



**Women want a low-dose birth control option.**

**Talk to your appropriate patients about Kyleena: a small, low-hormone, 5-year intrauterine device (IUD)<sup>1</sup>**



## IN AN ONLINE SURVEY OF 1000 WOMEN CONSIDERING HORMONAL BIRTH CONTROL<sup>2</sup>:

**50%** OF WOMEN (N=500) SAID THEY WERE OPEN TO USING A HORMONAL IUD

Survey respondents (N=1000) were asked to rate their level of agreement on statements regarding hormonal IUDs on a 7-point scale, with 1 representing "Completely Disagree" and 7 representing "Completely Agree." Results captured 5 and above.

**67%** OF WOMEN (N=502) SAID THEY WOULD LIKE TO HAVE A LOW-DOSE OPTION

Survey respondents (N=1000) were asked "When considering a birth control method such as an IUD, do you want a low-dose hormonal option?" Respondents responded using a 7-point scale, with 1 representing "Not At All" and 7 representing "Very Much So." Results captured 5 and above.

The survey conducted by Bayer in September 2019 included women aged 18-44 who were **currently taking or considering taking hormonal prescription birth control** in the next 12 months.

## WITH KYLEENA: HIGH CONTRACEPTIVE EFFICACY MAINTAINED OVER 5 YEARS<sup>1</sup>

- 98.6% cumulative efficacy over 5 years
- 99.8% efficacy at year 1
- >99% efficacy for each year of use

The efficacy of Kyleena over 5 years was studied in 1452 parous and nulliparous women aged 18-35.

Year 1: Pearl Index of 0.16; 95% upper confidence limit (CL) of 0.58; cumulative 5-year pregnancy rate, based on 13 pregnancies, estimated by the Kaplan-Meier method was 1.45%; 95% upper CL of 2.53%.

## INDICATION FOR KYLEENA

Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg is indicated for the prevention of pregnancy for up to 5 years. Replace the system after 5 years if continued use is desired.

## IMPORTANT SAFETY INFORMATION ABOUT KYLEENA

### Who is not appropriate for Kyleena

Use of Kyleena is contraindicated in women with: known or suspected pregnancy and cannot be used for post-coital contraception; congenital or acquired uterine anomaly, including fibroids if they distort the uterine cavity; known or suspected breast cancer or other progestin-sensitive cancer, now or in the past; known or suspected uterine or cervical neoplasia; liver disease, including tumors; untreated acute cervicitis or vaginitis, including lower

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# JUST OVER 6 MILLION WOMEN HAVE AN IUD, BUT MORE MAY BE APPROPRIATE CANDIDATES

## CONTRACEPTIVE METHOD USAGE IN THE UNITED STATES<sup>3</sup>



SOURCE: Bayer analysis of the National Survey of Family Growth 2017-2019.

National Survey of Family Growth is a CDC-conducted, national, multi-decade survey of US women 15-49 years of age. Interviews are face-to-face, voluntary, and confidential and seek to gain insight into family life, marriage and divorce, pregnancy, infertility, use of contraception, and general and reproductive health.

\*Implant (4%), injectable (4%), patch (1%), ring (2%), morning-after pill (0%), jelly or cream (0%), rhythm method (4%), other (not specified) (0%).

**57% OF YOUNG WOMEN (AGES 18-31)  
MISSED AN AVERAGE OF 3 OR MORE  
PILLS PER CYCLE (N=82)<sup>4†</sup>**

**A PATIENT USING ORAL CONTRACEPTIVES  
TYPICALLY TAKES 1826 ONCE-DAILY PILLS  
OVER 5 YEARS vs 1 IUD INSERTION<sup>1,5‡</sup>**

<sup>†</sup>A randomized controlled trial (N=82) tracked OC dosing for 3 months by electronic and wireless data collection. During the study period, half the participants (n=41) received a daily reminder text message.

<sup>‡</sup>Example of Nordette®—28 tablets over 5 years.

Counsel patients to check their threads once a month. Reexamine and evaluate patients 4 to 6 weeks after insertion and once a year thereafter, or more frequently if clinically indicated.

