DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: SEP 30 1997

From: Deputy Director for Clinical and Review Policy, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject: Humanitarian Device Exemption Approval of Rocket PLC
King's College Hospital Fetal Bladder Drainage Catheter - ACTION

To: Director, CDRH
Regulations Policy and Management Staff, Office of Policy
(HF-26) _____

ISSUE. Publication of a notice announcing approval of the subject Humanitarian Device Exemption (HDE).

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) an HDE approval order for the above referenced medical device (Tab B); and

(2) the availability of the summary of safety and probable benefit for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Kimber C. Richter
Kimber C. Richter, M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - Summary of Safety and Probable Benefit (SSPB)

DECISION

Approved ✓ Disapproved _____ Date 9/30/97

Revised by Elisa Harvey, D.V.M., Ph.D., CDRH, HFZ-470, 9/9/97, 594-1180

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. _____]

Rocket Medical PLC; Humanitarian Device Exemption Approval of King's College Hospital (KCH) Fetal Bladder Drainage Catheter

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the humanitarian device exemption application by Rocket Medical PLC, Tyne and Wear, England, under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the act), for the King's College Hospital (KCH) Fetal Bladder Drainage Catheter.

DATES: Petitions for administrative review should be submitted by (insert date 30 days after date of publication in the Federal Register).

ADDRESSES: Written requests for copies of the summary of safety and probable benefit and petitions for administrative review should be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., Rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Elisa Harvey,

Office of Device Evaluation,

Center for Devices and Radiological Health (HFZ-470),

Food and Drug Administration,

9200 Corporate Blvd.,

Rockville, MD 20850,

301-594-1180.

SUPPLEMENTARY INFORMATION: On June 9, 1997, Rocket Medical PLC, Tyne and Wear, England submitted an application for a humanitarian device exemption (HDE) of the King's College Hospital (KCH) Fetal Bladder Drainage Catheter to CDRH. The device is a fetal bladder stent and is indicated for fetal urinary tract decompression following the diagnosis of fetal post-vesicular obstructive uropathy in fetuses 18 to 32 weeks gestational age.

In accordance with the 21 CFR 814.116(a), this HDE was not referred to the Obstetrics and Gynecology Devices Panel, an FDA advisory committee, for review and recommendation because the information in the HDE substantially duplicates information previously reviewed by this panel.

On September 30, 1997, CDRH approved the application by a letter to the applicant from the Deputy Director of Clinical and Policy Review of the Office of Device Evaluation, CDRH.

A summary of the safety and probable benefit upon which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon

written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts under Part 14 (21 CFR Part 14). A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue(s) to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the Federal Register), file with the Dockets Management Branch (address above) two copies each of the petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 520(h) of the act (21 U.S.C. 360j(h))), 21 CFR 814.116(b), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: _____.

_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 1997

Rocket Medical PLC
c/o Mr. Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, Connecticut 06907

Re: H970001
KCH Fetal Bladder Drainage Catheter
Filed: June 9, 1997
Amended: July 11, July 30, August 25, and, September 5, 1997

Dear Mr. Keen:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your humanitarian device exemption (HDE) application for the KCH Fetal Bladder Drainage Catheter. This device is indicated for urinary tract decompression following the diagnosis of post-vesicular obstructive uropathy in fetuses 18 to 32 weeks gestational age. CDRH is pleased to inform you that your HDE is approved subject to the enclosed "Conditions of Approval". Please note, however, that as stipulated in section 520(m)(5) of the Federal Food, Drug and Cosmetic Act (the act)(21 U.S.C. 360j(m)(5)), this approval is only valid for a period of 18 months from the date of this approval order. An extension of approval may be requested in accordance with the procedures outlined in the "Conditions of Approval." You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are limited to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the act (21 U.S.C. 360j(e)) under the authority of section 515(d)(1)(B)(ii) of the act (21 U.S.C. 360e(d)(1)(B)(ii)). In addition, in order to ensure the safe use of the device, FDA has further restricted the device within the meaning of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act insofar as (1) the labeling shall specify the training requirements for practitioners who may use the device as approved in this order and (2) the sale, distribution, and use must not violate sections 502(q) and (r) of the act (21 U.S.C. 352(q) and (r)).

In addition to the above, an FDA inspection must find that your manufacturing facilities, methods, and controls for this device comply with the applicable Current Good Manufacturing Practice (CGMP) requirements as set forth in the Quality System Regulation (21 CFR Part 820). Such an inspection will be scheduled and conducted by your District Office. If you have any questions regarding the status of your GMP inspection, please contact your District Office or the Office of Compliance, CDRH at (301) 594-4695.

FDA wishes to remind you that failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

CDRH will publish in the Federal Register a notice of its decision to approve your HDE. The notice will state that a summary of the safety and probable benefit of the device upon which the approval was based is available to the public upon request. Within 30 days of publication of the notice of approval in the Federal Register, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act (21 U.S.C. 360e(g)).

Any information to be submitted to FDA regarding this HDE should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above HDE number to facilitate processing:

Document Mail Center (HFZ-401)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Elisa D. Harvey, D.V.M., Ph.D., at (301) 594-1180.

Sincerely yours,

Kimber C Richter

Kimber C. Richter, M.D.
Deputy Director of Clinical
and Review Policy
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: Les Todd
Quality Assurance and
Regulatory Affairs Manger
Rocket Medical PLC
Wear Industrial Estate
Washington Tyne and Wear
NE 37 1NE
ENGLAND

CONDITIONS OF APPROVAL FOR AN HDE

I. APPROVED LABELING

As soon as possible and before commercial distribution of the device, the holder of an HDE should submit three copies of the approved labeling in final printed form as an amendment to the HDE. The supplement should be submitted to the Document Mail Center (HFZ-401), Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

II. ADVERTISEMENTS

Advertisements and other descriptive printed materials issued by the HDE holder or private label distributor with respect to this device should not recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(e)) under the authority of section 515(d)(1)(B)(ii) of the act (21 U.S.C. 360e(d)(1)(B)(ii)), all advertisements and other descriptive printed material issued by the holder or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications.

III. HDE SUPPLEMENTS

Before making any change affecting the safety or probable benefit of the device, the HDE holder should submit a supplement for review and approval by FDA unless a "Special HDE Supplement" is permitted as described under 21 CFR 814.39(d)(2) or an alternate submission is permitted as described under 21 CFR 814.39(e). All HDE supplements or alternate submissions must comply with the applicable requirements under 21 CFR 814.39 of the Premarket Approval (PMA) regulation and under 21 CFR 814.106 of the Humanitarian Device Exemption regulation.

Since all situations which require an HDE supplement cannot be briefly summarized, please consult the HDE regulation for further guidance. The guidance provided below is only for several key instances. In general, an HDE supplement must be submitted:

1) When unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification; or

2) If the device is to be modified, and animal/laboratory or clinical testing is needed to determine if the modified device remains safe and continues to provide probable benefit.

