

# Lipiodol® Ultra Fluid

Ethyl ester of iodized fatty acids of poppy seed oil

**Indicated for Hysterosalpingography (HSG),**  
**another option for women's reproductive health**<sup>1-9</sup>

INFERTILITY  
EVALUATION

TUBAL  
IMAGING

UTERINE  
IMAGING

# Lipiodol® Ultra Fluid

## FOR HYSTEOSALPINGOGRAPHY



**Pharmaceutical form:** Lipiodol® Ultra Fluid 480 mg Iodine per mL, solution for injection 10 mL, ethyl esters of iodized fatty acids of poppy-seed oil

**Recommended dosage:** Up to 20 mL, depending on the volume of the uterine cavity



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# Lipiodol® Ultra Fluid indication

## *Hysterosalpingography*

- **Definition:** **radiological examination** to investigate the uterine cavity, Fallopian tubes & peritoneal cavity. It entails the injection of contrast medium and visualization under fluoroscopy. <sup>10</sup>
- CHARACTERIZATION OF HSG FINDINGS <sup>11</sup>

### Tubal abnormalities

- Tubal occlusion
- Salpingitis isthmica nodosum
- Polyps
- Hydrosalpinx
- Peritubal adhesions

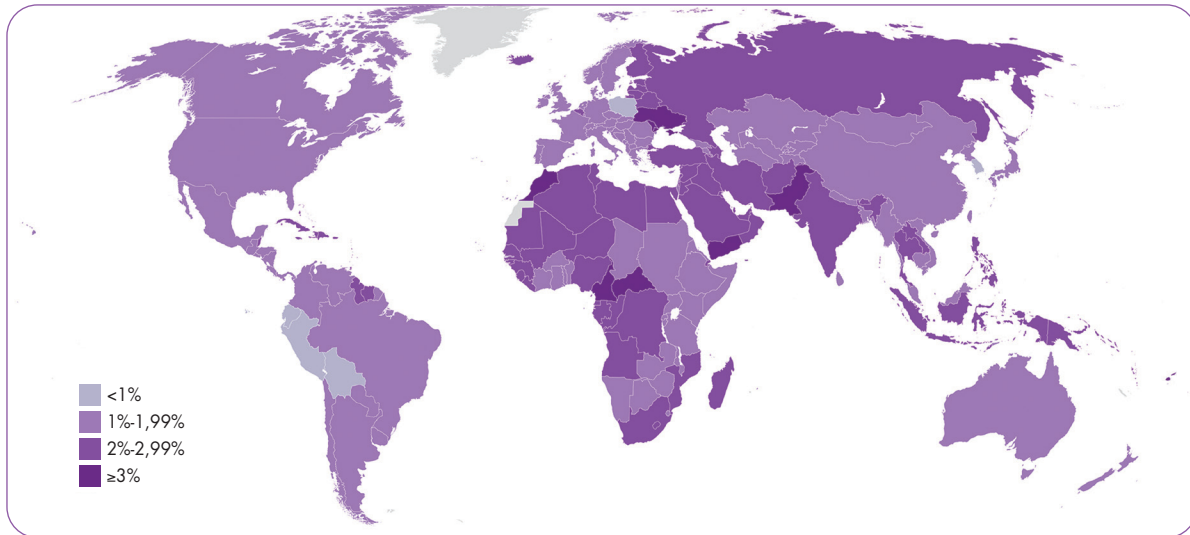
### Uterine cavity abnormalities

- Congenital anomalies
- Polyps
- Leiomyomas
- Surgical changes
- Synechiae
- Adenomyosis
- Müllerian duct anomalies

