

Què fer davant la dona portadora d'Essure® i que té SMA o dolor crònic?

Dra Montserrat Cubo Abert

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Dijous, 21 novembre'19
l'Acadèmia, **Barcelona**

DIT Essure®

Model ESS205: 4 nov 2002-2007



Model ESS305: 2007- juliol 2017



L'any 2002, la FDA va revisar les dades sobre seguretat i eficàcia com a part del procés d'aprovació de mercat, on es va determinar que es complien tots els criteris d'aprovació i els beneficis clínics superaven els riscos. Des de llavors, estudis addicionals de comercialització i assajos clínics patrocinats per l'empresa han continuat donant suport al perfil benefici / risc positiu i alternativa segura i viable a la lligadura de la trompa laparoscòpica.



Table 4–1: Overview of studies demonstrating safety and efficacy of Essure

Study number	IDE number	Study title	Study dates / countries	Women enrolled / Women underwent placement procedure
Studies supporting the initial Premarket Approval				
Phase IA / STOP 01	IDE G960052	STOP Device Placement Feasibility Study Using Hysteroscopic Visualization.	July 1998 – Nov 2000 / Australia, Europe, Mexico, US	99 / 95
Phase IB / STOP 06	IDE G960206	Evaluation of the Safety and Principles of Operation of the Selective Tubal Occlusion Procedure (STOP) Device in Women who are scheduled to undergo a hysterectomy.	Oct 1998 – Dec 2001 / Mexico and US	63 / 63
Phase II (STOP 10)	IDE G980152	Phase II Study – A Multi-Center Clinical Trial to Evaluate the Safety and Effectiveness of the STOP Device to Prevent Pregnancy in Women Who are Seeking Permanent Contraception.	Nov 1998 – June 2000 / Australia, Belgium, Spain, USA	269 / 227
Pivotal (STOP 2000)	IDE G000055	A Multi-Center Clinical Trial to Demonstrate the Safety and Effectiveness of the STOP Device in Providing Permanent Contraception.	May 2000 – 05 Dec 2007 / Australia, Belgium, Spain, UK, US	657 / 518

IDE = Investigational Device Exemption; STOP = Selective Tubal Occlusion Procedure; UK = United Kingdom; US = United States (of America).



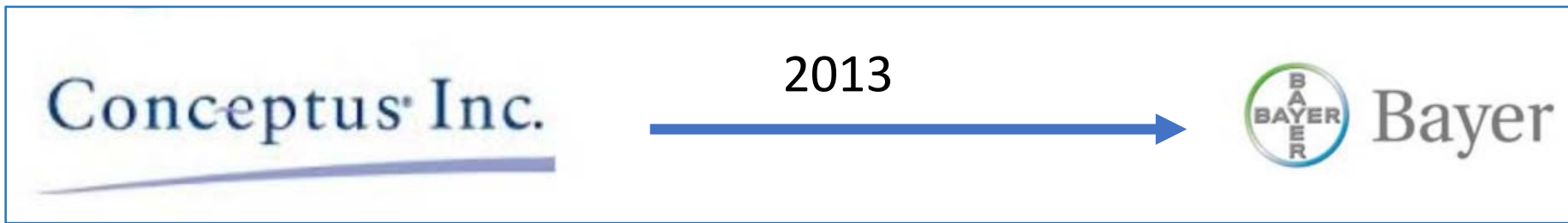
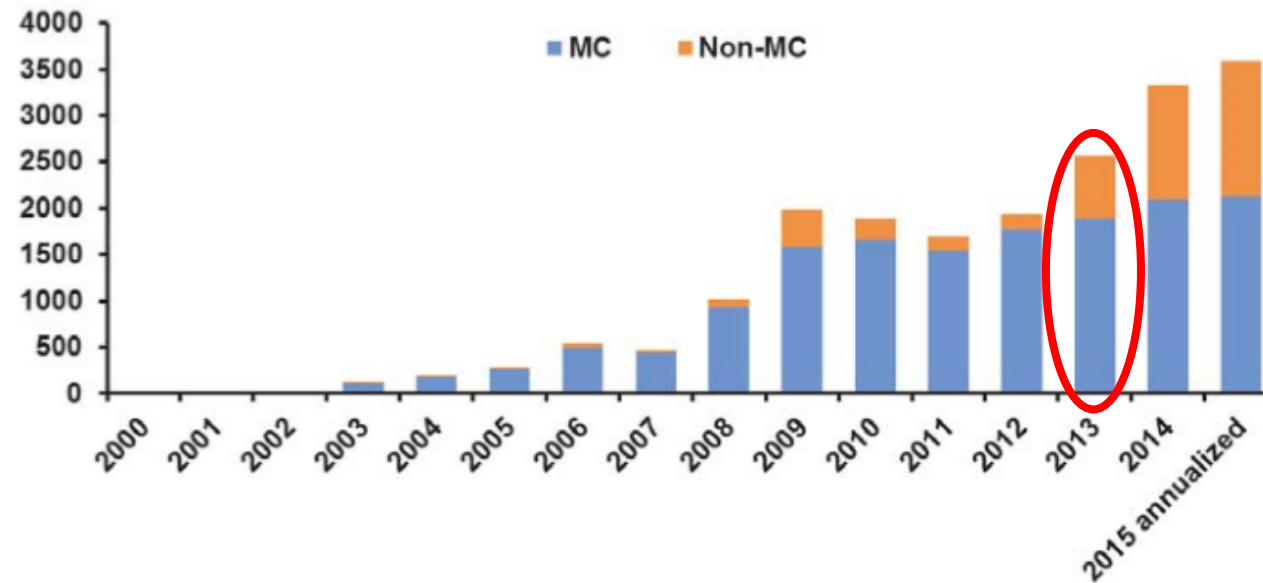


Figure 6-1: Adverse event reporting over time (data through 15 JUNE 2015)



MC = medically confirmed; Non-MC = not medically confirmed.