## IMPORTANT SAFETY INFORMATION ABOUT KYLEENA (continued)

### Who is not appropriate for Kyleena (continued)

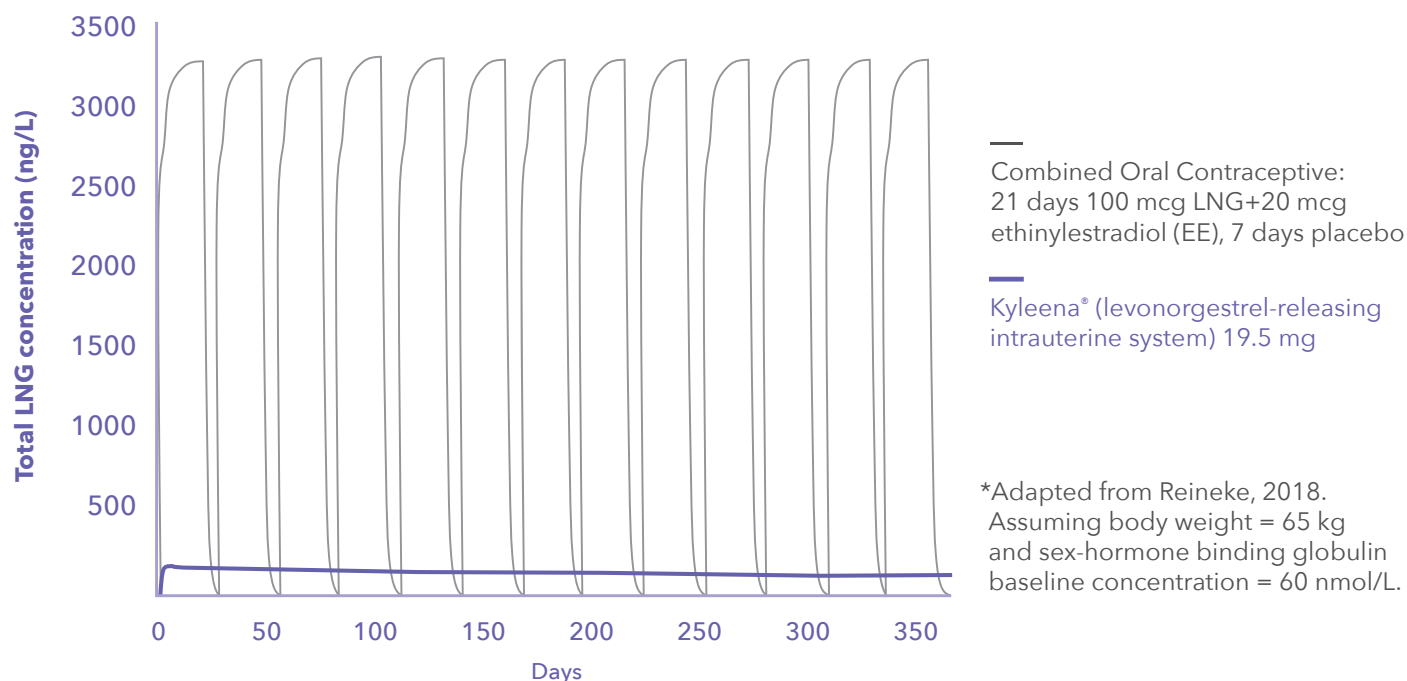
genital tract infections (e.g., bacterial vaginosis) until infection is controlled; postpartum endometritis or infected abortion in the past 3 months; unexplained uterine bleeding; current IUD; acute pelvic inflammatory disease (PID) or history of PID (except with later intrauterine pregnancy); conditions increasing susceptibility to pelvic infection; or hypersensitivity to any component of Kyleena.

