

Risk and Design

Bioengineering 100

Fall 2016

Attendance Policy

- Per the syllabus, in-class participation and surveys are 15% of your total grade
- You will earn 0.5pt/class up to 15 points max.
- There are 24 lectures and 12 discussions (starting 9/6)
- I highly recommend you attend discussion until week 6 as we will be assigning debate groups and topics in discussion.

Code of Ethics

- Assignment will be posted on bCourses by the weekend
- Draft #1 is due September 20th

Wrap up of Endoscope

FDA clears Olympus TJF-Q180V duodenoscope with design modifications intended to reduce infection risk

[SHARE](#)

[TWEET](#)

[LINKEDIN](#)

[PIN IT](#)

[EMAIL](#)

[PRINT](#)

For Immediate
Release

January 15, 2016

- On market since 2010
- 510k filed October 2014

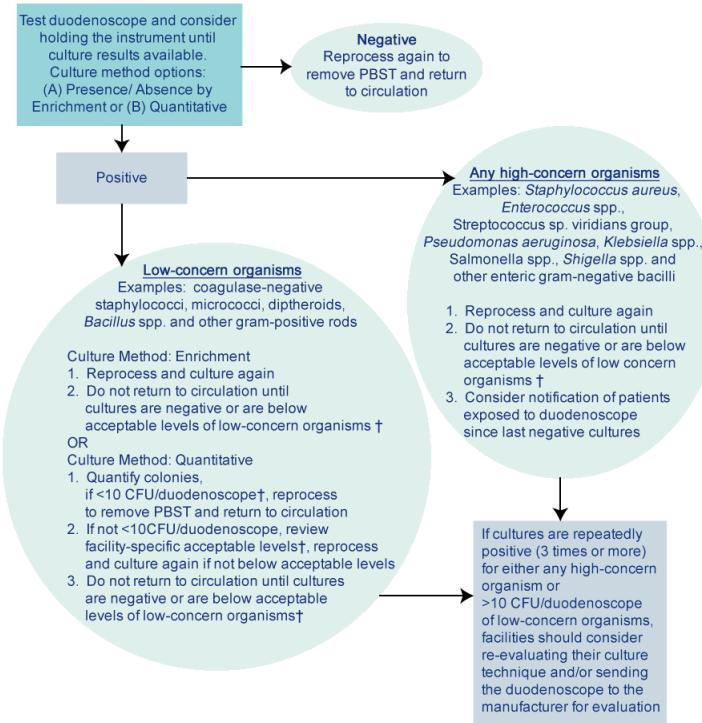


Olympus TJF-Q180V

- February 2016: began replacing elevator mechanism on existing models
- “The forceps elevator replacement will result in minor changes to the dimensional tolerance of the forceps elevator mechanism and O-ring. These changes will not be apparent through visual inspection.”
- New reprocessing protocol



CDC Interim Duodenoscope Surveillance Protocol



† The levels of low-concern organisms on a duodenoscope may vary depending on the reprocessing, handling, and culturing practices in a facility. Therefore, the acceptable level of these organisms can vary. Facilities can monitor the levels of low-concern organisms during the first month of surveillance testing to develop an appropriate baseline for those organisms. Typically, fewer than 10 CFU of these microbes does not require intervention; interpretation of culture results with ≥ 10 CFU of non-pathogenic microbes should be considered in the context of expected culture results at the facility

Definitions

Negative – A liquid enriched culture is not turbid

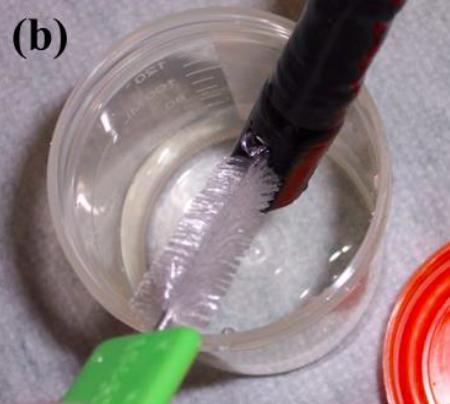
Positive – A liquid enriched culture is turbid

CFU – colony forming units

PBST – Phosphate buffered saline with Tween®-80 solution

Sampling Method

- Elevator/Channel:
 - Brush distal end
- Channel:
 - Flush with sterile water



(c)

CDC interim sampling method for the duodenoscope

Culture Method



Blood agar: hemolytic activity



Risk: A (very) brief introduction

Define ‘risk’

What is risk?

