IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA ATLANTA DIVISION

)	This Document Relates to All Cases
)	(1:20-md-02974-LMM)
LITIGATION)	
IN RE: PARAGARD IUD PRODUCTS LIABILITY)	MDL DOCKET NO. 2974

SEVENTH AMENDED NOTICE OF VIDEOTAPED FED. R. CIV. P. 30(b)(6) DEPOSITION OF THE CORPORATE REPRESENTATIVE FOR THE COOPER DEFENDANTS (CONCERNING 2019 AND 2024 PARAGARD LABEL CHANGES)

PLEASE TAKE NOTICE that pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs, by and through the Plaintiffs' Leadership Committee, will take the deposition upon oral examination of the Cooper Defendants with respect to the topics set forth below. The deposition will take place at 10 AM EST on September 23, 2025 at Harris Beach Murtha, One Century Tower, 265 Church Street, 9th floor, New Haven, CT 06510 and at 10AM EST on November 11, 2025 at Greenberg Traurig, LLP, 1717 Arch St #400, Philadelphia, PA 19103 before a notary public or other person authorized by law to administer oaths and take depositions, or at a mutually available time negotiated by the parties. The deposition will be recorded stenographically and by video recording. Plaintiffs reserve the right to use at the trial of this action the videotape recording of the deposition of the deponent pursuant to Fed. R. Civ. P. 32(a). Plaintiffs reserve the right to seek relief from the

Case 1:20-md-02974-LMM Document 1151 Filed 10/25/25 Page 2 of 39 court in the event Defendants do not properly prepare the designated person(s) to testify on behalf of Defendants with respect to each of the identified topics.

Defendants are hereby requested and required under the federal rules to designate and produce at the deposition one or more officers, directors, managing agents, or other persons who consent to testify on their behalf on the following matters and documents:

DEFINITIONS

The term "2019 Paragard Label Changes" specifically refers to the label sections which are highlighted on **Exhibit A** to this deposition notice.

The term "2024 Paragard Label Changes" specifically refers to the label sections which are highlighted on **Exhibit B** to this deposition notice.

SCHEDULE A: DEPOSITION SUBJECT MATTERS

- 1. The **substance** of the 2019 Paragard Label Changes and 2024 Label Changes, including the rationale for each of the changes made. To the extent any label changes are being considered at the present, this notice also covers the substance and rationale for those changes.
- 2. All formal regulatory submissions and FDA communications concerning the 2019 Paragard Label Changes and 2024 Label Changes.
- 3. **All information** considered by you concerning the 2019 Paragard Label Changes. This includes, but is not limited to, any analyses, reports, clinical data, post-market surveillance, adverse event reports, customer / physician feedback,

marketing and/or sales considerations and/or studies reviewed, considered and/or relied upon as part of the decision making process for the label changes.

- Third-party involvement in the 2019 Paragard Label Changes and 4. 2024 Label Changes. This includes external consultants, vendors, advisory boards, and industry groups.
- 5. The extent to which you considered any **competitor IUD labels** as part of or factored into the 2019 Paragard Label Changes and/or the 2024 Label Changes and the rationale for doing so.
- How the 2019 and 2024 Paragard Label Changes were incorporated into 6. Paragard packaging and marketing / sales materials, including any training and/or communications provided to physicians, the public, sales representatives, and marketing employees or third parties as a result of the 2019 and 2024 Label Changes. This specifically includes the substance of what was approved to be communicated to physicians, the public, sales representatives, and marketing employees or third parties assisting in the communications about the 2019 and 2024 label changes and who approved the substance of those communications.
- Any post label change monitoring or surveillance conducted by you 7. or on your behalf for the 2019 Paragard Label Changes and 2024 Label Changes. This includes any studies and/or reviews specifically assessing the impact of the new label change language. This does not include Paragard's routine pharmacovigilance and quality assurance activities.

SCHEDULE B: DOCUMENTS TO BE PRODUCED

- 1. All documents which the deponent has utilized or may need to refresh his or her recollection as to any of the subject matters referenced in **Schedule A**.
- 2. All documents the deponent consults or relies upon in preparation for the deposition.
- 3. All documents the deponent creates (or are created on his/her behalf) to address any of the subject matters referenced in **Schedule A.**
- 4. The most current CV and/or resume for each of the person(s) being deposed pursuant to this notice.

Dated: October 25, 2025

s/Erin Copeland

Erin Copeland TX Bar No. 24028157

FIBICH LEEBRON COPELAND & BRIGGS

1150 Bissonnet Street Houston, TX 77005 Tel: (713) 751-0025

Fax: (713) 751-0030

Email: ecopeland@fibichlaw.com

MDL Lead Counsel

CERTIFICATE OF SERVICE

I hereby certify that on November 11, 2025 Plaintiffs' Seventh Amended Notice of FRCP 30(b)(6) Deposition Concerning the 2019 and 2024 Label Changes and Request for Production of Documents was served electronically on Defendants via their lead and liaison counsel.

Dated: October 25, 2025 <u>s/Erin Copeland</u>

Erin Copeland TX Bar No. 24028157 FIBICH LEEBRON COPELAND & BRIGGS

1150 Bissonnet Street Houston, TX 77005 Tel: (713) 751-0025

Fax: (713) 751-0025

Email: ecopeland@fibichlaw.com

MDL Lead Counsel

Filed 19/26/25 William's disease (4) or (105 hair has not been removed (4)

A previously placed (10 or (105 hair has not been removed (4)

Hypersensity to any component of Paragard including copper or any trace
elements present in the copper components of Paragard (4)

-WARNINGS AND PRECAUTIONS-

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prepanely occurs. Herrow Paragint II preplanely occurs with Paragint in place (6.2).

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Seeth: Group A streptococcal intestion (6.2)

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with spotting. (6.9)
<u>MRI Safety Information</u>: Patients using Paragard can be safely scanned with MRI only under certain conditions. (5.10)

AOVERSE REACTIONS

Adverse reactions reported in clinical totals include anemia, backache, dysmenurines, dysmenurines, dysmenurines, dysmenurines, dysmenurines, dysmenurines, dysmenurines, dysmenurines, dana and caranipula, and walquitte, Gran and caranipula, and walquitte, Gran and caranipula.

To report SUSPECTED ADVERSE REACTIONS, contact CooperSurgical, Inc. at 1-877-727-2427 or FOA at 1-800-FDA-1088 or www.fda.gov/madwafch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient

intrauterine copper contraceptive

HIGHLIGHTS OF PRESCRIBING INFORMATION To say highlights do not include an the information occurs to a state years affectively. See full powers in a plantion with a PAP Paragard (intrauterina copper contrace ptive) into 1/2, Approvat 1984

--- INDICATIONS AND USAGE ingard is a copper-containing intrauterine system (IUS) indicated for prevention pregnancy in females of reproductive potential for up to 10 years. (1)

- DOSAGE AND ADMINISTRATION-

- DUSAGE AND ADMINISTRATION.

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-- CONTRAINDICATIONS-----

INDICATIONS AND USAGE DOSAGE AND ADMINISTRATION

- Pregnancy or suspiction of pregnancy (4) Accommittee of the uterus resulting in distortion of the uterine cavity (4) Acute parks: Inflammatory disease (PID) (4) Postpartum endometritis or possizionid endometritis in past 3 moniths (4) Known or suspected uterine or cervical madignancy (4)

FULL PRESCRIBING INFORMATION: CONTENTS*

DOSAGE AND ADMINISTRATION
2.1 Important Lossage and Astronomytics
2.2 Things of insertion
2.2 Things on instructions
2.4 Inspired instructions
2.4 Insertion Proceeding
2.5 Polystynomia Management of Peragato
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Sepsis
Pelvic Inflammatory Disease and Endometritis

- ADVERSE REACTIONS
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 DRUG INTERACTIONS
 USE IN SPECIFIC POPULATIONS
 8.1 Pregnancy
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- 13

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FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE enumerations and visage
 Paragard is indicated for prevention of pregnancy in females of reproductive potential for up to 10 years.

Expusion Wilson's Disease Bleeding Patiern Atlerations Magnetic Resonance Imaging (MRI) Safety Information Medical Diathermy

Debugge And An Amiliastration

1 important bossigs and Administration instructions

Paragard should only be insufed by a hasticary provider trained in

Paragard insoft on recordure, because lineation for Paragard is
difficient from that used for other hardwise systems. Heatingst

providers stoud become throughly handlar with the norticul, cround solucitional instifates, product insertion institutions, and prescribing internation institutions, and prescribing internation institutions, and prescribing international product and the finduct of the uteritic could pose and

Administration (2-of the before 10 years from the date of insertion (see

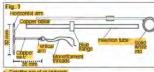
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Design and Antibitation (2.6). May repose Paraginal at the time of retrocoal with a new Paraginal at the time of retrocoal with a new Paraginal at the time of retrocoal with a new Paraginal at the time of retrocoal with a new Paraginal at the time of the second second

C	linical Situation	Recommended Timing of Paragard Insertion
1.	Start Paragard in females not currently using contraception	At any time during the menstrual cycle.
2.	Switch to Paragard from an oral, transdermal, or vaginal form of hormonal contraception or an injectable progestin contraceptive	At any time during the menstrual cycle; discontinue the previous method.
3.	Switch to Paragard from a contracaptive implant or other intrauterine system	Same day the implant or IUS is removed (insert at any time during the mensitual cycle).
4.	Insert Paragard after abordon or miscarriage	Immediately after abortion, atthough immediate placement has a slightly higher risk of expulsion than placement at other times, insertion after second trimester abortion is associated with a higher risk of expulsion than insertion after a first trimester abortion.
5.	insert Paragard after Childbirth	May Insert Immediately postparlum. Insertion before uterine involution is complete, which may not occur until the second postparlum month, has been associated with Increased risk of expulsion (see Warnings and Precautions (5.6,5.7).
		There appears to be an increased risk of perforation in lactating women (see Warnings and Precautions (6.6)).

Use strict aceptic leciniques throughout preparation (see Warnings and Precentions (5.4).

Prepare plasmert tools (e.g., speculum, corton swad, tenedum, uterine



- on of the uterus by performing a bi-manual
- examination.
 Insert a speculum and, using a cotton sweb, cleanse the cervix and vagina
 with an antiseptic solution.

with an antibegite solution. Apply a timesolution to the certix and use gentle traction to align the convical cane with the uterine cardy. Settly server a sector stories occurred to measure the digith of the other cardy. The uterius should accord to a depth of 8 to 9 cm secopt when the other cardy.

- 8.5 GEFUTE US
 DESCRIPTION
 CLINICAL PHARMACOLOGY
 12.1 Mechanism of Action
 NONCLINICAL TOUCOLOGY
 12.1 Carchogenidly, Mutayanichy, Imparm
 CLINICAL STUDIES
 HOW SUPPLIENTS ORAGE AND HANDLING
 PATIENT COURSELING INFORMATION

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Floure 3: Bending T-Arms of Paragard White in Sterile Packaging

Fig. 3

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Figure 2: Inserting Tipe of T-Arms of Paragard Into Insertion Tribe

Timing of Insertion r to Table 1 for recommended timing of Paragard Insertion.

Clinical Situation	Recommended Timing of Paragard Insertion
Start Paragard in females currently using contracep	
 Switch to Paragard from an oral, transdermal, or vaginal form of hormonal contraception or an inject progestin contraceptive 	At any time during the menstrual cycle; discontinue the previous method.
 Switch to Paragard from a contraceptive implant or o intrauterine system 	Same day the implant or IUS is removed ther (insert at any time during the mensional cycle).
Insert Paragani after abor or miscarriage	Immediately after abortion, although, immediate placement has a slightly higher risk of expulsion than placement at other times, insertion after second trinsater abortion is associated with a higher risk of expulsion than insertion after a first trinsater abortion.
5. Insert Paragard after Childbirth	May Insert Immediately postpartum. Insertion before uterine Involution is complete, which may not occur until the second postpartum month; has been associated with Increased risk of expulsion (See Warnings and Precaudions (6.6.5.7).
	There appears to be an increased risk of perforation in tactating women (see Warnings and Precautions (5.6)).