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Kyleena<sup>®</sup>  
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# KYLEENA ACTS LOCALLY AND PROVIDES LOW HORMONE LEVELS

## COMPARISON OF SIMULATED TYPICAL SERUM LEVONORGESTREL (LNG) CONCENTRATIONS<sup>4\*</sup>



## KYLEENA PROVIDES LOW DAILY RELEASE RATES<sup>1</sup>

	<b>KYLEENA</b> (levonorgestrel-releasing intrauterine system) 19.5 mg
Initial Release Rate	17.5 mcg/day after 24 days <sup>1</sup>
After Year 1	9.8 mcg/day <sup>1</sup>
Average in Vivo Release Rate	9.0 mcg/day over 5 years <sup>1</sup>

## IMPORTANT SAFETY INFORMATION ABOUT KYLEENA (continued)

### Clinical considerations for use and removal of Kyleena

Use Kyleena with caution after careful assessment in patients with coagulopathy or taking anticoagulants; migraine, focal migraine with asymmetrical visual loss, or other symptoms indicating transient cerebral ischemia; exceptionally severe headache; marked increase of blood pressure; or severe arterial disease such as stroke or myocardial infarction. Consider removing the intrauterine system if these or the following arise during use: uterine or cervical malignancy or jaundice. If the threads are not visible or are significantly shortened they may have broken or retracted into the cervical canal or uterus. If Kyleena is displaced (e.g., expelled or perforated the uterus), remove it. Kyleena can be safely scanned with MRI only under specific conditions.

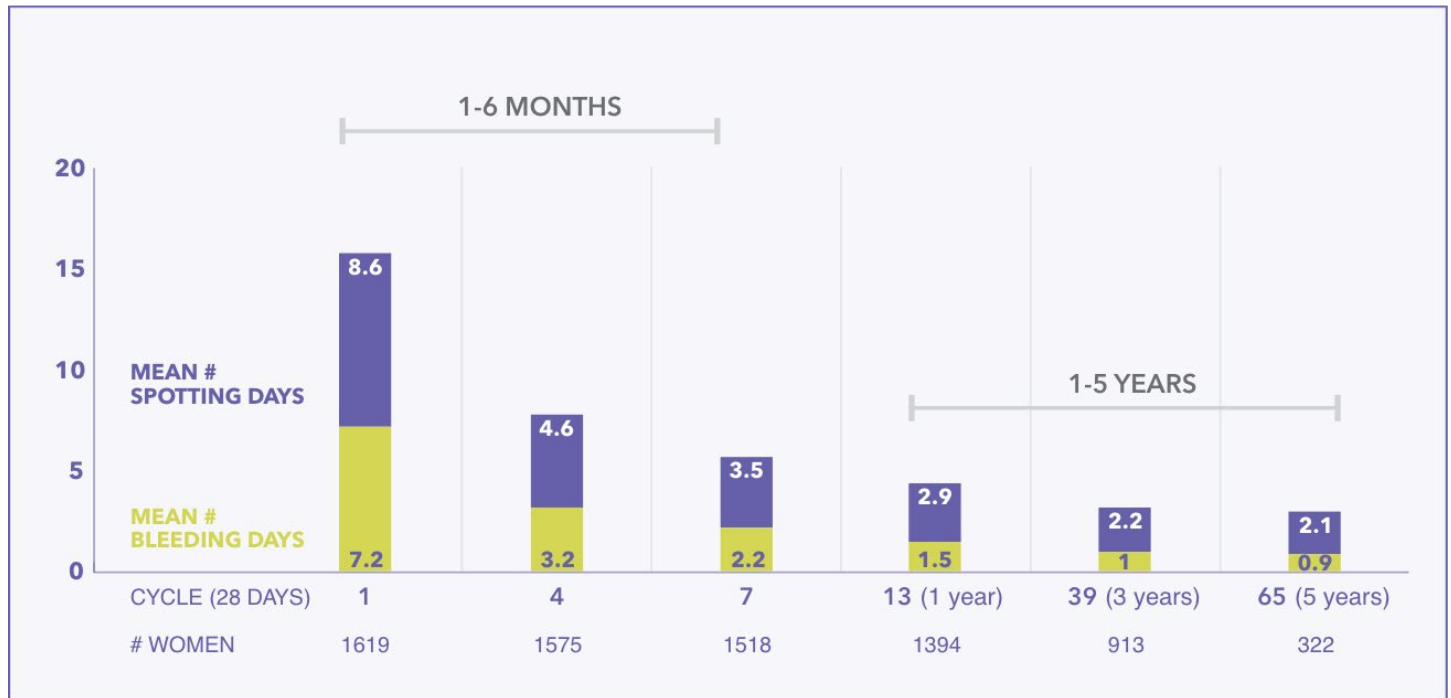
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# COUNSEL YOUR PATIENTS THAT THEY MAY EXPERIENCE SHORTER, LIGHTER PERIODS AFTER THE FIRST 3 TO 6 MONTHS WITH KYLEENA<sup>1</sup>