Symptoms Cited by Patients

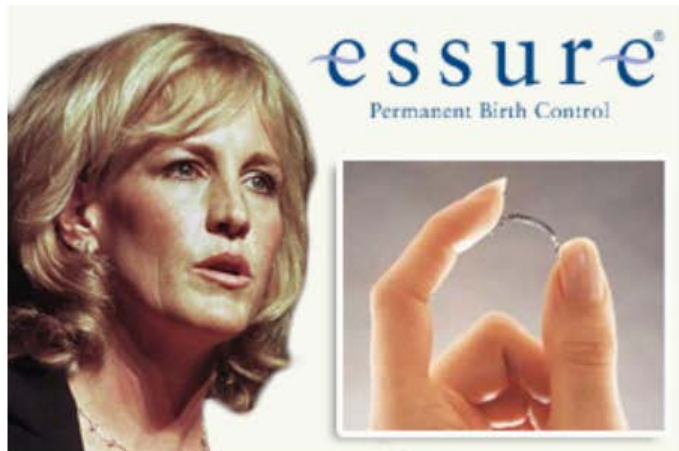
GYNECOLOGICAL			
<ul style="list-style-type: none"> Menorrhagia Menstrual irregularities Amenorrhea Constant spotting Metorrhagia Polymenorrhea Dysmenorrhea Hot flashes Premenstrual Dysphoric Disorder Loss of libido 	<ul style="list-style-type: none"> Pelvic pain Cramping Abdominal spasms Dyspareunia Breast tenderness Breast engorgement 	<ul style="list-style-type: none"> Pregnancy Miscarriage Early menopause Endometriosis Adenomyosis PCOS PID Adhesions 	<ul style="list-style-type: none"> Ovarian cysts Uterine cysts Uterine fibroids Fallopian tube cysts Uterine infection Bacterial vaginosis Yeast infections Vaginal discharge Urinary tract infections Cervical dysplasia
GENERAL	PAIN	NEUROLOGICAL	GASTROINTESTINAL
<ul style="list-style-type: none"> Fatigue Weight gain or loss Edema/swelling Excessive sweating Fevers Night sweats Insomnia General aches/pains Vitamin D deficiency B12 deficiency Dental caries, chipping Changes in vision Changes in hearing 	<ul style="list-style-type: none"> Abdominal pain Pelvic pain Low back pain* Leg pain Joint pain 	<ul style="list-style-type: none"> Headache/Migraine Dizziness Vertigo Paresthesia Weakness Tremors Cognitive ("fog") Memory loss Seizures Stroke symptoms Syncope Myasthenia gravis Multiple sclerosis 	<ul style="list-style-type: none"> Nausea Vomiting Diarrhea Constipation Metallic taste in mouth Heartburn Metallic taste Abdominal pain Abdominal cramping Gallstones Pancreatitis
RENAL/URINAY	DERMATOLOGICAL	MUSCULOSKELETAL	PSYCHIATRIC
<ul style="list-style-type: none"> Polyuria Incontinence Hematuria Kidney stones UTIs 	<ul style="list-style-type: none"> Rash, hives Alopecia Pruritis Easy bruising Dry skin Acne 	<ul style="list-style-type: none"> Back pain Joint pain Tendonitis Muscle spasms Rheumatoid arthritis 	<ul style="list-style-type: none"> Mood changes Depression Anxiety Panic attacks Mood swings Irritability
HEMATOLOGICAL	IMMUNOLOGICAL	CARDIOVASCULR	RESPIRATORY
<ul style="list-style-type: none"> Anemia (IDA) Blood clots, emboli IITP 	<ul style="list-style-type: none"> Food, chemical, metal sensitivities Difficulty fighting infections Frequent infections 	<ul style="list-style-type: none"> Palpitations Chest pain 	<ul style="list-style-type: none"> Sleep apnea Pulmonary embolism
ENDOCRINE	AUTOIMMUNE		
<ul style="list-style-type: none"> Hypoglycemia Thyroid disease Adrenal problems Degenerative bone disease 	<ul style="list-style-type: none"> SLE Rheumatoid arthritis Fibromyalgia Raynaud's Myasthenia gravis 		



Erin Brockovich Leads Fight Against Essure Birth Control

By F.A. Kelley October 17, 2013

438 0





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DE
ESSURE**



Violencia ginecológica - El anticonceptivo Essure

YouTube



Violencia ginecológica anticonceptivo Essure

Dentro del campo de la medicina viendo a la luz casos de implantes defectuosos con graves secuelas en los pacientes. Un claro ejemplo de esta negligencia...



PLATAFORMA ASOCIADA LIBRES DE...

@libreessure

Seguir

Sin quirófano hipoalergénicos, sin hormonas, sin ningún efecto secundario
Eso no se puede mover después de tantos años, como va a migrar?
A ver si se t ha subido un trozo a la cabeza

FACTOR DE CONFUSIÓN



12:50 - 11 nov. 2019

4 Retweets 7 Me gusta



CASTREJE-ABOGADOS retweeted

PLATAFORMA ASOCIADA LIBRES DE ESSURE @libreessure · 13 nov

Buscas ayuda

Has oído que #essure tiene efectos secundarios que no sabías

Vas a tu médic@, lo niega

Vas al ginecólogo, lo niega

Tú cuerpo empieza a fallar, hemorragias, dolor, desesperación

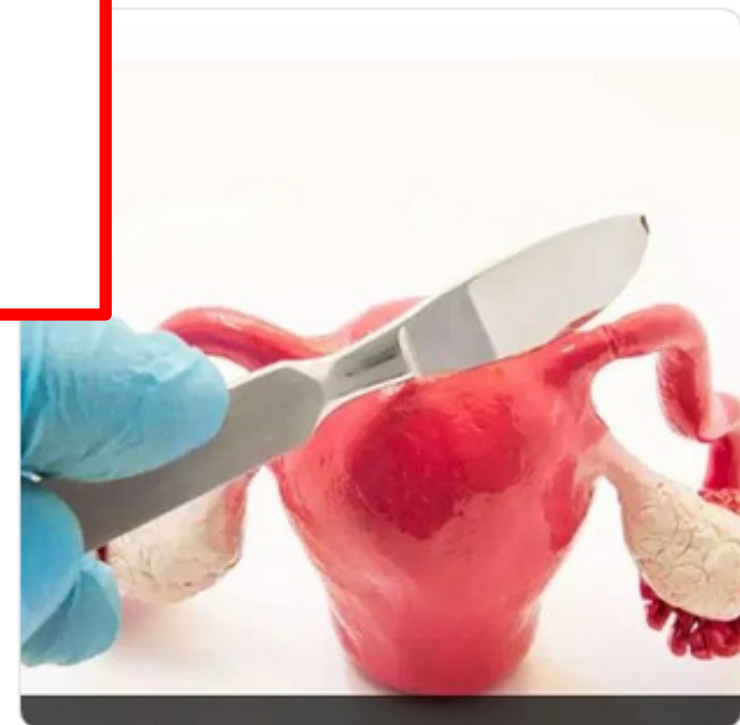
al médico:

amos :