HDE supplements submitted under 21 CFR 814.39(d)(2) "Special HDE Supplement - Changes Being Effected" are limited to the labeling, quality control, and manufacturing process changes as specified under this section of the regulation. This provision allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented upon acknowledgment by FDA that

the submission is being processed as a "Special HDE Supplement - Changes Being Effected." Please note that this acknowledgment is in addition to that issued by the Document Mail Center for all HDE supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software, or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of an HDE supplement before implementation and include the use of a *30-day HDE supplement* or *periodic postapproval report*. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence to the HDE holder that the alternate submission is permitted for the change. Before this can occur, FDA and the HDE holder must agree upon any needed testing, the testing protocol, the test results, the reporting format, the information to be reported, and the alternate submission to be used.

Please note that unlike the PMA process, a supplement may not be submitted for a new indication for use for a humanitarian use device (HUD). An HDE holder seeking a new indication for use for an HUD approved under the provisions of Subpart H of 21 CFR 814, must obtain a new designation of HUD status for the new indication for use and submit an original HDE application in accordance with §814.104. The application for the new indication for use may incorporate by reference any information or data previously submitted to the agency.

IV. POSTAPPROVAL RECORD KEEPING REQUIREMENTS

An HDE holder is required, for the duration of the period that a HUD is approved for marketing, to maintain records of the names and addresses of the facilities to which the HUD has been shipped, correspondence with reviewing institutional review boards (IRBs), as well as any other information requested by a reviewing IRB or FDA.

V. POSTAPPROVAL REPORTING REQUIREMENTS

Continued approval of the HDE is contingent upon the submission of postapproval reports required under 21 CFR 814.84 and 21 CFR 814.126 and extension requests under 21 CFR 814.120. In order to avoid duplicative reporting, the periodic postapproval reports required under 21 CFR 814.84(b) may be combined with a request for extension. Postapproval reports for supplements approved under the original HDE should be included in the next and subsequent periodic reports for the original HDE unless otherwise specified in the approval order for the HDE supplement.

A. As specified by section 520(m) of the act, an HDE is valid for a term of 18 months from the date of approval but can be extended at 18-month intervals. In order to avoid the risk of a lapse in marketing approval, the holder of an HDE wishing to obtain an extension should submit such a request to FDA at least 90 days prior to the expiration of the HDE. Three copies of the request for extension, with the outside envelope plainly marked "Request for Extension of HDE Approval", should be submitted to the Document Mail Center (HFZ-401), Office of Device Evaluation, Center for Devices

and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The submission should state the applicant's name and address, the HDE number, and should include the following information based upon the first 12 months of experience with the device following the most recent HDE approval or extension:

(1) An update of the information required under §814.102(a) in a separately bound volume;

(2) An update of the information required under §§814.104(c)(2), (c)(3), and (c)(5);

(3) The number of devices that have been shipped or sold and, if the number shipped or sold exceeds 4,000, an explanation and estimate of the number of devices used per patient. If a single device is used on multiple patients, the applicant shall submit an estimate of the number of patients treated or diagnosed using the device together with an explanation of the basis for the estimate;

(4) Information describing the applicant's clinical experience with the device. This shall include safety information that is known or reasonably should be known to the applicant, a summary of medical device reports made pursuant to 21 CFR 803, any data generated from postmarketing studies, and information (whether published or unpublished) that is known or reasonably expected to be known by the applicant that may affect an evaluation of the safety of the device or that may affect the statement of contraindications, warnings, precautions, and adverse reactions in the device labeling; and

(5) A summary of any changes made to the device in accordance with supplements submitted under §§814.108 and 814.39(b).

B. If the HDE holder does not wish to maintain marketing approval for the humanitarian use device and thus does not submit an extension request, a final report should be submitted no later than 90 days following the expiration of the period of marketing approval. Three copies, identified as "Final Report" and bearing the applicable HDE reference number, should be submitted to the Document Mail Center at the address provided above. The final report should include the following information required by 21 CFR 814.126(b)(1):

(1) An estimate of the number of patients who were treated or diagnosed with the device and the number of devices shipped or sold since initial marketing approval under the humanitarian device exemption. (If the number of devices shipped or sold exceeds 4,000 per year, an explanation and estimate of the number of devices used per patient shall be included. Similarly, if a single device is used on multiple patients, the applicant shall submit an estimate of the number of

patients treated or diagnosed using the device together with an explanation of the basis for the estimate.);

(2) Information regarding the retrieval or disabling of unused devices, a summary of results and conclusions with regard to the clinical use of the device, and a summary of the medical device reports submitted under 21 CFR 803; and

(3) A summary and bibliography of published and unpublished data, reports, and studies involving the device that are known to or that reasonably should be known to the applicant and were not previously submitted to FDA. If, after reviewing the summary and bibliography, FDA concludes that a copy of the unpublished or published information is needed, FDA will notify the holder that copies shall be submitted.

C. **ADVERSE REACTION AND DEVICE DEFECT REPORTING**

As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and probable benefit of the device, the holder shall submit three copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the Document Mail Center (HFZ-401), Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. Such reports should be submitted within 10 days after the HDE holder receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved HDE that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the HDE holder's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the firm. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the holder shall be included in the "Request for Extension of HDE Approval" described under "Postapproval Reports" above unless otherwise specified in the conditions of approval for this HDE. This

postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of occurrence for each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the HDE holder when determined by FDA to be necessary to provide continued reasonable assurance of the safety and probable benefit of the device for its intended use.

D. **REPORTING UNDER THE MEDICAL DEVICE REPORTING REGULATION**

The Medical Device Reporting regulation (MDR) (21 CFR 803) became effective on April 11, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices:

(1) may have caused or contributed to a death or serious injury; or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Events subject to reporting under the MDR regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements. FDA has determined, however, that such duplicative reporting is unnecessary. Therefore, whenever an event involving a device is subject to reporting under both the MDR regulation and the "Adverse Reaction and Device Defect Reporting" requirements, the report should be submitted in compliance with Part 803 and identified with the HDE reference number to the Division of Surveillance Systems (HFZ-531), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850. For questions regarding the MDR regulation, please call (301) 594-2735.

Events included in periodic reports to the HDE that have also been reported under the MDR regulation must be so identified in the periodic report to the HDE to prevent duplicative entry into FDA information systems.

Copies of the MDR regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Lane
Rockville, Maryland 20850

SUMMARY OF SAFETY AND PROBABLE BENEFIT

I. GENERAL INFORMATION

Device Generic Name: Fetal Bladder Stent

Device Trade Name: King's College Hospital (KCH)
Fetal Bladder Drainage Catheter

Applicant's Name and Address:

Rocket Medical PLC
Wear Industrial Estate
Washington Tyne and Wear
NE37 1NE
England

Humanitarian Device Exemption (HDE) Number: H970001

Date of Humanitarian Use Device Designation: June 24, 1997

Date of Panel Recommendation: The HDE was not taken to panel, as a PMA for another fetal bladder stent was reviewed by the Obstetrics and Gynecology Devices Panel on July 23, 1996.