**HSG - SIMPLE & ACCURATE PROCEDURE FOR TUBAL PATENCY & UTERINE INVESTIGATION**

# Infertility prevalence

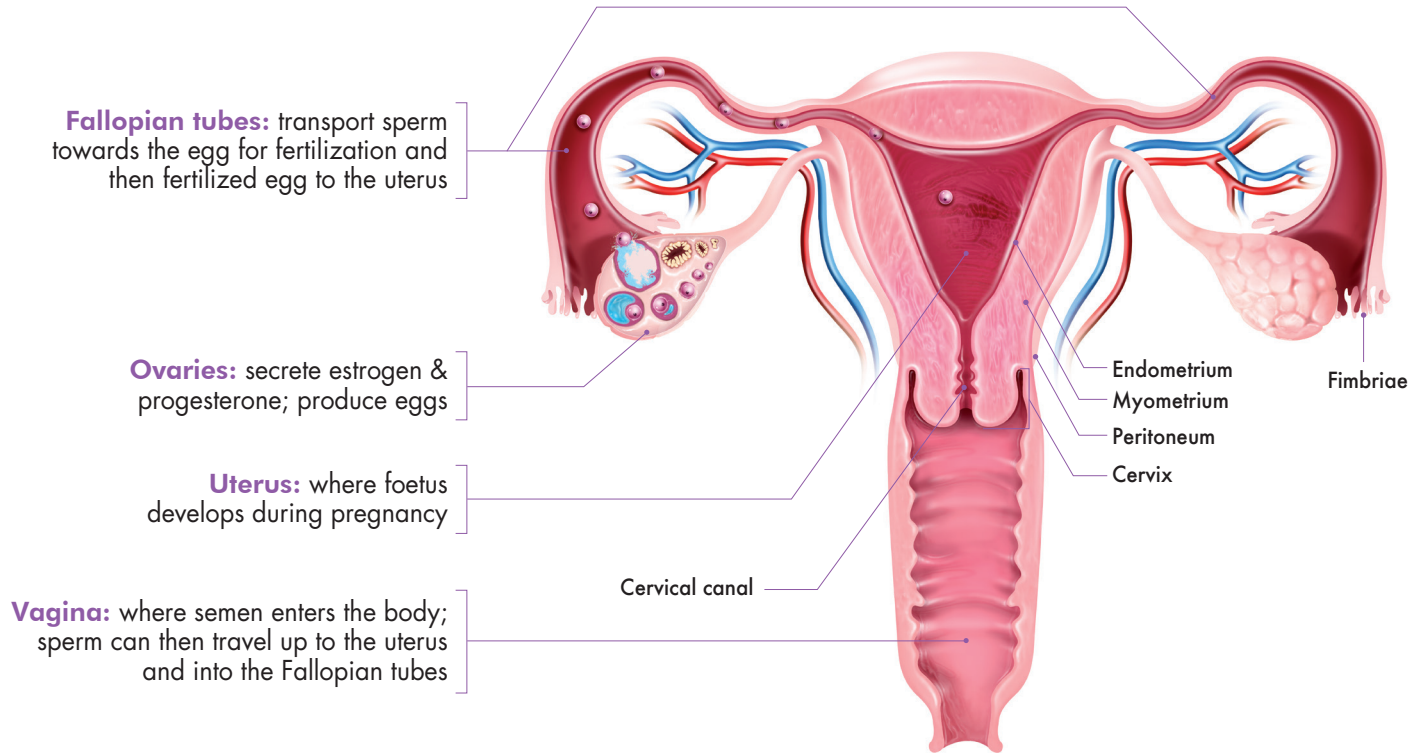
► PREVALENCE OF PRIMARY INFERTILITY AMONG WOMEN WHO SEEK A CHILD, IN 2010<sup>12</sup>