ón de la paciente"

SGOB

adgob



9



10

En esta entrevista, su presidenta, **Angélica del Valle**, explica con claridad **cuales son los objetivos de la asociación**. Entre ellos, la **retirada del producto** del mercado.



ASOCIACIÓN AFECTADAS POR essure

Esta organización tiene un **acuerdo con nuestro Bufete** para que la representemos y gestionemos la comunicación del caso.

Un buen día el diario **El Mundo** se hizo eco del asunto: **240 españolas denuncian secuelas tras un implante anticonceptivo**. El escándalo fue mediático pues numerosos grandes medios de comunicación lo difundieron.

Y nosotros seguimos publicando, por ejemplo, cómo las sociedades científicas que han recomendado el aparatito **hacen lobby para el fabricante, Bayer**. Hay que saber que el producto se introdujo en el mercado con pruebas científicas “pobres”. Así lo consideró la **Agencia de Evaluación de Tecnologías Sanitarias (AETS)** de Andalucía en 2004. Su informe se titula **Obstrucción selectiva tubárica mediante dispositivo Essure**.

En suma todo apunta a un pelotazo económico de una multinacional farmacéutica. Seguimos **investigando** y publicando y en breve comenzaremos la **acciones legales** del caso. Si quieres unirte a esta lucha jurídica rellena el formulario que encuentras a la derecha en **la web del Bufete**.



Ya están en marcha las denuncias de las afectadas por Essure: la indemnización podría llegar al millón de euros

NOELIA PÉREZ 03.05.2018 - 06:42H



- El despacho Castreje Abogados l
- Desde Bayer afirman: "No tenemo
- [Cinco mujeres nos cuentan sus](#)
- [Bayer: la suspensión del antico](#)

FACTOR DE CONFUSIÓN

A las mujeres afectadas "les han e
habido gente que ha cogido depre
hijos no queridos y con graves se
'vendido' el método con infalible y
abogado de las afectadas. Por este motivo, Cipriano asegura que pueden
reclamar indemnizaciones desde 10.000 por daño moral hasta el millón de euros
porque ha tenido un niño con gravísimos problemas.

tán tomando las afectadas es denunciar.
has, han recurrido al despacho de
render acciones legales, "tanto contra la
seguros de salud o a los ginecólogos
y las denuncias deben presentarlas por

separado. Cipriano Castreje Martínez, letrado titular, afirma a este periódico que,
como cualquier persona, tienen "derecho a la salud, a la dignidad, a ser
informadas sobre cualquier mecanismo que se implante sobre su cuerpo y los
efectos adversos que puede producirle. Es el derecho a ser reparadas de forma
integral del daño que les cause, en este caso, un producto sanitario y a la
reparación integral de dichos daños que le haya causado el producto o la mala
praxis médica si la ha habido".



Bayer va retirar de la comercialització el dispositiu Essure en el 2017.

No el van retirar per cap motiu relacionat amb la seguretat i l'efectivitat.



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I DE LA SALUT DE CATALUNYA I DE BALEARS

Dijous, 21 novembre'19
l'Acadèmia, **Barcelona**

DOLOR CRÒNIC



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Societat Catalana de **Contracepció**

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Dijous, 21 novembre'19
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Table 4–5: Adverse events by body systems, first year of reliance ($\geq 0.5\%$), (pivotal trial)

Adverse events by body system	Number (%)^a
Total number of women placed with at least one insert	476 (100%)
Abdominal	
Abdominal pain/abdominal cramps	18 (3.8%)
Gas/bloating	6 (1.3%)
Musculo-skeletal	
Back pain/low back pain	43 (9.0%)
Arm/leg pain	4 (0.8%)
Nervous/Psychiatric	
Headache	12 (2.5%)
Premenstrual Syndrome	4 (0.8%)
Genitourinary	
<u>Dysmenorrhea/menstrual cramps (severe)</u>	14 (2.9%)
<u>Pelvic/lower abdominal pain (severe)</u>	12 (2.5%)
Persistent increase in menstrual flow ^b	9 (1.9%) ^b
Vaginal discharge/vaginal infection	7 (1.5%)
Abnormal bleeding – timing not specified (severe)	9 (1.9%)
Menorrhagia/prolonged menses (severe)	5 (1.1%)
Dyspareunia	17 (3.6%)
Pain/discomfort - uncharacterized:	14 (2.9%)

^a Percentages reflect the number of events divided by the number of women in the trial. When numerous episodes of the same event were reported by one woman, each report was counted as a separate event. Therefore, percentages may over-represent the percentage of women who have experienced that event.

^b Eight women reported persistent decrease in menstrual flow



Table 7–9: Pain reported at follow-up visits in phase II study

Follow-up visit	Dysmenorrhea	Pelvic pain, Dyspareunia	Other pelvic pain	Other pain
3-month	29/203 (14%)	17/203 (8%)	5/203 (2%)	2/203 (<1%)
6-month	11/199 (6%)	3/199 (2%)	3/199 (2%)	1/199 (<1%)
12-month	5/196 (3%)	0	5/196 (3%)	0
18-month	2/193 (1%)	0	10/193 (5%)	2/193 (1%)
24-month ^a	8/194 (1%)	0	6/194 (3%)	6/194 (3%)
36-month ^a	7/182 (4%)	1/182 (<1%)	2/182 (1%)	1/182 (<1%)
48-month ^a	9/176 (5%)	2/176 (1%)	2/176 (1%)	2/176 (1%)
60-month ^a	4/171 (2%)	1/171 (<1%)	3/171 (2%)	2/171 (1%)

^a No data reported for some women that indicated other types of pain (N = 2 at 24 months; N = 1 at 36, 48 and 60 months).