- In the first 3 to 6 months of Kyleena use, patients may find that their number of bleeding and spotting days is higher and their bleeding patterns are irregular
- After 6 months, the number of bleeding and spotting days continued to decline for most women using Kyleena, but bleeding patterns may remain irregular

## MEAN NUMBER OF BLEEDING AND SPOTTING DAYS OVER THE COURSE OF 5 YEARS<sup>1</sup>



## IMPORTANT SAFETY INFORMATION ABOUT KYLEENA (continued)

### Pregnancy related risks with Kyleena

If pregnancy should occur with Kyleena in place, remove the intrauterine system because leaving it in place may increase the risk of spontaneous abortion and preterm labor. Advise her of isolated reports of virilization of the female fetus following local exposure to LNG during pregnancy with an LNG IUS in place. Removal or manipulation may result in pregnancy loss. Evaluate women for ectopic pregnancy because the likelihood of a pregnancy being ectopic is increased with Kyleena. Also consider the possibility of ectopic pregnancy in the case of lower abdominal pain, especially in association with missed menses or if an amenorrheic woman starts bleeding. Tell women about the signs of ectopic pregnancy and associated risks, including loss of fertility. Women with a history of ectopic pregnancy, tubal surgery, or pelvic infection carry a higher risk of ectopic pregnancy.

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# SOME PATIENTS EXPERIENCE AMENORRHEA AND INFREQUENT BLEEDING OVER 5 YEARS<sup>1</sup>

## BLEEDING PATTERNS FROM CLINICAL TRIALS (BY 90-DAY REFERENCE PERIODS)<sup>1</sup>

Kyleena	First 90 days N=1566	End of year 1 N=1371	End of year 5 N=530
Amenorrhea*	<1%	12%	23%
Infrequent bleeding <sup>†</sup>	10%	26%	26%
Frequent bleeding <sup>‡</sup>	25%	4%	2%
Prolonged bleeding <sup>§</sup>	57%	6%	1%
Irregular bleeding <sup>  </sup>	43%	17%	9%

\*Amenorrhea was defined as subjects with no bleeding/spotting throughout the 90-day reference period.<sup>1</sup>

<sup>†</sup>Infrequent bleeding was defined as subjects with 1 or 2 bleeding/spotting episodes in the 90-day reference period.<sup>1</sup>

<sup>‡</sup>Frequent bleeding was defined as subjects with more than 5 bleeding/spotting episodes in the 90-day reference period.<sup>1</sup>

<sup>§</sup>Prolonged bleeding was defined as subjects with bleeding/spotting episodes lasting more than 14 days in the 90-day reference period. Subjects with prolonged bleeding may also be included in one of the other categories (excluding amenorrhea).<sup>1</sup>

<sup>||</sup>Irregular bleeding was defined as subjects with 3 to 5 bleeding/spotting episodes and less than 3 bleeding/spotting-free intervals of 14 or more days.<sup>1</sup>

## CYCLES BECOME MORE CONSISTENT OVER TIME<sup>1</sup>

Minimal fluctuations in bleeding and spotting after first 6 months

- Bleeding: Mean number of days overall did not fluctuate more than 1.3 days per 28-day cycle
- Spotting: Mean number of days overall did not fluctuate more than 1.4 days per 28-day cycle

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# THE KYLEENA SATISFACTION STUDY (KYSS)<sup>7</sup>

## STUDY DESIGN

This prospective, noninterventive, multinational, single-arm cohort study took place in Belgium, Canada, Germany, Mexico, Norway, Sweden, Spain, and the United States (US). All participants were women with different or no previously used contraceptive methods (including women without previous contraception forming one of the subgroups) who had already decided to use Kyleena. In the US, the study was conducted at 12 sites in 100 women. In Belgium, Canada, Mexico, Norway, Sweden, and Spain, the sample size was N = 100 in each country. Germany contained the largest sample size of N = 500. The primary endpoint was to evaluate overall satisfaction with Kyleena at the end of the observation period (12 months) per country. The secondary endpoints included satisfaction with Kyleena at the end of the observation period (12 months) stratified by previously used contraceptive method and motivation for choosing Kyleena, pain severity at Kyleena insertion, ease of Kyleena insertion (investigator assessed), and other measures.