Frequency:

Probability of a hazardous event

Risk

Severity:
Consequence of hazardous event



Risk Management



ISO 14971

The manufacturer shall establish and maintain a process for identifying hazards associated with a medical device, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the control.

Identify, Evaluate, Mitigate

Risk Estimation

Determine Frequency and Severity for each identified Hazard.

Likelihood Number (L)	Likelihood of Occurrence Classification	Likelihood of Occurrence Description (during the lifetime of the device)
5	Frequent	Occurring quite often or at close intervals
4	Probable	Likely to happen or to become real
3	Occasional	Occurring from time to time, at irregular or infrequent intervals
2	Remote	Slight probability of occurrence
1	Improbable	Unlikely to ever occur

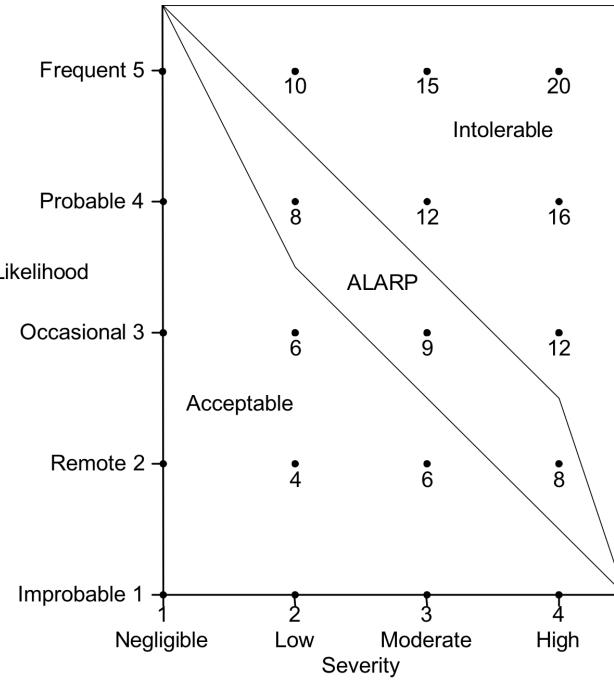
Severity Number (S)	Severity Classification	Severity Description
4	High	Potential of death or serious injury
3	Moderate	Potential of non-life threatening injury, pain, or direct or indirect exacerbation of existing non-life threatening condition
2	Low	Potential of minor injury, pain, or user discomfort
1	Negligible	No potential of injury, pain or discomfort

Risk Level =

severity * likelihood of occurrence

3 Scales: Intolerable, As Low as Reasonably Practicable, Acceptable

Risk Level		Severity (S)		Likelihood of Occurrence (L)
Intolerable	20	High	4	Frequent 5
Intolerable	16			Probable 4
Intolerable	12			Occasional 3
ALARP	8			Remote 2
Acceptable	4			Improbable 1
Intolerable	15	Moderate	3	Frequent 5
Intolerable	12			Probable 4
ALARP	9			Occasional 3
Acceptable	6			Remote 2
Acceptable	3			Improbable 1
Intolerable	10	Low	2	Frequent 5
ALARP	8			Probable 4
Acceptable	6			Occasional 3
Acceptable	4			Remote 2
Acceptable	2			Improbable 1
Acceptable	5	Negligible	1	Frequent 5
Acceptable	4			Probable 4
Acceptable	3			Occasional 3
Acceptable	2			Remote 2
Acceptable	1			Improbable 1



Risk Control



Intolerable Risks must be mitigated through design.