Table 7–10: Pelvic pain reported at follow-up visits (pivotal study)

Follow-up visit	Pelvic pain			
	Dysmenorrhea	Dyspareunia	Ovulatory	Other ^c
Baseline (N=518)	183 (35%)	22 (4.2%)	N/a	N/a
3-month post-device placement (N=467)	29 (6.2%)	29 (6.2%)	5 (1.1%)	32 (6.9%)
Post-alternative contraception				
3-month (N=440)	20 (4.5%)	10 (2.3%)	6 (1.4%)	26 (5.9%)
6-month (N=436)	15 (3.4%)	8 (1.8%)	3 (0.7%)	16 (3.7%)
12-month (N=460)	17 (3.7%)	15 (3.3%)	5 (1.1%)	27 (5.9%)
18-month (N=410)	14 (3.4%)	9 (2.2%)	10 (2.4%)	11 (2.7%)
24-month (N=435)	22 (5.1%)	9 (2.1%)	22 (5.1%)	13 (3.0%)
36-month (N=422) (data missing on 1 patient)	14 (3.3%)	7 (1.7%)	12 (2.8%)	6 (1.4%)
48-month (N=402)	3 (0.7%)	5 (1.2%)	6 (1.5%)	11 (2.7%)
60-month (N=386)	14 (3.6%)	8 (2.1%)	10 (2.6%)	9 (2.3%)
Recurrent (N=473)^a				
Persistent (year 1), (N=460) ^b	0	0	0	1 (0.2%)
Persistent (year 2), (N=435) ^b	0	0	0	1 (0.2%)
Persistent (year 3), (N=422) ^b	0	0	0	0
Persistent (year 4), (N=402) ^b	0	0	0	0
Persistent (year 5), (N=386) ^b	0	0	0	0

^a *Recurrent*: symptom reported at more than one visit.

^b *Persistent*: symptom reported at all prior visits.

^c *Other*: defined as pelvic pain that was not reported to be dysmenorrhea, dyspareunia or ovulatory pain.



Dolor crònic casos clínics i serie de casos: 0,16 – 4,2%

Bayer 2015: 3539 casos publicats/1.000.000 essures venuts = 0.3%




Original Article

Incidence and Risk Factors for Chronic Pelvic Pain After Hysteroscopic Sterilization

Amanda C. Yunker, DO, MSCR*, Jessica M. B. Ritch, MD, Erica F. Robinson, MD, and Cara T. Golish, DO

From the Department of Obstetrics and Gynecology, Vanderbilt University Medical Center, Nashville, Tennessee (all authors).





Journal of Obstetrics and Gynaecology

ISSN: 0144-3615 (Print) 1364-6893 (Online) Journal homepage: <http://www.tandfonline.com/loi/ijog20>

Essure® and chronic pelvic pain: A population-based cohort

J. E. Arjona Berral, B. Rodríguez Jiménez, E. Velasco Sánchez, B. Povedano Cañizares, J. Monserrat Jordan, J. Lorente Gonzalez & C. Castelo-Branco

Original Article

Hysteroscopic Essure Inserts for Permanent Contraception: Extended Follow-Up Results of a Phase III Multicenter International Study

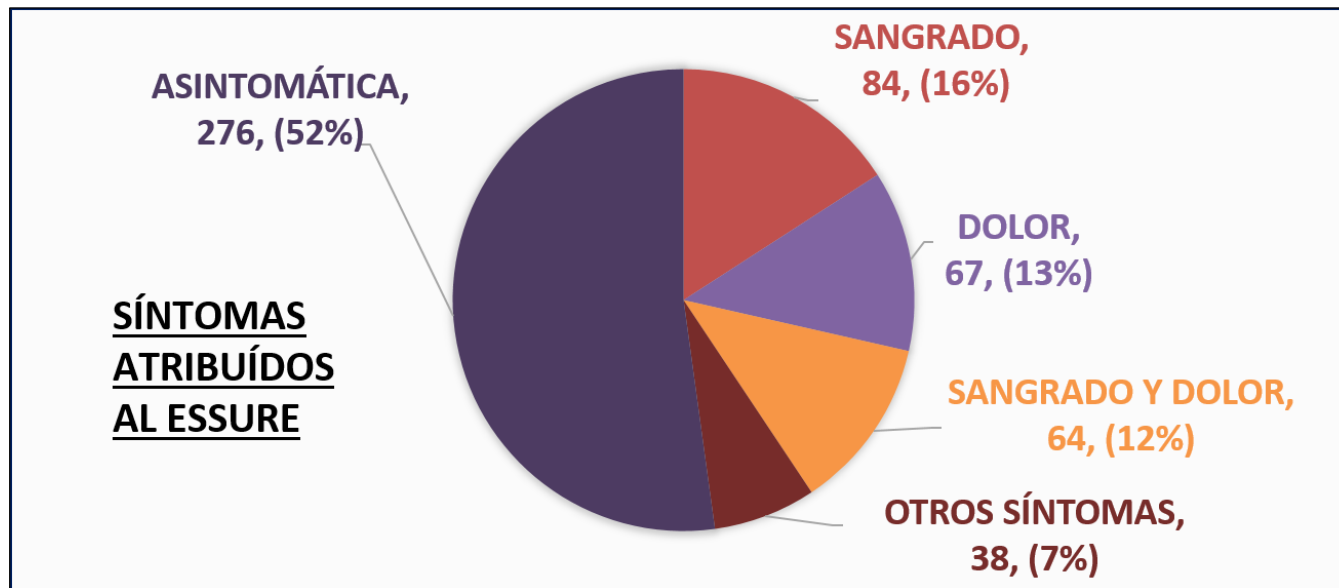
Scott G. Chudnoff, MD, MS*, John E. Nichols Jr, MD, and Mark Levie, MD

From the Department of Obstetrics & Gynecology and Women's Health, Albert Einstein College of Medicine and Montefiore Medical Center, Bronx, NY (Dr. Chudnoff and Levie), and Piedmont Reproductive Endocrinology Group, Greenville, SC (Dr. Nichols).