Date of Good Manufacturing Practices Inspection: A pre-approval inspection for this HDE was not performed. A routine GMP inspection, however, was performed on August 18, 1994, and a post-approval GMP inspection will be scheduled approximately eight months following approval of the HDE.

Date of Notice of Approval to Applicant: September 30, 1997

II. INDICATIONS FOR USE

The King's College Hospital (KCH) Fetal Bladder Drainage Catheter is intended for use in fetal urinary tract decompression following diagnosis of fetal post-vesicular obstructive uropathy in fetuses 18-32 weeks gestational age.

It is recommended that the following investigations are conducted to determine if the fetus is suitable for treatment with the KCH Fetal Bladder Drainage Catheter:

a. Ultrasound investigation to demonstrate lower obstructive uropathy, normally indicated by bilateral hydronephrosis, ureterostasis, megacystitis or oligohydramnios;
b. Fetal karyotyping to exclude chromosomal anomalies;
c. Serial vesicocentesis to evaluate fetal renal function through fetal urinary

biochemical parameters. The parameters and their respective cut-off values are shown below:

Na+ < 100 mg/dL
Ca++ < 8 mg/dL
Osmolarity < 200 mOsm/L
β-2-μ-globulin < 4 mg/L
Protein < 20 mg/L

III. DEVICE DESCRIPTION

The KCH Fetal Bladder Drainage Catheter is a nylon double pigtail stent (OD 2.1mm; ID 1.5mm). The coils are wound to 18mm diameter with 30mm between the coils. The proximal pigtail consists of a double coil (720°) oriented perpendicularly to the shaft of the stent so that it will lie flat against the external fetal abdomen in the amniotic sac. The distal pigtail consists of one and a half coils (540°) which are parallel to the shaft of the stent in order to hold the pigtail inside the fetal bladder. Both coils have three drainage holes offset 90°. The proximal and distal coil tips are supported by stainless steel catheter tip inserts for enhanced drainage and ultrasound visualization. The stent set includes a stainless steel inner stylet, and a nylon suture pad. The device is placed under ultrasonic visualization using a reusable stainless steel trocar/cannula assembly.

IV. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

The KCH Fetal Bladder Drainage Catheter should not be used in the presence of the following conditions:

- severe congenital abnormalities that jeopardize neonatal survival
- abnormal karyotype
- renal cortical cysts or evidence of renal failure

The warnings and precautions can be found in the Professional Labeling (Attachment 1).

V. ADVERSE EFFECTS OF THE DEVICE ON HEALTH

a. Reported Adverse Effects

Rocket Medical PLC currently has no reported adverse effects on file for the KCH Fetal Bladder Drainage Catheter. Rocket PLC reports that, to date, insufficient response has been yielded from the questionaire provided with the KCH Fetal Bladder Drainage Catheter. However, maternal chorioamnionitis has been identified as an

adverse effect for a similar legally marketed device in one out of fourteen cases studied.

Reported Side Effects

Rocket Medical PLC currently has no reported side effects on file for the KCH Fetal Bladder Drainage Catheter. Rocket PLC reports that, to date, insufficient response has been yielded from the questionnaire provided with the KCH Fetal Bladder Drainage Catheter. However, listed below are the side effects reported for a similar legally marketed device. From 18 stent placements in 14 fetuses, two types of side effects were reported:

- stent migration (6 cases)
- stent blockage (1 case)

c. Potential Adverse Events

- Ascites
- Maternal sepsis
- Amniotic fluid leak and/or complete rupture of the membranes
- Direct trauma to the fetus, such as intestinal perforation or amniotic band syndrome
- Uterine or placental injury or bleeding
- Preterm labor
- Spontaneous abortion

VI. ALTERNATE PRACTICES AND PROCEDURES

The only alternative procedures to the use of a fetal bladder stent are repeated periodic needle aspiration (vesicocentesis) from the fetal bladder or open fetal surgery. Currently, there is one other fetal bladder stent approved under an HDE. Without the use of a fetal bladder stent, vesicocentesis, or surgery, mortality of fetuses affected by this condition is high.

VII. MARKETING HISTORY

The concept design of the KCH Bladder Drainage Catheter was first proposed by Charles Rodeck, M.D., Senior Lecturer, Kings College Hospital, London. It was developed by Rocket Medical PLC between 1981-1984, and has been available since then. Sales statistics are only available from 1989 onwards and these demonstrate that approximately 4100 devices have been distributed worldwide.
The KCH Fetal Bladder Drainage Catheter has not been withdrawn from marketing for any reason related to safety or probable benefit of the device.

VIII. SUMMARY OF STUDIES

A. Preclinical Studies

1. Mechanical/Physical Properties

The finished sterilized nylon stents underwent testing for flow rate, tensile (break) strength, and curl strength. Testing was conducted on a sample of ten stents.

Flow Rate

Average flow rate was 25.79 +/- 1.2 ml/min, which is higher than flow rates for legally marketed ureteral stents. In addition, data from the published literature indicates that fetal urine output ranges from 0.03-0.77 ml/min. The flow rate for this stent can therefore easily accommodate the expected fetal urine output.

Tensile (Break) Strength

Mean break load was 3843 g +/- 320 g, which is comparable to tensile strength for legally marketed ureteral stents and slightly greater than the tensile strength for a legally marketed fetal bladder stent. This tensile strength is expected to exceed anticipated forces applied to it during its placement in a fetal bladder.

Curl Strength

The sponsor provided data on curl strength (force required to uncurl the stent) for the distal (fetal bladder) 540° curl, and the proximal (amniotic sac) 720° curl. Mean distal curl strength was 108 +/- 27 g, and mean proximal curl strength was 121 +/- 26 g. These strengths are greater than those reported for other legally marketed stents. Additionally, the design of the device is such that both curls would straighten prior to breakage of the main shaft.

2. Materials and Biocompatibility

The King's College Hospital (KCH) Fetal Bladder Drainage Catheter uses the following patient-contacting materials:

Stent	-	Nylon
Trocar assembly	-	Stainless Steel

This device is classified as a permanent implant. To support its biocompatibility, the sponsor submitted results of the following testing on the nylon tubing in support of the biocompatibility of this device:

1) cytoxicity;
2) implantation (intramuscular); and
3) systemic (acute) toxicity.

Tests utilized acceptable and established protocols. Results from this testing demonstrated no systemic toxicity, cytoxicity, or implantation reaction. Possible tests which may be applicable to this type of device which were not conducted include 1) sensitization; 2) genotoxicity; 3) irritation (or intracutaneous reactivity); 4) subchronic (subacute) toxicity; 5) chronic toxicity; and 6) carcinogenicity. The sponsor provided the following justification in lieu of additional biocompatibility testing:

"No further biocompatibility data is available for this device, but nylon and stainless steel have been used for many years in the medical industry, and have had a historically safe life. This particular device has not altered in composition for some 10 years now, in this period, we have received no complaints of the device regarding patient reaction to its use. We believe that this device is safe for the procedure intended."

