



# Best Practices - inserimento e rimozione -

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**S.I.C.**  
Società Italiana della Contraccezione

**COI**

**STARmed Co Ltd, Gedeon Richter, Theramex, Organon**  
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# Quali Efficacia contro il

modo?!

Requisito **fondamentale**  
(Pearl Index):

- **Efficacia teorica** (percentuale di gravidanze),
- **Efficacia d'uso** (percentuale di fallimenti in una popolazione e c (accettabilità, c

Method	Percent of Women with Pregnancy	
	Lowest Expected	Typical
No method	85.0%	85.0%
Combination pill	0.1	7.6
Progestin-only pill	0.5	3.0
IUDs		
Progesterone IUD	1.5	2.0
Levonorgestrel IUD	0.1	0.1
Copper T 380A	0.6	0.8
Implant	0.05	0.2
Injectable	0.3	3.1
Female sterilization	0.05	0.05
Male sterilization	0.1	0.15
Spermicides	6.0	25.7
Periodic abstinence		20.5
Calendar	9.0	
Ovulation method	3.0	
Symptothermal	2.0	
Post-ovulation	1.0	
Withdrawal	4.0	23.6
Cervical cap		
Parous women	20.0	40.0
Nulliparous women	9.0	20.0
Sponge		
Parous women	20.0	40.0
Nulliparous women	9.0	20.0
Diaphragm and spermicides	6.0	12.1
Condom		
Male	3.0	13.9
Female	5.0	21.0

X

tivo (Pearl

ento (numero  
del metodo

e):

rvata in una  
tori

# Quale è il migliore metodo?!

Prodotto	Metodo - durata	PEARL INDEX
<b>Impianto</b>	3 anni	0.05
<b>IUS-LNG 5 anni</b>	5 anni	0.2
<b>IUS-LNG 3 anni</b>	3 anni	0.33
<b>IUD</b>	5 o 10 anni	0.8
<b>Iniezione steriodea</b>	Iniezione 3 mesi	6

PI Pearl Index Prgenancies/Year

# LARC use in US – increasing trend

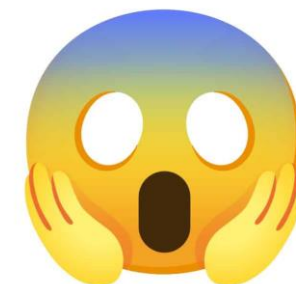
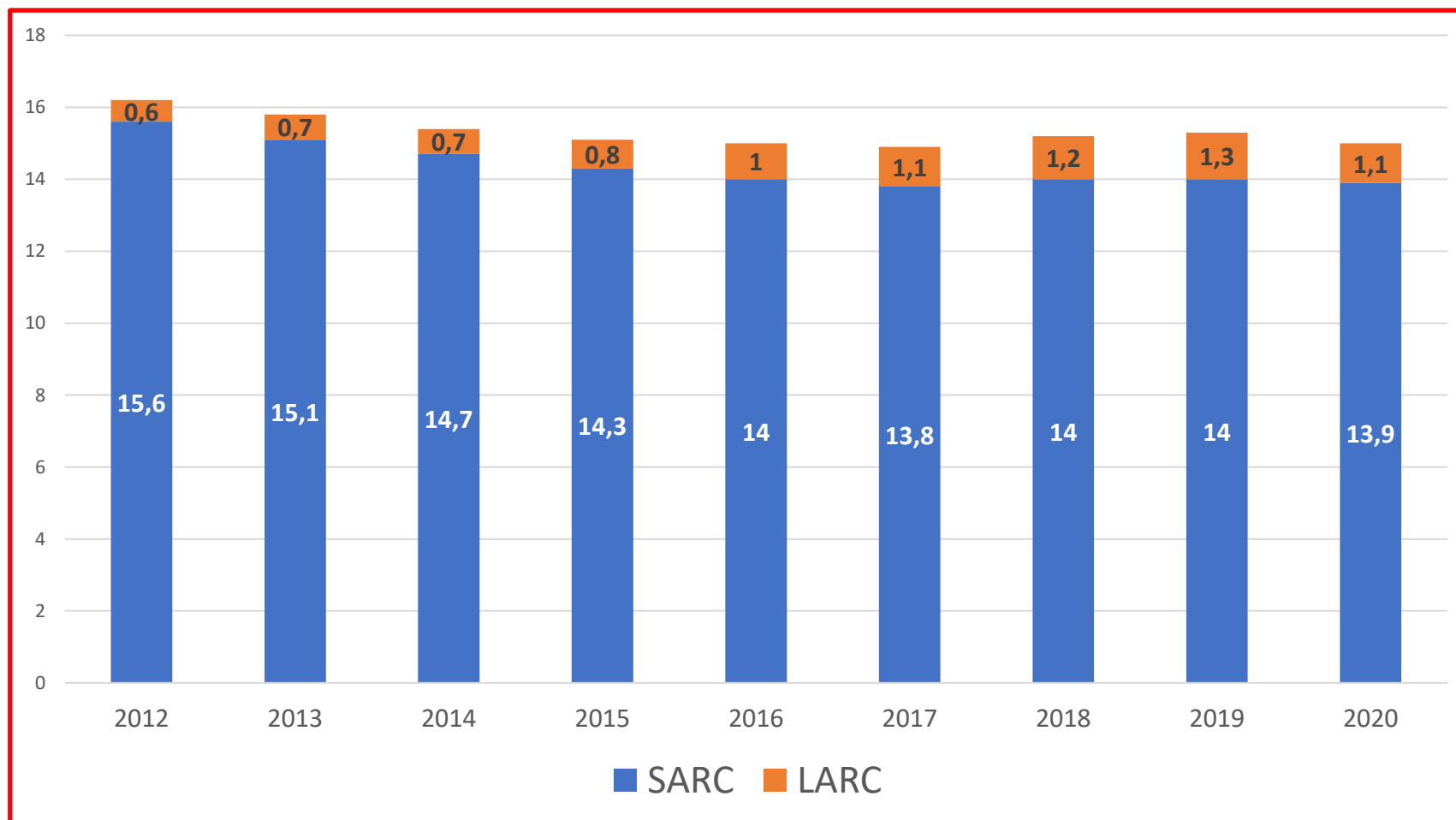


Table 1  
Trends in contraceptive use and method mix between 2008, 2012 and 2014 among all women ages 15–44, women at risk of unintended pregnancy and contraceptive users

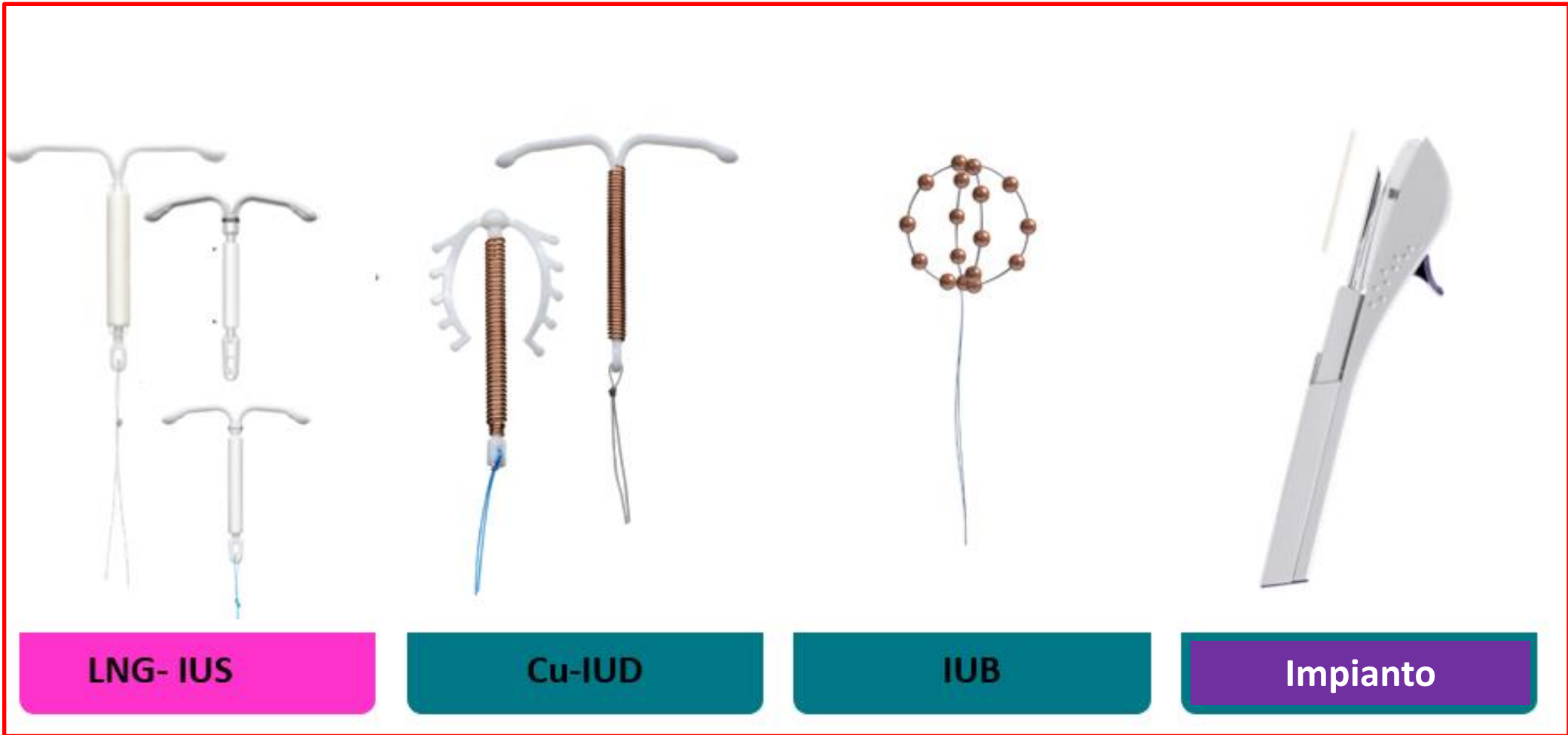
	2008 (n=12,279 weighted n=61,754,741)	2012 (n=5601 weighted n=60,887,363)	2014 (n=5699 weighted n=61,491,766)	% point change 2012–2014	p value 2012–2014	% point change 2008–2014	p value 2008–2014
Among all women							
Currently using a method	62.2	61.7	61.4	−0.3	.843	−0.7	.558
Not using a method	37.8	38.3	38.6	0.3	.843	0.7	.558
Among women at risk of unintended pregnancy <sup>a</sup>							
Currently using a method	89.0	90.0	89.6	−0.5	.607	0.6	.539
Not using a method	11.0	10.0	10.5	0.5	.607	−0.6	.539
Among contraceptive users, percent using each method							
Most or moderately effective methods	76.6	77.9	74.4	−3.5	.028	−2.2	.107
Sterilization	36.6	33.3	28.2	−5.1	.013	−8.4	<.001
Female sterilization	26.6	25.1	21.8	−3.4	.093	−4.8	.008
Male Sterilization	10.0	8.2	6.5	−1.7	.068	−3.6	<.001
LARC methods	6.0	11.6	14.3	2.7	.042	8.3	<.001
IUD	5.6	10.3	11.8	1.5	.231	6.2	<.001
Implant	0.5	1.3	2.6	1.2	.012	2.1	<.001
Moderately effective hormonal methods	34.0	33.0	31.8	−1.1	.537	−2.1	.165
Pill	27.5	25.9	25.3	−0.5	.774	−2.1	.191
Other hormonal methods (patch, ring, injectables)	6.5	7.1	6.5	−0.6	.458	0.0	.982
Coital methods	23.0	21.7	25.1	3.3	.036	2.1	.131
Condom	16.3	15.3	14.6	−0.7	.603	−1.8	.142
Withdrawal	5.2	4.8	8.1	3.2	<.001	2.9	.001
Natural family planning	1.1	1.4	2.2	0.8	.058	1.0	.009
Other methods <sup>b</sup>	0.4	0.4	0.6	0.3	.270	0.2	.416