- Arjona Berral JE. Essure® and chronic pelvic pain: a population-based cohort. J Obstet Gynaecol. 2014
- Adelman MR. Management of complications encountered with Essure hysteroscopic sterilization: a systematic review. J Minim Invasive Gynecol. 2014
- Yunker AC. Incidence and risk factors for chronic pelvic pain after hysteroscopic sterilization. J Minim Invasive Gynecol. 2015
- Conover MM. Incidence of opioid-managed pelvic pain after hysteroscopic sterilization versus laparoscopic sterilization. Pharmacoevidiol DrugSaf. 2015
- Chene G. Quality of life after salpingectomy and Essure removal procedure. JMIG 2019

Casuística Vall d'Hebron: retrospectiu 2015



Altes síntomas: cefalea (19), fatiga (7), disminución libido (7), dolores EEII (6)...



Enquesta telefònica any **2015: 529**
Essures® (1-6 anys)

Dolor **25%** (131/529)

5% dolor pèlvic crònic (30/529)

1% dismenorrea severa (6/529)

15% Dismenorrea leve (81/529)

6% molèsties inespecífiques (34/529)

Dolor crònic casos clínics i serie de casos:

Bayer 2015: 3539 casos publicats/1.000.000 essures venuts = 0.3%

Arjona 2014: Dolor crònic **0,16%** (7/4274) (els símptomes van desaparèixer al explantar el dispositiu)

Adelman 2014: 7 explantacions por dolor crònic, només 4 resolució complerta (els símptomes van desaparèixer al explantar el dispositiu)

Yunker 2015: Dolor als 3m= **8.1%** i 6 m = **4.2%** (n=458) (les dones amb antecedent de dolor crònic més probablement tenien dolor crònic post-procediment OR 6.15 (IC 2.09-18.05), La remissió de la simptomatologia després de l'explantació del dispositiu està fonamentalment relacionada amb la descripció d'una inserció difícil)

Conver 2015: Maneig del dolor crònic amb opioides. Grup histeroscòpia **0.88%** vs grup laparoscòpia **0,93%**

Maassen 2019: 39% resolució completa dels símptomes, cap millora 15% (n=93)

CheneG 2019: l'extracció laparoscòpica de l'Essure es tècnicament exitosa i s'associa a una millora de la qualitat de vida a curt i llarg plaç, així com en la reducció del dolor pèlvic



Arjona Berral JE. Essure® and chronic pelvic pain: a population-based cohort. J Obstet Gynaecol. 2014

Adelman MR. Management of complications encountered with Essure hysteroscopic sterilization: a systematic review. J Minim Invasive Gynecol. 2014

Yunker AC. Incidence and risk factors for chronic pelvic pain after hysteroscopic sterilization. J Minim Invasive Gynecol. 2015

Conover MM. Incidence of opioid-managed pelvic pain after hysteroscopic sterilization versus laparoscopic sterilization. Pharmacoepidemiol DrugSaf. 2015

Chene G. Quality of life after salpingectomy and Essure removal procedure. JMIG 2019

Casuística Vall d'Hebron: prospectiu 2019

52 explantacions i 6m-3 anys de seguiment

44 tenien algun tipus de dolor o més d'un

Dolor hipogastri continu
Dolor lumbar baix continu
Dismenorrea +/- irradiació cames i lumbar
Dispareunia
Dolor de cames
Cefalea
Dolor abdominal
Dolor punxant a hipogastri
Dolor de mans i peus
Dolor generalitzat

2015 (centro privado): <i>alergia al níquel, rash, hipermenorrea, cefalea, calambres EEII</i>
Dic 2015: <i>dolor hipogastrio, metrorragia, IUE, TVP, cefalea, pérdida de peso, hipertrichosis, dismenorrea, fatiga, cambios de humor</i>
Abril 2016: <i>dolor pélvico tipo "descargas eléctricas", dispareunia profunda</i>
Abril 2016: <i>dispareunia profunda</i>
Abril 2016: <i>hipermenorrea, dolor en hipogastrio, cefalea y fatiga.</i>
Mayo 2016: <i>dolor en ambas fosas ilíacas, alergia al níquel</i>
Mayo 2016: <i>dolor lumbar y en hipogastrio, dispareunia profunda, dolor en EEII, cefalea, fatiga, disminución libido, hipermenorrea</i>

15% Curació – 60% Millora - 23% sense canvis – 2% Pitjor

Complicacions quirúrgiques:

Onfalitis S.Pyogenes (UCI)
Hemoperitoni (ferro)
Cel.lulitis

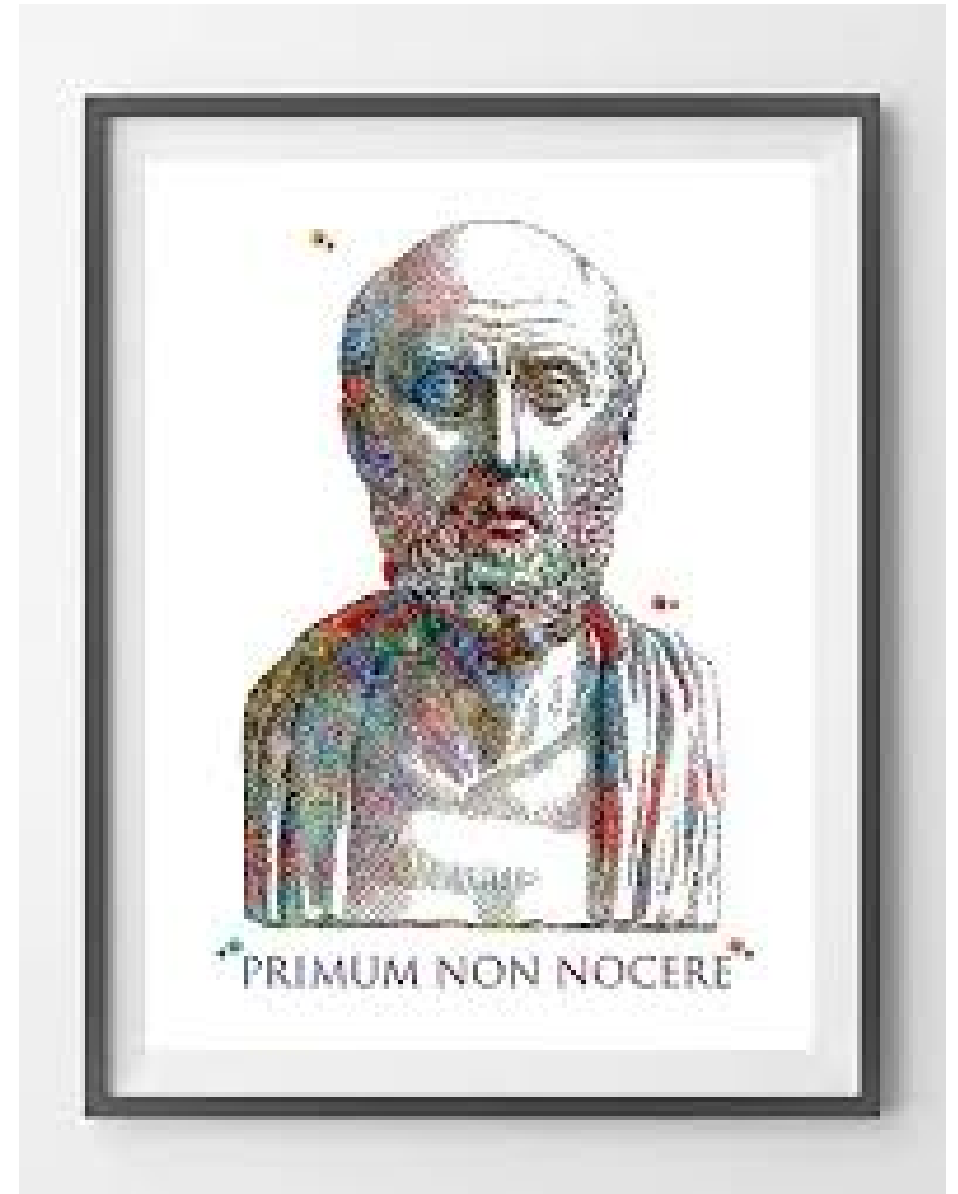
Confusió

Anticonceptius previs (adenomiosis??)

Camara 2017 recomana evitar la indicació errònia d'explantació del dispositiu



Maneig dolor crònic & Essure



Maneig dolor crònic & Essure

Anamnesis: dolor crònic previ, ACOs

Descartar altres causes conegudes de dolor

Informació sobre literatura i riscos i beneficis de la explantació quirúrgica vs maneig conservador. Només tenim un cas amb dolor que no s'ha operat

Explantació abans de remetre a la pacient a la consulta de DOLOR PÈLVIC CRÒNIC



CANVIS MENSTRUALS



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I DE LA SALUT DE CATALUNYA I DE BALEARS 

Dijous, 21 novembre'19
l'Acadèmia, **Barcelona**

Síndrom post-esterilització tubàrica (Williams 1951):
sanguat anormal i/o dolor, canvis en el comportament sexual
i en les emocions, exhacerbació dels símptomes
premenstruals.

Studies cited in ACOG "Practice Bulletin on the Benefits and Risks of Sterilization"
regarding menstrual patterns/changes during various procedures of sterilization:

- Bhiwandiwala PP et al. (Level II-3): Menstrual pattern changes following laparoscopic sterilization with different occlusion techniques: a review of 10,004 cases. Am J Obstet Gynecol 1983; 145:684-94. <http://www.ncbi.nlm.nih.gov/pubmed/6219585>.
- DeStefano F et al. (Level II-2): Long-term risk of menstrual disturbances after tubal sterilization. Am J Obstet Gynecol 1985; 152:835-41. <http://www.ncbi.nlm.nih.gov/pubmed/4040707>.
- Foulkes J, Chamberlain G. (Level II-3): Effects of sterilization on menstruation. South Med J 1985;78:544-7. <http://www.ncbi.nlm.nih.gov/pubmed/3992301>.
- Rivera R et al. (Level I): Menstrual patterns and progesterone circulating levels following different procedures of tubal occlusion. Contraception 1989;40:157-69. <http://www.ncbi.nlm.nih.gov/pubmed/2758840>.
- Sahwi S et al. (level I): Changes in menstrual blood loss after four methods of female tubal sterilization. Contraception 1989;40:387-98. <http://www.ncbi.nlm.nih.gov/pubmed/2582767>.
- Thranov I et al. (Level I): Hormonal and menstrual changes after laparoscopic sterilization by Falope-rings or Filshie-clips. Fertil Steril 1992;57:751-5. <http://www.ncbi.nlm.nih.gov/pubmed/1532561>.
- Rulin MC et al. (Level II-2): Long Term effect of tubal sterilization on menstrual indices and pelvic pain. Obstet Gynecol 1993;82:118-21. <http://www.ncbi.nlm.nih.gov/pubmed/8515910>.