Risk and Design: Another case study

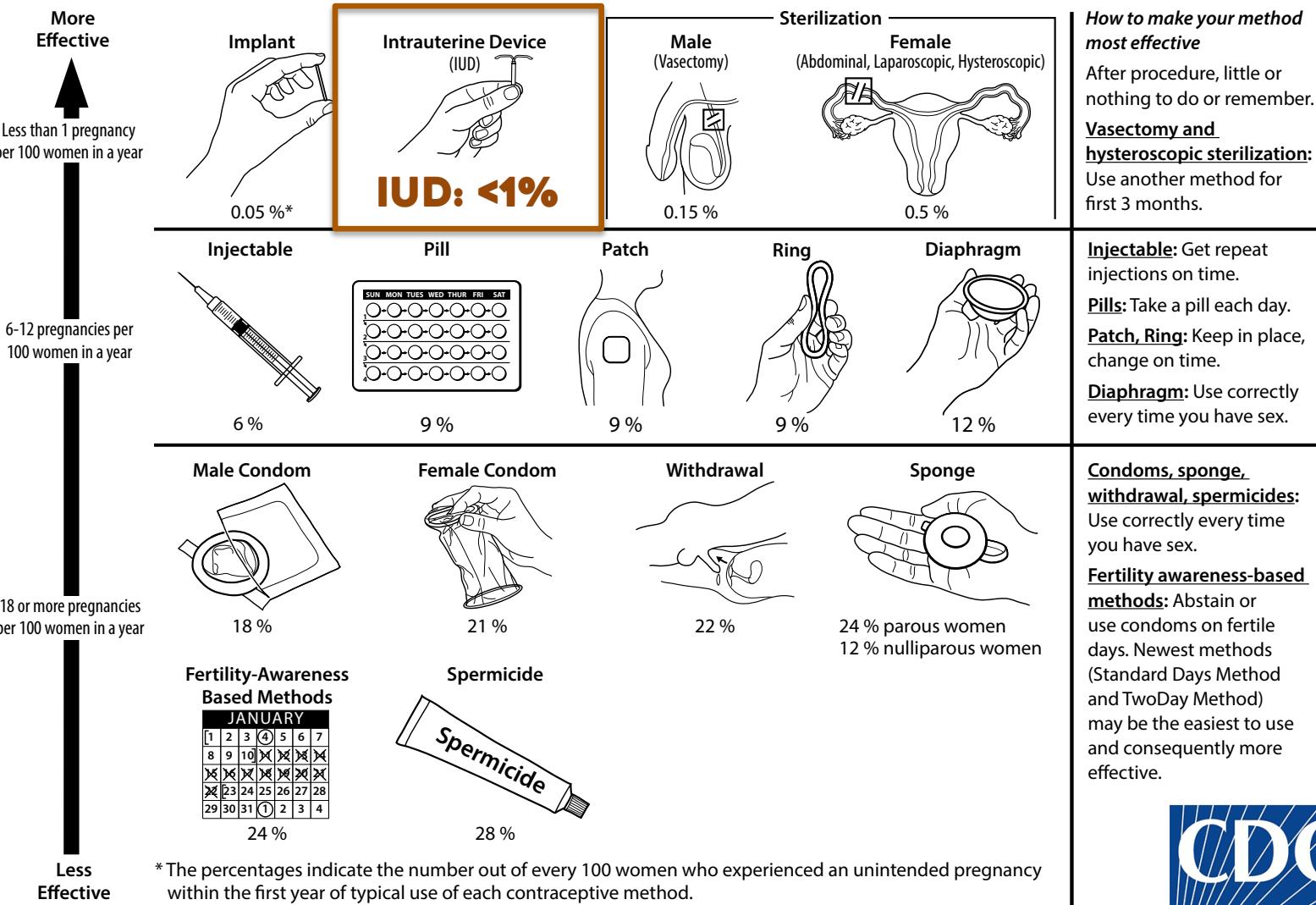


**WHAT
IS
THIS?**

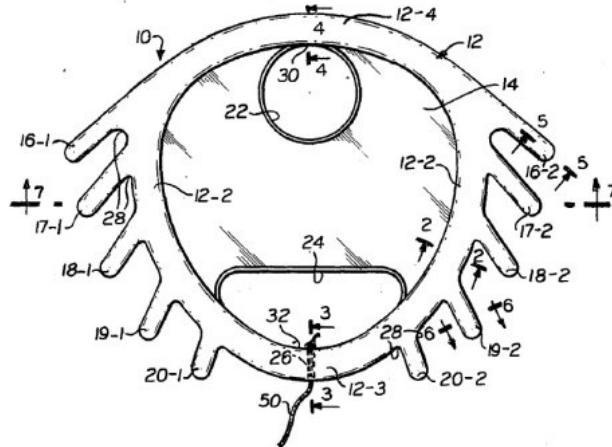


THE DALKON SHIELD IUD: A CASE STUDY

EFFECTIVENESS OF CONTRACEPTIVE METHOD



Hugh Davis and Irwin Lerner



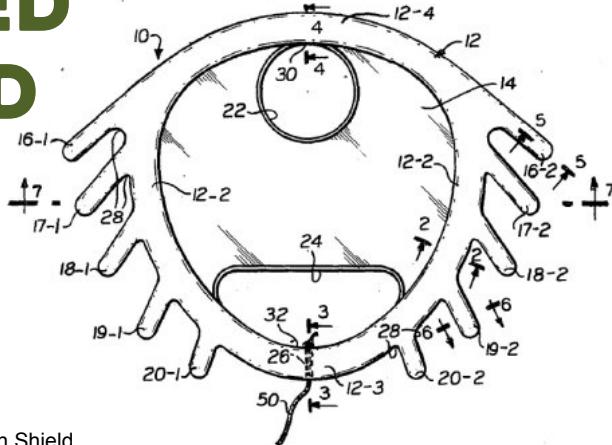
- Hugh Davis, MD
 - Johns Hopkins University
 - Proponent of alternatives to the pill
 - Inventor of several IUDs
- Irwin Lerner
 - Electrical engineer
 - Lerner Laboratories
- Dalkon patent was filed under Lerner Laboratories, and only listed Lerner as 'inventor'

Lerner Labs & Dalkon Corporation

- Lerner Labs was renamed Dalkon Corp
- Hugh Davis owned 35% of Dalkon Corp

What are the conflicts of interest here? What professional obligation does Davis have to Johns Hopkins? Can clinicians and researchers be objective in their evaluation of devices and drugs they may be paid consultancy fees for?

**PATENTED
& TESTED**



United States Patent 3782376, Dalkon Shield

**WHAT WAS SOLD &
INSERTED INTO WOMEN**



DALKON SHIELD

A-H-ROBINS

Dalkon Shield™—
the only IUD anatomically engineered*
for optimum uterine placement,
fit, tolerance, and retention.

The "second generation" IUD is here. It's the Dalkon Shield, anatomically engineered for maximum comfort and contraceptive effectiveness. The Shield is molded from a soft, flexible, resilient plastic that readily conforms to the shape of the uterine cavity and bends and gives with uterine contractions. This superior, rational design reduces the risk of expulsion, lessens cramping and bleeding and assures exceptional patient tolerance and comfort. Hard-plastic or metal IUD's, on the other hand, force the uterus to conform to their size and shape.

More effective contraception, better retention
A major factor in contraceptive effectiveness is believed to be the surface area of the device. The unique central membrane of the Dalkon Shield gives it the highest surface area to circumference ratio of all IUD's, assuring greater endometrial contact and minimal pregnancy rates.

