Bixby Center for Global Reproductive Health

UCSF University of California San Francisco

Beyond the Pill
Bringing the best science to contraceptive care

Protocol for Provision of the Contraceptive Implant

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This protocol was written by Patty Cason, RN, MS, FNP-BC, with contributions by Suzan Goodman, MD, MPH.

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Table of Contents

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Contraceptive Implant

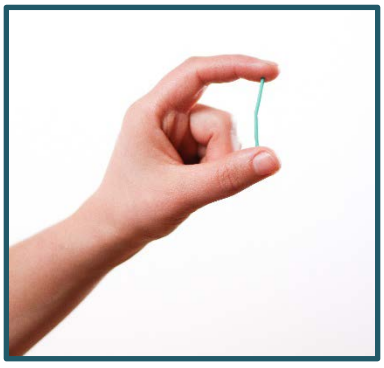
Currently in the United States there is one contraceptive implant. It is marketed under the brand NEXPLANON®.

- It is approved for use up to 3 years, and evidence suggests it is effective for 5 years.
- The implant is a progestin-only method. It contains **no estrogen.** The progestin in the implant is etonogestrel.
- The contraceptive effect of is achieved by suppression of ovulation and increased viscosity of the cervical mucus, although the dose of etonogestrel is not generally high enough to suppress endogenous estradiol.
- NEXPLANON® is a single rod that is 4cm long and 2mm in diameter
- The implant is made up of:
    1. A core containing etonogestrel
    2. A semi-permeable rate-controlling membrane made of EVA that elutes a moderate dose of etonogestrel in a steady state
    3. Barium sulfate to make it radiopaque.
- The implant is placed subdermally at the inner side of the upper arm
- It is immediately reversible upon removal.

Procedure for placement of an implant

All healthcare providers placing contraceptive implants must have completed an FDA mandated and controlled manufacturer sponsored training program for placement, removal and re-insertion.

Refer to the training materials and training video that are provided during the required course to review the technique for placement removal and re-insertion of the implant.



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Contraindications and precautions for implant use

Absolute contraindications

Contraindication for placement or continued use of an implant (MEC category 4):

- Pregnancy
- Breast cancer < 5 years since diagnosis
- Allergy to any component of the Nexplanon

Relative contraindications

Relative contraindication/caution regarding placement of an implant (MEC category 3):

- Breast cancer > 5 years since diagnosis with no evidence of disease
- Systemic lupus erythematosus (SLE) — when antiphospholipid antibodies are positive or unknown
- Severe decompensated cirrhosis, malignant liver tumors, hepatocellular adenoma
- Unexplained vaginal bleeding before evaluation
- Rule out pregnancy
- Consider the possibility that unpredictable bleeding with implant use is expected. Therefore, preexisting abnormal bleeding should not be ignored as it may delay diagnosis of malignancy.

Relative contraindication/caution regarding **continued** use of an implant if the following condition is diagnosed during use of an implant (MEC category 3-- continuation):

- Stroke (CVA)
- Ischemic heart disease
- Migraine with aura

Drug interactions

Some enzyme inducing anti-seizure medications and some antiretrovirals may decrease the effectiveness of the implant.

Serum levels of lamotrigine may decrease after a woman has an implant placed

Serum levels of cyclosporine may increase after a woman has an implant placed

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Counseling prior to placement

Counsel regarding bleeding changes

Before implant placement, provide counseling about potential changes in bleeding patterns during implant use. Most users of implants will have an alteration in their bleeding pattern. It is not possible to predict what a given woman's bleeding pattern will be like, and her bleeding pattern may change over time.

In general, if she has little or no bleeding initially, that will broadly predict her subsequent pattern. Unscheduled spotting or light bleeding is common with implant use. These bleeding changes are generally not harmful and may or may not decrease with continued implant use but bleeding patterns tend to get better (less bleeding/spotting) with time. Some women experience amenorrhea. Heavy prolonged bleeding is uncommon during implant use.

