

MAR 17 1995

K950729

510 (k) SUMMARY
FOR OLYMPUS DISPOSABLE CANNULA (BALL TIP)

Device Name: Olympus Disposable Cannula (Ball Tip)

Common/Usual Name: Disposable Ball Tip Cannula

Classification Name: Endoscope and Accessories

Predicate Devices: Disposable cannulae manufactured by Olympus, Wilson-Cook, Mill-Rose and Wiltek Medical.

Contact Person: Mr. Barry Sands
Olympus Corporation
Medical Instrument Division
4 Nevada Drive
Lake Success, NY 11042
(516) 488-0513

Summary Preparation Date: January 10, 1995

Statement of Intended Use

The Olympus disposable ball tip cannula is designed to be used for injecting solutions and contrast media during endoscopic procedures; optionally, a guide wire may be in position while fluids are injected.

Comparison to Predicate Devices

The Olympus disposable ball tip cannula is similar in design, function and intended use to currently marketed disposable cannulae manufactured by Olympus, Wilson-Cook, Mill-Rose, and Wiltek Medical.



MAR 17 1995

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Barry E. Sands
Regulatory Affairs Manager
Research and Development
Medical Instrument Division
Olympus America, Inc.
4 Nevada Drive
Lake Success, New York 11042-1179

Re: K950729
Olympus PR-23Q Disposable Cannula (Ball Tip)
Dated: February 10, 1995
Received: February 16, 1995
Regulatory Class: II
21 CFR 876.1500/Procode: 78 KOG

Dear Mr. Sands:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug and Cosmetic Act (Act). You may therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you may have under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose, and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(K) ROUTE SLIP

510(k) NUMBER K950729 PANEL GU DIVISION DRAER BRANCH
TRADE NAME OLYMPUS PR-230 DISPOSABLE CANNULA (BALL TIP)
COMMON NAME DISPOSABLE CANNULA (BALL TIP)
PRODUCT CODE _____

APPLICANT OLYMPUS AMERICA, INC.
SHORT NAME OLYMAMERA
CONTACT BARRY SANDS
DIVISION _____
ADDRESS 4 NEVADA DRIVE
LAKE SUCCESS, NY 110421179
PHONE NO. (516) 488-3880 FAX NO. (516) 326-9085
MANUFACTURER OLYMPUS AMERICA, INC. REGISTRATION NO. 2429304

DATE ON SUBMISSION 10-FEB-95 DATE DUE TO 510(K) STAFF 02-MAY-95
DATE RECEIVED IN ODE 16-FEB-95 DATE DECISION DUE 17-MAY-95
DECISION _____ DECISION DATE _____



Memorandum

Date _____
 from REVIEWER(S) - NAME(S) MIRIAM C. PROVOST, PH.D.
 Subject 510(k) NOTIFICATION K950729
 To THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices. (Tier I)
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes No

This 510(k) contains: (check appropriate box(es))

- A 510(k) summary of safety and effectiveness, or
- A 510(k) statement that safety and effectiveness information will be made available
- The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

Predicate Product Code w/panel and class:

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

78 KOG 876.1500 Class II

Additional Product Code(s) w/Panel (optional):

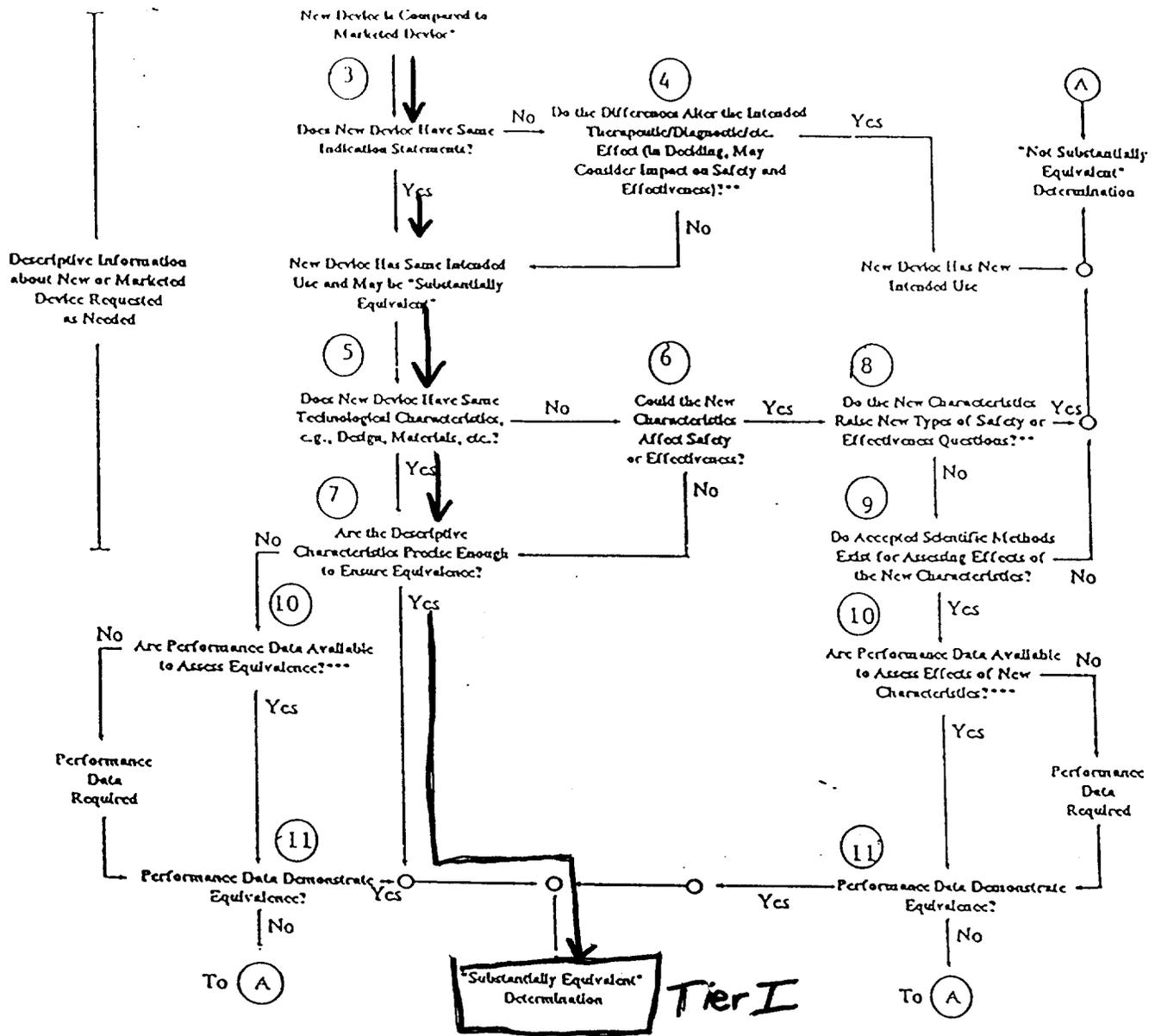
REVIEW: 9 C Derr
(BRANCH CHIEF)

6202 3/17/95
BRANCH CODE (DATE)

FINAL REVIEW: [Signature] 6 Yen
(DIVISION DIRECTOR)

3/17/95
(DATE)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



- 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

RRG/LLD 1/6/93
Rev. 9/24/93

**DRAERD Premarket Notification 510(k)
Screening Checklist**

510(k) Number &

Device Name K950729 - Olympus PR-23Q Disposable Cannula

Company Olympus America, Inc.

ITEM	PRESENT		NEEDED
	Yes	No	(Y/N/?)
1. General information (i.e., trade & classification name, Est. Reg. No., device class, meets special controls or a performance standards, etc.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reason for 510(k) - new device or modification	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Identification of legally marketed equivalent device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Proposed Labeling, Labels, Advertisements	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Description of new device/modification	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Intended use statement	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Diagrams, Engineering Drawings, Photographs	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Comparison of similarities/differences to named legally marketed equivalent device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Equivalent Device Labeling, Labels, Advertising	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Intended use of equivalent device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. List of all patient contacting materials in new device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comparison of materials to equivalent device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Biocompatibility information/data for patient contacting materials, OR Certification - identical material/formulation	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<u>NO</u> OR <input type="checkbox"/>
6. Performance data: Bench data	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<u>YES</u> NO
Animal data	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<u>NO</u>
Clinical data	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<u>NO</u>
7. Sterilization information	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Software validation & verification	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<u>NO</u>
9. 510(k) summary or statement	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. If Class III, Class III Certification & Summary	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<u>NO</u>
11. If kit, kit certification	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<u>NO</u>

FOR REVIEWER'S USE ONLY

RRG 9/24/93

DRAERD Premarket Notification 510(k)
SUPPLEMENTAL
Reviewer's Screening Checklist

DRAERD has been given the go ahead to continue with the DRAERD Premarket Notification 510(k) Screening Checklist program rather than switching to the ODE Premarket Notification (510(k)) Checklist for Acceptance Decision. However, some items appear in the ODE Checklist that were not in the early version of the DRAERD Checklist or Explanation of the Checklist. Therefore, the following items should be included as part of the DRAERD screening process:

510(k) Number: K950729

TIER (Circle) I / II / III

Expedited Review Requested: Y/N Granted: Y/N OR, FDA Identified Expedited: Y/N

ITEM

- | | <u>Yes</u> | <u>No</u> |
|---|------------|-----------|
| 1. Is the product a device? | | |
| 2. Is the device exempt from 510(k) by regulation or policy? | <u>X</u> | — |
| 3. Are you aware that this device has been the subject of a previous NSE decision?
If yes, does this new 510(k) address the NSE Issue(s) (e.g., performance data)? | — | <u>X</u> |
| 4. Are you aware of the submitter being the subject of an integrity investigation?
If yes, consult the ODE Integrity Officer, and has the ODE Integrity Officer given permission to proceed with the review? | — | <u>X</u> |
| 5. Is there a specific guidance document for this device or device issue(s)? | — | <u>X</u> |

In addition, the following item is new to the 510(k) review process. It will not be counted as a screening deficiency since it is new and "unknown" to the industry. It should be identified as a deficiency and requested as part of the technical review. The Explanation of the DRAERD Screening Checklist has been modified to include this information.