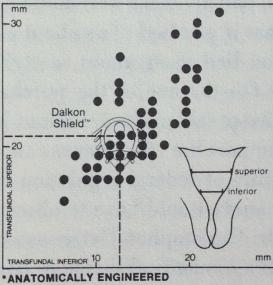
The fin design of the Shield helps keep it in place. Expulsive contractions directed against the broad upper portion of the device result in flaring and flexion of the apex, increasing resistance to expulsion.

Easy to insert

The Dalkon Shield mounted on its inserter comes in a sterile package. When the recommended procedure is followed, correct placement of the Shield high in the fundus is easily and safely accomplished.

- low pregnancy rate ... 1.1%
- low expulsion rate 2.3%
- high continuation rate .. 94%
- nulliparous model available

Contraindications: Pregnancy. Distortion of uterine cavity by myoma or congenital septum. Menometriosis. Acute or subacute salpingitis. Salpingitis. Chronic pelvic or endometritis. **Time of insertion:** Most authorities agree that the ideal time for insertion is 12 weeks post-partum. Insertion can be accomplished with greater ease and greater assurance that the patient is not pregnant if the time of insertion is scheduled during menstrual flow. **Side Effects:** Transient post-



Dalkon Shield™



insertion cramps noted by some women. Post-insertion syncope may occur in individuals. Spontaneous resolution of menstrual cramps in first cycle is not unusual. **Caution:** Sepsis may result from unclear technique. Perforation may result from traumatic insertion. Insertion is not recommended if uterus sounds less than 5 cm., or if cervical canal is stenotic by sounding. **Removal:** At the end of one year's replacement with a new Dalkon Shield is

A. H. Robins Company, Richmond, Va. 23220

ADVERTISED 1.1% PREGNANCY RATE

Average pregnancy rate for other
IUDs: over 2%

Average length of time that women
in Shield studies had worn the
device: less than 6 months

Marketed to general practitioners as
well as OB-GYNs.

A-H ROBINS

Dalkon Shield™—
the only IUD anatomically engineered*
for optimum uterine placement,
fit, tolerance, and retention.