Confusió

Anticonceptius previs
Estat perimenopàusic

Table 7–13: Bleeding reported at follow-up visits in phase II study

Follow-up visit	Irregular menses	Spotting	Changes in flow	Other and unspecified
3-months	not asked	not asked	not asked	not asked
6-months	3/199 (2%)	6/199 (3%)	3/199 (2%)	0
12-months	6/196 (3%)	5/196 (3%)	4/196 (2%)	0
18-months	9/193 (5%)	4/193 (2%)	5/193 (3%)	0
24-months ^a	4/194 (2%)	4/194 (2%)	10/194 (5%)	3/194 (1.5%)
36-months ^a	4/182 (2%)	3/182 (2%)	4 (182 (2%)	3/182 (1.6%)
48-months ^a	4/176 (2%)	3/176 (2%)	9/176 (5%)	3/176 (1.7%)
60-months ^a	16/171 (9%)	3/171 (2%)	11/171 (6%)	3/171 (1.8%)

^aNo data reported for some women that indicated other/unspecified bleeding (N=2 at 24 months; N=1 at 36, 48 and 60 months)



Table 7–14: Changes in menstrual function reported at follow-up visits (pivotal study)

Follow-up visit	Irregular menses	Bleeding between menses	Heavier than usual menstrual flow	Less than usual menstrual flow
Baseline, N=518	9 (1.7%)	12 (2.3%)	N/A	N/A
3-months post-device placement	48 (10.3%) N=467	110 (23.6%) N=466	89 (19.2%) N=463	56 (12.1%) N=463
Post-alternative contraception				
3-months	36 (8.2%) N=440	40 (9.1%) N=440	96 (21.9%) N=439	55 (12.5%) N=439
6-months	36 (8.2%) N=437	29 (6.6%) N=437	94 (21.6%) N=435	57 (13.1%) N=435
12-months	35 (7.7%) N=455	31 (6.7%) N=460	77 (16.8%) N=458	67 (14.6%) N=458
18-months	19 (4.6%) N=410	42 (10.2%) N=411	70 (17.0%) N=411	63 (15.3%) N=411
24-months	20 (4.6%) N=435	32 (7.4%) N=435	89 (20.6%) N=432	53 (12.3%) N=432
36-months	31 (7.4%) N=420	25 (6.0%) N=420	83 (20.2%) N=411	47 (11.4%) N=411
48-months	33 (8.4%) N=393	33 (8.3%) N=396	69 (17.9%) N=386	52 (13.5%) N=386
60-months	45 (11.7%) N=386	29 (7.5%) N=386	74 (19.6%) N=377	40 (10.6%) N=377
Recurrent ^a	70 (14.8%) N=473	89 (18.8%) N=473	177 (37.5%) N=472	110 (23.3%) N=472
Persistent (year 1) ^b	3 (0.7%) N=455	2 (0.4%) N=460	7 (1.5%) N=458	12 (2.6%) N=458
Persistent (year 2) ^b	0 (0.0%) N=435	1 (0.2%) N=435	4 (0.9%) N=432	3 (0.7%) N=432
Persistent (year 3) ^b	0 (0.0%) N=420	1 (0.2%) N=420	4 (1.0%) N=411	2 (0.5%) N=411
Persistent (year 4) ^b	0 (0.0%) N=393	0 (0.0%) N=396	3 (0.8%) N=386	1 (0.3%) N=386
Persistent (year 5) ^b	0 (0.0%) N=380	0 (0.0%) N=386	2 (0.5%) N=377	0 (0.0%) N=377

^a *Recurrent*: symptom reported at more than one visit during the follow-up period (ie, symptoms do not have to be reported on consecutive visits). The denominator ("N") is the sum of all unique women who responded over the course of their follow-up period. Not all women responded at all follow-up visits.

^b *Persistent*: symptom reported at all visits during the follow-up period. The denominator ("N") is the total number of unique women responding at the latest follow-up visit.

Studies with data on menstrual changes post-Essure placement

Study	Location / Design	Findings
<p>Kerin JF, Munday D, Ritossa M, Rosen D. Tissue encapsulation of the proximal Essure micro-insert from the uterine cavity following hysteroscopic sterilization. <i>J Minimally Inv Gynecol</i>. Mar-Apr 2007;14(2):202-204. http://www.sciencedirect.com/science/article/pii/S1553465006005474#</p>	<p>US, multicenter / Retrospective observational study of 545 women who underwent Essure placement, 1997-2005</p>	<p>Of the 545 placements, 20 (3.7%) required a subsequent diagnostic second look hysteroscopy for abnormal and/or heavy bleeding. Mean interval to second look, 19.73 months (SD 11.74). Findings included 2 endocervical polyps, 3 endometrial polyps, 1 submucosal myoma, 1 case benign hyperplasia. No evidence of visual epithelial abnormalities, tissue inflammation or abnormal vascular patterns.</p>
<p>Sinha D, Kalathy V, Gupta JK, Clark TJ. The feasibility, success and patient satisfaction associated with outpatient hysteroscopic sterilization. <i>BJOG</i> 2007 Jun;114(6):676-683. http://www.ncbi.nlm.nih.gov/pubmed/17516957</p>	<p>UK / Prospective cohort study, 112 consecutive Essure placements</p>	<p>Successful placement 103/112 (92%); HSG in 84/112 (75%); 100% tests satisfactory. 76/84 (90%) returned questionnaire. At 3 months: 20/76 (26%) reported persistent change in menstrual pattern, 14/76 (18%) reported heavier, 2/76 (3%) reported irregular, 1/76 (1%) reported intermenstrual spotting, 3/76 reported amenorrhea.</p>
<p>Miño M, Arjona JE, Cerdón J, Pelegrin B, Povedano B, Chacon E. Success rate and patient satisfaction with the Essure sterilisation in an outpatient setting: a prospective study of 857 women. <i>BJOG</i>. 2007 Jun;114(6):763-6. http://www.ncbi.nlm.nih.gov/pubmed/?term=17516970</p>	<p>Spain / Single center, prospective study of 857 women undergoing Essure</p>	<p>Successful placement 857/863(99%); 3 month follow up 100%. On survey, no woman reported <u>any change to volume or pattern of menstruation</u>.</p>