6. Address of manufacturing facility/facilities, and if applicable, sterilization site(s).

Administrative Reviewer Signature: _____

Elias Mallin

Date: 2-21-95

DRAERD REVIEWER RECORD FOR 510(K)s, IDEs, AND PMA SUPPLEMENTS

Document Control No. K950729 Principal Reviewer PROVOST

Date Assigned 2/23/95

Consulting reviews designated, as appropriate, by Branch Chief and lead reviewer, at the beginning of the review

<u>Specialty</u>	<u>Review Needed?</u>		<u>Reviewer</u>	<u>Dates</u>	
	<u>Yes</u>	<u>No</u>		<u>sent</u>	<u>Returned</u>
Clinical	<input type="checkbox"/>	<input checked="" type="checkbox"/>			
Engineering/ Physics	<input type="checkbox"/>	<input checked="" type="checkbox"/>			
Chemistry/ Biomaterials	<input type="checkbox"/>	<input checked="" type="checkbox"/>			
Biological/ Sterility	<input type="checkbox"/>	<input checked="" type="checkbox"/>			
Toxicology/ Biocompatibility	<input type="checkbox"/>	<input checked="" type="checkbox"/>			
Statistics	<input type="checkbox"/>	<input checked="" type="checkbox"/>			
Other _____	<input type="checkbox"/>	<input type="checkbox"/>			

3/93

DRAERD Quality Control -- to be completed by the Associate Director and, as appropriate, by the designated Medical Officer.

A. Associate Director QC Overview -- medical QC overview of this submission is believed necessary.

YES

NO

Initials/Date

B. If YES is noted above, Medical Officer QC Overview --

(1) Examination of the specialty reviews indicate there are remaining clinical issues that should be addressed -- see attached sheet for summary.

Initials/Date

(2) In my opinion, all pertinent clinical issues have been adequately addressed.

Medical Officer/Date
Final Signoff

Assoc. Director/Date
Final Signoff

4/93

DRAERD'S TRIAGE/TIER 1 PILOT PROGRAM
REVIEW CHECKLIST

510(k) NUMBER: K950729

CFR NO.: 876.1500 (COMPLETE ONLY IF SE)

YES OR NO

- YES 1. MANUFACTURER HAS COMPLETED ALL PARTS OF "MANUFACTURER'S STATEMENT OF SUBSTANTIAL EQUIVALENCE" AND HAS SIGNED FORM.
- YES 2. INDICATIONS FOR USE, LABELING, AND ALL CLAIMS ARE CONSISTENT WITH PREAMENDMENT OR LEGALLY MARKETED DEVICES.
- YES 3. IF DRAERD REQUIRES CONFORMANCE TO VOLUNTARY OR MANDATORY STANDARDS FOR THIS DEVICE, THE MANUFACTURER HAS SUBMITTED CERTIFICATION.

IF ALL CHECKS ARE "Y", THEN 510(K) IS SUBSTANTIALLY EQUIVALENT TO THE PREDICATE DEVICE. IF ONE ANSWER IS NO, THEN 510(K) MUST UNDERGO TIER 2 REVIEW.

_____ OPTIONAL SPOT CHECK TIER 2 REVIEW. (WRITTEN REVIEW ATTACHED.)

REVIEWER'S NAME Miriam C. Provost
Miriam C. Provost, Ph.D.

DATE 3/8/95

(ODE/DRAERD/PJM/LLY//DAS: 1/4/94)
(PJM 3¼ disc A:\TIER1CHK)

SUBSTANTIAL EQUIVALENCE (SE) DECISION MAKING DOCUMENTATION

K950729

REVIEWER: Miriam C. Provost, Ph.D

DIVISION/BRANCH: DRAERD/GRDB

TRADE NAME: PR-23Q Disposable Cannula

COMMON NAME: ERCP cannula

- | | YES | NO | |
|--|------------|-----------|------------------------------------|
| 1. Is the product a device? | ✓ | | IF NO STOP |
| 2. Device subject to 510(k)? | ✓ | | IF NO STOP |
| 3. Same indication statement? | ✓ | | IF YES GO TO 5 |
| 4. Do differences alter the effect or raise new issues of safety or effectiveness? | | | IF YES STOP - NE |
| 5. Same technological characteristics?* | ✓ | | IF YES GO TO 7 |
| 6. Could the new characteristics affect safety or effectiveness? | | | IF YES GO TO 8 |
| 7. Descriptive characteristics precise enough?* | ✓ | | IF NO GO TO 10
IF YES STOP - SE |
| 8. New types of safety or effectiveness questions? | | | IF YES STOP - NE |
| 9. Accepted scientific methods exist? | | | IF NO STOP - NE |
| 10. Performance Data Available? | | | IF NO REQUEST DATA |
| 11. Data demonstrate equivalence? | | | |

* per the manufacturer's Tier-1 certification statement

M E M O R A N D U M

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND
RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION**

DATE: March 8, 1995

FROM: Miriam C. Provost, Ph.D., Chemical Engineer
Gastroenterology and Renal Devices Branch

SUBJECT: K950729 - Olympus America, Inc.
PR-23Q Disposable Cannula

TO: The Record

The following is a Tier-I review of a premarket notification submission for the above device.

1. Intended Use

The disposable ball tip cannula is designed to be used for injecting solutions and contrast media during endoscopic procedures, optionally, a guide wire may be in position while fluids are injected.

2. General Information Summary

Life-supporting or life-sustaining:	NO
Implant (short-term or long-term):	NO
Software-Driven:	NO
Sterility:	YES
Patient Contacting Device:	YES
Single Use:	YES
Home or Prescription Use:	NO
Drug or Biological Product:	NO

Submission Provides:

Comparative specifications:	YES
Comparative laboratory data:	YES
Summary of Animal Testing:	NO
Summary of Clinical Testing:	NO
510(k) Statement:	YES
510(k) Summary:	NO

3. Device(s) to which equivalence is claimed:

Tier - I

4. Device Description.

The device consists of a hollow PTFE sheath with a distal ball-shaped metal end and a polysulfone main body at the proximal end.

5. Labeling

I have reviewed the labeling and the labeling is complete and consistent with what is expected for a ERCP cannula.

6. Recommendation

Substantially Equivalent - Tier 1 policy

ProCode: 78 KOG
Class: II
CFR #: 21 CFR §876.1500

Miriam C. Provost 3/8/95

Miriam C. Provost, Ph.D. Date

*ECB
3/17/95*

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

February 17, 1995

OLYMPUS AMERICA, INC.
4 NEVADA DRIVE
LAKE SUCCESS, NY 11042
ATTN: BARRY SANDS

510(k) Number: K950729
Received: 16-FEB-95
Product: OLYMPUS PR-23Q
DISPOSABLE
CANNULA (BALL
TIP)

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. Although the traditional timeframes for reviewing 510(k)s has been 90 days, it is now taking longer. These increasing response times have been caused by many factors, including a sharp increase in ODE's workload and increasingly complex device submissions. During 1992, we received about 1,500 more total submissions than we did the preceding year. We are troubled by these increases in response times and are making every effort to regain predictability in the timing of 510(k) reviews. Due to the increase in response times, CDRH has established a 510(k) Status Reporting System through which submitters may receive a status report on their 510(k) submissions(s) as follows:

- o Beginning 90 days after ODE receives your 510(k) submission, you may begin requesting status information. Submit requests via fax (301-443-8818) or via mail to:
 - 510(k) Status Coordinator
 - Division of Small Manufacturers Assistance (DSMA) (HFZ-220)
 - Center for Devices and Radiological Health, FDA
 - 5600 Fishers Lane
 - Rockville, Maryland 20857 USABecause of staff limitations, we cannot answer telephone status requests.
- o 510(k) status requests should include:
 - (1) submitter's name and mailing address;
 - (2) requester's name, affiliation with the 510(k) submitter, mailing address, fax number (if applicable), telephone number, and signature; and

- (3) 510(k) information, including product name, 510(k) number, date logged in by ODE (as identified in acknowledgment letter from ODE), and name of contact person identified on firm's 510(k) submission.

Enclosed is a suggested format that you may use to ensure that you include all of the required information.

- o Within three working days after DSMA receives a submitter's status request, DSMA will send the submitter a fax or letter that includes:
 - (1) the branch to which the 510(k) has been assigned;
 - (2) the last action, and date of that action, that CDRH has taken regarding the 510(k), e.g., logging in an amendment, preparing a decision letter; and
 - (3) the position of the 510(k) in the reviewer's queue.