Box 2 from US SPR:

Box 2. How To Be Reasonably Certain that a Woman Is Not Pregnant

A health-care provider can be reasonably certain that a woman is pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- Is ≤7 days after the start of normal menses
- Has not had sexual intercourse since the start of last normal menses
- Has been correctly and consistently using a reliable method of contraception
- Is ≤7 days after spontaneous or induced abortion
- Is within 4 weeks postpartum
- Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds),* amenorrheic, and <6 months postpartum

*Source: *U.S. Selected Practice Recommendations for Contraceptive Use, 2016 (US SPR)*.

Stanback J, Yacobson I, Harber L. Proposed clinical guidance for excluding pregnancy prior to contraceptive initiation. Contraception. 2017 Apr;95(4):326-330.

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Initiation of an implant

- There are no routine examinations or tests needed before implant insertion. Evidence suggests neither physical exam nor lab tests contribute substantially to safe and effective use of the contraceptive implant (SPR). Weight and BMI at baseline might be helpful for monitoring any changes and counseling women concerned about weight change perceived to be associated with their contraceptive method.
- An implant can be placed at any time if it is reasonably certain that the woman is not pregnant (See Box 1); waiting for a menstrual period is unnecessary.
- If it is not reasonably certain that the woman is not pregnant, she should be provided with a bridge contraceptive until it is reasonably certain that she is not pregnant*

  *Note that progestins have not been found to be teratogenic, and in a situation where a woman has had unprotected sex >5 days since her last menses, it is reasonable to discuss the risks and benefits of placement. In the context of a shared decision making process a woman may choose to have an implant placed even if it not certain that she will not subsequently be found to be pregnant. If she chooses to terminate the pregnancy, she could continue with use of the implant. If she elects to continue the pregnancy, she would have the implant removed.
- An implant can be placed immediately or at any time after either a vaginal or cesarean birth if it is reasonably certain she is not pregnant, whether she is breastfeeding or not.
- An implant can be placed immediately after surgical procedure for abortion or spontaneous abortion or post early pregnancy failure without a procedure or at the time of mifepristone during medication abortion or any time thereafter if it is reasonably certain she is not pregnant.

Need for back-up contraception

- If an implant is placed within the first 5 days since menstrual bleeding started, no back up is needed.
- If an implant is placed>5 days since menstrual bleeding started, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days (i.e. backup for 7 days).
- When switching to an implant from a CU IUC, a hormonal or barrier method, continue her previous method for 7 days after implant placement.
- < 21 days postpartum, no backup needed.
- ≥ 21 days postpartum and menses has not resumed, backup for 7 days.
- <7 days post-surgical procedure for spontaneous or elective abortion or post medication abortion or post early pregnancy failure without a procedure, no back up needed.
- >7 days post-surgical procedure for spontaneous or elective abortion or post medication abortion or post early pregnancy failure without a procedure, backup for 7 days.

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Use of emergency contraceptive pills prior to placement of an implant:

Consider providing ECPs at the time of implant placement if *:

- She had unprotected sexual intercourse since the start of her last menstrual cycle and:
  - It has been >5 days since menstrual bleeding started
  - She has had unprotected intercourse within the last five days
  - A pregnancy test is negative

Obtain a pregnancy test 3 weeks after placement in these circumstances.

*This also applies when switching from a Cu-IUC to an implant.

Backup after use of emergency contraceptive pills prior to placement of an implant:

- If a woman takes levonorgestrel ECP, backup for 7 days.
- If a woman takes Ulipristal acetate (UPA) ECP, backup for 14 days.