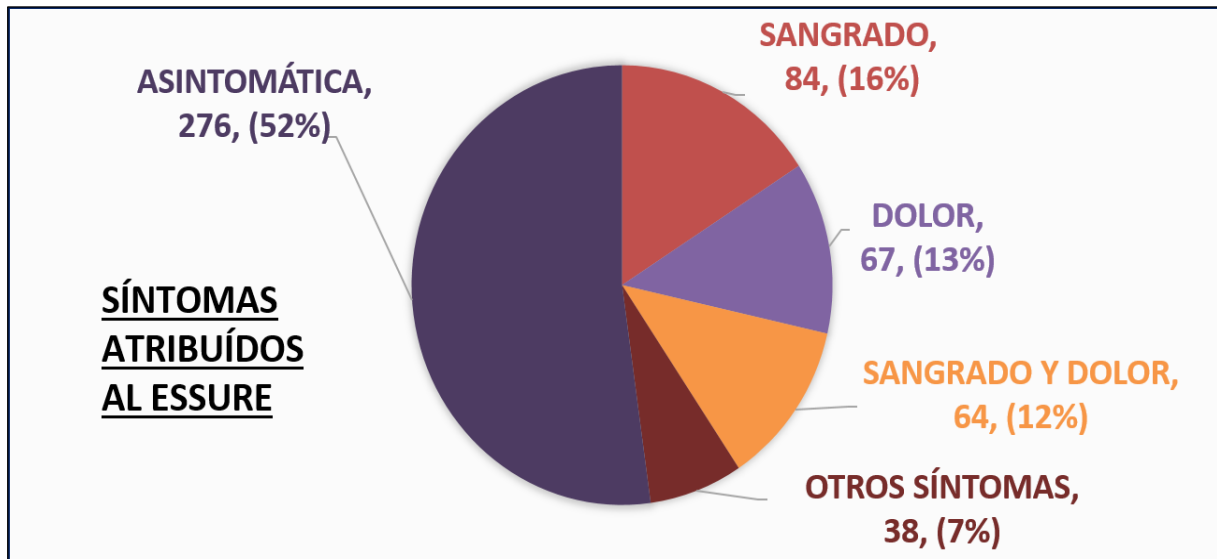


<p>Chern B and Siow A. Initial Asian experience in hysteroscopic sterilization using the Essure permanent birth control device. BJOG: an International J Obstet Gynecol. 2005;Sep(112):1322-1327. http://onlinelibrary.wiley.com/doi/10.1111/j.1471-0528.2005.00436.x/full</p>	<p>Singapore / Retrospective study, June 2001-December 2002, 80 women undergoing Essure placement</p>	<p>Successful placement: 77/80 (96.2%); 3 month confirmation test 67/77 (87%), 100% satisfactory; at 3 month follow up, <u>no patient complained of menstrual disturbance.</u></p>
<p>Ubeda A, Labastida R, Dexeus S. Essure: a new device for hysteroscopic tubal sterilization in an outpatient setting. Fertility & Sterility, Volume 82, Issue 1, July 2004, Pages 196–199. http://www.ncbi.nlm.nih.gov/pubmed/15237011</p>	<p>Spain / Prospective, observational study 85 women, July 2002 – July 2003</p>	<p>Successful placement: 81/85 (95%); 3 month confirmation test 75/81 (93%), 100% satisfactory. <u>No patients reported change to menstrual pattern.</u></p>
<p>Anderson S, Eriksson S, Mints M. Acta Obstet Gynecol Scand. 2009;88(6):743-6. Hysteroscopic female sterilization with Essure in an outpatient setting. http://www.ncbi.nlm.nih.gov/pubmed/19412802</p>	<p>Sweden / Retrospective review of 61 women who had Essure placed 2002-2007. Questionnaires sent 1-5 years post-procedure</p>	<p>Successful placement: 58/61 (95%); 3 month confirmation test 100%; 57/58 (98%) confirmation tests satisfactory. Questionnaire sent to all women; 50/61 (82%) returned. 9/50 (18%) reported heavier periods (none sought treatment) and 8/50 (16%) reported lighter periods.</p>

US = United States; UK = United Kingdom; SD = standard deviation; HSG = hysterosalpingogram.



Casuística Vall d'Hebron: retrospectiu 2015



Altes síntomas: cefalea (19), fatiga (7), disminución libido (7), dolores EEII (6)...



Enquesta telefònica any **2015: 529 Essures®**
(1-6 anys)

Sagnat anormal **28%** (148/529)

0,5% hipermenorrea anemitzant (3/529)

19% Sangrat més abundant (101/529)

11% Irregularitat menstrual (57/529)

2% sangrat intermenstrual (11/529)

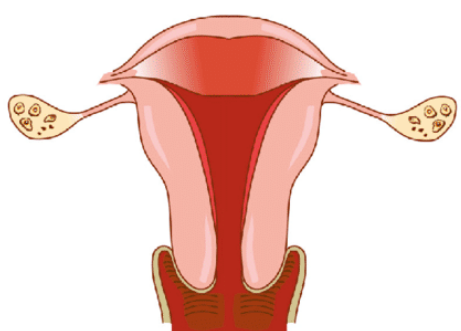
Maneig sagnat menstrual & Essure














Anamnesis: ACOs

PALM-COEIN

Informació sobre literatura i riscos i beneficis de la explantació quirúrgica vs maneig conservador. Consensuar el tractament sintomàtic conservador.

DIU levonorgestrel - histerectomia

P Polyp A:  B: 	Coagulopathy C H: 
A Adenomyosis C:  D: 	Ovulatory O I: 
L Leiomyoma E: 	Endometrial E J: 
M Malignancy F:  G: 	Iatrogenic I K: 
	Not otherwise classified N L:  M: 

A: USS view of polyp
 B: Hysteroscopic view of polyp
 C: MRI of adenomyosis
 D: USS of adenomyosis
 E: Hysterectomy specimen containing fibroids
 F: Hysterectomy specimen containing endometrial cancer
 G: Histology of endometrioid carcinoma
 H: Excessive bruising
 I: USS of polycystic ovary
 J: Progesterone receptor localisation in secretory phase
 K: levonorgestrel-releasing intrauterine system (LNG-IUS)
 L: Doppler USS of AV malformation
 M: Doppler USS of endometrial pseudo-aneurysm



KEEP
CALM

AND

PRIMUM NON
NOCERE



Moltes gràcies per la seva atenció

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