We request that 510(k) submitters make status inquiries no more than every four weeks. We do not have the resources to respond more frequently.

The SMDA also requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages 510(k) submitters to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. Since the law requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who asserts that their device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The

description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

As of March 9, 1993, FDA has implemented the Good Manufacturing Practice(GMP) Pre-Clearance Inspection Program for all class III devices that are being reviewed under the premarket notification program. A letter of substantial equivalence cannot be sent until the finished device manufacturing site(s) and sterilization sites(s) as appropriate, have been identified and FDA has determined that the manufacturer(s) is in compliance with the GMP regulation (21 CFR Part 820).

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/ Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

PREMARKET NOTIFICATION (510(k)) STATUS REQUEST

TO: 510(k) Status Coordinator
Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health, FDA
5600 Fishers Lane
Rockville, MD 20857
USA
Fax Number: (301) 443-8818

Please provide the status of the 510(k) identified below. Please send the information to the requester identified in section B by (check one):

fax
 mail

A. Sponsor Information:

- 1. Name of 510(k) sponsor: _____
- 2. Sponsor's mailing address: _____

B. Requester information:

- 1. Request name: _____
- Requester affiliation with sponsor: _____
- 3. Requester mailing address: _____

- 4. Request fax number (if applicable): _____
- 5. Requester telephone number: _____

C. 510(k) information:

- 1. Product name: _____
 - 2. 510(k) number: _____
 - 3. Date logged in by Office of Device Evaluation (ODE) (as identified in acknowledgment letter from ODE): _____
- Name of contact person identified on firm's 510(k) submission: _____

.....
I certify that the above information is accurate and truthful to the best of my knowledge.

(Rev:2)

Requester signature

II
K950729

OLYMPUS

OLYMPUS AMERICA INC.

4 NEVADA DRIVE
LAKE SUCCESS, NEW YORK
11042-1179

TEL (516) 488 3880
FAX (516) 222 0878

February 10, 1995

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

FDA/CDRH/OCE/DMC

16 FEB 95 11 57

RECEIVED

Re: 510 (k) Notification

Dear Sirs:

In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act, as Amended, Olympus Corporation is notifying the Food and Drug Administration of its intent to market the **Olympus Disposable Cannula (Ball Tip)**. The following information is being submitted to demonstrate that this device is substantially equivalent to a legally marketed, predicate medical device.

Classification Name:	Endoscope & Accessories
Common/Usual Name:	Disposable Cannula (Ball Tip)
Trade/Proprietary Name:	Olympus PR-23Q Disposable Cannula (Ball Tip)
Est. Registration No.:	2429304
Classification:	CFR 876.1500, Class II
Performance Standard:	None Established
Labeling/Advertising:	See Table of Contents
Substantial Rationale Equivalence:	See Table of Contents

Olympus is submitting the Disposable Cannula (Ball Tip) for Tier 1 review; enclosed please find the "Manufacturers Statement of Substantial Equivalence," as required for Tier 1 review.

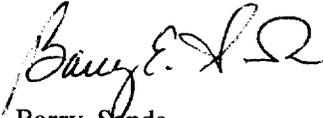
510(k) Notification

Page 2

February 10, 1995

Also attached is complete Pre-market Notification for the PR-23Q Ball-Tip Cannula. Section IV of this notification contains a summary of safety and effectiveness information upon which the substantial equivalence determination is based. If you have any questions regarding this submission, please contact the undersigned at (516) 488-0513.

Sincerely,



Barry Sands
Regulatory Affairs Manager
Medical Instrument Division

MANUFACTURER'S STATEMENT OF SUBSTANTIAL EQUIVALENCE

(To be provided with 510(k) notifications for Tier 1 devices)

STATEMENT OF INDICATIONS FOR USE:

The Olympus disposable ball tip cannula is designed to be used for injecting solutions and contrast media during endoscopic procedures; optionally, a guide wire maybe in position while fluids are injected.

CLAIMS:

The PR-230 disposable ball tip cannula will be marketed as a sterile, single use device.

This notification contains all of the information required by 21 CFR 807.81. A completed copy of the 'DRAERD Premarket Notification 510(k) Reviewer's Screening Checklist' is attached.

The subject device conforms to the following voluntary and mandatory standards:

AISI Standard for Materials; AAMI Overkill Method (Sterilization Validation.)

The subject device has the same technological characteristics as a legally marketed predicate device. Specifically, the features, specifications, materials, and mode of action are equivalent. If the subject device is a kit, all of the contents of the kit are either pre-Amendment devices or have been cleared for marketing through previous 510(k)s. The kit contains no drug or biologic product.

The above statements are accurate representations of this 510(k) premarket notification and of the device this firm intends to market. All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted (21 CFR 807.87(j)) to the best of my knowledge.

MANUFACTURER: Olympus Optical, Ltd; Tokyo, Japan

OFFICIAL CORRESPONDENT:

M. Nakamura
(signature)

Masashi Nakamura
(printed name)

Shirakawa Plant
QUALITY CONTROL GROUP MANAGER

TITLE:

DATE:

Feb-6-95

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PRE-MARKET NOTIFICATION

**DISPOSABLE BALL-TIP CANNULA
PR-23Q**

**OLYMPUS AMERICA INC.
4 Nevada Drive
Lake Success, NY 11042**

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I

SECTION I
INTRODUCTION

BACKGROUND

Cannulae are used during endoscopic procedures to gain entrance to the papilla of Vater during Endoscopic Retrograde Cholangio Pancreatography (ERCP). To address this market need, Olympus America, Inc. has marketed cannulae prior to 1976. Olympus America now intends to market a sterile disposable cannula with a ball shaped tip. This new cannula will be designated:

PR - 23Q Disposable Cannula (Ball Tip)

The difference between previously marketed Olympus cannulae and the PR-23Q is the introduction of a ball-shaped tip on the PR-23Q. This ball shaped tip is being offered to provide the physician with a round tip which permits easier, less traumatic cannulation than more tapered designs.

The PR-23Q accepts a standard 0.035" guide wire, such as the Olympus G35-2LB, G35-2LD (K933110). This cannula will be used as an accessory device to Olympus' line of gastrointestinal (GI) endoscopes. The design, material composition, and intended use have not significantly changed when compared to pre-Amendment cannulae and cannulae currently marketed by our competitors.

Ancillary Equipment:

The Olympus PR-23Q Ball Tip Cannula can be used with all duodenoscopes with an instrument channel of ϕ 2.2 mm or larger, and guidewires with diameters ranging from 0.018 in to 0.035 in.

REGULATORY HISTORY

Olympus has marketed cannulae prior to 1976 (reference Appendix A, Olympus 1975 price list). In addition, the Olympus PR-7Q metal tip cannula received FDA concurrence in 1990 (K902734, enclosed for reference as Appendix B). K902734 also approved several other cannulae with different tip designs. These devices all have the same basic geometry and materials, the only difference is the variations in tip design.

The disposable cannula PR-23Q will be used as an accessory with Olympus GI endoscopes. It is similar in design and intended use to cannulae used prior to 1976 or appear in K902734, and are currently marketed by Olympus. Based on the cannula tip design, this cannula is also similar to currently marketed competitive cannulae. Information on these competitor cannulae is provided in the following section. Product literature on these devices can be found in Appendix C - Substantially Equivalent Competitive Devices.

Similarity / differences with predicate device

The Olympus PR-23Q Disposable Cannula (Ball Tip) is substantially equivalent to the currently marketed Olympus PR-7Q (K902734) Metal Tip Cannulae. There are four major differences between the PR-7Q and the PR-23Q; these differences are presented below.

DIFFERENCE	Olympus PR-23Q	Olympus PR-7Q	RATIONALE
Sheath ID	φ1.3 mm	φ1.6 mm	To provide better flushability and injection capability than φ 1 mm ID
Sheath OD	φ1.9 mm	φ2.2 mm	Dependent on ID
Distal Tip Shape	Ball Tip	Metal Tip	Ball tip to provide easier insertability into the papilla
Flushing Port	Yes	No	Flushing port allows injection of contrast medium without the removal of the guidewire

The general design, functionality, and indications for use for the PR-23Q cannula are equivalent to those of the PR-7Q. These cannulae have the same principle of operation. The major difference between the cannulae is the shape of the distal tip. The ball shaped distal tip is currently being marketed by at-least two other endoscopic cannulae manufacturers.

COMPARISON TO PREDICATE CANNULAE

The following is a list of currently marketed cannula that are equivalent to the Disposable Cannula (Ball Tip) discussed above. Product literature on competitor devices may be found in Appendix C - Substantially Equivalent Competitor Devices.

<u>Product</u>	<u>Device No.</u>	<u>510(k)</u>
Olympus marked cannulation tube	6452	pre-Amendment
Olympus cannula with stylet	6455	pre-Amendment
Olympus metal tip cannula	PR-7Q	K902734
Wilson-Cook ball tip cannula	ERCP-1-HKB	K932205
Mill-Rose ERCP cannula - round tip	257	K802443
Wiltex Medical ERCP catheters	EC-10040	K894867

II

SECTION II
DEVICE DESCRIPTION

DESIGN AND CONSTRUCTION OF THE DISPOSABLE CANNULA (BALL TIP)

The Olympus Disposable Cannula (Ball Tip) consists of a hollow plastic sheath (tube) with a distal ball-shaped metal end and a plastic main body at the proximal end. Specifics on the geometries and materials can be found in the paragraphs that follow.