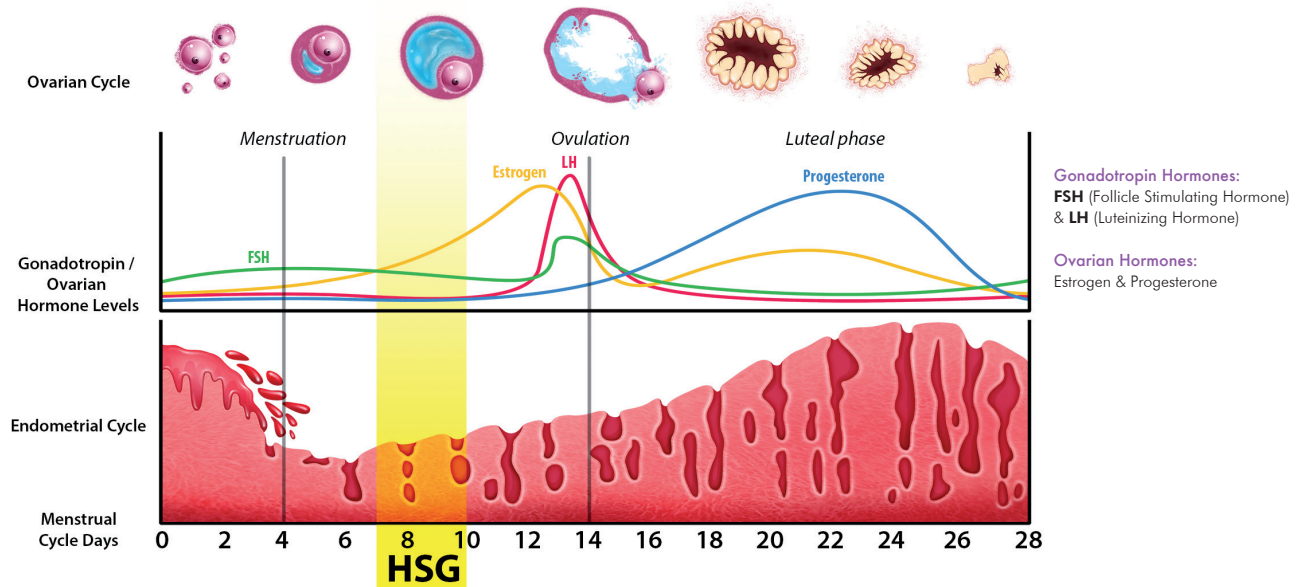
**INFERTILITY - A HUGE CLINICAL UNMET NEED OVER THE WORLD**



# The female reproductive system



# When to perform HSG <sup>13</sup>

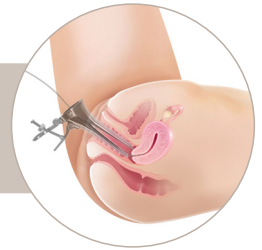


**HSG - PROCEDURE PERFORMED AFTER BLEEDING PERIOD & BEFORE OVULATION (IDEALLY BEFORE THE 12<sup>TH</sup> DAY OF THE MENSTRUAL CYCLE FOR WOMEN WITH NORMAL CYCLE LENGTH)**