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Follow up after placement of an implant

- No routine follow-up visit is required.
- Adolescents, women with relevant medical conditions or with multiple medical problems may benefit from a follow up visit after placement.
- Encourage a woman to call or return at any time to discuss side effects, concerns, if she desires removal or needs replacement of the implant.
- At other routine visits, providers who see implant users should assess the woman's satisfaction with her implant and if she has any concerns

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Evaluation / Management

Amenorrhea with implant in place

- History: Signs or symptoms of pregnancy
- Labs: pregnancy test
- Exam: as needed if pregnancy test is positive
- If not pregnant, reassure
- If not acceptable, counsel on other methods

Frequent or prolonged spotting or bleeding with implant in place

- History: Signs or symptoms of pregnancy, infection, lesion, malignancy
- Labs as indicated: pregnancy test, CT/GC, hgb, pap/HPV
- Exam: rule out pregnancy, cervical neoplasm, polyps, infection, fibroids
- If no evidence of lesion, infection or pregnancy, reassure.
- The following treatment options can be considered:
    - NSAIDS for 5–7 days
    - If use of estrogen is not contraindicated (10-20 days):
        - Low-dose combined hormonal contraceptives or
        - Estrogen: estradiol 1-2 mg or conjugated estrogen 0.625-1.25mg
- If not acceptable, counsel on other methods

Localization of a non-palpable implant

Refer to the manufacturers comprehensive instructions on localization that are provided during the FDA mandated placement and removal training

There is currently only one implant in distribution in the United States. It is marketed under the brand name NEXPLANON®. It is radiopaque and therefore can be seen by x-ray or CT scan. IMPLANON® is no longer manufactured however providers may come across women who still have an IMPLANON® in place. IMPLANON® is not radiopaque and therefore cannot be seen by x-ray or CT scan.

- If an implant is nonpalpable and the patient has no evidence of progestin effect:
    - A serum etonogestrel level can confirm that there is, or is not an implant present but cannot assess the location of an implant.
    - Call 1-877-467-5266 to request an assay from the manufacturer.
    - Advise a woman who is going to have an etonogestrel serum level drawn not to use any other contraceptive hormones.

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Localization of a non-palpable Nexplanon:

- If the implant is not palpable immediately after presumed placement, confirm its presence in the arm with 2-dimensional x-ray.
- If an implant is not palpable at a later date:
    - History: Signs or symptoms of pregnancy, bleeding pattern indicates progestin effect or not
    - Labs as indicated:
        - pregnancy test
        - serum etonogestrel level if not seen by x-ray

Localization of a non-palpable Implanon:

- Ultrasound scanning with a high-frequency linear array transducer (10 MHz or greater)
    - Sharp acoustic shadow below the implant in the transverse position
    - Implant is a small echogenic spot (2 mm) when viewed in transverse position
    - A larger footprint, on the order of 50 mm, is helpful in identifying the full length of the implant on longitudinal images. Select a superficial structure preset, and focus the beam superficially (assuming correct placement, <3 cm). Multiple focal zones can be used. In order to locate the implant, posterior acoustic shadowing is first identified. It is then possible to look for the echogenic focus or spot at the superior apex of the shadow, representing the actual implant. Turn the transducer 90 degrees to obtain a longitudinal view of the implant.
- Magnetic resonance imaging

Removal of a non-palpable implant:

- Advise the patient to abstain or use an additional contraceptive method, until the presence of the implant can be confirmed.
- If the woman presents for removal of an implant that is not palpable, **do not** attempt removal of a non-palpable implant.
- Refer non-palpable implants:
    - to a provider familiar with the anatomy of the arm
    - to remove the implant with guidance or after localization with imaging
    - in order to prevent damage to neural structures, vasculature and muscle near the implant

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CDC references

CDC Medical Eligibility Criteria:

1. Box 1 (categories)
2. Appendix C (progestin only methods)
3. CDC MEC Postpartum update re: implants
    a) Table 3
    b) Recommendations for Use of Other Contraceptive Methods During the Postpartum Period

Progestin-only hormonal methods, including progestin-only pills, depot medroxyprogesterone acetate injections, and implants, are safe for postpartum women, including women who are breastfeeding, and can be initiated immediately postpartum (categories 1 and 2).

Appendix C: Classifications for Progestin-Only Contraceptives

Citation: Centers for Disease Control and Prevention. U.S. Medical Eligibility Criteria for Contraceptive Use, 2016: MMWR 2016;65(3):1-96.