# ...in Italia

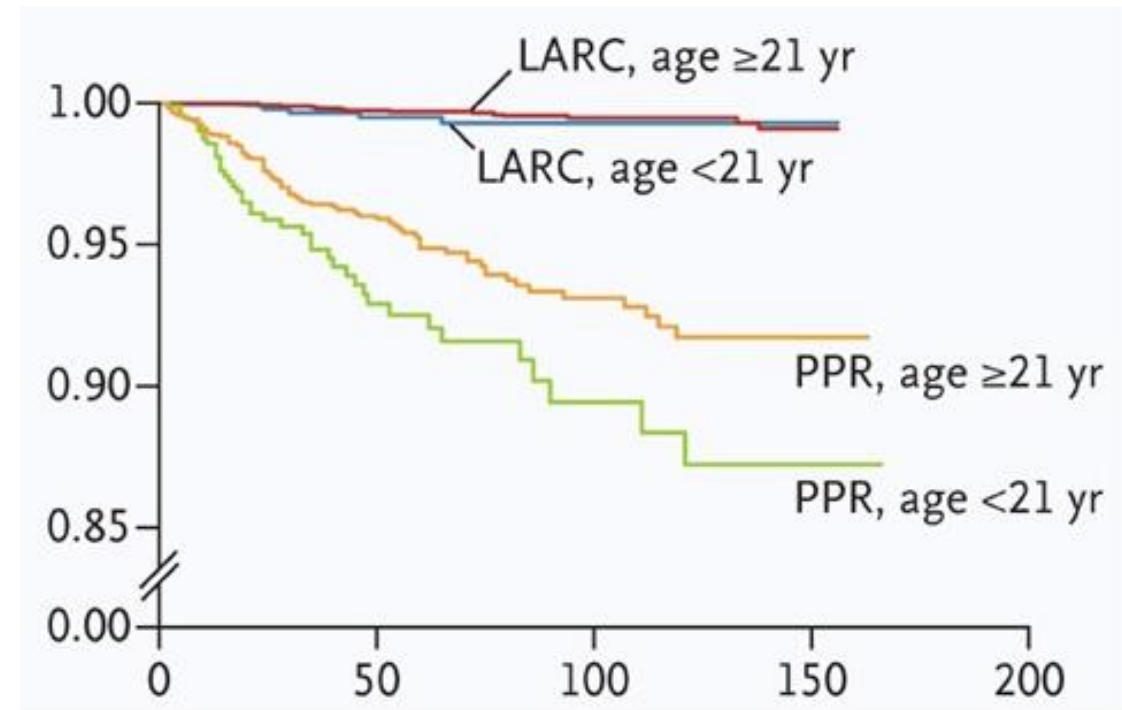
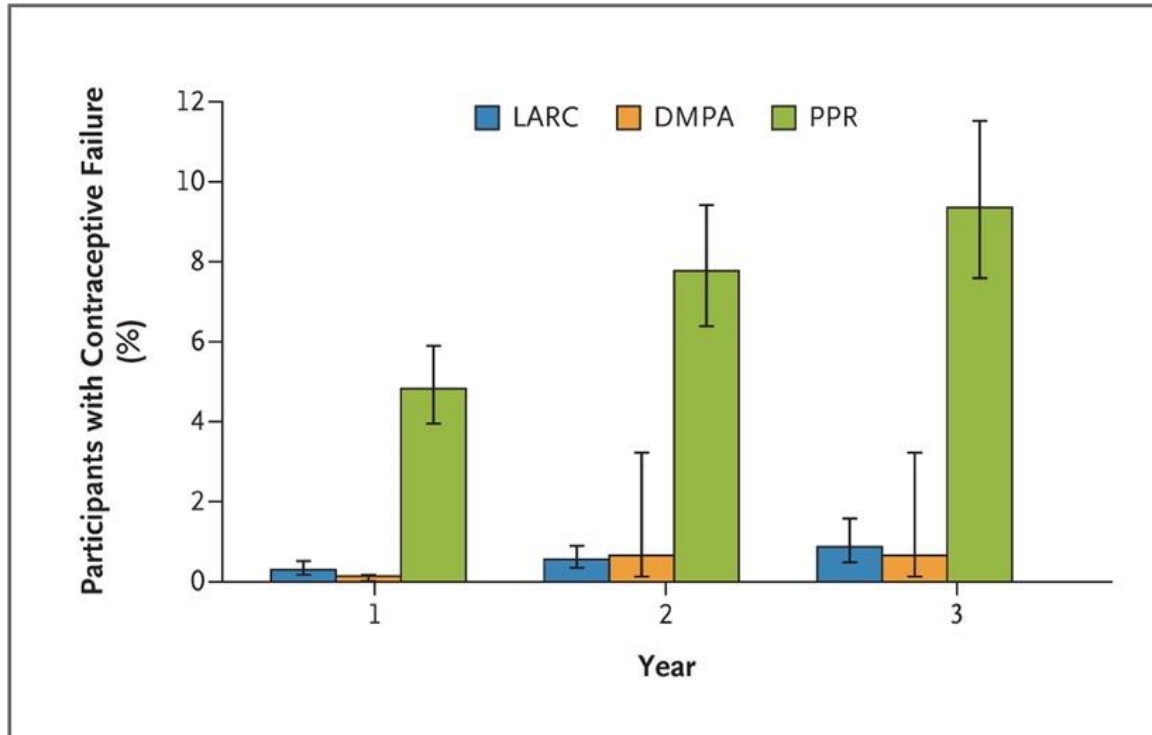


# LARCs oggi





Le donne che usano i SARC hanno **un aumento di 20 volte dei tassi di gravidanza indesiderata** rispetto a quelle che usano i LARC



**...la differenza si vede soprattutto nelle ragazze più giovani di 21 anni.**





# Contraceptive Effectiveness

Rates of Unintended Pregnancies per 100 Women

Family planning method	First-Year Pregnancy Rate <sup>a</sup> (Trussell & Aiken <sup>b</sup> )		12-Month Pregnancy Rate <sup>c</sup> (Polis et al. <sup>d</sup> )	Key
	Consistent and correct use	As commonly used	As commonly used	
Implants	0.1	0.1	0.6	0–0.9
Vasectomy	0.1	0.15		Very effective
Female sterilization	0.5	0.5		
Levonorgestrel IUD	0.5	0.7		1–9
Copper-bearing IUD	0.6	0.8	1.4	Effective
LAM (for 6 months)	0.9 <sup>e</sup>	2 <sup>e</sup>		
Monthly injectable	0.05 <sup>e</sup>	3 <sup>e</sup>		10–19
Progestin-only injectable	0.2	4	1.7	Moderately effective
Combined oral contraceptives	0.3	7	5.5	
Progestin-only pills	0.3	7		
Combined patch	0.3	7		20+
Combined vaginal ring	0.3	7		Less effective
Male condoms	2	13	5.4	
Standard Days Method	5	12		
TwoDay Method	4	14		
Ovulation method	3	23		
Other fertility awareness methods		15		
Diaphragms with spermicide	16	17		
Withdrawal	4	20	13.4	
Female condoms	5	21		
Spermicide	16	21		
Cervical cap <sup>f</sup>	26 <sup>g</sup> , 9 <sup>h</sup>	32 <sup>g</sup> , 16 <sup>h</sup>		
No method	85	85		

<sup>a</sup> Rates largely from the United States. Data from best available source as determined by authors.  
<sup>b</sup> Trussell J and Aiken ARA, Contraceptive efficacy. In: Hatcher RA et al. Contraceptive Technology, 21st revised edition. New York, Ardent Media, 2018.  
<sup>c</sup> Rates from developing countries. Data from self-reports in population-based surveys.  
<sup>d</sup> Polis CB et al. Contraceptive failure rates in the developing world: an analysis of Demographic and Health Survey data in 43 countries. New York: Guttmacher Institute. 2016.

Impianto: il metodo contraccettivo più efficace



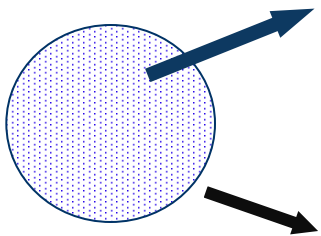
# Impianto sottocutaneo: com'è fatto?

Efficacia per 3 anni.

Dispositivo sottocute contenente 68 mg di etonogestrel, metabolita applicatore monouso.



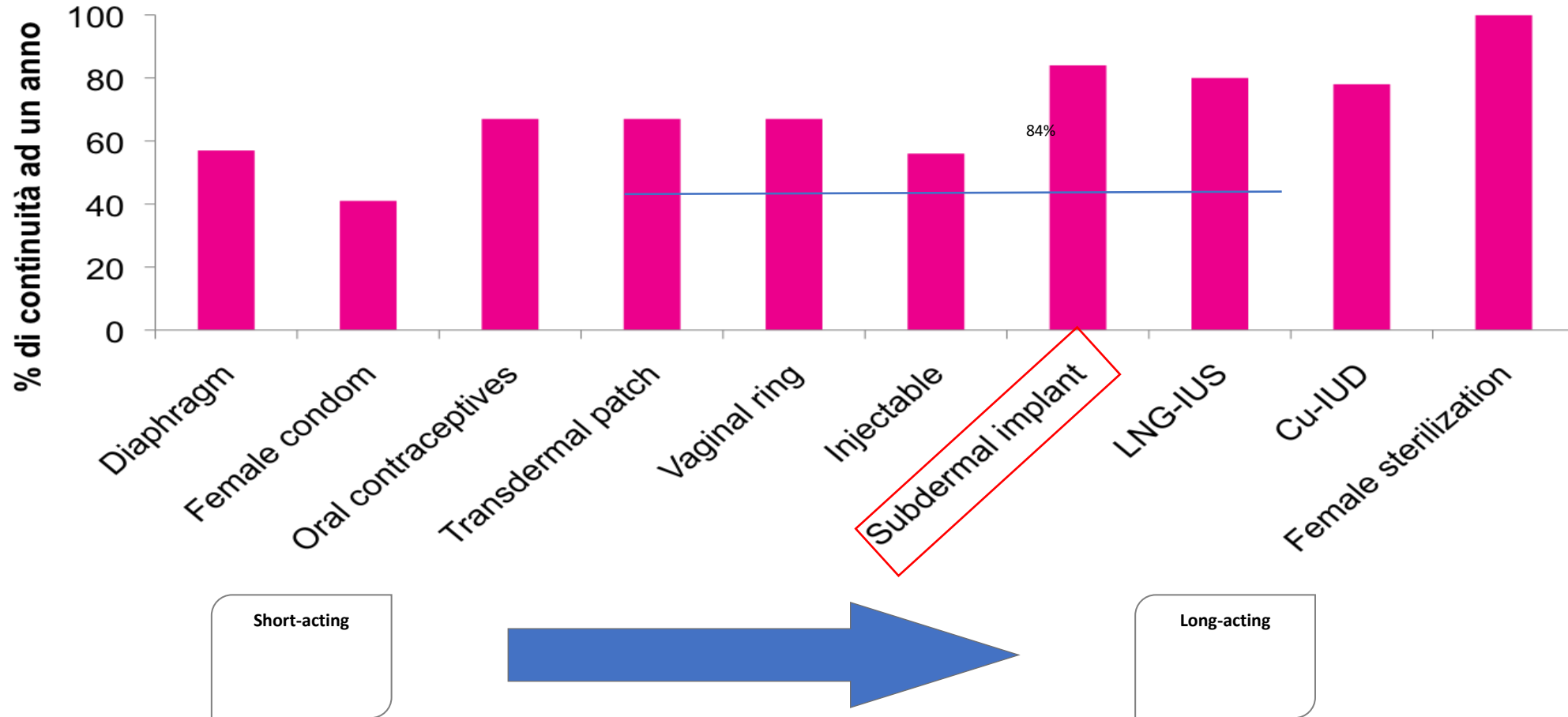
- Core:
- 37% ethylene vinyl acetate (EVA) copolymer
  - 60% etonogestrel (68 mg)
  - 3% barium sulfate (15 mg)



Rate-controlling membrane: (0.06 mm)  
100% EVA



# Impianto: il metodo reversibile **più continuato**



# Indicazioni di uso – opportunità di uso!

Post parto  
Durante l'allattamento

Secondo le linee guida  
FSRH (UK), l'inserimento  
dell'impianto dopo il parto  
è sicuro e altamente  
accettato dalle donne

L'impianto non influenza la produzione o la qualità del latte  
materno.



# Indicazioni di uso – opportunità di uso!

Donne affette da emicrania

Raccomandazioni secondo categorie MEC per l'eleggibilità dell'impianto sottocutaneo nelle donne affette da cefalea o emicrania



MAL DI TESTA	I	C
Cefalea (lieve o severa)	1	1
Emicrania (senza aura, età < 35 anni)	2	2
Emicrania (senza aura, età ≥ 35 anni)	2	2
Emicrania (con aura, a qualsiasi età)	2	3

*Classificazione valida solo in donne che non hanno nessun altro fattore di rischio per ictus*

## Categorie MEC per l'eleggibilità dei contraccettivi

**1** = Condizione per la quale non vi è alcuna restrizione all'uso del metodo contraccettivo.

**2** = Una condizione in cui i vantaggi dell'utilizzo del metodo contraccettivo generalmente superano i rischi teorici o comprovati.

**3** = Una condizione in cui i rischi teorici o comprovati superano di solito i vantaggi dell'uso del metodo.

**4** = Una condizione che rappresenta un rischio inaccettabile per la salute se il metodo contraccettivo viene utilizzato.

