**Template protocol for the Insertion of Copper Intrauterine Devices (Cu-IUDs) in location/service/organisation**

Version Number 1.1

|  |  |
| --- | --- |
| **Change History** | |
| **Version and Date** | **Change details** |
| Version 1.0  October 2023 | New template |
| Version 1.1  November 2023 | Additional indication of postpartum intrauterine contraception (PPIUC). |

This template protocol, for local adaptation, has been peer reviewed by the Reproductive Health PGD/protocols Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in September 2023. Note the working group and approving organisation(s) agreement to the content only applies to the national template and does not extend to any local adaptations made to any of the content which are solely the responsibility of the organisation authorising the PGD. The most up to date version of the template is available here: <https://www.sps.nhs.uk/home/guidance/patient-group-directions/templates/>

For advice on protocol use in practice/advised supporting governance please refer to [When Patient Group Directions are not required](https://www.sps.nhs.uk/articles/when-patient-group-directions-are-not-required/) and [About the SPS Medicines Governance Do Once Programme](https://www.sps.nhs.uk/articles/about-the-sps-medicines-governance-do-once-programme/)

Organisations should link to local infection control/PPE guidance relevant to the use of this product.

Each organisation using this protocol must ensure that it is appropriately reviewed and approved for use in line with the organisations’ governance system.

**Protocol development group**

|  |  |
| --- | --- |
| **Name** | **Designation** |
| Dr Cindy Farmer | Vice President, General Training  Faculty of Sexual and Reproductive Healthcare (FSRH) |
| Michelle Jenkins (Working Group Co-ordinator) | Advanced Nurse Practitioner, Clinical Standards Committee  Faculty of Sexual and Reproductive Healthcare (FSRH) |
| Vicky Garner | Deputy Chief Midwife British Pregnancy Advisory Service (BPAS) |
| Gail Rowley | Quality Matron British Pregnancy Advisory Service (BPAS) |
| Katie Girling | British Pregnancy Advisory Service (BPAS) |
| Julia Hogan | CASH Nurse Consultant MSI Reproductive Choices |
| Kate Devonport | National Unplanned Pregnancy Advisory Service  (NUPAS) |
| Chetna Parmar | Pharmacist adviser Umbrella |
| Helen Donovan | Royal College of Nursing (RCN) |
| Carmel Lloyd | Royal College of Midwives (RCM) |
| Clare Livingstone | Royal College of Midwives (RCM) |
| Kirsty Armstrong | National Pharmacy Integration Lead, NHS England |
| Dipti Patel | Local authority pharmacist |
| Emma Anderson | Centre for Pharmacy Postgraduate Education (CPPE) |
| Dr Kathy French | Specialist Nurse |
| Dr Sarah Pillai | Associate Specialist |
| Alison Crompton | Community pharmacist |
| Andrea Smith | Community pharmacist |
| Lisa Knight | Community Health Services pharmacist |
| Bola Sotubo | NHS North East London ICB pharmacist |
| Tracy Rogers | Director, Medicines Use and Safety, Specialist Pharmacy Service |
| Sandra Wolper | Associate Director Specialist Pharmacy Service |
| Jo Jenkins | Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service |

