

K940176

510(K) Summary

A. REQUIRED INFORMATION

1. Submitted by: Ackrad Laboratories, Inc. 70 Jackson Drive, Cranford, NJ 07016. Telephone number (908) 276-6390. Contact person: Bernard Ackerman, Ph.D. Date: December 28, 1993
2. Device name
Ackrad IUI Set for Intrauterine Insemination
3. Predicate devices
 - a. Royal Women's Coaxial Catheter Set model no. KJLLS-852100 and 852101 marketed by Cook OB/GYN of Spencer, Indiana (Exhibit 2). 510(K) No. K894837.
 - b. Ackrad H/S Catheter Set (K842231) (Exhibit 3)
4. Description of the device
The Ackrad IUI Set consists of two parts: a calibrating probe and an introducing catheter, each of which is accompanied by a placement sheath to aid in insertion. (Exhibit 1)

The calibrating probe is a clear flexible tube, closed and rounded at the distal tip. A movable stop is attached to assist in calibrating the depth of insertion. Five narrow bands, one cm apart, designate distances of 25, 26, 27, 28 and 29cm from the distal tip, with a wide band at 30cm from the tip. The proximal end is fitted with a two-cm length of large diameter tubing to serve as a handle. The outside diameter of the probe is 1.8 mm and the working length is 44.0 cm.

The introducing catheter is identical to the calibrating probe except that the distal end has an end port or side port within 3 mm of the tip, and the proximal end is fitted with a standard female luer-lock hub.

Both the probe and the catheter are composed of clear, naturally flexible polyurethane material. The movable stop is composed of clear polyvinyl chloride of a 55-60A durometer.

Both the calibration probe and the catheter have a placement sheath through which they pass as an aid in insertion. The sheath is composed of rigid polypropylene material, 20 cm long with an inside diameter of 3.4 mm and an outside diameter of 4.6 mm. The distal end is rounded to minimize trauma.

The ink used for the banding of the catheter and probe is No-tox no. M-1000, manufactured by the Colorcon Corp. of West Point, PA.

The device functions as a means of accurately injecting the donor sperm into the uterus of the receptor patient. The calibrating probe is first used to measure the proper depth for insertion. Then sperm is introduced into the uterus via the catheter and expelled at the proper depth. The placement sheath allows both the probe and the catheter to be advanced through the cervix of the patient easily and non-traumatically without buckling or inadvertently touching the vagina.

5. Intended Use

The Ackrad IUI Set is intended for use in cases where the recipient has had difficulty in achieving pregnancy in the customary way. The patient population comprises women generally ranging in age from 25 to 45.

The intended use is the same as the Royal Women's Coaxial Catheter Set (i.e. intrauterine insemination). The intended use is different from the Ackrad H/S Catheter Set which is used for a diagnostic procedure, hysterosalpingography. The H/S Catheter is passed into the uterus and delivers a quantity of contrast media for x-ray or ultrasound diagnosis. The IUI probe and catheter are passed into the uterus in exactly the same way, using the same placement sheath as the H/S Catheter and delivering the sperm into the uterus upon depression of an external syringe.

6. Technological Characteristics

The materials of the IUI set are virtually identical to those of the H/S Catheter. The only difference is that the polyurethane tubing of the H/S Catheter contains a radiopaque ingredient, while the identical polyurethane tubing of the IUI catheter and probe contains no additive and is clear. The placement sheath is identical in both devices. Both the marking ink and movable stop are FDA-approved materials and in any case do not contact body tissue during the procedure.

The Ackrad IUI Set is similar to the Royal Women's Coaxial Catheter set but differs in that the former is used in two separate insertions. The IUI Set differs from the H/S Catheter Set in that both the probe and catheter of the former have no balloon and the catheter is single, not double lumen. In addition, the IUI Set has marking bands ascribed to assess the depth of insertion, and is optically and radiographically transparent.

B. PERFORMANCE DATA

1. Non-clinical tests

Pull tests were conducted on the attachments of the proximal fittings of the probe and catheter. Five samples were tested, all samples resisted a force of 1 kg.

Ten samples were wiped over the banded area with a paper wipe soaked in warm water. No smearing or removal of the black markings was observed.