The "second generation" IUD is here. It's the Dalkon Shield, anatomically engineered for maximum comfort and contraceptive effectiveness. The Shield is molded from a soft, flexible, resilient plastic that readily conforms to the shape of the uterine cavity and bends and gives with uterine contractions. This superior, rational design reduces the risk of expulsion, lessens cramping and bleeding and assures exceptional patient tolerance and comfort. Hard-plastic or metal IUD's, on the other hand, force the uterus to conform to *their* size and shape.

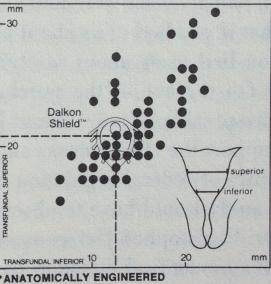
More effective contraception, better retention
A major factor in contraceptive effectiveness is believed to be the surface area of the device. The unique central membrane of the Dalkon Shield gives it the highest surface area to circumference ratio of all IUD's, assuring greater endometrial contact and minimal pregnancy rates.

The fin design of the Shield helps keep it in place. Expulsive contractions directed against the broad upper portion of the device result in flaring and flexion of the apex, increasing resistance to expulsion.

Easy to insert

The Dalkon Shield mounted on its inserter comes in a sterile package. When the recommended procedure is followed, correct placement of the Shield high in the fundus is easily and safely accomplished.

- low pregnancy rate ... 1.1%
- low expulsion rate 2.3%
- high continuation rate.. 94%
- nulliparous model available



Dalkon Shield™

Contraindications: Pregnancy. Distortion of uterine cavity by myoma or congenital septum. Menometrorrhagia. Acute or subacute salpingitis. Subacute pelvic peritonitis or endometritis. **Time of insertion:** Most authorities agree that the ideal time for insertion is 12 weeks post-partum. Insertion after accouche is for greater ease and greater assurance that the patient is not pregnant if the time of insertion is scheduled during menstrual flow. **Side Effects:** Transient post-

insertion cramps noted by some women. Post-insertion syncope may occur in individuals. Slight protrusion of menstrual tissue in first cycle is not unusual.

Caution: Sepsis may result from unclear technique. Perforation may result from traumatic insertion. Insertion is not recommended if uterus sounds less than 5 cm., or if cervical canal is found stenotic by sounding. **Removal:** At the end of one year's replacement with a new Dalkon Shield is

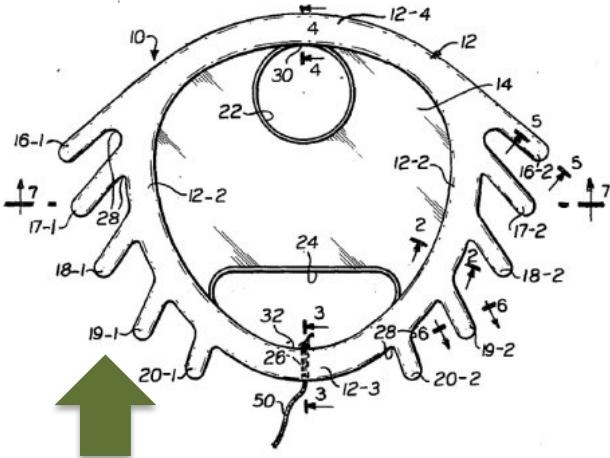


recommended. **Supply:** A carton contains 12 individual sterile packed and preloaded on disposable inserters ready to use. Available in Standard (multiparous) and Small (nulliparous) sizes.

A. H. Robins Company, Richmond, Va. 23220

**SOLD TO AH ROBINS
FOR \$750,000
(\$4.5 MILLION IN 2013)**

**1971-1974:
4 MILLION UNITS
SOLD WORLDWIDE**



'WINGS' TO DECREASE EXPULSION RATES

"When the Dalkon Shield appeared on the scene, we rejected its use on my say so. Why? Well it's a gruesome looking little device that I would not allow to be installed in myself, that's why. Furthermore, with those vicious spikes, its installation would present a serious problem for removal....

We have seen several patients with the Dalkon Shield put in elsewhere and several have been the most difficult to extract in the operating room under anesthesia. I regard... the Dalkon Shield as a poorly designed IUD and a veritable instrument of torture."