|  |  |
| --- | --- |
| **1. Staff competencies** | |
| **Authorised staff** | To complete locally to include those healthcare professionals who will be authorised to work under this protocol to insert a Copper Intrauterine device (Cu-IUD) |
| **Additional requirements** | The registered healthcare professional operating under this standardised protocol must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the devices listed in accordance with local policy.  Recommended requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or university or as advised in the RCN training directory. Individuals working under this standardised protocol should hold an in date FSRH Letter of Competence Intrauterine Techniques (LoC IUT) which has been achieved or recertified within the last 5 years.  Protocol users should have read thoroughly and be familiar with the [FSRH IUC guidance](https://www.fsrh.org/standards-and-guidaFSRH%20Clinical%20Guideline:%20Intrauterine%20contraception%20(March%202023,%20Amended%20July%202023)%20|%20FSRHnce/documents/ceuguidanceintrauterinecontraception/).  Immediate postpartum intrauterine contraception (PPIUC) insertion training is not part of the FSRH LoC IUT. The insertion procedure for immediate PPIUC is different to that of standard IUC insertion and should only be performed by those who have been trained in this technique. Theoretical training information for PPIUC can be found in the FSRH Member’s Training hub and clinicians should follow/develop local pathways for practical training.  Individuals working under this standardised protocol may be required to administer local anaesthesia in line with local protocols/PGDs.  The healthcare professional has completed training and is up to date with service requirements/specification for safeguarding children and vulnerable adults. (amend as per local policy).  The healthcare professional must ensure that they have an up-to-date certificate for Basic Life Support (BLS) and anaphylaxis as required by the employing Trust/organisation |
| **2. Clinical condition or situation** | |
| **Clinical situation** | Insertion of a copper Intrauterine device (Cu-IUD) |
| **Individuals included** | * Individuals from menarche to age 55 assessed as suitable for a CU-IUD as a long-acting reversible method of contraception. * If an individual meets the eligibility criteria for emergency contraception * Individual consents to treatment. |
| **Individuals excluded** | * Informed consent not given. * Individuals under 16 years of age and assessed as not competent using Fraser Guidelines. * Individuals 16 years of age and over and assessed as lacking capacity to consent. * Risk of pregnancy (unless meeting the criteria for insertion as emergency contraception) * Any reported unprotected sexual intercourse (UPSI) within the last 3 weeks (unless meeting the criteria for insertion as emergency contraception). * Over 48 hours and less than 4 weeks postpartum (note the Cu-IUD can be fitted immediately post-partum, post termination of pregnancy, ectopic pregnancy or miscarriage) * Postpartum sepsis * Post-abortion sepsis * Gestational trophoblastic disease with decreasing or, persistently elevated β-hCG levels or malignancy   **Cardiovascular Disease**   * For individuals with pre-existing arrhythmia, Eisenmenger physiology, single ventricle (or Fontan) circulation, long QT syndrome or impaired ventricular function, a vasovagal reaction could pose a serious risk of a significant cardiac event and therefore IUC procedures should be undertaken in a hospital setting.   **Cancers**   * Cervical cancer (initiation of Cu-IUD in patients awaiting treatment) * Endometrial cancer (initiation of Cu-IUD) * Cervical cancer (resulting in radical trachelectomy)   **Infections**   * Current or recurrent pelvic inflammatory disease (PID) * Known current chlamydial infection * Known gonorrhoea infections * Current purulent cervicitis or vaginitis * Known pelvic tuberculosis * HIV infection with CD4 <200cells/mm3   **Anatomical abnormalities**   * Distorted uterine cavity; congenital or acquired abnormality distorting the uterine cavity, including fibroids, incompatible with Cu-IUD insertion.   **Other Conditions**   * Unexplained vaginal bleeding suspicious of a serious medical condition, present before commencing the method * Organ transplant with complications * Previous endometrial ablation * Individuals with Wilson’s disease   Refer to the current FSRH CEU clinical guideline [Intrauterine Contraception](https://www.fsrh.org/Public/Standards-and-Guidance/Intrauterine-Contraception.aspx) and clinical guidance ‘switching’ for specific guidance about starting and switching IUC. |