**I**, inizio; **C**, continuazione.



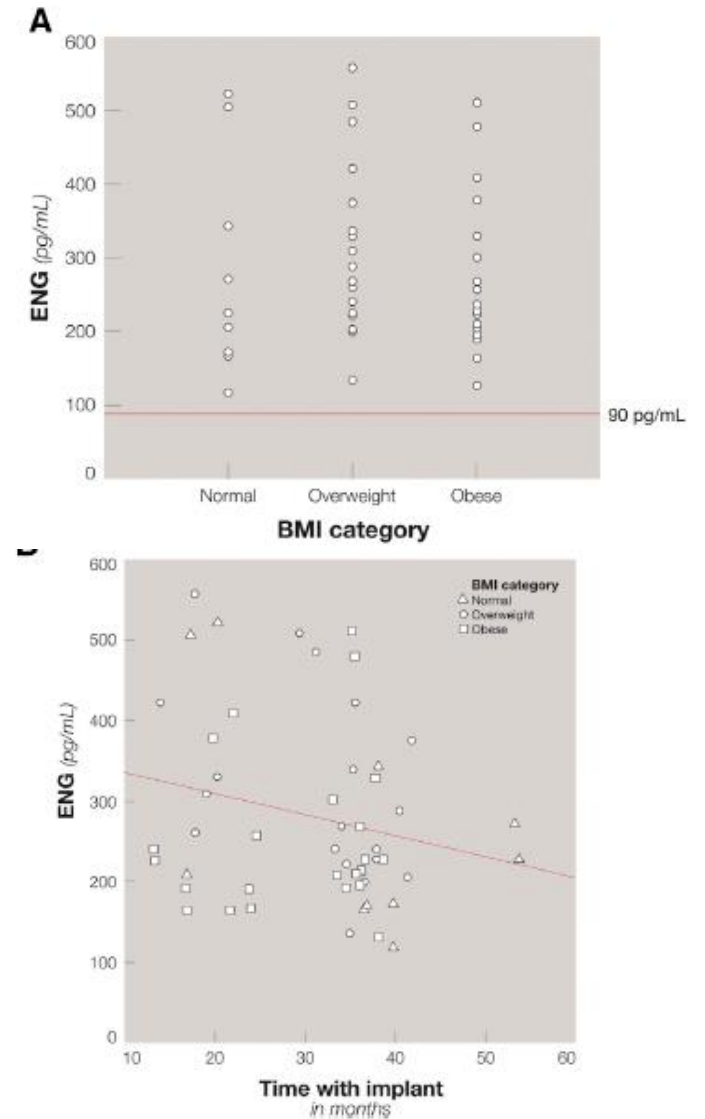
# Indicazioni di uso – opportunità di uso!

## Donne obese

In questo studio i livelli di etonogestrel si sono mantenuti sopra alla soglia minima per inibire l'ovulazione, per tre anni, in donne normopeso (IMC < 25 kg/m<sup>2</sup>), sovrappeso (IMC ≥ 25 and < 30 kg/m<sup>2</sup>) e obese (IMC ≥ 30 kg/m<sup>2</sup>)

Table 1  
Participant characteristics by BMI category.

	Normal (n=10)	Overweight (n=19)	Obese (n=22)
Age			
Median	27 {21–32}	29 {20–43}	27 {18–44}
Race			
Non-Hispanic white	0	3	1
Hispanic	8	16	21
African-American	2	0	1
Gravidity			
Median {range}	4 {1–7}	3 {0–15}	3 {0–11}
Parity			
Median {range}	2 {0–4}	1 {0–5}	1 {0–6}
Time since insertion (months)			
Median	38	35	34
Range	{17–54}	{14–42}	{13–39}
BMI			
Median	23	27	35
Range	{21–25}	{25–29}	{31–56}
ENG (pg/mL)			
Median	216	288	225
Range	{117–523}	{134–558}	{128–511}





# Indicazioni di uso – opportunità di uso!

Post L.194/78

Post aborto chirurgico e farmacologico

- Nella IVG sottocutanea immediata
- Nella IVG inseriti dopo aborto.
- Nella IVG può essere del misoprostolo

## 12.4 Starting the etonogestrel implant after **abortion**

The ENG-IMP can be safely started at any time after medical or surgical **abortion**.<sup>49</sup> The evidence indicates that the ENG-IMP can be inserted at the time of mifepristone administration without affecting the effectiveness of medical **abortion**.<sup>49</sup> If the ENG-IMP is initiated at the time of **abortion** or within 5 days after **abortion** it will be effective immediately with no requirement for additional contraception. If quick started thereafter, risk of existing pregnancy should be assessed prior to insertion and additional contraception (eg, condom use) is required for 7 days after insertion. See FSRH Clinical Guideline **Contraception After Pregnancy**<sup>49</sup> and also **Table 2**.

**L'ETN rilasciato dall'impianto sottocutaneo non interferisce con l'azione antagonista del mifepristone; si raccomanda pertanto di inserire l'impianto sottocutaneo al momento della somministrazione del mifepristone**



## FSRH Guideline Progestogen-only Implant







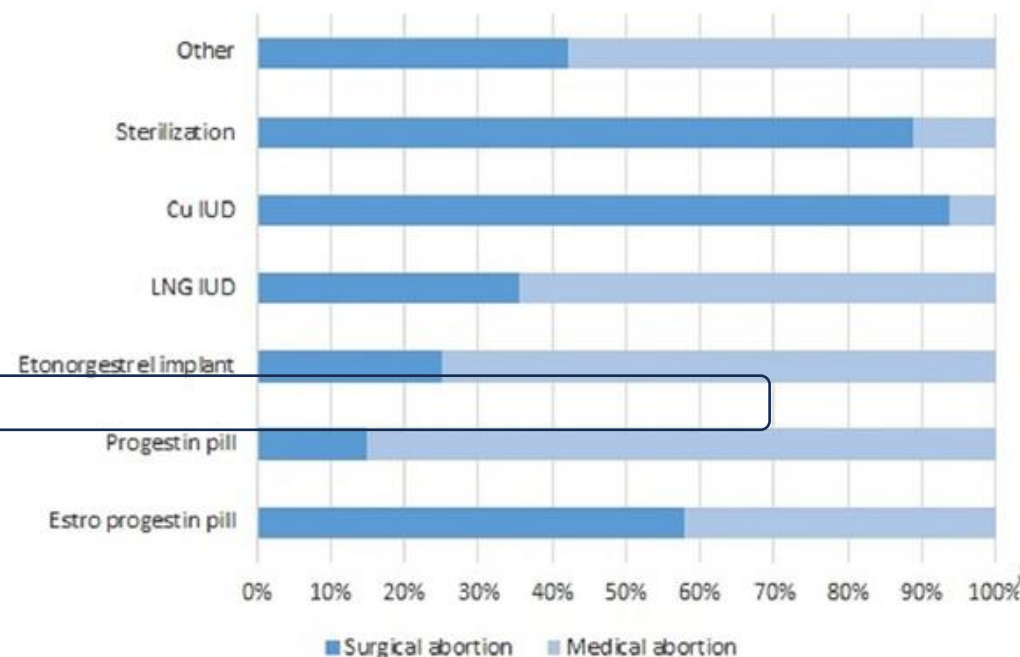
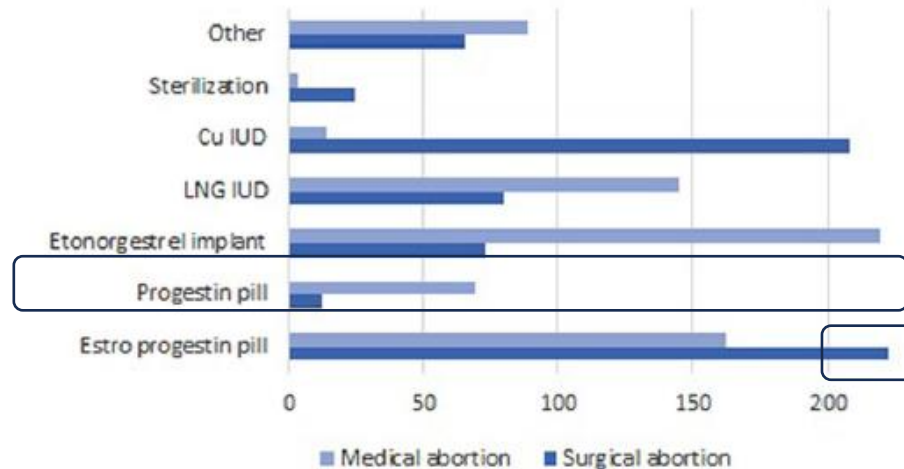
## The contraceptive choice at the time of a surgical and pharmacological abortion: a possible and effective option thanks to a dedicate counselling

Paola Algeri, Laura Colonna, Vanda Savoldi, Laura Imbruglia, Nunzia Mastrocola & Silvia Von Wunster

To cite this article: Paola Algeri, Laura Colonna, Vanda Savoldi, Laura Imbruglia, Nunzia Mastrocola & Silvia Von Wunster (2023): The contraceptive choice at the time of a surgical and pharmacological abortion: a possible and effective option thanks to a dedicate

Since the beginning of the study in 2013, we saw an **increment of LARC choice from 20% in 2010 to over 50% in 2013** when we started to perform a dedicate contraceptive counselling and all LARC methods were all available at purchase cost, at the time of abortion.

Absolute number

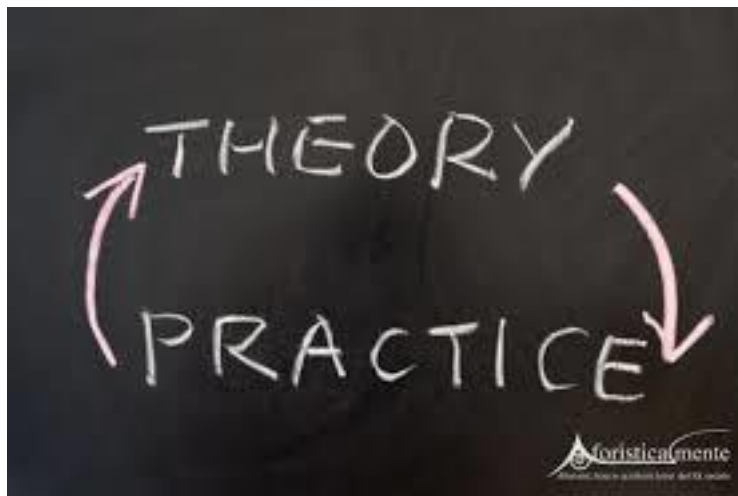


# Quando lo mettiamo?



L'IMPIANTO è efficace da subito se inserito nel timing raccomandato

Metodo precedente	Timing di inserimento
Nessuno	Giorno 1-5 del ciclo
Metodo combinato (COC, cerotto, anello)	Durante l'intervallo libero
POP – Progestogen Only Pill (DSG 75 mcg, DRSP 4 mg 24+4)	In qualunque momento
Impianto/IUS	Nello stesso giorno della rimozione
<b>Aborto del primo e secondo trimestre</b>	<b>Nello stesso giorno</b>
<b>Parto</b>	<b>Fin dalle prime ore del puerperio</b>



# Inserimento e Rimozione: è tutto semplice!

## Inserimento

- Procedura semplice e ambulatoriale<sup>2</sup>
- Durata media: **51 secondi**<sup>2</sup>
- Basso livello di fastidio per le donne<sup>3</sup>

## Rimozione

- Nel 99,6% dei casi l'impianto è palpabile e la rimozione è molto agevole<sup>4</sup>
- Durata media: **meno di 2 minuti**<sup>1</sup>

1. Rocca ML, et al. Pharmaceuticals (Basel). 2021;14(6):548  
2. Meirik O et al, Contraception. 2103;87:113-120.  
3. Bentsianov SD et al, J Pediatr Adolesc Gynecol. 2021;34:522–524.  
4. Reed S et al, Contraception. 2019;100(1):31-36.

