

Long-Acting Reversible Contraceptive Protocols for School-Based Health Centers

Updated June 2014



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Acknowledgements

The Neighborcare Health Long-Acting Reversible Contraceptive (LARC) Protocols for School-Based Health Centers (SBHCs) reflect a true team effort. Our SBHC medical team welcomed the national recommendations for adolescent use of LARCs and set a goal to adopt them into our practice. Our scope of care includes the full range of contraceptive options for adolescents and we are committed to reducing barriers to pregnancy prevention. Initially we participated in a Public Health – Seattle & King County grant for IUD and Implant training for SBHC clinicians, funded by the National Campaign to Prevent Teen & Unplanned Pregnancy. The Neighborcare Health SBHC nurse practitioner and physician assistant team developed and expanded our clinical skills, contributed to our early guidelines, and began to share resources. In 2010 we began to include LARC services in Neighborcare Health SBHCs. We intentionally started slowly. As a team we learned a great deal from our initial mentoring and LARC experiences. We wanted a common resource of easily accessible materials to guide our SBHC practice. The <u>LARC Protocols for SBHCs</u> is a compilation of our own tools and many adapted resources. We will continue to update them. These standards support our goal to provide high quality care in SBHCs. LARCs can be safely and reliably included in the scope of care for adolescents in a school-based health setting.

Special thanks to the Neighborcare Health SBHC Nurse Practitioners, Physician Assistant, and Health Educator. These colleagues are dedicated to SBHCs and youth in our community, and are grounded in Neighborcare Health's core values of social justice, cultural sensitivity, community, and excellence. The 2010 Neighborcare Health SBHC medical team included Lisa Krogman, Lib Montgomery, Auky Van Beek, Beth Upton and Helen Weems. Since 2010, we have been fortunate to add Erica Spielman, Therese Horan, Kearstyn Leu and Melissa Lo to our team. Katie Acker joined Neighborcare Health in September 2013 as a SBHC Health Educator focused on contraceptive decision-making and pregnancy prevention. And- to Lisa, Helen, and Auky- who bravely went first-my sincerest thanks. We continue to be grateful for the support and leadership of Marcus Rempel, Neighborcare Health Chief Medical Officer.

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Maya Berkowitz, Neighborcare Health VISTA member 2012-2013, deserves special recognition. Her thoughtful additions were invaluable to the development of this resource for SBHC clinicians.

Janet Cady, MN, ARNP Medical Director, School-Based Health Programs Neighborcare Health December 2013

LARC Protocols for SBHC

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GENERAL LARC RESOURCES



Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use



- .Key: .1 No restriction (method can be used)
- Advantages generally outweigh theoretical or proven risks
- .2 .3 .4 Theoretical or proven risks usually outweigh the advantages Unacceptable health risk (method not to be used)

Updated June 2012. This summary sheet only contains a subset of the recommendations from the US MEC. For complete guidance, see: http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm

Most contraceptive methods do not protect against sexually transmitted infections (STIs). Consistent and correct use of the male latex condom reduces the risk of STIs and HIV.

.Condition	Sub-condition	.Combined pill, patch, ring	.Progestin-only pill	.Injection	Jmplant	TNG-IUD	.Copper-IUD
		I C	I C	I C	I C	I C	I C
_Age		.Menarche to <40=1	_Menarche to <18=1	.Menarche to ≤18=2	_Menarche to <18=1	_Menarche to <20=2	-Menarche to <20=2
		.>40=1	.18-45=1	.18-45=1	.18-45=1	.>20=1	.>20=1
			.>45=1	.>45=2	.>45=1	_	
Anatomic	a) Distorted uterine cavity					4	4
abnormalities	b) Other abnormalities a) Thalassemia	1	1	1	1	2	2
Anemias	b) Sickle cell disease	2	1	1	1	1	2
	c) Iron-deficiency anemia	1	1	1	1	1	2
.Benign ovarian tumors	(including cysts)	1	1	1	1	1	1
"Breast disease	a) Undiagnosed mass	2*	2*	2*	2*	2	1
	b) Benign breast disease	1	1	1	1	1	1
	c) Family history of cancer	1	1	1	1	1	1
	d) Breast cancer ⁺						
	i) current	4	4	4	4	4	1
	ii) past and no evidence of current disease for 5 years	3	3	3	3	3	1
"Breastfeeding "(see also	a) < 1 month postpartum	3*	2*	2*	2*		
Postpartum)	b) 1 month or more postpartum	2*	1*	1*	1*		
"Cervical cancer	Awaiting treatment	2	1	2	2	4 2	4 2
"Cervical ectropion		1	1	1	1	1	1
"Cervical intraepithelial neoplasia		2	1	2	2	2	1
.Cirrhosis	a) Mild (compensated)	1	1	1	1	1	1
	b) Severe‡ (decompensated)	4	3	3	3	3	1
Deep venous thrombosis	a) History of DVT/PE, not on anticoagulant therapy						
(DVT) /Pulmonary	i) higher risk for recurrent DVT/PE	4	2	2	2	2	1
embolism (PE)	ii) lower risk for recurrent DVT/PE	3	2	2	2	2	1
	b) Acute DVT/PE	4	2	2	2	2	2
	c) DVT/PE and established on anticoagulant therapy for at least 3 months						
	i) higher risk for recurrent DVT/PE	4*	2	2	2	2	2
	ii) lower risk for recurrent DVT/PE	3*	2	2	2	2	2
	d) Family history (first-degree relatives)	2	1	1	1	1	1
	e) Major surgery						
	(i) with prolonged immobilization	4	2	2	2	2	1
	(ii) without prolonged immobilization	2	1	1	1	1	1
	f) Minor surgery without immobilization	1	1	1	1	1	1
Depressive disorders		1*	1*	1*	1*	1*	1*
	a) History of gestational DM only	1	1	1	1	1	1

.Condition	.Sub-condition	Combined nill	patch, ring	-	.Progestin-only pill	Iniaction		Inclant		TNG-IUD		.Copper-IUD	
		I	С	I	C	I	C	I	С	I	С	I	C
(DM)	b) Non-vascular disease				-								
Diabetes mellitus	(i) non-insulin dependent	2		1	2	1	2		2	2		1	
(cont.)	(ii) insulin dependent⁺	2			2	1	2		2	2		1	
	c) Nephropathy/ retinopathy/ neuropathy‡	/3/4	1/	1	2	:	3		2	2		1	
	d) Other vascular disease or diabetes of >20 years' duration‡	134	*//		2	:	3		2	2		1	
_Endometrial cancer‡		1		:	1	:	1		1	4	2	4	2
.Endometrial hyperplasia		1			1	:	1		1	1		1	
.Endometriosis		1			1		1		1	1		2	
_Epilepsy [‡]	(see also Drug Interactions)	1,	+		*		*		*	1		1	
"Gallbladder	a) Symptomatic	-								-		1	
_disease	(i) treated by cholecystectomy	2			2		2		2	2		1	
		2			2		2		2	2			
	(ii) medically treated	3										1	
	(iii) current	3			2		2		2	2		1	
	b) Asymptomatic	2			2		2		2	2		1	
"Gestational trophoblastic	a) Decreasing or undetectable β-hCG levels	1			1	:	1		1	3		3	
.disease	b) Persistently elevated B-hCG levels or malignant disease‡	1		:	1	:	1		1	4		4	
Headaches	a) Non-migrainous	1*	2*	1*	1*	1*	1*	1*	1*	1*	1*	1*	
	b) Migraine		_	_	-	-			_		_		
	i) without aura, age <35	2*	3*	1*	2*	2*	2*	2*	2*	2*	2*	1*	
	ii) without aura, age ≥35	3*	4*	1*	2*	2*	2*	2*	2*	2*	2*	1*	
	iii) with aura, any age	4*	4*	2*	3*	2*	3*	2*	3*	2*	3*	1*	
History of	a) Restrictive procedures	1	-	<u>2</u>	3		1		1	2	3	1	
bariatric	b) Malabsorptive procedures		- 1		1		1		1	1		1	
_surgery‡		COC P/R			3		1		1	1		1	
.History of	a) Pregnancy-related	2		:	1		1		1	1		1	
.cholestasis	b) Past COC-related	3		1	2		2		2	2		1	
"History of high "blood pressure "during pregnancy		2		:	1	:	1		1	1		1	
.History of pelvic surgery		1			1	:	1		1	1		1	
HIV	High risk	1			1	1	*		1	2	2	2	2
	HIV infected	1,	•	1	÷	1	*	1	*	2	2	2	2
	(see also Drug Interactions) ⁺												
	AIDS (see also Drug Interactions) ‡	1,			*		*		*	3	2*	3	2*
	Clinically well on therapy		If or	i treati	nent, se	e Drug	Interac	tions		2	2	2	2
"Hyperlipidemias		2/3			*		*		*	2*		1*	
.Hypertension	a) Adequately controlled hypertension	3,	ł	1	*	2	*	1	*	1		1	
	b) Elevated blood pressure levels (properly taken measurements)												
	(i) systolic 140-159 or diastolic 90-99	3		:	1	:	2		1	1		1	
	(ii) systolic≥160 or diastolic ≥100‡	4		:	2	:	3		2	2		1	

.Condition	.Sub-condition	. Combined pill, patch, ring .Progestin-only pill		.Injection	Jmplant	TNG-IUD	.Copper-IUD
	c) Vascular disease	I C	I C	I C	I C	I C	I C
Tuffermenterer	(Ulcerative colitis, Crohn's	4	2	3	2	2	1
.Inflammatory bowel disease	disease)	2/3*	2	2	1	1	1
.Ischemic heart	Current and history of	4	2 3	3	2 3	2 3	1
disease‡ .Liver tumors	a) Benign						
"Liver tumors	i) Focal nodular hyperplasia	2	2	2	2	2	1
	ii) Hepatocellular adenoma‡	4	3	3	3	3	1
	b) Malignant‡	4	3	3	3	3	1
.Malaria		1	1	1	1	1	1
.Multiple risk factors for arterial cardiovascular disease	(such as older age, smoking, diabetes and hypertension)		2*	3*	2*	2	1
.Obesity	a) ≥30 kg/m² body mass index (BMI)	2	1	1	1	1	1
	b) Menarche to < 18 years and \geq 30 kg/m ² BMI	2	1	2	1	1	1
.Ovarian cancer‡		1	1	1	1	1	1
_Parity	a) Nulliparous	1	1	1	1	2	2
	b) Parous	1	1	1	1	1	1
Past ectopic		1	2	1	1	1	1
Pelvic inflammatory	a) Past, (assuming no current risk factors of STIs)						
_disease	(i) with subsequent pregnancy	1	1	1	1	1 1	1 1
	(ii) without subsequent	1	1	1	1	2 2	2 2
	b) Current						
Peripartum	a) Normal or mildly impaired	1	1	1	1	4 2*	4 2*
cardiomyopathy‡	cardiac function						
	(i) < 6 months	4	1	1	1	2	2
	$(ii) \ge 6$ months	3	1	1	1	2	2
	b) Moderately or severely	4	2	2	2	2	2
"Postabortion	impaired cardiac function a) First trimester				4.0	4.0	1*
"POSIADOITIOII	b) Second trimester	1* 1*	1* 1*	1* 1*	1* 1*	1* 2	2
	c) Immediately post-septic	1*	1*	1*	1*	4	4
	abortion						
Postpartum (see also	a) < 21 days	4	1	1	1		
(see also Breastfeeding)	b) 21 days to 42 days						
	(i) with other risk factors for VTE	3*	1	1	1		
	(ii) without other risk factors	2	1	1	1		
	for VTE	_					
D i i i	c) > 42 days	1	1	1	1		
"Postpartum (in breastfeeding or "non-breastfeeding	a) < 10 minutes after delivery of the placenta					2	1
women, including	b) 10 minutes after delivery of the placenta to < 4 weeks					2	2
.post-cesarean	c) ≥ 4 weeks					1	1
section)	d) Puerperal sepsis					4	4
.Pregnancy		NA*	NA*	NA*	NA*	4*	4*
"Rheumatoid "arthritis	a) On immunosuppressive therapy	2	1	2/3*	1	2 1	2 1
	b) Not on immunosuppressive therapy	2	1	2	1	1	1
"Schistosomiasis	a) Uncomplicated	1	1	1	1	1	1
	b) Fibrosis of the liver‡	1	1	1	1	1	1
"Severe dysmenorrhea		1	1	1	1	1	2
"Sexually transmitted	a) Current purulent cervicitis or chlamydial infection or gonorrhea	1	1	1	1	4 2*	4 2*

.Condition	.Sub-condition	.Combined pill, patch, ring	.Progestin-only pill	Injection	Jmplant	TNG-IUD	.Copper-IUD
		I C	I C	I C	I C	I C	I C
.Sexually transmitted infections	b) Other STIs (excluding HIV and hepatitis) c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	1	1	1	1	2 2 2 2	2 2 2 2
(cont.)	d) Increased risk of STIs	1	1	1	1	2/3** 2	2/3* 2
_Smoking	a) Age < 35	2	1	1	1	1	1
-	b) Age ≥ 35, < 15 cigarettes/day	3	1	1	1	1	1
	c) Age ≥ 35, ≥15 cigarettes/day	4	1	1	1	1	1
"Solid organ	a) Complicated	4	2	2	2	3 2	3 2
_transplantation‡	b) Uncomplicated	2*	2	2	2	2	2
"Stroke‡	History of cerebrovascular accident	4	2 3	3	2 3	2	1
"Superficial	a) Varicose veins	1	1	1	1	1	1
"venous "thrombosis	b) Superficial thrombophlebitis	2	1	1	1	1	1
"Systemic lupus erythematosus‡	a) Positive (or unknown) antiphospholipid antibodies	4	3	3 3	3	3	1 1
	b) Severe thrombocytopenia	2	2	3 2	2	2*	3* 2*
	c) Immunosuppressive treatment d) None of the above	2	2	2 2	2	2	2 1
T1	d) None of the above	2	2	2 2	2	2	1 1
Thrombogenic mutations‡ Thyroid disorders	Simple goiter/	4*	2*	2*	2*	2*	1*
"Tuberculosis‡	a) Non-pelvic	1*	1	1	1*	1	1
_(see also Drug	b) Pelvic	1*	1*	1*	1*	4 3	4 3
Interactions) "Unexplained	(suspicious for serious condition)	2*	2*	3*	3*	4* 2*	4* 2*
vaginal bleeding	before evaluation						
Uterine fibroids		1	1	1	1	2	2
_Valvular heart disease	a) Uncomplicated	2	1	1	1	1	1
_Vaginal _bleeding	b) Complicated‡ a) Irregular pattern without heavy bleeding	4	2	2	2	1 1	1
patterns	b) Heavy or prolonged bleeding	1*	2*	2*	2*	1* 2*	2*
Viral hepatitis	a) Acute or flare	3 4 2	1	1	1	1	1
	b) Carrier/Chronic	1 1	1	1	1	1	1
Drug Interaction		1			1		
"Antiretroviral therapy	a) Nucleoside reverse transcriptase inhibitors	1*	1	1	1	2/3* 2*	2/3* 2*
	b) Non-nucleoside reverse transcriptase inhibitors	2*	2*	1	2*	2/3* 2*	2/3* 2*
	c) Ritonavir-boosted protease inhibitors	3*	3*	1	2*	2/3* 2*	2/3* 2*
"Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3*	3*	1	2*	1	1
	b) Lamotrigine	3*	1	1	1	1	1
Antimicrobial	a) Broad spectrum antibiotics	1	1	1	1	1	1
therapy	b) Antifungals	1	1	1	1	1	1
	c) Antiparasities	1	1	1	1	1	1
	d) Rifampicin or rifabutin therapy	3*	3*	1	2*	1	1

I = initiation of contraceptive method; C = continuation of contraceptive method; NA = Not applicable * Please see the complete guidance for a clarification to this classification: www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm ‡ Condition that exposes a woman to increased risk as a result of unintended pregnancy.