| **Cautions (including actions required)** | * If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. * If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. * Individuals taking anticoagulants or antiplatelets - refer to FSRH CEU Statement [Management of women taking anticoagulants or antiplatelet medications who request intrauterine contraception or subdermal implants](https://www.fsrh.org/news/new-guidance-on-management-of-anticoagulants-or-antiplatelet/) * Liaison with an individual’s multi disciplinary team (MDT) or clinical specialist may be required with certain conditions (e.g. inherited bleeding disorders, cardiac disease, taking anticoagulants, Ehlers-Danlos syndromes (EDS), Postural tachycardia syndrome (PoTS). * Individuals at risk of an adrenal crisis will usually need to increase their steroid dose prior to, and for 24 hours after, IUC insertion and should ideally have their IUC procedure scheduled for early morning. * If an individual with PoTS has a history of postural syncope, advice should be sought from their cardiologist, as it may be recommended that insertion should be undertaken in a hospital setting. * Individuals with cardiac arrhythmias (other than long QT) discuss with relevant clinician. * Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain |
| **Action for individuals excluded** | * Explain the reasons for exclusion to the individual and document in the consultation record. * Record reason for decline in the consultation record. |
| **Action if individual declines treatment** | Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options |
| **3. Description of treatment** | |
| **Name of device**  (product list may not be exhaustive – amend to reflect local product(s) held) | **Framed, banded copper arms:** Copper T380 A®, T-Safe® 380A QL,  T-Safe®380 A, Flexi-T®+ 380, TT 380® Slimline, Mini TT380® Slimline  **Framed, copper in stem only:** Nova-T®380, UT380 Standard®,  Neo-Safe®T380, Eurogine (Novaplus) T 380® Cu, Eurogine (Novaplus) T 380® Cu ‘mini’, UT380 Short®, Multiload® Cu375, Multi-Safe®375, Ancora®375 Cu, Load®375, Flexi-T®300  **Frameless:** GyneFix®330, GyneFix®200Insertion technique is different for the GynaeFix therefore specific training is required.  **Silver IUD:** Eurogine (Novaplus) T380® Ag, Eurogine (Novaplus) T380® Ag mini  **Note:**  this standardised protocol does not restrict which brands can be supplied – local formularies/restrictions should be referred to and the above list edited to reflect local formularies. See <http://www.mhra.gov.uk/spc-pil/> or <http://www.medicines.org.uk> for further information and further brand information including full details of adverse effects and interactions. |
| **Legal status** | Medical Device |
| **Route of administration** | Intra-uterine  Insert using aseptic or no-touch technique as per [FSRH guidance on intrauterine contraception](https://www.fsrh.org/standards-and-guidance/documents/ceuguidanceintrauterinecontraception/) or immediate PPIUC technique. |
| **Timing of Insertion and duration of use**  (product list may not be exhaustive – amend to reflect local product(s) held) | * One Cu-IUD to be inserted (after removal of previous LNG-IUD or Cu-IUD if required). * Insert on any day of the menstrual cycle if it is reasonably certain that the individual is not pregnant, with no need for additional protection * For guidance on [changing from one contraceptive method to another](https://www.fsrh.org/standards-and-guidance/fsrh-guidelines-and-statements/switching-or-starting-methods-of-contraception/), and when to start after an [abortion and postpartum](https://www.fsrh.org/standards-and-guidance/documents/contraception-after-pregnancy-guideline-january-2017/), refer to the Faculty of Sexual and Reproductive Healthcare (FSRH) guidelines. * Emergency contraception – Cu-IUDs can be inserted as emergency contraception if inserted within 5 days of the earliest episode of UPSI that cycle, or within 5 days of the earliest expected date of ovulation * Insert within 48 hours of birth (Immediate postpartum intrauterine contraception (PPIUC)). The insertion procedure for immediate PPIUC is different to that of standard IUC insertion and should only be performed by those who have been trained in this technique.   **Frequency of Cu-IUD insertion:**   * Effective for up to 10 years:   + **Framed, banded copper arms:** Copper T380 A®,  T-Safe® 380A QL, T-Safe®380 A, TT 380® Slimline * Effective for up to 5 years:   + **Framed, banded copper arms:** , Flexi-T®+ 380, Mini TT380® Slimline   + **Framed, copper in stem only:** Nova-T®380, UT380 Standard®, Neo-Safe®T380, Eurogine (Novaplus) T 380® Cu, Eurogine (Novaplus) T 380® Cu ‘mini’, UT380 Short®, Multiload® Cu375, Multi-Safe®375, Ancora®375 Cu, Load®375, Flexi-T®300   + **Frameless:** GyneFix®330, GyneFix®200   + **Silver IUD:** Eurogine (Novaplus) T380® Ag, Eurogine (Novaplus) T380® Ag mini * Note the FSRH supports extended use until menopause/age 55 of devices containing ≥300 mm2 copper when inserted over the age of 40 years |