It is believed that the biocompatibility testing already performed, along with the justification provided by the sponsor, the safe history of use of nylon and stainless steel in medical devices in general, and the long history of previous use of this device, precludes the necessity for further biocompatibility testing. The device does not pose a great risk of toxicity, due to the long safe history of use of nylon material and stainless steel in medical devices. In addition, although the device can be considered a "permanent" implant according to ISO-10993 Guidelines, its placement is nevertheless temporary in nature, not intended to remain in place following delivery of the fetus (up to 22 weeks). Therefore, it is **not** believed that chronic toxicity or carcinogenicity testing is necessary. The information provided by the sponsor is adequate to demonstrate that the device is biocompatible for the proposed intended use.

B. Clinical Studies

No clinical data was submitted by Rocket in their HDE application. However, supporting evidence from the published literature can be summarized as follows:

King (1993) estimated the incidence of fetal hydronephrosis at approximately 1 out of 800 pregnancies. The condition can spontaneously resolve about 50% of the time, with the least severe cases most likely to spontaneously resolve. Gunn et al. (1995) reported that in one series of 42 fetuses, congenital hydronephrosis

improved in utero in 28%, was stable in 36%, and progressed in 37% of fetuses. Harrison (1990) indicates that the sequelae of non-resolving early high grade obstruction are reduced urine output, oligohydramnios, pulmonary hypoplasia secondary to thoracic compression, and ultimately post-natal respiratory insufficiency and death. Vintzileos suggested in 1992 that for these fetuses, in utero surgery may be the only method for preventing the serious consequences of unresolved obstruction.

Numerous articles in the published literature address the use of fetal bladder stents for treatment of this disease. Vintzileos (1992), in a review of various indications for percutaneous intrauterine fetal shunting, suggested that "initial experience has suggested that prenatal surgical therapy may be of value in distal obstructive uropathy," while Camosy (1995), in a review of invasive fetal procedures, reports that "urinary diversion with a vesicoamniotic shunt placed under ultrasound guidance is now a routine procedure." This literature does support the use of fetal bladder stents in the treatment of fetal post-vesicular obstructive uropathy.

Vaughan et al. (1988) reported on the successful use of this specific device to treat another fetal disorder, pleural effusions. They point out that for this indication, only four of 47 cases in one study showed either blockage or dislodgement (no breakdown of how many of the four were blocked vs. dislodged). Nevertheless, this study does demonstrate that patency of this device was maintained in most patients in whom it was placed, and noted that complications of shunt placement (e.g., transient abdominal ascites) were rare. They also noted that "we have been using this equipment for vesicoamniotic shunting since 1982."

IX. CONCLUSIONS DRAWN FROM STUDIES

Results of toxicology testing in conjunction with the history of safe use of the device materials, provides sufficient assurance of biocompatibility for the proposed intended use of the device. Performance testing (flow rate, tensile strength and curl strength) adequately demonstrates that the device will perform as intended for the proposed intended use of the device. Together, these data provide reasonable assurance of the safety of the device.

Although no clinical data are presented as part of this submission, there is some clinical experience with the use of fetal bladder stents. Evidence from the published literature does suggest that the use of vesicoamniotic stents to treat posterior obstructive uropathy has become a viable and useful alternative to repetitive vesicocentesis or fetal surgery for the clinical community (perinatologists) who treat this disorder. Without the use of either a fetal bladder stent or other alternative procedures, the risk of death for the fetus is high. Given the reasonable assurance of safety of the device demonstrated through preclinical testing and probable benefit of the device as suggested in the literature, the risk of injury or illness from the use of the device is outweighed by the probable benefit to health of the device.

X. PANEL RECOMMENDATIONS

On July 23, 1996, the Obstetrics and Gynecology Devices Advisory Panel met to consider a PMA for a similar fetal bladder stent. The Panel determined that the limited clinical data that had been collected were inadequate to provide the assurance of safety and effectiveness required to recommend approval of a PMA. However, the Panel concluded that this is a life-threatening issue for the affected fetus, and that some device needs to be available. Based on the Panel's recognition of the need for this type of device, Rocket PLC submitted their HDE application for consideration.

XI. CDRH DECISION

CDRH has determined that, based on the data submitted in this HDE, that the KCH Fetal Bladder Drainage Catheter will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness, and issued an approval order on September 30, 1997.

XII. APPROVAL SPECIFICATIONS

Directions For Use: See labeling (Attachment 1).
Warning, Hazards to Health for Use of the Device: See indications, contraindications, warnings, precautions and adverse effects in the Labeling (Attachment 1).

XIII. REFERENCES

Camosy, P. 1995. Fetal Medicine: Treating the unborn patient. American Family Physician 52: 1385-1392.

Gunn, T.R., et al. 1995. Antenatal diagnosis of urinary tract abnormalities by ultrasonography after 28 weeks gestation: incidence and outcome. American Journal of Obstetrics and Gynecology 172: 479-486.

Harrison, M.R., Golbus, M.S., Filly, R.A. 1990. The Unborn Patient, Florida: Grunn and Stratton, pp. 277-341.

King, L.R. 1993. Fetal hydronephrosis: what is the urologist to do? Urology 42: 229-231.

Vaughan, J. I., Fisk, N.M., Rodeck, C.H. 1988. Fetal Pleural Effusions. Invasive Fetal Testing and Treatment, ed. C.R. Harman, Blackwell Scientific Publications, pp. 219-236.

Vinzileos, A.M., Campbell, W.A., Rodis, J.F. 1992. Percutaneous intrauterine fetal shunting. Operative Obstetrics, ed. L. Iffy et al., McGraw-Hill, pp. 110-113.

Rocketmedical

Rocket KCH
Fetal Bladder Drainage Catheter
(KCH Catheter)

Professional Labelling

&

Instructions for Use

PROFESSIONAL LABELLING:

Humanitarian Device: Authorised by Federal law for use in the treatment of Fetal obstructive uropathy.
The effectiveness of this device has not been demonstrated

CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician with appropriate training and experience.

1. DEVICE DESCRIPTION:

The device is a double pigtail stent with an outer tube diameter of 2.1mm and inner tube diameter of 1.5mm. The coils are wound to 18mm diameters, 30mm between the coils. The proximal pigtail being a double coil orientated perpendicular to the stent to allow the pigtail to lie flat against the Fetal abdomen. The distal pigtail is a one and a half coil orientated horizontally to the stent in order to hold the pigtail inside the Fetal bladder. Both coils have 3 side ports, with the distal coil tip being supported by a stainless steel tube for enhanced drainage and ultrasound visualisation.

2. INDICATIONS FOR USE:

The KCH Fetal Bladder Drainage Catheter is intended for use in fetal bladder decompression following diagnosis of fetal post-vesicular obstructive uropathy in foetuses of 18-32 weeks gestation.