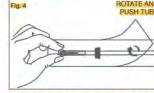


Figure 4: inserting Tips of T-Areis of Paragard into in

• Etiny the fluorib and index thigh closer logither on the <u>colosis</u> of the pixings to continue bending the arms until they are alongate the stem. Use the uniter hand to windraws the insuristic house stiplity so that the insertion take can be pushed and nobel over the tips of the T-Arms (see Figure 4.) Unit with 195 of the T-Arms should be in this insertion take. On our assures beginn the top the 195 of the T-Arms should be in this insertion take. On our assures beginn the purple collists, itsert sets with roll into bottom of the insertion take. On our assets the bottom of the 1950 on on taken to the 1950 on taken to take the 1950 on taken the 1950 o

Once the above steps are competed and Perugard is in the insertion true, grasp the insertion tubulat the open and of the pastages, adjust the blue hange so that the obtains from the bod of the Paragard insertion but is the same as the uterior digith measured with the vietne sound or use the startle

28(s) of the principle of the property of the principle o



Floure 6: Release T-Arms of Paragard in Clarus



Gently and carefully move the insertion tube opward stowerd the finite luterias, until signir realstance is left. This will ensure placers Paragard at the highest position within the dates (see Fig. Op not use the white rod as a planger to push or insert Paragam.

Figure 7; Placement of Paragard in Fundus of Literus



Hold the Insertion tube steady and withdraw the solid white rod (see Agure 8). Do not remove the solid white rod and the insertion tube at this same time to prevent accidental pulling of the threads.

Figure 8: Wilhdraw Solld White Red from Ulerus





If you suspect that Paragard is not in the cornect position, check place (with ultrasound, if necessary). If Paragard is not positioned comp within the uterus, remove it and replace it with a new Paragard. Do elesser an expelled or partially expelled Paragard.

See Perhipsional Management of Peringaria
Filizating Disconnist:

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in place. You should be sub-to visuals at met cirty the thinact. The length
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this victor from earth ray change with time However, or action to meeting
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the uticus. This threads can intract into the uterius or threak, or Paragaria
and notice, performed the uterius, or or expelled. Themse porting or the
carty, x-ray, or exonography may be required to locate Paragaria.

Jacob Remove Paragaria of this accommission exception or performed the uterius
Jacob Remove Paragaria of the Association expenses.

Timing of Renoval

Paragrad can be removed at any time prior to 10 years after insertit

Remove Paragrad no tater than 10 years after insertion. A new Paragrad no tater than 10 years after insertion. A new Paragrad no tater than 10 years after insertion. A new Paragrad no tater than 10 years after insertion. A new Paragrad no tater than 10 years after insertion.

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Homoval Instructions.

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The arms of Prasignard with thropise, putting gamily on the exposed threads.
The arms of Prasignard with thropise, putting and the mycomethic can make removine
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or hydrotroccopy may assist to removing an embeddied Paragrant.

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3 OUBAGE FORMS AND STREMGTHS
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storm werhally, wan a phonymathly 12 mig of copiet with swapped around
each late, of the hortest aim, with a single conjugate stress that the confidence of the confidence

4 CONTRAINDICATIONS
The use of Paragard is contraindicated when one or more of the following conditions exist:

Interest of Pasagers is both antibode with one of mile of the orbital management of suspicion of pregnancy [See Wannings and Precaudiors (5.1.5.2) and USe in Specific Papulations (4.11).

Abnormalities of the utreus resulting in distribution of the elastine castly acting the mile of the orbital services of the orbita

Adverse Read Lons (8.2) and Description (11)

5.1 Entire Language and Executions 5.5.1 Entire Language Longuage Longuage

S. 2. Riska with indiruslarius Prognancy.

If Intrastitatine prognancy cours with Paragard in piace and the strings are visible or can be entired to mit or certifications, remove Paragant locuses leaving fit in piace may horses the disc of spontaneous shortton and preherm stonce. Removal of Paragard rary sale or seruit is spontaneous shortton, in the sevent of an intrastierbe prognancy with Paragad, consists the Kollowing.

event or an intrauerier prepinacy with religion, consiste the exceeding. Sectic Abortion. In fernales becoming prepinant with an intrauterine system (IUS), including Pergard in place, septic abortion, with septicomia, septis shock, and death, may cooper (see Warnings and Precautions (5-3)). Septic abortion hybrially requires hospitation and retermine with intervenous antithotics. Septic abortion may result in sportureous abortion or a medical indication for programacy termination. A hybristerolomy may be required if severa-intection of the uterus occurs, which with result in permanent infettility.

The trends occurs, which will result in permanent intentity.

Confituration of Preparancy.

If a himsel becomes preparant with Paragand in place and If Paragand cannot be removed or the simal chooses not to have it removed, wern her that failties for removed or the simal chooses not to have it removed, wern her that for any other permanent in the removed of the simal chooses of the things, separation leaker, and remainter delethy. Persided case should include consenting about their clicks and that the should report immediately any for-like pyroptoms, lever, chills, coraming, path, bettering, variend deletage or feedings of the preparation that suggests complications of the preparation.

S.A. Septial Severe infection or septials, including Group A Strepticoccal Septial (SAS), have been reported inflowing intertion of IUSs, including Paragard. In some cases, severe pain occurred within hours of insertion intoleved by steptial within days. Escapat death from IAS is more littly intreament is designed, it is important to be swere of these rare but serious infections. Assignification for the product of the product of the product of the product in the control of the product of the product is serious infections. Assignification of the product is secretal to indeed to make the product of the product in the control of the product is secretal to indeed to make the product in the control of the product in the control of the product is secretal to the product in the control of the product in the control of the product in the prod

serious intrickins such as GAS [see Designe and Administration (2.3)].

5.4. Peints intriumating filteres are discensively: Insertion of Paragrad is mutatind coloid in the presence of known, or coupled Falls. Internating 10 Dissess (PTI) or condensities (See Contention. 260 see (See Contention. 260 see Co

PID can have serious consequences, such as tubal damage (leading to ectopic pregnancy or infertility), hysterectomy, sepsis, and death.

scropic reginancy or intercupy, nysaeriscomy, septis, and earth Females all Increased Blask for PDI.
PIO or monitoritis are often associated with a sexually transmitted interchain (617) and Paragrad does not provint against 51%. The risk of PIO or endometritis is greater for ternales who have multiple sexual partners, and also for lamables whose sexual partners, for multiple sexual partners, and also for lamables whose sexual partners, for multiple sexual partners, partners, Fernales who have had PIO or endometritis is an all normales of risk for a recurrence for it-efficient, in a particular, ascertish whether a leminal is all increased and or frame for multiple sexual partners, partners, partners, and the province of the partners of the partners

Asymptomatic PID
PID or endometritis may be asymptomatic but still result in tubal damage and its sequelar.

and its organization. Their immunity of TILO of Endometrick in Patheria Using Peraganal Remove Paragaral in cases of recurrent endometritis or PILO or If an acute spekth intection is severe or close not respond to Interdment. Prophylazdic artibiotics administered at the time of Insertion do not appear to lower the incidence of PILO.

Indistance of PID. Percept seasons and treat any hernale who develops signs or symptoms of PID. Perform appropriate testing for sexually transmitted inhiction and intellete attribute of PID. Perform appropriately larguard does not made to be removed immediately. Pleastess the patient in 48-72 fours. If no citizal improvement course, continue authoritics and consider removal of Paragrad. If the destallment of the process of the patient in 48-72 fours in entower the contract of the potential set of the patient in the patient in

nex to Learnin speed in Sealing from the Interest procedure. Actinomycosts has been associated with IDS use, including Panagant, Actinomycosts has been associated with IDS use, including Panagant segretary which women with Interest actions proceed in the found in the gential tract cubuses in health women without IDS. The applications of adiannyses-the organizate on a Paparaticious (IPAP) smaler in an asymptomatic IDS user is unknown, and the finding done does not always require IDS removal and treatment. When possible, confirm a PAP smear diagnosts with cultures.

5.5 Embedment

Appendix and appendix and a service of the service (EARS III) with IUSs, Installing copper IUSs, and an appendix and a service (EARS III) with IUSs, Installing women. The risk of periodizion may be increased if in IUS, such as Paragard, is inserted when the uterus is tood, etcoverted or not completely involved during the postpartum periodizion in IUS, such as if a stronglish control in IUSs and in IUSs and in IUSs and if a stronglish control and in IUSs and in IUSs and in IUSs and the island. Flore orable has in Individual to its orable of its promotion officer required to remove Paragard from the personal careful.

5.7 Expulsion Partial or complete expulsion of Paragard has been reported, resulting in the loss of contraspetive protection. The incidence of expulsion in the clinical trials with Paragard was approximately 2.9%. Consider further diagnostic triagging, such as x-4xy, to confirm expulsion fille US is not round in the direct. Paragard has been placed immediately after delivery, atthough the tisk of expulsion may be increased when the uterus is not completely involuted at the time of insertion. Remove a partially expelled Paragard.

5.8 William's Diseases Parayard may secontrate Wilson's disease, a rare genetic disease affecting copper exercisin; therefore, the use of Parayard is contraindicated in females of reproductive potential with Wilson's disease (see Contraindications (4)).

5.9 Bleeding Pattern Attarations
Paragard can after the bleeding pattern and result in heavier and longer menstrual cycles with intermenstrual spotting.

in two circular bits with Paragraft Paragraft

In the state of th

Under the scan confilling defined above, Paraguist is expected to produce a maximum himperature rise of less than 0.5° C after 15 minutes of continuous scanning. In pre-circular scanning, in ron-circular scanning, in ron-circular scanning, in ron-circular scanning, and the scanning artifact coused by the system extended tiess than 5 mm from the implant when imaged with a gradient echo pulse sequence and a 2.0° TMR1 system.

5.11 Medical Distinency
Medical equipment the mini-specime.
Medical equipment the mini-specime specimens of RadioPropusicy (RF) energy
such as distinently may cause health effects (by healing Issue) in females
with a metal-containing (IDI including Pergand. Aucid using high medical RF
transmitter deviates in females with Paragraf.

- sonitar devices in ferrales with Paragard.

 APPERSE REACTIONS

 Solving before scholars methods are discussed elsewine in the labeling:

 Escilar periodic scholars methods are discussed elsewine in the labeling:

 Escilar periodic scholars per Veranings and Prescussions (6.21)

 Finds authoring self-Veranings and Prescussions (6.21)

 Field in the scholars per Veranings and Prescussions (6.23)

 Prescussions 3.4

 Prescussions 3.4

 Prescussions 5.4

 Periodic field Prescussions (6.21)

 Entirely and Prescussions (6.21)

 Elevision field Mannings and Prescussions (6.21)

- Bleeding Pattern Alteraktens, Jose Warnings and Pressutions (6.9) 6.1. Chimical Thirds Earni Head Services and Control of the Services and May not reflect the crise observed in clinical greated.
 The drift of Services of the Services in the Clinical trials of another drug and may not reflect the crise observed in clinical greated.
 The UHO Services 1991 was a randomized, midrotiner, multiprolional shely of copper T LUSE, including Paragraf in 1,356 women outside the US. In the VHO State, UPOS were parsure and the mean use at amortiment was 29 years odd.
 and the Services of the Services of the Services of Composities Study, 64% when Pallabraces, 45% were multipraced, 65% wer

Table 2 shows discombination rates from the two clinical studies by adverse reaction and year.

Table 2: Summary of Raies* (No. per 100 Subjects) by Year for Adverse Reactions Causing Discontinuation

	1	Year										
	4	- 7	-8	4	5	6	7	1	9	16		
Number of Women at Stari of Year	4,932	3,149	2,518	1,121	672	621	563	403	423	325		
Expulsion	5.7	25	1.6	12	0.3	0.0	0.6	1.7	0.2	0.4		
Bleeding/Pain	11.9	9.8	7.0	3.5	3.7	27	3.0	2.5	22	3.7		
Other Medical Eveni	25	21	1.8	17	0.1	0,3	1.0	0,4	0.7	0.3		

"Rates were calculated by weighting the annual rates by the number of subjects starting each year for each of the US Composite Study (3598 subjects) and the World Health Organization (1996 subjects) trials.

sudjects) and the winter reactions have also been observed; anierda, backache, dysmenorimea, dyspareunia, complete or partial expulsion, prolonged menstrual flow, menstrual spotting, pain and cramping, and vaginitis.

6.2 Pastimizating Experience The following adverse restitions have been Menthland during ocsi-approva out on Paragram. Because these residence are reported voluntarily from a sopulation of uncertain days. It is not always possible to Intably, estimate that frequency or establish a case of arbitronite to very accessive.