## KYSS PARTICIPANTS WERE ASKED 2 QUESTIONS PERTAINING TO THEIR CONTRACEPTION USAGE BEFORE HAVING KYLEENA PLACED<sup>8</sup>:

The decision to use an LNG-IUS was made independently by the women after a discussion with their healthcare provider at participating study centers. These discussions were not prompted or scripted; the healthcare providers gave their routine counseling, after which the women could decide to use any contraception method.

### Why did you decide to stop your previous method of contraception?

Participants were asked to select from certain options, some of which include the following:

- Afraid the contraceptive method might not be very effective
- Problems with daily, weekly, or monthly contraceptive routine (intake, insertion, injection, application)
- Dissatisfaction with current contraceptive method
- Other, please specify

### Why did you decide to use Kyleena for contraception?

Participants were asked to select from certain options, some of which include the following:

- High contraceptive reliability
- No daily, weekly, or monthly contraceptive routine (intake, insertion, injection, application)
- Acts mainly locally
- Low hormone dose
- Estrogen-free contraception
- Small size
- Other, please specify

Understanding the effects of these variables on satisfaction rates may help healthcare providers assist in the counseling and method selection process.

## IMPORTANT SAFETY INFORMATION ABOUT KYLEENA (continued)

### Educate her about PID

Kyleena is contraindicated in the presence of known or suspected PID or in women with a history of PID unless there has been a subsequent intrauterine pregnancy. IUDs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion. Promptly examine users with complaints of lower abdominal pain or pelvic pain, odorous discharge, unexplained bleeding, fever, genital lesions or sores.

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# SAFETY RESULTS AND LIMITATIONS FROM THE KYSS STUDY

## TREATMENT-EMERGENT ADVERSE EVENTS (TEAEs) REPORTED IN $\geq 1\%$ OF WOMEN WHO RECEIVED KYLEENA IN KYSS (N=1129)<sup>8</sup>

ADVERSE EVENT	n (%)
<b>Reproductive system and breast disorders</b>	89 (7.9%)
Vaginal hemorrhage	21 (1.9%)
Dysmenorrhea	11 (1.0%)
Menorrhagia	11 (1.0%)
<b>Gastrointestinal disorders</b>	29 (2.6%)
Abdominal pain (lower)	16 (1.4%)
<b>Psychiatric disorders</b>	13 (1.2%)
<b>Skin and subcutaneous tissue disorders</b>	13 (1.2%)

Women who were using Kyleena most frequently reported TEAEs related to the reproductive system and breast disorders (89 patients, 7.9%), gastrointestinal disorders (29 patients, 2.6%), psychiatric disorders (13 patients, 1.2%), and skin and subcutaneous tissue disorders (13 patients, 1.2%). The most frequently reported TEAEs in women using Kyleena were vaginal hemorrhage (21 patients, 1.9%) and lower abdominal pain (16 patients, 1.4%). A total of 69 patients (6.1%) discontinued Kyleena due to TEAEs, 4 of these patients (0.4%) due to treatment-emergent serious adverse events.

## POTENTIAL STUDY LIMITATIONS<sup>8</sup>

- Given the noninterventive study design and limitations inherent to observational studies, findings generated from this study are subject to biases, such as selection bias, limitations to availability of historical medical data, and differences in treatment or reporting owing to local guidelines
- The study population was enrolled in selected countries and sites that might not be comparable to the nonparticipating population. This might also be a limiting factor in generalizing the results
- Investigators were chosen based on feasibility criteria, which might have resulted in decreased generalizability of the study results
- Selection bias could not be excluded completely because potential study participants were predominantly selected among those who wanted to change their previously used contraceptive method because of unsatisfactory experiences
- Since this kind of bias could not be ruled out, an additional group of women without previous contraception (new starters) were included. Results of this subgroup enabled putting the satisfaction results into the right perspective

