the micro-insert. It is also important to note any degree of proximal tubal filling with contrast even if the tube is occluded.

The following scale should be used to categorize assessment of tubal occlusion:

1. Tube is occluded at the cornua.

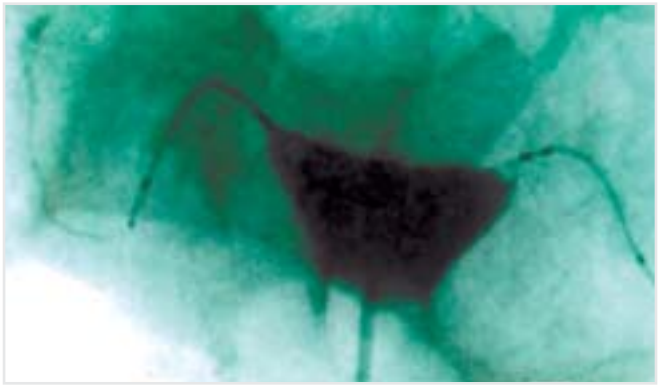


2. Contrast seen within the tube but not past any portion of the length of the outer coil of the micro-insert (i.e., past the distal end of the outer coil, see Radiographic Markers diagram on page 5)



On patient right, contrast in proximal tube

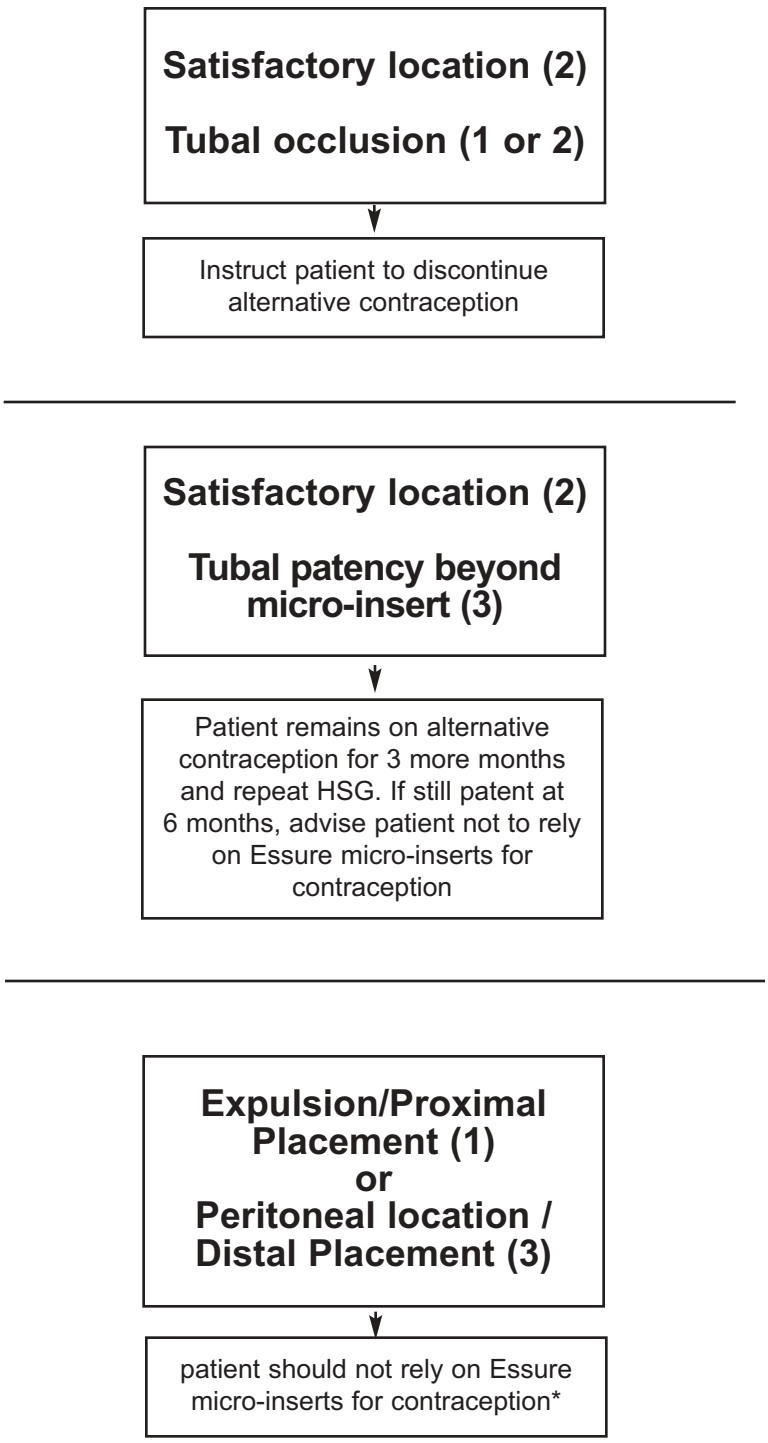
3. Contrast seen past the micro-insert or in the peritoneal cavity.



Patency beyond micro-insert

If tubal occlusion is rated to be in categories 1 or 2 above, and micro-insert location is satisfactory (category 2 above), then the patient should be instructed to discontinue alternative contraception. If occlusion is rated as a 3 and micro-insert location is satisfactory at the 3 month HSG, then the patient should remain on alternative contraception for 3 more months and have a repeat HSG. **If occlusion is again rated as a 3, then she should be advised to not rely on the Essure micro-inserts for contraception.**

3 Month HSG Algorithms



* Refer to the Physician Training Manual, Section 9 - Management of Technical Issues, for additional patient management recommendations