Cestroinies hal Disorders: abdominal distantion, nausea General Disorders and Administration Site Conditions: d

immune System Disorders: allergy to metals, hypersensitivity

intections and intestations: enfometritis/ulerine triaction Musculosteidal and Connective Tissue Oborders: muscle spasms Nervous System Oborders: tilzdress

Reproductive Bystem and Breast Disorders: amenorthea Sitin and Subculaneous Tissue Disorders: Stevens-Johnson syndrome

DRUG INTERACTIONS No drug-drug Interaction or drug-terbal supplement interaction studies have been conducted with Paragard.

B USE IN SPECIFIC POPULATIONS B.1 Pregnancy

a.1 Pregnancy Use of Paragraf is contraindicated for use in pregnant females because there is no need for pregnancy prevention in a ternals who is already pregnant and Paragraf may cause adverse pregnancy outcomes. If a female becomes pregnant with Paragrad in place, bethe as an increased risk of miscarriage, septis, prendure ident, and preventine delivery (see Contrandications 4) and Weradings and Percaudions (5.1 > 5.9) Author the lemale of the potential risks it pregnancy occurs with Paragraf in place.

Dublished studies on pregnancy outcomes exposed to copper IUSs report up to 27% interacting when the IUS was removed compared to 77% interacting when the IUS was removed compared to 77% interacting when the IUS remained in the uterus, Studies on Paregant and hitth defects have not been conducted.

8.2 Lacistion

9.2 Licetation IMEX Summan. We also defected in concentration of copper in human milk No difference has been defected in concentration of copper in human milk before and after treatment of copper in a breastled child or the effect on milk or ordication. The diversignment and milet the entire of the effect on milk the considered along with the miletih benefits of executionally along ordicated activative effects on the breastled child from the production.

8.4 Padishtic Litra. This productive potential. Chicary is expected to be the same for postremanched females of space (space) and chicary is expected to be the same for postremanched females (space) as of space.
Paragrad to not indicated in lemales before menerche.

8.6 Geriatric tise Paragard has not been studied in women over 65 years of age and is not indicated in this population.

11 DESCRIPTION

Paragura (Introductive occepts continosition) is a T-slaged Prevalence yielden (ILLS), messuring Ezem mortamital yand 28 mm-verterality, Wind 2 and mortamistr bub at the flo of the vertical stem, (See Equit's 1) (see Dosage and Administration (223) Ammonolithmat opports, min hand all size through the ILL, resulting in view white treads, each at least 10.5 cm is inspirit. Such in deciden and removal of this introductive paytem. The claims is made of polyathysis with beating suitable in 2d in deciding the introductions system white x-eq. P. again and accomplishing course paragraphisms of Trains in Mindou payathysis with beating suitable in 2d in deciding the introductions system where x-eq. P. again and accomplishing course paragraphisms of Trains in Mindou area to 300 and the services after an and amportant payathysis of the con-straints and the services of the services of the services of the services area to 300 and 22 mm². One Paragraph weight loss than one (i) years. Paragraph and its 200 and 22 mm². One Paragraph weight loss than one (i) years. Paragraph size that the services are also accomplished to the paragraph of the p

Paragard is pockaged together with an insertion table and sorts white rod in a Tyses" judylethylese pouch that is their technitized. A mowerise see frame on the insertion because it is the statistical of resemble see frame consisted careal and into the other is both (See Figure 1), pare Datage and domistical and 120 ft;

12. CLINICAL PHARMACOLOGY
12.1 Mathematical of Action
Cooper continuously insigned into the utarine cavity contributes to the
contravestive effectiveness of Paragord. Mechanisms by which cooper
antizaness contravestive effects (include historiesms with grown transport
and fortilization of an egg, and possibly prevention of implantation.

18 NONCLINICAL TOXICOLOGY
13.1 Cardinoomistly, Multiperistly, Impairment of Farthly
Advancts Ingrammanties in annivers to assess the cardinopenic potential or
a cooper-containing IUS mark not been performed.

The genotoxic potential of a copper-containing IUS has not been evalua

randomized, double-blind, comparative studies of copper T IUSs including Paragard in 2,536 women in the US. In the US study, 64% were nulliparous, 49% were nulligravids; 88% were under age 25 at the time of enrollment (median age 23 years old).

The pregnancy rate in the two clinical studies with Paragard was less than t pregnancy per 100 women each year (see Table 3).

Table 3: Pregnancy Rates" (Number of Pregnancies per 100 Women) by Year in the WillO and U.S. Studies

		Vear										
	1	2	8	4	5	6	7	8	9	10		
Pregnancy	0.7	0.3	0.6	0.2	0.3	0.2	0.0	0.4	0.0	0.0		
Number of Women at Start of Year	4,932	3,149	2,010	1,121	872	821	663	483	428	325		

"Rates were calculated by weighting the annual rates by the number of subjects starting each year for each of the US Composite Study (3536 subjects) and the World Health Organization (1396 subjects) triefs.

16 HOW SUPPLIED/STORAGE AND HANDLING

metrie undi (ALD Sabals-Si 28-1).

ESCH Peragent is wirts, Prabaved, and intessures 32 mm inordization of the anniversal control of the second of the second

17 PATIENT COUNSELING INFORMATION Advise the patient to read the FDA-approved patient labeling (Patient Information). Before Inserting Paragard, counsel patients on the following:

Sexually Transmitted Irriections: Advise petients that Paragant does not protect against HIV infection and other sexually transmitted diseases.

spread against in Virgonia and omer security retrinition diseases. Ecode Preparatory Anties positives to proof pregnancia and the evaluated immediately, as a pregnancy with Paragard in piece is more likely to be an ecolory pregnancy, and the fitse of ecoder pregnancy linealist interests of facility (see Warrings and Pesculdura (2.7.)). Interesting the Personalist (2.7.), and the proof of th Intravenois articloics. Septic abordion may result in spontaneous abordion or a market in indication for regrancy terrindion. A hybridendory may be required it severa linkshop of the status occurs, which will result in permanent infertile. It is required in the several network of miscratings, septis, premition labor and permature deliberal. Afters patients that a pregnancy must be followed closely and advise patients to report invavidately any symptom, such as or taking in fluid, or any other appropriate along the completations of the pregnancy (see Warmings and Precentions (5.5)). Spain deliberal or the pregnancy (see Warmings and Precentions (5.5). Spain Advise patients that supplies my occur after intention of Paragraph and to seek immediate brediment for frever and parkly capit histocratic solution (5.5). Summarised in the present of the properties of the prop

dill'i torrich, de unicate abspire si de l'accident de l'a

is interpret or expelled. These invarious and Presidents (5.5. 5.6. 5.7).

Residing, Pattine Allerations, Advise contents that heavier in relayer periods and spotting between periods may occut, instruct, patients to report continued or severe symptoms to their healthcare provider few Marriage and Presidents or Section 1. The patients of the Marriage and Presidents of the Section 1. The patients of the Marriage and Presidents of the Marriage and Presidents of the Marriage and Presidents of the Marriage of the Marriage and Marriage in the United Section 1. The Marriage is all in the Interest, which seculd deplete Presidents of the Marriage and Marriage in the Marriage and Marriage in the Interest of the Marriage and Marriage in the Interest of the Marriage and Marriage in the Interest of the t

any user parcor e angano sessés the threads.

Magnetic Resocurace Irusalon (IMBI) Sathéy Information: inform patients that Paragard can be satily seasons with MRI only under specific conflicter. Institute patients who will have an MRI to let their healthcare provider that they have Paragard per Merrolary and Presendors (5.1 Poly Medical Extilience) institute patients to tell their healthcare provider that they have Paragard prior to undergoing medical distituting [see Wennings and Presundors (5.11)].

Other Important Inf

rise patients to contact their healthcare provider if any of the following

- cur: Pelvic pain or pain during sax: Linusual vaginal discharge or gential sores Possible exposure to STIs HIV positive seroconversion in herself or he
- Possible exposure to 371s
 HIV positive serconnectation in herself or her partner
 Severe or prolonged vaginal bleeding
 Missad period
 hisse patients that they may use tampons or pads while wearing

@operSurgical

PRITEMENT INCOMESTION Pamgarc* ('per-uh-gahrd) (intrasturine copper contraceptive)

Paregard^a dees not protect against HIV injection (AIOS) or other year

Paraguer² does not protect applied thy inhiction (AOS) or other recursion transmitted intellection (STIs). Read this Patient you decide it Paraguer is Read this Patient Inhirmation carefully before you decide it Paraguer is right to you. This himmation clear out take the place of taking with your pyricologist or other hashlocar protection sho packetines in woman's health. If you have any questions double Paraguer, also, your healthcare provider from should also seem about other bits control methods to choose the cell table to be the fire you.

that is Paragard?

hat is Peragerd? Peragerd Is a cooper-remaing system that is praced in your uthrus your heathcure provider to prevent programmy for up to 10 yours. Paragerd can be removed by your heathcare provider at any time. Paragerd does my boostale any homorioses. Paragerd for the used whether or not you have given remit to a chile.

For agrical to a mind, feechie plazillo TT bitmped infrantierkon opsium with occupie with minds of amount the series and options on a mins of their. The first which timestes use timesteed to the dame (owner and) of peragrant. The timestes are the only perfort Feeragood you occur that when Feeragood is in your timestes, necessing unities a tampon admins, find tressed on the decord outside of your bodg.



What in your access where Paragon 27
Paragonal is Intended for use up to 10 years, but you can soco using
Paragonal as intended for use up to 10 years, but you can soco using
You could become pregnant as soon as Paragonal is removed; however, if
You could become pregnant as soon as Paragonal is removed; however, if
you do not weath to become pregnant up softout use and offer where of
birth control. Talk to your healthears provider about the best birth control
wholes for you.

What If I change my mind shout high comins and want to become pregnant in less than 10 years? Your haithnass provider can remove Paragant at any time before the 10 years after placement. You may become pregnant as soon as Paragant is

How does Paragard work?
Paragard works by preventing sperm from reaching the egg, preventing sperm from fertitiating the egg, or possibly preventing attachment (implication) in the uterus. Paragard does not stop your overtee from making an egg (ovulating) sech month.

then well does Paragned work for continuespillum?
The biolowing chart shows the channe of getting regners for women was used returned to the channe of getting regners for women was used returned maybe so fallow core. It seeks box on the chart contains as size of lettin control control on the chart contains as the control con

Paragard, an intrauterine system (IUS), is in the box at the top of the chart



- Who might use Paragand? You:

 You might choose Paragand? You:

 want food-param both control that provides a low chance of getting pregnant (see stitus) is in 100).

 want both control that were confirmed by up to 10 years a want of the control that were confirmed by up to 10 years a want of the control shall be reversible up to not need to take dely want a lattic control shall be offered by the control that deep want a lattic control shall be offered by the control that deep want a lattic control shall be only up to the shall be upon the shall be used to the union when the shall be upon the shall be

- want birth control that does not contain hormonies

 Doe not liese Paragrad if your:

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 * raive a condition of the laterus that changes the stape of the laterus

 * (P)

 * (P)

 * (P)

 * raive for all miniction is your iderus after a pregrancy or abortion in the
 peak of months

 * can get infections easily, For examply, Tyou:

 * have problems with your immune system

 * have multiple sexual painters or your partner has multiple sexual
 partners.

portons: - Hain or abbase - NEWWords drags - Hain or abbase - Hain which was annot not the ultitus or cervix - Hain or abbased your hight have cannot not the ultitus or cervix - Hain or unreplated flower general inflection nove in your cervix. - Hain or unreplated flower general inflection nove in your cervix. - Hain or will have in the substantial copper) - are allered to copper, polyterymen, or barrown substantial - Hain or are traditional experient in your directs sheady.

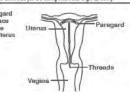
- fore having Paragard placed, fell your any of the conditions listed above slow heart beat (bradycardia) dizziness (syncope) salzures

- recently had a baby or it you are breastfeeding have AIDS, HIV, or any other sexually transmitted infection

How is Paragard placed? Paragard is placed in your sterus during an in-office visit.

Paragnatis placed in your sterms during an in-efficial volat.