3. CONTRAINDICATIONS:

The Rocket KCH Fetal Bladder Drainage Catheter should not be used in the presence of the following conditions:

- severe congenital abnormalities that jeopardise neonatal survival
- abnormal karyotype
- renal cortical cysts or evidence of renal failure

4. ADVERSE EFFECTS OF THE DEVICE ON HEALTH

a. Reported Adverse Effects

Currently there are no reported adverse effects on file for the KCH Fetal Bladder Drainage Catheter. However, listed below is the adverse effect reported by Cook Ob/Gyn for their Harrison Fetal Bladder Stent, which is similar to the KCH Fetal Bladder Drainage Catheter:

- Maternal chorioamnionitis (1/14 cases)

b. Reported Side Effects

Currently there are no reported adverse effects on file for the KCH Fetal Bladder Drainage Catheter. However, listed below is the adverse effect reported by Cook Ob/Gyn for their Harrison Fetal Bladder Stent, which is similar to the KCH Fetal Bladder Drainage Catheter. From 18 stent placements in 14 fetuses, two types of side effects were reported:

- Stent migration (6 cases)
- Stent blockage (1 case)

c. Potential Adverse Events

- Ascites
- Maternal sepsis

- Amniotic fluid leak and/or complete rupture of the membranes
- Direct trauma to the fetus, such as intestinal perforation or amniotic band syndrome
- Uterine or placental injury or bleeding
- Preterm labor
- Spontaneous abortion

4. CLINICAL EXPERIENCE

Note: Clinical studies have not been conducted to demonstrate the safety and effectiveness of the kch fetal bladder drainage catheter. However, preclincal studies of the performance and biocompatibility of this device provide reasonable assurance of the safety of the device. In addition, there is limited clinical experience from the marketing of the device, which has indicated no problems with the device in over ten years of use.

5. WARNINGS

Use of the KCH Catheter may cause the following complications

- Ascites
- Maternal sepsis
- Amniotic fluid leak and/or complete rupture of the membranes
- Direct trauma to the fetus, such as Fetal intestinal perforation
- Uterine injury or bleeding, placental bleeding
- Preterm labour

There is a possible risk that these complication may require subsequent intervention leading to spontaneous abortion and in rare cases loss of the uterus.

6. PRECAUTIONS

a. Patient / Diagnostic Evaluation:

A complete medical history should be obtained to determine conditions that might influence the selection of the procedure or to identify conditions that mediate contraindications to use of the device.

Physicians must evaluate each case on its individual merits and only use the device where there significant risk of renal or pulmonary damage if no intervention is made. The physician must have concluded that the risks to the fetus outweigh the potential risks of using the device.

It is recommended that the following investigations are conducted to determine if the fetus is suitable for treatment with the KCH Catheter.
1. Ultrasound investigation to demonstrate lower obstructive uropathy, indication are normally; bilateral hydronephorosis, utereostasis, megacystitis or oligohydramniosis.
2. Fetal karyotyping should be conducted to exclude chromosomal abnormality
3. Serial vesicocentesis to evaluate the fetal renal function through fetal urinary biochemical parameters. The parameters and their respective cut-off values are shown below:

- Na^{+} <100mg/dl
- Ca^{++} <8mg/dl
- Osmolarity <200mOsm/l
- β-2-μglobulin <4mg/l
- protein <20mg/l

b. Patient Counselling:

It is recommended that patients should be closely counselled by the physicians to inform them of the options and the risk and benefits of using the KCH Catheter.

It is recommended that the following items are discussed in detail and the patients concerns fully explored:

Puncture of the uterus and uterine membranes carries with t the risk of leakage of amniotic fluid and the potential complete rupture of he membranes.

Implantation of the KCH Catheter is an invasive procedure and carries with it the risk of infection and the development of chorioamnionitis. This could result in spontaneous abortion or the need for surgical termination. In rare cases intervention could lead to the loss of the uterus.

As with many international procedures during pregnancy there is a risk of premature labour.

Placement of the KCH Catheter will significantly reduce the risk of renal damage, however it does not completely remove the risk that the baby may have co-existing renal or pulmonary impairment on delivery and there may be the need to subsequently perform a renal transplant sometime in the future.

Fetal bladder drainage catheters can become dislodged or blocked and this may necessitate repeated procedures during the pregnancy to allow replacement and/or removal.

7. INSTRUCTIONS FOR USE:

Note: The use of tocolytic agents during and after the procedure may be advisable. Close observation of the condition of the fetus for any sign of preterm labour is mandatory.

a. Patient Preparation:

1. Perform ultrasound to ascertain position of the fetus. Manipulation of the fetus in utero may become necessary to allow the most advantageous access.

2. Sedate the mother if deemed advisable. Sedation of the fetus is not normally required, however if significant manipulation is required or there is excessive Fetal movement Fetal sedation may be required.

3. Establish using ultrasound that there is sufficient fluid in the amniotic space. Fetal obstruction uropathy commonly causes oligohydramniosis and amnio-infusion with 500ml-1000ml of warmed normal saline may be required depending on individual patient conditions..

4. At the time of amnio-infusion, it is advisable to administer intra-amniotic antibiotics due to the threat of choriomnionitis. A broad spectrum antibiotic such as nafcillin (500-1000mg) or a cephalosporin (1-2gm) to which penicillin-resistant Staphylococci are sensitive is recommended. (Note: Administration of specific antibiotics and dosages is dependent on the individual patient's condition, and should be determined by the physician on a a case-by-case basis.

5. Prepare the skin using suitable antibacterial skin prep. Local anaesthetic should be used at the puncture site.

6. Using a No.11 blade make a 5mm incision sufficient to allow insertion of the *trocar and cannula* assembly. (Fig 1.)

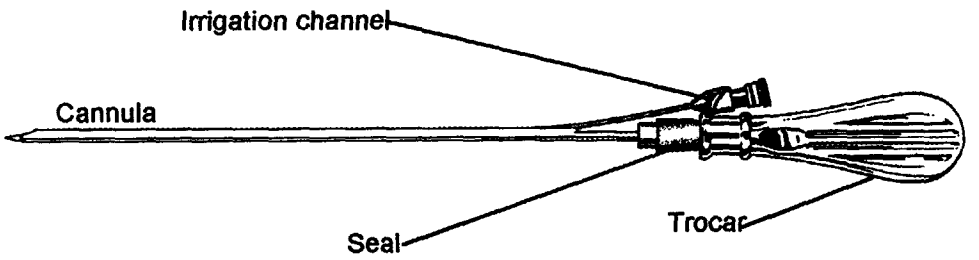

Fig. 1.

7. Under ultrasonic monitoring, introduce the *trocar and cannula* transabdominally into the uterus and Fetal bladder.

8. Aspiration of urine through the *irrigation channel* will confirm correct insertion into the Fetal bladder. Remove the trocar and further aspirate sufficient urine to prevent back flow up the open cannula. Remove the *seal* from the cannula.