U.S. Selected Practice Recommendations for Contraceptive Use, 2013

Appendix B When To Start Using Specific Contraceptive Methods

Contraceptive method	When to start (if the provider is reasonably certain that the woman is not pregnant)	Additional contraception (i.e., back- up) needed	Examinations or tests needed before initiation*
Copper-containing IUD	Anytime	Not needed	Bimanual examination and cervical inspection ⁺
Levonorgestrel-releasing IUD	Anytime	lf >7 days after menses started, use back-up method or abstain for 7 days.	Bimanual examination and cervical inspection ⁺
Implant	Anytime	lf >5 days after menses started, use back-up method or abstain for 7 days.	None
Injectable	Anytime	lf >7 days after menses started, use back-up method or abstain for 7 days.	None
Combined hormonal contraceptive	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	Blood pressure measurement
Progestin-only pill	Anytime	If >5 days after menses started, use back-up method or abstain for 2 days.	None

Abbreviations: BMI = body mass index; HIV = human immunodeficiency virus; IUD = intrauterine device; STD = sexually transmitted disease; U.S. MEC = U.S. *Medical Eligibility Criteria for Contraceptive Use*, 2010.

* Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI (weight [kg]/height [m]2) at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

+ Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's STD Treatment Guidelines (available at http://www.cdc.gov/std/treatment). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. MEC 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. MEC 3) (Box 2). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.







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How to be Reasonable Certain that a Woman is Not Pregnant

BOX 1. How To Be Reasonably Certain that a Woman Is Not Pregnant

A health-care provider can be reasonably certain that a woman is not 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: Labbok M, Perez A, Valdez V, et al. The Lactational Amenorrhea Method (LAM): a postpartum introductory family planning method with policy and program implications. Adv Contracept 1994;10:93–109.



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U.S. Selected Practice Recommendations for Contraceptive Use, 2013 Appendix C

Examinations and Tests Needed Before Initiation of Contraceptive Methods

The examinations or tests noted apply to women who are presumed to be healthy. Those with known medical problems or other special conditions might need additional examinations or tests before being determined to be appropriate candidates for a particular method of contraception. The U.S. Medical Eligibility Criteria for Contraceptive Use, 2010 (U.S. MEC), might be useful in such circumstances (5). The following classification was considered useful in differentiating the applicability of the various examinations or tests:

Class A: essential and mandatory in all circumstances for safe and effective use of the contraceptive method.

Class B: contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context; risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available.

Class C: does not contribute substantially to safe and effective use of the contraceptive method.

These classifications focus on the relationship of the examinations or tests to safe initiation of a contraceptive method. They are not intended to address the appropriateness of these examinations or tests in other circumstances. For example, some of the examinations or tests that are not deemed necessary for safe and effective contraceptive use might be appropriate for good preventive health care or for diagnosing or assessing suspected medical conditions. No examinations or tests are needed before initiating condoms or spermicides. A bimanual examination is necessary for diaphragm fitting. A bimanual examination and cervical inspection are needed for cervical cap fitting.

TABLE. Examinations and tests needed before initiation of contraceptive methods

	Contraceptive method and class							
Examination or test	Cu-IUD and LNG-IUD	Implant	Injectable	CHC	POP	Condom	Diaphragm or cervical cap	Spermicide
Examination								
Blood pressure	C	С	С	A*	С	С	С	С
Weight (BMI) (weight [kg]/height [m]2)	—†	—t	—†	t	t	С	С	С
Clinical breast examination	С	С	С	С	С	С	С	С
Bimanual examination and cervical inspection	A	С	С	C	C	C	Aş	С
Laboratory test								
Glucose	С	С	С	С	С	С	С	С
Lipids	С	С	С	С	С	С	С	С
Liver enzymes	С	С	С	С	С	С	С	С
Hemoglobin	С	С	С	С	С	С	С	С
Thrombogenic mutations	С	С	С	С	С	С	С	С
Cervical cytology (Papanicolaou smear)	С	С	С	С	С	С	С	С
STD screening with laboratory tests	—¶	С	С	С	С	С	С	С
HIV screening with laboratory tests	C	С	С	С	С	С	С	С

Abbreviations: BMI = body mass index; CHC = combined hormonal contraceptive; Cu-IUD = copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; HIV = human immunodeficiency virus; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pill; STD = sexually transmitted disease; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use, 2010.

* In cases in which access to health care might be limited, the blood pressure measurement can be obtained by the woman in a nonclinical setting (e.g., pharmacy or fire station) and self-reported to the provider.

+ Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

§ A bimanual examination (not cervical inspection) is needed for diaphragm fitting.

Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's STD Treatment Guidelines (available at http://www.cdc.gov/std/treatment). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. MEC 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. MEC 3). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.





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U.S. Selected Practice Recommendations for Contraceptive Use, 2013

Appendix D Routine Follow-Up After Contraceptive Initiation

These recommendations address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women. The recommendations refer to general situations and might vary for different users and different situations. Specific populations that might benefit from more frequent follow-up visits include adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions.

TABLE. Routine follow-up after contraceptive initiation

	Contraceptive method						
Action	Cu-IUD or LNG-IUD	Implant	Injectable	CHC	POP		
General follow-up							
Advise women to return at any time to discuss side effects or other problems or if they want to change the method. Advise women using IUDs, implants, or injectables when the IUD or implant needs to be removed or when a reinjection is needed. No routine follow-up visit is required.	Х	Х	Х	Х	Х		
Other routine visits							
Assess the woman's satisfaction with her current method and whether she has any concerns about method use.	Х	Х	Х	Х	Х		
Assess any changes in health status, including medications, that would change the method's appropriateness for safe and effective continued use based on U.S. MEC (i.e., category 3 and 4 conditions and characteristics) (Box 2).	X	Х	Х	Х	Х		
Consider performing an examination to check for the presence of IUD strings.	Х	-	-	-	-		
Consider assessing weight changes and counseling women who are concerned about weight change perceived to be associated with their contraceptive method.	Х	Х	Х	Х	Х		
Measure blood pressure.	-	-	-	Х	-		

Abbreviations: CHC = combined hormonal contraceptive; Cu-IUD = copper-containing intrauterine device; HIV = human immunodeficiency virus; IUD = intrauterine device; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pill; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use, 2010.





U.S. Selected Practice Recommendations for

Morbidity and Mortality Weekly Report

June 21, 2013

Contraceptive Use, 2013

Appendix E

Management of Women with Bleeding Irregularities While Using Contraception



Abbreviations: CHC = combined hormonal contraceptive; COC = combined oral contraceptive; Cu-IUD = copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; LNG-IUD = levonorgestrel-releasing intrauterine device; NSAIDs = nonsteroidal antiinflammatory drugs. * If clinically warranted, evaluate for underlying condition. Treat the condition or refer for care. + Heavy or prolonged bleeding, either unscheduled or menstrual, is uncommon.







U.S. Selected Practice Recommendations for Contraceptive Use, 2013

Appendix F Management of the IUD when a Cu-IUD or an LNG-IUD User Is Found To Have Pelvic Inflammatory Disease



Abbreviations: Cu-IUD = copper-containing IUD; IUD = intrauterine device; LNG-IUD = levonorgestrel-releasing IUD; PID = pelvic inflammatory disease. * Treat according to CDC's *STD Treatment Guidelines* (available at http://www.cdc.gov/std/treatment).



Effectiveness of Family Planning Methods



CS 242797



U.S. Department of Health and Human Services Centers for Disease Control and Prevention

CONDOMS SHOULD ALWAYS BE USED TO REDUCE THE RISK OF SEXUALLY TRANSMITTED INFECTIONS.

Other Methods of Contraception

Lactational Amenorrhea Method: LAM is a highly effective, temporary method of contraception.

Emergency Contraception: Emergency contraceptive pills or a copper IUD after unprotected intercourse substantially reduces risk of pregnancy.

Adapted from World Health Organization (WHO) Department of Reproductive Health and Research, Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP). Knowledge for health project. Family planning: a global handbook for providers (2011 update). Baltimore, MD; Geneva, Switzerland: CCP and WHO; 2011; and Trussell J. Contraceptive failure in the United States. Contraception 2011;83:397–404.

HOW WELL DOES BIRTH CONTROL WORK?



What is your chance of getting pregnant?

Revised 6/27/14

OOPS! EMERGENCY CONTRACEPTION: BIRTH CONTROL THAT WORKS AFTER SEX





for Global Reproductive Health

Bixby Center

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Revised 6/27/14



Emergency Protocols

Reaction	Signs & Symptoms	Management				
Hyperventilation	Rapid breathing, or trouble breathing Anxiety or fear May report tingling in hands and face Chest Pain Sweating Palpitations	 Obtain Vital Signs including pulse oximetry if available Remain with patient Provide gentle, calm reassurance Help to focus the client's breathing with slow, controlled breaths Use of a paper bag for re-breathing can be used cautiously, especially if neuro or cardiac concerns are present 				
	 Mild Symptoms: Itching, swelling around the injection site Hives may occur but do not progress to additional symptoms 	Mild Symptoms: • Obtain vital signs • Apply ice to the insertion site • Offer PO Diphenhydramine 25-50mg				
Allergic Reaction/ Anaphylaxis	 Severe Symptoms: Cough, shortness of breath, wheezing Worsening hives, flushed skin and as worsens, cool pale skin Swelling of mouth, tongue or throat Nausea, vomiting, diarrhea, abdominal pain Palpitations, rapid heart rate, low blood pressure, syncope, seizures, shock 	 Severe Symptoms: Call 911 Help assist the patient into a position of comfort Administer epinephrine 1:1000 IM in the same arm as insertion (if applicable) Obtain vital signs including respiratory rate and O₂ sat if available Place oxygen, (O²) at 4L/min via nasal cannula or mask Repeat vital signs every 2-3 minutes until EMS arrives Give PO Diphenhydramine 25-50mg or IM 50mg 				
Syncope or Vasovagal Reaction	 Confusion, fuzziness or sudden loss of consciousness Nausea, vision changes, feeling hot, skin paleness, lightheaded, yawning Drop in pulse rate, jerking or myoclonic movements, dilated pupils Diaphoretic reaction(sweating) Usually occurs in response to an obvious stress: a blood draw, injection or other medical procedure like an IUD insertion 	 Prevent patient from falling and assist them to the floor or exam table, elevate their legs and lower their head if possible Keep their head down and feet up Check for pulse and respiratory rate If patient does not become alert in 1-2 minutes, administer smelling/mineral salts and monitor closely If still symptomatic after 5-10 minutes, consider IUD removal Call 911 if their symptoms do not improve If improving- observe client until symptoms resolve and complete the visit. Vital signs should be repeated and documented as normal before the client is allowed to leave. 				
Blood Loss/ Shock	Slight bleeding Continuous bleeding	 Apply pressure with scopettes (IUD) or gauze (Nexplanon) until bleeding stops Place gauze pads over site and sustain direct and firm pressure; raise the bleeding injection site above the level of the patient's heart.(Nexplanon) Use sterile forceps with gauze pad or scopettes to apply firm and direct pressure to the bleeding cervix/site. If possible assist patient into the Trendelenburg position (IUD) Use Monsel's solution to help stop bleeding Check vitals- Call 911 if continues bleeding or not improving Give the patient oxygen (O²) @ 4L/min. 				
	Shock/ Call 911 if:	 SBP < 100 with symptoms HR > 120 with symptoms Nearing loss of consciousness or unconscious Give the patient oxygen (O²) @ 4L/min Check vitals every 2-5 minutes 				

SBHC Emergency Guidelines

May 2010

PURPOSE

- Provide guidance to SBHC staff during emergencies
- Clarify the SBHC & school staff roles/responsibilities when students present for care

HOT LIST/ACUTE ACTIVE EMERGENCY

Any life-limiting emergency

- Active Labor
- Allergic Reaction- anaphylaxis
- Actively attempting to harm self or others
- Change in level of consciousness
- Chest Pain
- New numbness- face or limbs
- Seizure

- Severe abdominal pain
- Severe difficulty breathing/choking
- Trauma and/or possible fracture
- "Worst headache of my life"

EMERGENCY- HOT	<u>URGENT CARE</u>	TODAY'S CARE	IMPORTANT CARE
 LIST Call 911 Initiate emergency care & support Notify SN & involve all SBHC staff Notify & involve school staff/adm/ 	 TO THE SCHOOL NURSE IF IN BUILDING If not available, contact SSD staff designee If SSD staff not available- to NH professional staff- OK TO INTERRUPT or BUMP 	 TO THE SCHOOL NURSE IF IN BUILDING If not available, contact SSD staff designee If SSD staff not available- to NH professional staff- Check with provider to prioritize 	 TO THE SCHOOL NURSE IF IN BUILDING If not available, contact SSD staff designee If SSD staff not available- Do not interrupt NH professional staff
 School stall/adm/ security Notify & involve parents (role of SN or SSD staff if available) Notify & involve supervisors & Program Manager 	 Trauma/ bleeding Plans to harm self or others Shortness of breath Feeling faint Acute vaginal bleeding Non-life threatening drug reaction Suspected neglect or abuse (Call CPS) 	 Swollen joint Stomach ache Crying/panic- able to calm down Mild suicidal ideations- with access to resources STD symptoms Plan B 	 Sore throat Family & peer conflicts Bereavement Acne Missed period STD questions
"This is an emergency &	"Stay here- we will get	"We will make time to	"We will schedule you
I will start first aid/CPR	someone to help you	see you sometime	for an appointment"
and call 911"	now"	, today"	

SBHC team roles during clinic emergencies:

Each staff member will provide care during an emergency to the best of their education, training, and professional judgment. Applicable WA State rules and regulations apply regarding parental rights to consent for care- verbal and in writing, minor's rights to consent for care, including emergency and confidential services, and Mandatory Reporting and Good Samaritan rules. For an overview:

http://www.washingtonlawhelp.org/documents/216941minors_health_care_rights.pdf?stateabbre_ v=/WA/

STAFF ROLES

SCHOOL NURSE

- Lead for all on site emergencies
- If the SN is not in the building, or not available, a SSD staff member is designated as back-up
- See SSD- Counseling Services Manual

SBHC staff will support the SN in the case of an emergency. If the School Nurse is not available, the SBHC staff will work together to maintain a safe environment, provide optimal care to the patient, and communicate as appropriate:

CLINIC COORDINATORS

MENTAL HEALTH THERAPIST NP/PA PROVIDER

Support for students/staff

- Lead in MH emergencies
 - Delegation & triage
 - **Delegation & triage**
 - Support for students/staff

Lead in med emergencies

- Communication & coordination
- Notification of school & security staff
- Crowd control

DOCUMENTATION:

SBHC staff will document care provided as appropriate to their role if involved in emergency care. If an enrolled student, documentation will be in NextGen.- CC staff can document what happened in the Communication template. If the person is not enrolled, document by using the Medical Summary-Visit Note, available on the DESKTOP of each Neighborcare computer. Non-enrolled patient care Visit Notes will be printed and kept in a locked file cabinet at the front desk



LARC Emergency Supplies

All emergency related supplies should be on hand prior to beginning your procedure. SBHC staff and/or the School Nurse are available to assist as needed.