A mechanical drawing of the Olympus PR-23Q Disposable Ball Tip Cannula can be found on the following page (page no. 5). Please refer to this drawing as required during the following discussion of the design and construction of the PR-23Q, and the predicate PR-7Q (K902734).

Geometry:

Both the PR-23Q and the predicate PR-7Q consist of a hollow sheath attached to a plastic main body at the proximal end. The only difference between the cannulae occurs at the distal tip, where the PR-7Q has a straight metal tip and the PR-23Q has a rounded (ball) tip. The table below lists some of the characteristics of the PR-23Q and the PR-7Q, as well as some characteristics of competitor products (Refer to Appendix C for competitor product literature).

Parameter	Olympus PR-23Q	Olympus PR-7Q (Predicate)	Wilson-Cook ERCP-1-HKB	Mill-Rose 258	Witek EC-10040
Sheath Length	1950 mm	1950 mm	2000 mm	2120 mm	2000 mm
Sheath Diameter	φ1.9 mm	φ2.2 mm	φ1.7 mm	φ1.7 mm	5 F
Min. Endoscopic Channel Diameter	φ2.8 mm	φ2.8 mm	not indicated	not indicated	not indicated

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

DESIGN AND CONSTRUCTION (CONT.)

Materials:

(b)(4) Specifications



INTENDED USE

The Olympus disposable ball tip cannula is designed to be used for injecting solutions and contrast media during endoscopic procedures; optionally, a guide wire may be in position while fluids are injected.

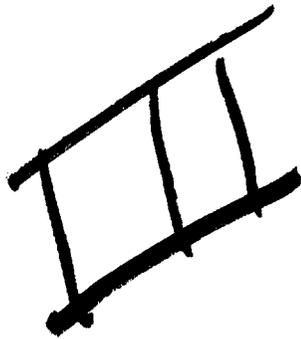
This cannula is designed to be used with equipment which conform to the specifications listed below:

PARAMETER	SPECIFICATION
Endoscope channel size	ϕ 2.8 mm (min.)
Guidewire diameter	ϕ 0.89 mm (0.035 in) max.

STERILITY CHARACTERISTICS

The disposable cannula (ball tip) will be marketed as sterile, single-use devices. Since these devices are sold as sterile, the following information is provided in accordance with the 510(k) memorandum #K90-1, February 12, 1990, 510(k) Sterility Review Guidance.

- | | |
|-------------------------------|--|
| 1. Method of Sterilization: | 30% Ethylene Oxide/70% CO ₂ |
| 2. Sterility Assurance Level: | 10 ⁻⁶ |
| 3. Validation Method: | AAMI Overkill Method |
| 4. Ethylene Oxide Residuals: | EtO - < 250 ppm
EC - < 250 ppm
EG - < 5000 ppm |
| 5. Packaging: | Polyethylene heat-sealed to paper |
| 6. Pyrogenicity: | We do not claim that the device is pyrogen free |



SECTION III
DEVICE LABELING

LABELING

The labeling for the PR-23Q labeling indicates that the device is sold sterile and is intended for single use. These are the same indications on the labeling for the PR-7Q (K902734).

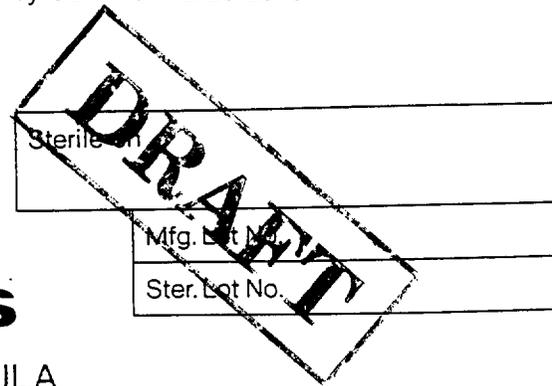
A draft copy of the PR-23Q instruction manual (peal-pack cover) is enclosed for reference on page 10.

ADVERTISING AND PROMOTIONAL MATERIAL

A draft copy of promotional literature is enclosed for reference on pages 11 and 12.

STERILE

▲
Peel back here



Contents of properly stored, unopened, undamaged package are sterile and ready to use.

OLYMPUS

DISPOSABLE CANNULA
(BALL TIP)
PR-23Q

WARNING : FOR SINGLE USE ONLY. DO NOT REUSE OR ATTEMPT TO RESTERILIZE.

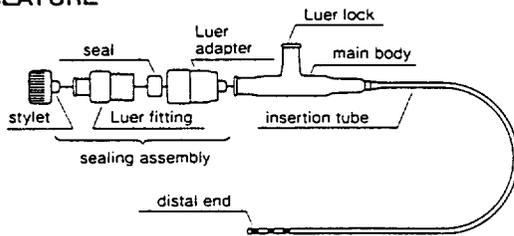
A. INTENDED USE

This product is to be used for injecting solutions and contrast media during endoscopic procedures in the biliary tree; optionally, a guide wire can be in position while fluids are injected. Do not use this product for any other purpose. Refer to the specifications below and the Endoscopic System Chart in the endoscope's instruction manual to ensure the product is compatible with the endoscope being used.

B. SPECIFICATIONS

Minimum endoscope channel size 2.8 mm
Maximum guide wire diameter 0.035 inch (0.89 mm)

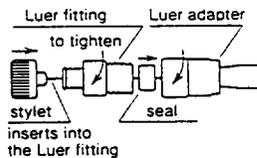
C. NOMENCLATURE



D. PREPARATION AND INSPECTION

Always have spare products available in the procedure room.

- Before removing the cannula from the package, inspect the package for damage. If the package has been previously opened or torn, do not use the cannula. DO NOT ATTEMPT TO RESTERILIZE. Aseptically remove the cannula from its sterile package and examine it for damage. If any damage or irregularity is found, do not use the cannula.



- Turn the Luer fitting clockwise to confirm that it tightens snugly into the Luer adapter. If the fit is not tight, fluids can leak from the fitting during injection.

E. INSERTION, USE, AND WITHDRAWAL

Before proceeding, be sure to read and thoroughly understand the instructions for all instruments which will be used during the procedure.

- Confirm that the stylet, sealing assembly, and main body are securely assembled.
- Carefully insert the cannula into the instrument channel. Using slow, short strokes pass the cannula through the instrument channel.
If the endoscope has a forceps elevator: Before inserting the cannula, raise

the forceps elevator completely. (A raised elevator will block the cannula from leaving the endoscope.) Advance the cannula until it contacts the raised elevator. Lower the elevator to allow the cannula to exit the channel. Carefully advance the cannula while gradually raising the elevator and viewing the endoscopic field. The tip of the cannula comes into view when it extends approximately 5 mm-20 mm from the tip of the endoscope.

Caution. Forcing the cannula through the channel can damage the endoscope or injure the patient. If the cannula encounters resistance during insertion, do not force it. Relax the endoscope's angulation mechanism until the cannula passes smoothly.

Caution. Advancing the cannula without viewing it endoscopically can injure the patient.

- When the cannula tip is in view endoscopically, fill a syringe with an appropriate fluid and attach it to the Luer lock on the main body. While observing the cannula tip, slightly depress the syringe plunger to confirm fluid flow.
- Advance the cannula tip to the target area and insert the cannula into the duct.
- Confirm that the Luer fitting is tightly sealed with the Luer adapter (check by turning it clockwise slightly). When the seal is tight, carefully begin injecting fluid into the duct. When the procedure is complete, lower the elevator and carefully withdraw the cannula.

If using a guide wire with the cannula:

Caution. Do not use a guide wire with an outer diameter greater than 0.035 inch (0.89 mm) with this cannula. A guide wire with a larger diameter can damage the cannula.

- Remove the stylet from the Luer fitting.
- Pass the guide wire into the Luer fitting and into the cannula. If the guide wire is difficult to pass, slightly loosen the Luer fitting until the wire passes smoothly. Advance the cannula to the target area following all instructions included with the guide wire.
- When the guide wire reaches the target area, turn the Luer fitting clockwise to tighten the sealing assembly and hold the wire in position.

Note. Before injecting fluid with the guide wire in position, confirm that the Luer fitting is securely tightend. Tightening the Luer fitting reduces the possibility of leaking and helps hold the wire in position.

If removing the cannula, leaving the guide wire in position:

If the endoscope has a forceps elevator, lower it. Loosen the Luer fitting and hold the guide wire in place. Carefully withdraw the cannula.

F. STORAGE

Store this product at room temperature in a clean, dry, well ventilated environment. Do not store in direct sunlight.