9. *The KCH catheter*, with its *guide wire* in place, (Fig.2) is then straightened gently by hand and inserted fully into the cannula using the *catheter pusher* as a guide. Remove the *guide wire and pusher*.

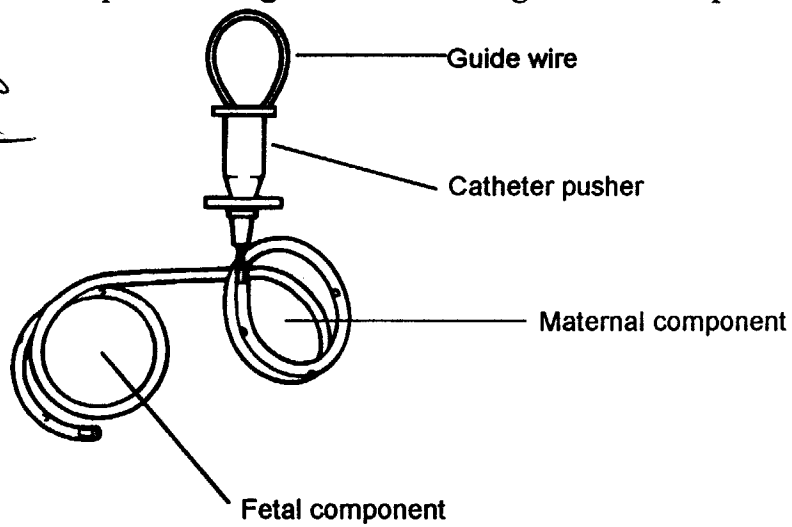

Fig. 2.

10. Using the *first stage pusher rod* (Fig.3) deliver the distal end of the catheter into the Fetal bladder. Under ultrasound control, confirm that the fetal component has coiled fully and is in the correct position.

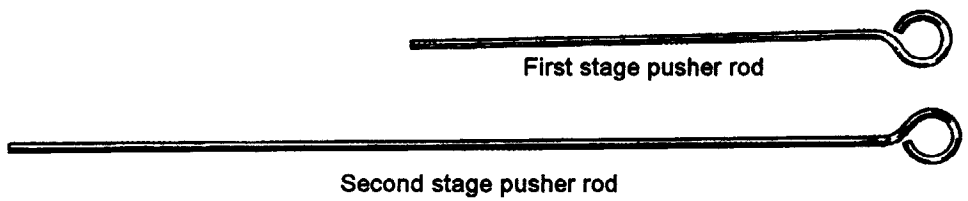

Fig. 3

11. Withdraw the tip of the cannula from the Fetal abdomen and insert the *second stage pusher rod* to deliver the maternal component into the amniotic cavity forming a vesico-amniotic shunt.

CAUTION: Ensure hat both coils are free and that no portion of the stent has been left in the uterine wall.

12. Once correct positioning has been confirmed, remove the cannula and dress the puncture site appropriately.

13. Document the procedure and correct positioning of the KCH catheter.

14. Monitor the Fetal bladder and ensure that the vesico-amniotic shunt is active and drainage is taking place and that there is no evidence of Fetal distress or onset of premature labour.

b. Follow up:

15. Serial ultrasounds should be performed within 24-72 hours to ensure correct function of the stent.

16. Ultrasound examinations should be performed weekly for the rest of the pregnancy to ensure continued function of the shunt.

c. Removal:

17. The KCH catheter can be removed using conventional aseptic technique following satisfactory paediatric urological evaluation.

8. REFERENCES:

Rodeck. C.H., Nicolaides. K.H. "Ultrasound "Guided Invasive Procedures in Obstetrics" in Clinics in Obstetrics & Gynaecology - Vol. 10, No.3, December 1983.

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Rocket KCH
Fetal Bladder Drainage Catheter
(KCH Catheter)

Patient Information

Humanitarian Device: Authorised by Federal law for use in the treatment of fetal obstructive uropathy.
The effectiveness of this device has not been demonstrated

CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician with appropriate training and experience.

DEFINITIONS

Amniocentesis: A procedure in which a sample of the amniotic fluid is taken and studied.

Amniotic Sac: The space around your baby which is filled with fluid.

Chorioamnionitis: An inflammation of the membrane surrounding your baby.

Chorionic Villus Sampling (CVS): A procedure in which a sample of the tissue in the placenta, which is the membrane surrounding your baby, is taken and studied.

Fetal Karyotype: A study of your baby's chromosomes.

Gestational Age: The time that has passed since your baby's conception.

Lower Obstructive Uropathy: A blockage in the urinary tract below the bladder.

Maternal Sepsis: An infection in the mother.

Open Fetal Surgery: The partial removal of a fetus from the uterus so surgery can be performed to correct a defect.

Urinary Ascites: The leaking of urine into your baby's abdomen.

Urinary Tract: The system which removes urine from the body.

Catheter: A tube inserted into a body cavity to allow movement of fluid.

Infuse: The addition of fluid into the body.

Ultrasound: This is how a doctor can look at your baby on a television screen.

WHY IS THERE PRESSURE IN MY BABY'S URINARY TRACT?

In normal pregnancy a baby's urine will drain from the kidneys into the bladder and then through the urinary tract and into the amniotic sac.

It appears that this is not happening with your baby who has a condition known as *lower obstructive uropathy*. This means that there is probably a blockage in your baby's urinary tract and the urine cannot flow freely into the amniotic sac.

The will cause pressure to build up in the urinary tract and if left untreated, could cause damage to your baby's lungs and kidneys. In severe cases this damage could lead to stillbirth or could cause your baby to die shortly after birth because the lungs or kidneys fail. It could also cause severe physical deformities.

The Kings College Hospital Fetal Bladder Drain or 'KCH Catheter' is designed to relieve the pressure in the baby's urinary tract. The KCH Catheter allows the urine to flow from the baby's bladder into the amniotic sac by by-passing the baby's urinary tract so relieving the pressure build-up.

CAN MY BABY BENEFIT FROM THIS PROCEDURE?

Your doctor will advise you if your baby might be suitable for this procedure, typically your baby will benefit if:

- Your pregnancy is between 18 to 32 weeks and has a blocked urinary tract.
- Your baby shows no physical deformities under a detailed ultrasound.
- A study of your baby's chromosomes, also called a fetal karyotype, shows no other serious defect.

WHEN CAN THIS PROCEDURE BE PERFORMED ?

A doctor can perform this procedure if your baby is not less than 18 weeks but no older than 32 weeks gestational age. Since each case is different, your doctor will be able to give you more information about you and your baby.

RELIEVING PRESSURE IN YOUR BABY'S URINARY TRACT:

An obstructed urinary tract is normally discovered during a routine ultrasound examination. Once identified your doctor will perform another, more detailed ultrasound examination, to ensure that your baby has no significant physical problems.