Available from: https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6503.pdf

Classifications for progestin-only contraceptives (POCs) include those for progestin-only pills, depot medroxyprogesterone acetate, and progestin-only implants (Box). POCs do not protect against sexually transmitted infections (STIs) or human immunodeficiency virus (HIV).\

BOX 1. Categories for Classifying Progestin-Only Contraceptives
1 = A condition for which there is no restriction for the use of the contraceptive method.
2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

TABLE. Classifications for progestin-only contraceptives, including progestin-only pills, DMPA, and implants*†

Condition	Category			Clarifications/Evidence/Comments
	POP	DMPA	Implants	
Personal Characteristics and Reproductive History				
Pregnancy	Not applicable	Not applicable	Not applicable	**Clarification:** Use of POCs is not required. There is no known harm to the woman, the course of her pregnancy, or the fetus if POCs are inadvertently used during pregnancy. However, the relation between DMPA use during pregnancy and its effects on the fetus remains unclear.
Age				
a. Menarche to <18 yrs	1	2	1	**Evidence:** Most studies have found that women lose BMD while using DMPA but regain BMD after discontinuing DMPA. It is not known whether DMPA use among adolescents affects peak bone mass levels or whether adult women with long duration of DMPA use can regain BMD to baseline levels before entering menopause. The relation between DMPA-associated changes in BMD during the reproductive years and future fracture risk is unknown (*1--41*). Studies find no effect or have inconsistent results about the effects of POCs other than DMPA on BMD (*42--54*).
b. 18--45 yrs	1	1	1	
c. >45 yrs	1	2	1	
Parity				
a. Nulliparous	1	1	1	
b. Parous	1	1	1	
Breastfeeding				**Clarification:** The U.S. Department of Health and Human Services recommends that infants be exclusively breastfed during the first 4--6 months of life, preferably for a full 6 months. Ideally, breastfeeding should continue through the first year of life (*55*).
a. <1 mo postpartum	2	2	2	

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TABLE. Classifications for progestin-only contraceptives, including progestin-only pills, DMPA, and implants*†

Condition	Category			Clarifications/Evidence/Comments
	POP	DMPA	Implants	
b. 1 mo to <6 mos postpartum	1	1	1	**Evidence:** Despite anecdotal clinical reports that POCs might diminish milk production, direct evidence from available clinical studies demonstrates no significant negative effect of POCs on breastfeeding performance (*56--90*) or on the health of the infant (*66,70,72,76--81,91--93*). In general, these studies are of poor quality, lack standard definitions of breastfeeding or outcome measures, and have not included premature or ill infants. Theoretical concerns about effects of progestin exposure on the developing, neonatal brain are based on studies of progesterone effects in animals; whether similar effects occur after progestin exposure in human neonates is not known.
c. ≥6 mos postpartum	1	1	1	
Postpartum (in nonbreastfeeding women)				
a. <21 days	1	1	1	
b. ≥21 days	1	1	1	
Postabortion				**Clarification:** POCs may be started immediately postabortion.
a. First trimester	1	1	1	
b. Second trimester	1	1	1	**Evidence:** Limited evidence suggests that there are no adverse side effects when implants (Norplant) or progestin-only injectables (NET-EN) are initiated after first trimester abortion (*94--97*).
c. Immediate postseptic abortion	1	1	1	
Past ectopic pregnancy	2	1	1	**Comments:** POP users have a higher absolute rate of ectopic pregnancy than do users of other POCs but still less than using no method.
History of pelvic surgery	1	1	1	
Smoking				
a. Age <35 yrs	1	1	1	
b. Age ≥35 yrs				
i. <15 Cigarettes/day	1	1	1	
ii. ≥15 Cigarettes/day	1	1	1	
Obesity				
a. ≥30 kg/m^2 BMI	1	1	1	

TABLE. Classifications for progestin-only contraceptives, including progestin-only pills, DMPA, and implants*†