GENERAL LARC EMERGENCY SUPPLIES:

- Ferric subsulfate (Monsel's)
- Gauze*
- Ammonium Carbonate capsules*
- Plenty of Gloves*
- Blood Pressure Cuff*
- Oxygen with mask*
- Stethoscope*
- Phone/clock/watch
- Diphenhydramine*

*included in SBHC emergency supply kits Not current SBHC standard: Atropine- given.Img/ml given IM or IV

For IUD insertions:

- Sterilized ring forceps with pre-wrapped gauze
- Extra set of insertion tools
- Extra packaged IUD
- Large Swabs

For Nexplanon Insertion:

- Extra needle and syringe
 -27G | ½ inch needle 3cc syringe
- Pressure dressing
- Steri-strips
- Extra packaged Nexplanon
- Lidocaine 1% w or w/o epinephrine









Consultation Resources (For Neighborcare Health SBHC Staff)	Address	Phone
	45 th Street	Backline: (206) 548-2972
neighborcare health	High Point	Backline: (206) 548-7444
	Rainier Beach	Backline: (206) 548-3636
	Rainier Park	Backline: (206) 461-3708 ×108
	Lake City	Backline: (206) 417-0775 X108
	Greenwood	Backline: (206) 782-9433
Public Health- Seattle and King County, Family Planning Clinics	Auburn Public Health Center 901 Auburn Way N., Auburn, WA 98002	(206) 296-8400
County, ranning rianning Clinics	Columbia Health Center 4400 37th Ave S., Seattle, WA 98118	(206) 296-4650
	Federal Way Public Health Center 33431 13th Place S., Federal Way, WA 98003	(206) 296-8410
	Downtown Public Health Center 2124 4 th Ave., Seattle, WA	(206) 296-4755
	North Public Health Center 10501 Meridian Ave. N., Seattle, WA 98133	(206) 296-4990
	White Center Public Health Center 9942 8 th Ave. SW, Seattle, WA 98106	(206) 477-0000
University of Washington OB/GYN	Anne-Marie Amies Oelschlager, MD	Office: (206) 598-5500 Email: aamies@u.washington.edu
	Sarah Prager, MD	(206) 221-2740 Email: pragers@uw.edu
Planned Parenthood of the Greater Northwest	Capitol Hill: 2001 E Madison, Seattle, WA 98122	(206) 328 -771 I
	First Hill: 1229 Madison Street. Suite 1040, Seattle, WA 98104	(800) 230- 7526
	University District: 5020 Roosevelt Way NE. Suite 1, Seattle, WA 98105	(206) 729-0453
	West Seattle: 9641 28th Avenue SW, Seattle, WA 98126	(206) 935-0152



LARC Coding in NextGen

NextGen automates most procedure codes and updates for any changes are done by billing. See NextGen screenshots under Nexplanon or IUD sections of the <u>Protocols</u>. EM Coding: select IMO to find related codes when submitting diagnosis. If you ever have a product malfunction, Neighborcare can still be reimbursed. Use modifier 53 when coding for the appointment and make sure to clearly document what happened.

Nexplanon: (not automated in NextGen)

The Nexplanon code is J7307

- The insertion code is 11981 billed with V25.5
- The removal code is 11982 billed with V25.43
- The removal and the insertion code on the same day is 11983 V25.43
 - This is only covered once every 3 years unless there is a product malfunction, see above.
- Follow-up visit for Nexplanon in place is V45.52

IUD: (automated in NextGen)

The code for a **ParaGard** IUD is J7300

The code for the **Mirena** IUD is J7302

The code for **Skyla** IUD is J7301

- For both codes 58300 is used for the Insertion V25.11
- For both codes 58301 is used for the removal V25.12
- The code for the removal and insertion on the same day is V25.13
- Follow-up visit for checking IUD is V25.42



LARC Supply Ordering List

Use	Item	Size	Qty	ltem #	Vendor
General	Sterile gauze sponges	2x2			PSS
General	Sterile gauze sponges	4x4			PSS
General	Disposable under pad- Chux	l7"x5"x24"			PSS
General	Gloves	Small			PSS
General	Gloves	Medium			PSS
General	Gloves	Large			PSS
General	Sterile Gloves	6.5			PSS
General	Sterile Gloves	7			PSS
General	Sterile Gloves	7.5			PSS
General	Sterile Gloves	8			PSS
General	Sterile Gloves	8.5			PSS
General	Enzomatic detergent	l gallon			PSS
General	Scrub brush	0			PSS
General	Self seal sterile pouches	5"x15"			PSS
General	Chlorhexadine Solution				PSS
General	Epi-pen				A-S Meds
IUD	Non-fenestrated drape	18"x26"			PSS
IUD	Single tooth tenaculum				PSS
IUD	Ring forceps				PSS
IUD	Walach flexi sound				PSS
IUD	Os finder- with measurement				PSS
IUD	Jumbo soft tip swabs	8" applicator			PSS
IUD	Betadine solution	32oz			PSS
IUD	Disposable vaginal speculum graves style with light source	Small			PSS
IUD	Disposable vaginal speculum graves style with light source	Medium			PSS
IUD	Disposable vaginal speculum graves style with light source	Large			PSS
IUD	Cytobrush	Laige			PSS
IUD	Long handled scissors				PSS
IUD	Long handled needle nose forceps				PSS
IUD	Exam drape	40"x48"			PSS
IUD	Maxi pads	077.05			PSS
IUD	Hot water bottle				PSS
IUD	Ammonia inhalant	.3ml			гээ
IUD					PSS
IUD	Dyna Lube	Individual pkts			
	Small metal cup	l oz			PSS PSS
IUD	Monsel's				
IUD	Bicarbonate				A-S Meds
Nexplanon	Tegaderm (or Select cohesive bandages)	1 (4) 2)			PSS
Nexplanon	Steri strips by 3M	1/4"x3"			PSS
Nexplanon	Syringe- for betadine	5cc	h		PSS
Nexplanon	Select cohesive bandages	2"x5 yards	box of 100		PSS
Nexplanon	Mosquito forceps - curved				PSS
Nexplanon	Mosquito forceps - straight				PSS
Nexplanon	Disposable scalpel #11				PSS
Nexplanon	Chlorascrub swab stick	10			PSS
Nexplanon	Needles	18 g 1"			PSS
Nexplanon	Needles	25 g l.5"			PSS
Nexplanon	Sodium bicarbonate				A-S Meds
Nexplanon	Lidocaine 1%- without epinephrine				A-S Meds
Nexplanon	Lidocaine 1%- with epinephrine				A-S Meds

www.neighborcare.org

Myths and Facts for Teens

Do you have questions about LARCs- Long-Acting Reversible Contraceptives? Here are answers to common questions and myths.

Myth: IUDs and Implants are not recommended for teens like me.

Fact: IUDs are used by teens all over the world. 25% of teens in Europe choose IUDs as their birth control. The IUD and the implant are recommended for teens by US health care providers. LARCs are safe and effective options for most teens. Current IUDs do not increase the risk of PID nor do they increase the risk if a woman has or gets gonorrhea or Chlamydia while using the IUD. Research also shows no difference in a woman's ability to get pregnant after using an IUD.

Myth: IUDs are painful

Fact: It is true that IUD insertion can be more painful for women who have never had a baby. Overall, women said that it was 'easier than I thought' or 'like I thought'. Long-term pain is uncommon and when there is pain- it goes down over time.

Myth: IUDs won't fit in my uterus or it will get stuck in my uterus.

Fact: IUDs are very small and fit almost all women. We have not seen any specific problem's putting IUDs into teens. IUDs must be removed by your health care provider. In most cases IUDs are easy and painless to remove. There are rare complications, but none that are specific to teens.

Myth: My parent's need to know if I get an IUD or implant.

Fact: We want you to involve your parents or guardians in your care when you are ready. In Washington State you are not required to tell your parents that you want or have an IUD or implant. You can come to your School Based Health Center for reproductive health needs and your care will be private. If you or someone else's life is in danger we will involve your parent's to keep you or others safe.

Myth: You can only get an Implant or an IUD if you are in a serious relationship.

Fact: Most females can get an IUD or an implant- even if they've not had sex. LARCs do not prevent against sexually transmitted infections (STI), so a condom or barrier is important to prevent STI's. Having an implant or an IUD does *not* increase the risk of getting an STI. The implant or IUD has positive benefits and are available to women for reasons other than pregnancy prevention.

Myth: I can't afford an Implant or an IUD.

Fact: We can help! You can either use your personal health insurance (through your parent or guardian) or you can apply for a state program called <u>Take Charge</u>. We want to protect your privacy and can help decide which program will work best for you. We will provide you with the care you choose regardless of payment.

Myth: IUDs and the Implant are not more effective than other birth control options.

Fact: IUDs and implants (Nexplanon) are more than 99.9% effective. Less than I out of 1000 women get pregnant while using these birth control methods. Other options like the pill, the ring or the patch are less effective for preventing pregnancy. These forms of birth control less effective for teens. There are more chances for forgetting or mistakes in those methods when compared to LARCs.

Resources:

Russo, J.A. "Myths and Misconceptions about Long-Acting Reversible Contraceptives (LARC)." *Journal of Adolescent Health* 52.45 (2013): 14-21.

www.neighborcare.org

Myths and Facts about Long-Acting Reversible Contraceptives

Do you have questions about LARCs- Long-Acting Reversible Contraceptives? Here are answers to common questions and misunderstandings about LARCs.

Myth: If I talk to my child about sex and birth control they will be more likely to have sex.

Fact: A study in the New England Journal of Medicine found that information offered to teens about birth control does not result in increased rates of sexual activity, earlier age of sex, or an increase in the number of sex partners.

Myth: IUDs and Implants are not recommended for teens

Fact: The IUDs available today are very different than the ones used 20 years ago. The American College of Obstetricians and Gynecologists (ACOG) recommended in 2012 that LARCs should be recommended as the *first choice option* for all teens.

Myth: IUDs cause Pelvic Inflammatory Disease (PID)

Fact: A study by the World Health Organization discovered that current IUDs do not increase the risk of PID overall. There is a higher risk of PID within the first 3 weeks of insertion. There is no increased risk of PID if a woman has or gets gonorrhea or Chlamydia while using the IUD.

Myth: IUDs cause infertility

Fact: Research studies have shown no difference in a woman's ability to get pregnant after using an IUD versus a woman who has never used an IUD.

Myth: IUDs are painful

Fact: Studies have shown that IUD insertion is more painful for women who have never given birth. 85% of all women who had an IUD put in described the pain at insertion as 'period pain' and 14% described it as 'severe abdominal pain'. Most women said that it was 'easier than I thought' or 'like I thought'.

Myth: IUDs and Implant cause ectopic pregnancy

Fact: Ectopic pregnancy is when a fertilized egg implants outside the uterus or womb. These pregnancies will not survive and are often dangerous. Research shows that LARCs cut down the risk of ectopic pregnancy, the same way they decrease the risk of normal pregnancy. **IF** a woman gets pregnant while using one of these birth control methods she may be at more risk for ectopic pregnancy.

Myth: IUDs and Implants can cause cancer

Fact: IUD's have shown in a study that they offer a protective effect against endometrial cancer. Copper IUDs (ParaGard) may also have a similar effect against cervical cancer. No study has ever shown that any of these methods cause cancer or increase the risk for cancer.

Myth: IUDs and Implants are not more effective than other birth control options.

Fact: IUDs and implants (Nexplanon) are more than 99.9% effective. Less than I out of 1000 women get pregnant while using these birth control methods. Other options like the pill, the ring or the patch are less effective for preventing pregnancy. These forms of birth control less effective for teens. There are more chances for forgetting or mistakes in those methods when compared to LARCs.

Resources:

Russo, J.A. "Myths and Misconceptions about Long-Acting Reversible Contraceptives (LARC)." Journal of Adolescent Health 52.45 (2013): 14-21.

Facts and Figures

Here is a summary of recent Long-Acting Reversible Contraception (LARC) research and recommendations:

Studies

- A study in the New England Journal of Medicine, <u>Effectiveness of Long-Acting Reversible</u> <u>Contraception</u>, states that information offered to adolescents about contraception does not result in increased rates of sexual activity, earlier age of first intercourse, or a greater number of partners.
- In 2012 The American College of Obstetricians and Gynecologists (ACOG) recommended a LARC method (IUDs or Implant) be offered as a first choice birth control option for teens.
- The National Campaign to Prevent Teen and Unplanned Pregnancy found that 13.5% of same-age relationships between 12-14 year olds include sex. If one partner is two years older that number doubles to 26%. If one partner is 3 or more years older 33% of relationships will include sex.
- Teen pregnancy rates among 15-19 year olds have declined sharply since the 1990s. Increasing use of contraception, specifically of long-acting reversible contraceptives, has contributed to the decline in pregnancy rates among adolescents.
- Each year nearly 750,000 young women, 15-19 years of age, get pregnant- according to a National Adolescent Health Information Center report on adolescent sexual behavior.
- Women who use IUD's are the most satisfied with their form of contraception compared to other methods. There are many benefits to LARCs other than pregnancy prevention.
- IUD's are the most popular form of reversible contraceptives in the world.

REFERENCES:

- 1. American College of Obstetricians & Gynecologists (ACOG). Adolescents and long-acting reversible contraception: implants and intrauterine devices. *Committee Opinion*; 2012; 539.
- 2. National Adolescent Health Information Center. http://nahic.ucsf.edu/
- 3. National Campaign to Prevent Teen and Unplanned Pregnancy. <u>http://thenationalcampaign.org/</u>
- 4. Winner, B, et al. Effectiveness of Long-Acting Reversible Contraception. NEJM (2012) 366;21.
- 5. Yen, S, et al. IUDs and Adolescents—An under-utilized opportunity for pregnancy prevention. J Ped Adol Gyn (2010) 23:123e128.