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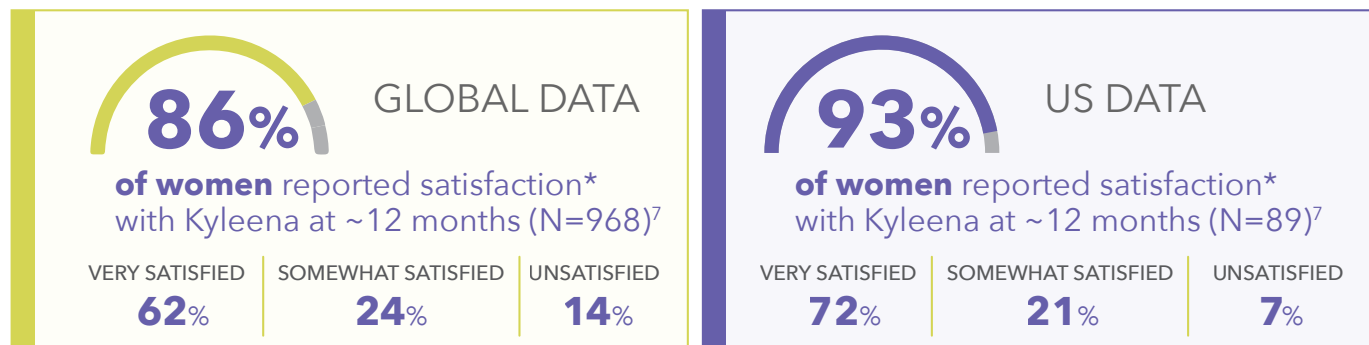
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# OVERALL SATISFACTION WITH KYLEENA<sup>7-8</sup>

**SATISFACTION WITH KYLEENA, EVALUATED AS THE PRIMARY ENDPOINT, AS OBTAINED FROM THE PATIENT QUESTIONNAIRE: HOW SATISFIED ARE YOU WITH KYLEENA?**

**Results were taken after 12 months or premature discontinuation<sup>7</sup>**



\*Satisfaction is defined as sum of women reported "very satisfied" or "somewhat satisfied"; "unsatisfied" is defined as sum of women reported "neither satisfied nor dissatisfied," "dissatisfied," or "very dissatisfied."

## IMPORTANT SAFETY INFORMATION ABOUT KYLEENA (continued)

### Educate her about PID (continued)

Inform women about the possibility of PID and that PID can cause tubal damage leading to ectopic pregnancy or infertility, or infrequently can necessitate hysterectomy, or cause death. PID is often associated with sexually transmitted infections (STIs). Kyleena does not protect against STIs, including HIV. PID may be asymptomatic but still result in tubal damage and its sequelae. In clinical trials with Kyleena PID occurred more frequently within the first year and most often within the first month after insertion.

### Expect changes in bleeding patterns with Kyleena

Spotting and irregular or heavy bleeding may occur during the first 3 to 6 months. Periods may become shorter and/or lighter thereafter. Cycles may remain irregular, become infrequent, or even cease. Consider pregnancy if menstruation does not occur within 6 weeks of the onset of previous menstruation. If a significant change in bleeding develops during prolonged use, take appropriate diagnostic measures to rule out endometrial pathology.

### Be aware of other serious complications and most common adverse reactions

Some serious complications with IUDs like Kyleena are sepsis, perforation and expulsion. Severe infection or sepsis, including Group A streptococcal sepsis (GAS), have been reported following insertion of a LNG-releasing IUS. Aseptic technique during insertion of Kyleena is essential in order to minimize serious infections, such as GAS. Perforation (total or partial, including penetration/embedment of Kyleena in the uterine wall or cervix) may occur, most often during insertion, although the perforation may not be detected until sometime later.