Condition	Category			Clarifications/Evidence/Comments
	POP	DMPA	Implants	
b. Menarche to <18 yrs and ≥30 kg/m^2 BMI	1	2	1	**Evidence:** Obese adolescents who used DMPA were more likely than obese nonusers, obese COC users, and nonobese DMPA users to gain weight. These associations were not observed among adult women. One small study did not observe increases in weight gain among adolescent Norplant users by any category of baseline weight (*98--105*).
History of bariatric surgery§				
a. Restrictive procedures: decrease storage capacity of the stomach (vertical banded gastroplasty, laparoscopic adjustable gastric band, laparoscopic sleeve gastrectomy)	1	1	1	**Evidence:** Limited evidence demonstrated no substantial decrease in effectiveness of oral contraceptives among women who underwent laparoscopic placement of an adjustable gastric band (*106*).
b. Malabsorptive procedures: decrease absorption of nutrients and calories by shortening the functional length of the small intestine (Roux-en-Y gastric bypass, biliopancreatic diversion)	3	1	1	**Evidence:** Limited evidence demonstrated no substantial decrease in effectiveness of oral contraceptives among women who underwent a biliopancreatic diversion (*107*); however, evidence from pharmacokinetic studies suggested conflicting results of oral contraceptive effectiveness among women who underwent a jejunoileal bypass (*108,109*). **Comment:** Bariatric surgical procedures involving a malabsorptive component have the potential to decrease oral contraceptive effectiveness, perhaps further decreased by postoperative complications, such as long-term diarrhea and/or vomiting.

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TABLE. Classifications for progestin-only contraceptives, including progestin-only pills, DMPA, and implants*†

Condition	Category			Clarifications/Evidence/Comments
	POP	DMPA	Implants	
Cardiovascular Disease				
Multiple risk factors for arterial cardiovascular disease (such as older age, smoking, diabetes, and hypertension)	2	3	2	**Clarification:** When multiple major risk factors exist, risk for cardiovascular disease might increase substantially. Some POCs might increase the risk for thrombosis, although this increase is substantially less than with COCs. The effects of DMPA might persist for some time after discontinuation.
Hypertension				
For all categories of hypertension, classifications are based on the assumption that no other risk factors exist for cardiovascular disease. When multiple risk factors do exist, risk for cardiovascular disease might increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive.				
a. Adequately controlled hypertension	1	2	1	**Clarification:** Women adequately treated for hypertension are at lower risk for acute myocardial infarction and stroke than are untreated women. Although no data exist, POC users with adequately controlled and monitored hypertension should be at lower risk for acute myocardial infarction and stroke than are untreated hypertensive POC users.
b. Elevated blood pressure levels (properly taken measurements)				
i. Systolic 140--159 mm Hg or diastolic 90--99 mm Hg	1	2	1	**Evidence:** Limited evidence suggests that among women with hypertension, those who used POPs or progestin-only injectables had a small increased risk for cardiovascular events than did women who did not use these methods (*110*).
ii. Systolic ≥160 mm Hg or diastolic ≥100 mm Hg§	2	3	2	
c. Vascular disease	2	3	2	**Comment:** Concern exists about hypo-estrogenic effects and reduced HDL levels, particularly among users of DMPA. However, there is little concern about these effects with regard to POPs. The effects of DMPA might persist for some time after discontinuation
History of high blood pressure during pregnancy (where current blood pressure is measurable and normal)	1	1	1	
Deep venous thrombosis (DVT)/ Pulmonary embolism (PE)				

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TABLE. Classifications for progestin-only contraceptives, including progestin-only pills, DMPA, and implants*†