Comparing LARCs: ParaGard, Mirena and Nexplanon

	Implant- Nexplanon	IUD- Mirena	IUD- ParaGard
Releases hormones?	Yes	Yes	No
How long?	3 years	5 years	10 years
What are some potential side effects (not including changes in bleeding)?	 16% Headache 12% Acne 6% Mood changes 10% Breast tenderness 12% Weight gain 	8% Headache7% Acne6% Mood changes5% Breast tenderness	Most common side effects are lower abdominal pain, cramps, back pain, spotting between first few periods
How might it affect my bleeding/periods?	Bleeding within the first 2 years: 22-30% no bleeding 34% infrequent bleeding 18% prolonged bleeding * 6% frequent bleeding **	Bleeding at 6 months:44% no bleeding25% infrequent or very light25% unscheduled spotting6% normal or heavy periodsBleeding at 2 years:50% no bleeding25% infrequent or very light11% unscheduled spotting14% normal or heavy periods	Bleeding at 2 months: 38% reported more menstrual pain 66% increased menstrual blood loss
Discontinuation Rates (% who had	Within first 6 months: 7% Within first 12 months: 15-20%	Within first 6 months: 7% Within first 12 months: 12-15%	Within first 6 months: 8% Within first 12 months: 16-22%
the device removed early)	Non-LARC method (She	pt, Pills, Patch, Ring) discontinuation rate	es after 12 months: 43-51%

*Prolonged bleeding: any episode of spotting/bleeding lasting greater than 14 days in 90 days

**Frequent bleeding: more than 5 bleeding/spotting episodes in 90 days

References: http://www.uptodate.com/contents/overview-of-intrauterine-contraception/abstract/90

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2702765/

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3548669/ http://www.nlm.nih.gov/medlineplus/news/fullstory 142509.html



Comparing Hormone Containing LARCs

	Skyla IUD	Mirena IUD	Nexplanon- Implant
How long?	3 years	5 years	3 years
How might it affect bleeding/periods?	Bleeding at 6 months: 3/100 no bleeding 19/100 infrequent or very light 12/100 frequent bleeding** 17/100 prolonged bleeding* 28/100 irregular bleeding Bleeding by year 3: 12/100 no bleeding 22/100 infrequent or very light 4/100 frequent bleeding** 3/100 prolonged bleeding* $20 \int 12 \int 12 \int 12 \int 10 \int 12 \int 12$	Bleeding at 6 months: 44/100 no bleeding 25/100 infrequent or very light 25/100 unscheduled spotting 6/100 normal or heavy periods Bleeding at 2 years: 50/100 no bleeding 25/100 infrequent or very light 11/100 unscheduled spotting 14/100 normal or heavy periods 20 10 10 10 5 0 15 10	Bleeding at 1 st , 2 nd and 3 rd 90 days: 17 days Bleeding within the first 2 years: 22-30/100 no bleeding 34/100 infrequent bleeding * 6/100 frequent bleeding ** 6/100 frequent bleeding ** 20 15 10 5 0 1st 90 days 2nd 90 days Per 90 days by 1 year I # Days bleeding
Side effects (not including changes in bleeding)	12/100 headache 15/100 acne 8/100 breast tenderness 19/100 abdominal pain 6/100 nausea	8/100Headache7/100Acne6/100Mood changes5/100Breast tenderness	16/100Headache12/100Acne6/100Mood changes10/100Breast tenderness12/100Weight gain
Discontinuation Rates (% who had device removed early)	Within 3 years: 21.9% Non-LARC meth	Within first 6 months: 7% Within first 12 months: 12-15% ord (Shot, Pill, Patch, Ring) discontinuation rates after 12 m	Within first 6 months: 7% Within first 12 months: 15-20%

*Prolonged bleeding: any episode of spotting/bleeding lasting greater than 14 days in 90 days

**Frequent bleeding: more than 5 bleeding/spotting episodes in 90 days



Comparing Bleeding Profiles of Hormone Containing LARCs



Hormone-Containing LARC Bleeding Rates

References:

http://www.uptodate.com/contents/overview-of-intrauterine-contraception/abstract/90; http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2702765/; http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3548669/; http://www.nlm.nih.gov/medlineplus/news/fullstory_142509.html; http://www.skyla-us.com/faqs.php

Non-Contraceptive Benefits of Hormonal LARCs: Provider Version



> Reduce the risk of iron-deficiency anemia

> Reduce pain and discomfort associated with menstruation:

- Reduce dysmenorrheal
- Reduce chronic pelvic pain that occurs with endometriosis and hemostatic disorders
- Treatment of menorrhagia
- Relieve premenstrual syndrome (PMS) and premenstrual dysphoric disorder (PMDD)
- Relieve menstrual migraines

Reduce risk for certain cancers:

- Treatment for endometrial hyperplasia
- Reduce risk of ovarian cancer

> Used for treatment of certain conditions:

- o Improve acne
- o Endometrial polyps
- o Endometrial carcinoma
- Peri-menopausal disturbances
- Uterine myomas
- Adenomyosis
- Hirsutism, or hyperandrogenetism
- o Infertility

*Significantly more research has been conducted with the hormonal intrauterine devices compared to the sub dermal implant; therefore more evidence is available to support the above mentioned benefits of the LNG IUS (hormonal IUDs).

Resources:

ACOG Guidelines on Noncontraceptive Uses of Hormonal Contraceptives. American Academy of Family Physicians. 2010. <u>nnw.aafp.org/afp</u>

Noncontraceptive Health Benefits of Contraceptive Methods. Guttmacher Institute

Fraser, I an S. Non-contraceptive health benefits of intrauterine hormonal systems. Contraception 82 (396-403). 2010.



Non-Contraceptive Benefits of Hormonal LARCs: For Teens

Hormonal Intrauterine Devices (IUD)
Mirena and SkylaHormonal Subdermal Implant:
NexplanonImage: Device of the state of the

Non-contraceptive benefits*

> Reduce period blood loss which reduces the risk of iron-deficiency anemia

> Reduce discomfort associated with periods:

- Less cramps and pelvic pain
- Helps with heavy or prolonged bleeding
- Relieve premenstrual syndrome (PMS) mood swings
- Relieve migraines

> Reduce risk for certain female cancers:

• Lowers the risk of ovarian and endometrial cancer

> Used for treatment of certain conditions including:

- o Acne
- Some problems with the lining of the uterus
- Small tumors on uterus
- Hormone imbalances
- Infertility

*Significantly more research has been conducted with the hormonal intrauterine devices compared to the sub dermal implant; therefore more evidence is available to support the above mentioned benefits of the (hormonal IUD.

Resources:

ACOG Guidelines on Noncontraceptive Uses of Hormonal Contraceptives. American Academy of Family Physicians. 2010. <u>nnnv.aafp.org/afp</u>

Noncontraceptive Health Benefits of Contraceptive Methods. Guttmacher Institute

Fraser, I an S. Non-contraceptive health benefits of intrauterine hormonal systems. Contraception 82 (396-403). 2010.

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COMMUNICATION WITH PRIMARY CARE PROVIDER

То	,		
Your patient,		DOB:/	/ has been seen at the
Neighborcare Health	are Health School-Based Health Clinic (SBHC.) Your patient		
received reproductive heal	th care and contrac	eptive counseling. We then	inserted:
🗆 Mirena IUD	🗆 Skyla IUD	□ ParaGard IUD	Nexplanon Implant
Your patient's long-acting r	eversible contrace	otive expires on:/	/
Keep this health informatic	on confidential. At 1	this time the parents/guardi	ans are:
□ Aware of contra	ceptive care	Not aware of contraceptiv	/e care
Thank you,			
X(Patient signature)		Date:	
(Patient signature)			
(Patient signature)			
(Patient signature) x (Provider signature) If you have questions ple Provider		Date:	
(Patient signature) X (Provider signature) If you have questions please Provider SBHC:	ease contact us:	Date:	
(Patient signature) x (Provider signature) If you have questions ple Provider	ease contact us:	Date:	



IMPLANT - NEXPLANON



Implant Pre-Insertion Counseling- BRAIDED Format

BENEFITS

- Nexplanon is safe, simple, and convenient to use
- Nexplanon lasts for 3 years!
- It is private
- Less than 1/1000 women who use Nexplanon for a year get pregnant.
- One study showed that 85% of women rated Nexplanon as good or excellent 6 months after insertion.
- Nexplanon is one of the few birth control options that do not contain estrogen- see MEC guidelines.
- For most women, periods become fewer and lighter. After one year, I out of 4 women who use Nexplanon will stop having periods completely.

RISKS

Initial bruising and tenderness at the implant site is common. Long term complications are extremely rare. The implant does not protect against sexually transmitted infections.

- Infection- Insertion site complications such as infection occur in less than 1% of patients.
- **Hormonal side effects-** May include headaches, nausea, acne, mood shifts and changes in period.
 - **Bleeding and cramping-** Irregular bleeding is the most common side effect for women using Nexplanon. Cramping and bleeding (like a period) on and off for the first few months, then irregular bleeding that gradually lessens over 6 months can be expected.
 - Weight gain- 1/10 women reported weight gain while using Nexplanon. The average weight gained in 1 year was 2.8 pounds and 3.7 pounds over 2 years.
 Scientific studies have not been able to prove that the weight gain is related to Nexplanon because women not on Nexplanon gained the same amount of weight.
 - Headaches- 1/10 women who use Nexplanon identify headaches and mild dizziness as a side effect.
- **Movement of the implant-** In some cases the Nexplanon can move slightly in the arm. In extremely rare cases it will need to be removed. If unable to palpate, the Nexplanon can be located with an X-ray or CT scan.
- Ectopic Pregnancy- Women not using birth control are at higher risk for pregnancy and therefore ectopic pregnancy than women using Nexplanon. Although highly unlikely, if a woman becomes pregnant while using Nexplanon, she is at an increased risk of ectopic pregnancy.

ALTERNATIVES

Other reversible forms of contraceptives- including IUDs

INQUIRIES

Welcome inquiries. Answer all questions in a clear, simple and straightforward manner.

DECISIONS

- If Nexplanon is selected, advise to allow 6 months for the body to adapt. Provide counsel that SBHC is available to aid with management of implant side effects.
- **Review health risks and/or contraindications** see MEC and consider other LARC options
- Unprotected sex in the last 10 days
- Pregnant or wants to become pregnant in the next year
- Unexplained vaginal bleeding
- Current or past history of cancer
- Liver disease, tumors, or cirrhosis
- Nexplanon continuation- review any history of migraine with aura, stroke, or heart disease, and consider alternative methods if positive

EXPLANATION OF METHOD & INSERTION

- Interferes with normal implantation of the egg in the uterus
- Prevents women from releasing an egg from the ovary
- Makes cervical mucus thicker- provides a barrier for sperm to pass through the cervix
- Description of arm anatomy and placement in the arm (description of female anatomy & function if needed)
- Prior to insertion- ibuprofen 800mg will be provided for pain management
- Weight, blood pressure, and pregnancy test results will be done
- Description of procedure including, "You will receive a shot of lidocaine to numb the area. The Nexplanon will be implanted using a needle. Your arm will be numb, so you should not feel it. It takes about 1 minute. The implant site will be bandaged and wrapped. You can take the wrap off 24 hours after your implant. Once you remove the wrap wash the area well with warm water and soap. The bandage will come off by itself 3-5 days after the implant is placed."
- Women report it was 'easier than I thought' or 'like I thought'.
- **Recommend a back-up method for I week after insertion.** If sexually active give patient condoms to use.
- Instruct patient not to lift heavy objects for the first 5-7 days post insertion
- Patients should return if their arm continues to hurt or hurts worst after 3-7 days, or signs of infection
- Pain management after the insertion can be addressed with resting the arm and ibuprofen- see handout for post-insertion

DOCUMENTATION

- The Nexplanon procedure will be documented in NextGen in the patients EHR.
- The patient and SBHC provider will fill out a ROI and a LARC Communication with PCP form- if the PCP is not part of Neighborcare. If part of Neighborcare- send NextGen communication to PCP.
- Send patient home with clear aftercare instructions and emergency contact information
- Check insurance status- Be sure insurance is current and valid: "Take Charge pending" OK if application is waiting for DSHS approval or Eligibility staff anticipates approval. Contact SBHC Eligibility for more information.


Implant Pain Management- Nexplanon

Our goal is to make the process of receiving the implant- Nexplanon as easy and painless as possible. Pain upon insertion and removal is minimal. It is important to counsel patients about the pain they may experience and attempt to minimize it. Effective counseling and accurate anticipation of the procedure is part of pain management.

Pain Management Options:

- Clarify and agree on visit goal. Address remaining questions or concerns.
- Optional: Give patient ibuprofen 800 mg at counseling visit to take I hour prior to insertion
 - Or offer patient ibuprofen 800 mg at the beginning of the insertion appointment if they did not take it prior to arriving
- Offer patient an ice pack to numb the area before the lidocaine shot
- Use an appropriate amount of lidocaine to numb the insertion site- see insertion protocol
- Apply pressure dressing firmly to avoid significant bruising
- Instruct patient not to lift heavy objects for the first 5-7 days post insertion
- Patients should return if their arm continues to hurt or hurts worst after 3-7 days, or if signs/symptoms of infection
- Offer coping strategies
 - Toys
 - Friend, parent, or other support person
 - Music
 - Hot water bottle or heating pad
 - Slow, deep breathing



Implant Insertion Supplies

Insertion supplies include:

- Ibuprofen 800mg tablets
- Nexplanon kit
- Gloves
- Chlorhexidine wipes (Chlorascrub Swab)
- Washable marker or Sharpie (optional)
- Lidocaine 1% with or without epinephrine
- Sodium bicarbonate (for use with lidocaine)
- Needles
 - 18 g l" to draw up
 - 25 g l.5" to inject
- 5cc syringe
- 2"x2" and/or 4"x4" gauze
- Steri-strip
- Bandage or Tegaderm
- Pressure dressing- Copan or ace wrap
- Ruler (supplied in Nexplanon kit)
- Absorbent pad for under arm
- Scissors (to cut strips or bandage)
- Access to emergency supplies









Implant Insertion Protocol- Nexplanon

Adapted from MERCK guidelines: http://www.nexplanon-usa.com/en/hcp/index.asp

Before Insertion:

- Complete counseling and thoroughly answer and questions- See Pre-insertion Implant counseling
- Patient signs consent form
- Document weight, BP and LMP. Annual GC/CT.
- Pregnancy test ordered, performed and results documented
- Review and document any allergies including: latex, betadine, and lidocaine
- Review insurance status
- There must be another SBHC staff in the clinic during the entire procedure.