First, your habilitary provider will searnine your pelvis to find the exact possibilities of your steams. Your habilitaries provider will stem facilities you require and error with an artisograp coulding and them, measure your usferus. Your healthcase provider will then stills a plastic from least order undersu. Your healthcase provider will then stills a plastic from granger and provider will then stills a plastic from granger and provider will be combarding your undersu. You within the east will extend into your seglers. The threader art intended so they any last long require a your seglers. The threader art intended so they any last long require a your seglers. The threader art intended so they are you for last your large with a your large facilities. I you may have soon the bedring Scrow soomen the lifetin, removed any or disty for a few markets selenvices for your hadriture provider, may ask you to like down until you are seeing bother, and to get up slowly.



Bould I check thet Paragard is in place?
Yes, you should check that Paragard is in proper position by felling the
threads. It is a good male to do into its time a month, Your resultance
provider should teach you have to check that Paragard is in place. First,
week your hards with soop and water. You can check by greating up to
the top of your vagine with clean ingers to fired the 2 threads. Do not you
mit threads.

You should be able to feel the short threads attached to Paragard with your finger.



If you set trangs in the length of the 2, timeds, you cannot set the imeals, or you can set any other part of langed other time to intensis. Caragaria may not be in the right possible are may not prevent programsy. Use bash-up birth control such as conforms an agermistely and sale year neatforce provides to check that Prangial is still in the right place. Faragard is accidentally removed, you may be at risk of pregna-

The properties of the properti

hat if I become pregnant while using Paragard?

Call your healthcare provider right away if you think you may be pregnant. If you get pregnant, while using Paragard, you may have an acticiple pregnancy. This means the pregnancy is not in your derus, thusual veginal steeding or abdominal tails especially with missed periods may be a sign of exhibit pergnancy.

vaginal shedding or abdominal pain especially with missed periods risay be a sign of exboric pregnancy. Ectocic pringrancy is a medical energiency that often requires surgey. Ectocic pringrancy on crease inferiend bleeding, intertitilly and even death. There are also risks if you git oregand write using Peragand and the pregnancy is in the utreus. Severe Restort, miscarriage, premature delivery, and even death can occur with pregnancies that continue with an intrautiente delevel, AUD, Because of this, your healthcare provider may for to remove Paragand, went Strught enemony, if may cause a miscarriage, if Paragand cannot be enemoned, task with your healthcare provider most the barrellins and risks of continuing the pregnancy.

If you contrave your pregnancy see your healthcare provider is not the control of the second of the control o

How will Paragand change my periods? Your period may become heavier and longer. You may also have #equant spotting between periods.

is it safe to breastfeed white using Perspard?
You may use Panagard when you are breastfeeling. The risk of Paragard becoming affects to remarked or going through the wall of the uterus is increased if Paragard is placed white you are breastfeeling.

Will Paragard Interiare with sexual Intercourse? You and your partner should not sel Panagard during Intercourse. Paragard to spiced in the vietus, not in the vigilina Screnitimes your portner may feel the threads. If this occurs, or if you or your partner experience pain during sax, talk with your healthcare provider.

Can I have an MRI with Paragard in place?
Paragard can be safely scarred with MRI only under specific conditions
Before you have an MRI, they our healthcare provider that you haw
Paragard, an intracterine device (NID), in place.

Belorn you have a medical procedure using heaf therapy tall your healthcare provider that you have Paragard in place. What are the possible after the Crangard?

armund can cause sedons side officia. Incindian

- urugari zan casas certous atias influcis, tracisolia; edeplej prepanea para flaminaterine prepanea; raisa: There are risks If you become prepanet with using Paragurd (see "Whet If I become prepanet withis using Paragurd"). Illie-dimentalishing attriclion: Lite-dimentaling interface or occur within the flat the days after Paragurd is placed. Call your healthcare provider liminatalishi if you sevelop sewer path or bover shortly after Paragurd is circled.
- Immediately If you bevolop severe pains or fiver shortly after Paragraf of petrick of, upshic inflammating demans (PID) or endometrials: Some LIUS users petrick interior calved petric inflammatory desause (PID) or endometrials are usually assually transmitted or endometrials are usually assually transmitted petrick to be set with other partners. PID and endometrials are usually assually transmitted partners has set with other partners. PID are endometrials are usually assually interest with other partners. PID are endometrials are usually treated with authorities, More serious cases of PID or endometrials may require any partnership assuals as freatibly, escolor bregamony, and petrick pain authorities. More serious cases of PID or endometrials may require any partnership assually any partnership assually provided with a start as PID can even cause death. In all your healthroad provider inglit severy your burseary of these signs of PID or endometrials be well-borrials (commeth analy or pelvic pain, parknership assually assu

the treath may supper with percentage and the tables. The risk of percentage of the supper whose confidence and other tables. The risk of perfort Ato 18 inchessed in threathering women, arguestiance Pranagard may partially or completely had could of the between by itself. This is called exposition Decreation occurs in about 2 out of 100 occurs. Purcessive plant, valgate before goting the processed of Paragard, point that perts worse, bleeding after placement, or not being able to held the threads may lapper with sequents. The value of percentage had been proper with sequents. The value of percentage in bleeding. You may have fleaster and longer periods, with sporting in between Boardstream to the beliefing in helder the manufacture provider if the bleeding into the result of the sporting of the period occurs of the period sporting occurs of the period occurs occurs. I not period occurs of the period occurs occurs of the period occurs occurs occurs of the period occurs occurs

- replante elepticity in women who rave has these continuous settler.

 Common data effective all Paragrant interest production (corrected or portion)

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Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

- Call your reathcare provider if you have any concerns about Paragard, Be sure to call if you:

- as your natural eventures you never up or international and a reason of the control of the contr

General information about the sate and effective use of Parugard.

Meliches are screenines prescribed for purposes other than those listed
in a Patient information leaff. You can ask your healthcare provider to
information about Paragard that is written for health profesolands. Paragard and its compon

Paragand^a is a registered trademark of CooperSurgical, Inc. The othe brands listed are trademarks of their respective owners. <u>CoperSurgical</u>

P.W. 1017008

For more information, call CooperSurgical, Inc. at 1-877-727-2427. This Patient information has been approved by the U.S. Food and Drug



NDA 018680/S-074

SUPPLEMENT APPROVAL

CooperSurgical, Inc. Attention: Regina Shih VP, Global Regulatory and Clinical Affairs 75 Corporate Drive Trumbull, CT 06611

Dear Regina Shih:

Please refer to your supplemental new drug application (sNDA) dated and received February 28, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Paragard (intrauterine copper contraceptive).

We acknowledge receipt of your amendment dated January 5, 2024, which constituted a complete response to our December 18, 2023, action letter.

This Prior Approval supplemental new drug application provides for a new inserter intended to facilitate the single-hand placement of Paragard.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

WAIVER OF 1/2 PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(I)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.1 Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Patient Package Insert with the addition of any labeling

http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry SPL Standard for Content of Labeling Technical Qs and As.²

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(I)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format* — *Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "Final Printed Carton and Container Labeling for approved NDA 018680/S-074." Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

www.fda.gov

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

NDA 018680/S-074 Page 3

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.³

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety- related information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR) 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination

³ For the most recent version of a guidance, check the FDA guidance web page at: https://www.fda.gov/media/128163/download.

http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf

⁵ http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

NDA 018680/S-074 Page 4

product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.⁶

If you have any questions, call Dorsa Jalali, Regulatory Project Manager, at 240-402-0543.

Sincerely,

{See appended electronic signature page}

Audrey Gassman, M.D.
Deputy Director
Division of Urology, Obstetrics, and Gynecology
Office of Rare Diseases, Pediatrics,
Urologic and Reproductive Medicine
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert
- Carton and Container Labeling

U.S. Food and Drug Administration Silver Spring, MD 20993 www.fda.gov

www.iua.gov

 $^{^{\}rm 6}$ https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products

Case 1:20-md-02974-LMM Document 1/18/31/2 Filled: 109/1/18/255 Filege: 12 of 39

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PARAGARD[®] safely and effectively. See full prescribing information for PARAGARD.

PARAGARD (intrauterine copper contraceptive) Initial U.S. Approval: 1984

RECENT MAJOR CHANGES	
Dosing and Administration (2)	06/2024

- INDICATIONS AND USAGE

Paragard is a copper-containing intrauterine system (IUS) indicated for prevention of pregnancy in females of reproductive potential for up to 10 years. (1)

- DOSAGE AND ADMINISTRATION -

- Insert a single Paragard at the fundus of the uterine cavity. Remove Paragard no later than 10 years from the date of insertion. (2.1)
- Insert and remove Paragard only if you are a healthcare provider trained on these procedures. (2.1)
- See the Full Prescribing Information for recommended timing of insertion preparation instructions, insertion procedures, postplacement management, and instructions on removing Paragard. (2.2, 2.3, 2.4, 2.5, 2.6)
- Following the insertion, examine the patient after her first menses to confirm Paragard is still in place. (2.5)

—DOSAGE FORMS AND STRENGTHS •

One sterile, T-frame IUS containing copper consisting of a T-shaped polyethylene frame with a total exposed copper surface area of $380 \pm 23 \text{ mm}^2$, (approximately 176 mg of wire wrapped around the vertical stem and an approximately 68.7 mg collar placed on each side of the horizontal arm) packaged with a sterile pre-assembled inserter as a single-use, disposable device in a tray. (3, 16)

- CONTRAINDICATIONS -

- Pregnancy or suspicion of pregnancy (4)
- . Abnormalities of the uterus resulting in distortion of the uterine cavity (4)
- · Acute pelvic inflammatory disease (PID) (4)
- Postpartum endometritis or postabortal endometritis in past 3 months (4)
- Known or suspected uterine or cervical malignancy (4)
- Uterine bleeding of unknown etiology (4)
- Untreated acute cervicitis or vaginitis or other lower genital tract infection (4)
- · Conditions associated with increased susceptibility to pelvic infections (4)

- Wilson's disease (4)
- · A previously placed IUD or IUS that has not been removed (4)
- Hypersensitivity to any component of Paragard including copper or any trace elements present in the copper components of Paragard (4)

WARNINGS AND PRECAUTIONS -

- <u>Ectopic Pregnancy</u>: Promptly evaluate women who become pregnant for ectopic pregnancy while using Paragard. (5.1)
- <u>Risks with Intrauterine Pregnancy</u>: Increased risk of spontaneous abortion, septic abortion, premature delivery, sepsis, septic shock and death if pregnancy occurs. Remove Paragard if pregnancy occurs with Paragard in place. (5.2)
- <u>Sepsis</u>: Group A streptococcal infection has been reported; strict aseptic technique is essential during insertion (5.3)
- Pelvic Inflammatory Disease (PID) and Endometritis: Before using Paragard, consider the risks of PID and endometritis. Promptly assess and treat patients with si ns and s m toms of PID. 5.4
- Embedment: Sur ical removal ma be necessar . 5.5
- <u>Perforation</u>: May reduce contraceptive effectiveness and require surgery.
 Risk is increased if inserted in lactating women and may be increased if inserted in women with fixed, retroverted uteri or noninvoluted uteri. (5.6)
- Expulsion: Partial or complete expulsion may occur. Remove a partially expelled Paragard. (5.7)
- <u>Bleeding patterns</u>: May be altered and result in heavier and longer bleeding with spotting. (5.9)
- MRI Safety Information: Patients using Paragard can be safely scanned with MRI only under certain conditions. (5.10)

- ADVERSE REACTIONS -

Adverse reactions reported in clinical trials include: anemia, backache, dysmenorrhea, dyspareunia, expulsion (complete or partial), prolonged menstrual flow, menstrual spotting, pain and cramping, and vaginitis. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact CooperSurgical, Inc. at 1-877-727-2427 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDAapproved patient labeling

Revised: 06/2024

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Paragard is indicated for prevention of pregnancy in females of reproductive potential for up to 10 years.

2 DOSAGE AND ADMINISTRATION

2.1 Important Dosage and Administration Instructions

- Paragard should only be inserted by a healthcare provider trained in Paragard's insertion procedures, because insertion for Paragard is different from that used for other intrauterine systems. Healthcare providers should become thoroughly familiar with the product, product educational materials, product insertion instructions, and prescribing information before attempting insertion of Paragard.
- Insert one Paragard at the fundus of the uterine cavity [see Dosage and Administration (2.4)].
- Remove Paragard on or before 10 years from the date of insertion [see Dosage and Administration (2.6)].
- May replace Paragard at the time of removal with a new Paragard if continued contraceptive protection is desired.
- Before considering use of Paragard, make sure that the female is an appropriate candidate for Paragard. Exclude pregnancy (consider the possibility of ovulation and conception) prior to use [see Contraindications (4) and Warnings and Precautions (5.2)].