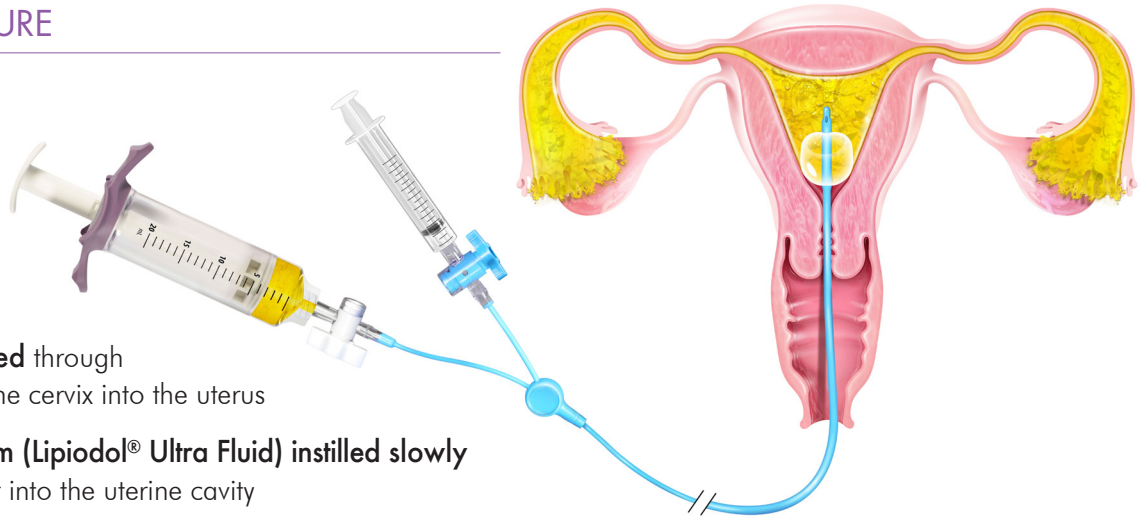
# HSG steps

## PATIENT PREPARATION

- ✓ The patient is **positioned on her back on a table** under a fluoroscope, bringing **legs up** into gynecological position
- ✓ Cervix must be **cleaned with an antiseptic** ✓ Vaginal **speculum** gently inserted for visualization of cervix



## ▶ HSG PROCEDURE



- 1 **Catheter inserted** through the opening in the cervix into the uterus
- 2 **Contrast medium (Lipiodol® Ultra Fluid) instilled slowly** through catheter into the uterine cavity
- 3 **Images taken** of the uterine cavity and Fallopian tubes





# Lipiodol<sup>®</sup> HSG: Endorsement by international clinical practice guidelines



## NICE Guidelines <sup>14</sup>

*«...The potential therapeutic effect of diagnostic tubal patency testing has been debated for over 40 years. Tubal flushing might involve water- or oil-soluble media. A systematic review of eight RCTs showed a significant increase in pregnancy rates with tubal flushing using oil-soluble contrast media when compared with no treatment...Tubal flushing with oil soluble contrast media was associated with an increase in the odds of live birth...[Evidence level 1a]...»*

*\*Hierarchy of evidence: 1a – Systematic review and meta-analysis of randomised controlled trials*



## American Society for Reproductive Medicine (ASRM) <sup>15</sup>

*«...Hysterosalpingography (HSG), using either a water- or lipid-soluble contrast media, is the traditional and standard method for evaluating tubal patency and may offer some therapeutic benefit...»*



## Canadian Fertility & Andrology Society (CFAS) <sup>16</sup>

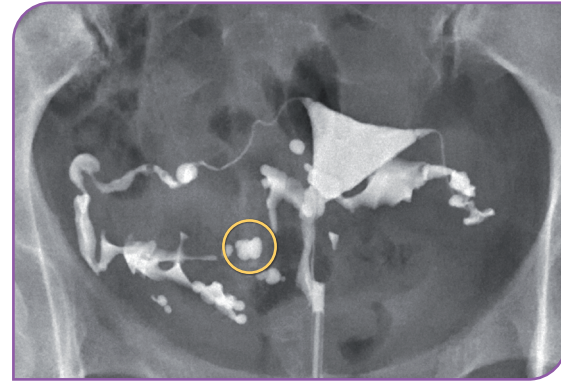
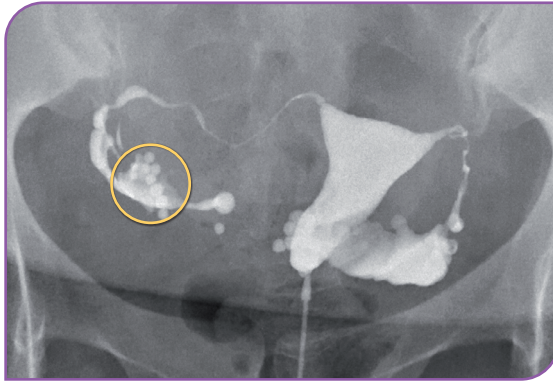
*«...Hysterosalpingography...: Water-soluble or oil-based radio-opaque contrast material is used to delineate the uterine cavity...»*

*«...HSG is generally accepted as the traditional, least invasive and most cost effective method of evaluation of tubal patency in low-risk women...»*