Insertion:

- Assemble all insertion supplies- See Nexplanon supply protocol
- Have the patient lie on her back on the examination table with her non-dominant arm flexed at the elbow and externally rotated so that her hand is positioned next to her head
- Identify the insertion site, which is at the inner side of the non-dominant upper arm about 8–10 cm (3–4 inches) above the medial epicondyle of the humerus. Nexplanon should be inserted subdermally just under the skin. (Use tool and notes supplied in training kit)
- Option- Mark the insertion site with a marker. Make two marks: first, mark the spot where the Nexplanon rod will be inserted, and second, mark a spot a few centimeters proximal to the first mark that will serve as a direction guide insertion.
- Clean the insertion site well with chlorhexidine swabs.
- Anesthetize the insertion area by injecting 2- 5cc of 1% lidocaine with or without epinephrine just under the skin along the planned insertion tunnel.
 - Option: Decrease pain during lidocaine injection by adding sodium bicarbonate in 1:9 or 1:10 ratio. Add .5cc sodium bicarbonate:4.5cc lidocaine
- Wait 10 minutes- verify arm is numb with the tip of a needle. Patient will feel pressure but no sharpness or pain if she is numb.
- Carefully remove the Nexplanon applicator from its blister pack. Hold the applicator just above the needle at the textured surface area. Remove the transparent protection cap by sliding it horizontally in the direction of the arrow away from the needle. The white colored implant should be seen when looking into the tip of the needle.
- Apply counter-traction to the skin around the proposed insertion.
- At a 30° angle insert the tip of the needle.

- Lower the applicator to a horizontal position. While lifting the skin with the tip of the needle, slide the needle to its full length. There may be slight resistance but do not exert excessive force. Insert the needle to its full length. Keep the needle parallel to the surface of the skin during insertion.
- Unlock the purple slider by pushing it slightly down. Move the slider fully back until it stops. The implant is now in its final subdermal position, and the needle is locked inside the body of the applicator.
- The applicator can now be removed.

Post Insertion:

- Check the applicator. The needle should be fully retracted and only the purple tip of the obturator should be visible
- Always have the patient and provider verify the presence of Nexplanon in the patient's arm immediately after insertion by palpation.
- Place Steri-strips over the insertion site and then apply a pressure dressing with gauze. The pressure dressing can be removed 24 hours after insertion.
- Fill out the user card and give it to the patient.
- After insertion dispose of the components of the Nexplanon insertion. The kit is single use.
- Needles and applicator need to be disposed of in the sharps or biohazard waste.
- Provide patient with verbal and written aftercare instructions.- See Nexplanon aftercare form
- Schedule a follow-up appointment within 4-6 weeks after insertion for management of any side effects.- See below
- If malfunction occurs, contact the manufacturer.

Manufacturer Information:

Merck: I-877-467-5266 available 8:00 AM to 8:00 PM (EST) Please keep the malfunctioning Nexplanon implant in case Merck wants to recall it.

Follow-up Visit:

I week after insertion: Optional- an appointment can be scheduled to check insertion site and address concerns regarding adjusting to Nexplanon.

4-6 weeks after insertion: The Nexplanon follow-up appointment is a 30 minute visit.

- Assess patient's ability to feel the implant
- Palpate the implant
- Assess residual pain, soreness or sensitivity changes in the area
- Assess change in health status, menstrual bleeding and cramping patterns, or other side effects
- Address any concerns and answer questions
- Reinforce ability to resume all activities
- Offer condoms for STI prevention
- Reinforce need for annual follow-up appointment including STI screening.



Implant Removal Supplies

Before removing Nexplanon, have these supplies prepared.

- Surgical drapes, gloves, antiseptic solution, marker (optional)- not shown
- Lidocaine 1% with epinephrine, needles, and syringe
- Sterile scalpel, forceps (straight and curved mosquito)
- Skin closure, sterile gauze, adhesive bandage and pressure bandages
- Assure emergency supplies are available.









Implant Removal Protocol

**Do not attempt Nexplanon removal if unable to palpate the exact location. Send patient for X-ray or CT scan.

Nexplanon Removal:

- Palpate the exact location of the Nexplanon. *If unable to palpate the Nexplanon- do not attempt removal.
- Prepare all necessary supplies- see removal supplies list
- Clean the site where the incision will be made and apply an antiseptic. Locate the implant by palpation and mark the distal end closest to the elbow. Mark location with a marker if helpful
- Anesthetize the arm by giving .5cc of lidocaine with epinephrine under the Nexplanon implant to numb area. Wait a few minutes and then check to make sure the area is numb.
- Push down the proximal end of the implant to stabilize it.
- Starting at the distal tip of the implant, make a longitudinal incision of 2mm towards the elbow, and grasp the Nexplanon
- Gently push the implant towards the incision until the tip is visible. Grasp the implant with forceps and gently remove the implant
- Confirm that the entire implant, which is 4 cm long, has been removed, if a partial implant is removed, the remaining piece should be removed.
- Close the incision with a Steri-Strip and apply an adhesive bandage.
- Apply a pressure bandage with sterile gauze.
- If the woman would like to continue using Nexplanon, a new implant may be inserted immediately after the old implant is removed using the same incision. See <u>Insertion</u> <u>Protocol.</u>





If encapsulated:

- If the implant is encapsulated, make an incision into the tissue sheath and then remove the implant with the forceps.
- Confirm that the entire implant, which is 4 cm long, has been removed. If a partial implant is removed, the remaining piece should be removed.
- If the woman would like to continue using Nexplanon, a new implant may be inserted immediately after the old implant is removed using the same incision.
- Place a band aid over the insertion site and then apply a pressure dressing with gauze. The pressure dressing can be removed 24 hours after insertion.

If Nexplanon tip is not visible:

- If the tip of the implant does not become visible in the incision, gently insert a forceps into the incision. Flip the forceps over into the other hand.
- With a second pair of forceps carefully dissect the tissue around the implant and grasp the implant
- Confirm that the entire implant, which is 4 cm long, has been removed, if a partial implant is removed, the remaining piece should be removed.
- If the woman would like to continue using Nexplanon, a new implant may be inserted immediately after the old implant is removed using the same incision.
- Place a bandage over the insertion site and then apply a pressure dressing with gauze. The pressure dressing can be removed 24 hours after insertion.

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NEXPLANON AFTERCARE INSTRUCTIONS

Remember:

- To prevent pregnancy you must use a back-up form of birth control for I week!
- For a few days, you may notice tenderness and swelling of the skin around the implant. •
- Bruising and color change of the skin around the implant may last for a week or two.
- Be gentle around the implant area of your arm for a few days. •
- Keep the pressure bandage on for 24 hours. Keep your arm clean and dry. After 24 hours- keep the area • clean with soap and water, and covered with a small bandage until completely healed.
- If Steri-strips were put on the insertion site, leave them in place until they fall off- usually within a week. •

After Healing:

- Do not worry about bumping the area. •
- You may touch or wash the area as usual. •

Return to your School-Based Health Center:

- 4-6 weeks after the Nexplanon was inserted
- Once a year for annual health visits •
- As needed for questions or concerns •

Call the School-Based Health Center if you:

- Have questions about the implant •
- Think you might be pregnant or have a sexually transmitted infection •
- Want the implant removed •

Or Have:

- Health changes, including, headaches, acne, pain, weight, or mood changes •
- Unusually heavy vaginal bleeding or other questions about periods •
- Arm pain
- Pus, or bleeding at the insertion site
- New health diagnosis or medications .

/	Nexplanon Insertion Date: Removal Date:
	If you have questions or concerns contact your provider:
	Provider name:
	Phone: (206) -
	After Hours Clinic Back-Up Line: (206) -
	If you ever have a life threatening health emergency- call 911

Adapted from Planned Parenthood of the Greater Northwest

neighborcare health Nexplanon Provider Skills Checklist

Clinician Name:	Date:		
		Developing	
Knowledge/ Preparation	Beginner	Developing Competency	Competent
Attend and receive certificate from the Nexplanon Clinical Training Program			i
Read Neighborcare LARC & Implant Protocols			
Shadow at least one insertion prior to demonstration of skills			
Identify contraindications, adverse reactions, and side effects			
Identify labs/exam required before Nexplanon insertion			
Identify possible complications for insertion & removal			
Identify parent/guardian awareness & insurance or Take Charge status			
Counsel for options, risks, benefits, side effects, and planned follow-up			
Utilize Choice Counseling Techniques			
Update patient health history and any contraindications identified			
Screen for allergies to etonogestrel, Betadine, lidocaine, silicone, polyethylene			
Perform or verify screening tests are done and reviewed			
Obtain signed Nexplanon consent form			
Obtain signed PCP Communication form and ROI if indicated			
Gathers supplies for procedure in exam room			
Identifies location of emergency supplies and staff availability			
Answer remaining patient questions			
Demonstrate Skills/ Procedure	Beginner	Developing Competency	Competent
Respect patient's privacy in preparation for insertion			
Position patient on table the non-dominant arm flexed at the elbow & externally rotated			
Identify insertion site- the inner side of the upper arm (8-10cm above the medial epicondyle of the			
humerus)			
Identify (and mark) the spot of insertion & a spot a few cm proximal from the first			
Clean insertion site with antiseptic solution			
Anesthetize insertion site- 2-5cc lidocaine 1% along insertion tunnel- may use sodium bicarbonate			
Remove the sterile Nexplanon applicator with the implant from the blister pack			
Hold the applicator correctly & remove the protective cap from the needle			
Stretch the skin around the insertion site			
Puncture skin with tip of needle at 30°- then lower the applicator to a horizontal position			
Lift the skin with the tip of the needle, slide the needle to its full length			
While maintaining correct position- unlock the slider, push it slightly down, move the slider completely back until it stops			
Remove the applicator and palpate the Nexplanon- verifying it is placed correctly			
Verify only the purple tip of the obturator is visible in the applicator			
Instruct patient how feel the implant- have them confirm its presence			
Apply Steri-strips at insertion site, wrap with a pressure bandage & sterile gauze			
Dispose applicator & all supplies in appropriate waste receptacle			
		Developing	
Post Insertion Skills	Beginner	Competency	Competent
Allow patient to rest before leaving			
Take BP and pulse- ensure stable vitals			
Accurately review all aftercare instructions with patient			
Schedule follow-up appointment per SBHC protocols			
Complete NextGen documentation of visit, procedure, and EM Coding			
Nexplanon Removal Skills (okay to complete on plastic model)	Beginner	Developing Competency	Competent
Demonstrate removal of an uncomplicated Nexplanon implant			
Demonstrate knowledge of a complicated Nexplanon removal and indications for referral			

Signature of Observer: ____

PRINTED: _____

Nexplanon Insertion & Removal | Clinical Training Program

INSERTION PROCEDURE

The basis for successful use and subsequent removal of NEXPLANON[®] (etonogestrel implant) is a correct and carefully performed subdermal insertion of the single, rod-shaped implant in accordance with the instructions. Both the healthcare provider and the woman should be able to feel the implant under the skin after placement.

All healthcare providers performing insertions and/or removals of NEXPLANON must receive instructions and training prior to inserting or removing the implant. Information concerning the insertion and removal of NEXPLANON will be sent upon request free of charge (1-877-467-5266).

Prior to inserting NEXPLANON, carefully read the instructions for insertion and removal as well as the Prescribing Information.

Before insertion of NEXPLANON, the healthcare provider should confirm that:

- The woman is not pregnant nor has any other contraindication for the use of NEXPLANON [see Contraindications in Prescribing Information]
- The woman has had a medical history and physical examination, including a gynecologic examination, performed
- The woman understands the benefits and risks of NEXPLANON
- The woman has received a copy of the Patient Labeling included in packaging
- The woman has reviewed and completed a consent form to be maintained with the woman's chart
- The woman does not have allergies to the antiseptic and anesthetic to be used during insertion

Insert the implant under aseptic conditions.

The following equipment is needed for the implant insertion:

- An examination table for the woman to lie on
- Sterile surgical drapes, sterile gloves, antiseptic solution, sterile marker (optional)
- Local anesthetic, needles, and syringe
- [®] Sterile gauze, adhesive bandage, pressure bandage



Figure 1



Figure 2













Step 1.

Have the woman lie on her back on the examination table with her non-dominant arm flexed at the elbow and externally rotated so that her wrist is parallel to her ear or her hand is positioned next to her head (*Figure 1*).

Step 2.

Identify the insertion site, which is at the inner side of the non-dominant upper arm about 8-10 cm (3-4 inches) above the medial epicondyle of the humerus (*Figure 2*). The implant should be inserted subdermally just under the skin to avoid the large blood vessels and nerves that lie deeper in the subcutaneous tissue in the sulcus between the triceps and biceps muscles [see *Warnings and Precautions* in Prescribing Information].

Step 3.

Make two marks with a sterile marker: first, mark the spot where the NEXPLANON implant will be inserted, and second, mark a spot a few centimeters proximal to the first mark *(Figure 2)*. This second mark will later serve as a direction guide during insertion.

Step 4.

Clean the insertion site with an antiseptic solution.

Step 5.

Anesthetize the insertion area (for example, with anesthetic spray or by injecting 2 mL of 1% lidocaine just under the skin along the planned insertion tunnel).

Step 6.

Remove the sterile preloaded disposable NEXPLANON applicator, carrying the implant, from its blister. The applicator should not be used if sterility is in question.

Step 7.

Hold the applicator just above the needle at the textured surface area. Remove the transparent protection cap by sliding it horizontally in the direction of the arrow away from the needle **(Figure 3)**. If the cap does not come off easily, the applicator should not be used. You can see the white colored implant by looking into the tip of the needle. **Do not touch the purple slider until you have fully inserted the needle subdermally, as it will retract the needle and prematurely release the implant from the applicator.**

Step 8.

With your free hand, stretch the skin around the insertion site with thumb and index finger (*Figure 4*).

Step 9.

Puncture the skin with the tip of the needle angled about 30° (Figure 5).

Continued on next page.



Figure 6



Figure 7



Figure 8

Step 10.

Lower the NEXPLANON[®] (etonogestrel implant) applicator to a horizontal position. While lifting the skin with the tip of the needle (*Figure 6*), slide the needle to its full length. You may feel slight resistance but do not exert excessive force. If the needle is not insérted to its full length, the implant will not be inserted properly.

You can best see movement of the needle if you are seated and are looking at the applicator from the side and NOT from above. In this position, you can clearly see the insertion site and the movement of the needle just under the skin.

Step 11.

Keep the applicator in the same position with the needle inserted to its full length. If needed, you may use your free hand to keep the applicator in the same position during the following procedure. Unlock the purple slider by pushing it slightly down. Move the slider fully back until it stops (*Figure 7*). The implant is now in its final subdermal position, and the needle is locked inside the body of the applicator. The applicator can now be removed. If the applicator is not kept in the same position during this procedure or if the purple slider is not completely moved to the back, the implant will not be inserted properly.

Step 12.

Always verify the presence of the implant in the woman's arm immediately after insertion by palpation. By palpating both ends of the implant, you should be able to confirm the presence of the 4-cm rod (*Figure 8*).

If you cannot feel the implant or are in doubt of its presence,

- Check the applicator. The needle should be fully retracted and only the purple tip of the obturator should be visible.
- Use other methods to confirm the presence of the implant. Suitable methods are: twodimensional X-ray, ultrasound scanning (USS) with a high-frequency linear array transducer (10 MHz or greater), X-ray computerized tomography (CT scan), or magnetic resonance imaging (MRI). If these methods fail, call 1-877-467-5266 for information on the procedure for measuring etonogestrel blood levels.

Until the presence of the implant has been verified, the woman should be advised to use a non-hormonal contraceptive method, such as condoms.

