South Staffordshire & Shropshire Healthcare NHS
NHS Foundation Trust

PATIENT GROUP DIRECTION
FOR THE SUPPLY AND ADMINISTRATION OF LEVONORGESTREL PROGESTOGEN ONLY INTRAUTERINE SYSTEM (IUS) MIRENA® and Jaydess®.

by registered nurses and midwives in Integrated Sexual Health services employed by South Staffordshire and Shropshire NHS Foundation Trust

This Patient Group Direction for use in South Staffordshire & Shropshire Healthcare NHS Foundation Trust and is authorised by:			
Position of Signatory	**Name**	**Signed**	**Date**
Medical Director	Dr Abid Khan		
Chief Pharmacist	Cathy Riley		
Director of Quality & Clinical Performance	Therèsa Moyes		
Director of Nursing	Alison Bussey		

The named below, being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to administer or supply Levonorgestrel IUS to patients in Integrated Sexual Health Services under this Patient Group Direction

Name	Job Title	Signed	Date

This Patient Group Direction is operational from 1st October 2017.
Review date: August 2019. Expires on 31st October 2019.
Replaces PGD 0217

Professional Responsibility

All registered nurses and non medical prescribers being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to administer or supply levonorgestrel IUS as specified under this Patient Group direction following demonstration of the competencies below;

Professional Responsibility / Competencies

1. The registered nurse will have undertaken appropriate training in order to carry out clinical assessments of patient that requires treatment according to the indication listed in the PGD
2. Qualification in contraception/sexual health (university modules/FSRH) **Note**: an introduction to contraception/ sexual health is not sufficient
3. Qualification/training in the insertion technique of the IUS **Note:** The FSRH Letter of Competence (LoC) in Intrauterine Techniques (IUT) is the gold standard
4. Is competent in the assessment of individuals using Fraser guidelines
5. Has undergone regular training and updating in safeguarding children and vulnerable adults
6. The nurse must be familiar with current FSRH clinical guidelines on insertion of Intrauterine contraception
7. All nurses will have received training in the management and treatment of anaphylactic shock on an annual basis
8. Each nurse will keep a record in their professional portfolio of the updates attended during every 12 month period – This information will also form part of the team's annual training plan
9. The nurse will have due regard for the NMC Code of Conduct, Scope of Professional Practice and Standards for Medicines Management (Nursing & Midwifery Council)
10. Undertaken appropriate training and possess the competencies for working under PGDs for the supply and administration of medicines
11. All registered nurses details and signature must be entered onto the PGD

For full product information, always refer to the latest SPC (Summary of Product Characteristics).

If the anaphylaxis is related to a medication, please remember to report to the CSM, via a Yellow Card Report (http://emc.medicines.org.uk)

Supply/Administration of	Levonorgestrel Intrauterine System (IUS) Mirena® and Jaydess®.
Legal Classification	Prescription Only Medicine
Black Triangle?	No
Type	Intrauterine System
Storage	Supplies will be available from central stock location. Information leaflets must be given. Any relevant documentation must be completed. Mirena® and Jaydess® are supplied in sterile packs which should not be opened until required for insertion and must be used by date of expiry. No special storage precautions required.
Condition to be treated	Contraception
Inclusion Criteria	Any individual age from 13 years of age or above presenting for contraception, where pregnancy is excluded and any genital infection has been successfully treated.
Exclusion Criteria	Before insertion, a complete personal and family medical history should be taken. Physical examination should be guided by this and by the exclusion criteria below, contraindications and warnings for use. Pulse and blood pressure should be taken and a bi-manual pelvic examination performed to establish the orientation of the uterus. **Personal Characteristics & Reproductive History** • Known or suspected pregnancy • Individuals under 16 years of age and assessed as not competent using Fraser guidelines • Individuals aged 16 years of age and over and assessed as not competent to consent • Known hypersensitivity to any constituent of the IUS • Less than 6 weeks postpartum • Puerperal sepsis • Immediate post septic abortion **Cardiovascular Disease** • Active or previous severed arterial disease including ischaemic heart disease, transient

	ischaemic attack myocardial infarction or stroke • Pre-existing cardiac conditions or severe or multiple risk factors for arterial disease • Thrombotic arterial or any current embolic disease • Acute venous thromboembolism **Cancers** • Current or past history of breast cancer • Cervical cancer (awaiting treatment) • Endometrial cancer • Benign liver tumour • Malignant liver tumour (hepatoma) • Malignancies affecting the blood including leukaemias in remission **Gastro – Intestinal Conditions** • Severe decompensated cirrhosis • Jaundice **Infections** • Current pelvic inflammatory disease (PID) • Chlamydial infection either symptomatic or asymptomatic • Current purulent cervicitis or gonorrhoea • Known pelvic tuberculosis **Anatomical Abnormalities** • Distorted uterine cavity; congenital or acquired abnormality distorting the uterine cavity including fibroids that are incompatible with IUS insertion **Other Conditions** • Systemic Lupus Erythematosus (SLE) with positive or unknown anti–phospholipid antibodies • Gestational trophoblastic disease with persistently elevated β-hCG levels or malignancy • Undiagnosed abnormal vaginal bleeding • Individual wishes to see a doctor • Unusually severe or frequent headaches • Chronic corticosteroid use • Past history of symptomatic functional ovarian cysts <u>Cautions:</u> • Ensure emergency drugs and equipment, including adrenaline are available for the treatment of anaphylaxis and emergencies according to local policy • Discuss with appropriate doctor/independent non-medical prescriber any medical condition or medication which the nurse is unsure/uncertain