2.2 Timing of Insertion

Refer to Table 1 for recommended timing of Paragard insertion.

Table 1: Recommended Timing of Paragard Insertion

	Clinical Situation	Recommended Timing of Paragard Insertion
1.	Start Paragard in females not currently using contraception	At any time during the menstrual cycle.
2.	Switch to Paragard from an oral, transdermal, or vaginal form of hormonal contraception or an injectable progestin contraceptive	At any time during the menstrual cycle; discontinue the previous method.
3.	Switch to Paragard from a contraceptive implant or other intrauterine system	Same day the implant or IUS is removed (insert at any time during the menstrual cycle).
4.	Insert Paragard after abortion or miscarriage	Immediately after abortion, although immediate placement has a slightly higher risk of expulsion than placement at other times. Insertion after second trimester abortion is associated with a higher risk of expulsion than insertion after a first trimester abortion.

	May insert immediately postpartum.
5. Insert Paragard after Childbirth	Insertion before uterine involution is complete, which may not occur until the second postpartum month, has been associated with increased risk of expulsion [see Warnings and Precautions (5.6,5.7)].
	There appears to be an increased risk of perforation in lactating women [see Warnings and Precautions (5.6)].

Note: The inserter provided with Paragard (see Figure 1) and the Insertion Procedure described in subsection 2.4 are not applicable for immediate insertion after childbirth. For immediate insertion post childbirth, remove the inserter and Paragard from the tray, move the button forward and then completely back to release the Paragard unit from the inserter and insert Paragard.

2.3 Preparation Instructions

Read the Preparation Instructions and Insertion Procedure before initiating Paragard insertion.

Before insertion:

- Do NOT remove the inserter from the tray before the arms are loaded into the insertion tube. The tray will be used
 to fold the Paragard arms down and load the IUS into the inserter.
- Use strict aseptic techniques throughout preparation [see Warnings and Precautions (5.4)].
- Prepare placement tools (e.g., speculum, cotton swab, tenaculum, uterine sound, scissors, and forceps).
- Consider use of an analgesic.
- Establish the size and position of the uterus by performing a bi-manual examination.
- Insert a speculum and, using a cotton swab, cleanse the cervix and vagina with an antiseptic solution.
- Apply a tenaculum to the cervix and use gentle traction to align the cervical canal with the
 uterine cavity.
- Gently insert a sterile uterine sound to measure the depth of the uterine cavity. The uterus should sound to a depth of 6 to 9 cm except when inserting Paragard immediately postabortion or immediately postpartum.
 - Insertion of Paragard may be associated with pain and/or bleeding, vasovagal reactions (e.g., syncope, bradycardia), or seizure, especially in patients with a predisposition to these conditions.
 - Insertion into a uterine cavity measuring less than 6 cm may increase the incidence of expulsion, bleeding, pain, and perforation.
 - If cervical stenosis is encountered, avoid undue force. Dilators and analgesia/local anesthesia may be helpful in this situation.

2.4 Insertion Procedure

Follow the insertion instructions exactly as described to ensure proper placement and avoid early release of Paragard from the inserter.

Use strict aseptic techniques throughout the insertion procedure [see Warnings and Precautions (5.4)/.

Step 1: Opening the Sterile Paragard Package

 Place the package containing Paragard (face-up) on a flat sterile field (see Figure 1). Open the pouch from the handle end where the arrow on the Placement Guide says "OPEN".

Figure 1: Inserter

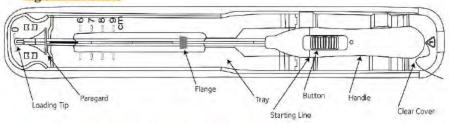
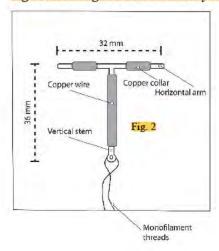


Figure 2: Paragard Intrauterine System (IUS)



- Remove the clear cover from the tray (not shown).
- Confirm that the top of the button is located at the starting line on the handle prior to loading Paragard.
- The inserter should remain in the tray until Paragard T-Arms are loaded.

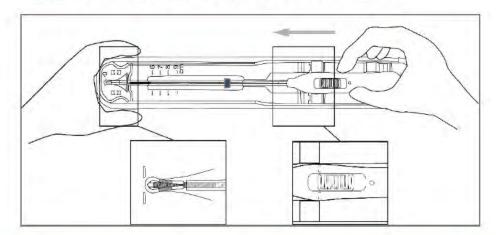
Do not slide the button on the handle before folding the arms in the tray.

Do not repeatedly slide the button forward and back as this may cause slack in the threads and may result in an unsuccessful placement.

Step 2: Loading Paragard into the Inserter

 Using sterile gloves, place one hand on the distal end of the tray and the other on the inserter handle. Slide the handle completely forward so that the Paragard advances into the Loading Tip folding the T-Arms of Paragard against the stem (see Figure 3).

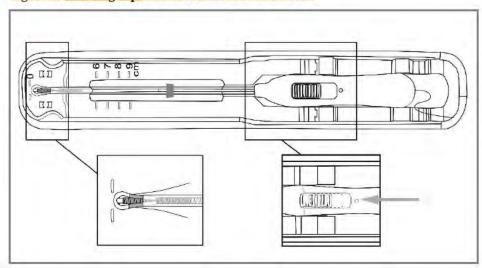
Figure 3: Folding Tips of T-Arms of Paragard using Loading Tip



Once the T-Arms are folded against the stem, slide the button on the handle completely forward to
advance the insertion tube over the tips of the T-Arms (see Figure 4). Only the tips of the T-Arms
should be in the insertion tube. Do not advance beyond the copper collars.

IMPORTANT: Do not leave the T-Arms of Paragard bent for more than 5 minutes, as the arms may not open properly.

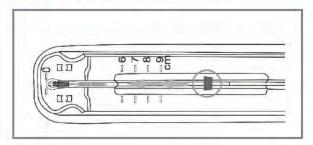
Figure 4: Inserting Tips of T-Arms into Insertion Tube



Step 3: Adjusting the Flange

- Once the above steps are completed and Paragard is in the insertion tube, adjust the blue flange.
 The tray is marked with centimeters and can be used to set the flange to the correct depth (see Figure 5).
- Adjust the flange so the distance from the top of Paragard (where it protrudes from the inserter) to
 the top of the flange is equal to the pre-measured uterine depth.

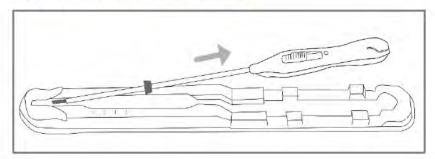
Figure 5: Adjusting the Blue Flange to sound depth



Step 4: Removing Inserter from Tray

- Ensure the button remains in the forward position.
- To remove the inserter from the tray, gently lift the handle out of the tray, then gently slide the inserter back and lift out of the tray. (see Figure 6).
- Upon removal from the tray, verify and rotate the blue flange as needed so that the horizontal arms
 of Paragard and the long axis of the blue flange and handle lie in the same horizontal plane to
 ensure the arms open in the proper direction.
- Confirm that both T-Arms are captured within the insertion tube.

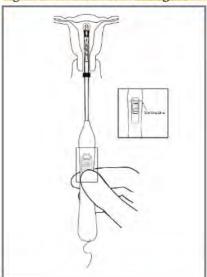
Figure 6: Removal of Inserter from Tray



Step 5: Inserting Paragard to the Fundus

- To orient the uterus in an axial position, apply gentle traction to the tenaculum. While holding the
 button forward, pass the loaded inserter through the cervical canal until the Paragard reaches the
 fundus of the uterus. This will ensure placement of Paragard at the highest possible position within
 the uterus.
- The blue flange should be at the cervix in the horizontal plane. The button should remain in the forward position (see Figure 7).

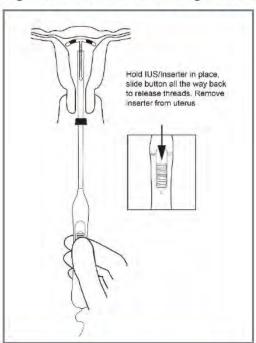
Figure 7: Inserter with Paragard at Uterine Fundus



Step 6: Releasing Paragard and Withdrawing Inserter

- Release the arms of Paragard by holding the handle steady and sliding the button all the way down (and you may feel a click). Do not stop at the starting line as it is not used for deployment.
- This releases the threads and the T-Arms of Paragard high in the uterine fundus (see Figure 8).

Figure 8: Release T-Arms of Paragard at Uterine Fundus



- Gently and slowly withdraw the inserter from the uterus and cervical canal.
- Only the threads should be visibly protruding from the cervix (see Figure 9). Trim the threads so that 3 to 4 cm protrude into the vagina.
- Measure and note the length of threads, date of placement and Paragard lot number.
- Discard the used inserter do not attempt to re-use the inserter because it is a single use device.

If you suspect that Paragard is not in the correct position, check placement (with ultrasound, if
necessary). If Paragard is not positioned completely within the uterus, remove it and replace it with
a new Paragard. Do not reinsert an expelled or partially expelled Paragard.

Figure 9: Appropriate Paragard Placement in Uterus



2.5 Postplacement Management of Paragard

Following placement:

- Examine the female after her first menses to confirm that Paragard is still in place. You should be
 able to visualize or feel only the threads. The length of the visible threads may change with time.
 However, no action is needed unless you suspect partial expulsion, perforation, pregnancy, or
 breakage.
- If you cannot find the threads in the vagina, check that Paragard is still in the uterus. The threads
 can retract into the uterus or break, or Paragard can break, perforate the uterus, or be expelled.
 Gentle probing of the cavity, x-ray, or sonography may be required to locate Paragard.
- Remove Paragard if it has been partially expelled or perforated the uterus [see Warnings and Precautions (5.6, 5.7)].

Do not reinsert a used Paragard.

2.6 Removal of Paragard

Timing of Removal

- Paragard can be removed at any time prior to 10 years after insertion.
- Remove Paragard no later than 10 years after insertion. A new Paragard can be inserted at the time
 of removal if continued contraceptive protection is desired.

Removal Instructions

- Use a speculum and visualize the cervix.
- Remove Paragard with forceps, pulling gently on the exposed threads. The arms of Paragard will
 fold upwards as it is withdrawn from the uterus.
- If removal cannot be accomplished by gentle pulling, consider checking Paragard location and assess for embedment and perforation (with imaging, if necessary).
- · Breakage or embedment of Paragard in the myometrium can make removal difficult /see Warnings

and Precautions, (5.5)]. IUS breakage may be associated with removal. Analgesia, paracervical anesthesia, cervical dilation, alligator forceps or other grasping instrument, or hysteroscopy may assist in removing an embedded Paragard.

- Make sure Paragard is intact upon removal.
- Removal may be associated with some pain and/or bleeding, vasovagal reactions (e.g. syncope, bradycardia), or seizure, especially in patients with a predisposition to these conditions.

3 DOSAGE FORMS AND STRENGTHS

Paragard is a T-frame copper-containing intrauterine system (IUS) consisting of a polyethylene frame with barium sulfate measuring 32 mm horizontally and 36 mm vertically, with approximately 176 mg of copper wire wrapped around the vertical stem and an approximately 68.7 mg copper wire collar placed on each side of the horizontal arm with a total exposed copper surface area is 380 ± 23 mm², packaged with a sterile pre-assembled inserter as a single-use, disposable device in a tray. A monofilament polyethylene thread is tied through the tip of the vertical stem resulting in two white threads, each approximately 36.5 cm in length. Figure 1 displays the contents of the package [see Dosage and Administration (2.3)].