Step 13.

Place a small adhesive bandage over the insertion site. Request that the woman palpate the implant.

Step 14.

Apply a pressure bandage with sterile gauze to minimize bruising. The woman may remove the pressure bandage in 24 hours and the small bandage over the insertion site after 3 to 5 days.

Step 15.

Complete the USER CARD and give it to the woman to keep. Also, complete the PATIENT CHART LABEL and affix it to the woman's medical record.

Step 16.

The applicator is for single use only and should be disposed in accordance with the Center for Disease Control and Prevention guidelines for handling of hazardous waste.

To report an adverse event or insertion/removal-related event, call 1-877-467-5266.

REMOVAL PROCEDURE

Before initiating the removal procedure, the healthcare provider should carefully read the instructions for removal and consult the USER CARD and/or the PATIENT CHART LABEL for the location of the NEXPLANON implant. The exact location of the implant in the arm should be verified by palpation. If the implant is not palpable, two-dimensional X-ray can be performed to verify its presence.

A non-palpable implant should always be first located prior to removal. Suitable methods for localization include: two-dimensional X-ray, ultrasound scanning (USS) with a high-frequency linear array transducer (10 MHz or greater), X-ray computerized tomography (CT scan), or magnetic resonance imaging (MRI). If these imaging methods fail to locate the implant, etonogestrel blood level determination can be used for verification of the presence of the implant. For details on etonogestrel blood level determination, call 1-877-467-5266 for further instructions.

After localization of a non-palpable implant, consider conducting removal with ultrasound guidance.

There have been occasional reports of migration of the implant; usually this involves minor movement relative to the original position. This may complicate localization of the implant by palpation, USS, CT, and/or MRI, and removal may require a larger incision and more time.

Exploratory surgery without knowledge of the exact location of the implant is strongly discouraged. Removal of deeply inserted implants should be conducted with caution in order to prevent injury to deeper neural or vascular structures in the arm and be performed by healthcare providers familiar with the anatomy of the arm.

Before removal of the implant, the healthcare provider should confirm that:

• The woman does not have allergies to the antiseptic or anesthetic to be used

Remove the implant under aseptic conditions.

The following equipment is needed for removal of the implant:

- An examination table for the woman to lie on
- Sterile surgical drapes, sterile gloves, antiseptic solution, sterile marker (optional)
- Local anesthetic, needles, and syringe
- Sterile scalpel, forceps (straight and curved mosquito)
- Skin closure, sterile gauze, adhesive bandage and pressure bandages

Steps for Removal



Step 1.

Clean the site where the incision will be made and apply an antiseptic. Locate the implant by palpation and mark the distal end (end closest to the elbow), for example, with a sterile marker **(Figure 9)**.

Figure 9



Figure 10

Step 2.

Anesthetize the arm, for example, with 0.5 to 1 mL 1% lidocaine at the marked site where the incision will be made (*Figure 10*). Be sure to inject the local anesthetic under the implant to keep it close to the skin surface.

Continued on next page.

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Step 3.

Push down the proximal end of the implant (Figure 11) to stabilize it; a bulge may appear indicating the distal end of the implant. Starting at the distal tip of the implant, make a longitudinal incision of 2 mm towards the elbow.

Step 4.

Gently push the implant towards the incision until the tip is visible. Grasp the implant with forceps (preferably curved mosquito forceps) and gently remove the implant (Figure 12).

Figure 11

Step 5.

If the implant is encapsulated, make an incision into the tissue sheath and then remove the implant with the forceps (Figures 13 and 14).



Step 6.

If the tip of the implant does not become visible in the incision, gently insert a forceps into the incision (Figure 15). Flip the forceps over into your other hand (Figure 16).

With a second pair of forceps carefully dissect the tissue around the implant and grasp

Step 7.

Figure 12



Figure 14

Step 8.

the implant (Figure 17). The implant can then be removed.

Confirm that the entire implant, which is 4-cm long, has been removed by measuring its length. If a partial implant (less than 4-cm) is removed, the remaining piece should be removed by following the instructions in section 2.3 [see Dosage and Administration (2.3) in Prescribing Information]. If the woman would like to continue using NEXPLANON, a new implant may be inserted immediately after the old implant is removed using the same incision [see Dosage and Administration (2.4) in Prescribing Information].



After removing the implant, close the incision with a Steri-Strip™ and apply an adhesive bandage.

Step 10.

Apply a pressure bandage with sterile gauze to minimize bruising. The woman may remove the pressure bandage in 24 hours and the small bandage in 3 to 5 days.





Figure 15



To report an adverse event or insertion/removal-related event, call 1-877-467-5266.

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INTERESTED IN USING THE IMPLANT (NEXPLANON)?

Here is some helpful information about what to expect and how it works.

What is the implant?	How does it work?	How well does it work?	How long can I use it?
 It's a tiny flexible tube that a health care provider puts under the skin of your upper arm. (not the one you use to write) It has a hormone in it that prevents you from getting pregnant. 	 In some women, it keeps the egg from leaving the ovaries. It makes the fluid in your cervix thick and sticky. This keeps sperm from getting inside your uterus and meeting an egg. 	 It is over 99% effective If 2,000 women used the implant for a year, only 1 might get pregnant. That's less than 1%. It is about 20 times more effective than birth control like the pill, patch, or ring. 	 You can use the implant for up to 3 years. A new one can be inserted at the end of 3 years
How is the Implant put in?	What do women like about the Implant?	What side effects does it have?	Do I need to do anything to make it work better?
 Your healthcare provider will numb your upper arm and then put it in just under the skin. You will have one small bandage over the implant and a larger bandage over it. After 1 day you remove the larger bandage and wash the area gently with warm water and soap. After a few days the smaller bandages will fall off naturally. 	 It lasts for 3 years. It's easy to use. It is private 	 Most women have changes in their periods- spotting and a decrease in periods over time. This is normal and not a problem 1 in 5 women report they had no period after 6 months of use. Some women said they exerienced mood swings, weight gain , headaches and other side effects. 	 Tell other health care providers you have Nexplanon- it might be important when making other health care decisions for you Once the Implant is in, use condoms to prevent pregnancy for the first week. After that count on the Implant to prevent pregnancy. Keep using condoms to prevent sexually transmitted infections.
	40mm long Actual Size	Want more information? • www.safeandeffective.or • www.nexplanon-usa.con • www.bedsider.org	-



Nexplanon Patient Consent Form

ETONOGESTREL IMPLANT

Radiopaque- For Subdermal Use Only

I understand the Patient Labeling for NEXPLANON. I have discussed NEXPLANON with my healthcare provider who answered all my questions. I understand that there are benefits as well as risks with using NEXPLANON. I understand that there are other birth control methods and that each has its own benefits and risks.

I also understand that this Patient Consent Form is important. I understand that I need to sign this form to show that I am making an informed and careful decision to use

NEXPLANON, and that I have read and understand the following points.

- NEXPLANON helps to keep me from getting pregnant.
- No contraceptive method is 100% effective, including NEXPLANON.
- NEXPLANON is an implant that contains a hormone.
- It is important to have the NEXPLANON implant **placed in my arm** when I know I am not pregnant.
- After the implant is placed in my arm, I should check that it is in place by gently pressing my fingertips over the skin where the implant was placed. I should be able to feel the implant.
- The implant must be removed at the end of three years. The implant can be removed sooner if I want.
- If I have trouble finding a healthcare provider to remove the implant I can call 1-877-467-5266 for help.
- The implant is placed under the skin of my arm during a procedure done in my healthcare provider's office. There is a slight risk of getting a scar or an infection from this procedure.
- Removal is usually a minor procedure. Sometimes, removal may be more difficult. Special procedures, including surgery in the hospital, may be needed. Difficult removals may cause pain and scarring and may result in injury to nerves and blood vessels. If the implant is not removed, its effects may continue.
- Most women have changes in their menstrual bleeding patterns while using NEXPLANON. I also will likely have changes in my menstrual bleeding pattern while using NEXPLANON. My bleeding may be irregular, lighter or heavier, or my bleeding may completely stop. If I think I am pregnant, I should contact my healthcare provider as soon as possible.
- I understand the warning signs for problems with NEXPLANON. I should seek medical attention if any warning signs appear.
- I should tell <u>all</u> my healthcare providers that I am using NEXPLANON.
- I need to have regular medical checkups and also at any time I am worried about problems related to the implant.
- NEXPLANON does not protect me from HIV infection (AIDS) or any other sexually transmitted infections.

After learning about NEXPLANON, I choose to use NEXPLANON.

(Patient Signature)

(Date)

WITNESSED BY:

The patient above has signed this consent in my presence after I counseled her and answered her questions.

(Name of Healthcare Provider)

(Healthcare Provider Signature)

(Date)

If Applicable:

I have provided an accurate translation of this information to the patient whose signature appears above. She has stated that she understands the information and has had an opportunity to have her questions answered.

(Signature of Translator)

(Date)

Source: Nexplanon Patient Consent Form- Merck Corporation



IUD – MIRENA & PARAGARD



IUD Pre-Insertion Counseling- BRAIDED Format

BENEFITS

- Easy to use
- It is private
- IUDs are effective reversible birth control methods. Only 2/1000 women get pregnant using the Mirena and 8/1000 using the ParaGard in the 1st year.
- Current regulations state that the Mirena is effective for 5 years with a cumulative failure rate of 7/1000 pregnancies and the ParaGard is effective for 10 years with a cumulative failure rate of 22/1000 pregnancies.
- IUD's have the highest user satisfaction rate of any contraceptive
- It is safe. 25% of teens in Europe choose it as their method of birth control. The current IUDs have been around for more than 10 years and millions of people have used it. The IUDs available now are much improved over IUDs used 20 years ago.
- The Mirena IUD has the lowest dose of hormone available in birth control.
- The ParaGard has no hormones.
- The Mirena IUD decreases menstrual flow and cramping for most women once the body adjusts to it.
- Typically a woman might take 2 months to adjust. Most women report they have adjusted by 6 months. The SBHC health care provider is available to help manage any side effects.

RISKS- Complications are low at 1.8%

• Expulsion

The IUD may fall out. This occurs in less than 8/100 women who have never had a baby. If it falls out a new one can be placed with a 70% chance it stays in the next time.

Infection

There is a 1/1000 risk of uterine infection in the first 21 days after the IUD has been inserted

*The IUD does not protect against STI's

• Perforation

Perforation occurs during 1/1,000 IUD insertions. After pregnancy- women are most at risk for perforation in the first weeks after giving birth. It is important to wait at least 6 week after delivery before having an IUD placed.

• Hormonal side effects

Hormonal side effects include headaches, nausea, acne, mood changes and changes in period

- 1/40 women stop Mirena due to bleeding and 1/20 stop due to cramping.

- Women can expect to have on and off cramping and bleeding like a period for the first few months, then irregular bleeding that gradually lessens over 6 months. By one year, 90% stop having their periods.

- 95/100 women state that they have not gained weight while using Mirena

• Non-hormonal side effects

Changes in a woman's period are a common side effect when using the ParaGard.

- Women can expect heavier, crampier periods with ParaGard. Some women get periods that are 2 days longer and twice as heavy. Typically it is reported that periods get 20% worse.

• Ectopic Pregnancy

Women not using birth control are at higher risk for pregnancy, and therefore ectopic pregnancy, than women using an IUD. Although highly unlikely, **if** a woman becomes pregnant while using an IUD, she is at an increased risk of ectopic pregnancy.

ALTERNATIVES

- Other reversible forms of contraception
- Refer patients with these conditions to specialists and non-SBHC clinics or hospitals:
 - Cardiovascular conditions with risk of syncope/bradycardia
 - Poorly controlled seizure disorder
 - Bleeding disorder or anti-coagulated
 - Known uterine anomaly
 - Prior unsuccessful attempt due to cervical stenosis or prior uterine perforation where an ultrasound may be necessary
 - High anxiety- use of anti-anxiety Rx for procedure
 - Wheelchair or need for accessible/adjustable exam table
 - Cerebral Palsy or other spasticity

INQUIRIES

Answer all questions in a clear, simple and straightforward manner.

DECISIONS

- If a woman decides on an IUD- counsel her to give it 6 months for the body to adjust.
- **Review any contraindications-** see MEC
 - Unprotected sex in the last 14 days for Mirena. ParaGard is okay if UPIC in last 5 days. Urine HCG tests are reliable 1 day post missed menses.
 - Currently pregnant or wants to get pregnant in the next year
 - Pelvic Inflammatory Disease (PID), mucopurulent cervicitis, or acute vaginal infection
 - Copper allergy or Wilson's disease- ParaGard is **not** an option.
 - Uterine abnormality
 - Uterine, cervical, liver, or breast cancer, or tumors
 - Unexplained genital or vaginal bleeding
 - Postpartum or postabortion endometritis in past 3 months
 - Current IUD still in place
 - Review and update health history for additional risks for an IUD

EXPLANATION OF METHOD

- Similarities and differences between Mirena, Skyla, and ParaGard
- Pregnancy Prevention

 Thickens cervical mucus to prevent sperm from the uterus (Mirena and Skyla)

-Thins the lining of the uterus (Mirena and Skyla)

-It prevents the egg from attaching to the uterine wall (ParaGard) -It prevents the egg from releasing from the ovaries (Mirena and Skyla)

• Description of female anatomy and IUD placement

• Description of procedure

-Will use a pelvic speculum

-Put a stabilizer on the cervix which might feel like a pinch

-Will need to see how deep the cervix is to get the IUD in the right place

-The feeling is often equated to a bad menstrual cramp for 5 minutes

-85% described the pain at insertion as 'period pain' and 14% described it as 'severe abdominal pain'

-Women said that it was 'easier than I thought' or 'like I thought'

-Comfort will be available- can listen to music, have a support person, and use a hot water bottle or heating pad

-Recommend arrangement for a ride home after the insertion appointment

• Description of pain relief options

Give 800mg ibuprofen at least 30 minutes before procedure. See pain management and aftercare documents.

DOCUMENTATION

- The IUD procedure will be documented in NextGen.
- The patient and SBHC provider fill out a ROI and a PCP Coordination form if the PCP is not part of Neighborcare. If part of Neighborcare- send communication to PCP.
- Send patient home with clear aftercare instructions and emergency contact information
- Check insurance status- Be sure insurance is current and valid: "Take Charge pending" is OK if application is waiting for DSHS approval or Eligibility staff anticipates approval. Contact SBHC Eligibility for more information.

• Post IUD insertion complications:

Contact: Mo Considine 360-725-1652 <u>Maureen.considine@hca.wa.gov</u>

Billing & Referral: Use IUD complication code and in claim comments write IUD complication.

- Take Charge will cover for pelvic US under these conditions.
- Confidentiality will be maintained.

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INTERESTED IN USING THE MIRENA IUD?

Here is some helpful information about how it works and what to expect.

What is the Mirena IUD?

- It's a small flexible piece of plastic that your health care provider puts into your uterus.
- •It is shaped like a T and has a hormone in it.
- •It has a small amount of hormones in it.