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# SATISFACTION RATE WITH KYLEENA IN WOMEN OF ALL AGES BY PARITY

## SATISFACTION WITH KYLEENA AS OBTAINED FROM THE PATIENT QUESTIONNAIRE: HOW SATISFIED ARE YOU WITH KYLEENA?<sup>7,8</sup>

Results were taken after 12 months or premature discontinuation<sup>7,8</sup>

### NULLIPAROUS



GLOBAL DATA

**87%**  
of women reported satisfaction\*  
with Kyleena at ~12 months (N=491)<sup>7</sup>

VERY SATISFIED	SOMEWHAT SATISFIED	UNSATISFIED
<b>62%</b>	<b>26%</b>	<b>13%</b>

### NULLIPAROUS

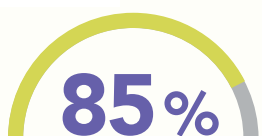


US DATA

**94%**  
of women reported satisfaction\*  
with Kyleena at ~12 months (N=65)<sup>7</sup>

VERY SATISFIED	SOMEWHAT SATISFIED	UNSATISFIED
<b>77%</b>	<b>17%</b>	<b>6%</b>

### PAROUS



GLOBAL DATA

**85%**  
of women reported satisfaction\*  
with Kyleena at ~12 months (N=477)<sup>7</sup>

VERY SATISFIED	SOMEWHAT SATISFIED	UNSATISFIED
<b>63%</b>	<b>22%</b>	<b>15%</b>

### PAROUS



US DATA

**92%**  
of women reported satisfaction\*  
with Kyleena at ~12 months (N=24)<sup>7</sup>

VERY SATISFIED	SOMEWHAT SATISFIED	UNSATISFIED
<b>58%</b>	<b>33%</b>	<b>8%</b>

\*Satisfaction is defined as sum of women reported "very satisfied" or "somewhat satisfied"; "unsatisfied" is defined as sum of women reported "neither satisfied nor dissatisfied," "dissatisfied," or "very dissatisfied."

## AGE DEMOGRAPHICS

US DATA (N=100)<sup>7</sup>

≤17: **3%**<sup>†</sup> 18-25: **54%** 26-35: **29%** >35: **14%**

GLOBAL DATA (N=1126)<sup>7</sup>

≤17: **3%**<sup>†</sup> 18-25: **36%** 26-35: **32%** >35: **30%**

<sup>†</sup>Safety and efficacy of Kyleena have been established in women of reproductive age. Efficacy is expected to be the same for postpubertal females under the age of 18 as for users 18 years and older. Use of this product before menarche is not indicated.

## IMPORTANT SAFETY INFORMATION ABOUT KYLEENA (continued)

### Be aware of other serious complications and most common adverse reactions (continued)

The risk of uterine perforation is increased in women who have recently given birth, and in women who are breastfeeding at the time of insertion. In a large US retrospective, postmarketing safety study of IUDs, the risk of uterine perforation was highest when insertion occurred within ≤6 weeks postpartum, and also higher with breastfeeding at the time of insertion. The risk of perforation may be increased if inserted when the uterus is fixed, retroverted or not completely involuted. If perforation occurs, locate and remove Kyleena. Surgery may be required.

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# EASE OF INSERTION AND PAIN AT INSERTION WITH KYLEENA

## KYLEENA SATISFACTION STUDY: SECONDARY ENDPOINTS

### Ease of Insertion<sup>8\*</sup>

Ease of insertion was a secondary endpoint, assessed by investigator at initial visit as easy, slightly difficult, or very difficult.<sup>8</sup>

#### GLOBAL DATA



of 1126 insertions were rated as "easy" by investigators

8% of 1126 insertions were rated as "slightly difficult" by investigators

1% of 1126 insertions were rated as "very difficult" by investigators

#### US DATA



of 99 insertions were rated as "easy" by investigators

7% of 99 insertions were rated as "slightly difficult" by investigators

3% of 99 insertions were rated as "very difficult" by investigators

There were 24 patients who reported at least 1 adverse event in the US.

Insertion may be associated with some pain and/or bleeding or vasovagal reactions (for example, syncope, bradycardia) or with seizure, especially in patients with a predisposition to these conditions. Consider administering analgesics prior to insertion.

\*Data shown are from the Full Analysis Set (FAS). A woman was included in the FAS if the first insertion attempt was successful. That means the FAS excluded subjects with unsuccessful insertion. The FAS was used for all primary and secondary analyses.