# Lipiodol® HSG: Findings

## Normal HSGs

Lipiodol® HSG showing normal uterine cavity & patent tubes

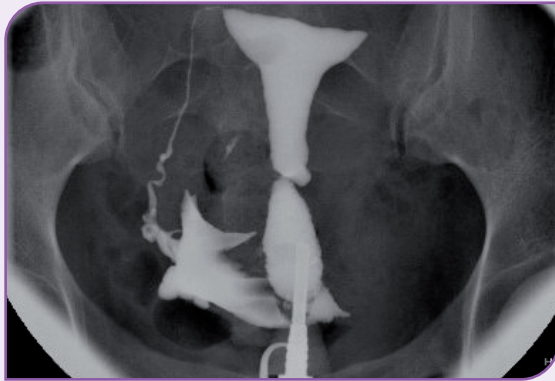


Courtesy: Pr. Velja Mijatovic & Dr. Kim Dreyer, Amsterdam University Medical Center (Netherlands)

○ Example of specific Lipiodol® droplets in the peritoneal cavity confirming tubal patency

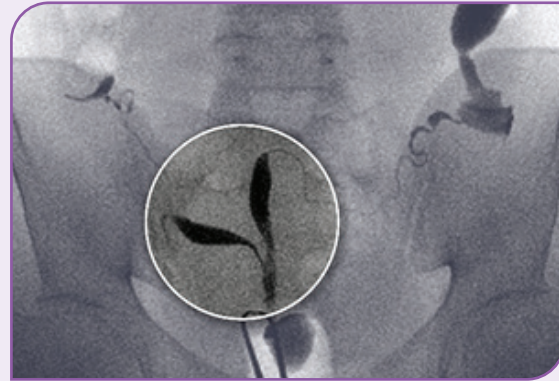
## Abnormal findings

Lipiodol® HSG showing uterine cavity with a filling defect near the left tube due to an endometrial polyp & normal right tube with patency



Courtesy: Pr. Velja Mijatovic & Dr. Kim Dreyer, Amsterdam University Medical Center (Netherlands)

Lipiodol® HSG showing Müllerian duct anomalies



Courtesy: Dr. Naile Bolca Topal, Uludag University (Turkey)

**LIPIODOL® FOR HSG - ACCURATE TUBAL & UTERUS IMAGING**

# Lipiodol<sup>®</sup> HSG: Safety

✓ **No evidence of difference between OSCM Lipiodol<sup>®</sup> & WSCM groups**<sup>6,7,17</sup>

- Miscarriage
- Ectopic pregnancy
- Infection
- Haemorrhage

*«...There were no significant differences in miscarriage, ectopic pregnancy & infection rates between tubal flushing with oil or water, or between oil plus water media versus water media only...»*

*NICE Clinical Guidelines 2013<sup>14</sup>*

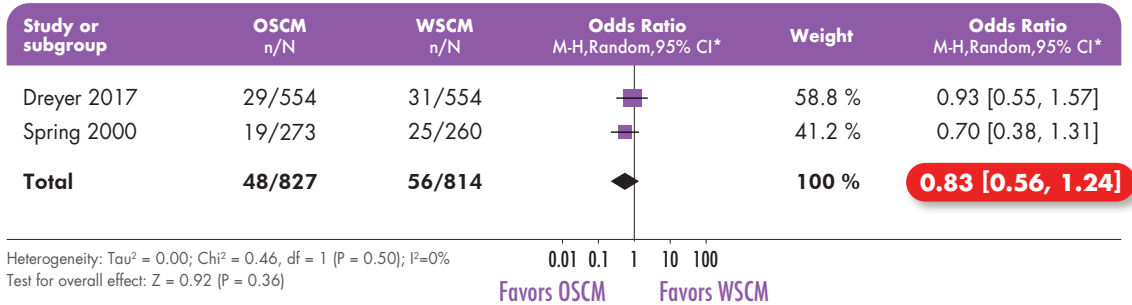
OSCM: Oil Soluble Contrast Medium (Lipiodol<sup>®</sup> Ultra Fluid) | WSCM: Water Soluble Contrast Medium