<p>OLYMPUS OPTICAL CO., LTD. San-Ei Building, 22-2, Nishi Shinjuku 1-chome, Shinjuku-ku, Tokyo, Japan</p>	<p>OLYMPUS AMERICA INC. 4 Nevada Drive, Lake Success, N.Y. 11042-1179, U.S.A.</p>
<p>OLYMPUS OPTICAL CO. (EUROPA) GMBH. (Premises/Goods delivery) Wendenstrasse 14-16, D-20097 Hamburg, Germany (Letters) Postfach 10 49 C8, D-20034 Hamburg, Germany</p>	<p>OLYMPUS KEYMED KeyMed House, Stock Road, Southend-on-Sea, Essex SS2 5QH, England OLYMPUS SINGAPORE PTE LTD BLK 211, Henderson Road #13-03, Henderson Industrial Park, Singapore 0315</p>

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI STATUS@fda.hhs.gov or 301-796-8118

MADE IN JAPAN

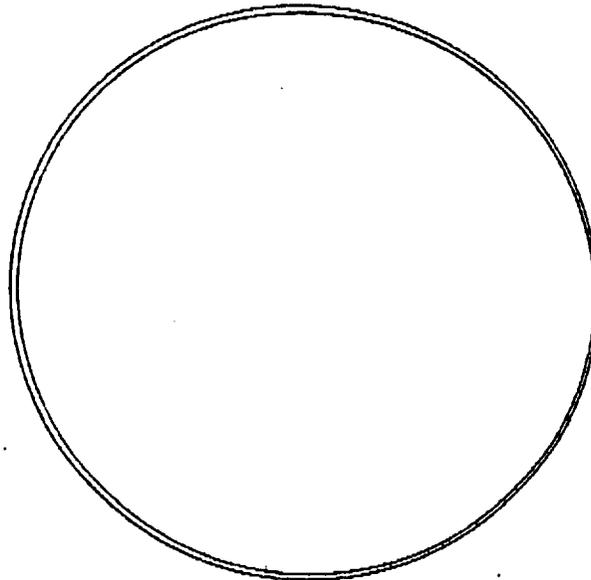
DRAFT



**Guldwire System + High Contrast Medium Flow Rate
Ball Tip Cannula**

Disposable Cannula (Ball Tip)

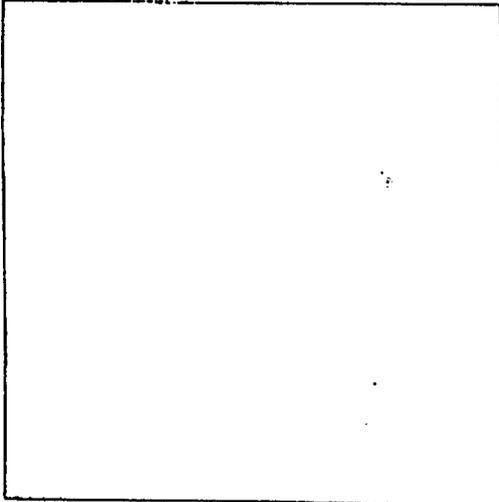
PR-23Q



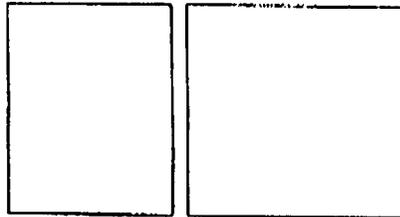
OLYMPUS

DRAFT

The Cannula with Easy Insertion and Fast, Multi-Procedure Efficiency.



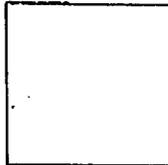
When ERCP is merely the commencement of multi-procedural treatment of the pancreatic and bile ducts, the wise endoscopist uses a PR-23Q. Not only does the ball tip of the PR-23Q make it extremely easy to insert, contrast medium can be injected at a high flow rate without requiring removal of the guidewire. The PR-23Q is disposable, eliminating the need for cleaning and minimizing the risk of cross-contamination, and can be used immediately upon removal from its sterile packaging.



Product Features

Ball Tip

The highly-evaluated ball tip guarantees optimum ease of insertion, and has been shown to be the preferred shape for the maximum range of clinical evaluations.



Disposable Type

Labor-saving, hygienic and efficient, the PR-23Q is ready to use on removal from its sterile packaging, eliminating washing, sterilization and the risk of cross-contamination, and engendering confidence in endoscopists and patients alike.

For Best Results

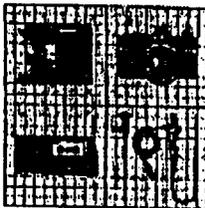
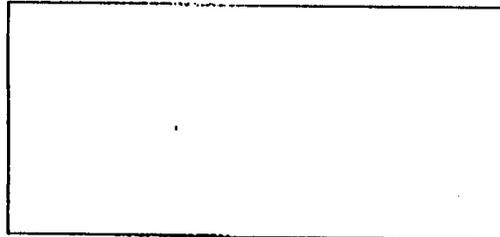
Ball-tip cannulae are compatible with OLYMPUS fiberscopes and videoscopes and exhibit maximum versatility when used with them.

Representing a marked advance over other cannulae, the PR-23Q allows high-flow rate injection of contrast medium while the guidewire is still in place. Not only does this eliminate tedious removal of the guidewire before completion of all procedures, together with the high-efficiency, maximum injection of contrast medium, it also provides better visibility during radiology.

0.035 Inch Guidewire System

The OLYMPUS 0.035 guidewire system permits the consecutive use of a range of post-ERCP accessories including papillotomy knives, cytology brushes, the balloon catheter and drainage tubes.

Specifications



Introducing... Model of
Management...
OLYMPUS
OLYMPUS OPTICAL CO. LTD.
OLYMPUS OPTICAL CO. (EUROPE) LTD.
OLYMPUS AMERICA INC.
OLYMPUS KEYMED
OLYMPUS BEASDADE PTE LTD.
OLYMPUS BEING REPRESENTATIVE OFFICE

Printed in Japan P442E-04836

HW

SECTION IV
SMDA 510(K) SUMMARY



510 (k) SUMMARY
FOR OLYMPUS DISPOSABLE CANNULA (BALL TIP)

Device Name: Olympus Disposable Cannula (Ball Tip)

Common/Usual Name: Disposable Ball Tip Cannula

Classification Name: Endoscope and Accessories

Predicate Devices: Disposable cannulae manufactured by Olympus, Wilson-Cook, Mill-Rose and Wiltek Medical.

Contact Person: Mr. Barry Sands
Olympus Corporation
Medical Instrument Division
4 Nevada Drive
Lake Success, NY 11042
(516) 488-0513

Summary Preparation Date: January 10, 1995

Statement of Intended Use

The Olympus disposable ball tip cannula is designed to be used for injecting solutions and contrast media during endoscopic procedures; optionally, a guide wire may be in position while fluids are injected.

Comparison to Predicate Devices

The Olympus disposable ball tip cannula is similar in design, function and intended use to currently marketed disposable cannulae manufactured by Olympus, Wilson-Cook, Mill-Rose, and Wiltek Medical.

A

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APPENDIX A
OLYMPUS 1975 PRICE LIST



PRICE LIST

OLYMPUS FIBERSCOPE ACCESSORIES CYTOLOGY BRUSHES

Effective Mar. 25, 1975

CODE #	DESCRIPTION	PRICE*
CYTOLOGY BRUSHES		
6380	type BC-2C For Models GFB, EF, EF-II, EF-B/B2, CF-SB	\$ 14.00
6381	type BC-1M For Models JF-B/D/B2.....	\$ 21.00
6382	type BC-1B For Models BF-5B2, CHF-B, BF-B2	\$ 20.00
6383	type BC-2J For Models GIF-D/D2, CF-MB/MB2, GF-B2, GIF-K, GF-BK	\$ 14.00
6385	type BC-2T For Models CF-LB/LB2	\$ 27.00
6386	type BC-1J For Model GIF-P	\$ 21.00
6387	type BC-6C For Model EF-PA	\$ 21.00
6388	type BC-3B For Model BF-5B.....	\$ 20.00
6389	type BC-4B For Models BF-4B, BF-4C2.....	\$ 20.00
6392	type BT/1.0/ 58/140 Bronchial Brush for Model BF-B2 (pkg. of 10 pcs.)	\$ 65.00
CHANNEL CLEANING BRUSHES		
6356	type BW-1M For Models JF-B/D/D2 & JF-B2	\$ 10.00
6357	type BW-2J For Models GIF-D/D2, CF-MB, EF-B/B2, EF, EF-II, GFB, GF-BK, CF-SB, GF-B2, GIF-K.....	\$ 8.00
6358	type BW-1B For Models BF-5B2, CHF-B, BF-B2	\$ 10.00
6359	type BW-2T For Model CF-LB	\$ 9.00
6360	type BW-1J For Models GIF-P, EF-PA.....	\$ 8.00
6361	type BW-3L For Model BF-5B.....	\$ 5.00
6362	type BW-4B For Models BF-4B, BF-4C2 (wire for channel cleaning).....	\$ 5.00
6363	type BW-3J For Model CF-MB2.....	\$ 8.00
6364	type BW-3T For Model CF-LB2.....	\$ 10.00

OLYMPUS CORPORATION OF AMERICA

MEDICAL INSTRUMENT DIVISION
2 NEVADA DRIVE/NEW HYDE PARK, NEW YORK 11040
AREA CODE (516) 488-3880

Cable: Olympoptic Newhydeparknewyorkstate

Telex: 125966 New York

*(all prices FOB New York —
freight prepaid and added)

TERMS: Net 30 Days
Prices and descriptions are subject
to change without notice.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