# Il materiale necessario

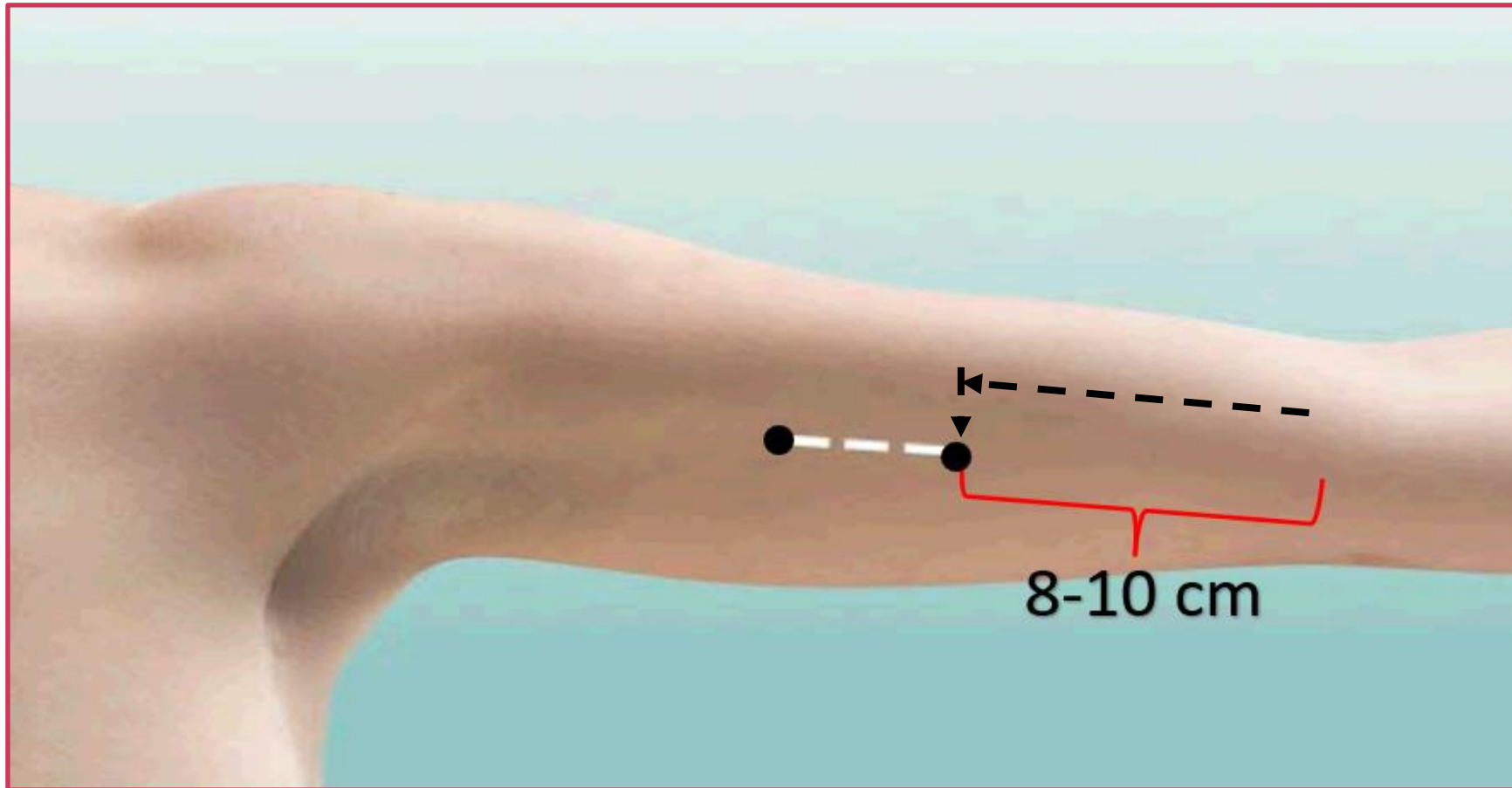
## Inserimento



## Rimozione



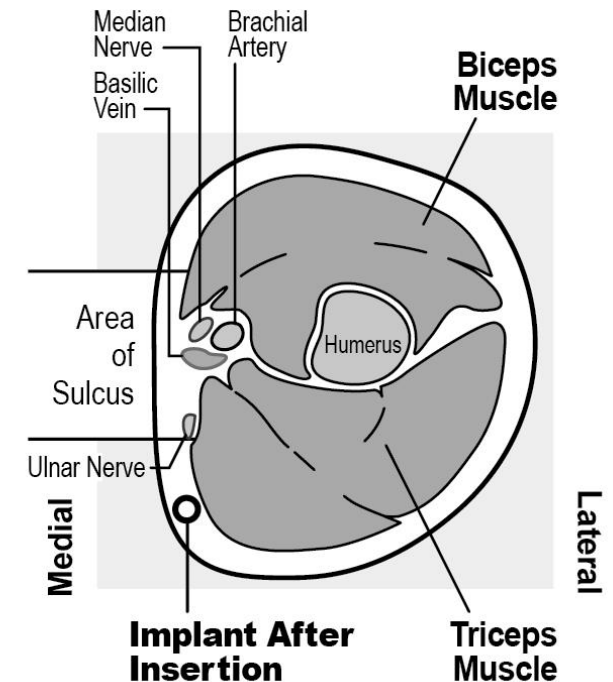
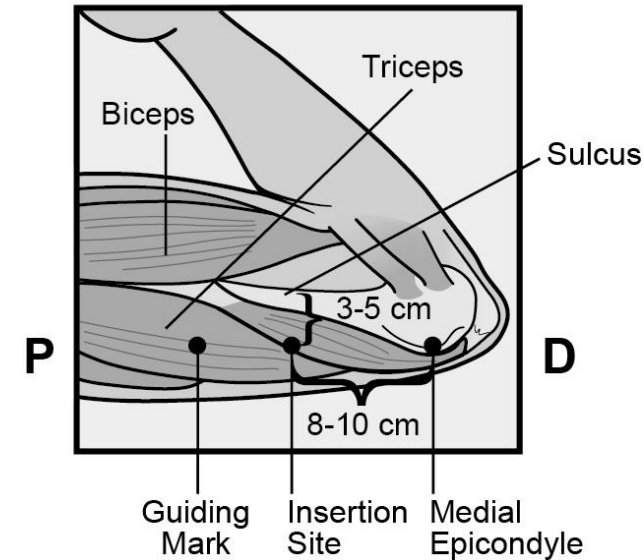
Posizione: Braccio non dominante, circa **8-10 cm** dall'epicondilo mediale dell'omero e **3-5 cm** posteriormente al solco (sulcus) tra i muscoli bicipite e tricipite





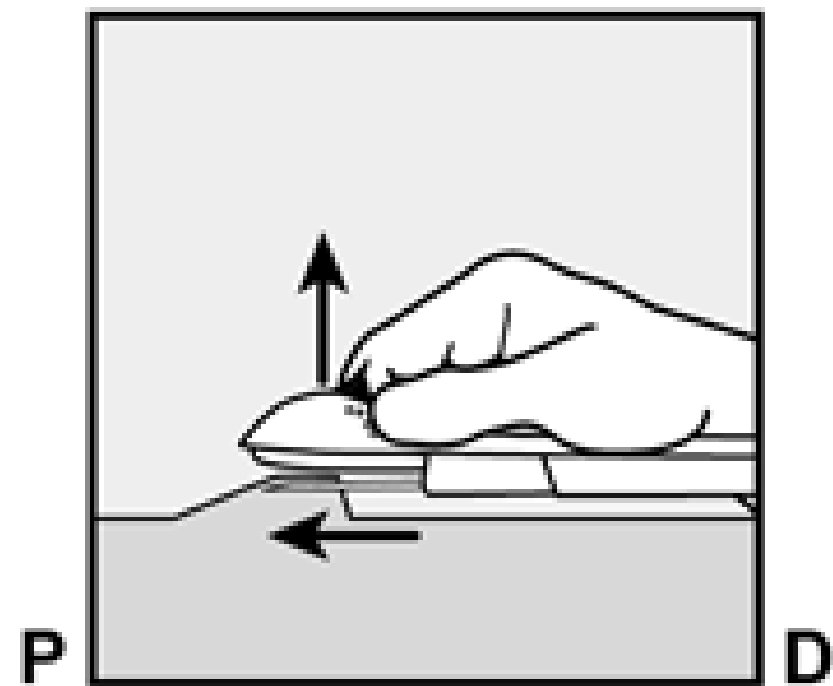
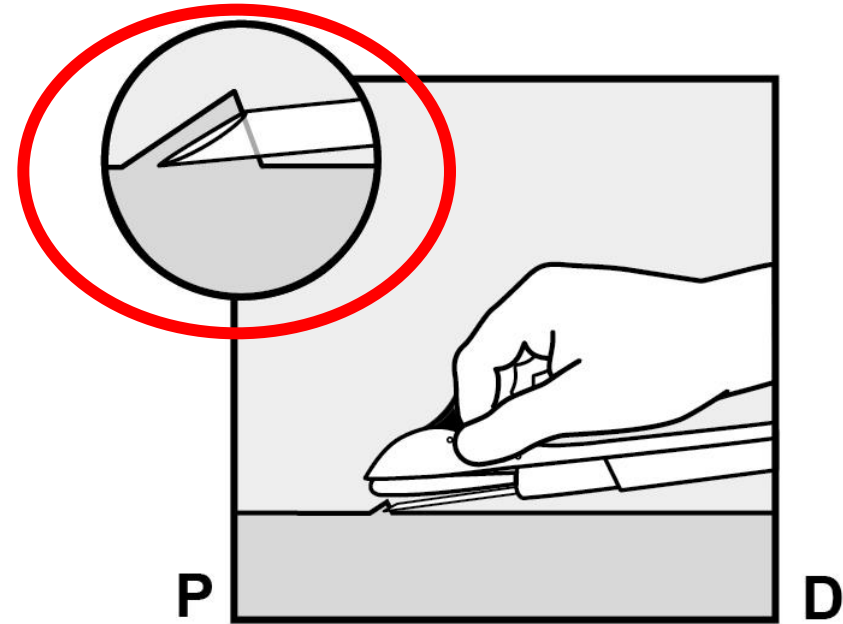
# Posizione corretta

- Identificare il sito di inserimento, che si trova sul lato interno del braccio non dominante.
- Il sito di inserzione sovrasta il muscolo tricipite a circa 8-10 cm dall'epicondilo mediale dell'omero e 3-5 cm posteriormente al solco (sulcus) tra i muscoli bicipite e tricipite
- **Questa posizione ha lo scopo di evitare i grandi vasi sanguigni e i nervi che si trovano all'interno e intorno al solco.** Se non è possibile inserire l'impianto in questa posizione (ad es. nelle donne con braccia molto magre), deve essere inserito il più lontano possibile dal solco
- **L'impianto deve essere inserito sottocute appena sotto la pelle.**



# Una volta inserito l'ago... **tirare sù**

1. Inserire l'ago fino a quando la smussatura (apertura inclinata della punta) è appena sotto la pelle (e non oltre). Se si inserisce l'ago oltre lo smusso, estrarlo fino a quando solo lo smusso si trova sotto la pelle.
2. Abbassare l'applicatore in una posizione quasi orizzontale.
3. **Per facilitare il posizionamento sottocutaneo, sollevare la pelle con l'ago mentre si fa scorrere l'ago per tutta la sua lunghezza.**
4. Potresti sentire una leggera resistenza ma non esercitare una forza eccessiva.
5. Se l'ago non è inserito per tutta la sua lunghezza, l'impianto non verrà inserito correttamente.
6. Se la punta dell'ago fuoriesce dalla pelle prima che l'inserimento dell'ago sia completo (**evenienza pressochè impossibile**), l'ago deve essere tirato indietro ed essere regolato nella posizione inferiore prima di completare la procedura di inserimento.

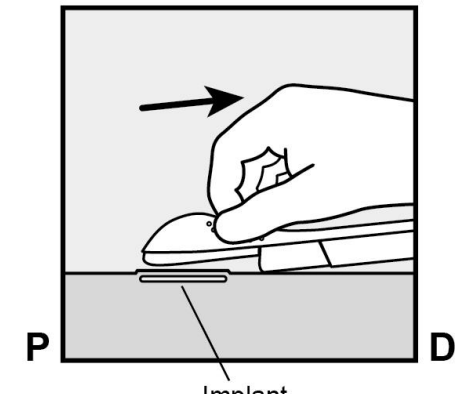
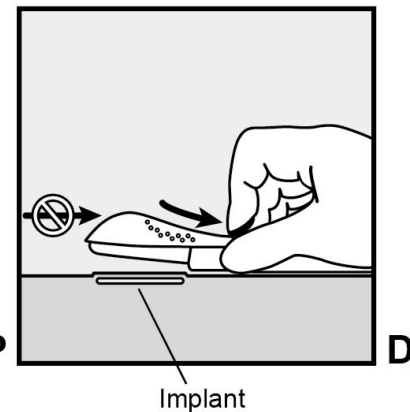
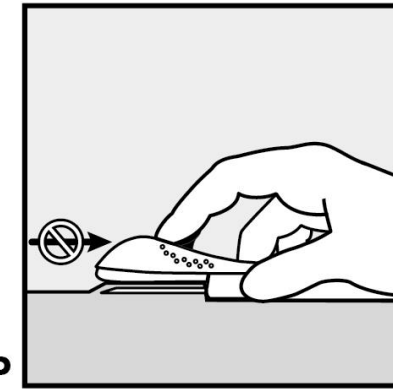
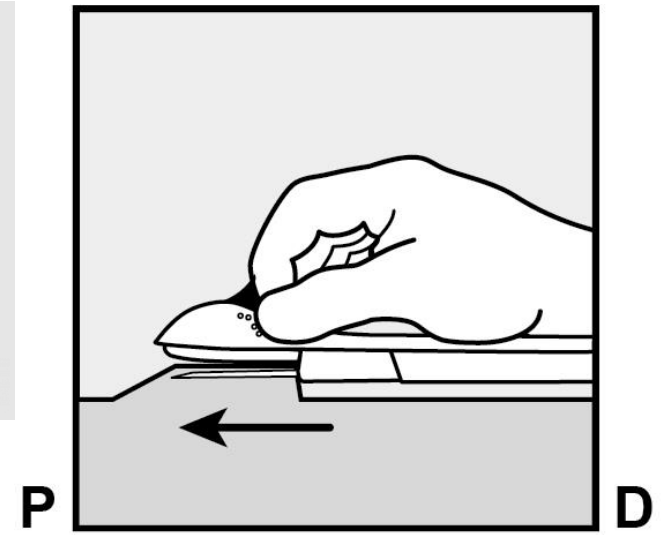




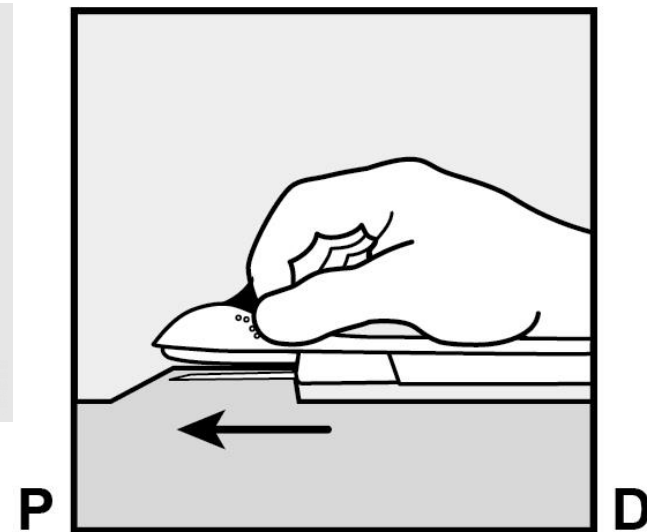
# Ci siamo quasi....