During the next 2 days your doctor will establish that there are no chromosomal problems with your baby. There are two routine methods

The first is called *chorionic villus sampling* or CVS. In CVS, the doctor inserts a fine catheter into your uterus and removes a small tissue sample. The second method is called *amniocentesis* and in this case, the doctor will insert a needle through your abdomen and remove a sample of your amniotic fluid. This tissue or fluid is studied to make sure your baby has no other serious problems.

Finally, the doctor may need to study your baby's urine over a short period to determine how well your baby's kidneys are functioning.

This is normally performed under local anaesthesia and occasionally sedation for you and the baby if he/she is moving around a great deal. The doctor will insert a needle through your abdomen and into your baby's bladder to remove a sample of urine. To do so, the doctor will infuse, or insert fluid, if there is not enough in the space between your baby and the wall of your uterus.

Your doctor may also perform an *amnio-infusion* by infusing warm saline or similar fluid.

PLACING THE KCH CATHETER

The KCH Catheter is placed using ultrasonic monitoring to show it's position on a TV screen. Your doctor will introduce a special needle through your abdomen and into the uterus and fetal bladder. (Fig 1.) Your doctor will then withdraw a little of your baby's urine through the needle to confirm it is in the correct place.

Your doctor will then insert the catheter down the needle and remove the guide wire (Fig 2.) He or she will position the catheter between your baby's bladder and the amniotic space using two 'pusher rods' which leave a coil of catheter in your baby's bladder and another coil outside in your amniotic space. This allows urine to drain from your babies bladder into your amniotic sac and relive the pressure in your baby's urinary system. (Figs 3 & 4)

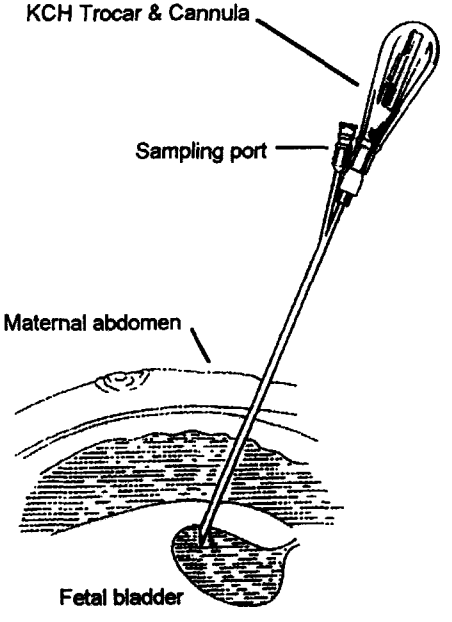


Fig 1 - Inserting the KCH Trocar & Cannula

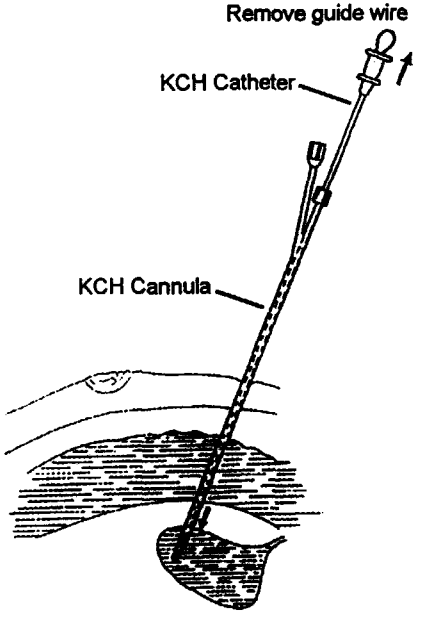


Fig 2 - Removing the guide wire

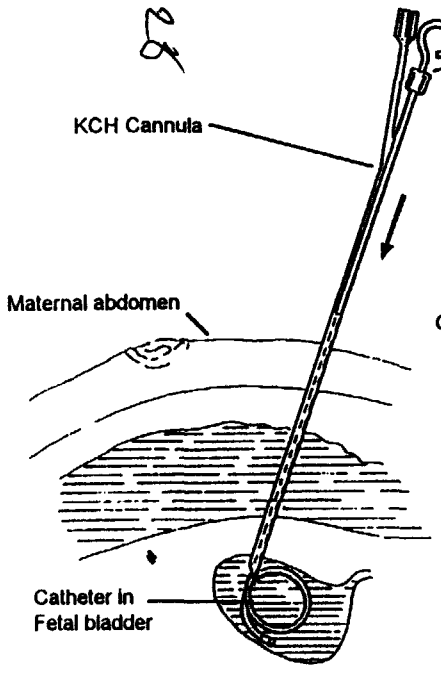


Fig 3: Expelling the catheter into the fetal bladder

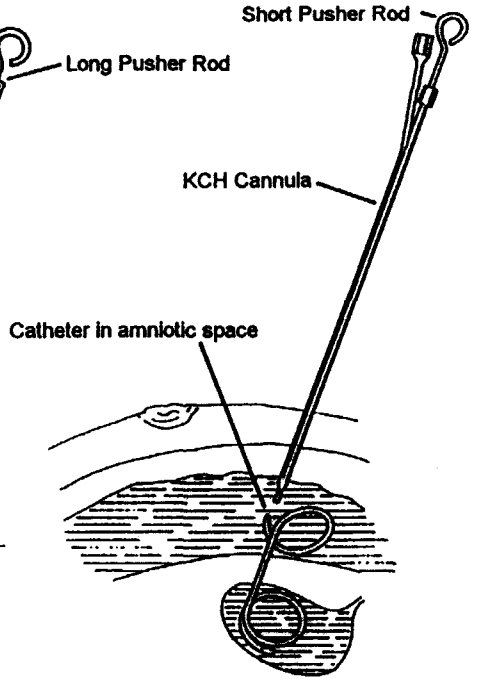


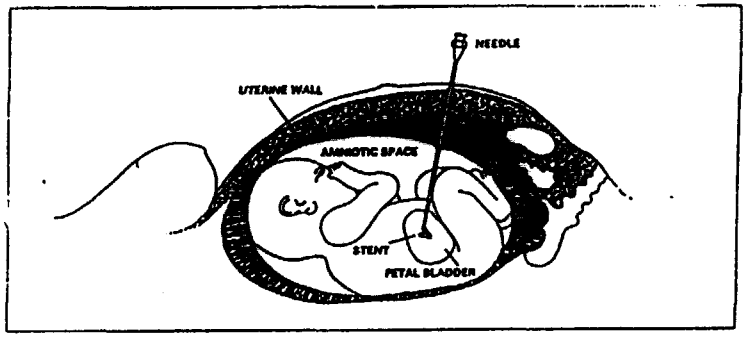
Fig 4: Expelling the catheter into the amniotic space

The whole process usually takes 15-30 minutes. The doctor will want you to stay in hospital for observation, but only long enough to make sure you and your baby are fit and well after the procedure.

Your doctor will regularly monitor you to ensure there are no early contraction and that the baby's heart rate is not abnormal or demonstrating any sign of distress.