How is the Mirena IUD put in?

- •The health care provider will use a small tube to gently place the IUD through the cervix into the uterus.
- •Some women have cramping when it is put in.
- •Your health care provider will help make a plan. Taking ibuprofen ahead of time can help.
- •There may be some cramping for a few days afterwards. This is normal and it will go away. You can take ibuprofen and/ or use a hot water bottle for the pain.

How does it work?

- It makes the fluid in your cervix thick and sticky. This keeps sperm from getting inside your uterus and meeting an egg.
- In some women, it keeps the egg from leaving the ovaries.

What do women like about the Mirena IUD?

- It lasts for 5 years.
- It's easy to use.
- •It can be used to treat heavy periods
- •It is private- no one knows.
- It is one of the most effective reversible birth control method.

How well does it work?

- •The Mirena IUD is over 99% effective.
- If 1,000 women used the hormone IUD for a year, only 1 might get pregnant. That's way less than 1%.

What side effects does it have?

- Most women have changes in their periods. Spotting and a decrease in periods over time. This is normal and not a problem
- •By 1 year 90% of women stop their periods.
- About 7 out of 100 women noticed that they had more headaches.
- Other side effects that less than 5% of women reported include change in mood, infection and other complications.

How long can I use it?

- •The current regulations state that Mirena will last for at least 5 years.
- •The new Skyla IUD will last 3 years.

Do I need to do anything to make it work better?

- •Once the IUD is in, use condoms to prevent pregnancy for the first week. After that -count on the IUD to prevent pregnancy.
- It is important to use condoms to prevent STIs-Sexually Transmitted Infections



Want more information?

- www.safeandeffective.org
- www.mirena-us.com
- www.bedsider.org

neighborcare health www.neighborcare.org

INTERESTED IN USING THE PARAGARD IUD?

Here is some helpful information about how it works and what to expect.

What is the Paragard IUD?	How does it work?	How well does it work?	How long can I use it?
 It's a small flexible piece of plastic that your health care provider puts into your uterus. It is shaped like a T and is wrapped with thin copper wire. 	 The copper wire kills sperm. The ParaGard may prevent the fertilized egg from implanting in the uterus. 	 The ParaGard IUD is over 99% effective. If 1,000 women used the ParaGard IUD for a year, only 2 might get pregnant. That's way less than 1%. 	•You can use the ParaGard IUD for up to 10 years.
How is the Paragard IUD put in?	What do women like about the ParaGard IUD?	What side effects does it have?	Do I ned anything to make it work better?
 The health care provider will use a small tube to gently place the IUD through your cervix into the uterus. Some women have cramping when it is put in. Your health care provider will tell you to take ibuprofen ahead of time. There may be some cramping for a few days afterwards. This is normal and it will go away. You can take ibuprofen and/ or use a hot water bottle for the pain. 	 It lasts for 10 years. It's easy to use. No one can tell you are using it. It is one of the most effective birth control methods that is also reversible. 	 Most likely you'll have changes in your periods. From some this means heavier periods or periods that last longer. Most women have more cramping with their periods. Some women report having back pain. Very rarely a woman get an infection from the IUD insertion process. 	 Once the IUD is in place, you do not need to do anything to prevent pregnancy. It is important to use condoms to prevent STIs- Sexually Transmitted Infections
ſ	-1 1/4" Across the top		
	bigger tha a penny.	 Want more i www.safeand www.paragar 	effective.org

www.bedsider.org



IUD Scheduling Protocol

Patient Counseling Session:

- Schedule a 30 minute counseling session for a patient who wants an IUD
- Patient will need a pregnancy test, weight, BP, pulse, and LMP
- IUD consent form- see IUD consent form
- Provide condoms or other BC for use prior to insertion
- Follow IUD pre-insertion counseling protocol- see counseling protocol
- Provide patient with any available educational materials
- Check parent/guardian awareness & confidentiality of service
- Check patient insurance status, send in any application for coverage needed
- Schedule an hour long insertion appointment after a complete counseling session and once the Take Charge application has been submitted (if applicable)

Patient Insertion Session:

- Schedule a I hour insertion session for a patient who has had a counseling session and wants to receive an IUD.
- At least one other SBHC staff member MUST be on site for the length of the appointment.
- Patient must have a pregnancy test, weight, BP, pulse, and LMP before insertion.
- It is strongly recommended the patient receive 800mg lbuprofen. Ideally at least I hour prior to insertion, but at least at the beginning of the insertion appointment for pain management- see pain management document.
- Verify patient has used reliable form of contraception for the last 14 days prior to insertion.
- Lot number and expiration date of the IUD recorded.
- Supplies prepared ahead of patient- see IUD supplies list
- Consent form checked and signed.
- Complete PCP Communication form and ROI if has community PCP not at Neighborcare.
- Have emergency materials prepared- see emergency supplies list.
- Aftercare Instructions given (include emergency follow-up)- see IUD aftercare.

Post Insertion Follow-Up:

- Schedule post-insertion follow-up appointment within 4-6 weeks of IUD insertion.
 - Perform a pelvic exam- *If* the patient is confident she can feel her own strings, has no dyspareunia, and no abnormal discharge- the pelvic exam is optional.
 - Make sure to ask about pain and bleeding, and use of condoms during first week.
 - Answer any follow-up questions or concerns
- In SBHCs a 2 week post-insertion appointment is also advised.



IUD Insertion Patient Consent Form

(Print First and Last Name)

(Date of Birth)

_understand and accept the following risks:

There is I chance in 1000 that the IUD could fail and I could become pregnant.

- If I do become pregnant with an IUD, there is an increased risk that the pregnancy would implant somewhere other than the uterus (ectopic pregnancy) and that I would lose the pregnancy.
- There is a 5 in 100 chance the IUD could fall out. (checking the strings can help detect this)
- There is a slightly increased risk of infection in the uterus and tubes (pelvic inflammatory disease or PID) for 20 days after the IUD is put in.
- There is a 1 in 1000 risk of perforation (poking a hole in the uterus) with insertion of the IUD. This could result in an Emergency Room visit and therefore a potential loss of confidentiality.

For Mirena or Skyla (Progesterone IUDs):

• I understand I may have the side effect of having no period and/or irregular bleeding and that it may take up to 6 months for my body to fully adjust to it.

For ParaGard (Copper IUD)

- I understand I may have the side effect of painful and/or heavy periods that may cause low blood count (anemia).
- I understand that if I have had unprotected sex in the last 5 days this IUD will work as emergency contraception and keep me from getting pregnant.
- I understand I need to see my health care provider if I miss a period.

For either IUD, I understand the need to see my health care provider if:

- I am having problems or concerns related to my IUD and need help managing my side effects.
- I develop signs of infection: pain, fever, abnormal vaginal discharge.
- I develop ongoing abnormal bleeding different from what has been explained to me.
- I cannot feel the strings.

After learning about the IUD and having my questions answered, I choose the _____ IUD.

(Patient Signature)

(Date)

WITNESSED BY:

The patient above has signed this consent in my presence after I counseled her and answered her questions.

(Name of Healthcare Provider)

(Healthcare Provider Signature)

(Date)

<u>If Applicable</u>: I have provided an accurate translation of this information to the patient whose signature appears above. She has stated that she understands the information and has had an opportunity to have her questions answered.

(Signature of Translator)

(Date)



IUD Pain Management

Our goal is to make the process of receiving an IUD as comfortable as possible. Pain upon insertion can be significant, and it is important to make sure to counsel patients about the pain they may experience and work to minimize it.

Pain Management Options:

- Give patient 800 mg ibuprofen at counseling visit to take I hour prior to insertion
- Offer patient 800 mg ibuprofen at the beginning of the insertion appointment if they did not take it prior to arriving
- Offer patient a hot water bottle or heating pad to relax the uterus prior to insertion to reduce cramping during the insertion.
- Encourage use of music, distractions, and a support person to help with pain
- Allow patient to rest for at least 15 minutes after insertion
- Encourage patient to arrange a ride home from school with a friend or family member
- Give patient ibuprofen 600-800 mg every 6-8 hours for 5-7 days and then to use as needed.
- Remind patients they can continue to use a hot water bottle or heating pad to help relieve cramps and take ibuprofen as needed (no more than 2400mg in 24 hours.)
- If ibuprofen and heat are not helping to manage pain, patients can come back for further follow-up as needed.



IUD Pre-Insertion Supplies

Supplies Needed:

NOTE: Always have a spare set readily available in case of contamination or malfunction

IUD insertion instruments, prepackaged and sterilized to include:

- Single tooth tenaculum
- Either a disposable uterine sound or a metal uterine sound with gauze or material wrapped around the pointed end to prevent piercing of paper and kit contamination
- Ring forceps- 4"x4" gauze (3) or 3 long, fat cotton swabs (antiseptic is poured over 3 swabs)
- Scissors- preferably long handled and monitor sharpness
- 3 long cotton swabs to stop bleeding from tenaculum site, and extra antiseptic/ blood from vault. Ring forceps and extra gauze can also be used for this.





- Disposable os finder
- Blue pad (or other absorbent pad) for exam table
- Modesty drape
- Heating pad/ hot water bottle
- Menstrual pad for patient
- Emergency supplies available



- Betadine solution (Chlorhexidine Gluconate for patients with an iodine allergy) in a cup or poured over swabs/gauze
- Exam lubricant to do bimanual exam
- Appropriate size Graves medal speculum or lighted plastic speculum
- Working gooseneck, standing lamp, or lighted speculum
- IUD package- make sure to record lot number, expiration date and insertion date in NextGen- enter the information in the procedure template or remove the sticker included with the IUD kit and attach it to the back of the consent form to be scanned into the system.
- Gloves (sterile optional)









IUD Insertion Protocol & Follow-Up

Pre- Insertion Checklist:

- □ Patient has signed consent form- see IUD consent form
- □ Patient has signed PCP Communication form & ROI, if indicated
- □ Patient has identified support person and/or ride home from school
- □ Verify insurance status
- □ Verify at least 2 of selected IUD are available on site (1 for back-up)
- □ Patient has received a menstrual pad
- □ Patient has gone to the bathroom and emptied her bladder
- □ Patient has a negative pregnancy test
- □ Obtain & document vitals including weight, BP and LMP
- □ Review patient allergies: latex, Betadine, or copper
- □ Verify the patient does not have contraindications for receiving an IUD- see IUD preinsertion counseling
- □ Update patient medication list to include IUD
- □ Answer all questions
- □ All supplies and emergency supplies are set-up for procedure- see IUD supply list and emergency supply list
- Exam table has been prepared with an absorbent pad and drape
- Patient has taken 800mg ibuprofen 30 minutes prior to the procedure, and if notoffer it during insertion visit- see <u>IUD Pain Management</u>
- □ Patient has received a hot water bottle or heating pad- see <u>IUD Pain Management</u>

IUD Insertion Protocol:

- Allow patient privacy to get undressed below the waist (they can leave their socks on)
- Wash hands thoroughly with warm water and soap
- Dry hands
- Put on a clean pair of medical gloves (latex free- especially if patient has a latex allergy)
- Perform a bi-manual exam: palpate for size and uterine orientation
- Put on a clean pair of gloves for the insertion
- Insert appropriate sized speculum (goal is to maximize cervical exposure while minimizing discomfort for patients)
- Clean the cervix with Betadine (unless patient has an allergy, in which case use the Chlorhexidine)
- Apply the tenaculum to stabilize the cervix (this may cause cramping)
 - Apply tenaculum to anterior lip of cervix if uterus in anteverted or anteflexed.
 - Apply tenaculum to posterior lip of cervix if uterus is retroverted or retroflexed.
- Insert the uterine sound (this may cause cramping.) Be patient. *Note:* a moderate amount of pressure at the internal os for a full minute may be necessary before the os releases.
- Open IUD package if uterus sounds to 6cm or longer (Mirena) or 5.5cm or longer (ParaGard)

MIRENA	PARAGARD
• Load the Mirena into the cannula by pulling gently on the strings at the base of the insertion tube	• Load the ParaGard into the insertion tube by folding down the two horizontal arms of the IUD and pushing it securely into the insertion
• Secure the threads in the cleft at the base of the cannula	tubeIntroduce the solid white rod into the insertion
• Using the measurement from the cervical sound set the flange (small	tube from the bottom, alongside the threads, until it touches the bottom of the IUD
 green ring) to the uterine depth Insert the cannula through the cervix, stopping 1 cm shy of the top of the 	 Using the measurement from the cervical sound set the flange (small blue ring) to the uterine depth.
 uterus and the flange on the cannula (may cause cramping) Tip: When inserting IUD add counter 	 Rotate the insertion tube so that the horizontal arms of the T and the long axis of the blue flange lie in the same horizontal plane. Insert the
traction by pulling on cervix with forceps while inserting IUD. This seems	cannula through the cervix to the fundus (the blue ring should be at the cervix)
to help with the insertion.Pull the slider back to the groove	• To release the arms of the ParaGard, hold the white rod steady and withdraw the insertion
 Wait 10 seconds (<i>This is critical</i>!) Advance cannula to fundus so the flange is flush with the cervix 	 tube no more than one centimeter Gently and carefully move the insertion tube upward toward the top of the uterus, until slight resistance is felt
Now, pull slider all the way backPull out IUD insertion cannula	 Hold the insertion tube steady and withdraw the white rod
	Pull out IUD insertion tube

NEXT:

- Using long scissors cut strings to 3cm. *Hint:* For reference- a Scopette (swab portion) is 3cm.
- Make sure to check for any bleeding- hold pressure for 30 seconds to 1 minute on tenaculum site as needed.
- If there is no unusual bleeding remove the speculum.

Post-Insertion Protocol:

- Allow patient to rest, lying down for a full 10 minutes.
- Monitor the patient carefully as she slowly changes position, until standing produces no dizziness.
- Take BP and pulse
- Monitor patient for at least 15 minutes after procedure
- Remind patient that they can expect to have cramps and spotting for bleeding on and off
- Encourage patient to call or come in with any questions
- Provide patient with 600-800 mg every 6-8 hours for 5-7 days post IUD insertion or as needed to manage pain and cramping- not to exceed 2400 mg/ 24 hours.- see Pain Management document
- Give patient <u>Aftercare Instructions</u> and emergency contact information.
- Instruct patient to use a back up method for the first week (condoms) to prevent pregnancy, and then use condoms for STI prevention
- Encourage patient to get a ride home from school after procedure
- Schedule two 30 minute IUD follow-up appointments: 2 weeks (optional) and within 4-6 weeks after insertion. During these visits make sure to answer any questions, concerns or pain management needs.- see <u>IUD Scheduling Protocol.</u>
- If malfunction occurs, contact the IUD manufacturer.

If you ever have a product malfunction or failed insertion Neighborcare can still be reimbursed. Use modifier 53 when coding for the appointment and make sure to clearly document what happened and that you used more than 1 IUD.

Consult ordering and contact information for Neighborcare LARC contracts.