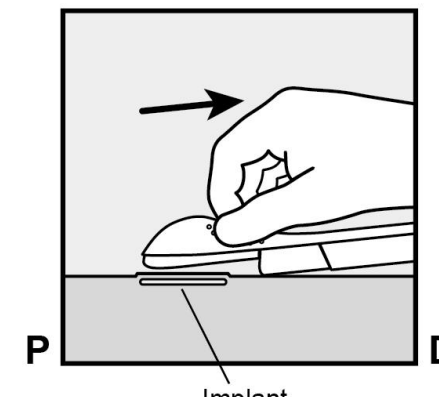
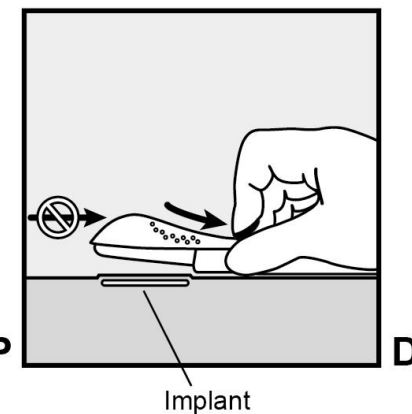
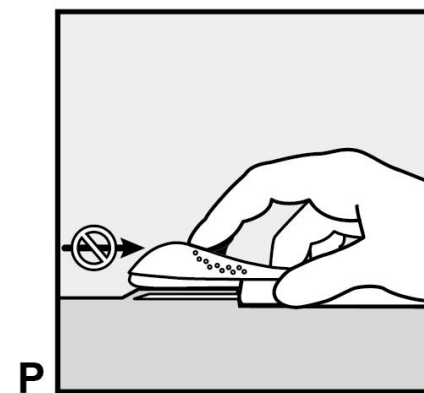
- Mantenere l'applicatore nella stessa posizione con l'ago inserito per tutta la sua lunghezza. Se necessario, è possibile utilizzare la mano libera per stabilizzare l'applicatore.
- Sblocca il cursore viola spingendolo leggermente verso il basso.
- Sposta il cursore completamente indietro fino a quando non si ferma.
- **Non spostare l'applicatore mentre si sposta il cursore viola.**
- L'impianto è ora nella sua posizione subdermica finale e l'ago è bloccato all'interno del corpo dell'applicatore.
- Ora l'applicatore può essere rimosso.



# Ci siamo quasi....



# Vediamo meglio....



# Eventi associati a inserimento e rimozione sono rari – Studio Real Life su 7.364 inserimenti e 5.159 rimozioni

Complicanze associate ad inserimento e rimozione di Nexplanon sono rare

**Table 2**

Insertion-related challenges reported by HCPs immediately after the Nexplanon insertion procedure: Numbers and incidence proportions per 1000 insertions (and 95% CIs)

	No. Insertions (N=7364)	Incidence proportion per 1000 insertions	95% CI
Difficulty removing the protection cap	93	12.6	10.2–15.4
Difficulty sliding the needle to its full length into the skin	30	4.1	2.8–5.8
Needle stick injury (to the HCP)	1	0.1	0.0–0.8
Difficulty unlocking the purple slider	6	0.8	0.3–1.8
Needle inserted too deep	2	0.3	0.0–1.0
Difficulty moving purple slider fully to the back	14	1.9	1.0–3.2
Needle inserted too superficially	1	0.1	0.0–0.8
Needle visible after insertion ( not fully retracted)	4	0.5	0.1–1.4
Other	29	3.9	2.6–5.7
Difficulty handling the device/visualization	17	2.3	1.4–3.7
Reaction at the insertion site	5	0.7	0.2–1.6
Difficulty penetrating the skin with the needle	3	0.4	0.1–1.2
Patient reaction to insertion procedure	4	0.5	0.2–1.4

# Complicanze associate ad inserimento e rimozione di Nexplanon sono rare

**Table 5**

Challenges encountered by HCPs during the Nexplanon removal procedure: Numbers and incidence proportions per 1000 removal procedures (and 95% CIs) by user status

	First-time users (N=3881)			Repeat/consecutive users (N=492)			All users (N=4373)		
	n	IP <sup>a</sup>	95% CI	n	IP <sup>a</sup>	95% CI	n	IP <sup>a</sup>	95% CI
Any event <sup>b</sup>	49	12.6	9.4–16.7	11	22.3	11.2–39.6	60	13.7	10.5–17.6
Encased in fibrotic tissue	22	5.7	3.6–8.6	7	14.2	5.7–29.0	29	6.6	4.4–9.5
Multiple attempts required	12	3.1	1.6–5.4	1	2.0	0.1–11.3	13	3.0	1.6–5.1
Implant too deep	7	1.8	0.7–3.7	4	8.1	2.2–20.6	11	2.5	1.3–4.5
Implant migrated	4	1.0	0.3–2.6	2	4.1	0.5–14.6	6	1.4	0.5–3.0
Other	12	3.1	1.6–5.4	2	4.1	0.5–14.6	14	3.2	1.8–5.4

<sup>a</sup> Incidence proportion per 1000 removals.

<sup>b</sup> Limited to one event per removal procedure.

# Consuelling con la paziente...

1095 pillole in tre anni,  
da assumere  
sempre alla stessa ora

1095 pillole  
in totale\*



1 impianto, bastoncino  
**efficace fino a 3 anni**  
che non richiede  
somministrazione quotidiana





# Pattern mestruale: Importanza del counseling

[Eur J Contracept Reprod Health Care](#). 2008 Jun;13 Suppl 1:13-28. doi: 10.1080/13625180801959931.

## The effects of Implanon on menstrual bleeding patterns.

[Mansour D<sup>1</sup>](#), [Korver T](#), [Marintcheva-Petrova M](#), [Fraser IS](#).

[Open/close author information list](#)

[+ Author information](#)

### Abstract

**OBJECTIVES:** To evaluate an integrated analysis of bleeding patterns associated with use of the subdermal contraceptive implant Implanon (etonogestrel, Organon, part of Schering-Plough) and to provide physician guidance to optimize patient counselling.

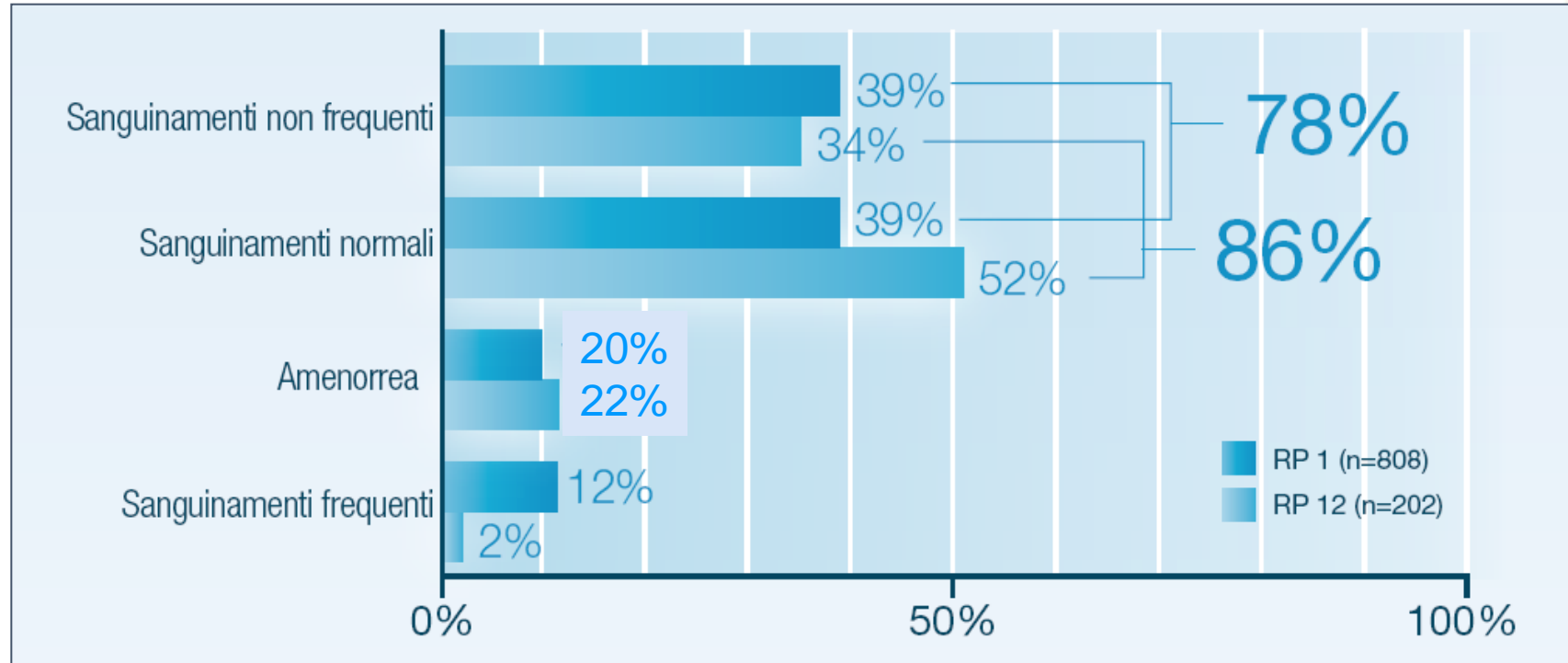
**METHODS:** Data from 11 clinical trials were reviewed (N = 923). Assessments included bleeding-spotting records, dysmenorrhoea, and patient-perceived reasons for discontinuation. Bleeding patterns were analysed via reference period (RP) analyses.

**RESULTS:** Implanon use was associated with the following bleeding irregularities: amenorrhoea (22.2%) and infrequent (33.6%), frequent (6.7%), and/or prolonged bleeding (17.7%). In 75% of RPs, bleeding-spotting days were fewer than or comparable to those observed during the natural cycle, but they occurred at unpredictable intervals. The bleeding pattern experienced during the initial phase predicted future patterns for the majority of women. The group of women with favourable bleeding patterns during the first three months tended to continue with this pattern throughout the first two years of use, whereas the group with unfavourable initial patterns had at least a 50% chance that the pattern would improve. Only 11.3% of patients discontinued owing to bleeding irregularities, mainly because of prolonged flow and frequent irregular bleeding. Most women (77%) who had baseline dysmenorrhoea experienced complete resolution of symptoms.

**CONCLUSION:** Implanon use is associated with an unpredictable bleeding pattern, which includes amenorrhoea and infrequent, frequent, and/or prolonged bleeding. The bleeding pattern experienced during the first three months is broadly predictive of future bleeding patterns for many women. Effective preinsertion counselling on the possible changes in bleeding patterns may improve continuation rates.

Mansour D et al, European Journal of Contraception and Reproductive Health Care 2008; 13 Suppl 1:13-28.