| **Off label use** | Best practice advice is given by the FSRH and is used for guidance in this standardised protocol.  This standardised protocol specifically includes inclusion criteria and dosage regimens which are outside the market authorisation for many of the available products but which are included within FSRH guidance:   * When inserted over the age of 40 years any Cu-IUD containing ≥300 mm2 copper can be retained as contraception until menopause/the age of 55 years * Initial insertion after day 7 of the menstrual cycle if it is reasonably certain that the individual is not pregnant * Postpartum insertion between 4-6 weeks |
| **Storage** | Devices must be stored securely according to manufacturer’s instructions. |
| **Adverse effects** | The Cu-IUD is generally well tolerated. The following possible adverse effects are commonly reported with Cu-IUD:   * Increase in menstrual blood loss * More painful menstrual bleeding * Intermenstrual bleeding   Insertion complications may include infection, expulsion, or perforation. Individuals should be advised on the signs that these may have occurred and the action to take if they become concerned. |
| **Management of and reporting procedure for adverse reactions** | * Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <http://yellowcard.mhra.gov.uk> * Record all adverse drug reactions (ADRs) in the individual’s clinical record. * Report via organisation incident policy. |
| **Additional facilities and supplies** | * Access to working telephone * Suitable waste disposal facilities * Immediate access to in-date anaphylaxis kit (IM adrenaline 1:1000) and emergency drugs including atropine and oxygen according to local protocol. |
| **Written information and further advice to be given to individual** | * Provide patient information leaflet (PIL) provided by the manufacturer. * Explain mode of action, side effects, risks and benefits of the Cu-IUD * Advise about the risks 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 unable to feel threads. * Advise when replacement of the Cu-IUD will be required. * Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs) * Ensure the individual has contact details of local service/sexual health services. |
| **Record keeping** | * The consent of the individual and   + If individual is under 13 years of age record action taken   + If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.   + If individual over 16 years of age and not competent, record action taken * Name of individual, address, date of birth * GP contact details where appropriate * Relevant past and present medical history, including medication and family history. * Any known allergies * Details of insertion procedure to include:   + Name of registered health professional   + Date of insertion   + Name/brand of Cu-IUD inserted   + Batch number and expiry date of product in line with local procedure   + Bimanual examination and speculum findings   + Uterine sounding   + Use of no touch technique   + Name of assistant/their role   + Analgesia or local anaesthetic used   + Problems encountered during insertion * Advice given, including advice given if excluded or declines treatment * Details of any adverse reactions and actions taken * Advice given about the device including side effects, benefits, and when and what to do if any concerns * Any referral arrangements made if required * Any administration outside the terms of the product marketing authorisation and additional advice given relating to this and advice given * A statement that administration is under a protocol. |
| * **4. References** | |
| **(accessed September 2023)** | * FSRH Clinical Guideline: Intrauterine contraception (March 2023)   [Intrauterine Contraception | FSRH](https://www.fsrh.org/Public/Standards-and-Guidance/Intrauterine-Contraception.aspx)   * Faculty of Sexual and Reproductive Healthcare (2016) UK Medical Eligibility Criteria for Contraceptive Use.   [UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) | FSRH](https://www.fsrh.org/Public/Public/Standards-and-Guidance/uk-medical-eligibility-criteria-for-contraceptive-use-ukmec.aspx?hkey=82727ce6-756b-4b88-a5ab-acaf27c48669)   * Faculty of Sexual and Reproductive Healthcare (2016 Clinical Guideline: Quick Starting Contraception (April 2017)   [FSRH Clinical Guideline: Quick Starting Contraception (April 2017) | FSRH](https://www.fsrh.org/Public/Documents/fsrh-clinical-guidance-quick-starting-contraception-april-2017.aspx)   * Faculty of Sexual and Reproductive Healthcare (2019) Service standards for record keeping   [FSRH Service Standards for Record Keeping (July 2019) | FSRH](https://www.fsrh.org/Public/Documents/fsrh-service-standards-for-record-keeping-july-2019.aspx)   * FSRH CEU Guidance: Switching or Starting Methods of Contraception (April 2023)  [Switching or Starting Methods of Contraception | FSRH](https://www.fsrh.org/Public/Standards-and-Guidance/Switching-or-Starting-Methods-of-Contraception.aspx) |