Letter to Frederick Clark, AH Robins from Dorothy Lansing, OB-GYN



**COPPER
DOPED
PLASTIC**

“With the addition of copper the Shield device is virtually 100 percent effective in preventing pregnancies.”
Hugh Davis in January 1971 Good Housekeeping magazine

“... it is essential that you avoid any suggestion or implication that the copper additives contribute to or enhance the contraceptive effectiveness of the Shield...” April 1971 Memo to AH Robin salesmen from John Burke, general sales manager for AH Robins

“I told him that I couldn’t, in good conscience, not say something about something that I felt could cause infections. And he said that my conscience didn’t pay my salary...” E Wayne Crowder, Quality control supervisor at Chap Stick

**MULTI-
FILAMENT →
STRING**



**DEATHS:
18-20 KNOWN**

**COMPLICATIONS:
4X MORE LIKELY**

**ACTUAL
PREGNANCY
RATE: ~5%**

**FRAGMENTED DALKON
SHIELD PARTIALLY
EMBEDDED IN THE UTERINE
WALL**





1984: RECALLED

**1985: AH
ROBINS FILED
BANKRUPTCY**

**218,000 CLAIMS
WITH ALMOST
\$3 BILLION
PAID OUT**

Who is ultimately responsible for
the safety and efficacy of drugs and
devices?

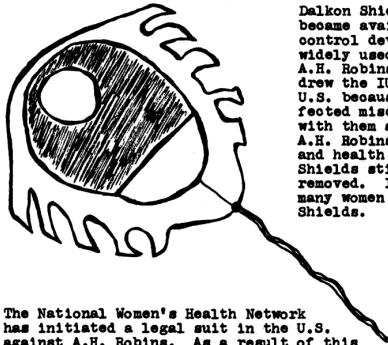


https://www.wired.com/wp-content/uploads/images_blogs/magazine/2011/07/ff_iud_f.jpg



https://www.wired.com/wp-content/uploads/images_blogs/magazine/2011/07/ff_iud7_f.jpg

The Fight Against Dalkon Shield IUD's



Dalkon Shield intra-uterine devices became available to women as birth control devices in 1969. They became widely used in a short time. By 1974, A.H. Robins, the manufacturer, withdrew the IUD from further sale in the U.S. because of the high rate of infected miscarriage and death associated with them already. Finally, in 1980 A.H. Robins issued a letter to doctors and health centres stating that all Shields still worn by women should be removed. In 1981, it is suspected that many women are still wearing Dalkon Shields.

The National Women's Health Network has initiated a legal suit in the U.S. against A.H. Robins. As a result of this action, the NWHN hopes that:

- Robins will be forced to admit to having information about dangerous design flaws of the Dalkon Shield before it was marketed
- the company will have to take financial responsibility for a world wide recall of the Shield
- individual women will be inspired to sue Robins for personal damages

JOIN US!

The Shield (as well as other IUD's) caused infections and uterine perforations leading to pain, hysterectomy and infertility. We want to force drug companies to take responsibility for their faulty and dangerous products!

The Women's Health Collective is joining the NWHN's suit in the U.S. on behalf of Canadian women who suffered from the effects of the Dalkon Shield. In Western Canada, women can get involved in action against A.H. Robins (and possibly other IUD manufacturers) by joining with us in the U.S. suit and/or by sending us their old Dalkon Shield IUD to be used as evidence in the hearing. You need not have worn an IUD to get involved!

If you would like to join us or get more information, phone or write the Vancouver Women's Health Collective 736-6696 or drop in at 1501 West Broadway. Vancouver.

Who are candidates for the Dalkon Shield?

The Nullip



The "Pill Reactor"



The "Clinic Patient"



The Disorganized Woman



The applications of the Dalkon Shield are so universal that they cut across all socio-economic lines. They include all women who are not sufficiently motivated to take the Pill, ranging from the clinic patient* to the busy mother-career woman who has so many worries and interests that taking a pill simply slips her mind. They also include poor patients who are disorganized she can't seem to get anything done on schedule.

A prime candidate is the young nullip who will settle for nothing less than the most modern, trouble-free method of birth control. For her the Dalkon

is taken off the Pill, others may have asked you to substitute another method of birth control. Again, the Dalkon Shield is the contraceptive method of choice because it has no general effects on the body, blood, or brain. It cannot alter hormonal balance -cause depression, headache, weight gain, or fluid retention. Nauseated menstrual irregularities are rare.

The modern woman also wants to be liberated from monotonous birth control devices such as the diaphragm. A few women can't use a diaphragm;

*Courtesy of a doctor. By Dr. Gary Egan at North Carolina Hospital Bureau of Public Health. About 400,000 women of a total population under age forty years in America are currently using Dalkon Shield as their contraceptive. Of 110 million women who are capable of getting pregnant the Dalkon