PRICE LIST

OLYMPUS FIBERSCOPE ACCESSORIES WASHING PIPES

CODE #	DESCRIPTION	PRICE*
6430	type PW-1H For Models EF, EF-II, EF-B/B2, CF-SB, GFB, GF-BK.....	\$ 10.00
6431	type PW-1L For Models GIF-D/D2, CF-MB/MB2, GF-B2, GIF-K.....	\$ 10.00
6432	type PW-1V For Models CF-LB/LB2	\$ 12.00
6433	type PW-2F For Model EF-PA	\$ 8.00
6434	type PW-2L For Model GIF-P	\$ 10.00
CANNULATION TUBES		
6452	Marked cannulation tube for Models JF-B/B2.....	\$ 12.00
6455	Cannula with stylet for Models BF-5B2*B2	\$ 8.00
FLUID CONTAINERS		
27	Fluid container w/pipe (screw-on type)	\$ 20.00
6128	Fluid container w/pipe (pressure-fit type)	\$ 20.00
6129	Fluid container only	\$ 8.00
6130	Pipe for fluid container (screw-on type)	\$ 12.00
6131	Pipe for fluid container (pressure-fit type)	\$ 12.00
6132	"O" ring for 6131.....	\$.20
RUBBER BLOWERS		
6350	type #1 One-tailed, with adaptor for Models GFB, GTF-A (for insufflation).	\$ 5.00
6349	Adaptor for #6350	\$.50
6352	type #2 Two-tailed (for channel cleaning).....	\$ 7.50

B

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APPENDIX B
K902734
FDA CONCURRENCE FOR PR-7Q

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

JUNE 21, 1990

OLYMPUS CORPORATION
ATTN: DANIEL DILLON
MEDICAL INSTRUMENT DIVISION
4 NEVADA DRIVE
LAKE SUCCESS, NY 11042

D.C. Number : K902734
Received : 06-21-90
90th Day : 09-19-90
Product : PR CANNULAS

-- The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug, and Cosmetic Act for the above referenced device has been received and assigned an unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Arthur S. Rosecrans

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

OLYMPUS

OLYMPUS CORPORATION
MEDICAL INSTRUMENT DIVISION
4 NEVADA DRIVE
LAKE SUCCESS, NY 11042-1179
Tel: (516) 488-3880
Fax: (516) 222-0878

K902734?

June 15, 1990

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Re: 510(k) Notification

Dear Sirs:

In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act, Olympus Corporation hereby notifies you of our intent to introduce **Olympus Sterile Disposable ERCP Cannulas** into interstate commerce for commercial distribution 90 days from the above date. 21 CFR 807 requires submission of the following additional information:

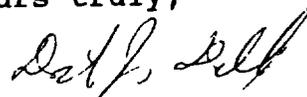
Classification Name: Endoscope and Accessories
Common/Usual Name: Sterile ERCP Cannulas
Trade/Proprietary Name: PR Cannulas
Est. Registration No.: 2429304
Classification: II
Performance Standard: None established.
Labeling/Advertising: See Section A for our draft labeling.
Substantial Equivalence: Substantial equivalence is based on previous cannulas marketed by Olympus (Section B).

510(k) Notification
Page 2
June 15, 1990

Our intent to market this device has not been revealed, is confidential, and exempt from public disclosure. We have taken precautions to protect the confidentiality of the intent to market the device and understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q). We will notify you when our intent is made public.

Please address all correspondence to the undersigned. If you have questions concerning this notification, please feel free to contact us. Thank you.

Yours truly,



Daniel J. Dillon
Regulatory Affairs Coordinator
Medical Instrument Division

DJD/tk

C

SS

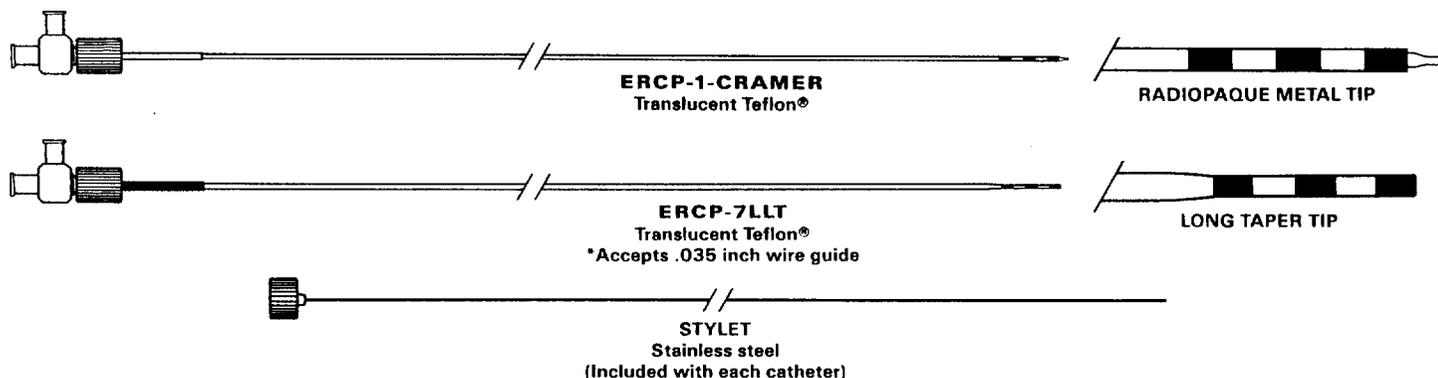
APPENDIX C
SUBSTANTIALLY EQUIVALENT COMPETITOR DEVICES

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16 E.R.C.P. CATHETERS

E.R.C.P. CATHETERS

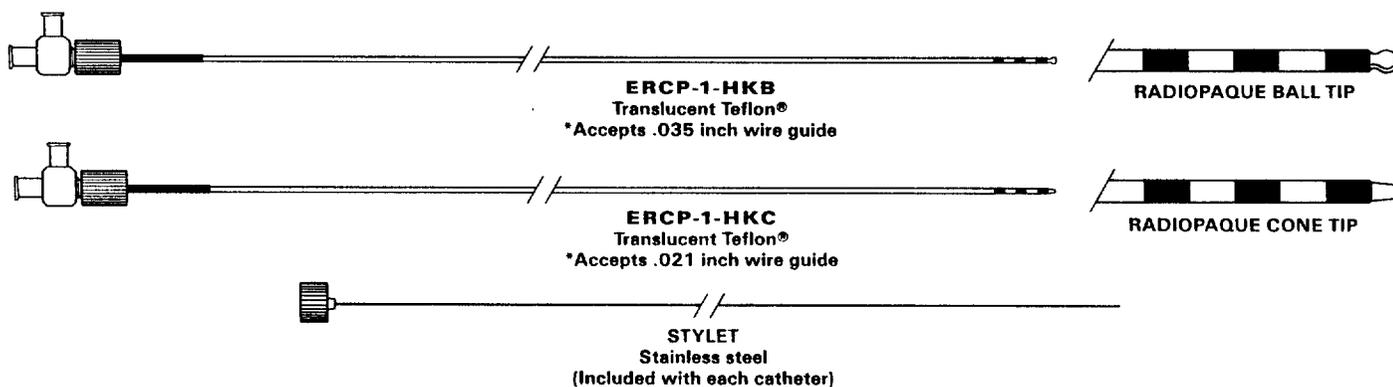
Used for cannulation of common bile and pancreatic ducts. All catheters have three, 3 mm etched markings at the distal tip and a double female 90° side-arm luer lock fitting. Supplied sterile in peel-open packages. Autoclavable.



ORDER NUMBER	CATHETER			STYLET	
	French Size	Length	Tip	Length	Remarks
ERCP-1-CRAMER	5.0	200 cm	Distal 1 mm 23 gage metal cannula	100 cm	For minor papilla
ERCP-7LLT	7.0	200 cm	Tapered to 5.0 French		
ERCP-1-M-SAA	For contrast injection with wire guide in place.				Stainless steel side angle body

HUIBREGTSE-KATON™ E.R.C.P. CATHETERS

Used for cannulation of common bile and pancreatic ducts. All catheters have three, 3 mm etched markings at the distal tip and a double female 90° side-arm luer lock fitting. Supplied sterile in peel-open packages. Autoclavable.



