

Results

Comparison of cumulative risk of pregnancy in "CREST study" vs. Essure® sterilization*

Method	Year				
	1	2	3	4	5
Bipolar	2.3	4.6	6.7	13.1	16.5
Unipolar	0.7	2.3	2.3	2.3	2.3
Silicone band	5.9	7.6	8.3	9.0	10.0
Spring clip (Hulka)	18.2	23.8	29.1	30.7	31.7
Interval salpingectomy	7.3	15.1	15.1	15.1	15.1
Postpartum salpingectomy	0.6	3.9	4.6	5.4	6.3
All "CREST" average	5.5	8.4	9.9	11.8	13.1
Essure®, posterior mean	0.5	1.0	1.6	2.0	2.6**

*Cumulative number of pregnancies/1000 women. ** Represents 75 Phase II patients who have completed 5 year follow-up. No patients in the Pivotal Study have reached the 5 year follow-up visit.

Effectiveness

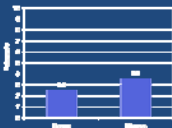
Age-adjusted Posterior cumulative Bayesian effectiveness rates (posterior means) for Essure: Phase II and Pivotal trials combined**

1 years	2 years	3 years	4 years	5 years
99.95%	99.90%	99.84%	99.80%	99.74%**

* Age adjustments are for comparison to CREST as a reference population.

** Represents 75 Phase II patients who have completed 5 year follow-up. No patients in the Pivotal Study have reached the 5 year follow-up visit.

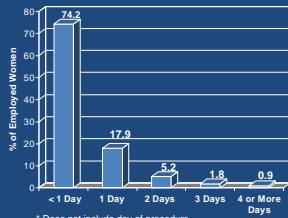
High Patient Satisfaction and Comfort



- 98% would recommend to a friend
- Ave. pain score less than menses

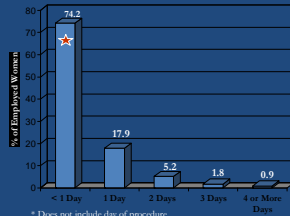
Levine M, Oudhoff S, Kaiser B, Levy B, Oyler D. Multicenter Trial of Hysteroscopic Sterilization in the Office Setting Under Local Anesthesia: Patient Assessment of Procedural Pain and Satisfaction. Abstract, AACB, 2007. Washington DC.

Days of Work Missed for Employed Women*



* Does not include day of procedure

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Phase II & Pivotal Status

Patients relying on bilateral Essure Micro-Insert for contraception with no reports of pregnancy (Years)

	< 1	1	2	3	4	5
Phase II N=194	1	193	183	173	168	41
Pivotal N=449	8	441	417	397	38	0
N Total # of Women		SUM Total months of reliance	MEAN Average months of reliance	STD DEV (months)	MAX (months)	
	643	28,290	44	11	64.3	

As of October 15, 2004

4 Year Effectiveness Rate

Year of Follow-up	Crude %	Adjusted %
1	99.96	99.95
2	99.92	99.89
3	99.87	99.84
4	99.83	99.79
5	99.79	99.72

Summary of raw and age-adjusted Posterior cumulative Bayesian effectiveness rates (posterior means) for Essure micro-insert in combined Phase II and Pivotal Studies. Age adjustments are for comparison to OSES as a reference population.

Ultimate Reliance Rates: Bilateral Placement

- 97% (449/ 464) reliance rate
- 0.6% (3/ 464) lost to follow-up
- 2.6% (12/ 464) adverse event preventing reliance
 - Expulsion
 - Perforation
 - Other unsatisfactory device location

Effectiveness Calculations: Phase II and Pivotal Trial Combined

- No reported pregnancies in women relying on Essure Procedure Micro-Insert in Phase II* or Pivotal trials
- **The combined four-year failure rate is 0%**
(95% CI 0-0.51%)

Clinical Trial Conclusions

- Highly effective
- Very high patient satisfaction
 - Well-tolerated placement procedure
 - Rapid return to work/ normal activities
 - Comfortable and safe
- No requirement for general anesthesia
- No requirement for incisions

Permanent Birth Control Options

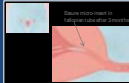
- Vasectomy



- Tubal ligation



- Essure procedure



PBC Procedure Comparison

	Essure procedure	Tubal Ligation	Vasectomy
Incisions/ punctures	None	1-2	1-2
Typical anesthesia	Local	General	Local
Average days to resume regular activities	1-2	4.4	2
Effectiveness rate	99.80% <small>(at 4 years of follow-up)</small>	99.16% <small>(at 2 years of follow-up)</small>	99.85% <small>(at 1 year of follow-up)</small>

Benefits of Hysteroscopic Sterilization to Patients *and* Physicians

Patient Benefits	Physician Benefits
No incisions	Virtually no exposure to major complications
Anesthesia options	May select no anesthesia, local, IV sedation or general
Quicker recovery	Little recovery room time needed, less personnel time needed for monitoring patient
Office setting	-Less invasive procedure that can be done in office or out-patient setting -No OR scheduling or waiting if done in office
Less pain/discomfort post procedure	High patient satisfaction
Competitively priced with tubal w/o the higher risks	Essure Procedure more economical, particularly if performed in office setting

Conclusions: Hysteroscopic Sterilization

- Non-incisional, transervical procedure
- Three technical hurdles successfully addressed:
 - Fallopian tube access
 - Device placement
 - Reliable retention
- Mechanism of action confirmed by histology and HSG
- Excellent patient satisfaction