4 CONTRAINDICATIONS

The use of Paragard is contraindicated when one or more of the following conditions exist:

- Pregnancy or suspicion of pregnancy [see Warnings and Precautions (5.1, 5.2) and Use in Specific Populations (8.1)]
- Abnormalities of the uterus resulting in distortion of the uterine cavity
- Acute pelvic inflammatory disease (PID) [see Warnings and Precautions (5.4)]
- Postpartum endometritis or postabortal endometritis in the past 3 months [see Warnings and Precautions (5.4)]
- Known or suspected uterine or cervical malignancy
- Uterine bleeding of unknown etiology
- Untreated acute cervicitis or vaginitis or other lower genital tract infection
- Conditions associated with increased susceptibility to pelvic infections [see Warnings and Precautions (5.4)]
- Wilson's disease [see Warnings and Precautions (5.8)]
- A previously placed IUD or IUS that has not been removed
- Hypersensitivity to any component of Paragard including to copper or any of the trace elements present in the copper component of Paragard [see Adverse Reactions (6.2) and Description (11)]

5 WARNINGS AND PRECAUTIONS

5.1 Ectopic Pregnancy

Evaluate for possible ectopic pregnancy in any female who becomes pregnant while using Paragard because a pregnancy that occurs with Paragard in place is more likely to be ectopic than a pregnancy in the general population. However, because Paragard prevents most pregnancies, females who use Paragard have a lower risk of an ectopic pregnancy than sexually active females who do not use any contraception.

The incidence of ectopic pregnancy in the clinical trials with Paragard (which excluded females with a previous history of ectopic pregnancy) was approximately 0.06%. Ectopic pregnancy may require surgery and may result in loss of fertility.

5.2 Risks with Intrauterine Pregnancy

If intrauterine pregnancy occurs with Paragard in place and the strings are visible or can be retrieved from the cervical canal, remove Paragard because leaving it in place may increase the risk of spontaneous abortion and preterm labor. Removal of Paragard may also result in spontaneous abortion. In the event of an intrauterine pregnancy with Paragard, consider the following:

Septic Abortion

In females becoming pregnant with an intrauterine system (IUS), including Paragard in place, septic abortion, with septicemia, septic shock, and death, may occur [see Warnings and Precautions (5.3)]. Septic abortion typically requires hospitalization and treatment with intravenous antibiotics. Septic abortion may result in spontaneous abortion or a medical indication for pregnancy termination. A hysterectomy may be required if severe infection of the uterus occurs, which will result in permanent infertility.

Continuation of Pregnancy

If a female becomes pregnant with Paragard in place and if Paragard cannot be removed or the female chooses not to have it removed, warn her that failure to remove Paragard increases the risk of miscarriage, sepsis, premature labor, and premature delivery. Prenatal care should include counseling about these risks and that she should report immediately any flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge or leakage of fluid, or any other symptom that suggests complications of the pregnancy.

5.3 Sepsis

Severe infection or sepsis, including Group A streptococcal sepsis (GAS), have been reported following insertion of IUSs, including Paragard. In some cases, severe pain occurred within hours of insertion followed by sepsis within days. Because death from GAS is more likely if treatment is delayed, it is important to be aware of these rare but serious infections. Aseptic technique during insertion of Paragard is essential in order to minimize serious infections such as GAS [see Dosage and Administration (2.3)].

5.4 Pelvic Inflammatory Disease and Endometritis

Insertion of Paragard is contraindicated in the presence of known or suspected Pelvic Inflammatory Disease (PID) or endometritis [see Contraindications (4)]. IUSs, including Paragard, have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion. In the clinical trials with Paragard, the incidence of PID that resulted in the removal of Paragard was approximately 0.1% [see Clinical Studies (14)].

Counsel women who receive Paragard to notify a healthcare provider if they have complaints of lower abdominal or pelvic pain, odorous discharge, unexplained bleeding, fever, or genital lesions or sores. In such circumstances, perform a pelvic examination promptly to evaluate for possible pelvic infection. Remove Paragard in cases of recurrent PID or endometritis, or if an acute pelvic infection is severe or does not respond to treatment.

PID can have serious consequences, such as tubal damage (leading to ectopic pregnancy or infertility), hysterectomy, sepsis, and death.

Females at Increased Risk for PID

PID or endometritis are often associated with a sexually transmitted infection (STI) and Paragard does not protect against STIs. The risk of PID or endometritis is greater for females who have multiple sexual partners, and also for females whose sexual partner(s) have multiple sexual partners. Females who have had PID or endometritis are at increased risk for a recurrence or re-infection. In particular, ascertain whether a female is at increased risk of infection (for example, leukemia, acquired immune deficiency syndrome (AIDS), intravenous drug abuse).

Asymptomatic PID

PID or endometritis may be asymptomatic but still result in tubal damage and its sequelae.

Treatment of PID or Endometritis in Patients Using Paragard

Remove Paragard in cases of recurrent endometritis or PID, or if an acute pelvic infection is severe or does not respond to treatment. Prophylactic antibiotics administered at the time of insertion do not appear to lower the incidence of PID.

Promptly assess and treat any female who develops signs or symptoms of PID. Perform appropriate testing for sexually transmitted infection and initiate antibiotic therapy promptly. Paragard does not need to be removed immediately. Reassess the patient in 48-72 hours. If no clinical improvement occurs, continue antibiotics and consider removal of Paragard. If the decision is to remove Paragard, start antibiotics prior to removal to avoid the potential risk for bacterial spread resulting from the removal procedure.

Actinomycosis

Actinomycosis has been associated with IUS use, including Paragard. Symptomatic women with known actinomycosis infection should have Paragard removed and receive antibiotics. Actinomycetes can be found in the genital tract cultures in healthy women without IUSs. The significance of actinomyces-like organisms on a Papanicolaou (PAP) smear in an asymptomatic IUS user is unknown, and this finding alone does not always require IUS removal and treatment. When possible, confirm a PAP smear diagnosis with cultures.

5.5 Embedment

Partial penetration or embedment of Paragard in the myometrium can make removal difficult. In some cases, surgical removal may be necessary. Breakage of an embedded Paragard during non-surgical removal has been reported [see Dosage and Administration (2.6)].

5.6 Perforation

Partial or total perforation of the uterine wall or cervix may occur during insertions, although the perforation may not be detected until sometime later. Perforation may reduce contraceptive efficacy and result in pregnancy. The incidence of perforation during or following Paragard insertion in clinical trials was 0.2% (13 out of 5344).

Delayed detection or removal of Paragard in cases of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal penetration, intestinal obstruction, abscesses and/or damage to adjacent organs.

A postmarketing safety study conducted in Europe (EURAS IUD) with IUSs, including copper IUSs, demonstrated an increased risk of perforation in lactating women. The risk of perforation may be increased if an IUS, such as Paragard, is inserted when the uterus is fixed, retroverted or not completely involuted during the postpartum period.

If perforation does occur, locate and remove Paragard promptly. Surgery may be required. Preoperative imaging followed by laparoscopy or laparotomy is often required to remove Paragard from the peritoneal cavity.

5.7 Expulsion

Partial or complete expulsion of Paragard has been reported, resulting in the loss of contraceptive protection. The incidence of expulsion in the clinical trials with Paragard was approximately 2.3%. Consider further diagnostic imaging, such as x-ray, to confirm expulsion if the IUS is not found in the uterus.

Paragard has been placed immediately after delivery, although the risk of expulsion may be increased when the uterus is not completely involuted at the time of insertion. Remove a partially expelled Paragard.

5.8 Wilson's Disease

Paragard may exacerbate Wilson's disease, a rare genetic disease affecting copper excretion; therefore, the use of Paragard is contraindicated in females of reproductive potential with Wilson's disease [see Contraindications (4)].

5.9 Bleeding Pattern Alterations

Paragard can alter the bleeding pattern and result in heavier and longer menstrual cycles with intermenstrual spotting.

In two clinical trials with Paragard, there were reports of oligomenorrhea and amenorrhea; however, a causal relationship between Paragard and these events could not be established. Menstrual changes were the most common medical reason for discontinuation of Paragard. Discontinuation rates for pain and bleeding combined were highest in the first year of use and diminished thereafter. The percentage of females who discontinued Paragard because of bleeding problems or pain during these studies ranged from 12% in the first year to 2% in Year 9. Females complaining of heavy vaginal bleeding should be evaluated and treated, and may need to discontinue Paragard [see Adverse Reactions (6.1)].

5.10 Magnetic Resonance Imaging (MRI) Safety Information



Non-clinical testing has demonstrated that Paragard is MR Conditional. A patient with Paragard can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3.0 T or 1.5T
- Maximum spatial field gradient of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, Paragard is expected to produce a maximum temperature rise of less than 0.5° C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the system extended less than 5 mm from the implant when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

5.11 Medical Diathermy

Medical equipment that contain high levels of Radiofrequency (RF) energy such as diathermy may cause health effects (by heating tissue) in females with a metal-containing IUD including Paragard. Avoid using high medical RF transmitter devices in females with Paragard.

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed elsewhere in the labeling:

- Ectopic pregnancy [see Warnings and Precautions (5.1)]
- Intrauterine pregnancy [see Warnings and Precautions (5.2)]
- Septic abortion [see Warnings and Precautions (5.2)]
- Group A Streptococcal Sepsis (GAS) [see Warnings and Precautions (5.3)]
- Pelvic Inflammatory Disease and Endometritis [see Warnings and Precautions (5.4)]
- Embedment [see Warnings and Precautions (5.5)]
- Perforation [see Warnings and Precautions (5.6)]
- Expulsion [see Warnings and Precautions (5.7)]
- Bleeding Pattern Alterations [see Warnings and Precautions (5.9)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The data described below reflect exposure in two trials [see Clinical Studies (14)].

- The WHO Study 79914 was a randomized, multicenter, multinational study of copper T IUSs, including Paragard in 1,396 women outside the U.S. In the WHO Study, 100% were parous and the mean age at enrollment was 29 years old.
- The U.S. Composite Study was a meta-analysis that evaluated randomized, double-blind, comparative studies of copper T IUSs, including Paragard in 3,536 women in the U.S. In the

U.S. Composite Study, 64% were nulliparous, 49% were nulliparavida, 68% were under age 25 at the time of enrollment (median age 23 years old).

Table 2 shows discontinuation rates from the two clinical studies by adverse reaction and year.

Summary of Rates* (No. per 100 Subjects) by Year for Adverse Reactions Table 2: **Causing Discontinuation**

	Year										
	1	2	3	4	5	6	7	8	9	10	
Number of Women at Start of Year	4,932	3,149	2,018	1,121	872	621	563	483	423	325	
Expulsion	5.7	2.5	1.6	1.2	0.3	0.0	0.6	1.7	0.2	0.4	
Bleeding/Pain	11.9	9.8	7.0	3.5	3.7	2.7	3.0	2.5	2.2	3.7	
Other Medical Event	2.5	2.1	1.6	1.7	0.1	0.3	1.0	0.4	0.7	0.3	

^{*}Rates were calculated by weighting the annual rates by the number of subjects starting each year for each of the U.S. Composite Study (3536 subjects) and the World Health Organization (1396 subjects) trials.

The following adverse reactions have also been observed: anemia, backache, dysmenorrhea, dyspareunia, complete or partial expulsion, prolonged menstrual flow, menstrual spotting, pain and cramping, and vaginitis.

Study CSIPD-001

The Paragard inserter that enables single-hand insertion was evaluated in Study CSIPD-001. A total of 117 females of reproductive potential aged 18 to 49 years, underwent Paragard insertion and were followed for up to 12 weeks of Paragard use. Subjects were predominantly white (76%), 45% were parous, and 35% were obese. Successful placement of Paragard with first attempt occurred in 91% of the subjects and 99% with two insertion attempts. Adverse reactions of special interest occurring during the study were IUS expulsion (2.6%), vasovagal reaction (2.6%), IUS malposition (1.7%), partial uterine perforation (0.9%), and IUS embedment (0.9%).

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of Paragard. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Gastrointestinal Disorders: abdominal distension, nausea

General Disorders and Administration Site Conditions: device breakage, pyrexia; copper wire breakage

Immune System Disorders: allergy to metals, hypersensitivity

Infections and Infestations: endometritis/uterine infection

Musculoskeletal and Connective Tissue Disorders: muscle spasms

Nervous System Disorders: dizziness

Reproductive System and Breast Disorders: amenorrhea

Skin and Subcutaneous Tissue Disorders: Stevens-Johnson syndrome

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7 DRUG INTERACTIONS

No drug-drug interaction or drug-herbal supplement interaction studies have been conducted with Paragard.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Use of Paragard is contraindicated for use in pregnant females because there is no need for pregnancy prevention in a female who is already pregnant and Paragard may cause adverse pregnancy outcomes. If a female becomes pregnant with Paragard in place, there is an increased risk of miscarriage, sepsis, premature labor, and premature delivery [see Contraindications (4) and Warnings and Precautions (5.1, 5.2)]. Advise the female of the potential risks if pregnancy occurs with Paragard in place.