Mirena or Skyla- Bayer: Mirena: <u>www.mirena-us.com</u> Skyla: <u>www.skyla-us.com</u> General contact information- (1-888-842-2937) Individual (as of 6/13)- Glen Butler at <u>Glen.Butler@bayer.com</u> or 541-579-1748. Keep the IUD in case Bayer it returned to them.

ParaGard: <u>http://www.ParaGard.com/</u> ParaGard info line: I-877-ParaGard (727-2427) The process of getting a replacement can take 4-6 weeks. Keep the IUD in case ParaGard wants it returned to them.

• Post IUD insertion complications:

Contact: Maureen 'Mo' Considine 360-725-1652 <u>Maureen.considine@hca.wa.gov</u>

Billing & Referral: Use IUD complication code and in claim comments write IUD complication.

- Take Charge will cover for pelvic US under these conditions.
- Confidentiality will be maintained.

Follow-up Visit Protocols:

2 weeks after insertion- optional follow-up visit:

- Ask about pain management and review pain management techniques
- Review use of condoms during first week post-insertion if had intercourse.
- Answer any follow-up questions, health status changes, or side effects
- Provide any necessary counseling

4-6 weeks after insertion:

- Answer any follow-up questions, health status changes, or side effects
- Assess ability to feel IUD strings
- Assess bleeding and cramping patterns
- Check for signs and symptoms of infection including:
 - -Pelvic pain or dyspareunia

-Fever

-Chills

-Nausea

-Vaginal discharge

- Ask about pain management and review pain management techniques
- Perform a pelvic exam to check IUD placement- *If* the patient is confident she can feel her own strings, has no dyspareunia, no pelvic pain, and no abnormal discharge- the pelvic exam is optional.
- Provide any necessary counseling
- Discuss annual CT/GC screening visit and begin regular Pap Smears at the age of 21

References: http://hcp.mirena-us.com/placement-and-removal/precise-placement.php http://hcp.paragard.com/ http://hcp.skyla-us.com/index.php



Post-Insertion IUD Cleaning Protocol

Once the IUD has been inserted, the patient is stable and has been observed in the clinic for at least 15 minutes the patient can be sent home.

- In a plastic tub in the sink mix warm water and Enzymatic Detergent and Presoak.
 ✓ 1-2 oz. of detergent to every gallon of warm water
- Wear gloves
- Scrub instruments with brush
- Allow instruments to soak for at least 5 minutes and no more than 20 minutes.







- Lay instruments on paper towel or other absorbent surface and allow to air dry
- Once instruments are dry insert into a self-seal sterilization pouch
- Seal and put into the clinic's plastic IUD courier box
- Send by Neighborcare courier to the specified clinic to be autoclaved Roosevelt- to 45th St Clinic

West Seattle & Chief Sealth- to High Point Clinic

• Expect to receive the sterilized instruments back in 4-7 days







IUD Removal Supplies

If string is visible:

- Ring forceps
- Speculum



For difficult removal:

If string is just visible try to grab strings with a cytobrush and long-handled needle nose forceps. If the strings can not be seen, refer to community resources. See <u>Consultation</u> <u>Resources.</u>

- Cytobrush
- Long-handled needle nose forceps



IUD Removal Protocol

Remember! If an IUD is removed mid-cycle and the woman has had intercourse within the preceding week, she is at risk of pregnancy unless a new IUD is inserted immediately following removal. Use a back up method for I week before removal if another IUD is not being inserted.

Pre-Removal Protocol:

- Offer patient an optional 800mg ibuprofen and heating pack or hot water bottle at least 30 minutes prior to removal- see pain management document
- Counsel patient on contraceptive options- encourage patient to leave with a new form of contraception
- Patient has gone to the bathroom and emptied her bladder
- Negative pregnancy test
- Obtain vitals including weight, BP and pulse
- Answer any questions
- Set up equipment (speculum and ring forceps) and emergency supplies for proceduresee removal supplies protocol and emergency supplies list
- Exam table has been prepared with a drape
- Verify patient allergies- make sure does not have an allergy to latex or Betadine

Removal Protocol:

- Remove IUD by applying gentle traction on the threads with forceps. The arms will fold upward as it is withdrawn from the uterus.
- Removal may be associated with some pain and/or bleeding or neurovascular episodes.
- If the threads are not visible and IUD is in the uterine cavity, it may be removed using a narrow forceps, such as an alligator forceps. This may require dilation of the cervical canal.
- After removal of IUD, verify it is intact.

Post-removal protocol:

- Allow patient to rest
- Take another set of vitals
- Monitor patient for at least 15 minutes after procedure
- Encourage patient to call or return to SBHC with any questions
- Ensure that the patient leaves with a supply of a new form of contraception. Encourage her to start it while in the office.
- Provide patient with 800mg of ibuprofen to be taken every 6-8 hours for 72 hours as needed after removal
- Give patient emergency contact information
- Encourage patient to get a ride home from school after procedure



IUD Provider Skills Checklist

Clinician Name:

Date: _____

Knowledge/Propagation	Desingen	Developing	Comercia
Knowledge/ Preparation	Beginner	Competency	Competent
Watch Ortho T380A and Berlex Lng IUS video and practice with plastic hand held model			
Thoroughly read Neighborcare LARC & IUD Protocols			
Shadow at least one IUD insertion prior to demonstration of skills			
Describe the differences between IUDs, including benefits, risks and expectations			
Identify contraindications, possible side effects, and adverse reactions			
Identify lab tests required before IUD insertion			
Identify parent/guardian awareness & insurance or Take Charge status			
Knowledge of IUD management in difficult situations, urgent, and emergency complications			
Offer patient centered information regarding the IUD and counsels regarding risks, benefits, side effects, and planned follow-up			
Facilitate the patient's decision regarding IUD use based on health history, preference, and risk factors			
Update patient history and any contraindications identified			
Screen for allergies to copper or levonorgestrel, as well as Betadine, lidocaine, silicone, polyethylene, etc.			
Perform or verify appropriate screening tests are done and reviewed			
Obtain signed IUD consent form			
Obtain signed PCP communication form, and ROI if indicated			
Gather materials necessary for IUD procedure in exam room			
Identify location of emergency supplies & staff availability			
Answer remaining patient questions			
Demonstrated Skills/ Procedure	Beginner	Developing Competency	Competent
Respect Patient's privacy in preparation for insertion & offers comfort			
Accurately perform bimanual exam and correctly estimates uterine size, position and cervical flexion			
Creates a sterile field including gloves			
Load IUD correctly if applicable			
Inserts speculum correctly, and explains clearly what is going to happen immediately prior to action- check for			
cervical inflammation			
Assess patient's tolerance and comfort level before, during and post insertion and offers comfort measures			
Places tenaculum on correct cervical lip			
Correctly sounds uterus and identifies appropriate size for IUD insertion (5.5cm-ParaGard, 6cm-Mirena)- asks for help as needed			
Sets flange to appropriate size (never 9-10cm)			
Inserts, places, and removes insertion tube correctly, leaving the IUD in place			
Demonstrates cutting strings to the correct length- 3cm			
Responds skillfully to urgent and emergent reactions (vasovagal, hemorrhage, etc.)			
Post Insertion Skills	Beginner	Developing Competency	Competent
Instructs patient on how to find their strings			
Allows patient to rest for at least 15 minutes before leaving	<u> </u>		
Takes BP and pulse before patient leaves to ensure stable vitals			
Accurately reviews all aftercare instructions with patient			
Schedules follow-up appointment per SBHC guidelines	<u> </u>		
Thoroughly documents procedure in NextGen			
IUD Removal Skills (okay to complete on a plastic model)	Beginner	Developing Competency	Competent
Demonstrates removal of IUD with the strings showing			
Demonstrates knowledge of removal when strings not visible and when to refer if unable to extract			

Signature of Observer: _____

PRINTED:



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IUD INSERTION AFTERCARE INSTRUCTIONS

Managing cramping and bleeding

After the insertion of your IUD today you may feel some cramping on and off for the next few days or weeks. Anti-inflammatory medications (i.e. ibuprofen, naproxen) are especially helpful for this type of discomfort. They work best when taken consistently for a few days at a time.

We recommend one of the below medications with food for 3 days, and then as needed for pain and cramping:

- Ibuprofen (Advil, Motrin, etc.) 200mg tablets. Take 3-4 tablets (600-800 mg total per dose) every 6-8 hours (maximum of 2400mg in 24 hours)
- Or
- Naproxen (Aleve) 220mg tablets. Take 2 1/2 tablets (550mg total per dose) every 12 hours

You may also have some light bleeding on and off for a few days to months. This is normal. If the bleeding is heavier than your period or if you are soaking a maxi pad or tampon in less than an hour for more than 2 hours you need to seek care. If you are concerned about your level of pain or bleeding, or if the pain is not helped by the above medications, call the clinic.

Periods after an IUD:

Your periods will probably be irregular and you may cramp more than usual for the first several months. If you think you are starting your period, start taking either ibuprofen or naproxen through the first few days of bleeding. This helps with both bleeding and cramping.

Prevent infection:

In order to prevent infection, we recommend that you don't insert anything into the vagina for the first 72 hours after insertion- this means no sex. After that point you can resume intercourse. We recommend using a condom for the first week after the insertion to prevent pregnancy and generally to prevent STI's.

Checking your strings:

The strings are attached to the IUD itself and extend through the cervix into the vagina. After each period you should reach inside and feel for your strings. First, find your cervix- it feels round, smooth and firm, like the end of your nose. You should then be able to feel your strings, and only your strings. They frequently get wrapped around or tucked behind the cervix- leave them there. If you ever feel plastic poking through your cervix, it could be the IUD itself. If that happens, do not have sex because you may not be protected. Call the clinic and make an appointment.

Details: The IUD has many benefits and is very effective birth control. Most women are very happy with having an IUD. Remember- it may take a few months to adjust fully to your IUD.

If you have questions or concerns contact your provider:	
Provider name:	
Phone: (206) - After hours call our Clinic Back-Up Line: (206) or your health provider's office.	
If you ever have a life threatening health emergency- call 911	



IUD Patient Assistance-ARCH Foundation

From ARCH Foundation website- January 15, 2014

What is the ARCH Foundation?

- The ARCH Foundation is a not-for-profit foundation established to assist low income patients who do not have insurance coverage for the Mirena[®] intrauterine contraceptive system.
- For patients such as these who meet specific eligibility criteria, the ARCH Foundation may be able to provide Mirena free of charge.
- Assistance is provided on a patient-specific basis according to predetermined eligibility criteria. Patients and providers must complete a one page application form prior to purchase to be considered for assistance. Retroactive assistance is not available.
- Assistance may also be available for qualified patients who require removal of Mirena.

Who Might Qualify?

The patient must meet all of the following eligibility requirements:

- ✓ Patient does not have access to insurance coverage for Mirena®.
- ✓ Patient meets the Foundation's financial eligibility criteria for assistance. Financial criteria are based on the Federal Poverty Level (FPL) and, therefore, financial eligibility varies with household size and will be determined on a case-by-case basis by the case coordinator.
- ✓ Patient is a U.S. resident under outpatient treatment by a qualified, U.S.-licensed healthcare provider.

How to Apply: English & Spanish applications: <u>http://www.archfoundation.com/application.htm</u>

Information for Health Providers & Clinics

- The healthcare provider and the patient must complete the application form.
- Healthcare providers and patients may contact the ARCH Foundation at 1-877-393-9071 to obtain an application and/or discuss whether a specific patient is likely to be eligible for assistance.
- Patient case coordinators are available to assist you and your patients with questions regarding the application and the application process.
- Review of the application will be completed in approximately two business days from receipt of a complete application.
- You and your patient will be notified in writing regarding the review of your patient's application for assistance. If assistance is approved, we will send the product to your office (as designated on the application).
- If your patient does not have insurance coverage for the insertion of Mirena we encourage you to provide free insertion of the donated Mirena unit.
- Similarly, in the spirit of assisting your low income, uninsured patients, we encourage you to accommodate an uncomplicated removal at no charge to the patient.

Because of the current demand for the units available through the ARCH Foundation, the Foundation must limit the number of Mirena units provided to 60 units per year. Once this limit has been reached, the Foundation will inform you that your annual allocation has been reached.



REFERENCES



References: Long-Acting Reversible Contraceptives

Selected Bibliography:

American College of Obstetricians & Gynecologists (ACOG). Adolescents and long-acting reversible contraception: implants and intrauterine devices. *Committee Opinion*; 2012; 539.

Centers for Disease Control and Prevention (CDC). U.S. selected practice recommendations for contraceptive use, 2013. MMWR; Morb Mortal Wkly Rep. 62: 25.

Hillard, P, et al. *Journal of Adolescent Health.* 2013; 52:4S. Entire supplement dedicated to adolescents and LARCs.

<u>McNicholas C</u>, <u>Peipert JF</u>. Long-acting reversible contraception for adolescents. <u>*Curr Opin Obstet Gynecol.*</u> 2012 Oct;24(5):293-8.

Secura GM, Allsworth JE, Madden T, Mullersman JL, Peipert JF. The Contraceptive CHOICE Project: reducing barriers to long-acting reversible contraception. *Am J Obstet Gynecol.* 2010 Aug;203(2):115.e1-7.

Whiteman MK, Tyler CP, Folger SG, Gaffield ME, Curtis KM. When can a woman have an intrauterine device inserted? A systematic review. *Contraception*. 2013; 87(5):666-73.

Winner, B, et al. Effectiveness of long-acting reversible contraceptives. *NEJM*. 2012; 366: 1998- 2007. Yen, S, et al. IUDs and Adolescents—An under-utilized opportunity for pregnancy prevention. *J Ped Adol Gyn* (2010) 23:123e128

Government & Community-Based Resources:

The Contraceptive Choice Project: <u>http://www.choiceproject.wustl.edu/#CHOICE</u>

Family Planning Resources, Washington State Department of Health:

http://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/HealthcareProfessionsandFacilities/PatientCareResources/FamilyPlanningResources.aspx

Guttmacher Institute: http://www.guttmacher.org/sections/contraception.php

National Adolescent Health Information Center: <u>http://nahic.ucsf.edu/</u>

The National Campaign to Prevent Teen & Unplanned Pregnancy: www.thenationalcampaign.org/; www.stayteen.org; www.bedsider.org; www.stayteen.org; www.bedsider.org; http://www.bedsider.org

Office of Adolescent Health- Reproductive Health, US Department of Health & Human Services: <u>http://www.hhs.gov/ash/oah/adolescent-health-topics/reproductive-health/index.html</u>

Public Health- Seattle & King County, Family Planning Program: http://www.kingcounty.gov/healthservices/health/personal/famplan/providers.aspx

Reproductive Health Access Project: <u>http://www.reproductiveaccess.org/</u>

Safe & Effective- California Family Health Council: http://www.safeandeffective.org/

LARC Products:

- Mirena: <u>http://hcp.mirena-us.com/index.php</u>
- Nexplanon: <u>http://www.nexplanon-usa.com/en/hcp/index.asp</u>
- ParaGard: <u>http://hcp.paragard.com/</u>
- Skyla: <u>http://hcp.skyla-us.com/index.php</u>