ORDER NUMBER	CATHETER			STYLET	
	French Size	Length	Tip	Length	Remarks
ERCP-1-HKB	5.0	200 cm	Ball tip	100 cm	For diagnostic and therapeutic E.R.C.P.
ERCP-1-HKC	5.0	200 cm	Cone tip	100 cm	For diagnostic E.R.C.P., stenotic papilla, minor papilla, and pediatric use

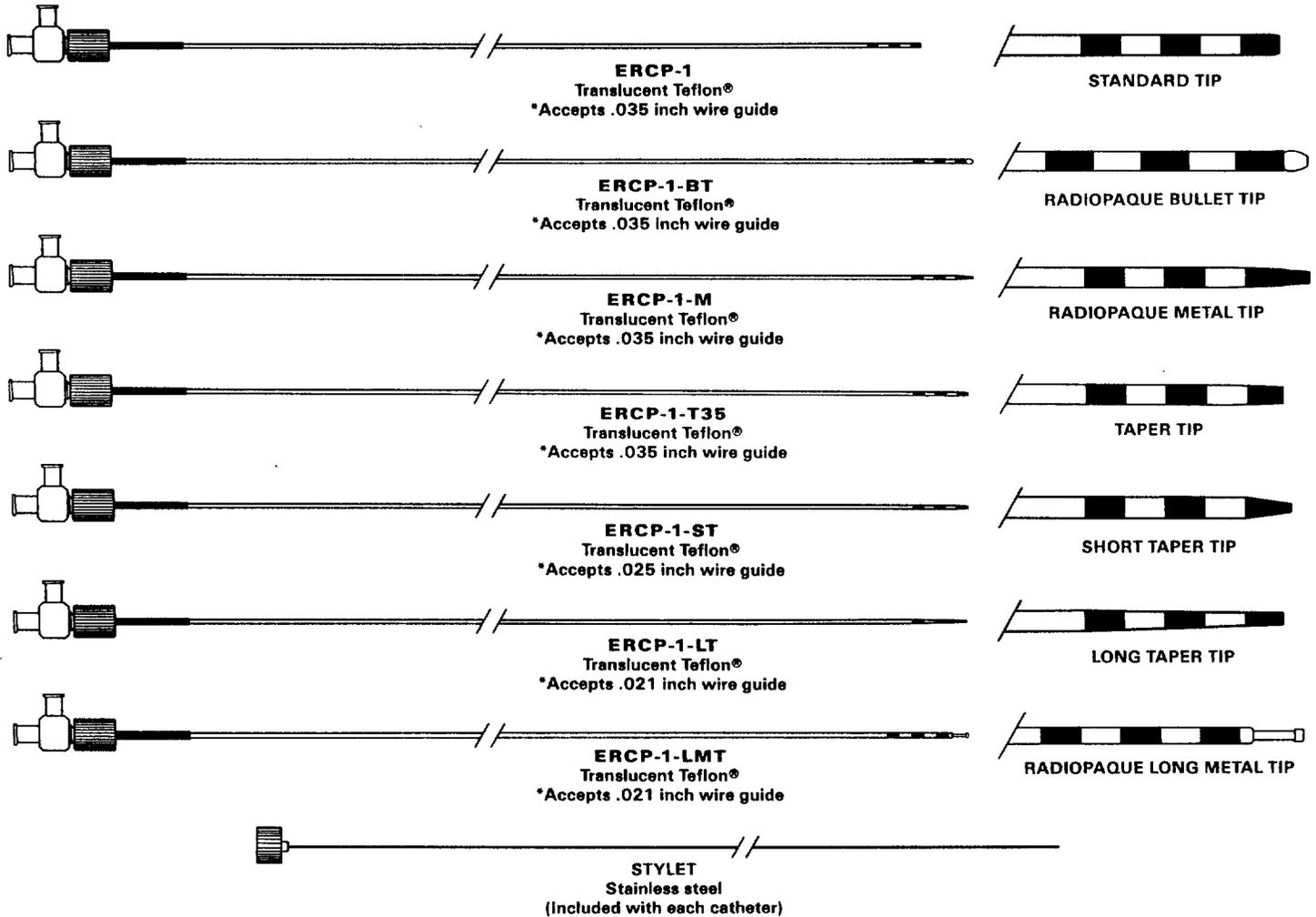
*Wire guide available separately.

SS

Wilson-Cook

E.R.C.P. CATHETERS

Used for cannulation of common bile and pancreatic ducts. All catheters have three, 3 mm etched markings at the distal tip and a double female 90° side-arm luer lock fitting. Supplied sterile in peel-open packages. Autoclavable.

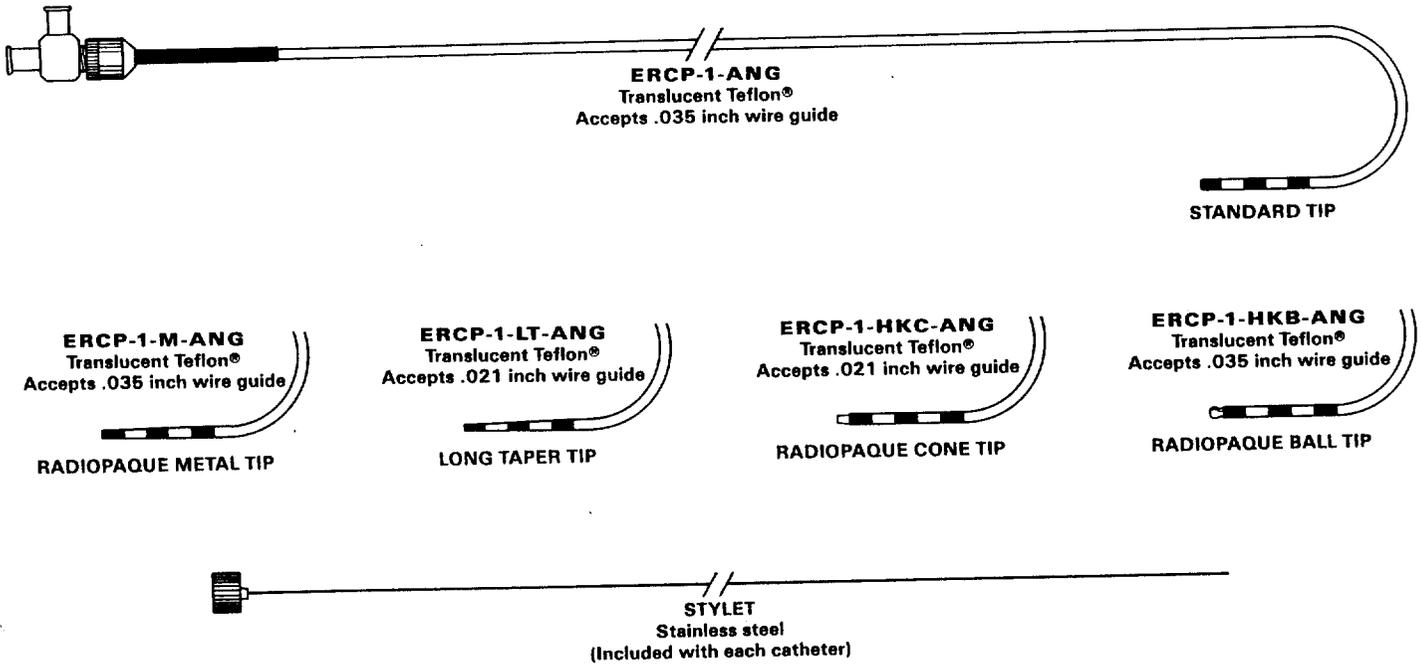


ORDER NUMBER	French Size	Length	CATHETER		STYLET	
			Tip	Length	Remarks	
ERC P-1	5.0	200 cm	Slightly beveled	100 cm	For diagnostic and therapeutic E.R.C.P.	
ERC P-1-BT	5.0	200 cm	Bullet tip	100 cm	For diagnostic and therapeutic E.R.C.P.	
ERC P-1-M	5.0	200 cm	Tapered to 4.5 French	100 cm	Radiopaque tip, disposable	
ERC P-1-T35	5.0	200 cm	Tapered to 4.5 French	100 cm		
ERC P-1-ST	5.0	200 cm	Distal 3 mm tapered to 3.5 French	100 cm	Short taper	
ERC P-1-LT	5.0	200 cm	Distal 9 mm tapered to 4 French	100 cm	For stenotic papilla	
ERC P-1-LMT	5.0	200 cm	Long metal tip	100 cm		

*Wire guide available separately.

ANGLED TIP E.R.C.P. CATHETERS

Used for cannulation of common bile and pancreatic ducts. Tip has a 180° angle. All catheters have three, 3 mm etched markings at the distal tip and a double female 90° side-arm luer lock fitting. Supplied sterile in peel-open packages. Disposable.



ORDER NUMBER	CATHETER			STYLET		Remarks
	French Size	Length	Tip	Length		
ERCP-1-ANG	5.0	200 cm	Slightly beveled	100 cm		180° angle
ERCP-1-M-ANG	5.0	200 cm	Radiopaque tip	100 cm		180° angle
ERCP-1-LT-ANG	5.0	200 cm	Tapered to 4 FR	100 cm		180° angle
ERCP-1-HKC-ANG	5.0	200 cm	Cone tip	100 cm		180° angle
ERCP-1-HKB-ANG	5.0	200 cm	Ball tip	100 cm		180° angle

Wire guide available separately.



WILSON-COOK® MEDICAL INC.
A COOK GROUP COMPANY

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI STATUS@fda.hhs.gov or 301-796-8118

ERCP CANNULAS & GUIDEWIRES

For more efficient ERCP diagnoses, the Mill-Rose family of cannulas provides excellent visibility of graduated markings and easier entry into the papilla with a variety of tip configurations.

All tapered tips are designed to pass over a guidewire to maintain the established pathway. The standard-taper and medium-taper models are compatible with .035 guidewires. The popular long-taper cannula is compatible with .021 guidewire.

Any combination of Mill-Rose cannulas can be purchased in an assortment box of five. Guidewires are available in two sizes, .035 (in.) and .021 (in.) and are sterile packaged.

◀#251 medium taper w/.035 guidewire

◀#252 standard taper w/.035 guidewire

◀#250-021 short taper w/.021 guidewire

◀#251-021 long taper w/.021 guidewire

PRODUCT NUMBER	DESCRIPTION	SHEATH DIAMETER	WORKING LENGTH	GUIDEWIRE COMPATIBILITY	PACKAGING (STERILE)
250-021	Short Taper E.R.C.P. Cannula	1.6mm	200cm	.021	1 each*
251	Medium Taper E.R.C.P. Cannula	1.6mm	200cm	.035	1 each*
251-021	Long Taper E.R.C.P. Cannula	1.6mm	200cm	.021	1 each*
252	Standard E.R.C.P. Cannula	1.6mm	200cm	.035	1 each*
259	Assortment Box of 5 Cannulas	N/A	200cm	N/A	5/box
260	.035 Guidewire	N/A	400cm	N/A	1 each
261	.021 Guidewire	N/A	200cm	N/A	1 each

*NOTE: Each type of cannula may be purchased in boxes of 5 units - add "B" to product number.