Published studies on pregnancy outcomes exposed to copper IUSs report up to 27% miscarriage when the IUS was removed compared to 77% miscarriage when the IUS remained in the uterus. Studies on Paragard and birth defects have not been conducted.

8.2 Lactation

Risk Summary

No difference has been detected in concentration of copper in human milk before and after insertion of copper IUSs, including Paragard. There is no information on the effect of copper in a breastfed child or the effect on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Paragard and any potential adverse effects on the breastfed child from Paragard.

8.4 Pediatric Use

The safety and effectiveness of Paragard have been established in females of reproductive potential. Efficacy is expected to be the same for postmenarcheal females regardless of age.

Paragard is not indicated in females before menarche.

8.5 Geriatric Use

Paragard has not been studied in women over 65 years of age and is not indicated in this population.

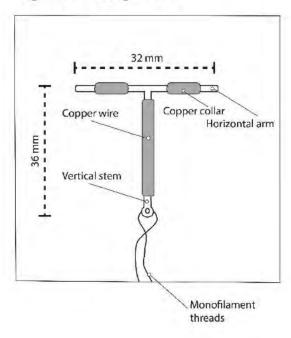
11 DESCRIPTION

11.1 Paragard IUS

Paragard (intrauterine copper contraceptive) is a T-shaped intrauterine system (IUS), measuring 32 mm horizontally and 36 mm vertically, with a 3 mm diameter bulb at the tip of the vertical stem. (See Figure 10) [see Dosage and Administration (2.3)]. A monofilament polyethylene thread is tied through the tip, resulting in two white threads, each approximately 36.5 cm in length, to aid in detection and removal of the intrauterine system. The T-frame is made of polyethylene with barium sulfate to aid in detecting the intrauterine system under x-ray. Paragard also contains copper (approximately 176 mg of wire wrapped around the vertical stem and an approximately 68.7 mg collar

placed on each side of the horizontal arm). The total exposed copper surface area is $380 \pm 23 \text{ mm}^2$. One Paragard weighs less than one (1) gram.

Figure 10 - Paragard IUS

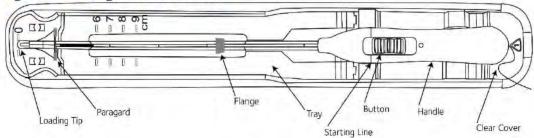


Paragard, its components, and the packaging are not made with natural rubber latex.

11.2 Inserter

Paragard is packaged with a sterile pre-assembled inserter as a single-use, disposable device in a tray and in a Tyvek® polyethylene pouch. A moveable blue flange on the insertion tube aids in gauging the depth of insertion through the cervical canal and into the uterine cavity (See Figure 11) [see Dosage and Administration (2.3)].

Figure 11 – Paragard with Inserter



12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Copper continuously released into the uterine cavity contributes to the contraceptive effectiveness of Paragard. Mechanism(s) by which copper enhances contraceptive efficacy include interference with sperm transport and fertilization of an egg, and possibly prevention of implantation.

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13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenicity, Mutagenicity, Impairment of Fertility

Adequate long-term studies in animals to assess the carcinogenic potential of a copper-containing IUS have not been performed.

The genotoxic potential of a copper-containing IUS has not been evaluated.

CLINICAL STUDIES

The efficacy of Paragard for use in females of reproductive potential for prevention of pregnancy for up to 10 years was demonstrated in two trials:

- WHO Study 79914 was a randomized, multicenter, multinational study of copper T IUSs, including Paragard in 1,396 women outside the U.S. In the WHO study, 100% were parous and the mean age at enrollment was 29 years old.
- The U.S. Composite Study was a meta-analysis that evaluated several randomized, doubleblind, comparative studies of copper T IUSs, including the Paragard in 3,536 women in the U.S. In the U.S. study, 64% were nulliparous, 49% were nulligravida; 68% were under age 25 at the time of enrollment (median age 23 years old).

The pregnancy rate in the two clinical studies with Paragard was less than 1 pregnancy per 100 women each year (see Table 3).

Table 3: Pregnancy Rates* (Number of Pregnancies per 100 Women) by Year in the WHO and **U.S. Studies**

		Year									
	1	2	3	4	5	6	7	8	9	10	
Pregnancy	0.7	0.3	0.6	0.2	0.3	0.2	0.0	0.4	0.0	0.0	
Number of Women at Start of Year	4,932	3,149	2,018	1,121	872	621	563	483	423	325	

^{*}Rates were calculated by weighting the annual rates by the number of subjects starting each year for each of the U.S. Composite Study (3536 subjects) and the World Health Organization (1396 subjects) trials.

16 HOW SUPPLIED/STORAGE AND HANDLING

Paragard (intrauterine copper contraceptive) is available in cartons of 1 (one) sterile unit (NDC 59365-5129-1).

Each Paragard is white, T-shaped, and measures 32 mm horizontally and 36 mm vertically, with approximately 176 mg of copper wire wrapped around the vertical stem and an approximately 68.7 mg copper wire collar placed on each side of the horizontal arms, and with a monofilament polyethylene thread tied through the tip of the vertical stem [see Dosage and Administration (2.3)]. The T-frame is made of polyethylene with barium sulfate. Each Paragard is packaged with a sterile pre-assembled inserter as a single-use, disposable device in a tray and in a Tyvek® polyethylene pouch.

Store at controlled room temperature: 59° to 86°F (15° to 30°C).

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Before inserting Paragard, counsel patients on the following:

<u>Sexually Transmitted Infections</u>: Advise patients that Paragard does not protect against HIV infection and other sexually transmitted diseases.

<u>Ectopic Pregnancy</u>: Advise patients to report pregnancies and be evaluated immediately, as a pregnancy with Paragard in place is more likely to be an ectopic pregnancy, and the risks of ectopic pregnancy include the loss of fertility [see Warnings and Precautions (5.1)].

Intrauterine Pregnancy: Advise patients to report pregnancies and be evaluated immediately, as an intrauterine pregnancy with Paragard in place, may result in septic abortion, with septicemia, septic shock, and possible death. Septic abortion typically requires hospitalization and treatment with intravenous antibiotics. Septic abortion may result in spontaneous abortion or a medical indication for pregnancy termination. A hysterectomy may be required if severe infection of the uterus occurs, which will result in permanent infertility. If Paragard remains in the uterus during a pregnancy, there is an increased risk of miscarriage, sepsis, premature labor and premature delivery. Advise patients that a pregnancy must be followed closely and advise patients to report immediately any symptom, such as flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge or leaking of fluid, or any other symptom that suggests complications of the pregnancy [see Warnings and Precautions (5.2)].

<u>Sepsis</u>: Advise patients that sepsis may occur after insertion of Paragard and to seek immediate treatment for fever and pelvic pain that occurs soon after insertion, as untreated sepsis can result in death [see Warnings and Precautions (5.3)].

<u>Pelvic Inflammatory Disease</u>: Advise patients that pelvic inflammatory disease (PID) may occur after insertion of Paragard and that PID can cause tubal damage leading to ectopic pregnancy or infertility, or can necessitate hysterectomy, or cause death. Advise patients to recognize and report promptly any symptoms of PID including development of menstrual disorders (prolonged or heavy bleeding), unusual vaginal discharge, abdominal or pelvic pain or tenderness, dyspareunia, chills, and fever [see Warnings and Precautions (5.4)].

Embedment, Perforation, and Expulsion: Advise atients regarding the risks of embedment erforation and expulsion and inform atients that in some cases removal of Paragard mag be difficult and surgical removal mag be necessary. Inform atients that erforation can cause infection, scarring, damage to other organs, pain, or infertility. Inform patients that excessive pain or vaginal

bleedin durin IUS lacement worsenin ain or bleedin after lacement or the inability to feel the IUS strings man occur with IUS perforation and expulsion. There is no protection from pregnancy if Paragard is displaced or expelled [see Warnings and Precautions (5.5, 5.6, 5.7).].

<u>Bleeding Pattern Alterations</u>: Advise patients that heavier or longer periods and spotting between periods may occur. Instruct patients to report continued or severe symptoms to their healthcare provider [see Warnings and Precautions (5.9)].

<u>Checking for Paragard</u>: Advise patients to check that Paragard is still in the uterus by reaching up to the top of the vagina with clean fingers to feel the two threads. Inform patients not to pull on the threads, which could displace Paragard. Advise patients to promptly report if there are changes in the length of the two threads, if they cannot locate the threads, or they can feel any other part of Paragard besides the threads.

<u>Magnetic Resonance Imaging (MRI) Safety Information</u>: Inform patients that Paragard can be safely scanned with MRI only under specific conditions. Instruct patients who will have an MRI to tell their healthcare provider that they have Paragard [see Warnings and Precautions (5.10)].

<u>Medical Diathermy</u>: Instruct patients to tell their healthcare provider that they have Paragard prior to undergoing medical diathermy [see Warnings and Precautions (5.11)].

Other Important Information:

- 1. Advise patients to contact their healthcare provider if any of the following occur:
 - Pelvic pain or pain during sex
 - Unusual vaginal discharge or genital sores
 - Possible exposure to STIs
 - HIV positive seroconversion in herself or her partner
 - Severe or prolonged vaginal bleeding
 - Missed period
- 2. Advise patients that they may use tampons or pads while wearing Paragard.

Manufactured by:

CooperSurgical, Inc.

Trumbull, CT 06611

PATIENT INFORMATION

PARAGARD® ('par-uh-gahrd) (intrauterine copper contraceptive)

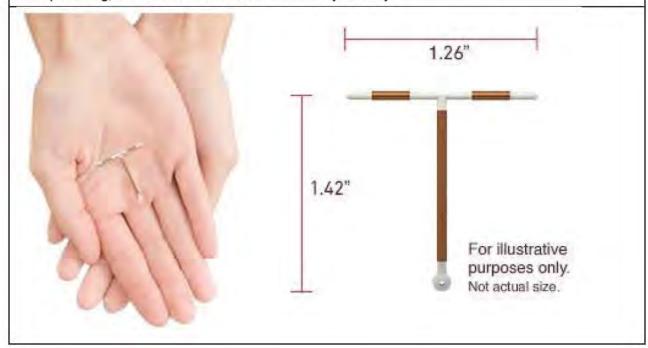
Paragard does not protect against HIV infection (AIDS) or other sexually transmitted infections (STIs).

Read this Patient Information carefully before you decide if Paragard is right for you. This information does not take the place of talking with your gynecologist or other healthcare provider who specializes in women's health. If you have any questions about Paragard, ask your healthcare provider. You should also learn about other birth control methods to choose the one that is best for you.

What is Paragard?

- Paragard is a copper-releasing system that is placed in your uterus by your healthcare provider to prevent pregnancy for up to 10 years.
- Paragard can be removed by your healthcare provider at any time.
- Paragard does not contain any hormones.
- Paragard can be used whether or not you have given birth to a child.

Paragard is a small, flexible plastic "T" shaped intrauterine system with copper wrapped around the stem and placed on arms of the "T". Two thin white threads are attached to the stem (lower end) of Paragard. The threads are the only part of Paragard you can feel when Paragard is in your uterus; however, unlike a tampon string, the threads do not extend outside of your body.



What if I need birth control for more than 10 years?

Paragard must be removed on or before 10 years from the date of insertion. Your healthcare provider can place a new Paragard during the same office visit if you choose to continue using Paragard.

What if I want to stop using Paragard?

Paragard is intended for use up to 10 years, but you can stop using Paragard at any time by asking your healthcare provider to remove it. You could become pregnant as soon as Paragard is removed; however, if you do not want to become pregnant you should use another method of birth control. Talk to your healthcare provider about the best birth control methods for you.

What if I change my mind about birth control and want to become pregnant in less than 10 years?

Your healthcare provider can remove Paragard at any time before the 10 years after placement. You may become pregnant as soon as Paragard is removed.

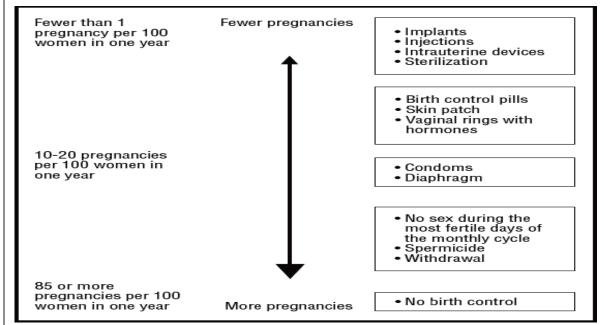
How does Paragard work?