Condition	Category			Clarifications/Evidence/Comments
	POP	DMPA	Implants	
a. History of DVT/PE, not on anticoagulant therapy				
i. Higher risk for recurrent DVT/PE (≥1 risk factors) • History of estrogen-associated DVT/PE • Pregnancy-associated DVT/PE • Idiopathic DVT/PE • Known thrombophilia, including antiphospholipid syndrome • Active cancer (metastatic, on therapy, or within 6 mos after clinical remission), excluding non-melanoma skin cancer • History of recurrent DVT/PE	2	2	2	
ii. Lower risk for recurrent DVT/PE (no risk factors)	2	2	2	
b. Acute DVT/PE	2	2	2	**Evidence:** No direct evidence exists on use of POCs among women with acute DVT/PE. Although findings on the risk for venous thrombosis with use of POCs in otherwise healthy women is inconsistent, any small increased risk is substantially less than that with COCs (*110--112*).
c. DVT/PE and established on anticoagulant therapy for at least 3 mos				**Evidence:** No direct evidence exists on use of POCs among women with DVT/PE on anticoagulant therapy. Although findings on the risk for venous thrombosis with use of POCs are inconsistent in otherwise healthy women, any small increased risk is substantially less than that with COCs (*110--112*). Limited evidence indicates that intramuscular injections of DMPA in women on chronic anticoagulation therapy does not pose a significant risk for hematoma at the injection site or increase the risk for heavy or irregular vaginal bleeding (*113*).
i. Higher risk for recurrent DVT/PE (≥1 risk factors) • Known thrombophilia, including antiphospholipid syndrome • Active cancer (metastatic, on therapy, or within 6 mos after clinical remission), excluding non-melanoma skin cancer • History of recurrent DVT/PE	2	2	2	
ii. Lower risk for recurrent DVT/PE (no risk factors)	2	2	2	
d. Family history (first-degree relatives)	1	1	1	
e. Major surgery				
i. With prolonged immobilization	2	2	2	

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TABLE. Classifications for progestin-only contraceptives, including progestin-only pills, DMPA, and implants*†

Condition	Category			Clarifications/Evidence/Comments
	POP	DMPA	Implants	
ii. Without prolonged immobilization	1	1	1	
f. Minor surgery without immobilization	1	1	1	

***** Abbreviations: STI = sexually transmitted infection; HIV = human immunodeficiency virus; POC = progestin-only contraceptive; DMPA = depot medroxyprogesterone acetate; BMD = bone mineral density; NET-EN = norethisterone enantate; BMI = body mass index; COC = combined oral contraceptive; HDL = high-density lipoprotein; POP = progestin-only pill; DVT = deep venous thrombosis; PE = pulmonary embolism; SLE = systemic lupus erythematosus; VTE = venous thromboembolism; MEC = Medical Eligibility Criteria; hCG = human chorionic gonadotropin; HPV = human papillomavirus; PID = pelvic inflammatory disease; AIDS = acquired immunodeficiency syndrome; IBD = inflammatory bowel disease; ARV = antiretroviral; LNG = levonorgestrel; NRTI = nucleoside reverse transcriptase inhibitor; NNRTI = non-nucleoside reverse transcriptase inhibitor; ETG = etonogestrel.
† POCs do not protect against STI/HIV. If risk exists for STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Consistent and correct use of the male latex condom reduces the risk for STIs and HIV transmission.
§ Condition that exposes a woman to increased risk as a result of unintended pregnancy.

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References

CDC Medical Eligibility Criteria:

1. Centers for Disease Control and Prevention, *Appendix K. Summary of Classifications for Hormonal Contraceptive Methods and Intrauterine Devices,* U.S. Medical Eligibility Criteria for Contraceptive Use, 2016, https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6503.pdf
2. Centers for Disease Control and Prevention, *Appendix J. Classifications for Emergency Contraception*, U.S. Medical Eligibility Criteria for Contraceptive Use, 2016,https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6503.pdf

CDC Selected Practice Recommendations:

1. Centers for Disease Control and Prevention, *Box 2. How To Be Reasonably Certain that a Woman Is Not Pregnant*, U.S. Selected Practice Recommendations for Contraceptive Use, 2016, https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf
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3. American College of Obstetricians and Gynecologists, *ACOG Committee Opinion #554: Reproductive and Sexual Coercion*, Obstetrics & Gynecology, 2013.

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2. Hognert H, Kopp Kallner H, Cameron S, Nyrelli C, Jawad I, Heller R, Aronsson A, Lindh I, Benson L, Gemzell-Danielsson K. Immediate versus delayed insertion of an etonogestrel releasing implant at medical abortion-a randomized controlled equivalence trial. Hum Reprod. 2016 Nov;31(11):2484-2490.

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