	of • Interacting medicines-see current BNF on interactions • Marked increase of blood pressure, see UKMEC 20156: https://www.fsrh.org/documents/ukmec-2016/
Action if excluded or patient declines	• Refer to appropriate doctor/independent non-medical prescriber • Discuss/offer alternative method • Document all actions taken • Record the refusal in the clinical record • Refer to appropriate doctor/independent non-medical prescriber where required • Discuss/offer alternative method • Document all actions taken
Reasons for seeking further advice from doctor	• Discuss with appropriate doctor/independent nurse prescriber any medical condition or medication of which the nurse is unsure • Should the patient meet any of the exclusion criteria
Administration Route	Intrauterine
Dose	• The standard IUS contains 52 milligrams of levonorgestrel which is delivered as daily dose of 20 micrograms/24 hour via an intrauterine delivery system (currently marketed as Mirena®). The initial release of levonorgestrel is approximately 20 micrograms per day reducing to approximately 10 micrograms per day after 5 years in women using this. • The smaller IUS contains 13.5 milligrams of levonorgestrel which is delivered as a daily dose of 6 micrograms/24 hours via an intrauterine delivery system (currently marketed as Jaydess®).
Administration Schedule	• Insert on day 1-7 of the menstrual cycle with no need for additional protection • It can be replaced with another system at any day of the menstrual cycle • For guidance on replacing or changing from one contraceptive method to another, and when to start after abortion and postpartum refer to FSRH guidelines

	Duration of Treatment: For as long as the individual requires the IUS and has no contraindications Maximum - The standard IUS (currently marketed as Mirena®) is licensed for 5 years for contraception. The smaller IUS (currently marketed as Jaydess®) is licensed for 3 years of contraception.
Warnings/Adverse Reactions	Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for full list and further information. This list may not represent all reported side effects of this medicine. The IUS is well tolerated. Some of the common side effects are; • Acne • Breast tenderness • Headache • Disturbance of bleeding patterns • Changes in mood • Weight change • Loss of libido Insertion complications may include infection, expulsion or perforation. In the event of untoward or unexpected adverse reactions: • If necessary seek appropriate emergency advice and assistance • Document in the individual's clinical record and inform appropriate doctor/independent non-medical prescriber • Complete incident procedure if adverse reaction is severe (refer to local organisational policy) • Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mhra.gov.uk.

	The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.
Advice/Management of Adverse Reactions & Follow-up Action	• Provide Manufacturer's Patient Information Leaflet (PIL) and discuss (including signs of expulsion, perforation and encouragement to check threads) • Explain mode of action, side effects, and benefits of the system • Advise about the risks of the system including failure rates and serious side effects and the actions to be taken • Advise about the possible symptoms of serious sequelae e.g. infection, ectopic pregnancy, expulsion and perforation and when to seek clinical advice. • Teach individual how to check threads and to seek clinical advice if not felt. • Provide a copy of the FPA leaflet on the IUS http://www.fpa.org.uk/sites/default/files/ius-your-guide.pdf • Offer condoms and advise on safer sex practices. • Encourage to give up smoking if appropriate • Ensure individual knows what to do if her medical condition changes in the future Ensure individual has the contact details of the service <u>Follow Up:</u> • Individual to return to clinic if she has any concerns and for re-examination 6 weeks after insertion • Review in 3 to 6 weeks after insertion.
Use in pregnancy and lactation	Not appropriate for PGD
Records	The authorised registered nurse must ensure the following is documented in the clinical record: • Individual's name, address and date of birth • GP contact details where appropriate • Attendance date • Reason for attendance • Relevant past and present medical and family history, including drug history • Any known allergy • Relevant examination findings • Inclusion or exclusion from PGD

	• A statement that supply and insertion is by using a PGD and the PGD number recorded • Advice given about the system, including side effects, benefits, and when and what to do if any concerns • Details of any adverse drug reactions and what action taken • Any referral arrangements • Any supply/administration outside the terms of the product marketing authorisation • The consent of the individual • If individual is under 13 years of age, record action taken • If individual is under 16 years of age document competency using Fraser guidelines • If individual is 16 years of age and over and not competent, record action taken • Record the name/brand, dose of the medication and quantity supplied and administered on the Medicines Supply Log • Record batch number and expiry date according to local policy or national guidelines • Record follow up and/or signposting arrangements • Any other relevant information that was provided to the individual • Name and signature (which may be an electronic signature) of the nurse supplying or administering the medicine