# Pattern mestruale: migliora col tempo...





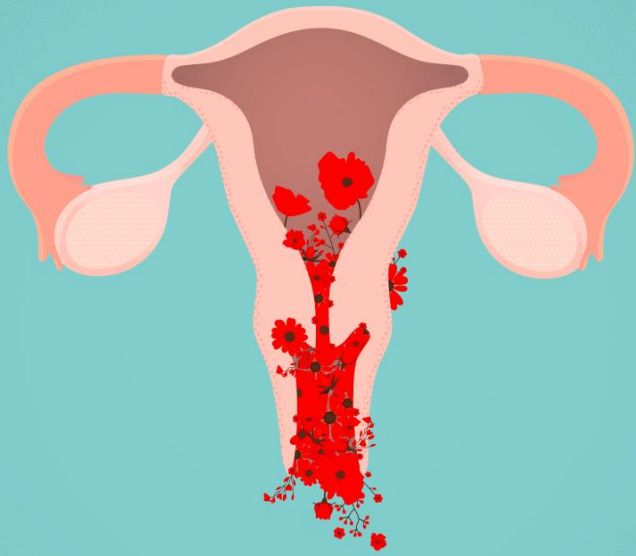
# Dati italiani



Table 1. Bleeding profile of total population during 12 months of treatment.

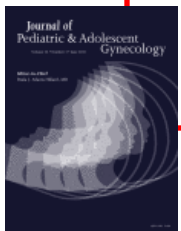
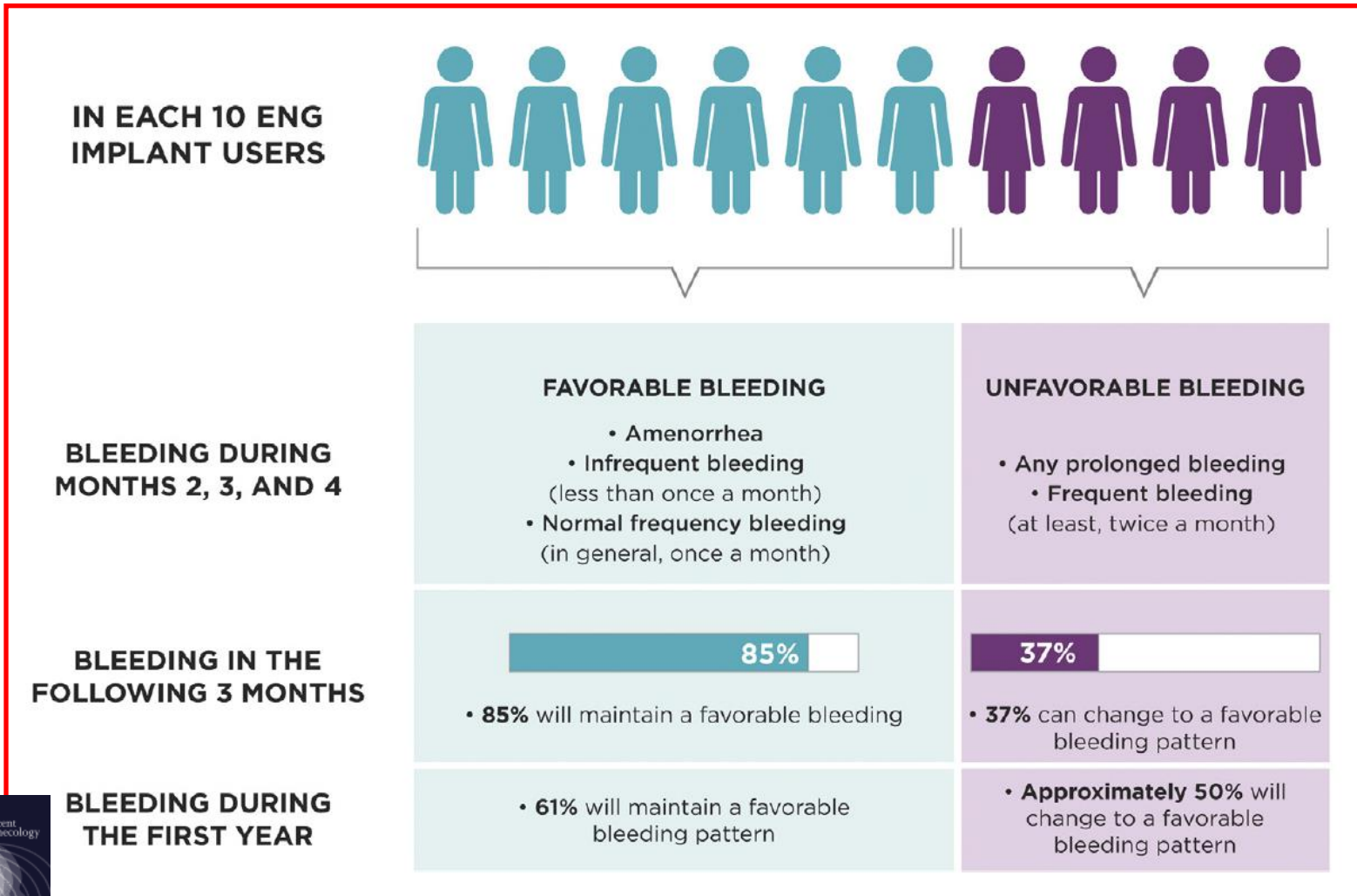
Bleeding profile	RP1 ( <i>N</i> = 86)	RP2 ( <i>N</i> = 86)	RP3 ( <i>N</i> = 80)	RP4 ( <i>N</i> = 78)
Amenorrhea	60 (69.8)	22 (25.6)	22 (27.5)	22 (28.2)
Infrequent bleeding	8 (9.3)	32 (37.2)	16 (20.0)	28 (35.9)
Normal bleeding	2 (2.3)	12 (14.0)	28 (35.0)	18 (23.1)
Frequent bleeding	14 (16.3)	14 (16.3)	8 (10.0)	8 (10.3)
Prolonged bleeding	2 (2.3)	6 (7.0)	6 (7.5)	2 (2.6)

Values are given as *n* (%). RP, reference period. Bleeding patterns were defined per 90-d periods from the implant placement to 12 months.



Unscheduled bleeding durante  
impianto

# Counselling nell'adolescente



Berlan ED et al,  
J Pediatric Adolesc Gynecol 2020;33:448-454

With courtesy G. Grandi

# Eventi avversi più riportati

Adverse event	Implanon, all studies† (N = 889)	
	Drug related	Total
Acne	15.3	16.1
Breast pain	9.1	10.6
Headache	8.5	12.9
Weight increase	6.4	7.1
Abdominal pain	4.3	8.1
Libido decrease	2.9	3.0
Dizziness	2.9	4.3
Injection site pain	2.6	2.8
Emotional lability	2.5	2.7
Influenza-like symptoms	2.1	6.9
Nausea	2.0	3.6



Urbancsek J. Contraception 1998, 58:109S-15S

With courtesy G. Grandi





# Continuiamo ...LARC<sub>s</sub> oggi



# Gynaecological procedures and associated pain



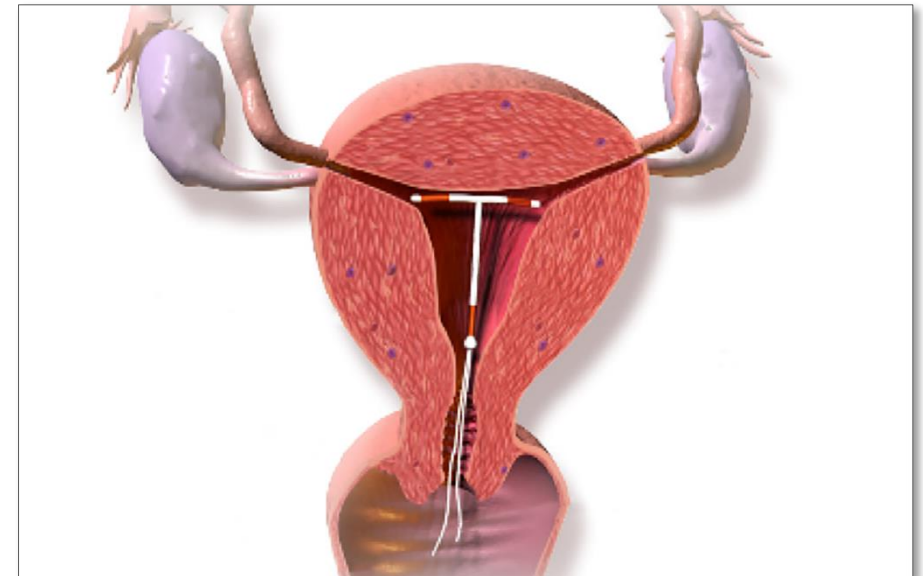


# IUC insertion is a common gynaecological procedure that is becoming more popular

- IUCs are long lasting
  - Long-acting reversible contraception (LARC) methods, such as IUDs are very effective because the woman does not have to remember to take or use contraception
  - Depending on the type of device, they can be effective for between 3 years and 10 years
- IUCs are low maintenance
  - Does not require the user to do anything once the device is inserted — can “fit and forget”
- Enhanced compliance for patients vs. ‘the pill’
  - Lower pregnancy rates compared to oral contraceptives
- Low frequency of side effects
  - Hormonal IUDs have lower exposure to hormones compared to oral contraceptives

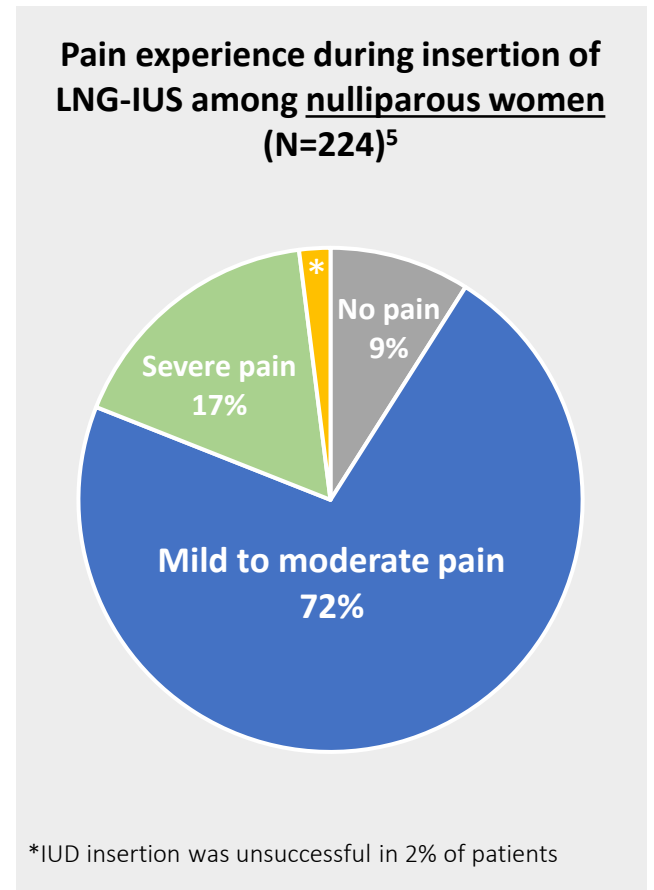
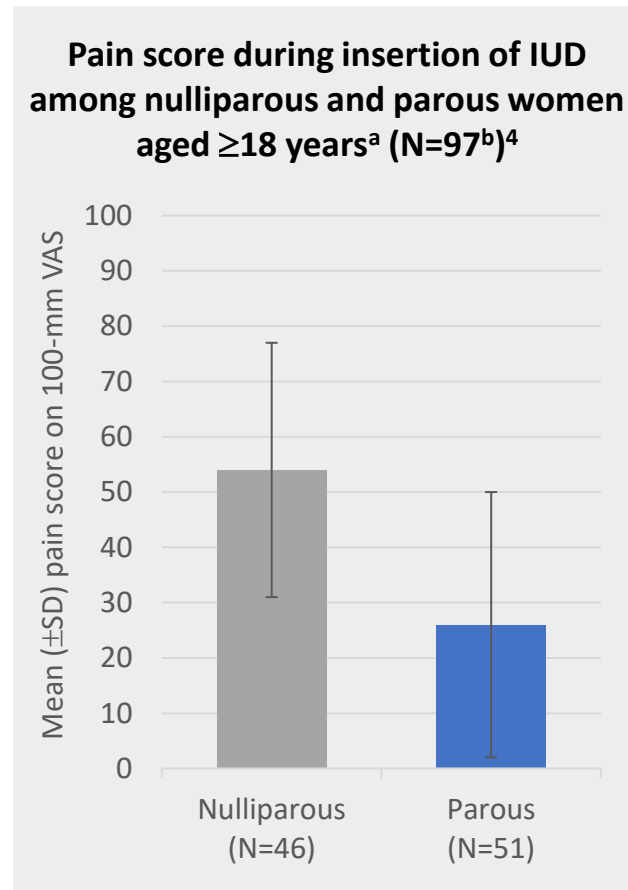
The intrauterine contraceptive (IUC) is one of the most effective methods of contraception

- >99% effective, as effective as sterilisation



# IUC insertion is associated with significant pain

- Providers underestimate the pain that women experience with IUD insertion<sup>1</sup>
  - In a secondary analysis of a randomised clinical trial, mean maximum pain score during IUD insertion **reported by patients on a 100-mm VAS was 64.8 mm (moderate to severe)** compared to 35.3 mm (mild to moderate) rated by the provider ( $p < 0.001$ )<sup>1</sup>
- Higher rates of pain during IUD insertion are observed in nulliparous vs parous women and can be a barrier to IUD use in young women<sup>2-4</sup>
  - >85% of nulliparous women report pain during IUD insertion, including ~20% with severe pain<sup>5,6</sup>