2. Laboratory tests

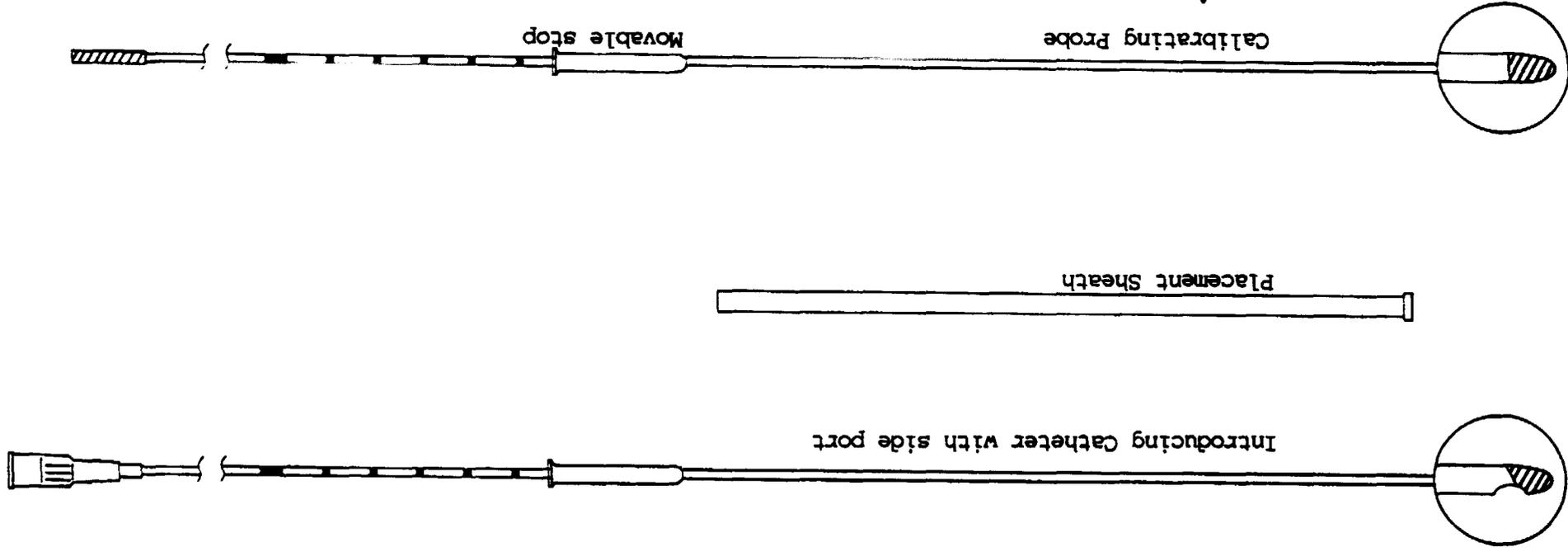
Prior to introducing the catheter into clinical testing studies were performed in which sperm were loaded into the catheter and incubated at 37°C overnight. Sperm motility as determined the next morning was not different from that of control sperm not incubated in the catheter.

3. Clinical testing

The IUI Set was used at the Reproductive Endocrinology and Fertility Services department of The Malden Hospital (100 Hospital Road, Malden, MA 02148) for intrauterine insemination procedures on female patients between the ages of 24 to 42 under informed consent conditions (see Exhibit 4). None of the patients experienced adverse affects and no complication occurred.

C. CONCLUSIONS OF SAFETY AND EFFECTIVENESS

The Ackrad IUI set is a safe and effective device for achieving pregnancy following intrauterine insemination. It has an advantage over existing devices in that it affords flexibility and ease of insertion in to the uterus.

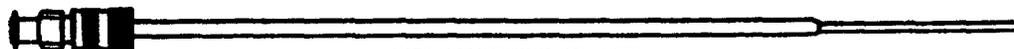


510(K)
ACKRAD IUI SET
Exhibit 1

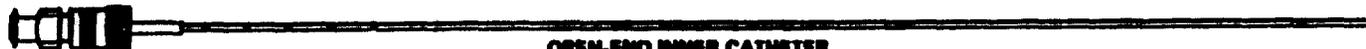
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ROYAL WOMEN'S COAXIAL CATHETER SETS

The translucent inner catheter is designed to fit coaxially through the larger diameter introducing catheter. Centimeter markings on the proximal portion of the inner catheter indicate the position of its distal tip relative to that of the introducing catheter. The introducing catheter is of a two-part design with an inner translucent sleeve extending 4 centimeters beyond the larger diameter portion. The inner catheter is available with either an open-end, or closed-end with side opening. Supplied sterile in peel-open packages.



INTRODUCING CATHETER
 8.5 French radiopaque Teflon®
 with 5.5 French translucent Teflon® tip



OPEN-END INNER CATHETER
 3.0 French translucent Teflon® 28 cm long



CROSS SECTION OF DISTAL TIP



SIDE OPENING INNER CATHETER
 Translucent Teflon®



CROSS SECTION OF DISTAL TIP

SET ORDER NUMBER	Remarks
KJLLS-882100	Open-end inner catheter and plastic fittings
KJLAS-882101	Side opening inner catheter and plastic fittings
KJLLS-882102	Open-end inner catheter and metal fittings
KJLLS-882103	Side opening inner catheter and metal fittings

REFERENCE

I. W. H. Johnston, M.D., A. Lopata, M.D., P. Leung, M.D., Reproductive Biology Unit, Royal Women's Hospital, Victoria, Australia.

COOK OB/GYN®
 A DIVISION OF COOK UROLOGICAL INC.
 1100 West Morgan Street P.O. Box 271
 Spencer, Indiana 47480 U.S.A.
 Phone: 812 829-8500 Telefax: 812 829 2022
 Toll Free: 800 541-5591 Telex: 6711525

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