## **Rare HSG complications may occur**

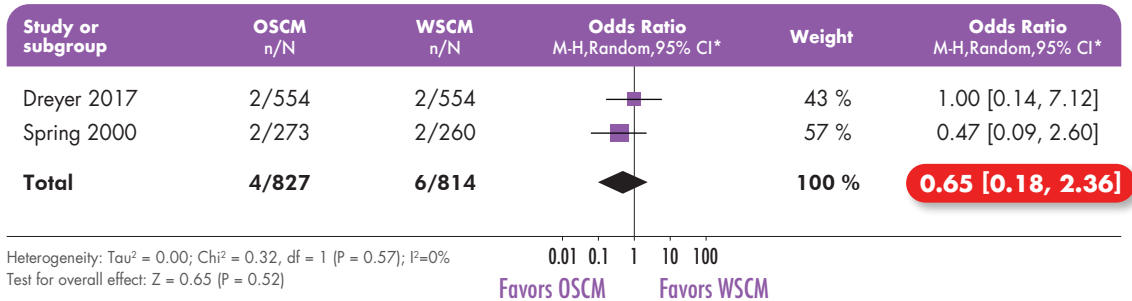
- Venous intravasation: Reported rate < 6.9%<sup>2,18</sup>
- Pulmonary embolism: Very rare cases which remained clinically asymptomatic (Reported rate 1.1%)<sup>19</sup>; No cases reported in a meta-analysis from 2019<sup>20</sup>
- Lipogranuloma: Reported rate < 0.1%<sup>21</sup>
- Thyroid dysfunction (contraindicated in case of confirmed hyperthyroidism): Low risk of transient hypo/hyperthyroidism; when biochemically observed, no clinical consequences reported<sup>22</sup>

**LIPIODOL<sup>®</sup> FOR HSG - A SAFE PROCEDURE**

## Miscarriage <sup>23</sup>



## Ectopic pregnancy <sup>23</sup>



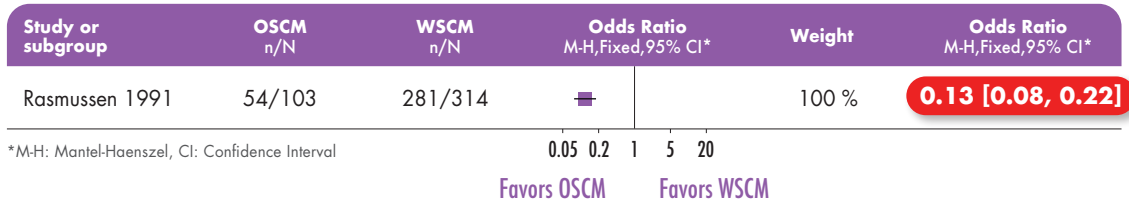
\*M-H: Mantel-Haenszel, CI: Confidence Interval

# Lipiodol<sup>®</sup> HSG: Pain

✓ Procedural pain level: No significant difference between OSCM & WSCM group <sup>7</sup>

	OSCM (Lipiodol <sup>®</sup> Ultra Fluid) N=554	WSCM (Telebrix Hystero <sup>®</sup> ) N=554	P value
Median pain score on visual-analogue scale	4.8 (3.0-6.4)	5.0 (3.0-6.7)	<b>0.28</b>

✓ Post-procedural pain reported less frequently in OSCM than in WSCM group <sup>6</sup>



LIPIODOL<sup>®</sup> FOR HSG - A WELL-TOLERATED PROCEDURE

# Lipiodol<sup>®</sup> HSG: Features & Benefits

Features	Benefits
▶ <b>Tube &amp; uterus visualizer</b>	<ul style="list-style-type: none"><li>• <b>Both tubes &amp; uterine cavity visualization</b></li><li>• <b>Accurate image quality</b> <sup>1,17,24</sup></li></ul>
▶ <b>Convenient</b>	<ul style="list-style-type: none"><li>• <b>Simple</b></li><li>• <b>Well-tolerated</b> - Less frequent post-procedural pain &amp; no significant difference in pain level during the procedure compared to WSCM group <sup>1,6,7,17</sup></li><li>• <b>Minimally-invasive</b></li></ul>

**LIPIODOL<sup>®</sup> EFFICACY & SAFETY FOR TUBAL PATENCY & UTERINE INVESTIGATION**



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