<sup>a</sup>Mean age 30.7 years (SD  $\pm$  8.4 years)

<sup>b</sup>Patients were in the placebo group of this RCT and did not receive pain relief or local anesthesia before or during IUD insertion  
IUD, intrauterine device; LNG-IUS, levonorgestrel-releasing intrauterine system; RCT, randomized controlled trial; SD, standard deviation; VAS, visual analogue scale

- Maguire K, et al. Contraception 2014;89:22–24; 2. Foran T, et al. Eur J Contracept Reprod Health Care 2018;23:379–86
- Anthoulakis C, et al. J Pediatr Adolesc Gynecol 2018;31:549–56.e4; 4. Dijkhuizen K, et al. Hum Reprod 2011;26:323–29
- Marions L, et al. Eur J Contracept Reprod Health Care 2011;16:126–34; 6. Suhonen S, et al. Contraception 2004;69:407

# Despite its effectiveness many women are deterred from use of IUCs because of fear of pain with insertion

## Factors associated with pain perception

More pain	Less pain
<ul style="list-style-type: none"><li>• Nulliparity</li><li>• Postmenopausal status</li><li>• History of dysmenorrhea</li><li>• Anxiety</li><li>• Anticipated pain</li></ul>	<ul style="list-style-type: none"><li>• Vaginal delivery</li><li>• Skilled provider</li><li>• Shorter operative time</li></ul>

RCT (N=2019), increases in pain were significantly ( $P<0.05$ ) associated with increasing age, lower parity, longer time since last pregnancy, and nonlactation<sup>2</sup>

# Evidence for efficacy with available products used to manage pain associated with IUC insertion

The latest Cochrane systematic review identified and evaluated 33 RCTs of interventions for preventing IUD insertion-related pain<sup>1</sup>

- Most trials were considered to be of moderate evidence quality
- Many were small studies without sufficient power to detect significant differences in pain scores
- 29 were published in the last five years; nearly all used modern IUC, either LNG-IUS or Cu-IUD
- Interventions included NSAIDs, lidocaine preparations, misoprostol and 'other':

NSAIDs	Naproxen, ibuprofen (both oral); ketorolac injection
Lidocaine	Lidocaine 2% topical gel; short-acting 4% gel; 2% intrauterine infusion; 10% spray; 1% injection (paracervical block); 2% injection (intracervical block); EMLA cream (lidocaine/prilocaine 5%*)
Misoprostol	Misoprostol 400 µg sublingually, buccally or vaginally Misoprostol 400 µg sublingually plus diclofenac
Other	Two nitric oxide donors (nitroprusside and nitroglycerine); an opioid (tramadol); a physical intervention (bladder emptying time); and an essential oil (lavender)

\*2.5% lidocaine and 2.5% prilocaine

Cu-IUD, copper-containing intrauterine device; IUC, intrauterine contraception; LNG-IUS, levonorgestrel intrauterine system; NSAID, nonsteroidal anti-inflammatory drug; RCT, randomised controlled trial

Managing pain associated with IUC insertion:

## What the guidelines say

The WHO Global Handbook on Family Planning **does not provide** referenced evidence for recommendations on pain management during IUC insertion



# Summary of evidence for pain interventions in IUC insertion

	LIDOCAINE						NSAIDs			OPIOID	MISOPROSTOL	
Route of administration	Topical				Injection		Oral			Oral	Sublingual (SL)/buccal or vaginal	
Dose	2%	2.5% + prilocaine 2.5%	4%	10%	1% paracervical	2% intra-cervical	400 mg – 800 mg	300 mg	550 mg	50 mg	400 µg	400 µg + diclofenac
Products	gel or inf.	EMLA 5%	gel	spray	10 ml	1.8 ml	Ibuprofen	Naproxen	Naproxen	Tramadol	Various	SL + oral
No. of participants (studies)	970 (6 studies, 2% gel <sup>1,4</sup> ; 1 study, 2% IU infusion)	212 (2 studies) <sup>2,3</sup>	218 (1 study)	200 (1 study)	145 (2 studies)	100 (1 studies)	2360 (4 studies)	50 (1 study <sup>b</sup> )	103 (1 study)	103 (1 study)	914 (8 studies and meta-analysis)	354 (2 studies)
Pain efficacy during IUD insertion based on VAS	No significant effect	Significantly better than placebo	Better than placebo during and after IUD	Better than placebo immediately after IUD	Better than placebo in 1 of 2 studies	No significant effect	No significant effect	Better than placebo at 1 and 2 h	Better than placebo	Better than naproxen 550 mg	No different / more pain and AEs vs placebo	No different to diclofenac or placebo
Conclusion	✗ 2% gel has no effect on pain during IUD insertion	✓ Evidence to support use of EMLA during IUD insertion <sup>2,3</sup>	(✓) (✓) (✓) Other lidocaine formulations (short-acting 4% gel, 10% spray and 1% paracervical block) warrant further investigation <sup>5–7</sup>			✗ No evidence to support 2% intracervical injection	✗ Ibuprofen prior to IUD insertion no better than placebo	? Naproxen and the opioid tramadol may have some benefit More evidence is needed			✗ Based on risk-benefit, guidelines recommend that misoprostol is not used for pain associated with IUD insertion	

<sup>a</sup>All data as evaluated in the systematic review by Lopez et al (2015)<sup>1</sup>, except studies by Abbas (2017)<sup>2</sup> and Conti (2019)<sup>4</sup>

<sup>b</sup>All patients in both groups received paracervical block (8 mL 1% lidocaine) during the procedure

AE, adverse event; IU, intrauterine; IUD, intrauterine device; NSAID, nonsteroidal anti-inflammatory drug;

VAS, visual analogue scale 0–10 or 0–100, 0 (no pain) to 10 or 100 (worst pain)

1. Lopez LM, et al. Cochrane Database Syst Rev 2015;7:CD007373

2. Abbas AM, et al. Contraception 2017;95:251–56

3. Tavakolian S, et al. Glob J Health Sci 2015;7:399–404

4. Conti JA, et al. Am J Obstet Gynecol 2019;220:177.e1–e7

5. Tornblom-Paulander S, et al. Fertil Steril 2015;103:422–27

6. Aksoy H, et al. J Fam Plann Reprod Health Care 2016;42:83–87

7. Grik DA, et al. Int J Reprod Contracept Obstet Gynecol 2013;2:263–67

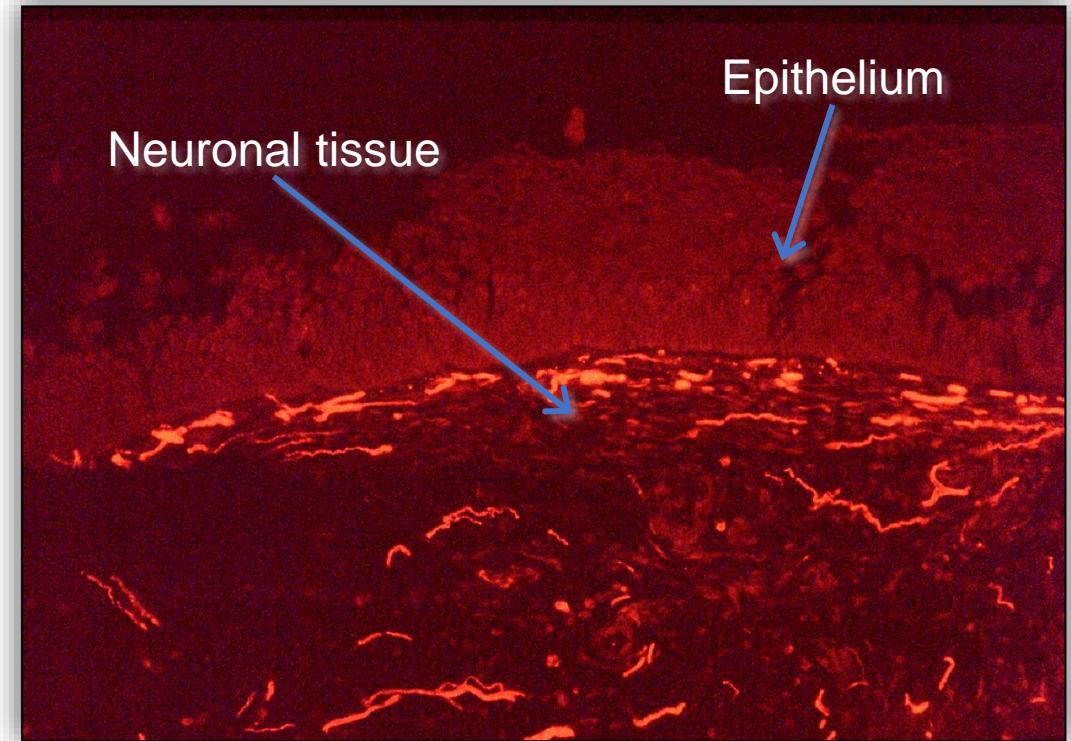


# Reproductive/visceral pain mechanisms and targets for treatment

## **Scientific rationale for topical anaesthesia with lidocaine gel**

The results of research on innervations in the non-pregnant cervix and uterus support a topical analgesic approach to manage pain from minor procedures

- The sensory nerves involved in pain associated with gynaecological procedures are localized superficially in the mucosa, just beneath the cervical epithelium and uterine endometrium<sup>1,2</sup>
- The nerves are therefore accessible to a locally applied pain killer<sup>3</sup>
  - Topical anaesthetics reversibly block nerve conduction near their site of administration by targeting free nerve endings in the dermis or mucosa<sup>2</sup>
  - Topical anesthetics are able to penetrate mucosal surfaces, such as the mouth, genitals and conjunctiva more easily than through a keratinized surface because of the absence of a stratum corneum<sup>2</sup>



Reproduced from Tingåker BK, et al. 2006<sup>2</sup>

# Reproductive/visceral pain mechanisms and targets for treatment

## Pain model for local anaesthetic efficacy in procedure-related pain

- Many gynaecological interventions involve instrumentation and/or biopsy that generate painful stimuli in both the cervix and the corpus uteri
- The degree of pain experienced is similar for these different interventions, as evidenced in published clinical trials [for examples, see [IUC insertion studies](#), [hysteroscopy studies](#), [endometrial biopsy studies](#)]
- Minimally invasive gynaecological surgery is considered to be a relevant pain model for mild to moderate acute somatic and visceral pain<sup>1</sup>

### IUC placement is a suitable pain model for demonstrating local anaesthetic efficacy

- IUC placement can produce a significant degree of pain, with individual variability from a little pain and discomfort to severe cramps with nausea and malaise<sup>2</sup>
- IUC placement can incur pain in many ways<sup>3–5</sup>
  - using a tenaculum to hold the cervix
  - using a tenaculum to straighten the uterine axis
  - inserting the sound
  - irritation of the endometrial cavity when the IUC is inserted
- Nulliparous women experience more pain during IUC-insertion, due to a narrower cervix, compared with women who have had vaginal deliveries<sup>3,6,7,8</sup>

1. European Medicines Agency. EMA/CHMP/970057/2011, December 2016

2. Murty, J. J Fam Plann Reprod Health Care 2003;29:150–51

3. McNicholas CP, et al. Am J Obstet Gynecol 2012;207:384 e1–6

4. Lopez LM, Beret al. Cochrane Database Syst Rev 2015 Jul 29;(7):CD007373

5. Tavakolian S, et al. Glob J Health Sci 2015;7:399–404

6. Hubacher D, et al. Am J Obstet Gynecol 2006;195:1272–77

7. Maguire K, et al. Contraception 2012;86:214–19

8. Ireland LD, Allen RH. Obstet Gynecol Surv 2016;71:89–98



**Optimizing Patient Comfort in Office-Based Gynaecological Procedures: Insights from Experts and the Literature on the Role of an Innovative Formulation of a Lidocaine Thermogel 4.2% for Local Pain Management**