### Pain at Insertion<sup>8\*</sup>

#### GLOBAL DATA



of women (n=1126) rated pain at insertion as none to moderate at initial visit:

#### Secondary endpoint categories:

NONE	MILD	MODERATE	SEVERE
33%	45%	18%	4%

#### US DATA



of women (n=99) rated pain at insertion as none to moderate at initial visit:

#### Secondary endpoint categories:

NONE	MILD	MODERATE	SEVERE
27%	46%	25%	2%

Counsel on insertion pain. Let your patients know that pain is a common side effect. Patients may experience pain, bleeding, or dizziness during and after placement. If symptoms don't pass within 30 minutes after placement, Kyleena may not have been placed correctly. The HCP should examine whether or not Kyleena will need to be removed or replaced.

## IMPORTANT SAFETY INFORMATION ABOUT KYLEENA (continued)

### Be aware of other serious complications and most common adverse reactions (continued)

Delayed detection or removal of Kyleena in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera. In addition, perforation may reduce contraceptive efficacy and result in pregnancy. Partial or complete expulsion of Kyleena may occur resulting in the loss of contraceptive protection. The risk of expulsion is increased with insertions immediately after delivery and appears to be increased with insertion after second-trimester abortion based on limited data.

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# SHE TRUSTS YOUR OPINION

## TALK TO HER ABOUT KYLEENA: A SMALL, LOW-HORMONE, 5-YEAR IUD



**ASK HER:**  
How important is it for  
you NOT to become  
pregnant in the next year?  
**COULD KYLEENA  
BE RIGHT FOR HER?**

For additional information  
and support, please contact  
your Bayer representative.

To learn more and download resources,  
including patient education information,  
visit [www.kyleenahcp.com](http://www.kyleenahcp.com).



### IMPORTANT SAFETY INFORMATION ABOUT KYLEENA (continued)

#### Be aware of other serious complications and most common adverse reactions (continued)

In the same postmarketing study, the risk of expulsion was lower with breastfeeding status. Remove a partially expelled IUD. If expulsion has occurred, a new Kyleena can be inserted any time the provider can be reasonably certain the woman is not pregnant. Ovarian cysts may occur and are generally asymptomatic, but may be accompanied by pelvic pain or dyspareunia. Evaluate persistent enlarged ovarian cysts. In clinical trials with Kyleena the most common adverse reactions ( $\geq 5\%$ ) were vulvovaginitis (24%), ovarian cyst (22%), abdominal/pelvic pain (21%), headache/migraine (15%), acne/seborrhea (15%), dysmenorrhea/uterine spasm (10%), breast pain/breast discomfort (10%), and increased bleeding (8%). Teach patients to recognize and immediately report signs or symptoms of the aforementioned conditions. Evaluate patients 4 to 6 weeks after insertion of Kyleena and then yearly or more often if clinically indicated.

For important information about Kyleena, please see the [Full Prescribing Information](#).

**References:** 1. Kyleena [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals; 2021. 2. Data on file. Bayer HealthCare Pharmaceuticals Inc. InCrowd Inc. Report; 2019. 3. Data on file. Bayer HealthCare Pharmaceuticals Inc. National Survey of Family Growth. 2017-2019. 4. Hou MY, Hurwitz S, Kavanagh E, Fortin J, Goldberg AB. Using daily text-message reminders to improve adherence with oral contraceptives: a randomized controlled trial. *Obstet Gynecol*. 2010;116:633-640. 5. Nordette [prescribing information]. Pomona, NY: Duramed Pharmaceuticals Inc.; 2019. 6. Reinecke I, Hofmann B, Mesic E, Drenth H-J, Garmann D. An integrated population pharmacokinetic analysis to characterize levonorgestrel pharmacokinetics after different administration routes. *J Clin Pharmacol*. 2018;58(12):1639-1654. 7. Stovall DW, Aqua K, Romer T, et al. Satisfaction and continuation with LNG-IUS 12: findings from the real-world Kyleena® satisfaction study. *Eur J Contracept Reprod Health Care*. 2021;26(6):462-472. doi:10.1080/13625187.2021.1975268 8. Data on file. Bayer Healthcare Pharmaceuticals Inc. 19186; Kyleena Satisfaction Study 1.0; 2017.



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