MILL-ROSE

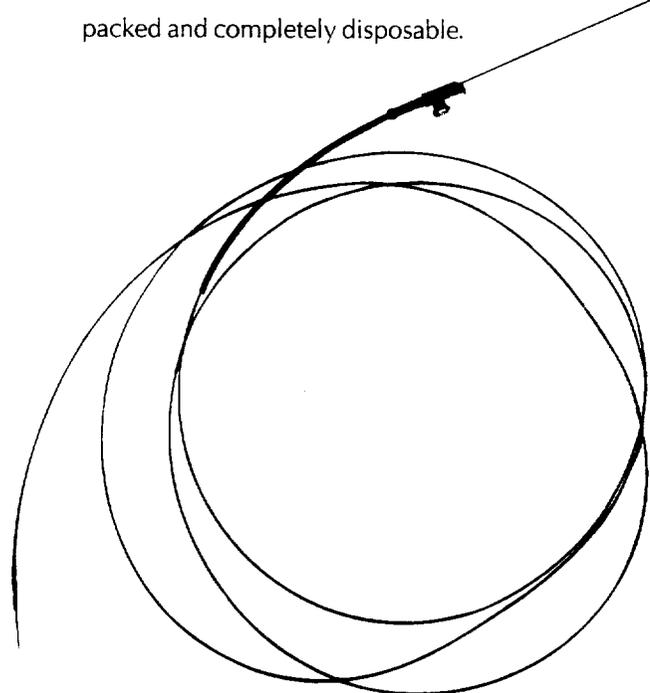
Metal-tip cannulas increase your options available when choosing a cannula for a specific procedure and offer a greater measure of visibility under fluoroscopy.

Three configurations of smooth metal tips are available, two of which are guidewire compatible. The KATON cannula has a blunt-needle tip. Both the round metal-tip and the hourglass metal-tip are compatible with .035 guidewires. All metal-tipped cannulas are sterile-packed and completely disposable.

←#253 KATON cannula w/blunt needle tip

←#257 round metal-tip cannula w/.035 guidewire

←#258 hourglass metal-tip cannula w/.035 guidewire



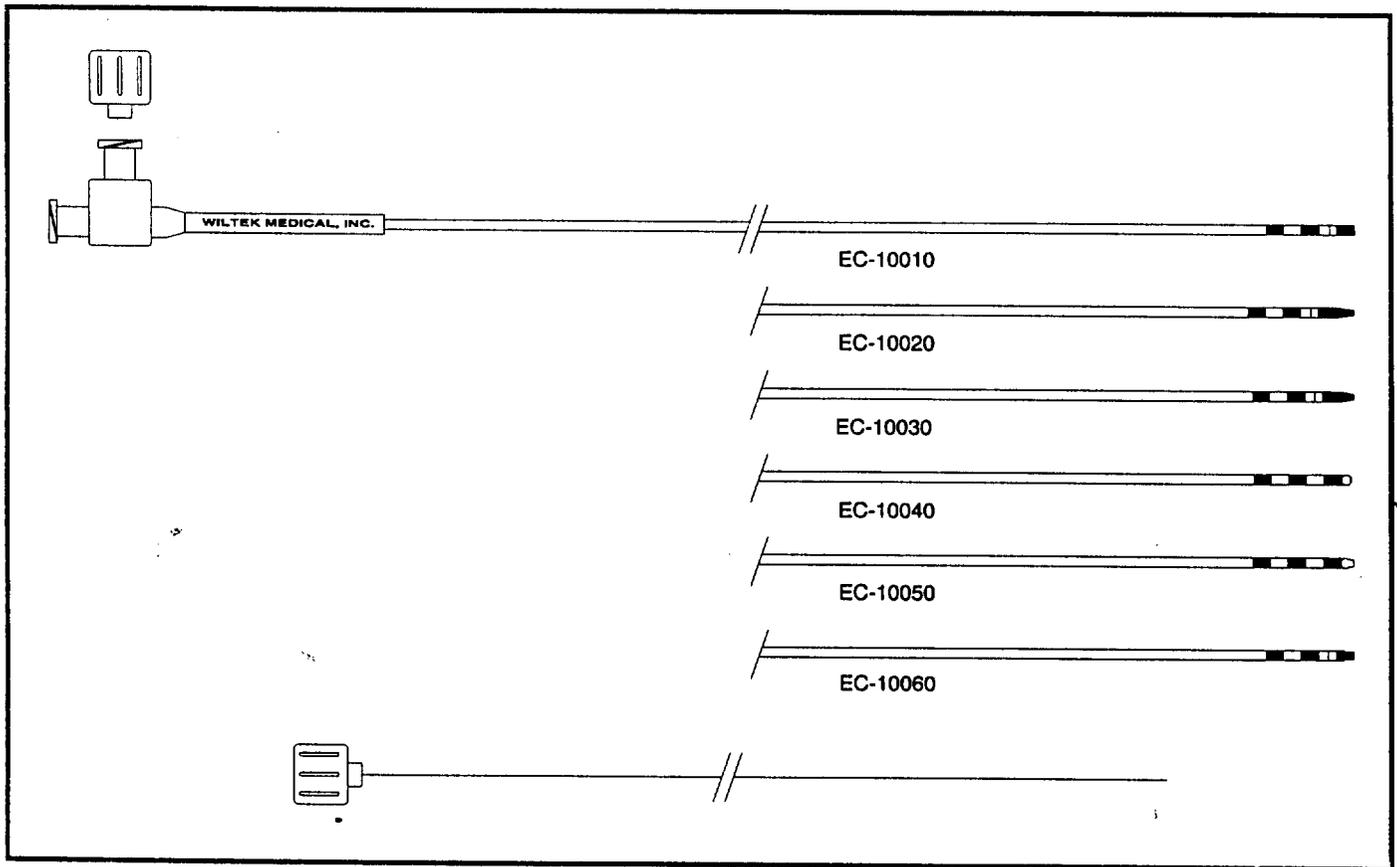
PRODUCT NUMBER	DESCRIPTION	TEFLON SHEATH DIAMETER	WORKING LENGTH	GUIDEWIRE COMPATIBILITY	PACKAGING (STERILE)
253	Blunt Needle Tip (KATON) Cannula	1.6mm	200cm	None	1 each
257	Round Metal Tip E.R.C.P. Cannula	1.6mm	200cm	.035	1 each*
258	Hour Glass Metal Tip E.R.C.P. Cannula	1.6mm	200cm	.035	1 each
259	Assortment Box of 5 Cannulas	1.6mm	200cm	N/A	5/box
260	1.5mm Guidewire	N/A	100cm	N/A	1 each
261	1.5mm Guidewire	N/A	100cm	N/A	1 each

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI-STATUS@fda.hhs.gov or 301-796-8118

*NOTE: Each type of cannula may be purchased in boxes of 5 units - add "B" to product number.

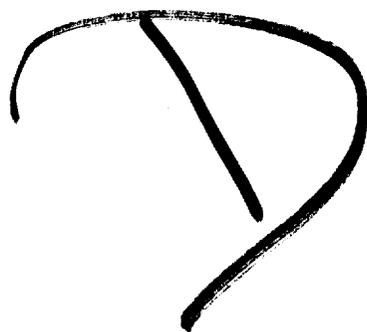
ERCP CATHETERS with RADIOPAQUE TIPS

CATALOG NUMBER	CATHETER DIAMETER	CATHETER LENGTH	TIP TYPE	COMPATIBLE WIRE GUIDE *	RADIOPAQUE MARKER TYPE
EC-10010	5 FRENCH (1.66 MM)	200 CM	STANDARD	.035"	PLATINUM BAND
EC-10020	5 FRENCH (1.66 MM)	200 CM	LONG TAPER	.035"	PLATINUM BAND
EC-10030	5 FRENCH (1.66 MM)	200 CM	SHORT TAPER	.035"	PLATINUM BAND
EC-10040	5 FRENCH (1.66 MM)	200 CM	BALL TIP	.035"	STAINLESS
EC-10050	5 FRENCH (1.66 MM)	200 CM	CONE TIP	.035"	STAINLESS
EC-10060	5 FRENCH (1.66 MM)	200 CM	NIPPLE TIP	.035"	PLATINUM BAND



AUTOCCLAVABLE - SUPPLIED STERILE IN PEEL - OPEN PACKAGES.
 *WIRE GUIDE AVAILABLE SEPARATELY.

WILTEK MEDICAL

A large, handwritten mark in black ink, resembling a stylized letter 'D' or a large checkmark. It consists of a curved top line and a straight vertical line on the left side, with a diagonal stroke extending from the top right towards the bottom left.A handwritten number '61' in black ink, located at the bottom center of the page.

APPENDIX D
CERTIFICATES OF IDENTICAL MATERIALS



Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015

Records processed under FOIA Request # 2015-4314; Released by CDRH on 12-29-2015