You will need to have your next ultrasound examination within 48-72 hours after the procedure and you will need follow-up ultrasound examinations every week until your baby is born.

The doctor will be examining the position of KCH Catheter and checking to make sure that it is functioning properly. Sometimes, through the baby's movement or by grasping it, the catheter may come out of your baby's bladder or become kinked or blocked. If any of these things happen, the baby's urine will no longer be able to drain into the amniotic space. Your doctor may need to repeat the procedure and replace the catheter.



Parts of Your Body and Your Baby's Body Affected By the Procedure

WHAT ARE THE RISKS ASSOCIATED WITH USING THE KCH CATHETER.

As with all surgical procedures there are some risks. These are those involved with the placement of the KCH Catheter:

- *Chorioamnionitis* is an inflammation of the fetal membrane and can result after any procedure, including placing a fetal bladder stent, in which a doctor places an instrument into your uterus during pregnancy. This condition may cause you to lose the fluid around your baby or may cause infection in your baby and possibly cause your baby to be stillborn.
- *Urinary ascites* is the leakage of urine into your baby's abdomen. This can occur as result of fetal stent placement although it usually resolves itself once the bladder has begun to drain through the catheter.

- Placing the fetal bladder stent could cause you to go into pre-term labour. This can happen after any surgery which goes into the uterus during pregnancy.
- There might be some minor bleeding from your uterus or the placenta and minor injury to your uterus caused by the passing of the insertion needle. Any light bleeding will usually stop after a short time.
- *Amniotic Band Syndrome* is a very rare abnormality where the extremities, such a fingers, toes or limbs, become trapped in part of the amniotic sac. Its cause is still unknown but some doctors believe that puncturing the amniotic sac as occurs when placing the KCH Catheter, may lead to this condition.
- Maternal sepsis is an infection in the mother which can happen as a result of placing any instrument into your uterus whilst you are pregnant. Your doctor will normally give you antibiotics before and after the procedure to help reduce this risk.
- Amniotic fluid may leak from the space between your baby and the wall of your uterus. This can happen any time after your doctor places an instrument into your uterus whilst you are pregnant.
- The needle could perforate your baby's intestine and may cause other damage if the doctor doesn't place it accurately. The whole procedure is carried out under ultrasound to minimise this risk.
- Once the stent is implanted, there is the risk that it may become obstructed or dislodged, resulting in the need for repeated stent placements.
- Placing a fetal bladder drain can cause you to abort or miscarry. This could also happen if there is an inflammation of the fetal membrane.

WHAT OTHER TECHNIQUES CAN BE USED TO TREAT MY BABY'S PROBLEM:

Your doctor can drain you baby's bladder by regularly inserting a needle into your baby's bladder. However, your doctor will need to do this as often as the pressure builds up to prevent damage to your baby's kidneys and lungs.

Some doctors can perform an open fetal surgery where the doctor removes your baby from your uterus far enough to repair the blockage. After the repair, the doctor would place your baby back in you uterus and your pregnancy would continue.

DECIDING IF FETAL BLADDER DRAINAGE IS BEST FOR YOU AND YOUR BABY

The decision to have the placement of the KCH Catheter or any other procedure to relieve the urinary pressure is an important decision and is up to you and your partner. You do not have to have this procedure performed. You have read about the potential risks of the procedure. You must understand these risks. You should also know the potential risks of leaving this condition untreated. The pressure build-up could damage your baby's lungs and/or kidneys. This could lead to physical deformity or to your baby's death.

If you are thinking about having this procedure performed, you should discuss it with your doctor as soon as possible. Your doctor will be able to explain this procedure to you in more detail.

Before you make this decision, you must understand that using the KCH Catheter cannot correct the original defect. It cannot correct the blockage in your baby's urinary tract, this will need to be treated after your baby is born. The KCH Catheter will only allow urine to drain from you baby's bladder so that your baby's lungs and kidneys can continue to grow without pressure during pregnancy.

If you have any other questions or concerns, please ask your doctor.

WARNING

Following insertion of the KCH Catheter
REPORT IMMEDIATELY any pain, bleeding or fluid loss to your doctor.
These abnormal conditions should be closely monitored.

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KCH Catheter Introducer Set

Warning: The KCH catheter introducer set must be thoroughly cleaned and sterilised according to a validated infection control procedure before use / reuse.

CLEANING & STERILISATION

Following the surgical procedure, remove the rubber seal from the top of the cannula by pulling and insert the large "Pusher Rod" through the cannula to remove any debris that may be present in the lumen.

Insert the irrigation trocar through the irrigation channel on the side of the cannula, again to remove any debris that may be present. Remove both trocar from the cannula and wash the entire unit including the pusher rods and rubber seal in a light detergent solution to remove blood and encrusted tissue.

Once clean, rinse the entire unit with deionised water, ensuring that water passes through both lumen of the cannula.

Reassemble the unit and inspect for any significant damage to the Trocar and cannula. Pay particular attention to the trocar facets to ensure they are well defined and sharp, check that the rubber seal is in good condition and has not perished, check that the irrigation channel trocar tip is a smooth blend into the body of the cannula and that the tip has not been damaged. Any signs of damage should be repaired prior to any further reprocessing.

Dry the unit and pack in such a manner as to prevent damage, per standard hospital procedures.

It is recommended to

STERILISE BY AUTOCLAVING @137°C / 2.5 BAR FOR A MINIMUM OF 3.5MINS OR AS PER VALIDATED AUTOCLAVE CYCLES.

IMMERSION IN GLUTERALDEHYDE SOLUTION IS NOT RECOMMENDED.

Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician or other licensed practitioner. This device should not be used without proper training.
Manufactured in the UK by:

Rocketmedical plc. Imperial Way. WATFORD. WD2 4XX

Issue 01 ZLABL00 21/08/97

Rocketmedical

Rocket KCH

Fetal Bladder Drainage Catheter

(KCH Catheter)

OUTCOME SURVEY

ROCKET MEDICAL PLC are required by the FDA to produce outcome data in support of an HDE application for the KCH Catheter. Please complete this information request and retain in the patient's chart until delivery, whereupon a copy of completed form should be returned to:

Medical Audit Unit. **ROCKET MEDICAL PLC**
Imperial Way. WATFORD. WD2 4XX. United Kingdom

Patient Name	
Type of Stent	KCH Catheter R57.405
Fetal gestational age at diagnosis:	
Fetal gestational age at implantation:	
Fetal gestational age at delivery:	
Fetal condition requiring procedure:	
Urinary biochemical profile of fetus at time of device placement:	
Fetal complications at time of placement or post_placement:	
Length of time device was in place:	
Fetal status additional to status requiring KCH Catheter:	
Success of procedure:	
Were any repeat procedures carried out, if so why?:	
Immediate outcome for mother and fetus:	
Maternal complications:	
Final outcome. (attach laboratory data and ultrasound prints if available)	
Live or still birth	
Date of delivery	
Physicians name	
Department	
Hospital	
Address	
Signature	**Date: dd/mm/yr**

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