*Maria Joao Carvalho, Karin Louise Andersson, in submission*

# Increasing awareness...

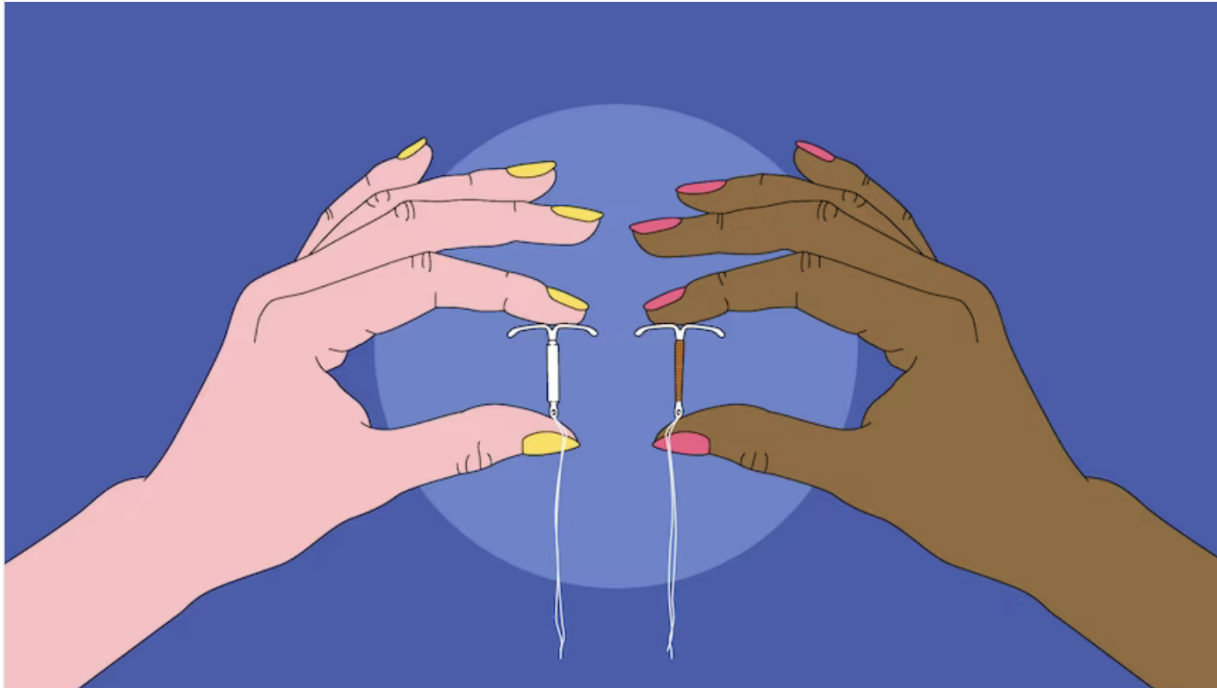
## Having an IUD inserted can be excruciatingly painful. Why aren't women being warned or given stronger pain relief?

By [Claudia Long](#) and [Ellie Grounds](#) for [triple j Hack](#) and [Background Briefing](#)

Posted Sun 30 Oct 2022 at 7:00pm, updated Mon 31 Oct 2022 at 3:53am

ABC NEWS

Just In Watch Live P



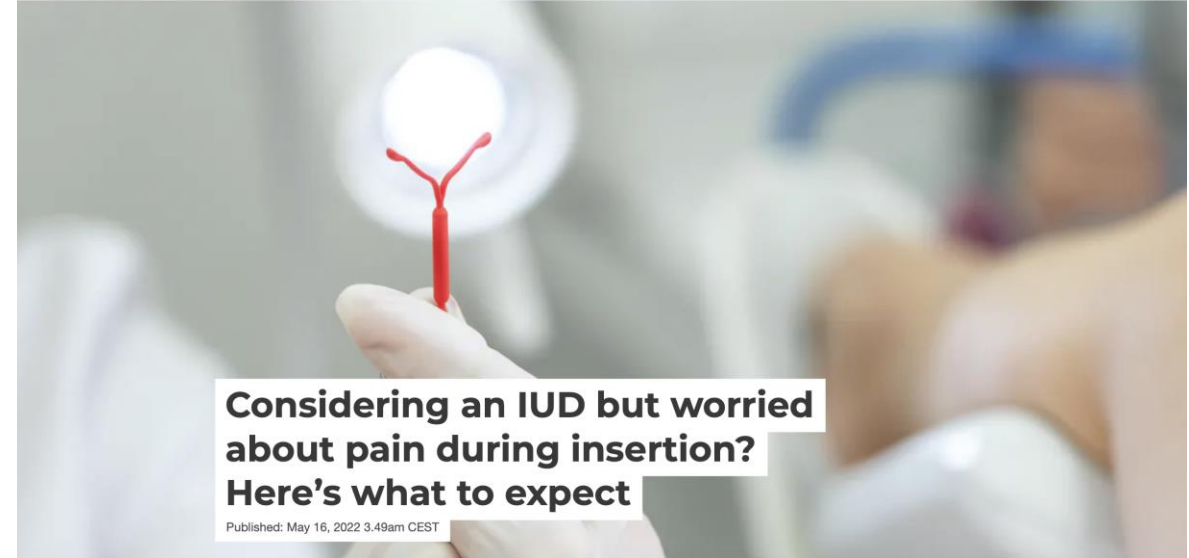
THE CONVERSATION

Academic rigour, journalistic flair

Search analysis, research, academics...

Considering an IUD but worried about pain during insertion? Here's what to expect

Published: May 16, 2022 3:49am CEST



Unmet needs!!  
...New generations



# Mechanisms of pain in the female reproductive system

**The perception of pain during gynaecological procedures originates from manipulation of the cervix and/or uterus**

- Pain arising from the cervix and uterus is an example of visceral nociception
  - Pain that comes from distension, injury or inflammation of hollow organs
- Visceral pain is diffuse, poorly localised, often referred to other body regions
  - Can be accompanied by disrupted motor and autonomic reflexes



# The most painful moments of IUD insertion procedure

**Uterine sounding – the most frequent time point of maximum pain. Providers underestimate pain during IUD insertion<sup>1</sup> (N=200)**

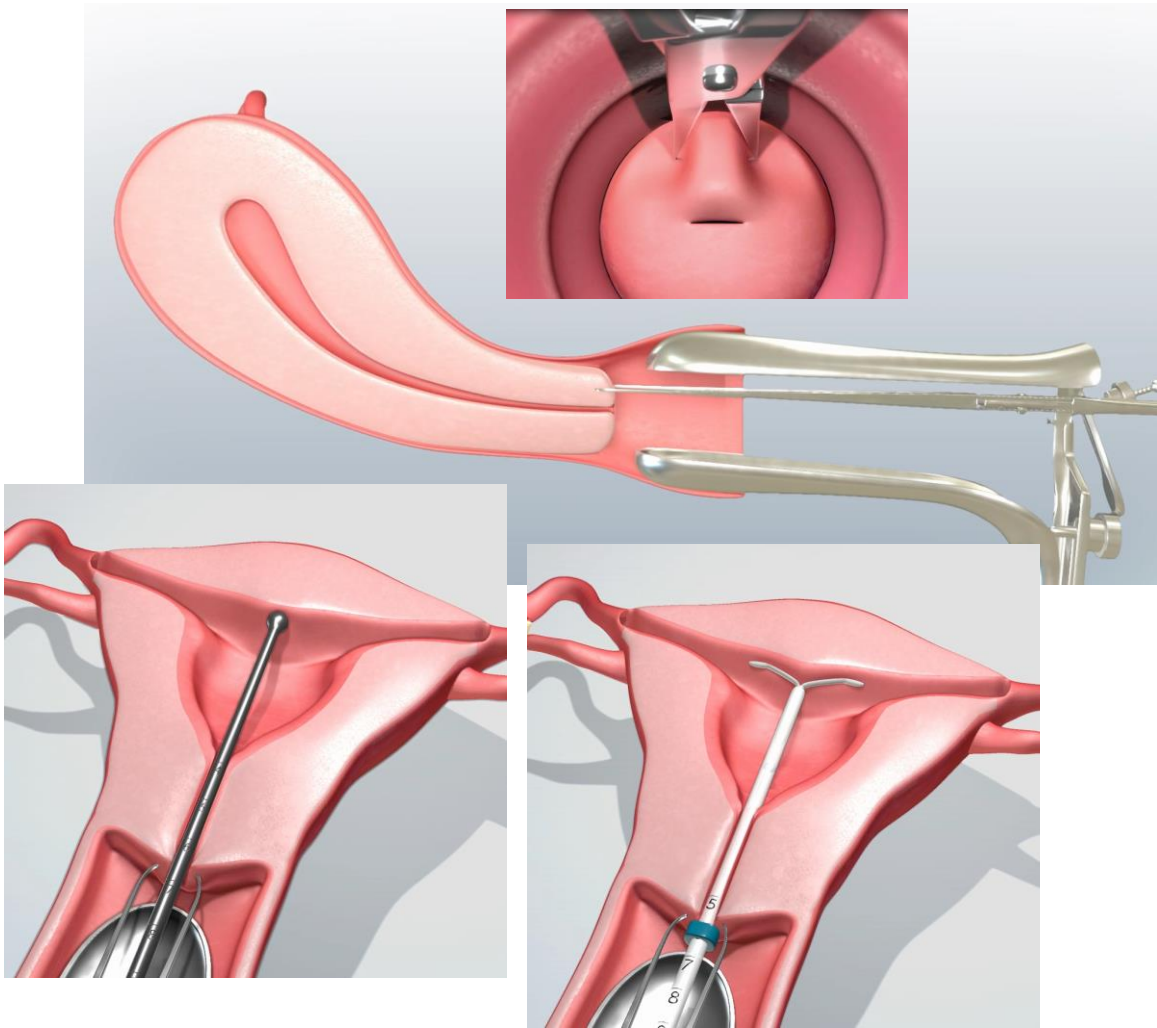
Pain scores on the 100 mm VAS

	VAS pain score mean (SD)
Patient reported	
Tenaculum placement	34.8 (25)
Uterine sounding	53.6 (29)
IUD insertion	50.9 (30)
Speculum removal	28.5 (27)

**The most painful time point was intrauterine sounding followed closely by IUD insertion<sup>2</sup>**

Pain scores reported during the IUD insertion procedure in placebo and lidocaine groups — both overall and stratified by parity

	Placebo (n=100)	Lidocaine (n=100)	p value
Tenaculum placement	34.3 (25)	35.4 (26)	.77
Uterine sounding	51.6 (25)	55.5 (30)	.33
IUD insertion	50.9 (32)	51.0 (31)	.98
Speculum removal <sup>a</sup>	20 (45)	20 (43)	.72



1. Maguire K, et al. Contraception 89 (2014);22-24  
2. Maguire K, et al. Contraception 84 (2012);214-219



# Come ridurre il dolore durante l'inserimento?



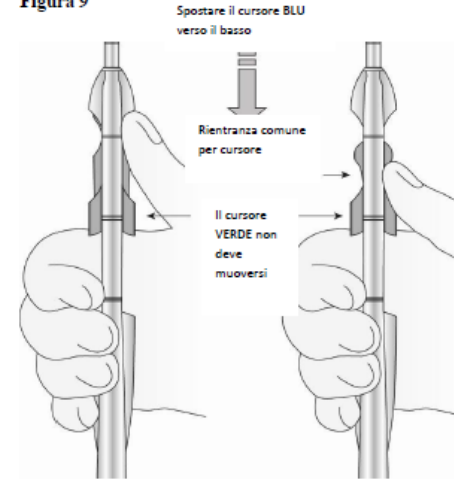
- ✓ Evitare quando è possibile le procedure dolorose pre-inserimento
  - pinza da collins, isterometro etc)

# Come ridurre il dolore durante l'inserimento?

## Meccanismo di inserimento

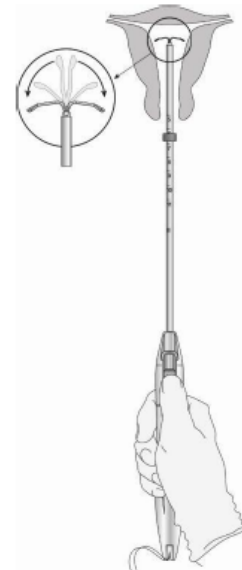
### RCP Inserimento di IUS-LNG nell'utero

Figura 9



• Usando il pollice o il dito, far scorrere delicatamente indietro solo il cursore BLU finché non si avverte resistenza. I cursori BLU e VERDE si fonderanno insieme per formare una rientranza comune per i cursori. Non spostare il cursore BLU più di quanto sia necessario per creare l'incavo. Mantenere il cursore VERDE in modo che i contrassegni a doppia linea sul cursore e l'impugnatura di inserimento rimangano allineati (Figura 9). Ciò consentirà ai bracci dello IUS di aprirsi nel segmento uterino inferiore. Non tirare ulteriormente indietro i cursori in quanto ciò potrebbe causare il rilascio prematuro dello IUS nella posizione errata.

Attendere 10-15 secondi per consentire ai bracci dello IUS di aprirsi completamente.





Gracia Lam, 2023 ©

SOCIAL JUSTICE & ACTIVISM, SOCIAL COMMENTARY

# Why Is Pain Relief Not Offered For IUD Insertion?

March 6, 2023 | By Georgia Moot



# Concludiamo...

- ✓ **TRICKS TECNICI**
  - ✓ Adeguata preparazione campo
  - ✓ – no pinza collins quando è possibile
  - ✓ - **pazienza** quando rimozione impianto – posizione comoda!

✓ **IMPORTANZA DEL COUNSELLING  
(come strumento di strategia!)**







Non chiedere  
"what is the matter with  
you?"

..ma chiedere  
"what matters to you?"



Grazie!

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**S.I.C.**  
Società Italiana della Contraccezione