Paragard works by preventing sperm from reaching the egg, preventing sperm from fertilizing the egg, or possibly preventing attachment (implantation) in the uterus. Paragard does not stop your ovaries from making an egg (ovulating) each month.

How well does Paragard work for contraception?

The following chart shows the chance of getting pregnant for women who use different methods of birth control. Each box on the chart contains a list of birth control methods that are similar in effectiveness. The most effective methods are at the top of the chart. The box on the bottom of the chart shows the chance of getting pregnant for women who do not use birth control and are trying to get pregnant.

Paragard, an intrauterine system (IUS), is in the box at the top of the chart.



Who might use Paragard?

You might choose Paragard if you:

- want long-term birth control that provides a low chance of getting pregnant (less than 1 in 100)
- want birth control that works continuously for up to 10 years
- want birth control that is reversible
- want a birth control method that you do not need to take daily
- are willing to use a birth control method that is inserted in the uterus
- want birth control that does not contain hormones

Do not use Paragard if you:

- are or might be pregnant
- have a condition of the uterus that changes the shape of the uterine cavity, such as large fibroid tumors
- have an untreated pelvic infection called pelvic inflammatory disease (PID) now
- have had an infection in your uterus after a pregnancy or abortion in the past 3 months
- can get infections easily. For example, if you:
 - o have problems with your immune system
 - o have multiple sexual partners or your partner has multiple sexual partners
 - o use or abuse intravenous drugs
- have or suspect you might have cancer of the uterus or cervix
- have unexplained bleeding from your vagina
- have an untreated lower genital infection now in your cervix
- have Wilson's disease (a disorder in how the body handles copper)
- are allergic to copper, polyethylene, or barium sulfate
- have an intrauterine system in your uterus already

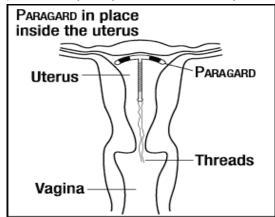
Before having Paragard placed, tell your healthcare provider if you have:

- any of the conditions listed above
- slow heart beat (bradycardia)
- dizziness (syncope)
- seizures
- recently had a baby or if you are breastfeeding
- AIDS, HIV, or any other sexually transmitted infection

How is Paragard placed?

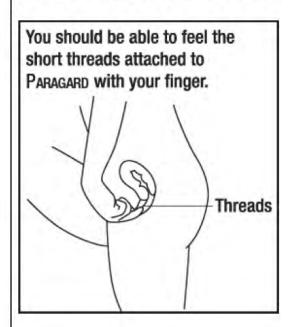
Paragard is placed in your uterus during an in-office visit.

First, your healthcare provider will examine your pelvis to find the exact position of your uterus. Your healthcare provider will then cleanse your vagina and cervix with an antiseptic solution and then, measure your uterus. Your healthcare provider will then slide a plastic tube containing Paragard into your uterus. The tube is removed, leaving Paragard inside your uterus. Two white threads will extend into your vagina. The threads are trimmed so they are just long enough for you to feel with your fingers when doing a self-check. As Paragard goes in, you may feel cramping or pinching. You may have some bleeding. Some women feel faint, nauseated, or dizzy for a few minutes afterwards. Your healthcare provider may ask you to lie down until you are feeling better, and to get up slowly.



Should I check that Paragard is in place?

Yes, you should check that Paragard is in proper position by feeling the threads. It is a good habit to do this 1 time a month. Your healthcare provider should teach you how to check that Paragard is in place. First, wash your hands with soap and water. You can check by reaching up to the top of your vagina with clean fingers to feel the 2 threads. Do not pull on the threads.



If you feel changes in the length of the 2 threads, you cannot feel the threads, or you can feel any other part of Paragard other than the threads, Paragard may not be in the right position and may not prevent pregnancy. Use back-up birth control (such as condoms or spermicide) and ask your healthcare provider to check that Paragard is still in the right place.

If Paragard is accidentally removed, you may be at risk of pregnancy, and should talk to a healthcare provider.

How soon after placement of Paragard should I return to my healthcare provider?

Call your healthcare provider if you have any questions or concerns (see "When should I call my healthcare provider?"). Otherwise you should return to your healthcare provider for a follow-up visit after your first menses after Paragard is placed to make sure that Paragard is in the right position.

What if I become pregnant while using Paragard?

Call your healthcare provider right away if you think you may be pregnant. If you get pregnant while using Paragard, you may have an ectopic pregnancy. This means the pregnancy is not in your uterus. Unusual vaginal bleeding or abdominal pain especially with missed periods may be a sign of ectopic pregnancy.

Ectopic pregnancy is a medical emergency that often requires surgery. Ectopic pregnancy can cause internal bleeding, infertility and even death.

There are also risks if you get pregnant while using Paragard and the pregnancy is in the uterus. Severe infection, miscarriage, premature delivery, and even death can occur with pregnancies that continue with an intrauterine device (IUD). Because of this, your healthcare provider may try to remove Paragard, even though removing it may cause a miscarriage. If Paragard cannot be removed, talk with your healthcare provider about the benefits and risks of continuing the pregnancy.

If you continue your pregnancy see your healthcare provider regularly. Call your healthcare provider right away if you get flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge, or fluid leaking from your vagina. These may be signs of infection.

It is not known if Paragard can cause long-term effects on the fetus if it stays in place during a pregnancy.

How will Paragard change my periods?

Your period may become heavier and longer. You may also have frequent spotting between periods.

Is it safe to breastfeed while using Paragard?

You may use Paragard when you are breastfeeding. The risk of Paragard becoming attached to (embedded) or going through the wall of the uterus is increased if Paragard is placed while you are breastfeeding.

Will Paragard interfere with sexual intercourse?

You and your partner should not feel Paragard during intercourse. Paragard is placed in the uterus, not in the vagina. Sometimes your partner may feel the threads. If this occurs, or if you or your partner experience pain during sex, talk with your healthcare provider.

Can I have an MRI with Paragard in place?

Paragard can be safely scanned with MRI only under specific conditions. Before you have an MRI, tell your healthcare provider that you have Paragard, an intrauterine device (IUD), in place.

Before you have a medical procedure using heat therapy tell your healthcare provider that you have Paragard in place.

What are the possible side effects of Paragard?

Paragard can cause serious side effects, including:

- ectopic pregnancy and intrauterine pregnancy risks: There are risks if you become pregnant while using Paragard (see "What if I become pregnant while using Paragard?").
- life-threatening infection: Life-threatening infection can occur within the first few days after Paragard is placed. Call your healthcare provider immediately if you develop severe pain or fever shortly after Paragard is placed.
- pelvic inflammatory disease (PID) or endometritis: Some IUS users get a serious pelvic infection called pelvic inflammatory disease (PID) or endometritis. PID and endometritis are usually sexually transmitted. You have a higher chance of getting PID and endometritis if you or your partner has sex with other partners. PID and endometritis can cause serious problems such as infertility, ectopic pregnancy, and pelvic pain that does not go away. PID and endometritis are usually treated with antibiotics. More serious cases of PID or endometritis may require surgery. A hysterectomy (removal of the uterus) is sometimes needed. In rare cases, infections that start as PID can even cause death. Tell your healthcare provider right away if you have any of these signs of PID or endometritis: low abdominal (stomach area) or pelvic pain, pelvic tenderness, painful sex, unusual or bad smelling vaginal discharge, chills, long-lasting or heavy bleeding, fever, genital lesions or sores.
- embedment: Paragard may become attached to (embedded) the wall of the uterus. This may make it
 hard to remove Paragard. Surgery may sometimes be needed to remove Paragard.
- perforation: Paragard may go through the wall of the uterus. This is called perforation. If this occurs, Paragard may no longer prevent pregnancy. If perforation occurs, Paragard may move outside the uterus and cause internal scarring, infection, damage to other organs, pain, or infertility and you may need surgery to have Paragard removed. Excessive pain or vaginal bleeding during placement of Paragard, pain or bleeding that gets worse after placement, or not being able to feel the threads may happen with perforation. You are not protected from pregnancy if Paragard moves outside the wall of the uterus. The risk of perforation is increased in breastfeeding women.
- expulsion: Paragard may partially or completely fall out of the uterus by itself. This is called
 expulsion. Expulsion occurs in about 2 out of 100 women. Excessive pain, vaginal bleeding during
 placement of Paragard, pain that gets worse, bleeding after placement, or not being able to feel the
 threads may happen with expulsion. You are not protected from pregnancy if Paragard is expelled.
- changes in bleeding: You may have heavier and longer periods with spotting in between.
 Sometimes the bleeding is heavier than usual at first. Call your healthcare provider if the bleeding remains heavier or longer and spotting continues.

reactions after placement or removal: Some women have had reactions such as dizziness (syncope), slowed heart rate (bradycardia), or seizures, immediately after Paragard was placed or removed. This happened especially in women who have had these conditions before.

Common side effects of Paragard include:

- anemia (low red blood cell count)
- pain during sex
- prolonged periods

- backache
- expulsion (complete or partial)
- spotting

- painful periods
- · vaginal discharge
- pain and cramping

vaginal irritation

This is not a complete list of possible side effects with Paragard. For more information, ask your healthcare provider. Tell your healthcare provider about any side effect that bothers you or does not

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

After Paragard has been placed, when should I call my healthcare provider?

Call your healthcare provider if you have any concerns about Paragard. Be sure to call if you:

- think you are pregnant
- have pelvic pain or pain during sex
- have unusual vaginal discharge or genital sores
- have unexplained fever, flu-like symptoms or chills
- might be exposed to sexually transmitted infections (STIs)
- are concerned that Paragard may have been expelled (came out)
- cannot feel Paragard's threads or can feel the threads are much longer
- can feel any other part of the Paragard besides the threads
- become HIV positive or your partner becomes HIV positive
- have severe, bleeding that lasts a long time, or bleeding that concerns you
- miss a menstrual period

General information about the safe and effective use of Paragard.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your healthcare provider for information about Paragard that is written for health professionals.

Paragard and its components are not made with natural rubber latex.

Paragard® is a registered trademark of CooperSurgical, Inc. The other brands listed are trademarks of their respective owners.

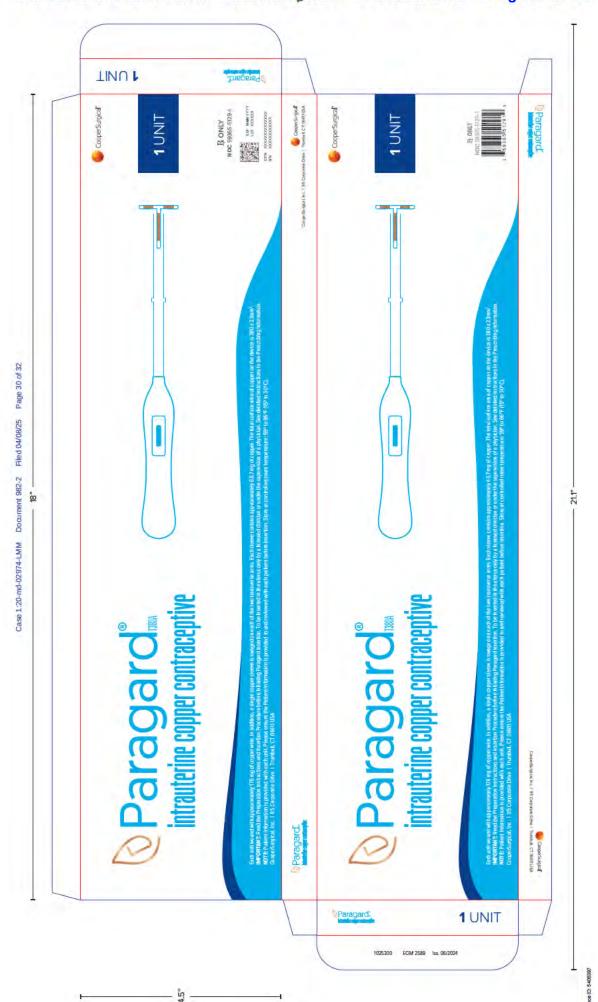
Manufactured by:

CooperSurgical, Inc.

Trumbull, CT 06611

For more information, call CooperSurgical, Inc. at 1-877-727-2427.

This Patient Information has been approved by the U.S. Food and Drug Administration



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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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